

Polyether Ether Ketone (PEEK) Carbon Fiber Composites May Improve Healing of Fractures Stabilized with Intramedullary Nails

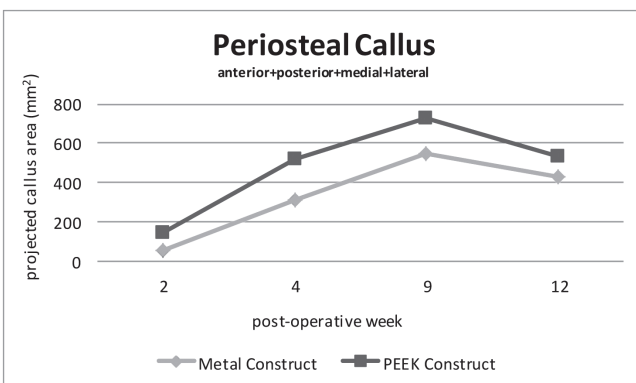
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Background/Purpose: Long bone diaphyseal fractures can be treated by using a number of methods. Intramedullary (IM) nailing represents a well-established approach for internal stabilization of bone fractures. Typical IM nail constructs consist of a metallic rod and placement of metallic screws at either end of the nail for stabilization. This study details the outcome of using a new material in the production of IM nail—PEEK-OPTIMA Ultra Reinforced, a carbon fiber–reinforced PEEK (polyetheretherketone) composite. The objective of this study is to compare bone healing of tibial osteotomy repaired with a PEEK carbon fiber composite IM nail to a traditional metallic construct in an established ovine fracture model. The study tested what effect lower modulus PEEK carbon fiber composite implants have on fracture healing in comparison with standard metallic constructs.

Methods: A 3-mm unilateral osteotomy defect was created in the left tibia of 10 sheep. Each animal was either assigned a PEEK or stainless steel (SS) nail for fracture stabilization. All animals were permitted immediate unrestricted weight bearing after surgery. Evaluation of bone remodeling was performed using CT, micro-CT (μ CT), and portable radiography. The PEEK composite and SS IM nails were geometrically identical (10 mm in diameter and 187 mm in length). The material construction of the PEEK composite IM nail provided 59% lower stiffness in 4-point bending when compared to the SS nail. The healing process was monitored via radiography and CT at regular intervals. The animals were sacrificed at week 12; healed tibiae were analyzed by μ CT.

Results: Bridging was observed on radiographs of all animals (5 of 5) implanted with the PEEK construct in contrast to the SS group (3 of 5). Callus formation of weekly radiographs was greater within the PEEK group, especially in the earlier time points: 158% ($P = 0.09$), 67% ($P = 0.08$), and 33% ($P = 0.10$) in weeks 2, 4, and 9, respectively. The callus formation in week 12 was 24% greater for the PEEK group when compared to the SS group ($P = 0.20$).



Conclusion: Improved healing in the form of complete bridging at an earlier time point and greater callus formation was seen in the PEEK nail group compared to the SS group. Potential reasons for the increased healing rate (bridging and callus) within the PEEK group are postulated to be enhanced dynamic loading and reduced stress shielding afforded by the lower modulus of the PEEK nail.

- The FDA has not cleared this drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an “off label” use). For full information, refer to page 600.