

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

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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 data 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.					
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1. INTRODUCTION:

The purpose of this multi-center randomized controlled trial (RCT) is to compare outcomes following early versus delayed weight bearing among individuals with a traumatic ankle fracture. This study will enroll patients 18 years and older, surgically treated for an ankle fracture at participating civilian trauma centers and military treatment facilities. Eligible patients will be identified during hospitalization for definitive treatment and enrolled prior to discharge or at the first post-op clinic visit. Patients that consent to participate will complete a baseline assessment at the first post-op clinic visit and will be randomized to early versus delayed weight bearing. Both treatment groups will receive standardized exercises that can be done at home or with a therapist. Outcomes will be evaluated at 6 weeks and 3, 6 and 12 months following definitive fracture fixation. All 6 week and 3- and 6-month evaluations will take place in the surgeon's outpatient clinic and involve clinical and radiographic assessments of healing as well as functional outcome surveys. The 12-month evaluation will be conducted by phone. Simultaneously, a pilot RCT will be conducted in patients 18 years and older, surgically treated with a unicondylar plateau fracture without joint impaction.

2. KEYWORDS:

Ankle fractures, Tibial Plateau Fractures, Early Weight Bearing

3. ACCOMPLISHMENTS:

What were the major goals of the project?

The specific aims of the project are: (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, pain and satisfaction between patients surgically treated for an ankle fracture randomized to early versus delayed weight bearing.; (3) To compare patterns of recovery in range of motion (ROM) between early versus delayed weight bearing; (4) To gather outcome data on patients surgically treated for unicondylar plateau fractures randomized to early versus delayed weight bearing

Task	Percentage Complete
Task 1: Study Initiation	
Develop protocol and Case Report Forms (CRFS): Month 3	100%
Develop standard weight bearing instructions and physical therapy program: Month 3	100%
Obtain local IRB and HRPO approval for all participating centers: Month 7	100%
Train Research Coordinators and certify centers to begin screening and enrolling patients: Month 7	100%
Task 2: Enroll and Follow Patients	
All patients enrolled: Month 46	100%
All patients followed: Month 58	70%
Task 3: Data Analysis	

Develop data files for analysis: Month 58	0%
Complete analysis and final report: Month 60	0%

What was accomplished under these goals?

- 1. Major Activities:** Our focus this past year was to enroll and follow patients across 19 participating centers. Enrollment into the study ended September 30, 2023. In total, 4529 patients have been screened and of these, 472 consented to enroll (433 patients enrolled had ankle fractures; 39 had tibial plateau fractures). We have enrolled and randomized 82% of our target sample of 526 ankle fractures. Our follow up rate overall is 78% (91% at 6 weeks; 86% at 3 months; 71% at 6 months and 60% at 12 months). We engaged 4 sites to collect additional data on participants using loadsol weight bearing insoles. To date, we have given weight bearing insoles to 26 patients. We received approval for a one year no cost extension to complete follow-up assessments through September 29, 2024.
- 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) circulate weekly data query reports that pull directly from REDCap to prospectively address data errors; (4) capture weight bearing data using loadsol insoles on patients enrolled at 4 centers; (5) host data safety and monitoring board meetings to review safety data and trial progress; and (6) host quarterly calls with research coordinators to review study progress with a focus on data cleaning.
- 3. Significant Results or Key Outcomes:** None to report.
- 4. Other Achievements:** None to report.

Describe the Regulatory Protocol and Activity Status

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 27 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 27 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: 304
Number of patients enrolled/original planned target: 23
Number of patients completed/original planned target: 0

- (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 27 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: 567
Number of patients enrolled/original planned target: 15
Number of patients completed/original planned target: 9

- (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 27 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: 217
Number of patients enrolled/original planned target: 44
Number of patients completed/original planned target: 16

(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 27 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: 56
Number of patients enrolled/original planned target: 18
Number of patients completed/original planned target: 2

(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 27 total): University of Texas Health Science Center, Houston*

This site is no longer participating in the 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: 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.

****This site is no longer participating. The one patient enrolled was a late ineligible and withdrawn from the study.**

PROTOCOL (7 of 27 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 27 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: 417
Number of patients enrolled/original planned target: 38
Number of patients completed/original planned target: 12

- (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 27 total): University Of Pennsylvania Medical Center*

This site is no longer participating in the study.

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 27 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: 163
Number of patients enrolled/original planned target: 24
Number of patients completed/original planned target: 4

(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 27 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: 218
 Number of patients enrolled/original planned target: 22
 Number of patients completed/original planned target: 11

- (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 27 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: 164
 Number of patients enrolled/original planned target: 15
 Number of patients completed/original planned target: 5

- (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 27 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: 216
Number of patients enrolled/original planned target: 8
Number of patients completed/original planned target: 6

- (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 27 total): University of Oklahoma Medical Center*

This site is no longer participating in the study.

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: 0

(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 27 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: 118
Number of patients enrolled/original planned target: 13
Number of patients completed/original planned target: 4

(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 27 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: 499
Number of patients enrolled/original planned target: 46
Number of patients completed/original planned target: 31

- (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 27 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: 438
Number of patients enrolled/original planned target: 53
Number of patients completed/original planned target: 24

- (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 27 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: 359
Number of patients enrolled/original planned target: 26
Number of patients completed/original planned target: 13

- (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 27 total): Womack Army Medical Center

Protocol [HRPO Assigned Number]: pending

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 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 27 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 4/1/2020*
- *Approved by local IRB 12/20/2020*
- *Submitted to HRPO 3/24/2021*
- *Approved by HRPO 4/12/2021*
- *Issued WRNMMC Command Start Letter: 12/15/2022*
- *Certified by the Coordinating Center 1/4/2023*

STATUS:

- (i) *Number of subjects recruited/original planned target: N/A*
Number of subjects screened/original planned target: 12
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 (21 of 27 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: 317

Number of patients enrolled/original planned target: 58
Number of patients completed/original planned target: 25

(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 27 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: 288
Number of patients enrolled/original planned target: 50
Number of patients completed/original planned target: 29

(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 27 total): University of Kentucky

Protocol [HRPO Assigned Number]: E00325.2v

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 6/21/21*
- *Approved by local IRB 11/3/21*

- Submitted to HRPO 1/20/22
- Approved by HRPO 5/15/22
- Certified by the Coordinating Center 7/6/22

STATUS:

- (i) Number of subjects recruited/original planned target: N/A
 Number of subjects screened/original planned target: 139
 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 (24 of 27 total): Henry Ford Hospital

Protocol [HRPO Assigned Number]: E00325.2y

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

Target required for clinical significance:

Target approved for clinical significance:

SUBMITTED TO AND APPROVED BY:

- Submitted to local IRB 7/12/2022
- Approved by local IRB 12/7/2022
- Submitted to HRPO 2/24/2023
- Approved by HRPO 3/17/2023
- Certified by the Coordinating Center 4/25/23

STATUS:

- (i) Number of subjects recruited/original planned target: N/A
 Number of subjects screened/original planned target: 4
 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:

PROTOCOL (25 of 27 total): Eskenazi Health

Protocol [HRPO Assigned Number]: E00325.2w

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 4/12/2022*
- *Approved by local IRB 5/12/2022*
- *Submitted to HRPO 5/17/2022*
- *Approved by HRPO 5/26/2022*
- *Certified by the Coordinating Center 9/11/23*

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:

PROTOCOL (26 of 27 total): University of Michigan

Protocol [HRPO Assigned Number]: pending

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

Target required for clinical significance:

Target approved for clinical significance:

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:

PROTOCOL (27 of 27 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. Obremsky, 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 opportunities for training and professional development has the project provided?

The Weight Bearing Physical Therapy Panel has provided key insights for a package of materials Nothing to report.
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?

Nothing to report.

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

We will complete follow-up assessments on study participants through September 2024 and continue to work closely with sites to resolve data quality queries. We will finalize the statistical analysis plan and prepare files for data analysis in late summer of 2024 when the study is finished.

4. IMPACT:

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

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report.

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

Nothing to report.

Changes that had a significant impact on expenditures

Nothing to report.

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

N/A

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

Publications, conference papers, and presentations

Journal publications.

Nothing to report.

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

Nothing to report.

Other publications, conference papers and presentations.

I. Leah Gitajn, MD; Roman M. Natoli, MD; Clay A. Spitler, MD; Reza Firoozabadi, MD, MA; Lauren M. Tatman, MD; Joshua L. Gary, MD; Michael Githens, MD; Richard E. Thompson, PhD; Andrea N. DeLuca, MHS ; Lisa Reider, PhD; Elizabeth Wysocki, MS; William Obremskey, MD, MPH and METRC “Radiographic Assessment of Ankle Fracture Displacement: A Validation Study”. Accepted by Foot and Ankle International 14May2022

Website(s) or other Internet site(s)

The Weight Bearing Study instructions, exercises, and optional log are located on this website: Wbs.metr.org

Technologies or techniques

Nothing to report.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

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
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<p>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.</p>
<p>Name: Lisa Reider, PhD Project Role: MCC PI Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 1.20 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.</p>
<p>Name: Karen Trochez Project Role: Program Manager, Vanderbilt Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 3.0 Cal months Contribution to Project: Ms. Trochez works with the study team on IRB documents, prime and HRPO submissions and local project management</p>
<p>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.</p>
<p>Name: Richard Thompson Project Role: MCC Statistician Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 0.84 Cal months Contribution to Project: Dr. Thompson developed the statistical plan and will act as the study statistician moving forward.</p>
<p>Name: Joseph Cave Project Role: Clinical Translational Coordinator II, Vanderbilt Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 3.6 Cal months Contribution to Project: Mr. Cave Rodriguez identifies, consents, enrolls and follows up with patients.</p>
<p>Name: Fidel Diaz-Moreno Project Role: Clinical Translational Coordinator II, Vanderbilt Researcher Identifier (e.g. ORCID ID): N/A Nearest person month worked: 4.8 Cal months Contribution to Project: Dr. Diaz-Moreno identifies, consents, enrolls and</p>

follows up with patients.	
Name:	Elizabeth Wysocki, MS
Project Role:	Coordinating Center Study Manager
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1.80 Cal months
Contribution to Project:	Ms Wysocki assisted the Project Director with corresponding with participating centers, finalizing the website, and conducting site implementation calls.
Name:	Brandon Ponce
Project Role:	Clinical Translational Coordinator II, Vanderbilt
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1 Cal months
Contribution to Project:	Mr. Ponce Rodriguez identifies, consents, enrolls and follows up with patients.
Name:	Elsa Rodriquez
Project Role:	Clinical Translational Coordinator II, Vanderbilt
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1 Cal months
Contribution to Project:	Dr. Rodriguez identifies, consents, enrolls and follows up with patients.
Name:	Andres Lisbos
Project Role:	Clinical Translational Coordinator II, Vanderbilt
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1 Cal months
Contribution to Project:	Dr. Lisbos identifies, consents, enrolls and follows up with patients.
Name:	Caroline LaHurd
Project Role:	Clinical Translational Coordinator II, Vanderbilt
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	1 Cal months
Contribution to Project:	Ms. Lahurd identifies, consents, enrolls and follows up with patients.
Name:	Jyoti Dubey
Project Role:	Coordinating Center Data Analyst
Researcher Identifier (e.g. ORCID ID):	N/A
Nearest person month worked:	3.0 Cal months
Contribution to Project:	Ms. Dubey works with Mr. Weston-Farber to create reports that are needed to manage the study. She will work directly with Dr. Thompson, the study statistician, to conduct data analysis for main results and secondary papers.
Name:	Elias Weston-Farber <i>(replaced Andre Hackman)</i>
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 is a programmer that is responsible for developing and maintaining data query reports and the analytic data system that produces report tables and data exports for analysis.

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: *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.*