INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Limb Health and Socket Pressure in Response to Powered Ankle Prostheses
SPONSOR: US Department of Defense
PI: Sashwati Roy PhD
Protocol # 12143

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent and Authorization form will give you information about this study to help you decide whether you want to participate. It is your choice whether or not you want to be in this research study. Please read this form, and ask any questions you have, before agreeing to be in this study.

STUDY SUMMARY

Advancements in prostheses for individuals with transtibial, or below the knee, amputations offer the potential for an increase in performance in areas related to mobility, quality of life, and allowing individuals to return to work sooner. We hope to discover if either of two FDA-cleared devices, the PROPRIO FOOT® from Ossur or the Empower ankle from Ottobock, offers better mobility or comfort than other prostheses.

This project is research and your participation in the study is voluntary.

You will be in the study between 11-14 weeks. There will be the following procedures:

- Evaluation for study participation, including limb measurements and weight at multiple visits.
- You will be asked to complete questionnaires at multiple visits.
- You will be asked to do multiple walking trials (including stairs, ramps, and flat surfaces) using the prosthetic you normally use, the PROPRIO FOOT, and the Empower ankle.
- You will be asked to exclusively wear each of the study prosthetic devices for one month instead of the prosthetic you normally wear.

The benefits of this study are that you may find the new devices allow for greater mobility than a standard prosthetic device.

The known risks are that you may fall while participating during the walking trials that will include stairs and ramps. You also may experience irritation with the new prosthetic device, which we will work to eliminate. There is also a risk of loss of confidentiality, which we will ensure your privacy by only allowing authorized team members access to your information. You may experience mild discomfort due to the reflective markers placed on your skin, as the adhesive may require mild pressure to remove them. There is also a risk that the tape we use could pull your skin when removed and cause mild discomfort.

For Women of Child Bearing Potential:

We are unsure of the risks to a fetus and cannot enroll women who are pregnant or planning to become pregnant. If you are a female of child bearing potential please attest below that you are currently not pregnant or planning to become pregnant and the date of your last menstrual period.

- I am currently not pregnant and not planning to become pregnant
  Date of last menstrual period (MM/DD/YYYY) _____

Please review the rest of this document for more details about this study and the things you should know before deciding whether to participate in this study.

WHY IS THIS STUDY BEING DONE?

We hope to find that the impact on the muscle and skeletal systems improves with the use of the PROPRIO Foot or the Empower ankle. We are asking you if you want to be in this study because you are an amputee that uses a prosthesis and can walk at the required level to be included in the study.

The study is being conducted by Sashwati Roy, PhD of the Department of Surgery at the Indiana University School of Medicine. It is funded by the Department of Defense.

HOW MANY PEOPLE WILL TAKE PART?

You will be one of 13 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your total participation time in the study will be 11-14 weeks. We also ask that you wear fitted shorts/athletic wear for these visits. Study team members will offer specific guidance on style. The number of visits will be based on your preference depending on your preferred time allocation. You will have the option to attend either 4 or 6 study visits. If opting for 4 study visits, visit 3 and 4 will be combined, as well as visit 5 and 6. The total time per participant to complete all visits will remain the same despite which option you choose.

Study Visit 1/Evaluation: This initial visit will take place at IU Health Methodist Hospital and will last about an hour. At this visit, you will need to be evaluated to see if you are a candidate for a prosthetic foot. This will involve examining limb length and limb to floor measurements (known as MPT-to-Floor). If it's determined that you are a candidate for the study, the following research activities will take place.

- You will complete the Socket Comfort Score (SCS) questionnaire, CLASS and Prosthetic Evaluation Questionnaire (PEQ-13) survey. These are measures of your comfort level and how the prosthetic is performing for you.
    - The SCS questionnaire measures the socket comfort of their artificial limb on a scale from 0-10, with 0 representing the most uncomfortable socket fit you can imagine and 10 representing the most comfortable socket fit.
    - The PEQ-13 will ask you questions related to the prosthesis and life with the prosthesis.
    - The CLASS survey will ask you question about the function and fit of your prosthetic socket
- Your weight will be measured.
- The following non-invasive limb health measurements will be performed:
    - Trans epidermal water loss measurement (TEWL): We will move a small probe over your skin to compare the relative humidity of your skin surface. This measures the health of your skin.
    - Laser Speckle Imaging (LSI): this is a non-invasive imaging technique that illuminates an object (like your leg) with laser light and observes the backscattered light pattern of light and dark areas. This pattern is called a speckle pattern and can help measure the blood flow to your skin.
- After you attend the initial study Visit 1/Evaluation and are found eligible to participate, you will undergo a randomization process (like the flip of a coin), resulting in you first obtaining

either the PROPRIO FOOT® by Ossur, or the Empower ankle by Ottobock. Regardless of which device you start out with, you will use both devices throughout your time in the study.

- A licensed prosthetist will perform pre-fitting and adjustments to ensure the research foot (Foot A) will be ready to deliver during your next visit

Study Visit 2/Baseline: The second visit will occur 1-2 weeks after the first study visit and will take place at the Gait Lab, located in the IU Health Neuroscience Center. This visit will last 2 to 2.5 hours, and you should wear tight-fitting clothing (such as exercise or yoga-style clothing). The following procedures will be performed during this visit:

- Digital Shape Capture: We will digitally capture the shape of your limb by using a scanner so that we can create a digital file of what the internal shape of your socket should be. This file will then be used with a computer software program to optimize the fit of your prosthesis.
- We will place pressure sensors inside your standard-of-care socket (the socket you normally use). The sensors will be taped into your definitive socket between the gel liner and the defective (laminated) socket and will never make contact with your skin. These sensors will record data during this study visit.
- Your weight will be measured.
- You will be asked to do multiple walking trials using stairs, ramps, and flat surfaces while wearing the prosthetic you normally use.
    - While you are doing these walking trials, you will have markers placed on your clothing or skin that allow a 3D motion camera to capture movement. These specially designed markers will track the movement and angles of your upper and lower extremities and allow us to study their motion. The reflective markers are easily removed after this information is collected. The cameras ONLY see these reflective markers' movement and nothing else.
    - Walking tasks and ascending/descending tasks on stairs and ramps will be completed with the use of force-sensing pads using the prosthetic you normally use.
- You will then be fitted with the research foot that you were randomized to receive first, and you will be asked to move and walk around for about 15-30 minutes to allow you to acclimate to the new foot.
- You will then repeat the walking trials, but this time you will wear the new research prosthetic foot (Foot A).
- The prosthetist will remove the pressure sensors from the socket after the walking trials are completed and before you leave.

After you've completed this visit, you will be asked to exclusively wear Foot A for 4 weeks in place of the prosthetic foot you usually wear.

Study Visit 3: After four weeks, you will return for Visit 3 at IU Health Methodist Hospital. This visit will last 1-1.5 hours. The following activities will take place during Visit 3:

- We will ask you if you have had any issues with Foot A or your general health since the last study visit.
- Your weight will be measured

- You will complete the Socket Comfort Score, CLASS and PEQ-13 questionnaires.
- Non-invasive limb health measurements will be performed (TEWL and LSI)
- A licensed prosthetist will perform pre-fitting and adjustments, ensuring the other research foot (Foot B) will be ready to deliver during your next visit.

Study Visit 4 (Study Visit 3 if opted for 4 Study Visits): Study Visit 4 will occur within a week after Visit 3. This visit will take place at the IU Health Neuroscience Center and will last 2-2.5 hours. You should wear tight-fitting clothing to this visit. The following activities will take place:

- We will ask you if you have had any issues with Foot A or your general health since the last study visit.
- Digital Shape Capture will be performed, like at Visit 2
- We will place pressure sensors inside the socket for Foot A. These sensors will record data during this study visit.
- Your weight will be measured.
- You will be asked to do multiple walking trials using stairs, ramps, and flat surfaces while wearing Foot A
    - We will place reflective markers on you to capture movement with the 3D motion camera.
    - You will do the walking trials twice: once with the device's battery on, and once with the battery off.
- The prosthetist will then remove Foot A and you will be fitted with the other research foot (Foot B).
- You will be asked to move and walk around for about 15-30 minutes to allow you to acclimate to the new foot.
- You will then repeat the walking trials, but this time you will wear the new research prosthetic foot (Foot B).
- The prosthetist will remove the pressure sensors from the socket after the walking trials are completed and before you leave.

After you've completed this visit, you will be asked to exclusively wear the research device (Foot B) for 4 weeks in place of the prosthetic foot you usually wear.

Study Visit 5 (Final Visit if opted for 4 Study Visits): Study Visit 5 or Final Visit, pending visit choice, will occur about 4 weeks after Visit 4. It will take place at IUH Methodist Hospital and will last around an hour. The following activities will take place during Visit 5:

- We will ask you if you have had any issues with Foot B or your general health since the last study visit.
- Your weight will be measured
- You will complete the Socket Comfort Score, CLASS and PEQ-13 questionnaires.
- Non-invasive limb health measurements will be performed (TEWL and LSI)

Study Visit 6: Study Visit 6 will be the final visit, and it will occur within a week after Visit 5. This visit will take place at the IU Health Neuroscience Center and will last up to 2.5 hours. You should wear tight-fitting clothing to this visit. The following activities will take place:

- We will ask you if you have had any issues with Foot A or your general health since the last study visit.
- Digital Shape Capture will be performed, like at Visits 2 and 4.
- We will place pressure sensors inside the socket for Foot B. These sensors will record data during this study visit.
- Your weight will be measured.
- You will be asked to do multiple walking trials using stairs, ramps, and flat surfaces while wearing Foot A.
    - We will place reflective markers on you to capture movement with the 3D motion camera.
    - You will do the walking trials twice: once with the device's battery on, and once with the battery off.
- The prosthetist will remove Foot B and remove the pressure sensors from the socket. They will then refit your original prosthetic foot, evaluate its alignment, and verify its comfort. Your participation in the study is now complete.

If you participate in this study, we may learn things about you from the study procedures that could be important or interesting to you. Depending on the information, you might need to meet with professionals with expertise to help you decide what to do with the information. We do not have money or funds available to cover the costs of any follow-up consultations or actions. We will share the following information with you:

During this study, we will learn things about you that you may find interesting but probably will not help you. Health care providers may not know what the information means or what to do about it. Examples include seeing information that you walked better with the study device(s). Some people find this kind of information confusing or stressful. You can choose whether to receive this information.

I wish to receive this information yes_____(initial)

No_____(initial)

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

Socket Comfort Score and PEQ-13 questionnaires: You may be uncomfortable while answering these questionnaires. While completing the questionnaires, you can skip any questions that make you uncomfortable or that you do not want to answer.

CLASS Survey (Comprehensive Lower Limb Amputee Socket Survey): this survey is a self report measure of socket fit that asks the subject to rate stability, comfort, appearance and suspension for their prosthetic socket.

Breach of confidentiality: Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you. Only trained and authorized study team

members will have access to your personal information. More information about how we will protect your information to reduce this risk is below.

The study procedures using the TEWL, LSI, Prosthetic devices, and the motion capture and gait analysis have minimal risks as described below:

Walking/Gait tests: Falling is always a risk when walking with a prosthesis. You will be able to perform all tasks at a speed you feel comfortable and may refuse to complete anything you are uncomfortable completing. Study staff will be near to you to provide assistance if needed.

Timed Up and Go test: You will stand from a seated position and walk approximately 3 meters and then return to a seated position. This activity will be timed by research staff. Falling is always a risk when walking with a prosthesis. You will be able to perform all tasks at a speed you feel comfortable and may refuse to complete anything you are uncomfortable completing. Study staff will be near to you to provide assistance if needed.

Motion Capture and Gait Analysis**:** Reflective markers will be placed on you with the goal of recording your movement while you walk. There is a slight risk that the removal of the markers could cause discomfort (like removing a band-aid).

Prosthetic devices: There is a minimal risk that you could lose your balance and fall when using either of the prosthetic devices. The team will work to minimize this risk and will be near you to provide assistance if needed.

TEWL probe: (Transepidermal water loss) This instrument is a non-invasive probe that is placed on the skin that measures water loss coming from the skin. There are no known risks with this probe.

Laser Speckle Imaging: **(LSI):** A non-invasive imaging device that measures blood flow, referring to the rate of blood flow through the vessels serving the skin. There are no known risks with this device.

There are no known risk involving the pressure sensors or Digital Shape Capture

Please see above regarding risks to a pregnancy on page 2.

There could be discomfort when adhesive materials are used when being removed from the skin.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured as a result of participating in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. No money or funds are set aside to pay for these types of injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled by signing this Informed Consent form.

WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

You may find the new devices allow for greater mobility than a standard prosthetic device, but we are not sure. We hope to learn things that will help other people in the future.

WILL I BE PAID FOR PARTICIPATION?

You will be compensated for your time and effort as follows with a study payment card that can be used like a debit or credit card, all payments will generally be available within 24 hours of the study visit.

- Study Visit 1: $50
- Study Visit 2: $50
- Study Visit 3: $100 (Payment of $150 will be compensated if opted for 4 study visits)
- Study Visit 4: $50
- Study Visit 5: $50 (Payment of $150 will be compensated if opted for 4 study visits)
- Study Visit 6: $100

If you miss a visit or do not finish the study, you will only be paid for visits you attend. You will not be paid for visits that you missed.

Since the visits are going to be long, lunches will be provided. Lunches will be catered, and no reimbursements or vouchers will need to be administered. You will not be charged for your lunch.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you for taking part in this study.

HOW WILL MY INFORMATION BE USED?

The study team will collect information about you from your medical records. This information, some of which may identify you, may be used for research-related purposes. This may include making sure you meet the criteria to be in this study, gathering information about your medical history to include in the research data, reviewing results of your medical tests for safety purposes, or to inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include:

- Radiology records
- Medical history/treatment
- Consultations
- Radiology films (like X-rays or CT scans)

If you agree to participate, you authorize the following to disclose your medical record information:

- Indiana University Health
- Indiana University Health Physicians
- IUMG – Primary Care Physicians
- Eskenazi Health
- Indiana Network for Patient Care (INPC)

The following individuals and organizations may receive or use your identifiable health information:

- The researchers and research staff conducting the study
- The Institutional Review Boards (IRB) or its designees that review this study
- Indiana University
- US or foreign governments or agencies as required by law
- Data safety monitoring boards and others authorized to monitor the conduct of the study
- The following research sponsors: Department of Defense
- State or federal agencies with research oversite responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - The United States Food and Drug Administration (FDA)

Information collected for this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

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.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study. Your personal information may be shared outside the research study if required by law and/or to individuals or organizations that oversee the conduct of research studies and these individuals or organizations may not be held to the same legal privacy standards as are doctors and hospitals.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the researcher, Sashwati Roy, PhD, at 317-278-2706. After business hours, please call 317-944-5000 and ask for Dr. Roy to be paged.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or offer input, contact the IU Human Subjects Office at 800-696-2949 or IRB@iu.edu.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study. Or, you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with IU Health or Indiana University.

If you change your mind and decide to leave the study in the future, the study team will help you withdraw from the study safely. If you decide to withdraw, please contact your study coordinator at 317.278.2715 and they will work with you to leave the study.

If you choose to withdraw your authorization for use and disclosure of your protected health information, you must do so in writing by notifying Sashwati Roy, PhD - IU Methodist Comprehensive Wound Center, 1701 N Senate Ave., Suite AG 048, Indianapolis, IN 46202.

If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

The researchers may stop your participation in the study even if you do not want to stop if the research team feels it is in your best interest. Also, this study could be stopped by the Department of Defense.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

PARTICIPANT'S CONSENT AND AUTHORIZATION

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this document to keep for my records.

Participant's Printed Name **Date**	**Printed Name of Person Obtaining Consent** **Date**
Participant's Signature	**Signature of Person Obtaining Consent**
Participant's Address	