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The Effects of Traditional Strengthening Exercises Versus Functional Task Training on Pain, Strength, and Functional Mobility in the 45-65 Year Old Adult with Knee Osteoarthritis

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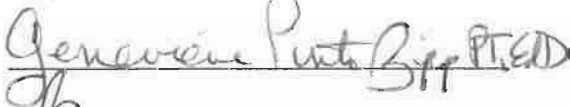
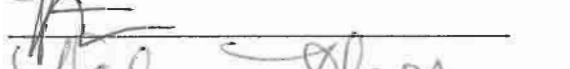

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ABSTRACT

THE EFFECTS OF TRADITIONAL STRENGTHENING EXERCISES VERSUS
FUNCTIONAL TASK TRAINING ON PAIN, STRENGTH AND FUNCTIONAL
MOBILITY IN THE 45-65 YEAR OLD ADULT WITH KNEE OSTEOARTHRITIS

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Chair, Dr. Genevieve Pinto-Zipp

Purpose: The purpose of this study was to examine whether traditional strengthening exercises (TE) or functional task training (FTT) would be more effective in decreasing pain and improving strength and functional mobility in the 45 to 65 year-old adult with knee osteoarthritis (OA).

Number of Subjects: A convenience sample of twenty individuals was randomly assigned into one of two groups: traditional strengthening exercise group (TE) or functional task training group (FTT).

Materials/Methods: Outcome data regarding the Western Ontario and MacMaster Universities Osteoarthritis Index, (WOMAC), Timed Up and Go (TUG), Berg Balance Scale (BBS), Stair Climb Test (SCT), quadriceps average peak torque, and normalized gait velocity using the GAITRite™ analysis system were taken at baseline, 6, and 12 weeks.

Data Analysis: A two-way repeated measures ANOVA was utilized to assess interaction effects. A one-way repeated measures ANOVA was used to interpret the significant interactions. Bonferroni method was used to examine pairwise

comparisons following significant interaction effects. Friedman's test was utilized for non-parametric data.

Results: The two-way repeated measures ANOVA for velocity ($p=0.03$) was statistically significant. To interpret significant interactions, a one-way repeated measures ANOVA compared the three means within groups (at baseline, week 6 and week 12) which was significant ($p=0.012$). Bonferroni method was used to examine pairwise comparisons. The results demonstrate that there was a significant difference between baseline and week 6 and baseline and week 12 ($p<.01$) for the FTT group. The p values for the interaction effect for peak torque/body weight ($p=.820$), WOMAC ($p=.684$), and TUG ($p=0.320$) were not significant. The BBS demonstrated significance for the FTT ($p=.001$).

Conclusions: There was a significant and clinically relevant improvement in gait velocity in the FTT group. While there were no significant group differences noted in self-reported or performance-based measures, greater improvements were noted in WOMAC scores, torque, TUG and the SCT for the FTT group. These preliminary findings indicate that FTT is an effective rehabilitation program for increasing strength, improving functional mobility and decreasing activity limitations associated with knee OA.

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DEDICATION

To my family, I am grateful for their support and understanding throughout this long and challenging journey.

To my friends and colleagues, especially Tom Donofrio who assisted me with the responsibilities associated with everyday operations of an academic program as well as my research.

To my husband for his insight, knowledge, support, and sense of humor which allowed me to be writing this dedication today. You are my soul mate and I could not have done this without you!

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CHAPTER I

INTRODUCTION

In adults, arthritis is the principal cause of disability and leads to work, recreational and social limitations (Hemlick et al. 2008). Arthritis represents an economic burden to society in that it has also been linked to cardiovascular disease, diabetes, dyslipidemia, hypertension, and insulin resistance (Velasquez & Katz, 2010). Osteoarthritis (OA) is the most common form of arthritis in the United States (Lawrence et al., 2008) in adults over the age of 45 (Hunter, McDougall & Keefe, 2009). Although the etiology has not been fully delineated, there is evidence to suggest that genetics, heredity, histology and biochemistry play a strong role in its development (Hinton, Davis, & Thomas, 2002). To date, no cure for the disease exists. However, evidence suggests that risk factors for the onset and progression of the disease are reducible or avoidable through lifestyle modifications such as weight loss, increased physical activity and dietary changes. Epidemiologic studies confirm that these modifications may help control the onset and progression of knee OA (Zhang, 2010). Therapeutic parameters proven to be successful in treatment include patient education, physical therapy, pharmacological agents, social support, assistive devices, and participation in arthritis programs. The effects of the disease accompany secondary impairments that include alterations in gait, varus/valgus alignment deformities, muscle imbalances and other maladies associated with aging (Altman, Hochberg, Moskowitz & Schnitzer, 2000).

In the lower extremity, OA affects all weight bearing joints that include the ankle, knee and hip. However, the knee is the most commonly affected joint (Diracoglu, Aydin, Baskent, & Celik., 2005; Moskowitz & Goldberg, 1988; Pisters et al., 2007) and is associated with greater symptomatology than any of the aforementioned joints (Diracoglu et al., 2005; Stratford, Kennedy, & Woodhouse, 2006). According to the World Health Organization, knee OA ranks the fourth most common cause of disability in women and the eighth in men (Simmons, Mathers, & Pfleger, 2000). Knee OA represents a major cause of pain and dysfunction and represents an economic burden to society. The United States spends more than \$56 billion per year on treatment and compensation for individuals with knee OA (Arthritis Foundation, 2009).

Radiographs confirm the diagnosis of knee OA. Radiographic and physical findings can include crepitus, joint space narrowing, edema, increased tissue temperature, bony hypertrophy, tenderness and varus or valgus deformities. Clinical symptoms of this disease for any individual afflicted may include any or all of the following: deterioration of articular cartilage, hypertrophic changes in bone, hardening of subchondral bone and presence of osteophytes, fissures, and periostitis that may serve as a mechanism of pain in individuals afflicted with OA (Vad, Hong, Zazzali, Agi, & Basrai, 2002). Stiffness associated with restricted activities and ultimate deconditioning is often associated with the disease (Dixon, Hinman, Creaby, Kemp, & Crossley, 2010; Leslie, 2000). Individuals with knee OA report morning pain and stiffness with activities of daily living (ADL's), making it difficult to get up from a chair, walk without pain and participate in community

activities such as walking (American Geriatric Society Panel on Exercise and Osteoarthritis, 2005). Gait deficits include a decrease in velocity, cadence, stride length, range of motion, angular velocity and vertical forces (Messier, Loeser, Hoover, Semble & Wise, 1992). According to the International Classification of Functioning, Disability, and Health (ICF), the effects of injury and illness on the dynamic nature of function are based on quality of life, overall health status and impairment associated with societal and environmental factors (Snyder et al., 2008). Activity limitations associated with these gait deficits arise from impairments such as decreased range of motion, flexibility, proprioception, instability, and muscle strength which ultimately results in restricted participation in social activities (Chung-Wei, Taylor, Bierma-Zeinstra, & Maher, 2010).

The treatment of the impairments, activity limitations and participation restrictions associated with knee OA utilize both pharmacological and non-pharmacological approaches. The regimen of therapy varies with the time and diagnosis of the disease. Primary care physicians manage symptoms with NSAIDs, acetaminophen, analgesics and opiates. However, recent evidence suggests that the analgesic effects of these pharmacologic agents may pose a potential threat to the gastrointestinal and cardiovascular system (Grainger & Cicuttini, 2004), and interfere with the histological maintenance of the joint (Hauser, 2010). Additionally, the use of NSAIDs and related analgesic agents only serve to suppress symptoms associated with the impairments and do not delay the progression of the disease (Hurwitz, Sharma, & Andriacchi, 1999). In fact, they may even mask symptoms that ultimately exacerbate the condition.

(Hauser, 2010). Pain continues to be an impairment that leads to limitations in activity and participation in some individuals treated with traditional medications such as acetaminophen and NSAIDS (Bjordal, Ljunggren, Klovning, & Slordal, 2004). Viscosupplementation is an alternative to reduce pain in the knee; however, the side effects include an increase in joint pain and effusion that may require joint aspiration. When combined with a strengthening home exercise program, viscosupplementation treatment demonstrates significant improvements in pain and function in OA subjects when compared to individuals who received viscosupplementation without exercise (Stitik et al., 2007). Since there was not an exercise group in this study, one does not know if exercise alone may produce similar results. Additionally, these treatments may be cost prohibitive for some individuals (Grainger et al., 2004). Bruyere et al. (2002) investigated the effects of oral glucosamine sulfate on the progression of knee OA, based on X-ray comparison at baseline and three years later, in 212 participants randomly assigned to an experimental and placebo group. Those individuals treated with the drug demonstrated 50% less joint space loss when compared to the placebo group. Similar results are noted in response to joint load. In cartilage, glycosaminoglycan content and chondrocyte number increased after exercise. Therefore, exercise can be considered as an alternative, as it provides a protective mechanism for cartilage loss (Roos & Dahlberg, 2005).

In conjunction with the pharmacological management of OA, there are several non-pharmacological approaches including patient education, topical

agents, weight reduction and participation in exercise programs (McCarberg & Herr, 2001). Participation in an exercise program is a recommended treatment in managing knee OA and may be one of the most effective therapies for preventing the disease progression and improving function in individuals with OA (Chung-Wei et al., 2010). Due to the significant increase in frequency of this disease, the American Geriatrics Society Pain on Exercise and Osteoarthritis (2005) suggests that preventing the progression should be a primary goal in treating individuals with OA. When radiographic evidence of the disease is present before the perception of pain, the benefits of a strengthening program may prevent progression that may lead to pain (McAlindon, Cooper, Kirwan & Drieppe, 1992). In cases where progression of the disease results in significant disability, surgery is required to restore function and eliminate pain. At present, surgical options include high tibial osteotomy, total knee arthroplasty and unicompartmental arthroplasty (Webster, Wittwer & Feller, 2003). Deyle (2000) reports that one year after completing a strengthening exercise program, fewer subjects required corticosteroid injections or a need for total knee arthroscopy (TKA) as compared to controls.

Considerable evidence in the literature confirms that strengthening exercises should be employed in the treatment of knee OA; however, confusion exists as to what exercises are the most appropriate and beneficial in meeting the needs of the patient with OA (Brousseau et al., 2005). Traditional exercises tend to focus on the isolation of one or more muscle groups (e.g., quadriceps) in an attempt to address the impairment. Alternately, functional task training

focuses at the **activity level** by strengthening and adapting postural strategies to environmental demands through functional task performance. This type of activity requires coordinated functional movements, task specific balance requirements and incorporates multiple muscle groups and joints working in multiple planes (de Vreede, Samson, Van Meeteren, Duursma, & Verhaar, 2005). Functional task training involves the performance of muscular control activities as well as balance and coordinated movement strategies required to function in an ever-changing environment such as walking up and down stairs and crossing a busy street. (deVreede, et al., 2005; Shumway-Cook & Woollacott, 1995).

In a pilot study, Blundell, Shephard, Dean, Adams and Cahill (2003) investigated functional task specific strength training in children with Cerebral Palsy. Children performed exercises similar to everyday tasks such as walking up and down ramps, picking up objects, step-ups and sit-to-stand activities. Motor skills and isometric strength improved secondary to functional task training. Activity limitations also decreased as evidenced by an increase in walking speed, cadence, distance and the ability to rise up independently from a low chair. One can infer that task specificity training is important in addressing impairments in structure and function and improving one's activity level ability to perform age appropriate functional tasks. A study involving older women yields similar results. In their study, deVreede et al. (2005) compared functional tasks and resistance strength training exercises on activities of daily living (ADL's) in a 12-week pilot study of 70-year-old healthy women. The functional task training

group performed exercises that included a vertical and horizontal movement component for endurance, strength, rising from a chair, stepping on a platform, putting objects on a shelf, and walking while carrying an object. The strengthening group used graded resistance elastic bands, dumbbells and cuff weights to strengthen all muscle groups in the extremities and trunk. Pre and post-test outcome measures included the Assessment of Activity Performance Scores (ADAP), timed up and go test (TUG), isometric strength tests, and leg extension power. ADAP scores were significantly greater in the functional group and isometric strength was greater in the strengthening group; however, the gains in this group were not sustained six months after training. The author's data supports that a 12-week training program consisting of functional task exercises was superior to resistance strength exercise in this population. When addressing disability in the elderly, additional evidence also suggests that functional task training may be more effective than resistance training in preventing functional decline by decreasing activity limitations and participation restrictions in this population (Fieo, Watson, Deary, & Starr, 2005).

Exercise programs designed to help us meet the activity and participation needs of our clients may influence their responsiveness to exercise (Fitzgerald & Oatis, 2004). Thus, creating an exercise program that focuses on functional task training at the activity level may improve exercise compliance and decrease the fear associated with traditional exercise (Campbell, 2005). To date, few studies report the use of functional task training exercise approach in the 45-65 year old

population diagnosed with knee osteoarthritis in addressing their level of activity and participation.

Problem Statement

Treatment of knee OA typically employs the use of non-pharmacological therapeutic exercises. While there is an extensive amount of research involving the effects of therapeutic exercise programs on strength, function and pain, few investigators compare traditional therapeutic exercise programs and functional task training exercise protocols. This 12-week study investigates the effects of traditional exercises and selective functional task training on strength, pain, gait and function in the 45-65 year old adults with OA of the knee.

Experimental Questions:

1. Which exercise protocol has a greater improvement on quadriceps muscle strength?
2. Which exercise protocol has a greater effect on reducing pain, stiffness and improving functional mobility as measured by the Western Ontario and McMaster Universities OA Index (WOMAC)?
3. Which exercise protocol has a greater effect on increasing gait velocity?
4. Which exercise protocol has a greater effect on improving functional mobility performance outcome measures?

Hypothesis:

Functional task training is more effective than traditional therapeutic strengthening exercise programs in decreasing pain and improving strength and functional mobility in 45-65 year old individuals with knee osteoarthritis.

CHAPTER II

REVIEW OF THE LITERATURE

Introduction

Osteoarthritis is the most common form of arthritis among adults 45 and older in the United States (Hunter, McDougall, & Keefe, 2009). It is a non-systemic disease primarily affecting the weight bearing joints of the lower extremity. Primary risk factors for knee OA include gender, congenital malformations, and age. Secondary risk factors include obesity, inactivity, muscle weakness, and heavy physical activity (occupation or recreational) trauma, and malalignment (Felson, 2006). Individuals with a history of injury to their anterior cruciate ligament or menisci were shown to develop knee OA 10 to 20 years post injury (Lohmander, Englund, Dahl, & Roos, 2007). Mechanical trauma can result in arthrological factors, such as varus/valgus deformities, leading to biomechanical modifications. Varus alignment is associated with an increase in adductor moment that is responsible for disease progression (Adriacchi, 1994; Mundermann, Dyrby, & Andriacchi, 2005).

Of the aforementioned factors, secondary risk factors are modifiable. Although difficult to determine which are factors for the development and progression of the disease, researchers agree that obesity is considered the primary risk factor in the progression of knee OA (Taylor, Heller, Bergmann, & Duda, 2004). Weight control, proper body mechanics and regular activity may

minimize or at least diminish pain and disability (AGS panel on exercise & osteoarthritis, 2010; Blagojevic, Jinks, & Jordan, 2009).

Diagnosis and Pathophysiology of the Disease

Recent research suggests the nature of knee OA to be a metabolically active process rather than a condition simply characterized by "wear and tear" of the joint. (Velasquez & Katz, 2010). Currently, researchers regard OA as a metabolic or biochemical phenomenon that involves destruction and remodeling of joints. C- reactive protein, an inflammatory marker, which is evident in early knee OA, can lead to its progression (Spector et al., 1997). Progression of the disease includes the appearance of synovial hyperplasia, osteophyte formation, and capsular thickening (Osteoarthritis, 2001). Osteophyte formation often occurs at the margin of the hyaline cartilage and synovium in response to changes in knee joint loading (Jewell, Watt, & Doherty, 1998). Therefore, osteophyte formation may be the body's attempt at self-repair and redistribution of forces across the joint. This appears to represent an effort by these joint components to reform the joint and surrounding tissues in response to the histochemical changes in cartilage. Although OA was originally thought to involve the articular cartilage, it is now considered a disease of the entire joint, affecting the whole body as a functional unit (McGibbon, 2002). In addition to the breakdown of articular cartilage, there is subchondral bone remodeling with cyst formation, sclerosis, synovial inflammation, muscle atrophy, spasm and ligamentous involvement. Chondrocytes, synovial leukocytes and bone

osteoblasts /osteoclasts produce cytokines, the inflammatory mediators associated with inflammation. Inadequate repair of cartilage results from the imbalance of the catabolic and anabolic processes that drive these inflammatory cytokines. Ultimately, these changes in the biomechanical properties of cartilage result in an abnormal increase in pressure on both the cartilage and subchondral bone (Martell-Pelletier, Boileau, Pelletier, & Roughley, 2008). Mechanoreceptors no longer provide adequate information to muscles, ligaments, tendons and joint capsules regarding cartilage load (Felson, 2006). As insult occurs to the joint, the body's response is to lay down additional bone to contend with compressional and functional forces placed on the joint. A decrease in cartilage volume accompanies a decrease in joint space, which may result in ligament laxity. As a result, loading rates are 21% greater than those in normal individuals (Fischer, White, Yack, Smolinsky & Pendergast, 1997). These physical and histological changes along with capsular thickening, for joint stability, may mark the beginning of the disease.

Confirmation of the structural and mechanical changes in the joint can be viewed radiographically. Physicians employ radiographs to establish the diagnosis and rule out other pathological processes. In 1963, the American College of Rheumatology adopted the Kellgren/Lawrence (K/L) classification based on radiographic evidence as the standard for grading OA severity (Table 1). The K/L scale correlates with MRI's in detecting osteophytes, cartilage defects and joint effusion (Hayes et al., 2005).

Table 1

Grades for Severity of Knee OA According to the Kellgren/Lawrence Scale (Kellgren et al., 1963).

Grade 1	Doubtful joint space narrowing and possible osteophyte lipping
Grade 2	Definite osteophytes and possible joint space narrowing
Grade 3	Moderate multiple osteophytes, definite joint space narrowing and some sclerosis, and possible deformity of bone ends
Grade 4	Large osteophytes, marked joint space narrowing, severe sclerosis, and definite deformity of bone ends

Positive findings associated with knee OA may include asymmetric joint space, loss of articular cartilage, subchondral sclerosis and cysts, and osteophytic formation (Altman et al., 2008; Blagojevic, Jinksy, Jeffery, Jordan, 2010). Although radiographs are used to confirm the diagnosis, the correlation between radiographs and symptoms is not always consistent (Leslie, 2000). The apparent progression in radiographic change does not always correspond to the degree of pain or to the level of functional ability (Blagojevic et al., 2010; Hunter et al., 2008; McAlindon et al., 1993). Thus, despite radiographic evidence, the individual may be asymptomatic (Osteoarthritis, 2001). The results of a survey administered by Peat, McCarney, and Croft (2001) demonstrate that in a population of individuals (mean age, 55 years), 50% had knee pain without radiographic evidence while the other 50% had radiographic evidence without knee pain. Additionally, the presence and extent of radiographic OA does not

predict its progression to a symptomatic state (Kim, Richard, Jones & Hegab, 2003).

Although radiographs are currently used to confirm a diagnosis of knee OA, Magnetic Resonance Imaging (MRI) may be superior in that it allows for direct visualization of the joint (Racunica et al., 2007), and may pick up early OA changes not viewed with radiographs (Watt & Doherty, 2003). To date, radiographs combined with clinical criteria prove to be an excellent and more cost effective alternative in the diagnosis of knee OA (Altman et al., 1986; Flores & Hochberg, 2003; Toivanen, 2007). This clinical classification criterion for idiopathic knee OA includes the presence of knee pain on most days of the month and at least one of the following: age over 50 years, morning stiffness less than 30 minutes in duration, crepitus on active joint motion. Furthermore, there should be radiographic evidence of osteophytes at joint margins. The combination of clinical and radiographic results increases the sensitivity (91%) and specificity (86%) of reaching a diagnosis of knee OA (Altman et al., 1986).

Prevalence and Incidence of OA

According to the Center of Disease Control (CDC), the prevalence of OA is dramatically increasing, and will continue to increase from previously reported numbers of 43 million to 60 million in the year 2020. The disease affects approximately 27 million people in the United States, 33% of whom are over the age of 65 (Lawrence et al., 2008; Sisto, & Malanga, 2006), and it is estimated that the number of individuals aged 65 and over will double in the next 20 years

(Adelman & Daly, 2001). Sixty percent of adults over the age of 50 are afflicted with this disease (Vad et al., 2002). The incidence of knee OA has risen by 22% from 1990 to 2005 (Flegal, Carroll, Ogden, Curtin, 2010). Ten percent of men and 13 percent of women over the age of 60 have symptomatic knee OA (Zhang & Jordan, 2010) and women have a 1.8 times greater likelihood of developing knee OA (Felson, 1997). Although knee OA is prevalent in the elderly, its presence is increasing steadily in middle-aged individuals (40 and over), and is the most frequently reported reason for orthopedic visits (Leslie, 2000). When compared to cardiovascular disease, knee OA is the most frequently encountered disability (Doherty, 2001) and is the primary reason for visits to a primary care physician in individuals over the age of 55 (Peat et al., 2001). Inactivity associated with the disease results in greater impairments and activity limitations which ultimately result in an increase in health care costs (Dunlop et al., 2010). In 2008, the annual cost for treating arthritis and its complications was almost 65 billion dollars in the United States (Zhang, 2008).

Contributing Factors

Obesity

According to the CDC (2005), obesity is a major health problem in our country. Statistics indicate obesity in the United States has doubled between 1971 and 1994 (Fiegel, Carroll, Kuczmarski & Johnson, 1998). Individuals with a body mass index (BMI) greater than 30 are considered overweight, except in those individuals with a low percentage of fatty tissue (Bray, York, & Delaney,

1992). Knee OA is more common in obese individuals than in those of normal body weight (Cooper et al., 2000; Murphy et al., 2008.) Obesity is considered the primary risk factor in the incidence of and progression of knee OA (Messier, et al., 2009; Taylor, Heller, Bergmann, & Duda, 2004). Astephen, Deluzio, Caldwell, and Dunbar (2008) suggest that two thirds of the world population is at risk for developing knee OA in their lifetime.

An obese woman and man with a BMI of 30-35 kg/m² have a four times greater, and 4.8 times greater, respectively, risk of developing knee OA when compared to lean individuals. After a knee injury, this risk increases three fold for women, and five to six fold for men (Spector et al., 1994). Additionally, a higher body mass index (BMI) correlates with a larger concentration of inflammatory mediators, which is associated with functional decline and disease progression (Wolfe, 1997).

During walking, ground reaction forces are exerted by the contact surface on the joints. These forces are augmented in obese individuals, resulting in an increase in knee joint load. Greater muscle force is required to withstand this additional load (Browning & Kram, 2007). As a consequence, obese individuals may chose to walk slower, since walking slower minimizes ground reaction forces and knee joint load. When compared to lean individuals, obese individuals walk with less knee flexion and generate less ankle and knee torque and power when walking at self-selected speeds (DeVita & Hortobagyi, 2003). This suggests that obese individuals may alter their gait to minimize forces

associated with a larger mass, and these alterations may result in compensatory motions at other joints (Bejek, Paroczai, Illyes, & Kiss, 2005).

In 2000, Cooper et al. conducted a prospective radiographic study involving 354 men and women with and without knee pain. In conjunction with radiographs, the subjects completed questionnaires regarding lifestyle, risk factors, medical history and leisure activities. The authors found that both obesity and knee trauma were strong predictors of incidence, as evidenced by a decrease in joint space, and that obesity is a significant variable in disease progression as these individuals demonstrated greater radiographic evidence. To determine the effect of knee OA over time, the Framingham study followed 1420 individuals with knee OA over a 30-year period (Felson et al., 1997).

Radiographs were obtained before and after the study which demonstrated there was a higher prevalence of radiographic changes in women and that overweight individuals are at higher risk for symptomatic and radiographic knee OA (Felson et al., 1997).

Malalignment

At the impairment level, malalignment increases the risk and progression of knee OA (Sharma et al., 2001; Sharma, Dunlop, Cahue, Song & Hayes, 2003); however, the association of incidence and malalignment continues to be investigated (Tanamas et al., 2009). Radiographs are utilized to assess mechanical knee joint alignment by locating the anatomic axis of the knee via the intersection of two lines, which identify the femoral and tibial axis. A varus angle

of 1-2 degrees constitutes neutral alignment (Peat, Mallen, Wood, Lacey, Duncan, 2008). In the elderly, malalignment greater than 5 degrees is associated with greater functional deterioration (Sharma et al., 2001). Varus malalignment is associated with radiographic evidence of decreased tibiofemoral joint space width and an increased external knee adductor moment, which is a marker of OA progression (Andriacchi, 1994; Mundermann, 2005). External knee adduction moments have been linked to an increase in medial knee joint load in individuals with knee varus deformities (Hurwitz, Sharma, & Andriacchi, 1999; Sharma, et al., 2001). Varus and valgus deformities increase the risk of medial and lateral OA progression respectively, which is augmented if an individual is overweight (Sharma, Cahue, & Dunlop, 2000). In the literature, a direct relationship between **has been noted** (Sharma et al., 2000; Sharma et al., 2003). An 18-month longitudinal study examining quadriceps strength and OA progression in individuals with malaligned and/or lax knees utilized baseline isokinetic strength testing and radiographs to determine the presence or absence of malalignment in 237 participants. Additional radiographs were taken 18 months later to assess the progression of the disease. Those individuals with malalignment or highly lax knees showed greater predictability of OA progression. Sharma et al. (2003) conclude that quadriceps-strengthening exercises may produce negative effects on this population. Since their study did not include any strengthening intervention, the negative impact of quadriceps strengthening on knee OA progression in this population is questionable (Sharma et al., 2003).

A subsequent 12-week study investigated the effects of varus malalignment (measured by using 3D motion analysis during gait) on pain and function in individuals with knee OA (Lim, Hinman, Wrigley, Sharma, & Bennell, 2008). Measures of knee varus/valgus laxity were assessed as well as isometric quadriceps and hamstring torque measures. Each participant completed the Western Ontario and McMaster Osteoarthritis Index (WOMAC), which is a 24-question self - assessment questionnaire regarding pain, stiffness and function. Bellamy, Buchanan, Goldsmith, Campbell and Stitt (1988) reported this test to be highly valid and reliable (ICC=.88-.93) for individuals with hip or knee OA. Performance measures included the step test, stair climb test and walking speed. Quadriceps exercises were performed over a 12-week period, which consisted of seated knee extension, short arc quads, straight leg raises and isometric knee flexion exercises with ankle weights and therabands. In this study, the severity of the disease was significantly associated with the degree of malalignment. Both the groups with neutral and malaligned knees had an increase in quadriceps strength and functional measures; however, the increase in quadriceps strength was not associated with an increase in the knee adduction moment in the group with malaligned knees, which may suggest that quadriceps strength may be indicated in this population. In fact, dynamic optimization (i.e. mathematical formulae) utilizing a 3D model for gait analysis demonstrates that during stance, the knee is stabilized in the frontal plane by the quadriceps and gastrocnemius muscles. This muscular stabilization of the knee serves as a mechanism to control the knee adduction moment (Shelbourne, Torry & Pandy, 2006).

Pain

Pain is the primary reason and most significant impairment for physician's visits as well as the ultimate cause for total knee replacements (O'Reilly & Doherty, 2003). Pain is the most common symptom in patients with knee OA and contributes to declines in functional activities such as rising from a chair, climbing stairs, and completing activities of daily living (ADL's) (Sharma et al., 2003). Individuals with knee OA usually describe their pain as a deep dull ache that is aggravated with weight bearing activities such as walking. By the year 2020, an estimated three million people in the United States will have a total knee replacement procedure performed secondary to end stage knee OA (Piva et al., 2010).

Clinicians employ the use of self-report questionnaires in the assessment of pain and function in individuals with knee OA. These include the Medical Outcome Study 36-Item Health Survey Questionnaire (SF-36), the Lower-Extremity Functional Scale (LEFS), the Knee Injury and Osteoarthritis Outcome Score (KOOS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The SF-36, LEFS and KOOS have been reported to be highly valid and reliable tools (Binkley, Stratford, Lott, Riddle, & The North American rehabilitation network, 1999; Roos & Toksvig-Larsen, 2003; Ware & Sherbourne, 1992).

Current research implicates either a nociceptive or neuropathic mechanism as causative agent of OA pain (Kidd, Langford, & Wodehouse, 2007). Central sensitization, the neuropathic mechanism, is thought to result in

modification of the central pain transmitting neurons arising from chronic nociceptor stimulation (Woolf & Salter, 2000). Chronic pain is associated with this central sensitization, which may lead to a hypersensitivity modulating pain transmission resulting in an active process of transmission in both the periphery and the cortex. This “plasticity” can result in excitatory inputs to nociceptive neurons, resulting in additional pain. This may explain why some individuals with OA experience pain in the absence of noxious stimuli (Woolf et al., 2000). Pain characteristics may provide some insights regarding the mechanism of pain. During one-on-one interviews with 52 individuals with hip OA and 92 individuals with knee OA, participants described their pain intensity, duration, and predictability. Many of the participants described their pain as having “pins and needles” and burning, indicating that the pain may be neuropathic in nature (Hawker, et al., 2008) . Individuals with neuropathic pain have hypersensitivity to pressure, cold, heat and light touch (Bennett, Attal, & Backonja, 2007). Intrusive night pain is evident in the later stages of the disease (Woolhead, Gooberman, Hill, Dieppe & Hawker, 2010). Pain at night can cause sleep disturbances in individuals with OA, which may be associated with fatigue, depression, anxiety and disability (Pawlikowska et al., 1994). Night pain is associated with a greater subjective report of fatigue and a reduced sense of well being in these individuals (O’Reilly et al., 2003).

Understanding OA pain from the patient’s perspective may be beneficial in determining the appropriate treatments for pain. However, since pain is subjective, individuals may have different descriptors of their pain. Due to these

variations, pain is difficult to measure (Woolhead, et al., 2010). Yet, an inverse relationship between pain and both strength and function has been reported in the literature (Fitzgerald, Childs, Ridge, & Irrgang, 2002). Additionally, self-reports of physical function may be interpreted by the person as the pain experienced with these activities rather than the ability to actually perform the activities. Since individuals tend to report a decrease in physical function when having pain, performance-based measures should be utilized to assess physical function (Stratford et al., 2006), as these measures are more sensitive to change and less influenced by pain than self-reported measures (Piva et al., 2010). Subject-reported measures of pain and disability do not always correlate with functional performance tests. Therefore, performance measures combined with self-reported measures will yield a more accurate outcome (Stratford et al., 2006).

Medication is often utilized to diminish pain experienced in advanced stages of knee OA. It has been reported that administration of NSAIDS to minimize pain can result in "analgesic arthropathy" due to excessive knee joint loading. Given the noted inverse relationship between pain, adductor moments and external knee flexion moments (Hurwitz, Sharma, & Andriacci, 1999), an excess of medication can disguise the body's recognition and response to pain. Normal cartilage homeostasis is a balance between degeneration and repair. It is well demonstrated that NSAIDS tip the balance in favor of the destructive activities, and in doing so, exacerbate the very condition for which they have been prescribed (Hauser, 2010). Although pain medication is utilized to promote

wellbeing, caution is advised in that overuse may result in progression of joint degeneration. Since pain is inherently a protective mechanism, excess use of analgesics may have shortcomings. Exercises based on improving strength and decreasing activity limitations may prove to be an alternative treatment and minimize the use of this medication in the knee OA population.

MECHANICS/PATHOMECHANICS

Gait

Gait is an automatic phenomenon requiring an intact neuromuscular and musculoskeletal system to coordinate and integrate the kinematic, kinetic, kinesthetic factors associated with it. Pain-free walking is a basic task required for normal locomotion and is an essential component for maintaining an independent life style (Bejek, Paroczai, Illyes, Kocsis & Kiss, 2006). Individuals with OA have difficulty with walking secondary to pain, stiffness and decreased flexibility (Van Baar, Assendelft, Dekker, Oostendorp & Bijlsma, 1999; Dixon et al., 2010). Their altered gait patterns, muscle atrophy, decreased range of motion, decreased strength, loss of function, and knee joint stiffness can lead to activity limitations (Slemenda, Brandt, Heilman, Mazzuca, & Braunstein, 1997; Gingac et al., 2006). Ultimately, painful walking may cause individuals to limit not only their level of activity but also their participation level in the community.

Any pathological process affecting changes in flexibility, stability, strength, power or neural input may produce alterations in temporal-distance parameters that quantify gait including velocity, cadence, step length and stride length (Perry,

1992; Perry & Burnfield, 2010). In the past, clinicians relied on observational gait analysis (OGA) to report on gait characteristics, which can be subjective as personal bias, and/or clinical experience may influence this assessment (Sisto, 1998). Technological advances remove the subjectivity from gait observation by utilizing instrumented gait analysis (IGA), which provides spatiotemporal information on individual gait patterns. Quantitative gait analyses have demonstrated significant gait discrepancies in patients with knee OA (Lafuente, Sanchez-Lacuesta, Soler, Poveda & Prat, 2000). The GAITRite™ is one such quantitative instrumented gait analysis using a walkway containing 13,824 sensors that process raw data into footfall patterns and computes temporal (timing) and spatial (distance) parameters. Mc Donough, Batavia, Chen and Kwon (2001) report the GAITRite™ to be valid and reliable when compared to validated pencil-and-paper and video-based methods with ICC>0.95 and ICC>0.93 respectively. Bilney, Morris and Webster (2003) examined the reliability and validity in 25 healthy adults aged 21-71 years old. The reliability of repeated measures for the GAITRite™ was good at preferred and fast speed for speed (ICC (3,1)=0.93–0.94), cadence (ICC (3,1)=0.92–0.94), stride length (ICC (3,1)=0.97), single support (ICC (3,1)=0.85–0.93) and the proportion of the gait cycle spent in double limb support (ICC (3,1)=0.89–0.92). The repeatability of the GAITRite™ measures was more variable at slow speed (ICC (3, 1) =0.76–0.91).

During normal walking, adults ambulate at a speed that minimizes excessive energy expenditure. Healthy 40-60 year old women and men walk between 1.35m/s and 1.41m/s respectively when ambulating at a comfortable

speed (Appendix F, Table 2). These values can increase to 1.94 and 2.19 m/s when individuals walk as fast as they can without running (Bohannon, 1992). Individuals with knee OA ambulate with significantly reduced walking speed, lower cadence, shorter stride length, and with a more prolonged stance phase of the gait cycle compared to age-matched controls (Adriacchi et al., 1982; Baliunas et al, 2002; Gok et al., 2002; Hurwitz et al., 2000). These adaptations may be attributed to limb avoidance secondary to pain (Al-Zahrani & Bakheit, 2002; Andriacchi, Galante, & Fermier, 1982; Baliunas et al., 2002). People with knee OA employ a re-programming mechanism of the neuromuscular system which alters normal patterns that may result in minimizing joint loading forces during gait (Robon, Perell, Fang & Guererro, 2000). Walking slower is also associated with a reduction in these joint forces. Values of approximately 25% less or greater, dependent on the parameter measured, have been reported for knee OA individuals when compared to controls (England & Granata, 2007). As the disease progresses, gait speed can be reduced as much as .55m/sec. in some individuals (Zoltan et al., 2006). Gait speed has been found to be directly proportional to single stance time and inversely proportional to double support time (Perry, 1992). Most importantly, a decrease in gait speed is associated with activity limitations (Edmund, 1997) and accounts for individual gait variations as well as force attenuation (Perry, 1992). During normal walking, the knee encounters compressive forces that are equal to three to six times an individual's body weight (Grainger & Cicuttini, 2004). This increase produces an augmented contact force at the knee joint (Kaufman, Hughes, Murray, Kai-Nan 2000). An

increase in walking speed requires augmented force and duration of the knee musculature to accommodate the increase in ground reaction force associated with faster walking speeds (Andriacchi et al., 1977). Thus, muscle activation is an important contributor to all joint forces about the lower extremity throughout the gait cycle.

The gait cycle constitutes both the stance and swing phase. The stance and swing phase, periods during which one (single support) or both feet (double support) are in contact with the floor, account for 62% and 38% of the gait cycle respectively when an individual walks at a rate of 80m/min (Perry, 1992). When the foot strikes the floor during load phase, external ground reaction forces are directed vertically through the ankle, knee and hip, causing the knee to flex. To counterbalance the external moment and minimize joint forces, the quadriceps must produce an internal moment large enough to balance the external moment to resist knee buckling and absorb the forces associated with these knee joint loads (Winter, 1991). Quadriceps weakness during this weight bearing phase may result in increased activity of the hip extensors and ankle plantarflexors to contribute to the net support moment (Oatis, 1994). It is interesting that while some individuals with knee OA may reduce their knee flexion at heel strike to minimize these ground reaction forces (Childs, Sparto, Fitzgerald, Bizzini, & Irrgang, 2004; Mundermann et al., 2005), others demonstrate an increase in knee flexion during the loading phase (Heiden et al., 2009), which requires a greater net internal moment to accommodate for this increased joint angle. Also, an increase in knee flexion (Baliunas et al. 2002, Childs et al., 2004) as well as

extension (Munderman, 2005) has been reported in the literature and further contributes to the knee instability seen in the individual with OA.

Knee instability (buckling, shifting, or giving out) in the OA population is associated with factors that include muscular weakness, ligament laxity, proprioception deficits, malalignment and pain (Fitzgerald, Irrgang, Piva, Irrgang, & Bouzubar, et al., 2004). These individuals adopt a “quadriceps avoidance gait” which limits the quadriceps eccentric muscle control at knee flexion, resulting in an increased knee joint load (Taylor, Bergmann, Heller, & Duda, 2004). In the event that this loss of stability is caused by the inability of the hamstrings or quadriceps muscles to generate adequate torque (Kannus & Jarvinen, 1997), muscular co-contractions stabilize the joint (Lewek, Rudolph & Synder-Mackler, 2003a). This increased muscle activity around the joint results in a “stiffness” that compensates for joint instability, but these co-contractions increase the energy expenditure associated with walking (Kuo et al., 2010). Furthermore, these contractions can increase the adductor moment (Heiden et al., 2009). In the normal knee joint, loads are disproportionately transmitted to the medial compartment (Morrison, 1968). Forces attenuated at the medial joint during gait constitute 60-80% of the total force transmitted across the knee joint, and are 2.5 times greater than lateral forces (Baliunas, Hurwitz, Ryals, Karrar, Case, Block: et al., 2002). As the ground reaction force passes medial to the knee, the knee joint attenuates 70% of the load (Andriacchi, 1994). There is an increase in the external knee adductor moment, in both early and late stance, which results in medial compartment load distribution across the tibial plateau (Andriacchi, 1994;

Teichtahl, Wluka, & Cicuttini, 2003; Lim et al., 2008). As this external ground reaction force passes medial to the knee, In the OA population there is a larger and more variable external knee adductor moment associated with walking when compared to normals, at terminal stance (Hurwitz, Ryals, Case, Block & Andriacchi, 2002), resulting in an increase in pain as the forces are augmented. Therefore, co-activation augments these forces and contributes to the progression of OA in the already compromised joint (Lewek et al, 2005) and can result in an increase in energy expenditure (Kuo & Donelan, 2010) in an individual who may already be experiencing fatigue (Bouzubar, & Fawzi, 2003).

Forces become greater during single limb support as the center of gravity (COG) shifts to the support leg with the trunk, and the hip adducts to maintain the center of mass over the stance foot (Oatis, 2004). A correlation has been noted between the severity of disease and single limb adduction moment during gait (Kim et al., 2003). These moments are further augmented as an individual walks faster; (Andriacchi, Ogle, & Galante, 1977; Thorp, Sumner, Block, Moio, Schott, & Wimmer, 2006); therefore, individuals with knee OA decrease their walking speed to decrease these external forces (Thorpe et al., 2006). Since these external knee adduction moments are greater in magnitude than those in the sagittal plane, individuals with knee OA utilize compensatory mechanisms to decrease joint loading (Al-Zahran et al., 2002; Bejek et al., 2006; Hurwitz et al., 1999). Subjects with medial joint compartment involvement may reduce the load by turning their foot outward, decreasing stride length and/or leaning their trunk toward the affected extremity. This allows the load to be distributed across the

entire joint for attenuation of ground reaction forces (Hurwitz, et al., 1999). These forces increase proportionally with overweight individuals. Body mass index (BMI) is linked with medial compartment OA and both are related to varus deformities (Sharma, et al. 2000). Since body mass is proportional to joint loading, overweight individuals may demonstrate even larger adaptations during gait (DeVita et al., 2003).

Finally, the ankle and/or hip can compensate for mechanical changes that result from knee pathology (Levangie & Norkin, 2002). Robon et al. (2000) found that subjects decreased plantarflexion moments during terminal stance to prevent anterior tibial advancement. The increase in dorsiflexion causes the tibia to displace anteriorly, therefore decreasing the in-line knee joint reaction force, thus preventing large compressive forces at the knee. Gait velocity can also be amplified by increasing the hip flexion moment during terminal stance in these individuals (Fisher et al., 1997; Robon et al., 2000). The increased hip flexor moment results in picking up rather than pushing off the foot to initiate initial swing. In both circumstances, these compensatory strategies serve to decrease knee joint forces and shorten stride length (Robon et al., 2000).

Stairs

Although stair climbing is similar to walking, the biomechanical demands are greater in this activity. A stair climbing task requires greater sagittal plane control as the moments increase threefold when walking up and down stairs (Levangie & Norkin, 2005) with greater knee extensor torque and power required

to perform this task (Mizner & Snyder-Mackler, 2005). Thus, the ability to efficiently ascend/descend stairs is dependent on both joint mobility and muscle strength (Perry et al., 2010). Negotiating stairs can be very challenging for individuals with knee OA (Whatling et al., 2008). Individuals with knee OA often report the need for a handrail to get up from a chair or climb a set of stairs. Women demonstrate greater knee flexion angles and larger knee external moments during both stair ascent and descent (Hughes, Kaufman, Morrey, Morrey & An, 2000), which may explain the increased incidence of OA in this gender (Felson, 1997).

When compared to level walking, the knee sustains a 12-25% greater joint load when climbing stairs (Whatling et al., 2008). Forces in single leg stance increase threefold for every one pound of body weight, therefore, obesity may adversely affect load distribution when climbing stairs (Felson, Reva, Dieppe, Hirsh & Helmich, 2003). Emphasis is placed on the knee and lower extremity muscles to advance the body forward against gravity while clearing the contralateral leg. As the body advances forward, the weight-bearing limb accepts the body weight from the contralateral limb as well as advancing the head, neck and trunk (HAT) over the limb. This requires the hip and knee extensors to load concentrically while the hip abductors maintain a level pelvis. Greater range of motion and larger internal moments are required with this activity at these joints (Kaufman, Hughes, Morrey, Morrey, & An, 2001). During weight acceptance at load phase, there are increased demands for the quadriceps muscles to absorb shock and maintain stability when accepting the

body weight. Individuals with advanced knee OA ascend stairs by decreasing peak external knee flexion moments while increasing the peak hip external moments (Asay et al., 2008), which results in a lateral trunk lean while ascending/descending stairs. This adaptive mechanism assists in unloading the medial joint compartment (Hunt, Wrigley, Hinman, & Benell, 2010). Advancing the leg during stair ascent is accompanied by a forward trunk lean, which appears to be a compensatory strategy to decrease knee joint load as it correlates with a reduction in net quadriceps moment (Asay et al., 2008). Although this strategy is effective for reducing joint forces, these compensations can alter lumbar spine biomechanics (Whatling et al., 2008).

Descending stairs places a greater demand on the knee. During weight acceptance at the load phase, there are increased demands for the quadriceps muscles to absorb shock and maintain stability when accepting the body weight in order to advance the swing limb. These eccentric quadriceps muscle contractions are associated with greater muscular control which, in turn, increases compressive forces on the knee joint (Radin, Paul, Rose, & 1972). It comes as no surprise that these individuals report more difficulty with this activity, as external knee flexion moments are six times greater with stair descent (Hughes et al., 2001).

Muscular Weakness

Arthrogenous muscle inhibition is a phenomenon described as muscle inhibition secondary to altered afferent input from a diseased joint. This results in

a reduction in efferent motor neuron stimulation of the quadriceps (Hurley et al., 1998).

In individuals with knee OA, joint effusion may prevent full voluntary activation of muscles that cross the joint. This phenomenon has been termed arthrogenous muscle inhibition (AMI), which results from abnormal afferent information elicited from the damaged joint (Hurley & Newham, 1993). AMI reduces the number of motor units supplying the major muscle group crossing the knee, i.e., quadriceps. This decrease in full muscular activation has a direct contribution to quadriceps muscle weakness and resultant muscle atrophy (Hurley et al., 1993; Stevens, Mizner, & Snyder-Mackler, 2003). Lewek, Rudolph and Synder-Mackler (2003b) report that the failure of the central nervous system (CNS) to activate the quadriceps muscle suggests that abnormal afferent information is sent to the motor neuron pool. The literature identifies investigative methods for activation failure. These include twitch interpolation and burst superimposition techniques. The former represents a single supplemental stimulus (delivered via electrical stimulation) applied to a voluntary maximally contracted muscle where the latter is delivered by a stream of supplemental stimuli (delivered in the same fashion). If there is additional recruitment greater than 5% elicited after the application of the electrical stimulus, the percent deficit is proportional to the degree of activation failure. A mathematical ratio that results in 1.0 implies full activation of a muscle (Lewek et al., 2003b). Hurley and Scott (1998) believe AMI may be part of the pathogenesis of degenerative joint diseases. As these muscles become weaker, the joint's ability to withstand

load diminishes. This added joint stress results in knee pain and subsequent gait alterations. Individuals modify their gait pattern by decreasing walking speed, lowering cadence, decreasing stride length and increasing stance phase to compensate for knee pain and/or instability.

Both normal (experimentally effused) and pathological knee joints (with effusion) exhibit full volitional quadriceps activation failure (Hurley et al., 1993). In a group of knee OA participants (mean age of 61) who reported little to no pain or joint effusion, maximal voluntary contraction (MVC), quadriceps activation or voluntary activation (VA) were 72.5% when compared to 93% in an age matched control group (Hurley et al., 1997). In the elderly, peak torque relative to body weight, was 20% less in individuals with symptomatic or radiographic evidence of knee OA (Slemenda et al., 1997). Quadriceps activation failure has been linked to a decline in physical function in individuals 45 years and older with knee OA (Fitzgerald, Piva, Irrgang, Bouzubar, & Starz, 2004), and is found to be the greatest single predictor of lower limb functional limitations, exceeding that of knee pain (Felson, 2006; Kijowski, Blakenbaker, Stanton, Fine & De Smet, 2006). These functional activity limitations are compounded in the elderly, as there is a 40 % decrease in strength of these muscles with advancing age (Jahagirdar & Kendre, 2010). Addressing deficits associated with knee OA in the middle-aged population may delay or lessen the development of these activity limitations.

In 2002, Berth, Urhuch and Awiszus examined maximal voluntary contractions in knee OA patients before and after a total knee arthroscopy (TKA)

and found similar results; however, after surgery, strength deficits persisted. In addition, the non-operational leg demonstrated a decrease in strength as compared to age-matched controls. After a three-year period, these investigators re-evaluated strength in the study participants. They found that although MVC's improved, quadriceps strength was still considerably lower when compared to controls. Other investigators examining this population found similar results in strength deficits (Fitzgerald, 2005; Stevens et al., 2003). Interestingly, Berth et al. (2002) found that even after an exercise intervention, their subjects employed compensatory mechanics in performing a sit-stand task one year post surgery, suggesting the need to incorporate functional training in an exercise program (Farquhar, Reisman, & Snyder-Mackler, 2008). Diminished quadriceps muscle strength has been associated with progression of the disease and may represent the initiation of knee OA on the quadrilateral limb (Zeni & Snyder-Mackler, 2010). The results of the "Chingford knee" study demonstrate that 50% of 45-64 year old obese females with unilateral OA developed incident changes in their contralateral knee over a two year period (Spector, Hart, & Deyle, 1994).

Rehabilitation Exercises for Knee OA

Several practice guidelines recommend exercise for individuals with knee OA. The Ottawa Panel (Brousseau et al., 2005), European League Against Rheumatism (EULAR) (Pendleton et al., 2003), American Academy of Orthopedic Surgeons (Voelker, 2009) and American College of Rheumatology (Altman, Hochberg, Moskowitz, & Schnitzer, 2000) reviewed numerous

randomized controlled studies regarding knee OA and developed exercise recommendations for treatment. Although recommendations vary, they all agree that exercise is an integral component in the treatment of knee OA. However, insufficient data exists to determine the frequency, duration and intensity of the exercise program. To date, only the Ottawa Panel (2005) has evaluated the specific exercises in relation to their outcomes, particularly for the management of pain and improvement in function.

The goal of an exercise program for knee OA is to minimize pain and improve function; however, systematic reviews of physical therapy interventions suggest this cannot be accomplished utilizing a specific approach (Jamtvedi et al., 2008). The literature supports strengthening, aerobic, flexibility, stability, mobility, proprioceptive and balance exercises in the treatment of individuals with knee OA (Devis-Comby, Cronan, & Roesch, 2006; Deyle, 2000; Fitzgerald, 2000; Huang et al., 2003; Hurley et al., 2002; Gur et al., 2002; McCarberg & Herr, 2001; Pendleton, et al., 2000). These types of exercises have been recommended with only moderate noted benefits in decreasing pain and improving function (vanBaar et al., 2001). Additionally, long term beneficial effects have not been extensively studied (Dunlop et al., 2010) and those that have indicate that the positive effects of exercise diminish and ultimately disappear over time (Pisters, Veenhof, deBakker, Schellevis & Dekker, 2007). Given that low levels of physical activity correlate with functional decline in the OA population, it is important that the activities associated with rehabilitation continue long after the completion of the rehabilitation program.

Recognizing the need to maintain physical function in this population, Dunlop et al. (2010) examined factors associated with aspects that would improve or control OA over a period of time. Longitudinal data, taken from the OA initiative study, included baseline measurements of the chair stand test, the 20 meter walk and completion of the PASE, which is a 26 question self-administered physical activity questionnaire. Questions are based on ADL's, purposeful exercise, sport activities and walking. They merged initial intake data from the OA initiative study (which included 2274, 45-79 year old participants) with data one year post and found that physically active adults had greater performance outcomes in function as evidenced by significant improvements in both the 20 meter walk and chair stand test. These findings suggest a correlation between a healthy active lifestyle and performance maintenance outcomes. Additionally, functional task training, where activities are designed to mimic ADL's may encourage a more active lifestyle, and therefore decrease functional limitations (Pisters et al., 2007).

Rehabilitation exercises that are designed to improve muscle strength are based on exercises that address the individuals' impairment rather than their functional limitations as defined by their activity and participation level. Isotonic, isokinetic and isometric strengthening exercise programs, which address impairments, have been utilized in knee OA protocols with positive significant results in strength gains (Huang et al., 2003); however, ADL's involve the integration of cognitive, perceptual and motor functions influenced by the variability of the individual's dynamic environment. (Mulder, 1991). Thus,

impairment-based exercises (e.g. quadriceps strengthening) may not effectively improve functional performance levels. Additionally, the inability to coordinate complex musculoskeletal control must also take into consideration environmental demands for effective performance of the task (Shumway-Cook & Woollacott, 1995).

Functional task training, task specificity and functional training have long been utilized in stroke rehabilitation (Carr & Shepherd, 1982). Practicing motor tasks in the context of the environment for which it is to be carried out has been found to promote motor learning. The theoretical framework supporting functional task training suggests that functional improvement necessitates practice of the actual task and that motor neuron pools are organized according to specific tasks, not specific muscles (Platz, 2004). The extent and efficiency of the motor skill transfer is enhanced by the performance of that task-specific activity (Schmidt & Lee, 2005), which increases muscle performance and sensorimotor integration, resulting in optimal functional performance (Ageberg & Roos, 2010).

An article often cited in evidence-based practice literature (Brousseau et al., 2005; Kelley et al., 2004; Krohn & Fitzgerald, 2006; Pisters et al., 2007) includes a longitudinal study that addressed the entire lower extremity in its treatment approach for knee OA (Deyle et al., 2000). Exercises were tailored for subjects with knee OA according to the individual's abilities. Significant improvements were noted for both self-reported (WOMAC) and functional performance (six-minute walk test) in the exercise group, which were sustained

one year after the study. Since benefits were sustained for one year after the study, individual tailoring of an exercise program that addresses functional limitations appears to be optimal (Fitzgerald & Kelley, 2004).

In 2001, McGibbon, Puniello, and Krebs examined the issue of practice organization in a cohort of 60 year-olds with OA who participated in either a strength training or functional task training program. While strength and walking speed increased in both groups, the functional task training group demonstrated a reduction of compensatory hip involvement associated with knee OA; whereas the strengthening group demonstrated an exaggerated compensatory gait pattern. This finding further supports previous findings that in an effort to decrease knee joint load, individuals with knee OA utilize compensatory strategies to augment work done at their ankle or hip (Levange et al., 2002; Robon et al., 2002). In a subsequent study by McGibbon, Krebs, and Moxley Scarborough (2003), a group of fifteen 62-85 year old participants with lower extremity arthritis were randomized to either a functional task training group or strength-training group. The functional task group performed various ADL's (e.g. rising from a chair, holding objects while walking, picking up laundry baskets and walking around obstacles, etc.), while the strength training group utilized graded elastic bands and performed extremity and trunk strengthening exercises. Environmental demands were addressed by varying the floor surface and step height in the functional task group. Both groups improved in strength; however, the functional task group demonstrated greater gains, 15.6% and 25.6% respectively. Gait speed also increased significantly in both groups. Normal gait

involves greater work at the ankle and knee than at the hip (Perry et al., 2010). The strength-training group increased their hip power, while the functional task group improved their walking speed by increasing ankle and knee power, indicating a return to more normal gait. The functional task group also demonstrated a significant decrease in double support time. Another important finding in this study was the reduction in knee torque during the chair rise test for the functional task group. This finding suggests this group was more functionally efficient in translating their anterior momentum into a more vertical one by decreasing trunk flexion which decreased hip and knee joint flexion. This is consistent with reductions of knee and hip torque. Since this activity was one of the tasks practiced in this group, it is evident that the extent and efficiency of the transfer of the task is enhanced by the performance of that task specific activity (Schmidt & Lee, 2005).

Although the literature is limited for functional task training in knee OA, the available data does support the benefits of functional task training. As previously mentioned, deVreede et al. (2005) found significant improvements in fitness scores of 70 year old women who performed functional task exercises compared with an age-matched group assigned to a traditional strengthening exercises. Whitehurst, Johnson, Parker, Brown, and Ford (2005) found similar results in their 12-week study of functional task exercises with an elderly population. The exercises included wall squats, single leg balance, star exercise, modified push-ups and walking over obstacles while carrying bags. The environment was varied by obstacle height, changing directions and walking backward. Outcome

measures were significant for the get up and go test (TUG), standing reach, sit and reach and self-report of physical function. In 2008, Milton, Porcari, Foster, Gibson, and Undermann modified the exercise program of Whitehurst et al. (2005) and added a control group to their study who were instructed to carry out their usual exercise regimen. Their results also indicated that the functional task group demonstrated significant improvements in performance tests. In a pilot study of 45-65 year old knee OA subjects, who were randomized to either a functional task training or traditional exercise group, Stutz-Doyle (2008) found the functional task training group demonstrated a significant increase in quadriceps muscle strength and gait velocity as well as greater improvements in TUG scores.

An exercise program tailored to the individual's diagnosis, lifestyle, habits and co-morbidities may well provide a rehabilitative program that may be more positively embraced and adhered to for a longer period (Pisters, et al., 2010). Although well documented as initially successful, strengthening exercise programs are often abandoned and the initial successful results are minimized (vanBaar, et al., 2001). Non-compliance with home exercise programs is an issue in people with knee OA secondary to several psychometric variables such as age, culture, fear and motivation (Campbell et al., 2005). Some older adults with knee OA believe that exercise and activity will exacerbate the pain and symptoms associated with this condition (Wilcox et al., 2006). Furthermore, exercise that requires additional equipment and special scheduling constraints may present obstacles in the course of rehabilitation. Activities that are part of a

person's lifestyle or personal history may be more readily adopted and adhered to over time (Veenhorf et al., 2006). Since there is limited information regarding the benefit of functional task training programs in the OA population over strength training exercises, further investigation is warranted in the knee OA population; therefore, the purpose of this study was to investigate whether functional task training would be more effective in decreasing pain, improving strength and increasing functional mobility in this population

CHAPTER III

METHODS

Subjects

Following approval from Seton Hall University Institutional Review Board and Essex County College (Appendix A, B), subject recruitment was initiated. A convenience sample of 25 subjects was recruited via flyers and web postings from the staff of Essex County College and Seton Hall University (Appendix E). Once subjects volunteered for the study, they were provided with a questionnaire packet to determine their eligibility for the study (Appendix C). If eligible, they met with the primary investigator who explained the study details, obtained their informed consent, and were randomized to one of 2 groups, the Traditional exercise group (TE) or the Functional task training group (FTT). Over a two year period, 25 subjects consented to participate. Five dropped out secondary to scheduling conflicts.

Inclusion Criteria:

Subjects were included in the study if they were between the ages of 45-65 years, had knee pain of four months or longer, were able to walk 100 feet without resting and without an assistive device, able to ascend/descend 9 stairs, able to lift a 4 pound box from the floor and stand up, were not taking anti-inflammatory medication, and had a diagnosis of knee OA based on radiographic results obtained by physician report.

Exclusion criteria:

Subjects were excluded from the study if they had any of the following: presence of a neurological disease, uncontrolled low or high blood pressure, uncontrolled cardiopulmonary or respiratory condition, the inability to rise from and return to a chair without assistance, any additional musculoskeletal diseases or surgeries, and were actively participating in an exercise program.

Instrumentation

Western Ontario and MacMaster Universities OA Index (WOMAC)

The WOMAC (Appendix J) is a self reported (verbal or visual analogue scale) 24-item questionnaire that focuses on pain (5 questions), stiffness (2 questions) and functional limitations (17 questions) related to knee osteoarthritis on separate visual analogue scales. Both 100 mm VAS scales and 5 point Likert scales are utilized. However, the VAS scale has been found to be more sensitive (Bellamy, 2002). It produces 3 subscale scores on pain, stiffness and function as well as a total score. Higher scores correlate with greater pain, stiffness and dysfunction. In this study, all subset and total scores were calculated and reported based on the 100 mm scale. The WOMAC is the only self-assessment questionnaire that provides an operational definition regarding lower extremity function which states "by this we mean your ability to move around and to look after yourself" (Stratford, Kennedy, & Woodhouse, 2006). Bellamy, Buchanan,

Goldsmith, Campbell and Stitt (1988) reported this test to be valid and reliable (ICC=.88-.93) for individuals with hip or knee OA. McConnell et al. (2001) have reported excellent validity, reliability and responsiveness for pain and function subscale and good reliability for stiffness subscale in this patient population.

Timed Up and Go Test

The Timed Up and Go Test assesses balance and mobility in older adults and has established reliability of ICC=.99 (Podsiadlo & Richardson, 1991). It requires the subjects to get up from a standard height arm chair and walk 3.0 meters to a designated finish line, turn around, walk back to the chair and sit down. Time to complete the test is recorded in seconds. Shumway and Cook (2000) report a score greater than 13.5 seconds is associated with predictability for falls in the elderly. Piva et al. (2004) have investigated reliability for this test and reported intertester reliability between ICC=.94 and ICC=.99 and intratester reliability between ICC=.72 and ICC=.98 in patients with knee OA.

The Stair Climb Test

The Stair Climb Test is a functional performance test that requires the subjects to ascend/descend nine stairs while holding on to a handrail. The time required to perform the task is recorded in seconds. A decrease in time required to perform the task indicates improvement. Stratford et al. (2006) reported a test-retest reliability of ICC=.90 in patients with knee and hip OA.

Berg Balance Scale (BBS)

The Berg Balance scale is a functional performance test that examines 14 common movement tasks such as sit-to-stand, stand-to-sit, standing with eyes closed, tandem walking, single leg stand, reaching, picking up an object from the floor, alternating foot on stool, looking over the shoulders and turning 360 degrees. The BBS is scored on a 0-4 point ordinal scale where 0 indicates the inability to perform the task and 4 indicates the ability to perform the task independently (Appendix H). Therefore, a total score of 56 indicates maximal independence. Piotrowski & Cole et al. (1994) report a test-retest reliability of $ICC=.90$ in the elderly. Noren et al. (2006) reported interrater reliability of $ICC=.97$ in patients with peripheral arthritis. Validity is reported to have moderate to high correlations with other performance measures such as the TUG, and gait speed (Hayes & Johnson, 2003).

GAITRite™

The GAITRite™ is an instrumented gait analysis using a walkway containing 13,824 sensors that process raw data into footfall patterns and computes temporal and spatial parameters. The mat is connected via serial port to a Dell laptop personal computer and trial data is collected at a sampling rate of 80 Hz. The system has a high test/retest reliability and high concurrent validity. McDonough, Batavia, Chen and Kwon (2001) reported the GAITRite™ to be valid and reliable when compared to validated pencil-and-paper and video-based methods with $ICC>0.95$ and $ICC>0.93$, respectively. Bilney, Morris and Webster (2003) examined the reliability and validity in 25 healthy adults aged 21-71 years old. The

reliability of repeated measures for the GAITRite™ was good at preferred and fast speed for speed (ICC (3,1)=0.93–0.94), cadence (ICC (3,1)=0.92–0.94), stride length (ICC (3,1)=0.97), single support (ICC (3,1)=0.85–0.93) and the proportion of the gait cycle spent in double limb support (ICC (3,1)=0.89–0.92). The repeatability of the GAITRite™ measures was more variable at slow speed (ICC (3, 1) =0.76–0.91). Based on this information, the GAITRite™ system has strong concurrent validity and test retest reliability. To eliminate the effect of leg length differences between subjects, normalized velocity is reported as cm/s/LL.

Biodex Multi-Joint Advantage v3.2

The Biodex Multi-Joint advantage v3.2 program is a standard non-invasive tool used to assess physical impairments prior to initiating and during a rehabilitation program. The Biodex was calibrated daily in accordance with the system manufacturer's instruction manual. Reliability and validity of measurements of the Biodex Multi Joint System have been reported by Drouin, Valovich-mcLeod, Shultz, Gansneder, & Perrin (2004) with ICC>.99 for peak torque knee extension in healthy individuals. To control for inter-subject variability, quadriceps muscle strength was measured utilizing the average peak torque/body weight ratio for all subjects.

Procedures

On the first day of the study, the subjects read and signed the informed consent. The principal investigator answered any questions the participants had

regarding the study. The subjects were randomly assigned to either the TE or FTT group by a research assistant, who was a physical therapist. Once assigned, an additional research assistant (a physical therapist, who will be referred to as the testing research assistant) performed all the testing procedures. Subjects answered questions regarding demographics as part of the GAITRite™ and Biodex program package (i.e. body weight, height, age, dominant leg). In addition, they completed the WOMAC questionnaire followed by performance tests. Performance measures from the GAITRite™, Timed Up and Go Test (TUG), Stair Climb Test, Berg Balance Scale, and Biodex strength measurements were administered by the testing research assistant in a random order and counter-balanced across all subjects in both groups. Both groups participated in a supervised exercise program in the Essex County College (ECC) Physical Therapist Assistant (PTA) laboratory two times a week over a twelve-week period. The primary investigator, another physical therapist, was blinded to group assignment and performance measures data. This investigator supervised both exercise programs.

Performance measure tests were completed at baseline, six week and twelve week periods. All tests were given in a random order and counter-balanced across all subjects in both groups. Subjects wore the same footwear for all tests. Bilateral leg length measurements were obtained by placing a metal measuring tape from the superior aspect of greater trochanter to a line on the floor bisecting the lateral malleolus. All data regarding age, height, weight and leg length were entered prior to gait trials. For the GAITRite™, a line was placed five

feet before and after the walkway to minimize the impact of acceleration and deceleration. Subjects walked at a self selected pace for five times. Data collection began at each initial footfall. Data for a particular trial was discarded, and redone, if the subjects began or ended at an incomplete footfall. For the Timed Up and Go Test, subjects rose from a standard height chair with armrests and walked (at a regular comfortable pace) for 3.0 meters to a finish line marked with a piece of white tape before turning around, walking back to the chair and sitting down. Data on five trials was recorded by the research assistant. For the stair climb test, the subject ascended/descended nine stairs at a comfortable pace and the time it took to perform the test was recorded. For the BBS, the research assistant followed the established protocol for the BBS. Quadriceps strength was assessed with the Biodex Multi-Joint System. The control panel was set in an "isometric mode". An isometric contraction is not accompanied by movement of the joint. The muscle is neither lengthened nor shortened, but tension changes can be measured. This mode is selected to measure the peak muscular force (torque) generated by the muscle. For all subjects, the seat cushion was positioned at a height of 27 inches above the platform, which is seven inches off the ground. The chair was adjusted for each individual so the subject's trunk was in a vertical position (flexed to 90 degrees at the hip) to ensure that the subject's knee rests comfortably against the front edge of the cushion. The subject's lower leg was attached to the arm of the apparatus with the knee flexed to 70 degrees. A padded support was attached with velcro above the ankle and a velcro strap was anchored across the anterior thigh to

stabilize the femur and hip. The subject was familiarized with the test procedure prior to testing and was verbally coached to push as hard as possible against the distal pad attached to their ankle. Visual feedback was provided via a computerized screen monitor which displays the amount of force utilized. Subjects executed an initial practice trial to familiarize themselves with the apparatus, followed by five testing trials which were averaged to obtain a mean score. The subjects completed five trials and the averages of quadriceps strength (peak torque/body weight) parameter was used for data analysis.

Exercise Protocols

Two exercise programs were utilized in this study. The TE program consisted of exercises that targeted the level of impairment (muscle strength), while the FTT program concentrated on exercises concerned with the body as a whole. The intensity of exercise was monitored based on the Borg Perceived Exertion Scale (Appendix I). The resistance load is equated with a moderately intense rating (#3) on the scale. As perceived exertion decreases, resistance/time is increased, thus ensuring the tailoring of the individual's needs to the increase in resistance (Topp, Woolley, Hornyak, Khuder, & Kahaleh, 2002).

Subjects in the TE program performed four-way straight leg raises (4 way SLR's), seated knee extension, wall slides, step ups, and ambulation on the treadmill. All exercises were supervised by the principal investigator. Three sets of eight repetitions were performed for each exercise. Weight/repetition

progression was based on subject's tolerance. Subjects ambulated on the treadmill at their own pace for a period that did not exceed 15 minutes. Functional tasks included sit to stand box lift, standing star exercise, walking up and down a ramp while holding a weight, ascending/descending stairs while holding a weight in the preferred hand, and walking indoors while passing a weighted ball from hand to hand. All exercises were supervised by the principal investigator. Subjects performed the exercises for one minute with (when indicated) a one pound weight. Progressions included either an increase in weight or time to perform the activity.

Data Analysis

Analysis of all data was done using the IBM Statistical Package for Social Science Software (SPSS) version 19.0 for Windows.

This study utilized a two-way design with one non-repeated measure of patient grouping and one repeated measure of time, or a 2x3 mixed design. Dependent measures included normalized gait velocity (cm/s/LL), performance test scores and average/peak torque to body weight. Independent variables included both levels of exercise. Descriptive statistics were used at baseline to determine demographic variables, which included age, gender, BMI, height, weight and leg length. Independent t-tests were performed to compare baseline statistics between randomized groups. To determine equivalence between groups for non-parametric data, the Mann Whitney U tests were utilized.

A Two-Way repeated measures ANOVA was performed to determine significance of group (TE and FTT), time (baseline, week 6 and week 12) and interaction of group and time (group x time) for all outcome measures. The group across time interaction would be of greatest interest since if it is significant, it means the groups are performing significantly different over time. To ensure sphericity, Mauchly's Test was utilized to test for the equivalence of the hypothesized and observed variance/covariance patterns. Significance suggests that there are unequal variances and covariances which are likely to yield an inflated Type I Error; therefore, the Greenhouse-Geisser epsilon correction was used for this data. If there was an interaction, then testing for simple effects was performed with multiple comparison tests utilizing post hoc paired t-tests with Bonferroni correction ($p < 0.01$) which was obtained by dividing the familywise error rate (0.05) by the number of tests performed. For the non-parametric data (BBS), the Friedman test was done, followed by Wilcoxin Signed Ranks with Bonferroni correction ($p < 0.01$) to determine evidence of the difference.

CHAPTER IV

RESULTS

Subject Characteristics and Baseline Outcome Measure Scores

Twenty subjects were divided into the TE (n=7) or FTT (n=13) groups. Results of an independent t-test show that there were no significant differences between groups regarding subject demographics, age (p=0.353), height (p=0.355), weight (p=0.721), BMI (p=0.871), right leg length (p=0.833) and left leg length (p=0.793) (Table 3). In addition, other insignificant differences between groups at baseline were the measures of self-reported WOMAC subsets: pain (p=0.807), stiffness (p=0.996), and function (p=0.531). Baseline measures for performance outcome measures were insignificant between groups for all of the following: average peak torque/body weight ratio (p=0.548), Berg Balance Scale (BBS), (p=0.304), stair climb test (SCT), (p=0.567), timed up and go test (TUG), p=0.970, and normalized velocity (p=0.787).

Table 3

Subject Characteristics and Measurements for Groups Traditional Exercise (TE) versus Functional Task Training (FTT)

Characteristics	TE (n=7)	FTT (n=13)	Significance
Age (years)	57.4(± 5.6)	55(± 5.3)	0.353
Gender			
Male	2	5	
Female	5	8	
Height (in.)	65.7(± 2.9)	67.1(± 3.1)	0.355
Weight (lbs.)	214.1(± 38.5)	219.8(± 30.7)	0.721
BMI kg/m ²	35.2(± 8.1)	34.7(± 4.9)	0.871
Leg length (cm.)			
Right	81.0(± 6.5)	81.7(± 7.6)	0.833
Left	81.0(± 6.5)	81.9(± 7.3)	0.793

Outcome Measures for Timed Up and Go (TUG)

Table 4 presents the means and standard deviations of TUG scores for both groups. Mauchly's Test found a highly significant assumption of sphericity, $W=.304$, $\chi^2(2)=20.247$, $p=.000$. A two-way repeated measures ANOVA demonstrates there was no interaction effect for Group and TUG scores, $F(2, 36) = 1.417$ $p=.253$ (Table 5). Main effect of time was found for both groups which demonstrates that there was a significance in TUG scores across time $F(2,36)= 9.661$, $p=.004$. Pairwise comparisons using Bonferroni's correction indicate that both groups significantly improved in scores over time ($p<0.01$); but the FTT group was better for lowering TUG scores between week 6 and week 12 as well as baseline and week 12. However, no significant difference for TUG scores was found between baseline and 6 weeks.

Table 4

Means and \pm Standard Deviations for TUG scores for both the TE and FTT group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Time	Mean (sec)	S.D.
TE	1	10.55	1.88907
	2	9.93	1.76863
	3	9.63	1.79006
FTT	1	10.49	3.31192
	2	9.30	1.75658
	3	8.42	1.19281

Table 5

Repeated Measures ANOVA for TUG

Effect	MS	Df	F	P	Greenhouse-Geisser
Group	5.413	1	.472	0.501	
Error	11.473	18			
Time	10.364	2	9.661	0.000	0.004*
Time x Group	1.520	2	1.417	0.256	0.253
Error	1.073	36			

Note:* $p \leq .05$

Outcome Measures for Stair Climb Test (SCT)

Table 6 addresses the means and standard deviations of SCT scores for the two groups. Mauchly's test found that an assumption of sphericity is highly significant, $W=.206$, $\chi^2(2) = 26.862$, $p=0.000$. A two-way repeated measures ANOVA demonstrates there was no interaction effect for Group and SCT scores $F(2, 36) = 7.46$, $p=0.079$ (Table 7). However, there was a main effect for time for both groups, $F(2, 36) = 11.436$, $p=0.002$, indicating that both groups improved after exercise. Pairwise comparisons using Bonferroni's correction indicated that differences occurred between baseline and week 6 as well as baseline and week 12 ($p<0.01$). Therefore, both groups improved in their ability to ascend/descend stairs after 6 and 12 weeks of exercise as compared to baseline; however, scores were lower in the FTT group.

Table 6

Means and \pm Standard Deviations for SCT scores for both the Traditional Exercise (TE) and Functional Task Training (FTT) group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Time	Mean(sec.)	S.D.
TE	1	13.8229	3.39176
	2	13.2000	3.22016
	3	12.7443	3.10723
FTT	1	15.0354	5.26861
	2	12.7469	3.20549
	3	11.5654	2.93465

Table 7

Repeated measures ANOVA for SCT

Effect	MS	Df	F	P	Greenhouse-Geisser
Group	.160	1	.004	0.948	
Error	37.210	18			
Time	24.878	2	11.426	0.000	0.002*
Time x Group	7.246	2	3.328	0.047	0.079
Error	2.177	36			

Note: * $p \leq .05$

Outcomes Measures for Average Peak Torque to Body Weight (PT/BW)

Table 8 presents the means and standard deviations of PT/BW. A two-way repeated measures ANOVA demonstrates that there was no interaction effect for group X time for torque scores $F(2, 36) = 0.099$, $p = 0.820$ (Table 9). Mauchly's test of sphericity was highly significant, $W = .457$, $\chi^2(2) = 13.309$, $p = 0.001$. There was a main effect for torque values across time $F(2, 36) = 17.324$, $p < 0.001$. Pairwise comparisons with Bonferonni's corrections showed that all three time points were significantly different from each other and that both groups generated significantly more average peak torque/body weight on the Biodex when compared to baseline ($p < 0.01$).

Table 8

Means and \pm Standard Deviations for Average Peak Torque/Body Weight Scores for the Traditional Exercise(TE) and Functional Task Training (FTT) group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Time	Mean(ft-lbs./	S.D.
TE	1	32.9286	16.34979
	2	38.1857	14.81704
	3	43.7429	21.83360
FTT	1	36.6923	11.11706
	2	42.7538	10.83841
	3	49.2692	10.57090

Table 9

Repeated Measures ANOVA for Average Peak Torque/Body Weight (PT/BW)

Effect	MS	Df	F	P	Greenhouse-Geisser
Group	291.277	1	0.601	0.448	.
Error	484.514	18			
Time	622.597	2	17.324	0.000	0.000*
Time x Group	3.543	2	0.099	0.906	0.820
Error	35.939	36			

Note:* $p \leq .05$

Outcome Measures for WOMAC Total Score and Subset Scores: Total WOMAC Scores (WT), WOMAC Pain (WP), WOMAC Stiffness (WS), and WOMAC Function (WF)

Tables 10, 12, 14 and 16 represent the means and standard deviations of WT, WP, WS, and WF scores. Mauchly's test of sphericity was highly significant for one subset, that of WS (stiffness), $W=.353$, $\chi^2(2)=17.723$, $p=.000$. Results of a two-way repeated measures ANOVA demonstrated there was no interaction effect for group total scores and any WOMAC subset : WT, $F(2,36)=1.744$, $p=0.189$ (Table 11); WP, $F(2, 36) = 1.279$, $p=0.291$ (Table 13); WS, $F(2,36) = 2.032$, $p=0.146$ (Table 15) ; WF, $F=.815$, $p=0.450$ (Table 17). However, there was a main effect of time for WP scores, $F(2, 36)=44.226$, $p=0.00$, WF scores, $F(2,36)= 14.918$, $p=0.00$ and WT scores, $F(2,36)= 37.131$, $p=0.00$, indicating a significant improvement after exercise. Pairwise comparisons show that there was a significant difference for time points for WT, WP, and WF at all time levels, $p<0.01$, indicating that there was a decrease in pain and an improvement in function in both groups from baseline to 12 weeks. WS pairwise comparisons show that there was a significant difference and improvement at 6 and 12 weeks compared to baseline, $p< 0.01$.

Table 10

Means and ± Standard Deviations for Total WOMAC Scores (WT) for the TE and FTT group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Variable	Time	Mean (mm.)	S.D.
TE	WT	1	814.42	312.80870
		2	491.42	90.48178
		3	386.00	173.13097
FTT	WT	1	783.23	193.06784
		2	583.82	269.75716
		3	277.15	177.07053

Table 11

Repeated Measures ANOVA for Total WOMAC Scores (WT)

Effect	MS	Df	F	P
Group	3443.546	1	.040	0.844
Error	85837.144	18		
Time	997993.14		37.131	0.000*
TimexGroup	46866.614	2	1.744	0.189
Error				

Note:* $p \leq .05$

Table 12

Means and ± Standard Deviations for WOMAC Pain Scores (WP) for the TE and FTT group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Variable	Time	Mean (mm.)	S.D.
TE	WT	1	158.71	41.6682
		2	107.71	30.2033
		3	80.57	40.4428
FTT	WT	1	152.46	59.1095
		2	106.42	57.9590
		3	50.61	42.8943

Table 13

Repeated Measures ANOVA for WOMAC PAIN (WP)

Effect	MS	Df	F	P
Group	2132.812	1	.384	0.543
Error	5553.574	18		
Time	36925.7	2	44.22	0.000*
Time x Group	1067.83	2	1.279	
Error	834.93	36		

Note:* $p \leq .05$

Table 14

Means and ± Standard Deviations for WOMAC Stiffness Scores (WS) for the TE and FTT group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Variable	Time	Mean (mm.)	S.D.
TE	WT	1	82.00	32.7719
		2	45.71	14.7842
		3	52.71	19.7460
FTT	WT	1	81.92	38.6274
		2	61.70	29.7911
		3	41.53	32.0562

Table 15

Repeated Measures ANOVA for WOMAC Stiffness (WS)

Effect	MS	Df	F	P	Greenhouse-Geisser
Group	34.085	1	0.17	0.897	
Error	35939.394	18			
Time	1246.632	2	14.198	0.00	0.00*
Time x Group	1698.072	2	.2.032	.146	0.158
Error	15041.746	36			

Note: * $p \leq .05$

Table 16

Means and ± Standard Deviations for WOMAC Function Scores (WF) for the TE and FTT group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Variable	Time	Mean (mm.)	S.D.
TE	WT	1	573.71	309.9718
		2	338.00	56.5568
		3	252.71	134.6251
FTT	WT	1	503.30	186.3949
		2	383.76	215.6873
		3	185.46	118.2276

Table 17

Repeated Measures ANOVA for WOMAC Function (WF)

Effect	MS	Df	F	P
Group	12806.418	1	.238	0.631
Error	53745.462	18		
Time	46618.558	2	19.076	0.000*
Time x Group	19929.558	2	.815	0.450
Error	24438.968	36		

Note: * $p \leq .05$

Outcome Measures for Gait Velocity

Table 18 presents the means and standard deviations of normalized velocity (MNV). A two-way repeated measures ANOVA demonstrates that the Group x Time interaction was significant $F(2, 36) = 3.85, p=0.031$. The assumption of sphericity was met. Tests for simple effects (using one-way repeated measures ANOVA) displayed no significant differences across time ($p=0.43, ns$) for the traditional group. However, the functional task training group displayed significant increases across time ($p < 0.01$). Pairwise comparisons with Bonferroni's correction showed that the functional training group walked significantly faster after 6 and 12 weeks of exercise compared to baseline ($p < 0.01$) (Table 19). Another way to show simple effects is to look at different slices of time and perform unpaired t-tests between the two groups. At baseline, there was no difference ($p=0.79$), as expected, because the groups were randomized. There was however, significance after 6 ($p=0.029$) and 12 weeks ($p=0.047$) for the FTT group being significantly higher compared to the TE group. Again, this indicates that this group walked significantly faster after 6 and 12 weeks of exercise ($p<0.01$).

Table 18

Means and ± Standard Deviations for Mean Normalized Velocity (MNV) for the TE and FTT group at baseline (Time 1), week 6 (Time 2), and week 12 (Time 3)

Group	Variable	Time	Mean (cm. /s/LL)	S.D.
TE	MNV	1	1.38	.27489
		2	1.32	.20097
		3	1.44	.10677
FTT	MNV	1	1.34	.29313
		2	1.59	.25835
		3	1.61	.25921

Table 19

Repeated Measures ANOVA for Mean Normalized Velocity (MNV)

Effect	MS	Df	F	P
Group	.251	1	1.910	0.184
Error	.131	18		
Time	.128	2	04.431	0.019*
Time x Group	.111	2	3.850	0.031*
Error	.029	36		

Note:* $p \leq .05$.

Outcome Measures for Berg Balance Scale (BBS)

A Friedman's test was conducted for the BBS separately for TE and FTT groups. Friedman's was not significant for the TE ($p=0.368$). However, it was significant for the FTT group ($p=0.001$). Wilcoxon Signed Ranks test was utilized for pairwise comparisons, indicating that week 6 and week 12 are significantly different from baseline ($p<0.01$), indicating that the FTT group improved their balance scores after 6 weeks of exercise. Table 20 contains the means and standard deviations for the BBS scores.

Table 20

Means and \pm Standard Deviations for Berg Balance Scale (BBS) for TE and FTT Group

Group	Time	Mean	S.D.
TE	1	55.00	1.4142
	2	55.42	.97950
	3	55.84	.78680
FTT	1	54.38	1.66024
	2	55.38	1.26085
	3	55.84	.37553

Right Lower Extremity Double Support Time (RDS) and Left Lower Extremity Double Support Time (LDS) for the Traditional Exercise (TE) and Functional Task Training (FTT) Group

Since there was an interaction effect for velocity, a two-way ANOVA was conducted to compare right and left double support time of the TE and FTT group. The assumption of sphericity was met. Results were analyzed for RDS (Table 21) and LDS (Table 22) using a two-way ANOVA with repeated measures on the factor of time. The Group x Time interaction was significant for RDS, $F(2,36)=3.265$, $p=0.050$ and for LDS, $F(2,36)=3.497$, $p=0.041$ for the FTT group. Tests for simple effects (using one-way repeated measures ANOVA) demonstrated significant increases across time for the FTT group for RDS ($p=0.002$) and LDS ($p=0.003$). Pairwise comparisons demonstrated there was a significance from baseline to week 6 and from baseline to week 12, indicating that there was less time spent in double support, $p<0.01$.

Table 21

Repeated Measures ANOVA for Right Double Support Time (RDS)

Effect	MS	Df	F	P
Group	0.036	1	3.498	0.078
Error	0.010	18		
Time	.003	2	1.827	0.176
Time x Group	.005	2	3.265	0.050*
Error	.002	36		

Note:* $p \leq .05$

Table 22

Repeated Measures ANOVA for Left Double Support Time (LDS)

Effect	MS	Df	F	P
Group	0.042	1	4.147	0.057
Error	0.10	18		
Time	.003	2	1.763	0.186
Time x Group	.006	2	3.497	0.041*
Error	.002	36		

Note:* $p \leq .05$

Power Calculation

An estimated sample size was calculated based on a large effect size and power of 80% utilizing IBM SPSS version 19.0 for Windows. Traditionally, one usually considers a “chief outcome variable” and does a power analysis (sample size determination) on that parameter. The rationale is that one should at least have a large enough sample of data to have sufficient power (probability) to detect a significant difference (if it exists) for at least the main outcome variable. Results indicated that an estimated sample size of 40 (20 per group) was required to achieve 80% power for all outcomes at the 5% level of significance. Due to the limitations in subjects who met the inclusion criteria as well as availability to participate in the length of the exercise program, data collection was stopped after 20 subjects in a period of 2 ½ years. Due to this fact, the observed power value for velocity was utilized from SPSS, version 19, which was .66 or 66%.

CHAPTER V

DISCUSSION

In this study, two rehabilitation approaches were utilized to examine if any significant differences existed in measures of strength, pain (as measured by the WOMAC self-assessment scores), gait velocity and functional outcomes on the Timed Up and Go Test, stair climb test and Berg Balance Scale (BBS). Results indicate that both groups improved in all measures of strength, pain and functional outcomes. However, an interaction effect was found for velocity, which was significant across all three testing periods for the functional task training group.

The demographic characteristics of the sample recruited for this study are consistent with those of individuals with knee OA observed in the current literature regarding age, weight and gender.

Muscle Strength

Regardless of the training module, both groups demonstrated an increase in strength over time. Noted improvements in the TE group were similar to those in the FTT group, expressed as a percent increase of 33% to 35%, respectively. At the conclusion of this study, values were found to increase from 146.4 ± 72.5 to 192.7 ± 97.1 and 163.2 ± 48.8 to 219 ± 47.0 for the TE and FTT groups, respectively. These values for subjects with knee OA are consistent with those reported in the literature after exercise (Fransen, Grosbie & Edmonds, 2003).

Although several authors report a direct relationship between quadriceps muscle weakness and pain (Alghamdi, Olney, & Costigan, 2004), others do not (Kaur & Verma, 2005). This study did not investigate this relationship, yet, a decrease in self-reported pain scores (WOMAC subset of pain) was found to be significant for both groups, which may indicate there may be a relationship with this cohort. An additional variable responsible for the decrease in muscle strength associated with knee OA is central activation failure (Hurley et al., 1998; Lewek et al., 2003; Slemenda et al., 1997). Since quadriceps activation failure is found to be significant in the elderly with knee OA, it may or may not be a factor in this study's subject population (Stevens, Binder-MacCleod & Snyder-Mackler, 2001). In fact, Lewek et al. (2004) found that quadriceps activation failure in individuals with knee OA (mean age, 52) did not differ significantly from aged matched controls and suggested that the slight decrease in activation was probably associated with disuse atrophy. Central activation is difficult to measure in a clinical setting and traditional strengthening exercises may be inadequate for those whose strength loss is due to activation failure (Fitzgerald et al., 2004). Measuring activation failure was beyond the scope of this study; therefore, improvements noted in torque after exercise represent an increase in muscle strength which may, or may not, be related to activation failure.

Although it was hypothesized that the FTT group would demonstrate greater strength gains, both groups performed similarly. However, both groups participated in exercises which involved activities requiring concentric and eccentric muscle control, and the literature suggests that and eccentric muscle

training results in greater strength gains (Gur et al., 2002). Interestingly, these results differ from those of the pilot study in which significantly greater gains were found in the FTT group (Stutz-Doyle et al., 2008). While this study did not support the findings of the pilot study, a plausible explanation is that the exercises were not identical, and when reflecting back to Gur et al., the changes in the exercise program could have accounted for the lack of differences between groups.

Gait Velocity

Regardless of group assignment, the FTT group walked significantly faster than the TE group after six weeks of task practice, which may have resulted from improved muscle activation and timing associated with task specific training. There was no significant change from six weeks to twelve weeks; yet, the increase from baseline to six weeks was substantial. The TE group walked a little faster, but this finding was not significant. Different activities in each group contributed to these observed effects. First, the FTT group practiced unilateral stance activities as part of their program, which may have transferred to the observed decrease in double support time (Schmidt & Lee, 2005). Secondly, unlike the FTT group who ambulated in the gym, the TE group walked on a treadmill, where the speed was fixed and externally paced by the treadmill, with no intertrial variability. The subjects entrained their movement to the treadmill speed, while the FTT group's gait speed was internally self-paced. Thus, the TE group's environment was constant and predictable, while the functional training group's environment was constantly changing and fluctuating, and therefore may

have resulted in greater variability in gait parameters. The FTT group ambulated around an open gym environment while tossing a ball from hand to hand, representing a dual task condition which requires attention to both walking and object manipulation. Interestingly, the literature suggests that dual-task practice supports that object manipulation with body transfer has been found to increase gait velocity more effectively than walking alone (Silsupadol, 2008), consequently accounting for this observed change in the FTT group.

Given that gait speeds ranged from an average of 108cm/s at baseline to 111 cm/s for the TE group and an average of 111 cm/s at baseline to 131 cm/s for the FTT group, one can see that there was a substantial difference in velocity for the functional task training group. Since a velocity change of 10 cm/s is considered substantial and clinically meaningful (Jaeschke, Singer & Guyatt, 1989), the noted increase of 20 cm/s demonstrates significant improvement for the FTT group.

Consistent with the significant difference in velocity, it is noted that the FTT group demonstrated a decrease in double support time indicating that they spent more time on one leg. Since external knee adduction moments are greater during single leg stance (Hurwitz et al., 1999; Al-Zahran et al., 2002; Bejek et al., 2006), and an increase in adductor moment is associated with greater pain, (Hurwitz, Ryals, Case, Block & Andriacchi, 2002), a decrease in double support time may indicate less knee pain for the subjects in the FTT group.

Pain, Stiffness and Function

Regardless of group assignment, there were no significant group differences in pain, stiffness and function, and both groups displayed significantly lower scores on the WOMAC. Both the TE and FTT group demonstrated significant decreases over time for pain from baseline to the completion of the study with a larger, yet non-significantly different decline in the FTT group. Overall, the results from this study are consistent with those found in the literature and suggest that regardless of group assignment, strengthening exercises decrease pain, stiffness, and improve self-reported function in individuals with knee OA (Deyle et al., 2005; Fransen & McConnell, 2001; Hinman, Heywood, & Day, 2007; Jamtvedt et al., 2008; van Baar et al., 1998). Change scores ranging from 17% to 26% from baseline are determined to reflect a minimally important clinical improvement (Barr, et al., 1994). In this study, the WOMAC total score demonstrated a decrease by 52% and 63% for the TE and FTT group, respectively, which display parity with those reported by Deyle et al., (2005). Since individuals tend to report a decrease in physical function when having pain, performance-based measures should be utilized in addition to self-reported questionnaires to assess physical function (Stratford et al., 2006), as these measures are more sensitive to change and less influenced by pain than self-reported measures (Piva et al., 2010).

Outcome Measures

Timed Up and Go (TUG)

The TUG scores were significantly different over time for both groups in the study; however, a greater change was observed for those subjects in the FTT group. This change, while not significant for groups, warrants further investigation. The TE group improved their time by 8.7% (.82 seconds), while the FTT group improved by 19.7% (2.076 seconds). Mean TUG scores have been reported between six and 11.2 seconds in community dwelling women without any known pathology. Published studies report that times of 8.5 seconds to 14 seconds indicate pre-clinical functional ability limitations (Fried, Young, Rubin, & Bandeen, 2001) and that a decrease of 1.5 seconds reflects a minimally clinically significant change (Piva et al., 2002). Therefore, improvements in TUG scores for the FTT group may indicate clinical significance. Even though both groups started out at approximately the same times at baseline, there was a substantial improvement in the FTT group. Since greater knee extensor torque is associated with a chair rising activity (Krebs et al., 2007), and both groups performed relatively similarly on strength measures, what can account for this difference? The author postulates that the difference appears to be related to the type and intensity of exercise performed in the FTT group. Specifically, activities practiced by this group required greater repetitions of functional tasks, such as sit to stand with a weighted box, which may transfer better to performance secondary to task specific training. In fact, McGibbons et al.

(2003) found that a sit to stand task translated to greater forward momentum. Faster rise times noted for the FTT group may indicate improvements in postural stability required to accommodate to larger changes in the center of gravity associated with this activity. These findings further support the plausibility of task-specific training in transfer to task performance.

Berg Balance Scale

In this study, both groups were not at risk for falls at the beginning of the study, and both groups consisted of high functioning individuals. The BBS has been noted to be less sensitive to change in individuals with high levels of balance abilities (Bogle & Newton, 1996). Despite this fact, there was an observed significant improvement in the FTT group. Balance is a complex, multifactorial phenomenon involving the vestibular, visual and somatosensory systems, so manipulating the task and environment, as was done with the functional task training group, may help to cope with the constraints of knee OA. Effective and timely muscle control is necessary to maintain balance, and static as well as dynamic control is required for both simple and challenging tasks (Hinman et al., 2002). Several studies demonstrate the relationship between knee pain and balance (Hinman et al., 2002; Jadelis et al., 2001) while others indicate that poor muscle strength and decreased proprioception are greater contributors to balance deficits (Bennell & Hillman, 2005). Jadelis et al. (2001) found that when subjects had greater muscle strength, pain did not influence balance performance. Postural control is a function of the aforementioned

physiological systems and together, they may be able to compensate for imbalances caused by pain or muscle weakness. However, a combination of pain, muscle weakness, and/or proprioception deficits may be better predictors of balance deficits associated with knee OA. One can also suggest that the repetition of the star exercise contributed to proprioceptive acuity and increased stability in the FTT group as it involves standing on one leg while reaching out with the other leg to touch all points of an outlined star. Perturbations associated with this leg movement provide challenges to this static task, thus requiring a coordination of movements that are shaped by environmental constraints. Since both group scores were relatively high at the initiation of the study, and both groups approached maximal scores on the BBS, this leads the author to question if the BBS is the best tool to assess balance deficits in this highly functional group. Further reflection on balance scores may suggest that balance may not be the primary consideration in this cohort.

Stair Climb Test

Interestingly, both the TE (increase of 7.8%) and the FTT group (increase of 23%) improved in stair climb times with greater improvements noted in the functional task training group. Again, if the study was adequately powered, this noted trend between groups may have been significant. As the FTT group practiced stair climbing as part of their exercise regimen, it was expected that they would perform significantly better. Although this was not the case, the p-value was approaching clinical significance. Researchers report that the stair

climb test performance is related to quadriceps strength (Asay et al., 2008; Mitzer et al.), pain and function (Stratford et al., 2006; Sowers, et al., 2006) and walking speed (Perera, Mody & Woodman, & Studenski, 2006) in individuals with knee OA. In this study, the larger observed improvements in the functional task training group for all of these variables reflect upon these findings. Another interesting finding from this study is that although the TE group performed step-ups, which are considered part practice of the stair climb task, they do not appear to be as beneficial as practice of the task as a whole, which suggests the benefits of whole task practice. In this case, since results in strength were similar, simplification of the task, through part practice, did not result in greater performance in the TE group. Since greater knee extensor torque and power are required when ascending/descending stairs (Mizner et al., 2005) and the FTT group spent more time performing this activity, the noted improvements may be a result of greater power associated with the additional time spent in task performance. Interestingly, there was no group effect as expected with task specific training (Schmidt et al., 2005), although, with a larger sample size, significant change may be noted.

Limitations

There are several limitations to this study. Based upon the pilot study and power analysis, it was determined that a sample size of 20 per group was required for each group to achieve 80% power at the 0.05 level for all measures tested. Despite attempts to secure this sample size, the study was concluded

after 2 ½ years of data collection due to lack of any new subjects. Therefore, the results should be interpreted with caution. In addition, the sample size for this study was unbalanced, TE group, n=7 and FTT group, n=13. The current power analysis was based on the velocity measure and was determined to be 66%.

Additionally, there may be some methodological limitations, which represent threats to internal and external validity. First, compensatory equalization of treatments can occur when research investigators favor one experimental group over the other. Since the principal investigator supervised both exercise groups, this cannot be ruled out. Next, the FTT group performed exercises similar to the testing protocol, which may have accounted for a testing effect in this group. However, given the design of the study, this is what was investigated. Lastly, the small n, and limited geographic range from which the subjects were recruited, may limit the generalizability of findings.

Additionally, performance tests utilized in this study may not have been sensitive enough to detect subtle changes in this highly functional age group. Future tests should include more challenging performance tests such as walking while changing directions and negotiating obstacles. Confounding variables include not controlling for bilateral knee involvement and weight loss as a result of the exercise program.

CHAPTER VI

CONCLUSION

Traditionally, exercises for knee OA concentrate on increasing strength with the assumption that functional improvement will follow. In this study, the FTT group demonstrated a slight improvement in strength (35%) when compared to the TE group (33%), which thus could not account for the functional ability differences seen between groups. However, the observed group effect for velocity in favor of the FTT may have been key in improving functional stability. In addition, although both groups demonstrated significant changes in time to rise from a chair and ascend/descend stairs, the observed change was greater in the functional task training group. Taken together, the data may suggest that increases in strength alone at the impairment level may not result in improved task performance. The FTT group performed exercises which required the subject to change directions, stand on one foot, and negotiate around other individuals and objects and may have resulted in greater task performance and muscular strength as completion of these activities required strength, coordination, balance, postural control, stability, mobility as well as the environmental demands associated with those tasks. Conversely, the TE group who practiced strengthening exercises with minimal gait training on the treadmill practiced more under a part practice model, which may have led to the observed findings.

There is a nonlinear relationship between impairment and function. Improvements in strength beyond a certain threshold fail to enhance functional performance. The existence of such a threshold may simply augment strength reserves without enhancing function (Bean, Vora, & Frontera, 2004). It is necessary to recognize if deficits at the impairment level are causative in limiting activities, so that if strength is an issue, dealing with the impairment at a more functional level may be more effective in the long term. Effectiveness of strengthening exercises can be maximized by introducing flexibility, coordination, balance, and mobility, which may transfer to an overall improvement in function. Repetition and task practice not only improves strength but reduces activity limitations associated with the impairment of decreased muscle strength. Ultimately, the inability to participate in activities at a social level has an impact on the quality of life in individuals with knee OA. Addressing the impairments and activity limitations associated with this disease in middle-aged individuals may delay and/or prevent the disabilities encountered in the elderly. The data from this study support that functional task training is a better option in improving walking speed in this 45-65 year old population with knee OA.

An exercise program tailored to the individual's diagnosis, lifestyle, habits and co-morbidities may well provide a rehabilitative program that may be more positively embraced and adhered to for a longer period (Pisters et al., 2010).

Future Areas of Study

Findings in this study provide evidence to support that FTT is an effective therapeutic approach in the rehabilitation in individuals with knee OA. Future studies should address larger populations with more sensitive performance measures as well as dual task performance. Longitudinal studies should be used to determine the effectiveness and adherence to this exercise program in the knee OA population, as morphological changes in pain may influence exercise adherence.

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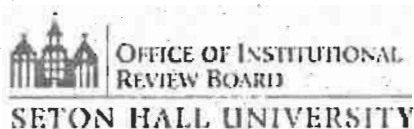
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APPENDICES

- A. IRB letter
- B. Essex County College letter
- C. Demographics Questionnaire
- D. Operational Definitions
- E. Volunteer Flyer
- F. Normal Gait Speed
- G. Letter to Physician
- H. Berg Balance Scale
- I. Borg Perceived Exertion Scale
- J. WOMAC questionnaire

APPENDIX A



March 24, 2010

Christine Stutz-Doyle
19 Highview Road
Caldwell, NJ 07006

Dear Ms. Stutz-Doyle,

The Seton Hall University Institutional Review Board has reviewed your Continuing Review application for your research proposal entitled "The Effects of Traditional Strengthening Exercises Versus Functional Task Training on Pain, Strength, and Functional Mobility in the 45-65 Year Old Adult with Knee Osteoarthritis".

You are hereby granted another 12-month approval, effective May 5, 2010. Your new stamped Consent Form and Recruitment Flyer are enclosed. Please make copies only of these stamped forms.

If any changes are desired in this protocol, they must be submitted to the IRB for approval before implementation.

Thank you for your cooperation.

Sincerely,

Mary F. Ruzicka, Ph.D.
Professor
Director, Institutional Review Board

cc: Dr. Genevieve Pinto-Zipp

APPENDIX B

**ESSEX COUNTY COLLEGE**

303 University Avenue, Newark, New Jersey 07102

(973) 877-3370

Office of Institutional Research

March 2, 2010

Professor Christine Stutz-Doyle
Physical Therapy Program
Essex County College
Newark, NJ

Dear Professor Stutz-Doyle,

Thank you for sending us your proposal, *The Effects of Traditional Strengthening Exercises Versus Functional Task Training on Pain, Strength and Functional Mobility in the 45-65 Year Old Adult with Knee Osteoarthritis*.

Our Institutional Review Board reviewed your proposal and is pleased to approve your continued research efforts at Essex County College.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Scott Drakulich'.

J. Scott Drakulich, Ed.D.
Associate Dean, Office of Planning, Research, and Assessment

An Equal Opportunity/Affirmative Action Employer

APPENDIX C

Please complete the following questions which will determine your eligibility for the study. The principal investigator will discuss the results with each participant.

Name: _____

Code # _____

	YES	NO
1. Are you presently walking with a cane, crutch or walker or any other assistive device?	<input type="checkbox"/>	<input type="checkbox"/>
2. Have you ever been diagnosed with a neurological disease?	<input type="checkbox"/>	<input type="checkbox"/>
3. Have you been experiencing knee pain (either off and on or constant) for at least four months?	<input type="checkbox"/>	<input type="checkbox"/>
4. Do you have an uncontrolled cardiopulmonary or respiratory condition?	<input type="checkbox"/>	<input type="checkbox"/>
5. Do you have a history of uncontrolled low or high blood pressure?	<input type="checkbox"/>	<input type="checkbox"/>
6. Do you suffer from any condition that may affect your balance?	<input type="checkbox"/>	<input type="checkbox"/>
7. Are you presently taking over the counter nonsteroidal anti-inflammatory drugs?	<input type="checkbox"/>	<input type="checkbox"/>
8. Are you currently engaged in any exercise program (1, 2-3x/wk.)?	<input type="checkbox"/>	<input type="checkbox"/>
9. Did your physician perform x-rays that confirmed knee osteoarthritis?	<input type="checkbox"/>	<input type="checkbox"/>
10. Are you able to stand on one foot, lift something from the floor, carry a weighted object, climb stairs and walk with a bag (weighing approximately one (1) pound for a period of 15 minutes?	<input type="checkbox"/>	<input type="checkbox"/>
11. Can you rise up from and return down to a chair without support or any assistive device?	<input type="checkbox"/>	<input type="checkbox"/>
12. Can you change positions (e.g. from lying down to sitting) without assistance from another person or support device of any sort?	<input type="checkbox"/>	<input type="checkbox"/>
13. Do you have any history of additional musculoskeletal diseases or surgeries?	<input type="checkbox"/>	<input type="checkbox"/>

APPENDIX D

OPERATIONAL DEFINITIONS

Activities of Daily Living (ADL's): the things we do every day in normal living including any activity we perform for self-care (such as feeding ourselves, bathing, dressing, grooming), work, homemaking and leisure.

Adductor moment: moment arm that is created from the distance of the mechanical axis to the center of the knee joint. This moment is increased with knee varus deformities and results in greater forces at the medial side of the knee

Cadence: the number of steps per unit time, expressed as steps/minute.

Closed Chain: An exercise in which the distal segment is fixed and the proximal segment is free to move in space

Concentric: strengthening exercise in which the muscle is lengthened as the limb moves away from its starting position

Double support: the period in walking when both feet are in contact with the ground, expressed in seconds or as a percentage of the stride period

Eccentric: strengthening exercise in which the muscle is lengthened as the bony segment returns to its neutral or starting position

Functional decline: loss of certain abilities related to function

Functional limitation: a level determined by the ability to perform task-oriented or functional motor activities

Functional task training: practice of tasks designed to mimic ADL's

Gait cycle: the elapsed time between the first contact of two consecutive footfalls of the same foot

Gait velocity: obtained by dividing the distance by the ambulation time: recorded in centimeters/second

Ground reaction force: generically refers to any force exerted by the ground on a body in contact with it. It is equal in magnitude and opposite in direction to the force that the body exerts on the supporting surface through the foot

HAT: head, neck and trunk

Instrumented Gait Analysis (IGA): techniques involving quantitative analysis of walking performance obtained from instruments measuring walking performance including but not limited to a subject's stability and balance, velocity and control, symmetry and movement of the upper and lower extremities and trunk, deformities, and influence of assistive devices.

Mechanical axis: the mechanical axis of the limb is drawn from the centre of the femoral head to the centre of the ankle on the AP film. The distance from the centre of the knee joint to the deviated mechanical axis line will reflect the size of the moment arm created at the knee by any such deformity

Moment: The product of a quantity and its perpendicular distance from a reference point; the tendency to cause rotation about a point or an axis.

Net support moment: the sum of the moments at the hip, knee and ankle during the stance phase of gait.

Normalized velocity: is obtained after dividing the average speed of walking by the average leg length and is expressed in leg length per second (LL/sec.). The average leg length is computed $(\text{left leg length} + \text{right leg length})/2$

Observational Gait Analysis (OGA): technique involving qualitative descriptions of walking performance from observations made of a subject's stability and balance, symmetry and movement of the upper and lower extremities and trunk, deformities, and influence of assistive devices.

Sagittal plane: is a vertical plane which passes from front to rear, dividing the body into right and left sections.

Self-report questionnaire: a type of survey, questionnaire or poll in which respondents read the question and select a response by themselves without researcher interference

Self selected velocity (speed): qualitative descriptor of a subject's self-selected rate of forward progression.

Step length: distance measured on the horizontal axis of the walkway from the heel point of the current footfall to the heel point of the previous footfall on the opposite foot. The step length can be a negative value if the subject fails to bring the landing foot heel point forward of the stationary foot heel point.

Stride length: distance measured on the line of progression between the heel points of two consecutive footfalls of the same foot (left to left).

Temporal gait variables: descriptors of gait including stance time, single-limb and double-support time, swing time, stride and step time, cadence and speed

Temporal distance measures: objective measures of the gait cycle include step/stride time and length, stance and swing time, period of double support, and base of support/stride width.

Torque: the moment of a force; the measure of a force's tendency to produce torsion and rotation about an axis.

Traditional Exercise: involve strengthening of one or more muscle groups at the impairment level (i.e. quadriceps)

Valgus: characterized by an abnormal outward turning of the bone; in the knee appearance is knock-kneed

Varus: characterized by an abnormal inward turning of the bone: in the knee appearance is bow-legged

APPENDIX E

**Volunteers between 45-65 years old
are needed for a study examining
how training protocols may affect
Osteoarthritis of the Knee**

The research will examine knee strength and walking characteristics in persons with osteoarthritis of the knee. The study will require a 12-week commitment and will involve attending 24 exercise sessions held in the Essex County College Physical Therapist Assistant Laboratory. These sessions will require your participation in an exercise program. If you are between the ages of 45 and 65, have Osteoarthritis of the knee and would like to help, please call:

Christine Stutz-Doyle
At Essex County College (973) 877-3456
E-mail Stutz@essex.edu

Seton Hall University
Institutional Review Board
MAY 05 2011

Expiration Date
MAY 05 2011

Approval Date



APPENDIX F

Age	Gender	Mean cm./sec.
40-49	men	132.8
	women	124.7
50-59	men	125.2
	women	110.5
60-69	men	127.7
	women	115.7

Normal Gait Speed (Oberg, Karsznia, & Oberg, 1993)

APPENDIX G
Letter to Physician

Dear Dr. _____,

I am a physical therapist and doctoral student at Seton Hall University conducting a preliminary research experiment to examine the effect of decreased quadriceps strength, knee pain and function in individuals with knee osteoarthritis. Your patient _____ has volunteered for this study that will be conducted over a 12 week period. _____ will be randomly assigned to either a traditional strengthening exercise or a functional task training group (those that mimic activities of daily living) (see attached, Appendix E). Pre, midpoint (6 weeks), and post-test measurements will be performed. These include quadriceps strength testing (using the Biodex, which is a standard non-invasive tool commonly used to assess strength), a survey for self-assessment of pain and function (WOMAC), and instrumental gait analysis which assesses temporal and spatial alterations in gait. In addition, they will be required to participate in three standardized tests (Berg Balance test, Stair-Climb Test and the Timed Up and Go test) which are currently used in physical therapy practice. The participants in this study will include males and females between 45-65 years of age with a diagnosis of knee osteoarthritis. Subjects will have no other medical issues and will function independently in their environment. Inclusion criteria include: a confirmed diagnosis of knee OA by physician with radiographic evidence, self reported pain of four months or greater, the ability to ascend and descend stairs (minimum 9 stairs), the ability to walk 15 minutes without an assistive device, the ability to lift a four (4) pound box from the floor and stand up, and no use of anti-inflammatory drugs. Exclusion criteria include: the presence of any neurological disease, uncontrolled blood pressure, uncontrolled cardiopulmonary condition, any history of additional musculoskeletal disease or surgeries, and the inability to rise and return from a chair without an assistive device and active participation in an exercise program.

If in your opinion, this patient can safely participate in this study, please indicate by signing below and returning it to me in the enclosed self-addressed envelope. In addition, can you please indicate the Kellgren/Lawrence grade (based on the patient's diagnosis) for research purposes.

If you have any questions, please do not hesitate to contact me at (973)877-3456. Thank you for your time and consideration in this matter.

Sincerely,

Christine Stutz-Doyle, PT, IDPT

Please sign and return to me in the self-addressed envelope provided. Thank you. _____ will ___ will not ___ be able to participate in your research project.

Patient Name _____

K/L radiographic Grade _____

Physician's Name: _____ Title: _____

(Please print)

Physician's Signature: _____ Date: _____

APPENDIX H

Berg Balance Scale

Name: _____ Date: _____

Location: _____ Rater: _____

ITEM DESCRIPTION SCORE (0-4)

Sitting to standing	_____
Standing unsupported	_____
Sitting unsupported	_____
Standing to sitting	_____
Transfers	_____
Standing with eyes closed	_____
Standing with feet together	_____
Reaching forward with outstretched arm	_____
Retrieving object from floor	_____
Turning to look behind	_____
Turning 360 degrees	_____
Placing alternate foot on stool	_____
Standing with one foot in front	_____
Standing on one foot	_____

Total _____

GENERAL INSTRUCTIONS

Please document each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if:

- the time or distance requirements are not met
- the subject's performance warrants supervision
- the subject touches an external support or receives assistance from the examiner

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5, and 10 inches. Chairs used during testing should be a reasonable height. Either a step or a stool of average step height may be used for item # 12.

APPENDIX I

Borg Perceived Exertion Scale

The Borg Perceived Exertion Scale gives you an idea of how hard your exercise feels. The amount of resistance should equal a moderately intense rating on this scale. Resistance should be increased or decreased according to the individual's tolerance.

0	Nothing at all
.5	Extremely weak
1	Very weak
1.5	
2	Weak
2.5	
3	Moderate
4	
5	Strong
6	
7	Very strong
8	
9	
10	Extremely strong
11	
▪	Absolute maximum

0 "Nothing at all" means that you don't feel any exertion whatsoever; e.g. no muscle fatigue, no breathlessness or difficulties breathing.

1 "Very weak" means very light. As taking a shorter walk at your own pace.

3 "Moderate" is somewhat but not especially hard. It feels good and not difficult to go on.

5 "Strong". The work is hard and tiring, but continuing isn't terribly difficult. The effort and exertion is about half as intense as "Maximal".

7 "Very strong" is quite strenuous. You can go on, but you really have to push yourself and you are very tired.

10 "Extremely strong-Maximal" is an extremely strenuous level. For most people this is the most strenuous exertion they have ever experienced.

APPENDIX J

INSTRUCTIONS TO PATIENTS

In Sections A, B, and C questions are asked in the following format. Please mark your answers by putting an "X" through the horizontal line.

EXAMPLES:

1. If you put your "X" at the left-hand end of the line as shown below, then you are indicating that you feel **no** pain.

No Pain _____ 1 Extreme Pain

2. If you put your "X" at the right-hand end of the line as shown below, then you are indicating that you feel **extreme** pain.

No Pain _____ 1 Extreme Pain

3. Please note:

- that the further to the right you place your "X", the **more** pain you feel.
- that the further to the left you place your "X", the **less** pain you feel.
- please do not** place your "X" **past either end of the line.**

You will be asked to indicate on this type of scale the amount of pain, stiffness or disability you have felt during the last 48 hours.

Think about your _____ (study joint) when answering the questions. Indicate the severity of your pain and stiffness and the difficulty you have in doing daily activities that you feel are caused by the arthritis in your (study joint).

Your study joint has been identified for you by your health care professional. If you are unsure which joint is your study joint, please ask before completing the questionnaire.

WOMAC OSTEOARTHRITIS INDEX VERSION VA3.1

Section A

PAIN

Think about the pain you felt in your _____ (study joint) caused by your arthritis during the last 48 hours.

(Please mark your answers with an "X".

QUESTION: How much pain have you had ...

1. when walking on a flat surface?	No _____ Extreme Pain Pain 1	Study Coordinator Use Only
2. when going up or down stairs?	No _____ Extreme Pain Pain 1	PAIN1 _____
3. at night while in bed? (that is - pain that disturbs your sleep)	No _____ Extreme Pain Pain 1	PAIN2 _____
4. while sitting or lying down?	No _____ Extreme Pain Pain 1	PAIN3 _____
4. while standing?	No _____ Extreme Pain Pain 1	PAIN4 _____
		PAIN5 _____

Section B

STIFFNESS

Think about the stiffness (not pain) you felt in your _____ (study joint) caused by your arthritis during the last 48 hours.

Stiffness is a sensation of decreased ease in moving your joint.

(Please mark your answers with an "X")

<p>6. How severe has your stiffness been after you first woke up in the morning?</p> <p>No 1 _____ Extreme Stiffness</p> <p>Stiffness</p>	<p>Study Coordinator Use Only</p> <hr/> <p>STIFF6</p>
<p>7. How severe has your stiffness been after sitting or lying down or while resting later in the day?</p> <p>No 1 _____ Extreme Stiffness</p> <p>Stiffness</p>	<p>STIFF7</p> <hr/>

Section C

DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities caused by your arthritis in your _____ (study joint) during the last 48 hours. By this we mean **your ability to move around and take care of yourself**. (Please mark your answers with an " X ".)

QUESTION: How much difficulty have you had ...

8. when going down the stairs?
 No | _____ | Extreme
 Difficulty | | Difficulty

9. when going up the stairs?
 No | _____ | Extreme
 Difficulty | | Difficulty

10. when getting up from a sitting position?
 No | _____ | Extreme
 Difficulty | | Difficulty

11. while standing
 No | _____ | Extreme
 Difficulty | | Difficulty

12. when bending to the floor?
 No | _____ | Extreme
 Difficulty | | Difficulty

13. when walking on a flat surface?
 No | _____ | Extreme
 Difficulty | | Difficulty

Study Coordinator
Use Only

PFTN8 _____

PFTN9 _____

PFTN10 _____

PFTN11 _____

PFTN12 _____

PFTN13 _____

DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities caused by your arthritis in your _____ (study joint) during the last 48 hours. By this we mean **your ability to move around and take care of yourself**. (Please mark your answers with an " X ".)

QUESTION: How much difficulty have you had ...

<p>14. getting in or out of a car, or getting on or off a bus? No _____ Extreme Difficulty _____ Difficulty</p> <p>15. while going shopping? No _____ Extreme Difficulty _____ Difficulty</p> <p>16. when putting on your socks or panty hose or stockings? No _____ Extreme Difficulty _____ Difficulty</p> <p>17. when getting out of bed? No _____ Extreme Difficulty _____ Difficulty</p> <p>18. when taking off your socks or panty hose or stockings? No _____ Extreme Difficulty _____ Difficulty</p> <p>19. while lying in bed? No _____ Extreme Difficulty _____ Difficulty</p> <p>Copyright © 1999 All Rights Reserved</p>	<p>Study Coordinator Use Only</p> <p>_____</p> <p>PFTN14</p> <p>_____</p> <p>PFTN15</p> <p>_____</p> <p>PFTN16</p> <p>_____</p> <p>PFTN17</p> <p>_____</p> <p>PFTN18</p> <p>_____</p> <p>PFTN19</p> <p>_____</p>
--	--

DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities caused by your arthritis in your _____ (study joint) during the last 48 hours. By this we mean **your ability to move around and take care of yourself**. (Please mark your answers with an "X".)

QUESTION: How much difficulty have you had ...		Study Coordinator Use Only
20. when getting in or out of the bathtub? No _____ Extreme Difficulty Difficulty		PFTN20 _____
21. while sitting? No _____ Extreme Difficulty Difficulty		PFTN21 _____
22. when getting on or off the toilet? No _____ Extreme Difficulty Difficulty		PFTN22 _____
23. while doing heavy household chores? No _____ Extreme Difficulty Difficulty		PFTN23 _____
24. while doing light household chores? No _____ Extreme Difficulty Difficulty		PFTN24 _____