COVER PAGE

Official Title: Hybrid Electrical-Mechanical Pump for Vacuum Suspension of Prosthetic Sockets

NCT ID Number: NCT04230512

IRB approval date: 1/14/2020

Participant Name: Click or tap here to enter text. Date:Click or tap to enter a date.

Title of Study: **Hybrid Electrical-Mechanical Pump for Vacuum Suspension of Prosthetic Sockets**

Principal Investigator: REDACTED

VA Facility: Jesse Brown VA Medical Center

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

By doing this study, we hope to learn how using a vacuum suspension pump with compressible elements affects the way lower limb prosthesis users walk. If you completed the laboratory testing portion of the study you already completed 2-3 hours of study participation. If you agree to also participate or just participate in the take-home trials, your participation will last two weeks.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

There are no direct benefits to you for participating, however, the information gathered may improve the quality of life for prosthesis users. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

There is a risk of falling during the experiment and a risk of loss of confidentiality. For a complete description of risks, refer to the Detailed Consent.

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. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is REDACTED at the Jesse Brown VA Medical Center. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is: REDACTED.

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

With this research we hope to learn if the compressible element in a vacuum suspension pump affects the torque applied at the bottom of the prosthetic socket. While vacuum suspension is a popular system for lower limb prosthesis users, the effect of the compression used to activate the mechanical pump has not been documented. This study will collect information on the torque applied at the bottom of the prosthetic socket as lower limb prosthesis users walk with a vacuum pump fit in-line with the prosthesis. During the take-home trials, this study will help us understand the benefit of using a hybrid system with mechanical and electrical pumps.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 2-4 years. The laboratory portion of the study is complete, and if you agree to participate in the take-home trial you will perform up to three visits to the lab and your participation will last two weeks. We expect that 20 people will participate in this research study at Jesse Brown VAMC.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

If you have participated in the laboratory tests, you have already completed 2-3 hours of the study and those laboratory tests are now complete. If you decide to take part in the take-home study you will be asked to come to the study site, the Jesse Brown VAMC Motion Analysis Research Laboratory at 680 N Lake Shore Drive, Suite 1100, Chicago IL 60611 for up to three visits. REDCATED and his staff will be present.

During the first visit, you will be asked about your current prosthesis type and use, amputation side and cause, fall history, activity level, and assistive device use. We will take measurements of your height, weight, and length of your residual limb. You will also be asked to fill out the following surveys and are free to skip any questions that you prefer not to answer:

1. Socket Comfort Score (SCS) – The SCS is a rating of comfort on a scale of 0 to 10 where 0 is the most uncomfortable socket fit imaginable and 10 is the most comfortable socket fit.
2. Activities-Specific Balance Confidence Scale (ABC) – Collects information on perceived balance confidence when performing activities of daily living.
3. Prosthetic Limb Users Survey of Mobility (PLUS-M) – Collects information on perceived functional mobility when using a prosthesis.

Following collection of background information, the prosthetist will fit a vacuum pump in-line with the prosthesis between the socket and either the prosthetic knee joint or prosthetic foot.

The pump is connected to your socket with a tube to create vacuum. We will use either your usual socket or a previously used 'check' socket if it has a tube connection. If you do not have a socket that has a tube connection, we will make a new ‘check’ socket for you to only be used during the study. We will take a cast of your limb and ask you to return for a second visit for fitting of the pump.

As a participant of the take-home tests, after the pump device has been fit to your prosthesis and you have accommodated by walking with it in the laboratory, you will use the pump device for two weeks while at home. During this time, the pump will record vacuum pressure in the socket. After two weeks you will return to the laboratory for a final visit so we can remove the pump and restore your original prosthesis. You will then provide feedback on your socket comfort, mobility, and your impressions of the pump from the past two weeks by filling out a survey and are free to skip any questions that you prefer not to answer.

If you agree to participate in this study, photographs and video recordings will be made of you during your visit. These pictures and recordings are a part of the data record. You will be given the option of allowing us to use these photographs or video recordings in medical and scientific presentations and publications, however, no other personal information about you would be included in these presentations and publications.

Please indicate your willingness to allow the use of these photographs and/or video recordings to be used for educational purposes and to be disclosed in medical and scientific presentations and publications.

Yes☐ No☐

You may ask questions at any time during the study visit. You may change your mind about staying in the study at any time during the study.

- It is expected you will walk with the pump and return it to us when testing is complete.
- You are expected to complete the questionnaires as instructed.
- You are expected to ask questions as you think of them and inform us of any concerns.
- If taking the device home, you are expected to keep the pump installed in your prosthesis until you return the device on your final visit, but also go about your day.

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Any procedure has possible risks and discomforts. The likely risks and discomforts expected in this study are no more than you would experience when walking in the community, which includes the risk of falling. However, if performing the laboratory testing, you will wear a safety harness while walking on the treadmill to protect against a fall.

There is the risk of potential loss of confidentiality. Information that identifies you will be used in this study and shared with the study sponsor and research staff. However, the research team will make every effort to protect your private health information and guard against any loss of privacy.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

The surveys may contain questions that seem personal or embarrassing. The questions may upset you. You may refuse to answer any of these questions. If the questions make you very upset, we will help you to find a counselor.

There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

Risks of the usual care you receive are not risks of this study. Those risks are not included in this consent form. You should talk with your health care providers if you have any questions about the risks of usual care.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There may be no direct benefits to you from taking part in this research study. However, the information we get from this study might ultimately improve quality of life for prosthesis users.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected by locking all paper documents in a filing cabinet that is located in a locked VA laboratory. Access to paper documents and electronic research data will be limited to REDACTED and his designated study team and will be stored on a secure VA computer. Data will be stored with a code, without your name or identifiers. For security, the data and the

Identifiers might be removed from the identifiable private information that are collected. After that removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

We will make every effort to keep the information collected for this study confidential.

People who will know you are a research subject include members of the research team. Otherwise, no information about you, or provided by you during the research, will be disclosed to others without your written permission, except there are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Institutional Review Board (IRB), our local Research and

Development Committee, and other study monitors may look at or copy portions of records that identify you.
A description of this clinical trial will be available on http://www.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.

master list linking your name and the code will be stored separately.

Health Insurance Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal laws and the federal medical or HIPAA Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by these laws and the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. While it is not the intent of this study, other information such as HIV status, drug, alcohol or STD treatment, genetic test results or mental health treatment may be viewed or collected, if necessary or if there are interviews or surveys where you, as the research subject, provide that information to the research team.

The research team may also need to disclose or share your information to others as part of the research and study progress. Others may include the following: Office of Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), the Government Accountability Office (GAO), the VA Institutional Review Board, and the local VA medical facility Human Research Protections Program.

Your health information disclosed pursuant to this authorization may no longer be protected by

While this study is being conducted you will have access to your research-related health records. This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you can ask a member of the research team to give you a form to revoke your authorization in writing. Your written request will be valid when the research team receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.
If you revoke this authorization, REDACTED and his or her research team can continue to use information about you which the research team has relied upon for the research and that

was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Federal laws or the HIPAA Privacy Rule regulations and may be subject to re-disclosure by the recipient.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WHAT WILL I BE PAID FOR MY PARTICIPATION IN THE STUDY?

If participating in the laboratory trials, you will be paid $100.00 for this study. If participating in the take-home trials, you will be paid $200.00 for your involvement upon returning the device to our laboratory on the final visit. You will be paid through direct deposit. To receive payment, you will need to complete an online vendor form that requires you to enter your social security number. Validated parking is available for the parking garage in this building.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.
Additional compensation, beyond paying for treatment, has not been set aside. For all study participants, compensation damages resulting from the negligence of federal government employees may be available in accordance with Federal Tort Claims Act. For additional

If you believe that you may have suffered a research related injury (physical, mental or emotional injury or injury caused by loss of confidentiality or privacy), contact:

DURING THE DAY: REDACTED at REDACTED

AFTER HOURS: REDACTED at REDACTED.

DO I HAVE TO TAKE PART IN THE STUDY?

It is up to you to decide whether or not to take part in this study. If you decide to take part you may still withdraw at any time. If you do not wish to be in this study or leave the study early, there will be no penalty or loss of benefits to which you are otherwise entitled. If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

information concerning claims for damages, you may contact VA District Counsel at (708) 202-2216. You have not waived any legal rights or released the hospital or its agents from liability for negligence by signing this form.

You can decide to leave the research study at any time without penalty or loss of benefits and this can be done by informing REDACTED of your desire to withdraw.

If you choose to withdraw from the study, the study team may continue to review the data already collected for the study but cannot collect further information, except from public records.

RIGHT OF INVESTIGATOR TO TERMINATE MY PARTICIPATION

The researchers also have the right to stop your participation in this study without your consent if they believe it is in your best interest. A possible reason for removal is visible signs of illness during the study visit.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

You may contact REDACTED at REDACTED with any concerns or complaints as to this research study.

If you want to talk to someone who is not involved in this research about your rights as a JBVAMC patient you should contact the Patient Advocate Office at the Jesse Brown VA Medical Center at (312) 569-7959.
If you have questions about your rights as a study participant, or you want to make sure this is

WHO COULD PROFIT FROM THE STUDY RESULTS?

The investigator has filed a patent application of the technology being studied. If a commercial product is developed or shown to be effective, the investigator may receive a part of the profits from any future sales of the product. You will not profit from any product or test that might result based on the research.

FUTURE USE OF DATA AND RE-CONTACT

De-identified data collected in this study will be retained in locked filing cabinets and password-protected computers in the VA laboratory for future research. These data will be accessible to the Principal Investigator, REDACTED, and his study team. You may be re-contacted in the future about participating in future research within the VA or outside the VA that involves persons with lower limb loss, but only with permission of the Principal Investigator, REDACTED, and if you first agree to be re-contacted.

a valid VA study, you may contact the Jesse Brown VAMC Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the Jesse Brown VAMC IRB at 312-569-6166 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The Principal Investigator, REDACTED, or one of the research study personnel has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this study and authorize the use and disclosure of your health information in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
Participant's Name	Participant's Signature	Date

FOR IRB USE ONLY

Jesse Brown VAMC IRB
Approval Date: April 5, 2024