Official Title: MyHand: An Active Hand Orthosis for Stroke Patients

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Scientific Background:

Stroke is the most common neurological disorder in the U.S. (Roger, et al., 2012). 15-30% of stroke survivors are permanently disabled and 20% require institutional care (Mackay & Mensah, 2004). Upper extremity hemiparesis is one of the most common consequences of stroke and a major cause of disability and decreased quality of life in stroke survivors (Roger, et al., 2012). Existing rehabilitation techniques are frequently ineffective in restoring a sufficient amount of hand function in the affected limb to enable independent completion of daily tasks. Robotic therapies have been developed as an exercise tool for stroke survivors to utilize as an adjunct to conventional therapy. Therapeutic robots have the potential to deliver high-intensity task specific training, that may make them beneficial for stroke survivors with upper extremity hemiparesis (Chang and Kim, 2013). There are a variety of robotic devices that have been developed for upper limb rehabilitation after stroke, ranging from large workstations to lightweight wearable devices with a variety of control strategies. Most of these devices have focused on the shoulder, elbow or wrist, with relatively few focused on hand rehabilitation. MyHand is a unique device prototype that was developed in a collaborative project between faculty in the Columbia University Departments of Mechanical Engineering and Rehabilitation and Regenerative Medicine. MyHand is a noninvasive device that is worn on the forearm and hand. It contains motors and "exotendons" that physically assist with finger movements. The device can be controlled by surface EMG signals from the ipsilateral forearm or by a contralateral shoulder harness.

References:

Chang, W. H. & Kim, Y. (2013). Robotic-assisted therapy in stroke rehabilitation. *Stroke, 15*(3). doi: 10.5853/jos.2013.15.3.174

Mackay, J & Mensah, G. A. (2004). The atlas of heart disease and stroke. Geneva, CH: World Health Organization.

Roger, et al., (2012). Heart disease and stroke statistics--2012 update: A report from the American Heart Association. *Circulation, 125*(1). doi: 10.1161/CIR.0b013e31823ac046

Study Objectives:

Primary Research Question: Is the MyHand prototype effective at assisting stroke survivors to complete functional tasks with their upper extremity following a training period of 4 weeks?

Hypothesis 1: (Primary) We anticipate that there will be an improvement in functional use of the impaired upper extremity after training with MyHand.

Hypothesis 2 (Secondary): We anticipate that training with MyHand will improve strength and/or coordination in the impaired upper extremity as demonstrated by improvements in impairment based outcome measures.

Study Design and Methods:

This is designed as a non-randomized interventional study of the effects of a 4-week training protocol with the MyHand device on functional and impairment based measures of upper extremity performance in stroke survivors with hemiparesis. Up to 24 community-dwelling chronic stroke survivors will be

recruited to participate in this study. Participants will complete the informed written consent process followed by screening procedures according to the following criteria.

Inclusion Criteria:

- Stroke diagnosis at least 6 months prior to start of study
- Passive range of motion: Wrist to neutral, Digits within normal limits
- Moderate muscle tone, i.e., Modified Ashworth Scale (MAS)≤2 in digits, wrist, and elbow
- Active Range of Motion: At least 30 degrees shoulder flexion, 20 degrees shoulder abduction, 20 degrees elbow flexion, finger flexion within functional limits
- Strength: At least trace palpable finger extension
- Able to successfully flex the fingers to form a grasp
- Unable to extend the fingers fully without assistance
- Intact cognition to provide informed written consent

Exclusion criteria were:

- Concurrent participation in another study
- Comorbid orthopedic condition/pain limiting functional use of the impaired upper extremity
- History or neurological disorder other than stroke
- Excessive spasticity (Greater than 2 on the MAS)
- Recent Botox injection to the affected limb (< 13 weeks)

Participants will be assessed at baseline and after completing the 4-week training protocol with the following outcome measures: Fugl-Meyer Upper Extremity Scale (UEFM), the Action Research Arm Test (ARAT), the Box and Blocks Test (BBT), the Modified Ashworth Scale (MAS). For baseline measurements, all outcome measures will be performed without the assistance of the device. To evaluate rehabilitative and assistive effects of the training protocol, participants will complete post-testing assessments under two conditions over the course of two sessions to avoid fatigue. One session of post-testing will involve administration of the UEFM, ARAT, and BBT without robotic-assistance (unassisted condition), while the other session will involve administration of the ARAT and BBT with robotic assistance (assisted condition). The UEFM will only be performed at post-testing in the unassisted condition because the UEFM assesses capacity of the arm primarily through gross motor tasks, and comparatively few grasping and pinching tasks. We thus presume that robotic assistance will have minimal influence on FM scores. All outcome measures will be administered by an occupational therapist who is not involved in the training program.

Next, participants will be fitted with the MyHand device and screened with the EMG classifier to determine if they will use the EMG or shoulder harness control method. During the control screening, a classifier algorithm will by trained with the subject's EMG signals from the involved forearm. A participant will be assigned to the EMG control if they pass the classifier or the shoulder harness if they fail. Each participant will be trained to use their assigned control method.

The training protocol involves 12 sessions (3 sessions per week for 4 weeks). Each session will involve 30 minutes of active training time in which participants will practice a variety of grasp and release tasks with everyday objects to simulate Activities of Daily Living according to a standardized protocol. Participants who require additional upper extremity support to aid use of the device may be fitted with the commercially-available Saebo Mobile Arm Support to unweight the arm during training. Each training session will be supervised by a trained occupational or physical therapist. At the completion of

the training protocol, participants' upper extremity function will be reassessed with the outcome measures to evaluate if the MyHand device may have utility as rehabilitative and/or assistive device.

IRB-Approved Protocol Amendments Since 11/14/18

- **12/10/18 Modification:** Study personnel change due to staff turnover
- **9/19/19 Modification:** Study personnel change due to addition of new PhD-student

Statistical Analysis Plan

We tested all the clinical outcome data and gains for normal distribution based on the residuals of our dependent variables with Shapiro-Wilk and visually with Q-Q plots. We also tested the homogeneity of variance using the Levene test. UEFM and ARAT passed normality and homogeneity test, and thus we applied paired sample t-tests. BBT failed the normality test. Therefore, we applied a nonparametric paired sample Wilcoxon test. Statistical significance was determined at $p < 0.05$.