

## In vivo Osseointegration of Two Types of Porous Metallic Implants

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**INTRODUCTION:** Bone attachment of metallic implants in orthopedics can be achieved through either cemented fixation or cementless biological fixation. In biological fixation, a porous structure on the implant's bone-contacting surfaces enables bone tissue to grow into the pores over time, creating a strong mechanical interlock for stable long-term fixation. As the patient population becomes younger and more active and additive manufacturing technology advances, the use of cementless biological fixation in orthopedics has been growing. To ensure successful *in vivo* performance, new designs of porous metallic implants must be assessed for biocompatibility, tissue reaction, mechanical behavior, and most importantly, osseointegration effectiveness. This study evaluated the osseointegration of a new laser-printed 3D titanium porous implant (Laser 3D) using an established pre-clinical animal model, with the well-established titanium plasma-sprayed (TPS) implants as a control group (Fig. 1). We hypothesized no difference between the two implant groups in mechanical push-out shear strength and bone ingrowth.

**METHODS:** Osseointegration of the two porous titanium implants was evaluated using an established ovine model (*Ovis aries* sheep) [1-4]. Each implant was fabricated as a cylinder (6 mm diameter, 25 mm length). Four skeletally mature adult male sheep (crossbred Merino Wethers) were used in this study, with euthanasia and assessment conducted at 4- and 12-weeks post-implantation. At surgery, three bicortical dowels were implanted per tibia, yielding a total of 12 cortical implantation sites per implant group per time point. In cancellous bone, a step drill was used to create four different implant fitting conditions on the distal femur: 1 mm interference (INT), line-to-line (LTL), 1 mm gap (1mm), and 2 mm gap (2mm). Mechanical push-out tests were conducted at the cortical bone-implant interface to calculate shear strength of the implant fixation at each time point. Histomorphometric image analysis quantified bone ingrowth at cortical and cancellous sites, using "bone per unit implant length" (BPUIL). BPUIL, defined as the bone and marrow tissue area integrated into the porous structure and normalized by implant length (unit: mm<sup>2</sup>/mm). Statistical comparisons were made between groups using push-out shear strengths and BPUIL measurements. Biocompatibility and tissue reactions were assessed with radiographic images and tissue harvests.

**RESULTS:** Radiographic images and tissue harvests confirmed no adverse tissue reactions in either implant group. Mechanical push-out tests showed that shear strength at the cortical bone-implant interface increased significantly from 4 to 12 weeks ( $p < 0.05$ ) (Fig. 2), with Laser 3D implants demonstrating higher shear strength than TPS ( $p < 0.05$  at 4 weeks). Histology and histomorphometry showed that both implants achieved substantial bone ingrowth by 4 weeks, with further increases at 12 weeks in concert with bone remodeling for both cortical and cancellous bone (Figs. 3 and 4). Bone ingrowth over time was more pronounced for Laser 3D implants compared to TPS. In cortical bone, Laser 3D implants showed significantly greater bone ingrowth than TPS at both time points ( $p < 0.05$ ) (Fig. 3), aligning with push-out shear strength comparison. In cancellous bone, Laser 3D's advantage over TPS was more notable at 12 weeks (Fig. 4). Cancellous bone showed significant bone ingrowth in INT, LTL and 1mm gap interface conditions. Only the 2mm gap interface condition showed less notable cancellous bone ingrowth.

**DISCUSSION:** Effective osseointegration is critical for successful biological fixation of porous metallic orthopedic implants. TPS implant represented a well-established technology used in orthopedics with decades of clinical success and was used as the control group. In comparison, the new Laser 3D porous implants demonstrated equivalent or superior performance in mechanical push-out shear strength and histomorphometric bone ingrowth. Both implant groups showed no adverse tissue reactions and promoted notable bone remodeling. The higher osseointegration observed in Laser 3D implants is likely due to greater porosity (~65% vs. ~35% for TPS) and possibly a surface topology that's more suitable to form an interlocked interface between bone tissue and the porous metal structure. At 12 weeks, Laser 3D implants showed a push-out shear strength of 36.9 MPa, which is at the high end of previously reported values for porous implants studied in similar animal models [1-4]. Bone ingrowth measurements were consistently higher for Laser 3D than TPS, across both cortical bone and multiple cancellous bone fitting conditions. This study suggests that the new Laser 3D implants could be a promising option for cementless bone fixation.

**SIGNIFICANCE/CLINICAL RELEVANCE:** Porous metallic implants are increasingly used in orthopedics for biological fixation, providing secure, long-term stability without the use of cement. By using an established ovine model, this study demonstrated favorable osseointegration outcome in both cortical and cancellous bone with the new Laser 3D porous implants compared to the mature TPS technology.

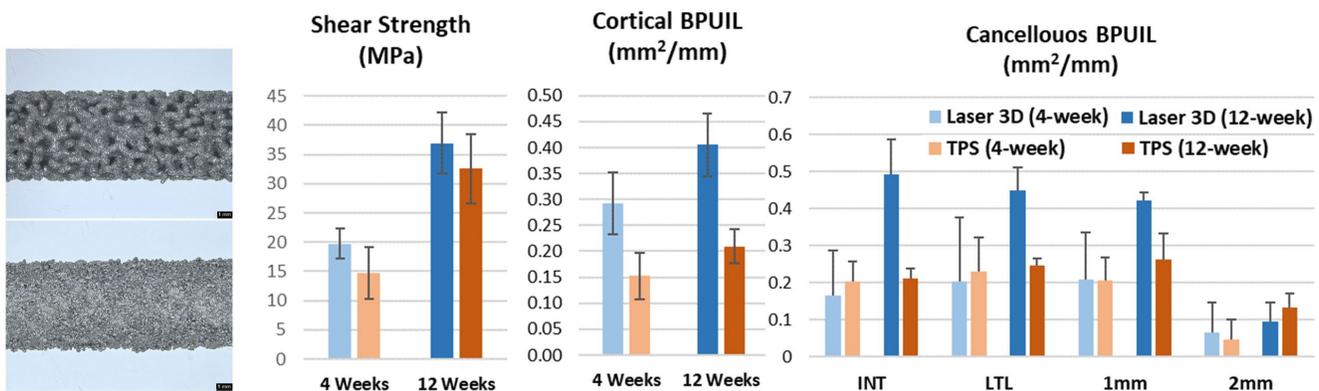


Fig 1. Microscopic images of the two implants (top: Laser 3D, bottom: TPS)

Fig 2. Shear strength results measured from push-out test.

Fig 3. Cortical bone ingrowth comparison.

Fig 4. Cancellous bone ingrowth comparison (INT: interference, LTL: line to line, 1mm: 1mm gap, 2mm: 2mm gap)

### REFERENCES:

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