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14. ABSTRACT

This multi-center prospective observational study enrolled and followed 244 patients ages 18-60 with open or closed fractures of the tibial plateau, pilon, ankle or calcaneus requiring surgical fixation. The goal of the study was to test the implementation of the Mobility Tool Kit, a chest mounted device that utilizes inertial measurement unites to assess gait quality, in orthopedic clinics. Secondary objectives were to establish normative gait data for patients with these injuries compared to age and gender matched patients without injury, and to identify thresholds using gait data that indicate risk for diminished function and complications. Patients were enrolled at the time of surgical fixation and gait assessments were conducted at 6 weeks, 3, 6, and 12 months post definitive fixation. Outcomes included measures of feasibility (number of mobility tool kit assessments completed, assessment burden, technical problems), patient reported measures of function and pain, and clinical complications ascertained from the medical record.

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1. Introduction

The purpose of this study was to determine the feasibility of implementing the Mobility Tool Kit, a chest mounted device that measures gait quality, in orthopedic trauma clinics around the country. The device was designed and validated by investigators at Atrium Health and utilizes inertial measurement units (IMU's) to measure lift acceleration, step time asymmetry, and upper body pitch and roll. These parameters were measured on patients with surgically treated lower extremity articular fractures while performing the 10m walk test, the timed up and go, and the 5 time sit to stand to better understand mobility recovery during the 12 months following surgery.

Specific 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 research consortium.

Specific Aim 2: Establish normative gait data for adult study participants with lower extremity articular injuries as well as a cohort of non-injured adults.

> *Sub-aim 2a:* Describe and compare 12-month recovery trajectories for participants with fractures of the tibial plateau, pilon, ankle and calcaneus.
>
> *Sub-aim 2b:* Describe and compare 12-month recovery trajectories for participants who experience injury related complications (e.g. nonunion, infection).
>
> *Sub-aim 2c:* Compare gait patterns in a cohort of non-injured controls to participants with fractures of the tibial plateau, pilon, ankle and calcaneus.

Specific Aim 3: Identify thresholds using gait data that indicate risk for diminished long-term function and select complications (e.g. malunion, hardware failure).

2. Key Words

Mobility Tool Kit
Inertial Measurement Units
Gait
Rehabilitation
Lower extremity fracture

3. Accomplishments

What were the major goals of the project?

The major goals of the project and the status of achieving these goals are summarized in the table below.

Task	Percentage of Completion
Task 1: Study Initiation	
Finalize protocol (month 6)	100%
Develop case report forms (month 6)	100%
Program and pilot test REDCap (month 6)	100%

Obtain initial IRB approval at JHU (MCC), CMC (PI site) and HRPO (month 6)	100%
Distribute approved protocol and obtain IRB approval at all participating sites (month 9)	100%
HRPO approval at each participating site (month 9)	
Develop training material for research coordinators (month 6)	100%
Train and certify sites to begin screening and enrolling patients (month 12)	100%
Conduct study initiation calls with each site once screening begins (month 12)	100%
Task 1a. Retraining and Recertifying Sites to Resume Research Activities Following COVID-19 Pause	
Re-train sites (month 27)	100%
Re-certify sites to screen and enroll (month 31)	100%
Task 2: Enroll and Follow Patients	
Enroll injured patients at all participating centers (month 46)	100%
Enroll non injured patients at two participating centers (month 39)	80%
Follow injured patients for one year (month 58)	100%
Generate and distribute monthly data queries to monitor data quality (month 58)	100%
Task 3: Data Analysis and Dissemination	
Develop final data files and conduct analysis (month 54)	100%
Facilitate focus groups of ortho trauma surgeons and physical therapists to get feedback on Mobility Tool Kit reports (month 60)	0%
Write final report for peer reviewed publication (month 60)	50%

What was accomplished under these goals?

The study was conducted at 6 United States trauma centers under the coordination of the Major Extremity Trauma Research Consortium (METRC). The trial was registered on clinicaltrial.gov (NCT04047030).

Participants

Eligible patients were between 18 and 60 years of age with an open or closed fracture of the tibial plateau, pilon, ankle, or calcaneus requiring surgical fixation. Patients were excluded if they had a Gustilo Type IIIB or IIIC injury, other injuries or neurological impairments that impact gait, or were unable to maintain follow-up.

Eligible patients were enrolled prior to hospital discharge or at the first post-operative clinic visit which is typically scheduled for 1-3 weeks following definitive fracture fixation. After consent, operative notes, and injury x-rays were reviewed by a three-member orthopedic surgeon adjudication committee to verify eligibility. Patients with injuries that were determined to be ineligible were withdrawn from the study.

The study launched 3 months prior to the shut-down of research activities due to the COVID-19 pandemic. Patients who were enrolled prior to the shut down and could not be brought back for in-person assessments were followed remotely.

Mobility Assessment

Follow-up study visits were scheduled to occur at 6 weeks, 3, 6, and 12 months following definitive fracture fixation. At each visit, participants completed the 10-meter walk, the 5 time sit to stand and the timed up and go tests while wearing the mobility tool kit device. Assessments were conducted by Research Coordinators who were trained by study team investigators. Data was transmitted via Bluetooth from the IMU to the computer and automatically uploaded to the cloud database for analysis and storage. This process was controlled by the cloud application developed for this project. If the cloud application could not be used, for example if there was no internet connection, the data was collected using a separate standalone application and the data manually uploaded to a REDCap database. Research Coordinators were required to demonstrate proficiency with implementing the cloud and manual based applications prior to enrolling a patient. Research Coordinators were encouraged to review video tutorials, the instruction manual, and a study visit checklist prior to each visit to ensure that the device was operating properly when patients arrived.

Outcomes

The primary outcome was feasibility of implementing the mobility tool kit across multiple orthopedic trauma clinics. We examined reasons that assessments could not be completed, duration of assessment, use of cloud versus manual-based applications, and application and user errors. We also asked patients to rate device comfort and difficulty performing assessments while wearing the device on a scale of 1 (very uncomfortable/very easy to perform) to 7 (very comfortable/very difficult to perform.

Secondary outcomes included (1) test specific gait parameters of lift acceleration, step time asymmetry, and upper body pitch and roll, and (2) the Patient Reported Outcome Measurement Information System (PROMIS) physical function (PROMIS PF) which assesses difficulty performing activities of daily living, and the PROMIS Pain Interference, which measures the degree to which pain interfered with performing daily activities.

Other outcomes included weight bearing and ambulation status, use of pain medication, physical therapy and occupational therapy services received, hospital readmissions, and clinical complications.

Sample Size

Our goal was to enroll 300 injured patients (75 tibial plateau, 75 pilon, 75 ankle and 75 calcaneus fractures), and 150 non injured controls.

Results

We screened over 1,600 patients and enrolled 279 between December 2019 and October 2022. Of the 279 patients enrolled, 19 (7%) were determined to be ineligible based on review by the adjudication committee, and 16 (6%) were enrolled prior to the COVD-19 shut down and could not be followed due to COVID-19 restrictions leaving 244 enrolled and followed patients (Figure 1). The COVID-19 pandemic impacted our ability to meet the original target sample size of the study. Due to lower-than-expected volume of some injuries (i.e. calcaneus) treated at participating centers we were unable to enroll an equal number of patients in each of the four fracture groups. Instead, we over-enrolled ankle fractures to increase overall sample size.

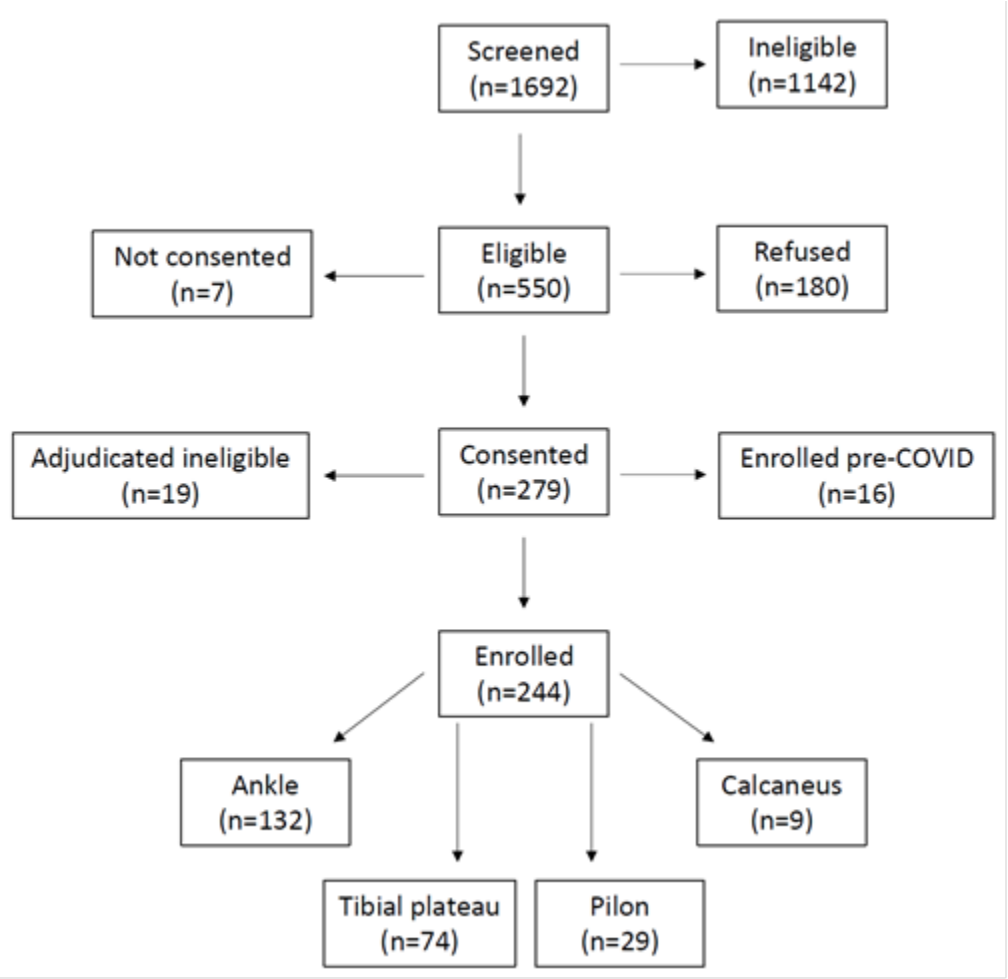


Figure 1. Patient screening and enrollment

Table 1 summarizes patient demographics overall and stratified by injury location. Most patients had ankle fractures (n=132, 54%) and tibial plateau fractures (n=74, 30%). Overall, the average age was 40 (SD: 12.3), over half of patients were female (53%), and non-Hispanic White (51%). Most patients had health insurance (85%) and reported their health as excellent or very good (56%).

Table 1. Patient Characteristics

	Overall (n=244)	Ankle (n=132)	Tibial Plateau (n=74)	Pilon (n=29)	Calcaneus (n=9)
Gender					
Male	110 (45%)	50 (38%)	42 (57%)	12 (41%)	6 (67%)
Female	130 (53%)	80 (61%)	30 (41%)	17 (59%)	3 (33%)
Missing/Prefer not to answer	4 (2%)	2 (2%)	2 (3%)	0	0
Age, mean (SD)	39.9 (12.3)	38.9 (12.8)	41.9 (12.3)	39.8 (10.2)	38.4 (10.7)
BMI, mean (SD)	31.0 (7.1)	32.2 (7.3)	29.4 (6.9)	29.5 (5.7)	29.8 (4.4)
Race/ethnicity					
Hispanic	43 (18%)	28 (21%)	8 (11%)	6 (21%)	1 (11%)
Non-Hispanic White	125 (51%)	65 (49%)	43 (58%)	13 (45%)	4 (44%)

Non-Hispanic Black	62 (25%)	33 (25%)	19 (26%)	7 (24%)	3 (33%)
Non-Hispanic, other or multiple races	8 (3%)	4 (3%)	2 (3%)	1 (3%)	1 (11%)
White, unknown ethnicity	1 (<1%)	0	0	1 (3%)	0
Black, unknown ethnicity	1 (<1%)	0	1 (1%)	0	0
Other or multiple races, unknown ethnicity	1 (<1%)	4 (3%)	0	0	0
Refused	1 (<1%)	0	0	1 (3%)	0
Missing	2 (1%)	1 (1%)	1 (1%)	0	0
Education, n (%)					
< High school	22 (9%)	9 (7%)	8 (11%)	5 (17%)	0
High school or GED	74 (30%)	38 (29%)	24 (32%)	8 (28%)	4 (44%)
> High school	144 (59%)	83 (63%)	41 (55%)	15 (52%)	5 (56%)
Missing	4 (2%)	2 (2%)	1 (1%)	1 (3%)	0
Current Tobacco User					
Yes	54 (22%)	27 (20%)	18 (24%)	8 (28%)	1 (11%)
No	189 (77%)	104 (79%)	56 (76%)	21 (72%)	8 (89%)
Missing or unknown	1 (<1%)	1 (1%)	0	0	0
Pre-injury health status					
Excellent	59 (24%)	22 (17%)	22 (30%)	12 (41%)	3 (33%)
Very good	79 (32%)	45 (34%)	24 (32%)	6 (21%)	4 (44%)
Good	78 (32%)	48 (36%)	21 (28%)	7 (24%)	2 (22%)
Fair	22 (9%)	12 (9%)	6 (8%)	4 (14%)	0
Poor	5 (2%)	4 (3%)	1 (1%)	0	0
Don't know	1 (0%)	1 (1%)	0	0	0
Marital status, n (%)					
Married, living with spouse	83 (34%)	38 (29%)	30 (41%)	10 (34%)	5 (56%)
Married, not living with spouse	3 (1%)	2 (2%)	0	1 (3%)	0
Living with partner	18 (7%)	12 (9%)	5 (7%)	0	1 (11%)
Separated	2 (1%)	0	1 (1%)	1 (3%)	0
Divorced	27 (11%)	15 (11%)	10 (14%)	1 (3%)	1 (11%)
Widowed	4 (2%)	1 (1%)	1 (1%)	2 (7%)	0
Never married	106 (43%)	63 (48%)	27 (36%)	14 (48%)	2 (22%)
Refused/don't know	1 (0%)	1 (1%)	0	0	0
Social Support Received in the last 2 weeks, n (%)					
Always	175 (71%)	94 (71%)	52 (70%)	23 (79%)	6 (67%)
Usually	36 (15%)	21 (16%)	9 (12%)	3 (10%)	3 (33%)
Sometimes	16 (7%)	8 (6%)	6 (8%)	2 (7%)	0
Rarely	4 (2%)	3 (2%)	1 (1%)	0	0
Never	8 (3%)	3 (2%)	4 (5%)	1 (3%)	0
Refused/don't know	4 (2%)	2 (2%)	2 (3%)	0	0
Missing	1 (0%)	1 (1%)	0	0	0
Comorbidity, n (%)					
None	101 (41%)	50 (38%)	29 (39%)	17 (59%)	5 (56%)

Diabetes	24 (10%)	12 (9%)	11 (15%)	0	1 (11%)
Cardiac disease	39 (16%)	23 (17%)	11 (15%)	4 (14%)	1 (11%)
Hematologic/vascular disease	8 (3%)	5 (4%)	3 (4%)	0	0
Pulmonary disease	14 (6%)	8 (6%)	4 (5%)	2 (7%)	0
Psychiatric conditions	43 (18%)	27 (20%)	13 (18%)	2 (7%)	1 (11%)
Other comorbidities	106 (43%)	60 (45%)	34 (46%)	8 (28%)	4 (44%)
Health insurance					
Yes	208 (85%)	114 (86%)	62 (84%)	24 (83%)	8 (89%)
No	36 (15%)	18 (14%)	12 (16%)	5 (17%)	1 (11%)

Table 2 summarizes treatment characteristics overall and by injury location. Nearly all patients received internal fixation. Over two thirds of the patients were required to wear a brace following definitive fixation and most patients (95%) were not given a prescription for physical therapy.

Table 2. Treatment Characteristics

	Overall (n=244)	Ankle (n=132)	Tibial Plateau (n=74)	Pilon (n=29)	Calcaneus (n=9)
Definitive fixation hospitalization length of stay, mean (SD)	2.0 (3.8)	1.3 (3.2)	3.1 (5.0)	2.0 (2.2)	2.2 (2.8)
Type of definitive fixation (internal vs external)					
Internal only	225 (92%)	123 (93%)	68 (92%)	27 (93%)	7 (78%)
External only	0	0	0	0	0
Internal and external	7 (3%)	2 (2%)	3 (4%)	2 (7%)	0
Other	11 (5%)	6 (5%)	3 (4%)	0	2 (22%)
Missing	1 (<1%)	1 (1%)	0	0	0
Given a prescription for Physical Therapy					
Yes	13 (5%)	2 (2%)	10 (14%)	0	1 (11%)
No	231 (95%)	130 (98%)	64 (86%)	29 (100%)	8 (89%)
Required to wear external brace					
Yes	167 (68%)	101 (77%)	35 (47%)	22 (76%)	9 (100%)
No	77 (32%)	31 (23%)	39 (53%)	7 (24%)	0

Feasibility

The number of patients who completed a follow-up visit was 223 (91%) at 6 weeks, 199 (81%) at 3 months, 160 (65%) at 6 months, and 125 (51%) at 12 months. The number of patients who were able to complete the performance tests while wearing the mobility tool kit device was 6% at the 6-week visit and 75% at the 12-month visit. At the 6-week visit, over 80% of patients were not cleared by their surgeon to weight bear and 14% were cleared to weight bear but unable to walk 10m unassisted. This was less of an issue at subsequent visits, though surprisingly, 70% of patients were still not cleared to weight bear or unable to walk unassisted at the 3-month visit. The Mobility Tool Kit assessments added an average of 21 minutes to the orthopedic clinic visit at 6 weeks. The assessments took less time during later visits, likely due to patient recovery in walking and Research Coordinator proficiency in conducting the assessments.

The other reasons why the Mobility Tool Kit assessments could not be completed can be classified into three broad categories:

- *Patient constraints*- Some patients were too overwhelmed by their injuries or were in pain and did not want to attempt the performance assessments. Some patients were unable to stick around to complete the assessment.

- *Envionment*- There were times when the right equipment was not available (i.e. a chair for the sit to stand test) or the hallway was too busy to do the walking tests.

- *Technical*- The biggest impediment to collecting mobility tool kit assessment data was lack of Bluetooth connectivity and data saving errors when using the cloud application. In many cases, these issues were resolved (i.e. switching to the manual system) and data was captured, but it caused delays in completing the assessments.

Table 3. Summary of Mobility Tool Kit Assessments by Study Visit

	6wk	3m	6m	12m
Number of visits completed	223	199	160	125
Mobility Took Kit Assessments Completed during the Visit				
Yes	14 (6%)	100 (50%)	126 (78%)	95 (75%)
No	210 (94%)	102 (50%)	36 (22%)	32 (25%)
Reason assessment not completed:				
Not cleared for weight bearing	173 (83%)	31 (31%)	4 (11%)	4 (13%)
Unable to walk 10m unassisted	29 (14%)	40 (40%)	3 (8%)	1 (3%)
Cleared for weight bearing but refused to do the test	1 (<1%)	6 (6%)	8 (22%)	6 (19%)
Other	7 (3%)	24 (24%)	21 (58%)	21 (66%)
Duration (minutes) of MTK performance assessments				
Mean (SD)	21.3 (26.9)	13.8 (9.5)	11.5 (6.8)	12.0 (11.7)
Range	7-100	4-74	4-60	3-94
Patient delays	0	2 (2%)	3 (2%)	1 (1%)
Technical delays	3 (21%)	19 (19%)	27 (21%)	15 (16%)
Other delays	1 (7%)	1 (1%)	5 (4%)	8 (9%)

Normative Gait Data

Tables 4 and 5 show vertical accelerations and step time for injured and uninjured limbs as recorded and analyzed by the mobility toolkit. Vertical or lift acceleration is a direct comparison to force exerted by each limb via the equation *Force = mass X acceleration.* It is expected that the overall magnitude of lift accelerations will increase while asymmetries will decrease as patients return to their pre-injury gait function. The step time, defined as heel strike to contralateral heel strike, includes the double support and contralateral swing (same side single support) time. The asymmetry between injured and uninjured time is expected to be low and further decrease with healing. It is expected that step time will have more clinical application when combined in the context of pitch and roll of the torso. Large asymmetries in step time would result in a patient walking in a large arc; therefore, compensations are made to maintain a straight path.

Table 4. Lower limb acceleration m/s^2 [Mean (SD)] for the 10m Gait test across a 12-month follow-up period.

	3 month				6 month				12 month			
	n	Injured	Uninjured	Asymmetry	n	Injured	Uninjured	Asymmetry	n	Injured	Uninjured	Asymmetry
Tibial Plateau	22	4.53 (1.32)	4.29 (1.39)	15.9% (11.3%)	34	4.65 (1.43)	4.55 (1.38)	13.5% (18.7%)	20	4.75 (1.49)	4.70 (1.53)	7.5% (5.6%)
Ankle	69	4.07 (1.30)	3.95 (1.31)	11.6% (15.1%)	56	4.70 (1.38)	4.62 (1.43)	7.7% (9.1%)	47	4.91 (1.41)	4.82 (1.49)	8.9% (13.0%)
Pilon	3	4.73 (1.91)	4.08 (1.59)	15.3% (3.2%)	12	4.90 (1.91)	4.64 (1.55)	19.2% (21.4%)	9	5.11 (1.27)	4.94 (1.21)	5.7% (5.2%)
Calcaneus	2	6.28 (2.62)	5.95 (1.66)	10.7% (4.8%)	5	4.81 (2.27)	4.46 (2.09)	7.8% (7.1%)	3	4.69 (0.70)	4.90 (0.14)	10.9% (4.2%)

Table 5. Step time (s) [Mean (SD)] for the 10m Gait test across a 12-month follow-up period.

	3 month				6 month				12 month			
	n	Injured	Uninjured	Asymmetry	n	Injured	Uninjured	Asymmetry	n	Injured	Uninjured	Asymmetry
Tibial Plateau	22	0.64 (0.09)	0.66 (0.14)	8.4% (6.7%)	34	0.64 (0.11)	0.63 (0.08)	4.6% (6.7%)	20	0.59 (0.07)	0.58 (0.08)	5.2% (7.7%)
Ankle	69	0.60 (0.06)	0.60 (0.08)	7.7% (10.0%)	56	0.59 (0.06)	0.60 (0.06)	4.0% (4.3%)	47	0.58 (0.05)	0.58 (0.04)	3.9% (3.6%)
Pilon	3	0.55 (0.04)	0.54 (0.04)	2.6% (1.3%)	12	0.58 (0.06)	0.57 (0.05)	7.6% (8.1%)	9	0.57 (0.06)	0.56 (0.06)	2.1% (1.7%)
Calcaneus	2	0.56 (0.05)	0.55 (0.02)	2.9% (1.7%)	5	0.62 (0.07)	0.58 (0.05)	11.6% (17.9%)	3	0.57 (0.02)	0.57 (0.03)	1.1% (0.7%)

Figures 2 and 3 represent the averaged peak pitch and roll values as subjects traversed the 10m span for the Gait test. Pitch is defined as forward torso angulation away from center. Roll is defined as lateral/side to side angulation of the torso with respect to center. The combined relationships of pitch and roll with acceleration and step time are intended outcomes of this study. A general reduction of roll magnitudes to a plateaued value is expected as gait patterns return to the pre-injured state. A similar trend is expected for pitch values, though increased accelerations with returning strength and functionality may simultaneously increase or maintain higher pitch magnitudes. Similarly, low asymmetry for acceleration with lower absolute magnitudes and low pitch may be an indication of a patient walking gingerly as a result of pain or instability. A detailed assessment of these variables and their relationships is underway. One of our goals was to examine the change in gait parameters over time. The number of people with 2 or more assessments is 109 (45% of the study population) which limits our ability to evaluate gait trajectories.

Figure 2. Plots of the Pitch magnitude (deg) across a 12-month follow up period for each injury classification.

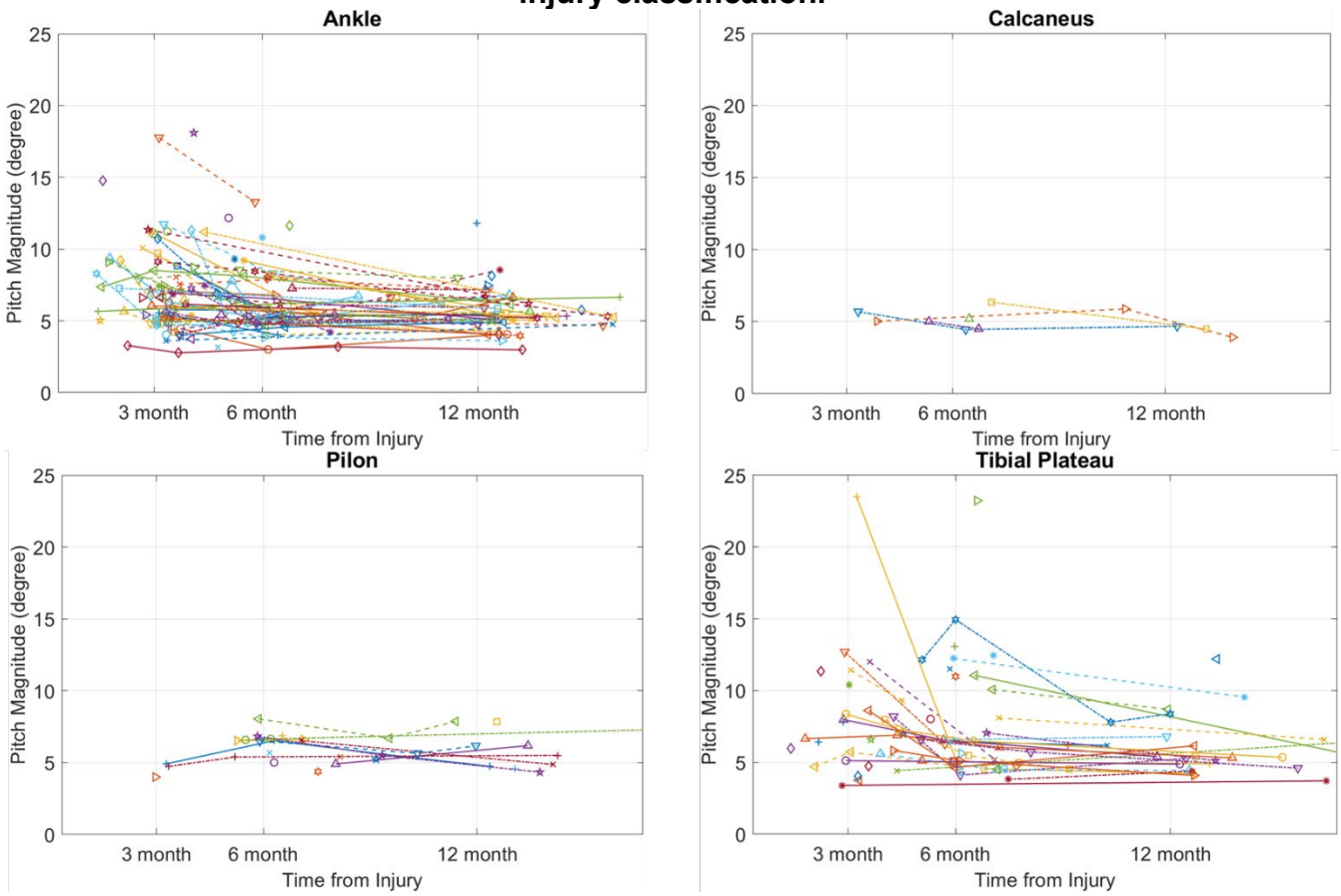
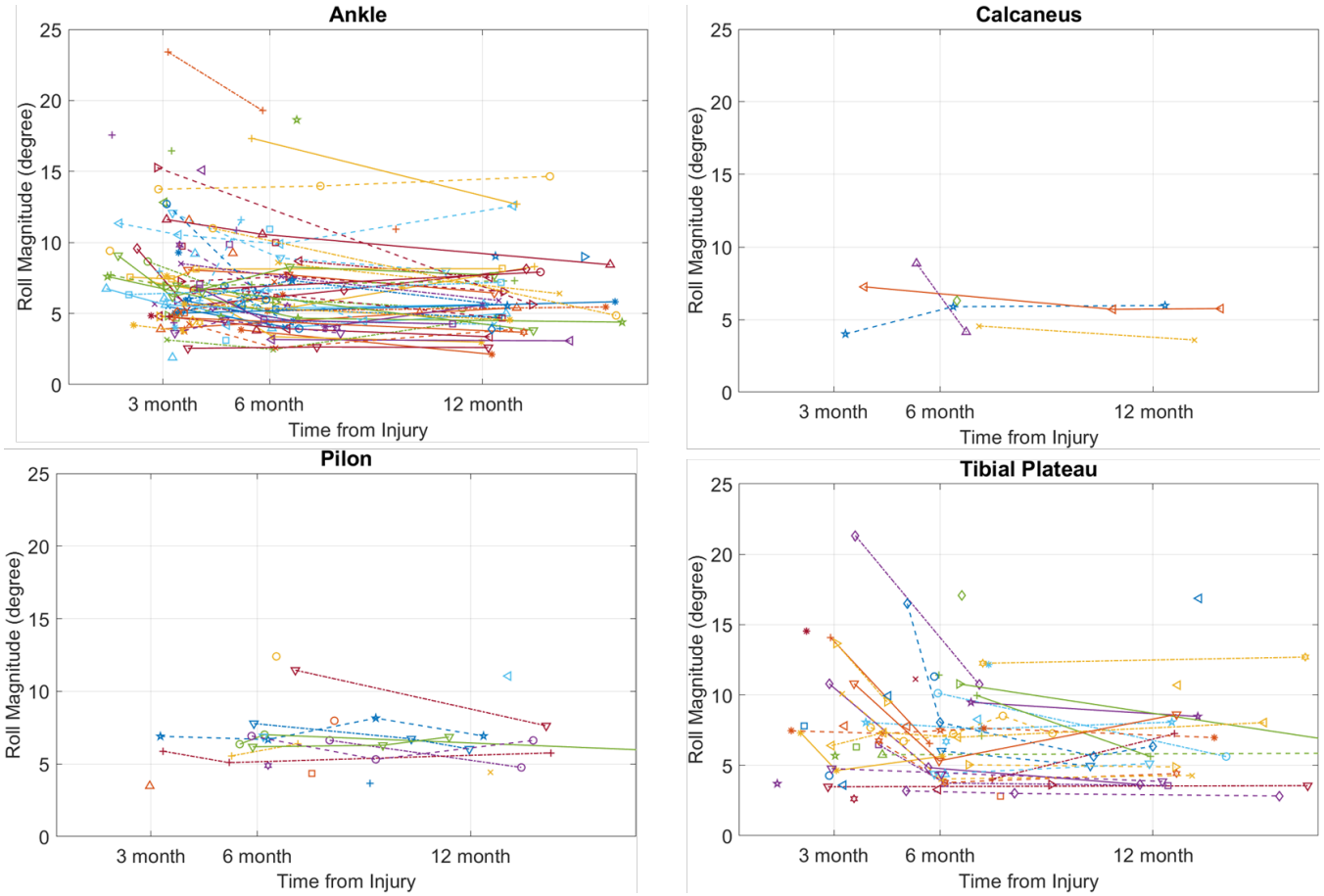


Figure 3. Plots of Roll magnitude (deg) across a 12-month follow up period for each injury classification.



Gait Thresholds Indicating Risk for Diminished Function and Complications

Table 6 and 7 present the PROMIS physical function (PF) and pain interference (PI) scores by study visit, stratified by injury location. The mean PF scores increased (improved) over time and the mean PI scores decreased (improved) over time. Analyses examining the relationship between Mobility Tool Kit gait data and patient reported outcomes are underway.

Table 6. PROMIS PF scores by study visit, stratified by injury location

	Overall		Tibial plateau		Tibial pilon		Ankle		Calcaneus	
	(n=244)		(n=72)		(n=32)		(n=131)		(n=9)	
	n	T score, mean (SD)	n	T score, mean (SD)	n	T score, mean (SD)	n	T score, mean (SD)	n	T score, mean (SD)
6wk	190	32.0 (8.0)	54	29.8 (8.5)	26	32.6 (7.5)	105	33.1 (7.9)	5	31.6 (3.1)
3m	175	38.6 (8.1)	49	35.9 (9.5)	23	36.2 (7.0)	98	40.5 (7.1)	5	38.3 (7.4)
6m	146	45.0 (7.8)	47	44.4 (7.1)	22	42.4 (8.4)	72	46.2 (8.0)	5	44.4 (8.8)
12m	129	47.8 (9.5)	38	46.7 (8.6)	19	45.9 (8.0)	70	49.0 (10.5)	2	47.1 (3.5)

Table 7. PROMIS PI scores by study visit, stratified by injury location

	Overall (n=244)		Tibial plateau (n=72)		Tibial pilon (n=32)		Ankle (n=131)		Calcaneus (n=9)	
	n	T score, mean (SD)	n	T score, mean (SD)	n	T score, mean (SD)	n	T score, mean (SD)	n	T score, mean (SD)
6wk	191	57.9 (8.6)	54	58.8 (8.5)	26	59.0 (7.8)	106	57.5 (8.6)	5	49.1 (10.3
3m	175	56.3 (8.4)	49	56.1 (7.6)	23	56.5 (8.6)	98	56.4 (8.7)	5	53.9 (9.8)
6m	146	54.2 (8.3)	46	55.4 (8.2)	22	55.4 (8.1)	73	53.2 (8.4)	5	53.7 (9.6)
12m	130	52.3 (9.9)	38	54.1 (10.8)	19	54.3 (8.6)	70	50.9 (9.7)	3	47.7 (7.8)

Table 8 presents the number of patients with a complication at each study visit. “Other” complications include syndesmotic instability, loss of reduction, skin breakdown, hamstring shortening, post traumatic arthritis, femur fracture, tendon irritation and lymphedema of the leg. Analyses examining differences in gait parameters among patients with compared to without a complication are underway.

Table 8. Complications reported among all patients enrolled in the study (n=244)

	Baseline	6wk	3m	6m	12m
Superficial site infection	0	8	3	1	0
Osteomyelitis	0	2	1	2	0
Abscess	0	1	2	2	0
Nonunion	0	0	0	2	2
Fixation failure	0	0	1	0	0
Reaction to hardware	0	0	1	0	0
Wound dehisence	0	5	3	0	0
Deep vein thrombosis	1	0	0	1	0
Pulmonary embolism	1	0	0	0	0
Breakage	0	0	0	0	1
Other*	0	2	1	4	4

Non-Injured Controls

We collected mobility tool kit assessments on 70 non injured adults (mean age: 36, 41% male). We recently finished data collection and are in the process of preparing the data files for analysis. We intend to compare gait parameters of non-injured adults to gait parameters of injured patients overall and by injury type.

4. Impact

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

Our overarching goal is to understand and measure the impact of injury on mobility given the importance of mobility to recovery to function and quality of life. Wearable devices are being used with more frequency in both research and clinical care.

- Describe the original intent of the Tool Kit device; going beyond step count to characterize gait quality; may be an important aspect of recovery; identify patients who need more PT; or mobility assistance devices.
  The Mobility Toolkit (hardware and software) was developed to address unmet needs in the clinical and research settings using a single wearable device that outputs objective measures of subcomponents of tests where only time to completion is traditionally recorded and utilized. The objective data captured by and exported from the toolkit is meant to provide insights into functional status and recovery trajectories that could be used to assist clinical decision-making processes. The objective measures allow for comparisons across different patient populations and injury characteristics.
- Goal of this project was to test the utility of this information. (i.e. does it discriminate between injuries? Can it predict functional outcomes and complications?)
- Did not anticipate that most patients would not be cleared to weight bear at 6 weeks (and even 3 months); we planned to bring patients back at visits that align with standard of care; even that was challenging.
- Data collection relied on Bluetooth® transmission from the wearable IMU to the application(s). Connectivity issues between IMU and computer/application(s,) whether a result of environmental factors, hardware malfunction, or coordinator errors, were the most frequent technical challenges to data collection. There were some challenges to implementing data collection in the clinic setting mostly related to Bluetooth connectivity and due to challenges with the Atrium Health firewall which are important lessons for designing future interventions and the use of this type of technology in the clinic.

What was the impact on other disciplines?

Nothing to report**.**

What was the impact on society beyond science and technology?

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

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

Not applicable.

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

6. Products

Journal publications.

Planned papers:

1. Feasibility of implementing a mobility assessment following lower extremity trauma in orthopedic clinics (manuscript underway).
2. Gait characteristics following lower extremity trauma compared with non-injured controls.
3. Gait characteristics of patients experiencing complications that require surgical intervention (eg, nonunion, infection, hardware failure).
4. Impact of demographic characteristics on gait parameters (eg, age, gender, BMI, chronic conditions).
5. Impact of demographic characteristics on recovery trajectories.
6. Comparison of gait parameters to patient-reported outcomes.
7. Ability of the gait parameters to distinguish between different injury patterns and severity of injury.
8. Utility of the gait parameters to informing rehabilitation protocols or need for intervention.

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)

Not applicable.

Technologies or techniques

Not applicable.

Inventions, patent applications, and/or licenses

Nothing to report.

Other Products

This study resulted in a dataset of participant demographics, injury and treatment characteristics, and outcomes for distribution and secondary data analysis.

We also developed a training manual and video on how to set up and conduct the mobility tool kit assessments.

7. Participants and other Collaborating Organizations

Personnel at METRC/JHU	**Role and Contribution to the Project**	**Calendar Months**
Renan Castillo	MCC PI: oversees scientific management	0.09
Lisa Reider	MCC Co-PI: oversees scientific management and management of coordinating center activities	1.2
Elizabeth Wysocki	MCC Project Director (replaces Andrea Deluca effective 03/01/20): manages overall study timeline, communication with sites, and regulatory reporting	2.4
Manisha Kumar	MCC Finance Manager: manages the sub agreements and financials for MCC and participating centers (left effective May 2022)	0.00
Rachel Soifer	MCC Data Analyst: will oversee database management for the study.	3.0
Elias Weston-Farber	Data Manager (replaces Andre Hackman): oversees REDCap programming and data reporting	3.0
Jiawei Bai	Biostatistician: (left effective January 2022) responsible for analyzing the MTK output	0.0
Jacek Urbanek	Biostatistician: responsible for developing an analysis plan for the study and overseeing Dr. Bai in analyzing the MTK output (left effective January 2020)	0.0
Personnel at Atrium Health	**Role and Contribution to the Project**	**Calendar Months**
Stephen Sims, MD	Principal Investigator: Dr. Sims is responsible for the research study. He leads the adjudication committee, supervises data quality, and will lead the protocol committee in manuscript development.	1.2
Rachel Seymour, PhD	Co-investigator: Dr. Seymour supervises the research team at Carolinas Medical Center and meets bi-weekly with Dr. Reider and Ms. Wysocki at the MCC.	8.7
Christine Churchill	Research manager: Ms. Churchill supervises all screening, enrollment, and follow-up at Carolinas Medical Center. She also works closely with the METRC Coordinating Center on regulatory for all enrolling sites.	7.2

Michael Gambuzza	Research coordinator: screening, enrollment, and follow-up of patients at Carolinas Medical Center.	6.0
Erica Grochowski	Research coordinator: screening, enrollment, and follow-up of patients at Carolinas Medical Center. Ms. Grochowski also provides support for regulatory approvals at the lead site.	1.9
Nahir Habet	Research engineer: Mr. Habet is responsible for ensuring that the Mobility Toolkit devices are operational at all sites and to assessing and assuring data quality.	11.2
Kate Hickson	Research coordinator: screening, enrollment, and follow-up of patients at Carolinas Medical Center.	0.5
Enosh Ishman	Research coordinator: screening, enrollment, and follow-up of patients at Carolinas Medical Center.	7.0
Priyanka Kamath	Data management coordinator: cleaning and analyzing data and producing tables and figures for the final report.	3.1
Ada Mayfield	Research coordinator: screening, enrollment, and follow-up of patients at Carolinas Medical Center.	10.3
Meera Sumith	Data management coordinator: cleaning and analyzing data and producing tables and figures for the final report.(in the role prior to Priyanka Kamath)	3.9
Shangcheng Wang	Research engineer: Dr. Wang, in collaboration with Mr. Habet, is responsible for ensuring that the Mobility Toolkit devices are operational at all sites and to assessing and assuring data quality.	3.0
Catherine Young	Research coordinator: screening, enrollment, and follow-up of patients at Carolinas Medical Center.	6.9
Ziqing Yu	Statistician: Mr. Yu collaborated with the team to ensure that the data necessary for analysis was captured and assessed for quality. Mr. Yu assured that the data from the mobility toolkit devices were analyzed properly. He worked with the team to determine the analysis plan and outline potential manuscripts.	6.3

Hass 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?

The following institutions participated in the study:

1. Carolinas Medical Center
2. San Antonio Military Medical Center

3. University of Kentucky Medical Center
4. University of Maryland Medical Center
5. University of Texas Health Science Center
6. Vanderbilt University Medical Center

8. Special Reporting Requirements
   Nothing to report.

9. Appendices
   Nothing to report.