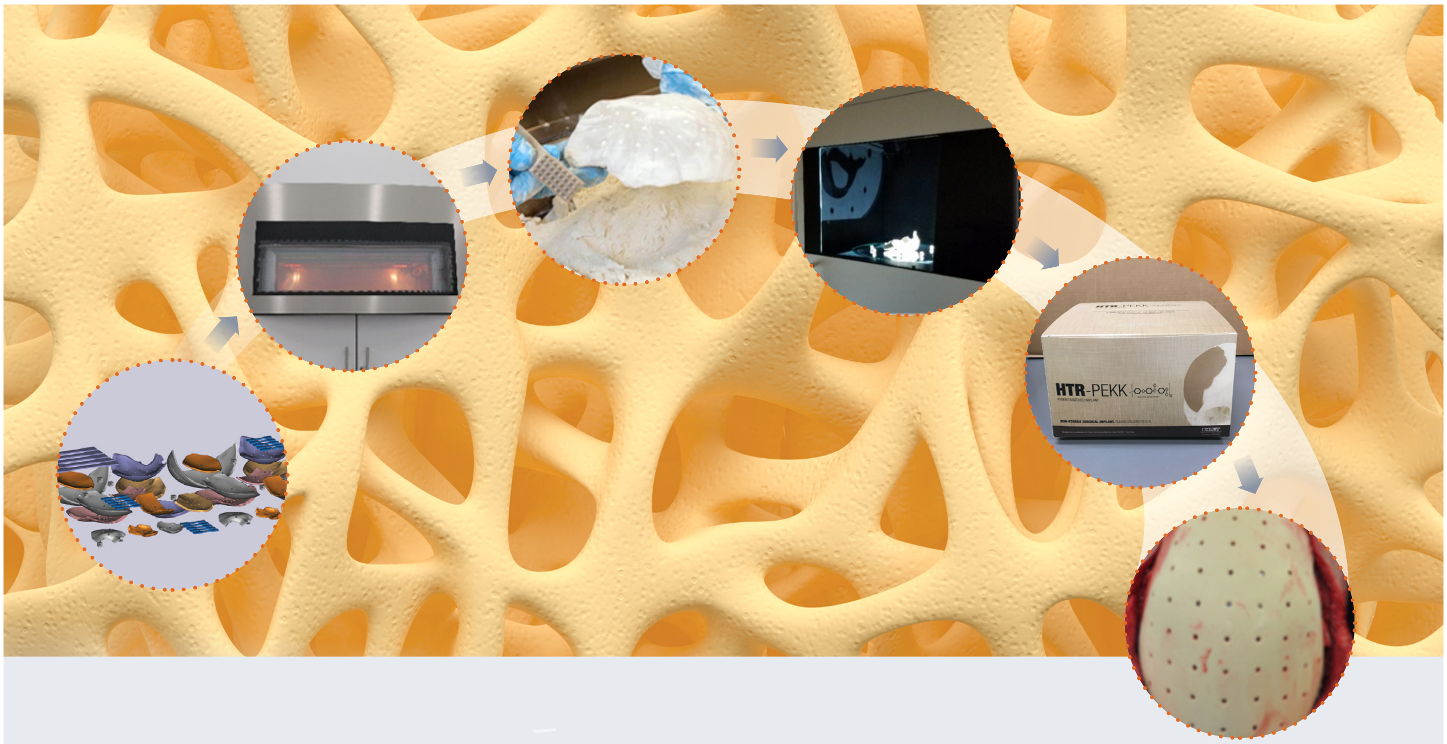
OsteoFab® Technology

Medical Device Platform



The Technology Foundation: PEKK Implantable Polymer System

Poly-ether-ketone-ketone (PEKK) is a biocompatible material that is part of the PAEK family of polymers. This family of polymers has been used extensively in medical devices including orthopedic, neurological, spinal, and cardiovascular implants for over 30 years.

The OXPEKK® Advantage: Biocompatibility and Performance

OXPEKK® is the proprietary high performance PEKK polymer formulation from Oxford Performance Materials, Inc. (OPM) for medical applications. OXPEKK materials meet the United States FDA and the European Union requirements for use in long-term human implantable medical devices. OXPEKK polymer has been tested per ISO 10993 biocompatibility testing standards. Test data and analytical extraction studies are included in our FDA Master File.

OsteoFab® Technology Platform: Reliability and Proven Path

The OsteoFab Technology Platform accelerates the speed at which implants are designed, manufactured, and cleared for sale. The OsteoFab platform combines design, material, manufacturing, quality management, and regulatory clearance into one streamlined process. The result is a faster and more predictable path to market.

OsteoFab® Surface Innovation: A Unique Environment for Bone

The combination of 3D printing technology and OPM's OXPEKK polymer results in an inherent rough surface that enhances bone formation.

QMSL-3001 Rev B per DCN B0155 OsteoFab Tech OPM©2017Oct12

3D Printing Process:

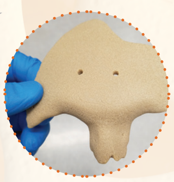
1. Digital build preparation

2. Selective laser sintering

3. Excavation of implant

4. Visual/Dimensional Inspection

5. Shipment to customer



6. Implantation

take action!

ONLINE
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SUPPORT
860.698.9300

More information:
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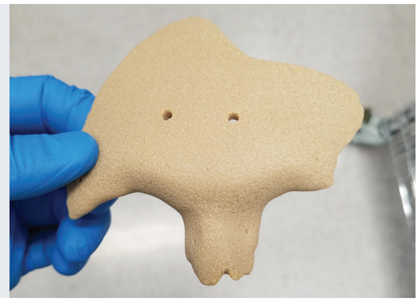
OPM's 3D Printing Advantage

Laser sintering is a 3D printing process that OPM uses to produce functional and critical parts like implants. It is a pure process that combines laser light and OXPEKK polymer. This manufacturing process enables complex design and yields a distinctive surface topography for bone attachment.

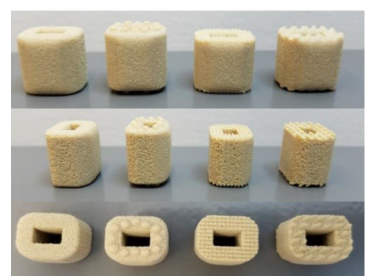
Complex geometries for series production (left) or anatomical design for patient specific CMF implants (right) are enabled by OPM's 3D printing technology



OXPEKK Material Comparison Matrix

	Bone	OXPEKK Neat	OXPEKK CF	OXPEKK Neat	PEEK[1,2]	PMMA[3]
Form	Cortical	3D Printed	3D Printed	Extruded	Extruded	Molded
Specific Gravity (g/cm3)	1.5-2	1.3	1.35	1.31	1.29	1.19
Tensile Strength (MPa)	53-135	83 (Ult)	108 (Ult)	138 (Yield)	100 (Yield)	62 (Yield)
Elongation at Break (%)	0.7-3.1	2.5	2.9	30+	20	10
Modulus of Elasticity (GPa)	6.9-27.4	3.5	7.0	4.4	3.4	3.1
Compressive Strength (MPa)	131-205	160	194	207	118	125.5

Static Expulsion Testing of Cervical Intervertebral Body Fusion Devices (Avg. Peak Load)			
No Teeth 136N	Cylindrical Teeth 129 N	Pyramid Teeth 232 N	Staggered Saw Teeth 281 N



Excellent Strength and Performance

- **Elastic modulus similar to bone**
- **Higher compressive strength than PEEK**
- **OsteoFab® spinal cages with expulsion resistance comparable to published values[4]**

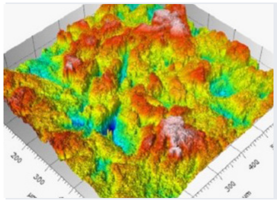
Benefits of the OsteoFab® Technology Platform

- **Efficient:** Digital design, refinement, and optimization
- **Effective:** Material and process enable facile fabrication of complex parts
- **Pure:** Laser sintering process only has two components: OXPEKK polymer and laser light
- **Safe:** FDA cleared patient specific cranial and facial devices, and a range of spinal implant systems

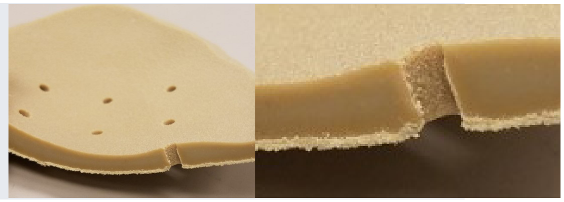
OsteoFab® Technology: The Right Surface for Bone

Surface and Antibacterial Properties

It has been well established that surfaces with micron-sized "peak-and-pit" like features enhance bone formation. The OsteoFab manufacturing process prints implants with a surface that stimulates osteoblast (bone forming cell) activity and mineralization. PEKK also exhibits antibacterial properties and an in vitro study showed decreased adhesion and growth of bacteria on the nanorough PEKK surface when compared to conventional PEEK surfaces.[5]



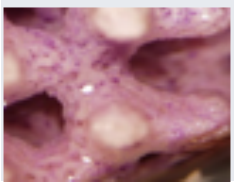
CLSM image of an OsteoFab implant that illustrates the rough "peak-and-pit" surface topography (left) and a cross section of a cranial implant that highlights the combination of a dense structure with a rough surface (middle and right)

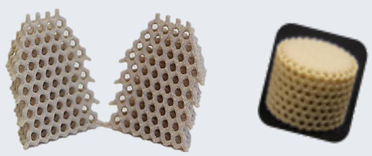


Stem Cells and Osteoblasts

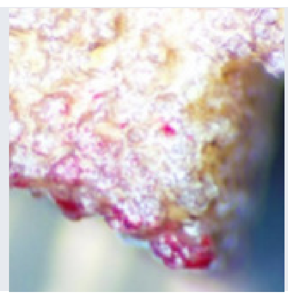
Designs manufactured via the OsteoFab process have inherent surface characteristics that make them conducive to attachment, growth, and differentiation of human mesenchymal stem cells.[6] These stem cells have been shown to differentiate into osteoblasts, which grow on 3D printed PEKK and proliferate to form colonies and new bone.[6] In another in vivo study, OsteoFab scaffolds seeded with adipose-derived stem cells induced vertical bone regeneration at the bone-scaffold interface in critical sized mandibular bone defects.[7]

Porous by design lattices printed via the OsteoFab® process





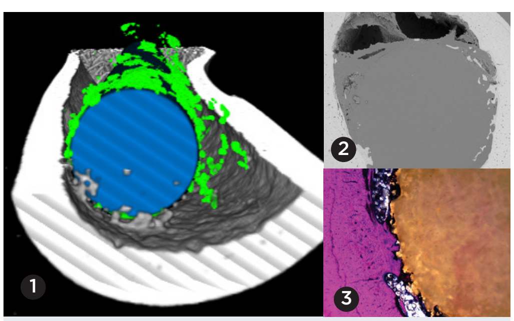
Colonies of osteoblast cells (purple, stained with crystal violet) are visible on the OsteoFab® lattice structure (left). Courtesy of Horowitz Lab, Yale University



Successful MC3T3 preosteoblast cell growth and subsequent mineralization on OsteoFab® substrate (alizarin red stain). Credit University of Hartford

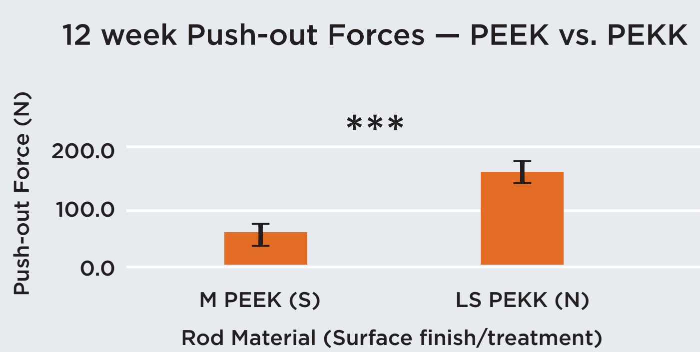
Animal Data

This in vivo study was conducted to evaluate bone response to PEKK polymer. Extruded and 3D printed PEKK rods were implanted in the femoral canals of New Zealand White rabbits and were harvested at 8 and 12 weeks. The bone response was characterized using micro-CT, SEM, and BSEM imaging techniques, as well as thin-section histology.



The images above are representative of the rabbit study:

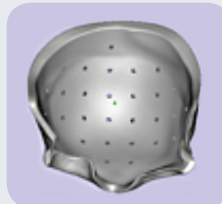
1. OsteoFab® rod implant in blue, with new bone in green, from a micro-CT rendering;
2. BSEM image of a cross section;
3. Corresponding histology slide (bone in pink/purple)



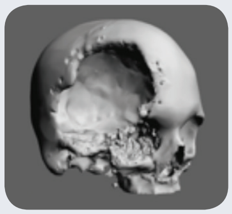
Average push-out force for machined PEEK (smooth) and 3D printed PEKK specimens; average ± SEM. ***$p<0.01$[8] Push-out testing performed on femoral rods. Results support histological findings of bone growth and attachment on OsteoFab® material.

OsteoFab® Patient Specific Cases

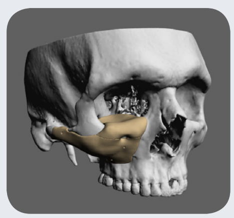
Bi-Frontal
Orbital

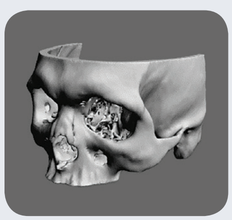
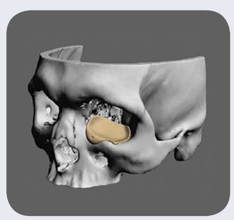
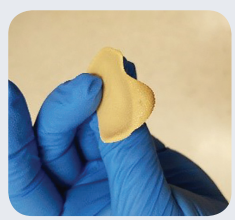

Right Frontal
Sphenoid Parietal
Orbital



Right Zygomatic
Maxillary Orbital
and Right
Orbital Floor


Left Orbital
Floor

[1] Invibio PEEK-Optima® per Invibio PEEK-Optima® Natural Typical Mechanical Properties (INV-TS-PN-E-0087-A) and PEEK-Optima® HA Enhanced Polymer Properties (S-MP-PHA-E-0133-A)

[2] Westlake Plastics MediPEEK-IM per MediPEEK Westlake Implant and Industrial Grade PEEK Physical Properties, San Diego Plastics, Inc.

[3] Polycast® Medical Grade PMMA

[4] V. Goel, "Expulsion Testing of an Anterior Cervical Intervertebral Fusion Cage: Factors Affecting Pull Out Resistance", ASME 2002 International Mechanical Engineering Congress and Exposition, pp. 395-396, 2002

[5] Antibacterial properties of PEKK for orthopedic applications, Mian Wang et al., International Journal of Nanomedicine, 2017

[6] Bone tissue engineering using polyetherketoneketone scaffolds combined with autologous mesenchymal stem cells in a sheep calvarial defect model, Carina Adamzyk et al., Journal of Cranio-Maxillo-Facial Surgery, 2016

[7] Three-Dimensionally Printed Polyetherketoneketone Scaffolds With Mesenchymal Stem Cells for the Reconstruction of Critical-Sized Mandibular Defects, Michael Roskies et al., The Laryngoscope, 2017

[8] Data on File at OPM

Not all data has been reviewed by the FDA at time of print.

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