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

Updated on: 03/18/2024

Number of Participants:

- 50 unilateral transtibial amputees (below the knee amputation)

Inclusion/Exclusion:

- AMPUTEE ELIGIBILITY
    - 18 years or older
    - unilateral bower limb amputee
    - 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 their prosthetic leg
    - Has 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

- AMPUTEE INELIGIBILITY
    - 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.

- Reasons for the inclusion and exclusion criteria:
    - We would like to involve participants, who are capable to walk in the community without additional assistive devices.
    - To ensure that there is enough muscles on their residual limb for EMG data collection, we would like to exclude those who have very short residual limbs. Congenital amputees are also excluded due to the fact that they may never develop the needed muscle patterns on their residual limb.
    - To ensure their safety, we need them to have a healthy residual limb with low risk of pressure ulcer (young amputees, pregnant people, and recent amputees usually have high risk of pressure ulcers).
    - Users of powered prosthetic ankle is excluded due to the fact that they could not be used for the comparison group and may cause bias in the randomization.
    - The safety harness has a limit of 300lbs, which is used to limit the maximum weight of the participants.

Recruitment:

- The participants will be recruited by flyers (27067: Group 1 - People with amputation - Flyer.docx) distributed at amputee clinics and amputee supporting groups.

Screening:

- Following the instruction on the recruitment flier, potential participants are encouraged to call the research team first.
- A researcher will conduct a phone screening procedure with the participant (see document 27067: Group 1 - People with amputation - Recruiting and Screening script.docx).
    - The researchers will write down the name and contact information in a separate paper, which will later be integrated into the master list, which is locked in PI's office, by the PI.
    - The contact information of the participants, who are not qualified, will be destroyed immediately through shredding.

Sign-Up and Scheduling:

- The participants are instructed to fill an online form provided by the NCSU accounting office to provide bank information and SSN, to setup the direct deposit to the participants. The research team has no access to these information, but is able to be aware whether the participants have finished this procedure. All the participants will be booked after they finished this procedure.
- After the screening, the research team will send out a when2meet link to let the participants choose the best testing time for them.
- After the participant selected a time slot, the researcher will contact the participants through email again to verify the schedule

Lab Visit Experience for Participants with lower limb amputation:

- Number of Lab Visits: 15 visits. Clinicians may recommend skipping some of the visits or tasks based on clinical evaluation and status of the participants.
- Length of Lab Visit: three hours maximum

1. First visit: the purpose of the first visit is to conduct consent and conduct measurements to decide walking speed and ABC (amputee balance confidence) score. All the task in the visit 1 will be conducted sequentially.
    a. Conduct participant consent, fill the consent form, and provide related payment information instructions
        i. The participant will be invited into the lab and provided the consent form (27067_ group 1 - people with amputation - consent form.docx) to review and sign.
        ii. The participant will be provided opportunities to ask questions about the protocol and decide whether they want to continue to be involved in the study.
        iii. After completing the consent form, the participants will fill the general information survey form (27067 group 1:general survey.doxc), which includes information about age, gender, body weight/height, reason of amputation, side of amputation, common prosthetic usage, and everyday

prosthetic usage time. Participants can ignore the questions, which they do not feel comfortable to answer.

iv. Instruction about online payment information
v. The participant will need to provide an email address, so the department accounting office can send them an email to guide them in filling in personal information to setup online payment transfer.
vi. The participants are instructed to respond to the email from NCSU accounting and told that they will need to provide their social security number and information about their checking account to get paid for their efforts.
vii. If they have issues about providing SSN or do not have a checking account, we are also offering gift cards for payment. Due to tax reporting challenges, gift cards are always the second option.

b. 10 meter walking test
    i. The participants will walk through a 10 meter walking test, so the research team could estimate their normal walking speed. This information will later be used to set the speed of the treadmill.
    ii. The participants will walk naturally at their self-selected walking speed to pass a 10 meter walk way three times.
    iii. A researcher will follow the participant and record the time needed to pass the walkway and use it to calculate the walking speed, which is averaged across three walking trials.
    iv. More detailed instructions can be found in “27067 group 1 - 10mwalktest.pdf”
c. ABC scale survey
    i. The participants will fill the survey form for the Activities-specific Balance Confidence (ABC) Scale, which is included in the file: “27067 group 1 - abc score.pdf”.
    ii. An experimenter will fill in the identification code of the participant as the name in advance.
    iii. The survey will be filled by the participant using a pencil provided by the research team.

2. Second visit: this visit is to ensure that the amputees’ own socket system can be integrated into the powered prosthetic leg and validate the effectiveness of the EMG interface. All participants will go through the same procedure.
    a. Adjust alignment
        i. A certified prosthetist, who is a verified contractor of NCSU, will check the socket of the participants.
        ii. The prosthetist will disconnect the prosthetic leg of the participants and mount the sockets with the powered prosthetic ankle, as shown in Fig. 1. The prosthetic ankle is designed with a bottom mounting point. By tightening the screws, shown in Fig. 2, a prosthetic socket can be fixed into the powered prosthetic ankle as shown in Fig. 1.

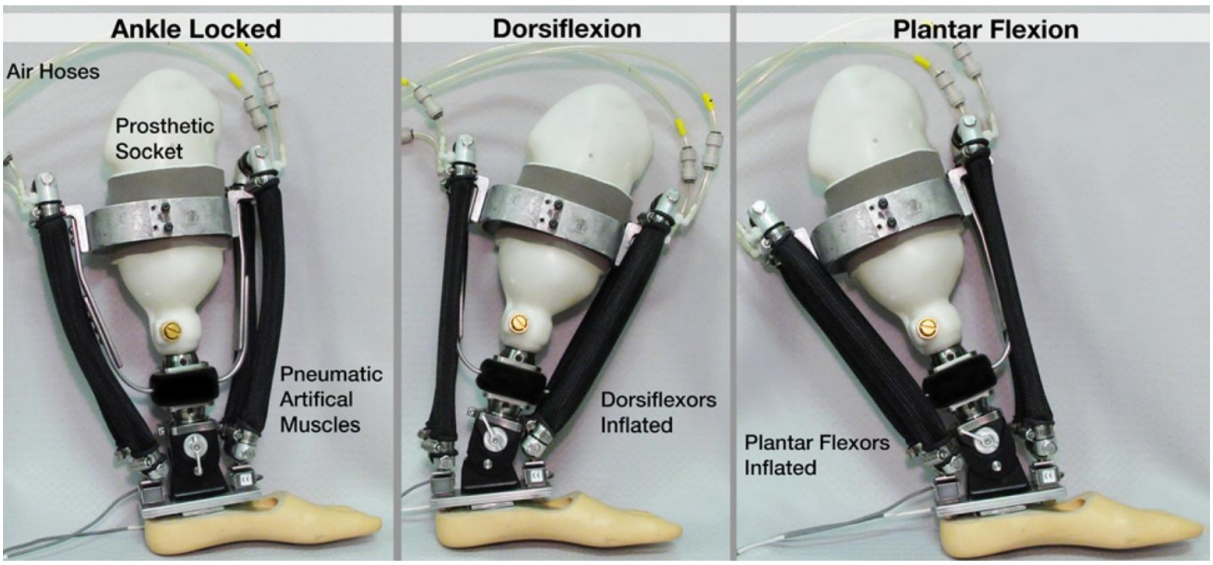

Fig. 1: The powered prosthesis in three different ankle positions. Two artificial muscles acted as dorsiflexors, and two artificial muscles acted as plantar flexors. The range of motion of the ankle with uninflated actuators was 25 deg of dorsiflexion and 35 deg of plantar flexion. The prosthetic socket was interchangeable so that the amputee's prescribed socket could be used. Standard stainless steel prosthetic components above the ankle and below the socket interface allowed for proper alignment.

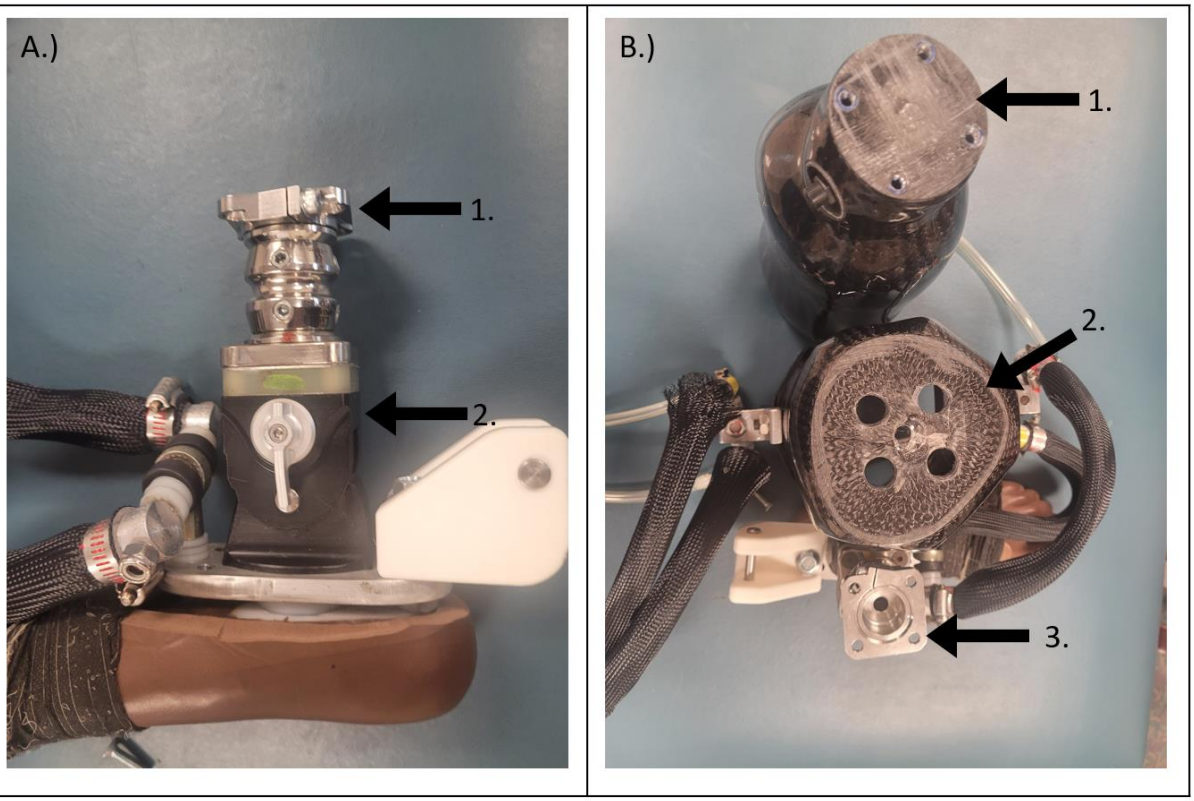

Fig. 2: mounting mechanism for a prosthetic socket onto the powered prosthetic ankle. A1) Side view of the pyramid adaptor which connects to an amputee's socket. A2) joint of pneumatic ankle attached to pyramid adaptor. B1) Base of amputee's prosthetic socket. B2) Base of the frame for the pneumatic ankle which holds the amputee's socket. B3) Top view of pyramid adaptor, which screws into the frame and prosthetic socket.

b. Integrate the EMG electrodes and check comfort
    i. Validate that the participants are not allergic to the mounting gel of the prosthetic electrodes. A dot electrode, which will be used in the prosthetic socket will be integrated into the prosthetic socket (as shown in Fig. 3), is given to the participant and the participant will stick the electrode on their forearm using the self-mounting tape. After five minutes, the participant will take the electrode off and the research team will check whether the skin is red or not. A red skin indicates that the participant may be allergic to the gel and should be excluded from the study.
    ii. The participant takes off the prosthetic socket and liner
    iii. The participant will clean the area, which is highlighted in the Fig. 4. A using medical alcohol pad and stick the low profile EMG electrodes (Fig. 3. B) using doubleside tapes. Additional medical tapes will be used to stablize related cables.
    iv. One experimenter will connect the cable from the electrodes with the preamplifier (Fig. 3.C).

v. The experimenter will connect the preamplifier with the EMG measurement system as shown in Fig. 3D.
vi. The participants sit comfortable in a chair and the prosthetist will ask the participants to image that they are moving their amputated ankle. One researcher will observe the displacement of the EMG signals on the computer screen to check whether there is crosstalking (both EMG provide large signals despite whether the instruction is dosiflexion or plataflexion) or disconnection (large signals even without imaging movement of the ankle).
vii. The participant will put on the prosthetic liner and socket by themselves. If the cable to the electrodes makes it difficult for the suspension system to maintain suction, the prosthetist will use medical tape, as shown in Fig. 8 to ensure suction.

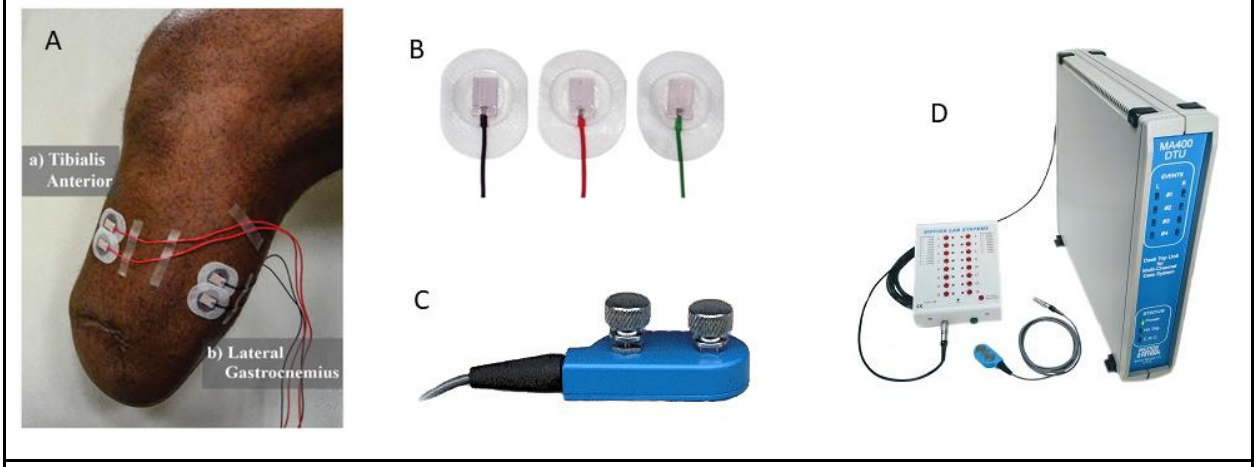

Fig. 3: A) the location to mount the EMG electrodes; B) electrodes used to be mounted on the amputees' residual limb; C) preamplifier used to enhance EMG signals; and D) amplifiers used to record the EMG signals.

c. EMG electrodes remove
i. A member of the research team will disconnect the EMG electrodes from the amplifier.
ii. The participants will remove the medical tape put on as mentioned in visit 1 step b.vii if applicable.
iii. The participants will take off their prosthetic socket and liner by themselves.
iv. The participants will take off the electrodes by gently pulling.
v. One researcher will inspect the skin where the electrodes were placed to check any skin damage.
vi. The participant will use alcohol pad (as shown in Fig. 4) to clean the skin where the electrodes are attached.
vii. The participants will take their liner and sockets on themselves.
viii. The participants will walk around briefly to check effectiveness of the socket.

d. discuss with the participants about their expectation of the next visit
    i. A researcher will describe what will be done in the next visit and ask the participants to inform the research team if any issues are noticed.

Fig. 4: alcohol pad used to clear the skin surface after the electrodes are removed. Similar product may be used to replace this one.

3. Third and fourth visits: baseline evaluation with powered prosthesis and passive prosthesis. Each participant will finish the two visits. One of the visits is dedicated to their own passive prosthesis and the other visit is for the powered prosthesis. The sequence of the evaluation is randomized. The tasks conducted in the two visits are generally identical. The only difference is that one of the visits uses the participants' everyday prosthetic foot and the other uses the powered prosthetic ankle (shown in Fig. 1)
    a. Checking EMG site
        i. One experimenter visually inspects the locations, where the EMG electrodes are placed to identify any bruise
        ii. Ask the participants whether they feel anything abnormal on their residual limb since the start of the experimental procedure.
        iii. The visit is canceled if a bruise is noticed.
    b. Verbal survey the participants about their comfort
        i. The experimenter will ask the participants whether they felt unusual exhausting from the last training or evaluation session.
        ii. The visit is canceled if the participant felt that it is to hard to finish the current test.
    c. EMG mounting (only in powered prosthesis visit)
        i. This is done following the procedure mentioned in visit 2, steps b.ii - b.vii.
    d. Mount the powered prosthetic ankle (only in powered prosthesis visit)
        i. A researcher will disconnect the prosthetic leg of the participants and mount the sockets with the powered prosthetic ankle, as shown in Fig. 1. The prosthetic ankle is designed with a bottom mounting point. By tightening the screws, shown in Fig. 2, a prosthetic socket can be fixed into the powered prosthetic ankle as shown in Fig. 1.

e. Protection harness mounting

i. The participant will wear a fall prevention suit (Marine Anti-gravity System) in a standing position with help from the experimenters as shown in Fig. 5.

ii. The research team has three systems with size (M, L, XL) for participants to choose from.

iii. The railing used to connect the fall protection gear is designed to support a weight carry robot for rehabilitation training. Our participants are usually much lower weight compared with the limit of the robot system (250lbs), which makes it very safe for our purpose.

iv. Before the testing, the researcher will wear the protection gear and rely on the railing for body weight support at least for 3 seconds by using a shorter connection cable. It is a quick test of the reliability of the protection system. The harness will be cleaned using alcohol wipe and spray every time after usage.

Fig. 5. procedure to put on the fall prevention suit

f. Marker mounting

i. identify the locations of markers on human body. Because the study will focus on the posture control, we will cover the motion of feet, shanks, thighs, torso, and head as seen in Fig. 6. For each body segments, we will mount no more than 5 markers with additional markers at hips, knees, ankles, and neck (two at each joint). So total less than 58 markers are adopted.

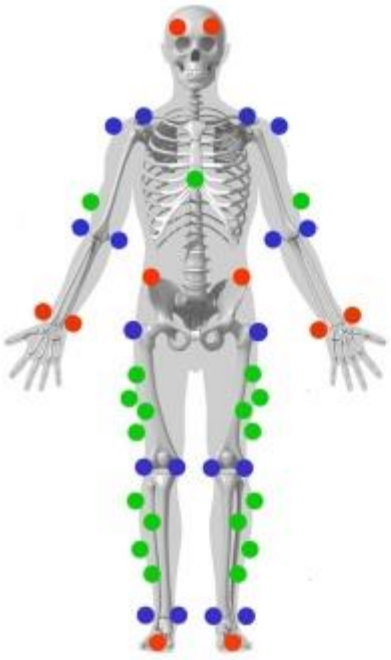

Fig.6: marker locations for the motion capture (dots shows the approximately marker locations).

ii. reflective markers (no energy stored) from VICON (as shown in Fig. 7) will be used in the study. Before mounting, the participants are instructed to clean the mounting area by the research team using alcohol pads as shown in Fig. 4. Two types of mounting will be conducted based on the location of markers.
    1. Condition one: base plate mounting. The markers will be sticked on small plastic plates using double side tapes (as shown in Fig. 7a) by the research team in advance. Then a researcher will attach the plastic plate to the human body using a soft velcro strap.
    2. Condition two: direct mounting. The research team will put double side tapes (as shown in Fig. 7b) under the bases of the markers. Under the direction of the research team, the participant will push the marker toward their own body gently. Then a research team member will enhance the mounting with a medical tape shown in Fig. 8.

Fig. 7: a) the plastic plates used to host the markers and b) the marker is mounted on body skin directly.

Fig. 8: Medical tape used to stabilize the markers (0.5 inch width and 2.7 mil thickness)

g. Postural sway (three conditions) The postural sway test is a measure of a person's ability to maintain balance while standing still. It involves measuring the amount of sway or movement that occurs in a person's body while they are standing in a stationary position. This test is commonly used in clinical settings to assess balance and gait disorders, as well as in research studies to investigate the effects of various interventions on balance. We will conduct the test in three conditions: 1) distance between foot is as wide as the shoulder, 2) distance between feet is twice as wide as the shoulder, and 3) distance between foot is as wide as the shoulder and the knee is bent to lower the center of gravity. Condition 1 is also tested first and Condition 2 and 3 are conducted in random sequence.
    i. the participant is standing on the treadmill (as shown in Fig. 9) with a protection harness connecting the rail.

Fig. 9: The split treadmill, which is used in the protocol.

ii. the physical therapist instructs the participant to get into one of the conditions and keep the arm on the side of the body
iii. the participant are instructed to sway as far forward and far backward as possible without taking a step either forward or backward
iv. a metronome is set at 0.25hz and the participant is instructed to finish one swing cycle in each beep
v. the participant will have 5-10 second to try to get a comfortable sway range
vi. After the verbal confirmation from the participant (“I am ready to start”), the sway efforts will last about 1-3 minutes to finish 60 sway cycles.
vii. After each condition, the participant will be offered 2 minute bread before the next one starts.

h. Timed Up and Go (TUG) Tests with/out secondary tasks are a clinical assessment used to determine a patient’s risk of falling. The TUG alone will be conducted first and the TUG with secondary tasks will be followed. Each test will be conducted three times with 2 min breaks between the TUG alone and TUG with secondary tasks. An illustration of this task can be seen in Fig 10.

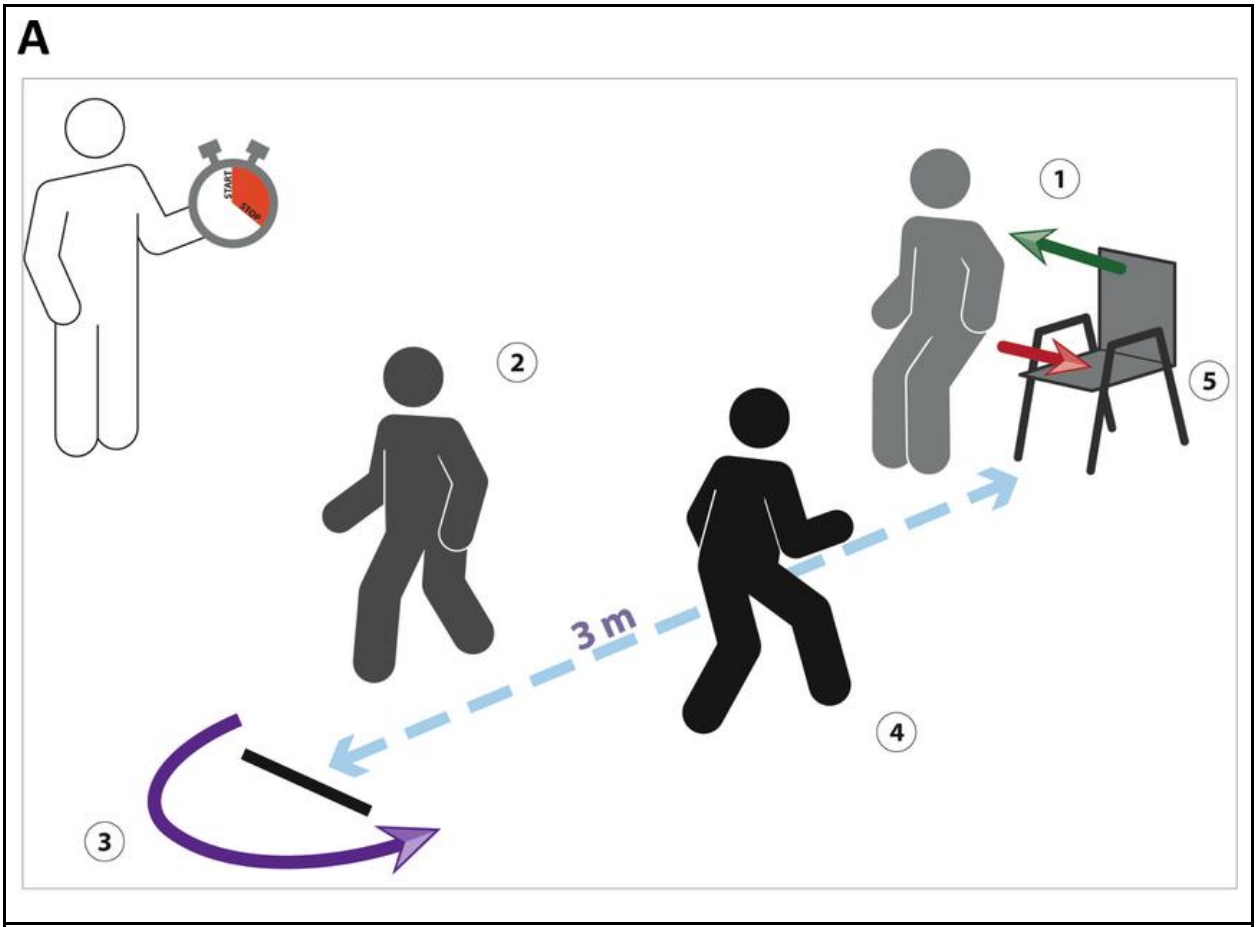

Fig. 10: setup of a TUG task. 1: on command, the subject rises from the armchair; 2: the subject walks 3 meters; 3: the subject turns around; 4: the subjects walks back to the chair; 5: the subjects sits back on the chair.

i. A researcher will position a chair in an open space leaving at least 4 meters in front of the chair for the participant to walk.
ii. The researcher will mark off a space 3 meters in front of the chair.
iii. The participant will start seated in the chair provided by the researcher.
iv. At the researcher's instruction, the participant will stand up from the chair, walk to the marked spot 3 meters in front of them, turn around, walk back to the chair, and sit down.
v. The researcher will start a time when they instruct the participant to stand, and end the timer when they sit back down.
vi. (optional) Secondary tasks are often incorporated into TUG tests to increase utility of the test in identifying fall risks. We will be using an auditory stroop task to evaluate the cognitive load of the participant.
    1. While performing the TUG task, a speaker will sound a 500ms sound clip of the word "High" or "Low" in either a high pitch (360Hz) or a low pitch (180Hz), although these frequencies may be adjusted based on individual needs to ensure there is a clear distinction.

2. After each word is played, the participant will be asked to verbally respond with “High” or “Low” based on the pitch of the sound, but not the word spoken.
3. The speaker will produce new sound clips in random intervals of 2-3 seconds, the participant will respond after each sound clip. The number of sound clips and the number of correct responses are recorded for later analysis.

i. Anticipated disturbance
    i. The participant will stand on the treadmill with feet shoulder width apart, one foot on each belt, facing the perturbation platform as illustrated in Fig. 11.
        1. The platform delivers perturbations through a hanging weight which is a soft weight ball selected to be approximately 10% of the participant’s body weight (BW) (± 5 lbs).
        2. The platform will be bolted to a rail, which is used for the patent protection, on the top of the treadmill.
        3. The weight is connected to a set of handlebars by 2 cords via a series of pulleys. An electromagnet is used in series with one of the cords to control the connection of the handlebars to the weight.
        4. When the electromagnet releases, the weight drops and causes the handlebars to either be pulled away from the participant or pushed towards them.
        5. An LED light at eye level with the participant will turn on exactly 1 second before the weight drops.
        6. The LED light will turn off exactly before the weight drops.
        7. Two different conditions will be tested:
            a. Condition 1: 10% BW Push, the handlebars will be pushed towards the participant.
            b. Condition 2: 10% BW Pull, the handlebars will be pulled away from the participant.
    ii. A researcher will adjust the height of the perturbation platform to ensure the handle bars are at shoulder height for the participant.
    iii. The participant will be instructed to reach out and hold onto the handlebars of the perturbation platform.
    iv. The participant will be instructed to try and brace for the perturbation and try not to move their feet as the perturbation occurs, however if they lose balance or feel unstable they may take a step to steady themselves.
    v. First, a round of practice trials will be held so the participant can be made aware of the strength of the perturbations that will occur.
        1. The participant will be informed on the direction of the perturbation with the handlebars either being pulled away or pushed towards them.
        2. The participant will complete each condition 3-10 times before evaluation.

3. For the repetition of each condition, the researcher will count down from 3 down to 1, timed so that they will say 1 just as the LED turns on.
4. For the other 2 repetitions of each condition the participant will rely solely on the LED to see when the disturbance will occur.

vi. For the evaluation portion of the task:

1. Each condition will be tested 10 times
2. For each of these trials the participant will rely on the LED to determine the timing of the weight drop.
3. In between conditions the participant will take a 2 minute break.

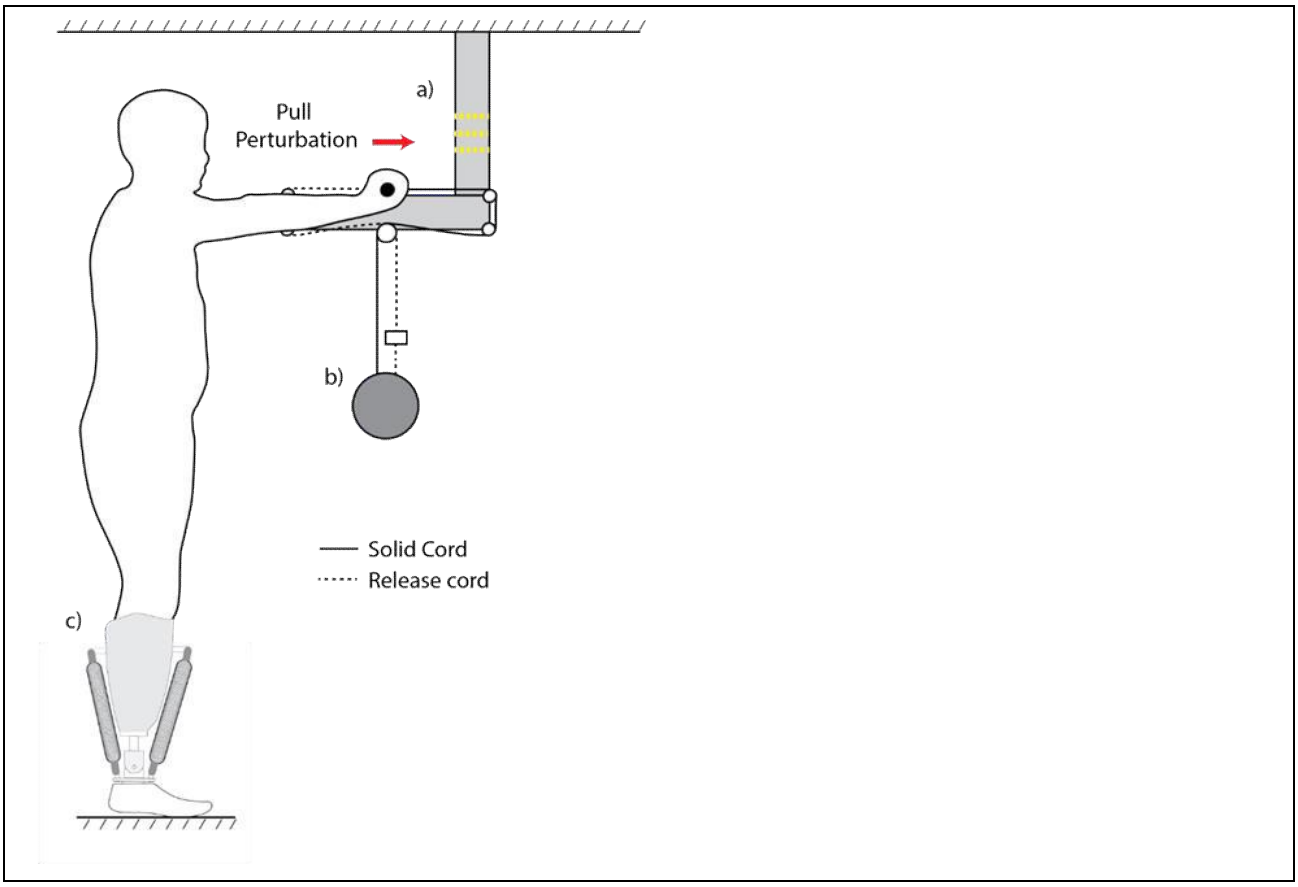

Fig. 11: **. Experimental Platform Illustration.** Participant stands upright while holding a handle bar at arm's length and shoulder height. The handlebar is attached to a suspended weight by two cords. One cord is directly attached to the weight (solid) and the other is attached to the weight with an electromagnet in series, that, when switched off severs the cord's connection with the weight (Release Cord). In this illustration the perturbation platform delivers a pulling perturbation on the participant. The direction of the perturbation is switched by changing the location of the solid and release cord. a) LED light. The LED light is switched off 0.6s before the electromagnet is released providing the participants with a notification of the impending perturbation. b) Perturbation load. Weight is normalized to the participants body weight (10%). c) Pneumatic Artificial Prosthetic Ankle.

j. Pick up objects from the floor
    i. Participant will stand at the edge of the treadmill, feet shoulder width apart with one foot on each force plate.
    ii. A weighted ball set to approximately 10% the participant's body weight will be placed on a platform elevated 20-30cm off the ground, depending on what's comfortable given the participant's height . The platform will be placed in front of the treadmill within arm's reach of the participant.
    iii. Participant will be instructed to squat down and lift the ball, keeping their feet stationary and planted on the treadmill, as can be seen in Fig 12.
    iv. The participant will repeat this procedure up for 20 trials with a two minute break after 10 trials.

Fig.12: Picking up object from floor

k. Stance Test (eye open, firm surface)

i. the participant will stand on the treadmill with the safety harness harness and hand rails to either side.
ii. the participant will be asked to stand with feet shoulder width apart so that one foot is on each force plate, and with their arms by their side.
iii. The objective of the task is to have the participant stand up straight and maintain stability and posture for a period of 30-60 seconds. Each trial of the quiet standing task will be evaluated on a score of 0-3 as follows:
    1. Participant stood stably (score = 3)
    2. Participant stood but was unstable (score = 2)
    3. Participant stood but was unable to stand still (score = 1)
    4. Participant unable to stand (score = 0)
iv. In this variation of the Stance Test, participants will be instructed to keep eyes open. They will stand directly on the firm surface of the treadmill.

l. Stance Test (eye closed, foam surface)
    i. This is done following procedures for previous the Stance Test as mentioned in, steps k.i-k.iii
    ii. In this variation of the Stance Test, participants will be instructed to keep eyes closed. They will stand on a foam block, 2.5in thick, for the duration of each trial as shown in Fig. 13.

Fig. 13: foam block and inclined surface used in stance tests.

m. Stance Test (eye closed, incline)
    i. This is done following procedures for previous the Stance Test as mentioned in steps k.i-k.iii
    ii. In this variation of the Stance Test, participants will be instructed to keep eyes closed. They will stand directly on an inclined surface, seen in Fig. 13.

n. Marker removing
    i. Participant will remove any medical tape used in direct mounting mentioned in steps f.i - f.ii

ii. Participant will gently pull off any reflective markers that were directly mounted
iii. A researcher will help to remove any base plate mounted markers mentioned in step f.i-f.ii
iv. A researcher will check to confirm all markers and medical tape have been removed removed
v. The participant will use an alcohol pad (as shown in Fig. 4) to clean where any tape had made direct contact with skin.

o. Protection harness removing
    i. A researcher will disconnect the harness from the mounting points highlighted in fig 5
    ii. The participant will undo the velcro straps and remove the harness
    iii. A researcher will take the harness and clean it using alcohol wipes and spray before putting it away.
p. EMG removal (optional)
    i. This is done following the procedure mentioned in visit 2, step c.
q. ABC score
    i. Participants will be given the Activities-specific Balance Confidence survey, included in “27067 group 1 - abc score.pdf”, to self report their confidence in not losing balance while performing various different daily activities.
r. Discuss the participants about their expectation of the next visit
    i. A researcher will describe what will be done in the next visit and ask the participants to inform the research team if any issues are noticed.

4. Fifth and sixth visits: these visits are dedicated to have the participants trained to regain muscle coordination, which is critical to use the powered prosthetic ankle. All the participants will go through these trainings. Based on whether the participants are selected as the powered prosthetic group (Group A) or the passive group (Group B), the participants will finish this training with the powered prosthetic leg or a passive prosthetic leg.
    a. EMG mounting
        i. This is done following the procedure mentioned in visit 2, steps b.ii - b.vii.
        ii. Group A will have to go through this procedure.
    b. Protection harness mounting
        i. This is done following the procedure mentioned in visits 3-4, step 3.
    c. Muscle coordination training
        i. The participant is seated in a chair (standard height) while wearing their prescribed passive prosthesis with the heel of their prosthetic foot in contact with the ground to minimize knee movement.
        ii. A computer monitor will be positioned in front of the participant at eye level as seen in Fig 14a.
            1. The monitor will display a UI as depicted in Fig 14b.
            2. A brief 1 minute training period will be given, where the participant will be able to see their EMG recordings as well as how those signals affect and move the cursor on the UI.
        iii. Participant will be asked to perform the following control tasks.

1. For task 1, Participant must change the color of as many blocks as possible from white to blue— when the cursor entered the boundaries of a block, the block turned blue and remained blue for the duration of the task.
    a. Each trial will last about 1-3 minute.
    b. Participant is given 3 minutes of rest between each trial
    c. The task will continue until performance is “saturated”, i.e. the subject was unable to acquire more than one new block per minute, or after 5 trials.
2. For Task 2, we changed the shading of the blocks that the subjects reached in Task 1 to a blue gradient scaled to the cumulative number of frames the cursor entered a block. When the cumulative number of frames reached a preselected number (about 500 usually), we changed the block color to a distinctly different navy blue color.
    a. The blocks that the subject was not able to reach during Task 1 were colored gray and there was no incentive to try and expand the reachable control input space.
    b. The task will continue until performance is “saturated”, i.e. the subject is unable to acquire more than one new navy blue block per minute, or until the end of the task.

iv. After completing the control tasks, these 2 tasks may be repeated while the participant is standing on the treadmill while wearing the safety harness and with access to handrails for support. This is to ensure the participant has a clear understanding of the input-output relationship between their residual limb and the device while both seated and standing.

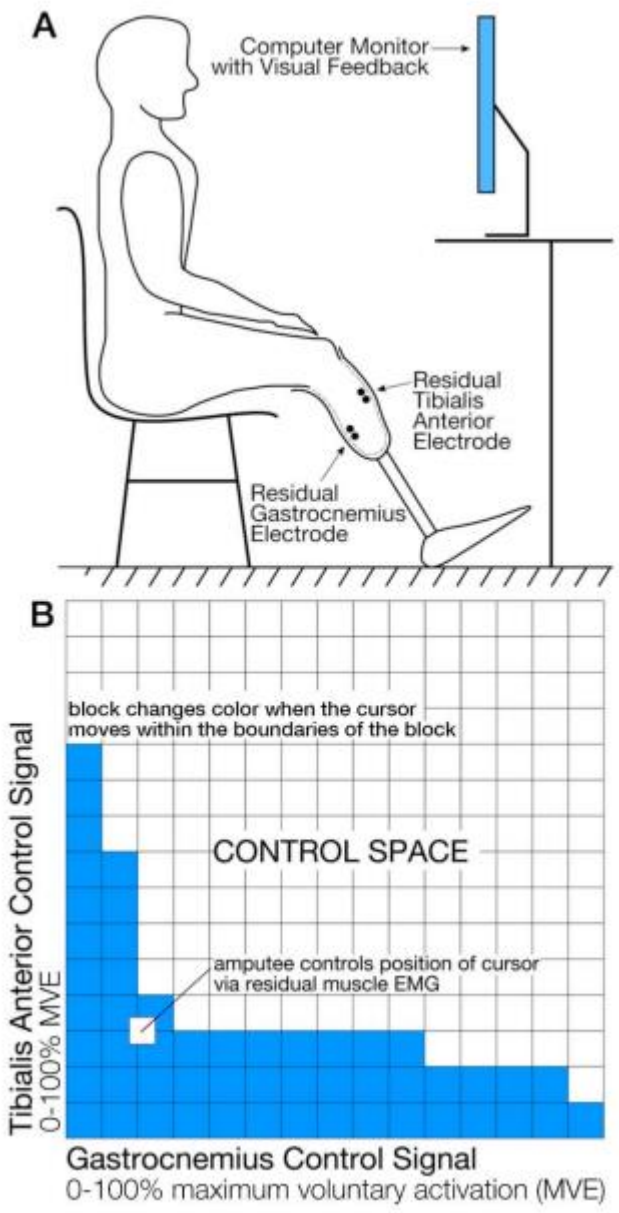

Fig. 14: A) Amputee subject seated while looking at computer monitor with knee at a comfortable angle with heel of prosthesis resting on the floor. B) Real-time visual feedback display where control goal is to change as many blocks from white to blue as possible. Block turns blue when computer cursor enters boundaries of the block

d. Prosthetic/virtual ankle control
    i. Participant will wear either their own passive device or the dEMG prosthesis.
    ii. For the passive device, the participant will be seated while they practice using EMG to control a virtual ankle, as seen in Fig 15b displayed on a screen set in front of them at eye level.
    iii. For the dEMG device, the participant will be asked to control the powered ankle while seated as seen in Fig 15c.
    iv. For both groups EMG activation for TA and GAS will be displayed for the participants.
    v. For both groups, after they have practiced EMG control while sitting down they will repeat the exercise while standing. A walker will be used in stance as needed to support the participant's balance while they practice the ankle control as seen in Fig 15d.

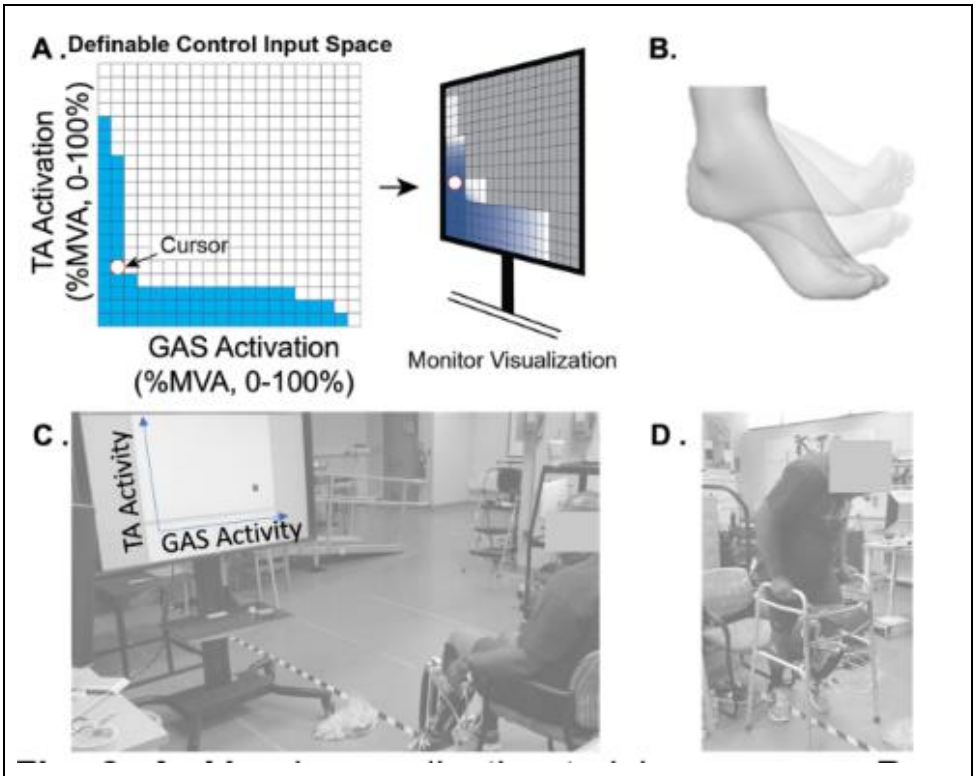

Fig. 15: A) Muscle coordination training program; B) Virtual foot posture matching program; C & D) Joint-level prosthesis control in sitting and stance.

e. Ankle posture test
    i. The participant sits in a chair comfortably. Two virtual ankles are displayed on a screen. One shows the expected position of the ankle and

one shows the current position of the ankle joint. The participant will use the EMG signals measured from their residual limbs to adjust the position of the virtual ankle to meet the referenced one.
        ii. For each trial, the reference ankle will start at the neutral position (both muscles are relaxing) and the ankle angle follows a sinusoid trajectory, which covers the ankle range of motion. The sinusoid signal will last five cycles for each trial and the frequency is set as 0.25, 0.5, 0.75, and 1Hz.
        iii. Participants will go through maximum 20 trials with a 2 minute break in every four trials. The trial also stops when the participants are able to meet the requirement in the highest frequency.
        iv. For participants, who will use the powered prosthetic foot, the procedure will be repeated with the powered prosthetic ankle as the output instead of the virtual ankle. For participants, who will use the passive foot, the PT will move the contralateral foot gentally, and ask the participant to follow the virtual ankle to follow the movement of the contralateral ankle.
    f. Protection harness remove
        i. This is done following the procedure mentioned in visit 3-4, step o.
    g. EMG electrodes remove (Group A only)
        i. This is done following the procedure mentioned in visit 2, step c.
    h. Discuss the participants about their expectation of the next visit
        i. A researcher will describe what will be done in the next visit and ask the participants to inform the research team if any issues are noticed.
5. Seven – eleventh visits: These visits are designed to give participants needed training, so participants are able to integrate the action of the powered prosthetic ankle with their full body motion for various tasks. To ensure that contribution of the training procedure to the performance changes are considered, all the participants will go through the training with the prostheses aligned with their group.
    a. EMG mounting (optional for patients use the powered prosthesis)
        i. This is done following the procedure mentioned in visit 2, steps b.ii - b.vii.
    b. Protection harness mounting
        i. This is done following the procedure mentioned in visits 3-4, step 3.
    c. Transition between sit and standing
        i. The participant will start the task seated in a chair.
        ii. The participant will be asked to lean forwards and stand up from the chair, using the armrests for support if needed.
        iii. The participant will remain in the standing position, standing up right with back straight, for a few seconds.
        iv. The participant will be asked to then transition from standing back to sitting in the chair.
        v. This process will repeat for up to twenty trials. The participant will be offered the chance to rest for 2-3 minutes after 10 trials finished.

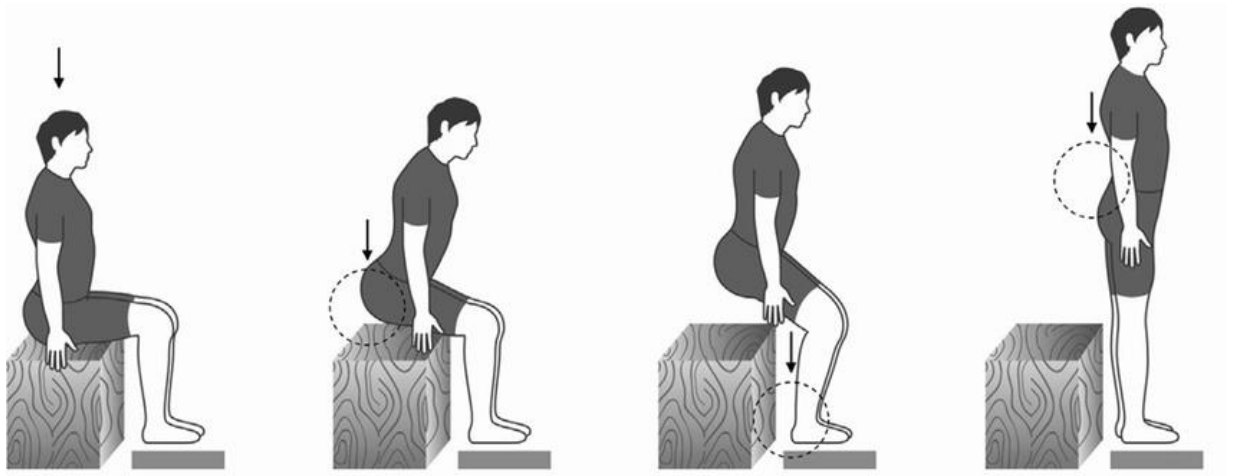

Fig 16: setup of the transition between sit and standing

d. Single limb balance
    i. While wearing the safety harness, the participant will begin by standing on the treadmill with feet shoulder width apart, with one foot on each of the treadmill belts.
        1. Handrails will be positioned on either side of the treadmill to use for support as shown in Fig. 9.
    ii. Participant will be asked to raise their non-prosthetic foot off the ground and to balance on their prosthetic side as long as they are comfortably able to do so.
    iii. The trial will end either when the participant's non-prosthetic foot touches the ground, or when the participant needs to use a handrail for support.
    iv. Between trials a stool will be provided to allow the participant to sit and rest until they are ready to resume.
    v. The trial will repeat 10 times..
e. Squats
    i. The participant will stand on the treadmill with feet shoulder width apart, toes facing forward, and one foot on each belt of the treadmill.
    ii. The participant will be asked to raise their arms out in front of them and slowly bend their knees and lower their body towards the ground while keeping their back straight and chest lifted
        1. If the participant feels unstable or unbalanced at any point they may use the handrails on either side of the treadmill to support themselves.
    iii. The participant will bring their body as low to the ground as they are comfortable doing while maintaining balance, ideally until their thighs are parallel to the ground.
    iv. The participant will try to hold at the lowest position for 3 seconds if possible.

v. The participant will straighten their knees to stand back up and return to the starting position.
vi. Squats will be done in sets of 3, with up to 5 sets done over the course of the visit.
vii. a 2 minute rest will be given after each set

f. Arm raise and reaching
    i. Participant will stand with feet shoulder width apart and both feet pointing forwards
    ii. Participant will raise their dominant arm to a 90 degree angle in front of them while making a fist with their hand
    iii. Participant will be instructed to “Reach as far as you can forward without taking a step”
    iv. After doing so and holding their position for a few seconds, the participant will be instructed to lower their arm and return to the standing position.
    v. The task will be repeated up to 10 times.
g. Postural sway
    i. This is done following the procedure mentioned in visits 3-4, step g.
h. Weight transfer
    i. Participants stand with feet shoulder-width apart and place equal weight on both feet.
    ii. Slowly shift the weight onto the prosthetic foot while keeping the knee slightly bent and the other foot flat on the ground.
    iii. Hold this position for three seconds and then shift the weight back onto both feet.
    iv. Repeat the process with holding time increases to 5 seconds or the participants find it difficult to increase the holding time.
    v. Conducting three more repetitions.
i. Rocker board on either limb
    i. The participants begin by standing on the rocker board, which is put on the treadmill, with their feet shoulder-width apart and parallel to each other. Hold onto the rails if necessary, for balance.
    ii. Shift the weight onto the prosthetic foot and allow the board to rock forward. Keep the knee slightly bent to absorb the movement and maintain balance.
    iii. Hold the forward position for 3-5 seconds and then rock back onto both feet.
    iv. As you become more comfortable with the movement, try increasing the range of motion and speed of the rocker board.
    v. Participant will stand with either their prosthetic foot or non-amputated foot on a rocker-board (as shown in Fig. 17) and the other foot on firm ground for 30-60 second.

Fig. 17: StrongTek Professional Wooden Balance Board used in the experimental procedure.

vi. The participant will complete two trials of the task with each foot with a minimum of four repetitions per trial.
vii. The number of repetitions may increase across days, as prescribed by the physical therapist, up to a maximum of 30 repetitions per day.
viii. Between trials a stool will be provided to allow the participant to sit and rest until they are ready to resume.

j. Stool stepping
   i. Participant stands in front of a stool (seen in Fig. 18) of approximately 4-8in height with handrails to either side to offer support.

Fig. 18: KLB Sport 31" Adjustable Workout Aerobic Stepper used in the experimental procedure.

ii. Participant is 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.
iii. Between trials a stool will be provided to allow the participant to sit and rest until they are ready to resume.

k. Stop and go walking
    i. While wearing safety harness, the participant will start by standing on the treadmill with feet shoulder width apart and with one foot on each belt of the treadmill.
    ii. The participant will be given a 1 minute warmup trial of normal walking at their preferred walking speed.
    iii. After the warmup the participant will be given a stool or chair to sit in and a rest period of at least 1 minute.
    iv. After the rest period the stool/chair will be removed and the participant will again stand.
    v. For each trial of the stop and go walking task:
        1. The participant will walk at their preferred walking speed
        2. After a predetermined amount of time between 20-40 seconds, a researcher will abruptly stop the treadmill.
        3. The treadmill will remain stopped for at least 20 seconds, or however long it takes for the participant to steady themselves and move into the standing position.
        4. The researcher will resume the treadmill at the preferred walking speed for 20-40 more seconds.
        5. The researcher will abruptly stop the treadmill again and allow at least 20 seconds for the participant to steady themself again.
        6. The trial will end once the participant steadies themselves and is standing without assistance from handrails.
    vi. There will be up to 10 trials over the course of the visit, with 2 minutes of rest between each trial.
l. Arise from chair is part of the Amputee Mobility Predictor (AMP) Assessment and is used alongside a series of other mobility tasks to quantify the overall mobility of an amputee.
    i. Participant is instructed to sit in a chair with the seat at a height between 40-50cm.
    ii. Participant is instructed to cross arms over chest.
    iii. Participant is instructed to stand up. Their performance is scored from 0-2 as follows:
        1. Unable to stand without assistance (score = 0)
        2. Able to stand but requiring multiple attempts (score = 1)
        3. Able to rise in a single attempt (score = 2)
m. Standing Reach Task is part of the AMP Assessment and is a clinical evaluation for determining the range of a participant's dynamic balance.
    i. Participant will stand on the treadmill while wearing the safety harness, keeping feet shoulder width apart and one foot on each belt of the treadmill.
    ii. Participant will wear safety harness and have arm rails available for support.
    iii. The participant will be instructed to raise their dominant arm 90 degrees in front of them while continuing to stand straight.

iv. A researcher will stand off of the treadmill in front of the participant and hold a ruler 12 inches from the participant's extended hand. The ruler will be aligned midline to the sternum.
v. The participant will be instructed to lean forward and grasp the ruler.
vi. the participant's performance will be evaluated on a score of 0-2 as follows:
1. Unable to grasp ruler (score = 0)
2. Able, but requires use of arms for support (score = 1)
3. Able without arm support (score = 2)

n. EMG electrodes remove
i. This is done following the procedure mentioned in visit 2, step c.

o. Protection harness remove
i. This is done following the procedure mentioned in visit 3-4, step o.

p. Discuss the participants about their expectation of the next visit
i. A researcher will describe what will be done in the next visit and ask the participants to inform the research team if any issues are noticed.

6. Twelfth-thirteenth visit (duplicate of Third and fourth visit). These visits are used to evaluate the impact of the training program on the performance of the participants to conduct tasks which are not included in the training procedure. Each participant will conduct the task with both passive and powered prosthetic legs on different days.
7. Fourteenth-fifteenth visits (duplicate of Third and fourth visit). These visits are used to understand the long term effects of the training program on the participants. These visits will be conducted three months after the 13th visits.

Devices Used in the Research:

- Powered ankle prosthesis
  - This is a custom built minimal risk device shown in Fig. 1.
  - The device is designed so that no moving parts are directly attached to the user's prosthetic socket.
    - This minimizes risk of personal injury and damage to the socket
  - The procedure for putting on this device is described in the second visit, step a.
  - Safety precautions, such as the fall prevention suit and handrails used throughout the study, will ensure the risk of falls while using the device is minimal.
- Disturbance system
  - This is a custom built minimal risk device illustrated in Fig. 11.
  - The system is securely attached to the ceiling minimizing risk of it falling and causing damage
  - The weight used to generate the disturbance will never exceed 10% of the participant's body weight, minimizing risk that the disturbance will cause the participant to fall or stumble.
  - A light will flash before the disturbance occurs, ensuring the participant isn't caught off guard by the disturbance and can brace accordingly.
- Fall prevention suit
  - This device is off the shelf by not a medical device
  - This device is used on label and as approved

    - This device is being used simply as a tool for fall prevention.
    - The procedure to put on this device is shown in Fig. 5.
- Instrumented treadmill (Registered Establishment Number: 1530895)
    - The device is off the shelf
    - The device is used on label and as approved
    - The device is being used simply as a tool for data collection in the research
    - The device is fixed on the ground and the participants will step on it after the treadmill is powered up. The participants will step off before the treadmill is powered off.
- VICON motion capture system (Registered Establishment Number: 1000377231)
    - The device is off the shelf
    - The device is used on label and as approved
    - The device is being used as a tool to collect data about body movement based on reflected markers which are attached to body segment
    - The device includes a series of cameras and does not contacted with the participants
- AMBU Neuraline 715 (Registered Establishment Number: 3004040397)
    - The device is off the shelf
    - The device is used on label and as approved
    - The device is used to collect EMG signals from muscles on human body
    - The device has a self-adhesive cover and can be mounted on the skin of body segment directly. Cleaning of the skin surface using alcohol pads are needed.
- M400 diagnostic EMG system from Motion lab system
    - The device is off the shelf
    - The device is used on label and as approved
    - The device is being used as a tool to collect EMG data from muscles on the body segment
    - The device is attached with the EMG electrodes and does not contact with the human body directly.
- Aeromats
    - This device is off the shelf by not a medical device
    - This device is used on label and as approved
    - This device is being used simply as a platform for participants to stand on it.
    - This device can be put on the floor directly.
- The Step Adjustable High Step Aerobic Platform
    - This device is off the shelf by not a medical device
    - This device is used on label and as approved
    - This device is being used simply as a platform for participants to stand on.
    - This device can be put on the floor directly.
- Element Fitness Slanted Step Risers
    - This device is off the shelf by not a medical device
    - This device is used on label and as approved
    - This device is being used to place the previously mentioned “The Step Adjustable High Step Aerobic Platform” at an inclined angle.

    - This device can be put on the floor directly.
- KLB Sport 31" Adjustable Workout Aerobic Stepper
    - This device is off the shelf by not a medical device
    - This device is used on label and as approved
    - This device is being used simply as a platform for participants to step on it.
    - This device can be put on the floor directly.
- StrongTek Professional Wooden Balance Board
    - This device is off the shelf by not a medical device
    - This device is used on label and as approved
    - This device is being used simply as a platform for participants to step on it.
    - This device can be put on the floor directly.

Risks Associated with each lab activity:

- Participants are exposed to the risk of pressure ulcers. This risk is unlikely. This risk comes from activities during visits 2-15 when EMG electrodes are used inside the socket.
    - The risks 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..
- Participants are exposed to low risk of fatigue and/or muscle soreness. This risk comes from activities during visits 2-15.
    - The risk from these activities are mitigated by
        - control the efforts of the participants by limiting length of each task
        - provide rests between tasks
        - permit the participants to end the experiments whenever they feel the fatigue or the sore muscle.
        - the clinicians will recommend skipping or combining tasks and visits based on the participants' situation to prevent fatigue and unnecessary training repeat (some participants may quickly reach their maximum capability, then additional training becomes unnecessary).
- Participants are exposed to the risk of fall. This risk is unlikely. This risk comes from activities during visits 2-15 when the activities are not conducted in a sitting position, or during the movement from one activity to another one.
    - The risks from these activities are mitigated by
        - provide fall protection harness during the experimental procedure
        - provide handrail or walker when the harness is not practical
- Participants are exposed to low risk of identity leak. This risk comes from these activities: screening, scheduling, and payment procedure. The risks from these activities are mitigated by
    - all the participants will be given a code name, so their 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 are accessible to PI only;
    - the W9 form and direct deposit setup is done through the standard procedure defined by NCSU, the research team does not collect sensitive information, such as SSN;
    - 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.

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.

Data Access and Security Plan Needed: No, Data are yellow. Sensitive data is not handled by the research team and is instead given right to the accounting office by the participant.

Is this a Clinical Trial: Yes, this is studying a health related outcome with an intervention.