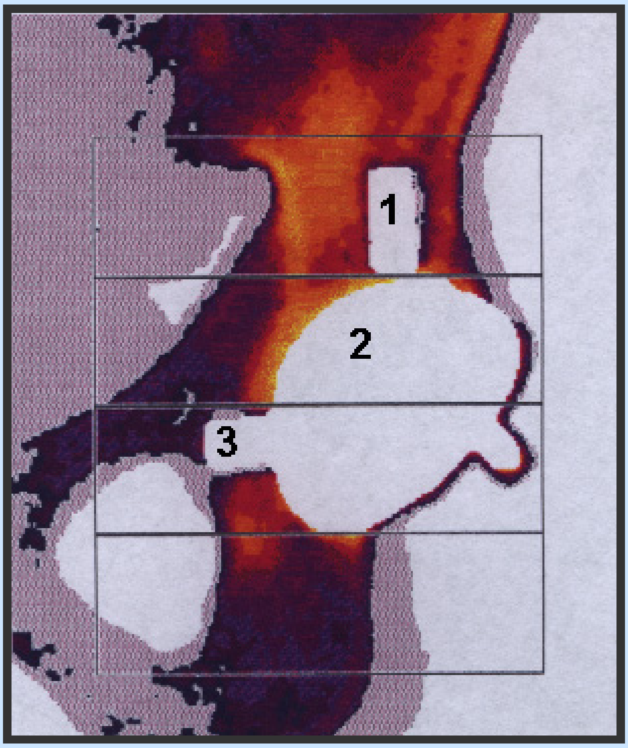
DEXA-scanning in description of bone remodeling and osteolysis around cementless acetabular cups

PhD Thesis

Mogens Berg Laursen



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Bone remodeling around HA-coated acetabular cups.

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Acta Orthopaedica.

Under review 06/2005.

Abstract

Introduction

Hip-revision surgery is frequently complicated by unexpected periacetabular osteolysis. Preoperative x-rays normally do not reveal sufficient information about the amount of osteolysis, but in the course of the operation, huge localized osteolytic lesions in the pelvic bone may appear. X-ray examinations often underestimate the extent of osteolysis, and CT-scans have not yet overcome the metal artifacts and high radiation doses to evolve into a useful tool in this matter.

Wear-particles from polyethylene are suspected to play a role in the development of osteolysis. HA-coating of implants seems to reduce the risk by sealing off the bone-implant interface.

DEXA-scanning has proven a sensitive tool in the assessment of bone mineral changes around femoral stems, and tibial plateaus. However, only few studies have focused on the bone mineral changes around acetabular components.

The aim of the present studies was to utilize DEXA-scanning as a simple tool to determine periacetabular osteolysis and to quantify the extent of osteolysis, including estimation of precision and accuracy of such a measure. Furthermore, a randomized controlled trial was conducted in order to study the effect of HA coating on bone mineral density changes around cementless acetabular components.

Material and Methods

To test reproducibility and accuracy of a certain scanning model and to elucidate how a difference in patient posture affected the result; we conducted a study with ten patients in each of three groups. We scanned to assess the influence of time since surgery, the difference between scanning in AP direction and the 45-degree iliac-oblique position, and finally the influence of controlled pelvic tilt.

To quantify the amount of bone loss in a controlled experimental cadaver model we performed a study comprising of 10 pelvic specimens.

Finally, we performed a clinical consecutive controlled randomized study. One hundred patients were operated with press-fit hemispherical cups +/- hydroxyapatite coating. Frequent DEXA-scans during the 3-year follow-up period were analyzed in order to analyze the pattern of bone remodeling around press-fit cups in the two groups.

Results

The study of different scanning positions revealed that DEXA-scanning in the AP position gave the best reproducibility. Pelvic tilt of more than 10 degrees affected reproducibility, and the intra observer variation was very low.
DEXA-scanning of the pelvic specimens before and after removal of bone corresponded very significantly with the amount of removed bone in all regions.

After 3 years, we neither found any differences between HA-coated cups and the standard cups, clinically nor measured by BMD. However, in one region, we found significantly better bone regeneration in the overweight and obese groups, compared to the normal weight patients; and the tendency was similar in the other regions.

Conclusion

DEXA-scanning has a high reproducibility, and has the ability to detect and quantify even small osteolytic lesion with high precision. In a controlled randomized trial, it proved reliable in the description of bone remodeling around prosthesis. We found no difference in bone remodeling between hydroxyapatite-coated and porous-coated cups.

Abbreviations

AP	Anterior-posterior
CT	Computed Tomography
CV%	Coefficient of Variation (Standard deviation/mean *100%)
DEXA	Dual Energy X-ray Absorptiometry
HA	Hydroxyapatite
HHS	Harris Hip Score
ROI	Region of Interest
SEE	Standard Error of the Estimate
THA	Total Hip Arthroplasty
TKA	Total Knee Arthroplasty

Introduction

This study was inspired by an unpleasant experience during surgery on a 32-year old female who had her 4-years old THA revised because of thigh pains, suspected to be due to the femoral stem. Preoperative x-rays revealed no suspicion of osteolysis, or cup loosening, and we planned to do a stem revision. Surprisingly the stem was well fixed, but the cup was loose, and in the course of the operation, we found a huge localized osteolytic lesion in the pelvic bone. The conditions for reimplantation were very unfavorable, as we had not anticipated the sudden need for homologous bonegraft.

Most patients with THA perform well, for many years. The different Scandinavian national registers report 10-year survival rates 95% or higher, even in younger patients. When osteolysis develops and prosthesis fails, the condition is a disaster for the patient, with a high impact to the rest of his life, and a huge bill for the healthcare system (Harris, 1995).

Wear-particles from polyethylene play a principal role in the development of osteolysis. In many well performed studies pseudo capsules and interface membranes from revision surgery and autopsy specimens have been analyzed by histomorphology, image analysis and light morphometric techniques and even immunohistochemistry; all pointing to the polyethylene as the worst offender. HA-coating of implants seems to reduce (but not remove!) the detrimental effect, presumably caused by a sealing of the bone to implant interface. (Bos and Willmann, 2001,Coathup et al., 2001,Frokjaer et al., 1995,Jensen et al., 2002,Neale and Athanasou, 1999,Oosterbos et al., 2004,Overgaard et al., 1997b,Overgaard et al., 1997a,Overgaard et al., 1997c,Soballe et al., 1990,Soballe et al., 1991b,Soballe et al., 1991a,Soballe, 1993,Rahbek et al., 2000)

An orthopaedic surgeon equipped with standard x-ray examinations often underestimates the extent of osteolysis, if the osteolysis is visible at all (Engh, Jr. et al., 2000). On suspicion of osteolysis it is possible to detect 94% of the lesions by combining the AP view with a 45 degree iliac-oblique, 45 and 60 degree obturator-oblique projections (Southwell et al., 1999).

Computed tomography could develop to the method preferred for detection and quantification of periacetabular osteolysis, if the infliction from metal artifacts could be overcome. Nevertheless, the radiation dose will probably be intolerable high for routine use, so this possibility remains a tool for experimental studies (Claus et al., 2004,Looney et al., 2002,Pitto et al., 2001,Wright et al., 2001).

DEXA-scanning was introduced for endocrinologic purposes, for the diagnosis and treatment control in osteoporosis and related diseases. Soon orthopaedic pioneers employed DEXA in several research applications with relation to osteoporotic fractures (Lauritzen and Lund, 1993,Petersen et al., 1998,Saleh et al., 2002).

Concerning orthopaedic implants, DEXA evolved into an established method for detection of bone mass changes around prosthesis. This development is based on numerous well-performed methodological works (Cohen and Rushton, 1995,Engh, Jr. et al., 2000,Gehrchen, 1999,Kilgus et al., 1993,Mortimer et al., 1996,Rahmy et al., 2000,Schmidt et al., 2002,Smart et al., 1996,Petersen et al., 1993,Petersen, 2000,Ming et al., 2005,Yamaguchi et al., 2003); and frequent publications of clinical trials reporting on 3, 5 or 10 year follow-up results, or

BMD differences between different coatings or prosthetic designs (Engh et al., 1994,Karrholm et al., 1999,Kiratli et al., 1996,Munting et al., 1997,Petersen et al., 1995a,Petersen et al., 1995b,Sabo et al., 1998,Wright et al., 2001,Yamaguchi et al., 2000).

Wilkinson and co-workers performed a study on acetabular periprosthetic Bone Mineral Density measurements, by using a DEXA-scanner. They proposed a model with four regions of interest to offer the highest precision in BMD measurements. Nevertheless, they did not consider the possibility of different patient positions(Wilkinson et al., 2001,Wilkinson et al., 2003).

Aim of the present studies

The aims of the present study were as follows:

1. To test the precision and accuracy of DEXA-scanning of the periprosthetic bone around hemispherical press-fit cups, as regards patient position and pelvic tilt.
2. To characterize a possible correlation between a well defined periprosthetic bone defect and a corresponding BMD-value.
3. To analyze the feasibility of DEXA-scanning of the peri-acetabular bone in a randomized series of 100 THA patients, as a tool for comparing the differences of a specific cementless cup with and without HA, and describe the pattern of bone remodeling around hemispherical cementless press-fit fixated acetabular cups in general.

Methods

Own Studies

Paper I

To test reproducibility and accuracy of the 4-ROI model proposed by Wilkinson and to show how a difference in patient posture affected the result, we conducted the study described in Paper I.
In brief, we picked 10 patients for each of three groups, and scanned to assess the influence of time since surgery, the difference between scanning in AP direction and the 45-degree iliac-oblique position, and finally the influence of controlled pelvic tilt. All scans were performed twice after complete repositioning.

Paper II

To quantify the amount of bone loss in a well-defined osteolytic lesion we went to the laboratory and performed an experimental study.
The research subjects were 10 pelvic specimens, in which we made artificial defects, and tested if the DEXA-scanner was able to detect and quantify them.

Paper III

Finally, we conducted a clinical consecutive controlled randomized study. The study comprising 100 patients was designed to investigate the performance of HA-coating of the cup in cementless THA; to describe the pattern of bone remodeling around hemispherical cementless press-fit fixated acetabular cups in general, and hereby testing the Wilkinson Regions in clinical practice.

Bone Densitometry

Measurement of Bone Mineral Content (BMC) and Bone Mineral Density (BMD) by Dual Energy X-ray Absorptiometry (DEXA) and Dual Photon Absorptiometry (DPA) was introduced in the seventies, for diagnosis and monitoring of treatment in the field of endocrinology (Gotfredsen, 1990). During the eighties and nineties, the methods and especially the software developed; and possibilities for selection of very specific Regions of Interest (ROI) and even exclusion of metal implants within the ROI brought the method into the field of orthopaedic implant research.

The accuracy of DEXA-scanners for measurements of bone mineral has previously been evaluated by other investigators. Experimental procedures performed on specimens of dried or ashed bone, with or without different materials to simulate soft tissues, have shown in vitro accuracy around SEE 1%. In clinical studies measuring the proximal femur in THA-patients or proximal tibia in TKA-patients, precisions around CV% 2-3 are reported (Gehrchen et al., 1995,Gehrchen, 1999,Petersen, 2000). The bone around the acetabular cup was first introduced into DEXA measurements by Sabo et al. (Sabo et al., 1998) who (Sabo et al., 1998)reported the first follow-up study of DEXA-scanning of cementless acetabular cups. They proposed a 3-ROI model defined according to the De Lee and Charnley zones (DeLee and Charnley, 1976). The accuracy was assessed by double measurement in 5 patients on 2 different days and they found a precision close to the values determined in our Paper I. Wilkinson and his co-workers, designed a 4-ROI model to test against Sabo's model, and found the best precision in the 4-ROI model with CV% ranging from 2.5 till 4.8 in the different ROIs (Wilkinson et al., 2001)

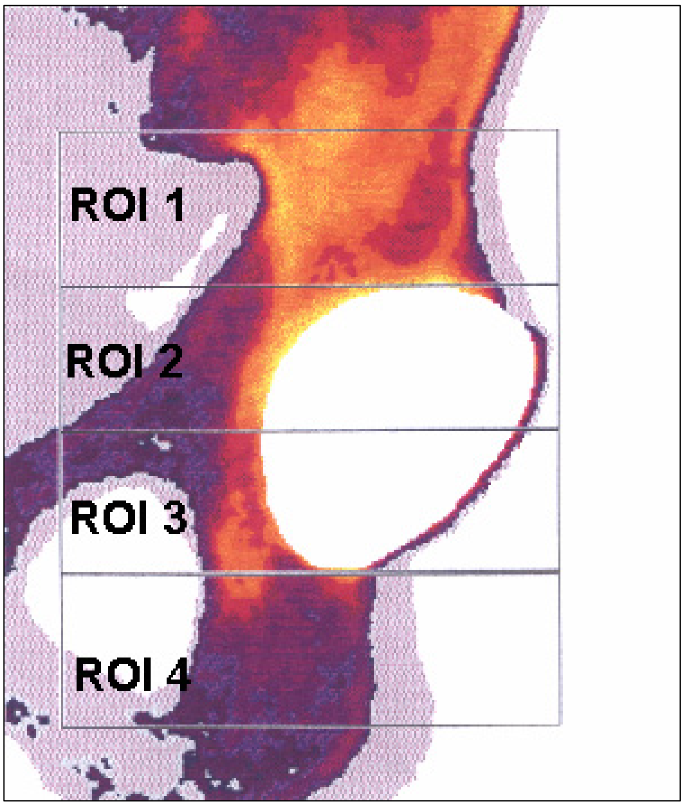

Figure 1. The 4-ROI model

The scanner used in the present studies was the NORLAND XR-36 Bone Densitometer: A pencil beam scanner using one x-ray tube as source, and two different detectors.
The stationary anode x-ray tube has a 100kV constant potential, and a constant current at 1mA. It is equipped with a samarium filter (K-edge = 46.8 keV) with a minimum filtration equivalent to 3 mm aluminum. The detectors are two NaI scintillation detectors in pulse counting mode. The software was version 3.9.4/2.1.0. Scanning was performed in the "research" mode with a speed of 60 mm/s, and a resolution of 1 x 1 mm pixels when scanning in living patients (Study I and Study III). In Study II, the resolution was increased to 0.5 x 0.5 mm pixels. Time consumed per scan, not considering positioning etc., was about 8-10 minutes. The "exclude high density" facility was always activated (excludes pixels with a density higher than 3.75 g/cm^2). We performed calibration daily, with two different phantoms, according to the prescriptions from the manufacturer.
The QA-reports following these procedures revealed the internal precision from XR-36 itself, expressed as CV%. During the 4 days of experiments described in paper II this precision varied between 0.54 and 0.67; and through the years of study III the range was from 0.41 to 0.71.

Limitations

Previously, the use of 'exclude high density' was reported as a problem in patients with cementless femoral stems, where the threshold at 3.75 g/cm^2 was exceeded in positions where no metal was present (Gehrchen, 1999,Wilkinson et al., 2001). We were warned against this problem, and it had our full attention, during the manual application of the ROIs. In six patients (all male) included in our clinical study (Paper III), we observed that a little part of ROI 3 in close proximity to the cup was excluded. The area did not change throughout the observation time, so there would be no influence from this problem to the measure in question: the BMD change over time. Hence we decided not to interfere, thereby leaving the clinical trial unaffected, to gain a true evaluation of the method in daily practice. If the reason for this finding is patient related, we have some suggestions: Compaction of the bone, or impaction of reamer-debris during the insertion procedure; or a fragment of cortical bone, abraded but not removed by the reaming procedure, was caught in the coating of the cup, and subsequently hammered deeper into the periacetabular bone.

The position where the phenomenon occurs is in the area of the acetabular teardrop. The teardrop is a U-shaped figure on AP X-rays. It is a complex geometric structure found to be in a constant position in the anteroinferior aspect of the acetabular wall. Its appearance changes with rotation of the pelvis or angulations of X-ray beams, as the teardrop represents a two-dimensional image of the tangents of a series of curves of varying radii (Bowerman et al., 1982,Katz, 1969,O'Sullivan et al., 1992). Similarly in the DEXA-scan, these superimposed curves of mostly cortical bone, could be the reason for BMD values above the 'metal threshold', where the scanner has measured the density of three bones combined in the teardrop area. The software must be considered in this problem too. In other systems, software allows for adjustment of the exclusion threshold, a feature we hope to see in the next up-date of our system.

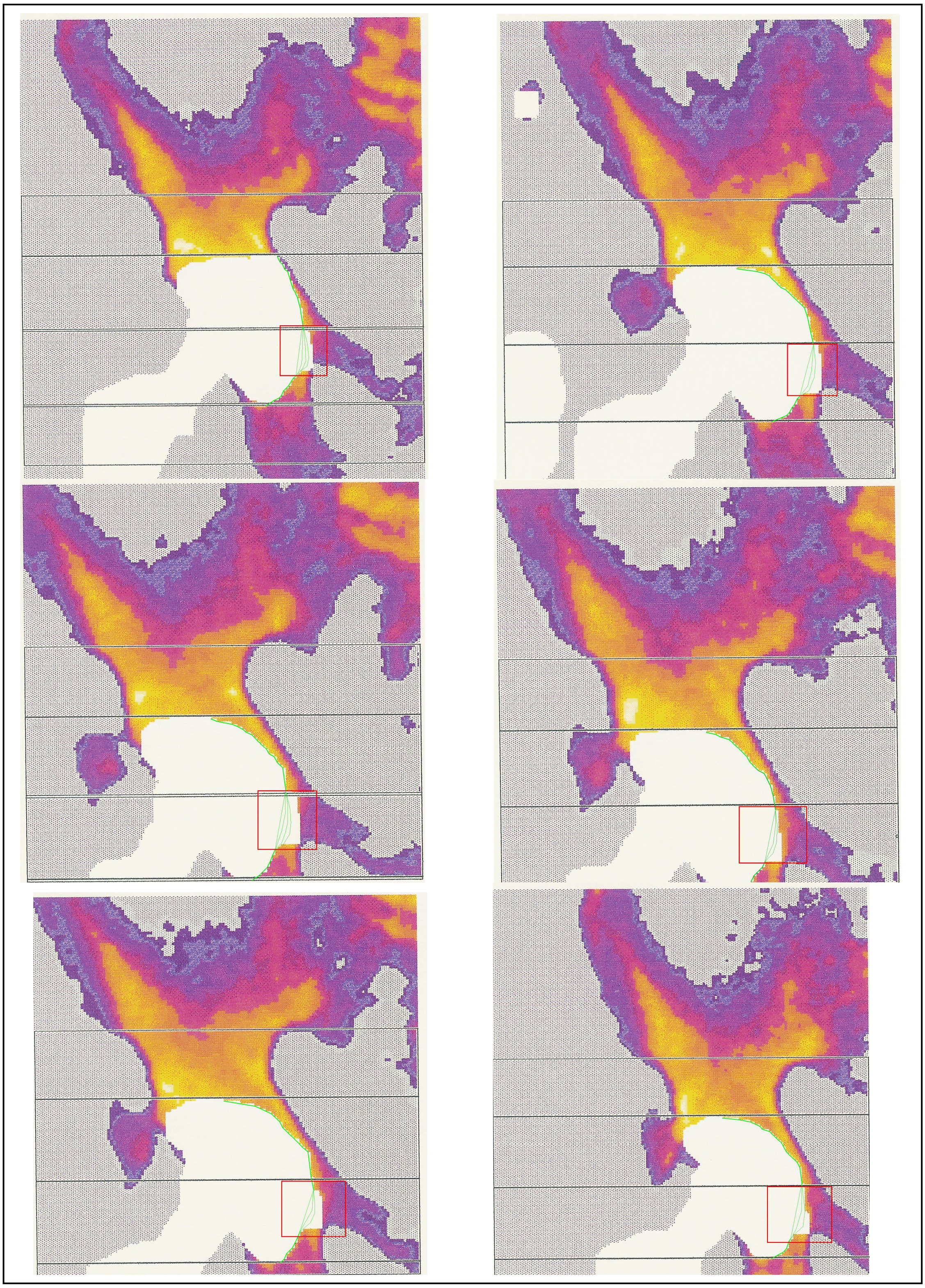

Figure 2. The 'Exclude high density' problem. Six scans (PostOP, 3, 6, 9, 12, 36 months) of one patient included in study III. The red boxes indicate the problematic area.

Our studies demonstrate the reproducibility and accuracy of the 4-ROI model (Paper I), and we also revealed data confirming the connection between removed bone and bone loss measured by DEXA (Paper II); previously this model has never brought about any enlightenment regarding BMD changes within persons in a time-span. In his first paper Wilkinson reported of the accuracy of the model (Wilkinson et al., 2001), and in the second paper subjects with aseptic loosening were compared to subjects with successful implants, and he found no differences in pelvic BMD(Wilkinson et al., 2003). We performed the first longitudinal study utilizing the 4-ROI model, and found no differences after 3 years, between two groups receiving different treatment. Perhaps there are no differences, or the model is inadequate to reveal the differences.

Surgery

All patients included in the studies reported in Paper I and Paper III were operated as follows: Surgery was performed in an operating room with laminar airflow. Single dose prophylactic methicillin 1 g was given i.v. pre-operatively. Anesthesia was provided with spinal infusion of a single dose of local anesthetic. During surgery, the patient was fixed in a lateral decubitus position, allowing exposure of the hip joint through a posterior approach, which is the standard approach in Denmark (99%) (The Danish Hip Arthroplasty Registry, 2003). The bony bed of acetabulum was prepared for cup-insertion by reaming-off residual cartilage and bone excrescences, maintaining the subchondral bone plate. Cup size was chosen 2 millimeters larger than the last reamer utilized, i.e. press-fit fixation (Schmalzried et al., 1994). Mobilization commenced the first postoperative day, although weight bearing was restricted for 6 weeks using two crutches.

All surgeons were experienced with the implants and the approach, but to conduct a clinical trial in a department with a large educational obligation, and an inclusion period lasting for 20 months, will involve many surgeons. In our series, four dedicated registrars were responsible for seven operations and seven specialists were in charge, either as surgeons or as supervisors, in 93 cases.

Clinical evaluation

The ultimate goals for total hip arthroplasty are good function and freedom from pain. Many different scoring systems have been designed to evaluate outcome after THA-surgery, and some of these are validated worldwide; among these the Harris Hip Score is the most widely used (Harris, 1969). This evaluation scale measures activities of daily living with up to 47 points, pain for 44, joint movement for 5 and absence of deformity of 4, in a total of 100 points. Harris originally proposed a sub grouping of the results in the classifications excellent, good, fair and poor; but later research indicates that the relevant parameter is the score change. HHS has been an integral part of the Danish Hip Registry since the initiation, and all Danish orthopaedic surgeons are familiar with the use of it, so it seemed natural to evaluate the outcome in our series by this well reputed instrument. Several authors have postulated a low detection rate of obvious differences, when applying HHS to short term follow-up studies; but on the other hand there is a worldwide consensus on the need for short, easy to answer, scoring systems (Garellick et al., 1998,Soderman and Malchau, 2001,Soderman et al., 2001). The possibility of too high impact from the pain-share of the HHS is still being considered, in the urge for a refined tool to evaluate outcome after THA. Nevertheless, the wish for pain-relief is usually one of the main causes for patients to undergo a THA operation. Hence, pains are bound to play an important part in clinical evaluation of treatment results. Other parameters than those provided by the HHS are desired for clinical evaluation of the THA performance, such as more sophisticated measures of the Range-of-Motion, leg length discrepancy and activities of daily living. These are very relevant when comparing different prosthetic alterations, but not applicable in the daily routine of a high-speed prosthetic clinic.

Laboratory procedures

Introduction

Experiments reported in Paper II were carried out in the Orthopaedic Research Laboratory at Farsoe Hospital in conjunction with the DEXA-lab and the X-ray department.

Specimens

Ten pelvic specimens were lent at the Anatomical Institute at Aarhus University. To minimize inter-object variation we decided to employ specimens of one sex only, and at the time of our experiments, the selection available comprised a majority of women, which we therefore chose. All soft tissues were removed mechanically, the hips were exarticulated and the spine was excised through discus L5-S1. The specimens were kept at 4°C between laboratory procedures. To facilitate handling, each specimen was fixed to a wooden plank of 2 x 10 x 80 cm using three screws through os sacrum. The left acetabulum was chosen for experiments, because one of the subjects had had a right hip replacement due to fracture sequelae. There was no macroscopic evidence of pathology.

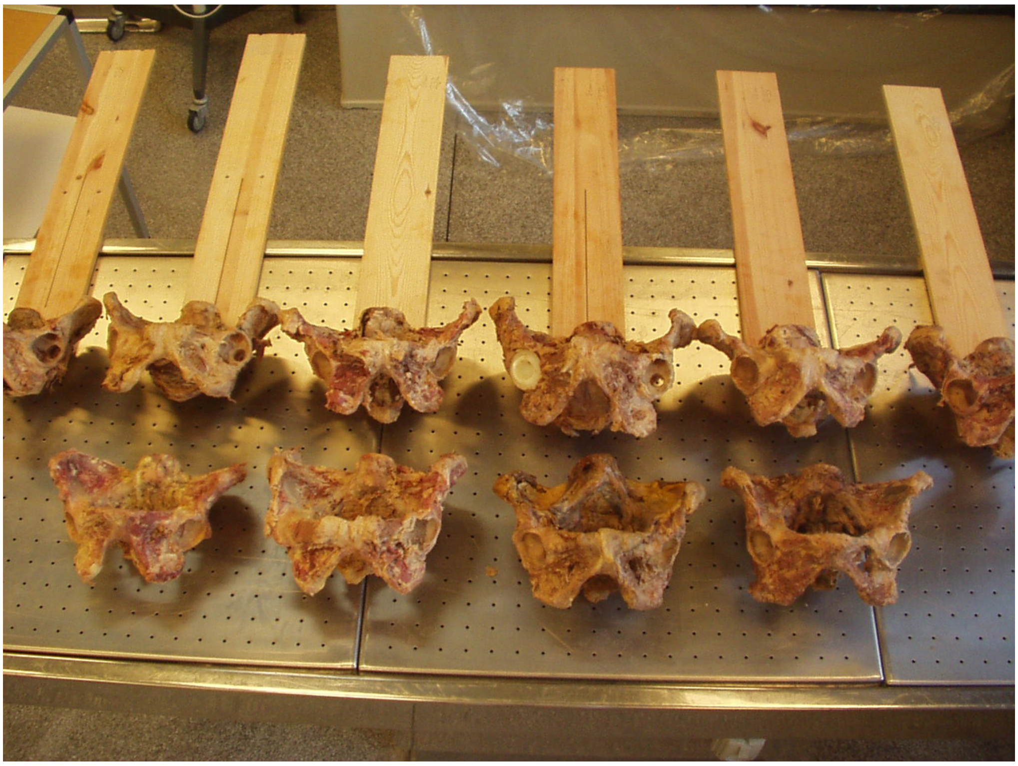

Figure 3. Ten pelvic specimens ready for ‘surgery’ in study II.

Implants

We used the Trilogy-cup® (Zimmer, Warsaw, Indiana, USA), shaped like a true hemisphere with a core of titanium alloy (Ti-6Al-4V) and covered with a fiber mesh of technically pure titanium.
The cups were modified as follows: To secure the exact re-positioning between procedures where the cup was removed, two barrels were attached to the outer rim. The barrels were cannulated for 2-mm Kirschner wires, perpendicular to the opening plane of the cup placed at the outer rim, at a 120-degree internal angle. To secure uniformity in the procedure of creating defects, each cup had three 2-mm holes. These holes were placed half a radius away from the center at 90-degree internal angles, and perpendicular to the outer plane of the cup. To adjust these placements to the different cup sizes, the angles were transformed to co-ordinates that could be entered into the equipment in our mechanical service facility.

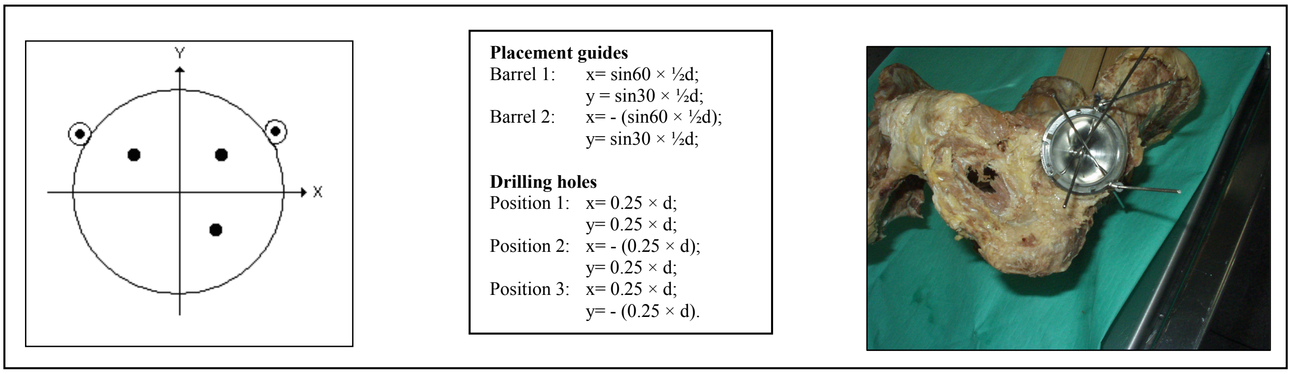

Figure 4. Implant modifications.

‘Surgery’

After the first insertion of the cups, two Kirschner wires were drilled through the barrels and the bone underneath. The entry and exit holes were marked, and the placement-guide-Kirschner-wires were removed, and double DEXA-scan was performed (baseline).

Creating defects

After the baseline scans, the drill-guide-Kirschner-wires were inserted through the drilling holes in the cups, and the cups were removed. A hole was drilled at each of the three K-wire marked positions with a cannulated 10-mm drill bit with depth stop at 10 mm. All drilling debris was collected into a test tube. When all three holes had been drilled, drill bits and drill-guide-Kirschner-wires were removed. The placement-guide-Kirschner-wires were then reinserted into their marked positions, and the cup was slid back into place with the placement-guide-Kirschner-wires in their corresponding barrels. DEXA-scan was repeated. The procedure of drilling and scanning was repeated twice, with drill bits of 10 x 20 mm and 20 x 20 mm. The last scan was done as double measurement in the same way as the first (end line-scans).

Measurement

DEXA-scans were measured according to the same 4-ROI model utilized in the other studies. The test tubes were kept at -80°C until the ashing procedure. We used a standard ashing protocol, consisting of drying at 110°C for 24 hours and ashing at 600°C for 24 hours (Griffin et al., 1993,Fink et al., 2002). Weighing of test tubes before use and after the ashing procedure was performed with a standard laboratory balance, a Mettler Toledo® type AE 163.

Limitations

A great deal of limitations must be considered, when extrapolating results from an in vitro study as described in paper II to a human situation.

The corpses were embalmed for a minimum of 6 months in a solution of alcohol and formaldehyde; this may influence the physical properties of the bone, but the solution is not considered having any effect on neither the mineral contents, nor the ash weights.

The specimens available originated from very old people (+80 years) who had donated their bodies to science and education. They had no macroscopic signs of osteoarthrosis, and therefore differ in at least two parameters from the population, to which we want to extrapolate results.

Implant placement appeared to be very reproducible concerning angles and rotation, but the seating could be discrepant between the drilling procedures, and during the different scanning séances.

Placement of the artificial osteolysis was chosen as collaboration between our clinical experiences and the practical use of the 4-ROI model; to achieve reasonable measurements, each osteolysis had to interfere with BMD measures of only one ROI. This optimized situation is of course very distant from the problems in the clinic, but necessary to attain reliable measures.

We produced our osteolysis in a very standardized way, as cylindrical defects in the immediate proximity to the prosthesis. Natural osteolysis does not always behave like that; they can even be separated from the implant by several centimeters of apparently normal bone (Looney et al., 2002,Mehin et al., 2004).

The drilling of the artificial osteolysis was executed with a surgical battery-driven electronic drilling machine, being very careful about the direction of the K-wires, the depth stop and the risk of compacting the debris into the surrounding bone. By not applying any pressure to the drilling machine, we hope that the amount of bone compacted into the sides of the defects was kept to a minimum. In order to measure the amount of bone removed from our artificial osteolysis, we were meticulous about collection of all the drilling debris after each drilling procedure; but the method leaves a risk of sampling errors.

Weighing of test tubes with a standard laboratory balance, a Mettler Toledo® type AE 163, which is subject to routine calibrations, but as any other measure the procedure contributes to the total variation among our results.

Radiology

A basic examination in hip surgery

The standard X-ray examination in THA-surgery is the AP and the lateral projections, used for initial diagnosis, postoperative verification and later follow-up situations. Evaluation of x-rays can be organized more or less methodically, from simple contemplation to systematized descriptions of radiolucent lines etc. distributed in different zones (DeLee and Charnley, 1976,Gruen et al., 1979).

Early failure obvious in standard x-rays

During the late eighties and the nineties, the first generation cementless acetabular prosthesis, the threaded type, was introduced. Unfortunately, causing frequent loosening problems within the period 5-10 years post implantation. When loosening commenced the fate of the arthroplasty was sealed: A rapid decrease of abilities, increased pains, and usually no doubt about the reason, once standard x-ray examination was performed (Grant and Nordsletten, 2004,Grubl et al., 2002,Keating et al., 1990,Tallroth et al., 1993,Robertson et al., 2005,Yahiro et al., 1995).

Late osteolysis is a challenge to x-rays

The current generation of porous coated hemispherical press-fit fixated cups perform better, with almost no revisions the first 10 years, but after that osteolysis begins to appear (Blacha and Gagala, 2004,Jiranek et al., 2004,Kim et al., 2003,Spicer et al., 2001,Harris, 1995). The development of late occurring osteolytic lesions has another pattern than the fast evolving course described for the earlier problems with previous generations of cementless cups. The clinical expression is very diverse, and seldom obvious from osteolysis.

Detection of osteolysis is important

Thus detection of osteolysis has become a major issue in the postoperative follow-up of THA patients, and several authors advocate for examinations every year after cementless arthroplasties; a very heavy socioeconomic burden to put on a surgical field that already bears the expenses of costly implants. Further sophistication of x-ray examinations for osteolysis involves manual digital processing, outlining the osteolysis, a very time consuming process (Mehin et al., 2004,Oparaugo et al., 2001,Soto et al., 2000). Southwell and coworkers proposed a method consisting of 3 additional oblique x-rays as complement to the standard x-rays, offering a detection rate of 94% of all osteolysis (Southwell et al., 1999), but again a method applying extra costs to the healthcare system and extra radiation doses to the patients.

New osteolysis-detection-tools needed

In conclusion, we have felt the inadequacy of x-ray examination as an osteolysis-detection-tool; performing a low detection rate, lack of quantification and inflicting heavily on radiation doses if attempts to increase detection rates are made. Therefore, there is a need for a new instrument to identify the subjects eligible for developing osteolysis. If such a measure were available, we could run more controls on the patients suspected of osteolysis, and let the rest off with less frequent visits.

Statistics

Paper I

Data were acquired by DEXA-scans of 30 patients divided in three different groups, every scan contributing four BMD values to the test. In group 1 and 2 all patients had four scans, two in each of the tested positions. In group 3, all patients had three scans, one in each position.

Statistic analysis was carried out using Intercooled Stata 8.0 for Windows (Stata Corporation, College Station, Texas, USA. Group 1 and 2 standard deviations were compared by F-test and *t*-test, which revealed no difference between the groups. This fact was the argument for merging the groups before testing the difference between the two positions using a Pitman's test.

Group 3 BMD values were plotted against the tilt-angle, and the BMD measures in the 0 degree tilted position were considered the "true" values. The curves show how the measures change with increasing degree of tilting. Values for error-bars were calculated as 1.96*S.D. to display whether the values at 10 and 20 degrees of pelvic tilt were inside or outside the 95% limits of the 0 degree value.

Intra observer variation was evaluated by measuring 20 scans in random order and re-measuring the same scans one week later by the same investigator in another random order (20 scans, 4 ROIs, makes 80 double measurements). 71% of the results were the same; the rest differed in a single pixel row.

Paper II

Attaining data comprised from DEXA-scanning and weighing of ash in test tubes. Each specimen had three locations, where defects were created. Each defect was performed in three steps (10x10; 10x20 and 20x20 mm) entailing one ash-weight each. The corresponding BMC values were calculated by subtracting the before drilling and the after drilling values accordingly.

This leaves 3 sets of data where each of the ten specimens has a baseline scan, and three "after drilling" BMC-differences with correlated ash weights; set one containing data for ROI 1 and ash weights from drilling in position 1, set two concerning ROI 2 and position 2 and set three for ROI 3 and position 3.

The statistical analysis was performed in the SPSS 12.0.2 for Windows, as a linear mixed model, considering within-subject variation by adding individual intercepts (hereby-assuming intra-class correlation). We performed the statistical analysis on the complete dataset, and after splitting up in groups according to ROI. Plotting the values raised the suspicion of greater variation in the higher values than in the lower, for that reason we transformed the dataset (ln (1+x), due to a few negative values), and performed the analysis again, with the same result.

The model diagnostics included a plot of residuals against the fitted values and a q-q plot of the residuals. These plots confirmed normally distributed errors and variance homogeneity and hence the adequacy of the analysis was approved.

We performed double measurements in the DEXA-scanner, and at the laboratory balance. Assuming that the instruments had only random errors, and adhering to ISO1998 International Standard and definitions of repeatability conditions (Ranstam et al., 2000) the repeatability limit for BMC measurements was 0.23 grams, SD 0.12, n 86; corresponding values for ash weights were 0.00097 grams, SD 0.00050, n 10. (Repeatability = $1.96 \times \sqrt{\Sigma d2/n}$, d = paired difference between repeated measurements of the same object, n = number of pairs of measurements).

Paper III

For this controlled randomized trial we calculated sample size as follows: To find differences exceeding BMD 0.25 g/cm2 (least relevant difference: δ=0.25), with a risk of type 1 error: α= 0.05 (20%), statistical power = risk of type 2 error: β= 0.2 (80%). Reading from statistical table (Armitage and Berry, 1994) gives sample size: 43 in each group, we chose 50 to accommodate for dropouts.

100 patients entered the investigation. Each patient had DEXA-scans post-OP and after 3, 6, 9, 12 and 36 months, every scan evaluated with the 4-ROI model. Furthermore, we registered age, sex, height and weight at the time for surgery, and HHS pre-OP and after 12 and 36 months.

Statistical analysis was limited to a plot of BMD changes against time, one line per treatment group (+/- HA) per ROI. The plots were practically identical, error-bars were calculated as 1.96*S.D.

Similar plots were done after stratifying for Body Mass Index, into the groups 'normal' (18-24.9 kg/m^2), 'overweight' (25-29.9 kg/m^2) and 'obese' (30-∞ kg/m^2); and not taking treatment group into consideration.

Results

Paper I

Scanning in the AP position was more reproducible than scanning in the lateral position. Tilting the pelvis within 10 degrees did not affect reproducibility, but further tilting compromises accuracy.
Intra observer variation was very low.

	AP			Lateral			PITMAN TEST			
	mean	mean diff.	n	mean	mean diff.	n	Ratio	95% CI		p
netROI	0.97	0.014	20	0.99	0.036	20	3.20	2.09	4.90	0
ROI1	1.12	-0.012	20	1.23	-0.014	20	3.38	2.13	5.35	0
ROI2	0.81	-0.009	20	0.84	-0.002	20	2.00	1.25	3.20	0.005
ROI3	0.76	0.030	20	0.72	-0.073	20	1.57	0.97	2.52	0.063
ROI4	0.78	-0.043	14	0.76	-0.107	8	1.81	1.00	3.27	0.051

Table 1. AP or Lateral? Head result of Pitman test is ‘Ratio’ (S.D. -lateral /S.D.-AP)

Paper II

The association between BMC and Ash weight shows high significance in each of the three regions. The results of the statistical analysis should be understood as follows: If a BMC difference of 0.821g is detected in ROI 1, it is corresponding to a defect where 1g of minerals has disappeared.

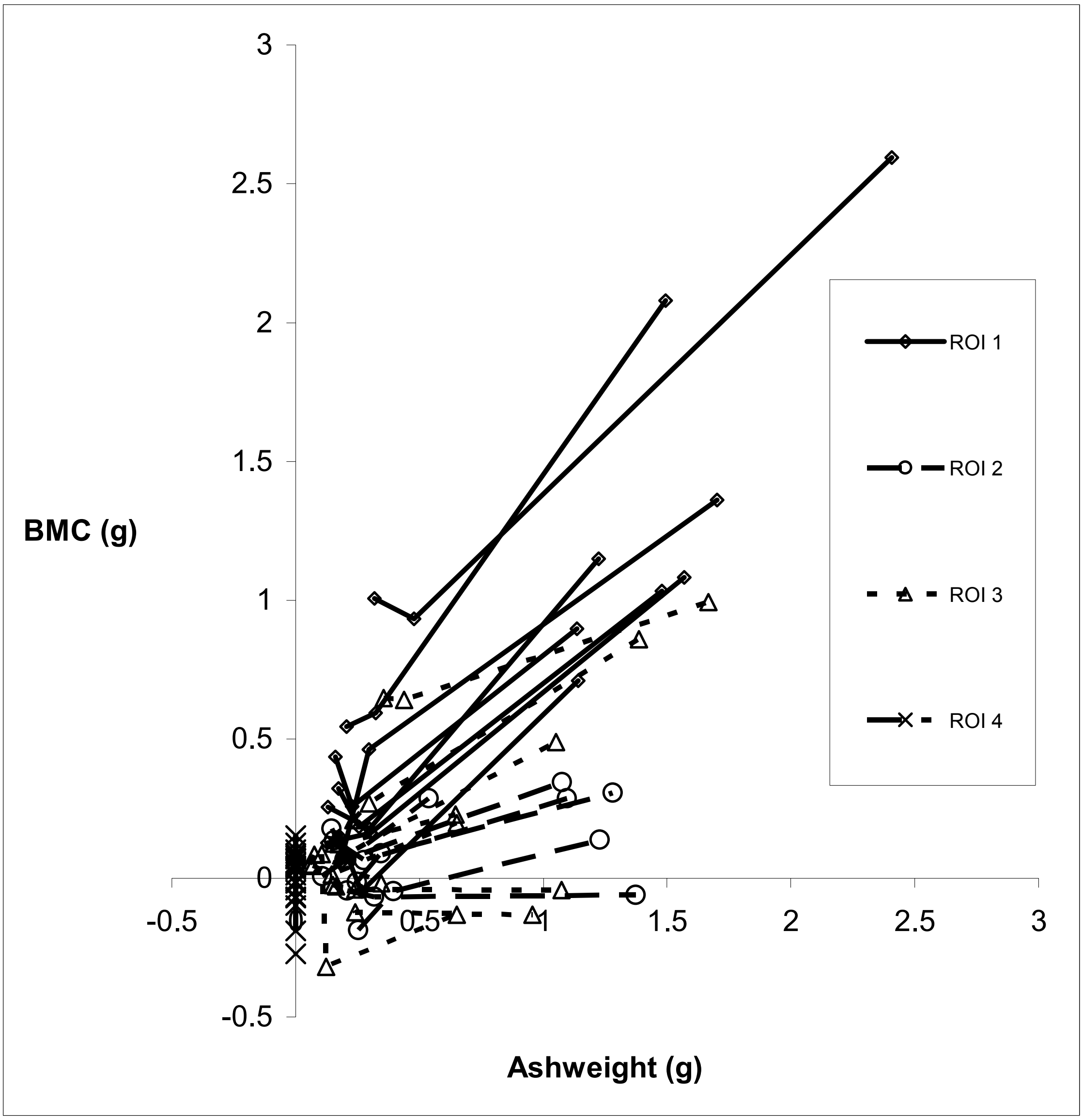

Table 2. Diagram showing relationship between ash weights and BMC – one line per specimen in each ROI.

Paper III

BMD Measurements showed no difference between the HA-coated cup and the standard cup, after 3 years. Clinically there were no differences either (HHS). When stratifying for Body Mass Index, into the groups ‘normal’ (18-24.9 kg/m^2), ‘overweight’ (25-29.9 kg/m^2) and ‘obese’ (30-∞ kg/m^2); and not taking treatment group into consideration, we found a clear tendency of better bone regeneration in the overweight and obese groups, compared to the normal weight patients. This difference was only significant ($p<0.05$) in ROI 3.

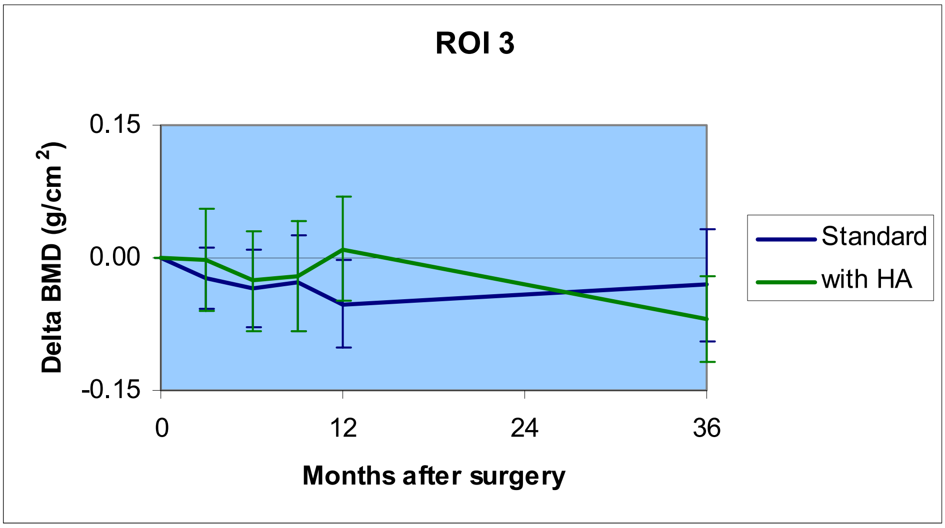

Table 3. ROI 3 results concerning +/- HA

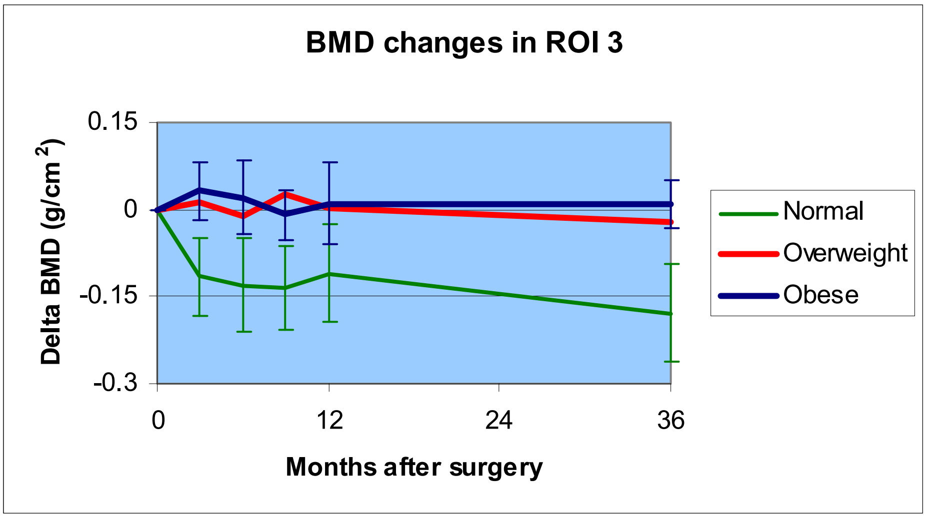

Table 4. ROI 3 Results concerning Body Mass Index

Discussion

The THA benchmark

Most THAs perform well, for many years. The length of in situ service of THAs is anticipated to continue increasing, if alterations in implant designs, fixation methods and surgical techniques turn out as improvements. Advances in the medical treatment of comorbidities have resulted in a longer life expectancy for patients; hence, the goal for longevity of THA is not yet defined.
A cohort of 329 arthroplasties with Charnley design prosthesis inserted with first-generation cementing technique between 1970 and 1972 is continuously followed. With more than 30 years in situ the revision rates for aseptic cup loosening is 7.3% (26% of the hips in the living cohort). Stem loosening has led to revision in 3.2% (10% of the living patients).
These data should be used as a benchmark with which to evaluate the efficacy of other designs (Callaghan et al., 2004,Huo and Muller, 2004).

Many parts and interfaces

The total hip arthroplasty can be divided into several parts, which each contributes with different problems. A metallic femoral stem and ball, attached to the femoral bone by cement, or by more or less biologically active coatings. A polyethylene socket attached to the pelvic bone with cement, or as a modular part of a metallic cup attached with coatings or cement. The bearing surfaces of the femoral ball and the acetabular socket are subjects to many changes these years (Santavirta et al., 2003).

Well performing femoral stems

Present techniques and designs of femoral stems, cemented and porous coated for cementless implantation, are frequently reported with 15-years survival rates above 96%, thus substantiating a hope of a performance even better than the Charnley benchmark mentioned above (Huo and Muller, 2004). Progress in cementless cup fixation seems to be directed in the right way too, but longer follow-up is needed before a new benchmark is recognized (Huo and Brown, 2003).

The cup problem

It is still discussed whether the current problems in cup fixation are caused by bio-incompatibility of the implanted devices (Konttinen et al., 2005), osteolysis (Harris, 1995) or it is two sides of the same coin. Others argue that retro-acetabular stress shielding is the point of the matter (Kim et al., 2003,Schmidt et al., 2002).

Particle disease

Synovial fluid containing PE-debris inside the pseudo synovial membrane, delivers a cyclic pressure during normal gait, to the bone-implant interfaces. Even in the situation of a well-fixed, bony-ingrown femoral stem, PE-debris can be observed in the interface at the tip of the stem. The particle disease has proved a major responsibility for development of osteolysis (Konttinen et al., 2005). Prevention against particle disease is aimed in two directions. First, to seal off the gap between implant and bone, HA-coating in experimental mountings has proven a significant effect in restraining PE particles from intruding into the interface (Rahbek et al., 2000). Secondly, the bulk in THA research today is occupied with the development of new articulating surfaces, to reduce wear debris.

Future of new implants

Regardless of which new implant, design, surface coating, fixation method or bearing surface to be on trial, we will have to investigate how the periacetabular bone reacts to it. The better tools we get, the sooner we shall be able to stop trials of unsatisfactory designs, avoiding unnecessary suffering in patients operated with faulty products.

Purpose of our studies

The aims of the present study were as follows:

1. To test the precision and accuracy of DEXA-scanning of the periprosthetic bone around hemispherical press-fit cups, as regards patient position and pelvic tilt.
2. To characterize a possible correlation between a well defined periprosthetic bone defect and a corresponding BMD-value.
3. To analyze the feasibility of DEXA-scanning of the peri-acetabular bone in a randomized series of 100 THA patients, as a tool for comparing the differences of a specific cementless cup with and without HA, and describe the pattern of bone remodeling around hemispherical cementless press-fit fixated acetabular cups in general.

We tested the 4-ROI model, which previously had proved adequate in preference to other models. We chose the model because of the high reproducibility, but we did not know anything about effectiveness in determination of osteolysis or stress shielding. Press-fit cups are expected to transmit strain forces to the acetabular rim and cause stress shielding in the bone surrounding the dome, thus the rectangular ROIs employed in our studies embrace areas in which to expect a rise in bone density as well as areas of expected density fall. Should the model be refined to distinguish smaller differences, a suggestion could be splitting up the ROIs in medial (dome-related) and lateral (rim-related) parts.

Data from Paper I are comparable to those reported by Wilkinson, except that we experienced a lower Ratio of S.D. in the ROIs 3 and 4, indicating a worse reproducibility in these regions. We have no plausible explanation for this. It is interesting to note that in the pelvic-tilt part of this study, the same trend affects the results of the 20-degree tilt, but not the results of the10 degree tilt. This finding can be explained from the longer distance between ROI 4 and the centre of the flexion

Data from Paper II (adjusted R^2= 0.933; 0,804; and 0,822 for the respective regions) are comparable to the animal experiments performed by Griffin, who reported a positive correlation between in vitro DEXA measurements and ash BMC (r = 0.99) and between in vivo DEXA measurements and ash BMC (r = 0.89). (Griffin et al., 1993).

HHS values in Paper III are comparable to most short-term follow-up reports of THA in healthy patients without comorbidities. BMD values in Paper III are different, however, from the values reported by Wilkinson (Wilkinson et al., 2001): 17 THA patients with cementless cups were scanned 13 and 26 months after implantation (no immediate post-operative values). Between these two points, they report of bone density gain in ROIs 1 and 4, and density loss in ROIs 2 and 3. With a little stretch of imagination, the above reported period can be transferred to the 12 and 36-month postoperative measurements in our series. The 100 patients in our study present hardly any changes at all in this period, for ROIs 1, 2 and 3; but we notice a density gain in ROI 4

Conclusions

We had an unpleasant experience, because of the inadequacy of standard x-ray examinations, and the situation led to the research described in the present thesis. We aimed

1. To test the precision and accuracy of DEXA-scanning of the periprosthetic bone around hemispherical press-fit cups, as regards patient position and pelvic tilt.
2. To characterize a possible correlation between a well defined periprosthetic bone defect and a corresponding BMD-value.
3. To analyze the feasibility of DEXA-scanning of the peri-acetabular bone in a randomized series of 100 THA patients, as a tool for comparing the differences of a specific cementless cup with and without HA, and describe the pattern of bone remodeling around hemispherical cementless press-fit fixated acetabular cups in general.

We found a useful method in DEXA-scanning of patients supine on the scanner table with acceptable reproducibility, as long as pelvic tilt of more than 10 degrees is avoided.
We found significant correlation between ash weight and BMD loss in an idealized laboratory mounting.
We applied our method to 100 patients, performed numerous DEXA examinations during a 3-year follow-up period and found no method-related difficulties.
The test could identify even small bony defects in the laboratory study, but we found no differences in bone remodeling in the clinical study related to the use of HA coating of the cups. After stratifying for Body Mass Index, we discovered differences in remodeling patterns between normal weight and overweight patients, i.e. maybe an effect from load on the bone around the cup.

Future research

We found no differences between HA versus non HA coated implants within a 3-year follow-up, but we aim to follow the patients included in Paper III with further DEXA-scans in the years to come. If the anticipated sealing-effect from the HA-coating provides any advantages, they are likely to appear as BMD might change in the future due to osteolysis.

Furthermore, we want to use the data from Paper III as reference parameters in a future study of patients scanned before a planned cup-revision, preferably combined with CT-evaluation of the amount of osteolytic lesions.

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First, I want to thank my wife Tina for working our family, kids, me, household and social contacts, briefing me of latest developments when appropriate, and when possible, keeping me in contact with real life.

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Paper I

DEXA-scanning of acetabulum in patients with cementless total hip arthroplasty.

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Abstract:

The aim of this study was to evaluate the reproducibility of BMD measurements of the periprosthetic bone in patients with hemispherical acetabular cups in cementless total hip arthroplasty (THA).

30 patients were treated for primary osteoarthrosis with cementless THA. DEXA-scanning was performed with a pencil beam bone densitometer (Norland XR-36).

Accuracy and reproducibility was determined by double measurements of BMD in four Regions of Interest (ROI). The influence of patient postures including various pelvic inclination angles was evaluated as well.

Pitman test for a combined netROI revealed a S.D. ratio of 3.2 for the AP scans related to the Lateral position. The Wilkinson Regions of Interest showed a high intra observer agreement. With pelvic tilt increasing till 20 degrees, the precision of DEXA-scanning decreased.

In conclusion, reproducibility of DEXA-scanning was high.

This study demonstrated that the patients can be scanned in the supine position, and BMD measurement of the periacetabular bone can be performed using the Wilkinson model with four rectangular regions of interest.

Key Words:

Accuracy – Bone mineral density (BMD) - Cementless total hip arthroplasty - Dual-energy X-ray Absorptiometry (DEXA) – Laboratory Techniques and Procedures

Introduction:

Worldwide more than 1 million hips are replaced each and every year, and the procedure is still on the increase. Generally, results are good, but one major concern is development of periprosthetic osteolysis (Schmalzried et al., 1998). For a decade, advances in understanding bone remodeling around prostheses, have concentrated on the tibial part of knee-prosthesis and the femoral components of THA (Mortimer et al., 1996,Petersen et al., 1993,Petersen, 2000,Ming et al., 2005,Yamaguchi et al., 2000). Little attention has been paid to the acetabular side, although two thirds of all revisions for aseptic loosening comprises an exchange of the cup (The Danish Hip Arthroplasty Registry, 2003,Havelin et al., 2000). Pelvic osteolytic lesions in the presence of THA appear in all directions seen from the acetabular component. Some cup-designs are associated with osteolysis in specific locations, other designs ‘produce’ lesions in other areas; nevertheless, no clear rules have been elucidated yet. The lesions are difficult to detect and quantify from plain X-rays, and consequently the amount of bone-loss is often underestimated, thus revisions becomes more extensive than anticipated.

A special developed x-ray set-up (Southwell et al., 1999) can visualize almost the whole outer surface of the cup, by combining the standard AP projection with 45-degree iliac-oblique and 60-degree obturator-oblique projections. Thus the method delineates eventual osteolysis, but fails to provide any quantitative measures.
Previous studies has anticipated a connection between low bone mineral content and loosening of implants (Onsten et al., 1993b,Onsten et al., 1993a,Soininvaara et al., 2002,Wilkinson et al., 2003,Yamaguchi et al., 2000) ; although there is no evidence (as yet) for a direct causal link, it is generally accepted that either focal bone loss (osteolysis) or regional bone loss (stress shielding) plays important roles in the development of aseptic loosening. If a reliable method for BMD measurements can be provided, its clinical use is bound to increase. Comparative studies of different prosthetic designs may accelerate; if one design causes BMD changes and the other design does not. If applied to routine check-ups, patients at risk of later prosthetic failure may be detected at an early stage, and patients without such risk signs, might be released from further control.
The works of Wilkinson et al. (Wilkinson et al., 2001) is the only well performed study available on acetabular periprosthetic BMD measurements. They conclude that a model with 4 regions of interest (ROI) – “The Wilkinson Regions” – offers the highest precision in BMD measurements. But they did not consider the possibility of different patient positions, or the risk of mal-positions (Lekamwasam and Lenora, 2003). Hence, the purpose of the present study was to determine the precision and accuracy of BMD measurements around cementless hemispherical metal-backed cups in THA, and to show how a difference in patient posture affects the result.

Material and Methods:

Experimental Subjects:

Thirty patients, all Caucasians, mean age 69 (38-85) years, were operated for primary osteoarthrosis with cementless THA. Informed consent was obtained from all patients. The investigations were approved by the local ethic committee (VN 98/24), and the national data protection agency (2001-41-1285). Patient demographics listed in Table 1 shows no differences between group 1 and 2 concerning age at operation, whereas the patients in group 3 were slightly younger.

Surgery:

Surgery was performed in an operating room with laminar airflow. Single dose prophylactic methicillin 1 g was given pre-operatively. Anesthesia was provided with spinal infusion of a single dose local-anesthetic. During surgery, the patient was fixed in a lateral decubitus position, allowing exposure of the hip joint through a posterior approach. The porous coated cementless acetabular cup is shaped like a true hemisphere (Trilogy®, Zimmer, Warsaw, Indiana, USA). The core is manufactured of titanium alloy (Ti-6Al-4V); it is covered with a fiber mesh of technically pure titanium, and lined with a standard polyethylene-liner. The bony bed of acetabulum was prepared for cup-insertion by reaming-off residual cartilage and bone excrescences, maintaining the subchondral bone plate. Cup size was chosen 2 millimeters larger than the last reamer utilized, i.e. press-fit fixation. The femoral component is a cementless plasma sprayed coated titanium alloy design (Bi-Metric®, BiometMerck, Warsaw, Indiana, USA), with a modular 28 mm CrCo femoral head. Mobilization commenced the first postoperative day, although weight bearing was restricted for 6 weeks using 2 crutches.

Patient grouping:
Patients were selected for three groups of 10 (5 females and 5 males in each group). In group 1 all patients were scanned a few days postoperative. BMD measurements were used for calculations of differences between AP and lateral positions. Patients in group 2 were scanned one year postoperative, their BMD values were also evaluated with regard to differences between AP and lateral positions. Group 3 was used for pelvic tilt measurements. There was no significant difference between group 1 and 2 concerning age or gender. Patients in group 3 were a little younger (Table 1). The subject of this methodological investigation was the accuracy and precision of DEXA-scanning measured by the 4-ROI model, BMD changes in the particular patient over a period of time is very interesting, but out of the scope of this report.

Scanning positions:
To assess the influence of time since surgery, patients in group 1 were scanned postoperatively before discharge from hospital, mean 7(5-13) days after surgery; and group 2 patients were investigated one year (mean 367 (361-373) days) after surgery. Patients included in group 1 and 2 were scanned in both the supine position; i.e. Anterior-Posterior (AP) scanner-beam direction; and in a 45-degree lateral tilted position. All scans were performed twice after complete repositioning. In the supine position, the legs were fixed in slight internal rotation, using standard equipment for femoral neck scan (Figure 1). The 45-degree lateral tilted position was chosen to transfer the 45-degree iliac-oblique X-ray technique described by Southwell et al. (Southwell et al., 1999) to the DEXA-scanner. The DEXA-scanner allows no changing in the directions of the beam, hence the 45-degree iliac-oblique projection was obtained by tilting the patients lateral, supported on a special foam cushion, constructed for this purpose (Figure 2).
Group 3 consisted of 10 patients who were examined before discharge from hospital, mean 6 (3-14) days after surgery. They were scanned in the supine position (AP), and in positions of 10 and 20 degrees pelvic tilt. In all scans, the legs were fixed in slight internal rotation, using standard equipment designed for femoral neck scan. A special pelvic tilt board with hinges in line with the L5-S1-discus, and buttresses under the legs was constructed to achieve the selected angles (Figure 3). The tilt board is a right triangle: The legs rests on the hypotenuse (a), which is 100 cm. long. 10 degrees (C) of flexion in line with L5-S1 required a vertical 17.4 cm. high buttress acting as the short side of the triangle (c), standing perpendicular to the scanner table (A). 20 degrees flexion was similarly achieved with a 34.2 cm. high buttress. Hence the geometric formula is: $c = (a * \sin C)/\sin A$.

DEXA-scanner:
Measurements were performed with a dual energy X-ray absorptiometer (Norland XR-36 Bone Densitometer: A pencil beam scanner using a stationary anode x-ray tube with 100kV constant potential. Anode current is constant at 1mA, and the samarium filter (K-edge = 46.8 keV) minimum filtration is 3 mm aluminum equivalent. The detectors are two NaI scintillation detectors in pulse counting mode. Software version 3.9.4/2.1.0.) Scanning was performed in the “research” mode at a resolution of 1 x 1 mm with a speed of 60 mm/s, with the “exclude high density” facility activated (excludes pixels with a density larger than 3.75 g/cm^2). We performed calibration daily, with two different phantoms, according to the prescriptions from the manufacturer.

Regions of Interest:

Four Regions of Interest (ROI) were used, modified from the regions defined by Wilkinson et al: (Figure 4). The aim of this model was to create simple rectangular ROIs. The medial and lateral borders of the regions were created by two vertical lines; one projected along the medial border of the obturator foramen, and the other along the lateral border of the femoral prosthesis. We placed the latter vertical line as a tangent to the most lateral point at the Ilium within the ROI1, to avoid femoral bone interfering with the results. The superior limit of ROI 1 was defined by a horizontal line lying 25 mm superiorly from a horizontal line touching the top border of the cup, which defined its lower limit. ROI 2 extended from here to a horizontal line bisecting the centre of the cup, and ROI 3 extended from here to the lower border of the cup. ROI 4 extended from the line marking the lower border of the cup to a further line lying 25 mm below that. The term netROI defines a global region of interest encompassing all four regions mentioned above.(Wilkinson et al., 2001).

Statistics:

Statistic analysis was carried out using Intercooled Stata 8.0 for Windows (Stata Corporation, College Station, Texas, USA. Standard deviations from different groups were compared by F-test and standard deviations from the same group were compared by Pitman’s test.

Results:

We found no statistical significant difference between the standard deviations of the pairwise differences in group 1 and group 2 and the two groups were merged for the following calculations.

Scanning in the AP position was more reproducible than scanning in the lateral position; the Pitman test is highly significant, except for the ROIs 3 and 4 (Table 3).

Tilting the pelvis within 10 degrees did not affect reproducibility, but further tilting will compromise accuracy, as seen in figure 5. The BMD measures in the 0 degree tilted position are considered to be the “true” values, and the curves shows how the measures change with increasing degree of tilting. For the 10 degree values the true value is within the 95% limits, but the 20 degree values are more divergent.

Intra observer variation was evaluated by measuring 20 scans in random order and re-measuring the same scans one week later by the same investigator in another random order (20 scans, 4 ROIs, makes 80 double measurements). 71% of the results were exactly the same; the rest differed in a single pixel row.

Discussion:

Results from the present study showed that scanning of the periacetabular bone can be performed as AP scans, with acceptable precision, and the time elapsed since surgery does not inflict on reproducibility. Furthermore we have shown that 10 degrees of pelvic tilt does not significantly affect the precision of the measurement, whereas 20 degrees does inflict the precision. These results can be transferred to a clinical setting: In further research we will be able to conduct a study where patients are scanned within a week after surgery. We can scan in the AP position, which is the least uncomfortable position for the patients. We know that patients at that stage do have pains, and these pains often results in tilting of the pelvis, but now we can accept a tilting up to 10 degrees.

Our results have certain limitations, however, since the patient groups were very small and specialized. The purpose of the present study was to elicit the precision and accuracy of BMD measurements around metal-backed cups, and to show how a difference in patient posture affects the result, prior to conducting a randomized study, utilizing the 4-ROI model as outcome measure. Patients eligible for surgery and research at our clinic are mainly as mirrored in the present study: Otherwise healthy persons with one or more osteoarthritic joint(s), evenly sex-distribution, age around 70 years. Extrapolating beyond this is not recommended.

In orthopedic research, DEXA-scanning has evolved into an established method for detection of bone mass changes around prosthetic implants. This development is based on numerous well performed methodological works(Cohen and Rushton, 1995,Engh, Jr. et al., 2000,Gehrchen, 1999,Kilgus et al., 1993,Mortimer et al., 1996,Rahmy et al., 2000,Schmidt et al., 2002,Smart et al., 1996,Ming et al., 2005,Yamaguchi et al., 2000). Clinical trials based on these works are frequently published, showing 3, 5 or 10 year follow-up, or BMD differences between different coatings or prosthetic designs (Engh et al., 1994,Karrholm et al., 1999,Kiratli et al., 1996,Munting et al., 1997,Sabo et al., 1998,Wright et al., 2001,Yamaguchi et al., 2000). The femoral part of THA or the tibial part of knee-prosthesis are the preferred subjects to investigation; whereas the acetabulum has been left aside.
To our knowledge, Onsten et al. (Onsten et al., 1993a) published the first description of DEXA-scanning of peri-acetabular bone in a study comparing patients with rheumatoid arthritis and patients with osteoarthrosis. Scanning was performed one week before total hip replacement; but they did not compare results with postoperative or later follow-up scans. The 2 ROIs were both placed cranial to the acetabulum. No data or other information on measurement accuracy was provided.
Sabo et al. (Sabo et al., 1998)reported the first follow-up study of DEXA-scanning of cementless acetabular cups: Their ROIs were defined according to the De Lee and Charnley zones. The accuracy was assessed by double measurement in 5 patients at 2 different days with CV% of 0.7, 0.8 and 2.4 in the 3 ROIs. The precision in region 1 and 2 seems to be close to the values found in the present study.
Wright and co-workers (Wright et al., 2001) used a model of computed tomography, with 5 ROIs. These were defined as 100 mm² circles on top of each other, the most distal region placed tangential to the cranial part of the cup. The paper provided no information on the height of the regions, except that regions were separated by 2.5 mm gaps. The reproducibility was assessed by double measurement (with repositioning in between) in 6 healthy volunteers (without THA), and presented as a correlation coefficient = 0.80 for the most distal level, and a correlation coefficient > 0.89 for the four most cranial levels. They did not discuss the possible differences between the patients with metallic implants and the volunteers without metal.

In another Computed tomography study Schmidt et al. reported a one year follow-up on a press-fit fixated cup. CT scans obtained 2 weeks and one year post-operatively were compared. ROIs were not defined, but some special software utilized, could differentiate between total-bone-density and cortical-bone-density. This measurement was performed in a whole CT-slice at a random part of the pelvic bone, cranial to the cup. They concluded that accurate assessment of implant fixation could be performed by their method, but the base for this conclusion was not further elucidated.
The very well conducted studies of Wilkinson and co-workers (Wilkinson et al., 2001) applied both the 3 ROI-model described by Sabo et al. (Sabo et al., 1998) and a simpler 4 ROI model. Both models were tested in the same patients as double measurements (with repositioning) both at the inclusion time and 13 months later. They concluded that the 4 ROI model was superior with a net CV% of 1.98.
Therefore, we decided to conduct further investigations of this model and we have shown that reproducibility is superior when the patient is supine. Furthermore, we have quantified the influence of pelvic tilt on these measurements.

Values in the present study are comparable to the values reported by Wilkinson, except that we must report a lower Ratio of S.D. in the ROIs 3 and 4, indicating a worse reproducibility in these regions. We have no plausible explanation for this, but are very aware for this finding, especially when using the method in ongoing studies. It is interesting to note that in the pelvic-tilt part of this study, the same trend affects the results of the 20 degree tilt, but not the results of the10 degree tilt.
This finding can be explained from the longer distance between ROI 4 and the centre of the flexion (the hinge in the tilt board was placed in line with L5-S1).
To transfer these results to a larger population of patients with cementless metal-backed hemispherical acetabular cups might be difficult, remembering that our setting was experimental, performed on selected patients, and not in a consecutive series. Another source of bias to the present investigation was the difference between the AP-scanning-position where patients were fixated, and the 45-degree lateral position, where the fixation device was not applicable.

We have shown here, the influence of patient positioning during scanning, and measured the accuracy. These results approve the method, and now the way is paved for further investigations. The measurements performed in this study are snapshots of the bone mineral status in the patients at that specific time. What is really interesting is the changes in BMD over time, after implanting a prosthesis. The next step will be to elucidate what the DEXA-scanning actually do measure concerning osteolysis around hemispherical cups, and finally we want to create a programme for early selection of patients at risk of aseptic loosening and preoperative planning for revision cases; i.e. to locate and quantify periacetabular osteolysis.

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Tables:

Table 1.: Patient demographics, and comparison of patient age in group 1 and 2.

Group	Median age at OP (range)	Gender F/M	Mean (95% CI)	F-test	*t*-test
1	71 (43-82)	5/5	71 (61.9-80.6)	F = 1.537 p = 0.532	*t* = -0.511 p = 0.692
2	74 (53-86)	5/5	74 (66.5-81.5)		
3	64 (39-77)	5/5	64 (55.8-71.8)		
1 and 2		10/10	73 (67.2-78.1)		
all	69 (38-85)	15/15	69 (65.2-74.2)		

Table 2.: Comparison of group 1 and 2 BMD-values.

	G1				G2						
AP	mean	mean diff.	σ_T	σ_W	mean	mean diff.	σ_T	σ_W	σ_W (G2)/ σ_W (G1)	p	dF
netROI	0.956	-0.001	0.280	0.018	0.981	0.028	0.163	0.021	1.168	0.651	9,9
ROI1	1.130	0.005	0.333	0.021	1.104	-0.029	0.190	0.024	1.149	0.686	9,9
ROI2	0.823	-0.016	0.210	0.019	0.798	-0.002	0.146	0.026	1.348	0.387	9,9
ROI3	0.796	0.060	0.261	0.041	0.725	0.001	0.164	0.061	1.496	0.246	9,9
ROI4	0.739	-0.051	0.348	0.041	0.890	-0.022	0.038	0.023	0.561	0.263	9,3
LATERAL											
netROI	0.958	-0.002	0.163	0.039	1.023	0.074	0.156	0.064	1.651	0.151	9,9
ROI1	1.204	0.030	0.200	0.042	1.246	-0.058	0.213	0.088	2.122	0.035	9,9
ROI2	0.824	0.026	0.267	0.038	0.847	-0.029	0.180	0.054	1.425	0.306	9,9
ROI3	0.708	-0.019	0.283	0.037	0.727	-0.126	0.237	0.101	2.719	0.006	9,9
ROI4	0.749	-0.018	0.264	0.018	0.802	-0.372	0.275	0.186	10.474	0.073	5,1

G1 is the group of ten patients scanned before discharge.
G2 is the group of ten patients scanned one year after the operation.
AP and **LATERAL** designates the two different scanning positions
mean is the mean BMD value of 2 scannings in each of the 10 patients (20 BMD values)
mean diff. is the average difference between the 2 BMD values in each of the 10 patients.
σ_T is the standard deviation (Total) of the 20 BMD values in the group
σ_W is the standard deviation (Within) of the pair-wise differences.
dF is degrees of freedom.

Table 3. Comparison of scanning positions AP and Lateral for the combined group 1 and 2.
AP or Lateral?

	AP					Lateral					PITMAN TEST					
	mean	mean diff.	σ_T	σ_W	n	mean	mean diff.	σ_T	σ_W	n	Ratio of S.D. (lateral /AP)	95% CI		t	p	df
netROI	0.97	0.014	0.23	0.020	20	0.99	0.036	0.16	0.051	20	3.20	2.09	4.90	-6.91	0	18
ROI1	1.12	-0.012	0.27	0.022	20	1.23	-0.014	0.21	0.065	20	3.38	2.13	5.35	-6.78	0	18
ROI2	0.81	-0.009	0.18	0.022	20	0.84	-0.002	0.23	0.046	20	2.00	1.25	3.20	-3.23	0.005	18
ROI3	0.76	0.030	0.22	0.051	20	0.72	-0.073	0.26	0.069	20	1.57	0.97	2.52	-1.98	0.063	18
ROI4	0.78	-0.043	0.30	0.035	14	0.76	-0.107	0.30	0.060	8	1.81	1.00	3.27	-2.17	0.051	12

AP and **LATERAL** designates the two different scanning positions
mean is the mean BMD value of 2 scannings in each of the 20 patients (40 BMD values)
mean diff. is the average difference between the 2 BMD values in each of the 20 patients.
σ_T is the standard deviation (Total) of the 40 BMD values in the group
σ_W is the standard deviation (Within) of the pair-wise differences.
dF is degrees of freedom.

Illustrations:

Figure 1: AP scanning position.

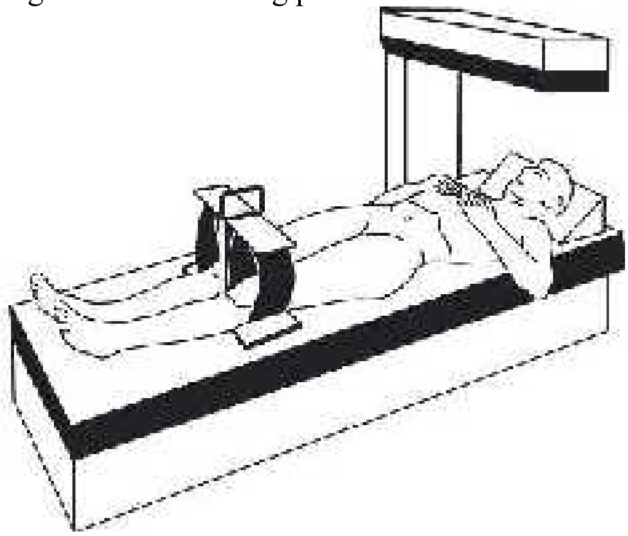


Figure 2: 45-degree lateral scanning position.

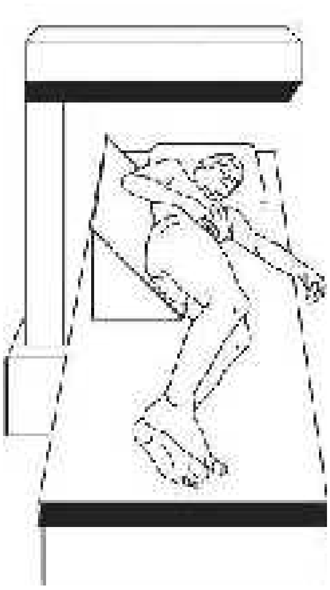


Figure 3: Pelvic flexion couch.

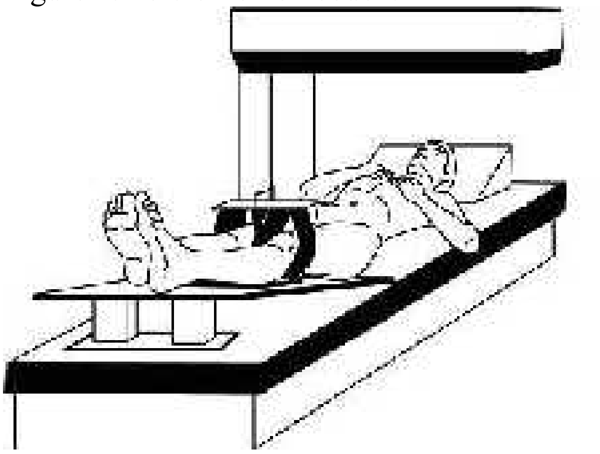


Figure 4: The modified Wilkinson Regions of Interest.

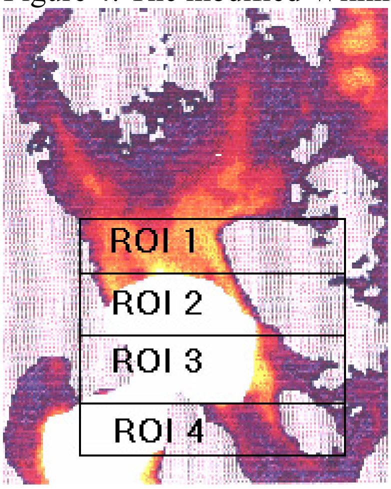
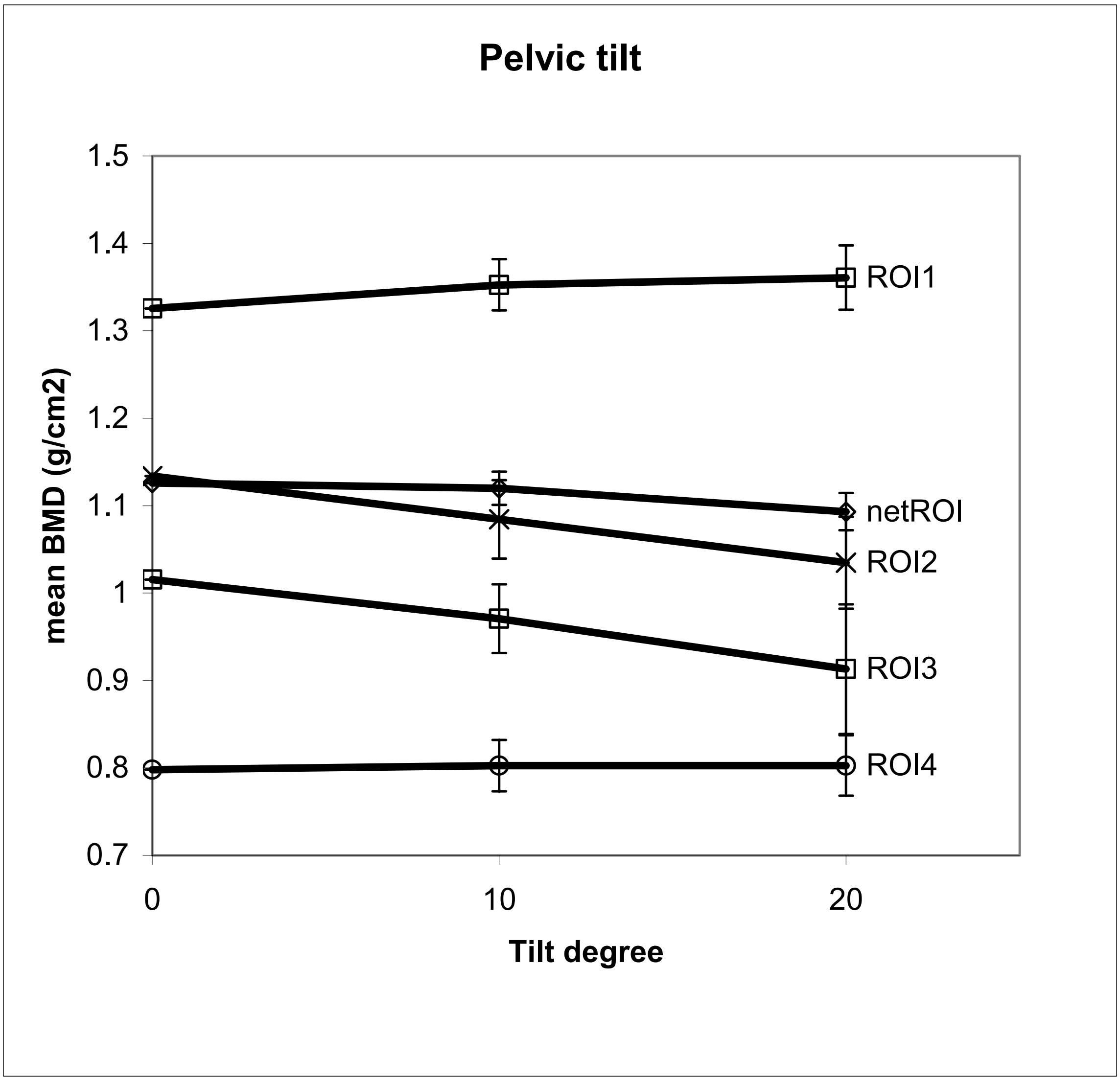


Figure 5. Influence of pelvic tilt



The BMD measures in the 0 degree tilted position are considered to be the “true” values, and the curves shows how the measures change with increasing degree of tilting. For the 10 degree values the true value is within the 95% limits, but the 20 degree values are more divergent.

Paper II

Detection of bony defects around cementless acetabular components in total hip arthroplasty. A DEXA study on ten human cadavers.

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Abstract

We studied the ability of DEXA in detecting bony defects around cementless acetabular components in total hip arthroplasty, by measuring BMC in ten post mortem retrieved human pelvic specimens. We created standardized defects behind inserted acetabular components and compared the ash weights of the removed bone to the corresponding BMC measures.

We found good correlation between the measured BMC differences and the corresponding ash weights. This leads to the conclusion that DEXA can detect even small defects in the bone adjacent to the cup.

Introduction.

Fixation of cementless acetabular components is dependent on the strength of the surrounding bone. Decreased BMC of periprosthetic bone might be a reason for socket migration (Onsten et al., 1993a).
Revision rates for porous-coated cups varies between 2,2% and 32% (Engh et al., 1994,Iwase et al., 2002,Jacobsen et al., 2003,Jazrawi et al., 1999,Reikeras and Gunderson, 2002,Soto et al., 2000,Spicer et al., 2001,Thanner et al., 1999) and osteolysis poses the greatest threat to long-term survival of cementless arthroplasties (Engh et al., 1994). Defects adjacent to the acetabular component are difficult to detect and quantify from plain X-rays (Zimlich and Fehring, 2000), and consequently the amount of bone-loss is often underestimated. By means of different oblique X-ray projections, detection of defects has become possible (Southwell et al., 1999), but the quantitative measure is still lacking. DEXA-scanning has evolved into an established method for detection of bone mass changes around prosthetic implants. This development is based on numerous well performed methodological works (Cohen and Rushton, 1995,Engh, Jr. et al., 2000,Gehrchen, 1999,Kilgus et al., 1993,Mortimer et al., 1996,Rahmy et al., 2000,Schmidt et al., 2002,Smart et al., 1996). Clinical trials based on these works are frequently published, showing 3, 5 or 10 year follow-up, or BMD differences between different coatings or prosthetic designs (Engh et al., 1994,Karrholm et al., 1999,Kiratli et al., 1996,Munting et al., 1997,Sabo et al., 1998,Wright et al., 2001,Yamaguchi et al., 2000). The femoral part of THA or the tibial part of knee-prosthesis are the preferred subjects to investigation; whereas the acetabulum has more or less been left aside.
Changes in pelvic periprosthetic BMC are best detected using a 4-ROI model (Wilkinson et al., 2001,Laursen et al., 2005b). The few scattered longitudinal studies published have shown a universal decrease in periacetabular BMC, but no localized demineralization (Korovessis et al., 1994,Sabo et al., 1998).

The purpose of this study was to investigate if DEXA is able to detect and quantify experimental defects around cementless metal-backed acetabular components.

Material and methods

Laboratory techniques

Ten female pelvic specimens were obtained from the Institute of Anatomy at the Aarhus University, after 6 months of preservation in a solution of alcohol and formaldehyde. All soft tissues were removed mechanically, the hips were exarticulated and the spine was excised through discus L5-S1. The specimens were kept at 4°C between laboratory procedures. To facilitate handling, each specimen was fixed to a wooden plank of 2 x 10 x 80 cm using 3 screws through os sacrum (Figure 1a). The left acetabulum was chosen for experiments, because one of the subjects had had a right hip replacement due to fracture sequelae. There was no macroscopic evidence of pathology. Preparation of acetabulum included removal of remnants of the joint capsule and the labrum, and reaming with a standard hemispherical reamer (Zimmer, Warsaw, Indiana, USA) to remove cartilage, but the subchondral cortical bone was preserved. A cementless cup of the same size as the last used reamer was chosen to avoid fractures during repeated cup insertions.

Implants

We used the Trilogy-cup® (Zimmer, Warsaw, Indiana, USA), shaped like a true hemisphere with a core of titanium alloy (Ti-6Al-4V) and covered with a fiber mesh of technically pure titanium.

The cups were modified as follows: To secure the exact re-positioning between procedures where the cup was removed, two barrels were attached to its outer rim. The barrels were cannulated for 2-mm Kirschner wires, perpendicular to the opening plane of the cup (Figure 2) placed at its outer rim, at a 120-degree internal angle. To secure uniformity in the procedure of creating defects, each cup had three 2-mm holes. These holes were placed half a radius away from the center at 90-degree internal angles, and perpendicular to the outer plane of the cup. To adjust these placements to the different cup sizes, the angles were transformed to co-ordinates that could be entered into the equipment in our mechanical laboratory. After the first insertion of the cups, 2 Kirschner wires were drilled through the barrels and the underlying bone. The entry and exit holes were marked, and the placement-guide-Kirschner-wires were removed. Before creating the defects, we measured the baseline BMC in each specimen twice, with the cup *in situ*.

Scanning technique

Measurements were performed with the Norland XR-36 Bone Densitometer (Dual Energy X-ray Absorptiometer), pencil beam, using a stationary anode x-ray tube; 100kV constant potential, 1mA constant anode current; samarium filter (K-edge = 46,8 keV); minimum filtration is 3 mm. aluminum equivalent. The detectors are two NaI scintillation detectors in pulse counting mode. Software version 3.9.4/2.1.0. Scans were performed in the "research" mode with a resolution of 0.5 × 0.5 mm and a speed of 60 mm/s. Calibration was performed daily with two different phantoms according to the manufacturer's prescriptions. The DEXA scans were measured according to the 4 ROI model of Wilkinson et al (Figure 3). (Wilkinson et al., 2001,Laursen et al., 2005b).

Creating defects

(A flow-chart for the laboratory procedures is shown in Figure 4.) After the baseline scans, the drill-guide-Kirschner-wires were inserted through the drill holes in the cups. The cups were removed. A hole was drilled at each of the three K-wire marked positions with a cannulated 10-mm drill bit with depth stop at 10 mm (Figure 5). All drilling debris was collected into a test tube. When all three holes had been drilled, drill bits and drill-guide-

Kirschner-wires were removed. The placement-guide-Kirschner-wires were then reinserted into their marked places, and the cup was slid into position with the placement-guide-Kirschner-wires in their corresponding barrels. DEXA scan was repeated. The procedure of drilling and scanning was repeated twice, with drill bits of 10 x 20 mm and 20 x 20 mm. The last scan was done as double measurement in the same way as the first (endline-scans).
In one specimen a set of supplementary scans were performed with metal spacers inserted into the defects (Figure 3b), and for visualization purposes the specimen was X-rayed with these metal spacers (Figure 6). The supplementary scans with inserted metal spacers revealed that the defect from position 1 was located in ROI 1, position 2 in ROI 2 and position 3 in ROI 3.

Ash weight
The test tubes were kept at -80°C until the ashing procedure. We used a standard ashing protocol, consisting of drying at 110°C for 24 hours and ashing at 600°C for 24 hours (Griffin et al., 1993,Fink et al., 2002). The test tubes were weighed before use, and after ashing using a Mettler Toledo® balance, type AE 163.

Data acquisition
The first and the last DEXA scan was performed twice in each specimen, for calculation of measurement repeatability. For other calculations, the first of the two results was employed. In one specimen (no. 251) there was a considerable difference between the two baseline scans. After reevaluation one of these was judged as a technical failure, and the corresponding data were omitted in further analysis. BMC differences were calculated from the DEXA scans performed after the drilling procedures with respect to the baseline scan. Ash weights were calculated as difference between the weight of the test tubes before use and after the ashing procedure, corrected for the average weight loss of ten empty test tubes that were exposed to the same ashing procedure (0,0001±0,0002 grams). To match the fact that the BMC differences were calculated with respect to the baseline scans, the ash weights of each defect were added as per drilling procedure. This leaves 3 sets of data where each of the ten specimens has a baseline scan, and three “after drilling” BMC-differences with corresponding ash weights; set one containing data for ROI 1 and ash weights from drilling in position 1, set two concerning ROI 2 and position 2 and set three for ROI 3 and position 3. (table 1)

Statistics
The clinical problem is: Can a measured decrease in BMC be correlated to a quantitative measure of missing bone? In this in-vitro study the hypothesis to test was: Can a measured difference in BMC be correlated to the amount of bone removed?
I.e. we adhere to the model that a straight line describes the correlation.
Sample size was given from practical circumstances: at the time for our experiments, the maximum obtainable number of specimens of the same sex, without acetabular pathology was ten.
The statistical analysis was performed in the SPSS 12.0.2 for Windows, as a linear mixed model, taking within-subject variation into account by adding individual intercepts (hereby assuming intra-class correlation). We performed the statistical analysis on the complete dataset, and after splitting up in groups according to ROI. Plotting the values raises the suspicion of greater variation in the higher values than in the lower (Fig 7), for that reason we transformed the dataset (ln (1+x), due to a few negative values), and performed the analysis again, with same result.
The model diagnostics included a plot of residuals against the fitted values and a q-q plot of the residuals. These plots confirmed normally distributed errors and variance homogeneity and hence the adequacy of the analysis was approved.

Ethics

The procedures were in accordance with the ethical standards of the committee of scientific ethics for Viborg and Northern Jutland County (Approval no. VN 98/24), and with the Helsinki Declaration of 1975, as revised in 1983. Informed consent was obtained, when the persons were still alive, and decided to donate their bodies to science and education.

Results

Statistical analysis performed on the total dataset showed no useful association between the values, but after splitting up on the different ROIs the association between BMC and Ashweight shows high significance in each of the three regions ($p<0.001$; adjusted R^2= 0.933; 0,804; and 0,822 for the respective regions). The difference between the regions is seen in the slopes in Figure 7 and table 2. All data are presented in table 1, and summarized as an output from the linear regression analysis in table 2. The results of the statistical analysis should be understood as follows: If a BMC difference of 0.821g is detected in ROI 1 it is corresponding to a defect where 1g of minerals has disappeared. No defects were created in ROI 4 in this study, hence the BMC measures from this region serves as controls for the measurements.

Repeatability.

In the calibration process, the DEXA scanner provides its internal precision CV. During the days of these experiments it varied between 0.54 and 0.67, according to the routine daily calibrations.

In the experimental set-up, we performed double measurements in the DEXA scanner, and when weighing out the test tubes. Assuming that the instruments had only random errors, and adhering to ISO1998 International Standard and definitions of repeatability conditions (Ranstam et al., 2000) the repeatability limit for BMC measurements was 0.23 grams, SD 0.12, n 86; corresponding values for ash weights were 0.00097 grams, SD 0.00050, n 10. (Repeatability = $1.96 \times\sqrt{\Sigma d^2/n}$, d = paired difference between repeated measurements of the same object, n = number of pairs of measurements).

Discussion

The purpose of this study was to investigate if DEXA can detect and quantify bony defects around cementless metal-backed acetabular components. In a cadaver model we created standardized defects of increasing sizes in different locations. The precision of the measurements, and the correlation between the measured BMC decrease and the actual amount of bone removed was very high in our experiments. Our primary conclusion is that in DEXA-scanning of the periacetabular bone, around cementless hemispherical metal-backed cups, the 4 ROI model (Wilkinson et al., 2001,Wilkinson et al., 2003) provides a sensitive measure of changes in bone mineral content. Clinically this provides a help in detection of osteolytic lesions , which is in contrast to the ability of standard radiographs (Engh, Jr. et al., 2000). In the future we hope to provide a useful guide, when planning revision cases suspected for osteolysis (need for special implants or tools and amounts of allograft etc.). (Schmalzried et al., 1998).

In a clinical study we have previously shown that the BMC measurement has a high reproducibility (Laursen et al., 2005b), the present study adds the fact, that the measured BMC values actually derives from the bone.

Relying on x-ray examination, a possible detection rate of 94% of all periacetabular defects can be obtained by adding 3 different oblique x-ray projections to the standard AP and lateral x-rays (Southwell et al., 1999). In contrast, the use if DEXA scanning provides an estimate of 1 gram defect per 0.821 gram measured BMC loss (95% CI: 0.716 - 0.926) by only DEXA scan in the AP-plane. Investigations in progress will show whether this is acceptable for clinical use. Positioning of the patient in the scanner is perhaps even more important than hitherto anticipated, since the complex 3D structure of the pelvis inflicts as great influence on the measurements as reported in this study. These problems will be examined in a future experiment.

If necessary, improvement of our method could combine the AP-scan with scans in other positions. Weaknesses in the present study are the procedure of sampling the drilling debris from the acetabulum, by picking it up with a forceps. Also the risk of compacting some of the bone debris into the surrounding tissue when drilling must be considered.

We believe that the interest of DEXA scanning of the periacetabular bone will certainly rise, with the need for documentation of long term results of the potential benefits from new prostheses or altered surgical procedures.

The present study demonstrated that even small osteolytic lesions can be detected by DEXA. If all patients were routinely DEXA scanned once or twice within the first post-operative year, the basis for later decision and careful planning of the revision procedure would be easier and more precise.

Acknowledgments

We want to thank Associate Professor Peter Holm-Nielsen, Institute of Anatomy, Aarhus University, Denmark; who kindly provided the specimens. We also wish to thank Associate Professor Malene Højbjerre and Associate Professor Søren Lundbye-Christensen, Statistical Laboratory, Institute of Mathematical Sciences, Department of mathematical Sciences,
Aalborg University, Denmark; for invaluable statistical guidance.
The study was supported by grants from Zimmer Scandinavia.

Tables with titles

Table 1:
All data

Specimen ID-No.	Procedure	ROI 1 BMC (g)	Hole 1 Ash (g)	ROI 2 BMC (g)	Hole 2 Ash (g)	ROI 3 BMC (g)	Hole 3 Ash (g)	ROI 4 BMC (g)
228	Before drilling 1	9.11		3.04		2.5		2.01
228	Before drilling 2	9.03		2.99		2.48		1.99
228	After drilling 10X10	8.85	0.13	2.9	0.16	2.37	0.15	1.93
228	After drilling 10X20	8.93	0.3	2.98	0.27	2.38	0.17	1.98
228	After drilling 10X20-1	7.96		2.75		2.27		1.94
228	After drilling 10X20-2	7.7	1.22	2.55	1.1	2.29	0.64	1.87
231	Before drilling 1	9.22		3.54		2.08		2.3
231	Before drilling 2	9.54		3.54		2.18		2.32
231	After drilling 10X10	9.07	0.18	3.41	0.1	2.04	0.07	2.29
231	After drilling 10X20	9.27	0.27	3.3	0.23	2.07	0.15	2.23
231	After drilling 10X20-1	8.51		3.22		1.89		2.32
231	After drilling 10X20-2	8.71	1.14	3.18	0.97	1.94	0.65	2.38
232	Before drilling 1	17.54		6.32		6.66		5.21
232	Before drilling 2	17.83		6.33		6.71		5.32
232	After drilling 10X10	16.53	0.32	5.83	0.22	6.01	0.36	5.08
232	After drilling 10X20	16.61	0.48	5.55	0.36	6.02	0.44	5.15
232	After drilling 10X20-1	14.94		5.54		5.67		5.22
232	After drilling 10X20-2	15.1	2.41	5.54	1.48	5.72	1.67	5.28
234	Before drilling 1	15.72		4.7		3.13		3.93
234	Before drilling 2	15.72		4.79		3.02		3.95
234	After drilling 10X10	15.18	0.2	4.69	0.21	3.14	0.18	3.86
234	After drilling 10X20	15.13	0.32	4.51	0.34	3.09	0.24	3.94
234	After drilling 10X20-1	13.65		4.22		2.74		3.84
234	After drilling 10X20-2	13.99	1.5	4.28	1.27	2.82	1.25	3.93
235	Before drilling 1	12.48		5.55		3.91		2.99
235	Before drilling 2	12.48		5.61		3.87		3.06
235	After drilling 10X10	12.04	0.16	5.37	0.15	3.7	0.23	3.04
235	After drilling 10X20	12.22	0.23	5.48	0.2	3.64	0.3	3.19
235	After drilling 10X20-1	11.58		5.2		3.05		2.94
235	After drilling 10X20-2	11.65	1.14	5.14	1.08	2.98	1.39	3.11

237	Before drilling 1	8.19		3.63		3.27		2.78
237	Before drilling 2	8.28		3.74		3.46		2.97
237	After drilling 10X10	7.87	0.17	3.65	0.25	3.3	0.16	2.86
237	After drilling 10X20	8.01	0.25	3.54	0.35	3.39	0.24	2.88
237	After drilling 10X20-1	7.16		3.32		3.4		3.06
237	After drilling 10X20-2	6.91	1.48	3.22	1.28	3.31	0.96	2.92
239	Before drilling 1	17.01		3.43		4.72		5.55
239	Before drilling 2	16.86		3.24		4.7		5.44
239	After drilling 10X10	16.67	0.26	3.39	0.29	4.58	0.17	5.67
239	After drilling 10X20	16.55	0.41	3.02	0.42	4.64	0.2	5.51
239	After drilling 10X20-1	14.79		2.87		4.23		5.62
239	After drilling 10X20-2	15.04	2.19	2.9	2	4.25	1.05	5.53
251	Before drilling 1	4.96*		0.86*		0.99*		0.96*
251	Before drilling 2	6.43		1.35		1.43		1.55
251	After drilling 10X10	6.31	0.1	1.34	0.11	1.39	0.06	1.45
251	After drilling 10X20	6.3	0.13	1.28	0.21	1.35	0.07	1.51
251	After drilling 10X20-1	6.02		1.06		1.45		1.43
251	After drilling 10X20-2	5.98	0.76	1.17	0.54	1.38	0.34	1.46
254	Before drilling 1	14.01		2.84		2		4.86
254	Before drilling 2	14.11		2.77		2.08		4.85
254	After drilling 10X10	13.96	0.18	2.89	0.21	1.92	0.11	4.8
254	After drilling 10X20	13.55	0.3	2.91	0.32	2.32	0.12	4.7
254	After drilling 10X20-1	12.65		2.9		2.13		4.82
254	After drilling 10X20-2	12.74	1.7	2.8	1.37	2.25	0.65	4.8
257	Before drilling 1	8.63		3.59		2.72		3.03
257	Before drilling 2	8.73		3.74		2.78		3.05
257	After drilling 10X10	8.51	0.13	3.78	0.25	2.74	0.15	2.99
257	After drilling 10X20	8.47	0.3	3.64	0.4	2.76	0.24	2.99
257	After drilling 10X20-1	7.55		3.45		2.76		3.1
257	After drilling 10X20-2	7.63	1.57	3.42	1.23	2.7	1.07	3.04

*: technical failure, data omitted in calculations.

Table 2:

Statistic output:						95% CI	
ROI	number of specimens	number of measurements	${}_{adj}R^2$	p	slope*	lower	upper
1	10	30	0.933	<0.001	0.821	0.716	0.926
2	10	30	0.804	<0.001	0.214	0.130	0.299
3	10	30	0.822	<0.001	0.273	0.150	0.396

Linear mixed model analysis of correlation between δBMC and δASHWEIGTH.

slope*: In a clinical setting: Example (ROI 1) for each detected 0.821g BMC difference 1g of minerals has disappeared.

Figures

Fig. 1a: Photo of specimen showing cup-placement.

Fig. 1b: Photo of specimen showing drill-guide-Kirschner-wire placement, and c) 20 × 20 mm defects.

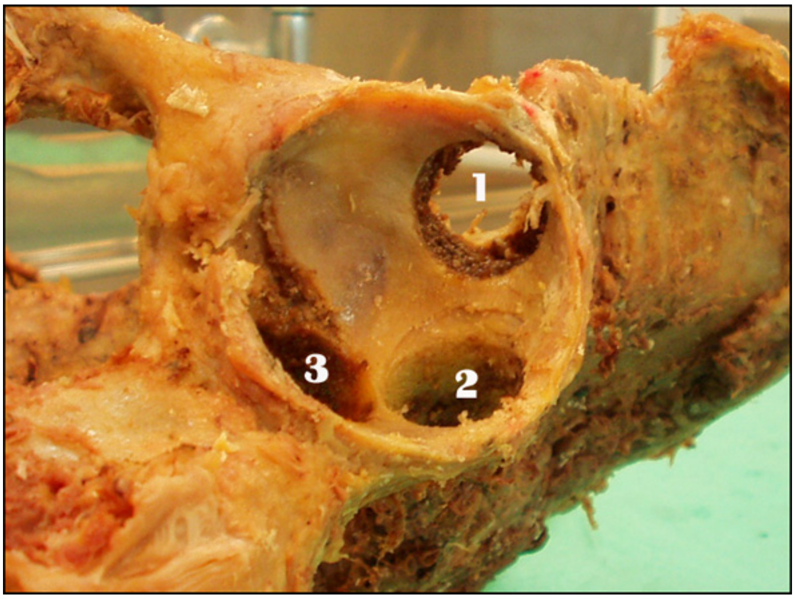

Fig. 1c: Photo of specimen showing 20 × 20 mm defects.

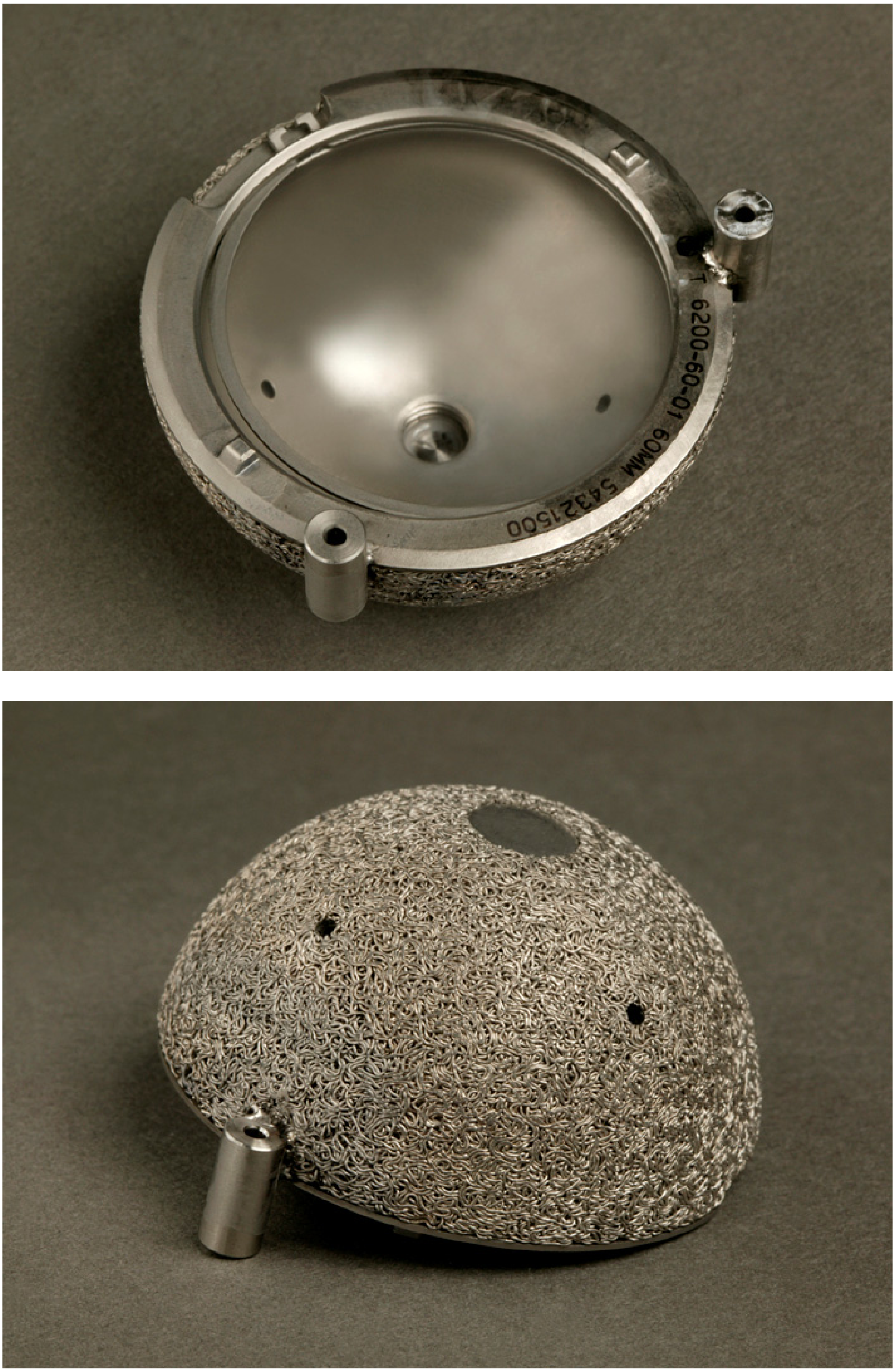

Fig. 2: Cup with placement-guide-barrels and drill-guide-holes.

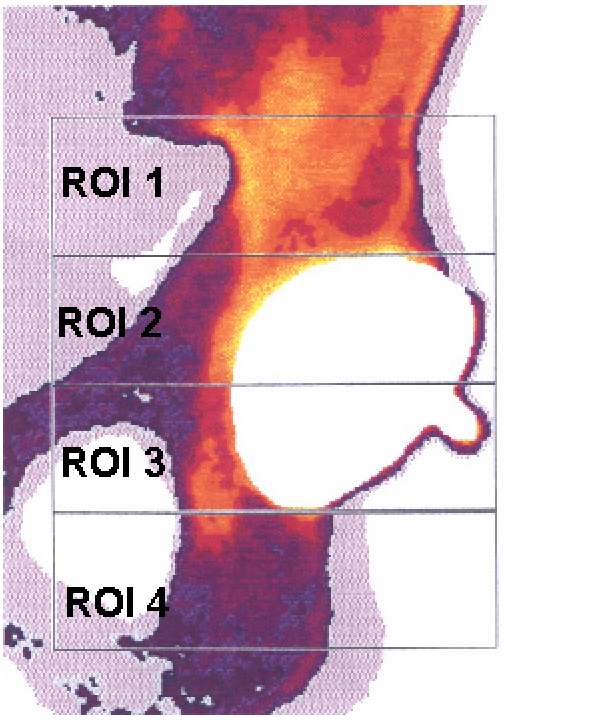

Fig. 3a: DEXA-scan marked with the modified Wilkinson Regions of Interest with 10 x 20 mm defects.

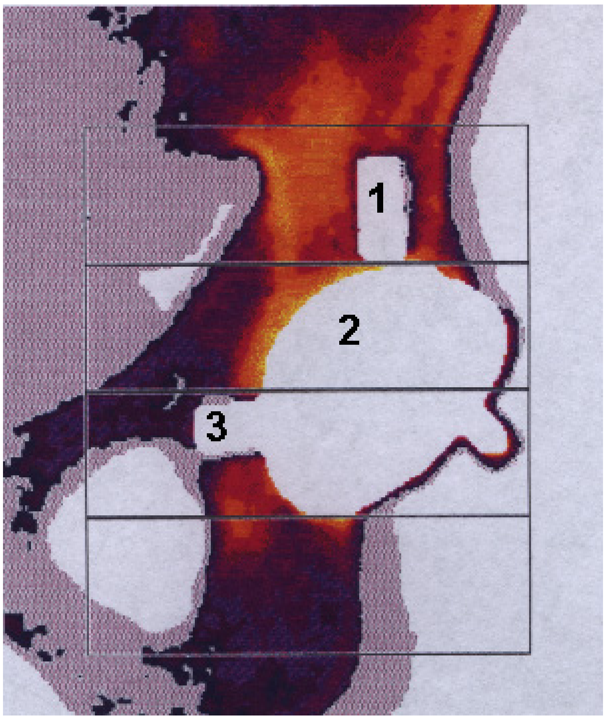

Fig. 3b: DEXA-scan marked with the modified Wilkinson Regions of Interest , same as 3a, but with metal spacers in the defects.

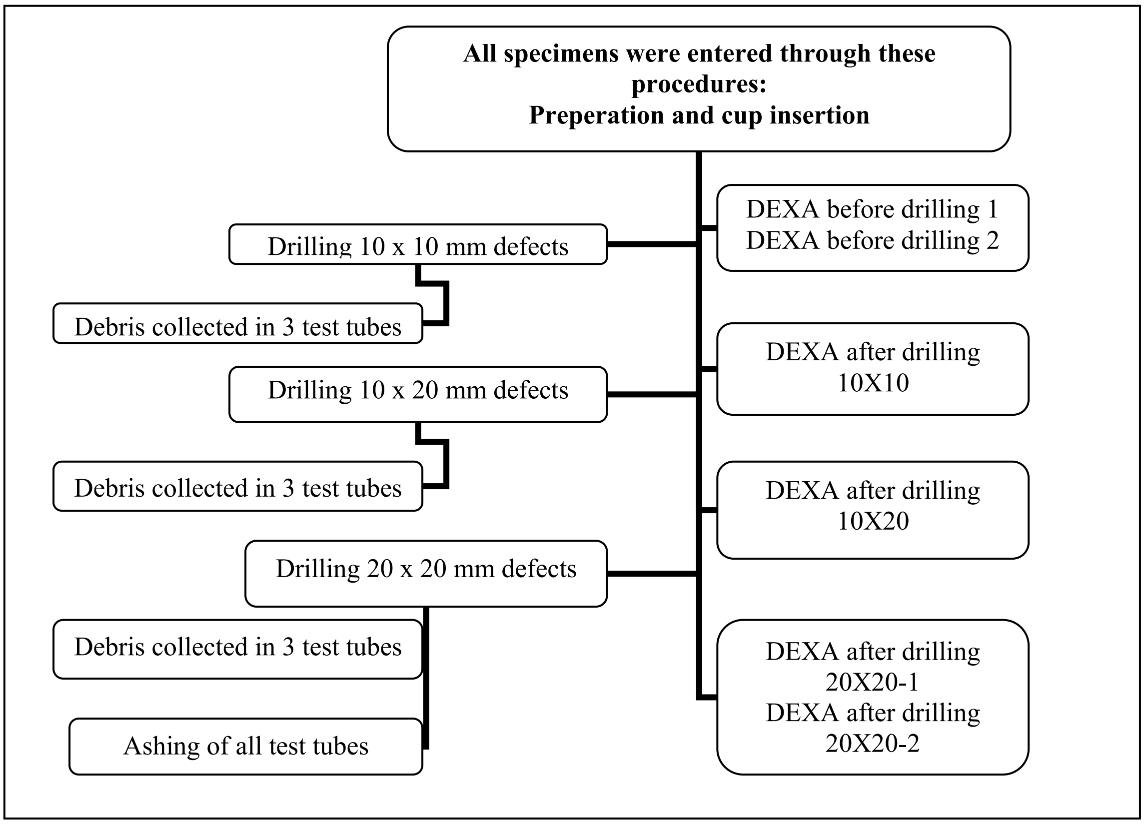

Fig. 4: Flow diagram for laboratory procedures.

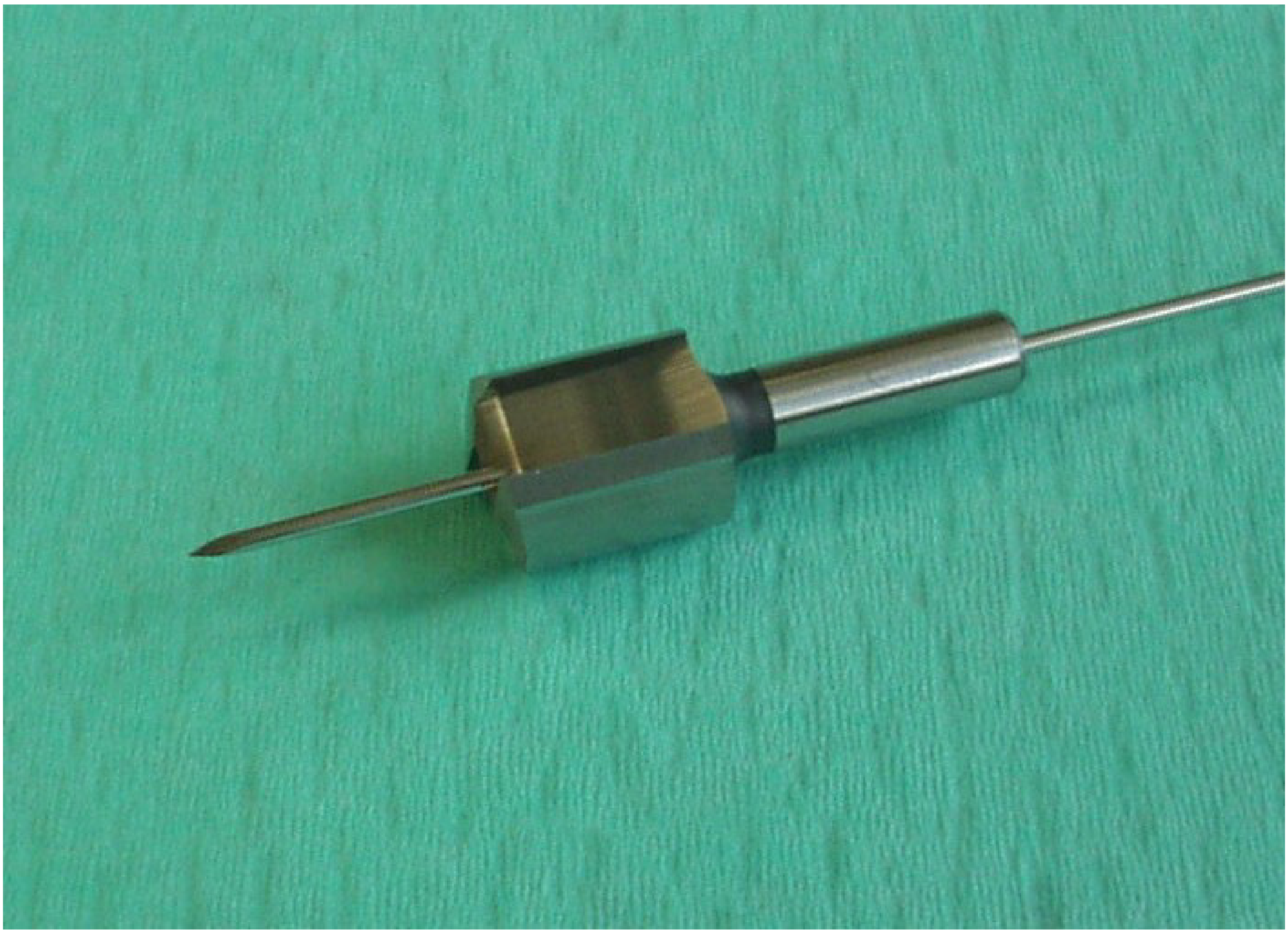

Fig. 5: Photo of 20 × 20 mm drill bit with Kirschner wire.

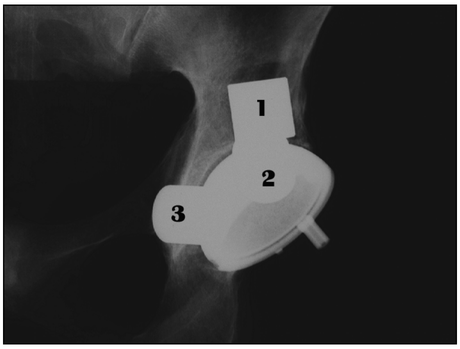

Fig. 6a: Radiological depiction of the cup with metallic spacers in 20 × 20 mm defects. AP.

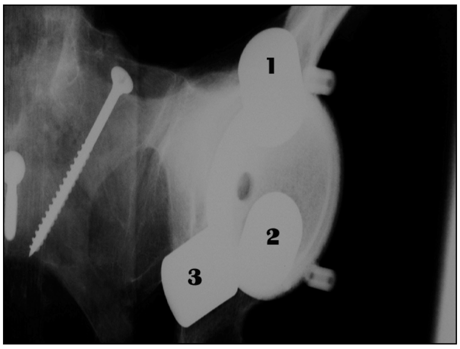

Fig. 7b: Radiological depiction of the cup with metallic spacers in 20 × 20 mm defects. 45º obturator oblique.

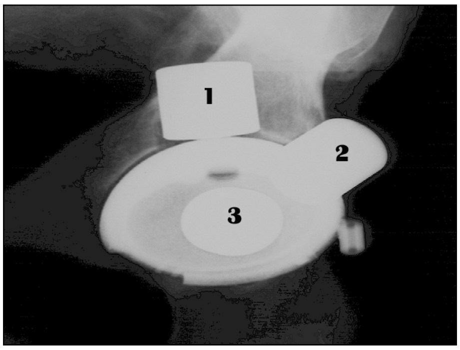

Fig. 8c: Radiological depiction of the cup with metallic spacers in 20 × 20 mm defects. Lateral view.

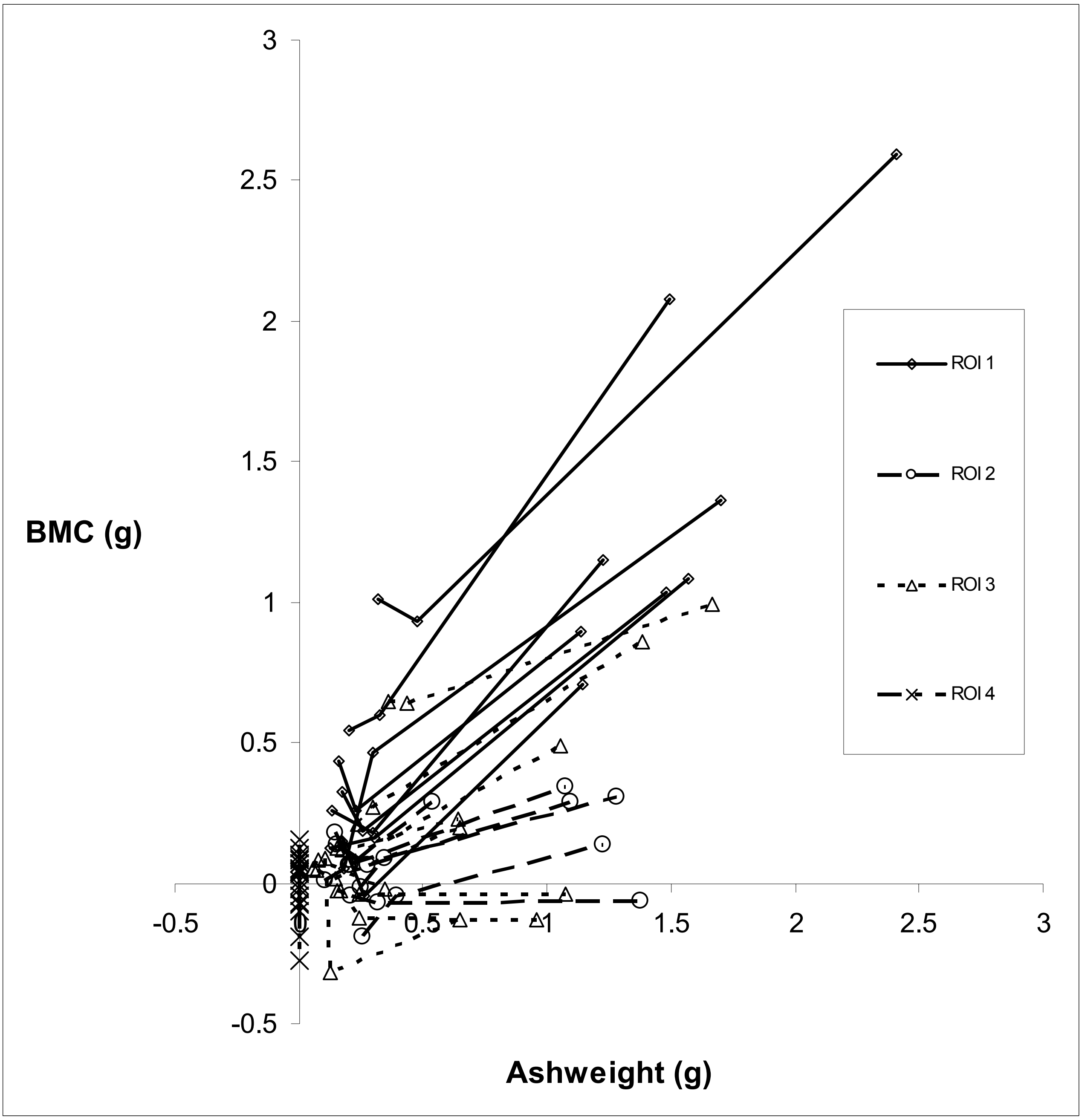

Fig. 7: Diagram showing relationship between ash weights and BMC – one line per specimen in each ROI.

Paper III

Bone remodeling around HA-coated acetabular cups.

A DEXA-study with 3 year follow-up in a randomized trial.

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Abstract

This study was designed to investigate the influence of HA-coating on bone remodeling around the cup in cementless THA.

100 patients gave informed consent to participate in a controlled randomized study. Randomization between porous coated Trilogy® and Trilogy Calcicoat ® was performed in the OR after the reaming procedure. The cup was inserted in press-fit fixation. The femoral component was a cementless porous coated titanium alloy stem (Bi-Metric®), with a modular 28 mm CrCo head. Effect parameters were Harris Hip Score (HHS) and Bone Mineral Density (BMD) determined by DEXA scanning.

Measurements revealed no difference between the two groups after 3 years, neither in clinical outcome nor in terms of bone remodeling. Patients with Body Mass Index above normal had a better bone mineral regaining pattern than normal weight patients. This finding supports the assumption that load is beneficial to bone remodeling. Advantages of better sealing of the bone-prosthesis interface, preventing polyethylene induced osteolysis, is still anticipated for the 5 or 10 year follow-up examinations.

Introduction:

Worldwide more than 1 million hips are replaced each and every year, and the procedure is still on the increase (Pedersen et al., 2005). Generally, results are good, but aseptic loosening and development of periprosthetic osteolysis offers great challenges for new developments in THA. For a decade, advances in understanding bone remodeling around hip arthroplasties, have concentrated on femoral components (Aldinger et al., 2003,Boden et al., 2004,Boden and Adolphson, 2004,Engh et al., 1994,Engh, Jr. et al., 1999,Gehrchen, 1999,Lekamwasam and Lenora, 2003,Li et al., 2004,Okano et al., 2002,Rahmy et al., 2004,Scott and Jaffe, 1996,Tanzer et al., 2001,Therbo et al., 2003,van Lenthe et al., 2002,Yamaguchi et al., 2003,Petersen, 2000,Mortimer et al., 1996). Little attention has been paid to the acetabular side, although two thirds of all revisions for aseptic loosening comprises an exchange of the cup (Havelin et al., 2000,Iwase et al., 2002,Havelin et al., 2000,The Danish Hip Arthroplasty Registry, 2003).

Femoral stems coated more or less extensively with hydroxyapatite are frequently reported having better long-term results than porous coated or grit-blasted prostheses, both in primary and revision settings (Aebli et al., 2003,Chatelet and Setiey, 2004,Porter et al., 2004).
A single, non randomized study reports poor results at long term follow-up on a HA- coated cup (Miyakawa et al., 2004), whereas two other non randomized studies reports good osseointegration and clinical performance of HA-coated cups at 2 and 5 year follow-up examinations (DAntonio et al., 1997,Tonino et al., 1995).
From experimental studies in animals we expect a positive effect from HA-coatings to occur in humans as well; in means of gap-healing and sealing of the bone-implant interface, maybe the solution to prevent debris particles from producing osteolysis and aseptic loosening (Soballe, 1993,Rahbek et al., 2000).

Wilkinson et al. performed the first studies on acetabular periprosthetic BMD measurements. They concluded that a model with 4 regions of interest (ROI) – 'The Wilkinson Regions' – offered the highest precision in BMD measurements (Wilkinson et al., 2001).
We went further in testing reproducibility and quantifying the model, and concluded that it could be useful in detection of periacetabular osteolysis (Laursen et al., 2005b,Laursen et al., 2005a).

The present study was designed to compare the differences in bone remodeling around a specific cementless cup with and without HA, and describe the pattern of bone remodeling around hemispherical cementless press-fit fixated acetabular cups in general.

Patients and Methods

From October 1998 till May 2000 we performed 247 unilateral cementless total hip arthroplasties at our clinic. 139 patients with primary osteoarthrosis, had no competing medical conditions, and were operated with pure press-fit fixated cups without additional screw-fixation. 100 of these gave informed consent to participate in this controlled randomized study (Fig. 1).
The procedure was approved by the local committee of scientific ethics. Informed consent was obtained prior to the operation.

Demography

All patients suffered from primary osteoarthrosis. None of them had previously had surgery in the operated hip. Mean age at surgery was 60 years (range: 33-78), there were 47 females and 54 males. Mean BMI was 29 (range 18-44) and mean Harris Hip Score preoperative was 51 (22-72). The group of 39 patients who refused to participate were 64 years (32-78); 17 females and 22 males; BMI 28 (20-41); preoperative HHS 49 (9-85) – we found no significant differences between this group and our two treatment groups.

Surgery:

Surgery was performed in an operating room with laminar airflow. Single dose prophylactic methicillin 1 g was given i.v. pre-operatively. Anesthesia was provided with spinal infusion of a single dose local-anesthetic. During surgery, patients were fixed in a lateral decubitus position, allowing exposure of the hip joint through a posterior approach. The bony bed of acetabulum was prepared for cup-insertion by reaming-off residual cartilage and bone excrescences, maintaining the subchondral bone plate. Cup size was chosen 2 millimeters larger than the last reamer utilized, i.e. press-fit fixation (Schmalzried et al., 1994). Mobilization commenced the first postoperative day, although weight bearing was restricted for 6 weeks using 2 crutches.

Prosthesis:

Envelope randomization was performed in the OR after the reaming procedure. The standard cup was the porous coated Trilogy® (Zimmer, Warsaw, Indiana, USA). The core is manufactured of titanium alloy (Ti-6Al-4V), and it is covered with a fiber mesh of technically pure titanium.
The study cup was identical to standard, but a supplementary layer of absorbable calcium (Calcicoat ®) was plasmasprayed to its outer surface. Calcicoat® is approximately 65% calcium hydroxyapatite and 35% tricalcium phosphate (HA/TCP). 50% crystalline and 50% in a soluble phase. The coating is plasma-sprayed to the titanium fiber metal surface in a thickness of approximately 70µm.
We used a standard polyethylene-liner with 10 degrees elevated rim. The femoral component is a cementless plasma sprayed coated titanium alloy design (Bi-Metric®, BiometMerck, Warsaw, Indiana, USA), with a modular 28 mm CrCo femoral head.

DEXA scanning

Measurements were performed with a dual energy X-ray absorptiometer (Norland XR-36 Bone Densitometer: A pencil beam scanner using a stationary anode x-ray tube with 100kV constant potential. Anode current is constant at 1mA, and the samarium filter (K-edge = 46.8

keV) minimum filtration is 3 mm aluminum equivalent. The detectors are two NaI scintillation detectors in pulse counting mode. Software version 3.9.4/2.1.0.) Scanning was performed in the “research” mode at a resolution of 1 x 1 mm with a speed of 60 mm/s, with the ‘exclude high density’ facility activated (excludes pixels with a density larger than 3.75 g/cm^2). We performed calibration daily, with two different phantoms, according to the prescriptions from the manufacturer. The scanner reported an internal precision CV% ranging from 0.41 till 0.71 during the years of this study.

Regions of Interest

Patients were placed supine on the scanner table, the position yielding the best reproducibility according to previous studies (Laursen et al., 2005b,Wilkinson et al., 2001,Wilkinson et al., 2003). Four Regions of Interest (ROI) were used, modified from the regions defined by Wilkinson et al: (Fig. 2). The aim of this model was to create simple rectangular ROIs. The medial and lateral borders of the regions were created by two vertical lines; one projected along the medial border of the obturator foramen, and the other along the lateral border of the femoral prosthesis. We placed the latter vertical line as a tangent to the most lateral point at the Ilium within the ROI 1, to avoid femoral bone interfering with the results. The superior limit of ROI 1 was defined by a horizontal line lying 25 mm superiorly from a horizontal line touching the top border of the cup, which defined its lower limit. ROI 2 extended from here to a horizontal line bisecting the centre of the cup, and ROI 3 extended from here to the lower border of the cup. ROI 4 extended from the line marking the lower border of the cup to a further line lying 25 mm below that.

Data collection

Patient data were recorded on submission, Harris Hip Score preoperative and after 1 and 3 years. DEXA-scanning was performed within one week after surgery and after 3, 6, 9, 12 and 36 months.

Statistics

The hypothesis to test was expressed as follows:
H_0: There is no difference between the two treatment groups in any of the four regions of interest concerning BMD change during the evaluation period. Significance level $p<0.05$ was selected.
Sample size was chosen to find differences exceeding BMD 0.25 g/cm^2 (least relevant difference: $\delta=0.25$), with a risk of type 1 error: $\alpha= 0.05$ (20%); statistical power = risk of type 2 error: $\beta= 0.2$ (80%). Statistical table (Armitage and Berry, 1994) reads sample size: 43 in each group, we chose 50 to accommodate for drop-outs.

Results

One patient died of unrelated course a few months after the operation. 10 patients (4 HA, 6 standard) had insufficient clinical examinations or unprocessable DEXA-scans after 3 years, leaving 89 (46 HA, 43 standard) patients with a complete set of data.

There were no revisions or recurrent dislocations in the observation time (neither in the 10-patient group with insufficient data sets).

Harris Hip Score rose from 53 to 92 in the study group and from 48 to 93 in the control group (ns). The group of 39 patients, who could have entered the study but refused, was not called for routine follow-up after 3 years, but their 1-year follow-up HHS data rose from 49 to 94.

Measurements of periprosthetic bone mineral density revealed no difference between the two groups after 3 years (Fig. 3). In ROIs 1 and 2 there was an initial decrease, followed by a restoration of bone density in the following years. In ROI 3 we observed a very slight decrease during the whole period. In ROI 4 density raised in the span of this investigation, from the very beginning.

When stratifying for Body Mass Index, into the groups normal 18-24.9 kg/m^2; overweight 25-29.9 kg/m^2 and obese 30-∞ kg/m^2, and not taking treatment group into consideration, we found a clear tendency of better bone regeneration in the overweight and obese groups, compared to the normal weight patients. This difference was significant ($p<0.05$) only in the ROI 3 (Fig. 4)

Discussion

In this controlled study randomized between HA and non HA coated cups, we found no differences after 3 years, concerning Bone Mineral Density or clinical outcome. We observed an initial decrease and subsequent partial regaining of BMD during the 3-year observation period. The reasons for BMD changes could be stress-shielding, osteolysis, physiological age-dependent changes or medical/pharmacological causes.
Osteolysis is not likely to occur within this short time span, neither should age-dependency cause any relevant loss. Patients taking any medication that could affect bone mineral density were not included in the study, and none of the included patients commenced such treatment in the course of the study.
Knowledge of osseointegrated porous-coated implants has mostly been brought about from retrieval studies which have contributed substantially to the basic understanding of the histological and radiographic confirmed durability of biological fixation (Sychterz et al., 2002). Other autopsy studies are indicative of the benefits from load transmission showing bone apposition primarily around the peripheral rim and at the peaks of the threads of screw cups (Bauer et al., 1993).

Finite element analysis

The use of a finite element model to examine stress-related bone changes in the acetabular region have predicted the distribution of bone density throughout the natural pelvis; and after insertion of two designs of cementless metal-backed acetabular cups. The simulations with fully fixed bone-implant interfaces predicted extensive loss of bone density medial and inferior to the prosthetic components. These results predicts that acetabular components with full bony ingrowth may induce significant stress-related bone remodeling due to an altered transfer of load (Levenston et al., 1993).

Stress shielding

Previously the term stress shielding was reserved for bone mineral loss in the proximal femur with distal fixated stems. Now we have to consider what happens in the acetabulum exposed to implantation of a press fit fixated device. Bone mineral decrease in short-term follow-up after press fit fixation of acetabular implants has been described in a CT study. Wright and co-workers proposes that the changes represent a response to a decrease in regional bone stress induced by the presence of the press-fit implant, and this might be considered as *retro-acetabular stress shielding*. (Wright et al., 2001).
The immediate benefit from our study is the contribution to comprehension of bone remodeling around the press-fit fixated hemispherical acetabular cup.

DEXA

A preliminary study on periacetabular bone mineral density around press-fit fixated threaded cups by DEXA scanning was reported using the original DeLee and Charnley regions. After 2 years they found demineralization in the medial and distal ROIs, whereas BMD in the proximal ROI was practically unchanged (Sabo et al., 1998). Wilkinson and co-workers, who introduced the DEXA model for BMD measurements employed in our studies found similar changes in a few patients followed for 13 months (Wilkinson et al., 2001,Wilkinson et al., 2003). In the present study we found a very different remodeling pattern: BMD decrease for 6-12 months in ROIs 1 and 2 to a steady state for the rest of the observation time; practically no changes in ROI 3; and a BMD increase during the whole period in ROI 4! Furthermore, our study elucidates an interesting difference between normal and overweight/obese patients –

we venture to suggest that the reason for the better remodeling pattern among these groups is a response to the higher load transfer to the bone-implant interface. Our findings could be taken into account for early weight-bearing without restrictions, a regimen recently shown to have no adverse effects to implant stability (Boden and Adolphson, 2004).

In summary

We found no difference regarding bone remodeling and clinical outcome in 100 patients followed 3 years after randomization between HA or standard porous coated cups inserted with press-fit technique. We intend to use the BMD value post operatively as our reference baseline for all subsequent BMD measurements in these patients; hence eventual developing osteolysis might be prooved at the planned 5 and 10 year follow-up examinations.

Acknowledgments

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This work was supported by Zimmer Scandinavia who friendly delivered the Trilogy® Calcicoat® prostheses.

Figures

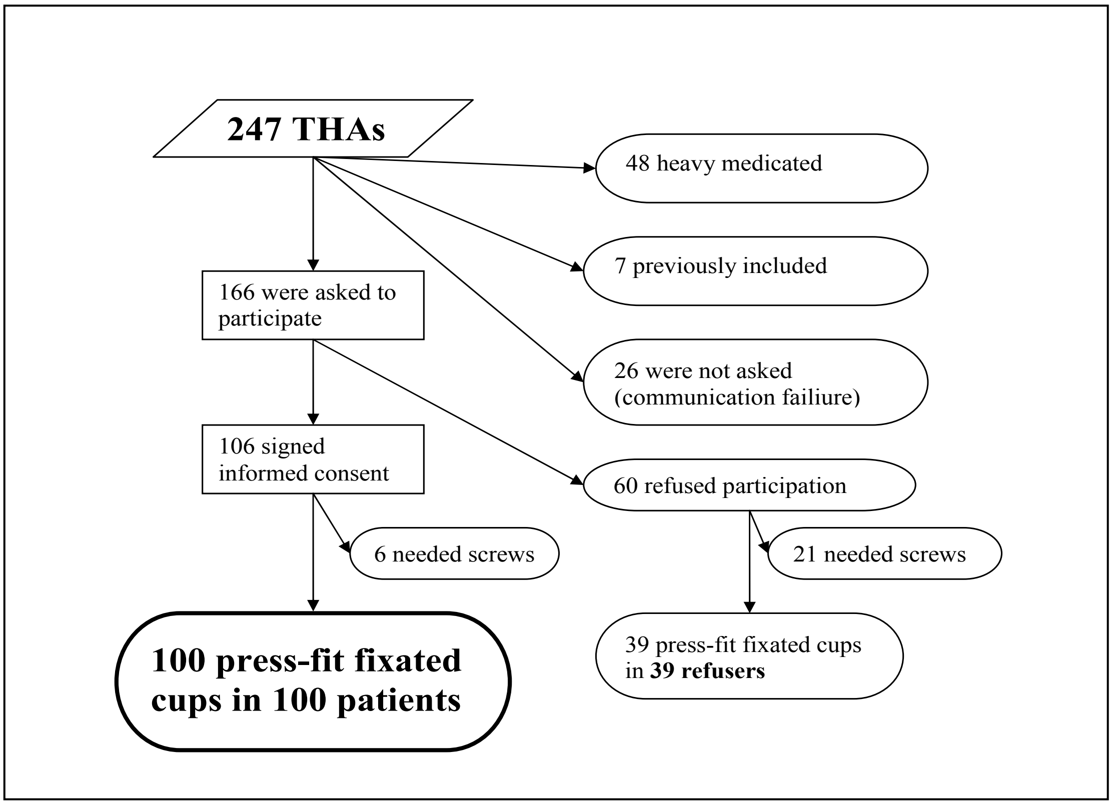

Figure 1. Inclusion diagramme.

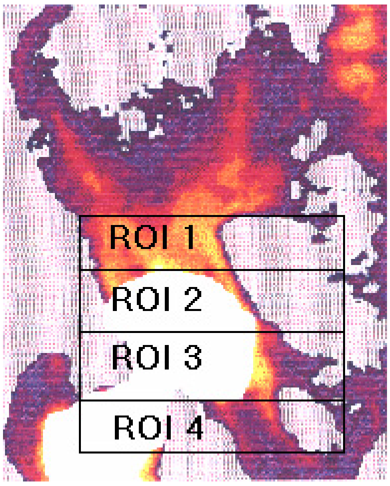

Figure 2. Modified Wilkinson Regions of Interest.

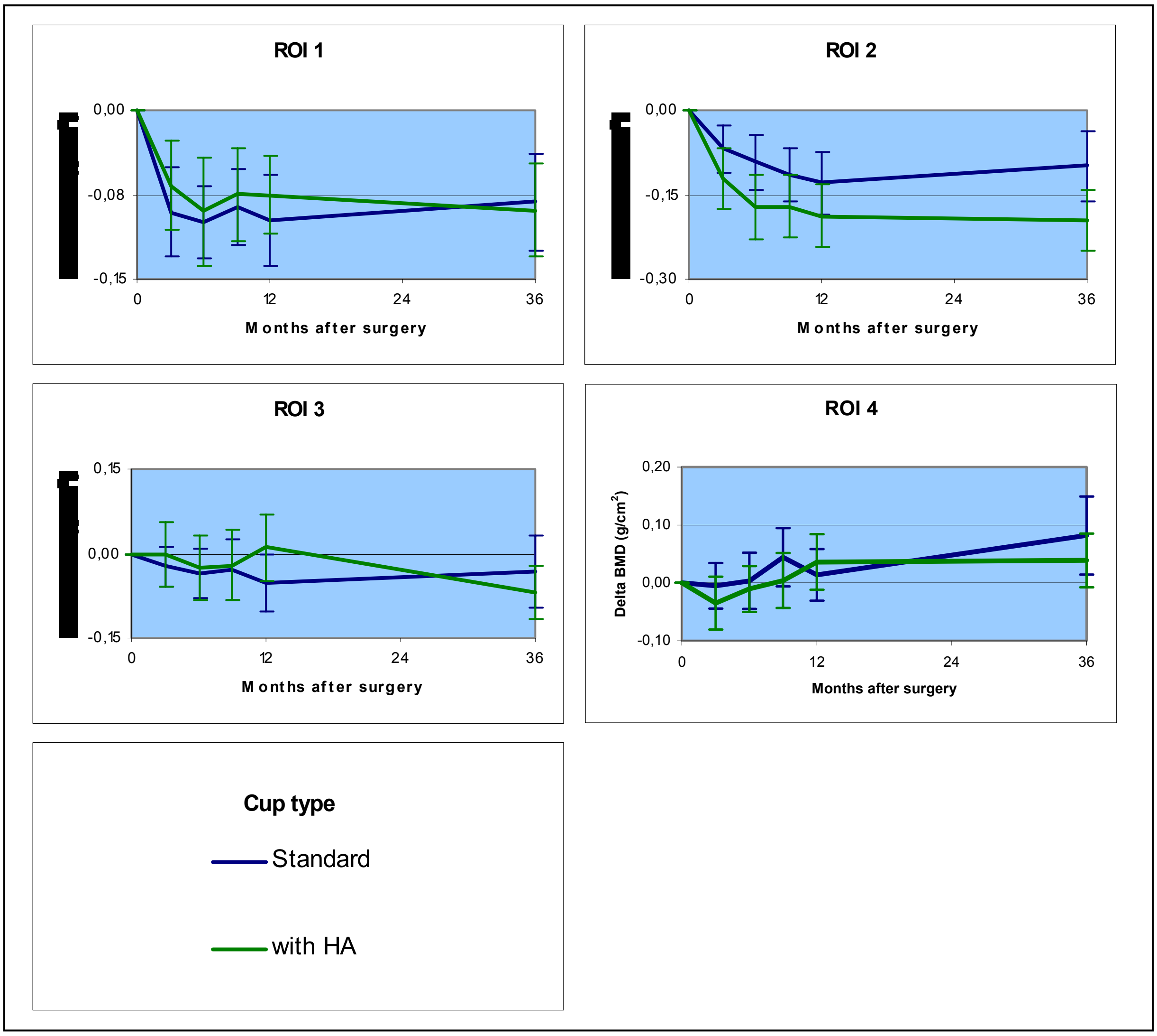

Figure 3. Bone Mineral Density changes in the different Regions of Interest. No significant differences between treatment groups.

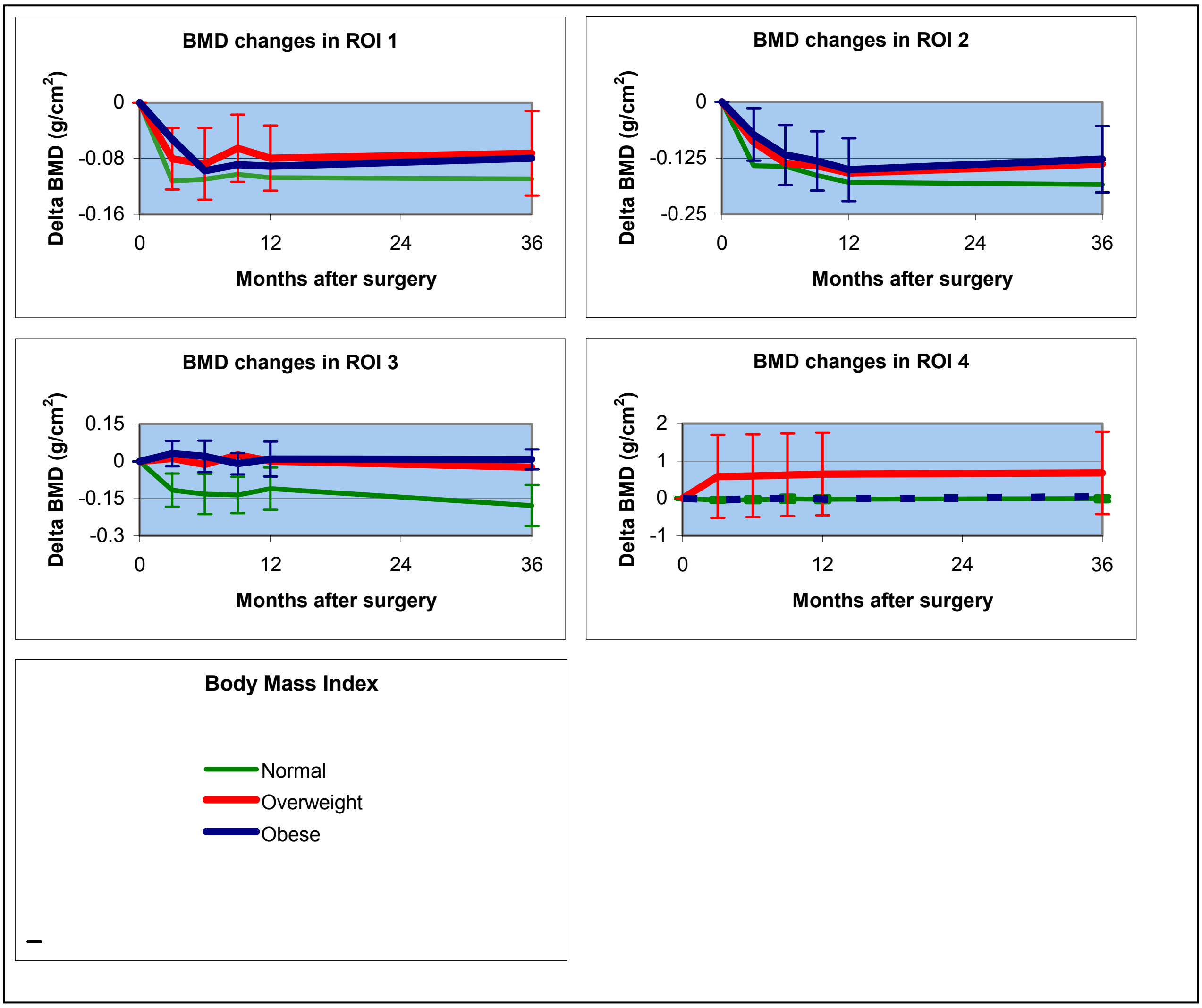

Figure 4. Influence of Body Mass Index on Bone Mineral changes. Similar differences in all regions, significant in ROI 3.

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Resumé på Dansk

Introduktion

En revisionsoperation udført flere år efter primær hofteprotesekirurgi bliver ofte kompliceret af uventede periacetabulære osteolyser. Præoperative røntgenoptagelser giver normalt ikke sufficiente oplysninger om antal og størrelser af osteolyser, men i løbet af operationen kan store lokaliserede osteolytiske læsioner i bækkenknoglerne dukke frem. Ved røntgenundersøgelse underestimeres omfanget af osteolyser, og CT-scanning kæmper fortsat med metal-artefakt problemer og høje strålingsdoser, og er derfor ikke blevet udviklet til et brugbart værktøj på dette område.

Udviklingen af osteolyser kan skyldes tilstedeværelse af slidpartikler fra polyethylen. Proteser der er overfladebehandlet med hydroxyapatit reducerer denne risiko ved en bedre forsegling af kontaktfladen mellem implantat og knogle.

DEXA-scanning er blevet at vigtigt redskab til udmåling af ændringer i knoglemineral indholdet omkring femur-stem og tibia-plateauer. Men der findes kun ganske få studier med fokus på tilsvarende ændringer omkring acetabulær komponenter.

Formålet med disse studier var at benytte DEXA-scanning som et simpelt redskab til påvisning og kvantificering af periacetabulære osteolyser, herunder bestemmelse af præcisionen ved en sådan måling. Desuden gennemførte vi en randomiseret kontrolleret undersøgelse for at undersøge effekten af hydroxyapatit overfladebehandling på ændringer i knogle mineral densiteten omkring ucementerede acetabulære komponenter

Materiale og Metoder

For at måle reproducerbarheden af en bestemt scanning model, og for at belyse hvordan ændringer i patient placeringen påvirkede resultatet, gennemførte vi en undersøgelse med tredive patienter fordelt i tre grupper. Vi analyserede om det havde nogen indflydelse på reproducerbarheden om patienten blev scannet umiddelbart efter operationen eller først et år efter, om der var forskel ved scanning i AP retning i forhold til et 45 grader skråt sideleje, og til sidst bestemte vi indflydelsen af kontrolleret fleksion af bækkenet.

Vi udførte et kontrolleret eksperimentelt studie på ti humane kadavere for at kvantificere mængden af knogle tab målt ved DEXA-scanning.

Til sidst gennemførte vi en randomiseret klinisk kontrolleret undersøgelse. 100 patienter blev opereret med indsættelse af en ucementeret hemisfærisk press-fit-fikseret acetabular skål +/- hydroxyapatit overfladebehandling. Hyppige DEXA-scanninger i en 3 års opfølgningsperiode blev analyseret for at beskrive knogleremodelleringsmønsteret omkring de indsatte ledskåle i de to behandlingsgrupper.

Resultater

Undersøgelsen af de forskellige scanningspositioner viste at DEXA-scanning i AP positionen gav den bedste reproducerbarhed. Bækkenfleksion på mere end 10 grader gav en dårligere reproducerbarhed, og intraobservatørvariationen var meget lav.

DEXA-scanning af kadaver bækkener før og efter kontrolleret fjernelse af knogle korresponderede signifikant med mængden af fjernet knogle i alle de undersøgte regioner.

Ved 3 års kontrolundersøgelserne fandt vi ingen forskel mellem de hydroxyapatit overfladebehandlede acetabularskåle og standard ledskålene, hverken på de kliniske resultater eller målt ved BMD. Men i en region fandt vi signifikant bedre knogleregeneration i de overvægtige og adipøse grupper, sammenlignet med de patienter der havde normal kropsvægt; en tendens der kunne genfindes i de øvrige regioner (ns).

Konklusion

DEXA-scanning har høj reproducerbarhed, og har mulighed for at detektere og kvantificere selv små osteolytiske læsioner med stor nøjagtighed. I en kontrolleret randomiseret undersøgelse, viste den sig brugbar til beskrivelse af knogleremodelleringsmønsteret omkring proteser. Vi fandt ingen forskel i knogleremodellering omkring hydroxyapatitoverfladebehandlede og standard ledskåle.