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

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INFORMATION ABOUT A UNIVERSITY OF WASHINGTON RESEARCH STUDY

Evaluation of the Northwestern University Sub-Ischial Socket for Persons with Transfemoral Amputation and Lower Mobility Levels (reference group)

What is this study about?

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 people like you wear the socket more and therefore walk more. Your role in this study is to provide reference data about what happens over time when the socket remains the same.

What will you be asked to do?

Participation in this study will last about 10 months and involves 8 remote survey assessments.

We will collect basic information about your amputation and your current socket and prothesis from your prosthetist or medical record. You will complete the same survey (either online, on paper, or by telephone) every 4 to 8 weeks for a total of 8 times. 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. Summary of the study sessions:

Study Session	When	Location	Study Activity	Duration	Payment for completed session
Sessions 1 - 8	Weeks 0, 4, 8, 12, 20, 28, 36 & 40	Home or place convenient for you	1 survey/ session	30 minutes/ session	$25/session $50: bonus for completing all sessions

Why might you want, or not want, to participate?

Being in this study will expose you to some risks:

- 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.

The alternative to taking part in this study is to not take part in this study.
You will not experience any direct benefit from being in the study.

How will we protect the information you provide?

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 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, and the Veterans Administration. By signing this document, you are authorizing this access.

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.

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 in 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 in this consent form.

The University of Washington is receiving financial support from the Department of Defense.

If you agree to take part in this research study, we will pay you $25 per survey assessment for up to 8 assessments. We will pay you a bonus of $50 at study completion if you complete all 8 survey assessments. If you complete all study sessions, you would receive a total of $250. You will receive payment via check within 2-4 weeks of each study session. You will only be paid for the study sessions you complete.

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.

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 the researcher listed in this consent form 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 listed in this consent form. 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.

What can you do if you want more information?

We are asking 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 or not. Please read the 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. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent."

Talk to someone else. If you want to talk about the study with someone who is not part of the study team, talk about your rights as a research subject, or to report problems or complaints about the study, contact the UW Human Subjects Division.

Study Team	Stefania Fatone, PhD, BPO(Hons), Principal Investigator, 206-685-7918 Dana Wilkie, Research Study Assistant, 206-221-2414 Alexandra Hinson, Research Study Assistant, 206-221-2414
UW Human Subjects Division	206-543-0098 hsdinfo@uw.edu

Participant's Statement

By signing this consent form, I confirm that the study has been explained to me and I volunteer to participate in the research. I have had a chance to ask questions. If I have questions later about the research or feel I have been harmed by participating in the study, I can contact a member of the research team or the UW Human Subjects Division using the information listed above. I will receive a copy of this consent form.

Printed name of participant Signature of participant Date

Consent Presenter Statement

By printing my name on this form, I am attesting that I have provided the participant with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant has 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