The evaluation of early and late results of using Codubix® cranial prosthesis

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Summary

The filling of the cranial defect is an essential problem in neurosurgery on account of the necessity of brain protection as well as for cosmetic reasons. The aim of this study was to evaluate the direct and distant outcome after polypropylene-polyester Codubix® prosthesis implantation. This research was based on the analysis of 41 patients treated surgically in the Department of Neurosurgery at the Jagiellonian University in Cracow between 1995-2004. All patients had the Codubix® prosthesis implanted. The implantation was performed either synchronically or after the surgery which caused the cranial defect.

Directly after the surgery proper healing of the prosthesis could be observed in all patients. The exception was one patient who died directly after the surgery but the cause of his death was not connected with the prosthesis implantation. Seven patients (17.1%) had the temperature temporarily elevated. Three had haematoma collection in the subgaleal space, one (2.4%) developed meningitis which was successfully treated with antibiotics, one (2.4%) suffered from temporary circulation disturbances of the scalp.

The late evaluation was performed with help of a questionnaire to which 30 patients (73.2%) responded. The answer ranged 73.2% (30 patients). In this group 16 patients (53.4%) described the cosmetic effect as very good, 10 patients (33%) as good and 4 (13.3%) as unsatisfactory. The commonest reason for the critical note was the depression of the plate which happened to 3 patients. The other 3 patients complained about inappropriate profile of the plate causing the asymmetry of the cranial vault. Seven patients felt temporary pain in the postoperative scar, in one case the pain was took as the friction between the prosthesis and bone margin.

Properly performed implantation of accurate bone prosthesis Codubix® is safe and usually brings a good cosmetic effect. Direct complications are transitional and occur in the small percent of cases. Distant examinations show generally good therapeutic results but implanted Codubix® requires suitable shape and careful fixation.

Key words: cranial defect, cranioplasty, Codubix® prosthesis

INTRODUCTION

A number of neurosurgical operations requires the removal of various sizes of skull fragments. During the operation accompanied by swelling of the brain, it is decided not to restore the bone flap with or without opening the dura mater, to leave the decompression. In some - rare with modern capabilities neuroanaesthesia cases - the restoration of the bone flap is not possible due to the swollen brain pushed beyond the opening. In case of some intracranial tumours which, by their growth lead to the destruction of bone tissue, the defect results from the need to remove the damaged tissue. In neurosurgical practice for many years supplements of bone defects of different materials have been used: autologous bone grafts, metal plates, artificial materials and biomaterials [1-3].

The perfect material for cranioplasty should combine features of easy availability, low manufacturing costs, ease of implantation, possibility to adjust to the natural curvature of the skull. It should not cause

any local and systemic reaction to a foreign body. Apart from giving the desired cosmetic effect, the prosthesis should be also provide mechanical and safety functions, protecting the intracranial structures against potential damage [4].

In this study - based on ten-year experience – the early and late treatment results in neurosurgical patients with bone defects of the skull cap using the Codubix® prosthesis were presented.

MATERIAL AND METHOD

The analysis included 41 patients treated in the Department of Neurosurgery, Jagiellonian University from January 1995 to October 2004 who underwent the implantation of the Codubix® skull bone prosthesis. In this group there were 22 women and 19 men, ranging in ages from 17 to 79 years (average of 46.8). The reason for using the material Codubix®, was to fill the bone defect and restore the anatomical shape of the head. Primary causes leading to the formation of the skull cavity are shown in Table 1.

In most cases, the direct cause for not restoring the bone flap during the operation, was developing or threatening cerebral oedema. The bone was removed also in cases of tumours infiltrating and destroying the skullcap such as meningioma, osteoma and lipoma. In one case of the meningioma surgery due to suppuration of the wound, it was decided to remove the bone flap 23 days after surgery. The surgical access determined the place of opening and the skill bone loss. Table 2 summarises the cranial area, in which intervention was performed.

In patients operated on tumours with bone destruction, plastic surgery was performed at the same time. In remote mode a prosthetic arthroplasty was usually performed within the first year after the initial surgery. The time between the operations was on average 11.1 months. In individual cases, the prosthesis was implanted after 3, 6 and 14 years after the removal of the bone flap.

All prosthetic procedures performed in remote mode were planned operations. Before the surgery the patients were examined neurologically and consulted internistically. All patients underwent computed tomography of the head locating the place for craniotomy. The patients were informed about the potential benefits and risks resulting from the plastic surgery.

The implantation of the Codubix® prosthesis was performed under general anaesthesia. The skin incision was performed on the scar track from the first procedure. Then the tendinous galea was dissected from the periosteum, and the periosteum from the synechia with the dura mater, if it was possible. The free bone edge was also exposed. Then, the prosthesis was adjusted with a pair of scissors. Holes were drilled in the bone and the prosthesis and sewn tightly to the free edge of the craniotomy bone. Locally in patients antibiotic "in the substantia". was given. The coats were sewn back in layers. In the immediate postoperative period, 5 of 31 patients used antibiotic administered intravenously, following the generally accepted indications.

Condition of the patients was assessed immediately after the procedure and in remote time. A survey was sent to obtain answers from 30 patients (73.2%). The questionnaire is presented in Figure 1.

RESULTS

Intraoperative course in all the operated patients was not complicated. Immediately after the neurological examination, there was no deterioration in patients' health. For several days after surgery in 7 patients increased body temperature was observed (above 38°C), which gave up after the application of antibiotics. In the immediate period after the operation in 4 cases swelling of the skin flap was observed - compresses of aluminium acetate were topically applied. In 3 patients hematoma

fluid was located under the skin-galea flap, requiring the evacuation by puncture. In the course of wound healing in one patient with anaemia blood flow disturbances in the flap skin were observed in the form of bruises, which resolved after the initiation of a therapy improving the blood flow (Nicergoline). In one case cerebrospinal meningitis was diagnosed on the basis of clinical symptoms and a lumbar puncture. General examination of the cerebrospinal fluid indicated a bacterial infection, but bacteriological examination did not confirm this suspicion. After antibiotics were dosed relief of the symptoms and the normalisation of cerebrospinal fluid was observed. In two patients inflammation in the leg veins was observed. They were treated with low molecular weight heparin with good effect.

Part of the complications after simultaneous surgeries was not associated with the implantation of the bone graft, but the nature of the primary surgery. In one patient, who underwent the removal of the frontoparietal meningioma combined with cranioplasty, there has been an accumulation of fluid under the cerebrospinal flap. Removal of the cerebrospinal fluid by lumbar puncture and flap puncture allowed the postoperative wound to heal. In patient operated on because of the left parietal bone osteoma on the fifth day after the tumour removal and implantation of the prosthesis, speech disorders with aphasia appeared. The CT scans revealed swollen left hemisphere of the brain. After applying the anti-oedematous treatment the speech disorders resolved within a few hours. In one case of a surgery of removing a huge convexity meningioma combined with cranioplasty, the patient died twelve hours after the surgery due to failure of the systemic circulation.

35 patients were discharged from the ward within the first week after the surgery. 5 patients left the department in the second week. Summary of direct complications after the cranioplasty is presented in Table 3. Late assessment of the treatment was obtained from 30 patients. Evaluation of the cosmetic effect of the surgery is shown in Table 4.

The main reason for the unsatisfactory effect was the plate collapsing after a few months from the operation, which occurred in 3 patients. One patient evaluated the effect as insufficient, and two as good due to the wrong profile of the Codubix® plates, causing asymmetry of the skull vault.

Seven patients reported the occurrence of persistent pain in the scar site, including one patient also feeling the friction between the prosthesis and the bone. Four patients complained of headaches occurring due to changes in weather conditions (variations in atmospheric pressure). Sensory disturbances characterised by paresthesia and hypoesthesia occurred in the operated area in 4 patients. Long-term complications of arthroplasty are shown in Table 5. In two patients operated primarily on meningioma the prosthesis had to be removed due to renewal of the tumour, respectively after 26 and 32 months after its implantation.

DISCUSSION

Literature describes the so-called trepanned syndrome characterised by headaches, dizziness, fatigability, decreased mood, increased sensitivity to vibration, discomfort over the bone rim [1,5]. In the tested study group, there were no such symptoms observed. However, the indications for surgery were clear, protecting the brain against possible injury and improving the cosmetic effect for the patient. Of particular importance was to fill defects in the frontal and temporal part of the skull. Defects in this region lead to significant irregularities in the facial skeleton, which may result in significant chronic discomfort, neurotic symptoms, even in extreme cases in mental disorders [1].

The early and late results show high usefulness of the Codubix® prosthesis in cranioplasty. The results do not differ from those presented by other authors for the same plastic material [6]. In our material immediately after the surgery the criterion for evaluation was the number and the nature of post-operative complications, but some patients had angioplasty performed during the same operation. In

these cases some complications (death due to heart failure, transient aphasia, cerebrospinal fluid accumulating under the skin-galea flap) need to be referred to the effects of the primary operation, rather than of the implantation of the prosthesis.

The lack of inflammatory and suppurative complications shows the safety of this type of prosthesis implantation. Only in one patient clinical symptoms of cerebrospinal meningitis of a non-serious nature were developed, but without any infectious pathogen.

Cosmetic results were evaluated within the late period after healing in of the prosthesis. A total of 86.7% of good and very good results came from patients who responded to the sent questionnaire. Overall, the positive results of the treatment confirm good quality of the material the prosthesis is made of, and a good ability to accurately adjust the prosthesis to the defect cavity, which allows for restoring natural skull curves. The Codubix® prosthesis combines all the best features of biomaterials used in cranioplasty, eliminating their negative features that might increase the risk of surgery. Characterised by high biocompatibility acquired by combining the technologies used for the preparation of other proven biomaterials. It is made of non-resorbable polyester and polypropylene yarn. The polyester yarn is responsible for the strength and resistance to bending and compression as well as for porosity. The polypropylene yarn which has low basis weight and a low melting point, gives the prosthesis adequate stiffness and hardness. Furthermore, Codubix® has excellent immunological characteristics, high resistance to bending strength, low weight, similar to the bone thermal conductivity, porosity, density, and zero absorption of hydrophilic liquids (water, blood, etc.). It is chemically inactive and resistant to low and high temperatures. Despite the high porosity it is resistant to infections, can be relatively easily modelled during the implantation and allows for further diagnostic imaging, without giving artifacts in computed tomography and magnetic resonance imaging (Fig. 2 and 3) [7,8]. The prosthesis is manufactured in several sizes with different curvatures. You can use the Codubix® plates in large cavities exceeding 100 cm^2 [9]. The Codubix® prosthesis was used in complex bone defects of the orbital area [10].

The unsatisfactory cosmetic effect was associated mostly with the collapse of the plate inside of the defect cavity. The reason for this is probably not sufficient fixation of the prosthesis with bone sutures or too small size of the plate. The same mechanism is probably responsible for the pain, due to friction between the edge of the bone and the prosthesis. Therefore, greater attention should be paid to the selection of the correct size and the shape of the prosthesis, its proper cutting and correct fixing.

Based on our own experience and experience of other authors it can be claimed that - as is the case of implants made of other materials – cranioplasty by means of Codubix® is safe in all areas. The operation in the area of open frontal sinuses may cause suppurative complications, and poor adjustment around the supraorbital may result in marginal necrosis of the skin [11].

CONCLUSIONS

1. Cranioplasty by means of the Codubix® prosthesis is a safe way to treat skull defects.
2. The cosmetic effect in patients after Codubix® implantation is generally good or very good. However, close attention needs to be paid to the selection of an appropriate curvature and size of the prosthesis and its proper fix.
3. Implantation of the Codubix® prosthesis can be performed directly in the first operation, if the operating conditions allow for it, or in a distant time.

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Table 1. Reasons of cranial defects

Original cause	Number of patients
Meningiomas	15 (36.5%)
Brain aneurysm	8 (19.5%)
Spontaneous intracerebral hematoma	3 (7.3%)
Osteoma convexity	3 (7.3%)
Arterio-venous angioma	1 (2.4%)
Intracerebral abscess	1 (2.4%)
Subdural empyema	1 (2.4%)
Traumatic epidural hematoma	1 (2.4%)
Traumatic subdural hematoma	1 (2.4%)
Traumatic subdural hematoma over and	1 (2.4%)
Astrocytoma	1 (2.4%)
Hemangioblastoma	1 (2.4%)
Subdural hygroma	1 (2.4%)
Lipoma in the scalp	1 (2.4%)
Hemangiopericytoma	1 (2.4%)
Metastatic tumour	1 (2.4%)
Total	41 (100%)

Table 2. Localisation of cranial defect

Defect area	Number of patients
Fronto-temporal	13 (31.7%)
Parietal	7 (17%)
One-side frontal	5 (12.1%)
Two-side frontal	4 (9.7%)
Fronto-parietal-temporal	4 (9.7%)
Parietal-occipital	4 (9.7%)
Fronto-parietal	2 (4.8%)
Parietal-temporal	1 (2.4%)
Temporal	1 (2.4%)
Total	41 (100%)

Table 3. Direct complications after surgery

Complication	Number of patients
Increase in body temperature (over 38°C)	7 (17%)
Swelling of the skin flap	4 (9.7%)
Subgaleal haematoma	3 (7.3%)
Ischemia of the skin flap	1 (2.4%)
Inflammation of the meninges	1 (2.4%)
CSF leak from the wound	1 (2.4%)
Transient aphasia	1 (2.4%)
Death	1 (2.4%)
Lower leg vein inflammation	2 (4.8%)
Total	41 (100%)

Table 4. Cosmetic effects of cranioplasty

Cosmetic effects	Number of patients
Very good	16 (53.4%)
Good	10 (33.3%)
Unsatisfactory	4 (13.3%)
Total	30 (100%)

Table 5. Late complications after implantation of Codubix® prosthesis

Complication	Number of patients
Pain in the scar	7 (23.4%)
Weather associated pain	4 (13.3%)
Paraesthesia	4 (13.3%)
Collapsed plate	3 (10%)
Improper profile	3 (10%)
Friction of the prosthesis	1 (3%)
Total	30 (100%)

Fig. 1. The example of the questionnaire is sent to patients

Dear Sir or Madam,
In view of the history of your surgery in the Department of Neurosurgery in Krakow you are kindly requested to complete and return the attached questionnaire.
In the envelope you will find a return envelope with a stamp.
We count on your answers, because only survey sent by all the operated patients allow for a comprehensive evaluation of the results of the treatment.
The questions concern the plastic surgery to fill a skull bone defect.
Please select the correct answer:

1. Was it worth to be re-operated in order to complete the bone defect?

1) YES
2) NO

2. How do you assess the cosmetic effect of the surgery to fill the skull bone defect?

1) VERY GOOD
2) GOOD
3) UNSATISFACTORY

3. Have you observed any irregularities in the healing of the head wound?

1) YES
2) NO
If yes, please write what kind of:
.....

4. Do you feel you any headache around the scar?

1) YES
2) NO
If yes, please describe the severity and nature of the pain:
.....

5. Do you feel you numbness or tingling around the scar?

1) YES
2) NO
If yes, please describe the nature and severity of these symptoms:
.....

6. Other comments on the effect of the treatment:

.....

Name and surname:

Thank you for answering the above questions. The gathered knowledge will serve to improve the care of the patients suffering from similar ailments.
Yours sincerely,

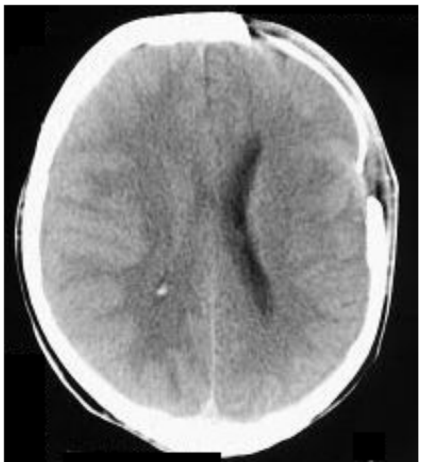

Fig. 2. Computed tomography of the head. State after evacuation of the epidural haematoma and removal of the bone fragment.

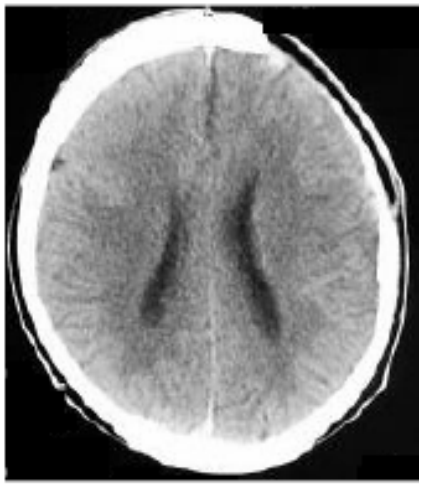

Fig. 3. State after Codubix® implantation.