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Authors

Greig, Danielle
Trikha, Rishi
Geiger, Erik J
et al.

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Metaphyseal Stem Tip Location is a Risk Factor for Aseptic Loosening of Cemented Distal Femoral Replacements

Danielle Greig, MD,
Rishi Trikha, MD,
Erik J. Geiger, MD,
Troy Sekimura, BS,
Jeffrey J. Eckardt, MD,
Nicholas M. Bernthal, MD[*]
Department of Orthopaedic Surgery, University of California, Los Angeles, Santa Monica, CA

Abstract

Background: The objective of this study was to describe the incidence of aseptic loosening (AL) of cemented stem distal femoral replacements (DFR) and to identify modifiable risk factors for its development.

Methods: A retrospective review was performed of 245 consecutive primary, cemented stem DFRs implanted at a single institution over a 40-year period. The primary outcome was revision surgery for AL. A multivariate analysis was performed to identify risk factors for AL. Radiographs were reviewed to identify stem tip location, which was defined as diaphyseal or metaphyseal. Implant survival to AL was compared using Kaplan-Meier analysis.

Results: AL and structural failure were the most common causes of implant failure (incidence 11.8%, 29/245). Younger age ($P = .002$), male sex ($P = .01$), longer resection length ($P = .04$), and nonmodular implants ($P = .002$) were all significantly associated with AL. After 1:1 matching, stem tip location in metaphyseal bone was independently associated with AL ($P = .04$). 36% (9/25) of implants that loosened had a stem tip located in the metaphysis vs only 8% (2/25) of implants that did not fail. 30-year survival to AL was lower for implants with a metaphyseal stem tip than implants with a diaphyseal stem tip (22.7% vs 47.6%; $P = .11$).

Conclusion: A stem tip location in metaphyseal bone is associated with diminished survival to AL. When templating before DFR, stem tip location can assist in identifying high-risk reconstructions that may benefit from alternative or supplemental fixation techniques to prevent the development of AL.

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[*] Address correspondence to: Nicholas M. Bernthal, MD, 1250 16th Street, Suite 2100, Santa Monica, CA 90404.

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Keywords

endoprosthesis; aseptic loosening; implant failure; distal femoral replacement; revision knee arthroplasty

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With advancements in imaging, medical therapy, biomaterials, and surgical technique, limb-salvage surgery has replaced amputation in recent decades as the standard of treatment for patients with musculoskeletal tumors around the knee [1–5]. Among the variety of reconstructive options available after segmental resection of a tumor, endoprosthetic reconstruction is the most widely used technique due to its considerable advantages including early weight-bearing, short hospitalizations, and component modularity, which enables cost-efficient implant customization [6–12]. In addition, indications for the use of endoprostheses continue to broaden outside of use for primary oncologic reconstruction. Because of shorter operative times than open reduction and internal fixation and allowance for early weight-bearing, distal femoral replacements (DFRs) are becoming an increasingly popular option for primary treatment of distal femur fractures in older patients [13,14]. In addition, DFRs are used in revision arthroplasty to address bone loss associated with total knee arthroplasty failure or periprosthetic fracture [15].

As prognosis for patients who undergo endoprosthetic reconstruction continues to improve, there has been an increased focus in recent literature on the long-term endurance of these implants [6,7,11,16,18]. While infection is the primary cause in the early postoperative period, aseptic loosening (AL) has been cited as the most common mode of failure in studies with long-term follow-up, with as many as 33% of implants requiring revision surgery for loosening by 10 years [16–19]. This risk is especially high after DFR compared with endoprosthetic reconstruction in other anatomic locations and is thought to be due to the rotational stress placed on the distal femur during gait [9,16–21].

Given the significant morbidity associated with AL as well as the expanding indications for DFR, identifying patients at high risk of AL and investigating strategies to prevent its development are paramount. Several studies have attempted to identify risk factors for ALafter DFR, with many demonstrating that resection length plays a significant role [20–22]. While this is important to note, resection length in oncology is generally determined by the extent of the tumor and the imperative to attain negative margins and is thus not easily modifiable. Surgeons only have direct control over their method of reconstruction. The modularity inherent to today’s endoprosthetic systems from multiple manufacturers means surgeons have options in stem diameter, shape, fixation method, and, perhaps critically, stem length. Decades ago, it was hypothesized that cemented DFR stems ending in the proximal femoral metaphysis may have higher loosening rates because they are subjected to increased bending stresses compared with more distal stems due to the relative offset differences between the intramedullary stem tip and the femoral mechanical axis in the dorsoventral plane [20]. Although the oncology community continued to investigate the impact of resection length on AL, little attention has been paid to stem tip location. Only recently has any group tried to identify radiographic predictors of AL controllable at the implant level with long-term follow-up [23].

The objective of this study was to use a 40-year, prospectively collected, single-institution database of primary, cemented DFRs to examine the incidence of AL and to identify risk factors for its development. Specifically, we hypothesized that stem tip location in proximal metaphyseal bone would be associated with an increased incidence of AL, thus favoring reconstructions that end in the femoral diaphysis. We also aim to create a simple binary reconstruction guide to help surgeons templating these complex procedures.

Methods

After obtaining institutional review board approval, a retrospective review was performed of all consecutive DFRs performed by 2 orthopedic oncology surgeons at a single institution between December 1, 1980 and December 31, 2019. Only primary, cemented stem DFRs were included for analysis. Demographic, oncologic, procedural, and outcome information was collected and analyzed.

Procedural and implant variables analyzed were obtained from the operative report and implant log and included stem length, stem width, segment length, and implant modularity (custom vs modular). Custom or nonmodular implants are defined by a monobloc femoral component. Resection length of the femur was also obtained from the operative report and confirmed by pathology. All procedures were performed as per a previously described surgical technique using modern generation cement technique [9,24]. Primary tumor resections were in accordance with widely accepted oncologic principles [24,25]. While there were improvements in metallurgy (casted to forged metals [2003]) and in implant design (custom to modular [1990]) throughout the study period, surgical technique remained consistent, specifically with regard to principles of tumor resection, canal preparation, and implant cementation, as well as postoperative rehabilitation protocols.

Radiographic analysis was performed by two independent observers based on postoperative films. Full length femur films or standing scanograms were used to calculate total femur length and length of remaining bony femur after resection. The proximal femoral metaphysis was defined on the anteroposterior radiograph from the tip of the greater trochanter to the distal aspect of the lesser trochanter (Fig. 1). This cutoff was used to define the length of stem located in diaphyseal vs metaphyseal bone, as well as stem tip location. If the tip of the stem was located proximal to the distal aspect of the lesser trochanter, it was considered metaphyseal, whereas if the tip was located distal to the distal aspect of the lesser trochanter it was considered diaphyseal.

The primary outcome of interest was implant failure secondary to AL. Implant failures were defined by amputation or major revision surgery. Bushing changes or planned expansions of growing constructs were not considered implant failures. Failures were classified in accordance with the Henderson system as one of the following: soft tissue failure (1), aseptic loosening (2), structural failure (3), infection (4), or tumor progression (5) [16]. AL was defined by the operating surgeon based on preoperative history and radiographs and was confirmed intraoperatively when motion between the bone-cement interface could be induced manually. Preoperative laboratory workup for infection as well as intraoperative cultures were confirmed negative for all cases defined as having AL. Time to failure was defined from date of index surgery to date of revision surgery or amputation.

Patients with AL were compared with patients who did not suffer implant failure of any cause (no failure [NF] group) to identify variables associated with the development of AL. Only patients with a minimum of 2 years of follow-up were included in this analysis. A Student t-test was used to compare continuous variables, while categorical variables were compared using a Fisher's exact test. 1:1 matching was performed for the AL and NF groups based on age (within 10 years), sex (M/F), implant modularity (Y/N), resection length (within 10 cm), and follow-up time (within 2 years). Matched cohorts were then analyzed for stem tip location and diaphyseal/metaphyseal stem lengths in accordance with aforementioned statistical methods. Kaplan-Meier analysis was used to assess survivorship to AL, with a log-rank (Mantel-Cox) test used to compare survivorship between groups of interest. Survival analysis was performed using GraphPad Prism (Version 8.4.2, GraphPad Software, San Diego, CA). Significance was defined as a *P*-value of <.05.

Results

245 primary, cemented stem DFRs were included for analysis. The mean patient age at the time of surgery was 27.6 years (range: 4.8-91.3 y). 43.3% of patients were men (106/245), and 56.7% were women (139/245). The most common diagnosis was osteosarcoma in 67.8% of patients (166/245) (Table 1). The second and third most common diagnoses were giant cell tumor (24/245, 9.8%) and chondrosarcoma (16/245, 6.5%), respectively. The primary diagnosis was nononcologic in only 2.9% of patients who underwent surgery for fracture (7/245). At final follow-up, 24.8% of patients with an oncologic diagnosis had died of disease (59/238), whereas 60.1% were without evidence of disease (142/238), 8.4% were alive with disease (20/238), and 6.7% had died of nondisease-related illness (16/238).

Average follow-up time was 12.2 years (range: 0.2-37.7 y). At final follow-up, 33.5% (82/245) of implants had undergone either amputation or revision surgery for failure (Table 2). The most common causes of failure were AL (11.8%, 29/245) and structural failure (11.8%, 29/245). Structural failures included implant fracture (n = 28) and periprosthetic fracture (n = 2). Failure due to infection occurred in 5.3% of patients (13/245), whereas failure due to tumor progression occurred in 4.1% (10/245). Soft tissue failure occurred in only one patient who underwent revision surgery for a 90° flexion contracture (1/245, 0.4%). Of the patients who underwent surgery for fracture (n = 7), there were 2 failures (1 soft tissue failure and 1 infection) and no cases of aseptic loosening. The incidence of amputation was 5.7% (14/245), of which 42.9% (6/14) were performed for infection and 57.1% (8/14) were performed for tumor progression. Overall median time to failure was 4.1 years (range: 0.05-33.6 y), which was longest for AL (8.7 years). Survival to AL was 92.9%, 78.3%, and 48.3% at 5, 15, and 30 years, respectively (Fig. 2).

Compared with patients whose implants did not fail (NF group), patients who suffered from AL were found to be younger at time of index surgery (21.0 years [95% confidence interval [CI]: 17.3-24.7] vs 28.5 years [95% CI: 25.9-31.1]; *P* = .002) and predominantly male (79.3% vs 54.0%; *P* = .01) (Table 3). Mean femoral resection length was significantly longer in the AL group (20.3 cm [95% CI: 17.7-22.9] vs 17.3 cm [95% CI: 16.5-18.1]; $P = .04$). The incidence of AL was 44.4% (4/9) for resections ≥30 cm in length, 15.4% (12/78) for resections 20-29.9 cm, and 8.5% (13/158) for resections <20 cm ($P = .006$). Survival to AL was 57.1% and 28.6% at 5 and 15 years, respectively, for resections ≥30 cm, 91.1% and 66.5% for resections 20-29 cm and 95.5% and 85.7% for resections <20 cm (Fig. 3A).

There was a significantly greater proportion of nonmodular implants in the AL group than the NF group (69.0% vs 36.8%; $P = .002$). 5-year survival of nonmodular implants was similar to that of modular implants (92.1% vs 93.5%). However, survival of nonmodular implants was lower than that of modular implants at 10 (85.2% vs 89.2%) and 15 years (68.6% vs 89.2%) (Fig. 3B).

Four patients in the AL group did not have radiographs available (4/29, 13.8%). Average follow-up time for matched patients was 21.2 years (range: 2.8-37.3 y). After 1:1 matching for age, sex, implant modularity, resection length, and follow-up time, metaphyseal stem length, metaphyseal stem percent, and stem tip location were found to be significantly associated with AL (Table 4). Compared with implants that did not fail, implants that suffered AL had longer mean metaphyseal stem length (1.3 cm [95% CI: 1.2-1.4] vs 0.2 cm [95% CI: 0.0-0.4]; $P = .02$), a greater mean percentage of stem in metaphyseal bone (7.5% [95% CI: 2.5-12.5] vs 2.2% [95% CI: 0.0-4.4]; $P = .05$) and were significantly more likely to have a stem tip ending in the proximal metaphysis vs the femoral diaphysis (36.0% [9/25] vs 8.0% [2/25]; $P = .04$). Survival to AL was lower for metaphyseal stem tips than diaphyseal stem tips at 5 (72.7% vs 84.6%), 15 (45.5% vs 71.2%), and 30 years (22.7% vs 47.6%) (Fig. 4).

Discussion

As an ever-increasing number of patients are able to outlive their endoprostheses, aseptic loosening has become an increasingly common cause of implant failure [16,17,20]. Unfortunately, studies to date have been unable to identify modifiable factors that may prevent the development of what many view as an inevitable long-term complication. AL results in substantial patient discomfort can be difficult to diagnose and often results in significant bone loss that makes revision surgery challenging [26]. As implant design continues to evolve and new strategies for bone-implant integration are developed, it is important to perioperatively identify patients at high risk of loosening and ensure appropriate measures are taken to mitigate this risk. This study identified AL as the number one cause of implant failure, complicating 12% of prostheses at long-term follow-up. Resection length, implant nonmodularity, and stem tip location were all associated with the development of loosening. Indeed, only 22.7% of implants with metaphyseal stem tips survived to 30 years compared with 47.6% of implants with all diaphyseal stems. This finding can aid in preoperative planning and suggests that alternative methods of fixation or different implant designs be considered when traditional long cemented DFR stems would otherwise end in the proximal femoral metaphysis.

This study supports prior literature that found longer resection length to be associated with AL [20,21]. Resections longer than 40% of total bone length have been found to be predictive of mechanical prothesis failure and overall implant survival [22]. While this is important to understand, resection length is dictated by the extent of the underlying tumor and is not modifiable. In addition, little has been offered explaining why resection length affects AL. Instead of focusing on resection length, our results suggest that surgeons should focus on its corollary: the remaining bone and its relation to the method of reconstruction. We show that cemented stems ending in the proximal femoral metaphysis have increased failure rates compared with stems ending in the femoral diaphysis. Unwin et al. hypothesized that increased loosening is the result of increased bending moments placed on proximal metaphyseal intramedullary cemented stems due to their increased mechanical offset compared with the weight bearing axis of the limb in the dorsoventral plane. This offset decreases as you move distally in the femur meaning diaphyseal fixation is not subject to the same stresses. Further, the authors point to the potential inadequacy of cancelous bone for proper cement interdigitation in the trochanteric region [20]. Both support our finding of increased risk for AL with cemented stems ending in the proximal metaphysis.

Recently, Piakong et al. submitted the first report on radiographic parameters that may help predict which cemented DFR stems will be at risk for AL. They found that the extent of osteolysis extending from the implant-bone interface was proportional to the risk for AL. Critically, they also found cortical expansion, or cortical hypertrophy at the cemented stem tip, was protective against AL. When cortical expansion was present—and it can only be present in stems that end in the femoral diaphysis—there were no instances of AL [23]. This supports our finding that diaphyseal stem tips have greater resistance against AL and should help guide surgeons preoperatively templating their reconstructions to consider alternative constructs if a traditional long cemented stem would end in the proximal metaphysis. Such alternatives include the addition of cross pins through the stem creating a bone-cement-prosthesis composite that is better able to resist rotatory stress and helps prevent loosening [27,28] (Fig. 5). Other techniques including custom short stems with supplemental screw fixation or extracortical plates have also shown promising results [29,30]. More recently, compressive osseointegration techniques have demonstrated improved outcomes compared with traditional cemented stems with regard to loosening in short diaphyseal segments [31]. While it is generally accepted that newer techniques such as compress and cross pin fixation are useful for short remaining proximal femoral segments, there are no clearly defined guidelines dictating when these options should be considered over traditional cemented stem techniques [27–31]. The results of this study suggest that templated stem tip location can be used as a gauge for when use of a cemented stem alone may place the patient at undue risk of AL.

This study also found that modular implants had improved survival to AL compared with older, custom implants. Modular implants are advantageous in that they are immediately available, do not require additional institutional approval, and can be tailored intraoperatively to meet desired parameters [9]. Schwartz et al found that modular components had greater survivorship than custom implants, although the authors acknowledge that this finding may not be solely due to the introduction of modular segments. As implants transitioned from custom to modular, they also underwent additional changes including the development of extramedullary porous coatings and the use of forged metals that could significantly reduce the incidence of fatigue fracture [9]. To this end, the improved survivorship to AL of modular implants seen in our study is likely multifactorial in nature, reflecting the evolution and improvement of implant design over the 40-year study period.

This study presents several limitations, including the inherent weaknesses associated with its retrospective design. The heterogeneity of the patient population and the evolution of implant design over time did not allow for exact 1:1 matching. Patients were unable to be matched for BMI due to incomplete data, a factor which may impact progression to AL. Furthermore, by analyzing stem tip location only in patients for which x-rays were available, selection bias may have been introduced as 4 patients with AL were excluded from analysis due to lack of imaging. These patients were treated before the institution of a central electronic medical record or received most of their postsurgical care, including imaging, at an outside institution and as a result may have differed in some way from the patients for which radiographs were available. In addition, stem length was not explicitly evaluated as a variable in this study as our study cohort used almost exclusively 5-inch stems. As 4-inch (90 mm) stems were not used in our study cohort enough to be analyzed as an independent variable, this study cannot directly assess the impact of using shorter, diaphyseal stems on aseptic loosening. As such, rather than directly suggesting using shorter stems to maintain a diaphyseal tip location, the results of this study instead recognize a high-risk group and note a population in whom alternative reconstruction may be considered. To this end, further investigation is needed to elucidate the impact of stem length and to ascertain the mechanism behind our clinical findings. Finally, we recognize that death is a competing risk for survivorship of oncologic endoprostheses and Kaplan-Meier (K-M) analysis may overestimate the risk of postoperative complications in this population [32]. Nonetheless, K-M analysis is still considered optimal for counseling individual patients on their risk for a postoperative complication, while competing risk analyses are optimal for health care policy planning [33]. Thus, we performed K-M analysis, consistent with many prior reports on long-term endoprosthetic survivorship [7].

Despite its limitations, this study is one of the largest published single institution cohorts of cemented stem DFRs with long-term follow-up, and the first to the authors' knowledge to examine the impact of stem tip location on AL. A metaphyseal stem tip location was associated with a 25% reduction in implant survival at 30 years as compared with a diaphyseal stem tip location. With this in mind, the risk of AL may be mitigated through careful preoperative planning and the use of alternative or supplemental fixation techniques in high-risk reconstructions.

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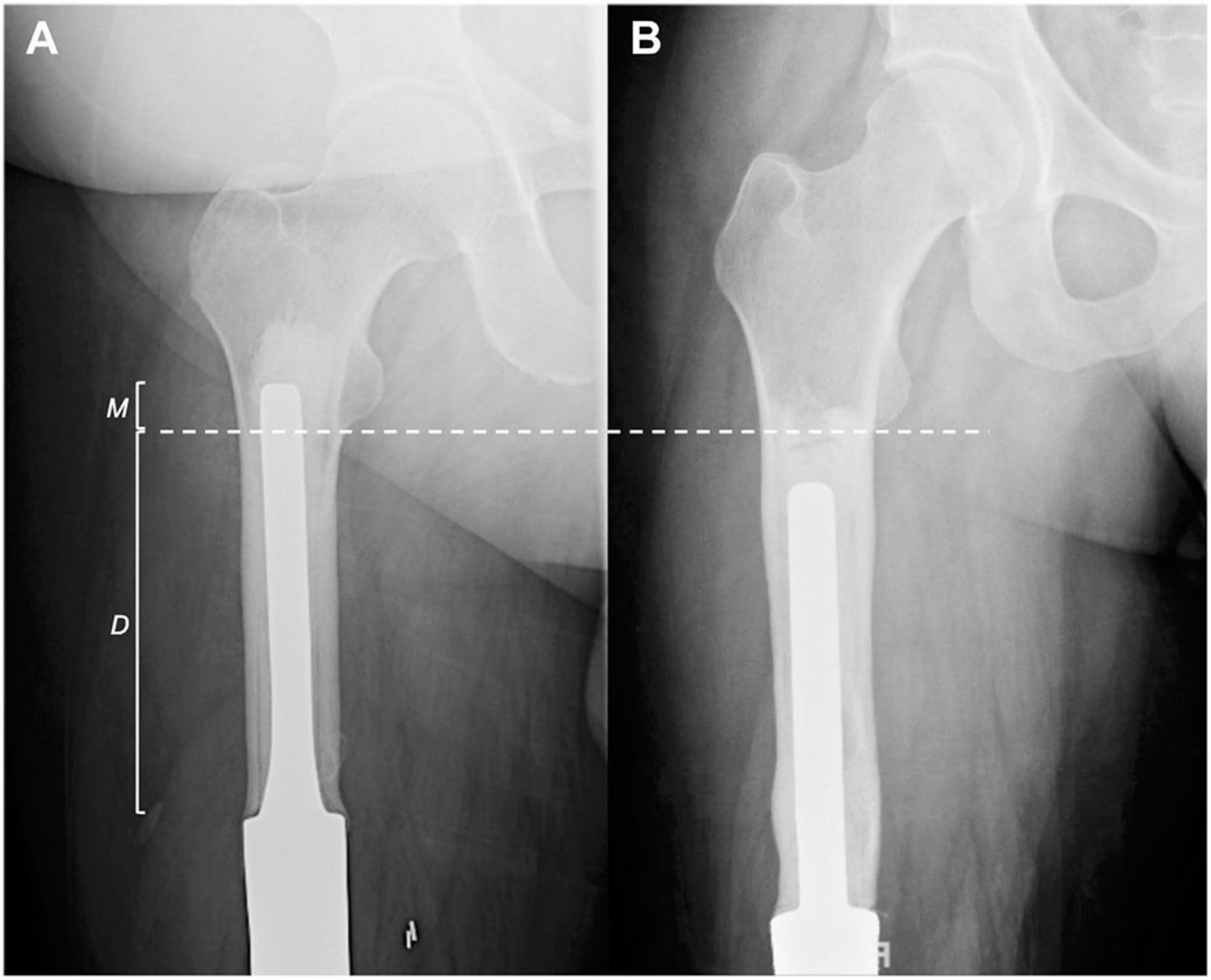

Fig. 1.

(A, B): Postoperative radiographs were used to define stem tip location. A horizontal line was drawn at the level of the inferior aspect of the lesser trochanter. The length of stem that extended proximal to this line was considered metaphyseal (M), whereas the length of stem distal to this line was considered diaphyseal (D). Stems that ended proximal to the line were defined as having a metaphyseal stem tip (A), whereas stems that ended distal to this line were defined as having a diaphyseal stem tip (B).

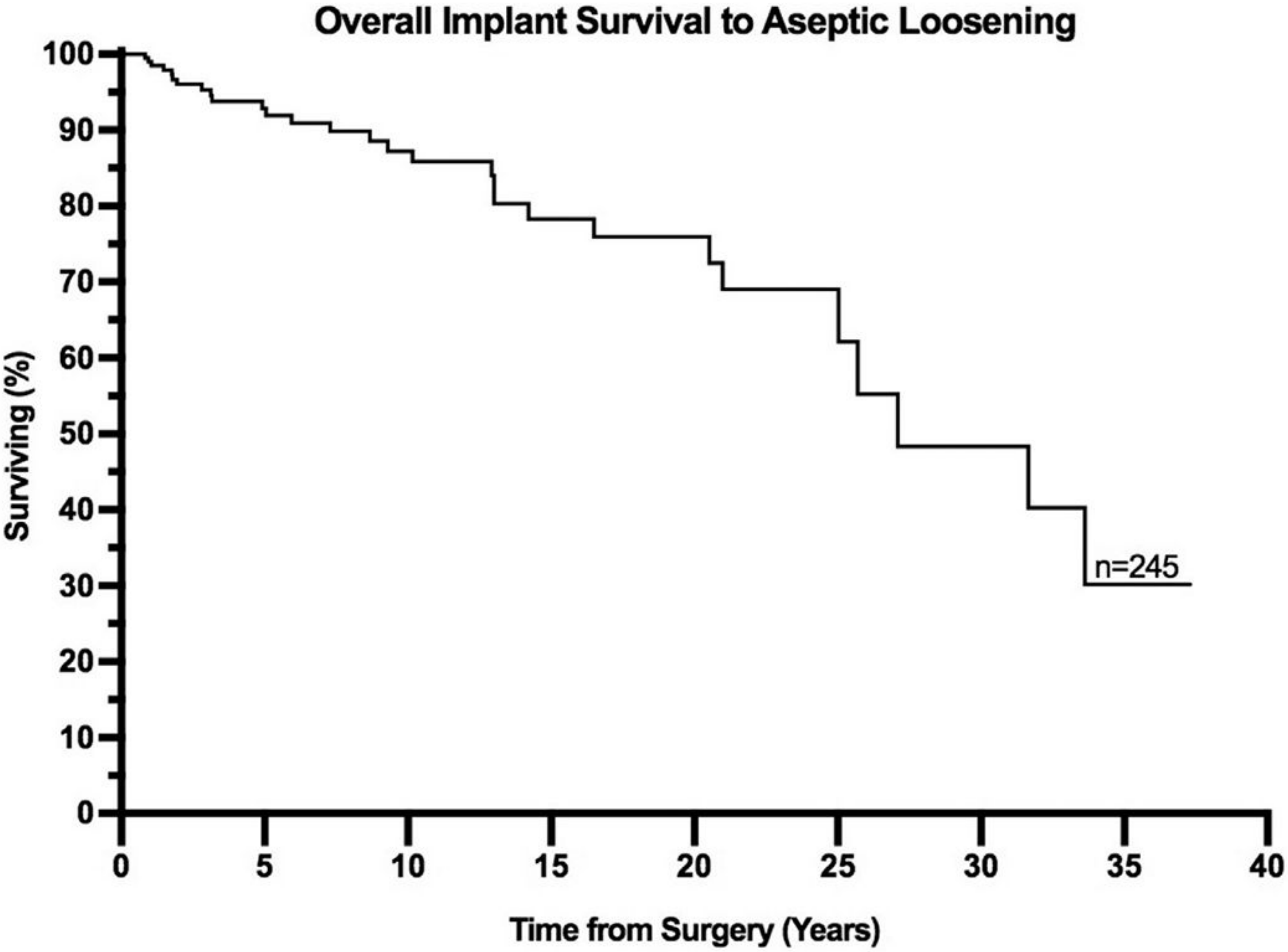

Fig. 2.

Kaplan-Meier curve representing overall implant survival with revision surgery for aseptic loosening as the end point.

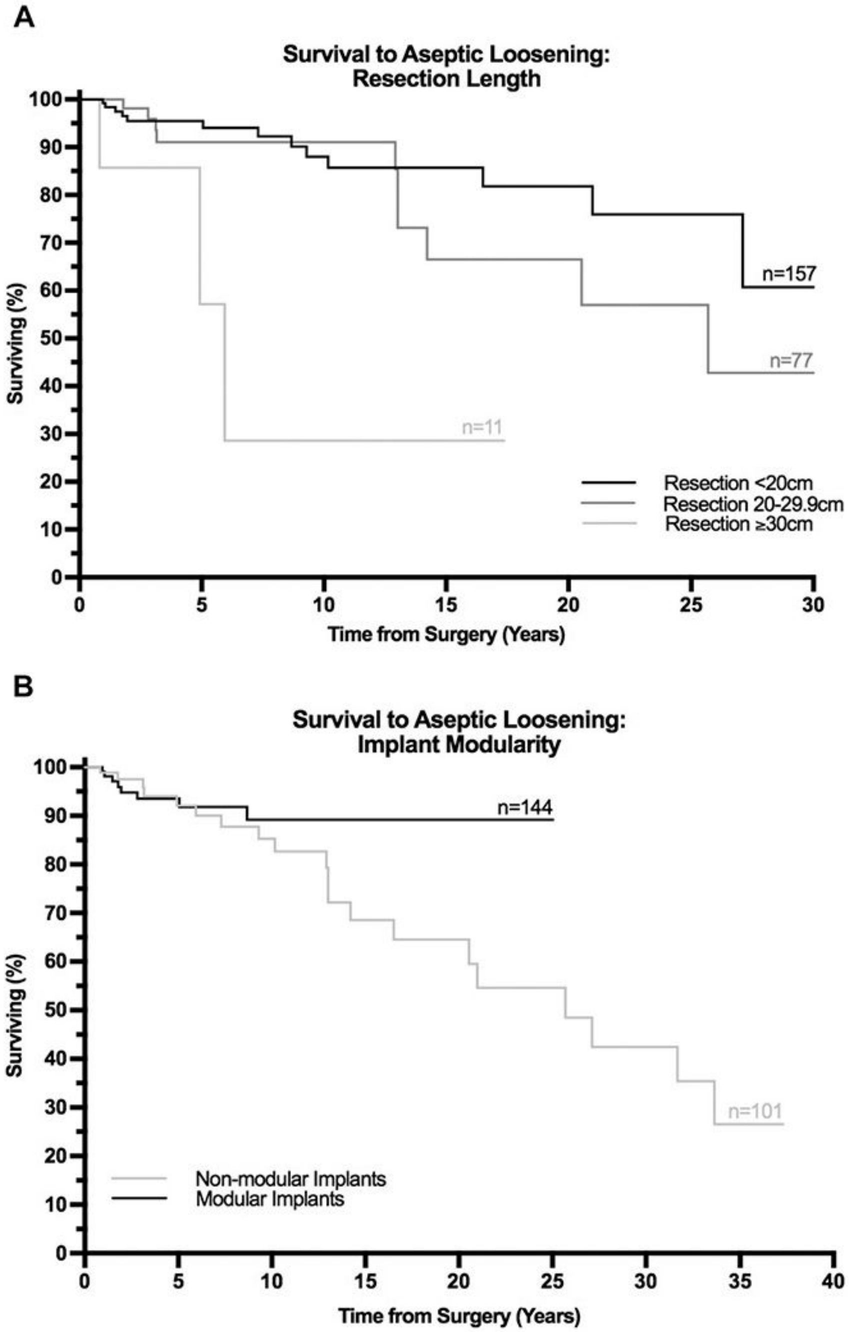

Fig. 3.

(A, B): Kaplan-Meier survival curves demonstrating risk factors for aseptic loosening. Longer resection lengths (A) and nonmodular implants (B) were associated with decreased survival to aseptic loosening ($P = .001$ and $P = .07$, respectively).

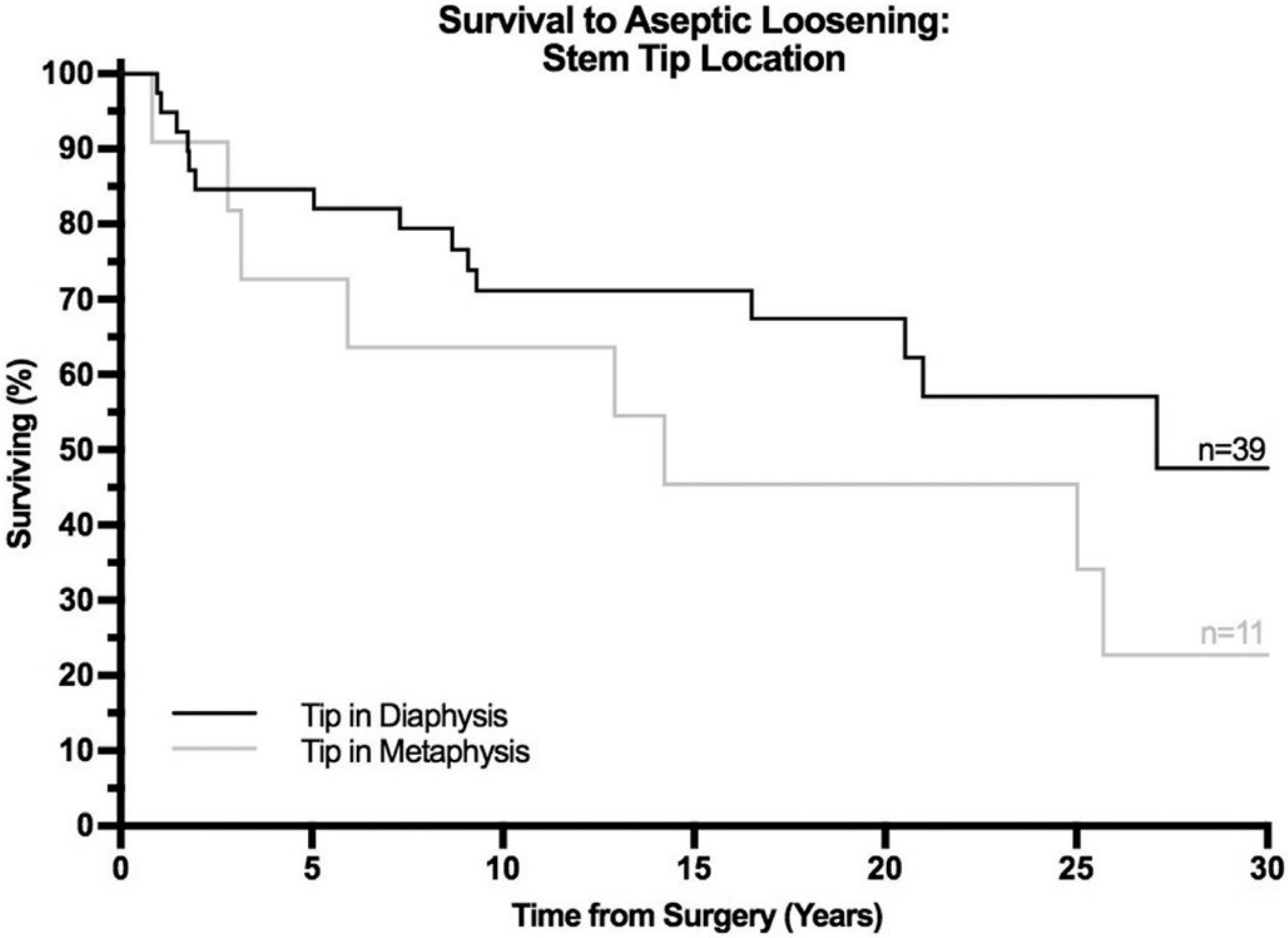

Fig. 4.

Survival to aseptic loosening by stem tip location. Implants with a stem tip ending in metaphyseal bone had decreased survival compared with implants with a stem tip ending in diaphyseal bone ($P = .11$).

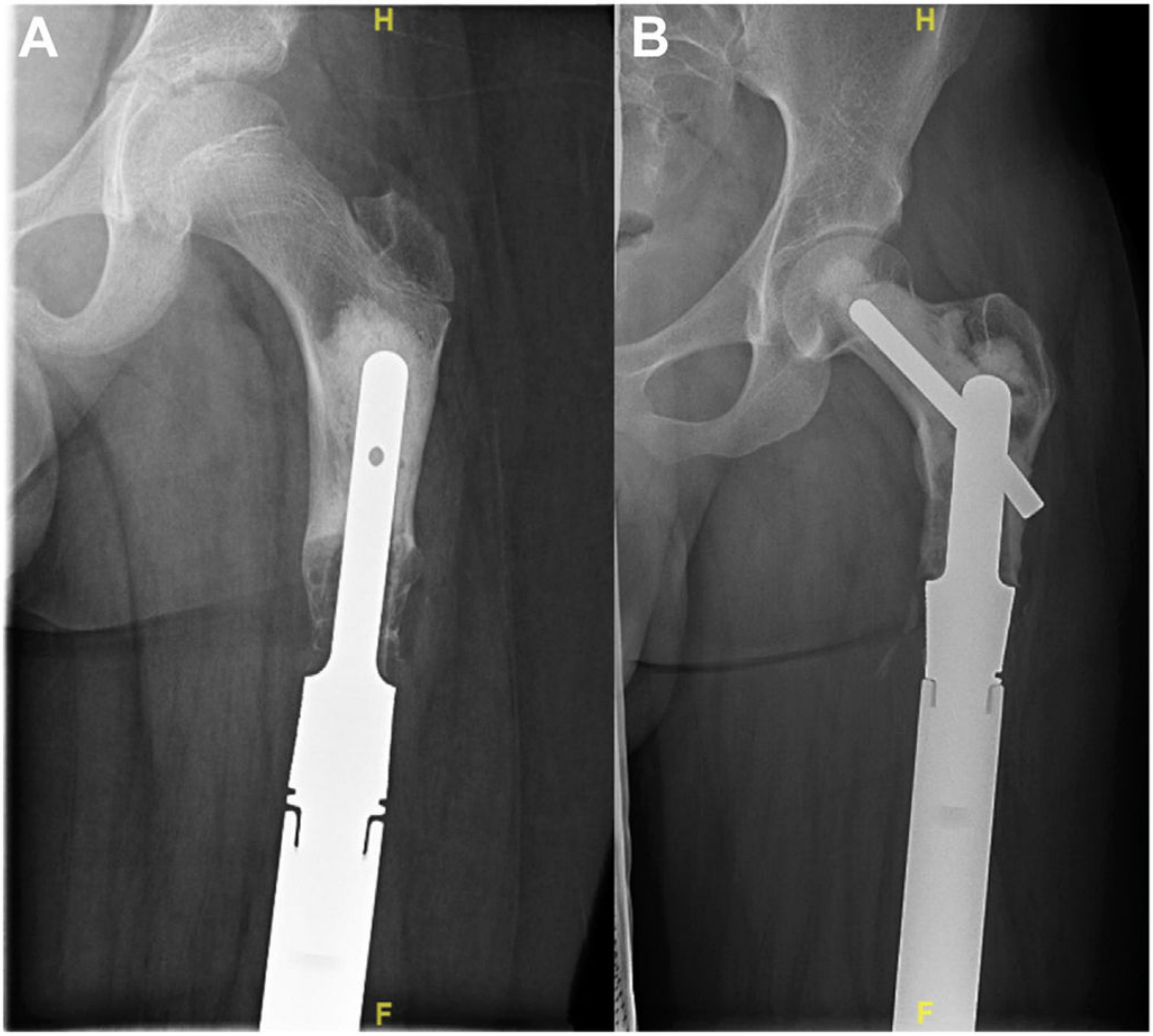

Fig. 5.

(A, B): Radiographs of the proximal femur 2.8 years postoperatively in a 9-year-old male with osteosarcoma demonstrating a metaphyseal stem tip that went on to aseptic loosening (A). He was treated with implant revision using custom cross pin fixation in the femoral neck, which remains stable without evidence of loosening 9 years postoperatively (B).

Table 1

Primary Diagnoses for Which Distal Femoral Replacement was Performed.

Diagnosis	Proportion of Patients (n)
Osteosarcoma	67.8% (166)
Giant cell tumor	9.8% (24)
Chondrosarcoma	6.5% (16)
Fracture	2.9% (7)
Metastatic disease	2.9% (7)
Metastatic renal cell carcinoma	1.2% (3)
Metastatic breast cancer	0.8% (2)
Other metastatic disease	0.8% (2)
Ewings sarcoma	2.4% (6)
Malignant fibrous histiocytoma	2.4% (6)
Soft tissue sarcoma	1.6% (4)
Desmoid	1.2% (3)
Fibrosarcoma	0.8% (2)
Other[a]	1.6% (4)

[a] 1 each of leiomyosarcoma, undifferentiated pleiomorphic sarcoma, lymphoma, and tenosynovial giant cell tumor.

Table 2

Modes of Failure of Cemented Distal Femoral Replacements.

Mode of Failure	Incidence (n)	Median Time to Failure (Y)
Soft tissue failure	0.4% (1/245)	0.4
Aseptic loosening	11.8% (29/245)	8.7 (range: 0.8-33.6)
Structural failure	11.8% (29/245)	8.4 (range: 0.5-22.6)
Infection	5.3% (13/245)	2.0 (range: 0.07-7.8)
Tumor progression	4.1% (10/245)	1.3 (range: 0.05-6.7)
Total	33.4% (82/245)	4.1 (range: 0.05-33.6)

Table 3

Risk Factors for Aseptic Loosening of Cemented Stem Distal Femoral Replacements.

Risk Factor	**Aseptic Loosening (n = 29)**	**No Failure (n = 163)**	***P*-Value**
Age (y)[a]	21.0 (17.3-24.7)	28.5 (25.9-31.1)	**.002**
Sex (M/F) (%)	79.3/20.7	54.0/46.0	**.01**
Resection length (cm)[a]	20.3 (17.7-22.9)	17.3 (16.5-18.1)	**.04**
Stem length (cm)[a]	13.0 (12.1-13.9)	12.7 (12.4-13.0)	.54
Stem width (mm)[a]	14.0 (13.1-14.9)	13.5 (13.2-13.8)	.32
Implant modularity (N/Y) (%)	69.0/31.0	36.8/63.2	**.002**
Follow-up (y)[a]	21.4 (18.0-24.8)	6.5 (5.3-7.7)	<**.001**

Bold indicates statistical significance (*P* value less than .05).

[a] Mean (95% confidence interval).

Table 4

Risk Factors for Aseptic Loosening Following 1:1 Matching for Age, Sex, Implant Modularity, Resection Length, and Follow-Up Time.

Risk Factor	**Aseptic Loosening (n = 25)**	**No Failure (n = 25)**	***P*-Value**
Age (y)[a]	19.8 (15.8-23.8)	21.8 (18.0-25.6)	.48
Sex (M/F) (%)	76.0/24.0	72.0/28.0	.75
Implant modularity (N/Y) (%)	64.0/36.0	56.0/44.0	.77
Resection length (cm)[a]	20.0 (17.2-22.8)	20.3 (18.5-22.1)	.86
% of Femur resected[a]	44.7 (38.9-50.5)	45.2 (41.6-48.8)	.89
Stem length (cm)[a]	13.0 (12.2-13.8)	12.7 (12.0-13.4)	.58
Diaphyseal stem length (cm)[a]	11.7 (10.7-12.7)	12.6 (11.7-13.5)	.20
% of Stem in diaphysis[a]	92.5 (87.6-97.4)	97.8 (93.9-100.0)	.11
Metaphyseal stem length (cm)[a]	1.3 (1.2-1.4)	0.2 (0.0-0.4)	<**.001**
% of Stem in metaphysis[a]	7.5 (2.5-12.5)	2.2 (0.0-4.4)	**.01**
Tip in diaphysis (Y/N) (%)	64.0/36.0	92.0/8.0	**.04**
Follow-up (y)[a]	22.7 (19.1-26.3)	19.6 (16.2-23.0)	.22

Bold indicates statistical significance (*P* value less than .05).

[a] Mean (95% confidence interval).