Title: InterACTION: A Portable Joint Function Monitoring and Training System for Remote Rehabilitation following Total Knee Arthroplasty

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Abstract

Background

Post-operative rehabilitation is essential to optimize outcomes following orthopaedic surgeries. Lack of patient compliance to this prescribed rehabilitation therapy has been reported to be as high as 65%. This lack of rehabilitation compliance effects patients by prolonging pain and dysfunction and diminishing quality of life and acts as a strain on the healthcare system by increasing the overall burden of care, including increased duration of rehabilitation, increased rates of readmission, and re-operation.

Purpose

The purpose of this pilot study is to ascertain if home-based therapy with monitoring via telemedicine can overcome barriers to compliance and improve rehabilitation.

Methods

Sixty patients following total knee arthroplasty will be monitored for up to 10 weeks during their outpatient physical therapy course. For the control group, 30 of these patients will undergo two to three weekly sessions with a physical therapist supplemented by unmonitored home-based exercises. The second group of 30 patients will fulfill their rehabilitation course with one to three sessions per week with a physical therapist and will use the interACTION home rehabilitation monitoring program to supplement these sessions. The patients in the interACTION group will use the device for the first two weeks of their rehabilitation in the clinic in order to become familiar with the device before home use. After the first two weeks the patient will be asked to take the device home and reduce their weekly outpatient visits by one visit per week. However, if the physical therapist feels it is best for the patient to deviate from the protocol, this is allowed. At the end of the 10-week rehabilitation course, rehabilitation compliance, costs, and patient outcomes will be analyzed for differences between the two groups.

Significance

If home-based therapy is successful, post-operative patients in the future would be allowed to perform guided rehabilitation therapy at home, and physicians would be able to monitor patients' rehabilitation progress without the limiting factor of patients being present onsite or performing the exercises incorrectly, potentially improving patient outcomes and lowering healthcare costs and expenditures.

Background

Adequate rehabilitation following total knee arthroplasty (TKA) is crucial to optimize patient function and quality of life. Attaining adequate strength and range of motion is essential to regain the function of the knee and permit patients to resume their regular activities after surgery. Despite acknowledgement of the importance of post-operative rehabilitation after TKA, the current system is far from perfect. First, patients are expected to perform their rehabilitation program once or twice a day following surgery, but traditional rehabilitation protocols generally include only one to three sessions of outpatient physical therapy per week. As a result, the patient is left to perform exercises unmonitored for the majority of their recovery period. Second, barriers to rehabilitation are a concern for patients, including limited mobility/access and growing copay expenses. Lastly, the fragmented nature of the physical therapy landscape does not provide the physician or patient with a guarantee of a standardized, proven course of rehabilitation. This also makes accurate and meaningful communication between the physical therapist and physician a difficult task.

Altogether, these difficulties strain the optimal delivery of rehabilitation following TKA. Overall compliance to a complete rehabilitation program under the current standard of care approach to rehabilitation has been shown to be as low as 35% (Sluijs, Phys Ther, 1993).

Non-compliance, defined as incomplete or incorrect execution of prescribed treatments, represents significant waste in healthcare and negatively affects outcomes leading to prolonged pain, greater activity limitations and participation restrictions, a longer duration of recovery, poorer quality of life, and the potential for increased hospital readmissions and additional surgical interventions (Martin, 2005). Use of telemedicine to monitor patients has overcome barriers to compliance and reduced costs in other fields of medicine (Elkjaer, 2012). Early attempts to implement telerehabilitation have demonstrated a strong potential for the success of this approach in improving compliance (Russell, 2010). However, effective, scalable monitoring of prescribed exercises is currently limited by lack of portable, accurate, precise, interactive, and cost-effective tools. To date, remote rehabilitation or home exercise programs for rehabilitation after surgery or injury lack adequate supervision, patient motivation, patient-therapist communication, and personalized treatment plans.

Physical therapists can promote compliance in conventional rehabilitation by tracking patient adherence using log books, existing mobile apps, or activity monitors. However, log books rely on patients for accurate data entry and provide no means for communication or corrective feedback, existing mobile apps cannot track joint motion or provide corrective feedback, and activity monitors do not measure joint-specific function (quantity and quality of motion). Thus, current tools fail to quantify exercise over time in or out of the clinical setting.

InterACTION is a joint motion monitoring and training tool consisting of a wearable, portable motion capture device and a web-based software application for recording

and transmitting data. Sensors, placed on either side of a joint, collect joint motion and position data. Data is stored on a Bluetooth paired tablet. Motion data collected by interACTION is analyzed and displayed in a customizable, joint-specific manner in patient and therapist modes. The patient uses the system as often as indicated by their physical therapist to learn about the prescribed exercises, follow a personalized exercise program, demonstrate adherence to the treatment plan, and communicate problems with their physical therapist and receive interactive feedback. Patients also have the ability to view their rehabilitation progress.

A web-accessible, password-protected portal allows a local or remote physical therapist to monitor the patient's progress. Physical therapists have access to the data to analyze patient progress and compliance and review computer-generated alerts. Capabilities in the clinician portal include assessment of patient data during exercises and activities of daily living (ADLs), weekly progress reports by reviewing changes in important variables (i.e. range of motion, pain, patient-reported activity, participation, quality of life). The ability to monitor progress ensures the patient's compliance to the treatment program and allows clinicians to update the patient's exercise regimen as needed.

Use of the interACTION system has the potential to allow physical therapists to improve patient-oriented outcomes, streamline utilization of clinical resources, and provide care more efficiently for a larger number of patients. In turn, patients will be more confident and compliant with performance of their prescribed exercise program and will receive feedback on their recovery progress. However, research is needed to demonstrate these hypothesized benefits of the interACTION system.

Significance

The interACTION telerehabilitation system provides flexibility and potential application at all stages of patient care, with easy implementation for patients at both the lower levels of the functional spectrum (e.g. immediately after joint surgery), as well as higher functioning individuals (e.g. >6 months post-op, athletes with persistent joint pain). The quality of care will improve as the therapist-patient relationship is strengthened by (i) providing valuable information about the patient's daily progress, (ii) improving compliance with the prescribed exercises, and (iii) facilitating communication/feedback between patient and physical therapist. By including physical therapists' guidance through the online activity manager and direct feedback, the patient will gain confidence that they are on the proper course for recovery. The physical therapist can monitor the progress of their patients to ensure joint function is improving and increase the patient's motivation and compliance to the prescribed therapy.

Methods

For this randomized treatment study, we will recruit 60 patients that have undergone total knee arthroplasty (TKA) that are being referred for post-operative outpatient physical therapy. After obtaining informed consent, and upon successful

screening/recruitment, subjects will be randomly assigned to one of two groups:

1. Control Group: Rehabilitation performed by a physical therapist and supplemented with a home exercise program for a maximum of ten weeks. Therapy will consist of two to three visits per week as prescribed by the physical therapist and based on the best interest of the patient. Patients will record their performance of the prescribed home exercise programs on a paper-based exercise log on a daily basis.
2. InterACTION Intervention Group: Rehabilitation performed by a physical therapist and supplemented by use of interACTION for a maximum of ten weeks. This will include two to three visits per week for two weeks in which the patient will use interACTION during routine outpatient physical therapy sessions to familiarize them with the system. After two weeks, the patient will be issued an interACTION device for home use that will guide them through their exercise program. At this point subjects in the interACTION group should continue to return to the outpatient rehabilitation facility, but reduce their weekly routine visit with their physical therapist by one during the next eight weeks of recovery, while concurrently using interACTION at home. Patients who attended two visits per week for the first two weeks should subsequently attend one visit per week. Patients who attended three visits per week for the first two weeks will subsequently attend one to two visits per week. However, if the physical therapist feels it to be in the best interest of the patient to deviate from the protocol, this is allowed.
   Note: InterACTION is currently under development, not a commercial application. The 3rd Party Developer was OpenArc, LLC (109 Vip Drive Suite 200, Wexford, PA 15090). The mobile application is currently supported on a Nexus tablet with Android operating system (specifically lollipop and kitkat versions). The mobile application and the kinematic sensors will be provided to the participant, the participants will NOT use a personal device.

Rehabilitation Compliance will be evaluated by the study team through the use of home exercise logs and interACTION reports. Logs will be reviewed at the follow-up visits with the research team. Outcome measures will be collected at baseline, 5 weeks (+/- 7 days) after enrollment, and upon discharge or a maximum of 10 weeks (+/- 7 days) after enrollment.

Outcomes

- Range of motion—Active and passive range of motion (ROM) will be measured with a standard goniometer while the patient lies in the supine position. Extension and flexion of each knee will be measured. Extension will be measured passively with a quad set and actively during a straight leg raise. The range of extension and flexion will be expressed as the difference between the involved and non-involved knees.
- Numeric Pain Rating Scale—Subjects will be asked to rate their level of pain currently and their level of worst & least pain in the past 24 hours on a scale from 0 (no pain) to 10 (worst pain imaginable).
- Activities of Daily Living Scale of the Knee Outcome Survey (ADLS)—The ADLS is a 14-item measure of symptoms and activity limitations for

individuals with a variety of knee impairments.

- Veterans RAND 12-Item Health Survey (VR-12)—The VR-12 is a 12-item patient-reported general measure of health-related quality of life that was adapted and developed from the RAND 36-Item Health Survey at the RAND Corporation and Medical Outcomes Study.
- Functional performance will also be tested in all patients. The following functional tests will be assessed at 5- and 10-week visits:
    - Six-minute Walk Test to assesses the subject's ability to walk community distances. The subject is asked to walk as far as possible in six minutes on a closed course with standing rest breaks as needed. The patient is free to use their preferred assistive device.
    - The Stair Climbing Test to test basic daily function in which a patient ascends and descends a standard flight of stairs as quickly and safely as possible, using their preferred gait pattern, assistive device, and hand rail.
    - The Timed Up and Go Test (TUG) in which the patient sits in a standard armed chair, rises, walks three meters, turns around, walks back to the chair and sits. Excessive time to complete the TUG can indicate mobility impairments and potential fall risks in elderly patients.
    - The Unilateral Balance Test in which the patient attempts to maintain single leg balance for up to two minutes, with the test ending when the patient loses balance enough to put the opposite foot on the ground.

Subjects will also undergo an interview to give a qualitative description of rehabilitation experience upon discharge from outpatient physical therapy or at the 10-week visit. This interview will entail an open-ended discussion with patients about their overall rehabilitation experiences, experiences with home exercises (either monitored or unmonitored), experiences with clinic-based workout sessions, and expenses incurred during the rehabilitation process.

Additionally, the physical therapists that are using the device with the study subjects will be interviewed to describe their experience with patient rehabilitation after surgery, and about their experience with the interACTION system.

The physical therapist will also be asked to complete the Clinician Survey, which will be administered by a research staff upon discharge of the patient, or a maximum of 10 weeks (+/- 7 days) after enrollment. All subjects participating in the study will be informed that their compliance will be evaluated by their physical therapist at this time of discharge, or a maximum of 10 weeks (+/- 7 days) after enrollment.

Statistical Analysis

For the baseline data, continuous variables were compared with the two-sample t-test and categorical variables were compared with Fisher’s exact test or a chi-square test.

For the primary outcome (value, ratio of ADLS to cost), the Wilcoxon rank sum test was used to compare between the Control Group and interACTION Group. P-Values below *p=0.05 were considered statistically significant for all outcomes. For the remainder of the cost analyses parameters (weeks of physical therapy, number of physical therapy visits, and total cost), a two-sample t-test was used to compare between groups.

For other clinical outcomes data, if the distribution was normal at each time point, then a repeated measures ANOVA was used. A repeated measures ANOVA was used to compare difference between groups for the ADLS, Passive ROM (flexion), and Active ROM (flexion). Otherwise, if some time points had normal data and others did not then a two-sample t-test was used for normally distributed data and the Wilcoxon rank sum test was used for non-normally distributed data.

For the functional performance tests that were assessed at the 5- and 10-week visits, a z-score (or standard score) was used to calculate a cumulative score for the Six-minute Walk Test (distance in feet), Stair Climb Test (time divided by steps), TUG (time), and Surgical Unilateral Balance (time). The z scores are the average of the z scores for each of the functional tasks. On average, the z scores are close to zero, meaning that the overall individuals within the group, the scores for each subject are not different than the mean score across all subjects. Differences between the cumulative z-scores were assessed using a two-sample t-test.

Recruitment Methods

Recruitment will be primarily done through UPP/CMI Orthopaedic Surgery clinics, which routinely care for patients that have undergone TKA. Patients will be identified through physicians who will be the primary medical provider in their perioperative care. Prior to the patient's first outpatient physical therapy visit, the study's research coordinator or research assistant will screen these patients, using the provided screening form, for inclusion/exclusion criteria and enroll/randomize those who meet the study's parameters. Subjects will not be recruited from skilled nursing facilities.

Recruitment flyers for the study will be made available at Orthopaedic Clinics and also at the Physical Therapist Outpatient Clinics. The flyer will be used to give potential patients information about the study and to enable them to contact us if they would like to participate. Potential patients may also be given flyers if they desire, so that they may have the contact information for the study in the event that the potential patient has any questions or concerns regarding the study.

Inclusion criteria

Males and females between 40 and 80 years of age that have undergone primary unilateral TKA who have been referred for post-operative outpatient physical therapy will be eligible to participate in this study. Additionally, eligible subjects also need to be able to perform pre-defined exercises that they would normally

perform in a physical rehabilitation program.

The Physical therapists that will be asked to complete the Clinician Survey must have a patient participating in the study to be considered eligible.

Exclusion Criteria

- Individuals outside the aforementioned age range (Adults <40 or >80 years of age)
- Patients with BMI >40 at the time of surgery (shown to predict poorer outcomes)
- Individuals who are not free of any co-disability or comorbidity that would specifically impede, disallow, or otherwise hinder performance of rehabilitation exercises
- Individuals who cannot physically receive or understand audio and visual feedback from the joint motion tracking system during or after performance of rehabilitation exercises.

This information will be acquired through the initial patient screening questionnaire given to potential participants during the recruitment period. These participants will be interviewed about their ability to use electronic data in the form of audiovisual feedback, about existing or pre-existing conditions that could negatively influence rehabilitation measures outlined in this study, and patients will be made aware that assistive devices can be used during the collection of all outcome measures.

The motion tracking sensors utilized in this study contain a wireless Bluetooth module that has been approved by the FCC and will not interfere with devices such as pacemakers, defibrillators, or other indwelling devices and therefore these patient's will not be specifically excluded.

Informed consent will be obtained after the screening procedures have been performed, but prior to performing any of the research interventions/interactions. The information obtained during screening is not of a sensitive nature and will only be used to determine if the subject is eligible for full participation in the study.

Participation in this study is completely voluntary. An investigator will go over the consent form with each participant who will then have the opportunity to ask questions and decide to participate. There is no possibility of coercion, as coercion to enroll in a research study would not depend on the research staff providing clinical care. Participation in this study does not influence current or future clinical care the participant may be undergoing.

Risks

Patients will perform a standard rehabilitation while wearing IMU motion-tracking sensors. A software application running on a tablet will wirelessly collect sensor data, display live motion data to guide patient performance of exercise tasks, and send performance data to servers for online review by the subject's physical

therapist. As these are standard rehabilitation exercises, there is no increased risk of pain or injury in performing these activities compared to the current standard method of performing the exercises. There is no risk of impaired rehabilitation due to decreased supervision. The use of IMU motion-tracking sensors poses no likely increased risk of physical or mental pain, or distress to the study subjects. There is no risk to the patients or others in their household of interference with in-dwelling electronic devices such as pacemakers or defibrillators.

Exercise data will be stored on both the tablet device and also transmitted during participant session. This data is de-identified, and the device is password protected using the device's native security. The data will be encrypted via SSL during transmission to the Microsoft Azure Cloud server, and also when accessing that server from Pitt's internal servers.

Data sharing was not identified or planned in this version, including contacts, texts, and geo-location information. As mentioned before, to prevent interception of exercise data, Exercise data will be stored on both the tablet device and transmitted during participant session. This data is de-identified, and the device is password protected using the device's native security. The data will be encrypted via SSL during transmission to the Microsoft Azure Cloud server, and when accessing that server from Pitt's internal servers.

The most likely infrequent risk to the subject may be discomfort from wearing the sensors as well as potential spillage of water/fluids on the device which could interfere with its functioning; however, there is no risk of electrical shock if the device gets wet. This device is designed to be comfortable to wear and is based on commonly used, commercially available body straps, and will come with usage precautions. Some subjects may also experience mild skin irritation from sweat build-up where the straps are worn. Patients will be able to communicate with their therapists in weekly visits or by phone regarding painful events or difficulties with exercise.

Participants will perform several different strength tests. Risks of injury will be minimized by allowing adequate time for warm-up, stretching, and familiarization with the task. Qualified individuals will administer the tests. Participants will be closely monitored by a member of the study staff. In the event that the participant needs first aid treatment, a certified athletic trainer, physical therapist, or orthopaedic surgeon will administer the appropriate care.

Participant confidentiality will be maintained at all times. All records will be assigned a case number. Information collected in this study will be stored in a locked file cabinet in a secure office and will be accessible only to the research staff. Electronic files will be stored on the UPMC and/or Pitt secure networks behind the firewall. Subjects will not be identified in any publications or presentation of the research results.

Potential Benefits

This study aims to increase knowledge related to use of the interACTION device to supplement post-operative rehabilitation after TKA. If the interACTION device leads to improved post-operative outcomes, patients in the future would benefit from use of the device to supplement their post-operative rehabilitation program. If beneficial, use of the interACTION device would result lead to the same or better outcomes with fewer in-clinic physical therapy visits, thus improving the value of care with lowered healthcare costs and expenditures.