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Use of a Self-Directed Exercise Program (SDEP) Following Selected Lower Extremity Fractures: A randomized clinical trial

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1. SCIENTIFIC AIMS

The care of extremity trauma has evolved over the past 25 years. In the era of prolonged skeletal traction and/or casting following extremity trauma, the use of post-injury supervised physical therapy (PT) was required to achieve good outcomes. Seminal changes in the care of extremity trauma include early long bone fracture fixation and stable joint reconstruction. These techniques allow for immediate ambulation with assistive devices, early joint range of motion and major muscle group activation. However, evidence on the use of more efficient and cost effective rehabilitation methods has not evolved at the same pace. Consequently, post-injury, clinic-based PT is often uniformly included as a standard of care rehabilitation protocol for uncomplicated extremity fractures. *No data exist to guide clinical decision making regarding the neccesity of this approach or to identify subgroups of patients who may be able to achieve similar outcomes using a standardized self-directed, home exercise program*. The impact of a home-based PT program on clinically relevant outcomes following isolated and uncomplicated lower extremity fracture has never been evaluated.

The purpose of this study is to compare the effectiveness and value of clinic-based PT and a home-based, self-directed exercise program (SDEP). The home exercise program will be developed by a team of physical therapists, orthopaedic trauma surgeons and experts in rehabilitation engagement in collabortion with patients recovering from traumatic lower-extremity injuries. The study will also determine which subgroups of individuals based on patient and injury characteristics are the best candidates for a home exercise program.

> **Hypothesis:** The overall hypothesis is that return to work/major activities as well as clinical and functional outcomes and health-related quality of life for patients who receive clinic-based PT will be similar to patients receiving SDEP.
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> Specific Aim 1: To compare the effectiveness of SDEP, exercise instructions given by physician and clinic-based PT for improving return to work/major activities, clinical and functional/performance outcomes and health-related quality of life in patients following selected lower-extremity fractures.
> Specific Aim 2: To determine which sub-groups of patients, based on patient and injury characteristics, are most likely to benefit from SDEP.
> Specific Aim 3: To compare the cost-effectiveness of clinic-based PT and SDEP.

2. BACKGROUND & SIGNIFICANCE

There is little clinical debate that patients with multiple extremity injuries or injuries with associated complex soft tissue damage or nerve deficits benefit from supervised PT. Prior

research from the LEAP Study examined the impact of PT on patients with high energy trauma injuries below the distal femur.[1] While the surgeons and PTs differed in their assessment of perceived need for PT,[2,3] evidence demonstrates the beneficial effect of PT for this patient population.[4] Research on combat-related lower extremity limb salvage patients showed a significant benefit and a higher return-to-duty rate following intense and focused rehabilitation combined with an integrated orthotic.[5-7] *However, the majority of lower extremity fractures seen in the military and civilan sectors are not combat related or of the severity of the LEAP limb salvage patients and, thus may not require intensive, clinic-based, supervised PT treatment.* Patients with isolated major lower extremity fractures may benefit from a self-guided, home-based post-injury exercise program. Studies evaluating home exercise programs for elective orthopaedic reconstruction surgery for joint replacement and ACL reconstruction have reported equivalent outcomes compared to in-person, supervised PT.[8-12] Because PT resources are critical, limited, and expensive in most civilan centers, identifying the patients who would most benefit from utilizing these resources could result in savings for both the patients and the health care systems, and lead to more efficient access to PT services by the population who needs them the most. In addition to health systems benefits, patients able to achieve positive outcomes through a home-based, self-directed exercise program would experience flexibility regarding when the exercises are performed.

PREVIOUS WORK DONE ON THE PROJECT

This study builds on a growing body of data that indicate, following various elective and traumatic orthopaedic procedures, patients who are provided structured self-directed home-based rehabilitation can achieve similar outcomes to those who receive traditional clinic based rehabiliation services.[12-23] Our institution recently completed an observational study assessing the outcomes of patients with severe ankle fractures with and without dislocation.[12] 47% of the patients (those in community based practice) received post-operative in-person, supervised PT, whereas 53% of the patients (those from an academic medical center) received only a surgeon directed home-based exercise program. At 6 months post injury, physical function outcomes measured by the Short Musculoskeletal Function Assessment (SMFA)[24] and Foot and Ankle Ability Measure (FAAM)[25] were similar. These data suggest that a structured, home-based exercise program is acceptable to patients and surgeons and that this may be an effective rehabilitation approach for post-fixation lower extremity fractures for selected injuries and in selected patients.

3. METHOD

We are proposing a pilot of a multi-center, randomized controlled trial that will compare clinic-based PT, self-directed, home exercise program (SDEP), and standard of care surgeon exercise instructions (SOC-SEI) in patients with selected lower-extremity fractures. Patients between the ages of 18-65 and with fractures of the femur or tibia treated with intramedullary fixation or with articular fractures of the distal femur (33A,B,C), proximal (41A,B,C) or distal tibia (43A, B,C) treated with plate fixation will be enrolled. Assessments will be conducted at baseline) and 3, 6, and 12 months after hospital discharge. Patients will complete a battery of questionnaires measuring psychosocial factors, return to major activities/work, pain, and health-related quality of life as well as performance-based tests with electronically augmented kinematic data capture via the Mobility Toolkit at each assessment visit. Range of motion and strength will also be

assessed using goniometry and a stabilized hand-held force gauge, respectively.

Inclusion criteria: Patients aged 18-65 with operative fractures of the femur and tibia (to include distal femur (33A, B), plateau (41A, B), pilon (43A, B), and selected ankle injuries (44A, B)) presenting to the Orthopaedic Surgeon for either acute care or for the follow-up of care performed elsewhere (within 14 days of the injury). All patients must be English or Spanish competent and able to be followed at the sites for at least 12 months following injury.

Exclusion criteria: Patients with ISS>18, bilateral lower-extremity injuries that preclude crutch ambulation, associated spine, pelvic, and/or acetabular fractures that otherwise alter weightbearing plans, type III B/C open fractures, Glasgow Coma Scale <15 at time of discharge, major peripheral nerve injury, or planned admission to a skilled nursing facility or inpatient rehabilitation facility, pregnant women, and patients diagnosed with a TBI will be excluded from the study.

Comparators: Patients will be randomized to one of three groups –

Insured patients

- Clinic-based PT: Patients will be referred to PT by the orthopaedic surgeon for enrollment into a clinic-based PT program per usual referral patterns at the surgeon's center. Patients will receive services based on their health care benefits defined by his or her insurance plan.
- SDEP: The full SDEP program, which will be developed by physical therapists, orthopaedic trauma surgeons, and investigators with experience in health behavior change, will be designed to maximize adherence/compliance with the program. The SDEP manual will provide detailed instructions on exercises, such as repetitions, frequency, and required equipment, which can be implemented in the home environment. The basis for the exercise regimen is derived from the AAOS sample home based exercise program available in handout form, which can be found at http://orthoinfo.aaos.org/topic.cfm?topic=A00672. The program provides instructions on exercises, repetitions or duration, frequency, and required equipment which can be implemented in the home environment.

Uninsured Patients

Patient with no access to health insurance will be approached for the study and randomized to the full SDEP program or standard of care/surgeon exercise instructions (SOC-SEI).

- SDEP: The full SDEP program, which will be developed by physical therapists, orthopaedic trauma surgeons, and investigators with experience in health behavior change, will be designed to maximize adherence/compliance with the program
- Standard of Care-Surgeon Exercise Instructions (SOC-SEI): stretching and range of motion instructions given by the treating surgeon or ACP.

Observational cohort

Patients who are unwilling to be randomized will be enrolled in an observational arm of the study. They will be asked to complete all baseline and follow-up assessments, and

participation in formal PT or SOC-SEI will be documented.

Data Collection: Patients will be assessed at baseline and then at 3, 6, and 12 months after hospital discharge. Demographic characteristics including co-morbidities, pre-injury health status and function, socioeconomic status, usual major activity prior to injury, education, and insurance status will be documented at the time of enrollment. Injury characteristics including associated injuries, hospital length of stay, and in-hospital complications will be collected. Fracture healing and weight-bearing status, as well as any complications, including readmissions and reoperations will be documented. Psychosocial characteristics that may impact outcomes (self-efficacy, patient activation, fear of movement/re-injury, resiliency, and depression) will be assessed at baseline and all follow-up visits.

Instrument	**Baseline**	**3 months**	**6-months**	**12-months**
Patient Characteristics	X			
Medical History	X			
Work Productivity and Activity Impairment Questionnaire (WPAI)	X	x	X	X
Paffenbarger Physical Activity Questionnaire	X	x	X	X
Pain Self-Efficacy Questionnaire (PSEQ)	X	x	X	X
Connor-Davidson Resilience Scale (CD-RISC)	X	x	X	X
Tampa Scale for Kinesiophobia (TSK)	X	x	X	X
Pain Catastrophizing Scale (PCS)	X	x	X	X
Veterans RAND 12 Item Health Survey (VR-12)	X	x	X	X
PROMIS Pain Interference Short Form		x	X	X
PROMIS Physical Function Short Form		x	X	X
PROMIS Global Health		x	X	X
Brief Pain Inventory (BPI)		x	X	X
Return to Usual Major Activity (RUMA)		x	X	X
Clinical Follow-up Form		x	X	X
Performance tests w/ IMU- at each clinic visit		x	x	x

Primary and Secondary Outcomes: The primary outcome measure for the study will be return to work/major activities. Secondary outcomes include the pain, functional status, health-related quality of life, physical activity, kinesiophobia, depression, psychosocial risk factors, time to recovery, range of motion assessed using a goniometer, and strength assessed using a stabilized hand held force gauge. Outcome measures covering multiple areas will be used to ensure that the potential benefits and/or limitations associated with selected interventions are effectively captured.

Secondary functional outcomes will be assessed with a battery of validated performance-based tests captured via the Mobility Toolkit (10m walk test, Timed Up and Go) at each clinic visit. The Mobility Toolkit is a HIPAA compliant, web-accessible, cloud-based application for

capturing performance tests in multiple clinics. It is built on a Microsoft Azure platform with custom MATLAB analytics. The mobility toolkit application currently allows us to gait test patients and compare their results over time (i.e. rehab trajectories) or compare results versus similar patients or matched non-injured controls. The data are captured by an Inertial Measurement Unit (IMU) that is chest-mounted, positioned at the top of the sternum using a simple harness (Figure 1). The IMU is a wireless-telemetry, 10 degree-of-freedom IMU which includes a tri-axial accelerometer, a tri-axial gyroscope, a tri-axial magnetometer and an onboard temperature sensor. Custom software has been developed to appropriately filter the raw data, establish a fixed global coordinate system (i.e. aligned with the body coordinate system), segregate gait segment data from turn data, and delineate and compile data for left and right strides for separate analyses. The software is also used to calculate quantitative descriptors of gait which are observable during subjective gait evaluation but not readily quantified. Set up and test time for the IMU is approximately 5 minutes and can be performed in almost any setting, including outpatient clinics.

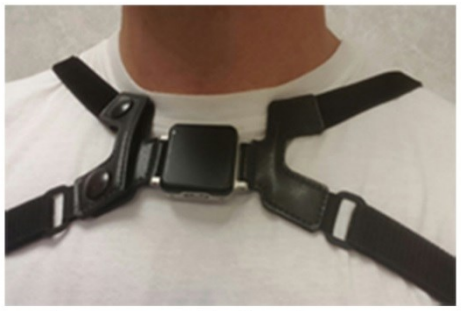

Fig. 1 IMU with chest harness

4. Sample Size and Analysis Plan. The primary purpose of this study is to provide preliminary estimates of efficacy of the intervention and data supporting the feasibility of randomizing patients to two alternate types of rehabilitation services. Data will be used to determine the need for, and to power, a larger randomized trial of the intervention. The sample size of 60 patients per arm will allow us to calculate a confidence interval for the difference in mean PROMIS Physical Function scores between the two treatment groups assuming a common standard deviation of PROMIS Physical Function scores in the treatment groups of 17.

5. Potential Risk

The is a small risk of falling during the performance tests. These tests will be performed under close supervision by trained Research Coordinators using standard operating procedures.

Any time information is collected for a study, there is a small risk of breach of confidentiality. However, this risk is not greater than the risk that already exists in clinical settings when handling medical data.

6. Potential Benefits

The physical therapy intervention may or may not be better than the physical therapy program that would be prescribed to the participant outside of this study. In addition, study participants may experience satisfaction in knowing that the results of the study could help determine the best physical therapy program

7. Data Management and Storage.

The Department of Orthopaedic Surgery utilizes the NIH-funded Research Electronic Data Capture (REDCap) project for all data management and stor-age. REDCap is a state of the art, metadata driven application for distributed data collection and data management in clinical studies.

Security. Privacy and security are central considerations for distributed data systems with ac-cess

to Personally Identifiable Information (PII). The overall private website will be secured with a challenge/response password protection mechanism. An additional level of security, requiring entry of a unique individual password, further protects access to the REDCap data management system. Numerous steps are being taken to maintain the integrity and security of the data system. First and foremost among these is the provision of careful training, certification, and guidance to all research staff. Each user account will have its own password and staff will be trained to recognize as misconduct the sharing of passwords.

Distributed Data System. The REDCap data management allows for a web-based, distributed data entry system using most web browsers to access an internet-connected database server. The system will permit research staff to have access to data as soon as they are entered, allow-ing for near-real-time recruitment reports and increased data entry availability and convenience for the clinical sites. The primary functions of the data system include the following existing fea-tures of the REDCap application: registration of all candidates for the trial; entry of all study data forms; inventory, management, and editing of study data; maintenance of full audit trails of all data entry and editing; and real time performance report generation. The REDCap data entry system also includes extensive data validation functionalities, including field level validation (i.e., checking the correct format and range of each entered item, intra-form validation, checking for logic errors, skip pattern violations across items on a form; and inter-form validation, checking for inconsistencies across forms).

Data Export and Reporting. REDCap has a number of built-in data export capabilities, includ-ing the capacity to directly produce data files for several common statistical analysis and data management packages (Microsoft Excel, SPSS, SAS, R, Stata). In addition, a well-developed report generation utility makes it possible to extract real-time information in support of performance monitoring, quality assurance, and Data and Safety Monitoring Board interim reports.

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