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TITLE: Comparative Effect of Commercially Available Custom Dynamic Orthoses (CDOs)

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14. ABSTRACT

The objective of this research is to provide first-of-its-kind comparative effectiveness data for commercially and clinically available CDOs, and identify factors most strongly associated with device preference and function. Our efforts primarily focus on outcomes associated with the form, fit, and resulting function with the devices. The project's specific aims are to (1) determine the comparative effect of custom dynamic orthosis type in individuals with limb impairment resulting from traumatic limb injury; (2) determine if study-provided custom dynamic orthoses improve function relative to no-device and standard-of-care conditions in individuals with impairment resulting from traumatic limb injury; and (3) identify factors that are associated with device preference and function. A multicenter, prospective, randomized, crossover, controlled clinical trial will be conducted to determine the effect of device type on patient outcomes. Study staff have been hired, the project sites have received local IRB approval and are awaiting HRPO approval prior to initiating collection.

15. SUBJECT TERMS

None listed.

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1. INTRODUCTION:

The objective of this research is to provide first-of-its-kind comparative effectiveness data for commercially and clinically available CDOs, and identify factors most strongly associated with device preference and function. Our efforts primarily focus on outcomes associated with the form, fit, and resulting function with the devices. The project's specific aims are to (1) determine the comparative effect of custom dynamic orthosis type in individuals with limb impairment resulting from traumatic limb injury; (2) determine if study-provided custom dynamic orthoses improve function relative to no-device and standard-of-care conditions in individuals with impairment resulting from traumatic limb injury; and (3) identify factors that are associated with device preference and function. A multicenter, prospective, randomized, crossover, controlled clinical trial will be conducted to determine the effect of device type on patient outcomes. The trial will compare two commercially available devices. The devices will also be compared to standard-of-care (SOC) and no-device (NONE) conditions to examine the effect on limb function. Physical performance measures, patient-reported outcomes, and biomechanical testing data will be used to fully evaluate device function and participant outcomes. The PI proposes that the data from this study will inform clinical care decisions in both military and civilian settings by improving the understanding of the benefits and limitation of available devices and the factors that contribute to patient satisfaction and dissatisfaction.

2. KEYWORDS:

Orthosis, Custom, Dynamic, Limb Trauma, Outcomes, Biomechanics, Gait, Physical Performance

3. ACCOMPLISHMENTS:

What were the major goals of the project?

	Months	Percent Complete
Major Task 1: Overarching Project Activities		
Subtask 1: Identify, hire and retain top quality staff and students	0-48	100%
Subtask 2: Obtain and maintain local IRB and HRPO regulatory approvals	0-48	100%
Subtask 3: Project team teleconferences	0-48	92%
Subtask 4: Complete study reports, presentations, publish and disseminate study results	10-48+	0%
<i>Milestone: Timely submission of progress reports</i>	3-48	92%
<i>Milestone: Submission of continuing review documents</i>	12-48	83%
<i>Milestone: Local IRB and HRPO approval at all sites</i>	6	100%
<i>Milestone: Submission of final report</i>	48	0%

Major Task 2: Project Standup		
Subtask 1: Establish CRADA and other required agreement	0-6	100%
Subtask 2: Finalize collection procedures and REDCap data management	0-6	100%
Subtask 3: Fabricate and distribute device mechanical testing systems	0-6	100%
Subtask 4: Staff training and collection procedure refinement	3-6	100%
<i>Milestone: All approvals and agreements in place</i>	6	100%
<i>Milestone: Ready to initiate recruitment and collection</i>	6	100%
Major Task 3: Patient Fittings		
Subtask 1: Work with vendors to finalize distribution and training plan	0-3	100%
Subtask 2: Inter-site coordination of fitting processes and CPO training	0-12	100%
Subtask 3: Completion of study fitting manual describing procedures	0-12	100%
<i>Milestone: Ready to initiate fittings</i>	6	100%
<i>Milestone: Patient fittings ongoing and logistics resolved</i>	12	100%
Major Task 4: Participant Testing		
Subtask 1: Staff training and methods verification	3-45	100%
Subtask 2: Ongoing data quality checks	9-42	100%
Subtask 3: Recruitment, enrollment and collection (31 Patients UI)	7-40	77%
Subtask 4: Recruitment, enrollment and collection (25 Patients MVHCS)	7-40	40%
Subtask 5: Recruitment, enrollment and collection (15 Patients WR)	12-40	27%
<i>Milestone: Enrollment complete</i>	33	52%
<i>Milestone: Collection complete</i>	40	17%
Major Task 4: Data Analysis and Publication		
Subtask 1: Data Analysis- Patient reported and performance measures	14-45	24%
Subtask 2: Data Analysis- Biomechanical and mechanical measures	14-45	21%
Subtask 3: Finalize and implement statistical analysis plan	40-45	0%
Subtask 4: Interpretation of results and manuscript preparation	40-45	0%
<i>Milestone: Analysis complete</i>	45	0%
<i>Milestone: Initial manuscripts</i>	48	0%
Specific Aim 1: Determine the comparative effect of custom dynamic orthosis type in individuals with limb impairment resulting from traumatic limb injury		
Specific Aim 2: Determine if study-provided custom dynamic orthoses improved function relative to no device, and standard of care conditions, in individuals with impairment resulting from traumatic limb injury		
Specific Aim 3: Identify factors that are associated with device preference and function		

What was accomplished under these goals?

Major Task 1

Study standup activities continue across all three sites. MVAHCS hired a research assistant, Matt Sauerbrey, to assist with recruitment and data collection. Existing staff continue to contribute to the project at all three sites. Project coordination is ongoing between sites. Weekly project teleconferences have been held to ensure consistency of study documents and verify methods across sites. All sites submitted and received approval for continuing review materials to their local IRB and HRPO.

MVA motion lab was under construction for a few months causing a delay in recruitment and biomechanical data collection at this site. The research team at MVAHCS scheduled follow-up study visits and recruitment appropriately before the lab was under construction and have resumed all biomechanical data collection now that construction is complete.

A 12 month no-cost extension was approved for the study through September 29, 2023. Delays were primarily due to the ongoing COVID-19 pandemic, and the additional time was requested to complete enrollment, testing and analysis. No additional funds were requested, and the extension does not involve a change in the objectives or scope of the project.

Major Task 2

Amendments were submitted and approved at UIA and MVAHCS by the local IRB to include risks related to casting and device wear to the informed consent document. UIA also submitted an amendment to add three physicians to the protocol to expand recruitment efforts. The REDCap randomization form SOC vs None was updated across all sites to include a field indicating testing order determined by randomizer. MVAHCS amended their subaward and updated their ICD to include shoe reimbursement for participants to meet their daily footwear needs with the study devices. These modifications do not increase risk to subjects or meet other requirements for HRPO submission. The Standard Operating Procedures Manual was updated to include more detailed study methods and shared with all sites.

WRNMMC and MVAHCS each received a CDO mechanical testing device and completed training.

Major Task 3

Patient fittings are ongoing at all sites.

Major Task 4

Deviations from desired center of pressure accuracy have been resolved at partnering sites. This data quality issue delayed collection at MVAHCS and initiation at WRNMMC, however, collection is now underway. WRNMMC and MVAHCS sent biomechanical data and MASTF data to UIA for review.

Recruitment, enrollment and collection are ongoing at all sites. UIA analyzed patient reported and physical performance measures data across all sites. Processed and analyzed biomechanical data and mechanical measures of CDOs.

Although COVID-19 had wide ranging effects on study activities, it is expected that with a one year no cost extension we will be able to complete our remaining major tasks in a manner similar to that initially planned over the next and future quarters.

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

Nothing to Report

How were the results disseminated to communities of interest?

Nothing to Report

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

During the next reporting period, recruitment, enrollment, and data collection will continue across all sites. Additional staff training and methods verification will take place across all sites.

Although COVID-19 had wide ranging effects on study activities, it is expected that with the one year no cost extension we will be able to complete our remaining major tasks in a manner similar to that initially planned over the next and future quarters.

4. IMPACT:

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

The ongoing discussions between the study team members and industry have advanced the way team members think about CDO fitting. These discussions have the potential to advance both industry and clinical practice in the future and will likely result in a future related grant submission.

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:

Nothing to Report

Changes in approach and reasons for change

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

Due to the concerns regarding COVID-19, research restrictions and social distancing guidelines resulted in the delay of recruitment, data collection, and manufacturing the final mechanical testing devices. Participant visits were postponed to decrease the risk to individuals for a period of time.

MVAHCS motion lab was under construction for a few months causing a delay in recruitment and biomechanical data collection at this site. The research team at MVA scheduled follow-up study visits and recruitment appropriately before the lab was under construction and have resumed all biomechanical data collection now that construction is complete.

At WRNMMC, two study participant devices developed small cracks in the footplates that was discovered at the end of the 3-month accommodation period. Since the cracking was minor and was not discovered until the end of the accommodation period, the fabrication companies have been contacted for awareness. Device was repaired by orthotist. No injury or other harmful event occurred. No further action is needed.

Changes that had a significant impact on expenditures

COVID-19 related delays in study activities resulted in a corresponding reduction in study related expenditures. Current expenditures align with the proportion of work completed, therefore, adequate funds remain for the completion of study activities.

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

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**
Journal publications.

Nothing to Report

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

Nothing to Report

Other publications, conference papers and presentations.

Nothing to Report

- **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: Jason Wilken, PhD
Project Role: Overall Award Principal Investigator;
UI Site Principal Investigator
Researcher Identifier (ORCID ID): 0000-0002-5556-7667
Nearest person month worked: 4
Contribution to Project: Study direction, site management, regulatory approvals,
review of patient fitting methods, work with vendors to
finalize distribution and training plan

Name: Molly Pacha, MS
Project Role: Research Associate
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 10
Contribution to Project: Data collection procedure refinement, regulatory
approvals, technical report preparation and submission.

Name: Natalie Glass, PhD
Project Role: Statistician
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 1
Contribution to Project: Preparation of study documentation in REDCap

Name: Michael Willey, MD
Project Role: Co-Investigator
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 1
Contribution to Project: Study direction, data collection, procedure refinement

Name: Megan Grunst
Project Role: Undergraduate Research Assistant
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 2
Contribution to Project: Data collection

Name: Andrew H. Hansen, PhD
Project Role: MVAHCS Site Principal Investigator
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 4
Contribution to Project: Site PI, Study standup activities

Name: *Kierra Falbo, CPO*
Project Role: *MVAHCS Research Orthotist*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *6*
Contribution to Project: *Study standup activities, data collection procedure refinement*

Name: *Matt Sauerbrey*
Project Role: *Research Assistant*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *2*
Contribution to Project: *Data collection*

Name: *Amber Wacek*
Project Role: *Research Physical Therapist*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *2*
Contribution to Project: *Data collection*

Name: *Bradford Hendershot, PhD*
Project Role: *WRNMMC Site Principal Investigator, Co-Investigator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *4*
Contribution to Project: *Site PI (starting 9/28/21, previously co-investigator), Study standup activities and overall project management*

Name: *Heidi Mahatan, MA*
Project Role: *WRNMMC Research Coordinator*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *2*
Contribution to Project: *Regulatory activities and programmatic support*

Name: *Clare Severe*
Project Role: *WRNMMC Biomedical Engineer*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *8*
Contribution to Project: *Data collection*

Additional individuals contributed less than 0.5 calendar months effort.

Name: *Patricia McCracken, DPT*
Project Role: *MVAHCS Research Physical Therapist*
Researcher Identifier (ORCID ID): *NA*
Nearest person month worked: *0.8*
Contribution to Project: *Study standup activities, data collection procedure Refinement*

Name: John Looft, PhD
Project Role: MVAHCS Study Staff
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 0.5
Contribution to Project: Study standup activities, data collection procedure refinement

Name: Juan Cave II, MSPO, CPO
Project Role: MVAHCS Research Orthotist
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 0.5
Contribution to Project: Data collection

Name: Brogan Comstock
Project Role: Research Assistant
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 0.5
Contribution to Project: Data collection

Name: Neil Goldstein, MS
Project Role: WRNMMC Research Coordinator
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 0.05
Contribution to Project: Regulatory activities

Name: Elisa Arch, PhD
Project Role: UD Site/Subaward Principal Investigator
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 0
Contribution to Project: Subaward PI, Study standup activities - CDO Testing Device

Name: Luke Nigro
Project Role: UD Site/Subaward Co-Investigator
Researcher Identifier (ORCID ID): NA
Nearest person month worked: 0
Contribution to Project: Study standup activities - CDO Device Testing

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 beyond the team initially described in the grant proposal.

8. SPECIAL REPORTING REQUIREMENTS
COLLABORATIVE AWARDS: QUAD CHARTS:

9. APPENDICES: