



## Cranial reconstruction with prefabricated 3D implant after a gunshot injury – A case report

### Rekonstrukcija defekta lobanje 3D implantatom nakon sklopetarne povrede glave

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#### Abstract

**Introduction.** Complex defects of skull bones with different etiology, still present the challenge in reconstructive surgery. The goldstandard for cranioplasty is the autologous calvarial bone graft removed during surgery which cannot be always applied, especially in gunshot wounds for sometimes complete bone destruction. Autologous reconstruction with split calvarial, rib bones or iliac bone graft is also possible. Materials routinely used for reconstructions like titanium mesh, polymethyl metacrylate (PMMA), and other have numerous disadvantages and limitations. **Case report.** We presented a patient with gunshot injury to the head with residual large bone defect in the frontal region, with involvement of the skull base, and open frontal sinus. After conservative treatment, six months after the injury, reconstruction of the residual bone defect was performed. The chosen material was computer-designed PEEK-OPTIMA® implant, manufactured on the basis of MSCT scan. This material has not been used in this region so far. The postoperative and follow-up period of the next 12 months passed without surgical complications, neurological deficit, with satisfactory functional and aesthetic results. **Conclusion.** Implanted bone replacement was designed and manufactured precisely according to the skull defect, and we found it suitable for the treatment of complex defects of the cranium. Early results are in favor of this cranioplasty method over standardized materials. Therefore, this material is expected to become a method of choice for reconstructive surgery of bony defects of the face and skull especially in complex cases.

#### Key words:

skull; prosthesis and implants; biocompatible materials; polyethylene glycols; polyetheretherketone; computer-aided design; reconstructive surgical procedures.

#### Apstrakt

**Uvod.** Kompleksni koštani nedostaci mogu imati različitu etiologiju i predstavljaju pravi izazov u rekonstruktivnoj hirurgiji. Zlatni standard kranioplastike je rekonstrukcija skinutom kosti lobanje, koja se u mnogim slučajevima ne može primeniti, naročito kod sklopetaranih povreda zbog destrukcije kosti. Rekonstrukcija autolognim graftom razdvajanjem kalvarija, rebrom ili ilijačnom kosti, takođe je moguća. Do sada primenjivani veštački materijali poput palakosa, titanijumskog meša i drugih, imaju brojne nedostatke i ograničenja. **Prikaz bolesnika.** Predstavljen je pacijent kome je nakon sklopetarne povrede glave ostao veliki koštani defekt frontalne regije sa zahvatanjem prednje lobanjske baze i otvorenim frontalnim sinusom. Nakon primarnog hirurškog zbrinjavanja i sprovedenog konzervativnog lečenja, šest meseci od povrede odlučeno je da se uradi rekonstrukcija nastalog koštanog defekta. Uzimajući u obzir sve relevantne medicinske faktore odlučeno je da se rekonstrukcija uradi primenom najsavremenijeg implantata od materijala PEEK-OPTIMA® koji je oblikovan na osnovu MSCT snimka u 3D tehnici. Ovaj materijal do sada nije korišćen na ovim prostorima. Neposredno i postoperativno praćenje sledećih 12 meseci pokazalo je tok bez komplikacija operativnog polja i neurološkog deficita, sa izuzetno zadovoljavajućim funkcionalnim i estetskim rezultatima. **Zaključak.** U toku primene ove nove hirurške intervencije uverili smo se da je proizveden implantat veoma precizno izrađen prema defektu i da je veoma pogodan kod zatvaranja kompleksnih i ekstenzivnih kranijumskih defekata. Naša prva iskustva idu u prilog očekivanju da će ovaj vid kranioplastike imati značajno mesto u rekonstruktivnoj hirurgiji defekata kostiju lica i glave.

#### Ključne reči:

lobanja; proteze i implantati; biokompatibilni materijali; polietilen glikoli; polieteterketon; kompjuterski podržan dizajn; hirurgija, rekonstruktivna, procedure.

## Introduction

Cranial defects are mainly caused by surgical intervention after various types of traumas, tumors, infections, congenital cranial anomalies and other causes. In most cases it is necessary to reconstruct them. The main objectives of cranioplasty are to restore the normal barriers protecting the intracranial structures, normalization of intracranial pressure, thus alleviating neurological deficits, but also to achieve satisfactory aesthetic results<sup>1-3</sup>. In cases of gunshot wounds to the head, bone is usually destructed, therefore not usable.

Cranioplasty is dating back to the prehistoric times when various materials, available at that time, were used. Historical data shows that golden and silver plates were used in some parts of the world<sup>1</sup>. These materials were also used in the recent history, but they are no longer in use due to low resistance even to the minimal trauma. Other materials such as steel and tantalum were discarded because of the excessive conductivity of heat and cold, weight, as well as inadequate radiopacity.

Due to its characteristics, autologous bone grafts remain still superior, despite many various synthetic materials. In some cases, it is not possible to preserve autologous bone graft, and the length of its own storage in the patient or in the bank is not unlimited. Gunshot wounds to the head lead to destruction and contamination of the calvarial bones, and, therefore, these bone defects are always a subject to delayed reconstruction.

Autologous bone graft, taken from another part of the body (calvarial bone, rib grafts, iliac bone) has many advantages like resistance to infections, growth potential, radiotransparency at no additional cost. At the same time, important downsides are two surgical fields<sup>4,5</sup>, and risks of incomplete take of the graft, due to resorption or infection<sup>6-8</sup>.

Therefore, there was the need for a material that would be a suitable replacement, as similar as possible to the characteristics of the bone tissue, resistant to infection, atoxic and biologically inert.

Methyl methacrylate (MM) is the most widely applied alloplast in use, particularly suitable for small defects, and some authors report its infection rates to be lower than rates achieved with autologous bones<sup>9</sup>, but infection rate is higher on large-size defects<sup>10</sup>. This material is cheap, momentarily available and easy to use. The limitations of this material are numerous when the defect is in contact with the sinuses, because of significantly increased risk of infection<sup>11</sup>.

In addition to MM, titanium mesh is in use, which is very difficult for design of complex defects, and sharp edges can lead to decubitus wounds<sup>12,13</sup>, as well as the problem of application in patients who have suffered radiation treatment.

Nowadays bioactive materials such as hydroxyapatite, kryptonite and many others are in use. But so far, no large study on these materials has been published, and surgical experience with them is also modest.

Materials used so far were insufficient when it comes to large and complex defects of the skull. Modeling was difficult or even impossible, and satisfactory functional and cosmetic results were not always achieved.

PEEK OPTIMA<sup>®</sup> is polyetheretherketone, which is structurally linear, aromatic polymer, and morphologically semicrystalline. The advantages of this material are excellent biocompatibility, combination of strength, stiffness and viscosity<sup>14</sup>, comparable to cortical bone. Manufacturers state that it has bone-like temperature conductivity of 0.4 W/Km. As for the radiological characteristics, there are no artefacts when using conventional imaging techniques such as X-Ray, computed tomography (CT), magnetic resonance imaging (MRI), and all conventional procedures for the sterilization are applicable (steam, ethylene oxide and gamma irradiation), and a resterilization is possible, as well. PEEK OPTIMA<sup>®</sup> can be additionally shaped at the operating room.

## Case report

We presented a 21-year-old male patient who sustained gunshot head injury of a frontal region. He was initially treated in a local health center, where he underwent primary surgical treatment, wound debridement and removal of bone fragments. Soft tissues and dura were reconstructed, however, the reconstruction of the skull defect was not performed. After the intervention the irregularly shaped bone defect (7 × 8 cm) remained, with the defect of the skull base and opened frontal sinus.

The patient was admitted to the Clinic for Infectious Diseases of the Military Medical Academy, Belgrade, Serbia, as an emergency with signs of meningeal irritation one month after primary surgical treatment. Urgent multislice computed tomography (MSCT) revealed signs of epidural and subdural abscess and pneumocephalus causing compressive effect to the brain parenchyma after which an emergency surgery was performed, and included wound revision with the evacuation of the epidural and subdural abscess and reconstruction of the dura mater and frontal sinus. The bone defect remained for the subsequent solving. He was discharged from the hospital two weeks later, in good clinical and neurological state with an oral anticonvulsive and antimicrobial therapy (Figure 1).

One month after discharge from the Clinic for Infectious Diseases of the Military Medical Academy, the patient reported in good general clinical state, with laboratory results showing no signs of infection, nor inflammation, with no pathologic neurological finding (Glasgow Coma Scale – 15). Complex defect of the skull engaging frontal and sphenoid bones was present, compromising both functional and aesthetic purpose of the bones. Polymethyl methacrylate (PMMA) or titanium mesh reconstructions were of probable unsatisfactory result, and the decision was made to use prefabricated 3D implant which would be precisely fitted to the contours of the bone to fulfill the defect as good as possible.

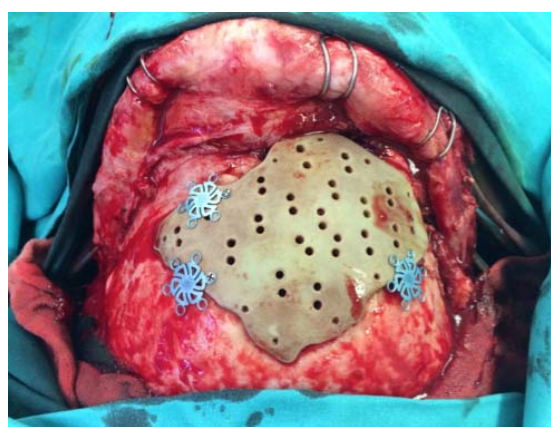
Surgery was scheduled for 6 months after discharge. The absence of signs of infection (both local and systemic) had to be repeatedly verified. MSCT was done (Figure 2) and the files were sent to the engineers in a “3Di company”, who had made a virtual 3D model of the patient. To design a virtual model, either an inversion or simulation model can be used. The inversion was based on the assumption that the



**Fig. 1 – Preoperative appearance of the patient: a) *En face*; b) Right halfprofile; c) Left halfprofile.**



**Fig. 2 – Preoperative multislice computed tomography showing a complex defect of the skull.**



**Fig. 3 – PEEK OPTIMA® implant fixed with titanium screws and stars.**

human skull is almost symmetric, and the simulation model is useful in cases of asymmetrical defects, in the midface area, whenever an inversion is impossible. In this case, the simulation model was used. In this method measurements and characteristics of the scanned skull contained in a data bank, are compared to a highly precise 3D representation of the patient's corresponding defect area. After designing a virtual model, it is forwarded to the surgeon, for consultation before completion of prosthesis creation, in order to make any possible adjustment, regarding thickness and the type of fixation of the implant. Fabrication of the implant was performed with three-axis computer numerical control drilling machine using selected material. In this case, the 3D implant is made from non-resorbable thermoplastic material PEEK OPTIMA®.

After the arrival of the implant, and preoperative preparation, cranioplasty was performed with the 3D implant previously cut, characteristic for bicoronal craniotomy. Due to the open frontal sinus, cranialisation with neuropatch was required. After preparing the bone defect edges of the skull, previously sterilized implant has been created, using titanium plates, and fastened with screws. The implant is attached to the bone with three titanium stars (Figure 3). The epicranial

aspiration drainage was also applied. A triple antibiotic therapy was administered to the patient after the surgery. Postoperative scan images showed that prosthesis completely filled the bone deficiency (Figure 4).



**Fig. 4 – Multislice computed tomography (3D reconstruction) on the first postoperative day showing the fixed PEEK OPTIMA® implant.**

The patient was discharged on the fifth postoperative day, with regular local and good overall status. At the check-up on the 12th postoperative day, stitches were removed, and the local status was very satisfactory. The patient was without neurological deficit. At the check-up one month after the operation, the patient showed himself completely satisfied (Figure 5). Postoperative follow-up the next 12 months showed the course without complications of the operative field and neurological deficits, neither was the forthcoming period expected to give any.

RIT<sup>®</sup> II is glass-ceramics polymer. It was introduced in 1982 and up to nowadays it has been used for building over 2,000 specifically designed implants. The material is biocompatible, firm, suitable for modelling during the intervention, and it does not cause any artefacts in MR/CT scans. The major flaw of this material is its price. PEEK-OPTIMA<sup>®</sup> is a kind of thermoplastics with high performances, linear aromatic polymer, with similar characteristic as BIOVERIT<sup>®</sup> II. It is in use for the last 30 years. In addition, material is



Fig. 5 – Postoperative appearance of the patient: a) *En face*; b) Right halfprofile; c) Left halfprofile.

## Discussion

Cranioplasty of complex bone defects represents a real challenge for the surgeons. Many materials commonly used have many drawbacks during designing phase, so that fully satisfactory functional and aesthetic results cannot be achieved. Cranioplasty performed at early state, reduces the risk of late epilepsy, as well as complications of neuropsychological nature. War gunshot wounds to the head are specific for their extensiveness due to large projectile primary bone destruction and primary polymorphic bacterial contamination, which, together with wounded skin scarring makes cranioplasty vastly complicated. Wounding is also resulting in large epidural cavity, which makes difficult the procedure furthermore.

The golden standard of cranioplasty after craniotomy is reconstruction with the autologous bone graft. In many cases such a bone cannot be used, due to complex multifragmentary fractures with bone destruction (as is the case in civilian and war gunshot wounds), tumor destruction, poor bone quality after chemotherapy and radiotherapy, so artificial materials are being commonly used in deferred cranioplasty.

Large individual diversity of the skulls, high functional requirements, as well as high aesthetic criteria represent a major challenge for the surgeon during selection and utilization of the materials for such an intervention. Industrially manufactured implants are unable to respond to all requirements set. Consequently, all this new technology has been developed for the creation of 3D referent implants and that is based on the data according to the prepared MSCT, so that each implant is made in shape of the defect, and is specific for each patient. Materials most often used for this purpose include BIOVERIT<sup>®</sup> II and PEEK-OPTIMA<sup>®</sup>. BIOVE-

successfully used for intraoperative modelling, can be sterilized by any method, and repeatedly, if required. Material is often used for secondary cranioplasty following infections, with excellent results<sup>15</sup>. It has shown a great success with patients who has been previously exposed to radiation, and with signs of radionecrosis and osteomyelitis<sup>16</sup>. The method of reconstruction presented in this paper provides achieving very precise and natural model, as well as for very unreachable regions such as base of a skull<sup>14</sup>.

The aim of skull reconstruction is adequate reconstruction of the defect without functional problems, and on the other hand as good aesthetic result as possible. Cranioplasty as a method of treatment has to be safe, fast and technically easily performed. Price quality *versus* rate of the procedure will certainly dictate further application<sup>17</sup>.

PEEK OPTIMA<sup>®</sup> personalized implants have been in use for 10 years in western countries with great success. Simplicity of the procedure, short postoperative flow and almost complete absence of complications are the main qualities emphasized for this material.

The biggest drawback of PEEK-OPTIMA<sup>®</sup> material is the implant price. A concrete case presented here costs more than ten thousands euros, which significantly raises expenses of the operation. Compared to a titanium mesh or MM, PEEK-OPTIMA<sup>®</sup> has several times higher price. Application of this material is a completely new practice for this medical center, therefore it is difficult to justify its usage according to its advantages, related to the days required for postoperative phase, and other eventual complications. However, even with high price for some complex defects, it still holds absolute indication for application, and this case represents only the beginning.

## Conclusion

Experience in reconstructive skull surgery shows that complex defects represent quite a challenge for a surgeon, in order to provide good functional achievement, and satisfying aesthetic results at the same time. Each material used previously showed certain drawbacks, as discussed. During application of this new surgical intervention, it is convincing that a produced implant was made precisely according to craniotomic defect, and that it fills in completely, following anatomic shape of the skull. Implant

edges meet the requirement of the defect, and are rounded, which prevents risk of decubitus wounds. At the same time, the duration of intervention is shortened, since the surgeon gets a well-prepared implant, and no additional time is necessary for modelling in the operation room. Early experiences prove that this method of cranioplasty is significantly more suitable than previous methods. As stated before, the biggest obstacle in routine application of the method is the high price of the material. There is a hope that the price will get lowered, and become available to a larger group of patients.

## R E F E R E N C E S

1. Durand JL, Renier D, Marchac D. The history of cranioplasty. *Ann Chir Plast Esthet* 1997; 42(1): 75–83.
2. van Heest A, Swiontkowski M. Bone-graft substitutes. *Lancet* 1999; 353(Suppl 1): S28–9.
3. Sanan A, Haines SJ. Repairing holes in the head: a history of cranioplasty. *Neurosurgery* 1997; 40(3): 588–603.
4. Whitaker LA, Munro IR, Sahyer KE, Jackson IT, Ortiz-Monasterio F, Marchac D. Combined report of problems and complications in 793 craniofacial operations. *Plast Reconstr Surg* 1979; 64(2): 198–203.
5. Jackson IT, Pellett C, Smith JM. The skull as a bone graft donor site. *Ann Plast Surg* 1983; 11(6): 527–32.
6. Shaffer JW, Field GA, Goldberg VM, Davy DT. Fate of Vascularized and Nonvascularized Autografts. *Clin Orthop Relat Res* 1985; (197): 32–43.
7. Goldstein J, Mase C, Newman HM. Fixed membranous bone graft survival after recipient bed alteration. *Plast Reconstr Surg* 1993; 91(4): 589–96.
8. Bok WK, Hong SK, Min KS, Lee MS, Kim YG, Kim DH. Cranioplasty using frozen autologous bone. *J Korean Neurosurg Soc* 2003; 33(2): 166–9.
9. Poetker DM, Pytynia KB, Meyer GA, Wackym AP. Complication rate of transtemporal hydroxyapatite cement cranioplasties: a case series review of 76 cranioplasties. *Otol Neurotol* 2004; 25(4): 604–9.
10. Park JS, Lee KS, Shim JJ, Yoon SM, Choi WR, Dob JW. Large defect may cause infectious complications in cranioplasty. *J Korean Neurosurg Soc* 2007; 42(2): 89–91.
11. Marchac D, Greensmith A. Long-term experience with methylmethacrylate cranioplasty in craniofacial surgery. *J Plast Reconstr Aesthet Surg* 2008; 61(7): 744–52; discussion 753.
12. Kuttnerberger JJ, Hardt N. Long-term results following reconstruction of craniofacial defects with titanium micro-mesh systems. *J Maxillofac Surg* 2001; 29(2): 75–81.
13. Ng ZY, Ang WJ, Nawaz I. Computer-designed polyetheretherketone implants versus titanium mesh ( $\pm$  acrylic cement) in alloplastic cranioplasty: a retrospective single-surgeon, single-center study. *J Craniofac Surg* 2014; 25(2): 185–9.
14. Lethaus B, Safi Y, ter Laak-Poort M, Kloss-Brandstätter A, Banki F, Robbenmenke C, et al. Cranioplasty with customized titanium and PEEK implants in a mechanical stress model. *J Neurotrauma* 2012; 29(6): 1077–83.
15. Hanasono MM, Goel N, de Monte F. Calvarial reconstruction with polyetheretherketone implants. *Ann Plast Surg* 2009; 62(6): 653–5.
16. Chacón-Moya E, Gallegos-Hernández JF, Piña-Cabrales S, Cobn-Zurita F, Goné-Fernández A. Cranial vault reconstruction using computer-designed polyetheretherketone (PEEK) implant: case report. *Cir Cir* 2009; 77(6): 437–40.
17. Spetzger U, Vougioukas V, Schipper J. Materials and techniques for osseous skull reconstruction. *Minim Invasive Ther Allied Technol* 2010; 19(2): 110–21.

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