Short-Term Outcomes of Cementless Modular Endoprostheses in Lower Extremity Reconstruction

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ABSTRACT

Modular megaprostheses can be used to reconstruct large osseous defects. They have historically utilized polymethylmethacralate (PMMA) cement for fixation to host bone. Newer designs incorporating stems that utilize cementless bone-ingrowth technology have become available. We performed a retrospective review of all patients treated at our institutions who have undergone endoprosthetic reconstruction of the proximal femur, distal femur and proximal tibial utilizing cementless fixation. The primary outcome was considered to be loosening or reoperation. Thirty-eight cementless modular megaprostheses were implanted as a subset of endoprostheses used for reconstruction from 2002 through 2007. The decision to use cementless implants was made by the primary surgeon based upon patient age, diagnosis, prognosis, bone quality, and surgeon experience. 23 distal femur, 13 proximal tibia and 2 proximal femur prostheses were implanted. Kaplan Meier estimated implant survival was 88% at 4 years. Three patients developed loosening of their prosthesis that required revision. There were no periprosthetic fractures or cases of implant breakage in our study. We demonstrate good short-term outcome of cementless fixation for tumor endoprostheses with a relatively low complication rate that is similar to previously reported results of contemporary cemented implants.

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INTRODUCTION

Modular endoprosthesis can be used to reconstruct bone defects resulting from a tumor resection, a metastatic lesion, failed internal fixation or nonunion, or failed total hip or knee arthroplasty [9,11,23]. Other techniques available include osteoarticular allografts and allograft prosthetic composites, however long-term results with these techniques have been less predictable [4,13,18,22,29]. Most current prosthesis designs rely upon polymethylmethacralate bone cement for fixation to the host bone [7]. Early cementless designs had a high rate of failure related to stem breakage and loosening [6,12]. Newer cementless designs have become available and we have begun to use these stems in a select group of patients treated with modular endoprosthetic reconstruction.

Most implanted modular endoprostheses rely upon polymethylmethacralate cement for fixation [7]. The experience of the arthroplasty community with cemented femoral and tibial components has been positive, with very low revision rates [25]. The long-term durability of cemented modular endoprostheses has not been as reliable, with revision rates of up to 69% at 10-years [26]. The most common mode of failure leading to revision surgery is aseptic loosening, which has been reported to account for up to 44% of revisions of modular endoprostheses [2,3,5,8,26,28,30]. This high rate of failure, and aseptic loosening in particular, may be due to the unique demands of reconstructing large osseous defects. Aseptic loosening can be the result of macrophage mediated osteolysis stimulated by particular wear debris or of mechanical failure of the implant-bone interface [21]. In addition, the length of the prosthesis increases the mechanical stress borne by the bone-cement or bone-implant interface [27]. Implants with larger bone resections, and therefore longer implants, have been shown to have a higher rate of failure [17,27]. Other potential mechanisms of failure of modular endoprostheses include infection, periprosthetic fracture, and implant breakage [2,12]. In the case of proximal femoral replacement, hip dislocation and recurrent instability are unique modes of failure [20].

In an attempt to increase the strength of the implant-bone interface, and to create a more durable bond, cementless designs have become available. Cementless stems have the advantage of allowing bone-ingrowth and therefore a dynamic bond that can respond over time to the stresses placed upon it [16]. Bone ingrowth, however, is dependent upon numerous mechanical and biologic factors. While the experience of the arthroplasty community has been positive, the effects of radiation and chemotherapy as well as the unique problems associated with oncology patients upon bone ingrowth into cementless stems is poorly understood.

Early cementless stem designs have had a high failure rate related to stem breakage [6,12]. Osteolysis and aseptic loosening also led to failure in up to 27% of patients [19]. These results were based upon the use of stems designed and implanted during the 1980s. Newer designs have recently become available, and the short-term results of these contemporary prostheses have not been reported to our knowledge. At our institution we have used cementless stems in the reconstruction of large osseous defects of the lower extremity in 37 patients. The goal of our study is to define our short-term results with this technique.

MATERIALS AND METHODS

We performed a retrospective review of all consecutive patients who underwent endoprosthetic reconstruction of the proximal femur, distal femur and proximal tibial utilizing cementless fixation at our institution from January 2002 through December of 2007. Patients treated with modular endoprosthetic reconstruction were identified through use of our electronic orthopaedic oncology database as well as billing records. All patients treated with cementless fixation and modular endoprosthetic reconstruction of large osseous defects were included in the study. 37 patients were identified, no patients were excluded. Prior to the study, approval was obtained from our institution's Investigational Review Board (IRB).

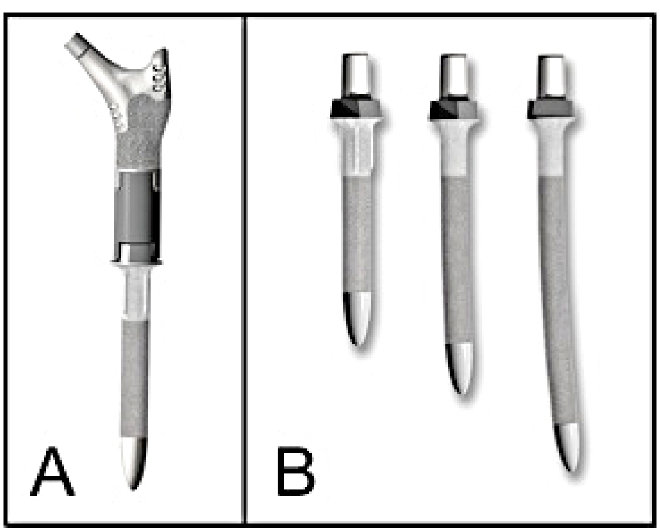

Figure 1. A. An example of a fully constructed modular proximal femoral endoprosthesis. B. Various options for the cementless stems. We have used the 127mm stems exclusively.

The population included in this study represents a portion of the total number of modular endoprosthesis used in the treatment of large osseous defects at our institution. Currently, we utilize both cemented and cementless prostheses as well as allografts and allograft prosthetic composites as part of our clinical practice. The decision to utilize a cementless modular megaprosthesis is made by the operating surgeon, is multifactorial, and includes patient age, perceived bone quality, diagnosis, prognosis, and the use of adjuvant therapies including radiation and chemotherapy.

In all cases the implants used were the Global Modular Replacement System (GMRS, Stryker, Kalamazoo, MI) (Fig. 1). Following resection of the tumor or removal of the previous failed implant, the diaphyseal canal was prepared. The bone end was cut perpendicular to its long axis, leaving a clean and even surface. In most instances a prophylactic circlarge wire was placed around the end of the bone to prevent fracture. The canal was then prepared by sequential reaming until good cortical chatter was obtained. A stem was then selected of the same diameter as the final reamer. In all cases the short straight stem (127mm) was used. A press-fit was then achieved by impacting the stem into the canal.

Data was gathered through review of the electronic and physical patient records and radiographs. All radiographs were interpreted by a single observer (MJW). Information regarding patient age, sex, diagnosis, previous surgery or reconstruction, type and location of implant, adjuvant therapy such as chemotherapy or radiation, post-operative complications and re-operations, loosening and implant failure were documented. Stage was assigned to malignant tumors based upon the Musculoskeletal Tumor Society (MSTS) staging system [10]. The Social Security Death Index (SSDI) was used to confirm mortality.

The primary outcome was considered to be implant failure; this was defined as failure leading to re-operation. Secondary outcome variables included loosening, patient survival and deep infection. Loosening was defined as implant subsidence or a contiguous radiolucent line on plain radiographs around the entire perimeter of the cementless stem. Deep infection included any infection that required operative debridement or any patient with positive cultures following joint aspiration.

Data was complied and statistical analysis was performed using Microsoft Excel (Microsoft, Redmond, WA) and Sigma Stat 3.5 (Systat, San Jose CA). Kaplan-Meier survival curves were constructed to demonstrate implant longevity and overall patient survival. The Fisher exact test was used to determine if history of a previous reconstructive surgery, perioperative chemotherapy, age, sex, diagnosis of malignancy, or anatomic location were associated with implant failure. Statistical significance was defined as a $p \leq 0.05$.

Median Age	38 (range 9-81)
Male Sex	70%
Right Side	54%
Malignant Tumor	31
Osteosarcoma	22
Chondrosarcoma	3
Other Primary Bone Sarcoma	4
Metasatic Carcinoma	2
Benign Tumor	3
Giant Cell Tumor of Bone	3
Failed Reconstructive Procedure	3
Failed Total Hip Arthroplasty	1
Failed Total Knee Arthroplasty	1
Tibial Nonuion Following ORIF	1

Table 1. Patient characteristics and principle surgical indications for endoprosthetic reconstruction.

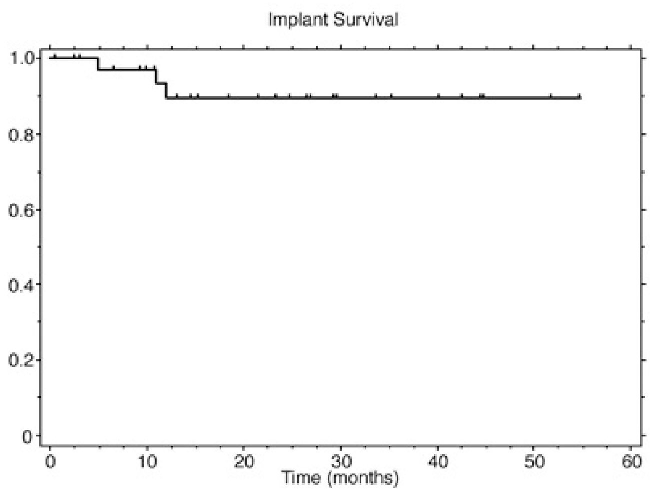

Figure 2. Kaplan-Meier plot demonstrating an estimated 89% 4-year implant survival

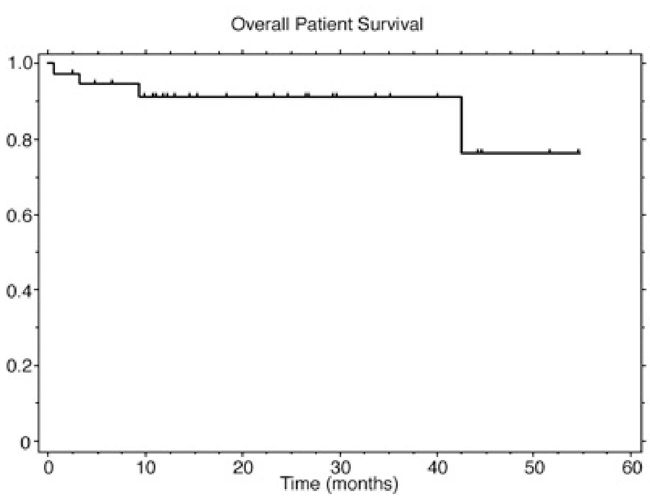

Figure 3. Kaplan-Meier plot demonstrating an estimated 78% 4-year overall patient survival.

Location of Prosthesis	37
Proximal Femur	2
Distal Femur	22
Proximal Tibia	12
Distal Femur and Proximal Tibia	1
Tibial Stem Diameters	
11mm	3
12mm	2
13mm	2
14mm	1
15mm	3
16mm	2
Femoral Stem Diameters	
11mm	2
12mm	3
13mm	6
14mm	5
15mm	4
16mm	3
17mm	1
18mm	1

Table 2. Anatomic location of prosthetic reconstruction and cementless stem sizes.

RESULTS

37 patients were implanted with 38 cementless modular endoprosthetic stems (Table 1). Mean follow-up was 23 months (+/- 15 months). One patient underwent reconstruction utilizing both distal femoral and proximal tibial components. Median patient age at the time of surgery was 38 (range 9-81). Seventy percent of patients were male. Eighty-four percent of patients underwent reconstruction following resection of a malignant tumor. Twenty-two distal femoral, 12 proximal tibial, 2 proximal femoral, and 1 combination of distal femur and proximal tibia stems were implanted (Table 2). Sixty five percent of patients underwent primary reconstruction following a tumor resection, while 45% had had a previous reconstructive procedure that was being revised for implant or allograft failure.

In the cohort of 37 patients there were 3 failures that required revision yielding a Kaplan Meier estimated implant survival of 89% at 4-years (Fig. 2). There were 2 cases of septic loosening and 1 case of failure of bone ingrowth that led to revision. There were no periprosthetic fractures, or direct implant failures or breakage in our series.

The Fisher exact test demonstrated that a previous reconstructive procedure ($p = 1.0$), male gender ($p = 0.21$), perioperative chemotherapy ($p = 1.0$), age greater than 37 ($p = 0.23$), diagnosis of a malignancy ($p = 1.0$), and anatomic location ($p = 1.0$) were not found to predict failure. Kaplan Meier estimated patient survival was 76% at 4-years (figure 3).

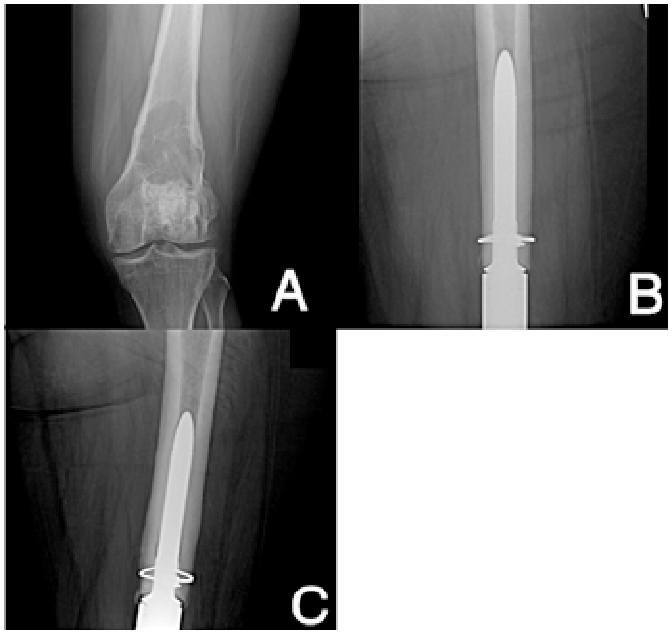

Figure 4. A. Initial radiographs reveal an aggressive appearing radiolucent mass of the left distal femur. Biopsy confirmed the diagnosis of osteosarcoma. B. Initial post-operative radiographs following resection of the distal femur and reconstruction with a distal femoral replacement fixed to the host bone with a cementless stem. A prophylactic circlage cable has been place around to cut end of the femur prior to stem impaction. The medullar canal of the femur is filled by the implant. C. At 3-years post-op, there has now been remodeling of the distal femur with hypertrophy of the cortical bone around the cementless stem. There is no radiographic evidence of loosening.

Figure 4 demonstrates the pre-operative and post-operative radiographs of a typical patient treated with a cementless modular megaprosthesis. This patient was a 45-year-old woman who presented with a high-grade, extracompartmental osteosarcoma of her left distal femur. Pre-operatively she received chemotherapy. The tumor was resected and a cementless stem and modular megaprosthesis were used to reconstruct her distal femur. Her post-operative course was uncomplicated. Initial radiographs revealed the components to be well seated and the cementless stem filling the medullary canal. Routine follow-up films at 3 years show the components to be well placed without signs of loosening. The diaphyseal bone appears to have remodeled and hypertrophied at the region of the bone implant interface. At 3-1/2 years she succumbed to metastatic disease.

DISCUSSION

The use of cemented and cementless stems both have a number of advantages and disadvantages. In the case of a cemented prosthesis, polymethylmethacralte (PMMA) bone cement is used to fix a smooth or fluted stem into the medullary canal of the host bone. The PMMA cement acts as a grout, conforming to imperfections on the surface of the implant and filling in the porous bone surface. The bone-cement and cement-implant bonds are formed immediately and there is no reliance upon bone growth, healing, or other biologic factors for implant fixation. However, the cement is inert and any micro-damage that occurs to the cement mantle may accumulate over time and can lead to loosening of the implant and eventual failure. When large bone defects are reconstructed, the implants used are often cemented into relatively smooth diaphyseal bone, which may result in a weak bone–cement interface [24]. Other potential mechanisms of failure include loosening from particle wear debris and osteolysis, infection, or periprosthetic fracture or stem breakage [2,8,30].

Cementless prostheses have a porous or grit blasted stem that is tightly impacted into the medullary canal of the host bone. Initial fixation is dependent upon friction between the implant and the bone. As the bone heals, it grows onto or into the interstices of the rough surface of the implant, creating a durable biologic bond between the prosthesis and the host bone [16]. As the prosthesis transmits loads through this interface to the host bone, any micro-damage that occurs to the bridging bone can be healed and remodeled. However, stable bone ingrowth is dependent upon numerous biological and mechanical variables. If bone ingrowth fails to occur, early loosening and failure can result. Similarly to cemented implants, cementless implants are also susceptible to osteolysis from particulate wear debris, infection and periprosthetic fracture [16].

While the experience with cementless fixation in the arthroplasty literature has been generally positive, the effects of adjuvant therapy on the biologic response of the host bone to cementless implants in sarcoma or cancer patients is unknown. Chemotherapy and radiation likely retard the healing process and may affect the overall strength and quality of the implant-bone interface. Our study was not designed to study the effect of chemotherapy and we have avoided using cementless stems in patients undergoing radiation treatment.

Zeegan et al. in a recent review of cemented modular megaprosthesis from one of our institutions, reported an 88% and 76% survivorship at 3 and 5-years, respectively [30]. The patients studied in this series were treated by the same operating surgeons as the cementless implants studied in this series and had similar outcomes. Similar results have been reported by numerous other authors, with a 3-year implant survival of 82-91% [1,14,15,17,26]. Our results with cementless prostheses are similar to these short-term results with cemented implants.

Earlier generations of cementless modular endoprosthesis had an unacceptably high failure rate due to implant breakage [12,19]. In our series there were no direct implant failures. This may reflect advances in component design, metallurgy, and manufacturing processes.

This study has a number of limitations. It is a small retrospective case series with a relatively short period of follow-up. However, it appears modular megaprostheses appear to have a promising role in the treatment of large osseous defects of the lower extremity and their use may be appropriate in a select group of patients.

The optimal patient population for treatment with both cemented and cementless stem fixation remains unclear. There is likely a subset of patients that may not benefit from the use of cementless implants. Further study and long-term findings may yield more information allowing specific recommendations to be made on which patient groups are most appropriate for cementless fixation.

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