Official Title: Randomized-controlled trial of an orthotic designed to equalize leg lengths for patients using a controlled ankle movement boot

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Study Protocol:

Background and purpose

Patients with foot and ankle injuries are often made weight-bearing as tolerated (WBAT) in a controlled ankle movement (CAM) boot at some point during their recovery and rehabilitation period. While WBAT in a CAM boot, patients often experience an asymmetric gait associated with the effective leg length discrepancy between the booted extremity (longer) and the contralateral extremity with a regular shoe (shorter). This asymmetry may cause balance problems or place strain on the patient's joints resulting in back, knee, and hip pain.

An orthotic has been designed that is added to the outside of a regular shoe in order to eliminate the effective leg length discrepancy between the booted extremity and the contralateral limb. Although this specific orthotic has not been studied, some proof of concept lies in studies that show that back pain can be managed with foot orthotics. The purpose of this study is to determine if using the leg-length-evening orthotic can improve balance and/or decrease the development of pain in the lower extremities and spine for patients who are WBAT in a CAM boot.

Inclusion criteria

1. Age at least 18 years old
2. Patients who are newly made WBAT in a CAM boot for at least two weeks

Exclusion criteria

1. Patient refuses.
2. Patient is incarcerated, incapacitated, or otherwise unable to provide appropriate informed consent.

Methods

This will be a randomized-controlled study in which eligible patients will be randomized to either the leg-length-equalizing orthotic intervention group or to a control group. At the end of a two-week period of immobilization, patients will receive a phone call and will be asked the following questions:

Over these last two weeks while walking in the CAM boot:

- How would you say your balance has been when walking (where 0 is terrible balance where you are falling all the time and 10 is perfect balance where you feel completely stable)?
- How many times have you tripped or stumbled?
- How many times have you fallen to the ground?
- How much pain were you having in your knees on a scale of 0-10 (where 0 is no pain and 10 is severe pain)?
- How much pain were you having in your hips on a scale of 0-10 (where 0 is no pain and 10 is severe pain)?

- How much pain were you having in your back/spine on a scale of 0-10 (where 0 is no pain and 10 is severe pain)?

Statistical Analysis

Statistical analyses were conducted in Stata Version 16.0 ® (College Station, TX, USA). Both intention-to-treat and as-treated analyses were conducted for all comparisons. T-tests (for continuous variables), Pearson's chi-squared tests (for categorical variables with expected cell counts ≥5), and Fisher's exact tests (for categorical variables with expected cell counts <5) were used to compare baseline demographics. Balance (primary outcome), pain, the numbers of trips and falls, and the number of feet walked per day were compared using the Wilcoxon rank-sum test (equivalent to the Mann-Whitney U test), as these were considered to be non-normally distributed variables. The level of significance was set at $p< 0.05$.

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Title of Study:	**Randomized-controlled trial of an orthotic designed to equalize leg lengths for patients using a controlled ankle movement boot**
Sponsor:	***Orthopedic Department***

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you will be wearing a controlled ankle movement (CAM) boot.

What is the purpose of this study?

The purpose of this study is to determine if a leg-length orthotic device that evens the walking plane to improve balance and decrease the development of pain in the back, knees, or hips while wearing the CAM boot.

How many study subjects are expected to take part in the study?

This study is open to both males and females, 18 years old and older who just progressed to a CAM boot for treatment. If you agree to participate in this study, you will be one of approximately 94 subjects enrolled at Rush University Medical Center.

What will you be asked to do?

If you decide to be a part of this study, you will be a part in one of two groups:

1. One group will wear the CAM boot on the injured leg and a normal shoe on the other leg.
2. Second group will wear the CAM boot on the injured leg and a leg-length-evening orthotic on the other leg. 40% of the subjects will be randomized into this group.

After a two-week period of wearing the CAM boot, both groups will receive a phone call and will be asked the following questions:

Over these last two weeks while walking in the CAM boot:

- How would you say your balance has been when walking (where 0 is terrible balance where you are falling all the time and 10 is perfect balance where you feel completely stable)?
- How many times have you tripped or stumbled?
- How many times have you fallen to the ground?
- How much pain were you having in your knees on a scale of 0-10 (where 0 is no pain and 10 is severe pain)?
- How much pain were you having in your hips on a scale of 0-10 (where 0 is no pain and 10 is severe pain)?
- How much pain were you having in your back/spine on a scale of 0-10 (where 0 is no pain and 10 is severe pain)?

How long will you be in the study?

The study will only require a single phone call after the two-week period.

What are the possible risks of the study?

The risks are similar to standard of care associated with the condition or injury you are being treated for.

Are there benefits to taking part in the study?

Subjects assigned to the group that uses the orthotic will receive the orthotic free of charge. Both groups will receive the phone call following the two-week period of wearing the CAM boot to provide an additional touchpoint of care.

What other options are there?

The only alternative to participating in this study is not to participate.

What about confidentiality of your information?

Records of participation in this study will be maintained and kept confidential as required by law. If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as clinical visits, surgery and any tests associated with these visits will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this study.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: **Kamran Hamid, MD at (312) 243-4244.** Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

Signature of Witness	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.