Future EVAR Devices

With novel designs and improvements in technology, many of the problems encountered in patients with aneurysmal disease can be solved.

BY MARK A. FARBER, MD

It has been 3 years since the FDA approved the latest device for infrarenal endovascular aortic repair (EVAR). Several devices with new design concepts and potential improvements have been introduced through clinical trials. These include the Enovus (Boston Scientific Corporation, Natick, MA), Aptus (Aptus Endosystems, Inc., Sunnyvale, CA), Aorfix (Lombard Medical Technologies, Oxford, England), and the Zenith Fenestrated and Branched (Cook Medical, Bloomington, IN). Each of these devices addresses a different challenge that exists with EVAR. Although the performance criteria of previous devices has been set extremely high, it remains to be seen whether any of these devices will outperform or increase the suitability for patients with challenging anatomy. The environment for clinical trial testing of EVAR devices has changed as a result of the excellent results obtained with current devices. No longer are there "no options" for the high-risk patient because advanced endovascular specialists have been trained across the country with access to numerous devices and techniques.

CURRENT LIMITATIONS

All currently approved devices have an infrarenal neck length requirement of 1.5 cm to provide successful exclusion of the abdominal aortic aneurysm (AAA). The 1.5-cm-length neck length requirement will not exclude the aneurysm in and of itself but is required to ensure adequate seal at the proximal fixation point. In addition, the neck must be free of significant thrombus and calcification and not be angled >60°. Implanting current devices outside these guidelines results in suboptimal outcomes and places the patient at increased risk of device failure and potential rupture.[1,2] Addressing these issues with newer devices may lead to an increase of suitability for EVAR from 10 to 40%. However, these improvements must not be at a detriment to current results, which provide >95% protection from rupture at 5 years.

Figure 1. The Enovus device with the gasket-sealing concept.

Although device iterations have led to both flared and tapered components for treating various iliac diameters, intentional hypogastric exclusion is still required in 10 to 20% of patients. Although most patients tolerate it, severe gluteal ischemia can have a significant impact on the patient's quality of life. Additionally, ischemic complications from bilateral embolizations have been reported.[3,4] A system designed to preserve hypogastric perfusion would improve outcomes in this group of patients.

Long-term durability may need to be addressed as larger longitudinal studies are published. Most patients with AAAs have a life expectancy of less than 10 years, and current device fatigue testing is required to simulate 10 years of stress. As devices are implanted into younger patients, these criteria may need to be altered.

SPECIFIC TREATMENT CONCERNS

Neck Quality

The amount of calcification and thrombus present in the aortic neck has been of concern to vascular interventionists because some devices rely on this region for both fixation and exclusion of the AAA. The degree of calcium and thrombus that is considered significant varies among physicians, however. In our experience, it has been the reason for exclusion for EVAR in only a small number of patients when compared to other anatomic factors. A novel concept introduced by the The Enovus device was to utilize a "gasket" concept to accomplish exclusion, which would potentially remedy this problem (Figure 1). This concept would allow sealing in the event of adverse neck characteristics, such as unusual shape and calcified and thrombotic regions. However, as the result of fixation stent fractures, the device is currently no longer in clinical trials. Whether other mechanisms, such as staples or biologic mechanisms, can be used to accomplish exclusion in the "poor-quality" necks remains to be seen.

Figure 2. The Aorfix device with flexible proximal to accommodate angled anatomy.

Neck Angle

When the angle of the neck to the axis of the aneurysm exceeds 60°, the success of EVAR declines. Multiple factors play a role in this unfavorable outcome. As the angle becomes more severe, the device does not align itself with the neck in a parallel fashion, thereby reducing the amount of apposition in the sealing region. In addition, the position of the device is generally lower in relation to the renal arteries because positioning becomes more difficult in an angled orientation.

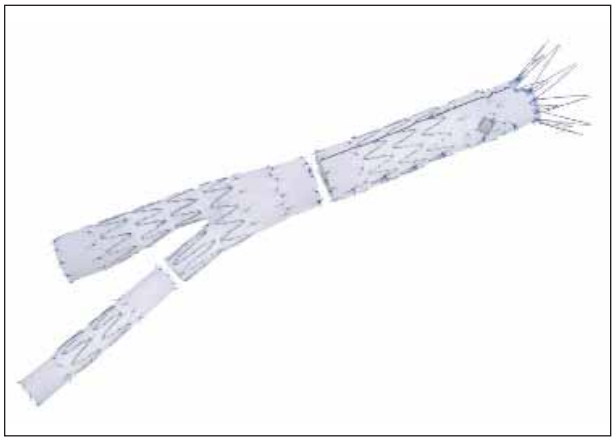
Device modifications that allow for a more flexible design in the sealing neck region without compromising fixation are being introduced (Figure 2). Keep in mind, however, that the forces acting downward on the device are greater in these severely angulated necks, and therefore, more robust fixation may be needed to secure the device appropriately. The correct balance between these two aspects must be considered as these devices are designed and tested.

Neck Length

Patients with short necks pose an extremely difficult problem for the vascular specialist. Although an infrarenal device can be implanted into a neck with <15 mm of length without increasing significantly major adverse outcomes, the future implications are sometimes dramatic. Many implantations into short necks can be accomplished with the impression that exclusion of the aneurysm has been accomplished based on intraoperative angiography; however, on follow-up, with more sensitive imaging, the patient is identified as having a type IA endoleak. Current fenestrated devices are extremely difficult to implant successfully when previous aortic endovascular repairs have been conducted, which therefore restricts the patients' future options to visceral debranching, open conversion, or observation, and excludes them from undergoing a fenestrated implant, especially when a short-bodied device is used. There have now been more than 2,000 fenestrated implantations worldwide. In the US, a few individuals have pioneered the majority of this work, and currently investigational sites are awaiting FDA approval to continue work on the fenestrated devices manufactured by Cook Medical (Figure 3). Initial results are extremely promising, and the technique has been described previously.[5,6] Although early results compared to traditional open surgery appear to provide improved outcomes with respect to perioperative morbidity and mortality, it remains to be seen whether the technique will provide mid- and long-term outcomes similar to that of standard EVAR.

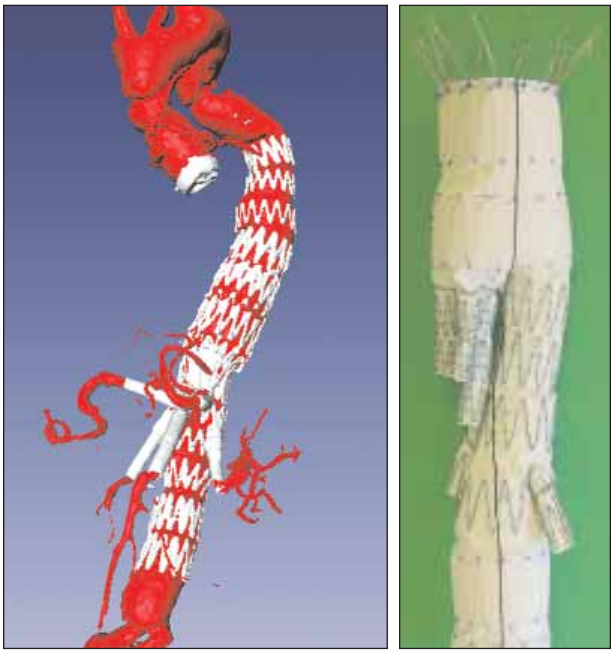
BRANCHED CONCEPTS

Current branched designs are underway to address



(Courtesy of Timothy A.M. Chuter, MD, and David Hartley.)

Figure 3. The Cook Medical fenestrated device.



(Courtesy of Timothy A.M. Chuter, MD, and David Hartley.)

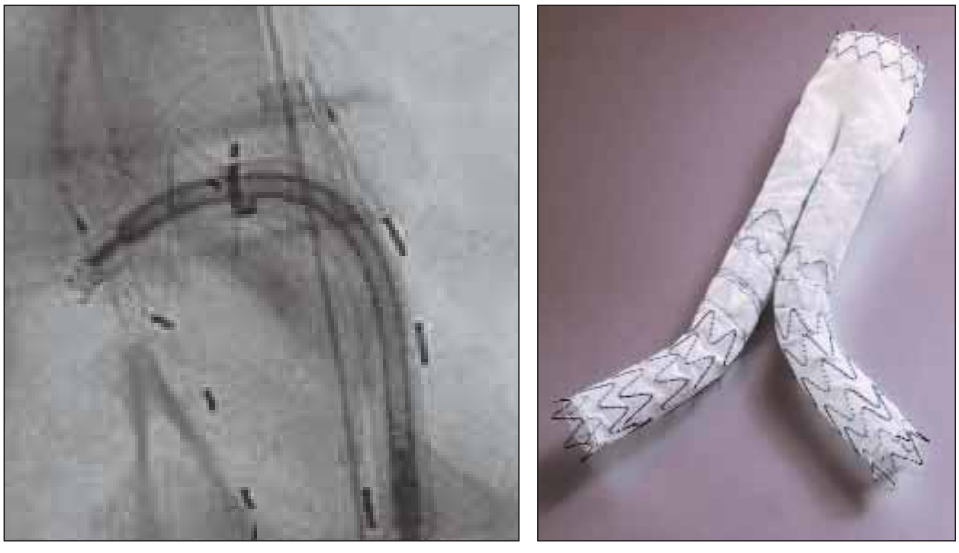
Figure 4. The Cook Medical branched device for TAAA.

two issues: hypogastric artery involvement and thoracoabdominal aortic aneurysm (TAAA). Iliac artery involvement occurs in 40% of all AAAs. The current standard of care is to embolize one hypogastric artery if it is not important in pelvic blood flow contribution. Although this provides an adequate sealing region in the external iliac artery, gluteal claudication, which can occasionally be severe, does develop. Despite reports of patients recovering after several months of collateral development, some patients never fully recover. In addition, there have been detrimental outcomes when both hypogastric arteries have been excluded,[3] even though some investigators have advocated its safety.[7] As a result, efforts are underway to provide branched iliac components to maintain hypogastric blood flow in this setting (Figure 4). Although early designs have been successful outside the US, no current trial is underway.

Recently, Chuter et al[8] reported on their initial experience with branched TAAA devices. These devices allow for the extension of this technology into the visceral segment; however, they are extremely complex (Figure 4). It is anticipated that several design improvements will be needed. These devices will remain in development for several years but will provide promise for advancements in this technology.

MIGRATION/FIXATION

Current data suggest that all devices can migrate and that migration is a time-dependent variable. This applies not only to infrarenal devices but also to those with transrenal fixation. It is difficult to draw any strong conclusions concerning the different migration risks among current devices. However, when used outside their instructions for use, devices have a greater risk of migration compared to clinical trial results.[1] Although current devices perform extremely well, this is an area of active research and a region for improvement with new devices. Endovascular stapling devices are being developed to improve fixation and attempt to eliminate any migration potential. Aptus Endosystems is currently conducting a phase 2 trial involving this concept with promising early results (Figure 5). Whether endovascular stapling eliminates the concern for migration is yet to be seen. An interventionist must be cautious because improvements in one aspect of a design can lead to other modes of failure, such as material fatigue and stent fracture. If this fixation technique is successful, it may be applied to other problematic areas such as component separation and type IA endoleaks that can often be difficult to address with current technology.



(Courtesy of Manish Mehta, MD.)

Figure 5. The Aptus device with endostaples.

METAL/FABRIC FATIGUE

Material fatigue has been seen in an extremely small number of devices. Current iterations have redundancy built into their design, and fatigue rarely plays a role in device failure after FDA approval. Although current designs are tested for 10 years of durability, additional testing may be necessary if long-term data suggest potential failure. Eliminating the metal-fabric interaction by designing absorbable stents or unsupported devices could eliminate these issues, however, obtaining a successful implant without these critical components could be extremely difficult to accomplish. As the bioengineering and material science technology develops, we may see additional options that do not exist today.

CONCLUSION

It has been more than 17 years since the first EVAR procedure was performed in humans. Current devices are extremely robust, provide excellent clinical outcomes, and are applicable to more than 60% of the population. Future device iterations are mainly aimed at improving applicability to a larger proportion of the population by addressing the proximal neck anatomic issues that currently exist. When initially designed, these problems were not recognized or completely understood. As the medical community continues to work together with design engineers, it is hopeful that these problems will be solved to benefit patients with aneurysmal disease. ■

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1. Fulton JJ, Farber MA, Sanchez LA, et al. Effect of challenging neck anatomy on mid-term migration rates in AneuRx endografts. J Vasc Surg. 2006;44:932-937; discussion 7.
2. Leurs LJ, Kievit J, Dagnelie PC, et al. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. J Endovasc Ther. 2006;13:640-648.
3. Bratby MJ, Munneke GM, Belli AM, et al. How safe is bilateral internal iliac artery embolization prior to EVAR? Cardiovasc Intervent Radiol. 2007 Oct 24. [Epub ahead of print]
4. Engelke C, Elford J, Morgan RA, et al. Internal iliac artery embolization with bilateral occlusion before endovascular aortoiliac aneurysm repair-clinical outcome of simultaneous and sequential intervention. J Vasc Interv Radiol. 2002;13:667-676.
5. Greenberg RK, Haulon S, O'Neill S, et al. Primary endovascular repair of juxtarenal aneurysms with fenestrated endovascular grafting. Eur J Vasc Endovasc Surg. 2004;27:484-491.
6. Haddad F, Greenberg RK, Walker E, et al. Fenestrated endovascular grafting: the renal side of the story. J Vasc Surg. 2005;41:181-190.
7. Mehta M, Veith FJ, Ohki T, et al. Unilateral and bilateral hypogastric artery interruption during aortoiliac aneurysm repair in 154 patients: a relatively innocuous procedure. J Vasc Surg. 2001;33:S27-32.
8. Chuter TA, Rapp JH, Hiramoto JS, et al. Endovascular treatment of thoracoabdominal aortic aneurysms. J Vasc Surg. 2008;47:6-16.