INDIANA UNIVERSITY INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Digital Weight Bearing Shape Capture Socket Technology to Preserve Limb Health and Improve Rehabilitation Outcomes

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IRB Protocol #15478

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

This study will compare the use of Symphonie Aqua Digital System, which is a new way to create a socket for prosthetics, to the current method that is generally used to create sockets. The study team will look at the differences in comfort and fit between the Symphonie Aqua Digital System and the current standard of care (SOC).

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

You will be in the study for approximately 12 weeks. There will be the following procedures:

- You will go through all the study visits using your current SOC socket (Socket A) and prosthesis. The socket is a device that goes between the skin of the limb and the prosthesis. The prosthesis is the entire device from the foot to the socket.
- You will then repeat all the study visits using the research system socket (Socket B) Symphonie Aqua Digital and a non-digital (as the backup) System. The backup system will be in place in case the digital system does not work. The digital system involves scanning the limb followed by creating the socket by a machine; whereas the non-digital (backup) works the same way except the creation of the socket will be completed by the prosthetist.
- You will be evaluated 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 (may include stairs, ramps, and flat surfaces) using the prosthetic you normally use SOC (Socket A) and the research socket (Socket B) Symphonie Aqua Digital System that will be created for you.

The benefit of this study is that the research socket (Socket B) creation methods may allow for greater mobility than a standard prosthetic device. But we do not know for sure. Some of the known risks are that you may fall while participating during the walking trials that will include stairs and ramps. You also may experience skin irritation with the research prosthetic device, which we will work to eliminate. There is also a risk of loss of confidentiality. We have procedures in place to protect your information.

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 out if Symphonie Aqua Digital System, a new method of socket creation, in a weight-bearing environment, may produce more successful fitting and comfortability outcomes than traditional sockets. We want to see if creating a socket while applying full-weight on your amputated limb will reveal a more anatomical shape of your residual limb, that will ultimately improve the fit of your prosthetic socket. Additionally, we want to see if a well-fitting socket will positively impact the overall health of your residual limb. This study involves the use of a new commercially available device called Symphonie Aqua Digital System and Symphonie Aqua System (non-digital) aka research socket (Socket B).

We are asking you if you want to be in this study because you are an amputee that uses a well-fitting 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 12 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Your total participation time in the study will be approximately 12 weeks.

Study Visit 1/Evaluation: The initial visits will take place at IU Health Methodist Hospital and will last about 3-4 hours. You should wear clothing that is comfortable for you while you may be participating in physical activity. If you do not have any comfortable-fitting clothes, please speak with research personnel. Research personnel will provide you with the appropriate clothing if you are unable to bring any during this visit. During this time, various measurements will be performed including:

- Digital weight bearing Shape Capture: We will digitally capture (via computer) the shape of your limb, that will create a digital file (computer 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. This image will be used to create a check socket (temporary socket) to confirm a correct anatomical and comfortable socket. Then the check socket (temporary socket) will be used to create a laminated final socket for home use and research outcomes. The check socket is temporarily used; whereas, the final socket is for long-term use. You will return in about one week to check the socket fitting. We may need you to return up to 3-4 additional times for more socket fittings for up to 6 weeks.

In addition, at this visit the following procedures will be performed while wearing the SOC socket (Socket A) during the visit:

- Baseline TEWL (Trans-Epidermal Water Loss) Measurements: This instrument is a non-invasive probe that is placed on the skin that measures water loss coming from the skin.
- Laser Speckle Imaging (LSI) measurements: A non-invasive imaging device that measures blood flow through the vessels serving the skin.
- Pressure Socket Sensors: In-socket sensors will be positioned into the SOC socket A which will aid in detecting the amount of weight placed on your amputated limb.
- Motion Capture Analyses and Walking Tests: small device containing sensors with Velcro will be placed on you with the goal of recording your movement while you walk in the SOC socket A.
- 6 Minute Walk Test (6MWT): Assesses your walking capacity on short distances by measuring the distance you cover walking for 6 minutes in the SOC socket A.
- Timed Up-and Go (TUG) Test: Assesses the general mobility and balance of your walking.
- Questionnaires (Houghton Scale, Socket Comfort Score, Veterans RAND 36-Item Health Survey). You will be asked questions about the fit and comfort of your socket A and ability to perform activities of daily living
- The prosthetist will remove the pressure sensors from the SOC socket A after the walking trials are completed and before you leave.

Study Visit 2/Baseline: The second visit will occur 6 weeks (+/- 14 days) after the first study visits and after all the fittings for the Weight Bearing systems (Socket B) have taken place. This visit will take place at Methodist Hospital. This visit will last 2 to 2.5 hours, and you should wear clothing that is comfortable for you while you may be participating in physical activity. This visit is the baseline visit for socket B (Symphonie Aqua Digital System socket). The following procedures will be performed while wearing the research socket B during this visit:

- Baseline TEWL (Trans-Epidermal Water Loss) Measurements.
- Laser Speckle Imaging (LSI) measurements.
- Pressure Socket Sensors.
- Motion Capture Analyses and Walking Tests wearing research socket B.
- 6 Minute Walk Test (6MWT). wearing research socket B
- Timed Up-and Go (TUG) Test. wearing research socket B
- Questionnaires (Houghton Scale, Socket Comfort Score, Veterans RAND 36-Item Health Survey)

The prosthetist will remove the pressure sensors from the socket B after the walking trials are completed before you leave.

At the end of study visit 2, the study team will fit and confirm alignment of the research socket B to be worn for the next 6 weeks.

Study Visit 3: After six weeks (+/- 14 days), you will return for Visit 3 at IU Health Methodist Hospital wearing the research socket B. This visit will last 2-2.5 hours. You should wear clothing that is comfortable for you while you may be participating in physical activity. This visit will be the final visit for socket B. This data will be collected and compared with the initial visit for socket B. The following activities will take place during Visit 3:

- Baseline TEWL (Trans-Epidermal Water Loss) Measurements.
- Laser Speckle Imaging (LSI) measurements.

- Pressure Socket Sensors.
- Motion Capture Analyses and Walking Tests wearing research socket B.
- 6 Minute Walk Test (6MWT) wearing research socket B.
- Timed Up-and Go (TUG) Test wearing research socket B.
- Questionnaires (Houghton Scale, Socket Comfort Score, Veterans RAND 36-Item Health Survey)
- The prosthetist will remove the pressure sensors from socket B after the walking trials are completed before you leave.

Upon completion of study visit 3, the prosthetist will remove the research socket B after completing the final study procedures, and either apply your SOC socket A or if chosen, leave the research socket B assembled for you. Upon completing study visit 3, your participation will be completed. The research socket B is made for you. If you would like to keep it, you will be allowed to keep it at no cost to you as described later in this consent form.

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:

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, Houghton Scale, and Veterans RAND 36-Item Health Survey: 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.

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 in How Will My Information Be Protected.

The study procedures using the TEWL, LSI, Prosthetic devices, and the walking tests have risks as described below:

Walking 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 help if needed.

Motion Capture Analyses: There is a minor risk of falling, as you will walk during this task. Study team members will be close by to support you if needed.

Prosthetic devices: There may be risks that we don't know about at this time. It is possible that you will experience discomfort such as sweat dry skin, rash, itching, irritation, blisters, high pressure in the socket, looseness in the socket, and mechanical rubbing which may cause a sore. 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. If you feel any discomfort, stop using the Research Socket (Socket B) immediately and contact study personnel to discuss the next steps.

TEWL probe: There are no known risks with this probe.

Laser Speckle Imaging (LSI): There are no known risks with this device.

6 Minute Walk Test (6MWT): 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 help if needed.

Timed Up-and Go Test (TUG): Falling is a possible risk when performing this test 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 you to help if needed.

Pressure sensor: There are no known risks associated with the pressure sensors.

Weight bearing shape capture: There are no known risks associated with the shape capture system.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

If you are injured because 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 research 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 card. Compensation will be distributed at the end of each visit. All payments will generally be available within 24 hours of the study visit.

You will be compensated up to $400 for participation ($100 per visit for 4 of the study visits). Additional visits for socket shape capture, fitting and alignment of sockets will be required but no payment is allocated.

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.

You will be allowed to keep the research socket B at no cost to you. If you decide to keep it, any further use is considered outside the scope of the research and the research personnel or prosthetist will not be able to provide any further support regarding the use. You will need to seek consultation with your doctor for any follow up and the study will not cover the costs for any follow-up consultations or actions.

WILL IT COST ME ANYTHING TO PARTICIPATE?

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

WHAT ARE THE OTHER TREATMENT OPTIONS?

There may be other options for treatment of your comfort level of the socket for your prosthetic limb. These options would include minor socket adjustments, in socket padding if your limb shape changes pads, prosthetic socks, or refined alignment.

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 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)
    - Department of Defense (DoD)
    - 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.

In the event of an emergency, you may contact Dr. Sashwati Roy at 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 Research Protection Program 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, and you will need to return the research socket B. If you decide to withdraw, please contact the 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	**Printed Name of Person Obtaining Consent**
Participant's Signature **Date**	**Signature of Person Obtaining Consent** **Date**
Participant's Address	