Functional Outcome of Vanguard XP vs CR: a single centre randomized controlled trial using three dimensional fluoroscopic analysis

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Ethical review	Approved WMO
Status	Completed
Health condition type	Tendon, ligament and cartilage disorders
Study type	Interventional

Summary

ID

NL-OMON50747

Source
ToetsingOnline

Brief title
Functional Outcome of Vanguard XP vs CR

Condition

- Tendon, ligament and cartilage disorders

Synonym
osteoartritis; joint wear

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Biomet Nederland B.V. ; de follow-up studie zal uit eigen middel van de Research Afdeling Orthopedie van de Sint Maartenskliniek worden gefinancieerd.

Intervention

Keyword: Arthroplasy, Bicruciate retaining, Knee, Osteoartritis

Outcome measures

Primary outcome

The posterior femoral rollback (i.e. translation) in mm from 30° flexion to 0° extension during the step-up test.The endpoint of this parameter is set at one year post-operative. This will be measured using MCM-based RFA (p18 in the protocol).

Secondary outcome

•the total anterior femoral rollback in mm from 0° extension to 90° flexion during the lunge test. This will also be done by using MCM-based RFA

•3D migration (i.e. translation and rotation) in mm of the tibial and femoral component of the implant up and until 2 years (7.5 years for follow-up), using model-based radiostereometric analysis (MB-RSA, p19 protocol)

•Lateral femoral lift-off in mm at 90° knee flexion during lunge test using MCM-based RFA.

•AP laxity of knee in mm from anterior to posterior using a rolimeter

•Functional power output of the leg using the Leg extension power rig

•Patient and Clinician Reported Outcome Measures (PROMS and CROMS)

•Operative information

Study description

Background summary

Total knee arthroplasty (TKA) is one of the most successful orthopedic operations, especially in terms of pain reduction and survival. Currently, two types of TKA design are the most common: the cruciate retaining (CR) TKA and the posterior stabilized (PS) TKA. The literature has shown mixed results concerning recovery of knee kinematics after placement of CR and PS TKAs. In contrast to TKA designs where one or both cruciate ligaments is removed, a bi-cruciate retaining (BCR) TKA can be hypothesized to lead to better functional outcome. A recent developed BCR TKA is the Vanguard XP (Biomet, Inc., USA). However, to date functional outcome of the Vanguard XP has not been properly studied to warrant this as a standard procedure.

Study objective

The primary objective is to compare the Vanguard XP with a CR TKA in terms of kinematics during functional tests using 3D fluoroscopy. The secondary objective is to compare both TKAs in terms of 3D migration of the prosthesis up until 2 years post-operative. With the follow-up study we want to investigate whether the micromotion between the BCR TKA and the bone stabilizes over time, from 2 until 7.5 years post-operative.

Study design

A single blind randomized trial with two groups (BCR vs CR).

Intervention

CR or BCR TKA (Vanguard System, Biomet, Inc., USA).

Study burden and risks

The extra amount of time over the two years that a patient invests in the study is about 11 hours (+2.5 hours for the follow-up participants). There is no additional risk other than the regular risks for a surgery of a primary TKA.
The questionnaires and physical examinations of the knee do not bring any extra burden and the additional radiological assessments have a total amount of radiation that leads to a very small extra risk.

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 non-inflammatory knee osteoarthritis, which is confirmed by radiology.
•Osteoarthritis is unilateral of bilateral with the contralateral knee functioning properly, not operated on in the last 6 months and not planned for TKA in the coming 2 years.
•Patient is set to receive a primary cemented total knee arthroplasty.
•Age between 40 and 75 years, inclusive.
•Patient plans to be available for follow-up until two years post-operative.
•Patient is in stable health (ASA-score <= 3) and is free of or treated for cardiac, pulmonary, haematological, or other conditions that would pose excessive operative risk.
•Patient has a correctable or <10º rigid (non-correctable) varus or valgus

deformity of the knee.
•Participants must be able to give informed consent and be cognitively intact.

Exclusion criteria

•Patient has a BMI > 35.
•Patient's expected physical activity after surgery is 2 or less on the UCLA Activity Scale.
•Patient has had previous hip replacement surgery in the last 6 months, or is planned to have a hip replacement in the next 6-12 months (because of the effect on function).
•Patient has had major, non-arthroscopic surgery to the study knee, including HTO.
•Patient has an active, local infection or systemic infection
•Prior high-energy trauma to the affected knee or prior history of anterior and/or posterior cruciate ligament rupture.
•Suspicion of anterior and/or posterior cruciate ligament rupture at clinical examination.
•Documented osteoporosis with patient in active medical treatment.
•Patient has an active, local infection or systemic infection.
•Patient has physical, emotional or neurological conditions that would compromise compliance with post-operative rehabilitation and follow-up.
•Bone quality compromised by disease, infection or prior implantation which cannot provide adequate support and/or fixation to the prosthesis
•Severe instability of the knee joint secondary to the absence of collateral ligament integrity and function
•Patient has knee flexion < 90 degrees
•Patient has fixed flexion deformity >10 degrees (passive extension lag)
•Patient has > 30 degrees extension deficit (active restraint to extension)
•Patient does not have a proper functioning patella tendon on the affected side; measured as inability of active extension of the knee
•Patient has quadriceps weakness on the affected side; score on MRC scale < 4
•Patient has rheumatoid arthritis, any auto-immune disorder, immunosuppressive disorder or a terminal illness.Intraoperative Exclusion
•If the anterior and/or posterior cruciate ligament are found missing or totally ruptured at direct intraoperative visualization. Patients excluded at this point will receive a CR prosthesis when PCL is retained or an anterior stabilized bearing prosthesis when the PCL is absent.(c) =

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	02-11-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Vanguard XP (bicruciate retaining total knee artroplasty)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-09-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	31-03-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-12-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL54336.048.15