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ORIGINAL ARTICLE

Functional and radiographic outcome after tumor limb salvage surgery using STANMORE megaprostheses

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Summary

Purpose: *To report the clinical and radiological outcome of limb salvage surgery with the STANMORE® megaprostheses.*

Methods: *We retrospectively studied 33 patients with musculoskeletal tumor limb salvage surgery using STANMORE® megaprostheses. Clinical evaluation was done using the Enneking and the Toronto Extremity Salvage Score (TESS). Radiographic evaluation was done using the International Society of Limb Salvage (ISOLS) score.*

Results: *At a mean follow-up of 18 months, 21 patients were alive with no evidence of disease and two patients were alive with metastatic disease; 9 patients died of metastatic disease and one patient of causes unrelated to the primary tumor. Local recurrence was not observed in any of the patients. The mean Enneking and TESS scores were 76 and 88.4%, respectively. The ISOLS score was excellent or good in 30 cases for bone remodelling, 30 cases for the interface, in 30 cases for anchorage, in 32 cases for the implant body, and in 33 cases for the articulation. Extracortical bone bridging greater than 25% was observed in 8 prostheses. Mechanical survival of the megaprostheses was 97% (32 megaprostheses). Complications included seroma and hematoma formation (12%), skin necrosis and dehiscence at the knee wound (9%), aseptic loosening and infection (6%), quadriceps tendon rupture and peroneal nerve palsy (3%).*

Conclusion: *The local recurrence-free survival in this series supports limb salvage surgery. The 97% survival rate of the megaprostheses suggests that the STANMORE® modular megaprostheses are valuable for reconstruction of bone defects after tumor resection.*

Key words: limb salvage, megaprostheses, megaprosthetic reconstruction, outcome, STANMORE®

Introduction

The goal of oncological surgery is to achieve complete tumor excision to optimize survival and minimize the risk of recurrence. Compared to amputation, limb salvage surgery does not compromise oncological principles [1], however, reconstruction of bone defects remains a challenge. Options for reconstruction after tumor excision include biological and megaprosthetic reconstruction, such as custom-made megaprostheses, osteoarticular allografts, allograft-prosthesis composites, arthrodesis, and rotationplasty at the knee joint [2-5]. Currently, limb salvage surgery and megaprosthetic reconstruction has become the method of choice to restore function and optimize patients' satisfaction since it provides early mobility, stability, improved quality of life, cosmetic appearance and emotional acceptance [3,4,6-10]. Compared to biological reconstructions, megaprostheses allow for early postoperative adjuvant treatments and a more predictable outcome [11].

Current improvements in implant materials and metallurgy have greatly increased the indications and durability of modern megaprostheses; custom-made and modular megaprostheses have been used to replace the femur, the hip joint, part of the pelvis, the knee joint, the humerus and shoulder joint, and parts of the ulna and radius in patients with malignant bone tumors and those with benign and aggressive but destructive bone lesions unsuitable for simple bone grafting. In addition, megaprosthetic reconstruction is justifiable in patients with poor prognostic factors, such as metastatic disease, multiple myeloma or pathological fracture at presentation [3,4,9,10,12].

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Many studies have investigated megaprostheses' survival rates after tumor resection, but the results cannot be summarized and systematic review cannot be performed, mostly because of the small number of patients and the different types of megaprostheses used. In this study we report the clinical outcome and complications from oncological management of patients with lower and upper extremity primary and metastatic bone tumors and soft-tissue tumors involving the bone using limb salvage surgery and reconstruction with the STANMORE® megaprostheses.

Methods

We retrospectively studied the files of 33 patients with musculoskeletal tumors treated with limb salvage surgery and reconstruction using STANMORE® modular megaprostheses (Stanmore Implants Worldwide Ltd, Middlesex, UK). There were 21 men and 12 women with a mean age of 49.4 years (range 15-77). Histological diagnoses included primary and metastatic bone tumors and soft-tissue tumors invading the bone; neoadjuvant and adjuvant treatments were administered as indicated (Table 1). All patients gave written informed consent to be included in this study. This study was approved by the Institutional Review Board/Ethics Committee of the authors' institution.

Standard techniques and oncological principles for wide tumor resection were used. The resection length was determined preoperatively by radiographs and computed tomography scans. All patients had wide tumor resection as confirmed by postoperative histological margins. Thirteen patients had distal femoral replacement, 11 had proximal femoral replacement (Figure 1 A,B), 3 had total femoral replacement, 2 had megaprosthetic knee reconstruction (Figure 2 A-C), 1 had proximal tibial replacement, 2 had total scapular replacement and reverse constrained humeral arthroplasty, and 1 had proximal humeral replacement. The

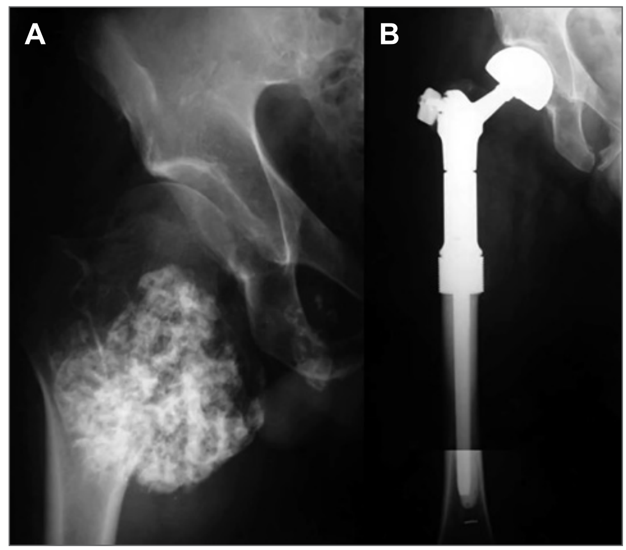

Figure 1. A: Radiograph of the right hip of a 45-year-old man with a grade 2 chondrosarcoma of the proximal femur (Patient 9). **B:** *En bloc* tumor resection and reconstruction with a bipolar proximal femoral megaprosthesis was done; 28 months postoperatively, the patient is alive with no evidence of local recurrence or distant metastases.

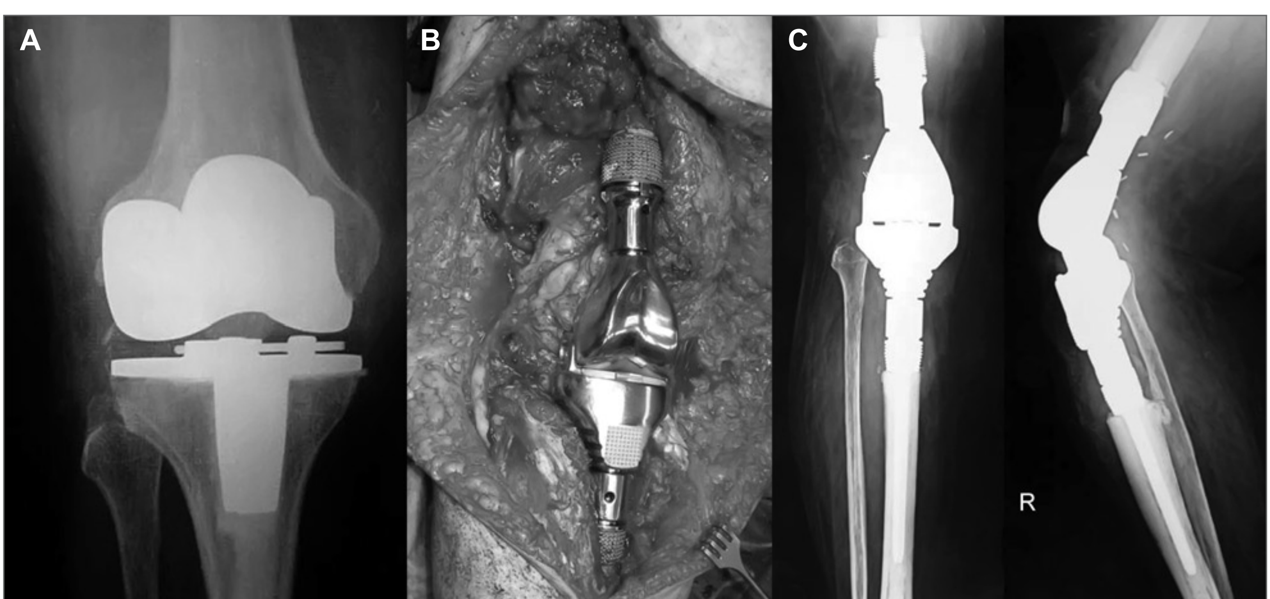

Figure 2. A: Radiograph of the right knee of a 69-year-old woman with synovial sarcoma of the knee initially misdiagnosed as arthritis (Patient 23). **B:** Extra-articular resection and **C:** reconstruction using a megaprosthetic knee joint was done; 14 months postoperatively, the patient is alive with no evidence of local recurrence or distant metastases.

Table 1. Details of the patients included in this study

Patient no.	Age sex	Tumor, location	Preop treatments	Megaprosthesis, length of resection (cm)	Postop treatments	Complications/ Re-operations	LR	Metastases	FU	MSTS scale (%)	TESS score (%)
1	16, M	Osteosarcoma, distal femur	Chemotherapy (4 cycles)	DF, 21.8	CT	Skin necrosis, dehiscence (knee wound) /Debridement, gastrocnemius flap coverage (healed)	–	–	NED (60 months)	Excellent (89)	98
2	56, M	Chondrosarcoma, distal femur	–	DF, 17.9	–	Limb-length discrepancy 2 cm	–	–	NED (54 months)	Excellent (87)	98
3	51, F	Metastatic renal cell carcinoma, distal femur	Chemotherapy	DF, 13.8	CT	Quadriceps tendon rupture/Tendon reconstruction using graft jacket	–	Spinal metastases (operated, infection, local spine recurrence)	DOD (49 months)		
4	70, M	Leiomyosarcoma, left groin, invading the proximal femur	Radiation therapy	PF, 15.7		Aseptic loosening (asymptomatic), seroma/Aspiration and antibiotics	–	Metastatic colon cancer	DNED (31 months)		
5	48, M	High grade soft tissue sarcoma, anterior thigh, invading the shaft of femur	Chemotherapy (4 cycles)	TF, 37	CT	Thoracotomy for lung metastases	–	Lung metastases	DOD (8 months)		
6	15, M	Osteosarcoma, distal femur	Chemotherapy (4 cycles)	DF, 31.9	–	Peroneal nerve palsy (recovered), hematoma/Aspiration and antibiotics	–	–	NED (36 months)	Excellent (85)	89
7	57, M	Ewing's sarcoma, scapula	Chemotherapy (4 cycles)	TS-reverse constrained shoulder prosthesis, (Tikhoff-Linberg type IV)	CT		–	Lung metastases	DOD (20 months)		
8	70, M	High grade liposarcoma, anterior thigh, invading the shaft of femur	–	TF, 34.8	–	Hematoma/Aspiration and antibiotics	–	–	NED (29 months)	Moderate (60)	79
9	45, M	Grade 2 chondrosarcoma, proximal femur	–	PF, 15.7	–		–	–	NED (28 months)	Excellent (85)	93
10	62, F	Dedifferentiated chondrosarcoma, distal femur	–	DF, 16.9	–	Resection of scull metastases	–	Scull and lung metastases	DOD (25 months)		
11	50, F	Multiple myeloma, proximal femur (failed internal fixation)	Chemotherapy	PF, 21.7	CT		–	–	NED (12 months)	Excellent (85)	89
12	77, M	Dedifferentiated chondrosarcoma, proximal femur, pathological fracture	–	PF, 26.2	CT		–	Lung metastases	DOD (3 months)		
13	40, M	Metastatic renal cell carcinoma, distal femur	Chemotherapy	DF, 19.9	RT	Aseptic loosening (asymptomatic)	–	–	NED (22 months)	Excellent (87)	95
14	19, M	Ewing's sarcoma, distal femur	Chemotherapy (4 cycles)	DF, 18.4	CT		–	Soft tissue metastases in the ipsilateral leg	NED (22 months)	Excellent (87)	98
15	62, M	Malignant fibrous histiocytoma, distal femur	–	DF, 16.2	CT	Infection, loosening/Debridement and antibiotics, need re-operation	–	–	NED (12 months)	Fair (50)	81
16	73, F	Metastatic neurofibrosacoma of the sciatic nerve, distal femur and proximal tibia	–	DF-PT, 19.5	Denied CT		–	Lung metastases	DOD (7 months)		
17	51, F	Metastatic breast carcinoma, proximal femur	–	PF, 20.7	–		–	–	NED (20 months)	Excellent (93)	100

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Patient no.	Age sex	Tumor, location	Preop treatments	Megaprosthesis, length of resection (cm)	Postop treatments	Complications/ Re-operations	LR	Metastases	FU	MSTS scale (%)	TESS score (%)
18	70, M	Metastatic carcinoma of the prostate, femur	Cytotoxic and hormonal chemotherapy	TF, 35.2	–		–	Distal tibia and foot metastases	19 months	Fair (57)	70
19	51, F	Parosteal osteosarcoma, proximal tibia and fibula	–	PT, 16.5	CT		–	–	NED (17 months)	Moderate (60)	79
20	50, M	Metastatic lung carcinoma, proximal femur	Chemotherapy	PF, 11.1	CT		–	Lung metastases	DOD (3 months)		
21	16, M	Ewing's sarcoma, distal femur	Chemotherapy (4 cycles)	DF, 24.4	CT		–	–	NED (15 months)	Excellent (80)	89
22	69, F	Metastatic lung carcinoma, proximal femur	–	PF, 19.6	CT	Mechanical loosening of trochanteric plate fixation/Trochanteric plate and screws removed at 1 year	–	–	NED (14 months)	Fair (54)	94
23	69, F	Synovial sarcoma in total knee arthroplasty	–	DF-PT, 22.2	–	Skin necrosis, dehiscence (knee wound) /Gastrocnemius flap, hyperbaric oxygen	–	–	NED (14 months)	Fair (57%)	66
24	27, M	Osteosarcoma, proximal femur	Chemotherapy (4 cycles)	PF, 17.2	CT		–	–	NED (14 months)	Good (70%)	89
25	35, F	Ewing's sarcoma, proximal femur	Chemotherapy (6 cycles)	PF, 18.7	–	Chemotherapy related complications	–	Lung metastases	DOD (12 months)		
26	49, M	Recurrent giant cell tumor of bone, proximal femur	Previous operations (curettage, bone grafting)	PF, 10.6	–		–	–	NED (14 months)	Excellent (89%)	98
27	33, F	High grade soft-tissue sarcoma, distal thigh, invading the distal femur	Chemotherapy (4 cycles)	DF, 25.9	CT	Seroma, infection/Debridement and antibiotics (healed)	–	Lung metastases (thoracotomy ×2)	13 months	Moderate (60%)	74
28	63, F	Metastatic breast carcinoma, proximal femur	–	PF, 12.7	–		–	–	NED (9 months)	Excellent (87%)	95
29	69, M	Dedifferentiated chondrosarcoma, proximal humerus	–	PH, 20.1	–		–	Lung metastases	DOD (4 months)		
30	40, M	Metastatic lung carcinoma, distal femur	–	DF, 24.4	CT		–	–	NED (6 months)	Excellent (85%)	96
31	52, F	Metastatic breast carcinoma, distal femur	Chemotherapy and radiation therapy	DF, 14.7	CT	Superficial dehiscence (knee wound)/ Wound dressing changes (healed)	–	–	NED (3 months)	Excellent (100%)	85
32	60, M	Metastatic lung carcinoma, scapula	–	TS-reverse constrained shoulder prosthesis, (Tikhoff-Linberg type IV)	CT		–	–	NED (3 months)	Moderate (60%)	89
33	16, M	Osteosarcoma, distal femur	Chemotherapy (4 cycles)	DF, 20	CT		–	–	NED (3 months)	Excellent (80%)	89

DF: distal femoral replacement, PF: proximal femoral replacement, DF-PT: distal femoral and proximal tibial replacement (megaprosthetic knee joint), TS-PH: total scapula and proximal humeral replacement, TF: total femoral replacement, PT: proximal tibial replacement, PH: proximal humeral replacement, LR: local recurrence, FU: follow-up, NED: alive-no evidence of disease, DOD: dead of disease, DNED: dead-no evidence of primary disease, MSTS: Musculoskeletal Tumor Society Rating Scale, TESS: Toronto Extremity Salvage Score, ISOLS: International Society of Limb Salvage CT: chemotherapy, RT: radiotherapy, preop: preoperative, postop: postoperative mean length of bone resection was 20.7 cm (range 10.6-37). A bipolar femoral head was used in all patients in whom a proximal or total femoral megaprosthesis has been used (Figure 3 A,B). Cemented stem fixation was performed in all cases.

Postoperative clinical and radiographic evaluation was done at regular intervals and at the latest examination for the purpose of this study. Follow-up and overall survival of the patients and the prostheses were calculated from the time of surgery to the last date of review or death. Local recurrences and metastases, complications and their management were recorded. The functional outcome was evaluated using the Enneking's system (Musculoskeletal Tumor Society Rating Scale, MSTS) to assess impairment [13] and the TESS to assess disability [14]. The Enneking's system is a subjective non-parametric system that encompasses several functional and emotional domains including pain, overall function, emotional acceptance, use of supports, walking capacity and gait cosmetics. Each parameter is rated as excellent (5 points), moderate (4 points), good (3 points), fair (2 points) or poor (1 point). The points are added, and the functional score is presented as a percentage of the maximum possible score. The results are graded as excellent (75-100%), good (70-74%), moderate (60- 69%), fair (50% -59%), and poor (<50%). The TESS system is a 30-item questionnaire that focuses on the patient's ability to perform activities of daily living. Both systems have been shown to be reliable, valid and responsive [13,14]. Radiological evaluation was performed according to ISOLS [15]; 6 parameters were used, including bone remodeling, interface, anchorage, implant body problem, implant articulation, and extracortical bone bridging.

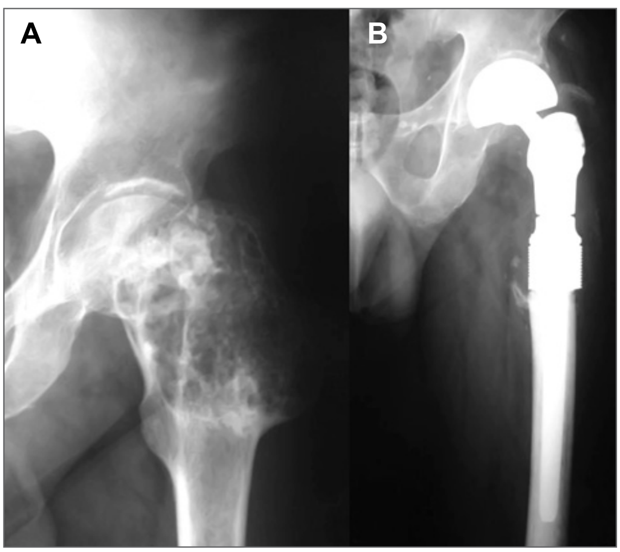

Figure 3. A: Radiograph of the left hip of a 49-year-old man with a recurrent giant cell tumor of the proximal femur (Patient 26). **B:** *En bloc* tumor resection and reconstruction with a bipolar proximal femoral megaprosthesis was done; 14 months postoperatively, there is no evidence of local tumor recurrence.

Results

At a mean follow-up of 18 months (range 3-60), 21 patients were alive with no evidence of disease and 2 patients were alive with metastatic disease; 9 patients had died of metastatic disease and one patient from causes unrelated to the primary tumor. Local recurrence was not observed in any of the patients during the period of this study (Table 1).

Survival of the megaprostheses was 97%; in one patient with proximal femoral replacement for metastatic lung cancer (Figure 4 A,B) mechanical loosening of the trochanteric plate fixation was observed 12 months

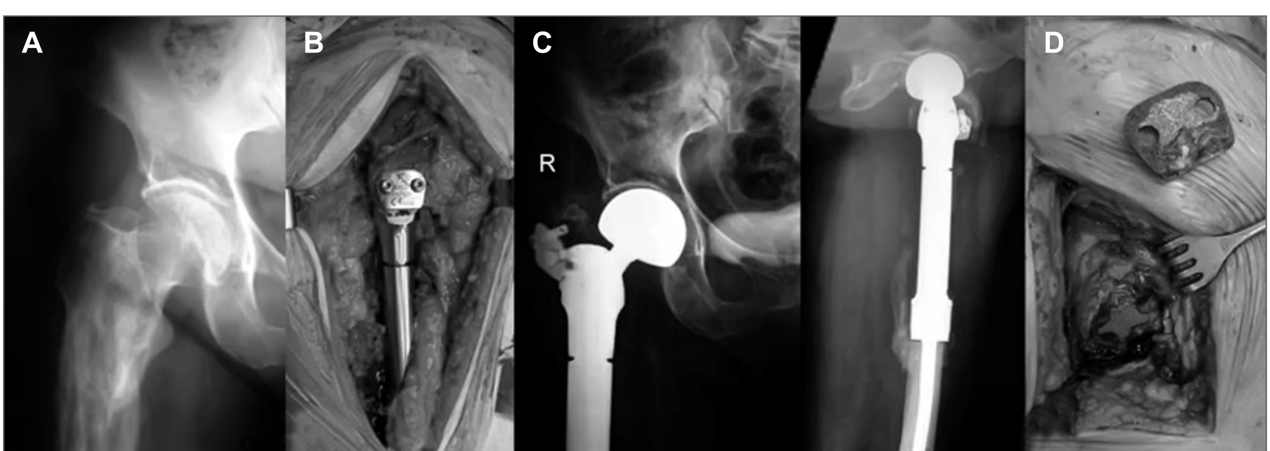

Figure 4. A: Radiograph of the right hip of a 69-year-old woman with lung cancer metastatic to the right proximal femur (Patient 22). **B:** *En bloc* tumor resection and reconstruction using a proximal femoral megaprosthesis. **C:** Mechanical loosening of the trochanteric plate was observed 12 months postoperatively. **D:** The trochanteric plate and screws were removed.

postoperatively (Figure 4 C); the trochanteric plate and screws were removed (Figure 4 D). Aseptic loosening was observed in 2 patients (6%) with proximal and distal femoral replacement due to improper cement technique of intramedullary fixation of the prostheses; in both patients aseptic loosening was asymptomatic and close follow-up was instituted. Infection occurred in 2 patients (6%) with distal femoral megaprostheses; these were treated by surgical debridement and antibiotics administration. Seroma and hematoma formation occurred at the femur in 4 patients (12%), and was treated with aspiration and antibiotic prophylaxis. Skin necrosis and dehiscence at the knee wound occurred in 3 patients (9%) with distal femoral replacement; wound coverage was obtained using the local gastrocnemius musculocutaneous flap in 2 and with wound dressing changes in 1 of these patients. Quadriceps tendon rupture occurred in 1 patient with a distal femoral reconstruction 1 month postoperatively; tendon reconstruction using human regenerative tissue matrix was done, and knee immobilization in full extension for 6 weeks was necessary. At the latest examination, nearly full range of motion was observed without re-rupture. Peroneal nerve palsy occurred in 1 patient (3%) with distal femoral replacement that recovered completely at 6 months.

The mean Enneking score (impairment) was 76% (range, 50-100%); 14 patients (61%) had a score > 80%, corresponding to excellent results. The mean TESS score (disability) was 88.4% (range 66-100). The best postoperative results regarding isolated parameters were achieved with respect to reduction of pain and walking ability, and participation in ordinary living activities. Hip procedures were found to have a higher mean functional score (mean 80.4%; range 54-93) (Table 1).

Excellent or good ISOLS scores were obtained in 30 cases for bone remodelling, 30 cases for the interface, 30 cases for anchorage, 32 cases for the implant body, and 33 cases for the articulation. Extracortical bone bridging of 75% was observed in 6 patients, 50% in 2 patients, 25% in 17 patients, and no extracortical bone bridging in the remaining (Table 2).

Table 2. Radiographic results of the patients included in this study (ISOLS score)

Parameter	*Excellent Patients, n*	*Good Patients, n*	*Fair Patients, n*	*Poor Patients, n*
Bone remodeling	25	5	3	–
Interface	30	–	3	–
Anchorage	24	6	3	–
Implant body	32	–	–	1 (trochanteric plate loosening)
Articulation	33	–	–	–
Extracortical bone bridging	–	6	2	17

Discussion

Long-term survival rates for tumor megaprostheses have failed to reach those of primary total joint replacements [1,3,7,8,10,11,16-19]. Implant-related complications are common, with failure rates of 17-52% at 5-10 years [20,21]. In this study, we evaluated the clinical outcome and complications in tumor patients treated with limb salvage surgery and reconstruction with the STANMORE® megaprostheses. Local tumor recurrence was not observed in any of the patients during this study. Megaprostheses' survival was 97%. One patient required reoperation for an implant-related complication.

The small number of patients, its retrospective design and short to mid-term follow-up may be considered important limitations. However, since randomized controlled studies are difficult in tumor patients, well-controlled studies are useful in evaluating the survival of the currently available megaprostheses. In addition, we did not control for the stem-femur geometry, patients' age, body mass, comorbidities and adjuvant treatments. Nonetheless, our incidence of implant failure and survival is consistent with other published series and represents a valid finding.

Because of the disadvantages of custom-made megaprostheses including the increased production time and lack of intraoperative modularity, modular megaprostheses became popular [18,22-25], and special reconstruction techniques have been developed [26,27]. The STANMORE® megaprostheses have the longest clinical history for primary oncological, metastatic and failed conventional prosthetic indications with a low complication rate [6,22]. First implanted in 1949, it was a custom-made prosthesis with cemented fixation and a single-axis hinged knee joint. Since 1991, a cementless version has been available with a hydroxyapatite-coated titanium stem to enhance extracortical bone bridging and a rotating hinge knee [6,22].

Aseptic loosening is the most common cause of mechanical failure of megaprostheses with a rate up to 31% [3,6,8,23,28,29]. At the distal femur, the risk of loosening significantly increases with the length of resection [6]. Suboptimal press-fit at the anchorage of the intramedullary stem or poor-quality cement fixation in diaphyseal bone, increased torque associated with greater resection length and fully constrained hinges, extraarticular resections with wide soft tissue resection, poor shock absorption of weight-bearing axes, and high activity, that means younger age of the patients, are the most common causes of aseptic loosening [6,7,22,30,31]. Cementless fixation becomes a problem if a very long section is resected, leaving a short proximal or distal remnant [18]. In the present series, aseptic loosening was observed in 2 patients (6%) with a proximal and distal femoral reconstructions that was attributed to improper cement fixation.

Infection rate of primary megaprosthetic reconstructions ranges from 2 to 35% [4,7,18,29,32] and up to 43% after revision surgery [4]. There are many factors that are difficult to control, including the large implant surface exposed to the environment during surgery, the lengthy and extensive open procedures, and the immunocompromised status of the patients secondary to chemotherapy [33]. Several methods have been devised to decrease the risk of infection including hygienic precautions, hydrophilic materials to minimize bacterial adhesion and impregnation with antiseptics and antibiotics, and use of titanium alloys or third generation silver-coated metals [34]. Flap coverage facilitates eradication of the infection and salvage of the prosthesis by providing well-vascularized tissues [35]. Muscle and musculocutaneous flaps such as the latissimus dorsi flap have shown better results compared to other flaps [35,36]. In the present study, skin necrosis and dehiscence at the knee wound occurred in 3 patients (9%). In 2 of these patients, surgical debridement and coverage using a gastrocnemius muscle flap was necessary.

Rupture of the extensor mechanism following proximal tibial resections occurs in 4-15% [3,7,11,30]. Biologic reconstruction is recommended [3] and preservation of the continuity of the extensor mechanism by periosteal elevation. Extracortical bone bridging has been considered responsible for stability of the megaprosthesis [16,22,37]. Others reported that extracortical bone bridging is a common radiological finding but it does not seem to contribute to additional stability [38]. In our series, although we cannot document stability by extracortical bone bridging, in none of the patients with aseptic loosening extracortical bone bridging was observed.

In the present study, 23 patients (70%) had a mean Enneking (impairment) and TESS (disability) functional score > 70% which corresponds to a good or excellent result; these results are consistent with the literature [10,19]. Hip procedures had a lower impairment and higher disability score (mean Enneking score 77%; mean TESS score 90.6%) compared to knee procedures (mean Enneking score 79.8%; mean TESS score 89.4%). The best results were achieved with respect to reduction of pain and walking ability, and participation in ordinary living activities. The Enneking score was only moderately correlated with the TESS score, as the two systems measure different concepts of function. Impairment (Enneking score) [13] is process-oriented and does not account for compensatory actions, while disability (TESS) [14] is goal-oriented such that compensatory actions such as stiff knee gait may affect the end result. These differing measurements would explain why factors such as gait cosmetics and use of supports were poorly related to the TESS.

In conclusion, the local recurrence-free survival in this series supports limb salvage surgery for musculoskeletal tumors of the extremities. Although at short-term, the 97% survival rate of the megaprostheses suggests that the STANMORE® modular megaprostheses are valuable reconstructions with a low rate of complications.

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