Official Title: Effects of a Hands Free Crutch on Walking Stability During Gait
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Hands Free Crutch

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Describe EACH of your subject populations

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***

Healthy able bodied adults.

Subject Inclusion Criteria:
-Male or Female
-Ages: 18 - 45
-Height between 5'2" and 6'6"
-Foot size that corresponds to available walking boots
-Healthy individuals without current complaint of lower extremity pain, spine pain, open wounds or active infection
-Full active pain free range of motion of the bilateral upper and lower extremities and spine
-Able to hop without pain
-Able to perform a full squat without pain
-Able to walk up and down a flight of stairs at normal walking speed without using the hand rail
-Able to stand on one leg for at least 30 seconds
-Able to read and write in English and provide written informed consent

Subject Exclusion Criteria:
-Weight greater than 270 lbs
-BMI greater than 35
-Maximum thigh circumference at top of the leg greater than 28"
-Prior medical or neuromusculoskeletal disorders that have limited their participation in work or exercise in the last 6 months
-Prior lower extremity injury proximal to the ankle requiring surgery or limiting function for greater than 6 weeks
-Prior back pain that recurs or has limited activities for greater than 6 weeks
-Diagnosed moderate or severe brain injury
-Diagnosis of a physical or psychological condition that would preclude testing (e.g. cardiac condition, clotting disorder, pulmonary condition)
-Uncorrected visual or hearing impairment(s)
-Require use of an assistive device
-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of pregnant individuals, and resulting inability to account for its effect on resulting outcomes, participants will be withdrawn from the study

Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

We anticipate the study will be completed in five sessions, with four biomechanical data collection sessions. The first session will require approximately one hour and each of the subsequent sessions will take approximately 2 hours each, for an approximate total of 9 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 in each session 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 balance confidence and patient preference, and use a motion capture system to investigate effects of assistive device on walking stability, balance, and gait biomechanics.

Each participant will be given one overnight period to accommodate to the boot, SAC or HFC prior to collection. Participants will then undergo testing in each study condition (BOOT, HFC + BOOT/HFC NO BOOT, SAC +BOOT/SAC NO BOOT, and NONE) to determine how the boot and/or the assistive device affects stability through whole body or segmental angular momentum and gait biomechanics. We will use well-established techniques to obtain a range of biomechanical gait data as individuals walk at self-selected and a controlled speed.

Personal/demographic and anthropometric information (e.g. age, biological sex, height, weight, leg length, shoe type, shoe length and width) 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.

Self-reported outcomes questionnaires will be used to evaluate participant balance confidence and device preference. These participant-centric assessments will provide insight that can be used to interpret other study findings. We have used the selected measures previously and expect that they will effectively capture device-related outcomes. Balance confidence will be assessed using the Activity-specific Balance Confidence (ABC) Scale, a reliable, valid, and sensitive self-reported assessment of balance. Device preference and device comfort will be assessed using standardized questionnaires, in a manner consistent with multiple other protocols. Participants will also report maximum pain with movement with use of the assistive devices on an 11 point numerical pain rating scale, in which 0 is no pain and 10 is the worst imaginable pain, consistent with other protocols and literature.

Techniques established and previously reported by Dr. Wilken will be used to collect gait biomechanics data. Ground reaction force and motion capture data will be used to characterize the motion and loading of the lower limb and assistive devices as participants walk on a level walkway at self-selected speed and a controlled speed based on leg length. 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. 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 walking trials will be analyzed using Visual-3D software package (C-motion Inc., Germantown, MD).

Five total sessions, with four sessions including biomechanical data collection, are required for completion of this study. Participants will be contacted via phone or email that they provided during study enrollment. Three attempts will be made to contact each participant for each data collection session if they fail to attend data collection session(s).

Data and recordings will be stored on a password restricted drive that only authorized individuals have access to. They may be retained indefinitely for the purposes of evaluating data quality.

Describe the analysis methods you will use, including, if applicable, the variables you will analyze

AIM1

There are four conditions in this study Aim, 1) BOOT, 2) HFC + BOOT, 3) SAC + BOOT and 4) NONE. Between condition statistical comparisons for each hypothesis will be conducted in a similar manner for each dependent measure (e.g. whole body angular momentum and segmental angular momentum in all three planes: sagittal, frontal, and transverse). H1.1. Paired t-test will be used to compare the HFC + BOOT and SAC + BOOT conditions. H1.2. One-way repeated measure ANOVAs will be used to test for a condition effect across the 4 conditions: 1) BOOT, 2) HFC + BOOT, 3) SAC + BOOT and 4) NONE. Paired t-tests with Bonferroni-Holm correction will be used for post-hoc comparisons.

AIM2
H2.1 A one-way repeated measures ANOVA will be used to test for a condition effect across the 4 conditions (1) BOOT, 2) HFC + BOOT, 3) SAC + BOOT and 4) NONE) on self-reported balance confidence using the ABC scale. Paired t-tests with Bonferroni-Holm correction will be used for post-hoc comparisons. H2.2 Paired t-tests will be used to assess participant device preference between 2) HFC + BOOT and 3) SAC + BOOT for: the device numerical scale (0-10), the device comfort scale, and the numeric pain rating scale (0-10).

AIM 3
H3.1 Two-way repeated measures ANOVAs will be used to test for main, and interaction effects across the 6 conditions for the primary dependent measures:
1) BOOT, 2) HFC + BOOT, 3) SAC + BOOT
4) NONE, 5) HFC NO BOOT, 6) SAC NO BOOT
Paired t-tests with Bonferroni-Holm correction will be used for post-hoc comparisons.

Provide the rationale or power analysis to support the number of subjects proposed to complete this study.

The number of participants proposed for this study are consistent with those from prior investigations by Dr. Wilken using angular momentum, which range from 10 to 30 participants. A total of 30 participants were included for this study due to the expected differences associated with the different mechanics of SAC and HFC use, along with the potential for post-consent screen failure, participant dropout in this study requiring repeat visits, or lost/missing data.

Literature cited / references (if attaching a grant or protocol enter N/A).

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2. Kaye HS, Kang T and LaPlante MP. Mobility device use in the United States. In: Education USDo, (ed.). San Francisco, California 2000.
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4. Dalton A, Maxwell D, Kreder HJ, et al. Prospective Clinical Evaluation Comparing Standard Axillary Crutches vs. the HANDS FREE Crutch. University of Toronto.
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8. Lim GA and MacLeod TD. Comparison of subjective and physical function outcomes using axillary crutches and a "HANDS-FREE CRUTCH" in comparison to no crutch, for mobility. California State University.