Brief Title: Peak plantar pressures while wearing a carbon fiber off-loading orthoses

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Carbon Fiber Off Loading Orthosis

Research Design and Methods

Model Development: A carbon fiber off-loading ankle foot orthosis will be fabricated for a study team member using the geometry consistent with the clinical standard at Orthotic & Prosthetic Design. The complete carbon fiber off loading orthosis (CFO) consisted of the carbon fiber composite (CFC) strut, leather calf support, and a leather and foam shoe. This representative CFO will serve as a baseline from which a finite element (FE) model will be built. The model will then be altered as desired to determine the effects of variable design characteristics.

First, a computed tomography (CT) scan of the CFO will be completed using a Siemens Biograph 40 scanner (0.71 x 0.71 x 0.60 voxel spacing). Individual structures of the CFO will be segmented and reconstructed in 3D. The CFC strut geometry and material properties are the greatest determining factors in CFO stiffness and mechanical performance and were the basis of the FE model. From the 3D reconstruction, the strut geometry will be traced, extruded, and meshed within Abaqus Explicit FE solver software. Thickness measurements of the strut will be confirmed with caliper measurements at various locations along its profile. Ten caliper measurements will be taken to verify the width of the strut. These measurements will be averaged and the traced profile extruded to the averaged value. Doing will keep the FE mesh consistent with the 3D reconstruction geometry but eliminate small geometric artifacts from segmentation of CT images.

The resulting model will be used in the FE analyses to determine deflection and stress responses of the strut under varied loads and with varied CFC fabrication techniques (i.e. layups). Material properties for the CFC and CFC-to-CFC layer interfaces will be derived from the manufacturer specifications and from prior investigations by our group (REF Zou JRRD 2014). Boundary and loading conditions will be imposed on the model to simulate forces applied during a typical gait cycle. Specifically, the top of the strut will be fixed in place and experimentally derived force data (from the subject for whom the CFO will be fitted) will be applied as a time-varying and location-varying vertical force that moved from the heel to the toe in correspondence with the subject's average ground reaction force trajectory during the stance phase of gait. In this way, stress and deflection throughout the strut will be measured throughout the entire step, from initial contact to toe off. These results will be cross referenced with a simple beam bending equation to confirm accuracy. Deflection of the strut will be measured as an indicator of energy return that can be expected in various CFC layups.

Model Execution / CFO Design Characteristic Perturbation: Preimpregnated CFC (prepreg CFC) is composed of a sheet of single layer carbon fibers embedded in resin. This material comes in two forms; one is unidirectional, in which the fibers of a single layer all follow the same direction, while the other is a 2x2 twill, in which the fibers are interwoven at 90 degree angles from each other, with half the fibers going in one direction and the other half going in the transverse direction. During brace fabrication, layers of CFC are added one at a time in varying directions depending on in which direction strength is needed.

During the course of this award, three CFC layups will be explored. The different layups were chosen after review of manufacturing techniques at Orthotic & Prosthetic Design prior to the award, review of existing literature, review of prior modeling results from our group, and through conversations with the CFC manufacturer. The goal of exploring the three layup schemes was to find the layup that 1) maximized deflection of the brace (i.e. indirect measure of energy return), while simultaneously 2) minimized stress within the brace (i.e. indirect measure of propensity for strut fracture and failure). The three CFC were each modeled with the same geometry (equal length and thickness), boundary conditions, and loading conditions.

> Layup A: Unidirectional fibers, two out of every three layers were oriented along the longitudinal direction while the third layer was oriented in the transverse direction. This pattern was repeated

throughout the layup. The 2x2 twill was used on the very top and bottom layers rotated at a 45 degree angle from the principle axis. (Expectation: Greater strength along longitudinal axis with some strengthening in the transverse direction)

Layup B: 2x2 carbon twill without any rotation between layers. Half the fibers were along the principle axis and the other half 90 degrees to the principle axis. The cross section of this layup had the same strength in the longitudinal direction as it did in the transverse. (Expectation: Strength in both the longitudinal and transverse direction)

Layup C: Unidirectional fibers all in the same direction along the principle axis, meaning all of the fiber strength was oriented in the longitudinal direction. (Expectation: Strength along the principal axis only, no fibers in the transverse direction).

In order to test the results of the FE model, we will create a new brace for the study team member and we will enroll 10 individuals who currently have a Gillette ankle foot orthosis and foot complication related to diabetes. Participants will attend an initial study visit when they will sign a consent and have a mold of their foot taken in order to design carbon fiber off loading brace.

Participant selection, Inclusion and Exclusion Criteria

Inclusion Criteria

1. Daily life includes a minimum of moderate activity level (variable cadence walking)
2. Have a Gillette or carbon off loading orthosis as a result of diabetes related foot impairments
3. Diagnosis of diabetes mellitus and peripheral neuropathy
4. Ability to ambulate in the community (K-level ≥ 2)
5. Age > 21 years

Exclusion Criteria (Must be a no)

1. Unable to ambulate and complete testing required for study participation.
2. Severe foot deformity of the hindfoot or any deformity of the foot with a dislocation resulting in a bony prominence on the plantar/weightbearing surface of the foot.
3. Neurological diseases that affects walking

Data Acquisition:

Participants who meet the inclusion/exclusion criteria will be identified by a member of the research team. A member of the research team will contact the participant to assess interest and schedule for testing. The first visit will begin with a member of the research team reading and explaining the informed consent document to the participant. After informed consent is obtained the research team member will create a mold of the participant's foot. The mold will be used in conjunction with the results from the FE model to create a new brace for the participant to be tested at a later date. The following tests will then be completed during the first visit:

1) Collection of medical and personal information: the participants will provide their and their doctor's contact information as well as medication list, a brief medical history, and information about activities of daily living.
2) Movement analysis: Reflective markers will be placed in various locations on the feet, legs, and body so we can record movements of the foot and leg while walking. We will place pressure sensing insoles into the participant's footwear to measure the amount of pressure when performing the activities listed during the recording. The participant will be recorded with the device or footwear while performing daily activities. The conditions under which they will walk with first will be randomized using a computer program which will generate a random order for the conditions. The recordings will be in a

format in which any information that identifies the participant is removed. The de-identified recording will be stored on a secure server, in a secured area behind locked doors. Only study personnel will have access to these computer files.

3) Questionnaires: Foot and Ankle Ability Measure and Quebec User Evaluation of Satisfaction with Assistive technology 2.0 questionnaire (asks questions about use, comfort, effectiveness, and professional services). The participant is free to skip any questions that they prefer not to answer.
4) Plantar pressure testing: the participant will be asked to walk across a surface barefoot. This test will occur during one of the study visits and will take place at 509 S. Euclid, Suite 216. St. Louis, MO. 63110 in the Applied Kinesiology Lab.
5) Neuropathy Assessment: Foot sensation will be measured using a monofilament and a biothesiometer. Monofilaments are similar to fishing line of different thicknesses, and will be placed on the bottom of the foot to test if the participant feels it touching the skin. A biothesiometer is a vibrating wand that will be placed on the bottom of the foot to test if the participant feels it.

Following the first visit, a new CFO will be fabricated based on the mold and on results from a FE model. The participant will pick up the orthosis at the offices of Orthotic and Prosthetic Design. The orthosis will be examined and modified for comfort. The participant will then wear the brace from 1 week. If the brace is causing discomfort or pain during this week the participant may return to have it modified. The participant will return to O & P Design after a week. If necessary, the brace will be adjusted to avoid any rubbing on the foot or ankle. The participant will then continue to wear the orthosis and can return to O & P Design at any time to have the brace examined and modified for comfort. Once the participant has worn the brace for two consecutive weeks with no issue, they will return to complete tests 1-5.

Statistical Analyses:

A repeated measures ANOVA will be used to test for differences of the primary measure of peak plantar pressure at the forefoot, midfoot, and heel during walking while the participants are barefoot, wearing the CFO consistent with current clinical standards, and wearing the new CFO fabricated based on the results of the FE model. Statistical significance was set at $p < 0.05$.