A prospective Randomized Single Blinded Clinical Study on TKA with and without Orthosensor

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON40578

Source
ToetsingOnline

Brief title
orthosensor study

Condition

- Bone and joint therapeutic procedures

Synonym
knee prostheses, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: BioMet,Stichting Ahorse Orthopaedie Atrium MC Parkstad

Intervention

Keyword: orthosensor, total knee arthroplasty

Outcome measures

Primary outcome

The primary outcome parameter is determined based on the main research question, which is *to assess patient outcome in TKA cases with OrthoSensor in comparison to TKA cases without using OrthoSensor*. Patient outcomes in this study include X-ray assessment, patient satisfaction, pain and function as measured by PROMS and objective outcomes as measured by sensor technologies (IMA and AM). The parameters produced by IMA and AM output are considered the most relevant outcome parameters, because they are objective, not dominated by pain and have previously been indicated as having high discriminative and diagnostic power to differentiate patients with end stage osteoarthritis from healthy subjects (23,24). From the sensor parameters, the walking speed is the most relevant. Recent studies showed that the walking speed is a powerful parameters as walking speed has the highest discriminative power in differentiating subjects with knee limitations from healthy subjects (23). In addition walking speed has previously been associated with general health and well being (19-22). Since the step frequency is 1) highly related to the walking speed, 2) easier to derive from IMA as it does not require the exact walked distance to be calculated (in contrast to walking speed) and 3) also derived from AM measurements, the step frequency is used as most important and clinically relevant outcome measure. The main study parameter used in this study is the step frequency.

Moreover the power calculation of this study is based on previous results using the step frequency as variable.

Secondary outcome

1. Perceived function, measured using KOOS-PS, New-KSS, FJS

2. Patient satisfaction measured using New-KSS

3. Pain measured usingNew-KSS

4. objectively measurde function: IMA Gait test (Step length, Step time asymmetry, Step time variability, Pelvic obliquity), IMA Sit-stand test (Bending angle), IMA Block step test (Asymmetry pelvic obliquity).

5. physical activity measured with AM: Quantity (# steps, # transfers, # walking bouts, # stair climbing events), duration (Duration walking, Duration sitting, duration standing, Duration high intense activities), quality (Intensity of activities, Distribution of walking bouts, Distribution of sitting events)

6. Prevalence of radiolucency, Location of radiolucency, Osteolysis as measured on X ray

Study description

Background summary

Nine percent of all knee replacements performed, are for a revision due to complications. Nearly half of all knee revisions can be attributed to a cause that may be prevented with correct ligament balancing. A balanced knee has many postoperative advantages. It contributes to improved alignment and stability. In addition ligament balancing helps to reduce polyethylene wear and aseptic loosening of the joint. In addition a patient with a balanced knee is more likely to have increased range of motion and proprioception and decreased pain. All these factors help to minimize the need for revision surgery. A balanced

knee can be achieved by correct ligament balancing. Different techniques (e.g. measured resection, balanced resection) and sequences for ligament release have been reported over the last years. However currently there is no consensus regarding the best method to produce a balanced knee (5).
Recently a new knee balancing system, able to address and quantify instability in TKA, the so called *OrthoSensor* VERASENSE**, has been introduced by Biomet. The Orthosensor is a trial bearing designed for use with the Vanguard® Complete Knee System, which is embedded with sensors and microelectronics to provide surgeons with quantifiable, real-time intra-operative data on soft-tissue balancing and kinetic tracking, through an uninterrupted surgical workflow to allow for personalized soft-tissue adjustments. The sensors wirelessly transmit information to a graphic display, allowing surgeons to quantify soft-tissue loads throughout the range of motion. This enables the surgeon to make informed adjustments to the soft tissues and implant placement in order to allow for overall knee balancing. Combining Biomet*s Vanguard ® Knee System with the OrthoSensor is aimed to take knee replacement surgery to a new level of precision by providing surgeons with actionable, intraoperative data to quantify and verify that they balance a knee implant properly during total knee replacement surgery.

Hypothesis: TKA with orthosensor results in a faster recovery and better clinical outcomes during short follow up compared to TKA without OrthoSensor.

Study objective

The current study evaluates the OrthoSensor and investigates whether the combination of the Vanguard® Knee System with the OrthoSensor results in a faster recovery and better clinical outcomes during short follow up compared to conventional TKA (Vanguard ® Knee System without Orthosensor).

The primary objective of this study is to assess patient outcomes in TKA cases with OrthoSensor in comparison to TKA cases without using OrthoSensor. The assessment will include postoperative recovery, radiography, patient satisfaction, pain and function.

The secondary objectives of the study is to establish correlations between intra-operative information related to the use of OrthoSensor parameters and patient outcomes.

Study design

This study is a prospective randomized blinded clinical study and will be carried out at the Atrium MC Heerlen, dept. Orthoapedic Surgery & Traumatology. Patients will be assigned a study number, blinded for the investigator. These study numbers will be randomized with the use of computer-generated random numbers (www.randomizer.org). In this way patients are assigned to one of the

two groups: one group receiving TKA with OrthoSensor and one group receiving TKA without OrthoSensor. In total 150 patients will be included and participate for a study period of 2 years.
Measurements will be performed at baseline and 6 weeks, 3 months, 6 months, 1year and 2 years after surgery. The measurements consist of written questionnaires and sensor-based motion measurements.

Intervention

The intervention concerns the use of the OrthoSensor by the surgeon during TKA.

OrthoSensor VERASENSE** has recently be introduced by Biomet. It is a trial bearing designed for use with the Vanguard® Complete Knee System. The OrthoSensor is embedded with sensors and microelectronics to provide surgeons with real-time knee kinetic data. The sensors wirelessly transmit information to a graphic display, allowing surgeons to quantify soft-tissue loads throughout the range of motion.

Description of the OrthoSensor:
The Kinetic Knee Balancer:
- Two articulations: Vanguard CR & PS
- Three Sizes: 63/67, 71/75, 79/83
- Five thicknesses: 10-18mm (through the use of different shims)

The graphic user interface:
- Housed on a LINK station which includes 27in iMac Screen, Keyboard, Mouse, Barcode scanner, and a magnet
- Designed to show the surgeon the
o M/L Load: - Central contact point of the load for each condyle
- Numerical and visual representation of average load
Dispersed
o Kinematic tracking
o Tray rotation
o Tiabial A/P slope
o Tibial Varus/valgus tilt

The intervention will not interfere with the usual treatment. The intervention from this study will not be a substitute for the care. Postoperative treatment is similar for the intervention group and control group. The only difference is the use of the OrthoSensor during surgery.

Study burden and risks

As in any surgical procedure, certain risks are associated with total joint arthroplasty. These risks include but are not limited to: anaesthetic and post-anaesthetic reactions (such as hyperaemia), allergic reactions to

prophylactic antibiotics or blood transfusions, damage to blood vessels or nerves or death. Post-operatively, a patient may experience thrombophlebitis, pulmonary embolus, dislocation, pain, limp, component loosening, osteolysis due to wear debris or the need for additional surgery. Fracture of the prosthesis is a potential complication.
As all patients recruited for this study are indicated for primary total knee arthroplasty with the device described in the protocol anyway, there is no known risk associated with participating in this study.

Pre-clinical, clinical, and mechanical testing of the used implants indicate that the above mentioned risks should not occur at a rate greater than that for any other type of total knee arthroplasty reported in the literature.

Since the hypothesis of this study is *TKA with OrthoSensor results in a faster recovery and better clinical outcomes (measured by radiography, patient satisfaction pain and function) during short follow up compared to TKA without OrthoSensor, patients may benefit from participation, when they are allocated to the intervention group. So patients operated with the use of the OrthoSensor may have less pain (high new KSS), may be more satisfied (higher new KSS subscore), may have better function (e.g. higher step frequency (IMA), lower KOOS-PS, more daily activity (AM)) and may have better outcomes on radiographs than the control group.

The measurements take place during the standard controls to the specialist. Patients do not need to travel extra. We only ask 10-15minutes extra or their time, after they have visited the specialist. In addition, patients are asked to wear an activity monitor (size of a USB stick) for 4 successive days. The activity monitor does not interfer with daily activities. A pilot study even showed that subjects did not experience the activity monitor as a burden.

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

- Patients diagnosed with osteoarthritis and indicated for TKA
- Patients treated prospectively with the Vanguard Total Knee System
- Patients providing informed consent

Exclusion criteria

- Age > 75 yrs
- BMI > 35
- Extreme varus valgus
- Patients who had a TKA on contra lateral side within the last 1 year
- Patients who will need lower limb joint replacement for another joint within one year
- Patients who require revision of previously implanted TKA
- Poor medical condition (e.g. patients with malignancy)
- Cognitive problems
- Language problems
- Patients diagnosed with rheumatoid arthritis, posttraumatic arthritis
- Not being eligible for being included due to any other medical conditions as decided by the ortopaedic surgeons of the Atrium MC

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	150
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-05-2014
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL47062.096.13