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Effect of a Lateral Wedge Insole Over a One Week Period in a Healthy Population

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EFFECT OF A LATERAL WEDGE INSOLE OVER A ONE WEEK PERIOD IN A HEALTHY POPULATION

by

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ABSTRACT

EFFECT OF A LATERAL WEDGE INSOLE OVER A ONE WEEK PERIOD IN A HEALTHY POPULATION.

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Medial knee osteoarthritis is a disease that is projected to affect approximately 45% of the U.S. population and is associated with significant morbidity, chronic pain, and limited activity. Laterally wedged insoles are used as an intervention to laterally shift the mechanical axis of the limb and decrease the external knee adduction moment, possibly indicating a shift in load distribution to the lateral compartment of the knee. The aim of this study was to examine the acute effects of a laterally wedged insole in those with valgus and normally aligned knees and to determine prolonged effects after the insole was worn for a one week period in a healthy population. Ten females with normally aligned knees and eight females with valgus aligned knees participated in this study. Participants walked at a normal, comfortable speed with and without the insoles during two testing sessions, before and after a one week period of wearing the insoles. Three dimensional kinetics and kinematics were recorded. Each participant's mean data was analyzed using a two-way repeated measures ANOVA (group (normal, valgus) x condition (pre-wedge, pre-nonwedge, post-wedge, post-nonwedge)). The results demonstrated that the valgus aligned group exhibited a 0.17 Nm/kg reduction in knee abduction moment when compared to the normally aligned group ($p=0.02$). Also, the valgus aligned group had a lower knee abduction angular impulse (-0.10 ± 0.01 Nms/kg) when compared to the normally aligned group (-0.16 ± 0.01 Nms/kg) ($p=0.00$). There was

a significant two-way interaction for vertical GRF at the instance of peak knee abduction moment ($p=0.01$). An independent t-test showed the valgus participants had a higher vertical GRF (12.04 ± 1.42 N/kg) when compared to the normal participants (10.7 ± 1.27 N/kg) during the post-nonwedge condition ($p=0.046$). A paired t-test revealed that the post-nonwedge condition exhibited a 0.40 N/kg decrease from the post-wedge condition in normal participants ($p=0.006$). Normal participants also exhibited a significant difference ($p=0.007$) between the post-nonwedge condition (10.7 ± 1.27 N/kg) and the pre-wedge condition (11.2 ± 0.89 N/kg). For the valgus group, participants exhibited a 0.43 N/kg decrease when the wedge was inserted during the post session ($p=0.046$). There was also a significant difference ($p=0.045$) between the post-nonwedge condition (12.0 ± 1.42 N/kg) and the pre-nonwedge condition (11.4 ± 1.20 N/kg). These results did not show a significant decrease in knee abduction moment; however, the differences seen in vertical GRF coincided with knee flexion angles. The valgus group demonstrated decreased vertical GRF and increased knee flexion with the insole, which could lead to a small decrease in knee abduction moment.

I dedicate this work to my parents Steve and Diane, and my husband Jared.

Thank you for your unending encouragement, support, prayers and love.

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NOMENCLATURE

WOMAC	Western Ontario McMaster Universities Osteoarthritis Index
RoM	Range of Motion
N	Newton
m	meter
kg	kilogram
BW	body weight
Ht	height
DEXA	Dual-energy X-ray absorptiometry
s	second
km	kilometer
h	hour
MRI	magnetic resonance imaging
min	minute
Hz	Hertz
ANOVA	Analysis of variance

Chapter 1: Development of the Problem

Background and Rationale.

Osteoarthritis is a disease that is associated with significant morbidity and is a leading cause of chronic pain and limited activity in the elderly population (Kuroyanagi et al., 2012). Approximately 12-16% of those above the age of 65 years are diagnosed with knee osteoarthritis, and it is estimated that approximately 45% of the U.S. population will develop knee osteoarthritis (Butler, Barrios, Royer, & Davis, 2011). The disease can result in significant economic burdens in both direct healthcare costs and indirect costs (Kuroyanagi et al., 2012), including the amount of disability experienced and the costs that accumulate from being absent at work (Hermans et al., 2012). The knee is the most predominant weight bearing joint, making it more susceptible than other joints to the development of osteoarthritis (Haim et al., 2011). Knee osteoarthritis typically affects the medial tibiofemoral joint compartment more often than the lateral compartment due to increased loading on the medial side of the knee during walking and other weight bearing activities (Hinman, Bowles, Metcalf, Wrigley, & Bennell, 2012). In fact, theoretical explanations demonstrate that mechanical loads passing through the medial compartment are approximately 2.5 times greater than loads transferred through the lateral compartment of the knee (Mundermann, Dyrby, Hurwitz, Sharma, & Andriacchi, 2004). Additionally, many individuals may have a knee malalignment that can increase the risk of medial and lateral knee osteoarthritis, especially a varus deformity that can further increase the stress on the medial side of the knee (Toda & Tsukimura, 2004). Therefore, knee osteoarthritis has become a growing issue for the general population, and further investigation is needed to examine the stress on the medial tibiofemoral compârtment.

A number of techniques have been used to diagnose an individual with medial knee osteoarthritis. Typically a patient will undergo radiological examination which is a static evaluation (Kuroyanagi et al., 2012). Most patients feel pain and discomfort while performing ambulatory activities, yet a static evaluation does not accurately evaluate impairment during such activities. Therefore, a dynamic evaluation is needed to evaluate disease severity and provide appropriate treatments for patients. Gait analysis has been used as a dynamic evaluation and the external knee adduction moment has been identified as a clinical indicator of medial knee osteoarthritis (Kuroyanagi et al., 2012). A static and dynamic evaluation can both be used to diagnose an individual with the disease, but a dynamic evaluation may be more efficacious for providing necessary treatment for the patient (Kuroyanagi et al., 2012).

There are several interventions that aim to manage the symptoms and delay the progression of medial knee osteoarthritis (Hinman et al., 2012). Arthroplasty is reserved for end-stage disease (Hinman et al., 2012), but most conservative interventions are designed to modify ambulatory loads at the knee (Erhart-Hledik, Elspas, Giori, & Andriacchi, 2012). Mundermann et al. (2004) found that the maximum knee adduction moment was linearly correlated with self-selected walking speed, indicating that a slower walking speed will reduce the stress on the medial side of the knee. Another intervention that is used to modify loads at the knee and has been frequently recommended in clinical guidelines for the management of medial knee osteoarthritis is the lateral wedge (Hinman et al., 2012). Laterally wedged insoles are designed to laterally shift the center of pressure under the foot to create a shift in the mechanical axis of the limb. Shifting the center of pressure will cause the knee adduction moment arm to decrease, thus decreasing the external knee adduction moment. Reducing the external knee adduction moment might indicate a shift in load distribution to the lateral compartment (Russell & Hamill, 2011).

The external knee adduction moment commonly used is the product of the ground reaction force and mediolateral distance between the center of pressure and the knee joint center. This method of calculating the joint moments, known as the projection method, is an effective tool for understanding which direction the ground reaction force vector would tend to rotate the joint (Desroches, Chèze, & Dumas, 2010) and researchers have suggested that it provides an indirect indication of dynamic knee joint load in the medial compartment (Hunt & Bennell, 2011; Russell & Hamill, 2011). However, calculating frontal plane knee moments using the projection method requires the assumption that the foot and lower leg are a single rigid body. Furthermore, this method does not include inertial moments, linear acceleration, or segment interactions. As such the projection method of determining the external knee adduction moment is over simplified and may underestimate frontal plane loading of the knee (Hof, 1992; Wells, 1981). An alternative method of calculating the frontal plane knee moment would be through a Newton-Euler, inverse dynamics, approach (Bresler). Calculation of joint moments through an inverse dynamics approach yields internal net joint moments (e.g., external knee adduction moment equals internal knee abduction moment) and is the result of all the internal forces acting about the joint, including moments attributable to muscles, ligaments, joint friction, and structural constraint. While the projection method and inverse dynamics approach would appear to yield joint moment calculations equal in magnitude but opposite in polarity, Wells (1981) showed that when compared to the inverse dynamics method, the projection method resulted in considerable errors in joint moment calculations at the knee and hip during gait. Therefore, it may be more appropriate to assess dynamic knee joint load in the medial compartment through calculation of the internal knee abduction moment using an inverse dynamics approach.

The effects of a lateral wedge in those diagnosed with medial knee osteoarthritis include reductions in knee adduction angular impulse and peak knee adduction moment (Hinman et al., 2012). A normal individual who has not been diagnosed with medial knee osteoarthritis can still experience a higher medial compartment load due to the body's natural alignment and the line of force during gait acting under the foot's center of pressure (Haim et al., 2011). Since a lateral wedge can decrease the forces on the medial compartment of the knee in those diagnosed with osteoarthritis, results have shown that it can also yield similar reductions in a healthy population (Crenshaw, Pollo, & Calton, 2000). Russell & Hamill (2011) found that a lateral wedge acutely reduced peak external knee adduction moment and angular impulse in normal weight and obese individuals without osteoarthritis.

Statement of the Problem

The question still remains whether the lateral wedge will produce the same effects over a prolonged period of time. In order to find many benefits for the use of the lateral wedge, more research needs to be performed to address other factors that could lead to a decreased risk of medial knee osteoarthritis. Therefore, knee alignment should be included to investigate the effects of a lateral wedge insole in a healthy population.

Statement of Purpose

The aim of this study was to 1) examine the acute effects of a laterally wedged insole in those with valgus and normally aligned knees, and 2)determine effects after the insole was worn for a one week period.

Null Hypotheses

The investigation initially will show no significant differences between the two knee alignments concerning kinematic and kinetic data while using the laterally wedged insole. After one week, the prolonged effects of the laterally wedged insole will not change from the acute effects.

Research Hypotheses

The investigation initially will show a significantly decreased peak internal knee abduction moment and decreased angular impulse of the internal knee abduction moment during gait with the use of a laterally wedged insole in those with valgus and normally aligned knees. After one week of acclimation, the changes seen with the lateral wedge will remain the same.

Independent Variables

- Gait condition (pre-without, pre-with, post-without, and post-with laterally wedged insole)
- Knee alignment (4-10°, and >10° tibiofemoral angle)

Dependent Variables

- Kinematic variables:
    - Sagittal plane joint angles:

        - Loading response knee flexion angle
        - Stance phase knee range of motion
    - Frontal plane joint angles:
        - Maximum stance phase knee adduction
        - Stance phase knee range of motion
        - Maximum stance phase ankle eversion
        - Stance phase ankle range of motion
- Kinetic variables:
    - Peak vertical ground reaction force
    - Peak posterior ground reaction force
    - Peak anterior ground reaction force
    - Peak stance phase internal knee abduction moment
    - Stance phase angular impulse of the internal knee abduction moment

Limitations of the Study

- The laterally wedged insole was not individually prescribed, which could have caused a variation in results.
- The participants used her own preferred walking shoes. Some shoes may have offered more support, or were worn more often than others.

Delimitations of the Study

- The participants' age ranged from 18-55 years of age.
- Any participant who had any lower extremity surgery was excluded.
- Any participant who experienced a lower extremity injury within the last six months that has affected her gait was excluded.

- Any participant who experienced any knee pain during gait was excluded.
- The study did not include any individuals who were diagnosed with knee osteoarthritis, or were treated for symptoms of knee osteoarthritis.

Assumptions of the Study

- The high-speed cameras, Model MX-F40 (Vicon Motion Systems Ltd., Oxford, England) and two Bertec Force Plates, Model 4060-NC (Bertec Corporation, Columbus, OH, USA), were accurately calibrated for each participant throughout the experiments.
- The participants performed the researcher's protocols properly, and wore the insole for the instructed time during the one week period.
- Inverse dynamics, link segment model assumptions:
    - A constant segment mass that can be represented by a point mass at the segment center of mass.
    - Segment center of mass locations remain fixed during movement.
    - Adjacent segments are connected by frictionless hinge joints.
    - Segment lengths remain constant during movement.
    - Segment moments of inertia remain constant during movement.

Operational Definition of Terms.

- Moment of force is the tendency of a force to rotate an object about an axis. In this study internal joint moments of force were defined as the net rotational effect of agonist and antagonist muscle forces about a joint.
- Angular impulse represented the effect of a joint moment on a system. It is defined as the moment of force acting over a specified period of time.

- Stance phase of gait was defined as the period of time when the ipsilateral foot was in contact with the ground.
- Loading Response was the period of time from ipsilateral initial contact to contralateral toe off.
- Peak vertical ground reaction force was the highest data value of the vertical ground reaction forces between the initial contact and maximum knee flexion.
- Peak posterior ground reaction force was the highest data value of the posterior ground reaction forces between the initial contact and maximum knee flexion.
- Peak anterior ground reaction force was the highest data value of the anterior ground reaction forces between the initial contact and maximum knee flexion.
- Initial contact was defined as the moment where vertical ground reaction force is higher than 10 Newtons.
- Range of Motion (RoM) was measured from the angle at initial contact until the angle at maximum flexion of a specific joint within the stance phase.

Chapter 2: Review of the Literature

Introduction

Knee osteoarthritis is a degenerative joint disease that is diagnosed in approximately 45% of the U.S. population, and 12-16% of those above the age of 65 years (Butler et al., 2011). The disease is related to the disruption of articular surfaces that may result in pain, stiffness, and significant impairment in functional ability (Butler et al., 2011). Pain and physical disability that is associated with knee osteoarthritis can result in significant economic burdens in both direct healthcare costs and indirect costs (Kuroyanagi et al., 2012). The indirect costs are associated with the amount of disability that is experienced and includes the cost from being absent at work (Hermans et al., 2012). The prevalence of this disease is expected to increase by 40% within the next 25 years due to aging and increased life expectancy (Kuroyanagi et al., 2012). While the precise etiology of the disease is unknown, there are several predisposing factors for the development of knee osteoarthritis. These factors include obesity, physical activity, sex hormones, quadriceps strength, and menisectomy (Cimen, Incel, Yapici, Apaydin, & Erdogan, 2004). Out of these risk factors, obesity can be modified by losing weight, which may decrease the risk of developing the disease and improve functioning in those already diagnosed (Messier, Gutekunst, Davis, & DeVita, 2005).

Obesity can increase the risk of knee osteoarthritis through direct effects associated with a higher knee joint loading (Sharma, Lou, Cahue, & Dunlop, 2000). Obesity may also influence local factors that mediate the mechanical impact of excessive body weight. One local factor that may develop in obese individuals is knee malalignment (Sharma et al., 2000). In a normally aligned knee, load is approximately

2.5 times greater on the medial compartment than the lateral compartment (Browning & Kram, 2007); however, if a varus malalignment develops, this can intensify the effect of the excess body weight on the medial compartment (Sharma et al., 2000). Incidentally, knee osteoarthritis is nine times more likely to develop in the medial compartment (Butler et al., 2011).

Statically, varus alignment can be measured through the mechanical axis alignment or the quadriceps angle. This angle is measured between two imaginary lines on the lower extremity. One imaginary line is drawn from the center of the femoral head to the center of the knee. The second imaginary line is drawn from the center of the knee to the center of the ankle. If the angle is positive, then it indicates varus alignment (Mundermann et al., 2004). Dynamically, varus alignment and medial joint load is measured through external knee adduction moment (Mundermann et al., 2004). During the stance phase of gait the ground reaction force vector is oriented medially to the knee creating an external knee adduction moment and compressing the medial tibiofemoral compartment. This external knee adduction moment is considered to be proportionate to the knee joint load. Unfortunately, knee joint load is difficult to measure, but during a three-dimensional gait analysis, external knee adduction moment provides a valid and reliable indirect indication of dynamic knee joint load in the medial compartment (Hunt & Bennell, 2011).

In order to diagnose a patient with medial knee osteoarthritis, several tests may be performed including a history questionnaire, physical examinations, and laboratory tests, but the most useful procedure is radiographic. Radiographs may be normal early in the disease, but as the disease progresses, radiographs show increased joint space narrowing.

Radiographs also show the presence of osteophytes, which are proliferations of bone and cartilage (Harris, 1993). Typically, radiographs can indicate the severity of the disease with the use of the Kellgren and Lawrence classification system. This system uses a scale of 0-4, in which grade 0 represents normal, grade I represents doubtful narrowing of joint space and possible osteophytic lipping, grade II represents definite osteophytes and possible narrowing of the joint space, grade III represents moderate multiple osteophytes, definite narrowing of the joint space, some sclerosis, and possible deformity of bone contour, and grade IV represents large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour (Brandt, Fife, Braunstein, & Katz, 1991). Another way to determine the severity of the disease is to administer the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The WOMAC is a cross-culturally validated and reliable examination that is used as an outcome measure in many interventional studies involving knee osteoarthritis. The examination consists of 24 items that are divided into categories of pain, stiffness, and function. Each item has five response options of none, mild, moderate, severe, and extreme. These responses correspond to scores of 0-4, with higher scores indicating a higher severity of the disease (Berger, Kean, Goela, & Doherty, 2012).

While there is not a cure for medial knee osteoarthritis, individuals who have developed into the advanced stages of the disease typically undergo surgical treatment. However, the mainstay for managing the condition and symptoms during the early and moderate stages of the disease is conservative treatment (Hinman et al., 2012). Conservative treatment is aimed at minimizing pain, maintaining and improving joint mobility, and decreasing functional impairment (Fang et al., 2006). The initial treatment of knee osteoarthritis is patient education, weight loss, physical therapy, and medication if necessary. Rehabilitative interventions involve altering the biomechanics of the knee, through the use of knee bracing, knee orthoses, or modified footwear (Schmalz, Blumentritt, Drewitz, & Freslier, 2006). A laterally wedged shoe insole is an option frequently recommended in clinical guidelines for the management of medial knee osteoarthritis (Hinman et al., 2012). This intervention is designed to laterally shift the center of pressure under the foot and shift the mechanical axis which results in a decreased moment arm of the external knee adduction moment and shifts the load distribution to the lateral compartment (Russell & Hamill, 2011).

A considerable amount of research has been performed with the use of the laterally wedged insoles for the treatment of medial knee osteoarthritis; however, few studies have examined the use of this intervention from a proactive approach. The purpose of this literature review was to examine the previous research developed on medial knee osteoarthritis, including the research performed on the biomechanics of those diagnosed with the disease, and research performed on the linkage between obesity and the disease. The review also examined the different interventions that have been assessed for the treatment of medial knee osteoarthritis, including bracing, modified footwear, and laterally wedged insoles. Lastly, the review examined the use of the laterally wedged insole in healthy populations to create a foundation for the prevention of medial knee osteoarthritis with the use of this intervention.

Biomechanics of Individuals with Medial Knee Osteoarthritis

The most common form of knee osteoarthritis occurs on the medial side of the knee, but there are cases in which the lateral side of the knee is affected (Butler et al., 2011). One study compared the lower extremity walking mechanics between those with medial and lateral knee osteoarthritis and a healthy population (Butler et al., 2011). There were 15 individuals in each group, and the participants in the osteoarthritis groups were diagnosed with a Kellgren-Lawrence grade of 2 or higher. A gait analysis was performed at an intentional walking speed for five trials while kinematic and kinetic data were recorded in the frontal plane. The group with medial knee osteoarthritis showed a significantly higher peak internal knee abduction moment (-0.420Nm/kgm ± 0.083) in comparison to the group with lateral knee osteoarthritis (-0.193Nm/kgm ± 0.111) and the group of healthy individuals (-0.326Nm/kgm ± 0.078). Also, those with medial knee osteoarthritis showed a significant higher knee adduction excursion (6.9^{o} ± 2.3) and peak rear foot eversion (6.2^{o} ± 5.0). Therefore, those with medial knee osteoarthritis experienced a greater medial knee joint load than those with lateral knee osteoarthritis and those without the disease.

In another study, Foroughi et al (2010) examined the altered dynamic alignment in those with medial knee osteoarthritis and how this alignment was related to knee adduction moment. They included 17 women who had been diagnosed with medial knee osteoarthritis according to the American College of Rheumatology criteria. The participants were matched with healthy, sedentary controls according to body mass index. The participants underwent a gait analysis during which kinematic and kinetic data was recorded as they walked barefoot along a 10 meter walkway at self selected habitual speed and maximal speeds, performing 5 trials for each speed. The results demonstrated that shank adduction angle was significantly greater in the group with osteoarthritis with the largest difference occurring at 30% of stance at habitual (5.12^{o} ± 2.8) and maximal speed ($4.94^{\circ} \pm 2.60$). An increased shank adduction angle typically would indicate a larger moment arm and cause an increased knee adduction moment; however, the knee adduction moment was not higher in the osteoarthritis group. Also, knee adduction moment was not exaggerated at maximal speed for either group.

When examining dynamic alignment in those with medial knee osteoarthritis, one is observing the amount of knee joint load during gait. Instead of having to calculate the knee joint load, one study aimed to develop a model that could aid in the prediction of knee joint load during walking (Hunt & Bennell, 2011). The study included 47 participants with symptomatic medial knee osteoarthritis and varus alignment. A gait analysis was performed while the participant walked barefoot at a self-selected pace. The model was able to explain 67% of variance in actual knee adduction moment with body mass, tibial angle, and walking speed being significant independent predictors. Sequential multiple linear regression revealed that body mass accounted for 41% of the variance in the peak knee adduction moment magnitude, while tibial angle explained 17% of the variance, and walking speed explained 9% of the variance. This showed that an increased body mass is the best predictor for an increased knee joint load, followed by tibial angle, and then walking speed.

While the previous study included participants with varus alignment, it has been suggested that those with medial knee osteoarthritis develop a varus thrust, an abnormal lateral knee motion that occurs in the early part of stance phase. Patients with medial knee osteoarthritis frequently and acutely increase the load across the medial tibiofemoral compartment. One study sought to measure the varus thrust quantitatively and compare this measurement with other dynamic and static evaluations associated with medial knee osteoarthritis (Kuroyanagi et al., 2012). The study involved two groups, one consisting of participants with medial knee osteoarthritis and one control group. The osteoarthritis group included 32 participants. Because some were diagnosed with bilateral osteoarthritis, the group included 44 knees total. The control group consisted of 10 healthy elderly participants without a history of knee pain or injury. Each participant performed 10 meters of level walking at a comfortable pace while gait kinematic and kinetic data were collected on each affected limb. All participants completed a Hospital for Special Surgery test in order to assess pain, knee walking function, range of motion, muscle strength, flexion deformity, and instability. The tibiofemoral angle was measured from a full length, anteroposterior, weight bearing radiograph including the hip and ankle with the lateral angle. The results showed that the amount of varus thrust significantly increased in those with higher Kellgren-Lawrence graded knees. Those with Grade IV knees averaged a varus thrust of $7.2^{\circ} \pm 5.3$, compared with Grade III knees who averaged $2.8^{\circ} \pm 1.4$, and Grade II knees who averaged $2.4^{\circ} \pm 1.3$. Also, the peak knee adduction moment significantly increased in knees with a higher Kellgren-Lawrence grade. The Grade IV knees experienced an average peak knee adduction moment of 6.9 %BW*Ht ± 2.2 in comparison to those with Grade III (3.9 %BW*Ht ± 1.2), and those with Grade II (3.6 %BW*Ht ± 1.5). The knee adduction moment had significant correlations with the amount of thrust (R=0.73) and the tibiofemoral angle (R=0.47). These results indicated that those with a higher severity of knee osteoarthritis experienced a greater amount of varus thrust and a higher peak knee adduction moment. The increased peak knee adduction moment may be influenced by the higher amount of varus thrust or the tibiofemoral angle itself.

Since the previous study (Kuroyanagi et al., 2012) found a higher knee adduction moment in those with medial knee osteoarthritis, Haim et al. (2011) examined the effect of the center of pressure location on the knee adduction moment during gait in women with medial knee osteoarthritis. They included 22 women with symptomatic bilateral medial knee osteoarthritis. All participants underwent a clinical evaluation in which lower limb alignment was measured using a double limb anteroposterior radiograph with the participant standing barefoot and having knees fully extended. The evaluation also included a functional assessment. The participants were instructed to wear a biomechanical device that consisted of two convex shaped elements attached to each foot, one underneath the forefoot and one under the hindfoot. The elements were attached using a platform shoe with two mounting rails on the sole. Each participant wore the biomechanical device in four different conditions including the platform without elements, the platform with elements placed at the neutral axis, the platform with elements placed at the lateral sagittal axis, and the platform with elements placed at the medial sagittal axis. A gait analysis was performed in each condition, with the participant walking at a self-selected velocity that was set with a metronome for each trial. Kinematic and kinetic data were collected over six trials in each randomized condition on the most symptomatic knee. Center of pressure trajectories were measured with a Pedar X Mobile insole pressure-measurement system for each condition throughout the different phases of gait. The results indicated that the center of pressure offset was significantly altered with medial and lateral translation of biomechanical elements from the neutral axis to the control setting. Peak knee adduction moment during the terminal stance phase was significantly decreased with the lateral sagittal axis configuration (0.43 Nm/kg ± 0.14) and increased with the medial sagittal axis configuration (0.54 Nm/kg ± 0.16). This model demonstrated that any intervention that alters the center of pressure toward the lateral side of the foot may result in less force on the medial side of the knee.

After examining the biomechanics of the lower extremities in those diagnosed with medial knee osteoarthritis, there are several factors during gait that must be considered. It is apparent that individuals with medial knee osteoarthritis exhibit increased peak knee adduction moments, peak knee adduction, knee adduction excursion, and peak rear foot eversion (Butler et al., 2011). Additionally, 67% of the variance of knee adduction moment can be explained by body mass, tibial angle, and walking speed (Hunt & Bennell, 2011), and varus thrust is correlated with knee adduction moments (Kuroyanagi et al., 2012). After examining the results from these studies, it is reasonable to suggest that those diagnosed with medial knee osteoarthritis have higher joint loads on the medial side of the knee, and experience several changes associated with gait.

Obesity and Medial Knee Osteoarthritis

Obesity is a risk factor for developing medial knee osteoarthritis, but it is unknown if obesity causes the disease. Weight loss and exercise are recommended by both the American College of Rheumatology and the European League Against Rheumatism for those who are diagnosed with the disease (Messier et al., 2005). After examining some of the biomechanical changes associated with medial knee osteoarthritis, one study found that body mass contributed to 41% of variance in knee adduction moment (Hunt & Bennell, 2011). Since it has been shown that knee adduction moment increases in those diagnosed with medial knee osteoarthritis, it is important to investigate the different effects that obesity may have on the knee as well.

One study examined the correlation of body mass index with radiographic disease severity in those diagnosed with knee osteoarthritis (Sharma et al., 2000). The study included 300 participants with varus and valgus alignment. Each participant underwent an assessment that determined knee alignment (varus or valgus), body mass index, leg dominance, and joint space width. For the knee alignment assessment, the participant stood barefoot facing forward for a radiograph. To measure joint space width, each participant stood in weight-bearing, semiflexed view to determine the narrowest point and then electronic calipers measured the interbone distance. The results showed a correlation between body mass index and medial joint space width ($r=-0.27$) as well as a correlation between body mass index and the narrowest tibiofemoral joint space width ($r=-0.29$) in the varus group. On the other hand, no correlations existed between body mass index and the lateral joint space width ($r=-0.10$) and narrowest joint space width ($r=-0.13$) in the neutral/valgus group.

While body mass index is a popular indicator of body composition, there are other ways to determine body composition. One study analyzed the relationship between obesity-related measurements and tibiofemoral joint space (Cimen et al., 2004). The study included 55 females diagnosed with knee osteoarthritis. The measures of body composition used included the calculation of body mass index, calculation using skinfolds taken with calipers, calculation of waist to hip ratio, and DEXA scan. Each participant also experienced an anteroposterior radiography in which she stood with feet together and knees in full extension. The radiograph was used to measure the tibial compartment on the medial and lateral sides. The results showed that the medial and lateral tibial compartment measures in obese participants were significantly lower than non-obese participants. Body mass index was correlated with DEXA scan information while the medial and lateral tibial compartments were both negatively correlated with body mass index, meaning that a person with a higher body mass had smaller tibial compartments. There was also a correlation between medial tibial compartment and leg lean mass, meaning that those with a smaller medial tibial compartment had less leg lean mass. No correlation values were stated for this study.

Since the previous studies suggest a relationship between obesity and knee joint space within static posture, gait should be examined to determine if obesity can cause a similar change in knee kinematics and kinetics as those diagnosed with medial knee osteoarthritis. Browning & Kram (2007) measured how obesity affects walking biomechanics in knee joint loads by determining ground reaction forces and lower extremity sagittal plane joint moments across a range of walking speeds while on a treadmill. The study included 10 obese individuals and 10 healthy individuals. Obese individuals were included in the study if body mass index was above 30 kg/m^2. Participants walked for two minutes with the right foot on the right treadmill and the left foot on the left treadmill, followed by walking only on the right treadmill for two minutes. The speed started at 0.5 m/s and was gradually increased for each trial until 1.75 m/s was reached. The results showed that absolute vertical ground reaction force was significantly greater for the obese group; however, the ground reaction force was decreased significantly at slower walking speeds in both groups. The time during the stance phase of gait was significantly increased, and the time during the swing phase of gait was significantly decreased at all walking speeds in the obese group. These results show that obese individuals do experience a greater amount of force in the lower extremity during gait, but slower walking speeds may help to decrease this force.

If obesity can cause some changes in gait mechanics, then it could be possible that weight loss could result in a positive change in gait mechanics. One study sought to determine if there is a significant and direct relations hip between weight loss and attenuation of knee joint forces and moments during walking after an eighteen month clinical trial of diet and exercise (Messier et al., 2005). The study included 316 participants with knee osteoarthritis who were sedentary, overweight and/or obese individuals. The participants were split into four groups including the diet only, exercise only, diet and exercise, and healthy lifestyle groups. The instructions for the 18 month trial were not stated for each group; however, there was mention of the use of the Arthritis, Diet, and Activity Promotion Trial from a previous study. The same test was performed before and after the intervention. Each participant was instructed to walk along a 7.3m course six times at his or her own walking speed. Kinematic and kinetic data were collected for each trial. The results showed significant associations between follow-up body mass, follow-up peak compressive, and peak resultant knee force. There was a significant reduction in body mass by an average of 2.6%. Weight loss was associated with a significant decrease in the average peak knee abduction moment, which was initially 33.52Nm ±1.31 and was 32.78Nm ±1.36 for the follow-up. Also, weight reduction resulted in a significant decrease for medial rotation moment from 18.45Nm±0.70 to 17.65Nm ±0.71 at follow-up. In other words, if weight loss does occur, then the amount of force on the knee will be decreased, including peak forces and moments.

By examining the association between obesity and medial knee osteoarthritis, one can determine if weight is a contributing factor to developing or the worsening medial knee osteoarthritis. Participants with a higher body mass index tend to exhibit a smaller tibiofemoral joint space width (Sharma et al., 2000). When examining gait in obese individuals, the absolute ground reaction force is significantly greater, and swing time of the affected leg is increased (Browning & Kram, 2007). If an obese individual decided to participate in a weight loss program and significantly decreased his or her body mass, significant decreases can be seen in peak knee abduction moment and medial rotation moment (Messier et al., 2005). The relationship between obesity and medial knee osteoarthritis is still in question, but these studies suggest that an increased body mass can lead to smaller joint space width and changes in gait that could be even more detrimental to the disease.

Medial Knee Osteoarthritis and Different Interventions

While losing weight is a great way to decrease the amount of knee joint load, other interventions may be useful for those with medial knee osteoarthritis. There are several different ways to alter gait whether it concerns devices that alter hip, knee, and/or ankle angles, or whether it alters the speed of walking (Browning & Kram, 2007). One study sought to determine whether walking speed is related to the maximum knee adduction moment and whether reducing walking speed is beneficial for patients with knee osteoarthritis (Mundermann et al., 2004). The study included 44 participants with medial knee osteoarthritis and 44 healthy participants who were matched according to sex, age, height, and weight. Each participant performed three walking trials at three different walking speeds. The walking speeds included slow, self-selected normal, and fast. The walking trials were performed in the participant's own pair of low-top comfortable shoes. Kellgren-Lawrence grades for both knees were determined with clinical and radiographic data, and each patient was instructed to stand with the tibial tubercle anterior in order to measure mechanical axes of all knee joints. The results showed that the maximal knee adduction moment was linearly correlated with self-selected normal walking speed for patients with knee osteoarthritis when data from patients with all disease severities were combined (R^2=0.089). When the data was stratified on the basis of disease severity, the maximal knee adduction moment was significantly higher in knees with a high Kellgren-Lawrence grade (3.80±0.89% body weight x height) than the controls and the knees with a low Kellgren-Lawrence grade (2.94±0.70% body weight x height). Varus alignment differed between those with more severe osteoarthritis (6.0±4.5°) and those with a less severe case (0.0±2.9°). These results demonstrate that those individuals with a higher severity of knee osteoarthritis experience a greater load on the medial side of the knee. It is more likely to decrease the medial knee joint load by slowing walking speed for those who have a less severe case of osteoarthritis.

A similar study analyzed the impact of gait speed on gait parameters and sought to set a standard walking speed for osteoarthritis patients (Bejek, Paroczai, Illyes, & Kiss, 2006). The study also compared gait patterns in patients with unilateral knee osteoarthritis to healthy control participants. The healthy group and the osteoarthritis group each had twenty participants. Gait performance was assessed for both groups in which ground reaction forces, cadence, step length, stride length, walking base, and joint angles were collected over six gait cycles. Also, gait asymmetry was calculated by the asymmetry value for all gait parameters comparing the osteoarthritic leg with the non-arthritic leg for those in the osteoarthritis group, and the dominant and non-dominant leg in the healthy group. The results showed that cadence, step length, walking base, and motion of the knee joint were significantly influenced by increasing the gait speed from 1-2 km/h, from 2-3 km/h, and 3-4 km/h in the healthy group. The same parameters were significantly influenced by increasing the gait speed in the osteoarthritis group with the addition of time of swing phase and double support phase. When the two groups were compared, significant differences were observed in cadence, step length, walking base, time of double support phase, and motion of the knee joint at equivalent gait speeds. Also, the asymmetrical value in patients with osteoarthritis was higher than the healthy group. The findings of the study indicate that biomechanical parameters depend on gait speed, and changes in gait parameters occur in patients with unilateral knee osteoarthritis compared to the gait patterns of healthy participants. When considering different interventions, one must consider the different shoe types and the amount of stiffness.

One study compared the effects of variable stiffness and constant stiffness footwear during a twelve month period (Erhart-Hledik et al., 2012). The study included 60 individuals with symptomatic medial compartment knee osteoarthritis who were between the ages of 40 and 80 years. Each participant underwent an MRI to evaluate cartilage thinning and osteophytes. Standing weight-bearing radiographs with fully extended knees were performed every six months. WOMAC tests were administered every month to determine physical function and pain. The participants were instructed to wear either variable stiffness shoes or constant stiffness shoes for at least four hours per day. The variable stiffness shoe was considered to be 1.3-1.5 times stiffer on the lateral side than the medial side. After 12 months, all participants came in for a final gait analysis. The participants performed three walking trials at self selected normal speed wearing three different shoes including variable stiffness shoes, constant stiffness shoes, and his or her personal walking shoes. The results showed that knees with a more severe case of osteoarthritis had greater varus alignment (7.7 ± 4.6^{o}). Post hoc tests revealed the total WOMAC score to be significantly reduced from baseline to 12 months by 34.9% for the variable stiffness group. WOMAC pain subscales were significantly reduced from baseline to twelve months by 31.5% for the variable stiffness group and 26.6 % for the constant stiffness group. There was a significant reduction in peak knee adduction moment with the variable stiffness shoes compared to personal shoes at 12 months. Both the variable stiffness and constant stiffness shoes can result in a better pain levels for those diagnosed with medial knee osteoarthritis, but the variable stiffness shoe showed better results for an increased overall quality of life.

While shoes are an important factor to consider when comparing different interventions, knee braces are also an option. Schmalz et al. (2010) investigated the biomechanical basis for valgus-inducing knee braces that were individually prescribed and fitted. Sixteen medial knee osteoarthritis patients participated in the study, and were grouped according to an osteoarthritis classification system developed by Kellgren-Lawrence grade. The patients had already been wearing the brace daily for a minimum of four weeks prior to the study. A subjective assessment was performed with each patient which included questions regarding the fit of the brace, wearing comfort of the components, appearance, and ease of use on a scale ranging from zero to six. Walking pain was measured with a visual analog scale ranging from zero to ten. Also, patients performed a gait analysis under two conditions, without the brace and with the brace. Kinematic and kinetic data were collected in 8- 10 trials for each gait condition. For the subjective assessment, the mean±SD pain-with-walking VAS score of 6.4±1.7 without the brace was significantly reduced to 3.3±1.9 when patients wore the brace. The wearing comfort at the thigh ranged between 4.3 and 4.9, which indicated a good comfort level for the brace. For the gait analysis, the mean walking speed significantly increased from 1.27 m/s without the brace to 1.36 m/s when the brace was worn. Cadence significantly increased from 107 steps/min without the brace to 110 steps/min with the brace. When the patients were not wearing the brace, the first vertical ground reaction force maximum was significantly decreased as opposed to wearing the brace (104% vs 109% body weight). The valgus inducing knee brace compensated for approximately 10% of the external knee adduction moment. This study suggests that the 10% reduction of external knee adduction moment is the main biomechanical mechanism of the knee brace that results in a reduction of joint force within the medial joint compartment and can lead to reduced pain and improved overall function.

The knee brace and laterally wedged insoles are two mechanical interventions that act on the underlying disease mechanisms in osteoarthritis patients to decrease or redistribute the mechanical load on the knee (Fantini Pagani, Hinrichs, & Brüggemann, 2012). One study compared the functional differences between the use of laterally wedged insoles and valgus bracing in patients with medial knee osteoarthritis (Van Raaij, 2010). The study investigated the use of these two interventions to determine if a reduction of pain and an improvement in WOMAC function scores occurred, and also to determine if these two treatments correct knee malalignment in the frontal plane. Ninety-one patients with symptomatic medial knee osteoarthritis were included in the study. The patients were randomly assigned to either a lateral wedge or a brace and were instructed to wear the intervention as much as tolerated for six months. The lateral wedge was fitted and inserted along the entire length of the foot with a 10 mm elevation. The knee brace was available in four sizes and consisted of a thigh shell and calf shell connected by aluminum hinges on medial and lateral sides. The patients recorded pain severity from a visual analog scale and WOMAC function score before and six months after the intervention was applied. Also, the hip-knee-ankle angle was recorded by a standing whole leg radiograph with and without the intervention before and after six months. The angle was calculated between two prolonged lines: one line of the center of the femur head to the top of the femoral notch and a second line from the center of the ankle to the center of the tibial spines. The results showed that pain severity, WOMAC function scores, and varus alignment improved similarly in both groups with a significant difference between baseline and six month scores. Patients with mild osteoarthritis showed more response from the lateral wedge than the knee brace. Also, after six months there was a higher compliance rate for the insole group (71%) compared to the brace group (45%). The recorded hours per week that the intervention was worn showed that the lateral wedge (57.8 hours) was worn more often than the brace (38.8 hours). Skin irritation was the main complaint for the knee brace. These results suggest that the lateral wedge may be a better alternative as opposed to the knee brace for the noninvasive treatment of medial knee osteoarthritis.

A similar study sought to compare the effects of two different knee orthoses and laterally wedged insoles on knee adduction moment in patients with medial knee osteoarthritis (Fantini Pagani et al., 2012). The study included ten patients who performed a gait analysis at a self-selected speed. Gait was assessed in four different conditions including without the orthosis, with an orthosis with a 4° valgus adjustment, with an orthosis with an 8° valgus adjustment, and with the laterally wedged insoles with a 4° incline. Each patient performed five trials in each condition, and the average kinematic and kinetic data were reported. A significant main effect was found for the second peak knee adduction moment among testing conditions. A post hoc analysis showed significant differences between a majority of conditions (without: 0.38 Nm/kg±0.16, 4° valgus brace: 0.31 Nm/kg±0.16, 8° valgus brace: 0.30 Nm/kg±0.16, insoles: 0.35 Nm/kg±0.16). Also, the knee adduction angular impulse differed among conditions (without: 23.62±10.58, 4° valgus brace: 20.27±11.06, 8° valgus brace: 19.45±10.12, insoles: 21.99±10.51; units in Nm/kg % stance phase). The brace with the 8° valgus adjustment had a significantly higher orthosis moment than the brace with a 4° adjustment during the first and second peak (32% and 30% higher). Overall, this study suggested that knee braces and laterally wedged insoles are effective for reducing the knee adduction moment, which could lead to a decreased knee joint load.

When considering the different treatments and interventions for osteoarthritis, it seems that walking speed, the type of shoe worn, the lateral wedge, and the knee brace may contribute toward a better quality of life. Bejek et al. (2006) demonstrated that a slower walking speed can result in biomechanical changes during gait in those with osteoarthritis, and those without. Mundermann et al. (2004) found that knee adduction moment can be reduced with a slower, but self-selected walking speed in those with medial knee osteoarthritis. This result was also seen when diagnosed individuals wore a variable stiffness shoe, which also led to decreased pain and improved function (Erhart-Hledik et al., 2012). Schmalz et al. (2010) found that an individually prescribed valgus-inducing brace reduced the external knee adduction moment, and this also resulted in decreased pain and improved overall function. When the lateral wedge and knee brace were compared, similar results were found for reducing the external knee adduction moment, which could possibly lead to decreased medial joint load (Fantini Pagani et al., 2012). Van Raaj et al. (2010) found similar results when comparing the lateral wedge and knee brace, but also found that these two interventions could lead to an improvement in varus alignment. All of these studies suggest that there are several options that can help to improve the quality of life in those with medial knee osteoarthritis.

Medial Knee Osteoarthritis and the Lateral Wedge

After examining the different forms of treatment for medial knee osteoarthritis, there appears to be a significant response from the lateral wedge. Since this intervention is an easy, comfortable, and economical way to improve the quality of life in those with medial knee osteoarthritis, it is important to investigate the different effects of the lateral wedge. One study evaluated the immediate effects of lateral wedge insoles on lower limb frontal plane biomechanics (Hinman et al., 2012). The study included 73 participants who had an average body mass index of 27 kg/m^2. They were diagnosed with medial knee osteoarthritis and reported knee pain for most days of the month preceding the study. The participants also reported knee pain above three on the eleven-point Likert scale during walking. A 5° lateral wedge was worn bilaterally inside the participant's own shoes along the full length of the lateral side. Kinematic and kinetic data were recorded for five successive trials while the participants walked at a comfortable pace along a 10 meter walkway with and without the intervention. The participants were unaware of the position of the force plates in order to keep their gait as normal as possible. The researchers ensured that the speed of gait did not vary more than 10% across trials. The results showed a significant reduction in the peak knee adduction moment (-0.22 Nm/BW*HT%) and the knee adduction angular impulse (-0.08 Nm/BW*HT%) with the lateral wedges. There was also a significant lateral shift in the center of pressure (-3.4 mm), significant increase in toe-out angle (-1.72°), and a slightly wider base of support (4.5 mm) seen with the lateral wedge. Other results included a decreased varus knee angle (-0.48°), shorter knee ground reaction force lever arm (-2.94 mm), and a more vertical femur in the frontal plane (-0.43°) with the use of the lateral wedge. A stepwise regression analysis was used to discover the central mechanism that explains the load reducing effect of the lateral wedge, and the only significant change that predicted the peak knee adduction moment was the knee ground reaction force lever arm.

A similar study also examined the frontal plane biomechanics with specific emphasis on lower limb joint moments with frontal plane pelvic alignment (Abdallah & Radwan, 2011). The study compared the effects of unilateral and bilateral application of lateral wedge insoles with medial arch supports. The study also investigated the inter-relationships among the joint moments with the use of the insoles. Twenty-one females who were diagnosed with medial knee osteoarthritis were included in the study. The average body mass index of the participants was 33 kg/m^2. The participants were randomly assigned to each wedged condition. Altogether, there were five different wedged conditions consisting of nonwedged bilateral inserts, a 6° wedged insert for the tested limb, 6° wedged bilateral inserts, an 11° wedged insert for the tested limb, and 11° wedged bilateral inserts. All lateral shoe inserts had medial arch supports. The participants were allowed to acclimate to each wedged condition by walking along a 10 meter walkway for a few minutes. Kinematic and kinetic data were collected during stance and mid-stance phase of three successful gait trials in all wedged conditions. The results showed a non-significant difference between the five wedged conditions and knee adduction moment; however, there was a significant increase in subtalar eversion moment with the increased degree of the wedge. A significant positive relationship existed between external hip and knee adduction moments during midstance phase of gait. Also, there was a significant negative relationship between the subtalar eversion moments and the external hip and knee adduction moments. This indicates that a lateral shift of the center of pressure may still reduce forces at the hip and knee, even though the wedges in this study did not provide significant results in reducing the knee adduction moment.

While biomechanics during gait are extremely important when testing an intervention, improvements in pain and function must also be examined. One study tested the effect and efficacy of a 5° lateral wedge for pain in those with medial knee osteoarthritis (Baker et al., 2007). The study included 90 participants who experienced moderate pain for two of five items on the WOMAC pain subscale and were 50 years or above in age. The average body mass index for the participants was 33 kg/m^2. Also, the participants showed only medial tibiofemoral narrowing on a posteroanterior semiflexed radiograph. The participants were randomly assigned to either a 5° lateral wedge insole or a neutral insole, which was flat and 1/8 inches thick. Randomization was stratified by two factors. One factor was whether the participant had a Kellgren-Lawrence grade of four or whether he/she had a grade lower than four. The other factor was whether the participant had unilateral or bilateral knee osteoarthritis. After the participants were randomized, they were instructed to wear the intervention for six weeks. Then, the participants underwent a washout period of four weeks without any form of intervention. At the end of the four weeks, the participants switched the interventions and wore their new form of treatment for six weeks. WOMAC scores were recorded at baseline, after three weeks, and after six weeks for each intervention. The treatment period effect was not significant with a six point difference between WOMAC scores of the lateral and neutral wedge. Secondary outcomes, which included two physical performance tests, were similar and not significant. Even though minor results were seen with the wedged insoles, it was not enough to prove that wedged insoles were efficacious for improved pain and physical function.

While the lateral wedge may produce some beneficial results for those with medial knee osteoarthritis, it is possible that the type of shoe that is being worn may influence these results. One study investigated the short-term effects of a full length lateral wedged insole combined with shock absorbing shoes (Fang et al., 2006). The study included 28 community dwelling individuals with medial knee osteoarthritis. The participants were given comfortable, light-weight, shock-absorbing shoes, along with a 4^{o}, full length lateral wedged insole. Some of the participants were given the lateral wedges bilaterally if both knees had medial osteoarthritis. Participants were instructed to wear the shoes and insoles for as many hours per day, and as many days per week as tolerated for four weeks. Also, the participants were instructed to continue taking their usual medications associated with osteoarthritis pain as needed. The WOMAC scale was given at baseline and after the four week intervention. The test consisted of a visual analog scale that indicated joint pain, stiffness, and physical function limitations. After the intervention, WOMAC subscales and total scores improved significantly from baseline. Approximately 50% of the individuals exhibited an improvement of 20% or more in WOMAC subscales. More than 10% of the individuals reported an improvement of 70% in WOMAC subscales. The question that indicated the most challenging activity showed that most individuals had a hard time with walking up and down stairs, and the scale for this question significantly improved from baseline (55.1±24.8) to post-intervention (41.4±25.4). Approximately 64% of the participants showed an improvement of 20%, while 7% reported a 70% improvement in the scale for this particular question. This study demonstrated that short term use of the wedged insoles and shock absorbing shoes may decrease pain, stiffness, and functional impairment in those with symptomatic medial knee osteoarthritis; although, it was difficult to determine whether the insole or the shoe led to these results.

A similar study sought to assess the effect of a six mm lateral wedged insole on both pain and function in patients with clinically and radiologically documented knee osteoarthritis (Koca, 2009). The study included 37 women who had knee osteoarthritis according to the American College of Rheumatology criteria and were classified as Kellgren-Lawrence grade II and III. The average body mass index for these participants was approximately 30 kg/m^2. Participants were sequentially randomized into two therapy groups including a group without an insole and a group wearing a six mm wedged insole with the posterior part of the calcaneus being tilted laterally at 5° to the floor. The group who experienced no insole were treated with parecetamol (1500 mg/day) and were instructed to perform quadriceps strengthening exercises for three months. The group with the insoles was instructed to use the insole all day long while performing the therapy prescribed for the other group for three months. Several factors were tested at baseline, after the first month of the intervention, and after three months of the intervention. Two of these factors included pain while walking and standing at rest during the previous twenty-four hours, which was recorded on a 100 mm visual analog scale. Other factors included pain and tenderness produced while under firm digital pressure and with the movement of the affected knee. This was scored according to the Doyle's Ritchie Index on a four point scale. The WOMAC scale was also administered. The results showed that the Ritchie index scores of both groups did not improve significantly after the first month of treatment but did show some significant improvements at the third month of treatment compared to baseline. The patients in the insole group showed significant improvements in pain and tenderness at the third month. The group with the insoles showed significant improvements in pain while at rest and standing at the third month. Also, the WOMAC pain and function subscales and total score were significantly improved after the first month and third month in the insole group only, excluding the stiffness scores. These results demonstrated that a lateral wedge insole significantly reduced pain while walking, standing, at rest, and with passive movement in patients with grade II and III knee osteoarthritis. More positive results were seen after three months instead of one month with the intervention.

Another study aimed to examine similar effects from the previous studies with the use of a laterally wedged insole (Hinman, Payne, Metcalf, Wrigley, & Bennell, 2008). The effects included walking pain, knee adduction moment, and static alignment; however, the study also aimed to evaluate age, baseline pain and function, disease severity, and immediate changes in pain and biomechanical parameters. The study included 40 community volunteers with medial knee osteoarthritis who were above the age of 50 years, reported knee pain on most days, had an average knee pain above three on an eleven-point Likert scale, and experienced knee pain while walking two blocks and/or climbing stairs. The average body mass index for the participants was approximately 30 kg/m^2. A biomechanical analysis was randomly conducted with and without the insole. The laterally wedged insole was given bilaterally, standardized, and approximately 5° in incline. The biomechanical analysis included a static alignment with a full leg anteroposterior weight-bearing radiograph being taken while each participant was barefoot and standing on a pair of wedged insoles. The participants used foot maps to control foot positioning across conditioning with the knees in full extension. These were taken with and without the lateral wedges. The biomechanical analysis also included a gait analysis in which each participant walked at a comfortable pace. After each participant underwent the baseline analysis, he or she was provided with insoles and were instructed to wear them inside his/her current footwear for three months in a progressive manner. Participants began wearing the insoles only for one hour, and progressively increased by one hour per day until the three months were completed. Another biomechanical analysis was given after the three month intervention period. Also, pain and function were measured using the WOMAC scale at baseline and post-intervention. The laterally wedged insoles resulted in an immediate reduction in all knee adduction moment parameters including a decrease in walking pain. Most participants demonstrated a reduction in first peak knee adduction moment, with five individuals experiencing an increase. After three months, WOMAC pain scores showed a 22% reduction, while WOMAC function showed a 20% reduction. The predictors of the outcome after the three month intervention showed that age correlated with WOMAC pain change, with older participants experiencing less improvement. Participants who experienced a greater reduction with the wedges reported less physical impairment. The inclusion of age, disease severity, and baseline WOMAC scores accounted for 24% of variance in pain score at three months with disease severity and change in walking pain as the only predictors. Also, there was 21% variance for WOMAC function with baseline WOMAC, change in walking pain, and change in first peak knee adduction moment as the only predictors. The results suggest that the laterally wedged insole can immediately reduce the knee adduction moment and walking pain in those with medial knee osteoarthritis. It is possible that disease severity, baseline function scores, and the magnitude of immediate change in walking pain could predict the outcome of wearing the insoles for a longer period.

While the previous studies used a lateral wedge with the same amount of incline for all participants, Barrios et al. (2009) assessed the clinical effects of individually prescribed, laterally wedged, contoured orthoses and walking shoes in participants with medial knee osteoarthritis. The study compared the initial, one month, and one year trial results for WOMAC subscale scores and performance scores from a six minute walk test and stair negotiation test. The study included 66 participants who were diagnosed with medial knee osteoarthritis, experienced knee pain, and were between the ages of 40 and 75 years. Each participant was block-randomized into groups based on osteoarthritis grade, gender, and age. For the initial trial, all participants performed the tests in their own shoes. Then the participants were fitted for the intervention and the more symptomatic knee was used. The wedges were prescribed using a lateral step down test from an eight inch step. Each participant stood on his or her affected limb while wearing a neutral orthosis. The participant was asked to grade the pain experienced during the test on a scale of one to ten. Then the same test was repeated with different wedges ranging from 5-15°. Whichever wedge resulted in the most pain relief during the step down test was the one prescribed to that participant for the intervention. After the wedges were prescribed, participants were instructed to gradually increase the wear time of the orthoses and shoes over a three to four day period. After two weeks, the participants reported any discomfort, and the intervention was adjusted. Once the participants could wear the shoe and wedge all day, they were encouraged to wear them as much as possible. For the one month and one year trials, the walk test and stair test were performed in the prescribed orthoses and walking shoes. For other testing, the WOMAC was used to measure pain, stiffness, and physical function. For the six minute walk test, participants were asked to rate knee pain before and after the test using a 100 mm visual analog scale, and pain change was measured. There was a five minute rest period, and then the participants started the timed stair negotiation test. For this test, the participants were asked to rate initial pain and the maximal amount of pain experienced while the participant ascended and descended 10 steps that were 7 inches in height. The time was recorded and the pain change was measured. Significant improvements were found for pain, stiffness, and physical function subscales of the WOMAC test from the initial to the one month trial, and from the initial to the one year trial; however, from the one month to the one year trial, only stiffness was significantly improved for those with the lateral wedge. Significant interactions in walking pain change and distance walked were demonstrated by both groups. For the stair negotiation test, there were significant improvements for pain change and time at the one month and one year trials compared to baseline in both groups. An individually prescribed wedge seemed to have improved pain, stiffness, and physical function in those with medial knee osteoarthritis.

A similar study evaluated the effect of an individually prescribed wedged orthotic device on frontal plane knee mechanics during walking (Butler, Marchesi, Royer, & Davis, 2007). The study included 20 patients diagnosed with medial knee osteoarthritis who experienced knee pain while walking. First the participants performed a lateral step down test to determine the amount of wedging that was needed. The test was performed on an eight inch step, and participants rated knee pain during the test. The amount of wedging was randomly altered by increasing by either 3° or 5° with a maximal amount of wedging being 15°. The participant was prescribed to the amount of wedging that caused maximal pain relief during the test. The lateral wedges were fit into walking shoes that were given to each participant. Participants were given a two week accommodation period, in which they followed a prescribed wearing program over the course of one week. After two weeks, a gait analysis was performed with each participant walking within 5% of his/her intentional walking speed for randomized wedged and nonwedged conditions. The results showed that wedged orthotics significantly reduced knee adduction excursion from $6.3^{\circ}\pm2.3$ to $5.6^{\circ}\pm2.3$. Wedged orthotics also resulted in a significant decrease in the first peak knee adduction moment from 0.379 Nm/kg*m ± 0.128 to 0.346 Nm/kg*m ± 0.122. The average degree of wedging used to produce maximal pain relief during the lateral step down test was 9.6°, while there was a positive correlation between the amount of wedging and the Kellgren-Lawrence grade of participants. The results indicated that an individually prescribed lateral wedge can reduce the amount of force at the knee in patients with medial knee osteoarthritis, and the amount of wedging needed increased with disease severity.

While the two previous studies investigated the use of individually prescribed lateral wedges, another study assessed the use of a laterally wedged insole with subtalar strapping of varying elevations (Toda, Tsukimura, & Kato, 2004). The study included 62 females diagnosed with medial knee osteoarthritis according to the American College of Rheumatology criteria. Participants were randomized into groups with different amounts of wedging, including 8, 12, and 16 mm. The participants were instructed to wear the lateral wedge without shoes for three to six hours per day for a period of two weeks. Also, all participants received a nonsteroidal anti-inflammatory drug orally twice per day. The level of pain was assessed according to the Luquesne Index of Disease Severity by a blinded research nurse. Each participant underwent a standing radiograph that was evaluated in the anteroposterior view using the Kellgren-Lawrence grade with and without the insole. Measurements were taken at baseline and post-intervention. Results showed that the use of the insoles with 16 mm incline produced significantly greater valgus correction of the tibiofemoral angle compared to the 8 mm wedge; however, the 16 mm wedge was associated with some degrees of discomfort. Remission scores significantly improved more with the 12 mm wedge than the 16 and 8 mm wedges, even though the valgus correction was smaller than that experienced with the 16 mm wedge. When considering routine use, these results suggest that the 12 or 8 mm wedge may be a better choice for comfort and effectiveness than the 16 mm wedge.

A similar study examined the use of a lateral wedge insole with elastic strapping of the subtalar joint, only the intervention period lasted over a longer duration (Toda & Tsukimura, 2004). The aim of the study was to assess the effect of this intervention on the femorotibial angle in patients with varus deformity of the knee. The study included 66 female outpatients with knee osteoarthritis in the medial compartment and a standing femorotibial angle more than 176° by radiography. Participants were randomly assigned to either a strapped insole or a traditional shoe inserted insole. The strapped insole was a urethane wedge with a 12 mm elevation that was fixed to an ankle-sprain support. The traditional shoe insert was a lateral sponge-rubber heel wedge with a 6.35 mm elevation. Participants were instructed to use the insole whenever wearing shoes for three to six hours per day for six months. Standing radiographs of the knee joints were taken at each assessment while the participant stood on one leg while in full extension with and without the insole. The Luquesne index score and Visual Analog Scale for participantive knee pain were assessed at baseline, and after the third and sixth month of the intervention. The Luquesne index was used to assess pain during nocturnal bed rest with full extension of the knee, duration of morning stiffness or pain getting up, pain with standing for 30 minutes, pain while walking, pain when getting up from a sitting position without the help of arms, maximum distance walked, ability to ascend and descend stairs, ability to squat, and the ability to walk on uneven ground. At the three month and six month assessment, the femorotibial angle was significantly decreased in the strapped insole group when compared to baseline. The strapped insole group also showed significantly lower participantive knee pain scores compared to baseline for the three month and six month assessment. These results demonstrated that an insole with a subtalar strap can maintain valgus correction of the tibiofemoral angle in those diagnosed with medial knee osteoarthritis for a period as long as six months.

While some of the previous studies have shown significant reductions in the knee-joint varus moments (Hinman et al., 2012), others have not (Abdallah & Radwan, 2011), indicating variation in the results of joint moments when the lateral wedge is used. One study aimed to determine whether the inconsistency of reducing the knee-joint varus moment with a lateral wedge in patients with medial knee osteoarthritis persists, and if so, identify the underlying mechanisms that can explain it (Kakihana, Akai, Nakazawa, Naito, & Torii, 2007). In order to provide more consistency in reducing the knee joint varus moment, the study investigated hip and subtalar joint angles as well. The study included 51 osteoarthritis patients with a varus deformity of the knee and 19 healthy controls that were matched according to age, height, and weight. The control group wore a 0° wedge that was placed under the entire foot and had an even thickness of five mm medially to laterally. The intervention group wore a 6° lateral wedge that was attached to the participant's bare feet with adhesive tape. Anteroposterior radiographs of both lower extremities were taken with participants standing barefoot and with knees in full extension. Hip-knee-ankle angles in the symptomatic leg of the osteoarthritis participants were used for static alignment, while the right leg was used for the control group. The Kellgren-Lawrence grade was used to assess severity of osteoarthritis. Participants were instructed to walk at a self-selected cadence and a three-dimensional gait analysis was performed along a seven meter walkway with a force platform located at midpoint. Averages were taken from five trials in each wedged condition. The results showed a negative correlation between knee joint varus moment and subtalar joint valgus moment in all controls and the majority of the osteoarthritis group. The subtalar joint valgus angle was significantly greater for the lateral wedge compared with the control wedge in both knee osteoarthritis patients and healthy controls. The osteoarthritis group showed a smaller decrease in knee joint varus moment, and a smaller decrease in subtalar joint valgus moment than the healthy group. The mediolateral ground reaction forces for the lateral wedge were significantly greater compared with those for the control wedge. There was a positive correlation between hip-knee-ankle angles and knee joint varus moment with the control wedge in both healthy controls and osteoarthritis patients, but the correlation was stronger in the healthy controls. These results demonstrate that the lateral wedge may decrease knee joint varus moment; although the healthy group found a greater decrease. This finding correlated with a less lateral shift in the center of pressure location during the stance phase.

The use of a lateral wedge for patients diagnosed with medial knee osteoarthritis seems to have several benefits. The benefits seem to be greater when the person has a less severe form of the disease, has a smaller initial WOMAC pain and function score, and has a larger magnitude of initial change (Hinman et al., 2008). A lateral wedge can lead to reductions in knee adduction angular impulse and peak knee adduction moment, which is explained by the change in the knee ground reaction force lever arm (Hinman et al., 2012). When examining the three joints of the lower extremity, an increased degree of the lateral wedge leads to an increased subtalar eversion moment, resulting in decreased external hip and knee adduction moment (Abdallah & Radwan, 2011). A reduced knee adduction moment represents a decreased medial knee joint force, which can lead to an improvement in pain and function depending on the amount of time that the lateral wedge is worn. It is recommended that the intervention be worn for at least one month to experience benefits (Koca, 2009). When the lateral wedge has a higher incline, there is a greater reduction in the medial knee joint force, but higher degrees of incline can be associated with discomfort (Toda et al., 2004). When the wedges are individually prescribed, participants tend to experience maximal pain relief (Butler et al., 2007). The use of subtalar strapping along with the lateral wedge showed a lower tibiofemoral angle and knee pain scores (Toda & Tsukimura, 2004). The same results that are seen with diagnosed individuals can be seen in healthy individuals when wearing the lateral wedge (Kakihana et al., 2007).

Effect of Wedges on the Prevention of Knee Osteoarthritis

While the previous studies examined the use of the lateral wedge on those already diagnosed with medial knee osteoarthritis, the next few studies focus on the prevention of the disease with the use of the lateral wedge. One study examined the effect of medially and laterally placed wedges on frontal plane knee loading during standing and walking (Schmalz et al., 2006). Also, the study sought to identify the interactions between compensatory movements at the ankle-foot complex and knee loading. The study included ten adults with a mean age of 34 years, a height of 178 inches, and body mass index of 73 kg/m^2. Participants underwent a joint loading examination and gait analysis in each randomized testing condition. The joint loading examination was performed using the Lasar Posture system in which the participant stood on the force plate in a standardized posture with both feet in an identical horizontal position with a similar distance between the medial edges of the feet. The Lasar Posture system allows the determination of the lever arm between the joint axes and the vertical component of the ground reaction force. This allows one to measure the ankle joint load. For the gait analysis, each participant walked ten times at a self-selected comfortable pace on level ground. The testing conditions included shoes with 10 mm medial wedges and ankle-foot orthoses, shoes with 10 mm medial wedge and support (rigid orthoses), shoes with 10 mm medial wedges, shoes only, shoes with 10 mm lateral wedges, shoes with 10 mm lateral wedges and support, and shoes with 10 mm lateral wedges and ankle-foot orthoses. During the second maximal vertical loading peak in stance phase, use of the medial and lateral wedges with the ankle-foot orthoses resulted in a significant decrease. Also, there was a significant reduction in acceleration when using the rigid ankle-foot orthoses with either medial (19 %BW ± 3) or lateral wedges (21 %BW ± 2). Knee extension moment during late stance phase was only significantly reduced with the lateral wedges and ankle-foot orthoses (0.47 Nm/kg ± 0.18). The joint loading examination revealed that ankle joint loading changed significantly in all testing conditions. When the rigid orthoses were added, the maximum values for the varus moment were significantly increased by 24% in the medial wedge and reduced by 30% in the lateral wedge. For treating osteoarthritis at an early stage, this study demonstrates that shoe wedges with the application of an ankle-foot-orthosis can decrease the medial knee joint load.

Another study aimed to determine if the changes in foot pressure patterns associated with a lateral wedge can predict changes in the knee adduction moment and ankle eversion moment (Erhart, Mundermann, Mundermann, & Andriacchi, 2008). The study included 15 physically active adults without pain or previous injury in the lower extremities. Each participant performed a gait analysis with a Footscan pressure mat located on the walkway. For each randomized condition, participants performed three walking trials for a slow, normal, and fast speed. The conditions included a 0°, 4°, and 8° laterally wedged shoe with uniform stiffness. The 4° and 8° shoes caused a significant increase in the maximum medial-to-lateral heel pressure ratio by 16.8% and 26.3%. These two conditions also caused a significant decrease in the first peak knee adduction moment by 8.2% and 13.2%, and a significant increase in ankle eversion moment by 69.6% and 130.6%. These results indicate that lateral changes in the foot pressure pattern can lead to a decreased medial knee joint load.

Another study aimed to quantify medial compartment loads during gait while using a lateral-wedged insole in a group of healthy individuals (Crenshaw et al., 2000). The study included 17 healthy participants without a history of lower limb surgery or disease. Participants were tested in the gait lab randomly for two conditions on the same day. One condition was without a wedged insole, and the other condition was with a custom fabricated insole that was laterally inclined by 5° along the full length of the insole from hindfoot to forefoot. Before testing began, participants were allowed an acclimation period of several minutes to walk up and down an eight meter walkway at a self selected pace. After the participant was comfortable, a trial was collected and cadence was calculated. The cadence was set on a metronome for the participant to walk for all testing trials. Five trials were collected for each condition and averaged; medial compartment loads were then calculated using an analytical model. This model included the contribution of the ground reaction force, mass moment of inertia of the shank and foot segments, and the kinematics and kinetics at the knee, while ligament forces, joint contact points, intercondylar distances, muscle moment arms, and orientations of muscle action were assumed to be constant. The results showed that the external varus moment about the knee was significantly reduced while using the lateral wedge during the stance phase of gait, especially at the two peaks that occur during maximum loading of the knee. The calculated medial knee compartment load was also significantly reduced with the lateral wedge; therefore, these results support the use of a lateral wedge to decrease the amount of force on the medial side of the knee.

The last study analyzed the influence of a laterally wedged insole on lower extremity kinetics and kinematics in obese and healthy weight women (Russell & Hamill, 2011). The participants included 14 participants in the obese group and 14 participants in the healthy weight group. Body mass index was used to indicate which group the participant belonged, with 30 kg/m^2 or over for the obese group and 20-25 kg/m^2 for the healthy weight group. All participants underwent a static knee joint alignment and gait analysis. For the gait analysis, each participant walked across the platform at 1.24 m/s and at a preferred speed for each condition. The first condition was with the insole, which contained an 8° lateral wedge, and the second condition was without the insole. The participants performed both conditions ten times at each speed and the average measurements were calculated. The results showed that there was a significantly reduced peak external knee adduction moment in the control and obese group while walking with the wedge. At the preferred speed, the control group reduced the peak external knee adduction moment by 1.8 Nm ± 2.2, and the obese group by 4.5 Nm ± 4.8. At the selected speed, the control group reduced the peak external knee adduction moment by

1.9 Nm ± 1.8, and the obese group by 3.6 Nm ± 3.9. The obese group exhibited greater peak moments than the healthy weight group at both walking speeds. The obese group had significantly greater angular impulse values than the healthy weight group. Also, ankle dorsiflexion in late stance and ankle eversion range of motion was significantly increased in both groups while using the insole. This study reveals that obese individuals have a higher medial knee joint load than non-obese individuals, but the lateral wedge tends to decrease the amount of joint load for both groups; therefore, a lateral wedge can be useful for participants in all weight categories.

After examining the use of lateral wedges in a healthy population, there seems to be several benefits that could possibly slow the onset of medial knee osteoarthritis. Lateral wedges with ankle-foot orthoses resulted in a decrease of vertical loading and acceleration during gait, with a reduced knee extension moment (Schmalz et al., 2006). Other changes that were seen included an increased medial-to-lateral heel pressure ratio, increased ankle eversion moment, and decreased peak knee adduction moment (Erhart et al., 2008). Also, increased ankle dorsiflexion was exhibited in the late stance phase of gait for obese and healthy weight participants. The obese participants also presented greater angular impulse values than the healthy weight individuals (Russell & Hamill, 2011).

Conclusion

Overall, it seemed that the major change associated with medial knee osteoarthritis was an increased external knee adduction moment, which indicated an increased amount of joint load on the medial side of the knee (Foroughi et al., 2010). Some of the contributing factors that were associated with the increase were body mass, tibial angle/knee alignment, walking speed, and disease severity (Hunt & Bennell, 2011). When comparing obese individuals with healthy weight individuals, the obese had a higher body mass, more varus alignment at the knee (Sharma et al., 2000), and a slower walking speed (Browning & Kram, 2007). This indicated that obese individuals may have had a higher external knee adduction moment than a healthy weighted individual. This could potentially lead to the development of medial knee osteoarthritis, or worsening of the disease. While weight loss is prescribed to prevent or manage the disease, other interventions aimed at decreasing the external knee adduction moment through a biomechanical aspect. Bracing and laterally wedged insoles have been shown to decrease the external knee adduction moment in those diagnosed with medial knee osteoarthritis; however, there was a higher compliance with the insole due to discomfort of the brace (Van Raaij, 2010). The laterally wedged insole also showed promising results for healthy participants by decreasing the external knee adduction moment (Russell & Hamill, 2011). Since most of the knee joint load occurs in the medial compartment for healthy individuals, this could be the cause for the prevalence of osteoarthritis occurring on this side of the knee. If the laterally wedged insole can decrease the external knee adduction moment and create an equal distribution of force across the knee, it is possible that the insole may slow the onset of medial knee osteoarthritis.

After reviewing the current state of literature it seemed apparent that lateral wedges have an acute effect on biomechanical factors associated with increased medial knee compartment loading. However, research on acclimation period and sustained affects of this intervention strategy remained equivocal. Also, it is uncertain whether the laterally wedged insole provided similar results in those with different knee alignments (varus and valgus). Therefore, to understand the full clinical impact of lateral wedges in individuals with medial knee osteoarthritis and those at risk for the disease, further research regarding a one week period in healthy individuals is imperative.

Chapter 3: Methods

Participants

Twenty female participants were recruited for the study between the ages of 18 and 55 years. Ten participants with a tibiofemoral angle greater than 10° were included in the valgus group (age: 22.5±2.37 yr, mass: 61.4±20.7 kg, height: 1.63±0.06 cm, tibiofemoral angle: 11.7±1.49°), and ten participants with a tibiofemoral angle between 4° and 10° were included in the normal group (age: 22.6±2.67 yr, mass: 61.6±7.18 kg, height: 1.66±0.07 cm, tibiofemoral angle: 7.6±2.27°). All participants were screened using a validated questionnaire before inclusion to ensure that each had not experienced any pain, injury, or diagnosis of arthritis in any form within the hip, low-back, knee, or ankle joints.

Normal values for the tibiofemoral angle still remain unclear; however, females tend to have more valgus knee alignment (Nguyen & Shultz, 2007). Lee et al. (2011) stated that an acceptable range for knee alignment was between 4° and 10°; therefore, this range seemed appropriate to classify normally aligned knees in the present study. Pilot testing was performed before the present study and several females had knee alignment within this range, while some had a higher knee alignment. Nguyen & Shultz (2007) found a range between 5° and 15.7° when measuring tibiofemoral angles, indicating that many females may have an extreme valgus alignment when having a tibiofemoral angle above 10°.

Static frontal plane knee alignment was measured using a goniometer to find the frontal plane tibiofemoral angle. The frontal plane tibiofemoral angle was defined as the angle formed by the anatomical axes of the femur and tibia in the frontal plane. The goniometer axis was placed over the knee center (midpoint between the medial and lateral joint line in the frontal plane), the stationary arm aligned along the line from the knee center to the midpoint between the anterior superior iliac spine and the most prominent aspect of the greater trochanter, and the movable arm aligned along a line from the knee center to the midpoint between the medial and lateral malleoli (Nguyen & Shultz, 2007). Prior to data collection, research approval from the Institutional Review Board of Old Dominion University and written informed consent from all participants was obtained.

Experimental Protocol

For all testing procedures, participants wore the same type of clothing, including spandex shorts and a tight fitting shirt or sports bra if needed. The participants wore their own shoes during all testing procedures. It was explained to the participants to choose a pair of athletic shoes that were regularly worn for a minimum of one month. General anthropometric data was taken for each participant, including height, weight, and shoe size.

To track lower extremity kinematics, 26 retro-reflective skin markers were placed on the participants (Weinhandl, Joshi, & O'Connor, 2010). Markers used exclusively for the standing calibration trial (calibration markers) included the left and right iliac crests and greater trochanters, and right leg later and medial femoral epicondyles, lateral and medial malleoli, first and fifth metatarsal heads. Additional tracking markers were placed on the left and right antero-superior iliac spines, left and right postero-superior iliac spines, two four-marker clusters attached to elastic Velcro straps on the thigh and shank segments, and a four-marker cluster secured on the heel counter of the shoe.

After markers were attached in the proper locations, a three second standing calibration trial was collected. After collection of this calibration trial, calibration markers were removed and participants practiced walking at a normal, self-selected speed with the right foot landing on the force plate until they felt comfortable.
Gait speed was monitored via an infrared timing system (Brower Timing Systems, Draper, UT) with sensors placed 2 m apart. The mean gait speed for each practice trial was calculated to determine each participant's preferred walking speed. The participant was then asked to perform this preferred walking speed for five successful trials. A successful trial was defined as one during which the target gait speed was maintained within 1% and the participant's entire right foot came into contact with the forceplate. The order of in which participants performed the target gait speeds was randomized to eliminate systematic variation.

Once these trials were collected, a laterally wedged insole (ProMed Products Xpress, Bolingbrook, IL) was added to the participant's shoes according to her shoe size. The laterally wedged insole was constructed of ethylene vinyl acetate material with a 9° incline along the rear lateral aspect of the insole. Each participant practiced walking with the inserted insole for ten minutes. Then, each participant repeated the same walking protocol that was done without the insole.

After all initial trials were collected, each participant was given a pair of laterally wedged insoles and a pedometer to track wear. Participants were instructed to wear the flat shoes with the inserted insoles throughout the following week. A graded protocol was used to achieve a certain number of steps per day while the insoles and shoes are worn. On the first day of the intervention, the participants were expected to achieve

2,000 steps or more while wearing the insoles and shoes. As each day progressed, the participants were expected to achieve at least 1,000 more steps/day until day seven, when they have accumulated at least 8,000 steps/day wearing the insoles and shoes. Each participant was required to record a daily log reporting the number of steps taken while wearing the insole each day, and what activities were done while wearing them. Also, participants were asked to record any adverse effects experienced. If a participant had two consecutive days that she did not meet the graded protocol within 500 steps, or had a single day that she did not meet the graded protocol by 1,000 steps, then that participant was excluded from the study. After the one week acclimation period had passed, each participant performed five more successful walking trials with the insole at preferred walking speed. The post-test protocol was similar to the pre test protocol with and without the wedged insole.

Instrumentation

Marker coordinate data was collected at 200 Hz using an eight-camera motion analysis system (Vicon, Centennial, CO, USA). Three-dimension ground reaction force data was measured at 1000 Hz using a Bertec force plate (Columbus, OH, USA) flush mounted with the floor.

Data Analysis

Data reduction was implemented with Visual 3D. Raw three-dimensional marker coordinate data and ground reaction force data was low-pass filtered through a fourth-order Butterworth zero lag filter with 12 Hz and 50 Hz cutoff frequencies, respectively. In order to describe the position and orientation of each segment, right handed Cartesian local coordinate systems were defined for the pelvis, thigh, shank, and foot segments.

Three-dimensional ankle, knee, and hip angles were calculated using a joint coordinate system approach (Grood & Suntay, 1983) and reported relative to the static standing trial. Ankle joints centers were defined as the midpoint between the medial and lateral malleoli markers (Wu et al., 2002) and knee joint center will be defined as the midpoint between the medial and lateral epicondyle markers (Grood & Suntay, 1983). The hip joint center was defined as 25% of the distance from the ipsolateral to the contralateral greater trochanter (Weinhandl et al., 2010). Body segment parameters were estimated from Dempster (1955), and joint kinetics were calculated using a Newton-Euler approach(Bresler). The joint moments reported in the distal segment coordinate system were normalized by the product of participant height and body mass. A vertical ground reaction force threshold of 15 N indicated initial foot contact and toe-off of the right foot. The discrete measures extracted as dependent variables included ankle, knee, and hip range of motion, peak internal knee adduction moment, and knee abduction angular impulse. The range of motion values were calculated from heel strike to the peak flexion, abduction, and internal rotation angles. All of these measures were recorded during the stance phase of gait.

Statistical Analysis.

Each participant's mean data was entered into a two-way repeated measures ANOVA (knee alignment (between 4^{o}-10^{o} and >10^{o}) x insole condition (pre-nonwedge, pre-wedge, post-nonwedge, post-wedge) to test statistical significance of the dependent variables. If a two-way interaction existed, independent and paired t-tests were implemented. All statistical analyses was conducted using SPSS (version 20.0, SPSS Inc, Chicago IL).

Chapter 4: Results

Twenty individuals were recruited to participate in this study (valgus group n=10; normal group n=10). However, one of the valgus group participants was excluded because she did not meet the walking requirements, and another valgus group participant dropped due to ankle discomfort experienced while wearing the wedge. The remaining samples consisted of 8 valgus participants (age: 22.9±2.47 yr; mass: 63.8±5.85 kg; height: 1.64±0.09 cm; 11.9±1.64°; steps with wedge: 40844±8972 steps), and 10 normal participants (age: 22.6±2.67 yr; mass: 61.6±7.18 kg; height: 1.66±0.07 cm; 7.6±2.27°; steps with wedge: 46300±11559 steps).

Group means and standard deviations for all dependent variables are located in Table 1. Mean ensemble curves over the stance phase of gait are presented for GRF (Mediolateral: Figure 1; Anteroposterior: Figure 2; Vertical: Figure 3), stance leg knee joint angles (Flexion: Figure 4; Abduction: Figure 5; Rotation: Figure 6), and stance leg knee joint moments (Flexion: Figure 7; Abduction: Figure 8; Rotation: Figure 9).

For knee abduction moment, there was not a significant two-way interaction (p=0.48). There was a significant main effect for the two groups of knee alignment (p=0.02) as the valgus aligned group exhibited a 0.17 Nm/kg reduction in knee abduction moment when compared to the normally aligned group. There was not a significant main effect for condition (p=0.90).

Similar results were seen with the knee abduction angular impulse. There was not a significant two-way interaction (p=0.60). Also, the main effect for condition (p=0.22) showed no significance. However, the main effect between the two groups had a significant relationship (p=0.00). The valgus aligned group had a significantly lower knee abduction angular impulse (-0.10±0.01 Nms/kg) when compared to the normally aligned group (-0.16±0.01 Nms/kg).

The mediolateral ground reaction force at peak knee adduction moment did not have a significant two way interaction (p=0.90). The main effects for group (p=0.89) and condition (p=0.44) were not significant.

There was a significant two-way interaction, condition×group, for vertical GRF at the instance of peak knee abduction moment (p=0.01). An independent t-test showed the valgus participants had a higher vertical GRF (12.04±1.42 N/kg) when compared to the normal participants (10.7±1.27 N/kg) during the post-nonwedge condition (p=0.046). A paired t-test revealed that the post-nonwedge condition exhibited a 0.40 N/kg decrease from the post-wedge condition in normal participants (p=0.006). Normal participants also exhibited a significant difference (p=0.007) between the post-nonwedge condition (10.7±1.27 N/kg) and the pre-wedge condition (11.2±0.89 N/kg). For the valgus group, participants exhibited a 0.43 N/kg decrease when the wedge was inserted during the post session (p=0.046). There was also a significant difference (p=0.045) between the post-nonwedge condition (12.0±1.42 N/kg) and the pre-nonwedge condition (11.4±1.20 N/kg).

For the knee flexion loading response, there was not a significant two-way interaction (p=0.09). In addition, there was not any significance between the groups (p=0.49) or conditions (p=0.19).

There was not a significant two-way interaction for the maximum knee adduction angle (p=0.48). The main effects between the groups (p=0.27) and conditions (p=0.85) were not significant.

For knee flexion range of motion, there was not a significant two-way interaction ($p=0.51$). There were not any significant main effects between the groups ($p=0.07$) or conditions ($p=0.83$).

Knee adduction range of motion did not demonstrate a significant two-way interaction ($p=0.83$). The main effects between the groups ($p=0.22$) and conditions ($p=0.79$) did not show any significance either.

There was not a significant two-way interaction for the maximum ankle eversion angle ($p=0.37$). The main effects were not significant between the groups ($p=0.10$) and conditions ($p=0.99$).

For ankle eversion range of motion, there was not a significant two-way interaction ($p=0.24$). The main effects between the groups ($p=0.40$) and conditions ($p=0.14$) were not significant.

Chapter 5: Discussion

After examining the acute effects of a laterally wedged insole in those with normal and valgus knee alignment, there was no change in the peak internal knee abduction moment or the angular impulse of the internal knee abduction moment during gait with the use of the insole. After one week of wearing the insole, the same results were seen concerning the internal knee abduction moment; therefore, we reject the alternative hypothesis.

It is possible that a lack of significance in the ankle eversion ROM and peak ankle eversion may have shown the wedge to be ineffective. The ankle is the first joint within the linked chain to be influenced by the wedges (Butler, Barrios, Royer, & Davis, 2009). The use of a lateral wedge results in an increase in the subtalar eversion moment arm, leading to a decrease in the knee adduction moment (Crenshaw et al., 2000). In this study, there were no significant changes in the subtalar joint with the use of the lateral wedge. It was noticed that the wedge seemed to have conformed to the participant's foot when being returned after the one week period. Some of the wedges were used repeatedly on different subjects; therefore, the material may not have been durable enough to withstand a person's weight. Also, the cushion of each participant's shoe may have absorbed the wedge, which may have resulted in less ankle eversion than was intended. Even though there were not changes seen in the subtalar joint, there was a two-way interaction in vertical GRF at the instance of peak knee abduction moment

Vertical ground reaction force can be affected by many factors such as body mass and proportion, joint alignment and coordination, and walking speed (Cook, 1997). Since the walking speed was controlled in this study, knee flexion was examined at peak KAM.

Mündermann, Dyrby, and Andriacchi (2005) found that a stiffer limb or decreased flexion would indicate an increased vertical GRF. Knee flexion increased when the wedge was inserted during the post session for valgus participants while vertical GRF decreased; therefore, knee flexion did coincide with vertical GRF for this particular session. However, the other significant differences indicated by the paired t-test did not coincide with knee flexion. Furthermore, subjects were allowed to wear their own athletic shoes; therefore, the same shoes that were worn during the pre-testing may not have been worn during the post testing. This could explain the differences seen in vertical ground reaction force from pre to post testing. Other studies have not found any significant changes in vertical GRF with the lateral wedge. Hinman et al. (2012) found that the insertion of the lateral wedge insoles resulted in a more vertically oriented GRF vector, but the actual magnitude was unchanged. This change in direction would only lead to a change in the moment arm associated with knee abduction moment (Jenkyn, Erhart, & Andriacchi, 2011).

Surprisingly, there was not a significant change in peak knee abduction moment. Maly, Culham, and Costigan (2002) found similar results indicating that a 5 degree lateral wedge insole produced a nonsignificant difference in peak knee adduction moment; however, gait speed was not controlled. Conversely, Russell and Hamill (2011) found a significant difference in peak knee abduction moment when wearing an eight degree lateral insole while gait speed was controlled In the current study, gait speed was uncontrolled as participants were allowed to complete walking trials at a self-selected preferred walking speed. Therefore, the methods used were more similar to Maly, Culham, and Costigan (2002) indicating that preferred gait speed may be a major factor in modulating peak knee abduction moments. Results have varied with the use of the lateral wedge in a healthy population and more research needs to be done.

Even though there was not a significant effect between conditions, there was a main effect for knee abduction moment showing that the group with valgus knee alignment had a lower knee abduction moment than the group with normal knee alignment. Harrington (1983) explained that the normal tendency was to transmit joint force through the medial side of the knee, and a large valgus malalignment was required before the center of pressure shifted into the lateral compartment. Johnson (1980) found that osteoarthritic subjects with a greater valgus malalignment experienced a decreased load on the medial compartment of the knee. Butler et al. (2011) found similar results, showing that those with lateral knee osteoarthritis exhibited a significantly lower peak knee abduction moment, knee adduction excursion, and peak knee adduction angle than those with medial knee osteoarthritis and non-osteoarthritic controls. However, Butler et al. (2011) did not measure static knee alignment. The current study examined static knee alignment along with kinetics and kinematics during gait. Also, previous studies examined those already diagnosed with osteoarthritis, while this study found that healthy individuals with different static knee alignment exhibit dynamic differences at the knee as well. This information may become useful when prescribing any type of lower extremity intervention or treatment, and knowing that those with normal knee alignment may react differently than those with valgus knee alignment.

There were several limitations to this study. The results showed a change in the vertical ground reaction force that could be affected by the shoes that each individual wore. Since each participant could wear their own shoes, it was possible that she wore different shoes during the two testing sessions. Also, each individual's shoes could vary in support and amount of wear. In future research, it should be required that the participants wear the same shoes for both testing sessions. In order to ensure this, it may be plausible to provide shoes for the testing sessions.

Another limitation that may have affected the results of the study is the type of exercise that each individual performed while wearing the insole during the week. Some participants were more athletic than others and performed more physical activity in duration and/or intensity. Perhaps physical activity while wearing the insole should have been restricted to only include walking. Also, the participants should have been instructed to stop wearing the insole once the minimum number of steps was achieved.

Overall, this study shows that the lateral wedge insole may or may not be beneficial to a healthy population. After the wedge was worn for one week, vertical ground reaction force decreased with the use of the wedge, regardless of knee alignment. Vertical ground reaction force may be a component in the calculation of knee abduction moment, but in this study was not significant enough to create a change in knee abduction moment. This study does suggest that those with valgus knee alignment exhibit a lower knee abduction moment than those with normally aligned knees, demonstrating that knee alignment may affect walking mechanics. Even though this study did not show a significant difference in knee abduction moment with the use of the wedge, other studies have. Therefore, more research needs to be performed on the effect of the insole in a healthy population. Future studies should examine a longer acclimation period, use participants with varus malalignment, and/or investigate the effect of different shoe types with the insole.

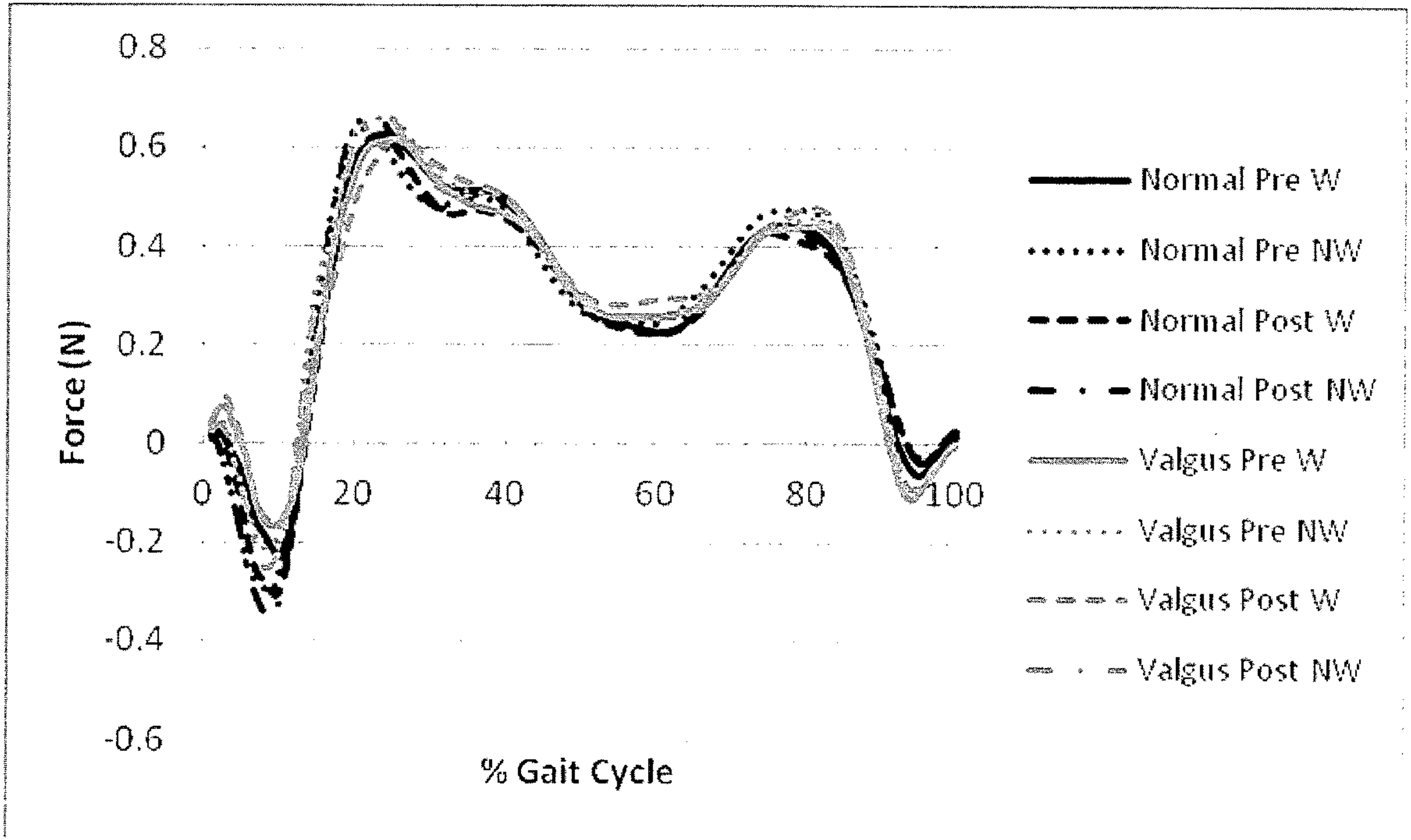

Figure 1. Average mediolateral GRF during the stance phase of gait.

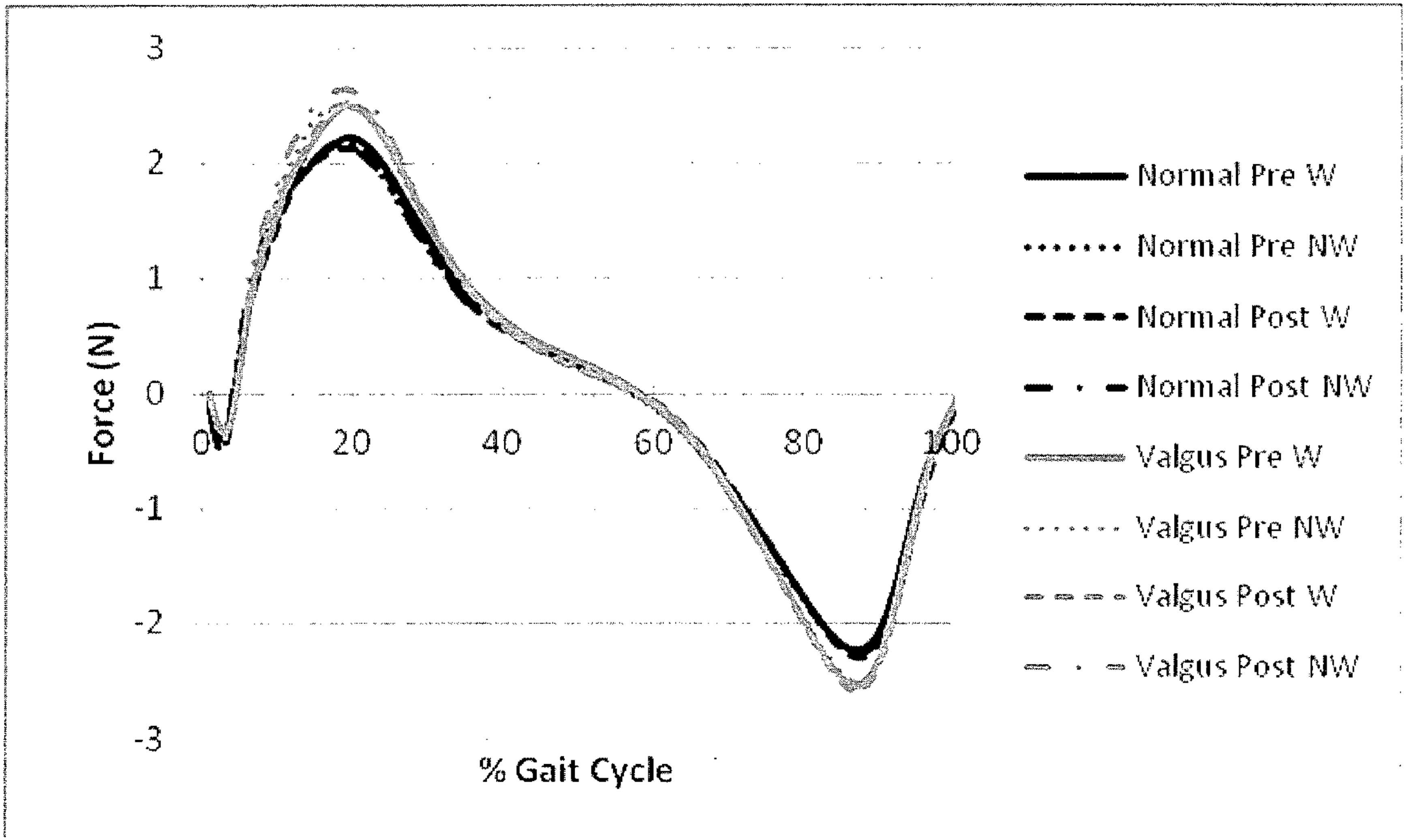

Figure 2. Average anteroposterior GRF during the stance phase of gait.

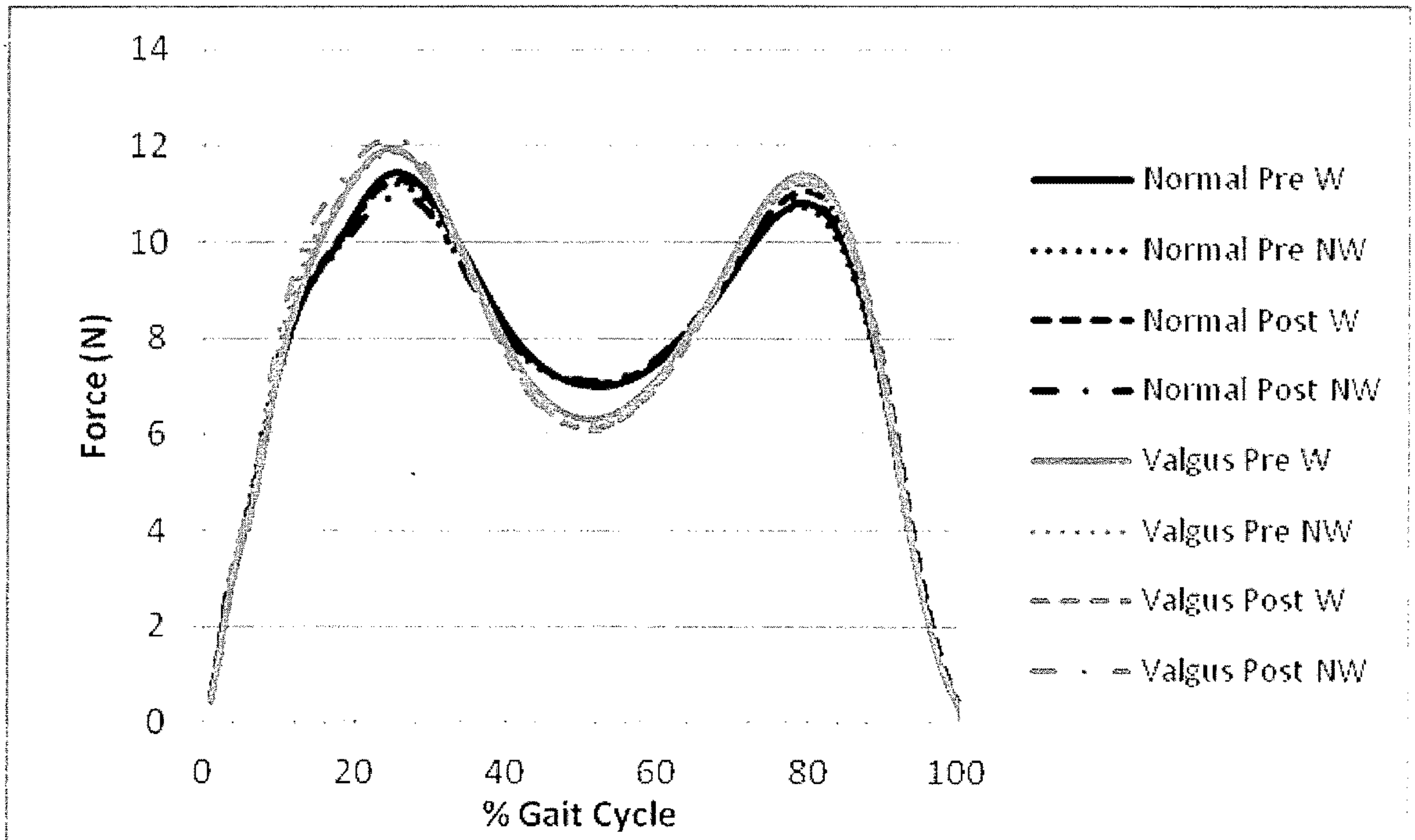

Figure 3. Average vertical GRF during the stance phase of gait.

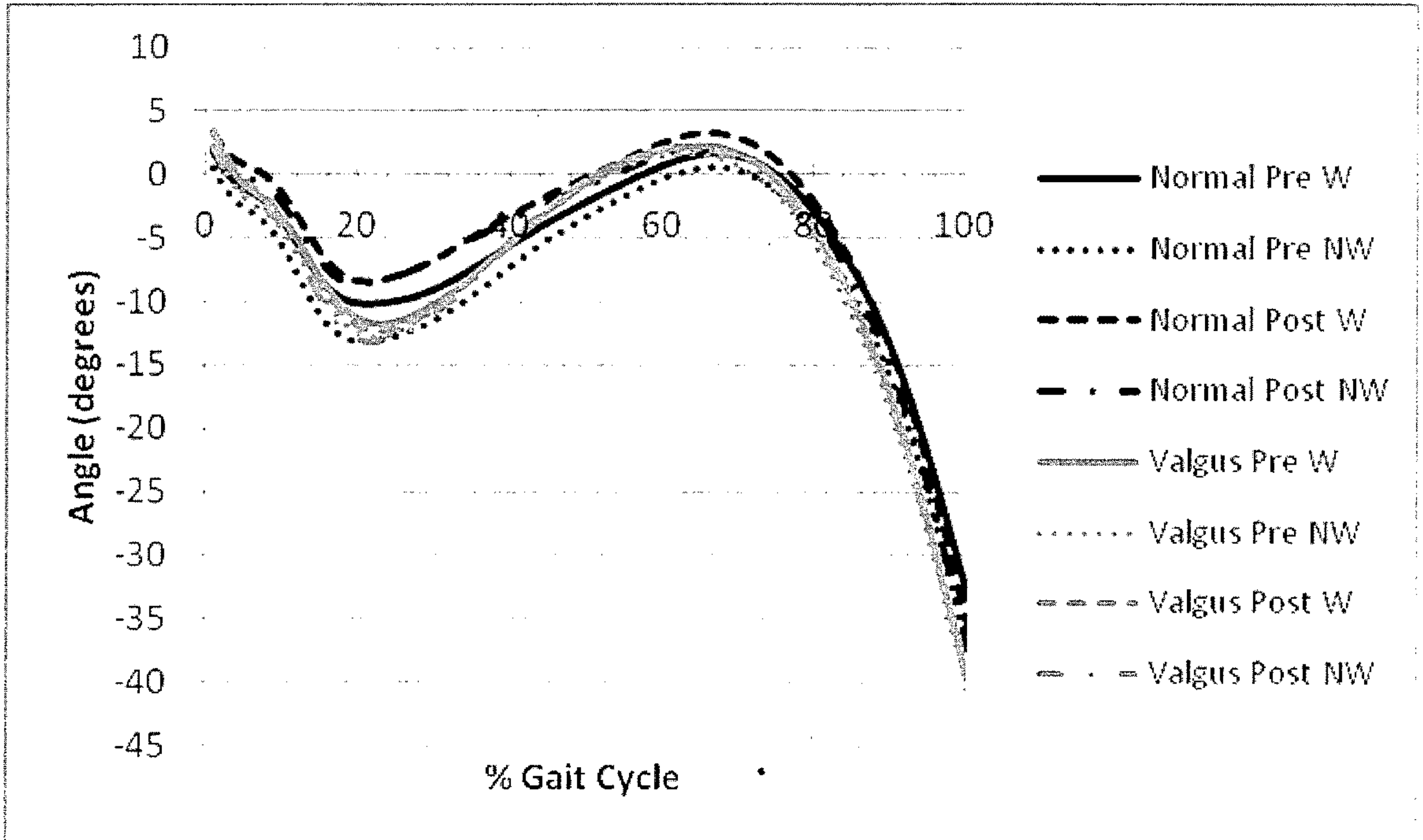

Figure 4. Average knee flexion angle during the stance phase of gait.

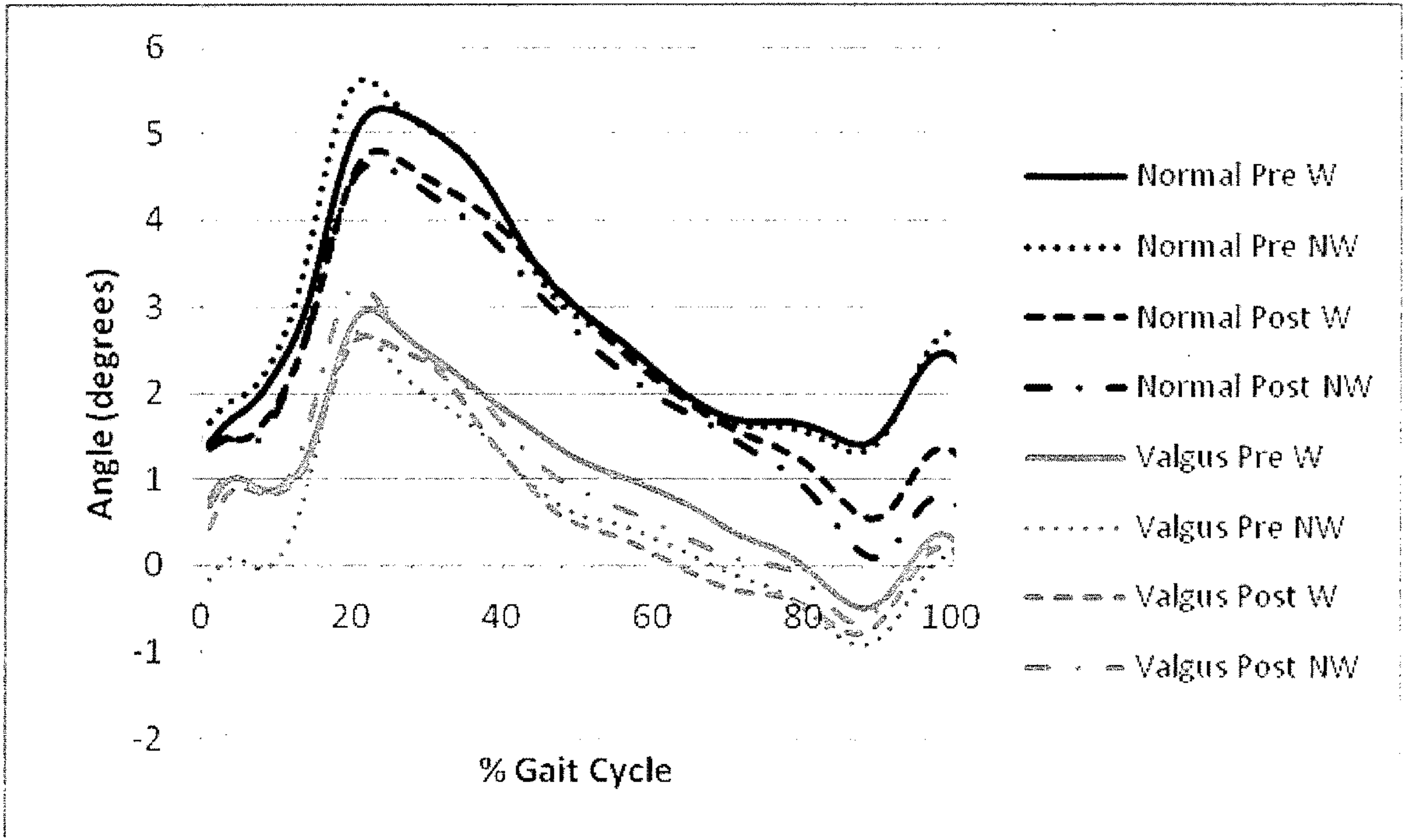

Figure 5. Average knee abduction angle during the stance phase of gait.

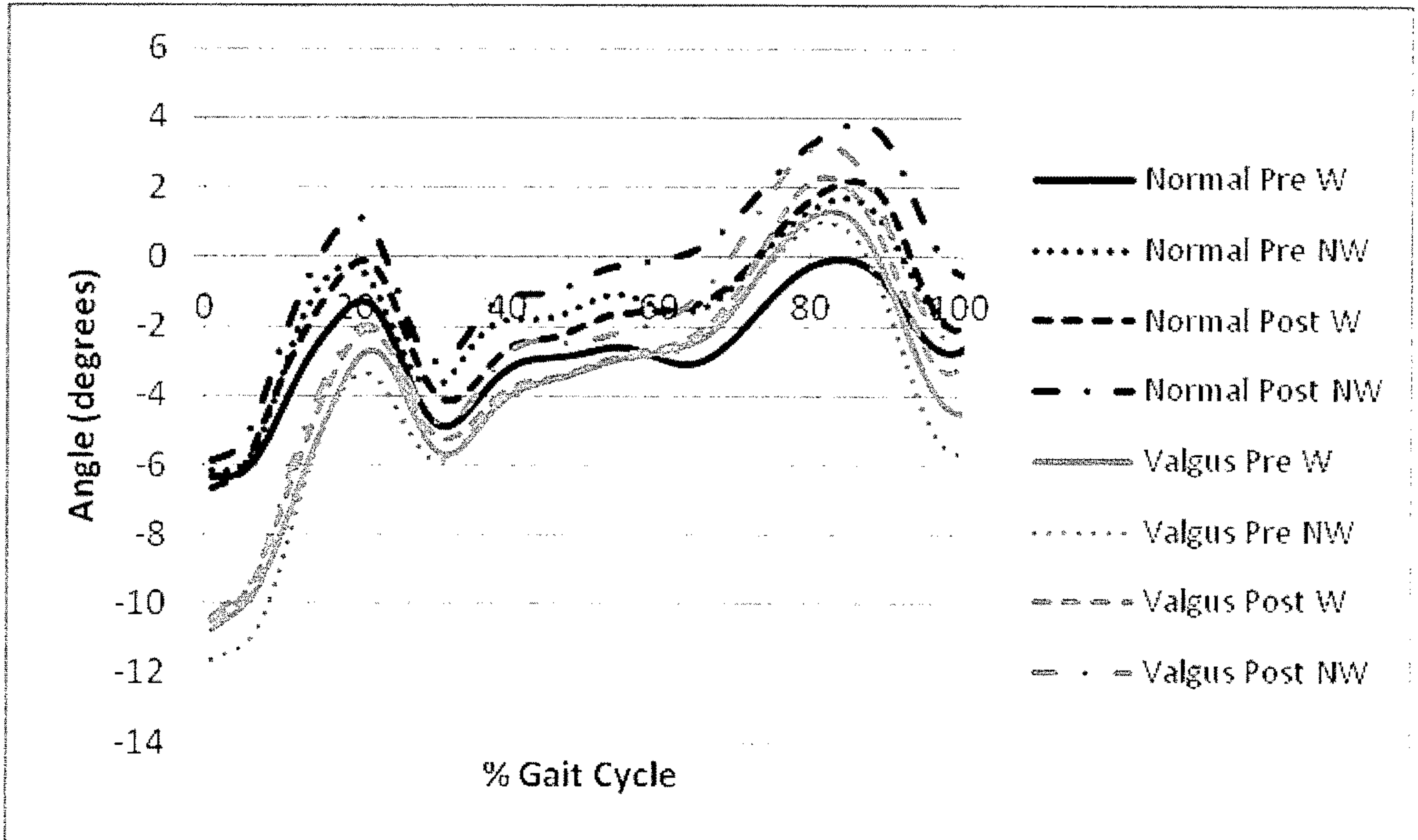

Figure 6. Average knee rotation angle during the stance phase of gait.

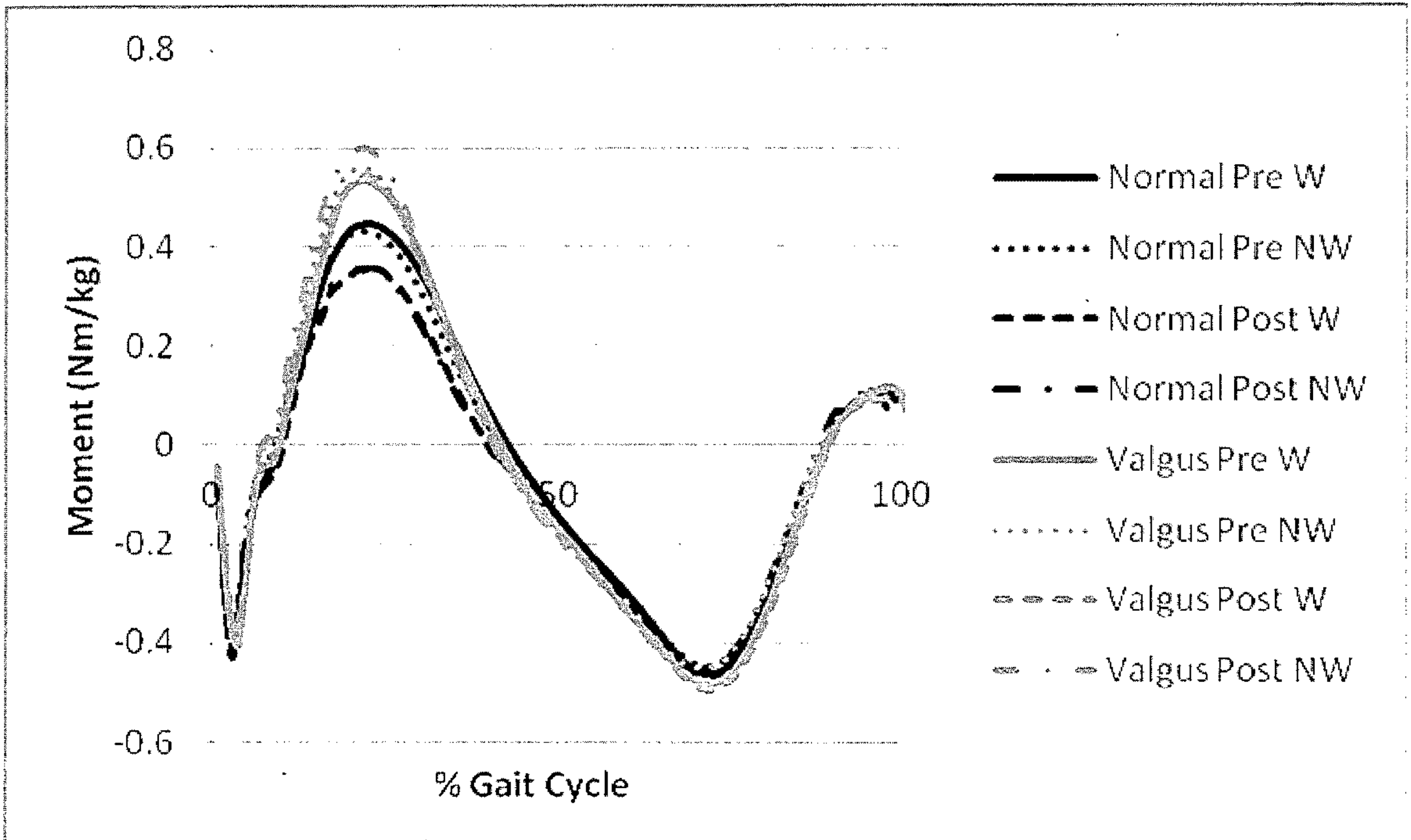

Figure 7. Average knee flexion moment during the stance phase of gait.

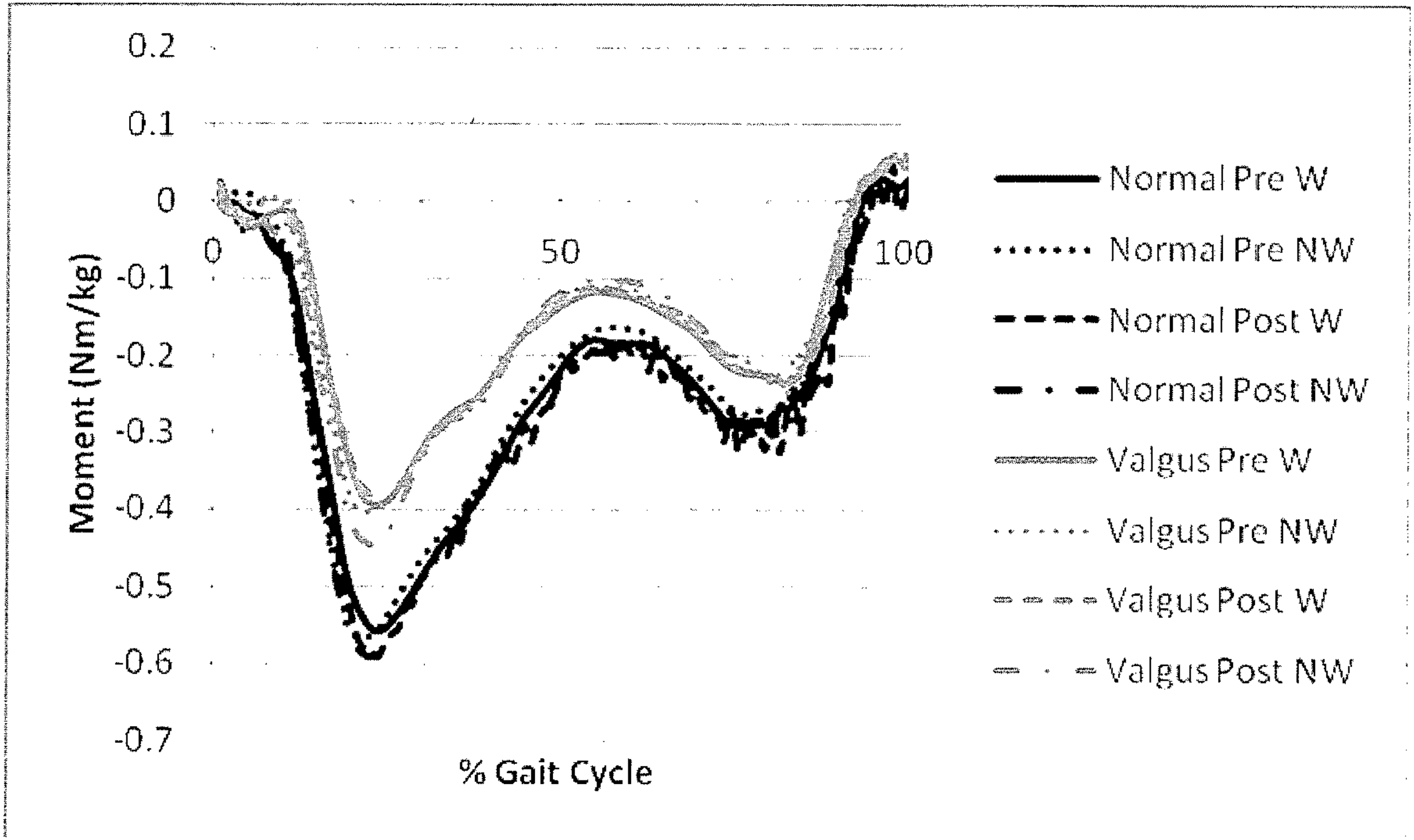

Figure 8. Average knee abduction moment during the stance phase of gait.

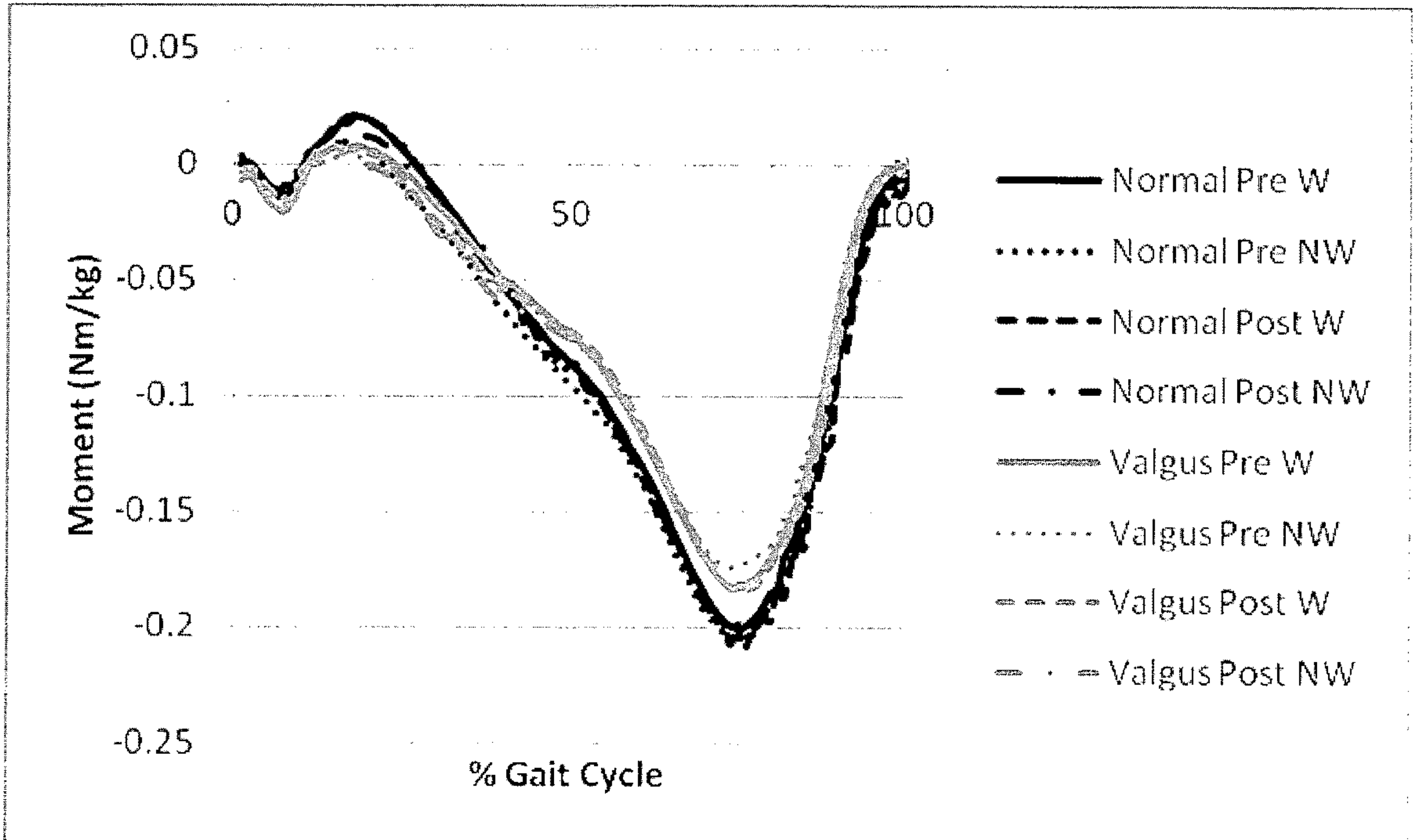

Figure 9. Average knee rotation moment during the stance phase of gait.

Table 1. Means, standard deviations, and significant interactions between normal and valgus knee alignment groups during pre trials with (pre W) and without the wedge (pre NW), and post trials with (post W) and without the wedge (post NW).

	Normal				Valgus			
	Pre NW	Pre W	Post NW	Post W	Pre NW	Pre W	Post NW	Post W
Peak Knee Abduction Moment (Nm/kg)[b]	-0.60 (0.13)	-0.63 (0.17)	-0.62 (0.13)	-0.62 (0.14)	-0.46 (0.16)	-0.43 (0.16)	-0.46 (0.14)	-0.43 (0.13)
Knee Abduction Angular Impulse (Nms/kg)[b]	-0.15 (0.04)	-0.16 (0.04)	-0.17 (0.04)	-0.17 (0.04)	-0.10 (0.04)	-0.10 (0.04)	-0.10 (0.03)	0.10 (0.02)
Mediolateral GRF at peak KAM (N/kg)	0.67 (0.13)	0.67 (0.15)	0.66 (0.17)	0.63 (0.16)	0.69 (0.25)	0.65 (0.21)	0.69 (0.20)	0.64 (0.23)
Vertical GRF at peak KAM (N/kg)[a]	10.9 (0.83)	11.3 (0.89)	10.7 (1.27)	11.1 (1.23)	11.4 (1.20)	11.6 (1.05)	12.0 (1.42)	11.6 (1.08)
Knee flexion loading response (deg.)	-13.3 (6.56)	-12.2 (7.13)	-8.95 (8.35)	-8.74 (7.27)	-12.9 (5.45)	-11.9 (3.28)	-13.3 (4.77)	-12.5 (4.88)
Knee flexion ROM (deg.)	39.0 (4.67)	39.0 (6.12)	40.5 (5.59)	40.0 (6.33)	43.9 (3.84)	44.1 (3.43)	43.3 (3.96)	44.2 (4.04)
Maximum knee adduction angle (deg.)	6.03 (2.16)	5.75 (2.58)	5.34 (2.99)	5.57 (3.64)	3.01 (1.83)	3.73 (2.06)	3.89 (1.40)	3.73 (1.88)
Knee adduction ROM (deg.)	-4.35 (1.93)	-4.31 (1.88)	-3.94 (1.74)	-4.22 (2.32)	-3.16 (0.95)	-3.04 (1.52)	-3.10 (1.76)	-3.29 (2.52)
Maximum ankle eversion angle (deg.)	-6.68 (2.34)	-6.57 (2.42)	-7.38 (3.03)	-7.26 (3.01)	-5.63 (2.05)	-5.62 (2.57)	-4.88 (1.80)	-5.15 (1.29)
Ankle eversion ROM (deg.)	8.82 (2.18)	9.49 (2.75)	9.59 (2.07)	10.2 (1.50)	10.2 (3.05)	11.4 (2.76)	9.52 (3.05)	10.6 (2.80)

[a]Significant condition×group interaction ($p<0.05$)

[b]Significant main effect for group ($p<0.05$)

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