PARTICIPANT INFORMED CONSENT FORM AND AUTHORIZATION TO USE AND DISCLOSE MEDICAL INFORMATION

STUDY TITLE: Clinical Outcomes Associated with At Home Use of Non-Powered vs. Powered Prosthetic Knees by K2-level Individuals with Transfemoral Amputations

STUDY INVESTIGATOR: Shane R Wurdeman, PhD

STUDY SITE: Hanger Clinic
7020 Easy Wind Dr, Suite 130
Austin, TX 78752

TELEPHONE: 402-290-8051 (24 hours)

SPONSOR: Liberating Technologies, Inc.

RESEARCH CONSENT SUMMARY

You are being asked to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can take part now and later drop out, and it won't be held against you.
- Ask all the questions you want before you decide.

How long will I be in this research?

Your expected participation in this research is approximately 9 months. Site visits will be scheduled for both test sessions and training sessions at the Hanger Clinic where you typically visit your prosthetist. You will be provided with a commercially available prosthetic foot, the Össur ProFlex-LP, to use for this study. You will test out three different knee conditions at home for 3 months each. For the two powered knee conditions, you will be fit with the Össur Power Knee and the Reboocon INTUY® Knee. For the passive mechanical knee condition, you will be fit with the Össur OFM-2, which is similar to your current knee.

Why is this research being done?

This study is evaluating two powered knees and one mechanical knee to identify the prosthetic knee that is best suited for K2-level users during different tasks. This will be done by collecting

measured, observed, and self-reported outcomes achieved through real-world use of the prosthetic knees.

What happens to me if I agree to take part in this research?

Your participation in this study will last nine months with three at-home study portions each lasting 3 months. You will be asked to attend 4 to 8 training visits for each prosthetic knee, conduct normal activity at home, report any falls, and complete a series of functional and self-report measures at the clinic. Site visits are anticipated to take approximately 2 to 4 hours. We will also be providing you with the Össur Pro-Flex LP, a commercially available foot that is compatible with the study knees, to use throughout the duration of the study. You are free to terminate a session and your participation in this study whenever you wish.

Could being in this research hurt me?

The main risks of the devices are those that exist for all lower-limb prostheses including injury from tripping, falling, or losing balance. Changing from one prosthetic knee to another may increase the risk of falls. You may also experience fatigue during in-clinic testing. See below section “What are the potential risks of being in the study?” for additional details, including steps being taken to reduce the risks .

Will being in this research benefit me?

You will get to experience an extended at-home trial period for the three knees being tested. Beyond this, participation in this study provides no further known direct benefit to you.

What other choices do I have besides taking part in this research?

Your alternative is to not take part in the research.

DETAILED RESEARCH CONSENT

In this consent form, “you” always refers to the subject.

WHAT IS THE PURPOSE OF THIS FORM?

You are being invited to participate in a research study conducted at **Hanger Clinic**. A person who takes part in a research study is called a research subject, or research participant. This part of the form provides detailed information about what will happen during the study. It is important that you read the following explanation of the proposed procedures.

WHAT SHOULD I KNOW ABOUT THIS RESEARCH?

- A member of the study staff will read through the consent form with you and discuss all the information.
- This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes your right to withdraw from the study at any time.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of medical care or benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don’t understand, ask questions.
- Ask all the questions you want before you decide.
- When you are informed of the study and have no more questions, you will then be asked if you agree to take part.
- If you agree, you will be asked to sign this consent form. Once you sign it, we will give you a signed and dated copy to keep.

You may show this consent form to family and friends before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study.

WHY IS THIS RESEARCH BEING DONE AND WHAT IS BEING STUDIED?

You are being asked to participate in this study because you are a K2-level prosthesis user. This means that you have the ability or potential for walking on low level barriers such as curbs, stairs, or uneven surfaces.

This study is evaluating two powered knees and one mechanical knee to identify the prosthetic knee that is best suited for K2-level users during different tasks. This will be done by collecting measured, observed, and self-reported outcomes achieved through real-world use of the prosthetic knees.

During this study, you will test 3 different knee conditions. You will be provided with the Össur Pro-Flex LP, a commercially available prosthetic ankle/foot compatible with all 3 test knees, to wear throughout the study. For each condition, you will wear one of the three test knees for

approximately 3 months. Once your testing has been completed, you will go back to using your original prosthesis.

Up to 26 people aged 18 and older will take part in this research.

HOW LONG WILL I BE IN THIS RESEARCH?

Your expected participation in this research is approximately 9 months. Participation will consist of site visits, training sessions, at-home wear of the devices, and functional tests and assessments at the beginning and end of each intervention condition as well as at your final training session for each condition. Site visits and training sessions will be scheduled at the Hanger Clinic where you typically visit your prosthetist. These visits will be scheduled at your convenience within certain time windows.

WHAT HAPPENS TO ME IF I AGREE TO TAKE PART IN THIS RESEARCH?

Your participation in this study will last nine months with three, 3-month take-home study portions. You will be asked to attend 4 to 8 training visits for each knee condition, conduct normal activity at home, report your falls, and complete a series of functional tests and assessments at the beginning and end of each knee condition as well as during your final training visit for each knee. During each condition, you will wear an activity monitor to track your daily step count.

Site visits will take approximately 2 to 4 hours. Additional visits may be scheduled if issues arise (issues with alignment, time constraints, etc.). You are free to terminate a session and your participation in this study whenever you wish. The specific study events are detailed below.

Site Visit 1

Before any study procedures are performed, you will be asked to read and sign this consent form. The study staff will collect information from you about your demographics (age, race, sex, etc.), your height, weight and type of prosthetic foot and socket suspension. You will then be fit with the first prosthetic knee by a certified prosthetist. This visit is expected to take approximately 2 hours.

Period 1: At-Home Participation Months 1-3

During the first month of the take-home period, you will be trained on the first knee condition and allowed time to acclimate to it. At a minimum, you will receive three training sessions to learn how to properly use the knee for a variety of daily activities and a fourth session to demonstrate the learned skills. At the first and last training sessions, you will be asked to complete a series of functional tests and self-report surveys on the knee. After the training sessions have been completed, you will be asked to continue using the knee in your daily life for the remainder of the 3-month take-home period.

Study staff will call you no more than weekly to record your responses to our custom fall questionnaire. You may be asked to provide additional notes of unforeseen events or issues you may be experiencing during this knee condition. Study staff will call or email you periodically to check-in and answer any questions you may have.

Site Visit 2

After 3 months of using the knee from condition 1, you will return for your second site visit. You will be asked to complete a series of functional and self-report measures on the first knee. Afterwards, you will be set up with the second prosthetic knee condition by a certified prosthetist. This visit is expected to take approximately 4 hours.

Period 2: At-Home Participation Months 4-6

This period is the same as Period 1, except with the second prosthetic knee being tested.

Site Visit 3

After 3 months of using the knee from condition 2, you will return for your third site visit. You will be asked to complete a series of functional and self-report measures on the second knee. Afterwards, you will be set up with the third prosthetic knee condition by a certified prosthetist. This visit is expected to take approximately 4 hours.

Period 3: At-Home Participation Months 7-9

This period is the same as Periods 1 and 2, except with the third prosthetic knee being tested.

Site Visit 4

At the end of Period 3, you will return to the clinic. You will be asked to complete a series of functional tests and self-report surveys on the third knee. After completing these measures, you will be set back up on your usual prosthetic knee and foot by a certified prosthetist. This visit is expected to take approximately 2 hours. This marks the end of your participation in the study.

WHAT ARE THE POTENTIAL RISKS OF BEING IN THE STUDY?

The main risks of the devices are those that exist for all lower-limb prostheses including injury from tripping, falling, or losing balance. Changing from one prosthetic knee to another may increase the risk of falls. You may also experience fatigue during in-clinic testing.

To reduce the risk of tripping, falling, or losing balance, a certified prosthetist will fit you with all prosthetic components. You will be provided with instructions, training, and acclimation periods for each knee condition. Safety methods (such as handrails, parallel bars, spotters, gait belts, overhead harnessing, etc.) will be available during in-clinic testing to reduce fall or trip hazards. Training will be conducted in a clinical setting before you are sent home with any new devices. If you feel as though the knee is giving you trouble at home, you may schedule a visit with the on-site prosthetist to fix any issues or configure you back on your usual socket if the problem persists. To reduce any fatigue during in-clinic training and testing, rests and break periods will be allowed and encouraged to ensure you are comfortable while training and performing tests with the devices.

There may be other risks that are unknown at this time.

Using a knee that you are unfamiliar with may increase the risk of falling. Therefore, pregnant women should not participate in the study.

WILL BEING IN THIS RESEARCH BENEFIT ME?

You will get the opportunity to experience an extended at-home trial period for the three knees being tested: two powered knees and one passive mechanical knee. Beyond this, participating in this study provides no further known direct benefit to you. Your participation in this study will expand the knowledge of the prosthetic community by further understanding how users benefit from each of the prosthetic knees being tested. This research will in turn help prosthetists make more informed clinical decisions when determining which devices are the best fit for their patients.

WHAT OTHER CHOICES DO I HAVE BESIDES TAKING PART IN THIS RESEARCH?

Your participation in this study is voluntary. You are free to withdraw consent and stop participation at any time. This research is not designed to diagnose, treat, or prevent any disease. Your alternative is to not take part in the research. Your refusal to participate or your withdrawal from the study will involve no penalty or loss of benefits to which you are entitled.

WHAT HAPPENS TO THE INFORMATION COLLECTED FOR THIS RESEARCH?

Records of your participation in this study will be held confidential, so far as permitted by law. However, your private information and your medical record may be shared with individuals and organizations that conduct or watch over this research, including:

- The research sponsor
- People who work with the research sponsor
- Government agencies, such as the Food and Drug Administration
- Sterling IRB, the Institutional Review Board (IRB) that reviewed this research

We may publish the results of this research. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. As with anything, there is the potential of a data breach, however we follow a strict protocol to keep your data secure and minimize this risk. By signing this consent form, you authorize the study investigators to release your study records to the sponsor, the FDA, and the IRB.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS RESEARCH?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the study staff at the phone number listed above on the first page.

This research is being overseen by Sterling IRB. An IRB is a group of people who perform independent review of research studies.

You may contact them at 888-636-1062 or info@sterlingirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

WHAT IF I AM INJURED BECAUSE OF TAKING PART IN THIS RESEARCH?

If you are injured or get sick because of being in this research, call the study investigator immediately. The study investigator will provide guidance for you to seek emergency medical treatment. Your insurance may be billed for this treatment. No other payment is routinely available from the study doctor or sponsor.

You do not waive any of your legal rights by signing this form.

CAN I BE REMOVED FROM THIS RESEARCH WITHOUT MY APPROVAL?

The study investigator or study sponsor can remove you from this research without your approval. Possible reasons for removal include:

- It is in your best interest
- You have a side effect that requires stopping the research
- You do not meet the eligibility criteria anymore
- You become pregnant
- The research is canceled by the FDA or the sponsor
- You are unable to keep your scheduled appointments

Data obtained in this study will become the property of the study investigator and study sponsor (Hanger and Liberating Technologies, Inc). If you withdraw from the study, data already collected from you will remain in the study.

WILL I BE PAID FOR TAKING PART IN THIS RESEARCH?

You will be compensated for the studys. You will receive $100.00 for each of the 4 Site Visit, for a total of $400.00 for completing all visits. You will also receive $100.00 upon completing 4 months, and $175.00 for completing 6 months of the study, for a total of $275.00 for reaching these take-home testing milestones. Upon completion of the study and return of study materials, you will receive an additional $245.00. The total anticipated payment for this study is up to $920.00.

ARE THERE ANY COSTS TO ME FROM PARTICIPATING IN THIS STUDY?

There are no costs to you for participating in this study. The knee prothesis that are being studied will be provided at no cost to you and you will not be charged for training or site visits for assessments.

CONSENT TO PHOTOGRAPH AND/OR VIDEOTAPE

_____ I give my permission to take photographs and/or videotape recordings of me during testing. I understand that these images may be used in medical or scientific publications and presentations. I give my permission to the study investigators to publish and present photographs and videos of me with the condition that they conceal my face and other identifying marks, such as birth marks or tattoos. I understand that the study investigators will not reveal my name or any other personal information about me.

_____ I do not give my permission to take photographs and/or videotape recordings of me during testing.

DATA REUSE AND CONTRIBUTION OF YOUR DATA TO A PUBLIC DATA ARCHIVE

The data from this study will also be contributed to publicly available databases and/or reused by the study investigators in future research. The purpose of this data reuse is to share your data with other researchers (or reuse the data ourselves) to make further advances in medicine, science, and teaching. Your data could be used for many different purposes. Most researchers will gain access to your data over the Internet. Before contributing your data, all information that identifies you as a subject in this study (including your name) will be encrypted using a random code. The only way to relate the code to yourself is by a “key” that the study investigators will maintain private. We will never reveal your identity, unless required to do so by law. The public database will not provide any direct access to your identity.

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 website at any time.

STATEMENT OF CONSENT

You agree that you have been given a chance to ask questions about this research study. These questions have been answered to your satisfaction. If you have any more questions about taking part in this study, you may contact:

Shane Wurdeman, Ph.D.
(402)-290-8051

Liberating Technologies, Inc. are being paid by the sponsor for your participation in this study.

Your participation in this research project is voluntary. You may quit the study at any time without harming your future medical care or losing any benefits to which you might be entitled. The investigator in charge of this study may decide at any time that you should no longer participate in this study.

By signing this form, you have not waived any of your legal rights.

Your signature documents your consent to take part in this research. You will be given a copy of this signed and dated form for your own records.

_____ _____
Study participant (Signature) Date

_____
Print participant's name

_____ _____
Person who explained this study (signature) Date