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Hydroxyapatite-Coated Distal Femoral Replacements

Preliminary Results

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A custom-designed, hydroxyapatite-coated distal femoral replacement was developed and implanted in five individuals at the authors' hospital. The indications for this type of prosthesis were a multiply failed cemented endoprosthesis in two individuals; a revision of an infected, previously cemented endoprosthesis in another; a primary low-grade sarcoma in a fourth, and a stage III giant cell tumor in the final individual. Mean follow-up time was 3.3 years (range, 2.9-3.5 years). The functional results, based on the Musculoskeletal Tumor Society (MSTS) criteria, were excellent in one patient (20%) and good in four patients (80%). Musculoskeletal Tumor Society functional scores ranged from 25 to 35 (mean, 29.8). No patient had thigh pain. All the femoral components appeared well fixed on radiographic evaluation. These preliminary results indicate that a hydroxyapatite-coated distal femoral replacement may represent a viable alternative to a cemented endoprosthesis for aggressive benign lesions and low-grade sarcomas requiring resection. In

addition, it appears to be a viable solution for failed cemented endoprostheses in individuals who have survived their disease.

The most important goal of oncologic surgery is to cure the patient. Any surgical intervention that does not place curing the patient above other considerations is suboptimal. Before the significant improvements in neoadjuvant and adjuvant therapies for bone tumors in the last 20 years, even the most radical surgeries for high-grade bone sarcomas resulted in mortality rates approximating 80%.⁵

Since that time, however, as the multidisciplinary approach to the diagnosis and treatment of bone tumors has evolved, prognosis has significantly improved. Furthermore, many studies have shown that these lower rates of recurrence and improved rates of survival are not limited to those patients undergoing amputation, but also extend to those undergoing limb salvage operations performed by experienced tumor surgeons.^{9,11,14,17,26,36} As a result, more emphasis is now being placed on the various limb salvage options. Some centers even rely on two separate surgical teams: one to perform the surgical resection, and a second to perform the reconstruction.²⁴

As prognosis continues to improve, the

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demands placed on the salvaged limb increase. Because the vast majority of bone tumors occur in young patients, patients who are ultimately cured of their tumor will need to depend on their salvaged extremity for decades. Patients now live longer and more active lives than their predecessors of 20 years ago. The combination of these factors test the durability of limb salvage reconstruction.

In the last 20 years, the field of joint replacement has also changed rapidly. Cementless fixation has become more popular as the search for longer-lasting prostheses has continued. Hydroxyapatite (HA) has been used extensively, both experimentally and clinically, and has shown great promise.^{1,4,6,20,23,27,28,37,40}

At the authors' hospital, five patients underwent distal femoral replacement with a HA-coated femoral stem (all in 1989). This is a report of the early results.

MATERIALS AND METHODS

Since 1980, 145 distal femoral replacements have been implanted at the authors' hospital. Five patients have undergone distal femoral replacement with a HA-coated titanium alloy femoral stem with a Noiles rotating hinge knee mechanism and a cemented tibial component (Techmedica, Camarillo, California) (Fig. 1). All five HA-coated distal femoral replacements were implanted in 1989. The endoprosthesis stems were designed to conform to the anterior bow of the individual femur. The HA coating was circumferential over the distal three-fifths to two-thirds of the femoral stem, and was applied via a plasma spray (Bio-Interfaces, San Diego, California). The properties of the coating were reported to be $\geq 62\%$ crystallinity, $\geq 90\%$ HA of the crystalline phase, and a calcium/phosphate ratio of 1.67 ± 0.05 . Tensile strength was reported as $\geq 5,0$ psi and shear strength as $\geq 2,500$ psi. The segmental portion of the distal femoral replacement was matte finished.

Before insertion of the endoprostheses, the femoral canals were reamed sequentially, and then broached with custom-made broaches. The

final broach was sized to exactly match the custom endoprosthesis. In revision cases, the most proximal cement from the previous implant was removed via a trochanteric osteotomy.

In general, only patients with an excellent long-term prognosis and no need for adjuvant treatment were considered for implantation of the aforementioned prosthesis. This resulted in three main groups for consideration: those presenting with Stage 3 benign tumors necessitating wide resection, those with low-grade malignancies requiring no adjuvant treatment, and those who had a failed endoprosthesis and required no further adjuvant therapy. The specific indications in our five patients were: a multiply failed cemented endoprosthesis in two individuals; a revision of an infected, previously cemented endoprosthesis in another; a primary low-grade sarcoma in a fourth; and a stage III giant cell tumor in the final individual. The HA-coated prosthesis was the first distal femoral replacement for two of the patients (Cases 4 and 5), the second for another patient (Case 2), the third for a fourth patient (Case 3), and the fourth for the final patient (Case 1). The average age at initial presentation was 23.2 years (range, 17–35 years). Average age at the time of distal femoral replacement with HA-coated femoral stem was 26.8 years (range, 20–40 years). There were three women and two men (Table 1).

Results were evaluated by the Musculoskeletal Tumor Society (MSTS) functional evaluation scale for tumors about the knee.¹⁸ According to MSTS guidelines, an excellent overall rating requires an excellent rating in at least six of the seven categories (motion, pain, stability, deformity, strength, functional activity, and emotional acceptance). A good overall rating requires six ratings of good or better. A fair rating requires six ratings of fair or better. Finally, a poor overall rating results from a poor rating in at least two separate categories. In addition, a quantitative score is determined by totaling points from each of the seven categories based on five points for excellent, three for good, one for fair, and none for poor (for a maximum score of 35).

A musculoskeletal radiologist assessed both the first available postoperative radiographs and the most recent radiographs. Significant findings, including bone quality, quality of fixation, evidence of loosening, stress shielding, osteolysis,

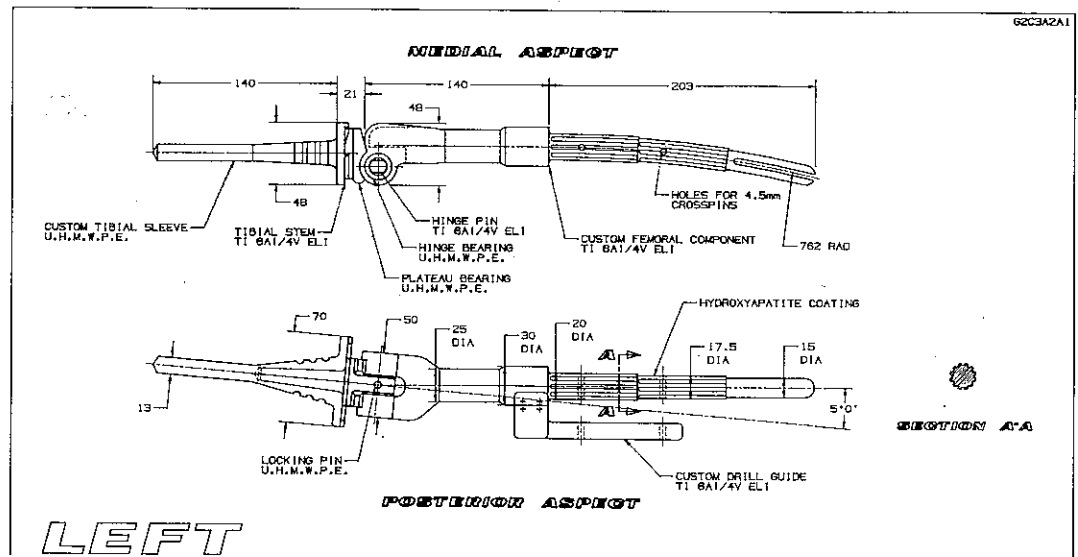


Fig. 1. Schematic of an HA-coated distal femoral replacement shows anteroposterior and lateral views of the entire prosthesis. The custom drill guide is removable. This prosthesis was used in Case 2. (Dimensions are in millimeters.)

evidence of infection or tumor recurrence, and any interval changes, were noted.

RESULTS

The five patients who underwent implantation of a HA-coated distal femoral replacement at this institution were observed for 2.9 to 3.5 years postoperatively (mean, 3.3 years).

A complication was seen in one of the five patients. This patient suffered minimally displaced patellar and proximal tibial fractures after falling on ice 7 months postoperatively. The fractures healed uneventfully in a cast, and the patient returned to her activities of daily living for the next 2.5 years, until the patient died. One additional patient had a reoperation 2 years postimplantation for a limited range of motion.

The most recent radiographs revealed a solid bone-prosthesis interface in all cases with no evidence of femoral loosening (Figs. 2A-2D). Three stems had evidence

of small amounts of stress shielding distally at the prosthesis-segmental replacement interface. Two of these three also had cortical hypertrophy at the most proximal site of HA coating on the stem (Figs. 3A and 3B). All patients had good preservation of bone stock. There was one case in which early tibial loosening was evident radiographically (though the patient remained asymptomatic).

The functional results according to the MSTs criteria are summarized in Table 1. All three patients who underwent revision distal femoral replacement merited a good rating, with scores ranging from 29 to 31 (mean, 29.7), while the two primary replacements resulted in one excellent rating (35 points) and one good rating (25 points).

Four patients remain alive and continuously disease free (CDF). The final patient died of unrelated causes 3.2 years after implantation, although she remained CDF through her last follow-up evaluation 2.9 years after implantation (and more than seven years since her initial diagnosis).

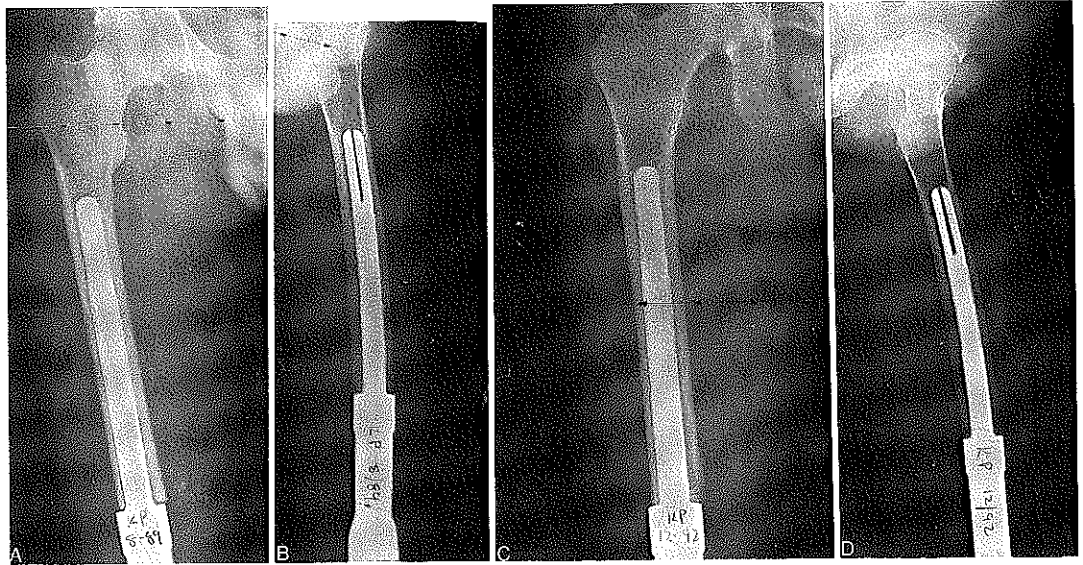
TABLE 1. Patients Who Underwent Hydroxyapatite-Coated Distal Femoral Replacements

Case	Primary Tumor	Gender, age at		Side	Indication for Operation	Previous DFRs	Tumor Recurrence**	Follow-Up Time (years)	MSTS Grade	MSTS Score	Radiographic Evaluation	Status
		Diagnosis (years)	Age at Surgery* (years)									
1	Low-grade osteogenic sarcoma	F, 35	40	L	Failed cemented DFR X 3	3	No	2.9	Good	29	Stable, no loosening	CDF until death UTD
2	Chondroblastoma	M, 15	20	L	Previously removed, infected, cemented DFR	1	No	3.3	Good	29	Radiographic tibial loosening, no femoral loosening	CDF
3	High-grade osteogenic sarcoma	F, 17	24	R	Failed cemented DFR X 2	2	No	3.5	Good	31	Stable, no loosening	CDF
4	Stage III giant cell tumor	M, 24	25	R	Stage III giant cell tumor	0	No	3.4	Excellent	35	Stable, no loosening	CDF
5	Low-grade osteogenic sarcoma	M, 25	25	R	Low-grade osteogenic sarcoma	0	No	3.3	Good	25	Stable, no loosening	CDF
MEAN								3.3		29.8		

CDF, continuously disease free; DFR, distal femoral replacement; UTD, unrelated to death.

* Implantation of hydroxyapatite-coated DFR.

** Tumor recurrence after implantation of HA-coated DFR.



Figs. 2A–2D. (A and B) Immediate postoperative films from Case 4. (C and D) Anteroposterior and lateral femoral radiographs in Case 4 obtained 3.3 years postoperatively demonstrate preservation of bone stock, good bone-implant interfaces, and no evidence of loosening.

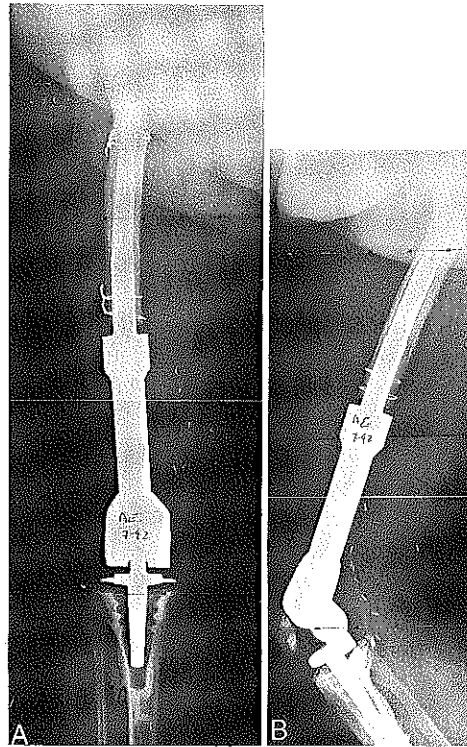
DISCUSSION

The rapid improvement in neoadjuvant and adjuvant therapy in the treatment of tumors in the last 20 years has resulted in vast improvements in overall survival and disease-free survival in patients undergoing limb salvage operations, as well as in those undergoing amputations.^{10,12,15,17,31,34,36} Most studies have shown that, with experienced oncologic surgeons, the rates of recurrence, disease-free survival, and overall survival are comparable for limb salvage surgery and amputation.^{9–11,14,17,26,34,36} Amputation, with its attendant physiologic, psychologic, and cosmetic shortcomings, has, therefore, been largely supplanted by limb salvage surgery.^{7,9,32} A poorly performed biopsy, however, may still require that an otherwise salvageable extremity be amputated.³⁰

The functional demands placed on the reconstructed lower extremity severely test the limits of surgical technique and technology. The results from the various types of reconstruction for tumors about

the knee (resection-arthrodesis, osteoarticular allografts, rotationplasty, and endoprosthetic replacement), rated on the MSTS functional rating scale, tend to be roughly equivalent, and clearly superior to amputation. However, these all have high complication rates (up to 50–60% or more), and the results remain far inferior to nontumor joint replacement operations, because of the more extensive surgery performed.^{2,7,9,11–14,16,19,24,26,29,33,42}

Endoprosthetic replacement is performed more commonly than any other limb salvage surgery at the authors' hospital, because of its better results at this institution.^{9–12,16,17,31,42} Five- to ten-year results were previously published.⁴² Although the early fixation is achieved by the bone cement, extracortical bridging, soft tissue scarring, or both may provide some late stability. Soft tissue scarring may also isolate the bone-cement interface from the joint fluid, its debris, and activated macrophages.⁴³ The quick rehabilitation of these patients allows even those patients with very short lifespans



Figs. 3A and 3B. Anteroposterior and lateral radiographs taken 3.5 years postoperatively in Case 3 show the entire extent of this revision prosthesis. Cortical hypertrophy at the most proximal extent of hydroxapatite coating, and mild stress shielding at the prosthesis-segmental replacement interface are evident.

to enjoy a significantly improved quality of life. However, anatomic factors (such as large patient size) can sometimes cause these prostheses to fail, as was seen in our Cases 1 and 3. The vast majority of distal femoral replacements that do fail tend to do so through aseptic loosening of the femoral component. Infection, although rare, can also cause failure, as was seen in our Case 2. The question of how to revise the failed cemented endoprosthesis and how to best treat low-grade tumors led to the insertion of five HA-coated distal femoral replacements at this institution.

Hydroxyapatite is a bioactive ceramic

that has been shown to be an osteoconductive (or osteophilic) material, both *in vivo* and *in vitro*.^{4,8,25,38,39,40} Extensive laboratory testing has revealed more rapid bony ingrowth, and improved early fixation of HA-coated prostheses.^{4,8,28,38,39,40} Retrieval studies also demonstrate early osseous integration of HA-coated femoral stems.^{1,23,37} Many authors have reported that the HA becomes chemically bonded to the host bone by apparently normal bone healing mechanisms.²⁸ Although long-term studies are not yet available, early reports of HA-coated total hip replacements reveal excellent clinical and radiographic results, including preservation of bone stock.^{6,8,20,40} Shinjo has even reported the reconstruction of a clavicular defect resulting from lymphoma with a composite of HA and autograft wrapped in Marlex mesh.³⁵

The criteria for consideration for a HA-coated distal femoral replacement at this institution are very strict. First, the patient must be expected to be a long-term survivor (such as a patient with a low-grade malignancy not requiring adjuvant treatment, or with a high-grade benign tumor which requires wide resection). Adjuvant therapy must not be considered for the patient, because this may interfere with the bone-HA interface. Those patients who have a failed distal femoral replacement are considered good candidates if they have survived their disease and require no further chemotherapy. Finally, the femur remaining after resection must be able to accommodate a fairly long femoral stem. These strict criteria have precluded the use of such a prosthesis in any patient at this institution other than the five patients herein reported.

The patients in our series fell into three groups. The first was comprised of two very large patients (one 5 ft 1 in tall and 240 lb, the other 6 ft tall with long femora with large canals) who had multiply failed cemented distal femoral replacements. The second group consisted of one patient: he had had a single distal femoral replacement

that failed because of infection. The third group consisted of two patients whose tumors did not require adjuvant treatment and who were treated primarily with HA-coated distal femoral prostheses.

In all cases, the femoral canals were reamed sequentially, followed by the use of custom-made femoral broaches. (The final broach used in each patient was sized to match the dimensions of the custom endoprosthesis made for that individual patient.) The prostheses were custom-made to recreate the anterior bow of the femur, thereby enhancing rotational stability.

The initial stability of such an endoprosthesis results from a mechanically tight fit in the canal, and this stability then allows for the microinterlock of the bone onto the prosthesis. Animal models have shown that a tight fit of the prosthesis in the canal is very important in the fixation of an uncemented prosthesis, and that HA-coating can, to some extent, overcome the disadvantage of an undersized stem.^{3,21,39} In addition, cadaver tests reveal that femora reamed to exactly the size of a proximal or distal femoral replacement stem experience more normal strain patterns than cemented stems, thereby theoretically reducing the deleterious effects of postoperative bone remodeling in the uncemented group.²⁴

The femoral components were mated to cemented tibial components via a rotating hinge knee. A rotating hinge-knee mechanism provides excellent stability and decreases stresses on the prosthesis and its fixation, thereby decreasing loosening rates.^{11,41}

Follow-up time was 2.9 to 3.5 years, and all patients had good to excellent MSTS functional results (with MSTS scores of 25–35 [mean, 29.8]) and resumed activities of daily living. All three revision cases (second, third, and fourth endoprostheses for one patient each) had good results and MSTS scores ranging from 29 to 31 (mean, 29.7), and the two primary cases resulted in one excellent result (35 points) and one

good result (25 points). The four surviving patients have remained CDF, and the patient who received her fourth endoprosthesis was CDF until death.

Radiographic evaluation showed stable implant fixation with no evidence of femoral loosening in any case. Three patients had radiographic evidence of small amounts of stress shielding distally at the bone-segmental replacement interface (implying some degree of stress transfer proximally to the bone-implant construct). Two of the three patients with the stress shielding also had hypertrophy at the level of the most proximal hydroxyapatite coating on the femoral stem. Good preservation of bone stock was noted in all cases. The only area of radiographic concern was the early evidence of tibial loosening seen in Case 2 at 3.3 years postoperatively (though this remains asymptomatic). As previously published, aseptic loosening of such a cemented tibial component is quite rare.⁴² Of note, this was a patient who had already undergone removal of a cemented distal femoral replacement and implantation of a cement spacer before implantation of the HA-coated distal femoral replacement.

Attractive features of this prosthesis are the preservation of bone stock, the apparently early and solid fixation, and the good function seen even in revision cases. Its early success in these selected patients is promising, and the HA-coated distal femoral replacement may represent a satisfactory long-term solution to the limb salvage quandary posed by the ever-increasing numbers of young, long-term survivors of bone tumors.

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