NSH 1432 PROTOCOL

TITLE

Continuous Monitoring Using a Smart Implantable Device to Compare Medial Parapatellar vs. Subvastus Approaches in Early Post-Operative Total Knee Arthroplasty Recovery

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None

INTRODUCTION

Total knee arthroplasty (TKA) is a highly effective intervention for end-stage knee arthritis, with two common surgical approaches: the Medial Parapatellar (MPP) approach and the Subvastus (SV) approach. Both techniques demonstrate similar long-term outcomes (6 months and beyond) in terms of functional scores, range of motion (ROM), and patient satisfaction, as documented in numerous studies. A key limitation in the literature, however, is the lack of day-by-day data on functional recovery and gait parameters in the crucial first 30 days post operatively - an important period when patients are regaining independence and returning to daily activities.

Persona IQ (Zimmer Biomet) is an FDA-approved smart knee implant that captures continuous, real-world gait data (ROM, step count, stride length, walking speed, etc.) directly from the tibial implant. Unlike external wearables, PIQ provides objective, high-frequency metrics directly from the implant[1]. By leveraging PIQ technology in combination with step-tracking wearables, this prospective study aims to fill the current gap by providing daily metrics about the patients pre-operatively and their recovery trajectories during the first 30 days post-operatively and correlating this data with standard PROMs. In this study, patients will be enrolled before surgery and followed longitudinally.

We hypothesize that the SV approach will demonstrate a quicker return to functional milestones in the early post-operative period compared to the MPP approach, even if long-term outcomes have no significant difference. Specifically, we anticipate improved gait metrics (ROM, step count, walking speed) and PROMs (KOOS Jr., NPRS & VR-12) from post-op day 1 to 30 in the SV group compared to the MPP group. The main primary outcome of this study will be step count. This study has the potential to enhance surgical decision-making and optimize rehabilitation protocols by identifying the approach that accelerates early functional recovery.

REVIEW OF LITERATURE

Existing studies comparing MPP and SV approaches typically report outcomes at discrete time points - post-operative day 1, week 4, month 3, and beyond[2–5]. These studies consistently demonstrate no significant differences in functional outcomes at 3 or 6 months and beyond post operatively[2–9]. They lack data, however, on recovery during the initial stages of TKA post operative recovery, a period when patients are most vulnerable to functional impairments, pain, and difficulty resuming daily activities. While a 2024 prospective study reported significantly improved early outcomes in the SV group compared to MPP at 1 and 3 months, it did not include continuous or real-time data within the first 30 days post-op, leaving this gap in our understanding of recovery during this critical period[5].

Smart technology, including PIQ can bridge this gap by capturing continuous gait metrics, providing a view of early recovery. Prior studies using external devices (Fary et al., 2023) demonstrated the feasibility of passive gait monitoring but lacked implant-based validation. Persona IQ offers a unique opportunity to directly measure in vivo knee kinematics and gait parameters through the recovery period.

Study Design

This is a single-institution, prospective randomized study. Patients of Dr. Bradbury, Dr. Naylor, and Dr. Guild undergoing primary total knee arthroplasty (TKA) at the Advanced Center for Joint Surgery (Sandy Springs, GA; Cumming, GA) will be screened for eligibility and approached during their pre-operative clinic visits. We plan to enroll 100-120 eligible once obtaining informed consent. For two weeks prior to surgery, enrolled patients will be asked to track their step count using the built-in iPhone Health application. If a patient routinely wears an Apple Watch or similar device, the step count data from the watch may also populate the iPhone Health application and will therefore contribute to the recorded step count. Patients will self-report their average daily step count on the day of surgery by showing the data from the application to research fellows. While recording step count, adherence will be recorded as the number of days with available iPhone Health data meeting validity criteria (≥500 steps). Days with 0–499 steps will not be considered valid unless the patient attests to medically-indicated low activity, in which the reason will be documented.

During surgery, all patients will receive a Zimmer Persona IQ utilizing a medial congruent bearing with a posterior cruciate ligament (PCL) sacrifice. All patellas will be resurfaced as well. This standardized implant choice was made to reduce variability and allow for direct comparison of functional outcome between surgical approaches. PIQ data will be accessed using the Canary Medical database. Patients will be followed for a minimum of 6 months post-operatively, during which they will complete digital patient-reported outcomes.

The surgical approach, MPP or SV, will be randomly assigned with an equal chance of receiving either. This randomization will be stratified by sex and age.

Inclusion Criteria:

- All patients older than 18 years of age who plan to undergo medial congruent polyethylene bearing primary TKA with a PIQ
- Eligible for both approaches
- Have an iPhone and willing to “wear” it for two weeks preoperatively to get an estimated average stepcount

- Provide informed consent
- Willing to complete follow ups

Exclusion Criteria:

- Patients with TKA revisions
- Patients with insufficient pre-operative range of motion in the operative knee (flexion contracture of > 20 degrees or < 90° of knee flexion)
- Patients with Contralateral TKA within study time frame
- Patients with TKA other than medial congruent polyethylene bearing
- Patients with bilateral surgery
- Patients without a valid and active email address
- Patients not willing or able to participate in study and follow-ups
- Patients who use assisted devices to ambulate
- Rheumatoid arthritis

Primary outcomes:

- Preoperative data
    - Preoperative goniometric functional range of motion
    - Step count
    - Pre-Operative Step Count via Force Therapeutics
        - In cases where pre-operative step count is missing or incomplete, patients can update force or discuss what range of activity they are classified in based on step count
- Continuous PIQ Data
    - Tibial ROM
    - Cadence
    - Walking speed
    - Stride length
    - Step count
    - Distance
- 6 week follow up data
    - Goniometric functional range of motion

Secondary outcomes:

- Time to achieving key milestones in daily activities (e.g. ability to perform basic household tasks such as taking out the trash)
- Veterans Rand 12-Item (VR-12) Health Survey (Preop, 6 weeks, 6 months)
- Procedure Satisfaction (6 weeks, 6 months)

- Numeric Pain Rating Scale (NPRS) (Force data)
- KOOS, JR. (Knee injury and Osteoarthritis Outcome Score for Joint Replacement) - Preop, 6 weeks, and 6 months
- Forgotten Joint Score - Preop, 6 weeks, 6 months

Other measures:

- Patient Demographics including
    - Age
    - Sex
    - Body Mass Index (BMI)
    - American Society of Anesthesiologists (ASA) score
- Surgical side (L/R)
- Comorbidities

ANALYSIS

Post-operative functional data will be extracted from the Canary Medical platform for all Persona IQ participants. Preoperative step count will be collected from each participant's iPhone. Descriptive and comparative statistical analyses will be conducted using this real-time data.

Data are broken down descriptively first to understand the distribution of the medial parapatellar and subvastus groups. Continuous data are presented as mean (standard deviation) and categorical data are presented as cell count (%). Shapiro-Wilks and Kolmogorov-Smirnov tests are used to assess the normality of the continuous data. T-tests are used to calculate P values for continuous data and Chi-squared tests are used to calculate P values for categorical data. Following this, an unadjusted and adjusted logistic regression are analyzed using PROMs as the dependent outcome. Significance is determined at P value < .05. All statistical analyses are done using R Studio (version 4.3.1, Vienna, Austria). Using a significance level of 5%, a power of 80% and an effect size of 0.3, we believe that 55-60 patients are needed for the MPP group and 55-60 patients are needed for the SV group to determine a difference of 1000 steps per day.

CONSENT PROCEDURE

Subjects will be identified via the surgical schedule and contacted during their pre-operative clinic visits. A research coordinator will explain the study and obtain informed consent. No study activities (e.g., device usage or data collection) will begin prior to consent. Patients may withdraw at any time.

COST AND COMPENSATION

As this is currently standard of care at Northside Hospital, no compensation will be given.

CONFIDENTIALITY OF DATA

Data will be stored within the ERPA system, Force Therapeutics. Force has a signed Business Associate Agreement (BAA) with Amazon Web Services. AWS enables covered entities and their business associates subject to HIPAA to leverage the secure AWS environment to process, maintain, and store PHI. For analytical purposes, data from Force will be transferred to a password-protected Excel file. All PIQ data will be accessed via the Canary Medical platform, which complies with HIPAA and secure health data standards. Patient identifiers will be removed from exported datasets and data will be stored in password-protected research files

POTENTIAL CONFLICT OF INTEREST

None

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   https://www.zimmerbiomet.com/en/products-and-solutions/specialties/knee/persona-iq.html

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