3D-SKULL
Cranioplasty

3D-SIDE
Patient-specific technology

Unique Product for Unique Patient

3D-Side
ISO 13485

Ensuring better medical performance

Adaptability

Accuracy

Cost-effectiveness

“One of the strengths of 3D-Side is their adaptability and flexibility. Regarding either the location or the clinical situation, 3D-Side is always able to adapt.”

Dr. Reuter – CHU de Liège, Belgique

WHAT IS 3D-SKULL?

3D-Skull is a patient-specific mold used to create a patient-specific cranial implant from polymethyl methacrylate (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 placed in the patient.

WHY USE 3D-SKULL?

INTEGRATED GENTAMICIN	ADAPTABILITY	ACCURACY

Medical performance

The implant material (PMMA, bone cement) is strong and ensures a high level of mechanical protection to the brain. Moreover, the integrated gentamicin (antibiotic) improves the long-term results of this technology.

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,...). 3D-Skull guarantees a perfect fit in any situation.

Cost-effectiveness

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

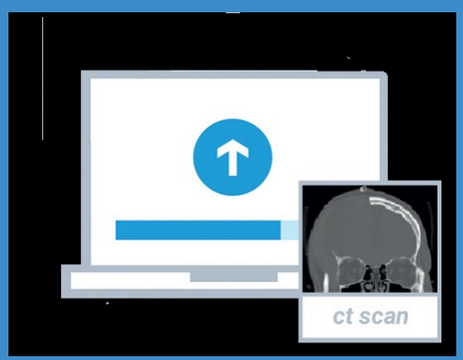
One-step resection & reconstruction

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 both a surgical guide and a custom-made 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 DOES IT WORK?

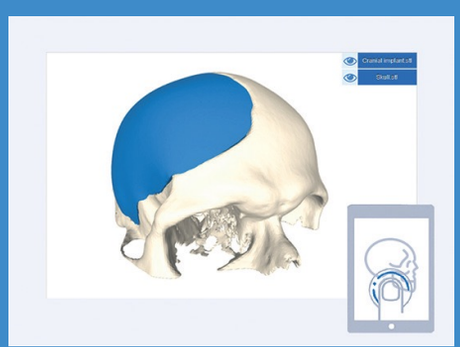
1 Upload images

The CT scan (and MRI if applicable) of the patient are uploaded on
https://3dside.3d-customize.com/upload



2 Supervise our Work

Validate the implant.
You receive a 3D-link to visualize and validate the implant in 3D. You receive a **3D-link** to visualize the implant in 3D.
The mold is produced and sent to your hospital for a standard sterilization.



3 Use during surgery No waiting time

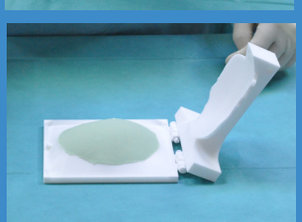
Create your implant. A nurse can do this.
Fill the mold with bone cement (PMMA) (Estimated time : 5 minutes, before the surgery.)

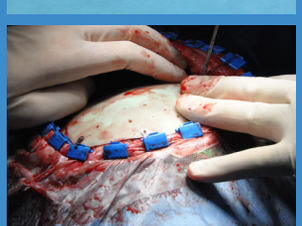
The implant is ready to use after cooling and hardening.

(Estimated time : 20 minutes, at the same time as making the incision.)

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

Reconstruction
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.





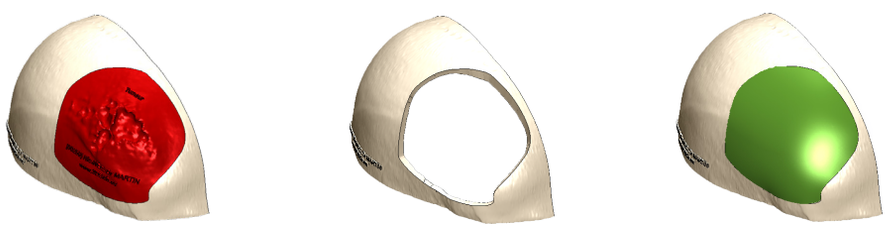
COMPLEX CASE

CHALLENGE

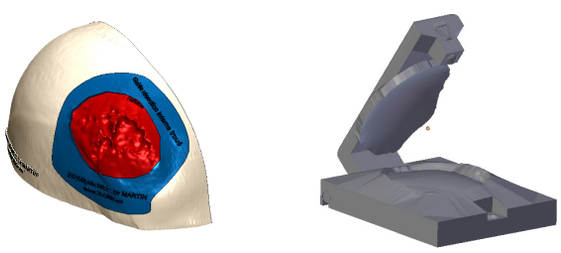
One-step tumor resection and cranial reconstruction of a lateral skull tumor

PLANNING & DESIGN

The patient presented a lateral skull tumor. The desired approach was to perform the resection and close the cranial defect in one surgery. Therefore, a planning was elaborated, including a guided resection with a patient-specific cranial implant reconstruction.
After receiving the scans via our Customize web platform, 3D-Side's engineers performed the segmentation of the images and the surgeon outlined the tumor on the platform through a dedicated tool. Based on the tumor shape provided by the surgeon, the engineers planned the resection and designed the surgical guide and the reconstruction implant, ensuring a perfect match.

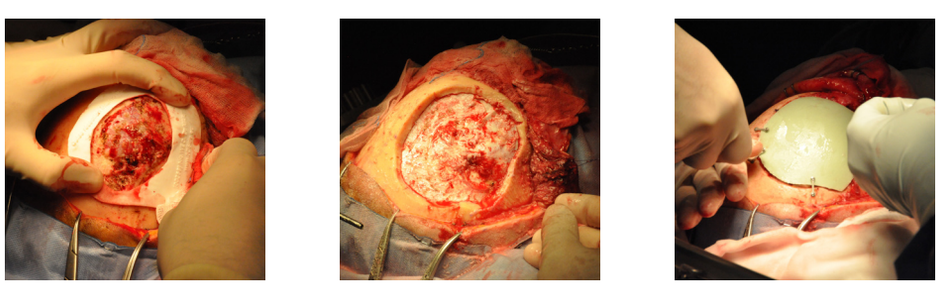


The use of the platform allowed a very short lead time thanks to an efficient surgeon-engineer collaboration. After the surgeon's validation of the design, 3D-Side's manufacturing team produced the surgical guide, implant mold and patient bone model in-house through 3D printing.



SURGERY

During the operation, the implant was made out of PMMA (bone cement) using the 3D-printed mold. The tumor was resected first, using the resection guide. Then, the implant was fitted into the skull defect, providing a perfect match.



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, 3D-Skull 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 3D-Skull?

3D-Side can deliver 3D-Skull one week after approval by the surgeon. 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. 3D-Skull 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 osseointegration ?

No. PMMA is a hard material with similar mechanical properties to cortical bone. You do not need to reinforce the implant with osseointegration (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 3D-Skull 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.

What kind of fixation can be used?

You can use your preferred osteosynthesis method, for example mini-plates, CranioFix®-type fixations or similar systems.

What do I do if the implant falls?

The only thing needed is to have sufficient bone cement (PMMA) 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): 134°C / 273°F.

What do I do if the implant does not fit?

The advantage of 3D-Skull in comparison to other implants 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 and reamed 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 with the physician for the delineation of the resection and provide patient-specific surgical guides. Moreover, since the implant can be adapted (reduced or enlarged), a perfect result can be obtained in any situation.

And compared to other technologies?

Compared to PEEK: our implant can be adapted (reduced or enlarged) ensuring a perfect fit.
Compared to TITANIUM: our implant will avoid metal artifacts and thermal conductivity.
Compared to CERAMIC: our implant is much stronger.
Compared to the three of them: our system has integrated gentamicin.

ABOUT 3D-SIDE

We are believers of 'together we are stronger'.

3D-Side is a Belgian company that has been developing and commercializing first class products for cranioplasty, bone tumor surgery and deformity correction for more than 10 years.
Based on this internal know-how, 3D-Side has developed an integrated platform: Customize. It connects surgeons, patients, and medical device companies to optimize and streamline preoperative planning, design and production of patient-specific medical devices.
Personalization is in our DNA. We believe a tailor-made solution for each patient and close collaboration with the surgical team are key to ensure a greater level of comfort and confidence in the OR, ultimately leading to a better clinical outcome and surgeon experience. Ensuring that life wins is at the heart of everything we do.

CONTACT US

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