Tesera Trabecular Technology® Porous Structure

A Weight-Bearing Ovine Study

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.[1,2] The pores are highly interconnected to allow migration and proliferation of cells and vascularization, the key to sustaining live bone within a porous structure.[3,4] 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.[5,6,7,8]

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.[9] Observations at 12 and 24 weeks were chosen because this early ingrowth is known to be an indication of successful fixation.[9] 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.

Figure 1: Bone plug with Tesera Trabecular Technology porous structure

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)

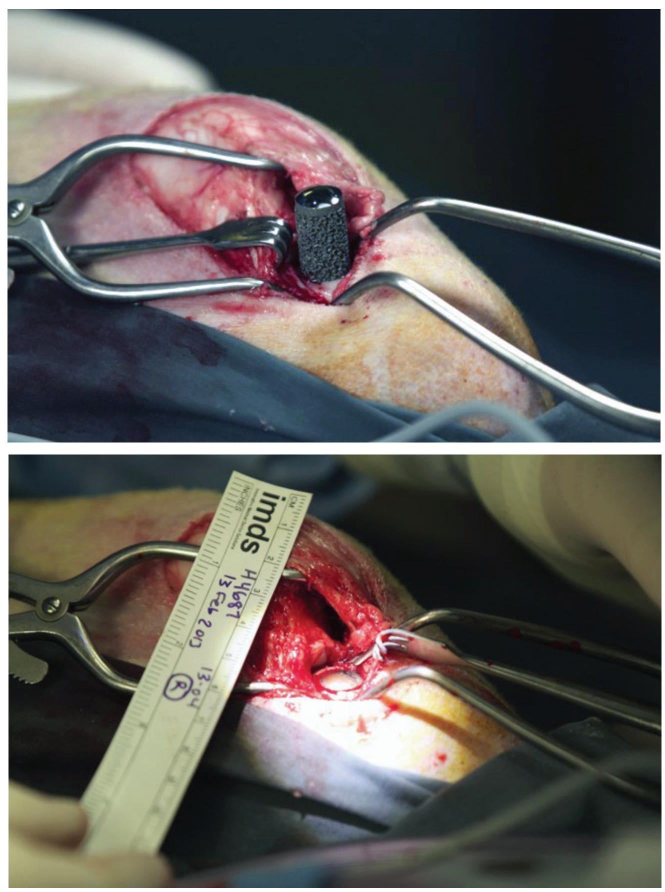


Figure 2: Surgical insertion of a Tesera bone plug

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 histomorphomic 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.

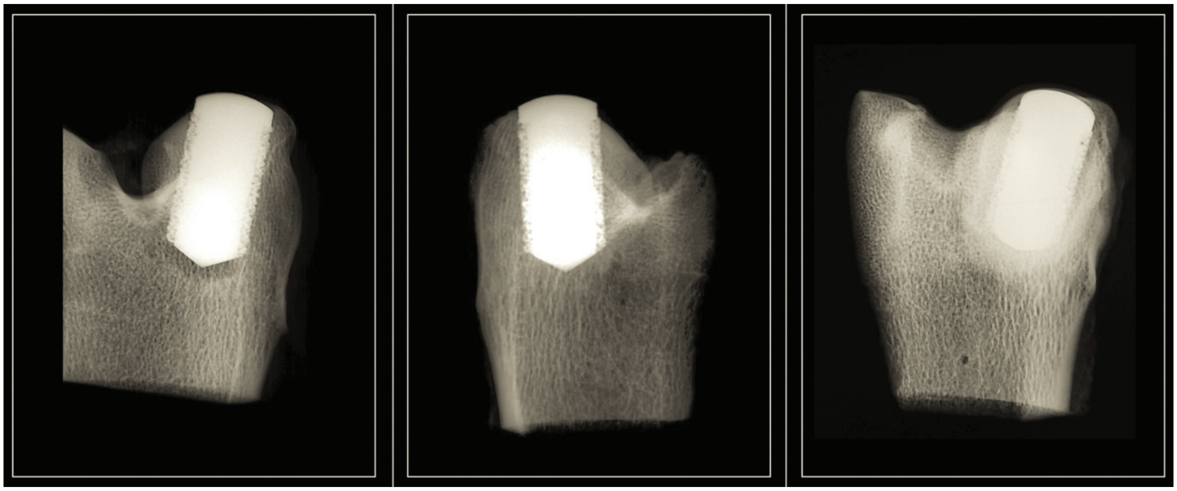
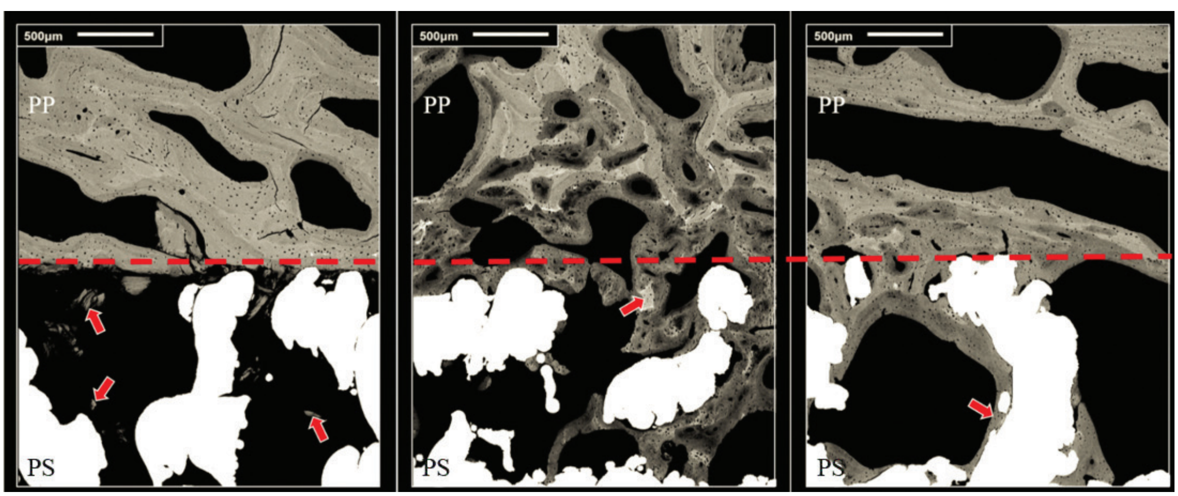


Figure 3: Radiographs of (from left to right) time 0, 12, and 24 week specimens

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)



(a) Time 0 *(b) 12 weeks* *(c) 24 weeks*

Figure 4: SEM images with backscatter detection (40X) of the Tesera porous structure (PS) and periprosthetic (PP) regions. White = titanium alloy; grey = bone; black = pore space and soft tissue. (a) Time 0 demonstrates a scratch fit with bone chips (arrows) within the porous structure. (b) This 12-week specimen has bone growth within the porous structure. The relatively darker grey of the bone within the porous structure indicates newer bone compared to the lighter grey of the host bone in the periprosthetic region. (c) This 24-week specimen has maturing bone within the porous structure, as indicated by the lighter grey color when compared to the dark grey of the bone in the 12-week specimen. Bone ongrowth (bone growing along the implant surface) was observed (arrow).

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)

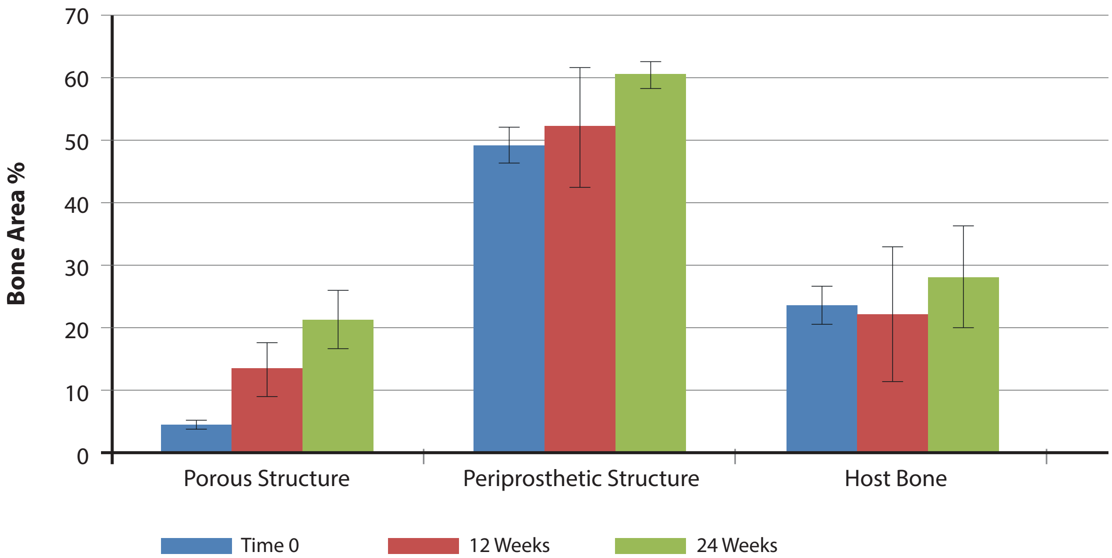


Table 1: Bone Area Analysis: Quantitative measurement of bone in and around the porous structure on SEM images

Mineral apposition rate

All of the 12- and 24-week samples exhibited double-labeled trabeculae at the porous structure interface, indicating viable and actively remodeling bone. (Figure 5)

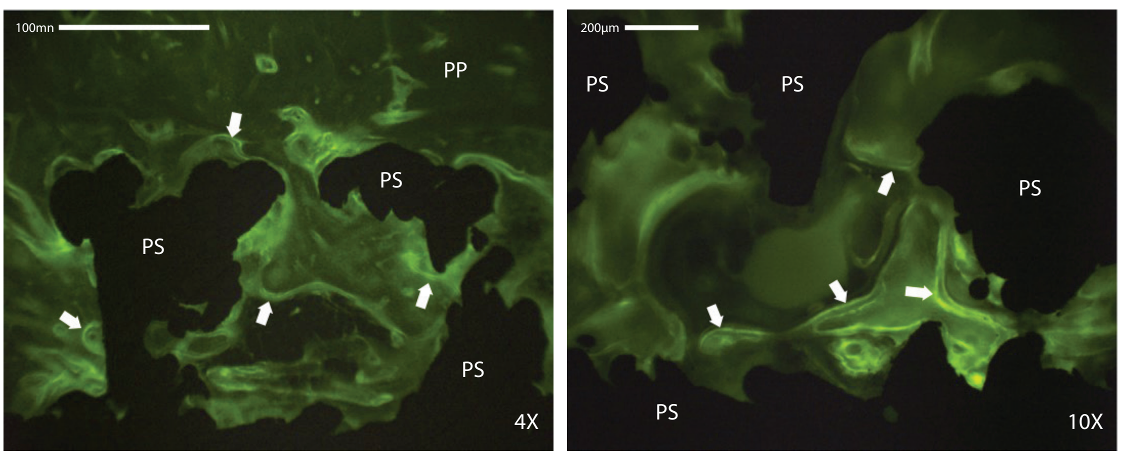
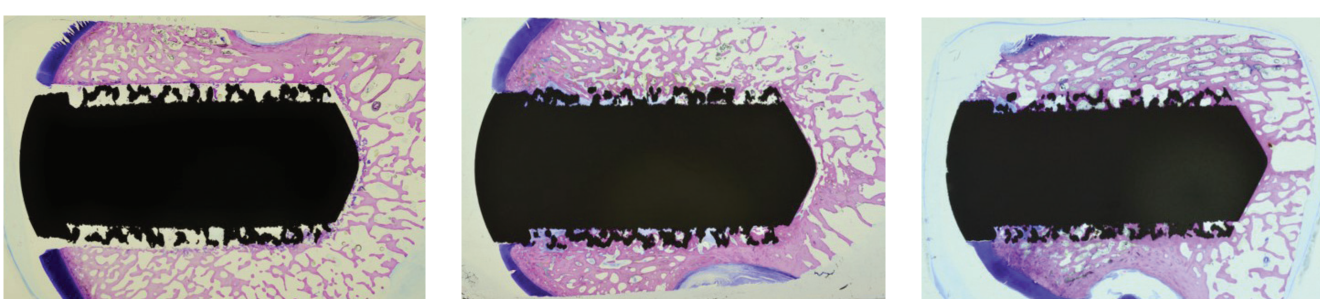


Figure 5: Flourochrome double-labeled trabeculae (arrows) within the porous structure (PS) and periprosthetic (PP) regions at 12 weeks.

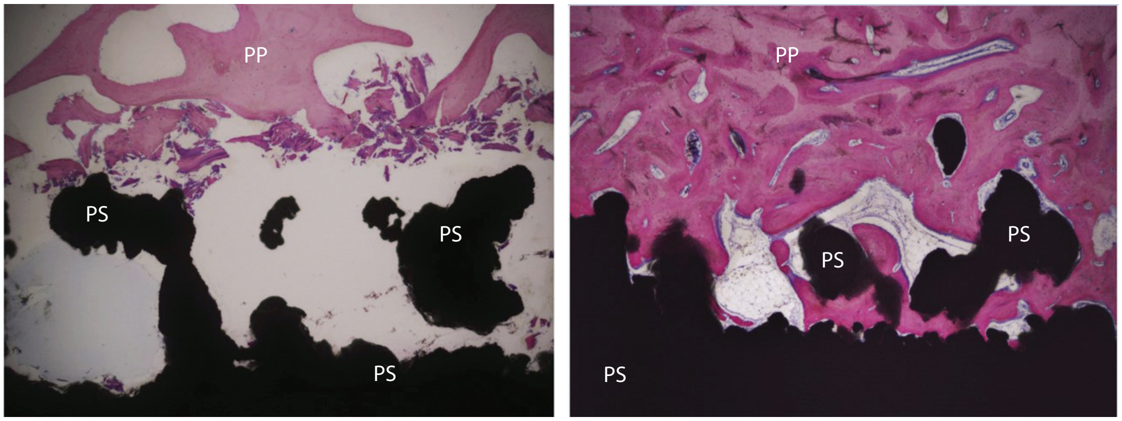
Light microscope

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)



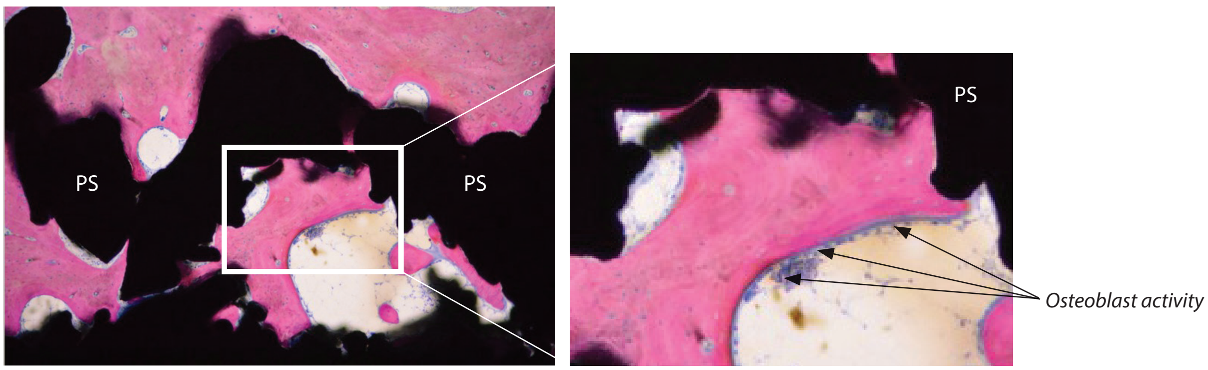
(a) Time 0 *(b) 12 weeks* *(c) 24 weeks*

Figure 6: Light microscope images of full specimens, showing excellent bone ingrowth by the 12 week time point.



(a) Time 0 *(b) 12 weeks*

Figure 7: Light microscope images of the porous structure (PS) and periprosthetic (PP) regions at (a) Time 0 and (b) 12 weeks.



(a) *(b)*

Figure 8: Light microscope image of 12-week specimen. (a) 10X magnification demonstrating bone attachment to porous structure (b) Detail image showing osteoblast activity (arrows) within the porous structure.

Conclusion

Histological and histomorphomic 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 Technoloby porous structure provides excellent skeletal attachment.

References

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