OsseoTi™ - Porous Titanium Alloy For Enhanced Bone Integration

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Statement of Purpose: OsseoTi™ (Biomet, Warsaw, IN) 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™ contains a porous architecture that mimics the porous structure of human cancellous bone (Figure 1). The physical properties of OsseoTi™ have been designed to enhance the potential for bone integration[3]. In this study, the interaction between bone and OsseoTi™ was analyzed in a sheep model.

Methods: Porous OsseoTi™ 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 specimen were ground and stained with Sanderson's rapid bone stain.

Results: OsseoTi™ porous metal structure showed excellent integration with host bone even after 4 weeks of 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™ and host bone (Table 1).

After 4 weeks, the histological analyses showed that new woven bone had thickened along the outer structure and had begun to penetrate the OsseoTi™ structure 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 structure had occurred to a greater degree than that at 4 weeks, as expected. 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. After 26 weeks, extensive bone ingrowth was observed and the samples were completely filled with new healthy bone (Figure 3). There was no evidence of adverse inflammation within or around the OsseoTi™ porous structure during the entire study.

Conclusions: OsseoTi™ is a porous Ti6Al4V structure that mimics the architecture of human cancellous bone. In the sheep study, OsseoTi™ showed excellent integration with host bone as early as 4 weeks post implantation. After 12 weeks, bone fusion was observed with bone bridging across a width of 8 mm, with bone filling the entire volume of porous samples after 26 weeks. OsseoTi™ structure has been designed for optimal interaction with bone and has the potential to enhance bone integration for orthopedic devices.

Table 1: Biomechanical push-out loads for OsseoTi™ after 4 and12 weeks of implantation

Push-out load (N)	4 wk	12 wk	26 wk
	4123	5560	6973

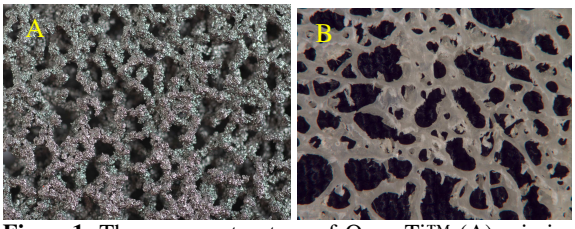

Figure1. The porous structure of OsseoTi™ (A) mimics the porous architecture of human cancellous bone (B)

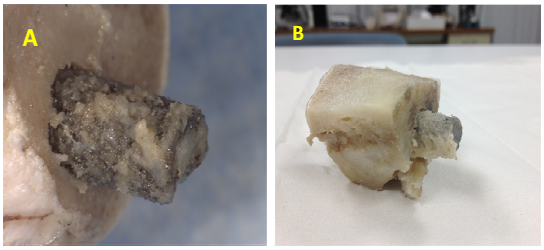

Figure2. OsseoTi™ push-out samples at (A) 4 weeks and (B) 12 weeks

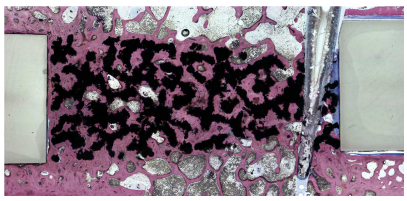

Figure3. Histological image at 26 week showing complete bone ingrowth across the entire volume of OsseoTi™ structure

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.