In vitro evaluation of a low-modulus mesh canine prosthetic hip stem

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Objective—To compare an electron beam melting–processed (EBMP) low-modulus titanium alloy mesh stem with a commercial cobalt-chromium (CC) stem in a canine cadaver model.

Sample Population—9 pairs of cadaver femora.

Procedures—EBMP stems of 3 sizes were placed in randomly chosen sides of femora (left or right) and CC stems in opposite sides. Stem impaction distances were recorded. Five strain gauges were attached to the femoral surface to record transverse tensile (hoop) strains in the femur during axial loading. Constructs were axially loaded 4 times to 800 N and 4 times to 1,600 N in a materials testing machine. Axial stiffness of constructs and bone surface strains were compared between EBMP and CC constructs.

Results—Stems were impacted without creating femoral fissures or fractures. Stem impaction distances were larger for EBMP stems than for CC stems. Mean axial stiffness of EBMP constructs was lower than mean axial stiffness of CC constructs. Subsidence did not differ between groups. Bone strains varied among strain gauge positions and were largest at the distal aspect of the stems. At a load of 1,600 N, bones were higher in CC constructs than in EBMP constructs for 2 of 4 medial strain gauges.

Conclusions and Clinical Relevance—EBMP stems were successfully impacted and stable and led to a focal decrease in bone strain; this may represent an acceptable option for conventional or custom joint replacement. (Am J Vet Res 2010;71:1089–1095)

Although cemented hip stems have been used successfully as part of total hip replacements in humans, their success rate has been reportedly lower in younger patients than in older patients. The long-term success of hip stems is affected by aseptic implant loosening, implant wear, and stress-mediated bone resorption (stress shielding). Cementless hip stems were originally developed in part because polymethylmethacrylate bone cement was considered to be a contributing factor to aseptic loosening of cemented hip stems. A portion of a cementless stem is textured or coated with porous surfaces for bone ongrowth and ingrowth. Stem stability relies on initial press fit and long-term bone ingrowth into the porous portions of the stems. Cementless stems are large and have a high stiffness (modulus of elasticity), which contributes to proximal femoral stress shielding. Shielding can lead to bone loss from the proximal portion of the femur, which is less when low-modulus stems are used. Low-modulus stems that are made from polymers or carbon fibers have been designed, and early clinical results have been mixed because of increased bone-implant interface stresses and suboptimal bone ingrowth. Successful early fixation and low bone loss have been achieved with a low-modulus stem with a forged CC core, polyaryletherketone midsection, and titanium fibermetal outer layer.

Geometrically complex structures may be manufactured layer by layer with solid free-form fabrication methods. Metal structures are made by projecting an energy beam (laser or electron) on a metal powder substrate and building one 50- to 100-µm-thick layer at a time while melting the layers together to form larger structures. Electron beam melting has been used to fabricate custom implants, osseointegrated prostheses, and lightweight cellular structures. The mechanical properties of EBMP implants may be tailored by adjusting the dimensions of metal scaffolds. The authors
designed and fabricated a low-modulus EBMP mesh prosthetic stem in a previous project. The objectives of the study reported here were to assess the stability and bone surface strains of low-modulus EBMP mesh stem constructs in cadaveric canine femora and compare them with a commercial cementless stem. We hypothesized that the low-modulus mesh stems would be stable and decrease bone surface strains, compared with results for the commercial cementless stems.

**Materials and Methods**

**Specimens**—Thirteen pairs of femora were collected from skeletally mature large-breed dogs that were euthanatized at a local animal shelter as part of population control programs. Soft tissue was cleaned from the femora. Cranio-caudal and mediolateral radiographic views were obtained, and a magnification marker was used. Cortical thickness in the subtrochanteric region was measured. The bones were wrapped in saline (0.9% NaCl) solution–saturated gauze, placed in plastic storage bags, and frozen at –18°C until stem implantation. Templates for CC implants were used to select implant sizes.

**EBMP stem design and fabrication**—The EBMP stems were designed to have outer surface dimensions identical to CC stems. The CC stems were selected because they were the only commercially available canine stems for which initial stabilization is achieved by use of press fit. Computer-aided design files of CC stems provided by the manufacturer were imported into a modeling software program and transformed into non-stochastic lattice structures with uniform cell sizes. The lattice structure included rhombic dodecahedron cells that were sized and oriented to have an elastic modulus approximating the modulus of cortical bone (Figure 1).

The compressive strength of the cellular structures was > 80 MPa, and their elastic modulus was approximately 12 GPa. The textured surface of the EBMP stems corresponded to the beaded surface of the CC stems. The surface was created by expanding the lattice so that it protruded from the stem by 0.25 to 0.75 mm in the region corresponding to the beaded region of CC stems (Figure 2). The distal aspect of the protruding region was hand filed to ensure a smooth transition between the protruding and the nonprotruding regions. The stem necks were machined by use of a computed numerically controlled machine to accept 17-mm-diameter prosthetic heads. Electron beam melting–processed stems corresponding to size 9, 10, and 11 CC stems were made. Only 3 stem sizes were built because of the logistical limitations of the project. Large stem sizes were selected to enhance the likelihood of detecting differences between EBMP and CC constructs. A size 12 stem was not built because, on the basis of the authors' clinical experience and the size of cadaver bones likely to become available, it seemed unlikely that cadaveric femora from a dog large enough to receive a size 12 stem would be available. The cranio-caudal and mediolateral widths of the smooth and beaded portions of the CC and EBMP stems were measured by use of a caliper. Similar measurements were made on the CAD files of the CC stems.

**Stem implantation**—The cranio-caudal radiographs were used as a template for estimation of mediolateral fit, and the mediolateral radiographs were used...
The femoral condyles were cut so that the femora measured approximately 14 cm. The distal portions of the femora were embedded into polymethylmethacrylate so that stems were directed distally and medially at a 10° angle to vertical (Figure 3). Metal heads (17 mm diameter, +3-mm neck length) were attached to the hip stems. Five unilateral strain gauges were glued to the femur to record transverse tensile (hoop) bone surface strains. Four were placed on the medial aspect of the bone and were evenly distributed along the length of the stem. One was placed on the lateral aspect of the femur at the distal aspect of the stem. Strain gauge levels and orientation were checked by use of calipers and were identical for paired femora. Polyurethane coating was applied over the strain gauges after attachment to reduce noise and prevent short circuits caused by the saline solution–saturated gauzes on bones. Data were collected with the input channels of the materials testing machine by use of a data acquisition board set up for a one-fourth bridge circuit. The strain gauges were attached to the bridge circuit, and the circuits were balanced for each gauge before testing. The constructs were matched to ultra-high molecular weight polyethylene cups mounted on the crosshead, axially preloaded at 20 N for 30 seconds, and loaded at 0.1 mm/min to 800 N 4 times on a materials testing machine. The constructs were preloaded again and then loaded at 0.1 mm/min to 1,600 N 4 times. Loads and strain gauge readings were recorded simultaneously during testing. Noise was reduced, and data were analyzed by use of the moving averages method for 30 periods. Stem position was measured with a caliper before and after testing. Subsidence was calculated as the difference between initial and final stem positions. Construct failure was defined as the occurrence of a femoral fissure or fracture or stem subsidence > 10 mm.

Statistical analysis—Strain gauge readings, loads, and actuator displacements were analyzed with statistical software. Paired Student t tests were used after confirmation that data were normally distributed. Surface strains for individual gauges on EBMP and CC constructs were compared within and among groups by use of 1-tailed tests. Construct stiffness was calculated from the linear portion of the fourth 800-N loading event and was compared between EBMP and CC constructs by use of 2-tailed tests. Initial and final drive distances, final stem position, and subsidence were compared within and among groups by use of 2-tailed tests. Significance was set at P < 0.05.

Results

Four pairs of femora were excluded from the study because they were too small (3 pairs) or too large (1 pair). Nine pairs were included in the study and were obtained from dogs with a mean weight of 38 kg (range, 25 to 48 kg). Mean ± SD (range) cortical thicknesses were 1.8 ± 0.4 mm (0.9 to 2.5 mm) medially, 1.6 ± 0.3 mm (0.9 to 2.2 mm) laterally, 2.2 ± 0.4 (1.3 to 2.8 mm) cranially, and 1.7 ± 0.4 (0.8 to 2.9 mm) caudally. Four size 9, 3 size 10, and 2 size 11 stem pairs were implanted. The templated stem sizes were 1 size larger on mediolateral radiographs than on craniocaudal radiographs for 5 dogs and were identical on medio-
lateral and craniocaudal radiographs for 4 dogs. The impacted stems were identical to the size determined via craniocaudal radiograph templates for 7 dogs and 1 size smaller for 2 dogs. No femur fissured or fractured during stem implantation of EBMP or CC stems. Mean width of the smooth portion of the CC stems was 1% larger than their corresponding CAD files (range, −1% to 4%). Mean width of the textured portion of the CC stems was 4% larger than the corresponding CAD files (range, 1% to 9%). Mean width of the smooth portion of the EBMP stems was 3% larger than the CC stems (range, 1% to 5%). Mean width of the textured portion of the EBMP stems was 6% larger than the CC stems (range, 5% to 8%). Mean ± SD initial drive distances were 18 ± 4 mm for EBMP stems and 10 ± 2 mm for CC stems (P = 0.054). Eight femora were overbroached during placement of EBMP stems and 4 during placement of CC stems. Mean final drive distances were 7 ± 2 mm for EBMP and 5 ± 2 mm for CC stems (P = 0.043). Mean stem positions were 2 ± 1 mm proximal to neck cuts for EBMP and −1 ± 2 mm for CC stems (P = 0.011). Mean construct stiffnesses were 995 ± 80 N/mm for EBMP and 1,606 ± 240 N/mm for CC stems (P < 0.001). Stem subsidence after loading to 1,600 N was 2.6 ± 1.1 mm for EBMP and 3.0 ± 1.6 mm for CC stems (7 pairs analyzed; P = 0.384; power = 0.900).

Bone surface transverse tensile (hoop) strains were higher at the distal than the proximal aspect of EBMP and CC stems (Table 1). Bone surface strains at 800-N loads did not differ significantly among groups. Bone surface strains at 1,600-N loads were lower for 2 gauges on the medial aspect of EBMP constructs and did not differ significantly for the other 3 gauges. One CC construct failed by subsiding >10 mm at a load of 800 N, and the EBMP construct from the opposite limb failed by developing a fissure at the medial aspect of the femoral neck at a load of 1,600 N. The cortices of that pair of bones were the thinnest of all cortices in the study. This pair was excluded from analyses of subsidence and bone surface strains. Another EBMP construct failed by subsiding >10 mm at a load of 1,600 N. This pair was excluded from analyses of subsidence and bone surface strains at 1,600 N.

### Discussion

This project compared the axial stability and bone surface hoop strains after implantation of 2 types of cementless prosthetic stems into canine femora. The low-modulus mesh stems were not damaged during implantation and testing and did not create femoral fissures or fractures during impaction. They did not subside more than did CC stems during axial loading. On the basis of these results, low-modulus mesh titanium implants could be considered for clinical applications.

The EBMP stems made for this study closely approximated the dimension of the commercially available CC stems. This was done so that the same instrumentation could be used for implantation and the stiffness and surface characteristics would be the only differences between stems. With this technology, stems could be made to any shape that could be implanted and even customized to patients with bone abnormalities. The EBMP stems were slightly larger and were inserted slightly more proximally in the femoral canal, compared with the CC stems. Even though EBMP and CC stems were built from identical CAD files, the slightly greater EBMP stem size was most likely attributable to the EBMP fabrication process that adds a 0.5-mm material allowance on built surfaces to allow for surface finishing. The size difference between EBMP and CC stems was larger for the textured portion of the stems than their smooth portion, most likely because another 0.5 mm was added to these surfaces for EBMP stems. That 0.5 mm created a stem surface that was slightly thicker than the CC textured surface that was made of 3 layers of heat-sintered, 0.25-mm-diameter beads.
Overbroaching was used for EBMP and CC stems to decrease the drive distance of the stems. Overbroaching appears to be a safe and effective method to avoid potential fissures that could result from size mismatches between cementless EBMP or CC stems and recipient femora. Although it was not known with certainty, the slight differences in EBMP and CC stem size appeared to cause construct geometry. The stems were impacted on the basis of the resistance to impaction felt by a surgeon (DJML) with extensive experience (>19 years) in placement of the cementless stems, rather than being impacted to a predetermined level. The surgeon’s intent was to impact EBMP and CC stems with the same force. The fact that equal impaction loads were used for EBMP and CC stems was indirectly confirmed by the fact that the slightly larger EBMP stems were placed in a slightly more proximal position than were the smaller CC stems. The stem impaction distance (final drive distance) was 2 mm longer for EBMP stems than for CC stems. The slight difference in impaction distance may have resulted from differences in mechanical properties of the textured surface of the EBMP stems, compared with the beaded surface of the CC stems. The textured mesh of the EBMP stem would likely be less stiff than the beads sintered on the solid core of the CC stem. It is possible, but unlikely, that the surgeon had an unintentional bias, leading to the impaction of EBMP stems with a larger force than the CC stems. Such a difference in impaction force could have led to an increase in bone surface strains, something that was not identified.

The EBMP and CC constructs were stable, as evidenced by the lack of clinically relevant subsidence after 1,600-N axial loads. A 1,600-N load was selected as the maximal load because it corresponded to loads used in a previous study of bone surface strains after cementless hip arthroplasty in dogs. The large load corresponded to approximately 5 times body weight. Although this load is greater than loads applied at a trot, it could approximate the axial loads placed on the femur at a gallop or during jumping. The lack of subsidence at these large loads may have been attributable in part to the fact that large stems were placed in this study. Experimentally, subsidence decreases when canal fill increases in canine femora. Also, large stems placed in a neutral position lead to a strain distribution that most closely matches the normal strain distribution in Greyhound femora, compared with undersized stems placed in a neutral or varus position. The authors of the present study currently place large CC stems in clinical patients. The EBMP constructs were approximately 40% less stiff than the CC constructs. Differences in construct stiffness resulted from structural differences; the porous titanium EBMP stems were approximately one-twentieth as stiff as solid CC stems.

The ability to detect differences between EBMP and CC constructs was limited by the small sample size in this study. As many matched pairs of large femora (n = 13) as possible were collected during the study period. Among those, 9 pairs were appropriately sized for the stems used in this study. The small sample size limited the ability to detect significant differences between groups and lowered the power of statistical tests. Mean hoop strains were decreased in 2 of 4 gauges on the medial aspect of the constructs when loaded to 1,600 N, likely because of the decrease in construct stiffness of EBMP constructs, compared with CC constructs. The hoop strains measured in this study were similar in magnitude to hoop strains reported in other canine studies. Most of the strain gauges were placed on the medial aspect of the bone because hoop strains are largest on the medial and cranial aspects of the bone after cementless stem placement in dogs. Large hoop strains were present at the distal aspect of the stem, in agreement with previous reports.

The large variability in bone surface strains in this study may have resulted from the heterogeneity of the bones and variability resulting from hand-performed stem impaction. Mechanical impaction decreases the variability in bone surface strains, compared with hand impaction. The impact of low-modulus stems on longitudinal bone surface tensile and compressive strains could not be assessed in this study because the linear strain gauges were placed transversely rather than longitudinally and rosette strain gauges were not used. Rosette strain gauges would have allowed a simultaneous assessment of longitudinal and transverse (hoop) strains. Also, rosette strain gauges would have increased the accuracy of strain gauge measurements because their response to loading is not influenced by errors in orientation. Low-modulus stems had a minor impact on longitudinal and tensile strains in an experimental study in canine femora, and they led to a decrease in bone loss, compared with stiffer stems, in an experimental trial. Our research group modeled the von Mises stresses present in canine femora after implantation of solid CC, solid titanium, and porous titanium stems and found that stress shielding in the subtrochanteric region was decreased in constructs with porous titanium stems. Low-modulus stems in human femora lead to increased (but physiologic) compressive longitudinal strains in the proximal and medial aspect of the femur under axial loading and increased (supraphysiologic) transverse strains in the proximal and medial aspect of the femur under torsional loading. In humans, and possibly in dogs, low-modulus stems may require customized anatomic features to avoid placing excessive transverse strains on the proximal portion of the femur.

The stability of EBMP constructs and the impact on bone surface strains could have been more fully characterized by placing torsional loads instead of, or in combination with, axial loads. Torsional stem stability is an important component of the initial stability of cementless prosthetic stems. In human femora, hoop strains are larger during torsional loading than during axial loading and hoop strains are lowered by the use of low-modulus stems. A full characterization of the mechanical properties of low-modulus mesh stems should also include fatigue testing of the stems because implant strength is also reduced in low-modulus stems.

Only 3 constructs failed during axial loading, even though the loads placed on the constructs represented approximately 2.5 and 5 times the body weights of the dogs. One CC construct failed by subsiding excessively at a load of 800 N. The cortices of that construct were the thinnest of all cortices in the study, and subjectively, little resistance
was encountered during broaching, suggesting poor bone quality. The EBMP stem in the opposite paired bone also failed, but this occurred during application of the 1,600-N load. That femur also had thin cortices. This suggests that femora with thin cortices, where broaching encounters little resistance, may be predisposed to stem subsidence or femoral fissures after cementless hip arthroplasty. Bone mineral content and density in dogs are affected by age and sex and may vary among breeds.4 Age, sex, and breed, however, were not available for the dogs included in this study. Although peak stresses increase as cortical thickness decreases in human femora receiving prosthetic stems, a correlation between bone mass and stem subsidence was not identified in an in vitro study of 9 pairs of cadaveric human femora. The low-modulus stems made for this study have the advantages of a simple design and require minimal finishing of the neck region after EBM fabrication. The low-modulus stems had lattice structures that protruded over areas corresponding to the beaded region of CC stems. The mechanical properties of the low-modulus stems could potentially be optimized by changing cell sizes or geometric features. For example, decreasing cell size on the stem surface might increase the coefficient of friction (scratch fit) of protruding areas without substantially affecting stem stiffness. The long-term clinical response to the EBMP stem used in this study is unknown. The distal portion of the EBMP stem was porous, which could potentially lead to distal ingrowth and excessive periosteal bone loss. Distal bone ingrowth might be avoided by covering the stem surface with a thin, perforated titanium skin, which would increase the modulus of the distal portion of the stem. Increasing the size of the internal metal scaffold could decrease that modulus. The perforations should be sufficiently large to allow the removal of unprocessed titanium powder. Because stem stability primarily results from the contact of the textured portion of the stem with endosteal bone, modifications of the distal portions of the stem are unlikely to influence the mechanical properties of the constructs. Because of its relatively simple manufacturing process and acceptable mechanical performance, the stem design and fabrication process used in this study could be considered for clinical applications. This may be particularly applicable to custom applications in which the desired stem size and shape are different from presently available stems.

References


