Original Article

Total femur prosthesis in oncological and not oncological series. Survival and failures

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ABSTRACT

Total femur prosthesis (TFP) can be used in both oncological and prosthetic revision surgery. A retrospective analysis of 32 patients receiving a TFP at a single Center between 2002 and 2018 was performed. The average follow-up was 60 months. Revision implant free survival (RIFS) of the implants was 87% at 5 and 10 years and 72% at 15 years. Overall implant survival (OIS) of the prosthesis was 90% at 5, 10 and 15 years. Complications observed: two soft tissue failures, two infection failure and one tumor progression failure.

1. Introduction

Total femur prosthesis (TFP) was used for the first time in the treatment of massive bone loss.^{1,2} Fields of application are two: oncological reconstructions as limb-sparing procedure to avoid amputation and revision surgery for failures of primary and revision prostheses.³

The first TFP was implanted in 1952 and the second was reported to have been implanted in 1965 using a custom made endoprosthesis in vitallium with good functional results at 6 months.⁴ The first reconstruction with total femur prosthesis after resection of malignant tumors was described by Marcove et al.⁵

It is known that the number of patients undergoing revision of hip and knee prosthesis is dramatically grown and surgeons have to deal reconstructions after massive bone loss.

Hoell et al. defined the oncological indications to implant a TFP: the lack of the great trochanter; the combined periprosthetic infection of the hip and knee with a small intact part of the femoral diaphysis or when the tips of the stems touch; poor quality of the femoral bone diaphysis and inadequate fixation of the stems in the distal and proximal femur. At least 12 cm of bone must be present to ensure adequate fixation of the stem.⁶

The oncological indications could be: involvement for a length greater than 70–80% of the bone segment with or without extension in soft tissue; when less than 12 cm of femoral bone necessary for an adequate fixation of the femoral stem remains; the concomitant

presence of more lesions or skip lesions in the femoral segment.

Designs of TFP are improved³ and several studies described their use, even if with limited numbers.^{2,7–21} Some of these studies reported the results of TFP together with proximal or distal femur mega-prosthesis, becoming difficult to draw conclusions about the specific complications of TFP. To facilitate the definition of megaprosthesis complications, the comprehensive International Society of Limb Salvage (ISOLS) failure-mode classification was published in 2011,²² with modification for expandable reconstructions in 2014.²³

The aim of our retrospective study is to evaluate revision implant free survival (RIFS) and overall implant survival (OIS) of TFP and the complications that can lead to revision and implant failure.

2. Patients and methods

A retrospective analysis of 32 patients undergone total femoral prosthesis (Fig. 1) at a single center between 2002 and 2018 was performed.

All patients gave their consent for the use of clinical information at the time of study admission. 19 female (59%) and 13 male (41%) with a mean age at diagnosis of 54.2 years (range = 13–82) were included.

Twenty-three patients had implanted TFP for oncological reasons. Four Ewing Sarcomas, four chondrosarcomas, four osteosarcomas, one malignant giant cell tumor, one malignant fibrous histiocytoma, one recurrent aneurysmal bone cyst previously treated with curettage and

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Fig. 1. Total femur prosthesis x-ray.

plate, one fibrosarcoma, one pleomorphic soft tissue sarcoma, six metastases (three kidney, two breast and one uterine leiomyosarcoma).

In 20 patients the tumor involved the femoral segment for an extension greater than 75% of the length. TFP was used since one of the two joints of the femur could not be saved. A patient with pleomorphic sarcoma presented size > 20 cm with mass surrounding the femur from proximal to distal with involvement and interruption of cortical bone. Malignant fibrous histiocytoma of soft tissue was treated with excision and postoperative radiotherapy and a TFP was implanted after fracture, non-union of bone and failure of mega-prosthesis of the proximal femur. In one osteosarcoma the tumor was located simultaneously in the proximal and distal femur with pathological fracture. In three metastases a TFP was implanted after progression and failure of intramedullary nail. In four primary tumors (one Ewing Sarcoma, one fibrosarcoma, one chondrosarcoma and one malignant giant cell tumor) the TFP was implanted after failure of the first reconstructive implant (Table 1).

Nine patients implanted a TFP for non-tumoral reasons. Two cases after total knee replacement failure: one after total knee replacement and the other one after knee prosthesis revision and periprosthetic fracture. Five after failure of total hip revisions (four for aseptic loosening and one for infection) and two after revision of both hip and knee prostheses (Table 1).

In twenty-two patients a lateral approach was used, while in eleven a double medial and lateral surgical approach was performed (Fig. 2). The mean surgical time was of 277 min and the average hemoglobin loss was 4.65 points (range = 0.7–8.9).

The knee joint was reconstructed with rotating hinge system in 31 cases, and with fixed hinge in 1 case.

At the hip joint, 12 bipolar heads were used, while the acetabular cup was implanted in 20 cases; 9 press-fit and 11 cemented. 7 with double mobility system and 4 with constrained insert. All implants were Waldemar Link (Hamburg, Germany), except one HMRS Stryker (Michigan, US). Seven prostheses were silver coated (21.9%). Tibial stem was cemented in 27 patients, and cementless in 5.

The average follow-up was 60 months (range = 0–310 months). The data were obtained from the clinical database, prosthetic database, and operating registers of our Center.

Functional results were evaluated with Musculoskeletal Tumor Society (MSTS) score.²⁴ The postoperative complications were

classified according to Henderson Classification.²²

Revision-free implant survival (RFIS) was defined as the time from implantation to the first revision with or without partial replacement of the prosthetic components. Overall implant survival (OIS) was defined as the time from implantation until complete removal of the prosthesis for infection, aseptic loosening, or amputation. The overall limb survival (OLS) was assessed as the time from implantation of Total Femur Replacement to amputation of the limb.

3. Statistical analysis

Categorical variables are presented as total frequencies and percentages; continuous variables are described in means and ranges. Kaplan–Meier analysis was performed to calculate survival rates. Univariate Cox regression analysis was used to identify risk factors and hazard ratios. The information was evaluated with MedCalc Version 19.0.5 and a p-value < 0.05 was considered statistically significant.

4. Results

In 12 patients (37.5%), TFP was the first implant. In the remaining 20 patients (62.5%), a TFP was performed after failure of previously implants. In patients treated for oncologic reasons, 10 patients (43.5%) received chemotherapy before prosthetic implantation, 8 (34.8%) after implants, 10 adjuvant radiotherapy (43.5%), and 6 (26.1%) both adjuvant chemotherapy and radiotherapy. Patients treated with revision implants had an average of 1.28 procedures (range = 1–6) before TFP. Preservation of the extensor mechanism of the lower limb was possible in 30 patients (87.9%). In two patients a TFP was implanted with an arthrodesis component at the knee joint. Both were non-oncological cases. The mean MSTS score in the group before revision or additional procedures was 17 (4–30).

Revision Free Survival (RFS) of the implant using Kaplan – Meier analysis was 87% at 5 and 10 years and 72% at 15 years (Fig. 3). In 3 patients the revision was performed at 5 years, and in 2 patients at 15 years.

Overall Survival (OS) of the prosthesis was 90% at 5, 10 and 15 years (Fig. 4). In 2 patients we observed an implant failure at 5 years, and in one patient at 15 years. Complications observed in 5/32 patients (15.6%) required a total of 9 further operations (Table 2).

Henderson classification type 1 failures (soft-tissue failures) were observed in 2 patients. In one patient, superficial wound infection by *Staphylococcus Epidermidis* was found and surgical debridement with antibiotics therapy after one months from index surgery was performed. In a second patient with culture negative wound dehiscence, a debridement was performed. In both cases the wound healed uneventfully.

Type 2 failure (aseptic loosening) and Type 3 failure (structural) were not observed in our series.

Type 4 failures (deep infection) were observed in 2 patients. They were managed with long-term suppressive antibiotics but eventually, hip disarticulation was required in both cases.

In one case infection was sustained by *E Coli* and in the second by *Staphylococcus Aureus*, *Enterococcus Faecium* e *Pseudomonas Aeruginosa*.

The incidence of hip dislocations was 6.3% (2 patients). One was treated with closed reduction without surgery and it was not considered among failures, one with concurrent infection was considered and treated as type 4 failure.

All infections occurred late (more than 24 months) at a mean of 130 months, 33 months in one case and 227 in the other one.

The distribution of silver-coated implants was comparable between the revision surgery group and the primary implants group (20% vs 25%). 25% silver coated total femur prosthesis as first implant, 20% as revision implant.

Type 5 failure (tumor progression) was observed in only one patient treated for malignant Giant Cell Tumor. Although the margins were free

Table 1

Demographic details, diagnosis, indication for the implant, and number of operation before TFP.

	FOLLOW-UP (Months)	AGE	GENDER	DIAGNOSIS	ONCOLOGICAL	PREVIOUS SURGERY
1	152	69	M	Total hip arthroplasty (THA) and Total knee arthroplasty (TKA) revision	NO	- THA - TKA - Removal of THA and implant of cement spacer
2	149	58	F	Chondrosarcoma	YES	- No Previous Surgery
3	69	22	M	Ewing Sarcoma	YES	- No Previous Surgery
4	2	64	F	Uterine Leiomyosarcoma bone metastasis	YES	- Intramedullary nail
5	.172	35	M	Ewing Sarcoma	YES	- Intramedullary nail
6	74	76	F	THA revision	NO	- THA
7	26	51	M	Kidney bone Metastasis	YES	- Distal femur megaprosthesis
8	7	40	M	Malignant Giant Cell Tumor	YES	- Intramedullary nail
9	97	73	M	THA revision	NO	- Proximal femur megaprosthesis
10	153	42	F	Chondrosarcoma	YES	- Proximal femur megaprosthesis - Revision on infected megaprosthesis
11	19	58	F	Malignant fibrous histiocytoma	YES	- Intramedullary nail - Proximal femur megaprosthesis
12	15	30	M	Chondrosarcoma	YES	- No Previous Surgery
13	0	66	F	Breast Bone Metastasis	YES	- Intramedullary nail
14	123	84	F	TKA revision	NO	- TKA - Revision of TKA with megaprosthesis
15	1	42	M	Ewing Sarcoma	YES	- No Previous Surgery
16	141	40	M	Osteosarcoma	YES	- No Previous Surgery
17	56	82	M	Chondrosarcoma	YES	- Intramedullary nail
18	64	73	F	TKA revision	NO	- TKA
19	80	76	F	Recurrence Aneurismal bone cyst	YES	- Curettage, bone, osteosynthesis with plate
20	310	39	F	Osteosarcoma	YES	- No Previous Surgery
21	2	49	M	Ewing Sarcoma	YES	- No Previous Surgery
22	0	13	F	Osteosarcoma	YES	- No Previous Surgery
23	24	67	F	THA revision	NO	- THA - Revision of THA - No Previous Surgery
24	31	50	F	Breast Bone Metastasis	YES	- No Previous Surgery
25	39	59	F	Fibrosarcoma	YES	- Intramedullary nail
26	2	46	F	Pleomorphic sarcoma of soft tissue	YES	- No Previous Surgery
27	2	14	M	Osteosarcoma	YES	- No Previous Surgery
28	36	40	F	THA and TKA revision	NO	- Plate - Second plate - THA - Proximal femur megaprosthesis - TKA - Cement spacer with antibiotics
29	36	66	F	THA revision	NO	- THA - Proximal femur megaprosthesis - Cement spacer with antibiotics
30	29	69	M	Kidney Bone Metastasis	YES	- No Previous Surgery
31	5	64	F	THA revision	NO	- THA - THA revision - Plate femoral diaphysis
32	4	77	F	Kidney Bone Metastasis	YES	- Intramedullary nail

Fig. 2. A medial and lateral surgical approach.

of disease after resection, local recurrence was observed during the first six months. The recurrence required an hindquarter amputation.

At the last follow-up, 3/32 patients (9.4%) had been treated with an amputation. The mean overall limb survival time was 56 months.

Fig. 3. Revision Implant Free Survival at 5-10-15 years.

5. Discussion

The reconstruction of large bone defects of the femur after tumor resection or following the failure of revision prosthetic implants

Fig. 4. Overall Implant Survival at 5-10-15 years.

presents a challenge for orthopedic surgeons. Reconstruction with TFP restores femoral integrity and allows patients to walk. In TFP the functional capacity, even if reduced, is always higher than that obtained with hip disarticulation.²

In this study we investigated the OS and RFS of implants on a series of 32 total femur prostheses and the different types of failure classifying them according to the comprehensive ISOLS failure-mode classification.^{22,23}

In our study, RFS of total femur prosthesis was 87% at five years and 72% at 15 years, and OS of the implant was 90% at five, ten and fifteen years. Only 3 patients underwent amputation. Meddellin et al. observed revision-free survival at five years and ten years of 71% and 63%, respectively.³ Sewell et al., using the same Classification system, reported 33% failure rate and RIFS of 56% at 5 years.²¹

Our study has several limitations. First limitation is the number of implants in our series, but indication for TFP is rare in oncological and revision surgery. Second limitation is the series with different types of tumoral conditions with different prognoses. Third limitation: different resections of the soft parts were performed with different degrees of implant stability during the 16-year interval of our study. It is also difficult to refer to a guideline when a TFP is implanted since it requires simultaneous hip and knee replacement together with the extensive removal of soft tissues of the thigh.

In literature infection rates in TFP range from 3%²⁰ to 22%.² In our study it was 6.2%. Infection is the most common cause of implant removal.^{19,25} Hardes et al. reported a 17.6% infection rate in the titanium group and 5.9% in the silver-coated group in a series of 51 patients with tumor implants.²⁶

We observed only 2 deep infections which were treated with long-term targeted antibiotic therapy without a favorable outcome. In both cases the limb was not saved, requiring hip disarticulation. In one case the amputation was the primary surgical procedure for the infection. In the second case the amputation was performed after 5 revision procedures and the last of them with a silver coated total femur prosthesis. Meddellin et al. reported 18% of infections on a series of 81 patients without differences between cancer and non-cancer patients and without finding an increased risk of infection in patients undergoing radiation and chemotherapy.³ Knee prosthesis revision had a greater risk of infection and an adequate coverage with soft tissue of the implant was considered an important factor to prevent possible infections.²⁷ Similar percentages have been reported by other authors in their series.^{18,28,29}

The main factors that can influence the survival of the prostheses are previous procedures, extent of the wound and size of the implant. Friesecke et al. reported a median of 3.7 previous procedures in TFP with increased risk of infection and failure.³⁰ Meddellin et al. reported a risk of infection in patients with previous intervention three times higher than in primary implant (8% vs 25%; $p = 0.001$).³ Our lower inferior infection rate may be linked to a lower number of surgical procedures, median of 1.28 procedures (1–6) before total femoral

Table 2
Type of complications observed according to Henderson Classification.

SURGICAL COMPLICATION HENDERSON CLASSIFICATION	DIAGNOSIS	ONCOLOGICAL	DESCRIPTION	THERAPY	RIFS	OIS
1	Osteosarcoma	YES	Superficial wound infection (Staphylococcus Epidermidis)	Antibiotics therapy and debridement	141	145
1	Kidney Carcinoma Metastasis	YES	Superficial wound failure	Debridement	1	4
4	Knee Prosthesis Revision	NO	Deep infection (E. Coli)	long-term suppressive antibiotics, afterwards amputation	33	33
4	Osteosarcoma	YES	Deep infection (S. Aureus, E. Faecium and P. Aeruginosa)	long-term suppressive antibiotics, afterwards amputation	227	287
5	Giant Cell Tumor	YES	Tumor progression	Amputation	4	4

implantation.

The same authors did not report a reduction in the infection rate after silver coated implants.³ Other authors have pointed out that the reduction in the silver concentration occurring after two years from implantation, entails similar risks of late infection.³¹ In our limited experience the use of silver coated TFP did not contribute to prevent or cure the infection.

Structural failure and soft tissue failure depend on the characteristics of implant. Previous studies documented that the use fixed knee hinges avoids axial instability.¹¹ In contrast, Medellin et al. actually observed a double failure rate in fixed hinge implants compared to rotating hinge (11% vs 5.3%).³ In our series, we did not observe axial instability in 31 rotating hinge implants, indeed in our opinion rotating-hinge knee prostheses offer stability and a fair amount of rotation with functional advantages compared with a fixed hinge.

Friessecke et al. did not find clear advantages and disadvantages using rotating or fixed hinge at the knee implants in a series of 100 patients. However, they believe that a constrained, axially guided prosthesis should be used rather than a stabilized surface replacement and that only a constrained prosthesis can provide adequate stability of the knee.³⁰

In our series we did not observe patellar pain or patellar instability. We did not observe aseptic loosening of tibial stems and acetabular components, despite the aseptic loosening is reported in the literature with percentages ranging from 2.4 to 15.4% for cemented stems and from 0% to 8% for cementless implants.²⁹

We did not observe type 3 failures linked to structural breakages. Toepfer et al. reported only 2 failures of type 3. Structural failures are reported particularly at the level of the hinged-knee joint. The incidence of prosthetic component failures in megaprothesis reported from 0% to 7.7% with lower incidence in TFP than proximal femur and distal femur implants. This aspect could be related to the absence of diaphyseal femoral stems which is a well known cause of failure of megaprothesis. Furthermore the reduced mobility and activity in the population carrying a TFP is another reason for the lower percentage of breakages of prosthetic components.²⁹

A reduction in hip dislocation of about 6.5 times was reported with the use of the bipolar head compared to the cemented acetabular components or small diameter heads.³ Unfortunately the bipolar heads are associated with long-term acetabular failure resulting in protrusio acetabuli or lateral erosion of the acetabulum, as reported by Chandraseker et al. They reported failures after 10 years suggesting that bipolar heads in TFP implants should only be used if life expectancy is less than 10 years.³² Hip instability and long term durability can be achieved with the new generation implants with dual mobility components.

We observed two type 1 failures due to wound dehiscence resolved with wound debridement and antibiotic therapy, but no differences of hip stability were observed between 20 patients with acetabular cups and 12 patients with bipolar heads. We observed only two hip dislocations, one treated with closed reduction without surgery and the other after infection and classified as a type 4 complication. In one case we had used a cemented constrained cup, in the second case a dual mobility cup.

The low number of dislocations could be related to the accurate closure of the capsule around the prosthetic neck and to the suture of the residual soft tissue. Postoperatively, a pelvic brace limiting the rotation with controlled flexion was always used for 4 to 12 weeks.

Bickels et al. reported that acetabular preservation, capsule repair, and reconstruction of the adductor mechanism can reduce hip dislocation.³³ Ruggeri et al. stressed the importance of the accurate surgical closure of the capsule and the reinforcement of soft tissues to avoid the need for acetabular replacement.¹⁹

Even Putman et al reported low percentages of dislocations (2/29 or 6.9%) probably due to the almost systematic use of dual mobility implants.³⁴ Dual mobility showed great utility in tumor resections.^{35,36}

In our experience we usually reattach the abductors muscles directly to the prosthetic implant. In alternative TREVIRA tube or LARS can be a useful tools to stabilize the residual soft parts to the prosthetic body in cases of extensive loss of muscular components, although there is the concern to increase the infection risk.

We also remember how in this surgery the removal of the fibrous tissue result of previous operations can be limited by the amount of soft tissues needed to cover the prosthesis itself. This could lead to limb length discrepancy caused by the contracture as reported in three cases by Sevelde et al.²⁸

Type 5 complication was observed only in one patient treated for malignant giant cell tumor. Ruggeri reported amputation as treatment after local recurrence in patients with total femur implant.¹⁹ The possibility of saving the limb after local recurrence is low due to the potential contamination of the entire thigh.¹⁶ This aspect is also related to the histotype and staging of different tumors.

In conclusion TFP offers better functional results than amputation and represents valid option in limb salvage surgery after total or subtotal oncological resection of the femur, and in prosthetic revision surgery when the quality of the residual bone does not guarantee adequate fixation of the prosthetic stem. Infection is the most fearsome complication and the number of previous surgeries is a risk factor. The use of rotating hinge system allows for adequate stability at the knee level. We did not observe aseptic loosening of acetabular component. Bipolar heads and dual mobility acetabular components provided adequate stability of the hip joint.

Declaration of competing interest

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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