Future TEVAR Devices

What should the next generation of TEVAR devices bring?

BY W. ANTHONY LEE, MD

There is currently one FDA-approved commercially available device for endovascular repair of aortic aneurysms (TEVAR) in the US (TAG, Gore & Associates, Flagstaff, AZ). At least two other devices, the TX2 (Cook Medical, Bloomington, IN) and the Talent Thoracic (Medtronic CardioVascular, Endovascular Innovations, Santa Rosa, CA), have completed the pivotal phase of their clinical trials and are presently undergoing the premarket approval (PMA) process. This article outlines some of the unmet challenges that the next generation of TEVAR devices must address in order to advance the therapy to the next level of treatment of the entire thoracic and abdominal aorta.

CHALLENGES

The technical challenges during TEVAR include anatomic and physiologic factors that are unique to this aortic segment. A significant number of thoracic pathologies occur in close proximity to either the arch and/or the mesenteric vessels. Especially in aneurysmal disease, there can be significant angulation and tortuosity involving the arch and the transdiaphragmatic segment secondary to elongation and remodeling of the aorta in response to chronic hypertension that is not readily corrected even with superstiff guidewires (Figure 1). Catheter-guidewire manipulations in these areas or inadvertent coverage of critical aortic branches can result in devastating neurologic complications or mesenteric ischemia. The area of treatment is more remote from the point of entry of the endovascular devices as compared to the abdominal aorta, and degenerative diseases of the thoracic aortic segment are frequently associated with concomitant aneurysmal and/or occlusive disease of the abdominal aorta resulting in tandem segments of tortuosity and ectasia that must be traversed.

The aortic impulse may be significant as the interventionist nears the aortic valve and can have an adverse impact on accurate positioning and stabilization of the devices. The myocardial strain from transient afterloads imposed during deployment or adjunctive ballooning may risk ischemic complications. Finally, although aortic diseases in general primarily affect men, the relative proportion of women is greater in the thoracic aorta than in the abdominal aorta. Women also tend to have smaller access vessels, which are generally more involved with calcific occlusive disease, and the larger profiles of thoracic devices as compared to abdominal endografts result in a higher incidence of access-related complications and the need for iliac conduits.[1]

Figure 1. Severe aortic tortuosity both in the abdominal and thoracic aorta.

UNMET NEEDS AND NEXT-GENERATION DEVELOPMENTS

Profile

Current thoracic endografts are large with outer diameters ranging from 23 F

(3.14 F=1-mm diameter) to 28 F. Nearly 50% of women who undergo TEVAR require an iliac conduit. Hydrophilic coatings represent a significant improvement, but they still cannot overcome intrinsically small and diseased iliac arteries that do not significantly dilate. Although the need for alternative access techniques can never be completely eliminated, the next generation of thoracic endografts should aim for a 30% reduction in current profile, with a maximum outer diameter of 20 F for the largest endograft sizes, which may reduce the need for iliac access to <10% for women and almost zero for men.

> "Current catheter designs unfortunately have an intrinsic flexion point between the proximal shaft where the endograft is loaded and the distal shaft near the handle."

Trackability

The delivery catheter carrying a thoracic endograft must potentially traverse at least three tandem segments of significant tortuosity—the abdominal aorta, the distal thoracic aorta, and the arch. Current catheter designs unfortunately have an intrinsic flexion point between the proximal shaft where the endograft is loaded and the distal shaft near the handle. Pushability is lost after passage of each successive segment due to the serial frictional resistance and the noncoaxial vector forces transmitted along the delivery catheter. This is exacerbated when the delivery catheter becomes bent at the flexion point as it curves around a tight angle. In these situations, continued pushing can paradoxically retract the proximal end of the delivery catheter from its forward position as the shaft distal to the flexion point advances away from the axis of the aorta. More significantly, even if the delivery catheter were able to eventually reach the target, it may be damaged to the point that deployment of the endograft may not be possible. Although, in theory, a stiffer guidewire may remediate this situation, even the stiffest wires (eg, Lunderquist, Cook Medical) available are inadequate in certain cases, and the only option is to use a transbrachiofemoral wire (Figure 2). Therefore, the solution is not to design a stiffer guidewire, but to design a next-generation delivery catheter that has a balanced combination of added flexibility and stiffness to overcome these compound tortuosities.

Deployment

Although the importance of accuracy and controlled deployment cannot be overstated when it comes to endovascular aortic repair in general, it is even more so for the thoracic aorta as the consequences of misdeployment are significantly greater. To date, most of the attention in the design and development of endograft delivery systems has focused on proximal accuracy. It is now time

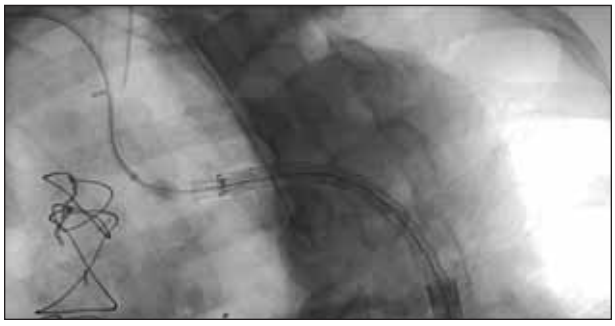

Figure 2. Transbrachiofemoral wire. A guidewire is introduced from the right brachial access site and brought out using a snare through the femoral artery. Note the guide sheath that protects the innominate artery from a potential "cheese-cutter" injury by the wire and can also be used for control angiography.

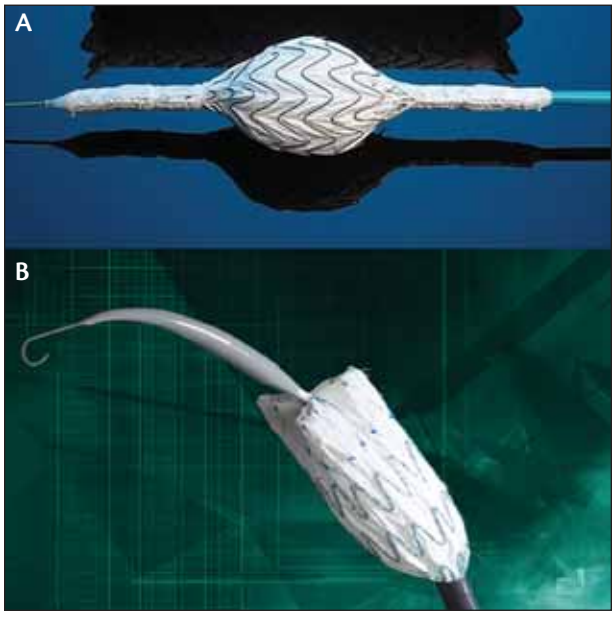

Figure 3. Partially deployed TAG device, which expands out from its midsegment to both ends. This type of deployment is dependent on the initial fixation of the middle of the device against a section of the aortic wall. During this process, as the endograft detaches itself from the delivery catheter and conforms to the aortic lumen, it has a tendency to retract from each end, especially in tortuous anatomy and with longer devices (20 cm) (A). Typical "pin-and-pull" unsheathing mechanism of the TX2 device, which deploys in several stages using a sequential system of trigger release wires (B).

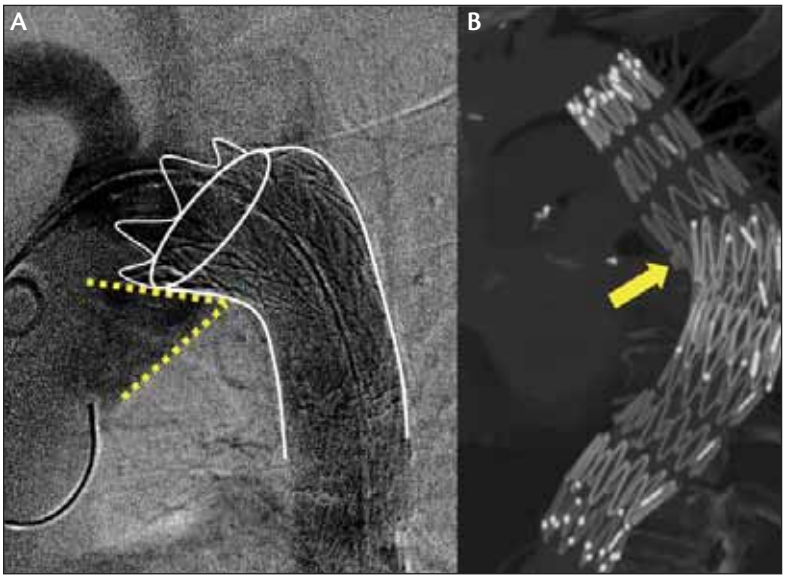

Figure 4. Malapposition of a TAG device along a tight inner curve of the arch. Note how the device has completely lifted off the aortic wall (yellow dotted line) and can become a source of a type IA endoleak or, even worse, collapse of the endograft (A). A TX2 device in which the top of the distal component did not fully appose the bottom of the proximal component due to an acute angle in the mid-descending thoracic aorta (yellow arrow) (B).

to focus on distal accuracy. Although the current state of design may partly reflect the generally held bias of some inherently greater importance of the arch vessels as compared to the mesenteric vessels, it is also largely due to the direct application of conventional "pin-and-pull" methods of deploying self-expanding stents to aortic endografts. This method allows a controlled and accurate deployment of the proximal end of the endograft, but unfortunately, it affords little of the same for the distal end. The only device that does not deploy in this manner is the TAG device, which interestingly deploys starting from the middle of the device and outwards in both directions in a single step (Figure 3). This type of deployment represents a case study in faulty design in that it combines the lack of control of a single-step mechanism and lack of accuracy at both proximal and distal attachment sites. If the interventionist accepts the fact that thoracic pathologies involve the distal thoracic aorta as often as the proximal segment, the next-generation thoracic delivery system should allow the same level of deployment control and accuracy it currently provides the proximal end of the endograft to its distal attachment site.

Conformability

The Achilles' heel of current thoracic devices is the aortic arch. Nearly all devices have a minimum radius of curvature to which it can conform and below which malapposition of the endograft to the inner curve can occur (Figure 4). This can lead to type IA endoleaks and even complete endograft collapse.[2] Tight arch curvatures can occur at both ends of the age spectrum with completely different diseases. In the younger population, endovascular repair has been used for blunt thoracic transections. In the elderly population, the primary indications remain as aneurysmal and other degenerative diseases. In the latter group, the elongation and remodeling of the aorta can result in a very sharply angulated arch usually distal to the left subclavian artery with the apparent displacement of the great vessels to the ascending segment of the thoracic aorta. The inner curve acts as a fulcrum over which the proximal edge of the endograft hangs over the ascending aorta. Currently, the only design that can partially overcome this problem involves a proximal bare stent. Although in most cases this is not a problem, there have been rare reports of aortic perforations and retrograde dissections that were associated with bare stents used to repair type B aortic dissections.[3] The next-generation endograft must be able to conform to the aortic arch over a wide range of curvatures without the need for bare stents.

Pathology-Specific Designs

Although the only FDA-approved on-label indication for TEVAR is for degenerative aneurysms, the techniques and devices have been successfully applied to treat a wide variety of pathologies not typically encountered in the abdominal aorta. These other entities include dissections, intramural hematomas, penetrating ulcers, traumatic transections, second-stage elephant trunk procedures, postsurgical pseudoaneurysms, and aortoesophageal and aortobronchial fistulas. Despite the promising early results of these procedures, device-related limitations have also become apparent. Currently, the smallest thoracic device that is available can be used in a 23-mm (internal diameter or 25-mm outer diameter) aorta. In younger patients with traumatic transections, the aortic diameter is typically 16 mm to 20 mm. Oversizing these endografts beyond their recommended range may result in graft infolding and endoleak. Therefore, stacked cuffs or modified abdominal devices delivered through makeshift long introducer sheaths have been used to repair these injuries

Figure 5. Endovascular repair of a type B dissection with a Gore TAG device. Note the severe infolding of the endograft in its midsection due to the rapidly tapering gradient of true lumen diameter.

because abdominal endovascular delivery catheters usually are not long enough to reach the proximal thoracic aorta. Endovascular repair of complicated, acute Stanford type B (Debakey type III) aortic dissections has yielded encouraging short-term results in terms of achieving seal of the primary tear and restoration of true lumen and branch vessel flow.[4] However, in nearly all of these cases, the endograft must extend to the left common carotid artery and accommodate significant differentials in lumen size between the proximal and the compressed distal true lumen (Figure 5). The next-generation thoracic endovascular systems will have pathology-specific device modifications that will allow a more tailored treatment than a one-device-fits-all paradigm.

Management of Branch Vessels

One of the main obstacles that has limited endovascular aortic therapy to two discrete and separate segments—the descending thoracic aorta and the infrarenal aorta—are the branch vessels, specifically, the arch vessels proximally and the visceral-renal vessels in the middle. Despite successful application of branched and fenestrated endograft technology in more than 1,000 cases around the world, current designs have, to some degree, piggybacked on existing nonbranched constructs with regard to the delivery system and the endograft itself. It is conceptually analogous to building a new addition on a house—it is functional, but you will always know that it is an addition. The challenge for the next generation is to start with a clean drawing board and truly think outside the box to design a brand-new aortic endovascular system—the endograft and the delivery mechanism—from the ground up with the single-minded goal of treating the entire thoracic and abdominal aorta from the aortic valve to the hypogastric arteries.

CONCLUSION

The goals outlined in this article for the next-generation thoracic endograft are intended as a wish list rather than any concrete vision of the future. This list of unmet needs is neither meant to be complete nor in any order of priority. It would be unfair, however, to end the discussion about the current technology on anything but a positive note. There is no question that introduction of endovascular therapy for the thoracic aorta has made a significant impact on the treatment of high-risk patients with potentially lethal problems. Despite all of their shortcomings, current thoracic devices work very well for their designed purpose in a large proportion and variety of cases, and many patients have clearly benefited from the technology. ■

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