Can Sensory Feedback Training Improve the Biomechanical and Metabolic Effects of Using Passive or Powered Lower Limb Prostheses During Walking for Veterans With Transtibial Amputations?

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Subject Name: _____ **Date:** _____

Title of Study: Can Sensory Feedback Training Improve the Biomechanical and Metabolic Effects of Using Passive or Powered Lower Limb Prostheses During Walking for Veterans with Transtibial Amputations?

Principal Investigator: Alena Grabowski **VAMC**: 554

VA Investigator: Alena Grabowski **COMIRB#** 19-0971

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?

We do not yet know how real-time visual feedback training of peak propulsive force affects the performance of people with a lower extremity amputation using passive-elastic and powered ankle-foot prostheses. Our primary objective is to enhance the use of prosthetic technology to improve the rehabilitation and function of people with lower limb amputations.

This study plans to learn more about how different visual feedback of peak propulsive force affects walking performance.

You are being asked to be in this research study because you:

1. are between 18-67 years old

2. have a unilateral below the knee amputation and are at least 6 months post-amputation.

3. have at least a K3 Medicare Functional Classification Level, which is defined as a person who has the ability or potential for ambulation with variable cadence. A person at K3 MFCL is a typical community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic or exercise activity that demands prosthetic use beyond simple locomotion.

4. have no known cardiovascular, pulmonary, or neurological disease or disorder

Other people in this study

Up to 40 people from your area and/or around the country will be enrolled in the study.

What happens if I join this study?

If you join the study, you will be asked to complete four experimental sessions at the VA ECHCS/University of Colorado Applied Biomechanics Lab. The first day will be an acclimation and tuning session. During this session, we will ask you to perform strength tests on an isokinetic dynamometer. Then, we will align and tune the emPOWER battery-powered ankle foot prosthesis to you and ask you to walk using this prosthesis. This acclimation session will require approximately 2 hours of time. Each of the additional three sessions will be on a separate day at the same time of day, and require approximately 2 hours of time. You will be asked to walk on a force measuring treadmill and to match different targets of propulsive (push-off) force.

On each day, we will measure your height, weight, and limb segment lengths. Then, we will place reflective markers on your legs and torso using double-sided tape. These markers will allow us to track your body position using our motion capture system. We will also record the forces you exert on the ground using a force-measuring treadmill. Further, on days 2-4 we will measure your leg muscle activity using wireless electrodes that will be placed over your muscles using double-sided tape and your metabolic rates from the air that you breathe out into a mouthpiece. On days 2-4, we will ask you to perform a 30-60 sec walking trial at 1.25 m/s using your own prosthesis.

Day 1 – Acclimation Session. We will determine the strength of your lower limb muscles using an isokinetic dynamometer (Biodex Medical Systems, Shirley, NY). Then, our prosthetist will align the emPOWER (BiONX, Ottobock, Duderstadt, Germany) battery-powered ankle-foot prosthesis to you. We will attach reflective motion capture markers to your legs and pelvis using double-sided tape and Velcro straps, and tune the emPOWER prosthesis by having you walk on a force-measuring treadmill at 1.25 m/s for a series of ~45 sec trials. Then, we will give you additional time to walk using the emPOWER prosthesis.

Days 2, 3 and 4 – Experimental Sessions. We will ask you to fast and drink nothing but water for at least 2 hours prior to each experimental session. On each day, we will attach reflective motion capture markers to your legs and pelvis using double-sided tape and Velcro straps, and surface electrodes over your leg muscles using double-sided tape and elastic wraps. We will mark the locations of each electrode with “permanent” marker on your skin. Then, we will ask you to walk for 30-60 sec at 1.25 m/s (2.8 mph) using your own prosthesis.

On Days 2, 3, or 4, we will ask you to walk at 1.25 m/s on a dual-belt force-measuring treadmill while we measure your metabolic rates, biomechanics, and muscle activity using your own passive-elastic prosthetic foot for:

1) 5 min with no visual feedback

2) 5 min with real-time visual feedback of affected leg (AL) peak propulsive force from the “no feedback” condition, and 5 min with no visual feedback

3) 5 min with real-time visual feedback of +20% greater AL peak propulsive force than the "no feedback" condition, and 5 min with no visual feedback

4) 5 min with real-time visual feedback of +40% greater AL peak propulsive force than the "no feedback" condition, and 5 min with no visual feedback

5) 5 min with real-time visual feedback of AL peak propulsive force and unaffected leg (UL) peak propulsive force, and 5 min with no visual feedback

On Days 2, 3, or 4, we will ask you to walk at 1.25 m/s on a dual-belt force-measuring treadmill while we measure your metabolic rates, biomechanics, and muscle activity using the emPOWER battery-powered ankle-foot prosthesis for:

1) 5 min with no visual feedback

2) 5 min with real-time visual feedback of AL peak propulsive force from the "no feedback" condition, and 5 min with no visual feedback

3) 5 min with real-time visual feedback of +20% greater AL peak propulsive force than the "no feedback" condition, and 5 min with no visual feedback

4) 5 min with real-time visual feedback of +40% greater AL peak propulsive force than the "no feedback" condition, and 5 min with no visual feedback

5) 5 min with real-time visual feedback of AL peak propulsive force and UL peak propulsive force, and 5 min with no visual feedback

We will enforce 5 minutes of rest between trials. During the real-time visual feedback trials, we will ask you to match the power magnitude displayed on a computer screen placed in front of you with your AL and/or UL for those 5 minutes. You will be asked to perform a maximum of 35 minutes of walking per day and each experimental session will require ~2 hours of time. The total time commitment for this study is approximately 8 hours; 2 hours per day over 4 days.

This research study is expected to take approximately 3 years. Your individual participation in the project will take 4 days and occur over 2 weeks.

All procedures are for research purposes only.

What are the possible discomforts or risks?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed. Rare, unknown, or unexpected risks also may occur.

Discomforts you may experience while in this study include:

Potential Risks.
1. There is a small risk of falling during the experimental trials.
2. There is a potential risk of physical discomfort from wearing any type of prosthesis.
3. The adhesive used for motion capture and muscle activity measurements may produce slight discomfort or irritation.
4. The metabolic analysis mouthpiece may produce slight discomfort or irritation.
5. Confidential information will be collected as part of this study; therefore, there is a risk of disclosure.

Protections against Risks (corresponds directly to the Potential Risks listed above).
1. You will have access to parallel bars on the treadmill and an overhead safety harness in case you need to catch yourself in the unlikely event of a fall.
2. If you become fatigued, you may ask to rest or stop the study at any time.
3. Before participating, you will be asked if you have any adhesive allergies and if you do, we will use tight-fitting clothing to attach the motion capture markers and hypoallergenic tape to attach surface electrodes.
4. You may ask to remove the mouthpiece, rest or stop at any time.
5. Significant efforts will be made to guard against the disclosure of confidential information. All data collected will be de-identified so that your identity is protected; however, the data collected poses no apparent risk to your privacy. We will implement a data and safety-monitoring plan to ensure your privacy. To de-identify your data, you will be given a unique code, and only the research team will have access to the key (linking the code to participant identifiers), which will be kept in a locked cabinet in a locked office. The key will be destroyed upon study completion.

Other possible risks include:

There is a risk that people outside of the research team will see your research information. We will do all we can to protect your information, but it cannot be guaranteed.

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 the 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 the study?

This study is designed for the researcher to learn more about how visual feedback of peak propulsive force affects the performance of people with a below the knee amputation using passive-elastic and

powered prostheses. This study is not designed to treat any illness or to improve your health. Also, there may be risks, as discussed in the section describing the discomforts or risks.

Who is paying for this study?

This research is being sponsored by the Department of Veterans Affairs.

Will I be paid for being in the study?

You will be paid $50.00 for each visit in this study. The total amount possible to be paid to you is $200.00 if you complete all of the visits. If you leave the study early or if we have to take you out of the study, you will be paid only for the visits you have completed.
It is important to know that payments for participation in a study are taxable income.

The VA will be disbursing payments. Your SSN will be collected and used to report this taxable income to the IRS.

Will I have to pay for anything?

There will be no cost to you for participation in this study. However, some veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of this study. If you decide to participate in this study, you cannot be charged nor your insurance billed, for research-related interventions or procedures that are required by the protocol.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission, if the study doctor thinks that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

What happens if I am injured or hurt during the study?

Every reasonable safety measure will be used to protect your well-being. The VA Eastern Colorado Health Care System (ECHCS) will provide necessary medical care and treatment for any injury that is a result of participation in this study for veterans, in accordance with applicable federal regulations (38 CFR 17.85). Compensation for such an injury may be permitted by applicable federal laws and/or

regulations. The VA is not required to provide treatment for injuries in research studies if the injuries are caused by your non-compliance with study procedures.

You should inform your care provider(s) if you decide to participate in this research study. If you have questions about an injury related to the research, call Dr. Alena Grabowski at 303-492-5208 during work hours or 720-435-4270 outside of work hours.

Who do I call if I have questions?

The researcher carrying out this study at the VA is Dr. Alena Grabowski.
You may ask any questions you have now. If you have any questions, concerns, or complaints later you may call Dr. Alena Grabowski at 303-492-5208 during work hours or 720-435-4270 outside of work hours. You will be given a copy of this form to keep.

If you have questions regarding your rights as a research subject, concerns or complaints about this research study, please call the Colorado Multiple Institutional Review Board (COMIRB) office at 303-724-1055. This is the Board that is responsible for overseeing the safety of human participants in this study. If you want to verify that this study is approved or if you would like to obtain information or offer input, please contact the VA Research Office at 720.857.5092

How will my private information be protected?

Taking part in this study will involve collecting private information about you. We will keep all research records that contain your identifiable health information confidential to the extent allowed by law. Records about you will be kept in a locked filing cabinet within the PI's locked office (Clare Small Building, room 103). Identifiable data will not be shared with anyone outside of the immediate research team. Data security for storage and transmission for electronic data stored on desktop computers will be managed via a secure network and password access. Power-on passwords will be established for all portable computing devices. Electronic data (non-identifiable health information) that is collected during experimental sessions will be stored on computers protected with passwords and only accessible to the research team. We will be collecting social security numbers. You can withhold your social security number and still participate.

A description of this clinical trial will be available on http: http://www.clinicaltrials.gov. 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.

Photography, Video, and Audio Recordings

Pictures and/or video recordings may be taken of you during the study with your permission. Images and recordings of you could be used for scientific presentations. Any images or recordings that include identifiable information, such your face, will be masked to maintain confidentiality. All images

and recordings will be kept on a password-protected computer that only the research team will have access to.

The study team has explained that by signing this Informed Consent Document, you voluntarily and without separate compensation authorize pictures and/or voice recording(s) to be made of you by the researcher while you are participating in this study. You also authorize disclosure of the picture and/or voice recording to Dr. Alena Grabowski. The said picture, video, and/or voice recording is intended for the following purposes: scientific presentations.

The study team has also explained that you will not receive any royalty, fee or other compensation for such use. If you refuse to grant consent, there will be no effect on any VA benefits to which you may be entitled. You may at any time exercise the right to cease being filmed, photographed or recorded, and may rescind your consent for up to a reasonable time before the picture, video or voice recording is used.

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.

Health Information Portability and Accountability Act (HIPAA)

Who will see my research information?

There are rules to protect your private health information. Federal and state laws and the federal medical law, known as the 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 the HIPAA 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. They may also collect other information including your name, address, date of birth, and information from your medical records such as your medical history.

The research team may also need to disclose your health information and the information it collects to others as part of the study progress. Others may include:

- Federal agencies such as the Food and Drug Administration (FDA), the General Accountability Office (GAO), the Office of the Inspector General, Office for Human Research Protections (OHRP), and the VA Office of Research Oversight (ORO) that protect research subjects like you, may also copy portions of records about you.
- People at the Colorado Multiple Institution Review Board

- The investigator and research team for this study
- The sponsor, the Department of Veterans Affairs Rehabilitation, Research, and Development Service (group paying for the study), study monitors or agents for the sponsor
- Officials at the institution where the research is being conducted, and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research
- Our local VA Research and Development Committee
- University of Colorado Boulder Applied Biomechanics Lab

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility or you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office 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, Dr. Alena Grabowski and her research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

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.

Is there other information I need to know?

Disclosure of Results. You will receive a general report of the aggregate results or any results specific to you.

Agreement to be in this study

I have read this form or it has been read to me. A member of the research team has explained the study to me. I have been told about the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

By signing this form below, I voluntarily consent to participate in this study and authorize the use and disclosure of my health information for this study. I will receive a copy of this consent after I sign it. A copy of this consent form will be placed in my medical record.

Subject's Signature: _____ Date: _____

Print name: _____

☐ Witness of Signature: _____

☐ Witness of consent process: _____

Consent form explained by: _____ Date: _____

Print name: _____.