Title: A Unique Body-Powered Terminal Device With Enhanced Grasping Capabilities for Individuals With Upper Limb Loss

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Protocol and Statistical Analysis Plan

1. Study Aim, Background, and Design

Rates of upper limb prosthesis disuse and abandonment are dramatically high. It is estimated that at least 20% of individuals with upper limb loss do not use a prosthetic device. Furthermore, evidence suggests that 30-50% of individuals who do use a prosthetic device do not use it regularly. This high rate of disuse is a direct consequence of the functional deficits of commercially available prostheses; 74% of non-prosthesis-users indicate that they would be willing to consider the use of a prosthetic device if it exhibited a significant technological improvement and an affordable price. This studied attempted to address this clinical need with a novel prosthesis that prioritizes functionality, durability, and practicality.

Based on a detailed review of commercial prosthesis functionality, prosthesis user needs, and an investigation of real-world prosthesis use, we have identified a significant functional gap in the commercial market and intend to develop a prosthetic device to address the unmet clinical need. Namely, we have identified the need for a durable prosthesis that is able to serve as both a pushing/pulling tool as well as an effective grasping/gripping device.

We have developed a novel prosthetic terminal device to eliminate the functional tradeoffs of the clinical standard of care: body powered voluntary open hooks. This device is enabled by a novel mechanism that provides nonbackdrivable behavior in a simple and durable package. This study attempted to validate the device through a series of thorough assessments to ensure that it is capable of real-world deployment with respect to its durability and grasping functionality. This assessment is a vital first-step towards clinically de-risking this novel device.

2. Participant Population

The participant population consisted of healthy adults (over the age of 18 years). Participants were recruited from around the Ann Arbor area. Upon identification of a potential participant, the laboratory screener initiated contact to assess eligibility based on inclusion and exclusion criteria and, if appropriate, scheduled the first visit. During the study, participants underwent prosthetic adapter fitting, training, and outcomes testing.

3. Study Procedures

Participants were recruited and provided informed consent before enrolling in this study. After informed consent, lab personnel fit each participant with an able-body adapter that allows a healthy individual to utilize a prosthetic terminal device. Lab personnel confirmed proper fit of the device and harness before training. Training focused on safe and effective manipulation of objects using the terminal device, such as clothespins and other objects utilized in the Southampton Hand Assessment Protocol. After training, the clinical outcomes and data were collected.

The same protocol was performed by participants with three terminal devices: A) the novel prosthetic hook, B) the control hook (with a light spring), and C) the control hook (with a heavy spring). Ordering of the assessments was randomly determined for each participant.

This study used a standardized clinical hand assessment tool: the Southampton Hand Assessment Protocol (SHAP). SHAP has previously been used to assess prosthesis function and consists of 26 tasks that involve manipulating abstract objects as well as simulating common activities of daily living. Each task is timed by the subject by hitting a button at the start and end of the task. The task completion times are then averaged for our primary outcome measure.

In addition to SHAP, participants performed a modified version of the clothespin relocation task. In this task, participants are asked to move clothespins of different spring stiffnesses from one position to another on a desktop apparatus. The primary outcome measure is completion time, with shorter completion times indicating better performance for a given clothespin.

After the experiments, participants completed the Borg Rating of Perceived Exertion (RPE) and the NASA Task-Load Index (TLX) in order to capture estimates of effort and exertion.

4. Statistical Analysis Plan

The primary outcome measure for this work is the average completion time for the SHAP. We hypothesized that users would exhibit decreased completion times when using the novel prosthetic hook as compare to the control hook with the light spring.

Furthermore, we hypothesized completion times with the novel prosthetic hook and the control hook with the heavy spring would be comparable.

A secondary outcome measure for this work was the average completion time for the Clothespin Relocation task. Our hypotheses for this task were that users would exhibit decreased completion times when using the novel prosthetic hook as compare to the control hook with the light spring. Furthermore, we hypothesized completion times with the novel prosthetic hook and the control hook with the heavy spring would be comparable.

For survey outcome measure (RPE and TLX), we hypothesized that the novel prosthetic hook and the control hook with the light spring would score comparably, while the novel prosthetic hook would show lower scores than the control hook with the heavy spring.

To assess these differences, a paired t test can be used (paired across study participants). Moreover, a Bonferroni correction accounts for multiple comparisons (i.e. comparing to commercial device with both a high and low stiffness spring). Note that study participants underwent the experimental protocol in a randomized order of devices to mitigate any effects associated with intervention ordering.

5. Research Risks

The risks of the experimental part of the study are small.

• Risks include minor skin irritation, minor muscle soreness, and fatigue.

• There is some risk that subjects' identities may be revealed as a result of participating in this study.

• There are no other known social, legal, or other risks in these experiments.

6. Funding Sources

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