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Compressive Osseointegration of Tibial Implants in Primary Cancer Reconstruction

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Abstract Compressive osseointegration technology, which provides immediate, mechanically compliant endoprosthetic fixation, has been adapted for massive proximal tibial reconstructions in an attempt to avoid aseptic failure encountered with conventional stems. A retrospective review of 16 patients with resected tumors was undertaken to determine whether compressive osseointegration can provide durable anchorage of tibial implants. Medical records, radiographs, and clinical examinations were reviewed to assess surgical, local disease control, and prosthetic outcomes. The average age was 18 years (range, 12–42 years). Diagnoses included osteosarcoma (12), Ewing sarcoma (two), chondrosarcoma (one), and undifferentiated sarcoma (one). Minimum followup was 2 years (mean, 4.5 years; range, 2–10.3 years); no patient was lost to followup. There were no local recurrences. Four patients developed metastatic disease; one patient died of his primary tumor, and another died from a chemotherapy-related malignancy. Complications included one early deep infection that ultimately resulted in prosthetic loosening and the need for an above-knee amputation. There were two late deep infections; prosthetic retention was achieved with débridement and antibiotics. One patient developed aseptic loosening and underwent revision; the other 15 implants provided stable osseointegration at last followup. Compressive osseointegration technology can thus achieve acceptable short-term endoprosthetic fixation results and may reduce the risk of aseptic loosening reported with conventional tibial stems.
Level of Evidence: Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

The author certifies that he has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.
The author certifies that his institution has approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.

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Introduction

A good deal has been reported about the outcomes of massive distal femoral endoprosthetic reconstructions after tumor resection. Recent studies have described distal femoral endoprosthetic survivorship at 10 years to range upward of 80% [6, 31, 39]. Less is known about proximal tibial oncologic reconstructive outcomes for a number of reasons. First, although the incidence of proximal tibial tumors ranks next to distal femoral lesions, the latter remain roughly twice as common [48]. Second, amputation is more often necessary for proximal tibial neoplasms because of neurovascular involvement. Third, the comparatively greater challenges posed by the reestablishment of extensor mechanism function after proximal tibial resection have led to the use of a variety of tibial reconstructive methods, including arthrodesis [12], allografts [10, 14, 43], and alloprostheses [5, 17, 51] with relatively fewer endoprosthetic reconstructions. Furthermore, although intermediate-term (ie, 5–10 years) prosthetic survivorship of a variety of distal femoral implants is reasonably predictable and acceptable [6, 33, 41, 45], tibial endoprosthetic reconstruction is more challenging

principally because of the biomechanical demands placed on tibial stems. Two- to 5-year failure rates resulting from aseptic loosening have ranged from 3% to 46% in a variety of series [19, 22, 24, 26, 29, 34, 35].

Compressive osseointegration technology was developed in an attempt to provide secure, long-term anchorage of oncologic endoprostheses by using a spring-loaded device to achieve compliant prestress fixation, thus avoiding complications of stress shielding and particle-induced osteolysis [8, 15, 27, 36]. Initial distal femoral radiographic results have confirmed progressive bone hypertrophy at the prosthetic interface [3] and early clinical comparisons with cemented stems [4] have demonstrated equivalent prosthetic survivorship at 2 years.

For primary tumor proximal tibial resections managed with compressive osseointegration reconstructions, the purposes of this study were to determine (1) the rates of local control and prosthetic survival; (2) the frequency and nature of surgical complications; (3) and the outcome of prosthetic revision.

Materials and Methods

I retrospectively reviewed 16 patients with resected malignancies reconstructed with a proximal tibial Compress® device (Biomet, Inc, Warsaw, IN) between April 1998 and September 2006. There were seven males and nine females with an average age of 18 years (range, 12–42 years). Diagnoses included osteosarcoma (12), Ewing's sarcoma (two), chondrosarcoma (one), and undifferentiated sarcoma (one). Distal femoral Compress® devices, initially introduced in 1993, were granted US Food and Drug Administration clearance in December 2003. On a custom off-label basis, Compress® implants have been available for proximal tibial reconstructions since 1998. The minimum followup was 2 years (mean, 4.5 years; range, 2–10.3 years). No patient was lost to followup. Prior Institutional Review Board approval was obtained for this retrospective review.

Previously published methods of proximal tibial resection and endoprosthetic reconstruction were followed [7, 13, 16, 18, 23, 28, 30, 36, 50]. A sufficient amount of proximal tibia was removed to achieve negative surgical margins. Resection length averaged 17 cm (range, 13–24 cm); remaining distal tibial segments averaged 20 cm (range, 11–25 cm); percentage of tibia resected averaged 46% (range, 35%–65%). The tibial canal was reamed to allow placement of a 10-mm anchor plug and a centering sleeve of at least 12 mm diameter. Compression force (in pounds) was as follows: 400 (five), 600 (10), and 800 (one); two short custom spindles were used. Over time, we have empirically preferred 600-pound small, short hydroxyapatite spindles for tibial reconstructions. Twelve patients underwent extensor mechanism reinforcement and soft tissue coverage with a gastrocnemius flap.

Continuous passive motion of the knee was begun 48 hours after surgery or as soon as permitted by the plastic surgery staff. Quadriceps sets and straight leg raising exercises were begun 2 weeks after surgery, but progressive resistive exercises were not undertaken. In contrast to rehabilitation of patients with cemented stems, for which full weight can be borne immediately, weightbearing on the tibial Compress® implant was withheld for 3 months postoperatively, after which time weightbearing was advanced at a rate of 25% of body weight per week.

Followup visits for routine clinical and radiographic examinations generally occurred at 2, 6, and 12 weeks and at 3-month intervals thereafter. Medical records were reviewed to obtain demographic data, including age, gender, diagnosis, and treatment information. Operative reports were studied to record technical factors, including implant length relative to remaining distal tibial length, compression force, and spindle length. Major complications such as aseptic loosening, infection, local recurrence, periprosthetic fracture, need for further surgery, metastatic disease, and death were recorded. Device-related mechanical failure was defined as the need for revision secondary to aseptic loosening.

I assessed postoperative radiographs at 3- to 6-month intervals for indications of technical error (pin malposition or migration) and for evidence of device-related failure (lucency at the bone-prosthetic interface, endosteal erosion, loss of compression distance, gross loosening, and implant breakage).

Results

There were no local recurrences. Four patients had metastatic disease at last followup. Two deaths occurred; one patient died secondary to osteosarcoma, and one developed myelofibrosis.

Surgical complications included one early deep infection that ultimately resulted in prosthetic loosening and the need for an above-knee amputation. There were two late deep prosthetic infections; prosthetic retention was achieved with débridement and antibiotics. There were two nondisplaced tibial fractures, not associated with the hardware, which were treated nonoperatively. There were no prosthetic fractures or other forms of mechanical breakage. All patients were able to walk without an assistive device.

There was one device-related aseptic mechanical failure of the Compress® device (Fig. 1). At 3.2 years after the index procedure, revision to a slightly longer Compress® tibial replacement was successfully accomplished. All

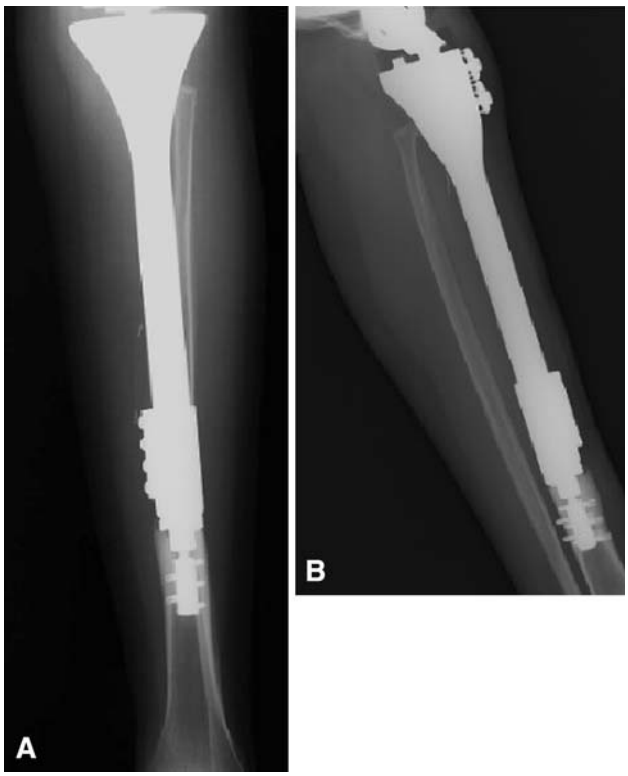

Fig. 1A–B Anteroposterior (**A**) and lateral (**B**) radiographs of failed Compress® proximal tibial replacement demonstrates radiolucencies at the bone-prosthetic interface and loss of compression distance.

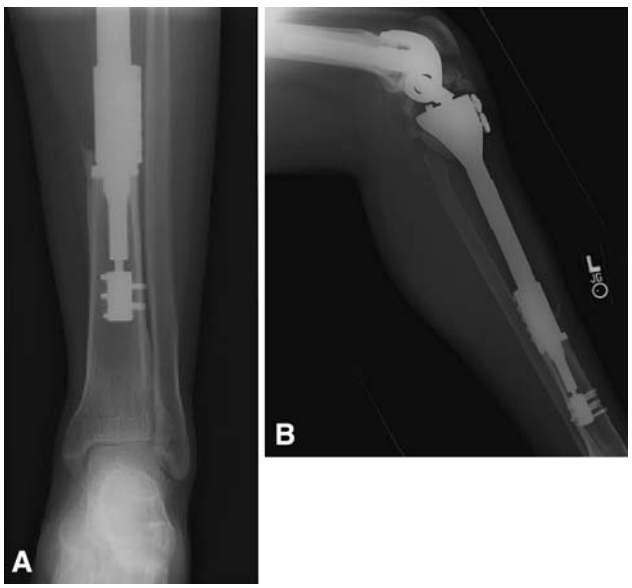

Fig. 2A–B Anteroposterior (**A**) and lateral (**B**) radiographic images demonstrate stable osseointegration of a Compress® proximal tibial replacement at 9.3 years postimplantation.

other implants demonstrated radiographic signs of stable osseointegration as evidenced by bone hypertrophy at the prosthetic interface and lack of stress shielding (Fig. 2). Design modifications over the study period, in terms of compression force or spindle type, did not correlate with any observable changes in the degree of osseointegration.

Discussion

The rationale of this study was to better understand the short-term outcomes of compressive osseointegration technology when used for reconstruction of massive defects after primary oncologic resection. The primary aims were the determination of prosthetic survival and management of revisions. The secondary aims were documentation of local control and surgical complications.

Limitations of this study include the small number of patients, the lack of control subjects, and the limited followup. The limited study size makes statistical analysis difficult, especially in terms of meaningful calculation of implant survival analysis. With average 4.5-year followup, the data in this study should be viewed as preliminary with results needing to be further developed to substantiate conclusions regarding prosthetic longevity. However, given the relative infrequency of primary oncologic proximal tibial reconstructions, this review of 16 patients is one of the larger series of uncemented devices and the only one that relates to compressive osseointegration technology. Except for the two patients who died, all of the patients reported continue to be examined regularly so the longer-term durability of the implant can be determined.

Effective reconstruction of massive defects after resection of proximal tibial neoplasms is challenging for several reasons. First, as compared with femoral presentations, the size of tibial tumors and the close proximity of surrounding neurovascular structures often render decision-making regarding limb salvage difficult. As compared with distal femoral tumors, achieving local control of tibial lesions more often necessitates amputation. The correspondingly fewer patients who do receive prosthetic reconstructions may still be at high risk for local recurrence. Although not directly a product of osseointegration technology, the finding that all patients in this study demonstrated local control is nonetheless reassuring in terms of validating a limb salvage approach in a carefully selected population.

A second difficulty of tibial prosthetic reconstruction is the considerable biomechanical stress placed on conventional tibial intramedullary stems, which has been associated with relatively high rates of mechanical failure resulting from prosthetic fracture and aseptic loosening. Determination of the influence of mechanical failure on rates of proximal tibial prosthetic survivorship, based on the extant literature, is difficult. Many studies combine outcomes of proximal tibial implants with those from other anatomic locations, including the distal and proximal

femur [2, 5, 9, 20, 21, 26, 29, 31, 32, 38–40, 42, 44, 47, 49, 51]. When reported separately, proximal tibial results frequently detail all-cause failure combining the effects of infection, local recurrence, fracture, and other mechanical issues on prosthetic retention [26, 29, 31, 32, 47]. Some papers have few patients and/or short followup [1, 2, 9, 37, 52, 53], whereas some that describe experience extending over several decades combine the findings with several distinct proximal tibial implant designs and surgical techniques [5, 26, 29, 32, 39, 42, 47]. To the extent that rates of proximal tibial endoprosthetic mechanical failure can be determined from the literature over the past 20 years, most authors report figures of 10% to 30% failure at 5- to 10-year followup (Table 1). The most promising long-term results were reported by Myers et al, who described a 9% rate of aseptic loosening in 99 rotating hinge devices at 15 years of followup, although seven prosthetic fractures should be added to estimate the actual mechanical failure rate [34]. Subsequently, this group reported longer experience with a variety of proximal tibial implants, for which mechanical failure rates of 37.5% and 59.4% were reported at 10 and 20 years, respectively [25]. The addition of porous- or hydroxyapatite-coated collars at the bone-prosthetic interface seems to hold the promise of improving longevity of conventional cemented or uncemented stems [9, 34, 46]. This study of primary oncologic reconstructions was undertaken to specifically determine the intermediate-term mechanical failure rate of a single type of proximal tibial endoprosthesis that uses a novel means of achieving compressive osseointegration. At an average of 4.5 years followup, only one prosthetic failure resulting from mechanical loosening of the implant was noted. This result compares favorably with other types of proximal tibial implants reported in the literature. The Compress® device would thus seem to provide an effective means of providing stable fixation for massive proximal tibial reconstructions after primary oncologic resection. Initial results suggest Compress® technology may well serve to avoid the problems of prosthetic breakage, stress shielding, and particle-induced osteolytic loosening that are associated with conventional tibial stems.

A third problematic aspect of tibial reconstruction involves soft tissue coverage and the consequent risk of prosthetic infection. One patient without flap coverage in this series developed an infection that ultimately necessitated an amputation; the two other patients who developed a deep infection retained their implants, perhaps in part because they had received a flap as part of their index procedure. The utility of the gastrocnemius flap in decreasing the risk of tibial prosthetic infection and in improving extensor mechanism reconstitution serves to makes its use routine [7, 11].

A final challenge of tibial reconstruction is the frequent need to salvage short metadiaphyseal fragments remaining

Table 1. Proximal tibial endoprosthetic mechanical failure rate at intermediate followup

Study	Year	Device description	Patients (number)	Average followup (years)	Mechanical failure rate	Comment
Jeys et al. [25]	2008	Cemented custom constrained and rotating hinge	136	10	31.4	Mechanical failure rate (31.4%)
Myers et al. [34]	2007	Cemented custom constrained hinge	95	5	16	Aseptic loosening (16%) plus five prosthetic fractures
Myers et al. [34]	2007	Cemented custom rotating hinge, hydroxyapatite collar	99	5	3	Aseptic loosening (3%) plus seven prosthetic fractures
Flint et al. [19]	2006	Uncemented modular constrained hinge	44	3	6.8	Stem breakage (two); rotational instability (one)
Gosheger et al. [20]	2006	Uncemented modular rotating hinge	42	4	9.5	Aseptic loosening (three); stem breakage (one)
Ahlmann et al. [2]	2006	Cemented modular rotating hinge	30	3	10	Fatigue fracture (two); aseptic loosening (one)
Torbert et al. [44]	2005	Cemented modular rotating hinge	26	5	19.2	Mechanical failure (three); aseptic loosening (one); dislocation (one)
Natarajan et al. [35]	2003	Cemented custom constrained and rotating hinge	133	5	10.5	Fracture revision (seven); aseptic loosening (five); disassembly (one); bending (one)
Kawai et al. [26]	1999	Uncemented (five) and cemented (two) rotating hinge	7	2 to 7	28.6	Tibial yoke breakage (two)
Horowitz et al. [24]	1991	Cemented custom constrained hinge	16	5	25	Aseptic loosening (three); articulation fracture (one)

after tumor resection or revision. The "bone-sparing" nature of the Compress® device (as little as 43 mm of bone can be implanted) and the relative ease of revision after infection, fracture, or mechanical loosening (the device is readily removed and as little as 1 cm of additional bone needs to be resected at the time of reimplantation) are highlighted by the successful revision of the sole case of mechanical failure (Fig. 1) [36].

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