CT analysis of the acetabular bone density behind the isoelastic RM press fit cup: Answer for prevention of stress shielding.

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The pattern of BMD behind the press fit isoelastic acetabular component during the two years after implantation.

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON31842

Source
ToetsingOnline

Brief title
Prevention of stress shielding through isoelasticity.

Condition

- Bone and joint therapeutic procedures

Synonym
failure of the acetabular prosthesis, stress shielding

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Mathys AG;Betlach Zwitserland,Mathys

Medical

Intervention

Keyword: acetabular, CT, isoelasticity, stress shielding

Outcome measures

Primary outcome

The main study parameter is bone mineral density (BMD). BMD is determined as

the mean mineral content (g/cm3) on a CT, measured in a zone of interest.

Measurements are performed 1 week post operative , 6 months and 2 year

(primairy endpoint) post operative.

Secondary outcome

Osteolyses, pain, functional outcome and adverse effects.

Study description

Background summary

The two types for fixating a THA are: cemented and non-cemented. During the last decades both types of fixation have undergone many modifications to optimize the primary en secondary (long term) fixation. Because of the developments in medicine the patients who require a THA are getting younger, live longer therefore necessitating THA revisions.
The main cause for THA revision is aseptic loosening. The acetabular part of the THA has been largely overlooked because of the femoral problems during the last 30 years. Now the acetabular part is being extensively studied to optimise the life expectancy of the acetabular component. Attention has been diverted, after solving the fixation problem, to the insert material and the retro acetabular stress shielding principle.

Wolff's law states that bone in a healthy person or animal will adapt to the loads it is placed under. If loading on a particular bone increases, the bone will remodel itself over time to become stronger to resist that sort of loading. The converse is true as well: if the loading on a bone decreases, the bone will be adapted and become weaker.
The definition of stress shielding reads: Osteopenia occurring in bone as the

result of removal of normal stress from the bone by an implant. Metal backed cups have an elastic modulus which is much lower in comparison with acetabular bone. This difference leads to a non physiologic distribution of compressive forces behind the acetabular cup. Peripheral rim overloading due to the rigidity of the cup results in bone mineral density (BMD) elevation in the peripheral zones and BMD decline in the retroacetabular zone behind the cup (Wright et al 2001). The elastic modulus of PE lies closer to that of the acetabular bone. This proximity results in a more physiologic load transfer trough the acetabular cup resulting in none / less stress shielding in the entire retroacetabular region.

Finite element models (FEM) have provided data concerning the retroacetabular BMD decline (Weinans 1993, Huiskes 1987). At this time further FEM studies are undertaken to investigate the rate and ROI of stress shielding in press fit isoelastic acetabular components (this PhD thesis). The precise development of aseptic loosening from stress shielding is only theoretical; the numbers of published articles are increasing pointing towards the possible clinical relevance. (Cambridge group Field et al 2006, Pitto et al 2006). Sabo et al 1998 points to the sequence of lowering of BMD and implant failure for CLS femoral implants.

Study objective

The pattern of BMD behind the press fit isoelastic acetabular component during the two years after implantation.

Study design

Prospective cohort clinical trial with 25 patients, included within 1 year at a rough estimate.

Intervention

Placement of the press fit RM acetabular cup in cojoint with the CLS Spotorno uncemented femoral stem.

Study burden and risks

BMD measurements can be performed using duel energy X-ray absorptiometry (DEXA), computer tomography (CT) has been adopted to provide higher resolution and 3D femoral and acetabular BMD measurements. Differentiation between cortical and cancellous bone provide a better insight into the BMD. The disadvantage of a higher radiation dose has been mentioned, however modern techniques and selecting ROI*s lower the dose to approximately 0,5 -1,0 mSv. Our own estimation (measured during a simulation) of radiation dosage during this study is 1-2 mSv per CT scan. The mean background radiation dosage which a

normal functioning persoon will endure each year is 2.5 mSv (Health Council of the Netherlands 2007). We believe that there are no adjuvant risks concerning the radiation dosage during this study. A relative risk analysis shows that decreasing risk for adverse effects due to radiation dossage with the aging of the patient. Because our patient selection is made up of patients with primairy OA of the hip we believe that there are no adjuvant risks.
The RM press fit cup is a proven prosthesis which is beeing used in many countries throughout Europe.

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

Patient selection:
- Unilateral THA

- Diagnosis: primary osteoarthritis (OA)
- No heterolateral complaints / symptoms fitting OA
- Patients should be - Informed consent should be given

Exclusion criteria

Exclusion criteria*s:
- No bone metabolism diseases
- No anti osteoporotic supplements and oestrogen medications
- Previous acetabular operative reconstructions (Bilateral)
- Post operative complications such as infections, recurrent luxations, acetabular fractures, non compliance with normal post operative care / rehabilitation program.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO

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	NL19766.091.07