Early Equivalence of Uncemented Press-fit and Compress® Femoral Fixation

German L. Farfalli MD, Patrick J. Boland MD,
Carol D. Morris MD, Edward A. Athanasian MD,
John H. Healey MD

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Abstract Bone ingrowth promises more durable biologic fixation of megaprotheses. The relative performance of different types of fixation is unknown. We compared the fixation of two forms of biologically fixed femoral components: an intramedullary uncemented press-fit stem (UCS; Group 1, 50 patients) and a Compress® uncemented fixation (CPS; Group 2, 41 patients). In Group 1, the overall Kaplan-Meier prosthetic survival rates were 85% at 5 and 71% at 10 years. Most failures were long-term developments. Aseptic loosening was the primary cause of failure. Stem diameters less than 13.5 mm and a diaphyseal/stem coefficient greater than 2.5 mm were associated with decreased prosthetic survival. In Group 2, the overall rate of CPS survival was 88% at 5 years. Failure of femoral fixation or fracture during the first year was the main reason for revision. Five-year survival rates were similar between the groups and we observed no difference in the functional success of the implants. We found no failures after 1-year followup in Group 2 (CPS). Any difference in prosthetic survival can only be proven by longer-term study or a randomized trial.

Level of Evidence: Level III, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

Introduction

Prosthetic reconstruction after distal femoral tumor resection is an accepted treatment approach for the majority of patients and can maintain good knee function [17]. Longevity of the reconstruction is a major concern, however, especially in young and physically active patients who place high demands on the prosthesis. Long-term complications are frequent with aseptic loosening being the most common long-term complication in tumor endoprostheses [14, 16, 26, 28, 31]. Various forms of prosthetic fixation have been developed to meet the need for short- and long-term success in patients after tumor resection. Uncemented tumor prostheses may be advantageous in the long term because of their potential for bone ingrowth to provide durable biologic fixation of megaprotheses [4, 6, 9, 18, 22]. They may also have less risk of aseptic loosening [9, 11, 14, 27, 32–34]. The best method to achieve this goal is unknown.

Traditional intramedullary uncemented press-fit stems are the most commonly used method of prosthetic fixation that relies on bone ingrowth. The long (eg, typically 150 mm) stiff stems provide secure fixation but produce stress shielding of the femur [9, 11, 14, 32–34]. The Compress® Compliant Pre-Stress Implant (Biomet, Warsaw, IN) (Fig. 1) has a radically different design concept to achieve bone ingrowth fixation. Although also an intramedullary device, it uses stored energy to provide compliant self-adjusting compression through a shorter (8-cm) traction bow segment. These forces are intended to

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Each author certifies that his institution has approved the reporting of this study and that all investigations were conducted in conformity with ethical principles of research.

G. L. Farfalli, P. J. Boland, C. D. Morris,
E. A. Athanasian, J. H. Healey (✉)
Orthopaedic Surgery Service, Department of Surgery, Memorial
Sloan-Kettering Cancer Center (Affiliated with Weill Medical
College of Cornell University), 1275 York Avenue, Suite A342,
New York, NY 10021, USA
e-mail: healeyj@mskcc.org

promote biologic fixation over a convex milled surface at the end of the femur. Simultaneously, the implant transmits stress to the intervening cortex and induces bone hypertrophy. It minimizes stress shielding and seals the medullary canal from particulate debris and osteolysis [3, 4, 10, 12, 16].

We hypothesized that between the two fixation methods, there was: (1) no difference in prosthetic survival; (2) no difference in nonseptic complications; (3) no difference in the factors associated with prosthetic survival; and (4) no difference in the ISOLS functional scores in each domain of the scoring system.

Fig. 1A–B Prostheses used include (A) uncemented stem distal femoral endoprosthesis replacement (Finn Knee prostheses; Biomet, Warsaw, IN) and (B) the Compress® Compliant Pre-Stress Implant (Biomet).

Materials and Methods

We retrospectively reviewed all 124 patients treated with limb salvage for tumors of the distal femur undergoing primary reconstruction of a defect after resection or revision of a failed distal femoral tumor reconstruction who underwent reconstruction with one of two uncemented implants between November 1989 and August 2006. Patients treated from 1989 until the availability of the Compress® were treated with the press-fit uncemented stem. Thereafter, they received the Compress®. There was no selection bias. A minimum followup time of 2 years was required for inclusion unless failure occurred earlier. We excluded 17 patients with less than 2 years followup (all had well-fixed implants, including 16 who died of their disease and one who had a secondary amputation because of regional recurrence), 12 patients who underwent reconstruction with an allograft-prosthetic composite, and four patients with septic loosening. This left 91 patients for review: 50 patients (Group 1) with an uncemented traditional long press-fit stem (UCS) and 41 (Group 2) with a Compress® prosthesis (CPS) with an uncemented short (8 cm) traction bar. Patients in both groups received chemotherapy according to our protocol at that time [19, 23, 24]. Adjuvant chemotherapy was resumed after healing of the surgical wound. We had prior approval of the study by our Institutional Review Board.

The 50 patients in Group 1 had the following characteristics. Tumor diagnosis was osteosarcoma in 37 patients, chondrosarcoma in two, low-grade osteosarcoma in two, Ewing's sarcoma in two, leiomyosarcoma in two, a prosthetic revision in two, giant cell tumor in one, soft tissue sarcoma in one, and malignant fibrohistiocytoma in one. The minimum followup in Group 1 was 3 months (average, 88 months; range, 3–207 months). Twenty-nine patients were women and 21 men with an average age at the time of surgery of 26 years (range, 9–58 years; Table 1).

The 41 patients in Group 2, including the first 23 who were part of the FDA device registration study, had the following characteristics. Reconstruction was performed for osteosarcoma in 20 patients, prosthetic revision in 12,

Table 1. Differences between groups

Feature	Group 1 (UCS)	Group 2 (CPS)
Number	50 patients	41 patients
Diagnosis	OS: 37; CS: 2; LGO: 2; EWS: 2; LMS: 2; revision: 2; GCT: 1; STS: 1; MFH: 1	OS: 20; revision: 12; GCT: 3; CS: 2; LGO: 2; MFH: 2
Followup	88 months (range, 3–207)	45 months (range, 3–97)
Age	26 years (range, 9–58)	27 years (range, 7–62)

UCS = uncemented stem; CPS = Compress® uncemented fixation; OS = osteogenic sarcoma; CS = chondrosarcoma; EWS = Ewing's sarcoma; STS = soft tissue sarcoma; LMS = leiomyosarcoma; MFH = malignant fibrohistiocytoma; GCT = giant cell tumor; LGO = low-grade osteogenic sarcoma.

giant cell tumor in three, chondrosarcoma in two, low-grade osteosarcoma in two, and malignant fibrohistiocytoma in two. The minimum followup in Group 2 was 3 months (average, 45 months; range, 3–85 months). Twenty patients were women and 21 men with an average age at the time of surgery of 27 years (range, 7–62 years) (Table 1).

All patients in Group 1 underwent distal femoral resection with at least 1 cm of bony clearance margin in the proximal femur and were reconstructed with the same Finn/OSS rotating hinged knee replacement platform (Biomet). The Finn/OSS Knee permits movement in three directions (flexion-extension, rotation, and distraction) between femoral and tibial components. Because it has a weightbearing rotating tibial articulation, weightbearing is distributed throughout the prosthesis and not borne by the axle alone [8].

The uncemented, press-fit stem prostheses (UCS) have the same articulation and femoral shaft design as the Compress®. Femoral components were press-fit with 5 cm of intramedullary plasma-sprayed porous coating surfaces in all patients. The plasma-sprayed porous coating covered the circumference of the stem. This surface provides initial implant stability through a scratch-fit fixation obtained by enhanced surface roughness, maximizing short- and long-term ingrowth through random, noninterconnected pores and pore size distribution. Also, this type of porous surface creates a barrier to migrating debris particles, reducing the likelihood of osteolysis [20, 21]. These implants also have 5 cm of extramedullary porous coating adjacent to the femoral osteotomy site to enhance bone bridging between host bone and the prosthesis (Fig. 1). The remainder of the stem had cutting splines to establish immediate rotational control. The length of the intramedullary portion of the femoral stem had a mean of 15.2 cm and a mode of 15 cm (range, 9.0–22.5 cm). There was no difference in the length of femoral resections between the two groups. The mean diameter of the femoral stem was 13.4 mm (range, 10.5–17.5 mm). We used a curved femoral stem with a 50° radius in 41 patients, and a straight femoral stem was used in the remaining nine patients. Stem design was based on implant availability and matching the degree of implant curvature with the femoral shape. Thirty patients received autogenous bone grafting of the prosthetic bone junction site covering the extramedullary porous surface. There was no such surface to bone graft in the Compress® implant so none of them were grafted for this purpose. We measured femoral diaphysis diameter at the midpoint of the prosthetic stem.

The CPS also attaches the Finn rotating hinged platform to the host bone (Fig. 1). It has a porous-coated titanium surface with a conical section mounted perpendicular to the anatomic axis of the femur. Belleville washers are loaded over the intramedullary traction bar. These circular washers

have a curved cross-section and, when compressed by a nut tightened axially over the traction bar, they act like a spring, generating a force proportional to the amount of their deformation. Compressive forces obtained with this mechanism ranged from 400 to 800 lb. The resulting compression provides immediate fixation of the implant to bone related to the normal force and coefficient of friction at the interface. Bone ingrowth develops over time promoted by the compressive forces. Furthermore, the compressive force transmitted to the bone results in bone hypertrophy at the prosthetic interface attaching biologically to the plasma-sprayed porous coating platform and hypertrophy of the bone between the anchor plug and the bone-prosthetic interface. We applied compression forces at the bone-prosthetic interface commensurate with the cortical bone thickness as per the manufacturer's instructions (400 lbs in nine cases, 600 lbs in 21 cases, 800 lbs in the remaining 11 cases). The mean diameter of the intramedullary plug was 12.8 mm (range, 10–18 mm).

We used the functional assessment that was prospectively measured with the use of the revised 30-point functional classification system established by the International Society of Limb Salvage and the Musculoskeletal Tumor Society [7]. Residents seeing the patients recorded these scores.

We measured the outer cortical width and stem thickness ratios using a PACS system (Centricity®; General Electric Medical Systems, New York, NY). The measurements were made independently by two individuals (GLF, JHH) blinded to the outcomes. The mean femoral diaphysis outer diameter at this level was 33.6 mm (range, 22–42 mm). We calculated the relative prosthetic-shaft diameter by dividing the femoral diaphysis diameter by the prosthetic stem diameter (diaphysis/stem) (Fig. 2). The mean diaphyseal/stem coefficient was 2.6 (range, 1.7–3.3).

We considered a prosthesis to have failed when it was removed for any cause. Bushing failure that necessitated bushing exchange or a superficial infection was considered a minor complication and not failure of the prosthesis interface. Although infection is a major problem in megaprosthesis reconstruction, it confounds the analysis of fixation. Because of the high frequency of infection exceeding other prosthetic failures, this complication would prevent analysis of other factors. Therefore, we excluded these from the analysis but have continued to keep them in the report for completeness.

The survival of the two prosthetic devices were estimated with the use of the Kaplan-Meier method starting on the date of the operation and ending on the date of removal or the latest followup. We performed Cox regression analysis to determine whether age, gender, the percentage of the femur that had been resected, bone grafting at the femur-prosthesis junction, the length of uncemented

Fig. 2 Coefficient diaphysis/stem. This coefficient was obtained through the division between the femoral diaphysis diameter and the prosthetic stem diameter. DD = diaphysis diameter; SD = stem diameter.

femoral stem, the diameter of the uncemented stem or the Compress® plug, the amount of compression, the coefficient between diameter of the femoral diaphysis divided the diameter of the stem, approach used (anteromedial or anterolateral), the shape of the stem (straight or bowed), and the use of chemotherapy were independent prognostic factors. We used Fisher's exact test to compare the gender, age, and numbers of failures at 5-year followup between two groups. To evaluate the performance of the relationship between the diaphyseal/stem coefficient and the mechanical failures, sensitivity, specificity, positive predictive value, negative predictive value, and test accuracy as measured with Youden's J statistic were used. We used receiver operating characteristic (ROC) curves to examine the relationship between sensitivity and the false-positive rate (1-specificity) to attribute a predictive model to the diaphyseal/stem coefficient. We used SPSS 15.0 for Windows (Chicago, IL) for statistical analyses.

Results

Hypothesis 1 was rejected. The number of failures and 5-year survival rates were similar between the two groups ($p = 0.1$ and $p = 0.9$, respectively). The overall survival of the entire series was 85% at 5 years (standard error [SE], 4%) and 73% at 10 years (SE, 6.9%). The mean prosthetic duration was 157 months (SE, 10; 95% confidence interval,

Fig. 3 Kaplan-Meier curve shows the overall uncemented prosthesis survival.

Fig. 4 Kaplan-Meier curve shows the differences in prosthetic survivorship between groups. UNC = uncemented stem; CPS = Compress® uncemented fixation.

137–177) (Fig. 3). In Group 1, the overall Kaplan-Meier prosthetic survival rates were 85% (SE, 5.3%) at 5 and 71% (SE, 7.7%) at 10 years (Fig. 4). The mean prosthetic duration was 155 months (SE, 12; 95% confidence interval, 132–178 months) (Table 2). Of the 50 UCS prostheses, 13 failed. In Group 2, the overall Kaplan-Meier prosthetic survival rates were 88% (SE, 5.1%) at 5 years (Fig. 4). The mean prosthetic duration was 75 months (SE, 4; 95% confidence interval, 67–83 months) (Table 2). Of

Table 2. Comparison of the results between groups

Feature	Group 1 (UCS: n = 50)	Group 2 (CPS: n = 41)
Survival rate at 5 years	85%	86%
Failures	13 cases	5 cases
Cause of revision (number)	AL: 12; PF: 1	FF: 4; FR: 1
MSTS score	25.7	26.8

UCS = uncemented stem; CPS = Compress® uncemented fixation; AL = aseptic loosening; PF = prosthetic fracture; FF = femoral fracture; FR = femoral resorption; MSTS = Musculoskeletal Tumor Society.

Fig. 5 Patient with a mechanical failure in the Compress® uncemented fixation group. This case shows distal bone resorption with a secondary failure of the Compress® mechanism at 11 months followup.

the 41 CPS prostheses, the prosthetic was removed from five patients because of failures. Four of these had a femoral fracture and one had a distal bone resorption with secondary failure of the Compress® mechanism (Fig. 5). It was a fracture through necrotic bone in the compression space and did not involve the pin sites. It was treated with a cemented standard stem prosthesis. The fractures occurred 3 to 12 months postoperatively. In all cases, mechanical failures manifested a lack of bone hypertrophy or even some bone resorption. Four of these had a femoral fracture and one had a distal bone resorption with secondary failure of the Compress® mechanism. The failure in the patient with bone resorption with a secondary failure of the Compress® mechanism occurred at 11 postoperative months. Cemented prostheses were used in three patients

and revision Compress® in two patients. Failed fixation with very short residual bone stock can be reconstructed with allograft extension of the tube such as with the “telescope” method [12]. Four patients needed a second surgery at an average of 2 months (range, 1–4 months). Three were the result of a femoral fracture proximal to the anchor plug. These fractures occurred in areas where there was residual cortical thinning resulting from revision surgery that left an unprotected bone defect proximal to the CPS anchor plug. Two fractures were treated with a combination of a plate and strut allograft, and the remaining patient was treated with a strut allograft alone. None of the fractures extended to the anchor plug fixation pins, destabilized the anchor plug, or resulted in loss of compression or fixation of the implant. None of these patients underwent implant removal. One other patient sustained a superficial wound infection.

Hypothesis 2 was rejected. Short-term complications were few and were similar for the two methods of stem fixation. Only two complications required implant removal. One patient needed revision surgery with a prosthetic exchange because of a periprosthetic fracture at 3 postoperative months. The remaining patient had an aseptic loosening at 12 months followup. Long-term failures were more frequent. Eleven patients needed revision surgery as a result of aseptic loosening of the femoral stem. The average time until revision surgery was 69 months (range, 3–142 months). Seven patients needed a second surgery at an average of 79 months (range, 1–137 months). Five were the result of polyethylene failure and one resulting from implant body failure (disengagement of an extensible prosthesis when the components were maximally lengthened) and the remaining one because of superficial wound infection. None of these patients underwent revision of the femoral fixation or implant removal.

Hypothesis 3 showed only one major difference associated with implant failure. Stem diameter was the only factor that predicted survivorship of the uncemented stems. Prosthetic stem diameter under 13.5 mm predicted lower ($p = 0.037$) prosthetic survival. A diaphyseal/stem coefficient over 2.5 also predicted lower ($p = 0.000$) prosthetic survival. The diaphyseal/stem coefficient of 2.5 from our entire patient cohort had a sensitivity of 92%, a specificity of 96%, a false-positive rate of 4%, a false-negative rate of 8%, a positive predictive value of 92%, a negative predictive value of 96%, overall accuracy of 95% for prosthetic failures, and a Youden’s index of 88%. The ROC curve analysis demonstrated an optimal diaphyseal/stem coefficient cut point of 2.50 with an area under the curve of 0.851 (SE, 0.54; 95% confidence interval, 0.74–0.95) (Fig. 6). No relationship was found between the prosthetic outcome and the age ($p = 0.7$), gender ($p = 0.9$), the percentage of the femur that had been

Fig. 6 Receiver operating characteristic (ROC) curve analysis demonstrated an optimal diaphyseal/stem coefficient cut point of 2.50 with an area under the curve of 0.851 (standard error, 0.54; 95% confidence interval, 0.74–0.95). Diagonal segments are produced by ties.

Table 3. Comparison of mean Musculoskeletal Tumor Society scores between groups

Measure	Group 1 (UCS: n = 50)	Group 2 (CPS: n = 41)
Pain	4.4	4.7
Function	4	4.1
Acceptance	4.3	4.7
Supports	4.2	4.5
Walking	4.4	4.5
Gait	4.2	4.3
Total score	25.7	26.8

UCS = uncemented stem; CPS = Compress® uncemented fixation.

resected ($p = 0.7$), approach used (anteromedial or anterolateral; $p = 0.9$), the diameter of the Compress® plug ($p = 0.5$), the use of chemotherapy ($p = 0.1$), or amount of compression ($p = 0.6$).

Hypothesis 4 was rejected because functional scores were good in most patients and were similar for both types of reconstruction. In the patients who retained the Compress® prosthesis (36 cases), the Musculoskeletal Tumor Society (MSTS) functional score at last followup was 26.8 of 30. Function was rated as 26 to 30 points in association with 30 reconstructions, 20 to 25 points in four, and 15 to 19 in two patients (Table 3). For the patients who retained

the press-fit stemmed prosthesis (37 cases), the mean MSTS functional score at last followup was 25.7 of 30.

Discussion

Bone ingrowth promises more durable biologic fixation of megaprotheses. Two distinct devices are traditional long stem devices and the short stem Compress® Compliant Pre-Stress Implant intended to reduce stress shielding and enhance biologic fixation. The relative performance of different types of fixation is unknown. We therefore hypothesized there would be: (1) no difference in prosthetic survival between the two devices; (2) no difference in nonseptic complications; (3) no difference in the factors associated with prosthetic survival; and (4) no difference in the ISOLS functional scores in each domain of the scoring system.

Our study has several principal limitations. First, the study has limited scope to detect some differences, including survival, between the groups. We explored 11 variables that are postulated to influence prosthetic survival in the Cox model, limiting its power. Thus, some of these could be important and we failed to identify this. Furthermore, there may be other variables that we did not capture or analyze. Some reviewers dismiss this possibility, but it actually may be more important than the relative power of known variables to assess the contribution to failure of a totally new form of fixation technology (Compress®). Second, although it was a sequential study of patients undergoing limb salvage, some reviewers believe there may have been selection bias because of the patients who underwent amputation (5% of our patients during this time). How this may have biased the results of prosthetic survival in those whose limbs were spared is concerning to some. Third, the UCS procedures were performed earlier and had longer followup. The relatively short followup of the Compress® implants limits our ability to project their long-term survival. Furthermore, the predominance of their failures in the first year and success thereafter raises the possibility that they will outperform the uncemented press-fit stems. Short followup leaves this possibility in the speculative realm.

We found no differences between the two new methods of uncemented prosthetic fixation for tumor prostheses. Prosthetic reconstruction has advantages such as the maintenance of motion and immediate functional restoration. However, although high prosthetic survival rates have been reported [3, 25], complication and long-term failure rates have also been high [5, 13, 16, 29, 30]. With longer followup, aseptic loosening replaces infection as the principal mode of failure [5, 11, 12, 15–17, 23, 25, 29, 31]. Because patients are living longer, it is even more

important to extend the survivorship of our prosthetic reconstructions. The two methods of fixation studied in this work are based on different strategies for biologic fixation that have the potential to accomplish this [1, 2, 4, 10, 18]. We found both achieve good early prosthetic survivorship, there is continued deterioration of results in the uncemented press-fit stem, and there is need for longer-term followup of the Compress® device to establish its ultimate failure rate. Patients treated with CPS prostheses showed a survival rate of 88% at 5 years, and patients with UCS prostheses showed a survival rate of 85% during the same period. A review of the literature shows similar or even lower midterm results. Previous reports demonstrated survival rates ranging from 67% to 90% [2, 10, 15, 16, 25, 27, 34]. These two implants thus seem to have survivorship at least comparable with other designs for distal femoral replacement.

Complications and factors predictive of survival showed some important differences between the two prosthetic groups. The main difference between the groups was the time distribution when complications occurred. In the CPS group, most complications occurred during the first postoperative year, whereas in the UCS group, failures occurred over the entire followup period. This low rate of failures after the first postoperative year could be because of stable radiographic osteointegration and bone hypertrophy that avoid the stress shielding and loosening observed with long stems [1, 2, 4, 6, 18].

The prosthetic-stem ratio was highly sensitive and specific for predicting failure. Based on this retrospective analysis, we recommend that it be tested as a guide to select stem size when using this implant. None of the other factors we studied predicted outcome or had clinical usefulness.

The fourth question was answered by both groups having high MSTs functional scores. This is not surprising because the magnitude of resection was the same and the knee implant was identical for the two groups. It confirms that the method of fixation of the femoral stems had no functional consequences between these two prostheses over the terms of the study.

Our data suggest the CPS prosthesis has similar 5-year survival compared with the UCS prosthesis (88% versus 85%), but in the CPS group, no failures were observed after 1-year followup; therefore, CPS fixation may improve prosthetic long-term survival. Additional studies with longer followup will allow us to assess the ongoing potential for CPS failure. Uncemented press-fit stem diameter under 13.5 mm and a diaphysis/stem coefficient over 2.5 predicted lower prosthetic survival.

Based on our experience with the Compress® device, we recommend CPS for revision of cemented and uncemented prostheses whenever there is adequate bone stock at the junction and throughout the remaining bone. It is

particularly suited for narrow intramedullary canals and short residual bones that cannot accommodate a standard length stem.

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