

Insights into Impaired Arm Motor Control on Bilateral and Unilateral Functional Activities after Injury: A Kinematic Study
NCT02778529
10/26/2021

Protocol

Objectives

Overall objectives

This study is being performed to assess how certain chronic disabilities - stroke, UE amputation, SCI, CP - differ from healthy subjects in their ability to perform ADLs. By studying the kinematics of the respective cohort of study participants as they are assessed performing common ADLS, our research team aims to better understand how impaired neural pathways, and pathways that have been impaired at various points along the pathway, deleteriously affect ADLs in patients with differing long-term disabilities.

Background

Bilateral functional tasks are a salient part of ADLs and require cooperation from each limb. The division of labor between limbs is characteristic of various functional tasks. At one end of the bilateral functional task spectrum are symmetric tasks that require the two limbs to do similar movements, e.g., simultaneous reach to grab a large ball. At the other end are the more complex asymmetric or discrete tasks that require the two limbs to take on different roles during a task, e.g., the widely studied asymmetrical drawer task. Here, the hands contribute with dissimilar task components in that one hand performs a postural role while the other takes on a manipulative one. Behavioral studies in able-bodied subjects tell us that although the limbs may engage in separate activities, they have strong temporal and spatial interactions including a tendency toward frequency and phase locking between limbs in rapid movements, amplitude coupling, direction coupling, and mutual accommodation or interference. Stroke survivors with hemiparesis have difficulty performing both unilateral and bilateral functional

tasks. Depending on the severity of the stroke, the grasping and manipulation aspects of the functional tasks are difficult to be performed. Their hemiparesis results in an upper limb that is characterized by weakness, abnormal synergies, and impaired coordination. The deficits are seen both within the segments of a limb (inralimb) and between limbs (interlimb). Interlimb coordination deficits, both temporal and spatial, often lead to sequential and segmented, poorly timed movements during bilateral functional tasks. In bilateral symmetrical tasks, stroke subjects have more difficulty maintaining the symmetry of the task than their able-bodied counterparts. For example, in a rhythmic circle drawing task, there may be greater phase discrepancy between the limbs of patients with hemiparesis when compared to healthy patients. In asymmetric bilateral tasks, the tendency displayed by healthy persons to synchronize their arms in time and space may be disrupted in stroke survivors resulting in more uncorrelated movements between arms. The effects of stroke caused by impaired brain integration are not dissimilar from a disruption to the neural connective process caused by a spinal cord injury (SCI), or a change in muscle activity caused by a UE amputation. The bilateral assessment system (BiAS) system which will be used in this study is low-cost, portable to other environments such as the home, easily donned on and off the wrist, and able to measure right and left arm kinematics after therapy. "Effects of Stroke." National Stroke Association. Web. 10 Apr. 2014. <http://www.stroke.org/site/PageServer?pagename=effect>. Johnson M, Wang S, McGuire J, et al. (2011). Bilateral assessment of functional tasks for robot-assisted therapy applications. Med Biol Eng Comput. NIH Public Access. Callin S and Bennett M. (2008). Assessment of neuropathic pain. The Oxford Journal. Mathiowetz V, Volland G, Kashman N, Weber K. (1985). Adult Norms for the Box and Block Test of Manual Dexterity. The American Journal of Occupational Therapy. Vol 39, Num 6. Boissy P et al. (1999). Maximal grip force in chronic stroke subjects and its relationship to global upper extremity function. Clinical Rehabilitation. Vol. 13, p. 354-362.

Study Design

Design

Cross-sectional study comparing bilateral ADL activities for stroke survivors, SCI paraplegics, UE amputees, adults with CP, and healthy controls. The study participants will perform 4 ADL tasks with the BiAS passive robots. From these tasks, the BiAS robots will provide information regarding position, velocity, distance, displacement, etc. This, along with video information provided by the 3D Kinect, an ECG and an EEG neuroheadset, will be used as the basis of our data and aid in informing members of the research team on how the respective impairments affected upper limb kinematics on ADL tasks.

Study duration

1) We estimate that it will take one year from the date of IRB approval to enroll all subjects and complete the study. 2) The subject's participation in the study will be limited to approximately 3 - 4 hours. This allows for up to 1.5 hours for the participant to review and sign the informed consent with study personnel present, and for several common clinical therapy practices to be performed. The remaining time will be spent using the BiAS robot system. 3) Projected date of the proposed study: 5/15/14 to 5/15/15.

Characteristics of the Study Population

Target population

Stroke survivors with hemiplegia; UE amputees; SCI paraplegics; adults with cerebral palsy; and healthy controls.

Subjects enrolled by Penn Researchers

40

Subjects enrolled by Collaborating Researchers

0

Vulnerable Populations

Children Form

Pregnant women (if the study procedures may affect the condition of the pregnant woman or fetus) Form

Fetuses and/or Neonates Form

Prisoners Form

Other

☒ **None of the above populations are included in the research study**

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject recruitment

A member of the research team using various databases such as Epic, Sunrise, Penn Data Store, and the Uniform Data System (UDS) that is particular to Penn Rittenhouse, will be used to identify potential subjects. After identifying subjects via the study's inclusion/exclusion criteria, a flyer will be mailed out, and then if necessary, direct follow-up by phone or email will follow. Additionally, physicians with significant patients in the "target population" will be approached by a member of the Rehabilitation Robotics Lab and asked to participate in the recruitment of study subjects. Physicians will be asked to refer any interested subjects to the lab's research coordinator. The coordinator will then reach out directly, either by phone or email, and schedule a time for the patient to come into the lab. More broadly, a flyer will be posted both at the Penn Institute for Rehabilitation Medicine and Good Shepherd Penn Partners Penn Therapy and Fitness outpatient therapy practices with the contact information of the lab's research coordinator. Possible study participants will also be directly solicited at the monthly Stroke Support Group, SCI Injury Support Group, and Amputee Support Group meetings, which are led by clinicians from Penn Rittenhouse. A member of the Rehabilitation Robotics Lab will briefly explain the research, and a handout with contact information will be provided should they want to contact our team for further information. Healthy volunteers will be recruited both from the flyer and word of mouth.

Will the recruitment plan propose to use any Penn media services (communications, marketing, etc.) for outreach via social media avenues (examples include: Facebook, Twitter, blogging, texting, etc.) or does the study team plan to directly use social media to recruit for the research?

No

The following documents are currently attached to this item:

There are no documents attached for this item.

Subject compensation*

Will subjects be financially compensated for their participation?

Yes

The following documents are currently attached to this item:

There are no documents attached for this item.

If there is subject compensation, provide the schedule for compensation per study visit or session and total amount for entire participation, either as text or separate document

We will offer \$15.00 in compensation by check. In order for subjects to be compensated, they will have to provide their SSN on the W-9 form.

Study Procedures

Suicidal Ideation and Behavior

Does this research qualify as a clinical investigation that will utilize a test article (ie- drug or biological) which may carry a potential for central nervous system (CNS) effect(s)?

No

Procedures

Participation in the study will include the following steps: 1) Informed Consent: After arrival, subjects will review and sign the consent form with study personnel present. 2) Pre-Assessments: A member of the research team will evaluate the subjects' upper extremity and assess their ability to use it. Subjects will be evaluated using a battery of assessments such as, but not limited to, the Box and Block, Pin and Prick, and grip strength using a dynamometer. 3) Break: Subjects will be given a 15 minute break. 4) BiAS passive robot system: Subjects will be introduced to the device and each wrist will be placed on to the end of each robot. As common therapy tasks are performed by the subject, the BiAS devices will collect the data along with the video from 3D Kinect, an ECG and the EEG neuroheadset. After each of the 4 ADL activities, subjects will be asked about their level of exercise and discomfort, if any. After subjects finish all exercises with the BiAS, they will be thanked for their participation in the study. 5) Video and photos may be collected to determine subject quality of ADL movement.

The following documents are currently attached to this item:

There are no documents attached for this item.

Deception

Does your project use deception?

No

Analysis Plan

From the 4 ADL tasks, the BiAS robot will provide information regarding the position and velocity of the wrist of each arm. The 3D Kinect connect will provide additional information about whole arm kinematics and track both shoulder and elbow positioning. Emotiv's EEG neuroheadset is capable of gross neuro-signal acquisition and interpreting a participant's conscious thoughts and intent, as the 4 ADLs are performed. An ECG will record electrical activity of the heart over the course of the session. Additionally, a custom Matlab program will be used to generate additional measures that characterize the movement - measures such as distance, displacement, time, velocity, acceleration and jerk. This data will be used to analyze the upper arm movements of different groups of subjects and make conclusions about how the respective disabilities affected upper limb kinematics of ADL tasks. Surface EMG will also be used to collect data that will be analyzed to verify muscle activity over time.

The following documents are currently attached to this item:

There are no documents attached for this item.

Are you conducting research outside of the United States?

No

Subject Confidentiality

All study personnel will have access to a locked file cabinet containing consent forms, evaluation assessments, and collected data. The locked file cabinet will be located at Penn Rittenhouse, Rehabilitation Robotics Lab, 1800 Lombard Street, Philadelphia, PA, 19146. Both electronic data and hard-copy records will be kept for 10 years; they will be kept on password protected computers. After 10 years, documents will be destroyed by secure shredding at Penn Rittenhouse and electronic data will be deleted from computers. Research subjects will be identified in the research data by code, and at no time will a direct link exist between collected data and research subjects. When data results are reported they will be presented in aggregate form (i.e. group characteristics only) and no individual identifiers will be used.

Sensitive Research Information*

Does this research involve collection of sensitive information about the subjects that should be excluded

from the electronic medical record?

No

Data Disclosure

Will the data be disclosed to anyone who is not listed under Personnel?

Carol Wamsley and Aaron Thrush - the certified therapists - will have access to PHI. However, they are considered UHPS employees and have now been listed under Key Personnel.

Data Protection*

- ☒ **Name**
- ☒ **Street address, city, county, precinct, zip code, and equivalent geocodes**
- ☒ **All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- ☒ **Telephone and fax number**
- ☒ **Electronic mail addresses**
- ☒ **Social security numbers**
 - Medical record numbers**
 - Health plan ID numbers**
 - Account numbers**
 - Certificate/license numbers**
 - Vehicle identifiers and serial numbers, including license plate numbers**
 - Device identifiers/serial numbers**
 - Web addresses (URLs)**
 - Internet IP addresses**
 - Biometric identifiers, incl. finger and voice prints**
- ☒ **Full face photographic images and any comparable images**
 - Any other unique identifying number, characteristic, or code**
 - None**

Does your research request both a waiver of HIPAA authorization for collection of patient information and involve providing Protected Health Information ("PHI") that is classified as a "limited data set" (city/town/state/zip code, dates except year, ages less than 90 or aggregate report for over 90) to a recipient outside of the University of Pennsylvania covered entity?

No

Consent

1. Consent Process

Overview

Interested subjects will be contacted and a questionnaire will be administered via phone to determine eligibility. PHI from subjects declining to participate and be consented after the phone screening will be discarded. Subjects will receive a consent form at least 24 hours in advance of the study session. This will allow subjects sufficient time to read over the form on their own, and come up with any questions or concerns prior to the commencement of the session. Before the session begins, study personnel will review the consent form and experimental procedure with the subject and answer any questions. The subject will then be given the opportunity to sign the consent form, with study personnel witnessing. Any subjects that decline to sign the consent form will be dismissed at that time.

Risk / Benefit

Potential Study Risks

Subjects may experience fatigue or muscle strain if ADL tasks are considered too intense. Frustration derived from difficulty in performing the tasks is possible. Task intensity will be kept low in order to reduce the confounding effect of fatigue on experimental results. After each exercise, subjects will be questioned regarding the difficulty of the task, intensity, and their level of discomfort level. At that time, the protocol will be adjusted accordingly. Subjects will be given ample time to rest as part of the experimental protocol.

Potential Study Benefits

There are no direct, major benefits to a particular subject. Participation will help advance rehabilitation robotics research.

Risk / Benefit Assessment

The risks involved are minimal - fatigue, frustration, minor muscle strain. There are no immediate direct benefits to study participants. Possible benefits to society are significant, as according to the American Heart Association, every year, 15 million people suffer a stroke. Most people survive the stroke, but have subsequent problems and many require assistance for activities of daily living.

General Attachments

Statistical Analysis

Given our small sample size, for every calculated metric, a standard score was determined by dividing the difference between the average of the metric for the healthy subjects and the value of the subject in question by the standard deviation within the healthy population. Abnormal was characterized as having a standard score greater than or equal to 2 or less than or equal to -2, which is equivalent to greater than 2 standard deviations from the healthy subject mean.