

EARLY PERIPROSTHETIC FEMORAL BONE REMODELLING USING DIFFERENT BEARING MATERIAL COMBINATIONS IN TOTAL HIP ARTHROPLASTIES: A PROSPECTIVE RANDOMISED STUDY

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Abstract

The present study was performed to test the hypothesis that different bearing materials have an impact on femoral bone remodelling within the first year after a total hip arthroplasty. A total of 225 patients with osteoarthritis of the hip or avascular necrosis of the femoral head were included in this randomised prospective study. All patients had an identical hybrid total hip arthroplasty (cemented BiMetric stem and cementless RingLoc acetabular cup) except for the bearing materials: polyethylene-on-zirconia (n = 78), CoCr-on-CoCr (n = 71), or alumina-on-alumina (n = 76). Bone mineral density (BMD) was measured with Dual-energy X-ray absorptiometry (DEXA) in seven Gruen zones adjacent to the femoral implant. The DEXA scan was performed within one week after surgery and was repeated one year postoperatively. There was no significant difference in periprosthetic BMD change between the three groups. After twelve months the relative BMD decrease was highest in the proximal part of the femur, - 6.2% in the greater trochanter region and - 12.7% in the lesser trochanter region. In the distal zones the relative BMD decrease was -5.3, -4.2, -2.1, -2.3, and -5.6%, respectively. The use of different bearing materials had no significant impact on femoral bone remodelling adjacent to the cemented hip stem within one year after surgery.

Key Words: Bearing materials, alumina, CoCr, zirconia, ultra-high molecular weight polyethylene (UHMWPE), Dual-energy X-ray absorptiometry (DEXA), wear debris, hip arthroplasty, bone remodelling.

Introduction

The major long-term complication in hip arthroplasty is aseptic loosening as a result of an excessive periprosthetic bone loss (Havelin *et al.*, 2000; Lucht, 2000; Malchau *et al.*, 1993).

After a total hip arthroplasty the periprosthetic bone is influenced by changes in loading pattern. The change in loading pattern may according to Wolff's law (J. Wolff, 1892) lead to hypertrophic or atrophic bone zones adjacent to the stem. The degree of bone remodelling depends on design and flexibility of the stem (Ang *et al.*, 1997; Zerahn *et al.*, 1998; Gibbons *et al.*, 2001), the method of fixation (Kroger *et al.*, 1998), bone quality (Therbo *et al.*, 2003), and probably the periprosthetic vascularisation (Santavirta *et al.*, 1990; Hupe *et al.*, 2000).

Aseptic chronic inflammation has been demonstrated in the periprosthetic tissue concurrently with the biomechanical changes (Lassus *et al.*, 1998; Bauer and Schils, 1999). This inflammation has been linked to the foreign body particles produced from the bearing materials (Willert *et al.*, 1990; Harris, 1991; Harris, 1994; Ingham and Fisher, 2000). The particles are phagocytized by macrophages causing an activation of the cells leading to a granulomatous inflammation (Santavirta *et al.*, 1990). The foreign body response to particles is believed to accelerate the periprosthetic bone resorption and implant loosening (Athanasou *et al.*, 1992; Horowitz and Gonzales, 1996; Horowitz and Gonzales, 1997; Bauer, 2002).

The bearing material combination most frequently used is CoCr-on-polyethylene. This combination has been shown to produce considerable amounts of polyethylene wear particles. In contrast alumina-on-alumina, zirconia-on-polyethylene, and CoCr-on-CoCr bearings have been shown to have low wear rates (Amstutz *et al.*, 1996; Willmann, 1998; Willmann, 2000). Wear resistant bearing materials have been suggested to reduce the rate of aseptic loosening since wear particles are believed to induce bone resorption.

A chronic inflammation can develop within weeks and the periprosthetic bone remodelling is most rapid within the first six months after a hip arthroplasty (Kiratli *et al.*, 1992; Nishii *et al.*, 1997; Wixson *et al.*, 1997). Hence, the present study examined the mean BMD changes at the initial phase after a hip arthroplasty.

Dual-energy X-ray absorptiometry (DEXA) (Cohen and Rushton, 1995a; Kroger *et al.*, 1996; Okano *et al.*, 2002) is an excellent technique to evaluate minor changes

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in the periprosthetic BMD compared to conventionally radiography (West *et al.*, 1987).

The aim of the present study was to test the hypothesis that changes in bone mass are influenced by differences in bearing materials at the initial phase after a hip arthroplasty.

Material and Methods

Study design

The local ethical committee approved the present prospective and randomised trial, (KF) 01-355/98. A total of 225 patients had a primary hybrid total hip replacement at the Orthopaedic Clinic, Frederiksberg University Hospital. The same type of stem and shell was used in all patients. The inclusion lasted from January 2001 to January 2003. The patients participating in the trial had either primary osteoarthritis or avascular necrosis of the femoral head, and had given their written informed consent.

Patients were excluded if they were younger than eighteen years of age, demented, with active infection, previous surgery of the hip, osteoporosis, marked bone loss which could prevent adequate fixation of the prosthesis, inflammatory diseases, severe vascular insufficiency of the affected limb, severe instability or deformity, abnormal gait due to other reasons i.e. poliomyelitis. After surgery, all the patients were informed about the bearing materials used. Postoperative mobilisation and pain relief followed standard procedures of the department.

Randomisation

The patients were randomly allocated to receive one of three bearing material combinations. A computer performed the randomisation (MS Excel 2000 - Rand programme) and the randomisation number was kept in a closed envelope, which was opened prior to the operation.

Surgery

Preoperatively all hips were templated. A posterolateral approach was used. A distal hand reamer reamed the medullary canal to two millimetres above the stem diameter. Then a broach reamed the proximal part to the same size. Pressurisation cementation technique was used for the femoral component. The acetabulum was reamed size to size and the cementless component was inserted using the press fit method.

Bearing material

The different bearing material combinations used in the study are given in Table 1.

In order to reduce wear the articulating liner surface of the cup was inlaid with an insert made from CoCr alloy or alumina ceramic in order to reduce the production of wear. The metal and alumina liners were made by moulding a CoCr or alumina inlay into the ultra-high molecular weight polyethylene (UHMWPE) (ArCom™; Biomet, Warsaw, IN, USA) by a sandwich construction. The polyethylene was Argon packaged compression moulded polyethylene (ArCom™). With respect to the ceramic liner, the plastic component of the liner was machined in two steps (pre and post ceramic component insertion) by computer controlled machining. The ceramic component was inserted in the plastic component by calibrated pressing to a press-fit position indicated by a fixed distance between the top of the inserted ceramic and the top of the plastic. The thickness of the sandwich polyethylene varied from 4.1 to 6.6 mm depending on the size of the liner. The thickness corresponded to the apical area and the plastic component was not a wear surface.

Stem and acetabular components

The cementless acetabular component was a Universal RingLoc® (plasma sprayed porous coated with seven screw holes, Ti-alloy; Biomet). Screws were used when needed.

The stem used was a BiMetric Interlok™ (collarless plasma sprayed porous coated, Ti-alloy, straight stem, bi-taper (Biomet), cemented with Palacos R-40 with Gentamicin® (Merck, Darmstadt, Germany) (Fig. 1).

The stem sizes used varied from eight to seventeen millimetres. The additional lateralized off set range was from five to nine millimetres. The standardised neck angle

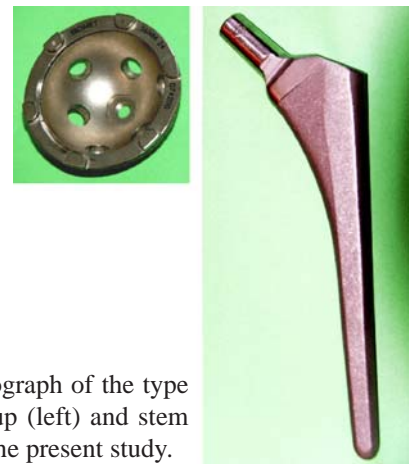


Figure 1. Photograph of the type of acetabular cup (left) and stem (right) used in the present study.

Table 1. Bearing materials in the study

Articulation	RingLoc insert	Modular head ⁵
I	Polyethylene ¹	Zirconia ² (ZrO ₂)
II	CoCrMo ³	CoCrMo
III	Alumina ⁴ (Al ₂ O ₃)	Alumina (Al ₂ O ₃)

¹) ArCom, Biomet, Warsaw, IN, USA. ²) ZrO₂ head Biomet Merck, Warsaw, IN, USA. ³) M2a, CoCrMo Alloy, ISO 5832-12 1996 and ASTM 1537, Biomet Merck, Warsaw, IN, USA. ⁴) Ceracup, Biolox Forte, Biomet, Warsaw, IN, USA. ⁵) 28 millimetres in diameter. The Zirconia and Alumina modular heads are made from sintered high purity zirconium oxide and aluminium oxide ceramics.

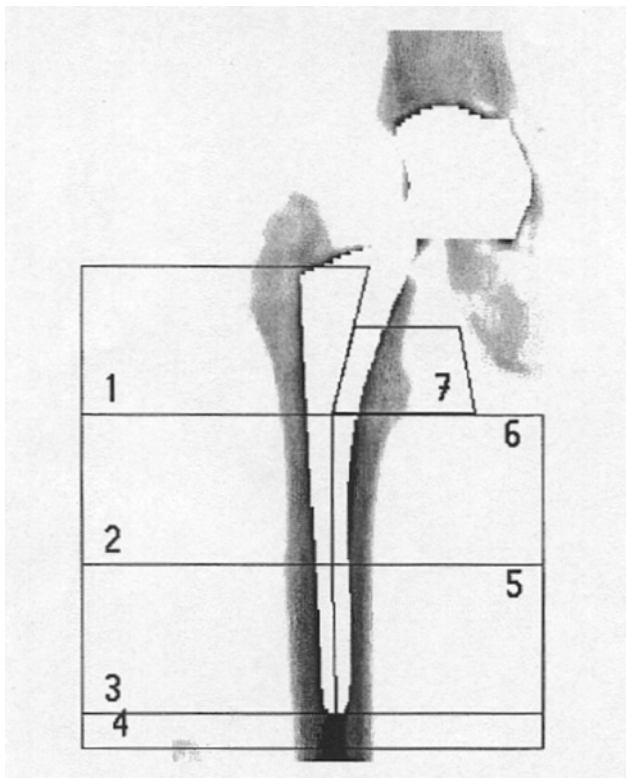


Figure 2. Regions of interest Gruen zone 1-7.

was 135 degrees. A centralizer was used for correct alignment in cemented application.

Bone mineral density (BMD)

Bone mineral density was determined by DEXA (Lunar DXP IQ#7160, Lunar Corporation, Madison, WI, USA; Software DPX-IQ X-Ray Bone Densitometer with SmartScan™ Version 4.7e). The patients were placed in supine position with extended knee and hip during the scanning procedure. The foot was fixed in a neutral position and the distal part of the thigh was supported by a moulded foam cushion. The scan window included the entire prosthesis from the acetabulum to at least one centimetre below the tip of the stem. Gruen zones (Gruen *et al.*, 1979) were positioned based on the neck and the tip of the prosthesis (Fig.2). The software automatically subtracted the implant from the bone. The periprosthetic bone mineral density (BMD) of the operated hip was measured within one week postoperatively. The procedure was repeated after one year.

Reproducibility of measurements

Two scans were performed in twenty-three patients in order to test the reproducibility of the procedure. The patients were repositioned after leaving the couch between the two scans.

Reproducibility depending on rotation

Repeated measurements were performed on a cadaver femur with an inserted femoral stem to assess reproducibility depending on rotation. The cadaver femur was placed in a water bath and scanned seventeen times in rotations from fifteen degrees outward rotation to fifteen degrees inward rotation with increments of five degrees.

X-rays

All patients had an x-ray within the first postoperative days. The x-ray was repeated one year later. All x-rays were analysed for changes in position and radiolucent lines in the seven Gruen zones mentioned earlier.

Statistical analysis

Statistical comparison of the groups was performed with ANOVA and students t-test (10.05 SPSS Inc. Chicago). The sample size was calculated by the equation (significance level 0.05; power 0.8).

$$n_1 = n_2 = 2(t_{2a} + t_b)^2 SD^2 / MIREIDIF^2$$

$$n_1 = n_2 = 2(1.96 + 0.84)^2 0.2^2 / 0.1^2 = 63$$

Twelve patients were added to n in each group to compensate for patients that may be lost to follow-up.

Results

A total of 188 patients (123 females, 65 males) were successfully scanned immediately postoperatively and after twelve month. Specifications of the groups in term of height, weight, and age are presented (Table 2).

Evaluation of changes in periprosthetic bone mineral density

The BMD (g/cm²) measured postoperatively and after one year is presented in Figure 3. There was no significant difference in the periprosthetic BMD between the groups one year after surgery. The periprosthetic BMD level (g/

Table 2. Gender distribution and antropomorphometric data +/- 1SD for the three groups of prostheses.

	Polyethylene-Zirconia		CoCr-CoCr		Alumina-Alumina	
	M	F	M	F	M	F
N	26	38	24	38	15	47
Height (cm)	175 (SD 6.4)	165 (SD 5.8)	175 (SD 5.6)	165 (SD 5.0)	174 (SD 7.9)	165 (SD 11.8)
Weight (kg)	86 (SD15)	72 (SD11)	82 (SD10)	73 (SD 16)	84 (SD 17)	71 (SD 12)
Age (years)	69 (SD 8.5)	67 (SD13)	70 (SD 13)	69 (SD 10)	67 (SD 12)	72 (SD 10)

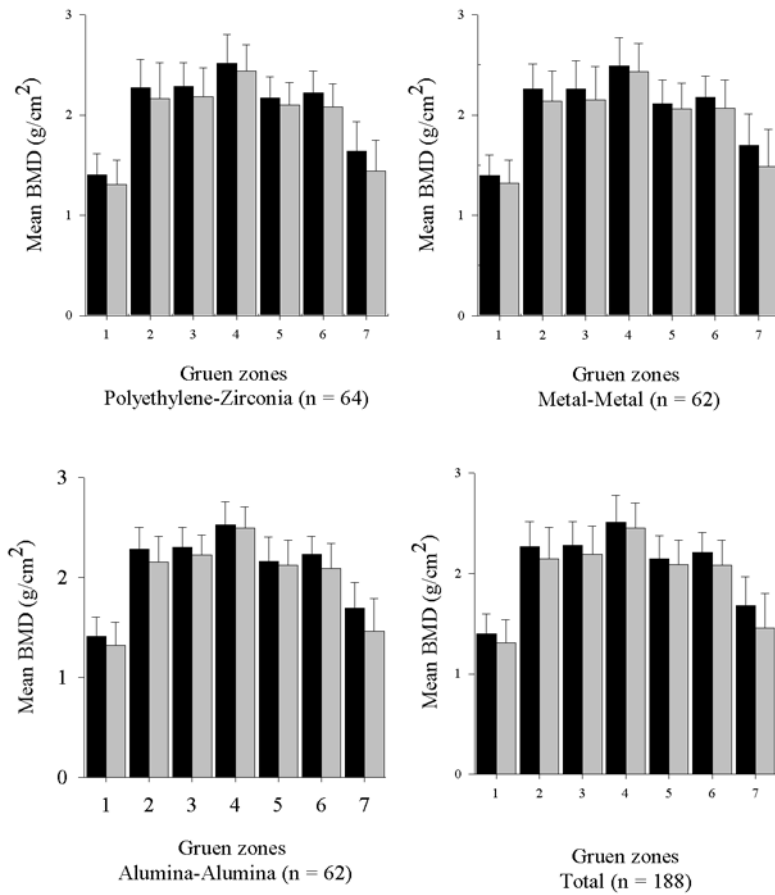


Figure 3. Absolute BMD (g/cm²) measured immediate postoperatively (black) and one year postoperatively (grey) for each Gruen zone (p<0.001).

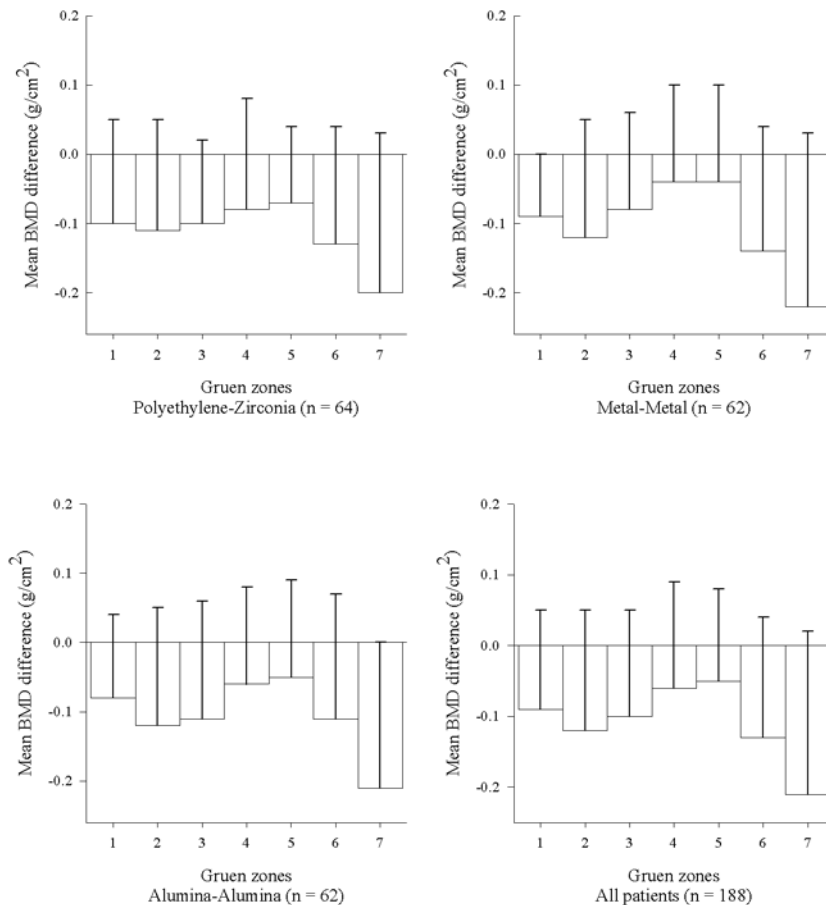


Figure 4. BMD difference in g/cm² between the postoperative level and after one year.

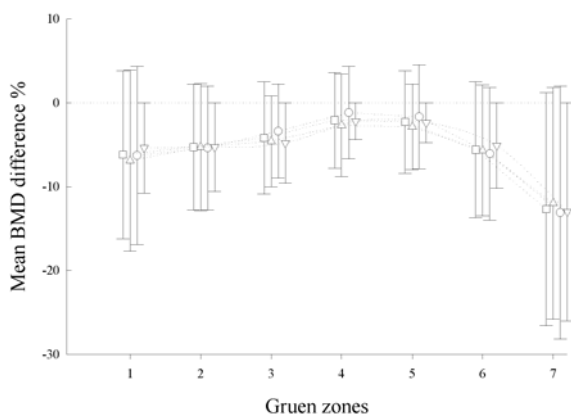


Figure 5. The relative BMD difference was calculated for each Gruen zone between the postoperative level and after one year (\square Polyethylene-Zirconia, \triangle CoCr-CoCr, \circ Alumina-Alumina, ∇ All patients).

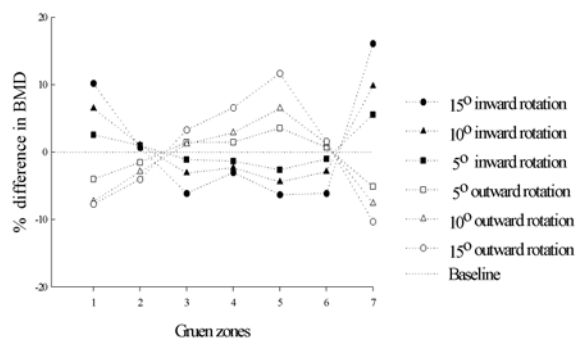


Figure 6. Variations in BMD in Gruen zone 1 through 7 adjacent to a cemented stem in a cadaver femur depending on rotation in increments of 5 degrees from a neutral position. Relative differences in percent were given on the basis of 17 scans for each increment of rotation.

cm^2) decreased significantly in all Gruen zones during the first year after surgery independently of the bearing materials used. BMD changes are summarised in Figure 4.

There was no significant correlation between changes in BMD and body mass index, gender, or age

The mean BMD decrease ranged from 0.04 (g/cm^2) (zone four and five in the metal-metal group) to 0.22 (g/cm^2) (zone seven in the metal-metal group). The relative BMD changes determined as percentage of the preoperative value are shown in Figure 5. After one year the relative bone loss was highest in the proximal part of the femur, -6.2% in the greater trochanter region (Gruen zone 1) and a -12.7% in the lesser trochanter region (Gruen zone 7). In the distal zones the mean BMD decreased -5.3, -4.2, -2.1, -2.3, and -5.6%, respectively (Fig. 5).

Reproducibility of measurements

The reproducibility was tested in twenty-three patients. The reproducibility given as the coefficient of variation (CV) for Gruen zones 1 to 7 is given in Table 3.

Reproducibility depending on rotation

In the phantom the mean BMD (g/cm^2) in neutral position was 1.479 (SD 0.0035), 2.050 (SD 0.026), 2.106 (SD 0.053), 2.463 (SD 0.025), 2.173 (SD 0.029), 2.457 (SD 0.028), 1.939 (SD 0.035), from Gruen zone 1 to 7, respectively. The relative differences in BMD are given in Figure 6.

In Gruen zone 7, the mean BMD changed more than 2 SD's for each 5 degrees of rotation. If rotation was kept within ± 5 degrees, the mean BMD value for all other Gruen zones varied less than ± 2 SD's except for outward rotation in Gruen zone 5.

X-rays

Radiolucent zones exceeding two millimetres were not demonstrated in any of the patients except for one patient in the polyethylene-zirconia group. This patient had

periprosthetic osteolysis in Gruen zone seven (DEXA scan of this patient was unsuccessful). This patient was revised, and cultures were positive for deep infection with *Staphylococcus epidermidis*.

Discussion

The present study is to our knowledge the only randomised prospective study measuring the periprosthetic bone remodelling using three different bearing material combinations.

We have not been able to demonstrate any significant changes in bone remodelling after hip arthroplasty related to bearing materials. The present study demonstrates a pattern of early periprosthetic bone resorption similar to other studies of cemented hip arthroplasties (Cohen and Rushton, 1995b; Nishii *et al.*, 1997).

The most rapid change in the periprosthetic BMD can be demonstrated within the first year after surgery (Nishii *et al.*, 1997). After a total hip arthroplasty the loading pattern changes around the implant and the result is atrophy of the proximal femoral bone. Factors influencing this process include stem shape and stiffness as well as type of

Table 3. Coefficient of variation (CV) and standard deviations (SD) on twenty-three double measurements of BMD adjacent to a cemented femoral stem.

Zone	CV (%)	SD (g/cm^2)
Gruen 1	3.9	0.056
Gruen 2	3.1	0.072
Gruen 3	2.5	0.059
Gruen 4	3.9	0.099
Gruen 5	2.2	0.048
Gruen 6	3.4	0.076
Gruen 7	4.7	0.083

fixation. Since the present study used identical stems and shells for all the three groups of different bearing materials, the similar changes for each group support the thesis that early bone remodelling is mainly due to stress shielding. This assumption is supported by Soininvaara *et al.* who concluded that the periprosthetic bone loss was mainly a result of stress shielding since bone resorption also occurred in the distal femur after a total knee arthroplasty (Soininvaara *et al.*, 2004).

The reproducibility of the method used in the present study was examined and was found to be precise. These findings were below the observed values of bone remodelling and demonstrated that DEXA is a reliable method in assessing BMD changes after only one year provided careful positioning is undertaken especially with regard to rotation. However, DEXA cannot determine the reason for changes in bone density. It can not be excluded that wear particles have influenced bone resorption.

A canine study suggests that particles may accelerate bone resorption (Shanbhag *et al.*, 1997). Other studies have demonstrated that the magnitude of bone resorption in retrieved periprosthetic tissue at the time of revision is influenced by the number and shape of polyethylene particles, macrophages, and the degree of granulomatous inflammation (Livermore *et al.*, 1990; Schmalzried *et al.*, 1992; Maloney *et al.*, 1993; Jasty *et al.*, 1994; Shanbhag *et al.*, 1994; Dowd *et al.*, 2000; Green *et al.*, 2000). Thus, a reduced wear rate may not be the only variable predicting the inflammatory response and the degree of bone resorption.

The present study did not measure the mean BMD decrease in the femoral metaphysis, but a previous study tested the combined effect of the prosthetic load and wear particles in a canine model. In one group, particles were added into a proximal femoral gap around a hip implant and another group had a hip implant only and served as control. After twenty-four weeks one animal of eight in the implant group and six animals of seven in the implant and particle group developed periprosthetic radiolucencies with endosteal scalloping (Shanbhag *et al.*, 1997). This finding suggests that particles may accelerate bone resorption. *In vitro* macrophages with intracellular particles have been demonstrated to possess the capability to provide bone resorption without the influence of stress shielding (Athanasou *et al.*, 1992).

A non-invasive method for evaluating the particle accumulation in the periprosthetic tissue is not available. At present, it is only possible to examine the particles produced *in vivo* at time of revision or by a biopsy from *in situ* implants. Thus, a correlation of the granulomatous inflammation, the concentration of particles, and the periprosthetic bone remodelling is difficult to evaluate.

Vascular injury may result from the reaming process and thermal injury from hardening of the cement. It is not clear to what extent the vascular injury influences bone resorption. Previous studies have found that the periprosthetic blood flow was significantly reduced in the proximal femur when measured immediately after surgery (elMaraghy *et al.*, 1999; Hupel *et al.*, 2000). However, in the present study, we believe that there were no differences

in blood supply between the three groups as identical stems and insertion techniques were used.

It is reasonable to believe that the foreign body response and thus the local bone resorption can be induced after one year for two reasons:

(1) Particles can be expected in the pseudosynovial membrane early after the mobilisation of the patient. A calculation from a mean annual volumetric wear rate demonstrated that a person with a total hip arthroplasty (CoCr-UHMWPE) generates between 75000-150000 polyethylene wear particles with each step taken (Dowson, 2001).

(2) macrophages with intracellular foreign body material *in vitro* have the capability of low grade bone resorption when placed on a bony surface (Athanasou *et al.*, 1992). Furthermore macrophages with intracellular particles have been found in the pseudosynovial membrane as early as seven months postoperatively, although from failed implants (Doorn *et al.*, 1996; Mochida *et al.*, 2001).

Thus, the timing is unpredictable in the cascade of inflammation from the initial steps to implant loosening. For these reasons evaluation of the cellular response to a biomaterial is relevant after one year or even earlier. Otherwise, information can be lost regarding different stages in the inflammatory response. As the periprosthetic bone remodelling is stabilised within the first two postoperative years, the initial changes are relevant to monitor.

Early loosening and extended bone resorption have been described in previous studies using wear resistant bearing surfaces. A retrospective study using alumina-alumina bearings found osteolysis in 22 % of the implants at a follow-up at 5 to 10.4 years and a gross examination revealed evidence of ceramic wear (Yoon *et al.*, 1998). A retrospective study using CoCr-CoCr bearings had a revision rate of 10 % because of aseptic loosening at a 28 years follow-up (Brown *et al.*, 2002). A study using polyethylene-on-zirconia found aseptic loosening in 14% of the implants at 5.8 years follow-up and osteolysis in 21.7% of the femoral implants (Allain *et al.*, 1999). In these retrospective studies, stem design and method of fixation were different. Thus, it was not possible to compare the outcome or to conclude to what extent the bearing materials contributed to bone resorption. It can be concluded that using wear resistant bearings alone does not prevent early periprosthetic bone resorption.

The CoCr and the alumina were both hard materials compared to polyethylene. The capability of absorbing impact load is reduced in hard materials compared soft materials such as polyethylene. To compensate for this difference the bearings used in the present study had a layer of polyethylene integrated between the metal or ceramic bearings and the acetabular shell.

Conclusion

The present study does not indicate that different types of bearings have significant impact on femoral bone remodelling adjacent to a cemented femoral stem within the first year after surgery.

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Discussion with Reviewers

B.A. Rahn: What is the influence of biomechanics and of disturbed blood supply on periprosthetic bone remodelling, and how could these components eventually influence the outcome, or camouflage minor differences caused by different pairings of materials?

Authors: Biomechanics have the highest known impact on periprosthetic bone remodelling in the sense of stress shielding. The present study was made to evaluate the influence of different bearing materials and hence used identical stems and shells in all three groups to evaluate the influence of this particular variable. The influence of the particles on bone remodelling in the present study was below the detectable limit. Although periprosthetic bone remodelling is also correlated to the periprosthetic vascularisation this variable can be ruled out due the use of identical stems, insertion method, and shells in all groups.

J. Antoniou: At one year the only significant variable that would affect BMD around the implant is not the bearing surface but the implant itself (i.e., modulus of the material). So the results are totally expected. The point that you might see a difference with the different surfaces is at least after 5 years after the implantation.

Authors: Periprosthetic bone remodelling after a total hip arthroplasty evaluated by BMD change is most pronounced within the first years postoperatively due to stress shielding. Steady state is expected after two years (Nishii *et al.*, 1997). The study was set up to rule out changes in BMD caused by a chronic inflammation due to wear particles. Since accumulation of particles can be expected almost immediately after surgery, a granulomatous inflammation can be expected at this early stage. In a previous study, we demonstrated a chronic inflammation in the pseudosynovial membrane one year after the operation in well functioning hip arthroplasties (Nygaard *et al.*, submitted for publication).

From the initial steps of inflammation to loosening of the implant, the time lap is unpredictable. For these reasons a biological evaluation of the cellular response to a

biomaterial it is relevant after one year or even earlier. Otherwise, information can be lost regarding different stages in the inflammatory response.

B.A.Rahn: Was there a correlation between age and body mass index with BMD loss for the total region of interest?

Authors: There was no significant correlation between age and BMD loss in the present study for patients aged

50 to 85. Because of outliers among the youngest and oldest patients there seemed to be an overall correlation between age and BMD loss particularly for men. The authors believe however, that statistical analysis including these outliers would lead to unsubstantiated conclusions. Body mass index was not found to have any influence on BMD changes either.