Effects of Shock Absorbing Insoles on Knee Pain, Functional Mobility, and Lower Extremity Biomechanics in Persons with Symptomatic Knee Osteoarthritis

By
Judy L. Foxworth

A dissertation submitted to the faculty of the University of North Carolina At Chapel Hill in partial fulfillment of the requirements for the degree of PhD in the School of Medicine (Human Movement Science Curriculum)

Chapel Hill
July, 2007

Approved by

Advisor: Darin Padua, PhD, ATC

Carol Giuliani, PT, PhD

Janet Freburger, PT, PhD

Leigh Callahan, PhD

Stephen Messier, PhD

ABSTRACT

JUDY FOXWORTH: Effects of Shock Absorbing Insoles on Knee Pain, Functional Mobility, and Lower Extremity Biomechanics in Persons with Symptomatic Knee Osteoarthritis

(Under the direction of Darin Padua)

Osteoarthritis (OA) is a progressive, chronic disease causing pain, limited function, and decreased quality of life.

Purpose: To investigate the effects of shock absorbing insoles (SAI) on knee pain, functional mobility and lower extremity biomechanics in persons with knee OA and to identify any modifiers of the effects of SAI on knee pain.

Methods: Sixty community-dwelling seniors (age 63.9 ± 8.8 years) with knee OA and pain completed a demographic form, Western Ontario and McMaster University Osteoarthritis Index, Arthritis Self Efficacy Scale, and three walking tasks under two conditions: 1) with SAI placed inside the shoe and 2) shoes alone. The walking tasks were: 1) usual pace; 2) fast pace; 3) six minute walk test (6MWT). After each walking task, participants rated their knee pain. Participants also completed a three dimensional (3-D) gait analysis.

Data Analysis: Separate one-way within subject repeated measures ANOVA's were used to compare outcome variables. An ANCOVA was used to determine if subject characteristics modified the effects of the SAI on knee pain during the 6MWT.

Results: Participants reported significantly less pain after walking six minutes while wearing the SAI (26 ± 25.7 mm) as compared to shoes alone (31.4 ± 28 mm, $F_{1,59} = 5.067$, p

= .028, *ES* = .079, $1-\beta=60$). No significant differences in knee pain (with or without SAI) were found during the other walking conditions. From the 3-D gait analysis, there were no significant differences in the time to reach peak vertical ground reaction force (VGRF), peak VGRF, loading rate, peak knee flexor moment or average knee moment between the two conditions. No significant interactions were found between select physical characteristics and changes in knee pain during the 6MWT while wearing the SAI.

Conclusion: The use of SAI appears to decrease knee pain in persons with knee OA when walking for sustained periods. Weight, knee OA severity, WOMAC score, hip-knee-ankle angle or ASES pain subscore do not appear to modify the effects of the SAI on knee pain during the 6MWT. Kinetic variables associated with an increase in shock absorption were not significantly different during the SAI condition.

ACKNOWLEDGEMENTS

A doctoral dissertation may appear to be solitary work; however, to complete a project of this magnitude it really "takes a village". My committee surrounded me with invaluable expertise which they freely shared. I would like to thank them for not giving up on me while I attempted to accomplish many things at once. It is through their mentorship that I was able to complete this process. First, I would like to thank my chair, Dr. Padua, for his patience and guidance throughout the dissertation phase. His ability to help students organize seemingly impossible tasks into doable projects, certainly helped when I was overwhelmed. To Dr. Giuliani, my thanks for her unwavering belief in me and for always asking the hard questions which usually began with "so what does that mean". The University of North Carolina (UNC) is fortunate to have a professional of her stature, who consistently demonstrates a commitment to teaching, research and student success. I would like to thank Dr. Janet Freburger for her many edits, statistical expertise, assistance on other research projects, and moral support throughout my tenure at UNC. To Dr. Callahan, my thanks for her mentorship during previous research experiences through the Thurston Arthritis Center and for her invaluable input into this project. To Dr. Messier, my thanks for his willingness to share vast knowledge and expertise regarding biomechanics and knee osteoarthritis. I look forward to future research collaborations with members of this wonderful committee.

I would like to thank Dr. Jordan Renner, MD who tirelessly read all of the radiographs and would not accept remuneration. His graciousness speaks to his desire to help students succeed. I would also like to thank Impluse Footcare, LLC (Durham, NC) for their generous donation of the shock absorbing insoles used in this study.

I worked full-time as a faculty member at Winston Salem State University (WSSU) for the six years it took to complete all of the doctoral requirements. A special thanks goes to the chair of the WSSU physical therapy program for fully supporting a research sabbatical to complete this project. I would also like to thank the WSSU PT faculty who supported my sabbatical by accepting extra responsibilities. In addition, I appreciate the WSSU Research Initiation Program award of $10,000, which directly supported this dissertation project.

Last, but certainly not least, I would like to thank my long time partner, Debbie for her endless support throughout this and previous academic ventures. Her academic achievements inspired me to strive further than I thought I could. There were many days that the only reason I continued in this quest was simply because she believed I could. I thank her for not only providing emotional support but also physical support by taking over household responsibilities and child care, especially in the last six months of this project. To my daughter, Skylar, my thanks for providing me with endless opportunities to put life in perspective. I look forward to sharing my love of learning with her. I thank her for putting up with what I know must have felt like endless weekends of very little “Mommy time”. Finally, I can say “Mommy is done working now”!

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER 1

INTRODUCTION

Osteoarthritis (OA) is the most prevalent, progressive form of arthritis affecting more than 20 million Americans [1-3] and causing a tremendous health care burden.[4] Persons with OA seek medical care at about twice the rate of non-affected persons [1] with direct costs of nearly $60 billion dollars in the United States.[1] When factoring in work–related losses, this burden increases to $155 billion dollars per year.[2]

The prevalence of OA has age and gender specific patterns. In general, the prevalence of OA increases with age.[1-3, 5, 6] Less than 5 percent of people between 15 and 44 years of age report symptoms of OA [1]; however, the prevalence of OA drastically increases beyond this age range. In the year 2000, 80% of persons 65 years and older in the United States were affected by OA.[4] There is a higher prevalence of OA in men prior to age 50, while after age 50, women are more likely to be affected.[2]

Because of the strong association with age, the prevalence of OA is anticipated to increase by epic proportions. It is estimated that by the year 2012, OA will be the fourth largest health impact among women and eighth among men.[5] According to the Center for Disease Control[7], the population of 65 and older has been growing at a rate nearly twice as fast as their younger counter-parts. It is expected over the next twenty years that persons over the age of 65 will dramatically increase as baby boomers age. The population is also living longer. The average life span for a person living in America is 77.9 years.[7] The combination of longer life span and the strong relationship between OA and age is certain to increase the impact of OA on society. More people, living longer, will require more services for the management of chronic diseases including OA.

Osteoarthritis may affect one or more joints and is classified as either primary or secondary OA. Primary OA is often referred to as idiopathic OA because the etiology of the disease is unknown.[8] Non-modifiable risk factors for primary OA include age, gender and genetics.[9] Persons are classified with secondary OA when the etiology of the disease can be attributed to one or more modifiable risk factors.[8] Modifiable risk factors for the development and/or progression of knee OA include joint laxity[5], joint malalignment[10], muscle weakness[11], obesity[12], and repetitive high rates of impact loading[13] of the lower extremities. Social factors such as low education level and low socioeconomic status may also influence the progression of OA.[14] While the diagnosis of OA includes primary and secondary classifications, this classification has not been widely used in research focusing on OA.

Osteoarthritis is characterized by a break-down of articular cartilage leading to radiographic changes, and symptoms including pain, stiffness, joint inflammation and crepitis.[8] The natural history of OA results in irreversible damage to joint structures, including cartilage, bone and joint capsule.[15] The impact of OA on disability is significant. Disability is usually defined as needing some assistance with walking and difficulty climbing stairs.[3] For persons with knee OA the risk of disability is greater than any other medical condition with the exception of cardiovascular disease.[16] Factors linked to disability in patients with OA include pain [3,1,6], muscle weakness [1,3,4], joint stiffness [6] and changes in balance.[3,17,18]

The knee joint is the most common weight bearing joint involved in OA.[3, 4, 18] Evidence indicates 11% of women and 7% of men aged 63 to 75 years reported symptomatic knee OA.[4] In that same cohort, 31% of males and 34% females had radiological signs of knee OA. The knee's vulnerability to osteoarthritis is in part due to poor joint design and lack of lateral stability.[11] The knee joint is particularly vulnerable because of the tremendous repetitive impact loading which occurs during functional activities such as walking and stair climbing.[15]

At this time there is no known cure for OA. The focus of current treatments for knee OA is either palliative or surgical. The goal of both approaches is to decrease joint pain to decrease functional limitations.[19-21] Palliative treatments may include either pharmacological or nonpharmocological modalities.[20, 22] The American College of Rheumatology recommends a combination of both pharmacological and non-pharmocological treatments for the medical management of knee OA.[20] Surgical interventions such as a total joint replacement are only recommended for those with severe pain who have not responded to previous medical management.[20, 21] Nonpharmocological interventions include patient education, weight loss (if overweight), exercise programs, shock-absorbing footwear, heel wedged orthotics and bracing. [20, 21]

In order for nonpharmocological interventions to be effective in the treatment of knee OA, they must be accessible and cost effective. As discussed previously, repetitive impact loading, which occurs in functional activities such as walking has been associated with the progression of knee OA.[15] A shock absorbing insole placed in the shoe should decrease the compressive joint loading up the kinetic chain to the knee. Shock absorbing insoles range in price from $10 to $50 depending on the brand and can be purchased without a doctor's prescription at most general stores.

There is research supporting the use of SAI in other young active populations to reduce overuse injuries and increase comfort.[23-26] However, there is very little empirical evidence to support the use of SAI in seniors. If proven effective in reducing pain in persons with knee OA, shock absorbing insoles would be a simple and easily implemented intervention to allow persons with knee OA to perform functional activities such as walking with less pain.

<u>Purpose:</u>

The purpose of this study is to examine the immediate effects of shock absorbing insoles on knee pain, functional mobility, and lower extremity biomechanical characteristics in persons with knee osteoarthritis (OA). A second purpose is to determine whether certain demographic, lower extremity alignment, or health-related characteristics modify the effects of the shock absorbing insoles.

Specific Aim 1: To determine the immediate effects of shock absorbing insoles (SAI) on knee pain during walking, walk distance, and gait speed in persons with symptomatic knee OA.

<u>Research Question 1</u>**:** What is the effect of SAI on knee pain measured using a visual analog scale (VAS) during walking in persons with symptomatic knee OA?

Hypothesis: Persons with symptomatic knee OA will report less pain on the VAS during walking tasks while wearing SAI.

Table 1.1 Outcome measures for Aim 1 - Research Question 1.

Task	SAI	
	Without	With
6 min. walk	VAS	VAS
Fast Gait Speed	VAS	VAS
Self-Selected Speed	VAS	VAS

<u>Research Question 2:</u> What is the effect of SAI on distance walked in persons with symptomatic knee OA?

Hypothesis: Persons with symptomatic knee OA will walk farther during the 6 minute walk while wearing SAI.

Table 1.2. Outcome measures for Aim 1 - Research Question 2.

Task	SAI	
	Without	With
6 min walk	Distance	Distance

<u>Research Question 3:</u> What is the effect of SAI on gait speed in persons with symptomatic knee OA?

Hypothesis: Persons with symptomatic knee OA will walk faster while wearing SAI.

Table1.3. Outcome measures for Aim 1 - Research Question 3.

Task	SAI	
	Without	With
Fast Gait Speed	Time	Time
Self-Selected Gait Speed	Time	Time

Specific Aim 2: To determine the immediate effects of shock absorbing insoles on lower extremity biomechanical characteristics in persons with symptomatic knee OA.

<u>Research Question 1:</u> What is the effect of SAI on lower limb kinetics during the loading response of the stance phase of walking in persons with symptomatic knee OA?

Hypothesis 1: Persons with symptomatic knee OA will have a decrease in the rate of loading during the loading response of stance while wearing a SAI.

Hypothesis 2: Persons with symptomatic knee OA will have an increase in the time to peak vertical ground reaction force (VGRF) during the loading response of stance while wearing a SAI.

Hypothesis 3: Persons with symptomatic knee OA will have a decrease in the peak vertical ground reaction force (VGRF) during the loading response of stance while wearing a SAI.

Hypothesis 4: Persons with symptomatic knee OA will have a decrease in the external knee extensor moment during the loading response of stance while wearing a SAI.

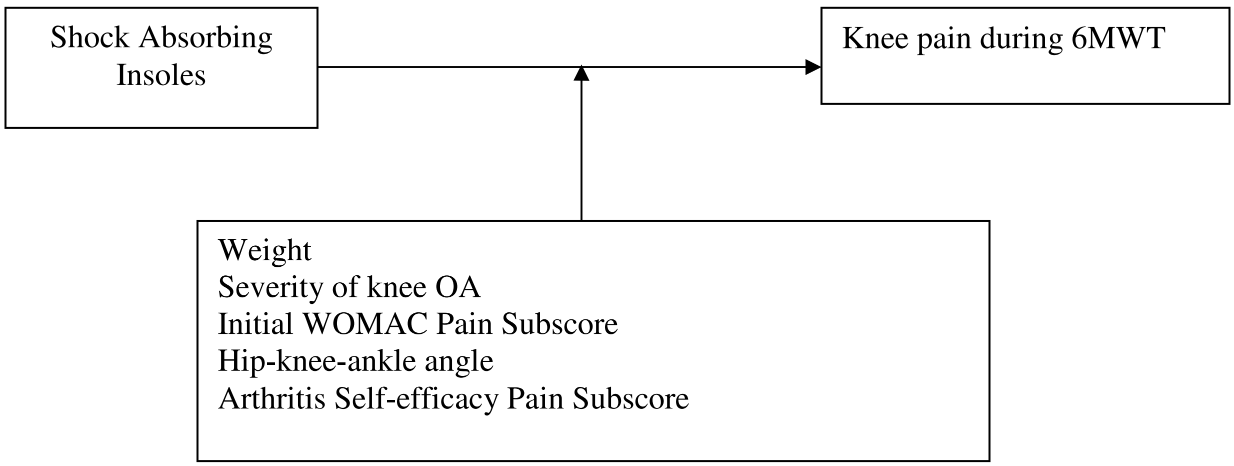
Hypothesis 5. Persons with knee OA will have a decrease in the sagittal plane external average knee moment during loading response of stance while wearing a SAI.

Table 1.4. Outcome measures for Aim 2 - Research Question 1.

Task	SAI	
	Without	With
Rate of Impact Loading	Times BW/sec	Times BW/sec
Time to peak VGRF	Sec	Sec
Peak VGRF	N	N
Peak external knee flexion moment during loading response of stance	N/ kg * HT	N/kg * HT
Average external knee moment during loading response of stance	N/ kg*HT	Nm/kg*HT

Specific Aim 3: To determine whether subject characteristics of body weight, severity of OA, initial pain level, hip-knee-ankle angle and Arthritis Self Efficacy score (ASES) modify the effects of the SAI on knee pain.

Figure 1.1 Model depicting predicted modifiers of shock absorbing insoles.



Research Question 1**:** Does weight, severity of OA, initial pain level, hip-knee-ankle angle and Arthritis Self Efficacy pain score (ASES) modify the effects of SAIs on pain during the six-minute walk?

Hypothesis 1: Lighter weight people will report a greater decrease in pain, relative to heavier people, during the six minute walk while wearing SAIs.

Hypothesis 2: People with less severe knee OA as measured by the KL grading scale will report a greater decrease in pain during the six minute walk while wearing SAIs.

Hypothesis 3: People with less pain as measured by the WOMAC pain subscale will report a greater decrease in pain during the six minute walk while wearing SAIs.

Hypothesis 4: People with less hip-knee-ankle angle will report a greater decrease in pain during the six minute walk while wearing SAIs.

Hypothesis 5: People with a higher sense of self-efficacy regarding pain, as measured by the Arthritis Self-efficacy Pain Subscale, will report a greater decrease in pain during the six minute walk while wearing SAIs.

CHAPTER 2

LITERATURE REVIEW

This chapter is divided into 5 sections: 1) OA of the Knee: Pathophysiology, Pain, & Functional Limitations; 2) Measures of Pain & Functional Mobility; 3) Biomechanics of Gait in People with Knee OA; 4) Treatments for Knee OA; and 5) Shock-Absorbing Insoles. Each section will describe the most current literature regarding the topic area.

OSTEOARTHRITIS OF THE KNEE: PATHOPHYSIOLOGY, PAIN & PHYSICAL ACTIVITY

The pathophysiology of osteoarthritis is characterized by progressive cartilage damage and sclerosis of the underlying subchondral bone. Osteoarthritis develops when the extracellular matrix in the articular cartilage fails secondary to proteoglycan depletion. [27] The cartilage loses its normal stiffness and "bottoms out" more easily with repeated or prolonged loading. Normal weight-bearing forces are delivered to a thinning articular cartilage causing more of the forces to be absorbed by the underlying bone. Bone is formed in response to this additional mechanical loading causing an increase in the subchondral bone density.[27] This feed-forward mechanism guarantees a progression of symptoms over time.

Knee OA and Pain

Knee pain is the primary symptom which urges persons with knee OA to visit the doctor.[5] Joint pain and stiffness are primary indicators of the presence of OA and are usually mild in the beginning and progresses with disease severity.[5, 8] Pain intensity is variable and usually worsens after activity or prolonged inactivity.[5] Pain may occur at rest and at night with more advanced joint involvement.[5] Pain control is the major goal of recommended OA treatment regimes for both nonsurgical and surgical interventions.[20, 21]

There is strong evidence that pain is poorly correlated with radiological disease in osteoarthritis.[5, 28] Physicians routinely use the Kellgren-Lawrence scoring system [29] to diagnosis OA and determine the disease severity. This classification system depends on the presence of joint space narrowing and bony changes as viewed with radiographs. The grading scale is from 0 – 4 with a grade of 0 given when there is no evidence of joint changes and a grade of 4 given when the most severe bony changes are noted.[29] Clinically, it is common for a person with severe knee pain to have only mild radiographic changes. It is also equally common for a person to have mild symptoms in the presence of severe joint radiographic evidence of disease. The literature supports this clinical finding. In a group of elders with knee OA (n = 50), there was not a significant correlation between pathology (Kellgren-Lawrence grading scale) and pain (r=.06).[28] Radiographs are the gold standard to diagnose knee OA.[29] However, after initial diagnosis, radiographs are not helpful to determine disease progression.[5]

Longitudinal studies of persons with knee OA indicate that pain is one of the primary factors which impacts function.[28, 30-31] Persons with greater knee OA pain intensity at baseline were more likely to report a decline in function over a three year period.[30] In a group of fifty community dwelling elders with knee OA, pain was positively correlated (r = .80) with self reported function.[28] Greater knee pain severity has also been shown to be associated with early functional limitations in women with knee OA.[31] Knee OA pain increases the likelihood of having clinically relevant changes in function over a two year period in people 46-56 years of age with knee OA, even after adjusting for age, gender and BMI.[32] These studies support the idea that pain is a significant contributor to decreased function in those with knee OA.

Joint pain is a primary symptom of knee OA and impacts both self-reported and physical performance functional abilities in those with knee OA. Research suggests that those with greater knee pain not only have more functional deficits but also have a greater decline in function with time. Therefore, any proposed intervention for knee OA should have a primary objective of decreasing pain.

Knee OA and Physical Activity

Physical activity is associated with a range of health benefits and its absence can have harmful effects on overall health and well being. Inactivity can increase the risk of other systemic diseases such as cardiovascular disease, obesity, and diabetes.[7] The CDC recommends that adults engage in at least 30 minutes of moderate-intensity physical activity 5 – 7 days per week.[7] Seventy percent of the estimated 60 million Americans with arthritis currently do not meet the recommended guidelines for physical activity.[3]

People with knee OA who participate in physical activity programs can improve function without an increase in pain.[33, 34] In fact, most studies report a decrease in pain after completing some sort of physical activity.[33, 35] For example, participants with knee OA (n=90) randomly assigned to complete either a quadriceps exercise or walking program reported significantly less pain ($p<.001$) after three months compared to those in the no exercise group.[33] Researchers conducting a large randomized clinical trial (N=600) investigating the effectiveness of a home exercise program for individuals with knee pain secondary to OA, reported a significant reduction in pain for the exercise groups compared to the non-exercise group at 6, 12, 18 and 24 month follow-up.[35] Results from another randomized trial (n=365) comparing aerobic exercise and resistance exercise to a health education program in older adults with knee osteoarthritis indicated a reduction in knee pain of 12% and 8% respectively for the exercise groups.[34] Even though the evidence is overwhelmingly in favor of exercise to reduce knee pain in persons with osteoarthritis, physical inactivity is very common, especially among the elderly with OA.

Persons with knee OA may be more interested to begin and continue exercise programs if they feel they can control their symptoms. Self-efficacy (SE) regarding symptom management has been determined as an important factor in exercise participation, adherence and effectiveness of nonpharmocological interventions.[36] Self-efficacy is defined as the belief in one's capability to do a specific task or achieve a certain result.[37] Research supports SE as an influential factor in determining physical function in persons with knee OA.[28, 30, 38] Sharma and colleagues [30] reported SE scores predicted both self-report and physical performance measures over a 3-year period in persons with knee OA (n=257). Participants (n=51) completing a community based exercise program, (PACE - people with arthritis can exercise) emphasized the important role of SE in maintaining physical activity.[39]

Summary Of Activity Level In Persons With Symptomatic Knee OA

Moderate physical activity is recommended by the CDC to improve overall health and well being however, a very small percentage of people with knee OA participate in regular exercise. People with symptomatic knee OA walk slower in an attempt to decrease knee pain. This slower walking speed further reduces aerobic capacity and may impact the capability of these individuals to develop and/or maintain a more active lifestyle.

The literature also supports the importance of self-efficacy in persons with knee OA. People with knee OA and high pain self-efficacy believe they can perform activities and have some influence over their pain. It is reasonable to assume that a shock absorbing insole may assist in decreasing the overall forces experienced by the knee joint during walking. A decrease in knee joint forces should decrease knee pain. An intervention which aides in decreasing knee pain during functional mobility may encourage people to engage in more physical activity. Positive benefits of continued physical activity include a reduction in knee pain and better weight management in those with knee OA. [40]

MEASURES OF PAIN, FUNCTIONAL MOBILITY, AND SELF-EFFICACY

This section presents a review of the psychometric properties of and rationale for the measures that will be used in this study to assess pain, functional mobility, and self-efficacy.

Pain Visual Analog Scale: A common way to assess pain is by the use of a pain Visual Analog Scale (VAS). The VAS is a self-report instrument consisting of a 100 mm horizontal or vertical line.[41] The line is anchored with two extremes of pain on either end: "no pain" and "worst imaginable pain". Participants are asked to rate their pain intensity by placing a single mark across the line. The clinician then measures the distance from the "no pain" anchor to the mark placed on the line. This distance is the score and can range from 0 to 100 with a higher score indicating more severe pain. This measure has been tested with patients suffering from both acute and chronic pain. Convergent construct validity has been reported as high as .95 when the VAS was compared to a numeric pain scale.[42] The VAS has excellent test-retest reliability (.71 - .99).[43] The minimum clinically significant difference on the VAS is 28 mm.[43] The VAS is a valid and reliable measure of pain which can be used to quantify pain in those with knee OA.

Gait Speed: Gait speed (GS) is considered by some to be the best measure of functional mobility.[43] It combines both spatial and temporal measurements of gait by providing information on the distance walked in a given amount of time. Gait speed is generally reported in meters per second (m/s). Testing takes less than 1 minute and is easily administered in a clinical or lab setting. Both intrasession (15 minute interval, r=0.97)) and intersession reliability (from 1 day, r=0.93 to 3 week interval, r=0.95) has been reported to be very good.[43]

Individuals with symptomatic knee OA are limited in simple mobility tasks such as walking community distances. Walking is a common functional activity required for activities of daily living and is a component of functional mobility.[43] In a group of elders with knee OA, there was a significant correlation between pain and self-reported function ($r=.80$, $p<.001$) as measured by the WOMAC physical function subscale.[28] Even patients with unilateral painful knee OA have been found to walk more slowly than healthy controls.[44] A large cross-sectional study (n = 139) found that persons with symptomatic knee OA walked slower (1.09 m/s) than those without knee OA (1.17 m/s).[45] Messier et al[18] recently reported subjects with knee OA demonstrated not only slower walking speeds, but also shorter stride lengths and a greater step width than age-matched controls. The same gait strategies were observed in middle aged females with early (stage 1) medial knee OA compared to healthy females.[46]

The altered gait strategies, especially slower walking speed, in persons with knee OA may be a compensatory strategy to decrease forces across the knee joint thereby decreasing pain.[18, 47, 48] Soft tissue forces such as muscle contractions are the major source of forces across any joint in the body. Slower walking speeds require less muscle contractile force to be developed by the quadriceps.[47] Messier et al[49]reported that slower walking speed resulted in lower joint forces and moments in persons with knee OA compared to healthy controls. These data support the hypothesis that slower walking speeds is a learned compensation to decrease pain.

Current research supports that mobility impairments precede impairments in activities of daily living (ADL) in a well functioning population.[50] In a healthy population of elderly persons age 75 and older, gait speed (GS) alone was able to predict hospitalization, new falls and the requirement of a caregiver in a two year follow-up.[50] These data indicates that slow GS in a healthy population may be the first indication that more compromising functional difficulties are imminent. Previous studies have determined that GS greater than 1 meter per second (m/s) is normal for healthy older adults.[17, 40, 51]. Gait speed of 1.3 m/s is needed to be able to cross an intersection safely.[40]

Six-Minute Walk Test: Another performance based mobility task is the six-minute walk test (6MWT). This test was originally developed to assess exercise tolerance among individuals with respiratory diseases [52] and is often used to assess mobility performance in older adults. [52] The 6MWT is a global assessment of functional mobility which summarizes both strength and endurance deficits due to cardiovascular and musculoskeletal systems .[53] Participants are asked to cover as much ground as possible in 6 minutes. The test should ideally be conducted in a long corridor which minimizes turns.[43] Reliability of the 6MTW has been reported to be very good (ICC = .98) in persons with arthritis.[53]

There are also standardized two and four minute walk tests which have been used to assess functional mobility in elderly populations. The 6MWT, however, is the most commonly used test to assess functional mobility with older adults with symptomatic knee OA.[53] In a large randomized controlled trial (N=252) evaluating the effects of diet and exercise in people with symptomatic knee OA [53] those who completed an exercise program alone or diet and exercise program showed significant improvement in distance walked during the 6MWT. There were no reports of participants not being able to complete this test secondary to pain.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): The WOMAC is a widely used multidimensional, disease specific, self-report survey originally developed for people with hip and/or knee OA.[53] It consists of 24 questions concerning joint pain, stiffness and physical function.[30] Three subscores can be calculated with the maximum score of twenty for joint pain; eight for joint stiffness and sixty-eight for physical function. The subscores can be reported individually or summed and reported as the WOMAC index or global score. For both the global and subscores, lower scores indicate lower level of symptoms and/or disability.[30, 33, 35, 40] This survey can be completed in five to ten minutes keeping the participant burden low.[33, 35, 40]

The WOMAC is available in a VAS version and a Likert scale version. The VAS version uses the previously described 100 mm line for participants to rate the degree of pain, stiffness and level of physical disability. The anchors on the VAS version are “no difficulty, pain or stiffness” and “extreme difficulty, pain or stiffness”. The VAS version is easy to administer, but labor intensive to score. For that reason, the Likert version of the WOMAC is used more often.[37] The five-point Likert version uses an ordinal scale of 0 to 4 corresponding with the adjectives none, mild, moderate, severe and extreme.

The psychometric properties of the WOMAC have been well studied.[37] Test-retest reliability for the pain subscales (.64 to .74) and the physical function subscales (.68 - .92) are good.[37] However, the test-retest reliability of the stiffness subscale (.48 - .58) was not as reliable.[54] Convergent construct validity of the physical function subscale with the SF-36 show good agreement (Spearman's rank correlation coefficient = .75).

The WOMAC in its entirety and subscales have been used extensively in the literature to address self report outcomes in person with knee OA. The WOMAC global score have been used to classify people with knee OA into poor and good outcomes in longitudinal studies.[47] The WOMAC physical function subscore is often used in research studies as a primary measure of self-reported physical function. [47] The WOMAC pain subscore has also been used to assess knee pain.[47] The WOMAC pain subscore is made up of questions regarding pain when performing certain activities over the last forty-eight hours, therefore it is not appropriate to use as a measure of pain while completing a specific task.

Arthritis Self-Efficacy Scale: Self-efficacy can be evaluated by the Arthritis Self-Efficacy Scale (ASES). This tool is a self-administered disease-specific questionnaire consisting of 20 questions. Three subscales scores can be compiled: physical function self-efficacy (FSE); pain management self-efficacy (PSE); and other symptoms self-efficacy (OSE).[47] Participants are asked to choose a number on a scale from 10 (very uncertain) to 100 (very certain) to indicate their certainty they can perform a task. A higher score indicates higher SE. This questionnaire takes approximately 10 minutes to complete. Test-retest reliability of the ASES was investigated in 91 people completing the survey twice within an average of 9 days. Pearson correlation coefficients were reported to be .87 for PSE, .85 for FSE and .90 for OSE.[55] There is no gold standard for comparison with the ASES to determine validity. However, physical self-efficacy as measured with the ASES significantly correlated with task performance assessed in the client's home (r=.61).[48] Pain SE and levels of clinical pain reported on the Arthritis Impact Scale are moderately correlated (rho = .62).[56]

Summary of Measures

Functional mobility is affected by knee pain and can be measured by both physical performance and self-report measures. The pain VAS is a valid and reliable tool used to measure a person's perception of pain. It is used extensively in both research and clinical settings. The WOMAC is a self-report instrument designed specifically to assess joint pain, stiffness and physical function. It can be used to classify persons with knee OA into different functional categories, different levels of physical function and pain. The ASES is a self-administered tool designed to assess a person's self-efficacy in regards to pain control, physical self efficacy and symptoms related to OA. Gait speed is a valid and reliable measure of both temporal and spatial attributes of ambulation. The 6MWT assesses endurance deficits secondary to multiple systems and is a good indicator of overall physical function. All of these measures are readily used to assess people with knee OA.

THE BIOMECHANICS OF GAIT IN PEOPLE WITH KNEE OA

This section discusses the kinetic and kinematic changes that take place in individuals with knee OA. Prior to a discussion of abnormal biomechanics, a review of the biomechanics of normal gait is presented.

Normal Gait

The phases of normal walking have been well described.[47] A typical gait cycle consists of a stance and swing phase of one lower extremity. The stance phase is further subdivided into weight acceptance, single limb support, and limb advancement. [47] The weight acceptance phase is the most demanding. It involves the abrupt transfer of the body weight onto a limb which has an unstable alignment. Weight acceptance comprises the first 10% of the gait cycle and is subdivided into two stages: initial contact and loading response. Initial contact is described as the instant the foot touches the floor. Loading response begins just after initial contact and continues until the opposite foot leaves the floor.[47] The primary objective of the loading response is shock absorption which requires substantial muscle contractions of the lower extremity.[47]

At the end of swing phase, the foot is falling toward the ground. When the foot hits the ground (initial contact) the momentum of the foot (and superincumbent body) is stopped by the ground. Using Newton's Third Law, the forces exerted by the ground (ground reaction forces, GRF) on the foot are equal to, but opposite in direction, of the forces exerted by the foot (foot forces) on to the ground. The amount of force exerted onto the foot (GRF) is directly related to the rate of change in momentum of the foot and superincumbent body as it comes to a stop. The rate of change in momentum is determined by the speed of the foot and the overall mass which must be decelerated during heel strike.[55]

The GRF generated during the stance phase of walking can be measured using a force plate. During normal walking the vertical GRF demonstrates a very distinct curve with two peaks. The first peak is referred to as the “weight acceptance” or “loading” peak and is usually slightly greater than the body weight. A larger than body weight vertical GRF is needed to decelerate the downward movement of the body. The second peak is referred to as the “propulsion peak” and represents the force needed to propel the body forward.[48]

The impact of the heel striking the ground during normal gait sends a stress wave up the lower limb.[56] Knee flexion at heel strike, the heel pad and articular cartilage in joints are the body’s natural defenses against the detrimental effects of these stresses.[55] Ankle plantarflexion and knee flexion occurring after initial contact are important shock absorbing mechanisms of the lower extremity.[47] The heel pad absorbs up to 80% of the tibia acceleration in human cadaver specimens.[24] There is also support that confinement of the heel pad within the heel counter of a shoe augments the heel pad’s ability to absorb shock by limiting the amount of heel pad compression at heel strike.[57]

Sagittal plane knee motion during the stance phase of normal walking is well described.[48] At heel strike the knee is flexed approximately 5 degrees and it continues to flex to 15 to 20 degrees during the loading response. This additional knee flexion serves as a shock absorption mechanism as the body weight is transferred from the opposite limb. Shock absorption is a functional obligation of the knee.[47] Knee flexion during this period is controlled by an eccentric action of the quadriceps. Following this initial flexion, the knee extends to nearly full extension until heel off (when the heel lifts off the ground). Knee extension during the stance phase is a result of a concentric quadriceps contraction.

A moment is the tendency of a force to cause a rotational movement about an axis. It is defined by the product of the force times the perpendicular distance of that force from the axis of movement.[58] Joint moments can be described in all three planes or as a resultant. A resultant moment is the sum of all the moments acting on a joint secondary to bony and soft tissue forces. In gait, both forces and moments are measured on the distal segment (foot) by the force plate. By using the inverse dynamic procedure, joint moments and forces can be calculated for more proximal segments.[58] Moments can either be described as external (secondary to forces on the extremity) or internal (secondary to the muscles to counteract the external moments). According to Newton's third law, internal moments are equal in magnitude, but opposite in direction, to the external moments.

The sagittal plane moments of the knee during the stance phase of normal gait have been well described.[47] At heel strike there is a brief external extension moment (first 4% of the gait cycle). This quickly changes to an external flexion moment during the loading response.[47] The quadriceps acts eccentrically to control the amount of knee flexion during this period of gait.[47]

Biomechanical Changes in Walking Associated with Knee OA

Abnormal biomechanical stresses occurring during the loading response that lead to changes in the articular cartilage and the underlying subchondral bone are thought to play a significant role in the development of OA in the lower extremities.[20] Repetitive loading of the lower extremities that occurs during normal walking has been identified as a risk factor for the progression of knee OA.[13] There is a greater potential for damage to both articular cartilage and the subchondral bone when the loading is more rapid.[13]

Animal studies suggest that repetitive impulsive loading in joints is a likely source of harmful stress leading to joint degeneration.[59-61] Excised bovine joints were exposed to oscillating impulsive peak loading equal to the maximal load experienced by the tissue in vivo. In all of these joints, articular cartilage wear developed and progressed rapidly.[60] Simon et al [59] subjected the knee joints of live guinea pigs to repetitive high rate (25 Hz) longitudinal impact loading over a 3 week period. Degenerative changes of the knee such as tibia stiffness and cartilage fibrillation were apparent in these animals.[59] Knee joints of live rabbits were subjected to a much briefer period of repetitive loading which more closely resembled the loading rate of normal walking.[61] Impulsive loads equivalent to 1.5 times the animal's body weight was delivered 40 times a minute for 20 -40 minutes per day. All the joints developed stiffness of the underlying subchondral bone and multiple trabecular microfractures which is consistent with damages found in joints with degenerative joint disease.[61]

Changes in Knee Flexion

Several studies indicate that people with knee OA have less peak knee flexion during the stance phase of walking.[44-46, 51] Messier and colleagues [51] performed gait analysis on adults with knee OA (n=15) and age, mass and gender matched control subjects (n=15). They reported those with knee OA demonstrated decreased knee extension (mean = 5.5 degrees) during gait. Kaufman et al[45] performed 3D gait analysis on persons diagnosed with grade 2 knee OA (n=139) and healthy participants (n=20) while walking. Results from these analyses indicated persons with knee OA had a mean of 6 degrees less peak knee motion than normal subjects ($p<.001$). Al-Zahrani & Bakheit [44] performed gait analysis on participants with severe knee OA (n=58) and healthy age and sex matched controls (n=25). The healthy subjects exhibited a mean of 14.3 degrees of knee flexion during loading response while the OA subjects only exhibited 4.4 degrees of knee flexion during this same time period. In a study conducted by Gok et al[46] females (n=13) with medial knee joint OA demonstrated significant decrease in knee flexion during stance compared to healthy females. One study was found which reported no significant differences in midstance knee flexion during stance between participants with knee OA (n=31) and a comparison group of asymptomatic controls (n=31). However, the knee OA participants in this study ranged from mild to severe knee OA and results were not reported according to severity.[12]

Walking with a "stiff" knee or a decrease in knee flexion during the loading response of gait causes a decrease in the shock absorbing ability of the lower extremity. A possible mechanical pathogenesis of osteoarthritis is presented by Radin et al[62] (Figure 2.1.). A loss of shock absorption leads to higher loads distributed across the knee joint which results in a breakdown of articular cartilage. Even slightly higher loads delivered repetitively to the weight-bearing surfaces of the knee joint may cause articular cartilage to breakdown.[59]

Changes in Impact Loading Rates

It has been suggested that repetitive high impact loading rates could be a causal factor in the development of knee pain.[13] Gait analyses were performed on subjects who had a history of activity-related tibiofemoral pain (n=18) and a control group (n=14). The knee pain group demonstrated a significantly higher loading rate (67.6 ± 22 BW/s) than the control group (47.9 ± 14.4 BW/s). The knee pain group demonstrated altered eccentric muscle control of the quadriceps and less knee flexion during stance. The authors concluded that the knee pain group demonstrated ineffective energy-absorbing mechanisms which resulted in hitting the ground harder and faster. They termed this as "microklutziness" and suggested it plays a role in the development of OA.[62]

Loading rate is a measure of shock absorption during the weight acceptance phase. One way of computing the loading rate is by dividing the vertical ground reaction force at the weight acceptance peak by the time it took to reach that peak.[51, 63] The lower this number, the more shock absorption is taking place. This method of computing loading rate does not factor in the presence of a heel transient. A heel transient is a distinctive part of the vertical GRF.[55] It is a sharp spike in the vertical GRF which occurs at the moment of initial contact or heel strike.[55] It represents the termination of movement of the foot. It is very short (10 – 20 ms) and is superimposed on the upslope of the ground reaction force. This heel transient is very difficult to obtain when wearing shoes, in fact, less than 20% of the population demonstrate a heel transient while walking with shoes.[55]

An important distinction in the way impact loading rates are discussed can be demonstrated in the Radin et al[62] study. All the subjects in this study walked barefoot which allowed the measurement of the heel transient. Impact loading rates calculated on the slope of the heel transient should not be compared with those calculated on the slope of the weight-acceptance peak. Not enough information was given in this study to calculate the impact loading rate based on the peak vertical ground reaction force during the weight-acceptance curve.

Messier and colleagues [51] compared impact loading rates while walking at a controlled speed (between 1.12 and 1.34 meters per second) among adults with symptomatic knee OA (n=15) and a group of age, mass, and gender-matched control subjects (n=15). They found no difference in the impact loading rate of the affected knee, but did report an increased loading rate in the unaffected leg at heel strike. [51] Chen et al[64], measured ground reaction force during walking with a group of healthy young adults (n=20), healthy elderly adults (n=15) and group of elderly with knee OA (n = 20). They reported an increase in the time to achieve peak vertical ground reaction force during the weight acceptance curve and a slight decrease in the weight acceptance peak in the elderly group with knee OA. The researchers interpreted this to have an overall effect as to decrease the impact loading forces in persons with knee OA. However, they did not actually compute or report impact loading rates. They also did not adjust the kinetic data for walking speed even though they reported the elderly knee OA group walked at a significantly slower speed than the other groups.

Changes in Sagittal Plane Moments

There is conflicting evidence concerning sagittal plane moments of the knee during gait in individuals with knee OA. Kaufman et al[45], found OA subjects had lower internal knee extensor moments. Baliunas et al[12], reported no significant differences in knee moments between the group of OA subjects and the comparison group. Al-Zahrani and Bakheit[44] noted higher knee extensor moments during gait in the subjects with knee OA. Messier et al[49], reported a 33.3% higher peak knee extension moment in an OA group. However, when the joint moments were adjusted for walking speed, there was not a significant difference. Higher knee extension moments have the potential to increase knee joint forces which, applied over a long period, may result in gradual degradation of the articular cartilage.[49]

EFFECTIVE TREATMENTS FOR KNEE OA

The most common approach to the management of knee OA is a combination of drug therapy and non-pharmacologic strategies. These are discussed below.

Drug Therapies

The most common drug therapies include Acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDS) and COX-2 specific inhibitors. Acetaminophen has a lower risk of side effects and is often the first line of treatment to control pain in persons with knee OA.[20] In clinical trials both NSAIDs and COX-2 inhibitors were more effective than acetaminophen in reducing pain.[65]

All of these drug therapies have known side-effects which may exclude an individual from participating in drug regimens.[20] Acetaminophen is one of the safest analgesics, but can be associated with hepatic toxicity in patients with existing liver disease.[20] For many patients, symptomatic relief is not attained with acetaminophen. NSAIDs are often recommended as the next pharmacological intervention. NSAIDs are effective in relieving symptoms, however, are strongly associated with adverse gastrointestinal events such as peptic ulcers and upper gastrointestinal bleeding.[20] COX-2 inhibitors are drugs which can control the symptoms associated with OA and decrease the incidence of gastric complications.[20, 66] However, high dosages of COX-2 inhibitors are associated with an increase risk of myocardial infarction, stroke and renal insufficiency.[66]

These pharmacological interventions are very costly. A cohort in New Mexico living with OA incurred a mean cost of $4684.00 (U.S. dollars) per year for outpatient services which included drug therapies.[65] Prescription drug costs for those OA patients averaged $1184 per year which was spent on NSAIDs, gastric acid secretion reducers and antidepressants. [65]

Custom-Fabricated Foot Orthotics

Custom fabricated, wedged foot orthotics is a non-pharmacological strategy with proven efficacy in persons with knee OA.[67-70] Reports of clinical outcomes of lateral wedged insoles have been positive. Wolfe and Brueckmann[70] reported that lateral wedged insoles produced a decrease in resting and walking pain, and promoted an increase in activity level in persons with knee OA. Sasaki and Yasuda[67] reported lateral wedged insoles and medication (n= 67) reduced pain and improved walking tolerance in patients with medial knee OA compared to medication alone (n=40).

It is theorized that a rigid foot orthotic can better control foot motion and decrease frontal plane movements and forces at the knee. For example, a person with medial knee OA who exhibits knee varus would be treated with a lateral wedged foot orthotic to decrease medial knee loading. Yasuda & Sasaki [71] suggested the lateral wedged insoles changed the spatial position of the femur and tibia to a more upright position, thereby decreasing the forces on the medial side of the knee. Recent investigations have disputed this theory. Static radiographical analysis of persons with medial knee OA (n=12) failed to identify differences in the hip-knee-ankle angle when standing with and without lateral wedged orthotics.[69] Based on these studies it is unclear as to the mechanism by which custom fabricated orthotics improve symptoms associated with knee OA.

Ogata et al[72] used an unidirectional accelerometer attached to the skin over the tibia to measure frontal plane movements of the lower leg in people without knee OA (n=40), those with unicompartmental medial knee OA (n= 38) and unicompartmental lateral knee OA (n=10). People with medial knee OA demonstrated a medial thrust of the tibia during the stance phase of walking while those with lateral knee OA demonstrated a lateral thrust of the tibia during this same period. In persons with medial knee OA, the lateral thrust of the tibia was significantly reduced with the placement of a 5 degree lateral insole in the shoe. In persons with lateral knee OA, the medial thrust of the tibia was significantly reduced by placement of a 5 degree medial insole in the shoe.[72] They concluded that placement of a properly wedged insole in the shoe could alter the loading of the knee thereby decreasing the progression of knee OA.

Research involving three-dimensional motion analysis of walking with wedged insoles has produced mixed results regarding the biomechanical effects of wedged insoles. Kerrigan et al[68] compared lateral inclined wedged insoles of 5 degrees and 10 degrees with a non-wedged even thickness insole placed in the shoe of participants with medial knee OA (n=15). Peak knee varus torque was significantly reduced when wearing both the 5 and 10 degree wedged insoles, but not when wearing an insole. The authors concluded that this reduction in knee varus torque in persons with medial knee OA could possibly slow the progression of the disease.[68] Maly et al[69] reported no differences in the knee adduction moment when walking with or without a 5 degree heel wedge. They concluded that a lateral heel wedge did not reduce the loading on the medial knee joint. One possible explanation for this different finding is that they only placed the wedged orthotic under the heel, while Kerrigan et al used a lateral wedge under the entire foot. Neither of these studies evaluated the effectiveness of the wedged orthotics in decreasing knee pain.

Although the literature generally suggests that custom fabricated foot orthotics are effective for pain relief of persons with medial knee OA, orthotics are expensive and often not covered by insurance plans. A health practitioner must also gain advanced training to properly make and fit wedged orthotics to gain maximal benefit. It is possible that some rural areas do not have appropriately trained personnel to offer this service. Custom foot orthotics range in price from $250 to $450 depending on the materials used and the health care professional who provides them. For those with limited disposable income and/or who live in rural areas, this intervention may not be a viable option.

Knee Braces

A knee brace which is designed to unload one side of the knee joint during weight bearing activities is another external intervention which has been proven clinically effective.[73, 74] These "unloader" knee braces utilize a 3-point bracing system to prevent varus or valgus thrust when walking. A load-shifting brace significantly reduces the varus moment in persons with medial knee OA (n=5).[73] Knee bracing has been reported to be more effective in relieving pain in those with moderate to severe (10 degrees) varus or valgus deformity.[74] Generally, the cost of a custom knee brace ranges from $650 to $950. Knee bracing is contraindicated in persons with OA of both compartments of the knee.[74] Brace migration, skin breakdown, obesity, cost and patient comfort are significant barriers to patient compliance with knee bracing.[73, 74]

Sociobehavioral Interventions

Sociobehavioral interventions are less expensive non-pharmacological strategies with proven efficacy in pain reduction for persons with OA.[3] Proven interventions include strength training and aerobic exercises[33, 75, 76], diet and exercise[40], walking programs[33], improving patient education regarding OA, and developing self-efficacy to manage the consequences of the disease.[37] Participants who completed a three month home exercise program (n=30) or walking program (n=30) reported significant improvement in function and knee pain compared to those who did not exercise (n= 30).[33] Data also indicate that participation in an exercise program reduced the incidence of an Activities of Daily Living (ADL) disability. Penninx et al[76], reported that persons with knee OA who did not complete an exercise program (n=80) were .57 times more likely to develop an ADL disability compared to those who completed either a resistance strengthening program (n=82) or an aerobic exercise program (n=88). Even obese older adults have reported an increase in health related quality of life after completing an eighteen month treatment program including a combination of diet and exercise.[75]

Although exercise improves pain and function in persons with knee OA, long-term adherence is essential to maintaining these gains.[77] Because exercise programs are usually offered as an adjunct therapy and not as part of the medical management of OA, it is estimated that only 2% of the population with OA participates in these types of interventions.[19] Some barriers to participation may include lack of availability, low self-efficacy, cost, lack of trained personnel to lead groups, and adverse weather conditions.

Summary of Treatments for Knee Osteoarthritis

A combination of both pharmacological and nonpharmocological treatments have been proven effective in managing pain and functional decline in persons with knee OA.[22] Custom wedged foot orthotics and knee bracing are expensive and not readily available to the general public. Resistance and aerobic exercise programs are cost effective interventions for pain control and weight reduction, however, long term compliance is low. Walking programs are a low cost, easily accessible exercise intervention which have been proven effective in improving physical function without an increase in knee pain. However, a person with knee pain may be resistant to begin a walking program for fear that knee pain will increase. Shock absorbing insoles are a low cost, readily accessible adjunct to existing shoe wear which may decrease knee pain and improve mobility and encourage people with knee OA to move more.

SHOCK ABSORBING INSOLES

The use of shock absorbing insoles (SAIs) has been suggested for people with knee OA to decrease pain and improve mobility during weight-bearing activities.[22] Repetitive impact loading is a proven risk factor for the development of degenerative changes in both articular cartilage and subchondral bone.[60-62] Augmentation of the body's natural shock absorbing mechanisms would seem beneficial for individuals with musculoskeletal disease.[24] Shock absorbing materials in shoes have been proven to attenuate forces experienced by weight-bearing joints. Athletic shoes, which incorporate shock absorbing materials in their design, lower tibial "shock" (as measured with an accelerometer) compared to leather-soled shoes.[57]

Theoretical Framework for Testing Effectiveness of SAI

Basic biomechanical principles can be applied to normal walking to better understand the forces placed on the body. Newton's Laws describe how bodies react to forces placed upon them. The impulse-momentum relationship is based on Newton's Law of Acceleration (F=ma) and describes how forces acting over a period of time can affect a body in motion. Impulse is equal to the product of force (newtons) and the time (seconds) that force acted on the body; momentum is measured by the product of mass and the change in velocity. This relationship can be expressed in the following equation: $F * t = mv_{final} - mv_{initial}$. In order to change the momentum of an object, a greater force can be applied over a shorter period of time or a smaller force over a longer period of time.

One way to affect the forces needed to control the momentum of the body is to increase the time it takes for the body to come to a stop. By manipulating the impulse-momentum equation to isolate force, one can see the relationship "time" has in controlling momentum ($F = mv_{final} – mv_{initial}/ time$). Since time is in the denominator, an increase in the amount of time it takes to bring the body to a stop decreases the force requirements. An example of this phenomenon would be walking on a compliant surface versus walking on concrete. The compliant surface deforms and increases the amount of time it takes for the body to come to a stop. This surface acts as an external device which increases the bodies shock absorption capabilities.

At heel strike, there is an impact load that must be absorbed by the body. Shock absorption can be quantified by measuring the impact loading rate during weight bearing activities such as walking. The heel pad, ankle plantar flexion and knee flexion are the body's natural shock absorbing mechanisms in the lower extremity. People with knee OA tend to walk with a stiffer knee decreasing the shock absorption capabilities of the lower extremity. Walking with a stiffer knee would seem to increase the amount of repetitive impact loading. Animal studies support the significant role repetitive loading plays in the development and progression of knee OA. A shock absorbing insole is an intervention which may decrease the amount of loading experienced by the knee during walking thereby altering pain and functional mobility deficits associated with knee OA.

Shock absorbing insoles (SAI) placed inside the shoe are a potential external mechanism to increase shock absorption by decreasing the forces up the kinetic chain. When the foot hits the ground, the SAI deforms. This material deformation increases the amount of time it takes for the body's momentum to come to a stop. This increase in time should theoretically decrease the forces acting up the kinetic chain. An increase in the deformation time will decrease the loading rate. A decrease in loading rate produces less force on the tibia and the more proximal joints.[24]

Biomechanical testing supports the shock attenuation theory of SAI.[63] Significant differences in vertical GRF, time to peak impact force and impact loading rates were reported in healthy subjects (n= 16) while wearing SAIs compared to wearing leather soled shoes.[63] The researchers concluded that SAI could decrease the impact loading force by as much as 11%.

<u>SAI Material Characteristics</u>

Shock absorbing insoles made of a viscoelastic material are best suited to attenuate the repetitive forces during gait.[55] A viscous material will allow slow, progressive deformation with an increase in loading which will allow the load to be dispersed on to a larger area, thereby absorbing more energy.[58] The deformation should happen slowly to prevent the material from bottoming out in which case, little energy would be absorbed.

Elasticity is another property that is important in the make up of an effective SAI. An elastic material rebounds quickly to assume the original shape when the load is removed. A viscoelastic material combines the material property and will absorb forces with heel impact, yet rebound quickly to be ready for the next step.[55] Finally, SAI should be comfortable so that individuals will wear them. Comfort has also been linked to a decrease in injury frequency in a group of military recruits.[23]

Literature on the Effectiveness of SAIs

SAIs have been used to prevent overuse injures and to improve comfort and performance in military recruits.[23, 78, 79] Schewellnus et al[78], randomly issued neoprene shoe inserts to 237 new military recruits to be worn with regular issue military boots. After nine weeks of basic training, the experimental group reported significantly less overuse injures to the lower leg and foot as compared to those who did not receive the inserts (n=1151). Windel et al[79], used a repeated measures design to compare four different types of soft shoe inserts worn in military boots. A foot pressure measuring device placed in the shoe determined the pressures over selected areas of the plantar surface of the foot. In this study, they concentrated on the heel pressures during heel strike while running. They found all soft inserts used in this study significantly reduced heel pressures when compared to the "no insert" condition.

In another study, military recruits (n=103) reported significantly improved comfort when wearing soft insoles in their military boots as compared to the control group (n=103).[23] A subset of these recruits (insert group = 34; control = 45) returned an injury assessment four months after beginning the study. The frequency of foot, knee and low back pain was 1.5% to 13.4% lower for those wearing the inserts when compared to the control group.[23]Severity of injuries or the characteristics of the subset of participants were not reported.

There is some evidence to support the effectiveness of shock absorbing insoles in reducing lower extremity and back pain. Nursing students who regularly stood and walked 8 – 10 hours per day were randomly divided into an insert (n=51) or control (n=49) group. The insert group was asked to wear viscoelastic insoles while working. Both groups completed pain surveys at the end of the work day for a period of five weeks. The insert group reported significant reductions in both the duration of post-work pain and the frequency of pain during work.[25]

There is also evidence to support the use of shock absorbing insoles to control foot motion. It is standard practice to prescribe a rigid orthotic to control over pronation in the foot.[80] Mcpoil and Cornwall [80] used a single subject design to compare the rearfoot and forefoot impulse while walking and running with both a rigid and shock absorbing insole in a 20 year old female with a history of excessive pronation and stress fractures in the foot and lower leg. Impulse refers to the amount of vertical force acting over time and can be used as an indicator of shock attenuation.[80] They reported that both during walking and running the shock absorbing insole significantly reduced the rearfoot impulse compared to the rigid orthosis. They concluded that shock absorbing insoles should be considered when a reduction of forces is desired, even for persons with motion control issues.[80] However, there was no follow-up to determine the long term effects of SAI on lower extremity pain nor was there an assessment of foot kinematics.

Others have suggested that both motion control and shock absorption can occur with a SAI. Eng & Pierrynowski[81] investigated the use of SAI with rubber medial wedges placed in both the rear and forefoot on adolescent females complaining of patellofemoral pain and excessive pronation (n= 10). They determined a SAI with medial posting significantly reduced knee frontal plane movement while walking.[81] This was something that was previously considered only possible with rigid foot orthotics.

Only one study was found investigating the effectiveness of SAI on persons with degenerative joint conditions. Voloshin and Wosk [26] placed an accelerometer on the participant's (n= 10, age range 16 – 45 years) tibial tuberosity with elastic straps to register bone vibration. Participants walked with and without viscoelastic inserts at a controlled speed. They reported a 42% reduction in shock waves when wearing the viscoelastic insert compared to shoes alone. No mention was made of the location of the OA symptoms or radiographic evidence of severity. The researchers concluded that viscoelastic inserts were effective artificial shock absorbers and issued them to patients (n=60) to investigate clinical improvement. They issued SAI to patients with headaches, metatarsalgia, and knee pain (45%). After 18 months of use, patients were reevaluated for clinical symptoms. Seventy-eight percent of the subjects reported an abolishment of symptoms while 17% reported a satisfactory result. The researchers concluded that SAI were an effective intervention to reduce shock waves on the musculoskeletal system in persons with degenerative joint disease. This study, however, has many limitations including a heterogeneous sample and lack of details on subjects and the method. Conclusions on the effectiveness of SAIs for subjects with knee OA cannot be made from this study

Summary of Literature

It is clear from the cited research that shock absorbing insoles have the capability of assisting in the attenuation of impact forces on the lower extremity during weight bearing activities. A surprising lack of empirical evidence exists to document the effectiveness of SAI in persons with knee OA. Most of the research testing the effectiveness of SAIs was either performed on healthy subjects or younger individuals with overuse injuries. . Individuals with knee OA are generally older and more sedentary individuals.

Shock absorbing insoles are currently a recommended intervention for persons with hip and knee OA to decrease pain.[3, 21] Repetitive impulsive loading across the joints of the lower extremity is a recognized risk factor for the development and progression of knee OA. Theoretically, SAI would seem to be an easy choice to decrease the attenuation of the vertical ground reaction forces. Also they are inexpensive and are readily available to a vast majority of the public with knee OA. The efficacy of SAI on this population is not known .

This study will fill a void in the literature by evaluating the effectiveness of a commercially available shock absorbing insole on knee pain, functional mobility and kinetics in persons with documented evidence and symptoms of knee OA. It is possible that some people may benefit more than others with the use of SAI. This study also seeks to identify those participants who may maximally benefit from the use of SAIs.

Figure 2.1. Outline of the hypothesis of joint degeneration as described by Radin et al. [13]

Impulsive loading

↓

Trabecular microfracture

↓

Bone remodeling

↓

Resultant stiffening of the bone

↓

Increased stress in articular cartilage

↓

Cartilage breakdown

↓

Joint degeneration

CHAPTER 3

METHODS

Research Design:

This study was a quasi-experimental, one group, pretest posttest design. The independent variable was shock absorbing insole. The outcome measures were knee pain after walking, functional mobility, and biomechanical characteristics of the lower extremity during walking.

Subjects

Sixty community dwelling older adults were recruited by several different methods: a mass email was sent to the WSSU university faculty, staff and students; a newspaper ad was placed in the local Sunday paper; and flyers, informational sessions and word of mouth communication was used at local YMCA's, churches and outpatient rehabilitation facilities. A sample size of 60, determined a priori, provided 80% power to detect a 10 mm change in the primary outcome measure (VAS Pain score) (Appendix A). Interested individuals were screened over the phone to determine whether they met the following inclusion criteria: 1) 50 years of age or older; 2) radiographic evidence of knee OA in the test extremity (K-L grading scale = 1 to 4); 3) Knee pain (WOMAC pain subscore of 4 or more and report moderate pain on at least 1 listed activity in the WOMAC) on most days[82]; 4) able to speak, write, and understand English; 5) able to walk 25 feet without an assistive device; 6) wear a shoe size available in the lab

(Women's 6 – 10 and Men's 8 – 14); and 7) able to attend two sessions of data collection within 14 days. Individuals were excluded if they: 1) were currently wearing some type of foot orthosis (custom or over-the counter); 2) had lower extremity surgery of the test leg in the past 12 months; 3) had a total knee replacement on the involved leg; 4) had hip and/or ankle OA in the involved leg; or 5) had a neuromuscular disorder which affected their walking ability.

Participant Incentives: Each participant received a free radiograph to properly stage knee OA severity. At the completion of the study, each participant also received a pair of shock absorbing insoles and a pair of soft-sole brand socks used in the study.

Instrumentation

All data were collected in the Kate B. Reynolds (KBR) Human Performance Laboratory located in the FL Atkins Building on the campus of Winston Salem State University. This is a 900 square foot research lab equipped with a ViconPeak gait analysis system with 8 optielectric (60 Hz) cameras interfaced with an event and video control unit, AMTI force plate, and a Pentium 4 microcomputer equipped with a 250-gigabyte hard drive and VGA color monitor. There was also a 7.3 meter raised walkway with two embedded AMTI force plates. A photoelectric timing device interfaced with a digital timer (model 65301, Lafayette Instrument Co, Lafayette, Inc) was placed beside the walkway (4.2 meters apart) to accurately measure gait speed to the nearest .01 second.

All participants wore the same type of shoe (Avia Cantilever, model 2051) and sock (Sofsole low cut) to control for the effects of variable shoe and sock types. This decision was based on pilot testing where participants were allowed to wear their own "walking shoes" and socks during testing. Frequently the shoe's insoles were not removable and/or the heel counter was not deep enough to accommodate the shock absorbing insole. In addition, socks worn varied in thickness. The lab shoe and socks worn in this study had identical construction for both men and women. The shoes had an easily removable insole and a deep heel counter. The midsole was made from compression molded EVA and featured a curved last which is designed to work with the curvature of the human foot to promote natural foot strike. Shoes were available in whole and half sizes (Men's 8 – 14; Women's 6 – 10). If a woman wore larger than a size 10, she was fitted with a man's shoe.

Shock absorbing insoles: The intervention in this study was an off-the-shelf shock absorbing insole (SofSole Athletes Plus, Implus Inc, Durham, NC) available in most athletic shoe stores, retailing for $19.99. The insole is full-length with a curved last made of a type of closed cell foam called *Implus XP*. Specific details of the composition of the *Implus XP* foam are propriety protected and unavailable The SAI also has extra implus material at the heel (durometer reading of 60) and metatarsal area (durometer reading of 55) for added shock absorption. This particular SAI was recommended by the manufacture for repetitive activities such as running and walking.

Primary Outcome Measure

The primary outcome measure was knee pain intensity, measured on a visual analog scale (VAS) after walking at a self-selected pace, fast pace and 6MWT. The scale consists of a 100 mm horizontal or vertical line (Appendix B) [41]anchored with two descriptors : "no pain" and "worst imaginable pain". Participants were asked to rate their pain intensity by placing a single mark across the vertical line. The distance from the "no pain" anchor to the mark placed on the line was measured and recorded. This distance is the score and can range from 0 to 100. A higher score indicates more pain. This measure has been tested with patients suffering from both acute and chronic pain. Concurrent construct validity has been reported as high as .95 when the VAS was compared to a numeric pain scale.[42] In a study of ninety-one patients with rheumatoid arthritis, the VAS pain scale had excellent test-retest reliability (ICC = .94).[83] The minimum clinically significant difference on the VAS pain scale as reported by a group of subjects with temporomandibular pain was 28 mm.[43]

Secondary Outcome Measure

Several secondary outcomes were also assessed including gait speed, distance walked during the 6MWT, WOMAC, Arthritis Self-Efficacy Scale (ASES), and lower extremity kinetic data.

Gait speed (GS) is the best measure of functional mobility.[43] In this study both self-selected and fast gait speed were assessed. Testing takes less than 1 minute and is easily administered in a clinical or lab setting. In a study investigating the reliability of gait speed in persons with knee OA, self-selected gait speed intrasession reliability (15 minute interval, ICC=0.94) and intersession reliability (1 week interval, ICC=0.95) was high.[43] The photoelectric timing device measured the participant's gait speed over the central 4.2 m to the nearest .01 second. Gait speed is generally reported in meters per second (m/s).

Six-minute walk test (6MWT). Subjects were instructed to walk for 6 minutes and to cover as much ground as possible. The test is scored by measuring the distance traveled in meters. Results of the 6MWT are significantly correlated to treadmill time and symptom-limited maximal oxygen consumption (r = 0.52 and r = 0.53, respectively) and have a 3-month test-retest reliability of 0.86.[43] The test should ideally be conducted in a long corridor which minimizes turns.[43] Participants in this study walked along a 300 foot corridor (eight feet wide) located just outside the KBR research lab in the FL Atkins building.

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The WOMAC is a widely used multidimensional, disease specific, self-report survey originally developed for people with hip and/or knee OA.[52] It consists of 24 questions about joint pain, stiffness, and physical function (Appendix C). Three subscores can be calculated with the maximum score of 20 for joint pain; 8 for joint stiffness, and 68 for physical function. The subscores are generally reported individually. For all of the subscores, higher scores indicate higher level of symptoms and/or disability.[53] This survey can be completed in five to ten minutes keeping the participant burden low.[43] Test-retest reliability for the pain subscales (.64 to .74) and the physical function subscales (.68 - .92) are good.[53]

Arthritis Self Efficacy Scale (ASES). The ASES is a self-administered disease-specific questionnaire consisting of 20 questions on the certainty with which different arthritis-related tasks are performed (Appendix D). Questions are scored on a 10 point scale ranging from 1 (very uncertain) to 10 (very certain). Three subscales scores (10 – 100) physical function self-efficacy (FSE); pain management self-efficacy (PSE); and other symptoms self-efficacy (OSE) can be calculated by taking the mean of the subscale items.[37] A higher score indicates higher self-efficacy (SE). The questionnaire takes approximately 10 minutes to complete. Test-retest reliability of the ASES has been reported to be from .87 - .90 for the different scales.[37] Pain SE and levels of clinical pain reported on the Arthritis Impact Scale are also moderately correlated (rho = .62).[54]

Gait Analysis: Three-dimensional kinematic gait data were collected using ViconPeak motion analysis system and software (ViconPeak Performance Inc, Denver, CO). This system uses eight infrared cameras recording at 60 Hz to capture the motion of the reflective markers which are placed on bony landmarks of the participant. Forces (Fx,Fy.Fz) and moments (Mx,My,Mz) were collected from AMTI (American Medical Technology Inc, Watertown, MA) force plates embedded into the raised walkway and integrated with the motion capture system to allow simultaneous kinetic data collection at a sampling frequency of 600 Hz. The raw analog data were amplified (gain = 4000 for all six channels), scaled to newtons and matched to the kinematic data.

Infrared photoelectric timing device interfaced with a digital timer (model 65301, Lafayette Instruments, Los Angeles, CA) placed beside the walkway 4.2 m apart measured gait speed to the nearest .01 second.

Additional Measures: Demographic information, a brief medical history, and current medications for knee OA were also obtained from each subject. Demographic information (Appendix H) included contact information, gender, date of birth, marital and working status and level of education, On the brief medical history form (Appendix I), participants indicated if they had been diagnosed and currently treated for any of the listed medical conditions. If they had been diagnosed with any of the medical illnesses, they were asked if it limited their activities and, specifically, if it affected their walking ability. They were also asked to indicate if they had ever undergone a total knee replacement. The medication list (Appendix J) listed different classifications of common OA drug treatments including prescribed and over the counter medications. Participants were asked to only check if they were currently taking that classification of drug. Specific drug names or dosage was not recorded.

Procedures:

Each participant received a radiological exam and completed two lab visits to minimize the effects of fatigue. Please refer to Figure 3.1 for a pictorial representation of the testing protocol. Eligible subjects were scheduled for the initial lab visit and asked to identify the most symptomatic knee for radiographic evaluation. The primary investigator contacted the radiologist with the participant's date of birth and involved leg and received a physician's referral for the radiographs via fax. Participants were sent letters verifying the date and time of the first lab visit. The letter also contained directions to the facility and a parking pass for the WSSU campus.

Lab Visit 1:

The study was explained to the participants and they completed an informed consent prior to any data collection. Participants then completed the following forms: , demographic, medical history, medication list, the WOMAC questionnaire, and the ASES. Participants were then oriented to the lab equipment and anthropometric measurements necessary for the biomechanical gait analysis were taken and recorded. The participant was then fitted with a pair of lab walking shoes and socks and given the opportunity to accommodate (approximately 10 minutes) to walking in those shoes.

Participants then completed both the self-selected gait speed test and the fast gait speed test (in that order) under both conditions (with and without SAI). The order the conditions were tested was randomly determined prior to the visit. The testing ended with the 6MWT under one of the SAI conditions (randomly chosen). Details of the procedures for each of the functional mobility tasks are as follows:

1) *Self Selected Gait Speed:* Participants walked down a raised 7.3 meter walkway. The photoelectric timing device interfaced with a digital timer was set up in the central 4.2 meters of this walkway. This method of only measuring the central portion of the walkway ensured the participant was neither accelerating nor decelerating. The timing device was placed on tripods at the beginning and end of the capture area so that the beam was at the level of the participant's pelvis. Participants completed two trials of walking at their self-selected speed and the time elapsed was recorded to the nearest .01 second. The distance (4.2m) was divided by the elapsed time (sec) to determine gait speed (m/sec). Participants rated their pain intensity on the VAS after completing both trials. Refer to Appendix K for data collection form.

2) *Fast Gait Speed:* Participants were also asked to complete two trials walking "as fast as you safely can" along the same 7.3 meter walkway. The timing device was again utilized to determine the time it took to walk the central 4.2 m recorded to the nearest .01 seconds. Results of the two trials were averaged and reported in meters/second. After completing both trials, participants rated their pain intensity on the VAS. Refer to Appendix K for data collection form.

3) *Six Minute Walk Test:* A 300 foot hallway located just outside the KBR lab was used for this test. This hallway was marked with tape every twenty-five feet. The subject's resting blood pressure was measured. Participants with a resting blood pressure of 200 systolic or 110 diastolic, were not allowed to complete this test. Participant's were asked to "cover as much ground as possible" by walking back and forth along the walkway for six minutes. The tester recorded the number of hallway laps completed. At the end of six minutes, the participant stopped and the tester marked the position of the participant on the floor with tape. The tester

then measured the distance from the nearest twenty-five foot marker to the place where the participant stopped. This distance was added to the known distance walked (one lap = 91.4 m). Participants rated their pain intensity on the VAS after completing the six minute walk. Refer to Appendix K for data collection form.

After completing the functional mobility tasks, the participant was given the radiograph referral and directions to the Comprehensive Rehabilitation Plaza in Winston-Salem, NC where the radiographs were performed.

Radiographic Screening An anterior-posterior weight-bearing knee x-ray was used to identify tibiofemoral arthritis. The participant's knee was flexed to 15 degrees, and the beam was centered on the joint space. The minimum joint-space width of the knee was measured using a 0.1 mm graduated magnifying lens to assess disease progression. Severity of tibiofemoral OA was measured using the K-L grading scale (Grade 0 – 4).[29] The literature supports excellent intrarater reliability with severity scores (ICC = .88 - .91).[84] Participants with a K-L grading scale of 1 – 4 were eligible for this study.

A standing full length weight-bearing x-ray was used to determine mechanical hip-knee-ankle (knee varus/valgus) angle. The participant stood with equal weight on both lower extremities without footwear, positioned so that the tibial tubercles faced forward and the midheel and second digit of each foot are aligned with pieces of tape placed perpendicular to the frontal plane. The x-ray beam was centered on the test knee at a distance to allow visualization of the hip and foot. Depending on limb size, a setting of 100-300 milliampere-seconds and a kilovoltage of 80-90 was used. The physician measured the mechanical hip-knee-ankle angle to determine the amount of knee malalignment. The mechanical axis refers to the angle formed by a line drawn from the center of the femoral head to the center of the tibial spine and a line drawn from the tibial spine to the center of the ankle joint. Hip-Knee-Ankle angles greater than 180 degrees were in a valgus position while angles less than 180 degrees were in a varus position.[85] Intrarater reliability of radiographic measurement of the mechanical axis of the knee is very good (ICC = .98 - .99).[86]

The primary investigator transported all radiographic films (identified only by subject ID) from the Comprehensive Rehab Outpatient Center (Winston-Salem, NC) to Dr. Jordan Renner MD (Associate Professor, Radiology, UNC-CH School of Medicine) who was the primary radiograph reader. Each set of films were accompanied with a data form (Appendix L) . Dr. Renner completed the data forms and returned them to the primary investigator.

<u>Lab Visit 2:</u>

The second lab visit was scheduled within 14 days of the first lab visit. To confirm that pain levels were comparable between visits, the WOMAC pain subscale was administered again at the second visit. The 6MWT was repeated with or without the SAI as was determined in the initial visit. Participants then completed the biomechanical gait analysis.

Procedure for Gait Analysis: Gait analysis was only performed using a self-selected speed. Subjects changed into standardized test clothing (black shorts and top) and reflective markers were placed (using the modified Helen Hayes Marker Set) on the following body parts: sacrum, bilateral ASIS, mid thigh using a wand, lateral epicondyle of the femur, tibia using a wand extender, lateral malleolus, heel marker, and 2nd head of metatarsal (modified from originally described marker set). The marker placement modification was required by ViconPeak to better integrate with their software. An extra marker was also placed on the anterior right thigh to easily identify the right leg. Subjects completed 6 acceptable walking trials at their self-selected walking speed under each condition (with and without SAI). An acceptable trial was defined as a trial which the participant's entire foot was placed on the force plate and all markers were visible throughout the trial. The order of the testing (with and without the SAI) was completed in the same order as the functional mobility testing. Subjects were allowed an accommodation period of 10 minutes between conditions and were allowed to rest between trials as needed.

Data Reduction:

Self selected gait: Gait speed was averaged over the two trials for each condition (self-selected and fast) and recorded as the average self selected gait speed with (SSGSI) and without (SSGSN) the SAI. The VAS scales were measured to the nearest millimeter for each condition and recorded.

Fast gait: The gait speed recorded for the fast walking trials under each condition (with and without SAI) were averaged together and recorded as the average fast gait speed with SAI (FGSI) and without the SAI (FGSN). The VAS scales were measured to the nearest millimeter for each condition and recorded.

Six Minute Walk: The distance walked to the nearest inch with the SAI (6MWI) and without the SAI (6MWN) was recorded and converted to meters. The VAS scales completed after each condition were measured to the nearest millimeter and recorded.

Gait analysis: Operational definitions: Initial contact was determined by the first time point when the vertical ground reaction force (VGRF), as measured by the force plate, exceeded zero. Loading response began at initial contact and ended when the VGRF reached the peak force during the weight acceptance curve of the ground reaction force curve (Figure 3.2). The rate of loading was determined by dividing the peak VGRF of the weight acceptance curve by the time it took to reach that peak (LR = peak VGRF/time to peak VGRF).

Gait analysis data reduction: All kinetic data were reduced and analyzed using the Peak Motus KineCalc software version 8.0 (ViconPeak Performance Inc, Denver, CO). Raw kinematic data under each condition were filtered using 4^{th} order Butterworth low pass digital filter with a cut off frequency of 6 Hz.[87] The smoothed coordinate data, GRF, gravitational and inertial forces served as input to an inverse dynamics model to calculate selected 3-dimensional knee external moments. Refer to Appendix E for detailed calculations. Each individual selected trial was time normalized to the stance phase of the gait cycle. Refer to Appendix F for gait analysis data collection form. Previous pilot testing confirmed reliability of these measures (Appendix G).

Three out of six trials under each condition were chosen for data analysis. Only trials with GS within $\pm$ 3.5% of self-selected walking speed were used for data reduction. Outcome variables were recorded from each of the selected three trials and then averaged together for each condition (with and without SAI) for further data analysis.

Peak vertical ground reaction forces (F_z) were normalized to body weight (N) to make valid comparisons across subjects. Kinetic variables included loading rate during loading response; time to peak VGRF, peak VGRF, peak external knee flexor moment and average sagittal plane knee moment during loading response of stance. The external peak knee flexor moment during the loading response of gait and the averaged external knee moment during loading response were normalized by the product of body mass and height (kg*m).[88]

Data analysis:

Separate one-way, within subject repeated measures ANOVA's were conducted to determine the effect of SAI on each of the outcome variables. Shock absorbing insoles was the within subject factor with 2 levels (with and without SAI). Separate one-way, within subject repeated measures ANCOVA's were conducted to determine whether subject characteristics (e.g., weight, OA severity, etc.) modified the effects of SAI on knee pain after completing the 6MWT. To further explore the data, we performed post hoc analysis by computed pain change scores reported during the 6MWT both with and without the SAI (pain without SAI – pain with SAI). Negative numbers indicated a decrease in pain. We determined quartiles for each variable and used the participants in the lowest and highest quartiles for comparison using an independent sample t-test with the change scores in 6MWT as the dependent variable. We used an ANOVA when more than two groups were to be compared. All tests were 2-sided with the alpha level set at .05. All analyses were conducted using SPSS ver 15.

Figure 3.1. Summary of Data Collection

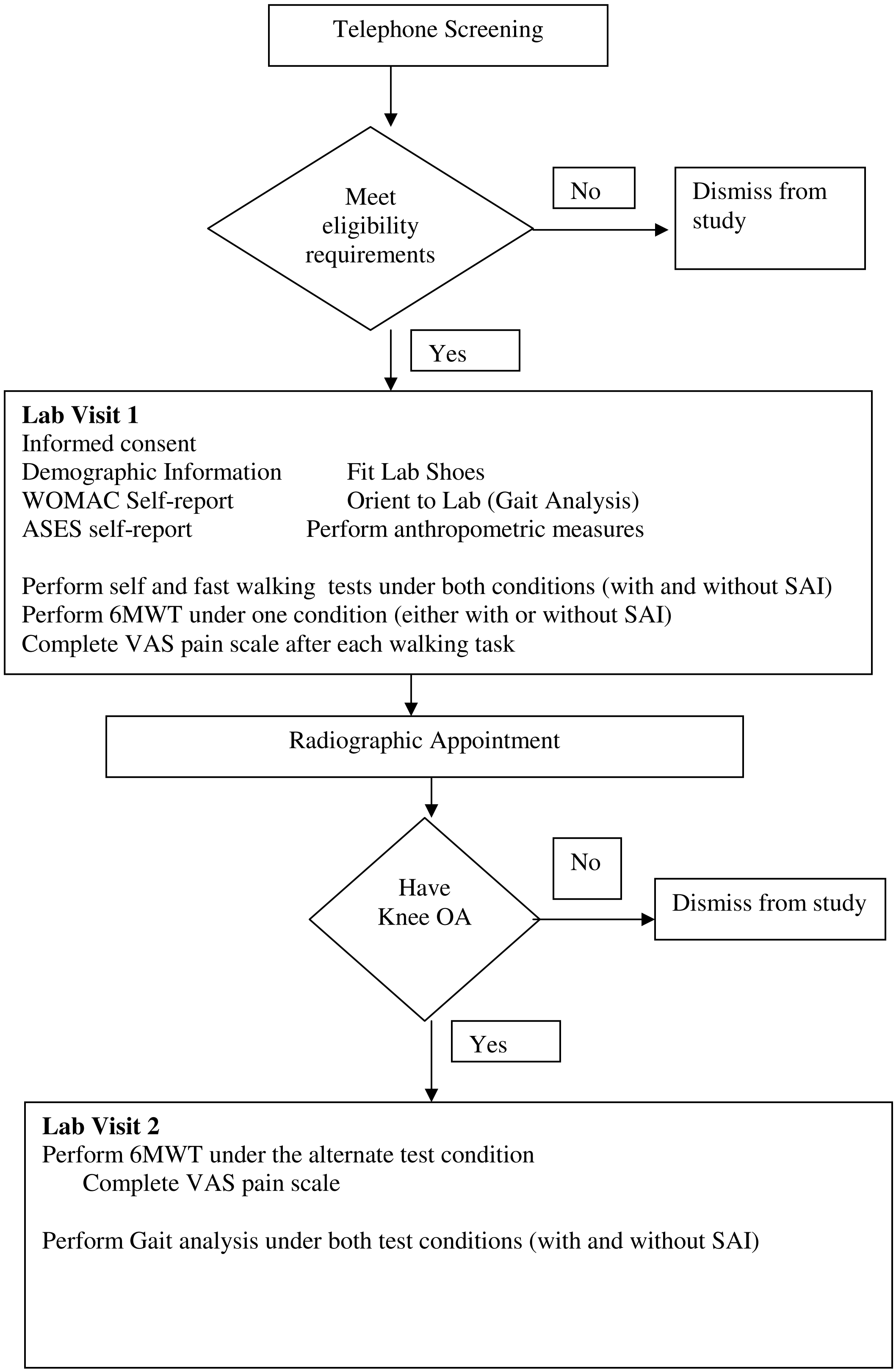
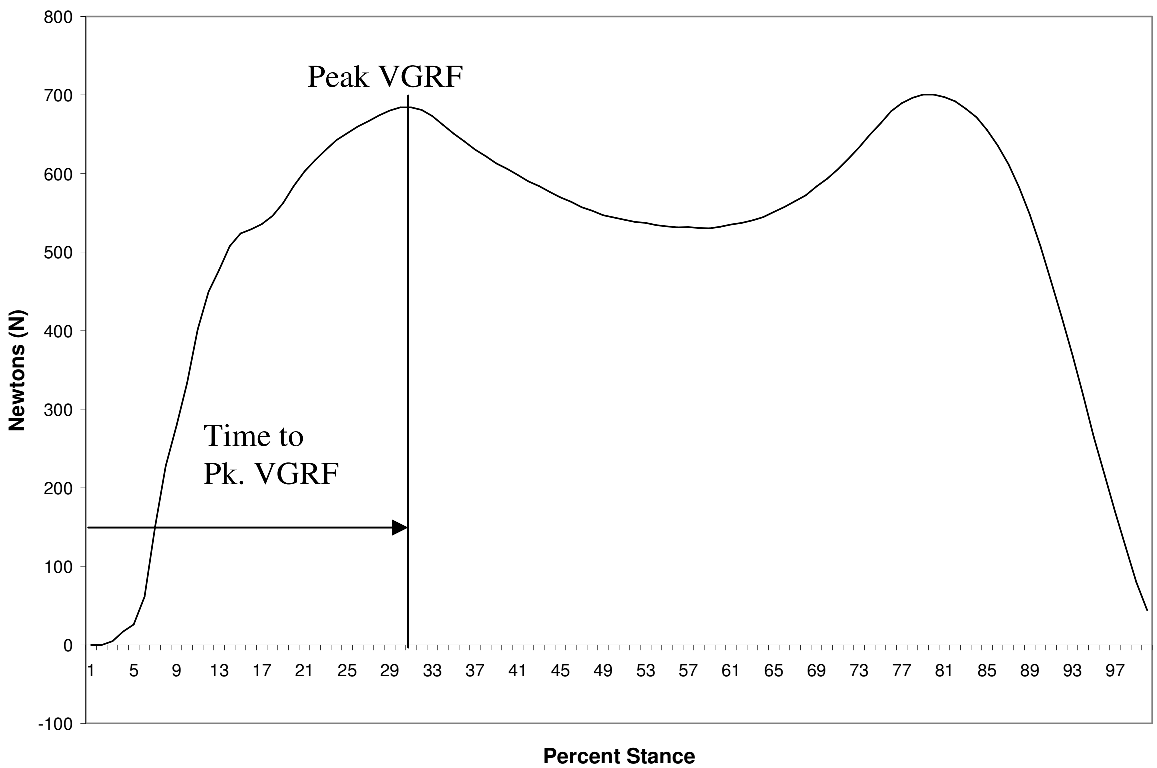


Figure 3.2. Typical ground reaction force during stance phase of walking at self-selected speed. Peak VGRF and time to peak VGRF during load acceptance phase of stance is identified. Stance is shown in percent time.



CHAPTER 4

RESULTS

Ninety-four individuals were screened via telephone. Sixty-nine participants met all criteria and were invited to participate in the study. Four participants dropped out of the study prior to getting the required x-ray. The reasons for the participant dropout varied: one person fell and broke his hip; one person an unexpected trip for an extended period; two people dropped out for unknown reasons. Five participants were excluded secondary to lack of radiographic evidence of knee OA. The final sample consisted of 60 community-dwelling senior adults (23 males, 37 females). Participant demographic descriptive information is listed in Table 4.1 and 4.2.

The dependent variables were knee pain, gait speed, distance walked and kinetic variables which occurred during loading response of the stance phase of gait. All kinetic variables of interest occurred during loading response of the stance phase of the gait cycle. Kinetic variables included time to peak vertical ground reaction force (VGRF), peak VGRF, loading rate, peak and average sagittal plane external knee moment. The independent variable was shock absorbing insoles (SAI). Comparison of baseline WOMAC pain subscores (table 4.1) for the two testing days did not reveal a significant difference (t_{60} = 1.043, p = .301).

All functional mobility outcome variables and pain measures were within two standard deviations of the mean, therefore, all data (n = 60) for these variables were used in the data analysis. Data from the gait analysis were not analyzed for two subjects secondary to camera malfunction during data collection. Of the remaining participants (n = 58), moment data were unavailable for one person. Therefore, analysis of force plate data was conducted on all 58 participants, while analyses on moment data were conducted on only 57 participants. *Apriori* alpha levels were set at $p < .05$ for all analyses.

Two participants reported having a total knee replacement (TKR) on the non-tested limb.. Only a few characteristics differed from the group mean. They had a higher BMI (36.3 and 40.9), walked at a slower self-selected speed (.98 m/sec, and .75 m/sec) and walked a shorter distance on the 6MWT (303.9 m and 296.8 m). All other variables were very close to the group mean. Analyses were conducted both including and excluding the data from these two individuals. Although the means and significance levels changed slightly, there was no change in the outcomes on any variable (Appendix M). Therefore, data reported include all participants.

Aim 1 – Pain and Functional Mobility Outcome Measures

Knee pain was the primary dependent variable (Table 4.3, Figure 4.1). Participants reported significantly less pain after walking six minutes while wearing the SAI (26 $\pm$ 25.7 mm) as compared to shoes alone (31.4 $\pm$ 28 mm, $F_{1,59} = 5.067$, $p = .028$). Effect size (ES) was small (.079) while power (1-β) estimates were moderate (.60). No significant differences were found when comparing the participants who reported a decrease in pain (57%, n = 34) while wearing the SAI compared with those who actually reported an increase in pain (32%, n = 19). Post hoc t-test performed on these two groups revealed no differences in age, BMI, number of comorbidities, initial WOMAC pain subscore, or ASES pain subscore (table 4.4). A higher percentage of retired people (35%) and those with a college degree (53%) reported a decrease in pain while wearing the SAI compared to those who reported an increase in pain (16% retired; 47% college).

There were no significant differences in knee pain while walking with or without the SAI during self selected walking speed ($F_{1,59}$ = 0.26, p = .873, ES < 0.001, $1\text{-}\beta$ = .053), or fast walking speed ($F_{1,59}$ = 3.611, p = .062, ES = .058, $1\text{-}\beta$ = 0.464). There were no significant differences in functional mobility outcome measures when wearing the SAI as compared to not wearing the SAI (table 4.5, figure 4.2). Specifically, no statistical differences were found in self selected gait speed ($F_{1,59}$ = .032, p = .859, ES = .001, $1\text{-}\beta$ = .054) or fast gait speed ($F_{1,59}$ = .792, p = .377, ES = .013, $1\text{-}\beta$ = .141). Likewise, there was no difference in the distance walked (table 4.5, figure 4.3) during the six minute walk while wearing the SAIs compared with not wearing the SAIs ($F_{1,59}$ = 1.105, p = .297, ES = .018, $1\text{-}\beta$ = .179).

Based on these findings the use of SAI appeared to decrease pain when a person with symptomatic knee OA walked for a sustained period of time (e.g. 6 minutes). However, the use of SAI did not influence pain during shorter walking distances at either the slow or fast walking speed. The use of a SAI did not change self selected walking speeds, allow faster walking speeds, or allow more distance to be covered during a timed walking test.

Aim 2: Biomechanical Outcome Measures

There were no significant differences in the biomechanical outcome measures that occurred during loading response (heel strike to time of peak vertical ground reaction force) while wearing SAIs versus shoes alone (table 4.6, figure 4.4, 4.5, 4.6). There were no significant differences in the time to reach peak VGRF ($F_{1,57}$ = .343, p = .560, ES = .006, $1\text{-}\beta$ = .089), peak VGRF during loading response ($F_{1,57}$ = 2.648, p = .109, ES = .044, $1\text{-}\beta$ = .360) or loading rate ($F_{1,57}$ = .486, p = .489, ES = .008, $1\text{-}\beta$ = .105) between the two conditions.

Knee external moments occurring in the sagittal plane during the loading response were analyzed between both conditions (table 4.6, figure 4.7). The peak external moment was not significantly different between the two conditions ($F_{1,56}$ = .020, p = .887, ES <.001, $1\text{-}\beta$ = .052). The average external moment during this time frame was also not significantly different between the two conditions ($F_{1,56}$ = .848, p = .361, ES = .015, $1\text{-}\beta$ = .148). The kinetic variables most closely associated with an increase in shock absorption were not changed with the use of a SAI during self-selected walking speeds.

Aim 3 – Do Subject Characteristics Modify The Effects of SAIs?

Physical characteristics of participants were used as covariates when comparing pain recorded after the six minute walk test (6MWT) for both conditions (table 4.7). One participant was unable to complete the ASES and was excluded from analysis on that outcome variable only. There were no significant interactions with SAI and participant weight ($F_{1,58}$ < .001, p = .987, ES < .001, $1\text{-}\beta$ = .050), knee OA severity ($F_{1,58}$ = 1.185, p = .281, ES = .020, $1\text{-}\beta$ = .188), or hip-knee-ankle angle ($F_{1,58}$ = .059, p = .809, ES = .001, $1\text{-}\beta$ = .057). The baseline pain (WOMAC pain subscore) did not modify the effects of SAI ($F_{1,58}$ = .843, p = .362, ES = .014, $1\text{-}\beta$ = .147). The ASES pain subscore also did not have an interaction effect with the SAI ($F_{1,57}$ = 2.670, p = .108, ES = .045, $1\text{-}\beta$ = .362),

Post hoc analysis examining the five variables we most suspected to modify the effects of SAI on pain reduction (weight, knee OA severity, initial pain, knee malalignment, and self-efficacy) during the 6MWT revealed no significant differences between participants in the lowest and highest quartiles for each of the targeted characteristics (table 4.8).

Heavier people (range 102.2 – 141kg., n = 15) reported a larger decrease in pain (2.4 ± 21.1 mm) versus lighter weight participants (range 54 – 72.8kg, n=15, change in pain = .2 ±

12.2 mm, 4.67, t_{28} = .414, p = .682, figure 4.8). People with less severe knee OA (K-L grade 1, n=20) reported a larger decrease in pain (9 $\pm$ 18.1 mm) while wearing the SAI compared to those with a K-L grade 4 (4.1 $\pm$ 20.3 mm, n = 13, t_{31} = -.725, p = .474 , figure 4.9).

We hypothesized participants with less pain as measured by the WOMAC pain subscore would report less pain during the 6MWT while wearing the SAI. Since no significant differences were found between the two WOMAC pain subscores on the two different testing days, only the initial WOMAC pain subscore (range 4 – 20) was used in the post hoc analysis. Participants with a high initial WOMAC pain subscores (range = 10 – 17, n = 16) reported a larger decrease in pain when wearing the SAI (15.4 $\pm$ 17.5 mm) as compared to participants with a low initial WOMAC pain scores (range 4 – 6, n=21, decrease in pain = 4.7$\pm$ 15.5 mm, t_{35} = 1.972, p = .057, figure 4.10).

Participants with a varus alignment (n = 41) reported the greatest decrease in pain while wearing the SAI (6.6 $\pm$ 20.3 mm) versus those with a valgus alignment (4.3 $\pm$ 11.3 mm, n = 13) or those with neutral alignment (1 mm, n = 6). No significant difference were found between the groups ($F_{2,57}$ = .463, p = .632, figure 4.11). Participants with a mild varus knee angle ($\leq$3 degrees, n= 18) reported a greater decrease in pain (8.5 $\pm$ 22.4 mm) when wearing the SAI during the 6MWT as compared to those with a more severe varus angle of the knee (> 7 degrees, n = 15, decrease in pain = 6 $\pm$ 20.9 mm). However, no significantly difference was found (t_{31} = .326, p = .747, figure 4.12). There were fewer persons with valgus alignment (n = 13), however, the same pattern was still present. Those with mild valgus ($\leq$ 2.5 degrees, n = 3) reported a larger decrease in pain (10.6 $\pm$ 19.4 mm) compared to those with more severe valgus ($\geq$ 5 degrees, n = 4, decrease in pain = 5 $\pm$ 8.1 mm).

Those who reported a higher level of self efficacy (ASES score > 78, n=16) only reported a very small decrease in pain (1 $\pm$ 18.5 mm) during the 6MWT when wearing the SAI. In contrast, those with lower ASES score regarding pain (n = 16, ASES score < 52) reported a much larger decrease in pain (12.3 $\pm$ 20.1 mm, figure 4.13). However, the difference between these two groups was not significant ($t_{30} = -1.641$, $p = .111$).

In summary, no significant interactions were detected between the pain reported while walking and any of the listed covariates. Post hoc analyses suggests that participants who were heavier, had mild malalignment, higher level of initial pain and lower pain self-efficacy benefited more from the SAI.

Table 4.1. Participant (n = 60) demographic information (mean, standard deviation and 95% confidence interval).

	Mean	SD	95% CI	Frequency; Percentage
Age (years)	63.9	8.8	61.6 – 66.2	
BMI (Kg/m^2)	31.9	7.1	30.1 – 33.7	
Comorbidities	1.6	1.5	1.2 – 2.0	55% - High Blood Pressure 23% - Diabetes 33% - Low Back Pain 8% - Heart Disease
Number of Medications for OA	1.7	1.1	1.4 – 2.0	
Knee OA Severity Rating (K-L scale)	2.47	1.2	2.16 – 2.77	Grade 1 (n = 19; 32%) Grade 2 (n = 8; 13%) Grade 3 (n = 19; 32%) Grade 4 (n = 14; 23%)
WOMAC pain score (4 – 20) Baseline 1	7.77	2.8	7.05 – 8.49	
WOMAC pain score (4 – 20) Baseline 2	7.47	2.8	6.7 – 8.19	

Table 4.2. Participant (n = 60) demographic information (frequency and percentages).

	Frequency; Percentage
Gender	Males (n = 23; 38%) Females (n = 37; 62%)
Race	White (n = 38; 63%) Black (n = 20; 33%) American Indian (n = 2; 3%)
Social Status	Married (n = 41; 68%) Divorced (n = 11; 18%) Widowed (n = 8; 13%)
Highest Level of Education	Some High School (n = 3; 5%) High School (n = 11; 18%) Some College (n = 9; 15%) Associates Degree (n = 7; 12%) Bachelor's Degree (n = 11; 18%) Postgraduate Degree (n = 19; 32%)
Work Status	Working Full Time (n = 24; 40%) Working Part Time (n = 8; 13%) Retired (n = 17; 28%) Unemployed (n = 2; 3%) Homemaker (n = 5; 8%) Disabled/ Unable to work (n = 4; 7%)

Table 4.3. Participant (n = 60) VAS Scores (mm) indicating amount of knee pain during walking tasks while wearing the SAI and without the SAI. *Indicates significance difference (p < .05).

	With SAI			**Without SAI**						
Dependent Variable	**Mean**	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**	**F-value**	***p*-value**	**ES**	**Power**
VAS Pain Scale (mm): Self Selected speed	15.7	13.7	12.1 - 19.1	15.4	17.6	10.8 – 19.9	0.026	0.875	<.001	.053
VAS Pain Scale (mm): Fast speed	18.0	16.4	13.7 - 22.2	22.0	23.5	15.9 - 28.0	3.611	0.062	0.058	0.464
VAS Pain Scale (mm): Six-Minute Walk	26.1	25.7	19.4 - 32.7	31.4	28	24.1 - 38.6	5.067	0.028*	0.079	.60

Figure 4.1. Effect of Shock Absorbing Insole (SAI) on Visual Analog Scores (VAS) for pain during Self Selected Gait, Fast Gait, and Six-Minute Walk Tests. * Indicates a significant decrease in VAS during the Six-Minute Walk Test With SAI compared to the Without SAI condition ($p < 0.05$).

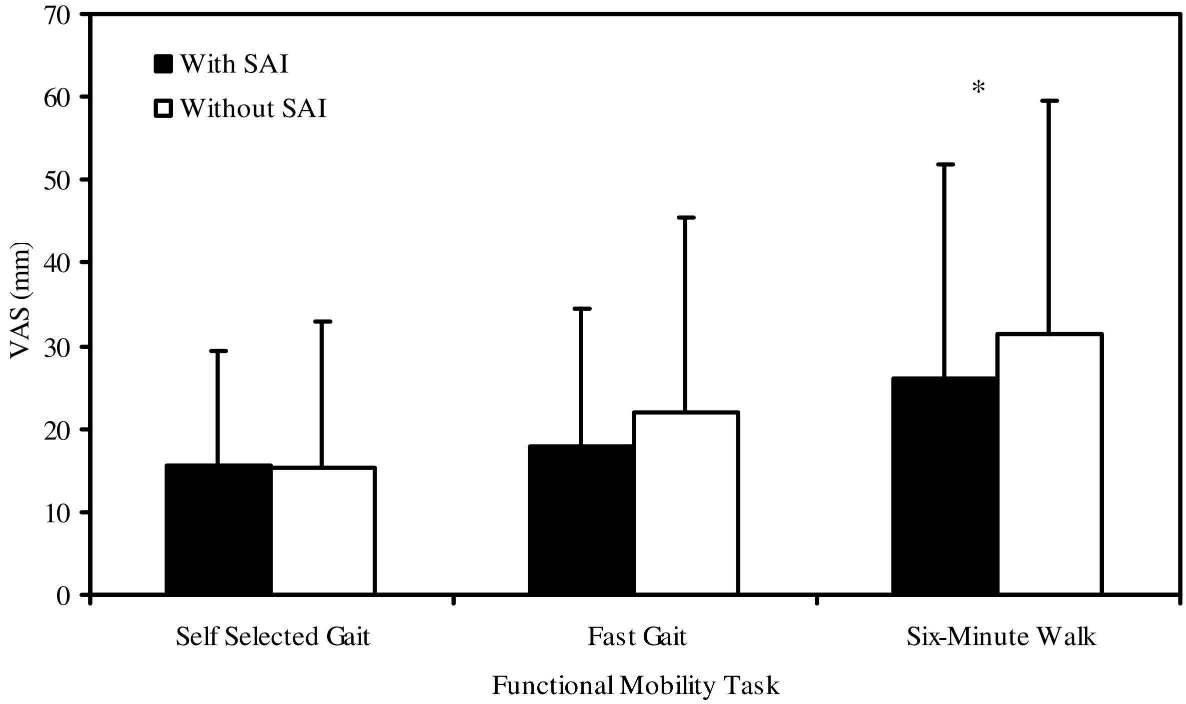


Table 4.4. Comparison of participants who reported a decrease in knee pain (n=34) while walking with the SAI versus those who reported an increase in pain (n=19). Change score means (pain during 6MWT without SAI – pain during 6MWT with SAI), standard deviations and t-test results for each of the characteristics tested.

	Reported decrease in pain (n=34)		**Reported increase in pain (n=19)**				
Characteristic	**Mean**	**SD**	**Mean**	**SD**	**t-value**	***p*-value**	**95% CI of the difference**
Change Score	-16	14.9	11.8	13	-6.8	* <.001	-40 – 19.6
Age	63.9	9.7	63.4	8.4	.212	.833	-4.8 – 5.9
BMI	31.8	6.4	33.2	8.6	-.683	.498	-5.6 – 2.8
Comorbidities	1.65	1.5	1.21	1.3	1.063	.293	-.388 – 1.3
Initial WOMAC Pain subscore†	8.3	3	7.6	2.7	.891	.377	-.9 – 2.4
ASES Pain subscore§	61.9	20.2	66.1	14.5	-.804	.425	-14 – 6.4
Distance walked without SAI	438.9	125.1	468.1	101.6	-.869	.389	-96.7 – 38.3
Distance walked with SAI	453.5	130.5	453.4	87.6	.003	.997	-67.3 – 67.5

†Western Ontario McMasters Arthritis Index pain subscore. §Arthritis Self-Efficacy Pain subscore.

Table 4.5. Participant (n = 60) functional mobility measures walking with and without the SAI.

	With SAI			**Without SAI**						
Dependent Variable	**Mean**	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**	**F-value**	***p*-value**	**ES**	**Power**
Self-selected Gait Speed (m/sec)	1.06	.27	.99 – 1.13	1.06	.25	.99 – 1.12	0.032	0.859	0.001	0.054
Fast Gait Speed (m/sec)	1.42	.33	1.34 – 1.51	1.45	.35	1.36 – 1.53	0.792	0.377	0.013	0.141
Distance walked during 6MWT (meters)	450.7	115.3	420.9 – 480.5	441.7	126.9	408.9 – 474.4	1.105	0.297	0.018	0.179

Figure 4.2. Effect of Shock Absorbing Insole (SAI) on gait speed for self-selected and fast walking mobility tasks.

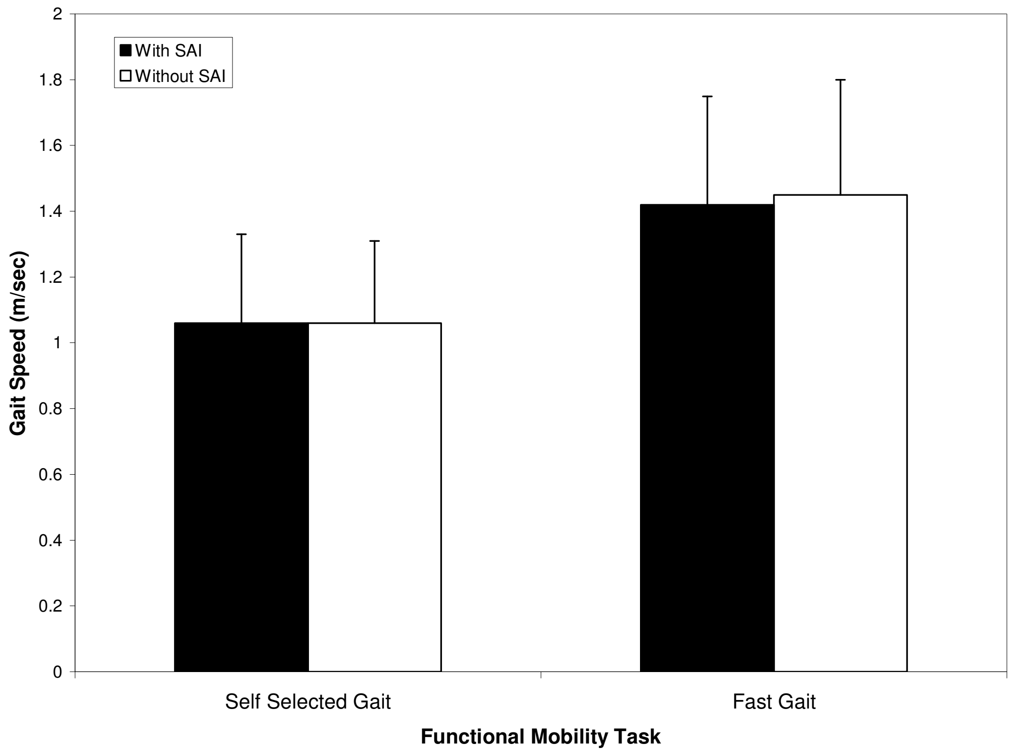


Figure 4.3. Effect of Shock Absorbing Insole (SAI) on the distance walked during the Six-Minute Walk Test.

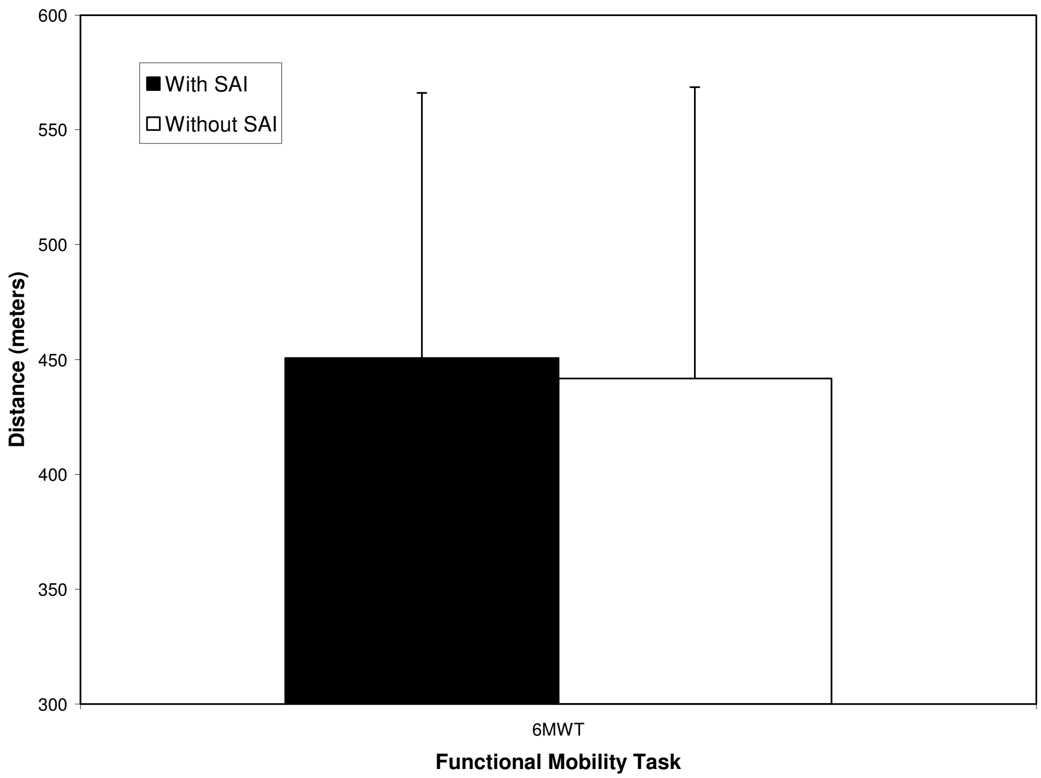


Table 4.6. Biomechanical outcome measures (n=58) during walking at self-selected walking speeds both with and without SAI.

	With SAI			**Without SAI**						
Dependent Variable	**Mean**	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**	**F-value**	***p*-value**	**ES**	**Power**
Time to peak VGRF (sec)	.198	.057	.183 – .213	.200	.064	.183 – .216	0.343	0.560	0.006	0.089
Peak VGRF (times BW)	1.08	.09	1.06 – 1.11	1.07	.09	1.05 – 1.10	2.648	.109	0.044	0.360
Loading Rate (times BW/sec)	5.94	1.87	5.45 – 6.43	5.87	1.79	5.4 – 6.34	0.486	0.489	0.008	0.105
Peak Knee Moment† (N/BW*HT)	-.174	.157	-.215 - -.132	-.175	.143	-.213 - -.137	0.020	.887	<.001	.052
Average Knee Moment† (N/BW*HT)	-.012	.093	-.037 - -.013	-.018	.082	-.039 - .004	0.848	0.361	0.015	0.148

†External sagittal plane knee moment (n= 57) during loading response of stance. Negative number indicates flexion moment.

Figure 4.4. Effect of Shock Absorbing Insole (SAI) on time to peak VGRF during self-selected walking speeds

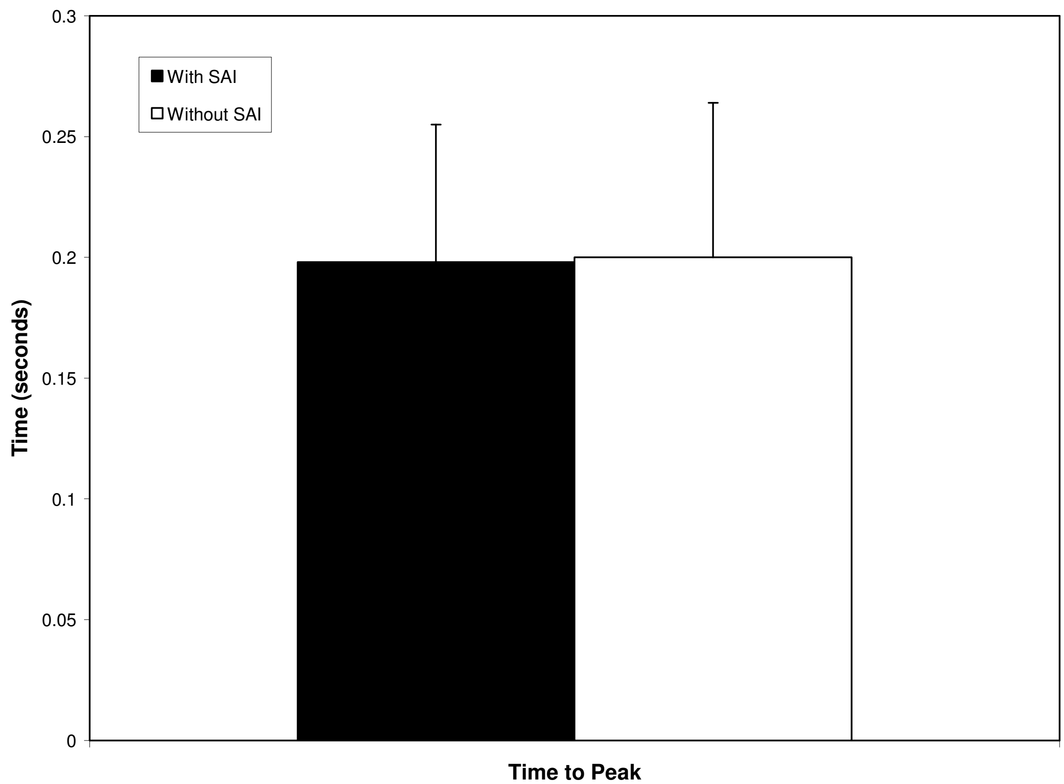


Figure 4.5. Effect of Shock Absorbing Insole (SAI) on peak vertical ground reaction force (VGRF) during self-selected walking speeds. Ground reaction force is normalized to body weight in newtons.

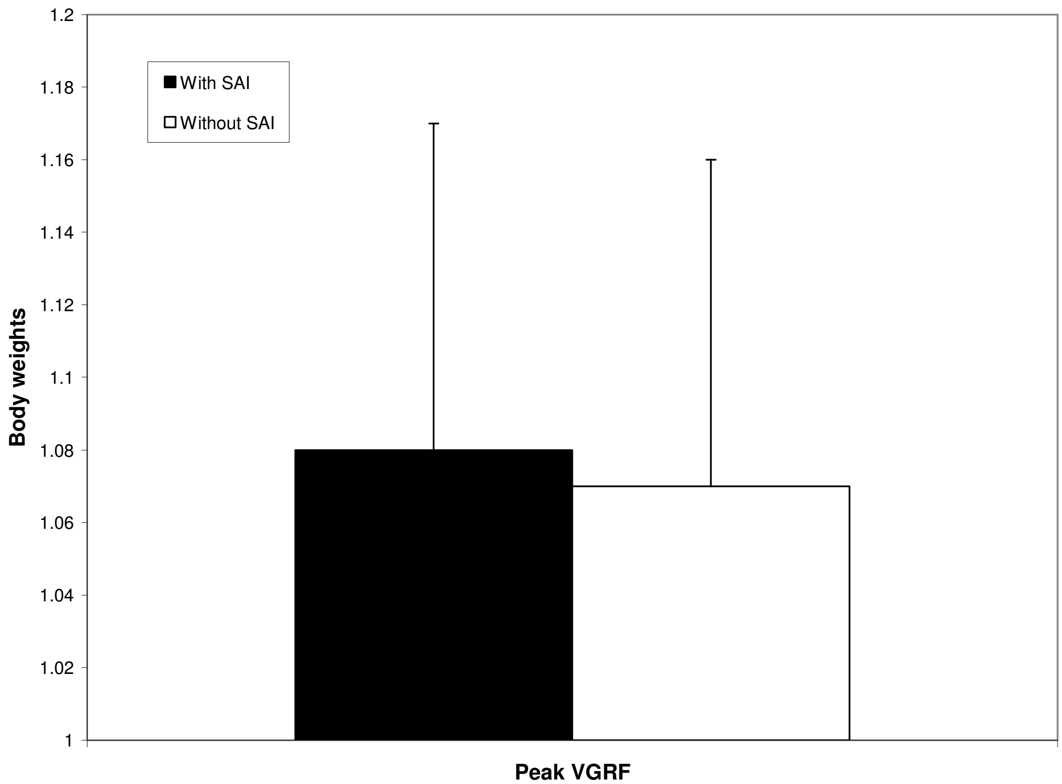


Figure 4.6. Effect of Shock Absorbing Insole (SAI) on Loading Rate during self-selected walking speeds. Loading Rate was calculated using the normalized peak VGRF/time to peak VGRF.

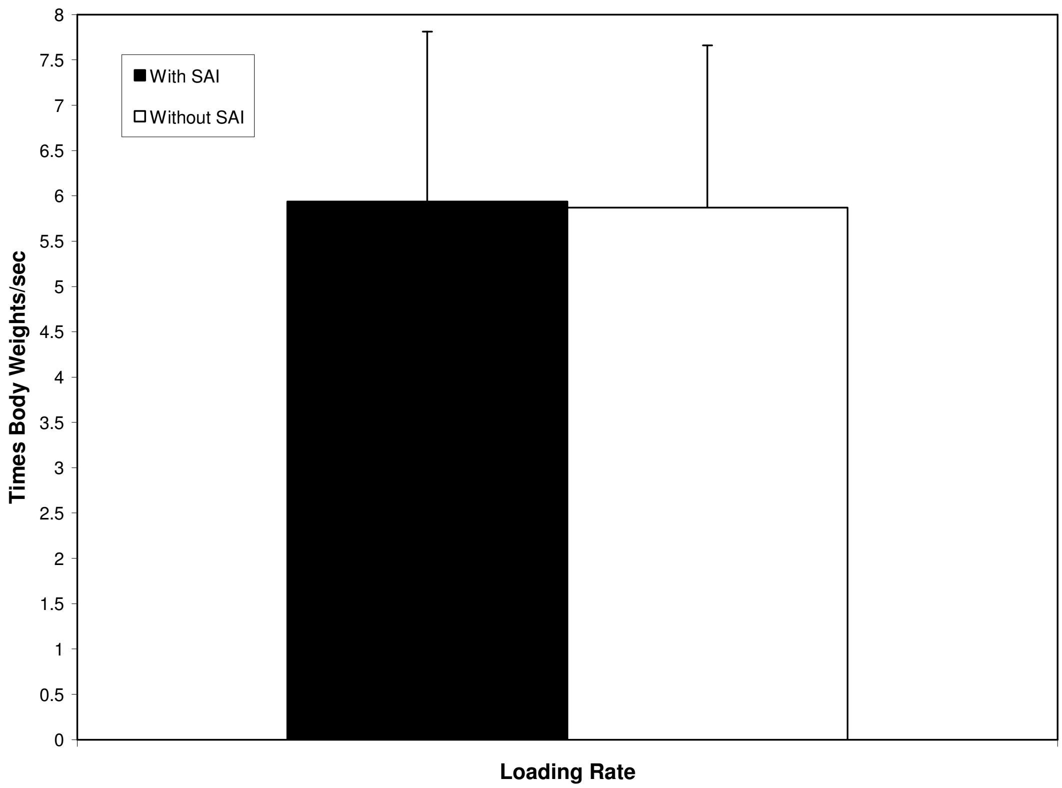


Figure 4.6. Effect of Shock Absorbing Insole (SAI) on external sagittal plane knee moments during loading response of the stance phase of gait while walking at self-selected speeds. Moments were normalized to the product of body weight * height. All moments listed are external knee flexion moments.

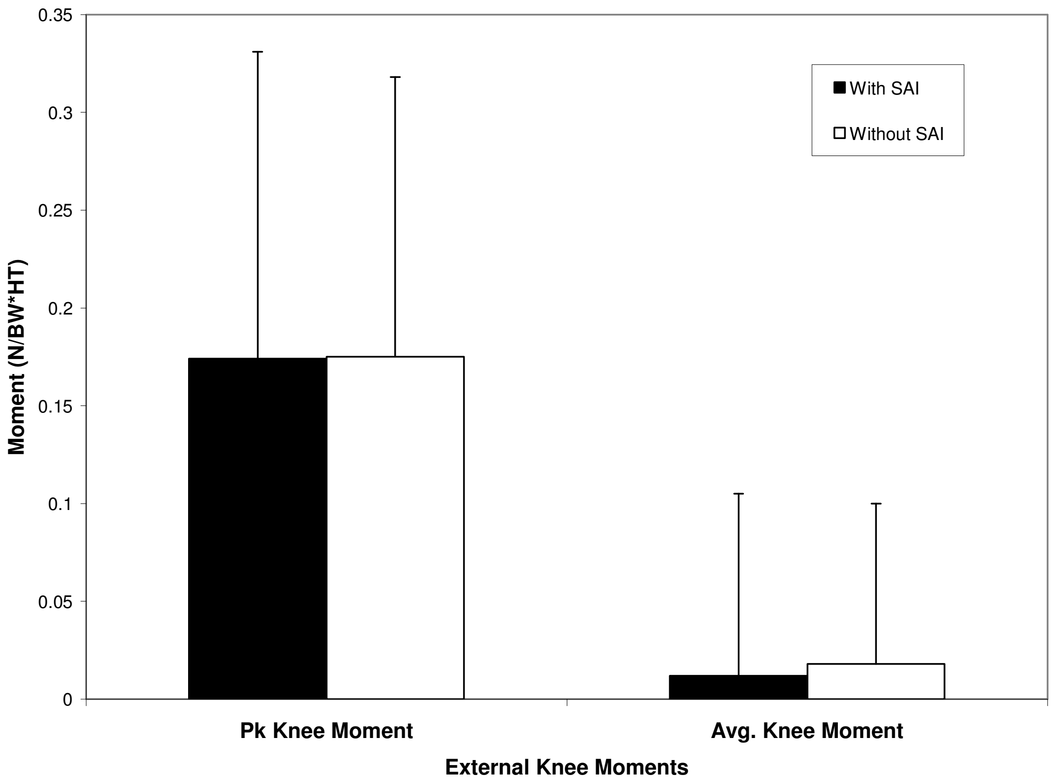


Table 4.7. Analysis of covariance interaction results with pain reported during 6MWT.

Covariate	F-value	*p*-value	ES	Power
Body Mass	<0.001	.987	<0.001	0.05
Knee OA severity	1.185	.281	0.020	0.19
HKA angle[†]	.059	.809	0.001	0.06
WOMAC initial pain[‡]	.843	.362	0.014	.147
ASES pain subscore[§]	2.670	.108	.045	.362

[†]Mechanical hip-knee-angle angle.
[‡]Western Ontario McMasters Arthritis Index pain subscore.
[§]Arthritis Self-Efficacy Pain subscore

Table 4.8. Change score means (pain during 6MWT without SAI – pain during 6MWT with SAI), standard deviations and t-test results for each of the covariates using the 1st and 4th quartile as group cut points. Negative numbers indicate decrease in pain.

Covariate	n (1st/4th)	Mean change in VAS 25th quartile		Mean change in VAS 75th quartile		t-value	*p*-value	95% CI of the difference
		Mean	SD	Mean	SD			
Body Mass	15/15	.2267	12.22	-2.14	21	.414	.682	-10.3 – 15.5
Knee OA severity	20/13	-9	18.1	-4	20.4	-.725	.474	-18.7 – 8.9
HKA angle† Varus	18/15	-8.5	22.4	-6	20.9	.326	.747	-13 - 18
HKA angle† Valgus	3/4	-10.6	19.4	-5.6	8.1	-.518	.627	-32.5 – 21.6
WOMAC initial pain‡	21/16	-4.7	15.5	-15.4	17.5	1.972	.057	-.32 – 21.8
ASES pain subscore§	16/16	-12.3	20.1	-1.1	18.5	-1.641	.111	-25.2 – 2.7

†Mechanical hip-knee-angle angle. ‡Western Ontario McMasters Arthritis Index pain subscore. §Arthritis Self-Efficacy Pain subscore

Figure 4.8. Effect of Shock Absorbing Insole (SAI) on knee pain change scores as measured on the Visual Analog Scores (VAS).
Change scores = VAS without SAI – VAS with SAI.
Negative number indicate a decrease in pain.

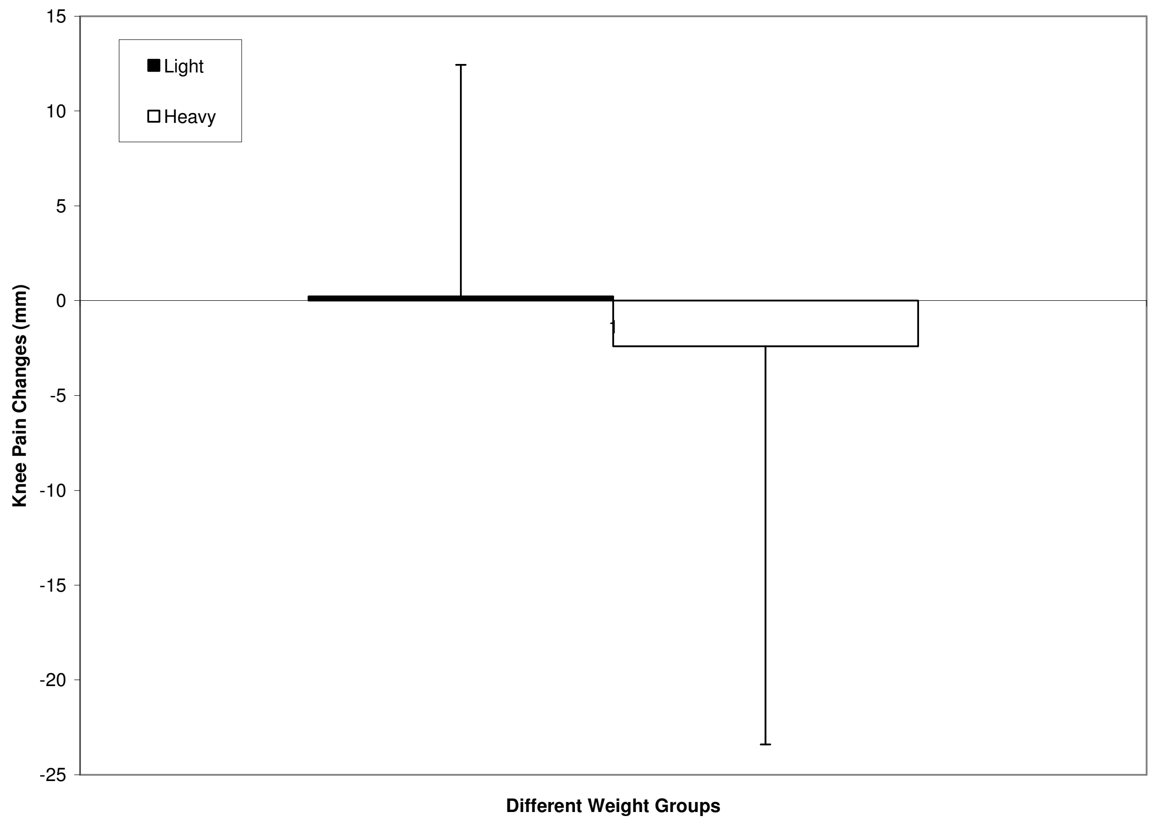


Figure 4.9. Effect of Shock Absorbing Insole (SAI) on knee pain change scores during the six-minute walk test as measured on the Visual Analog Scores (VAS). Change scores = VAS without SAI – VAS with SAI. Scores indicate a decrease in knee pain when wearing SAI.

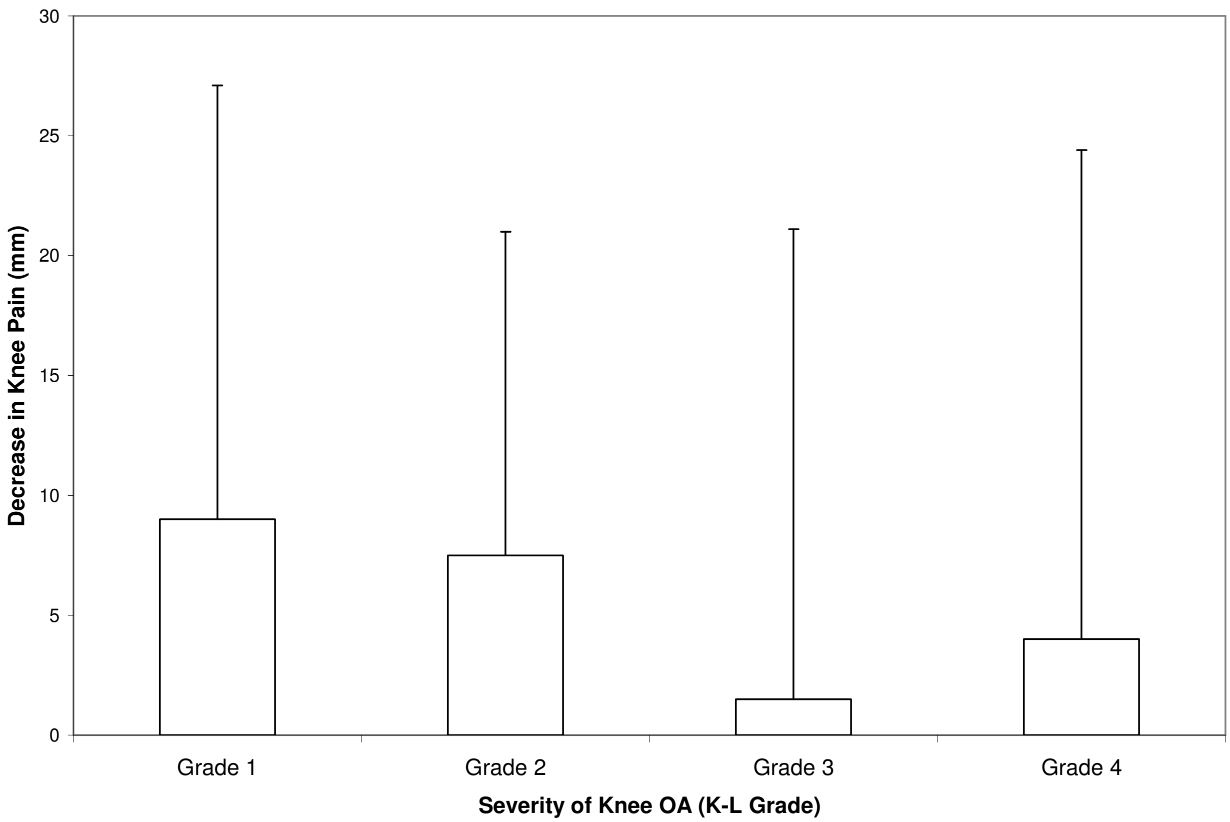


Figure 4.10. Effect of Shock Absorbing Insole (SAI) on knee pain change scores as measured on the Visual Analog Scores (VAS).
Change scores = VAS without SAI – VAS with SAI.

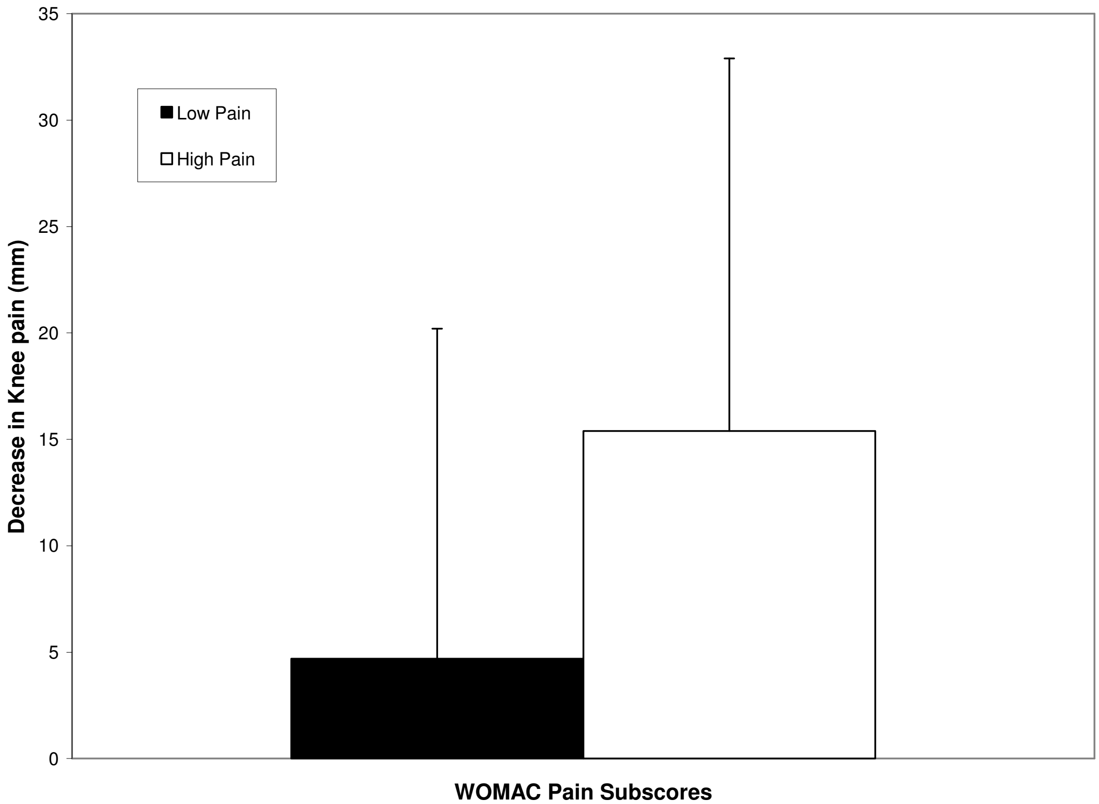


Figure 4.11. Effect of Shock Absorbing Insole (SAI) on knee pain change scores as measured on the Visual Analog Scores (VAS) on people with different HKA alignment. Change scores = VAS without SAI – VAS with SAI. Negative scores indicate a decrease in pain.

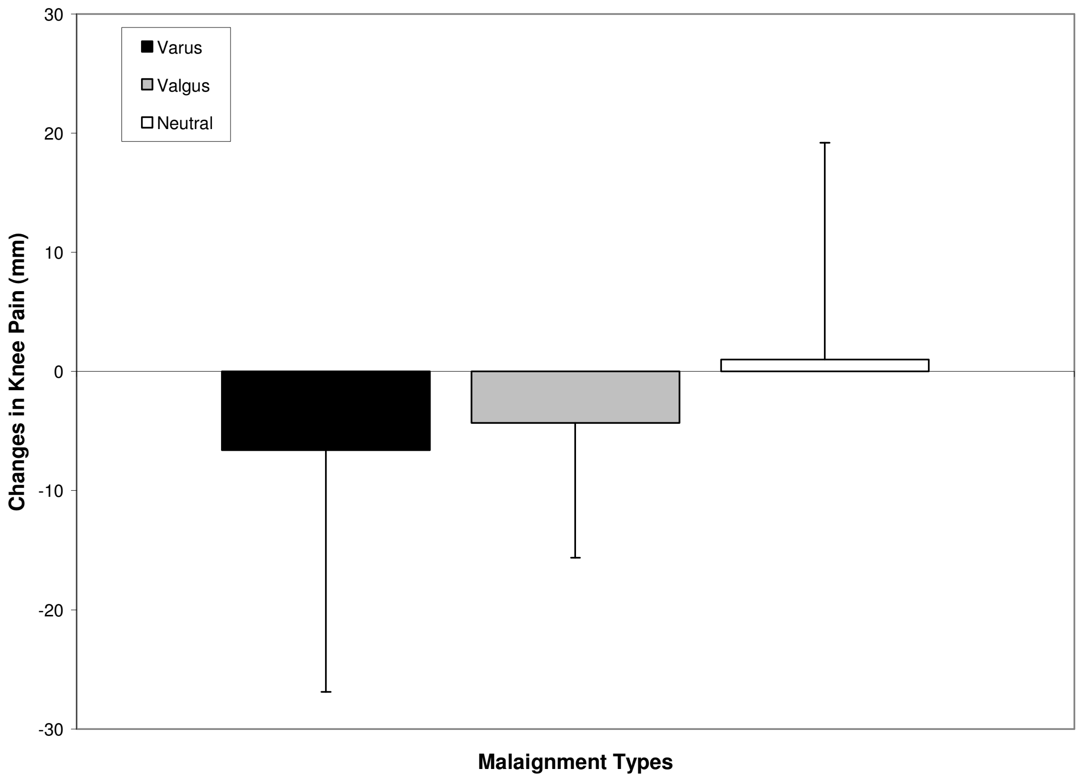
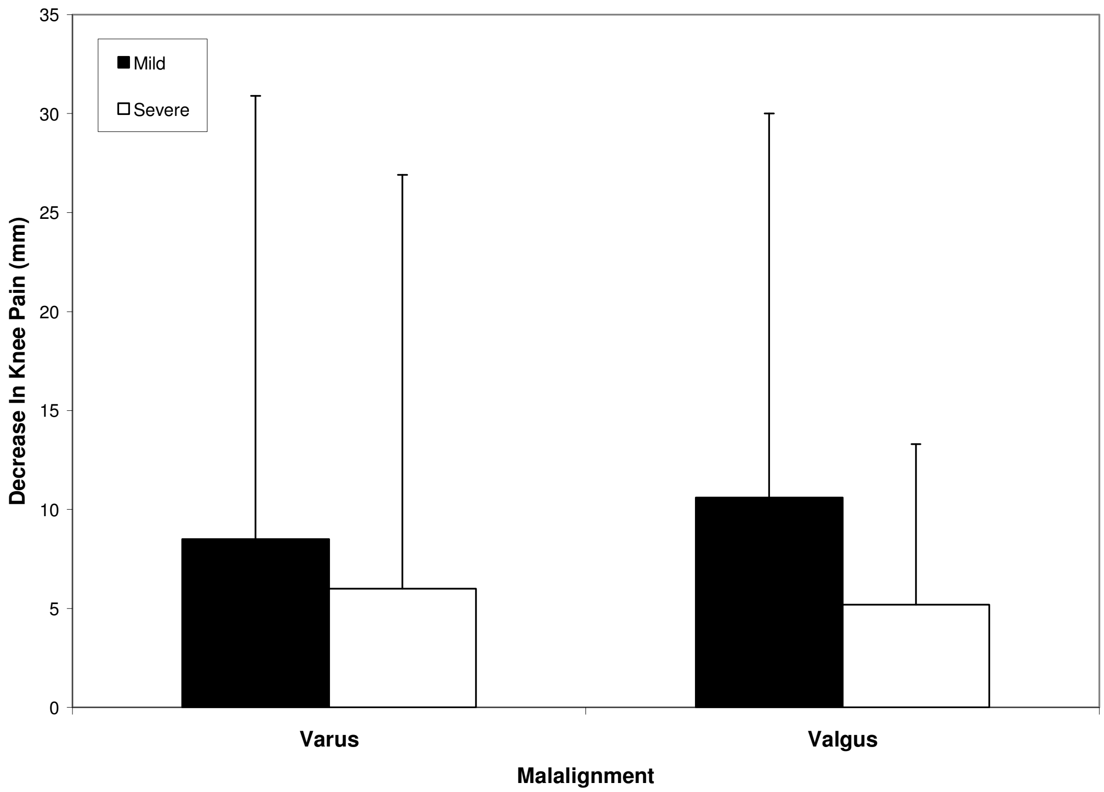


Figure 4.12. Effect of Shock Absorbing Insole (SAI) on knee pain change scores as measured on the Visual Analog Scores (VAS) on people with mild or severe varus or valgus malalignment. Change scores = VAS without SAI – VAS with SAI.



Chapter 5

Discussion

Primary Outcome: Effects of SAI on Knee Pain

The primary outcome for this investigation focused on the immediate effects of shock absorbing insoles (SAI) on knee pain in persons with symptomatic knee OA. The primary finding was a significant decrease in knee pain during the 6MWT when wearing SAIs. No differences were found in knee pain during shorter walking tasks, functional mobility measures or kinetic variables.

Our primary hypothesis was that knee pain would diminish when wearing the SAI during functional walking tasks. Our data did not support this hypothesis for either the self-selected walking or fast walking tasks. Participants reported almost identical knee pain on the VAS (change score = .26) when walking with and without the SAI at a self-selected speed. The literature suggests that people with knee OA choose a self-selected walking speed which minimizes pain.[51] This would explain the low amount of pain reported for the self-selected walking speed condition. It is possible that the pain measure had a floor effect for the SAI condition when walking at the self-selected pace due to subjects walking at a speed that already minimized their pain.

To our knowledge, this is the first study which evaluated pain during walking a short distance immediately after placement of a shock absorbing insole. Thus, we cannot directly compare our findings to previous research. All other studies reporting pain, used the

WOMAC pain subscore to evaluate knee pain over the last forty-eight hours.[51, 69]

Participants reported more pain when walking at a fast pace both with and without the SAI compared to walking at a self-selected speed (table 4.3). The higher pain during fast walking was an expected outcome because faster walking causes a higher ground reaction force which in turn increases the forces on weight-bearing joints[89] and results in increased knee pain.[90] When walking at the fast speed, participants reported less pain walking with the SAI; however, this decrease in pain was not significant ($p = .062$). Greater variability of pain values while walking with and without the SAI at the fast pace suggested the change in pain varied more among participants than during the self-selected speed. The increased variability in pain values during the fast walking conditions may have decreased our statistical power ($1\text{-}B = .47$) and limited the ability to detect a significant decrease in pain while wearing the SAI during fast walking conditions.

It is reasonable to assume that those who walked faster at either the self-selected or fast walking speed may have experienced more pain and therefore had a different outcome with the SAI. To further investigate potential factors that may have influenced the lack of a significant decrease in pain when walking at a self-selected speed we investigated the influence of walking speed on pain by dichotomizing the sample into slow walkers (< 1.0 m/sec, n = 24) and fast walkers (>1 m/s, n = 36). Faster walkers reported slightly more pain relief (-6.7 ± 18.4) than slower walkers (-3.3 ± 18.6) during the self-selected walking task, but no significant differences were found ($t_{58} = .711$, $p = .480$). Faster walkers had about the same pain relief as slow walkers during the fast walk task while wearing the SAI (slow walkers: -4.7 ± 17.7 mm; fast walkers: -3.5 ± 15.4 mm; $t_{58}=.274$, $p = .785$).

Most participants (97%) reported the insoles were more comfortable in all the walking conditions. Even with increased comfort, there were no significant decreases in knee pain when wearing the SAI during the shorter walks. The degree of shoe comfort when wearing shock absorbing insoles has been linked with a reduction of self-reported lower extremity injuries in military recruits over a four month period.[23] The authors concluded that short-term comfort was an important factor in long-term injury prevention. Our data suggest that an increase in shoe comfort does not equal a decrease in short-term knee pain in this population. It is unknown what the long-term effect of SAI would be.

The most important finding of our study was that of decreased pain when wearing the SAI during the 6MWT. This finding supports our hypothesis that participants would report less knee pain when walking longer distances while wearing a SAI. Participants reported a higher pain level under both conditions for the 6MWT compared with the shorter walking tasks (self-selected walk and fast walk) and reported a significant decrease in pain after walking for 6 minutes while wearing the SAI ($p = .028$) as compared to wearing only the test shoes. Small but significant changes in knee pain are supported in the literature. Small changes in VAS pain scores (13 mm) were found to be significant in a group with symptomatic knee OA who took Glucosomine for 12 weeks.[91] However, it is still questionable that the small change in knee pain (5.5mm on VAS) reported in this study was clinically significant. We were unable to find a definition of a minimal clinically significant change in knee pain in a population with symptomatic knee OA, however, other in trauma patients ,9 mm was clinically significant.[92, 93] It has also been suggested that people with greater pain require a greater change in the VAS score to achieve clinically significant pain relief.[93]

Most of the literature addressing knee pain in those with knee OA has used the WOMAC pain subscore for comparisons at different time periods.[30, 35, 40] The WOMAC pain subscore was used in this study to determine baseline pain, but because the WOMAC is not sensitive to pain changes in the same day it was not used to evaluate knee pain during walking tasks in this study. No literature was found to compare our results in VAS pain scores after the 6MWT over such a short intervention period. All the available research found measuring immediate effects of an intervention were biomechanical studies which did report knee pain.

Certain participants clearly benefited more than others from the SAI during the 6MWT. We explored the data to see if some common characteristics could be discovered. No significant differences were found when comparing the participants who reported a decrease in pain (57%, n = 34) while wearing the SAI compared with those who actually reported an increase in pain (32%, n = 19). Post hoc t-test performed on these two groups revealed no differences in age, BMI, number of comorbidities, initial WOMAC pain subscore, or ASES pain subscore. A higher percentage of retired people (35%) and those with a college degree (53%) reported a decrease in pain while wearing the SAI compared to those who reported an increase in pain (16% retired; 47% college). We also explored the kinetic data to determine if any significant differences could be found. Those who reported less pain on the 6MWT when wearing an SAI demonstrated a significantly higher peak external knee flexor moment (-.21 $\pm$ .14 Nm/kg*m; $t_{49} = -2.178$, $p = .034$) compared to those who reported an increase in knee pain (-.11 $\pm$ .138 Nm/kg*m). Although this is an interesting finding, it is important to remember that the gait analyses were performed at slower GS over a much shorter distance than the 6MWT. Therefore, we cannot make any inferences about the change in knee moment and reported pain during the 6MWT. No significant differences were found in the time to peak VGRF (p = .923), peak VGRF (p = .917) or rate of loading (p = .624).

It has been suggested in the literature that African Americans are more likely to use complimentary medicine.[94] In a large study investigating the use of complimentary and alternative medicine (CAM) usage in persons with arthritis, African Americans were much more likely (89.1%) to report CAM usage compared to Caucasians (78%).[94] In this investigation, a greater percentage of African Americans (60%) reported a decrease in pain during the 6MWT versus only 45% of Caucasians. African Americans (n = 20) also reported a larger decrease in pain while wearing the SAI during the 6MWT (-8.4 mm) compared to Caucasians (-4 mm), however, this difference was not significant (p=.399).

Examination of potential modifiers

Another aim of this study was to determine if we could identify participant characteristics that might modify the effects of SAI. We hypothesized that weight, severity of knee OA, presence of varus/valgus knee angle as determined by x-ray, initial WOMAC pain subscore, and/or Arthritis Self-efficacy (ASES) pain subscore would potentially be modifiers of the effectiveness of SAIs. Our results indicate that none of the proposed participant characteristics measured in this investigation modified the effects of the SAI on pain.

It is well documented that obesity and knee OA are strongly related.[30] A direct relationship between body mass and knee joint forces has been reported.[18] In a group of overweight and obese adults with symptomatic knee OA, it was determined that for every one pound of body weight lost, there was a 4-pound decrease in joint loading at the knee for each step.[18] This supports the theory that the lighter the person is, the less forces are placed across the knee and therefore, potentially less knee pain. Symptoms associated with OA, such as joint pain, have not been well studied in either average or obese individuals.[9] We hypothesized that lighter participants would report less pain than heavier participants while wearing the SAI. Our data did not support our hypothesis (p = .682). No differences were found in pain change scores between lighter people (range 54 – 72.8 kg, n=15) and heavier people (range 102.2 – 141 kg., n = 15).

We hypothesized that participants with less severe knee OA as measured by the K-L grading scale would report less pain during the 6MWT while wearing the SAI. No significant differences were found between participants with grade I (change in pain = -9 mm, n=20) and participants with grade IV (change in pain = -4.1 mm, n = 13; p = .474). Participants with grade III knee OA severity reported the least amount of change in pain (-1.5 mm) during the 6MWT while grade II benefited almost as much as grade I (change in pain = -7.5 mm). This is not a surprising finding since it is generally accepted that severity of knee OA as graded on x-ray does not correlate well with symptoms.[5, 28] These data support that people with even the lowest grade of knee OA severity as measured by x-ray may benefit from SAI during longer walking distances.

We hypothesized participants with less pain as measured by the WOMAC pain subscore would report less pain during the 6MWT while wearing the SAI. Our data does not support this hypothesis (p = .057). Thirty-five percent of the sample reported very low levels of pain at the beginning of this study (WOMAC pain subscore < 7, range 4 – 20). As previously mentioned, it is possible that there was a floor effect with the pain measure.

The amount and presence of knee malalignment has been linked to knee OA progression and functional decline.[10] A landmark population study (n = 237) supports the idea that varus alignment of the knee is associated with medial knee OA progression and a valgus alignment of the knee is associated with lateral knee OA.[10] In our investigation, people with a varus alignment (n = 41) reported the greatest decrease in pain while wearing the SAI (- 6.6 mm) versus those with a valgus alignment (-4.3 mm, n = 13). However, this decrease in pain did not reach a significant level (p = .632). A greater degree of malalignment has been associated with higher pain levels.[10] Therefore, it was hypothesized that people with less malalignment would report less pain during the 6MWT. Although we did not find a significant difference (p = .627), we did notice a consistent finding of those with a lower degree of malalignment benefited more than those with a large malalignment. Participants with a mild varus knee angle reported the largest decrease in knee pain during the 6MWT (-8.5 $\pm$ 22.4 mm) as compared to those with a more severe varus angle (-6 $\pm$ 20.9 mm). There were fewer persons with valgus alignment (n = 13). However, the same pattern was still present. Those with mild valgus reported a larger decrease in pain (-10.6 $\pm$ 19.4 mm) compared to those with more severe valgus (-5.6 $\pm$ 8.1 mm).

Self-efficacy is the belief that one has the capability to manage a situation to attain a desired outcome. Social cognitive theory states how well people complete a task is better predicted by their beliefs of their capabilities versus their actually capability.[95] Self-efficacy as measured on the Arthritis Self-Efficacy Scale (ASES) has been associated with higher function and lower pain in those with symptomatic knee OA.[96] The questions that make up the pain self-efficacy subscore focus on the participant's ability to manage their pain both with and without medications. We hypothesized that those with a higher ASES pain subscore would report less pain while completing the 6MWT with the SAI. However, our data failed to support our hypothesis. In this investigation, those who reported a higher level of self efficacy (n=19, ASES score = 82.2) only reported a very small decrease in pain (< 1 mm on the VAS scale) during the 6MWT when wearing the SAI. In contrast, those with lower ASES scores regarding pain (42.1, n = 16) reported a much larger decrease in pain (12.3 mm on the VAS scale). These data suggest that pain self-efficacy is not a significant factor in modifying the effects of the SAI. Pain self-efficacy has been more closely correlated with self-report functional difficulty, whereas, functional self-efficacy has been more highly correlated with actual physical performance.[28] Furthermore, in a group of women with knee OA, functional self-efficacy explained 51% of the variance of the distance walked during the 6MWT while BMI, quadriceps strength and pain self-efficacy together only explained another 12% of the variance.[96] No literature was found which identified the relationship between pain self-efficacy and pain with performing a physical task.

In summary, we have no evidence to support that any of the selected patient characteristics modified the effects of the SAI during the 6MWT. However, interesting observations were made in regards to who experienced the most pain relief. Those who reported the most pain relief during the six minute walk while wearing the SAI were African American, had a grade 1 knee OA severity, complained of milder knee pain, and had a mild knee malalignment regardless of the direction of the malalignment.

Effect of SAI on Functional Mobility

Another aim of this investigation was to determine if SAI changed the functional mobility of persons with knee OA as measured by self-selected walking speed, fast walking speed and distance walked in the 6MWT. There were no significant differences for walking speed (self-selected or fast) or distanced walked with SAI or without SAI. The self-selected walking speeds in this study (1.06 $\pm$ .27 m/s) seem reasonable when compared to the literature. A large cross-sectional study (n = 139) of persons with symptomatic knee OA demonstrated a similar self-selected walking speed (1.09 m/s).[45] The slightly higher gait speed reported in that study can be explained by the younger mean age (57 years) of the sample versus the sample in the current investigation (64 years). Much lower walking speeds (.55 m/sec) have been reported in persons with the severest form of knee OA.[44] Our sample consisted of participants with all severity levels with only 23% demonstrated the most severe grade of knee OA on x-ray. No studies were found which reported fast walking speeds in people with knee OA.

The study was designed to examine the immediate effects of the SAI. Walking is a highly repetitive task which individuals perform frequently. Self-selected walking speed is associated with a participant's "normal walk". In fact, the instructions to the participants were to "walk at your typical pace". The fast walking speed was also a self-selected pace. Participants were asked "to walk as quickly and as safely as you can". Therefore, it was not surprising to find participant's walking speed did not change with the simple addition of a SAI. It is possible that over a longer period of accommodation (weeks) of wearing the SAI, participants may adopt a different gait speed, however, we are unable to speculate on that outcome with these data.

We hypothesized that participants would walk further during the 6MWT while wearing the SAI. However, there were no significant differences found between the two SAI conditions. Predicted 6MWT walking distance equations which account for individual height, weight, and age for both healthy males and females are available in the literature.[97] All subjects walked within the lower limits of predicted 6MWT distances under both conditions.

While pain was decreased during the 6MWT when wearing the SAI there was no associated increase in distance walked. We have identified two possible reasons why people did not walk further even when reporting less pain while wearing the SAI during the 6MWT. First, participants chose their walking speed. Even though they were instructed to walk at a pace to "cover as much ground as possible" during the time period, participants were able to walk at any pace. Previously we discussed that even fast walking speeds were extremely consistent. That consistency would account for the lack of change in walking distance during a timed walk. Second, it is possible that the distanced walked during the 6MWT was affected by limited cardiovascular fitness as opposed to knee pain. Many of the participants were overweight or obese and demonstrated labored breathing during and immediately after the 6MWT.

Effect of SAI on Lower Extremity Biomechanics

Previous work investigating shoes with shock absorbing capabilities or shock absorbing insoles have indicated a reduced number of lower extremity injuries.[23, 25, 26, 78] These researchers hypothesized that the decrease in injuries were secondary to an decrease in forces up the kinetic chain as a result of wearing a SAI. We hypothesized that participants would demonstrate a decrease in the rate of loading (LR = peak VGRF/time to VGRF) when wearing the SAI because of the increased shock absorbing capabilities of the insole. We did not find a significant difference in the rate of loading rate between the two insert conditions ($p = .486$).

Our loading rates (5.87, 5.94 BW/sec) were somewhat lower than previously reported (6.59 BW/s) in persons with knee OA.[51] This can be explained by the higher walking speed (1.12 – 1.34 m/sec) of the participants in the previous study compared to our participants

(1.06 m/sec). A decrease in loading rate can be accomplished by either increasing the time to achieve peak VGRF or by decreasing the peak VGRF or a combination of both. We expected the time to reach peak VGRF would be longer in the SAI condition. However, a decrease in the time to peak VGRF occurred in the SAI condition (without SAI : .200s; with SAI: .198s).

Forty percent (n=24) of our sample walked at a speed less than 1 m/sec. There is a limited amount of time one can devote to load acceptance during the stance phase. It is possible that these slow walkers may have already maximized the time available for load acceptance during stance, therefore the addition of a SAI would not have increased the time to peak GRF. In disease free individuals, the time to peak VGRF is estimated to be 12% of the stance time but can be much greater in people who walk slowly.[47] Reported time to peak VGRF during loading response for people with knee OA is 25 – 28% of the stance time[51, 98] and 21% of the complete gait cycle time.[64] Our participants demonstrated slightly longer time to reach peak VGRF (no SAI 28.6% stance; with SAI 28.9% stance). Those who walked the slowest (.49 m/sec) took the longest to reach peak VGRF (no SAI = 45% stance; with SAI = 44% of stance). However, when just analyzing the results of the fast walkers (>1 m/s), the same trends (no difference between conditions and higher loading rate with SAI) were found.

We hypothesized that peak VGRF during the loading response of stance would be decreased while walking with the addition of a SAI inside the shoe; however, our data did not support this hypothesis. Similarly, there was no change in time to peak VGRF while wearing the SAI. Peak VGRF values during walking with (1.08 times BW) and without (1.07 times BW) the SAI were very similar to those found in other gait studies investigating walking patterns of people with knee OA (.91 – 1.06 times BW).[46, 51, 64] The slightly lower peak VGRF values found in the literature correspond to slower walking speeds (.9 m/s) versus our faster mean walking speed (1.06 m/s). Our results reveal a very small increase in the peak VGRF while wearing the SAI. Our findings are in an agreement to the work of Shiba et al[63]who reported a similar increase in peak VGRF of 1.8 – 2.1 %BW when comparing different types of SAI to shoes alone.

The majority of the studies found that comparing shoe inserts with a control condition used either a skin or a bone placed accelerometer to detect tibial loading rate and cannot be directly compared to our data.[26, 57, 99] In general, these studies support a small but significant decrease in tibial loading rate when wearing shock absorbing foot wear.

Only one study was found which used a force plate to determine changes in peak VGRF and reported time to peak VGRF.[63] The authors concluded the attenuation of impact forces by the shock absorbing insole materials averaged 11%. Upon careful inspection of their data, the greatest decrease in the slope of the impact loading curve occurred when a shock-absorbing material resembling athletic shoe construction was placed in the shoe. They found no difference in impact loading between different thicknesses of other SAI materials placed in the shoe. These results suggest that an athletic shoe was more effective in decreasing loading rate than a SAI. Our data lends support to this idea. It is possible our control condition (athletic walking shoe) already provided an excellent source of shock absorption, there by, the addition of a SAI would not be of added benefit.

We hypothesized that the addition of a SAI would increase the external knee flexor moment. However, our data indicated no difference in the external flexion moment of the knee when wearing the SAI versus the control condition. This would indicate that even with the slight increase in loading rate, there is no difference in knee joint loading when wearing the SAI. This is a positive finding which supports the use of SAI for walking.

The external knee flexion moment reported in this investigation (with SAI: .174 ± .16 Nm/kg*m), without SAI: .175 ± .14 Nm/kg*m) is within the range reported by previous investigations (.29 ± .16 Nm/kg*m).[100] Others have reported slightly higher external knee flexor moment of 1.1 Nm/kg*m[12] and 1.31 Nm/kg*m for females and 1.47 Nm/kg*m for males.[45] The differences could be explained by higher mean BMI of our participants. There is also some evidence which supports people with increased BMI protect their knees by decreasing the internal knee extensor moment.[45]

To our knowledge, this is the first study which compared sagittal plane kinetics when using a SAI. Eng and Pierrynowski[81] reported no differences in sagittal plane walking kinematics with the addition of a SAI, however, they did not measure joint kinetics.

Measurement of knee joint moments provides a more direct indication of actual knee joint loads.[12] The knee kinetic pattern during level walking in persons with knee OA have been well described.[12, 44, 45, 51, 100, 101] The most important sagittal plane knee moment during loading response is the external flexion moment which occurs in response to the body weight aligning behind the center of mass.[47] The external knee flexion moment is equal and opposite to the internal knee extension moment which controls knee flexion during the loading response. This internal moment is primarily generated by muscle, soft and boney tissue forces in response to the external moment. A large internal knee extension moment would indicate all of the soft and boney structures around the knee (including the muscles) are working harder to control knee flexion. Most of the current literature concerning insoles in people with knee OA is devoted to investigate effectiveness of wedged insoles. The theory behind wedged insoles is that they effect frontal plane movements and joint moments. Overall, wedged insoles have been found effective in decreasing the external adductor moment in persons with knee OA.[68, 72]

We also reported the average of the external knee moment from heel strike to peak VGRF. This measure takes into account the forces at the knee over a period of time during the stance phase versus just one point in time. The average external sagittal plane knee moment was less (.012 $\pm$ .09 Nm/kg*m) when wearing the SAI as compared to no SAI (.018 $\pm$ .08 Nm/kg*m) but this difference was not statistically significant ($p = .361$). This finding indicates that during loading response of stance, there was no change in sagittal plane forces on the knee when wearing the SAI.

In summary, we did not see any changes in our kinetic dependent variables while wearing the SAI. Thus, decreases in pain during the 6MWT with the SAI cannot be explained by changes in peak VGRF, time to peak VGRF, rate of loading or external knee flexion moments. The lack of change in the kinetic variables agrees with the lack of change in the pain and functional mobility measures during the short walking tests. It is not clear why individuals experienced decreased pain during the 6MWT. It is possible that changes in biomechanics occur after prolonged walking.

Limitations and Future Research

It is possible that our sample was not representative of the population with knee OA. However, we feel our sample was a good representation of the population with knee OA. In general, we would expect a group of individuals with knee OA to be older, mostly female, and overweight or obese.[102] More women than men (62%, 38% respectively) participated in this study. The sample as a whole had a mean BMI of 31.9 and the mean age of this sample was 64 years. One-third (33%) of the sample was African American. The 2000 Census report indicated that Forsyth County was 25.6% African American and 68.6% White. In a recent study of over 3000 participants in North Carolina, radiographic knee OA prevalence in African Americans was estimated to be higher (32.4%) than their Caucasian counterparts (26.8%). [103]. However, it is a well documented that African Americans participate in research at a lower rate.[104] This sample was convened from the general public from the Winston-Salem area who met inclusion criteria without specific racial targets. Even so, this sample exceeded the average research participation rate of 31% for African Americans as well as the local population statistics (25%). All of the study data were collected at a historical black university/college (HBCU) campus and participant recruitment was focused on local churches and low income senior service programs which most likely enhanced minority participation.

A possible limitation to this project was that two lab visits were required to rule-out fatigue as a confounding variable for the 6MWT. We controlled for differed levels of pain on testing days by having participants complete a WOMAC pain questionnaire on both data collection days. Results indicate pain levels were not significantly different. Another concern was that participant drop out would be high because of the two visits. There were only four people who dropped from the study before completion. Three of these participants called to report an unforeseeable event which prevented the second visit. No one reported the second visit was an excessive burden to complete the study.

Our theory of how SAIs would work to decrease pain revolved around changes in the sagittal plane, therefore, only sagittal plane moments were evaluated. The lower extremity is a closed kinetic chain with redundancy in the system. Even though we had a sound rationale for looking for changes in the sagittal plane, because of this redundancy, changes may have occurred elsewhere in the system. It is possible that some modification occurred in either the frontal or transverse planes of the knee. Likewise, changes in hip or ankle moments could explain the decrease in knee pain when wearing the SAI while walking longer distances. We also only analyzed gait biomechanics at a self-selected gait speed over a short distance. Gait analysis in future studies should include ankle, knee and hip kinematics/kinetics in all planes as well as more challenging tasks such as fast walking..

The type of shoes worn during the control condition was also a possible limitation. It is possible that the athletic shoes chosen for this study already had adequate shock absorbing qualities for walking at self-selected speeds. Therefore, the addition of a SAI was of no greater benefit. Previous studies compared insoles to leather sole shoes or military boots. It is possible that new materials and better construction of walking/running shoes may make a shock absorbing insole obsolete for people who want to walk at typical speeds. Because of the higher forces generated when running or fast walking, the results of this study cannot be generalized to those activities. People with knee OA are continually urged by health care practitioners to begin and maintain a walking program. When walking for exercise, people tend to walk at a greater speed than "typical" walking speed. Therefore, gait analysis performed at higher walking speeds to determine if SAI have an added shock absorbing benefit over athletic shoes alone would add to the current body of knowledge.

The method used to measure the rate of loading could have been a limitation to this study. The use of a force plate to determine the rate of loading has been suggested as a valid noninvasive technique. However, the most accurate method to measure shock absorbing properties occurring during gait is an accelerometer surgically mounted to the tibia. Other studies found comparing insoles used an accelerometer to determine immediate vertical accelerations at heel strike and/or loading response. This was an impractical method for this study but should be considered for future investigations.

A few limitations occurred with the 6MWT. We are unsure if participants gave their maximal effort during the 6MWT for both test conditions. We could have administered the standardized rate of perceived exertion (RPE) scale after each 6MWT to document participant perception of effort given during the task. It is also possible that participants changed the way they walked during the 6MWT. We were unable to rule this out as a possibility because we did not perform a gait analysis before and after the 6MWT. Future studies should include the investigation of effectiveness of shock absorbing insoles on knee pain when wearing the SAI for physical activity over an extended time period. This time period should be long enough to allow gait modifications to occur if present, but short enough to disallow "bottom out" the SAI. Comparative gait analysis could occur after a period of prolonged walking on the same day (6 – 10 minutes) or after using the SAI over an extended time (2 – 4 weeks).

Clinical Relevance

Shock absorbing insoles have the potential capability to decrease knee pain and promote comfortable mobility in persons with knee OA during weight-bearing activities for prolonged time periods (e.g. 6 minutes of walking). Shock absorbing insoles are currently a recommended intervention for persons with hip or knee OA to decrease pain. Our investigation supports the current belief that SAI decreases knee pain in persons with knee OA when walking long distances. However, the biomechanical mechanism of how the SAI decreases pain has not been found. It has been assumed that SAIs would attenuate the vertical ground reaction forces, thereby, decreases forces up the kinetic chain. Our data do not support this assumption. This investigation gives some support to the use of SAI for relief of knee pain when walking long distances. However, it is possible that current athletic shoe construction offers adequate shock absorbing for walking shorter distances at slower gait speeds.

Conclusion

Community dwelling adults with symptomatic knee OA reported a significant reduction in knee pain after walking for six minutes while wearing the SAI. No participant characteristic was found which identified someone who might potentially benefit from the use of a SAI suggesting all persons benefited equally. There were no significant differences in the loading rate or the sagittal plane knee moments. Similar decreases in knee pain were not found when walking short distances (4.3 m) at either self-selected or fast walking speeds. No changes in functional mobility parameters (gait speed or distance walked during 6MWT) were noted. Most people reported an increase comfort level when the SAI were placed in the shoe. However, this increase in foot comfort did not translate into a decrease in knee pain when walking short distances.

Appendix A:

Summary of power analysis for all outcome measures based on sixty (60) participants.

Outcome Measure	Mean	Standard Deviation	Clinically Significant Change	Power
VAS (mm)	41	26.7	10	.81
Gait speed (m/sec)	1.0	.1	.3	1
Gait endurance 6MWT (meters)	425	11.5	50	1
Loading rate	5.48	.94	1	1
Peak external knee moment during loading response	.016	.014	.5	1

Appendix B

VISUAL ANALOG SCALE

Worst Imaginable Pain

No Pain

Baseline: ____________________ **Post Walk:** ____________________

Test: Self Selected Walk Fast Walk 6MWT

Condition: With SAI Without SAI

Appendix C

WOMAC LK3.1 QUESTIONNAIRE **WOMA**

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 " ✗ ".)

QUESTION: **How much pain have you had . . .**

1. when walking on a flat surface?

none	mild	moderate	severe	extreme	Study Coordinator Use Only
❑	❑	❑	❑	❑	PAIN1 ______

2. when going up or down stairs?

none	mild	moderate	severe	extreme	
❑	❑	❑	❑	❑	PAIN2 ______

3. at night while in bed? (that is - pain that disturbs your sleep)

none	mild	moderate	severe	extreme	
❑	❑	❑	❑	❑	PAIN3 ______

4. while sitting or lying down?

none	mild	moderate	severe	extreme	
❑	❑	❑	❑	❑	PAIN4 ______

5. while standing?

none	mild	moderate	severe	extreme	
❑	❑	❑	❑	❑	PAIN5 ______

English for USA - V2

Section B

STIFFNESS

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

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

(Please mark your answers with an " ✗ ".)

6. How **severe** has your stiffness been **after you first woke up** in the morning?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

7. How **severe** has your stiffness been after sitting or lying down or while resting **later in the day**?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

Study Coordinator Use Only

STIFF6 ______

STIFF7 ______

English for USA - V2

Section C

DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities caused by the 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 " ✗ ".)

QUESTION: **How much difficulty have you had . . .**

Question	none	mild	moderate	severe	extreme	Study Coordinator Use Only
8. when going down the stairs?	❑	❑	❑	❑	❑	PFTN8 ______
9. when going up the stairs?	❑	❑	❑	❑	❑	PFTN9 ______
10. when getting up from a sitting position?	❑	❑	❑	❑	❑	PFTN10 ______
11. while standing?	❑	❑	❑	❑	❑	PFTN11 ______
12. when bending to the floor?	❑	❑	❑	❑	❑	PFTN12 ______
13. when walking on a flat surface?	❑	❑	❑	❑	❑	PFTN13 ______

English for USA - V2

DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities caused by the 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 " ✗ ".)

QUESTION: **How much difficulty have you had . . .**

Study Coordinator Use Only

14. getting in or out of a car, or getting on or off a bus?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

PFTN14 ______

15. while going shopping?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

PFTN15 ______

16. when putting on your socks or panty hose or stockings?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

PFTN16 ______

17. when getting out of bed?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

PFTN17 ______

18. when taking off your socks or panty hose or stockings?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

PFTN18 ______

19. while lying in bed?

none	mild	moderate	severe	extreme
❑	❑	❑	❑	❑

PFTN19 ______

English for USA - V2

DIFFICULTY PERFORMING DAILY ACTIVITIES

Think about the difficulty you had in doing the following daily physical activities caused by the 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 " ✗ ".)

QUESTION: **How much difficulty have you had . . .**

Question	none	mild	moderate	severe	extreme	Study Coordinator Use Only
20. when getting in or out of the bathtub?	❑	❑	❑	❑	❑	PFTN20 ______
21. while sitting?	❑	❑	❑	❑	❑	PFTN21 ______
22. when getting on or off the toilet?	❑	❑	❑	❑	❑	PFTN22 ______
23. while doing heavy household chores?	❑	❑	❑	❑	❑	PFTN23 ______
24. while doing light household chores?	❑	❑	❑	❑	❑	PFTN24 ______

English for USA - V2

Appendix D

Arthritis Self-Efficacy Scale

In the following questions we'd like to know how your arthritis pain affects you. For each of the following questions, please circle the number which corresponds to your certainty that you can perform the following tasks.

Self-efficacy pain subscale:

How certain are you that you can decrease your pain quite a bit?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

How certain are you that you can continue most of your daily activities?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

How certain are you that you can keep your arthritis pain from interfering with your sleep?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

How certain are you that you can make a small-to-moderate reduction in your arthritis pain by using methods other than taking extra medication?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

How certain are you that you can make a large reduction in your arthritis pain by using methods other than taking extra medication?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Self-efficacy function subscale:
We would like to know how confident you are in performing certain daily activities. For each of the following questions, please circle the number which corresponds to your certainty that you can perform the tasks without an assistive device or help from another person. Please consider what you routinely can do, not what would require a single extraordinary effort. **AS OF NOW, HOW CERTAIN ARE YOU THAT YOU CAN:**

Walk 100 feet on flat ground in 20 seconds?
(This is the equivalent of walking the walkway four times)

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Walk 10 steps downstairs in 7 seconds?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Get out of an armless chair quickly, without using your hands for support?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Button and unbutton 3 medium-size buttons in a row in 12 seconds?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Cut 2 bite-size pieces of meat with a knife and fork in 8 seconds?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Turn an outdoor faucet all the way on and all the way off?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Scratch your upper back with both your right and left hands?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Get in and out of the passenger side of a car without assistance from another person and without physical aids?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Put on a long-sleeve front-opening shirt or blouse (without buttoning) in 8 seconds?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Self-efficacy other symptoms subscale:
In the following questions, we would like to know how you feel about your ability to control your arthritis. For each of the following questions, please circle the number which corresponds to the certainty that you can now perform the following activities or tasks.

HOW CERTAIN ARE YOU THAT YOU CAN:

Control your fatigue?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Regulate your activity so as to be active without aggravating your arthritis?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Do something to help yourself feel better if you are feeling blue?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Manage your arthritis symptoms so that you can do the things you enjoy doing?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Deal with the frustration of arthritis?

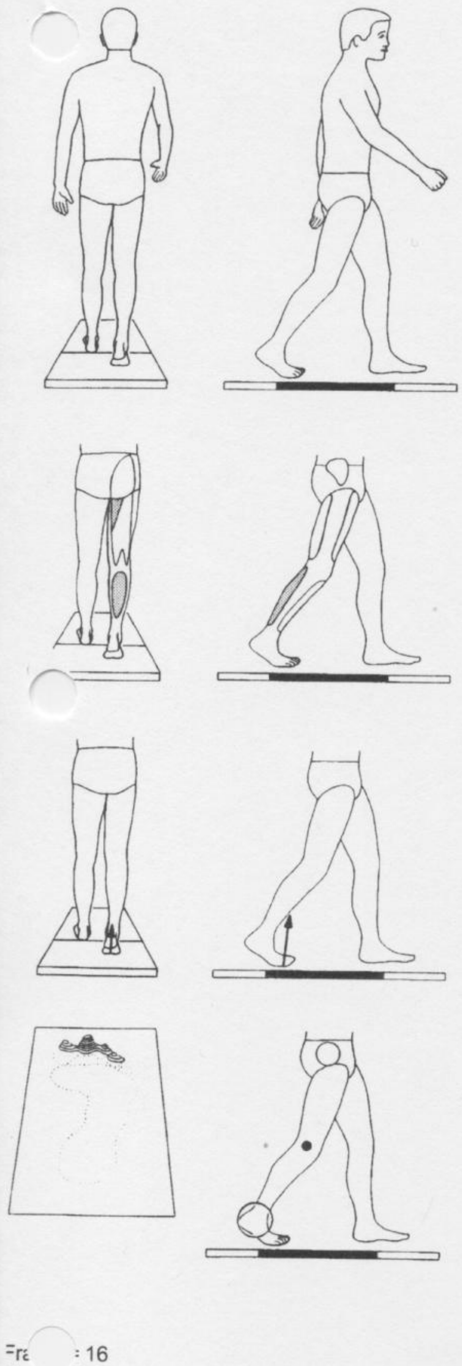
Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

As compared to other people with arthritis like yours, how certain are you that you manage arthritis pain during your daily activities?

Very Uncertain 1 2 3 4 5 6 7 8 9 10 Very Certain

Appendix E

Inverse Dynamics Calculations[103]



as follows:

$$\mathbf{p}_{Prx.1} = \mathbf{p}_{R.Hip} - \mathbf{p}_{R.Thigh.CG} \quad (B.123)$$

and

$$\mathbf{p}_{Dis.1} = \mathbf{p}_{R.Knee} - \mathbf{p}_{R.Thigh.CG} \quad (B.124)$$

where the subscript 1 refers to the right thigh. The residual (Res) moment acting on the right thigh is

$$\mathbf{M}_{Res.1} = -\,\mathbf{M}_{R.Knee} - (\mathbf{p}_{Dis.1} \times \mathbf{F}_{R.Knee}) + (\mathbf{p}_{Prx.1} \times \mathbf{F}_{R.Hip}) \quad (B.125)$$

The rate of change of angular momentum for the right thigh may be calculated using the standardised form of Equations B.82 to B.84. Then, application of the angular analogue of Newton's second law yields the following:

$$M_{R.Hip.x} = \dot{H}_{1x} - \mathbf{i}_1 \bullet \mathbf{M}_{Res1} \quad (B.126)$$

$$M_{R.Hip.y} = \dot{H}_{1y} - \mathbf{j}_1 \bullet \mathbf{M}_{Res1} \quad (B.127)$$

$$M_{R.Hip.z} = \dot{H}_{1z} - \mathbf{k}_1 \bullet \mathbf{M}_{Res1} \quad (B.128)$$

Adding these components gives

$$\mathbf{M}_{R.Hip} = M_{R.Hip.x}\,\mathbf{i}_1 + M_{R.Hip.y}\,\mathbf{j}_1 + M_{R.Hip.z}\,\mathbf{k}_1 \quad (B.129)$$

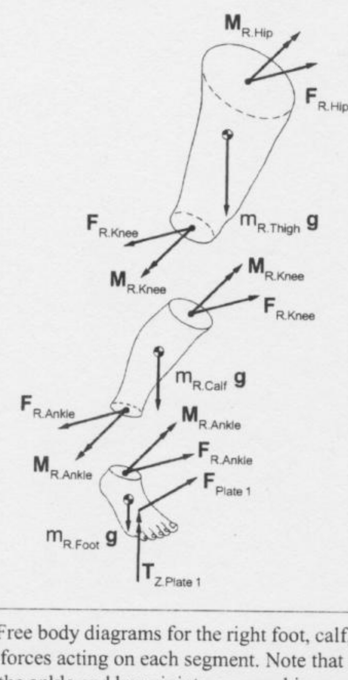


Figure B.3 Free body diagrams for the right foot, calf, and thigh, showing the external forces acting on each segment. Note that the forces and moments at the ankle and knee joints are equal in magnitude but opposite in direction, depending on the segment concerned (Newton's third law).

We can express the resultant joint force (**F**; Equations B.120 to B.122) and resultant joint moment (**M**; Equation B.129) in terms of a body-based coordinate system:

$$F_{R.Hip.PrxDis} = \mathbf{F}_{R.Hip} \bullet \mathbf{i}_{1} \quad (B.130)$$

$$F_{R.Hip.MedLat} = \mathbf{F}_{R.Hip} \bullet \mathbf{k}_{Pelvis} \quad (B.131)$$

$$F_{R.Hip.AntPos} = \mathbf{F}_{R.Hip} \bullet \mathbf{l}_{R.Hip} \quad (B.132)$$

Also,

$$M_{R.Hip.IntExt} = \mathbf{M}_{R.Hip} \bullet \mathbf{i}_{1} \quad (B.133)$$

$$M_{R.Hip.FlxExt} = - \mathbf{M}_{R.Hip} \bullet \mathbf{k}_{Pelvis} \quad (B.134)$$

$$M_{R.Hip.AbdAdd} = - \mathbf{M}_{R.Hip} \bullet \mathbf{l}_{R.Hip} \quad (B.135)$$

See the right leg free body diagrams in Figure B.3.

Left Foot. Application of the linear form of Newton's second law to the left foot yields the following:

$$F_{L.Ankle.X} = m_{L.Foot}\ddot{X}_{L.Foot.CG} - F_{Plate2.X} \quad (B.136)$$

$$F_{L.Ankle.Y} = m_{L.Foot}\ddot{Y}_{L.Foot.CG} - F_{Plate2.Y} \quad (B.137)$$

$$F_{L.Ankle.Z} = m_{L.Foot}(\ddot{Z}_{L.Foot.CG} + 9.81) - F_{Plate2.Z} \quad (B.138)$$

The proximal (Prx) and distal (Dis) moment arms may be calculated as follows:

$$\mathbf{p}_{Prx.6} = \mathbf{p}_{L.Ankle} - \mathbf{p}_{L.Foot.CG} \quad (B.139)$$

and

$$\mathbf{p}_{Dis.6} = \mathbf{p}_{Plate2} - \mathbf{p}_{L.Foot.CG} \quad (B.140)$$

where

$$\mathbf{p}_{Plate2} = DX2\mathbf{I} + DY2\mathbf{J} + 0\mathbf{K} \quad (B.141)$$

(The subscript 6 indicates the left foot.) The residual (Res) moment acting on the left foot is

$$\mathbf{M}_{Res.6} = \mathbf{T}_{Plate2} + (\mathbf{p}_{Prx.6} \times \mathbf{F}_{L.Ankle}) + (\mathbf{p}_{Dis.6} \times \mathbf{F}_{Plate1}) \quad (B.142)$$

and

$$\mathbf{T}_{Plate2} = 0\mathbf{I} + 0\mathbf{J} + T_{Z.Plate2}\,\mathbf{K} \quad (B.143)$$

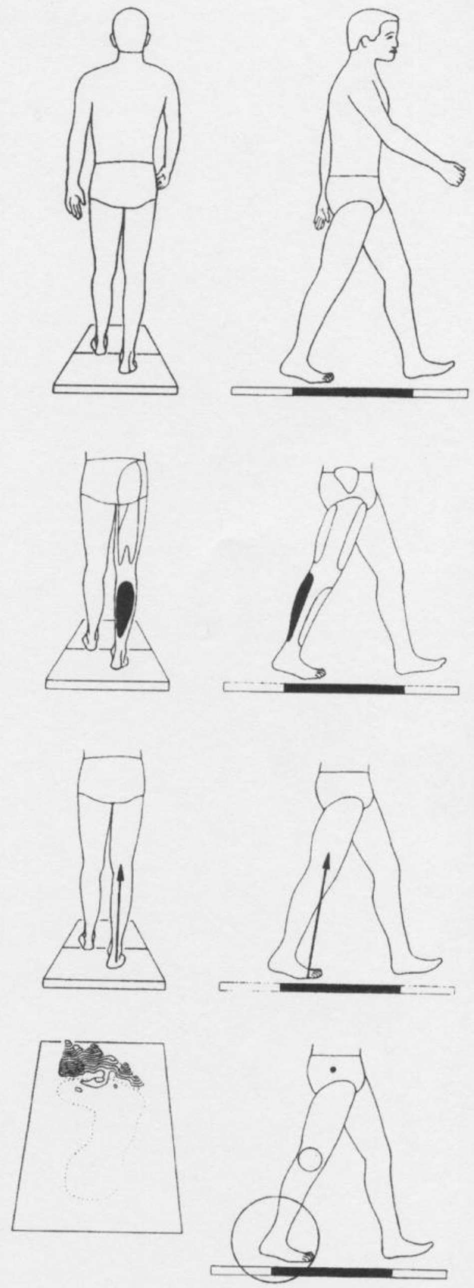
The rate of change of angular momentum for the left foot may be calculated using the standardised form of Equations B.82 to B.84. Then, application of the angular analogue of Newton's second law yields

$$M_{L.Ankle.x} = \dot{H}_{6x} - \mathbf{i}_{6} \bullet \mathbf{M}_{Res.6} \quad (B.144)$$

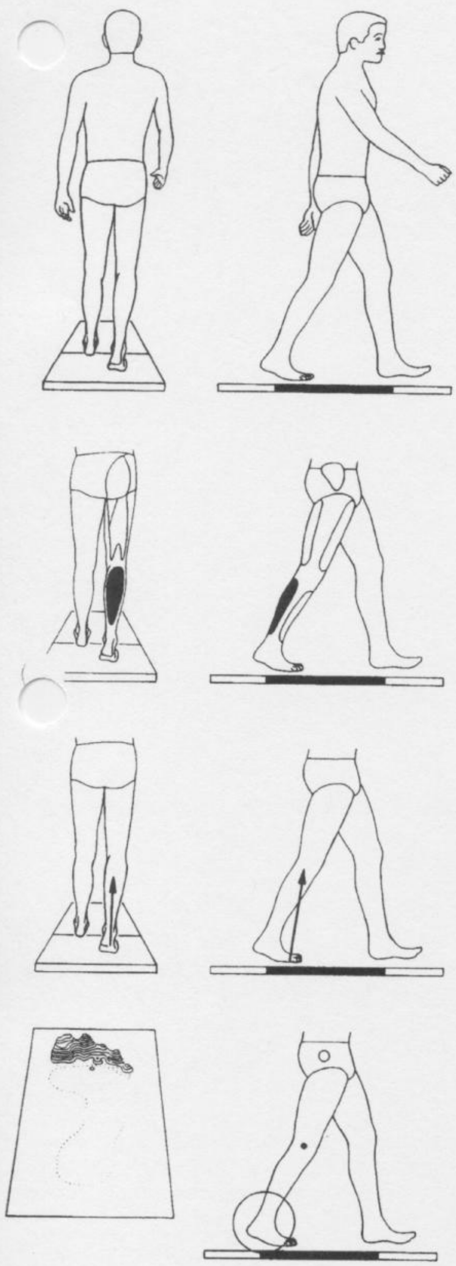
$$M_{L.Ankle.y} = \dot{H}_{6y} - \mathbf{j}_{6} \bullet \mathbf{M}_{Res.6} \quad (B.145)$$

and

$$M_{L.Ankle.z} = \dot{H}_{6z} - \mathbf{k}_{6} \bullet \mathbf{M}_{Res.6} \quad (B.146)$$



Frame = 14
Time = 0.52 s



Fr... = 15
Time = 0.56 s
Right heel-off

Adding these components gives

$$\mathbf{M}_{L.Ankle} = M_{L.Ankle.x}\,\mathbf{i}_6 + M_{L.Ankle.y}\,\mathbf{j}_6 + M_{L.Ankle.z}\,\mathbf{k}_6 \qquad (B.147)$$

Again, we can express the resultant joint force (**F**; Equations B.136 to B.138) and resultant joint moment (**M**; Equation B.147) in terms of a body-based coordinate system:

$$F_{L.Ankle.PrxDis} = \mathbf{F}_{L.Ankle} \bullet \mathbf{i}_6 \qquad (B.148)$$

$$F_{L.Ankle.MedLat} = -\,\mathbf{F}_{L.Ankle} \bullet \mathbf{k}_4 \qquad (B.149)$$

$$F_{L.Ankle.AntPos} = \mathbf{F}_{L.Ankle} \bullet \mathbf{l}_{L.Ankle} \qquad (B.150)$$

Also,

$$M_{L.Ankle.InvEve} = -\,\mathbf{M}_{L.Ankle} \bullet \mathbf{i}_6 \qquad (B.151)$$

$$M_{L.Ankle.PlaDor} = \mathbf{M}_{L.Ankle} \bullet \mathbf{k}_4 \qquad (B.152)$$

$$M_{L.Ankle.VarVal} = \mathbf{M}_{L.Ankle} \bullet \mathbf{l}_{R.Ankle} \qquad (B.153)$$

Left Calf. Application of the linear form of Newton's second law to the left calf yields the following:

$$F_{L.Knee.X} = m_{L.Calf}\,\ddot{X}_{L.Calf.CG} - F_{L.Ankle.X} \qquad (B.154)$$

$$F_{L.Knee.Y} = m_{L.Calf}\,\ddot{Y}_{L.Calf.CG} - F_{L.Ankle.Y} \qquad (B.155)$$

$$F_{L.Knee.Z} = m_{L.Calf}(\ddot{Z}_{L.Calf.CG} + 9.81) - F_{L.Ankle.Z} \qquad (B.156)$$

The proximal (Prx) and distal (Dis) moment arms may be calculated as follows:

$$\mathbf{p}_{Prx.4} = \mathbf{p}_{L.Knee} - \mathbf{p}_{L.Calf.CG} \qquad (B.157)$$

and

$$\mathbf{p}_{Dis.4} = \mathbf{p}_{L.Ankle} - \mathbf{p}_{L.Calf.CG} \qquad (B.158)$$

where the subscript 4 refers to the left calf. The residual (Res) moment acting on the left calf is

$$\mathbf{M}_{Res.4} = -\,\mathbf{M}_{L.Ankle} - (\mathbf{p}_{Dis.4} \times \mathbf{F}_{L.Ankle}) + (\mathbf{p}_{Prx.4} \times \mathbf{F}_{L.Knee}) \qquad (B.159)$$

The rate of change of angular momentum for the left calf may be calculated using the standardised form of Equations B.82 to B.84. Then, application of the angular analogue of Newton's second law yields the following:

$$M_{L.Knee.x} = \dot{H}_{4x} - \mathbf{i}_4 \bullet \mathbf{M}_{Res4} \qquad (B.160)$$

$$M_{L.Knee.y} = \dot{H}_{4y} - \mathbf{j}_4 \bullet \mathbf{M}_{Res4} \qquad (B.161)$$

$$M_{L.Knee.z} = \dot{H}_{4z} - \mathbf{k}_4 \bullet \mathbf{M}_{Res4} \qquad (B.162)$$

Adding these components gives

$$\mathbf{M}_{L.Knee} = M_{L.Knee.x}\,\mathbf{i}_4 + M_{L.Knee.y}\,\mathbf{j}_4 + M_{L.Knee.z}\,\mathbf{k}_4 \qquad \text{(B.163)}$$

We can express the resultant joint force (**F**; Equations B.154 to B.156) and resultant joint moment (**M**; Equation B.163) in terms of a body-based coordinate system:

$$F_{L.Knee.PrxDis} = \mathbf{F}_{L.Knee} \bullet \mathbf{i}_4 \qquad \text{(B.164)}$$

$$F_{L.Knee.MedLat} = -\,\mathbf{F}_{L.Knee} \bullet \mathbf{k}_2 \qquad \text{(B.165)}$$

$$F_{L.Knee.AntPos} = \mathbf{F}_{L.Knee} \bullet \mathbf{l}_{L.Knee} \qquad \text{(B.166)}$$

Also,

$$M_{L.Knee.IntExt} = -\,\mathbf{M}_{L.Knee} \bullet \mathbf{i}_4 \qquad \text{(B.167)}$$

$$M_{L.Knee.FlxExt} = \mathbf{M}_{L.Knee} \bullet \mathbf{k}_2 \qquad \text{(B.168)}$$

$$M_{L.Knee.AbdAdd} = \mathbf{M}_{L.Knee} \bullet \mathbf{l}_{L.Knee} \qquad \text{(B.169)}$$

Left Thigh. Application of the linear form of Newton's second law to the left thigh yields the following:

$$F_{L.Hip.X} = m_{L.Thigh}\ddot{X}_{L.Thigh.CG} - F_{L.Knee.X} \qquad \text{(B.170)}$$

$$F_{L.Hip.Y} = m_{L.Thigh}\ddot{Y}_{L.Thigh.CG} - F_{L.Knee.Y} \qquad \text{(B.171)}$$

$$F_{L.Hip.Z} = m_{L.Thigh}(\ddot{Z}_{L.Thigh.CG} + 9.81) - F_{L.Knee.Z} \qquad \text{(B.172)}$$

The proximal (Prx) and distal (Dis) moment arms may be calculated as follows:

$$\mathbf{p}_{Prx.2} = \mathbf{p}_{L.Hip} - \mathbf{p}_{L.Thigh.CG} \qquad \text{(B.173)}$$

and

$$\mathbf{p}_{Dis.2} = \mathbf{p}_{L.Knee} - \mathbf{p}_{L.Thigh.CG} \qquad \text{(B.174)}$$

where the subscript 2 refers to the left thigh. The residual (Res) moment acting on the left thigh is

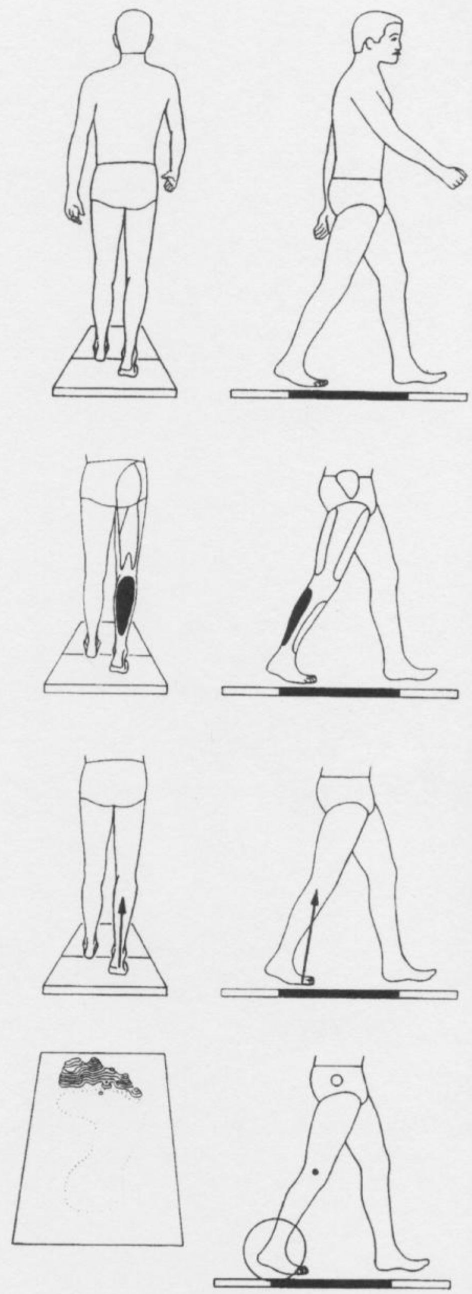
$$\mathbf{M}_{Res.2} = -\,\mathbf{M}_{L.Knee} - (\mathbf{p}_{Dis.2} \times \mathbf{F}_{L.Knee}) + (\mathbf{p}_{Prx.2} \times \mathbf{F}_{L.Hip}) \qquad \text{(B.175)}$$

The rate of change of angular momentum for the left thigh may be calculated using the standardised form of Equations B.82 to B.84. Then, application of the angular analogue of Newton's second law yields the following:

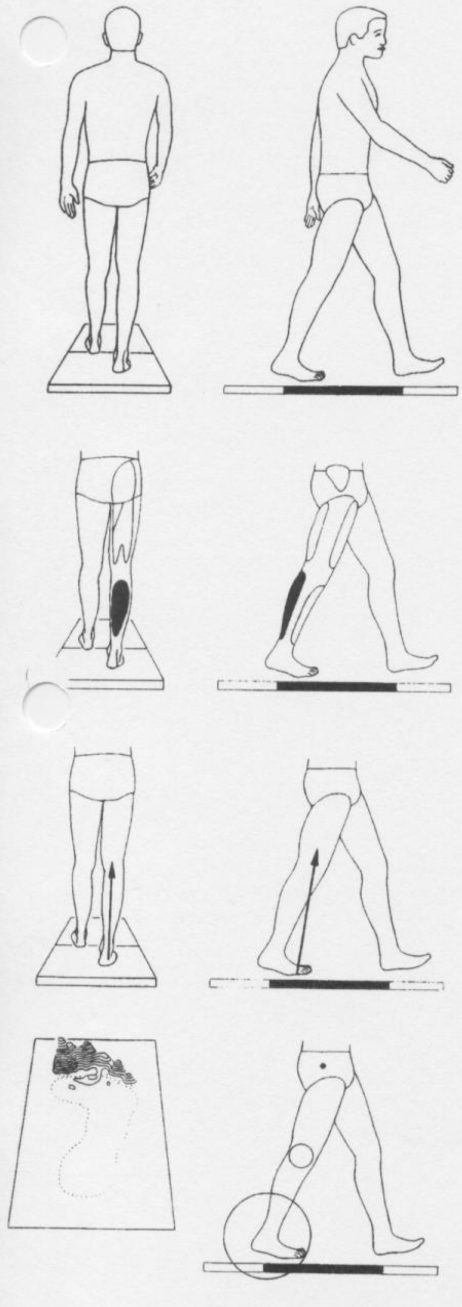
$$M_{L.Hip.x} = \dot{H}_{2x} - \mathbf{i}_2 \bullet \mathbf{M}_{Res2} \qquad \text{(B.176)}$$

$$M_{L.Hip.y} = \dot{H}_{2y} - \mathbf{j}_2 \bullet \mathbf{M}_{Res2} \qquad \text{(B.177)}$$

$$M_{L.Hip.z} = \dot{H}_{2z} - \mathbf{k}_2 \bullet \mathbf{M}_{Res2} \qquad \text{(B.178)}$$



Frame = 15
Time = 0.56 s
Right heel-off



Adding these components gives

$$\mathbf{M}_{L.Hip} = M_{L.Hip.x}\,\mathbf{i}_2 + M_{L.Hip.y}\,\mathbf{j}_2 + M_{L.Hip.z}\,\mathbf{k}_2 \qquad \text{(B.129)}$$

Again, we can express the resultant joint force (**F**; Equations B.170 to B.172) and resultant joint moment (**M**; Equation B.179) in terms of a body-based coordinate system:

$$F_{L.Hip.PrxDis} = \mathbf{F}_{L.Hip} \bullet \mathbf{i}_2 \qquad \text{(B.180)}$$

$$F_{L.Hip.MedLat} = -\,\mathbf{F}_{L.Hip} \bullet \mathbf{k}_{Pelvis} \qquad \text{(B.181)}$$

$$F_{L.Hip.AntPos} = \mathbf{F}_{L.Hip} \bullet \mathbf{l}_{L.Hip} \qquad \text{(B.182)}$$

Also,

$$M_{L.Hip.IntExt} = -\,\mathbf{M}_{L.Hip} \bullet \mathbf{i}_2 \qquad \text{(B.183)}$$

$$M_{L.Hip.FlxExt} = -\,\mathbf{M}_{L.Hip} \bullet \mathbf{k}_{Pelvis} \qquad \text{(B.184)}$$

$$M_{L.Hip.AbdAdd} = \mathbf{M}_{L.Hip} \bullet \mathbf{l}_{L.Hip} \qquad \text{(B.185)}$$

See the left leg free body diagrams in Figure B.4.

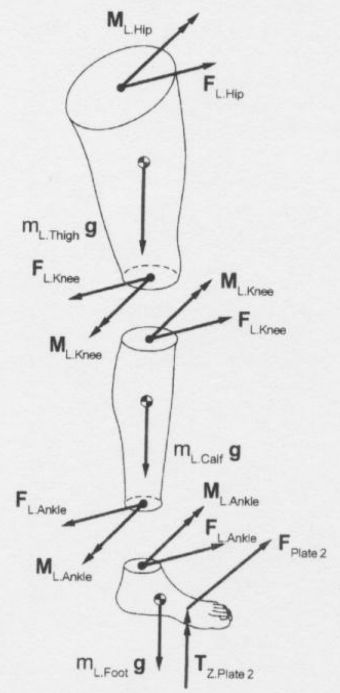


Figure B.4 Free body diagrams for the left foot, calf, and thigh, showing the external forces acting on each segment. The forces and moments at the ankle and knee joints are equal in magnitude but opposite in direction, depending on the segment concerned (Newton's third law of motion).

Appendix F

Subject ID _______ Weight (kg) _______ Height (m) _______ Date: ________

GAIT ANALYSIS DATA COLLECTION FORM

Without SAI					With SAI			
Gait Speed	S#NItrial#	Data Collected	Path ID		Gait Speed	S#WItrial#	Data Collected	Path ID
	____NI01					___WI01		
	____ NI02					___WI02		
	____ NI03					___WI03		
	____ NI04					___WI04		
	____ NI05					___WI05		
	____ NI06					___WI06		

NOTES:

Appendix G

Reliability of kinetic measures.

Outcome Measure	**$ICC_{(3,3)}$** without SAI (SEM)	**$ICC_{(3,3)}$** with SAI (SEM)
Loading rate	.941 (.23)	.944 (.19)
Peak external knee extension moment during Loading Response	.981 (.002)	.976 (.002)

Appendix H

Participant Intake Form

☐1 Mr. ☐2 Mrs. ☐3 Ms. ☐4 Miss ☐5 Dr.

Sex

☐1 Male ☐2 Female

Date of Birth

|___|___-|___|___-_______
Month Day Year

First Name Middle Name Last Name

Street Address

City State Zip Code

Home Phone
( )

Work Phone
( )

Marital Status

☐1 Married
☐2 Separated/Divorced
☐3 Living with significant other
☐4 Widowed
☐5 Single

Height________ _________ Feet Inches

Weight____________ Pounds

What is your race / ethnicity? Please check all that apply to you.

☐1 American Indian or Alaska Native
☐2 Asian
☐3 Black or African American
☐4 Native Hawaiian or Other Pacific Islander
☐5 White
☐6 Hispanic or Latino
☐7 Not Hispanic
☐8 Other Race

What is the highest degree or level of school you have completed?

☐1 8th grade or less
☐2 Some high school
☐3 High school graduate/ GED
☐4 Some college, but no degree
☐5 Associate degree (AA, AS)
☐6 Bachelor's degree (BA, BS)
☐7 Postgraduate degree

Which best describes your current work situation? Please check only one.

☐1 Working FT
☐2 Working PT
☐3 Student
☐4 Leave of Absence
☐5 Unemployed
☐6 Homemaker (full time)
☐7 Homemaker (need help from others)
☐8 Disabled, unemployed or retired due to ill health
☐9 Retired (not due to ill health)
☐10 Other (specify): ______________________

Appendix I

Brief Medical History

The following is a list of common health problems. In the first column, please check (√) the box if you have the problem. If you do check the box, please complete the second and third columns as well.			
	Do you have the problem?	Do you receive treatment for it?	Does it limit your activities?
1. Heart Disease	☐ Yes	☐ Yes	☐ Yes
2. Angina (Chest Pain)	☐ Yes	☐ Yes	☐ Yes
3. Pacemaker	☐ Yes	☐ Yes	☐ Yes
4. Uncontrolled Diabetes	☐ Yes	☐ Yes	☐ Yes
5. High Blood Pressure	☐ Yes	☐ Yes	☐ Yes
6. Lung Disease	☐ Yes	☐ Yes	☐ Yes
7. Diabetes	☐ Yes	☐ Yes	☐ Yes
8. Ulcer or Stomach Disease	☐ Yes	☐ Yes	☐ Yes
9. Kidney Disease	☐ Yes	☐ Yes	☐ Yes
10. Liver Disease	☐ Yes	☐ Yes	☐ Yes
11. Anemia/Other Blood Disease	☐ Yes	☐ Yes	☐ Yes
12. Cancer	☐ Yes	☐ Yes	☐ Yes
13. Depression	☐ Yes	☐ Yes	☐ Yes
14. Back Pain	☐ Yes	☐ Yes	☐ Yes
15. Rheumatoid Arthritis	☐ Yes	☐ Yes	☐ Yes
16. Fibromyalgia	☐ Yes	☐ Yes	☐ Yes
17. Vascular Disease	☐ Yes	☐ Yes	☐ Yes
18. Infection	☐ Yes	☐ Yes	☐ Yes
19. Inflammatory Bowel Disease	☐ Yes	☐ Yes	☐ Yes
20. Psoriasis	☐ Yes	☐ Yes	☐ Yes

Appendix J

Medications

For each medication category below, please check the medications you currently take for your arthritis. Indicate ALL the medications you take, whether a medical doctor prescribes them, or not. *Do not indicate your medication dose or the number of pills you take.*

☐ **Over the counter pain relievers** (for example, Anacin, Nuprin, Bayer, Advil, Bufferin, Tylenol, Excedrin, Aleve, Motrin, etc.):
☐ **Prescribed pain relievers** (for example, Ultram, Vicadin, Tylenol 3, etc.)
☐ **Prescribed Nonsteroidal anti-inflammatory drugs (NSAIDS)** (for example, Naprosyn, Voltaren, Clinoril, Indocin, Relafen, Celebrex, Vioxx, etc.)
☐ **Glucocorticoids** (for example, Prednisone, prednisolone, cortisone, decadron, etc.)
☐ **Anti-rheumatic medications** (for example, Methotrexate, gold shots, Arava, Plaquenil, Enbrel, Auranofin, Sulfasalizine, Imuran, Penicilliamine, Cytoxan, Remicade, etc.)
☐ **Muscle relaxants** (Flexeril, Parafon, Forte, Robaxin, Soma, etc.)
☐ **Antidepressants or drugs that help you sleep** (Elavil, Nortriptyline, Pamelor, Prozac, Sinequan, Zoloft, Tylenol PM, Ambien, etc.)
☐ **Viscosupplements (or hyaluronic acid substitutes) for treatment of Osteoarthritis** (Hyalgan, glucosamine, chondroitin, Synvisc, etc.)

Appendix K

Functional Mobility Data Collection Form

Condition: With Insert Without Insert

Self Selected Gait Velocity:

Trial 1: __________ sec Average: ___________ sec

Trial 2: __________ sec 4.2 meters/ Avg time = ________ m/sec

Post walk VAS Score: ______________

Fast Gait Velocity:

Trial 1: __________ sec Average: ___________ sec

Trial 2: __________ sec 4.2 meters/ Avg time = ________ m/sec

Post Walk VAS Score: ______________

6 Minute Walk Test:

Resting BP (prior to test): _____________

Distance walked: __________ feet _______ in. _______ meters

Post Walk VAS Score: _____________

Laps: ____________

Assistive Device? Y N What kind?: ____________

Appendix L

RADIOLOGIC EVALUATION

DATA FORM

Knee: Left Right

K-L Grading (OA Severity): 0 1 2 3 4

Medial Joint Space: ______________mm

Lateral Joint Space: ______________ mm

Anatomical Hip-Knee-Ankle Angle: _____________ degrees

Mechanical Hip-Knee-Ankle Angle: ______________ degrees

Evaluated by: ____

Dr. Jordan Renner, MD

Appendix M

Results of statistical analysis excluding participants with Total Knee Replacement (TKR)

Dependent Variable	With SAI			Without SAI						
	Mean	**SD**	**95% CI**	**Mean**	**SD**	**95% CI**	**F-value**	***p*-value**	**ES**	**Power**
VAS Pain Scale (mm): Self Selected speed (n=58)	15.7	13.7	12.1 – 19.3	22	23.6	10.6 – 19.9	.069	.793	.001	.058
VAS Pain Scale (mm): Fast Gait Speed (n=58)	18.1	16.6	13.7 – 22.4	22	23.6	15.8 – 28.2	3.298	.075	.055	.431
VAS Pain Scale (mm): 6MWT (n=58)	25.8	25.6	19.1 – 32.5	31.5	28.2	24.1 – 38.9	5.334	.025	.086	.622
Time to peak VGRF (sec) (n =56)	.197	.06	.182 - .212	.199	.06	.182 – .215	.196	.660	.004	.072
Peak VGRF (times BW) (n=56)	1.08	.09	1.06 – 1.10	1.07	.09	1.05 – 1.10	1.958	.167	.034	.280
Loading Rate (times BW/sec) n=56)	5.92	1.78	5.4 – 6.4	5.92	1.77	5.4 – 6.4	.083	.775	.002	.059
Peak Knee Moment[†] (N/BW*HT) (n=55)	-.178	.14	-.217 - -.141	-.176	.155	-.218 - -.134	.096	.758	.022	.061
Average Knee Moment (N/BW*HT) (n=55)	-.014	.093	-.04 - -.011	-.021	.081	-.043 - .001	1.253	.268	.023	.196

REFERENCES

1. Buckwalter JA, Saltzman C, Brown T. The Impact of Osteoarhtritis. *Clinical Orthopaedics and Related Research.* 2004(427s):S6-S15.

2. Lawrence R, Helmick C, Arnett FC. Estimates of the prevalence of arthritis and selected musculoskeltal disorders in the United States. *Arthritis & Rheumatism.* 1998;41:778-799.

3. Felson D, Lawrence R, Dieppe P, Hirsch R, Helmick C. Osteoarthritis: New Insights. Part 1: The Disease and its risk factors. *Annals of Internal Medicine.* October 2000 2000;133(8):635-646.

4. Corti M, Rigon C. Epidemiology of osteoarthritis: Prevalence, risk factors and functional impact. *Aging Clin Exp Res.* 2003;15(5):359-363.

5. Swagerty DJ, Hellinger D. Radiographic assessment of Osteoarthritis. *American Family Physician.* 2001;64(2):279-286.

6. Schurman D, Smith RL. Osteoarthritis Current treatment and future prospects for surgical, medical and biological intervention. *Clinical Orthopaedics and Related Research.* 2004;427S:S183-S189.

7. CDC CfDC. Adult Participation in recommended levels of physical activity, United States, 2001 and 2003. *Morbidity and Mortality Weekly Report.* December 2 2005;54(47):1208-1212.

8. Lee P. Diagnosis and medical managment of conditions with Arthritis. In: Walker J, Helewa A, eds. *Physical Rehabilitation in Arthritis*. 2nd ed. St. Louis, Missouri: Saunders; 2004:49-78.

9. Felson DT, Goggins J, Niu J, Zhang Y, Hunter D. The effect of body weight on progression of knee osteoarthritis is dependent on alignment. *Arthritis & Rheumatism.* December 2004;50(12):3904-3909.

10. Sharma L, Song J, Felson DT, Cahue S, Shamiyeh E, Dunlop DD. The role of knee alignment in disease progression and functional decline in knee osteoarthritis. *J Am Med Assoc.* 2001;286:188-195.

11. Slemenda C, Brandt K, Heilman D, Mazzuca S, Braunstein E, Katz BP. Quadriceps weakness and osteoarthritis of the knee. *Annals of Internal Medicine.* 1997;127:97-104.

12. Baliunas AJ, Hurwitz DE, Ryals AB. Increased knee joint loads during walking are present in subjects with knee osteoarthritis. *Osteo & Cartilage.* 2002;10:573-579.

13. Radin E, Yang K, Riegger C, Kish V, O'Connor J. Relationship between lower limb dynamics and knee joint pain. *Journal of Orthopaedic Research.* 1991;9:398-405.

14. Mili F, Helmick CG, Zack MM. prevalence of arthritis: analysis of data from the US Behavioral Risk Factor Surveillance System, 1996-99. *Journal of Rheumatology.* 2002;29(9):1981-1988.

15. Felson DT. Risk Factors for Osteoarthritis. *Clinical Orthopaedics and Related Research.* 2004;427S:S16-S21.

16. Guccione AA, Felson DT, Anderson JJ, Anthony JM, Zhang Y, Wilson PW. The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *Am J Public Health.* 1994;84:351-358.

17. Marsh A, Rejeski WJ, Lang W, Miller M, Messier S. Baseline Balance and Functional decline in older adults with knee pain: The observational arthritis study in seniors. *Journal of American Geriatrics Society.* 2003;51:331-339.

18. Messier S, Paul D, Cowan R, Seay J, Young H, Marsh A. Do older adults with knee osteoarthritis place greater loads on the knee during gait? A preliminary study. *Arch Phys Med Rehabil.* April 2005;86:703-709.

19. Hochberg M, McAlindon T, Felson D. Osteoarthritis: New Insights part 2: Treatment approaches. *Annals of Internal Medicine.* November, 2000 2000;133(9):726-737.

20. Altman R, Hochberg M, Moskowitz R, Schnitzer T. Recommendations for the medical management of osteoarthritis of the hip and knee. *Arthritis & Rheumatism.* September 2000;43(9):1905-1915.

21. Jordan KM, Arden NK, Doherty M, et al. EULAR recommendations 2003: an evidence based approach to the management of knee osteoarthritis. *Annals of Rheum Dis.* 2003;62:1145-1155.

22. Felson DT, Lawrence RC, Hochberg M, et al. Osteoarthritis: New Insights Part 2: Treatment approaches. *Annals of Internal Medicine.* November 7 2000;133(9):726-737.

23. Mundermann A, Stefanyshyn D, Nigg BM. Relationship between footwear comfort of shoe inserts and anthropometric and sensory factors. *Medicine & Science in Sport & Exercise.* 2001;33(11):1939-1944.

24. Noe DA, Voto SJ, Hoffmann Ms, Askew MJ, Gradisar IA. Role of the calcaneal heel pad and polymeric shock absorbers in attenuation of heel strike impact. *J. Biomed. Eng.* January 1993;15:23-26.

25. Tooms RE, Griffin JW, Green S, Cagle K. Effect of Viscoelastic Insoles on Pain. *Orthopedics.* 1987;10(8):1143 - 1147.

26. Voloshin A, Wosk J. Influence of Artificial Shock Absorbers on Human Gait. *Clinical Orthopaedics and Related Research.* 1981;160:52 - 56.

27. Aigner T, McKenna L. Molecular pathology and pathobiology of osteoarthritic cartilage. *Cellular and Molecular Life Sciences.* 2002;59:5-18.

28. Harrison A. The influence of pathology, pain, balance, and self-efficacy on function in women with osteoarthritis of the knee. *Physical Therapy.* September 2004;84(9):822-831.

29. Kellgren JH, Lawrence JS. Radiological assessment of osteoarthritis. *Annals of Rheum Dis.* 1957;16:494-501.

30. Sharma L, Cahue S, Song J, Hayes K, Pai Y-C, Dunlop D. Physical Functioning Over Three Years in Knee Osteoarthritis. *Arthritis & Rheumatism.* December 2003;48(12):3359-3370.

31. Ling SM, Fried LP, Garrett ES, Fan M, Rantanen T, Bathon JM. Knee osteoarthritis compromises early mobility function: the women's health and aging study II. *Journal of Rheumatology.* January 2003;30(1):114-120.

32. Paradowski PT, Englund M, S LL, Roos EM. The effect of patient characteristics on variability in pain and function over two years in early knee osteoarthritis. *Health and Quality of Life Outcomes.* September 2005;3:59-64.

33. Evcik D, Sonel B. Effectiveness of a home-based exercise therapy and walking program on osteoarthritis of the knee. *Rheumatology International.* 2002;22:103-106.

34. Ettinger WH, Burns R, Messier S, et al. A randomized trial comparing aerobic exercise and resistance exerces with a health education program in older adults with knee osteoarthritis. The Fitness Arthritis and Seniors Trial (FAST). *Journal of American Medical Association.* Jan 1 1997;277(1):25-31.

35. Thomas KS, Muir KR, Doherty M, Jones AC, O'Reilly SC, Bassey EJ. Home based exercise programme for knee pain and knee osteoarthritis: randomised controlled trial. *British Medical Journal.* October 5 2002;325:1-5.

36. Focht B, Rejeski WJ, Ambrosius WT, Katula JA, Messier S. Exercise, Self-efficacy , and mobility performance in overweight and obese older adults with knee osteoarthritis. *Arthritis & Rheumatism.* 2005;53(5):659-665.

37. Lorig K, Chastain RL, Ung E, Shoor S, Holman H. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. *Arthritis & Rheumatism.* 1989;32(1):37-44.

38. Rejeski WJ, Miller M, Foy C, Messier S, Rapp S. Self-efficacy and the progression of functional limitations and self-reported disability in older adults with knee pain. *J Gerontl B Psychol Sci Soc Sci.* 2001;56:S261-265.

39. Schoster B, Callahan LF, Meier A, Mielenz T, DiMartino L. The People with Arthritis Can Exercise (PACE) program: a qualitative evaluation of participant satisfaction. *Prev Chronic Dis [serial online].* Jul [date cited] 2005.

40. Messier S, Loeser RF, Miller GD, et al. Exercise and Dietary Weight Loss in Overweight and Obese Older Adults With Knee Osteoarthritis. *Arthritis & Rheumatism.* 2004;50(5):1501 - 1510.

41. Scott J, Huskisson EC. Graphic representation of pain. *Pain.* 1976;2:175-184.

42. Bolton JE, Wilkinson RC. Responsiveness of pain scales: a comparison of three intensity measures in chiropractic patients. *Journal of Manipulative Physiotherapy.* 1998;21:1-7.

43. Finch E, Brooks D, Stratford PW, Mayo N. *Physical Rehabilitation Outcome Measures*. second ed. Baltimore, MD: Lippincott, Williams & Wilkins; 2002.

44. Al-Zahrani KS, O BAM. A study of the gait characteristics of patients with chronic osteoarthritis of the knee. *Disability and Rehabilitation.* 2002;24(5):275-280.

45. Kaufman K, Hughes C, Morrey B, Morrey M, An K. Gait characteristics of patients with knee osteoarthritis. *J Biomech.* 2001;34:907-915.

46. Gok H, Ergin S, Yavuzer G. Kinetic and kinematic characteristics of gait in patients with medial knee arthrosis. *Acta Orthop Scand.* 2002;73(6):647-652.

47. Perry J. *Gait Analysis: Normal and pathological function*. New York, NY: McGraw-Hill, Inc; 1992.

48. Simoneau GG. Kinesiolgy of Walking. In: Neumann DA, ed. *Kinesiology of the Musculoskeletal System*. St. Louis, Missouri: Mosby, Inc; 2002:523-569.

49. Messier S, Gutekunst D, Davis C, DeVita P. Weight loss reduces knee-joint loads in overweight and obese older adults with knee osteoarthritis. *Arthritis & Rheumatism.* July 2005;52(7):2026-2032.

50. Montero-Odasso M, Schapira M, Soriano ER, et al. Gait velocity as a single predictor of adverse events in health seniors aged 75 years and older. *The Journals of gerontology Biological Sciences and Medical sciences.* October 2005;60A(10):1304-1309.

51. Messier S, Loeser RF, Hoover JL, Semble EL, Wise CM. Ostearthritis of the knee: effects on gait, strength, and flexibility. *Arch Phys Med Rehabil.* 1992;73(1):29-36.

52. Bellamy N, Buchanan WW. A preliminary evaluation of the dimensionality and clinical importance of pain and disability in osteoarthritis of the hip and knee. *Clinical Rheumatology.* 1986;5:231-241.

53. McConnell S, Kolopack P, Davis AM. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC): a review of its utility and measurement properties. *Arthritis Care and Research.* 2001;45:453-461.

54. Keefe FJ, Lefebvre JC, Maixner W, Salley AN, Caldwell Jr. D. Self-efficacy for arthritis pain: relationship to perception of thermal laboratory pain stimuli. *Arthritis Care and Research.* 1997;10:177-184.

55. Whittle MW. Generation and attenuation of transient impulsive forces beneath the foot: a review. *Gait and Posture.* 1999;10:264-275.

56. Collins JJ, Whittle MW. Impulsive forces during walking and their clinical implications. *Clin Biomech.* 1989;4(3):179 - 186.

57. Lafortune MA, Henning HM. Cushioning properties of footwear during walking: accelerometer and force platform measurements. *Clin Biomech.* 1992;7(3):181 - 184.

58. Hamil J, Knutzen K. Biomechanical Basis of Human Movement. *Biomechanical Basis of Human Movement*. Baltimore, MD: Williams & Wilkins; 1995:427- 452.

59. Simon SR, Radin E, Paul IL, Rose RM. Response of joints to impact loading II. Invivo behavior of subchondral bone. *J Biomech.* 1972;5:267-272.

60. Radin E, Paul IL. Response of joints to impact loading I. In vitro wear. *Arthritis & Rheumatism.* May-June 1971;14(3):356-362.

61. Radin E, Ehrlich MG, Chernack R, Abernaethy PJ, Paul IL, Rose RM. Effects of repetitive impulsive loading on the knee joints of rabbits. *Clin Orthop Rel Res.* Mar-April 1978;131:288-293.

62. Radin E, Burr DB, Caterson B, Fyhrie D, Brown TD, Boyd RD. Mechanical determinants of osteoarthrosis. *Semins Arthritis Rheum.* Dec 1991;21(3 Suppl 2):12-21.

63. Shiba N, Kitaoka HB, Cahalan TD, Chao EY. Shock-absorbing effect of shoe insert materials commonly used in management of lower extremity disorders. *Clinical Orthopaedics and Related Research.* 1995;310:130 - 136.

64. Chen CP, Chen MJ, Pei YC, Lew HL, Wong PY, Tang SF. Saggittal Plane Loading Response During Gait in Different Age Groups an in People with Knee Oasteoarthritis. *American Journal of Physical Medicine & Rehabilitation.* 2003;82:307-312.

65. Mapel DW, Shainline M, Paez K, Gunter M. Hospital, pharmacy and outpatient costs for osteoarthritis and chronic back pain. *J Rheumatology.* 2004;31(3):573 - 583.

66. Felson DT. Osteoarthritis of the Knee. *The New England Journal of Medicine.* February 2006;354:841 - 848.

67. Sasaki T, Yasuda K, . Clinical evaluation of the treatment of osteoarthritic knees using a newly designed wedged insole. *Clin Orthop Rel Res.* 1987;221:181-187.

68. Kerrigan DC, Lelas JL, Goggins J, Merriman GJ, Kaplan R, Felson DT. Effectiveness of a Lateral-Wedge Insole on Knee Varus Torque in patients with Knee Ostearthritis. *Arch Phys Med Rehabil.* July 2002;83:889-893.

69. Maly M, Culham EG, Costigan P. Static and dynamic biomechanics of foot orthoses in people with medial compartment knee osteoarthrtis. *Clinical Biomechanics.* 2002;17:603-610.

70. Wolfe S, Brueckmann F. Conservative treatment of genu valgus and varum with medial/lateral heel wedges. *Indiana Med.* 1991;84(9):614-615.

71. Yasuda K, Sasaki T. the mechanics of treatment of the osteoarthritic knee with a wedged insole. *Clin Orthop Rel Res.* August 1987(215):162-172.

72. Ogata K, Yasunaga M, Nomiyama H. The effect of wedged insoles on the thrust of osteoarthritic knees. *International Orthopaedics.* 1997;21:308-312.

73. Self B, Greenwald R, Pflaster DACRA-. A biomechanical analysis of a medial unloading brace for osteoarthritis in the knee. *Arthritis Care Res.* 2000;13(4):191-197.

74. Pollo F, Jackson R. Knee bracing for unicompartmental osteoarthritis. *J Am Acad Orthop Surg.* January 2006;14(1):5-11.

75. Rejeski WJ, Focht B, Messier S. Obese older adults with knee Osteoarthritis: Weight loss, exercise and quality of life. *Health Psychology.* 2002;21(5):419-426.

76. Penninx W, Messier S, Rejeski WJ, et al. Physical Exercise and the prevention of disability in activities of daily living in older persone with OA. *Arch Intern Med.* 2001;161:2309-2316.

77. Sullivan T, Allegrante JP, Peterson MG, Kovar PA, MacKenzie CR. One-Year followup of patients with Osteoarthritis of the knee who participated in a program of supervised fitness walking and supportive patient education. *Arthritis Care and Research.* 1998;11(5):228-233.

78. Schwellnus M, Jordaan G, Noakes T. Prevention of common overuse injuries by the use of shock absorbing insoles: a prospective study. *Am J Sports Med.* 1990;18(6):636-642.

79. Windle CM, Gregory SM, Dixon SJ. The shock attenuation characteristics of four different insoles when worn in a military boot during running and marching. *Gait and Posture.* 1999;9:31-37.

80. McPoil TG, Cornwall MW. Rigid versus soft foot orthoses. A single subject design. *Journal of American Podiatric Medical Association.* 1991;81(12):638 - 642.

81. Eng JF, Pierrynowski MR. The effect of soft foot orthotics on three-dimensional lower-limb kinematics during walking and running. *Physical Therapy.* Sept 1994;74(9):45-49.

82. Goggins J, Baker K, Felson DT. What WOMAC Pain Score Should Make a Patient Eligible for a Trial in Knee Osteoarthritis? *The Journal of Rheumatology.* 2005;32(3):540 - 542.

83. Ferraz MB, Quaresma MR, Aquino LR, Atra E, Tugwell P, Goldsmith CH. Reliability of pain scales in the assessment of literate and illiterate patients with rheumatoid arthritis. *Journal of Rheumatology.* August 1990;17(8):1022 - 1024.

84. Gunther K, Sun Y. Reliability of radiographic assessment in hip and knee osteoarthritis. *Osteo & Cartilage.* 1999;7:239-246.

85. Kraus V, Vail TP, Worrell T, McDanial G. A comparative assessment of alignment angle of the knee by radiographic and physical examination methods. *Arthritis & Rheumatism.* 2005;52(6):1730-1735.

86. Rauh M, Boyle J, Phillips M, Bayers-Thering M, Krackow K. Reliability of measuring long-standing lower extremity radiographs. *Orthopedics.* 2007;30(4):299-303.

87. Winter DA. Biomechanics and motor control of human movement. second ed. New York: John Wiley & Sons, Inc; 1990:75-93.

88. Moisio K, Sumner D, Shott S, Hurwitz D. Normalization of joint moments during gait: a comparison of two techniques. *Journal of Biomechanics.* 2003;36:599-603.

89. Keller TS, Weisberger AM, Ray JL, Hasan SS, Shiavi RG, Spengler DM. Relationship between vertical ground reaction force and speed during walking, slow jogging and running. *Clin Biomech.* 1996;11(5):253 - 259.

90. Andriacchi TP, Galante JO, Fermier RW. The influence of total knee replacement design on walking and stair-climbing. *J of Bone Joint Surg (Am).* 1982;64:1328-1335.

91. Bennett A, Crossley K, Brukner P, Hinman R. Predictors of symptomatic response to glucosimine in knee OA: an exploratory study. *British Journal of Sports Medicine.* 2007;January.

92. Kelly AM. Does the clinically significant difference in visual analog scale pain scores vary with gender, age, or cause of pain? *Acad. Emerg med.* Nov 1998;5(11):1086 - 1090.

93. Bird SB, Dickson EW. Clinically significant changes in pain along the visual analog scale. *Ann Emerg Med.* Dec 2001;38(6):639-643.

94. Katz P, Lee F. Racial/ethnic differences in the use of complementary and alternative medicine in patients with arthritis. *J Clin Rheumatol.* February 2007;13(1):3-11.

95. Bandura A. Health promotion from the perspective of social cognitive therory. *Psycol Health.* 1998;13:623-649.

96. Maly M, Costigan P, Olney S. Determinants of self efficacy for physical tasks in people with knee osteoarthritis. *Arthritis & Rheumatism.* February 2006;55(1):94-101.

97. Enright PL, Sherrill DL. Reference equations for the six-minute walk in health adults. *Am J Respir Crit Care Med.* 1998;158:1384-1387.

98. Childs JD, Sparto PJ, Fitzgerald GK, Bizzini M, Irrgang JJ. Alterations in lower extremity movement and muscle activation patterns in individuals with knee osteoarthrtis. *Clin Biomech.* 2004;19:44-49.

99. Johnson GR. The effectiveness of shock-absorbing insoles during normal walking. *Prosthet Orthot Int.* 1988;12(2):91-95.

100. Teixeira LF, Olney S. Relationship between alignment and kinematic and kinetic measures of the knee of osteoarthritic elderly subjects in level walking. *Clinical Biomechanics.* 1996;11(3):126-134.

101. Mundermann A, Dyrby CO, Andriacchi TP. Secondary gait changes in patients with medial compartment knee osteoarthritis. *Arthritis & Rheumatism.* 2005;52(9):2835-2844.

102. Issa SN, Sharma L. Epidemiology of Osteoarthritis: An Update. *Current Rheumatology Reports.* 2006;8:7 - 15.

103. Vaughan CL, Davis B, O'Connor J. Dynamics of joints. In: Vaughan CL, Davis BL, O'Connor J, eds. *Dynamics of human gait.* Vol 2: Kiboho Publishers; 1999:102 - 106.

104. Durant R, Davis R, St. George D, Williams IC, Blumenthal C, Corbie-Smith G. Participation in Research Studies: Factors Associated with Failing to Meet Minority Recruitment Goals. *Elsevier Inc.* Accessed 6 - 2, 2007.