Title: The Effects of Heel Distraction Height on Foot Loading with Carbon Fiber Custom Dynamic Orthoses

NCT Number: Not Yet Assigned

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Study Protocol

Purpose and Procedures:

Carbon fiber custom dynamic orthoses (CDOs) have been used to improve function, reduce pain, and offload the foot and ankle for individuals with a number of conditions affecting the lower extremity.[1-3] CDOs consist of a proximal cuff that wraps around the leg just below the knee, a posterior carbon fiber strut that bends to store and return energy during mid to late stance, a semi-rigid carbon fiber footplate, and, in some cases, a foam heel wedge placed in the shoe. Unloading ankle foot orthoses (AFOs) have also been used for a number of lower extremity conditions, including traumatic injuries, in effort to reduce forces and pressure acting under the foot.[4-6] Unloading AFOs have been created using many different designs, which include a proximal cuff just below the knee, a rigid strut (made of metal, plastic, etc.), and some sort of foot component (footplate, shoe, etc.).

Both CDOs and unloading AFOs have shown varying levels of success in reducing forces acting on different regions of the bottom of the foot during gait.[3-6] Based on previously published data and initial data collections, CDOs have been shown to successfully offload the forefoot during gait but have had differing results for the hindfoot and midfoot.[3] Offloading AFOs have shown to reduce plantar pressures in the midfoot and hindfoot with some increases observed in the forefoot.[4] The differences in loading may be related to a distinct difference between CDOs and unloading AFOs: CDOs do not suspend, or distract, the foot away from the footplate.[3]

The purpose of this study is to determine the effects of CDOs and heel distraction height (the distance between the heel and the footplate) on foot loading as well as patient reported pain and comfort. In this study, forces acting under the foot will be measured using wireless Loadsol insoles (Novel GMBH, St. Paul, MN) as participants walk without an orthosis (NoCDO) and with a CDO with three different posterior strut lengths resulting in three different levels of heel distraction (0cm, 1cm, 2cm) at self-selected and controlled speeds. Participants will be provided a lift for the contralateral limb to reduce the effects of leg length discrepancies during walking. Loadpad force measuring sensors (Novel GMBH, St. Paul, MN) will be used to measure forces within the CDO proximal cuff, ensuring it is fastened the same across testing conditions. After walking in each condition, participants will complete questionnaires concerning pain and orthosis comfort.

Objectives and Specific Aims:

Specific Aim 1: Determine the effects of CDO use, and heel clearance, on foot loading during gait.

Specific Aim 2: Determine the effects of CDO use, and heel clearance, on patient-reported pain.

Specific Aim 3: Determine the effect of heel clearance on patient-reported comfort.

Background and Significance:

Orthoses are one intervention available for individuals with lower extremity impairments. Carbon fiber custom dynamic orthoses (CDOs) have been used to improve function, reduce pain, and offload the foot and ankle for individuals with different conditions affecting the lower limb.[1-3] Unloading ankle foot orthoses (AFOs) have also been used for a number of lower extremity conditions, including traumatic injuries, in an effort to reduce forces and pressure acting under the foot.[4-6] CDOs consist of a proximal cuff that wraps around the leg just below the knee, a posterior carbon fiber strut that bends to store and return energy during mid to late stance, a semi-rigid carbon fiber footplate, and, in some cases, a foam heel wedge placed between the CDO and the shoe. Unloading AFOs have been created using many different designs, all of which include a proximal cuff just below the knee, a rigid strut (made of metal, plastic, etc.), and some sort of foot component (footplate, shoe, etc.).

CDOs and unloading AFOs have shown success in reducing forces acting on the bottom of the foot but have greater success in different regions.[3-6] These differences may stem from a distinct difference between CDO

and unloading AFO designs: CDOs do not suspend, or distract, the foot away from the footplate.[3] CDOs have been shown to successfully offload the forefoot during gait, but initial data collections have shown differing results for the hindfoot and midfoot.[3] Forefoot unloading has been observed in mid- to late stance as forces are transferred through the orthosis away from the foot to the proximal tibia within the proximal cuff.[3] Offloading AFOs have shown to reduce plantar pressures in the midfoot and hindfoot, with increases observed in the forefoot.[4] Unloading AFOs are designed to suspend the foot away from the ground, footplate, or shoe by transmitting forces around the injured foot, ankle, and distal tibia through the orthosis to the proximal cuff and the proximal end of the tibia.[7] This may explain the hindfoot and midfoot offloading that is not always observed with CDO use.

Few studies have investigated the effects of unloading AFO design on foot offloading, but limited results have shown that the footplate, ankle motion, and distraction height (the distance between the heel and the footplate) may impact loading. Some studies have shown that unloading AFOs have completely offloaded the hindfoot when the heel is distracted away from the footplate.[4] CDOs are currently designed to have the heel resting on the footplate, and including distraction height may improve hindfoot offloading. Unloading AFO studies have shown that a rigid footplate combined with restricted ankle motion resulted in greater reductions of plantar pressure under the whole foot than when walking with the ankle unrestricted.[4, 5] The stiff posterior strut and footplate used with many CDOs are known to control ankle motion throughout gait and may improve offloading capabilities of the CDO when the heel is distracted away from the footplate.[8, 9] A better understanding of how heel distraction height impacts foot loading during CDO use will help to guide future CDO design and provision, particularly for individuals who experience pain with limb loading.

Inclusion Exclusion Criteria:

Inclusion Criteria:

1) Ages 18–50 years

2) Unilateral injury or disease affecting the muscle, bones, or nerves in the lower leg

3) Use a modular carbon fiber custom dynamic orthosis (CDO)

4) Mechanical pain with limb loading (>4/10 on Numerical Pain Rating Scale)

5) Ability to walk 50 feet at a slow to moderate pace

6) Ability to walk without a cane or crutch

7) Ability to read and write in English and provide written informed consent

Exclusion Criteria:

1) Diagnosis with a moderate or severe brain injury

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

3) Ankle weakness resulting from spinal cord injury or central nervous system pathology

4) Nerve, muscle, bone, or other condition limiting function in the contralateral extremity

5) Rheumatoid or inflammatory arthritis

6) Necrosis of any bones in the foot or ankle

7) Pain of 8/10 or greater during walking

8) Uncorrected visual or hearing impairments

9) Require use of a knee stabilizing device to perform daily activities (i.e., Knee ankle foot orthosis, knee orthosis, etc.)

10) Pregnancy; Per participant self-report. Due to the expected small number of pregnant individuals and resulting inability to account for its effect on resulting outcomes, participants will be withdrawn from the study

11) Body mass index greater than 40 kg/m2

Design and Methods:

We anticipate the study will be completed in one visit lasting approximately 2-3 hours. Although we will attempt to collect all data in the specific order listed, the number of study activities completed, and the specific order of completion will be dependent on participant, staff, and study equipment availability. There is a chance that additional visits may be required to complete all study activities. The order of events for each group is listed below.

TESTING PREP 1

• Calibrate sensors

NoCDO TESTING

• Zero sensors

• Sitting/standing trials

• Walking trials

• Numerical pain rating scale

TESTING PREP 2

• Calibrate sensors

CDO TESTING (0cm, 1cm, 2cm in randomized order)

• Zero sensors

• Sitting/standing trials

• Walking trials

• Numerical pain rating scale

• Comfort and Smoothness questionnaire

Potentially eligible participants will answer pre-screening questions prior to signing the informed consent document. If they meet all the inclusion and none of the exclusion criteria, they will review the informed consent document with a member of the research team. After signing the informed consent document, participants will be screened using the post-screening checklist. If participants fail to meet the inclusion or exclusion criteria, their participation will end at that point.

Personal/demographic and anthropometric information will be used to fully characterize the study participants. Demographic factors include characteristics that are independent of the health condition but can potentially influence physical performance and an individual's course of recovery. We will collect multiple variables that have been previously associated with outcomes including race, ethnicity, and education, as well as additional information such as type of musculoskeletal condition, surgical history, current device, and duration of CDO use. Anthropometric and demographic information such as age, biological sex, study limb (left or right), height, weight, leg length, shoe type, shoe length and width. Participant's medical records may be accessed to confirm musculoskeletal condition information.

Patient-reported outcomes questionnaires will be used to evaluate participant pain and comfort. These patient-centric assessments will provide insight that can be used to interpret other study findings. We have used the selected measures in the target population and expect that they will effectively capture device-related outcomes. Participants will complete comfort (0cm, 1cm, 2cm) and pain (NoCDO, 0cm, 1cm, 2cm) questionnaires after walking in the study conditions.

Comfort will be assessed using a modified version of the Socket Comfort Score, a reliable, valid, and sensitive measure of device fit and comfort.[10] 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 publications by the research team.[11] Comfort and smoothness scores range from 0 = most uncomfortable to 10 = most comfortable.[10]

Pain will be assessed using a standard 11-point numerical pain rating scale, in which 0 = no pain and 10 = worst pain imaginable, in a manner consistent with multiple other protocols.[12, 13] Using this highly reliable approach, participants will be asked to rate their pain at the start of each session and during testing for each condition.

Wireless force measurement sensors will be used to measure forces acting within the CDO. Loadpad sensors (Novel GMBH, St. Paul, MN) will be placed in the proximal cuff and Loadsol insoles will be placed in the shoe and in the CDO footplate to measure forces acting on the leg and the foot. The Loadsol system has been found to be accurate, precise, and repeatable in measuring plantar pressures during normal gait.[14, 15] Data will be collected as participants sit, stand, and walk without a brace (NoCDO) and in each of the CDO conditions (0cm, 1cm, 2cm) in a randomized order. A washable, skin-safe, marker will be used to make small marks on the participants leg to ensure the proximal cuff does not move between testing conditions.

Video recordings and pictures of the participants will be collected throughout testing, and participants will be informed as videos or pictures are being recorded. Video recordings will be taken as participants are walking, and the camera will be positioned to the best of the research staff's ability so the top of the field of view will be at the participant's shoulders to minimize the likelihood of capturing the participant's face. Pictures of the participants leg and orthosis will be taken during sitting and standing trials for quality control purposes. Collection of video recordings and standard photos is required during testing for quality control purposes. Files will be stored securely as described in section X.4 and will only be available to members of the research team. Video recordings and pictures will be removed from the camera after being transferred to the secure network drive server and will be retained to facilitate future analysis consistent with "Data Storage for Future Use" section in the informed consent document.

Statistical Analysis Plan

Analysis Methods:

Data quality will be reviewed throughout the course of the study. Continuous measures will be assessed using histograms, and descriptive statistics will be reported in study presentations and publications. A p-value <0.05 will be used to determine significance. Statistical analysis will include a one-way repeated measures analysis of variance (ANOVA) to determine main effects of CDO use and heel clearance (NoCDO/0 cm/1 cm/2 cm). Post-hoc pairwise comparisons will be completed using paired sample t-tests if data is normally distributed, and Wilcoxon Signed Rank tests if data is not normally distributed.

Power Analysis:

There is a lack of information available concerning heel clearance with CDO use. As such, a power analysis was conducted using previously published foot loading data from individuals who have experienced traumatic lower limb injuries walking with (169.3¬ ± 36.4kPa) and without (230.0 ± 47.5kPa) a CDO.[3] Using the reported mean and standard deviations, 12 participants will be required to detect a significant change in foot loading with more than 90% power. To account for participant attrition and the potential for participants to be found ineligible after being enrolled in the study, 20 individuals will be included regulatory submissions. Prior work investigating CDO design characteristics have been adequately powered with similar numbers.

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