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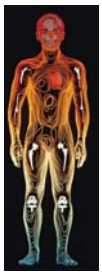

Porous and Bioactive PEEK Implants for Interbody Spinal Fusion

Porous and bioactive PEEK interbody spinal fusion devices have been designed and manufactured to address a clinical need for enhanced osteointegration with the fusion mass.

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Back and radicular pain is the leading cause of activity and productivity loss amongst adults of any age in the United States [Ref. 1]. In many cases, surgical intervention is required, including at least 5,000 interbody spinal fusion cages implanted each month in the U.S. alone [Ref. 2]. The total U.S. market for spinal fusion implants was valued at nearly $4 billion in 2008 [Ref. 3]. Interbody spinal fusion is used to alleviate pain caused when a herniated, bulging, or flattened intervertebral disc impinges on the spinal cord or nerve root. The disc and vertebral endplates are removed and an interbody fusion cage is inserted in the disc space (Fig. 1) to restore vertebral height, promote fusion of bone tissue between adjacent vertebrae and, thus, mechanically stabilize the spine [Ref. 2].

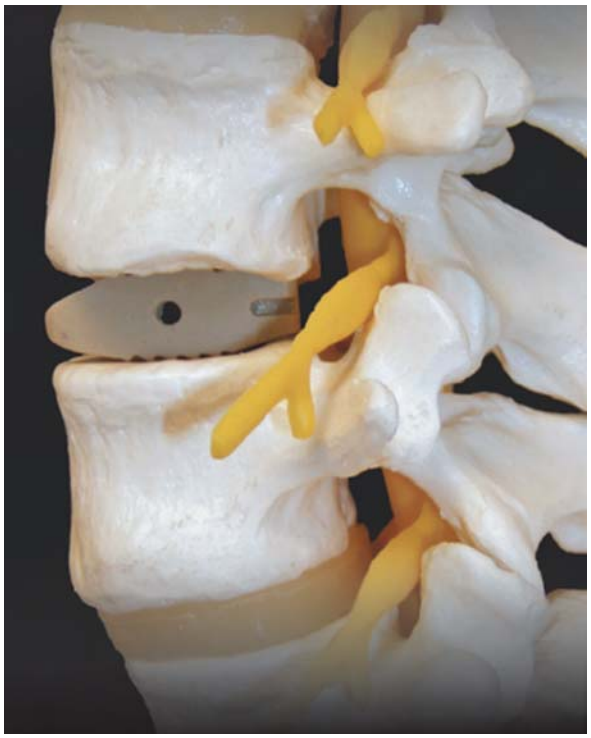
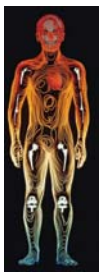


Fig. 1 — Model of the lumbar spine showing a PEEK interbody spinal fusion cage inserted into the L3-L4 disc space. Note that posterior fixation with a plate and pedicle screws is not shown.

Fig. 2 — Examples of commercially available cervical (left) and lumbar (right) PEEK interbody spinal fusion cages manufactured by Medtronic Sofamor Danek.

Polyetheretherketone (PEEK) cages (Fig. 2) have many attractive characteristics for spinal surgeons and patients [Ref. 4,5]. Radiolucent PEEK enables post-operative radiographic assessment of fusion, which is inhibited by the high x-ray attenuation of titanium. PEEK also exhibits a modulus of elasticity similar to bone, enhancing load transfer to tissue in the cage, and seems to demonstrate a relative lack of subsidence compared to alternatives. Finally, PEEK implants eliminate the need for limited human allograft sources and the possibility of donor source contamination.

Despite the above advantages, current PEEK (and titanium) fusion cages are dense and bioinert, which limits incorporation into the fusion mass and the subsequent implant stability. Moreover, the center cavity of the cage must be augmented with osteoinductive agents, such as autograft, demineralized bone matrix and/or bone morphogenetic protein (BMP) in order to promote fusion. PEEK interbody fusion cages used in conjunction with BMP have been shown to produce high fusion rates [Ref. 4]. However, surgeons are left to question the necessary amount of fusion mass to be achieved around the PEEK implant for clinical success as bioinert materials are encapsulated by a layer of fibrous tissue. Allograft and autograft remain the only available option capable of being incorporated into the fusion mass through direct apposition of bone tissue. For these reasons, some surgeons remain reluctant to use PEEK implants.



Porous and Bioactive PEEK Implants

Novel porous and bioactive PEEK implants were designed and manufactured to address a clinical need for enhanced osteointegration with the fusion mass for improved mechanical stability and longevity (Fig. 3). Potential new implant designs include (1) solid implants, (2) porous scaffolds, and (3) various combinations thereof. The porous scaffold architecture was designed for bone ingrowth with 75-90 vol% interconnected porosity at pore sizes ranging 200-500 µm [Ref. 6]. Micro-computed tomography (Scanco µCT-80, Medical, Bassersdorf, Switzerland) was used to examine the internal pore structure (Fig. 4). The material comprising scaffold struts and/or fully dense portions of implants was composed of PEEK reinforced with 20 or 40 vol% whisker-shaped hydroxyapatite (HA) crystals (Fig. 5). HA whiskers were both embedded in the PEEK matrix to act as a reinforcement and exposed on free surfaces [Ref. 6] to provide bioactivity as sites for protein adsorption, cell attachment, and, ultimately, direct apposition of bone tissue. HA is a close synthetic equivalent to human bone mineral and is well-known to promote bioactivity and osteoconduction in polymer composites [Ref. 5,7].

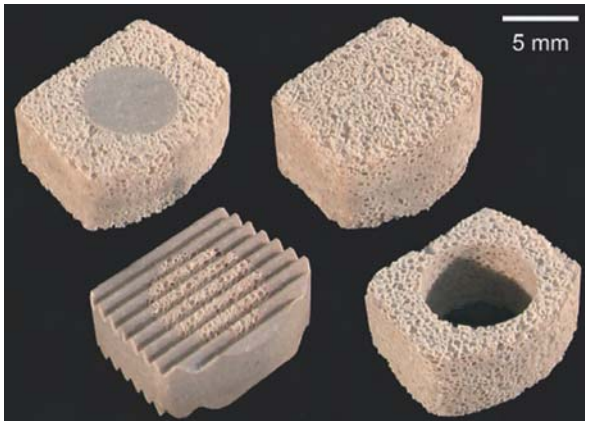


Fig. 3 — Novel cervical spinal fusion cages composed of PEEK reinforced with 20 or 40 vol% HA whiskers and various designs for placement of porosity (75-90%) in place of, or in addition to, the dense material.

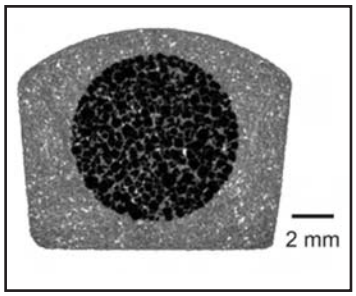


Fig. 4 — Micro-computed tomography image slice at the center of an implant showing continuity of scaffold struts (gray) and pores (dark), the pore size, and that the porogen was completely removed.

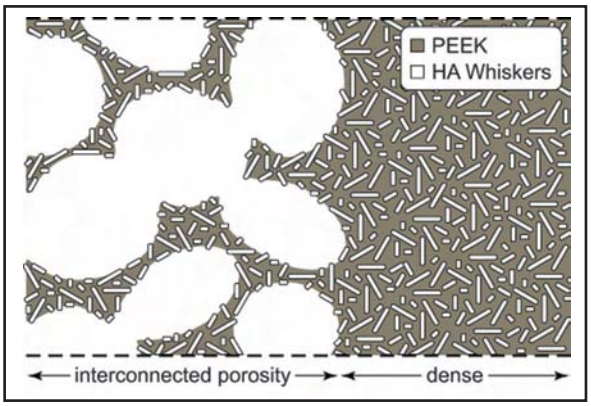


Fig. 5 — Schematic diagram showing a PEEK matrix with HA whisker reinforcements embedded in the matrix and exposed on free surfaces.

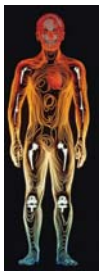
The example implants shown in Figure 3 were prepared using a powder processing approach to mix the HA whiskers, PEEK powder (450PF, Invibio, Lancashire, UK) and a salt porogen (sacrificial template used to create porosity upon removal), followed by compression molding and particle leaching to remove the porogen. Grooves and other features were readily machined, even in porous scaffolds, prior to particle leaching. Implants with combinations of dense and porous material were prepared using specially fabricated dies for loading and consolidating separate powder mixtures prior to compression molding the entire implant at elevated temperature. This ensured that the material comprising solid and porous regions for the implant was continuous (Fig. 5). The size and shape of the porosity was controlled by that of the porogen particles. The HA whiskers were prepared using a hydrothermal precipitation method [Ref. 8]; as-synthesized whiskers exhibited a mean length and aspect ratio of ~20 µm and ~8, respectively.

Preliminary tests indicated that the compressive failure load was in excess of 10 kN for implant designs including a region of dense material (Fig. 3). Previous studies have demonstrated that the mechanical properties of dense HA whisker reinforced polyetherketoneketone (PEKK) [Ref. 9] and porous HA whisker reinforced PEEK [Ref. 10] were similar to those of human cortical bone and vertebral trabecular bone, respectively (Table 1). Polymers reinforced with HA and other calcium phosphates were first conceived as bone-analog biomaterial enabling mechanical properties to be tailored to mimic those of bone tissue [Ref. 15]. However, despite hundreds of studies over the last thirty years [Ref. 7,16], very few HA reinforced polymers have been able to mimic the mechanical

Table 1 — Elastic modulus and ultimate tensile strength

The elastic modulus (*E*) and ultimate tensile strength (*UTS*) of dense HA whisker reinforced PEEK composites was similar to that of human cortical bone tissue in the longitudinal anatomic direction, and the apparent compressive elastic modulus (*E*) and yield strength (*YS*) of porous HA whisker reinforced PEKK scaffolds was similar to that of human vertebral trabecular bone.

Uniaxial Tension	**Porosity (%)**	**Apatite Content (vol%)**	***E* (GPa)**	***UTS* (MPa)**
Dense HA whisker reinforced PEEK [9]	~0	0-40	4-19	25-118
Human cortical bone [11,12]	~5-10	~40	16-23	80-150
Uniaxial Compression	**Porosity (%)**	**Apatite Content (vol%)**	***E* (MPa)**	***YS* (MPa)**
Porous HA whisker reinforced PEKK [10]	75-90	0-40	1-190	0.002-2.7
Human vertebral trabecular bone [13,14]	~80-95	~40	20-500	0.5-4



properties of bone tissue at comparable levels of porosity and reinforcement. A major reason for this is that the integrity of the HA/polymer interface is typically limited to mechanical interlock, with little or no chemical bonding, and nearly all prior studies have utilized equiaxed powders of HA or other calcium phosphates. Improved load transfer from matrix to reinforcement is commonly achieved in composites through the use of high aspect ratio fibers. Therefore, the use of single crystal HA whiskers, with an as-synthesized mean aspect ratio of ~8, resulted in significantly improved static [Ref. 17] and fatigue properties [Ref. 18] when directly compared to equiaxed powder reinforcements.

Conclusion

The ability to manufacture interbody spinal fusion cages with tailored levels and placement of (1) bioactive reinforcements in the PEEK matrix and (2) porosity in the implant creates new opportunities for implant design, which may translate into new treatment options for the spinal surgeon and improved care for the spinal patient. MPMD

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References

1. A. Praemer, S. Furner, D.P. Rice, Musculoskeletal conditions in the United States. American Academy of Orthopaedic Surgeons (Park Ridge, IL), 1999.
2. O. C. McAfee, Interbody Fusion Cages in Reconstructive Operations on the Spine. J. Bone Joint Surg., 81A, p. 859-880, 1999.
3. Research and Markets: In 2008 the Total U.S. Spinal Implant Market was Valued at $4.75 Billion – The U.S. Market for Spinal Implants, MiS and VCF Report 2009. Thomas Reuters, April 6, 2009.
4. J.M. Toth, M. Wang, B.T. Estes, J.L. Scifert, H.B. Seim III, A.S. Turner, Polyetheretherketone as a biomaterial for spinal applications. Biomaterials, 27, p. 324-334 2006.
5. S.M. Kurtz, J.N. Devine, PEEK biomaterials in trauma, orthopedic, and spinal implants. Biomaterials, 28, p. 4845-4869, 2007.
6. G.L. Converse, T.L. Conrad, C.H. Merrill, R.K. Roeder, Hydroxyapatite whisker reinforced polyetherketoneketone bone ingrowth scaffolds. Acta Biomaterialia, in press.
7. K. Rezwan, Q.Z. Chen, J.J. Blaker, A.R. Boccaccini, Biodegradable and bioactive porous polymer/inorganic composite scaffolds for bone tissue engineering. Biomaterials, 27, p. 3413-3431, 2006.
8. R.K. Roeder, G.L. Converse, H. Leng and W. Yue, Kinetic Effects on Hydroxyapatite Whiskers Synthesized by the Chelate Decomposition Method. J. Am. Ceram. Soc., 89, p. 2096-2104, 2006.
9. G.L. Converse, W. Yue, R.K. Roeder, Processing and tensile properties of hydroxyapatite-whisker-reinforced polyetheretherketone. Biomaterials, 28, p. 927-935, 2007.
10. G.L. Converse, T.L. Conrad, R.K. Roeder, Mechanical properties of hydroxyapatite whisker reinforced polyetherketoneketone composite scaffolds. J. Mech. Behav. Biomed. Mater., 2, p. 627-635, 2009.
11. D.T. Reilly, A.H. Burstein, The elastic and ultimate properties of compact bone tissue. J Biomechanics, 8, p. 393-305, 1975.
12. S.C. Cowin (Ed.), Bone Mechanics Handbook, 2nd Edition. CRC Press LLC (Boca Raton:, FL), 2001.
13. E.F. Morgan, T.M. Keaveny, Dependence of yield strain of human trabecular bone on anatomic site. J. Biomechanics, 34, p. 569-577, 2001.
14. T. M. Keaveny, E. F. Morgan, G. L. Niebur, O. C. Yeh, Biomechanics of Trabecular Bone. Annu. Rev. Biomed. Eng., 3, p. 307-333, 2001.
15. W. Bonfield, M. D. Grynpas, A. E. Tully, J. Bowman, J. Abram, Hydroxyapatite reinforced polyethylene - a mechanically compatible implant material for bone replacement. Biomaterials, 2, p. 185-186, 1981.
16. R.K. Roeder, G.L. Converse, R.J. Kane, W. Yue, Hydroxyapatite Reinforced Polymer Biocomposites for Synthetic Bone Substitutes. *JOM*, 60, p. 38-45, 2008.
17. R.K. Roeder, M.S. Sproul and C.H. Turner, "Hydroxyapatite whiskers provide improved mechanical properties in reinforced polymer composites," *J. Biomed. Mater. Res.*, 67A [3] 801-812 (2003).
18. R.J. Kane, G.L. Converse and R.K. Roeder, "Effects of the reinforcement morphology on the fatigue properties of hydroxyapatite reinforced polymers," *J. Mech. Behav. Biomed. Mater.*, 1 [3] 261-268 (2008).

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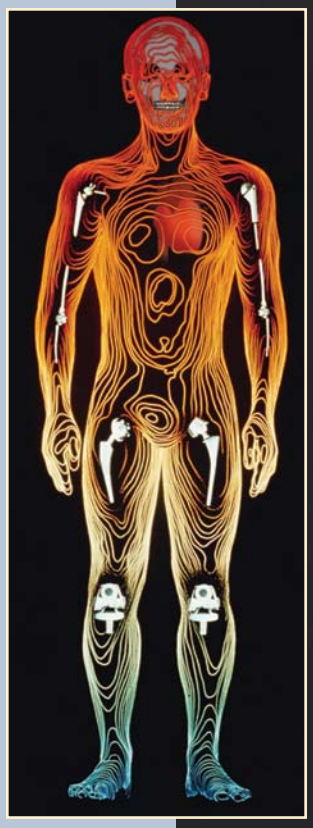

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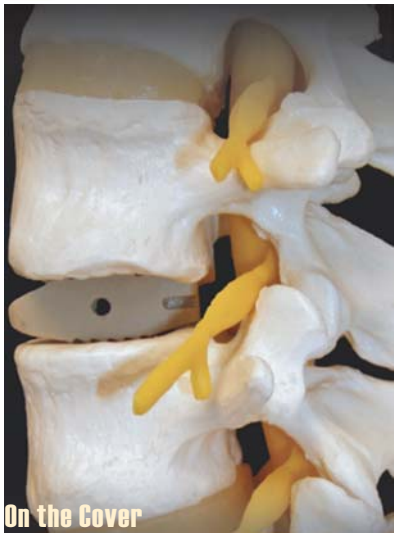

On the Cover

In this model of the lumbar spine, the disc and vertebral endplates are removed and a PEEK interbody fusion cage is inserted in the disc space. Interbody spinal fusion helps alleviate pain resulting from a herniated, bulging, or flattened intervertebral disc impinging on the spinal cord or nerve root. Image courtesy of R. Roeder, University of Notre Dame. www.nd.edu/~amebio

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