

## **Invibio® Biomaterial Solutions PEEK-OPTIMA® Natural Polymer used in Patient Specific Cranial Implants**

In recent years PEEK-OPTIMA® Natural polymer has been used increasingly within patient specific implants due to the desire for larger repairs with a high degree of complexity. PEEK-OPTIMA Natural patient specific implants for cranioplasty offer advantages over typical cranioplasty materials such as Titanium in terms of radiolucency, ease of fixation and lack of thermal conductivity. PEEK-OPTIMA is bioinert and therefore has no detrimental effect on the tissue surrounding the implant.

The following provides a list of recent literature related to the use of PEEK-OPTIMA Natural.

Paper	Key findings
<p><b>Maxillofacial Reconstruction Using Polyetheretherketone Patient Specific Implants by “Mirroring” Computational Planning</b></p> <p>Scolozzi, 2012, <i>Aesthetic Plastic Surgery</i></p>	<p>Use of PEEK PSI in patients where previous repair using autograft bone has failed due to resorption. Mirroring technology takes the shape from the undamaged side of the face to produce a CAD/CAM part to fill defect. 2 year follow-up on both patients revealed no complications. Longer term follow-up of a previous patient (6 years) also shows no complications.</p>
<p><b>Reconstruction of Frontal Bone Using Specific Implants Polyether-Ether-Ketone</b></p> <p>Camarini et al. 2011, <i>The Journal of Craniofacial Surgery</i></p>	<p>Details the use of PEEK in a patient with an aesthetic complaint 2 years after initial reconstruction following facial trauma. PEEK was selected over PMMA/porous polyethylene due to its bio-inertness and the ease of fit in surgery. The strength allows anatomic adaptation combined with high stability. 18 months after implantation there were no complications observed.</p>

<p><b>Cranioplasty with Customised Titanium and PEEK Implants in a Mechanical Stress Model</b></p> <p>Lethaus et al. 2011, <i>Journal of Neurotrauma</i></p>	<p>Comparison of the structural changes in PEEK-OPTIMA and Titanium implants under quasi static loading. Both PEEK and Titanium withstood forces higher than those capable of causing skull fracture. However, Ti withstood much higher forces transferring damage to the skull model. This suggests that PEEK may provide better protection to the surrounding bone in cases of trauma following cranioplasty.</p>																				
<p><b>Craniofacial Reconstruction with Bone and Biomaterials: Review Over the Last 11 Years</b></p> <p>Neovius et al. 2010, <i>British Journal of Plastic Surgery</i></p>	<p>Review of the infection rates reported in the literature for the range of materials used in craniofacial reconstruction. The rates are summarized in the following table:</p> <table border="1" data-bbox="613 625 1404 1035"> <thead> <tr> <th>Material</th> <th>Range of Infection Rates in Literature</th> </tr> </thead> <tbody> <tr> <td>Autograft</td> <td>0 - 33</td> </tr> <tr> <td>Allograft</td> <td>0 - 9.5</td> </tr> <tr> <td>PMMA</td> <td>9.2 - 16</td> </tr> <tr> <td>HA</td> <td>0 - 20</td> </tr> <tr> <td>Calcium Phosphate</td> <td>0 - 20</td> </tr> <tr> <td>Porous Polyethylene</td> <td>0 - 5.6</td> </tr> <tr> <td>Titanium Mesh</td> <td>0 - 2.3</td> </tr> <tr> <td>Titanium PSI</td> <td>0 - 6.7</td> </tr> <tr> <td>PEEK</td> <td>0 (No data in this area available)</td> </tr> </tbody> </table> <p>These rates highlight that there are incidences of infection reported for the majority of materials used in this application. Infection rates appear to be strongly linked to placement (high rates when in contact with the nasal sinus) and also operating time.</p>	Material	Range of Infection Rates in Literature	Autograft	0 - 33	Allograft	0 - 9.5	PMMA	9.2 - 16	HA	0 - 20	Calcium Phosphate	0 - 20	Porous Polyethylene	0 - 5.6	Titanium Mesh	0 - 2.3	Titanium PSI	0 - 6.7	PEEK	0 (No data in this area available)
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<p><b>Calvarial Reconstruction with Polyetheretherketone Implants</b></p> <p>Hanasono et al. 2009, <i>Annals of Plastic Surgery</i></p>	<p>PEEK-OPTIMA<sup>®</sup> PSIs were used in 6 patients who had infections following prior surgery. Previous implants included PMMA and bone graft/HA cement. PEEK was selected due to its strength, bio-inertness and resistance to radiation. All repairs were successful and no failures were observed in the six patients with follow-up times up to 16 months.</p>																				
<p><b>Use of Customised Polyetheretherketone (PEEK) Implants in the Reconstruction of Complex Maxillofacial Defects</b></p> <p>Kim et al. 2009 <i>Arch Facial Plastic Surgery</i></p>	<p>This paper describes the use of PEEK PSIs in 4 patients with a 16 – 20 month follow up. PEEK was selected as the implant material for these procedures due to the combination of its high strength and malleability which makes intraoperative modifications easy. Operating time was decreased in these cases due to accurate fit of the implants due to the ability to prefabricate them prior to operating. No complications were observed for these patients.</p>																				

<p><b>PEEK Implants for Cranioplasty of Complex Cranial Defects</b></p> <p>Frederic et al., 2008, <i>Journal of Cranio-Maxillofacial Surgery</i></p>	<p>Discusses the use of PEEK PSIs in 4 cases; 3 following removal of a primary implant following septic osteolysis and 1 following carcinoma. The aesthetic outcome in large, complex defects is praised and the surgical procedure quoted as being quicker and easier.</p>
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