AWARD NUMBER: W81XWH-15-2-0068

TITLE: Ambulatory and Non-Ambulatory Benefits of Lower Limb Exoskeleton Use, with and without FES, in Clinical and Community Settings

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14. ABSTRACT

This research investigates the extent to which regular walking in an exoskeleton will provide mobility, health, and recovery benefits to individuals with spinal cord injury. The research is comprised of three sub-studies. The first investigates prospective benefits while walking in an exoskeleton; the second investigates prospective additional benefits when the exoskeleton is supplement with lower limb functional electrical stimulation; and the third investigates prospective benefits during home and community use. As of this annual report, both the first and second studies are underway. The first is nearly complete, with 20/24 subjects either enrolled or completed. The second has recently begun at Vanderbilt and Mayo Clinic, with 5/24 subjects enrolled or completed. Overall, the study is approximately one year behind original schedule, due primarily to unexpected delays in the approval processes. All three studies should be completed at full enrollment with an anticipated one-year no-cost extension.

15. SUBJECT TERMS

spinal cord injury, paraplegia, exoskeleton, physical medicine and rehabilitation, rehabilitation research, legged mobility, neuromuscular impairment, neural and functional recovery

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1. INTRODUCTION:

This research investigates the extent to which regular walking in an exoskeleton will provide mobility, health, and recovery benefits to individuals with spinal cord injury. The research is comprised of three sub-studies. The first investigates prospective benefits while walking in an exoskeleton; the second investigates prospective additional benefits when the exoskeleton is supplemented with lower limb functional electrical stimulation; and the third investigates prospective benefits during home and community use. The respective studies will characterize effects of exoskeleton walking on pain, spasticity, bowel and bladder function, body-mass index (BMI), bone mineral density (BMD), cardiovascular health, well-being, potential neurological recovery, and level of mobility. The research is being conducted at three sites – Vanderbilt Medical Center, Mayo Clinic, and the Tampa VA – each of which is conducting the same study protocol. The first two studies, each of which are conducted in a clinical setting, will enroll 24 subjects total (8 per study site), while the third, which is a take-home study, will enroll 6 subjects total (2 per study site). Due to approval delays, the research is approximately one year behind the original schedule, but all studies are expected to be completed with full enrollment pending a one-year no-cost extension. At this point, the first and second studies are underway, with 20 of 24 subjects enrolled or completed in the first study, and 5 of 24 enrolled or complete in the second study.

2. KEYWORDS:

spinal cord injury; paraplegia; exoskeleton; physical medicine and rehabilitation; rehabilitation research; legged mobility; neuromuscular impairment; neural and functional recovery

3. ACCOMPLISHMENTS:

The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

The following narrative provides a description of progress:

This research entails three sub-studies. Studies 1 and 2 enroll 24 subjects each, while study 3 is exploratory and will enroll a total of 6 subjects. As such, the studies 1 and 2 are scheduled (in the SOW) to take the first approximately 3.5 years of the research project, while study 3 is scheduled to occur over the final 6 months of the project. At this point in the project, study 1 was scheduled to be complete, while study 2 was scheduled to be 80% complete. At this point, the project is progressing well, although due to unexpected approval delays in the first 18 months, the project is about one year behind schedule. Specifically, study 1 has 20/24 subjects enrolled or complete, while study 2 has 5/24 enrolled or complete. Despite being behind schedule, the project is expected to complete all three studies at full enrollment pending a one-year no-cost extension. The table below outlines progress with respect to the SOW milestones.

The following table outlines the major tasks there were scheduled to start and be in progress during previous reporting periods:

Task/Milestone	Description	Target Completion Date/Quarter	Status
Major Task 1	Finalize Protocol and Obtain IRB/HRPO Approval for Study 1	Apr 2016 or Y1Q3	COMPLETED
Major Task 2	Conduct Study 1	Jan 2018 or Y3Q2	IN PROGRESS (20/24 subjects enrolled or completed)
Major Task 3	Finalize Protocol and Obtain IRB/HRPO Approval for Study 2	Jan 2018 or Y3Q2	IN PROGRESS (completed at VU and Mayo, in progress at Tampa)
Major Task 4	Conduct Study 2	Jan 2019 or Y4Q2	IN PROGRESS (5/24 subjects enrolled or completed)
Major Task 5	Finalize Protocol and Obtain IRB/HRPO Approval for Study 3	Jan 2019 or Y4Q2	NOT YET STARTED
Major Task 6	Conduct Study 3	Sept 2019 or Y4Q4	NOT YET STARTED

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.

- Major activities during Y3:
    - 11/24 subjects for Study 1 enrolled or completed during Y3, for a total of 20/24 Study 1 subjects.
    - Study 2 protocol received IRB/HRPO approval at VU and Mayo.
    - Exoskeletons at VU and Mayo were modified to include FES functionality.
    - Clinical staff at VU and Mayo underwent training to use FES functionality.
    - Study 2 protocol under review at Tampa VA. Note that this delay in approval is not a delay in the study, since Tampa is at full capacity enrolling Study 1 participants. We expect Study 2 approval at Tampa in Y4Q1 (2018 Q4), which will not result in a study delay.
    - 5/24 subjects for Study 2 were enrolled or completed during Y3, for a total of 5/24 Study 2 subjects.

- Specific objectives:
    - Conduct and complete Study 1.
    - Receive IRB/HRPO approval for Study 2.
    - Modify exoskeletons for FES functionality.
    - Train staff for FES functionality.
    - Initiate conduct of Study 2.

- Significant results or key outcomes:
    - Study 1 is nearing completion.
        - Mayo has completed Study 1.
        - Vanderbilt has 2 subjects left to enroll.
        - Tampa has 2 subjects left to enroll.
    - Study 2 is underway at VU and Mayo.
        - Mayo has completed 2 subjects, has 2 more in treatment.
        - Vanderbilt has completed 1 subject.
        - Tampa is awaiting IRB approval.

- Other achievements: None yet.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" 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.

Clinical staff at all study sites attended an initial 3-day course and obtained training and certification to use exoskeletons in clinical practice. Clinical staff at Mayo and Vanderbilt have subsequently attended a 2-day course and obtained training and certification to use exoskeletons with FES in clinical practice.

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.

No results yet to disseminate. Study 1 will be complete within the quarter, after which we will perform analysis of the data and prepare results for dissemination.

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.

1) Complete Study 1. This is expected to be completed in Q4 of 2018.
2) Obtain IRB/HRPO approval of the Study 2 protocol for Tampa. This is expected to be completed in Q4 of 2018.
3) Upgrade Tampa exoskeletons for FES functionality, and train Tampa clinical staff for FES functionality.
4) Enroll or complete another 15 Study 2 subjects (for a total of 20/24).
5) Obtain IRB approvals for Study 3.

4. **IMPACT:** Describe 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 at this point.

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 at this point.

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 to report at this point.

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.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

No changes in objectives or scope.

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.

Study 1 approval took much longer than expected, and as result our study started approximately one year behind schedule. Since receiving IRB/HRPO approval, Study 1 has proceeded smoothly. We have had some occasional minor equipment problems, but most of that is resolved. We have had a couple subjects have to withdraw for non-study-related reasons, but enrollment and treatment have largely gone well. We have had some adverse events, but very few related to the study, and no serious adverse events. Study 2 has started and is also going well. Of the three studies, Study 2 is the most challenging from a clinical perspective. We expect to complete all three studies with full enrollment with a one-year no-cost extension.

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.

None significant. We may need to stretch funding for the NCE, but we are approximately on target with regard to spending.

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

None to report.

Significant changes in use or care of vertebrate animals.

None to report.

Significant changes in use of biohazards and/or select agents

None 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).*

None yet to report.

  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).*

None yet 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.*

None yet 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.

None yet to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. In addition to a description of the technologies or techniques, describe how they will be shared.

None yet to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. State whether an application is provisional or non-provisional and indicate the application number. 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.

None yet 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;*
  - *biospecimen 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.*

None yet 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: Dr. Michael Goldfarb
Project Role: PI, Vanderbilt lead researcher
Researcher Identifier: ORCID ID 0000-0002-6622-095X
Nearest person month worked: 3
Contribution to Project: Dr. Goldfarb is coordinating the research effort.

Name: Ms. Sheri Dixon
Project Role: Vanderbilt study coordinator
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Ms. Dixon is the Vanderbilt study coordinator, has been assembling IRB and HRPO applications for Vanderbilt and all sites, has set up the REDCap database, and the overall project (i.e., multi-site) study coordinator.

Name: Ms. Christina Durrough
Project Role: Vanderbilt lead physical therapist
Researcher Identifier: n/a
Nearest person month worked: 3
Contribution to Project: Ms. Durrough has been assisting with design and assembly of the protocol and data recording notebooks, and is responsible for exoskeleton use and oversight.

Name: Dr. Kristin Zhao
Project Role: Mayo lead researcher
Researcher Identifier: ORCID ID 0000-0001-7598-8197
Nearest person month worked: 2
Contribution to Project: Dr. Zhao is leading the research effort at the Mayo Clinic.

Name: Ms. Megan Gill
Project Role: Mayo Clinic lead physical therapist
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Ms. Gill has been administering the study protocol on the two subject currently enrolled at Mayo.

Name: Mr. Tyson Scrabeck
Project Role: Mayo study coordinator
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Mr. Scrabeck has authored and assembled IRB and HRPO applications for the Mayo site.

Name: Mr. Daniel Veith
Project Role: PT
Researcher Identifier: n/a
Nearest person month worked: 1
Contribution to Project: Mr. Veith oversees treatment for some subjects.

Name: Mr. Michael Boyd
Project Role: PT assistant
Researcher Identifier: n/a
Nearest person month worked: 1
Contribution to Project: Mr. Boyd oversees treatment for some subjects.

Name: Dr. Walter Kremers
Project Role: Statistician
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Dr. Kremers is the study statistician.

Name: Mr. Zachary Pohlkamp
Project Role: PT assistant
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Mr. Pohlkamp oversees treatment for some subjects.

Name: Dr. Sam Phillips
Project Role: Tampa VA lead researcher
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Dr. Phillips leading the research effort at the Tampa VA.

Name: Mrs. Padmaja Ramaiah
Project Role: Tampa VA study coordinator
Researcher Identifier: n/a
Nearest person month worked: 1
Contribution to Project: Mrs. Ramaiah has authored and assembled IRB and HRPO applications for the Tampa site.

Name: Mrs. Lisa Goff
Project Role: PT
Researcher Identifier: n/a
Nearest person month worked: 2
Contribution to Project: Mrs. Goff is the lead PT at Tampa.

Name: Mrs. Anita Wadwani
Project Role: PT
Researcher Identifier: n/a
Nearest person month worked: 1
Contribution to Project: Mrs. Wadwani is one of the clinical PTs at Tampa.

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.

There has been no significant net change in active support for the study PI or co-PIs.

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:
<u>Organization Name:</u>
<u>Location of Organization: (if foreign location list country)</u>
<u>Partner's contribution to the project</u> (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.*

Organization Name: Mayo Clinic
Location of Organization: Rochester MN
Partner's contribution to the project (identify one or more)

- Collaboration: Mayo is one of the three study sites conducting the study protocol.

Organization Name: Tampa VA
Location of Organization: Tampa Bay FL
Partner's contribution to the project (identify one or more)

- Collaboration: Tampa is one of the three study sites conducting the study protocol.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

9. APPENDICES:

Ambulatory and Non-Ambulatory Benefits of Lower Limb Exoskeleton Use, with and without FES, in Clinical and Community Settings

Log no. SC140121

Award no. W81XWH-15-2-006

PI: Michael Goldfarb **Org:** Vanderbilt University **Award Amount:** $2,344,016

Study Aims

- Study 1: Determine extent to which regular walking in an exoskeleton provides health benefits, functional or neurological recovery, and legged mobility to non-ambulatory or poorly-ambulatory individuals with SCI.
- Study 2: Determine extent to which regular exoskeletal walking, when supplemented with functional electrical stimulation (FES) of leg and trunk muscle groups, will result in enhanced therapeutic and neurological benefits relative to exoskeleton use without FES.
- Study 3: Determine extent to which regular use of an exoskeleton in the home and community will result in enhanced therapeutic and neurological benefits relative to exoskeleton use in a clinic, to determine the extent to which the level of mobility provided by the exoskeleton will be amenable to home and community use, and to characterize the level of compliance of exoskeleton use.

Study 2 subject walking with FES-assisted exoskeleton.

Accomplishments and status: Mayo has completed Study 1; Vanderbilt is treating its fifth and sixth (of eight) subjects for Study 1; Tampa is treating its fifth and sixth subject (of eight) subjects for Study 1. Vanderbilt has completed one subject for Study 2; Mayo has completed two subjects for Study 2 and currently has two more in treatment. In total, all sites have enrolled 20/24 Study 1 subjects (discounting withdrawals), and 5/24 Study 2 subjects.

Timeline and Cost

Budget Year	15/16	16/17	17/18	18/19
Activity/Dates	09/30/15-09/29/16	09/30/16-09/29/17	09/30/17-09/29/18	09/30/18-09/29/19
IRB/HRPO				
Enrollment				
Study 1				
Study 2				
Study 3				
Publication				
Estimated budget ($k)	$597	$578	$593	$581

Updated: 10/29/2018

Budget Year 1 Goals

- ✓ IRB/HRPO approval for Study 1
- ✓ Study 1 underway

Budget Year 2 Goals

- ❑ Study 1 complete (status: 20/24 enrolled or complete)
- ✓ IRB/HRPO approval for Study 2 (status: approved at VU and Mayo)

Budget Year 3 Goals

- ✓ Study 2 underway (status: 5 subjects enrolled or complete)
- ❑ Study 2 80% complete (~18 subjects complete)
- ❑ Study 3 IRB/HRPO review initiated

Budget Year 4 Goals

- ❑ Study 2 complete
- ❑ Study 3 complete

Comments/Challenges/Issues/Concerns

All sites have enrolled 20/24 Study 1 subjects (discounting withdrawals), and 5/24 Study 2 subjects. Project is about one year behind schedule, mostly resulting from approval delays. All studies should be completed at full enrollment with anticipated one-year no-cost-extension.

Budget Expenditure to Date

Projected Expenditure: $1758k (assuming even burn rate through project)

Actual Expenditure: $1705k