OsseoTi Porous Metal For Enhanced Bone Integration *an Animal Study*

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OsseoTi Porous Metal is made out of Ti6Al4V alloy that is highly biocompatible, has excellent corrosion resistance, and has a proven history of clinical success.[1, 2] OsseoTi Porous Metal contains a porous architecture that mimics the porous structure of human cancellous bone (Figure 1). The physical properties of OsseoTi Porous Metal have been designed to enhance the potential for bone integration.[3] In this study, the interaction between bone and OsseoTi Porous Metal was analyzed in a sheep model.

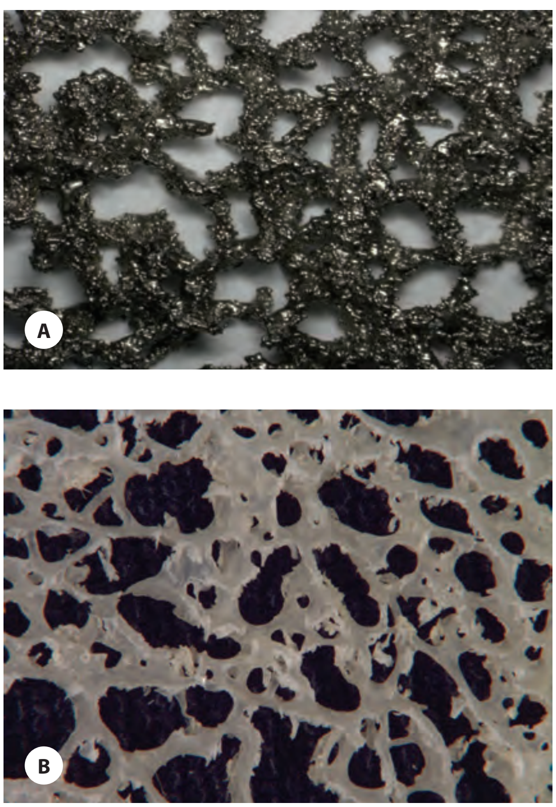

Fig. 1
The porous architecture of OsseoTi Porous Metal (A) mimics the porous architecture of human cancellous bone (B)

METHODS

OsseoTi Porous Metal cylindrical samples (20 mm long, 8 mm in diameter) were implanted bilaterally into cylindrical defects created in the distal femur and proximal tibia of sheep. The animals were sacrificed after 4, 12, and 26 weeks, with the explants harvested and processed for biomechanical push out testing (N = 9) and histological evaluation (N = 3) at each time point. For the biomechanical push-out testing, the specimens were mounted in custom fixtures and were subjected to compressive loading in the medial-lateral direction to quantify the ultimate shear push-out strength. For histological evaluation, the specimens were processed for undecalcified PMMA embedding. Longitudinal sections of the specimens were ground and stained with Sanderson's rapid bone stain.

RESULTS & DISCUSSION

The OsseoTi Porous Metal structure showed excellent integration with host bone as early as 4 weeks post implantation. This was apparent by a large amount of tissue attached to the outer surface of the push-out sample (Figure 2). After 12 weeks, the implant integration with host bone increased, as expected, as illustrated by a continuous layer of bone tissue attached to the outer surface of the implant (Figure 2). The biomechanical testing data confirmed the strong integration between OsseoTi Porous Metal and host bone, and showed that the mechanical stability increased from 4 weeks to 26 weeks (Table 1).

Table 1
Biomechanical push-out loads for OsseoTi Porous Metal after 4, 12, and 26 weeks of implantation[3]

	4 weeks	12 weeks	26 weeks
Push-out load (N)	4066.1	5609.6	6973.0

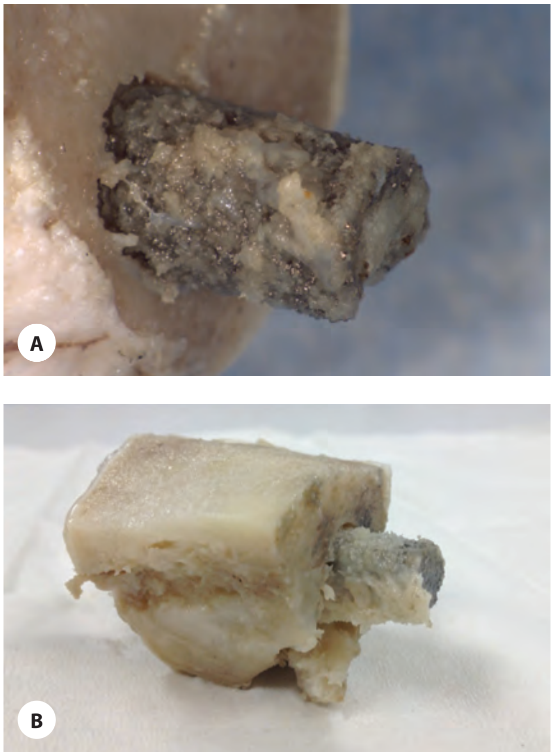

Fig. 2
OsseoTi Porous Metal push-out samples at (A) 4 weeks and (B) 12 weeks

After 4 weeks, the histological analyses showed that new woven bone had thickened along the outer structure and had begun to penetrate the OsseoTi Porous Metal in the form of thin trabeculae. When in contact with metal, the bone was often very closely attached such that gaps were not apparent. After 12 weeks of implantation, the extent of bone ingrowth and remodeling onto and inside the OsseoTi Porous Metal had occurred to a greater degree than that at 4 weeks, as expected. At 26 weeks, in some regions, bone fusion was observed, with new bone growing from both sides of the implant and bridging across a sample thickness of 8 mm as shown in Figure 3. In addition, very close attachment was observed between bone and the metal. There was no evidence of adverse inflammation within or around the OsseoTi Porous Metal during the study.

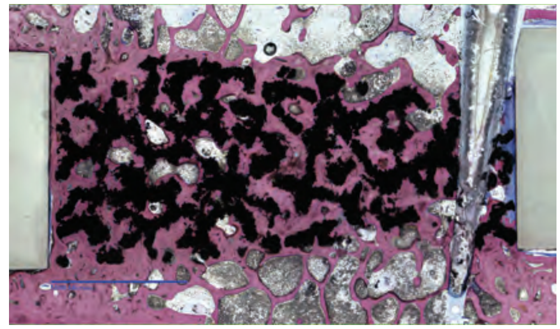

Fig. 3
Histological image at 26 weeks showing bone fusion across 8 mm thickness of OsseoTi Porous Metal structure. Bone is shown in pink and metal in black.

CONCLUSION

OsseoTi Porous Metal is a porous Ti6Al4V structure that mimics the architecture of human cancellous bone. In the sheep study, OsseoTi Porous Metal showed excellent integration with host bone as early as 4 weeks post implantation. At 12 weeks, bone ingrowth and remodeling was observed with good bone apposition onto the metal structure. At 26 weeks, in some regions bone bridging was observed, fusing across an 8 mm thickness of the implant. To our knowledge, no other synthetic biomaterial has demonstrated fusion across a 8 mm defect in cancellous bone after 26 weeks of implantation. OsseoTi Porous Metal has been designed for optimal interaction with bone and has the potential to enhance bone integration for orthopedic devices.

REFERENCES

1. Long M, Rack HJ. Titanium alloys in total joint replacement – A materials science perspective. (1998) Biomaterials 19:1621-1639.
2. Woodell-May J, Kumar M. In vitro comparison of cell proliferation on Ti6Al4V and Tantalum Metal. ORS 2007, Poster # 1578.
3. Data on file at Biomet, Inc. Protocol #12-04/12-07.

Evaluation of bony ingrowth implant materials in an *in vivo* sheep long bone defect model. Animal testing is not necessarily indicative of clinical performance.

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