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

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Protocol

COLORADO MULTIPLE INSTITUTIONAL REVIEW BOARD
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Protocol #: 14-0838
Project Title: Biomechatronics Development Lab Myoelectric Controller protocol

Principal Investigator: Richard Weir
Version Date: 07/19/22

I. Hypotheses and Specific Aims: The purpose of this protocol is to provide guidelines for research and development of more intuitively controlled myoelectric prosthesis. Self-identified adult volunteers will be used for convenience sampling for the population served.

II. Background and Significance: Currently available multi-joint prostheses cannot be fully utilized because there are fewer control inputs than the number of joints that need to be controlled. Based on the work in the field of neuroscience, it has been shown that grasping is a 'low dimensional' task (i.e. – only 2-3 control inputs are necessary). We will develop control paradigms and upper limb prostheses components to control a multi-joint prosthetic hand using currently available clinical practices and investigate which dimensions are most important for prosthetic devices.

III. Preliminary

Studies/Progress Report:

IV. Research Methods

A. Outcome Measure(s):
Outcome measures include completion rate, time to completion and path efficiency metrics as well as position of the arm, wrist, and hand during these tasks. Additional outcome measures may include time of use, types of actions performed, location information (GPS), and/or power consumption. These metrics help define the performance of the postural control paradigm for EMG control and design of advanced prosthetic hands.

B. Description of Population to be Enrolled:
The subject population will consist of a convenient sample of adult volunteers, both able bodied and limb deficient. The subjects will have various ethnicity, age, and gender. An estimated total of 60 subjects will be enrolled. The subjects must be able to understand and follow directions in English, assessed by their ability to respond during the recruitment and consent process. Exclusion criteria include any subjects that are not able to understand the procedures or are taking blood thinners. Subjects will be recruited via flyers placed at the Anschutz or Auraria campuses, flyers emailed to organizations that work with our target population, or in-person at conferences and events to which we have been invited.

Because of the potentially long distances we will need to travel to meet with participants and the demands of work on other researchers we will not be able to have more than one researcher travel at a time. In order to ensure the safety of a single researcher traveling to a participant's location, we will enforce the following safety procedures:

When traveling to off-site locations, researchers only a licensed and insured driver in a well-maintained vehicle with appropriate equipment for conditions will drive. Driver has AAA membership which will be used in case of emergency. Experimentation will only take place during normal business hours when other research staff can be reached in case of unanticipated emergency.

We will keep a log in the lab describing where we are traveling and with whom we are meeting. We will only travel to participants with whom we have previous contact and have determined to be safe. Traveling researcher will keep a cell phone with them and check in with other researchers in the lab at least every 3 hours via cell phone to confirm that they are safe.

C. Study Design and Research Methods

The experiments will take place at the Biomechatronics Development Laboratory in the Children's Hospital on Anschutz campus, the University of Boulder Campus, and/or during normal at-home use. The participant will come up to 3 times for up to 4 hour sessions. An optional at-home use period can take place for up to 6 months. During this session the participant will be asked to control a virtual hand (a 3D image of a hand on the computer screen) and/or a prosthesis by contracting the muscles in the forearm and to manipulate physical objects on the table. The only devices coming into contact with the participant will be standard of care myoelectric control and motion capture equipment including surface and intramuscular electromyographic (EMG) sensors. Other equipment to be used in the laboratory include a data glove (Cyberglove II by Cyberglove Systems, LLC), vibrating motors, reflective markers (OptoTrak, Northern Digital Inc), and electrogoniometers (Biometrics Goniometer, Motion Lab Systems, Inc.). During at-home use, subjects will use standard of care surface EMG sensors installed into a prosthetic socket. Standard of care procedures involving palpation of the subject's arm will be used to locate the best position on the arm for the surface and Intramuscular EMG and motion capture sensors. The EMG sensors measure muscle activation levels and send the information to the computer to enable the control of the virtual hand or prosthesis. The motion capture sensors and goniometers give us a measurement of the position of the arm. A training period will be followed by several tests to measure the intuitiveness and functionality of several versions of the controller. Different versions of the controller will be presented to the subject in a randomized order. The subject will be expected to try and acquire target hand postures displayed on the screen using this control interface. Subjects will likewise be given a training period to practice moving the physical objects.

Additionally, we may travel to the subject's preferred location (*e.g.* home or office) to conduct testing with surface EMG, motion capture, goniometers, or video. This will allow us to maximize recruitment and include subjects who live too far from the Anschutz campus to participate.

Video will be taken from behind and will not include identifying information such as the subject's face. Video will be used to record arm and shoulder motion during the experiment to be analyzed later. This allows us to determine whether compensatory motion is affected by different prostheses.

An optional home-use period may take place. A prosthetic limb system using surface EMG sensors and a prosthetic hand will be sent home with the subject. It will be used during everyday activities. The surface EMG sensor will be permanently installed into the prosthetic limb system and will not need to be replaced. The subject will be asked to use the prosthetic limb system as their primary prosthetic limb (daily use) unless it is not appropriate due to the task/environment. The home-use period will last up to 6 months.

D. Description, Risks and Justification of Procedures and Data Collection Tools:

We will be acquiring muscle activity data for the control of a prosthesis using Electromyography (EMG) in conjunction with motion capturing devices and finger mounted force sensors. Surface EMG allows us to create pattern recognition of a composite muscle signal, and intramuscular EMG allows us to focus on particular muscles, or muscle slips. Risks of Surface EMG and motion capture are possible minor skin discomfort from the medical tape/adhesive used to attach sensors to the skin and/or from preparation of skin for attachment. The intramuscular EMG electrodes introduce a minimal risk of infection, and nerve injury as well as minimal bleeding. Any injury to nerves is temporary and may involve numbness or pain. When the procedure is finished, the electrodes will be removed. All equipment and insertion sites will be sterilized in accordance to standard of care procedures. The Intramuscular EMG electrodes may be used in conjunction with surface EMG or as an alternative to surface EMG. If you feel that you have been harmed while participating in this study, you should inform Richard Weir at 847-912-1032 immediately.

E. Potential Scientific Problems:

Potential scientific problems include a lack of subjects with upper-limb amputation and the inability of subjects to learn the postural control paradigm to a high level.

F. Data Analysis Plan:

Data will be processed with standard techniques in MATLAB (Mathworks, Inc.) in order to produce the metrics described previously (completion rate, time to completion, and path efficiency).

G. Summarize Knowledge to be Gained:

The development of more intuitive and functional prosthesis controllers will augment the quality of life for people with upper-limb amputation.

H. References:

N/A