Evaluation of a Novel Additive Manufactured Porous Ingrowth Biomaterial in a Canine Model

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INTRODUCTION: Porous surfaces developed over the past few decades have been shown to promote tissue ingrowth for enhanced implant fixation. The development of additive manufacturing techniques have allowed for greater precision in building these complex structures. The purpose of this study is to mechanically evaluate the biological fixation of a novel additive manufactured porous implant in a canine transcortical model.

METHODS: A canine transcortical model was used to evaluate the performance of laser rapid manufactured (LRM) titanium cylindrical implants (5.2 mm diameter, 10 mm length). The implants were approximately 50-60% porous with a mean pore size of 450 µm and have a random interconnected architecture with irregular pore sizes and shapes that are designed to mimic cancellous bone. A lateral approach to the femoral diaphysis was used to prepare a 5 mm unicortical, perpendicular drill hole. The transcortical implants were press-fit into the final drill hole. Six femora were harvested at 4 and 12 weeks post implantation, radiographed and prepared for mechanical push-out testing to assess the shear strength of the bone-implant interface. For push-out testing, the freshly harvested bone was supported in a metal cradle with the implant centered over a 5.8 mm diameter hole. Each implant was pushed out of the femur with a cylindrical plunger of 6.35 mm diameter attached to the cross-head of a servohydraulic MTS 858 Mini Bionix testing machine (MTS Systems, Eden Prairie, MN USA). Load was applied to the implant at a cross-head speed of 0.05 cm/min until the bone-implant interface ruptured or there was compressive collapse of the implant as defined from the peak on the load-deformation curve. Data for shear strength was expressed as a mean with 95% CI. An unpaired Student's t -test was used to compare statistical significance between the 4 and 12-week results. $p<0.05$ was considered significant.

RESULTS SECTION: The post-mortem contact radiographs demonstrated substantial condensation of bone around the implants at both 4 and 12 weeks. All the implants were successfully pushed out after 4 weeks of implantation. The mean shear strength at 4 weeks was calculated to be 21.6 MPa (95% CI 17.2 to 26.0). At 12 weeks, four of the implants were successfully pushed out with a mean shear strength calculated to be 39.9 MPa (95% CI 29.8 to 50.9). The increase in shear strength between the 4 and 12 week time period was significant ($p=0.0001$). The remaining two implants at 12 weeks had compressive failure before rupture of the bone-implant interface with a load of over 2000 N. This suggests that the shear strength values were higher than those calculated from the successful tests at 12 weeks.

DISCUSSION: At 4 and 12 weeks, the LRM titanium implants consistently exhibited peri-implant bone condensation and high mechanical shear strength, consistent with osseointegration. The shear strength was markedly higher than that previously reported at 4 weeks time for other biomaterials and porous coatings such as tantalum[1] (18 MPa) and cobalt chrome beads[2] (9.3 MPa). These results demonstrate that this novel 3D printed porous structure promotes biological fixation in a canine model.

SIGNIFICANCE/CLINICAL RELEVANCE: This study confirmed the suitability of a novel additive manufactured porous ingrowth biomaterial for biological fixation by bony ingrowth in a canine model.

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