Wearable motion sensor(s) to measure change of physical function in patients after total knee replacement.

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The primary endpoint is based on the abovementioned primary study parameters:* A selection of wearable motion sensors that is suitable to measure change in physical function of TKR patients after surgery. In addition, the relation between these...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON45809

Source
ToetsingOnline

Brief title
Wearable sensor for rehabilitation

Condition

- Other condition
- Joint disorders

Synonym
kneeprosthesis, total knee replacement

Health condition

totale knie vervangende operatie

Research involving
Human

Sponsors and support

Primary sponsor: Imec Nederland
Source(s) of monetary or material Support: Stichting Imec Nederland

Intervention

Keyword: gait analysis, inertial sensor, recovery, total knee replacement

Outcome measures

Primary outcome

The primary objective of this study is to determine which wearable motion sensors are suitable to measure change in physical function of TKR patients after surgery. Following this objective, we will explore if the changes in physical function, as measured with wearable sensors, is related to the PROMs. Physical function is specified as a selection of functional parameters (e.g. walking speed, step length, symmetry). All of these functional parameters can be determined using wearable motion sensors, with methods we have developed in our previous study on healthy subjects. However, each motion sensor-based calculation has a certain accuracy. Therefore, we will determine the change of each functional parameter using reference devices/software (pressure insoles, Xsens kinematics software, ECG patches). If the change of the functional parameter in TKR patients is bigger than the accuracy of the motion sensor-based calculation, the motion sensor is suitable to measure change of physical function.

General function PROM is defined as score on the KOOS-PS, with a difference bigger than 2.2 within a subject as minimal clinical improvement threshold.

Specific function PROM is defined as score on the PKIP, with sub scores on: stability, confidence, satisfaction and modification of activities. Both the sensor-based features and the PROMs are measured at multiple points in time (5x). To account for individual progress over time on both measures, the difference between baseline (pre-operative) and each follow-up measurement will be calculated. The relation between each functional parameter and the score on the PROMs will be explored.

For an extensive description of the analysis and the endpoints, see protocol section 10.

Secondary outcome

* Relation between pre-operative expectation (of multiple ADL) of the subject and the surgeon, and the PROMs.
* Relation between patient specific parameters (biometrics, lifestyle, comorbidities, mental fitness), and the PROMs.
* Correlation between subject reported acute pain/confidence (from VAS) and sensor based features (physiological and movement) during ADL.
* Correlation between the activity level at home of the wrist worn device (fitbit) and the smartphone based (Sentiance application).

For an extensive description of the analysis and the endpoints, see protocol section 10.

Study description

Background summary

Total knee replacement (TKR) is a successful surgical intervention for patients with advanced osteoarthritis (OA) to reduce pain and improve physical function. However, about 20% of the patients is not satisfied one year after TKR. Therefore, it is necessary to gain knowledge about the factors involved in dissatisfaction and ultimately help patients who are unsatisfied as early as possible.

At this moment, Patient Reported Outcome Measures (PROMs) are the only standardized way to measure success and recovery rate of TKR. A wearable sensor system could provide an unobtrusive and inexpensive way to determine recovery rate during rehabilitation.

Wearable sensors are used more often to measure physical function and movement non-invasively over longer periods of time. Inertial measurement units (IMUs) containing accelerometer, gyroscope, magnetometer and in some cases barometers have been used to study kinematics during activities of daily living (ADL), e.g. walking, stair climbing, getting up from a chair. Other sensors, such as pressure insoles, smartwatches and smartphones have been used to track activity level in a more generic way. A smartwatch with electrodes has been used to measure skin conductance, to determine physiological stress response to both acute and transient stimuli. Taken together, there are enough sensors that can be used to measure physical function of patients after TKR, but the question remains which one is the best.
In a previous study at Imec, we have measured several healthy volunteers with multiple wearable sensors: IMUs, pressure insoles, smartwatch with electrodes on the skin and an ECG-patch. The results of this study show that these sensors can be used to calculate multiple parameters of physical function during multiple activities of daily life (ADL). Where each method has a certain accuracy (for example +/- 1 degree in calculation of the knee angle). Multiple of these functional parameters are known to be important in physical recovery after TKR. It remains to be determined which sensor is suitable to measure change in physical function of TKR patients after surgery.

The aim of this study is to determine which wearable motion sensors are suitable to measure change in physical function of TKR patients after surgery.

Following this objective, we will explore if the changes in physical function, as measured with wearable sensors, is related to the PROMs. The results of this study can be used to monitor patients during their recovery and provide insight in the cause of unsatisfied patients after TKR.

Study objective

The primary endpoint is based on the abovementioned primary study parameters:
* A selection of wearable motion sensors that is suitable to measure change in physical function of TKR patients after surgery. In addition, the relation between these functional parameters and PROMs.

Secondary endpoints:
* Relation between pre-operative expectation (of multiple ADL) of the subject and the surgeon, and the PROMs.
* Relation between patient specific parameters (biometrics, lifestyle, comorbidities, mental fitness), and the PROMs.
* Correlation between patient reported acute pain and physiological stress response/ movement patterns during ADL.
* Correlation between the activity level at home of the wrist worn device (fitbit) and the smartphone based (Sentiance application).
Rationale behind these objectives can be found in Chapter 2 of the Investigation Protocol.

Study design

The data required for this study will be gathered from 25 patients with osteoarthritis (wearing) of the knee, who will undergo TKR. In total, the subjects will be measured at five separate sessions: pre-operative (2-4 weeks), post-operative at 2 days, 2 weeks, 6 weeks and 12 weeks. Each measurement session is the same and takes about 45 minutes.
At each measurement session , the following wearable sensors will be used:
- 15 IMUs on the lower and upper legs, pelvis, fore and upper arms, shoulders, chest, head and feet.
- Pressure insoles in shoes (left and right)
- Smartwatch (right arm)
- ECG-sensor on chest patch.
At the first measurement session there will be asked 2 additional questionnaires: Hospital Anxiety and depression scale, HADS: 14 questions, expectation questionnaire based on multiple ADL: 22 questions. For the rest of the measurement session, and each other session, the subjects will be asked to do the following:
- 2 questionnaires (KOOS-PS: 7 questions, Patient knee implant performance, PKIP: 24 questions)
- Let researcher apply all abovementioned sensors
- Perform the following activities. After each activity the subject will be asked to rate the pain and confidence during that specific activity on a visual analog scale (VAS).
o Walking at self-selected normal speed (40m).
o Stand up out of normal and deep chair (seat is 40cm from the ground)
o Timed Up and Go (TUG) (see Appendix)

o Getting in and out of a bed
o Pick keys up from the ground
o Stair climbing (at self-selected speed) 12 steps up and down.
o Standing still (10s)
o Passive Range of Motion (ROM) of knee and hip of the dominant leg. Lying on a bed, the research assistant will bend the knee and extend hip.
In case the subject is not able to perform the activity, the activity will be skipped and continued with the next one.

In between the measurement sessions, the subjects receive an activity monitor (Fitbit) to take home. They will be asked to wear the monitor as much as possible for 4 days after the session. In addition, the subjects will be provided the option of installing an application on a mobile phone (their own, or one provided by the researchers). The subject will be asked to carry the mobile phone with them for 4 days.
Both the Fitbit and the application measure the movement of the subject outside the sessions, and the Fitbit also measures the heartrate. The data of these devices will be collected at each measurement session, so the subjects do not have to have access to the internet.

For this study, the following patient information will be gathered from the orthopaedic surgeon or the principal investigator:
- Biometrics of the subject
- Comorbidities
- Details of the surgical intervention and type of implant.
- Medication during and after surgery.
- Questionnaire about expectation from the surgeon about the physical activities possible for the patient 3 months after the surgery (see folder F. vragenlijsten).

Intervention

- Answer questionnaires
- perform ADL, while wearing multiple sensors on the body.
- wear an activity monitor (Fitbit) and the optional mobile phone with application at home.

Study burden and risks

No significant risks or immediate benefits are expected for the participants. A potential small risk consists of skin irritation due to the wearing of the activity monitor or the ECG-patch. This risk is mitigated with the exclusion criteria and the instructions of the researcher for using the activity monitor. The additional burden for the subjects consists of: the time it takes to carry out the measurements (approx. 45 min per session) and the time it takes to travel to the hospital for 3 additional appointments. The traveling expenses

will be reimbursed.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- patient with knee osteoarthritis undergoing primary total knee replacement of one knee within 3 months.
- age > 18 years
- informed consent
- willing to travel to hospital for 3 additional visits

Exclusion criteria

a) Subjects with an artificial joint/limb in the lower body.
b) Subjects diagnosed with and/or taking medication for any musculoskeletal, neurological disorder or inflammatory arthritis.
c) Subjects who are pregnant or likely to become pregnant
d) Subject with known allergy to adhesive Ag/AgCl electrodes
e) Subjects using medication with phototoxic side effects: Tetracylines, Doxycycline, Phenothiazines, Dacarbazine, Ketoprofen, Lomefloxacin. In order to exclude possible local skin irritation from prolonged irradiation by LED-light (from activity monitor).
f) Patients that do not want to be informed in case of incidental findings.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2019
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL67391.015.18