Unmet Needs With Current Thoracic Devices

Significant opportunities remain for research and development.

BY ALI AZIZZADEH, MD, FACS

The first open thoracic aneurysm repair was reported by Cooley and DeBakey in 1952.[1] Open repair became the gold standard for all lesions of the thoracic aorta over the next five decades. A minimally invasive alternative, endovascular repair, was pioneered independently by Volodos in Russia (1986) and Parodi in Argentina (1991).[2,3] Using this new, disruptive technology, the first series of 13 patients undergoing thoracic endovascular aortic repair (TEVAR) using physician-made devices in the United States was reported by Dake in 1994.[4] The first thoracic device, however, did not gain US Food and Drug Administration (FDA) approval until 2005 (Figure 1).

The significant lag time from concept to market reflects the challenges involved in designing a device that can treat the wide-ranging pathologies of the thoracic aorta. The lesions in the thoracic aorta can range from penetrating aortic ulcer and intramural hematoma to aortic dissection, aneurysmal degeneration, and traumatic injury. As a result, the patient's age, aortic diameter, and blood flow velocities are widely variable. Moreover, in comparison to the abdominal aorta, the thoracic aorta is more compliant and subject to higher displacing forces as well as longitudinal loads arising from flow, pressure, and motion. There are also longer segments of disease that require coverage with relatively shorter landing zones. All of the above factors make the thoracic aorta a very challenging anatomical bed and, naturally, a significant area of opportunity for research, development, and innovation (Figure 2).

EARLY EXPERIENCE

The United States physician experience with TEVAR after FDA approval barely spans a decade. As with any new, disruptive technology, the early years have been marked by rapid adoption of this therapy into the armamentarium of surgeons who treat aortic disease. The on-label indication started with aneurysms but rapidly evolved into isolated lesions and finally expanded into aortic dissection.

Figure 1. The GORE® TAG® Thoracic Endoprosthesis was the first thoracic device to gain US FDA approval in 2005.

Today, all lesions of the thoracic aorta can be treated on label with an FDA-approved device. In addition to expanding indications, new techniques have evolved to mitigate the challenges and complications associated with TEVAR. With the first-generation devices, physicians learned to use unique tips and tricks to maximize the applicability of this treatment modality to their patients. Naturally, with increased experience and use, a number of failure modes emerged (Figure 3). In a 2009 summary, Lee discussed a wide range of failure modes related to delivery, deployment, conformability, device collapse, component separation, stent fracture, and fabric tear in first-generation devices.[5] These findings further stressed the importance of follow-up surveillance imaging in patients who undergo TEVAR.

Second-Generation Devices

As expected, second-generation thoracic devices provided a significant forward leap in meeting the challenges of the thoracic aorta. There has been an expansion in available device diameters that are able to treat a wider range of pathologies. The newer-generation devices

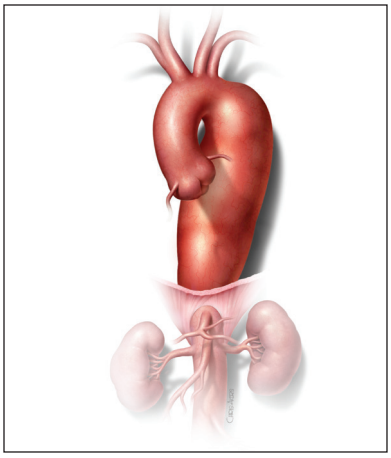

Figure 2. The descending thoracic aorta, compared to the abdominal aorta, is more compliant and subject to higher displacing forces and longitudinal loads arising from flow, pressure, and motion. The longer segments of disease and shorter landing zones make it a challenging anatomical bed.

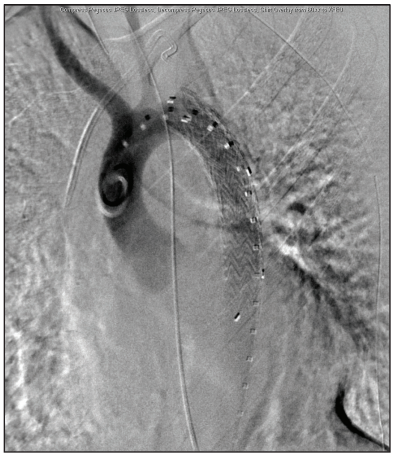

Figure 3. Inadequate inner-curve apposition or bird-beaking in a young patient with traumatic aortic injury. A narrow radius of curvature is noted in the aortic arch.

Figure 4. The Conformable® GORE® TAG® Thoracic Endoprosthesis is a second-generation thoracic device.

are more conformable, maintain improved inner curve apposition, and perform in a wide range of anatomic and physiologic environments (Figure 4).

Many of the complications associated with the first-generation devices, such as bird-beaking and collapse, have been significantly reduced. As the technology and physician expertise have improved, the therapy is being applied to increasingly more complex and challenging clinical scenarios. As a result, significant opportunities for research and development remain. These opportunities for development can be broadly categorized into three areas: delivery, deployment, and postdeployment.

OPPORTUNITIES FOR DEVELOPMENT

Delivery

Delivery can be defined as the ability to place the device into its intended location. The incidence of access complications in the early days of TEVAR approached 20%.[6] Lower device profiles and improved operator experience have significantly reduced the incidence of access complications. There has also been a major shift from open femoral exposure toward totally percutaneous aortic interventions.

The current delivery systems include sheathless as well as integrated-sheath device platforms. There are advantages and disadvantages associated with each. A sheathless platform requires placement of a separate sheath for delivery. The advantage is that multiple devices can be delivered through a single sheath. The access vessel has to be traversed only once, with a hypothetically lower risk of trauma in difficult anatomies. It is important to note that sheaths are measured based on their inner diameter, so access site measurements have to account for that difference in diameter. Conversely, devices with an integrated sheath platform do not require a separate sheath. The access vessels have to be traversed more than once when multiple pieces are required. Measurements are based on the device delivery system outer diameter.

Regardless of the delivery system, opportunities exist to reduce device profiles. In addition, devices with improved flexibility and trackability are useful in patients with challenging anatomies.

Deployment

The origin of the word deploy is from the French word *déployer*, which means "to unfold." For the purpose of this article, deployment can be defined as the process of unfolding or releasing the device from its delivery profile into its final diameter. Deployment accuracy would be the ability to deploy the device at its intended location. To achieve a high degree of deployment accuracy, operator control is necessary to offset the dynamic nature of the target anatomy or landing zone.

The force of the cardiac output results in significant caudal displacement forces that can cause wind socking during deployment. There is also significant movement

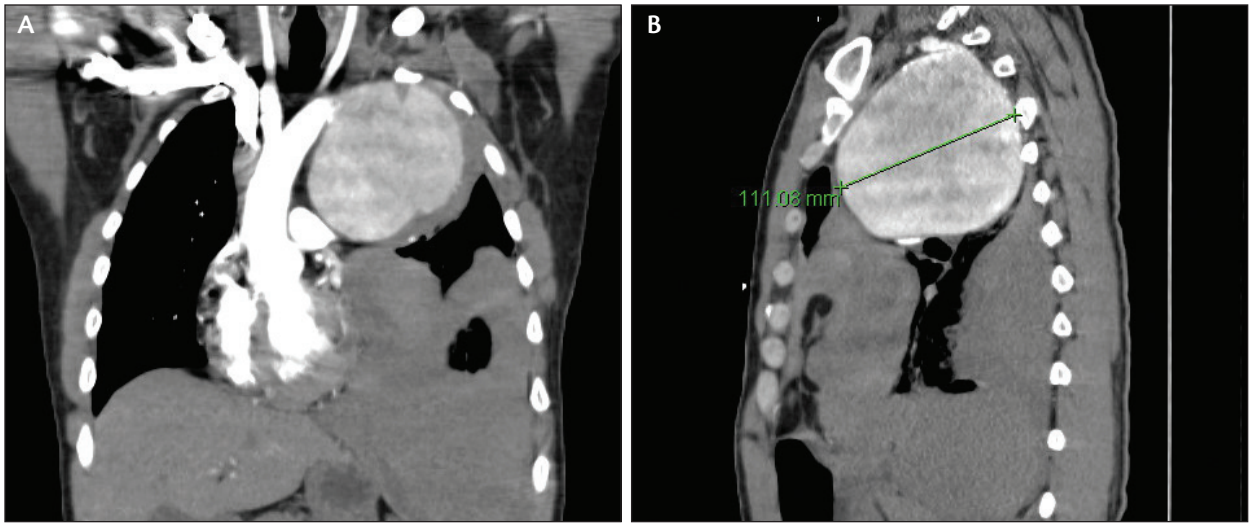

Figure 5. Coronal (A) and sagittal (B) CTA of a 47-year-old man with a history of open aortic coarctation repair who presented with an 11 cm ruptured descending thoracic aortic aneurysm.

within the aorta, depending on the stage of the cardiac and respiratory cycles. In addition, built-up energy from tortuous and angulated anatomy can shift the device further proximal or distal than the intended location. The device frequently travels on a wire placed in the centerline of the aorta. After deployment, however, the device often hugs the outer curve. This may cause an unpredictable shift in the device position, resulting in suboptimal deployment. This effect can be very pronounced in patients who have large aneurysms and a very short proximal landing zone (Figures 5 and 6).

Ideally, the operator should have the ability to make fine adjustments to accommodate the dynamic nature of these factors. Naturally, a multiple-stage deployment system would be more desirable than a single-stage one. This would allow the operator to fine-tune the device deployment in the intended delivery location. One solution would be to have an intermediate-diameter profile during the first phase of deployment.

Adjustments can be made as necessary to fine-tune the device location. It would be critical to have free flow through the device at this interval to avoid wind socking and caudal displacement. An additional angiogram can be done at this time for confirmation. The device should be placed against the outer curve of the aorta to minimize movement during the final stage of the deployment, which can be done by applying forward tension on the guidewire. With the device in its final intended position, the deployment can be completed.

Postdeployment Modification

Even after achieving a high degree of deployment accuracy, there are additional maneuvers that can be

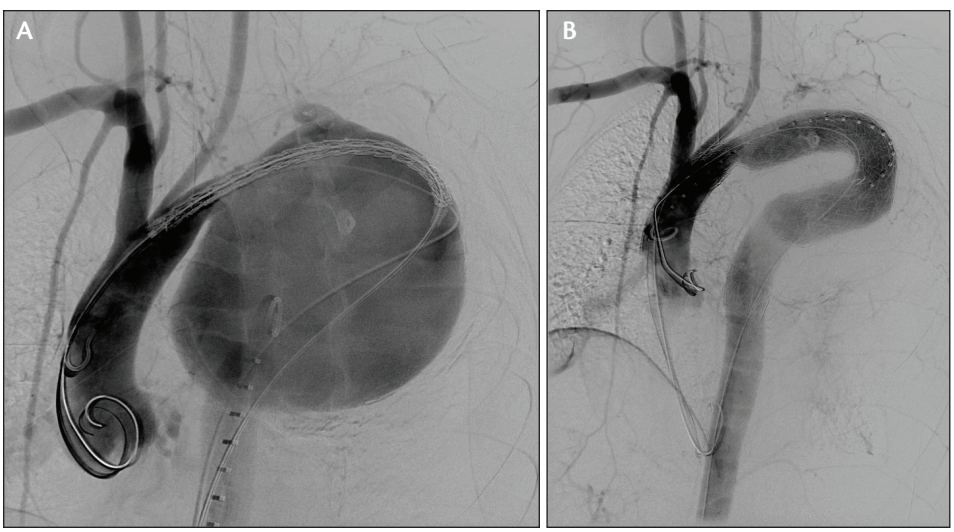

Figure 6. Diagnostic (A) and completion (B) angiograms after TEVAR in the patient shown in Figure 5. The devices appose to the outer curvature of the aneurysm.

done to improve device apposition to the inner curvature of the aorta. This is often performed with the help of postdeployment angioplasty using a compliant balloon. Further advancements in device design can allow the operator to articulate the proximal end of the device. Such capabilities can help eliminate bird-beaking and maximize the seal zone. FDA-approved endostaples are another useful tool that can be applied to high-risk landing zones, although endostaples have not been tested with all devices.

Branched Devices

Lesions affecting the thoracic aorta can extend to the aortic arch or abdominal aorta. In such cases, endovascular repair may require coverage of the left subclavian or celiac arteries. An off-the-shelf, branched device can expand the application of TEVAR in patients who require extended coverage. Two branched device platforms designed for the left subclavian artery are currently under investigation. The application of this off-the-shelf, branched technology to lesions of the thoracic aorta holds great promise.

Follow-Up

The significance of follow-up surveillance imaging protocols cannot be overemphasized. A number of studies have shown that delayed complications, such as endoleak or migration, can occur in late follow-up, even after an initial stable repair.[7] Adequate follow-up often allows physicians to intervene on complications of TEVAR before they can have catastrophic consequences. The benefits of follow-up imaging protocols have to balance against the harmful effects of cumulative radiation. Yearly CT scans over the lifetime of a young trauma patient can quickly add up to significant radiation exposure. Alternative follow-up strategies should be investigated. Implantable pacemakers that provide diagnostic information during interrogation are in common use today. Future endograft designs could provide real-time information in a similar fashion without the need for contrast or radiation.

CONCLUSION

Significant progress has been made during the past decade in the disruptive technology we now call TEVAR. There have been major advances in device design, physician expertise, clinical care, and research. Future progress will undoubtedly make this technology applicable to a wider spectrum of patients. ■

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