Initial Experience With the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis

An overview of device characteristics and case reports from the first three worldwide implantation procedures.

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Endovascular aortic aneurysm repair (EVAR) has become the first choice of treatment in patients with abdominal aortic aneurysms (AAAs) and suitable anatomy. Approximately 40% of the patients do not meet the anatomical requirements for EVAR because of inadequate necks or involvement of side branches. In these patients, innovative techniques to incorporate the visceral arteries have expanded the indications of EVAR using parallel, fenestrated, and branched stent-grafts. Large clinical series and systematic reviews have shown high technical success and lower morbidity and mortality rates compared to historical open surgical repair.[1-5]

Current challenges with the techniques of visceral endovascular incorporation are the limited physician access to fenestrated and branched stent-grafts, excessive time delay required for patient-specific customizations, and lack of a bridging stent-graft that is specially designed to target the visceral arteries. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE) introduces a novel concept, which is based on the GORE® EXCLUDER® AAA Device platform using a nitinol stent frame and conformable ePTFE technology. The device is intended to be used with the balloon-expandable GORE® VIABAHN® BX Endoprosthesis or the self-expandable GORE® VIABAHN® Endoprosthesis covered stent-grafts, offering two alternative options to tailor treatment to the patient's anatomy. It is currently being investigated in early feasibility clinical trials intended for endovascular repair of thoracoabdominal and pararenal aortic aneurysms. The first implantation was performed by Dr. Pierre Galvagni Silveira and colleagues at the Universidade Federal de Santa Catarina in Florianopolis, Brazil, and the first United States implantation was recently performed by Dr. Gustavo Oderich and the Mayo Clinic team in Rochester, Minnesota. This preliminary report summarizes the device characteristics and the initial clinical experience with the first three patients treated worldwide.

DEVICE DESCRIPTION

The TAMBE is an off-the-shelf, modular, multi-component system (Figure 1) composed of a proximal multibranched aortic component, a distal bifurcated component, and iliac limb extensions. The preferred side branch component is a specially designed balloon-expandable covered stent-graft, the GORE VIABAHN BX Endoprosthesis. Unique characteristics of the GORE VIABAHN BX Endoprosthesis bridging stent-graft are that it couples the radial force, reliable deployment, and relative low profile (7–8 F) of a balloon-expandable stent-graft with flexibility comparable to a self-expandable stent-graft. The side branch components have CBAS® Heparin Surface.

The TAMBE has been designed with retrograde renal portals. The first three clinical cases that are described herein used two retrograde renal portals and two antegrade portals for the celiac axis and superior mesenteric artery (SMA). Device dimensions include proximal diameters of 26, 31, and 37 mm; length of 215 mm; and distal diameter of 20 mm. An alternate configuration is being evaluated, utilizing four antegrade portals. This antegrade configuration is not yet approved for use in existing clinical studies. A 22-F transfemoral introducer is required for the aortic device, and a 12-F brachial or axillary artery introducer is needed for access into the antegrade portals.

Figure 1. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis with two antegrade portals for the celiac axis and SMA and two retrograde portals for the renal arteries. The portals are bridged to the target visceral arteries using a GORE® VIABAHN® BX Endoprosthesis, which is also shown.

The aortic component allows for placement of through-and-through preloaded guidewires, eliminating the need to catheterize the portal to access the target vessel. To facilitate placement of the guidewires and prevent guidewire wrapping within the aorta, a specially designed triple-lumen catheter is inserted from the brachial approach and exteriorized via the femoral access.

ANATOMICAL FEASIBILITY

Anatomical feasibility of the TAMBE is based on predictable anatomy of the visceral arteries as previously reported by Mendes and colleagues.[6] It is anticipated that > 80% of patients with complex abdominal or thoracoabdominal aortic aneurysms (TAAAs) will meet the requirement of vessel incorporation. Limitations precluding anatomical feasibility include excessive angulation, unsuitable targets because of small diameter, occlusive disease or early bifurcation, and previous open or endovascular aortic repair with a short distance between the renal arteries and the aortic bifurcation.

TECHNIQUE

The initial experience with the TAMBE and a general approach to endovascular TAAA repair are outlined in the following sections. Variations in this technique reflect physician preference, center experience, and patient anatomy.

Perioperative Management

Preventive measures for spinal cord injury have been adopted in most centers with larger clinical experience with endovascular TAAA repair. These measures have been applied to all patients undergoing endovascular TAAA repair with > 5 cm coverage above the celiac artery. At the Mayo Clinic, preventive measures have included permissive hypertension with target mean arterial pressure ≥ 80 mm Hg, routine prophylactic cerebrospinal fluid drainage, early lower limb reperfusion, neuromonitoring to adjust intraoperative cerebrospinal fluid pressure and mean arterial pressure goals, and staged repairs for extensive TAAAs.

Preadmission is considered in patients with chronic kidney disease and an estimated glomerular filtration rate < 60 mL/min and those of advanced age and very complex anatomy. Patients undergo gentle bowel preparation with intravenous hydration with bicarbonate infusion and oral acetylcysteine. Acetylsalicylic acid is started or continued prior to the operation. Perioperative antibiotics are administrated intravenously prior to incision and are redosed up to 24 hours after the procedure.

General Approach

The operation is performed under general endotracheal anesthesia with fixed imaging in a hybrid endovascular suite. Ideally, the option of fusion imaging facilitates branch catheterization and minimizes contrast use. Intraoperative blood salvage ("cell-saver") may be considered if difficulties or prolonged operating time are anticipated. The use of iodinated contrast is minimized using small hand injections and diluted contrast for aortography.

Patients are positioned supine with the imaging unit oriented from the head of the table. Arterial access is achieved via bilateral femoral and left brachial approaches. The brachial artery is accessed high in the axilla, unless the artery is small (< 4 mm), in which case, it can be accessed in the infraclavicular fossa. Percutaneous bilateral femoral access is used whenever possible, except for in patients with high femoral bifurcations or dense calcifications. The patient is systemically heparinized with an intravenous bolus of heparin (80–100 units/kg), which is administered immediately after femoral and brachial access are established. The activated clotting time is kept > 250 seconds and is rechecked every 30 minutes. A continuous drip of heparin (500–1,000 units/ hour) is also started, and diuresis is induced with intravenous mannitol and/or furosemide.

Device Deployment

There is variation in the deployment sequence of the TAMBE in the first three cases. Figures 2 through 4 reflect preferences used in the third TAMBE case, which was performed at the Mayo Clinic, to optimize lower ischemia reperfusion. After through-and-through access is established (Figure 2A), the device is loaded in the three guidewires and advanced into position with the

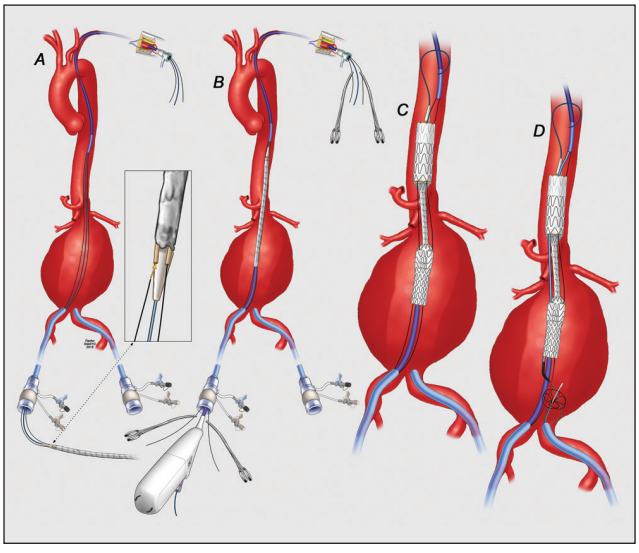

Figure 2. Procedure steps include placement of through-and-through preloaded wires (A), device positioning with antegrade portals above the celiac axis and SMA and retrograde portals below the renal arteries (B), partial deployment (C), and rerouting of guidewires to the left femoral access site using a snare (D).

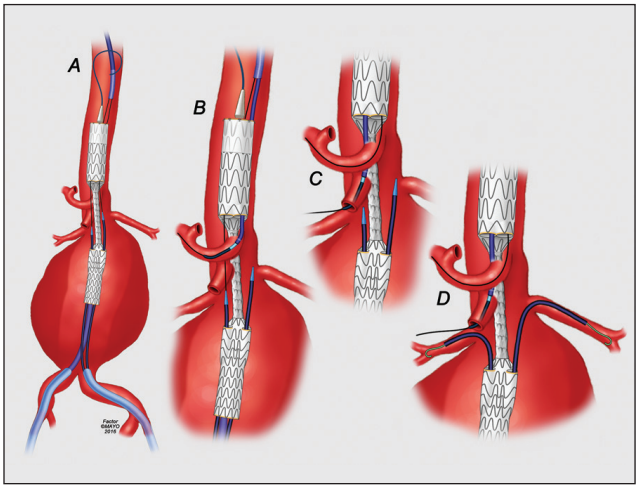

Figure 3. Placement of 7-F COOK® FLEXOR® ANSEL Guiding Sheaths into the renal portals (A) followed by selective catheterization of the celiac axis (B), SMA (C), and renal arteries (D).

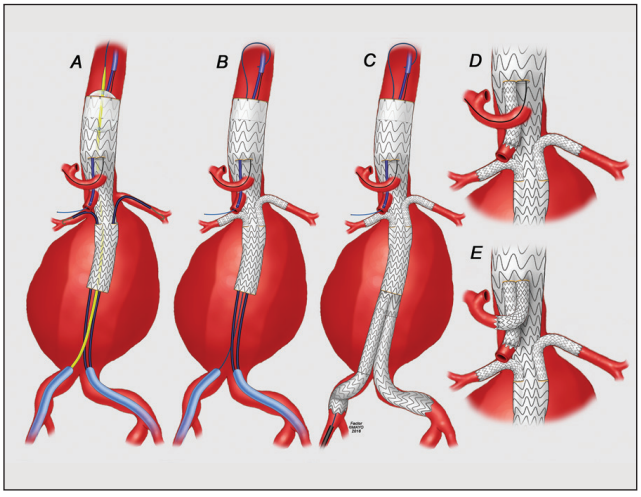

Figure 4. Dilatation of the proximal neck after device deployment (A) followed by placement of renal stent-grafts (B) and bifurcated distal device and iliac limbs with restoration of lower limb perfusion (C). The procedure is completed by placing the SMA and celiac stent-grafts (D, E).

antegrade portals above the celiac and SMA and both renal portals approximately 2 to 3 cm below the renal arteries (Figure 2B). The device has a stepwise deployment system, which allows the top part of the device to be partially constrained and the mid-segment to be completely constrained, facilitating branch vessel catheterization (Figure 2C). Catheters are advanced sequentially from the brachial access via each of the preloaded 0.014-inch guidewires and used to reroute the wires to the left femoral approach using a snare (Figure 2D).

Using the preloaded guidewires, 7-F COOK® FLEXOR® ANSEL Guiding Sheaths are advanced into the renal portals (Figure 3A). An 8-F COOK® FLEXOR® RAABE Guiding Sheath is advanced from the left brachial approach into the celiac axis portal (Figure 3B). The celiac axis is catheterized using a "buddy" catheter and TERUMO RADIFOCUS® GLIDEWIRE® ADVANTAGE Guidewire, which is exchanged for a 0.018-inch stiff guidewire that is placed within the distal splenic artery. The sheath is withdrawn over the 0.018-inch wire and reintroduced over the preloaded SMA guidewire into the SMA portal (Figure 3C). The SMA is catheterized, and an 8-F COOK FLEXOR RAABE Guiding Sheath is advanced over a 0.035-inch COOK® AMPLATZ Fixed Core Wire Guide into the SMA. Both preloaded 0.014-inch through-and-through guidewires are withdrawn via the renal sheaths to allow space within the 12-F brachial sheath. Sequential renal catheterization is performed via the femoral approach (Figure 3D), and the 7-F COOK FLEXOR ANSEL Guiding Sheaths are advanced into each of the renal arteries over 0.035-inch COOK® ROSEN Wire Guides.

The TAMBE is completely deployed once all vessels are secured. This step is optional, given that the device can be kept constrained and the side branches can be deployed even prior to completely opening the mid-segment. However, to minimize lower extremity ischemia time and to allow immediate balloon dilatation of the proximal landing zone, the device can also be completely deployed as depicted in Figure 4A. A COOK® CODA® Balloon Catheter is used to dilate the proximal sealing zone and the visceral segment of the aorta. The renal GORE VIABAHN BX Endoprosthesis stent-grafts are deployed first (Figure 4B), followed by placement of the bifurcated distal device and iliac limbs (Figure 4C). Flow is restored to both lower extremities while femoral guidewire access is maintained using a percutaneous technique. The procedure is completed by placing the SMA and celiac GORE VIABAHN BX Endoprosthesis stent-grafts in a sequential fashion (Figure 4D and 4E), followed by completion angiography.

EARLY FEASIBILITY STUDIES

The early feasibility studies aim to evaluate the first-in-human experience with the TAMBE in 10 patients enrolled in up to six United States centers and one non–United States center. For the United States early feasibility study, the National Principal Investigator for the early feasibility study is Dr. Michel Makaroun from the University of Pittsburgh Medical Center. Inclusion criteria for the study are restrictive to select patients who fit ideal anatomical conditions for branch vessel incorporation, without excessive tortuosity, angulation, occlusive disease, or excessive aortic debris. Anatomical requirements are aneurysm involvement of the renal and mesenteric arteries that is not suitable for EVAR using standard devices, presence of parallel-walled sealing zones in the distal thoracic and in the common iliac arteries, four-vessel visceral branch anatomy with minimum diameter of 4 mm, no early bifurcation or significant occlusive disease,

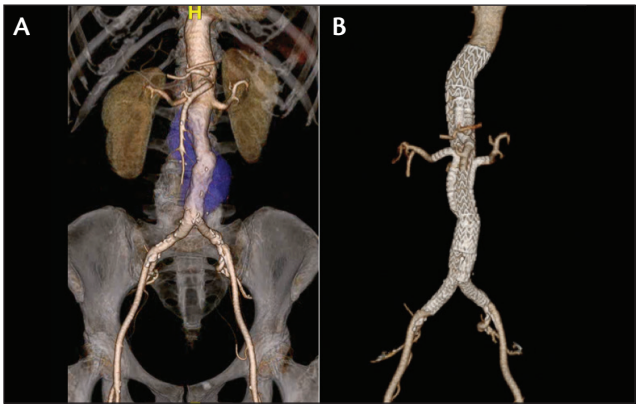

Figure 5. The first worldwide case performed in Florianopolis, Brazil, by Dr. Pierre Galvagni and colleagues at the Universidade Federal de Santa Catarina. Preoperative (A) and postoperative (B) CTA demonstrating widely patent stent-grafts and no endoleak at 1 year.

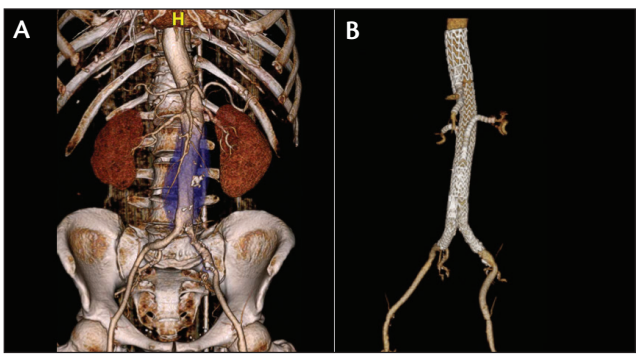

Figure 6. The second worldwide case performed in Florianopolis, Brazil, by Dr. Pierre Galvagni and colleagues at the Universidade Federal de Santa Catarina. Preoperative (A) and postoperative (B) CTA demonstrating widely patent stent-grafts and no endoleak at 1 year.

absence of significant atheromatous debris within the aorta, and no previous open repair or EVAR.

Preliminary Early Results

Three patients have been successfully implanted with 100% technical success and no branch vessel complications, endoleaks, ruptures, or conversions. The following sections provide a brief description of these first three cases.

Cases 1 and 2

The first and second TAMBE implants were performed in Florianopolis, Brazil, by Dr. Pierre Galvagni Silveira and colleagues at the Universidade Federal de Santa Catarina. The first patient was a 68-year-old woman with a 5.2-cm complex AAA (Figure 5), and the second was a 56-year-old man with a 5.6-cm complex AAA (Figure 6). The first patient had a history of hypertension and chronic obstructive pulmonary disease, and the second had hypertension. Implantation of the TAMBE was completed with no technical problems in either patient, with widely patent branches and no postoperative complications. The patients were dismissed from the intensive care unit on the first day and from the hospital on the fourth and third postoperative days, respectively. The first patient developed an occlusion of the right common femoral artery access site early after dismissal, which required a 1-day readmission to the hospital for open surgical thrombectomy. Both patients completed 1-year follow-up with no other complications and had repeat computed tomographic angiography (CTA) studies, which demonstrated successful aneurysm exclusion with no endoleaks, no sac enlargement, and widely patent side stent-grafts.

Case 3

The third patient was a 79-year-old man with large 9-cm type IV TAAA. His medical history was notable for past smoking, hypertension, hyperlipidemia, ischemic cardiomyopathy, and moderate chronic obstructive pulmonary disease. CTA demonstrated a large 9-cm aneurysm with aortic irregularity starting at the level of the celiac axis (Figure 7). The patient underwent endovascular repair using the TAMBE and was dismissed home on postoperative day 3 with no complications.

DISCUSSION

The TAMBE is currently under investigation and offers the potential benefits of an off-the-shelf stent-graft with wide anatomical applicability and ease of technical implantation using conformable technology and a specifically designed bridging stent-graft. The retrograde renal portal offers potential advantages in select patients with an up-going renal artery configuration or in those with a narrow aortic segment and limited space between the SMA and renal origins to fit an all-antegrade design. Off-the-shelf availability will decrease or eliminate any time delay in treating a large aneurysm, which currently averages a minimum of 8 weeks with patient-specific stent-grafts. Finally, the versatility of multiple branches, preloaded guidewires, constrained mid-segment, and stepwise deployment system all facilitate procedural steps, decreasing the need for a high degree of precision during device implantation, which is a requirement for fenestrated stent-grafts.[3]

The TAMBE is the first TAAA device design to be developed with a specific bridging stent-graft. Characteristics of this stent-graft include its balloon-expandable platform with the benefits of reliable deployment and radial force needed to treat visceral targets, coupled with conformability and flexibility, which is comparable to what can be achieved with a self-expandable platform. Results of this stent-graft combination need to be compared with traditional visceral incorporation techniques using either fenestrations or

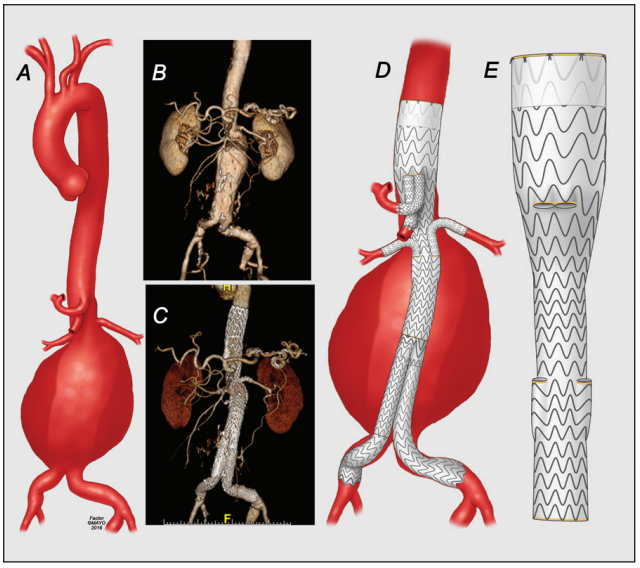

Figure 7. The third worldwide and first United States case performed at the Mayo Clinic in Rochester, Minnesota, by Dr. Gustavo Oderich and colleagues. Artist depiction shows the aneurysm (A) and preoperative (B) and postoperative (C) CTA. Artist depiction of the treated aneurysm (D) and the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (E).

branches. Previous studies have shown that occlusion rates are exceptionally low for renal fenestrations (2%–5% at 5 years), but some disadvantages are the risk of type I or III endoleaks originating from the fenestration attachment or even branch disconnection, particularly when fenestrations are to target vessels that originate from large aortic segments.[1-5] Unfortunately, there is no consensus on the ideal stent-graft, and investigators have used a wide combination of self-expandable stent-grafts or balloon-expandable covered stent-grafts, with or without reinforcement with a self-expandable bare-metal stent-graft, limiting future comparisons. Although the GORE VIABAHN BX Endoprosthesis has all the ideal characteristics that are needed to optimize patency and seal with the portals and target vessels, long-term data with larger clinical experiences are needed using retrograde designs for adequate comparisons with other fenestrated, branched, and parallel stent-graft techniques.

Simplification of the procedure steps is a critical area of improvement when dealing with complex EVAR cases. The TAMBE uses preloaded guidewire systems, which have been previously described with fenestrated and branched endografts. The guidewires eliminate the need to catheterize the portals prior to catheterization of the branch itself. Because the bridging stent-graft is balloon expandable and conforms, several of the steps needed with self-expandable stent-grafts (postdilatation and reinforcement with bare-metal stent-grafts) are eliminated. These improvements, which aim to simplify procedure steps, may help to significantly reduce procedure time and the deleterious consequences of prolonged lower extremity ischemia, including the risk of spinal cord injury and other systemic complications. Still, there are important limitations to the TAMBE, as with any other endovascular technique used to incorporate visceral branches. The most important limitations are inadequate renal artery anatomy because of small diameter, multiple accessory renal arteries, or early bifurcation; difficult access; and lack of adequate landing zones.

CONCLUSION

Techniques of branch vessel incorporation continue to evolve. The TAMBE offers a novel concept using ePTFE and conformable technology. Its use with the GORE VIABAHN BX Endoprosthesis stent-graft to target visceral arteries will greatly facilitate steps of the procedure. The experience accumulated in select centers during the early feasibility study allows for initial testing and proof of concept of this design with first-in-human application in order to evaluate device concept with respect to clinical safety and functionality. ■

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