AWARD NUMBER: W81XWH-18-1-0810

TITLE: Effect of Early Weight Bearing on Rehabilitation Outcomes in Patients with Unicondylar Proximal Tibia Fractures and Bimalleolar Ankle Fractures

PRINCIPAL INVESTIGATOR: William Obremskey, MD

CONTRACTING ORGANIZATION: Vanderbilt University Medical Center
1161 21st Ave S STE D3300 MCN
Nashville, TN 37232-0011

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

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Effect of Early Weight Bearing on Rehabilitation Outcomes in Patients with Unicondylar Proximal Tibia Fractures and Bimalleolar Ankle Fractures

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-2-0810

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
William Obremskey M.D., M.P.H., M.M.H.C.

E-Mail: William.obremskey@vumc.org

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Vanderbilt University Medical Center
1161 21st Ave S STE D3300 MCN
Nashville, TN 37232-0011

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

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The overall objective of this study is to provide definitive evidence that early weight bearing is safe in patients with operatively treated ankle fracture injuries and results in better outcomes. We hypothesize that clinical complications will be similar in patients in the early and delayed WB group and that patients in the Early WB Group will return to usual major activity (i.e. work, active duty, school) sooner and achieve better functional outcomes than those in the Delayed WB Group. As a consequence, the number of work days lost and costs associated with lost productivity will be lower for the Early versus the Delayed WB group. We will also conduct a pilot study of early vs. delayed weight bearing in patients surgically treated for unicondylar plateau fractures. Smaller clinical series and biomechanical date indicate that early weight bearing is safe and patients with these injuries may benefit from early weight bearing as well. A study of these injuries will provide important information with regard to safety and outcomes that is currently lacking and provide data to help power a definitive trial.

15. SUBJECT TERMS
NONE LISTED

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	29	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Specific Aims: (1) To compare clinical outcomes and return to usual major activities in patients surgically treated for an ankle fracture randomized to early versus delayed weight bearing. ; (2) To compare measures of function and pain between patients surgically treated for an ankle fracture randomized to early versus delayed weight bearing.; (3) To compare range of motion (ROM) between early versus delayed weight bearing; (4) To estimate the cost effectiveness of early versus delayed weight bearing in adult patients surgically treated for an ankle fracture; (5) To gather outcome data on patients surgically treated for unicondylar plateau fractures randomized to early versus delayed weight bearing .

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Ankle fractures, Tibial Plateau Fractures, Early Weight Bearing

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

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

Major Tasks:

Task 1: Study Initiation

- Develop protocol and Case Report Forms (CRFS): Month 3
- Develop standard weight bearing instructions and physical therapy program: Month 3
- Obtain local IRB and HRPO approval for all participating centers: Month 7
- Train Research Coordinators and certify centers to begin screening and enrolling patients: Month 31

Task 2: Enroll and Follow Patients

- All patients enrolled: Month 46
- All patients followed: Month 58

Task 3: Data Analysis

- Develop data files for analysis: Month 58
- Complete analysis and final report: Month 60

Site Specific Progress:

TOTAL PROTOCOLS: **20** 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 19 other sites participating in this research will obtain IRB approval. In total, the protocol will be reviewed by 20 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 23 total): Johns Hopkins Bloomberg School of Public Health

Protocol [HRPO Assigned Number]: [E00325.2a]

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 526 participants with ankle fractures; 100 participants with tibial plateau fractures

Target approved for clinical significance: N/A

Submitted to and Approved by:

- *Submitted to JHSPH IRB 5/23/19*
- *Approved by JHSPH IRB 6/26/2019*
- *Submitted to DoD HRPO 7/16/19*
- *Approved by DoD HRPO 8/19/2019*

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 5/20/20 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 23 total): San Antonio Military Medical Center

Protocol [HRPO Assigned Number]: E00325.2o

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB* 9/27/2019
- *Approved by local IRB* 2/11/2020
- *Submitted to HRPO* 2/24/2020
- *Approved by HRPO* 3/18/2020
- *Certified by the Coordinating Center* 3/23/2020

STATUS:

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

Number of subjects screened/original planned target: 181
Number of patients enrolled/original planned target: 11
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 23 total): Carolinas Medical Center

Protocol [HRPO Assigned Number]: E00325.2f
Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB* 8/22/2019
- *Approved by local IRB* 11/21/2019
- *Submitted to HRPO* 11/22/2019
- *Approved by HRPO* 12/30/2019
- *Certified by the Coordinating Center* 1/29/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 162
Number of patients enrolled/original planned target: 6
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 23 total): Dartmouth Hitchcock Medical Center

Protocol [HRPO Assigned Number]: E00325.2j
Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 8/20/2019*
- *Approved by local IRB* 1/17/2020
- *Submitted to HRPO 2/3/2020*
- *Approved by HRPO 2/25/2020*
- *Certified by the Coordinating Center 3/18/2020*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 114
Number of patients enrolled/original planned target: 17
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 23 total): Hennepin County Medical Center

Protocol [HRPO Assigned Number]: E00325.2b

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 8/23/2019*
- *Approved by local IRB 9/13/2019*
- *Submitted to HRPO 9/18/2019*
- *Approved by HRPO 10/30/2019*
- *Certified by the Coordinating Center* 1/29/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 29
Number of patients enrolled/original planned target: 9
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 23 total): University of Texas Health Science Center, Houston

Protocol [HRPO Assigned Number]:

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 9/24/2019*
- *Approved by local IRB 10/8/2019*
- *Submitted to HRPO 10/8/2019*
- *Approved by HRPO* 10/30/2019
- *Certified by the Coordinating Center* 2/3/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 13
Number of patients enrolled/original planned target: 1
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 23 total): University of Florida, Jacksonville *

This site did not execute a contract and decided not to participate in this study.

Protocol [HRPO Assigned Number]:

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: n/a

Target approved for clinical significance: n/a

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB pending*
- *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 (8 of 23 total): University of Indiana Methodist Hospital

Protocol [HRPO Assigned Number]: E00325.2h
Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 8/15/2019*
- *Approved by local IRB 12/11/2019*
- *Submitted to HRPO* 12/11/2019
- *Approved by HRPO* 12/31/2019
- *Certified by the Coordinating Center* 1/29/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 188
Number of patients enrolled/original planned target: 13
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 23 total): University Of Pennsylvania Medical Center

Protocol [HRPO Assigned Number]: E00325.2m
Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial

Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB* 10/11/2019
- *Approved by local IRB* 2/18/2020
- *Submitted to HRPO 2/20/2020*
- *Approved by HRPO* 2/25/2020
- *Certified by the Coordinating Center* 5/19/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 2
Number of patients enrolled/original planned target: 0
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 23 total): University of Pittsburgh Medical Center

Protocol [HRPO Assigned Number]: E00325.2s

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 10/20/2019*
- *Approved by local IRB* 5/20/2020
- *Submitted to HRPO* 7/21/2020
- *Approved by HRPO* 7/31/2020
- *Certified by the Coordinating Center* 9/22/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 59
Number of patients enrolled/original planned target: 6
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 23 total): University of Alabama Medical Center

Protocol [HRPO Assigned Number]: E00325.2k

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 7/31/2019*
- *Approved by local IRB* 1/7/2019
- *Submitted to HRPO* 2/11/2020
- *Approved by HRPO* 3/13/2020
- *Certified by the Coordinating Center* 5/6/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 78
Number of patients enrolled/original planned target: 11
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 (12 of 23 total): University of California San Francisco Medical Center

Protocol [HRPO Assigned Number]: E00325.2q

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 9/27/2019*
- *Approved by local IRB 4/6/2020*

- *Submitted to HRPO 5/27/2020*
- *Approved by HRPO 11/6/2020*
- *Certified by the Coordinating Center 11/30/20*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 29
Number of patients enrolled/original planned target: 2
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 (13 of 23 total): University of Maryland R Adams Cowley Shock Trauma Center

Protocol [HRPO Assigned Number]: E00325.2d
Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 8/7/2019*
- *Approved by local IRB* 10/30/2019
- *Submitted to HRPO* 11/8/2019
- *Approved by HRPO* 2/6/2020
- *Certified by the Coordinating Center* 2/18/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 97
Number of patients enrolled/original planned target: 4
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 (14 of 23 total): University of Oklahoma Medical Center

Protocol [HRPO Assigned Number]: E00325.2n

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 8/23/2019*
- *Approved by local IRB* 10/2/2019
- *Submitted to HRPO* 1/16/2020
- *Approved by HRPO* 3/13/2020
- *Certified by the Coordinating Center* 3/18/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 18
Number of patients enrolled/original planned target: 1
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 (15 of 23 total): University of Virginia Medical Center

Protocol [HRPO Assigned Number]: E00325.2g

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 9/5/2019*
- *Approved by local IRB* 11/26/2019
- *Submitted to HRPO* 12/4/2019
- *Approved by HRPO* 12/6/2019
- *Certified by the Coordinating Center* 5/19/2020

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target:46
Number of patients enrolled/original planned target: 5

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 (16 of 23 total): University of Washington Harborview

Protocol [HRPO Assigned Number]: E00325.2l

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 9/5/2019*
- *Approved by local IRB 10/25/2020*
- *Submitted to HRPO 2/26/2020*
- *Approved by HRPO 3/10/2020*
- *Certified by the Coordinating Center 6/9/2020*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target:157
Number of patients enrolled/original planned target: 19
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 (17 of 23 total): Vanderbilt University Medical Center

Protocol [HRPO Assigned Number]: E00325.2i

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 8/12/2019*
- *Approved by local IRB* 10/29/2019
- *Submitted to HRPO* 10/29/2019
- *Approved by HRPO* 2/6/2020
- *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: 199
Number of patients enrolled/original planned target: 27
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 (18 of 23 total): Wake Forest Baptist Health

Protocol [HRPO Assigned Number]: E00325.2e
Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 8/29/2019*
- *Approved by local IRB 10/28/2019*
- *Submitted to HRPO 11/13/2019*
- *Approved by HRPO 12/6/2019*
- *Certified by the Coordinating Center 4/15/2020*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 78
Number of patients enrolled/original planned target: 6
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 (19 of 23 total): Womack Army Medical Center

Protocol [HRPO Assigned Number]:

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 4/10/2020*
- *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 (20 of 23 total): Walter Reed National Military Medical Center

Protocol [HRPO Assigned Number]:

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance:

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB April*
- *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 (21 of 23 total): Inova Fairfax Hospital

Protocol [HRPO Assigned Number]: E00325.2t

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 6/26/2020*
- *Approved by local IRB 7/15/2020*
- *Submitted to HRPO 7/24/2020*
- *Approved by HRPO 8/4/2020*
- *Certified by the Coordinating Center 9/11/2020*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 93
Number of patients enrolled/original planned target: 17
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 (22 of 23 total): University of Wisconsin

Protocol [HRPO Assigned Number]: E00325.2p

Title: Effects of Early Weight Bearing Rehabilitation Outcomes in Patients with Traumatic Ankle and Tibial Plateau Fractures

Target required for clinical significance: 35

Target approved for clinical significance: 35

SUBMITTED TO AND APPROVED BY:

- *Submitted to local IRB 1/13/2020*
- *Approved by local IRB 3/17/2020*
- *Submitted to HRPO 3/23/2020*
- *Approved by HRPO 4/16/2020*
- *Certified by the Coordinating Center 7/14/2020*

STATUS:

(i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 95
Number of patients enrolled/original planned target: 10
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 (23 of 23 total): Vanderbilt University Medical Center

Protocol [HRPO Assigned Number]: E00325.1a
Title: A Pilot Study to Test Feasibility and Function of Weight-Bearing Sensors," Submitted by William T. Obremskey, Vanderbilt University Medical Center, in Support of the Proposal, "Effect of Early Weight Bearing on Rehabilitation Outcomes in Patients with Unicondylar Proximal Tibia Fractures and Bimalleolar Ankle Fractures
Target required for clinical significance: N/A, for insole pilot only (approved for n=8 participants)
Target approved for clinical significance: N/A for insole pilot only (approved for n=8 participants)

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1. **Major Activities**: In the last year, we continued to enroll and follow patients. Of the 22 centers we engaged to participate, 2 are no longer participating (Houston and Jacksonville), 3 are pending IRB approval (Walter Reed National Military Medical Center, Womack Military Medical Center and University of Kentucky), and 17 centers are actively screening and enrolling patients. In total, 1,638 patients have been screened and of these, 377 (23%) were eligible. Of the 377 eligible patients, 170 (45%) consented to enroll; 149 with ankle fractures and 21 with tibial plateau fractures.

2) **Specific Objectives:** (1) Provide on-going training to site teams of research coordinators, surgeons and physical therapists on the study procedures, implementing the intervention and data collection; (2) circulate weekly dashboard reports to monitor progress on screening, enrolling and following patients; (3) follow-up with sites to address data errors and queries on case report forms; (4) finalized instructions for loadsol weight bearing insoles, tested remote data collection and identified sites to participate.
3) **Significant Results or Key Outcomes:** none to report
4) **Other Achievements:** none to report.

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

The Weight Bearing Physical Therapy Panel has provided key insights for a package of materials that will help to ensure robust delivery of intervention arm information and monitoring of fidelity to treatment arms.

All sites have received two trainings, on the **IRB Submission Process** and **Study Implementation.**

How were the results disseminated to communities of interest?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We plan to enroll and follow patients at all participating centers. We will initiate data collection using loadsol weight bearing insoles at 4 participating centers.

4. **IMPACT:** D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. CHANGES/PROBLEMS: *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Due to the COVID-19 pandemic, no patients were screened or enrolled between March 17 and May 5, 2020 which will cause delay in meeting recruitment goals. We were granted additional funds and a one-year extension to bring on new centers and allow more time to enroll. We are also working with larger centers to engage smaller hospitals within their system who treat more injuries that meet the inclusion criteria (i.e. isolated fractures).

Changes that had a significant impact on expenditures

Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to report.

Nothing to report.

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

None to report.

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to report.

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

The Weight Bearing Study instructions, exercises, and optional log will be located on this website: Wbs.metrc.org

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding,

prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

- *data or databases;*
- *physical collections;*
- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Name:	William Obremskey, MD
Project Role:	Principal Investigator
Researcher Identifier https://orcid.org/0000-0002-8942-1842	
Nearest person month worked:	1.0
Contribution to Project:Developed Protocol for pilot and draft for primary grant, Recruited members of the PC committee and participating centers.	
Name:	Ellen Mackenzie, PhD
Project Role:	Co-Investigator
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.24 Cal months
Contribution to Project: during this period.	Dr. MacKenzie oversaw coordinating center activities
Name:	Lisa Reider, PhD
Project Role:	MCC PI
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.80 Cal months
Contribution to Project:	Dr. Reider developed the pilot study protocol;

developed the center participation survey; conducted study planning meetings, drafted the study protocol and worked with the MCC team to establish the overall study timeline.
Name: Steve Wegener, PhD Project Role: MCC Co-I Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 0.24 Cal months Contribution to Project: Dr. Wegener will provide expert input in to the Weight Bearing training instructions and quality assurance of those instructions across sites.
Name: Richard Thompson Project Role: MCC Statistician Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 0.60 Cal months Contribution to Project: Dr. Thompson developed the statistical plan and will act as the study statistician moving forward.
Name: Elizabeth Wysocki *(Replaced Andrea Deluca)* Project Role: Coordinating Center Project Director Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 2.0 Cal months Contribution to Project: Ms Wysocki overall study timelines, submitted protocol amendments and developed site initiation training, developed x-ray sub-study, and worked with Study Manager to conduct site implementation calls.
Name: Kevin McLaughlin Project Role: Coordinating Center Physical Therapist Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 1.50 Cal months Contribution to Project: Developed physical therapy materials used in the study; monitors range of motion, PT call logs and patient interaction with the exercise website for quality.
Name: Brianna Fowler Project Role: Coordinating Center Study Manager Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 1.80 Cal months *(Effective 01/2021)* Contribution to Project: Ms Fowler assists the Project Director with corresponding with participating centers, finalizing the website, and conducting site implementation calls.

Name:	Chris Witczak, MBA
Project Role:	Coordinating Center Financial Manager
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.60 Cal months
Contribution to Project:	Mr. Witczak set up the study account and prepared subaward paperwork for participating centers.
Name:	Linda Gai
Project Role:	Coordinating Center Data Analyst
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.13 Cal months *(No longer on the project effective 02/21)*
Contribution to Project:	Ms. Gai oversaw database management for the study. The analyst will also support the analysis of the data under the supervision of the study investigators.
Name:	Andre Hackman
Project Role:	Coordinating Center Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.00 Cal months
Contribution to Project:	Mr. Hackman maintained study case report forms and REDCap for data collection.
Name:	Elias Weston-Farber *(replaced Andre Hackman)*
Project Role:	Coordinating Center Research Assistant
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	0.60 Cal months
Contribution to Project:	Mr. Weston-Farber maintains study case report forms and REDCap for data collection.
Name:	Karen Trochez
Project Role:	Clinical Translational Coordinator III, Vanderbilt
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3 Cal months
Contribution to Project:	Ms. Trochez works with the study team on IRB documents, prime and HRPO submissions and local project management.
Name:	Charles Pritchett
Project Role:	Research Analyst 1
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2 Cal months
Contribution to Project:	Mr. Pritchett identifies and enrolls patients and assists with local project management.
Name:	Elsa Rodriguez

Project Role:	Clinical Translational Coordinator II, Vanderbilt
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2 Cal months
Contribution to Project:	Dr. Rodriguez identifies, consents, enrolls and follows up with patients.
Name:	Fidel Diaz Moreno
Project Role:	Clinical Translational Coordinator II, Vanderbilt
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	2 Cal months
Contribution to Project:	Dr. Rodriguez identifies, consents, enrolls and follows up with patients.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)

Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES: *Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.*