Clinical Translation of Porous PEEK for Spinal Applications: From Benchtop to Bedside

F. Brennan Torstrick[1], David. L. Safranski[1,2], Nathan Evans[1], Robert E. Guldberg[1], Ken Gall[3].
[1]Georgia Institute of Technology, [2]Vertera Spine, Inc., [3]Duke University

Statement of Purpose: Degenerative disc disease (DDD) affects >60% of individuals over the age of forty. DDD is typically treated by spinal fusion of the neighboring vertebrae with approximately 500,000 procedures performed domestically each year. Many interbody fusion devices (i.e. cages) are made from polyether-ether-ketone (PEEK) due to its high strength, radiolucency, and similar stiffness to bone. However, current smooth-surfaced PEEK cages have been associated with fibrous encapsulation and implant migration, resulting in failed fusion rates as high as 11-15%. Therefore, a technology to enhance the osseointegration and fixation of PEEK cages would address a significant unmet need of spine surgeons and patients. Recently, the first all-PEEK cage possessing a porous architecture received FDA 510(k) clearance and is currently in clinical use. The purpose of this abstract is to present key studies to aid the translation of porous PEEK from a university lab to a clinically used spinal fusion device.

Methods: All porous PEEK samples were created using a proprietary process in which the porous PEEK architecture was grown directly from the underlying solid PEEK. Micro-computed tomography (µCT) was used to characterize the pore structure [1]. The cellular response to porous PEEK was assessed by measuring osteocalcin and calcium content of mouse pre-osteoblast (MC3T3-E1) cultures at 2 weeks in osteogenic media and compared with that of smooth PEEK and plasma sprayed titanium coated PEEK (TiPEEK) as a clinical control group (n=5) [2]. Osseointegration of porous PEEK was investigated in a rat femoral segmental defect model (n=6). All surgeries were approved by the Georgia Tech IACUC. Implants with one porous face and one smooth face were press fit into an 8 mm femoral defect and stabilized with a polysulfone plating system. Animals were euthanized at 12 weeks and explants were embedded in plastic, sectioned and stained with Goldner's Trichrome [1]. Mechanical characterization followed ASTM F1147-05 and F1160-05 to assess tensile adhesion strength and cyclic shear strength of the porous structure and TiPEEK. Compressive behavior and pore structure was characterized *in situ* using a compression device compatible with µCT [3].

Results: µCT analysis of the porous PEEK architecture is summarized in Figure 1. Cell cultures grown on porous PEEK produced greater levels of osteocalcin and calcium compared to smooth PEEK and TiPEEK ($p<0.01$, Tukey). Histological examination at 12 weeks showed mineralized bone closely apposed to the pore walls and a substantial fibrous capsule surrounding the smooth PEEK face. Tensile adhesion strength was 24.6 MPa for the porous PEEK compared to 19.2 MPa for TiPEEK. Cyclic shear life at 8 MPa was over 10M cycles for the porous PEEK compared to 2.6M cycles for TiPEEK. The µCT compression data revealed that the sample can deform up to 40% of its original size and still offer high porosity for ingrowth (over 50% porous, or ~70% of the original open space at 14MPa). Following these initial results, FDA 510(k) clearance was obtained in late 2015 for a cervical fusion cage that utilizes this technology (Figure 3).

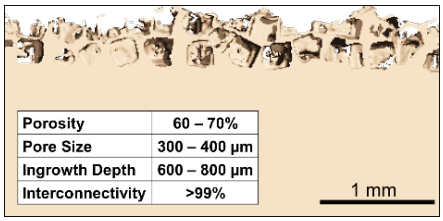

Figure 1: MicroCT of porous PEEK. Scale bar is 1mm.

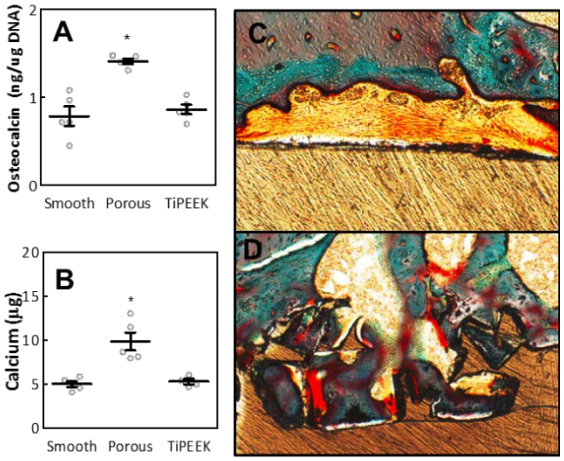

Figure 2: Osteogenic differentiation markers of MC3T3 cell cultures showing (A) osteocalcin and (B) calcium content at 14 days in osteogenic media (*$p<0.01$, Tukey). 12 week histology of bone ingrowth at (C) smooth and (D) porous faces. Osteoid stains red, mineralized bone stains blue, fibrous tissue stains orange.

Figure 3: Porous PEEK cervical fusion cage.

Conclusions: Porous PEEK has been created with controlled pore size, porosity and pore depth that could better support the osteogenic differentiation of pre-osteoblasts compared to smooth PEEK and TiPEEK. *In vivo*, porous PEEK has exhibited robust bony ingrowth which could enhance implant stabilization. Porous PEEK possessed superior mechanical properties to TiPEEK coatings, likely resulting from the direct growth of the pores from the bulk PEEK to form a continuous interconnected layer. From the µCT compression, porous PEEK can maintain an open porosity for bone ingrowth under relevant loads for cervical spine. The porous PEEK technology was rapidly translated into a FDA 510(k) cleared product.

References:

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