Participant Information Sheet

Study Title: Lower-limb joint kinematics effect on the pressure in the socket interface and the

residuum in transtibial amputees
Researcher: Patricia Acosta Carrazco, Supervisors: Peter Worsley, Martin Warner

ERGO number: 41449

Please read this information carefully before deciding to take part in this research. It is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

I am a rehabilitation medical doctor and a research student at the University of Southampton, currently undertaking a Masters program in research. The aim of this research is to establish the relationships between the way you move and the pressures inside your prosthetic socket. This will enable us to better understand how we can protect the residual limb during activities of daily living. For this we are recruiting a small number of below knee amputees.

Why have I been asked to participate?

You have been asked to take part as you have a below knee amputation on one side and you currently have your own prosthesis.

What will happen to me if I take part?

You will be asked to sign a consent form to participate in this study. A date will be arranged to assess your movements in a specialist laboratory. Before starting the study procedure and movement analysis you will be requested to change into shorts and a t-shirt. At the biomechanics gait laboratory, you will be requested to fill in two forms about prosthesis comfort, pain, your quality of life. Then, you will perform the test known as “Time Up and Go”, where you will be seated in a chair, then stand-up and walk to three meters and then turn back to the chair to sit down at your own pace. All this will be measured by a timer. Next step will be to analyse your walking, where we will place markers on your lower limb and on your prosthesis. For this you will be required to wear a pair of shorts (changing facilities will be provided). A pressure sensor device will be placed inside your prosthesis, the device is a thin plastic sheet that measures the pressure between your limb and your prosthetic. You will be requested to perform walking in a self-speed where you feel comfortable. You will be asked to walk the length of the biomechanics lab (10 meters) up to five times. The walking will be recorded, and data will be analysed through the Vicon® system (which is a commercial system device to analyse human movement). All these activities described will be in one session lasting around 1 to 2 hours.

Are there any benefits in my taking part?

There will be no direct benefit to taking part in the study. If you have travelled from the local community, you will given the cost of travel expenses incurred. The results of the study will help to inform us about the relationship between the socket of the prosthesis and the residual limb to improve future prosthesis adaptation in persons with lower limb amputations.

Are there any risks involved?

We will minimise your risk of falling looking carefully in our laboratory environment, avoiding wet floors or any objects placed around the room. No irregular terrains are included in this study. At the time of markers placement, some people may experience an allergic reaction to the adhesive. The pressure sensors attached to the socket interface may also evoke a skin allergic reaction. All steps will be taken to minimise any risks and if a skin reaction is observed the tests will stop. You may bring a companion along with you for support during the test session if you wish.

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Will my participation be confidential?

The data collected in the study will be stored and handled following the University of Southampton data protection policy and in accordance with the Data Protection Act 2018. Full confidentiality will be maintained by keeping all personal data in a locked filing cabinet where only research team have access. All electronic personal data will be stored on password protected computers. Your anonymity will be ensured by giving you a unique ID number before any data collection. There is a possibility that data obtained will be use in future studies by the researchers involved in this study, by researchers from other departments within the University, or by researchers from other universities. If the data is to be used by researchers not directly involved in the study only anonymised data will be made available. The researchers will have no access to your personal details.

What should I do if I want to take part?

You will need to get in contact with the research team through the following email: pac1g17@soton.ac.uk, or Office phone number: 02380 598990.

What happens if I change my mind?

You are free to withdraw from the research process at any time without your rights being affected and any data collected will be destroyed.

What will happen to the results of the research?

All results obtained from this study will be analysed and published. The anonymised research data will be available for future research projects. Research data will be stored for a minimum of 10 years for staff and postgraduate research students, as per University of Southampton policy.

Where can I get more information?

Contact for further details will be to Patricia Acosta Carrazco, e-mail: pac1g17@soton.ac.uk.

What happens if something goes wrong?

In the unlikely case of concern or complaint please contact the Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Thank you for taking the time to read the information sheet and considering taking part in the research study.

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