User-driven Retrospectively Supervised Classification Updating (RESCU) System for Robust Upper Limb Prosthesis Control

NCT04043234

December 29, 2023

This study will compare the use of RESCU [Experimental] Prosthesis with a [Standard] pattern recognition prosthesis in a clinical setting and in unsupervised daily activity. The protocol will follow a single case experimental design (SCED) to compensate for the limited size of the patient population. Each of the participants will use the Standard and Experimental and systems over a 35-day period. The Standard system will include a multi-articulated hand, eight EMG electrodes, and a commercially-available pattern recognition controller. The *RESCU* system will also use the multi-articulated hand, similar to the Standard system, but will differ with respect to incorporating eight *IBT Element Electrodes* (as required for pattern recognition control) and the *RESCU* control software.

Participants: We will recruit a total of 10 unilateral trans-radial amputees based on the inclusion and exclusion criteria noted in the Clinical Protocol. Note: the *RESCU* system is applicable to a range of amputation levels, but this study is focused on trans-radial amputees as they represent the largest population of users.

Procedures: After informed consent and medical clearance are completed, participants will be fitted by the study prosthetist.

On **Day 0**, the participant will be evaluated with the Standard prosthesis. A series of *Measures* (as defined in the next paragraph) will then be recorded. The participant will then take the prosthesis home for 1 week, and daily use data will be recorded. The participant will return to the clinic for **Day 7** *Measures* and download of the daily use data. During this same session, the participant will be fit with the second system, instructed on the controller's use, and *Measures* will be recorded. There will be no washout period as the prosthesis is expected to be in daily use. The participants will go home for a four-week period and return on **Day 35** for a second set of *Measures*. At this time, the participant will be asked which prosthesis he/she prefers, and this will be the prosthesis that they return home with at the end of the study.

There are limited functional outcome assessment options for the planned comparison. However, we will test functional measures at the clinic appointments, examine daily use data, and administer several qualitative surveys to assess participant outcomes.

Measures (each appointment day): **First**, a validated measure of upper extremity impairment will be used: the *Activities Measure for Upper Limb Amputees (AM-ULA)*. The AM-ULA is a clinician-graded measure of activity performance for adults with upper limb amputation that considers task completion, speed, movement quality, skillfulness of prosthetic use, and independence to quantify how functional an individual is while using their prosthesis. A higher score indicates overall greater prosthesis functionality. This test has been validated for normative data.

Second, we will ask participants to record daily use data with the Standard and Experimental systems:

Mean Daily Prosthesis Use Duration: Our hypothesis is that *RESCU* will improve prosthesis acceptance. In addition to the subjective measures used below, we will measure the mean duration of daily prosthesis use as a proxy for improved prosthesis acceptance. We will compare the mean daily use for the Standard and Experimental systems, hypothesizing that the Experimental system will be used more than the Standard system. **This will be our primary outcome measure.**

Third, we will use a suite of validated survey instruments directly related to prosthesis use and satisfaction. These instruments are the Orthotics and Prosthetics User Survey Upper Extremity Functional Status (OPUS-UEFS) [53], the Trinity Amputation Prosthesis Experience Scale (TAPES), and various Patient Reported Outcomes Measurement Information System (PROMIS) subscales (e.g., Pain Interference, Satisfaction Short Form 8a). In addition, we will report the percentage of participants that preferred the *RESCU* system.

Statistics: Our primary outcome measure will be the mean daily prosthesis use duration. We hypothesize that the mean daily use for those using the Standard system will be increased from 4.0 to 6.0 hours. In order to detect such a difference, using a paired t-test calculating the mean difference between the use of the two systems, and assuming no period effect and no carryover effect, 10 pairs of measurements would be needed. A two-sided t-test achieves 80% power to infer that the mean difference is not 0.00 when the total sample size of a 2x2 cross-over design is 20 (10 patients), the actual mean difference is 2.00, the standard deviation of the paired differences is 3.00, and the significance level is 0.050.

Data analysis: 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 uses of the two systems. We will specifically examine whether daily use improves by week of use. Personal

characteristics will be used to stratify analyses as applicable. As stated above, we will compare the mean daily use duration of the two systems using a paired t-test, and attempt to determine if there is a period effect, i.e., trend over time. We will also test to assure that there is no sequence effect. We anticipate that the system preferred by the participant will also demonstrate an increased mean daily use duration.