ISRCTN54967983 https://doi.org/10.1186/ISRCTN54967983

Periprosthetic bone mineral density (BMD) around two different stems in total hip arthroplasty

Submission date
06/08/2010

Recruitment status
No longer recruiting

Registration date
18/08/2010

Overall study status
Completed

Last Edited
18/08/2010

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Study information

Scientific Title
Periprosthetic bone mineral density (BMD) around two different stems in total hip arthroplasty: an observational longitudinal study

Study objectives

To monitor the bone mineral density (BMD) around a well known approved femoral implant and a new short stem design femoral implant. The data is used to validate a finite element model of both implants.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee approved on the 23rd May 2006 (ref: 4226)

Study design
Observational longitudinal study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Osteoarthritis of the hip

Interventions
In all patients the Metha short stem (monoblock with 130° CCD angle and 0° ante-, retrotorsion) or the Bicontact stem (AESCULAP AG, Tuttlingen, Germany) was implanted by three experienced senior surgeons over a standard lateral approach in supine position. The cementless short stem implant is made of a titanium forged alloy and has a proximal rough titanium micro-porous coating. An additional 20 µm dicalciumphosphate layer is applied electrochemically. The stem is anchored metaphyseally within the closed ring of the femoral neck. The Bicontact stem is designed for proximal fixation and load transfer to bone. According to the implant design and the Plasmapore-coated proximal part the secondary implant stability is achieved by proximal anchoring and cancellous bone ingrowth. Pre-operatively, 1 week after surgery, 6 month and 12 month after implantation the patients were examined clinically (Harris Hip Score) and underwent DXA examinations.

All patients underwent full weight bearing post-operatively. DXA scans were performed using a HOLOGIC Discovery A S/N 80600 device (Hologic Inc., Waltham, MA). The BMD (g/cm2) of the operated hip was measured using the "metal-removal hip" scanning mode. Conventional Gruen's zones were adapted to the short stem design. Each patients individual ROIs were saved on the Hologic system and were used for all following measurements to reduce bias. The images were analyzed using the dedicated Windows analysis software (version 11.2). The patients were placed in supine position with the affected leg in 20° internal rotation. The foot was secured in the Hologic foot positioning device in order to obtain reproducible rotation in all patients to limit measurement errors, since it has been demonstrated that rotation influences the BMD.

DXA precision was assessed on all subjects. The patients underwent sequential DXA examinations of the contralateral unoperated hip and the proximal femur - taken preoperatively and one week later. Additional quality controls were done every morning for the DXA equipment according to the manufacturer's guidelines, to verify the stability of the system, and did not show any shift or drift during the entire study period. The device used in our study was

therefore chaacterised as stable. The same observer (ML) analysed all DXA examinations. A Student's t-test was used to test the hypothesis of a difference between the means at the different measurement time points in the Harris hip Score as a normal distribution was ascertained. The Shapiro-Wilk-tests did not show a normal distribution in the DXA measurements, the Wilcoxon signed-ranks test was used to statistically compare the density changes over one year. A $p<0.005$ was considered significant. Data analysis was performed with SPSS (11.05 SPSS Inc. Chicago, Illinois). After two years the Bicontact branch was ended, but the Metha branch will continue for additional two years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
BMD (g/cm^2) in Gruen Zones 1 - 7 per DEXA, measured 1 day pre-operatively, and 1 week, 6 months, 1 year, 2 years, 3 years and 4 years post-operatively.

Key secondary outcome(s))
Harris Hip Score per questionaire and clinical examination, measured 1 day pre-operatively, and 1 week, 6 months, 1 year, 2 years, 3 years and 4 years post-operatively.

Completion date
31/12/2014

Eligibility

Key inclusion criteria
1. Indication for unilateral implantation of the Bicontact stem or the Metha short stem due to osteoarthritis of the hip
2. Patients' ages between 35 and 70 years of either sex
3. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Manifestly overweight (body mass index [BMI] greater than 35 kg/m^2)
2. History of previous surgeries on the same hip
3. Femoral fractures

4. Metabolic bone diseases
5. Use of steroids or other drugs affecting bone metabolism
6. Intraoperative cracks
7. Severe osteoarthritis of the contralateral hip
8. Received total hip arthroplasty (THA) on the contralateral hip during the study period
9. Patients in whom an event leading to restricted weight bearing on the ipsi- or contralateral hip occurred

Date of first enrolment
01/06/2008

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Orthopädische Klinik Medizinische Hochschule Hannover im Annastift
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Sponsor information

Organisation
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany)

ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: SFB 599, D6)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration