Title: PRMRP FPA: Iterative design of Custom Dynamic Orthoses to reduce articular contact stress

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Study Protocol:

Purpose and Procedures:

The primary purpose of this line of research is to investigate the effects of custom carbon fiber dynamic ankle foot orthosis (CDO) design on the forces and articular contact stress at the ankle in order to reduce the development of post traumatic osteoarthritis in the ankle, which often occurs following severe ankle injury. The proposed study will provide evidence that can be used by certified prosthetists orthotists (CPOs) and physicians when choosing the CDO design with the goal of offloading the ankle and reducing contact stress.

In this research study, adult participants who have sustained a traumatic ankle fracture of the tibial pilon in the last five years will be fit with a CDO(s) with different designs. Each participant will be evaluated using a series of study measures under each of the three bracing conditions in a randomized order (CDO-A, CDO-B, CDO-C) as well as when they are not wearing any device (NoCDO). Physical performance measures will incorporate tests of agility, speed, and lower limb power to ensure that the device design changes don't negatively affect physical function. Questionnaires will be used to evaluate participants' current and desired activity level, pain with and without CDO use, satisfaction with the devices, perception of comfort and smoothness between devices, and preference between CDO designs. Semi-structured interviews will be completed to fully capture the perspective of the participant. A motion capture system will be used to evaluate walking biomechanics, allowing for comparisons between conditions, by use of computerized motion capture and force plates in the floor, as individuals walk at a self-selected and a controlled speed based on leg length. Force measuring sensors will be used to assess forces acting within the CDO. Muscle activity data will be collected using DELSYS EMG sensors. We will also complete mechanical testing of the devices and collect demographic and anthropometric data about the participant and the CDO(s).

Objectives and Specific Aims:

Aim 1: Determine the effect of CDO design modifications on ankle contact stress.

Aim 2: Determine the effect of CDO design modifications on physical function and gait biomechanics.

Background and Significance:

Post-traumatic osteo-arthritis (PTOA) is a significant problem caused by chronic, increased, contact stress and fracture severity. Surgical fracture reduction has been the mainstay of intra-articular fracture (IAF) treatment for decades, but it is not the only factor influencing joint contact stresses. Furthermore, even with the best surgical effort, there often remains residual incongruity that leads to elevated contact stress. Recent advances in bracing provide an attractive complementary treatment solution. CDOs have been used to dramatically improve function and reduce pain in hundreds of service members with traumatic limb injury [6-10]. CDOs are comprised of a proximal cuff sitting just below the knee, a posterior strut used to store and return energy, a semi-rigid foot plate, and a heel cushion between the footplate and shoe [11]. These components can be varied to influence the forces and motions experienced by the limb [11-14], which in turn influence the forces on the foot and the activation of muscles that cross the ankle [8, 15, 16]. Recent findings indicate that this can decrease load transfer across the ankle, which implies that CDOs may be able to be effectively tuned to reduce articular contact stress.

Inclusion/Exclusion Criteria:

Tibial pilon fracture participants:

Inclusion Criteria

- Between the ages of 18 and 65
- Sustained unilateral fracture of the tibial pilon within the preceding 5 years
- The fracture has completely healed
- Ability to walk 50 feet without use of an assistive device (cane, crutch, etc.)
- Ability to walk at a slow to moderate pace

- Shoe size between women's 8 and 13.5 or men's 6.5 and 13

- Ability to read and write in English and provide written informed consent

- Individuals with elevated contact stress according to model generated using standing CT images (will be answered after completing visit one)

Exclusion Criteria

- Pain > 6/10 while walking

- Increase in pain during testing of 3/10 or greater

- Neurologic, musculoskeletal (including bilateral fractures) or other condition limiting function of the contralateral extremity

- Medical or psychological condition that would preclude functional testing (ex. moderate or severe brain injury, stroke, heart disease)

- Wounds to the calf that would prevent CDO fitting

- Fractures secondary to neuropathy or severe osteopenia

- Classification as non-ambulatory

- Previous fractures near the tibial pilon on the involved limb

- Surgery on involved limb anticipated in the next 6 months

- Requirement of a knee stabilizing device (i.e. KAFO, KO…) to perform daily activities

- Visual or hearing impairments that limit walking ability or limit the ability to comply with instructions given during testing

- BMI greater than 40

- Pregnancy

Healthy able-bodied participants:

Inclusion Criteria

- Between the ages of 18 and 65

- Shoe size between women's 8 and 13.5 or men's 6.5 and 13

- Healthy individuals without a current complaint of lower extremity pain, spine pain, or medical or neuromusculoskeletal disorders that have limited participation in work or exercise in the last 6 months

- Full active range of motion of the bilateral lower extremities and spine

- Ability to hop without pain

- Ability to perform a full squat without pain

- Ability to read and write in English and provide written informed consent

Exclusion Criteria

- Diagnosed moderate or severe brain injury

- Prior lower extremity injury resulting in surgery or limiting function for greater than 6 weeks

- Diagnosis of a physical or psychological condition that would preclude testing (e.g. cardiac condition, clotting disorder, pulmonary condition)

- Visual or hearing impairment that would interfere with instructions given during testing

- Require an assistive device
- Wounds to the foot or calf that would prevent CDO use
- BMI greater than 40
- Pregnancy

Design and Methods:

Personal/demographic and anthropometric information will be used to fully characterize the study participants (race, ethnicity, education, date and mechanism of injury, injury characteristics, surgical history, current device (if any), age, biological sex, study limb (left or right), height, weight, leg length, shoe type, shoe length and width).

Physical performance measures provide an objective and responsive assessment of an individual's functional mobility. The four square step test (4SST) is a standardized and widely used test of balance and agility where a 1-inch pipe is placed on the floor in the shape of a Maltese cross. The patient is instructed to begin in the back-left quadrant then to move 1) forward, 2) sideways right, 3) backward, then 4) sideways left, then to move in the reverse direction back to the original quadrant. The sit to stand 5 times (STS5) test is a well-established measure of lower limb muscle strength, endurance, and mobility where patients are instructed to start the test sitting with their arms folded across their chest and with their back against a standard chair. Patients are then instructed to stand up and sit down 5 times as fast as possible, avoiding touching their back to the chair during each repetition.

Patient-reported outcomes questionnaires will be used to evaluate participant physical function, activity level, pain, comfort, satisfaction, and preference in addition to multiple other relevant outcomes. The Orthotics Prosthetics Users' Survey (OPUS) is a leading measure for evaluating satisfaction with orthotic devices and services will be used to evaluate device comfort, form, and fit. Comfort and smoothness will also be assessed using a modified version of the Socket Comfort Score where comfort scores range from 0 = most uncomfortable to 10 = most comfortable, and from 0 = least smooth to 10 = most smooth. Pain will be assessed using a standard 11-point numerical pain rating scale, in which 0 = no pain and 10 = worst pain imaginable at the start of each session, and at multiple points while walking in each condition. Participants will be asked to rate the three brace designs (CDO-A, CDO-B, and CDO-C) on a standard 11-point scale, where 0 = worst imaginable device and 10 = best imaginable device, upon completion of their final testing session. The University of California, Los Angeles (UCLA) activity score is a 10-level rating scale that is used to both qualitatively and quantitatively define an individual's current and/or desired level of activity. The Patient Reported Outcomes Measurement Information System (PROMIS) will be used to evaluate physical function. Semi-structured interviews will also be used to fully capture the patients' perspectives, experience, and opinions associated with the device options they experienced as part of the study.

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 an over ground walkway at self-selected speed and a controlled speed based on leg length. Retro-reflective markers will track the position and orientation of body segments and force plates imbedded in the floor will capture ground reaction forces. Muscle activity will be measured using DELSYS EMG sensors bilaterally for the soleus, tibialis anterior, medial gastrocnemius, rectus femoris, gluteus medius, biceps femoris, and vastus medialis muscles.

Force measurement sensors will be used to measure forces acting within the CDO. For group three, Loadpad sensors (Novel GMBH, St. Paul, MN) will be placed within the proximal cuff to measure how tightly the proximal cuff is fastened. In-shoe plantar pressure distribution will be measured using the LoadSol system (Novel GMBH, St. Paul, MN) during over ground trials for all groups.

Statistical Analysis Plan:

Analysis Methods:

The distributions of study measures will be characterized using descriptive statistics. 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.

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 were sufficient to detect differences associated with AFO stiffness in a recent study by Dr. Wilken (PMID: 25193884).

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