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THE UNIVERSITY OF NEW SOUTH WALES
SYDNEY • AUSTRALIA



**THE UNIVERSITY
OF QUEENSLAND**
AUSTRALIA

Perception and Performance Following Lower Limb Amputation

Approval No HREC 07247 (UNSW)

This booklet contains important information. Please ensure you read this booklet thoroughly and understand all the information contained within it before finalising your decision to participate in this study.

If you do decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice. Revocation of consent forms are contained within this booklet. It is important to keep this booklet once you have read it.



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PARTICIPANT INFORMATION STATEMENT

QUESTIONNAIRES

Participant selection and purpose of study

You are invited to participate in a study of functional outcome following lower limb amputation. We hope to learn how you rate your rehabilitation and level of functioning.

You were selected as a possible participant in this study because you are a member of (*insert amputee support group*). (*Insert amputee support group*) has sent you this package.

Description of study and risks

If you decide to participate, we will place your name on a register managed by A/Prof. Anne Simmons, Head of the Graduate School of Biomedical Engineering, University of New South Wales.

This part of the study into Perception and Performance Following Lower Limb Amputation requires the completion of three questionnaires. We are interested in gaining information about how you perceive your quality of life, mobility and functioning.

The first questionnaire is called the Short Form 36 (SF-36). It is a generic measure of health related quality of life, severity of illness and demographics¹. The SF-36 is estimated to take 10 to 15 minutes to complete.

¹ Condie, E.C., Scott, H., Treweek, S., *Lower Limb Prosthetic Outcome Measures: A Review of the Literature 1995 to 2005*, Journal of Prosthetics and Orthotics 2006; **18**(1S): pp. 13 – 29, http://www.oandp.org/jpo/library/2006_01S_013.asp



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The Functional Measure for Amputees (FMA) is a specific measure of amputee function. Embedded within the FMA questionnaire is the Locomotor Capabilities Index (LCI-5), which measures amputee mobility. The FMA questionnaire is expected to take 15 minutes to complete.

The final questionnaire to be used is called the Prosthesis Evaluation Questionnaire (PEQ). This questionnaire measures prosthetic-related quality of life. Although completion time is not reported, finishing the PEQ is expected to take 30 minutes.

Completing all three questionnaires should not take more than one hour of your time. Should you choose to complete Option Two (see cover letter), you will only be required to complete these three surveys once. If you choose to participate in Option One (see cover letter), these surveys will need to be completed twice. In the first instance you may complete them at a time and location of your choosing. The second time will require you to complete these surveys on the day, and prior to the commencement, of biomechanical testing.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

Confidentiality and disclosure of information

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission, except as required by law. If you give us your permission by signing the consent form, we plan to



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use the results for research and peer reviewed publications. In any publication, information will be provided in such a way that you cannot be identified.

Feedback to participants

Upon completion of this study a brief written report will be made available to you summarising the findings. This will be mailed or emailed to you.

Your consent

Your decision whether or not to participate will not prejudice your future relations with the University of New South Wales, the Graduate School of Biomedical Engineering or the University of Queensland. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without prejudice.

If you have any questions, please feel free to contact A/Prof. Anne Simmons via email (a.simmons@unsw.edu.au) or via telephone ((02) 9385 3232).

Complaints may be directed to the Ethics Secretariat, The University of New South Wales, SYDNEY 2052 AUSTRALIA (phone 9385 4234, fax 9385 6648, email ethics.sec@unsw.edu.au). Any complaint you make will be investigated promptly and you will be informed of the outcome.

This booklet is yours to keep.



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PARTICIPANT INFORMATION STATEMENT

BIOMECHANICAL TESTING

Participant selection and purpose of study

You are invited to participate in a study of functional outcome following lower limb amputation. We hope to learn the biomechanics of every day tasks with a lower limb amputation, particularly walking. We are specifically interested in speed, joint and muscle forces, energy cost and the residual limb/socket interface pressure during walking.

You were selected as a possible participant in this study because you are a member of (*insert amputee support group*). (*Insert amputee support group*) has sent this to you.

Description of study and risks

If you decide to participate, we will place your name on a register managed by A/Prof. Anne Simmons, Head of the Graduate School of Biomedical Engineering, University of New South Wales.

This part of the study into Perception and Performance Following Lower Limb Amputation involves the completion of three questionnaires and biomechanical testing. There are two expected outcomes. Firstly, we will learn the biomechanics of every day tasks in people with a lower limb amputation. Secondly, this information along with the information obtained from the questionnaires will be analysed to determine whether relationships between how you think and how you perform exist.



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Upon receiving your expression of interest to participate in this study a researcher will contact you to ensure that you are still willing and able to participate. If this is still the case, a time for you to attend the appropriate testing site (Sydney or Brisbane) will be arranged. A series of biomechanical tests will be performed while you wear your regular prosthesis.

Prior to undergoing biomechanical testing, it will be necessary to complete the three questionnaires (SF-36, FMA and PEQ) again. Personal details and some basic measurements will also be recorded.

You will only be required to attend the testing site once for this study. During this time we will need to:

- Record your personal details
- Complete the three questionnaires
- Measure your mass and height
- Record the type and level of amputation
- Record the type of prosthesis you usually use
- Measure the residual limb length
- Complete the Amputee Mobility Predictor (AMP) questionnaire
- Perform biomechanical testing, including:
 - Gait analysis
 - Balance tests
 - Timed walking tests
 - Residual limb/socket interface pressure

This should not take more than 4 hours of your time.

The Amputee Mobility Predictor questionnaire involves a series of tests to determine your mobility potential. Activities include sitting, sitting and reaching, standing up from a chair, sitting down onto a chair, turning around, stepping over obstacles and climbing and



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descending stairs. This questionnaire is a standardised measure and has been used throughout the world.

Biomechanical testing involves a suite of different tests, all of which are non-invasive and painless.

Gait analysis involves the placement of several small (1cm diameter), spherical markers on the body and prosthesis. They are attached using double sided tape and are quite easy to remove. Once the markers have been fitted you will be asked to walk in a straight line while several specialised video cameras capture the way in which you move. This may need to be repeated several times. Gait analysis has the ability to tell the researchers many different aspects of your walking. The basic data is called temporospatial data. This includes how long your steps are (stride length), how many steps you take in a minute (cadence), how fast you walk (speed) and how often you take a step (frequency). The next type of information is kinematic data. This gives an indication of how far and how quickly your joints are moving. The final type of information we will record from your analysis is called kinetics. Kinetics tells us how much force and power your joints are experiencing. With all these factors we are able to obtain an accurate picture of your walking ability, and identify any irregularities.

Balance testing will be conducted whilst wearing the markers. You will be asked to perform three different tests, each of which may need to be repeated several times. During each task you will be asked to stand on a force plate. This device can be considered a very sophisticated scale. The tests will last for as long as you can hold your balance, up to a period of 30 seconds. The first test involves you standing on both limbs, with subsequent tests involving standing on one leg – first your intact limb and then your prosthesis. Hand



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rails are provided to ensure that, in the unlikely case you lose balance, you do not fall.

The time walking test is a measure of your aerobic capacity. This study will adopt the Six Minute Walk Test (6MWT). For a period of six minutes you will be asked to walk around a level track. The distance you walk in this time period will be recorded and will be used as an indicator of your fitness and prosthesis comfort. The Six Minute Walk Test will be performed once.

The final test involves measuring the pressure between your residual limb and the prosthetic socket. This will be incorporated into the Six Minute Walk Test. To measure the pressure, you will be asked to remove your prosthesis. Small patches (20mm x 20mm) will then be placed over the skin of your residual limb. You will then be asked to don your prosthesis as you would normally. The patches should be almost unnoticeable, and discomfort should not be experienced. Once you, and the researchers, are satisfied with the position and comfort of the patches you will be asked to complete the Six Minute Walk Test.

All these tests are non-invasive and painless. To be included in this study it is a requirement that you are able to walk confidently and independently. Although highly unlikely, it is possible that you may lose your balance during any of these tests. This is most likely to happen during the balance tests. Hand rails are provided to prevent falls.

While these tests are used for research they do have the potential to identify possible problems with your prosthesis. If problems are identified, the physiotherapist will discuss with you the cause of the problem and liaise with your primary prosthetic provider.



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We cannot and do not guarantee or promise that you will receive any benefits from this study.

Biomechanical testing is not a routine clinical tool and does not substitute for regular visits to your prosthetist or physiotherapist. If you do decide to participate in this study please do not forego your regular visits to your primary prosthetic provider.

Confidentiality and disclosure of information

Any information that is obtained in connection with this study and that can be identified with you will remain confidential and will be disclosed only with your permission, except as required by law. If you give us your permission by signing the consent form, we plan to use the results for research and peer reviewed publications. In any publication, information will be provided in such a way that you cannot be identified.

Recompense to participants

Out of pocket expenses such as transport to and from the testing site will be reimbursed to a maximum of \$100 upon submission of receipts.

Feedback to participants

Upon completion of this study a brief written report will be made available to you summarising the findings. This will be mailed or emailed to you.

Your consent

Your decision whether or not to participate will not prejudice your future relations with the University of New South Wales, the Graduate School of Biomedical Engineering or the University of Queensland. If you decide to participate, you are free to withdraw



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REVOCATION OF CONSENT

QUESTIONNAIRES

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the Graduate School of Biomedical Engineering, the University of New South Wales or the University of Queensland.

.....
Signature

.....
Date

.....
Please PRINT Name

The section for Revocation of Consent should be forwarded to A/Prof. Anne Simmons (Graduate School of Biomedical Engineering, UNSW).



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