Partners Human Research Committee
Detailed Protocol
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Project: A Randomized Controlled Trial: EVENup Orthotic Shoe Lift Intervention during CAM Walker Boot Treatment of Nonoperative Ankle Fractures

I. Background and Significance

A variety of foot and ankle injuries can be treated effectively through the use of a controlled ankle movement (CAM) walker boot.[1–5] CAM walker boots protect the injured area by restricting foot and ankle motion, providing a stable platform to distribute forces while bearing weight, and allowing the user to rollover the foot during ambulation because of a rocker bottom-shaped sole.[6] Such qualities lend the CAM walker boot to provide ankle support that can be advantageous compared with other commonly used methods.[7] Despite their utility, CAM walker boots create a simulated leg-length discrepancy (LLD)[6], which can result in altered biomechanics during ambulation.[8,9] Additionally, a LLD can be associated with lower back and joint pain.[10]

We have previously conducted a study that suggests a relationship exists between CAM walker boot treatment and pain at sites other than the extremity being treated.[6] There have been several randomized controlled trials (RCTs) examining a relationship between the correction of inherent LLD with insole inserts and lower back pain.[11,12] Furthermore, there has been a past RCT[13] and there is a current RCT[14] examining a relationship between the use of the EVENup orthotic shoe lift[15] to correct CAM walker boot simulated LLD and pain at sites other than the extremity being treated. However, these studies were not conducted with patient populations with uniform injuries. To the best of our knowledge, an RCT has not been conducted with the EVENup orthotic shoe lift to examine this relationship in a uniform patient population with nonoperative ankle fractures. This RCT aims to assess the efficacy of the EVENup orthotic shoe lift, towards reducing and even preventing such pain that may be associated with this common course of treatment.

II. Specific Aims

Controlled ankle movement (CAM) walker boot treatment may result in contralateral and ipsilateral lower extremity and lower back pain, due to creating a simulated leg-length discrepancy (LLD). We hypothesize that intervention with the EVENup orthotic shoe lift may prevent or reduce the intensity of pain that can occur during and persist after the course CAM walker boot treatment. We will address our hypothesis through completing the aims listed below:

AIM 1. Prospectively identify and enroll a population of patients with nonoperative ankle fractures that require CAM walker boot treatment in an RCT at Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, BWH/MGH Health Care Center at Foxborough, 850 Boylston, and 100 Brigham Way. Patients assigned to Group I, the

control group, will receive standard-of-care treatment with a CAM walker boot. Patients assigned to Group II, the intervention group, will wear an EVENup orthotic shoe lift on the contralateral foot, in addition to receiving standard-of-care treatment with a CAM walker boot for the ankle fracture.

AIM 2. Evaluate the differences in pain that are experienced by patients in the two groups. The pain explored will include that experienced as contralateral or ipsilateral lower extremity joint pain or low back pain while wearing a CAM walker boot, as well as pain that persists at these secondary sites, following the termination of CAM walker boot treatment.

III. Subject Selection

Pending approval from the Institutional Review Board (IRB) and patient informed consent, we will prospectively identify 100 patients with a nonoperative ankle fracture that necessitates treatment with a CAM walker boot during clinic at Brigham and Women's Hospital, Brigham and Women's Faulkner Hospital, BWH/MGH Health Care Center at Foxborough, 850 Boylston, and 100 Brigham Way.

All patients enrolled in the study must have an injury that requires wear of a CAM walker boot for at least six weeks and have ambulation ad libitum without other aids (e.g. crutches, canes, scooters, wheelchairs, etc.). Patients will be excluded from the study if they are a recent post-operative patient for lower extremity injury, have an additional acute injury to a lower extremity or back other than the foot or ankle injury being treated by the CAM walker boot at the time of initiation of treatment, have an ongoing or history of lower extremity joint injury, arthritis, or back pain or have restricted weightbearing as instructed by a physician (i.e. for ankle fracture that cannot weight bear). Additionally, pregnant women and non-English speaking patients will not be eligible for this study.

IV. Subject Enrollment

Subjects will be included in this study if they are eligible to receive treatment with a CAM walker boot for a nonoperative ankle fracture, for a period of at least six weeks. Once the patient is deemed eligible for the study because of their injury, the physician will ask if the patient is interested in hearing more regarding the research study we are conducting. If the patient agrees, the study staff will explain in depth the study aims and protocol during the office visit. At this time, the study staff will consent the patient, and it will be made clear that the patient will be able to rescind their participation at any time during the study for any reason, and that this will not impact their continued care at the Brigham Foot and Ankle Clinic. Brigham Foot and Ankle physicians will be available for any additional questions if needed. The study staff will stress that the study is voluntary, provide all information regarding alternate treatment options, and remind patients that even if they do consent, they will have the opportunity to withdraw participation at any time for any reason. Any subjects who agree to participate will then be asked to fill out questionnaires as a means to obtain initial data.

All patients who consent will be randomly divided into two equal sized groups (n=50) — Group I and Group II. We will randomize our patients using a random number generator. Group I will be randomized to receive CAM walker boot treatment and Group II will receive CAM walker boot treatment with the EVENup orthotic shoe lift as an intervention. Cross-over will not be explicitly offered between the groups, but if participants in Group I utilize an orthotic shoe lift of their own volition, this will be documented. All participants will be evaluated using an intention-to-treat (ITT) approach, where each subject will be analyzed according to their randomization assignment, regardless of actual treatment received.

V. Study Procedures

Initial Visits:

Initial data taken for all patients at the time of enrollment will include demographics (age, sex, race, medical co-morbidities, medications, BMI, smoking history), injury or diagnosis being treated, history of lower extremity pain or low back pain (i.e. hip, knee, back pain), history of lower extremity or low back surgery or injury (i.e. hip or knee replacement, prior fracture) and functional outcome scores using the following surveys:

- Foot and Ankle Ability Measure (FAAM) pertaining to the injured foot or ankle
- Visual Analog Scale (VAS) of pain for each lower extremity joint or low back (low back, right / left hip, knee, ankle, foot, other)

Patients in Group I will be assigned to receive a course of CAM walker boot treatment for a period of six weeks.

Patients in Group II will be assigned to receive a course of CAM walker boot treatment with an EVENup orthotic shoe lift to be worn on the contralateral foot for a period of six weeks.

The opportunity for crossover from Group I to Group II will be permitted if patients develop severe pain. These patients can attempt to remediate their pain by using an EVENup orthotic shoe lift, which are readily available for their purchase in a variety of settings.

Follow Up Assessments:

With regard to clinic visits, all patients in Groups I and II will be seen in the clinic at six weeks to assess the outcomes of the prescribed treatments. Visits will occur at any of the previously mentioned clinic sites. If the fracture has not completely healed, previously prescribed treatment may be extended until healing has been deemed achieved at subsequent follow up visits. Total duration of the prescribed treatment will be recorded for each patient. Additionally, alternative treatment options may be utilized at the physician's discretion if healing has not been achieved with a CAM walker boot. This cohort of patients will not further progress in the study.

Outcomes:
Outcomes for both Group I and Group II will be taken at initiation of boot wear, at six weeks after initiation of the boot, at twelve weeks after initiation of the boot, and at twenty-four weeks after initation of the boot. We will use the following surveys to measure the outcomes of our patients:

- Foot and Ankle Ability Measure (FAAM) pertaining to the injured foot or ankle
- VAS of pain for each lower extremity joint or low back (low back, right / left hip, knee, ankle, foot, other)

Initial data and all outcome scores will be obtained from subjects using the web-based Partners affiliated Research Electronic Data Capture (REDCap) (Vanderbilt University, Nashville, TN). Use of REDcap will either be done in person on Partners approved devices with the guidance of study staff, or from home using an email-based system of delivery. The latter will require the obtaining of email addresses from subjects and the sending of encrypted study materials securely with the 'send secure' function. Participants can also receive unencrypted emails if they acknowledge the risks, and that Partners will not be held responsible.

VI. Biostatistical Analysis

We will prospectively identify patients who have been diagnosed with nonoperative ankle fractures that require CAM walker boot treatment, at the previously stated clinic sites. Through a one-sided power analysis, with an alpha = 0.05 and 80% power, we determined that a minimum of 42 participants would be need to be enrolled in each group to detect a 40% reduction in CAM walker-boot associated pain, compared with a previously reported occurrence of associated pain in 67% of patients.[6] For this reason, we aim to enroll 100 patients in this study, with 50 patients in each of the two arms. Any patients over the age of 18, regardless of gender or ethnicity, who fit the previously stated criteria will be recruited. The study will end after 100 subjects are enrolled.

The primary outcome measurements will be the change in VAS of pain at secondary sites and FAAM from the start of prescribed treatment to six weeks after initiation of bootwear. Our secondary outcome measurements will be the change VAS of pain at secondary sites and FAAM at twelve weeks after initiation of the boot, and at twenty four weeks after initiation of the boot. We will use an ITT approach, where each subject will be analyzed according to their randomization assignment, regardless of actual treatment received. We will use a t-test to compare change in outcome measurements between the two arms.

Patient responses to the VAS and FAAM forms will be collected via REDCap. All statistical analysis and data accumulation will be performed using Microsoft Excel (Microsoft Corporation, Redmond, WA). This includes means, ranges, SD and percentiles.

VII. Risks and Discomforts

Risks to the subject are very minimal. Because this is a prospective study, there is a risk of noncompliance by the patients, for which reason patient cooperation is important. Risks of CAM walker boot wear include the potential for delayed recovery and/or re-injury. There is also previously reported risk of CAM walker boot-associated pain[6], which we aim to study the reduction or elimination of in this RCT. Additionally, the EVENup orthotic shoe lift increases the elevation of the foot contralateral to the CAM walker boot, although this should not impart any additional risk to patients.

VIII. Potential Benefits

There is no additional benefit to participants in Group I, as they will receive the standard course of CAM walker boot treatment. Potential benefits for participants in Group II include the reduction or prevention of the occurrence of pain, particularly contralateral or ipsilateral lower extremity joint pain or low back pain, due to the simulated LLD compensation provided by the EVENup orthotic shoe lift. If a clinically significant difference is found to exist between treatment arms within this study, these results will guide our future clinical practice in recommending orthotic shoe lifts to patients receiving CAM walker boot treatment.

IX. Monitoring and Quality

The study is not expected to affect the safety of any subjects involved. In order to ensure the safety of subjects, the principal investigator will review all outcome data at the standard follow-up visits and record any adverse events. If adverse events occur, the principal investigator will review the reasonable cause for the event and determine if the research should be altered or stopped.

All data will be collected, viewed, recorded, and analyzed only by study staff listed. The VAS and FAAM measures that the patients will complete at initial visit, six weeks after initiation of the boot, twelve weeks after initiation of the boot, and twenty-four weeks after initiation of the boot data will be recorded in the REDCap database and will be stored on password-protected Partners computers. Only study staff will have access to the digital database.

X. References

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