Title: Personalizing MPK Prescription for Individuals With Transfemoral Amputation

NCT: NCT06399471

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Key Information for Personalizing Microprocessor Knee (MPK) Prescription for Individuals with Transfemoral Amputation:

What Am I Being Asked to Do?

You are being asked to be a volunteer in a research study. This page will give you key information to help you decide if you would like to participate. Your participation is voluntary. As you read, please feel free to ask any questions you may have about the research.

What Is This Study About and What Procedures Will You be Asked to Follow?

The purpose of this research study is to personalize the prescription process for prosthetic knees. This may help clinicians prescribe a prosthetic knee for someone with an above the knee amputation. In this study, you will be fit with three commercially available prosthetic knees and a research prosthetic knee and foot. You will take each of the three commercially available prosthetic knees home for a 1-week trial period. We expect participation in this study to occur over the span of 4 weeks. Total time may be longer depending on your own schedule and the availability of each of our knees.

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

Common risks associated with walking in a prosthesis are falls, muscle fatigue and skin irritation. To minimize risks, you will be asked to wear a safety harness while in the lab. During lab sessions, we will give rest periods and ask about discomfort, which we will address.

A final risk is that you might prefer a different prosthetic knee after completing the study. You may or may not be able to obtain this knee through your clinician and/or insurer. We will provide all information to you that you request about your performance. We will not provide you with a prosthetic knee to take home following the study. You are required to return each study prosthetic knee that you wear at home for the 1-week take-home period.

Failure to return the prosthetic knees to the lab will result in the need to file a police report and may also lead to a participant being sued by the insurance company and/or the manufacturer.

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 may assist researchers in understanding which prosthetic knees are best for individuals with amputation. As compensation for your participation in this study, we are offering $20/hour for your time in the lab and an additional $300 when you complete the full study.

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: Personalizing Microprocessor Knee (MPK) Prescription for Individuals with Transfemoral Amputation
Investigators: *Aaron Young, PhD; Kinsey Herrin, MSPO, C/LPO; Teresa Snow, PhD; DeLana Finney, MSPO, C/LPO*

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, 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.

Purpose:
The purpose of this research study is to personalize the prosthetic prescription process for prosthetic knees. This may help us better understand which individuals are best suited for certain types of technology.

You are being asked to participate in this study because you have a lower limb amputation. In this research study, we will be recording from sensors placed on your lower body and prosthesis. We will record motions and forces from your limbs as you walk in the lab. You will be asked to fill out several surveys regarding your opinions of the different prosthetic knees you use.

Inclusion Criteria:
You may participate in this study if you meet the following criteria:
-A unilateral transfemoral amputation of the lower limb at least six months post fitting of definitive lower extremity prosthesis
-Habitual use of a lower extremity prosthesis in daily living activities (based on assessment of a physiatrist and/or prosthetist and patient self-report)
-Aged between 18 to 75 years
-K3 or K4 level ambulators who can perform all locomotor tasks of interest (based on assessment of a physiatrist and/or prosthetist)

Exclusion Criteria:
You will be excluded from participating if any of the following apply to you:
-Individuals with any significant neuromuscular or musculoskeletal disorder or other comorbidity that would interfere with participation (based on assessment of the physiatrist and/or prosthetist and patient self-report)
-Individuals who have open wounds on their residual limb
-Individuals with known visual impairments that would prevent them from safely operating a prosthesis during over ground walking or ascending stairs (based on assessment of the physiatrist and/or prosthetist and patient self-report)
-Individuals with known hearing impairments or who use hearing aids that would prevent them from responding to an auditory instruction (based on assessment of the physiatrist and/or prosthetist and patient self-report)

-Individuals who are currently pregnant (based on patient self-report) due to slight risk of falling during experiments

Procedures:

After you provide consent, the skin over muscle areas of interest may be cleaned with alcohol and might be shaved by a disposable shaver. Sensors such as motion markers and step counters will be placed on the surface of your leg and/or prosthesis. A heart rate monitor will record your heart rate. Video cameras will record your movement and capture the sensor positions. This will allow us to study the leg motion. You do not have to wear any sensors you do not want to wear.

You will be fit with four different prosthetic knees over several weeks so that we can compare your responses to each prosthetic knee. You will be allowed to take the three commercially available prosthetic knees home, but you are required to return them to the lab. While in the lab, you will have the option to use a safety harness, crutches, or safety rails when wearing any prosthetic knee while in the lab. After we put on the harness and prosthetic knee, you will walk at a comfortable speed over ground or on a treadmill. When you become comfortable and demonstrate that you can walk safely without stumbling, you will be asked to perform other tasks such as walking on ramps, stairs, beams, a treadmill and standing up and sitting down. The beam is very low in height and sits only ~2" inches off the ground. As you complete these activities, you can choose to use hand rails and other aides—such as a gait belt, crutches, or a cane—instead of the safety harness if the experimenter deems it safe for you to do so. When you practice doing these activities, we will make some adjustments to the prosthetic knee(s) so that it works as well as possible for you. If you feel comfortable, we may ask you to walk outside the lab such as in a building stairwell or outdoors on the Georgia Tech campus. This will let you practice community ambulation in a more realistic setting. You may choose not to do any activity you do not feel comfortable with. You will have as much time as you like to practice doing these activities. Data will be collected from you while you practice to help us adjust your prosthetic knee. After you have finished practicing, you will leave with the prosthetic knee to wear it in your normal home and community environment for 1 week. A sensor to collect data about the number of steps you take will be attached to the prosthesis and/or your shoes. This sensor does not record where you go. You do not have to wear any sensors you do not want to wear. Then you will return to the lab so that we can collect data for the experiment. You are required to return each prosthetic knee that you are fit with. We will keep your clinically prescribed prosthetic knee in the lab while you wear the study prosthetic knee at home. The number of visits required to the lab depends on the amount of time it takes to adjust the prosthetic knee and the amount of time you need to practice the activities with the prosthetic knee. You will need to visit us a minimum of 5 times for data collection and practice using the prosthetic knees. Each visit will last between 2-6 hours and will not involve more than 30 minutes of continuous movement. We estimate the total time commitment to be between approximately 40-50 hours. We expect participation to span over a total of 4 weeks for the entire study, but you may participate for a longer period depending on your personal schedule and the availability of our prosthetic knees for use. You are required to return each prosthetic knee that you are fit with.

Risks or Discomforts:

The prosthetic knees have hydraulics and sensors. This type of device is classified as a 'prosthetic component' and is an FDA Class I device. This means that it is a low-risk type of

medical equipment. Although these procedures are very safe and commonly used in our lab, your participation in this study may involve the following risks:

The primary risk would be due to falls, regardless of the prosthetic knee being used. To minimize this risk, you will be asked to wear a safety harness and initially walk with handrails until you become comfortable using the prosthetic knee(s) and demonstrate that you can use it without falling. Should you fall during this familiarization session, the harness will support you. When walking over ground, you will still have the option of wearing the safety harness, access to hand rails or other walking aids, and may be supported by staff members using a gait belt as you complete the activities. When you take the prosthetic knee home, you will not have access to our hand rails or harness system any longer, but you may use any walking aids that you wish.

A second risk is muscle soreness and fatigue. Muscle soreness is a common problem when walking with a new prosthesis. To prevent this, experimental sessions will be kept as short as possible. We will provide adequate rest periods between trials and you will be questioned often about any discomfort.

A third risk is skin irritation. Skin can become irritated while using any prosthesis and it may also become irritated by adhesive sensors. Additionally, your residual limb will be checked prior to and after the study to check for skin irritation. If you have discomfort in your residual limb during the study, we will give time for the socket to be removed to check for any skin irritation. To avoid the risk of skin irritation, you will use your normal, take-home socket throughout the study.

A fourth risk is that you may find that you prefer a different prosthetic knee after completion of the study. You may or may not be able to obtain this prosthetic knee through your clinical provider and/or insurer. We will provide all information to you that you request about your performance in the various knees. The goal of this study is not be to provide you with a knee to take home following the study.

A final risk is that failure to return the prosthetic knee will result in the need to file a police report. A police report will be filed if you have failed to return the prosthetic knee 1 month (30 days) after your initial fitting date when you take the prosthetic knee home. Your name and identifying information may be shared with other offices at Georgia Tech, the police, the insurance company and/or the manufacturer. If you do not return the prosthetic knee, you may be sued by the insurance company or the manufacturer.

Benefits:

There will be no direct benefit to you by your participation in this research study. Our goal is to optimize the prosthetic prescription process for people with above the knee amputations. The long-term goal of this research is to improve the ability of people with amputations to be able to walk better and more easily: including walking on level surfaces, stairs, ramps, hills and other activities.

Compensation to You:

You will not be charged for any study-related procedures. You will be compensated by the hour for your participation while in the lab at a rate of $20 per hour and will be compensated an additional $300 if you complete the full study. Because you will be paid by the hour for your

time in the lab, and time to fit, tune and acclimate to the prosthetic knee in the lab can vary depending on the individual participant, it is difficult to estimate an exact amount of total compensation for a participant. However, given our estimate of 40-50 hours in the lab, a participant may be compensated up to $1300 for participation in this study. You will also be compensated for parking and travel costs. Food and drinks will be provided during the study and meals will also be provided depending on the time of day of the study.
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 provided at the end of each visit to the lab.

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.

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. We will not use any videotapes, photographs, recordings, or other identifiable information about you in any future presentation or publication without your consent. Videotapes, photographs, recordings are used for data verification and analysis and are stored on password protected computers and only study personnel will have access to them. When this study is complete, videotapes, photographs, recordings will be kept for archival purposes.

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 will be stored securely. Only the Principal Investigators and 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 may 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 an official area. People who have access to your information include the Principal Investigators, research study personnel and the DoD. 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 and the Department of Defense (study funder) may access your records to make sure the study is being run correctly and that information is collected properly.

If you fail to return the prosthetic knee within 1 month (30 days) after your initial fitting appointment date when you take the prosthetic knee home, your name and any identifying

information may be shared with other offices at Georgia Tech, the police, the insurance company and/or the manufacturer.

We will comply with any applicable laws and regulations regarding confidentiality.

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

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.

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.

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. You may contact the study PI, Aaron Young at telephone number 404-385-5306 or by email at Aaron.Young@me.gatech.edu or co-PI, Kinsey Herrin at telephone number 404-894-6269 or by e-mail at Kinsey.herrin@me.gatech.edu.

Questions about Your Rights as a Research Participant:

If you have any questions about your rights as a research participant, you may contact:

The Georgia Tech IRB
irb@gatech.edu

If you sign below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this study.

_____
Participant Name (printed)

_____ _____
Participant Signature Date Time

_____ _____
Signature of Person Obtaining Consent Date Time

Consent to Store and Share your De-Identified Information:

Please check one of the following:

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

_____ 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.

Consent to Store and Share your De-Identified Information:

Please check one of the following:

_____ I agree to allow my video recordings and photographs to be used for teaching, publications or presentations.

_____ I **DO NOT** allow my video recordings and photographs to be used for teaching, publications or presentations. These may only be used for this specific study.