

TECHNOLOGY OVERVIEW

PEEK-OPTIMA Natural polymer paving the way for custom CMF implants

- ▶ Can be used in large complex reconstruction cases following trauma, cancer or infection
- ▶ Better patient outcomes with comparable¹ overall costs versus other materials
- ▶ Shorter operating room time, surgical ward and ICU stay^{2,3}



Custom cranial plate made from PEEK-OPTIMA Natural. This product is not available for distribution and implantation, worldwide.

Unique attributes for custom cranioplasty

- ▶ Light-weight, non-metallic alternative to titanium
- ▶ Modulus similar to bone
- ▶ Reduced stress shielding
- ▶ Strong, especially beneficial in the frontal bone region, prone to impact
- ▶ Compatible with CAD/CAM milling processes, for a more precise implant fixation, while still allowing intra-operative fine-tuning of contours
- ▶ Can withstand multiple steam sterilization cycles
- ▶ Radiolucent and artifact-free imaging on CT and MRI, facilitating post-operative monitoring
- ▶ Permeable to ultrasound, allowing visualization of intracranial parenchymal and vascular structures⁴

MATERIAL BENEFITS

Benefits of custom PEEK-OPTIMA Natural implants

- ▶ High aesthetic outcomes and patient satisfaction⁵⁻⁹
- ▶ Good outcomes in large or complex defects¹⁰
- ▶ Radiotherapy can be used in oncology cases⁷
- ▶ Significantly lower complication rates compared to autologous bone²

Challenges with other material options

Autologous bone

- ▶ Non-customizable using patient's own bone
- ▶ Store in abdominal cavity or freeze prior to second surgery
- ▶ Potential for bone resorption resulting in less than ideal aesthetics often leading to a second surgery¹¹

Poly-methyl-methacrylate (PMMA)

- ▶ Exothermic curing process raising potential for thermal necrosis¹²

Titanium (mesh or plate)

- ▶ Challenges with implant exposure^{13,14} temperature sensitivity¹⁵ and artifact generation on MRI¹⁶
- ▶ Association between some forms of metal hypersensitivity and higher rates of titanium plate exposure¹⁷

Lower post-operative complications and implant failures with PEEK implants¹⁸

| | PEEK vs. Autologous Bone | | PEEK vs. Titanium | |
|-----------------------------|-----------------------------|--------------------|----------------------|------------|
| | PEEK | Autologous Bone | PEEK | Titanium |
| Complication rates | 0% | 37.0% | 16.7% | 30.1% |
| | | 7.69-fold* | | 7.87-fold* |
| Implant failure rates | 0% | 10.9% | 8.3% | 26.5% |
| | | 1.74-fold* | | 5.88-fold* |

*Increased odds ratio over PEEK cranioplasty group

CLINICAL EVIDENCE

Beneficial patient outcomes compared to metal

- ▶ Lower complication rates^{13,19}
- ▶ Lower implant failure rates¹⁹
- ▶ Brain function improvement¹⁴
- ▶ Cosmetic satisfaction¹⁴

Complication and cranioplasty implant failure rates¹⁹

| | PEEK-OPTIMA Natural | Titanium | Titanium + Acrylic |
|--------------------------|------------------------|----------|-----------------------|
| Complication rates | 0% | 80% | 43% |
| Implant Failure rates | 0% | 60% | 43% |

Brain function improvement, cosmetic satisfaction and overall lower complication rates¹⁴

| | PEEK-OPTIMA Natural | Titanium |
|---|---------------------|----------|
| Brain function improvement | 25.3% | 10.9%* |
| Cosmetic satisfaction | 94.7% | 80.9%* |
| Complications | | |
| Overall complication rate | 17.3% | 31.8%* |
| Post-operative new epilepsy episodes | 4.0% | 18.2%* |
| Post-operative implant exposure | 1.3% | 9.1%* |
| Surgical site infections | 2.7% | 6.4% |
| Post-operative hematoma | 4.0% | 7.3% |
| Subgaleal effusion | 8.0% | 10.9% |
| Re-operation rates | 1.3% | 10.0%* |

*p<0.05

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