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Review Article

Preoperative Planning for Physician-Modified Endografts Using a Three-Dimensional Printer

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The medical uses of three-dimensional (3D) printing are evolving at a rapid pace. The current roles and the future outlooks of this technology for physician-modified endovascular graft (PMEG) in patients with juxtarenal aneurysm are discussed. Fenestrations of PMEG are designed taking into account the geometry of the stent graft. Designing of such stent grafts is extremely complicated, especially when PMEG is planned for the angulated portion of the aorta. A 3D model enables the designing of branch fenestrations, with consideration for the geometrical adaptation of the stent graft in a complex aortic anatomy. With the aid of 3D-printing technology, patients with juxtarenal aortic pathologies can be treated using fenestrated stent grafts, preserving the vital organ circulation and securing a robust length of proximal sealing zone.

Keywords: abdominal aortic aneurysm, paravisceral, juxtarenal, endovascular aneurysm repair, simulation

Introduction

Medical uses of three-dimensional (3D) printing are evolving at a rapid pace. With the recent progress in imaging technologies, its utilization has spread to various fields and in more advanced ways. This article focuses on the applications of 3D printing in physician-modified endovascular graft (PMEG) for juxtarenal aortic pathologies.

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Endovascular Aneurysm Repair (EVAR) for Juxtarenal Aortic Pathologies

Many methods have been developed for managing aortic branches during EVAR for juxtarenal aortic pathologies. They are categorized into debranching procedures, parallel grafts, and branched or fenestrated devices.[1] Basically, these techniques require the proximal sealing zone beyond the lowest renal artery. Debranching procedure is a hybrid approach, which necessitates bypass surgeries for the covered visceral branches. Parallel grafting requires visceral stents or stent grafts running conceptually parallel to the aortic stent graft. The blood flow for the parallel grafts (chimney or snorkel) is supplied proximally or distally to the aortic stent graft. If the visceral stent grafts run between two overlapped aortic stent grafts, they are referred to as sandwich grafts. Branched or fenestrated endovascular repairs use modified stent grafts. Fenestrated stent grafts have openings on the graft surface to perfuse visceral branches, proximal to which the aortic device is deployed. There are various types of fenestrations, such as scallops and fenestrations with or without stent struts.[1] Depending on anatomical conditions, a fenestration without stent struts is designed to be stented. Branched stent graft is defined as a modified stent graft with a tubing form of (stent) graft sewn into the fenestration. PMEG is designed and used to cover the unmet needs of commercially available branched or fenestrated devices. It should be noted that the use of all of these techniques, including debranching, parallel graft, and PMEG, is regarded as an off-label application.

Basics of 3D Printing

3D printing is a process of making 3D solid objects from a digital file, for instance, CAD (computer-aided design) formatted in STL (standard triangulated language). The files are created using 3D modeling software, either from the ground up or based upon the data generated by 3D scanners, such as computed tomography (CT) and magnetic resonance imaging (MRI). "Slicing" is a process in which a

3D model is virtually divided into hundreds or thousands of horizontal layers. It can be performed using slicing software or processed either in 3D modeling software or in the 3D printer itself. 3D printing is an "additive manufacturing" process, where an object is created by laying down the successive layers. At present, additive manufacturing process is classified into six methods: sheet lamination, (Vat) photopolymerization, material extrusion, binder jetting, material jetting, and powder jet fusion. Stereolithography is a photopolymerization method.[2] It employs photopolymer resin commonly used as a material for cardiovascular models. The objects are printed out with supporting structures that serve to attach the part to the elevator platform.

Clinical Applications of 3D Printing

The clinical value of 3D printed models started to be recognized in the craniomaxillofacial field since the late 1980s,[3] and its application extended to the fields of tumor and cardiovascular imaging. The medical importance of these models has also been confirmed in case reports of patients with congenital heart disorders (CHD).[4–6] The appropriateness guidelines for 3D printing have been developed by the Special Interest Group (SIG), which was established by the Radiological Society of North America (RSNA).[7] The utilization of 3D models of complex CHD, such as truncus arteriosus and total and partial anomalous pulmonary venous return, for medical education and surgical simulation has been ranked as 8 or 9 (7–9: usually highly appropriate). Conversely, 3D printing for consideration of the endovascular or surgical treatment for aortic aneurysmal disease has been ranked as 5 (4–6: maybe appropriate), and the creation of 3D models for designing patient-specific aortic stents has been rated as 7 (usually appropriate).

Fenestration Planning

Stent-graft fenestration should be planned manually beforehand using medical 3D-imaging software. The planning should take into account a vessel centerline, post-deployment adoption of stent graft to the anatomy, and the relationship of the fenestration and stent struts of the selected device.[8] A detailed record of fenestration plan, branch artery takeoff angles, superior mesenteric artery (SMA) angle set at 0°, the heights (length between the proximal edge of the stent graft and the center of the branch opening), and the sizes must be kept. It is also useful to take snapshots of the stent-graft sample from various angles, with colored self-adhesive marking seals (Tack Title, Kokuyo Co., Ltd., Osaka, Japan) placed onto the planned locations.

Creation of 3D Model

CT angiography (CTA) images are used to create CAD files of the proximal landing zone. Mimics inPrint 3.0 (Materialise NV, Leuven, Belgium) creates CAD files of hollow aortic models with branch vessel orifices. To maintain the wall transparency of 3D models, the wall thickness has been set within 1.0–1.5 mm. 3D object is printed using a 3D printer (Form 2, Formlabs Inc., Somerville, MA, USA) utilizing clear resin materials (Formlabs Inc., Somerville, MA, USA). Total manufacturing time varies from 7 to 12 h, depending on the volume of the photopolymerized material, including the 3D objects and supports. Resin residuals on the surface are cleaned with 2-propanol, and the supports are removed from the model (**Fig. 1**).

Validation of Fenestration Design Using 3D Models

From the CTA data, a region of interest is selected (**Fig. 2A**). Two types of hollow transparent 3D models are created, namely, longitudinally split and unsplit types (**Figs. 2B** and **2C**). Both can be used as "aortic skin."[9] A stent-graft sample, which is planned to be used for the procedure, is deployed inside the 3D model, the proximal height of the device being adjusted as planned previously. For the split type model, two parts must be securely attached to each other with rubber bands (**Fig. 3A**). Otherwise, gaps may appear between the parts, causing misalignment of the fenestration in vivo. To optimize the locations of fenestrations relative to the stent struts, the deployment height and rotation of the stent graft may have to be adjusted frequently. Hence, the split type would be preferable for this process. After the optimization, the heights of the branch holes and the relationship between the holes and stents are

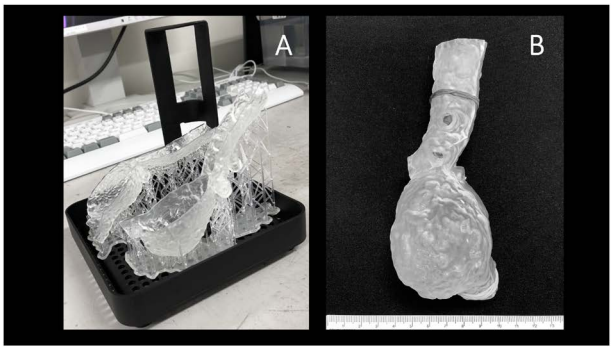

Fig. 1 Three-dimensional (3D) models before and after cleaning (**A** and **B**).
The supports are removed from a model after cleaning of the residual resin using ethanol. Split type of 3D model for juxtarenal abdominal aortic aneurysm is presented with rubber bandages (see **Fig. 2**).

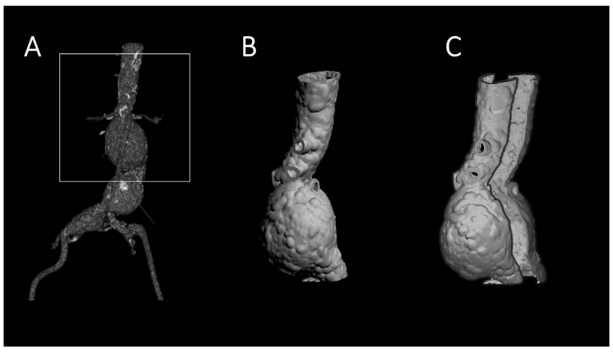

Fig. 2 Preparation of three-dimensional (3D) files.
Volume-rendered image of juxtarenal abdominal aortic aneurysm (**A**) and 3D models (**B** and **C**) are created by the software. Rectangular region in **A**: the region of interest of the model. The longitudinally split and unsplit types (**B** and **C**) are created.

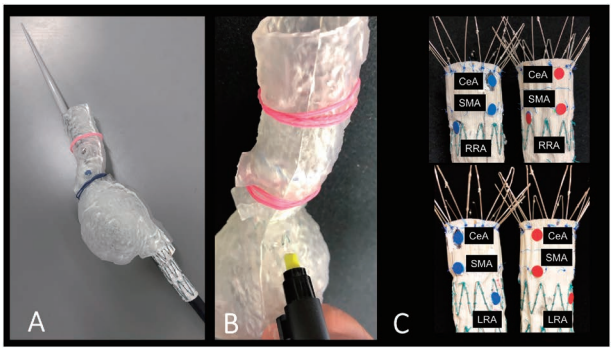

Fig. 3 Preoperative planning using three-dimensional (3D) models.
(**A**) The fenestrated device is deployed according to the preoperative planning. A case using a split type of 3D model is presented. (**B**) The position of fenestration on the stent graft is marked using a felt-tipped marker. A case using an unsplit type of 3D model is presented. (**C**) Comparisons between the plans. The plans can be validated bidirectionally. Blue markers were used for the preoperative planning without 3D modeling, whereas red markers were located on the fenestrations indicated by a method using a 3D printer. Note the difference in the RRA locations. After repeated deployment simulation, the RRA fenestration was located as indicated by the planning using the 3D model.
CeA: celiac artery; SMA: superior mesenteric artery; LRA and RRA: left and right renal artery

recorded accurately. The deployment height and locations of fenestrations are marked on the surface of the model and the stent graft using a felt-tipped marker (**Fig. 3B**). The results should be compared with the manual planning to decide on the final preoperative plan (**Fig. 3C**). If necessary, the deployment simulation using a long unsplit tube type of model should be performed for further validation.

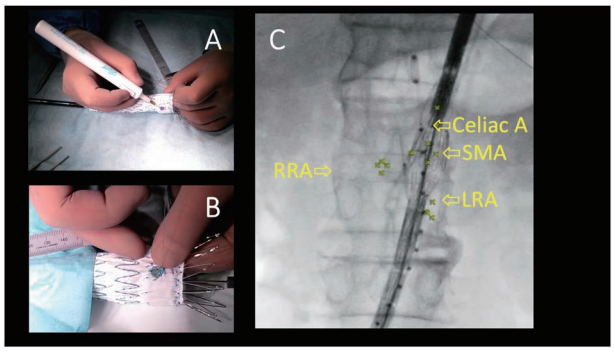

Fig. 4 Back table fenestration and three-dimensional branch marking.
The markings are accurately reproduced onto the surface of the stent graft to be implanted. The fenestration holes are made using a cautery (**A**). Locking 4-0 Ethibond sutures (Ethicon, a Johnson & Johnson company, Somerville, NJ, USA) and 0.014 micro-coil (**B**) are used to reinforce all fenestrations. The fenestrated device is re-sheathed into the deployment sheath. Branch openings of the Celiac A, SMA, and RRA or LRA are marked three-dimensionally using rotation angiography performed after insertion of the deployment sheath (**C**). These markers were used as references to optimize the location of fenestrations.
Celiac A: celiac artery; SMA: superior mesenteric artery; LRA and RRA: left and right renal artery

Back Table Stent-Graft Fenestration

The stent-graft fenestration is performed on the back table during the operative preparation process (induction of anesthesia and surgical access to the common femoral arteries). The markings are accurately reproduced onto the surface of the stent graft to be implanted. The fenestration holes are made using a cautery (**Fig. 4A**). Locking 4-0 Ethibond sutures (Ethicon, a Johnson & Johnson company, Somerville, NJ, USA) and a 0.014 micro-coil (IDC 18, Boston Scientific, Marlborough, MA, USA; **Fig. 4B**) are used to reinforce all fenestrations. The fenestrated device is then re-sheathed into the deployment sheath. If FEVAR (fenestrated endovascular aneurysm repair) must be performed in an urgent situation, fenestrations may be directly marked onto the pre-implanted stent graft on the back table using the sterilized 3D models. The printing material must be biocompatible and sterilized for this purpose.[10]

Deployment of Fenestrated Device

The PMEG is deployed into the patient's aorta using the alignment of the targeted branches as reference mark. To protect the targeted branches, guidewires are placed to some branches before the deployment. Alignment of the fenestrations should be verified by performing continu-

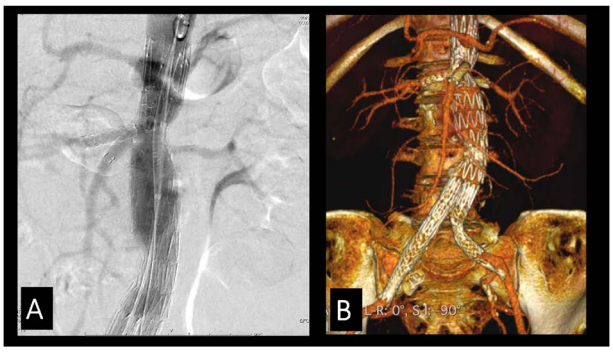

Fig. 5 Physician-modified endograft using Zenith Flex.
Completion angiography (**A**) and computed tomography angiography (**B**) of a juxtarenal abdominal aortic aneurysm case are presented. Fenestrations are made for the superior mesenteric artery, right artery, and left renal artery (fenestrations without stent strut).

ous fluoroscopy if the branch is cannulated. 3D branch marking, using CT fusion technologies or rotation CT, is helpful for the deployment. At our institute, the openings of renal and splanchnic branches are marked three-dimensionally using rotation angiography after insertion of the deployment sheath (**Fig. 4C**). The top bare stents are usually constrained until the alignment of fenestrations is confirmed. Therefore, the second or third proximal fenestration (usually the SMA, right artery, or left renal artery) is used as the index fenestration.

After the index fenestration is aligned to the targeted vessel opening, the graft is further deployed stepwise, adjusting or optimizing the alignment of the other fenestrations. Deployment simulation, using a 3D model and a sample stent graft, is useful to identify the index fenestration, especially in multi-fenestrated cases. Bare metal or covered stents are placed as connection stents in the small fenestrations and their corresponding target arteries to avoid wind shuttering.[11] If balloon-expandable stents are used, the stent-graft sides of the ends are flared to prevent type 3 endoleak. Flaring may be also feasible for secondary intervention. At our institute, PMEG has been performed using Zenith Flex (Cook Medical LLC, Bloomington, IN, USA; **Fig. 5**) or Valiant (Medtronic Vascular, Santa Rosa, CA, USA; **Fig. 6**). Completion angiography and CTA are performed to assess the patency of visceral branches and the presence of endoleak.

Discussion

The first patent relating to 3D printing, describing a photopolymer rapid prototyping system, was filed in 1980 by Kodama.[12] In 1986, Hull invented stereolithography apparatus (SLA) and introduced the first commercial 3D printing system.[13] 3D printing was initially used for

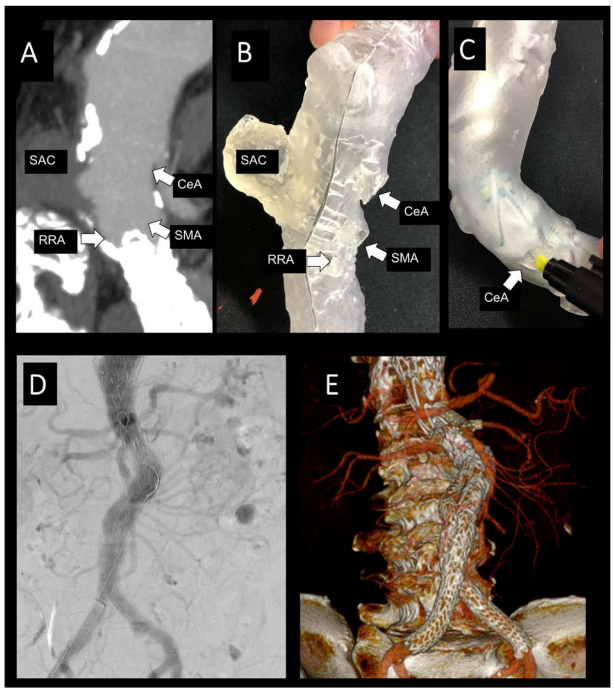

Fig. 6 Physician-modified endograft (PMEG) using Valiant Captivia.
A case of saccular type of suprarenal aneurysm (**A**) is presented. Previously, the patient was stent-grafted using Excluder (W. L. Gore and Associates, Flagstaff, AZ, USA). PMEG with four fenestrations plan was planned and validated using the three-dimensional model (**B**, **C**). Fenestrations are made for the CeA (a large fenestration not intended to be stented) and SMA, RRA, and LRA (fenestrations intended to be stented). Completion angiography (**D**) and postoperative CTA (**E**) are shown.
SAC: saccular aneurysm; CeA: celiac artery; SMA: superior mesenteric artery; LRA and RRA: left and right renal artery; CTA: computed tomography angiography

industrial prototyping and developed for use in a variety of fields. It facilitates more personalized medical intervention, including surgical planning and implant design, in the healthcare field. This technology will continue to develop and have a greater influence on healthcare.

FEVAR is a treatment option for complicated juxtarenal aortic pathologies.[14] Adoption of this technique is extremely slow due to regulatory problems as well as the planning and procedural complexity. Although one commercial fenestrated stent graft for distal arch aneurysms has been approved in 2012, no juxtarenal fenestrated stent grafts are available in Japan. FEVAR has been performed only for high-risk patients with local ethical committee approval or for research purposes. Slow adoption may be caused also by the possibility of life-threatening consequences after misalignment of the fenestrations, and the impact of the failure cannot be neglected. Thus, there should be a reliable and trustworthy way for a 3D plan to be validated.

The first clinical application of 3D printing for PMEG was performed by Huang et al., when they printed a 3D overlay (aortic skin) of a juxtarenal aortic aneurysm.[9] Starnes et al. developed a method that outputs the fenestration plan as a 3D cylindrical model, which can be used to modify the standard endografts from multiple manufacturers on the back table.[15] PMEG planning using 3D printing technologies could produce a remarkable result, but fenestration–branch ostium mismatch occurred due to the anatomical deformation of the host aorta, straightening of the aorta, and visceral artery displacement by endograft delivery system insertion.[15,16] If post-deployment 3D anatomy of the aorta could be accurately predicted, these errors could have been prevented. A 3D model enables the designing of branch fenestrations, with consideration for the geometrical adaptation of the stent graft.

Current technologies cannot make an accurate numerical prediction for the results of the interaction between the device and native aorta.[17] Deformation of native aorta and resultant geometrical change of vessel openings are important aspects, especially for severely angulated cases. If a 3D model using a softer material is printed and the locations of fenestrations are compared with those in the hard model, the deformation pattern may be predicted to such an extent that the mismatch can be mitigated by accommodating the sizes and locations of fenestrations or by setting externalized guidewires for difficult fenestrations.[18] Problems on deformation may, however, be solved in the near future. CAD model files will be formatted not on STL but on the other additive manufacturing file format,[19] upon which 3D printers may accurately reproduce a physiological property of the aortic model in terms of the deformation.

In conclusion, the current roles and future outlooks of 3D printing for juxtarenal PMEG are discussed. With the aid of this rapidly evolving technology, patients suffering from complex juxtarenal aortic pathologies may be treated with stent-graft technologies, preserving blood circulation to vital organs and extending the length of proximal sealing zone.

Ethical Consideration

The surgical procedures presented here were performed after the approval of our institutional ethical review board (#18-72). A written form of informed consent was obtained from each patient.

Disclosure Statement

The authors have no conflicts of interest to disclose with regard to the present study.

Author Contributions

Conception and design: HM
Data collection: HM, YT, YM, TN, JT
Investigation and 3D Printing: HM, YT, YM, TN, JT
Writing the manuscript: HM
Critical review and revision: all authors
Final approval of the article: all authors
Accountability for all aspects of the work: all authors

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