University of Pittsburgh
School of Health and Rehabilitation Sciences
Department of Rehabilitation Science and Technology
Prosthetics and Orthotics Program

6425 Penn Ave, Suite 403
Pittsburgh, PA 15206
http://www.shrs.pitt.edu/MSPO/

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

Title: A comparative analysis between College Park Sidekick Feet and conventional stubby prosthesis.

PRINCIPAL INVESTIGATOR:
Angela DeCandia, BS

Masters of Science in Prosthetics and Orthotics
School of Health and Rehabilitation Sciences
Department of Rehabilitation Science and Technology
6425 Penn Ave, Suite 403
(412) 624-6475

CO-INVESTIGATORS:
Sarah Peterson, MS

School of Health and Rehabilitation Sciences
Department of Rehabilitation Science and Technology
6425 Penn Ave, Suite 403
(412) 383-6757

FUNDING SUPPORT:
This study is being funded primarily by the School of Health and Rehabilitation Sciences Prosthetic and Orthotic departmental support and College Park.

Why is this research being done?

To evaluate the proclaimed benefits and functions of the new College Park Sidekick feet. Comparing this new device to the existing conventional stubby feet will allow practitioners and patients to choose the most appropriate device for them. It is anticipated that you will report increased feeling of balance and stability as well as a decrease in exertion when wearing the sidekick feet. The purpose of this study is to test the overall function of the sidekick feet in real life environments and to provide bilateral above knee amputees with additional information on a new device.

Who is being asked to participate in the research study?

You will be eligible to participate if you are a bilateral transfemoral amputee between the ages of 18 and 65 who can successfully ambulate on stubby prosthesis and are classified as a K2 ambulator. A K2 ambulator is identified as someone who has the ability or potential for ambulation with the ability to transverse low level environmental barriers such as curbs, stairs, or uneven surfaces. Additionally, you must own their own pair of conventional stubby prosthesis with standard adaptation componentry.

You will be excluded from the study if you are dependent on an assistive walking device or wheelchair (may use devices occasionally but should be able to ambulate without them), or use a prosthesis that does not allow change of feet with standard adapters.

What procedures will be performed for research purposes?

If you decide to take part in this research study, you will undergo the following procedures:

Experimental Procedures:

If you are eligible and willing to participate, you will be asked to come to the University of Pittsburgh Bakery Square location for one testing session that will last about an hour.

This session will be comprised of an explanation of the testing protocol, proper fitting of the sidekick prosthesis, a 10 meter walk test, a Timed Up and Go test (TUG) and completion of a balance confidence question using a visual analog scale and a rated perceived exertion (RPE) scale after each trial.

The 10 meter walk test and TUG test will be performed in the Prosthetics and Orthotics main classroom. You will be asked to wear comfortable clothing that allows access to make adjustments to your prostheses. You will be required to wear a gait safety belt during each test trial.

<u>Testing Protocol</u>

A 10 meter walk test will be administered on a level sound surface and a gravel surface. The test will take place under four different conditions; 1) stubby prosthesis on level surface 2) stubby prosthesis on gravel surface 3) sidekick prosthesis on level surface 4) sidekick prosthesis on gravel surface. Each trial will be performed 3 times and the completion times will be averaged. There will be a 2-minute break between each 10-meter test and a 30-minute break when changing the feet style. During the 30-minute break you will change from the conventional stubbies to the sidekicks and the proper resistance will be set. You will be given about 20 minutes to rest and 10 minutes to walk around with the new feet style. You will walk a total of 10 meters. The intermediate 6 meters will be measured to allow for acceleration and deceleration. You will be instructed to walk at a comfortable, leisure speed.

A gravel surface will be constructed using a tarp and gravel. This surface will be used as an uneven surface in comparison to a level ground surface for the 10 meter walk test.

The TUG test will be performed on just the level surface using a standard chair with arm rests. You will begin seated in a chair. A piece of tape is placed 3 meters away, clear for you to see seated in the chair. On the word "GO" you will stand up, walk to the line on the floor, turn around and sit back in the chair. Time will be recorded from the word "GO" until you are seated, with your back firmly against the chair. You will be wearing the G-Walk technology to analysis the movement at the pelvis. Three trials will be performed using each foot type and you will receive a 5 minute rest between the individual trials and a 10 minute rest between the foot change.

The G-walk technology is a Bluetooth wireless system that is worn around the waist with an ergonomic belt allowing you to move freely without any restrictions. This device can collect spatio-temporal parameters, general walking kinematics and pelvis kinematics. Validated protocols with this device include the TUG test and a standard walking protocol.

What are the possible risks, side effects, and discomforts of this research study?

<u>10 Meter Walk and TUG Test</u>

The most common risk associated with this test is a fall risk. This risk is taking into consideration with preparatory actions as you will wear a gait belt and the principle investigator will walk along side providing supervision. Training, and proper education can be performed to allow you to feel comfortable performing the tests. Possible consequences from falls may result in bruising, fractures, sprains, minor cuts or abrasions, and damage to prosthetic device. For those who are less physically active it is recommended that you properly stretch and become comfortable on the prosthetic devices before initiating the testing trials.

Should you experience any pain or discomfort during the testing procedures, you will be given the opportunity to rest or terminate the testing session. If in fact injury does occur, the investigators listed on the front page of this consent form will

administer immediate and appropriate first aid care. In the event of any adverse event or injury, the investigators will refer you for proper medical treatment.

The investigators listed on the front page of this consent form will take every precaution to watch for and prevent any possible adverse event. These precautions include proper instructions, correct testing sequences, proper subject positioning, proper prosthetic alignment and proper testing procedures. You will be given the opportunity to complete practice trials, which allow for familiarization with the tasks. If you experience any pain or discomfort during the testing procedures you will be given the opportunity to rest or terminate the testing session.

Breach of confidentiality is a possible risk of any research study. To minimize this risk, all data obtained will be secured and no information linking your data to you will be kept with your file. Further, any information identifiable to you will be destroyed after 7 years and your data will only be retained anonymously.

What are the possible benefits from taking part in this study?

As a participant you are given the opportunity to ambulate in a newer design of stubby prosthetics and may further decide whether they are a device you may personally be interested in. In addition, the results of this study may add to the existing claims that the new Sidekick design facilitates ambulation and provides increased stability by allowing greater motion at the ankle joint.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if any new information develops during the conduct of this research study, which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

None of the services and/or procedures you receive during this research study will be billed to you or your health insurance. If you receive a bill or believe your health insurance has been billed for something that is part of the study, notify a member of the research team.

Will I be paid if I take part in this research study?

Should you participate in this research study and complete all testing procedures you will be compensated with $25.

Who will pay if I am injured as a result of taking part in this study?

If you believe that the research procedures have resulted in an injury to you, immediately contact the principal investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC.

Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as confidential (private) as possible. Your identity on these records will be indicated by a case number rather than by your name. You will not be identified by name in any publication of research results unless you sign a separate form giving your permission (release).

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to identifiable information related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

Finally, your research data may be shared with investigators conducting similar research; however this information will be shared in a de-identified manner (without identifiers).

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose your information for 7 years following final reporting and publication of the study, for the purposes described above. After the minimum required retention period, 7 years, all identifiable information and links to identifiers will be destroyed and the data maintained anonymously.

Is my participation in this research study voluntary?

Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will

not be allowed, in general, to participate in the research study.) Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research information recorded for, or resulting from your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

In the event of a medical emergency involving a musculoskeletal injury, participation in the research study will immediately halt. You will undergo a primary assessment by the PI who is a certified and licenses Athletic Trainer. The PI will refer you to your Primary Care Physician if necessary. Regardless of completion of each tests, you will be compensated the full amount of $25.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh.

If I agree to participate in this research study, can I be removed from the study without my consent?

You may be removed from this study in the event that you are unable to perform the required tasks. All investigators have the right to withdraw you from this study if you have developed a musculoskeletal injury. Any injury will be determined by the investigators through questioning and physical examinations. The principle investigator is a certified and licensed Athletic Trainer in the state of PA who will perform a primary injury evaluation if a musculoskeletal injury is expected. You will undergo a basic evaluation and if a musculoskeletal injury is suspected the primary investigator will refer you to your primary care physician for follow-up.

****

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form.

Any questions I have about my rights as a research participant will be answered by the Human Subject Protection Advocate of the IRB Office, University of Pittsburgh (866-212-2668). By signing this form, I agree to participate in the research study. A copy of this consent form will be given to me.

_____
Participant's Name (Print)

_____ _____
Participant's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have carefully explained the nature and purpose of this research study to the above named individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date