Evaluation of a Novel PEEK Titanium Composite (PTC) Interbody Cage in an Ovine Lumbar Interbody Fusion

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INTRODUCTION: The majority of interbody devices for spine fusion are PEEK. Other interbody devices use a rough 2D titanium surface or full porous titanium or tantalum cores, which have been shown in-vitro and in-vivo to promote osteoinduction and osteointegration, respectively. Combining the increased osteogenic environment that titanium provides and the minimized subsidence and radiolucency from PEEK, a unique interbody device has been developed. This PEEK Titanium Composite (PTC) implant consists of two 3-dimensional porous titanium alloy Ti6Al4V endplates with a PEEK core. This study examines the PTC implant and its efficacy to cause intervertebral body fusion in an ovine lumbar spinal fusion model relative to a similar PEEK implant.

METHODS: This study was done according to a Colorado State University IACUC approved protocol. Specifically, 34 mature female sheep (all 3+ years of age) underwent interbody fusion at L2-L3 and L4-L5, with each animal having one level treated with the PTC device and the other level with the all-PEEK version of the device (location randomized). For supplemental fixation a pedicle screw system was used (4.5x30 mm polyaxial screws, 5.5 mm rod). The graft window of the interbody cages was filled with an iliac crest autograft harvested during device implantation. The implants had similar size with a footprint of 9 mm x 23 mm x 7 mm, 0 degrees of lordosis, and a 0.3 cm central opening. Eight (8) animals were sacrificed at each time point, which included baseline, 8, 12 and 16 weeks post-surgery. Baseline (0 weeks) animals were done using fresh cadavers from another study. Post sacrifice, animal spines were carefully dissected and separated into each functional spine unit (FSU, i.e. L2-3 and L4-5).

Biomechanical Testing: Each FSU underwent non-destructive testing yielding range of motion (ROM) and stiffness. This was done using pure moments up to 6 N-m in flexion-extension, lateral bending and axial rotation without applying off-set moments or forces. Imaging: Subsequently FSUs underwent microcomputed tomography (microCT) scanning at a resolution of 37 \(\mu\)m yielding bone volume fraction (BV/TV) and bone mineral density (BMD) within the graft window of each device. MicroCT was not performed for the baseline animals. Histology: Histomorphometry was performed for each FSU (2 sections per FSU in the sagittal plane) yielding core and superior/inferior surface region bone and soft tissue area fraction. Bone ingrowth within the PTC pores was also determined. In addition, qualitative scoring of bony fusion using four blinded reviewers was performed using both the microCT 3D reconstructions and the histology slide images. A 5-point scale was used with a score of 1 indicative of a non-union and a score of 5 indicative of total bridging of the graft window with calcified tissue. Graphs illustrate mean±standard error with the PTC values normalized to the PEEK values for the corresponding outcome measure and time point (PEEK = 100%).

RESULTS: Animals were monitored daily with no abnormal findings attributed to the investigational implants. Biomechanical Testing: Axial stiffness increased significantly over time for the PTC group only (\(p<0.01\)), with an accompanied significant decrease in ROM (\(p=0.01\)). Lateral bending stiffness increased significantly over time for both groups (PTC \(p=0.02\); PEEK \(p<0.01\)) with an accompanied significant decrease in ROM (PTC \(p<0.01\); PEEK \(p<0.01\)). Flexion-extension ROM was significantly decreased for only the PTC group between 8 and 18 weeks (\(p=0.02\)). For all three loading directions the PTC group had significantly greater stiffness than the PEEK group across time (\(p=0.05\) for all, Figure 1). Imaging: MicroCT analysis showed a significant increase in bone volume density (\(p=0.04\)) and bone mineral density (\(p=0.02\)) in the graft window at 8 weeks for PTC vs. PEEK. Histology: Histologic analyses showed that the percent bone present in the graft window was significantly greater for PTC than PEEK at 8 weeks (51\% vs. 36\%, \(p=0.05\)). In addition, there was a significant decrease in soft tissue for PTC compared to PEEK at 12 weeks (29\% vs. 42\%, \(p=0.05\)). Furthermore, it was shown that the superior (cranial) and inferior (caudal) endplates of the PTC implant had greater bone presence with less soft tissue than the PEEK endplates (\(p<0.05\)). Additionally bone ingrowth into the porous PTC endplates was found to be 40.0±5.9\% at 8 weeks. Finally, fusion scores were found to be significantly greater for PTC vs. PEEK at 8 weeks for both microCT (4.0 vs. 2.8, \(p<0.01\)) and histology (3.9 vs. 2.6, \(p<0.01\)) evaluation methods.

DISCUSSION: In an ovine model for spine fusion the PEEK Titanium Composite interbody device led to a significant reduction in ROM and significant increase in stiffness relative to a standard PEEK device. These biomechanical findings were reinforced by the presence of significantly more bone in the core in addition to ingrowth into the novel 3-dimensional titanium endplates. The results indicate that a PEEK Titanium Composite interbody device could potentially lead to a faster and more robust intervertebral fusion relative to a standard PEEK device.

SIGNIFICANCE: To the author’s knowledge this is the first interbody spacer, which combines PEEK and 3D-printed titanium end-plates into a single porous interbody device for lumbar spine fusion procedures. This is also the first time such a device has been tested in a large animal study.

Figure 1: Normalized stiffness for PTC device for all three biomechanical tests. Each represented PTC stiffness was normalized to the PEEK average stiffness for the corresponding loading pattern and time point. Pound-sign (#) indicates that the PTC group had significantly greater stiffness than the PEEK group across time (\(p<0.05\), 2-way ANOVA).

Stiffness with PTC (Normalized to PEEK)

Axial Rot. | Flex/Ext | Lateral Bend
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Baseline | 100% | 100% | 100%
8 Weeks | 120% | 120% | 120%
12 Weeks | 120% | 120% | 120%
18 Weeks | 120% | 120% | 120%

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