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Custom-made cast titanium implants produced with CAD/CAM for the reconstruction of cranium defects

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E. Heissler, F.-S. Fischer, S. Bolouri, T. Lehmann, W. Mathar, A. Gebhardt, W. Lanksch, J. Bier: Custum-made cast titanium implants produced with CAD/CAM for the reconstruction of cranium defects. Int. J. Oral Maxillofac. Surg. 1998; 27: 334–338. © Munksgaard, 1998

Abstract. Titanium implants for the reconstruction of bony skull defects, using data from three-dimensional spiral computer tomography, have been described by other authors[4,5]. Instead of milling the implants from a titanium block, an advanced method of rapid prototyping for a fine casting process is presented. Casting *vs* milling offers several advantages. It is possible to form very thinly tapered structures and to obtain more complex geometrical structures with smaller diameters. Many geometrical forms, which cannot be milled for technical reasons, can be produced using this technique.

Key words: cranioplasty; alloplastic materials; titanium; biocompatibility; computer tomography; computer aided design (CAD); computer aided manufacturing (CAM); rapid prototyping.

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The continued search for new methods and materials to reconstruct the neurocranium and splanchnocranium testifies to the fact that, so far, no satisfactory solution has been found[2,8,12–14].

Progress made in spiral computer tomography (CT), as well as improvements in computer-aided design/computer-aided manufacturing (CAD/CAM) has opened up new perspectives for designing and producing implants[11].

Titanium is considered to be the most biocompatible alloplastic material[3]. However, its material properties render it difficult to work with and it must be produced for the application preoperatively. By means of spiral CT, exact data of the cranial bone structures may be collected. The data obtained suffices to construct three-dimensional images of the cranium, to enable virtual processing (CAD) and to either mill a model directly from titanium blocks – as described by other authors[4–6] – or to sinter a polycarbonate model for casting which can be completely burnt out, i.e. rapid prototyping[1]. Unlike the "lost wax" method by direct modelling on steriolithographic skull replicas, this method allows an exact cast-shrinkage compensation.

Using CAD/CAM makes it possible to mirror intricate anatomical structures from the healthy side to the defect: for example, to produce a zygomatic bone implant, following a one-sided trauma, by using the mirror data from the healthy side.

Material and methods

Technique

Transversal 2-mm spiral CT (Somatom® plus, Siemens, Erlangen, Germany) with 3D reconstruction of the cranium were made.

For the production of the titanium implant, software was used which was originally designed for industrial application in the car industry. Therefore, the data formats of the CT had to be converted to the VDAFS (Association of German Car Manufacturers Surface Converter) data standard that can be read by virtually all CAD/CAM programs. The data was then filtered, thinned out and modelled by the usual methods of surface restitution of the bordering surfaces. The result was fed into the CAD system (STRIM® 100, Matra Datavision Inc., Andova, MA, USA), which runs on a UNIX platform. The data of the border of the cranial defect represent the framework from which the implant can be constructed. The virtual implant was designed on the CAD system. It is of primary concern that the edges be modelled to attain maximum bone contact to promote integration. The implant also has to have a perfect fit so that it will "snap" into the bone defect, eliminating the need for further retaining devices.

The virtual implant can be described in the data format of the stereolithography ma-

Table 1. Details of patients

Patient no.	Sex	Age (years)	Complications	Follow up (in months)
1	m	26		24
2	m	27	Infection	(6) 23
3	f	28		22
4	m	21		22
5	m	30	Convulsion upon removal of drain	21
6	f	31		20
7	m	33		19
8	m	25		18
9	m	29		17
10	m	23		16
11	f	34		15
12	m	25	15 ml exudate	11
13	m	35		8
14	m	22		7
15	m	30		6

chine (STL-format). It is then produced on the stereolithography machine (rapid prototyping) as a polycarbonate model using selective laser sintering. The rapid prototyping process takes advantage of the ability to produce models in various scales. The shrinkage which can be expected in the micro precision casting, has already been compensated for in the model.

To achieve good surfaces, the polycarbonate model is waxed and cast guides are applied. It is embedded in a ceramic pan, poured under vacuum spin-cast conditions and finally sandblasted. Fig. 3 shows the titanium implants before insertion into the patient.

Patients

Fifteen patients from 21 to 35 years of age (12 men and 3 women) underwent a titanium cranioplasty to cover their skull defects. All of them had suffered a trauma, and nine of them had had primary treatment with an acrylic implant which had been removed because of infection. In five patients an expander was first inserted to increase soft tissue volume. The defect size was from 4×5 cm up to 6×10 cm. Details of the patients are presented in Table 1. The defect geometry ranged from simple (Fig. 2b, c) up to complex (Fig. 2a), including the orbital rim and the malar region. The finished sandblasted implants weighed from 48 g to 78 g and had a thickness of 1.2–3.2 mm. Between 30 and 50 perforations with a diameter of 2.5 mm were made to facilitate wound drainage, reduce weight and reduce the risks in case of intracranial pressure-increase.

All implants were inserted via a high occipital mono- or biparietal incision, using the old scars as access where possible. After exposure of the defect, minor corrections to the bone contours were often necessary. The implants were brought in place using some pressure and fixed wíth titanium miniscrews. Fig. 4 shows the intraoperative situation after insertion of the implants. A vacuum drain was inserted in all patients.

Perioperatively, antimicrobial prophylaxis was administered using 2 g cefotiam twice daily for about seven days.

Results

In 12 patients the postoperative period was uneventful. The operation lasted from 55 to 135 minutes. Postoperatively a control CT-scan showed a good fit of the implants on all edges. In one patient early infection occurred necessitating removal of the implant. It was probably caused by leakage from an imperfect fit of the implant at one edge. In one case the patient had a convulsion during removal of the vacuum drain. An EEG showed complete visual response with minor frontal disorders. No special therapy was given and the patient did not have further convulsions during the 21 months following surgery.

In one patient an exudate of approximately 15 ml was aspirated subcutaneously and sent for microbiologic examination. The result was negative and no further swelling occurred. In a follow-up period from 6 to 24 months (mean 16.6 months) no further infections or other problems appeared. Fig. 5 represents the postoperative situation after wound healing.

Discussion

Skull defects have to be covered to protect the brain from trauma and for cosmetic reasons. Several methods are available to achieve stable and esthetically pleasing results. Bone grafts from adjacent skull bone can be used to cover the defect[9,10,15]. The disadvantage of this method is that it significantly increases the trauma caused by the surgery and the operating time. Resorption of the transplanted bone might also occur.

Alloplastic materials can be produced before the operation is begun[16].

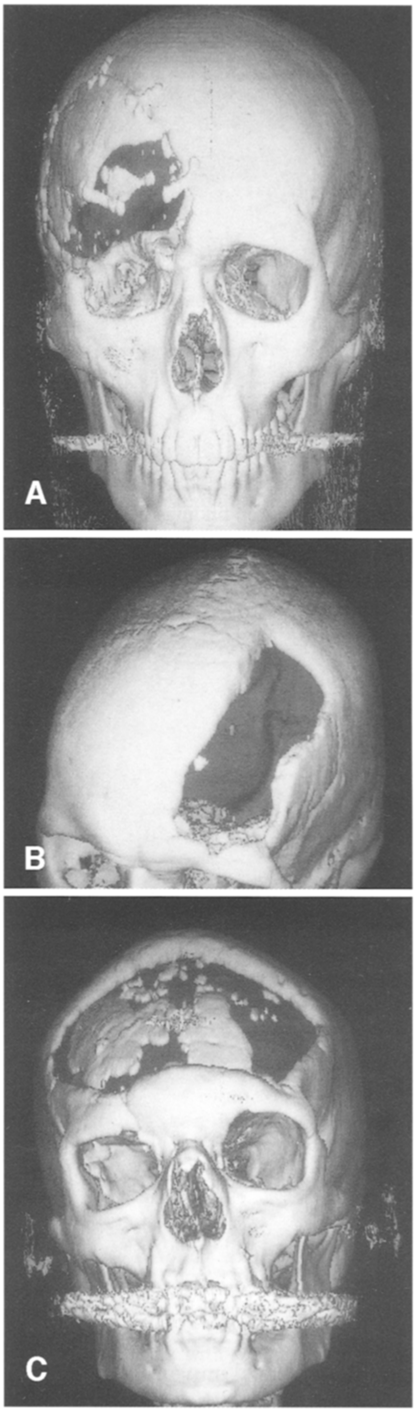

Fig. 2. A–C) Initial 3D-CT of patients A–C.

Fig. 1. A–D) Initial findings of patients A–D with bony skull defects.

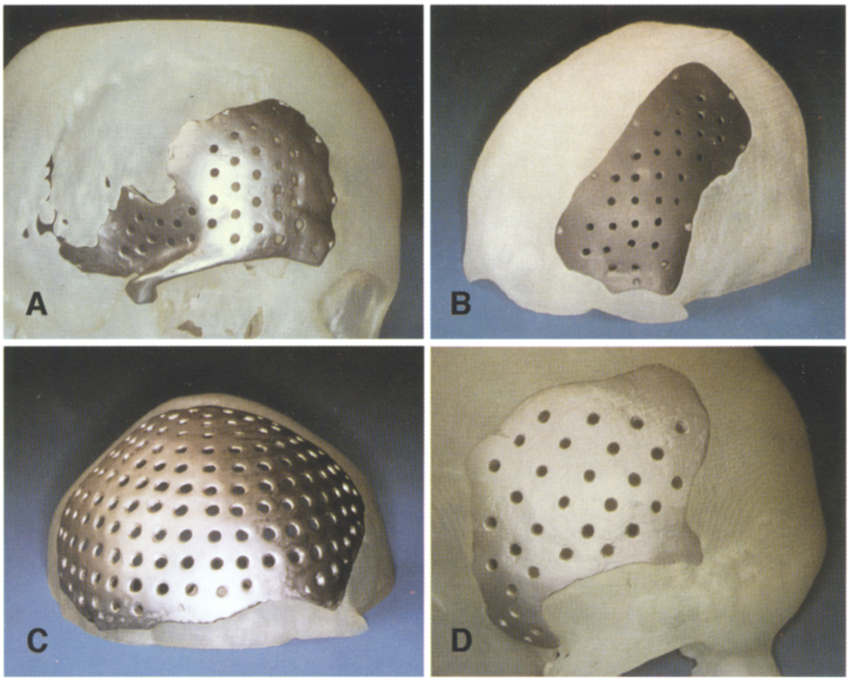

Fig. 3. A–D) Stereolithography of patients A–D with custom-made cast titanium implant.

The prefabricated implant helps to keep the operation time short. Even large defects, for which it might be difficult to harvest enough autologous bone, can be covered.

We prefer titanium over other alloplastic material for its good biocompatibility and for its strength[3]. Nine of the patients had prior reconstruction with methylmetacrylate, which had to be removed because of complications.

Initially the titanium implants were produced from wax, which was modelled in the defect of a stereolithographic replica of the patient. This also seems to be a very easy solution avoiding almost all the computer-based data processing. It has the disadvantage that it cannot account for the shrinkage during the casting of the metal. The CAD/CAM-based implant production allows the implant to be scaled. The expected shrinkage of the titanium can already be compensated for during the design of the implant.

The computer-based data processing makes it possible to mirror structures from the contralateral healthy side to fit the defect. This facilitates the design process, especially in patients who need reconstruction of complex anatomical structures like the zygoma.

Some authors prefer to mill the titanium implants[4–6] from a titanium block. Casting versus milling the titanium implant offers the advantage of being able to form very thinly tapered shapes. This may become even more important when constructing zygomatic bones or producing titanium spaceholders to promote guided tissue regeneration of skull defects[7].

Complex geometrical structures with small diameters can be produced with significantly more precision. The rim of the implant can be designed in such a way that it extends over the edge of the bone. This leads to good stability at the bone–implant interface. When milling from a block, large quantities of titanium might have to be removed, with heavy wear on tools and considerable time loss. Handling of extremely complex, thin-walled structures requires much time and effort when milling, which is not the case in the rapid prototyping procedure combined with a fine casting process. Many geometrical forms which cannot be milled for technical reasons, can often be produced using rapid prototyping.

Custom-made cast titanium implants for cranial defects offer several advantages for the patient and the surgeon. The results are predictable and esthetically very pleasing. Operating time and the trauma caused by the operation are considerably less compared with techniques using autologous bone.

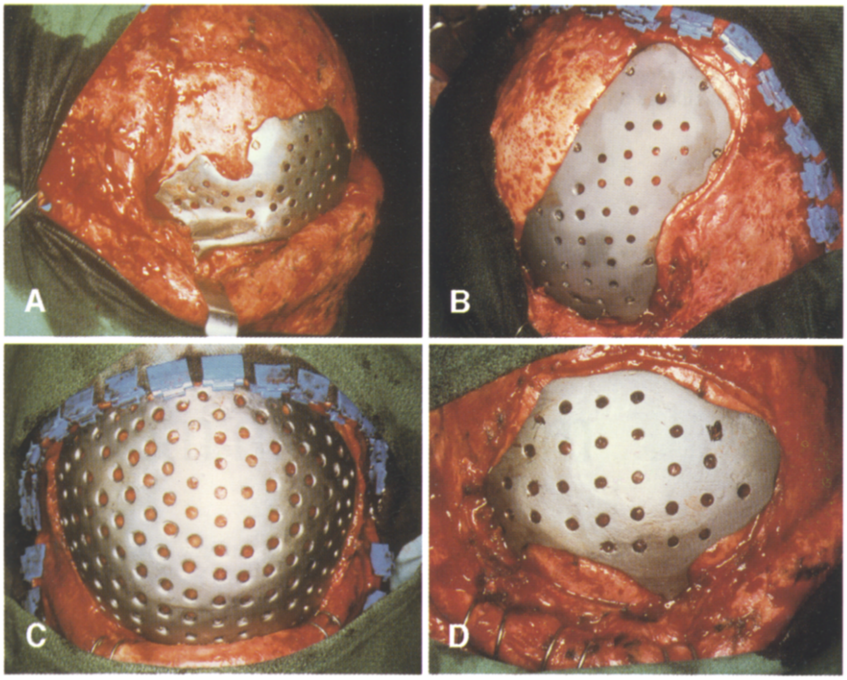

Fig. 4. A–D) Operation site with implants *in situ*, fixed with titanium osteosynthesis-miniscrews (patients A–D).

Fig. 5. A–D) Patients 2–4 weeks postoperatively.

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