AWARD NUMBER: W81XWH-18-1-0815

TITLE: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery Following Lower-Extremity Trauma

PRINCIPAL INVESTIGATOR: Stephen Sims, MD

CONTRACTING ORGANIZATION: The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System Charlotte, NC

REPORT DATE: October 2020

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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October 2020	Annual Report	30Sep2019-29Sep2020

4. TITLE AND SUBTITLE

The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery Following Lower-Extremity Trauma

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-1-0815

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S):
Stephen Sims, MD

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The Charlotte-Mecklenburg Hospital Authority
d/b/a Carolinas HealthCare System
1000 Blythe Blvd.
Charlotte, NC 28203

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Background: The proposed effort directly involves the development and validation of standardized measures to objectively assess and improve rehabilitative outcomes, including multi-extremity trauma following neuromusculoskeletal injury. It involves the direct application of the Mobility Toolkit Project, which is a HIPAA-compliant, web-accessible, cloud-based application for data acquisition and quantitative analysis of performance-based measures (PBMs) in multiple wide-spread clinic and therapy settings. The proposed effort addresses the feasibility of data collection in clinical settings and describing the recovery trajectories for lower-extremity injuries in active duty and civilian orthopaedic trauma patients.
Objective/Hypothesis: The purpose of this study is to (1) evaluate implementation in multiple clinical centers in the context of a large orthopaedic research consortium; (2) generate normative data for patients with lower extremity articular injures and non-injured controls: and (3) to identify thresholds that indicate risk for diminished long-term function and complications.
Specific Aims: The specific aims are to (1) Determine the feasibility and burden of implementing the Mobility Toolkit in a clinical setting, in the context of a large, multi-center research consortium, (2) Establish normative data for adult patients with articular injuries (proximal tibia, pilon, ankle fracture and ankle fracture-dislocation, hind foot) as well as a cohort of non-injured adults, and (3) Identify thresholds that indicate risk for diminished long-term function and select complications (eg, malunion, hardware failure, range of motion complications). In addition, an exploratory aim 4 is to develop algorithms to translated AHRS data for additional physical performance measures selected by the Protocol Committee made up of orthopaedic surgeons, physical medicine and rehabilitation physicians, and physical therapists.
Study Design: The proposed study will prospectively enroll and follow 350 patients aged 18-55 with lower-extremity injuries. Each of the study sites will be provided with the Mobility Toolkit clinical data acquisition systems which consists of a tablet computer Bluetooth-paired with inertial sensor package for capturing patient kinematic data. Sites are also provided with internet access to the cloud-based Mobility Toolkit central site analytics and user database which allows real-time data analysis and report transmission back to the data acquisition site. During these visits, participants will also be asked to complete the PROMIS Physical Function and Mobility and Pain Interference subscales and provide information about physical therapy they have received. Data regarding injury related complications will be obtained from medical records. Instrumented assessment using the AHRS will also be conducted on 150 non-injured adults matched to the injured cohort on age and gender. These individuals will be assessed once. After completing the assessments, non-injured participants will be asked to complete a brief health questionnaire as well as the PROMIS assessments. Data collected on injured patients and non-injured controls will form the bases for reports that plot recovery trajectories the year following injury with respect to key gait parameters that may be adversely affected by injury. These reports will allow clinicians to compare patient progress to other patients with similar injuries and relative to non-injured adults.
Military Benefit: Lower-extremity injuries, ranging from simple to complex, are common during both war and peacetime and represent a significant portion of unfitting conditions and those qualifying for medical discharge. The opportunity to objectively measure rehabilitation following lower-extremity injury and to establish trajectories of recovery for specific injury patterns would represent a significant advance in the measurement of patient outcomes. Expected recovery trajectories for specific injuries are particularly important when one considers the cost to train and retain active duty personnel. The ability to predict with some certainty expected outcomes and times to final outcome would significantly affect fitness decisions on a patient by patient basis. The information will be used to aid in *targeting physical therapy resources and interventions to specific variables documented to impede physical performance*, improve return to duty and duration of time spent away from the unit.

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
					USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	23	

TABLE OF CONTENTS

1. INTRODUCTION:

The Mobility Toolkit (MTK) is a single chest mounted device that utilizes inertial measurement units (IMUs) to assess gait quality. The purpose of this project is to test the implementation of the Mobility Toolkit in multiple trauma centers around the country and generate normative data on lower-extremity injuries common among military and civilian patients. The long-term goal is for this to be a clinical tool for evaluating recovery progress. This study is an important first step in establishing feasibility and in creating a normative set against which patient progress can be measured.

2. KEYWORDS:

Articular Injuries, Long-Term Function, Feasibility, Normative Data

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Accomplishments:

1) Specific Objectives:
2) Significant Results or Key Outcomes:
3) Other Achievements:

Major Tasks:

Task 1: Study Initiation

- Finalize protocol (month 6)
- Develop case report forms (month 6)
- Program and pilot test REDCap (month 6)
- Obtain initial IRB approval at JHU (MCC), CMC (PI site) and HRPO (month 6)
- Distribute approved protocol and obtain IRB approval at all participating sites
- Develop training material for research coordinators (month 6)
- Train and certify sites to begin screening and enrolling patients (month 12)

Task 2: Enroll and Follow Patients

- Enroll injured patients at all participating centers (month 27)
- Enroll non injured patients at two participating centers (month 27)
- Follow injured patients for one year (month 39)
- Generate and distribute monthly data queries to monitor data quality (month 39)

Task 3: Data Analysis and Dissemination

- Develop final data files and conduct analysis (month 42)

- Facilitate focus groups of ortho trauma surgeons and physical therapists to get feedback on Mobility Tool Kit reports (month 44)
- Write final report for peer reviewed publication (month 48)

Site Specific Progress:

TOTAL PROTOCOLS: **11** Note: A single master Human Subject Research Protocol will be required to complete the Statement of Work. This protocol will be approved at Johns Hopkins Bloomberg School of Public Health, as well as the USAMRAMC HRPO. Once approval has been obtained, each of the 10 other sites participating in this research will obtain IRB approval. In total, the protocol will be reviewed by 11 IRBs, plus the USAMRAMC HRPO. Future iterations of this report will reflect the status of the protocols at these sites as they are submitted and approved.

PROTOCOL (1 of 11 total): Johns Hopkins Bloomberg School of Public Health

Protocol [HRPO Assigned Number]: [E00324.1a]

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma (Master Protocol)

Target required for clinical significance: 300 injured participants and 150 non-injured volunteers

(Two sites will be enrolling non-injured volunteers and that will begin next year. We will report on each sites progress of the injured participants.)

Target approved for clinical significance: N/A

Submitted to and Approved by:

- *Submitted to JHSPH IRB*
- *Approved by JHSPH IRB 6/5/2019*
- *Submitted to DoD HRPO*
- *Approved by DoD HRPO 8/19/2019*
- *JHSPH Continuing Review Approval: 4/23/20*

Status:

(i) Number of subjects recruited/original planned target: N/A
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
JHSPH IRB approval on 6/15/20 for a protocol amendment to conduct some research activities remotely (e.g. consent; follow-up) due to COVID if needed.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None

PROTOCOL (2 of 11 total): Carolinas Medical Center

Protocol [HRPO Assigned Number]: E00324.1b

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/20/19*
- *Approved by local IRB 8/20/2019*
- *Submitted to HRPO 9/9/2019*
- *Approved by HRPO 9/17/2019*
- *Certified by the Coordinating Center 11/27/2019*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 69/N/A
Number of patients enrolled/original planned target: 10/38
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (3 of 11 total): University of Texas Health Science Center, Houston

Protocol [HRPO Assigned Number]: E00324.1c

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/3/2019*
- *Approved by local IRB 8/26/019*
- *Submitted to HRPO 8/27/2019*
- *Approved by HRPO 9/17/2019*
- *Certified by the Coordinating Center 3/10/20*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: 0/38
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (4 of 11 total): Mission Hospital

Protocol [HRPO Assigned Number]: E00324.1d

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/1/2019*
- *Approved by local IRB 7/18/2019*
- *Submitted to HRPO 9/4/2019*
- *Approved by HRPO 10/11/2019*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (5 of 11 total): University of Maryland, R Adams Cowley Shock Trauma Center

Protocol [HRPO Assigned Number]: E00324.1f

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/25/2019*
- *Approved by local IRB 10/23/2019*
- *Submitted to HRPO 11/01/2019*
- *Approved by HRPO 2/25/2020*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (6 of 11 total): Vanderbilt Medical Center

Protocol [HRPO Assigned Number]: E00324.1e

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/17/19*
- *Approved by local IRB 10/21/2019*
- *Submitted to HRPO 10/21/2019*
- *Approved by HRPO 11/01/2019*
- *Certified by the Coordinating Center 12/13/2019*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 62/NA
Number of patients enrolled/original planned target: 7/38
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (7 of 11 total): University of Kentucky

Protocol [HRPO Assigned Number]: E00324.1g

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/25/19*
- *Approved by local IRB 9/30/19*
- *Submitted to HRPO 10/30/2019*
- *Approved by HRPO 12/20/2019*
- *Certified by the Coordinating Center 2/20/2020*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 7/N/A
Number of patients enrolled/original planned target: 2/38
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (8 of 11 total): Washington University, Barnes Jewish Hospital

Protocol [HRPO Assigned Number]: E00324.1i

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 07/01/2019*
- *Approved by local IRB 12/2019*
- *Submitted to HRPO 01/07/2020*
- *Approved by HRPO 4/03/2020*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: 0/38
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (9 of 11 total): San Antonio Military Medical Center

Protocol [HRPO Assigned Number]: E00324.1h

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 9/1/2019*
- *Approved by local IRB12/06/19*
- *Submitted to HRPO 1/6/2020*
- *Approved by HRPO 2/19/20*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (10 of 11 total): Walter Reed Military Medical Center

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 2/6/20*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A

Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

PROTOCOL (11 of 11 total): Womack Army Medical Center

Protocol [HRPO Assigned Number]:

Title: The Mobility Toolkit: Electronically Augmented Assessment of Functional Recovery following Lower-Extremity Trauma

Target required for clinical significance: 38

Target approved for clinical significance: N/A

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 1/17/20*
- *Approved by local IRB pending*
- *Submitted to HRPO pending*
- *Approved by HRPO pending*
- *Certified by the Coordinating Center pending*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: N/A
Number of patients enrolled/original planned target: N/A
Number of patients completed/original planned target: N/A

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
None.

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
None.

What was accomplished under these goals?

Specific Aims: (1) Determine the feasibility and burden of implementing the Mobility Toolkit in a clinical setting, in the context of a large, multi-center research consortium. (2) Establish normative data for adult patients with articular injuries (proximal tibia, pilon, ankle fracture and ankle fracture-dislocation, hind foot) as well as a cohort of non-injured adults (3) Identify thresholds that indicate risk for diminished long-term function and select complications (eg, malunion, hardware failure, range of motion complications).

Major Activities: During Year 2, eight of ten enrolling sites received HRPO approval. The study team at Carolinas Medical Center provided on-site training on the mobility toolkit device and data collection procedures at 6 centers. Upon completing training activities, 4 centers were certified to screen and enroll patients. Procedures were put in place to allow a three- member adjudication panel to prospectively adjudicate eligibility through REDCap as patients are enrolled. The first patient was enrolled in December, 2019 at Carolinas Medical Center. Between December 2019 and March 2020, a total of 136 patients were screened at 3 of the 4 certified centers. Of the 136 patients screened, 40 met eligibility criteria and 21 patients provided consent. Of the 21 patients who provided consent, 2 were determined to be ineligible by the adjudication committee and 19 were eligible and enrolled. Screening and enrolling stopped effective March 16, 2020 due to the COVID-19 virus. During this time sites were instructed to collect follow-up data remotely (i.e. participant reported outcomes) until it was determined safe to bring patients back to clinic to resume Mobility Tool Kit data collection.

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

All sites have had the opportunity to be trained in Mobility Toolkit data collection remotely, and all sites will receive on-site training before initiating the study

How were the results disseminated to communities of interest?

N/A

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

We plan to provide refresher training to all sites remotely and resume patient screening and enrolling by January 2021.

4. **IMPACT:**

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

N/A

What was the impact on other disciplines?
N/A

What was the impact on technology transfer?

N/A

What was the impact on society beyond science and technology?

N/A

5. CHANGES/PROBLEMS:

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.

Nothing to report.

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

Due to the COVID-19 pandemic, no patients were screened or enrolled between March 17 and September 30, 2020. In order to address the aims of this study, the MTK assessments are essential and requires Research Coordinators to interact closely with study participants and ensure proper cleaning of the device between each use. For this reason, enrollment will resume when Research Coordinators are allowed back in clinic and to be in close contact with patients. This will cause delays in meeting our targets. Most centers are now able to work in clinic and the study team plans to resume participant enrollment in early January. The protocol has been updated to allow for remote enrollment and non-MTK data collection to minimize time spent with participants. The study team will work with each center to develop a reopening plan that allows for safe collection of MTK data. For example, bringing patients in for research only visits in a location separate from the clinic and hospital.

Changes that had a significant impact on expenditures

The effort reporting during the last two quarters of this year reflects minimal activity on the project since research activities were on hold. The salary support for the period April – Sep for the personnel was as below:

- Renan Castillo: Reduced to a minimum of 1%
- Lisa Reider: Reduced to a minimum of 1%
- Andrea Deluca: 0% *No longer at Hopkins, hence replaced by Elizabeth Wysocki*
- Elizabeth Wysocki: *Salary support charged only for March 2020*
- Manisha Kumar: 0%
- Jiawei Bai: 3.5% (Outside of METRC)
- Jacek Urbanek: 3.5% (Outside of METRC)
- Andre Hackman: Supported at 3% Oct-Sep. 0% for Apr-Sep. *Replaced by Elias Weston-Farber*
- Elias Weston-Farber: Supported at 3% for Oct-Mar. 0% for Apr-Sep.

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 of biohazards and/or select agents

Nothing to report.

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**

The CMC team has developed a stand-alone app for Mobility Toolkit data collection that has been tested at their site and at University of Kentucky.

- **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?

Personnel	Role and Contribution to the Project	Calendar Months
Stephen Sims	Principal Investigator	0.27
Rachel B. Seymour	Site Co-PI; oversees management at the site and coordinates with the coordinating center	0.78
Nahir A. Habet	Research Engineer	1.31
Christine A. Churchill	Research Manager	1.20
Maggie Elizabeth Brownrigg	Research Coordinator, patient screening, enrollment and followup	0.34
Robert Mayberry	Research Coordinator has left CMC	0.08
Renan Castillo	MCC PI; oversees scientific management	0.24
Lisa Reider	MCC Co-PI; oversees scientific management and management of coordinating center activities	0.66
Andrea Deluca	MCC Project Director managed overall study timeline, communication with sites, and regulatory reporting	0.75
Elizabeth Wysocki	MCC Project Director (replaces Andrea Deluca effective 03/01/20); manages overall study timeline, communication with sites, and regulatory reporting	0.21
Manisha Kumar	MCC Finance Manager; manages the subagreements and financials for MCC and participating centers	0.18
TBD	MCC Data Analyst; will oversee database management for the study.	0.00
Andre Hackman	Data Manager oversaw REDCap programming and data reporting	0.18
Elias Weston-Farber	Data Manager (replaces Andre Hackman) ; oversees REDCap programming and data reporting	0.18
Jiawei Bai	Biostatistician; responsible for analyzing the MTK output	0.42
Jacek Urbanek	Biostatistician; responsible for developing an analysis plan for the study and overseeing Dr. Bai in analyzing the MTK output	0.42

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.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

The Mobility Toolkit: Electronically augmented assessment of functional recovery following lower-extremity trauma

OR170181, W81XWH-17-PRORP-CTRA

PI: Stephen Sims, MD **Org:** Carolinas Medical Center **Award Amount:** $2,000,000

Study Aims

Specific Aim 1: Determine the feasibility and burden of implementing the Mobility Toolkit in a clinical setting, in the context of a large, multi-center consortium.

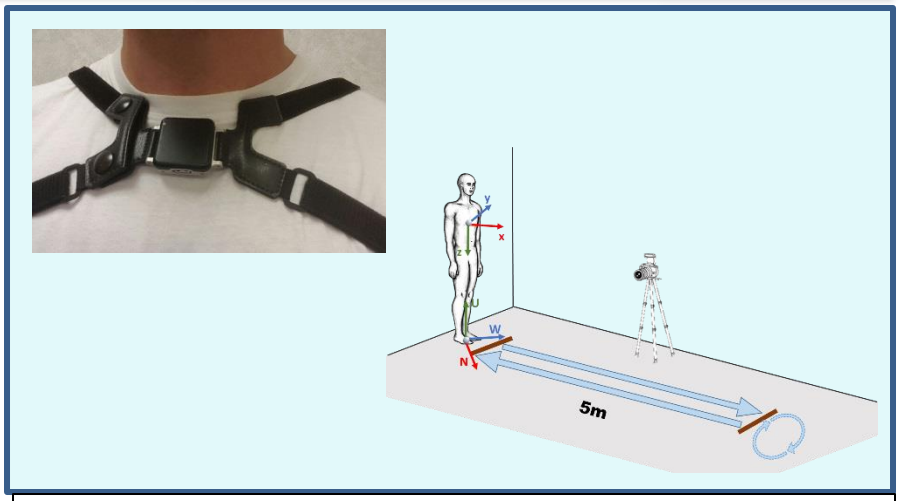
Specific Aim 2: Establish normative data for adult patients (N=300) with articular injuries (proximal tibia, pilon, ankle fracture and ankle fracture-dislocation, hind foot) as well as a cohort of noninjured controls (N=150).

Specific Aim 3: Identify thresholds that indicate risk for diminished long-term function and select complications (eg, malunion, hardware failure, range of motion complications).

Exploratory Aim 4: Develop algorithms to translated AHRS data for additional physical performance measures selected by the Protocol Committee made up of orthopaedic surgeons, physical medicine and rehabilitation physicians, and physical therapists.

Approach

To prospectively collect data on targeted injuries that occur frequently in the military and civilian populations, and to follow those patients through recovery.



Inertial Measurement Unit (IMU): integration of accelerometers, gyroscopes, and magnetometers with onboard data acquisition

Timeline and Cost

Activities	CY	18	19	20	21
Protocol Development and Approval; Coordinator training					
Patient Enrollment and baseline data collection					
Follow-up and data quality assurance activities					
Data analysis					
Budget ($2,000,000)		**$400k**	**$500k**	**$600k**	**$500k**

Updated: 11/1/2020

Goals/Milestones

CY19 Goals – Protocol Development and Approval

X Protocol submitted for master approval at PI site and MCC

X Protocol submitted for approval at all participating centers

X Train staff at sites and initiate data collection

CY19-20 Goals – Enrollment and Data Collection

X Enroll patients and obtain follow-up visits

X Collect study data

X Engage in monitoring and quality assurance activities to ensure high quality data

CY20-21 Goal – Data Analysis and Reporting

☐ Complete data analysis and reporting requirements

Comments/Challenges/Issues/Concerns: n/a

Budget Expenditure to Date

Projected Expenditure: $ $1,100,197

Actual Expenditure: $ $465,377.11