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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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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.

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.

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
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TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

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:** *Provide a brief list of keywords (limit to 20 words).*

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

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

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?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project

progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

I. **Major Task 1:** Initiation of the investigation and getting started.
Finalizing the investigation's protocol and providing the needed training for staff members and treating therapists:

- Prepare Regulatory Documents, the Research Protocol and IRB applications for local IRB committee and for the HRPO review
    - Obtain Local IRB approvals at Kessler Foundation
- Obtain needed equipment, orthoses and supplies
    - Robotic exoskeleton orthoses have been purchased and are available at Kessler Foundation to be used in the project. Four MyoMo orthotic units are available (2 left sided and two right sided)
- Preparation of data collection forms
  An initial version of data collection has been developed (January- 2019).
- Following up on the Regulatory Documents, the Research Protocol and IRB applications for local IRB committee and for the HRPO review
    - The initial approval of the Kessler Foundation IRB has been completed
    - The approved KF-IRB was submitted to the DoD-HARPO for further review and approval.
    - On April 01, 2019, we have received recommendations from HARPO to obtain further approvals from KF-IRB on amendments requested by HARPO.
      The requested recommendations were approved by KF-IRB office on April 11, 2019.
    - Updated documents were sent to DoD-HARPO on April 11, 2019 for final approvals and to get started in the study.
- A 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
    - Two potential candidates with SCI have been identified to be participating in the study, and will be invited for consenting and in-person screening as soon as therapists are training by MyoMo company
- Finalizing research protocol and provided in-depth training to study staff members on administering the study treatments and evaluations for individuals with SCI.
- Obtaining IRB continuation approval from local office (KF-KIR):
    - Continuation application submitted on 07-30-2019, copies of the application are attached
    - Minor amendment on the protocol (with no changes to the original SOW) was submitted on 09-30-2019. Copies of the submitted documents and currently approved consent forms are attached
- Amendments have been made on the CRF and of data collection forms
    - Refined versions of the CRF and data collection sheets are included on this report.
- Changes to study staff members (therapists and research assistant):
    - Research Assistant (Peter Niewrzol, M.S) was hired on the study.
    - Daniella S. Nath, OT has accepted another position outside Kessler institute for Rehabilitation, and Jennifer Murphy, OT is not available any more to do research activities due to changes in her duties in the in-patient therapy gym at KIR.

Currently, the study includes a total of five 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:

- *Farris Fakhoury, PT, DPT*
- *Alisha, K Sheridan, OT*
- *Marissa Prezzano, OT*
- *Alyssa Attanasio, OT*
- *Dasgupta, Monica, 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

II. **Major Task 2:** Investigating the therapeutic improvement of MyoPro orthosis. (On-going)
III. **Major Task 3:** Investigation the assistive improvements of the MyoPro orthosis. (On-going)
IV. **Major Task 4:** Determination of neuromuscular adaptations. (On-going)

- A data collection space used for evaluations, assessments and training (if needed) has been equipped with the needed evaluation systems and materials and currently is ready to perform the needed valuations as needed. Data collection and outcomes include:
    - Motion capture system to record kinematics of upper extremity during ADL and functional activities.
    - EEG outcomes
    - EMG outcomes
    - Strength and gripping outcomes
    - TMS combined with EMG and kinematics outcomes.
- Two candidates with SCI have been identified to participate in the study. Subjects are consented, screened and currently are enrolled in the study.

Another four potential candidates with SCI have been recruited to participate in the study. They are lined-up and interested to participate and within the following a few weeks will be invited to consent and get an in-person screening for potential enrollment in the study

activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

- 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.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."
Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Recruitments of subjects to participate in the research investigation:
    - We have four 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.
    - If these subjects qualified based on in-person determination by research staff members, therapists and, clinicians he/she will be enrolled in the study for baseline evaluation, and then start receiving rehabilitation training as indicated in the study protocol.
    - Recruitment for additional subject is on-going
    - 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.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report yet.

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?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

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?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report yet.

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Nothing major to Report.

Slight delay in the enrollment of subjects as we needed to have the therapists fully certified and trained on utilizing the MyoMo orthotic device and on the proper administration of the evaluation assessments (e.g. GRASSP outcome measurement) before we enroll subjects in the study.
Also great amount of effort and time was invested during the process of getting the regulatory approval from the local IRB office and HRPO.
Comments on resolving this minor delay include the following:

- Going forward, this is not an issue since all of the OTs involved in the study are currently trained and fully ready to provide training and evaluation for study participants.
- Minor amendments on the consent inclusion criteria (with no changes to the original SOW) was requested and approved. These minor changes will increase the availability for potential subjects and candidates for enrollment in the study.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to Report

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

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

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: *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

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

  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Not yet. We expect to produce several publications, conference papers and scientific presentations that will be the result of the unique data that are collected in the research investigation. Due to the uniqueness of the potential data from this pilot investigation, we will be reporting (in short papers and journal articles) the findings and results as early as possible. We are planning to start our dissemination progress by submitting findings on in case study reports and eventually expand it to journal articles.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each*

one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding,

prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

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: *Peter Niewrzol*
Project Role: *Research Assistant*
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: *3*
Contribution to Project: *Mr. Niewrzol is the newly hired RA on the study. He 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?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.
Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.