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Informed Consent for Participation in Research

Project Title:

Toward Restoration of Normative Postural Control and Stability using Neural Control of Powered Prosthetic Ankles

Protocol Number: 26076

Protocol is approved by NC State University IRB

Approval Period:

07/14/23 – 07/13/24

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Amputee Consent Form

Title of Study: Toward Restoration of Normative Postural Control and Stability using Neural Control of Powered Prosthetic Ankles (eIRB # 27067)

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Funding Source: National Institute of Health

What are some general things you should know about research studies?

You are invited to take part in a research study that is a joint collaboration between NC State University and the University of North Carolina at Chapel Hill. Your participation in this study is voluntary. You have the right to be a part of this study, to choose not to participate, and to stop participating at any time without penalty. The purpose of this study is to investigate the effects of training with a direct electromyographic (dEMG) controlled powered prosthetic ankle for transtibial amputees. This will be done by 1) mounting FDA approved surface electrodes on your residual limb to record dEMG signals, 2) connecting your prosthetic socket to our custom powered prosthetic ankle and 3) involving you in a series of training and evaluation tasks such as sitting, standing, squatting, and walking under various conditions with both your personal prosthetic device and our dEMG controlled powered prosthetic device.

You are not guaranteed any personal benefits from being in this study. Research studies also may pose risks to those who participate. You may want to participate in this research because the collected information may benefit people with lower limb amputation by advancing applications in direct neural control for lower limb prosthetic devices. You may not want to participate in this research because you might be exposed to the risk of fall, fatigue, and identity leakage.

Specific details about the research in which you are invited to participate are contained below. If you do not understand something in this form, please ask the researcher for clarification or more information. A copy of this consent form will be provided to you. If, at any time, you have questions about your participation in this research, do not hesitate to contact the researcher(s) named above or the NC State IRB office. The IRB office's contact information is listed in the *What if you have questions about your rights as a research participant?* section of this form.

What is the purpose of this study?

The purpose of the study is to investigate the effects of training to use dEMG control of a powered prosthetic ankle on transtibial amputees.

How many people will be in the study?

There will be approximately 50 amputee 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:

- 18 years or older
- Unilateral lower limb amputee (below the knee)

- K-level 2 or higher (who are frequent prosthesis users and may benefit from the proposed prosthesis training and use of dEMG controlled powered prosthesis)
- Amputation occurred over 2 years ago
- At least 1 year of experience using your prosthetic leg
- Have used the current socket for at least 6 months without a significant skin issue or major modification
- Are willing to come to NC State University's Centennial Campus to participate in research and be photographed while doing research activities

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

- Have a very short residual shank (the length of the residual limb is ≤15% of the length of intact limb)
- cannot perform functional ambulation in the community on a daily basis without assistive devices
- Cognitive or visual impairment that affects the participant's ability to provide informed consent or to follow simple instructions during the experiments
- Congenital amputees
- Amputees who use powered prosthetic ankles
- Weight more than 300lbs
- Pregnant Person
- Allergic to latex, which is often contained in medical tapes.

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. Review and complete this consent form
2. After you finish the consent form, you will fill a general information survey, which is used to collect some basic information about you, including age, weight, reason of amputation and so on.
3. For the remainder of your first visit:
    a. You will need to conduct a 10-meter walking test to evaluate your walking speed
    b. You will fill out a survey on your confidence with your balance
    c. You will be placed into one of two groups
        i. Group A will train with the powered prosthetic ankle
        ii. Group B will train with their own passive prosthetic device
4. For the second visit you will:
    a. Be fitted with our pneumatic powered prosthetic ankle with the help of a certified prosthetist.
    b. Have dEMG sensors mounted on your residual limb to test the control of the powered prosthetic.
5. For the third and fourth visits we will do a baseline evaluation with both your own passive device and the dEMG ankle, you will go through the following experimental procedures:
    a. You will complete a verbal survey on your comfort with the procedures thus far.
    b. You will have dEMG sensors mounted on your residual limb.
    c. You will wear a protective harness to protect from falls
    d. You will wear the pneumatic powered prosthetic ankle

e. You may be asked to wear a haptic feedback vest which will be controlled by a computer to provide vibrotactile stimulations through a grid of small vibrating motors inside the vest. You will be asked to put on the vest and use the size adjusting straps to ensure a comfortable fit.
f. Researchers will tape reflective motion capture markers on your limbs, hip, torso and head.
g. You will participate in the following experimental tasks:
    i. Postural Sway:
        1. You will start by stand on the treadmill
        2. You will be asked to sway as far forward and as far backwards as is possible without needing to take a step
        3. You will be asked to sway in rhythm with a metronome set to 0.25hz
        4. You will be asked to do this task under 3 conditions:
            a. Feet shoulder width apart
            b. Feet twice your shoulder width apart
            c. Feet shoulder width apart with knees bent
        5. Each round will last approximately 1.5 minutes with 2 minutes of rest in between each round.
    ii. Timed Up and Go (TUG):
        1. You will start seated in a chair in an open space.
        2. A researcher will instruct you to stand up from the chair, walk to a marked spot 3 meters in front of the chair, turn around, walk back, and sit down in the chair again.
        3. You may be asked to perform a secondary “stroop” task while you walk, in which a speaker will play audio clips of someone saying the word “high” or “low” in either a high pitch or low pitch. After each audio clip you will be asked to identify if the audio was played at a high or low pitch.
    iii. Anticipated disturbance
        1. You will start by standing on the treadmill, facing the anticipated disturbance platform.
        2. You will be asked to hold onto the handlebars on the platform.
        3. A weighted ball, set to be approximately 10% of your body weight, will be connected to a series of pulleys on the platform.
        4. When an LED on the platform flashes on, the ball will drop 1 second later and cause the handlebars to either be pushed towards you or away from you.
        5. You will be instructed to try and brace for the perturbation and to try and not move your feet, however if you feel you are losing balance you may take a step to maintain balance.
        6. You will receive 6 training trials, followed by 10 evaluation trials.
            a. You will be given 5 minutes of rest after every 3 training trials, and every 5 evaluation trials.
    iv. Pick up objects from floor
        1. You will start by standing on the treadmill with feet shoulder width apart.
        2. A weighted ball weighing approximately 10% of your body weight will be placed on a platform between 20-30 cm off the ground.

3. You will be instructed to squat down and lift the ball while keeping your feet stationary and on the treadmill.
4. You will be asked to repeat this task up to 20 times, with a 2 minute rest every 10 trials.

v. Stance test
1. You will be asked to stand on the treadmill and maintain balance for a period of 30 seconds.
2. You will be asked to perform this task under the following conditions:
   a. Eyes open while standing on firm surface (treadmill)
   b. Eyes closed while standing on a foam surface (_cm thick foam block)
   c. Eyes closed while standing on an inclined surface (25 degrees)

6. For the fifth and sixth visits we will focus on training with the dEMG system to improve your muscle coordination, you will go through the following experimental procedures:
   a. You will have dEMG sensors mounted on your residual limb.
   b. You will wear a protective harness to protect from falls
   c. You will wear the pneumatic powered prosthetic ankle
   d. You will participate in the following experimental tasks:
      i. Muscle coordination training
         1. You will start seated in a chair in front of a computer screen.
         2. The screen will display a grid with a cursor in it.
         3. The cursor will move based on the readings from the dEMG sensors on your residual limb.
         4. By flexing different muscles in your residual limb you will be able to move the cursor.
         5. Through a series of control tasks you will be asked to move the cursor to different positions on the grid as a form of training to give you better control of your muscle coordination.
         6. If in group A, this task will be repeated while you are standing and wearing the powered prosthetic ankle.
      ii. Prosthetic/virtual ankle control
         1. You will be asked to take a seat while wearing either your passive prosthetic device or the powered prosthetic ankle.
         2. If wearing your passive device, you will control a virtual ankle displayed on a computer screen in front of you
         3. if wearing the powered prosthetic ankle, you will control that ankle while remaining seated
         4. For either condition you will be asked to practice controlling the ankle by moving it to different positions
         5. If in group A you will be asked to repeat the task while standing with the assistance of a walker for support.
      iii. Ankle posture test
         1. You will be asked to take a seat in front of a computer screen
         2. The screen will show 2 virtual ankles, one shows the current position of the ankle joint based on your dEMG signals and the other shows a target position for you to move the ankle to.

3. In each trial the target ankle will start moving up and down in a continous motion
4. You will be asked to try and match the movement of the target ankle
5. The speed that the ankle moves at will increase over the course of the trials.
6. You will have a 2 minute break after every 4 trials.
7. You will do a maximum of 20 trials, the task will end early if you can match the ankle angle at its highest speed.

7. For visits 7 - 11 we will work on training exercises using the dEMG prosthetic ankle, you will go through the following experimental procedures:
    a. You will have dEMG sensors mounted on your residual limb.
    b. You will wear a protective harness to protect from falls
    c. If in group A you will wear the pneumatic powered prosthetic ankle
    d. You will participate in the following experimental tasks:
        i. Transition between sit and standing
            1. You will begin seated in a chair
            2. You will be asked to lean forward and stand up from the chair
            3. After standing and maintaining balance for a few seconds you will be asked to return to the seated position
            4. This task may be repeated up to 20 times, with 2-3 minute rest periods after 10 trials.
        ii. Single limb balance
            1. You will begin by standing on the treadmill
            2. You will be asked to raise your non-prosthetic foot off the ground and to balance on the prosthetic side as long as you can comfortably do so.
            3. You may sit and rest between trials.
            4. This will repeat for 5 trials.
        iii. Sit-to-stand progression
            1. You will begin by seated on a platform
            2. You will be instructed to lean forward and stand up as you did in the “Transition between sit and standing” task.
            3. After each trial, the platform will be lowered by 2 in.
            4. This will be repeated for up to 5 trials.
        iv. Squats
            1. You will begin by standing on the treadmill
            2. You will be asked to raise your arms in front of you and bend your knees in a squat, lowering your body as low to the ground as you are comfortable doing.
            3. You will be asked to hold this position for 3 seconds
            4. You will straighten your knees to return to the standing position
            5. We will do these in sets of 3, with 5 total sets over the course of the visit
            6. a 2 minute rest will be given after every set
        v. Arm raise and reach
            1. You will begin in the standing position
            2. You will be instructed to raise your dominant arm out in front of you and reach as far forward as you can without taking a step

3. You will hold this position for 3 seconds then return to the standing position
4. this will repeat 3 times

vi. Postural sway
1. This task will be identical to the one described previously in section 5.f.i.

vii. Weight transfer
1. You will begin by standing on the treadmill with equal weight on both feet
2. You will be instructed to slowly shift your weight onto your prosthetic foot.
3. You will hold this position for 3 seconds before shifting your weight back to both feet.
4. You will repeat the task 4 more times, each time increasing the amount of time you hold the shifted position by 5 seconds.

viii. Rocker board balance
1. You will stand on the treadmill with one foot on a rocker board and the other on solid ground.
2. You will be instructed to put weight on the rocker board and lean forward.
3. You will need to hold this position for 3 seconds before returning to the neutral position.
4. For each trial, you will perform this task twice with both your prosthetic and non-amputated foot.
5. The number of trials you will perform will increase each visit.

ix. Stool Stepping
1. You will stand in front of a stool of approximately 4-8in height with handrails to either side to offer support
2. You will be instructed to step their non-prosthetic limb onto the stool, hold it there for approximately 2-3 seconds, then step back down off of the stool.
3. You will be offered a chance to rest after each trial

8. For visits 12-15 you will go through the same procedures as with the 3rd and 4th visits.

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

The total amount of time that you will be participating in this study is 45 hours.

Minimal Risk, Non-Invasive, Not Significant Risk Experimental Device

During this study we will be using an experimental powered prosthetic ankle. Although the device is not FDA approved, it is a non-invasive and minimal risk device. The device will be attached to your socket through a standard pyramid connector, and since no moving components will be attached directly to you or your socket the risk of personal injury or damage to your socket is minimal.

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Recording and images

If you want to participate in this research, you must agree to be photographed. If you do not agree to be photographed, you cannot participate in this research

Risks and benefits

There are minimal risks associated with participation in this research. The risks to you as a result of this research include

- You are exposed to a low risk of pressure ulcers
  - The risk from these activities are mitigated by
    - Recruitment of participants who are used a socket with good fit;
    - Using EMG electrodes with very low profiles, less than 1mm thickness and soft
    - inspecting any potential skin damage before and after if the EMG electrodes are used.
- You are exposed to low risk of fatigue and muscle soreness
  - The risk from these activities are mitigated by
    - Control your total efforts by limiting the total testing time
    - provide you rests between tasks
    - permit you to end the experiments whenever you feel fatigue.
- You are exposed to a low falling risk
  - The risk from these activities are mitigated by
    - Use of a safety harness while walking on treadmill
    - Presence of handrails accessible during all activities that require standing or walking
- You are exposed to low risk of identity leak. This risk comes from these activities: screening and scheduling.
  - The risks from these activities are mitigated by
    - you will be given a code name, so your name is not linked with any saved data;
    - the name and contact information will be written down in a master list, which is locked in the PI's office and is accessible to PI only.
    - the W9 form and direct deposit setup is done using the standard procedure defined by NCSU and handled by the Department of Biomedical Engineering, the research team does not collect sensitive information, such as SSN or banking information;
    - the payment form will be transferred to the department immediately after the experimental procedure; and
    - destroying all the contact information, which are recorded on the master list, at the end of the project, by shredding.

The direct benefits of this study are: over the course of the training visits many of the tasks mirror those used in physical therapy to strengthen patients and increase their muscle control and coordination, and so you may gain such benefits over the course of these visits.

The indirect benefits are: the amputee population as a whole might benefit from knowledge gained from the proposed study, because our careful designed study has the potential to enable advancements in direct neural control of lower limb prosthetics and provide better user experiences for lower limb amputees by improving their control over their prosthetic device.

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Right to withdraw your participation

You can stop participating in this study at any time for any reason. To do so, just stop any research activity that you are doing or contact the researcher, He Huang, at hhuang11@ncsu.edu and 919-515-8541. If you choose to withdraw your consent and to stop participating in this research, you can expect that the researcher(s) will redact your data from their data set, securely destroy your data, and prevent future uses of your data for research purposes wherever possible. This is possible in some, but not all, cases.

Confidentiality, personal privacy, and data management

Trust is the foundation of the participant/researcher relationship. Much of that principle of trust is tied to keeping your information private and in the manner that we have described to you in this form. The information that you share with us will be held in confidence to the fullest extent allowed by law.

Protecting your privacy as related to this research is of utmost importance to us. There are very rare circumstances related to confidentiality where we may have to share information about you. Your information collected in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety. In other cases, we must report instances in which imminent harm could come to you or others.

How we manage, protect, and share your data are the principal ways that we protect your personal privacy. Data that will be shared with others about you will be re-identifiable

> **Re-identifiable**. Re-identifiable data is information that we can identify you indirectly because of our access to information, role, skills, combination of information, and/or use of technology. This may also mean that in published reports others could identify you from what is reported, for example, if a story you tell us is very specific. If your data is re-identifiable, we will report it in such a way that you are not directly identified in reports. Based on how we need to share the data, we cannot remove details from the report that would protect your identity from ever being figured out. This means that others may be able to re-identify from the information reported from this research.

Future use of your research data

To help maximize the benefits of your participation in this project, by further contributing to science and our community, your de-identified information will be stored for future research and may be shared with other people without additional consent from you.

Compensation

- Each participant will be paid $25/hour with a minimum 2 hour for a visit. If the participant decides to quit the experimental procedure, they will be paid based on the $25 per hour that they spent with the research team or $50. The one with the higher number will be used.

- Travel cost of the participant will also be reimbursed. If the round trip from the participants' home to our testing site is longer than 30 minutes, the study subjects will be paid for their

travel time. The travel time will be rounded to the nearest 15 mins. One hour travel time will be counted as 1.6 hour experimental time if participants' vehicles are used for commuting. The round trip time will be calculated using Google Map from the home address of the participant to1900 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 later one will be used.

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 if you are a student?
Your participation in this study is not a course requirement and your participation, or lack thereof, will not affect your class standing or grades.

What if you are an employee?
Your participation in this study is not a requirement of your employment, and your participation or lack thereof, will not affect your job.

Sponsorship and funding
This research is funded by NC State University. 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 researcher(s) listed at the top of this form about the funding and sponsorship.

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, He 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 and understand the above information. All of the questions that I had about this research have been answered. I have chosen to participate in this study with the understanding that I may 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. You will be asked to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.

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☐ **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.