Study Protocol

Effects of a Compliant Arm Support on Post-stroke Upper Extremity Range of Motion

Principal investigator:	Allison Okamura
	Professor
	Department of Mechanical Engineering
	Stanford University
	Stanford, CA, USA
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Author	Cole Simpson
	Redwood City, CA, USA
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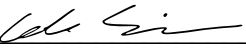
Signature page

Principal investigator: 

Allison Okamura

Author 

Cole Simpson

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I. Introduction

The aim of this study is to test in a single-center self-controlled study whether a custom lightweight, low-cost compliant exoskeletal arm support assists stroke survivors to achieve a greater reachable workspace area with the impaired arm and whether any such effect might persist when the device is no longer in use.

This protocol and statistical analysis plan will give more detailed descriptions of the methodology, analyses, and endpoints of this study.

II. Aims and objectives

The aim of this study is to test the efficacy of an experimental compliant arm support designed to support shoulder abduction in human users. We consider two ways in which such a device might be helpful for stroke survivors: (1) improved functionality while using the device and (2) residual benefits that persist after use of the device. In Section III, we describe the protocol we developed to examine whether our device increases the reachable workspace area and whether any improvements persist for a short period of time after an intervention.

III. Study design

The study is a single-arm pilot study designed to assess whether an experimental compliant arm support (1) assists stroke survivors to achieve a larger reachable workspace area and (2) whether a short assisted exercise trial causes a residual increase in reachable workspace area caused by a reduction in flexor synergy activation.

III.a. Participant recruitment

Candidate participants will be identified in one of the following manners:

(1) referral from treating physician through the Stanford Neurology & Neurological Sciences and Physical Medicine & Rehab clinics (both outpatient). Patients with clinic appointments and history of stroke will be screened under a waiver of authorization for recruitment, guided by inclusion/exclusion criteria. The physician will discuss the study with the patient and if the patient agrees, a physician or coordinator from the study team will approach the patient after the patient's clinic appointment.

(2) through a database in which stroke survivors from the community have indicated their interest in participating in Stanford stroke research studies and filled out a form to add themselves to a database. Study personnel may contact individuals directly from that list.

(3) from a list of subjects who enrolled in other stroke research studies at Stanford and indicated that they are interested in participating in more stroke studies. These are current patients of the study physicians. Study personnel may contact these individuals directly.

Once identified, candidate participants will be contacted via phone call and asked to answer a few questions to establish eligibility and interest. Participants will be scheduled only if they express interest and meet the inclusion criteria determined during the phone screening.

To be included in the study, all participants must:

- be at least 18 years of age
- be greater than 6 months post stroke
- exhibit passive abduction to 90 degrees at shoulder
- exhibit reduced active (retro)flexion/extension at shoulder when abducted to 90 degrees
- exhibit reduced active flexion/extension at the elbow

Participants will be excluded from all assessments if they:

- are unable to give informed consent
- are unable to comprehend and follow instructions
- have a condition (other than stroke) affecting sensorimotor function
- show evidence of unilateral spatial neglect
- are unable to sit in a chair (without armrests) for at least 2 hours (transfer from wheelchair acceptable)

We do not have pilot data to power our study. However, previously published studies using similar methods have typically examined 6-12 participants. We aim to enroll up to 10 participants.

III.b. Study protocol

When a participant arrives for the study session, time will first be allocated to review the consent document and answer any questions. Once participants have granted their informed consent, non-invasive clinical assessments will be administered by the study personnel for demographics purposes. These assessments include: the Upper Extremity portion of the Fugl-Meyer Assessment (FMA) and simple tests for joint range of motion, visual/tactile neglect, and scapula-humeral rhythm.

Our protocol consists of a set of assessments performed with each of 2 support conditions: (1) unassisted and (2) using our experimental device. In each assessment, we will measure the reachable workspace area and a proxy for flexor synergy activation. To assess reachable workspace area, participants will be coached to individually flex and extend the elbow and shoulder to trace the largest possible circle while keeping the hand and elbow raised to the height of the shoulder while arm kinematics are measured using an optical motion capture system (Phasespace Impulse X2E, San Leandro, CA, USA). Participants will trace 6 circles per measurement, 3 in each direction (clockwise or counterclockwise) with the order randomly determined. As a proxy measurement for flexor synergy activation, the arm will be placed in a configuration known to activate the flexor synergy — arm raised to shoulder height with the elbow bent 90˚ with the hand placed directly in front of the sternum — while the activation of the biceps muscle is recorded using electromyography (Delsys Bagnoli 2 system, Natick, MA,

USA). Each participant will complete the first set of assessments unassisted to establish baseline measurements. Participants will then complete a trial while wearing our experimental device. A trial consists of a workspace and flexor synergy evaluation with the assigned support followed by a ten-minute intervention trial. In this intervention trial, participants will perform the same clockwise and counterclockwise circular movements with the hand used to measure the reachable workspace. The direction of the circular movements will be randomly determined and repeated for 1 minute. Up to three 1-minute rest periods will be allowed as needed. The support will then removed and participants will perform another workspace and flexor synergy assessment with no support to test for any effects of the exercise. Participants will then rest for 30 minutes before performing another workspace and synergy assessment to determine whether any exercise effects have worn off.

IV. Analyses

The subsections below will describe data processing and analyses performed to compute the primary outcome measures.

IV.a. Reachable workspace area computation

Motion capture data is low-pass filtered at 20 Hz using an 8th order, zero-phase shift Butterworth filter. Any gaps in the marker trajectories caused by temporary occlusions (less than 0.2 seconds) of the marker are filled using cubic interpolation. Any occlusions lasting longer than 0.2 seconds are ignored in our analyses rather than interpolated to avoid generating incorrect data. We compute the reachable workspace area of the hand using the boundary function in Matlab, which computes a concave boundary around the input data and returns the area of that boundary. We disregard datapoints in which the hand (defined as the marker on the ulnar epicondyle) or elbow (defined as the marker on the lateral humeral epicondyle) fall below 20 cm below the height of the shoulder (defined as the marker on the acromion).

IV.b. Estimate of flexor synergy activation (biceps electromyography)

Recorded electromyograms (EMG) are high-pass filtered with a cutoff frequency of 30Hz, rectified, and then low-pass filtered with a cutoff frequency of 6Hz to create linear envelopes. All filters are 8th order, zero-phase shift Butterworth filters. We use the average of this linear envelope as the estimate for flexor synergy for a given trial.