

PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Influence of patient-related characteristics on early migration in calcar-guided short-stem total hip arthroplasty: A two-year migration analysis using EBRA-FCA

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Implant migration of a modern total hip prosthesis was assessed using a Computer assisted technique in a two year follow-up. Full weight-bearing was allowed directly after surgery. Patients were divided into groups regarding gender, age, weight, BMI and offset version. Influence of Patient related characteristics on subsidence was assessed. Clinical Scores were analyzed.

Brief Summary in Scientific Language

Short-stems have gained popularity in THA over the last years. Because of excellent clinical results, indications have been expended to young but also elderly and obese patients. However, long-term results are lacking. The purpose of this study was an evaluation of the influence of gender, age, weight, body mass index (BMI) and offset version of the stem on short-stem migration in correlation to the clinical outcome.

Implant migration of metaphyseal anchoring, calcar guided short-stems was assessed by "Einzel-Bild-Roentgen-Analyse" (EBRA-FCA, femoral component analysis) in a two year follow-up. Full weight-bearing was allowed directly after surgery. Patients were divided into groups regarding gender, age, weight, BMI and offset version. Influence of Patient related characteristics on axial subsidence was assessed. Harris Hip Score (HHS) and satisfaction on visual analogue scale (VAS) were analyzed.

Organizational Data

- DRKS-ID: **DRKS00009834**
- Date of Registration in DRKS: **2015/12/30**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**



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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **323/13 , Ethik-Kommission der Universität Ulm**

Secondary IDs

Health condition or Problem studied

- ICD10: **M16.1 - Other primary coxarthrosis**
- ICD10: **M16.7 - Other secondary coxarthrosis**

Interventions/Observational Groups

- Arm 1: **Retrospective analysis of axial subsidence of 216 implanted short-stem THA (optimys, Mathys Ltd. Bettlach) using EBRA-FCA Software on postoperative radiographs.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Axial Subsidence of Short-Stem (measured in mm by EBRA-FCA Software on postoperative radiographs) postoperatively, after 6 weeks, after 6 months, after 12 months, after 24 months.

Secondary Outcome

Patient related influences on subsidence (statistical Analysis of clinical data in regard to axial subsidence) + Clinical Scores (Harris Hip Score (HHS) and satisfaction on visual analogue scale (VAS)) during follow-up mentioned above.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **St. Josefs Hospital Wiesbaden, Wiesbaden**
- Medical Center **Universitätsklinikum Ulm, Orthopädie, Ulm**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/03/15**
- Target Sample Size: **216**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

a minimum follow-up of two years; a series of at least three consecutive standardized radiographs accepted by the EBRA-FCA software and acceptance of the direct postoperative and the 24 months follow-up radiograph.

Exclusion criteria

Missing consent

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ Commercial (pharmaceutical industry, medical engineering industry, etc.)

**Mathys Ltd., Bettlach
Robert Mathys Str. 5**

Commercial (pharmaceutical industry, medical engineering industry, etc.)

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Switzerland

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Fax: [---]*

E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/11/03**

Trial Publications, Results and other documents

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.