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What Are the Long-term Surgical Outcomes of Compressive Endoprosthetic Osseointegration of the Femur with a Minimum 10-year Follow-up Period?

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Abstract

Background Endoprosthetic reconstruction after oncologic resection of bone tumors requires stable fixation between the prosthesis and residual host bone. Compressive osseointegration has been developed as an alternative to traditional stemmed implants to address the challenges and complications of achieving this fixation. Sufficient time has now passed from the advent of compressive implants to

allow for an assessment of the intermediate-term and long-term results of this form of fixation.

Questions/purposes At a minimum follow-up of 10 years after implantation of a compressive osseointegration device for oncologic reconstruction: (1) What is the risk of periprosthetic fracture, aseptic loosening, or implant breakage resulting in revision surgery for endoprosthesis

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One author (RLR) certifies receipt of personal payments or benefits, during the study period, in an amount of USD 10,000 to USD 100,000 from Zimmer Biomet.

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Ethical approval for this study was obtained from the University of Utah, Salt Lake City, UT, USA.

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removal? (2) What is the long-term cortical response at the host-endoprosthesis interface as visualized on plain radiographs?

Methods A single-center, retrospective study was performed between 2002 and 2010, in which 110 patients with primary bone sarcoma of the proximal or distal femur were considered for oncologic resection and reconstruction. Patients were considered for a compressive osseointegration endoprosthesis if they were 50 years of age or younger, had not previously received femoral radiation, had no metabolic disease impairing bone healing, were not diagnosed with metastatic disease, and had life expectancy greater than six months. Of the 110 patients, 25 were treated with a compressive osseointegration implant of the proximal or distal femur, and 85 patients were treated with conventional stemmed implants or amputation because of older age, advanced disease, metabolic comorbidities, inability to tolerate a nonweightbearing postoperative period, or in the case of rotationplasty, patient preference. All patients who received this device during the period of study were considered eligible for inclusion in this review. The median (range) age was 18 years (7 to 50), and 13 of 25 patients were men. Five patients died of disease before the minimum follow-up duration of 10 years; two underwent amputation due to local recurrence and three died with the implant in situ, leaving 20 patients for complete analysis. Median follow-up was 144 months, and all 20 surviving patients had a minimum follow-up of 10 years (121 to 230 months). The primary endpoint was reoperation and implant removal for periprosthetic fracture, aseptic loosening, or mechanical breakage of any component of the compressive device in the endoprosthesis. In final analysis, death was considered a competing event to revision surgery, and cumulative incidence was reported after competing-event analysis. A secondary aim was radiographic evaluation of the host-implant interface to assess the long-term cortical response to compressive osseointegration.

Results Spindle fracture or loosening was noted in three patients, and the remaining 17 patients maintained the compression device until the final follow-up. The risk of reoperation for aseptic loosening, periprosthetic fracture, or mechanical breakage of the implant using a competing risks estimator was 12% at 10 years (95% CI 0% to 26%). These complications occurred within 29 months of the index surgery; no patients had implant loosening or mechanical breakdown after this initial period. On radiographic assessment, 14 patients demonstrated cortical hypertrophy of the bone-implant interface, six patients had maintenance of the native cortical contour, and no patients had cortical atrophy or narrowing at the implant interface.

Conclusion Long-term follow-up in patients with compressive osseointegrative endoprosthetic devices demonstrated no late revisions because of periprosthetic fracture, aseptic loosening, or implant breakage in this cohort with a

minimum 10-year follow-up. There was no evidence of late-onset cortical atrophy or stress shielding at the host-implant interface. This study supports the long-term stability of the interface between host bone and the endoprosthesis in compressive osseointegration devices.

Level of Evidence Level IV, therapeutic study.

Introduction

Surgical resection of a bone tumor in the appendicular skeleton often leaves an osseous defect that results in complex orthopaedic reconstruction. To address such segmental osseous defects, modular, metallic endoprostheses have been developed and are now widely used [1, 4, 5, 10, 12, 15, 22, 29, 31, 33]. However, agreement about how best to achieve stable, durable, and reliable fixation of the endoprosthetic implant to the residual host bone has yet to be established [15, 16]. Most proximal or distal femur endoprostheses rely on fixation through an intramedullary stem that attaches to the host bone through either direct ingrowth or grout fixation through cementation. However, an alternative method of fixation through a compressive osseointegrative design has been available since 2003.

The three modes of fixation of a metallic endoprosthesis to the residual femur—cemented stems, press-fit stems, and compressive osseointegration—each have advantages and disadvantages [6, 21, 24-26]. The advantages of cemented and uncemented stemmed implants are the patient's ability to immediately bear weight on the implant because of inherent stability of the construct and the simplicity of implantation. The disadvantages of the stemmed options are the requirement for sufficient bone length to be available for the stem, potential stress shielding and loss of bone stock over time, episodes of aseptic loosening because of a lack of ingrowth or disruption of the cement mantle, and loss of bone stock during revision scenarios when the stems must be revised because of loosening or infection [9, 11, 13, 17, 27, 28, 30, 32]. Compressive osseointegration was developed to address some of the disadvantages of stemmed implants [2]. The compression device uses a short plug and spindle placed into the residual intramedullary canal, which is then affixed with cross-pins and tensioned such that the end of the host bone is compressed onto the end surface of the endoprosthesis. The compressive nature of the implant attempts to induce bone growth at the implant-host interface through mechanisms described by Wolff's law [2, 7, 19]. Theoretically, this induces thicker, stronger bone, whereas stemmed implants may lead to bone loss in this same interfacing area because of stress shielding. In addition to avoiding stress shielding, another potential advantage of compressive osseointegration is the short intramedullary footprint of the device. This provides two potential benefits: First, the requirements for residual

bone to use the device are thought to be less than the required bone length for conventional, stemmed implants. Second, there is a possibility for minimal additional bone resection in common revision scenarios. A substantial disadvantage of this compressive device, as noted in previous studies, is the occurrence of spindle fracture in the first few years after implantation [8, 14, 18, 20].

The question of the durability of compression osseointegration, particularly with regard to the late occurrence of periprosthetic fracture, component breakage, or aseptic loosening, has yet to be fully answered because the device is relatively new, and no studies of which we are aware have described late outcomes of compressive osseointegrative devices in a cohort with long-term follow-up at more than 10 years minimum. We have previously published our experience with compressive osseointegrative endoprostheses in the femur with short-term follow-up [3, 20]. Now that nearly 20 years have passed from the time of the FDA's approval for use in the United States, long-term follow-up is now possible for these devices and is presented in this study.

We therefore asked: At a minimum follow-up of 10 years after implantation of a compressive osseointegration device for oncologic reconstruction: (1) What is the risk of periprosthetic fracture, aseptic loosening, or implant breakage resulting in revision surgery for endoprosthesis removal? (2) What is the long-term cortical response at the host-endoprosthesis interface as visualized on plain radiographs?

Patients and Methods

Study Design and Setting

We performed a retrospective study at an orthopaedic oncology referral center with patients who had received a compressive osseointegration endoprosthesis. Although the use of cemented stems, press-fit stems, or compressive implants varied among practicing surgeons, the compressive osseointegrative device was the preferred implant offered to patients meeting appropriate criteria at our institution. We estimate that 10 to 20 proximal or distal femur replacements for primary bone sarcoma are performed at our institution each year.

Participants

Between 2002 and 2010, 110 patients were referred to our institution for management of primary bone sarcoma of the proximal or distal femur. By institutional preference, all patients with primary bone sarcoma localized to the proximal or distal femur were considered for a compressive osseointegration endoprosthesis when technically possible,

as well as if patients were 50 years of age or younger, had not previously received femoral radiation, had no metabolic disease impairing bone healing (including diabetes or osteoporosis), were not diagnosed with metastatic disease, and had life expectancy greater than 6 months (Fig. 1). The 25 patients meeting these criteria who were treated with a compressive osseointegration endoprosthesis after oncologic resection were considered eligible for this review. The remaining 85 patients were excluded and treated with traditional stemmed implants or amputation due to older age, metastatic or recurrent disease, metabolic comorbidities, inability to tolerate the required nonweightbearing postoperative period, or in the case of rotationplasty, patient preference. Chemotherapy was not considered a contraindication. Nononcologic proximal or distal femur reconstructions were not considered in this study.

Descriptive Data

The median (range) age of this cohort at the time of surgery was 18 years (7 to 50), and 13 of 25 patients were men. Originally, 25 patients underwent surgical resection of a primary femoral bone sarcoma and subsequent reconstruction with a compressive osseointegration device during the data collection period. Five patients died of disease before 10 years: three patients died with the implant in situ, and two with amputations due to local recurrence, leaving 20 patients (10 men and 10 women) available for final analysis (Table 1). The surviving patients were followed with clinical examinations and radiographs for at least 10 years (range 121 to 230 months), with no patients lost to follow-up before 10 years. All patients had a primary sarcoma of bone, with osteosarcoma being the most common (14 patients), followed by malignant fibrous histiocytoma of bone (three patients), Ewing sarcoma (two patients), and chondrosarcoma (one patient). In this cohort, 16 patients had a distal femur replacement and four patients had a proximal femur replacement. Of the five patients who did not survive to a minimum of 10 years, none had loosening at the compressive interface nor breakage of the endoprosthesis. Two underwent amputation due to local recurrence at 14 and 44 months. The remaining three patients died of disease at a median (range) of 30 months (16 to 71) without experiencing a complication of their endoprosthesis.

Data Sources and Measurement

Postoperative follow-up for all patients was completed according to the surveillance recommendations of the National Comprehensive Cancer Network's Bone Sarcoma guidelines until the patients reached 10 years from surgery [23]. After 10 years, follow-up was performed yearly for

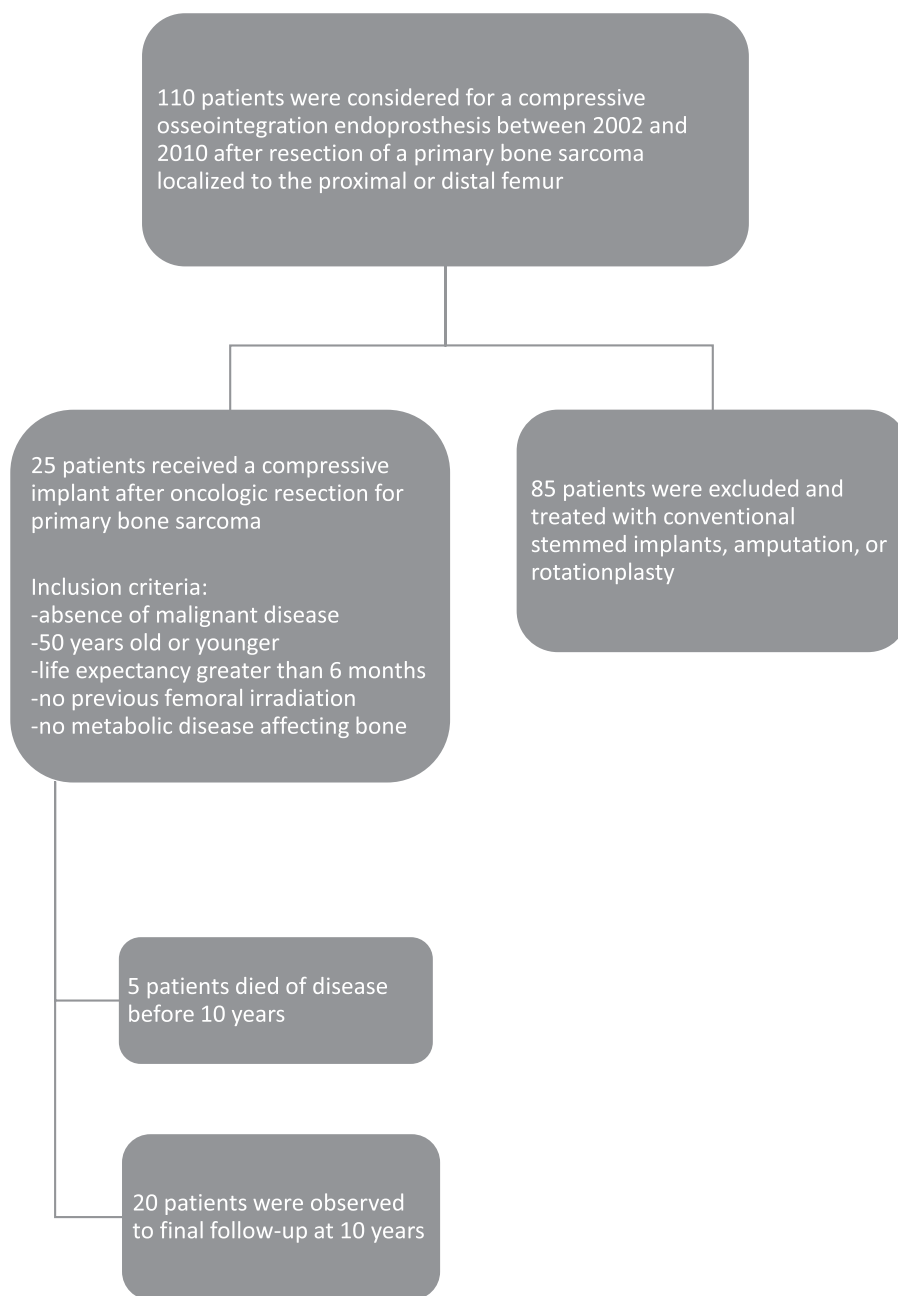


Fig. 1. Flowchart depicting selection process with inclusion and exclusion criteria. Ultimately 20 patients were evaluated on final analysis.

monitoring of the orthopaedic implant. As a part of the initial oncologic follow-up and the subsequent orthopaedic hardware surveillance, radiographs of the entire femur were taken during these visits. Patients who were temporarily lost to follow-up before 10 years and could not return for an in-person assessment were contacted and interviewed by telephone, assessed by local orthopaedic surgeons, and had radiographs taken and forwarded for our review.

Surgical Technique

The results from a portion of this cohort have been published, and the surgical technique is described in detail in those articles [3, 20]. In brief, the Compress® (Biomet) osseointegration device was used according to the manufacturer's technique guide. All procedures were performed by our sarcoma service. The extent of bone and

Table 1. Demographic data and oncologic diagnosis of 20 patients receiving a compressive osseointegration endoprosthesis for primary sarcoma of bone

Parameter	Value
Age in years at the time of surgery, median (range)	18 (7-50)
Gender	
Men	10
Women	10
Follow-up in months, median (range)	144 (121-230)
Diagnosis	
Osteosarcoma	14
Chondrosarcoma	1
Ewing sarcoma	2
Malignant fibrous histiocytoma of bone	3
Anatomic location	
Proximal femur	4
Distal femu	16
Percentage of bone remaining after resection, median (range)	51 (21-69)

soft tissue resection was dictated by the tumors, with the goal of a wide surgical margin of the sarcoma. Bone cuts were made under irrigation, perpendicular to the long axis of the femur, with an attempt to minimize thermal necrosis of the bone. An appropriate-sized plug and spindle were selected based on preoperative plans and intraoperative reaming of the canal; for procedures in patients with canals that would not accommodate the diameter of the smallest available off-the-shelf construct (10 mm and 12 mm), a custom plug and spindle were used. Once the Compress device was secure, the remainder of the construct was assembled using the manufacturer’s Orthopedic Salvage System (Biomet). Bipolar hemiarthroplasty components were used in proximal femur replacements, and a rotating hinge was used as the knee in distal femur replacements. Postoperatively, patients were kept nonweightbearing for 6 weeks, with progression to weightbearing as tolerated thereafter. The use of antiinflammatory drugs was discouraged perioperatively and before full ingrowth of the bone was noted.

Radiographic Assessment

We assessed the reaction of the residual host bone at the bone-implant junction on a simple 3-point scale, based on the contour of the host bone as it approached the implant at the final follow-up (Fig. 2). If the contour of the cortical bone narrowed as it approached the face of the spindle, it was given 1 point. If the contour of the cortical bone continued to

the spindle without altering its contour or had only one cortex of widening, it was given 2 points. If two or more of the cortices widened from the natural contour of the femur as it articulated with the spindle face, this was rated as hypertrophy and was given 3 points. Although not a validated system, we attempted to use this simple grading scale to assess the biologic response at the host-endoprosthesis interface. Two raters (JG, JMB) performed the assessment, in an unblinded fashion, given the constraints of the images obtained. There were no disagreements in the scores obtained, so an adjudicator was not used.

Bias

Although randomized allocation of stemmed or compressive implants is likely a superior way to address the questions raised here, such a trial is unlikely because the conditions being treated are rare. Although single-institution, retrospective studies are more feasible, they do carry an inherent risk of bias. This study carries a risk of selection bias as the compressive implants were allocated to younger patients with fewer comorbidities, whereas

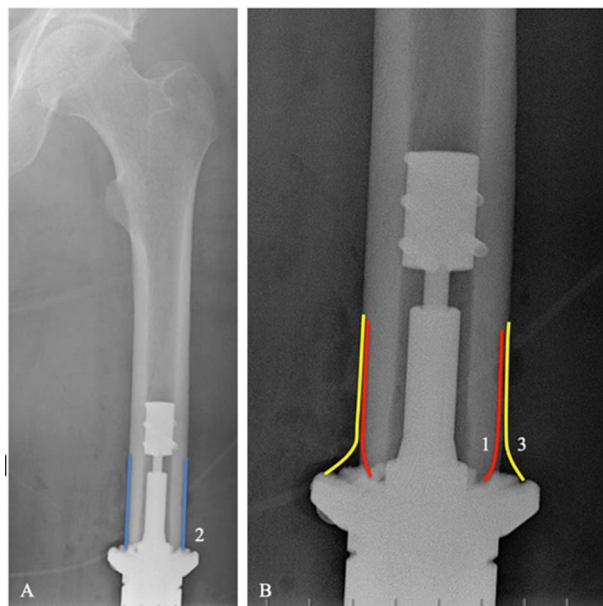


Fig. 2. A-B These radiographs show the bone reaction at the host bone–implant interface. The radiographic grading scale for the postoperative response of the host bone to the compression device is shown. **(A)** The line labeled “2” represents no change in the contour of the cortex from the normal anatomy as it interfaces with the platform of the device spindle. **(B)** The line labeled “1” represents atrophy of the cortex and narrowing of the native contour of the femur at the interface, and line labeled “3” demonstrates widening or hypertrophy. A color image accompanies the online version of this article.

conventional stemmed implants were allocated to older patients. There is a risk of transfer bias when assessing implant longevity in patients with bone sarcomas, as (1) patients are often distributed across a wide geographic region due to low disease prevalence, imposing serious constraints on clinical follow-up, and (2) the potential for death during the observation period. In this study, no patients were lost to follow-up before the 10-year study cut-off, and we used a competing risks estimator to evaluate death as a competing event for revision surgery in reference to the patients who died before 10 years. When necessary, outside clinicians forwarded postoperative imaging for our review.

Primary and Secondary Study Outcomes

The primary outcome of this study was the cumulative incidence of periprosthetic fracture, aseptic loosening, or implant breakage resulting in revision surgery and implant removal, evaluated at a minimum 10 years after surgery. Assessment of these events was made throughout ongoing postoperative surveillance. Attention was also given to additional revision procedures not resulting in implant removal. The secondary outcome was evaluation of the host-endoprosthesis interface in compressive osseointegration devices with a simple 3-point grading system describing an atrophic, normal contour, or hypertrophic cortical reaction at the interface as visualized on plain radiographs.

Ethical Approval

This study was approved by the institutional review board at the University of Utah, Salt Lake City, UT, USA.

Statistical Analysis

Descriptive statistics of patient demographics and surgical complications were compiled, including frequency of periprosthetic fracture, aseptic loosening, mechanical breakage, and revision surgery for other causes. Kaplan-Meier survival curves were made based on the time to revision surgery and implant removal for aseptic loosening, periprosthetic fracture, or mechanical breakage, as well as for any cause of reoperation. Because five patients died before 10 years, we performed a competing risk analysis with periprosthetic fracture, aseptic loosening, or breakage of the endoprosthesis and death as competing events. Follow-up time was censored for two patients at amputation for disease progression, and cumulative incidence for each competing risk was estimated using the “cuminc” function (R statistics software).

Results

Reoperation for Aseptic Loosening, Periprosthetic Fracture, or Mechanical Breakage

The revision risk for periprosthetic fracture, aseptic loosening, or implant breakage on the competing risk estimator was 12% at 10 years (95% CI 0% to 26%). Two patients sustained a fracture of the implant spindle, and one patient had aseptic loosening. Each of these events occurred within 29 months of the index surgery; no patients had loosening or mechanical breakage after this initial period. All three episodes were treated with revision to another Compress device, which then survived beyond the minimum 10-year follow-up period without complications (range 128 to 183 months).

Revision surgery without implant removal was performed in 11 of 20 patients in this cohort (Table 2). The most common indication for revision surgery was infection, which occurred in four patients. Three patients did not retain the device at the final follow-up examination. Of these, two had local recurrence of disease; one was treated with amputation and the other with rotationplasty. The third patient who did not maintain the implant until final follow-up had an infection, which was treated with a two-stage revision and conversion to a total femur replacement 126 months after the index surgery. Late revision surgery, defined here as revision surgery 5 years after the index surgery, included infection (two patients), resurfacing of an unresurfaced patella (two patients), and polyethylene exchange for wear (one patient). All late complications, except for one infection, occurred after 10 years.

When considering all indications for reoperation, the cohort had a median (range) time to reoperation of 66 months (3 to 145) (Fig. 3). Infection as a cause for revision occurred nearly 5 years after the index procedure (average 59 months), and mechanical breakdown and aseptic loosening occurred at a median of 16 months from surgery (3 to 29) (Fig. 4).

Radiographic Assessment of Bone-Endoprosthesis Interface

In the radiographic assessment of the interface between the host bone and the face of the spindle, 14 of 20 patients demonstrated hypertrophy of bone at the interface, and 6 of 20 patients had an articulation that was in line with the native femoral contour at the final follow-up examination. No patients had atrophy or narrowing of the cortex as the bone approached and contacted the face of the spindle segment. Additionally, once a hypertrophy reaction was noted radiographically, it did not regress in any patients.

Table 2. Surgical outcomes of 20 patients receiving a compressive osseointegration endoprosthesis for primary sarcoma of bone

Parameter		All patients (n = 20)	Proximal femoral	Distal femoral
			replacement (n = 4)	replacement (n = 16)
Was the reconstruction revised for any reason?	No	9	2	7
	Yes	11	2	9
Reconstruction failure resulting in implant removal	Aseptic loosening	1	0	1
	Structural failure	2	0	2
	Periprosthetic fracture	0	0	0
Other causes of revision surgery	Infection	4	2	2
	Local recurrence	2	0	2
	Polyethylene exchange	1	0	1
	Patellar resurfacing	2	0	2
Bone reaction at the interface with the prosthesis at the final follow-up	Atrophy or narrowing of the cortex	0	0	0
	In line with the native cortex	6	1	5
	Hypertrophy or widening of the cortex	14	3	11

Discussion

It has been nearly 20 years since the advent and FDA approval of compressive osseointegration endoprostheses for use in orthopaedic oncology surgery. As such, sufficient time has now passed to allow for an investigation of the longer-term outcomes of these devices. In this study, patients received an endoprosthetic reconstruction with a compressive osseointegration device as part of their local control treatment of a primary sarcoma of bone and were followed for a minimum of 10 years, with none lost to follow-up. This review identifies aseptic loosening and implant breakage as relatively early complications of compressive osseointegrative devices,

occurring before 29 months in this study. Long-term radiographic evaluation confirms cortical durability at the bone-endoprosthesis interface, with no evidence of stress shielding. These findings validate compressive osseointegration implants as viable additions to existing endoprosthetic devices available for orthopaedic oncologic reconstructions, with few observed complications after the first postoperative years.

Limitations

This study has several limitations. Notably, this study was not designed to assess the survivorship of endoprostheses in

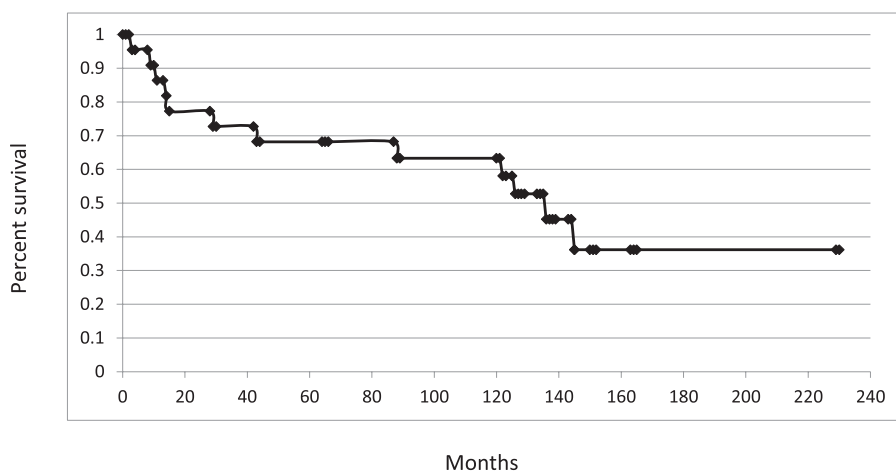


Fig. 3. This Kaplan-Meier curve demonstrates the survivorship of a compressive osseointegration endoprosthesis for primary sarcoma of bone when considering all causes of revision surgery.

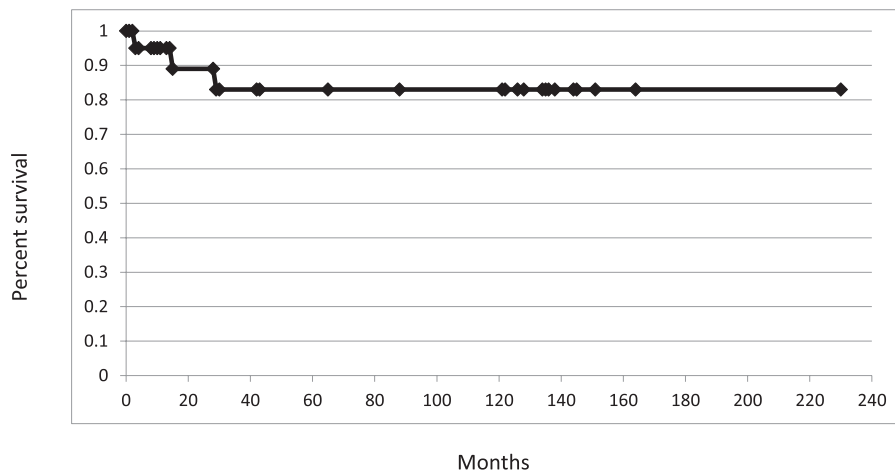


Fig. 4. This Kaplan-Meier curve demonstrates the survivorship of a compressive osseointegration endoprosthesis for primary sarcoma of bone when considering failure because of aseptic loosening, periprosthetic fracture, and implant mechanical breakage.

general or compare compressive osseointegration to traditional stemmed implants. Specific attention was given to the rates of aseptic loosening, periprosthetic fracture, and implant breakage to assess the durability and reliability of the residual host bone-to-compression device interface over time. The small number of patients in this series does not allow assessment of risk factors that may lead to revision or removal of a compression endoprosthesis in general or instability of the host bone-prosthesis interface specifically. Likewise, the small sample size, nonrandom allocation of the treatment, and absence of a control group precludes making a comparison to conventional stemmed implants, whether cemented or cementless. Because the treating physicians were involved with collection and review of clinical information pertinent to this study, a degree of assessment bias must be acknowledged. Finally, despite this study having equal numbers of men and women, this study is too small to perform a gender analysis, and we cannot assume these results apply equally to both genders.

Discussion of Key Findings

An important finding of this study was that once osseointegration was established, later aseptic loosening or implant breakage at the host-implant junction were not common late causes of revision. Three of 20 surviving patients experienced disruption of this interface; two had a breakage of the implant spindle and one had aseptic loosening. These events occurred early in the postoperative course, occurring at a median (range) of 16 months postoperatively (3 to 29). Once the implant was fixed to the bone, as evidenced by radiographic stability of the interface or hypertrophy of the bone at the interface, we did not observe loss of fixation or spindle

fracture. We rated the osseous response on a simple 3-point scale, largely to investigate whether the host bone-prosthesis interface was characteristically one of hypertrophy, atrophy, or simply maintained bone stock. Stress shielding is a known complication of stemmed implants. Of the 17 patients with a compression device still implanted after a minimum of 10 years (range 121 to 230 months), none had radiographic evidence of stress shielding or cortical bone loss at the interface with the prosthesis at the final follow-up (Fig. 5). Indeed, 14 of 20 patients demonstrated femoral hypertrophy at the endoprosthesis junction, and 6 of 20 maintained the native contour of the cortex to the endoprosthesis interface.

The findings presented in this paper are consistent with data from prior studies that have reported the short-term and intermediate-term outcomes of compressive osseointegration endoprostheses. One study reported on 82 patients with the Compress device who had a mean follow-up duration of 43 months [14]. In their series, eight patients had implant disruption at the interface with bone: three because of aseptic loosening and five for periprosthetic fracture. Extrapolating to 10 years of follow-up, the authors reported an anticipated survivorship of 80%. Of the 28 patients in their series who had longer than 5 years of follow-up, only one had mechanical breakdown after the 5-year interval. Another case series of compressive osseointegration endoprostheses reported on 74 patients with at least 2 years of follow-up [8]. They found that the 5-year and 10-year survival rates were 91% for spindle breakage and 92% for rotational breakdown, considering these events as distinct modes of failure and extrapolating the data using Kaplan-Meier curves. Similar to other series, their average time to spindle breakdown was in the short term (average of 23 months after surgery), and there were no spindle fractures after 5 years. Finally, a third study found similar results in their series of 101 oncologic and

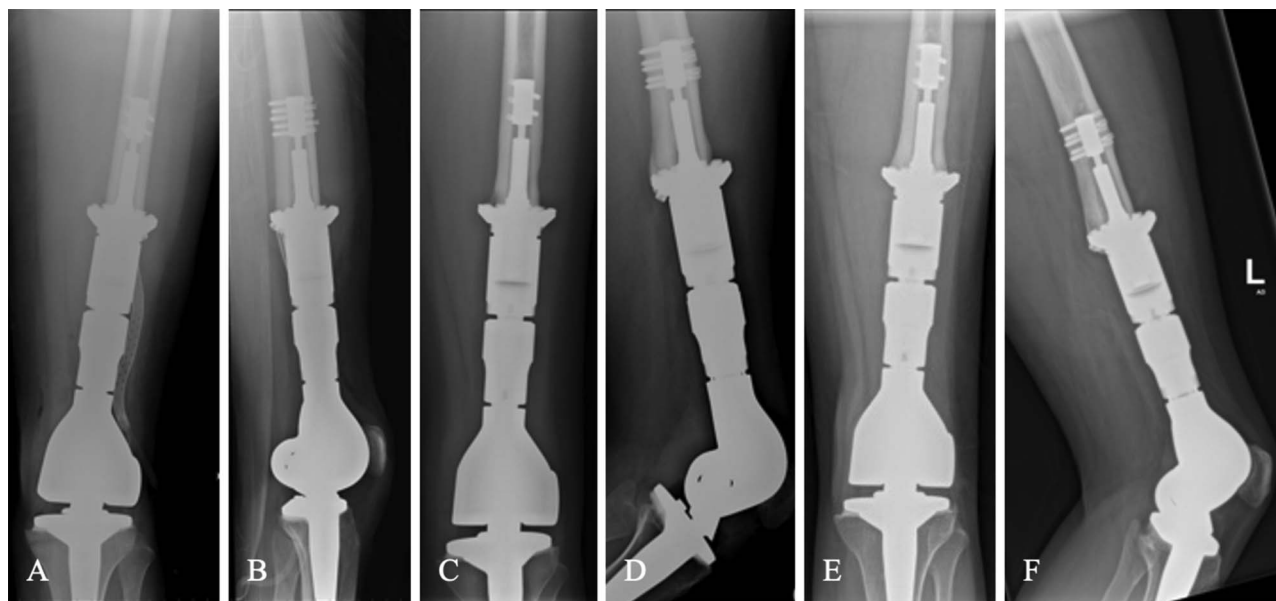


Fig. 5. A-F These radiographic images characterize compressive osseointegration in a 19-year-old patient with more than 10 years of follow-up after distal femur resection and reconstruction with a compressive osseointegration device for osteosarcoma. Immediate postoperative (A) AP and (B) lateral radiographs are shown. (C) AP and (D) lateral radiographs 14 months after surgery are shown, with the first signs of consolidating cortical hypertrophy at the residual bone–prosthesis interface. Final (E) AP and (F) lateral radiographs 12 years after surgery are shown, with cortical widening noted on the medial, lateral, and posterior cortices. This response was recorded as hypertrophy (Type 3). This patient had no complications or revisions of the endoprosthesis through final follow-up to 145 months.

nononcologic femoral reconstructions with a compressive device in patients with a minimum follow-up of 2 years [18]. Their rate of aseptic loosening was 5%, with the last episode of loosening occurring approximately 4 years after surgery. These published studies and others have reported on a similar theme: aseptic loosening, periprosthetic fracture, and spindle breakage of the compressive device occur at a rate of 10% to 15% within a few years of oncologic surgery. The addition of the current series to the pool of available studies suggests that these results are reliable and there is reason to suggest that late complications—occurring 10 or more years after surgery—of the device because of aseptic loosening, periprosthetic fracture, or implant breakage are not a common occurrence. Previous studies, as reviewed above, suggested that late failure of compressive osteointegration due to mechanical breakage is not a common complication; this study follows those patients and documents the actual outcomes of this cohort in the 10- to 20-year follow-up period. To our knowledge, this has not been done before.

Conclusion

Long-term follow-up in this cohort of patients with compressive osseointegration endoprostheses demonstrated no late occurrences of aseptic loosening or mechanical breakdown of the implant. No such events occurred beyond

29 months after surgery, even with a minimum of 10 years of follow-up. There was no radiographic evidence of cortical atrophy or stress shielding. These data help to confirm earlier studies suggesting that compressive osseointegration endoprostheses are durable at the host bone–prosthesis interface once the implant survives the short-term postoperative period.

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