Porous Asymmetrical Beaded Coating Bone Ingrowth Evaluation using an Ovine Bilateral Long-Bone Model

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INTRODUCTION: Titanium plasma spray (TPS) and sintered coatings have been two of the predominant fixation technologies for orthopedic devices for the last two decades. Porous coated materials can provide early mechanical stabilization preventing early micromotion due to their increased surface. Their capacity for osseointegration also offers the advantage of a better long-term fixation, good biofunctionality and biocompatibility. Porous biometals such as sintered titanium beads and plasma sprayed metal powders onto a solid metal core have obtained relatively good implant stabilization and represent an alternative for the fixation of acetabular cups and hip prostheses into mineralized bone. A GLP-compliant non-inferiority study was performed to identify biocompatibility and performance characteristics of a new porous sintered commercially pure titanium (cpTi) asymmetrical beaded coating in comparison to titanium plasma spray (TPS) using an ovine bilateral long-bone insertion model. The specific objective was to quantify bone ingrowth and remodeling phenomena using radiography, histopathology, histomorphometry and mechanical push-out strength following 4, 12 and 26 weeks of implantation.

METHODS: Bone ingrowth in presence of a new porous sintered cpTi asymmetrical beaded coating (100-300µm pore size range, 60% porosity) was evaluated in comparison with a cpTi plasma spray (TPS) coated over Ti6Al4V ELI titanium (6mm Ø x 25-mm L dowels). Seven (7) skeletally mature female sheep (1-3 y.o.; 50-75kg; Rideau Arcott Hybrids) underwent a series of bilateral press-fit insertions in hindlimb long bones: three (3) epiphyseal and three (3) diaphyseal sites were implanted for a total of 12 surgical sites per animal. All surgical procedures and animal husbandry adhered to protocols approved by the IACUC of an AAALAC-certified preclinical testing facility. Following surgery, all animals were allowed to recover for either 4, 12 or 26 weeks in a climate-controlled room with permitted activity *ad libitum*. At termination, cancellous explants were isolated using a diamond saw, transferred to 70% EtOH, processed for non-decalcified histology, infiltrated with PMMA, then microground (Exakt 400 CS) in order to obtain undecalcified slides ($\phi \leq 60\mu m$). Histomorphometry was performed on Goldner's Trichrome stained slides to quantify osseointegration and linear bone apposition. Histopathology was evaluated for prevalent inflammatory cells, necrosis/osteolysis, neovascularization, and new bone formation. Cortical samples were kept frozen at -80°C for mechanical push-out with a loading applied at a rate of 2.54mm/min until a displacement of 5mm or failure. Force, displacement and shear strength were also measured. Equal variance test or normality test were used with a t-test. When either equal variance test or normality test failed, a Mann-Whitney Rank Sum Test was performed.

RESULTS: The sintered cpTi porous asymmetrical beaded coating demonstrated a progressively higher mean new bone-implant contact (BIC; 48.58mm, 95.71mm, 139.55mm; 4, 12 and 26 weeks respectively; Fig. 1 and 2), compared to the traditional TPS coating BIC which remained relatively similar overtime (36.49mm, 33.00mm, 44.73mm; 4, 12 and 26 weeks respectively; Fig. 1 and 2). Mean bone ingrowth was also higher in presence of the asymmetrical cpTi beads regardless of implantation time. The mean bone area within pores appeared to slightly increase over time for the sintered cpTi beaded coating and remained relatively similar at all time points for TPS-coated dowels. Under mechanical push-out testing (Fig. 3a), the mean stress obtained with the sintered cpTi beaded coating appeared greater (17.4 MPa, 36.6 MPa and 40.8 MPa; 4, 12 and 26 weeks respectively; Fig. 3b) than that of the control article regardless of time (12.3 MPa, 30.0 MPa, 34.2 MPa; 4, 12 and 26 weeks respectively; Fig. 3b).

DISCUSSION: The porous sintered cpTi beaded coating has demonstrated a normal healing process, exhibited excellent safety and biocompatibility as evidenced by a mild tissue reaction as well as a solid bone fixation in a sheep bilateral long-bone press-fit insertion model. The mean BIC and bone ingrowth within pores tended to increase over time in the asymmetrical coating and remained relatively similar at all time points for the TPS group. Taken together, the BIC and mechanical push-out testing demonstrate that both asymmetrical sintered beading and TPS coating provide a solid, increasing bony fixation following implantation. The statistically significant differences between the groups were likely due to the different porous structure of the test and control devices.

SIGNIFICANCE/CLINICAL RELEVANCE: A novel porous sintered commercially pure titanium asymmetrical beaded coating is considered to have the strength and stability to be used in structural applications. This porous coating allowed an improved osteoconduction corresponding to a solid, increasing bony fixation required in acetabular cup implantation, knee prostheses and other clinical osseointegration indications.

IMAGES:

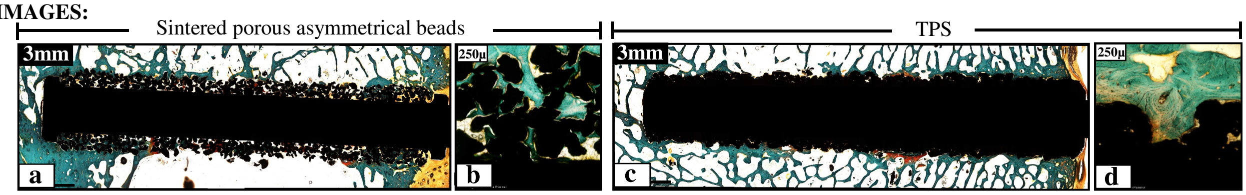

Figure 1. Exakt-microground longitudinal sections of sintered cpTi porous asymmetrical beaded (a) coating showing pores (b) colonized with mineralized bone and superior osseointegration compared to TPS (c,d) after 26 weeks of implantation using an ovine long-bone insertion model (Goldner's Trichrome, 4 and 10x).

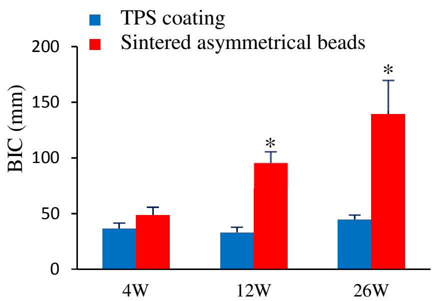

Figure 2. Osseointegration results showing bone-implant contact for sintered cpTi porous asymmetrical beading *vs*. TPS (*significantly different from TPS; p≤0.05).

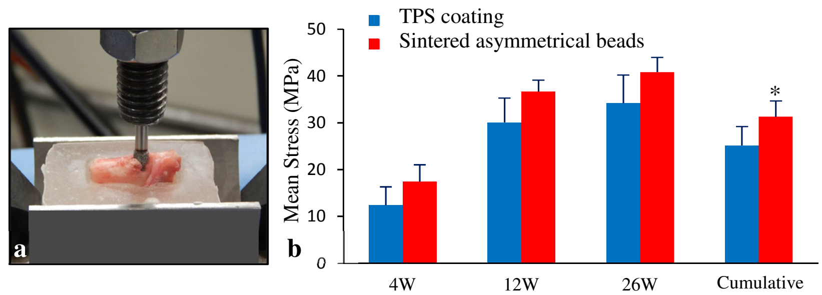

Figure 3. (a) Mechanical push-out test set up. (b) Mean stress (MPa) for sintered cpTi porous asymmetrical beading and TPS (*significantly different from TPS; p≤0.05).