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Clinical usability evaluation of an adaptive templates fitting system for socket design

Submission date
22/05/2025

Recruitment status
Recruiting

Registration date
04/06/2025

Overall study status
Ongoing

Last Edited
09/01/2026

Condition category
Other

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
When someone loses a limb, getting a well-fitting prosthetic socket—the part that connects the limb to the artificial leg—is essential for comfort and mobility. However, making a good socket is a complex process that takes a lot of time and skill. With over 7,000 amputations each year in England, NHS prosthetic services are under pressure, facing long waiting times and high rates of socket rejection.

To help with this, researchers at the University of Southampton and Radii Devices Ltd. have developed a new digital tool called the Adaptive Templates Fitting System (ATFS). This tool uses past data and computer models to help prosthetists (specialists who design prosthetics) create better-fitting sockets more efficiently. The study aims to test how easy ATFS is to use in real NHS clinics and whether it can improve the socket design process.

Who can participate?
There are two groups of participants in this study:
Group A: Prosthetists working at NHS prosthetic centres in Bristol, Cambridge, and Norwich. They must have experience using computer-aided design (CAD) software.
Group B: Adults aged 18 or over who have had a below-knee (transtibial) amputation and are due to receive a new prosthesis as part of their regular care. They must be able to understand English and talk about how their socket feels.

What does the study involve?
The study has two stages:
Stage One: Prosthetists will be trained to use ATFS and will design sockets for patients during their normal work. They'll be observed and interviewed to gather feedback. The software will be improved based on their input.
Stage Two: Prosthetists will use the final version of ATFS on their own, and their experiences will be compared to standard methods.
Patients will receive sockets designed using ATFS as part of their usual care. Up to 17 prosthetists and 46 patients will take part.

What are the possible benefits and risks of participating?
There are no direct health benefits for participants, but the study could help improve prosthetic care in the future. Benefits may include more comfortable sockets, faster design times, and quicker delivery of prostheses.

Risks are low because the study is part of standard NHS care. Any problems, such as discomfort or issues with the socket, will be handled according to NHS procedures. All participants will give informed consent and can leave the study at any time without affecting their care or job.

Where is the study run from?
-Bristol Centre for Enablement (North Bristol NHS Trust)
-Chaston House, Cambridge (Cambridge University Hospitals NHS Foundation Trust)
-Re-enablement Services Centre, Norwich (Norfolk Community Health and Care NHS Trust)
-It is sponsored by Radii Devices Ltd., based in Bristol.

When is the study starting and how long is it expected to run for?
The study began in November 2024 in Bristol and in January 2025 at the other two sites. It will run until December 2025, lasting about 14 months in total.

Who is funding the study?
The study is funded by an Innovate UK Biomedical Catalyst Grant, in partnership with Opcare Ltd., the University of Southampton, and Radii Devices Ltd. (UK)

Who is the main contact?
Dr Jennifer Bramley, jenny@radiidevices.com

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
317901

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 57956, Protocol number: 283-04A-04

Study information

Scientific Title
An evaluation of clinical usability-related safety of an adaptive templates fitting system to support prosthetics socket design

Study objectives
The key research question is: What is the clinical usability of the Radii Devices ATFS, that suggests prosthetic socket design shapes based on learning from past designs and combines technology with the experience and expertise of the clinician?

Research Objective Following the preceding study (IRAS ID: 313408, EGRO NO: 76033, REC REF: 22/YH/0215, 01/02/23 – 31/08/23), the objective of this study is to evaluate the clinical usability of the ATFS that combines Adaptive Templates technology with the experience and expertise of the clinician to provide optimal socket design support: Stage One of the study will explore the strengths and limitations of the in-clinic usability of the ATFS to inform its further development, and; Stage Two of the study will assess the in-clinic usability of the ATFS and verify the safety of its use.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 14/04/2024, London - Dulwich Research Ethics Committee (Health Research Authority, 2nd Floor, 2 Redman Place Stratford, London, E20 1JO, United Kingdom; +44 207 104 8109; faye.siewierski@hra.nhs.uk), ref: 24/LO/0126

Study design
Interventional clinical usability evaluation

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Prosthetic socket design

Interventions
Group A – Prosthetists
Prosthetists participating in Stage One (the iterative usability testing phase) are first informed about the study via their clinic lead and invited to participate. If interested, they receive a Participant Information Sheet (PIS) and an invitation letter and are given the opportunity to ask questions before providing informed consent. They then attend a one-off in-person training session with study researchers, designed to familiarise them with the Adaptive Templates Fitting System (ATFS) and guide them through an example case. This session takes approximately 60 minutes. Once trained, the prosthetist uses the ATFS in a real patient case to support socket design, thinking aloud while using the system and being recorded for usability analysis. A researcher is present to support as needed. The use of ATFS typically takes around 30 minutes per case.
Prosthetists then follow standard care processes for check socket fitting and definitive fitting appointments, incorporating the ATFS where necessary for any digital socket adjustments. After the definitive socket has been delivered, each prosthetist takes part in a semi-structured interview lasting approximately 30 minutes to provide feedback on their experience. Depending on the software development needs, prosthetists may repeat this process for at least one

additional patient case. The total duration of participation for Stage One is typically 2–3 months, depending on clinic schedules and the number of usability testing iterations.
In Stage Two (the summative usability testing phase), prosthetists who did not participate in Stage One will first receive training (if needed) and provide informed consent. They then use the final version of the ATFS independently, without support or verbal commentary, during one patient case. After delivering the definitive socket, they participate in a follow-up interview focused on their experience and comparisons with their standard CAD/CAM workflow. This stage typically lasts around 4–6 weeks per prosthetist.

Group B – Patients
Patients with transtibial limb loss are invited to participate in the study via letter and the Participant Information Sheet (PIS) sent to them ahead of their scheduled assessment appointment. At the appointment, they have the opportunity to ask questions before providing informed consent if they wish to take part. Participation in the study does not alter the clinical pathway—each patient receives the same sequence of visits as per normal care. During the assessment appointment, their residual limb is scanned using a 3D scanner, and the prosthetist uses the ATFS to design the socket (approximately 30 minutes of additional time related to study procedures).
Patients then attend a check socket fitting and a definitive socket fitting appointment as part of their usual care. Standard clinical outcome measures—such as socket comfort score (measured from 1-10)—are taken by the prosthetist at these visits. After final adjustments and delivery, the patient receives their new socket. No additional study visits are required, and any follow-up care is managed through existing NHS pathways. Participation for patients typically lasts 4–6 weeks from assessment to receipt of the final socket.

Intervention Type
Other

Primary outcome(s)
1. Usability of the ATFS is measured using a semi-structured interview with the prosthetist at post-definitive socket delivery (per patient case)
2. Prosthetist confidence and experience with the ATFS is measured using a semi-structured interview conducted by the study researcher at post-definitive socket delivery
3. Perceived usability and clarity of ATFS training materials is measured using a semi-structured interview conducted by the study researcher at post-definitive socket delivery
4. Socket comfort is measured using the Socket Comfort Score (SCS) at the definitive socket fitting appointment

Key secondary outcome(s))
1. Time taken for initial rectification and socket design using the ATFS is measured using direct observation and meeting recording at the assessment appointment in Stage One
2. Time taken for initial rectification and socket design using the ATFS is measured using system log data at the assessment appointment in Stage Two
3. Prosthetist-reported typical design time using standard CAD/CAM software is measured using self-report at the assessment appointment

Completion date
31/03/2026

Eligibility

Key inclusion criteria
Group A: Prosthetists:
1. Prosthetists working with patients recruited as participants in the study
2. Are willing to design a socket using the ATFS

Group B – Adults with limb loss:
1. Over the age of 18 years
2. Have had a transtibial amputation
3. Deemed ready to cast for a new prosthesis by the clinical team as per usual care at the prosthetic centre
4. Able to understand verbal and written English and give informed consent

Participant type(s)
Health professional, Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
110 years

Sex
All

Total final enrolment
0

Key exclusion criteria
Group A: Prosthetists
1. Not familiar with using CAD software technologies for socket design
2. Unwilling to design a socket using the ATFS

Group B – Adults with limb loss:
1. Contraindication to be fitted for a prosthetic socket
2. Unwilling for their prosthetist to design their socket using the ATFS
3. Unable to answer verbal questions (as per normal fitting appointment) on their socket fitting and comfort

Date of first enrolment
20/01/2025

Date of final enrolment
24/03/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
North Bristol NHS Trust
Bristol Centre for Enablement, Jupiter Rd, Patchway
Bristol
England
BS34 5BW

Study participating centre
Cambridge University Hospitals NHS Foundation Trust, Addenbrooke's Rehabilitation Clinic
Addenbrooke's NHS Trust Hospital, Hills Road
Cambridge
England
CB2 0DA

Study participating centre
Norfolk Community Health and Care NHS Trust, Re-enablement Services Centre
Julian Hospital Site, 201 Bowthorpe Road
Norwich
England
NR2 3UD

Sponsor information

Organisation
Radii Devices Ltd

Funder(s)

Funder type
Industry

Funder Name
Radii Devices Ltd

Results and Publications

Individual participant data (IPD) sharing plan

All information collected during the course of the study will be kept strictly confidential. Information will be held securely on paper and electronically at Radii Devices Ltd, including appropriate storage, restricted access, on password protected Radii Devices machines, and disposal arrangements of patients' identifiable details on their consent form. Participants will not be identified in the results of the study. Data will be archived for a minimum period of 10 years following the end of the study. Personal data will be processed according to GDPR.

Data will be made available as part of Open Access rules for UKRI funded research at the point of publishing the study results. At the point of sharing a preprint of a paper submitted for publication, or at latest the point of publication of the paper, a raw data file would be posted on the public 'ePrints' University of Southampton repository which would include data such as a table of general participant information, selected and generalised to an extent to avoid participant identification (i.e. Participant gender, age (highest resolution in 5-yr time ranges), time since limb absence (in 5-yr time ranges), reason for limb absence (in general, i.e. vascular disease, trauma, etc.), and the participants' outcome results (i.e. the socket comfort score)).

More granular data generated in the study would not be made generally available. For example, the participants' exact ages and time since amputation, 3D scans of their residual limbs or corresponding socket designs, transcripts of their think-aloud practice with the software and interviews, would not be published. As a standard clause for publications from University of Southampton, readers will be requested to contact researchdata@soton.ac.uk to request access to more granular data, at which point a conversation would begin between the researchers and those requesting the data, to understand the requested purpose / types of analysis, and if agreed to proceed, entry into a formal Data Sharing Agreement to confirm restrictions such as requirements for, for example, Secondary Data Analysis ethical approval, restrictions to share the data further, etc. The University of Southampton's policy in this area is given here: Home - Research Data Management - LibGuides@Southampton at University of Southampton Library.

Radii Devices Ltd.
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IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Group A	24/10/2024	04/06/2025	No	Yes
Participant information sheet	Group B	24/10/2024	04/06/2025	No	Yes
Protocol file		15/03/2024	04/06/2025	No	No