Custom made cranioplasty prostheses: our experiences in skull reconstructions

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Abstract: *The treatment of cranial bone defects is a growing problem in current neurosurgical practice. The main lesions leading to cranioplasty are: decompressive craniectomies, tumoural pathology, multi-fragmentary fractures of the skull, infection, bone re-absorption and rejection of the graft. Nowadays there is an increased use of decompressive craniectomies not only in treatment of posttraumatic cerebral oedema but also for relieving raised intracranial pressure in catastrophic cerebrovascular incidents. This has led to a considerable number of patients surviving those events and having a surgical bone defect to be corrected. The patient's own bone flap is not an ideal solution due to problems of conservations, bone deformations after freezing, infection and/or re-absorption of the implant. The available materials include polymethylmethacrylate (PMMA), titanium, ceramics and other resin and alloy types. The ideal material for cranioplasty must be: viable, inert malleable, available radiolucent, sterilizable, stable biocompatible and inexpensive. Unfortunately no artificial material fulfils all stated requirements. The aim of our work is to demonstrate our experiences and evolution of surgical techniques from free hand modelling of the implant to custom made devices from processing of CT images and using rapid prototyping and rapid manufacturing techniques.*

Key words: *cranial defect, polymethylmethacrylate, titanium, rapid prototyping, rapid manufacturing*

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1. INTRODUCTION

The management of patients after injuries or diseases resulting in deformational consequences usually requires the implantation of either autologous tissues or biocompatible/biodegradable implants that replace missing parts of the tissue, usually bone (Drstvenšek et al., 2007). The treatment of cranial bone defects is a growing problem in current neurosurgical practice. There are various origins of cranial defects including trauma, tumours, congenital deformities or postoperative defects due to the surgical procedure itself (Spetzger et al., 2010).

Cranioplasty is simply defined as a reconstruction of a cranial defect. It is one of the oldest known neurosurgical procedures, dating from the year 3000 B.C., when the Paracas Indians in Peru performed procedures to correct large cranial defects. The use of coconut shells by South Sea islanders guarantees that man has probably been performing cranioplasties for a long period of time. Petronius in 1565 used a gold plate to repair cleft palates. This was the first use of an alloplastic material to repair a defect. J. van Meekren is credited with the first bone graft in history when in 1670 he used canine bone to repair a skull defect in a Russian. Merrem in 1810 transplanted bone in dogs. In 1821 P. von Walther performed the first human autogenous bone graft. In 1873 Macewen reimplanted calvarias bone fragments after treating them with dichloride of mercury(http://www.aaos.org/news/aaosnow/jan08/reimbursement2.asp, http://onlinelibrary.wiley.com/doi/10.1002/bjs.18003915820/abstract, http://dx.doi.org/10.1016/S0266-4356(98)90459-4).

Nowadays the cranioplasty is a commonly performed procedure. The main lesions leading to it are: decompressive craniectomies, tumour pathology which infiltrating the skull, multi-fragmentary fractures of the skull, infection, bone re-absorption and rejection of the graft (Staffa et al., 2007). In modern neurosurgery there is an increased use of decompressive craniectomies not only in treatment of posttraumatic cerebral oedema but also for relieving raised intracranial pressure in catastrophic cerebrovascular incidents. This has led to a considerable number of patients surviving those events and having a surgical bone defect to be corrected. Autologous tissues are always the first choice of surgeons, if they are available. But often, the patient's own bone flap is not an ideal solution due to problems of conservations, bone deformations after freezing, infection and/or re-absorption of the implant. Then an artificial implant has to be made to fulfil physical, aesthetical and functional demands. The ideal material for cranioplasty prostheses construction must be viable and thereby capable of growth and resistant to infection, inert, malleable and easily contoured, available, radiolucent, sterilizable, stable (durable, non-biodegradable), nonconductive, nonionizing, noncorrosive, biocompatible, esthetically pleasing and inexpensive. The available materials include polymethylmethacrylate (PMMA), titanium, ceramics and other resin and alloy types (Boyne, 2001; Cenzi & Guarda-Nardini, 1995). Unfortunately no artificial material fulfils all stated requirements.

The overall goal of skull reconstruction is an appropriate closure as well as the perfect cosmetic result. There are different methods of cranioplasty for reconstruction of the bony skull. The procedure should be safe, fast, easy to handle and also low cost (Spetzger et al., 2010). Suitable skull implant cannot be prefabricated by means of serial production. In such cases custom-made implants using rapid prototyping (RP) technology are a perfect solution. Reverse engineering is a technology which creates a computer-aided design (CAD) model of a real structure. The RP is a technology which produces physical objects from virtual CAD models (Drstvenšek et al., 2007; Drstvenšek et al., 2008; Chrzan et

al., 2012). The aim of our work is to demonstrate our experiences and evolution of surgical techniques from free hand modelling of the implant to custom made devices from processing of CT images and using rapid prototyping and rapid manufacturing techniques.

2. PATIENTS AND METHODS

Before the era of cranioplasty prosthesis manufacturing based on reverse engineering technology prosthesis were manually adjusted to each patient by a neurosurgeon during surgery. In this presentation two illustrative cases of free hand modelling are shown.

Nine custom-made cranial implants were produced using data obtained from computed tomographic scanning of the defect using computer-aided design and rapid prototyping techniques. Each patient in this study, affected with a skull defect, was the subject of an individual project to produce a custom-made device. Between March 2007 and July 2012, nine cranial prostheses were manufactured. These implants were used for 8 men and 1 woman who were previously treated with craniectomy. The mean age of treated patients was 35 years (range 23 – 66). The mean time between craniectomy and the cranioplasty was 12 months (range 8 - 22).

2.1 Reconstruction by use of CT images.

The production of such implants starts by capturing a three-dimensional data set of the skull by transforming sets of CT or MRI two-dimensional pictures into a three-dimensional, digital model, using one of the available conversion software, such as Mimics (Materialise), RapidForm (Inus Tecnology), 3D doctor (Able Software), Amira (Marcury Computer), or another. CAD modelling of the implant was performed using several reverse engineering software packages. The basic idea is to mirror the entire skull and then perform the Boolean operation of subtracting the original skull from the mirrored one. The result should be a three-dimensional model of the implant. Due to the skull not being entirely symmetrical, the subtracted part does not always fit into the original skull perfectly. Therefore some additional fine tuning should be made to the implant model using 3D animation software.

Production of real models. Reconstructed model is then used as the basis on which modelling of missing area takes place. The finished digital model is manufactured using one of the RP or rapid manufacturing (RM) technologies. RM products are usually made of titanium that can be directly used as implants. PR products are used as patterns for further processing using one of the rapid tooling (RT) techniques. From among RM techniques, silicone rubber moulding (SRM) is the first choice for making implants out of biocompatible polymethylmethacrylate (PMMA) better known as bone cement among surgeons, or plexiglass among engineers. The implants were manufactured using selective laser sintering (SLS) and the PolyJet^{TM} procedure. SLS was chosen to produce a skull, since this technology produces rigid and resistable polyamide parts because the material is relatively cheap, and consumption is much lower compared to the FullCure series of materials used in PolyJet procedures. However, we observed that in a case of smaller parts such as the implant for cranioplastic surgery SLS models were too rough especially if the model was intended to be used as a prime part for silicone rubber mould production. Because of its better performance in terms of surface and dimensional quality a PolyJet procedure was used to produce the implants' models. Real models of the skull and the implant were then used for

testing dimensional accuracy and as a communication tool between the engineer and the medical doctor during the phase of operation planning.

2.2. Production of biocompatible implant.

A modified SRM procedure was used for the production of biocompatible implant. A SRM mould was made using normal frame to hold the silicone and the pattern. Unfortunately, it is impossible to use an exact required amount of the material since the bone cement comes in preset quantities for both sterile components and require use of the whole amounts of both components to avoid lagging of residual monomers, as a consequence of insufficient mixing ratio. The excess amount of material forms certain extra features in the parting plane of the mould that have to be manually removed after moulding. This requires some cutting and grinding of the implant to achieve the initial shape, and satisfactory fitting of the implant.

2.3. Titanium implant.

Polyworks is used for modelling of missing part by mirroring the original model of the skull over a nose plane and subtracting the original model from the mirrored one. If the implant is made out of Ti6Al4V than higher density of material requires thinner walls to obtain approximately the same weight of the implant as of the missing bone material.

Polyworks enabled shaping of missing part using guiding curves, called polylines. Polylines start and end tangentially to the skull's geometry in the connection point. Several polylines were used to create a surface that connected them thus forming an outer surface of the future implant. The surface was copied to get a necessary thickness and edges further on adapted to fit into the opening in the skull. To enable an effective communication between the two (or more) involved in the process a prototype of both, skull and implant is needed. The prototypes were made on two types of RP machines: (i) skull was produced on EOSINT P380, selective laser sintering (SLS) machine, out of polyamide. The procedure was used due to its low production cost in case of large parts; (ii) the implant was made using EDEN 330, PolyJet printer because of its high accuracy and good surface finish.

Fixing points need to be defined and produced beforehand since drilling of Ti-alloy is impossible with tools available in an operating theatre. Defining places for fixtures is a point, which requires a close cooperation between a surgeon and an engineer – producer of implant. After defining the fixtures' positions the model of implant was remodelled and fixtures added. STL files were sent to be produced on EOSINT M270, selective laser melting (SLM) machine, out of Ti6Al4V alloy.

2.4. Implantation.

Before the operation the implants underwent gas sterilization. During the surgical procedure surgeon has to dissect carefully subcutaneous scar tissue and avoid injuring dura mater to prevent cerebrospinal fluid fistula after the procedure this would lead to wound healing problems. The implant was inserted into the skull and surgeon must ensure adherence between the bone edge and the implant. This usually requires some additional drilling of the implant. Then implant is fixed by titanium plates and screws. After the operation all patients underwent CT and clinical follow-up.

3. RESULTS

All patients had large and complex-shaped cranial defects. Mostly, the aetiology was traumatic brain injury (TBI) (6 cases) among which four patients underwent decompressive craniectomy with haematomas evacuation and two patients were treated for depressed skull fractures. The other pathology included a decompressive craniectomy for brain haemorrhage, one case of tumour infiltrating the skull and the osteomyelitis after operation for subdural empyema. The clinical follow-up was from 1 to 63 months (mean 22). In our experience there were no infective complications, reabsorption, rejections or spontaneous fractures. However one patient temporarily deteriorated after the operation and in two patients we encountered wound healing problems which could be resolved without consequences. The coverage and the aesthetic results were good in all cases. For the pre-manufactured prosthesis the mean time in the operation hall was reduced for approximately 30 minutes, being the time needed for the polymer to set, and for the surgeon to manually finish the implant.

4. CASES REPORTS

4.1. Free hand modelling of the implants

Case A. A male patient ZJ suffered a severe brain injury in a road traffic accident (fall from a car). He was admitted to the neurosurgery after he was found in the gutter. His head wound was dirty and coated with the soil. Initially debridement of the brain, duraplasty and craniectomy was performed (Figure 1 and 2). The patient survived but was left with huge cranial defect. After three years he underwent cranioplasty with free hand modelling of the PMMA in the operating room which resulted in acceptable cosmetic result (Figure 3).

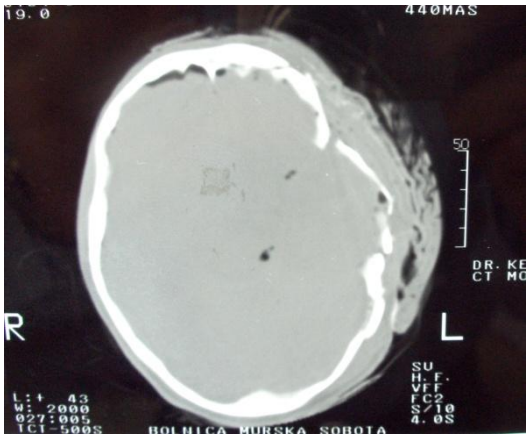

Figure 1 CT showing multifragmented open depressed skull fracture.

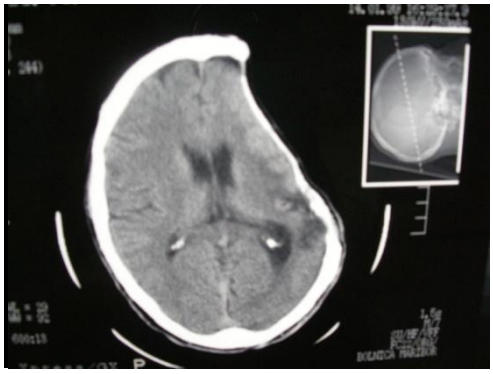

Figure 2 Cranial defect after surgical debridement.

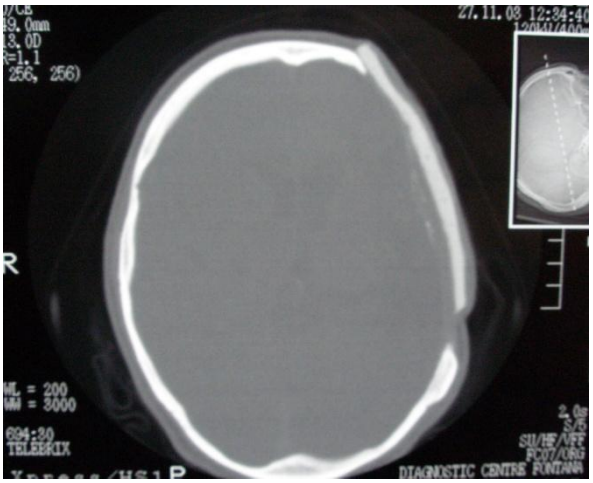

Figure 3 Free hand reconstructions with PMMA.

Case B. A male patient BJ sustained severe brain injury (topple down 4 metres). CT scan showed severe left hemisphere oedema and parieto-temporal haematoma. He underwent extensive decompressive craniectomy and haematoma evacuation. A gradual clinical recovery was seen and three months after the trauma he returned to our department to cover the site of previous craniectomy. His bone cover which was preserved in the bone bank was used. Unfortunately it did not fit into the cranial defect and the outcome was not very good (Figure 4).

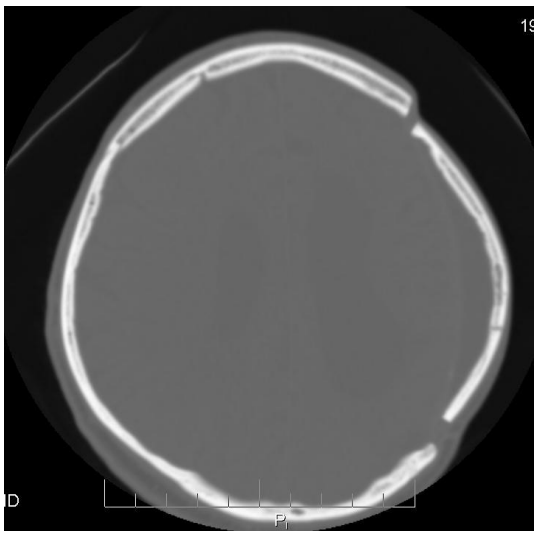

Figure 4 Shrinking of the calvarian bone graft after freezing in the bone bank.

4.2. Custom-made implants

Case 1. A 34 year old male patient PD with initial Glasgow Coma Scale score (GCS) 6 was operated for spontaneous intra cerebral haematoma (ICH). An intracranial pressure (ICP) probe and external ventricular drainage (EVD) were inserted, but the ICP could not be controlled. A decompressive craniectomy was performed (Figure 5). After intervention the ICP could be better controlled and patient's state started to improve. After 8 months the patient was readmitted to the neurosurgical department for a cranioplastic procedure. The patient was in a wheelchair, complaint with still present dysphasia and complete spastic weakness of the right upper extremity and serious paresis of the right lower extremity. After preparations (Figure 6), cranioplasty with PMMA was carried out to replace the missing part of the skull. This was the first case of RP&T implant production and implantation in Slovenia. As described in "Patients and Methods" PolyJet RP technology was used for implant model. The whole setup was sterilized by autoclave. The final implant was produced by neurosurgeon in the operating room. The postoperative course required another procedure due to wound dehiscence, but the final outcome was excellent (Figure 7).

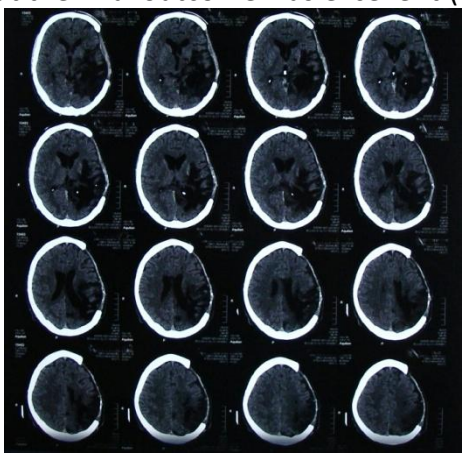

Figure 5 Cranial defects after decompressive craniectomy.

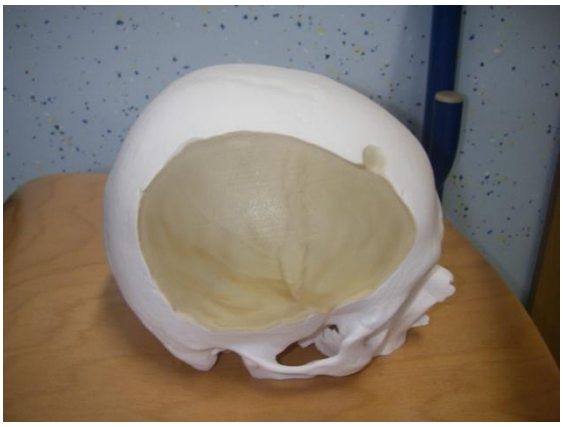

Figure 6 Real model of the skull and the implant.

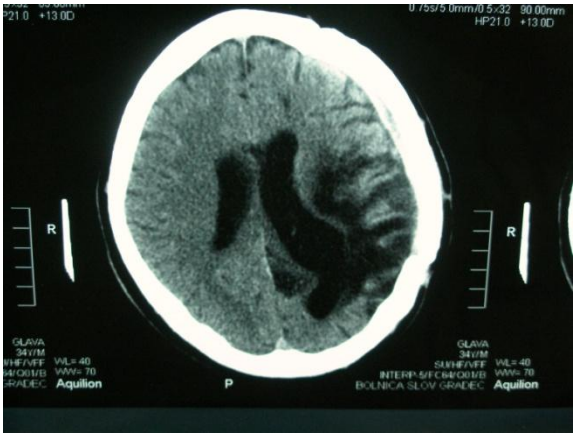

Figure 7 CT after reconstruction of the skull defect.

Case 2. 36-year old male patient PD sustained a severe head injury during the car accident. X – Ray and CT scan revealed the depressed skull fracture of the left frontal and temporal bone. The patient underwent surgery and the bone was cleaned and re-implanted. After one year however the bone has to be removed due to the inflammation and rejection of the bone. The patient was successfully treated with antibiotics. After six months the patient underwent the diagnostic workup and titanium implant was fabricated (Figure 8) which was successfully implanted in the correct place, replacing the missing bone (Figure 9). Postoperative control X-ray and CT scan of the skull revealed the normal skull shape. The postoperative course was uneventful.

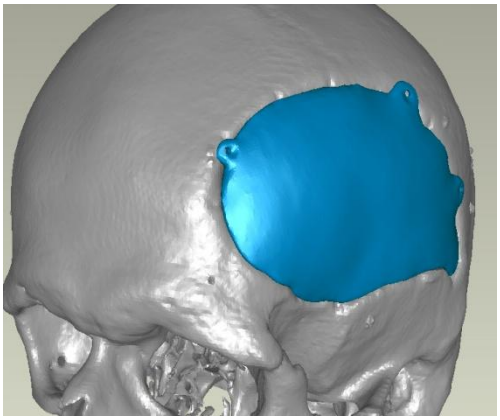

Figure 8 3D reconstruction of the skull.

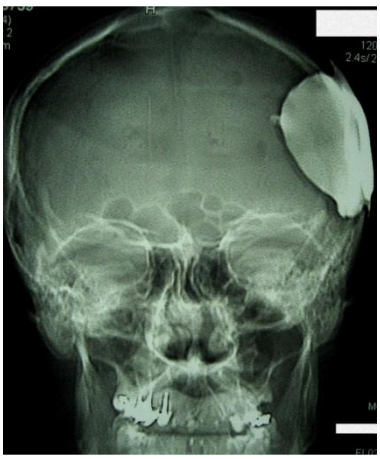

Figure 9 X ray of the skull after the implantation of the titanium implant.

Case 3. 50-year old man AĐ sustained head injury when he fell from a roof. His initial GCS upon the admission was 15. Half an hour later he deteriorated to GCS 4. The CT scan revealed brain oedema, subdural haematoma (SDH) and major brain shift. He was immediately treated with decompressive craniectomy and evacuation of SDH. The EVD and sensor for the ICP monitoring were inserted. Later he developed hydrocephalus and ventriculo-peritoneal shunt was inserted. After one year patient remained in vegetative state with huge cranial defect (Figure 10). A reconstruction surgery was performed. First, the engineers manufactured the implant from titanium, which was too heavy (huge skull defect), so we decided for the same procedures as in first case with minimal changes. In that case the PMMA implant was manufactured in a non-sterile environment before the operation. The implant was sterilized by gas sterilization and implanted (Figure 11). After the surgery patient temporarily deteriorated and his condition was critical for several weeks. Then he recovered but remained in persistent vegetative state.

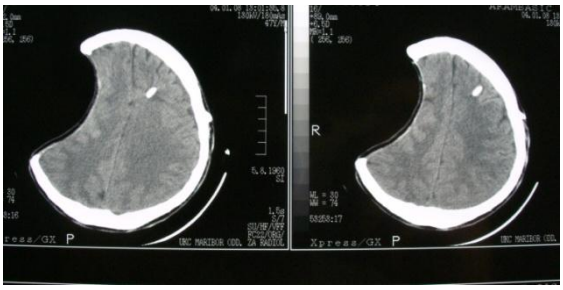

Figure 10 Compression of the brain due to large cranial defect on the right side and ventricular drainage.

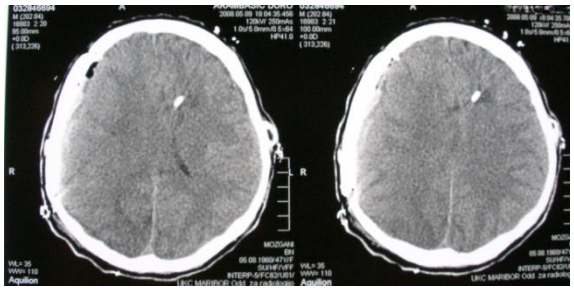

Figure 11 After the reconstruction of the cranial vault a good reexspansion of the brain is seen.

Case 4. 66-year old male patient PV suffered an acute subdural haematoma due to TBI. He underwent a right fronto-parietal decompressive craniectomy and haematoma evacuation. Eight months after the trauma, the patient made a good recovery. He was readmitted for reconstruction surgery. The PMMA implant was manufactured before the surgery. After gas sterilization the custom-made prosthesis was implanted. After few days minimal edge necrosis of skin flap developed which was successfully treated by the plastic surgeon. The subsequent recovery was uneventful (Figure 12).

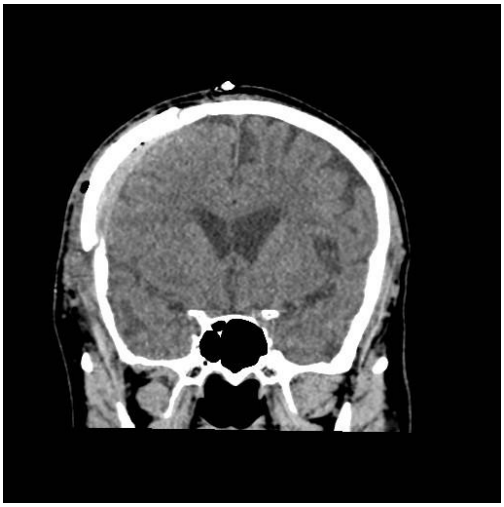

Figure 12 CT after reconstruction of a large right parietal bone defect.

Case 5. 25-year old man BA was injured during the work in the forest (a big branch fell on his head). He was found unconsciousness (GCS 8). CT revealed extensive acute SDH on the left side, extensive contusions and severe left hemisphere oedema. He immediately underwent a large left craniectomy and haematoma evacuation. After one month the cranial defect was reconstructed by his own bone which was deposited in the bone bank. Unfortunately, the osteomyelitis developed and re-operation was needed to evacuate the pus and the bone. This left the patient with a huge cranial bone defect (Figure 13). A year later the PMMA implant was manufactured before for the reconstructive surgery. The implant underwent gas sterilization and was successfully implanted into the huge left cranial defect (Figure 14). Some drilling was needed during the surgery to achieve better fitting of the implant because of slightly thicker implant's edges. The patient made excellent recovery.

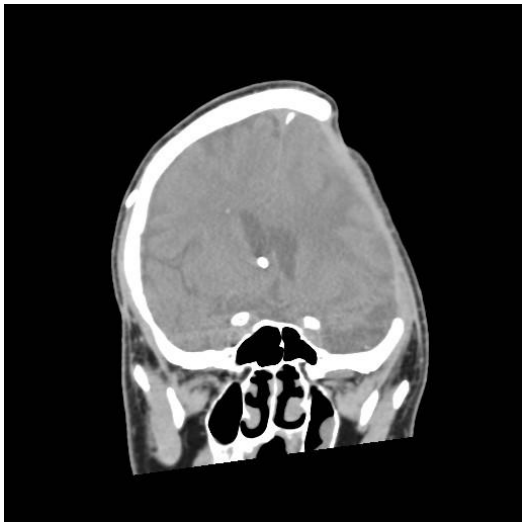

Figure 13 CT scan of a huge cranial defect after removal of an infected bone graft.

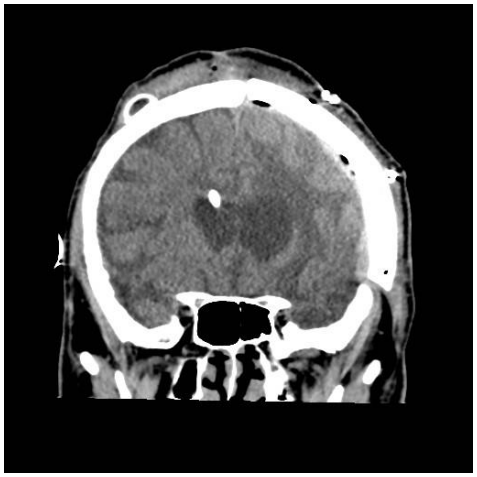

Figure 14 CT after reconstruction showed slightly thicker implant edges.

Case 6. 25-year old male patient FS sustained head injury with comminutes fracture in the right parietal region (blow by iron rim). CT revealed also right hemisphere oedema. He underwent right parietal craniotomy. After debridement the artificial dura was placed and covered with parts of the patient's own skull fragments. The cosmetic effect was unsatisfactory (Figure 15, 16). After rehabilitation he was readmitted for cranioplasty. CT revealed extensive brain defect in the left parietal region and numerous small bone fragments. During the reconstruction surgery we dissected the unsteady bone in the temporal region and covered the defect with artificial dura. Then we fitted the previous manufactured and sterilized custom-made prosthesis with some drilling. Finally we fixed the implant with the plates and screws (Figure 17). The postoperative course was uneventful.

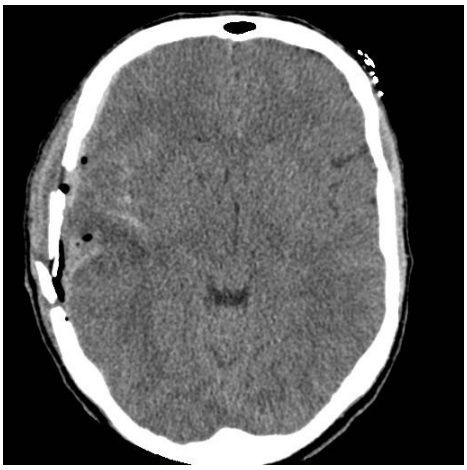

Figure 15 CT scan of the head showing a depressed skull fracture with multiple bone fragments.

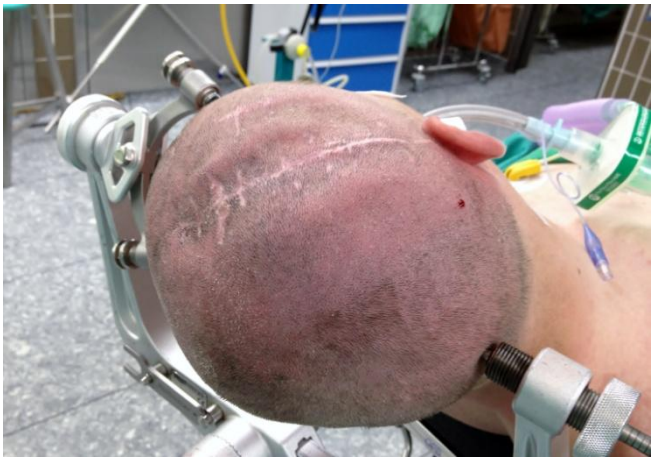

Figure 16 After surgical debridement the patient was left with a depression of the skull.

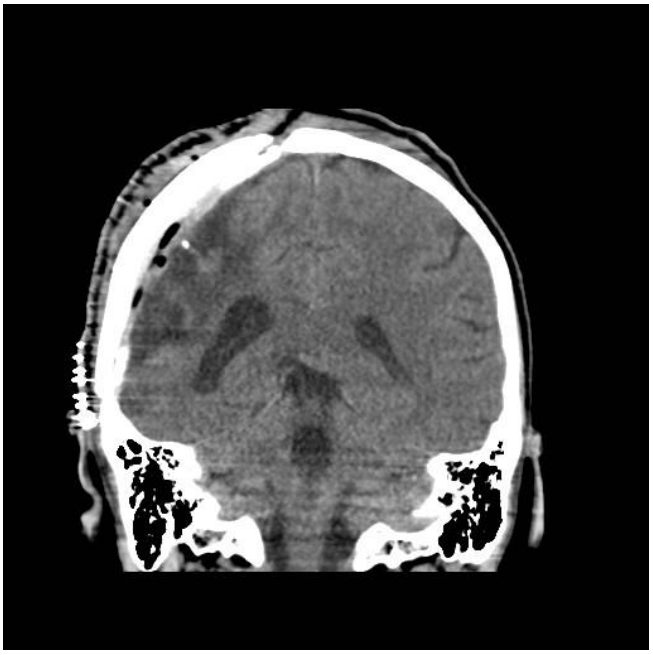

Figure 17 CT scan after reconstruction.

5. DISCUSSION

Most patients with large focal skull bone loss after craniectomy are referred for cranioplasty. Indications for cranioplasty are: (i) protection from trauma (blunt or penetrating) in area of skull defect from craniotomy or posttraumatic; (ii) relief of symptoms due to craniotomy defect (headache, pulsatile pain); (iii) cosmetic restoration of external skull symmetry.

Synthetic materials can be used as substitutes when the bone is heavily comminuted or contaminated. The most common heterologous material used is PMMA, followed by autologous bone, titanium mesh, hydroxy-apatite (powder, cement, porous and dense), polyester, titanium plate and also novel material such as polyetheretherketone (PEEK).

Not long ago prosthesis was manually adjusted to each patient by a neurosurgeon during surgery. The problem of reconstructing the smooth symmetrical and rounded contours of the skull is complex. Outcomes can be improved by the use of patient specific implants; however, high costs limit their accessibility (Gerber et al., 2010).

During free hand modelling of the PMMA implant a great care must be taken, because the polymerized state is reached with the generation of an exothermic reaction. The curing cement may cause devastating thermal injury to the brain if it is allowed to cure in contact with the cortex. The threat of thermo necrosis of tissue exposed to the exothermic curing of PMMA at the implant site can be eliminated by (i) place the material in a plastic bag and mould it to the underlying defect using copious amounts of cold normal saline; (ii) by fabricating a custom acrylic plate pre-surgically. Prefabricating has several advantages: (i) complete polymerization resulting in non permeability to body fluids; (ii) shortening of operative time; (iii) giving assurance to improved physical properties such as compressive, impact and sheer strength. Yamamoto et al. (1997) reported that the acrylic flap, preformed before the operation, can be sterilized with gamma irradiation or gas sterilization and used for cranioplasty.

In last few years several trials demonstrated the potential of virtual modelling and RP in clinical medical praxis. Cranial area is very suitable for these technologies due to relatively low mechanical stresses that occur in this area and due to significant impact of aesthetical demands (Cenzi & Guarda-Nardini, 1995).

Combined with traditional CT scanning techniques rapid technologies (prototyping and tooling) can be used as instruments for better three-dimensional visualization and treatment of patients. They also improve the overall performances of medical and nursing staff thus influencing the quality of medical service. Although the procedure itself is not new it opens new possibilities for medical staff as well as for engineering and industrial applications. Our first case from 2007 showed also some imperfections in the described procedure that tried to be avoiding in the following cases. For example, our first SRM mould was made using a normal frame to hold the silicone and the pattern. Pattern-holders were purposely made out of 5 mm steel wires in order to make some room for excess PMMA compound. Experiments showed that the initial release opening were miss-positioned and too small. The produced implant was too thick and uneven compared to the RP model. Therefore, the mould was modified with some extra release openings. As mentioned, in the first case the mould was sterilized using autoclave in order to ensure sterile implant which was produced by the surgeon in the operation hall.

Instead of sterilizing the tool by autoclave, the next implants were sterilized by means of gas sterilization. These implants were manufactured in a non-sterile environment before the operation. On this way we shorten the procedure by approximately 30 minutes, being the time needed for the polymer to set, and for the surgeon to manually finish the implant (Drstvenšek et al., 2007; Drstvenšek et al., 2008).

Selection of material to replace the cranial vault is complex due to the diversity of existing products.

Acrylic cranioplasty is suitable for all regions of the skull except for areas which are in direct contiguity with functional paranasal sinuses. PMMA can be used directly to fabricate a plastic implant before the time of surgery. Favourable properties of acrylic resins are strength, aesthetic qualities, inertness, availability, thermal nonconductivity, ease of application. However, acrylic resins and other polymers, because of their failure to incorporate biologically, remain as foreign bodies with risks of infection, brittleness, stationary size and exposure. With a pore size of 50 μm, bacteria may colonize within the plate. PMMA is well tolerated for cranioplasty, but macrophages aggregate around implants and methyl methacrylate particles have been found in the liver. Through many years of usage there have been no reports of malignancy associated with implanting acrylic resin. The plastic is well tolerated by the adjoining tissue. In general, the cosmetic result with PMMA is

favourable. Large plates may give the head flattened appearance, and wire mesh must be imbedded for defects >15 cm^2 to prevent fracture of these brittle prostheses. Struts with titanium mesh or miniplates have been suggested for use to improve the cosmetic results, but this technique is more costly.

Titanium is expensive and difficult to prefabricate. Just as is the case with the other metallic biomaterials, the use of titanium and its alloys is however limited by their low frictional wear resistance and by the possibility of the release of their constituents into the surrounding biological environment. Now, the only way in which the problem can be solved is to develop new methods of materials engineering such that would permit producing surface layers to prevent the release of the material constituents into the surrounding tissues and by a good biocompatibility (Ebner et al., 2006).

Solid state, high porosity hydroxy-apatite (HA) offers a good support for bone regeneration within the prostheses, enabling integration of the heterologous material with low post-implant infective risk. A model of the cranium is made in epoxy resin by stereolithography and the prosthesis is built on this model using a ceramic sintering process. Principal limitations of this method are the need for stereolithography process, the poor malleability of the material and the high cost (Staffa et al., 2007).

A polyetheretherketone (PEEK) computer-designed implant is an excellent, but unfortunately expensive option in patients with large facial and cranial bone defects. The material is inert and does not produce artifacts on tomography or magnetic resonance. Advantages for its use are less surgical time and it is highly adaptable. It does not require remodelations as is sometimes necessary when using bone or PMMA. If it eventually has to be replaced, it can be sterilized and used again (Chacon-Moya, 2009). The mechanical properties of PEEK provide better protection when used for cranioplasty compared to titanium implants (Lethause et al., 2012).

Complications from cranioplasty are dividing into general complications and complications related to the type of implant used. If a large prefabricated plate does not follow the cranial contours, compression of the underlying brain and internal herniation may result and death may occur. Infection in a plate with subsequent meningitis or cerebral abscess formation may lead to permanent morbidity or even death. Plates may loosen and erode the skin. Acrylic plates, especially brittle, may fracture and injure the underlying brain or protrude through the skin. It is necessary to obliterate contiguous paranasal sinuses months before implanting any plate. Otherwise the alloplastic material or devitalized autogenic bone is subject to external microbial colonization. Metallic and plastic plates are foreign bodies that become encapsulated by host tissue. Infection remains the predominant concern for all foreign bodies, and if infection does occur, these foreign bodies must be removed. Autogenic bone grafts are initially nonviable and therefore are subject to infection. This grafts latter may resorb or lead to cosmetically undesirable ridges. Overall, the failure rate due to complications such as rejection, prosthesis movement, infection, and aesthetic inefficacy is from 14 to 22% (Moreira-Gonzales et al., 2003). Mortality rate for cranioplasty is very low (0.2 to 0.8%). Infection rates range between 1 to 8%. Rish et al., (1979) in series of 491 cranioplasties, reported a 3.7% infection rate and a 3.1% loss of the cranioplasty.

Until now in our group of patients we didn't have any major complications which would lead to implant removals. We had however some problems with adjusting the implants during the surgery, but this could be solved with additional drilling. After the surgery we also experienced some problems with wound healing in some of our patients and two of them needed another procedure.

6. CONCLUSION

Cranioplastic is not the only intervention where both, surgeon and patient can benefit from custom-made implants. Custom-made bespoke implants technically improve the procedure, release some stress by enabling effective pre- surgical planning as well as reduce costs and, most importantly, decrease morbidity and mortality of patients by means of shortening the time of anaesthesia, time of the surgical procedure, by decreasing infection complications, etc. So the manufacturing of individually adjusted prostheses should be commonly used in patients planned for cranioplasty with synthetic material. The variability of surgical defects and challenges in cranial reconstruction highlights the importance of a strategic approach to evaluate both the defect and the clinical circumstance (Tadros & Constantino, 2008). Reconstruction of the cranial defect is a multidisciplinary process that should include experts in imaging and in reconstruction materials. The onus of responsibility remains on the surgeon to evaluate each patient and select the optimal management.

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