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ONCOLOGY

Endoprosthetic replacement of the proximal tibia for oncological conditions

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Aims

The proximal tibia (PT) is the anatomical site most frequently affected by primary bone tumours after the distal femur. Reconstruction of the PT remains challenging because of the poor soft-tissue cover and the need to reconstruct the extensor mechanism. Reconstructive techniques include implantation of massive endoprosthesis (megaprosthesis), osteoarticular allografts (OAs), or allograft-prosthesis composites (APCs).

Methods

This was a retrospective analysis of clinical data relating to patients who underwent proximal tibial arthroplasty in our regional bone tumour centre from 2010 to 2018.

Results

A total of 76 patients fulfilled the inclusion criteria and were included in the study. Mean age at surgery was 43.2 years (12 to 86 (SD 21)). The mean follow-up period was 60.1 months (5.4 to 353). In total 21 failures were identified, giving an overall failure rate of 27.6%. Prosthesis survival at five years was 75.5%, and at ten years was 59%. At last follow-up, mean knee flexion was 89.8° (SD 36°) with a mean extensor lag of 18.1° (SD 24°). In univariate analysis, factors associated with better survival of the prosthesis were a malignant or metastatic cancer diagnosis (versus benign), with a five- and ten-year survival of 78.9% and 65.7% versus 37.5% ($p = 0.045$), while in-hospital length of stay longer than nine days was also associated with better prognosis with five- and ten-year survival rates at 84% and 84% versus 60% and 16% ($p < 0.001$). In multivariate analysis, only in-hospital length of stay was associated with longer survival (hazard ratio (HR) 0.23, 95% confidence interval (CI) 0.08 to 0.66).

Conclusion

We have shown that proximal tibial arthroplasty with endoprosthesis is a safe and reliable method for reconstruction in patients treated for orthopaedic oncological conditions. Either modular or custom implants in this series performed well.

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Introduction

The proximal tibia (PT) is the anatomical site most frequently affected by primary bone tumours after the distal femur; up to 15% of osteosarcomas and 11% of Ewing's sarcomas are located in the PT.[1-3] For several decades, limb salvage (rather than amputation) has been standard for lower limb tumours.[4] Reconstruction of the PT remains challenging because of the poor soft-tissue cover and the need to reconstruct the extensor mechanism, and therefore these are more likely to fail compared to equivalent techniques used for the distal or proximal femur.[5-8] Reconstructive techniques include implantation of massive endoprosthesis (megaprosthesis), osteoarticular allografts (OAs), or allograft-prosthesis composites (APCs).[9-16] Endoprosthetic reconstructions have lower reoperation and failure rates, although functional recovery after APC may be better.[17-19] Survival of massive endoprosthesis has been reported as 42% to 85% at five years and 22% to 86% at ten years;[4,20–27] modular systems and rotating-hinge prosthesis have been generally associated with better outcomes than fixed-hinge reconstructions.[28–30] The most common cause for

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Table I. Histological diagnosis of primary or metastastic tumour.

Diagnosis	Patients, n
Osteosarcoma	27
Chondrosarcoma	14
Metastatic renal carcinoma	5
Ewing's sarcoma	4
Giant cell tumour	4
Spindle cell sarcoma	4
Adamantinoma	2
Leiomyosarcoma	2
Lymphoma	2
Metastatic breast cancer	2
Metastatic prostate carcinoma	2
Angiosarcoma	1
Malignant giant cell tumour	1
Malignant PEComa	1
Metastatic bowel cancer	1
Metastatic neuroendocrine carcinoma	1
Multiple myeloma	1
Myofibroblastic sarcoma	1
Sarcoma non-specified	1

PEComa, perivascular epithelioid cell tumour.

Table II. Failures and survival (Henderson classification system).[36]

Failure	5 yrs survival, %	10 yrs survival, %
All types	75.5	59
Type I (soft-tissue failure)	94.4	83.7
Type II (aseptic loosening)	86.7	86.7
Type III (structural failure)	98.3	98.3
Type IV (infection)	97	85.4
Type V (tumour progression)	96.8	96.8

failures are aseptic loosening and infections, the latter occurring in up to 40% of patients.[31,32] After the routine adoption of the medial gastrocnemius flap, however, infection rates appeared to decrease substantially.[4,33-35] Reported prosthesis survival varies widely among studies, probably because the definition of failure varies between reports; authors have only recently adopted a uniform method for reporting.[18,36] Physical function after PT resections depends to a large extent on the success of reconstruction of the extensor mechanism. In the past, several techniques have been used with different results. In OA and APC, it is possible to suture patellar remnants directly to allografts with good functional results.[37,38] However, after endoprosthetic reconstructions, patellar remnants are generally sutured to the prosthesis and the gastrocnemius flap with different techniques and poorer functional results.[8,37-45] The aim of the current study was to investigate the performance and survival of proximal tibial endoprostheses with the Stryker METS hinge prosthesis using the definitions of failure developed by Henderson et al,[36] and identify factors influencing outcomes in a cohort of patients treated in the Royal National Orthopaedic Hospital.

Methods

This was a retrospective analysis of clinical data relating to patients who underwent proximal tibial arthroplasty in our regional bone tumour centre from 2010 to 2018. Inclusion criteria were: proximal tibial arthroplasty for neoplastic or post-neoplastic conditions (revisions after PT arthroplasty failures for tumour); 24 months of minimum follow-up; and endoprosthetic arthroplasty with modular (METS modular proximal tibia, fixed- or rotating-hinge; Stryker, USA) or custom-made prosthesis (Stryker). Exclusion criteria were: arthroplasties for non-neoplastic conditions; follow-up less than 24 months; diaphyseal tibial arthroplasties; and use of a custom-made non-invasive growing prosthesis.

Two independent reviewers (FS, PC) collected data from clinical records; if there was no consensus, a third opinion was collected (CG). Endoprosthesis failures were grouped using the Henderson classification system.[36] Prognostic factors included age, sex, aggressiveness (benign, malignant, or metastatic), type of intervention (revision or primary), year of intervention (before or after 2014), American Society of Anesthesiologists (ASA) grade,[46] reconstruction length, radiotherapy, chemotherapy, use of a medial gastrocnemius flap, type of prosthesis (custom or modular), type of hinge, fixation method (cemented or press-fit), extensor mechanism reconstruction technique, and hospital length of stay. Mean extensor lag and mean knee flexion as reported in the clinical records were analyzed in order to understand the success of reconstruction of the extensor mechanism.

Statistical analysis. Categorical data were described by frequency and percentage.

Survival analysis. Revision-free survival (RFS) was identified as the endpoint, and the survival time was defined as the time from implantation to the date of revision. Survival curves were calculated using the Kaplan-Meier method. A total of 15 risk factors were assessed in the survival analysis (age, sex, aggressiveness, type of intervention, year of intervention, ASA grade, reconstruction length, radiotherapy, chemotherapy, use of a medial gastrocnemius flap, type of prosthesis, type of hinge (fixed or rotating), fixation method, extensor mechanism reconstruction technique, and hospital length of stay), including each factor in a univariate Cox regression model. A competing risk analysis was also performed to study prosthesis survival, including tumour aggressiveness as fixed covariate and death for all causes as secondary event added to prosthetic failure. The results of the Cox regression were expressed using hazard ratios (HRs) with its related 95% confidence interval (CI) and p-value. Differences were considered statistically significant at p

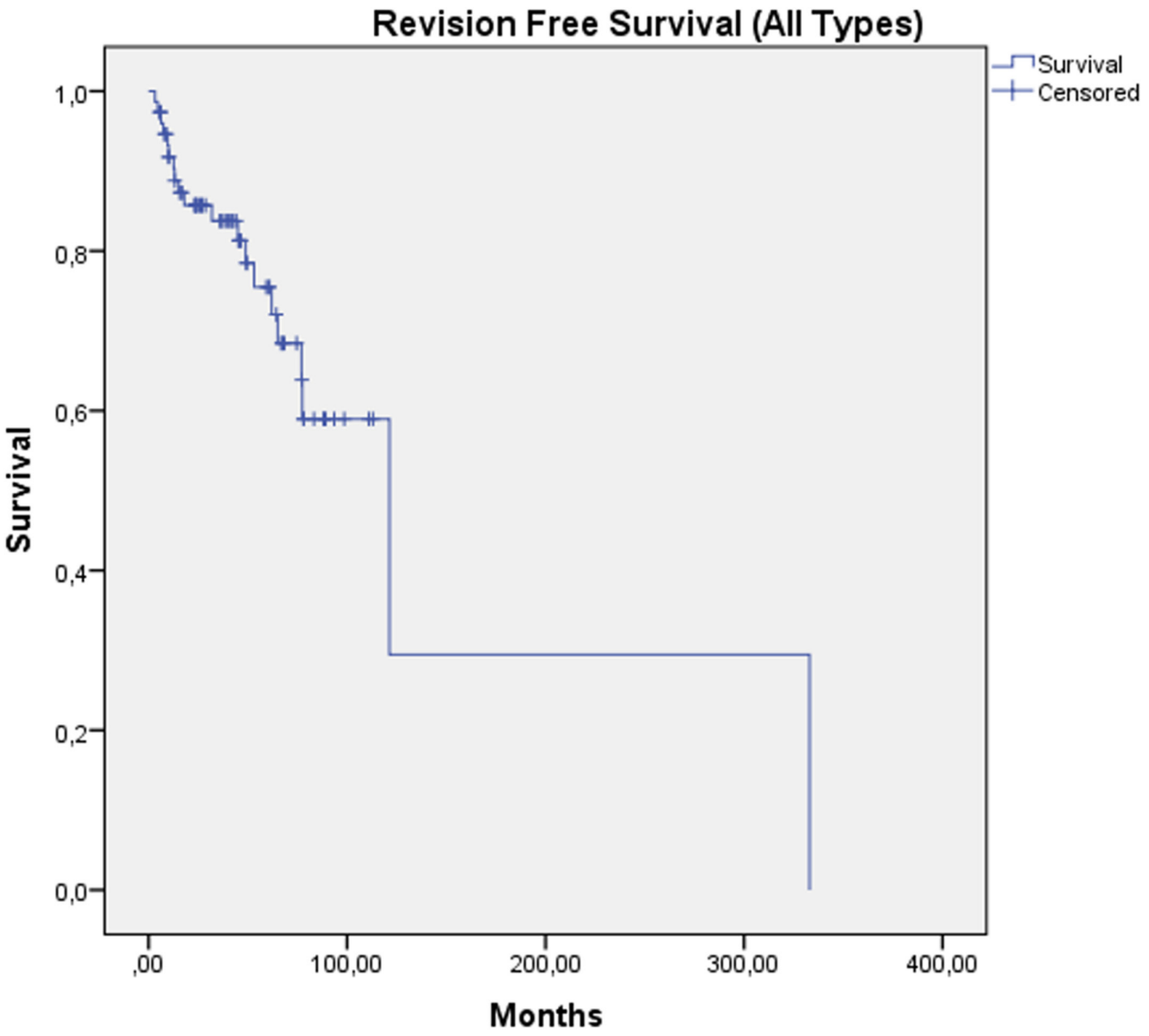

Fig. 1

Overall prosthesis survival (any type of failure).

< 0.05. All analyses were performed using the SPSS v.25 software package (IBM, USA).

Results

A total of 76 patients fulfilled the inclusion criteria and were included in the study. Mean age at surgery was 43.2 years (12 to 86, standard deviation (SD) 21); 38 patients were male and 38 female. The mean follow-up period was 60.1 months (5.4 to 353). At the time of the latest follow-up, 38 patients were continuously disease-free (CDF), 13 were alive with disease (AWD), and 25 had died from the disease. In 68 patients (89.5%), a primary proximal tibial arthroplasty was implanted, while eight patients (10.5%) underwent a revision of a previous failed implant (after treatment of neoplastic conditions). Overall, 67 patients (82.5%) underwent implantation of a modular prosthesis and nine patients (17.5%) underwent implantation of a custom implant. A total of 68 endoprostheses had a rotating hinge and eight had a fixed hinge. All prostheses were cemented. In total, 58 patients (76.3%) had a diagnosis of primary malignant bone tumour, with tibial osteosarcoma being the most frequent, while 14 had metastatic bone disease and four had benign conditions (Table I). In 63 cases (82.9%), a rotational medial gastrocnemius flap was used to cover the prosthesis after implantation; in most cases, the extensor mechanism was reconstructed with direct suture of patellar

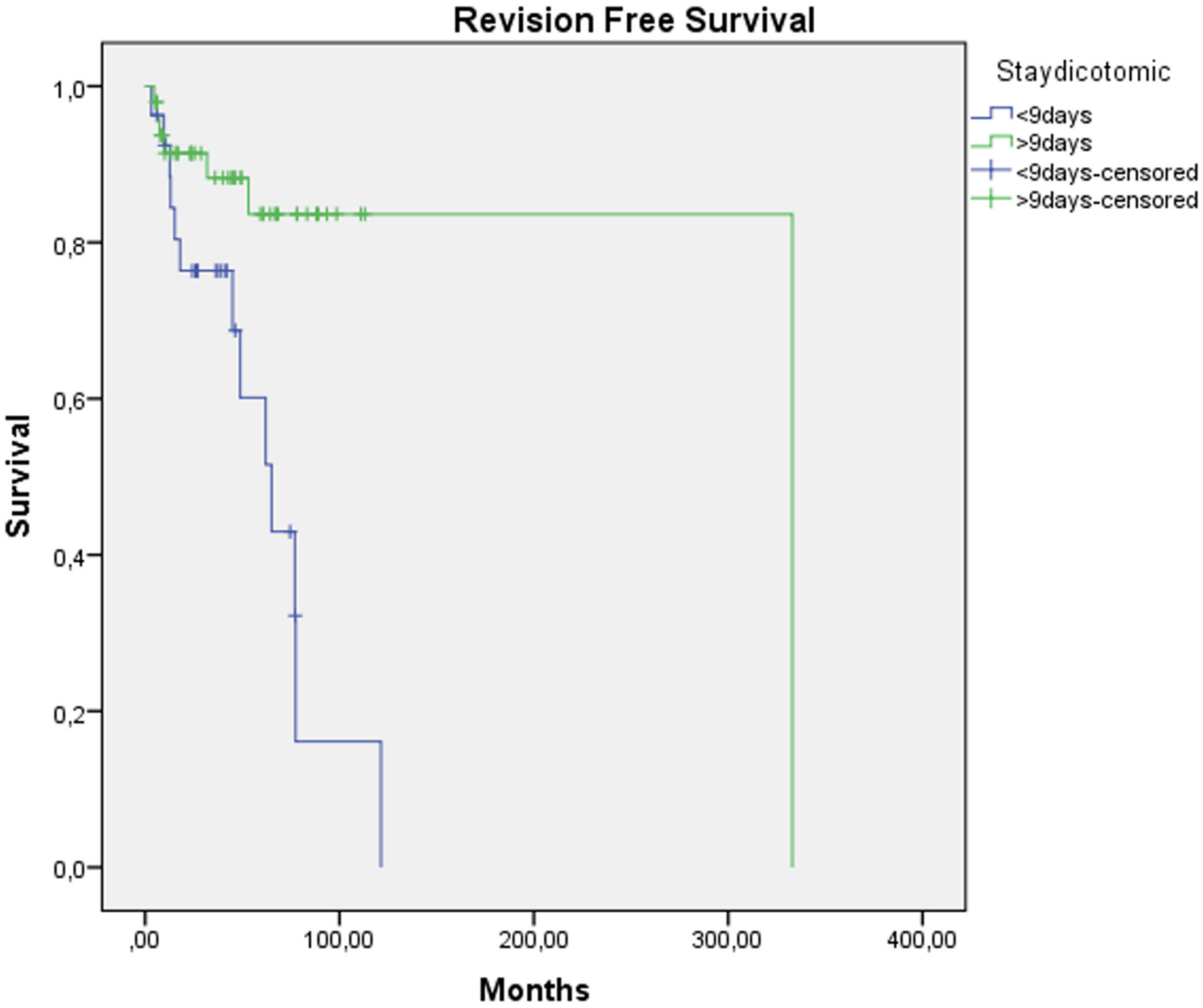

Fig. 2

Overall prosthesis survival stratified by length of stay. 'Stay dicotomic' is a variable which divides the study group in patients who stayed in hospital for less than nine days, and patients who stayed in hospital for more than nine days.

tendon remnant to the distal part of medial gastrocnemius flap (in some cases in addition to a direct suture on a Trevira tube add-on).

Prosthesis survival. A total of 21 failures were identified, giving an overall failure rate of 27.6% (Table II). Prosthesis survival at five years was 75.5%, and at ten years was 59% (Figure 1). Patients' survival at five and ten years was 64.4% and 53.2%, respectively, with 25 deaths over the study follow-up time (33%). At last follow-up, mean knee flexion was 89.8° (SD 36°) with a mean extensor lag of 18.1° (SD 24°).

In univariate analysis, factors associated with better survival of the prosthesis were a malignant or metastatic cancer diagnosis (versus benign), with a five- and ten-year survival of 78.9% and 65.7% vs 37.5% (p = 0.045), while in-hospital length of stay longer than nine days was also associated with better prognosis, with five- and ten-year survival rates at 84% and 84% vs 60% and 16% (p < 0.001) (Figure 2). The time to revision for patients with benign tumour diagnoses was similar to those with malignant diagnoses (mean 48.9 months (SD 12) vs 55.4 months (SD 16)). Rotating-hinge prosthesis showed better outcomes compared to fixed-hinge prostheses, with a five-year RFS to aseptic loosening of 95.8% compared to 53.3% in the fixed-hinge group. However, this trend was not statistically significant (p = 0.072). In multivariate analysis, only in-hospital length of stay was associated with longer survival (HR 0.23, 95% CI 0.08 to 0.66) (Table III). Patients staying less than nine days were younger (mean age 34.8 years (SD 15) vs 47.9 years (SD 23)), had fewer primary procedures (77.8% vs 95.9%), and had a lower mean ASA

Table III. Univariate analysis of risk factors for revision-free survival.

Factor	HR (95% CI)	p-value
Aggressiveness		
(0) malignant primary or metastatic; (1) benign	0.3 (0.08 to 0.9)	0.045
Length of hospital stay		
(0) < 9 days; (1) > 9 days	0.2 (0.08 to 0.59)	0.002
Type of prosthesis		
(0) modular; (1) custom	0.2 (0.02 to 1.5)	0.107
Type of hinge		
(0) fixed; (1) rotating	0.9 (0.2 to 4.3)	0.988
Age		
(0) > 20 yrs; (1) < 20 yrs	1.3 (0.4 to 4.1)	0.618
Sex		
(0) male; (1) female	1.1 (0.4 to 2.6)	0.941
Chemotherapy		
(0) yes; (1) no	2.2 (0.7 to 6.1)	0.136
Reconstruction length		
(0) < 12 cm; (1) > 12 cm	1.3 (0.4 to 3.9)	0.631
Year of intervention		
(0) < 2014; (1) > 2014	0.9 (0.3 to 2.7)	0.873
Type of intervention		
(0) primary; (1) revision	1.2 (0.5 to 2.4)	0.693
ASA grade		
(0) < 2; (1) > -2	0.3 (0.1 to 1.9)	0.535
Radiotherapy		
(0) yes; (1) no	24.3 (0.2 to 27.15)	0.373
Medial gastrocnemius		
(0) yes; (1) no	0.9 (0.2 to 4.3)	0.943
EM reconstruction		
(0) direct suture on MG; (1) others*	2.2 (0.8 to 6.2)	0.116

*Other techniques of reconstruction: Kirschner wires, cerclages, suture on bone autograft, etc.
ASA, American Society of Anesthesiologists; CI, confidence interval; EM, extensor mechanism; HR, hazard ratio; MG, medial gastrocnemius.

grade (1.96 (SD 0.6) vs 2.34 (SD 0.7)). A competing risk analysis was performed focusing on tumour aggressiveness as prognostic factor and death for all causes as secondary event; this analysis confirmed that patients with malignant or metastatic tumour diagnosis had a better prosthesis survival compared to patients who had a benign diagnosis (HR: 95% CI 0.11 to 0.52, p < 0.001).

Discussion

We have shown that proximal tibial arthroplasty with endoprosthesis is a safe and reliable method for reconstruction in patients treated for orthopaedic oncological conditions. Both modular and custom implants in this series performed well.

The overall incidence of prosthesis failures was 27.6% in our series with a five- and ten-year survival of 75.5% and 59%, respectively. Our results are in keeping with other published series (Table IV), in which prosthetic survival at five years ranges from 60% to 94%, and at ten years from 22% to 74%. Grimer et al[4] reported a ten-year survival of only 37% in one of the largest series. The variation in survival rates may be partly explained by the fact that each series had a different definition of prosthesis failure. For this reason, we chose to use the Henderson classification for megaprosthesis failures,[36] which has been adopted as a standard method for reporting outcomes after endoprosthetic reconstruction; to the best of our knowledge, only two other published series have used this system.[9,18]

Our intention in this large study was to review the performance of a particular implant system and therefore the patient group contained a range of diagnoses, and primary or revision surgeries. There were several findings that warrant discussion, including the fact that a benign diagnosis and a shorter stay in hospital (less than nine days) were both associated with higher rates of revision.

Patients with a benign diagnosis had a 37.5% prosthesis survival rate at five and ten years, compared to those with a primary bone tumour or metastatic bone disease who had a five- and ten-year prosthesis survival of 78.9% and 65.7%, respectively. However, the number of patients with a benign diagnosis was small (n = 4) and they all had giant cell tumours of bone. The higher revision rate was for aseptic loosening and might be related

Table IV. Literature review.

Study	Year	Use of gastrocnemius flap	No of patients	Mean FU, mths	5 and 10 yrs survival, %	Mean extensor lag, °	Failure classification
Abboud et al[20]	2003	No	22	24	ND	7.5	ND
Ahlmann et al[21]	2006	Yes	30	37.3	82/52	ND	ND
Albergo et al[9]	2017	Yes	88	114	82/56	13.5	Henderson
Bickels et al[8]	2001	Yes	55	24	ND	ND	ND
Cho et al[32]	2012	Yes (92%)	62	98	--/74	16	ND
Flint et al[22]	2006	Yes	44	60	73/--	7	ND
Griffin et al[47]	2005	ND	25	114	74/68	ND	ND
Gosheger et al[42]	2001	ND	43	45.6	62/--	ND	ND
Grimer et al[4]	1999	Yes (ND)	151	ND	--/37	30	ND
Ilyas et al[23]	2000	Yes	15	42	ND	23	ND
Mavrogenis et al[24]	2013	Yes (87%)	225	56	82/76	12	ND
Müller et al[18]	2016	Yes (26%)	23	62	--/79	11.4	Henderson
Myers et al[29]	2007	Yes	194	176.4	Fixed: 68/39; Hinged: 88/75	ND	ND
Natarajan et al[25]	2003	Yes	133	59.4	85/--	18	ND
Schwartz et al[28]	2010	Yes	52	96	94/86	18	ND
Song et al[19]	2012	Yes (92%)	62	98	--/74	35	ND
Wu et al[30]	2008	Yes	44	84	Custom: 44/22; Modular: 81/65	ND	ND
Wunder et al[16]	2001	Yes	64	ND	ND	ND	ND

--, not available; FU, follow-up; ND, not determined.

to the greater activity and longer patient survival in this group; however, a competing risk analysis confirmed the reduced risk of failure in patients with malignant or metastatic tumour diagnosis even considering death as a secondary event.

Surprisingly, we discovered a relationship between implant survival and in-hospital length of stay. A length of stay longer than nine days was associated with lower revision rates for all types of failure in both univariate and multivariate analysis. When patients staying less than nine days were compared to those staying longer, there was no statistically significant difference in terms of sex, diagnosis, or type of prosthesis. However, in the group of patients staying less than nine days, patients were younger (mean age 34.8 years (SD 15) vs 47.9 years (SD 23)), had fewer primary procedures (77.8% vs 95.9%), and had a lower mean ASA grade (1.96 (SD 0.6) vs 2.34 (SD 0.7)).

Although infection rates in the PT are relatively high, the overall incidence of failure from infection was 6.6%, only the third most frequent cause of failure (Table II). Wound failure is common in this anatomical location and in patients with oncological conditions, and this low rate likely supports the routine use of a medial gastrocnemius flap to provide better soft-tissue coverage. Although Donati et al[15] did not find a major reduction of infection rates with the use of a medial gastrocnemius flap, in a similar UK setting Grimer et al[4] and Jeys et al[33] reported a dramatic reduction of infection rates after its introduction. We cannot make any conclusions in terms of the impact of a gastrocnemius flap on the risk of infection, given that in our cohort only a small number of patients did not receive a flap. Furthermore, we did not find a link between infection and length of resection, use of chemotherapy, and age.

Rotating-hinge prostheses appeared to have better outcomes compared to fixed-hinge prostheses, especially regarding aseptic loosening failures, with a five-year RFS to aseptic loosening of 95.8% in rotating-hinge prosthesis group compared to 53.3% in the fixed-hinge group. However, this trend wasn't statistically significant ($p = 0.072$). We did not show better outcomes for custom-made compared to modular prostheses, although a previous study showed better outcomes linked to modular prostheses.[30]

Finally, failures type II and III, linked to structural failures and aseptic loosening, appear to plateau after five years; on the other hand, infection failures did not show this pattern since there was an increase over time (Table II). Therefore, it could be advisable to keep a high level of infection suspicion during follow-up time for many years. Any change in clinical conditions (i.e. new onset of pain, redness, or oedema) should be investigated in order to exclude any prosthetic infection.

Although not formally assessed, records reported a mean extensor lag of 18° (SD 24°) and a mean knee flexion of 90° (SD 36°). Extensor lag is frequent after proximal tibial arthroplasty and has an important

impact on functional recovery.[38] It has been reported that it is generally worse in endoprosthetic reconstruction than in APC or allograft.[15,17,19,41,48] Several techniques have been proposed for reliable patellar tendon reconstruction.[37] These include adding an autologous bone graft in the interface between the tendon and the prosthesis,[8,49] and transfer of the proximal fibula with its tendon attachment with medial gastrocnemius flap reinforcement.[44] Our technique is similar to that described by Natarajan et al,[25] with a direct suture of the tendon remnants to the gastrocnemius flap; their paper reported an extensor lag of 18°, very similar to ours.

In conclusion, endoprosthetic reconstruction of the PT after tumour resection, using this design as part of a modular or custom system, is a safe and reliable technique, associated with similar failure rates to those in the literature. The routine use of a medial gastrocnemius flap appeared to be reliable and associated with an acceptably low infection rate.

Take home message

- This study showed that endoprosthetic reconstruction of the proximal tibia is a safe and reliable method.
- Both modular and custom prostheses were associated with good clinical outcomes.
- For unclear reasons, patients who stayed in hospital for more time developed fewer failures, especially fewer infections.

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