Osseointegration and Defect Repair with a New Porous Titanium Screw in Ovine Long-Bone Models for Gap-Healing, Osteonecrosis, and Bone Ingrowth

Robert A. Poggie, PhD[1], Louis-Philippe Lefebvre, Eng, MSc[2], Stéphanie Grenier, PhD[2], Madeleine Chagnon, DVM, MSc[3], Michel Assad, PhD[3]
[1]BioVera Inc., Notre-Dame-de-l'Île-Perrot, QC, Canada; [2]NRC, Boucherville, QC, Canada; [3]AccelLAB Inc., Boisbriand, QC, Canada

Disclosures: Robert A. Poggie (3B; AmorChem), Louis-Philippe Lefebvre (N), Stéphanie Grenier (N), Madeleine Chagnon (N), Michel Assad (N). This preclinical study was funded by AmorChem.

INTRODUCTION:

Fracture fixation of small bones remains clinically challenging for pathologies relating to tenuous retrograde blood supply. Non-union and late treatment can disrupt vascular supply leading to avascular necrosis (AVN) and other complications. For example, acute scaphoid fractures are among the most common traumatic injuries to the upper extremity and account for 50-80% of carpal injuries[1]. The annual incidence has been estimated at 8 and 38 in 100,000 for women and men respectively[2]. Surgical treatments may be performed using vascularized bone grafting, but are often associated with postoperative complications including autogenous bone site morbidity and significant blood loss. Percutaneous fixation has become the standard of care with the introduction of headless compression screws. However, solid screws without bone grafting are often ineffective in cases of osteonecrosis. The objective of this study was to test the hypotheses that porous titanium (Ti) compression-screw technology would facilitate vascularization and subsequent bone conduction, improve strength of fixation, and increase the rate of bone healing when compared to conventional titanium headless compression screws.

METHODS:

Six (6) female Dorset sheep (>18mo.; 75-90kg) were prepared for bilateral hind limb surgeries using either 40% porous Ti (NRC) or conventional solid Ti (Acutrak) headless and cannulated compression screws (all Test and Control Articles: Ø=3.3-3.8mm; L=15mm). The study protocol was approved by an IACUC Committee and conformed to both AAALAC and CCAC regulations. The first model evaluated non-union following a bone core removal (Ø=8mm; L=8mm) from the proximal tibia and screw placement in the middle of the defect, leaving a 2-mm peripheral gap. The 2nd model simulated osteonecrosis with a 2nd bone core removal (Ø=14mm; L=8mm) from the distal femur, submersion in liquid N_2, and screw fixation of the devitalized bone core. The 3rd model quantified bone ingrowth and torsional strength at mid-diaphyseal tibial cortical locations. Live post-op x-rays and CT-scans (Siemens) were performed to confirm positioning. Ovine cohorts were euthanized after 6 and 12 weeks of implantation. Bone ingrowth was reconstructed by Micro-CT (SkyScan 1172 Model) and quantified with histomorphometry. Explanted screws were sectioned longitudinally, processed for undecalcified histology, infiltrated with PMMA, microground (Exakt 400 CS), and stained with Goldner's Trichrome. Digital images were analyzed for bone-implant contact and volumetric bone ingrowth. Torsional strength was recorded with a continuous digital torque meter at necropsy.

RESULTS:

Following 6 weeks of implantation in the non-union model, 75% of new bone formed adjacent to porous Ti, as opposed to 38% with control conventional Ti screws. At 12 weeks, porous titanium screws exhibited 89% new bone formation as opposed to 79% for controls. Below the actual gap, bone also filled 99% of the area within threads in porous Ti implants *vs.* 83% for controls at 12 weeks post-implantation. Following bone devitalization (osteonecrosis model), porous Ti showed up to 51% of new bone formation within its cannulated center as opposed to $\leq$3% for conventional screws. For the bone ingrowth model (**Figure 1**), linear bone apposition reached 55% for porous Ti *vs.* 36% (controls). Limited by failure of the Allen driver, the maximum torque obtained by porous screws was 0.78Nm as opposed to 0.42Nm for controls. Histopathology revealed excellent safety and biocompatibility as evidenced by a mild tissue reaction.

DISCUSSION:

Superior bone apposition, volumetric bone ingrowth and torsional strength were observed using the porous titanium screw, likely attributed to its interconnected porosity and higher surface area. A beneficial bone conduction effect was especially pronounced within the screw cannula. The clinical implication is that porous titanium does not occlude bone ingrowth and vascularization is observed within the fixating compression device itself, translating into an increased early post-op stability, as well as an improved bone fixation and healing.

SIGNIFICANCE:

Internal fixation with porous titanium compression screws increases the strength of fixation and the potential for bone ingrowth in more clinically challenging conditions of non-union and osteonecrosis.

REFERENCES:

[1] Hackney L.A. and Dodds S.D. Curr. Rev. Musculoskelet. Med.; 4(1): 16-22, 2011.
[2] Meermans G. and Verstreken F. Clin. Orthop. Relat. Res.; 470(6): 1673-1681, 2012.

ACKNOWLEDGEMENTS:

The authors would like to sincerely thank Dr. Paul A. Martineau and Dr. Edward J. Harvey (McGill University Health Centre), who co-developed this porous implant with the National Research Council of Canada.

IMAGES:

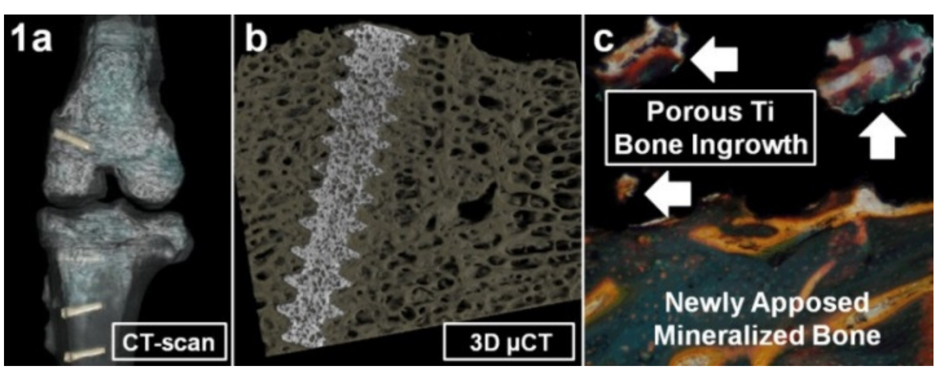

Figure 1. Porous titanium epiphyseal and mid-diaphyseal implant positioning (a; Siemens Somatom Sensation 16, CT-scan). Osseointegration into explanted porous screws visualized via Micro CT (b; SkyScan 1172, µCT) and following Exakt-microground undecalcified histology at 12 weeks post-implantation (c; Goldner's Trichrome, 10X).