Study title: Sub-Ischial Socket for Transfemoral Amputation and Lower Mobility

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UNIVERSITY OF WASHINGTON AND HANGER CLINIC
CONSENT FORM
Evaluation of the Northwestern University Sub-Ischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels (intervention group)

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KEY STUDY INFORMATION

This research study will determine whether a new prosthetic socket design, which is supposed to be more comfortable than current prosthetic socket designs, will help you wear the socket more and therefore walk more. We are inviting you to take part in the study because you have an above-the-knee amputation and wear a prosthesis. This page is to give you key information to help you decide whether or not to participate. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is above.

WHY ARE WE DOING THIS STUDY AND WHAT WILL YOU BE ASKED TO DO IF YOU PARTICIPATE?
We will first monitor you in your current socket for 3 months to establish a baseline regarding your wear and activity of the prosthesis. This will be done by attaching two sensors to your prosthesis that will measure temperature inside the socket and steps, as well as asking you to complete surveys (online, on paper, or by phone) every 4 weeks. Then your prosthetist will fabricate a new sub-ischial socket for you. Once you start wearing that socket every day, we will again monitor you for 6 months using the same sensors and asking you to complete the same survey every 4 weeks.

WHY MIGHT YOU NOT WANT TO BE IN THIS STUDY?
Adjusting to a new socket takes time and may rub your residual limb or cause redness, blistering or sores. Adapting to a new socket may also increase your risk of stumbling, tripping and falling. It is also possible that being repeatedly asked questions about your everyday life (e.g. symptoms of depression) may be upsetting.

WHY MIGHT YOU WANT TO BE IN THIS STUDY?
The new socket may be more comfortable and improve your ability to get around.

DO YOU HAVE TO TAKE PART IN THE STUDY?
If you decide to take part in the study, it should be because you really want to volunteer. If you decide not to take part, you will not lose any services, benefits, or rights you would normally have. You will still receive treatment from your prosthetist. You can choose to withdraw at any time during the study.

Researchers' Statement

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

What is the purpose of the study?

The purpose of this research is to determine whether a new prosthetic socket design, which is supposed to be more comfortable than current prosthetic socket designs, will help you wear the socket more and therefore walk more.

What does my participation in the study involve?

Participation in this study will last about 10 months and involves up to 7 in person-visits and 11 remote survey assessments spread over 3 periods as shown below.

Summary of the study sessions:

	Study Session	When	Location	Study Activity	Duration	Payment for completed session
Baseline monitoring period	Session 1	Week 0	Hanger Clinic (in-person)	Answer questions about amputation, current socket, and prothesis; perform physical tasks; sensors/activity monitor attached; 1 survey	2 hours	$60: in-person visit $40: survey
	Sessions 2 - 4	Weeks 4, 8 & 12	Home or place convenient for you	1 survey/session; replace & return sensors	30 minutes/ session	$40/session
Socket fabrication		Up to 4 visits	Hanger Clinic (in-person)	Casting and fitting socket	1-2 hours/visit	$60/visit
Intervention monitoring period	Session 5	Week 0	Hanger Clinic (in-person)	Receive new socket; perform physical tasks; sensors/activity monitor attached; 1 survey	1-2 hours	$60: in-person visit $40: survey
	Sessions 6 - 9	Weeks 4, 8, 12, & 16	Home or place convenient for you	1 survey/session; replace & return sensors	30 minutes/ session	$40/session
	Session 10	Week 20	Hanger Clinic (in-person)	Assess new socket fit; perform physical tasks; sensors/activity monitor attached; 1 survey	1-2 hours	$60: in-person visit $40: survey
	Session 11	Week 24	Home or place convenient for you	1 survey/session; replace & return sensors	30 minutes	$40: survey $50: bonus

Baseline Monitoring Period

To begin the study, you will attend an in-person visit with a prosthetist who will collect basic information about you, your amputation, your current socket and prothesis, and your ability to get around. We will ask you questions and ask you to perform physical tasks such as transfers, standing balance, and walking. The prosthetist will also attach sensors to your socket and prosthesis. The in-person visit will take about 2 hours.

During this baseline monitoring period, you will wear a small temperature sensor inside your current socket that allows us to measure how much the socket is being worn, as well as wearing a small step counter attached to your prosthesis to measure how much you walk. The temperature sensor and the step counter can record for 4 weeks. To replace the sensors over time, you have the option of going to your prosthetist and letting him/her switch them out, or we will mail you new sensors to attach along with a pre-paid envelope to mail back the sensors that are full of data.

Beginning on the same day as your in-person visit, you will also complete the same survey (online, on paper, or by telephone) every 4 weeks for a total of 4 times during the baseline monitoring period. The survey includes questions about how your current socket influences your everyday life, including questions about socket comfort, mobility, and balance, as well as questions about your physical and emotional well-being, including symptoms of depression. You may refuse to answer any question. Each survey assessment will take about 30 minutes to complete.

Socket Fabrication Period

Upon completion of the baseline monitoring phase, you will attend up to 4 in-person visits with a prosthetist to make the new socket. The new socket is different from current socket designs because it is made to fit over the thigh without touching the pelvis. The new socket is worn over a gel liner and would be attached to your current prosthetic knee and foot. The process of casting and fitting the socket is the same as you are familiar with from your routine prosthetic care. Each in-person visit will take about 2 hours.

After you receive the new socket, the prosthetist will be available to you as needed throughout the study to address any socket fit issues.

Intervention Monitoring Period

Once the new socket is ready for you to take home to wear, the prosthetist will collect information about your ability to get around using the new socket. The prosthetist will also attach the temperature sensor and step counter to your new socket and prosthesis. The day you receive the new socket is when the intervention monitoring period begins. Hence, beginning on the same day as you receive your new socket to take home, you will also complete the same survey as before, every 4 weeks for a total of 7 times during the intervention monitoring period. You will also wear the same sensors to measure how much the socket is worn and how many steps are taken.

5 months after receiving your new socket, you will attend an in-person visit with the prosthetist to ensure the socket is ok to continue wearing after the study ends. The prosthetist will collect

information about your mobility in the socket, similar to the first baseline visit, and attach new sensors and an activity monitor to your socket/prothesis. This visit will take about 1-2 hours.

1 month later, you will complete the final survey assessment. You will also use a pre-paid envelope to mail back the sensors and activity monitor. At this point, your participation in this study is complete.

If you like the new sub-ischial socket, you will be able to keep it at the end of the study and your prosthetist will provide any adjustments needed while you continue wearing it. You and your insurance will not incur any costs for routine socket adjustments needed after the study ends, but any major repairs or replacement of the socket will incur a cost to you and/or your insurance.

What are the risks?

Being in this study will expose you to some of the same risks you experience as an above-the-knee prosthesis user:

- The standard clinical process of making an above-the-knee prosthetic socket involves some loss of modesty and privacy given the intimate fit of the socket with your thigh.
- As an above-the-knee prosthesis user you are at a greater risk for stumbling, tripping and falling than people who do not use a prosthesis. The risk of stumbling, tripping and falling may be increased when adapting to a new socket.

Additionally:

- If you have not worn a silicone liner before and don't know that you are allergic to silicone, there is the possibility that you may experience itching, brief skin reaction, or an allergic reaction to the silicone liner. Where necessary you should consult your primary physician about an allergic reaction. Medical coverage for consulting your primary physician will be your responsibility.
- It is possible that the new socket may cause discomfort and/or pain in the residual limb. It may rub your residual limb and cause redness, blistering, or a sore, just as any new or ill-fitting socket may do. Your prosthetist will work with you to make adjustments to the socket to address these problems. Left unattended, an ill-fitting socket may lead to severe skin breakdown. If the residual limb develops a wound, infection could occur. Where necessary you should consult your primary physician about skin breakdown. Medical coverage for consulting your primary physician will be your responsibility.
- It is possible you may experience other issues from transitioning to and wearing a new socket, these include:
    - low back pain
    - residual limb fluid volume loss/shrinkage
    - loss of suspension
    - muscle cramping, limb discoloration, tingling or numbness from residual limb
    - constriction/too much compression
    - residual limb muscular fatigue
    - loosening of prosthetic component

The above issues are usually transient and can be addressed by the prosthetist making adjustments to your socket and/or prosthetic alignment. Some will disappear as you accommodate to wearing and walking in the new socket.

- It is possible that you may experience fatigue and/or boredom while answering the survey questions.
- There is the risk that being asked questions about your everyday life, such as symptoms of depression and/or mental well-being, may be upsetting.
- It is possible that someone could find out you were in this study and could find out information about you. The researchers have procedures in place to lessen the possibility of this happening.

Are there alternatives to participating in this study?

There may be other prosthetic socket designs available to you if you choose not to participate in this study. We recommend you speak to your prosthetist about the different options that may be available to you.

Are there any benefits to participating in this study?

The new socket may be more comfortable and increase your ability to get around. However, you might not experience any benefit from being in the study.

Who is funding this study?

The University of Washington is receiving financial support from the Department of Defense. Hanger Clinic is receiving financial support for this research from the United States Department of Defense (DOD) under a subcontract from University of Washington.

How is my information kept confidential?

All the information you provide will be confidential. Your name and other identifying information will be linked to a unique study number. Your study number will not include any information that can identify you. All data we collect from you will be coded with your study number and stored securely. The study team will use REDCap, an online database to collect and store your information. The information in REDCap will include information that will identify you, such as your name and contact information. REDCap is a secure system for data storage used in many research studies. REDCap requires a username and password to log-on and is encrypted. REDCap is stored on a secure server. The study team is able to choose who has access to log-on to REDCap and see your information. Access will only be given to Hanger Clinic and University of Washington study team members. The link between your identifying information and study data will be destroyed after the record retention period required by law.

Government or university staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The U.S. Food and Drug Administration (FDA) reserves the right to review study data that may contain identifying information.

Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the US Department of Defense (DOD), the DOD Human Research Protections Office, the Veterans Administration, and collaborators at Hanger Clinic. By signing this document, you are authorizing this access.

A description of this clinical trial will be available on http://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.

If a research staff member finds out you have plans or intent to harm yourself or others, s/he may refer you to or contact an appropriate individual or institution. We will not ask you about child or elder abuse, but if you tell us about child or elder abuse or neglect, we may be required or permitted by law or policy to report to authorities.

You may be withdrawn from the study without your consent if the researchers believe it is in your best interest or if you are not able to fulfill the study requirements.

Will I be paid for taking part in this study?

If you agree to take part in this research study, we will pay you $60 per in-person visit for up to 7 visits and $40 per survey assessment for 11 assessments. We will pay you a bonus of $50 at study completion if you complete all 11 survey assessments. If you complete all study visits you would receive up to $910. You will receive payment via check within 2-4 weeks of each study visit. You will only be paid for the study visits you complete.

Please note that additional visits to the prosthetist may be needed to adjust the socket. You will not be paid for these additional visits. Also, parking and transportation costs related to the in-person visits will not be covered.

If you earn $600 or more in subject payments from the University of Washington during this calendar year, the UW Financial Management Office will report this to the Internal Revenue Service as Miscellaneous Income.

How will my study information be used?

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

The information that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the study information. If we do so, that information may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, the UW Human Subjects Division will decide if we need to get additional permission from you.

We will not provide you with your individual results from this study.

Is there anything else I should know about the study?

You may refuse to participate and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

For female participants, because a pregnancy may affect your ability to wear a prosthetic socket, you will be withdrawn from the study if you become pregnant during the course of this study.

A copy of the consent form will be emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.

What if I think I have been injured by any research procedures?

If you think you have experienced a medical problem or injury because of participating in this study, please contact Stefania Fatone, PhD, at 206-685-7918 right away. She will refer you for treatment.

The costs of the treatment may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on a number of factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP.

The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form.

Participant's Statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098. I will receive a copy of this consent form.

Printed name of participant Signature of participant Date

Consent Presenter Statement

I have provided this participant and/or their legally authorized representative (LAR) with information about this study. The participant/LAR has been given sufficient time to consider participation and I have answered any questions they had. The participant and/or their LAR indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent Date

Copies to: Researcher
Participant