If appropriate for this study, a scanned copy of the signed consent form should be uploaded to the participant's Epic/EMR record.

Patient I.D. plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: Evaluating Myoelectric Pattern Recognition for Improved Prosthesis Control

Application No.: IRB00256686

Sponsor/Supporter/Funded By: National Institutes of Health

Principal Investigator: Nitish Thakor, Ph.D.
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You are being asked to join a research study. Participation in this study is voluntary. Even if you decide to join now, you can change your mind later.

1. Research Summary (Key Information):

The information in this section is intended to be an introduction to the study only. Complete details of the study are listed in the sections below. If you are considering participation in the study, the entire document should be discussed with you before you make your final decision. You can ask questions about the study now and at any time in the future.

The purpose of this study is to investigate ways to improve the use and stability of prosthetic limbs. Specifically, we are evaluating a strategy called pattern recognition. The study will include both amputee and non-amputee subjects; you are being asked to take part in this study because you have unilateral or bilateral transradial amputee or transhumeral limb loss. If you choose to join the study, you will be asked to participate in one or more of the following: a short-term assessment protocol spanning one or multiple 30 minute-2 hour training sessions, a long-term assessment evaluation that will involve taking the a prosthesis home for 1-16 months, a functional task assessment that should last no more than 3 hours, and a series of subjective questionnaire that will take 30 minutes or less to complete.

There is no direct benefit to you from participating in this study. There are minimal risks expected in this study, which are described in more detail later in this consent form. You will be paid for your participation in this study depending on which assessments you complete.

2. Why is this research being done?

This research is being done to study methods to improve the stability of an emerging myoelectric prosthesis control strategy called pattern recognition. A myoelectric prosthesis is an artificial limb that is controlled by the nerve signals from a person's muscles, but uses an outside source for its power. Specifically, in this study we are evaluating different methods to improve performance. We will measure the accuracy, stability, and efficacy of these methods.

Are there any investigational drugs/devices/procedures?

Multiple different devices will be used in this research study including controllers, electrodes, and sensors. The use of these devices in this research study is investigational. The word "investigational" means that the devices are not approved for marketing by the Food and Drug Administration (FDA). All of the devices being used in this study are considered non-significant risk.

Who can join this study?

In this study, we will enroll both amputees and non-amputees who are 18 years of age or older. You are being asked to take part in this study because you have unilateral or bilateral transradial amputee or transhumeral limb loss.

3. What will happen if you join this study?

If you agree to be in this study, we may ask you to participate in one or more of the following study activities:

Short-Term Assessment Protocol:

You will be asked to come for one or multiple sessions lasting about 30 minutes to 2 hours at a mutually agreed upon time. For most subjects this period will last no more than a total of 12 hours over 4 weeks. This will take place at The North Charles Building, Johns Hopkins University, at Johns Hopkins Hospital, or at the office of Infinite Biomedical Technologies.

The purpose of the experiment is to collect preliminary electromyography (EMG) data. This data will be used to train next-generation pattern recognition control strategies while also familiarizing the subject with how to produce reliable movements with a pattern recognition system. You will wear a cuff that looks like an arm band that has been fitted with electrodes to record muscle signals on the surface of the skin. The cuff serves to apply a small amount of compression that keeps the electrodes in the same place relative to the skin surface. You may also be asked to wear multiple tracking markers which allow us to determine your limb and finger positions in space relative to your body. Once the electrodes and tracking markers are attached properly, you will be asked to perform the following tasks:

- Train a movement classification algorithm either by mimicking cues on a computer screen or by performing motions from a specified subset in a freeform manner. These will consist of elbow, wrist, and hand motions (specifically a variety of common grasps) that should be performed with your phantom limb.
- Attempt to reproduce the set of trained grasps while controlling a virtual or physical prosthetic limb.
- Attempt to control a virtual or physical prosthetic limb to interact with simple household objects.

This preliminary recording may consist of multiple sessions on the same day. Regardless of the amount of sessions required, the total amount of time spent in the experiment should not last more than twelve hours. You may be asked to wear the disconnected electrodes and tracking markers in between sessions to test the stability of the movement classifier over the course of multiple sessions. You may or may not be coached by a study team member regarding the way in which pattern recognition algorithms decode movements. The study team member may guide you through multiple periods where data will be collected to train the pattern recognition system. You will train a movement decoder, observe the decoder's strength, and learn how to make it more reliable.

Long-Term Pattern Recognition Evaluation:

You may be asked to participate in a long-term study of a pattern recognition enabled prosthesis. You will be provided with a custom fit myoelectric prosthesis instrumented with an embedded proportional or pattern-recognition controller and training software installed on a laptop/tablet to take home. Prior to receiving the pattern recognition prosthesis, you may be trained to help strengthen your muscles. This pre-prosthetic training period will be no longer than 1 month.

Prior to taking the system home, you will be provided with some instruction and training on the use of the prosthesis in the clinic. This training period will take 1-2 days and will take place at a prosthetic clinic.

You will be asked to use the prosthesis daily over the course of 1 – 16 months. You will be asked to return to the study site and complete standardized functional tests at set intervals throughout the study period.

After the completion of the initial time period, you will return to the study site and will be provided with a different proportional or pattern recognition controller. If it did not occur in the first stage you may be trained to help strengthen your muscles. This pre-prosthetic training period will be no longer than 1 month. Prior to taking the system home, you will be provided with some instruction and training on the use of the prosthesis in the clinic. This training period will take 1-2 days and will take place at a prosthetic clinic. As with the first period, you will be asked to use the prosthesis daily over the course of 1 – 16 months. You will be asked to return to the study site and complete standardized functional tests at set intervals throughout the study period.

Each day, after putting on the prosthesis, you may choose to run through a training protocol using the provided software. You will choose the hand, wrist, and/or elbow movements that you wish to use that day. You will then mimic cues on the computer screen to train the pattern recognition algorithm and practice virtual movements to ensure a satisfactory level of control. If prosthesis control becomes unsatisfactory during use, you have the option to retrain using the software.

During the entire take-home period, the system may monitor your daily prosthesis usage. Specifically, it will monitor and log the time stamped surface EMG input and prosthesis functions used. Additional limb and finger tracking information may also be recorded when required. You may be asked to log on to provided software on a regular basis to download the data onto a PC or phone application. This process will take no more than 5 minutes. This data will be de-identified and will be retrieved by the study team during visits to the study site. You may also be asked to perform a virtual evaluation at regular intervals to document changes in control over time. You will then disconnect from the computer and go about normal daily activities while using the prosthesis. You also may be asked to complete a short feedback survey/log to document use and any issues experienced throughout the day.

At the end of the study, you will return to the study site for final performance measurements and will return the pattern recognition equipment. If you have any issues at any time with the system during the take-home period, please contact the principal investigator, Nitish Thakor, at (443) 336-8500 for additional support.

Functional Tasks with a Pattern Recognition Prosthesis:
This experiment will be conducted to test the level of control that you are able to achieve with a pattern recognition-controlled prosthesis. You will put on a custom fabricated prosthesis or a generic socket and complete various tasks. Tasks include: "box and blocks" (moving small blocks across a barrier); "reach-grasp-release" tasks (moving various sized objects from one area to another); "target achievement control" (acquiring a specific grasp with a specific proportionality); and activities of daily living rooted in functional outcome measures designed for upper-limb disabilities, such as the "Southampton Hand Assessment Protocol" (SHAP).

You may be outfitted with motion tracking sensors or be tracked by a camera-based motion tracking system during the performance of the task. You may be connected through a cable or wirelessly to a computer for data collection. Our goal is to complete these tasks in a single day, but you may be asked to return on subsequent days for additional testing.

Overall completion time of a functional assessment is not expected to exceed 3 hours.

Subjective Questionnaire(s)
You may be asked to complete questionnaires to evaluate your satisfaction with the prosthesis control strategy, as well as its performance and functionality based on your personal experiences. For example, they will ask you to rate the difficulty of different activities involving the prosthesis.

You will be asked to sit on a chair in front of a table. You will be handed up to seven questionnaires and the study staff will provide a brief overview of the questionnaire(s). You will then be given as much time as needed to complete the questionnaire(s). At any time, you will be allowed to ask the study staff any questions about the questionnaire(s). You may be asked to complete these questionnaires several times during the study.

Overall completion time of questionnaire(s) is not expected to exceed 30 minutes.

Equipment:
EMG signals will be recorded from electrodes placed in either a compressive arm band worn on your arm or a custom-fitted prosthetic socket. Tracking instruments may be attached to the outside of the arm or fingers. Data will be transferred to a computer and stored for further offline analysis at a later time.

If possible, if you would like to try your current myoelectric prosthesis using pattern recognition control, you may volunteer to have an interchangeable controller introduced to your current prosthesis or simply connect the silicone electrode cuff to another prosthesis to see pattern recognition capability in a practical setting. We will have functional test platforms available for you to compare your virtual prosthesis performance to your actual prosthesis performance. Again, this testing will consist of basic object manipulation tasks.

For long term testing with your myoelectric prosthesis, we may need to add additional electrodes to the socket in order to interface with the pattern recognition controller. The additional electrodes should not add discomfort.

Will research test results be shared with you?

This study involves research tests that we do not expect will be useful for your clinical care. We will not share these results with you.

How long will you be in the study?

You will be in this study for up to four weeks. If you choose to participate in the long-term, at-home study, you will be enrolled for 1-16 months.

4. What happens to data that are collected in the study?

If you join this study, your data will be used to answer the research question and publish the findings of this study. You will not own your research data. If researchers use your data to create a new product or idea, including those that may have commercial value, you will not benefit financially from those efforts.

Johns Hopkins researchers and their collaborators may use the data collected in this study for future research purposes and may share some of the data with others.

Sharing data is part of research and may increase what we can learn from this study. Often, data sharing is required as a condition of funding or for publishing study results. It also is needed to allow other researchers to validate study findings and to come up with new ideas. Your data may be shared with researchers at Johns Hopkins and other institutions, for-profit companies, sponsors, government agencies, and other research partners. Your data may also be put in government or other databases/repositories.

Because science constantly advances, we do not yet know what future use of research data may include. This future research may be unrelated to the current study and may include outside collaborators.

We (Johns Hopkins) will do our best to protect and maintain your data in a safe way. One of the ways we protect data is by limiting the uses of the information and the type of information that is shared, especially your personal information. This may occur through data sharing agreements and review by oversight groups within Johns Hopkins.

If data are used or shared with types of information that may be likely to identify you, such as your name, address or medical record number, further institutional review and approval would be required. In these cases, Johns Hopkins will review whether additional consent from you is required.

Generally, if your data are used/shared without any personal identifiers or with information that is less likely to identify you (such as the date of a procedure), further review and approval is not needed.

Data sharing could change over time, and may continue after the study ends.

The use and sharing of your data is required for participation in this research study. If you are not comfortable with the use and sharing of your data in future research without further consent, you should not participate in this study.

5. What are the risks or discomforts of the study?

The risks associated with the testing or training sessions are comparable to those of everyday living. Possible risks include the following:

Computer Tasks

You will be viewing a computer screen and making simple arm and hand motions for no more than five minutes at a time with about half of each data collection session consisting of "rest" movements in which you will be instructed to relax the tested arm and hand.

EMG

The risks of the EMG sessions include the possibility of slight skin irritation at the site of electrode cuff placement and slight discomfort when the electrode cuff is removed if one or more electrodes stick to body hair.

The cuff can be tight fitting, and to prevent unnecessary discomfort, several cuffs of various sizes are available to achieve both comfort and the desired compression that prevents electrode displacement. This is more desirable than the repeated application and removal of adhesive disposable electrodes.

Long-term Evaluation

If you choose to participate in the long-term study, but do not typically wear a prosthetic device, you may become fatigued from the extra weight or experience discomfort from normal sweat build-up in the socket. This discomfort will decrease as you become more familiar with wearing a prosthesis full-time.

Interviews or questionnaires

You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

Identifiable private information

There is the risk that information about you may become known to people outside this study.

6. Are there benefits to being in the study?

There is no direct benefit to you from taking part in this study. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

You may be paid depending on which experiments you complete. You will receive $20 to $50 for each session completed (for a maximum of $200). You will also be reimbursed for travel expenses. Payments will be in the form of petty cash, a gift card, or an anonymous prepaid visa card.

You may be required to provide your social security number to be paid for taking part in this study. Federal tax law requires that you report your research payments when you file your taxes. If your total

payments from Johns Hopkins exceed $600 per year, Johns Hopkins will report these payments to the Internal Revenue Service and you will receive a 1099-MISC form from us.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or share your health information that it has already collected if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You fail to follow instructions.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

12. How will your privacy be maintained and how will the confidentiality of your data be protected?

HIPAA Authorization for Disclosure of Protected Health Information

What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Johns Hopkins Medicine and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff who may be a part of Johns Hopkins Health System, Johns Hopkins University or the Johns Hopkins Applied Physics Laboratory. Additionally, we may share your information with other people at Johns Hopkins, for example if needed for your clinical care or study oversight. To improve coordination of your research and clinical care, some information about the study you join will be included in your electronic medical record.

By signing this form, you give permission to the research team to share your information with others outside of Johns Hopkins. This may include the sponsor of the study and its agents or contractors,

outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team.

We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

How will your information be protected?
Data will be safeguarded by restricted access to testing sites as well as with removal of subject names from testing information. Only randomly assigned numbers will be used to associate performance with an individual. This disassociated data will be available to all study team members. A key, relating subjects to assigned numbers, will be maintained in a secure location by a co-investigator and verified by the principal investigator.

13. What is a Certificate of Confidentiality?

Your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

14. What does a conflict of interest mean to you as a participant in this study?

A researcher has a financial or other interest in this study.

In some situations, the results of this study may lead to a financial gain for the researcher and/or Johns Hopkins University. This financial interest has been reviewed in keeping with Johns Hopkins' policies.

It has been approved with certain conditions, which are intended to guard against bias in how the study is conducted, how the results are analyzed, and how participants are protected.

If you have any questions about this financial interest, please talk to Rebecca Greene at (973) 796-4423. This person is a member of the study team, but does not have a financial interest related to the study. You may also call the Office of Policy Coordination 410-361-8667 for more information. The Office of Policy Coordination reviews financial interests of researchers and/or Johns Hopkins.

15. What other things should you know about this research study?

During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.

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. If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

What is the Institutional Review Board (IRB) and how does it protect you?
This study has been reviewed by an Institutional Review Board (IRB), a group of people that reviews human research studies. The IRB can help you if you have questions about your rights as a research participant or if you have other questions, concerns or complaints about this research study. You may contact the IRB at 410-502-2092 or jhmeirb@jhmi.edu.

What should you do if you have questions about the study?
Call the principal investigator, Nitish Thakor at (443) 336-8500. If you wish, you may contact the principal investigator by letter. The address is on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-502-2092.

16. Optional Study Components:

This part of the consent form is about optional component(s) of the study that you can choose to take part in or not. You can still take part in the main study even if you say "no" to this/these optional component(s).

Future Contact
We would like your permission for our research team to contact you in the future. Please note that your decision below does not prevent other researchers at Johns Hopkins from contacting you about other research.

Please sign and date your choice below:

YES ☐ _____ _____
Signature of Participant Date

No ☐ _____ _____
Signature of Participant Date

17. What does your signature on this consent form mean?

Your signature on this form means that you have reviewed the information in this form, you have had a chance to ask questions, and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR AND A COPY MUST BE GIVEN TO THE PARTICIPANT. IF APPROPRIATE FOR THIS STUDY, A SCANNED COPY OF THE SIGNED CONSENT FORM SHOULD BE UPLOADED TO THE PARTICIPANT'S EPIC/EMR RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).