Title: Heel Wedges and Carbon Fiber Custom Dynamic Orthoses to Control Knee Biomechanics

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Study Protocol

Purpose and Procedures:

The primary purpose of this line of research is to investigate the effects of combined carbon fiber custom dynamic orthosis (CDO) and medial-lateral wedge use on biomechanics during gait in an effort to reduce unilateral knee compartment loading. In this research study, pilot data will be collected from a cohort of healthy adult participants with no history of lower limb injuries or functional deficits. Participants will be evaluated using a series of study measures under each of the four conditions; without a brace (NoCDO), with a brace and no wedge (CDO), with a brace and a medial wedge placed in the shoe (Medial), and with a brace and a lateral wedge placed in the shoe (Lateral). Testing order will be randomized for each participant. Participants will walk on a level-ground walkway at self-selected and controlled speeds. Physical performance measures will incorporate tests of agility, speed, and lower limb power to ensure that the device and wedge don't negatively affect physical function. Questionnaires will be used to evaluate participants' pain and perception of comfort and smoothness for each condition.

Objectives and Specific Aims:

Specific Aim 1: Determine the effect of CDO alignment on lower limb mechanics during gait in a cohort of healthy individuals.

Specific Aim 2: Determine the effect of CDO alignment on physical function and patient reported outcomes in a cohort of healthy individuals.

Background and Significance:

Osteoarthritis (OA) affects nearly 27 million people in the United States alone, and accounts for approximately $2,600 - $7,500 in out of packet expenses each year.[2] Knee OA can affect the medial, the lateral, or both compartments of knee. Treatment of OA can include a number of options such as medial-lateral wedging under the foot, knee orthoses, or ankle foot orthoses (AFOs). In the case of unilateral medial compartment knee OA unloader knee braces are commonly used to decrease knee adduction moments in an attempt to offload the knee. Similar efforts have been completed with the use of medial-lateral wedge placed in the shoe under the heel of the foot. Wedging was shown to stabilize biomechanics over time, preventing increases in knee adduction moment over a one-year period compared to neutral wedging. In another study, an ankle foot orthosis with a lateral strut was used in an effort to move the center of pressure position, thereby altering frontal plane knee moment. Use of this AFO resulted in improved pain, stiffness, and physical function scores when assed using the Western Ontario and McMasters Universities Arthritics Index (WOMAC).

CDOs consist of a cuff that falls just below the knee, a carbon fiber spring that runs the length of the calf and bends to store and return energy during gait, and a footplate the acts as a lever arm to bend the posterior strut. CDOs stabilize the ankle, and this may allow for greater affects at the knee when frontal plane alignment is adjusted. Similar to application of medial-lateral heel wedges in the shoe, placing medial-lateral wedges under a CDO may also reduce knee adduction moments. The purpose of this study is to determine if medial-lateral wedging combined with CDO use alters knee biomechanics, physical function, and patient reported outcomes.

Inclusion Exclusion Criteria:

Patient Inclusion Criteria

1) Between the ages of 18 and 45

2) Healthy without current complaint of lower extremity pain, spine pain, open wounds or active infections, or medical or neuromusculoskeletal disorders that have limited their participation in work or exercise in the last 6 months

3) Able to hop without pain

4) Able to perform a full squat without pain

5) Ability to speak and understand English

Patient Exclusion Criteria

1) Medical or neuromusculoskeletal disorders that have limited their participation in work or exercise in the last 6 months

2) Diagnosed with a moderate or severe brain injury

3) Lower extremity injury resulting in surgery or limiting function for greater than 6 weeks

4) Injuries that would limit performance in this study

5) Diagnosed with a physical or psychological condition that would preclude functional testing (e.g. cardiac condition, clotting disorder, pulmonary condition)

6) Uncorrected visual or hearing impairment(s)

7) Require use of an assistive device

8) Unhealed wounds (cuts/abrasions) that would prevent CDO use

9) BMI > 35

10) Pregnancy

Design and Methods:

Personal/demographic and anthropometric information will be used to fully characterize the study participants. We will collect multiple variables that have been previously associated with outcomes, including race, ethnicity, and education to characterize the cohort. Anthropometric and demographic information, such as age, biological sex, height, weight, leg length, shoe type, shoe length and width will also be used to characterize the cohort.

Patient-reported outcomes questionnaires will be used to evaluate participant pain and comfort and smoothness. Comfort and smoothness will be assessed using a modified version of the Socket Comfort Score, a reliable, valid, and sensitive measure of device fit and comfort.[3] These measures have been shown to effectively capture patient perception, are responsive to simple modifications to CDO device function, and will be applied in a manner consistent with a prior publication by the research team.[1] Participant will be asked to report their pain using a standard 11-point numerical pain rating scale, in which 0 = no pain and 10 = worst pain imaginable, at the start of session and at multiple points during testing.[4, 5] Semi-structured interviews will also be used to fully capture the participants perspectives, experience, and opinions associated with the study testing conditions.

Physical performance measures provide an objective and responsive assessment of an individual's functional mobility. Activities of daily life require performance of a range of functional tasks that require balance, agility, speed, and power. The four square step test (4SST) is a standardized and widely used test of functional mobility that requires rapid changes in direction that are often problematic following lower limb injury. The measure has good to excellent reliability and validity across multiple patient populations and groups and is a key dependent measure in most CDO-related studies to date and has demonstrated ability to detect changes in function in individuals with limb trauma and CDOs.[6-8, 9] The sit to stand 5 times (STS5) test is a well-established measure of lower limb muscle strength, endurance, and mobility.[10] The STS5 test has excellent reliability and good validity across a broad range of patient populations.[10-20]

Ground reaction force and motion capture data will be used to evaluate the motion and loading of the lower limb as participants walk on an over ground walkway at self-selected speed and a controlled speed based on leg length.[21, 22] The ability to collect reliable data across sites has been previously

demonstrated.[23] Previously established methods will be used to assess lower limb motion and moments.[22]

Statistical Analysis Plan

Analysis Methods:

All the primary dependent variables will be evaluated using similar statistical approaches within each group. One-way repeated measure ANOVAs will be used to evaluate the effect of CDO alignment. Paired t-tests with Bonferroni-Holm correction will be used for post-hoc comparisons. Multiple trials will be collected for each condition during testing.

Power Analysis:

The number of participants proposed for this study are consistent with those from prior investigations by Dr. Wilken related to CDO design. Thirteen participants was sufficient to detect differences associated with AFO stiffness in a recent study by Dr. Wilken (PMID: 25193884).

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