Functional Outcomes of Dexterous Fingertip Prosthesis for Partial Hands

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1. Background and Introduction

Liberating Technologies, Inc. (LTI) has developed a dexterous prosthetic fingertip that will be fit onto an existing partial-hand prosthesis and allow for an additional fine grasp. The device will interface with research participant's existing prostheses and use the same control strategy that is used for their everyday use.

2. Study Rationale

Research participants will conduct functional tasks with and without the dexterous fingertip prosthesis in order to evaluate the utility of the device.

The rationale for this study is to compare the functional outcomes of a dexterous prosthetic fingertip prosthesis to a standard partial hand prosthesis.

3. Objectives

The primary objective of this study is to test the functional outcome measures of a dexterous prosthetic fingertip prosthesis as compared to a standard partial hand prosthesis.

Partial hand prosthesis users will be recruited for the study and consented with an approved protocol. Research participants will schedule a time to conduct the testing and be informed of study details.

Functional outcome tests will be used to guide tasks for participants to manipulate everyday objects. Performance measures will be scored for each device.

4. Study Design

This study will pilot test the dexterous fingertip prosthesis with a small number of subjects (5-10). The study will be conducted in a single site visit at Össur Academy in Dublin, Ohio or LTI in Holliston, MA. Subjects may be asked to come back for an additional site visit if data collection hasn't been completed.

Partial hand prosthesis users will be recruited for the study and consented with an approved protocol. Research participants will schedule a time to conduct the testing and be informed of study details. Both new and experienced partial-hand prosthesis users will be targeted.

Up to two different technologies will be assessed:

- Hand configurations
    - Partial hand + dexterous fingertip
    - Partial hand (patient's usual configuration)

Researcher participants will use the prosthetic devices to manipulate common objects as a test of dexterity and utility. Functional outcome measures, such as the Jebsen-Taylor, SHAP, and Peg Board tasks, will be utilized to standardize and evaluate these tasks. Testing will be conducted and scored by occupational therapist standards.

5. Study Population

Persons with partial hand limb absence who are current prosthesis users will be recruited for this study through the LTI and Össur clinician network. Prosthetists may be contacted with the need for research subjects and, if interested, will be given flyers to hand out to their patients. If subjects are interested in participating, they can call the number on the flyer and speak with the investigators. In addition, previous research participants who have given permission to be contacted for future studies may be contacted directly to assess interest in participating in this study.

A minimum of 5 subjects will be recruited for this study.

6. Participant Eligibility

Research participants must be 18 years or older and must be current users of partial hand prostheses. Users who utilize myoelectric partial hand prostheses will be preferred. Patients who have at least 4-5 digit involvement will be targeted.

The subjects must be able to read, write, and speak English in order to be properly consented and to express their thoughts to the study personnel, and they must be willing and able to complete the activities outlined in the study.

Subjects in this study will not be discriminated by sex or race.

The risks to pregnant people and fetuses are unknown and therefore pregnant people should not participate in the study and will be screened by self-disclosure.

7. Study Methodology

Subjects will be introduced to the partial hand prosthesis configuration and be instructed on how to operate it to complete functional outcome tasks.

1. After informed consent is obtained, subjects will be scheduled for a single site visit to Össur Academy or LTI.
2. For this study, participants will use their existing everyday prosthesis to interface with the partial hand prostheses being tested.
3. At the start of the study session, subjects will doff their prosthesis and the dexterous prosthetic fingertip will be added onto their index finger.
4. Subjects will be provided with and don the prosthetic device being tested. Subjects will be trained on how to operate the dexterous fingertip gripper and be allowed time to practice using it until they are comfortable to proceed.
5. The devices will be tested in a randomized order and include the following configurations:
    a. Dexterous fingertip on a partial hand prosthesis
    b. Partial hand prosthesis (without the dexterous fingertip)
6. Subjects will be guided and conduct functional outcome tests that involve picking up and placing everyday objects (beans, coins, pegs, spoon, cloth, etc.), such as the tasks outlined in the Jebsen-Taylor and Peg Board functional tests. Each sub-task in the functional test will be scored by occupational therapist standards.
7. After a round of functional testing is done, subjects will doff the prosthesis and don the next device configuration.
8. Subjects will repeat the functional tests with each device configuration. After the final condition, the subject will have completed the study.

The study session should span 3-5 hours.

8. Study Conduct

Subjects will be consented and screened for eligibility criteria. If they decide to participate, they will schedule a time to conduct the study session at Össur Academy in Dublin, OH or LTI in Holliston, MA.

Subjects may withdraw at any time by simply telling the investigators they wish to stop their participation.

If a subject withdraws from the study, the data that were collected from them can still be used, and the withdrawn subjects may be replaced with a new subject. Deviations from the protocol that increase risks for subjects will be reported to New England IRB for approval prior to being implemented.

Subjects will be compensated $50/hour for the time spent participating in the study. For an anticipated total time of 4 hours, the total payment would be $200. Any travel for study events will also be reimbursed for by mileage at the IRS rate per mile driven.

9. Study Treatment

This study is not a means of providing any sort of medical treatment to its participants. The purpose of the study is to evaluate a dexterous fingertip prosthesis with functional outcome measures. No drugs will be administered to the participants.

10. Evaluation of Adverse Events

Based on past testing and data collection, no adverse events are expected. Adverse events could include muscle fatigue from the functional outcome tests. Participants will be encouraged to pause the testing if they experience any fatigue or discomfort in their muscles.

All unanticipated problems involving risk to subjects or others, serious adverse events related to participation in the study and subject deaths related to participation in the study will be promptly reported to the New England IRB (NEIRB). A written description of the adverse event will be stored in the study file maintained by the Principal Investigators. Also, the protocol will be reviewed in light of the adverse event to determine if modifications need to be made to prevent the event from occurring again. Major modifications to the research protocol and any modifications that could potentially increase risk to human subjects must be submitted to the NEIRB for approval prior to implementation.

11. Ethical Considerations

There is no direct benefit to the user.

The protocol, consent form, and recruitment flyer will require IRB review and approval. The principal investigator will be in continuous communication with New England IRB and will forward information to the co-investigators. Subjects' participation is voluntary and they may withdraw from participation in the study at any time by simply telling any one of the investigators that they wish to stop. The investigators may choose to terminate a subject's participation if the subject experiences discomfort or injury or if significant findings either good or bad develop during the course of this study. If they desire to do so, subjects' will also have the option to discuss any concerns regarding the study activities or the investigators with an impartial staff member of the New England IRB, whose duty is to hear and review such concerns and provide advice or take any other appropriate actions.

The investigators will ensure the anonymity of all participants in this study. After completing the consenting process, subjects will be assigned a random identification number. The number will be used on all test data associated with the subject. No personal identifiers will be associated with the data collected from the subjects during the various tests. The PI will have a master document linking the subject name with ID number, and it will be stored on a password protected computer, with only the PI and co-investigators having access to the master list. Test data will be kept at the test sites and stored in a secure manner depending on the media: either a password protected computer with access limited to the co-investigator, or in a locked filing cabinet in the investigator's office. A copy of the test data will also be retained by the PI in the program folder, also stored in a secured manner.

12. Study Monitoring and Oversight

The oversight of the study falls on the co-investigators. They will be responsible for ensuring the study follows the approved protocol and for reporting any deviations or adverse events that occur during the study to New England IRB. De-identified data, photos, and videos will be kept indefinitely to show in scientific presentations and publications. Photos will not contain any identifying information about the subject. The photographs will not include the subject's face or any identifying marks such as tattoos. If identifying photographs happen to be received from a subject, they will be immediately de-identified by either cropping or blurring using photo-editing software.

Additionally, representatives of the United States National Institutes of Health are eligible to review research records as a function of their responsibility to protect subjects in research.

13. Investigational Product Management

The technologies tested in this study are systems that interface with the research participants' existing prostheses. Users will be eliciting the same control strategy that they would use to control their usual partial hand prosthesis. The technologies in this study will test various configurations that connect to participants' existing prosthetic hands using standard prosthetic connections.

Dexterous Fingertip Prosthesis

LTI has designed a dexterous fingertip prosthesis that will be added on to an existing partial hand prosthesis. The device is a mechanical replacement for the pointer finger in a prosthetic partial-hand. The device will allow for a grasp designed for small objects and fine-motor tasks. Users will be instructed on how to use the dexterous fingertip and the modified hand that it resides on.

i-Digits

The commercially available i-Digits Access/Quantum partial hand prostheses will be used in the study. A configuration of the hand will have the above dexterous prosthetic fingertip in place of the standard pointer finger. Users unfamiliar with controlling this device will be instructed and allowed to practice.

14. Data Analysis

The study will compare the how well subjects score on the functional tests with the different partial hand prosthesis configurations. Functional tasks will be scored based on measures such as time to complete a specified task.