Title: Effects of Malleo-Lok Stiffness on Lower Limb Mechanics

NCT Number: 04806100

Date: April 11, 2023

Study Protocol:

Purpose and Procedures:

The primary goal of this line of research is to understand the effects of ankle foot orthosis (AFO) stiffness on gait biomechanics and overall joint level stiffness. An improved understanding of the effects of stiffness on joint and limb mechanics will benefit the future prescription of AFOs.

The primary purpose of this research study is to determine if the stiffness of a commercially available ankle foot orthosis (Malleo-Lok, Bio-Mechanical Composites, Des Moines IA) impacts gait biomechanics and overall joint level stiffness. Previously published research suggests that AFO stiffness can affect gait biomechanics and patient preference. However, previous studies have focused on traditional posterior strut devices with the strut aligned in the frontal plane to allow sagittal plane deflection. The Malleo-Lok is a novel, low-profile carbon fiber device with two laterally positioned struts aligned in the sagittal plane. The proposed study will provide insight that can be used by certified prosthetists orthotists (CPOs), physical therapists, and physicians to select the device that bests meets their patients' needs.

The secondary purpose of this research study is to determine the within session repeatability of a novel approach for in-vivo AFO stiffness testing. AFO stiffness testing is typically performed using mechanical testing systems without accounting for the interaction of the individual and the device. The novel in-vivo AFO stiffness testing approach will be completed twice within the session to evaluate repeatability, and determine if the approach differentiates between NoBrace, compliant AFO, and stiff AFO conditions. Non-invasive, wireless, surface electromyography sensors and retroreflective markers will be placed on the participants lower limb to measure muscle activity and movement, respectively. Force plates embedded in the floor will be used to measure forces on the limb to calculate joint moments. Participants will be given visual feedback to minimize the effects of muscle activity on measured joint stiffness. Participants will stand and sit with their foot (side with the Malleo-Lok AFO) on the force plate embedded in the floor and bring their knee forward over their stationary foot to deflect the device while minimizing muscle activity.

In this study, lower limb stiffness and gait mechanics will be evaluated in healthy, able-bodied adult participants across three conditions; "NoBrace" where participants are asked to walk normally with no bracing, "Stiff" where participants are asked to walk while wearing a Malleo-Lok with stiff struts, "Compliant" where participants are asked to walk while wearing a Malleo-Lok with compliant struts. Testing will occur in a randomized order. Questionnaires will be used to quantify participants' pain and perceived comfort and smoothness during walking. A motion capture system will be used to evaluate walking biomechanics and overall ankle joint level stiffness, allowing for comparisons between conditions. Small reflective markers will be placed on the participant's skin and lower limb forces, and body motion will be assessed using computerized motion capture cameras and force plates in the floor. Muscle activity data will be collected using non-invasive wireless surface electromyography sensors.

Objectives and Specific Aims:

Aim 1: Determine the effect of Malleo-Lok stiffness on lower limb mechanics during gait.
Hypothesis 1.1: We hypothesize that increasing stiffness of the Malleo-Lok will result in decreased ankle range of motion and increased knee flexion during gait.
Hypothesis 1.2: We hypothesize that increasing Malleo-Lok stiffness will results in an earlier, faster center of pressure progression

Aim 2: Determine the effect of Malleo-Lok stiffness on overall joint level stiffness.
Hypothesis 2.1: We hypothesize that measured stiffness will progressively increase between the NoBrace, Compliant and Stiff conditions.

Aim 3. Determine the within-session reliability of a novel in-vivo weight bearing approach to evaluating AFO

stiffness.
Hypothesis 3.1: We expect the novel approach to demonstrate excellent within-session reliability.

Background and Significance:

A1) Ankle foot orthoses (AFOs) are medical devices often used to support the foot and ankle during daily activities. AFO device stiffness can influence the level of support provided and motion at the ankle. There is a general consensus that increasing AFO stiffness decreases overall ankle range of motion[1-3] noticeably reducing peak ankle dorsiflexion[1,2,4-7] and plantarflexion.[1,8] In addition to effects at the ankle, AFO stiffness has been found to affect the knee during gait, with increased stiffness generally resulting in increased knee flexion at initial contact[1] increased peak knee flexion during stance phase[1,3,8,9] and decreased peak knee extension.[1,4] However, previous studies have focused on traditional posterior strut devices with the strut aligned in the frontal plane to allow sagittal plane deflection. The effect of lower profile devices with laterally positioned struts are poorly understood. In this study we will determine if the Malleo-Lok, a novel carbon fiber brace utilizing lateral struts, produces similar effects, and determine the effect of device stiffness.

A2) Although AFO stiffness is known to influence overall device function for some design approaches[1] AFO stiffness has only been loosely measured in the clinical setting[1,10] and is often subjectively chosen for each patient based on certified prosthetist orthotist (CPO) knowledge and prior experience. Multiple research teams have developed and tested methods to quantify AFO stiffness.[11-20] These methods are typically best suited for a research facility and involve a custom mechanical testing system. The testing rigs usually clamp the foot plate of the AFO to a rigid platform and move the proximal cuff[11-15] to quantify AFO stiffness around the anatomic ankle joint center[11,14,19] or the device axis of rotation.[15] Although testing devices have successfully estimated AFO stiffness, they generally fail to take into account the interaction between the device and biological limb. One device was built for use in a clinical space to test AFO stiffness while the patient is wearing their AFO.[16] However, the footplate is once again secured to a rigid platform, which is then rotated about the estimated anatomic ankle joint center to determine the overall limb stiffness while wearing the AFO.[16] This approach does not include the vertical load on the limb that likely influences device-limb interaction during gait. In this study we are testing a novel approach to measuring AFO-limb stiffness about the biologic ankle joint center to better represent the effects of AFOs on limb stiffness during gait.

A3) AFO-limb stiffness testing will use the same motion capture system used to collect gait biomechanics. The ability to collect reliable gait data across sites has been previously demonstrated[21,22] and the same techniques will be applied to this measurement. Muscle activity will be measured using non-invasive surface electromyography sensors on the skin. AFO-limb stiffness will be measured twice during the testing session in order to determine within-session reliability of the novel AFO-limb stiffness testing procedures.

Inclusion Exclusion Criteria:

Patient Inclusion Criteria
- Between the ages of 18 and 45
- 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
- Able to hop without pain
- Able to perform a full squat without pain
- Ability to speak and understand English

Patient Exclusion Criteria
- Diagnosed with a moderate or severe brain injury
- Lower extremity injury resulting in surgery or limiting function for greater than 6 weeks

- Injuries that would limit performance in this study
- History of recurrent ankle sprains or chronic ankle instability
- Diagnosed with a physical or psychological condition that would preclude functional testing (e.g. cardiac condition, clotting disorder, pulmonary condition)
- Uncorrected visual or hearing impairment(s)
- Require use of an assistive device
- Unhealed wounds (cuts/abrasions) that would prevent AFO use
- BMI > 35
- 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

Design and Methods:

We anticipate the study will be completed in one visit. The approximate time to complete study activities is 3-4 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.

Potential participants will answer pre-screening questions as listed on the Pre-Screening Checklist over the phone before scheduling visit one, or in person during the first visit. If they meet all inclusion and exclusion criteria they will be consented to participate. Following consent, subjects will be screened using the post-screening checklist. If subjects fail to meet the inclusion or exclusion criteria, their participation will end at that point.

We will collect anthropometric and demographic information, have participants complete questionnaires concerning pain and comfort and smoothness, and use a motion capture system to investigate effects of ankle orthosis stiffness on gait biomechanics and joint level stiffness. Study participants will undergo an evaluation of characteristics relevant to device design, such as anthropometrics (height, weight, etc.), ankle joint stiffness, and pain, among other factors.

Each participant will be given time to accommodate to the brace prior to collection. Participants will then undergo testing in each study condition (Stiff, Compliant, NoBrace) to determine how orthosis stiffness affects gait biomechanics and overall joint stiffness. We will use well-established techniques to obtain a range of biomechanical data as individuals walk at self-selected and controlled speeds.

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 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, comfort and smoothness. 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.

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.[23] 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.[24] Comfort scores range from 0 = most

uncomfortable to 10 = most comfortable, and from 0 = least smooth to 10 = most smooth.[23]

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.[25,26] Using this highly reliable approach, participants will be asked to rate their pain at the start of each session, and report their pain with movement in the device (if any) during each walking condition.

Ground reaction force and motion capture data will be used to evaluate the motion and loading of the lower limb and CDO devices as participants walk on a level walkway at self-selected speed and a controlled speed based on leg length.[21,27] 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.[21,27] A minimum of three non-collinear reflective markers placed on the skin to minimize skin-bone movement will be used to determine kinematics for the segments of interest (foot, shank, thigh, pelvis, trunk, arms and head). A pointer wand with a rubber tip will be used to identify bony landmarks for segment coordinate system definition. Visual 3D software (C- Motion Inc.) will be used to calculate segment and joint angles and velocities. Force plates imbedded in the floor will capture ground reaction forces. Data from successful trials will be analyzed using Visual-3D software package (C-motion Inc., Germantown, MD).[21] The ability to collect reliable data across sites has been previously demonstrated.[22] Techniques established by Dr. Wilken will be used to assess ankle peak dorsiflexion, joint moments, and power.[21] The movement of the center of pressure (COP), the weighted average location of all ground reaction forces, has been directly related to prosthetic and orthotic device design, function, and participant preference.[24,28-30] The peak velocity of the COP and the time to peak will be determined as a percentage of stance, in a manner consistent with prior work by the research team.[24]

Muscle activity will be measured using non-invasive surface electromyography sensors on the skin. A total of 8 EMG electrodes will be placed on the participant, with 4 on each leg to measure activation of the soleus, tibialis anterior, and medial gastrocnemius and peroneus longus. EMG data will be collected bilaterally in the lower limbs and during normal walking and during in-vivo ankle stiffness testing. Participants will be given visual feedback to minimize the effects of muscle activity on measured joint stiffness. Participants will stand and sit with their foot (side with the Malleo-Lok AFO) on the force plate embedded in the floor and bring their knee forward over their stationary foot to deflect the device while minimizing muscle activity.

Video recordings will be collected during walking trials. Recordings will include walking on the level over ground surface in each condition and at each walking speed. The camera will be positioned so the top of the field of view will be at the shoulders to minimize the likelihood of capturing the participants face, and the files will be stored securely as described in section X.4 and will only be available to members of the research team. Collection of video recordings is required during testing for quality control purposes. Video recordings will be removed from the video 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:

There is one independent variable (IV) in this study, stiffness of the ankle brace (compliant and stiff). All the primary dependent variables (e.g. ankle moments, ankle range of motion, push-off power, ankle joint stiffness) will be evaluated using similar statistical approaches within each group. One-way repeated measure ANOVAs will be used to evaluate the effect of brace stiffness. Paired t-tests with Bonferroni-Holm correction will be used for post-hoc comparisons. Multiple trials will be collected for each condition during in-vivo ankle-CDO stiffness testing. Intraclass correlation coefficients and minimal detectable changes values will be calculated for in-vivo ankle-CDO stiffness between the average measurement for time point 1 and time point 2.

Power Analysis:

The number of participants proposed for this study are consistent with those from prior investigations by Dr. Wilken related to AFO design. Thirteen participants was sufficient to detect differences associated with AFO stiffness in a recent study by Dr. Wilken (PMID: 25193884). A total of 20 participants were included to adequately evaluate reliability in Aim 3.

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