Title: Novel Lower-Limb Prostheses: Comparing Adherence, Perspiration, and Residual Limb Skin Health in a Hot, Humid Environment and During Activities of Daily Living

NCT03900845

Informed Consent Form Document Date: 17Mar2022

Consent to participate as a Research Subject in:

Comparing how well prosthetic systems stay put in hot and humid conditions, during everyday activities, and how they affect skin health

SUMMARY OF STUDY: Many people with below-knee amputations suffer from heat and sweat trapped inside their prostheses. Heat and sweat can cause skin problems and serious discomfort. We want to test whether different types of prostheses, during times of profuse sweating, can help keep the limb from slipping off, keep the residual limb skin healthy, and be more comfortable.

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:
Jocelyn Berge, MSE
G. Eli Kaufman, MS

Study Title:
Novel Lower-Limb Prostheses: Comparing Adherence, Perspiration, and Residual Limb Skin Health in a Hot, Humid Environment and During Activities of Daily Living

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

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 contact number at (206) 764-2962 or Principal Investigator at (206) 277-6724. After business hours (nights and weekends), please call our after-hours number at (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?

This research study will compare two lower-limb study prostheses with your prothesis to see which one is better at providing a secure, comfortable fit when worn in conditions that make you sweat a lot. We will also compare how well each prosthesis maintains residual limb skin health after worn for two weeks.

We will approach up to 200 people with a below-knee amputation to be in this study. In total, we will enroll up to 40 people to be in this 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 Health Care System (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 4-7 study visits that may span up to 2 months. If we find data are missing or corrupt, we may ask you to do another study visit.

We will ask you to not consume caffeine, tobacco, and alcohol for 2 hours before each visit and not to put anything on your skin for 12 hours before each visit.

We may call and/or email you to remind you about upcoming study visits.

Baseline Visit

This visit will take up to 3 hours. We will ask you to sit down and take off your prosthesis. If your limb is sweaty, we will dry it off with a towel. After you have sat with your prosthesis off for 15 minutes, we will use a specialized instrument to measure your skin health. To take the measurements, we will touch a few places on your legs with the instrument's handheld probes. If you have thick leg hair, we may need to shave a small patch (about the size of a quarter) to allow the instrument to get a good reading. We will also ask you to rate how comfortable your socket is on a 0-10 scale.

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

Self-Selected Walking Speed Test. We will ask you to walk several times at your own pace for about 65 feet back and forth in a straight hallway. You will do this test using your own prosthesis.

Prosthetic Fitting

These visits will take up to 2 hours each. During this study, we will ask you to wear two study prostheses and your own prosthesis. One of the study prostheses is a new, commercially-available, prosthesis that has a unique liner with holes in it that allow sweat to flow away from the skin. The other study prosthesis is an experimental design that has a bodyweight-activated pump to create airflow between the prosthesis and the skin. Our research prosthetist will make sure you can use both of the study prostheses. The fitting process might start during the first study visit, but it may take place over 2-3 visits.

Once both study prostheses fit well, we will randomly assign you (like flipping a coin) to wear one of the study prostheses during your usual daily activities for 2 weeks. During the daily use periods, please check your limb for redness and/or irritation twice a day. If you notice any issues, please contact us as soon as possible for instructions.

Step Count

During each 2-week daily use period, an electronic step counter taped to the prosthetic pylon/ankle will collect step-count data. The data will be collected from the step counter when you return for the next study visit. The step counter will not store any identifiable information about you, only your daily step counts.

Heart Disease Risk Screening

During the Baseline Visit or prosthetic-fitting visits, we need to make sure you are not at high risk for heart problems. To determine your risk, we will ask you some questions about yourself. We will ask your age, sex, and whether or not you are a smoker. We will ask whether you have a diabetes diagnosis or are on any medication to treat high blood pressure. Then we will take your blood pressure.

We will also need to know your cholesterol levels. Cholesterol levels are measured with a blood test. If you had a blood test in the last 2 years during a doctor's visit, we will try to get your cholesterol levels from your medical record. If you receive care at the VA or the UW, we will look at your medical record to get this information. If you do not receive care at the VA or the UW, we will ask you to call your doctor to find out your cholesterol levels. If you prefer, we can call your doctor for you. However, before we can call your doctor, you will need to sign a Release of Information Form that gives us permission to make the call.

If you have not had a blood test in the last 2 years or we cannot obtain your results from your medical record or from your doctor, then we will ask you to have a blood test at VA Puget Sound. The blood test will be free of charge to you and the lab may directly notify you of the test result. The blood test will only measure your cholesterol levels.

If we determine that your risk of heart problems is too high for this study, we will advise you to follow-up with your regular medical care provider, and you will not be able to participate further in the study.

Study Visit: Study Prosthesis 1

This visit will take up to 3 hours. After you use the first study prosthesis for 2 weeks, we will ask you to return to the VA for a data collection visit. We will ask you to drink about 8 to 15 ounces of water (a full water bottle) 2 hours before your study visit and to bring a pair of shorts and a T-shirt to wear. We will provide you with this clothing if you prefer. We will repeat the steps described above in the Baseline Visit to measure skin health and get your rating of the socket comfort.

While the prosthesis is off, we will make sure the socket and other key components are dry and we will weigh them. We will give you fresh, dry socks to wear during the procedures. We will ask you to

change into the T-shirt and shorts and put the prosthesis back on. A private area to change will be provided.

We will ask you to wear a wristwatch-style heart rate monitor during the study visit. We will also place a small absorbent pad on the calf of your intact leg to collect sweat. The pad will be attached to the skin using a sticky waterproof covering to prevent sweat loss. We will also draw a mark on the skin of your residual limb at the top edge of the socket liner so we can measure how much the liner slips.

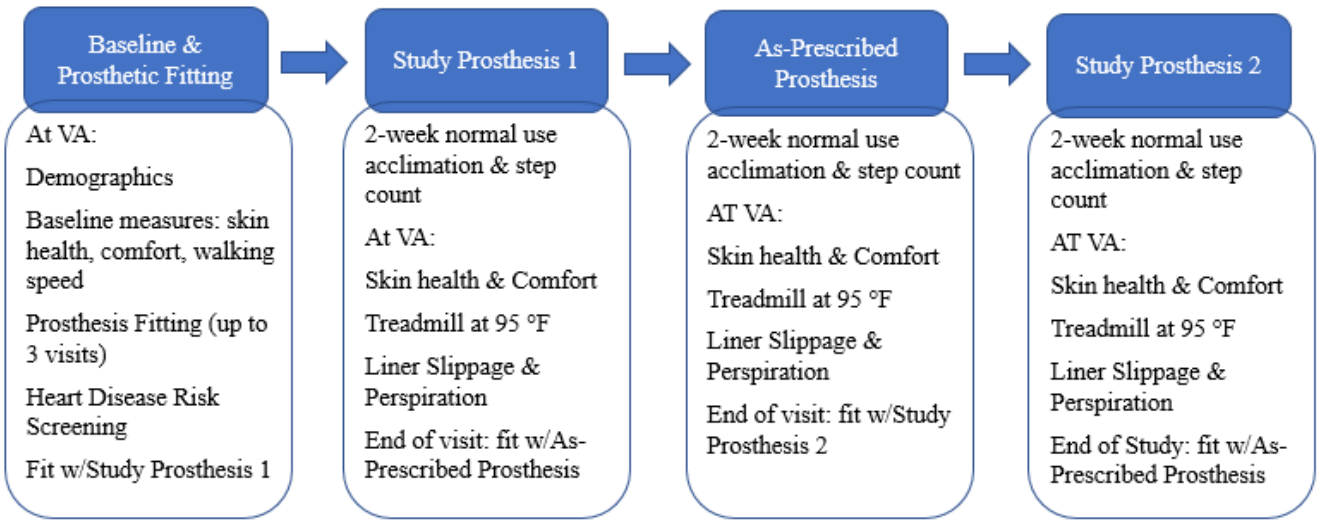
When you are ready, we will have you enter the climate-controlled space set at 95°F and 50% relative humidity. We will ask you to sit for 30 minutes, and then we will then have you walk on a treadmill at the same speed you did during the hallway walk for up to 30 minutes or until you feel like the prosthesis may slip off. If your heart rate gets too high, we will ask you to stop walking on the treadmill and move to a cooler room to rest. You can drink as much needed during the test. Handrails and a chair will be present in case you feel unsteady or wish to take a break.

When the treadmill walk is done, you will sit and rest in a space set to 68°F and 50% relative humidity for up to 30 minutes. We will ask you take off the prosthesis and we will measure how much the socket liner has slipped down. We will dry off your residual limb with an absorbent towel to collect the sweat remaining on your skin and remove the absorbent pad from your other leg. We will weigh the towels, prosthetic components, socks, and absorbent pad to see how much moisture you lost on your lower limbs by sweating.

Our prosthetist will fit you with your as-prescribed prosthesis and we will tape the step counter to it. You will wear your prosthesis during your normal daily activities for the next 2 weeks.

Study Visits: Personal Prosthesis & Study Prosthesis 2

This visit will take up to 3 hours. After 2 weeks of using your prosthesis, we will ask you to come back to the VA for the next data collection visit. We will ask you to do the same procedures you did with Study Prosthesis 1. At the end of the visit, you will be fit with the other study prosthesis; then, repeat the 2 weeks at home and the data collection visit. At the end of the last study visit, our prosthetist will re-fit you with your 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. Videos will be recorded without sound.

<u>DATA REPOSITORY</u> (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. This data repository is housed at VA Puget Sound Health Care System. 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 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:

Study prostheses. It is possible you might trip and/or fall and hurt yourself (for example getting a bruise, scrape, or joint soreness) while you wear the study prostheses at home and in the community. We will make every effort to monitor you closely to reduce this risk while you are at the VA. The research prosthetist will evaluate you before you go home with the study prostheses. 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, excessively dry skin, or other soft tissue irritation (for example a blister) from walking with the study prostheses. This might happen during study sessions or while you use the study prostheses during your normal daily activities.

Shaving (if needed). You may have razor burn and some embarrassment as the hair grows out from the areas shaved for the skin health tests.

Walking tests. You may get overly hot and tired from walking in the hot room. Although unlikely, this could cause you to faint or have a cardiac event. We will be tracking your heart-beats per minute to make sure your heart-rate does not go above a safe limit. You can also rest and cool off as needed.

Heart disease risk screening. You may feel stress or anxiety if we discover that your risk of having heart problems is too high for this study or that your cholesterol levels are high. If this occurs, you should discuss these results with your regular doctor.

Blood draw. If you need a blood draw for the screening test, the insertion of the needle into your arm may cause pain and/or a small bruise around the site. This is a usual risk that can happen with blood tests.

Absorbent pad. The waterproof covering of the absorbent pad worn on your intact limb may cause mild discomfort and irritation while in use or when removed. The removal feels similar to removing a Band-Aid.

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 stays more securely on the limb in hot and humid conditions while also keeping your skin healthly and remaining comfortable.

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
- Department of Defense (study sponsor)
- 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 Internal Revenue Service, and the U.S. Department of the Treasury
- The VA committees that oversee research
- Dr. Bruce Sangeorzan (medical monitor)
- Seattle Institute for Biomedical and Clinical Research (the nonprofit institute that works with VA Puget Sound to conduct research) 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 Department of Defense committees that oversee research, including the Department of Defense Institutional Review Board and supporting staff, will have access to your de-identified 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 ClinicalTrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Safekeeping and storage

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.

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.

Upon study completion
Once this study is completed, we will not use the study code linking you to your data 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; including any video and photographs that obscure your identity.

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.

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 may include health insurance companies who are being billed for medical costs. This record will be kept according to the VA records retention policy.

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 $600 for completing the entire study. 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/.

You will be paid after your participation in the study is finished. If you are screened out or withdrawn before finishing all the study procedures, we will compensate you on a prorated basis based on how many of the study procedures you completed as follows: $100 for completing the baseline visit, $200 for completing the prosthetic fitting visit(s), $100 for completing study visit for Study Prosthesis 1, $100 for completing study visit for personal prosthesis, and $100 for completing study visit for Study Prosthesis 2. You will also receive any applicable travel compensation.

You will receive payment by check. The check will be mailed to you about 2-8 weeks after your last study visit or you can pick it up within the same time frame 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.

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