Physician-modified endovascular grafts, with fenestrations added to accommodate major branch vessels, provide a means for endovascular treatment of abdominal aortic aneurysms that are adjacent to the renal arteries. Manual measurements of vessel origin locations from computed tomography images, however, take time and can lead to errors in the positions of the fenestrations. To make the fenestration process faster and more accurate, we have developed a procedure to create custom templates that serve as patient-specific guides for graft fenestration. We use a three-dimensional printer to create a clear rigid sleeve that replicates the patient’s aorta and includes holes placed precisely at the locations of the branch vessels. The sleeve is slipped over the graft, the locations of the openings are marked with a pen, and the fenestrations are created after the sleeve is removed. Custom fenestration templates can potentially save procedural costs and make minimally invasive aortic aneurysm repair available to more patients. (J Vasc Surg 2015;61:1637-41.)

Minimally invasive endovascular repair of abdominal aortic aneurysms (AAAs) has been shown to reduce mortality and morbidity associated with open repair. Unfortunately, not all patients presenting with AAAs are candidates for endovascular repair. The reasons for exclusion predominantly involve lack of a suitable proximal aortic neck, which is required for stable fixation without covering major branch vessels. Multibranched or fenestrated endografts offer one solution to this problem but generally with increased costs and long manufacture/delivery times.

On-site physician modification of endovascular grafts for branch vessel preservation is an alternative treatment strategy for juxtarenal AAAs. In these cases, fenestrations are added to standard commercial stent grafts to accommodate patient-specific vessel origin sites. The opening locations are determined from the vessel origins visualized in computed tomography (CT) images. Longitudinal distances are measured on the graft, and the relative angular locations are specified as “clock” positions relative to a reference point. However, potential barriers to wider use of physician-modified endovascular grafts are (1) preoperative planning time for measuring the fenestration locations from CT data, (2) time in the operating room required to map the opening locations to the endograft, (3) accuracy of the placement of the openings, and (4)
optimum location of all openings to avoid stent struts. To address these issues, we have developed a method to create patient-specific fenestration templates that allow for faster and more accurate endograft modification.

METHODS

We use a patient’s CT image data to create a three-dimensional (3D) printed rigid sleeve that replicates the proximal neck of their aorta, including openings at the locations of the branch vessel origins. The creation of a custom fenestration template for a patient with a juxtarenal AAA is presented in Figs 1-3. The protocol was approved by the University of Washington Institutional Review Board, and the patient gave informed consent.

We use custom software developed at the University of Washington Cardiovascular Research and Training Center to outline the aorta in a patient’s CT image data set.9

Fig 2. Fenestration template computer-assisted design model. The lumen contours shown in Fig 1 were converted to a solid model format compatible with a three-dimensional (3D) printer. A, Polygon model of the aneurysm proximal neck. B, Combined display of the proximal neck model and cylinders at each of the branch vessel origins. The cylinder diameters are set to match the branch vessel opening diameters as measured from the original computed tomography (CT) images. SMA, Superior mesenteric artery. C, The result of the Boolean difference between the proximal neck object and each cylinder is a hole in the aorta model at the location of each of the branch vessel origins.

aorta lumen is manually traced, and point markers are placed at specific 3D locations to indicate the origins of the branch vessels (Fig 1).

Next, custom software developed in the MATLAB programming environment (The MathWorks, Natick, Mass) is used to convert the lumen outlines into a computer model that defines a sleeve whose inner surface represents the aorta lumen (Fig 2, A). The holes at the locations of the branch vessels are created by first constructing cylindrical objects in 3D space that are centered at the branch origin points (Fig 2, B). Rhinoceros 5 computer-aided design software (Robert McNeel & Associates, Seattle, Wash) is then used to subtract the sections of the aorta mesh that are intersected by the cylinders, effectively “punching holes” in the aorta mesh model. The result is a computer mesh model with openings at the branch vessel origin locations (Fig 2, C).

Finally, a stereolithography 3D printer (4D Parts Direct, Broadview Heights, Ohio) is used to produce a clear rigid sleeve that includes holes placed precisely at the locations of the branch vessels (Fig 3). The clear printing material allows visualization of the stent struts during positioning of the graft in the template (Fig 2, C).

Our template-based fenestration procedure was validated by deploying a custom fenestrated graft in an aorta phantom. The phantom was created by embedding a commercially available flexible AAA model (Aortic Aneurysm 1808-2; Pacific Research Laboratories, Vashon Island, Wash) in an agar block (Fig 4, A and B). The phantom was scanned by CT (Fig 4, C), and a template was designed and printed to match the four branch vessels. This custom template was used to create fenestrations in a standard Zenith Flex endovascular graft (Cook Medical, Bloomington, Ind). The sleeve was slipped over the unsheathed graft and rotated to optimize the positions of the holes relative to the stent struts. The locations of the openings were marked with a pen (Fig 5, A), and the fenestrations were cut with an electrosurgical device after the sleeve was removed (Fig 5, B). The graft was resheathed and then deployed in the phantom under visual guidance using alignment of the simulated celiac artery and superior mesenteric artery origins for reference.

Alignment of the fenestrations was verified by performing continuous fluoroscopy as each branch was targeted with a guidewire introduced through the right iliac branch of the phantom. Guidewires were successfully introduced in each of the four branch vessels (Fig 6), confirming that the graft fenestrations specified by the 3D-printed template were properly aligned with the phantom branch vessel origins.

DISCUSSION

We have demonstrated a procedure to create a template based on each patient’s anatomy that provides a simple and accurate guide for on-site placement of graft fenestrations. Without the template, fenestration planning time for physician-modified grafts varies with experience and case complexity. Early in the experience of one coauthor (B.W.S.), the time required for workstation measurements was 1 to 2 hours. After performing >150 physician-modified endograft procedures, this planning time has decreased to ~30 minutes per case. In the operating room, manual measurement of fenestration locations on the graft takes ~15 minutes.

The template preproduction time, including manual outlining of the aorta and the subsequent computer processing steps, currently takes ~30 minutes. This time could be reduced by incorporating automated image segmentation to generate the lumen outlines. Printing time for the template shown in Fig 3 (6.3 cm long, 2-mm wall thickness) was 9 hours, which would allow production of a template for use the next day. Although this current printing time makes the template method impractical for patients with a ruptured AAA, it would still be
applicable to symptomatic patients. Also, printing times will likely decrease in the future as 3D printing technology matures.

Use of the template saves time in the operating room because all of the relative distances of the fenestrations are established by the template; the surgeon is not required to perform any measurements at the time of device deployment. The template transparency allows for rapid assessment of the fenestration locations relative to the stent struts, and most importantly, the potential for measurement errors is eliminated.

Another benefit offered by the 3D printed template is the potential to shift the preoperative planning steps from the surgeon to an outside provider. Manufacture at a centralized processing facility, based on electronically transferred images, would make template guides available to any clinical site performing endovascular repair of AAAs. The raw image data could be sent to the service provider, and the fenestration guide could be shipped back to the surgery site. Clear printing materials are available that are compatible with gas sterilization methods, so templates could be sterilized before shipment or at the clinical site. Therefore,

Fig 5. Graft fenestration and deployment for validation. A, An unsheathed graft is inserted in the fenestration template and the branch vessel origins are marked with a pen. B, Fenestrations are cut with an electrocautery device after removal of the template.

Fig 6. Fluoroscopic confirmation of proper alignment of the graft fenestrations with each of the branch vessels in the abdominal aortic aneurysm (AAA) phantom. A guidewire was successfully deployed through the openings in the fenestrated graft into each of the branch vessels. Gold markers sewn around the graft openings are visible for each fenestration. A, Celiac artery; B, Superior mesenteric artery; C, Left renal artery; D, Right renal artery.
individual clinical sites would not require expertise with image segmentation, computer-assisted design software, or 3D printing. This approach could lead to wider use of fenestrated endografts for elective repairs and treatment of symptomatic AAAs.

CONCLUSIONS

Custom fenestration templates provide for fast and accurate placement of all fenestrations, without the need for manual measurements. The use of the fenestration template with a standard graft provides an off-the-shelf solution for endovascular treatment of juxtarenal AAAs. Pending U.S. Food and Drug Administration approval, this technique has the potential to save procedural costs and make minimally invasive AAA repair available to more patients with challenging anatomy.

REFERENCES


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