A 10 year retrospective clinical study on the balanSys bicondylar total knee endoprosthesis.

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The primary goal of this study is to determine the 10-years results of at least 50 balanSys TKA patients with respect to clinical and radiological outcome.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON36144

Source
ToetsingOnline

Brief title
balanSys 10 years

Condition

- Bone and joint therapeutic procedures

Synonym
osteoarthritis, primary total knee replacement

Research involving
Human

Sponsors and support

Primary sponsor: Mathys Medical Ltd
Source(s) of monetary or material Support: Mathys Ltd Bettlach;Switzerland

Intervention

Keyword: balanSys, endoprosthesis, knee

Outcome measures

Primary outcome

The primary goal of this study is to determine the 10-years results of at least 50 balanSys total knee arthroplasty (TKA) patients with respect to clinical and radiological outcome. To achieve these goals physical examination, knee and VAS scores, radiological evaluation, subjective questionnaire (KOOS) and a survival analysis are used.

Survival analysis

Parameters of the clinical and radiological evaluation are:

• Range of motion (flexion and extension deficit)

• Anterior-posterior laxity

• KSS and KOOS

• VAS pain and satisfaction

• Position of the implant

• Radiolucencies

Secondary outcome

Furthermore, a safety analysis including complications and a survival rate of this prosthesis will be made.

Complications:

- excessive migration of one of the two components

- trauma

- revision

- mobilisation under anaesthesia

- infection

- patella(sub) luxation

Study description

Background summary

For several decennia, different types of total knee arthroplasty (TKA) are used as implants for osteoarthritis or rheumatoid arthritis knees. This is done with very good results. Decreasing pain and increasing functional abilities of daily life, like walking and climbing stairs, are important aims of a TKA. Many new prostheses have been developed since that time due to a growing demand of functionally good prostheses. They differ from each other with respect to their geometrical design and degree of joint stability. However, industries keep searching for even better prostheses with respect to achieved functioning, stability and survival rates.
In 1998 Mathys Ltd Bettlach (Bettlach, Switzerland) introduced the first type of TKP (balanSys bicondylar endoprothesis) that is implanted with a ligament-referenced technique instead of a bone-referenced technique. Hypothetically this should optimize the tensioning of the ligaments around the knee and improve the knee stability in extension as well as in flexion during daily activities as walking and stair climbing.

Study objective

The primary goal of this study is to determine the 10-years results of at least 50 balanSys TKA patients with respect to clinical and radiological outcome.

Study design

This study is performed as a cross-sectional design by retrospectively evaluating the first series of balanSys total knee prostheses implanted during the period 1998 till 2003 in our clinic. It is an internal quality control of a CE-marked prosthesis 10 years after the introduction.

Study burden and risks

The patients will visit the clinic for a (standard) clinical and radiological examination. We think that there are no risks for the patients in participating in this study.

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 that received the first series of the BalanSys bicondylar total knee endoprosthesis during the period of 1998 till 2003. Patients are identified through the hospital database.

Exclusion criteria

Patients who refuse to visit the hospital for the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-09-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL37085.072.11