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TITLE: Monitoring Prosthetic and Orthotic Function in the Community

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13. SUPPLEMENTARY NOTES

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.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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1. INTRODUCTION

The activity level of service members (SMs), and how it relates to their injury, prosthetics/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 proposal 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: IMUs, a Smartwatch, and a smart phone database application to monitor prosthetic/orthotic usage, gait parameters, type of activity, asymmetry, and perceived effort. In order 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 IMU, 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 different 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 in 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):
A Fitbit Charge 5 Advanced Fitness Health Tracker with built in GPS, stress management tools, sleep tracking, and 24/7 heart rate monitoring was purchased. An Apple Watch SE with GPS was also purchased. These two devices were compared for ease of use, battery life and ability to integrate data into other applications. These two smartwatches will be compared for accuracy during the next reporting period.

Integration of Database Application (Aim 1):
The Smartabase Human Performance Platform was originally considered to integrate the IMU and the smartwatch and update data in real time, both for the user, clinician, and researcher. Instead, an IOS-mobile application project has been started to track the outcomes of the user when testing the IMU devices (See Appendix for further visual description). A 2021 Apple 10.2-inch iPad (Wi-Fi, 256GB) was purchased for the development of the IOS application. As part of his graduate training, graduate student Bryce Fuller has spent a great deal of time was used to learn all the necessary aspects of creating applications in the IOS language. There has been a lot of positive development in this application with being able to successfully create a prototype that can function to simply switch between screens and has the ability to input specific data such as Name, Date and User Notes which allows them to describe the activity that was done during the IMU recording. Progress is ongoing and will included on adding more function to the second prototype so that it may be able to save any data that is stored to a local file system for later use. This application will eventually be integrated with REDCap, a software available for free to REDCap Consortium Partners, which included 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 recruited, and data can be exported to various statistical programs for analysis.

IRB Application for Laboratory Testing and Verification (Aim 2)
A testing protocol to test and verify the portable monitoring in the lab on the Computer Assisted Rehabilitation Environment (CAREN) system was developed. Subjects will 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 was approved by USF's IRB on Sept. 8th, 2022. IRB documentation and application was uploaded to eBRAP for HRPO review. NHRC is in the process of getting IRB approval for their site.

c. **What opportunities for training and professional development has the project provided?**
Biomedical Engineering Master's Student, Bryce Fuller, participated in an independent research study course under the guidance of PI, Dr. Stephanie Carey, related to this project. The independent course consisted of in-depth research of the different methods in converting raw IMU data to gait parameters in lower limb orthotic/prosthetic users and learning how to write code based on the methods presented. Bryce Fuller will continue his training by completing the integration of the portable measuring device (Aim 1) for this master's thesis. 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?**
Nothing to Report

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

For the next reporting period, the plan is to have a working prototype that can be used to conduct the experiments with lower limb amputees in the laboratory environment (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 2023.

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**
There was a delay in the transfer of funds especially to the NHRC. The first graduate student (USF) hired for the project had medical issues and had to take a leave of absence from school and was no longer available to work on the project. Two other graduate students were hired, but there was a delay while they were onboarded to the project. The IRB approval took much longer than expected due to understaffing, COVID restrictions and change in study personnel. The testing protocol was approved by USF IRB in Sept. 2022 but is currently being reviewed by HRPO.
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**
Nothing to Report

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.
Nothing to Report
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,*
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.*
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 has begun work on IMU placement and gait parameter calculations*
Funding Support:	

Name:	*Caleb Stallion*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	1
Contribution to Project:	*Mr. Stallion has worked on the software application and the smart watch integration*
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*
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 worked on the CRADA agreement between USF and NHRC. She will also complete the IRB process for 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?**
Nothing to Report

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 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 Appendix

9. APPENDICES

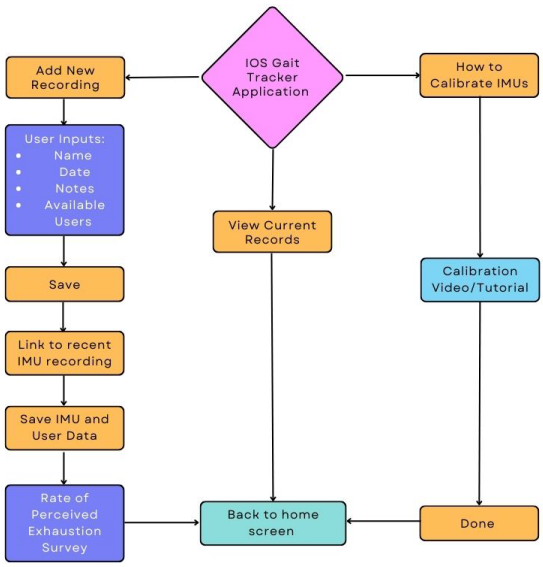

Figure 1. Flowchart showing application's functions and user inputs/outputs

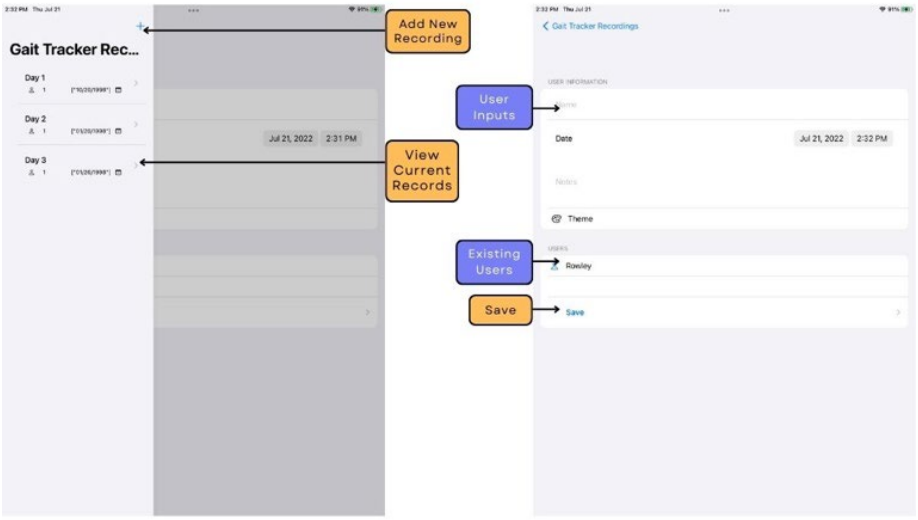

Figure 2. Current application progress on the iPad