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Area of Expertise: Brain and Nerve Surgery (Neurosurgery)

Title: Contributions of the three-dimensional printer to craniostynostosis surgery.

Short title: Benefits of modelling before craniostynostosis surgery.

Abstract

Purpose: In craniostynostosis surgery, it is essential to reduce the duration of the operation and minimize blood loss. Currently, the use of three-dimensional printers and bioprinters is on the rise, and this article aims to investigate the impact of this technology on craniostynostosis surgery.

Materials and methods: The files of patients who underwent open craniostynostosis surgery were examined. The group without 3D-printed preoperative modeling was designated as Group 1 (5 patients), and the group with 3D-printed preoperative modeling was designated as Group 2 (12 patients). The files of all cases were retrospectively reviewed and compared, focusing on their erythrocyte replacement needs, operation durations, and demographic information.

Results: The average age in the 1st group was 13.70 months, and the average age in the 2nd group was 9.1 months. While the average volume of ES replacement was 190 mL in the first group, it was 142 mL in the second group. The need for erythrocyte replacement was found to be less in cases with 3D-printed preoperative modeling. Additionally, while the mean operation duration was 3.3 hours in the 1st group, it was 2.4 hours in the 2nd group. The average follow-up period in the first group was 2.37 years, and in the second group, it was 2.05 years—no complications developed in any of our cases.

Conclusion: This study demonstrates that preoperative modeling using a three-dimensional printer reduces the duration of surgery and requires less blood transfusions.

Keywords: Craniostynostosis, pediatrics, surgery.

Makale başlığı: Üç boyutlu yazıcının kraniyosinostoz cerrahisine katkıları.

Kısa başlık: Kraniosinostoz cerrahisi öncesi modellemenin faydaları.

Öz

Amaç: Kraniosinostoz ameliyatında ameliyat süresinin kısaltılması ve kan kaybının en aza indirilmesi esastır. Günümüzde üç boyutlu yazıcıların ve biyoyazıcıların kullanımı artıyor ve bu makale bu teknolojinin kraniosinostoz cerrahisindeki etkisini araştırmayı amaçlıyor.

Gereç ve yöntem: Açık kraniosinostoz ameliyatı geçiren hastaların dosyaları incelendi. 3D baskılı preoperatif modellemenin yapılmadığı grup Grup 1 (5 hasta), 3D baskılı preoperatif modellemenin yapıldığı grup ise Grup 2 (12 hasta) olarak belirlendi. Tüm olguların dosyaları retrospektif olarak incelendi ve eritrosit replasman ihtiyaçları, operasyon süreleri ve demografik bilgileri dikkate alınarak karşılaştırıldı.

Bulgular: 1. grupta yaş ortalaması 13,70 ay, 2. grupta ise yaş ortalaması 9,1 ay oldu. Ortalama ES replasman hacmi birinci grupta 190 mL iken, ikinci grupta 142 mL idi. Ameliyat öncesi 3D baskılı modelleme yapılan olgularda eritrosit replasman ihtiyacının daha az olduğu görüldü. Ayrıca ortalama ameliyat süresi 1. grupta 3,3 saat iken 2. grupta 2,4 saattir. Birinci grupta ortalama takip süresi 2,37 yıl, ikinci grupta ise 2,05 yıl olup hiçbir olgumuzda komplikasyon gelişmedi.

Sonuç: Bu çalışma, üç boyutlu yazıcı kullanılarak yapılan ameliyat öncesi modellemenin ameliyat süresini kısalttığını ve daha az kan nakli gerektirdiğini göstermektedir.

Anahtar kelimeler: Kraniosinostoz, pediatri, cerrahi.

Introduction

With technological advancements, three-dimensional printers and bioprinter applications are increasingly utilised in the healthcare field. It enables the creation of three-dimensional (3D) models of cranial anatomical structures by reverse engineering applications of data obtained from radiological studies.

3D printers have numerous applications in various medical fields, providing a convenient and cost-effective method for producing cranial models. This technology enables the surgical team to rehearse the procedure on the 3D model preoperatively, thereby enhancing effectiveness during the operation itself.

Craniosynostosis is the premature fusion of the sutures, resulting in head shape anomalies, ophthalmological problems, and neurodevelopmental issues. Treatment of craniosynostosis involves excision of the prematurely fused suture and correction

of associated skull deformities, aiming to promote cranial vault development [1]. Open cranial vault remodeling and endoscope-assisted craniosynostosis surgery techniques are used in craniosynostosis surgery [2]. The patients in this study underwent surgery using the open cranial vault remodeling technique. The preferred timing of surgery is for those under one year of age. This surgery, performed at a young age, is prone to many complications. Rehearsing the surgery on a complete model before the actual procedure can help prevent complications. This study aims to investigate the potential benefits of 3D-printed preoperative modelling in patients who have undergone open craniosynostosis surgery.

Materials and methods

Permission was obtained from the SBÜ Bursa High Specialisation Training and Research Hospital Clinical Research Ethics Committee (date: 13.12.2023 and number: 2011-KAEK-25 2023/12-22), and data from 17 patients who underwent open craniosynostosis surgery were retrospectively evaluated from the medical records.

In this retrospective study, data obtained from patient archives include demographic information, clinical diagnosis, examinations, clinical history, operation duration, erythrocyte suspension (ES) replacement needs, and cosmetic follow-ups of patients. Preoperative planning was conducted for 5 of our patients using 3D modeling and 3D imaging.

The device used for 3D modeling is Ultimaker 3 Extended, which is an FDM-type printer. Nozzle (hot tip) diameter is 0.4 mm, filament diameter is 2.85 mm. The slicing software used is Ultimaker Cura.

Statistical analysis

Mann-Whitney U test and Fisher's Exact test were used to analyse the data. Means and standard deviations are stated for continuous variables, while categorical variables are presented as percentages. Statistical significance was considered significant if $p < 0.05$. THE IBM SPSS 26.0 program was used to analyse the data.

Results

The data from cases operated on using modelling and those operated on without 3D-printed preoperative modeling were compared. The group without 3D-printed preoperative modeling was designated as Group 1, and the group with 3D-printed preoperative modeling was designated as Group 2 (Figures 1 and 2).

The average age in the first group was 12.83 (12.83 ± 12.97) months, and the average age in the second group was 9.20 (9.20 ± 3.49) months. The 2nd group was

found to be a younger age group. The average weight of the cases in the 1st group was 9458.33 (9458.33±3360.59) gr, and the average weight of the cases in the 2nd group was 8100 (8100.00±2073.64) gr. The average weight of the patients in the 2nd group was lower. In the first group, there were six boys and six girls, and in the second group, all cases were boys. The average hospital stay in the first group was 5 days, and the average hospital stay in the second group was 5.6 days (Tables 1, 2, and 3). The types of craniosynostosis seen in patients between group 1 and group 2 were also evaluated. No statistically significant superiority was detected (Table 4).

While the average ES replacement volume was 190.83 mL (190.83±80.53) in the first group, it was 142.00 mL (142.00±44.38) in the second group. The average ES requirement was lower in the patients who underwent 3D-printed preoperative modeling (group 2). Additionally, while the operation duration was 3.3 (3.33±0.98) hours in the 1st group, it was 2.4 (2.40±0.55) hours in the 2nd group. The average operation duration in the second group was found to be shorter (Tables 2, 3).

Although no statistically significant results were obtained between the two groups in the analysis, the Cohen's d value for "Surgery Duration (hours)" fell within the large effect size category, with a value of 1.17, while the "Preoperative + Postoperative Blood Supplementation" variable showed a medium effect size. Although clinically meaningful trends were observed, statistical significance was not reached. Therefore, further studies with a larger sample size are needed.

The average follow-up period in the 1st group was 28.5 (28.50±21.27) months, and in the 2nd group, the average follow-up period was 24.60 (24.60±15.93) months. When the accompanying anomalies were examined, in the first group, two patients had Chiari malformation (16.7%), one patient had Apert Syndrome (8.3%), one patient had Chitayat syndrome (8.3%), two patients had vision loss (16.7%), and one patient had epilepsy (8.3%). Chiari malformation was detected in 1 patient (20.0%) in the 2nd group (Tables 1, 3, 5).

All patients were followed in the postoperative pediatric intensive care unit, and no complications developed in any of our cases.

Discussion

Experience is required to understand complex pathologies such as craniosynostosis. This has created potential opportunities for the application of 3D modeling and printing techniques in the medical field [3].

Three-dimensional rapid prototyping was first described by Kodama et al. [4] in 1981, and its initial application in surgical planning was reported by Anderl et al. [5] in 1994. Past and ongoing advances in medical imaging methods, such as CT and MRI, have driven both the clinical and academic development of 3D rapid prototyping in the medical context.

Many 3D printers and various printing technologies are available to perform three-dimensional printing of anatomical models. A 3D printing technology should be selected based on the structure of the planned models (e.g., bone, muscle, heart), particularly considering size and precision requirements. FDM (Fused Deposition Modelling), SLS (Selective Laser Sintering), and TIJ (Thermal Inkjet Printing) are printer technologies frequently used in the healthcare field [6]. In 40 studies reviewed in the literature, the benefits of its use were reported, particularly in aneurysms, skull base surgery, spinal surgery, craniosynostosis, transsphenoidal surgeries, craniotomies, and tumour surgeries. It has been stated that the majority of these are used in vascular surgeries [7].

Bowen et al. [8] use 3D models as cutting guides to reduce working time. He also states that with 3D modeling, the risk of complications and the need for transfusion are significantly reduced. However, the study did not make a comparison with cases without modeling, and data on operation durations and transfusion needs were not presented [8].

Elbanoby et al. [9] performed 3D printing-guided surgery in the treatment of unicoronal craniosynostosis with orbital dysmorphism, concluding that using 3D models as a guide reduces residual deformity. In our series, we did not have any unicoronal craniosynostosis cases in the modelled group, so we could not compare our results with the authors'.

In another study, three-dimensional models were created in isolated brachycephaly cases. These models enable a more accurate evaluation of 3D images, providing easy and virtual operational planning, which shortens operational time. It has been emphasized that they reduce risks and complications and offer an excellent tool for parental cooperation [10].

Although the use of cadavers has a significant place in assistant training, there are cases where it is not accessible due to its cost. With 3D modelling, models that reveal the pathology of the disease can be created at very low costs, depending on the raw materials used to produce tissue and organ models. Three-dimensional

printers have uses in a wide variety of medical applications and offer an easy and cost-effective way to produce cranial models [11]. As a result, the development of printers and their application in the healthcare field have yielded significant benefits for patients and physicians.

In addition to surgical modelling, 3D modelling has now begun to be used in patient and assistant training [12]. One of the most significant advantages of surgical modelling is that it provides surgeons with a simulation before the procedure, thereby shortening the surgical time. In this context, shortening the duration of anaesthesia offers significant comfort to the patient in the postoperative period. It can help prevent side effects that may develop by reducing exposure to anaesthetic agents. Thus, it provides excellent benefits to both the patient and the surgeon by increasing surgical safety [13, 14]. The craniosynostosis model created using biopolymer enables surgeons to receive realistic tactile feedback when manipulating the patient's bone and to perform major procedures for anatomical correction before surgery [14].

The main limitation of the study is the limited number of patients and insufficient sample size for different types of synostosis. In our study, although clinically significant trends were observed, statistical significance was not reached. Therefore, further studies with larger sample sizes and the same type of craniosynostosis cases are needed.

Another limitation is that since the preparation of the 3D cranial model and the preoperative rehearsal on this created model are time-consuming processes, a significant proportion of the patients with delayed clinical referral miss the opportunity of 3D-modeling-assisted surgery, due to the fact that these patients require urgent surgery before the time window for surgical intervention expires.

To conclude, it was determined that the average surgery duration was shorter and the average volume of ES replacement was less in cases of 3D printer-assisted craniosynostosis surgery compared to cases without 3D-printed preoperative modeling. It is also beneficial in terms of planning the operation. We believe that performing craniosynostosis surgery in the preoperative model will shorten the duration of surgery, thereby reducing the volume of ES replacement. However, due to the previously mentioned limitations, the data obtained from this study are preliminary, and (preferably prospective) multicenter studies with larger sample sizes and standardized protocols are needed in order to achieve more precise conclusions.

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Conflict of interest: The authors declare that they have no conflicts of interest.

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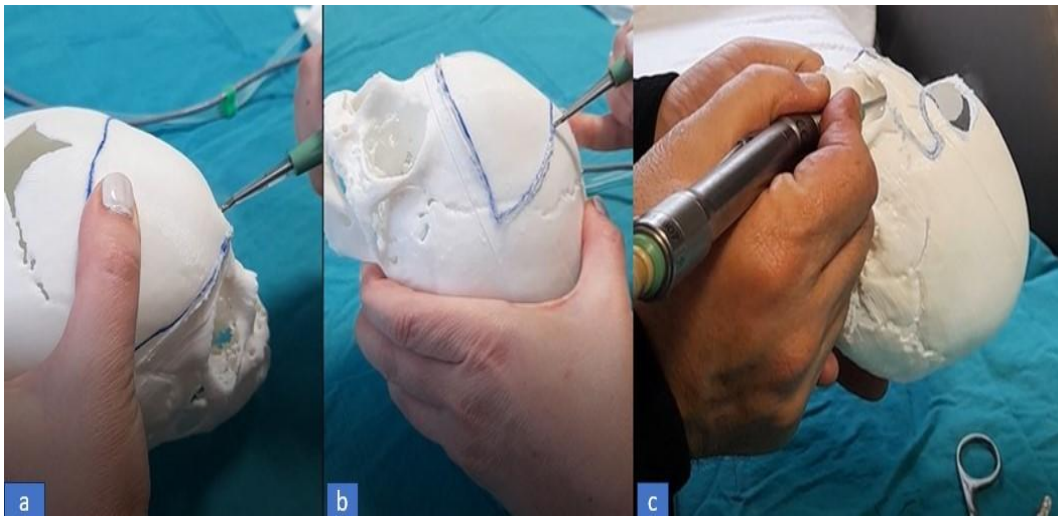
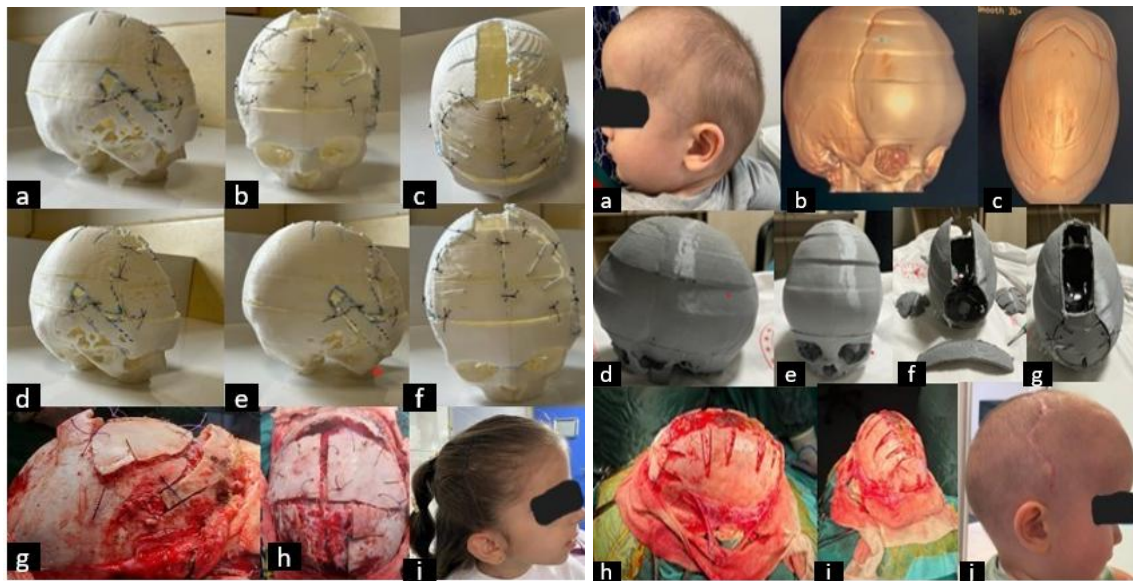


Figure 1. Surgery on 3D-printed preoperative modelling. a, b: bifrontal craniotomy with the help of a bone cutter. c: removing the orbital bar with the help of a bone cutter.



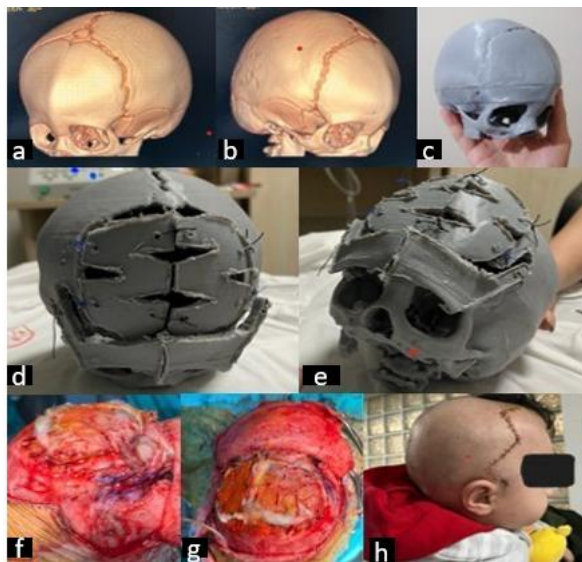
Case1

Case2



Case3

Case4



Case5

Figure 2. Case 1: a,b,c: 3D-printed preoperative models. d,e,f: surgery photos, g,h: photo of the patient at last check-up. Case 2: a,b,c: 3D-printed preoperative models, d,e,f,g,h: surgery on 3D modelling, i: photo of the patient at last check-up. Case 3: a,b,c,d,e,f: surgery on 3D modelling, g,h: surgery photos, i: photo of the patient at last check-up. Case 4: a: preoperative photo, b,c: preoperative 3D CT images, d,e,f,g: surgery on 3D modelling, h, i: surgery photos, j: photo of the patient at last check-up. Case 5: a,b: preoperative 3D CT images, c: 3D-printed preoperative models, d,e: surgery on 3D modelling, f,g: surgery photos, h: photo of the patient at last check-up

Table 1. Without 3D-printed preoperative modeling cases (Group 1) and 3D-printed preoperative modeling cases (Group 2)
(Demographic and clinical data)

Group	Cases	Age (month)	Gender	Type of craniosynostosis	Follow-up (year)	Weight (kg)	Syndrome	Helmet
Group 1	1	4	Male	Brachycephaly	3	5.5	-	-
	2	5.5	Female	Scaphocephaly+brachycephaly	2	8	Apert	+
	3	7	Female	Right anterior plagiocephaly	2	7	-	-
	4	7	Female	Scaphocephaly +brachycephaly	3	10	-	-
	5	30	Female	Brachycephaly +trigonocephaly	4	11	Chitayat, Chiari	-
	6	9	Male	Brachycephaly	7	11	-	-
	7	12	Male	Right anterior plagiocephaly	1	10	-	+
	8	8	Male	Left anterior plagiocephaly	2	10,5	-	+
	9	9	Female	Scaphocephaly	0,5	6	-	+
	10	7	Female	Scaphocephaly	1	6,5	-	+
	11	8	Male	Trigonocephaly	1	10	-	+
	12	48	Male	Pansynostosis	2	18	Chiari	+
	Mean±standard deviation	12.875±3.11127			2.375±0.707107	9.458±8.838835		
Group 2	1	11	Male	Brachycephaly	3	9,5	-	-
	2	4,5	Male	Trigonocephaly	3	7	-	-
	3	9	Male	Brachycephaly, scaphocephaly, trigonocephaly	3	9	Chiari	-
	4	14	Male	Scaphocephaly	1	10	-	-
	5	7	Male	trigonocephaly	3	5	-	-
	Mean±standard deviation	9±2.828427			2,05	7.25±3.181918		

Table 2. Without 3D-printed preoperative modeling cases (Group 1) and 3D-printed preoperative modeling cases (Group 2) (Surgical results)

Group	Cases	Operation Duration (hours)	Preop+postop Blood replacement (ml)	Hospitalisation (day)
Group 1	1	3	175	3
	2	5	290	3
	3	5	145	8
	4	3	220	4
	5	3	200	6
	6	4	290	9
	7	3	100	4
	8	3	300	4
	9	2	120	4
	10	2	160	4
	11	3	50	4
	12	4	240	7
	Mean±stand ard deviation	3.333±0.707107	190.833±45.96194	5±2.828427
Group 2	1	2	120	10
	2	2	190	5
	3	3	190	7
	4	3	100	3
	5	2	110	3
	Mean±stand ard deviation	2 ± 0	115±7.071068	6.5±4.949747

Table 3. Patient characteristics

Variable		Group 1	Group 2	p value	z value
Age (Month)*		12.83±12.97	9.20±3.49	0.879	0.83
Gender‡	Female	6 (50.00)	0 (0.0)	0.102	
	Male	6 (50.00)	5 (100.0)		
Weight (gr)*		9458.33±3360.59	8100.00±2073.64	0.328	0.29
Preop+postop Blood replacement (ml)*		190.83±80.53	142.00±44.38	0.234	0.21
Operation Duration (hours)*		3.33±0.98	2.40±0.55	0.082	0.06
Follow-up (month)*		28.50±21.27	24.60±15.93	0.959	0.96
Hospitalisation (day)*		5.00±2.00	5.60±2.97	0.879	0.87

*Mean ± standard deviation (Mann Whitney U Test) ‡n (%) (Fisher's Exact Test)

Table 4. Type of craniosynostosis

Type of craniosynostosis	Group 1	Group 2	p value
Brachycephaly ‡	5 (41.7)	2 (40.0)	0.999
Scaphocephaly ‡	4 (33.3)	2 (40.0)	0.999
Plagiocephaly ‡	3 (25.0)	0 (0.0)	0.515
Trigonocephaly ‡	2 (16.7)	3 (60.0)	0.117
Pansynostosis ‡	1 (8.3)	0 (0.0)	0.999

‡n (%) (Fisher's Exact Test)

Table 5. Accompanying anomalies

Accompanying anomalies	Group 1	Group 2	p value
Chiari Syndrome ‡	2 (16.7)	1 (20.0)	0.999
Apert syndrome ‡	1 (8.3)	0 (0.0)	0.999
Chitayat syndrome ‡	1 (8.3)	0 (0.0)	0.999
Vision loss ‡	2 (16.7)	0 (0.0)	0.999
Epilepsy ‡	1 (8.3)	0 (0.0)	0.999

‡n (%) (Fisher's Exact Test)

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