Three-dimensional printing-guided fenestrated endovascular aortic aneurysm repair using open source software and physician-modified devices

Vladimir Barón, MD,[a] *and* Romeo Guevara, MD,[b] *Bogotá, Colombia*

ABSTRACT

Fenestrated endovascular aneurysm repair is frequently used for juxtarenal and pararenal aortic aneurysms. In urgent cases, however, the use of premanufactured patient-specific devices is not an option. Physician-modified endografts may be used to treat these patients but require experience and a steep learning curve for accurate planning to position fenestrations and to perform the graft modifications. Despite experience, a margin of error in placing fenestrations always exists, and a mismatch possibility between the fenestration and vessel ostium can lead to increased cannulation time and stent complications, including target vessel loss. Aortic three-dimensional printing has been widely described in medicine for simulation, training, and surgical planning. Commercial software is currently under investigation for planning of fenestrated endovascular aneurysm repair at high costs. We describe an effective and inexpensive technique using free computer-aided design software to create a real 1:1 aortic 3D model that can easily be printed and quickly sterilized. This aortic model can be used to create a physician-modified endograft and to place fenestrations in an accurate way, with potential for shorter and more precise procedures and better long-term results. Two cases are presented to illustrate the technique, demonstrating that 3D printing is a valuable tool to plan, design, and create fenestrated devices more accurately. (J Vasc Surg Cases and Innovative Techniques 2019;5:566-71.)

Keywords: FEVAR; 3D printing; Juxtarenal aneurysm; Physician-modified endograft

Fenestrated endovascular aneurysm repair (FEVAR) was developed to treat patients with abdominal aortic aneurysms with short or absent infrarenal neck. According to several series, FEVAR has proven good results in terms of mortality, technical success, and vessel preservation, although it remains a complex technique that requires accurate planning and advanced endovascular skills.[1] Fenestrated stent grafts are commercially available in a custom-made fashion, but design and manufacturing take time, usually 6 to 8 weeks in Latin America.

Patients at high risk for open surgery, presenting with juxtarenal or complex aortic aneurysms, and requiring urgent or emergent treatment have been treated with different endovascular techniques, including parallel grafts, hybrid procedures, and physician-modified endografts (PMEGs). Both custom-made fenestrated devices and PMEGs offer similar results in terms of technical success, with PMEGs offering immediate availability for those high-risk patients in the emergent setting.[2-4]

The evolution of medical imaging has allowed surgeons to improve surgical planning, especially for endovascular procedures. As computed tomography (CT) imaging has rapidly advanced in the last decade, high-resolution three-dimensional (3D) images can routinely be obtained to visualize complex vascular anatomy. However, even with this improvement in technology, the 3D image is still limited to viewing on a two-dimensional screen. With 3D modeling, the individual complexities of a patient's anatomy can be seen and analyzed with a real-size model in one's hands.[5]

The history of 3D printing started in 1981 and now has multiple commercial and industrial applications, including diverse medical fields. It has been widely recognized in vascular surgery as an effective method for planning and simulating treatment of complex aortic diseases. It is also an effective tool for teaching and training for complex procedures, reducing the learning curve.[5-7]

Actual planning for surgeon-modified FEVAR is based on CT angiography images that are processed with dedicated software to determine vessel origins, diameters, distance between them, and clock orientation. However, this technique has limitations: planning requires time and can be long according to experience; endograft modification takes time, usually 60 to 150 minutes; and high precision is required to minimize the risk of mismatch and misalignment that complicates cannulation and stent patency.[8]

From the Department of Vascular and Endovascular Surgery, Hospital Universitario Mayor Mederi and Hospital San Ignacio[a]; and the Department of Vascular Surgery, Hospital Militar Central.[b]

Author conflict of interest: none.

Correspondence: Vladimir Barón, MD, Department of Vascular and Endovascular Surgery, Hospital Universitario Mayor Mederi-Hospital San Ignacio, Calle 127 #20-16, Office 417, Bogotá, Colombia (e-mail: vbaron@hotmail.com).

The editors and reviewers of this article have no relevant financial relationships to disclose per the Journal policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

2468-4287

https://doi.org/10.1016/j.jvscit.2019.08.006

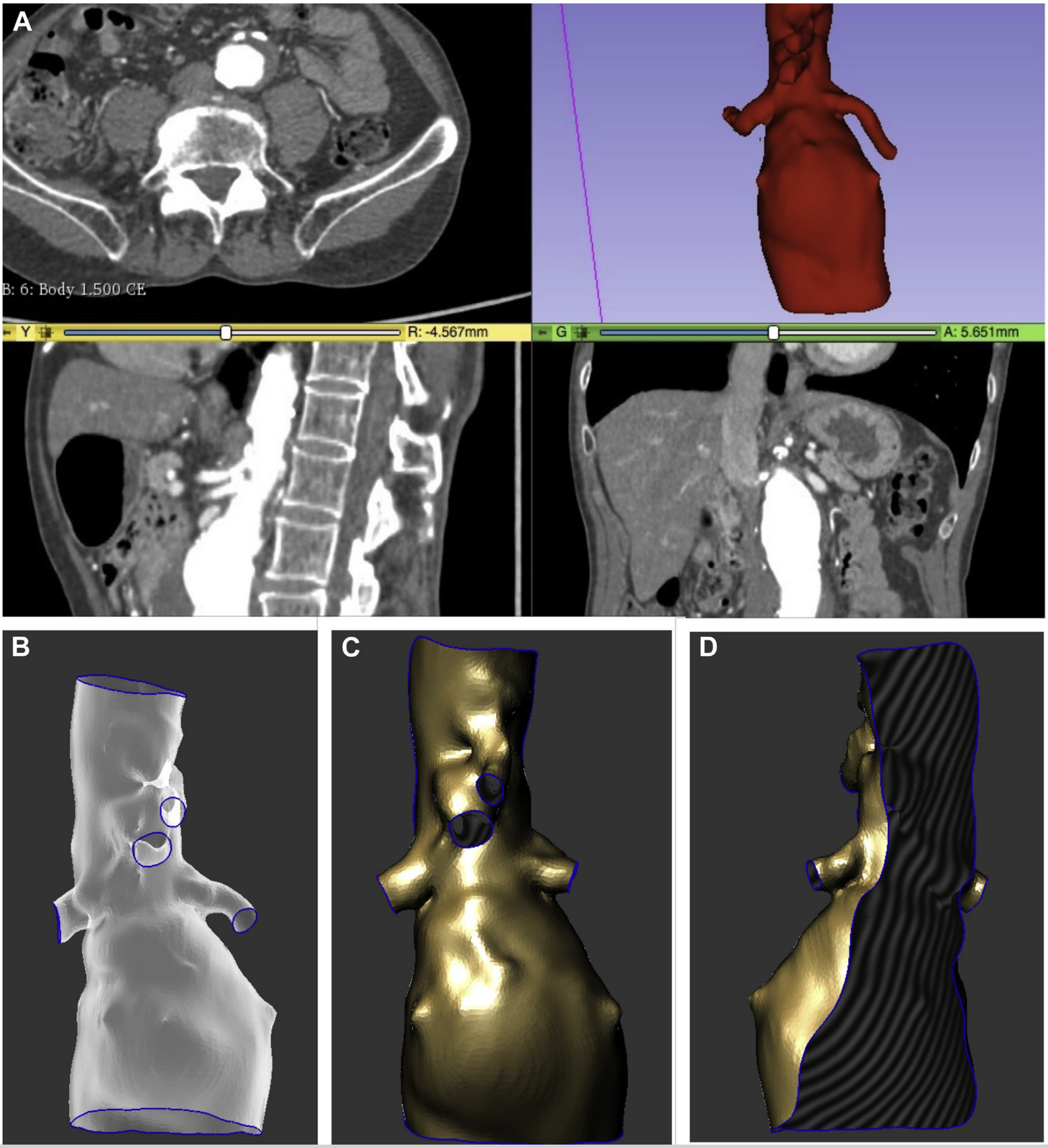

Fig 1. Aortic aneurysm three-dimensional (3D) model creation. Segmentation is performed with 3D Slicer software using the computed tomography (CT) Digital Imaging and Communications in Medicine files. Multiplanar views and the software tools are used to obtain an aortic 3D model that is saved as an STL file **(A)**. This file is exported to a computer-aided design software (Meshmixer) by which the original model is converted into a hollow piece **(B)**. The aortic surface is analyzed, and the vessels and posterior half of the aorta are cut to obtain a final template model that replicates the exact anatomy of the patient **(C** and **D)**.

The advantage of 3D printing is to convert two-dimensional Digital Imaging and Communications in Medicine images from a CT scan into a real 3D model that replicates the exact anatomy of the diseased aorta, having a clear image of the pathologic process. We describe our technique using free software to print a whole aortic 3D model and also a template of the aortic visceral segment (anterior half of the aortic wall) that incorporates the origin of each target vessel, not just the vessel orifice. We describe the technique in detail and present two cases to illustrate it. Both patients gave consent for publication of this report.

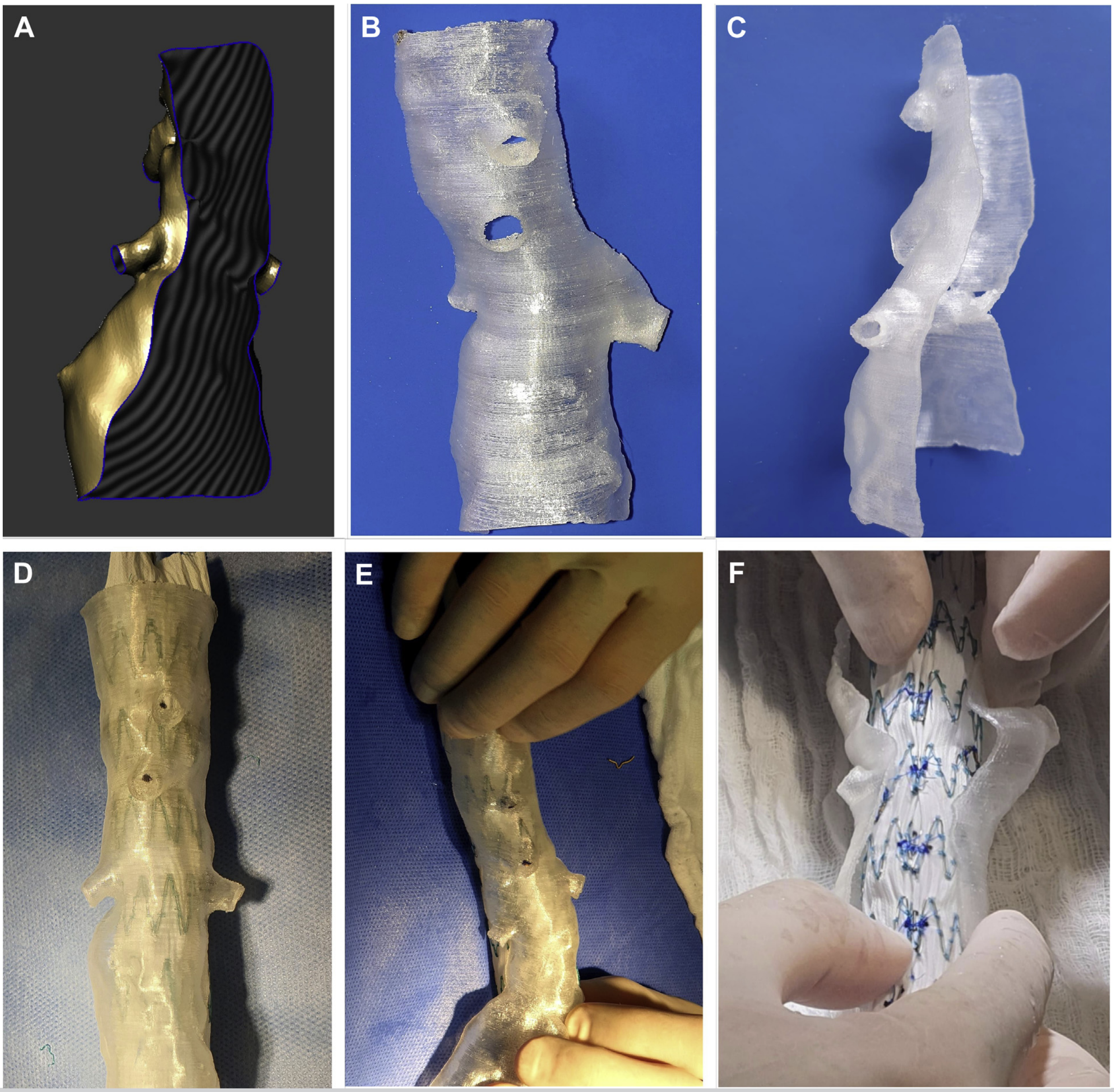

Fig 2. Aortic template file is exported to a commercial three-dimensional (3D) printer and printed with medium to high resolution **(A)**. Transparent aortic template printed with polylactic acid polymer and compatible with gas sterilization **(B** and **C)**. Preparation of physician-modified endograft (PMEG), marking fenestrations according to preoperative plan **(D)** and using the sterilized aortic template to verify that fenestrations match the target vessel origin **(E)**. Final check of constrained device, planning ahead for cannulation and stenting strategy **(F)**.

METHODS

Volume segmentation (3D Slicer). The process to create the 3D model requires a fine-cut (≤1 mm) CT scan of the abdominal aortic aneurysm and takes only 15 minutes to be completed. The CT Digital Imaging and Communications in Medicine files are loaded into a medical free and open source segmentation software, 3D Slicer version 4.10 (other free or commercially available software could be used). Using multiplanar views and the software cutting and softening tools, the infrarenal aorta and its branches are segmented to obtain a 3D image that is saved as an STL file (stereolithography file format). Because the inner lumen of the aorta is segmented, the model size is increased by 10% to preserve the accuracy of the original aortic size (Fig 1, *A*).

Postprocessing (Meshmixer) and printing. The STL file created in 3D Slicer is exported to another free computer-aided design software called Meshmixer by which the final models are created for printing. With this

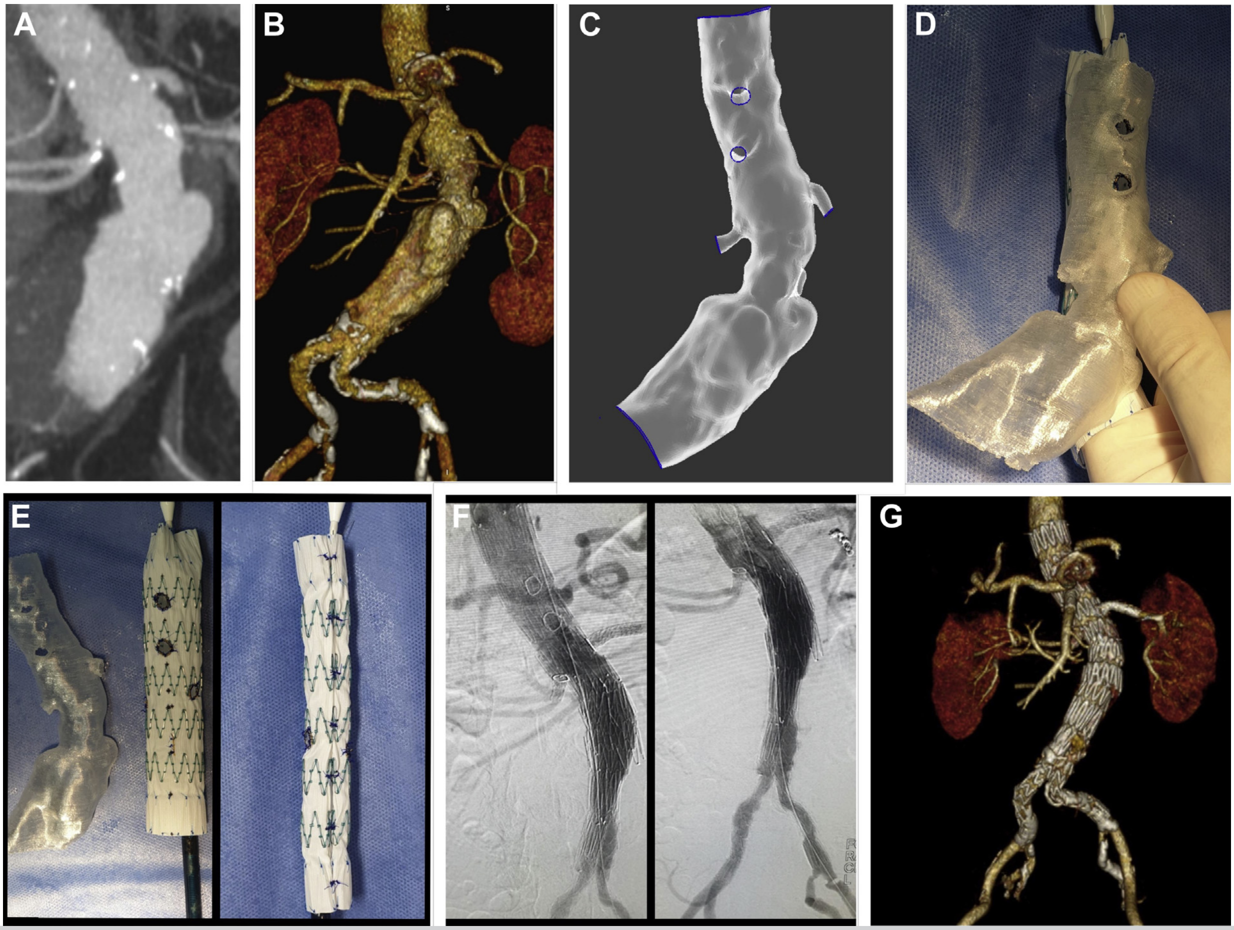

Fig 3. Case 1. Computed tomography (CT) scan shows a 65-mm juxtarenal aneurysm with a healthy visceral aortic segment **(A)** and suitable anatomy for a fenestrated endovascular repair **(B)**. An aortic three-dimensional (3D) model, created in Meshmixer **(C)**, is printed and sterilized in a relatively short time. The 3D aortic template is used to place fenestrations in a Cook Zenith TX2 device, which is modified on a back table as described by Oderich and Ricotta[8] **(D** and **E)**. Final angiographic result after an uneventful procedure and successful cannulation of visceral and renal vessels **(F)**. Follow-up CT scan reveals patent target vessels with no endoleaks **(G)**.

program, a solid model is converted into a hollow piece. With the inspector option, all possible surface defects are analyzed and corrected, and then the renal and visceral vessels are cut, keeping about 1 to 2 cm of each vessel (Fig 1, *B*). Finally, the posterior half of the aorta is eliminated, keeping the anterior wall as a template, and this final model is saved again as an STL file ready to be printed after another 15-minute process (Fig 1, *C* and *D*).

Model printing. The final 3D design is exported as an STL file and printed on a 3D printer with medium to high resolution. The printing materials are a thermoplastic polymer called polylactic acid and a polyethylene terephthalate glycol-modified filament; a hard and transparent model is formed that is compatible with gas sterilization. Printing time is about 1 hour for a half aortic template or 2 hours for a complete model and costs around U.S. $20 dollars (Fig 2, *A*-*C*).

Case planning. The case is planned as previously described by Oderich and Ricotta,[8] measuring distances and clock positions of the target vessels. Using multiplanar and centerline reconstructions, lengths, diameters, and clock positions are determined. The final plan is compared with the 3D model, correcting any possible misalignments, and the aortic model in finally sterilized with the Sterrad gas system (Advanced Sterilization Products, Irvine, Calif).

Modification of PMEG. The selected graft is usually a tubular thoracic Cook Zenith TX2 platform device (Cook Medical, Bloomington, Ind), modified on a back table inside the operating room with a strict sterile technique. Once the graft is unsheathed, the fenestrations can be marked according to the previous plan, and the 3D template is placed on top of the graft, verifying that the fenestrations will match perfectly with the target vessel

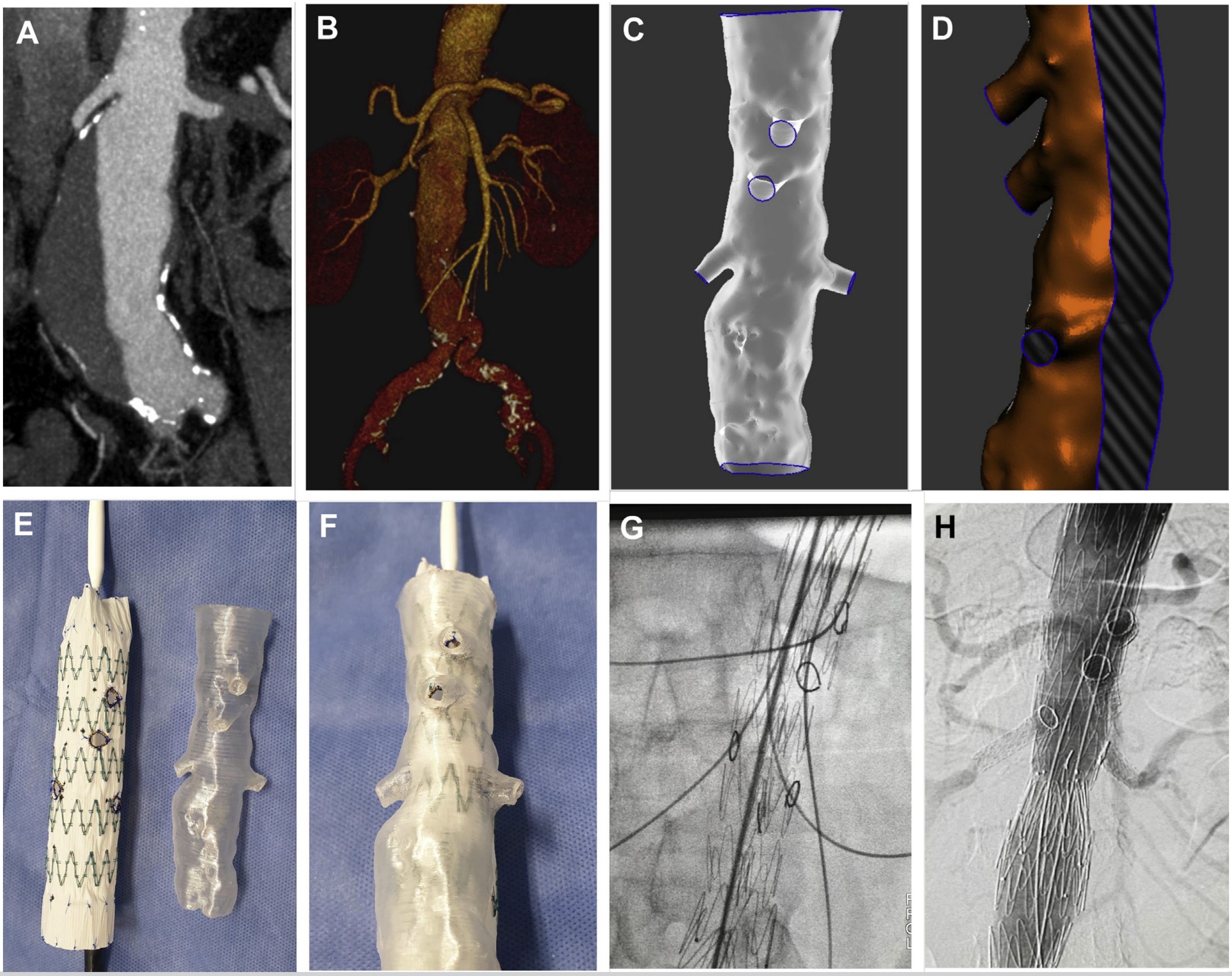

Fig 4. Case 2. A 77-year-old man with a symptomatic aortic aneurysm, unfit for open repair. Computed tomography (CT) scan reveals a juxtarenal aneurysm with suprarenal aorta and visceral and iliac arteries adequate for endovascular fenestrated repair **(A** and **B)**. Three-dimensional (3D) hollow aortic model created with 3D Slicer and Meshmixer software **(C)** and aortic template file ready for printing **(D)**. A Cook Zenith TX2 device was modified with the same technique, using the sterilized aortic model to place fenestrations accurately **(E** and **F)**. Only 20 minutes was required to cannulate all four target vessels **(G)**, and complete endovascular repair was finished with no complications and technical success **(H)**.

origin (Fig 2, *D-F*). If any of the stent struts are located within the possible fenestration sites, the template can be rotated until a perfect position for the fenestrations is found. The graft modification is performed as described by Oderich and Ricotta,[8] creating each fenestration with an ophthalmic cautery and reinforcing the orifice with a gold nitinol wire from a snare. Once all fenestrations are ready, the device is constrained to allow rotation, using one of the Pro-Form wires from the same graft. Finally, the stent graft is resheathed, using 1-0 silk sutures to tie each stent up. The device is then ready for implantation.

CASE REPORTS

Case 1. An 82-year-old man was seen in the emergency department with a 1-week history of back and abdominal pain. A contrast-enhanced CT scan revealed a 65-mm juxtarenal abdominal aortic aneurysm (Fig 3, *A* and *B*). He had a history of coronary artery disease and chronic obstructive pulmonary disease and was considered unfit for open repair. An urgent FEVAR was planned with a four-fenestration PMEG and a bifurcated distal component. A 30—× 140-mm ZDEG Zenith Cook device was deployed and positioned inside the 3D model; each of the four ostia were marked, avoiding the struts and correcting fenestration positions 1 to 3 mm from the initial plan (Fig 3, *C-E*). Modifications were performed as previously described. The device was implanted using Advanta V12 bridging stents (Maquet, Wayne, NJ) and a bifurcated distal body. The repair was performed with no complications, cannulating four vessels in 30 minutes with a total procedure time of 180 minutes and optimal angiographic result (Fig 3, *F*). The patient was discharged after 2 days in the intensive care unit and 4 days in the hospital. A follow-up CT scan revealed patent bridging stents and target arteries and no endoleaks at 6 months (Fig 3, *G*).

Case 2. A 77-year-old man with a 5.5-cm symptomatic juxtarenal abdominal aortic aneurysm was admitted with abdominal pain (Fig 4, *A* and *B*). A 7-mm aneurysm sac growth in the last 6 months was evident. Because of his history of coronary artery disease, acute myocardial infarction 1 year before admission, and left ventricular ejection fraction of 36%, the patient was considered unfit for open repair. An endovascular approach was decided with a four-vessel PMEG and a bifurcated distal component. A 32-mm TX2 Zenith Cook device was modified using the patient-specific aorta 3D model, with the same technique as described before, and correcting the position of renal fenestrations up to 3 mm (Fig 4, *C-F*). Advanta V12 stents were used as bridging stents for all target vessels. The patient underwent endovascular repair without complications; the procedure time was 160 minutes, and only 20 minutes was required to cannulate all four target vessels (Fig 4, *G* and *H*). The patient's recovery was uneventful, and he was discharged on postoperative day 3 after a 2-day intensive care unit stay. Six-month follow-up CT angiography revealed patent target vessels and no endoleaks.

DISCUSSION

The 3D printing of a real 1:1 scale model of a patient-specific aortic aneurysm for FEVAR planning is described. In addition to being a useful tool for teaching, simulation, and preoperative rehearsal of complex cases, 3D printing can be used to conduct urgent or emergent endovascular repairs of complex aortic diseases, preparing and printing an aortic model in a relatively short time (90 minutes for a half aortic template).[7]

The advantages of 3D printing include universal availability and low cost (free software and low printing costs). The 3D printing-guided FEVAR with a modified stent graft may result in more precise planning, reducing surgical time and potentially improving overall outcomes, with reduced contrast material volume and fluoroscopy time.[9]

Conventional planning is usually performed using multiplanar images and centerline flow analysis that do not accurately represent in vivo vessel orientation. Using 3D aortic models that retain the target vessels optimizes the fenestration design and possibly the cannulation pathways. Depending on the access used (brachial or femoral), cannulation can be facilitated if the fenestration height is adjusted according to a real 3D model.

Planning a FEVAR procedure requires proficiency, but even among experienced surgeons, device planning may result in variability of fenestration size, location, and vessel diameters. Malkawi et al[10] demonstrated that stent grafts created manually by four endovascular surgeons and compared with corresponding custom grafts created by a manufacturer showed significant differences in size, fenestration location, and stent diameters. We believe that with use of printed 3D models, FEVAR procedures can be performed using PMEGs, designed with great accuracy, decreasing the variability in planning and design. A larger number of cases and future studies are required to validate this technique, which could potentially have a significant impact on FEVAR planning and device design.

CONCLUSIONS

Aortic 3D models and prints can be created using open free software at low cost. Early experience demonstrates that 3D printing is a useful technology to design PMEGs with high accuracy that may facilitate the precise location of fenestrations for a faster and more efficient procedure. This technique helps reduce procedure and fluoroscopy time and could improve long-term outcomes. A larger number of cases and longer follow-up are necessary to confirm early results.

REFERENCES

1. Schanzer A, Simons JP, Flahive J, Durgin J, Aiello FA, Doucet D, et al. Outcomes of fenestrated and branched endovascular repair of complex abdominal and thoracoabdominal aortic aneurysms. J Vasc Surg 2017;66:687-94.
2. Bruen KJ, Feezor RJ. Endovascular chimney technique versus open repair of juxtarenal and suprarenal aneurysms. J Vasc Surg 2011;53:904-5.
3. O'Donnell TFX, Boitano LT, Deery SE, Schermerhorn ML, Schanzer A, Beck AW, et al. Open versus fenestrated endovascular repair of complex abdominal aortic aneurysms [published online ahead of print February 1, 2019]. Ann Surg doi: 10.1097/SLA.0000000000003094.
4. Dossabhoy SS, Simons JP, Flahive JM, Aiello FA, Sheth P, Arous EJ, et al. Fenestrated endovascular aortic aneurysm repair using physician-modified endovascular grafts versus company-manufactured devices. J Vasc Surg 2018;67:1673-83.
5. Marone EM, Auricchio F, Marconi S, Conti M, Rinaldi LF, Pietrabissa A, et al. Effectiveness of 3D printed models in the treatment of complex aortic diseases. J Cardiovasc Surg (Torino) 2018;59:699-706.
6. Hangge P, Pershad Y, Witting AA, Albadawi H, Oklu R. Three-dimensional (3D) printing and its applications for aortic diseases. Cardiovasc Diagn Ther 2018;8(Suppl 1):S19-25.
7. Benefits of 3D printed models in vascular surgery for planning, training and patient education. Available at: https://vascularnews.com/3d-printed-models-dorweiler/. Accessed March 31, 2019.
8. Oderich GS, Ricotta JJ. Modified fenestrated stent grafts: device design, modifications, implantation, and current applications. Perspect Vasc Surg Endovasc Ther 2009;21:157-67.
9. Starnes BW, Heneghan RE, Tatum B. Midterm results from a physician-sponsored investigational device exemption clinical trial evaluating physician-modified endovascular grafts for the treatment of juxtarenal aortic aneurysms. J Vasc Surg 2017;65:294-302.
10. Malkawi AH, Resch TA, Bown MJ, Manning BJ, Poloniecki JD, Nordon IM, et al. Sizing fenestrated aortic stent-grafts. Eur J Vasc Endovasc Surg 2011;41:311-6.

Submitted May 3, 2019; accepted Aug 20, 2019.