นิพนธ์ต้นฉบับ

Original Article

การวิจัยทางคลินิกเพื่อศึกษาผลการผ่าตัดปิดกะโหลกโดยใช้เทคโนโลยีพิมพ์สามมิติราคาถูก

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บทคัดย่อ

วัตถุประสงค์ : การผ่าตัดปิดกะโหลกมีวัตถุประสงค์เพื่อรักษาภาวะกะโหลกแหว่ง วัสดุที่ใช้ในการผลิตกะโหลกเทียมมีหลายชนิด ซึ่งมีข้อดีและข้อเสียแตกต่างกัน ยังไม่มีข้อสรุปแน่ชัดเกี่ยวกับวัสดุที่ดีที่สุด สำหรับประเทศไทยนิยมใช้ Polymethylmethacrylate (PMMA) ในการผลิตกะโหลกเทียมมากที่สุด แต่ PMMA ยังมีข้อเสียบางประการ ได้แก่ ประการที่หนึ่ง การขึ้นรูปกะโหลกเทียมทำได้ยาก ศัลยแพทย์ต้องใช้มือปั้น ทำให้ได้กะโหลกเทียมที่ไม่สวยเหมือนกะโหลกเดิม มีความบิดเบี้ยว และศีรษะผู้ป่วยผิดรูป ประการที่สอง ขณะ PMMA แข็งตัว จะมีปฏิกิริยาคายความร้อน ซึ่งทำให้มีการบาดเจ็บต่อผิวสมองและเนื้อเยื่อบริเวณแผลผ่าตัด ปัจจุบันมีการนำเทคโนโลยีพิมพ์สามมิติมาประยุกต์ใช้ในการผลิตกะโหลกเทียม ซึ่งสามารถแก้ไขข้อเสียของ PMMA ได้ การศึกษานี้มีวัตถุประสงค์เพื่อประเมินผลลัพธ์ทางคลินิก ความสวยงาม และภาวะแทรกซ้อน ของการผ่าตัดปิดกะโหลกโดยใช้กะโหลกเทียมด้วยเทคโนโลยีพิมพ์สามมิติ ที่ผลิตขึ้นเองในโรงพยาบาลชลบุรี

วิธีการศึกษา : รูปแบบการวิจัยเป็นการศึกษาแบบไปข้างหน้า โดยมีกลุ่มควบคุมในอดีต (prospective study with historical control group) กลุ่มไปข้างหน้า (3D printing group) ได้แก่ ผู้ป่วยที่ได้รับการผ่าตัดใส่กะโหลกเทียมโดยใช้เทคโนโลยีพิมพ์สามมิติ ที่ผลิตขึ้นเองในโรงพยาบาลชลบุรี (3D printed PMMA implant) ในระยะเวลา สิงหาคม 2564 - กรกฎาคม 2565 จำนวน 16 ราย กลุ่มควบคุม ได้แก่ ผู้ป่วยที่ได้รับการผ่าตัดใส่กะโหลกเทียมที่ผลิตด้วยการขึ้นรูปด้วยมือ ในระยะเวลาสองปีก่อนทำการศึกษา จำนวน 17 ราย การเปรียบเทียบผลลัพธ์ของทั้งสองกลุ่ม โดยใช้ chi-square test สำหรับข้อมูลกลุ่ม, student's t-test สำหรับข้อมูลต่อเนื่อง และวิเคราะห์ความสัมพันธ์โดยใช้ multivariable Gaussian regression

ผลการศึกษา : ค่าเฉลี่ยเวลาผ่าตัดของกลุ่มพิมพ์สามมิติเท่ากับ 60.50 นาที กลุ่มขึ้นรูปด้วยมือเท่ากับ 112.06 นาที (P<0.001), การสูญเสียเลือดระหว่างผ่าตัดของกลุ่มพิมพ์สามมิติเท่ากับ 153.12 ซีซี กลุ่มขึ้นรูปด้วยมือเท่ากับ 250.0 ซีซี (P=0.041), ระยะเวลานอนโรงพยาบาลของกลุ่มพิมพ์สามมิติเท่ากับ 3.94 วัน กลุ่มขึ้นรูปด้วยมือเท่ากับ 8.65 วัน (P<0.001), ค่าเฉลี่ยคะแนนความสวยงามของกลุ่มพิมพ์สามมิติ (4.75) สูงกว่ากลุ่มขึ้นรูปด้วยมือ (3.05) (P<0.001), พบอาการชักหลังผ่าตัดในกลุ่มพิมพ์สามมิติ 1 ราย (6.25%) ในกลุ่มขึ้นรูปด้วยมือ 7 ราย (41.18%) (P=0.009), ทั้งสองกลุ่มมีอัตราภาวะแทรกซ้อนของแผลผ่าตัดไม่แตกต่างกัน (18.17% และ 17.65% ตามลำดับ; P=1.00)

สรุป : ผู้ป่วยที่ได้รับการผ่าตัดใส่กะโหลกเทียมด้วยเทคโนโลยีพิมพ์สามมิติ มีผลลัพธ์ของการผ่าตัดดีกว่า ช่วยลดอัตราการชัก และมีความสวยงามมากกว่า ซึ่งกะโหลกเทียมชนิด PMMA ที่ผลิตด้วยเทคโนโลยีพิมพ์สามมิติมีขั้นตอนการผลิตไม่ซับซ้อน ต้นทุนราคาถูก สามารถผลิตเองได้ในโรงพยาบาล จากผลการศึกษานี้ ผู้วิจัยสรุปว่าผลิตภัณฑ์ชนิดนี้ เป็นทางเลือกที่ดีสำหรับการผ่าตัดปิดกะโหลก

คำสำคัญ : การวิจัยทางคลินิก, การผ่าตัดปิดกะโหลก, เทคโนโลยีพิมพ์สามมิติ

Polymethylmethacrylate Cranioplasty using Low-cost 3D Printing Technology: Clinical Trial

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Abstract

Objectives : Various materials are available for cranioplasty, but a consensus on the best options has not yet been reached. The most utilized material is Polymethylmethacrylate (PMMA). However, there are certain drawbacks

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associated with its use. Firstly, the manual molding process can be challenging, potentially resulting in an asymmetrical implant that does not resemble the original skull's aesthetic. Secondly, the exothermic reaction occurring during the procedure poses a risk of brain tissue injury. Fortunately, introducing 3D printing technology offers a solution to these PMMA-related disadvantages. This study aimed to evaluate the clinical outcomes, cosmetic results, and complications associated with in-hospital fabrication of 3D-printed cranioplasties.

Materials and Methods : This is a prospective study incorporating a historical control group. The prospective group (3D printing) encompasses patients who underwent cranioplasty utilizing prefabricated 3D-printed PMMA implants within the period of August 2021 to July 2022 (n=16). The control group consisted of 17 consecutive patients who had undergone cranioplasty two years prior. Comparisons between the two groups were performed using the chi-square test for categorical data and the student's t-test for continuous data. The clinical endpoint was analyzed by multivariable Gaussian regression for correlated data.

Results : In the 3D printing group, the mean operative time was 60.50 minutes compared to 112.06 minutes in the conventional group (P<0.001). Intraoperative blood loss was 153.12 cc in the 3D printing group and 250.0 cc in the conventional group (P=0.041). The length of stay was significantly shorter in the 3D printing group (3.94 days) compared to the conventional group (8.65 days) (P<0.001). The mean cosmetic score was higher in the 3D printing group (4.75) than in the conventional group (3.05) (P<0.001). Seizures occurred in 1 case (6.25%) in the 3D printing group and 7 cases (41.18%) in the conventional group (P=0.009). The rate of wound complications did not differ between the two groups (18.75% and 17.65%, respectively; P=1.00).

Conclusions : The 3D-printed PMMA implants resulted in superior clinical outcomes, fewer seizures, and excellent aesthetics. Their manufacturing process was both simple and cost-effective. Based on these findings, we conclude that the presented 3D printing technique is a favorable choice for cranioplasty.

Keywords: 3D printing, cranioplasty, polymethylmethacrylate, custom implants, cranial defect

Introduction

Cranioplasty is a reconstructive surgery performed to address cranial defects, most commonly resulting from decompressive craniectomy for refractory intracranial hypertension. There are various causes of intracranial hypertension, including traumatic brain injury (TBI), cerebral infarction, intracranial hemorrhage, tumors, and infections, among others. Once the primary cause has been addressed and the patient's condition has improved, reconstruction of the cranial defect is undertaken.[1-5] The objectives of cranioplasty include brain protection, alleviating symptoms associated with the syndrome of trephined (such as headaches, dizziness, pain at the defect site, and neurological deterioration), and achieving cosmetic enhancement. Furthermore, the improved appearance resulting from cranioplasty enhances the patients' mental and social confidence.[6-10]

There are various types of materials available for cranioplasty, including autogenous bone graft, polymethylmethacrylate (PMMA), hydroxyapatite, polyetheretherketone (PEEK), and titanium, among others. Each material possesses its own set of advantages and disadvantages. However, a consensus regarding the best material has yet to be reached. Hydroxyapatite, PEEK, and titanium, although effective, have limited usage due to their high cost.[11,12] Autogenous bone graft has several advantages, such as being inexpensive, simple to operate, and eliciting a low immune response from the host. However, it also presents disadvantages such as bone resorption, difficulties in storage, and infection risk.[13,14] In Thailand, PMMA is a popular choice for cranioplasty, primarily due to its strength, affordability, good biocompatibility, and radiolucency (which allows for unimpeded radiography). Nevertheless, PMMA is associated with the risks of infection, exothermic reaction, and lack of bone union and regeneration properties.[15,16]

In addition, PMMA has a complex preparation process known as implant casting. In the conventional technique, the preparation of PMMA implants is performed in the operating room during surgery. Following the elevation of the scalp flap, the dura is exposed. The acrylic powder and liquid monomer (Benzoyl peroxide) are mixed to prepare the bone cement. The viscous mixture is then applied onto the skull defect, overlying the brain. Manual casting is carried out using the skull edge and brain surface as a template. The bone cement undergoes polymerization and hardens within 15-20 minutes, resulting in an exothermic reaction with temperatures reaching around 70-120 degrees Celsius. This method leads to the creation of implants that are asymmetrical and lack the aesthetic appeal of the original bone and skull. Moreover, the exothermic reaction poses a risk of thermal injury to the brain and surrounding tissues.[17-20]

Currently, 3D printing technology is being utilized to create prefabricated implants. This approach enables the production of exquisite and patient-specific implants, resulting in symmetrical skulls. Moreover, it reduces the duration of the operation and eliminates the risk of thermal injury.[21-29] However, limited patient access remains a challenge due to the high cost of 3D-printed cranioplasties produced by private companies. Fortunately, the cost of 3D printers has decreased, and there are freely available software options for designing implants. Consequently, numerous techniques for 3D-printed cranioplasty have emerged in the past decade. Some of these techniques are simple, cost-effective, and can be implemented within hospital settings.[30-33] As a result, patients, particularly those in developing countries, receive improved treatment and experience an enhanced quality of life. The objective of this study was to evaluate the clinical outcomes, cosmetic results, and complications associated with in-hospital fabrication of 3D-printed cranioplasties.

Materials and Methods

Study design

This prospective study with a historical control group was conducted at the Department of Surgery, Chonburi Hospital, Thailand, during the period from August 2021 to July 2022. The study protocol was approved by the Institutional Review Board of Chonburi Hospital. Written informed consent was obtained from all patients or their guardian/representative, when applicable.

Patient population

The prospective group (3D printing) consists of patients who underwent cranioplasty with 3D printing technology at Chonburi Hospital from August 2021 to July 2022. The inclusion criteria, all of which were required, were as follows: 1) age greater than or equal to 13 years; 2) patients with skull defects due to decompressive craniectomy; 3) cranioplasty performed using a 3D printed PMMA implant. The exclusion criteria were as follows: 1) skull defects caused by factors other than decompressive craniectomy; 2) the use of materials other than PMMA. Since 2021, almost all cranioplasties at Chonburi Hospital have been performed using 3D printed PMMA implants.

The historical control group consists of patients who had a skull defect due to decompressive craniectomy and underwent cranioplasty with the conventional technique (PMMA implant under manual casting). A retrospective review of medical records was conducted for 17 consecutive patients who had undergone cranioplasty two years prior to the study period.

PMMA implant using 3D printing technology (Figure 1)

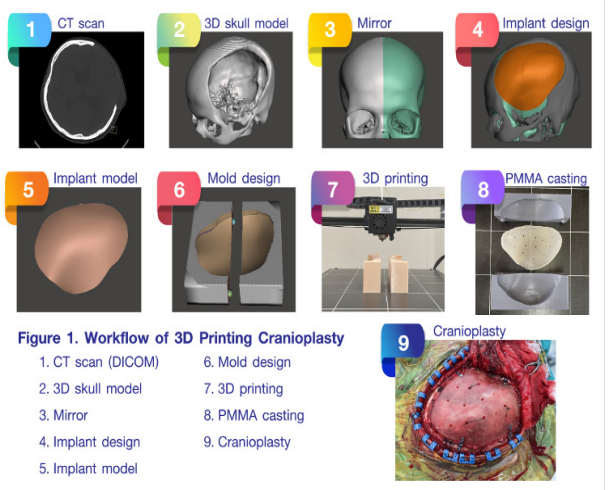

Figure 1 Workflow of 3D printing cranioplasty

The CT data of the skull defect, in DICOM format, was imported to create a 3D skull model using the 3D Slicer software (Surgical Planning Lab, Boston, MA).[34] The 3D skull model was then exported to the Standard Tessellation Language (STL) format. The implant was designed based on a virtual 3D skull model in STL format using the MeshMixer software (Autodesk, Inc., California, USA).

For hemi-cranial defects, the intact contralateral skull was mirrored to create the newly designed implant. In the case of bifrontal or bilateral skull defects, the CT data of a patient with an intact skull (before craniectomy) or a person of the same age and sex were used as a template.

The virtual mold was designed as an external surface with a closed border mold that can be disassembled. The mold was 3D printed using polylactic acid (PLACTIVE AN1™, Copper3D) on an Anycubic Chiron printer (Shenzhen Anycubic Technology Co., Ltd.). To fabricate the PMMA implant, acrylic powder and Benzoyl peroxide (liquid monomer) (Cranioplastic™, DePuy Synthes, Raynham, MA) were mixed. The contact surface of the mold was lubricated with petroleum jelly (Vaseline®; Unilever PLC) to prevent adhesion between the mold and the PMMA implant. The polymerization reaction was initiated, and the viscous bone cement was then poured into the 3D printed mold. The bone cement was spread evenly to achieve a uniform thickness and allowed to solidify. The PMMA implant was then removed from the mold by disassembling it. Multiple small holes were created in the PMMA implant. Lastly, the implant was polished and sterilized in preparation for the final cranioplasty procedure.

Cranioplasty procedure

All patients underwent the cranioplasty procedure under general anesthesia and received prophylactic cefazolin, 2 grams. The previous surgical incision was reopened, and the scalp and temporalis muscle were elevated away from the dura. The edge of the skull defect was exposed. If adjustments were needed, the implant edge was trimmed using a bone rongeur or a high-speed drill. Dural retention sutures were performed. The implant was secured to the skull with titanium miniplates at least three sites, depending on its size. A drain was placed, and the muscle and scalp were returned to their appropriate positions and closed.

Outcome measurements

The outcome measurements included operative time, blood loss, length of stay (LOS), Glasgow Coma Score (GCS), complications, and cosmetic outcome. The complications comprised seroma, wound infection, wound dehiscence, implant failure, chronic wound pain, and seizures. Seizures were defined as new-onset seizures occurring after cranioplasty up to the 6-month follow-up period, excluding seizures that occurred before surgery. The enrolled participants were regularly evaluated at the outpatient department for a duration of 6 months.

Cosmetic assessment

The aesthetic evaluation involved a satisfaction questionnaire that utilized a 5-point Likert Scale, with the following rating options: 1 - very dissatisfied, 2 - dissatisfied, 3 - moderate, 4 - satisfied, 5 - very satisfied. For fully conscious patients with a GCS of 15 and no cognitive impairment, the questionnaires were directly administered to the patients. In cases where patients were not fully conscious (GCS<15), information was obtained from caregivers or relatives. The satisfaction questionnaires for the conventional group were conducted via telephone.

Statistical Analysis

Statistical analyses were performed using STATA version 14 (licensed). The data were presented as numbers (%) and means with standard deviations (SD). Comparisons between the two groups were performed using the chi-square test for categorical data and the Student's t-test for continuous data. The clinical endpoint was analyzed by multivariable Gaussian regression for correlated data. A p-value < 0.05 was considered statistically significant.

Results

Characteristics of patients

TABLE 1 Baseline characteristics

	3D Printing (n=16 implants)	Conventional (n=17 implants)	p-value
Male, n (%)	14 (87.50)	14 (82.35)	1.000
Age (yr), mean SD	38.87±13.36	29.12±10.14	0.024
Pre-operative GCS, mean ± SD	13.44±2.39	14.53±1.33	0.113
Post-operative GCS, mean ± SD	13.63±2.06	14.70±0.99	0.061
Etiologies, n (%)			
SDH	10 (62.50)	13 (76.47)	0.791
ICH	3 (18.75)	3 (17.65)	
Ischemia	2 (12.50)	1 (5.88)	
AVM	1 (6.25)	0 (0.00)	
Craniectomy site, n (%)			
Right FTP	5 (31.25)	12 (70.59)	0.024
Left FTP	10 (62.50)	3 (17.65)	
bifrontal	1 (6.25)	2 (11.76)	
Timing of cranioplasty (months), mean±SD	17.09±34.20	25.41±28.95	0.455
Size (cm^2), mean±SD	75.82±34.05		
Printing time (hour), mean±SD	9.27±4.55		
Trimming, n (%)	9 (56.25)		

GSC = Glasgow Coma Score; SDH = subdural hematoma; ICH = intracerebral hemorrhage; AVM = arteriovenous malformation; FTP = frototemporoparietal

Table 1 displays the baseline characteristics of patients in the 3D Printing and conventional groups. The 3D printing group comprised 15 patients with a total of 16 implants. Among them, one patient had bilateral frontotemporoparietal (FTP) defects that required two implants. In this group, there were 14 males and one female, with a mean age of 38.87 years. The etiologies for decompressive craniectomy were as follows: traumatic subdural hematoma (SDH) (10, 62.50%), intracerebral hemorrhage (ICH) (3, 18.75%), ischemic stroke (2, 12.50%), and AVM (1, 6.25%). The craniectomy sites were as follows: right FTP 5 (31.25%), left FTP 10 (62.50%), and bifrontal area 1 (6.25%). The mean duration between craniectomy and cranioplasty was 17.09 months. The average implant size was 75.82 cm^2, and the mold printing timed 9.27 hours. Edge trimming was performed on 9 implants.

The conventional group consisted of seventeen patients (17 implants), including 14 males and 3 females, with a mean age of 29.12 years. The etiologies for decompressive craniectomy in this group were traumatic SDH (13, 76.47%), ICH (3, 17.65%), and ischemic stroke (1, 5.88%). The craniectomy sites were as follows: right FTP 12 (70.09%), left FTP 3 (17.65%), and bifrontal area 2 (11.76%). The mean duration between craniectomy and cranioplasty was 25.41 months. The baseline characteristics of the two groups were similar, except for age and defect sites. Notably, the 3D printing group predominantly had left-sided defects, while the conventional group predominantly had right-sided defects.

Complications

TABLE 2 Complications

	3D Printing (n=16 implants)	Conventional (n=17 implants)	p-value
Wound complication	3 (18.75)	3 (17.65)	1.000
Seroma, n (%)	3 (18.75)	1 (5.88)	1.000
Infection, n (%)	0 (0.00)	1 (5.88)	1.000
Wound dehiscence, n (%)	0 (0.00)	1 (5.88)	1.000
Chronic pain, n (%)	0 (0.00)	1 (5.88)	1.000
Seizure, n (%)	1 (6.25)	7 (41.18)	0.039

Wound complications were observed in 3 patients in each group, accounting for 18.75% in the 3D printing group and 17.65% in the conventional group (P=1.00). The specific complications are outlined in Table 2. Within the conventional group, one case of chronic pain was reported (5.88%), while no instances of chronic pain were recorded in the 3D printing group. There were no incidents of implant failure in either group. The occurrence of seizures exhibited a statistically significant difference between the groups, with 1 case (6.25%) in the 3D printing group and 7 cases (41.18%) in the conventional group (P=0.039). The risk difference was calculated as -29.22 (95%CI -57.11 to -13.41, P=0.040) (Table 4).

TABLE 3 Clinical endpoints

	3D Printing (n=16 implants)	Conventional (n=17 implants)	p-value
Operation time (min), mean±SD	60.50 ± 13.97	112.06 ± 36.82	<0.001
Blood loss (cc), mean±SD	153.12±100.77	250.0 ± 154.11	0.041
LOS (day), mean±SD	3.94 ±0.68	8.65 ± 4.40	<0.001
1-month cosmetic score, mean±SD	4.75 ± 0.45	3.05 ± 1.34	<0.001
6-month cosmetic score, mean±SD	4.75 ± 0.45	3.05 ± 1.34	<0.001
Seizure, n (%)	1 (6.25)	7 (41.18)	0.039

LOS = length of stay

TABLE 4 Difference between groups of Clinical endpoints

	parameter	effect	95% CI		P-value
			Lower	Upper	
Operation time	Mean difference	-52.79	-72.47	-33.12	<0.001
Blood loss	Mean difference	-96.87	-186.76	-6.98	0.036
LOS	Mean difference	-4.71	-6.91	-2.50	<0.001
seizure	Risk difference	-29.22	-57.11	-13.41	0.040

a adjusted by surgery site

b adjusted by age surgery site

multivariable gaussian regression for correlated data

LOS = length of stay

Clinical endpoints

The results of the clinical endpoints are presented in Tables 3 and 4. The average operative time was 60.50 minutes in the 3D printing group and 112.06 minutes in the conventional group (P<0.001). The mean difference was -52.75 (95%CI -72.47 to -33.12, P<0.001). Intraoperative blood loss was 153.12 cc in the 3D printing group and 250.0 cc in the conventional group (P=0.041). The mean difference was -96.87 (95%CI -186.76 to -6.98, P=0.036). The length of stay was 3.94 days in the 3D printing group and 8.65 days in the conventional group (P<0.001). The mean difference was -4.71 (95%CI -6.91 to -2.50, P<0.001). At one and six months after cranioplasty, the average cosmetic score was 4.75 in the 3D printing group and 3.05 in the conventional group (P<0.001). Figure 2 illustrates the before and after images of a patient who underwent cranioplasty using the proposed technique. This patient reported being very satisfied (5 points) with the cosmetic outcome.

Figure 2 : Before (A, B) and after (C, D) cranioplasty using 3D-printed PMMA implant for bifrontal defect.

Discussion

This prospective study compared 3D printing with conventional techniques for cranioplasty using a PMMA implant. The results showed that 3D printing was superior to the conventional group in terms of clinical endpoints, aesthetics, and postoperative seizure rates. Computer-aided design (CAD) for implant manufacturing reconstructed the skull defect more accurately and beautifully compared to manual casting.[21,26,27,30,31] It achieved this by utilizing the mirror image of the intact contralateral skull as a template for repair. As a result, the postoperative head contour was completely symmetrical on both sides. Hand casting, on the other hand, could not achieve the same level of beauty as the 3D printing technique. During surgery, the surgeon couldn't visualize the contralateral patient's skull due to it being covered with a sterile drape. Even if there was a picture of the patient hanging in the operating room, hand casting could not achieve the same symmetry as the 3D printing technique. The aesthetically pleasing head contour provided by the patient-specific 3D printed implant not only brings satisfaction to the patient but also boosts their confidence in social interactions.

The analysis using multivariable Gaussian regression (Table 4) demonstrated that 3D printing yielded better results than the conventional group in the following aspects: 1) reduced operative time by 52 minutes; 2) decreased intraoperative blood loss by 96 cc; 3) shorter length of hospital stay by 4 days; and 4) a twenty-nine-fold decrease in seizure occurrence.

In the 3D printing group, we used a prefabricated PMMA implant that could be promptly fixed to the skull after elevating the scalp and muscle. This eliminates the requirement for manual casting of the PMMA implant during the surgery, which typically takes approximately 60 minutes. By avoiding prolonged exposure of the wound during manual casting, we can minimize cumulative blood loss. The combination of a shorter surgical duration and reduced blood loss contributes to improved recovery and fewer complications. Furthermore, it enables faster patient discharge, allowing them to return home more quickly.

No significant differences were observed in terms of wound complications and chronic pain between the two groups. This lack of distinction can be attributed to the similarity in surgical procedures and the use of the same material, PMMA, in both groups.

Seizures are one of the most common complications of cranioplasty, occurring in 3.35% to 29% of cases.[10,35,36] Pikis et al. reported that intraoperative PMMA casting can lead to severe side effects due to thermal damage and chemical toxicity caused by methylacrylate monomer contamination.20 PMMA consists of acrylic powder and liquid monomer, which undergo polymerization—an exothermic reaction that occurs at temperatures between 70 and 120 degrees Celsius—resulting in the solidification of the PMMA implant. In the conventional technique, there is a risk of heat-induced brain damage during manual molding on the brain surface. Additionally, methylacrylate monomer is highly cytotoxic and acts as a strong lipid solvent. Saline irrigation of the PMMA prosthesis during cranioplasty could potentially expose neural tissue to residual methylacrylate monomer, leading to neuronal damage.[37,38] These factors contribute to the high seizure rate of 41% observed in the conventional group in this study. However, the use of prefabricated PMMA implants in 3D printing offers advantages. It eliminates thermal injury and neurotoxicity, resulting in significantly fewer seizures compared to the conventional group. In fact, the occurrence of seizures is reduced by a factor of 29 with the use of prefabricated PMMA implants.

Currently, 3D printing technology is extensively used in cranioplasty, employing a range of techniques for implant design, printing, materials, and molding.[21-33] The technique presented in this study offers several advantages, including favorable surgical outcomes, reduced seizure occurrence, and excellent aesthetic results. Moreover, it is a cost-effective solution that can be manufactured within the hospital premises. All manufacturing programs utilize free software, and the cost of a desktop 3D printer is approximately 20,000 baht (576 USD). The polylactic acid material costs 200 baht (6 USD) per case, while PMMA costs 15,000 baht (432 USD) per case. Additionally, the PMMA implant is covered by the Thailand government insurance, making it a more affordable option compared to other alloplastic materials. The total cost of a 3D printed PMMA implant for a single patient does not exceed 16,000 baht (460 USD). One disadvantage of this method is the additional preoperative implant manufacturing process, which includes 30 minutes of implant design, 9 hours of mold printing (with the printer operating autonomously, freeing up doctors to attend to other tasks), and 30 minutes of implant casting. However, this process can be conveniently conducted at home or in the office, offering simplicity and greater convenience compared to intraoperative fabrication.

This study has two notable limitations. First, it is a historical control study where the comparator and 3D printing groups underwent cranioplasty at different times. Second, the short follow-up period of six months may not capture long-term complications associated with the presented 3D printing cranioplasty technique. Despite these limitations, the results of this study highlight numerous advantages of 3D printing cranioplasty. We believe that the technique presented in this study shows promise as a choice for cranioplasty, and we sincerely hope that sharing this knowledge will contribute to the development of improved cranioplasty techniques in the future.

Conclusions

This comparative study showed that 3D-printed PMMA implants yielded superior clinical outcomes, fewer seizures, and excellent aesthetic results. Additionally, they were associated with a straightforward manufacturing process and low cost. Based on these findings, we conclude that the presented 3D printing technique is a favorable choice for cranioplasty.

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