Does Specialized Footwear or an Ankle Brace Reduce Pain and Improve Mobility for People with Ankle Arthritis?

We are inviting you to be in a research study. The purpose of this Consent Form is to give you the information you will need to help you decide whether to be in the study. Please read this form carefully.

You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear.

Your participation in this study is entirely voluntary. Please take as much time as you need to discuss the study with your doctors, family, and friends. The decision to participate or not is yours. If you choose to participate, you have the right to withdraw from the study at any time.

Principal Investigators
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William Ledoux, PhD
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Study Title:
Do Rocker Bottom Shoes and Ankle-Foot Orthoses Reduce Pain and Improve Mobility for Ankle Osteoarthritis Patients?

This study is being conducted by the Center for Limb Loss and MoBility (CLIMB) through a grant from the Department of Veterans Affairs.

1. Who can I contact with questions while I am in this research study?

During business hours (8:00 a.m. – 4:30 p.m.):
Study contact: 206-764-2991

After business hours (nights and weekends):
Study Contact: 206-764-2991

If you are experiencing a medical emergency, call 911 or go to the emergency room.

The study researcher(s) listed above must be contacted immediately if:
- You think you may have been harmed or injured as a direct result of this research.
- You have any questions regarding your study related medical care issues.

You may also contact the Institutional Review Board (IRB) at (206) 277-1715 if you:
- Would like to speak with a neutral party who is not involved with this study.
- Have questions, concerns, or complaints about the research.
- Would like to verify the validity of the study.
- Have questions about your rights as a research subject.

2. What is the purpose of this research study?

Ankle osteoarthritis (OA) is a painful, progressive condition that can severely limit physical activity and reduce quality of life. Rocker-bottom (RB) shoes (with front-to-back curved soles) and ankle-foot orthoses

(AFOs) (a type of ankle brace) are common non-surgical treatments to manage ankle OA, but their ability to reduce pain and increase mobility has not been fully evaluated. The purpose of this study is to evaluate the ability of RB shoes and AFOs to improve mobility by alleviating pain and reducing joint motion when compared to a standard shoe.

We will approach people with ankle OA and people who do not have foot and ankle pain about this study. We hope to enroll up to 100 people with ankle OA and up to 50 people who do not have foot and ankle pain in this study. We may approach up to 3,000 people about this study if needed.

All procedures in this study are research related and provide no clinical treatment.

3. What will I be asked to do in this research study?

Visits and length of participation

- **Study Group 4: Three month study (remote)**
  Your participation will occur over 3 months. During this time period, we will ask you to do four sets of assessments and three periods (3 weeks each) of wearing study-provided footwear during your normal daily activities. The assessments may include the following assessments: demographics, anthropometrics, brief pain rating, questionnaires, and qualitative questions. Detailed descriptions of these activities are described below. In addition, we will ask you to wear a StepWatch Activity Monitor (a step counter) and to do brief daily and weekly pain ratings and ask you about any pain medications you took for the pain over the course of the entire study.

Assessement 1 (up to 4 hours)

To confirm that you are eligible to be in this study, we may ask you some questions about your medical history related to your foot and ankle and your ability to walk.

Female participants: If you are pregnant, you cannot participate in this study.

The following procedures may be performed during this visit and over the course of the study:

- **Demographics:** We will ask you some questions, such as your age, race, ethnicity, Veteran status, and previous and current health.
- **Anthropometrics:** We will ask you to tell us your weight, waist circumfrence, and height
- **Brief Pain Rating:** We may ask you to rate (on a scale of 1-10) what your pain level is now, what your average pain level was this week, and what your maximum pain level was this week.
- **Daily Pain Rating and Pain Medication Use:** We may ask you to rate (on a scale of 1-10) what your pain level is now, what your average pain level was in the past 24 hours, and what your maximum pain level was in the past 24 hours. We may also ask you what, if any, pain medication you took.
- **Questionnaires:** We may ask you to complete some questionnaires about your ankle pain and physical functions. The questionnaires may be answered on a tablet, paper, and/or in an interview format.

- **Qualitative questions:** We will ask you several questions about the study-provided footwear, such as whether or not you liked it (and why) and if you would wear it if you were not part of this study.

- **Study Footwear:** We may ask you to wear a StepWatch Activity Montior (a step counter worn on your ankle) and three different types of study footwear (that we provide) over the course of the study: standard walking shoes, RB shoes, and an AFO with the standard shoes. You will wear each set of study footwear in a randomized order (like flipping a coin) during your normal daily activities for a 1-week acclimation period and a 2-week continuous wear period. For all takehome footwear conditions a fitbit zip may be clipped or taped to the shoe, ie., if you are wearing the shoes you could have a fitbit zip attached to them. The fitbit will be synced during the VA visits and will only record number of steps. A separate account for each fitbit will be created and the the account number will be recorded and stored on the private VA network. There will be no additional methods to link the fitbit data to you..Additonal footwear conditions (such as barefoot or own shoe) may be used during the initial visit.

  We will provide you with an instruction sheet to take home. We will have you try on the footwear and StepWatch to make sure they fit properly before you leave. At any point in the study, please contact us if you have questions or if the study footwear is painful or uncomfortable. We may ask you to come to the VA to resolve any fit issues.

We may call and/or email you to remind you about upcoming study assessments. You can opt out of the study at any time. You can change your mind at any time.

Study Group 4: Take home study (remote)

In-home/community activities: Study Footwear Period 1 (3 weeks)

You will need to wear the StepWatch throughout this 3-week period. You will complete the online Daily Pain Rating and Pain Medication Use survey (on paper or via Ilumivu).We will call you once per week to check in and ask you to do the brief pain rating (the same one you did during Study Visit 1 over the phone or via Ilumivu, a confidential phone app). During the in-home weeks, you may receive phone or electronic (email or via Ilumivu) contact reminding you to wear the selected footwear for the suggested number of hours and reminding you to record the number of hours you have worn the selected footwear in the log. Ilumivu, is a non-VA app downloaded onto your phone. Data will be captured by this non-VA entitiy. This app and its developers do not have any information that can be linked back to you. Only the researchers at the VA will know your Ilumivu participant ID. As Ilumivu is not sponsored by the VA, we recommend that you read their privacy policy and ensure you feel comfortable for data being collected by this app and stored on their servers. The data collected will be accessed only by the study research staff and stored on the VA network.

Acclimation period: On Day 1, you will wear the study footwear for 1 hour. From that day forward, you should add 1 hour of wear per day until the seventh day is reached. For example, on Day 2, you will wear the study footwear for 2 hours; on Day 3, you will wear the study footwear for 3 hours.

Continuous wear period: For the next 2 weeks, you will wear the study footwear throughout the day during your normal daily activities. We will contact you as needed to schedule a check in.

If at any point during the study a proper and comfortable fit cannot be achieved with the study footwear, we may ask you to wear your own shoes for a 1-week washout period (while continuing the other study procedures). Then, if you want to continue in the study, you will jump forward to the next study footwear.

Assessment 2 (up to 4 hours)

After the 2-week continuous wear period, we will ask you to repeat the initial assessment procedures.

At the end of this visit you will return to your own footwear andcontinue wearing the StepWatch.

In-home/community activities: Washout Period 1 (1 week)

For the next week, we will ask you to wear your own footwear and the StepWatch and complete the online Daily Pain Rating and Pain Medication Use survey. We will call you to check in and ask you to do the brief pain rating. If you need to delay your next phase, we will call you and ask you to do the weekly pain rating and questionnaires as an interview over the phone or via Ilumivu to keep this portion of the data collection on schedule.

In-home/community activities: Footwear Period 2 (3 weeks)

You will need to wear the StepWatch throughout this 3-week period and complete the online Daily Pain Rating and Pain Medication Use survey. We will continue to call you once per week to check in and ask you to do the brief pain rating.

Acclimation period: You will follow the same 1-week acclimation period instructions that you did during Footwear Period 1.

Continuous wear period: For the next 2 weeks, you will wear the study footwear throughout the day during your normal daily activities. We will contact you as needed to schedule your next visit.

Assessment 3 (up to 4 hours) & In-home/community activities: Washout Period 2 (1 week)

We will ask you to repeat the same procedures you did during Study Visit 2. This will be followed with a 1-week washout period. We will ask you to do the same things you did during Washout Period 1.

In-home/community activities: Footwear Period 3 (3 weeks)

You will need to wear the StepWatch throughout this 3-week period. We will continue to call you once per week to check in and ask you to do the brief pain rating.

Acclimation period: You will follow the same 1-week acclimation period instructions that you did during Footwear Periods 1 and 2.

Continuous wear period: For the next 2 weeks, you will wear the study footwear throughout the day during your normal daily activities. We will contact you as needed to schedule your next visit.

Assessment 4 (up to 4 hours)

We will ask you to repeat the same procedures you did during Assessments 2 and 3. At the end of this visit, you will need to return the StepWatch and the study footwear.

A diagram of all study activities is provided at the end of this Consent Form.

Registry (optional)

We will ask you if you would like to become part of our Center's Subject Registry. We use the Subject Registry to recruit subjects for different research studies. If you are interested, we will give you a separate Consent Form to sign. If you decide to participate in the Subject Registry, we will include information collected during this study about your foot/alignment type, in the registry. This information will help us determine if other research studies might be a good fit for you.

Repository (optional)

We have a database, called a repository, where we will store data from this study. We will use the data in the repository to answer new research questions in the future. The data will not include any information that could identify you, such as your name or social security number. We will ask you to sign a separate Consent Form to include you study data in the repository.

Additional use of de-identified data

Throughout the course of the study, we will place a copy of the de-identified study data, with the study assigned codes, in publicly accessible online data repositories. This study data will not contain information that could be used to identify you. Because the de-identified data set will be publicly available, it may be used by others for any purpose. If you do not want your de-identified data to be posted, you cannot participate in the study.

4. What are some risks of joining this research study?

The procedures in this study may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk or if any of the risks included in this form increase significantly, even if you have completed the study. You may be asked to sign an updated Consent Form to document that this new information has been explained to you. Below are the study-related risks known at this time:

Study footwear and StepWatch: You may experience mild soreness, pain, or soft tissue irritation from walking with unfamiliar footwear. If you have ankle OA, you may experience an increase in ankle pain. These things might happen during or shortly after the study visits. In addition, it is possible that you might trip and fall during the walking procedures in the lab, or while at home and in the community, while wearing the study assigned footwear. You may experience minor discomfort, soft tissue irritation, or skin break down (e.g. skin blister) in response to wearing the study assigned footwear and/or the StepWatch.

Confidentiality: Although we will make every effort to keep your information secret, no system for protecting information can be completely safe. It is still possible that someone could find out you were in this study and find out information about you. Section 7 describes how we will protect your privacy to the best of our ability.

5. What are some benefits of joining this research study?

There are no direct benefits to you for participating in this study. This research has the potential to benefit society by providing evidence about the effectiveness of conservative treatments for ankle OA. Treating patients conservatively (as opposed to surgically) reduces medical cost, recovery time, and the risks to patients.

6. Are there other ways I could receive these benefits?

This is not a treatment study. Your alternative to participating in the study is to not participate.

7. Who will see my information and where will it be stored?

Your research information will be kept confidential. However, some data will be shared, communicated, or stored during or after this research study.

If we learn you intend to harm yourself or others, we must report this information to appropriate authorities.

The following list of people or groups may know that you are in this study. They may have access to your research records, which may include your medical records:

- Research team members (both VA and University of Washington employees)
- Other federal agencies including, but not limited to, the Food and Drug Administration (FDA), the Office for Human Research Protection (OHRP), the VA Office of Research Oversight (ORO), the VA Office of the Inspector General (OIG), and the Government Accountability Office (GAO)
- The VA and University of Washington committees that oversee research
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research)
- The VA Puget Sound Fiscal Department, Internal Revenue Service (IRS), and U.S. Department of the Treasury will be provided with your full name, address, phone number, and social security number in order to authorize payment for your participation in this study

The access to your records, including your medical records, could be either for study-related purposes or to make sure your study record meets all legal, compliance, and administrative requirements. The reviewers will protect your privacy.

Confidentiality: Your identity (including any photographs or video recordings that could identify you) will be strictly confidential. Data that could be used to identify you will be stored on the VA secure server and in locked cabinets in locked offices at VA Puget Sound. Only study personnel will have access to the identifiable information that we collect from you.

To make sure no one other than study personnel can match you to your data, we will use a unique study code instead of identifying information, such as your name or social security number, to code (label) your study data. The key to the code will be stored separately from the data in a locked office or in a protected electronic file on a secure server at VA Puget Sound. We will securely store the code linking you to your data in accordance with the VA records retention policy (which will be a minimum of 6

years after the study has been completed). After destruction, we will not be able to match you to your data.

The video camera and the recording media (such as SD cards, optical disks) will be stored in a locked office at VA Puget Sound. Photos and videos that do not contain identifiable information may also be stored on password-protected computers. Some of the questionnaires/interview data will be collected and stored on a tablet. This data will only be associated with your study code and will not contain information that could identify you.

All coded data will be kept indefinitely, including any video and photographs that obscure your identity. De-identified data, with study assigned codes, will be transmitted to our offsite staff and collaborators for research purposes. If you decide to sign our Repository Consent Form, your data will also be placed indefinitely in our repository to be used in future research studies.

In the future, researchers may write publications using the information collected from this research study. Any future publications will not include any identifying information about you without your approval in writing.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Medical Record: If you are a VA patient, you already have a VA medical record. If you are not a VA patient, we may create a VA medical record for you if you. The creation of a VA medical record for the purposes of this study does not entitle you to any services at the VA beyond those services to which you are otherwise entitled. If needed, we will put information about you from this study into your medical record. All approved users of the national VA medical records system can have access to your medical record. This may include health insurance companies who are being billed for medical costs. This record will be kept forever.

We will use the information that we collect for this study only for research purposes, not for profit. However, in the future, researchers may use this research information to develop new ways treat ankle OA. Neither you nor your family will gain financially from discoveries made using the data you provide.

8. What are some other things to think about before I decide to join this research study?

The VA requires some Veterans to pay co-payments for medical care and services. You will still have to pay these co-payments as long as they are not related to this research study.

If you participate in Study Group 4, you will receive $400 after you complete all study procedures.

If you are screened out during the first visit, you will be compensated $50. If you stop participating in the study before you finish all of the procedures for your group, you will be paid on a pro-rated basis for the number of days that you participated. The rate will be based on which study group you are in.

You will receive payment by check. Checks will be mailed about 6-8 weeks after you finish the study, or you can pick up your payment within the same timeframe at VA Puget Sound in Seattle. In order for

these payments to be processed, you will be asked to give your full name, social security number, telephone number, and address. You may receive an Internal Revenue Service (IRS) Form 1099.

9. What will happen if I decide I don't want to be in this research study later?

You do not have to take part in this study. If you are in this study, you can withdraw at any time. If you decide not to participate or to withdraw, no action will be taken against you; for instance, you will not lose your VA benefits.

The Principal Investigator or a study clinician has the right to terminate your participation in this study. This termination will not require your consent.

If you decide to withdraw from the study, no new information will be collected from you. Information already collected up to that point will continue to be used for the study. If you decide to withdraw, or if you are terminated from the study, a person from the study team will contact you to discuss returning the study equipment.

10. What will happen if I am hurt in this research study?

If you are injured as a result of participation in a VA-approved research study, the VA will provide you with the necessary medical treatment. You will not be charged for this treatment. Veterans who are injured because of being in this study may receive payment under Title 38, United States Code, Section 1151. Veterans or non-Veterans who are injured may receive payment under the Federal Tort Claims Act. You do not waive any legal rights by signing this Consent Form.

11. What am I agreeing to by signing this form?

I have read or have had read to me all of the above. The study has been explained to me, including a description of what the study is about and how and why it is being done. All of my questions have been answered. I have been told of the risks and/or discomforts I may encounter in the study, of the possible benefits of the study, and of the other choices of treatment that are available to me.

My rights as a research subject have been explained to me and I voluntarily consent to participate in this study. I will receive a copy of this Consent Form.

I agree to participate in this research study as described in this document.

_____ _____

Subject Signature Date

_____

Print Name of Subject

Study Group 1, 2, 3, & 4
Assessment 1:
Demographics
Anthropometrics
Functional assessments
Brief Pain Rating
Questionnaires
Qualitative questions
CT scan (not group 4)
Biplane (group 1)
Provide StepWatch
Provided footwear 1
Study Group 2, 3 & 4
Group 1 complete
In Home/Community Condition 1 (3 wks):
Acclimation – 1 week
- StepWatch
- Study footwear (day-1: 1hr; day-2: 2hrs; +1hr/day thru day 7)
Continuous Wear– 2 weeks
- StepWatch
- Study footwear full time
- Weekly pain rating & qualitative questions
Assessment 2:
Download SW data
Demographics
Anthropometrics
Functional assessments
Brief Pain Rating
Questionnaires
Qualitative questions
CT scan (not group 4)
Biplane (group 3)
Provided footwear 2
In Home/Community Washout 1 (1wk):
- StepWatch
- Self-selected shoes (non-study)
- Weekly pain rating
In Home/Community Condition 2 (3wks):
Acclimation – 1 week
- StepWatch
- Study footwear (day-1: 1hr; day-2: 2hrs; +1hr/day thru day 7)
Continuous Wear– 2 weeks
- StepWatch
- Study footwear full time
- Weekly pain rating & qualitative questions
Assessment 3:
Download SW data
Demographics
Anthropometrics
Functional assessments
Brief Pain Rating
Questionnaires
Qualitative questions
CT scan (not group 4)
Biplane (group 3)
Provided footwear 3
In Home/Community Washout 1 (1wk):
- StepWatch
- Self-selected shoes (non-study)
- Weekly pain rating
In Home/Community Condition 3 (3wks):
Acclimation – 1 week
- StepWatch
- Study footwear (day-1: 1hr; day-2: 2hrs; +1hr/day thru day 7)
Continuous Wear– 2 weeks
- StepWatch
- Study footwear full time
- Weekly pain rating & qualitative questions
Assessment 4:
Download SW data
Demographics
Anthropometrics
Functional assessments
Brief Pain Rating
Questionnaires
Qualitative questions
CT scan (not group 4)
Biplane (group 3)
Return StepWatch and footwear
Groups 2, 3, & 4 complete