DUAL-ENERGY X-RAY ABSORPTIOMETRY MEASUREMENT OF BONE MINERAL DENSITY AROUND POROUS-COATED CEMENTLESS FEMORAL IMPLANTS

METHODS AND PRELIMINARY RESULTS

DOUGLAS J. KILGUS, EVA E. SHIMAOKA, JOHN S. TIPTON, ROBERT W. EBERLE

From the University of California, the Veterans Administration Medical Center, and the Grant Orthopaedic Research Institute, Los Angeles, USA

The measurement of bone mineral density in defined areas around metal implants has improved with the development of dual-energy X-ray absorptiometry. We used this technique to compare the bone mineral density adjacent to metal cementless femoral implants with that of identical regions of bone in normal proximal femora.

We studied the anteroposterior views only of 72 femora which contained total hip implants and 34 non-operated femora. We compared the regional bone mineral density of bone adjacent to proximally porous-coated and distally porous-coated implants of one design, to measure the relative differences in the remodelling changes induced by different amounts of porous coating. We also measured differences in bone density with time and with variations in implant size (and therefore stiffness).

The greatest decrease in bone mineral density (34.8%)

occurred in the most proximal 1 cm of the medial femoral cortex around relatively stiff, extensively porous-coated implants. The next most severe decrease (20% to 25%) was in the next most proximal 6 cm of the medial femoral cortex. Small, progressive decreases in bone mineral density continued for five to seven years after implantation.

There is concern about adverse remodelling after the implantation of extensively porous-coated implants. The development of durable hip implants may depend upon devising prostheses which will minimise stress remodelling and also maintain long-term fixation. A reliable measurement of postoperative stress remodelling adjacent to metal implants would therefore be of value. This has become possible with the development of dual-energy X-ray absorptiometry (DEXA), which can measure bone mineral density (BMD) in a reproducible, precise and accurate manner.

Previous efforts to quantify BMD adjacent to metallic implants have used various imaging techniques such as dual-photon analysis, MRI, CT scans, and quantitative CT scans. All these have been hampered by the inconsistent and irregular effects of the metal implants on the images, and attempts to quantify decreases in proximal BMD adjacent to porous-coated hip implants have been restricted to gross observation and quantitative gray-scale analysis of radiographs.

Recent developments in the technique of DEXA have significantly improved its ability to quantify regional BMD in a reproducible manner. Further improvements in software analysis techniques for quantifying BMD adjacent to metal implants (DPX; Lunar Corporation, Madison, Wisconsin) prompted us to compare regional BMD adjacent to femoral hip implants within the femur of a given patient and between different patients (Kiratli et al 1991; McCarthy et al 1991).

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D. J. Kilgus, MD, Assistant Professor
Division of Orthopaedic Surgery, UCLA School of Medicine, 1000
Veteran Avenue, Room 22-72, Los Angeles, California 90024, USA.

E. E. Shimaoka, MD
Department of Pathology, Harbor/UCLA Medical Center, 1000 W.
Carson Street, Torrance, CA 90509, USA.

J. S. Tipton, BS, Research Assistant
Orthopaedic Surgery Section, Veterans Administration Hospital, West
Los Angeles, Sawtelle and Wilshire Boulevards, West Los Angeles,
California, USA.

R. W. Eberle, BS
Grant Research Institute, 720 Broad Street, Columbus, Ohio 43215,
USA.

Correspondence should be sent to Dr D. J. Kilgus.

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Many factors in stem design are likely to affect local bone remodelling, but we specifically examined, in one design of stem, the effects of different amounts of porous coating, stem stiffness (stem diameter), and time since operation.

We present the protocol that we used and its rationale, together with our preliminary results.

PATIENTS AND METHODS

Dual-energy X-ray absorptiometry. The technique has been satisfactorily used to evaluate the spine and femoral neck (Kelly et al 1988; Wahner et al 1988; Ho et al 1990; Kiratli et al 1991). Ho et al (1990) reported an accuracy error of 9% in a cadaver study and a correlation of $r = 0.881$, $p \leq 0.001$, between scanned BMD and ash density. O'Keefe (1991) found an accuracy of 5.1% in phantoms. The reported short-term precision is 0.4% to 1.5% (Kelly et al 1988; Mazess et al 1989; Sartoris and Resnick 1989, 1990). Long-term precision was stable for 180 days with a coefficient of variation of 0.2% to 0.6% (Kelly et al 1988; Wahner et al 1988; Mazess et al 1989; Pacifici et al 1990; Sartoris and Resnick 1990). DEXA is considered to be superior to the older, widely accepted, technique of dual-photon absorptiometry in terms of radiation dose, image resolution, scanning time and precision (Kelly et al 1988; Wahner et al 1988; Pacifici et al 1990; Sartoris and Resnick 1990).

DEXA software has recently been modified to allow the measurement of BMD adjacent to metal implants. We used a Model DPX scanner (Lunar Corporation, Madison, Wisconsin) which has a k-edge filter for separating the X-ray spectrum into two specific energy bands. New software developments allowed scanning in the anteroposterior plane of an area of 24×8 cm, including the entire femoral component, the surrounding femur, and an envelope of soft tissue. Quality assurance was performed daily before use.

Bone mineral content (BMC, in grams) and area (cm^2) were measured, and the BMD was calculated within each region of interest using an automated algorithm which also included a software-driven edge-detection algorithm. Areas of the scan in which the X-ray beams were attenuated by the metal implant were automatically subtracted from the scan results. In addition, a standardised soft-tissue 'baseline' region around the implant was defined which, in the analyses, was also subtracted from all regions of interest to give bone-density values independent of local soft-tissue inhomogeneities.

Precision. A precision study using DEXA was performed on ten patients who had undergone primary total hip replacement with AML implants (DePuy, Warsaw, Indiana). Their implanted femora were scanned four times in succession (except for one patient who had only three scans). For each scan, the patient was placed supine on the scan table with standard knee and foot supports

which placed the femur in neutral rotation. Between scans, we repositioned the patients by having them get off and then back on to the scan table and by replacing the positioning supports thereby reproducing the standard position. Each patient's set of three or four scans was completed within three hours.

The BMD of each region of interest was normalised to the BMD of the most distal region of interest to reduce patient-to-patient variation. The overall average precision for all ten patients was 3.8% (2.6 to 4.7) with a standard deviation of 1.2%.

Accuracy. A simple phantom was used to evaluate the accuracy of DEXA. A measured amount of calcium hydroxyapatite powder was packed into a lucite container measuring $2.7 \times 2.7 \times 11$ cm to provide a density of 0.910 g/cm^2 on the two-dimensional scan, a value within the observed range of femoral bone density. The phantom was scanned sandwiched between 24.8 cm lucite plates to simulate a soft-tissue envelope. When analyses were completed on the hydroxyapatite-packed lucite, the distal portion of a femoral implant of 13.5 mm diameter was overlaid on to the phantom and analyses were repeated using the standard regions of interest.

Initial analysis of the phantom as a whole showed an accuracy of 1.1%. Actual density was 0.910 g/cm^2 while DPX-measured density was 0.900 g/cm^2 . After the AML template had been added, the densities of six distal regions of interest were calculated. The average accuracy was 5.4%.

An effort was also made to assess the accuracy by performing an analysis of the bone ash of a human cadaver thigh which was scanned in the DPX scanner using the standard protocol after implantation of an AML femoral component. We were, however, unable to control accurately several important variables. These were the ability to resect the precise segments of cadaver bone which had been scanned for each region of interest, the thickness of the bone saw kerf which removes a significant amount of bone, and the ability to obtain reliable bone-ash weights from the small number of samples. Thus, we were unable to obtain reliable data from these initial efforts and further work is in progress.

Defining the regions of interest. Preliminary analyses of non-operated femora revealed that BMD varied greatly between the different patients and over the length of the normal femur. To compare the BMD of different femoral regions between patients and the remodelling differences in BMD between implanted femora and control femora, we therefore had to calculate the relative regional BMD values of individual femora. We selected a single region to serve as the reference baseline region for each patient to which the relative BMD values of other regions in that patient could be normalised. The difference between any specific region of interest and the baseline reference region of a given patient could then be used to compare identically located regions of interest of other patients.

The mid-diaphyseal region of the femur showed the

least variation in BMD, and we therefore chose the diaphyseal cortex adjacent to the most distal 5 cm of the femoral implants as the reference baseline region for each patient. This corresponded to the section of diaphyseal bone adjacent to the 5 cm non-porous-coated distal portion of both the extensively (four-fifths) and proximally (one-third) coated implants. The reference baseline region was then divided into two areas, one medial and one lateral to the implant, for comparison with the more proximal regions of interest of the respective medial and lateral cortices.

The regions of interest were referenced from a location on the femoral implant, thus allowing comparison of identical regions of interest in different patients. Six additional medial and lateral regions of interest of the femur were defined more proximally (Fig. 1). Each

Fig. 1

The location of the medial and lateral regions of interest (ROIs) (1 to 6) in relation to the reference baseline (RB) zone. The distal edge of the porous coating was at (a) in extensively coated stems and at (b) in proximally coated stems.

was 2 cm in height and contained all the bone between the implant and the soft tissues as viewed in an anteroposterior direction.

We were concerned that reaming of the femoral canal at the time of hip replacement in the reference baseline region might have had an effect on its BMD value. A comparison study was therefore performed and the region with the least local variability was found to be that adjacent to the distal non-porous-coated portion of the implants.

The commercially available software did allow the

default selection of regions of interest based on the location of the most medial edge of the lesser trochanter, but our work showed less variability between the regions of interest referenced manually from a location on the implant.

By restricting our studies to the anteroposterior view we maximised the number of patients we could study and minimised the number of variables.

AML study. DEXA scans were obtained in the anteroposterior plane on the operated proximal femoral region of patients who had undergone total hip arthroplasty with cementless prostheses between 1984 and 1991. Of the 72 patients, 46 had extensively porous-coated implants and 26 had only proximally coated implants.

Because there are significant variations in regional BMD in natural non-operated femora, it was necessary to develop a control group of BMD scans of control femora. Thirty-four patients therefore underwent DEXA scans of their contralateral non-operated proximal femora. To analyse the identical regions of bone which had been studied in the operated femora, we had to shield the same sections of bone which had been shielded by the femoral implants in the patients of the experimental study groups. To do this, the DEXA scanner software was modified to allow the image of the femoral implant to be transposed over the scan image of the (control) contralateral nonoperated femora of the study patients before analysis.

The average age of the patients was 65 years (42 to 85) at the time of the DEXA scan. The average ages for the subgroups were 68 years for extensively porous-coated, 60 years for proximally porous-coated and 65 years for those whose unoperated femora were scanned. The preoperative diagnoses leading to hip arthroplasty were osteoarthritis in 72%, osteonecrosis in 22%, rheumatoid arthritis in 2%, postfracture in 2%, and others in 2%.

In all patients AML femoral components of identical design had been used varying only in size (Fig. 2) and amount of porous coating. All were made from cobalt-chrome alloy, were of a straight-stem, collared design, and had porous coatings of sintered cobalt-chrome beads (Porocoat: DePuy, Warsaw, Indiana). The proximally coated prostheses had porous coating of only the proximal one-third of the implants while in the extensively coated group the coating extended over the proximal four-fifths. The fixation of all femoral components which had been implanted for one year or longer ($n = 17$ proximal group; $n = 34$ extensive group) was graded radiographically as bone ingrown, on the classification of Engh and Bobyn (1985). Each group was subdivided according to the time since implantation (Table I). Analyses were performed to assess the effects of implant stiffness (implant diameter) and time on regional BMD.

Statistical analysis. To control both for the effects of stem stiffness and length of time since implantation for the subgroups, we used a repeated measures analysis of

Fig. 2

Number of each implant size in both proximally and extensively coated stems.

covariates to compare the data curves of the regional BMD results. We considered stem diameter as a covariant, and time since surgery as a grouping variable divided into three time categories.

RESULTS

Normal variations of regional BMD. BMD values from the DEXA scans of the control and operated femora in various subgroups are shown in Table I. The analysis of the average BMD of the 12 standard regions of interest (six medial and six lateral) and the two reference baseline regions of the non-operated control femora is illustrated in Figure 3. These results show that, on average, the BMD of normal femora decreases progressively as the regions of interest move proximally from the mid-diaphyseal region to the base of the femoral neck. Medially, the average BMD at the base of the femoral neck was approximately 62% of that of the mid-diaphyseal bone of the medial side of the femur. Laterally,

Table I. Raw data and percentage changes on reference base with SD for 46 extensively coated, 26 proximally coated and 34 control hips

Extensively coated implants												
				Time since implantation (yr)								
All implants (n = 46)				0 to 1.9 (n = 17)			2 to 4.9 (n = 11)			5 to 7 (n = 18)		
Medial	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD
1	0.56	31.41	15.42	0.60	36.51	16.24	0.59	29.85	9.88	0.50	27.53	16.16
2	0.96	51.57	16.39	1.08	63.66	17.91	0.90	45.52	8.27	0.81	43.91	10.63
3	1.13	60.92	17.06	1.19	71.01	16.97	1.22	61.94	13.14	0.94	50.78	11.31
4	1.48	80.43	18.81	1.47	88.64	20.64	1.64	83.25	9.63	1.31	70.95	14.58
5	1.65	89.28	15.25	1.57	94.42	15.61	1.80	91.33	5.45	1.54	83.18	14.90
6	1.79	97.76	12.77	1.67	100.57	16.54	1.90	96.67	5.48	1.77	95.77	10.44
RB	1.85	100.00	0.00	1.69	100.00	0.00	1.98	100.00	0.00	1.86	100.00	0.00
Lateral	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD
1	0.77	43.31	9.48	0.68	42.04	8.86	0.50	42.30	12.98	0.80	45.12	7.84
2	0.81	45.85	11.06	0.86	52.98	12.11	0.95	42.01	9.01	0.73	41.46	8.00
3	1.22	68.26	12.79	1.22	74.02	12.61	1.04	66.90	12.32	1.13	63.66	9.74
4	1.56	87.55	14.47	1.52	92.37	13.19	1.31	87.79	12.51	1.48	82.86	11.90
5	1.73	97.41	12.19	1.65	101.15	12.18	1.48	98.98	8.81	1.65	92.92	10.54
6	1.82	102.71	7.63	1.68	102.65	10.18	1.63	105.32	5.03	1.79	101.17	5.61
RB	1.77	100.00	0.00	1.64	100.00	0.00	1.74	100.00	0.00	1.77	100.00	0.00
Proximally coated implants												
				Time since implantation (yr)								
All implants (n = 26)				0 to 0.9 (n = 9)			1 to 1.9 (n = 10)			2 to 6 (n = 7)		
Medial	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD
1	0.75	38.67	19.59	0.71	36.69	18.73	0.75	39.14	13.11	0.83	40.53	29.37
2	1.10	56.94	15.85	1.03	51.57	11.10	1.10	57.95	20.62	1.27	62.42	12.86
3	1.33	68.88	14.63	1.25	63.23	11.45	1.33	69.42	12.67	1.52	75.37	19.46
4	1.65	85.28	11.29	1.55	77.61	7.86	1.62	84.54	5.76	1.94	96.18	13.09
5	1.80	93.01	7.81	1.78	89.05	6.14	1.79	92.99	5.79	1.98	98.14	9.97
6	1.85	95.76	5.36	1.85	93.16	3.57	1.87	96.77	6.03	1.97	97.66	5.65
RB	1.94	100.00	0.00	1.98	100.00	0.00	1.93	100.00	0.00	2.02	100.00	0.00
Lateral	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD	Raw	% Norm	SD
1	0.87	49.15	15.63	0.75	43.66	6.27	0.83	45.80	6.90	1.14	44.35	6.29
2	0.96	54.78	14.22	0.90	52.76	8.65	0.94	52.16	10.70	1.14	53.69	8.67
3	1.35	77.87	13.61	1.29	76.01	11.49	1.35	74.60	8.71	1.58	77.13	11.41
4	1.60	92.31	10.20	1.54	91.06	10.36	1.58	87.44	13.15	1.87	91.74	10.00
5	1.73	99.44	7.56	1.70	99.81	7.45	1.73	95.68	8.46	1.94	99.67	7.04
6	1.77	101.31	5.82	1.75	102.13	7.87	1.79	99.45	9.58	1.91	102.97	7.87
RB	1.75	100.00	0.00	1.70	100.00	0.00	1.81	100.00	0.00	1.86	100.00	0.00

Non-operated controls (n = 34)

Medial	Raw	% Norm	SD
1	1.27	62.34	10.89
2	1.31	64.06	9.34
3	1.55	76.30	12.23
4	1.87	91.79	8.42
5	1.97	96.32	5.38
6	1.98	97.36	5.46
RB	2.04	100.00	0.00
Lateral	Raw	% Norm	SD
1	0.89	47.63	6.37
2	1.17	62.61	9.49
3	1.57	84.43	8.52
4	1.83	98.15	6.94
5	1.93	103.42	6.64
6	1.94	104.00	5.14
RB	1.87	100.00	0.00

the average BMD of the region at the junction of the lateral cortex and the base of the greater trochanter was about 63% of that of the lateral mid-diaphyseal bone, and the average BMD of the lower portion of the greater trochanter was only 48% of that of the lateral mid-diaphyseal cortex. These findings correlate with both the relative thinning of the cortical bone more proximally as the femur increases in diameter and the contribution of the cancellous bone to the structure of the metaphyseal area of the femur.

The effect of extensive porous coating. No significant decrease in average BMD was observed in the most distal regions of interest (zone 6) medially or laterally. These zones corresponded to the distal end of the porous coating. Radiographically, these regions of interest consistently showed a marked increase in endosteal density, both medially and laterally, corresponding to the endosteal 'spot welds' of bone to the implant described by Engh and Bobyn (1985).

Moving proximally from the distal end of the

Fig. 3

Regional percentage variations in BMD on medial and lateral sides over the length of the proximal femur in 34 non-operated control femora.

Fig. 4

Normalised BMD values in the medial and lateral sides of the femora of 18 patients who had extensively coated implants for five to seven years.

implant in 2 cm high regions of interest, the average BMD decreased slightly more in implanted than control femora (Fig. 4). In the proximal regions containing the lesser trochanter and medial femoral neck (medial zones 2 and 3), the average BMD was 20% to 25% less than that of the control femora (Fig. 5). In the most proximal regions of interest (zone 1, medially and laterally) the average BMD was further decreased. It is important to

Fig. 5

Differences in percentage changes in BMD between 18 femora with extensively coated implants at five to seven years and 34 non-operated femora.

note, however, that the most proximal zone (zone 1) on the medial side consistently contained only small amounts of bone as a result of the rounding-off of the medial cortex at the calcar. This region corresponded to the widest portion of the proximal end of the femoral implant. Radiographically, these areas appeared osteopenic and rounded off, as is often seen after total hip arthroplasty, either cemented or cementless. Laterally, the low BMD value of the most proximal region of interest (zone 1) corresponded to the cancellous bone of the greater trochanter.

The femora containing the extensively coated implants were subdivided into three groups according to period of time since operation: 1 to 23 months, 24 to 59 months, and 60 to 84 months. At each time interval, the average BMD decreased slightly in all regions compared with that of the control femora (Fig. 6). The repeated measures analysis of covariates showed significantly different BMD curves for the different time intervals ($p \leq 0.001$).

The effects of proximal porous coating. The distal edge of the porous coating corresponded to zone 3 medially and laterally on the scans of the proximally-coated implants (Fig. 7). There was little change in BMD in comparison with the control femora in zones 4, 5 and 6 which were distal to the distal end of the porous coating (Fig. 8). On the medial side, there were insignificant increases in the average BMD, and on the lateral side, insignificant decreases.

In zone 2 medially, there was no significant change, although there was radiographic evidence of endosteal densification in most cases. In zone 1 medially, there was again a marked decrease in average BMD, corresponding

Fig. 6

Graph showing regional BMD of the medial cortices in extensively coated hips related to time interval since operation. Repeated measures analysis of covariates showed the curves to be significantly different ($p \leq 0.001$).

to the rounded-off, radiographically osteopenic region immediately distal to the collar of the implant.

As regards time-related changes, the femora containing proximally porous-coated implants showed qualitatively different results from those with more extensively coated implants (Fig. 9). The lowest average BMDs were observed in the shortest time interval after operation; at increasing time the average BMD increased slightly at all regions along the femur. Again, using the repeated

measures analysis of covariates, each curve was significantly different ($p \leq 0.001$).

The effect of stem diameter. The effect of femoral implant stiffness, as it varied with the diameter of the implant, was assessed for femora containing the extensively coated implants, using repeated measures analysis (Fig. 10), and considering the implant diameters as separate covariates. Because of the small number of the smallest and largest implants (10.5 and 16.5 mm), this analysis was restricted

Fig. 7

Percentage variation in regional BMD in seven proximally coated femora at two to six years.

Fig. 8

Difference in percentage changes in regional BMD between seven femora with proximally coated implants at two to six years and 34 control femora.

to the most commonly used implant sizes (12.0, 13.5 and 15.0 mm; see Fig. 2).

The BMDs of the smaller (12.0 mm) implants were only slightly decreased from those of the non-operated control femora except at the most proximal region (zone 1) where the implants are much wider and stiffer. The average BMDs about the larger implants (13.5 and 15.0 mm) were decreased, as expected. The greatest differences in BMD compared with the control femora occurred for the larger stems in zone 3 (average decrease 24%), and in zone 1 immediately below the femoral collar (average decrease 34%). Overall, each of the curves for regional BMD for the different implant diameters was significantly different ($p \leq 0.028$).

DISCUSSION

The need for scans of contralateral femora. Because we did not initially appreciate the magnitude of the naturally-occurring regional variations in BMD in normal femora, our earliest analyses of the implanted femora overestimated the decreases in BMD which were caused by stress remodelling. Before the development of software which

allowed us to transpose the image of the prosthetic implant on to the contralateral bone-density scan, we could not define precisely identical regions of interest in the control femora. To measure accurately the regional changes in BMD caused by implant-induced alterations in stress remodelling, the naturally-occurring variations must be taken into account.

We have found that defining the regions of interest in relation to part of the implant is the most reproducible method of localising identical regions of interest, both

between patients and in repeated studies of the same patient. Caution is needed in the analysis of certain unique situations. There are much greater variations in BMD where regions of interest are both very small and extremely osteopenic, for example, in the most proximal centimetre of the medial femoral cortex below the implant collar. At this site there is rounding off and extreme stress remodelling of the cortical bone; in some revision cases the femoral cortices are very thin. High variations in BMD are also observed in repeated scans

Fig. 9

Graph showing BMD of the medial cortices of proximally coated femora related to time interval since operation. Repeated measures analysis of covariates showed the curves to be significantly different ($p \leq 0.001$).

Fig. 10

Graph showing the BMD of the medial cortices of 27 extensively coated femora related to implant diameter, in comparison with 34 non-operated control femora. Repeated measures analysis of covariates showed that the curves were significantly different ($p \leq 0.028$).

of regions where the bone density is very irregular, as in areas of heterotopic bone.

Radiographic estimates of changes in BMD. References from radiological literature are often quoted which suggest that visual recognition of decreases in bone density on radiographs requires changes in bone density in the range of 30% to 50%. Our results do not confirm these suggestions. Changes in bone density were obvious on all radiographs taken over one year after operation, even although the greatest decreases in BMD were of the order of 35% in comparison with the control femora.

Review of the relevant papers (Ardran 1951; Lachman 1955; Ho et al 1990; O'Keeffe 1991) suggests that some of the early articles have been frequently misquoted. Laboratory testing has shown that changes in BMD of only 7% are detectable on serial radiographs when there is a high ratio of trabecular to cortical bone (O'Keeffe 1991).

AML study. It has been shown that increased stress remodelling is produced by stiffer femoral implants (Engh and Bobyn 1985, 1988; Engh, Bobyn and Glassman 1987; Bobyn et al 1992). Our results confirm these findings. The curve of the regional BMD for the relatively flexible, 12.0 mm diameter implants revealed only slight decreases in BMD in comparison with non-operated controls, but the curves for the larger, stiffer 13.5 and 15.0 mm implant diameters showed significantly greater decreases. The range of implant sizes that we studied was a sample of the implant diameters used in our predominantly male patient population. Because we used fewer small-diameter, less stiff 10.5 and 12.0 mm implants than would be expected in a population with more female patients, we consider that our values for decreases in regional BMD may overestimate the average BMD

decreases in a more normal patient population. In addition, the eight-year average age difference between the younger proximally porous-coated group and the older extensively porous-coated group of patients may have caused slight differences in their relative average BMD.

Future analysis. Our study was motivated by concern about the potentially adverse remodelling effects of the use of extensively porous-coated implants. We have tried to develop a method which will allow the reproducible comparison of periprosthetic BMD in different regions in one patient and the subsequent comparison of these in different patients.

Our study evaluated previously operated patients according to time and implant diameter. More valuable data will be obtained by longitudinal studies of these same patients and by prospective comparison between patients with different types of hip implant. More important information will be available from studies performed in the lateral plane. Another useful approach will be the comparison of radiological bone remodelling with DEXA analysis; this should provide valuable early information on the design and use of femoral prostheses.

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