

Hydroxyapatite-Coated Proximal Ingrowth Femoral Stems

A Matched Pair Control Study

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A matched pair study of 2 groups of 42 uncemented total hip replacements were compared retrospectively after a minimum 3-year followup. Forty-two hips were implanted with a hydroxyapatite coating on the proximal femoral patched porous surfaces; 42 hips had patched porous-coated stems without hydroxyapatite. There were no clinical differences between the matched groups by any criteria of measurement. There was no statistically significant difference between the matched groups for femoral stem fixation at all followup intervals. At the 3-year followup, 90% of the femoral stems in the hydroxyapatite porous group, and 83% in the porous control group achieved stable bony fixation. Hydroxyapatite-coated femoral stems demonstrated accelerated bone remodeling characterized by proximal cancellous hypertrophy. The percentage of femoral stems exhibiting cancellous hypertrophy was significantly greater at all followup intervals. This study did not demonstrate any clinical advan-

tage of hydroxyapatite being added to a porous-coated surface. The radiographic changes of bone remodeling seen with hydroxyapatite are not known to improve durability of the hip arthroplasty. This study again condemns the use of patched porous-coating and titanium-bearing surfaces.

The initial success with cemented total hip arthroplasties has led to expanded indications for this technique to younger and more functionally active patients with advanced coxarthrosis. Unfortunately, long-term studies with this age group of patients have proven disappointing.^{7,19,20,27,35} Dorr et al¹⁹ studied 81 cemented total hip arthroplasties in patients younger than 45 years old reviewed at 9- to 10-year followup, and there were 58% clinically satisfactory results with a revision rate of 33%. At an average 16-year followup, 67% of this group of hips were revised.¹⁸ These results were supported by Mittelmeier and Heisel,³⁵ who reported a 66% failure rate in patients 20 to 40 years of age at the 15-year followup.³⁵

The development and clinical use of porous-coated joint implants occurred because of poorer results in young active patients and the appearance of osteolysis. First-generation porous-coated hip replacements have demonstrated encouraging results at 3 to 7 years.^{5,22,23,36} The early experience with

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bony ingrowth systems reveals major concerns regarding the consistency of achieving bony ingrowth into porous implants because of variations of age, bone stock, concurrent medical illnesses, implant design, and surgical technique.^{4,6,9,11,12,15,21,26,37} In an effort to improve the rate and quantity of biologic fixation of uncemented total hip systems, orthopaedic researchers have examined the use of an adjuvant surface coating of hydroxyapatite on femoral and acetabular implants.^{13,31,32} Central to the rationale for the use of hydroxyapatite with total hip implantation is the concept that this substance is recognized as a friendly environment, and once coated onto a porous surface, osteogenic cells will readily attach to and proliferate on this surface.^{1,33} Hydroxyapatite has shown good ability to provide bone ingrowth fixation to implants in animal and clinical dental use.^{14,24,30,39} D'Antonio et al¹⁶ have reported good short-term results with hip replacements using hydroxyapatite-coated textured hip stems. These experiments confirmed that the use of hydroxyapatite as an osteoconductive medium enhanced the rate of bone formation.

In an attempt to study the effect of hydroxyapatite on hip replacement surgery, the authors retrospectively compared the results of patients with hydroxyapatite porous-coated hip replacements with a matched group with porous-only hip replacements. Matched groups were used because there was no prospectively randomized study.

MATERIALS AND METHODS

From a pool of 230 patients, 2 groups of 42 each were matched to be compared. The study could not be done as a randomized prospective study because the hydroxyapatite porous-coated hips were implanted under the Food and Drug Administration control for an investigational device exemption. Patients were matched retrospectively, who had been observed in a prospective manner so that sequential data were available.

Forty-two cementless Anatomic Porous Replacement-I primary hips (Intermedics Orthopaedics, Austin, TX) were implanted with hydroxyapatite coating on the proximal porous surfaces. A control group of 42 hips was matched for age, gender, weight, diagnosis, Charnley activity class,⁸ bone quality type as described by Dorr et al,¹⁸ and surgical technique.¹⁰ Assurance was made that each matched pair had equivalent distal femoral stem filling of the canal. Patients with hydroxyapatite-coated total hip arthroplasties were matched 1 to 1 to control patients. Preestablished criteria for matching included patients of the same gender, bone type, activity level, and diagnosis. The match for age was within 5 years, and the match for weight was within 25 pounds. Within the Charnley activity class, there was 1 patient who was not matched directly (Charnley A matched to Charnley B). One patient with congenital dysplasia of the hip was matched to a patient with avascular necrosis; these single deviants for these patient matches were done because the patients were known to the investigators and were otherwise an excellent match. The demographic data of the 2 matched groups are presented in Table 1.

The Anatomic Porous Replacement-I primary hip was made of titanium alloy (Ti-6Al-4V) and

TABLE 1. Hydroxyapatite Porous Versus Porous Control Demographics

Parameter	Hydroxyapatite Porous	Porous
Gender	24 male 18 female	24 male 18 female
Age \pm SD (years)	55.0 \pm 11.4 Range, 23–73	56.5 \pm 11.7 Range, 22–71
Weight \pm SD (pounds)	177 \pm 39 Range, 124–275	175 \pm 39 Range, 120–272

SD = standard deviation.

had cancellous structured patched porous coating (CSTi Intermedics Orthopaedics, Austin, TX) proximally placed on the anterior, posterior, and medial surfaces. The porous surfaces were applied via a heat sintering process. There was a porous-coated collar and an anatomic posterior bow (Fig 1). All Anatomic Porous Replacement-I femoral heads in this study were made of titanium alloy. The pore size was 450 microns, and porosity was 55%. The pore size was increased to 750 microns on the hydroxyapatite-coated implants to accommodate the partial closure of pores that occurs when hydroxyapatite is sprayed onto the porous coating. The average pore size after application of the hydroxyapatite coating was $490 \mu\text{m} \pm 30 \mu\text{m}$. The average thickness of the hydroxyapatite coating was $55 \mu\text{m} \pm 5 \mu\text{m}$. Penetration of hydroxyapatite was throughout the porous coating down to and including the substrate of the metal stem. The application was by a plasma spray method developed by Calcitek, Inc (Carlsbad, CA). The hydroxyapatite coating was applied circumferentially around the metaphyseal region of the femoral component. The hydroxyapatite was removed from the nonporous-coated areas by using hydroxyapatite powder microblasted at the metal surface, leaving the coating only over the porous patches. The hydroxyapatite porous coating used on this implant has been analyzed chemically by the manufacturers (Intermedics Orthopaedics Inc, Austin, TX) and is reported to be 94% pure hydroxyapatite, with 6% nonhydroxyapatite phasic substances such as tricalcium phosphate. Hydroxyapatite crystallinity was 72%. Specific gravity was reported at 3.02, with a calcium to phosphate ratio of 1.75:1. Mate-

rials tested by the manufacturer showed that the hydroxyapatite bond to titanium-alloy substrate had a shear strength of 34 to 48 megapascals and a tensile strength of 45 to 48 megapascals.

The sockets for the porous control group were patched porous hemispheres with a cluster hole pattern. The hydroxyapatite porous cups had identical geometry but were fully porous coated. The hydroxyapatite coating was applied as described for the femur.

Patients were seen every 3 months for the first year, and then yearly thereafter. Clinical results were based on the Harris Hip Score.²⁸ Thigh pain was classified as clinically significant if the patient required medication or the use of a cane for the thigh pain. Radiographs were evaluated for evidence of fixation, bone remodeling, and osteolysis by a zonal interface analysis as developed by Gruen et al.²⁵ All radiographs were reviewed sequentially by 1 of the authors (TAG), blinded as to which patients received hydroxyapatite implants. A modified Engh scale for use in proximal ingrowth devices was used to grade radiographic fixation in each patient (Table 2).¹⁰ Acetabular fixation was evaluated radiographically by a modified classification of DeLee and Charnley¹⁷ (Table 3).³⁴

The statistical analyses for the results in this study were done as follows. The mean age and weight values were compared using the 2-tailed Student's t-test.³⁸ The gender and disease diagnosis of the 2 groups was compared using Chi-squared analysis.³⁸ Harris Hip Scores, whether compared as a whole or evaluated as separate components of pain and limp, were compared using the Wilcoxon Rank-Sum test.³⁸ A separate

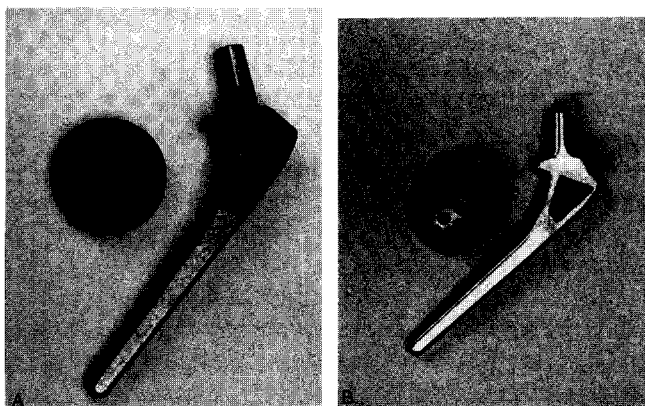


Fig 1A-B. Porous Coated Anatomic Porous Replacement-I primary hip stem and acetabular cup with (A) and without (B) hydroxyapatite coating.

TABLE 2. Modified Engh Skeletal Fixation Score for Femur

Fixation Grade	Radiolucency by Zone	
	Porous Surface	Smooth Surface
Bone ingrowth, stable IA	None	None, 1 or 2 zones
Bone ingrowth, stable IB	None	3 to 5 zones
Bone ingrowth, stable IC	None	All 6 zones
Fibrous ingrowth, stable II	Zone 7	All 6 zones, lines parallel prosthesis, no component migration
Fibrous ingrowth, unstable III	Zone 7	Variable, lines diverge from prosthesis or component migration

comparison test was performed for each followup interval. Osteolysis rates in the 2 groups were compared using Chi-squared analysis. Radiographic fixation scores were compared in a similar fashion using the Wilcoxon Rank-Sum test at each followup interval. An alpha level of 0.05 was used to indicate statistical significance in all tests described above ($p \leq 0.050$).

RESULTS

The 2 cohorts of patients were tightly matched with reference to all chosen study parameters (Table 4). In no category was the value <0.5 . In the categories of gender, bone type, diagnosis, and Charnley class, the 2 matched groups were nearly identical. The matched groups reflected active individuals with good femoral bone stock. The majority of patients were rated as Charnley functional Class A or B. In each group, 11 patients had Dorr Type A bone, and 29 patients Dorr Type B bone, indicating

good osteogenic potential for bone ingrowth.¹⁸

At the 3-year followup, the Harris Hip score averaged 95.1 points (range, 65–100 points) in the hydroxyapatite porous group and 95.8 points (range, 59–100 points) in the porous control group. There was no difference at any time in clinical results between the hydroxyapatite porous and porous groups. Hip scores when compared as matched cohorts were not statistically different at any followup interval. When evaluated separately by pain and limp, there was no statistically significant difference (Table 5). In the hydroxyapatite porous group, 35 patients had excellent results, 4 good, 1 fair, and 1 poor. In the porous-only group, 38 patients had excellent results, 3 good, 0 fair, and 1 poor.

The modified Engh radiographic fixation scores of the matched pairs also were compared at each followup interval. As with the

TABLE 3. Modified DeLee/Charnley Skeletal Fixation Score for Acetabulum

Fixation Grade	Radiolucency by Zone	
Bone ingrowth, stable	IA	None
	IB	One zone
	IC	Two zones
Fibrous ingrowth, stable	II	Complete RLL <2 mm all zones
Fibrous fixation, unstable	III	Progressive RLL zone III, complete RLL ≥ 2 mm all zones, or socket migration

RLL = radiolucent line.

TABLE 4. Statistical Comparison of Hydroxyapatite Porous Versus Porous Control

Variable	Probability Level	Method
Gender	1.00	Chi-squared
Bone type	1.00	Chi-squared
Charnley class	0.98	Chi-squared
Diagnosis	0.90	Chi-squared
Weight	0.78	Two-tail Student's t-test
Age	0.56	Two-tail Student's t-test

clinical results, femoral stem fixation was not statistically different between the matched groups. The comparison of the modified Engh fixation score shows a probability level (Wilcoxon Rank-Sum) at 6 months of 0.67, at 1 year 0.30, 2 years 0.29, and 3 years 0.32. In the hydroxyapatite porous group, 38 (90%) stems achieved bone ingrowth fixation (Grade IA, IB, or IC) at 3 years. In the porous control group, 35 (83%) femoral stems achieved fixation grades of IA, IB, or IC.

There was only 1 revision in the study, a hydroxyapatite porous femoral stem, for significant femoral osteolysis with resultant mechanical loosening. The mechanical fail-

ure rate, defined as revision or radiographic Type III fixation, was 5% in each group at the 3-year followup.

There was also no difference between the groups in the incidence of osteolysis. At the 3-year followup, osteolysis was observed around 7 (17%) femoral stems in each group. Acetabular osteolysis was not detected in either group. Proximal femoral osteolysis (Gruen Zones 1 and 7) was observed in 3 (7%) in the hydroxyapatite porous group and 2 (5%) in the porous control group. Distal femoral osteolysis (Gruen Zones 2-6) was noted in 4 (10%) hips in the hydroxyapatite porous group and 5 (12%) hips in the porous control group.

Patients with hydroxyapatite-coated femoral stems were noted to have increased bone remodeling characterized by proximal cancellous hypertrophy (Fig 2). Figure 3 compares the incidence of proximal bone remodeling detected on serial radiographic examinations. The percentage of femoral stems exhibiting cancellous hypertrophy was significantly greater at all followup intervals with hydroxyapatite-coated stems.

Patients with hydroxyapatite-coated acetabular components demonstrated significantly improved fixation over their porous control counterparts. Radiographic fixation scores were significantly better in the hydroxyapatite porous group at all followup intervals. The comparison of the modified DeLee-Charnley fixation scores favored hydroxyapatite porous fixation with a probability level (Wilcoxon Rank-Sum) of 0.002 at 6 months, 0.05 at 1 year, 0.007 at 2 years, and 0.002 at 3 years. At the 3-year followup, the

TABLE 5. Statistical Comparison of Function of Hydroxyapatite Porous Versus Porous Control

Parameter	Probability Value (Wilcoxon)
Pain	
6 months	0.27
1 year	0.95
2 years	0.45
3 years	0.26
Thigh pain	
6 months	0.80
1 year	0.44
2 years	0.23
3 years	0.40
Limp	
6 months	0.72
1 year	0.66
2 years	0.09
3 years	0.86

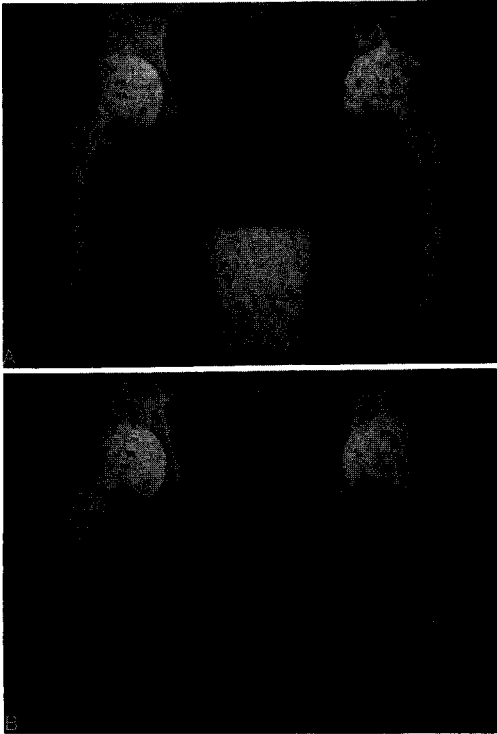


Fig 2A–B. (A) Example of cancellous hypertrophy around proximal femoral stem in a patient who received a hydroxyapatite porous Anatomic Porous Replacement-I total hip arthroplasty on the right side and a porous Anatomic Porous Replacement-I total hip replacement on left 1.5 years postoperative. (B) Radiograph of patient 1.5 years later. Compared with the left hip, the proximal cancellous bone around the right hip is more dense and is aligned along the lines of weight-bearing stress (arrows). This creates medial and lateral buttresses, the so-called buttress sign.

hydroxyapatite porous group had 39 (93%) cups with Grade IA fixation and 3 (7%) with Grade IB fixation. The porous control group had 26 (62%) hips with Grade IA fixation, 14 (33%) with Grade IB fixation, and 2 (5%) with Grade IC fixation.

DISCUSSION

These results do not demonstrate any clinical or radiographic value for the use of hydroxy-

apatite added to patched porous coating. This matched group study was controlled for the effects of age, gender, bone quality, activity level, weight, diagnosis, and surgical technique to allow for objective comparison.

A hydroxyapatite coating on a proximal third patched porous-coated femoral stem did not significantly alter clinical performance at 3 to 5 years. No significant differences were found with any clinical parameter measured. It should be noted that the 2 groups were relatively small and that differences may exist which were undetectable within this study. At the 3-year followup, overall hip scores demonstrated 95% good or excellent results in the hydroxyapatite porous group and 98% good or excellent results in the porous control group.

Hydroxyapatite coating did not deter osteolysis, nor did it increase the rate of osteolysis, as some critics feared. Bloebaum et al^{2,3} reported on the retrieval analysis of 14 hydroxyapatite-coated femoral implants of various designs and demonstrated the presence of hydroxyapatite particulate debris within periprosthetic soft tissue and polyethylene inserts of femoral stems revised for osteolysis. However, in stems that were well fixed with no osteolysis, hydroxyapatite particulate debris was not identified. This indicates that with mechanically loose femoral implants hydroxyapatite particles are released, whereas particles are not generated at a measurable rate in stable hips. Other data would support no increase of osteolysis caused by hydroxyapatite. A titanium-alloy femoral head that now is known to scratch and burnish easily may play a significant role in the incidence of osteolysis in a study group of relatively young, active patients. The authors no longer use titanium alloy as an articulating surface.

One advantage identified for hydroxyapatite coating is that bone remodeling is accelerated. The authors' data show that addition of the hydroxyapatite coating resulted in earlier appearance of cancellous hypertrophy on radiographs. This is in agreement with the Hofmann et al²⁹ study that confirmed the bidirectional closure of gaps between bone and

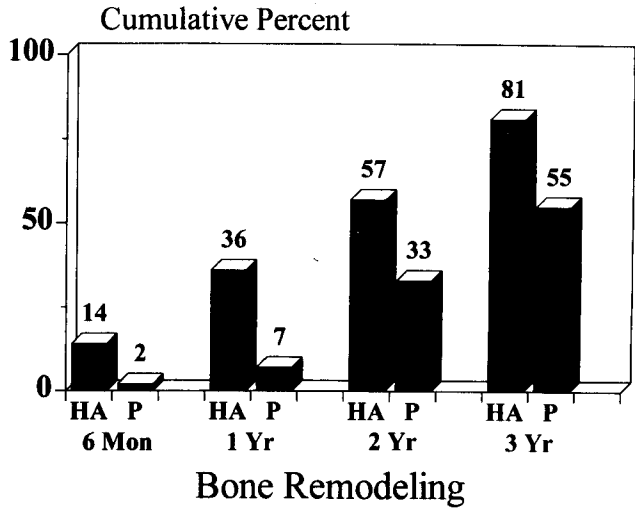


Fig 3. Incidence of bone remodeling hydroxyapatite porous versus porous control group. Bone remodeling occurs at earlier time intervals in the hydroxyapatite porous group. Bone remodeling is defined as the presence of cancellous hypertrophy in Gruen Zones I or VII, or both.

hydroxyapatite-coated substrate. Whether this will result in increased survival of the femoral stems is not known.

The incidence of femoral osteolysis (17% in each group) in this study further implicates the use of patched porous coating. This incidence of osteolysis is 10 times higher than in a circumferentially coated Anatomic Porous Replacement-I stem. At the Combined Meeting of the Orthopedic Associations of the English Speaking World in Toronto, Canada, in June 1992, Friedman reported on the same Anatomic Porous Replacement-I stem used by the authors, but with a circumferentially hydroxyapatite-coated textured surface, and had an osteolysis rate of only 1.7% in a 3-year followup. The authors believe that the incidence of osteolysis would probably be less with a circumferentially coated stem as suggested by Galante and Jacobs.²³

The socket data in this study condemn the use of patched porous coating. Ninety-three percent of hydroxyapatite porous sockets had no radiolucent lines evident on radiographs, as compared with 62% of patched porous-only sockets. The porous-only sockets were patch porous coated, whereas the hydroxyapatite porous sockets were fully porous coated. Whether the hydroxyapatite porous group was improved because of be-

ing fully porous coated or because of the addition of hydroxyapatite cannot be determined.

In conclusion, this study does not demonstrate any clinical advantage to the use of hydroxyapatite porous over porous-only hip stems. Clinical hip scores, radiographic fixation scores, and incidence of osteolysis are nearly identical between 2 matched groups. More rapid bone remodeling may suggest better durability with hydroxyapatite-coated stems, but this cannot be proven. Most likely, the failure rate will be similar because the incidence of osteolysis is the same. Perhaps circumferential porous coating combined with the advantages of bone remodeling seen with hydroxyapatite will promote durability. Certainly this study again demonstrates the poor protection against osteolysis afforded by patched porous coating with or without hydroxyapatite. The use of titanium alloy as an articulating surface is not recommended because it burnishes and abrades easily, and certainly was a contributing factor in the high rate of osteolysis seen in this study.

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