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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25871

Source
Nationaal Trial Register

Brief title
FOX

Health condition

Patients receiving a primary total knee with a functional anterior cruciate ligament.

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Biomet Nederland B.V.

Intervention

Outcome measures

Primary outcome

To quantify the kinematics during functional tests the posterior femoral rollback (i.e. translation) in mm from 30° flexion to 0° extension during the step-up test will be measured. The endpoint of this parameter is set at one year post-operative.

Secondary outcome

• The kinematics during functional tests are also quantified by measuring the total anterior femoral rollback in mm from 0° extension to 90° flexion during the lunge test.

• 3D migration (i.e. translation and rotation) in mm of the tibial and femoral component of the implant referenced to the bone.

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

• AP laxity of the knee in 20° and 90°, 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)

Study description

Study objective

By retaining both cruciate ligaments with a bicruciate retaining total knee prosthesis will result in better post-operative knee kinematics and functionality.

Study design

The patients included in the study will be seen at several moments: pre-operative, operation/direct post-operative, and 3 months, 6 months, 1 year and 2 years post-operative.

Intervention

Participants will be randomly assigned to receive either the cruciate retaining or bicruciate retaining TKA both of which are commercially available and have a CE mark (Vanguard System, Biomet, Inc., USA).

Contacts

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Eligibility criteria

Inclusion criteria

• Patient with non-inflammatory knee osteoarthritis, which is confirmed by radiology.

• Osteoarthritis is unilateral or 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, on the day of the operation.

• 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 <10° rigid (non-correctable) varus or valgus deformity of the knee.

• Participants must be able to give informed consent.

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 physical, emotional or neurological conditions that would compromise compliance with post-operative rehabilitation and follow-up.

• Bone quality compromised by disease or infection 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 measured by research nurse

• Patient has rheumatoid arthritis, any auto-immune disorder, immunosuppressive disorder or a terminal illness.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2015
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-12-2015
Application type:	First submission

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
NTR-new	NL5399
NTR-old	NTR5524
Other	NL54336.048.15 : 610

Study results

Summary results
n/a