



REVIEW

Endoprosthetic proximal femur replacement: Metastatic versus primary tumors[☆]

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Tumor

Abstract

Few studies have examined the impact of underlying diagnosis on the functional and oncologic outcomes following endoprosthetic proximal femur replacement (PFR). We performed a retrospective review of 61 consecutive cemented bipolar PFR in 59 patients for treatment neoplastic lesions with a minimum follow-up of 24 months. Twenty-two patients had primary bone tumors and 39 had metastatic disease. Average follow-up for the 30 surviving patients was 55.4 months and the mean postoperative survival for the 29 patients who died was 12.2 months. Patients with primary tumors demonstrated significantly better functional outcomes than those with metastatic disease, with mean Musculoskeletal Tumor Society functional scores of 80.2 and 66.8%, respectively ($p = 0.0002$). Age correlated inversely with functional scores ($r = -0.48$; $p = 0.0002$), while femoral resection length did not. Preoperative pathologic fracture did not appear to adversely impact final functional outcomes. The Kaplan–Meier 5-year implant survival estimate was 92.5%, with aseptic loosening as the endpoint. Both functional results and survival are increased for primary tumors versus metastatic disease following PFR. However, PFR results in excellent local disease control, reliable pain relief and good functional results in both groups, with prosthesis survival exceeding that of the patient in many cases.

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Introduction

The proximal femur is an exceptionally common location for primary malignant and benign aggressive tumors, and is the most common site in the appendicular skeleton for metastatic disease [1,2]. While many primary sarcomas may have historically required hindquarter amputation, limb salvage is now a viable option for local disease control in most patients [3,4]. Many destructive metastatic lesions can be managed with systemic treatments and radiotherapy in addition to internal fixation or intramedullary stabilization. However, unpredictable long-term survival in patients with metastatic disease [1,5,6] and reports of frequent construct failures in stabilized metastatic lesions [7–10] have caused persistent and increasing interest in more durable reconstructions.

Reconstructive options for proximal femur replacement (PFR) include osteoarticular allografts [11], radiated or autoclaved autografts with or without prosthetic composites [12], allograft–prosthesis composites [11,13–16], and segmental endoprosthetic reconstruction with custom [17–19] or modular [2,14,19,20–24] implants. Of these, the first two alternatives have not gained wide acceptance due to high failure rates and generally poor long-term functional outcomes [11,12]. Likewise, custom implants have largely been abandoned due to the decreased cost, increased availability, and intraoperative flexibility afforded by modular implants. Allograft–prosthetic composites (APC) offer theoretical advantages over megaprotheses in terms of bone stock restoration, tendon reattachment, and subsequent superior function. However, these advantages have been inconsistently realized in several studies and may come at the expense of increased complication rates due to infections, nonunions, and fractures [13–16]. With modern modular implants, endoprosthetic reconstruction has consistently demonstrated good implant longevity and acceptable, reproducible functional results [2,19–24]. The longevity of PFR also compares favorably with endoprosthetic reconstructions in other anatomic regions [18,23–27].

Though several prior studies have examined the results of endoprosthetic PFR for treatment of destructive tumors, few studies have analyzed the potential impact of diagnosis (metastatic disease versus primary tumor) [2,14], patient age, preoperative pathologic fracture, and femoral resection length [28] on functional outcomes. The purpose of this study is to report the oncologic and functional results of a consecutive series of patients treated with modular cemented bipolar PFR with particular attention to these issues.

Materials and methods

After obtaining Institutional Review Board approval, we performed a retrospective review of a consecutive series of patients who underwent limb salvage via proximal femur resection with endoprosthetic reconstruction for treatment of aggressive benign or malignant disease at two institutions between 1993 and 2003. The musculoskeletal oncology services at both institutions utilize similar techniques of resection and reconstruction. Inclusion criteria for this study included all patients who underwent segmental endoprosthetic reconstruction of the proximal femur for treatment of primary bone tumors or metastatic disease with actual or impending pathologic fracture. Patients treated with internal or intramedullary fixation with or without curetting of the lesion, amputation, or APC reconstruction were excluded.

Patient medical records were reviewed to determine patient demographics, diagnoses, indications for surgery, operative technique, femoral resection length, perioperative complications, and oncologic and functional outcomes. Functional outcomes were assessed utilizing the system adopted by the Musculoskeletal Tumor Society (MSTS) [29]. Then, each patient's peak postoperative score was reported and analyzed in an effort to mitigate against the deleterious effects on patient function and performance status of progressive disease (i.e., for the metastatic disease cohort). Subgroup analysis of MSTS scores was performed on the basis of patient age, femoral resection

length as measured from the tip of the greater trochanter, oncologic diagnosis (metastatic diseases versus primary tumor), and the presence or absence of preoperative pathologic fracture.

For the first 2 years postoperatively, primary bone tumor patients were evaluated with radiographs of the femur every 3 months. Computed tomography and radiographs of the chest were obtained at alternating 6-month intervals during this period. Surviving patients were evaluated semiannually for an additional 3 years and then annually thereafter for local recurrence or pulmonary metastases.

The resection criteria for metastatic disease included large destructive lesions (not amenable to or prone to failure following intramedullary or internal fixation with or without curetting), progressive lesions (despite optimal chemotherapy, bisphosphonate therapy, and/or radiotherapy) which were at risk for (or sustaining) pathologic fracture (Mirels [30] score ≥ 8) in patients with an estimated life expectancy of greater than 3–6 months. The presence of multiple metastases was not an absolute contraindication to the procedure.

Operative technique

All surgical procedures were performed or directly supervised by an attending surgeon fellowship-trained in musculoskeletal oncology. Prophylactic antibiotics (a first generation cephalosporin for nonallergic patients or vancomycin or clindamycin for allergic patients) were administered between 1 h and 20 min prior to incision. The antibiotics were continued for 48 h postoperatively or until the surgical drain was removed, whichever was later. Surgery was performed in the lateral decubitus position under general anesthesia.

A direct posterolateral approach was utilized and biopsy tracks, when present, were elliptically excised en bloc with the specimen. The femur was isolated and cut distally using an oscillating saw. The cut was made at least 2 cm from the distal portion of the lesion, as measured on coronal magnetic resonance (MRI) imaging from the tip of the greater trochanter. Cancellous bone was curetted from the medullary canal distal to the diaphyseal osteotomy and sent for intraoperative frozen section to confirm a negative margin. The greater trochanter was either preserved and osteotomized (if a safe tissue margin could be achieved) or resected with the specimen and the abductor tendon was transected distally and tagged for reattachment to the prosthesis. The femur was then dissected circumferentially with a cuff of normal muscle tissue for primary tumors; marginal resections were accepted for metastatic lesions. All resections were intraarticular. The hip capsule was released with a racquet-shaped incision extending longitudinally along the lateral aspect of the femoral neck proximally and wrapping circumferentially in the basicervical region, and the iliopsoas tendon was released. The resected specimen was measured on the back table to estimate the required replacement length and then sent for permanent pathology.

Gowns, gloves and instruments were changed between the resection and reconstruction portions of the procedure. In addition, new sterile cover drapes were placed on the operative field. All reconstructions were performed with

the Modular Segmental Replacement System (MSRS) endoprosthesis (Stryker Orthopaedics, Mahwah, NJ). Trial implants were employed prior to final implantation to assess for appropriate limb length and hip stability. All femoral stems were cemented utilizing modern techniques and fixed with a 1–2 mm polymethylmethacrylate cement mantle after reaming the host femur to 2 mm larger than the stem diameter. Stems were cemented in a position to correspond to approximately 20° of femoral neck anteversion. Bipolar articulating head segments were used in all patients and no primary resurfacing of the acetabulum was performed in this series.

The surgical wound was then irrigated thoroughly and the capsule was repaired using a purse-string stitch circumferentially around the prosthetic neck with 5-mm woven polyester tape (Mersilene, Ethicon, Inc., Somerville, NJ). Greater trochanter or abductor tendon repair was then performed directly to the prosthesis utilizing Mersilene tape and reinforced with number five braided nylon suture to the adjacent vastus lateralis and fascia. The iliopsoas tendon was not repaired in all patients, but when practicable it was secured directly to the prosthesis with Mersilene tape. The wound was closed in layers over one or two 10-mm closed suction drains and the skin incision was closed with staples. After application of a sterile dressing, an abduction pillow was placed and the patient was rolled to the supine position, extubated, and transferred to the recovery room.

Rehabilitation began on postoperative day number one with immediate weight bearing as tolerated with crutches or a walker. Patients were educated regarding dislocation precautions and continued ambulating with an assistance device until 6 weeks postoperatively. Then, abductor strengthening exercises were initiated and assistance devices were weaned as tolerated.

Statistical analysis

Statistical analysis was performed using SPSS v.15.0 (SPSS Inc., Chicago, IL). Descriptive statistics were performed for all groups. Potential correlations between variables were analyzed using Pearson product moment correlation analysis. Differences between groups of continuous variables were analyzed utilizing Student's *t*-test, and multivariate analysis was performed utilizing multiple linear regression. Patient and implant survivorship were assessed using the Kaplan–Meier method, with differences in survival assessed via the Log Rank (Mantel–Cox) test. By convention, differences were considered statistically significant for an alpha value of $p < 0.05$.

Results

Demographic information

Our review identified 59 consecutive patients with 61 PFR's who satisfied the inclusion and exclusion criteria. Thirty-three patients were male and 26 were female. The mean age was 58 years (range, 10–88). The indication for surgery was primary malignancy of bone in 21 patients, metastatic disease in 37 patients (39 PFR), and aggressive benign disease

in one patient. All patients were followed for a minimum of 2 years postoperatively unless death supervened.

Follow-up and oncologic outcomes

Twenty-nine patients died at a mean of 12.2 months after PFR (range, 2–34 months). Twenty-four patients died of malignant disease and five patients died of nononcologic etiologies. The average follow-up was 55.4 months (range, 24–152 months) for the 30 surviving patients (Table 1). Eighteen patients (16 with metastatic disease and two with primary bone malignancies) presented with pathologic fractures. No patient sustained a local recurrence of disease or required additional limb salvage surgery or amputation within the follow-up period, for a limb salvage rate of 100%. The Kaplan–Meier 5-year overall patient survivorship estimate was 71.4% (95% confidence interval (CI), 47.7–87.8%) for primary malignancies and 38.5% (95% CI, 23.8–55.3%) for metastatic disease ($p = 0.01$; Fig. 1).

Functional outcomes

Overall, the mean MSTS functional score was 71.7% (range, 43.3–93.3%). Specifically, the mean MSTS scores were 80.2% for primary tumors and 66.8% for metastatic disease. The difference between the groups was statistically significant ($p = 0.0002$). The mean MSTS score for patients with metastatic disease and preoperative pathologic fractures was 66.0% versus 67.2% for those without fractures ($p = 0.78$). Only two patients with primary sarcomas presented with pathologic fracture and they were not included in this analysis to avoid introduction of bias due to the difference in outcomes detected between primary tumor and metastatic disease patients.

There was a statistically significant inverse correlation between age and the MSTS scores ($r = -0.48$; $p = 0.0002$). Also, there was a statistically significant difference in age by diagnosis, with means of 50.3 years (10–88) for primary tumors and 62.1 years (35–82) for metastatic disease ($p = 0.01$). Multiple linear regression analysis demonstrated that both increasing age ($p = 0.002$) and metastatic disease ($p = 0.004$) were statistically significant predictors of worse MSTS scores. Mean femoral resection length was 14.1 cm (range, 10–27 cm) and did not correlate significantly with MSTS score ($p = 0.87$).

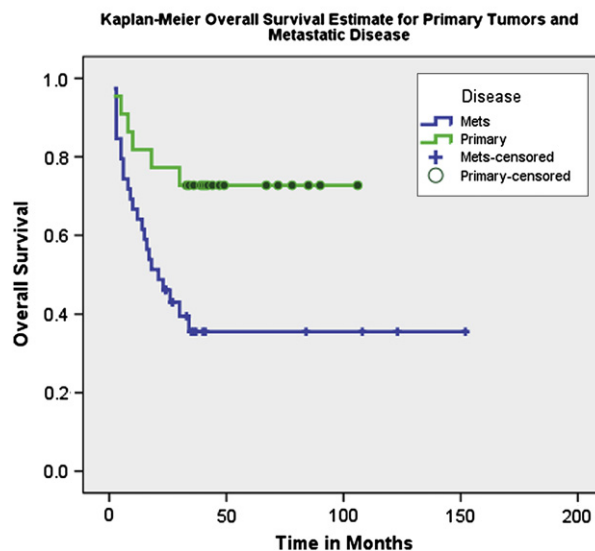


Figure 1 Kaplan–Meier overall patient survivorship estimate for primary versus metastatic tumors treated with proximal femur resection and cemented bipolar modular endoprosthetic reconstruction.

Complications and implant longevity

Six patients underwent reoperations during the follow-up period. Three implants (4.9%) developed deep postoperative infections (at 3 weeks, 5 weeks, and 7 months postoperatively, respectively) requiring irrigation, debridement, and intravenous antibiotics. All three of these prostheses were salvaged. Four implants (6.6%) dislocated in the follow-up period, one of which required open reduction. These patients were then managed with a period of abduction bracing and physical therapy without further dislocations. No implants were formally revised for chronic instability. Two implants were revised for aseptic loosening at 33 and 47 months postoperatively, respectively. The 5-year Kaplan–Meier implant survival with aseptic loosening as the end point was 92.5% (95% CI, 82.1–97.4%). Finally, one patient (1.6%) underwent acetabular resurfacing for symptomatic wear at 42 months postoperatively with retention of the femoral component. The 5-year Kaplan–Meier implant survivorship with reoperation for any reason as the end point was 79.2% (95% CI, 66.5–88.1%).

Table 1 Summary of key data for 61 endoprosthetic proximal femoral reconstructions in 59 patients

	PFR (n)	Age (years)	Pathologic fracture	Femoral resection length (cm)	MSTS score (%)	Survival (months) ^a	Follow-up (months) ^b
All patients	61	58.0 (10–88)	18	14.1 (10–27)	71.70 (43.3–93.3)	12.2 (2–34)	55.4 (24–152)
Primary tumor	22	50.3 (10–88) ^c	2	14.7 (10–27)	80.2 (53.3–93.3) ^c	12.2 (2–30)	56.8 (33–106)
Metastatic disease	39	62.1 (35–82)	16	13.1 (10–22)	66.80 (43.3–90.0)	12.2 (2–34)	54.3 (24–152)
Without pathologic fracture	23	63.1 (35–82)	—	12.6 (10–21)	66.00 (43.3–90.0)	14.3 (3–34)	74.9 (24–152)
With pathologic fracture	16	60.6 (46–77)	16	14.4 (10–22)	67.20 (46.7–86.7)	8.0 (2–30)	36.4 (24–84)

Data are presented as means (range). PFR, proximal femoral reconstructions; MSTS, Musculoskeletal Tumor Society.

^a Of deceased patients.

^b Of patients surviving at last follow-up.

^c Statistically significant difference, $p < 0.05$.

Two additional patients had limb length discrepancies of >1.5 cm which were managed nonoperatively. One patient experienced a superficial wound dehiscence which resolved with local wound care in the early postoperative period. There were no periprosthetic or implant fractures.

Discussion

Proximal femoral reconstruction implants were designed primarily to treat patients with primary bone tumors. Using these implants and other reconstructive, local, and systemic treatment modalities, limb salvage is feasible in most sarcoma patients with acceptable functional and oncologic outcomes [3,4]. The treatment of metastatic skeletal disease generally consists of systemic chemotherapy and bisphosphonates, supplemented with local external beam radiation therapy for symptomatic lesions. For progressive lesions limited to the femoral head and neck, conventional total hip (THA) or hemiarthroplasty has been utilized with favorable results [6,31]. Intramedullary or internal (plate and screw) fixation with or without curetting and cement supplementation has been the historical treatment of choice for peritrochanteric and diaphyseal lesions which progress despite these modalities and are at risk for pathologic fracture. Many patients are still candidates for these intralesional treatments, especially if the degree of bone destruction is not massive and the primary tumor is radiosensitive, permitting a reasonable expectation of poststabilization local control.

However, the outcomes of internally-stabilized metastatic lesions are often unfavorable, with radiographic union rates averaging only 35% [32], local recurrence rates as high as 48% [7], and construct failure rates ranging from 12 to 23% [7–10], with the latter reaching 44% in long-term survivors [10]. Furthermore, concerns exist regarding the iatrogenic spread of metastatic disease throughout the distal femur with intramedullary stabilization techniques [7,33]. Simultaneously, modern systemic treatments have led to an increasing number of long-term survivors with metastatic disease [2,7,24]. These considerations have compelled more aggressive operative measures to achieve local control and restore function in select patients with metastatic disease, although selection criteria remain controversial due to the guarded prognosis and substantial potential perioperative morbidity and mortality [15,34,35]. In the present series, the average survival of metastatic disease patients succumbing to disease was only 11.2 months (range, 2–34 months), but no patient died of perioperative complications and 12 patients (13 PFR) had long-term survival ranging from 24–152 months.

Once the decision to attempt resection and perform PFR has been reached in either a metastatic disease or primary tumor patient, the next critical step is to choose the optimal reconstruction technique for the individual. The most common alternatives for this are APC and endoprosthetic PFR. Advantages of the APC technique include bone stock restoration, more direct “biologic” tendon reattachment, and putatively improved implant stability and function. Results with this technique have been mixed, with generally increased complication rates [11,13–16,35] but comparatively improved abductor function [14–16]

when compared to megaprosthesis cohorts or historical controls. Two studies reported trends toward improved MSTS functional scores with APC [14,16], while McGovern and associates [15] reported disappointing overall functional results for APC without an internal endoprosthetic control group. We believe that APC do have a role in proximal femoral reconstructions, particularly in younger, primary tumor patients with a more favorable prognosis in whom the greater trochanter and iliopsoas can be preserved.

In contrast, endoprosthetic PFR affords reliable functional results while avoiding the risks of nonunion, allograft greater trochanter or body fracture, and the relatively higher incidence of postoperative infection seen following APC reconstructions. Prior studies of endoprosthetic PFR have reported relatively consistent MSTS functional scores ranging from 67.7 to 80% [2,14,16,21–23]. We found an overall mean MSTS score of 71.7%, with a significant difference in functional scores between patients with primary tumors (80.2%) and those with metastatic disease (66.8%; $p = 0.0002$). Metastatic disease patients were significantly older than primary tumor patients (mean age, 62.1 versus 50.3 years; $p = 0.01$), and age had a significant negative correlation with MSTS scores ($r = -0.48$; $p = 0.0002$). However, regression analysis demonstrated that both patient age ($p = 0.002$) and diagnosis ($p = 0.004$) were significant independent predictors of MSTS functional scores. Some of the apparent discrepancy in functional results in our series may be a reflection of the impact on general health and functional status of metastatic disease burden in potentially moribund patients. However, MSTS scores were analyzed from the patients' peak postoperative performance status and the average functional score amongst long-term survivors with metastatic disease was 76.4%. To our knowledge, only two prior studies of endoprosthetic PFR have compared MSTS scores between primary tumor and metastatic disease patients. Both of these studies demonstrated marginally higher scores in the primary tumor group and neither study found these differences to be statistically significant [2,14]. Also, the potential impact of patient age was not assessed in those studies.

We did not find a correlation between functional outcome and femoral resection length. In a series of 31 PFR, Morris and coauthors [28] reported no clear correlation between functional and radiographic results, including resection length. Additional prior studies have examined the relationship between resection length and implant longevity with variable results [18,24,36]. The low incidence of aseptic loosening in the present series did not allowed meaningful statistical analysis of any potential impact of femoral resection length on implant longevity.

An additional point of controversy in PFR is the longevity and stability of the hip articulation. Numerous oncologic series have demonstrated improved stability and decreased dislocation rates with bipolar hemiarthroplasty versus total hip reconstruction with acetabular resurfacing [27,39]. Dislocation rates ranged from 1.7–11.1% [2,8,14,19,21–23,28] for hemiarthroplasty and 6.5–22% [2,8,10,17,35] for THA. Bickels et al. [19] reported a dislocation rate of only 1.7% in 57 patients treated with hemiarthroplasty utilizing a similar meticulous capsular and abductor repair to our

series. Four patients (6.6%) dislocated in our series, with one of these requiring reoperation for open reduction but not revision of components. These two studies demonstrated that with modern surgical techniques and capsulotendinous reconstruction, hemiarthroplasties are therefore demonstrably more stable than THA.

Preservation versus resurfacing of the native acetabulum is also a controversial topic because of the potential metastatic disease progression that may involve the acetabulum, generate polyethylene wear and the development of prosthetic arthropathy in long-term survivors of PFR. Habermann et al. [37] suggested that as many as 83% of metastatic disease patients may have occult involvement of the acetabulum when biopsied. In spite of this, low rates of late clinical acetabular involvement have been reported and most authors still prefer hemiarthroplasty due to the aforementioned increase in joint stability [6,28,31]. Additionally, most patients with metastatic disease undergo postoperative radiotherapy to consolidate local therapy for disease control, which may further decrease the incidence of clinically relevant acetabular metastases.

The potential for late acetabular wear is an even more contentious issue. Although reported rates vary widely, revision to THA has been required in as many as 37% of hip fracture patients [38] and 25% of patients with osteonecrosis [39] treated with hemiarthroplasty. However, results of hemiarthroplasty for oncologic indications have generally been more favorable, with acetabular conversion rates ranging from 0 to 9.5% [21,22]. In a recent review of 447 hemiarthroplasties for tumor treatment, Cannon and coauthors [40] reported only seven (1.6%) conversions to THA, with only two conversions each for metastatic disease progression and groin pain secondary to acetabular wear, respectively. In their series, the mean amount of linear medial migration was only 2 mm, with proximal migration of 3 mm in patients with a minimum of 5-year follow-up. Furthermore, the introduction of an acetabular component increases potential device-related complications, as Menendez et al. [2] reported higher revision rates for THA versus bipolar hemiarthroplasties in PFR. Only one patient in our study required secondary acetabular resurfacing for symptomatic wear (1.6%). Although several authors have demonstrated that subsequent implant longevity and functional results are not necessarily compromised by reoperations and implant revisions [27,41,42], avoiding this is clearly desirable. We therefore advocate bipolar hemiarthroplasty in oncology patients for both improved stability as well as favorable native acetabular longevity with low revision rates.

Good results have been documented utilizing press-fit implants for PFR [28]. However, it is uncertain as to how adjunct radiotherapy affects bone ingrowth in these implants. In contrast, cemented implants decrease concerns regarding postoperative radiotherapy, reduce the risk of intraoperative fracture, and are immediately stable for unrestricted weight bearing postoperatively. Good, reproducible long-term results have been reported with cemented PFR, with 5- and 10-year implant survival consistently approaching or exceeding 80–90% with aseptic loosening as the end point [2,17–19,21,23,27]. These findings are consistent with our own, with Kaplan–Meier 5-year survivorship estimates of 92.5% for aseptic loosening and 79.2% for reoperation for any reason.

The incidence of other complications was acceptably low in the present series. We had three deep infections (4.9%), a rate that is consistent with that reported in other previous studies [2,14,19–23]. All of these prostheses were salvaged with debridement, irrigation, and intravenous antibiotics. No patient in our series developed local recurrence of disease and there were no periprosthetic or distal pathologic fractures due to falls or progression of metastatic disease. Two patients had limb length discrepancies greater than 1.5 cm, but neither required operative treatment.

Study limitations

The present series was a retrospective review and, although much of the data was prospectively recorded in our sarcoma database, is therefore susceptible to the same limitations and biases as all retrospective studies. Our current duration of follow-up is intermediate; all patients were followed for a minimum of 2 years unless death supervened, with the mean follow-up approaching 5 years. We do not doubt that both our implant and patient survivorship will further decline with longer follow-up. Nonetheless, this paper is a homogeneous, consecutive series of cemented, bipolar modular PFR for treatment of metastatic disease or primary tumors of bone. Additionally, it is among the largest series published to date on modular PFR [2,8,21].

Conclusion

Cemented bipolar modular proximal femoral replacement results in good hip stability and implant longevity for treatment of proximal femur tumors. As expected, functional results and patient survival are increased for primary tumors compared to metastatic disease. In spite of these differences, endoprosthetic reconstruction results in excellent local disease control, reliable pain relief and good functional results in surviving members of both groups, with the prosthesis frequently outlasting the patient.

Conflict of interest statement

Dr Temple is a paid consultant of Stryker. The other authors wish to report no additional real or potential conflicts of interest with regard to the present study, its performance, or its topic(s).

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