Experience with Codubix implants use to close bone defects of the cranial vault in neurocancer patients

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Plasty of cranial vault defects is rarely used in neurooncology. They occur during surgery for bone tumour ingrowth, during decompressive surgery for uncontrollable brain swelling, in infectious complications, such as wound infection followed by the development of bone graft osteomyelitis. In 2013, the Department of Neurosurgery, P. A. Herzen Moscow Oncology Research Institute, tested and put into practice the new synthetic polymer Codubix (Tricomed, Poland) as a Codubix implant (plate). The latter was used to perform 15 operations to close bone defects of cranial vault in 15 patients, including delayed defect closure in 11 cases and one-stage one (i.e. bone defect closure with simultaneous tumour resection) in 4.
Key words: neurooncology, cranioplastic surgery, Codubix implants.

Cranioplasty is a skull reconstruction after surgical operations, trauma, infections, etc.

One of the first mentions of cranioplasty dates back to the sixteenth century, when Fallopius Gabriele (1523-1562) described a method to supplement a bone defect using a gold plate. In 1668 Van Meekrem described a cranioplasty case that was performed in a Russian nobleman after being wounded with a sword. A dog cranial vault bone was used for this plasty.

With varying success in cranioplasty there were the following materials used: celluloid (1890), aluminium (1893), platinum (1929), silver (1950), "witalij" - alloy of cobalt and chromium (1943), tantalum (1942), stainless steel (1945), polyethylene (1947) [1, 2].

Plastic surgery of the cranial vault bones and the skull base is used in a limited number of cases. The basic causes of bone defects in neuro-oncology patients are: swelling of the skull bone, bone flap infection, decompression operations at uncontrolled swelling of the brain substance.

For cranioplasty currently three types of grafts are used: autograft (patient's bone tissue), allograft (bone fragments taken from the dead), xenograft (titanium, cyanoacrylate, polymer implants, etc.).

It is preferred to use autografting for each type of transplantation. However, in cases where this is not possible, xenografts should be used. We use xenografts prepared basing on a titanium mesh, acrylic glass (palacos and others), as well as synthetic polymer implants (Codubix plates).

Modern implants for cranioplasty must meet several requirements: biocompatibility, no carcinogenic effect, plasticity, the possibility of sterilisation, the possibility of combining with a stereolithography method, the ability to heal in the adjacent bone tissue without scarring with the connective tissue (osseointegration), compatible with neurovisualisation methods, mechanical strength, low heat and electricity conductivity, acceptable price, minimal risk of postoperative complications.

One of the currently used materials corresponding to most of the above mentioned requirements, is the Codubix synthetic material.

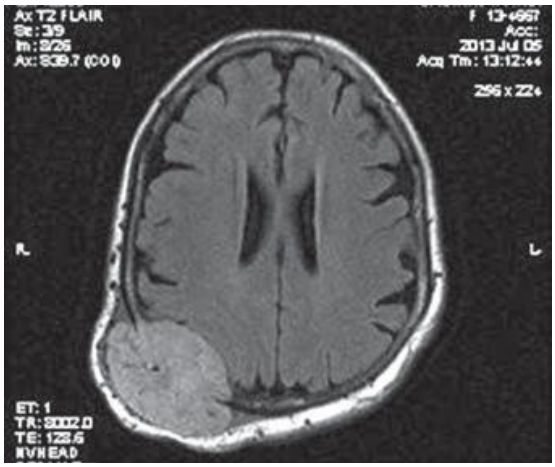


Figure 1. MRI scan of patient S. before the surgery. The protuberance on the right side of the parieto-occipital region.

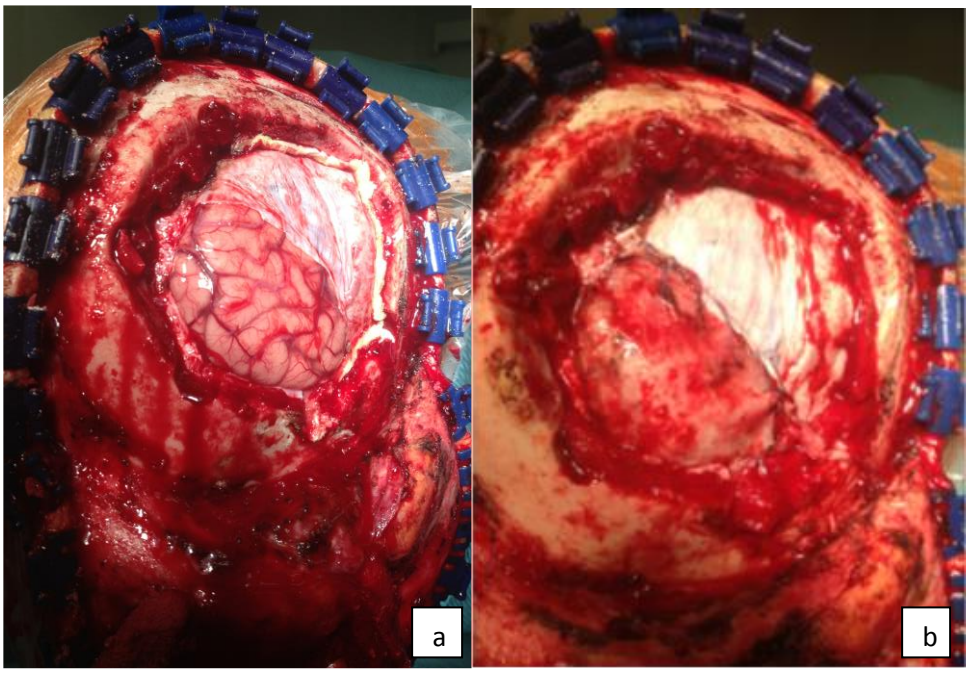


Figure 2. a – defect of the dura mater, b – plasty of the dura mater defect.

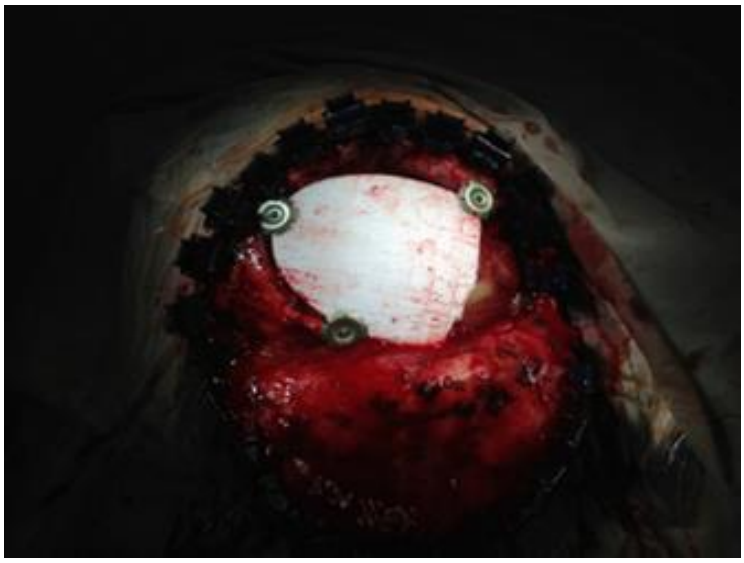


Figure 3. Bone defect closed with a Codubix plate.

Codubix is a Class III medical device in accordance with the regulations contained in Annex 8 of the Directive 93/42 EEC. It is distinguished by high biocompatibility due to the combination of technologies used in the production of other proven biomaterials. It is knitted of polyester and polypropylene yarn (polyester 110 DTEX F33 - polypropylene Torlen 56 DTEX F24). The non-resorbable polyester yarn provides adequate flexural and compressive strength as well as porosity. The polypropylene yarn is characterised by low specific weight and a low melting point, providing sufficient rigidity and hardness of the prosthesis.

The implants (Codubix plates) have very good immunological characteristics, light weight, thermal permeability comparable to that of natural bone, porosity, density, and total lack of liquid absorbency (water, blood, etc.). They are resistant to mechanical damage caused by external forces (high flexural strength) due to the ability to return to its original shape after deformation. They are chemically inactive, resistant to high and low temperatures. Despite the high porosity they are resistant to infection, are relatively easy to shape during the implantation and allow to perform diagnosis without artefacts [3].

In 2013, the Department of Neurosurgery, P. A. Herzen Moscow Oncology Research Institute, tested and put into practice the new synthetic polymer Codubix (Tricomed, Poland) as a Codubix implant (plate). In the period from February 2013 to February 2014 the product was used to perform 15 operations to close bone defects of cranial vault in 15 patients, including delayed defect closure in 11 cases and one-stage closure (i.e. bone defect closure with simultaneous tumour resection) in 4.

As for the defect location the patients can be divided as follows: the frontal bone defect (3), parietal bone defect (5), parieto-occipital bone defect (4), frontotemporal bone defect (4).

In 3 patients the defect was a result of an infected surgical wound, which led to the removal of the bone flap. In 2 patients during the surgical removal of swelling the bone flap could not be fixed back, due to the vast swelling of the brain substance, for additional decompression. In 10 patients the swelling went into the bone structure so they had to be partially removed. It should be emphasised that in 6 of these patients the skull bone defects were caused by benign tumours (meningioma, facial granuloma).

For cranioplasty standard Codubix plates of different sizes were used. They were adjusted during the operation to the skull defect by means of standard instruments.

Here are the descriptions of two exemplary clinical cases.

Female patient S., 56 years, diagnosis: left kidney cancer T3bN0M1 level IV, metastases to the lungs and bones. Histological diagnosis: metastatic renal cell carcinoma.

In early 2013 the patient noticed a painful hard bulge in the right part of the occipital-parietal area, which at the moment she came to P. A. Herzen Moscow oncology research institute was 5 x 5 cm **(Figure 1)**. In April 2013, during a survey carried out in connection with pain in the lumbar spine, the patient was diagnosed with left kidney cancer with metastasis to the lungs and bones (vertebrae and right occipital-parietal area). In the institute at the first stage, due to the high risk of pathological fracture and spinal canal stenosis, on June 5, 2013, laminectomy at the L_{III} - L_{IV} vertebrae with transpedicular fixation at the L_{II} - L_{V} vertebrae was performed. At the second stage, on July 15, 2013, left nephroureterectomy and para-aortic lymphadenectomy was performed.

On August 5, 2013, a surgery was performed - microsurgical removal of metastatic extra-intracranial swelling of the right occipital-parietal area of the dura mater defect plasty using local tissues and bone defect plasty using a Codubix plate.

Description of the operation. The patient was in a sitting position, the extra-intracranial fragment of oedema was removed with an arcuate slit surrounding the oedema and the fragment was faced downwards. The osteo-plastic trepanation of the occipital-parietal area was performed at 1 cm distance from the visible edges of the oedema. The bone flap was removed along with the extracranial fragment of the oedema. The dura mater was overgrown with oedema at the 3 x 2 cm area. The resection of the dura mater was made at a distance of 0.3 cm from the oedema. The arachnoid mater was intact **(Figure 2 a)**. The dura mater plasty with a free periosteal flap fixed around with surgical knots and additionally sealed with BioGlue fibrin glue **(Figure 2 b).** Plasty of the bone defect by means of the Codubix plate, pre-adjusted to the defect size **(Figure 3)**. Soft tissues were sewn back layer by layer.

Subsequently, the patient received a recommendation to continue the treatment with temsirolimus.

Male patient M., 27 years, diagnosis: middle cranial fossa meningioma on the right side. Histological diagnosis: meningothelial meningioma.

At the beginning of July 2013, the patient noticed decreased vision, and therefore turned to an ophthalmologist and was directed to a CT scan. The computed tomography was carried out on July 15, 2013 and indicated middle cranial fossa oedema on the right side **(Figure 4, a, b).** The patient came to the P. A. Herzen Moscow Oncology Research Institute, where on July 30, 2013, were microsurgical removal of the middle cranial fossa oedema was performed. The oedema was removed radically (**Figure 5)**. For additional infratemporal decompression, the bone flap (bone coating) set in place was reduced in the lower part. The postoperative period passed without complications. Within seven months after the surgery, there was no oedema recurrence. Nevertheless, there remained the problem of a bone defect. On February 27, 2014, a bone defect reconstruction surgery right hand part of the temporal lobe was performed by means of a Codubix plate with the use of a stereolithographic model.

Description of the operation. The patient was in a supine position with the head rotated to the left, scalp soft tissue dissection was performed along an old scar in the right side of the fronto-temporal region. The aponeurotic flap was separated from the temporal bone. The bone defect was separated **(Figure 6)**. A Codubix plate prepared using a stereolithographic model was placed into the bone defect and fixed by means of Craniofix implants. The bone defect was completely filled **(Figure 7)**. The soft tissues were sewn back.

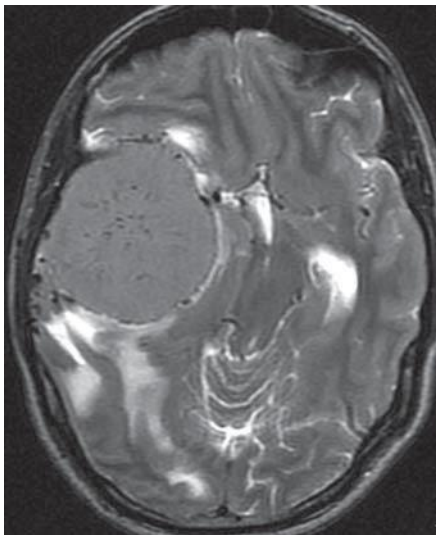
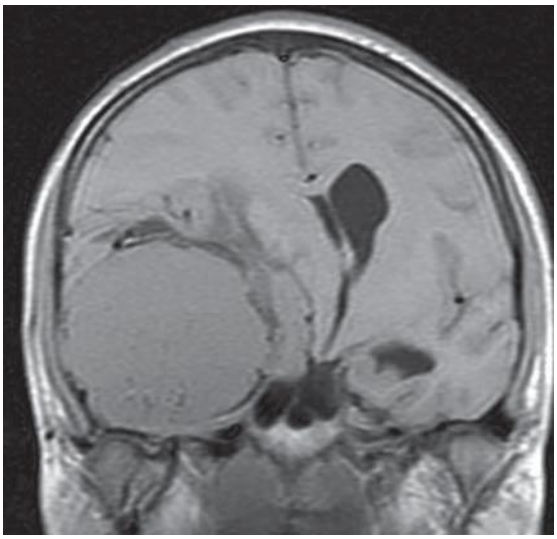
a  b 

Figure 4. MRI scan of patient M. before the surgery. Oedema of the right part of the middle cranial fossa (a, b).

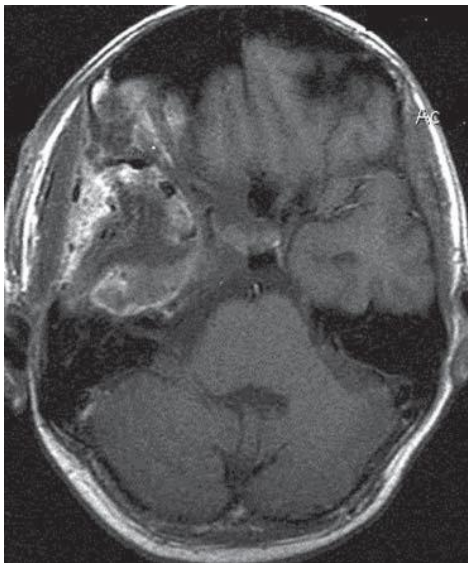


Figure 5. MRI scan of patient M. on the first day after the oedema removal

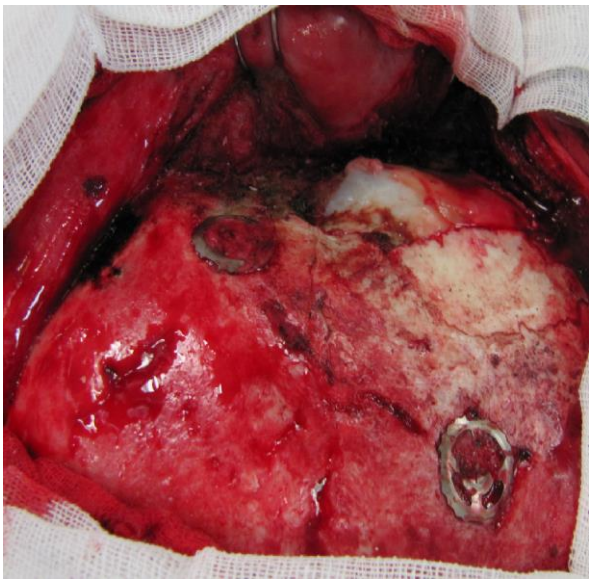


Figure 6. Postsurgical view of the bone defect of the right temporal region.

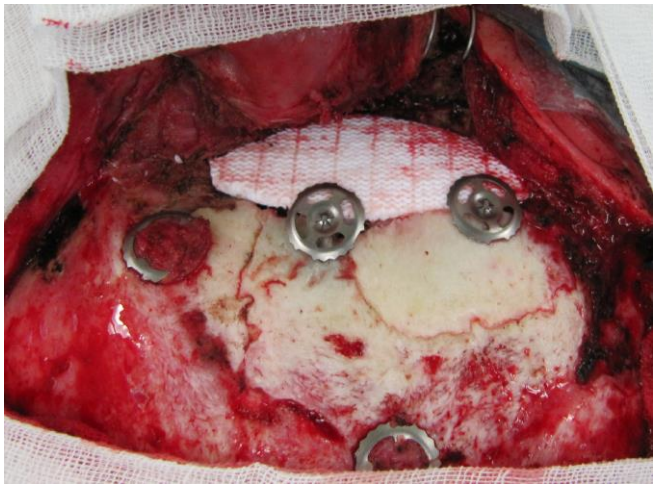


Figure 7. Codubix implant modelled to the size of the defect fixed with craniofix clamps.

Summary

Our experience shows that the Codubix synthetic material ("Tricomed", Poland) has the characteristics necessary for xenotransplants, such as high biocompatibility, high rigidity, low specific weight, chemical inertia, thermal permeability comparable to that of natural bone, high porosity for osteocyte ingrowth.

The Codubix plates are relatively easy to shape and are perfect for filling in skull bone defects. At the same time they do not cause significant tissue reaction, which reduces the risk of postoperative complications.

Conflict of interest: the authors declare no conflict of interest.

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