Ten Steps

A standardized 10-step approach to the planning and sizing of a fenestrated endovascular aortic aneurysm repair.

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or patients with short-neck and juxtarenal aortic aneurysms, conventional endovascular aneurysm repair may not provide durable aneurysm exclusion due to a compromised proximal seal zone. In response to this concern, fenestrated endografts were described in the late 1990s that were designed to extend the seal zone above the renal arteries while maintaining flow to critical branch vessels. 1-3 A commercially available option was studied in the United States in 2009,4 with favorable technical results and patient outcomes.⁵ The Zenith Fenestrated (ZFEN) abdominal aortic aneurysm (AAA) endovascular graft (Cook Medical) gained US Food and Drug Administration (FDA) approval for use in the United States in April 2012. At the time of this publication, it remains the only commercially available fenestrated device in the United States for the treatment of short-neck AAAs (necks \geq 4 mm in length).

There are some notable technical considerations for the planning and execution of fenestrated repair. Although infrarenal endovascular aneurysm repair can often be planned quickly and accurately, the technical success of fenestrated aneurysm repair is contingent upon meticulous preoperative planning. Steps include processing axial CTA images in software capable of generating three-dimensional models and enabling centerline measurements, then carefully measuring the exact locations of the target vessels. There are manufacturing restrictions, based on engineering boundary condition constraints, that must also be considered (please find these listed at fencheck. cookmedical.com). The anatomy must be scrutinized to ensure that a ZFEN device is appropriate, and then the exact configuration must be chosen.

We recently reported on the adoption of ZFEN technology in the United States since FDA approval.⁶ A ninefold increase in the number of orders placed per month was seen; however, the vast majority of trained providers ordered fewer than five devices per year. We hypothesized that this skewed adoption pattern may, in part, relate to the perceived complexity of technical planning and sizing. Although previous studies have demonstrated good inter- and intraobserver agreement in fenestrated planning, these studies relied solely upon experienced fenestrated planners,^{7,8} leaving the

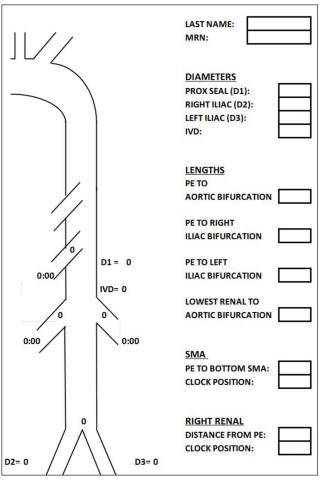


Figure 1. A simple template for recording measurements.

generalizability to less experienced surgeons unknown. Therefore, the following sections describe a standardized 10-step approach to the planning and sizing of fenestrated endovascular aneurysm repair utilizing the ZFEN technology and introduce a simple template (Figure 1) that can be used to record the necessary measurements.

STEP 1: CENTERLINE PLACEMENT

The patient's aortic anatomy is first evaluated by processing a recent CTA of the abdomen and pelvis



Figure 2. Create and adjust the centerline.

using three-dimensional reconstruction software. An aortic centerline is made, extending from the suprarenal aorta to each iliac artery. This allows for all subsequent measurements to be made orthogonal to the centerline of flow. The centerline is then manually adjusted to reflect the way in which the stent graft is anticipated to lie within the aorta as a result of any tortuosity (Figure 2).

STEP 2: MARKER PLACEMENT

With the centerline in place, the curved planar reformat (CPR) views, in a "straightened view" of the aorta, are used to place a marker in the center of each of the visceral artery origins. The celiac and superior mesenteric arteries (SMAs) are first marked, and then the CPR view is rotated to identify the origin of the renal arteries (Figure 3). The aortic bifurcation and each iliac artery bifurcation are also marked.

STEP 3: DETERMINE THE PROXIMAL EDGE OF THE ENDOGRAFT

This step is critical, as it determines which branch arteries will need to be incorporated into the repair to ensure a durable proximal seal into healthy aorta. The instructions for use (IFU) specify a minimum acceptable proximal seal zone of 1.5 cm. We are more conservative and use a minimum of 2 cm of healthy parallel walled aorta for the proximal seal zone. The start of the aneurysm is identified on CPR view, then a distance of 2 cm proximal to this is measured (Figure 4); this level of the aorta is assessed to ensure that it is a healthy segment. The one ZFEN graft specification rule that must be followed is that the distance from the top of fabric to the first small fenestration must be 15 mm or greater. In order to comply with this rule, a distance of 15 mm is measured proximally from the highest of the renal arteries within the proximal seal zone. If this brings the measurement above the previously marked 2-cm seal zone, then the proximal edge must be moved to this position. This proximal edge marker serves as the reference from which all



Figure 3. Mark the target vessels.



Figure 4. Choose the proximal edge.

subsequent measurements are determined. The proximal edge marker also dictates how the SMA will be incorporated into the repair. If the bottom of the SMA is within 12 mm of the proximal edge, then it can be incorporated with a scallop. If the distance is > 12 mm from the proximal edge, a large fenestration must be used.

STEP 4: MEASURE REQUIRED DIAMETERS

Three measurements are obtained over the length of the seal zone, the largest of which will be used as the diameter measurement to select an appropriately sized proximal seal stent consistent with the diameter sizing guidelines in the IFU (we target 10%–15% oversizing in our practice). The inner aortic diameter is also measured at the level of the renal arteries. Finally, the distal seal zone diameters are measured in each common iliac artery.

STEP 5: MEASURE REQUIRED LENGTHS

Three categories of length measurements are obtained: the length from the proximal graft edge to the center of each visceral branch, from proximal edge to aortic bifurcation, and from proximal edge to each iliac bifurcation.



Figure 5. Mark clock positions of the target vessels.

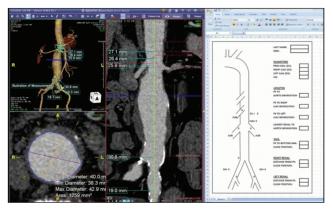


Figure 6. Ensure that all diameters, lengths, and clock positions have been defined.

STEP 6: MEASURE TARGET ARTERY CLOCK POSITIONS

A clock position measurement, rounded to the nearest 15-minute interval, is required for each of the vessels incorporated into the repair (Figure 5).

STEP 7: CHOOSE THE PROXIMAL FENESTRATED COMPONENT

The "two-proximal-seal-stent" design is routinely chosen. The diameter is selected consistent with the diameter sizing guidelines in the IFU (we use 10%–15% oversizing in our practice) for the proximal seal zone diameter. The length is chosen to ensure a minimum of 20 mm of length between the bottom of the fenestrated endograft and the aortic bifurcation to facilitate placement of the bifurcated component (Figure 6).

STEP 8: INDICATE SCALLOP/FENESTRATION DESIGN

For scallops, the depth and clock position are noted. For all fenestrations, the length from the proximal edge to the middle of the target vessel is measured. For the

renal arteries, a small fenestration with a height of 8 mm is routinely chosen. The inner aortic diameter is measured at the level of each of the fenestrations.

STEP 9: CHOOSE THE DISTAL BIFURCATED COMPONENT

A range of bifurcated device sizes exists and can be used. The "universal bifurcated" design is routinely used in our practice; this measures 76 mm from the top of the graft to the contralateral gate. The ipsilateral limb extends an additional 28 mm. Both limbs are 12 mm in diameter. The proximal diameter of the bifurcated device is 24 mm to match the distal diameter of the fenestrated component.

STEP 10: CHOOSE THE ILIAC LIMBS

Iliac limbs are chosen with appropriate oversizing to ensure seal in each common iliac artery (we routinely target 10% oversizing).

CONCLUSION

Using a simple template and a standardized 10-step approach, all of the necessary information to successfully plan and order a custom ZFEN device can be obtained.

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