

BONE DENSITY STUDY OF THE PROXIMAL FEMUR AFTER HIP ARTHROPLASTY WITH POROUS-COATED IMPLANTS

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ABSTRACT

Progressive loss of bone mineral density around the femoral component of total hip replacement continues to pose a threat to long term prosthetic survival. A linear study was undertaken to measure bone mineral density on a monthly basis following total hip arthroplasty in 11 male patients. The opposite femur was used as the control measurement. Bone mineral density was unchanged at two months following surgery but demonstrated significant decrease as compared to the non-operated side at three months and thereafter. There appears to be a continually progressive reduction in bone mineral density values in most zones up to six months. Initial loss of bone mineral density may reflect a change in vascularity of periprosthetic bone with progression to mechanical stress shielding. Further study of this phenomenon utilizing both cemented femoral stems and stems coated with bioactive ceramic appears to be warranted.

Key words: bone mineral density; osteoporosis; Gruen zones; orthoped software; dual energy x-ray absorptiometry; total hip arthroplasty.

INTRODUCTION

Total hip arthroplasty (THA) remains the mainstay of treatment for degenerative arthritis of the hip. In the past 30 years this operation has proven to be a safe and efficacious way for managing disabling hip pain in the adult (1).

Initial surgical procedures involved the use of methacrylate bone cement to secure prosthetic components to the host bone (2).

With aging of this bone cement in a biologic environment progressive loosening and breakdown of the bone cement and cement prosthetic junction were seen (3). The significant factor contributing to this failure in total hip arthroplasty is resorption of bone from the proximal femur. This bone loss is associated with prosthetic loosening, subsidence, fracture of the femur and fracture of the prosthesis (4). Several long term studies

of cemented total hip arthroplasty have shown significant proximal femoral bone resorption (3,5,6,7).

Porous coated femoral prostheses designed for bone ingrowth fixation were developed in an attempt to prevent this type of bone resorption and prosthetic failure (8,9,10). A wide variety of prosthetic configurations and metal alloys as well as non-metal materials have been utilized for this purpose. In those prosthetic designs in which satisfactory bone ingrowth has been achieved, the short and midterm results tend to be the equivalent of those seen with cemented implants (11,12,13,14,15). Severe bone resorption is seen with large prosthetic stems that are extensively porous coated and fill most of the canal (11,13). Resorption tends to be more pronounced in patients over 50 years of age and with arthroplasties in which there is evidence of significant bone ingrowth (1,10,11,16). With increasing follow-up, there is a tendency for the supporting bone around the femoral prosthesis to undergo a variety of changes. This change, referred to as "stress shielding", demonstrates that bone in close contact with the prosthesis tends to lose some of its structural strength because of the stress which would normally be applied to the bone is bypassed by way of the prosthesis. This bypass results in diminished stress to the bone and a diminished biologic stimulation to increased bone density. The concern over the substantial undetected loss of bone which may cause clinical problems has demanded the quantitative assessment of bone mineralization and encouraged the development of dual energy x-ray absorptiometry (DEXA). This method has been used in limited longitudinal studies to evaluate changes in periprosthetic bone marrow after total hip arthroplasty.

Since the prosthesis that we were using was deliberately designed (15) in an effort to

promote uniform bone ingrowth in the proximal 60% of the femur and avoid distal fixation, thus minimizing stress shielding, it was felt to be an appropriate prosthesis for a longitudinal study which would detail the changes in bone density from the early postoperative period through to six months to one year of follow-up.

Bone mineral density presumably will change dramatically with the insertion of the prosthesis into the proximal femur. This initial response to surgery may be an important trigger to ongoing and later changes in the bone. Therefore we felt it was important that the patients undergo sequential bone density measurement.

DEXA which is superior to the older technique of dual-photon analysis, in terms of image resolution, precision, and radiation dose, and also, the modified orthopedic software (version 1.2; Lunar Corporation, Madison, Wisconsin, U.S.A) has made it possible to quantify bone mineral density (BMD) adjacent to metallic implants with a significantly improved ability. In DEXA, two filtered energies of 38 and 70 keV are attenuated differently in soft tissue and bone and the transmitted radiation is recorded by a scintillation detector.

The modified Gruen zone analysis allows the boundary between zones 1-2 and 6-7 (Fig. 1), of the widely accepted seven Gruen zones (17) to coincide with the porous coating level. The rest of the implant is equally divided for regions 2,3 and 5,6. Zone 4 is placed below the distal tip. Using the new analysis, the change in BMD adjacent to the porous coating can be measured separately.

The prosthesis used is proportionate in length and diameter ranging from 11 millimeters in diameter/110 millimeters in length to 18 millimeters in diameter/180 millimeters in length (15). There are proximal fins to assist in rotational stability; the proximal 60% has a rough or porous surface. The

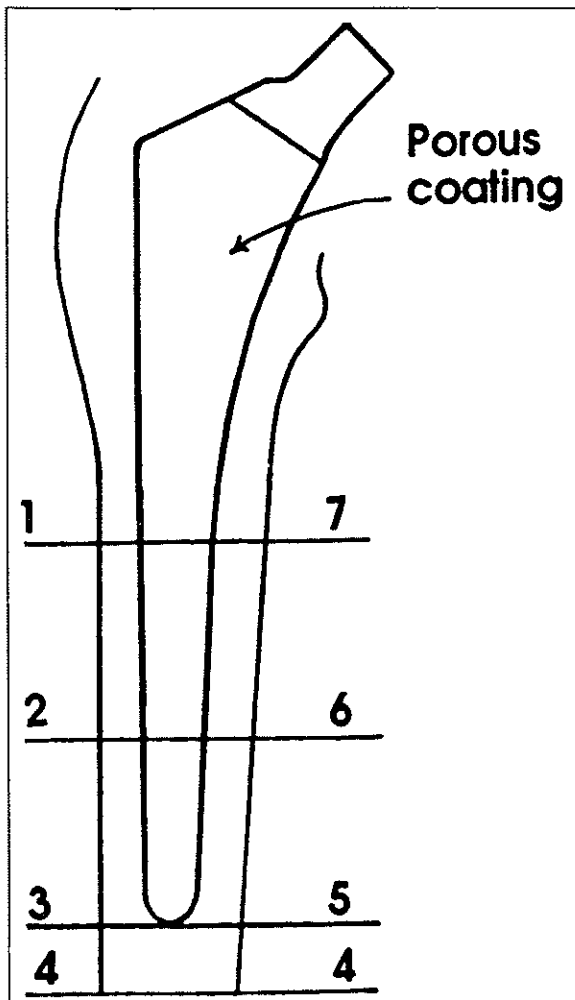


Fig. 1. The placement of the seven Gruen zones are modified so the boundary between zones 1-2 and 6-7 coincides with the porous coating level. The implant length less porous length is equally divided for regions 2,3 and 5,6. Zone 4 is placed below the implant tip.

prosthesis is manufactured of cast cobalt chrome, this material having been chosen because of its proven biocompatibility.

The prosthesis is inserted by performing a posterior approach to the hip. The acetabulum is replaced by a metal shell with an inner liner of polyethylene; the femoral head is replaced by femoral stem which is mated to the prosthetic femoral head by a Morse taper. The patients are permitted immediate weight bearing following their surgery.

The clinical results with the prosthesis over the past eight years have been excellent (18,19). There have been no incidences of stem failure from fatigue fracture; there has been a less than one percent revision rate on the femoral side at eight years. Plain radiographic review of the reponse of the bone to the stem suggests 95% or more of all stems are bone ingrown. In an effort to determine the sequence and extent of early bone apposition to the femoral stem the current study was undertaken.

PATIENTS AND METHODS

Eleven male patients with monolateral THA were enrolled in the study within six months after surgery (those patients who could not stay with the study until its completion are not included here). The patients' age ranged from 29-67 (average 52) years. All patients were operated on by the same surgeon, and in all of them osteoarthritis was the reason for THA.

In all patients an anteroposterior scan of the operated proximal femur (THA) and of the contralateral non-operated femur was performed sequentially each month until six months after operation. All scans were obtained by the same operator. The scan window included all Gruen zones starting from at least one centimeter below the tip of the prosthesis. Bone mineral content (grams), area (cm^2), and BMD (g/cm^2) were obtained for each of the seven Gruen zones of both the THA and non-operated sides.

The x-ray beams attenuated by the metal implant, relative to bone in the low energy beam, were automatically subtracted from the scan results. The densitometer (Model DPX; Lunar Corp.) was operated in the slow mode and with $250 \mu\text{A}$ current; the pixel size was $0.6 \times 1.2\text{mm}$. The radiation dose was 4.8 mR per scan, thus permitting repeat measurements with negligible risk to the patient. The

instrument's stability was checked routinely.

On follow up repeat visits, the current scan was compared to the baseline scan of the same individual. Using the compare feature, a comparison to the contralateral side was also made. The regions of interest (ROI) were manually adjusted to account for individual anatomy. All patients were examined during regularly scheduled appointments; no complications were registered in any case.

Precision studies with DEXA were performed on two groups of subjects. For non-operated side, four healthy adult volunteers were scanned, three subjects for three times and one for five times in succession. For THA side, three of the patients were scanned for three times and one patient volunteer scanned for five times in sequence.

In order to reproduce the standard positioning each time, the patient was placed on the scan table with standard knee and foot support. Between scans, the patient got off and then back on to the scan table. Each set of three or five successive scans were completed within two or three hours, respectively, and entire measurements were carried out within two weeks. Comparisons between zones of two sides were performed by means of student t-test for paired data. One-way ANOVA was applied to detect the difference among the zones, and the pairwise comparisons among the zones were done by Scheffe test.

RESULTS

Mean BMD values, standard deviations, variability in terms of CV%, and t-values of each Gruen zone for both the THA and THA-free sides were determined monthly for six months after operation. The results for the first week are provided in Table 1 and for one, two, three, and six months after insertion, in Tables 2 through 5, respectively.

The BMD values of THA-free sides were significantly higher than the corresponding values for THA sides mostly in zones 2,3,5 and 6 in three and six months following operation (Student t-test for paired data) (Tables 4 and 5). Although not presented here, the BMD values obtained for the same zones in month of four and five were also significantly higher for the THA-free side. The actual P-value for zone 3 in month six was 0.068 (Table 5). The BMD values obtained for THA and THA-free sides one and two months after insertion were not significantly different (Tables 1 and 2).

Reproducibility (precision) of measures as calculated in terms of CV% is displayed in Fig. 2. In the THA side, precision errors ranged from 0.9 to 2.3%, except for zone 7 (calcar) which was as 6.7%; in the THA-free side, the error was lower ranging from 0.4 to 1.8%.

Since BMD value in zone 4 was less different from patient to patient, all seven zones of each side were normalized to BMD value of corresponding zone 4. As it is evident from Fig. 3A, there has been continually progressive reduction of BMD values in most zones, in month two through month six after operation. Relative to zone 4, the BMD values for zones 7,6,5,3 and 2 of THA side were 11.9,7.6,5.3 and 6.2%, respectively, in the four months period (month two through month six). Using contralateral comparisons, BMD measurement after three months following THA, reveals reductions of 8.4%, 14.4%, 10.5%, 5.5%, 9.9%, 12.5%, and 11.4% in zones 1,2,3,4,5,6, and 7, respectively. The variability of BMD of each zone in the THA-free side (Fig. 3B) was negligible during the study.

DISCUSSION

The response of endosteal and cortical bone to intramedullary devices is poorly understood. It is recognized that the endosteal

Table 1. BMD measurement within first week after operation. Mean BMD value (g/cm²), SD (g/cm²), and CV% are given for each Gruen zone in six patients.

Gruen zone	THA side			Scheffe-test	THA-free side			Scheffe-test	t-test	
	BMD(mean)	SD	CV%		BMD(mean)	SD	CV%		t-value	P-value
1	1.245	0.284	22.77	A	1.226	0.236	19.28	C	-0	-
2	1.700	0.206	12.14	A	1.673	0.203	12.16	BAC	-0	-
3	1.696	0.258	15.23	A	1.652	0.241	14.56	BAC	-1	-
4	1.692	0.262	15.51	A	1.720	0.231	13.48	BAC	0	-
5	1.852	0.305	16.48	A	1.881	0.225	11.99	A	0	-
6	1.819	0.270	14.84	A	1.847	0.197	10.67	BA	0	-
7	1.328	0.159	11.94	A	1.264	0.137	10.85	BC	-2	-

Table 2. BMD measurement one month after operation. Mean BMD value (g/cm²), Sd (g/cm²), and CV% are given for each Gruen zone in six patients.

Gruen zone	THA side			Scheffe-test	THA-free side			Scheffe-test	t-test	
	BMD(mean)	SD	CV%		BMD(mean)	SD	CV%		t-value	P-value
1	1.180	0.311	26.42	A	1.170	0.252	21.52	B	-0.12	-
2	1.599	0.288	18.04	A	1.639	0.191	11.66	AB	0.44	-
3	1.522	0.222	14.56	A	1.588	0.197	12.42	AB	0.67	-
4	1.526	0.126	8.25	A	1.679	0.208	12.41	AB	1.82	-
5	1.702	0.271	15.98	A	1.794	0.188	10.47	A	0.38	-
6	1.675	0.244	14.57	A	1.755	0.165	9.38	AB	0.56	-
7	1.179	0.080	6.86	A	1.215	0.074	6.16	AB	0.53	-

Table 3. BMD measurement two months after operation. Mean BMD value (g/cm²), SD (g/cm²), and CV% are given for each Gruen zone in eight patients.

Gruen zone	THA side			Scheffe-test	THA-free side			Scheffe-test	t-test	
	BMD(mean)	SD	CV%		BMD(mean)	SD	CV%		t-value	P-value
1	1.184	0.259	21.9	C	1.256	0.244	19.4	C	2.1	<0.1
2	1.645	0.222	13.5	AC	1.785	0.271	15.2	BA	2.6	<0.05
3	1.603	0.213	13.3	AC	1.733	0.270	15.6	BA	2.1	<0.1
4	1.698	0.323	19.0	AC	1.808	0.274	15.2	BA	1.9	<0.1
5	1.772	0.248	14.0	A	1.883	0.193	10.2	A	1.3	-
6	1.745	0.244	14.0	BA	1.862	0.197	10.6	A	1.9	<0.1
7	1.237	0.291	23.5	BC	1.359	0.193	14.2	BC	1.7	-

Table 4. BMD measurement three months after operation. Mean BMD value (g/cm²), SD (g/cm²), and CV% are given for each Gruen zone in nine patients.

Gruen zone	THA side			Scheffe-test	THA-free side			Scheffe-test	t-test	
	BMD(mean)	SD	CV%		BMD(mean)	SD	CV%		t-value	P-value
1	1.194	0.309	25.9	A	1.303	0.258	19.8	A	1.2	-
2	1.555	0.445	28.6	A	1.816	0.343	18.9	A	4.5	<0.01
3	1.549	0.408	26.3	A	1.731	0.301	17.4	A	2.4	<0.01
4	1.708	0.417	24.4	A	1.807	0.353	19.5	A	2.4	<0.05
5	1.721	0.445	25.9	A	1.910	0.394	20.6	A	4.1	<0.01
6	1.653	0.442	26.7	A	1.889	0.387	20.5	A	4.7	<0.01
7	1.154	0.327	28.3	A	1.303	0.262	20.1	A	1.5	-

Table 5. BMD measurement six months after operation. Mean BMD value (g/cm²), SD (g/cm²), and CV% are given for each Gruen zone in seven patients.

Gruen zone	THA side			Scheffe-test	THA-free side			Scheffe-test	t-test	
	BMD(mean)	SD	CV%		BMD(mean)	SD	CV%		t-value	P-value
1	1.228	0.295	24.05	A	1.286	0.244	18.99	A	1.29	-
2	1.640	0.478	29.12	A	1.808	0.345	19.10	A	2.45	<0.05
3	1.574	0.424	26.95	A	1.760	0.297	16.89	A	2.22	<0.1
4	1.792	0.373	20.84	A	1.829	0.344	18.79	A	1.12	-
5	1.746	0.433	24.79	A	1.912	0.429	22.43	A	2.66	<0.05
6	1.662	0.423	25.43	A	1.869	0.401	21.45	A	2.58	<0.05
7	1.171	0.309	26.42	A	1.377	0.259	18.77	A	2.18	<0.1

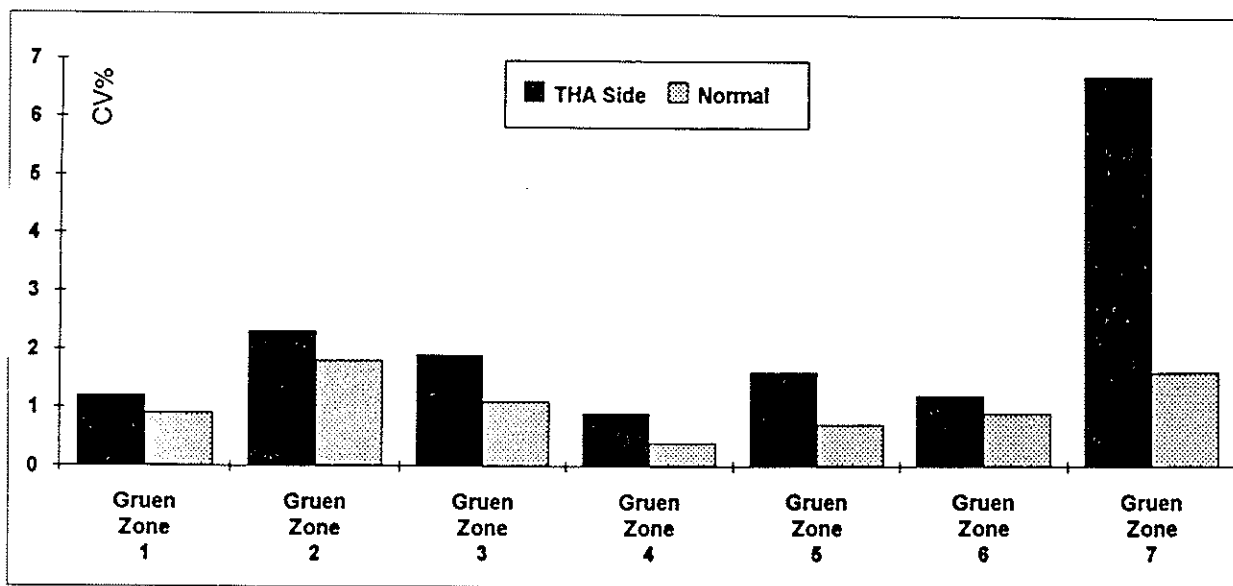


Fig. 2. Reproducibility of BMD determination of multiple consecutive measures carried out in three patients for THA side and for corresponding regions of interest in three healthy volunteers; both were performed within a time interval of two weeks.

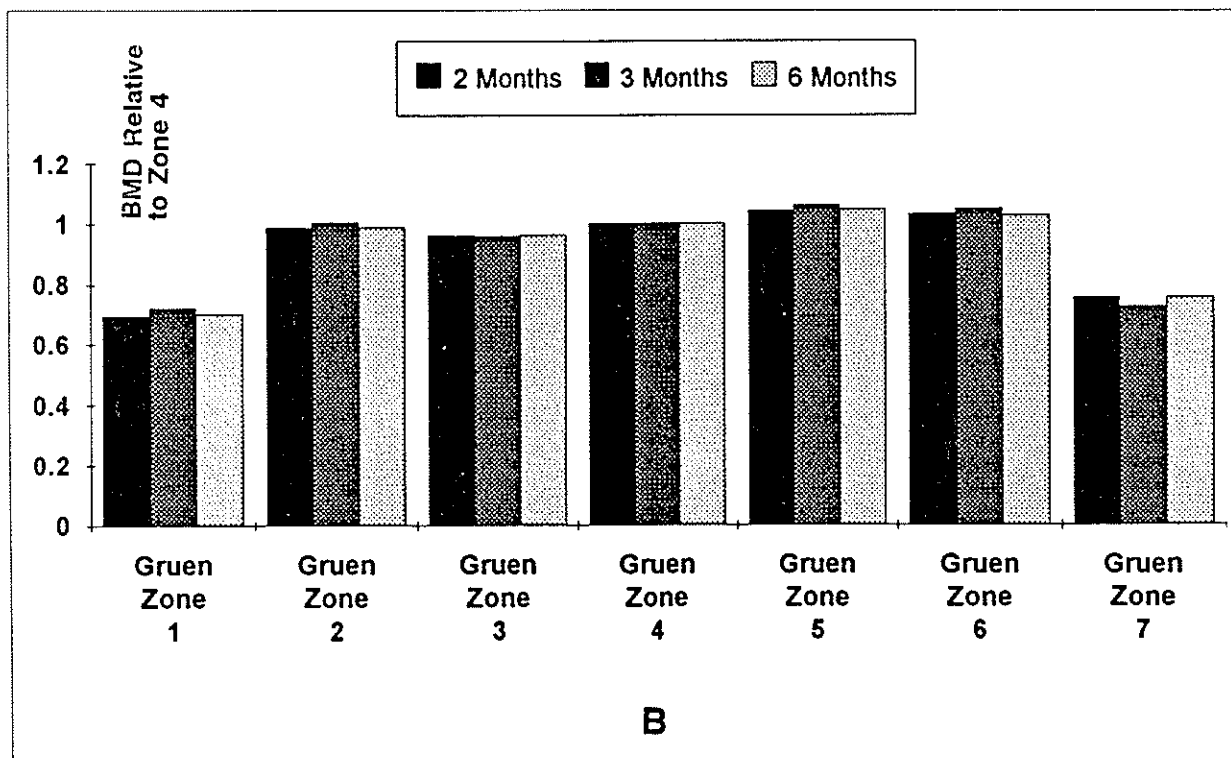
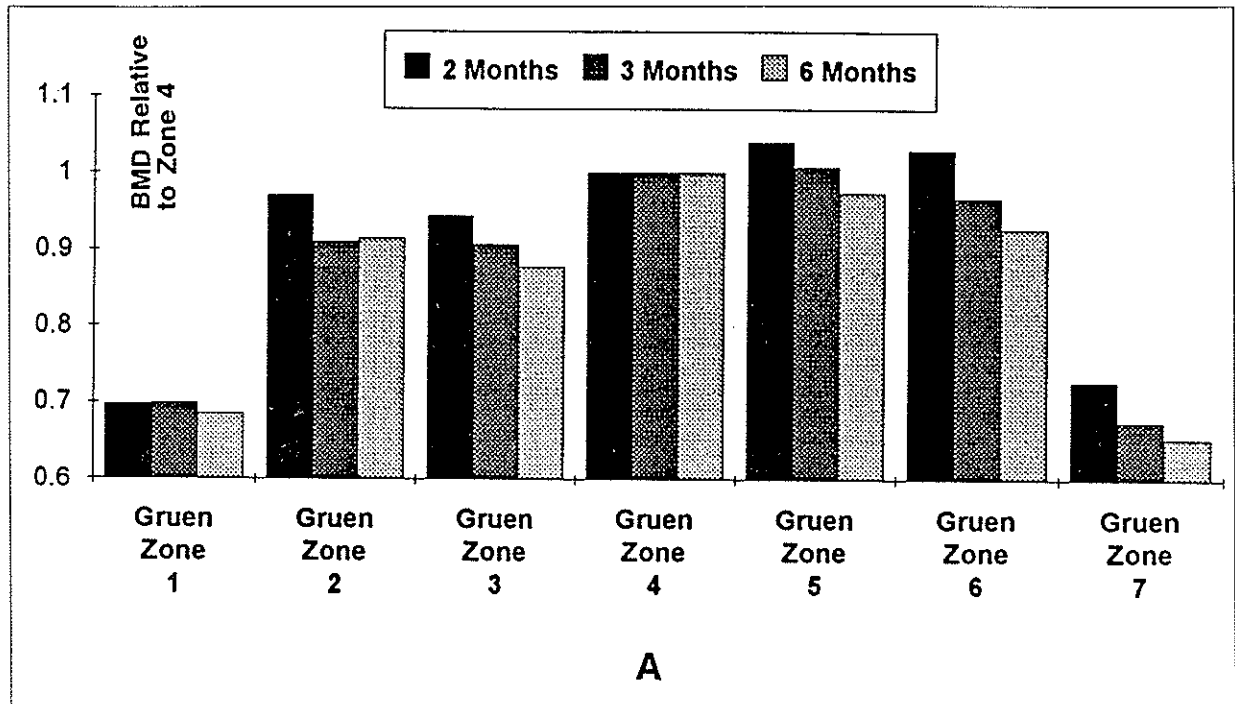


Fig. 3. Relative BMD determination of each Gruen zone for THA side (A) and THA-free side (B) at two, three, and six months after operation.

blood supply is disturbed or destroyed by the reaming which precedes insertion of most intramedullary devices. It is anticipated that the endosteal response to the reaming, broaching and insertion of a THA stem would closely parallel the response seen following the insertion of any other intramedullary device. This involves some loss of endosteal bone secondary to avascular necrosis, rapid revascularization of the cortical bone and endosteum via periosteal vessels and finally the re-establishment of endosteal circulation around the intramedullary device.

An analysis of the BMD in these patients suggests that this response is operational in patients undergoing non-cemented total hip replacement utilizing the St. Michael's hip prosthesis.

The BMD measurement within the first week of operation demonstrates no change between the operated side and the non-operated side. This similarity between bone mineral density in both sides persisted up to one month after operation. This corresponds to the time of endosteal avascularity and periosteal reaction with attempted endosteal healing.

By two months after operation in those Gruen zones most sensitive to changes in the endosteal blood supply, significant difference in the BMD between the operated side and the non-operated side was evident. This statistically significant difference persisted at three months and at six months.

The rate of bone deposition around non-cemented hip arthroplasty stems is influenced by many factors including the quality and quantity of bone present prior to operation, type of prosthesis used, accuracy of fit of the prosthesis, surface geometry and texture, and vascularity of the bone into which the prosthesis has been implanted. If there is

significant endosteal disturbance at the time of prosthesis insertion, presumably the revascularization phase is more prolonged and this may have a significant bearing on the quality and quantity of bone ingrowth in the more proximal cancellous zones of the femur. In the more distal metaphysis and diaphyseal region of the femur where there is less cancellous bone and a more intimate fit between the stem of the prosthesis and the endosteal cortex, time to revascularization may be appreciably shorter resulting in more rapid and more complete bone ingrowth.

It is unlikely that the differences in BMD reflect disuse osteoporosis in the operated hip since with the prosthesis used patients are allowed full weight bearing as soon as possible after surgery and most are walking with a single cane by four to six weeks after operation and without external aids by three months after surgery.

It would appear likely that this initial loss of BMD which might be attributed to the disturbance of the endosteal blood supply, persists up to six months after surgery perhaps as a consequence of stress shielding.

There may be a continuum as yet unrecognized between the primary response of bone to the endosteal manipulation and the eventual radiographic appearance of stress shielding which might not be apparent for some months or even years after the operation.

A comparison group of patients in whom cemented stems have been used might help to elucidate the role of endosteal intrusion and the late manifestations of the presence of hip arthroplasty on the surrounding bone; a similar group of patients in whom the prosthesis has been coated with bioactive ceramic might further demonstrate the role of enhanced osteogenesis in the speed of

revascularization and endosteal bone deposition.

This study confirms the finding by McCarthy et al (20) that bone loss around the prosthesis is significant and progressive. Richmond et al (21) recently reported BMD change of 5-31% in the first year after uncemented THA, using the Gadolinium-based dual-energy absorptiometer (DP3, Lunar Corp.). In our study, using contralateral comparisons, BMD reductions of up to 12.5% in three months and up to 15% in six months after operation seemed to confirm the above finding. Our calculation of precision error (<3%, except for the calcar region of the THA side) was well below the measured BMD values.

This study further confirmed the work by Richmond et al that a decrease in BMD in the region directly below the calcar occurs within the first year. The calcar region of the THA side showed the highest BMD reduction with respect to the non-operated side in month six and the second highest (11.4% vs 12.5% for zone 6) in month three following operation. The calcar demineralization has previously been described by Engh et al (22) as a characteristic feature in the uncemented press fit femur; they also demonstrated that partial calcar resorption detected by DEXA has a positive prognostic value.

Scheffe test showed that the average BMD changes among the zones were basically insignificant, perhaps because of the smaller sample size, closely spaced scan times, and unseasonal measurements which may have masked real bone mass changes.

For reproducibility, coefficients of variation (CV) in the non-operated side were good and comparable to the results obtained by standardized scans in a different study (25). On the THA side, CV's were higher due to the lower bone density; this was especially true for the calcar region because of the paucity of

bone in the same location.

The effect of rotation of the leg was considered to be negligible in this study: Kiralti et al (26) found that rotation of 5 in any direction did not elevate precision error appreciably. In another study (27), there was no significant change relative to 0 rotation in the range of -30 to +30 in Gruen zones 1,3,4,6, and 7, and no significant difference in the range -10 to +10 in zones 2 and 5.

Even with the present x-ray densitometer which has a good reproducibility, monitoring of patients may still include some degree of uncertainty such as biological variations, patient positioning, seasonal variations, instrument's instability, and the number of measurement points. Although data processing has been automated, however, some decisions like the selection of reference point is left to the operator, the fact we believe to be of concern in particular.

CONCLUSION

The loss of BMD around non-cemented total hip implants appears to be initially related to endosteal revascularization following disturbance of the blood supply at the time of primary prosthetic insertion. This BMD loss persists at least up to six months following surgery and may be interpreted eventually as stress shielding. Further work regarding the role of disturbance of endosteal vascularization following total hip replacement appears to be warranted to elucidate individual factors which may be important in the prevention of such bone loss.

It has become evident that bone density is strongly related to fracture risk, and DEXA has proven to be a very effective tool in quantifying bone changes following THA. We have shown in the present study that significant BMD changes in the THA side relative to the non-operated side can be obtained as early as

three months after operation. Further studies are recommended to fully explore the clinical potential of such early BMD changes detection.

RECOMMENDATIONS FOR FUTURE STUDIES

1. Measurements in more patients and also beyond six months are encouraged to determine if reversal of bone loss occurs over time.
2. Pre-operative determination of bone density would be useful both on the operated and non-operated femur to determine starting point of mineralization.
3. Evaluation of other prosthetic types should be of interest.
4. Because of incomplete biologic stability for up to one year, it would be worthwhile to examine the probable off-loading of the operated limb to the normal side.

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