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No adverse effects of early weight bearing after uncemented total hip arthroplasty

A randomized study of 20 patients

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Background Few guidelines are available whether early weight-bearing after an uncemented total hip arthroplasty (THA) can be recommended or not. Stability and ingrowth may be jeopardized by immediate loading of the implant while functional recovery may be promoted and periprosthetic demineralization reduced.

Patients and methods We did a prospective study of 20 patients who were operated on with a hydroxyapatite-coated (HA), uncemented total hip arthroplasty with a tapered stem because of unilateral arthrosis, and randomized the patients to the immediate (I) or late (L) weight-bearing (after 3 months) group. The shoe on the operated side was equipped with an auditory device signaling when the patient placed a load on the extremity. The clinical assessment was done with the Harris hip score at the time of the operation and after 12 and 24 months. Radiographs and dual-energy x-ray absorptiometry (DEXA) were evaluated for migration, femoral remodeling and bone mineral density (BMD) after 3, 6, 12 and 24 months. Tc-scintigraphy was done after 6, 12 and 24 months.

Results Postoperatively, the Harris hip score showed no group difference. After 3 months, we noted a large reduction in BMD around the stem prosthesis. This was most marked in the proximal regions and the bone loss was significantly larger in zone 1, 4 and 5 in the L group. Distally, the BMD normalized with time, but the loss of bone persisted in the proximal zones after 24 months. An initial increase in the scintigraphic uptake ratio in all zones in both groups declined with time, but it was still increased on the operated side after 24 months. Several radiographic signs of bone remodeling were seen, but the patterns were similar in both groups.

Interpretation We found no adverse effect of immediate weight bearing with this prosthesis.

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Initial stability is a prerequisite for bone ingrowth onto uncemented implants (Søballe et al. 1993, Jasty et al. 1997). Immediate weight-bearing after an uncemented THA may cause micromovements at the bone-implant interface, jeopardizing stability and ingrowth of the implant (Radl et al. 2000), therefore protected weight bearing for 3 months has been advocated (Wirtz et al. 1998). On the other hand, early weight-bearing might promote the patient's rehabilitation and functional recovery (Rao et al. 1998, Kishida et al. 2001) and also reduce the postoperative BMD loss caused by immobilization.

We determined whether immediate weight-bearing after implantation of a tapered HA-coated uncemented femoral stem affects postoperative function or the ingrowth of the prosthesis. We also investigated BMD and the postoperative scintigraphic pattern.

Patients and methods

From September 1996 to September 2000, 23 patients less than 65 years of age with unilateral primary arthrosis were operated on with an uncemented prosthesis and included in this study. The inclusion criteria were: good general health, good

Figure 1. The HA-coated Bi-Metric modular femoral stem.

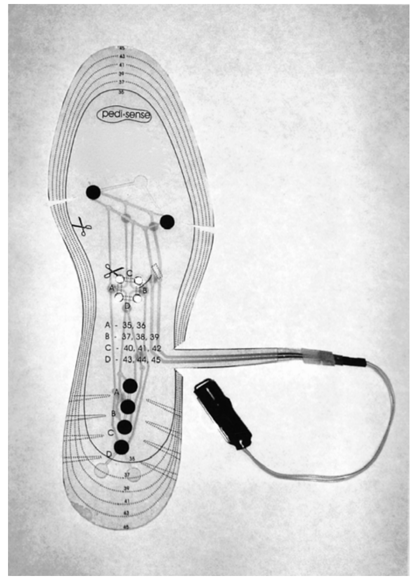

Figure 2. The battery-operated auditory device (pedi-sense).

bone quality with no cortical thinning or defects and no abnormality of the proximal medullary canal, no previous hormonal therapy, other medication or illness known to affect bone metabolism. The number of patients in this study was chosen without ”power calculation”. However, if larger groups of patients should be needed to reveal bone mineral differences between the groups, then the small differences at hand would have small clinical implications. The patients were operated on with an uncemented prosthesis (Bi-Metric femoral stem and Romanus cup, Biomet Inc., Warsaw, Indiana, USA). This has a tapered stem (3°) in which the proximal 30% of the stem has a porous (100–200 μm) coated surface with plasma-sprayed HA (thickness 40–70 μm, crystallinity 50–70%, purity > 95%), (Figure 1). The femoral component is available in 11 proportional sizes and has a modular head of cobalt-chrome. Femoral reaming was done line to line and care taken to bury completely the porous-coated portion in bone extending into the proximal cortical region. This portion of the femur has been shown to provide a stronger attachment strength, and is an area in which bone ingrowth can be expected (Laine et al. 2000). All patients were operated on by a senior surgeon via a standardized posterior approach without removal of the greater trochanter or section of the abductor muscles of the hip.

Before the operation, the patients were randomly assigned to immediate (I) or late (L) weight bearing by use of a sealed envelope. The study was approved by the Ethics Committee of Karolinska Hospital (Dnr 95-152, Dnr 99-52). The patients also gave their informed consent before inclusion in the study.

All but 3 patients, who were unwilling to participate further (2 in the I group and 1 in the L group), were followed postoperatively. They comprised 11 women and 9 men. In the I group, the mean age of the 10 patients was 54 (44–59) years, and in the L group, the mean age of the 10 patients was 55 (44–63) years at operation. The sex distribution was similar in both groups.

The patients were given a battery-operated, pressure-activated auditory device incorporated in the sole of the shoe (pedi-sense, Aggero Produkt & Affärsutveckling AB, Gothenburg, Sweden). The auditory signal monitored the degree of weight bearing by encouraging (I group) or discouraging (L group) the patients from carrying a load during the early rehabilitation period, thus serving as a feedback for the patient during the first 3-month period. The sole has 2 pressure-activated sensors in the forefoot and 1 in the heel (Figure 2). The load was calibrated, using 2 loading devices, with either “spots”, which increased the sensitivity or “rings”, which reduced the sensitivity of the sole.

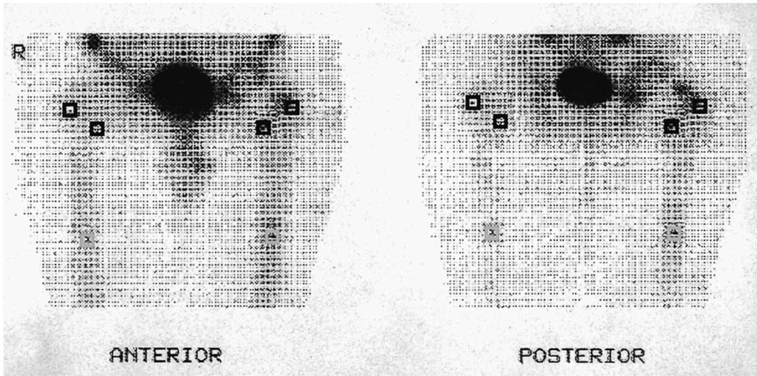

Figure 3. A scintigram showing the 3 ROIs in Gruen's zones 1, 4 and 7. The prosthesis is visible on the left side.

The patients in the I group used the auditory device during their hospital stay to encourage maximal weight bearing. Among these patients, the sole was calibrated to emit a buzzer sound when the patient carried a full load on the forefoot or heel on the operated leg, thereby providing information about occurrence and duration of weight-bearing. These patients also had a home exercise program including instructions to carry full weight on the operated leg for 6 seconds with support only of their balance. They were told to walk with 1 crutch alone or without external support, when possible. In this group, the auditory device was not used outside the hospital. In the L group, the load permitted was 10% of the body weight—i.e., about the weight of the leg. The loading devices ("spots" and "rings") were assembled and mounted on the sole to obtain the load desired. In the L group, this auditory device warned the patients by emitting a buzzer sound when the load was too high. These patients were instructed to use the auditory sole always when walking and to record the rate of the sounds emitted. They learned about protected weight-bearing by using 2 crutches for 3 months and used the device during this time. They were also given a program for home exercises including protected weight-bearing. Thus, in the I group, the auditory device provided information as regards limb loading during the stance phase of the gait. In the L group, this device gave a signal which helped them to avoid an excessive loading of the limb.

The clinical rating was determined by the Harris hip score (1969). The patients were examined radiographically and with DEXA at operation and after 3, 6, 12 and 24 months. At 6, 12 and 24 months, a technetium scintigraphy was also done.

Bone mineral evaluation

The BMD of the periprosthetic femur was measured in the coronal plane by a dual-energy x-ray absorptiometer, DEXA (DPX-L, Lunar Co., Madison, Wisconsin, USA). During scanning, the patient was placed supine with standard knee and foot supports and the femur in neutral rotation. The scanner was equipped with a software for measuring femoral periprosthetic bone mineral (Mazess et al. 1989). This software detected the interface between the bony part and the prosthesis stem on the basis of density changes and simulated the stem in the form of a prosthesis mask which was superimposed on the healthy side. The healthy hip was scanned at the same level and BMD in 7 regions of interest (ROIs), based on Gruen's zones (Gruen et al. 1979), were analyzed. The values were expressed as areal BMD, g/cm^2. The ratio of the operated side to the control side was calculated. In addition, the longitudinal changes on both sides were recorded. To avoid the perioperative effect of surgery on periprosthetic BMD, we made the first measurement within the first days after the operation, as proposed by Kröger et al. (1996) and Nishii et al. (1997).

Scintigraphic evaluation

We measured the scintigraphic activity, using a low-energy, general purpose collimator on a General Electric MAXXUS dual head gamma camera (GEMS, General Electric Co., Milwaukee, Wisconsin, USA). The patients received an intravenous injection of 440 MBq of 99mTc-labeled methylene-diphosphonate. The imaging was done after about 4 hours. No flow or blood pool images were taken. With the patients in a standardized position, anterior and posterior views of the upper femur were taken. On the prosthetic side, 3 regions of interest (ROIs) were drawn corresponding to the periprosthetic bone in Gruen's zones 1, 4 and 7. The length of the prosthesis was considered. The length of the prosthesis was considered in the same way as in the DEXA-measurements. Thereafter, these 3 ROIs were mirror imaged and transferred to the unoperated upper femur (Figure 3). The same procedure was used for the anterior and posterior views. The counts per pixel were obtained in each of the 12 ROIs and the mean value from the anterior and posterior views was determined. To obtain an uptake ratio, the value of the operated side was divided by the corresponding value of the contralateral side for each zone. The longitudinal changes were also recorded and expressed as an uptake ratio. The effective dose to the patient during the examination was about 3 mSv, which is about the average dose received during routine lumbar and pelvic radiographs.

Radiographic evaluation

Standardized anteroposterior and lateral radiographs were taken immediately after operation and 3, 6, 12 and 24 months later. Blinded critical analysis of the radiographs was done by comparing the early postoperative films and using Engh et al.'s (1990) criteria. Migration of the femoral implant was considered possible if there was a change in the vertical distance from the easily-identified inferior border of the coating to the most medial point of the lesser trochanter. A vertical migration of 5 mm or more was considered to indicate definite subsidence (Malchau et al. 1995). The prosthesis was classified as unstable if the alignment of the femoral component had changed. The presence of new endosteal bone bridges occurring along the femoral prosthesis (spot welds) was assessed with Geesink and Hoefnagels' method (1995). Radiolucent or radiodense/reactive lines around the femoral implant were noted and mapped in the 7 Gruen zones in the coronal plane. Other radiographic changes in the femur—i.e., distal cortical hypertrophy, distal endosteal bone bridging (pedestal sign), atrophy of the calcar region, focal osteolysis (scalloping) and ectopic ossification, using Brooker et al.'s classification (1973) were also recorded.

Precision

To estimate the precision error of the DEXA method, we have previously made double measurements in 10 patients, with complete reposition of the patient and the scanner. We found that the precision error of the DEXA method was 1–4% in Gruen's zones and that of the scintigraphic method was 3–6% in Gruen's zones 1, 4 and 7 (Bodén et al., unpublished data).

Statistics

The median values (25–75 percentiles) were calculated for absolute and percentage changes in BMD and scintigraphic activity. The Wilcoxon signed-rank test (paired observations) and the Mann-Whitney U-test (unpaired observations) were used. The statistical analyses were performed on a Power Macintosh G3/300 computer with the statistical package StatView SE+Graphics. Differences were considered significant at p-values < 0.05.

Results

Clinical outcome

The median Harris hip scores before surgery were 46 (38–56) in the I group and 50 (38–55) in the L group. They improved to 98 (92–100) (I group) and 99 (93–100) (L group), respectively, at the 2 year examination. We found no difference in these scores between the groups at operation ($p= 0.8$) or postoperatively ($p= 0.7$).

Bone mineral changes

At operation, no side difference was noted in BMD between the hips in either group (Figure 4). After operation, we found a marked reduction in BMD on the operated femur in almost all zones in both groups after 3 months, which was greatest in zones 1 and 7 where it was reduced by 21% in the L group ($p = 0.005$). The reduction in BMD was significant, as compared to the unoperated side in all zones, but after only 3 months in zone 4 in the I group. There was a significantly greater BMD loss in the L group in zones 1, 4 and 5 after 3 months.

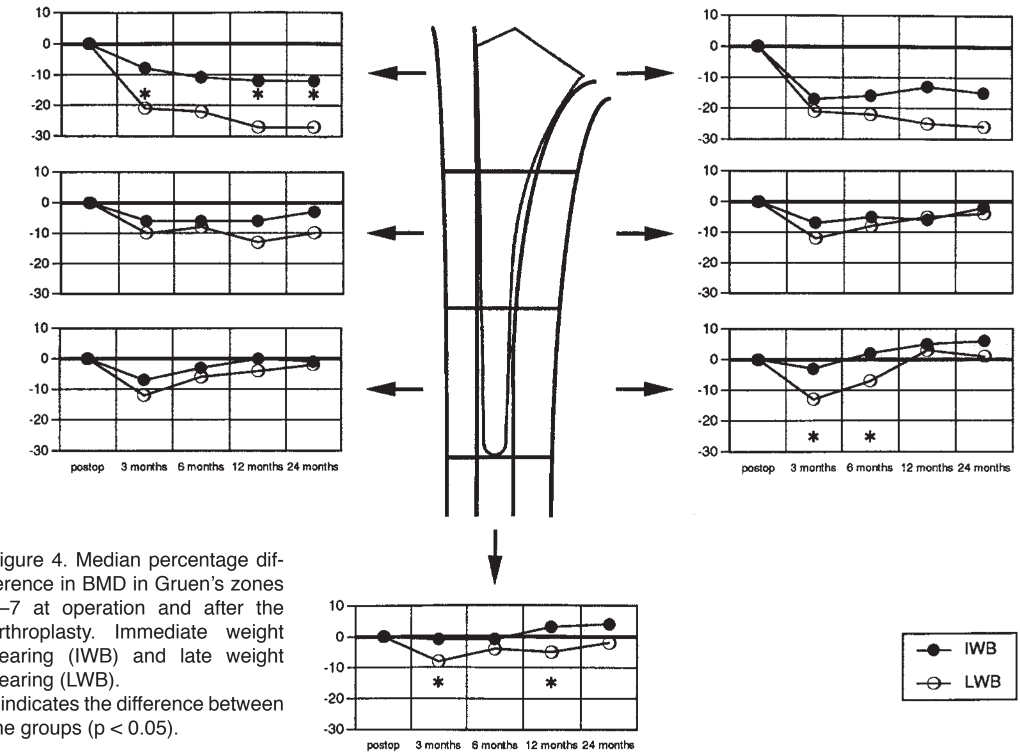

Figure 4. Median percentage difference in BMD in Gruen's zones 1–7 at operation and after the arthroplasty. Immediate weight bearing (IWB) and late weight bearing (LWB).
* indicates the difference between the groups ($p < 0.05$).

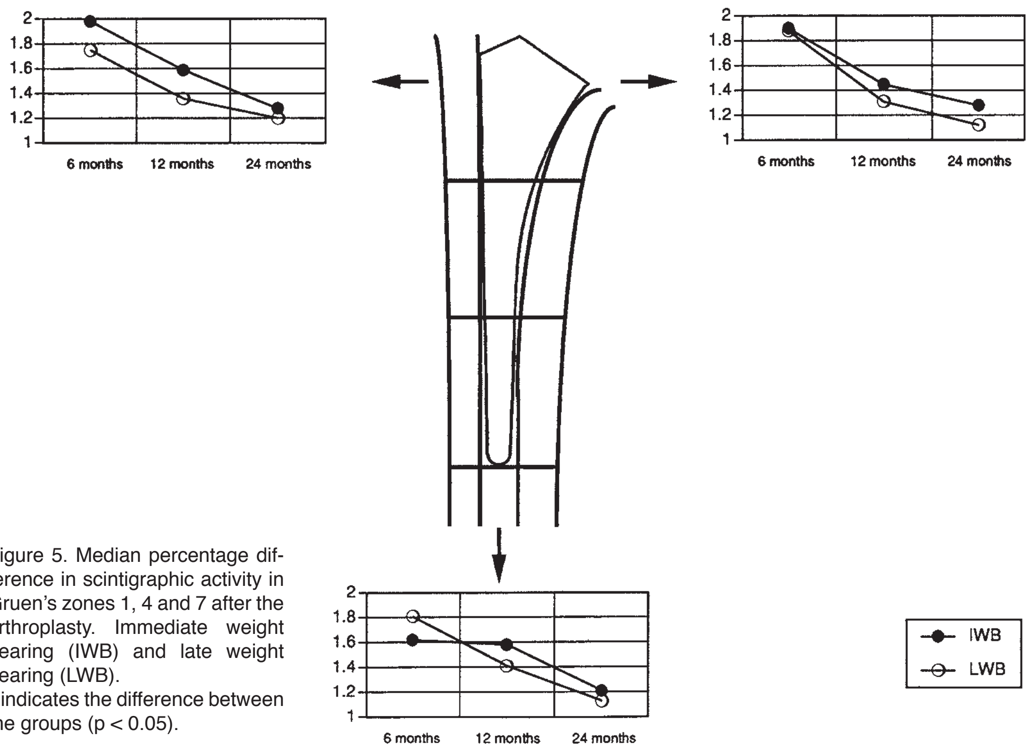

Figure 5. Median percentage difference in scintigraphic activity in Gruen's zones 1, 4 and 7 after the arthroplasty. Immediate weight bearing (IWB) and late weight bearing (LWB).
* indicates the difference between the groups ($p < 0.05$).

Femoral bone remodeling at 2 years

A	B	C	D	E	F	G	H	I	J
I group									
1	0	6	3,4,5	6	5	no	0	no	2
2	0	1,2,7	no	no	3	no	0	no	3
3	0	1,6	no	no	3	no	0	no	2
4	0	1	no	no	1	no	0	no	1
5	1	no	no	5	0	no	0	no	1
6	0	1,6,7	no	3,4,5	1	no	2	no	0
7	0	1,7	no	3,4,5	2	no	0	no	0
8	0	7	no	no	0	yes	0	no	0
9	0	1	no	no	0	no	0	no	0
10	0	1	no	no	0	yes	0	no	0
L group									
1	0	1,2	no	3,4,5	7	no	0	no	0
2	0	1,2,6,7	no	3	1	yes	0	no	0
3	0	1,7	no	3,4,5	3	no	0	no	3
4	2	7	no	4,5	0	yes	0	no	0
5	2	2	no	no	0	no	0	no	1
6	0	7	no	no	0	no	0	no	0
7	0	1	no	4,5	0	no	1	no	0
8	0	1	3,4,5	3,4,5	1	no	0	no	3
9	0	2,6	no	no	1	yes	0	no	1
10	1	no	no	no	0	yes	0	no	1

A Patient no.
B Migration, mm
C Spot welds (Gruen)
D Radiolucent lines (Gruen)
E Radiodense/reactive lines (Gruen)
F Distal cortical hypertrophy, mm
G Pedestal sign
H Calcar atrophy, mm
I Focal osteolysis (Gruen)
J Ectopic ossification (Brooker)

However, after 2 years this group difference was seen in zone 1 alone. Therefore, the postoperative reduction in BMD showed no relation to weight-bearing in most zones. Proximally, neither group recovered from the initial bone loss during the follow-up period, while distally, the I group recovered faster (Figure 4). We found no change in BMD on the healthy side in either group postoperatively.

Scintigraphic findings

In both groups, we noted a significantly higher scintigraphic uptake ratio than on the healthy side in all zones after 6 months (162–198% in the I group and 175–188% in the L group), (Figure 5). The periprosthetic scintigraphic activity declined with time, however, after 24 months, it was still higher in all regions except in zone 4 in the I group. There was no difference in scintigraphic uptake between the groups in any zone at any time.

Prosthesis fixation

One stem migrated 1 mm in the I group and 3 stems migrated 2 mm, 2 mm, and 1 mm, respectively in the L group (Table). Since we found no migration of 5 mm or more, no definite subsidence was considered to have occurred. Radiographically, all femoral components seemed to be well-fixed and several stems in both groups showed evidence of bone ingrowth (spot welds) (Table).

Bone remodeling

New bone bridges (spot welds) in almost all stems (9 stems in each group) had developed, especially in zone 1 where they could be seen in 7 and 5 hips, respectively. Radiolucent lines were found in 1 patient in each group. Radiodense/reactive lines were also noted in about half of the hips, mainly in zones 3, 4 and 5. No hips had such lines surrounding the entire stem. Distal cortical hypertrophy, ranging from 1 to 7 mm, was found in about half of the hips in both groups. A tip sclerosis (pedestal sign; zone 4) was noted in 2 patients in the I group and in 4 in the L group. Calcar atrophy was seen only in 1 hip in each group. No focal osteolysis was observed. 5 hips in each group showed ectopic ossification.

Discussion

Most knowledge about uncemented implants under various loading conditions is based on animal models in which the bone turnover is known to differ significantly from humans. Søballe et al. (1993) suggest that, in canine models, there is an interval when an externally applied mechanical stimulus may facilitate bone ingrowth onto titanium implants; however, when the critical level of this “window” is exceeded, bone formation is depressed. If this applies to humans, the micromotions that occurred with our prosthesis seem to be within the critical level, regardless of immediate or late loading. The geometry and surface morphology of the implant are important factors in stability (Berzins et al. 1993) and ingrowth (Overgaard et al. 1999). An HA-coated implant seems to stimulate ingrowth more than an uncoated implant under loaded conditions. Earlier studies with prostheses of a similar uncemented, tapered, hydroxyapatite-coated design (Kärrholm et al. 1994, Önsten et al. 1996, Ström et al. 2003) have shown minimal migration of the femoral component after 2 years, which is a reason for why we did not use roentgen stereophotogrammetry (RSA) in this study.

Compliance with recommended limited weight-bearing is low (Tveit and Kärrholm 2001). Winstein et al. (1996) found the greatest compliance when the patient received an immediate feedback during rehabilitation. An auditory device, which signals when the leg carries a load, could help the patient to control the degree of weight-bearing when walking (Andersson et al. 2001). It is also easy to use in ambulatory patients.

The DEXA method has permitted measurement of the amount of bone near a metallic implant (Kröger et al. 1996, 1997). The accuracy error of DEXA in the femur is less than 3% (Mazess et al. 1989). The precision error of the method is also small (1.0–5.3%), (Kröger et al. 1996).

In our study, we detected no significant difference between the groups in the radiographic signs of bone ingrowth (Engh et al. 1990). No stem migrated significantly, and nearly all of the femurs in both groups showed the formation of endosteal bone bridging (spot welds) after 2 years. In both groups, we found patients with reactive (radiodense) lines, which some authors ascribe to implant instability (Engh et al. 1990, Jasty et al. 1997). However, in no case did the lines extend into the proximally coated area.

Stress-shielding and disuse atrophy are thought to be the main factors causing the loss of BMD after THA (Engh and Bobyn 1988). Weight-bearing theoretically affects these factors (Venesmaa et al. 2001). The resorptive changes in the proximal part of the femur after an uncemented THA seems to be closely related to biomechanical factors (Van Rietbergen et al. 1993). After insertion of the stem, loading forces on the entire periprosthetic femur are redistributed and the bone remodels to adapt to the new environment by changing its bone mass (Wolff 1892). As early as 3–6 months after implantation of an uncemented stem, longitudinal studies by many authors have shown a great loss of BMD in the proximal femur. Thereafter, the BMD stabilizes during the first postoperative year (Nishii et al. 1997, Venesmaa et al. 2001). In the calcar area, where maximal bone resorption is expected, the bone loss in these studies has varied between 16% and 30%. We did not measure the BMD preoperatively because Nishii et al. (1997) and Venesmaa et al. (2001) have shown that the best way to compare longitudinal BMD changes is to use the immediate postoperative measurement as a baseline value, thereby avoiding the changes in BMD caused by the operation.

Postoperatively, we found a marked BMD reduction in the operated femur, the largest reduction being in zones 1 and 7. After 2 years, we found no significant difference in BMD loss between the groups (except zone 1), thus the late postoperative reduction in BMD occurred irrespective of weight-bearing. Engh and Bobyn (1988) have shown that distally-coated femoral implants are more prone to proximal bone atrophy and resorption than more proximally-coated stems. Although the Bi-Metric femoral stem is HA-coated only in the proximal region, we found a marked BMD loss in this region in both groups. Early loading of the implant should theoretically reduce the diffuse osteopenia caused by disuse, but it would also increase the stress-shielding effect, with an increase in the regional redistribution of bone mass. A different pattern of remodeling would be expected in early- versus late-loaded prostheses. In this material, the differences between the groups accorded with this theory, but some differences were not significant (Figure 4).

The scintigraphic pattern seems to vary with different uncemented stem designs (Rosenthall et al. 1991). An increase in scintigraphic activity under the tip has been reported by some authors (Kröger et al. 1997, Moilanen et al. 1997) and may be caused by persistent mobility of the prosthesis at the tip (Gruen et al. 1979). Others have claimed that an increase in the uptake is associated with bone ingrowth on HA-coated surfaces (Rahmy et al. 1994). We found a similar distribution of the scintigraphic activity proximally, where the Bi-Metric prosthesis is HA-coated, and under the tip during the 2-year follow-up.

In our study, all patients showed a marked increase in scintigraphic activity around the prosthesis, which amounted to between 162% and 198% after 6 months and was seen in all 3 zones. In a study using single photon emission computed tomography, Kröger et al. (1997) found a significant correlation between an increase in scintigraphic activity and a decrease in BMD of the lesser trochanter. This might be related to a change in loading conditions leading to remodeling of bone. However, we could not confirm this since we found no relationship between scintigraphic activity and bone resorption in either group. Moreover, neither scintigraphy nor DEXA could evaluate prosthetic fixation or bone ingrowth. Some of the patients in this study have also participated in another study of the functional recovery after this postoperative regime (Andersson et al. 2001). However, in that study 24 patients were followed regarding hip extension, muscle strength, gait velocity, pain and walking pattern and only for 24 weeks. Thus, this study includes other parameters and is extended to 2 years.

In summary, only a few guidelines are available in the literature about the postoperative treatment of choice for best ingrowth of an uncemented stem. Hardly any comparative clinical studies have been reported to date which favor early weight-bearing (Rao et al. 1998, Kishida et al. 2001). However, early weight-bearing lowers hospitalization costs, reduces the risk of deep venous thrombosis (Leali et al. 2002) and can be expected to promote functional recovery (Andersson et al. 2001). In our study, we found that immediate weight-bearing had a positive effect on the reduced BMD around the prosthesis, especially in the distal part.

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No competing interests declared.

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