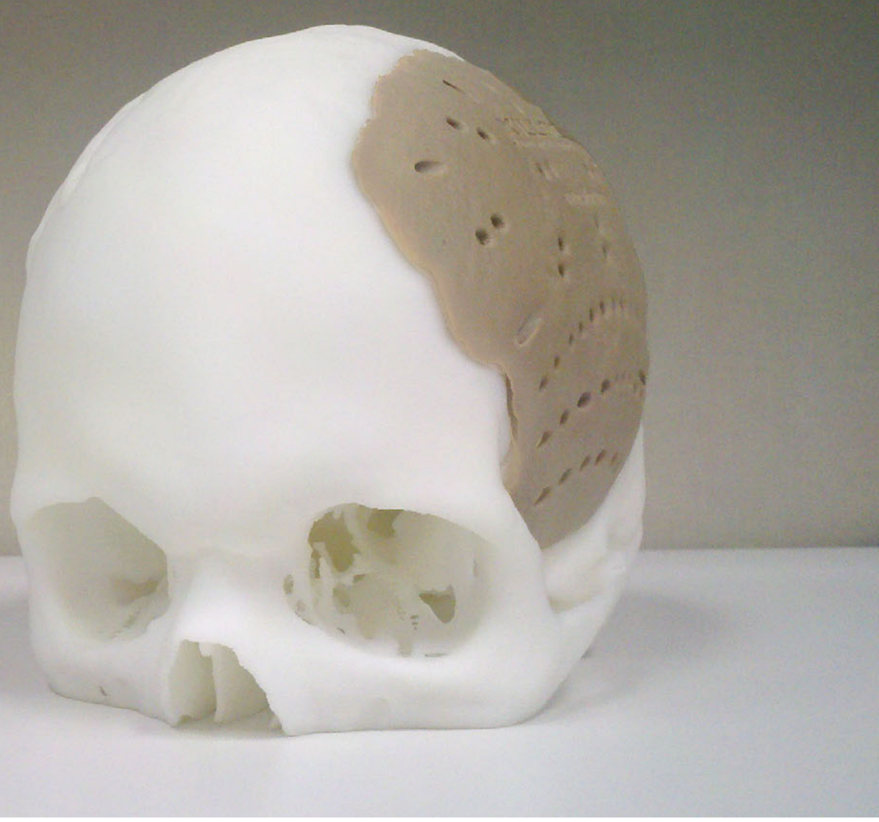

PEKK Pioneer: Additive Manufacturing of Customised Cranial Maxillo-Facial Implants

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The global market for additive manufacturing technologies is set to double in 2012-17. While much of this expansion will be in product design and prototyping, a growing niche of custom-made, one-of-a-kind implantable devices are being made from computer aided design (CAD) files drawn up using a patient's actual anatomical dimensions. The attraction of these is that fit can be improved substantially, compared with more traditional generically-sized products. A leading light is USA-based Oxford Performance Materials, co-founded by Scott DeFelice.

Oxford Performance Materials (OPM) was founded in 2000 as a supplier of PEKK (polyetherketoneketone) polymer compounds and stock shapes for industrial applications under the brand OXPEKK. As its name suggests, PEKK is part of the same family of high-performance polyether ketone polymers that PEEK belongs to and exhibits similar properties.

During 2003-09 OPM enjoyed a partnership with DSM and part ownership by Arkema before those shares were bought back by OPM in 2011. In 2006 OPM produced its first ever biomedical material for long-term orthopaedic implant and achieved ISO 13485 certification.

In 2011, under its OsteoFab brand, OPM produced and shipped its first custom-made long term implantable medical device using select laser sintering (SLS) additive manufacturing. The device is a cranial maxillo-facial (CMF) plate for skull reconstruction.

Since the first product was made, OPM has manufactured approximately 50 long-term implants for use outside the USA. The majority are CMF plates for procedures like craniotomy (skull surgery to gain access to the brain or reconstruction) and orbital and mandibular reconstruction (corrective surgery to the face and jaws, respectively).

At the time of going to press, OPM expects to receive its first 510(k) clearance of a long term implantable additively manufactured device for sale in the US market by Q2 2013.

The technology is also suitable for manufacturing devices for the replacement of small bones in the hands and feet and other non-load bearing applications.

The devices are made by a process called selective laser sintering (SLS), an additive manufacturing procedure which melts molecules of OPM's OXPEKK polymer powder one layer at a time. Precise layer thickness is strictly confidential but a typical build would have several thousand layers of material.

The laser is controlled by a computer, which reads data from a three-dimensional CAD file. The CAD file contains the dimensions for the device and is created from the patient's CT or MRI scan. OPM uses an P800 SLS machine under special license from German additive manufacturing machine supplier EOS.

When commenting on the manufacturing process, Scott told *Medical Plastics News* that an additive process inherently provides a better orthopaedic device than machining—a subtractive process.

"The additive manufacturing process allows for the design and production of anatomically and physiologically optimised implants as it enables better load distribution compared to other manufacturing methods such as machining or moulding."

Scott also points out that the material has a natural surface "roughness" and this is thought to improve osteointegration. The company's website quotes a study published in March 2011 by Timothy Ganey, director of research at the Atlanta Medical Center, which suggests that PEKK offers improved osteointegration compared with titanium.

In terms of regulation and compliance, Scott explains that he takes an "end-to-end" approach to validation. "Busy surgeons are not accustomed to the detail required with patient-specific design and manufacturing. They rely on their suppliers to ensure parts are compliant."

OPM approaches compliance by establishing business processes which deal with every possible event that could cause interference during design, production and distribution, including power outages and even handling by the surgeon. Every product is shipped with the appropriate technical documentation.

In terms of leadtime, if OPM receives a CAD file on a Friday a device can be built by the Tuesday and shipped the following Friday. Typical turnaround time is under two weeks.

When asked about the possibility of developing more advanced materials for additively manufactured implants, for example those containing radiopaque additives such as barium sulfate or antimicrobials, Scott said: "We'd look at the economics of any such project and see if it's feasible. In fact, the development of custom materials is a historic competence within the firm."

With all this knowhow, it's not surprising that OPM's horizon is flushed with opportunity. Scott says that partnerships built through the supply of OXPEKK pellets and stock shapes, means that not only is OPM a direct supplier of bespoke devices to major orthopaedic companies but it can also deliver directly to surgeons around the world.

Typical properties of PEKK OsteoFab product

Specific gravity	1.31 g/cm^3 (81.8 lb/ft^3)
Tensile strength (break)	83 Mpa (12,000 psi)
Tensile modulus	3,940 Mpa (571,000 psi)
Elongation (break)	2.5%
Flexural strength	180 Mpa (26,000 psi)
Flexural modulus	3,640 Mpa (528,000 psi)
Compressive strength	160 Mpa (23,000 psi)

All numbers represent typical in-plane values

Electrospinning Creates Degradable Load Bearing NanoFibre Cell Scaffolds

Researchers at the University of Pennsylvania, USA, have taken a step forward in the engineering of load bearing fibrous tissues for regenerative medicine, according to work published last year in the US journal *Proceedings of the National Academy of Sciences*.

It is hoped that the work will help medical scientists working to find bioengineered replacements for tendons, ligaments, the meniscus of the knee and other weight-bearing tissues.

Nano-fibre cell scaffolds are already being used by orthopaedic surgeons to guide tissue growth in an organised way. However, there has been reports that uptake has been slow due to poor osseointegration of the tissue along the scaffolds.

The researchers in Pennsylvania have found a way of producing nanofibrous polymer scaffolds which they say have a loose enough structure for cells to colonise inside while still being able to direct them in order for new tissue to grow in the desired direction without impediment.

According to a report in US science news website *Phyorg.com*, the fibres are the product of electrospinning two polymers—a slow degrading polymer and a water soluble polymer. While the first polymer is designed to degrade in the body, the water soluble polymer can be selectively removed prior to the scaffold's use to increase or decrease the spacing between the fibres. The resulting matrix can have cells added to it to grow tissue inside or outside the body.