Title: Pivot-Flex Foot: Optimal Coupling Ratio Between Transverse and Sagittal-plane Motions Using a Torsionally Adaptive Prosthesis for Individuals With Lower Limb Amputation

NCT03532100

Informed Consent Form Document Date: 31Mar2021

Consent to participate as a Research Subject in:

Using a Computer-Controlled Prosthesis to Develop a New Prosthetic Foot

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.

Principal Investigator:
Glenn Klute, PhD

Research Staff:
Krista Sanchez, MS, Investigator

Study Title:
Pivot-Flex Foot (Part 1)

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.

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: 206-764-2962
Glenn Klute, PhD: 206-277-6724

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?

The natural foot and ankle joint work together to twist/turn horizontally (relative to the leg) and flex forward and backward (landing and pushing off the ground) during walking. This paired twisting and flexing motion is important for balancing and turning while walking. It also helps manage how the twisting forces created during walking are felt through the body. The ability of current prosthetic limbs to manage these forces is limited. People who use a prosthetic leg often develop soft tissue injuries from the socket and limb rubbing/twisting against each other. The purpose of this research study is to develop

a new prosthetic foot, called the **Pivot-Flex Foot (PFF)**. The PFF will be designed to act more like a natural foot and ankle joint while walking.
This research study will take place in two parts. In this part of the study, we will use our computer-controlled **Torsionally Adaptive Prosthesis (TAP)** to evaluate different turning- and flexing-paired motion settings. The TAP is a motorized prosthesis that can be programmed to pair turning and flexing motion at different proportional rates. The results from this part of the study will be used to help design the PFF.

We will enroll up to 40 people with a below-knee amputation to be in this part of the study. We may approach up to 200 people about this study if needed.

In the second part of the study, we will compare the PFF to a standard-of-care prosthetic foot. We might contact you about participating in the second part of the study.

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

Visits and length of participation

All study procedures will be done at VA Puget Sound in Seattle. All procedures are research related and provide no clinical treatment. If you agree to participate in this study, we will ask you to come to VA Puget Sound for two study visits that may last up to 4 hours each. If we find data are missing or corrupt, you may be asked to do another study visit. You will be provided rest breaks throughout the procedures and may request one at any time. We may call and/or email you to remind you about upcoming study visits. You can opt out of the study at any time.

STUDY VISIT 1

We will examine your residual limb and prosthesis to determine if you can participate in the study. The research prosthetist may adjust your prosthesis to optimize how it fits and make sure the TAP can be fit to your socket. If you cannot continue in the study, you will still be paid for your effort.

We will ask you some questions about yourself, such as your age, race, ethnicity, and Veteran status.

Self-Selected Walking Speed (SSWS) Tests

We will ask you to walk several times at your own pace for about 65 feet back and forth in a straight hallway. We will also ask you to walk at your own pace several times around a ~3-foot radius circle. You will do these tests using your own prosthesis.

Torsionally Adaptive Prosthesis (TAP) Tests – Straight Line Walking

We will ask you to do a series of walking tests with the TAP while we record your movements with an infrared camera system. We will provide you with a tight-fitting shirt and shorts to wear and a private area to change in. We will record a series of standard body measurements such as your height, weight, and leg length. We will use double-sided tape to attach up to 70 small reflective markers with double-sided tape to specific locations on your hands, trunk, legs, and feet. The markers work with the infrared camera system to record your movements while you walk. The infrared cameras only record the location of the markers; they do not record a picture of your body.

The research prosthetist will fit the TAP to your socket. The TAP will be connected to a computer and power source with long wires. The wires will be routed out of the way so you will not trip over them. The TAP will be programmed with five different paired motion ratio settings. The different settings will change how the prosthesis feels (more or less compliant).

We will ask you to do a series of walking tests on each setting. The settings will be selected in a random order, like flipping a coin. You can practice walking on each setting until you feel confident/stable. When you are ready on the first setting, you will walk back and forth several times at your SSWS over force measurement plates embedded in the floor. We may also ask you to stand still on the plates for short periods of time. Once we have enough information about the first setting, we will ask you to rate on a 0-10 scale how satisfied you are with the setting. We will ask you to repeat the same process with the other four TAP settings.

After you test all five TAP settings, the research prosthetist will re-fit your as-prescribed prosthesis. We will set up your next study visit before you leave or we will call you later to schedule it.

STUDY VISIT 2

Torsionally Adaptive Prosthesis (TAP) Tests – Circle Walking

At this visit, we will ask you to repeat the TAP test procedures that you did during Visit 1. However, this time we will ask you to walk at your SSWS around a ~3-foot radius circle several times on each TAP setting. After you test all five TAP settings, the research prosthetist will re-fit your as-prescribed prosthesis.

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. The original file will be securely stored or deleted. Videos will be recorded without sound. Only videos and photos that cannot identify you would be used in research publications and presentations.

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 respository, but this is optional.

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:

- You may experience some stress or inconvenience by coming to VA Puget Sound for multiple visits.

- **Walking with the TAP:** You may feel some emotional discomfort while wearing the tight-fitting clothing during the study sessions. Visitors or other observers are not allowed in the lab unless you agree that they can be there, and you can change your mind at any time.

  You may feel some physical discomfort when we remove the markers taped to your skin. The tape may pull on your hair as the markers are removed. This will feel similar to removing a Band-Aid.

  It is possible you might trip and/or fall and hurt yourself during the walking procedures. We will make every effort to monitor you closely to reduce this risk. Please tell us immediately if you feel unbalanced during any of the procedures. You may feel some emotional or physical stress while getting used to wearing an unfamiliar prosthesis.

  You may experience mild to moderate muscle soreness, pain, or other soft tissue irritation from walking with the TAP. This might happen during or after the study sessions. You may feel fatigued from walking during the study sessions. You will be allowed to take breaks between walking sessions, and you can stop walking at any time if needed.

  It is possible the TAP could have a mechanical failure and cause a soft tissue injury, laceration, or other minor injury such as knee or ankle joint soreness. The TAP has been thoroughly tested on a benchtop. A certified prosthetist will also evaluate the TAP.

- **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. However, society may benefit from the results of this study through an improved lower-limb prosthesis that helps people with an amputation walk better and reduces the incidence of soft tissue injuries to the residual limb.

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
- 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 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 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 for future use in scientific presentations and publications.

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 written approval.

All coded data will be kept indefinitely, including any video and photographs that obscure your identity. De-identified data, with study codes, will be transmitted to our offsite staff 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.

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.

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 for the development of lower-limb prosthetics. 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.

We will pay you $50 an hour for the first hour of each visit and then $30 an hour for each remaining hour of each visit to VA Puget Sound. If you are traveling 20+ miles one way for an appointment (40+ miles total), we will provide compensated mileage rates in accordance with the Veterans Affairs Beneficiary Travel program. Current mileage rates can be found at https://www.va.gov/HEALTHBENEFITS/vtp/beneficiary_travel.asp.

If you are traveling via ferry for an appointment, we will provide full ferry fare compensation. We will not offer compensation for other individuals traveling to the appointment with you. Current ferry fare rates can be found at https://www.wsdot.wa.gov/ferries/fares/. If we determine that the study is not a good fit for you, you will still be compensated for the first hour of the visit and receive any applicable travel compensation.

You will receive payment by check. Checks will be mailed to you about 6-8 weeks after each visit or you can pick them up at VA Puget Sound in Seattle = within the same timeframe. 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.

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

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Print Name of Subject