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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 3.5 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 endoprosthetics 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
demands placed on the salvaged limb in
crease. 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 fac-
tors test the durability of limb salvage re-
construction.

In the last 20 years, the field of joint re-
placement has also changed rapidly. Ce-
mentless 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 prom-
ise.1,4,6,20,23,27,28,37,40

At the authors' hospital, five patients un-
derwent 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 re-
placement with a HA-coated titanium alloy fem-
oral stem with a Noriles 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 ≥62% crystallinity, ≥90% HA
of the crystalline phase, and a calcium/phosphate
ratio of 1.67 ± 0.05. Tensile strength was re-
port as ≥5 psi and shear strength as ≥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 cus-
ton 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 pre-
senting with Stage 3 benign tumors necessitating
wide resection, those with low-grade malignan-
cies requiring no adjuvant treatment, and those
who had a failed endoprosthesis and required no
further adjuvant therapy. The specific indica-
tions in our five patients were: a multiply failed
cemented endoprosthesis in two individuals; a
revision of an infected, previously cemented en-
doprosthesis 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 replace-
ment 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 Musculoskele-
tal Tumor Society (MSTS) functional evaluation
scale for tumors about the knee.18 According to
MSTS guidelines, an excellent overall rating re-
quires an excellent rating in at least six of the
seven categories (motion, pain, stability, defor-
mity, 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 over-
all rating results from a poor rating in at least
two separate categories. In addition, a quantita-
tive 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, evi-
dence of loosening, stress shielding, osteolysis,
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>
<thead>
<tr>
<th>Case</th>
<th>Primary Tumor</th>
<th>Gender, age at Diagnosis (years)</th>
<th>Age at Surgery (years)</th>
<th>Side</th>
<th>Indication for Operation</th>
<th>Previous DFRs</th>
<th>Tumor Recurrence**</th>
<th>Follow-Up Time (years)</th>
<th>MSTS Grade</th>
<th>MSTS Score</th>
<th>Radiographic Evaluation</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low-grade osteogenic sarcoma</td>
<td>F, 26</td>
<td>40</td>
<td>L</td>
<td>Failed cemented DFR x 3</td>
<td>3</td>
<td>No</td>
<td>2.9</td>
<td>Good</td>
<td>29</td>
<td>Stable, no loosening</td>
<td>CDF until death UTD, CDF</td>
</tr>
<tr>
<td>2</td>
<td>Chondroblastoma</td>
<td>M, 16</td>
<td>20</td>
<td>L</td>
<td>Previously removed infected, cemented DFR</td>
<td>1</td>
<td>No</td>
<td>3.3</td>
<td>Good</td>
<td>29</td>
<td>Stable, no loosening</td>
<td>CDF</td>
</tr>
<tr>
<td>3</td>
<td>High-grade osteogenic sarcoma</td>
<td>F, 17</td>
<td>24</td>
<td>R</td>
<td>Failed cemented DFR x 2</td>
<td>2</td>
<td>No</td>
<td>3.5</td>
<td>Good</td>
<td>31</td>
<td>Stable, no loosening</td>
<td>CDF</td>
</tr>
<tr>
<td>4</td>
<td>Stage III giant cell tumor</td>
<td>M, 24</td>
<td>25</td>
<td>R</td>
<td>Stage III giant cell tumor</td>
<td>0</td>
<td>No</td>
<td>3.4</td>
<td>Excellent</td>
<td>35</td>
<td>Stable, no loosening</td>
<td>CDF</td>
</tr>
<tr>
<td>5</td>
<td>Low-grade osteogenic sarcoma</td>
<td>M, 25</td>
<td>25</td>
<td>R</td>
<td>Low-grade osteogenic sarcoma</td>
<td>0</td>
<td>No</td>
<td>3.3</td>
<td>Good</td>
<td>25</td>
<td>Stable, no loosening</td>
<td>CDF</td>
</tr>
</tbody>
</table>

**Mean**

<table>
<thead>
<tr>
<th>Gender, age at Diagnosis (years)</th>
<th>Age at Surgery (years)</th>
<th>Follow-Up Time (years)</th>
<th>MSTS Grade</th>
<th>MSTS Score</th>
<th>Radiographic Evaluation</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.3</td>
<td>20.8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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. 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. Amputation, with its attendant physiologic, psychologic, and cosmetic shortcomings, has, therefore, been largely supplanted by limb salvage surgery. A poorly performed biopsy, however, may still require that an otherwise salvageable extremity be amputated.

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.

Endoprosthetic replacement is performed more commonly than any other limb salvage surgery at the authors’ hospital, because of its better results at this institution. Five- to ten-year results were previously published. 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. The quick rehabilitation of these patients allows even those patients with very short lifespans...
that has been shown to be an osteoconductive (or osteophilic) material, both in vivo and in vitro.\textsuperscript{4,8,25,38,39,40} Extensive laboratory testing has revealed more rapid bony ingrowth, and improved early fixation of HA-coated prostheses.\textsuperscript{4,8,26,38,39,40} Retrieval studies also demonstrate early osseous integration of HA-coated femoral stems.\textsuperscript{1,23,27} Many authors have reported that the HA becomes chemically bonded to the host bone by apparently normal bone healing mechanisms.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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 prosthetic 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.\(^2\)\(^3\)\(^4\) 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.\(^2\)\(^4\)

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.\(^1\)\(^1\)

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.\(^2\) 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.

References


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