

## Intramedullary Bone Stabilization Device Using a Light-Curable Monomer

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**Statement of Purpose:** With an aging population contributing to the growing number of fracture incidences, there is a compelling need for a method of fracture repair to successfully mend osteoporotic bone. Traditional methods of bone fixation using metal rods and screws are associated with high overall complication rates and are not effective for osteoporotic patients. IlluminOss Medical, Inc. (East Providence, RI) has developed a novel device for percutaneous bone stabilization utilizing a light-curable polymer system that conforms to each patient's unique intramedullary canal. We evaluated the feasibility of deployment and local and systemic biocompatibility of the IlluminOss system cured *in situ* as a bone stabilization system in an animal model.

**Methods:** Sheep studies were conducted under approved Institutional Animal Care and Use Committee protocols. Tibia in nineteen sheep were implanted with a single photodynamic balloon stabilization system (PBSS) comprised of a polyethylene terephthalate (PET; Dacron) balloon (OD x length, 11 x 160 mm) filled with a monomer and cured *in situ* for 800 sec with a 436 nm light source, and harvested at 30, 90 or 180 days. Thirty six additional sheep received a mid-shaft short oblique tibial osteotomy that was stabilized with either external fixators or external fixators combined with an intramedullary PBSS (OD x length, 13 x 160 mm) and were evaluated at 8, 12 and 26 weeks postoperatively. Healing and safety were evaluated by radiographic analysis, micro computed tomography ( $\mu$ CT) and/or histopathology.

**Results:** In non-fracture sheep tibias, there were no significant macroscopic or microscopic observations at any time. Implants conformably filled the medullary space, with complete apposition to the diaphyseal cortical bone (Figure 1). Active cortical bone remodeling and apposition of new periosteal and/or endosteal bone were observed at all time points. Osteotomized sheep tibia showed continuous bone formation inside the osteotomy gap up to nearly complete bridging at 26 weeks with no significant toxic effects when fixation was augmented by the conformable PBSS (Figure 2A). The periosteal callus size gradually decreased over time and was similar in both treatment groups (Figure 2B). Foamy macrophages were observed locally at the implantation site in some PBSS-treated animals and clusters of foamy macrophages were observed in local lymph nodes both in controls and PBSS-treated animals. No inhibition of endosteal bone remodeling and/or vascularization were observed with the PBSS.

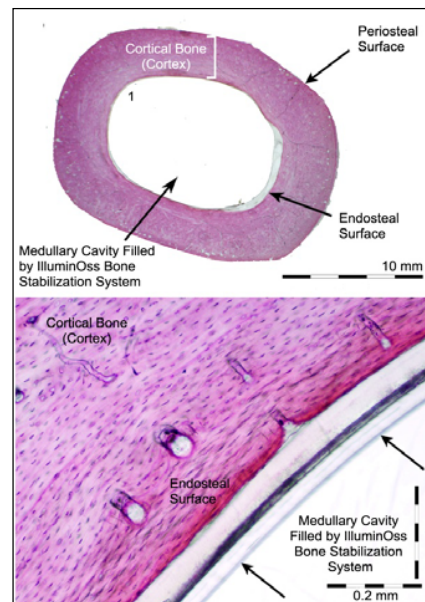


Figure 1. Example of diaphyseal sheep tibia 30 days post-treatment. Numeral 1 signifies area of higher magnification in the lower panel. In higher magnification image (lower panel), note complete apposition of the PBSS (eg, arrows) to the endosteal surface of the cortex.

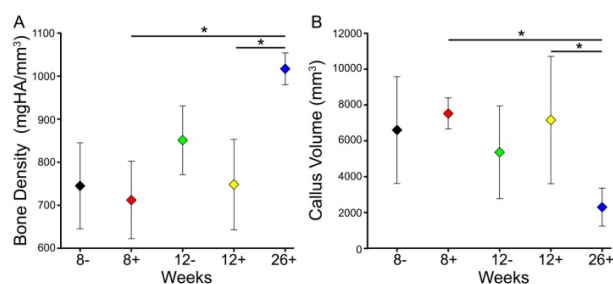


Figure 2. New bone density (A) and callus volume (B) as determined by  $\mu$ CT over 26 weeks. Fractured sheep tibia were stabilized with a 3/3 type Ia external fixator and double connecting bar (-) or a 2/2 type Ia external fixator, double connecting bar, and 13 x 160 mm intramedullary PBSS (+). Values are mean  $\pm$  sd; \* denotes statistically significant group differences.

**Conclusions:** Intramedullary application of a light curable PBSS is a safe, feasible method for IM fixation, offering conformable stabilization in the main plane of fracture alignment and force. The IlluminOss PBSS achieves such fixation in a personalized manner and with minimal adverse effects.