TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™

Orthopaedic Surgery Research
Phone: (806) 743-2569 ● 4A144B
Email address: Nancy.swinford@ttuhsc.edu

PROTOCOL 3.5 2/8/2017

Study Title: Comparative Effectiveness of an Activity-Specific Monitoring Device (StepRite) on Short Term Outcomes in Adults after Total Knee Arthroplasty			
Principal Investigator	**Department**	**School/Campus**	**Email Address**
George W. Brindley, MD	Orthopaedic Surgery	SOM Lubbock	George.brindley@ttuhsc.edu
Sub Investigator's			
Matthew Blue, MD	Orthopaedic Surgery	SOM Lubbock	Matthew.blue@ttuhsc.edu
Matthew Ferguson, MD	Orthopaedic Surgery	SOM Lubbock	Matthew.ferguson@ttuhsc.edu
Jordan Simpson, MD	Orthopaedic Surgery	SOM Lubbock	Jordan.b.simpson@ttuhsc.edu
Robert Andy Davies PT DTP	UMC Physical Therapy	Lubbock	Robert.davies@umchealthsystem.com
Brenton Albracht, MD	Orthopaedic Surgery	SOM Lubbock	brenton.albracht@ttuhsc.edu
Nancy Swinford, CCRC	Orthopaedic Surgery	SOM Lubbock	Nancy.swinford@ttuhsc.edu

Abstract:

Partial Knee Arthroplasty (PKA) or Total Knee Arthroplasty (TKA) is a procedure commonly used in severe degeneration of the knee joint due to osteoarthritis. With an increasing number of PKA's and TKA's performed in a population that is aging during a time where the amount of healthcare dollars allotted to rehabilitation is declining, there is a need to develop remote monitoring of rehabilitation and to engage and optimize self-management of recovery.

Current management of PKA and TKA recovery is typically performed in the out-patient setting and is highly protocol driven. A typical case might be seen by the physical therapist 2-3x/week for 8-10 weeks to perform specific exercises and to monitor progress (i.e. compliance with ROM and strengthening exercises). One recent study suggested that variation in patients' independent exercise and activity after arthroplasty surgery may contribute to variable functional gains [1].

We are proposing that the StepRite device developed by MedHab, (a shoe insert that collects functional data) will reduce cost and improve the efficacy of rehabilitation in total knee arthroplasty patients.

Background

Tele-rehabilitation is an emerging method of delivering healthcare. It is likely to become more prevalent as technology improves and funding for clinic appointments diminishes. Recent studies have shown that tele-rehabilitation can be as effective as conventional treatment, as is well tolerated by both patients and healthcare professionals [2, 3].

The StepRite system developed by MedHab (http://www.medhab.com/) allows the physical therapist to monitor physical activity and exercise remotely, thereby reducing the need for frequent out-patient visits. A thin insole placed inside the shoe measures foot contact pressure and acceleration. This information is translated into quantitative feedback about exercise compliance and performance measures comparing the surgical side with the non-surgical side. Real time feedback during exercise and weight-bearing activities is

provided to the patient, and a HIPAA secured user interface website also displays this information in an online dashboard for both physical therapists and the physician.
With the advent of federally mandated bundled payments for total joint replacement, active management of the rehabilitative process postoperatively with quantifiable data will be necessary to ensure financial stability.
Given the potential for improving patient engagement with rehabilitation, this study proposes a treatment model which includes monitoring activity outside of the clinic using the StepRite device and using a combination of outpatient appointments and remote consultations with therapists.

Significance of this study

The significance of the proposed study includes the projected benefit to the patients in terms of attaining clinical outcomes quicker and to the medical system in terms of managing cost for the provision of services. Subjects are expected to demonstrate improved compliance to patient tailored rehabilitation protocols which will lead to more rapid attainment of clinical outcomes versus present traditional rehabilitation methodologies. The expected level of, and rate of, attainment of clinical outcomes will translate to an overall reduction of cost to the medical system by reducing the need to engage in additional processes or the need to protract the time required to attain clinical outcomes, where either or both in combination can increase rehabilitation expenditures.

Objectives

To compare the efficacy of StepRite in a prescribed physical therapy program verses traditional in-facility physical therapy program after partial or primary total knee replacement using validated survey tools to evaluate patient progress, including patient self –reporting of progress and surgeon appraisal of patient performance post-operatively.

To compare the overall cost of post-operative rehabilitation of patients involved in traditionally employed regimens versus those using the StepRite device.

Hypothesis and specific aims

The aim of this study is to evaluate whether improved clinical outcomes as well as reduction in cost in provision of care can be better affected through the use of the Steprite device as compared to the use of traditional rehabilitation modalities.

We will seek to reject the null hypotheses that 1) there is no difference between clinical outcomes attained between patients using the Steprite device and those using traditional rehabilitation modalities and that 2) there is no reduction in cost to the medical system when patients use Steprite versus other conventional methods of rehabilitation.
By rejecting the null hypothesis we will accept the alternate hypothesis that, through the use of the Steprite device, not only will patients achieve overall clinical outcomes faster but there will be an associated decrease in cost burden to the medical system and the differences observed will be statistically significant as compared to rehabilitation of patients not using the Steprite device.

Patients who use the device post-surgery will demonstrate superior short-term improvements (i.e. 3 months post-surgery) with respect to self-reported functional outcomes and gait parameters, compared to a control group not using the device. The patients will self-report through the use of validated survey instruments including the KOOS survey (knee injury and osteoarthritis outcome score), LEFS (lower extremity functional scale) and/or KSS (knee society score), the latter of which includes a section for surgeon evaluation of patient functionality post operatively.

Study Design and Methods

This is a point of care clinical trial; a trial that functions to integrate research within a clinical setting that has the ability to readily deliver either modality of the proposal. This type of study design relies on provider referral of patients to be approached for consent, after which randomization to one of two treatment groups is facilitated; a control group of 15 patients participating in conventional rehabilitation regimens and an experimental group of 15 patients who will participate in the same rehabilitation regimen but facilitated

through the use of Steprite. Importantly, care for patients is delivered as part of current adopted standards utilizing outcome measurements, the use of which and the interpretation of which is already built into care provided by the clinical facility, thereby negating the need to develop additional outcome measures. Recruitment of 30 patients will come from the investigators' normal patient population, among patients who are scheduled for partial or total knee arthroplasty. As there is no change in post op care for these patients from the investigators standard protocols other than monitoring and enforcement of home protocols, the same therapists involved in investigators' normal patient care will be involved with both arms of the study.

For this study, 30 patients represents a sample size deemed acceptable as a starting point. There are no other published studies using Steprite in comparative design trials. Determinations of sample size needed for this study, using 80% power and significance of 0.05, incorporate the use of a time frame in days or weeks for completion of the rehabilitation protocols that would allow for the detection of clinically significant differences between the group using Steprite and those using conventional therapies only. Given that conventional therapies can include skilled nursing, home health and outpatient visits and given that the need for each of these is highly variable dependent on the patient, it is difficult to assign a time value for determinations of sample size.
With that, a sample size of 30 participants divided into two groups represents an initial starting point, with the potential of incremental addition of more patients in order to achieve significance between the two study groups.
Statistical significance will be evaluated utilizing a standard t-test for two group comparison.

In preparation for the study, MedHab Inc. will at their expense train all involved investigators and therapists in the fitting and use of the StepRite device. Medhab will also train a lead therapist designated by the lead investigator to be in charge of overseeing and monitoring, ensuring proper use of the device. There is no cost to the patient, hospital or other funding entity for participation in this study. Medhab LLC will assume all costs associated with the training, application, device and use of the StepRite product for the full course of this study.

Subjects for this study will be recruited from the patient population seen by the investigators during the normal course of business. There will be no outside recruitment of individuals or advertising as to the presence or use of the monitoring device to entice new patient referral. Prospective candidates will be asked by the lead investigator at the time they are designated surgical candidates. All documentation related to the study will be reviewed with the patient by the lead physician or his designee who is appropriately trained in discussing patient recruitment. Final decision and randomization to control or StepRite use will be done as part of the preoperative checkup just prior to surgery where both operative consent and study consent are discussed and signed.

Randomization:

Once a patient agrees to the study they would be sequentially randomized into whether or not they receive StepRite. The patients will be randomized to every other eligible patient gets the intervention. (ie: 1,3,5,7,9… will get StepRite ; 2,4,6,8 will not get StepRite) 15 Intervention subjects will be recruited and 15 control subjects will be recruited with an extra 5 patients to account for attrition and withdrawals.

Schedule of events

The intervention group will receive the StepRite device with standard conventional care and the control group will receive standard conventional care only. Both groups will receive outpatient, home health, and /or 24 hour physical therapy treatment plans per their surgeon's standard of care. The control group will undergo the conventional outpatient treatment program to 8 weeks as normally prescribed by the lead investigator. This consists of a twice weekly outpatient appointment with a physical therapist and prescribed home exercise program (see attached physical therapy protocol).
The patients randomly selected to wear the StepRite inserts will be fitted and instructed along with the patient's designated care giver in their use including initial pre-op measurements prior to their surgical date so that data collection can begin on the 1st day of rehab after surgery

Those patients not selected to wear step rite will receive instructions preoperatively of their expected therapy regimen and receive their baseline functional evaluation of the knee
Both groups will be given log sheets to record their activity at home and when seen by the physical therapist. These will be returned and collected by the therapist weekly and scanned into/ kept in the patient's medical record file. A paper copy will be kept in the coordinator's office, 4A144B with the consent forms and any other study documents.
Both groups will also have routine self-assessment questionnaires (appendices 3, 4 KOOS and KSS) and functional testing performed by the PI and PT during the patient's regular clinic visit as standard of care.

Outcome measurements performed just after surgery and at time of discharge from hospital and standard of care post-surgical clinic visits to 8 weeks will indicate if any patients are experiencing unexpected delays in progress. Subjects will be visited at home by the Home Health therapists, and will visit and receive telephone consultations with the outpatient therapists, who will be able to monitor the patients' conditions and intervene if there are any problems related to the use of the device. The StepRite device will provide the therapist with more information about the patients' activity levels and progress than would usually be available to them and so is not expected to have any safety implications. The device and App. will prompt the patient with voice and text to complete their exercises as they are needed, while collecting data.

Device Flow Chart: *standard of care post-op*

The research coordinator will consent the patient prior to the surgery
The research coordinator will document the following information for the device on the device data collection form. (See attached)

a. Name of patient
b. Email of patient
c. Phone number of patient
d. Surgery date
e. Expected date of discharge

The patient's information will then be entered into the steprite™ system and a patient account will be created by the Research Coordinator

Physical therapy will schedule the study protocol via the steprite™ system and enter the physical therapy start date as day after discharge.
MedHab™ sponsor (Matt Brown) will contact the patient for the patient account set up and to obtain the following signatures required by MedHab (see attached)

a. HIPAA
b. Assignment of Benefits

MedHab™ will help the patient load the app, provide an overview of the app, and forward a tutorial video
MedHab™ will send the steprite™ device to the study Research Coordinator at TTUHSC
TTUHSC Orthopaedic Surgery
Clincial Trials Coordinator, Nancy Swinford
3601 4th st. MS 9436
(t)806-743-2569 (f)806-743-2541

The Research coordinator will fit the patient with the device, pair, and connect the device at time of discharge.
Patient will leave the hospital with the steprite™ device and instructions to charge device overnight for use the next day.
Patient will begin exercise regimen prompted by the StepRite App on the cell phone.
Physical therapy will communicate with the patient per the therapy protocol
Physical therapy is to work with patient per standard of care protocol with the addition of 3 patient outcome surveys, (KOOS, KSS, and the Lower Extremity functional scale) (see attached) at 4, 6, and 8 weeks post op, and the PI will see the patient as standard of care at visits 2, 6, and 12 weeks post-op. The 2 week patient outcome surveys will be completed at the 2 week standard clinic visit with the assistance of the study coordinator. All documents and data collection forms from physical therapy and clinic will be

scanned into the patients chart for review and kept in a locked file cabinet in the research coordinators office 4A144B.
Physical therapy advises the PI and MedHab two weeks prior to close of therapy on close out or extension procedure if needed.
The PI and MedHab extends the therapy or communicates the close out procedure with the patient.

Control Subject flow

The control group will have all Post-op standard of care as the device group without the use of the device.

Device Information

The device to be used in the study is the StepRite, manufactured and supplied by Medhab LLC. The device is considered exempt from IDE regulations, as it is a diagnostic device. It has been approved as a Class I medical device by the FDA.

The StepRite device consists of a thin insole which is placed inside the shoe.
The insole contains pressure sensors which record pressure data when exercises are performed, and contains an accelerometer, which records acceleration of the foot and is used to calculate velocity and activity levels.
A wireless connection between the insole and a cell phone application allows transfer of data.
The cell phone application will be supplied.
The cell phone application displays real-time feedback of pressure distributions to the user, and connects wirelessly to the Medhab servers to upload data onto the secure web interface, for access by the physical therapist or physician.
The device does not impart energy to the user.
The patient or designated care giver will be responsible for placing the insoles on their charging platform nightly.

Indicate the number of patients/charts/surveys/specimens needed.

The total number of patients needed in this study is 30, we will request a total of 35 to account for possible Attrition or withdrawals. 15 will be fitted with the StepRite device and 15 will follow the normal postoperative protocol without the device and be considered control subjects.

Inclusion criteria

Unilateral Partial or Total knee arthroplasty.
Age 45-75 yr. old
BMI <35
Access to Wi-Fi
Have appropriate smart phone and knowledge of use
Be willing to place StepRite app on their personal phone

Exclusion criteria

History of neuromuscular disorder (e.g. Parkinson's, Polio, or stroke).
Pregnancy
History of cognitive disease that would preclude ability to navigate smart phone

Method of identifying and recruiting subjects.

Recruitment will come from the investigators normal patient population who are scheduled for a partial or total knee replacement. The Investigators will identify and consult the research coordinator to assess eligibility.

Compensation given to subjects.

There will be no compensation given to subjects. They will be allowed to keep the insoles and access the app for at home therapy at no cost to them for as long as the device works.

Describe the site(s) where study will be done.

The main clinical/surgical portion of the study will take place at Texas Tech University Health Sciences Center department of Orthopaedic Surgery and University Medical Center Lubbock. The physical therapy departments used for this study will be the investigators preferences and standard of care, therefore they would be used if not on the study and are not study specific.

MedHab LLC (StepRite) will be collecting data from several sites to compare outcomes and cost. The secondary sites utilizing this device and doing similar studies are Covenant with Dr David Shephard as the lead investigator, the Lubbock Heart Hospital with Dr Jeff Headric as the lead investigator, and Texas Health Resources with Dr. Hohman as lead investigator. All the secondary sites will use their standard of care preferences for clinical/surgical and physical therapy. TTUHSC will not be collecting data nor in any way be affiliated with the secondary study sites. They will acquire their local IRB approval for each site separately using similar device protocols.

Risks

There is a risk of loss of confidentiality, we will have measures in place to help prevent any loss of personal information. During the course of this study there are no new or additional steps required of the subjects from what is considered the standard protocol for the lead investigator. The only alteration may be reduced travel and outpatient visit by the patient if compliance and functional improvement noted by the therapist.
StepRite imparts no energy to the patient and poses no hazard to patient well being
Subjects will be free to withdraw from the study at any time and revert to conventional rehabilitation treatment.

Possible benefits to subjects

There is a possibility the device group patient could benefit from the device prompting them to do their own exercises regularly, which could lead to a faster recovery and better physical therapy outcomes. We are hoping the participation in this study may help us learn how we can design rehabilitation programs to be more effective in the future.

Confidentiality measures

StepRite / MedHab will have access to non-PHI patient data collected by the device stored on their HIPPA compliant server and be available only to the lead investigator. All PHI will be kept separate from the study data in a locked filing cabinet or on a password protected computer in the research coordinators office in 4A144B.

Data Collection and Monitoring

Data recorded by the StepRite device will be transmitted wirelessly to the HIPAA secured web interface managed by Medhab. Clinicians will be able to log into the website with a password to review the progress of each patient.
Data recorded by the PI and physical therapist on the functional motion of the knee will be recorded in paper form and kept with the completed KOOS questionnaire and Knee Society Score (KSS) and scanned into the patients HIPPA protected chart.

Upon completion of patient's part in the study MedHab will contact UMC and the Therapy departments to acquire actual costs of these services. This will be done to compare the overall cost of management of the post-operative rehabilitation of a patient in traditional rehabilitative regimen vs. use of StepRite,

Actual Cost information for the patient's full rehabilitation will be requested and collected by the Hospital and released to MedHab at the end of the study and supplied to the lead investigator for analysis.

References

[1] Franklin PD, McLaughlin J, Boisvert CB, Li W, Ayers DC. (2006). Pilot study of methods to document quantity and variation of independent patient exercise and activity after total knee arthroplasty. J. Arthroplasty. 21:157-163.

[2] Tousignant M, Boissy P, Moffet H, Corriveau H, Cabana F, Marquis F, Simard J. (2011). Patients' satisfaction of healthcare services and perception with in-home telerehabilitation and physiotherapists' satisfaction toward technology for post-knee arthroplasty: an embedded study in a randomized trial. Telemed J E Health. 17(5):376-382.

[3] Russell TG, Buttrum P, Wootton R, Jull GA. (2011). Internet-based outpatient telerehabilitation for patients following total knee arthroplasty: a randomized controlled trial. J Bone Joint Surg Am. 92(2):113-120.

[4] Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. (1998). Knee Injury and Osteoarthritis Outcome Score (KOOS)--development of a self-administered outcome measure. J Orthop Sports Phys Ther. 28(2):88-96.

[5] Roos EM, Toksvig-Larsen S. (2003). Knee injury and Osteoarthritis Outcome Score (KOOS) - validation and comparison to the WOMAC in total knee replacement. Health Qual Life Outcomes. 1:17-26.

[6] Rastogi R, Davis AM, Chesworth BM. (2007). A cross-sectional look at patient concerns in the first six weeks following primary total knee arthroplasty. Health Qual Life Outcomes. 5:48-56.

[7] Lienhard K, Schneider D, Maffiuletti NA. (2013). Validity of the Optogait photoelectric system for the assessment of spatiotemporal gait parameters. Med Eng Phys.35(4):500-504.

[8] Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM (2011). Measures of knee function: International Knee Documentation Committee (IKDC) Subjective Knee Evaluation Form, Knee Injury and Osteoarthritis Outcome Score (KOOS), Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS), Knee Outcome Survey Activities of Daily Living Scale (KOS-ADL), Lysholm Knee Scoring Scale, Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Activity Rating Scale (ARS), and Tegner Activity Score (TAS). Arthritis Care Res (Hoboken). 63(Suppl 11):S208-228.