PARTICIPANT INFORMATION SHEET

Remote capture of patient data for bespoke socket design

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This information sheet forms part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. Please read this information sheet carefully and ask one of the researchers named above if you are not clear about any details of the project.

1. What is the purpose of the project:

The aim of this proposal is to develop a photogrammetry approach to capture residual limb shape and volume information remotely, from which a well-fitting socket can be designed for upper and lower limb prosthesis (the device replacing the missing limb) for people who have one or more amputations.
Photogrammetry is the science of making reliable measurements using photographs. Low-cost photogrammetry will be exploited, where photographs and/or videos of the amputee's residual limb captured remotely will be analysed to produce a three-dimensional representation of the shape of the residuum. This approach needs to be validated using an accurate three-dimensional measurement like a three-dimensional scanner. The validation of this approach will be the starting point for a new study on remotely designing bespoke sockets.

2. Why have I been selected to take part? [or Who can be a participant?]

You have been included because you have one or more limb amputation/s.

3. Do I have to take part?

It is completely up to you to decide if you would like to participate. Before you decide to take part, we will describe the project and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. However, if at any time you decide you no longer wish to take part in this project you are free to withdraw, without giving a reason.

4. What will I be asked to do?

You will be asked to attend a single session in a laboratory environment at the University of Bath which will last approximately 2 hours. You will be asked to maintain a stable position (either sitting or standing), while a researcher take measurements of your residual limb with two different techniques; one will be a three-dimensional scanner system (see Figure 1 below for details) and the other the new photogrammetry system (using either a mobile phone or a video camera). Supporting tools/parallels bars or chairs will be available to make sure that you are safe and comfortable during the data collection. Each data recording will last for a maximum of 2 minutes, but you will be allowed to rest at any time if you need.
You can wear your normal clothes and prosthesis. The residual limb will be the only part uncovered for the duration of the test.

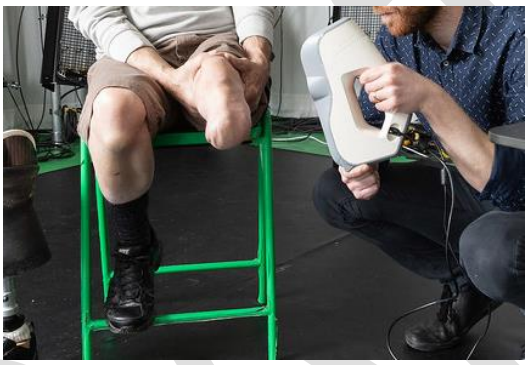

Figure 1: Example of a portable 3D Scanner

5. What are the exclusion criteria? (are there reasons why I should not take part)?

You must have a limb difference to be able to partake. You must be older than 18 years with no recent history of epilepsy, injury/serious postoperative complications/wounds, which would impair your ability to wear a prosthesis. Level of amputation could be above, below or through the knee, (for lower limb amputees) and above, below or through the elbow (for upper limb amputees).
You also need to consent to have your limb photographed.

6. What are the possible benefits of taking part?

By participating in this research, you will get an insight into the research environment of furthering prosthetic technology. Direct benefits to you will include an indication of your residual limb shape and volume. This information may be useful to monitor the status of the residual limb and you will get a digital file of your limb if you wish. Whilst we cannot offer any financial incentives for taking part in this study, you will be reimbursed for any travel expenses (up to £100, depending on your location). This project will help us to obtain preliminary results to demonstrate the ability to obtain patient data remotely to create bespoke socket designs. This will enable further investigations in the future to advance remote socket creation.

7. What are the possible disadvantages and risks of taking part?

Neither of the measurement techniques involved are invasive and should not present any risk to you. Both scanning techniques to measure the shape and volume of your residual limb, do not involve any contact with your body (you may be asked to have attached some reference markers that are easily removable after the test). Flashlights can be visible during the scan, but they are similar to the one you see when you take a picture with the flash, with no health risk.

8. Will my participation involve any discomfort or embarrassment?

We do not expect you to feel any discomfort or embarrassment if you take part in the project. However, if you do feel uncomfortable or appear distressed at any time, the researcher will stop right away. Here you can also find the contacts for a couple of charities that can support you, in case you need:

- The limbless association: https://limbless-association.org
- Blesma, the limbless veterans: https://blesma.org

9. Who will have access to the information that I provide?

All reasonable steps will be taken to ensure that all results of this study pertaining to individuals will be treated with confidentiality. In any manuscripts, reports or publications resulting from this study, codes rather than names will be used. Therefore, you will not be able to be identified in these reports and publications.

10. What will happen to the data collected and results of the project?

All data collected during the project including personal, identifiable data will be treated as confidential and stored on a password protected file on the University of Bath's secure server. This storage of data will be done in accordance with current UK data protection legislation. All identifying data will be deleted at the end of the study. All other data will be stored on the University secure data server for at least 10 years. Your name or other identifying information will not be disclosed in any presentation or publication of the research. We might take pictures of the experimental session if you consent, but you will be not identifiable, since those pictures will be focused on the residual limb.

After the project has finished, if you are interested, you can contact one of the researchers via the email indicated below and we will provide you with a summary of the project results. You will find the details at the end of this information sheet. This summary will not include any identifiable information and will show the overall findings of the project.

Once this project is completed, other researchers at the University of Bath or collaborators may conduct related research projects which would benefit from the use of anonymised data that you have provided.
Further use of your anonymous data will only occur with the University of Bath's approval and data will continue to be stored in accordance with current UK data

protection legislation. Therefore, your name or other identifying information will not be disclosed in any presentation or publication of the research.

11. Who has reviewed the project?

This project has been given a favorable opinion by the University of Bath, Research Ethics Approval Committee for Health (REACH) [reference: XX XXXX XXX].

12. How can I withdraw from the project?

You can withdraw from the project at any time without providing a reason for doing so and without any repercussions.

If for any reason you wish to withdraw your data, please contact an identified researcher within two weeks of your participation. After this date it may not be possible to withdraw your data as some results may have been published or anonymised. Your individual results will not be identifiable in any way in any presentation or publication.

13. University of Bath privacy notice

The University of Bath privacy notice can be found here: https://www.bath.ac.uk/corporate-information/university-of-bath-privacy-notice-for-research-participants/.

14. What happens if there is a problem?

If you have a concern about any aspect of the project you should ask to speak to the researchers who will do their best to answer any questions. If they are unable to resolve your concern or you wish to make a complaint regarding the project, please contact the Chair of the Research Ethics Approval Committee for Health:

Professor James Betts
Email: health-ethics@bath.ac.uk.

15. If I require further information who should I contact and how?

Thank you for expressing an interest in participating in this project. Please do not hesitate to get in touch with us if you would like some more information.

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