University of Southampton | NHS North Bristol NHS Trust | opcare | radii devices

Would you like to have a socket designed with the aid of a new software?

'The Adaptive Templates Fitting System' - A computer-aided process for supporting socket design based on previous successful clinical practice

Who? We are looking for people over 18 with a below-knee amputation, interested in participating

Why? To understand the strengths and weaknesses of using the new software to support socket design

Aim To evaluate using the new software in-clinic to support socket design

Helping development of software to support clinicians in designing sockets, which could lead to...

- Improved socket fit
- Reducing number of fitting sessions

What?

Fitting a socket designed by your prosthetist using the Adaptive Templates Fitting System software.

Let your clinician know if you are interested

Please read the participant information sheet for further information and email the team to ask any questions: Jenny@radiidevices.com

Quick Study Overview - Please see full participant information on following pages

IRAS ID: 317901 ERGO: 81419
REC reference: 24/LO/0126

Participant Information Sheet

Title of study: Clinical usability evaluation of Adaptive Templates Fitting System for socket design

We would like to invite you to take part in this two-stage research study. Before you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve.

Please take your time to read the information below carefully and ask questions if anything is not clear, or if you would like more information before you decide to take part in the study. You may like to discuss it with others, but it is your choice whether to take part. If you are happy to participate you will be asked to sign a consent form at the end of your assessment appointment with your prosthetist.

What is the purpose of the study?
Prosthetic socket comfort and fit is important in ensuring people can get the greatest benefit from their prosthetic limb. Researchers from the University of Southampton and Radii Devices Ltd are working with your clinic to develop a new tool intended to support the design of prosthetic sockets. We are developing socket design 'templates', based on patterns in past, successful designs. This involves your prosthetist using new computer aided design software, which provides your prosthetist with a suggested starting point for your new socket design, based on people who were similar to you. Then, they can modify the template, based on knowledge from their own experience and relationship with you, to further personalise it to your needs. We call this software the 'Adaptive Templates Fitting System (ATFS), and the findings from this study will be used to further develop it for use in wider clinical practice.

The objective of this study is to understand the strengths and limitations of the Adaptive Templates Fitting System software when used in-clinic and inform its further development. The in-clinic usability of the Adaptive Templates Fitting System to support prosthetic socket design, will then be tested. The time it takes to design your socket will also be captured, to compare with the current methods of socket design in use at your clinic.

Why have I been invited?
You have been invited to participate in this study because you have had a below-knee amputation and are about to have an assessment appointment with your clinician to discuss your new prosthetic socket.

To take part in the study, you also need to meet the following criteria. You must:

- Be over 18 years old.
- Require a new socket.

- Be able to follow the verbal instructions required for clinical assessments carried out within fitting sessions.
- Be willing to fit a socket designed by your prosthetist using the Adaptive Templates Fitting System.
- Be able to provide written informed consent.

You would not be able to take part in the study if you meet any of the following exclusion criteria; if:

- You have an amputation that is not a below-knee amputation (e.g. above-knee, through the ankle, etc).
- You don't require a new prosthetic socket at this time.
- You are unwilling for your prosthetist to design your socket using the Adaptive Templates Fitting System.
- You are unable to answer verbal questions (as per normal fitting appointments) on your socket fitting and comfort.

You will have time to ask any questions at your assessment appointment. Then if you are happy, you will be asked to sign a consent form to show you have agreed to take part.

Do I have to take part in the study?
No, it is up to you.

What will taking part involve?
Firstly, your involvement in this study will form part of your usual care and according to the NHS Trust's most up-to-date infection prevention and control guidance. If you meet the eligibility criteria and you would like to participate you will be asked to sign a consent form to confirm your participation and that you have read and understood this information. This will happen while at your assessment appointment, and you will be able to ask your prosthetist any questions at any point. If you require a new socket your prosthetist will take a scan of your limb using a 3D scanner as per normal care. Your prosthetist will apply the Adaptive Templates Fitting System in designing a socket for you.

At your fitting appointment you will try on your socket. You will trial the socket as per normal care with your prosthetist observing you walking, recording your socket comfort score, discussing the socket fit with you, and making adjustments to the socket as required. After both yourself and your prosthetist are happy, you will take your new socket home. This procedure matches your normal care pathway except that the socket will have been designed with the aid of the Adaptive Templates Fitting System rather than the standard CAD/CAM socket design process for the clinic. You will be able to keep the socket after the study as per usual care. As part of the usual care procedures for your clinic, your experience using your socket will be recorded and managed by your prosthetist.

The existing normal standard of care pathways for your clinic are available to you to address any concerns following when you take your new socket home, i.e., planned review appointments with your prosthetist or you may contact the clinic directly.

What are the possible benefits of taking part?
If you decide to take part in this study, during your fitting session you will be able to trial a socket designed with the aid of Adaptive Templates Fitting System software. There are no other direct benefits from taking part in the study. However, through doing this you will be helping to further knowledge regarding socket design and informing further development of the software, which could lead in future to enhanced socket comfort and minimising the time involved with designing sockets, leading to improving the speed of delivery of prosthetic limbs.

What are the possible harms of taking part?
There are no anticipated physical or psychological risks involved in taking part in this study. Your safety will be ensured at all times and your prosthetist will remain with you throughout. As part of the usual care procedures for your clinic, your experience using your socket will be recorded and managed by your prosthetist.

What will happen if I decide not to take part?
You do not have to take part in this study. If you decide not to take part, your care will not be affected in any way.

What will happen if I don't want to carry on with the study?
It is very important for you to understand that your participation is voluntary and you may withdraw from the study at any time, without giving a reason. Your withdrawal will not affect your legal, medical rights or future treatment in any way. If you wish to withdraw, please let your prosthetist know and contact the study researchers using the details provided below.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the study researchers who will answer your questions. If you remain unhappy and wish to speak to someone else, you can contact Jenny Bramley, Radii devices Clinical Lead (jenny@radiidevices.com) or Patient Advice and Liaison service (PALS) at your local NHS Trust (contact details on the final page). The normal NHS complaints mechanisms are also still available to you.

Will my taking part in this study be kept confidential?
Your personal information will remain anonymous, and we will not share your information with any other organisation or party outside of the study research team and/or relevant NHS Trusts. Your healthcare team at the prosthetics centre will be aware of your involvement in the study.

Your completed consent form will be added to your medical record to record your participation. Study researchers will not have access to any medical records. Apart from your consent form, the only information recorded from your participation will be any socket comfort scores that you provide during your fitting appointments.

Individuals from regulatory authorities (people who check that the study is carried out correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

You will be assigned a participant number so that no data can be linked to you directly. Any information that we gather in relation to this study will be kept strictly confidential. All documents will be identified by code number (and not by any of your personal identifiable information) and kept securely, either under lock and key or via encrypted and password protected computers (in accordance with the General Data Protection regulation and the UK Data Protection Act, 2018).

Upon your consent, photographs (not showing your face) may be taken during the use of the ATFS for the purposes of reporting the clinical investigation research findings publicly and for marketing the ATFS. If you lose ability to give consent or participate, you will be withdrawn from the study and identifiable data already collected with consent will be retained and used in the study. No further data will be collected, or any other research/study activities/procedures carried out in relation to you.

Radii Devices Ltd is the sponsor for this study and will act as the data controller, which means they are responsible for looking after your data and using it properly. It is expected that the anonymised collected data will be stored in the repository of Radii Devices Ltd for at least 10 years after the study. This repository is highly secure to protect the stored data. All files will be kept in compliance with the Company's Data Protection Guidelines prior to being deposited in the repository. More information on Radii Devices Ltd Data Protection Privacy Notice can be found here: https://www.radiidevices.com/privacy

How will we use information about you?
The information collected about you (e.g. your name) will be used only for the research study or to check your records to make sure that the research is being done properly. To safeguard your rights, we will use the minimum personal-identifiable information possible. People who do not need to know who you are will not be able to see your personal-identifiable information. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so that we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

You can find out more about how we use your information by asking one of the study research team or by visiting www.hra.nhs.uk/information-about-patients/.

What will happen to the results of the research study?
If you wish, we will send you a summary of the findings of the full study upon completion. Post-analysis anonymised data will be used in publications and presentations to display the work, and to inform further development of the Adaptive Templates Fitting System software. You will not be identified in any report or publication. If you would prefer your data to not be included in research publications at any time during or after the study, please inform the study researchers. However, once the data have been analysed we will be unable to withdraw your contribution.

Where can you find out more about how your information is used?
You can find out more about how we will use your information at www.hra.nhs.uk/information-about-patients/, by asking one of the research team members, or by sending an email to Jenny Bramley, Radii Devices Clinical Lead (jenny@radiidevices.com).

Who is organising the research?
Radii Devices Ltd are the sponsor of the study, partnering with the University of Southampton **(ERGO 81419)** and Opcare Ltd. (a prosthetics and orthotics services supplier to the NHS). In the interests of transparency, involved academics Prof Alex Dickinson and Prof Peter Worsley are academic co-founders of Radii Devices Ltd and declare a small shareholding.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. The London-Dulwich Research Ethics Committee has given a favourable opinion of the study. This has also been reviewed by the Medicines & Healthcare Products Regulatory Agency (MHRA), as it focussed on the evaluation of a medical software application (IRAS 317901, REC reference 24/LO/0126).

Further information and contact details
For further information about this project please contact the study researchers detailed in this information sheet, or if you would like to find out more about being involved in the study, or if you are unhappy about anything to do with the study, please contact:
Jenny Bramley (Radii Devices Clinical Lead Researcher):
Jenny@radiidevices.com,
Professor Alex Dickinson (University of Southampton)
alex.dickinson@soton.ac.uk
NHS Trust R&D contact: Malcolm Dixon, 0117 414 9330, research@nbt.nhs.uk
Patient Advice and Liaison Service - 0117 414 4569, pals@nbt.nhs.uk