Trabecular Metal Endoprosthetic Limb Salvage Reconstruction of the Lower Limb

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Abstract: Currently, porous tantalum (trabecular metal) implants are widely accepted and frequently used for primary and revision hip and knee replacement surgery. This study examines the results of porous tantalum endoprostheses used to reconstruct large skeletal defects following resection of bone tumors. Seven custom tantalum implants were used to reconstruct 7 patients following resection for skeletal sarcomas in the femur and proximal tibia. Patient ages ranged from 13 to 71, with a mean of 34 years. Minimum patient follow-up was 6 years. The average Musculoskeletal Tumor Society functional evaluation score was 95 % of normal. There were no infections, hardware failures, or adverse events. One implant was revised 98 months post insertion because of fibrosis, loss of motion and loosening. In this small clinical series, the use of porous tantalum for limb salvage reconstruction is shown to be safe, to successfully provide osteointegration and soft tissue ingrowth, and to facilitate return of limb girdle muscle function. **Keywords:** trabecular metal, limb salvage, endoprosthesis, megaprosthesis, sarcoma, tantalum.

Limb salvage surgery has become the standard of care for treatment of most skeletal sarcomas. This surgery requires resection of the cancer as well as normal bone and soft tissue to achieve adequate surgical margins. This tumor resection often leaves the surgeon with a large defect requiring extensive reconstructive effort to provide a functional limb. Biologic reconstructions using allografts or autografts have had a long history of use in such surgeries [1,2]. They continue to be mainstays of treatment, but they are fraught with significant complications including nonunion, fracture, donor site morbidity, failure of fixation, prolonged immobilization, and graft resorption. When they occur, these complications often require multiple reoperations. To avoid the risk of graft-related complications, metal endoprostheses have arisen as the treatment of choice in many situations. These large metal implants typically have no suitable attachment for the limb girdle musculature or ligaments. The use of biomaterials to both improve current biologic fixation of implants as well as to withstand the increase in cyclic loading that has arisen from the longer life spans of limb salvage surgery patients have been investigated [3-5]. Examples of these biomaterials include cobalt chrome alloys and titanium. The use of metallic endoprosthesis is complicated by failure due to periprosthetic loosening, wear debris, metal fatigue and failure, and infection [3,6-10].

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This study introduces a novel biomaterial, trabecular metal (porous tantalum, Implex/Zimmer, Allendale, NJ; Warsaw, Ind) as a material for use in endoprosthetic (or megaprosthetic) reconstruction. Early canine laboratory studies comparing porous tantalum to other porous substrates demonstrated that porous tantalum allowed soft tissue attachment and had strength and bone ingrowth characteristics comparable to conventional porous materials while remaining biologically inert [4,5,11]. In this study, 7 custom porous tantalum endoprosthetic/ megaprosthetic arthroplasties were performed in 7 patients after lower limb skeletal sarcoma salvage surgery. This small, retrospective series was reviewed to evaluate whether an endoprosthesis using porous tantalum has potential advantages over conventional designs. The durability of implants using porous tantalum for limb salvage was also examined. This series describes the early use of porous tantalum in large custom implants designed to fill massive skeletal voids following limb salvage surgery.

Materials and Methods

Limb salvage candidates with lower extremity skeletal sarcomas presenting between 1997 and 2000 were evaluated for implantation of porous tantalum implants. Patients were selected based on the availability of custom trabecular implants and chemotherapy scheduling. Because each component was custom designed and made, added additional manufacturing time excluded many patients. Seven patients met inclusion criteria for this study and received custom porous tantalum implants to reconstruct massive bone defects following lower limb salvage resection for skeletal sarcomas.

One proximal tibial implant (patient 3), 1 proximal femoral implant (patient 6), and 5 distal femoral implants were used for limb salvage arthroplasty between April 1997 and October 2000 (Table 1). The index arthroplasty was a primary joint arthroplasty in 6 patients and a revision total knee arthroplasty in 1 patient (patient 7) who developed an osteosarcoma above a loose primary cementless total knee arthroplasty. The 5 men and 2 women ranged in age from 13 to 71 years, with a mean age of 34 years at time of arthroplasty. All but the eldest (patient 7) had preoperative and postoperative chemotherapy, whereas patient 7 had adjuvant chemotherapy.

Prior to limb salvage, the sarcomas were staged following the method of Enneking. The sarcomas were classified as IIB (high grade extracompartmental) in 5 patients and IIA (high grade intracompartmental) in 2 patients [12].

Follow-up ranged from 26 months to 122 months with a minimum follow-up of 6 years in survivors. The mean time of follow-up was 81 months. Six patients remain alive as event-free survivors. Patient 7 died from disease progression at 26 months post arthroplasty and is thus excluded from the long-term results.

Implant Design and Manufacture

Candidate patients were assessed by standard templated radiographs, computed tomography (CT) scans, and magnetic resonance imaging. Surgical margins were planned and preoperative measurements sent to the custom engineers. Once blueprints met final surgeon approval, the implant was manufactured (Implex Corporation), whereas the patient was receiving chemotherapy.

The implant design goals were to fill the skeletal defect, restore joint function, and provide stable

Table 1. Porous Tantalum Patient Data

Patient Number and Sex	1 M	2 M	3 M	4 F	5 M	6 M	7 F	
Age (y) at LSS	37	48	35	9	17	19	71	Range, 9-71
Diagnosis stage	OGS-IIB	MFH-IIB	OGS-IIB	OGS-IIB	OGS-IIB	EWS-IIA	OGS-IIA	
Site	DF	DF	PT	DF	DF	PF	DF	
Mega insertion:	0	0	0	47	0	0	0	
Months after LSS	revision @ 98							
LSS length cm	12	12	10	15	15	15	15	Range, 10-15
Chemotherapy	Periop	Periop	Periop	Periop	Periop	Periop	Postop	
% Necrosis	80	50	20	99	90	99	0	
Months of follow-up	103	72	82	82	108	79	26	Range, 26-108
Outcome	EFS	EFS	EFS	EFS	EFS	EFS	DOD	Min. follow-up, 72 mo
MSTS score (%)	80	97	100	93	100	100	93	$\mu = 95$

LSS, limb salvage surgery; OGS, osteogenic sarcoma; MFH, malignant fibrous histiocytoma; EWS, Ewing's sarcoma; DF, distal femur; PF, proximal femur; DT, distal tibia; EFS, event-free survivor; DOD, dead of disease; Periop, perioperatively; Postop, postoperatively.