Patient Specific 3D Printed Diabetic Insoles to Reduce Plantar Pressure

NCT05301478

October 16, 2022

Consent to participate as a Research Subject in:

NOVEL CUSTOM FOOT ORTHOTICS TO IMPROVE FOOT HEALTH

SUMMARY OF STUDY:
In this research study, we are evaluating if novel custom foot orthotics improves foot health and mobility for people who are at increased risk of developing foot ulcers. We are comparing different methods of custom foot orthotic fabrication in people who are at increased risk of developing foot ulcers and individuals who are not. Participating in this study involves coming to the VA Hospital in Seattle for up to 12 study visits, lasting up to four hours.
If you are eligible and choose to participate, you will:
• Wear custom foot orthotics during in laboratory testing for up to four hours
• Receive a foot health assessment
• Walk through our laboratory space so we can see how the orthotics affect your body movement.
• You may be asked to wear an orthotic device at home, between study visits, and will be called periodically during this time period.
You will be paid for participating in the study.

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.

[redacted]

Study Title:
Novel Custom Foot Orthotics to Improve Foot Health

This study is being conducted by the Center for Limb Loss and MoBility (CLiMB) through a grant from the VA Center for Innovation.

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

During business hours (8:00 a.m. – 4:30 p.m.):
Study contact: [redacted]

After business hours (nights and [redacted]

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 medical care issues specifically related to the study.

You may also contact the Institutional Review Board (IRB) at [redacted] 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?

The current standard for prevention of plantar foot ulcers (open sores or wounds on the bottom of the foot) for at-risk individuals is specialty diabetic shoes and custom foot orthotics (CFOs). CFOs are meant to cushion the plantar surface of the feet, evenly spread out the pressures on the bottom of the feet, and selectively offload areas of increased pressure. The purpose of this study is to determine if novel custom foot orthotics (N-CFOs) reduce foot pressures for VA patients that are at an elevated risk for foot ulcers.

The target population of the proposed research is Veterans with diabetes and other diseases that may lead to a higher risk for foot ulcers, infections, and amputation. However, during the N-CFOs development phase, anyone over the age of 18 years is potentially eligible to participate.

The targeted enrollment for this study is 250 participants from Veterans Affairs Puget Sound Health Care System (VA Puget Sound). 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?

There are two study groups, as described below:

☐ **Study Group 1: In Laboratory**

All research procedures will be conducted at VA Puget Sound in Seattle in session(s) lasting up to 4 hours. You will not take home any study devices, but we may ask you to visit the laboratory up to 12 times. Additional visits may be schedueld though phone contact. Detailed descriptions of these activities are described below.

☐ **Study Group 2: Take Home**

All research procedures will be conducted at VA Puget Sound in Seattle in session(s) lasting up to 4 hours; however, we will ask you to take home and wear the study devices and may ask you to visit the laboratory up to 12 times in 24 months. Visits may be schedueld though phone contact or at the previous visit. Detailed descriptions of these activities are described below.

Your expected participation is _____visits over the course of _____months.

Research Procedures

During each study visit, the following procedures will be performed for study purposes only. Some of the procedures have various choices. It will be made clear which you will perform by the checkboxes below:

- **Demographic information:** We will record your age, body weight, height, and body mass index (BMI).

- **Health history:** We will ask you if you have diabetes (Type 1 or Type 2). If yes, we will ask you how many years since your diabetes diagnosis.

- **Clinical lower extremity/foot evaluation:** We will check your feet for swelling, pulse, the presense or lack of sensation in your feet, the presence of wound or ulcer and assess skin health using skin-health measurement tools, and foot deformity. We will also ask you about your previously used CFOs.

- **Foot scan:** We will take a foot impression using one or more of the following methods:

  ☐ **Foam crush box.** From a sitting or supported standing position, we will ask you to place one foot at a time into a box containing lightweight crushable foam. The study orthotist may push on the top of your foot to help compress the foam. You will then lift your foot out of the box, leaving an impression in the foam. Foam-box impressions take about 30 seconds per foot.

  ☐ **Direct digital scanning.** From a sitting or supported standing position, we will ask you to lift one foot at a time and hold it steady while the researchers capture a three-dimensional impression using a handheld scanner. Scanning takes about 30 seconds per foot.

  ☐ **Flatbed scanner.** We will ask you to stand on the flatbed scanner, which is similar to a paper scanner. The researchers will scan the sole of each foot to capture a three-dimensional image. Scanning takes less than one minute.

  ☐ **Plantar pressure scanner.** We will fit your shoes with insoles that record in-shoe pressures under each foot during walking. The insoles will be attached with wires to a data acquisition unit; the wires are routed so they are not a trip hazard. Care will be taken to ensure that the insoles fit comfortably.

  ☐ **EMED pedar pressure measurement system.** We will ask you to remove your shoes and then walk barefoot in a straight line for about 20 feet over an instrumented platform in our Motion Analysis Laboratory. This platform is flush with the surface of the floor. This platform measures the distribution of pressure beneath the surface of the foot, providing additional baseline data about how your body weight is distributed during walking. This procedure will be repeated several times.

☐ **In-shoe embedded ultrasonography.** We will ask you to walk in a pair of our instrumented footwear that includes an ultrasound probe mounted on force transducers embedded in the sole of the shoe, positioned under the second metatarsal head. You should not feel the probe.

☐ **Computed tomography (CT) scan.** We hope to do the CT scan during the first visit; however, the scan may be taken during any of the study visits depending on scheduling needs. If you are a woman of child-bearing potential, a pregnancy test will be conducted prior to the scan. If you are pregnant, you will not be eligible for this method of scan.

If scheduling a CT scan at VA Puget Sound proves to be difficult, we may schedule the CT scan at a third-party vendor (a fee-for-service CT scanner). We will provide you with the address of the vendor. A study identification code will be entered in the name field of the CT scan file along with age in years (if 89 or younger). We will not share any of your personal identifiers; the vendor will not store any of your personal identifiers (such as your name, address, or social security number) in their files. The vendor will make a copy of the CT scan by burning it onto a CD and then mailing it to the VA via traceable shipping, or a study staff member will pick up the CD.

☐ **LineUP.** We will use our LineUP system which uses a lower radiation dose, weight-bearing CT scan, and/or use clinical resources at VA Puget Sound. The scan will start at the mid-tibia (lower leg) and extend down to include your feet. If you are a woman of child-bearing potential, a pregnancy test will be conducted prior to the scan. If you are pregnant, you will not be eligible for this method of scan.

☐ **Existing scan.** If you have a VA medical record, we will access it to collect information related to your foot/ankle diagnosis, related clinical treatment, and to check to see if you have already had a CT scan within the last 5 years.

If your medical records are not at the VA and you had a CT at a different medical facility within 5 years, we will ask you sign a Release Form so that we can obtain copies of these records. If possible, we will use the previously collected images for our dataset and analyses so that you do not have to be exposed to additional radiation.

The CT scans and any other requested clinical notes from outside the VA will be delivered via the following methods:

- The images and other clinical treatment information may be burned to CD(s) or DVD by Harborview Medical Center or other facility and mailed to us via traceable shipping.
- A designated study staff member will pick up the CD(s) or DVD from Harborview Medical Center or other facility and transport it to the VA.
- Information about lower extremity diagnoses and clinical treatment may be provided to designated study staff over the phone. The information will be labeled with a study code (no identifiers) and added to study data.

- **CFO fabrication:** Once a foot impression has been obtained, CFOs and/or N-CFOs will be fabricated (created from a mold) for you. Fitting of CFOs and/or N-CFOs will take place within 6 weeks of the first visit. We will contact you to schedule the second visit for fitting of the CFOs. CFOs and/or N-CFOs may require modification in order to ensure a proper fit in your shoes. Any necessary modifications will take place during the second visit during fitting or any visit thereafter.

  ☐ **Survey.** To help determine footwear compliance, we will have you complete a survey to determine the amount of time spent in bed, out of bed, wearing socks, slippers, other footwear or diabetic shoes. This may be done over the phone, on Ilumivu, or in lab with pencil and paper.

    - Ilumivu is a non-VA app that you can download onto your phone. Although we will capture study data through Ilumivu, this app and its developers will not have any information that can be linked back to you. Only the researchers at the VA will know your Ilumivu participant identifiers. As Ilumivu is not sponsored by the VA, we recommend that you read their privacy policy and ensure you feel comfortable with 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.

  ☐ **User experience questions.** We will ask you open-ended questions about your experience using CFOs and/or N-CFOs. For example, we may ask what you like and do not like about the CFOs, how and when you use the CFOs, and questions about the comfort. We may add your responses to our study data.

  ☐ **Gait lab testing.** We will ask you to change into a tight-fitting shirt and shorts (that we provide) in a private changing area. We will record a series of standard body measurements such as height, weight, and leg length. We will use double-sided tape to attach up to 100 small reflective markers to specific locations on your hands, arms, head, trunk, legs, and feet.

  Then we will ask you to do a series of walking tests while we record the movements with an infrared camera system. The infrared cameras only record the location of the markers; they do not record a picture of your body.

  We will also collect study data by force plates embedded in the floor of the lab and while you are walking on the instrumented treadmill.

  ☐ **Walking tests.** We will ask you to perform several walking tests during each study visit. The total duration of all walking tests will be no more than 90 minutes per visit. During the laboratory walking tests, the motion analysis camera system will record the position of the retroreflective markers that we will place on you. The sensors and insoles will record data during the walking procedures. You will perform up to three different walking tests during study visits as described below:

☐ You will walk at a self-selected speed about 65 feet down a straight hallway. You will do this three times so we can determine your average walking speed.

☐ You will walk on a level instrumented treadmill several times at 1.5 meters per second (m/s)—just over 3 miles per hour—or less. You will walk no longer than 30 minutes each time with the opportunity to rest at any time and between each session. We may ask you to walk at different speeds (not faster than 1.5 m/s), but you will only need to walk at speeds at which you are comfortable.

☐ You will walk across the lab (less than 30 feet) several times while stepping on force plates embedded flush with the floor at a speed of 1.5 m/s or less. You will have the opportunity to rest after each session as needed. We may ask you to walk at different speeds (not faster than 1.5 m/s), but you will only need to walk at speeds at which you are comfortable.

We may ask you to rate the walking sessions during the activity. For instance, we may ask you to score on a scale of 1-10 how hard the activity is for you ("1" being Not at All; "10" being Very, Very Hard).

- **At-home monitoring:** Finally, we may ask you to conduct at-home monitoring to record your physical activities with and without the CFOs and/or N-CFOs.

  ☐ **Physical activities.** While you are away from the VA lab, you will wear a provided activity monitor (StepWatch and/or Fitbit) to record your physical activities.

  ☐ **Check-ins.** Once per week, we may call/email/message you through Ilumivi (whichever you prefer) to have you complete a check-in qualitative assessment.

You may refuse to answer any question or item in any test, inventory, questionnaire, or interview.

Study Footwear

In either study group (in laboratory or take home), you may be asked to wear our control shoes (such as New Balance walking shoes, Dr. Comfort diabetic shoes, or similar) or your own shoes.

Photos and Video

We may take videos and/or photos of you during portions of this study for documentation and use in research publications. To protect your identity and privacy, all videos and photos will be edited later to de-identify the images (for example, we will blur your face and any tattoos or other identifying marks). No sound will be recorded to prevent voice identification.

Subject Registry (optional)

We will ask you if you are interested in joining our Center's Subject Registry. This registry is used to recruit participants for studies being conducted by our Center. If you choose to join the registry, you

will sign a separate Consent Form. We will add data from this study regarding your foot type to the Subject Registry. This will help us determine which studies may be a good fit for you in the future.

Additional use of de-identified/coded data

Throughout the course of the study we will place a copy of all de-identified/coded data in publicly accessible online data repositories. Once posted, the data will publicly accessible to search, retrieve, and analyze for any purpose. If you do not wish to have a copy of your de-identified/coded data placed in online repositories you can choose not to participate in the study. Your de-identified data will be shared with the PI's research team at the University of Washington.

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

The study procedures may involve risks that are currently unknown. We may need to contact you if we learn of a new study risk, even if you have completed the study. If any of the risks included in this Consent Form become significantly updated during this study, we may ask you to sign an updated Consent Form to document that this new information has been explained to you. You will have the right to decide either to continue with the research study or to withdraw.

Below are study-related risks that are known at this time:

Plantar foot ulcer. You may develop a plantar foot ulcer using CFOs or N-CFOs; however, this risk is very similar to what is encountered during daily life for study participants.

Radiation. Your CT scans involves exposure to radiation. The radiation dose you will receive is approximately 20 millirem. For comparison, the average dose to the U.S. population from natural background radiation sources is 300 millirem per year, and the maximum annual occupational dose limit for radiation workers is 5,000 millirem. The risk of harm from this amount of radiation is low and no harmful health effects are expected; however, your risk of harmful effects may increase if you are exposed to more procedures that involve radiation. Harmful effects could include cancer or genetic changes. You will not have more than one tradition CT scan or one LineUP scan taken of your feet and ankles.

There may be unknown risks to you or your unborn baby if you are pregnant during exposure to radiation; therefore, if you are pregnant, you cannot participate in this study.

Injury. It is possible that you may experience an injury, such as a blister, arising from rubbing inside the shoe.

Falling. There is a risk of falling while participating in study activities. We will be monitoring you closely, but please tell us if you feel unbalanced at any time.

Physical risks. The increase in physical risks by being in this study only represent a small increase from those encountered in daily life of the participant population.

By signing this Consent Form, you are not consenting no non-VA research procedures. You should review any risks associated with the insoles with your regular healthcare providers.

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 pressure ulcers. Treating patients conservatively (as opposed to surgically) reduces medical costs, 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 at the VA and University [redacted]
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research)
- 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
- The VA Puget Sound Fiscal Department, the 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 UW committees that oversee research, including the UW Institutional Review Board and supporting staff, will have access to your study records but not your medical records

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.

A description of this clinical trial will be available on https://www.clinicaltrials.gov, as required by U.S. Law. 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 will create a VA medical record for you. The creation of a VA medical record for you 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.

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 record will be retained in accordance with the VA records retention policy.

Study code and link

Your identity (including any photos or videos that could identify you) will be strictly confidential. Only study personnel will have access to the identifiable information that we collect from you. We will not place any identifiable information (such as your name or social security number) on any research data. Instead, we will assign a unique study code to identify your information.

We will keep the master list that links your name to your study code in a secure-access computer specifically for research data. The master list will be stored in a password-protected folder and will only be accessed by the authorized study staff members.

Safekeeping / Storage

To protect the confidentiality of the information obtained about you during this research study, we will take many preventative measures. Any paper study documents we have, received, or created will be secured in locked file cabinets accessible only to study staff. Any electronic study records will be kept in electronic folders on the secure VA network with access to the specific folders restricted to designated study staff.

Upon study completion

Once this study is completed, we will not use the study code linking you to your data, including any recordings and transcriptions, for any additional research. We will store the code linking you to your data in a secure database or in a locked filing cabinet in accordance with the VA records retention policy (which will be a minimum of 6 years after the study has been completed). We will keep your coded data indefinitely.

In the future, researchers may write about the information collected from this research study. Any future publications or articles will not include any identifying information about you without your approval in writing. Neither you nor your family will gain financially from discoveries made in the future using the information 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 1, you will receive $30 an hour for all visits to the lab.

If you participate in Study Group 2, you will receive $30 an hour for all visits to the lab and an additional $30 per month for participating in the at-home portion.

Since this is a VA-funded study, we offer payment via Electronic Fund Transfer (EFT) or by check. In addition to reducing the time it takes to receive the funds, receiving the payment via EFT also reduces the risk of fraud and gives the VA visibility of the payment from issuance to the day it is deposited.

If you choose to be paid via EFT, we will need you to complete VA Form 10091. Once completed, you can submit the form to the Agent Cashier's Window (Veterans Lobby, Building 100) or to someone on the study team. If you have previously used EFT for other types of VA reimbursement, you will continue to be paid in this manner.

You may also choose to receive payment by check. Checks will be mailed about 6-10 weeks after your final study visit or you can pick up your payment within the same timeframe at VA Puget Sound in Seattle.

To comply with Internal Revenue Service (IRS) guidelines, we will collect your social security number. You may receive an 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.

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