

Project Title: Adaptive Hip Exoskeleton for Stroke Survivors With Gait Impairment

NCT Number: NCT05536739

Date: 09/09/2025

Key Information for: Powered Hip Exoskeleton for Stroke Survivors with Gait Impairment:

What Am I Being Asked To Do?

You are being asked to be a volunteer in a research study. The name of the study is listed above. This document has important information about the reason for the study such as what you will do if you choose to be in this research study, and the way we would like to use information about you and your health. Your participation in this study is entirely voluntary.

What Is This Study About and What Procedures Will You be Asked to Follow? The purpose of this study is to see if using a powered hip or ankle exoskeleton will help you to move better. We will have you walk with the robot across different walking conditions such as walking up/down a ramp. While walking, you will be provided with hip or ankle assistance from the robot. Additionally, we will have different sensors attached to your body to record your movement. Your participation in this study may involve multiple sessions with each experiment lasting no more than 6 hours. You do not have to return for any additional session that you do not want to be a part of.

Are There Any Risks or Discomforts you Might Experience by Being in this Study?

Common risks of using an exoskeleton are fall and stumble. At all times when walking on the instrumented treadmill systems in the terrain park on the CAREN platform, you will be required to wear a safety harness. While walking in the overground biomechanics lab, a safety harness may be required if the experimenter teams deem it necessary as a precaution. If the procedure either does not need a harness or no harness exists for the specific experimental activity, then a gait belt will be used to prevent falls. At any time, you may request to use the safety harness system in the lab for any reason. This may prevent the experimental team from collecting all study data, but any study procedures that can be conducted with the use of the harness will be performed. While walking out of the lab experimenter space, a gait belt will be used and a spotter will be next to you to assist should you stumble. There is a higher risk of falls for procedures conducted outside of the lab environment, and you may choose to opt out of performing any protocols outside of the lab if you are not comfortable doing so. Also, there will be a physical emergency stop button that can shut down the entire device when pushed. The experimenter can reach this button at any time during the experiment to shut down the machine if you feel uncomfortable and/or in danger. Additionally, another emergency stop button will be next to you at all times so you can also shut down the device at any time. Another common risk is skin irritation from wearing the exoskeleton. We will ensure that the exoskeleton is properly fitted and check in with you periodically regarding comfort. You are encouraged to share any discomfort you feel and can stop the experiment at any time for any reason.

What Are the Reasons You Might Want to Volunteer For This Study?

You are not likely to benefit in any way from joining this study. However, your participation in this study will assist researchers in understanding how to better program and build exoskeleton devices to help people with neurological disorder to move better. As compensation for your time, we will pay \$25/hour.

Do You Have to Take Part in the This Study?

It is fully your decision if you wish to be in this study or not. If you choose not to participate or choose to participate and later determine you no longer wish to, you will not lose any rights, services, or benefits as a result of your withdrawal. The study is completely voluntary.

CONSENT DOCUMENT FOR ENROLLING ADULT PARTICIPANTS IN A RESEARCH STUDY

Georgia Institute of Technology

Project Title: Lower Limb Powered Exoskeleton Device for Gait Assistance Principal

Investigator: Aaron Young, PhD

Protocol and Consent Title: Powered Hip Exoskeleton for Stroke Survivors with Gait Impairment

Version: 09/09/2025

Supporting Funding Source: National Institute of Health – Improving Community Ambulation for Stroke Survivors Using Powered Hip Exoskeletons with Adaptive Environmental Controllers, National Institute of Health - A New Framework for Self-Adaptive Artificial Intelligence to Personalize Assistance for Patients Using Robotic Exoskeletons and Prostheses.

You are being asked to be a volunteer in a research study. This document has important information about the reason for the study such as what you will do if you choose to be in this study. This document also contains the way we would like to use information about you. Your participation in this study is entirely voluntary.

Purpose:

The purpose of this research study is to develop a smart robot for helping you to walk better. The study will have participants up to 43 individuals.

You are being asked to participate in this study because you have a history of stroke that limits movement in your lower body. Once you participate, you will be walking with or without a hip or ankle exoskeleton robot, with or without a sensor suit, and with or without a biofeedback device. The possible exoskeletons that can be used are the Dephy bilateral ankle exoskeletons (commercial device), a custom-built bilateral active ankle exoskeleton, and an active hip exoskeleton (research device). We will be recording data from sensors placed on the robot and/or the sensor suit and/or your body to measure different information when you move. This will be done by comparing how you walk with and without the robot and/or biofeedback while you do different tasks such as walking, going up and down the stairs and ramps as well as talking while walking, etc. From this study, we will use the data to make our robot smarter and more efficient.

Exclusion/Inclusion Criteria:

You can participate in this study if:

- You are between 18-85 years of age
- You had a stroke at least 6 months prior to study involvement
- You are community dwelling, which means you do not live in an assisted living facility
- You are able to provide informed consent to participate in the study activities
- You can safely participate in the study activities (per self-report)
- You must have a Functional Ambulation Category (FAC) score of 3 or above, which means you can walk without the assistance of another person



Figure 1. Powered Hip Exoskeleton

You will be excluded from the study if:

- You require a walker to walk independently
- You have a shuffling gait pattern on overground
- You have a Functional Ambulation Category (FAC) score of 2 or lower, which means you require the assistance of another person in order to walk
- You have a significant secondary deficit beyond stroke (e.g. amputation, legal blindness or other severe impairment or condition) that in the opinion of the Principal Investigator (PI), would likely affect the study outcome or confound the results
- For exoskeleton-only studies, the exoskeleton device does not fit appropriately or safely, as determined by the research team during the fitting assessment.

Procedures:

After you consent to the experiment, you may undergo the Fugl-Meyer Lower Limb Assessment and the Mini-BESTest during your first visit. These tests will help us evaluate your functional capabilities before proceeding with the exoskeleton trials. Following these assessments, the hip (Figure 1) or ankle (Figure 2 and 3) exoskeleton robot will be adjusted in size so that it comfortably fits your body size. The back of the exoskeleton robot is attached with a waistbelt or back plate piece which holds the electronics such as the computer and the battery. This plate is attached with shoulder straps which can be worn to make sure that the device is not too heavy for you to wear. Additional sensors, such as motion and muscle sensors will be placed on the surface of your leg, the sensor suit (Figure 4) and/or exoskeleton robot. You might be asked to wear an additional biofeedback system. This consists of a small backpack holding electronics, batteries, and a small speaker, leg straps for holding the motion sensors, and a buzzing band housing several mini vibratory motors. This device adds minimal weight and should not add any restrictions to your movement. Video cameras will record your movement and record the sensor data placed on your body. You may be asked to wear a tightly fitted face mask that tells us how much energy you are using (metabolic cost) while you walk with the exoskeleton robot. The metabolic mask will be adjusted so that it does not give you any discomfort in both skin and breathing.



Figure 2. Dephy ankle exoskeleton

After you are fitted with exoskeleton robot and biofeedback device, you will be asked to walk on a treadmill. There is a safety handrail for the treadmill that you can request to use if you need additional assistance. Initially, you will be asked to walk at a comfortable speed on a leveled treadmill in order to acclimate you to the device. Data will be recorded at this comfortable walking speed to measure the walking characteristics we may base the biofeedback upon. Once that information has been gathered, if biofeedback is being used, you will work with the clinician and experimenters to determine the best location for vibrational feedback. You will help us determine the most sensitive location near or around the upper leg while standing and walking while vibrational cues are provided. Multiple locations may be tested until we find one you are most comfortable with. We will be looking to find what range of vibrations you can feel, where you can feel them best, and if you can distinguish changes in vibration magnitude. When you become comfortable and showed that you can walk safely with the robot without stumbling, you may be asked to walk at different walking speeds and inclination levels with and/or without biofeedback. This range of levels will only change within your walking capability and you will not be asked to walk in a condition which can cause discomfort. If you feel comfortable using the exoskeleton robot, you may be asked to complete simple activities such as walking over ground, walking up and down ramps, walking up and down stairs, stepping over obstacles, standing up, sitting down and talking while walking. While you do these different tasks, we will change the robot to behave differently to test our controllers. We may also change whether you receive biofeedback or not. Instructions will be given to you about what you should feel and hear before you start walking with the biofeedback device. Instructions will be given to you about what you should say during tasks in which you will be talking and walking at the same time. You may be asked to provide verbal or written feedback on the assistance or biofeedback as well as your preference comparing different assistive modes. As you complete these activities, there will be personnel to provide supervised guarding as needed, and other aids such as a safety harness or gait belt to make sure that you are safe from falling. When you practice doing these activities, we will make some adjustments to the exoskeleton robot so that it works the best for you. After, if you feel comfortable doing so, we may ask you to walk outside the laboratory such as a building stairwell and/or outdoor terrain on the Georgia Tech campus. This will let you practice walking in a more realistic environment. Finally, you may be asked to complete a survey on the exoskeleton and/or biofeedback system, with surveys such as a System Usability Scale and Orthotic Prosthetic User Survey and other surveys to understand your perceptions of the device. You do not have to answer any questions you do

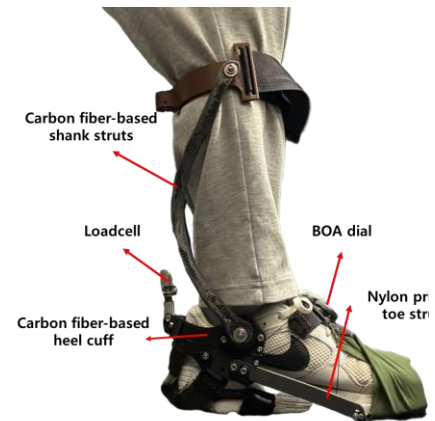


Figure 3. Custom-built bilateral active ankle exoskeleton.



Figure 4. Sensor suit.

not want to.

You can choose to not do any of these activities you do not feel comfortable with. You will have as much time as you like to practice doing these activities. If you need more than six hours of practice or it takes longer than six hours for us to have you adjust to exoskeleton robot, we will ask you to come in on another day to continue the experiment. These do not need to be consecutive days. Data that will be recorded from you while you practice these tasks help us adjust the robot better. After you have finished practicing, we will collect the data for the actual experiment. We will ask you to complete each task that you have practiced multiple times. You will be given rest periods in between repetitions. The number of visits required to come to the lab depends on the amount of time it takes to adjust the robot for you and the amount of time you need to practice the activities with the robot. You may need to visit us for multiple sessions for experimental data collection and practice using the exoskeleton. Each visit will last between 1-6 hours and will not involve more than 30 minutes of continuous movement. You do not have to return for any additional sessions that do you do not want to be a part of.

Risks or Discomforts:

The exoskeleton robots and biofeedback device have motors and sensors. The investigational devices being used in this study are low-risk and are being used for research purposes only. Safety and efficacy of the device have not been determined and the device has not been approved by the FDA. Although these procedures are very safe and commonly used in our lab, your participation in this study will involve the following risks: falls resulting in injury, muscle soreness and/or fatigue, skin irritation, and bodily discomfort from wearing equipment. The primary risk of injury in this protocol would be due to falls, regardless of the device being used. To minimize this risk, you will be asked to wear a safety harness or gait belt and walk until you become comfortable using the exoskeleton device(s) and demonstrate that you can use it without falling.

The Fugl-Meyer assessment and Mini-BESTest involve physical movements that may pose a fall risk. The Mini-BESTest will be performed in a larger space where you will wear a gait belt and parallel bars will be provided to reduce fall risk. A lead examiner and an assistant will constantly monitor your safety during these exams.

At all times when walking on the instrumented treadmill system, either in the terrain park on the CAREN platform, you will be required to wear a safety harness. While walking in the overground biomechanics lab, a safety harness may be required if the experimenter teams deems it necessary as a precaution. If the procedure either does not need a harness or no harness exists for the specific experimental activity, then the study team will provide handrails and/or a spotter to ensure to prevent falls. At any time, you may request to use the safety harness system in the lab for any reason. This may prevent the experimental team from collecting all study data, but any study procedures that can be conducted with the use of the harness will be performed. While walking out of the lab experimenter space, you will be provided with a spotter who can assist should you stumble. There is a higher risk to procedures outside of a lab environment, and you may choose to opt out of performing any protocols outside of the lab if you are not comfortable doing so. Also, there will be a physical emergency stop button that can shut down the entire device when pushed that the experimenter can reach during any time of the experiment to shut down the machine if you feel uncomfortable and/or in danger.

A second risk is minor muscle soreness and fatigue. Muscle soreness is a common problem when walking with a new wearable device. To prevent this, experimental sessions will be kept as short as possible, adequate rest periods will be provided between trials, and you will

be questioned often about any discomfort. A third risk is skin irritation. Skin can become irritated while using any exoskeleton and it can also cause blisters where the thigh, shank, and waist cuffs touch the user's body. To avoid the risk of skin irritation, you will use properly fitted user cuffs constructed by a trained lab member. Additionally, the limb will be checked periodically for skin irritation. Skin irritation and desensitization can also occur from the vibrating motors used in the biofeedback system. To avoid this risk, the location of vibrational feedback will be checked periodically, and vibrational feedback will be limited to that during the trials to limit the amount of desensitization that will occur. The metabolic system you may be asked to wear tells us how much energy you are using while you walk. This system is safe, but may be uncomfortable for you to wear as it involves a mask over the face and must be tight to create a seal. There will be different size masks that can be optimally fit to you. The metabolic mask will be adjusted so that it does not impede your vision during the experiment. Risks include transmission of communicable diseases and discomfort. To protect you against infection, the mask and monitor will be properly disinfected between uses, and will always be handled with disposable sanitary gloves. Also, antibacterial filters will constantly be used within the metabolic mask.

To address fatigue and ensure your comfort, frequent breaks will be provided whenever needed and you will be asked and encouraged to take breaks whenever needed. You have the right to stop any test at any time if you feel unsafe or uncomfortable. Your safety is our top priority throughout all assessments and procedures.

To mitigate risks associated with providing snacks, we will offer a variety of options with clear allergen labeling. You will be asked about any food allergies or dietary restrictions beforehand to ensure safe snack options are available.

Benefits:

Lower limb exoskeletons are designed to improve a person's ability to move and perform tasks. These devices can be used to enhance both able bodied individuals and patients with gait deficiencies to overcome their current limitations by assisting joint motion with power through the robotic device. They can even allow disabled individuals with complete loss of movement (i.e. spinal cord injury patients) to regain walking abilities. Different controllers implemented in the exoskeleton device are necessary to effectively understand the user's current state. This study is focused to maximize the exoskeleton technology to enhance user's movement by intellectually understanding the user's intention of different movements.

Compensation to You:

You will not be charged for any study-related procedures. You will be paid for your time in this study at a rate of \$25/hour. You will be given the choice of compensation via check which will be issued through USPS mail to your home (or a provided) mailing address or a gift card which will be provided at the end of each visit to the lab.

The Finance Department at Georgia Tech will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. U.S. Tax Law requires that a 1099-misc be issued if

U.S. tax residents receive \$600 or more per calendar year. If non-U.S. tax residents receive more than \$75, mandatory 30% withholding is required. Your address and Tax I.D. may be collected for compensation purposes only. This information will be shared only with the

Georgia Tech department that issues compensation, if any, for your participation.

Storing and Sharing your Information:

Your participation in this study is gratefully acknowledged. It is possible that your information/data will be enormously valuable for other research purposes. By signing the consent form, you consent for your de-identified information/data to be stored by the researcher and to be shared with other researchers in future studies. If you agree to allow such future sharing and use, your identity will be completely separated from your information/data. Future researchers will not have a way to identify you. Any future research must be approved by an ethics committee before being undertaken.

Use of Photographs, Audio, or Video Recordings:

We may want to use some of the photographs, audio, or video recordings of you in public presentations related to the research. The attached MODEL RELEASE FORM outlines several possible uses and asks for your specific written consent to use these items in each way. We will not use any videotapes, photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent.

Confidentiality:

The only possible identifier linking you to this study is the video and photographs taken during testing. The video will only be published if you give permission (permission form listed below). Your face can be blocked out upon request. You will be given a research subject number that will be used instead of your real name in potential published studies. Research records including the video will be stored in a password protected secured network where only the research members

can have an access. Only the Principal Investigators and direct research study personnel will have access to the research records that include your personal information.

After completing the study, videos may be used in teaching, publications or presentations. You can refuse permission for us to use your video in these settings. You will need to give or refuse permission for these at the end of this form. This consent form will be filed securely in the locked cabinet where only the PI will have an access to it. People who have access to your information include the Principal Investigators and research study personnel. Representatives of regulatory agencies such as the Office of Human Research Protections (OHRP), the Food and Drug Administration, and entities such as the Georgia Tech Office of Research Integrity Assurance can access your records to make sure the study is being run correctly and that information is collected properly. We will comply with any applicable laws and regulations regarding confidentiality.

The sponsor of the study, National Institutes of Health, has the right to review study records as well.

Costs to You:

There are no costs to you, other than your time, for being in this study.

Participant Rights:

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.
- You have the right to change your mind and leave the study at any time without giving any reason and without penalty.

- Any new information that may make you change your mind about being in this study will be given to you.
- You will be given a copy of this consent form to keep.
- You do not waive any of your legal rights by signing this consent form.

Requirements of Certificate of Confidentiality policy that applies to research conducted or supported by NIH involving a participant's identifiable or sensitive information (data and/or biospecimens):

We have obtained a Certificate of Confidentiality from the National Institutes of Health to help us keep your information confidential. This Certificate provides a way that researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Questions about the Study:

If you have questions or concerns, or any illness or injury during your time in this study, you should call us promptly. Aaron Young, PhD is in charge of this research study and can be reached at telephone number 404-385-5306 or by e-mail at aaron.young@me.gatech.edu.

In Case of Injury/Harm:

If you are injured as a result of being in this study, please contact Principal Investigator, Aaron Young, Ph.D., at telephone (404) 385-5306. Neither the Principal Investigator nor Georgia Institute of Technology has made provision for payment of costs associated with any injury resulting from participation in this study.

Questions about Your Rights as a Research Participant:

If you have any questions about your rights as a research participant, you may contact Georgia Institute of Technology Office of Research Integrity Assurance at IRB@gatech.edu.

This section ____DOES or ____DOES NOT apply to you:

Clinical Trial Information:

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Participant Name (printed) Date

Participant Signature Date

Participant's Legal Authorized Representative Signature Date

Signature of Person Obtaining Consent Date

Consent to Store and Share your Information:

I agree that my de-identified information/data may be stored and shared for future, unspecified research. SIGNATURE _____

I **DO NOT** allow my de-identified information/data to be stored and shared for future, unspecified research. These may only be used for this specific study. SIGNATURE _____

I consent to have my name and contact information shared for recruiting purposes for future, unspecified research.

SIGNATURE _____

I **DO NOT** consent to have my name and contact information shared for recruiting purposes for future, unspecified research.

SIGNATURE _____

If you would like to remove your contact information from the database in the future, you may do so at any time by contacting a member of the study team and asking them to remove your information from the database.

(if yes, on media usage) block face? (Signature, Yes/No) Yes / No