Title: Lower limb prostheses for individuals who carry infants, toddlers, and other loads.

NCT07159490

Informed Consent Form Document Date: 4Aug2022

Consent to participate as a Research Subject in:

LOAD CARRIAGE

SUMMARY OF STUDY: For individuals with lower-limb amputations, sudden changes in weight on a prosthesis, such as when carrying a toddler or groceries, can make it hard to walk and maintain balance. We are gathering information that can help clinicians prescribe prostheses that will help when carrying heavy loads. We will do this by asking you to wear four prostheses while walking on a treadmill and carrying a load to simulate an infant, toddler, or other heavy item.

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 Investigator:
Glenn Klute, PhD

Research Staff:
G. Eli Kaufman, C/LPO
Krista Cyr, MS
Elise Campbell, MS

Study Title:
Lower-Limb Prostheses for Individuals Who Carry Infants, Toddlers, and Other Loads

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

During business hours (8:00 a.m. – 4:30 p.m.), please call the Study Coordinator at 206-764-2962 or the Principal Investigator at 206-277-6724. After business hours (nights and weekends), please call 206-214-5813. If you are experiencing a life-threatening situation, 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 medical care issues specifically related to the study.

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?

Prosthetic feet help create a more natural gait by attempting to replicate the body's natural function and mobility of the foot and ankle such as body support, forward motion, and balance control. Clinicians prescribe prosthetic feet based on the patient's weight and self-reported activity level. A heavier and/or more active individual is prescribed a stiffer prosthetic foot.

Prosthetic feet are manufactured with a range of stiffness, and each category of stiffness is intended to suit a somewhat narrow body-weight range and activity level. However, we know that the amount of weight being supported by the prosthetic foot can change very quickly, such as when an individual carries an infant, toddler, or other heavy item. In addition, the effects of this additional weight can vary depending on where the load is being carried; for example, on the back like a backpack, in front of the body, or on either side. Because of this, we want to gather information about how weight carried in these different positions affects the performance of different types of prosthetic feet and their stiffness.

In total, we will enroll up to 40 people with a below-knee amputation to be in this study. You are eligible for this study because:

- You are a unilateral transtibial amputee;
- You are between the ages of 18 and 75;
- You have benefit with a prosthesis and have been using it for at least 6 months;
- You do not use heel-stiffening wedges or bumpers in your prosthesis;
- You wear your prosthesis at least 4 hours per day and are moderately active;
- You can be fitted with the study prostheses; and
- You do not have disorder, pain, or other injury that interferes with your gait.

All study procedures will take place here at VA Puget Sound Health Care System (VA Puget Sound) in Seattle. All procedures are research related and provide no clinical treatment. Study participation will take place over two study visits. However, we may need you to repeat a few procedures in a third visit if we discover missing or corrupted data after the second visit. Each visit will last approximately 4 hours.

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

Study Visit 1

Once we have completed the informed consent process, we will ask you to walk at your own pace for 20 meters (about 65 feet) down the hallway while wearing your own prescribed prosthesis. We will ask you to do this three times to get an average of your self-selected walking speed. We will also collect demographic information, body height and weight, and details about your prescribed prosthesis.

The study prostheses will then be fit, in random order (in no particular order) and aligned by our licensed and certified prosthetist. You will continue to use your existing socket and suspension system, but the pylon length may need to be adjusted to fit the different study prosthetic feet. We will then ask you to walk around for 5 to 10 minutes while wearing each study prosthetic foot with no added load

and then again with up to 30 pounds of added load. We will ask you to carry the load four different ways—on your back like a backpack, in front of your body, and on both left and right sides. You can take a break at any time. After you have tried on all of the study prostheses, you will be refitted with your prescribed prosthesis.

Study Visit 2

After at least one overnight rest period, we will ask you to come back to VA Puget Sound for your second study visit. We will ask you to change into tight-fitting clothing that we will provide in a private area. We will then place reflective markers using double-sided medical tape on different areas of your body, including hands, arms, torso, legs, and feet. For your prosthetic limb, markers will be placed parallel to locations on the intact limb. While you walk, the motion of each reflective marker will be automatically recorded by infrared cameras. The recorded images will appear on a computer screen as a stick figure and will allow us to study your walking style. The data from these images will allow us to measure how you walk and how the different prosthetics and loads compare.

Next, we will place wireless, surface electromyography electrodes on your leg and butt muscles to measure the electrical signals of your muscles as you move. We may need to shave, scrub, and clean your skin with a sterile alcohol swab in the places where we'll place the electrodes. We will then use double-sided medical tape to attach up to 16 electrodes and their transmitters to your skin. The transmitters will send signals from the electrodes on your muscles to a receiver in one of our computers.

You will then be fitted with each study prosthetic foot in random order. After the first prosthesis is fit, you will walk on a treadmill at your self-selected walking speed that we determined during the first study visit. We will then ask you to walk for one minute with no load and then walk for one minute four more times with added load weights, each time carried in a different position. Biomechanical data will be collected during each one-minute trial using a camera and force plates embedded in the split-belt treadmill. You can take a break at any time.

After each load condition, we will ask you to rate your satisfaction with the performance of the study prosthesis on a scale from 1-10. We will ask you complete these walking tests with all four study prostheses and with the weighted backpack in all four locations (back, front, intact side, prosthetic side).

Photos and Video Recording

During the procedures, we may take photographs and/or video recordings of you for procedure documentation, data analysis, and potential use in research publications and presentations. These images may include your entire body, but we will create an anonymized copy of them during data processing. Your face will be blurred out, and tattoos and other distinguishing marks will either be covered beforehand or blurred out to protect your identity. Videos will be recorded without sound.

Data Repository (optional)

We have a database, called a repository, where we store data from previous research studies. We will use the data in the repository to answer new research questions in the future. We will ask you to sign a separate Consent Form in order to include your study data in the repository, but this is optional.

Subject 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 type. This information will help us determine if other research studies might be a good fit for you.

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:

- **Falling.** While you are doing study activities in our lab, there is a risk that you may fall and hurt yourself. We will take steps to prevent this. For example, we will allow you to take any necessary breaks. Also, there are no obstacles on the floor.

- **Fatigue.** You may get tired during the sessions. During the walking periods, you may become tired from carrying the extra load (about 30 pounds) on your body. You are encouraged to tell a member of the research team if you need to take a break. If you become tired, you will be allowed to rest until you are comfortable. You can also stop participating.

- **Pain or Discomfort.** You may also experience mild pain or discomfort during walking or from wearing a study prosthesis. The investigators will closely monitor your pain throughout your participation. Any pain or discomfort is not expected to be any greater than your typical post-injury levels. If your pain increases beyond baseline levels, we will ask if you would like to rest or discontinue the study. You may also feel slight skin irritation when we remove the double-sided tape and electrodes. You may also feel skin irritation if we need to shave your skin for the electrodes. If your skin irritation increases beyond expected levels, you may ask to discontinue the study.

- **Injury.** If your limb loss is related to diabetes or a dysvascular condition, you may be at risk of injury to the intact limb due to carrying the study loads. To reduce this risk, we will ask you to wear footwear during the study. Our research prosthetist will discuss these issues with you to establish study suitability.

- **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 is no direct benefit for participating in this study. However, the information we are collecting may help future patients and Veterans with below-knee amputations.

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

This study is voluntary and for research purposes only. The alternative to the study is to not take part in it.

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
- 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 committees that oversee research
- The VA Puget Sound Fiscal Department 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.

Your data (including any photographs or video recordings that could identify you) will be strictly confidential. 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.

Study 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. 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 for future use in scientific presentations and publications.

We are working with researchers at the University of Texas on this study. The information we gather during your data collection will be shared with them but no information that identifies you will be shared.

Once this study is completed, we will not use the study code linking you to your data, including any photographs and video recordings, for any additional research, unless you agree to have your study data stored in the Data Repository as described in Section 3. 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. Your insurance will not be charged for any costs related to the research.

We will pay you $50 for the first hour of each study visit and an additional $30 an hour for the rest of each study visit.

If you travel 20 miles or more one way for study visits (40 miles or more total), we will provide compensated mileage rates in accordance with the Veterans Affairs Beneficiary Travel program. This amount may fluctuate. To ensure accuracy, study staff will check to make sure the most up-to-date amount is being used prior to adding travel compensation to total compensation amount. Current mileage rates can be found at https://www.va.gov/HEALTHBENEFITS/vtp/beneficiary_travel.asp.

If you travel by ferry for study visits, we will provide full ferry fare compensation. We will not offer compensation for other individuals traveling to the study visits with you. To ensure the most up-to-date fares are used, study staff will check the Washington State Department of Transportation ferry fare website (https://www.wsdot.wa.gov/ferries/fares/) prior to adding ferry fare compensation to

total compensation amount. We will determine if travel compensation is required based on contact information recorded during enrollment.

If we determine that you are not a good fit for the study and cannot do the procedures, we will compensate you for the first hour of the visit and any applicable travel compensation.

Payments will be dispersed in cash or by check. We will mail the checks about 6-8 weeks after the final visit.

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 has the right to stop your participation in this study; for example, if Dr. Klute feels it is necessary for your safety or if it is discovered that you do not meet the study requirements. Stopping your participation 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.

The VA is not obligated to reimburse medical expenses due to your non-compliance with study procedures as described in this Consent Form or otherwise communicated to you by study personnel.

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