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TITLE: Optimizing Ankle-Foot Orthotic Prescription Using an Emulation Test-Drive Strategy

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CONTRACTING ORGANIZATION: Henry M. Jackson Foundation, for the Advancement of Military Medicine, Inc.

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14. ABSTRACT
The commercial market for ankle-foot orthoses (AFOs) offers such a broad array of options, yet limited evidence to guide current AFO prescription, which instead relies on clinician intuition, training, experience, and qualitative manufacturer-produced guides. Thus, matching an AFO with optimal mechanical properties to the unique needs and abilities of a given patient is challenging. The inability to test-drive different designs is an unmet need that is holding back patient care, and for which a viable solution is being provided in this proposal. We propose to optimize the process of selecting the optimal AFO for a patient using an AFO emulator to adjust AFO mechanical properties in real-time via software interface, rather than using the resource-intensive trial-and-error approach currently practiced in clinical settings.

15. SUBJECT TERMS
Extremity Trauma, Emulation, Orthosis, Prescription

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1. INTRODUCTION:

Ankle foot orthoses (AFOs) are often necessary to overcome mobility limitations related to lower limb neuromusculoskeletal injury. While the availability of AFOs for improving function is expanding, options remain limited and especially relative to ankle-foot prostheses. There is a critical need to better optimize AFO designs and provide evidence-based tools to guide their prescription. This study utilizes an exoskeleton capable of emulating AFOs by modulating the magnitude and/or timing of torque. The study will determine if brief, in-lab assessments (with emulated AFOs) can predict longer term preference, satisfaction, and mobility outcomes after community trials with the actual AFOs. It will also compare the experience of walking with different actual AFOs to the corresponding emulated versions with the AFO emulator. A participant-blinded, randomized crossover study will recruit up to fifty-eight individuals with lower limb musculoskeletal injuries who currently use an AFO. Participants will walk on a treadmill with three different actual AFOs and corresponding emulated AFOs for the "in-lab" assessments. For the "community trials", participants will wear each of the actual AFOs for a two-week period during activities of daily living. During each AFO condition, performance-based and self-reported measures of preference and mobility will be compared between short- and long-term assessments (i.e., following a two-week community trial period), and between in-lab trials (with the emulated and actual AFOs).

2. KEYWORDS:

Extremity Trauma, Emulation, Orthosis, Prescription

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Primary Task	Timeline (mo)	Status
Regulatory Approvals	1-6	75%
Equipment Purchases	1-3	0%
Training	ongoing	50%
Data Acquisition	1-36	
Mechanical Testing	1-9	75%
Human Subjects Testing	9-36	0%
Data Analysis	10-36	25%
Dissemination	10-48	10%

What was accomplished under these goals?

Regulatory Approvals: External IRB approval (via WIRB) of the WRNMMC protocol/site was initially approved on 12 OCT 2022 and acknowledged by WRNMMC IRB (8 NOV 2022). We received OHRO approval for WRNMMC (memo dated 2/27/2023). WIRB has also now processed and approved the continuing review for WRNMMC (extending protocol expiration to 10/10/2024); acknowledged by OHRO. For VAPSHCS, the submission package has passed local IRB pre-review (endorsed on 7/27/2023) and the corresponding modification to add VAPSHCS to the WIRB package was submitted, currently awaiting review/approval. The SIBCR SOW was expanded to move HJF personnel at VAPSHCS to SIBCR (completed 5/1/2023). This removes the limitation on what research HJF personnel can do at VAPSHCS and transferred the purchase of the Humotech emulator.

Equipment Purchases: For WRNMMC, the emulator purchase/sales agreement was executed after the full executed CRADA (6/1/2023); we expect delivery in early 2024. For VAPSHCS, final agreements are still pending. Design of the emulator end-effector, in collaboration with Humotech, continued throughout the latter parts of Y2 (meeting monthly). We have identified several potential paths for ways to modulate footplate stiffness in the emulator to better replicate those properties. Anthropometric data has been evaluated to provide insight to the required dimensions of the end effector such that a wide range of participant geometries can be accommodated.

Training: Ongoing. With the expected initiation of study activities in early Y3, at WRNMMC we have interviewed and selected a Biomedical Engineer to support this study.

Data Acquisition:

Mechanical Testing: mechanical testing procedures have been developed and implemented. Data collections are ongoing.

Human Subjects Testing: N/A, awaiting full regulatory approvals.

Data Analysis: ongoing (mechanical testing).

Dissemination: initial knowledge dissemination has begun related to mechanical testing (as noted in the Y1 annual report). In Y2, we have drafted a protocol manuscript- awaiting registration on clinicaltrials.gov before submission.

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

Although not explicitly designed to provide training or professional development, staff at both sites continue to expand skillsets related to the inherent equipment/methodologies and broader research process. And, once primary data are available we expect future opportunities for knowledge translation among numerous key stakeholders (DoD and VA clinical teams), facilitated by the Clinical Affairs Division of the EACE.

How were the results disseminated to communities of interest?

Although still early in the larger study timeline, initial (mechanical testing) data has been disseminated through traditional scientific channels (i.e., scientific conferences and peer-reviewed journals); see section 6 below.

What do you plan to do during the next reporting period to accomplish the goals?

In the next reporting period (Y3, Q1), we expect to receive IRB approval for activities at both sites, as well as finalize agreements for VAPSHCS. Pending registration of the study on clinicaltrials.gov (currently awaiting review feedback/approval) we will publish a protocol paper (target submission to PLOS One). We will otherwise continue to hold biweekly and monthly meetings with the study team, including Humotech, to finalize emulator design and identify potential delivery dates. Pending progress updates, it is likely that emulator delivery will be scheduled in Y3, late Q1 or early Q2 (with this we plan to host an official project kick-off).

4. IMPACT:

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

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report

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

Although we have (finally!) navigated the many challenges associated with the creation and execution of agreements at both sites, the project remains substantially delayed relative to the original SOW. Despite IRB approval (at WRNMMC), we cannot begin study activities until emulator delivery; as such, the earliest initiation of data collection will occur in Y3, ~Q2 (vs. planned Y1, Q3. We will do our best to make up for lost time but will undoubtedly require extensions to achieve enrollment targets. We will update on this status in Y3 quarterly reports.

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**

The following manuscript is in preparation (will acknowledge funding support from this award):

Shuman, B.R., Hendershot, B.D, Morgenroth, D.C., Russell Esposito, E. A Patient-Centered 'Test-Drive' Strategy for Ankle-Foot Orthosis Prescription: Protocol for a Randomized Participant-Blinded Trial. *PLOS One* (fully drafted)

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

Nothing to report

Other publications, conference papers and presentations.

- **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: Dr. Bradford Hendershot
Project Role: Overall and WRNMMC Site Principal Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Overall project management

Name: Ms. Clare Severe
Project Role: Research Engineer
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Support to WRNMMC study preparatory and regulatory activities

Name: Ms. Heidi Mahatan
Project Role: Program/Portfolio Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Support budgetary and regulatory activities

Name: Dr. David Morgenroth
Project Role: VAPSHCS Principal Investigator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: project management for VAPSHCS activities

Name: Dr. Benjamin Shuman
Project Role: VAPSHCS Study Lead
Researcher Identifier (e.g. ORCID ID): 0000-0002-6976-8021
Nearest person month worked: 3
Contribution to Project: Support to VAPSHCS study initiation, regulatory activities, and local study lead

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?

Seattle Institute for Biomedical and Clinical Research (SIBCR); Seattle, WA
Dr. Morgenroth participates in meetings with Drs. Hendershot (overall project PI) and Shuman to provide input/guidance and discuss project-specific regulatory documents and strategy as well as agreements with Humotech.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *N/A*

QUAD CHARTS: *N/A*

9. APPENDICES: *N/A*