

# EVAR in 3D:

## The Seattle Experience

Insight into the creation and use of Aortica Corporation's AortaFit software application to generate 3D-printed, patient-specific, fenestrated endograft templates for treating juxtarenal abdominal aortic aneurysms.

**WITH BENJAMIN W. STARNES, MD, FACS**

**Three-dimensional (3D) printing has become an increasingly common manufacturing process, including the use of industrial, medical, and recreational units for creating custom molds in a variety of applications. However, this is still quite novel to the vascular field. Can you tell us how and when your research into 3D custom printing for aortic applications began?**

I began modifying off-the-shelf infrarenal endografts to create personalized fenestrated endografts in April 2007, 5 years before the first commercially available fenestrated endograft came to market in the United States. In 2011, we received FDA approval for our ongoing physician-sponsored investigational device exemption (IDE) clinical trial, where I have continued making these modifications under an FDA protocol to treat patients with juxtarenal abdominal aortic aneurysms (JAAAs).

Early on in this experience, I realized that the complexity of graft planning and the potential for human error needed to be addressed. Specifically, I was interested in automating the planning process as much as possible to get consistent and accurate fenestrated graft plans. The next question was how to easily and consistently apply a graft plan to an off-the-shelf endograft. A 3D-printed fenestration template was a reasonable choice because these templates can be made quickly and customized to each individual patient. The template is a hollow cylinder with holes corresponding to fenestration locations that slides over an endograft so that a physician can create the fenestrations in the endograft to match the origin of the branch arteries.

**How does the Aortica process work, specifically?**

Aortica Corporation was founded to simplify and advance the endovascular treatment of complex aortic diseases, such as JAAA, so that more patients can benefit

from this effective and minimally invasive therapy. There are several technologies in development at Aortica; we are currently evaluating clinical use of a patient-specific 3D-printed template to create a personalized fenestrated endograft.

An abdominal CT scan is loaded into the AortaFit software application (Aortica Corporation), and within minutes, a fenestrated graft plan is returned that is specific to that patient. The software analyzes the CT scan and determines the precise location of fenestrations for the branch arteries. The computer algorithms are based on my years of experience manually planning hundreds of cases. The software also generates a digital 3D template file that is then sent to a 3D printer.

The resulting physical template is processed, sterilized, packaged, and delivered to the hybrid operating suite. As the patient is being prepped in the room, I prepare the endograft under sterile conditions on the back table. I simply slide the template over a partially released infrarenal endograft, mark the fenestration locations through the template, and remove the template. Then, the fenestrations are cut and reinforced. Finally, the endograft is reconstrained in the delivery system and is ready for implantation in the patient according to standard practice.

The fenestration template is being used to validate the underlying graft plan in our study. For more wide-scale use, the automated graft plan could be used by a graft manufacturer to construct a fenestrated endograft that is shipped directly to a physician so that no back-table modifications would be necessary.

**In a standard complex case (ie, not a rupture), what is the typical timeline of the procedure, from patient presentation to graft implantation?**

In a nonemergent setting and with a CT scan that confirms the diagnosis of JAAA, a graft plan can be

generated by the software within minutes and the corresponding template can be printed in a few hours. With electronic-beam sterilization of the template and expedited shipping, we could have a template ready for a procedure in just a few days. The entire graft modification procedure takes less than an hour and is done in parallel to prepping the patient on the table. In our current study in nonemergent patients, we typically schedule implantation within 2 to 3 weeks of diagnosis.

### **What are the possibilities in a rupture setting?**

With a 3D printer and means of sterilization on-site, it is conceivable that ruptured aneurysms, at least contained ruptures, could be treated the same day with personalized fenestrated endografts. However, given that our printer and sterilizer are currently off-site, we haven't used a template in a rupture setting.

In the case of a rupture to be treated with a fenestrated endograft, I must manually plan the case and modify an off-the-shelf endograft using calipers to make distance and angle measurements directly on the graft. Otherwise, the procedure is quite similar.

### **What can be learned about a patient's anatomy using the AortaFit software, and how might this assist in case planning?**

Similar to available commercial software packages, the AortaFit software application can display the CT data in the axial, coronal, and sagittal planes and can generate a volumetric reconstruction of the aorta and branch vessels, which can be manipulated in 3D space. The software user need only select the aorta and branch vessels by clicking the mouse in the flow channels of those vessels using any of the three anatomic planes. The software automatically crops and segments the anatomy of interest and then calculates centerlines of flow for the aorta and branch vessels, as well as the junction points between the aorta and branch vessels.

The user must select which vessels to fenestrate and then the software calculates the distances from the proximal fabric edge of the endograft along an aortic centerline, which has been automatically adjusted to account for the interaction between the endograft delivery system and the angulated aorta. Branch artery takeoff angles are calculated based on the junction point of the branch artery (ie, where the branch artery centerline intersects the aortic flow channel) with the superior mesenteric artery (SMA) always set to 0°. We can fenestrate for the celiac artery, SMA, and renal arteries.

Operators know that delivery systems do not follow the centerline of aortic flow in angulated aortas.

Manually adjusting the centerline has proven difficult for those learning the technique of planning fenestrated cases. By accounting for the expected path of the delivery system through the aorta, the AortaFit software algorithms return accurate distance measurements for fenestration locations.

### **How applicable is this printing and planning process to today's available endovascular aneurysm repair devices?**

Part of our study is to determine which of the currently available endografts are amenable to physician modification using the 3D-printed template. We now have approval to evaluate seven different endografts from the major manufacturers (Cook Medical, Gore & Associates, Medtronic, Terumo Aortic). Each endograft and its delivery system has advantages and disadvantages. We have been clinically successful with several different grafts, and we are continuing to evaluate them.

### **Are there potential applications for this software in collaboration with commercially available fenestration platforms?**

We see the future of this technology in partnership with one or more endograft manufacturers. If we are successful in generating accurate fenestrated graft plans in minutes, then it makes sense to deliver those plans to manufacturers who can construct the finished fenestrated product and ship it directly to the physician. Although the 3D-printed templates combined with physician modification allow us to validate our graft plans, widespread adoption of this technology is likely contingent on a physician sharing a CT scan and quickly getting a personalized endograft in return.

### **What can you tell us about the regulatory process in researching 3D-graft customization in the United States?**

I suppose the ultimate use of 3D printing technology would be to physically print the entire patient-specific fenestrated endograft, and maybe one day that will be possible, just as it is for certain other implantable medical devices. However, we do not yet have the materials and capabilities to print clinically acceptable endografts. It's conceivable that 3D-printed fenestration templates could be advanced through the regulatory process as a surgical planning tool, but that would still require physicians to modify existing endografts, which must be done under an IDE protocol. This would certainly limit the use of the technology and is not a desirable way to move forward commercially. As such, we are not pursuing a regulatory path for the templates.

### What does your physician-sponsored IDE specifically cover?

Our study allows for the evaluation of the safety and effectiveness of physician-modified endografts for the treatment of patients with elective, symptomatic, or ruptured JAAs who are not candidates for open repair. We are also now evaluating the use of the 3D-printed template generated from the AortaFit software on up to seven endografts approved for use in the study. We recently finished enrolling our first 150 patients and gained approval for another 150 patients.

### Is it too early to ask about potential reimbursement avenues?

The likely path to commercialization and widespread adoption of this technology is through partnership with one or more endograft manufacturers. Reimbursement will likely come for the fenestrated endograft system, as it does today, rather than for the AortaFit-generated graft plan or physical template.

### What can you share about your initial results to date?

We have published on the early and midterm results for patients in our study who had their fenestrated grafts manually planned.<sup>1,2</sup> In addition, the procedural and perioperative results from the first 30 patients treated with fenestrated endografts planned by AortaFit technology and using the 3D-printed templates were recently published in the *Journal of Vascular Surgery*.<sup>3</sup> All 30 AortaFit-planned and physician-modified endografts were successfully implanted, with preservation of 97% of branch arteries and a final proximal seal zone length of 42 mm. Three renal arteries were not cannulated during the index procedure but that was unrelated to graft planning. There were no type Ia or type III endoleaks through 30 days. The 30-day major adverse event rate was 16.7%. The results compare favorably with those from patients who had manually planned grafts, and we see this as early validation that the AortaFit graft plans are accurate. Follow-up will continue for 5 years for all patients in the study.

### Unique devices and applications may also have unique failure modes. What might it look like if something goes wrong using 3D-printed planning?

There can be problems associated with 3D printing. Human errors in programming or preparing the printer or unexpected environmental changes in temperature, humidity, or vibrations can impact the printing process. Therefore, as part of the manufacturing process, we

check each fenestration template against the original graft plan by making caliper measurements on the templates prior to sterilization. In this way, we can identify any templates that do not meet the specifications of the original AortaFit graft plan. Having a reliable printer in a stable environment is key to printing success.

### What concerns are there regarding the durability of custom fenestrations?

We have found our custom fenestrations to be very durable, likely both as a result of our cutting and sewing technique and the underlying robust nature of today's endograft platforms. We routinely evaluate fenestration and branch vessel patency during scheduled patient follow-up visits. Occasionally, we are fortunate enough to examine explanted grafts in deceased patients. Although no patients in our study have died from their aneurysms past the first 30 days, when patients do pass away, we have had the opportunity to retrieve the implants. Once the tissue is removed, the grafts themselves and the fenestrations look remarkably similar to the day of implantation; this has held true even for a graft retrieved after 7 years in one patient.

### Is the use of a specific printer required, or can the software be applied to the printer of the center's choosing?

The AortaFit software produces a digital template file that could be used by a variety of 3D printers. However, not all printers produce the same quality or precision. For clinical use, we chose a high-speed, reliable, and very high-resolution stereolithography printer. This printer has also allowed us to use a transparent material for the template (laser-cured, epoxy-based resin), which is not always an option with other printers. We have not tried other printers, so I am not certain how alternative models might compare.

### Will incorporation of 3D printing into an aortic practice require specific training and proctoring?

It would if the patient-specific templates were to be the product. However, that is not the likely path forward for this technology. Physician modification of endografts and the requirement for an IDE would prohibit commercial success for fenestration templates.

### If AortaFit comes to market, what does rollout look like? How would the technology be incorporated into practices?

The most likely path forward will be to incorporate the AortaFit planning technology into the manufactur-

ing process for a fenestrated endograft, rather than commercializing the software and associated templates, which would still require physician modification of endografts and an IDE study. Once fully validated, we believe the widest adoption of this technology will come from a model where a treating physician shares a CT scan with a graft manufacturer and receives a personalized fenestrated endograft ready for implantation into the patient. Success will depend on the accuracy of the fenestrated graft plans and the speed with which the grafts can be delivered to the destination.

Simplified fenestrated endograft implantation should be well-received given the superiority of the treatment compared with the alternatives and the ease with which the procedure can now be done. Still, implanting a fenestrated endograft in a patient, although made simpler with accurate planning, requires endovascular skills that must be developed through training and in practice. ■

1. Starnes BW, Tatum B. Early report from an investigator-initiated investigational device exemption clinical trial on physician-modified endovascular grafts. *J Vasc Surg.* 2013;58:311-317.
2. 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.
3. Starnes BW, Tatum B, Singh N. Procedural and perioperative results in patients treated with fenestrated endovascular aneurysm repair planned by automated software in a physician-sponsored investigational device exemption trial of physician-modified endografts. *J Vasc Surg.* 2018;68:1297-1307.

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