

CLINICAL CASE STUDY

Additively manufactured polyether ether ketone (PEEK) skull implant as an alternative to titanium mesh in cranioplasty

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Abstract

Cranioplasty is used for skull defects, involving lifting the scalp and restoring the contour of the skull with the original skull piece, titanium mesh, or solid biomaterial. Additive manufacturing (AM) technology, known as three-dimensional (3D) printing, is now utilized by medical professionals to develop customized replicas of tissues, organs and bones, offering a valid option with perfect anatomic fitting in the individual and skeletal reconstruction. Here, we report a case that underwent titanium mesh cranioplasty 15 years ago. The poor appearance of the titanium mesh weakened the left eyebrow arch and resulted in the formation of a sinus tract. Cranioplasty was performed using an additively manufactured polyether ether ketone (PEEK) skull implant. PEEK skull implants have been successfully implanted without any complications. To our knowledge, this is the first reported case of direct use of fused filament fabrication (FFF)-fabricated PEEK implant for cranial repair. The FFF-printed PEEK customized skull implant could possess simultaneously with adjustable material thickness and more complex structure, tunable mechanical properties, and low processing costs compared with traditional manufacturing processes. While meeting clinical needs, this production method is an appropriate alternative for promoting the use of PEEK materials in cranioplasty.

Keywords: Cranioplasty; Three-dimensional printing; Additive manufacturing; Polyether ether ketone; Fused filament fabrication

1. Background

Cranioplasty is mainly used for skull defects caused by a previous operation or injury, so as to reconstruct the continuity of the skull and restore the normal anatomical structure^[1]. Titanium mesh is a commonly used material for cranioplasty, generally performed without precise anatomical markers^[2]. However, radiographic examinations are inevitably affected by artifacts in patients with titanium implants. Implant exposure and deformation as a result of external force are known complications of titanium mesh cranioplasty and are usually managed by implant removal or exchange^[3].

Polyether ether ketone (PEEK) is a potentially suitable biomaterial for cranioplasty due to its prominent characteristics, such as good biocompatibility, low radiographic artifacts, and elastic modulus similar to cortical bones^[4]. Previous clinical case reports have demonstrated the successful application of the patient-specific subtractive manufacturing PEEK skull implant with good precise anatomic, esthetic reconstruction that resulted in fewer postoperative complications^[5,6]. Nonetheless, the inherent drawback associated with the subtractive manufacturing of PEEK skull implants was their processing methods that hindered the repair of complicated skull defects. Subtractive manufacturing PEEK is expensive because a great deal of materials could be wasted. Additionally, this technique sometimes requires piecing multiple implants together due to the complex anatomy; situations that require piecing multiple implants include cranioplasty for large-scale cranial defects and repair of complex anatomical structures^[7].

Additive manufacturing (AM) is a process of joining materials to make objects from three-dimensional (3D) model data using a layer-by-layer method, which is opposed to subtractive manufacturing methodologies^[8]. To fabricate low-cost PEEK orthopedic implants with large and complex anatomical structures, additive manufacturing techniques were used to meet patient-specific demands. AM custom-made PEEK implants have been used in the reconstruction of chest wall defects and mandibular defects repair in recent studies because of the advantages in the aspects of cost and individual skeletal reconstruction^[9-11]. However, studies on AM custom-made PEEK skull prostheses are limited.

Here, we present a case of a patient who underwent titanium mesh exchange with the fused filament fabrication (FFF)-fabricated PEEK implant. The feasibility of using an FFF-fabricated PEEK implant to repair skull defects with complex geometries was demonstrated in this study.

2. Case presentation

In June 2022, a 33-year-old male was admitted to the Department of Neurosurgery of the Affiliated Hospital of Southwest Medical University due to skin dimpling of the left eyebrow arch. After admission, the 3D reconstruction of head computed tomography (CT) was performed (Figure 1A–C), the defect area includes the left frontal bone and supraorbital, with an area of about 80 cm². Other laboratory examinations and tests showed no obvious abnormalities.

Fifteen years ago, this patient underwent a left forehead tumor resection and titanium mesh cranioplasty due to the left frontal osteoma. The resection range includes the left supraorbital and part of the frontal bone, and a cranioplasty was performed using titanium mesh. In recent months, the patient felt that the left forehead became flat and collapsed, resulting in an asymmetric appearance of left and right sides of the forehead. This caused a severe negative impact on his life, so he came to the hospital for treatment.

The specifications of PEEK implants suitable for this patient are discussed. A 3D model was used in the computer to reconstruct the skull's appearance after using the PEEK implant (Figure 1D–F). We increased the overall curvature of the PEEK implant and reduced the thickness of the edge of the PEEK implant during the designing process (Figure 1F). On the one hand, the increase of curvature can prevent the compression of the brain tissue caused by the implant, and make the appearance of the left and right sides of the forehead more symmetrical, meeting the patient's esthetic requirements. On the other hand, the thickness of the cranial margins of the patients was not uniform. The skull was relatively thin in the center of the skull defect and relatively thick in the periphery, the thin PEEK implant edge ensures a tighter bond between the implant and the skull, making it easier to fix the implant to the skull. Using this embedded PEEK implant for cranioplasty is visually and functionally superior to covered cranioplasty^[12].

The flow chart of the FFF printing of the PEEK skull implant is shown in Figure 2A. Surgical-grade PEEK filament with a diameter of 1.75 mm was bought from Shaanxi Jugao-AM Medical Technology Co., Ltd. (China) for FFF. The as-designed skull implant model was imported into slicer software for slicing and then loaded into the FFF machine (Xi'an Jiaotong University) (Figure 2B). The actual stress condition of a PEEK skull implant in the clinical application should be considered during data processing to ensure that the anisotropy will not affect the service life of the implant. The concentric circle path filling method was chosen to manufacture the PEEK skull implant. The FFF

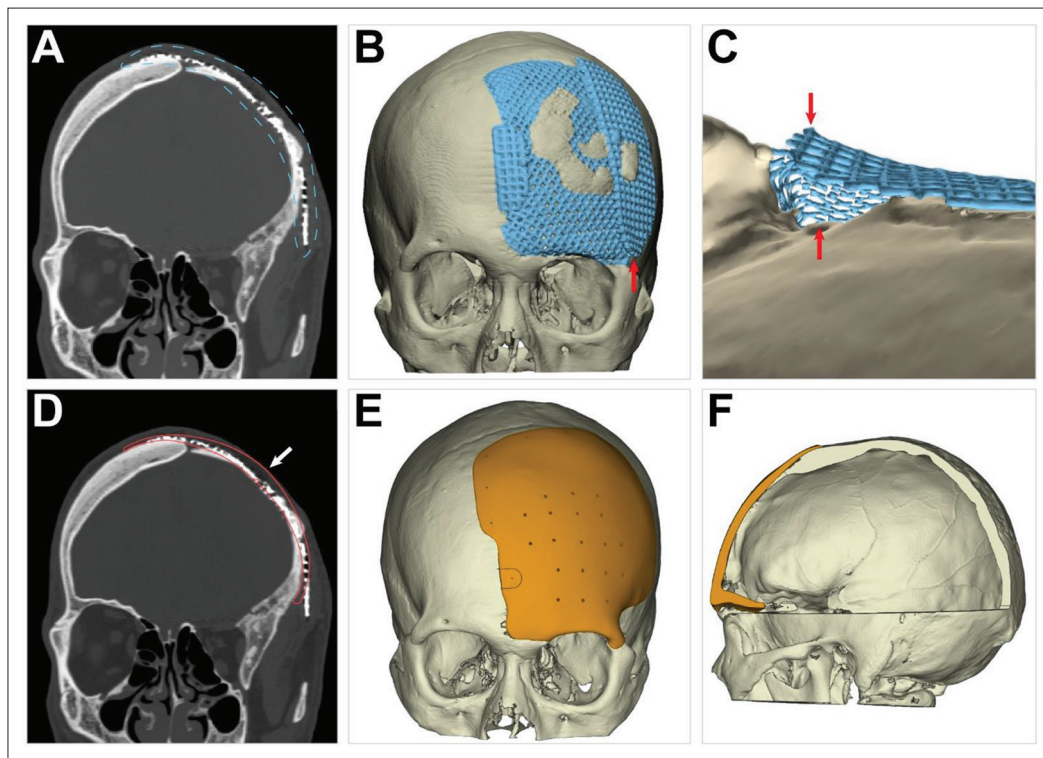


Figure 1. Three-dimensional reconstruction of head CT before surgery and computer design of PEEK implant. (A) Head CT shows the defect of the left frontal bone and the imaging performance after cranioplasty with titanium mesh. (B) The 3D reconstruction of head CT shows the anatomical relationship between the titanium mesh and the skull from the coronal views, and the protruding part of the titanium is seen (indicated by red arrow). (C) The 3D reconstruction of head CT from the horizontal direction shows that the protruding part of the titanium and the gap between the titanium mesh and the skull. (D) Designing the scope of PEEK implants from sagittal CT (indicated by the white arrow). (E) Three-dimensional model of the designed PEEK implant. (F) The 3D reconstruction from coronal CT of the head shows thickness inhomogeneity of the skull and changes in the curvature of PEEK implants.

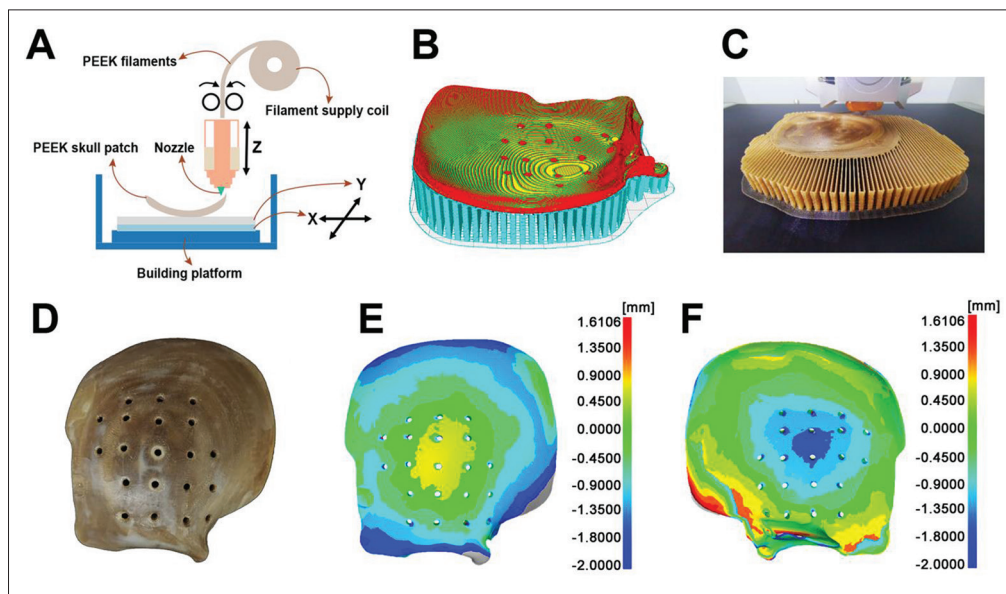


Figure 2. Schematic illustration of the process to fabricate the FFF-printed PEEK skull implant. (A) Flow chart of the FFF printing of PEEK skull implant. (B) Printing data processing and acquiring control parameters. (C) FFF printing of the PEEK skull implant. (D) The FFF-printed PEEK prosthesis of the skull. (E, F) Comparison between the FFF-printed PEEK skull implant and the patient-specific designed PEEK skull prostheses. The front (E) and back (F) views of the printing accuracy are shown.

machine (printer model: Surgeon Pro) automatically printed the PEEK skull implant layer-by-layer, as shown in Figure 2C. For the fabrication of the as-designed PEEK skull implant, the printing parameters of FFF such as layer thickness, nozzle diameter, bed and chamber temperature, nozzle temperature, and printing speed were set at 0.2 mm, 0.4 mm, 20°C, 430°C, and 40 mm/s, respectively. The macroscopic image of the FFF-printed PEEK prosthesis skull is shown in Figure 2D.

The weight of the FFF-printed PEEK skull prosthesis was approximately 42.79 g. The size of the skull implant reached 12 cm × 10 cm. Before clinical application, several mechanical properties were tested by a third-party inspection institution (National Additive Manufacturing Product Quality Supervision and Testing Center). Subsequently, we further compared the relevant parameters with previous reports on the mechanical properties of the human skull^[13]. The elastic modulus of the skull and 3D-printed PEEK implants are 8.51 GPa and 3.45 GPa, the tensile strengths are 67.73 MPa and 96 MPa, and the flexural strengths are 82 MPa and 154 MPa (Table 1). The printed PEEK implant was scanned with a 3D scanner (XTOM-MATRIX) to obtain the actual size of the implant. Then, the deviation between the design model and the printed PEEK implant was analyzed by the built-in analysis software (Figure 2E and F).

Table 1. Comparison of mechanical properties between the skull and 3D-printed PEEK implants

Mechanical properties	Skull ^[13]	3D-printed PEEK implant
Elastic modulus (GPa)	8.51	3.45
Tensile strength (MPa)	67.73	96
Flexural strengths (MPa)	82	154
Impact toughness (kJ/m ²)	49	80

Then, we compared the degree of integration of the skull made by stereolithography appearance technology with the titanium mesh and PEEK implants from various angles before surgery (Figure 3A–F). We found that the newly regenerated bone was tightly bound to the implanted titanium mesh, and a clear gap was formed between the skull and the titanium mesh in the temporal area (Figure 3A–C). In order to avoid further damage to the newly regenerated bone on the dura after peeling the titanium mesh, we appropriately increased the curvature of the central part of the PEEK implant. Although some scholars have considered that the increase in curvature may cause the collapse of patient's scalp incision due to excessive tension^[12], this patient had no significant incision complications. In addition, during the production process, we filled the gaps in the temporal region according to the patient's skull anatomy (Figure 3B and E). Finally, we found

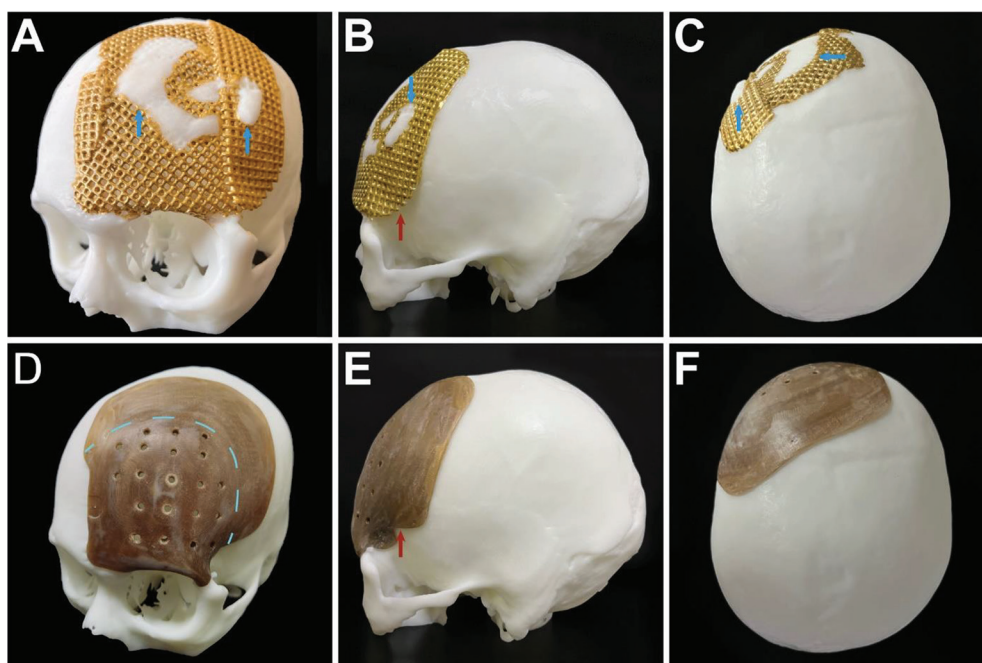


Figure 3. The preoperative matching between skull defects model and PEEK material. (A–C) The skull defects model made by stereolithography technology shows the positional relationship between the skull and titanium. The newly regenerated bone (indicated by the blue arrow) merged with the titanium mesh. In the temporal area (B), a clear gap between the titanium mesh and skull (red arrow) can be observed. (D–F) The PEEK implant was fabricated by FFF technology for preoperative matching. The inner side of the blue line is the PEEK implant of uniform thickness, and the outer side is the thinning wing (D). In the temporal part (E), the PEEK skull implant shows a tight fit for the skull defects model (red arrow) in the preoperative matching.

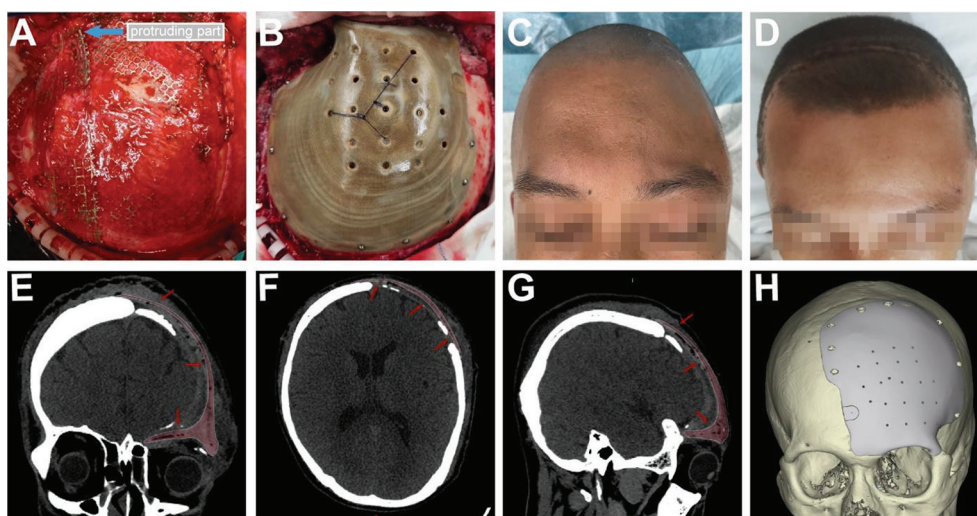


Figure 4. Clinical implantation and postoperative effect of FFF-fabricated PEEK skull prosthesis. (A,B) During the operation, the titanium was replaced with an FFF-fabricated PEEK skull implant. The protruding part of the titanium could be observed (blue arrow) and was resolved after switching to the PEEK implant, and the PEEK implant was fixed to the skull using titanium nails. (C,D) The appearance of the patient's forehead before (C) and after (D) the implantation of PEEK skull prosthesis. (E–H) A follow-up 3D reconstruction of the head CT after the cranioplasty reveals the positional relationship between the FFF-printed PEEK skull implant and the skull defects. The PEEK implant is indicated by red arrows.

that the PEEK implant was more closely combined with the skull, making the appearance anatomically symmetrical.

The PEEK implant was processed in surgical grade, including ultrasonic cleaning, ethylene oxide sterilization, sterilizing using autoclave, and soaking with iodophor prior to intracranial implantation. The anesthesia and surgery were going well. We first separated and removed the deformed titanium mesh, and then, the PEEK implant made by 3D printing was placed. In the final step, we used the designed overlap to fix the PEEK implant directly on the skull with titanium nails without using PEEK connectors, which can shorten the operation time as well as reduce the surgery costs, the risk of implant infection and related complications (Figure 4A and B). The FFF-manufactured PEEK skull implant was successfully implanted with a well precise anatomic and esthetic reconstruction (Figure 4C and D). A subgaleal drainage tube was placed at the end of the operation, and the patient woke up after surgery. Except for intraoperative antibiotics, no antibiotics were used during the perioperative period, and the head wounds were routinely disinfected in the ward. There were no symptoms of fever or wound infection during the hospital stay. The 3D reconstruction of head CT was re-examined before discharge (Figure 4E–H).

3. Discussion

We present here the first reported case of cranioplasty with FFF-fabricated PEEK material. Cranioplasty is a mature technique, which is mainly used for skull defects caused by various reasons, such as trauma, tumor invasion,

and surgical resection, and the technique could alleviate cognitive and functional deficits by reinstating the regular cerebrospinal fluid dynamics and improving brain perfusion^[1]. The repair materials mainly include autologous bone, polymethyl methacrylate, titanium mesh, PEEK, and several other materials^[3,14]. At present, titanium mesh is a commonly used material for cranioplasty. However, titanium mesh has several limitations, such as high thermal conductivity, easy formation of imaging artifacts during medical examinations, and high susceptibility to deformation by external force and implant exposure^[3,15]. The patient in this case underwent autologous bone resection and titanium mesh cranioplasty 15 years ago. In recent years, the skin of the patient's left brow arch has thinned and a sinus tract has formed. The collapse of the left forehead and the skin sinus significantly affected his quality of life. This performance is consistent with previous findings by Singh *et al.*^[16].

PEEK materials are widely used in medical fields, such as maxillofacial surgery for midfacial skull reconstruction, dental implantology, joint replacement, ophthalmology for fabrication of artificial corneas, long bone replacement, spine surgery for spinal stability reconstruction, and intervertebral disk reconstruction replacement^[17–19]. The application of PEEK material for cranioplasty was first reported in 2007^[20]; it has been lauded as a potential material in surgery because of its prominent characteristics, such as good biocompatibility, radiolucency, toughness, biological inertness, and other characteristics that meet the needs of the human body and surgeons^[5,21,22]. Recent meta-analysis results show that using PEEK material for cranial repair has

a lower complication rate compared to autologous bone, and a lower implant failure rate compared with titanium mesh^[21].

However, the production process of traditional PEEK implants for clinical use is complicated. First, the defective skull model is reconstructed by computer, and then the appropriate PEEK implant is designed by computer-aided design/computer-aided manufacture technology. Then, the cube of PEEK material is step-by-step cut and polished, and processed into the final shape of the patient's physiological structure. This subtractive manufacturing method requires a large amount of PEEK raw material, which contributes to huge waste^[23]. In addition, for complex anatomical structures, conventional production methods can only piece together the materials of multiple PEEK implants, which also complicates the production process and increases the production cost. Recently, two technologies, selective laser sintering (SLS)^[24,25] and FFF^[26], have been promoted for the shaping of PEEK materials. Both of them can process PEEK raw materials into desired shapes. The material consumption and the toughness of the FFF technology were significantly better compared with that of the SLS technology, making FFF technology gradually widely used^[27].

In this report, we combine FFF technology with specific temperature control. To control the mechanical properties of PEEK implants, this technique uses a cooling fan to rapidly cool the PEEK filaments ejected from the nozzle. The PEEK material was rapidly cooled during extrusion, and the desired PEEK material skull implant with both strength and toughness was obtained (Figure 2D). Except for tensile strength, the mechanical properties of the 3D-printed PEEK implants are superior to those of the skull^[13]. In addition, PEEK implants made by FFF have higher impact toughness than skulls, and can better protect brain tissue from damage caused by external force. This AM technology can help save raw materials and reduce costs. Importantly, the AM technology is more suitable than the traditional subtractive manufacturing technology for fabricating complex anatomical structures, especially those in the skull base and maxillofacial junction regions^[22,28]. Notably, a preclinical study has provided a morphological and structural quantitative assessment of 3D-printed PEEK implants for cranial reconstruction and suggested that 3D-printed PEEK implants are safe for use in cranioplasty^[29]. To the best of our knowledge, the case we reported herein is the first known clinical application of PEEK material made by FFF technology in cranial repair. In order to significantly reducing the production cost of PEEK implants, this process produces implants with better appearance that not only deliver increased surgical satisfaction, but also improve quality of life without increasing the financial burden on patients.

5. Conclusion

As an established surgical method, cranioplasty has been modified many times, and the ideal material has been long sought for use in cranioplasty. 3D-printed PEEK skull implant, which is characterized by high strength, high toughness, and excellent biocompatibility for cranioplasty, can be prepared instantly, and the production process is rather cost-efficient. For the first time, we applied a PEEK implant manufactured by FFF technology to cranioplasty in a patient who did not complain of any implant-related complications during the hospital stay.

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Conflict of interest

The authors declare no conflicts of interest.

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Writing – review & editing: Jiaqi Zhang, Yanwen Su, Jianhua Peng

Ethics approval and consent to participate

The protocol was approved by the ethics committees and research boards of the Affiliated Hospital of Southwest Medical University (KY2021133). The consent to release medical information and the consent to participate in the study were obtained from the subject.

Consent for publication

Consent was obtained from the patient for publication of this case report and relevant images.

Availability of data

Further inquiries regarding the raw data can be directed to the corresponding author.

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