Study Protocol

Feasibility of Home Monitoring after Primary Total Knee Arthroplasty

Principal Investigator: Carlos Higuera, MD

Email: higuerc@ccf.org

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Background

Over one million primary total hip and total knee arthroplasties (TKAs) are being performed annually in the United States, and it is projected that 1.26 million TKAs will be performed by the year 2030.[1] Simultaneously, there is a projected shortage of trained orthopaedic surgeons to care for these patients.[2] Telemedicine and innovative home-based technologies to monitor patient outcomes after surgery have gained increasing attention.[3] This was possible due to the recent technological advances in telecommunication, allowing the development of commercially-available, easily-accessible, and low-cost home monitoring and virtual rehabilitation systems to allow clinicians to monitor the patient's adherence to post-operative rehabilitation and treatment protocols, particularly for relatively low-risk patients in which a normal recovery is expected.

Recently, emerging evidence has shown that home monitoring systems may have comparable efficacy to conventional follow-up clinic visits in monitoring patient progress postoperatively.[4–7] Studies have also shown this technology may aid in lowering the cost of healthcare delivery to these patients while they are being monitored in real-time.[8,9] In addition, it has been shown that postoperative interventions cost between 37% to 40% of the total episode payment for primary total joint arthroplasty.[10] Therefore, with the recent paradigm shift from "volume-based" to "value-based" healthcare, the use of modern technology allowing optimal patient outcomes while decreasing cost becomes extremely relevant.[11]

Objectives

In this pilot study, the objective was to assess a novel technology for postoperative home-based monitoring and communication for patients who underwent primary TKA. We specifically evaluated 1) the accuracy of patient mobility and knee range of motion (ROM) measurements obtained using home-based monitoring, and 2) the ability of the technology to monitor physical therapy compliance and collect patient-reported outcomes.

Eligibility

Data will be prospectively collected from a total of 10 patients over the age of 18 years who are scheduled for elective primary TKA. All enrolled patients must meet the following eligibility criteria.

Inclusion Criteria:

1. Scheduled for unilateral primary TKA
2. Reside within 75 miles (driving distance) from the hospital
3. Expected to be discharged home with hospital home care
4. Have wireless internet connectivity in their home

Exclusion Criteria:

1. Scheduled for revision or simultaneous bilateral TKA
2. English is not considered their preferred language for healthcare discussions
3. Body mass index (BMI) greater than 45 kg/m^2
4. Enrolled in another research study

Methods

The monitoring technology that will be used in this study was developed by Vivanta Care (Chagrin Falls, Ohio, USA). The system consists of two sensors, each attached to an adjustable strap. One sensor is to be worn 4-6 cm above the knee and the other sensor is to be worn 4-6 cm below the knee and are used together to capture knee ROM. Patients will be instructed to wear these sensors during seated flexion and extension home exercises that are prescribed by the physician (up to 3 times per day) as part of their home therapy routine. Additionally, an activity sensor that tracks the number of steps taken is included for patients to wear on their wrists. Information collected with all three sensors will be transmitted securely between the patient and health providers through an application on a tablet computer that is supplied to each patient preoperatively once he/she consents to participate in the study. This application is also utilized as a timer for the timed up and go (TUG) test, to collect patient reported outcomes, and to guide the patient through the prescribed home therapy exercises. Patients are provided with instructions to connect to the existing wireless internet at home prior to the date of surgery to confirm the connection. Proper installation is verified automatically by the tablet computer cloud server and all communication pathways (sensor ↔ tablet computer ↔ internet ↔ health provider) are verified automatically.

Data Collection:

All patient-reported and functional measurements will be collected electronically via the in-home monitoring system at the intervals specified in the table below and manually by a clinician preoperatively, during one homecare visit per week, and at the 4, 8, and 12 week clinical follow-up visits. The Knee injury and Osteoarthritis Outcome Score (KOOS) consists of 5 subscales (Pain, other Symptoms, Function in daily living, Function in sport and recreation, and knee related Quality of life (QOL)). However, we will only assess KOOS Pain, Function (using the KOOS – Physical Function Shortform) and QOL for this study. Each section is scored independently from the others on a 0-to-100 transformed scale, where zero represents extreme knee problems and 100 represents no knee problems. Functional measures such as the maximum attainable ROM and the number of steps taken will be tracked using sensors worn by the patient. The ROM sensor values will be verified with range of motion measurements taken using a goniometer during therapy and MD visits. Patients will be asked to return all equipment at the time of their 12 week clinic visit.

		Frequency	
Outcome Type	**Scale**	**Electronically Monitored**	**Collected at Follow-up Visit**
Patient-Reported	KOOS Pain	qwk	q4wk
	KOOS Function	qwk	q4wk
	KRQoL	qwk	q4wk
	VAS Pain	tid	q4wk
Function Measure	ROM	tid	q4wk
	TUG	tid	q4wk
	Rehabilitation Compliance	qd	q4wk

qwk = every week; q4wk = every 4 weeks; tid = three times a day; qd = every day; KOOS = Knee injury and Osteoarthritis Outcome Score; KRQoL = knee related quality of life; VAS = visual analog scale; ROM= range of motion; TUG = timed up and go.

Statistical Analysis

A sample of 10 patients will be used as a proof of concept and can be used to refine future sample size calculations. Statistical analysis will be primarily descriptive. The Wilcoxon signed-rank test will be used to evaluate the agreements between the home-monitoring and clinician-based measurements to yield a concordance correlation coefficient the represents a measure of reliability of the method.

References

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