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Proximal Femur Replacements for an Oncologic Indication Offer a Durable Endoprosthetic Reconstruction Option: A 40-year Experience

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Abstract

Background Proximal femur replacements (PFRs) are an effective surgical option to treat primary and metastatic tumors causing large bony defects in the proximal femur. Given the relative rarity of these indications, current studies on PFR for oncologic indications are generally limited by

patient volume or relatively short-term follow-up. Because recent advances in systemic therapy have improved the prognosis of patients who undergo limb salvage surgery for musculoskeletal tumors, data on the long-term durability of endoprosthetic reconstructions have become increasingly important.

Questions/purposes (1) How does the long-term survival of cemented bipolar PFRs compare with patient survival in patients who underwent PFR for benign, aggressive, and metastatic tumors? (2) What are common reasons for revisions of primary PFRs? (3) Which factors are associated with survival of primary PFRs? (4) What is the survivorship free from conversion of bipolar PFRs to THA?

Methods Between January 1, 1980, and December 31, 2020, we treated 812 patients with an endoprosthetic reconstruction for an oncologic indication. All patients who underwent a primary PFR for an oncologic indication were included in this study. The study cohort consisted of 122 patients receiving a primary PFR. Eighteen patients did not reach a censored endpoint such as death, revision, or amputation within 2 years. Thirty-three patients died within 2 years of their surgery. Of the 122 patients with primary PFRs, 39 did not reach a censored endpoint and have not been seen within the past 5 years. However, the mean follow-up time for these patients was longer than 10 years. The Social Security Death Index was queried to identify any patients who may have died but might not have been captured by our database. To allow for adequate follow-up, endoprosthetic reconstructions performed after December 31, 2020 were excluded. The mean age at the time of the index surgery was 48 ± 22 years. The mean follow-up time of surviving patients was 7 ± 8 years. All PFRs were

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
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performed using a bipolar hemiarthroplasty with a cemented stem, and all implants were considered comparable. Demographic, oncologic, procedural, and outcome data including prosthesis survival, patient survival, complication rates, and rates of conversion to THA were analyzed. Patient, prosthesis, and limb salvage survival rates were generated, with implant revision as the endpoint and death as a competing risk. Statistical significance was defined as $p < 0.05$.

Results Generally, patients with benign or low-grade (Stage I) disease outlived their implants (100% patient survival through 30 years; $p = 0.02$), whereas the opposite was true in patients with high-grade, localized Stage II disease (64% patient survival at 5 years [95% CI 49% to 76%]; $p = 0.001$) or widespread Stage III metastatic disease (6.2% patient survival at 5 years [95% CI 0.5% to 24%]; $p < 0.001$). Primary PFR implant survival at 5, 10, 20, and 30 years was 97% (95% CI 90% to 99%), 81% (95% CI 67% to 90%), 69% (95% CI 46% to 84%), and 51% (95% CI 24% to 73%), respectively. Eight percent (10 of 122) of primary PFRs were revised for any reason. The most common causes of revision were aseptic loosening (3% [four of 122]), infection (3% [three of 122]), breakage of the implant (2% [two of 122]), and tumor progression (1% [one of 122]). Follow-up time was the only factor that was associated with revision of primary PFRs. Neither segment length nor stem length were associated with revision of primary. Six percent (seven of 122) of PFRs were converted to THA at a mean 15 ± 8 years from the index procedure. Survivorship free from conversion to THA (accounting for death as a competing risk) was 94% (95% CI 85% to 99%), 86% (95% CI 68% to 94%), and 77% (95% CI 51% to 91%) at 10, 20, and 30 years, respectively.

Conclusion Cemented bipolar PFRs for an oncologic indication are a relatively durable reconstruction technique. Given the relative longevity and efficacy of PFRs demonstrated in our study, especially in patients with high-grade or metastatic disease where implant survival until all-cause revision was longer than patient survival, surgeons should continue to seriously consider PFRs in appropriate patients. The relative rarity of these reconstructions limits the number of patients in this study as well as in current research; thus, further multi-institutional collaborations are needed to provide the most accurate prognostic data for our patients.

Level of Evidence Level III, therapeutic study.

Introduction

With the development of multiagent chemotherapy protocols alongside advancements in imaging, endoprosthesis design, and surgical technique, implant survival for patients undergoing endoprosthetic reconstructions for an

oncologic indication continues to improve [2, 21, 27]. As a result, limb salvage surgery has largely replaced amputation to treat appendicular sarcoma while achieving comparable oncologic outcomes [1, 9, 11, 31]. The proximal femur is one of the most common sites of primary sarcomas and is the most common site of appendicular bony metastasis [3, 18, 24]. Although a variety of treatment modalities exist for tumors causing substantial bone defects in the proximal femur, reconstruction with endoprosthetic proximal femur replacement (PFR) has emerged as one of the preferred surgical treatments owing to implant modularity, off-the-shelf availability, and stability that allows for early weightbearing [7, 15, 18, 26, 38].

Despite its advantages, however, PFRs are associated with major complications, including instability, aseptic loosening, mechanical failure, periprosthetic fracture, and infection [6, 14, 15, 18, 24]. Because enhanced survivorship of oncologic patients challenges the durability of these endoprosthetic reconstructions, revision surgery is becoming increasingly common [39]. Given that a large proportion of patients who undergo PFR for neoplastic indications are relatively young, these patients are expected to live beyond the time when their implant would need a revision procedure while still enjoying an active lifestyle [40]. Understanding the durability of primary implants and identifying factors that contribute to a need for revision is therefore paramount. Current studies reporting on the survivorship of primary PFRs in the oncologic population are limited by patient volume or relatively short follow-up [4, 6, 15-17, 19, 24, 36, 37]. Furthermore, although current oncologic studies report low rates of conversion of bipolar PFR to THA, interest in acetabular wear has prompted debate regarding the use of THA over hemiarthroplasty in the primary setting in young, active patients [16, 18, 24, 25, 35, 37].

We asked: (1) How does the long-term survival of cemented bipolar PFRs compare with patient survival in patients who underwent PFR for benign, aggressive, and metastatic tumors? (2) What are common reasons for revisions of primary PFRs? (3) Which factors are associated with survival of primary PFRs? (4) What is the survivorship free from conversion of bipolar PFRs to THA?

Patients and Methods

Study Design and Setting

We performed a retrospective study of our institution's endoprosthesis database. This collected database contains demographic, oncologic, procedural, and outcome data on 812 endoprosthetic reconstructions performed for an oncologic indication at our institution from January 1, 1980,

until December 31, 2020. We did this to provide an expanded cohort and longer-term follow-up after a prior publication from our institution [4].

Patients

All patients who underwent a primary PFR for an oncologic indication were included in this study. The study cohort consisted of 122 patients receiving a primary PFR. Of those, 15% (18 of 122) of patients did not reach a censored endpoint such as death, revision, or amputation within 2 years. Thirty-three patients died within 2 years of their surgery. Of the 122 patients with primary PFRs, 39 did not reach a censored endpoint and have not been seen within the past 5 years. However, the mean follow-up time for these patients was longer than 10 years. The Social Security Death Index was queried to identify any patients who may have died but might not have been captured by our database [32]. To allow for adequate follow-up time, procedures performed after December 31, 2020, were excluded.

Descriptive Data

The study cohort was 53% (65 of 122) female and 47% (57 of 122) male. The most common diagnoses were metastatic disease (22% [27 of 122]), chondrosarcoma (21% [26 of 122]), and osteosarcoma (17% [21 of 122]). Tumors were staged according to the Enneking system [12]: benign conditions or low-grade, malignant Stage I disease (n = 29); high-grade, localized Stage II disease (n = 56); and Stage III disease (n = 37), consisting of primary sarcomas with metastases, lymphoma, myeloma, or metastatic

disease of bone (Table 1). Kaplan-Meier curves were constructed to demonstrate the survival of patients with Stage I, Stage II, and Stage III disease. The mean age at the time of surgery was 48 ± 22 years. The mean follow-up time of surviving patients was 7 ± 8 years.

Surgical Technique

All procedures were performed by one of two oncologic surgeons (JJE and NMB) at a single institution using a bipolar head and cemented stem. Procedural and implant variables including stem length, segment length, and implant modularity were obtained from operative reports and confirmed via implant logs. All implants were bipolar, cemented hemiarthroplasties. The first 32 implanted prostheses were custom-designed, monoblock implants. The remaining implants since 1990 were manufactured using forged stems and titanium modular segments. These prostheses are all generally comparable and thus were all analyzed together. All implants were manufactured by Zimmer Biomet, Stryker, DePuy Synthes, or Howmedica. Although there were changes in implant design, manufacturer, and metallurgy over the study period, surgical technique remained consistent regarding principles of tumor resection, canal preparation, implant cementation, and soft tissue closure as described in our group's prior publications [4, 5, 10, 22, 33].

Postoperative Care

Patients with primary sarcoma and metastatic disease were treated with chemotherapy or radiation according to the accepted standard for their respective histology. Patients

Table 1. Diagnosis and Enneking classification of tumor types at index surgery

Diagnosis	Benign or low-grade (Stage I), n (n = 29)	High-grade (Stage II), n (n = 56)	Metastatic (Stage III) ^a , n (n = 37)	Total, n (n = 122)
Chondrosarcoma	13	13		26
Osteosarcoma		20	1	21
Ewing sarcoma		13	3	16
Malignant fibrous histiocytoma		3		3
Fibrosarcoma		2		2
Soft tissue sarcoma		5		5
Giant cell tumor	3			3
Hemangioma	1			1
Other benign disease	12			12
Lymphoma			2	2
Multiple myeloma			4	4
Metastatic carcinoma to bone			27	27

^aIncludes patients with sarcomas metastatic at diagnosis, lymphoma, multiple myeloma, and metastatic carcinoma to bone.

were seen in clinic at regular follow-up intervals postoperatively, and underwent wound checks and AP and lateral radiography of the proximal femur and chest imaging according to standard surveillance protocols.

Primary and Secondary Study Outcomes

Our primary study goal was to determine how implant survival compared against patient survival. This was determined by a chart review that was independently performed by three different reviewers (RT, DEG, and TEO) as well as by survivorship estimates. Data were collected from the last known follow-up date. Prosthesis survivorship was defined as revision of the stemmed component for any reason. We also sought to identify common reasons for revision; we stratified revisions as being because of aseptic loosening, breakage of the implant itself, infection, or tumor progression. Aseptic loosening was based on preoperative history and radiographs and was confirmed intraoperatively when motion between the bone-cement or implant-cement interfaces could be induced manually. Preoperative laboratory workup and intraoperative cultures were confirmed negative for all patients identified as having aseptic loosening. Infections were diagnosed based on the Musculoskeletal Infection Society criteria [23], and intraoperative cultures were confirmed to be positive for all patients. Superficial wound infections treated with antibiotics alone or superficial irrigation and debridement were not included in revision for infection in the current study. Time to revision was defined in quantitative years from the date of the index surgery to the date of revision surgery or amputation.

Our secondary study goal was to determine which factors were associated with survival of PFRs. This was achieved through chart review. We also sought to determine the survivorship free from conversion to THA. All indications for conversion to THA were based on clinical symptoms of groin pain in addition to radiographic evidence of acetabular wear. We also determined the rate of limb salvage, with limb salvage being defined as avoiding an amputation for any reason.

Ethical Approval

Ethical approval for this study was obtained from the institutional review board of the University of California, Los Angeles (IRB#10-001857).

Statistical Analysis

We compared the revision and nonrevision groups using a t-test for continuous variables or Fisher exact test for categorical variables. These values are reported as means and

SDs. Patient, prosthesis, and limb salvage survival rates were generated, with implant revision as the endpoint and death as a competing risk to allow for a competing risks analysis. Follow-up for patients who died of disease was defined as the timepoint of their last clinical encounter. Patients who were lost to follow-up were included in this analysis based on their status at their last clinical follow-up or if they were identified to have died through our Social Security Death Index search. The statistical analysis was performed using the log-rank method (Mantel-Cox) [34] using GraphPad Prism (Version 8.4.2, GraphPad Software). Significance was defined as a p value < 0.05.

Results

Implant Survival Versus Patient Survival

Generally, patients with benign (Stage I) disease outlived their implants, whereas the opposite was true for patients with aggressive (Stage II) and metastatic (Stage III) tumors. For patients with low-grade or benign tumors, there was 100% disease-specific survival at 30 years. For patients with high-grade localized disease, survival was 64% (95% CI 49% to 76%) at 5 years, 62% (95% CI 47% to 74%) at 10 years, and 54% (37% to 68%) at 20 and 30 years. For patients with Stage III metastatic disease, survival was only 6% (95% CI 0.5% to 24%) at 10 years (Table 2). When stratifying according to disease stage, patients with benign or low-grade Stage I disease generally outlived their implants ($p = 0.02$). Conversely, the interval from implant survival to all-cause revision was longer than patient survival among those with high-grade localized Stage II disease or widespread Stage III metastatic disease ($p = 0.001$ and $p < 0.001$, respectively) (Fig. 1).

Common Causes of Revision

Ten of 22 patients with primary PFRs underwent revision at a mean 8 ± 7 years postoperatively. Among primary PFRs, 3% (four of 122) of patients underwent revision for aseptic loosening, 3% (three of 122) underwent revision for infection, 2% (two of 122) underwent revision for breakage of the implant, and 0.8% (one of 122) underwent revision for tumor progression (Table 3). A total of 4.9% (six of 122) of patients had one or more dislocations postoperatively, all of which were successfully treated with closed reduction. No patients with hip dislocations had revision of the stemmed component, and thus were not considered to have implant failures (Supplemental Table 1; <http://links.lww.com/CORR/B165>).

Primary PFR implant survival at 5, 10, 20, and 30 years was 97% (118 of 122 [95% CI 90% to 99%]), 81% (99 of

Table 2. Competing risk survivorship data for implant, patient, and limb salvage

Survivorship	5 years	10 years	20 years	30 years
Implant survival ^a				
Implant (n = 122)	97 (90 to 99)	81 (67 to 90)	69 (46 to 84)	51 (24 to 73)
Patient survival				
Low-grade tumors (I) (n = 29)	100 (NA)	100 (NA)	100 (NA)	100 (NA)
High-grade tumors (II) (n = 56)	64 (49 to 76)	62 (47 to 74)	54 (37 to 68)	54 (37 to 68)
Metastatic tumors (III) (n = 37)	6 (0.5 to 24)	6 (0.5 to 24)	NA	NA
All tumors (n = 122)	57 (27 to 66)	51 (40 to 60)	41 (30 to 52)	36 (23 to 50)
Limb salvage				
Limb salvage (n = 122)	99 (95 to 100)	98 (88 to 99)	98 (88 to 99)	98 (88 to 99)

Data presented as % (95% CI). ^aSurvivorship free from any reoperation.

122 [95% CI 67% to 90%]), 69% (84 of 122 [95% CI 46% to 84%]), and 51% (62 of 122 [95% CI 24% to 73%]), respectively. Only two patients had an amputation, for an overall survival of limb salvage rate of 98% at 36 years. Indications for amputation included local recurrence (0.8% [one of 122]) and infection (0.8% [one of 122]).

Factors Associated With Survival of PFRs

Follow-up time was the only factor associated with failure (5 ± 6 years in the nonrevised group compared with 18 ± 9 years in the revised group; $p < 0.001$). Neither segment length (184 ± 112 mm in the nonrevised group and 217 ± 89 mm in the revised group; $p = 0.34$) nor stem length (132 ± 31 mm in the nonrevised group and 133 ± 24 mm in the revised group; $p = 0.97$) were associated with failure. Age (49 ± 22 years in the nonrevised group and 43 ± 16 years in the revised group; $p = 0.32$) and gender (53% women in the nonrevised group and 60% in the revised group; $p = 0.66$) were also not associated with failure (Table 4).

Conversion From Bipolar to THA

Survivorship free from conversion to THA (accounting for death as a competing risk) was 94% (95% CI 85% to 99%), 86% (95% CI 68% to 94%), and 77% (95% CI 51% to 91%) at 10, 20, and 30 years, respectively. The mean age at the time of conversion was 35 ± 23 years. One patient was 72 years old at the time of conversion to THA; all other patients were younger than 41 years. The mean time to conversion from the index surgery was 15 ± 8 years. All conversions were performed for groin pain and radiographic evidence of acetabular wear. After conversion, one patient experienced recurrent dislocations and was treated with an open reduction and acetabular cup

revision with retention of the cemented stem. Otherwise, no patients underwent subsequent surgery after conversion to THA.

Discussion

The proximal femur is the most common location in the appendicular skeleton for metastatic disease and is a common site for primary malignant and benign sarcomas [3, 18, 24]. Although the decision to perform endoprosthetic reconstruction, allograft reconstruction, internal fixation, or even amputation should be made on a per-patient basis, PFR is becoming the most widely accepted method to treat primary and metastatic tumors of the proximal femur in adults [8, 24, 37]. The current published reports of PFRs, however, are limited both by patient volume or relatively short follow-up time [4, 6, 15-17, 19, 24, 36, 37]. As such, the current study used a large database with nearly 40 years of follow-up to better describe implant

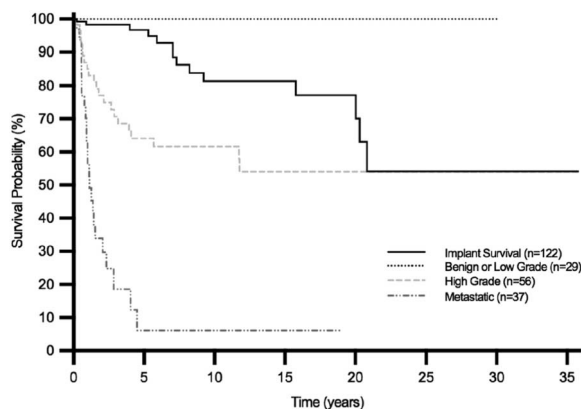


Fig. 1 This Kaplan-Meier curve demonstrates implant survival after PFR compared with patient survival, stratified by disease stage and using a competing risk analysis.

Table 3. Reasons for revision of proximal femoral replacements

Revision reason	Number of revisions	Time to revision in years	Number of subsequent revisions
Aseptic loosening	3 (4 of 122)	8 ± 8	25 (1 of 4)
Implant breakage	2 (2 of 122)	16 ± 1	0 (0 of 2)
Infection	3 (3 of 122)	3 ± 4	67 (2 of 3)
Tumor progression	0.8 (1 of 122)	7	0 (0 of 1)
Total	8 (10 of 122)	8 ± 7	30 (3 of 10)

Data presented as % (n) or mean ± SD.

survivorship and the associated reasons for revisions of cemented bipolar PFRs. Our findings suggest that surgeons should continue to consider PFRs in the appropriate setting, given the relative longevity and efficacy of these prostheses. This is especially true for patients with high-grade or metastatic disease, in whom implant survival is generally longer than patient survival. Furthermore, lengthy continued follow-up is imperative for this patient population, given that complications resulting in revision surgery can occur well after a patient’s index surgery.

Limitations

Functional outcome data were not included in this analysis and thus introduces a degree of assessment bias. Although survival is a crude endpoint, some patients may have implants that are intact and are not revised but painful for various reasons, such as soft tissue-related pain, chronic infections treated with antibiotic suppression, or subjective instability. Furthermore, patients may have acetabular wear but may be more resilient to pain, or elect not to undergo conversion to a THA. As such, these results are objective and do not consider the subjective way in which a patient feels. Additionally, all surgical procedures were performed by two surgeons at one institution using a bipolar head and cemented stem. This prevents the comparison of PFR to alternative reconstruction techniques including allograft reconstruction or internal fixation. Furthermore, because our database only pertains to endoprostheses, we cannot

comment on these alternative techniques. Although this can be considered a limitation, the consistency of surgical technique allows for reliability among surgeons using bipolar heads with cemented stems. Another limitation to the current study is the inclusion of custom-designed monoblock prostheses. We feel these are generally comparable to the currently used prostheses and thus elected to include these monoblock prostheses in the analysis. Furthermore, this study did not have an a priori power analysis and, given the relative rarity of PFR indications in addition to the 40-year period of treatment in this study, we acknowledge the current study may be underpowered to detect risk factors for revisions.

Implant Survival Versus Patient Survival

Generally, patients with benign tumors outlived their reconstructions, while patients with malignant or metastatic tumors most commonly did not. This is consistent with other studies that reported implant survival greater than patient survival in patients suffering from metastatic or high-grade disease [4, 24]. It is important to avoid repeat visits to the operating room—especially in a generally sicker patient population, in whom continuation of systemic therapy is paramount—and ensure these implants remain functional throughout these patients’ lifetimes. As such, the durability of the endoprosthetic reconstructions in the current study demonstrates that PFRs are a reasonable surgical treatment for patients with high-grade or metastatic disease. The

Table 4. Factors associated with revision of proximal femoral replacements

	Total	Not revised	Revised	p value
Number of patients	122	112	10	
Age in years	48 ± 22	49 ± 22	43 ± 16	0.32
Gender, women	53 (65 of 122)	53 (59 of 112)	60 (6 of 10)	0.66
Follow-up in years	7 ± 8	5 ± 6	18 ± 9	< 0.001
Segment length in mm	189 ± 109	184 ± 112	217 ± 89	0.34
Stem length in mm	132 ± 31	132 ± 31	133 ± 24	0.97

Data presented as mean ± SD or % (n).

current study also suggests that patients with low-grade disease should be preoperatively counseled that they could undergo a revision procedure at some point.

Common Causes of Revision

Primary PFRs demonstrated a revision rate of 8.2% (10 of 122 implants). Infection, implant breakage, and aseptic loosening accounted for most of the revisions performed in this series. Rates of aseptic loosening in the current study are generally consistent with the 1% to 3.6% rates reported by others [6, 24, 29, 37]. Infection rates range from 4.9% to 12%; however, there is likely variability in diagnostic criteria [6, 24, 37]. Furthermore, in recent reports, an overwhelming majority of infections occurred within 6 months [6, 24]. Infection rates in PFRs are typically lower than infection rates for distal femur replacements and less than that of total femur replacements [30, 34]. Although the explanations for this difference are likely multifactorial, a meticulous soft tissue reconstruction using the large muscles of the hip for implant coverage might mitigate the infectious burden in PFRs. Since the publication of our group's prior study [4], five additional revisions occurred; two of these patients had early infections. This could be attributed to increased diagnostic recognition immediately postoperatively. Regardless, the infection rate in the current study, and for PFRs in general, is relatively low. Further multicenter randomized controlled trials such as the Prophylactic Antibiotic Regimens in Tumor Surgery trial are needed to develop effective infectious prevention and treatment regimens [28]. Five percent (six of 122) of primary bipolar PFRs in the current study resulted in dislocation; all patients who were treated with closed reduction did not undergo revision surgery. Prior research suggests there is an increased risk of instability after THA compared with hemiarthroplasty [15]. Patients having reconstructions for tumors often have a higher risk of dislocation than patients undergoing elective arthroplasty because key para-articular soft tissues such as the capsule and hip abductor musculature are lost to gain adequate tumor margins.

Factors Associated With Survival of PFRs

The current study showed that, as expected, increased follow-up time was associated with an increased risk of revision after primary PFRs, but stem length and segment length were not. This is contrary to what has been shown for distal femoral replacements, in which stem tip location and longer resection length were associated with the development of aseptic loosening [13, 20]. One possible explanation for this is that the stem tips of distal femoral replacements are generally

more distal than those of PFRs, and thus may be subject to a lower magnitude of deforming forces and subsequent micromotion over time. The stem tips of distal femoral replacements may also be in weaker metaphyseal bone. This may also explain the overall lower risk of aseptic loosening after PFR than after distal femoral replacement [13].

Conversion From Bipolar to THA

Only 6% (seven of 122) of primary bipolar PFRs underwent conversion to THA for radiographic acetabular wear and associated groin pain at a mean 15 ± 7.7 years from the index surgery, again highlighting the relative longevity of bipolar PFRs. Theil et al. [37] demonstrated that the radiographic prevalence of acetabular wear was 28.6% in oncologic patients undergoing bipolar PFR. However, only 4.6% of patients in that study underwent conversion to THA, further demonstrating the durability of bipolar hemiarthroplasties even in the presence of radiographic wear. In our study, the low conversion rate to THA at a relatively long time after the index surgery as well as the relatively low incidence of dislocation of bipolar hemiarthroplasties supports the existing reports favoring the use of bipolar hemiarthroplasty over THA in patients undergoing PFR for an oncologic indication.

Conclusion

The current study demonstrates that cemented-stem bipolar PFRs for an oncologic indication are a relatively durable reconstruction technique. This highlights the longevity and efficacy of PFRs as an endoprosthetic reconstructive option, especially in patients with high-grade or metastatic disease. For the proper oncologic indications, surgeons should thus feel confident about using a PFR. This study provides important prognostic data for counseling patients on their expected postoperative outcomes after limb salvage surgery. Given the relative rarity of these indications, however, multi-institutional collaborations with larger patient populations are undoubtedly still needed to further identify risk factors for revision and ultimately help guide surgical management of this complex patient population in an evidence-based manner.

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