Inspire® 3D Printed Trabecular PEEK™: A New Paradigm for Interbody Fusion

A New Paradigm for PEEK Implant Design and Manufacturing

Traditional polyetheretherketone (PEEK) implants are hydrophobic and exhibit properties known to impede integration with bony host tissues. This can lead to fibrous encapsulation of the implants.

Regarding the bone-material interface, PEEK's surface topography and implant architecture play larger roles than the material itself. For example, using salt porogens, porosity can be incorporated into compression-molded PEEK, enabling superior surface ongrowth of bone compared to standard PEEK.[1,2] However, bony ongrowth regions of these implants are limited to their exterior surfaces that abut the vertebral endplates. Bone through-growth and complete osseointegration of the entire implant cannot occur.

To achieve full osseointegration while optimizing implant strength and matching the structure of bone, a revolutionary process for 3D printing trabecular PEEK implants has been developed. This process, termed Fused Strand Deposition™, utilizes 3D printing to create a trabecular PEEK™ structure with fully interconnected porosity. This proprietary process prints a bone-like trabecular scaffolding within each implant that has both high strength and fatigue resistance, while producing stiffness that matches Young's modulus for cancellous bone (~1 GPa). These trabecular PEEK implants support direct bony attachment and bony through-growth driven by the implant topography, eliminating fibrous encapsulation of the device.

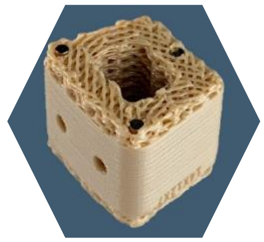

Figure 1. Inspire® 3D Printed Trabecular PEEK Cervical Interbody Implant.

Inspire® 3D Printed Trabecular PEEK Implant

The structure of the 3D printed PEEK implant (Figure 1) drives its mechanical properties and its osseointegrative potential. The implant architecture of the Inspire® 3D Printed Trabecular PEEK interbody device (Curiteva, Tanner, AL) combines a fully interconnected trabecular structure with interconnected porosity that mimics bone. This provides optimal strength and stiffness while maximizing the surface area for bony ingrowth and ongrowth. The pores are diamond-shaped and have a size distribution between 100 to 600 microns, matching human bone. In addition, hydroxyapatite is chemically bonded to all the implant's surfaces, inside and out (Figure 2). On a cellular level, this interconnected trabecular porosity and hydroxyapatite coating[3] support bone graft retention and stimulate cells to mature and produce more bone tissue inside the pores. Bone cells can migrate through the implant (osteoconduction) and produce more mature bone tissue inside the pores and at the cellular level (osseointegration). The bone ingrowth onto the surface of and through the interior of the implant creates a strong mechanical interlock with the surrounding host bone, resulting in higher

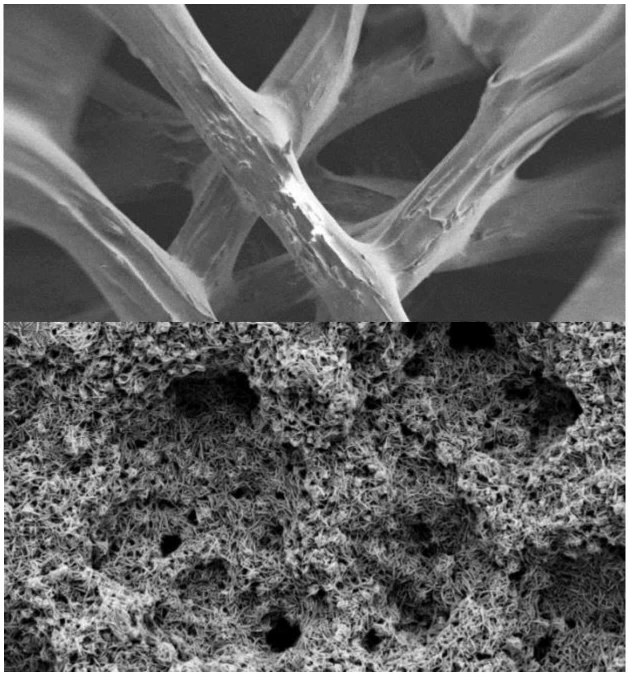

Figure 2. SEM of 3D Printed Trabecular PEEK structure (100x) and HA$^{FUSE®}$ surface modification (40,000x).

osseointegration strength. Biomechanical testing proves these advanced, FDA-cleared, porous trabecular PEEK interbody implants have superior strength compared to compression-molded porous PEEK implants. This strength is a result of strain-induced crystallization as the PEEK is 3D printed (the process has been likened to pulling taffy) and the resulting trabecular structure, which acts like a system of interconnected trusses.

Achieving Osteoconduction and Osseointegration

Interspersed within the implant's trabecular structure, the pores are diamond shaped and have micron-scale surface roughness that yields a hydrophilic surface for bony apposition. The osteogenic potential is augmented by the addition of sub-micron hydroxyapatite crystals (HA^{FUSE}) that are bonded to the implant surfaces. This surface modification stimulates bone to anchor directly onto the 3D printed PEEK device.

3D Printed Trabecular PEEK Implant Preclinical (Ovine) Testing

Four-year-old ewes (ovine) were implanted with 3D printed Trabecular PEEK in a validated model investigating bone ingrowth and through-growth in bi-cortical (tibial) and cancellous (femoral) defects. By the 12-week timepoint, significant, viable bone had grown completely through the interconnected porosity and demonstrated appropriate hallmarks of physiologic bone architecture. Specifically, active osteoblasts and deposited osteoid, osteocytes, angiogenic blood vessel formation, and mature bone were observed throughout the implant (Figure 3).

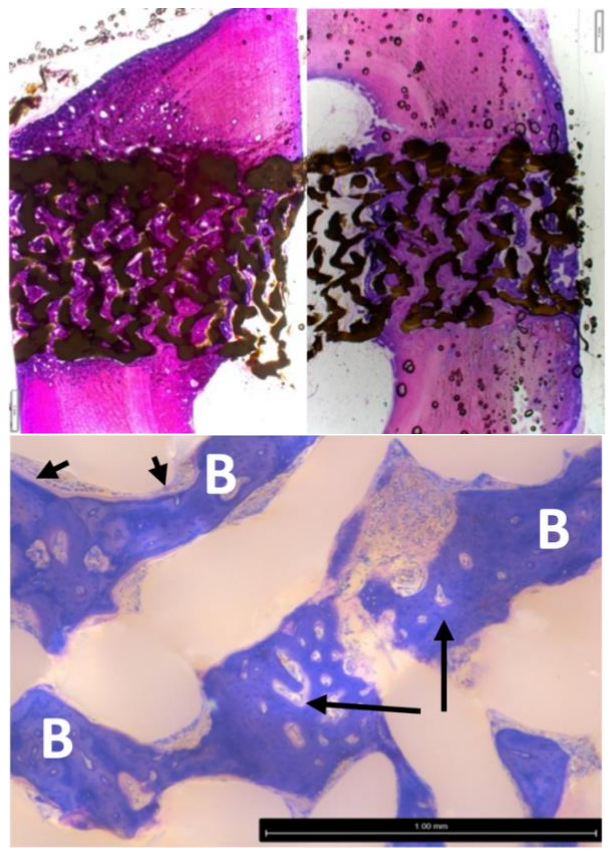

Figure 3. Twelve-week ovine study histology. Top image, complete osseointegration. Bottom image, physiologic, viable bone anatomy throughout the implant (short arrows show osteoid, long arrows show blood vessels, and B indicates bone).

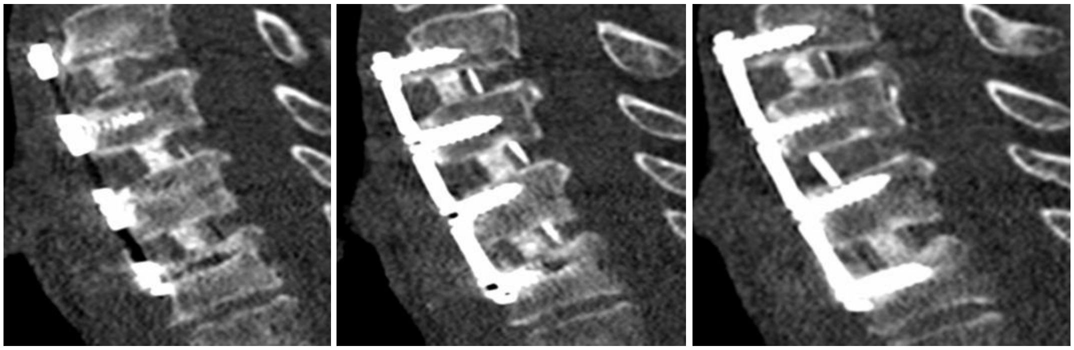

Figure 4. Sagittal computed tomography (CT) images of C3-6 (3-level) fusion at 6 weeks postoperative (Inspire® implants with MagnetOs® graft material).

Early Clinical and Radiographic Outcomes

A registry of patients treated with the Inspire® 3D printed PEEK implants has enrolled more than 300 patients who have undergone single-level or multi-level anterior cervical discectomy and interbody fusion. Eighty patients have undergone 3-level or more anterior fusions, and a total of 585 levels have been fused. At clinical and radiographic follow-up between 3 and 6 months pospostoperatively, no pseudarthroses have been identified. There have been no reoperations in this early clinical study (Figure 4).

Conclusions

For spinal interbody implants, PEEK offers material characteristics that are superior to metal, such as stiffness that more closely matches cancellous bone and radiolucency. However, standard PEEK implants are hydrophobic and not as conducive to bony ongrowth and through-growth as titanium. The FDA cleared Inspire® 3D Printed Trabecular PEEK implant has superior strength and mechanical stability when compared to compression molded porous PEEK. Importantly, advanced 3D printing endows trabecular PEEK with the potential for osteointegration of the entire implant through integrated diamond shaped cavities, surface roughness, and hydroxyapatite surface nano-texturing. Early clinical experience with this advanced material has demonstrated excellent patient outcomes.

Contributors

Kevin T. Foley, MD; Randall F. Dryer, MD; Erik M. Erbe, PhD; and J. Kenneth Burkus, MD

Erik M. Erbe, PhD, is a paid employee of Curiteva. The remaining contributors have no disclosures.

References

1. Carpenter RD, Klosterhoff BS, Torstrick FB, Foley KT, Burkus JK, Lee CSD, Gall K, Guldberg RE, Safranski DL. Effect of porous orthopaedic implant material and structure on load sharing with simulated bone ingrowth: a finite element analysis comparing titanium and PEEK. *J Mech Behav Biomed Mater*. 2018;80:68-76.

2. Torstrick FB, Safranski DL, Burkus JK, Chappuis JL, Lee CSD, Guldberg RE, Gall K, Smith KE. Getting PEEK to stick to bone: the development of porous PEEK for interbody fusion devices. *Tech Orthop*. 2017;32(3):158-166

3. Johansson P, Jimbo R, Kozai Y, Sakurai T, Kjellin P, Currie F, Wennerberg A. Nanosized hydroxyapatite coating on PEEK implants enhances early bone formation: a histological and three-dimensional investigation in rabbit bone. *Materials*. 2015;8(7):3815-3830.