Abstract: A study of bone ingrowth into Tesera Trabecular Technology bone plugs was conducted in a sheep femur model. Analyses including percent bone area, mineral apposition rate, and histological examination were completed for time 0, 12-week, and 24-week specimens. The results revealed no implant-associated adverse effects on the host bone and demonstrated excellent new bone formation and remodeling within and adjacent to the porous structure.

Introduction
Tesera Trabecular Technology is a porous structure created using electron beam manufacturing (EBM) or direct metal laser sintering (DMLS). In this additive manufacturing process, components are built up layer by layer from titanium alloy powder, enabling the repeatable production of intricate geometries. The morphology of the Tesera structure was designed based on published guiding principles for successful bone ingrowth. The structure has a gradient pore structure, with porosity ranging from 57% near the solid portion of the implant to 91% at the outer surface of the porous structure, which addresses the known trade-offs between porosity and strength. The pores are highly interconnected to allow migration and proliferation of cells and vascularization, the key to sustaining live bone within a porous structure. The average pore diameter is about 500 µm; in the literature, the pore sizes observed to result in bone ingrowth are in the range of 100-500 µm, with pore sizes at the upper end of this range recommended for vascularization.

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As a clinically relevant model of early bone growth into the Tesera structure, a study involving weight-bearing bone plugs in sheep was designed based on the work of Willie, et al. Observations at 12 and 24 weeks were chosen because this early ingrowth is known to be an indication of successful fixation. Willie, et al. also observed a peak in the rate of bone ingrowth at the 24-week time point.

Materials and Methods
Implant description
Fifteen cylindrical implants with Tesera structure on the circumferential surface were custom-made for this study. The bone plugs were 23.2 mm from the proximal tip to the high-point of the distal articulating surface with an 8.9-mm solid core and a 1.15-mm thick porous structure, for a total diameter of 11.2 mm. (Figure 1) The distal surface had a polished radius for weight-bearing articulation with the tibial surface.

Surgical protocol
Surgeries were performed at IMDS Discovery Research (Logan, Utah). Twelve sheep underwent unilateral surgical implantation of a porous titanium plug in the medial femoral condyle. The condyle was prepared with an 11-mm reamer inserted to a depth of 22 mm, perpendicular to the condyle surface. The plug was then inserted with the distal polished end of the plug flush to the condyle surface. (Figure 2)

Six sheep were euthanized at 12 weeks and six at 24 weeks. Three of the sheep sacrificed at 12 weeks were operated contralaterally post-mortem to represent the time 0 controls. Thus, this study included 12 ovine subjects and 15 operated specimens. After sacrifice, the operated condyles were extracted and placed in a formalin-filled container and transferred for histological study.
Histological and histomorphometric examination

Processing and analysis of the 15 specimens was conducted by the Bone and Joint Research Laboratory (Salt Lake City, Utah). Specimens were first dissected, photographed, and radiographed. (Figure 3) Then, 2-3 mm thick PMMA-embedded sections were prepared, and high-resolution contact radiographs were made. SEM imaging with a backscatter electron (BSE) detector was used to further examine the sections and to analyze the percent bone area in and around the porous structure. Fluorochrome labeling techniques were used to measure mineral apposition rate, and then the sections were stained and examined using a light microscope.

Results

Bone area analysis

Sixteen SEM images with BSE detection were taken at three levels along the length of the plug within the porous structure and in the periprosthetic region; host bone images were taken randomly 3-5 mm from the implant surface. These images demonstrated an excellent scratch fit at time 0, ingrowth at 12 weeks, and maturing bone and osteointegration at 24 weeks. (Figure 4)

The amount of bone was measured quantitatively in each image and reported as percent area. The bone area in the periprosthetic and host bone regions did not change significantly from time zero to 12 weeks and showed a slight increase at the 24-week endpoint. However, the amount of bone within the porous structure increased significantly at both the 12- and 24-week end points. (Table 1)
Table 1: Bone Area Analysis: Quantitative measurement of bone in and around the porous structure on SEM images

Figure 5: Fluorochrome double-labeled trabeculae (arrows) within the porous structure (PS) and periprosthetic (PP) regions at 12 weeks.

Light microscope

The histological evaluation found no adverse cellular reaction in response to the porous structure. Excellent bone attachment and osteoblast activates were observed within the porous structure of 12- and 24-weeks specimens. (Figures 6-8)
Conclusion

Histological and histomorphometric examination of explanted Tesera bone plugs revealed no implant-associated inflammation or other adverse effects on the host bone. Bone area analysis of SEM images found significant bone ingrowth within the 12-week specimens, which doubled for the 24-weeks specimens. Mineral apposition rate imaging revealed the formation of viable bone trabeculae within the porous structure. Light microscopy also showed continuing bone formation with osteoblast activity at 12- and 24-week time points. Thus, the experimental results of this animal model demonstrated excellent early new bone formation and remodeling within and adjacent to the porous structure, suggesting that Tesera Trabeucaler Technology porous structure provides excellent skeletal attachment.

References

2 Coating Evaluation per ASTM F1854-09 (Lab report K12076592-4). Data on file with KYOCERA Medical Technologies, Inc.