Title: User-Independent Intent Recognition on a Powered Transfemoral Prosthesis

NCT: NCT05537792

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Key Information for User-Independent Intent Recognition on a Powered Transfemoral Prosthesis

What am I Being Asked To Do?

You are being asked to be a volunteer in a research study that involves using a powered prosthetic device. This page will give you key information to help you decide if you would like to participate. Your participation of voluntary. As you read, please feel free to ask any questions you may have about the research.

What is this Study About and What Procedures Will You be Asked to Follow?

The purpose of this study is to improve methods of controlling robotic legs. We will ask you to walk with the powered device in a range of walking tasks (i.e. overground walking, ramps, and stairs). You will be asked to wear certain sensors that measure your performance as you complete these walking tasks. We will fit the powered device to you and ensure you feel comfortable with a tuning session. After this session, we will begin the formal collection. You will need to visit us a minimum of 2 times for experimental data collection and practice using the prosthesis. Each visit will last between 2-6 hours and will not involve more than 30 minutes of continuous movement.

Are There Any Risks or Discomforts you Might Experience by Being in this Study?

The primary risk of injury in this protocol would be due to falls, regardless of the prosthesis being used. To minimize this risk, you will be asked to wear a safety harness and initially walk with handrails until you become comfortable using the prosthetic device(s) and demonstrate that you can use it without falling. Other minor risks involve muscle soreness, fatigue, and skin irritation. If you feel any discomfort or have any concerns, please notify the researchers at any time during the experimental protocol. No task is mandatory. The researchers will only have you perform the tasks with which you feel comfortable.

What Are the Reasons You Might Want to Volunteer For This Study?

You are not likely to benefit in any way from joining this study. However, your participation in this study may assist researchers in understanding how to configure methods for improving the control of powered robotic legs to help assist users in the best manner possible. As compensation for your time, we will pay you $25/hr.

Do You Have to Take Part in the This Study?

It is fully your decision if you wish to be in this study or not. If you choose not to participate, or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology
Project Title: User-Independent Intent Recognition on a Powered Transfemoral Prosthesis

Investigators: *Aaron Young, PhD; Kinsey Herrin MSPO, L/CPO, FAAOP; Krishan Bhakta; Jonathan Camargo; Jairo Maldonado-Contreras; Sixu Zhou;*

Protocol and Consent Title: User-Independent Intent Recognition on a Powered Transfemoral Prosthesis Version: 04/20/2021

You are being asked to be a volunteer in a research study. This document has important information about the reason for the study, what you will do if you choose to be in this research study, and the way we would like to use information about you and your health. Your participation in this study is entirely voluntary.

Purpose:

The purpose of this research study is to improve methods of controlling artificial legs. Up to 50 individuals will participate in this study.

You are being asked to participate in this study because you use a prosthetic knee and foot in your clinically prescribed prosthesis. We are teaching the computer your movements so that it can recognize your intentions and provide helpful assistance during walking. In this research study, we will be recording from sensors placed on a prosthesis and electric signals measured from muscles in your leg to see if we can develop better computer programs to help predict what you want the prosthesis to do.

Exclusion/Inclusion Criteria:

You may participate in this study if you are between 18-75 years of age with no history of neurological injury, gait pathology, or cardiovascular condition that would limit your ability to ambulate for multiple hours. You may not participate if you are pregnant due to the risk of falling. If you do become pregnant, you must notify the study doctor and you will be withdrawn from the study. If you use a prosthesis, you must use a prosthetic knee and foot in your clinically prescribed prosthesis. You must have a Medicare/Medicaid ambulatory designation level of K3 or K4 to successfully complete this experiment as it requires subjects to walk ascend/descent stairs and ascend/descend ramps.

Procedures:

After you are consented, the skin over muscle areas of interest will be cleaned with alcohol and will be shaved by a disposable shaver. Self-adhesive or stainless steel electrodes will be placed on your skin over your leg muscles. The areas may include the buttock, hip, thigh and calf. All of the electrodes are connected to instruments and computers that record the needed information. Additional sensors, such as motion markers will be placed on the surface of your leg and/or prosthesis. Video cameras will record your movement and capture the markers positions enabling us to study the leg motion. You will also be asked to wear a system that tells us how much energy you are using while you walk with your prosthetic device. Two types of devices will be used depending on the different activities performed (Parvo & COSMED K5 metabolic systems). The Parvo metabolic cart is another type of equipment that is used to measure energy expenditure. It is a stationary cart that can be used when the user is ambulating over the treadmill. For dynamic overground, ramp, or stair trials, a portable system (COSMED K5) will be used to measure the energy expenditure.

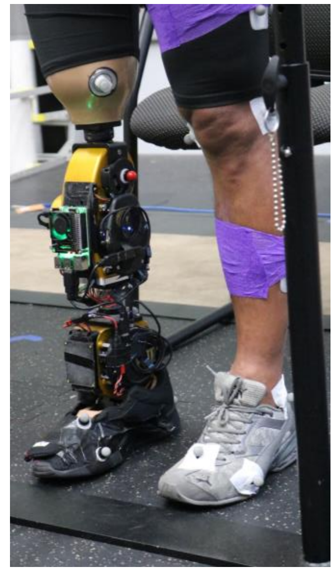

Figure 1: Motorized Prosthesis

You will be fit with two artificial legs (but only one at a time); one will be very similar to the leg you currently use. This leg is body-powered. We may ask you instead to walk in your everyday use prosthesis if it is suitable. You will always be using a safety harness, crutches, or safety rails when wearing this leg. The second leg has motors and is electrically-powered. You will also be asked to wear a safety harness when wearing the motorized leg. After we put on the harness and prosthetic leg, you will be asked to walk at a comfortable speed on two different treadmills. When you become comfortable and demonstrate that you can walk safely without stumbling, you will be asked to change the speed and incline level of the treadmill. If you feel comfortable using the prosthetic device(s), you will be asked to complete simple activities such as level walking, walking up and down ramps, walking up and down stairs, stepping over obstacles, and standing up and sitting down while different environmental disturbances occur. You will be asked to walk over a gait mat to record standard biomechanical information such as step time, step width, and symmetry to understand the differences between prostheses. As you complete these activities, you can choose to be provided with hand rails and other aides—such as a gait belt, crutches, or a cane—instead of the safety harness if the experimenter deems it safe for you to do so. When you practice doing these activities, we will make some adjustments to the prosthetic device(s) so that it works as well as possible for you. If you feel comfortable doing so, we may ask you to ambulate outside the lab such as a building stairwell or outdoors on the Georgia Tech campus. This will let you practice community ambulation in a more realistic setting. You can choose not to do any activity you do not feel comfortable to do. You will have as much time as you like to practice doing these activities. If you need more than six hours practice or it takes longer than six hours for us to adjust your prosthesis, we will ask you to come in on another day to continue the experiment. These do not need to be consecutive days. Data will be collected from you while you practice to help us adjust your prosthesis. After you have finished practicing, we will collect data for the experiment. We will ask you to complete each task that you have practiced multiple times. You will be given rest periods in between repetitions. The number of visits required to the lab depends on the amount of time it takes to adjust the prosthesis for you and the amount of time you need to practice the activities with the prosthesis. You will need to visit us a minimum of

2 times for experimental data collection and practice using the prosthesis. Each visit will last between 2-6 hours and will not involve more than 30 minutes of continuous movement. We estimate the total time commitment to be between 10-25 hours.

<u>Risks or Discomforts:</u>
The artificial leg(s) has motors and sensors. The device being tested has not been approved by the FDA. Although these procedures are very safe and commonly used in our lab, your participation in this study may involve the following risks: The primary risk of injury in this protocol would be due to falls, regardless of the prosthesis being used. To minimize this risk, you will be asked to wear a safety harness and initially walk with handrails until you become comfortable using the prosthetic device(s) and demonstrate that you can use it without falling. Should you fall during this familiarization session, the harness will support you. When walking outside of the treadmill, the safety harness and other safety measures will be employed including having access to hand rails or other walking aids, and may be supported by staff members using a gait belt as you complete the activities.

A second risk is minor muscle soreness and fatigue. Muscle soreness is a common problem when walking with a new prosthesis. To prevent this, experimental sessions will be kept as short as possible, adequate rest periods will be provided between trials, and you will be questioned often about any discomfort. A third risk is skin irritation. Skin can become irritated while using any prosthesis and it may also become irritated by adhesive electrodes. To avoid the risk of skin irritation, you will use either a properly fitting socket(s) constructed by a certified prosthetist or your normal, take-home socket. Additionally, the residual limb will be checked periodically for skin irritation. To reduce the irritation associated with adhesive electrodes, your leg will be wiped with alcohol to remove adhesive and electrode gel residue after the electrodes are removed.

The system you will be asked to wear to tell us how much energy you are using while you walk with your prosthetic device(s) is very safe, but may be uncomfortable for you to wear as it involves a mask over the face and must be tight. Risks include transmission of communicable diseases, aspiration of contaminants, and irritation from wear, choking /strangulation, and discomfort. To protect you against infection, the mask and monitor will be properly disinfected between uses, and will always be handled with disposable sanitary gloves. Also, antibacterial filters will always be used with the metabolic mask to prevent aspiration of contaminants.

If you are asked to walk on the gait mat, there are potential risks of muscle soreness and fatigue. You will be given adequate rest periods between different activities. Furthermore, a safety harness, handrails, or gait belt will be provided.

General risks associated with testing any electrical device include fire and electrical shock. These risks will be avoided by keeping the device away from water or open flame sources. Researchers will always be vigilant about the conditions of the testing environment. Although the researchers have tried to avoid risks, you may feel that some procedures are not within your ability or would put you outside your comfort level. If you feel any discomfort or have any concerns, please notify the researchers at any time during the experimental protocol. No task is mandatory. The researchers will only have you perform the tasks with which you feel comfortable.

Benefits:

There will be no direct benefit to you by your participation in this research study. The long-term goal of this research is to improve the ability of people with amputations to be able to walk better and more easily: including walking on level surfaces, stairs, ramps, hills and other activities. The benefit to the population of lower limb amputees could be substantial.

Compensation to You:

You will not be charged for any study-related procedures. If you are an amputee, you will be paid $25/hr (rounded to the next full hour). You will be given the choice of compensation via check which will be issued through USPS mail to a home (or a provided) mailing address or a gift card which will provided at the end of each visit to the lab. Meals are not reimbursed for either local or out of town participants.

The Finance Department at Georgia Tech will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year. In the event you become unable to complete the experiment in its entirety you will receive compensation for your involvement up to the point where you were unable to continue. As an hourly participant, this means that you will receive a stipend rounded to the nearest hour when participation ended.

U.S. Tax Law requires that a 1099-misc be issued if U.S. tax residents receive $600 or more per calendar year. If non-U.S. tax residents receive more than $75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the Georgia Tech department that issues compensation, if any, for your participation.

Confidentiality:

The only possible identifier linking you to this study is the video and photographs taken during testing. The video will only be published if you give permission (permission form listed below). Your face can be blocked out upon request. You will be given a research subject number that will be used instead of your real name in potential published studies. Research records will be stored securely. Only the Principal Investigators and research study personnel will have access to the research records that include your personal information.

After completing the study, videos may be used in teaching, publications or presentations. You may refuse permission for us to use your video in these settings. You will need to give or refuse permission for these at the end of this form.

This consent form will be filed securely in an official area. People who have access to your information include the Principal Investigators and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP), the Food and Drug Administration, and entities such as the Georgia Tech Office of Research Integrity Assurance.

The sponsor of this study, National Institutes of Health, has the right to review study records as well.

We will comply with any applicable laws and regulations regarding confidentiality.

<u>Costs to You:</u>
There are no costs to you, other than your time, for being in this study.

<u>In Case of Injury/Harm:</u>
If you are injured as a result of being in this study, please contact Principal Investigator, Ph.D., at telephone (404) 385-5306. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.

<u>Participant Rights:</u>

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.
- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

<u>Requirements of Certificate of Confidentiality policy that applies to research conducted or supported by NIH involving a participant's identifiable or sensitive information (data and/or biospecimens):</u>

We have obtained a Certificate of Confidentiality from the National Institutes of Health to help us keep your information confidential. This Certificate provides a way that researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Questions about the Study:

If you have questions or concerns, or any illness or injury during your time in this study, you should call us promptly. Aaron Young, PhD is in charge of this research study and can be reached at telephone number 765-426-1951 or by e-mail at aaron.young@me.gatech.edu.

Questions about Your Rights as a Research Participant:

If you have any questions about your rights as a research subject, you may contact Georgia Institute of Technology Office of Research Integrity Assurance at IRB@gatech.edu.

Clinical Trial Information:

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 Web site at any time.

OPTIONAL CONSENT:

We may want to use some of the photographs, audio, or video recordings of you in public presentations related to the research. There is a media release form attached that outlines several possible uses and asks for your specific consent to use these items in each way. If you agree to allow these items to be used after this research study is over, please read, initial, and sign the media release form in addition to this consent form. We will not use any photographs, recordings, or other identifiable information about you in any future presentation without your consent.

Please check the line next to the statement which indicates your preference for the use of your testing videos in our presentations:

Allow usage of video for teaching/publication/presentation: Yes / No

Uncensored video can be used: Yes / No

Censored video can be used: Yes / No

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

____
Participant Name (printed)

____ ______________
Participant Signature Date

____ ______________
Signature of Person Obtaining Consent Date