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Study Title: Towards Efficient Personalization of Computerized Lower Limb Prostheses via Reinforcement Learning in a Clinical Setup – Prototype Test

Protocol Number: 28186

Protocol is approved by NC State University IRB

Approval Period:

07/24/25 – 07/23/26

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Informed Consent Form for Participation in Research

Title of Study: Towards Efficient Personalization of Computerized Lower Limb Prostheses via Reinforcement Learning in a Clinical Setup
IRB Protocol: 28186
Principal Investigator : He (Helen) Huang (hhuang11@ncsu.edu 919-515-0417)
Co Investigator: Ming Liu (mliu10@ncsu.edu 919-515-8541)
Funding Source: NIH
NC State Faculty Point of Contact: He (Helen) Huang (hhuang11@ncsu.edu 919-515-0417)

You are invited to take part in a research study. Here are some important things to know:

- Your participation in this study is voluntary. You can choose not to participate without penalty. If you decide to participate and change your mind, you can stop participating at any time without penalty.
- The purpose of this research study is to understand the feasibility and effectiveness of using reinforcement learning to personalize robotic prosthetic legs for lower limb amputees.
- You will be asked to participate in a series of up to eight lab visits, each lasting up to three hours, where you will be fitted with powered prosthetic knees and complete walking tasks on level ground, ramps, and stairs. During these visits, the prosthesis will be personalized using reinforcement learning or manual tuning, and your walking performance will be evaluated through various walking tests and feedback sessions.
- You are not guaranteed any personal benefits from being in this study. Research studies may pose risks to those who participate.
- You may want to participate in this research because it offers the opportunity to contribute to the development of more personalized and effective robotic prosthetic legs, which may improve comfort, mobility, and quality of life for people with lower limb amputations. You will also receive financial compensation for your time and effort. You may not want to participate in this research because the study involves multiple lengthy lab visits (up to eight, each lasting up to three hours), which may be time-consuming and physically demanding. There are also low risks of fatigue, discomfort, or falls during walking tasks, and you may experience inconvenience or minor risks related to fitting and using experimental prosthetic devices. Additionally, you may have concerns about providing personal information for payment or about the possibility of not benefiting directly from the study.
- If you have questions about your participation in this research at any time, do not hesitate to contact the researchers named above.
- If you have questions about your rights as a research participant, do not hesitate to contact the NC State IRB office via email at IRB-Director@ncsu.edu or via phone at 1-919-515-8754.

Please read the rest of this consent form for more specific details of this research. If you do not understand something, please ask the researcher for clarification or more information.

What is the purpose of this study?

The purpose of this study is to understand the feasibility and effectiveness of using reinforcement learning to personalize robotic prosthetic legs for lower limb amputees. As an artificial intelligent approach, reinforcement learning based prosthesis controllers adjust the behavior of prosthesis legs to set gait features, such as foot clearance, to a preselected level automatically. This capability permits prosthetists to reach targeted gait performance without knowing how the leg is controlled.

How many people will be in the study?
There will be approximately 30 participants in this study.

Am I eligible to be a participant in this study?
In order to be a participant in this study, you must agree to be in the study and be unilateral transfemoral amputees who:

1. are at K3 or higher K level
2. have more than one year after amputation, have completed their rehabilitation, and fully acclimatized to the socket
3. have used the current socket and prosthetic legs for at least 3 months without any significant skin issues or major modifications to the socket
4. are between 18-75 years old
5. can comfortably walk 6 minutes without pausing to rest
6. are willing to be photographed and video/audio recorded while participating in research activities.

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You cannot participate in this study if you do not meet the inclusion criteria or

1. if you have major communication or neurocognitive deficits that affect your ability to follow instructions and provide feedback
2. significant health issues such as seizures, heart diseases, or stroke that would expose you to a higher risk during study tasks
3. a very short residual thigh (less than 15% of the length of the unimpaired limb)
4. are under 1.50 meters (5 feet) in height or over 116 kilograms (255 pounds) in weight
5. or if you are a current user of the PowerKnee device

What will happen if you take part in the study?
If you agree to participate in this study, you will be asked to do all of the following:

1. Complete a phone screening and provide basic contact information to determine eligibility.
2. Attend up to eight lab visits (each up to three hours), including three initial visits for consent, surveys, and prosthetic fitting and acclimation, and five experimental visits for prosthesis personalization and evaluation.
3. Fill out general information and balance confidence surveys, and complete walking tests (two-minute and ten-meter walk) to assess your baseline mobility.
4. Undergo measurement of your residual limb and review of your prosthetic socket and skin by a prosthetist, who will also determine sensor placement locations.
5. Be fitted with a powered prosthetic knee (either a prototype or commercial device) and a fall prevention harness for safety.
6. Acclimate to walking with the experimental device on a treadmill, level ground, ramps, and stairs, with safety measures in place.
7. Participate in prosthesis personalization sessions, where a specialist or non-specialist prosthetist will adjust control parameters using manual tuning or with the aid of learning algorithms while you perform walking tasks and provide feedback.
8. Complete post-tuning walking evaluations on level ground, ramps, and stairs, with gait performance measured using specialized equipment.
9. Fill out payment forms after each visit to receive compensation for your participation.

10. You will be provided a copy of your research data so that you can confirm the accuracy of the information collected. You can indicate if there's any information or identifiers you want us to delete or not share.

The total amount of time that you will be participating in this study is 12-32 hours.

The following procedures are experimental:

- The study tests new ways to personalize the control settings of both the prototype and a commercial powered knee (PowerKnee™) using reinforcement learning. Reinforcement learning is a type of artificial intelligence that automatically adjusts the knee's movement patterns based on your walking performance and feedback, aiming to find the most comfortable and stable settings for you as an individual.
- These experimental procedures are designed to see if the powered knee, when personalized using reinforcement learning, can improve your walking on level ground, ramps, and stairs compared to standard manual tuning. The prototype device and the reinforcement learning-based tuning are not yet approved for general clinical use, and their safety and effectiveness are still being evaluated in this research setting.
- You will be closely monitored during all activities, and safety measures such as a fall prevention harness and handrails will be used to minimize risks.

This study is a clinical trial. A description of it will be available on www.clinicaltrials.gov, as required by U.S. law. A summary of this study's results will be posted to this website a year after the study is completed. However, it will not include any information that can directly identify you. You can search the clinical trials website at any time to review this study's results once they are posted.

This study involves testing the safety or efficacy of a medical device. The study uses two medical devices: an unapproved prototype powered knee and the approved Össur Power Knee™. Here, the reinforcement learning algorithm expands the functionality of the PowerKnee beyond its initial design.

The prototype powered knee is a research device designed by the investigators and is not yet commercially available. Its primary function is to serve as a powered prosthetic knee joint, providing active assistance to support walking, ramp and stair climbing, and other mobility tasks for individuals with lower limb amputation. This device is being evaluated for its safety and effectiveness in a research setting and is not yet approved for general clinical use.

The Össur Power Knee™ is an approved, commercially available powered prosthetic knee. Its primary function is to provide motor-powered assistance during walking, standing, and ascending or descending ramps and stairs, helping to restore lost muscle function, improve gait symmetry, and reduce user fatigue. In this study, it is being used as a comparison device and as a platform for testing new personalization methods.

The Institutional Review Board at NC State University, which is responsible for reviewing projects that involve human participants, has reviewed this project and determined that the devices being studied are considered "Not Significant Risk" Devices.

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Recording in research

The research team would like to record you for research purposes if you agree. The recording will only occur while you are participating in research activities. If you do not want this information collected, you will not be able to participate in this research. Please select the sentence(s) that you agree to:

_____ It's okay to photograph me
_____ It's okay to record audio and video of me
_____ It's okay to track my movement

We would like to use these recordings and your image for research analysis, including reviewing and transcribing your feedback, evaluating your walking performance, and documenting the fitting and personalization procedures. Images, audio, and video may be used in research presentations, academic publications, and educational materials, but your identity will be protected and any identifying features will be blurred or removed unless you give explicit permission.

We will keep these recordings and images for at least five years after the completion of the study to allow for thorough analysis, publication, and potential follow-up research, after which they will be securely deleted or destroyed according to university policy.

Benefits to participating in this research

There are no direct benefits to your participation in the research. The indirect benefits are the opportunity to contribute to the advancement of prosthetic technology, specifically the development and evaluation of new methods for personalizing powered prosthetic knees. Your participation may help improve the design, comfort, and function of future prosthetic devices for people with lower limb amputations. The knowledge gained from this research could lead to safer, more effective, and more adaptive prostheses, potentially reducing the risk of falls and improving mobility and quality of life for future users.

Risks to participating in this research

The risks to you, as a result of participating in this research, include a low risk of fatigue from walking tasks, a low risk of falls during mobility activities, a low risk of pressure ulcer, and a low risk of identity leak due to the collection of contact and payment information. These risks are mitigated through several measures:

- Fatigue: The total testing time is limited, rest breaks are provided between tasks, and you can stop or pause participation at any time if you feel tired.
- Falls: You will wear a fall prevention harness and have access to handrails during all walking, ramp, and stair activities. All tasks are supervised by trained research staff and prosthetists to ensure your safety.
- Pressure ulcer: because the research does not affect socket fitting, you are not exposed to abnormal pressure compared to everyday activities. The risk from these activities is mitigated by routine inspection of residual limb at the end of each session, as well as prolonged gap between visits if skin color changes are observed.
- Identity leak: Your data will be coded so your name is not linked to the saved research data. Contact information is kept in a secure, locked location accessible only to the principal investigator, and sensitive payment information is handled directly by the university's accounting office. All contact information will be destroyed at the end of the project.

These steps are designed to minimize risks and ensure your safety and privacy throughout the study

Emergency medical treatment

If you are hurt or injured during the study session(s), the researcher will call 911 for necessary care. There is no provision for compensation or free medical care for you if you are injured as a result of this study.

What data will be collected about me and are there risks associated with that?

The data that are collected about you include your name and contact information (for scheduling and payment), demographic information (such as age, height, weight, side and reason of amputation, time since amputation, and K-level), details about your current prosthesis and suspension system, results from walking and balance tests (such as the two-minute walk test, ten-meter walk test, and Activities-specific Balance Confidence Scale), measurements of your residual limb, gait performance data (speed, step length, gait symmetry) collected using wearable sensors and instrumented walkways, and audio, video, and movement recordings during lab activities . These data are indirectly identifiable, meaning that while your name will not be linked to the research data, a code key exists that could potentially link your identity to your data, and some recordings (audio, video) are considered identifiable.

The risks to you as a result of collecting this information include a low risk of identity leak, such as unauthorized access to your personal or payment information, or the possibility that someone could recognize you in audio or video recordings. These risks will be mitigated through several data protection measures by NC State data protection standards: your name and contact information will be stored separately in a locked file accessible only to the principal investigator, all research data will be coded and stored securely, sensitive payment information will be handled directly by the university's accounting office, and all contact information will be destroyed at the end of the project. Audio and video recordings will be handled with care, and any identifying features will be removed or blurred before sharing or publication unless you give explicit permission.

If you are a student, this study will not include the collection of your student records. Only research data related to your participation in the prosthetic device study will be collected and accessed by members of the research team as described above. The dataset will remain indirectly identifiable for the duration of the study and will be de-identified to the extent possible before any data is shared outside the research team.

How will my identity and the data about me be stored and protected?

After all data is collected, the researchers will go through the data and remove all direct identifiers and retain indirect identifiers with the data. A master list that connects your real identity to the dataset using a code will be created and stored separately from the research data in a locked cabinet in the principal investigator's office, accessible only to the PI. After the study is over, we will permanently delete the master list. It is unlikely your identity could be deduced from your responses in the dataset without the master list.

We will go through your responses, survey forms, and any transcripts or recordings and do our best to remove or replace any information that can identify you directly. Examples of information we will remove include your name, contact details, social security number, email address, and any other unique identifiers such as device numbers or full face images. We will also recode or remove specific dates, geographic information, and other details that could indirectly identify you. After we do this, it is unlikely your identity could be deduced from your responses.

All electronic data will be stored on password-protected, encrypted computers or secure university servers, and paper records will be kept in locked cabinets. Only authorized members of the research team will have access to the data, and all personal contact information will be destroyed at the end of the project. Audio, video, and photographic records will be handled with additional precautions to protect your confidentiality, including blurring or removing identifying features before any sharing or publication, unless you give explicit permission.

Who can access my data and how will my data be shared and used in the future?

For administrative purposes, we may share your name with the NC State University Accounting Office to process your payment for participation. The information we share with them will not be associated with your individual research data or responses; it is used solely for payment processing.

Because this study is funded by the NIH, de-identified data about you—including demographic information, prosthetic device usage, gait performance data, and survey responses—may be shared with the larger research community through controlled-access data repositories, in accordance with NIH data sharing policies. Your data will not be directly identifiable, but we cannot guarantee complete anonymity now or in the future.

We would like to keep, use, and share your individually identifiable data with others for future unspecified research. In order to do this, we need your additional consent, which can be found after this document. If you do not provide additional consent, then any data we store, use, and share with others for future research will not be identifiable.

Access to your identifiable data will be limited to authorized members of the research team and, as required, to regulatory agencies such as the FDA. De-identified data may be shared with other researchers for scientific purposes, but all reasonable efforts will be made to protect your privacy and confidentiality in accordance with NC State data protection standards and NIH policies.

In summary, your data will be used for research purposes, shared with regulatory agencies if required, and may be shared with the broader research community in a de-identified form. Identifiable data will only be shared for future research with your explicit consent.

How will the data about me be reported to the public and are there risks associated with that?

Even though we will not directly identify you when we share the results of our study, it's still possible someone could figure out who you are from the information we will include. This is because we will report the data as summary statistics for a small group (about 30 participants) and may include specific demographic information such as age range, amputation level, and years since amputation, as well as descriptions of individual experiences or unique feedback related to prosthesis use. Because of the small sample size and the specific nature of lower limb amputation, someone familiar with the local

amputee community or your clinical history may be able to recognize your participation or link your responses to you.

As a result of possible re-identification, the risks to you or others you know include the potential for loss of privacy, unwanted disclosure of health or mobility status, or being associated with the study in ways you did not intend. We will take steps to minimize these risks by removing direct identifiers, aggregating data whenever possible, and only sharing de-identified data in publications and presentations. However, complete anonymity cannot be guaranteed due to the detailed nature of the study population and procedures.

Right to withdraw your participation

Your participation is voluntary. Even if you agree initially, consent is an ongoing process. You can stop participating at any time for any reason. To do so, you can tell any member of the research team during a lab visit, contact us by phone or email, or simply choose not to continue with any scheduled study activities. You can also contact the researcher, Ming Liu, at mliu10@ncsu.edu and 9195158541. Or you can contact the faculty advisor for this research, He (Helen) Huang, at hhuang11@ncsu.edu and (919) 515-5218.

If you withdraw, we will immediately stop any procedures or data collection that may be happening. We will also delete any data that has already been collected from you whenever possible. However, if your data has already been de-identified or included in aggregated results or published materials, we may not be able to remove it. After your data is de-identified, it will no longer be possible to link your responses to you, and we will not be able to delete your specific data from the study at that point.

Compensation

For your participation in this study, you will receive $45 per hour for each hour you spend with the research team, with a minimum payment of $90 per visit (equivalent to two hours). If you withdraw from the study before it ends, you will still be compensated at a rate of $45 per hour for the time you have already participated, or $90, whichever amount is higher. Travel cost will also be reimbursed. If the round trip from your home to our testing site is longer than 30 minutes, you will be paid for your travel time. The travel time will be rounded to the nearest 15 minutes. One hour travel time will be counted as 1 hour experimental time ($45 per hour) if you use your own vehicle. The round trip time will be calculated using Google Map from your home address to 1900 Entrepreneur Drive, Raleigh, NC. If the paid travel time leads to a lower payment compared with what is calculated based on the University approved standard mileage rate, the latter one will be used.

What if you are a student?

Your participation in this study is not a course requirement. Your participation or lack thereof will not affect your class standing, grades, or relationship with your instructors or advisors.

What if you are an employee?

Your participation in this study is not a requirement of your employment. Your participation or lack thereof will not affect your job.

Research collaborations

This research project is a cooperative effort between the following entities: North Carolina State University and Arizona State University.

Sponsorship and funding

This research is funded by the National Institutes of Health (NIH). This means that the sponsor is paying the research team for completing the research. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. If you would like more information, please ask the researchers listed at the top of this form about the funding and sponsorship.

Inventions and patents

Dr. He (Helen) Huang is the inventor of the prototype powered knee that is part of this research and is being evaluated in this study. Dr. Huang is also a part-owner of technology related to powered prosthetic devices, to whom the patent for the prototype powered knee has been licensed. If the technology is licensed at NC State University, an ICF disclosure in Sophia (the Office of Research Commercialization database at the University) must state that the University and the inventor may benefit from the invention. If this patent or approach is successful at some point in the future, NC State University and Dr. Huang may receive financial benefits. If you would like more information, please ask the researchers listed at the top of this form.

What if you have questions about this study?

If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the researcher, Ming Liu, at mliu10@ncsu.edu and 919-515-8541. You can also contact the faculty advisor for this research, Dr. He (Helen) Huang, at hhuang11@ncsu.edu and (919) 515-5218.

What if you have questions about your rights as a research participant?

If you feel you have not been treated according to the descriptions in this form, or your rights as a participant in research have been violated during the course of this project, you may contact the NC State IRB (Institutional Review Board) office. An IRB office helps participants if they have any issues regarding research activities. You can contact the NC State University IRB office at IRB-Director@ncsu.edu, 919-515-8754, or fill out a confidential form online at https://research.ncsu.edu/administration/participant-concern-and-complaint-form/

Consent to participate

By signing this consent form, I am affirming that I have read the above information. All of the questions that I had about this research have been answered. If I consent to participate, I understand that I can stop participating at any time without penalty or loss of benefits to which I am otherwise entitled. I am aware that I may revoke my consent at any time.

☐ **Yes, I want to be in this research study.**

Name_____ **Today's Date** _____

☐ **No, I do not want to be in this research study.**

☐ **Thank you for your consideration.**