THA with Hydroxyapatite Granules at Cement–Bone Interface

15- to 20-year Results

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Abstract To augment cement–bone bonding, we interposed hydroxyapatite granules at the cement–bone interface (bioactive bone cement technique). Hydroxyapatite granules (2–3 g) were smeared on the bone surface of the acetabulum and femur just before cementing. We used porous hydroxyapatite granules 300 to 500 μm in diameter from 1986 to 1988 (first generation) and granules 100 to 300 μm in diameter from 1989 to 1991 (second generation). We followed 151 patients (222 hips) in the first generation and 170 patients (252 hips) in the second generation. The minimum followup was 15 years (mean, 17.3 years; range, 15–20 years). Radiolucent lines or spaces less than 1 mm were observed in four hips (1.8%) in the first generation and in 15 hips (6.2%) in the second generation. Osteolysis was observed in one hip (0.5%) in the first generation and six hips (1.6%) in the second generation. We observed loosening in two cups (0.8%) in the second generation. The long-term clinical results suggest the interface bioactive bone cement technique

combined with our other techniques results in low incidences of radiolucent lines (spaces) and osteolysis, and may increase the longevity of cemented THA. The data suggest the larger hydroxyapatite granules performed better than smaller ones.

Level of Evidence: Level III, therapeutic retrospective cohort series. See the Guidelines for Authors for a complete description of levels of evidence.

Introduction

The cement–bone interface is one of the critical factors for the longevity of cemented THA. Cementing technique has improved with the advent of cement guns, pulsatile lavage, and intramedullary bone plugs for the femur [12–14], and flanged sockets for the acetabulum [16]. Multiple small anchoring holes in the acetabulum improve the mechanical bonding at the cement–bone interface. Even with these contemporary techniques, cement penetration is often limited, especially in the acetabulum [2, 23, 24]. Furthermore, physicochemical bonding cannot be expected because bone cement is not osteoconductive.

To augment cement–bone bonding, we attempted a new technique 20 years ago to achieve an enduring physicochemical bond by interposing osteoconductive crystal hydroxyapatite (HA) granules at the cement–bone interface [19]. This technique—the interface bioactive bone cement (IBBC) technique—provides bioactivity on the surface of bone cement for prosthetic fixation. We found the integrity of the cement–bone interface was substantially improved in a rabbit model when HA granules were interposed at the interface [17, 20]. We began using the technique for selected cases in 1984 and have used it for all cases of THA and TKA since 1987. Two sizes of HA granules were

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serially used from 1986 to 1991. Before 1988 we used HA granules 300 to 500 μm in diameter but after 1989 HA granules 100 to 300 μm in diameter became available and we used these. The 10-year clinical results for THA revealed an overall loosening rate of 3.2% for acetabular components and 0% for femoral components in 218 hips [19].

In addition to the short-term effects based on the bioactivity of HA granules, this technique might have possibilities for improving the long-term survival of prostheses by preventing particle-induced osteolysis and by resisting age-related osteoporosis. In a rabbit model, this technique is reportedly effective in preventing particle-induced osteolysis [15], while the long-term clinical results have not yet been reported.

We first questioned if survival rate was different between the two groups. We then asked whether there would be differing rates of radiolucent lines, osteolysis and loosening with the two granule sizes.

Materials and Methods

We prospectively followed 401 consecutive patients (562 hips) who underwent THA with the interface bioactive bone cement technique from 1986 to 1991 (Table 1). During the study period, two sizes of porous HA granules were manufactured. Before 1988 (first generation), we used HA granules 300 to 500 μm in diameter in 151 patients (222 hips). After 1989, HA granules 100 to 300 μm in diameter became available and we used these in 170 patients (252 hips). Power analysis indicated that the required effect size in this study was 0.17 for the chi-square tests between first and second generations. The diagnosis

was degenerative osteoarthritis secondary to acetabular dysplasia in 494 hips, rheumatoid arthritis in 54 hips, and avascular necrosis in 14 hips. The average age at operation was 60.7 years (range, 32–83 years). The minimum followup was 15 years (mean, 17.3 years; range, 15–20 years). Thirty-eight patients (40 hips) died within 14 years of surgery. Three patients underwent revision procedures due to late infection. Four patients had fractured femora 2 years, 3.5 years, 4.5 years, and 6 years after the operation. Thirty-five patients (41 hips) were lost to followup. Thus, we were able to follow 321 patients (474 hips) with a followup rate of 90.8% at 15 years postoperatively.

Both sizes of granules were manufactured using the same process. Synthetic porous HA was prepared by sintering at 1200° C in air, and then crushing into granules (Sumitomo-Osaka Cement Co Ltd, Chiba, Japan). The granules were sieved to sort by size. We preferred using smaller granules from 1989 to 1991 (second generation) because the smaller HA granules seemed easier to use in surgery.

The operative technique and postoperative care were the same in the first- and second-generation patients. Acetabular bone deficiencies were supplemented by structural autogenous bone graft fixed with screws. Patients walked with partial weight bearing for 1 week postoperatively, after which full weight bearing was allowed as tolerated.

All operations were performed by the senior author (HO) through an anterolateral approach or transtrochanteric approach in the supine position. The transtrochanteric approach was indicated only for cases of Crowe Type IV and postosteotomized hips. In all cases, a cobalt-chromium alloy femoral component (Bioceram Type 6; Kyocera Co. Ltd, Kyoto, Japan) with an alumina ball was used in combination with an all-polyethylene acetabular component (PHS socket; Kyocera Co. Ltd, Kyoto, Japan). A 28-mm alumina ball was used in almost all cases, except for the last 15 cases in which a 22-mm alumina ball was used. The stem was grid-blasted and triple-tapered with a collar. For the acetabular side, several small anchor holes were made after reaming. Hemostasis was achieved by administering hypotensive anesthesia (approximately 90 mmHg), using temporal compresses at the bleeding points with bone paste obtained by acetabular reaming, and rinsing with hydrogen peroxide followed by compressive gauze packing. The HA granules (2–3 g) were smeared on the bone surface by gauze or finger just before the acetabular component was cemented. The porous HA granules adhered easily to the wet bone surface. CMW-I bone cement (CMW Laboratories Ltd, Blackpool, UK) was used in all cases. For the femoral side, hemostasis was achieved by hypotensive anesthesia and with a hydrogen peroxide rinse followed by compressive gauze packing. The HA granules

Table 1. Demographic data

Variable	First generation (1986–1988)	Second generation (1989–1991)
Patients/hips	192/265	209/297
Mean age (years)	62.5 (39–80)	59.1 (32–83)
Diagnosis		
OA secondary to dysplasia	227	267
RA	30	24
AVN	8	6
Dead (patients/hips)	21/21	17/19
Lost to followup (patients/hips)	18/20	17/21
Revision	1	2
Fracture	1	3
Followup (patients/hips)	151/222	170/252

OA = osteoarthritis; RA = rheumatoid arthritis; AVN = avascular necrosis.

(2–3 g) were smeared on the inner surface of the prepared femoral canal using a long, straight Kocher clamp and a longitudinally split silicone tube (10-mm diameter, 3- to 5-cm length) (Fig. 1). This half-split silicone tube acted as an elastic spatula, adapting its shape to the irregular inner surface of the femora. The femoral component was fixed with second-generation cementing techniques using an intramedullary bone plug and a cement gun [19]. These procedures resulted in two to three layers of HA granules on most of the cement–bone interface; bone cement directly contacted bone without interposition of HA granules in some parts where HA granules failed to be smeared [18, 19].

The presence of radiolucent lines, osteolysis, loosening, and stress shielding was determined using plain anteroposterior radiographs. The locations of radiolucent lines

Fig. 1 The HA granules were smeared on the cadaveric femur using a long straight Kocher clamp with a longitudinally split silicone tube. After smearing, the femur was cut in half to show the inner surface.

were identified according to the zones described by DeLee and Charnley [6] for acetabular components and the zones described by Gruen et al. [8] for femoral components. In THA using the interface bioactive bone cement technique, radiolucent lines are observed as spaces at the cement–HA layer interface, not at the HA layer–bone interface, because HA granules bond to bone. Osteolysis was defined as a focal area of balloon-shaped lucency. Loosening was defined as a lucency at the cement–HA layer interface more than 2 mm from the acetabulum. Stem subsidence was calculated by measuring the distance between tip of greater trochanter and lateral top of stem collar and considered only if greater than 2 mm.

All radiographs were evaluated at final followup by three independent surgeons (HO, SK, YD) in a blinded fashion. Interobserver variability analysis was performed using Kappa statistic. The maximum Kappa coefficients of radiolucent lines among the three observers were 0.67 at the acetabulum in the first generation, 0.68 in the second generation, 0.72 at the femur in the first generation and 0.87 in the second generation. Those of osteolysis were 0.66, 0.57, 0.66, 0.66, respectively. That of loosening was 0.80 at the acetabulum in the first generation. Loosening at the acetabulum and femur was not detected in the second generation, thus the Kappa coefficient was not calculated.

We used the Kaplan-Meier method [10] to determine survival. Revision for any reason was considered the end point. For the patients lost to followup, the survival time was listed as 0 in the analysis. The difference in survival between the two generations was determined by log-rank test. We used a chi-square test to compare the incidence of radiolucent lines in the two generations and Fisher's exact probability test to compare the incidence of osteolysis in the two generations. Level of significance was set at $p < 0.05$.

Results

The cumulative survival rate in the two groups was similar: 91.7% (range, 88.4%–95%) at 15 years and 91.7% (range, 88.4%–95%) at 17 years in the first generation; 91.2% (range, 88%–94.5%) at 15 years and 91.2% (range, 88%–94.5%) at 17 years in the second generation (95% confidence interval).

We observed radiolucent lines of less than 1 mm in the acetabulum in two hips (0.9%) at Zone 3 and in three hips (1.4%) at Zone 4 in the first generation and in five hips (2%) at Zone 3 and in 13 hips (5%) at Zone 4 in the second generation (Fig. 2). Radiolucent lines in the acetabulum in both generations appeared within 3 months; they were nonprogressive after 3 months and did not influence the clinical outcome (Fig. 3A–C). The incidence of radiolucent

Fig. 2 The incidence of radiolucent lines in both generations is shown. HA = hydroxyapatite.

lines in the acetabulum was higher ($p = 0.02$) in the second generation. Radiolucent lines of less than 1 mm were observed in the femur in four hips (1.8%) at Zone 1 and in one hip (0.4%) at Zone 7 in the first generation and in 15 hips (6.2%) at Zone 1 and in eight hips (3.1%) at Zone 7 in the second generation (Figs. 2, 4A–B). The incidence of radiolucent lines in the femur was higher ($p = 0.02$) in the second generation. Radiolucent lines in the femur were also nonprogressive.

Osteolysis in the acetabulum was observed in one hip (0.5%) in Zones 1 and 2 in the first generation and in two hips (0.8%) in Zone 1 in the second generation. There was no difference in the incidence of osteolysis in the acetabulum between the generations. Osteolysis in the femur was observed in one hip (0.5%) at Zone 7 in the first generation and in four hips (1.6%) at Zone 7 in the second generation. We observed no difference in the incidence of osteolysis in the femur between the two generations.

We found lucencies greater than 2 mm in the acetabulum in two second-generation hips (0.8%) at 1 and 3 years postoperatively, but these had not progressed at the latest followup and revision surgery had not been performed. In these cases lucencies were observed at the cement–HA layer interface, not at the HA layer–bone interface, and the cement was separated from the HA layer. On a plain radiographs, the HA layer was observed as a vaguely sclerotic zone that was different from a sharply sclerotic

Fig. 4A–B A radiolucent line of less than 1 mm in the femur is observed in (A) Zone 7 (arrow) after 6 months and did not change (B) after 18 years.

line around the radiolucent line. Separation began in Zone 4, extended to Zone 3, and then stopped (Fig. 5). Because the cups had tilted into Zone 1, we observed no lucency in this zone. We observed no lucencies in the femur in either the first or the second generation.

Discussion

To augment cement–bone bonding in cemented THA, we interposed HA granules at the cement–bone interface. From 1986 to 1988, we used porous HA granules 300 to 500 μ m in diameter. Smaller HA granules 100 to 300 μ m in diameter became available in 1989 and we used these from 1989 to 1991, since the smaller HA granules seemed easier to use in surgery. We compared cohorts with large and small HA granules. Then the presence of radiolucent lines, osteolysis, and loosening was investigated. The

Fig. 3A–C A radiolucent line in the acetabulum was not detected (A) 2 weeks after surgery, while (B) it was obvious in Zone 4 (arrow) 1 year later. Note the radiolucent line is present at the cement–HA layer interface. The radiolucent line did not change (C) 17 years after surgery.

Fig. 5 A radiograph taken 14 years postoperatively shows separation in the acetabulum. Due to lack of anchor holes, separation occurred 3 weeks after surgery. The separation began in Zone 4, extended to Zone 3 and then stopped. A screw was broken due to loosening of the cup.

cumulative survival rate in the two groups was similar. The incidence of radiolucent lines in both the acetabulum and femur was significantly higher in the second generation. There was no difference in the incidence of osteolysis in the acetabulum and femur between generations. We found lucencies greater than 2 mm in only two cups in the second generation.

We note several limitations when comparing our study to the reported literature. In our series, 87.9% of the patients had osteoarthritis secondary to acetabular dysplasia, and acetabular bone deficiencies were supplemented by structural autogenous bone graft in most cases. Therefore, these sometimes more difficult reconstructions might not reflect those in other populations; we presume in a population dominated by primary OA the results would be at least as good if not better. We used an alumina ball for all cases, and we did not measure the wear of polyethylene; however, the bearing combination might affect particle-induced osteolysis. Besides using HA granules, we paid particular attention to complete hemostasis by hypotensive anesthesia, compression at the bleeding points, and rinsing with hydrogen peroxide. We believe these additional techniques reduced blood interposition at the cement–bone interface and might be responsible for the radiographic

results. However, to confirm the advantage of using HA granules, a comparison with and without the interface bioactive bone cement technique would be important. We have a limited number of patients who have had bilateral THA with the interface bioactive bone cement technique in only one side, and we plan to compare the outcomes of the two hips.

From the Finnish Arthroplasty Register, the survival rate of cemented THA was reported to be 88% at 10 years [22]. To improve the longevity of cemented THA, finger-packing cementing has been replaced by the so-called second-generation cementing technique (use of a distal cement plug and retrograde filling of the femoral canal with cement). In the finger-packing cementing technique, the revision rate of acetabular components was 7.3% at the average followup of 13.4 years and that of femoral components was 3.2% at the average followup of 15.2 years [3]. With the second-generation cementing technique, the survival rate seemed to improve at a minimum 15 years (88%) [12], but the comparison between these two cementing techniques from a minimum of 25-year followup study demonstrated no difference [11]. Focusing on the acetabular component, the revision rate of acetabular components was 7.3% and that of femoral components was 3.2% after a minimum followup of 30 years [3]. The failure rate of acetabular components has not been reduced by the use of contemporary cementing techniques [1, 13]. For patients with osteoarthritis secondary to developmental dysplasia, revision surgery due to aseptic loosening of the acetabular component is more common. The outcome of cemented THA for osteoarthritis secondary to dysplasia may be less reliable (survival rate of 78% at 20 years for all revisions [5]; 75% at 15 years for loosening [9]), thus new challenges have been expected. From our long-term results, the survival rate was 91.2% at 17 years. We found loosening in two acetabular components without the need for revision surgery during the followup time. We found no loosening in the femur. These superior results we attributed to the effects of interposed HA granules.

The cement–bone interface is considered one of the weak points of cemented THA. To augment that interface, we applied a new cementing technique to achieve an enduring physicochemical bond at the cement–bone interface by interposing HA granules. This technique covers the bone cement with HA granules at the interface, producing a custom-made HA-coated cemented implant. Because the HA used for cementless HA-coated prostheses contains amorphous HA in part [26], this type of HA is absorbed in the years following surgery [7]. In contrast, the HA granules in our technique are pure crystal and were scarcely absorbed [4, 25], suggesting the osteoconductive activity can continue indefinitely even after the onset of osteoporosis due to aging.

In THA with the interface bioactive bone cement technique, radiolucent lines can be observed as spaces at the cement–HA layer interface, not at the HA layer–bone interface, on plain radiographs. Histologic studies of retrieved specimens suggest most HA granules are incorporated into remodeled trabeculae and a highly convoluted cement–bone interface is maintained for the long term [18]. From these findings, we consider the HA layer–bone interface stronger biomechanically than the cement–HA layer interface. Thus we presume the low incidence of radiolucent lines and the separation at the cement–HA layer interface are due to the effects of HA granules.

We tried to use smaller HA granules because they seemed easier to surgically implant. However, smaller granules sink more easily into the blood. Blood interposed and made a space between the HA granules and cement, thus preventing bonding between the cement and HA layer. In contrast, larger granules can jut out from accumulated blood and do not create a space between the HA granules and the cement. A larger granule is more likely to bond to both cement and bone. Thus, the use of smaller granules may have been the reason the incidence of radiolucent lines was substantially higher in the second generation.

We acknowledge three concerns when using HA granules at the bone–cement interface: loss of interdigitation of cement, third-body wear, and stress shielding. For cement fixation, the strength of the cement–bone interface depends on the physical properties of the opposing surfaces, the contact area, and the extent of penetration of cement into bony trabeculae [11]. In the interface bioactive bone cement technique, HA granules fill up the porosity of bony trabeculae and prevent cement penetration following loss of interdigitation of cement. Consequently, we recommend making small anchor holes in the acetabulum for initial fixation.

When using HA in THA, inflammatory reactions due to fragmented HA and the risks of third-body wear are concerns. Histologically, we confirmed negligible foreign body reactions in retrieved specimens over 10 years postoperatively [18]. Another study reported the wear rate using an alumina head with the interface bioactive bone cement technique in 111 hips [21]. The linear wear rate depended on the thickness of the polyethylene. These rates were 0.14 mm, 0.15 mm, 0.12 mm, 0.06 mm, and 0.08 mm per year with polyethylene thicknesses of 7 mm, 8 mm, 9 mm, 10 mm, and 11 mm, respectively. There were no untoward clinical complications attributed to the use of HA granules.

The long-term clinical results indicate the interface bioactive bone cement technique results in low incidences of radiolucent lines and osteolysis; thus, longevity of the cemented THA may increase using this technique. We believe the primary long-term problems are osteoporosis due to aging and osteolysis related to implant wear.

Because the bioactivity of crystal HA continues for a long time, the effects of interposed HA granules may have an affect on the occurrence of osteoporosis and osteolysis.

Acknowledgments We thank Dr. Yuichi Doiguchi for radiographic measurements.

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