Study Protocol NCT-05091918

Limited Market Release – MotionSense Clinical Use Evaluation

Rev. 02

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Contents

1.0 Introduction

To date a number of studies have been performed to inform the design of the Motionsense wearable hardware and mobile application (Figure 1). This wearable system will seek FDA Class I status (see Appendix F1-4) and allows evaluating the knee flexion angle during activities of daily living and during physiotherapy, while also tracking secondary metrics (often derived from the knee flexion). This system consists of two sensor nodes that are placed above and below the knee joint respectively. This is achieved by means of daily and weekly patch, whereby the weekly patches are first applied to the patients' skin and intended to stay on for at least a week. Subsequently, the daily patches connect the sensor nodes to these weekly patches. The sensor nodes shall thus be removed daily as they require daily (overnight) charging. A detailed description of the system is provided in Appendix A.

Figure 1 – Schematic design of the Motionsense system consisting of sensor nodes (left), daily and weekly patches (middle) and mobile application (right).

The data collected through the wearable and mobile app are shared with a cloud infrastructure, hereafter referred to as OrthoLogIQ. This is a HIPAA compliant database infrastructure that provides the surgeon and care team with remote access to the patient profile to review the daily activity data, assigned home exercise program and compliance therewith, pictures uploaded by the patient, …

A primary outcome from these wearable devices is the knee range of motion, absolute knee flexion angle, knee active time, steps and successful repetitions of prescribed physiotherapy exercises. These metrics are tracked and reported by the companying mobile application.

During the proposed study, the MotionSense wearable system will be used by patients undergoing TKA surgery leading up to and after their surgery. The patients will be using the system to monitor their recovery during daily activities, log daily pain scores and patient reported outcomes while also supporting their prescribed home exercise program. Each patient will thereby participate in outpatient physiotherapy in line with their current standard of care, while the physiotherapist will leverage the opportunities of the presented platform to give the patient personalized reminders for their patient-

specific home exercise program. The surgeon / research nurse will additionally be able to monitor the patients recovery remotely as the sensor / app data is shared to the OrthoLogIQ platform.

The primary goal of this observational study is to evaluate the usability of the Motionsense system in a typical patient environment, while also documenting the physiotherapists' decisions in advancing patients' home exercise program.

2.0 Study Objectives

The primary objectives of this study are to evaluate:

- **OBJ1.1:** Evaluate patient and practice compliance with the MotionSense wearable system
    - Hours of MotionSense use per day in office
    - Number of days use after / prior to surgery
    - Filled out questionnaires
    - Home exercise program
    - Patient onboarding time in surgeon clinic
- **OBJ1.2:** Document home exercise program prescribed to patients throughout their individualized recovery progress by surgeons and physiotherapists

The secondary objectives of this study are:

- **OBJ2.1:** Correlate functional and patient reported outcome metrics
- **OBJ2.2:** Evaluate convenience of using the MotionSense system
    - Number of leg registrations performed (per day)
    - Number of (weekly / daily) patches used
    - Number of wound pictures shared with surgeon office
- **OBJ2.3:** Establish normative recovery data for the primary outcome metrics captured by the MotionSense system
    - Daily VAS pain scores
    - Daily Steps
    - Knee active and weight bearing time
    - Range of Motion
    - Gait quality

3.0 Research Plan

3.1 Study Design

The study is designed as a prospective, observational study including a maximum of 50 patients that are scheduled for total knee arthroplasty and will be participating in outpatient physiotherapy as part of their standard of care recovery pathway.

The study aims to replicate an actual use scenario of the Motionsense system, involving longitudinal follow-up of the patients starting 2-4 weeks prior to surgery up to 90 days after surgery. Patients will be recruited through the surgeon clinic, and subsequently use the MotionSense system at home and in collaboration with their physiotherapist who will assign adequate exercises to the patient. At the end of their 90-day recovery window, the patients' experience with the MotionSense system will be evaluated using a phone interview by the research nurse.

3.2 Patient Journey

The patients will be using the Motionsense system for up to 120 consecutive days during this study. During the study, the patients will be interacting with the **principal investigator (PI), physiotherapist (PT) and research nurse (RN)** at the following time intervals:

- **Initial Checkpoint:** patient consent and enrolment
  - Introduction to the study and patient consenting by Principal Investigator
  - System introduction (involving IFU – see Appendix A) and installation by Research Nurse
  - Initial, pre-operative exercise prescription (by Surgeon)
  - Evaluation of comorbidities (Charlson Comorbidity Index – Patient Reported)
  - Evaluation of expectations (HSS Expectations)

- **Pre-operative at home use:** prehab and questionnaires
  - Patient reported outcomes collected through app: KOOS and PROMIS-10 questionnaires
  - Daily pain scores
  - Pre-operative home exercise program completed
  - Pre-operative gait assessment (incl. use of walking aids)
  - Baseline activity data for activities of daily living (steps, weight bearing time, knee active time, range of motion)

- **Day of Discharge:** 2 to 3 days after surgery
  - Home exercise program updated by Surgeon
  - LACE questionnaire (Research Nurse)

- **Post-operative at home use:** home exercise and questionnaires
  - Patient reported outcomes collected through app: KOOS and PROMIS-10 questionnaires (at 2weeks / 6weeks / 90 days post-operative)
  - Daily pain scores
  - Post-operative gait assessment (2 times per week)
  - Post-operative home exercise program completed
  - Monitoring of daily activities

- **Outpatient Physiotherapist Visit:** starting 7-14 days after surgery
  - Home exercise program updated by Physiotherapist
  - Review of ADL activity by Physiotherapist
  - Changes in home exercise program documented and motivated in PT journal

- **Remote Monitoring:** throughout
  - Home exercise compliance and ADL activity level reviewed by Research Nurse / Surgeon
  - Logging of surgical complications (ER-visits / re-admissions / …)

- **Final Checkpoint:** phone interview by Research Nurse
  - System compliance – evaluate moment of drop-off
  - Usability questionnaire including Net Promoter Score

Beyond these checkpoints with the health care professionals involved in the study, the patient will use the system on a daily basis and will be asked to fill out a daily pain score through the mobile application. The patient's daily flow while at home will look as follows:

- Wake-up
- Application of the sensors on the leg and sensor alignment by resting the operated foot on a block and standing upright (support can be used in case of perceived instability – see Figure 2)
- Activities of daily living registration
- Home exercise completion (exercises prescribed by supervising physiotherapist)
- Sensor take-off
- Charging sensors overnight so they are ready for next-day use

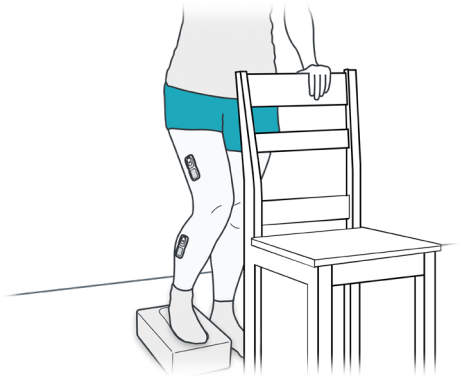

Figure 2 – Sensor alignment procedure performed by the patient on a daily basis by resting the operated leg on the block and using a chair in front for support in case of perceived instability.

3.3 Home Exercise Program

A library of 12 exercises is provided in the MotionSense mobile application. The physiotherapist has the ability to select any of these exercises and appoint them to the patient for their home exercise program as deemed necessary by the clinician. This library of exercises was distilled from recommendations by the American Association of Orthopaedic Surgeons (AAOS) and in collaboration with consultant surgeons and physiotherapist. The exercises consist of:

- Warm up
- Knee straightening stretches
- Sitting knee bends
- Sitting assisted knee bends
- Quad isometrics
- Short arc quads
- Long arc quads
- Straight leg raises
- Sit to stands
- Heel slides
- Prone hamstring curls
- Standing knee bends

The decision process of the physiotherapist in assigning these exercises will be documented in the journal that the physiotherapist is keeping (referred to as *PT Journal* - see Appendix C). Should exercises that are outside of the abovementioned library be indicated for the individual patient, these exercises will be documented in the PT journal and assigned to the individual patient through the current standard of care.

3.4 Setting

All patients will be recruited under supervision of the principal investigator, Paul Jacob MD, from the Oklahoma Joint Reconstruction Institute.
A research nurse linked to the orthopaedic practice will manage the study participants, collect consent forms and assure completion of the forms. A group of physiotherapists will also participate in the study to assign the relevant exercises to the patients and guide the patients' recovery as part of their standard of care.

3.5 MotionSense and OrthoLogIQ

OrthoLogIQ is a cloud-based, HIPAA compliant data collection, dashboarding and reporting platform, which enables health care providers to monitor their patients pre- and post-operatively with the use of the MotionSense wearable and mobile application. OrthoLogIQ is designed to enable hospitals, practices and healthcare providers monitoring and collecting various data points on their patient population throughout their episode of care. OrthoLogIQ users can collect a pre-operative patient baseline (Comorbidities, patient reported outcomes, VAS pain scores, activities of daily living, range of motion and correlate that to post-operative outcomes surveys, activity levels, home exercise program compliance and patient satisfaction. In addition, the dashboard provides health care providers with the ability to remotely monitor the recovery of their patients in terms of pain scores, daily activities, range of motion, exercise compliance etc.

3.6 Materials

For the duration of the study, the patient will be provided with:

- **Weekly patches:** these weekly patches go directly on the knee. Initially the patient will be provided with 9 x 2 weekly patches, upon request more weekly patches can be obtained through the surgeon clinic.
- **Daily patches:** the daily patches are used to connect the sensors to the weekly patches and shall be replaced every time the sensors come off the leg. Initially the patient will be provided with 63 x 2 daily patches though refill packs can be provided through the surgeon clinic should the patient run out of patches.
- **Box:** including two sensor nodes, a charger with power cord, instructions for use and a sensor alignment block

The accompanying MotionSense mobile application will be available for download through the app store. The patient will be assisted with this installation process by the research nurse involved in onboarding the patient.

3.7 Participants

The study participant will represent a range of typical intended users of the Motionsense System. More specifically, the following selection criteria will be used:

- Planned to undergo unilateral total knee surgery in the coming 4 weeks
- Age 50 to 80
- BMI not exceeding 35
- Owns a smartphone (agnostic to brand or type)
- Patient does not have severe skin conditions that would potentially result in irritation or harming the skin when applying the weekly patches.

Beyond that, the study should aim to recruit patients with various socio-economic backgrounds, various levels of motivation as well as a wide range of educational level.

A total of 50 participants will be recruited for the study. Recruitment for this study will be managed by the Principal Investigator. Through the orthopaedic practice, the surgeon office has regular access to patients matching the profile of intended users. In addition, the surgeon has close contact with the participating physiotherapists while the research nurse is employed by the surgeon office. Participants will provide their written informed consent prior to participation (Appendix F).

3.8 Data Collection

In general, the data collection in this study is focused on assessing the primary and secondary goals of the study as listed in section 2.0. This leads to various sources of data collection:

- **Patient journal:** pre-operatively, the patient will fill out a number of questionnaires on paper form to frame potential comorbidities / socio-economic status / expectations.
- **Physiotherapist journal**: the physiotherapist will fill out a document following each physiotherapy visit to document the prescribed exercises along with the motivation for assigning these exercises and setting the targets for these exercises.
- **Wearable & App data capture:** during the patients' daily use of the wearable and interaction with the mobile application, the sensor will capture activities of the patients' daily life as well as their exercise completion by storing a series of variables on the patient's phone and sharing this data to a HIPAA compliant database. More specifically, this data capture involves:
  - **ADL:** the patients' activities of daily living is captured by the sensors, involving an hourly histogram of the patients knee flexion angle, an hourly total of a patients' active minutes, an hourly total of a patients' weight bearing time, an hourly total of a patients' time wearing the sensor.
  - **Gait:** at predefined time intervals (2 x per week), the patient will be prompted to walk for 1 minute while the sensors log the raw signals and share this data with the OrthoLogIQ database. This data can be further evaluated from cloud, looking at cadence, range of motion during gait, …
  - **Exercises:** the performed exercises and completion of the daily exercises will be recorded by the mobile application.
  - **Pain scores:** the patient will be asked to report their daily pain scores through the mobile application.
  - **Patient Reported Outcomes:** patients will be asked to complete a KOOS and PROMIS-10 questionnaire through the mobile application at distinct time intervals throughout their recovery pathway.
- **Patient interviews**
  - At the end of the study, the patient will join a phone interview while responding to a series of usability questions specific to their use of MotionSense during the recovery after surgery. In addition, the patient will be asked about any complications and/or re-admissions that they experienced during their 90d recovery window after surgery.

4.0 Ethical Considerations

Eligible participants may only be included in the study after providing written consent to participate. Before the study session, each participant will be provided with details of the structure, confidentiality requirements and anonymity of the research, and will be invited to give informed consent via signing of an informed consent form (Appendix B).

At enrolment each participant will be assigned a unique participant number that will be used for data collection, and subsequent analysis and reporting purposes. All non-identified data will only be accessible by members of the research group for the specific purpose of the study.

4.1 Consent forms

All patients will consent to participation in this IRB approved, prospective observational study per the consent form in appendix B.

4.2 Compensation

Patients will not be compensated for this study as incentivizing them might potentially affect the outcome of the study.

5.0 Study Outline

	Tasks & Environment		
Timescale	Surgeon Clinic	PT Clinic	Home
2-3 weeks prior to surgery	○ Patient Consent ○ Onboarding with MotionSense (incl. timing) ○ Fill out patient journal ○ Assign pre-operative exercises	N/A	N/A
Prior to surgery	N/A	N/A	○ Home exercises ○ Gait assessment (2x / week) ○ Pain scores ○ PROMs (KOOS & PROMIS10)
Day of Surgery	N/A	N/A	N/A
Discharge	○ Re-install MotionSense sensors ○ Complete LACE questionnaire ○ Assign early-post-operative exercises	N/A	N/A
After discharge	○ Log complications / interactions with the clinic (e.g. additional patches)	Log assigned exercises and reason for assignment Log active / passive range of motion	○ Perform home exercises using sensor ○ Wear sensors during daily activities ○ Complete gait assessments (2x / week) ○ Report pain scores ○ Complete PROMs ○ Upload wound pictures as deemed necessary
90d after surgery	○ Phone interview with patient	N/A	N/A