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# RESECTION OF TUMORS OF THE CRANIAL BONES WITH SINGLE-STEP DEFECT RECONSTRUCTION USING A PERSONALIZED IMPLANT

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**Background.** In patients with skull bone tumors, it was demonstrated that not only the oncological but also the cosmetic result has a significant influence on the long-term outcome. The traditional approach to the surgical treatment of tumor lesions of the skull bones is removal of the tumor and intraoperative modeling an artificial bone flap without a template. Recently, the technology of simultaneous resection and computer-aided design/computer-aided manufacturing (CAD/CAM) cranioplasty has received more and more attention.
**Aim.** To compare the results of surgical treatment of patients with tumors of the cranial bones using the traditional approach (intraoperative formation of a plate to close the defect) and simultaneous resection followed by plastic surgery of the defect with a personalized implant made using preoperative virtual modeling.
**Materials and methods.** The study included 24 patients with tumors of the skull or meningiomas with extracranial growth. Depending on the surgical procedure, patients were divided into 2 groups: group 1 ($n = 13$) – the technology of simultaneous resection and CAD/CAM cranioplasty; group 2 ($n = 11$) – where surgery was performed using a traditional approach based on intraoperative modeling an artificial bone flap without a template.
**Results.** There were no statistically significant differences between groups in gender, age, time of surgery, blood loss, or time in hospital. The use of simultaneous resection and CAD/CAM cranioplasty did not demonstrate a statistically significant better result in terms of maintaining skull symmetry compared to the traditional approach. All patients had a good cosmetic result and there were no complications.
**Conclusion.** The technology of simultaneous resection and CAD/CAM cranioplasty is an effective method of treating patients with neoplasmas of the skull bones. Despite the absence of statistically significant differences in the results of treatment of cranial bone tumors between this method and the traditional approach based on intraoperative modeling an artificial bone flap without a template this method seems to be a more precise providing the best cosmetic effect in patients with lesion in fronto-orbital region.

**Keywords:** CAD/CAM, cosmetic outcome, drilling template, single-step resection and reconstruction, skull bone tumors, titanium cranioplasty, custom-made implants, skull reconstruction

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## INTRODUCTION

In patients with skull bone tumors, it was demonstrated that not only the oncological but also the cosmetic result has a significant influence on the long-term outcome of treatment [1, 2]. The functional and esthetic results of an operative intervention particularly matter when the facial skeleton bones are affected, where restoring the congruence of the skull presents a challenge [3, 4].

The traditional approach to the surgical treatment of tumor lesions of the skull bones is to remove the tumor and perform a single-step reconstruction of the arising defect with intraoperative modeling with autologous bone transplants, titanium, or other synthetic materials [5]. Another option is two-stage operative treatment, first removing the tumor and then reconstructing of the skull defect with a priorly produced implant [6]. However, choosing the two-stage approach requires an individual assessment of the risks of complications involving repeat surgeries to achieve the best cosmetic effect possible.

To make the surgical resection more radical and achieve the optimum congruence of the skull, preoperative virtual planning and intraoperative navigation may be used [4, 5, 7, 8].

There has been an increasing number of publications presenting the results of single-step resection of bone tumors and skull defect reconstruction with an individual implant, based on virtual planning of resection margins [5, 9–11].

**The aim of the study** is to compare the results of surgical treatment of patients with skull bone tumors using the traditional approach (intraoperative formation of a plate to close the defect) and single-step resection followed by reconstruction of the defect with a personalized implant produced using preoperative virtual modeling.

## MATERIALS AND METHODS

**Patients.** The study included 24 patients (7 men and 17 women) with neoplasms of the skull bones or of meninges with extracranial growth. The median age of the patients was 45 years (ranging from 24 to 82 years). The criterion for inclusion into the study was whether the patient had a tumor affecting the skull bones, which was removed followed by a single-step restoration of the arising defect.

Since the sample contained a wide range of pathologies, the indications for operation depending on the particular clinical situation were as follows: (1) the presence of a substantial cosmetic defect; (2) progressing tumor growth; (3) (in the event of tumor invasion into the cavity of the skull) the presence of brain edema and neurological symptoms; (4) the necessity to verify the process.

All patients underwent single-step tumor removal and skull defect closing. Depending on the method of operative intervention, the patients were divided into two groups: group 1, preoperative planning of the bone resection area and producing individual implants to restore the defect; group 2, operative intervention using the traditional approach with intraoperative formation of a plate to close the skull defect. The characteristic features of the surgical intervention chosen were discussed with each patient individually, and voluntary informed consent for operation was obtained.

**Preoperative planning of the resection area and producing an individual implant for cranioplasty.** Planning a single-step resection and restoration of the defect with an individual implant was performed in several stages in cooperation with experts from the manufacturing companies LOGEEKS DM (Logeks, LLC, Novosibirsk, Russia), ITK Endoprint, LLC (Moscow, Russia), and ICONLAB (IconLab GmbH, Nizhny Novgorod, Russia).

In the first stage, the tumor resection margins are marked by the operating surgeon based on 0.5-mm computed tomography slices (Fig. 1, *a2, a3*). Then the plate is virtually modeled and the obtained computer image is processed and optimized, and the surface is prepared for further work. After the preparation is completed, the line of the forthcoming resection and the edges of the future plate are marked, based on the defect (Fig. 1, *b1*). As the next step, the anatomical shape of the missing bone part is created, based on the healthy left side of the patient's skull (Fig. 1, *b2*). Subsequently, the surface is brought to the required thickness, which will become that of the final plate (Fig. 1, *b3*). The thickness is chosen with a safety margin, so that it would fit the skull in the best possible way after the skull model is cut out of the prepared plate. In the next stage, the interim result obtained is used to build a 3D grid to make the structure lighter and ensure better tissue integration with the surface of the plate. In the last design stage, the skull model is cut out of the plate model (Fig. 1, *c1, c2*). From then on, it is all based on templates. The resection template is prepared based on the actual defect, namely the resected area (Fig. 1, *c3*). Models of the skull and resected area are produced to be used as templates for preoperative modeling (Fig. 1, *d1–d3*). Producing the titanium plate involves the stages of DMLS growth, sanding, ultrasonic washing, and disinfection.

**Operative intervention.** The operation for group 1 patients followed all the stages of the virtually modeled operative intervention (Fig. 2).

The operative intervention takes place under general anesthesia according to the preoperative virtual plan. After selecting the skull surface with the neoplasm, the template is installed and the osteotomy line is drawn on its edges (see Fig. 2, *b2, b3*). Then osteotomy is performed along the line and the tumor is removed within the healthy bone (see Fig. 2, *b4*). Then the implant is installed on the skull defect area and fixated with screws (see Fig. 2, *b5*).

The operative intervention for group 2 patients was performed using the traditional technology, with the plate to close the skull defect being modeled intraoperatively (see Fig. 2, *c2–c4*).

Another example of using the preoperative planning of the resection area and producing an individual implant is presented in Fig. 3.

**Group comparison parameters.** Retrospective analysis was used to compare the groups by duration of hospitalization, plate installation time, intraoperative blood loss volume, and the presence of postoperative complications. The data from multispiral computed tomography (MSCT) were analyzed in the software Vidar Dicom Viewer 3.1 to assess the defect area and cranial index of symmetry (CIS) [12, 13].

**Statistical data processing.** The data were calculated and analyzed using the software Statistica 10.0 (StatSoft Inc., USA) and statistically processed using the $\chi^2$-test with Yates's correction, Man –Whitney U test, and Pearson's $\chi^2$ test. Considering the non-normal distribution of the data obtained, the indicators are calculated and presented as medians as well as 25th and 75th percentiles (Me [$Q_1$; $Q_2$]). Statistically significant differences were considered those with $p < 0.05$.

## RESULTS

**Comparability of groups.** The general characteristics of patients in both groups is shown in Table 1. The median age of the patients in group 1 was 39 years; in group 2, 49 years ($p = 0.29$). There was no statistical difference in the men/women ratio between the two groups. The groups also

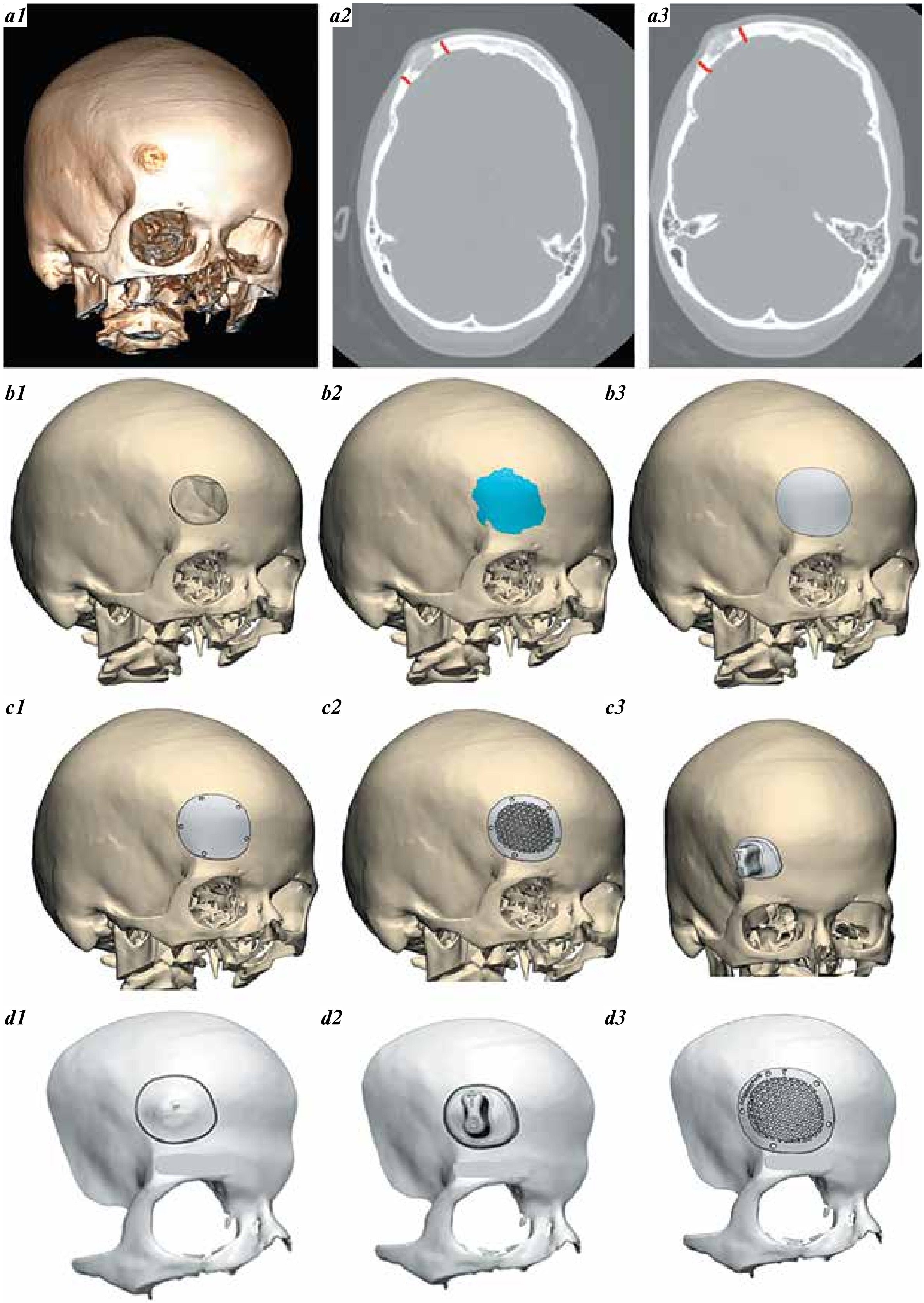


**Fig. 1.** *Preoperative modeling of single-step bone tumor resection and reconstruction of the formed defect based on the surgeon's planning of resection margins (a1–a3); 3D modeling of tumor resection area and anatomical shape of the resected part of the bone (b1–b3); 3D modeling of the implant, fixation points and resection template (c1–c3); preoperative planning templates (d1–d3)*

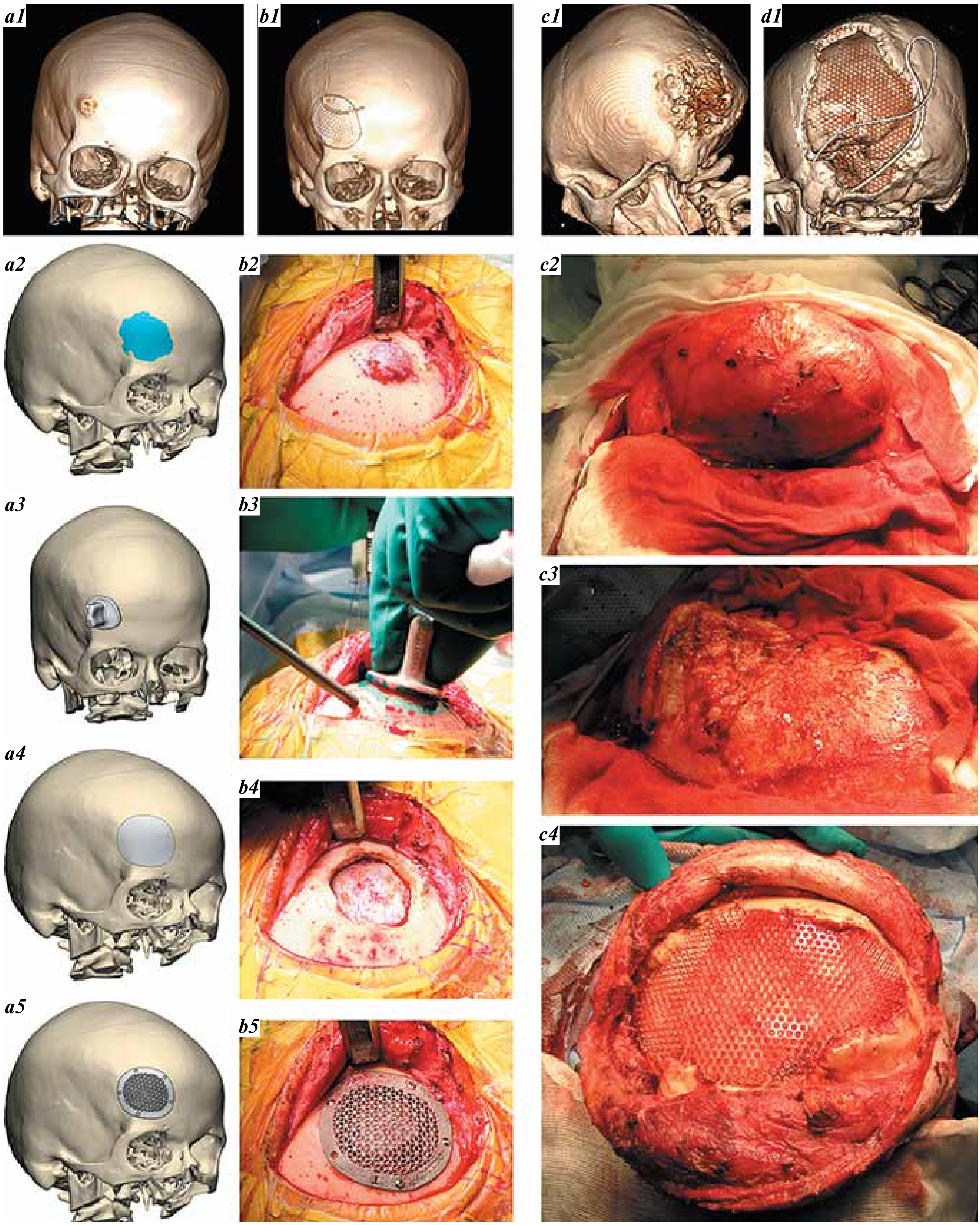


**Fig. 2.** *Resection of cranial bone tumors (a–d) with single-step defect reconstruction using preoperative modeling based on additive technologies (b2–b4) and traditional approach (c2–c4). The female patient, 40 years, with tumor of the frontal bone (a1) underwent single-step surgery with resection and bone defect reconstruction using a titanium implant (b2–b5) in accordance with preoperative virtual planning of resection margins (a2–a5) using osteotomy template (b3) and simultaneous cranioplasty (b5). The male patient, 51 years, with giant adamantinoma of the occipital bone (c1) underwent single-step tumor resection and defect reconstruction using the Reperen material (c2–c4)*

turned out to be compatible in regard to the histological structure of the bone-affecting neoplasms, with the meningioma, hemangioma, and osteoma being the most common. The vast majority of the patients had cranioplasty performed using titanium plates, though both groups contained patients with the skull defect reconstruction performed with polymer materials Rekost® (group 1) and Reperen® (group 2) by IconLab GmbH, LLC, Russia.

**Results of operative interventions.** According to MSCT, both groups were comparable in terms of the defect area. Using preoperative 3D modeling did not demonstrate a statistically significant better result in terms of maintaining skull symmetry compared to the traditional approach (Table 2).

The position of implants in group 1 patients corresponded to the preoperative planning in every case. No revision operative interventions were performed. No additional intraoperative modeling of the implant was required in most of the cases, except for one patient, in whom it was performed with the supraorbital nerve branches preserved. In the event of extensive fibrous dysplasia, it was impossible to use the template due to the shape and size of resection.

In groups 1 and 2 patients, the plates were fixated on 3 [3; 4] and 4 [4; 6] points respectively ($p = 0.12$) (Table 3). The total operating time was not marked by a statistically significant difference in the two groups, amounting to 85 minutes in group 1 and 115 min in group 2 ($p = 0.87$) (see Table 3). The intraoperative blood loss did not differ between the groups and would not exceed 450 ml.

The groups did not differ significantly as to the duration of inpatient hospitalization: 5 [4; 7] postoperative bed-days in group 1 and 4.5 [4; 8] in group 2 ($p = 0,94$).

Good cosmetic results were achieved in all patients. There were no complications.

**Таблица 1.** *Общая характеристика пациентов*

**Table 1.** *General characteristics of patients*

| Characteristic | Group 1 (*n* = 13) | Group 2 (*n* = 11) | *p* |
|---|---|---|---|
| Gender distribution, *n*: | | | |
| men | 2 | 5 | 0.12*; |
| women | 11 | 6 | 0.24* |
| Age, Me [Q1; Q2], years | 40 [35; 61] | 49 [39; 61] | 0.4** |
| Histological type of the tumor, *n*: | | | 0.71*** |
| meningioma | 4 | 3 | |
| hemangioma | 3 | 2 | |
| osteoma | 3 | 3 | |
| eosinophilic granuloma | 0 | 1 | |
| metastasis | 1 | 1 | |
| cholesteatoma | 1 | 0 | |
| hondroblastoma | 1 | 0 | |
| fibrous dysplasia | 1 | 0 | |
| neurinoma | 0 | 1 | |
| adamantinoma | 0 | 1 | |
| Affected area, *n*: | | | |
| facial skeleton | 8 | 4 | 0.2***; |
| outside of facial skeleton | 5 | 7 | 0.41*** |
| Affected side, *n*: | | | 0.2*** |
| left | 5 | 5 | |
| right | 8 | 4 | |
| medial | 0 | 2 | |
| Implant material, *n*: | | | |
| titanium | 12 | 7 | 0.11*; |
| polymer | 1 | 4 | 0.22* |

**Fisher's exact test and $\chi^2$-test with Yates's correction; **Mann–Whitney' U-test; ***Pearson's $\chi^2$-test.*
***Note.** Here and in table 2, 3: Me – median; [Q1; Q2] – 25th and 75th percentiles.*

## DISCUSSION

The technology of reconstruction of extensive and complicated skull defects using individual implants produced with computer modeling is the most promising field in neurosurgery and maxillofacial surgery [14–17]. Because of its optimum functional and cosmetic results, it is the first-choice technology in clinical practice as compared to the traditional approach based on intraoperative modeling of the implant. Single-step bone tumor resection and skull defect reconstruction with an individual implant based on virtual planning of resection margins should also be considered the most promising approach for skull bone tumors, especially in the facial skeleton.

Such operations for bone tumor resections with single-step cranioplasty using a preproduced template have been described in the literature as exemplified by patients with fibrous dysplasia and meningiomas with extracranial growth [9–11, 18]. This method appears more convenient for use in routine clinical practice, as compared to the traditional intraoperative modeling of the implant without a template [1, 19] or with a stereolithographic model [20].

This study did not reveal any statistically significant differences in terms of achieving the congruence of the skull shape. However, we did not remove any skull bone tumors with immediate intraoperative modeling of implants in patients with neoplasms in the facial skeleton if there was a high risk of pronounced cosmetic defect. Thus, the results of this study show that no individual implant is required in most cases of resecting skullcap bones, since the standard titanium plate is fairly easy to adjust to a specific defect. However, when removing tumors in the facial skull, using the preoperative modeling of the individual implant and resection with a template appears more preferable to achieve the optimum cosmetic effect. In this light, this technology constitutes a uniform approach to the removal of skull bone neoplasms, whatever the localization of the focus. It should also be noted that using a template to define the bone resection margins cannot substitute navigation systems, in particular when there is no extracranial component of the tumor and/or it is poorly visualized [8, 21]. The two technologies complement each other in defining the tumor margins [7].

In our study, both groups turned out to be comparable in terms of the intraoperative blood volume loss, duration

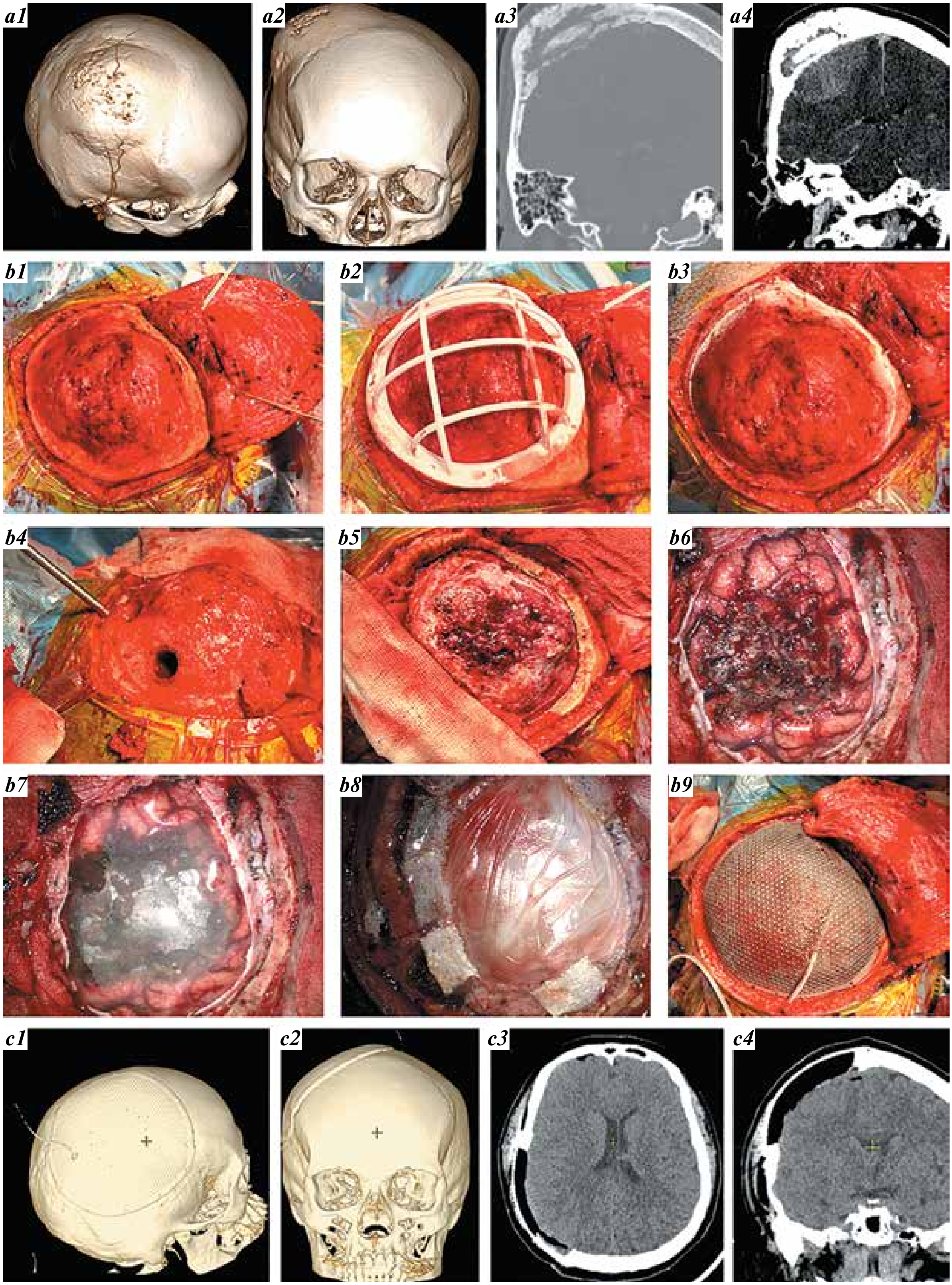


**Fig. 3.** *Resection of giant hyperstatic meningioma of the right parietal bone and extra- and intracranial growth (a1–a4 , b1) with single-step defect reconstruction using preoperative 3D modeling (c1–c4). At the extracranial stage, craniotomy margins (b3) were marked on the preoperative resection template (b2), then craniotomy was performed using several burr holes (b4, b5). Under surgical microscope, resection of the intracranial tumor component (b5) tightly intertwined with the surrounding brain tissue (b6) was performed. At the final stage, after installation of subdural membrane for prevention of scarring process (b7), combination reconstruction of the dura mater using an implant, fibrinogen/thrombin sponge and fibrin glue (b8) was performed. Then the defect was reconstructed using the titanium plate manufactured at the preoperative stage (b9)*

**Table 2.** *Analysis of multispiral computed tomography data, Me [Q1; Q2]*

| Indicator | Group 1 ($n$ = 13) | Group 2 ($n$ = 11) | $p$ |
|---|---|---|---|
| Defect area, cm$^2$ | 7.6 [5.9; 8.3] | 7.7 [2.6; 20.2] | 0.9* |
| Cranial index of symmetry, % | 97.8 [96.5; 98.4] | 97.7 [96.8; 98.4] | 0.93* |

**Mann–Whitney' U-test.*

**Table 3.** *Intraoperative data. Me [Q1; Q2]*

| Indicator | Group 1 ($n$ = 13) | Group 2 ($n$ = 11) | $p$ |
|---|---|---|---|
| Blood loss volume, mL | 100 [50; 250] | 125 [50; 150] | 0.48* |
| Number of fixation points | 4 [3; 7] | 4 [4; 6] | 0.4* |
| Operative time, min | 180 [75; 310] | 115 [55; 180] | 0.51* |

**Mann–Whitney' U-test.*

of operative intervention, and duration of postoperative inpatient stay. Besides, no patients in either group had any postoperative complications. Despite the comparability, the technology of modeling according to the preoperatively produced template and producing an individual implant can be said to have a number of advantages compared to the traditional methods. More precisely, it takes less time and material resources at the preoperative preparation stage, since the modeling takes place virtually and not physically; and it also requires shorter operation time, since using a template helps increase the speed and precision of the resection stage, while the cranioplasty stage takes less time since the plate does not need to be modeled during the operation [3].

Various alloplastic materials are used for cranioplasty, such as hydroxyapatite, polymethyl methacrylate, polyetheretherketone, titanium, as well as other materials currently in active development [17, 22–24]. Each one of these has its advantages and disadvantages as well as certain potential biotoxicity, except for hydroxyapatite. Most of the standard materials listed above are suitable to be used in preoperative computer modeling [25]. This study featured titanium as the main material for reconstruction, since it can close the defect area most completely and allows for intraoperative correction of the bone resection size. Also, in the case of kidney cancer metastasis, the defect was reconstructed with the bone substitute material Rekost-M, leading to a good result, corresponding to the examples described above where polymer materials were used successfully for single-step tumor resection and reconstruction [11, 26].

When the skull bones are affected by a tumor, the choice of material for reconstruction may be an important point in light of radiation therapy that may potentially be needed later. Titanium is the optimum material for single-step tumor removal with defect reconstruction for benign tumors. This technology can be used for surgical resection of malignant tumors as well [27], but as titanium reflects radiation intensely, the risk of developing radiation ulcers in the soft tissues of the head increases [28]. As to malignant tumors, it should also be noted that it is necessary to minimize the time between computed tomography and producing a template, considering the rapid invasive growth of such tumors.

Our study was limited to a small patient sample, since tumors affecting the skull are fairly rare. Hence there is no consensus whether a single-step reconstructive operation using preoperative computer modeling of an individual implant is imperatively necessary. There are numerous tailored approaches to modeling and producing the implant and to choosing the material for the plate. The problem unresolved as yet is the absence of a universal system of assessing cosmetic results, with most of the analysis dedicated to patient satisfaction with the cosmetic results of the operation.

## CONCLUSION

The technology of single-step bone tumor resection and skull defect reconstruction with an individual implant based on virtual planning of resection margins is an effective method of treating patients with neoplasms of the skull bones. Even though there are no statistically significant differences in the results of treatment of skull bone tumors between this method and the traditional approach based on intraoperative plate modeling, the virtual modeling of the operation with producing an individual implant appears to be more precise, providing the best cosmetic effect in operative interventions in the facial skeleton.

The present-day field of treating skull bone tumors offers many tailored solutions for single-step removal of tumors and skull defect reconstruction, providing good oncological and esthetic results to some extent. However, most of the research results come down to descriptions of single cases or case series. Further research involving more patients is needed to standardize the method described.

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**Authors contributions**

K.S. Yashin: development of the concept and design of the study, obtaining data for analysis, analysis of the data obtained, review of publications on the topic of the article, article writing;
R.D. Zinatullin: obtaining data for analysis, forming a final database;
I.S. Bratsev: development of an analysis methodology, analysis of the data obtained;
D.V. Dubrovskiy: obtaining data for analysis;
A.Yu. Ermolaev, M.V. Ostapyuk: obtaining data for analysis, editing of the article;
M.A. Kutlaeva, M.V. Rasteryaeva: analysis of computed tomography data;
I.A. Medyanik, L.Ya. Kravets: development of the concept and design of the study, editing of the article, approval of the final version of the article for publication.

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