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Thoracic Branch Endoprosthesis: Early Case Experience and the Clinical Trial

An evaluation of the device's capabilities and early clinical experience.

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Since the introduction of thoracic endovascular aortic repair (TEVAR) for the treatment of aortic aneurysms more than 20 years ago, indications have expanded and it is now extensively applied to successfully treat a variety of conditions involving the thoracic aorta. Current use of a total endovascular approach, however, is limited to pathologies confined to the descending aorta due to the presence of critical branch vessels in the aortic arch. Unfortunately, up to 40% of thoracic aortic aneurysms extend into the aortic arch, resulting in a significant number of patients who may not be eligible for a completely endovascular repair.

Branched endografts for aortic arch pathology were initially investigated in the form of homemade prototypes in 1999[1] and have subsequently been studied using both custom-made devices and devices intended for eventual commercial use that are only available for investigational use in the United States at this time.

The GORE® TAG® Thoracic Branch Endoprosthesis* (TBE) is a novel, single-branch stent graft designed and initially studied for the treatment of thoracic aortic aneurysms with an intended proximal landing in zone 2, with the single branch extending into the left subclavian artery (LSA). Based on promising preliminary results observed in the zone 2 study,[2] the application of the device was expanded and studied to target pathologies involving zones 0 and 1, with the branch extending into the brachiocephalic artery or left common carotid artery (LCCA), respectively.

DEVICE DETAILS

The TBE is a modular system, consisting of two key components intended for off-the-shelf use—a main aortic component and a side branch component (Figure 1). The system also includes an optional aortic extender implant and an additional optional accessory, referred to as the GORE® DrySeal Side Branch Introducer Sheath.* The

Figure 1. Assembled aortic and side branch components of GORE® TAG® Thoracic Branch Endoprosthesis.

implant components are made of a nitinol-based stent frame with an expanded polytetrafluoroethylene (ePTFE) graft.

The main aortic component is offered from 10 to 20 cm in length, and it features sealing cuffs on both ends and proximal bare apices which aid in generating a circumferential seal. A unique characteristic of the main aortic component is the integrated inner portal that allows insertion, seal, and anchoring of the modular side branch component. The portal is oriented in a retrograde fashion so that delivery of the side branch is performed through the same femoral artery access used for the main component.

The side branch component is a tapered nitinol-based ePTFE stent graft. The luminal surface of the side branch component features a covalently bound heparin coating

*Caution: Investigational device. Limited by United States law to investigational use.

Figure 2. Distal end of the aortic component delivery system with a removable guidewire tube to facilitate guidewire passage through the internal portal. The device is advanced in the aorta over the guidewire exiting the end hole and the second wire placed within the target branch artery.

(CBAS Heparin Surface), for thromboresistance purposes. There are three distinct sections in the side branch component—the leading branch vessel segment, the middle tapered segment, and the trailing internal portal segment. The leading 15 mm branch vessel segment is designed to provide a circumferential seal in the branch vessel. The middle tapered segment is 20 mm long. The trailing 25 mm constitutes the internal portal segment, which provides a seal at the main aortic component portal and features three anchoring apices. The optional aortic extender is similar to the main aortic component without the portal and includes bare apices on the distal end. Each implant component is available in various sizes, offering a variety of possible combinations to accommodate patient anatomies.

PERFORMING THE PROCEDURE

Treatment in zone 2 can be completed without any adjunctive surgical procedure. The device is delivered through a transfemoral route. First, guidewires are inserted into the aorta and the branch vessel. Depending on the individual arch anatomy and physician preference, through-and-through (brachial-to-femoral) guidewire access may also be used to facilitate the delivery of the side branch. The main aortic component is then introduced over both guidewires. A removable guidewire tube is provided to aid passage of the guidewire through the pre-cannulated internal portal (Figure 2). The device is advanced into the proximal descending segment, where care is taken to remove any crossing of the guidewires by twisting the delivery catheter to undo any wire wrap. Then, the device is positioned within the arch and deployed. After deployment of the aortic component, the delivery system is withdrawn. The GORE® DrySeal Side Branch Introducer Sheath and dilator are then advanced over the branch guidewire, through the portal of the aortic component and into the target branch artery. The dilator is then removed and the side branch component is advanced through the sheath to the target branch artery. Once the device is properly positioned within the branch artery, the sheath is withdrawn into the aorta and the self-expanding side branch stent graft is deployed. Treatments intended to land in zones 0-1 require a first stage surgical revascularization procedure of the LCCA and/or the LSA. A variety of strategies can be used, depending on the segment treated and the specific anatomy of the patient, including:

- LCCA to LSA bypass
- LSA and LCCA double transpositions
- LCCA transposition with LSA bypass
- Right common carotid artery (RCCA) to LCCA bypass with LSA transposition
- RCCA to LSA bypass with reimplantation of the LCCA

Suture ligation or coiling is required as well to prevent retrograde type II branch endoleaks.

EARLY OUTCOMES

Two separate feasibility and early feasibility investigational device exemption studies of the device system have completed enrollment for the treatment of aortic aneurysms in zone 2 and zone 0/1, respectively.

TABLE 1. LESION CHARACTERISTICS

	Zone 2	Zone 0/1
Number of Patients	31	9
Type of Aneurysm		
Fusiform	12	2
Saccular	19	7
Maximum Aneurysm Diameter (mm)*		
Mean (Standard Deviation)	54.8 (10.9)	63.8 (7.8)†
Range	39.7–77	54–75.5†
Total Treatment Length (cm)*		
Mean (Standard Deviation)	17.3 (8.2)	19.7 (4.7)†
Range	10–32.7	15–26.5†

*As measured for case planning; †N=8

TABLE 2. PROCEDURAL DETAILS

	Zone 2	Zone 0/1
Deployment Successful	100%	100%
Procedural Survival	100%	100%
Side Branch Patent at End of Procedure	100%	100%
Procedure Time (min)		
Mean (Standard Deviation)	204.5 (111.6)	216.1 (89.5)
Range	85–560	95–378
Length of Stay (days)		
Mean (Standard Deviation)	5.1 (4.2)	14.8 (13.2)
Range	1–19	3–43

Short-term results from both TBE feasibility trials were recently published.[2] In total, 40 patients were treated with the device—eight patients with a proximal landing zone in Ishimaru zone 0, one patient in zone 1, and 31 patients in zone 2. Lesion characteristics are listed in Table 1. The primary endpoints of 1) successful access and deployment of the device and 2) primary patency of the side branch stent graft (assessed by angiography after the procedure) were achieved in 100% of patients (Table 2). In addition, primary patency of the side branch at 1 and 6 months has also been evaluated, and only one case of side branch thrombosis with loss of patency at 6 months has been observed in the zone 2 study.

COMPLICATIONS

Potential complications of the procedure include those associated with TEVAR: access site complications, endoleaks, retrograde aortic dissection, aortic rupture, paraplegia, stroke, stent fracture/kinking/migration. Complications involving the side branch component, such as occlusion, fracture, or kinking, are also possible.

Seven patients were noted to have at least one procedural/post-procedural endoleak in the zone 2 study. Most of these had resolved spontaneously by the time of the 1-month CT imaging. In one case, the endoleak was diagnosed as a type III endoleak identified between the side branch and the aortic component on the CT scan at

CASE PRESENTATION

An 81-year-old woman with a history of hypertension and arthritis presented with a growing, asymptomatic, 65-mm fusiform aneurysm (Figure 3A). This aneurysm developed distal to the origin of the LSA and encompassed the proximal two-thirds of the descending thoracic aorta. The left vertebral artery was dominant. Its configuration suggested that endovascular repair required Ishimaru zone 2 coverage for optimal proximal seal.

The patient was approached with right femoral access with the intent to achieve through-and-through access via the left brachial artery. A distal-to-proximal deployment of two overlapping Conformable GORE TAG Devices and a proximal TBE was intended. An occluded proximal LSA was identified (Figure 3B), suggesting that side branch delivery may be difficult. To facilitate this, a large collateral vessel was cannulated and a COOK® ROSEN wire guide placed into the collateral vessel (Figure 3C). To avoid the difficulty with wire wrap, which would potentially jeopardize LSA access, a GORE DrySeal Introducer Sheath was advanced into the mid-descending aorta. The TBE was then advanced into the mid-arch aorta using an aortic COOK® LUNDERQUIST® extra-stiff wire guide, and with the side branch port precannulated with the COOK ROSEN wire guide. The device was deployed accurately in zone 2 (Figure 3D). The side branch device was then advanced through the side branch portal and deployed proximal to the first branch vessel from the LSA (Figure 3E). Completion angiography revealed patency of the side branch and exclusion of the aneurysm sac (Figure 3F). Notice that the nonorthogonal position reveals that the side branch can exit and assume a nonvertical position (Figure 3G).

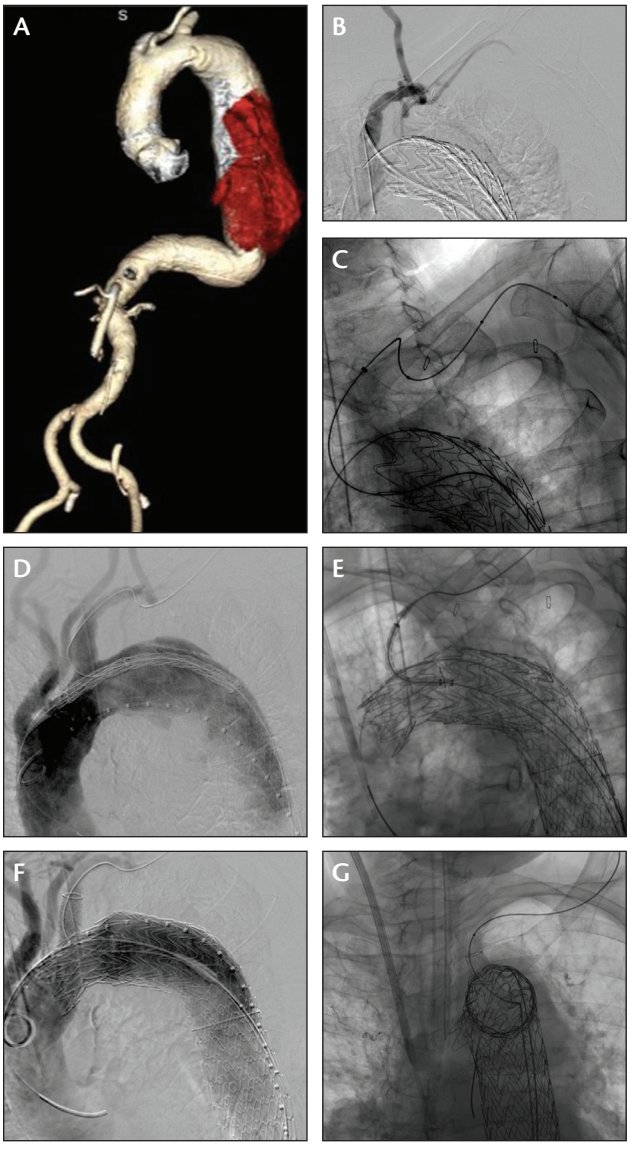

Figure 3. Procedural images depicting deployment of the GORE® TAG® Thoracic Branch Endoprosthesis.

1 month, but it was not evident on subsequent follow-up imaging. Two type II endoleaks, however, were still present at 6 months without associated aneurysmal enlargement. There have been no endoleaks in the nine patients treated in zone 0/1.

As with any procedure involving the thoracic aorta, there is the risk for neurologic complications secondary to either embolization or obstruction/occlusion of the side branch stent graft. In the first series of 40 patients, there were three cases of periprocedural stroke–one case in zone 2 and two cases in zone 0. In addition, one zone 2 patient experienced spontaneous occlusion of the LSA branch graft, where the graft was patent on the CT scan at 1 month, but it was occluded on the 6-month evaluation. Because the patient was asymptomatic, revascularization was not performed. There have been no instances of spinal cord ischemia. No aortic ruptures or retrograde dissection occurred.

The promising data from the two feasibility studies have provided support to initiate a pivotal trial with larger patient cohorts. It is anticipated that 40 investigative sites in the United States will participate in enrolling a minimum of 135 patients with aortic arch aneurysms, requiring placement of the proximal extent of the aortic stent graft in zone 0, 1, or 2. In addition to this aneurysm cohort, separate arms of the trial will include enrollment of up to an additional 300 patients with other lesions, including dissection and traumatic injuries, involving zones 0, 1, and 2. Thus, the pivotal clinical trial design has the potential to study a maximum of 435 patients with 5-year follow-up.

The pivotal trial will assess a composite of events through 1 year, including device technical success and the absence of device, procedure, and aortic-related adverse events. As of this writing, a small number of patients have been enrolled in the pivotal trial at several sites. Full participation at the 40 investigative centers is anticipated by spring 2017.

CONCLUSIONS

The TBE is a single-branch, modular stent graft system designed for use in the aortic arch, which allows a novel approach for treating arch pathologies while avoiding or reducing the use of adjunctive open surgical procedures. Preliminary data from two feasibility studies have shown promising short-term results and a low incidence of complications relative to surgical repair. A pivotal trial with larger patient cohorts is underway. The pivotal trial will include the study of additional pathologies (e.g., dissection, trauma with involvement of zones 0, 1, and 2) and will provide further insight regarding long-term durability of the device. At the time of writing, the device is only available for investigational use. ■

1. Inoue K, Hosokawa H, Iwase T, et al. Aortic arch reconstruction by tranluminally placed endovascular branched stent graft. Circulation. 1999;100:II316–321.
2. Patel HJ, Dake MD, Bavaria JE, et al. Branched endovascular therapy of the distal aortic arch: preliminary results of the feasibility multicenter trial of the Gore thoracic branch endoprosthesis. Ann Thorac Surg. 2016;102:1190–1198.

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