

Initial Experience With the GORE® TAG® Thoracic Branch Endoprosthesis*

A potential new option to address the current therapeutic limitations for Zone 2 aneurysms.

BY MICHAEL D. DAKE, MD

Historically, standard thoracic endovascular aneurysm repair (TEVAR) has been limited to anatomies with proximal necks of 15 mm to 20 mm. Unfortunately, many patients who may benefit from endovascular treatment with disease in the proximal segment of the descending thoracic aorta may not have the required proximal neck.

In order to gain the additional neck length needed for successful repair, the left subclavian artery is typically covered during TEVAR. This coverage has been associated with perioperative stroke¹ and spinal cord ischemia.² To aid in mitigating these problems, the Left Subclavian Artery (LSA) can be revascularized through left subclavian bypass or transposition; however, these methods require a surgical component to the procedure. The GORE® TAG® Thoracic Branch Endoprosthesis (Figure 1), which is currently undergoing a feasibility study in the United States, offers a complete endovascular solution for aneurysms that involve the proximal descending thoracic aorta.

This article discusses the current investigational experience with the GORE TAG Thoracic Branch Device and highlights its unique potential to treat this challenging anatomy.

DEVICE OVERVIEW AND IMPLANTATION TECHNIQUE

The GORE TAG Thoracic Branch Device has an Aortic Component with an internal portal that allows insertion, seal, and fixation of the Side Branch Component, and an optional Aortic Extender for proximal extension if necessary. An additional investigational accessory used in conjunction with the GORE TAG Thoracic Branch Device is the GORE® DrySeal Side Branch Introducer Sheath.

The Aortic Component comes in device diameters of 21 mm to 53 mm, allowing an aortic treatment range of



Figure 1. The GORE TAG Thoracic Branch Endoprosthesis system.

16 mm to 48 mm. The device features sealing cuffs on both ends and a partially uncovered stent on the proximal end to aid in wall apposition.

The Side Branch Component took several years to develop to meet the many demands of the aortic arch in terms of movement, translation, and cardiac pulsation. It is covered with the CBAS® Heparin Surface, a covalently bound heparin designed for thromboresistance. The Side Branch Component was designed with three distinct segments: the branch vessel, the middle tapered, and portal segments. The branch vessel segment is deployed into the perfused side branch vessel and is designed for optimal circumferential seal. The portal segment docks within the Aortic Component

and has three anchors to prevent any slippage or migration. The middle tapered segment is flexible, allowing the Side Branch Component to accommodate arch movement.

The Aortic Component is delivered over both a side branch wire and main aortic wire. To improve the ease of aligning the device with the branch vessel, the unique delivery system features a pre-cannulated side branch wire.

There are two different portal diameters that accommodate a wide range of Side Branch Components to create numerous possible device configurations. The Side Branch Component is available in 8 mm to 20 mm diameters with a treatment range of 6 mm to 18 mm. To implant the GORE TAG Thoracic Branch Device, the guidewires are first inserted into the aorta and branch vessel. The Aortic Component is then introduced over both guidewires into position within the arch. After deployment of the Aortic Component, the GORE DrySeal Side Branch Introducer Sheath is advanced through the Aortic Component. The dilator is removed, and the Side Branch Component is advanced and deployed.

OVERVIEW OF THE FEASIBILITY STUDY

This nonrandomized, multicenter, prospective feasibility study is being conducted at six clinical investigative sites in the United States with the objective of assessing the feasibility of the GORE TAG Thoracic Branch Device. A minimum of 20 and a maximum of 40 subjects will be enrolled into the study. Enrolled subjects will be followed after the initial treatment for five years or until termination of the trial. The primary objective of the study is to assess the feasibility of the use of the GORE TAG Thoracic Branch Device to treat aneurysms involving the proximal descending thoracic aorta that require placement of the proximal extent of the aortic stent-graft in Zone 2 (LSA) (Figure 2). Dissection and trauma patients are excluded from the current study.

The primary endpoints of the study are successful access and deployment of the GORE TAG Thoracic Branch Device and procedural side branch patency assessed by angiography at the conclusion of the endovascular procedure. The secondary endpoints include one-month side branch primary patency and one-month device-related endoleaks, both assessed by an independent core lab.

The next phase of the study will assess the GORE TAG Thoracic Branch Device for the treatment of aneurysms in the aortic arch that require placement of the proximal extent of the device in Zone 0 (Brachiocephalic) and Zone 1 (Left Common Carotid). This study was approved

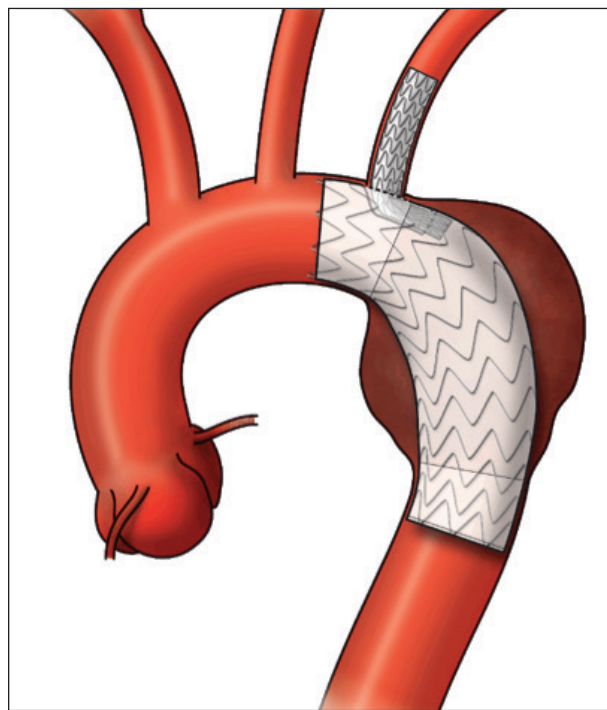


Figure 2. The GORE TAG Thoracic Branch Endoprosthesis placed in Zone 2 of the thoracic aorta.

as an Early Feasibility study in May 2014. The primary and secondary endpoints for the Zone 0/1 clinical trial are the same as Zone 2. Finally, the same six sites from the Zone 2 trial will participate in the Zone 0/1 trial, with patient follow-up continuing to five years.

CASE STUDY

An 84-year-old man presented with a dumbbell-shaped aneurysm that was initially diagnosed by a chest radiograph (Figure 3). The proximal lobe of the aneurysm had a maximum diameter of 48 mm, and the diameter of the distal component was 68 mm. Treatment with a traditional Conformable GORE® TAG® Device would require coverage of the left subclavian artery due to the lack of proximal neck distal to the left subclavian artery. By using the GORE TAG Thoracic Branch Device, the LSA remains perfused while treating the aneurysm.

Wires were placed in the ascending aorta and into the LSA. The Aortic Component was tracked into place, and the device was then torqued to ensure the portal was properly aligned with the LSA ostium. After achieving the desired alignment, the Aortic Component was deployed. The GORE DrySeal Side Branch Introducer Sheath was advanced over the wire, and tracked easily through the tortuous anatomy. The Side Branch Component was advanced through this

CASE IMAGES

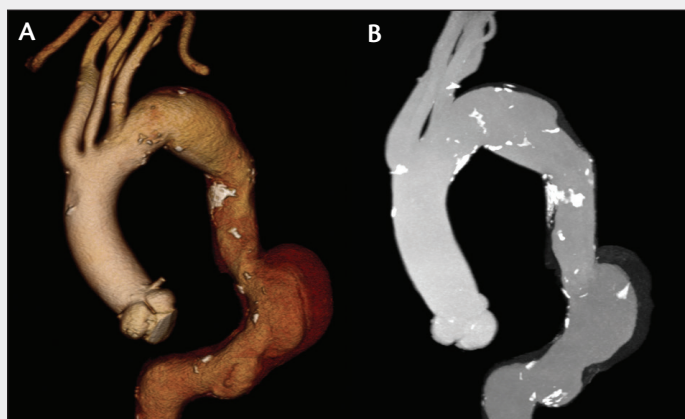


Figure 3. A 3-D (A) and 2-D (B) preoperative CT.

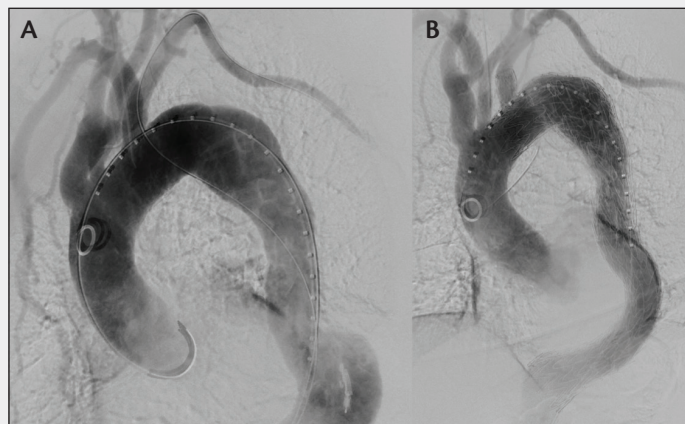


Figure 4. An initial procedural aortogram of the patient's anatomy (A) and a final aortogram of the device showing successful exclusion of the aneurysm (B).

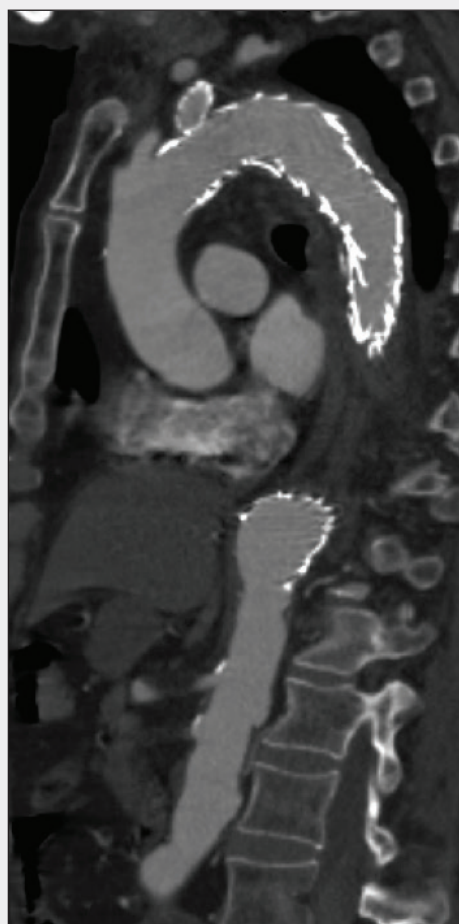


Figure 6. Postoperative CT scan.

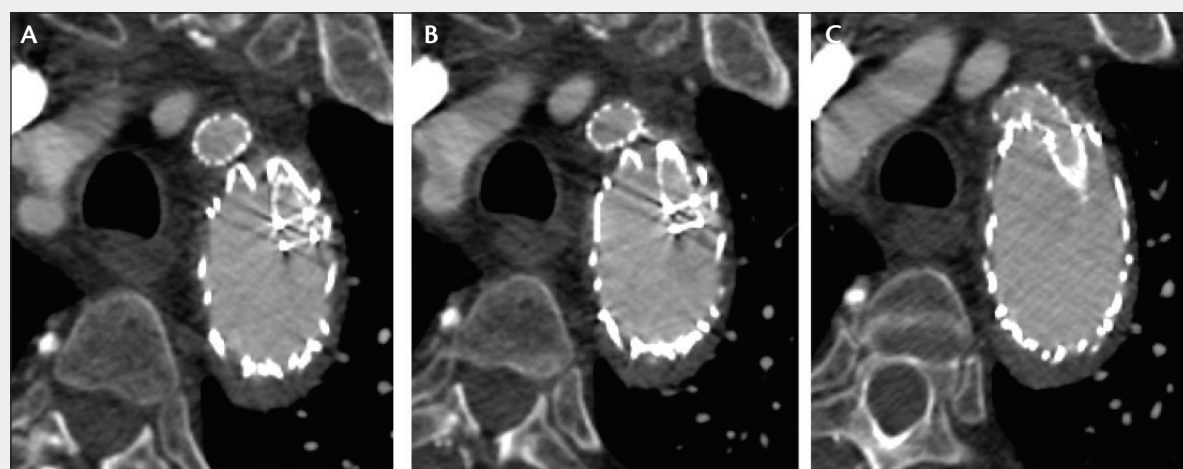


Figure 5. Postoperative CT axial slices of the GORE TAG Thoracic Branch Device focusing on the side branch.

sheath, the sheath was withdrawn, and the Side Branch Component was positioned in line with the portal, and deployed. Because the total treatment length was 27 cm, the traditional Conformable GORE TAG Device was implanted to extend coverage distally. Figure 4 shows an initial aortagram of the patient anatomy and a final aortagram after device deployments, showing successful exclusion of the aneurysm. At one month, CT follow-up showed a patent Side Branch perfusing the LSA and thrombosis of the aneurysm sac around the distal device (Figures 5 and 6).

CONCLUSION

The GORE TAG Thoracic Branch Device has potential to provide an entirely endovascular approach to Zone 2 aneurysms, which has previously been an anatomical presentation necessitating surgical involvement. Anticipated application of the technology for other Zone 2 patholo-

gies (e.g., dissection, trauma) and more proximal Zone 1 and 0 aortic disease awaits further clinical trial outcomes and FDA guidance. ■

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2. Buth J, Harris PL, Hobo R, et al. Neurologic complications associated with endovascular repair of thoracic aortic pathology: incidence and risk factors. a study from the European collaborators on stent/graft techniques for aortic aneurysm repair (EUROSTAR) registry. *J Vasc Surg.* 2007;46:1103-1110.