นิพนธ์ต้นฉบับ ***Original article***

The Use of Customized Cranioplasty Implant Formed with Desktop 3D-Printer Using 3D-Printed ABS Plastic Compare with Methyl Methacrylate Resin in Cranioplastic Patient

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บทคัดย่อ The purpose of this study was to evaluate the utilization, efficacy, effectiveness and complications in delayed cranioplasty patients using a 3D-printed cranioplasty compared with delayed cranioplasty patients using self-curing methyl methacrylate resin that was traditionally molded by hand in Phranangklao Hospital. A prospective study was used to evaluate the efficacy and safety of 3D-printed cranioplasty compared with conventional cranioplasty. Twenty-eight consecutive patients who underwent delayed cranioplasty from June 2018 to December 2020 in Phranangklao Hospital were evaluated. Age, sex, initial diagnosis, operative time, length of stay and complications from surgery occurring within 1 year after surgery were analyzed using distribution of frequency, percentage, mean and standard deviation. Differences were tested with likelihood ratio chi-square and independent samples t test. The 3D-printed cranioplasty group had shorter operation time than the conventional cranioplasty group ($p<0.05$). In the 3D-printed cranioplasty group, complications were greater than the conventional cranioplasty group ($p<0.05$). No serious complications were found from the materials used. The use of a 3D-printed cranioplasty using ABS plastic could be done at a hospital-level, satisfactorily safe and effective. Significantly reduce the time of surgery. No serious complications from the material used were found.

***Abstract*:** **customized cranioplasty; skull defects; PMMA; ABS; 3D-printed cranioplasty**

Introduction

In many cases, a wide craniectomy was a surgical necessity. Especially in cases where a rapid reduction in intracranial pressure was required due to brain swelling from various causes such as head injury, post-operative brain edema, hemorrhagic stroke, etc., or in cases where the original skull had to be removed due to an infection of the skull, skull tumors, etc. When the patient's clinical symptoms improved, brain swelling subsided, neurological condition stabilized, and there were indications for skull restoration. The patient will have surgery for delayed cranioplasty.

At the moment, the materials used for cranioplasty[1] can be classified into two categories:

1. Autogenous bone grafts such as patient's original skull flap[2], bones from other body parts such as ribs, iliac bones, and so on.

2. Alloplastic materials such as polymethylmethacrylate (PMMA)[3-7], porous polyethylene (PE)[5-6,8], polyetheretherketone (PEEK)[3-4,6,9-11], titanium[3,5-6,12-13], ceramic[5-6] and others.

Although using autogenous bone grafts for cranioplasty was simple, convenient, perfectly fit, and less expensive, there were still significant problems, including bone flap resorption after cranioplasty[14-16] and serious complications such as infection[17].

Many studies had been conducted to investigate the fabrication of the cranioplastic flap using various materials[4-6,8-9,14,17-18]. No method had yet been accepted as an ideal standard.

According to current standard, patients were treated with self-curing methyl methacrylate resin (Codman Cranioplastic® type 1 - slow set). Because the material had to set and harden after an acrylic implant was manually molded in an operating room, the surgery took a long time. Furthermore, hand forming made it impossible to shape the cranioplastic flap with traditional symmetry or to perfectly fit to the skull defect. It is even more difficult in the case of complicated or curved parts of the skull, such as the corner of the temporal bone.

At the moment, 3D printing technology is being used in a variety of medical applications[7,18] and can be done manually at the hospital level. Various 3D printing materials were easily accessible.

Acrylonitrile butadiene styrene (ABS) plastic was another inert thermoplastic polymer[19-23] that could be used to make prostheses parts[23-26] that were inexpensive and readily available on the market. It had good properties such as being strong, tough, flexible, able to withstand tensile force, not brittle, excellent weather resistance, chemical resistance, heat resistance, high temperature resistance, having a high melting point, being insoluble in water, being light in weight, and being easily polished to work. However, it had a disadvantage: it had a strong odor and was extremely sensitive to workpiece warping during the 3D printing process.

Although, at temperatures above 400 °C (750 °F), ABS can decompose into its constituents: butadiene (carcinogenic to humans), acrylonitrile (possibly carcinogenic to humans), and styrene (reasonably expected to be a human carcinogen)[19,27]. However, ABS was stable to decomposition and inert under normal conditions at temperatures ranging from 20 to 80 °C (4 to 176 °F)[19].

The researcher was interested in studying and presenting the method of forming a cranioplasty formed with a 3D printer using ABS material, including an evaluation of the efficacy, effectiveness, and complications of delayed cranioplasty patients using 3D printed cranioplasty using ABS plastic compared to conventional hand-formed self-curing methyl methacrylate resin (Codman Cranioplastic® type 1 - slow set) in Phranangklao Hospital.

This study provided basic education information on how to form cranioplasty with a 3D printer using ABS or other materials. The 3D printed technique could be applied to other organs such as facial bones, limbs, and so on in the future. The applications of this research were useful as a model for other hospitals to follow.

The objectives of this study were to assess the efficiency, effectiveness, and complications of delayed cranioplasty patients using 3D-printed cranioplasty using ABS plastic compared to delayed cranioplasty patients using conventional self-curing methyl methacrylate resin in Pranangklao Hospital.

Material and Methods

This was a prospective study. Data was gathered from patients who underwent delayed cranioplasty at Phranangklao Hospital between June 1, 2018 and December 31, 2020. Age, gender, initial diagnosis, operative time, length of stay, and complications from surgery occurring within one year of surgery were all collected. Data on sex, age, and initial diagnosis were analyzed using frequency, percentage, mean, and standard deviation distributions. The likelihood ratio chi-square was used to analyze data on operative time and hospital stay. Complication data were analyzed using the independent-samples t test.

The research protocol was approved by the Ethics Committee of Phranangklao Hospital, Phranangklao Hospital, Thailand, under protocol number EC15/2563.

Indications for cranioplasty were aesthetic, young age, working age, high risk of injury at the site of the skull defect, and Trephined syndrome[1].

The duration of cranioplasty was determined by the resolution of brain edema, improvement of neurological symptoms, and the absence of infection risk[1].

The 3D-printed cranioplastic patient group consisted of willing participants in this study. Retrospective data were used to compile the conventional cranioplasty patient group. Because of the small number of patients, the randomized control trial method could not be used in this study.

Inclusion criteria were that the patients had an indication for cranioplasty, that the period of cranioplasty was not less than 6 months, that they were between the ages of 10 and 70, and that they were voluntary patients.

Exclusion criteria included pregnancy, inability to attend required follow-up visits, and involuntary patients.

Due to the small number of patients, the data for the conventional cranioplasty group were collected from three neurosurgeon staffs: four patients by senior staff, three patients by another senior staff, and eight patients by the researcher. The researcher collected all of the data for the 3D-printed cranioplasty group.

Cranioplasty Implant 3D-Reconstruction Modeling Technique

Cranioplasty implants were reconstructed using the patient's CT or MRI scan data. Data was processed to create a 3D model from 2D images. using a Macbook Air notebook computer (13'' screen, 2017, CPU 1.8 GHz Dual-Core Intel Core i5, 8 GB 1600 MHz DDR3 memory, Intel HD Graphics 6000 1536 MB image processor) via program OsiriX 12.0 (OsiriX MD version 12.0 of Pixmeo SARL Switzerland for iOS and macOS).

The 3D model created by OsiriX 12.0 was adjusted and its integrity was changed. Missing parts of the skull defect were re-created with Blender (version 2.83.5, freeware and open source from The Blender Foundation (2002), Netherlands for Linux, Windows and macOS). The edited 3D model was checked and damaged parts were repaired with MeshMixer (version 3.5, freeware from Autodesk Research (2020), USA for Windows and macOS)

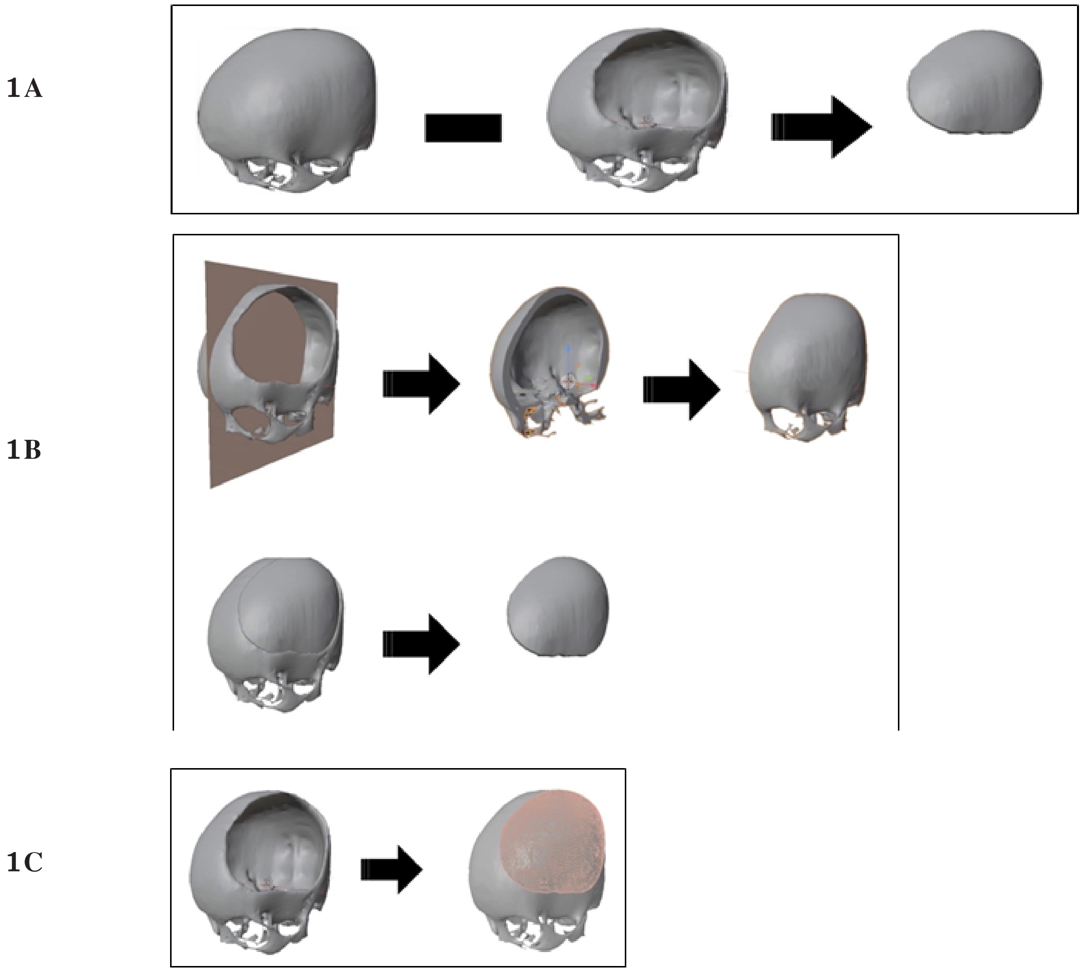
The researcher used three methods to create a cranioplastic implant based on the CT scans available from the patient (Figure 1).

If CT scan results were available both before and after craniectomy, a cranioplastic implant was created using the boolean subtraction method (Figure 1A).

If CT scan results were available only after craniectomy, a cranioplastic implant was created using the reflection method (Figure 1B).

In the absence of a pre-craniectomy CT scan results and the inability to compare with the other side for any reason, a cranioplastic implant was created using the reconstruction method (Figure 1C).

Figure 1 Three methods for reconstructing a cranioplasty implant.



(1A) The subtraction method for preparing cranioplastic implants. The pre-craniectomy CT results were compared to the post-craniectomy CT results, and the images were boolean subtracted.

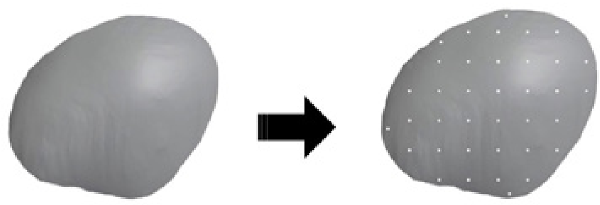
(1B) The reflection method for preparing cranioplasty implants. The normal side of the skull was reflected, and then boolean subtraction with the craniectomy side was performed. The cranioplastic implant was created by simulating from the normal side.

(1C) The reconstruction method for preparing a cranioplasty implants. The cranioplastic implant was created by program simulation.

After obtaining the customized cranioplastic implant design, holes with a diameter of 2 millimeters and a distance of 2 centimeters were made across the entire cranioplastic implant. There were two objectives of holes making. First, exudates are drained through perforations in the bottom of the cranioplastic implant in order to prevent subgaleal collection and the build-up of exudates under the implant. Second, holes on the edge of the cranioplastic implant utilized as a fixing place for the implant's fixation to the skull using soft stainless steel wire (Figure 2).

Following the creation of the cranioplastic implant by an emulator, the final printing was provided by Ultimaker Cura (version 4.6.2, free program from Ultimaker BV, Netherlands for Linux, Windows and macOS) with CreatBot brand 3D printer FDM (Fused Deposition Modeling), Model F160 (Henan Suwei Electronic Technology Co., LTD., China, $2,248) using medical grade ABS filament (1.75 mm FILOALFA® ABS-3d FC by Elix filament collaboration with ELIX Polymers, Biocompatible: ISO 10993-1[28], USP Class VI[29,30], Food contact approved material

Figure 2 Pre-poring method.



Remark: Holes were constructed across the entire cranioplastic implant to drain exudates from the bottom of the cranioplastic implant and along the cranioplastic implant edge to serve as a fastening place for the cranioplastic implant with skull.

acc. EU No 10/20111 and 21 CFR FDA, 31.97 €/700 g, density 1.06 g/cm^3).

Cranioplasty Operative Techniques

The cranioplastic implant was sterilized by drying Ethylene Oxide gas at 60 °C[31-32]. The cranioplasty surgery was performed according to standard surgical techniques. The cranioplastic implant was placed in the subgaleal fibrosis layer. The cranioplastic implant can be modified using a high-speed drill in the case that any sections are misaligned or need to be personalized, such as thick temporal muscle tissue. The 0.5 mm diameter soft stainless steel wire was used to secure the cranioplastic implant to the skull. Redivac drain was implanted for at least 7 days or until the exudate was reduced to prevent subgaleal collecting. Following surgery, patients received 1 gram of an antibiotic of the cefazolin type intravenously every 6 hours for 7 days.

Results

From June 1, 2018 to December 31, 2020 at Phranangklao Hospital, there were 28 cranioplastic patients, both in the conventional cranioplasty group and the 3D-printed cranioplasty group, 24 males (85.7%), 4 females (14.3%), a total of 28 surgical operations. A total of 15 patients had traditional cranioplasty, requiring 15 procedures, while 13 patients underwent 3D-printed cranioplasty using ABS plastic, requiring 13 surgeries. Patients ranged in age from 8 years and 8 months to 58 years and 8 months, with a mean age of 34.81±15.17 years.

In conventional cranioplasty group, there were right craniectomy 7 cases (46.7%), left craniectomy 8 cases (53.3%). In 3D-printed cranioplasty group, there were right craniectomy 7 cases (53.8%), left craniectomy 6 cases (46.2%).

The initial diagnoses were from acute subdural hematoma in 16 cases (57.1%), acute epidural hematoma 4 cases (14.3%), intracranial hemorrhage 2 cases (7.1%), brain tumors 1 cases (3.6%), depressed skull fracture 1 cases (3.6%), cerebral contusion 1 case (3.6%), infected previous cranioplasty 1 case (3.6%), cerebral edema after cerebral infarction 1 case (3.6%), cerebral edema after ruptured aneurysm 1 case (3.6%), details are shown in Table 1.

The conventional cranioplasty group were 13 males (86.7%), 2 females (13.3%), patients ranged in age from 17 years to 58 years, with a mean age of 29.43±12.42 years. The 3D-printed cranioplasty group were 11 males (84.6%), 2 females (15.4%), patients ranged in age from 19 years to 67 years, with a mean age of 41.46±14.47 years.

Acute subdural hematoma was the leading cause of craniectomy in both groups of patients. There were 8 cases (53.3%) in the conventional cranioplasty group, 7 cases (53.8%) in the 3D-printed cranioplasty group.

In the 3D-printed cranioplasty group, ABS plastic weighing between 21 and 55 g was employed (19.81 - 51.89 cm^3), average 36.77±10.21 g (34.69±9.63 cm^3). 3D modeling time was average about 2 hours/case. The print time ranged from 7.69 to 27.71 hours, with an average of 15.32±5.18 hours.

Table 1 Patient's characteristics, including gender, age, and initial diagnosis requiring craniectomy

Variables	Conventional cranioplasty group		3D-printed cranioplasty group		Total	
	n	%	n	%	n	%
Sex						
Male	13	86.7	11	84.6	24	85.7
Female	2	13.3	2	15.4	4	14.3
Age (years)						
Under 30	11	73.3	3	23.1	14	50.0
30-50	2	13.3	7	53.8	9	32.1
Above 50	2	13.3	3	23.1	5	17.9
Initial diagnosis						
acute subdural hematoma	8	53.3	7	53.8	16	57.1
acute epidural hematoma	2	13.3	3	23.1	4	14.3
intracerebral hemorrhage	2	13.3	0	0.0	2	7.1
brain tumor	1	6.7	0	0.0	1	3.6
depressed skull fracture	1	6.7	0	0.0	1	3.6
cerebral contusion	1	6.7	0	0.0	1	3.6
infected previous cranioplasty	0	0.0	1	7.7	1	3.6
cerebral infarction	0	0.0	1	7.7	1	3.6
ruptured aneurysm	0	0.0	1	7.7	1	3.6

The average operative time of the conventional cranioplasty group was 95.33±16.95 minutes, the average operative time of the 3D-printed cranioplasty group was 56.15±11.02 minutes. When testing the difference of operative time between the two groups using independent samples t test, there was a statistically significant difference at the 0.05 level (Table 2).

Mean Length of stay after surgery in the conventional cranioplasty group was 8.73±2.52 days, in the 3D-printed cranioplasty group was 8.15±.56 days. The difference of length of stay between the two groups was tested using independent samples t test. There were no statistically significant differences in both groups.

Surgical complications occurring within 1 year after surgery in the conventional cranioplasty group was subgaleal CSF collection 1 case (6.7%) (Table 3).

Complications in the 3D-printed cranioplasty group was subgaleal CSF collection 4 case (30.8%), surgical wound dehiscent 3 cases (23.1%), implant failure 3 cases (23.1%). The difference in surgical complications between the two groups was tested using likelihood ratio chi-square showed a statistically significant difference at the 0.01 level.

Table 2 Operative time and length of stay in hospital after surgery

Variables	The conventional cranioplasty group			The 3D-printed cranioplasty group			t-value	p-value
	Min	Max	Mean±SD	Min	Max	Mean±SD		
Operative time (min.)	65	125	95.33±16.95	35	75	56.15±11.02	-7.399	<0.001*
Length of stay after surgery (days)	5	16	8.73±2.52	8	10	8.15±.56	-0.810	0.425

SD=standard deviation

* Statistically significant at p<0.05

Table 3 Surgical complications occurring within 1 year after surgery.

Variables	The conventional cranioplasty group		The 3D-printed cranioplasty group		Total		χ^2	p-value
	n	%	n	%	n	%		
Surgical complications							9.740	0.008*
No complications	14	93.3	6	46.2	20	71.4		
With complications	1	6.7	7	53.9	8	28.6		
- subgaleal CSF collection	0	0.0	4	30.8	4	14.3		
- wound dehiscent	1	6.7	3	23.1	4	14.3		
- implant failure	0	0.0	3	23.1	3	23.08		

* Statistically significant at p<0.05

Discussion

Cranioplasty with autogenous bone grafts has been performed for many years. It was first mentioned in 1950[14,33-35]. Although the results were satisfactory, there were still storage issues, and resorption of the skull flap was a major issue. Prosthetic skulls have been invented in the last 30 years[36] using a variety of materials such as methyl methacrylate, hydroxyapatite-based ceramics or cement, titanium, polypropylene, polyester, and polyethylene.

The properties of the materials used for ideal skull closure were viable, capable of growth (ability to grow, germinate, or connect together), resistant to infection, radiolucent, thermally nonconductive, did not conduct strong magnetic currents, stable, did not break easily, nonionizing and noncorrosive, beautiful fit to the original skull, easy to form, convenient, inexpensive, and sterilizable[37,38]. However, no material currently possesses all of these properties.

The advantages of using autogenous bone grafts were that they were simple to use, had a beautiful shape, were less expensive, had fewer surgical complications, were viable, capable of growth, and were resistant to infection. The benefits of using an alloplastic materials skull flap included ease of use, easy storage, moldability, and no resorption.

Because of the benefits mentioned above, cranioplasty using self-curing methyl methacrylate resin material is now popular. However, molding by hand in the operating room prolonged the surgery due to the need to wait for the material to harden. And forming by hand made an aesthetic skull shape or traditional symmetry impossible. Especially when the skull defect was large, in the area of complex parts of the skull, or in a very angled corner, such as the temporal crest corner.

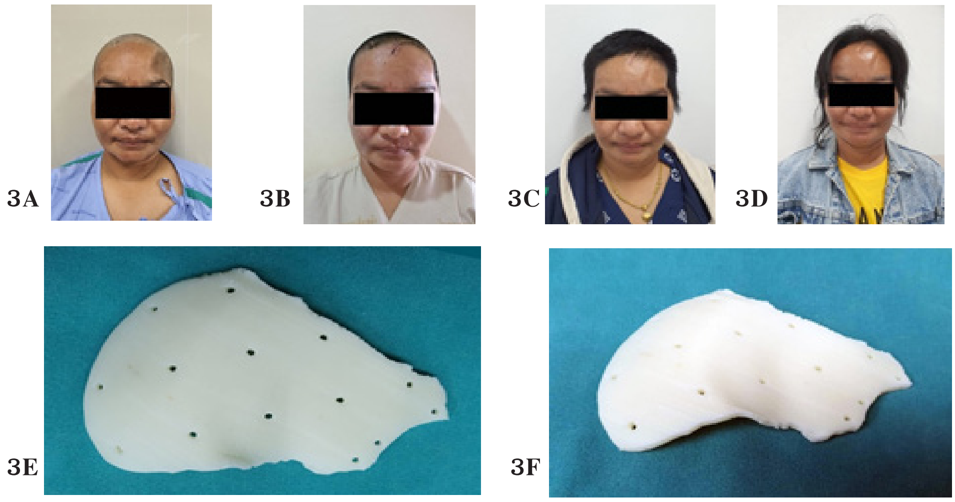
Nowadays, 3D printer technology has improved usability. It is less expensive and more accessible. There are various print materials available. It can be used in a variety of medical applications[7,18]. However, there are no suitable materials for use as a prosthetic organ, particularly the cranioplastic flap, and it has not yet been widely adopted.

According to the findings of this study, the biocompatible Acrylonitrile butadiene styrene plastics obtained ISO 10933-1 and USP Class VI were safe for use in the fabrication of prostheses, were inexpensive, and readily available on the market. It had good properties such as being strong, tough, flexible, able to withstand tensile force, not easily brittle, excellent weather resistance, chemical resistance, heat resistance, high temperature resistance, having a high melting point, being insoluble in water, being light in weight, and being easily polished to work. The disadvantages were a strong odor, but only when the workpiece was heated while being formed. There was no smell after the work was completed, and it had no effect on its use. Workpiece shrinkage could be avoided by keeping the temperature constant while forming the workpiece.

The significant advantage of 3D-printed cranioplasty implants was that they could be molded to fit prominent parts such as the temporal ridge (Figure 3) and had excellent curvature and contouring in large implants, which were difficult to produce with traditional hand-formed self-curing methyl methacrylate resin implants (Figure 4).

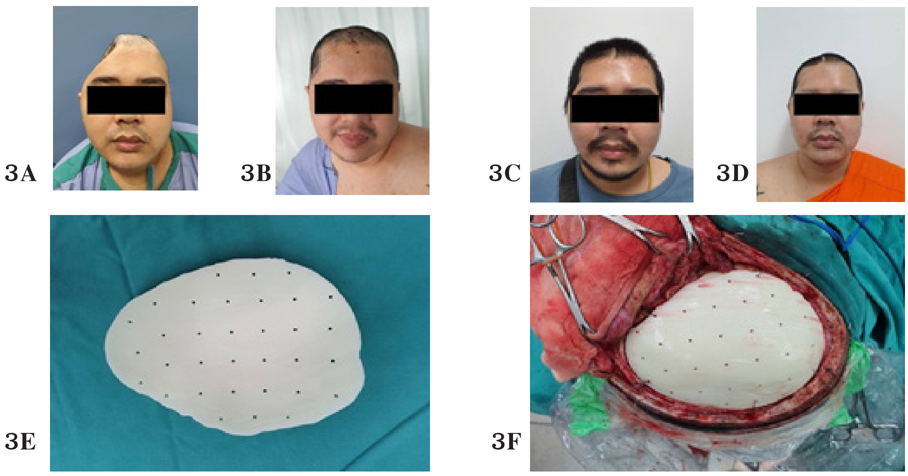
The operation time in the 3D-printed cranioplasty group was statistically significantly faster than in the conventional cranioplasty group at the.001 level, with a mean surgical time of 56.15±11.02 minutes. The conventional cranioplasty group took 95.33±16.95 minutes. Because the 3D-printed cranioplasty group did not have to waste time forming and waiting for the artificial skull to stabilize, it took only 58.90% of the time as the conventional cranioplasty group. The 3D-printed cranioplasty is aesthetically pleasing and fits perfectly to the original skull.

Figure 3 A 43-year-old female patient underwent fronto-parietal craniectomy following Lt A-com aneurysm surgery



Note: (3A) Prior to cranioplasty, the craniectomy site was across the prominent part of the temporal ridge. (3B) The patient one week after surgery. (3C) The patient two months after surgery. (3D) The patient one year after surgery. (3E, 3F) The pre-poring 3D-printed cranioplasty implant demonstrates a prominent part of the temporal ridge that is difficult to produce with a traditional hand-formed self-curing methyl methacrylate resin implant.

Figure 4 A 26-year-old male patient underwent a wide craniectomy following a motorcycle accident that resulted in traumatic brain injury



Note: (4A) The craniectomy site was depressed prior to cranioplasty due to a large skull defect. (4B) The patient one week after surgery. (4C) The patient two months after surgery. (4D) The patient one year after surgery. (4E, 4F) The pre-poring 3D-printed cranioplasty implant demonstrated good curvature and contouring, which were difficult to achieve with traditional hand-formed self-curing methyl methacrylate resin implants.

There was a statistically significant difference in surgical complications. Surgical complications were found to be higher in the group using a 3D-printed cranioplastic implant than in the group using a conventional implant. The main complication was subgaleal CSF collection. Although the skin was retracted and tightened as a result of the scalp's rapid expansion, the insertion of a 3D-printed implant caused a gap between the implant and the subgaleal layer. This gap created a space for fluid accumulation and exudation. All four cases of subgaleal CSF collection complications occurred within a week of the radivac drain being removed. The resulting subgaleal CSF collection resolved spontaneously within one month of follow-up treatment without the need for specific treatment. The researcher recommends that the radivac drain be left in place for at least a week and that there be no exudate for at least three days.

The wound dehiscent caused by the rapid high surface tension of the scalp after the insertion of a 3D-printed cranioplastic implant was a secondary complication. The skin contracted due to the high surface tension. In the first case, wound dehiscence occurred three months after surgery and was treated with re-suture. At the seventh month after surgery, wound dehiscence recurred, so the cranioplastic implant was removed to avoid further serious complications. Second case, wound dehiscence occurred one month after surgery and was treated with re-suture. At the tenth month after surgery, wound dehiscence recurred, so the cranioplastic implant was removed to avoid further serious complications. Third case, wound dehiscence occurred at the tenth month after surgery, so the cranioplastic implant was removed to avoid further serious complications. The researcher noticed that all three patients had thin scalp thickness. According to the researcher, patients should be closely monitored in order to detect complications and treat them as soon as possible.

In comparison to other customized 3D-printed cranioplastic implant material studies, the failure rate of 3D-printed cranioplastic implants made of ABS plastic (23.1%) was higher than that of PEEK (12.5%), but lower than that of titanium (25%)[39].

However, no infection, a serious complication, was found in either group of cranioplasty patients, and no complications were found directly from the materials used. As a result, using a 3D-printed cranioplastic implant made of ABS plastic is both safe and effective.

The advantages and disadvantages of using a 3D printer-molded customized cranioplasty implant made of ABS plastics versus a cranioplasty implant made of the original hand-molded self-curing methyl methacrylate resin vary. The selection must be based on the patient's suitability and the hospital's capabilities.

We hope that the findings of this study will be applicable in other hospitals. Including as a guideline and basic information for a future study on how to mold replacement body parts with a 3D printer and apply as a medical device or various surgical aids for those interested.

However, this was only the beginning of the era of a 3D-printed cranioplastic implant made of ABS plastic, which required more research with a larger population and a longer follow-up period for definitively accurate results.

Conclusion

In conclusion, Pranangklao Hospital could perform 3D printed customized cranioplasty implants made of ABS plastics. It was satisfactory that it was both safe and effective. The use of a 3D printed customized cranioplasty implant to cover the skull defect allowed the skull defect to be closed more quickly. Significantly reduced operative time. There were no complications caused by the materials used. As a result, it is a viable option for cranioplasty patients.

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บทคัดย่อ: การศึกษาเปรียบเทียบระหว่างการใช้กะโหลกศีรษะเทียมที่ขึ้นรูปเฉพาะบุคคลด้วยเครื่องพิมพ์สามมิติโดยใช้พลาสติก ABS และการใช้กะโหลกศีรษะเทียม Methyl Methacrylate Resin ที่ขึ้นรูปด้วยมือ ในผู้ป่วยที่ผ่าตัด Cranioplasty

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วารสารวิชาการสาธารณสุข 2565;31(เพิ่มเติม 2):S376-S388.

การศึกษานี้มีวัตถุประสงค์เพื่อประเมินการใช้ ประสิทธิภาพ ประสิทธิผล และภาวะแทรกซ้อน ในผู้ป่วย delayed cranioplasty ที่ใช้กะโหลกศีรษะเทียมที่ขึ้นรูปด้วยเครื่องพิมพ์ 3 มิติ โดยใช้พลาสติก ABS เปรียบเทียบกับผู้ป่วย delayed cranioplasty ที่ใช้ self-curing methyl methacrylate resin ที่ขึ้นรูปด้วยมือแบบเดิม ในโรงพยาบาลพระนั่งเกล้า เป็นการศึกษาแบบเก็บข้อมูลไปข้างหน้า โดยทำการเก็บรวบรวมข้อมูลจากผู้ป่วยที่ได้รับการผ่าตัดนำกะโหลกศีรษะออกและทำการปิดกะโหลกศีรษะในภายหลังในกลุ่มที่ใช้กะโหลกศีรษะเทียมที่ขึ้นรูปด้วยเครื่องพิมพ์ 3 มิติ โดยใช้พลาสติก ABS เทียบกับกลุ่มที่ใช้กะโหลกศีรษะเทียมแบบเดิม ตั้งแต่วันที่ 1 มิถุนายน พ.ศ. 2561 ถึง 31 ธันวาคม พ.ศ. 2563 ในโรงพยาบาลพระนั่งเกล้า โดยรวบรวมข้อมูลเกี่ยวกับลักษณะทั่วไปของคนไข้ เพศ อายุ โรคที่เป็นสาเหตุในการผ่าตัดเปิดกะโหลกศีรษะ ระยะเวลาในการผ่าตัด ระยะเวลาในการนอนโรงพยาบาลหลังผ่าตัด และภาวะแทรกซ้อนจากการผ่าตัดที่เกิดขึ้นภายในระยะเวลา 1 ปีหลังการผ่าตัด วิเคราะห์ข้อมูลโดยการแจกแจงความถี่ร้อยละ ค่าเฉลี่ย และส่วนเบี่ยงเบนมาตรฐาน ทดสอบความแตกต่างด้วยสถิติ likelihood ratio chi-square และ independent samples t test ผลการศึกษาพบว่า ระยะเวลาในการผ่าตัดในกลุ่มที่ใช้กะโหลกศีรษะเทียมที่ขึ้นรูปด้วยเครื่องพิมพ์ 3 มิติ เร็วกว่ากลุ่มที่ใช้กะโหลกศีรษะเทียมแบบเดิมอย่างมีนัยสำคัญทางสถิติที่ระดับ 0.05 ภาวะแทรกซ้อนจากการผ่าตัดในกลุ่มที่ใช้กะโหลกศีรษะเทียมที่ขึ้นรูปด้วยเครื่องพิมพ์ 3 มิติ สูงกว่ากลุ่มที่ใช้กะโหลกศีรษะเทียมแบบเดิมอย่างมีนัยสำคัญทางสถิติที่ระดับ 0.05 ไม่พบภาวะแทรกซ้อนรุนแรงจากตัววัสดุที่ใช้ สรุปได้ว่าการใช้กะโหลกศีรษะเทียมที่ขึ้นรูปด้วยเครื่องพิมพ์ 3 มิติ โดยใช้พลาสติก ABS สามารถทำได้เองในระดับโรงพยาบาล ปลอดภัย และมีประสิทธิผลเป็นที่น่าพอใจ ช่วยลดระยะเวลาในการผ่าตัดลงอย่างชัดเจน ไม่มีภาวะแทรกซ้อนจากตัววัสดุที่ใช้ และไม่พบภาวะแทรกซ้อนจากการผ่าตัดที่รุนแรง

คำสำคัญ: กะโหลกศีรษะเทียม; การผ่าตัดเปิดกะโหลกศีรษะ; กะโหลกศีรษะเทียม 3 มิติ; เครื่องพิมพ์ 3 มิติ; พลาสติก ABS