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Cause of infection in proximal tibial endoprosthetic reconstructions

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Abstract
Introduction The underlying cause of proximal tibial prosthetic failure by infection is unclear. We asked: (1) Is resection amount related to prosthetic infection? (2) What other risk factors are related with infection? (3) What are the survivorship and functional outcomes of proximal tibial endoprosthetic reconstruction?
Methods Sixty-two patients who underwent modular proximal tibial megaprosthesis reconstruction were analyzed. Follow-up duration averaged 98 months (range 26–240 months). Associations between prognostic variables and prosthesis survival were assessed.
Results The 10-year prosthetic survival of the 62 implants was 73.9 ± 11.7%. Prostheses were removed in 16 (25.8%) patients for infection and 3 of the 16 underwent amputation. Resection of >37% ($P = 0.016$) of the tibia was found to be related to infection. Application of chemotherapy ($P = 0.912$) and use of synthetic material to fix the patella tendon ($P = 0.2$) were not found to influence prosthetic survival. Functional outcomes (determined by the MSTS system) of the 52 patients that maintained a mobile joint averaged 24.2 (81%) (range 18–28).
Conclusions Our study suggests that the amount of bone resection is related with prosthetic failure by infection, however, the contribution of other risk factors should not be underestimated.

Keywords Proximal tibia · Tumor prosthesis · Infection

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Introduction

Limb salvage surgery of the proximal tibial tumor is notorious for its high complication rate [1–5]. Among the alternative reconstructive options for tumors involving this location, prosthetic implantation is the most commonly used method and has several well-known advantages [6–9]. The reported high risk of infection (up to 30%) dropped significantly after the routine use of a gastrocnemius muscle flap [2]. Nevertheless, short and long term survivals of endoprosthetic reconstruction are plagued by the high risk of revision for any reason [2–4, 10].

As in the case of the distal femur, the non-tumor related causes of failure of proximal tibial endoprosthetic reconstruction are infection, metal failure, and loosening. The incidences of metal failure and loosening vary across studies, and depend on prosthetic design (custom vs. modular, fixed vs. rotating hinge) and mode of fixation (cemented vs. non-cemented) [2, 3, 7, 11, 12]. However, infection is a leading cause of implant removal regardless of the aforementioned variability in prosthetic implantation. The unique anatomical features of the proximal tibia seem to be the reason as to why this site has a greater risk of wound infection. Nevertheless, it would appear reasonable to surmise that infection is also dependent on amount of bone resection. However, reports that have addressed the impact of the extent of bone resection on prosthetic failure in this location have produced conflicting results, and even in studies that have suggested a relation between amount of bone replaced and failure, the role of bone resection extent on infection is unclear [2, 8, 11, 13].

Accordingly, we sought to determine (1) whether resection amount is related to prosthetic infection, (2) whether risk factors other than resection length are related with infection, and (3) the survivorship and functional outcomes of proximal tibial endoprosthetic reconstruction.

Materials and methods

One hundred and twenty-nine patients who had undergone proximal tibial resection and reconstruction for a benign or malignant bone tumor using a megaprosthesis between January 1990 and March 2009 were retrospectively identified in our computerized database. Sixty-seven of these patients were excluded for the following reasons: (1) switched from a temporary arthrodesis (29 patients), (2) the use of a pasteurized bone prosthesis composite (27 patients), (3) less than a 2-year follow-up (except for patients that experienced failure) (8 patients), and (4) incomplete data (3 patients). Accordingly, 62 patients who underwent primary tumor prosthesis reconstruction of the proximal tibia constituted the study cohort. Follow-up duration averaged 98 months (range 26–240 months).

The factors assessed were age, gender, diagnosis, use of chemotherapy, use of indwelling port system, preoperative WBC count, percentage and length of resection, prosthesis type and mode of fixation, methods of patella tendon reconstruction, use of gastrocnemius local flap, operation time, transfusion amount, and duration and type of postoperative antibiotics.

There were 39 males and 23 females of average age of 26 years (range 12–65 years). The demographic data and types of reconstructive methods are described in Table 1. Histologic diagnoses were osteosarcoma in 41 patients, malignant fibrous histiocytoma of bone in 3, giant cell tumor in 14, Ewing's sarcoma in 1, and 1 case of each of synovial sarcoma, malignant peripheral nerve sheath tumor, and liposarcoma. Forty-five patients with a primary high-grade sarcoma received chemotherapy. No patient received local radiotherapy. Twenty-eight (45%) patients had indwelling port system. Peripheral WBC count of more than 3,000/μl was indicated for surgery. Average preoperative WBC count was 6,290/μl (range 3,050–9,810/μl). In all patients, tumor extirpation involved intraarticular resection of the proximal tibia. A cuff of normal soft tissue and at least a 2 cm margin of normal bone (as determined by a magnetic resonance scan) were removed to achieve a tumor free margin. Lengths of resected proximal tibiae ranged from 6 to 19 cm (mean 12.1 cm), and percentages of tibial bone resected ranged from 17 to 58% (mean 35.4%). In terms of hinge mechanisms, two types of prosthesis were used for reconstruction. Eighteen (29%) patients were implanted with a fixed hinge Kotz Modular Femur and Tibia Resection System (KMFTR®; Stryker Howmedica Osteonics, Rutherford, NJ), whereas the remaining 44 (71%) patients received a rotating hinge endoprosthesis [MUTARS® (Modular Universal Tumour and Revision System, Implantcast, Buxtehude, Germany) in 17 (27%) patients, and the Link® Endo-Model™ Modular Knee Prosthesis System (Hamburg, Germany) in 27 (44%) patients]. The stems of all three prosthesis were fixed with cement in 12 (19%) cases, whereas the remaining 50 (81%) cases were treated by non-cemented fixation. Reconstruction of the extensor mechanism involved reattachment of the patella tendon to the anterior tibia prosthesis using a trevira tube [14] or marlex mesh in 35 (56.6%), and in 6 (9.6%) patients the tendon was fixed with a screw. In 6 (9.6%) patients, the anterior tibia cortex/tuberosity was salvaged and secured to the tibial prosthesis with cables. In 15 (24.2%) patients with insufficient remnant patellar tendon, the position of the patella was maintained using nonabsorbable sutures to the gastrocnemius

Table 1 Patients demographics

Variables	Number of patients (%)
Age, mean (range)	26.5 (12–65)
<20 years	28 (45.2)
≥20 years	34 (54.8)
Gender	
Male	39 (62.9)
Female	23 (37.1)
Diagnosis	
Osteosarcoma	41 (66.1)
Giant cell tumor	13 (21.0)
Bone MFH	3 (4.8)
Ewing's sarcoma	1 (1.6)
Solitary myeloma	1 (1.6)
Soft tissue sarcoma	3 (4.8)
Prosthesis	
Kotz	18 (29.0)
Endo	26 (41.9)
Mutars	18 (29.0)
Patellar tendon reconstruction	
Bone block	6 (9.7)
Suture to gastrocnemius muscle	15 (24.2)
Suture to mesh	35 (56.5)
Screw to metal	6 (9.7)
Gastrocnemius flap	
Done	57 (91.9)
Not done	5 (8.1)
Total	62 (100)

MFH malignant fibrous histiocytoma

muscle flap. Medial gastrocnemius rotation flap was used to provide coverage for the prosthesis and reinforce extensor mechanism repair in 57 (92%) patients. Average operation time was 217 min (range 130–380 min). Average amount of transfusion was 2 units of packed RBC (range 0–7 units). Antibiotic prophylaxis in all cases consisted of intravenous second generation cephalosporin combined with aminoglycoside for 1 week. However, the duration of antibiotics administration was extended up to 2 weeks according to the amount of drainage and wound status. Postoperatively, patients were allowed touch weight-bearing in a long leg cast/splint with the knee in 10° of flexion for 6 weeks. Thereafter, range of motion exercise using a continuous passive motion (CPM) machine was applied and weight-bearing was gradually progressed to full weight-bearing as tolerated at 12 weeks.

Prosthetic failure was defined as the removal of the original prosthesis for any cause. A bushing failure necessitating exchange was considered a minor complication and not as a prosthesis failure. Time to failure (months) was defined as the time that elapsed between first surgery and date of prosthetic removal. After surgery, patients were seen monthly until 2 years postoperatively, at 3-month interval until 5 years, and at 6-month interval thereafter. Functional results were assessed at final follow-up visits using the Musculoskeletal Tumor Society (MSTS) System [15].

Survival curves were determined using the Kaplan–Meier method and inter-group differences in survival were determined using the log-rank test. In order to determine the optimum cut-off point of resection percentage for the prediction of prosthetic failure, a receiver operating characteristic (ROC) curve was plotted. Sensitivity, specificity, and predictive values of resection percentage for prosthetic failure were then calculated at the resection percentage cut-off. Analyses were performed using SPSS version 13.0 (SPSS Inc, Chicago, IL), and P values of <0.05 were considered significant.

Results

Resection of >37% ($P = 0.016$) of the tibia was found to be related to infection, and a resection length of >12.5 cm ($P = 0.076$) was found to increase the risk of prosthetic failure due to infection (Table 2). However, use of chemotherapy ($P = 0.912$), use of indwelling port system ($P = 0.795$), use of synthetic material to fix the patella tendon ($P = 0.2$), transfusion amount ($P = 0.944$), operation time ($P = 0.873$), preoperative WBC count ($P = 0.669$), duration of postoperative antibiotics ($P = 0.444$), and type of prosthesis ($P = 0.761$) were not found to influence prosthetic survival. The diagnoses of patients necessitating resection of <37% were osteosarcoma (21), GCT (7), 1 case each of synovial sarcoma, MFH of bone, Ewing’s sarcoma, and solitary myeloma.

Table 2 Association between survival of 62 prosthesis and clinical variables

Variables	Univariate	
	5-year survival	*P* value
Age		
<20 (*n* = 28)	65.8 ± 9.5	0.162
≥20 (*n* = 34)	85.3 ± 6.1	
Gender		
Male (*n* = 39)	78.1 ± 7.0	0.796
Female (*n* = 23)	73.7 ± 9.3	
Diagnosis		
Osteosarcoma (*n* = 41)	74.7 ± 7.0	0.587
Others (*n* = 21)	81.0 ± 8.6	
Chemotherapy		
Done (*n* = 45)	76.3 ± 6.7	0.912
Not done (*n* = 17)	76.5 ± 10.3	
Indwelling port system		
Used (*n* = 28)	72.5 ± 9.1	0.795
Not used (*n* = 34)	79.4 ± 6.9	
Preoperative WBC count		
≤6,000/µl (*n* = 38)	76.1 ± 7.0	0.669
>6,000/µl (*n* = 24)	76.9 ± 9.3	
Percentage of resection		
≤37% (*n* = 32)	89.7 ± 5.7	0.016
>37% (*n* = 30)	62.5 ± 9.0	
Resection length		
≤12.5 cm (*n* = 36)	82.7 ± 6.5	0.076
>12.5 cm (*n* = 26)	68.2 ± 9.4	
Type of prosthesis		
Fixed hinge (*n* = 18)	71.8 ± 10.7	0.761
Rotating hinge (*n* = 44)	78.4 ± 6.5	
Synthetic material to fix patella tendon		
Used (*n* = 42)	72.4 ± 7.3	0.204
Not used (*n* = 20)	84.7 ± 8.1	
Operation time		
≤180 min (*n* = 20)	75.0 ± 9.7	0.873
>180 min (*n* = 42)	77.5 ± 6.7	
Transfusion amount		
<2 unit (*n* = 24)	79.2 ± 8.3	0.944
≥2 unit (*n* = 38)	75.0 ± 7.3	
Duration of postoperative antibiotics		
<7 days (*n* = 18)	72.2 ± 10.6	0.444
≥7 days (*n* = 44)	78.8 ± 6.3	
Total	76.7 ± 10.8	

CI confidence interval, *ND* not done, *TPL* tumor prosthesis length, *SL* stem length

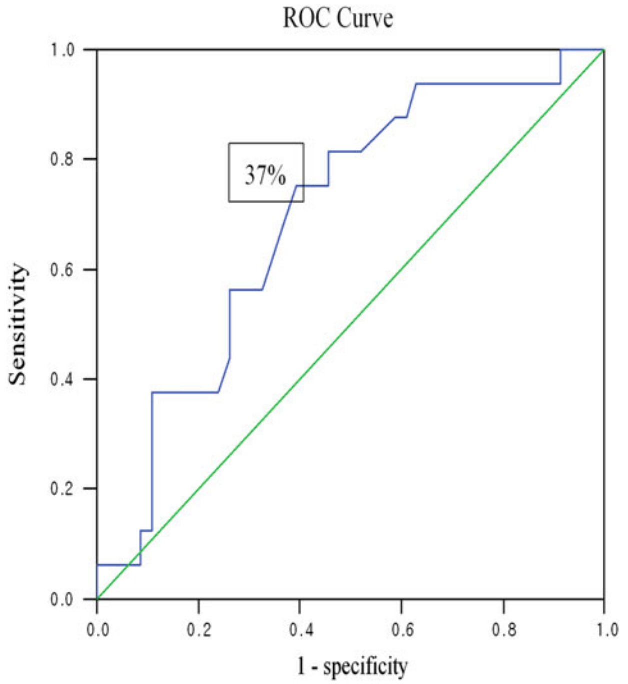

Fig. 1 Receiver operating characteristic (ROC) curve analysis demonstrated an optimal cut-off point at a percentage resection of 36.7% with an area under the curve of 0.693 (standard error, 0.073; 95% confidence interval, 0.549–0.837; $P = 0.022$)

ROC curve analysis showed that the percentage of bone resected predicted subsequent prosthetic failure with an area under the curve of 0.693 (standard error 0.073; 95% confidence interval 0.549–0.837; $P = 0.022$). The cut-off value at the left upper corner of curve, indicative of optimum threshold, was 36.7% (Fig. 1). At this level, percentage resection had a sensitivity of 75%, a specificity of 61%, a positive predictive value of 40%, and a negative predictive value of 87.5% for predicting prosthesis failure due to infection.

The 5- and 10-year survivals of the 62 implants were 76.7 ± 10.8% and 73.9 ± 11.7%, respectively, and mean survival was 80 months (Fig. 2). Three (4.8%) of the 62 patients underwent amputation due to uncontrolled infection, and 46 of the 62 (74.2%) retained the prosthesis implanted at index surgery at a mean follow-up of 90.1 months (range 29–215 months). All 16 (25.8%) removals were due to infection (Table 3). In one patient, with a giant cell tumor, concomitant local recurrence and infection developed at 240 months postoperatively. In 10 (62.5%) of the 16, infection developed within 12 months of the index procedure, whereas in the remaining 6 patients infection developed later (median 11.8 months postoperatively, range 2–240 months). Final limb statuses of the 16 patients that developed an infection were: arthrodesis in 7, mobile joint in 6, and amputation in 3; another 4 patients had complications that did not result in failure, but nevertheless required further surgery. These included revisions for bushing wear ($n = 2$), patella ligament rupture ($n = 1$), and for peri-prosthetic fracture ($n = 1$). Additional conservatively managed complications were superficial wound infection ($n = 1$) and femoral condyle fracture ($n = 1$).

Functional outcomes (determined by the MSTS system) of the 52 patients that maintained a mobile joint averaged 24.2 (81%) (range 18–28), and the average functional scores of the 37 rotating hinge and 15 constraint prostheses were 25.8 and 24.6, respectively. All patients maintained daily living and occupation-related activities; 28 patients (54%) had intermediate restriction (function category 4), 22 (42%) had recreational restriction (3 points), and 2 (4%)

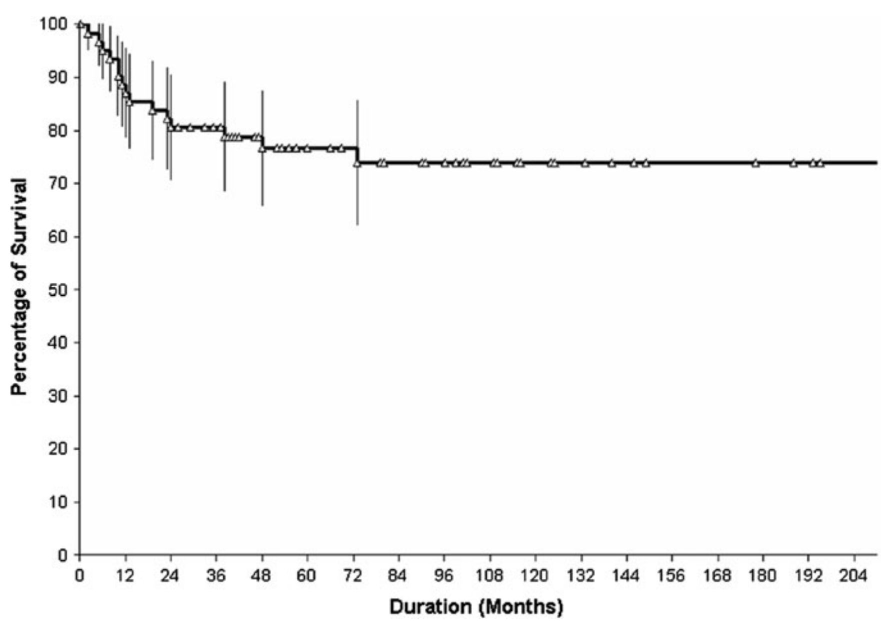

Fig. 2 The 5- and 10-year survivals of the 62 implants were 76.7 ± 10.8% and 73.9 ± 11.7%, respectively

Table 3 Data of 16 of 62 patients with prosthetic failure due to infection

Type of complication	Average duration from index operation (range)	Type of prosthesis		Resection length/ resection percentage	Final limb status	Final functional score
		Fixed hinge (18)	Rotating hinge (44)			
Infection	34 (2–240) months	6 (33%)	10 (23%)	13.4 (8.0–19.0) cm/39.4 (22.2–57.6)%	Mobile joint (6)	23.0
					Arthrodesis (7)	22.6
					Amputation (3)	21.3
Local recurrence	240 months	1 (6%)	0 (0%)	15.0 cm/44.1%	Arthrodesis	22.0
Total		6 (33%)	10 (23%)	–	–	

had intermediate occupational restriction (2 points). Range of motion at most recent assessments revealed mean knee flexion of 94° (range 40–130°), mean passive extension of 1.4° (range 60–10°), and mean active extension lag of 16° (0–60°). Thirteen (25%) patients achieved full active extension, and 39 (75%) demonstrated a residual mean active extensor lag of 35° (range 10–60°).

Discussion

An understanding of the underlying factors that lead to prosthetic failure is important to secure the longevity of prostheses in orthopedic oncology, and infection is the predominant cause of proximal tibial endoprosthetic replacement failure. Possible factors associated with infection after proximal tibia reconstruction included poor soft tissue coverage, compromised vascular supply, immuno-suppression related to chemotherapy, and amount of bone resection [2, 9, 16]. Previous reports that have addressed the correlation between the bone resection length and infection have produced debatable results confounded by mechanical failure [2, 8, 13]. We hypothesized that as the amount of bone replaced by a prosthesis is increased, the area uncovered by a local flap will inevitably widen and increase the risk of infection. This study suggests that amount of bone replaced by prosthesis is related with failure by infection, however, the contribution of various risk factors should not be underestimated.

The present study is limited by a non-homogeneous cohort in terms of underlying disease, the administration of chemotherapy, mode of fixation, and type of prosthesis. However, our primary interest was not to determine disease specific implant survival but rather to identify the underlying mechanism leading to infection. Despite the aforementioned variability in the study cohort, our experiences provide additional data that contribute to our understanding of the factors related to infection.

Published implant survival rates of proximal tibia vary presumably due to diagnostic heterogeneity, implant designs, and modes of fixation (Table 4). Nevertheless, our findings are similar to previous reports involving modular type prosthesis and uncemented fixation. Intriguingly, all failures in our patients originated from infection. However, cementless prostheses, which were used in more than 80% of our patients, generally have a low rate of loosening [7, 11, 17]. Therefore, for modular cementless tumor prostheses, which are applied in most proximal tibial reconstructions, infection is the major threat to longevity. In the largest series conducted on periprosthetic infections, the infection rate for the entire cohort of 1,240 patients was 11%, whereas that for 247 cases with a proximal tibial location was 23.1%, which is comparable to our rate of 25.8% [18]. In this previous report, the infection rate of the pelvic location was 23%. High infection rates for the pelvic location may be due to long operation times, extensive exposures, and the possibility of remaining dead space [19–21]. In comparison, despite the introduction of the local rotation flap, the infection rate of proximal tibial location is still high considering the magnitude of the surgical procedure [3, 11]. Contrary to our result, Grimer et al. [2] failed to find an association between infection and other parameters, such as, age, percentage of bone replaced, use of chemotherapy, or previous surgery. Although we cannot explain inconsistencies regarding the relation between infection and amount of bone resection, the findings of this previous study may have been confounded by the inclusion of patients with or without a gastrocnemius flap.

Given that in our cohort most patients received a gastrocnemius flap, the increased risk of infection for greater magnitudes of resection may be due to limited prosthesis coverage by the flap. Larger resection will inevitably create a bare area in which the prosthesis coverage is by overlying

Table 4 Comparison with previous studies

Author	Case no./mean FU (years)	Type of prosthesis	Implant survival (%)		Loosening (%)	Implant fracture (%)	Infection (%)	LR (%)	Amputation (%)
			5 years	10 years					
Myers et al. [3]	194/14.7	Custom made, cemented	32[a]	61[a]	22[b]	5.1	19.5	5.1	17.5
Grimer et al. [2]	151/6.7	Custom made, cemented	NA	63[a]	NA	3.3	28	16	17
Natarajan et al. [16]	133/5.0	Custom made, cemented	84.5	NA	3.7	12[c]	12	3	2.3
Schwartz et al. [4]	52/8.0	Custom made (23), modular (29) cemented	93.8	86.4	13.4	1.9	5.8	5.8	9.6
Wu et al. [13]	44/7.1	Custom made (9), modular (35) cemented	44.4[d]/ 81.4[e]	22.2[d]/ 65.3[e]	2.3	13.6	15.9	2.3	13.6
Flint et al. [7]	44/5.0	Modular, uncemented	73	NA	0	4.5	16	4.5	15.9
Gosheger et al. [17]	42/3.8	Modular, uncemented	61.7	NA	7.1	2.4	16.7	NA	NA
Griffin et al. [11]	25/9.3	Modular, uncemented	74	68	0	8.0	20	0	NA
Current series	62/7.5	Modular, uncemented (50) cemented (12)	77	74	0	0	25.8	1.6	4.8

NA not assessed, *LR* local recurrence

[a] Reported percentage of implant revised

[b] 22 of 95 fixed hinge prosthesis

[c] Periprosthetic fracture

[d] Survival of custom made prosthesis

[e] Survival of modular prosthesis

skin alone. We presume that this plays a role in the high risk of infection in this location, but it remains unclear whether the infection rate can be reduced by more aggressive soft tissue coverage or by decreasing the proportion of prosthesis uncovered by bone (e.g., use of segmental telescoping allograft-prosthesis composite).

Contributory cause to the infection other than resection amount would be use of chemotherapy and application of synthetic material to fix the patella tendon. The use of aggressive adjuvant chemotherapy mandates patients in an immunocompromised state, and they are at risk of infection thereafter or in the months after surgery. In our study, though use of chemotherapy did not have significance, 9 (75%) of 12 infected patients in chemotherapy group developed infection within 1 year from operation. On the contrary, only one of four infected patients in non-chemotherapy group did so. Therefore, loss of statistical significance of applied chemotherapy is probably due to the small number of cases in this study. Additionally, although there was only a trend of increased infection ($P = 0.2$) in patients who applied synthetic material (mesh or trevira tube) to fix the patellar tendon, 13 (30.9%) of 42 patients with this material developed infection, while 3 (15%) of 20 patients without this material had infection. We think the controlled use of this synthetic material may decrease the infection rate to some extent.

Summarizing, the present study suggest that percentage of bone resection is related to prosthetic failure by infection. However, due to the multi-factorial nature of infection in this site, the contribution of other risk factors should not be underestimated.

Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

Conflict of interest Each author certifies that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might constitute a conflict of interest in connection with the submitted article.

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