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Early Experience Using the GORE® TAG® Conformable Thoracic Stent Graft With ACTIVE CONTROL System: Why It Is My Preferred TEVAR Device

A new TEVAR delivery system allows staged, predictable endograft deployment and in situ angulation control, while avoiding windsocking and bird-beaking.

BY GIOVANNI B. TORSELLO, MD; MARTIN AUSTERMANN, MD; AND GIOVANNI F. TORSELLO, MD, BA

The introduction of thoracic endovascular aortic repair (TEVAR) has completely changed clinicians' attitudes and approaches in the treatment of thoracic aortic pathologies.¹ Since the advent of TEVAR, we have witnessed endovascular repair being applied to treat increasingly complicated disease states in challenging aortic anatomies. Thoracic endografting provides a therapeutic option to an increasing number of patients who are not good candidates for open repair or who prefer a minimally invasive approach.²

Over the years, much progress has been made to improve TEVAR in terms of the design of both the stent graft and the delivery system. However, despite recent advancements, TEVAR is not free from complications, and challenges with bird-beaking and windsocking continue to be a problem, especially in the aortic arch. Failure to conform to arch anatomy may increase the risk of type I endoleak, which, if left untreated, can result in aortic rupture and possibly death. Windsocking due to high blood flow velocity and pressure in the aortic arch can lead to difficulties with precise deployment. This is especially true with deployment mechanisms where the proximal end opens while the distal end remains constrained. Predictability of deployment is also important at the level of the distal landing zone to avoid covering of the visceral arteries.

To overcome these challenges, the new GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System* introduces novel features that help to enhance deployment accuracy and stent graft apposition and to fully take advantage of the stent graft's conformability.

TECHNICAL CONSIDERATIONS

The GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System combines the familiar



Figure 1. The new GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System and associated accessory devices. The stent graft design remains the same as the previous-generation Conformable GORE® TAG® Device.

Conformable GORE® TAG® Device with a novel nested handle delivery system. The stent graft remains the same as the Conformable GORE TAG Device and therefore has the same conformable stent graft design with sutureless graft attachment, oversizing windows that enable optimized radial fit, and indications and anatomic requirements. The principle of operation is also maintained, with a fiber deployment mechanism that is actuated to release the self-expanding stent graft from a constraining sleeve.

The delivery system, however, is different and now features a nested handle that separates stent graft expansion into two deployment steps, each requiring actuation of a separate handle component (Figure 1). Deployment consists of four required steps and two optional angulation steps. Removal of the primary deployment handle deploys the stent graft to its intermediate diameter, initiating device opening from the leading to the trailing ends (Figure 2). At this intermediate



Figure 2. The nested handle of the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System enables stepwise deployment and optional angulation of the device. This figure shows the device deployed to its intermediate diameter after removal of the primary deployment handle.

stage, the angulation control dial is now accessible and the user has the first opportunity for optional angulation of the proximal end of the stent graft by rotating this dial. Removal of the secondary deployment handle deploys the stent graft to its full diameter, initiating deployment from the trailing to leading ends. The angulation control dial remains accessible even after full expansion, and the user has a second opportunity for optional angulation at full diameter. Throughout the deployment, the stent graft is secured onto the catheter via a lock wire. This ensures control of device positioning throughout the procedure until removal of the lock wire handle. Finally, the angulation assembly handle is removed to withdraw the angulation fiber mechanism.

The GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System has two important features to improve deployment predictability through accuracy and control: staged deployment and in situ angulation control of the proximal end of the stent graft. With staged deployment, the nested handle delivery system design enables the stent graft to deploy in two distinct steps (Figure 3). Removal and actuation of the first primary deployment handle opens the device along its entire length to its intermediate diameter, which is approximately 50% of its nominal diameter. Importantly, this deployment to intermediate diameter is designed to allow continuous blood flow both through the lumen of the stent graft and around the device. This feature ensures hemodynamic stability throughout the procedure, even in the aortic arch with its characteristic high blood flow pressure and velocity. A unique advantage of this design is that blood pressure does not have to be aggressively reduced because the blood flow into the distal aorta is not compromised. The lack of windsocking forces that tend to push the device distally during device opening helps to ensure precise positioning of the stent graft in the aorta. Because

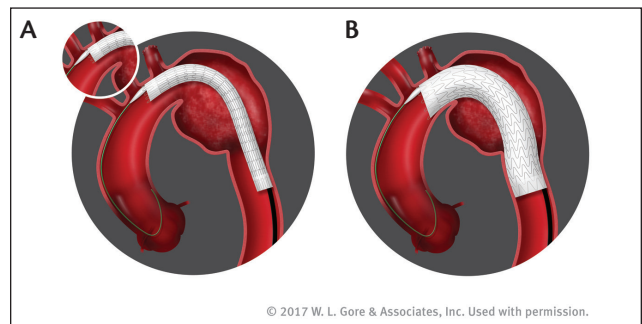


Figure 3. Staged deployment allows the device to first be opened to an intermediate diameter along its entire length while ensuring continuous blood flow (A). A separate deployment step expands the device to its full diameter (B).

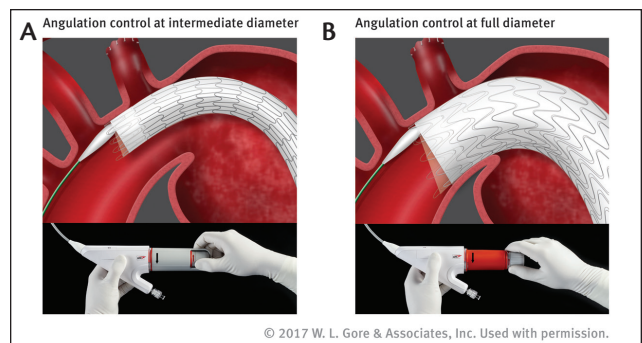


Figure 4. The optional angulation feature can be used at both intermediate (A) and full (B) diameter stages. By nesting the stent rows along the inner aortic curve, angulation helps to achieve orthogonal device placement in tight arches.

there is little or no wall apposition at this intermediate diameter, it is possible to make refinements in the stent graft positioning. If required, it is also possible to modify the C-arm gantry angle to remove device parallax and maximize every millimeter of the landing zone. Removal and actuation of the secondary deployment handle opens the device to its full diameter. A lock wire secures the stent graft to the catheter, ensuring that the user maintains control of the device and its positioning throughout the procedure until the lock wire is removed as one of the final deployment steps.

Angulation of the proximal end of the stent graft is an optional feature that allows for more orthogonal placement of the stent graft. The benefit of angulation becomes evident in angulated aortic arch anatomies, where the wall apposition along the inner aortic curvature can sometimes lead to the formation of a bird beak. The GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System allows the user to adjust the angulation and orthogonal placement of the proximal end of the stent graft in situ, depending on the individual anatomic needs of the patient. Angulation control is possible during the two phases of deployment, at intermediate diameter

and after the stent graft has expanded to its full diameter (Figure 4). Because this is an optional feature, the clinician can decide during deployment whether and to what degree angulation is beneficial in that specific anatomy. This ability to optimize proximal device apposition may help to avoid complications such as type Ia endoleak.

CASE REPORT

A 79-year-old man with a documented medical history of a type B aortic dissection presented with thoracic pain (Figure 5). A CT scan revealed an aneurysm of the false lumen and collapse of the true lumen (Figure 6). Endovascular exclusion of the aneurysm was deemed to be appropriate to prevent aneurysm rupture. TEVAR planning was based on a thoracoabdominal thin-slice CTA. The preoperative maximum outer-outer thoracic diameter was 57 mm. Proximal neck length and diameter were measured using the vessel centerline-of-flow technique.

The procedure was performed in a hybrid endovascular suite using fusion imaging under general anesthesia.³ The right femoral artery was accessed percutaneously using the preclose technique, which has been described elsewhere.⁴ During the procedure, intravenous heparin was administered to reach an activated clotting time corridor of 250 to 300 seconds. A 22-F GORE® DrySeal Sheath was placed. Under fluoroscopic guidance, two 34-mm-diameter GORE TAG Conformable Thoracic Stent Grafts were implanted. A permissive hypotension of < 100 mm Hg systolic blood pressure sufficed. The first 200-mm-long GORE TAG Conformable Device was placed with the proximal end just below the origin of the left subclavian artery (Figure 7). At intermediate diameter, it was observed that positioning of the device could be optimized by modifying the C-arm angle to remove device parallax.

The device was then deployed to its full diameter, and angulation of the endograft was performed. The device conformed to the aortic arch, with no bird beak on the inner curvature. A second device was placed for distal extension with the same diameter and a length of 10 cm, aiming for an overlap of 5 cm. After deployment of the stent graft, completion angiography was performed to ensure adequate placement of the graft and to rule out endoleaks (Figure 8). Postoperatively, mean arterial blood pressure was kept between 80 and 100 mm Hg in order to reduce the risk of ischemic spinal cord injury. Cerebrospinal fluid drainage was not performed, as we abandoned it as a prophylactic measure several years ago.⁵

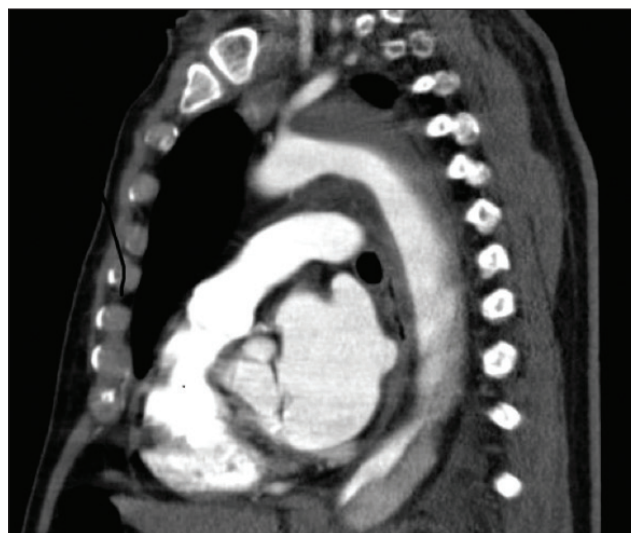


Figure 5. A CT scan showing a type B aortic dissection treated by best medical treatment.



Figure 6. One year later, the patient presented with thoracic pain. The CT scan shows remodeling of the proximal descending aorta with an aneurysm of the false lumen and collapse of the true lumen.

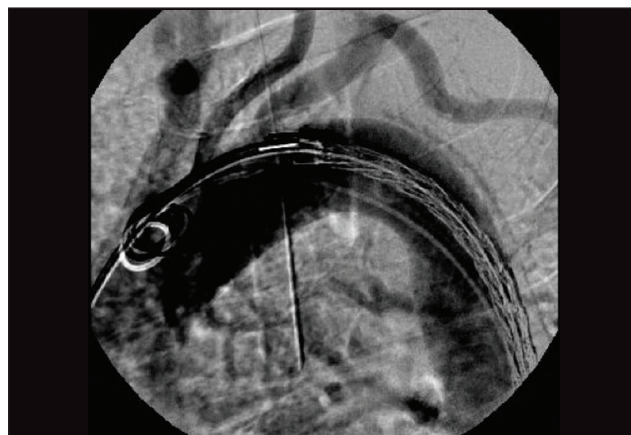


Figure 7. The first 200-mm-long GORE® TAG® Conformable device was placed with the proximal end just below the origin of the left subclavian artery and deployed to its intermediate diameter. The position of the device could be optimized by removing device parallax and adjusting the device position.

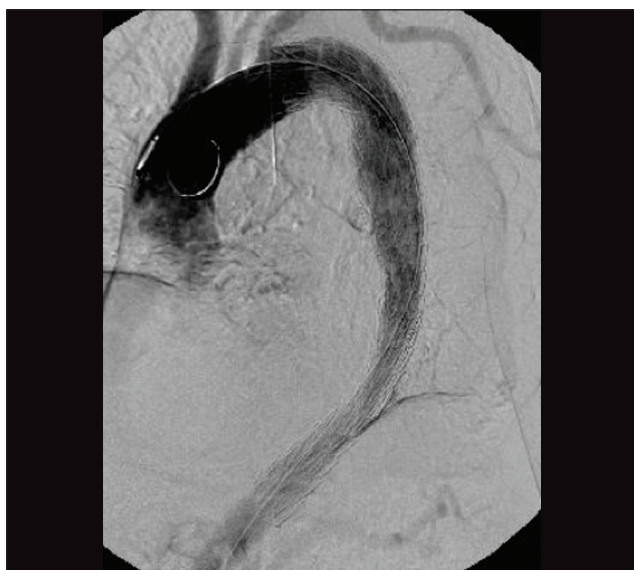


Figure 8. After deployment of the device to its full diameter, the completion angiogram shows adequate placement of the graft in the arch without any endoleak.

A postoperative CT scan revealed exclusion of the aneurysm with no endoleak and good perfusion of the left subclavian artery (Figure 9) and visceral arteries. The patient had no neurologic complications and was discharged from the hospital a few days later. At 3 months, the patient is doing well. A control CT scan is planned 6 months after the procedure.

CONCLUSION

The Conformable GORE TAG Endoprosthesis was already widely recognized for its conformable stent graft design and its proven history across broad indications. With the new features of staged deployment and angulation control, the GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System represents a new development in TEVAR device design that enables in situ adjustments in stent graft positioning and apposition and sets a new standard for the conformability and control that can be expected of a TEVAR device. A prospective controlled registry, the SURPASS registry, will include the experience of up to 20 centers across Europe and will show the performance of the new system in the real world. ■

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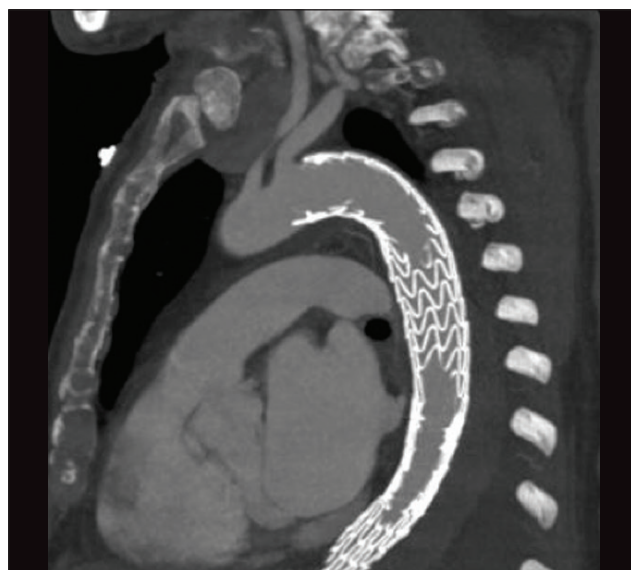


Figure 9. The postoperative CT scan shows exclusion of the aneurysm with no endoleak and good perfusion of the left subclavian artery.

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Precision and Accuracy in the Distal Landing Zone

A case report demonstrating the precise deployment qualities of the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System.

**BY HENCE J.M. VERHAGEN, MD, PhD; SANDER TEN RAA, MD, PhD;
AND MARIE JOSEE VAN RIJN, MD, PhD**

Stent graft deployment systems for thoracic endovascular aortic repair (TEVAR) are often designed with a focus on proximal landing accuracy due to the common challenges associated with implantations in arch anatomies and with landing zones near the supra-aortic branch vessels. However, precision of the distal graft deployment is also critical to good clinical outcomes, especially in patients whose aortic disease extends near the visceral arteries. Precise deployments in such distal anatomies can be challenging because of the tendency for the stent graft to move upward in the aorta, which often occurs as the device expands off of the catheter and finds apposition with the aortic vessel wall. As devices adapt to the surrounding anatomy, their positioning may deviate from the path taken by the guidewire and catheter, resulting in upward movement from the intended target location.

New developments in TEVAR deployment systems enable device control and deployment precision in distal as well as proximal target landing zones. In the following case, we present an aneurysm patient who was successfully treated using the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System.*

CASE REPORT

A 74-year-old man was transferred from an outside hospital to our center with complaints of a sudden onset of severe pain between the shoulder blades. He was hemodynamically stable with a systolic blood pressure of > 180 mm Hg. An urgently performed CT scan including very late-phase imaging revealed an intramural hematoma (IMH) extending from the origin of the left subclavian artery (LSA) to the level of the celiac trunk without any further complications.

His past medical history included stage 3 chronic obstructive pulmonary disease, hypertension, and an open aortic repair with a bifurcated graft for a large abdominal aortic aneurysm (AAA) 6 years earlier. Furthermore, he was known to have a thoracic aortic



Figure 1. CTA image of the distal aortic arch at the level of the LSA. A clear, thick layer of IMH is seen, excluding a healthy proximal landing zone.

aneurysm (TAA) that was approximately 57 mm in diameter, which was closely monitored over the recent years and showed minimal growth.

The patient was treated with continuous β -blocker infusion (labetalol) with rapid normalization of blood pressure to approximately 120 mm Hg systolic and relief of all pain symptoms. An urgent TEVAR was considered but due to the lack of healthy proximal (Figure 1) and distal sealing zones, the presumed high risk of paraplegia, as well as his favorable response to antihypertensive treatment, a conservative approach was chosen.

Images on a repeat CTA after 10 days were unchanged, and the patient was discharged in good condition. Further CTA imaging 1 month after presentation showed no further aortic dilatation and clear resolution of the thickness and extent of the IMH. Further optimization of medical treatment of cardiovascular risk factors was established during outpatient visits.

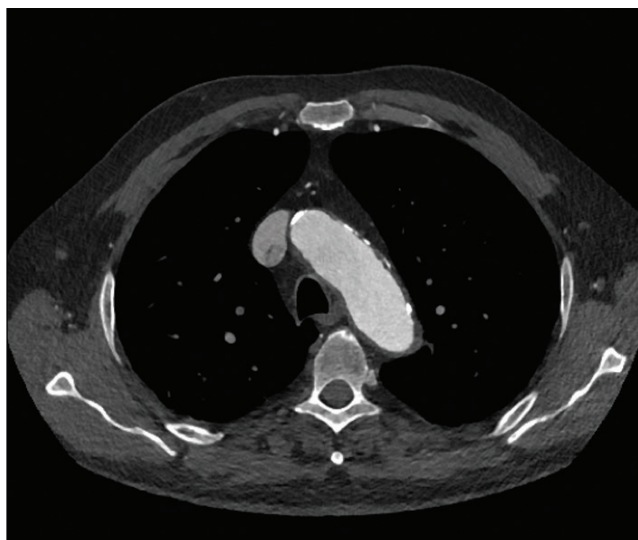


Figure 2. CTA image of the distal aortic arch at the level of the LSA. The thick IMH has almost completely vanished, resulting in a relatively healthy proximal landing zone.

Six months after onset of his IMH, he returned for a scheduled follow-up visit including new imaging that showed almost complete resolution of the IMH (Figure 2) and a slight increase in maximum diameter to 59 mm. He was discussed in our aortic group again, and the decision was made to continue following a conservative strategy up to a maximum diameter of > 60 mm, as his risk of paraplegia was presumed to be far above average due to the extensive coverage of the thoracic aorta by TEVAR, in addition to his former open AAA repair.

CTA 6 months later showed further dilatation of the TAA to 63 mm, and the decision was made to offer minimally invasive treatment by TEVAR. Due to his specific anatomy, a graft with optimal deployment precision was necessary, especially distally, as deployment of the graft close to the origin of the celiac trunk in order to maximize the distal sealing zone was presumed essential. For this purpose, the new GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System seemed to be the ideal device.

First, a spinal drain was inserted for neuroprotection, after which the patient was placed under general anesthesia. Through open access, a 24 Fr GORE® DrySeal Flex Introducer Sheath was placed through the right common femoral artery. The proximal GORE TAG Conformable Device (40 mm diameter, 200 mm length; with 15%–20% oversizing) was inserted up to the level of the distal arch, and a pigtail catheter was placed into the ascending aorta through the same sheath. After digital subtraction angiography (DSA) with the image intensifier at 45° left anterior oblique, the proximal device was deployed, aiming just distal to the LSA (length of proximal landing, 35 mm). The GORE TAG Conformable Device deployed exactly at



Figure 3. Deployment of the proximal device at intermediate diameter with continuous blood flow (A) and at full diameter (B).



Figure 4. Accurate placement of the distal device at the level of the celiac trunk.

the intended position, with no change in position during the different deployment steps (Figure 3).

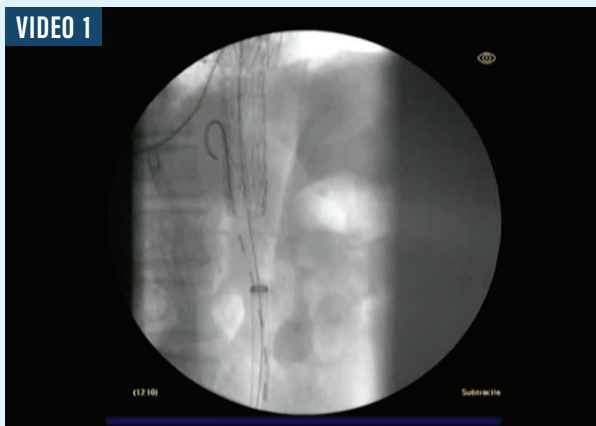
The distal device (40 mm diameter, 200 mm length) was then inserted, and DSA was performed with the image intensifier at 50° right anterior oblique for optimal visualization of the origin of the celiac trunk. Deployment followed the intuitive steps, and again, perfect placement of the GORE TAG Conformable Device was achieved, this time aiming the distal part of the stent graft in order to be as close as possible to the celiac trunk (Figure 4; Videos 1 and 2). The intervention lasted < 90 minutes, and the patient recovered uneventfully with full neurologic function. Postoperative CTA showed complete exclusion of the TAA with optimal coverage of available proximal and distal landing zones (Figure 5).

DISCUSSION

The GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System includes several

WATCH THE ANGIO

VIDEO 1



Angiography of the distal device at its intermediate diameter. Staged deployment to intermediate diameter allows for visualization, and if necessary, refinement of the stent graft position. At this stage, there is no vessel wall apposition and continuous blood flow is ensured.

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VIDEO 2



Angiography of the distal device during secondary deployment to full diameter. The device opens from trailing to leading end during this step, thus allowing for vessel wall apposition and passive fixation on the distal end before the rest of the device is opened. A lock wire keeps the stent graft secured to the catheter throughout the deployment to enable control and stability throughout the procedure.

goremedical.com/angio2

unique features that contributed to the successful treatment of this patient. First, the nested handle design of the deployment system remained very easy to use despite the increased number of steps for staged deployment and angulation. Given our success with the straightforward deployment of the existing Conformable GORE® TAG® Thoracic Endoprosthesis, we wondered whether the added steps and functionality of the new device would complicate the deployment process, as more steps would have to be remembered. However, we found the operative steps to be exceptionally easy and intuitive with absolute ease of mind during the procedure.

Second, the device was very stable during the deployment process. We were able to achieve perfect positioning of the first stent graft in the aortic arch just distal to the LSA without any movement during deployment. We were pleasantly surprised that no windsock effect was noted, likely due to the primary deployment to intermediate diameter, allowing continuous blood flow through the graft during the entire deployment process. This lack of windsock effect was observed again during the distal device placement as well.

Last, and most importantly for this case, the new deployment system enabled very precise and predictable distal device placement. Most thoracic stent grafts show brisk and clear upward movement of the distal device during the last stages of deployment when placed at the level of the celiac trunk, making it difficult to land the graft exactly at the intended position. In this case, exact positioning of the distal device was key in order to achieve sufficient sealing length. This worked perfectly with the GORE TAG Conformable Thoracic Stent Graft due to the hemodynamic stability of the staged deployment but also the lock wire that ensured that the device remained fixed onto the catheter throughout the deployment process.

Staged deployment to intermediate diameter provides an opportunity to refine device placement during deployment, but because we did not observe any changes in device position during the different deployment stages and were pleased with the precision with which the device landed at the target, we did not need to make any adjustments. Furthermore, because secondary deployment to full diameter is designed to open the device from the trailing to leading end, this allowed us to visualize and control precise distal positioning of the device and to gain

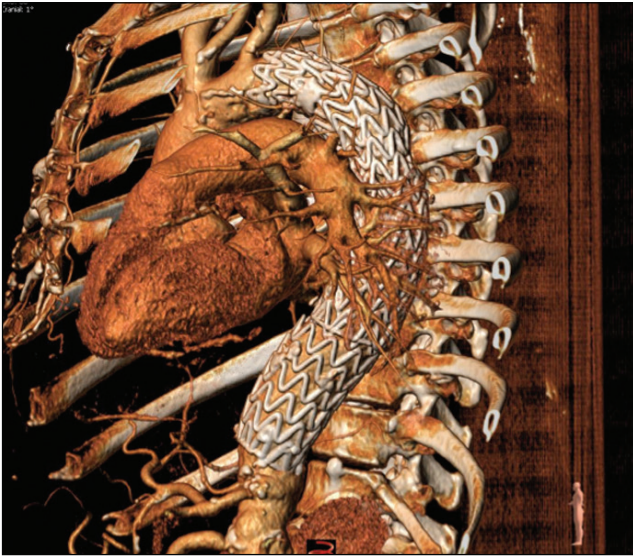


Figure 5. Postoperative CTA demonstrating successful exclusion of the aneurysm with optimal device placement at both proximal and distal landing zones.

full vessel wall apposition just proximal to the celiac trunk before completing this deployment step.

CONCLUSION

The GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System includes new design features like staged deployment and lock wire fixation of the

device to the catheter that enhances control and precision throughout the deployment process. These advancements are beneficial in ensuring accurate device placement and maximizing seal length in anatomies where the distal, as well as proximal, landing zone is critical. Importantly, the system remains easy to use and the handle operation is intuitive. ■

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Early Results and Lessons Learned With the GORE® TAG® Conformable Thoracic Stent Graft With ACTIVE CONTROL System

Device-related factors that are designed to overcome the existing limitations in TEVAR.

BY DITTMAR BÖCKLER, MD; MORITZ S. BISCHOFF, MD; VERA ZIPSE, BSc;
AND PHILIPP GEISBÜSCH, MD

Over the past 3 decades, since its introduction by Dake et al in the 1990s,¹ thoracic endovascular aortic repair (TEVAR) has become the first-line modality for the treatment of thoracic aortic pathologies.² Clinical registries such as the RESTORE II registry,³ the TRAVIATA registry,⁴ and the multicenter European Conformable GORE® TAG® Thoracic Endoprosthesis Registry⁵ demonstrated that a majority of aortic pathologies involve the arch with landing zones 0–3.⁶ Many parameters influence technical and clinical outcomes in TEVAR due to the arch (Figure 1). Besides patient-related (eg, underlying disease or emergency setting) and procedure-related factors (eg, intraoperative imaging), device-related parameters such as stent graft design, conformability, radial force, and placement accuracy significantly contribute to the early technical success of the procedure.

TEVAR IN THE AORTIC ARCH

The aortic arch is a challenging environment for many anatomical and device attribute reasons such as tortuosity, the windsock effect, and others. As the indications for TEVAR expanded over the years to include patients with unfavorable anatomy, the limitations of some stent grafts became evident. Many patients have tortuous, calcified, or even small access vessels. Additionally, tortuosity of the descending thoracic aorta and angulation of the aortic arch makes trackability of most delivery systems difficult, increasing the risk of peripheral and cerebral embolization or vessel wall damage. Rupture of iliac vessels and retrograde dissection of the aortic arch have been described as possible complications of thoracic stent grafting.^{7,8} The “gothic” arch configuration and the high-pressure environment in the aortic arch may lead to failure in trackability/delivery and deployment issues, thus contributing to type I endoleaks. The design of most

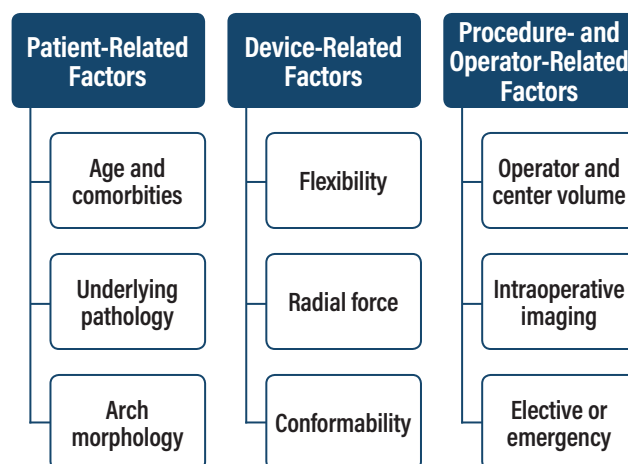


Figure 1. Factors influencing technical and clinical outcomes in TEVAR. Adapted with permission from Böckler D. TEVAR in the aortic arch—influence of the proximal landing zone on outcome. In: Greenhalgh RM, ed. *Vascular and Endovascular Controversies Update: 1978–2015*. London, UK: BIBA Medical; 2015.

thoracic stent grafts was derived from experience with devices for the infrarenal aorta. Furthermore, the currently available devices were intended to treat the straight tube segment of the descending aorta, and so deployment of a stent graft in the arch remains challenging.

CURRENT LIMITATIONS OF PERFORMING TEVAR

In general, current device-related limitations while performing TEVAR are introduction profile (up to 24 Fr), accuracy and control during deployment, stent graft conformability, inner curve apposition, preservation of aortic branches, and long-term durability. Additionally,

other limitations such as stroke, spinal cord injury, and endoleaks are well documented in the literature.

Use of a device in the distal aortic arch requires perfect conformability and good apposition to the inner curve of the aortic wall to avoid endoleaks, migration, or compression/collapse. Severe arch angulation resulting in lack of inner curve apposition remains a well-documented limitation of commercially available thoracic devices. Therefore, further product research and device development were necessary to produce devices specifically designed to meet the requirements of patients with different pathologies and treatment in different segments of the aortic arch and descending thoracic aorta.

To better understand and address these clinical challenges and design issues, Gore & Associates created benchtop models to replicate real patient anatomies with severe arch angulation and challenging landing zones. This research supported the development of the next-generation device, which fulfills the need for a conformable thoracic stent graft to meet a broad range of anatomies, combined with an innovative deployment system that provides enhanced control, positioning, and wall apposition during deployment: the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System.*

STENT GRAFT DEVELOPMENT AND EVOLUTION OF THE NEXT-GENERATION SYSTEM

Since its first commercial use in 1998, more than 125,000 GORE® TAG® Devices have been distributed worldwide. The original GORE TAG Device was modified in 2003 to eliminate the clinically observed spine wire fracture failure mode. Innovation of stent graft design and improvement of device performance was continued with the Conformable GORE TAG Thoracic Endoprosthesis, which was engineered for endovascular repair of the descending thoracic aorta with special consideration given to the unique anatomic and physiologic characteristics of patients presenting with pathologies involving the aortic arch such as aneurysm, traumatic aortic transection, and aortic type B dissection. The new GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System, which recently became commercially available in Europe, maintains all attributes of the Conformable GORE TAG Device and adds new tools (Figure 2).

The new delivery system enhances control during deployment and vessel wall apposition. Compared to the current one-step deployment that opens the stent graft from the center toward both ends, the new staged deployment first opens the stent graft to an intermediate diameter from leading to trailing end. This is then followed by a separate handle action that completes stent graft expansion to full diameter from trailing to leading end.



Figure 2. The evolution of Gore's TEVAR device, from the original GORE® TAG® Device to the Conformable GORE® TAG® Endoprosthesis and, most recently, the new GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System.

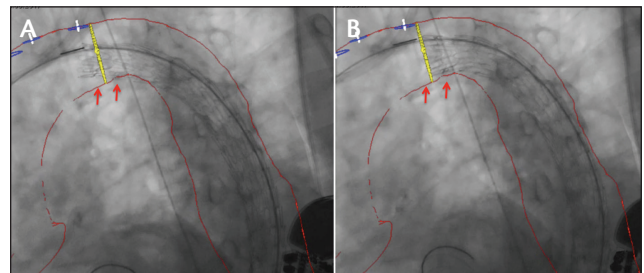


Figure 3. Intraoperative fluoroscopy before (A) and after (B) angulation and refinement of stent graft position at the intermediate stage of deployment. The red arrows indicate the improved apposition of the device at the inner arch curvature.

Angulation along the inner curvature is possible at both intermediate- and full-diameter stages. It is optional and can be skipped at the discretion of the implanting physician. It is important to remember that angulation is irreversible; however, the auditory, visual, and tactile feedback during angulation allows for a slow and controlled adjustment of orthogonal positioning of the proximal end of the stent graft (Figure 3).

The olive is now precurved and is designed to facilitate self-orientation of the stent graft to the outer curve in the aortic arch. A lock wire keeps the stent graft attached to the catheter throughout the procedure. In comparison to the current Conformable GORE TAG Device, the new-generation device comes with two constraining sleeves rather than one.

The two case reports that follow demonstrate our early experience with the new GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System.

CASE REPORT 1

A 40-year-old man presented with an asymptomatic progressive postcoarctation aneurysm of 42 mm diameter

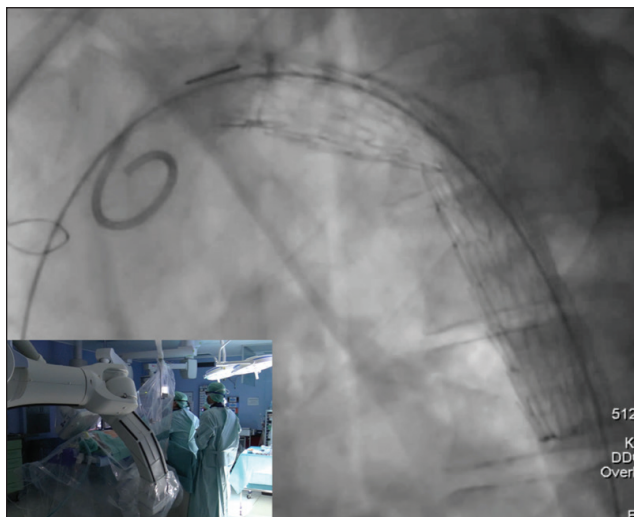


Figure 4. On intraoperative fluoroscopy, parallax correction of the C-arm was adjusted according to the gold band marker on the proximal end of the device. A perpendicular angle to the aorta can be confirmed when the gold band appears as a straight line, rather than an ellipse.

after two previous open surgical repairs. He was treated with TEVAR in July 2017 at our institution to prevent rupture and aortic-related death. The left subclavian artery (LSA) was revascularized by a staged left carotid-subclavian bypass to create a sufficient proximal landing zone and to prevent endoleak from the LSA. After percutaneous right common femoral access was achieved, routine implantation steps for the GORE TAG Conformable Thoracic Stent Graft were followed using a double-curved stiff wire nested into the aortic valve, eliminating stored energy by first advancing past the target location and pulling the device back to the intended landing zone and by pushing the guidewire and device to the outer curvature during deployment. Upon deployment to intermediate diameter, the gold band demarking the edge of the graft material was clearly

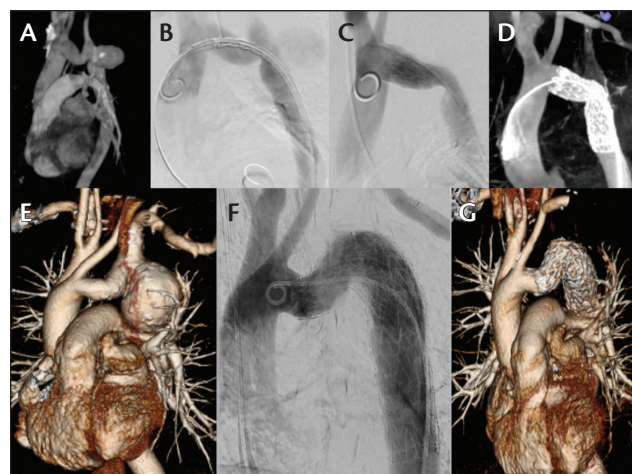


Figure 5. Preoperative three-dimensional (3D) CTA (A), intraoperative digital subtraction angiography at predeployment (B) and after full deployment (C), and intraoperative on-table cone-beam CTA (D) of a successful GORE TAG Conformable Thoracic Stent Graft implantation in a 40-year-old man with a postcoarctation aneurysm of 42 mm. The bottom three images demonstrate preoperative 3D CT reconstruction (E), completion angiography (F), and postoperative 3D CT reconstruction (G).

observed. At this intermediate-diameter stage, parallax correction was used to optimize device positioning before initiating full and final deployment (Figure 4). Pre- and postoperative images demonstrating successful exclusion of the aneurysm are shown in Figure 5.

CASE REPORT 2

A 72-year-old woman with a descending thoracic aortic aneurysm (62 mm maximum diameter) presented for endovascular treatment. The distal landing zone was 20 mm in length. Using fusion imaging and apnea, the third, most distal device was placed just at the level of the

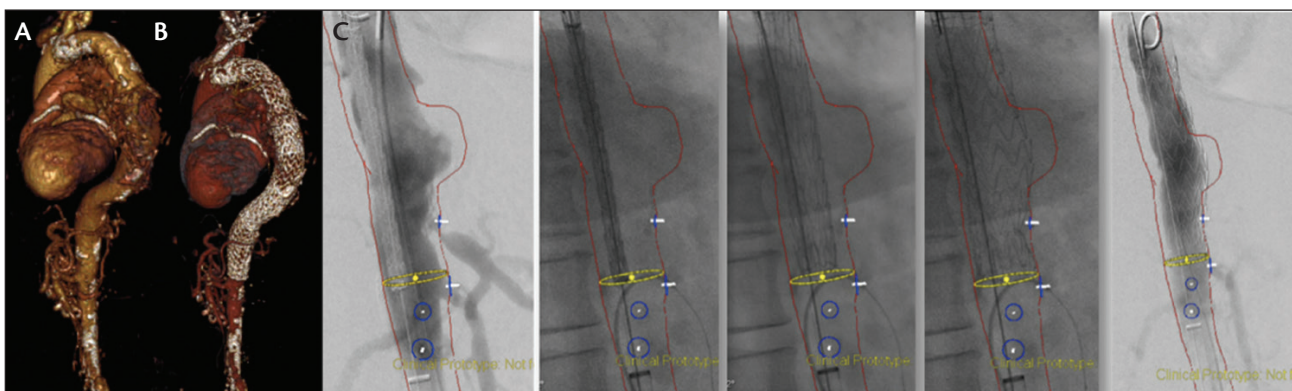


Figure 6. Pre- and postoperative CT scans shows the thoracic aneurysm of the patient before (A) and after (B) treatment. Intraoperative placement of the distal device at the level of the celiac trunk (C).



Figure 7. The device is constrained within two sleeves, which stay in place and are “sandwiched” between the stent graft and the aortic wall at the outer curve after deployment. The precurved olive is designed to enable self-orientation of the device toward the outer aortic curve.

celiac trunk. The deployment was precise and accurate. This was enabled by the secondary deployment to full diameter opening from trailing to leading ends, which is a unique feature in the design of TEVAR devices (Figure 6).

DISCUSSION

With respect to our site’s early experience of 15 cases with the GORE TAG Conformable Thoracic Stent Graft with ACTIVE CONTROL System for different indications, we have learned that staged deployment enables refinement of device placement and angulation, especially in the intermediate phase. Because the device is designed to ensure continuous blood flow throughout the procedure, it enables precise stent graft placement without any time pressure, which is a new and beneficial experience for operators. The hemodynamic stability led our site to abandon rapid pacing altogether when using this device. Staged deployment also allows for visualization of stent graft positioning and parallax correction according to the radiopaque gold band at the proximal stent graft end and to refine device placement with additional angiography, if needed. Optional angulation was used in 40% of all procedures so far. Although the partially uncovered stent row has always been part of the landing zone per the Conformable GORE TAG Device’s instructions for use, the

BENEFITS OF THE GORE® TAG® CONFORMABLE THORACIC STENT GRAFT WITH ACTIVE CONTROL SYSTEM

1. Approved for aneurysms, isolated lesions, and type B aortic dissections
2. Radial force adapted to underlying disease
3. Highly conformable and therefore ideal for aortic arch pathologies
4. No significant bare stent lengths, which mitigates risk of retrograde dissections
5. Short precurved olive
6. Unsheathed device allows the use of multiple devices with one access
7. Staged deployment for parallax correction, with no rapid pacing necessary
8. Stent graft attached onto the catheter for total placement control
9. Deployment from trailing to leading ends allows for accurate landing at the celiac trunk level
10. There is time to optimize accuracy, angulation, and apposition
11. A good device for teaching new operators

presence of two sleeves instead of one makes it even more critical to case plan accordingly (Figure 7).

The secondary deployment sequence to full diameter from trailing to leading ends, combined with the attachment of the device to the catheter via the lock wire, provides full control during the entire deployment process. The device was preferably chosen for patients with short or challenging distal landing zones close to the celiac trunk or superior mesenteric artery. For this reason, the GORE TAG Conformable Thoracic Stent with ACTIVE CONTROL System is now our first-choice stent graft, not only in the arch (zone 0–2, especially in dissection and trauma cases) but also in zone 4.

The profile of all available sizes (21–45 mm) has not changed compared to the Conformable GORE TAG Device, but access problems have not been an issue in our experience so far. This new device is conceptually designed to overcome the previously described limitations of TEVAR devices that are currently commercially available on the market.

The *Benefits of the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System* sidebar summarizes my personal arguments of why this became my device of first choice since its commercial launch in Europe in July 2017.

CONCLUSION

Based on our preliminary experience, the staged deployment and optional angulation of the new GORE TAG Conformable Thoracic Stent Graft optimizes device placement and accuracy. Early experience is extremely convincing and preliminary results are very promising. The device is designed to overcome the described existing limitations in TEVAR. Larger studies and longer follow-up are needed to prove these early observations. The SURPASS registry has already begun in Europe to address these endpoints. ■

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LSA Preservation During TEVAR: Insights From the International GREAT Registry

An overview of our experience with the Conformable GORE® TAG® Thoracic Endoprosthesis.

BY DENNIS R. GABLE, MD, AND WILLIAM T. BRINKMAN, MD

The use and technologic advances of thoracic aortic endografts continue to increase and provide a less invasive option to treat a variety of thoracic aortic pathologies including aneurysm, dissection, intramural hematoma, traumatic transection, fistula, and penetrating ulcer. Coverage of the left subclavian artery (LSA) allows for increased utilization of thoracic endovascular aortic repair (TEVAR) in patients who otherwise would have anatomic limitations that may prevent endovascular repair due to a short proximal landing zone.¹

By covering the LSA, surgeons may gain at least 2 cm of proximal landing zone in which to place the stent graft. In fact, LSA coverage is performed in up to 40% of TEVAR procedures to ensure an adequate seal in the proximal landing zone.² In most cases, coverage of the LSA without revascularization is well tolerated by patients, and endoleak is prevented due to thrombosis of the proximal 1 cm of LSA coming off the arch. However, the risk for limb ischemia as well as a posterior circulation stroke and an increased risk of paraplegia due to reduced collateral spinal perfusion pathways remain major concerns.

Despite the frequency with which the LSA is covered, it remains controversial whether revascularization of the LSA should be performed and, if so, which method of revascularization is most effective.³ There is support for routine LSA revascularization based on findings from the EUROSTAR registry, which reported a significantly higher incidence of spinal cord ischemia or stroke (8.4%) in patients who did not undergo LSA revascularization compared to patients who were revascularized (0%; $P = .49$).⁴

In certain cases, LSA revascularization is required; absolute indications include patients with a previous patent left internal mammary artery–left anterior descending artery bypass or a dominant left vertebral artery. The presence of a left upper extremity dialysis graft is a relative contraindication to LSA coverage without revascularization except in emergent situations. Revascularization should be strongly considered in patients

with additional risk factors for spinal cord ischemia such as those who have previously undergone open infrarenal surgical revascularization or prior endovascular aneurysm repair (EVAR) of the infrarenal aorta. LSA revascularization should also be considered for cases where stent graft coverage is planned for a long segment of the thoracic aorta, as the LSA is a key source of blood flow to the upper spinal cord. Atresia or occlusion of the right vertebral artery or stenosis/occlusion of the hypogastric arteries are both indications for revascularization to assist in avoiding spinal cord ischemia.

The 2010 Society for Vascular Surgery guidelines recommend preoperative revascularization of the LSA when possible in nonemergent cases, although this recommendation was made based on a low level of evidence.⁵ The published guidelines outline the following based on the best available evidence, as assessed by the grading of recommendations assessment, development, and evaluation (GRADE) system⁵:

- In patients who need elective TEVAR where achievement of a proximal seal necessitates coverage of the LSA, routine preoperative revascularization is suggested (GRADE 2, level C)
- In select patients who have anatomy that compromises perfusion to critical organs, routine preoperative LSA revascularization is strongly recommended (GRADE 1, level C)
- In patients who need urgent TEVAR for life-threatening acute aortic syndromes where achievement of a proximal seal necessitates coverage of the LSA, LSA revascularization should be individualized and addressed expectantly on the basis of anatomy, urgency, and availability of surgical expertise (GRADE 2, level C)

A systematic review and meta-analysis of peer-reviewed studies demonstrated that the results of studies investigating intentional LSA coverage during TEVAR with versus without revascularization were mixed. Some studies demonstrated increased risks for stroke, extremity

ischemia, and/or spinal cord ischemia, whereas others found no increased risk for postoperative morbidity.¹ After combining the results of these 51 studies, all of which had a retrospective observational design, the analysis found that LSA coverage without revascularization was associated with a significantly increased risk of extremity and vertebrobasilar ischemia and a trend toward increased paraplegia and anterior circulation stroke. In exchange, revascularization was associated with a 4% chance of phrenic nerve injury.

Even in the setting of revascularization of the LSA prior to TEVAR, cerebrovascular flow patterns in the left vertebral artery can be affected. In a cohort of 74 patients who underwent carotid duplex studies before and after TEVAR with LSA bypass, decreased postoperative antegrade flow was seen in the left vertebral artery, with a concomitant decrease in peak systolic velocity.⁶ In contrast, the peak systolic velocity increased in the right vertebral artery and right internal carotid artery. If and how these hemodynamic changes impact clinical events after TEVAR are unknown. Notably, these data were not compared with findings from patients who did not undergo LSA revascularization prior to TEVAR. The authors hypothesized that the retrograde flow in the LSA established with a carotid subclavian bypass may play a role. Larger studies are needed to determine the significance of this finding in relation to postoperative neurologic events in patients undergoing LSA revascularization before TEVAR. Ultimately, the question of when and whether to revascularize the LSA before or during TEVAR remains unanswered, with no available level 1 evidence.

OPTIONS FOR REVASCLARIZATION

Carotid-Subclavian Artery Bypass

Carotid-subclavian artery bypass is a procedure that has shown exceptional results.^{7,8} It is the preferred technique for patients with a left vertebral artery originating very proximally off of the LSA, as extensive proximal dissection is not required for completion. The procedure is typically performed through a supraclavicular incision beginning over the clavicular head of the sternocleidomastoid muscle and extending laterally approximately 3 to 4 cm. Dissection is carried down to the level of the jugular vein, which is reflected medially, allowing access to the common carotid artery (CCA). The vagus nerve and the sympathetic chain are posteriorly identified and preserved. The scalene fat pad is mobilized off of the anterior scalene muscle. The phrenic nerve runs along the surface of the anterior scalene muscle and should be identified to avoid injury. Care must be taken to avoid the thoracic duct, which runs posteriorly to the left carotid artery and internal jugular vein. If the thoracic duct is encountered in

the dissection, it should be ligated to avoid postoperative lymphocele.

A prosthetic graft, as compared to an autologous venous conduit, is considered the conduit of choice in carotid-subclavian bypass. In 1986, Ziomek et al showed that 5-year patency rates were superior with prosthetic grafts compared to autogenous vein grafts (94.1% vs 58.3%, respectively; $P < .01$).⁷ These results were supported by Law et al who demonstrated 5-year patency rates of 95.2% for polytetrafluoroethylene grafts, 83.9% with Dacron grafts, and 64.8% with saphenous vein grafts.⁸

Carotid-Subclavian Artery Transposition

Carotid-subclavian artery transposition allows revascularization of the LSA without the use of any prosthetic graft material. The disadvantage to subclavian transposition is that it requires more extensive dissection to gain proximal control and mobilize a sufficient length of the subclavian artery to allow tension-free anastomosis to the carotid artery. Because of these limitations, transposition is contraindicated in patients with an early origin of the vertebral artery and in those with a patent left internal mammary artery–coronary artery bypass graft.

Transposition is typically performed through a short medial transverse incision made just above the level of the clavicle. Dissection is carried down between the heads of the sternocleidomastoid muscle, the omohyoid muscle is divided, and the jugular vein is retracted laterally. On the left, the thoracic duct should be identified and ligated. Dissection of the CCA is performed, ensuring preservation of the vagus nerve. The vertebral vein is divided to gain access to the subclavian artery, which is controlled as proximally as possible and must be done proximal to the vertebral artery to preserve posterior cerebral circulation. The subclavian artery is then divided to perform an end-to-side anastomosis to the CCA. Transposition has excellent outcomes with good patency rates. Duran et al reported a patency rate of 96.3% at 53.8 months in 126 patients who underwent transposition.⁹

THE GREAT REGISTRY

The Global Registry for Endovascular Aortic Treatment (GREAT) is an industry-sponsored initiative designed to tabulate real-world patient outcomes and device performance with up to 10-year follow-up in patients treated with aortic endografts (EVAR or TEVAR) developed by a single device company (Gore & Associates).¹⁰ The prospective registry includes data from 114 centers (high and low volume, academic and nonacademic) using Gore's commercially available aortic endograft products in the United States, Europe, Australia/New Zealand, and Brazil. The registry recently completed enrollment of over 5,000 patients.¹⁰ We sought to evaluate



Figure 1. The Conformable GORE® TAG® Thoracic Endoprosthesis.

the documented experience with the Conformable GORE® TAG® Thoracic Endoprosthesis regarding LSA coverage and revascularization strategies (Figure 1). All patients undergoing TEVAR using the device and with a zone 2 proximal landing and LSA-only involvement were identified. Cases with a chimney procedure, thoracoabdominal aneurysm, type A dissection, or incomplete procedural information were excluded.

A total of 79 patients met the study criteria. Of these, 42 patients (53%) underwent LSA revascularization and 37 (47%) did not. Eight (10%) postoperative complications related to coverage or revascularization of the LSA were reported. Among the patients who were revascularized, complications included paraplegia (n = 1), spinal cord ischemia manifesting as bilateral lower extremity weakness and requiring lumbar drainage (n = 1), recurrent laryngeal

nerve injury during surgical debranching (n = 1), and one type Ia endoleak requiring embolization of the stump of the LSA (n = 1). Patients who did not undergo LSA revascularization had the following postoperative complications: subclavian steal syndrome requiring left carotid-to-left subclavian bypass (n = 2), stroke (n = 1), and increased expansion of descending thoracic aneurysms requiring explantation and graft replacement (n = 1). Procedural survival was 100% in both groups, and total hospital length of stay did not differ between treatment strategies (Table 1).

DISCUSSION

The worldwide experience with the Conformable GORE TAG Thoracic Endoprosthesis with zone 2 landing demonstrates that a variety of aortic pathologies can safely be treated via TEVAR with this device. Interestingly, the registry demonstrates that surgeons elected to revascularize the LSA in roughly only half of instances of zone 2 proximal landing zones. This finding reflects the ongoing debate regarding the advantages and disadvantages of LSA revascularization in the absence of strong evidence-based guidelines to direct practice patterns.

Also of note were the roughly equal rates of perioperative complications (approximately 10%) related to this decision in both groups. Although the incidences of complications were similar, the morbidities experienced by patients in each group were naturally different. For example, two patients undergoing revascularization were not spared complications related to spinal cord ischemia despite the proposed advantage of revascularization to reduce this complication, whereas no cases of spinal cord ischemia were reported in the nonrevascularized group. Another revascularized patient suffered recurrent laryngeal nerve injury during surgical debranching, a risk that patients are not exposed to if they are not revascularized. Meanwhile, nonrevascularized patients were at risk for stroke and extremity ischemia, neither of which were reported in the revascularized group.

Although the sample size and event rates were not sufficient for statistical analysis to compare LSA revascularization versus nonrevascularization, these findings reflect the experience documented in peer-reviewed literature over the last decade. For now, the GREAT registry demonstrates the safety of the Conformable GORE TAG Thoracic Endoprosthesis for TEVAR requiring zone 2 landing. Optimal LSA management strategies can only be understood through continued experience with, and evaluation of, this endograft and other thoracic aortic endografts. One of the new technologic advances that may play a role in decreasing the risk of revascularization while allowing for LSA perfusion through an endovascular

TABLE 1. COMPARISON OF PATIENTS WHO UNDERWENT LSA REVASCULARIZATION VERSUS THOSE WHO DID NOT

	LSA Revascularized (n = 42)	LSA Not Revascularized (n = 37)	P Value
Pathology	–	–	.36
Aneurysmal	5 (12%)	8 (22%)	–
Nonaneurysmal	37 (88%)	29 (78%)	–
Procedural survival	42 (100%)	37 (100%)	–
Length of stay, median (range)	9 d (2–27 d)	9 d (2–62 d)	–
Any LSA-related complication	4 (9.5%)	4 (10.8%)	1.00
Abbreviation: LSA, left subclavian artery.			



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Figure 2. The GORE® TAG® Thoracic Branch Endoprosthesis.

approach is the new GORE® TAG® Thoracic Branch Endoprosthesis (TBE)* (Figure 2). Pivotal studies are currently ongoing, and outcomes from this study will be available in the near future. These results may offer new options and improve the outcomes for this patient population. ■

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Optimizing TEVAR Outcomes in Acute and Subacute Type B Aortic Dissections

Procedural planning and intraoperative techniques to increase the likelihood of success.

BY BRUCE TJADEN, MD, AND ALI AZIZZADEH, MD, FACS

The use of thoracic endovascular aortic repair (TEVAR) for the treatment of acute and subacute type B aortic dissections (a/sTBADs) can challenge even the most experienced vascular surgeon. Deciding which patients to treat, selecting the appropriate endograft, sizing the device correctly, and minimizing technical difficulties and complications are all critical steps and require careful thought and planning. In this article, we provide a summary of considerations and best practices to optimize outcomes in TEVAR for a/sTBAD.

DEFINING AND TRIAGING ACUTE AND SUBACUTE TYPE B AORTIC DISSECTIONS

For the purposes of this discussion, we will define acute type B aortic dissections (aTBADs) as those in which the onset of symptoms occurred < 14 days before presentation. Subacute type B aortic dissections (sTBADs) are those in which the onset of symptoms occurred between 14 to 90 days before presentation, and chronic dissections are those in which the dissection is older than 90 days. Malperfusion is defined as clinical end-organ ischemia affecting the brain, spinal cord, viscera, kidneys, and/or lower extremities.

The first clinical question that becomes important in the care of patients with a/sTBAD is who to treat. Patients with malperfusion mandate expeditious treatment—with each minute of critical malperfusion, the potential for poor outcomes and death increases (Figure 1). Similarly, in the rare patients who present with acute dissection

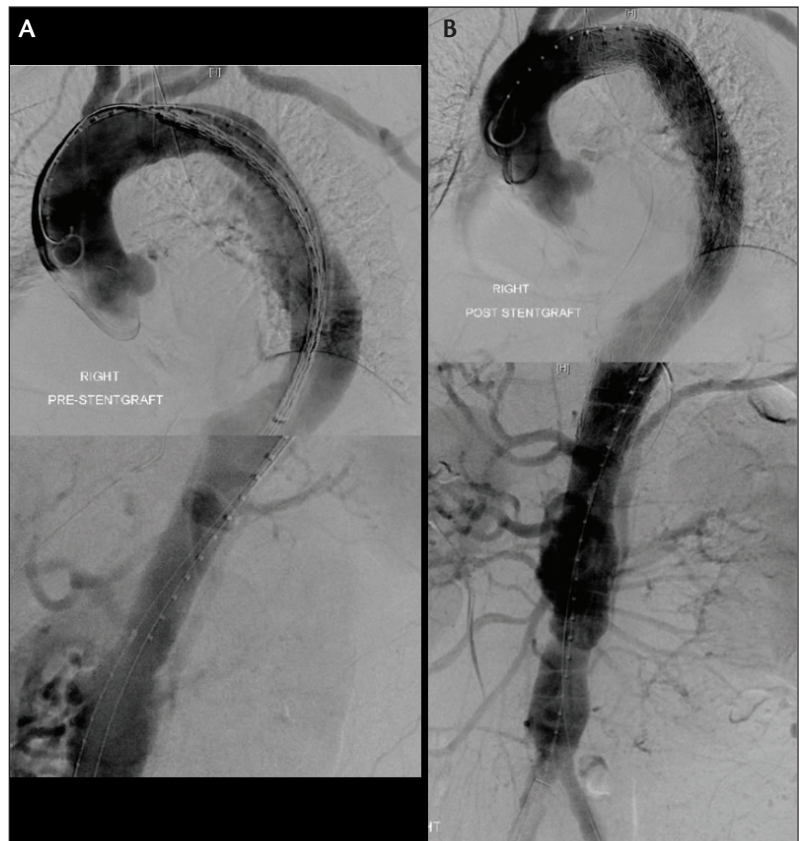


Figure 1. A 56-year-old man presented with an acute complicated TBAD with visceral and left lower extremity malperfusion. He was treated with two Conformable GORE® TAG® Devices. The pre-TEVAR imaging demonstrates poor filling of the mesenteric vessels (A), whereas the post-TEVAR imaging shows brisk filling throughout the renovisceral segment as well as both iliac arteries after TEVAR (B).

complicated by rupture, emergency treatment to seal the site of extravasation is required.

However, in patients with uncomplicated a/sTBAD, the benefits of TEVAR must be balanced against

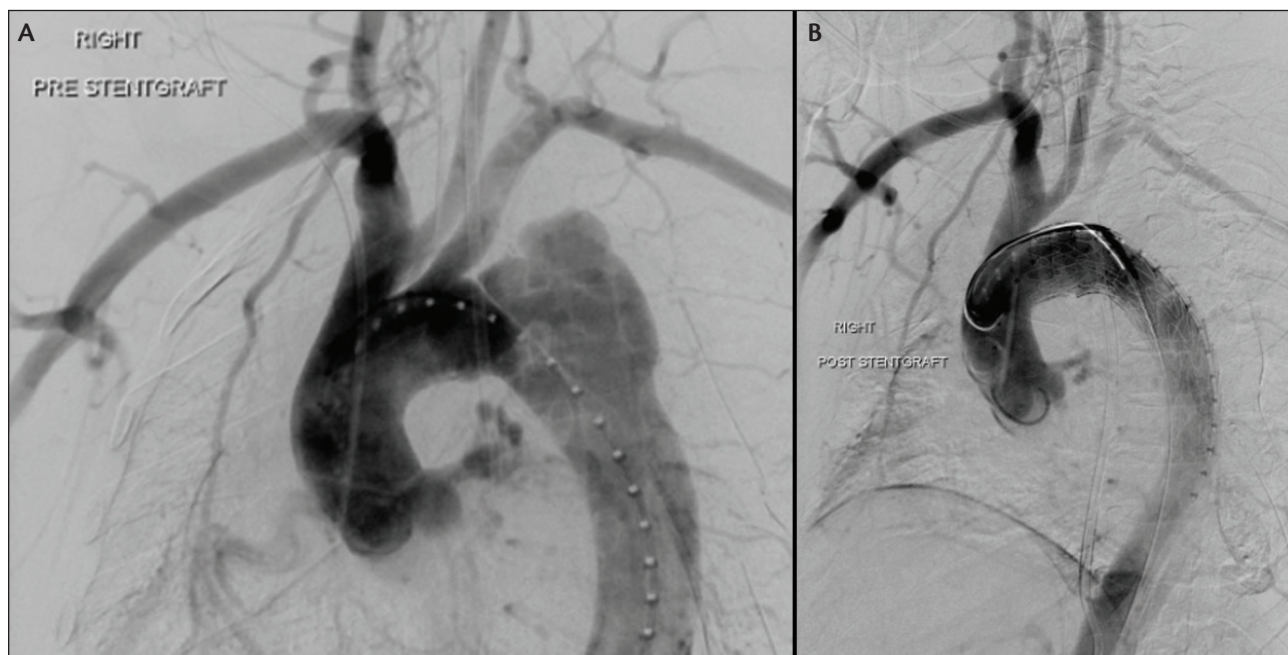


Figure 2. A 55-year-old woman initially presented with acute uncomplicated TBAD. She was managed medically but developed renal malperfusion during the subacute phase, mandating repair. During TEVAR, angiography revealed interval development of a contained rupture (A). IVUS confirmed that the dissection extended into the distal aortic arch. The operative plan was modified, and a Conformable GORE® TAG® Device was deployed with intentional LSA coverage. A completion angiogram revealed adequate filling of the LSA through retrograde vertebral flow, exclusion of the diseased aorta, and brisk distal TL filling (B). She was followed expectantly and did not require LSA revascularization.

the risks of perioperative complications. In order to choose the best therapy for an individual patient, it is important to know which patients are more likely to fail on medical therapy alone. Our large institutional series of uncomplicated TBADs revealed that patients with a total aortic diameter of > 44 mm at any location were more likely to require intervention and had an increased risk of mortality compared to those with a smaller aortic diameter (< 44 mm). Similarly, patients with a false lumen (FL) diameter > 22 mm had decreased intervention-free survival. Patients older than 60 years had an increased risk of mortality when compared to younger patients.¹ Furthermore, in our clinical experience, a/sTBAD patients with “borderline” malperfusion symptoms such as intermittent nausea and vomiting, prolonged ileus, or fluctuating pulse exams seem more likely to progress to frank malperfusion requiring urgent TEVAR. Another high-risk subgroup is patients with refractory pain and hypertension despite medical therapy. Studies have shown that these patients do significantly worse compared to those who have no pain or refractory hypertension.² Patients with these high-risk features should be carefully considered for TEVAR, sooner rather than later, to avoid the risks of delayed complications.

Next, a decision must be made as to the timing of TEVAR. There is evidence that the risks of perioperative complications such as rupture, retrograde type A dissection (RTAD), and mortality are decreased if TEVAR is delayed until the subacute time frame.^{3,4} For this reason, it is our practice that patients with uncomplicated a/sTBAD and high-risk features are treated medically for 2 to 6 weeks and then undergo elective endovascular repair.

PLANNING ENDOVASCULAR REPAIR

Landing Zones

There are multiple goals of TEVAR for aortic dissection: to close the proximal entry tear, alleviate malperfusion, prevent or treat rupture, pressurize the true lumen (TL), and induce FL thrombosis. However, the unique anatomy of each dissection often makes this a complex task. The proximal landing zone must be in an area of normal aorta that is unaffected by dissection. Since the proximal tear is often just distal to the left subclavian artery (LSA), we most often plan on landing the endograft at the distal edge of the LSA. Occasionally, we may position the leading edge of the device fabric partially covering the ostia of the LSA to gain additional seal zone and to ensure that the entry tear is covered. It is not uncommon

for a small component of intramural hematoma (IMH) to extend along the outer curvature of the aorta proximally in a retrograde fashion, even though there is no overt dissection flap in that area. We generally do not consider the presence of limited retrograde IMH to be a contraindication to landing in that region, as long as the most proximal part of the device is in nondissected aorta.

In approximately 40% of cases, coverage of the LSA is required to seal the proximal entry tear. In the emergent setting, we typically cover the LSA without revascularization unless hard indications for revascularization are present (Figure 2). These include previous coronary artery bypass grafting using a left internal mammary graft, an occluded right vertebral artery, and termination of the left vertebral artery in the posterior inferior cerebellar artery. In the absence of these absolute indications for revascularization, we manage patients expectantly and perform a subclavian-to-carotid transposition or carotid-subclavian bypass if signs of upper extremity ischemia or spinal ischemia develop.

Sizing and Device Selection

Choosing an appropriately sized endograft is critical in the treatment of a/sTBAD. There is evidence that the risk of RTAD increases with more aggressive oversizing.⁵⁻⁷ RTAD developed in 16 of the 1,010 patients (1.6%). For this reason, we size 1:1 (0%–5% oversizing) at the proximal (nondissected) aorta. Distally, we will usually tolerate a small degree of oversizing, as the consequences of stent graft–induced dissection in this location are less dire than those associated with RTAD. For the distal landing zone, we measure the entirety of the aortic diameter (TL + FL), as the septum in a/sTBAD is usually fairly pliable and should be expanded toward the outer wall of the aorta by the radial force of the endograft, increasing the likelihood of favorable remodeling.

In many cases, the aortic diameters are such that a single endograft (or two endografts with or without a tapered device) can be used to complete the repair and seal both proximally and distally. However, there are cases in which the discrepancy between the proximal and distal landing zones is pronounced with a significantly smaller distal aorta. During TEVAR for aneurysm, the smaller distal device can be implanted first with the larger proximal device landed within it. However, in the setting of a/sTBAD, placement of the distal piece may seal off a reentry tear, leading to increased pressure in the FL and increasing the risk for RTAD. In this setting, a three-piece repair can be implemented, with the proximal device being implanted first, then the distal smallest device, and last, a middle bridging device that is sized to seal within both the proximal and distal endografts.

In addition to sizing, the device structure appears to be a risk factor for complications including RTAD. A recent meta-analysis of 8,969 patients from 50 publications reported that the incidence of RTAD was higher in patients who had proximal bare stents, more proximal landing zones, and were treated for dissection compared to aneurysm.⁷

Length of Coverage

As previously stated, coverage of the primary entry tear is the principal goal in TEVAR for a/sTBAD. We consider an improvement in TL diameter and coverage of large distal fenestrations to be high-priority secondary goals. The desire to improve aortic remodeling with longer segment coverage has to be balanced with the risk of paraplegia due to intercostal artery coverage. We have noted that aortic remodeling often stops at the distal extent of the covered aorta. For this reason, we prefer to cover down to the level of the diaphragm to maximize the extent of aortic remodeling. In general, we use contrast angiography and intravascular ultrasound (IVUS) to aid us in determining the ideal amount of aortic coverage; if the mesenteric and renal vessels demonstrate brisk systolic filling and no signs of dynamic ostial compromise by the septum, we may leave the distal thoracic aorta uncovered.

INTRAOPERATIVE TECHNIQUES

We routinely employ several adjunctive techniques to facilitate efficient and effective TEVAR in the setting of a/sTBAD. We begin by using ultrasound guidance for femoral access. It is critical to visualize the common femoral bifurcation and the artery's point of emergence from under the inguinal ligament to avoid low or high sticks. Preclosure is performed using the ABBOTT PERCLOSE® PROGLIDE Suture-Mediated Vessel Closure System, each rotated like a key approximately 45° off midline before firing to produce two crossing sutures for vessel closure.

We are proponents of IVUS in TEVAR for a/sTBAD for several reasons. During initial wire insertion, IVUS allows for confirmation of wire and catheter placement within the TL. It also helps to localize the primary entry tear and any significant distal fenestrations. Next, it can be used to rule out the presence of ascending aortic involvement and to confirm that the proximal landing zone is in an area of healthy aorta not affected by dissection. IVUS also allows confirmation of the aortic measurements obtained by CT scan, helping to reduce the chances of unintentional oversizing. Furthermore, IVUS can demonstrate the dynamic changes in TL and FL sizes throughout the cardiac cycle, both before and after device implantation. If

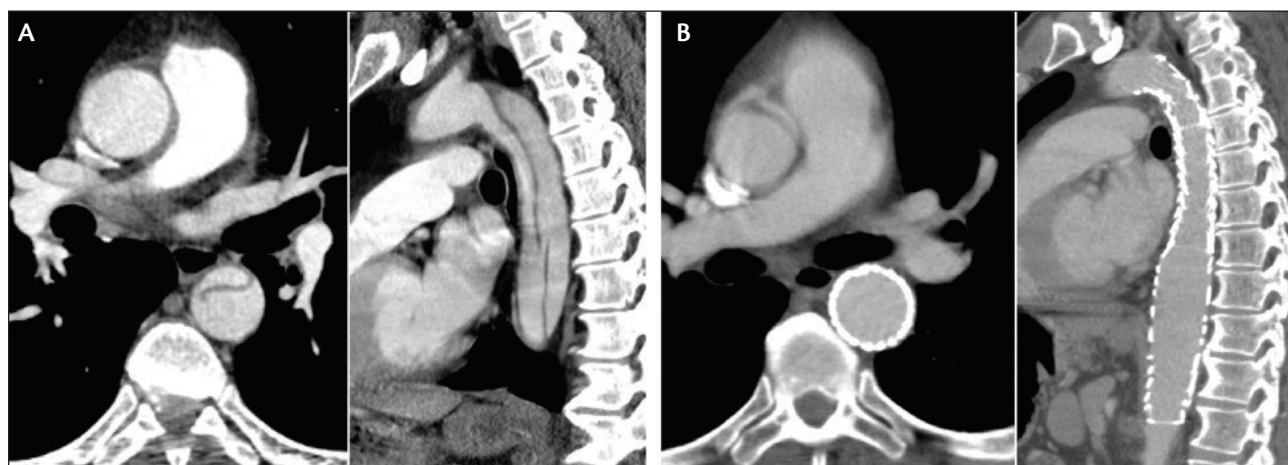


Figure 3. A 75-year-old man presented with an acute complicated TBAD with a large fenestration in the mid descending thoracic aorta (A). TEVAR resulted in exclusion of the diseased aorta, with excellent aortic remodeling seen at 6 months and no endoleak (B).

we see an improvement in TL diameter after the proximal device implantation and no sizeable fenestrations between the trailing end of the endograft and the celiac axis, we may elect not to cover the remaining thoracic aorta. Finally, IVUS can assess branch vessel compromise and determine whether any additional treatment is indicated in cases of static obstruction.

In order to avoid RTAD and new distal dissection, we do not routinely perform balloon expansion of the endograft in cases of a/sTBAD. In fact, we will often tolerate a markedly compressed appearance of the graft, with the expectation that, over time, the outward radial force of the nitinol stent graft will gradually expand the TL and hopefully obliterate the FL.

After device implantation and confirmation of a satisfactory result with angiography and IVUS, we turn our attention to hemostasis in the groin(s). After cinching and locking the sliding knots of the ABBOTT PERCLOSE PROGLIDE Suture-Mediated Vessel Closure System, we feed them through a section of tubing cut from the side arm of a sheath to fashion a Rumel-type tourniquet, which holds additional pressure on the arteriotomy and provides a conduit to deliver a small aliquot of thrombin directly to the arterial wall to help achieve hemostasis. We have previously described this technique and find it very useful to prevent troublesome oozing or hematoma formation.⁸ With careful attention to meticulous technique during initial femoral access and this closure strategy, we are able to perform an entirely percutaneous operation in the vast majority of our TEVAR cases.

PERIOPERATIVE TECHNIQUES

Our perioperative management of a/sTBAD patients primarily revolves around preventing or treating spinal cord ischemia (SCI). We ask our anesthesiologist

colleagues to place a lumbar drain (LD) preoperatively in almost all cases, unless: (1) the patient has hostile back anatomy (multiple lumbar operations or fusions, infection in the area, etc.); (2) the patient is hemodynamically unstable due to rupture; (3) the duration or severity of end-organ malperfusion suggests that rapid TL expansion is of paramount importance; or (4) the drain has been attempted several times by a senior attending anesthesiologist without success. If the drain cannot be placed, we generally follow these patients expectantly. However, a LD may need to be placed postoperatively as an attempt to rescue a case of postoperative SCI.

Once a LD is in place, management of cerebrospinal fluid (CSF) drainage proceeds according to our previously published protocols.⁹ In essence, this involves draining up to 15 mL/h of CSF in order to maintain CSF pressure < 10 mm Hg in a neurologically intact patient or draining an unlimited amount of CSF in order to maintain a CSF pressure < 5 mm Hg in a patient with SCI. Transfusion, supplemental oxygenation, and the administration of pressors or inotropes are also used as needed to optimize spinal cord perfusion pressure.

POSTOPERATIVE ISSUES

If no neurologic deficits are present, the LD is typically clamped on the morning of the first postoperative day and removed on the second postoperative day. Patients are usually seen in the clinic for follow-up with a postoperative CTA at 4 weeks. After that, they are seen at 6 and 12 months for a surveillance CTA and yearly thereafter (Figure 3).

CONCLUSION

Management of patients with a/sTBAD remains a challenge. Application of TEVAR as the treatment of choice

for patients with complicated a/sTBAD reflects a significant paradigm shift in the last decade. There is an expanding role for TEVAR in patients with uncomplicated a/sTBAD with high-risk features, but additional studies are required to further define optimal patient selection and treatment strategies in this cohort. Our strategies, as previously detailed, have helped us to achieve favorable outcomes in the endovascular treatment of a/sTBAD. ■

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