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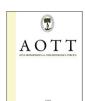
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Modular cementless prosthetic reconstruction after resection of lower extremity malignant tumor

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ABSTRACT

Introduction: The aim of the study is to report the preliminary clinical and functional outcomes of a modular cementless tumor resection prosthesis system (Megasystem-C®, Waldemar Link GmbH&Co. KG, Hamburg, Germany) in patients undergoing limb salvage surgery with wide resection in a lower extremity primary or metastatic malignant bone tumor.

Material and methods: Fifty-two consecutive patients (33 male and 19 female; mean age 37.1 years (range, 16 to 79) with primary or metastatic lower extremity malignant bone tumor who underwent wide resection and reconstruction with cementless Megasystem-C[®] system were included in the study. Patients were analyzed for age at diagnosis, gender, type and localization of the tumor, time of follow-up, patient and prosthesis survival, complications, oncological and functional outcomes.

Results: Mean follow-up time was 43.2 months (range, 8 to 66). Cumulative patient survival rate was 92.3 percent and cumulative prosthetic survival rate was 65.4 percent. 18 complications were recorded and 9 of them required revision (17.3 percent). Mean overall Musculoskeletal Tumor Society score score was 72.7 percent (range, 52 to 86). Subgroup analyzes demonstrated no difference in complication rates, overall patient or prosthetic survivals. Functional scores according to age, diagnosis and location of the reconstruction also were not significantly different.

Conclusion: The preliminary short-term follow-up results revealed that, the new generation modular cementless endoprosthetic system offers promising clinical and functional outcomes with reasonable complication rates.

Level of evidence: Level IV, Therapeutic study

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Introduction

The life expectancy of patients with malignant bone tumors increased after improvements in the knowledge for tumor biology, advances in diagnostic abilities, adjuvant treatment modalities and surgical techniques. ^{1,2} Because of this, functional status of the patient becomes a major issue in the treatment. Limb-salvage surgery offers better functional outcomes and quality of life without a reduction in survival or an increase in morbidity when compared to amputation. ^{3–6} Selection of the type of limb-salvage procedure is based on the tumor location and the patient

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characteristics with aiming a durable reconstruction and favourable functional outcomes. $^{7-9}$

Endoprosthetic reconstruction is a reliable option in periarticular tumor resections. It provides component modularity, improved fixation, near anatomic appearance and good-to-excellent functional results. 10–13 Modular endoprosthetic systems have either cemented and cementless stem fixation options. Early reports stated that, cemented modular systems were associated with intermediate to long-term problems of aseptic loosening, mechanical breakage and infection with high failure rates. 14–16 Thereof, cementless stems have gained acceptance in limb sparing surgery to minimize the risk of failure. Recent studies demonstrated that, cementless prosthetic systems have favourable outcomes in terms of infection and aseptic loosening. 17–19

The aim of this prospective case series is to report the preliminary clinical and functional outcomes of a modular cementless

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tumor resection prosthesis system with titanium tapered stem that has splines for cementless fixation.

Patients and methods

After obtaining institutional review board approval, we prospectively followed our patients who underwent limb reconstruction with the Megasystem-C® modular prosthesis system (Waldemar Link GmbH&Co. KG, Hamburg, Germany) after wide resection of a lower extremity malignant tumor, starting in 2008 up until 2012, in our institution. Inclusion criteria were to have malignant primary or metastatic tumor in femur and tibia which was histologically proven by biopsy, reconstruction with cementless stem fixation and prosthetic replacement as a primary reconstructive procedure. Patients with pelvic tumor, reconstruction with cemented stem fixation, reconstruction with a different modular prosthetic system and prosthetic replacement after a previously failed reconstructive surgery were excluded.

Fifty-two consecutive patients with primary or metastatic lower extremity malignant bone tumor who underwent wide resection and reconstruction with cementless Megasystem-C® system were included in the study. Mean age at diagnosis was 37.1 years (range, 16 to 79). There were 33 male and 19 female patients. Twenty nine of the patients had a right-sided and twenty-three of them had a left-sided tumor. Diagnosis was osteosarcoma in 17, metastatic disease in 11, Ewing sarcoma in 7 patients, giant-cell tumor in 5 patients, chondrosarcoma in 5 patients, multiple myeloma in 3 and liposarcoma, leiomyosarcoma, synovial sarcoma and neurofibrosarcoma in one patient each. Average follow-up time was 43.2 months (range, 8 to 66).

The reconstruction was in proximal femur in 18 patients, distal femur in 18 patients, proximal tibia in 10 patients and total femoral replacement in 6 patients. Detailed description of patient information including demographics is summarized in Table 2.

Patients were analyzed for age at diagnosis, gender, type and location of tumor, follow-up time, patient and prosthesis survivals, complications such as infection, dislocation, implant failure, aseptic loosening and soft-tissue related problems, oncological and functional outcomes.

Functional outcomes were determined with the revised Musculoskeletal Tumor Society (MSTS) rating scale.²⁰ Failure of reconstruction was classified as described by Henderson et al (Table 1).²¹ According to this, failed reconstruction was defined as a reconstruction that required revision of the complete or failed portion of prosthesis, fixation of a periprosthetic fracture, soft-tissue reconstruction to restore joint stability such as instability, tendon rupture or aseptic wound dehiscence or endoprosthetic removal without revision and amputation.

Statistical analyzes were performed with the SPSS statistical software package (version 20.0; SPSS, Chicago, Illinois). Kaplan—Meier analyzes were used to determine the patient and prosthesis survivals. Chi-square tests were used to determine a significant difference between overall, region, age or diagnosis-specific complication rates. Kruskal—Wallis test was also used to analyze overall and region-specific functional scores. For all

Table 1Classification of the mode of failure in tumor resection prosthesis reconstruction as described by Henderson et al.

Type of failure		Description
Mechanical	1	Instability, tendon rupture, aseptic wound dehiscence
	2	Clinical and radiographic evidence of aseptic loosening
	3	Periprosthetic or prosthetic fracture
Non-mechanical	4	Infection requiring removal of prosthesis
	5	Recurrence or progression of tumor

analyzes, a p score less than 0.05 was seeked for a statistical significance.

Results

Survival analysis

At the final follow-up, 48 patients were alive (92.3%) and implants were free of problems in 43 patients (82.3%). Kaplan—Meier survival analyzes revealed that, 5-year cumulative patient survival rate was 91.5% (Fig. 1). With allowing prosthetic removal as an endpoint, 5-year cumulative implant survival rate was 65.4% (Fig. 2). There was no significant difference in the region specific prosthetic survivals (p = 0.332).

Oncological outcomes

Histopathologic evaluation have revealed tumor free surgical margins in all of the patients. Despite this, local recurrence or distant metastasis occurred in four patients. There were three patients with local recurrence; an 18 years-old male with osteosarcoma in the distal femur, a 60 years-old male with a lung carcinoma metastasis in the proximal femur and a 61 years-old male with a rectum carcinoma metastases in the distal femur. These patients were dead at the 22nd, 13th and 8th month, respectively, due to heavy metastasis. The fourth patient was a 16 years-old male with Ewing sarcoma in the proximal tibia with lung metastasis. The patient was dead 11 months after surgery due to pulmonary failure.

Complications

There was a total number of 18 complications (34.6 percent). The most common complications were infection (13 percent) and soft-tissue related problems (11 percent). Six patients had softtissue related problems such as simple skin necrosis and aseptic wound dehiscence at the early postoperative period, which were all treated with debridement and skin grafting, so did not require revision of the prosthesis. Nine patients (17.3 percent) had failure of reconstruction requiring revision. There was no soft-tissue problem (Type 1 failure) requiring revision. There was no aseptic loosening (Type 2 failure) in any patients. The segmental failure of the prosthesis due to design which was classified as structural (Type 3) failure occured in two patients. One of them had proximal femoral and the other had total femoral reconstruction. These two patients were revised at the first and third months, respectively. No periprosthetic fracture or dislocation occurred in any patients. Seven patients (3 distal femur, 3 proximal tibia and 1 proximal femur) had periprosthetic infection (Type 4 failure) which was successfully managed with two-staged revision surgery. First, prosthesis removed, antibiotic-loaded spacers implemented and proper parenteral antibiotic administrated. After eradication of infection, second stage was performed with modular endoprosthesis. All of these seven patients were infection free at the latest follow up. Local tumor recurrence was observed in three patients (Type 5 failure). Distribution of complications according to the type of reconstruction and diagnosis are summarized in Tables 3 and 4.

Functional outcomes

Mean overall MSTS score of the study cohort was 72.7 percent (range, 52 to 86). Functional scores of patients with different anatomical regions are summarized in Fig. 3.

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