Cover Page

Official Title of the Study: Teleoperation Experimental Comparison With Able-bodied Subjects

Document Date: November 27, 2024

NCT Number: NCT05048394

Statistical Power and Design

Data Analysis

Functional measure and subjective measure data will be gathered and evaluated carefully by study team members without conflicts of interest to determine the distribution of all scores in the population studied and the variability of scores within and between the two study groups.

Evaluating the efficacy of the *Semi-Autonomous Myoelectric Control Algorithm*:

Hypothesis 1 (primary): We hypothesize that use of *Semi-Autonomous Myoelectric Control Algorithm* will improve dexterity relative to the standard-of-care prosthetic treatment. To validate this hypothesis, we will compare the two treatments (Treatment 1 vs. 2) during a single laboratory-based session using a task involving the transfer of a fragile object, recording the transfer success rate. We will use an Anderson-Darling test to check for normality. If the sample is normally distributed, we will use a two-sample Student's t-test to compare Treatment 1 and 2. If the sample is not normally distributed, we will use a Wilcoxon Rank Sum test to compare Treatment 1 and 2. If the hypothesis is correct, then we expect Treatment 1 (the *Semi-Autonomous Myoelectric Control Algorithm*) to show a significantly higher transfer success rate than Treatment 2.

Hypothesis 2 (secondary): We hypothesize that use of *Semi-Autonomous Myoelectric Control* will also provide improved assistance with prolonged gross motor movements. To validate this hypothesis, we will compare the two treatments (Treatment 1 vs. 2) during a single laboratory-based session using a task involving holding an object in the air for 2 minutes and recording the number of times the object is dropped. We will use an Anderson-Darling test to check for normality. If the sample is normally distributed, we will use a two-sample Student's t-test to compare Treatment 1 and 2. If the sample is not normally distributed, we will use a Wilcoxon Rank Sum test to compare Treatment 1 and 2. If the hypothesis is correct, then we expect Treatment 1 (the *Semi-Autonomous Myoelectric Control Algorithm*) to show a significantly fewer drops than Treatment 2.

Power Calculation

Power was calculated using the 'sampsizepwr' package in MATLAB (version 2018a). The primary outcome measure, transfer success rate of the fragile object, was used to inform the power calculation. We used an average success rate of 59.2% ± 20.7% from [1]. We selected a z-test for normally distributed data with a known standard deviation to derive the number of subjects necessary to detect a 20% difference in success with 80% power. The result of this calculation indicated that a sample size of 9 subjects will achieve a power greater than 80%.

References

[1] E. D. Engeberg and S. Meek, "Improved grasp force sensitivity for prosthetic hands through force-derivative feedback," *IEEE Trans. Biomed. Eng.*, vol. 55, no. 2, pp. 817–821, 2008.