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TITLE: The Efficacy of Upper Extremity Wearable Robotic Orthosis on Improving Upper Extremity Motor Function and Activities of Daily Living in Persons with Spinal Cord Injury

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CONTRACTING ORGANIZATION: Kessler Foundation, West Orange, NJ

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E-Mail:

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14. ABSTRACT

This pilot investigation has been initiated and all study staff members have received full training for the collection of unique outcome measures and providing unique rehabilitation and assistance using a novel robotic exoskeleton orthosis (MyoMo device) for persons with SCI.
We (researcher, clinicians and therapists), with assistance from the manufacturer (MyoMo) have established a training program schedule on the utilization of MyoMo orthosis specifically for individuals with SCI which will is followed during enrollment in this research study.
We have able to get some preliminary data that is included in this report and this data has been used to submit a Level II to the CDMRP-OPORP to include a wider range of utilization with a larger number of participants.

15. SUBJECT TERMS

Progress update and listing of main accomplishments to initiate this novel line of work for persons with SCI and orthotic utilization and rehabilitation.
We have submitted a paper to the International conference on Wearable Robotics (WeRob 2020) and is accepted and was chosen for oral presentation (Attached). This presentation will be provided virtually due to the unfortunate situation of COVID-19. There will also be a live discussion session where other researcher will be interacting with us with questions/answers on the paper

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1. INTRODUCTION:

Spinal cord injury (SCI) is a medically complex and life-disrupting condition. Each year in the United States, there are approximately 17,500 new traumatic SCI cases, including many active service members, and veterans. In about half of these cases, the injury involves some part of the arm and or hand, representing significant disability and increased patient dependence and strain on their families. Even though restoration of upper extremity function in people with SCI remains a **high priority in rehabilitation and in the field of assistive technology,** there are currently few **powered wearable devices** developed specifically for increasing upper extremity activity, particularly wrist and hand function. The impact of the current study is to provide the evidence to directly affect rehabilitation treatment options by using the technology, as well as to provide an evidence based platform for the introduction of home based strategies for the recovery of hand and arm functions for increasing activity of daily living and quality of life in individuals with iSCI. The outcomes of the study are also expected to provide information for the development of next-generation assistive technologies to better serve those with disabilities. Further, these results will establish the first guidelines of a powered robotic orthosis (MyoPro) for persons with iSCI.

2. KEYWORDS:

SCI rehabilitation and assistive technologies, upper extremity rehabilitation, upper extremity orthotic system, Activity of daily living, function activities in persosns with SCI

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: To investigate the effects of the MyoPro as a therapeutic orthotic tool for improving wrist/hand/UE motor function by comparing the outcome measures between the SB group and control group.
Specific Aim 2: To investigate the effect of the MyoPro as an assistive orthotic tool for increasing UE ADL by comparing the outcome measures between the Myo-Pro group and SB group.
Specific Aim 3: To determine intervention and daily use-caused neuromuscular adaptations that promote movement recovery and ADL.

What was accomplished under these goals?

I. **Major Task 1:** Initiation of the investigation and getting started (Completed)

- Refinements and optimization on the utilization techniques of the orthotic device (MyoMo device) have been discussed with the MyoMo manufacture.
  Finalized the investigation's protocol and providing the needed training for staff members and treating therapists.
- Prepared continuation application and Regulatory Documents, the Research Protocol and IRB applications for local IRB committee and for the HRPO review
  - Obtain Local IRB continuation approvals at Kessler Foundation
- Obtained needed equipment, orthoses and supplies for new participants in the study
- An updated detailed explanation and supplementary material has been provided to all therapist which will be followed during evaluations/assessments and training in the study.
  - Provided a presentation/talk to all involved therapists and comprehensive explanation of the study details were discussed: Including procedures for recruitment, screening, timeline, evaluations and rehabilitations procedures
- Finalized research protocol and provided in-depth training to study staff members on administering the study treatments and evaluations for individuals with SCI.
  Currently, the study includes a total of four therapists who are involved in the research study and assist with the study (Recruitment and interventions). All of the OTs are fully trained on the needed treatments and administration of outcomes. Therapists are as follows:
  - *Amanda Engler, DPT*
  - *Alyssa Attanasio, OT*
  - *Alisha, K Sheridan, OT*
  - *David O'Brian, OT*
- Provided on-site training sessions for treating therapists and study staff members (at Kessler Foundation):
  - **MyoMo training: provided by MyoMo company**
    - First on-site training (07-17-2019), covered the following aspects:
      - Training on initial measurements and determination of potential subjects in the research study.
      - Details on the utilization techniques of the MyoMo orthotic device
      - Two subjects with disability participated in this training session and study therapists received hands-on training with the MyoMo orthotic device.
    - Second on-site training (08-07-2019), covered advanced features of the orthotic system, as follows:
      - Reviewed of MyoPro orthotic and key functions
      - Practiced therapy routines, therapy treatment guide
      - Practiced all study protocol, routines, dosing, and collection of outcomes along with treatment examples
      - Two subjects with disability participated in this training session and study therapists received hands-on training with the device.
      - Generated a therapy schedule using the MyoMo orthotic device specifically for persons with SCI when enrolled in this research study. This training schedule was finalized with input from study staff members and researchers from MyoMo company during the on-site trainings.
  - GRASSP training: provided by the developer of the outcome measure (Dr. Sukhvinder Kalsi-Ryan).
    - A training webinar was scheduled and provided on 08-14-2019.
    - Complete explanation and description of all aspects of the GRASSP measure
    - Training resulted in certifying all four therapists to administer this important outcome measure for participants with SCI.

⇨ **Milestone Achieved on (Major Task 1):** Investigation Initiation, finalizing protocol and starting of participants' recruitment have been completed

All study staff member (PTs/OTs, RAs) have received needed training to carry the research activity of this investigation.

- **A total of a total of twenty** subjects with SCI have been recruited and eight enrolled in the study.
  - Seven of those have completed 18 sessions of training sessions
  - We have collected several data collection sessions at Baseline and Post-training to evaluate several research domains and outcomes.
  - The eighth subjects is currently completing the training activities in the following week.
- Two new participants have been contacted for enrollment in the study:
  - One participant passed the over-the phone screening and will be coming for the in-person screening in the following week.
  - On participant failed over-the-phone screening.
- Changes to study staff members (therapists and researcher):
  - Amanda Engler, PT, PHD was hired at Kessler Foundation as the main therapists ion this study to provide treatment sessions and evaluations.
  - David Obrien, OT (Kessler institute for Rehabilitation) has been added to the study to assist the other therapists in providing rehabilitation and evolution sessions to study participants.
  - Salli AlRabadi, M.S. have been added to study as a research assistant (Kessler Foundation) to assist with data collection, analysis and entry.
- Online training webinar have been provided to training the two newly added therapists (David and Amanda) on the administration of the GRASSP evaluation. Both are now certified to do the GRASSP evaluation.

II. **Major Task 2:** Investigating the therapeutic improvement of MyoPro orthosis. (On-going)

A preliminary results report on two of the outcomes generated for this task is attached to this report:

a. **Biomechanical evaluation:** an extension to the initial analysis of these outcomes (Hand grip- angles and force) addressing a dynamic gripping test was completed and data has been prepared for journal article submissions.
   Copies of the accepted and finalized papers to the EMBC are attached. These papers will be published and PubMed indexed with a DOI number.

b. **Transcranial Magnetic stimulation (TMS):** Analysis is ongoing.
   More detailed and comprehensive analysis and interpretation of the data is on-going.

III. **Major Task 3:** Investigation the assistive improvements of the MyoPro orthosis. (On-going)

Major Tasks 2 and 3:

Data collection and analysis is ongoing. Data analysis of the following outcomes is ongoing while including more participants into the study data directory:

- EEG combined with EMG during hand/arm activates (upper extremity evaluation)
- Strength and gripping outcomes
- TMS assessment with EMG data outcomes.
- A complete battery of medical assessments, including:
  - GRASSP measure
  - ISNCSI outcome
  - CUE-Q evaluation
  - Modified Ashworth scale test

  Data of these outcomes have been processed and reports are generated to look at changes due to the provided training in the study.
- MATLAB scripts have been updated to be used for post-processing the collected data and to initiate data analysis procedures for the ROM, EMG, EEG and strength measures

IV. **Major Task 4:** Determination of neuromuscular adaptations. (On-going)

Enrollment and recruitment of participants:

Recruitment of a total of twenty subjects of whom eleven failed the phone/in-person screening, and eight have enrolled into the study (one will enroll next week). Their status is as follows:

i. Six completely finished study's activities.
ii. One dropped out of the study. As reported previously (April 15th, 2021), The participant has completed baseline testing and received 4 training sessions and then was not able to continue due to a kidney-stone that required hospitalization. Participant's primary physician recommended not to do any training session until kidney stone is removed.
iii. One is actively participating in the study and receiving training sessions.

What opportunities for training and professional development has the project provided?

- Provided on-site training sessions for treating therapists and study staff members (at Kessler Foundation):
    - **MyoMo training: provided by MyoMo company**
        - On-site training (01-2020), covered the following aspects:
            - Training on initial measurements and determination of potential subjects in the research study.
            - Details on the utilization techniques of the MyoMo orthotic device
            - Two subjects with disability participated in this training session and study therapists received hands-on training with the MyoMo orthotic device.
            - Reviewed of MyoPro orthotic and key functions
            - Practiced therapy routines, therapy treatment guide
            - Practiced all study protocol, routines, dosing, and collection of outcomes along with treatment examples
            - Two subjects with disability participated in this training session and study therapists received hands-on training with the device.
            - Generated a therapy schedule using the MyoMo orthotic device specifically for persons with SCI when enrolled in this research study. This training schedule was finalized with input from study staff members and researchers from MyoMo company during the on-site trainings.
        - Virtual training on performing the GRASSP evaluation was provided to the study therapists.

How were the results disseminated to communities of interest?

The following papers/abstracts have been generated;

1. Two full grant proposals were submitted to the:
    - CDMRP-OPORP (Level II)
    - CDMRP-SCIRP (Clinical Trial Award)
2. One paper to the International conference on Wearable Robotics (WeRob 2020) was accepted and presented (oral presentation). This paper has been published, Citation is as follows:
    - G. J. Androwis, S. Kirshblum, and G. Yue, "The Utilization Effects of Powered Wearable Orthotics in Improving Upper Extremity Function in Persons with SCI: A Case Study," Cham, 2022: Springer International Publishing, in Wearable Robotics: Challenges and Trends, pp. 473-477.

1. Final versions of two papers have been prepared and subkmitted for publication as part of the EMBC 2021. They will both be PubMed indexed (Submitted paper is attached).
2. An abstract was submitted to Military Health System Research Symposium and was accepted for presentation (acceptance letter is attached).

Continuing to generate additional abstracts, conference papers, scientific presentations and potentially manuscript publication (comparing post training to pre-evaluation).
We are planning to have a few abstracts, conference papers, scientific presentations and potentially manuscript publication (comparing post training to pre evaluation).

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- We have requested a no-cost-extension to complete the needed number of participants into the study. The request has been approved to extend the study until next year (10/15/2022).
- Recruitments of subjects to participate in the research investigation:
    - Enroll more participant and provide the needed rehabilitation training and evaluation to generate needed outcome and scientific evidence related to the aims of this investigation.
    - We have a number of potential subjects who are currently lined-up to be scheduled for an in-person consenting/screening in the following a few weeks. This number is likely to increase due to our in-place mechanisms of finding new candidates for participation in the study.
    - Data collection and analysis is also on-going to obtain results and findings needed to provide the objective evidence supporting the study's specific aims.
    - Our plan is focused on the following:
- Our focus is to increase enrollment of participants into the study. Recruitment for additional subject and inviting them to the lab for consenting and screening.
    - Enrollment of participants into research projects has been challenging due to COVID-19 virus, but we believe that it is getting more promising as more people get vaccinated and more patients get more comfortable coming to research projects.
- Working on dissemination the work already created by doing the following:
    - Continue to pre-processing, data analysis and preparation of the collected outcomes from subjects already enrolled in the study.
    - Submitting manuscripts for publication.

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

- We have provided a great review of the investigated system through the paper which was accepted for presentation at the International conference on Wearable Robotics (WeRob 2020). This presentation was provided virtually due to the unfortunate situation of COVID-19. There was also a live discussion session where other researcher were interacting with us with questions/answers on the paper.
- Grants submitted: Two full grant proposals were submitted to the:
    - CDMRP-OPORP (Level II)
    - CDMRP-SCIRP (Clinical Trial Award)

- One paper to the International conference on Wearable Robotics (WeRob 2020) was accepted and presented (oral presentation). This paper has been published, Citation is as follows:
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- Final versions of two papers have been prepared and submitted for publication as part of the EMBC 2021. They will both be PubMed indexed (Submitted paper is attached).
- An abstract was submitted to Military Health System Research Symposium and was accepted for presentation (acceptance letter is attached).

We anticipate when enough data and outcomes are available on the evaluation of this orthotics assistive technology that rehabilitation and managements for upper extremity in persons with SCI will benefit from these findings and will result in improvement for the activity of daily living and function movements. The impact of the current study is to provide the evidence to directly affect rehabilitation treatment options by using the technology, as well as to provide an evidence based platform for the introduction of home based strategies for the recovery of hand and arm functions for increasing activity of daily living and quality of life in individuals with iSCI. The outcomes of the study are also expected to provide information for the development of next-generation assistive technologies to better serve those with disabilities. Further, these results will establish the first guidelines of a powered robotic orthosis (MyoPro) for persons with iSCI, for specifically improving function, activity of daily living and quality of life. Data generated from this clinical trial investigation will advance the field of orthotics and prosthetics outcomes-related rehabilitation research and patient care. Therefore, this knowledge product will justify the utilization of such orthotic technology in individuals with SCI, including a large population of veteran in the VA system.

What was the impact on other disciplines?

Nothing to Report

What was the impact on technology transfer?

:

Nothing major to Report yet.
We believe that the initiation and established of this line of work in persons with SCI while supported with clinical, functional, object and subjects outcome measure will indeed have a great benefit on translating the utilization of this orthotic device for upper extremity assistance and rehabilitation.

What was the impact on society beyond science and technology?

Nothing to Report yet.

5. CHANGES/PROBLEMS:

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing major to Report.

Although, the situation of COVID-19 is not finalized and is still affecting enrollment of participants into the study.
We will be requesting a no-cost-extension to complete the needed number of participants into the study
Our plan is:

- To enroll as many subjects as possible in the following a few months.

Changes that had a significant impact on expenditures

Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

3. One paper to the International conference on Wearable Robotics (WeRob 2020) was accepted and presented (oral presentation). This paper has been published, Citation is as follows:
   - G. J. Androwis, S. Kirshblum, and G. Yue, "The Utilization Effects of Powered Wearable Orthotics in Improving Upper Extremity Function in Persons with SCI: A Case Study," Cham, 2022: Springer International Publishing, in Wearable Robotics: Challenges and Trends, pp. 473-477.
4. Final versions of two papers have been prepared and submitted for publication as part of the EMBC 2021. They will both be PubMed indexed (Submitted paper is attached).
5. An abstract was submitted to Military Health System Research Symposium and was accepted for presentation (acceptance letter is attached).

Books or other non-periodical, one-time publications.

Nothing to Report

Other publications, conference papers and presentations.

One paper to the International conference on Wearable Robotics (WeRob 2020) was accepted and presented (oral presentation). This paper has been published, Citation is as follows:

- G. J. Androwis, S. Kirshblum, and G. Yue, "The Utilization Effects of Powered Wearable Orthotics in Improving Upper Extremity Function in Persons with SCI: A Case Study," Cham, 2022: Springer International Publishing, in Wearable Robotics: Challenges and Trends, pp. 473-477.

An abstract was submitted to Military Health System Research Symposium and was accepted for presentation (acceptance letter is attached).

- **Website(s) or other Internet site(s)**

Nothing to Report

- **Technologies or techniques**

Nothing to Report

- **Inventions, patent applications, and/or licenses**

Nothing to Report

- **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: *Ghaith Androwis*
Project Role: *Research Scientist*
Researcher Identifier (e.g. ORCID ID): *0000-0001-8465-9141*
Nearest person month worked: *3*
Contribution to Project: *Dr. Androwis is the PI of the project and is responsible for the overall administration and direction of the research protocol, IRB applications and any paperwork needed to obtain needed approvals for this research investigation.*
Dr. Androwis has been working to arrange and prepare study staff member to become fully training on the utilization of the study training systems and evaluation equipment.
Further, Dr. Androwis has finalized the study's data collection space/equipment and he, with assistance from study team members, have conducted evaluations of participants with SCI.

Name: *Salli Alrabadi, MS*
Project Role: *Research Assistant*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *3*
Contribution to Project: *Ms. AlRabadi is the newly hired RA on the study. She has been assisting in finalizing the CRF and data sheets in addition to providing any support needed by the PI, Dr. Androwis regarding potential subjects scheduling, purchase orders, calibration of equipment and preparation of materials and training.*

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to Report

What other organizations were involved as partners?

Nothing to Report

8. **SPECIAL REPORTING REQUIREMENTS**
   COLLABORATIVE AWARDS:
   QUAD CHARTS:

9. **APPENDICES:**