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TITLE: Monitoring Prosthetic and Orthotic Function in the Community

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14. ABSTRACT

The activity level of these service members (SMs) and how it relates to their injury, prosthetics/orthotic prescription, and ability to return to work is not well understood. There is a need to better understand how lower limb prosthesis or orthosis users function in the community outside the lab to inform clinical decisions. The goal of this project is to verify a portable monitoring system's ability to measure prosthetic and orthotic function in the community and in return to duty situations. This project addresses the FY20 OPORP focus area of **prosthetic and orthotic device function** by testing a portable monitoring system that can be used in community and military relevant activities to analyze variables that are relevant to measuring patient outcomes and prosthetic/orthotic use outside of a laboratory or clinic.

15. SUBJECT TERMS
None listed.

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1. INTRODUCTION

The activity level of service members (SMs), and how it relates to their injury, prosthetic/orthotic prescription, and ability to return to duty is not well understood. There is a need to better understand how lower limb prosthesis or orthosis users function in the community outside the lab to inform clinical decisions. The main objective of this study is to verify a portable monitoring system to measure prosthetic and orthotic function in the community and in return to duty situations. Collecting accurate outcome measures in the community via an easy-to-use portable system will better inform the user and the clinical team and help to improve prescription, care, and return to duty strategies. The investigators at the University of South Florida (USF) are collaborating with the Naval Health Research Center (NHRC) to optimize time and resources. The monitoring system will integrate the following products: Inertial measurement units (IMUs), a Smartwatch, and a smart phone database application to monitor prosthetic/orthotic usage, gait parameters, type of activity, asymmetry, and perceived effort. To verify the systems' accuracy, subjects will be tested while performing several community relevant activities (e.g., walking, sitting, running, stair climbing) in a biomechanics laboratory setting while wearing the portable monitoring system within a motion capture space. The system will also be tested in a community setting to determine ease of use and comfort and its ability to aggregate data via the smart phone database application. This project will collect preliminary data on persons using a lower limb prosthesis or orthosis to develop appropriate hypothesis and statistical power for future clinical studies. These future studies will test the clinical applications of this portable monitoring system. There are several potential uses for the system including allowing the users to monitor their rehabilitation progress and health, better communication between the clinical team and patient, and a tool for researchers to collect and aggregate data in real world settings.

2. KEYWORDS:

Inertial Measurement Unit (IMU), prosthesis, orthosis, gait, activity monitoring

3. ACCOMPLISHMENTS:

a. **What were the major goals of the project?**

The specific aims of this project include:

• Aim 1 Integrated Portable Monitoring System: Integrate commercially available inertial measurement units (IMUs), a Smartwatch and a smart phone database application for appropriate tracking of outcomes by researchers and clinicians.

• Aim 2 Laboratory Testing and Verification: Verify the portable measuring system's ability to measure and distinguish the type, amount and quality of various activities by collecting portable measuring system data simultaneously with laboratory-based measures.

• Aim 3 Community Based Testing and Proof of Concept: Field test the portable measuring system to determine ease of use, comfort and data aggregation capabilities.

Wide-spread and long-term use of the mobile monitoring tool could have great impact on larger clinical studies in the future where community-based evaluation is needed.

b. **What was accomplished under these goals?**

Integration of IMUs (Aim 1):

The Xsens Dot Set that includes five IMUs, a charging station and straps was purchased. One of the main accomplishments has been identifying the different methods to accurately extract gait parameters from IMUs through a review of literature. The positive aspect of this current research shows that there are many ways to report gait parameters from the raw data given from the IMUs, which helps to test the quality of the data presented from the IMUs themselves. Many of these methods are complex and require a great deal of steps/understanding of proper IMU placement, coding for conversion of raw data into gait parameters and axis calibration with regards to aligning its coordinate system with the body. In addition, most literature references the use of two or more IMU devices in its trials to achieve gait

parameters such as gait stance/swing phases and joint angles. More development will be made in this field to properly achieve the outcomes presented in the previous section.

Smartwatch Comparison (Aim 1):
After comparison of smart watches, an Apple Watch Series 8 with GPS was chosen for integration. The Apple watch will be used to collect the following parameters: activity type, exercise (use of device) duration, heart rate, gait parameters, gait asymmetry and hard falls. The specific gait parameters will include step count, step length, gait speed, steadiness levels (classified as OK, Low, or Very Low), and double support time. The watch will also be set up to allow for the user to provide comments, which will be necessary during Phase 2 testing outside the laboratory.

Integration of Database Application (Aim 1):
This application will eventually be integrated with REDCap (Research Electronic Data Capture), a software available for free to REDCap Consortium Partners, which includes USF. REDCap is a web-based electronic data capture (EDC) tool used for research studies. Databases can be customized for studies' needs, data can be collected and tracked, subjects can be securely communicated with, and data can be exported to various statistical programs for analysis. For this project, REDCap will serve as the central database to securely store gait parameters collected from IMUs and the Apple Health app. The platform allows for customized database structures and data forms, aligning with the specific data collection requirements.

REDCap's flexible API will be utilized to seamlessly integrate our Flutter-based app with the REDCap database. This will enable smooth transfer of collected gait parameters into the centralized database, ensuring real-time data management and analysis. REDCap will serve as an administrator dashboard and be used for real-time data entry and validation to enable instant visibility into the collected gait parameters. This will allow for the improved iterations of the user dashboard needed for data collection outside the laboratory setting (Aim 3).

The workflow for the iterative application design that will be used if the following:

1. Detailed report and documentation of how the app should look like
2. Sketch for user-centric design
3. Create a mock-up design (Get feedback and update in every iteration)
4. UX/UI (User Interface) Design (Get feedback and update accordingly)
5. Work on building the app (Write code for front-end design based on features and parameters)
6. Testing the front-end design and working performance
7. Data integration on apps from IMUs and Apple Health (Back-end)
8. Back-end integration and updating the data
9. Data processing (if required)
10. Testing of the app performance
11. App Deployment

IRB Application for Laboratory Testing and Verification (Aim 2)
A protocol to test and verify the portable monitoring in the lab on the Computer Assisted Rehabilitation Environment (CAREN) system was developed. The testing protocol requires subjects to walk on inclines, declines, side slopes at varying walking speeds while wearing the integrated portable monitoring system. Gait parameters such as distance, speed, stride length, swing phases, and asymmetry will be measured with the portable system and lab-based system and compared. The study has been approved by University of South Florida's Institutional Review Board (IRB), the Naval Health Research Center's IRB and the Office of Human and Animal Research Oversight (OHARO).

An algorithm was developed to investigate the accuracy of wearable inertial measurement unit sensors by producing gait parameters, to be compared against a gold standard motion capture system. Two inertial measurement units (IMUs) were placed in the lower limb region, specifically in the shank region of each leg. The algorithm extracts raw acceleration data from the IMUs to calculate gait parameters such as stride length, stride time, step length, step time, stance time, swing time and cadence. A preliminary study was conducted with ten healthy participants walking on the CAREN system simulating

a flat road, a road with small hills and a road with medium level hills. Gait parameters were calculated from the IMUs and from the traditional motion capture system using 22 reflective markers (Figure 1). Gait parameters extracted and calculated from the IMUs were within an acceptable range when compared to the results displayed from the motion capture system. Details of this study were reported in a biomedical engineering master's thesis [1].

Figure 1. Image showing placement of the IMU sensors on the lower limb region (left) and the set-up with reflective markers on the motion base treadmill (right).

References:
[1] Fuller, Bryce, "Evaluating the Accuracy of Inertial Measurement Units in Detecting Gait Parameters for Lower Limb Prosthesis and Orthosis Users," MS thesis in Biomedical Engineering, University of South Florida, June 2023.
https://digitalcommons.usf.edu/cgi/viewcontent.cgi?article=11166&context=etd

c. **What opportunities for training and professional development has the project provided?**
Bryce Fuller completed his master's thesis in biomedical engineering on the topic of evaluating IMUs to detect gait parameters, which is part of the integration of the portable measuring device (Aim 1). He will work with another graduate student to expand his knowledge of app development in several software languages.

d. **How were the results disseminated to communities of interest?**
Information on progress of the project has been disseminated through a thesis by Bryce Fuller available through the University of South Florida digital commons website:

Fuller, Bryce, "Evaluating the Accuracy of Inertial Measurement Units in Detecting Gait Parameters for Lower Limb Prosthesis and Orthosis Users," MS thesis in Biomedical Engineering, University of South Florida, June 2023. https://digitalcommons.usf.edu/cgi/viewcontent.cgi?article=11166&context=etd

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

We have submitted documentation for a no-cost extension so the project period can be extended to Sept. 30th, 2024. For the next reporting period, the working prototype of the entire measurement system will be used to conduct experiments with subjects using a lower limb orthosis or prosthesis on the CAREN system (Aim 2). Preliminary testing of the IMU placement and accuracy of gait parameter measurements may be disseminated at the conference for the American Academy of Orthotists and

Prosthetists in March 2024. The remaining period will be used to complete community based testing and proof of concept.

4. IMPACT:

a) **What was the impact on the development of the principal discipline(s) of the project?**
Nothing to Report
b) **What was the impact on other disciplines?**
Nothing to Report
c) **What was the impact on technology transfer?**
Nothing to Report
d) **What was the impact on society beyond science and technology?**
Nothing to Report

5. CHANGES/PROBLEMS:

a) **Changes in approach and reasons for change**
Nothing to Report
b) **Actual or anticipated problems or delays and actions or plans to resolve them**
The CAREN system had some problems with the computer that controls the platform as well as some other minor maintenance issues. The CAREN system had to be repaired and was unable to be used for the study for several months. These issues have been resolved and a new maintenance contract on the CAREN system has been established.
c) **Changes that had a significant impact on expenditures**
Nothing to Report
d) **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
A minor change to the testing protocol was implemented and approved by the IRBs and OHARO. For healthy subjects only, an addition to weights added to the ankle to create asymmetry was added to the testing protocol. This was to allow for testing of the monitoring system to accurately determine gait asymmetry with healthy subjects prior to testing with subjects using a prosthesis or orthosis.
e) **Significant changes in use or care of human subjects**
Nothing to Report
f) **Significant changes in use or care of vertebrate animals.**
Nothing to Report
g) **Significant changes in use of biohazards and/or select agents**
Nothing to Report

6. PRODUCTS

a) **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.

Fuller, Bryce, "Evaluating the Accuracy of Inertial Measurement Units in Detecting Gait Parameters for Lower Limb Prosthesis and Orthosis Users," MS thesis in Biomedical Engineering, University of South Florida, June 2023. https://digitalcommons.usf.edu/cgi/viewcontent.cgi?article=11166&context=etd
b) **Website(s) or other Internet site(s)**
Nothing to Report
c) **Technologies or techniques**
Nothing to Report
d) Inventions, patent applications, and/or licenses
Nothing to Report
e) **Other Products**

Nothing to Report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name:	Stephanie L. Carey
Project Role:	*PI*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	*Dr. Carey hired and advised graduate students. She completed IRB submission and reporting. She will continue to guide graduate students as testing continues. She is also responsible for reports.*
Funding Support:	

Name:	M. Jason Highsmith
Project Role:	*Co-I*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	0.8
Contribution to Project:	*Dr. Highsmith assisted in testing protocol and recruitment flyer development. Dr. Highsmith will recruit orthosis and prosthesis users for the testing.*
Funding Support:	

Name:	Bryce Fuller
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	2
Contribution to Project:	*Mr. Fuller completed a thesis on IMU placement and gait parameter calculations.*
Funding Support:	

Name:	Saif Farrag
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Mr. Farrag assisted Bryce Fuller with data collection and will continue to work on application development.*

Funding Support:	

Name:	*Pinata Sessoms, PhD*
Project Role:	*PI, NHRC site*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Dr. Sessoms worked on the testing protocol and strategy for IMU integration. She and Dr. Silder will be responsible for data collection at the NHRC site.*
Funding Support:	

Name:	*Amy Silder, PhD*
Project Role:	*Co-I, NHRC site*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Dr. Silder completed the CRADA agreement between USF and NHRC. She also completed the IRB process for the NHRC site and will assist Dr. Sessoms with data collection and analysis at the NHRC site.*
Funding Support:	

a) **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
Bryce Fuller graduated and is no longer working on the project.
Saif Farrag is a new graduate student working on the project at the USF site.

b) **What other organizations were involved as partners?**
- **Organization Name:** Naval Health Research Center
- **Location of Organization:** San Diego, CA
- **Partner's contribution to the projec**t
  - **Financial support**
  - **In-kind support**
- **Facilities**: NHRC will recruit and test subjects with the same protocol as USF site.
- **Collaboration:** Subcontract on the project. Will collect data at NHRC.
- **Personnel exchanges**
- **Other.**

8. SPECIAL REPORTING REQUIREMENTS

a) **COLLABORATIVE AWARDS:** Nothing to Report
b) **QUAD CHARTS:** See attachment

9. APPENDICES