Safety and Efficacy of PEEK Intramedullary Nail Fixation System using an Ovine Tibial Fracture Repair Model

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Statement of Purpose: Long bone diaphyseal fractures can be treated by different means: external coaptation, intramedullary (IM) interlocking nails, plates and screws, and external skeletal fixators. Bone repair using an interlocking IM nail involves the insertion of a metallic rod within the medullary canal to align the bone fragments. The placement of locking cortical screws at either end of the nail provides further stabilization, neutralizing axial compression and rotation. A new construct composed of a polymer composite system is proposed in this study. The objective was to evaluate the safety and efficacy of a new polymer composite IM nail fixation system compared to a conventional metallic one. The specific objective was to compare remodeling phenomena using sequential radiographs and computed tomography (CT) as well as post-mortem µCT, light and fluorescent histology.

Methods: Twelve (12) skeletally mature female sheep (Dorset, Rideau Arcott Hybrids) underwent a unilateral transverse mid-diaphyseal tibial ostectomy with a 5-mm gap and stabilization by either a carbon-fiber reinforced polymer composite (ϕ10mm x 18.5cm, PEEK-OPTIMA® Ultra Reinforced; Invibio Biomaterial Solutions) or metallic (ϕ10mm x 18.5cm, stainless steel; Innovative Animal Products) interlocking IM nail fixation system and four (4) bicortical interlocking screws (ϕ4.5mm). The study protocol was approved by the Institutional animal care and use committee (IACUC) of AccelLAB, a fully AAALAC and CCAC-certified research center. Animals were allowed unrestricted weight-bearing in environment-controlled rooms for 12 weeks. Computed tomography (CT-Scan; Somatom Sensation 16, Siemens) and radiographs (Mobillett X-Ray; Siemens) were performed at 2, 4, 9, and 12 weeks post-op to evaluate ostectomy reduction and bone remodeling. In parallel, successive fluorescent markers were injected intramuscularly (IM) at 4, 6 and 9 weeks post-surgery (oxytetracycline, calcein green and xylenol orange, respectively) to measure mineral apposition rates (MAR) at different healing stages. At termination, implanted tibiae were removed and cut into 5-cm cross-sectional sections at the mid-diaphyseal portion over the ostectomy site, which were µCT-scanned (Skyscan Micro CT, Model 1172). The samples were then processed for non-decalcified histology, PMMA-embedded, microground and polished down to 20-60 µm (Exakt 400 CS, Micro Grinding System) to produce sagittal sections. An image under fluorescence microscopy was first captured. Non-decalcified sections were then stained using a modified Goldner's Trichrome stain. Digital captures were analyzed by histomorphometry (Image Pro Plus) to quantify bone callus width and soft tissue area.

Results: All unilateral implantation procedures were successful. One animal died during CT-scan anesthesia and another suffered secondary fracture unrelated to the implant. All other animals maintained good health status throughout the study. CT-scan imaging revealed that callus formation was apparent after 4 weeks and gradually remodeled over time for both groups. Radiographs of the ostectomy sites showed a slightly superior healing with PEEK nails. Under fluorescent microscopy, the MAR between calcein green and xylenol orange labels (6 to 9 weeks) appeared to be slightly superior with PEEK nails. Histomorphometry using Goldner-stained slides revealed that the mean bone callus width was significantly lower with PEEK nails. Histopathologically, no adverse effects attributable to the implant materials could be identified such as necrosis, degeneration or infection. The tissue reaction was relatively similar in both groups. Bone union characterized by a gap filled predominantly with woven bone and associated with varying degrees of callus formation was observed in both implant types.

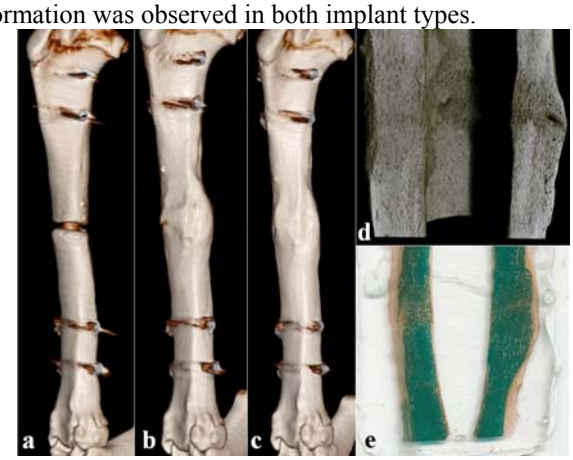

Figure 1. CT-scans of PEEK IM nail remodeling after 1, 9 and 12 weeks post-op (a-c). *Ex vivo* µCT and histology of ostectomy site (d-e).

Conclusions: A new polymer composite intramedullary nail fixation implant exhibited excellent safety and biocompatibility as evidenced by a mild tissue reaction, without evidence of obvious adverse effects. Live CT-scans of the ostectomy site and callus width reduction seem to illustrate that the fixation of long-bone diaphyseal defects are better supported by PEEK polymers with a slightly superior healing and improved bone remodeling. PEEK IM nail may represent an improved mode of fixation for healing and remodeling in this model when compared to standard stainless steel IM nails.

References: Aydin N. Int Orthop 2011;35:135-141. Lu Y. Vet Surg 2009; 38(4):467-476. Pluhar GE. J Bone Joint Surg 2006;88:960-966. Wilson DJ. J Orthop Trauma 2009;23:702-709.