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

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Protocol and Statistical Analysis Plan

1. **Study Aim, Background and Design**

The primary scientific challenge that this research aims to address is to accurately decode user intent and apply this information to improve control of powered prostheses. The fundamental challenge is to allow users to intuitively control a robotic assistive device by applying wearable sensing technology either in the device or on the user. This is an especially significant research challenge now that advanced mechatronic prosthetic devices have come onto the clinical market and are actively being developed by different research and industry groups. These devices have vast potential to help improve the lives of individuals with a major lower limb amputation, but control systems for such devices need significant improvement [1], [2]. A smart and reliable control interface greatly enhances the user experience in any enterprise and is especially important for controlling complicated mechatronic assistive devices. Users may abandon or under-utilize the technology if the interface between the user and the device—the control system—does not function in an intuitive manner that is safe and convenient for them to use. This proposed research focuses on bridging this important gap.

It is important to further develop prosthetic control technology because of the large impact new technology can have on health outcomes for their potential users. Prosthetic technology is useful to individuals who have suffered from a major lower limb amputation which affects over 650,000 people in the United States [3]. These amputations cause significant disability and decreased quality of life [4]. It results in asymmetric gait that is energetically unfavorable [5] and slower self-selected walking speeds [6] compared to non-amputees. These impairments are due to a variety of reasons such as trauma, disease condition (such as diabetes), congenital limb deficiency, and cancer. There is a critical need for improving the walking capabilities of individuals who have suffered a lower limb amputation to increase their community mobility, independence and ultimately their quality of life.

New and exciting advances have been made on integrating microcomputers, sensors and actuators in mechanical devices to augment lower limb prosthetic technology to solve this need [7], [8]. These devices can help patients reduce their metabolic energy expenditure [9] and traverse more difficult terrain that is often encountered in community ambulation such as slopes, curbs, uneven ground, and stairs. A gap of commercial systems is a lack of sophisticated and robust intent recognition. They instead often rely on the user either using a key fob or performing a set of unintuitive movements unrelated to the movement itself (such as rocking back and forth on the prosthesis) to transition between different modes of operation. Powered prostheses would benefit greatly from an enhanced intent recognition system that seamlessly, automatically, and naturally transitions the device between different modes based on the user's desired activity. Our goal is to develop and evaluate such an intent recognition system that is ready to be deployed in the field on state-of-the-art powered prostheses. These systems can help improve clinically meaningful outcomes in amputee patients including reducing their metabolic cost of walking and increasing their preferred ambulation speed. Additionally, the ability to traverse different terrains more effectively will help improve their community ambulation capability and overall independence as these are commonly encountered outside the home.

One solution that we have previously used to perform intent recognition is to use advanced pattern recognition technology from the machine learning community. Pattern recognition techniques are advantageous because they allow users to be able to seamlessly and automatically shift between modes without having to stop and press buttons on a key fob or perform an unintuitive movement. Instead, we can design a system that recognizes the patterns of sensor information that are generated when humans move and predict a person's movement flow to optimally control both the timing and magnitude of power generation or absorption during movement. One of our previous accomplishments – published in IEEE Transactions on Neural Systems and Rehabilitation – demonstrated that by training pattern recognition systems with transitions between different modes improved the accuracy compared to previous studies from 84.5% to 93.9% [10] .

Several leading edge laboratories have studied pattern recognition techniques to improve intent recognition [10]–[13] – including our own previous work – but a significant drawback to these systems are that they are highly user-specific and rely on acquiring large amounts of training data from each subject. Part of this project will focus on developing a user interface that does not need user dependent training data. Voice recognition software previously required users to train the system with their own voice commands and only a relatively small number of people used it. In contrast, state-of-the-art voice recognition software used in cell phones today does not require any user dependent training and is widely adopted. Similarly, intent recognition systems for prostheses must innovate and provide intent recognition systems that require minimal user specific training so that patients will be willing to use them. We propose to do this through novel sensing technology, smarter algorithms, and adapting to each individual user's patterns. We need an innovative approach to achieve an intent recognition system that can be quickly applied to different users without hours of training time or the need for user specific recalibration. A broad goal of this project is to develop signal processing techniques and novel pattern recognition algorithms to enable user-independent intent recognition for powered lower limb prostheses. We will implement a novel adaptation algorithm that will adapt our intention recognition system to new individuals and provide speed-variable prosthetic assistance – eliminating the need to for any user dependent training. These algorithms will be implemented on the Open Source Leg (OSL) powered prosthesis, which was designed by collaborator Dr. Elliott Rouse [14]. A minimum group of ten individuals who use a prosthetic knee and foot in their clinically prescribed prosthesis will be trained on the powered leg and will complete the experiment. We will compare the accuracy of the intent recognition systems in walking speed estimation and also measure other clinically meaningful parameters including self-selected walking speed and relevant biomechanics. We expect adapted systems to exhibit advantages in walking speed estimation error compared to non-adapted systems and provide appropriate powered response for each walking speed during treadmill and overground walking.

2. Participant population

Subjects must fit into one of two categories stated in the study design section: able bodied individuals, and disabled individuals/amputees. Disabled individuals are considered

part of a vulnerable population. This group will be protected through the use of safety equipment such as hand rails and a safety harness for the case of stumbles and falls. The goal is to collect data from at least 10-15 participants from the amputee population.

Participants will be between 18-75 years old. Inclusion criteria includes subjects must be between 18-75 years of age, use a prosthetic knee and foot in their clinically prescribed prosthesis (except for the able bodied subjects). Subjects must be at K3 or K4 ambulatory level according to the Medicare/Medicaid designation as the study requires subjects to walk, ascend/descent stairs and ascend/descend ramps. Subjects will be excluded if they have any history of a neurological injury, gait pathology, or a cardiovascular condition that would limit their ability to ambulate for multiple hours during the experimental sessions. Pregnant subjects will also be excluded to the risk of a fall during the experiment.

All participants that meet the appropriate criteria will be recruited through official flyers and verbal scripts, even if they are already known to the researchers. Flyers will be posted around the campus of Georgia Institute of Technology, in designated advertising areas. Additionally, word of mouth recruiting will use a script with similar language as the flyers. Recruiting materials are attached as separate documents including a flyer and e-mail script. Permission will be obtained from participants before using any information for research purposes that has individual identifiers attached.

3. Study Procedures

This will be a single-visit study. If participants are not able to complete the study during their first visit, they will be asked to return. All testing will take place at the Georgia Tech Manufacturing Institute (GTMI) at the Georgia Institute of Technology. Testing will last between 2-3 hours with no more than 30 minutes of continuous movement and visits will be scheduled at the convenience of the participants.

Able bodied individuals may be fitted with a commercialized assistive walking device, iWALK (user manual attached as separate document), that has been adapted in order to be used with the prosthetic device. This is to ensure controllers are functioning before a subject comes in and walks on the prosthetic device. During all testing participants are instructed to vocalize any concerns or discomfort to researchers. At any time if participants are uncomfortable, they have the right to quit the study with no penalty. The first visit will last no longer than 4 hours. If the participant obliges, they will be asked to return for additional visits, scheduled at their convenience. During additional visits, human participants will be asked to perform typical tasks such as standing, sitting, or walking, in a safe and monitored environment. Tests will begin on a treadmill with a security harness and or gait belt, based on the level of comfort of the participant. If the participant feels comfortable, testing will be moved from the treadmill to the floor for supported and then freestanding walking. Another type of treadmill is a force-instrumented treadmill incorporated into the Computer Assisted Rehabilitation Environment (CAREN). This treadmill is embedded in a large platform that is able to move in six degrees of freedom, allowing the application of disturbances during standing or walking by moving the platform. During all types of testing in which subjects are asked to respond to environmental disturbances, they will be required to wear a safety harness. During tests, verbal feedback

from the participants will be used to improve the comfort of the devices. Participants are instructed to notify researchers if they feel unsafe, and may quit the study at any time without penalty. Testing will first be conducted on able-bodied individuals until the PI feels that it is safe to transition to disabled individuals/amputees. Testing with disabled individuals will only occur after initial tests can be run without functional errors involving either hardware or software. Once the software and control system of the devices are thoroughly tested on able bodied users the optimized device be used for testing with disabled individuals. Additionally, participants may be asked to wear EMG sensors, markers for measuring biomechanics, other mechanical sensors (such as IMUs) and a metabolic mask. One of the metabolic masks and heart rate monitor comprise an FDA approved metabolic system called the COSMED Fitmate Pro. Another type of a metabolic measurement system may be used such as the ParvoMedics TrueOne 2400 metabolic cart. The Fitmate Pro or ParvoMedics system will be demonstrated to the participant, after which they will choose whether or not they are willing to use this system. All participants will be guided through the following general procedure during their visits, requiring action on their part:

- Participants will be briefed about the details of and their rights during the study.
- The prosthetic and attachment interface will be fit to the participant, along with any additional data collection equipment.
- Participants will be guided through the specific activities of the study, detailed already.
- Participants will receive assistance removing any hardware used during the study.

Other equipment may be utilized to measure biomechanics of the user during ambulation. Specifically, we will be using a VICON motion capture analysis system. This will also us to measure biomechanical similarities and differences while using the powered prosthesis compared to the sound side limb. Also, some protocols will require the use of an EMG (electromyography) system to measure muscle activity across different ambulation tasks. Three systems may be used which includes the Delsys Trigno Wireless EMG system, Biometrics Ltd. EMG system, and COAPT EMG system. All of these systems will use electromyography sensors that will be placed on the surface of the user's skin.

In order to also measure functional clinical measures, a Protokinetics gait mat will be utilized to measure common measures such as step length, step time, and symmetry. This system is just a mat that users will need to walk on top similar to walking overground. Users will be in a harness and have the options for handrails or gait belt if needed.

Throughout the tests there will be a camera recording the session. The purpose of the camera is to record performance for future analysis. The participant will always have the right to stop the test and/or take a break. The participant may also choose to discontinue participation at any time.

This study will ask participants to walk on treadmill and overground settings to adapt pre-trained (baseline) walking speed estimation machine learning (ML) models to user-specific data. The adaptation pipeline self-labels and updates models with user data in real-time. We explore two methods of self-labeling referred to as Direct Integration (DI) and Ground Truth (GT). DI computes walking speed labels using heel-to-heel foot

displacements measured by a foot inertial measurement unit (IMU). GT provides labels that are the true treadmill speed (for treadmill trials) or center-of-mass speed (for overground trials). Treadmill speed profiles follow either a staircase profile (P1) or a triangular profile (P2). Overground walking is constrained to a 5-meter straight path between two cones. Adapted models are renamed based on the environment (P1, P2, or OVG) and labeling method (DI or GT) used. Models are evaluated on how well they can estimate the current speed (forward estimation). Additionally, we provide biomimetic assistance that scales with estimated walking speed.

4. Statistical Analysis Plan

A repeated measures ANOVA will be conducted to examine the impact of different forward estimators on the real-time forward estimation error, which served as the dependent variable. In this analysis, the forward estimator functioned as the intra-subject factor, with multiple measurements taken for each subject across different conditions. Instances of significant differences were further explored using Tukey's Honesty Significant Difference test to conduct detailed comparisons between specific groups. Paired t-tests were used to compare the offline forward estimation error of each adapted forward estimator with the baseline during overground walking. The error served as the dependent variable in these analyses.

5. Research Risks

The main risk of the study is a possible fall. Each participant will be given ample time to get accustomed to using the devices. This adjustment period will involve getting used to balancing with the given device or control method. In this adjustment period, participants run the highest risk of falling. However, to manage this risk, there will be rails around the treadmill at all times, which the user may hold to prevent falls. Based on the participant's comfort, there are varying levels of additional treadmill support or padding. After the adjustment period, if the participant is comfortable enough for freestanding walking there will be spotters next to them at all times. When testing the prosthetic, there is an additional risk of irritation caused by the method of attachment. The level of risk varies depending on the walking style and skin sensitivity of the participant. To reduce the likelihood of irritation, amputees will use their own prosthetic socket and non-amputees will use a commercial assistive walking device. The instruction manual for the commercialized assistive walking device (iWALK) is attached as a separate document.

Participants are strongly encouraged to vocalize any discomfort to try and prevent irritation from occurring. If irritation does occur, brief medical care in the form of disinfectant wipes and/or a Band-Aid will be provided. In the unlikely event of an irritation too severe for a Band-Aid, the participant will be referred to a physician. Any adverse events will be reported to ORIA within the regulated time frame. If the metabolic system is used by the participant, there are slight risks associated with the system. They include transmission of communicable diseases, aspiration of contaminants, irritation from wear, choking/strangulation, and discomfort. To protect 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.

To prevent irritation subjects are strongly encouraged to notify a researcher if they feel pain or discomfort. Careful attention will be paid to the position of the chords, to avoid entanglement and possible choking or strangulation. Verbal communication is strongly encouraged throughout testing to act as a preventative measure for discomfort. 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.

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. No undue psychological risks are anticipated during this study, and volunteers retain the ability to stop testing at any point. Privacy will be maintained during testing via an enclosed indoor testing environment by monitoring the perimeter for unauthorized personal; no significant privacy risks are anticipated.

6. Confidentiality

Participants will sign a consent form before participating which explains that no identifiers linking them to this study will be included in any sort of report that might be published except for the video taken. Participant faces will be blocked out upon request. They will be given a pseudonym different from their own name that will be referred to in studies published, if at all. Participants will be assured in the informed consent that the data will be used only for studies that are consistent with the original research purpose.

This consent form will be filed securely in an official area. People who have access to 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, the DoD, and entities such as the Georgia Tech Office of Research Integrity Assurance may access participant records to make sure the study is being run correctly and that information is collected properly.

Information about participants related to this study will be kept confidential to the extent permitted or required by law.

When the data is stored, it will no longer be linked to the subject's personal information. There will be a master list stored separately that connects the subject identifiers with their personal information, for when they need to be contacted. The data will be kept on the computers of the research personnel only. These computers will all be password protected to prevent nonauthorized access to the data. Data will be transmitted electronically between researchers. The master list of subjects and their personal information will not be transmitted in any form between researchers. This master list will only be in the possession of the PI and researcher responsible for recruiting. It will not be shared with anyone else in any way.

7. Benefits

The goal of this research is to improve upon the existing design processes of prostheses and exoskeletons for the future, and there are no foreseen direct benefits from this study. Participation in these tests may help any person that may someday need or want one of these devices. These tests will not benefit participants personally unless they intend to use these types of devices in the future.

8. Compensation

We will compensate amputees at a rate of $25/hour (rounded to the next full hour). Subjects 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.

9. Costs

There are no direct costs to study participants. The costs to participants for this study will most likely be only their time and energy. Participants will be responsible for covering any unforeseen costs including, but not limited to, transportation to the research location, parking expenses, food, or child care.

10. Alternatives

Participants are informed that participation in this study is voluntary. It is made clear that they have the right to change their mind and leave the study at any time without giving any reason and without penalty. Any new information that may make participants change their minds about being in this study will be given to them.

11. Consent/Assent Process and Documentation of Consent/Assent

After being informed about the study through recruitment by way of flyers, e-mail or word of mouth, participants will be given a consent form outlining details about the study. The consent form provides detailed information about the study procedures. When reading through the consent form potential participants are encouraged to vocalize any questions they have including, but not limited to, inquiries about testing procedure, risks of the study and participant rights. Questions will be answered by the researcher personnel conducting the study. Participants will be given as much time as they need to make a decision about whether or not to participate. During this process, as well as throughout testing it will be made clear that participants may chooses to end the study at any time, no questions asked, and will not face any negative repercussions. Signing of the consent form will take place in person where researchers present will answer any questions then obtain their signatures. This consent form will be filed securely in an official area that can only be accessed by Principal Investigators of this study and research study personnel. Participants will be given a copy of this consent form and do not waive any legal rights by signing it.

The only personal information we will collect is the participant's name, telephone, email, and contact information. This information will not be published in the research results, nor will it be used to perform data analysis. This information will also not influence the results of the research. We only collect this information so we can contact the participants and refer to them by their names during conversation.

12. Investigator's Qualifications

The PI, Dr. Aaron Young, has conducted a number of experiments similar to this one with amputees. The devices will be designed using the same process that has proven successful for a wide variety of robotic and robotic assistive devices built by collaborator-PI Rouse's Neurobionics Lab. The OSL device was manufactured in house at the Montgomery Machining Mall at Georgia Tech, The testing of this device was IRB approved previously at Georgia Tech with a similar protocol (H16351). A recent paper has been published on the design of the OSL device [14]. Additionally, all students listed on the IRB are members of the EPIC lab and are very familiar with the devices. All members listed on this IRB protocol have CITI training.

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