Flexion with the Journey II BCS Total Knee System.
A Prospective, Non-randomized, Consecutive Series, Observational Study.

Published: 05-03-2014
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The primary objective of the study is to investigate the maximal flexion ability of the Journey II BCS total knee system one year after surgery. The secondary objective is to assess patient satisfaction, clinical, functional and radiological...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON40614

Source
ToetsingOnline

Brief title
Flexion with the Journey II BCS Total Knee System

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
cartilage damage, osteoarthrosis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Smith & Nephew Orthopaedics AG

Intervention

Keyword: Journey II BCS, Maximal flexion, Total Knee Arthroplasty

Outcome measures

Primary outcome

Maximal passive knee flexion measured on a lateral X-ray one year after

surgery.

Secondary outcome

Clinical, functional and radiological performance as measured with: active

flexion (lying and standing), KSS, EQ-5d, KOOS, Kujala, Forgotten Knee Score,

VAS Satisfaction, number and type of Adverse Events, Hip-Knee-Ankle angle,

Patellar tilt & displacement.

Study description

Background summary

The Journey II BCS claims a renewed right to an active lifestyle by delivering unmatched function, motion and durability through natural motion in TKA. Natural motion will result into high flexion ability. The range of knee flexion and maximum knee flexion influences a patient*s ability to perform important activities of daily living and may therefore directly influence overall quality of life. When this new knee system will facilitate a high knee flexion, this will be depicted in a superior knee function. In addition, a high flexion ability will result in high clinical and functional outcome scores and high patient satisfaction.

Study objective

The primary objective of the study is to investigate the maximal flexion

ability of the Journey II BCS total knee system one year after surgery.
The secondary objective is to assess patient satisfaction, clinical, functional and radiological performance up to two years.
The ultimate goal is to compare the clinical and functional results of this cohort with the cohorts in the Journey I BCS and Genesis II RCT.

Study design

A prospective, non-randomized, consecutive series, observational study.

Intervention

Journey II BCS total knee system, including patella resurfacing.

Study burden and risks

Patients participating in this study will not being barred by any additional risk other than the regular risks for a surgery of a primary TKA. The patients will visit the clinic at regular follow-up moments up to one year, and will receive a reimbursement for the two year visit. These visits take ±30 min extra than regularly because at these moments the patient visits also the research nurse for data collection. The questionnaires and physical examinations of the knee do not bring any extra burden. The additional radiographic assessment (long leg X-ray at 3 months and X-rays at two year visit) increases the total amount of radiation only slightly. However, the total amount of radiation falls within the limits of the ICRP (International Commission of Radiological Protection).

Contacts

Public
Sint Maartenskliniek

Oberneuhofstrasse 10d
Baar 6340
NL
Scientific
Sint Maartenskliniek

Oberneuhofstrasse 10d
Baar 6340
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Patient presents with non-inflammatory knee osteoarthritis (radiologically confirmed), requiring total knee arthroplasty
• Patient is 40 to 70 years of age, inclusive
• Patient plans to be available for follow-up through two years postoperative
• Patient is in stable health and is free of or treated for cardiac, pulmonary, haematological, or other conditions that would pose excessive operative risk
• Patient has <10 degrees fixed (non-correctable) varus or valgus deformity
• Orthopaedic surgeon is member of the Knee Reconstruction Unit SMK

Exclusion criteria

• Patient is known to have insufficient femoral or tibial bone stock
• 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 or knee replacement surgery in the last 6 months
• Patient is planned to have additional hip or contralateral knee replacement in the next 6 months
• Patient has had major, non-arthroscopic surgery to the study knee, including osteotomy around the knee
• Patient has an active, local infection or systemic infection
• Patient has physical, emotional or neurological conditions that would compromise compliance with postoperative rehabilitation and follow-up
• Patient has grade 3 collateral ligament insufficiency (complete tear of ligament)
• Patient has knee flexion <90 degrees
• Patient has fixed flexion deformity >10 degrees
• Patient has rheumatoid arthritis, any autoimmune disorder or immunosuppressive disorder
• Patient is pregnant or plans to become pregnant during course of study

• Patient has a known sensitivity to materials in the device and/or cutting blocks
• Patient has >30 degrees extension deficit

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-10-2014
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

Date:	05-03-2014
Application type:	First submission
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	NL47198.048.13
Other	wordt in NTR geregistreerd

Study results

Date completed:	10-01-2018
Actual enrolment:	62