Author
User
Status
Innovative
Category
Case report

Custom surgical implants using additive manufacturing

Drs. Drs. Jules Poukens[1,4], Ing. Paul Laeven[2], Ing. Maikel Beerens[2], Drs. David Koper[1], Dr. Dr. Bernd Lethaus[1], Prof. Dr. Dr. Peter Kessler[1], Prof. Dr. Jos Vander Sloten[3], Prof. Dr. Ivo Lambrichts[4]

Similar to the current developments in dentistry, CAD/CAM and Additive Manufacturing (AM) are getting increasing attention in the medical sector as well. One of the most important medical fields is cranio-maxillofacial surgery where defects of the face (e.g. absence of a nose, ear, or eye) have a severe psycho-social impact. Innovative software options and additive manufacturing methods enable the conversion of scans into a virtual three-dimensional model, virtual design of medical parts and subsequent production of these custom implants from a solid or resorbable material.

The introduction of AM and related technologies in medicine is a breakthrough in treatment modalities for very complex patient cases that have been untreatable before. And what is more, they are reducing operating time and patient discomfort. These new options might serve as a stepping stone to the possibility of 3D printing of organs in the future. In this article, the use of additive manufacturing in cranio-maxillofacial surgery is demonstrated by showing a case where a young patient underwent reconstruction of a large skull defect.

Background

Skull defects, as a result of trauma or tumour surgery, usually lead to esthetic and functional disturbances in the patient. Thanks to recent technological developments, skulls can be reconstructed utilizing computer-aided design and manufacturing processes. An implant that exactly fits the defect can be manufactured pre-operatively on the basis of data derived from a CT scan.

The implant can be produced either indirectly or directly. Indirect manufacturing implies that the implant will be fabricated using a rapid prototyping model of the skull as template, while in direct manufacturing, an implant will be produced by a computer-controlled machine without the need of a skull model. Different materials such as titanium, plastics and ceramics can be processed by different manufacturing technologies (high-speed milling, casting and additive manufacturing).

Factors affecting the complexity of the case

The difficulty of design and manufacturing of custom implants depends on the size of the defect, whether or not the defect crosses the midline of the skull and the involvement of the orbital rim. The anatomical location of the defect is, of course, also important since the bone thickness varies along the skull. The thickness of the bone has to be taken into account when designing the implant, especially the part that will be fixed to the skull bone.

Case example

The following case illustrates the planning and production procedure of a custom skull implant for a patient with a skull defect. In this case, additive manufacturing was used for the production of a custom skull implant for the first time in Europe.

The patient had undergone surgery for decompressing the brain after trauma. One of the bilateral bone flaps became necrotic, leaving a large skull defect at the right side (Fig. 1).

Design

A multispiral scan was made with 0.5 mm slice thickness and the scan data converted into STL data by using Mimics (Materialise, BE-Leuven). This software is able to generate an accurate 3D model from the CT data (Fig. 2).

[1] Department of Cranio-Maxillofacial Surgery, Maastricht University Medical Center, The Netherlands
[2] Department of Medical Engineering, IDEE, Maastricht University Medical Center, The Netherlands
[3] Department of Mechanical Engineering, BMGO, K.U. Leuven, Belgium
[4] Department of Basic Medical Sciences, Faculty of Medicine, University Hasselt, Belgium

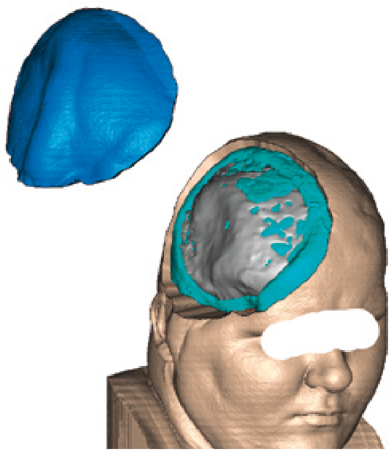

Fig. 1: The patient has a large skull defect.

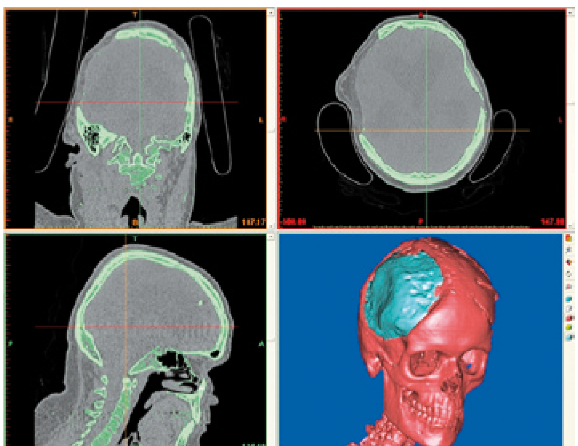

Fig. 2: A 3D model is generated from the CT data.

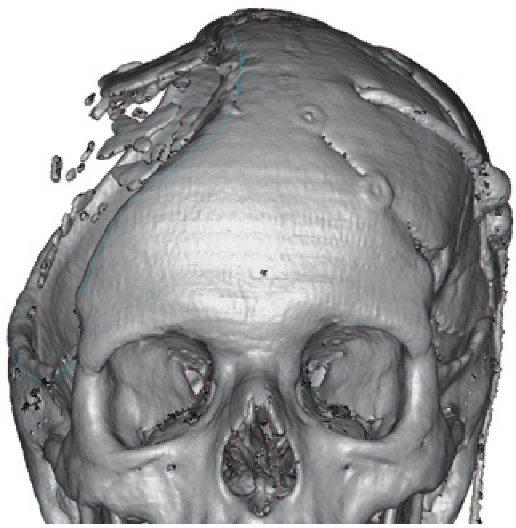

Fig. 3: The virtual model of the patient's head: meninges and loose bone parts are visible.

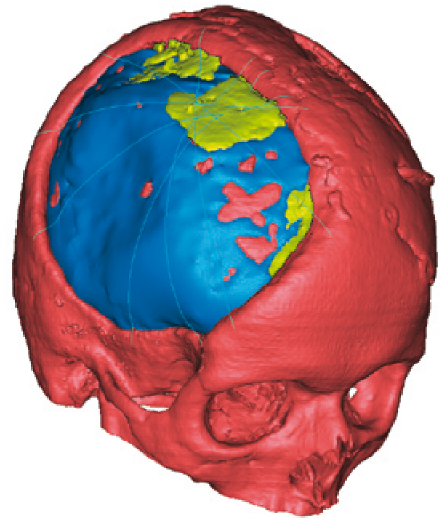

Fig. 4: Color-coded representation of the defect including bone parts and the meninges as well as guiding curves.

Then, the STL data were imported into 3-matic (Materialise). During design of the implant, different shapes were created and tested virtually. The implant had to fulfil different requirements: it had to close the defect successfully and – at the same time – reconstruct the contour of the patient's facial forehead without stretching the skin too much.

For the virtual design of the implant, loose bone parts on the meninges and the meninges itself were used as a reference (Fig. 3). First, guiding curves were designed based on these reference points (Figs. 4 and 5) to indicate the optimal curvature of the implant. For reconstruction of the shape, mirroring of the contralateral side was used as well. After having set the surface guidelines, they were utilized for surface design to make sure that the meninges was not touched (Fig. 6).

Another important clinical factor that had to be taken into account was the attachment of the chewing muscle. To maximize its attachment, a number of holes were designed to which the chewing muscle could be sutured during surgery (Fig. 7). Five fixation lips were added on the virtual model to allow fixation of the implant to the remaining skull. The entire design process took 16 hours.

Electron Beam Melting

The titanium implant was subsequently manufactured using Electron Beam Melting. With this type of additive manufacturing technology, metal parts are produced by melting metal powder in a layer-wise manner. The material is melted by an electron beam in

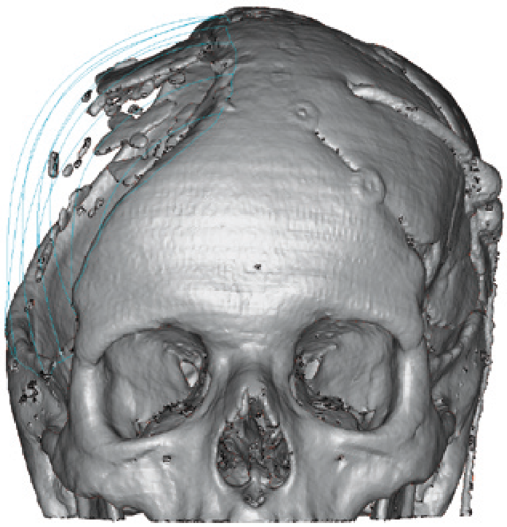

Fig. 5: Design of the guiding curves from frontal view.

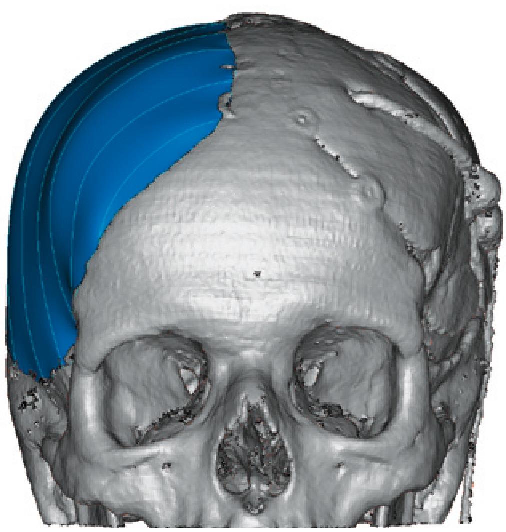

Fig. 6: Surface design

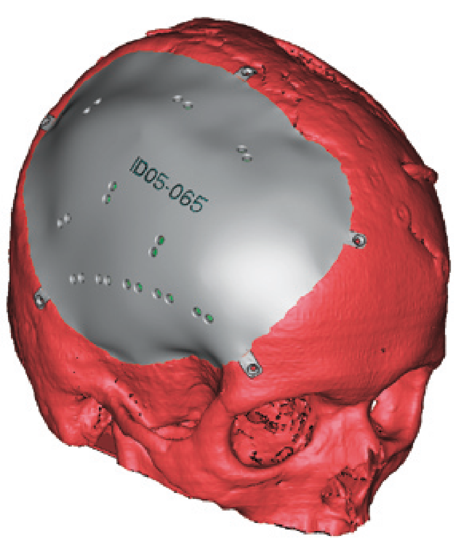

Fig. 7: A number of holes are designed to facilitate attachment e.g. of the chewing muscle.

a vacuum chamber, which ensures a high purity of the material. Due to the combination of a high power energy source with a clean production environment, high strength properties of the final piece are achieved.

In the present case, the implant was manufactured out of a medical Grade V titanium alloy in 12 hours by Fruth Innovative Technologien (D-Parsberg).

A rapid prototyping model of the skull was used as a validation tool to check the fit of the implant (Figs. 8 and 9). Afterwards, the implant was cleaned and sterilised.

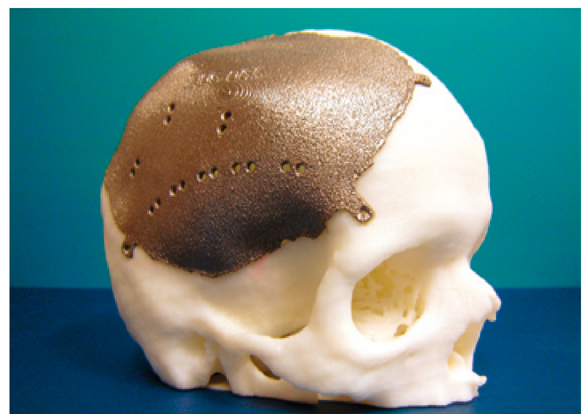

Fig. 8: The fit of the titanium implant ...

Fig. 9: ... is checked on the physical model.

Surgery

The operation was performed in general anesthesia. After preparation of the scalp flap (Fig. 10) and freeing of the skull defect from the periosteum and dura mater, the implant could be seated properly and showed a perfect fit (Fig. 11). The implant was fixed to the skull with five short titanium screws (length 3 mm and diameter 1.5 mm). The skin flap

Fig. 10: A scalp flap is prepared ...

Fig. 11: ... and the implant is placed.

was then repositioned and sutured. Two drains were left in to prevent haematoma.

Discussion

AM enables the production of custom implants made in a solid or resorbable material, or even in multiple materials. The introduction of AM and related technologies in medicine is a breakthrough in treatment modalities for very complex patient cases. Large skull defects demand for state-of-the-art technology and treatment. The progress due to these technological advances is regarded as a stepping stone opening up new options in the future. CUSTOM-IMD (www.custom-imd.eu) is a European funded project (sixth framework) and many research institutions, hospitals and companies are working together in order to develop and disseminate these new technologies. For now, implants manufactured in this way are very expensive and only a few expert centres are able or have the ability to produce them. Dissemination of knowledge and use of these custom implants will surely enable technicians to produce implants at lower cost for a larger group of patients in near future.

Auch online unter: www.ddn-online.net

Dr. Jules Poukens M.D, D.M.D.
Maastricht, The Netherlands

- 1986-1989 M.D, D.M.D at the Catholic University Leuven (B)
- 1998-1994 graduate studies in Oral and Maxillofacial Surgery, University Freiburg i. Br.
- since 1994 lecturer-researcher at the Department of Cranio-maxillofacial Surgery, University Maastricht, The Netherlands
- since 2009 lecturer-researcher at the Department of Basic Medical Sciences, University Hasselt, Belgium
- Coworker EU funded projects on medical rapid prototyping and manufacturing (PHIDIAS, CUSTOM-FIT and CUSTOM-IMD)

Contact: Jules.poukens@scarlet.be