A Comparative Study of Bone Ingrowth into Porous Metallic Materials

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INTRODUCTION
Bone ingrowth into porous metallic materials has been used for implant fixation in orthopedic devices. Materials with an extensive clinical history include sintered spherical beads of titanium and cobalt chrome alloys and sintered titanium mesh. These systems have performed well, but have perceived limitations based on a relatively low porosity and high modulus. To address these limitations, several novel porous metallic materials have been developed that mimic the structure of cancellous bone, with approximately twice the porosity of traditional coatings, and a correspondingly lower modulus. This study evaluated the osseous response to three novel porous materials in an animal model. We hypothesized that (1) the experimental materials will have similar bone ingrowth compared to the controls and (2) that there will not be a significant difference in bone ingrowth between the foam materials.

METHODS
Titanium and cobalt chrome foams were manufactured in bulk form by a repliform sintering process (Biofoam™, Wright Medical Technology, Arlington, TN). Tantalum foam metal specimens were manufactured by a repliform chemical vapor deposition process (Trabeucal Metal™, Zimmer, Warsaw, IN). The three foam metal types have reported porosities of 68% (Ti), 69% (CoCr) and 75-85% (Ta). The pore sizes ranged from 400 – 600 um for all three materials. Sintered titanium bead implants were manufactured (Orchid Stealth Medical, Memphis, TN) by pre-sintering beads in graphite molds and then fully sintering the beads using the typical process for implant coatings.

Cylindrical implants of the experimental and control materials were implanted bilaterally with line-to-line reaming into the distal femora and proximal tibiae of 16 nearly mature, male New Zealand white rabbits. One cadre was sacrificed after three weeks (N=3 per group) and one at twelve weeks (N=5 per group).

The most distal 2-3 mm cross sections from the femur and the proximal sections from the tibia were ground and polished. High-resolution contact radiographs were made of each section for measurement of the appositional bone index (ABI), or the percent of bone in contact with the implants. Bone area analysis consisted of quantitatively measuring the amount of bone present in the porous coating and periprosthetic regions using back-scatter electron microscopy (BSE) imaging. Digital BSE images were taken at 20x and 40x magnification with a resolution of 1024 x 768 pixels, to determine bone growth around and in the implants.

For each time point and anatomical site, ABI scores and bone ingrowth analyses for the four materials were compared using univariate analysis of variance (ANOVA) followed by post hoc analyses with a Bonferroni test (Stata 10.0, College Station, TX). P < 0.05 was considered statistically significant. Assuming an α=0.05 and a β=0.80, power analysis showed that a minimum of 3 rabbits per group were needed to detect a 20% difference between control and treatment specimens.

RESULTS
ABI: At the three-week time point, the femoral ABI was evaluated with the two most distal time sections. A significant difference was noted between the groups (anova p-value = 0.0107) and a Bonferroni post-hoc test indicated that CoCr had a significantly lower ABI when compared with titanium foam (p=0.041), tantalum foam (p=0.011) and titanium beads (p=0.053). When the most distal section was evaluated, no significant differences were noted amongst the four materials. At 12 weeks there were no significant differences in ABI when the most distal and two most distal sections were analyzed.

BSE Periprosthetic and Bone Ingrowth: A comparison of femoral and tibial bone ingrowth in the periprosthetic region and in the implants at both the 3-week and 12-week time points did not reveal significant differences across the four materials. (Figure 2).

DISCUSSION
These data confirm our hypotheses. For the femoral ABI, titanium foam was the only material to show an increase from 3 to 12 weeks. At 3 weeks, titanium foam yielded a significantly lower ABI than titanium beads and CoCr. There was a trend for the titanium foam to have less ABI than tantalum at 3 weeks. There were no differences at 12-weeks between any of the materials. For the tibial ABI, titanium foam and tantalum foam had ABIs of 100% at 3 and 12 weeks. CoCr showed an increase in ABI from 3 to 12 weeks. Titanium beads showed a decrease in ABI from 3 to 12 weeks. At 3 weeks, CoCr showed significantly less ABI that the other materials. At 12 weeks, there were no differences in ABI amongst all four materials in the tibia. For BSE periprosthetic and bone ingrowth, there were no significant differences between any of the materials at both the 3-week and 12-week time points on both the femoral and tibial sides.