Project Title: Comparative Effectiveness of Socket Casting Methods: Improving Form and Fit

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Permission to Take Part in a Human Research Study

Title of Research Study: ***Comparative Effectiveness of Socket Casting Methods: Improving Form and Fit***

Investigators: ***Steven Gard, PhD at Northwestern University***

Supported By: This research is supported by the Department of Defense.

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

If your prosthetist is also involved in this research study, please note that he is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have a lower limb amputation and use a prosthesis to stand and walk.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

This research is being done to understand if a new method of taking a cast of your amputated limb can improve socket fit and function. Traditionally a cast of the amputated limb is made while you are seated and plaster bandages are wrapped around your limb and massaged by the prosthetist. The cast then has to be filled with plaster and the resulting model further sculpted to a shape that will evenly distribute pressure over your amputated limb when standing and walking. It is challenging with this approach to achieve totally even pressure distribution in the socket and subsequent modifications during the check socket fitting are required to ensure a comfortable fit is achieved. A newer method of standing pressure casting with a water cylinder has been proposed to make this process of taking a cast more consistent and efficient. By standing in a pressurized water cylinder while the plaster cast is taken, even pressure distribution over the amputated limb is achieved without any need for subsequent sculpting of a plaster model. The check socket should therefore fit comfortably without additional modifications. This study will test whether the new pressure casting system is better than hand casting in terms of achieving a more comfortable initial socket fit.

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How long will the research last and what will I need to do?

We expect that you will be in this research study for 3 weeks.

You will be asked to allow two prosthetists to make four casts of your amputated leg using two casting techniques (two hand casts and two standing pressure casts) and then allow one of these two prosthetists to fit two check sockets, one made using each of the casting techniques.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

Is there any way being in this study could be bad for me?

It is possible that the new standing pressure casting procedure will be more difficult for you than the typical casting procedure which is done in a seated position. The main risk from participating in the study is that you might fall while maneuvering your amputated limb into and out of the pressure cylinder during the casting process. We will minimize this risk by providing something for you to hold onto while you are standing.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

Will being in this study help me any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include the fabrication of a more comfortable fitting check socket which could be used by your prosthetist to make you a new definitive socket if you are in need of one as part of your clinical care.

Results of study participation will not be shared with participants or their primary care provider as it is unlikely that subjects would benefit medically or otherwise from the information.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at at 312-503-5718. This is the phone number for Dr Steven Gard, the lead investigator at Northwestern University.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.

- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

This is a multi-site study with Northwestern University as the primary site and coordinating center. The other sites participating in this study are the Minneapolis VA Health Care System and INAIL (Italian Workers Compensation Authority) in Italy. The study will last 3 years and we expect about 30 people to be enrolled at eachsite out of 90 people in the entire study internationally.

What happens if I say "Yes, I want to be in this research"?

Study visits will take place at the Northwestern University Prosthetics-Orthotics Center (NUPOC) located at 680 N Lake Shore Drive, Suite 1100, Chicago IL 60611 or the Scheck and Siress Hanger Clicnic located at 1701 Woodfield Rd Suite 555, Schaumburg IL 60173.

The process for casting and fitting check sockets is the same as the standard-of-care clinical process you have previously experienced when receiving a new prosthetic socket.

You will be required to participate in 3 study visits.

Visit 1: At the first visit, we will collect information about you including your age, gender, height, weight, smoking history, whether you have diabetes, the cause of your amputation, and time since your amputation. Additionally, your functional mobility, residual limb length and tissue type (soft/firm), sensitivity or painful areas on the residual limb, and current socket/prosthesis design will be assessed. This visit should take approximately 2 hours.

Visit 2: At the second visit, two prosthetists will take four casts of your amputated limb. Each prosthetist will cast your limb using the hand casting and standing pressure casting techniques. The order in which these casts will be taken will be randomly determined (e.g. by flipping a coin). The time it takes to complete each cast will be timed by a research assistant. This visit should take approximately 3 hours.

Visit 3: At the third visit, one of the prosthetists will fit a check socket made from each of the casting techniques. The order in which these sockets will be fit will be randomly determined (e.g. by flipping a coin). You and the prostheitsts will not be told which socket was made with which casting technique. You will be asked to put on each socket. The amputated limb and socket will then be placed on a sturdy surface and you will be asked to place as much weight as you can tolerate on amputated limb. The amount of weight placed on the amputated limb will be recorded using a bathroom scale placed under the socket. While you are in this position, you will be asked to rate socket comfort on a 10 point scale, where 0 is the least comfortable socket you can imagine and 10 the most comfortable socket you can imagine.

The prosthetist will then assess the socket fit using a standardized check list. To achieve a satisfactory socket fit, the prosthetist may make modifications to the socket. If the socket fit is deemed to be unsatisfactory, the prosthetist may choose to re-make the socket. Socket modifications and number of re-makes, along with the time taken to achieve a satisfactory socket fit will be recorded by a research assistant.

Once you and the prosthetist are satisfied with the fit of the socket, you will again be asked to put on the socket and place as much weight as you can tolerate on the amputated limb. The amount of weight placed on the amputated limb will be recorded along with your rating of socket comfort will be recorded.

This process will then be repeated for the other check socket. This visit should take approximately 4 hours.

If you indicate in the **Optional Elements** section below that you agree, we may contact you for future research participation.

The research prosthetist may audio or video record you to aid with prosthetic fitting and troubleshooting. Agreement to be recorded is not required for participation in this research. You may indicate in the **Optional Elements** section below if you agree to allow the research prosthetist to take audio and video recordings and, if so, how they may be used.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for attending all study visits and providing feedback on the socket fit and comfort.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are otherwise entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical and prosthetic treatment.

Any data collected up to the time you leave the research study will be kept and used by the investigator as part of the study.

Detailed Risks: Is there any way being in this study could be bad for me?

Being in this study will expose you to many of the same risks as you are regularly exposed to by being a person with a lower limb amputation who uses a prosthesis:

(1) The standard clinical process of making a prosthetic socket involves some loss of modesty given the need for the research prosthetist to touch your residual limb.
(2) It is possible that the new standing pressure casting procedure will be more difficult for you than the typical casting procedure which is done in a seated position. The main risk from participating in the study is that you might fall while maneuvering your amputated limb into and out of the pressure cylinder during the casting process. We will minimize this risk by providing something for you to hold onto while you are standing.
(3) It is also possible that the skin on your amputated limb may become irritated from multiple socket casting and check socket fittings. The amputated limb will be checked frequently during each study visit by the prosthetist to ensure that irritation or rubbing are dealt with as they would be clinically. Any red marks should resolve within a few minutes of cast and check socket removal. If they do not and if the prosthetist is concerned, then the testing session will be terminated if there are no other means of addressing the irritation or rubbing.

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This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will it cost me anything to participate in this research study?

Taking part in this research study will not lead to any costs to you.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a more comfortable check socket since that is the intent of developing a better casting technique.

Since the check sockets made for this study are made to uniquely fit you, you will be allowed to keep the one that fits best at the end of the study. However, you would need to take that check socket to your prosthetist in order to continue the process of receiving a new socket based on that fitting. The research team is not responsible for anything you chose to do with your check socket.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution, the US Department of Defense (DOD), and the DOD Human Research Protections Office. If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Results of the proposed work will be published in peer-reviewed journals and presented at national and international meetings. Publications and presentations will contain summary statistics.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Data collected will be coded using a six-digit identifier based on the following rubric: site # and subject #. Subjects data will be coded sequentially based on enrollment using a two-digit code, e.g., 01, 02, etc. Subjects will be assigned a study code at enrollment and all study related forms/files will be labelled only with the study code. Despite these measures, we cannot guarantee anonymity of your personal data.

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Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include failure to attend study visits without notice.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

If you become ill or are injured as a result of this study devices or procedures you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the researchers about any illness or injury.

The university will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

If you agree to take part in this research study, we will pay you $50 per visit up to a total of 3 visits for your time and effort. We only pay for the study visits completed. You will be paid by check upon completion of the study. We can also provide discounted parking passes for the 222 Huron Street Parking Garage for study visits that take place at NUPOC.

The Accounting Services at Northwestern University will be given your name, address, and Social Security Number in order to issue a check for your study participation. Study payments are considered taxable income and reportable to the IRS. A Form 1099 will be sent to you if your total payments are $600 or more in a calendar year.

Optional Elements:

The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

I agree	I disagree	
_____	_____	The researcher may audio or video record me to aid with prosthetic fitting and troubleshooting. The researcher will not share these recordings with anyone outside of the immediate study team.
_____	_____	The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification.
_____	_____	The researcher may contact me in the future to see whether I am interested in participating in other research studies by the Principal Investigator of this study.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent