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ABSTRACT

Background: Recent technologic advances capable of measuring outcomes after total knee arthroplasty (TKA) are critical in quantifying value-based care. Traditionally accomplished through office assessments and surveys with variable follow-up, this strategy lacks continuous and complete data. The primary objective of this study was to validate the feasibility of a remote patient monitoring (RPM) system in terms of the frequency of data interruptions and patient acceptance. Secondarily, we report pilot data for: (1) mobility; (2) knee range of motion (ROM), (3) patient-reported outcome measures (PROMs); (4) opioid use; and (5) HEP compliance.

Methods: A pilot cohort of 25 patients undergoing primary TKA for osteoarthritis was enrolled. Patients downloaded the RPM mobile application preoperatively to collect baseline activity and PROMs data, and the wearable knee sleeve was paired to the smartphone during admission. The following was collected up to 3 months postoperatively: mobility (step count), ROM, PROMs, opioid consumption, and HEP compliance. Validation was determined by acquisition of continuous data and patient tolerance at semi-structured interviews 3 months post-operatively.

Results: Of the 25 enrolled patients, 100% had uninterrupted passive data collection. Of the 22 available for follow-up interviews, all found the system motivating and engaging. Mean mobility returned to baseline within 6 weeks and exceeded preoperative baseline by 30% at 3 months. Mean knee flexion achieved was 119°, which did not differ from clinic measurements ($p=0.31$). Mean KOOS improvement was 39.3 after 3 months (range:3-60). Opioid use typically stopped by post-operative day 5. HEP compliance was 62% (range:0-99%).

Conclusions: In this pilot study, we established the ability to remotely acquire continuous data for TKA patients, who found the application to be engaging. RPM offers the newfound ability to more completely evaluate the TKA patient in terms of mobility and rehabilitation compliance. Study with more patients is required to establish clinical significance.

Key words: remote patient monitoring, wearable technology, machine learning, total knee arthroplasty (TKA), mHealth, telemedicine

Introduction

Critical barriers in defining the value of elective orthopaedic surgery, specifically total knee arthroplasty (TKA), include reliable outcome capture and patient compliance. Outcome measurement after TKA, however, has traditionally been accomplished with periodic in-office assessments, validated surveys, or both, without continuous data. Both of these methods have inherent limitations related to subjectivity, objectivity, cost-effectiveness, and time. Recent technologic advances, namely smartphones, wearable sensors, and machine learning processes, have grown commonplace and engendered the field of mobile health, or mHealth, which may mitigate these post-operative patient monitoring issues following TKA [1]. A remote patient monitoring (RPM) platform that uses wearable technology may be employed to holistically capture the status of a patients after TKA to provide both continuous subjective and objective data. Such a system that leverages commercially available technologies, such as the smartphone, offers the ability to provide additional insight into the patient's recovery including home exercise plan compliance with physical therapy and overall mobility. Moreover, the opportunity to communicate value and manage expectations with the creation of post-operative milestones is now possible. The omnipresent sensors present on consumer mobile devices, such as the iPhone (Apple, Cupertino, California) or Android (Google, Mountain View, California), passively capture knee data amenable to interpretation by a machine learning algorithm that can display real-time feedback for the post-TKA joint.

Although several studies have demonstrated promise in the utilization of wearable technology in TKA rehabilitation, previously employed platforms are limited by the lack of interconnectivity between applications, poor user engagement, high cost of sensors and deployment, and inability to scale [2–4]. In order to address these barriers, a machine learning-based RPM system using an open source software development kit (SDK) designed for commercially available smartphones was designed (Focus Ventures, Santa Monica, California). In recent years, there has been growth in the usage of SDKs to design open source technology that may be incrementally updated and readily shared with software developers, thereby obviating the concerns of prior attempts to integrate mHealth into clinical practice [5,6]. SDKs have advanced to include machine learning capacity, allowing the software to automate processes through pattern recognition and principles of artificial intelligence, probability theory, statistical physics, data mining, and pattern recognition from empirical data [7,8]. The advances in the sensors of modern smartphones and wearables have permitted the development of this RPM system to gather user data passively from the accelerometer, gyroscope, and magnetometer to filter and process complex data, "learn" a given motor task after minimal repetitions, assess compliance for both repetitions and form, and then report feedback with real-time analysis [9,10]. The validation of an SDK that can learn complex spatial movements to assess for compliance with TKA therapy exercise, when coupled with PROMs and other functional data, may portend favorable adoption of mHealth by reducing the amount of time patients spend accessing care while simultaneously reducing systemic costs and improving physician efficiency for high value healthcare delivery [11–13].

To date, no open source, scalable SDK capable of learning and analyzing complex spatial movements has been developed or validated in the clinical setting of an RPM system that integrates with commercially available smartphones for the surveillance of patients following lower extremity arthroplasty, namely TKA. The RPM system studied presents the newfound opportunity to holistically capture the patient's recovery in the form of continuous data, objective mobility and joint-specific metrics, pain management data, and home exercise program (HEP) compliance. While the promise of such a system is great during a time whereby cost containment and patient experience are invaluable in the new value-based era of orthopaedics, validation is prerequisite to determine feasibility prior to scalability. Validation for this RPM system was defined by the presence of an uninterrupted stream of continuous daily patient data, as well as patient acceptance of the technology via semi-structured interviews. As such, the primary objective of this study was to validate the feasibility in terms of the frequency of data interruptions and patient acceptance. Secondarily, we report the pilot data in terms of: (1) mobility; (2) knee range of motion (ROM), (3) patient-reported outcome measures (PROMs); (4) opioid use; and (5) HEP compliance. We hypothesized the older subpopulation of patients would have technical challenges and require oversight, causing data loss. Overall, we expected patients to engage with their recovery data and HEP compliance to be consistent with the previously reported rate of 30% [14].

Materials & Methods

A cohort of 25 patients undergoing primary TKA for osteoarthritis at our hospital were enrolled into the study under IRB approval and registration on ClinicalTrials.gov and RedCap data compliance standards. Funding was acquired in the form of grant support from the Orthopaedic Research and Education Foundation.

Patient Cohort

Patient inclusion criteria were as follows: (1) patients undergoing primary TKA for osteoarthritis, (2) patients who have an iOS smartphone and carry it with them daily, (3) patients who reside in a home and not a facility or rehabilitation center, (4) patients under the age of 80 years, (5) patients who preoperatively are not dependent on assist devices for more than a year due to the injury beyond the affected knee or other functional reasons, (6) patients discharged to home. Exclusion criteria as follows: (1) patients with inflammatory or post-traumatic arthritis, (2) patients receiving active or maintenance treatment for cancer or solid organ and/or marrow transplant, (3) patients with any other medical issues limiting mobility and function, including cardiopulmonary, gastrointestinal, and hematologic comorbidities, (4) patients with a history of periprosthetic joint infection of any joint, (5) patients who have a history of native septic arthritis in the operative joint, (6) patients who are functionally immobilized or residing anywhere other than a home (nursing facility, rehabilitation centers), (7) patients who preoperatively use an assist device for more than a year (i.e. cane, walker) for joints other than the knee undergoing TKA during the study, (8) patients over the age of 80 years, (9) patients discharged anywhere besides home from the hospital (i.e. skilled nursing facilities or acute rehabilitation centers). Patients on long-term anticoagulation were not excluded.

Procedure

Patients downloaded the (Focus Ventures, Santa Monica, California) mobile application ("app"), termed "TKR," onto their personal iPhones (Apple, Cupertino, California) to record preoperative mobility (daily steps) and PROMs (KOOS JR, KOOS-QOL Domain, VAS Pain) two to four weeks prior to surgery. During the hospital admission, the knee sleeve was paired with the patient's iPhone via Bluetooth. Postoperatively, the patient was instructed to perform daily exercises and a weekly survey, which the TKR app notified the patient to complete. Between the knee sleeve and the smartphone, the following five data points were acquired: mobility (daily step count; passive), weekly ROM check (knee flexion; active), weekly PROMs (KOOS Jr, KOOS-QOL Domain, VAS Pain; active), opioid consumption (number of tablets in past week; active), and home exercise plan (HEP) compliance (minimum daily requirement of at least 10 repetitions from a single set of exercises; active). A schematic of data transmission from sleeve and smartphone to the dashboard and on to the machine learning algorithm is depicted in **Figure 1.** The TKR app was patient-facing and provided patients with full access to their data as well as an avatar depicting their knee ROM in real time while performing each repetition from any of the four available sets of exercises in **Figure 2**.

Mobility data was continuously and passively recorded by the smartphone through the smartphone's native sensors (accelerometer, gyroscope, magnetometer). From a technical standpoint, the sleeve used was a simple neoprene sleeve (**Figure 3**) with two Bluetooth sensors that transmitted spatial orientation changes in three dimensions to the smartphone, which processed the data using the machine learning algorithm software and recorded the ROM, as previously validated for accurate measurement in the shoulder [15]. The knee sleeve was worn part-time only when performing home exercise program exercises independent of therapist supervision. In other words, the function of the sleeve was to actively record the weekly joint-specific data: ROM check and daily compliance check. The smartphone functioned to pair with the sleeve, provide automated reminder notifications, and serve to passively and actively collect data. The smartphone passively recorded mobility via step count and actively collected weekly PROMs surveys, including opioid consumption. Prior to study initiation, we recorded the difference in knee flexion between the app and a goniometer measurement by a single clinician across 10 different knees for 5 arbitrary angles each (range: 5º-135º), which revealed a mean difference of 7.2º found to be statistically equivocal (p=0.41).

Validation

Validation was defined by the presence of an uninterrupted stream of continuous daily patient data and patient acceptance of the technology via semi-structured interviews. If a day passed without a single data point transmitted, this was considered a disruption in the RPM system. Semi-structured interview questions at 3 months postoperatively can be found in **Table 1.**

Continuous RPM Data Collection

Data collected from the 25 enrolled patients were as follows: (1) mobility; (2) knee ROM, (3) patient-reported outcome measures (PROMs); (4) opioid use; and (5) HEP compliance. Mobility was measured passively and as daily steps, as determined by the internal proprietary iOS algorithm combining input from location services (i.e. GPS tracking), accelerometer, gyroscope, and magnetometer on all iPhones. Knee ROM was measured actively and prompted of all patients to perform over the weekend to determine max flexion with the heel slide. The surgeon received a notification if the patient did not reach 90 degrees of flexion at 2 weeks. Similarly, PROMs and number of opioid tablets used in the past 7 days were measured actively and prompted over the weekend. The surgical and postoperative pain protocol entailed a preoperative assessment for patients at risk for opioid dependence, intraoperative spinal and local anesthesia, and a seven-day course of postoperative opioid tablets. HEP compliance was measured actively, and patients received daily reminders from the first postoperative day to the 90th to perform exercises. The percentage of days out of 90 whereby patients performed at least one set of 10 repetitions was reported. Short demo videos reminding patients on how each exercise is performed was available prior to initiating exercise.

Privacy

All data was deidentified and stored on a HIPAA-compliant server on the cloud (Amazon Web Services, Seattle, Washington). The patient cohort was followed for three months post-operatively with all aforementioned five data points stored on a dashboard visible to only the patient and surgeon, using password-protected login credentials.

Participants were assigned a random patient identification (ID) number that was then be used for all documentation and further study analysis. The data collected from the app was associated with each participant from the user ID entered in the app. The only data transmitted to the SDK software was the ID number and the associated ROM, HEP compliance, steps, and PROMs data. The investigators recorded the data in REDCap with the associated ID number, and the key corresponding patient information to the ID number was stored in a binder in a locked IRB office at the authors' institution. No participant personal health information data was logged at any point on the app or the smartphone.

Statistical analysis

A t-test was used to assess agreement between clinician-derived ROM versus wearable-derived ROM at 3 months. Descriptive analysis was employed to summarize the results from the semi-structured interviews. A priori power analysis indicated a 94% chance of detecting a large effect size and a 60% chance of detecting a medium effect size at the 5% confidence level with a cohort of 25 patients. All data analysis was performed using Microsoft Excel analytics software version 14.5.4 (Microsoft Corporation; Redmond, WA). A p-value cutoff of <0.05 was used to determine statistical significance.

Results

A total of 25 patients were prospectively enrolled and followed from two to four weeks preoperatively to 12 weeks post-operatively. Of the 25 enrolled, mean age was 64.3, 56% female, and the mean BMI was 33.3. Since downloading the TKR app, no data disruptions requiring technical intervention occurred for a single patient in this 14-week period. The outcome metric with zero loss was the passively collected daily step count, the surrogate for mobility.

A total of 22 patients were available for semi-structured interviews at three months follow-up (88%). Three patients were unavailable for three-month follow-up, each citing complicating factors including a family emergency, chronic pain, and psychiatric conditions. On a scale of 1-10 in order of increasing difficulty, patients rated the RPM system 2.6. All patients found the RPM system “motivating” or “engaging.” Patients cited the following reasons for engagement with the system: facile user experience of the app, real-time feedback with the avatar and dashboard, daily notifications. All patients reported they would recommend the RPM system to other patients recovering from TKA. The most common commentary that emerged from 8 of the 22 patients (36%) was related to the sleeve’s low battery life, which required charging once every three days. A total of 11 of the 22 patients (50%) specifically requested more exercises to advance their regiment.

On average, mean mobility returned to baseline within 6 weeks and exceeded preoperative baseline by 30% at 3 months (mean: 4,654 steps per day, range: 1,154-12,108 steps per day). Mean knee flexion achieved was 119°, which did not differ from 12 week clinic measurements ($p=0.31$). Mean KOOS improvement was 39.3 points after 3 months (range: 3-60). Opioid use typically stopped by post-operative day 5. One patient had a spike in pain at five weeks upon returning to work, which led the team to make contact with the patient via phone and schedule an earlier follow-up appointment. Daily HEP compliance was 62% (range: 0-99%). **Figure 4** and **Figure 5** depict two example patients from the pilot with data graphically depicted.

Of the patients who did not follow up for semi-structured interviews at 12 weeks, all three did not achieve 90° of flexion by 2 weeks, and their mean HEP compliance was 13.3% and KOOS increase of 15.

Discussion

This pilot study represents the introduction of a scalable RPM platform in lower extremity arthroplasty that leverages several commercially available technologic advances and techniques, from the smartphone to machine learning algorithms to wearable sleeves to open source SDKs. While commercial availability without additional hardware beyond a disposable sleeve suggests cost effectiveness, the primary objective of this study was to first determine if validation of an RPM system predicated on continuous data would be feasible and acceptable to patients in the routine clinical pathway following TKA. Not only was the system low maintenance, it also provided a continuous stream of previously immeasurable data without any loss, portraying a more accurate picture of the patient's recovery following TKA. A total of 88% of patients were available for semi-structured interviews, and all recommended the platform to others and found it to be "engaging," "motivating," and easy to use. Data from 22 patients were available including mobility, weekly ROM checks, PROMs (KOOS and VAS scales), opioid use, and HEP compliance. While not enough patients were available to provide reliable benchmarking thresholds, this pilot data establishes the precedent for future studies to more completely capture recovery after TKA. Our hypothesis of patients engaging with their data in the mobile application was upheld. However, our other hypotheses were disproven as there was no data loss from technical issues and the HEP compliance of 62% was nearly double that of the previously reported rate of 30% [14].

The current paradigm of capturing patient data relies on administrators, postal mail, or faxed questionnaires, which represent inefficient and costly processes that merely portray a small portion of a patient's recovery. However, the emphasis on delivering "high value" care relies on objective, accurate, and specific data up to 90 days postoperatively under the Bundled Payments for Care Improvement (BPCI) initiative [16]. Presently, 90% of post-operative recovery occurs out of sight from care teams documenting progress [20]. This RPM system combines several recent technologic advances to demonstrate functionality in aggregating individualized “small data” on a daily basis for the post-TKA patient. As more patients are enrolled, population-level commonalities and differences may be analyzed for contributing factors (i.e. socioeconomic status, gender, age, and comorbidities) to guide expectation management, shared decision-making, optimization of any modifiable risk factors, and future policy. The growing ubiquity of smartphones with nearly 77% of Americans owning a smartphone unlocks the potential of mHealth and wearable sensors that can be analyzed by a machine learning algorithm [17]. With the introduction and validation of this cost-effective and readily usable technology, the practice and study of orthopaedics may be fundamentally changed in several dimensions. Visualization of personal health data in terms of mobility (steps per day), range of motion (maximum knee flexion), HEP compliance, and PROMs serves not to just provide previously elusive holistic data for expectation management and patient-specific counseling but also may increase engagement [18]. To surgeons, administrators, and policy makers, this technology provides the objective parametric data needed to communicate the business model of lower extremity arthroplasty. Specifically, knowledge of the preoperative state in terms of function, pain, and limitations in activities of daily living may be postoperatively compared to determine the “value” of the TKA [19]. On the other hand, this technology offers surgeons the opportunity to identify potential causes of unfavorable outcomes by capturing therapy noncompliance despite a thorough discussion of expectation management and a well-executed surgical plan.

The results of this study and RPM system offered two potentially important insights: patient engagement and newfound outcome metrics in mobility and HEP compliance.

Several factors contributed to patient engagement: (1) user-friendly TKR app interface; (2) an avatar providing real-time motion feedback of the joint during exercise; (3) a chart demonstrating daily progression; and (4) direct notifications encouraging exercise and self-assessment. In addition to the feedback from patients reporting ease of use (2.6 of 10), the finding that half of the interviewed patients requested more advanced exercises and the high HEP compliance rate of 62% suggests motivation, although a randomized control trial would be necessary to fully assess this effect. The availability of mobility data in the form of daily steps for patients who travel with their smartphones is a sufficient surrogate to paint a data-driven portrait of a patient's health after TKA. Knowledge that compliance is being monitored may induce an unintentional, albeit beneficial, Hawthorne effect whereby patients are more likely to comply with exercises. With the rise of telemedicine visits, this RPM system requires no additional effort from the surgeon seeking to better evaluate the TKA patient's recovery across a spectrum of subjective, objective, joint-specific, mobility-based, and pain-related parameters. With the recent creation of RPM codes (i.e. Current Procedural Terminology codes 99453, 99454, 99457) by CMS reimbursable for Medicare patients, margins up approximating $350 per patient outside of the bundle for early adopters are advertised, offering the fiscal incentive for both surgeons and hospitals to purchase such RPM systems to improve reimbursement beyond patient engagement and data collection. With platforms that require no additional hardware outside of a patient's personal smart device and a disposable sleeve approaching less than $20 per sleeve at economies of scale, there exists the potential for economic arbitration resulting in synergistically vested parties across patients, surgeons, hospitals, and payers.

Despite the promise of this data, this study has limitations. First and foremost, the data represents a small cohort with no broadly generalizable conclusions. Multivariate analysis was impossible to derive patient-specific insights due to the small sample size. Compliance of the system is potentially underestimated, as patients may not have performed exercises using the system if they exercised with a physical therapist. The major innovation of this RPM system extends beyond the passive, disjointed capture of outcomes to transform any smartphone into an instrument for reliable, continuous data capture. However, the 23% of Americans who do not presently own a smartphone unable to use this platform are at risk for selection bias, potentially worsening access disparities [17]. Additionally, opioid use was collected on a weekly basis, and thus was potentially subject to recall bias by patients. It is important to consider that our threshold for defining daily compliance was low, as performance of only one of four available exercises with 10 repetitions may not be enough to constitute significant rehabilitation. However, despite these limitations, this pilot study represents an initial validation of this machine-learning based wearable technology.

The emergence of wearable and smartphone technologies serendipitously arrives at a time in which the field of orthopaedic surgery is focused on cost savings, increased efficiency, and the reexamination of how we assess patient outcomes. With alternative pay models, namely the BPCI Initiative in lower extremity arthroplasty, reducing cost and physician resources required to quickly identify the patient who is thriving after surgery versus those who are not remains a potential application. Thus, RPM technology powered by mHealth, machine learning, and an open source SDK may offer the long-awaited breakthrough in telemedicine that harmonizes with value-based medicine. Moreover, the potential to skip routine surveillance in well patients provides the opportunity to decompress the busy surgeon’s clinic and save the patient's time, as seen in **Figure 6**. In summary, the RPM system was found to be a reliable, low maintenance, and well-received platform for the patient recovering from TKA. Preliminary data indicates a new frontier in lower extremity arthroplasty whereby RPM may be a feasible option to engage patients, quantifiably communicate procedural value, efficiently survey patients postoperatively, and build a novel registry of movement data for further study. Though promising, more studies are required to evaluate the clinical significance of the intervention and harness its full potential to effect change on the levels of population health, policy, and true medical transformation.

Tables

Table 1. List of semi-structured interview questions asked 12 weeks after TKA

Semi-Structured Interview Questions
How easy did you find the technology to use on a scale of 1-10? (1 easiest, 10 most difficult)
Did you feel the technology's feedback motivated you in your recovery from TKA? (Yes or No)
Would you recommend the technology to others recovering from TKA? (Yes or no)
Do you have any suggestions or areas of improvement?

FIGURE LEGENDS

Figure 1. A schematic of the RPM system depicting the wearable knee sleeve transmitting motion data to the smartphone, which then transmits this and all other data (steps, PROMs, opioid use) to the dashboard, which then is analyzed by the machine-learning algorithm and instantaneously transmitted back to the patient while being stored on the care team dashboard.

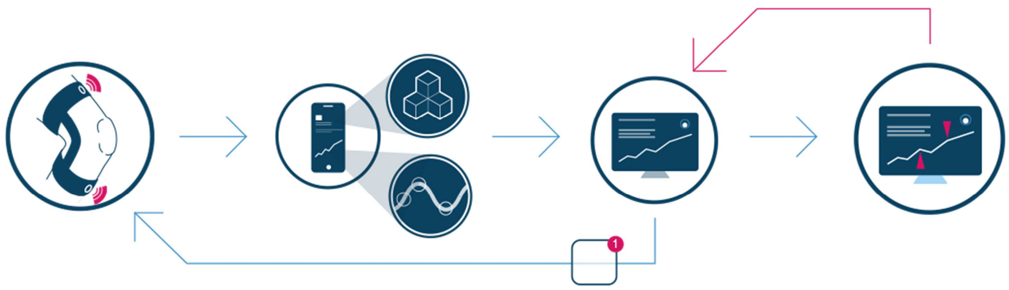


Figure 2. Schematic of four available exercises available post-TKA to enrolled patients: straight leg raise (top left), heel slide (top right), standing hamstring curls (bottom left), long arc quads (bottom right).

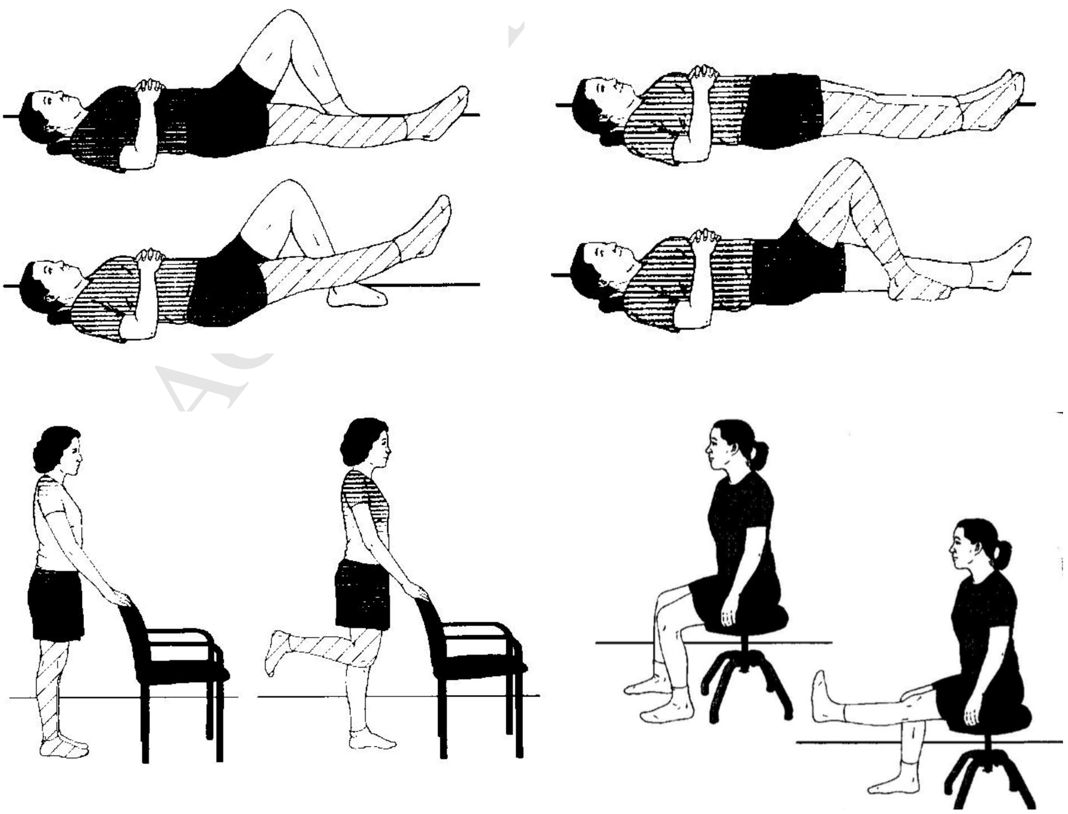


Figure 3. Photograph of the simple knee sleeve with Velcro straps and Bluetooth-enabled sensors that transmit positional data directly to the smartphone for machine-learning analysis and real-time display of ROM.

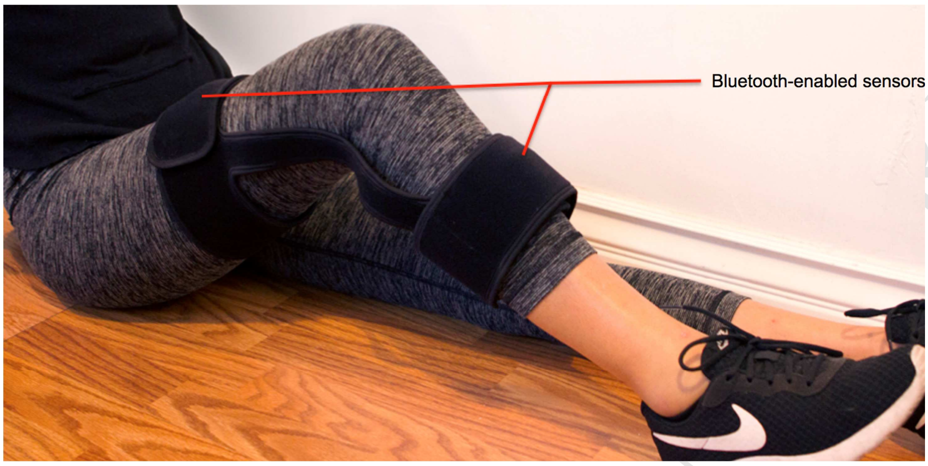


Figure 4. Example dashboard of a patient who was moderately compliant (34%) and achieved maximum satisfaction at 10 weeks, baseline mobility at 6 weeks, and no pain by 6 weeks.

Figure 5. Example dashboard of a patient who was highly compliant with HEP (88%), sustained a spike in pain five weeks into her recovery that correlated with an additional clinic visit, and still reached maximum satisfaction at 12 weeks with return to mobility baseline at 6 weeks.

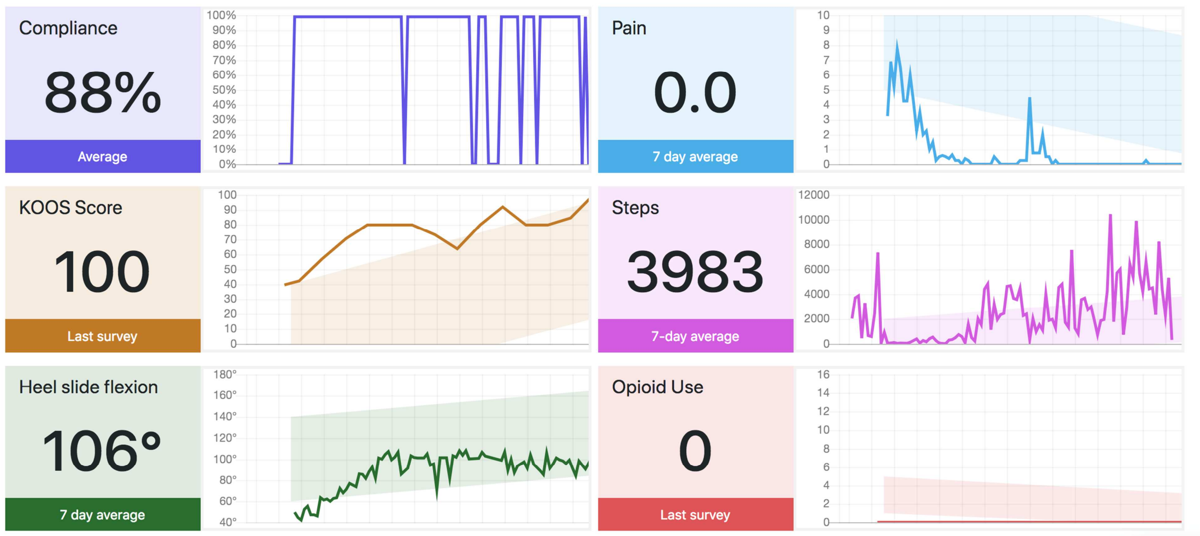
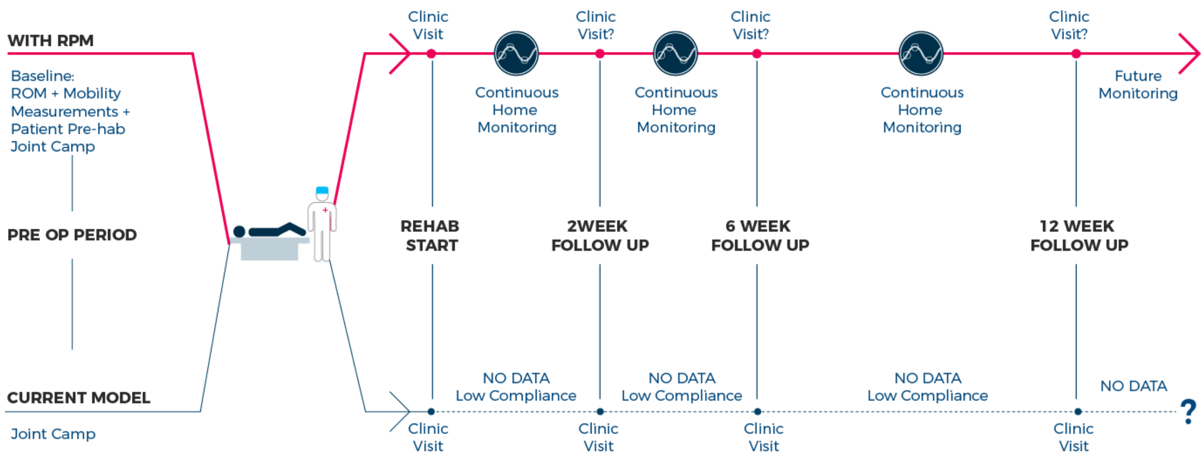


Figure 6. Schematic representing potential paradigm shift in post-operative monitoring of TKA with the RPM system.



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