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Radiographic, Functional, and Oncologic Outcomes of Cemented Modular Proximal Femur Replacement Using the "French Paradox" Technique

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ABSTRACT

Background: Endoprostheses are frequently used in the management of tumors involving the proximal femur. Aseptic loosening is a common complication that has been linked to the cementing technique. The "French paradox" is well-known cementing technique in the arthroplasty literature. No previous reports have assessed loosening in proximal femur replacements using this technique. We examined rates of femoral stem aseptic loosening in proximal femur replacements, functional outcomes, complications, and oncologic outcomes.

Methods: We conducted a retrospective review of 47 patients who underwent proximal femur replacement between 2000 and 2019. Two reviewers evaluated preoperative and postoperative radiographs using the International Society of Limb Salvage scoring system and Barrack criteria for stem loosening. The acetabulum was evaluated according to the criteria of Baker et al. Functional outcomes were assessed using Musculoskeletal Tumor Society (MSTS) score and Toronto Extremity Salvage Score. The mean follow-up was 44 months.

Results: The mean International Society of Limb Salvage scores for the 2 reviewers were 86% ± 6% and 84% ± 6%. The first reviewer graded femoral stem loosening as "possibly loose" in 2 patients, one of whom was graded as possibly loose by the second reviewer. The 2 reviewers found no acetabular erosion in 16 (70%) and 15 (65.4%) patients, respectively. The mean Musculoskeletal Tumor Society score and Toronto Extremity Salvage Score at last follow-up were 61% and 72%, respectively. Twenty complications occurred in 13 patients, and 5 patients experienced local recurrence.

Conclusion: Despite complications, we showed favorable femoral component survival rates. Cementing the proximal femur prosthesis with tight canal fit and thin cement mantle is a viable option for the short and medium term.

Level of Evidence: III.

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The use of endoprostheses has become the standard following proximal femoral resection for aggressive metastatic and primary bone tumors [1]. Bone quality is a major concern in this population, however, because of the systemic and local effects of adjuvant therapy. Therefore, these implants are frequently cemented to achieve immediate stable fixation, without the need for bone ingrowth or healing, and to allow the patient to return to activity, with the expectation that the implant will outlast the patient [2]. Apart from bony neoplasms, these implants have been used as salvage for failed hip arthroplasty with significant bone loss secondary to loosening or infection with demonstrated satisfactory results [3].

Aseptic loosening at the bone-cement interface is a well-known complication of these implants and has been linked to bone quality, implant design, and cementing techniques. Although improvements in implant design and cementing techniques have substantially reduced the rate of aseptic loosening, this complication remains highly challenging, especially in the context of severe bone loss [2,4]. One cementing technique for the femoral stem in the arthroplasty literature is known as the "French paradox" [5,6]. This technique entails performing line-to-line reaming of the femoral canal and tightly fitting a large, smooth surface femoral stem of the same diameter as the last reamer placed into the femoral canal, achieving a stable configuration. The result is a thin, incomplete cement mantle that only fills the gaps between the implant and the endocortical bone [5,6]. It also allows insertion of the largest stem diameter that fits the medullary canal. Although this cementing technique is not commonly reported, aseptic loosening is infrequently reported following use of the French paradox cementing technique [2,7–9]. To our knowledge, however, no previous reports in the literature have assessed the incidence of aseptic loosening specifically in proximal femur replacements with use of the French paradox cementing technique. Thus, in the present report, we sought to examine (1) rates of femoral stem loosening in proximal femur replacements, (2) functional outcomes and complications, and (3) oncologic outcomes including local recurrence and implant survival.

Materials and Methods

A retrospective review of all patients who underwent proximal femur replacement between 2000 and 2019 at our institution was conducted after obtaining institutional ethics approval.

The inclusion criterion was a cemented proximal femur replacement for a primary or secondary tumor. Exclusion criteria were as follows: revision arthroplasty, lack of follow-up, or major pelvic reconstruction for pelvic tumors. Additionally, patients with follow-up less than 2 years were excluded from the radiographic and survival analyses. Medical records of identified patients were searched for patient demographics, diagnoses, use of adjuvant therapies, surgical treatment, complications, revision surgery, and local recurrence.

All patients had appropriate staging studies, including plain radiographs and magnetic resonance imaging scans of the pelvis and whole femur. Computed tomography scans were used as needed to identify the extent of acetabular involvement and to plan acetabular resurfacing. Further local and systemic staging studies were completed as deemed necessary by the operating surgeon.

Surgical Technique

All operations were performed by the 2 senior authors (R.T. and K.G.). Global Modular Replacement System implants (Stryker, Kalamazoo, MI) were used in all surgeries. A direct lateral approach was used in all cases. The proximal femoral muscular and capsular attachments were systematically detached 1 to 2 cm from the femur and the sciatic nerve was retracted and protected. For some cases the greater trochanter could not be preserved; otherwise, a trochanteric osteotomy was performed. The vastus lateralis was detached and reflected distally if feasible. The gluteus maximus was similarly detached from its proximal femur insertion and reflected posteriorly. The distal femoral segment was prepared by using successive straight canal reamers. Final reaming had to correspond to the 2-mm increment size of the available femoral stems. Canal reaming was stopped once adequate cortical contact was achieved and significant reaming products were obtained. The next size down face reamer (2 mm less) was used to accommodate the curved shoulder at the stem body interface. The trial stem used matched the size of the definitive stem and did not account for cement mantle thickness. Then, the trial components were assembled, and a trial reduction of the hip joint was attempted to ensure adequate anteversion, hip joint stability, and limb length. Following this, the canal was prepared and irrigated and a cement restrictor was inserted distally. The canal was dried carefully with a tampon sponge with a suction attachment but without adrenaline. Then, vacuum-mixed cement containing antibiotics (Simplex P, Stryker Orthopaedics, Mahwah, NJ) was inserted into the femoral canal, using a gun but without pressurization. Cement restrictor was not used if the femoral stem ends in the distal metaphysis or if we used long femoral stems.

The definitive components were implanted into the canal with proper alignment until the cement hardened. In some instances, long, curved femoral stems did not match the trial used because of the femoral bow; however, we implanted the tightest stem possible. Additionally, stem size <13 was avoided whenever possible to decrease the risk of stem fatigue fracture [10]. In our cohort, 31 patients (66%) had short straight stems (127 mm), and 16 patients (34%) had long bowed stems (203 mm). If the greater trochanter was preserved, it was reattached to the implant with cerclage cables and a claw plate (Dall-Miles, Stryker Orthopaedics). When possible, the hip capsule was tightened over the neck of the implant to imprison the bipolar head and improve joint stability. If the greater trochanter was involved, the abductor tendons were tenodesed to the fascia lata with the hip in abduction using heavy nonabsorbable sutures. No attempts were made to reconstruct the capsule with synthetic material. Additionally, no bone grafting was done over the porous surface of the implant because studies have not shown bone growth into the porous-coated shoulder of the implant [11]. Patients were allowed full weight-bearing immediately after surgery with the use of a cane or crutches and delayed hip abductor strengthening. Adjuvant radiotherapy and chemotherapy were administered as appropriate.

Radiographic Analysis

Plain radiographs were assessed blindly by 2 independent reviewers (A.N. and A.A.). The first available postoperative and most recent radiographs were carefully assessed in patients with minimum 2-year follow-up according to the guidelines proposed by the International Society of Limb Salvage (ISOLS) [12]. Six parameters were used: bone remodeling, interface, anchorage, implant body problem, implant articulation, and extracortical bone bridging. Additionally, the radiographs were examined for femoral stem loosening after being divided into "Gruen zones" [13] on both anteroposterior and lateral images on the basis of well-accepted criteria developed by Barrack et al [14]. Femoral stem loosening was graded as not loose, possibly loose (radiographic evidence of a radiolucent zone at the cement-bone interface between 50% and 100%), probably loose (continuous 100% lucent line around the cement mantle without evidence of migration), or definitely loose (migration of the cement or the implant). Furthermore, we assessed for acetabular erosion by using the criteria of Baker et al [15] as follows: (0) normal, (1) narrowing of articular cartilage without erosion, (2) acetabular bone erosion with early migration, and (3) protrusio acetabuli.

Functional Outcome

The Musculoskeletal Tumor Society (MSTS) score and the Toronto Extremity Salvage Score (TESS) were administered preoperatively and during follow-up postoperatively to assess functional outcome. The MSTS form uses 6 categories and was completed by

clinicians to evaluate function based on pain, upper extremity and lower extremity–specific function, and emotional acceptance [16]. The TESS is a validated measure developed to evaluate physical disability in patients treated with limb salvage surgery. It is a self-administered questionnaire that rates perceived difficulty in performing specified activities of daily life from the patient's perspective. The TESS includes items on activity limitations in daily life such as restrictions in body movement, mobility, self-care, and performance of daily tasks [17].

Complications

Overall complications were defined as the occurrence of an adverse event at any time point during the follow-up period and were reported as an event rate. We divided complications into intraoperative, local, and systemic complications. Intraoperative complications were recorded as neurovascular injury, iatrogenic fracture, massive blood loss (defined as > 2.5 L), and death. Systemic complications were defined as major adverse events occurring within 30 days of surgery including pneumonia, deep vein thrombosis, pulmonary embolism, cerebrovascular accident, fat embolism, and death. Local complications were defined as the rate of adverse events at the surgical site at any time postoperatively, including surgical site infection, wound dehiscence, implant failure, and dislocation. Local tumor recurrence was defined as clinical or radiographic evidence of disease recurrence at the surgical site.

Statistical Analysis

Descriptive analysis included demographics, tumor characteristics, operative characteristics, and complications. Independent *t*-test was conducted for continuous variables. Furthermore, in this cohort implant failure and death were determined to be competing events. A cumulative incidence estimator was used to determine the probability of each competing event, including the one of interest, the implant failure in patients with minimum 2-year follow-up. Gray's test was used to evaluate differences between patients diagnosed with sarcoma and metastasis in the presence of competing events. A *P* value of less than .05 was considered statistically significant.

Results

A total of 56 patients were identified and 47 met the criteria for inclusion and were included in the study. The excluded cases were 4 revision arthroplasty cases, 3 internal hemipelvectomies with major pelvic reconstruction, and 2 patients who had no follow-up after surgery. The mean age of the cohort was 59 ± 17 years (range, 15-89 years), and 59% of the patient population was male. Twenty-eight patients (59.6%) had metastatic tumors, 15 (31.9%) had primary bone tumors, and 4 (8.5%) had soft tissue sarcomas. The diagnoses of primary bone tumors were as follows: chondrosarcoma in 10 patients (67%), osteosarcoma in 2 patients (13%), Ewing sarcoma in 2 patients (13%), and postradiation sarcoma in 1 patient (7%). Pathologic fractures were present in 17 patients (36%). Two patients (4%) had prior total hip arthroplasty for hip osteoarthritis. Preoperative radiotherapy was used in 9 patients (19%), postoperative radiotherapy in 20 patients (42.5%), and combined preoperative and postoperative radiotherapy in 8 patients (17%). Neoadjuvant chemotherapy was used in 8 patients (17%) and adjuvant chemotherapy in 20 patients (43%). The mean clinical and radiographic follow-up was 44 months (range, 1-228 months). Sixteen patients (34%) had a follow-up time of more than 4 years.

A radiographic analysis for patients with a minimum 2-year follow-up (n = 23) demonstrated a mean ISOLS score of 86% ± 6% for the first reviewer compared to 84% ± 6% for the second reviewer. Using the criteria of Barrack et al, the first reviewer graded femoral stem loosening as possibly loose in 2 patients (8.6%), compared with 1 patient (4.3%) graded the same by the second reviewer. Both reviewers identified the same patient (Fig. 1A). Four patients had visible extracortical bridging in plain radiographs. No components were scored as probably or definitely loose. The patients graded as having possibly loose femoral stems were asymptomatic and had follow-up times of 3 and 4 years, respectively. Furthermore, the 2 reviewers found no acetabular erosion in 16 (70%) and 15 (65.4%) patients, respectively (Table 1). Only 1 patient (4.3%) was found to have protrusio acetabuli as a result of a pathologic fracture in his acetabulum 4 years postoperatively (Fig. 1B).

A total of 20 complications occurred in 13 patients (27.6%; Table 2). One patient had an intraoperative complication consisting of a femoral shaft fracture that was treated with 3 cerclage Dall-Miles cables. The 30-day rate of systemic complications was 13% (6/47), with 2 perioperative deaths at 2 and 4 weeks after surgery. Locally,

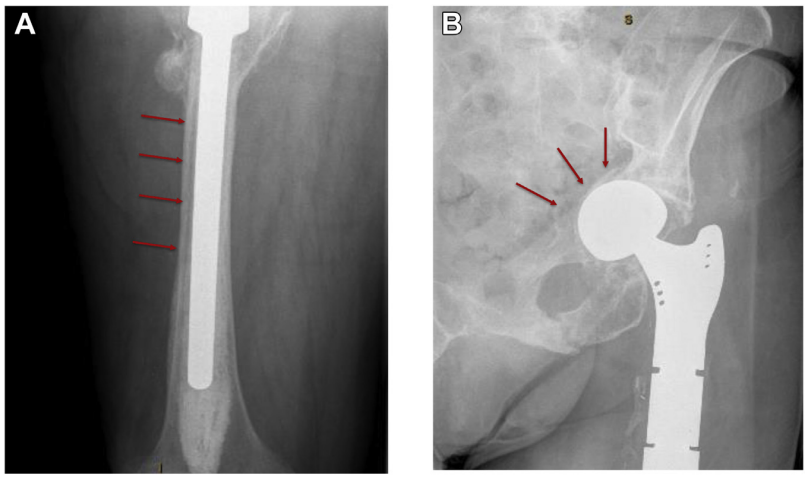

Fig. 1. (A) Radiographic evidence of radiolucent zone at the cement-bone interface between 50% and 100%. This implant was called possibly loose. (B) Protrusio acetabuli due to pathologic fracture in the acetabulum following bipolar head replacement at 4 years postoperatively.

Table 1
Acetabular Grading According to Barrack et al Criteria in Patients Who Had a Minimum Follow-Up of 2 Years (N = 23).

Grade	Reviewer 1	Reviewer 2
0	16 (70%)	15 (65.4%)
1	5 (21.4%)	6 (26%)
2	1 (4.3%)	1 (4.3%)
3	1 (4.3%)	1 (4.3%)

2 patients had deep infection (13%), and both required reoperation. One had a single-stage revision of the modular components of the implant augmented with antibiotic-loaded cement with multiple washouts, while the other underwent a 2-stage revision to a cementless implant for low-grade chronic infection that occurred 3 years following the primary surgery. Despite the latter case, no septic loosening was recorded. Hip dislocation was the most frequent local complication, with 9 dislocations in 4 patients (8.5%). Four dislocations occurred in 1 patient who had a prior acetabular replacement, whereas 5 dislocations occurred in 3 patients with bipolar heads. There were no amputations.

MSTS scores were available for 25 patients (50%). The mean MSTS score at last follow-up was 61% (range, 25%-88%) compared with 51% (range, 0%-94%) preoperatively ($P = .08$). The mean MSTS score at last follow-up for patients with primary bone tumors was 75% (range, 57%-88%) compared with 57% (range, 40%-82%) in the metastatic group ($P = .01$). On the other hand, the mean TESS at last follow-up was 72% (range, 16%-99%) compared with 55% (range, 8%-92%) preoperatively. TESS at last follow-up was comparable between the metastatic and the primary bone tumor patients (74% vs 79%, $P = .68$). Scores were available for 25 (53%) patients.

The overall competing risk estimates for mortality and revision for all causes at 5 years were 34.6% (95% confidence interval [CI], 18.8%-63.6%) and 8.4% (95% CI, 2.2%-31.9%) for patients with minimum 2-year follow-up (n = 23; Fig. 2). For patients diagnosed with metastasis, competing risk estimates for mortality and revision for all causes in patients with a minimum 2-year follow-up were 67% (95% CI, 43%-92.6%) and 7.7% (95% CI, 1.2%-50.6%) at 5 years. For patients diagnosed with sarcoma, these figures were 7% (95% CI, 1.1%-47.2%) and 9.3% (95% CI, 1.3%-68.8%; Fig. 3). The lower death risk of the patients diagnosed with sarcoma compared with the metastasis patients ($P = .004$) did not increase significantly the risk of revision ($P = .71$).

No implants required revision for either loosening or metal failure. A total of 23 (49%) patients died: 3 (13%) with metastatic disease, 1 (4.3%) with soft tissue sarcoma, and in 19 (82.6%) the precise reason and timing of death were unknown. These 19 patients were found to have advanced cancer at either their initial presentation or follow-up. Clinical and radiographic signs of recurrence were observed in 5 patients (10.6%). Of these, 3 were metastatic tumors and 2 were soft tissue sarcomas. None of these patients required reoperation for recurrence as they also displayed systemic disease and were treated with adjuvant therapy only.

Table 2
Local and Systemic Complications in Patients With Proximal Femur Replacement.

Complication	N (%)
Death	2 (4)
Intraoperative fracture	1 (2)
Pneumonia	1 (2)
PE	2 (4)
DVT	1 (2)
Deep SSI	2 (4)
Seroma	1 (2)
Hematoma	1 (2)
Dislocation	4 (8.5) patients had 9 dislocations

PE, pulmonary embolism; DVT, deep vein thrombosis; SSI, surgical site infection.

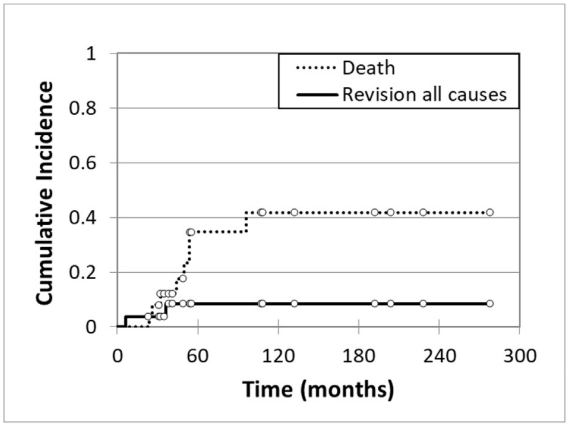

Fig. 2. Competing risk estimates for mortality and revision for all causes in patients with a minimum 2-year follow-up were 34.6% (95% CI, 18.8%-63.6%) and 8.4% (95% CI, 2.2%-31.9%) at 5 years. CI, confidence interval.

Discussion

With recent advances in medical treatment, cancer patients are surviving longer. The population of patients diagnosed with proximal femur tumors is diverse, and their oncologic survival, variable. Many survivors can expect to have very active lifestyles. Therefore, the focus of many researchers has shifted toward assessing functional outcomes and implant longevity [18–20]. While many have published research on the functional outcomes of proximal femur replacement, few have discussed implant longevity or loosening. A proposed mechanical limitation in a massive endoprosthesis is fixing a cylindrical stem into a canal made cylindrical, which theoretically leads to aseptic loosening [21]. In the French paradox cementing technique, the large stem inside the medullary canal may lead to a stable construct with a 3-point configuration of the implant within the bone, augmented by the thin, inconsistent cement mantle [22]. This technique has been shown to be effective in the primary arthroplasty literature [8]; however, its efficacy in

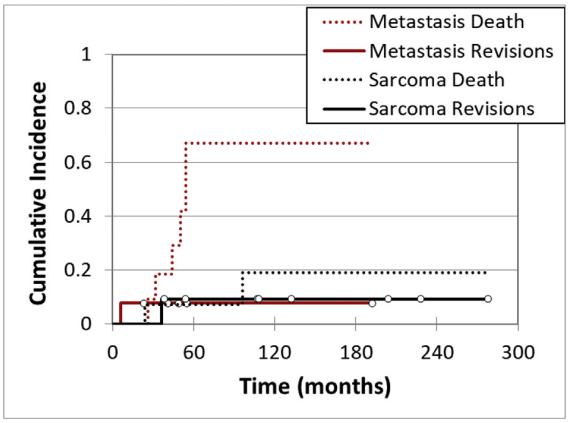

Fig. 3. For patients diagnosed with metastasis, competing risk estimates for mortality and revision for all causes in patients with a minimum 2-year follow-up were 67% (95% CI, 43%-92.6%) and 7.7% (95% CI, 1.2%-50.6%) at 5 years. For patients diagnosed with sarcoma, these figures were 7% (95% CI, 1.1%-47.2%) and 9.3% (1.3%-68.8%).

proximal femur replacement remains unknown. Theoretically, the inconsistent thin cement mantle provides a rough and irregular surface at the bone-implant interface that may limit the torsional movement of the implant inside the cylindrical medullary canal. In the present study, we aimed at assessing the rates of femoral stem loosening in proximal femur replacement and at assessing functional, clinical, and oncologic outcomes.

Good results have been documented for cementless endoprosthetic fixation, with implant survival rates ranging from 78.7% to 100% at 10 years [10,23]. However, bone ingrowth after radiotherapy and fatigue fractures of screws or stem remained a concern. Similarly reproducible results have been reported with the use of cemented implants, with survival approaching 80% to 90% at 10 years [1,24,25]. With the use of standard cementing techniques, aseptic loosening remains the most common indication for endoprosthetic revision, with reported rates reaching up to 11.2% [26]. In a radiographic study by Chandrasekar et al [27], 1 patient (2.7%) was found to have aseptic loosening according to ISOLS guidelines in a cohort of 37 patients with a minimum follow-up of 18 months. The same group reported their long-term follow-up results of over 25 years and documented a 49% rate of aseptic loosening with a median time to revision at 5 years from the index surgery [4]. In the present study, we performed an objective analysis using ISOLS scores and the Barrack et al criteria to evaluate the femoral stems. We reported only 1 or 2 patients to be "possibly loose" in patients with minimum 2-year follow-up; neither has required revision surgery.

Acetabular erosion has been a concern in patients undergoing bipolar hemiarthroplasty for non-neoplastic conditions and can lead to conversion to total hip arthroplasty in up to 36% of cases [28]. However, a recent randomized study by Bhandari et al [29] found no difference in secondary procedures, function, and quality of life in 718 patients assigned to total hip or hemiarthroplasty for displaced femoral neck fractures. In the cancer population, revision rates after bipolar proximal femur replacement are reported to range from 0% to 8% [26,30]. Age younger than 40 years and long follow-up (greater than 63 months) have been identified as risk factors for acetabular resurfacing [31]. In unipolar replacements, revision rates can reach up to 36%, especially in young patients (aged younger than 21 years) and patients with prolonged survival [32]. Similar to previous studies, we used the criteria of Baker et al to assess for acetabular erosion. We found 6 patients (26%) with narrowing of the joint, 1 patient (4%) with acetabular erosion, and 1 patient (4%) with protrusio acetabuli. None required revision for acetabular erosion.

Dislocation is a well-known complication of proximal femur replacement. Reported rates of dislocation can reach up to 16% in patients with acetabular resurfacing [33] and up to 7% in patients with unipolar or bipolar head replacement [10,34]. This is often caused by the wide resection of soft tissues around the hip, including the capsule and abductors. In line with the literature, we encountered 9 dislocations in 4 patients (8.5%). Several techniques have been suggested to reduce the rate of this complication. Some authors have suggested capsular reinforcement with a synthetic material, with a dislocation rate of up to 6% [35]. Others have suggested the use of a dual-mobility cup, with dislocation rates of up to 9.8% [31,36]. In this study, we did not reconstruct the capsule and the majority of cases were bipolar replacement. Our dislocation rate was relatively similar.

Regarding survival, a recent nationwide cohort reported a 5-year survival rate of 72% for primary bone tumors and 33% for metastatic disease [37]. In the present study, patients with primary bone tumors had significantly better survival than did the metastatic group (68% vs 17% at 10 years). However, this did not increase the risk of revision surgery. Regarding local recurrence, rates in the literature range from 4% to 28% [27]. In our study, 5 patients (10.6%) experienced local recurrence: 3 patients with metastatic disease (10.7% [3/28]) and 2 with soft tissue sarcoma (50% [2/4]). The average time to recurrence was 23 months in the metastatic group and 12 months in the soft tissue sarcoma group. These patients had systemic disease at the time of local recurrence, and it was decided to treat them with adjuvant therapy only.

We acknowledge several limitations to our study. First, the study was a retrospective review. Second, the study sample was small and heterogeneous. Third, the relatively short follow-up period was due to either death or lack of compliance to visit. This is a well-known but considerable study limitation and highlights the difficulty of studying the metastatic patient population. The surgical outcome is unknown in the group lost to follow-up and may lead us to overestimate the benefit of surgery, especially early in the postoperative course. It is possible that these patients represent the group with more aggressive biology and a higher disease burden who subsequently experienced worse outcomes. Many of our patients were referred to our supraregional cancer facility for their proximal femur disease but they received their oncologic treatment in other centers. They did not return for further follow-up for unknown reasons that may have included death, oncologic complications managed at local hospital, intensive adjuvant treatments, did not wish to travel, or other reasons. It is likely that we are underestimating the rates of complications in this cohort nevertheless, 49% of the patients had a follow-up longer than 2 years. Fourth, functional scores were available for only 25 patients (50%), again illustrating the difficulty of following these patients.

Conclusion

In summary, proximal femur replacement using the French paradox cementing technique provided good radiographic outcomes demonstrated favorable femoral component survival rates on the short and medium term. Acetabular erosion necessitating revision surgery in tumor patients is rare. Despite significant complications, these implants provide reasonable clinical and functional outcomes. Longer follow-up is required for further confirmation of these results.

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