SoftHand Comparison Study

NCT05328934

June 2, 2025

MAYO CLINIC

Name and Clinic Number

Approval Date: **June 2, 2025**
Not to be used after: **June 1, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Toward use of the synergy-based SoftHand Pro for activities of daily living by persons with transradial limb loss: A multi-site clinical trial

IRB#: 21-005070

Principal Investigator: Kristin Zhao, Ph.D., and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to compare the performance of two prosthetic devices and observe how quickly people improve in grasping and manipulation tasks with each device. You have been asked to take part in this research because you have upper extremity (arm) limb loss.
What's Involved	Study participation involves a few in-clinic testing and assessment visits using your own prosthetic and one of the two study prosthetics (determined randomly), followed by an 8-week take-home trial of the study prosthetic. At the end of this take-home trial, tests and assessments will be repeated.

	After a 4-week washout period, testing and assessment will be repeated, this time using the other study prosthetic (the one you didn't use in the first take-home trial). At the end of this take-home trial, tests and assessments will again be repeated.
Key Information	The primary inconvenience of this study is the time commitment involved. Participation involves several lengthy clinic visits as well as extended at-home use of the study's prosthetic devices. The study team will strive to accommodate work schedules and life circumstances as much as possible.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Kristin Zhao, Ph.D. **Phone:** (507) 284-8942 **Study Team Contact:** Tyson Scrabeck **Phone:** (507) 538-1016 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

A description of this research study will also be available on http://www.mayo.edu/research/clinical-trials. This Web site will not include information that can identify you. You can search this Web site at any time.

Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have experienced upper extremity (arm) limb loss.

Why is this research study being done?

The purpose of this study is to compare peoples' performance with two myoelectric prosthetic devices, the experimental SoftHand Pro (SHP) and the commercially available Össur i-Limb, and to observe the rate of improvement in grasping and manipulation tasks with each device.

Information you should know

Who is Funding the Study?
The National Institutes of Health (NIH) is funding the study. The NIH will pay the institution to cover costs related to running the study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

It will take you about 5 months to complete this research study. During this time, we will ask you to participate in about 8-10 study visits. The majority of your participation will involve the use of the SHP and i-Limb during activities of daily life in and outside the home.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

Pre-trial visits (1st)
These visits will take place over the course of 1 or more days, depending on your availability and other factors affecting the research. Visits can be conducted at our laboratory, or you may choose a different place to conduct the visits, such as your home, at your preference. If you choose to conduct visits off-site, one or more study staff members will travel to your choice of locales, up to 120 miles away from the study site closest to you.

During the first visit, a prosthetist from Hanger Clinic will assess your existing socket for proper fit and suitability for the study. Because of the novel batteries associated with the test hand, a second forearm section may need to be made for your prosthesis. This may require you to meet the prosthetist at the local Hanger Clinic laboratory.

We will assign you by chance (like a coin toss) to begin the study first with either the SHP or the i-Limb. You and the Principal Investigator can't choose which device you start with. You will have an equal chance of being assigned to either device first.

The second visit will involve baseline testing using your existing prosthetic. These tests consist of grasping and manipulating a variety of small objects to assess your coordination, dexterity, and function. We will also ask you to fill out questionnaires asking about your quality of life and your own assessment of your ability to function in daily activities. Then you will take some time to practice with the device you were randomized to, to help you get used to the new device. Finally, study staff will train you in the use of the new device for use in activities of daily living, as well as some basic troubleshooting and maintenance instruction. This visit will take about 6 hours.

The third visit will involve baseline testing using the new device. This testing will be the same as the grasping and manipulating testing from the second visit, except it will be done with the new device. If you experience pain due to brachial plexopathy or neuropathy, you will be asked to rate your pain in the arm which is using the experimental hand before and after testing. This visit will take about 6 hours.

We will collect some demographic information from you which will help us analyze results, such as how long it has been since your limb loss, and which hand was dominant prior to your limb loss.

Home trial with first prosthetic device
You will take home the device you were randomized to start the study with for a period of 8 weeks. You will need to wear and use the device for daily activities for at least 50% of each day while you are awake. Instructions will be provided regarding what kinds of activities to avoid while wearing and using either prosthetic; these instructions are the same as you would receive for other commercially available devices. Study staff will be available during the entire study to answer any questions and troubleshoot problems; based on your preference, and the issue at hand, consultation could be done via telephone, Zoom, or in-person.

After the first week, you will be contacted to provide feedback and discuss any adjustments needed with the device or suggestions for how to use it.

At the end of weeks 2 and 5, study staff will visit you at your home or a place of your choosing to download usage information from the prosthetic. You will also be asked to fill out four short questionnaires about your physical function and symptoms.

Post-trial visit (1st)
At the end of the 8-week period, you will perform the same series of tests and questionnaires you did at the second visit and the end of weeks 2 and 5, after which you will return the experimental hand. This visit will take about 6 hours.

Washout period
After you complete a trial with the first device, you will have a period of 4 weeks where you will be asked to go back to using your personal prosthetic device as normal.

Pre-trial visits (2nd)
At the end of the 4-week washout period, you will repeat the same series of tests and questionnaires, this time using the device you did not use during the first trial (the second device).

During the first visit, you will take some time to practice and get used to the second device. Then, study staff will train you in the use of the second device for activities of daily living, as well as some basic troubleshooting and maintenance instruction. This visit will take about 3 hours.

The second visit will involve baseline testing using the second device. This testing will be the same as the testing from the pre-trial visit with the first device, except it will be done using the second device.

Home trial with second prosthetic device
All of the events and activity that happened during the first take-home trial will be repeated during another 8-week period, this time using the second device.

Post-trial visit (2nd)
At the end of the second 8-week period, you will perform the same series of tests and questionnaires you did during the post-trail laboratory visits with the first device, after which you will return the experimental hand.

During the functional testing visits, you will be video recorded while performing the assessments. These videos and still-shots from the videos, which may include your full face image, will be shared with study team members from Arizona State University, Hanger Clinic, and the Italian Institute of Technology, and will assist the researchers in assessing outcome measures, troubleshooting and technical support, and interpreting and reporting the results. Images from the session may be used as part of a presentation or publication; if used, any personally identifying features will be blurred or cropped out.

What are the possible risks or discomforts from being in this research study?

The risks of this research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life. As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. It is for the benefit of research. However, others with upper extremity limb loss may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study.

These tests and procedures are:

- visits and consultations
- socket fabrication
- biomechanical testing
- questionnaires

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will be provided with passes for parking in Mayo Clinic facilities during study visits.

Additionally, you will be paid up to $2,000 for participating in the study; $1,000 for each half of the study you complete. If you are not able to complete the study, you will be paid $150 per visit completed. If you are able to complete the entire study, you will receive $2,000.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information collected in this study, allowing the information to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. To safeguard your confidentiality, data obtained will be coded, research materials will be stored in cabinets accessible only to the study staff, and digital data will be kept on secure computer servers.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT

stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Authorization to Use and Disclose Protected Health Information (HIPAA)
During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Researchers involved in this study at other institutions.
- Representatives from Arizona State University, Hanger Clinic, and the Italian Institute of Technology.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building, PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.+++++++

	/ /	: AM/PM
Printed Name	Date	Time

Signature