SKULLPT

Ensuring better medical performance and cost effectiveness
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@ Dr Vaz - University Hospital St-Luc - EU

An achieved objective!
WHAT IS SKULLPT?

SkullPT is a patient specific mold that can create a patient specific cranial implant from polymethylmethacrylate (PMMA, bone cement) during surgery.

Based on the CT-scan of the patient, the mold is manufactured and delivered to the hospital for final sterilization. By setting PMMA in the mold, an implant is created in the OR. In just a few minutes the implant is ready to be fixated in the patient.

WHY USE SKULLPT?

A perfect fit

The accuracy of the implant is very high due to the latest technologies used for design and manufacturing. Moreover, the implant material (PMMA) is well known and allows one to adapt the implant if the surgical reality differs from the CT-scan (fibrosis, open sinus, movement artefacts,…). SkullPT guarantees a perfect fit in any situation.

Cost effectiveness

The engineering work (image processing, design, validation, …) is at least as complicated as other custom-made implants. However, our manufacturing process and efforts to optimize workflow enable us to lower our fabrication costs. This allows us to provide a cost-effective implant of high quality.

One step resection & reconstruction

When a resection is needed, planning is performed to delineate the resection area (on a CT-scan or MRI). All information is merged on the CT-scan, the resection is planned in 3D, and a surgical guide and an implant are designed. Intraoperatively, the guide and the implant are used to obtain, in just one surgical intervention, an accurate resection and reconstruction with a patient specific cranial implant.
HOW TO USE SKULLPT?

1. **Provide Images**

Upload your images
Drag & Drop:
www.3d-cranioplasty.com

2. **Supervise our Work**

Validate the implant
You receive a **3D-link** to visualize the implant in 3D.

3. **Use during Surgery**

   **No waiting time**

Create your implant; a nurse can do this.

Fill the mold with **bone cement - before the surgery**.

*(estimated time: 5 min)*

The implant is ready to use after cooling and hardening

*(estimated time: 20 minutes - at the same time as making the incision.)*

This is performed by a nurse during preparation of the instruments. No additional step is needed during surgery.

**Reconstruct**

Place the implant in the skull defect.
Adapt it to your needs (drill holes, ream borders,...) if necessary. Fix it in place using your preferred osteosynthesis system.
COMPLEX CASES

Surgeon  Dr Reuter
Hospital  CHU Liège
Challenge  Resection of a lateral skull tumor followed by a reconstruction. 3D-Side plans the resection and reconstruction and provides the adequate tools.

Lateral Resection prior to Frontal Reconstruction

Planning
The tumor delineation was performed by Dr Reuter, on the CT-scan (no MRI was needed). The lateral tumor resection (red) and reconstruction (green) were planned with our 3D design software.

Production
The resection guide (blue) and reconstruction mold were designed and 3D-printed. Furthermore, an anatomical model of the patient’s skull is produced, offering extra support during surgery.

Surgery
First the lateral part is resected using the resection guide. Next, the implant is produced and placed into the skull defect, perfectly complementing it. This enables one to meet the facial harmony requirements.
FREQUENTLY ASKED QUESTIONS

Why a mold and not a final implant?
Making a molding during the surgery offers the presence of antibiotics in the implant! Moreover, SkullPT enables the implant to be adapted in the OR if necessary while offering lower costs and a reduced lead time.

How long does it take to receive SkullPT?
3D-Side can deliver SkullPT one week after approval. The lead time can be reduced for priority cases.

Is a mold as accurate as an implant?
Yes, it is. The accuracy of the molding is within a tolerance of 0.4mm. SkullPT delivers the correct shape and thickness to the PMMA.

Does the process take more time in the OR?
You do not lose time in the OR since the implant is prepared by a nurse during patient preparation. It takes about 5 minutes to mix the cement and then the implant takes 20 minutes to harden to be ready for implantation.

Does your implant allow osteointegration?
No. PMMA is a hard material with similar mechanical properties to bone. You do not need to reinforce the implant with osteo-integration (necessary for brittle material such as a ceramic/HA). Moreover, compared to other anatomical locations (e.g. the hip), applied forces are less significant on the skull and bone ingrowth will therefore not be highly stimulated. The long-term results are very good using this technology.

Does SkullPT avoid any exothermic reaction inside the patient?
The exothermic polymerization of the PMMA happens inside the mold. Therefore, there will be no heat damage occurring to the surrounding tissues, in contrast to PMMA shaped directly onto the patient's skull in the operating room.

How do I fix the implant in place?
You can use your preferred osteosynthesis method, for example mini-plates, craniofix or similar systems.
What do I do if the implant falls down?
The only thing needed is to have sufficient cement in stock. You can use the mold again if you need to make a new implant.

What are the sterilization recommendations?
Autoclave (steam sterilization cycle): 18 minutes - 134°C / 273°F

What do I do if the implant does not fit?
The advantage of SkullPT in comparison to its competitors is that one can manufacture a patient-specific implant using a well-known material (PMMA with antibiotics as an option) allowing the surgeon to make any adjustments during surgery, as needed. The implant can be drilled or fresh PMMA can be added to fill an unexpected gap.

How can I ensure accuracy for a one-step resection and reconstruction?
3D-Side has been an expert in bone resection for more than 10 years. We collaborate in delineation of the resection and provide specific surgical guides. Moreover, since the implant can be adapted (reduced or enlarged), a perfect result can be obtained in any situation.
ABOUT 3D-SIDE

3D-Side is a Belgian company which develops, manufactures and markets patient specific products for bone surgery based on 3D technologies. Its mission is to offer patient specific medical devices to allow planning of complex surgeries with incomparable quality. In addition to these products, 3D-Side also provides medical companies with «Customize», a web platform for efficiently marketing custom-made devices.

CONTACT US

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