Plugging the Medullary Canal to Reduce Bony Overgrowth, Heterotopic Ossification, and Stump Pain Following Amputation

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Disclosures: All referenced bone cap-related technologies are patent pending.

INTRODUCTION: Heterotopic ossification (HO), bony overgrowth, and stump pain are common post-traumatic complications that hinder prosthetic fitting and weight-bearing activities. Of lower limb amputees, 29.8% require re-hospitalization, with 14.5% (23.5% for above-knee amputations) requiring stump revision. Moreover, 43% experience significant stump pain, often linked to HO or bony overgrowth at the distal stump, leading to ulcers and skin perforation. Up to 65% of combat-related limb-loss patients develop HO. Symptomatic HO can delay rehabilitation due to required prosthetic modifications. The current standard of care leaves the medullary canal open, potentially contributing to bony overgrowth, HO, and stump pain by allowing growth factors to escape. To combat this, our team developed a "bone cap" to close the distal stump to reduce HO, bony overgrowth, and pain. We hypothesized that closing the medullary canal would reduce these pathologies.

METHODS:
Trauma-induced HO was modeled in sheep using a combination of surgical and trauma factors:

- Periosteal disruption
- Above-knee amputation (allowing growth factors to escape the canal)
- Autograft bone chips placed at the disruption site
- Simulated blast trauma using an air cannon
- *Staphylococcus aureus* ATCC 6538 biofilm inoculation
- Tourniquet for 45 minutes
- Negative pressure wound therapy (NPWT) with subdermal foam removed after 3-7 days

Animal work was performed at Utah State University under IACUC and ACURO approvals. The air cannon was optimized and safety-tested in a previous study, allowing high-powered air bursts to be administered mid-shaft femur creating deep tissue trauma.

Study Groups:

- **Group 1** (**Open Canal**, n=5): Medullary canal left unaltered (current clinical practice).
- **Group 2** (**Bone Cement**, n=5): Canal filled with bone cement.
- **Group 3** (**Bone Cap**, n=5): Canal capped with a titanium porous-coated (PC) implant (Figure 1).

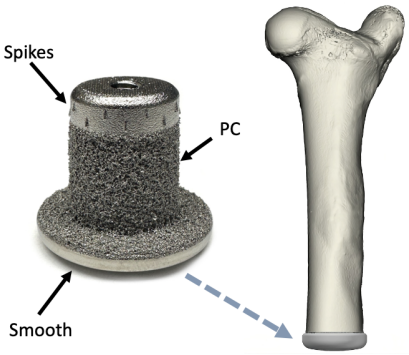

Figure 1: Photographs of the titanium porous coated (PC) bone cap and a 3D bone model. The initial fixation spikes help with implant stability, circumferential base limits bony overgrowth, and a smooth surface helps with soft tissue articulation.

All sheep received the above trauma factors. Postoperatively, animals resumed weight-bearing on three limbs and were monitored for 6 months.

RESULTS:

- **Group 1** (Open Canal, n=5): 100% developed bony overgrowth, with 80% exhibiting extensive HO (Figure 2).
- **Group 2** (Bone Cement, n=5): 0% HO or bony overgrowth, but cement degraded and started falling out of the medullary canal by 6 months.
- **Group 3** (Bone Cap, n=5): 80% showed no HO or bony overgrowth at the distal stump. All caps exhibited some distal bone resorption.

DISCUSSION: Pain was not monitored in this study but would be an outcome measure in a human scenario. The standard open-canal approach resulted in extensive HO and bony overgrowth. Bone cement prevented HO but degraded over time, making it unsuitable for a long-term solution. The bone cap considerably reduced HO and overgrowth compared to Group 1 (Open Canal), indicating a strong potential to improve post-amputation outcomes. However, future design improvements and surgical refinements are required to minimize potential periosteal reactions from over-reaming, cortical thinning, and/or distal bone resorption.

SIGNIFICANCE: This model identified a critical gap and offers a translational solution to reduce revision surgeries and improve prosthetic outcomes.

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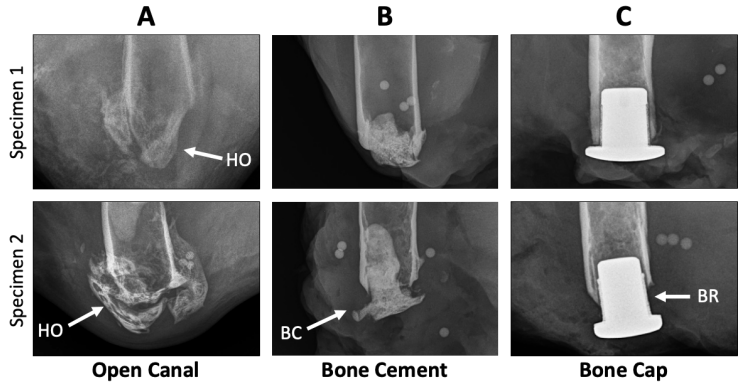

←**Figure 2:** Radiographs of representative specimens from each group at 6 months. (A) Open canal group showing extensive HO and bony overgrowth from the resected surface. (B) Bone cement (BC) group showing cement degradation with material beginning to come loose from the canal. Note the absence of HO. (C) Bone cap group showing no HO. However, distal bone resorption (BR) was observed, suggesting design modifications are needed to maintain bone strength.

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