



3D patient specific implants for cranioplasty. A multicentre study

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ABSTRACT

This article presents a multi-centre study cohort study on 50 patients with cranial defects of multiple etiologies (trauma, decompression, tumour surgery, etc.) operated in 10 hospitals. In all patients the neurosurgeon repaired the cranial defect using 3D printed and CNC milling and drilling grafts or Patient Specific Implants, from two world known manufacturers, custom made in accordance with the data obtained from the patient's 3D CT reconstruction.

INTRODUCTION

Cranioplasty is defined as the surgical intervention performed to repair cranial defects following trauma, surgical decompression, tumour surgery, congenital anomalies or growing skull fractures. The implications of cranioplasty are psychological, aesthetic and functional. The history of cranioplasty dates back to 7000 BC. with archeologic evidence (1, 2) supporting the use of both inorganic and organic materials. Although many methods have been described there is little consensus regarding the optimal solution for such cases.

MATERIALS AND METHODS

We started a multicentre cohort study on patients with cranial defects of multiple etiologies (trauma, decompression, tumour surgery, etc.) operated in 10 hospitals having enrolled in study a total of 50 patient from which 16 were female 34 were male, 22 from urban , 28 from rural area of Romania, age between 5-68 years old. Regarding etiologies: 31 were trauma, 16 were decompression and 3 were tumour. In all patients during the surgery were repaired the cranial defects using Patient Specific Implants made by 3D printing and Cad Cam manufacturing (Cnc milling and drilling) methods using specific data obtained from the patient's 3D CT reconstruction using a very clear scanning protocol.

Keywords

3d printing,
 Cnc milling and drilling,
 cranioplasty, Peek, titanium,
 Bioverit, trauma, tumour,
 decompression,
 neurosurgery, reconstruction,
 patient specific implant



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CT – scan protocol

Algorithm	optimised for bone
Contrast material	no
Matrix	at least 512 x 512 Pixel
Gantry Tilt	no
Change of thickness	no
Change of spacing	no
Patient Position	back position preferred
Patient Orientation	head first
Thickness Orientation	axial preferred
Slice thickness (Z)	1 mm (reconstructed)
Pixel resolution (X,Y)	0.5 – 0.7 mm
Field of View	quadratic
Table feed (Spiral CT)	<3 mm per Rotation

FIGURE 1. CT scan protocol used to create specific data to be converted in a 3D dynamic precise model.

Centres and Hospitals involved in this study were as follows: 1. Sanador Clinic Hospital, 2. Emergency Hospital “Bagdasar - Arseni”, 3. Emergency Clinical Hospital “Floreasca”, 4. University Emergency Clinical Hospital, 5. “M.S. Curie” Clinical Emergency Hospital for Children, 6. “Grigore Alexandrescu” Emergency Hospital for Children ,7. Medlife Metropolitan Hospital, 8. Elias Emergency University Hospital, 9. “Sf.Pantelimon” Emergency Hospital, Bucharest, Romania and “Prof. Dr. Nicolae Oblu” Emergency Clinic Hospital, Iasi, Romania.

The follow up varies from 1 to 9 years. Materials used for implants: Peek, Titanium Alloy and Bioverit (ceramic glass). Distribution of implant materials from our study was: 45 cases with Peek, 4 cases with Titanium Alloy, 1 case with Bioverit.

Procedure: In almost all cases, the procedure is the same. DICOM data files are collected and archived into a zip file and sent encrypted, through a secure transfer platform, with a dynamic password, that has to be communicated each time, to recipients and that is internet safe and keeps all info strictly confidential.

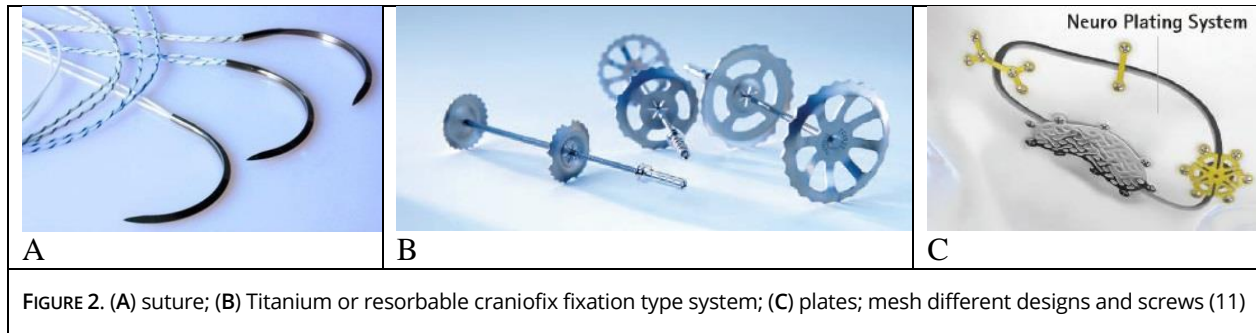
Files are extracted, verified if scanning protocol was respected and if they are qualified to be transformed in “.stl” extension files or other software extension used to see bone defect, compare it with standard anatomic models, with contra-lateral side of the same patient and create a 3D dynamic model of cranium with all defects and of patient specific implant that has to fit perfectly into that defect. The

3D model (pdf file with 3D media option activated) is sent and presented by manufacturer directly to the surgeon with several comments regarding: surrounding soft tissue, sizes, distances, thickness and a lot of other parameters, including material together with an approval letter that has to be stamped and signed by the surgeon. The surgeon will reply (in written) to the manufacturer with its comments regarding all of the above and in some steps will conclude if he agrees or not, on the proposed 3D model. If the response is affirmative and all legal and financial issues are agreed upon by all parts, the manufacturer will start to produce the implant, respecting all safety and regulations of EU, regarding Patient Specific Implants. That will be delivered in the country of the surgeon, directly to its hospital OR during a period of 5-15 days. In some emergency cases, the implant can be delivered within 48 hours, with a set of legal documents and a passport for the implant; the passport contains all of the important info that patient has to have, after surgery. If the Implant came unsterile and very well packaged, it will be sterilized to 134 °, 1-2 cycles 20 minutes, 24-48 hours prior the day of surgery.

Depending on the size of bone defect, anatomical area, position on cranium and risk of infection (frontal, sinus, zygomatic area) the surgeon will decide upon the best material for the implant (Titanium alloy, Peek or ceramic glass) and what fixation systems are best for the implant. The most common and used materials are: non-resorbable

suture 2.0, Titanium, Peek or bio-resorbable craniofix type implants that use a special tool for anchoring and fixation, Titanium 2-4-6 holes plate 1.3/1.6/2.0 mm and 1.3/1.6/2.0 mm, different

designs (straight, double-Y plate, adjustable mesh or pre-contoured) screws locking or non-locking 3-5 mm length.



CASE REPORT

Female, 23 years old. Event that caused trauma: Car accident 28.11.2018;

At the time of the arrival at the Clinical Emergency Hospital, the patient had intracranial pressure with a peak of 80 mmHg (standard values: 20 mmHg) Glasgow score 3 (GCS) state of coma;

Procedure: The surgeon opted for cranial resection with dural plasty (optional: can be done with artificial dura);

Observation: Cerebral edema post-trauma

malign, with progressive values 32-46-62-80 mmHg in spite of conservative treatment;

Secondary, a large craniectomy FTPO (fontal-temporal-parietal-occipital) and dural plasty with temporal muscle and periosteum is performed. The craniectomy was performed in the 3rd day after the car accident;

The cranioplasty surgery was performed in 14.01.2019 (47 days after car accident and 44 days after craniectomy), that means a short term cranioplasty.

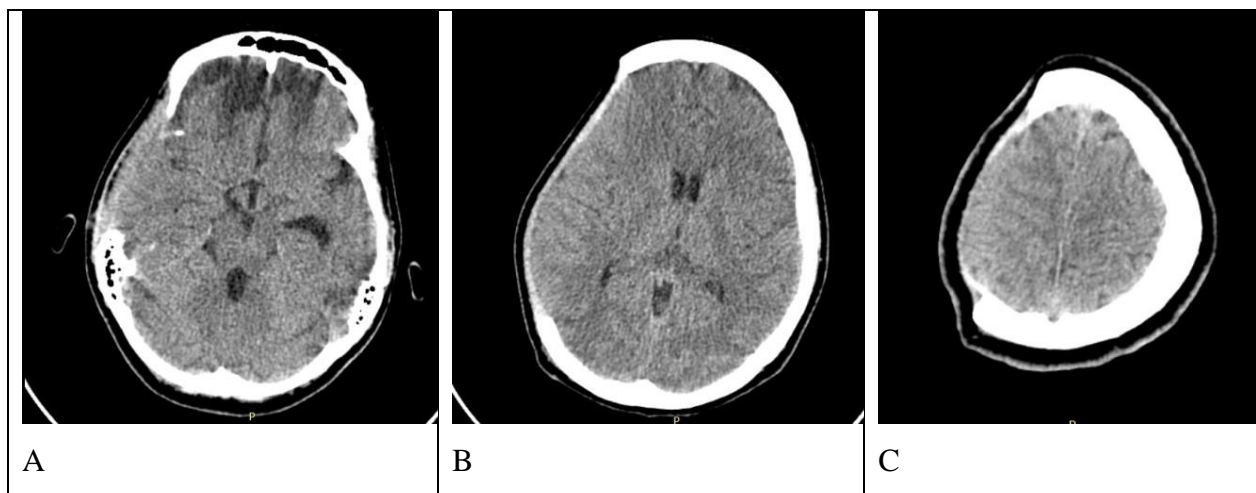


FIGURE 3. (A, B, C): CT scan images done respecting above scanning protocol.

CT DICOM files are sent, analysed by the manufacturer and result is a 3D model that is sent directly to the surgeon for discussion and legal approval. There are cases when CT DICOM files are rejected, because they are not done as required by the protocol and they are not accurate enough and cannot be used for 3D model and also for implant construction.

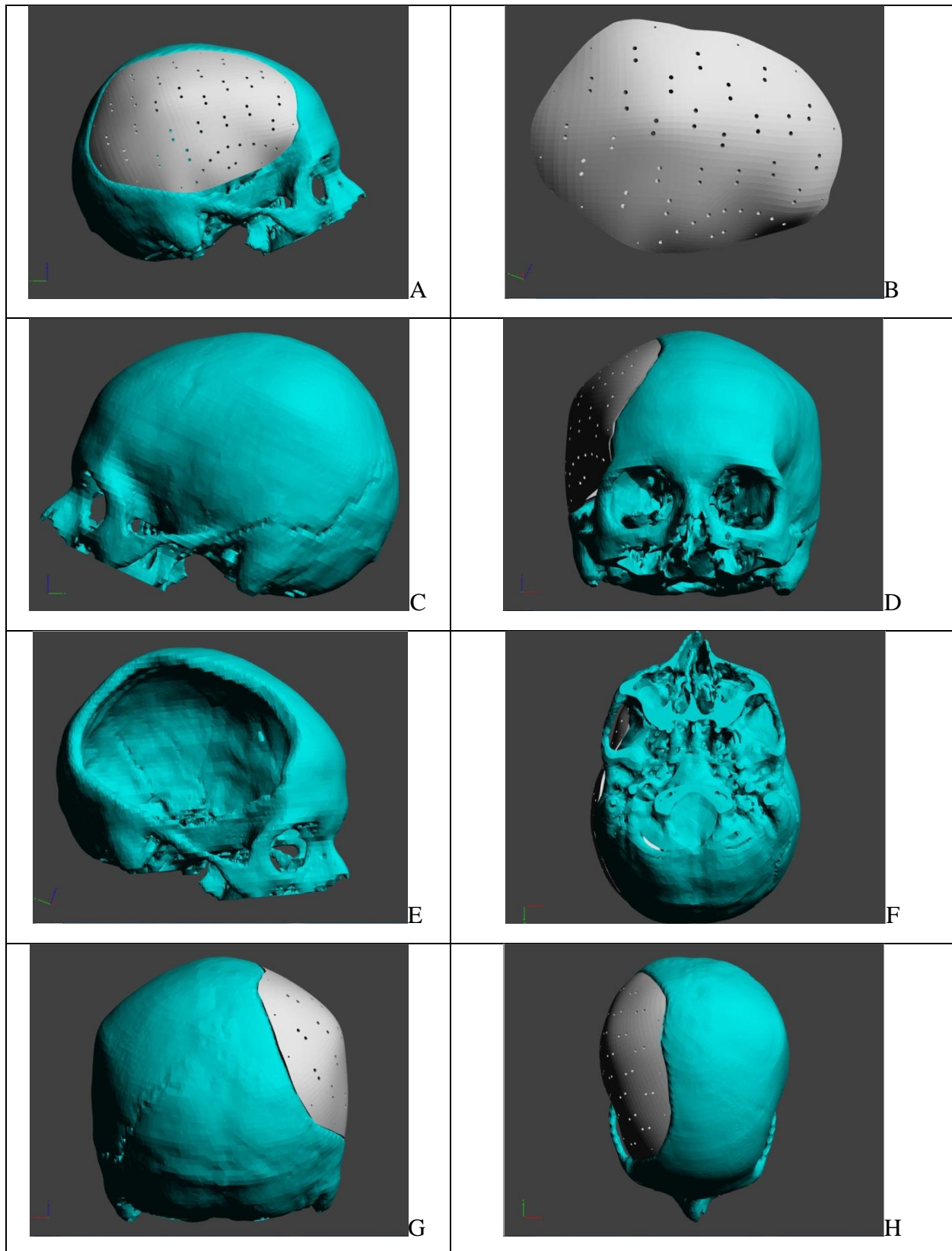
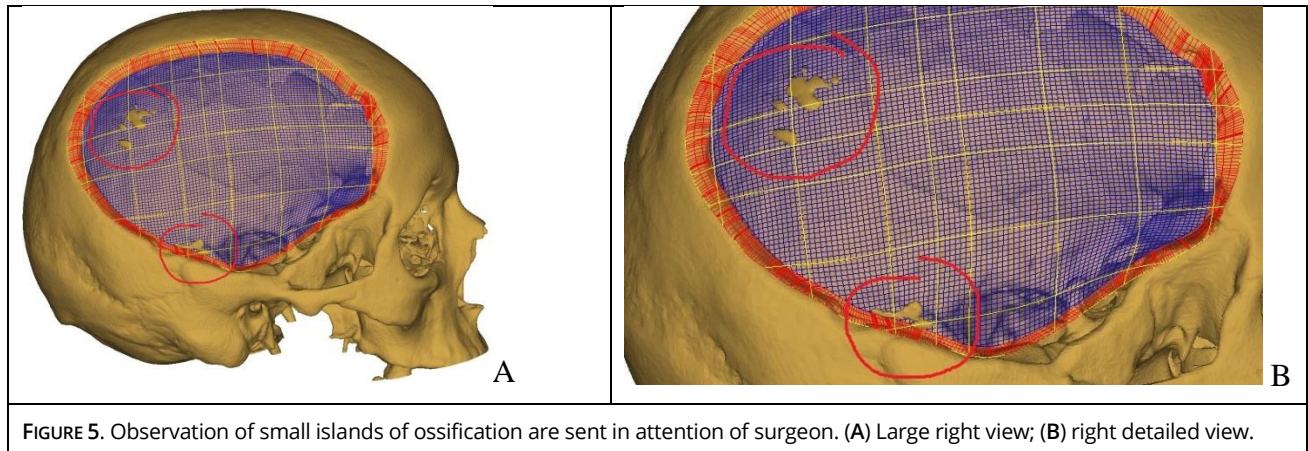
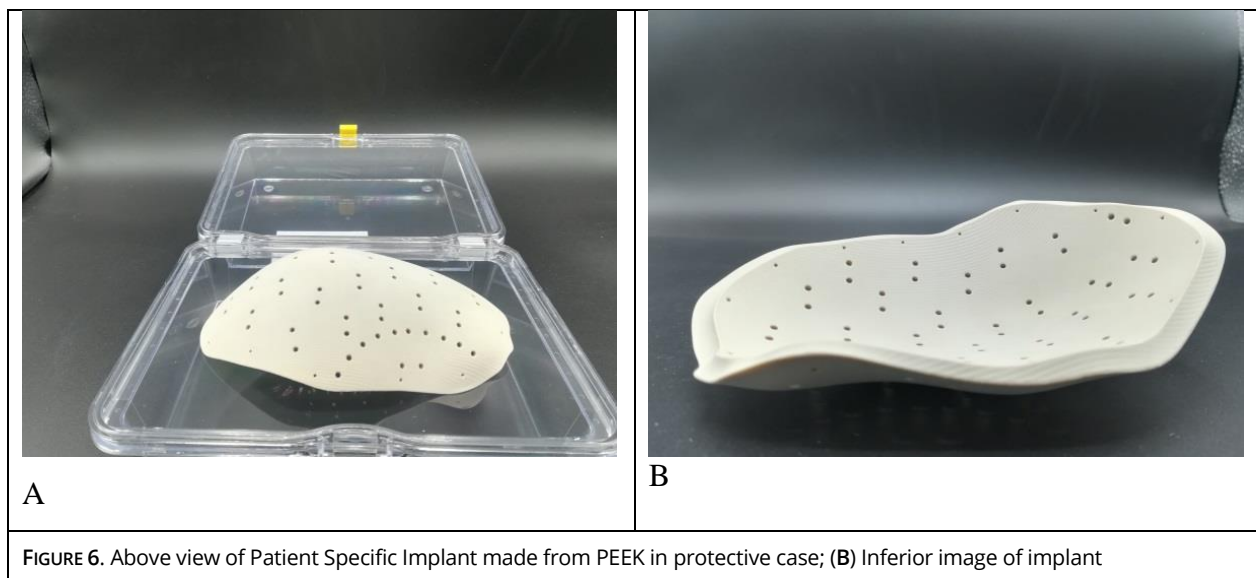


FIGURE 4. Presentation for surgeon of a 3D model proposed by manufacturer using Adobe Acrobat 3D pdf. file where model can be visualized dynamic, 3d in motion. Are presented screenshots as follows: (A) right view with implant; (B) proposed model of implant; (C) left view; (D) frontal view with implant into defect; (E) right view without implant; (F) below view; (G) rear view with implant; (H) above view with implant in place.

A team of specialists in cranial reconstruction communicate to the surgeon (in writing): any possible complications, details regarding sizes of implants, remaining bone, distances and surrounding soft tissues, options for manufacturing materials, fixation systems (Titanium Alloy, Peek, Bioverit – ceramic glass) (9,10) to help him take the most efficient decision. (Figure 4)



The surgeon requested that the implant had to be made from Peek –Optima®(polyether-ether –ketone) as being optimal (weight, strength, hardness) in case he needs to make small adjustments intra-op; he also requested suture holes, each 1 cm on implant margin, assuming that the fixation systems could be suture and craniofix type systems. (Figure 3, 4)



The method of implant manufacturing: Cad Cam manufacturing (Cnc milling and drilling) from an initial rectangular block of Peek. The final volume of implant was 548 cm³.

In the case presented above, for fixation of the implant, non-resorbable sutures were used and small drills of 1-2 mm on perimeter of cranial defect

at equal distances were performed, in order to allow the insertion of titanium craniofix type fixation system (with a 20mm diameter). The patient received its own passport of implant (with all the important details in it: data of production and surgery, surgeon details, sizes in mm ad weight & material of implant). (Figure 6)

RESULTS AND DISCUSSION

In the presented case, the cranioplasty surgery was performed with a Patient Specific Implant from Peek, respecting all sizes and anatomy of the patient; the implant fitted perfect into the defect and the surgery was shorter (with about 1-2 hours) because the cranioplasty solution was already created beforehand for that specific patient and implemented in only 1 step; there were no complications after the surgery and a visible aesthetic result for a female patient.

Regarding the general study: There were a total of 50 patients treated with Patient Specific Implant that proved significant aesthetic, functional and psychological improvements after the cranioplasty surgery. Minor complications occurred in several cases, that were related to cranioplasty fixation systems and scalp complications (related to initial trauma), and two cases of wound infection (one related to the type of suture used and the other wound contamination without suture defect). There were no fatalities and no long-term complications.

CONCLUSION

- Custom 3D implants for cranial reconstruction are a safe and viable solution that has been available for some time;
- Superior aesthetics and good functional outcomes can be achieved with a 3D patient specific implant (where other common methods fail: cement, PMMA broken implants, etc.);
- A Patient Specific Implant is made 1 time for 1 single Patient and involves multiple parties, each with their own responsibilities: the patient and his family, the surgeon, the hospital, the manufacturer, the project manager;
- Our study proves the fact that this method can be safely implemented even in surgical centres with no prior experience, using 3D custom made implants;
- Nevertheless, the financial aspect of using such an implant is the main factor that negatively influences the addressability of such a technique to the general public. At this time Patient Specific Implants in Romania are paid by patients and are expensive, but very reliable and effective at the same time;

- We can appreciate that the number of cranioplasty cases done with PSI (Patient Specific Implants) would be 10 times more in Romania, if a National Program for Neurosurgery would cover the costs of such implants;
- This method would also increase the economy of the Ministry of Health's budgets, due to a reduced period of post-op recovery and minimal rate of re-interventions and complications.

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