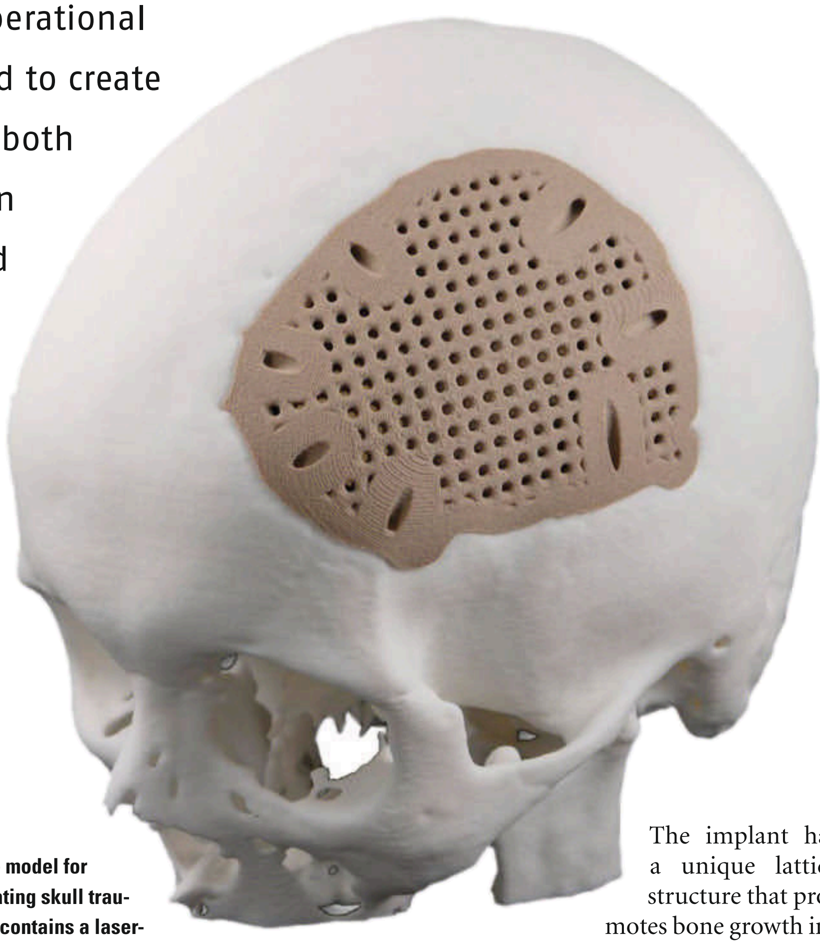
The First Laser-Sintered Skull Implant

Interdisciplinary Research. As part of a European-funded study, an interdisciplinary group of companies and research institutes has developed a skull prosthesis made from PEEK material to operational fruition. Laser-sintering is used to create a unique lattice structure that both covers the asymmetrical hole in the deformed cranial bone and provides an ideal platform for osseointegration.



The model for treating skull trauma contains a laser-sintered PEEK implant (photos: EOS)

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Now that knee and hip replacement have become routine, the next challenge in artificial human bone is certainly the skull. Whether through birth defect, accident or disease, any breach of the cranium jeopardizes the fragile brain and needs fixing as quickly as possible. Yet, since every patient's injury is unique, replacing that lost bone must be done on a case-by-case basis.

Titanium-plate cranial implants, customized with CAD/CAM-processed CT data (computed tomography), have been the most-used solution to date. But the material and the machining methods approved to produce them can be expensive and time-consuming. Furthermore, titanium is relatively stiff compared to bone and in some forms can be temperature-conductive after implantation. This can lead to long-term issues with fit and comfort in the skull.

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PEEK as a Titanium Alternative for Implants

More recently, researchers have turned their attention to cranial implants made from PEEK (polyetheretherketone). PEEK's lighter weight, strength, biocompatibility and other characteristics make it a realistic alternative to titanium. Recently, a line of custom-milled PEEK-based skull implants made by a U.S. company received FDA approval. And the first ever laser-sintered PEEK cranial implant prototype has now been created by a team of doctors, design engineers and materials specialists working together in a European Union-funded research project called Custom IMD (see box page 48).

The implant has a unique lattice structure that promotes bone growth into the implant and can only be created with this additive-manufacturing technique. Final laboratory tests and animal trials are still underway.

Once PEEK had been selected for the "cranial section" of the research project, EOS GmbH, Krailling, Germany, a leading manufacturer of laser-sintering machines, was asked to join in. Its Eosint P 800 **(Fig. 1)** laser-sintering system is the first to operate at the temperatures of up to 385 °C which are needed for processing high-performance polymers like PEEK. While the company can supply technical grade EOS PEEK HP3 (with an even higher melting point than standard PEEK), in this case it was decided to use the established PEEK formula.

As an implant material PEEK provides mechanical flexibility and translucency to →

Fig. 1. Eosint P 800 laser-sintering system used to manufacture high-temperature PEEK cranial implant prototypes for Custom IMD research project

CT, x-ray and MRI scans and its chemical stability and high melting point accommodate all methods of sterilization. When used in conjunction with additive manufacturing, PEEK can be laser-sintered into highly complex geometries that promote osseointegration, i. e. the progressive attachment of osteoblasts, the body's cells that generate bones, to the structure of the implant. Conventionally machined or molded implants (either titanium or PEEK) can include holes to accommodate this tendency for bone ingrowth. Laser-sintering can produce much more intricate structures, free of the constraints of traditional methods.

To further promote bone growth, the finished structure was infiltrated with a bioabsorbable polymer filled with 50 %-hydroxylapatite, the calcium-phosphate complex that is the primary mineral component of natural bones and teeth and gives them their rigidity. The polymers and bioceramics were provided by SupraPolix BV and Xpand biotechnology BV, both from The Netherlands. After the polymer-filled PEEK implant geometry would be surgically attached to the skull with titanium screws using a newly developed fixing design, osteoblaths are expected to infiltrate the polymer, connect with the implant itself, and replicate many characteristics of the original bone.

Scaffold Design Promotes Integration of Osteoblasts

Although laser-sintering can now produce prototypes of the PEEK cranial implant within a few hours, it took several years of collaboration between physicans, technicians and designers to develop. AZM University Hospital Maastricht/The Netherlands and the University of Hasselt/Belgium provided medical advice and analysis.

The first step in the systematic design evaluation process was to make a side-by-side comparison of a solid laser-sintered titanium skull plate and a PEEK one, both based on CAD models built from patient-specific CT scan data. Finite-element analysis (FEA) of the mechanical properties of the two designs showed that the PEEK version needed to have a thickness of 8 to 9 mm, which corresponds to the thickness of the skull. Since fixing the PEEK plate in place could not be done with the thin clips that worked in titanium, tangential holes were designed for screws to attach the plate directly to the skull **(Fig. 2)**.

The next step in the evolution of the design was to create a scaffold understructure with internal spacing that would promote osseointegration. Much like interwoven struts under the arch of a bridge, the scaffold would distribute weight and provide good strength while using less material. Working together using a commercial design software, the engineering team provided input as to the optimum thickness of the struts, the neurosurgeons proposed lattice dimensions that would be ideal for bone cell infiltration, and the polymer group suggested pore size parameters for accommodating the bioabsorbable material. The ultimate design, a uniform scaffold with edges cut to shape, showed significant stress peaks in FEA simulations, and insufficient mechanical strength in testing.

Fig. 2. An early design showing the PEEK scaffold structure that was manufactured in one piece by laser-sintering. While it was a good fit, it offered little scope for osseointegration

Software-Assisted Optimization of the Implant Design

So the group turned to a new type of design software from Within Technologies Ltd., U.K. that generates scaffolded lattices that can be customized to follow the contours of any desired part shape. Within Technologies' enhance tool controls not only the design of the internal lattice (resolution, strut thickness and topology), but also the width of the part's walls or skin in a fluid and continuous fashion. Once an object is defined, the Within Technologies model is integrated with

! Custom IMD

The goal of the Custom IMD project (Customized Implantable Medical Devices), which involved 22 partners from seven European countries, was to achieve supply chain integration of fully customizable medical implants, with cranial, dental and spinal applications, in a variety of metals and plastics. The ultimate aim was a 48-hour turnaround and lower medical expenses for every patient needing an implant.

→ **www.CustomIMD.com**

FEA in a feedback loop that allows rapid iteration between optimizing the design and seeing how it will perform under stress **(Fig. 3)**.

The complex CAD geometries that are produced for this evaluation process are excellent candidates for laser-sintering, according to Within Technologies' managing director, Dr. Siavash Mahdavi **(Fig. 4)**. "We've been working with additive manufacturing in metal spine, hip and other implant geometries for a few years now. This Custom IMD cranial implant research was our first PEEK design," he says.

Employing the new software, the group came up with scaffold geometry that satisfied the requirements for the cranial implant. Mechanical properties were targeted to meet all required ISO values for PEEK. A rim was added around the edge of the part to give it a solid border for optimum fit to existing skull bone. With this version, no stress peaks were found in the structure.

The implant prototype could withstand greater than 100 MPa of pressure with minimal deflection, and any stress at impact dissipated quickly without being transferring to the brain. Further input from one surgeon led the group to add additional holes inside the rim border for even greater potential for osseointegration **(Fig. 5)**. "This kind of last-minute design change was easy to modify with the software and could be promptly manufactured, then re-verified with physical testing," notes Dr. Mahdavi.

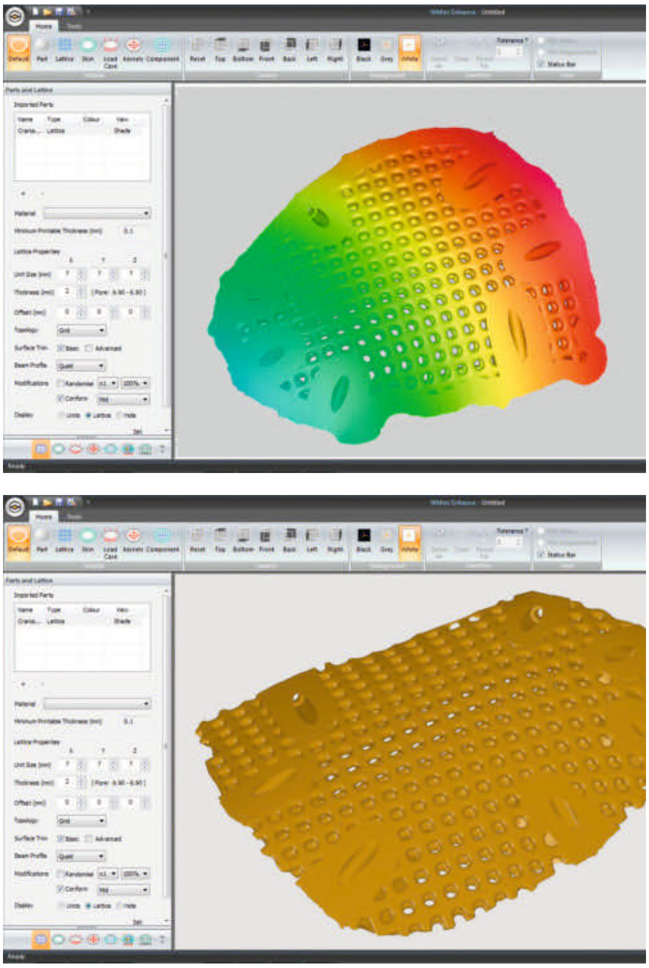

Fig. 3. Screen shots showing Within software lattice creation and analysis

(figure: Within)

Advantages for Both Patients and Physicians

With their idealized design validated for strength, the research team still wanted to prove out their concept with the kinds of additional ISO-standards testing that future FDA applications would require. FDA approves materials in finished devices, not materials alone, so every new device configuration requires complete re-certification. They subsequently performed:

- Polymer-infiltration trials confirmed the uniform distribution of the polymer and the benefits of the roughened lattice surface, which further promotes strong attachment to the polymer.
- Sterilization (electron beam) validation showed that the molecular weight of the PEEK samples was the same before and after electron beam treatment, demonstrating no degradation.
- A biocompatibility testing proved the implant to be non-cytotoxic, non-haemolytic, non-pyrogenic, non-irritant and causing no sensitization response. →

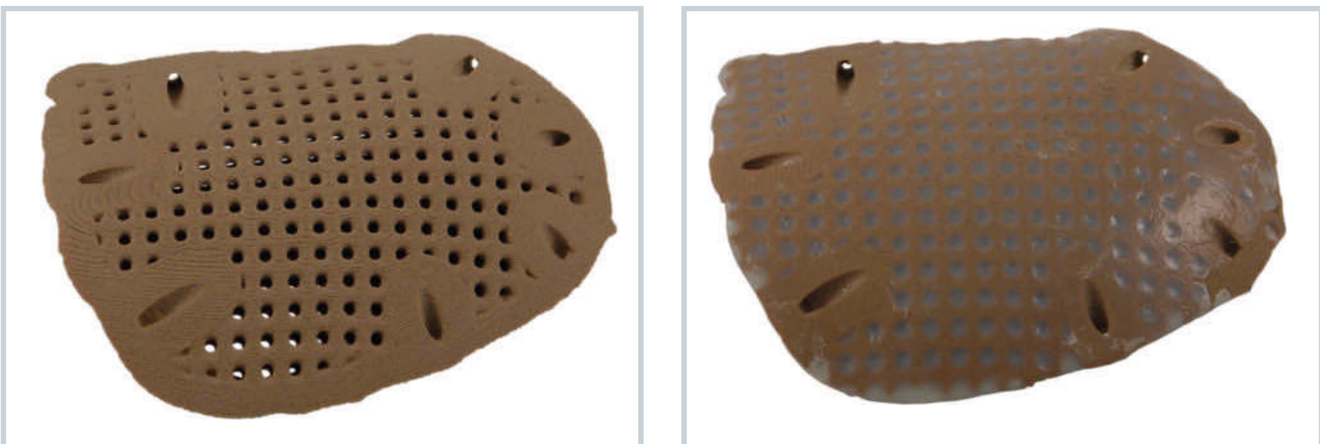

Fig. 4. A bioabsorbable hybrid material of polymer/ceramic (right) was incorporated into the finished PEEK implant model (left) to promote bone growth. The figure shows an earlier model as yet without rim

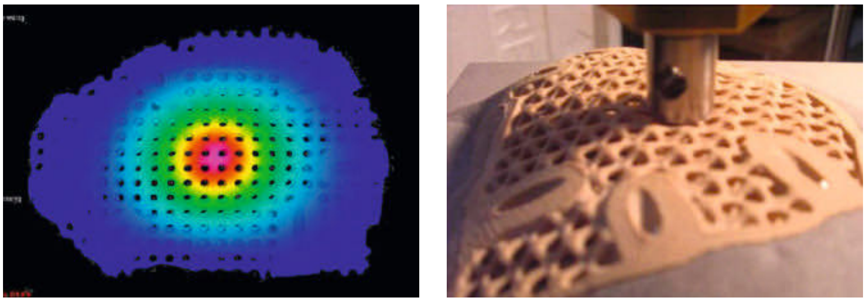

Fig. 5. The researchers compared the FEA results (left) with values obtained in mechanical tests with a view to identifying the strength of various implants and establishing whether the implant remains in place or is displaced by an impact

The socioeconomic benefits of future laser-sintered PEEK implants could be considerable. With precise customization and better fit, such implants would require less time in surgery and provide greater comfort to the patient. There are labor and material savings as well as potential improved health gain.

Adds Dr. Mahdavi, “Now that both custom implant design and rapid manufacturing can be done, we envision a future where any surgeon in the world can simply send the MRI scan of their specific cranial implant requirements to a single computer that creates the CAD design, prepares an FEA validation report, then sends the data to an additive manufacturing machine where the part is quickly built. The part is then returned to the doctor.

From the technical side, therefore, all the prerequisites are in place: from data generation to implementation of the ideal lattice structure for the specific deformation through to the layered construction of the implant. This study makes an excellent starting point for developing further patient-specific implants from PEEK. In order for these to be actually used on humans, the main goal now is to further refine the process chain. ■

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