Title: Operant Conditioning of Loading Response During Locomotion in Able-bodied Individuals and People After Stroke

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SYRACUSE UNIVERSITY
Department of Mechanical and Aerospace Engineering

Protocol Title: Closed-loop Control and Operant Conditioning of Loading Response to Improve Locomotor Function

Principal Investigator/Key Research Personnel

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Introduction:

The purpose of this form is to provide you with information about participation in a research study and offer you the opportunity to decide whether you wish to participate. You can take as much time as you wish to decide and can ask any questions you may have now, during or after the research is complete. Your participation is voluntary. If you choose to participate, you can change your mind at any time and withdraw from the study. The PI or a staff member will describe this study to you and answer all your questions.

What is the purpose for this research study?

The purpose of this research study is to develop a protocol using a wearable ankle device for improving gait function in people post-stroke. The study investigates the effects of wearing the ankle device during treadmill walking in muscle activity, joint motion, and gait performance. The ultimate goal of the study is to develop an effective gait strategy to restore lost function in the paretic leg function and improve quality of life in stroke survivors by improving their mobility.

What will I be asked to do?

If you enroll in this research study, you will be asked to complete a demographics questionnaire and answer questions about your health and physical functioning. The questionnaire collects data on your age, weight, history of neurological injuries or impairments, medical history including any recent orthopedic injuries, and ability to

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exercise. Data collection will take place in 021 Link Hall at Syracuse University. Only the study staff has access to the private research laboratory. At least two members of the staff will always be present. You are advised to wear comfortable clothing.

Placement of wearable sensors and robotic ankle device fitting (10-15 minutes). You will obtain a diagram to place electrode pads and electromyography (EMG) sensors. The study staff will assist you with placement. EMG sensors are glued using biocompatible tape to affix the sensors to the skin. Surface electrode pads are placed on the posterior tibial nerve to apply electrical stimulation and assess your muscle responses. The electrodes have gel to adhere to the surface of the skin. You are asked to maintain your natural standing posture during electrode fitting. Electrodes are disposable after use.

The robotic ankle device is attached to your calf and foot using an orthosis and Velcro straps. You will be asked to remove your shoe on your paretic leg and place your foot onto the orthosis to interface the device. The device is aligned with your ankle joint. Adjustments can be performed in a standing position assisted by the study members. The fit should not be uncomfortably tight, but tight enough to prevent relative, unwanted displacement. A safety belt can be used to prevent a fall during fitting, if needed. Wearable sensors will be placed on the surface of your muscles, across your joints or at bony landmarks using Velcro straps to measure your gait performance and muscle activity. Heart rate and blood pressure are monitored. You will wear a safety harness to prevent falling. You will have access to an emergency stop button to immediately halt the experiment. You can verbally request the staff to press the emergency stop button.

Warm-Up Procedure (5-10 minutes). Gait kinematics, muscle activity and ground reaction forces are recorded while you walk on the treadmill with and without wearing the ankle device. While standing, the treadmill's belt will be turned on using the slowest possible speed. Then, you will be asked if the speed is comfortable and if the answer is "Yes" small speed increments will be applied. If the answer is, "No," the belt speed will be adjusted until the participant is at a comfortable, fast walking pace. The study staff will request your verbal feedback as you get accustomed wearing the device.

Treadmill Walking Sessions (60-90 minutes). Each session includes short bouts of treadmill walking (4-6 minutes per bout) with rest periods in between bouts.

(a) Familiarization session: ankle rotations will be applied randomly every 2-3 cycles using the device. You will be asked to walk normally on the treadmill without resisting or interfering with the device. This session will be used to familiarize yourself with the system and customize the software.
(b) Baseline conditioning session: you will complete baseline trials wearing the ankle device while your muscle activity is recorded. You will be asked to walk on the treadmill without resisting the applied rotations by the device. You will not be provided with visual feedback or instructions during walking.
(c) Conditioning session: you will complete conditioning trials in which you will walk on the treadmill wearing the ankle device while your muscle activity is recorded. The researchers will provide instructions using a screen displaying your gait performance.

Cool down (5 minutes). You will walk on the treadmill at a slow speed without wearing the device. The staff will help you take off the device and gently remove the wearable sensors.

Time commitment for participation

The session can take up to 2 hours (fitting the ankle device and wearable sensors, performing the warm-up, bouts of treadmill walking, rest breaks, and cool down), but the target is between 1-1.5 hours. If the experiment ends early due to time constraints, you may be asked to participate again for a full session, but you can decline at any time. You may take a rest break at any time during the experiments. You will not be asked to participate in more than 3 sessions within a week and no more than 40 sessions for the total duration of the project. If you enroll in one session, you may be invited for follow-up sessions, but you can decline your future participation.

What are the possible risks of participation in this research study?

Your risks by participating in this study are similar to risks when participating in other forms of weight bearing activity, conventional physical therapy and exercise. Precautions and safety guidelines will be taken as the ones used in conventional physical therapy and exercise such as walking overground or on a treadmill. The risks by participating in this study are minimized through the conducted careful medical screening. A safety harness provides fall protection without restricting your motion.

The risk associated with treadmill walking is no greater than the risk of regular over ground walking by ambulatory patients or healthy individuals. The sessions could result in muscle soreness and/or joint stiffness; however, these symptoms should not persist after 2-3 days and are comparable to typical post-workout soreness. There is a minimal risk for muscle strains and/or ligament and/or bone damage during testing, but the forces used for this study are well within safety limits. Hardware and software constraints are implemented to limit the power output of the motors to avoid joint rotations at excessive speeds or torques. You and the staff members will have immediate access to emergency stop buttons that can be pressed at any time for any reason that will halt the experiment and stop the motion of the belt. You can verbally request a study member to stop the experiment if needed (e.g., you are feeling uncomfortable, fatigued, or for any reason). If you become tired, you may request a break to rest at any time.

The electrical stimulation may be slightly uncomfortable, but this results in a non-harmful tingling-like temporary condition usually resolved in a time period of seconds to minutes from the onset of the stimulation. Careful adjustment of the stimulus intensity and electrode placement should minimize any discomfort. Exposure durations necessary to cause significant harm are not likely to occur. There is a very small possibility that the stimulating electrodes can produce minor skin irritation, itchiness or burn. This is extremely unlikely because commercial electrodes and leads will be used that minimize this risk and the stimulator limits the stimulation to safe levels. The equipment being used is highly dependable and well maintained. All experimental procedures adhere to the best practices advocated by the vendors of the equipment utilized in the study as described in the manufacturer manuals. Visual inspection of the skin in the areas of the applied ankle

device and EMG sensors will be conducted before and after placement and throughout the experiments to detect potential skin irritation.

Staff members will continuously ask how you feel during the experiment regarding the adhesion of the sensors to your skin, wearing the ankle device, etc. Blood pressure (BP) and heart rate (HR) are monitored. If BP and HR reach a level outside of the safe region or if you feel to faint, light-headed or nauseated, the protocol will be stopped immediately, and medical action will be taken.

In the event of an adverse medical event, standard facility emergency procedures will be followed. The facility emergency procedures involve one member of the study staff calling 911 (emergency medical technicians (EMTs)) and following the advice provided by EMTs over the phone and finding the AED, while another member beginning to CPR immediately. The AED will be used as needed as soon as it arrives to the research laboratory. CPR will be provided continuously until professional emergency medical services arrive. The study personnel are CPR and AED trained, and ready to aid if the participant is not responsive, has no pulse and is not breathing normally.

As the participants should have no known cardiac disease, the risk of a cardiac event during our experimental procedures is extremely low. In the event that autonomic dysreflexia or a cardiac event is suspected by either the participant or the study personnel, the study will be stopped immediately, and local EMTs will be called, and the participant will be taken to an emergency medical center, if recommended by the EMTs.

What are the possible benefits of participation in this research study?

There are no direct benefits from participation in this study. It is possible that you may see improvements your own functional ability and strength, but any benefit cannot be guaranteed. The most promising findings are related to the advancement of the scientific knowledge since they may be important for improving function and mobility in the long term. It is expected that findings from this project will be essential and critical in developing and evaluating effective therapies for improving the quality of life, in people after stroke. A better understanding of the effects of gait therapies on mobility may lead to better rehabilitative treatments and effective interventions. Hence, the technical advancements will fill a gap in the technology to improve walking function in people after a stroke, while the only major risks are related to the exercise.

How will my privacy be protected?

To protect your privacy, only you and the research staff will be present in the private laboratory at any given time (i.e., testing will take place for one study participant at a time). The PI will collect and use your private information. Data and information will be obtained in a private location, e.g., the PI's laboratory in 021 Link Hall, where only the research staff members have access (a door key or a code is needed to enter the laboratory). The

doors of the laboratory are closed during data collection. Only one participant will be present in the laboratory at any given time for experimental data collection.

The research staff will take appropriate steps to protect any information they collect about you and ensure your privacy. However, because this research will be conducted in a laboratory setting, there is still slight risk that information about you or your privacy cannot be guaranteed (i.e., could be revealed accidentally). Phone and email can also be used to contact you, but the use of phone and email will be limited to the PI's office and laboratory. The primary method of collection of your private data is a one-on-one interview using IRB approved questionnaires and forms.

The type of information obtained in the study will be written from the completion of forms. Verbal communication may be used for recruitment (phone call). Digital data is collected during experimental testing related to human gait performance as described above. Regarding your privacy when applying the wearable sensors and electrodes, a schematic will be provided to self-apply the devices and be assisted by the staff only as needed. Wearable sensors are placed on the surface of visible leg muscles and joints (minimal inspection is needed).

How will my data be maintained to ensure confidentiality?

Your gait performance will be recorded during the session. The collected sensor data will be compiled and processed for statistical analysis. Moreover, the following information may be collected, used, and shared:

- Your name, phone number, and e-mail address
- Information about your medical history to determine eligibility for the study
- Questionnaires about your physical functioning, health, medical status
- Data generated from the study activities such as walking ability
- Audio, video, and photographic images (if you consent to) for demonstration purposes

This information will be kept confidential (i.e., your identity needs to be retained or can be associated with your information and data). Your confidential data may be collected, used, and shared only by the research staff to determine if you can participate in the study and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. However, the research staff will not collect or require proof of your test results. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and phone calls.

The participant’s information collected as part of the study will not be used or distributed for future research studies even if all the identifiers are removed. Confidential data will be maintained in paper and an electronic spreadsheet stored in a desktop computer. The paper participation records will be kept in locked file cabinets in the laboratory and/or

offices, and the digital data will be stored on password-protected computers/servers or encrypted electronic storage devices in the offices and laboratory of the research team.

The data in paper format will be shared using mail. Digital data will be shared via email using a private message and an encryption service (e.g., Proofpoint encryption) to send the attachment. Identifiable data will only be shared between the PI and the members of the research team described in the first page of this document. De-identified data will be shared with government and funding agencies in the form of plots, graphs, and tables to report the outcomes of research in annual reports (including final reports) and presentations. The PI expects that confidential data will not be shared with funding agencies or sponsors.

Once your information is collected, it becomes part of the research record for this study. Your identity will be kept confidential to the extent provided by law. Your name will not be used in any report and will not be associated with the data in any way. The potential risks of loss of confidentiality will be minimized through assigning all data collection instruments a unique code without individual identifying information. A standard code use alphanumeric characters will be assigned to the participants based on the chronological order of enrollment in the study. There will not be a direct link between your information and the gathered data (other than your assigned participant's code) without the access of the password-protected database that contains the participant identification information matched with the data. Regulations pertaining to protection of participants and eliminating identification will be followed. Only the PI and study staff will have access to your confidential data and linked identifiers. Professionals at Syracuse University such as the Institutional Review Board Office, government agencies and the study sponsors may have access to de-identified data obtained from the study.

Will photographs, audio, video, or film recording be used?

Photographs, videos and audio recordings may be recorded if your consent is obtained. Before storage, pictures and videos are edited to exclude, blur, or add a black box to your face as an effort to keep your confidentiality. The PI and staff members listed in the first page of this document will have access to photographs, videos or audio recordings.
With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified/included on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/or audio recordings are shown or heard, others may be able to identify you.

The PI will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. Photograph(s), video and/or audio recordings will be shown under his direction to

students, researchers, doctors, or other professionals and persons. Photographs, videos and audio recordings may be used to illustrate and demonstrate the gait intervention in publications and presentations at national/international conferences.

Please indicate under what conditions the PI has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ For the purposes of **education at Syracuse University,** the PI may keep the following for an indefinite period in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ For the purposes of **education at Syracuse University and for presentations at scientific meetings outside the University**, the PI may keep the following for an indefinite period in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

Will I receive compensation for participation?

Monetary compensation per session is provided at a rate of $20/hour up to two hours (i.e., $40 per session in cash) regardless of future withdrawal. If a session is cut-off short, the participant will receive the full compensation for 2-hours (i.e., $40). Therefore, compensation will not be prorated. *Payments to U.S. Citizens, Permanent Residents and Resident Aliens that equal or exceed $600 per calendar year are subject to tax withholding and Syracuse University will report the amount to the Internal Revenue Service (IRS) on Form 1099. Payments to nonresident alien participants that equal or exceed $300 per calendar year are subject to tax withholding and are generally reported to the Internal Revenue Service on Form 1042-S. This information will not be linked to any of the study data and will only be used for payment purposes.*

What are my rights as a research participant?

- Your participation is voluntary
- You may skip and/or refuse to answer any question for any reason without penalty
- You are free to withdraw from this research study at any time without penalty
- If you withdraw your consent, you will not lose any benefits to which you are entitled

If you decide to withdraw your consent, please contact a staff member to stop your participation. If you withdraw, your information will no longer be collected. However, information that has already been collected may be used to the extent that the researchers have used it in this research study.

Whom may I contact with questions now, during, or after the research is complete?

For questions, concerns or more information regarding this research (including if you experience an injury or have questions about any discomforts that you experience while participating in this study), you may contact the Principal Investigator, Dr. Victor Duenas, PhD., Assistant Professor, Department of Mechanical and Aerospace Engineering, 247 Link Hall, Syracuse, NY 13244, phone 315-443-3924, email: vhduenas@syr.edu.

If you have questions or concerns about your rights as a research participant, you may contact the Syracuse University Institutional Review Board at (315) 443-3013.

Agreement

All my questions have been answered, I am 18 years of age or older, and by signing this consent form, I agree to participate in this research study. I have received a copy of this form for my personal records.

_____ Date: _____
Printed name of the Participant

_____
Signature of the Participant

_____ Date: _____
Printed name of the Researcher

_____
Signature of the Researcher