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TRUST IS EARNED

An overview of clinical outcomes
and advanced treatment options for
endovascular aortic repair.

TRUST IS EARNED

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Trust is Earned: Insights From the 5,000 Patients Enrolled in GREAT

An overview of early data on the outcomes of this multicenter, prospective registry for all commercially available Gore aortic endografts.

BY ROSS MILNER, MD, FACS, AND DENNIS GABLE, MD, RVT, FACS

The Global Registry for Endovascular Aortic Treatment (GREAT) is the largest reported company-sponsored registry of commercial aortic endovascular products with more than 5,000 subjects enrolled and 10 years of follow-up planned. The GREAT methods have been previously published.¹ GREAT is an international, multicenter, prospective registry designed to capture data on all commercially available Gore aortic endografts, including the GORE® EXCLUDER® AAA Endoprosthesis, GORE® EXCLUDER® AAA Endoprosthesis featuring C3® Delivery System, GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), GORE® TAG® Thoracic Endoprosthesis, and Conformable GORE® TAG® Thoracic Endoprosthesis. The registry was approved to include both on-label and off-label use of any of these devices in all aortic pathologies.

The registry was designed to capture serious adverse events as defined as an event that results in: 1) death; or 2) deterioration in the health of the patient by either a life-threatening illness or injury, permanent impairment of a body structure or a body function, requiring inpatient hospitalization or prolongation of existing hospitalization, or a medical or surgical intervention to prevent life-threatening illness, injury, or permanent impairment to a body structure or a body function.² Subjects were enrolled from 114 sites in 13 different countries. Another aspect of GREAT is that there were minimal inclusion and exclusion criteria for enrollment into the database in order to capture real-world clinical practice. This article provides an overview of enrollment and a broad understanding of the current data.

ENROLLMENT DETAILS

Enrollment began in August 2010 and ended in October 2016, when the goal of more than 5,000 subjects was reached. The first subjects enrolled were from European sites and focused exclusively on the GORE EXCLUDER AAA Endoprosthesis featuring C3 Delivery System. Brazil was the next region to begin enrollment, followed by Australia and New Zealand, the United

States, and additional European sites. Final enrollment numbers by region were 193 subjects in Australia/New Zealand, 400 subjects in Brazil, 1,852 subjects from Europe, and 2,580 subjects from the United States (Figure 1).

Demographics of the entire cohort (Table 1) include 81.3% men and 18.7% women. Reported race was 85.6% white/Caucasian and 5.5% black/African American. The mean (standard deviation) age was 71.7 (10.4) years with a range of 18 to 98 years. Over 28 diverse pathologies were reported as the initial reason for treatment. Of those pathologies, 92.8% were treated for primary endovascular repair and the remaining were reinterventions on previous endovascular and open surgical procedures. Medical history reveals that the most common comorbidities across the entire cohort include hypertension (81.8%), hypercholesterolemia (61%), tobacco use (54.3%), coronary artery disease (37.4%), chronic obstructive pulmonary disease (24.1%), cardiac arrhythmia (21.1%), and any type of cancer (20.6%). Nearly 16% of the subjects had a previous aortic repair, with the majority being for an abdominal aortic

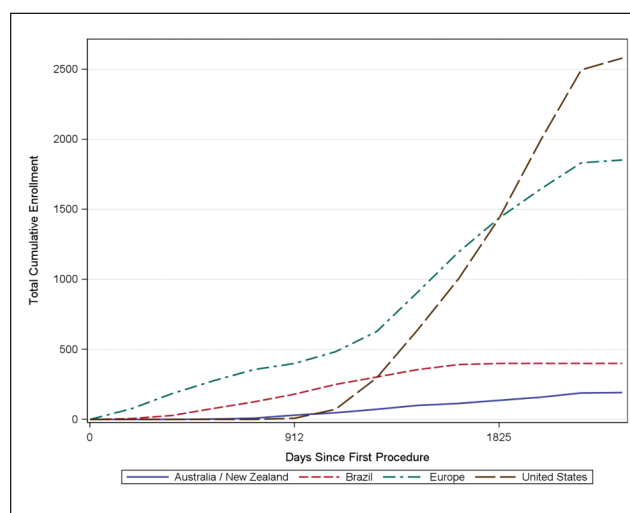


Figure 1. Global enrollment over time, by region.

TABLE 1. DEMOGRAPHICS

	All Sites
Number of Subjects Enrolled	5,025
Gender	
Male	81.3%
Female	18.7%
Race	
White or Caucasian	85.8%
Black or African American	5.5%
Asian/Oriental	0.9%
American Indian or Alaskan Native	0.4%
Middle Eastern	0.3%
Native Hawaiian or Other Pacific Islander	0.3%
Other	2.1%
Unknown	4.7%
Age (Years)	
Mean (Standard Deviation)	71.7 (10.4)
Median	73
Range	(18, 98)
BMI	
Mean (Standard Deviation)	27.6 (5.4)
Median	26.8
Range	(8.9, 64.6)

aneurysm, and 17.5% reported having a previous stent placement—primarily coronary stents.

The majority of the subjects underwent cut-down access (57.7%), but a large portion (49%) also reported percutaneous access (Table 2). Femoral artery access sites were reported in 98% of the subjects. Sites can report multiple access methods and anatomic location for any individual subject as needed. The procedural survival for the entire cohort is 99.8%. Although the standard of care for hospital stay differs among countries, the mean (standard deviation) hospital stay was 5.4 (7.5) days and a median of 3 days.

The GREAT protocol does not dictate a follow-up visit schedule, but rather recommends that sites adhere to their standard of care advised by the indications for use of each individual Gore aortic endograft. Typical endograft imaging is at 1 month, 6 months, and annually thereafter

TABLE 2. TREATMENT DATA

	All Sites
Number of Subjects Enrolled	5,025
Access Method	
Percutaneous	49%
Cut-down	57.7%
Surgical Conduit	2.3%
Endovascular Conduit	0.9%
Aortic Branch Vessel Procedure	
	17.1%
Access Site	
Femoral Artery	98%
Iliac Artery	2.4%
Infrarenal Aorta	0.4%
Brachial	3.2%
Other	1.5%
Procedure Survival	
	99.8%
Hospital Stay (Days)	
Mean (Standard Deviation)	5.4 (7.5)
Median	3
Range	(0, 156)

unless, at the discretion of the treating physician, it is required more frequently. Mean follow-up for the entire cohort as of November 2016 was 14.9 months, with 88.9% having at least one follow-up visit reported.

EARLY RESULTS FROM TWO AORTIC SEGMENT COHORTS

With a cohort of more than 5,000 subjects, there are many ways to look at the data. One way is by the segment of the aorta being treated. GREAT defined five aortic segments based on the pathology treated and the reported landing zone. The five segments are 1) ascending: includes all ascending pathology and other pathologies; 2) arch: includes aortic arch aneurysm, aortic arch aneurysm rupture, and other pathologies; 3) descending thoracic: includes descending thoracic aortic aneurysm, ruptures, and dissections along with aorto-esophageal fistula, aorto-bronchial fistula, traumatic aortic transection and dissection, as well as other pathologies; 4) thoracoabdominal: includes

TABLE 3. KEY OUTCOMES: DESCENDING THORACIC AORTA

	Procedure	1 Month	6 Months	1 Year	2 Years	Total (Procedure-2 Years)
Number of Subjects With Any Follow-Up*	834	830	551	387	195	834
Subjects With Any Event Below	17 (2%)	74 (8.9%)	51 (9.3%)	31 (8.0%)	13 (6.7%)	165 (19.8%)
Mortality	1 (0.1%)	27 (3.3%)	21 (3.8%)	18 (4.7%)	11 (5.6%)	78 (9.4%)
Stroke/TIA†	1 (0.1%)	8 (1.0%)	4 (0.7%)	3 (0.8%)	0 (0%)	15 (1.8%)
Paraplegia/Paraparesis/Spinal Cord Ischemia‡	4 (0.5%)	3 (0.4%)	1 (0.2%)	1 (0.3%)	0 (0%)	9 (1.1%)
Device-Related Reinterventions‡	2 (0.2%)	22 (2.7%)	21 (3.8%)	11 (2.8%)	1 (0.5%)	54 (6.5%)

*Subjects are counted in the denominator if they had any follow-up start of window; all subjects with initial procedure date are counted in Procedure and Total windows.

†Only those considered serious adverse events.

‡All reinterventions include any invasive or minimally invasive measure related to the initial aortic procedure performed at any time following the initial procedure; device-related reinterventions include any invasive or minimally invasive measure related to a deficiency of the device(s) implanted into the aorta performed at any time following the initial procedure.

TABLE 4. PRIMARY OBJECTIVE INCIDENCE RATES: DESCENDING THORACIC AORTA

	Procedure	1 Month	6 Months	1 Year	2 Years	Total (Procedure-2 Years)
Number of Subjects With Imaging and/or Event*	834	409	334	272	123	834
Type IA	2 (0.2%)	3 (0.7%)	1 (0.3%)	4 (1.5%)	1 (0.8%)	11 (1.3%)
Type IB	2 (0.2%)	6 (1.5%)	2 (0.6%)	4 (1.5%)	2 (1.6%)	15 (1.8%)
Type II	1 (0.1%)	4 (1%)	5 (1.5%)	1 (0.4%)	0 (0%)	11 (1.3%)
Type III	1 (0.1%)	2 (0.5%)	0 (0%)	0 (0%)	1 (0.8%)	4 (0.5%)
Type IV	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Subjects are counted in the denominator if they either had imaging reported in window and/or reported event; all subjects with initial procedure date are counted in Procedure and Total.

thoracoabdominal aortic aneurysm and/or rupture and other pathologies; and 5) abdominal: includes abdominal aortic aneurysm and rupture along with aorto-duodenal fistula, all iliac aneurysms, and other pathologies. This article will focus on early outcome results for the two largest cohorts treated within the descending thoracic (n = 834) and the abdominal aorta (n = 3,981).

Descending Thoracic Aorta

There are 834 subjects that meet the definition of treatment within the descending thoracic aorta. The following section will report on that specific cohort of subjects with any follow-up through 2 years post-procedure (Table 3). The overall mortality rate through 2 years is 9.4%. The stroke and paraplegia/paraparesis/spinal cord ischemia rates through 2 years are 1.8% and 1.1% respectively. The overall intervention rate for

subjects treated within the descending thoracic aorta is 12.1%, of which 6.5% are device related. The device-related reinterventions are mostly due to endoleaks. There have been six conversions to open repair reported. The overall serious endoleak rate for this cohort through 2 years is 4.8%, which is mostly due to type I and type II endoleaks (Table 4). There are only three reported device migrations and no device fractures or compressions.

Abdominal Aorta

There are 3,981 subjects that meet the definition of treatment within the abdominal aorta. The following section will report on that specific cohort of subjects with any follow-up through 2 years post-procedure (Table 5). The overall mortality rate through 2 years is 6.8% (Figure 2). The overall intervention rate for subjects treated within the abdominal aorta is 6%, of which 3.5%

TABLE 5. KEY OUTCOMES: ABDOMINAL AORTA

	Procedure	1 Month	6 Months	1 Year	2 Years	Total (Procedure-2 Years)
Number of Subjects With Any Follow-Up*	3,981	3,960	2,762	2,068	1,175	3,981
Subjects With Any Event Below	38 (1%)	159 (4%)	153 (5.5%)	117 (5.7%)	93 (7.9%)	511 (12.8%)
Mortality	1 (0%)	48 (1.2%)	91 (3.3%)	72 (3.5%)	57 (4.9%)	269 (6.8%)
Stroke/TIA†	3 (0.1%)	14 (0.4%)	17 (0.6%)	13 (0.6%)	7 (0.6%)	51 (1.3%)
Paraplegia/Paraparesis/Spinal Cord Ischemia‡	1 (0%)	2 (0.1%)	0 (0%)	0 (0%)	0 (0%)	3 (0.1%)
Device-related Reintervention‡	9 (0.2%)	40 (1%)	43 (1.6%)	33 (1.6%)	30 (2.6%)	140 (3.5%)

*Subjects are counted in the denominator if they had any follow-up start of window; all subjects with initial procedure date are counted in Procedure and Total windows.

†Only those considered serious adverse events.

‡All reinterventions include any invasive or minimally invasive measure related to the initial aortic procedure performed at any time following the initial procedure; device-related reinterventions include any invasive or minimally invasive measure related to a deficiency of the device(s) implanted into the aorta performed at any time following the initial procedure.

TABLE 6. PRIMARY OBJECTIVE INCIDENCE RATES: ABDOMINAL AORTA

	Procedure	1 Month	6 Months	1 Year	2 Years	Total (Procedure-2 Years)
Number of Subjects With Imaging and/or Event*	3,981	2,309	1,558	1,491	857	3,981
Type IA	4 (0.1%)	8 (0.3%)	7 (0.4%)	4 (0.3%)	4 (0.5%)	27 (0.7%)
Type IB	4 (0.1%)	7 (0.3%)	6 (0.4%)	3 (0.2%)	3 (0.4%)	22 (0.6%)
Type II	4 (0.1%)	8 (0.3%)	24 (1.5%)	29 (1.9%)	18 (2.1%)	75 (1.9%)
Type III	0 (0%)	1 (0%)	4 (0.3%)	0 (0%)	0 (0%)	5 (0.1%)
Type IV	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

*Subjects are counted in the denominator if they either had imaging reported in window and/or reported event; all subjects with initial procedure date are counted in Procedure and Total.

are device related. The device-related reinterventions are primarily reported as associated with type II endoleaks (Table 6). There have been 13 conversions to open repair reported. There is only one reported device migration, two compressions, and no device fractures.

Overall Mortality

The 1-year mortality rate for the entire cohort is 7.9% and the aortic-related mortality rate is 2.1% through 1 year. Aortic-related mortality is defined as one of the following: procedure death; death before 30 days; death prior to hospital discharge date; if there was reintervention and the patient died within 30 days; and if death at any time is reported as aortic-related rupture, endoleak, aneurysm, aneurysm repair, aortic and/or false lumen dilatation, dissection, embolus, occlusion, stenosis, thrombosis, surgery, stent insertion, intrathoracic aneurysm repair, and aortic disorder.

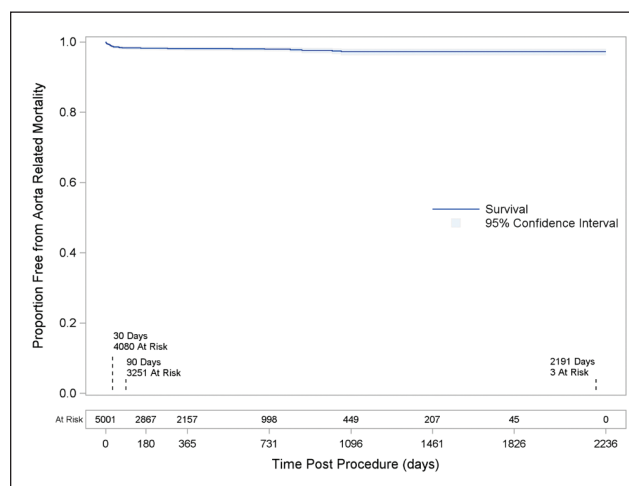


Figure 2. Kaplan-Meier for proportion free from aorta-related mortality.

CONCLUSION

The GREAT registry provides one of the most robust collections of real-world data (both on-label and off-label use) on the treatment of multiple aortic pathologies currently available worldwide. Although early in the follow-up, it is obvious that the use of aortic endograft devices, and in particular the use of the multiple Gore endoprotheses outlined above, provide a useful modality for addressing the multiple aortic pathologies seen in everyday practice. Validation has been provided for initial outcomes in that the peri-procedural complication rates are very low for elective and emergent cases while low rates of serious adverse outcomes are being maintained through follow-up. In the treatment of descending thoracic aortic pathologies, we can see that the risks for stroke, paralysis, and post-operative/peri-operative mortality often seen in open surgical repair remain low in repairs performed. In addition, reintervention rates remain quite low, at least out to 2 years. Patients treated for abdominal aortic pathologies also receive similar benefits.

To date, there have been more than 100 presentations using GREAT data at regional, national, and international congresses. In addition, there have been five publications of GREAT data with several manuscripts currently under review at multiple peer-reviewed journals. As the GREAT registry continues to collect data and mature over time, it will allow us to further evaluate and report on specific aortic pathologies that other studies may not have been

able to report on in large numbers due to the number of patients available in those studies. There are numerous studies and data groups already working on various topics. Ideally these studies will allow us to continue to gain insight to help us offer patients the best treatment modalities and methods using the endovascular approach to treat aortic pathologies. ■

1. Loa J, Dubenec S, Cao P, et al. The Gore Global Registry for Endovascular Aortic Treatment (GREAT): objectives and design. *Ann Vasc Surg*. 2016;31:70-76.

2. International Organization for Standardization. Clinical investigation of medical devices for human subjects—good clinical practice. ISO 14155:2011.

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Preservation Matters

Clinician and patient perspectives from the first bilateral iliac branch endoprosthesis procedure in the United States.

WITH SHARIF H. ELLOZY, MD, AND JOHN GRIECO

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When John Grieco, a competitive triathlete, was diagnosed with aneurysms in his abdominal aorta and both iliac arteries (Figure 1) in January 2015, he thought he would never compete in a triathlon race again. Only 48 years old at the time, he was concerned about the potential lifestyle-limiting effects of the reduced lower-extremity bloodflow that was a likely outcome if he pursued the initial repair options presented to him. Just when he thought he was out of options, he was referred to Sharif H. Ellozy, MD, who told him about the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), a device undergoing clinical investigation in the United States at the time.

Endovascular Today met with Dr. Ellozy and Mr. Grieco to talk about this unusual case and how bilateral branches impacted his post-procedure quality of life and preserved his ability to compete.

Mr. Grieco, tell us about your lifestyle before your diagnosis.

Mr. Grieco: My lifestyle was very active. My wife Melissa and I both really enjoy cycling, swimming, and running, so we took up the sport of triathlon. We were typically doing those activities for 10 to 14 hours in a given week.

How did your lifestyle affect how you sought treatment?

Mr. Grieco: Figuring out how to take corrective measures and continue that lifestyle was a big factor in the process. Of course, I was hoping for a 100% solution—I didn't just want to have surgery and a process that kept me alive. After my first doctor did his examination and explained the surgery, he looked at me and leaned in and said, "You may never run or cycle again." I wasn't ready to throw in the towel, so I looked back at him and asked, "Are there any other options?"

What were your sources of education on endovascular and open repair?

Mr. Grieco: I didn't know anything other than what an aneurysm was—I knew nothing about the locations of my aneurysms or the treatment for my specific issue. When I started to research, I got a bit more depressed because I came to realize that I could possibly have a very different lifestyle after the surgery. I did a lot of Internet searches, naturally, trying to find reputable sites for the doctors' qualifications, looking up abdominal aortic aneurysms (AAAs), endovascular aortic repair (EVAR) and understanding what that meant, understanding what the risks were associated with either treatment option. At the same time, I went to see some solid doctors at a couple of different hospitals. I also called a doctor friend of mine who I'd known for a number of years, and I asked him to direct me through medical care, the selection of a surgeon, and making good decisions.

What informed your decision to ultimately select endovascular therapy?

Mr. Grieco: It was a kind of process of elimination. I originally had a vascular surgeon suggest that open surgical repair was the best option because I was young, healthy, and active, so the typical risks of a more substantial operation were less significant. He recognized the fact that there wasn't a complete solution with traditional EVAR. I then saw another doctor, Dr. Michael Marin, who also confirmed that traditional EVAR wouldn't be a complete solution. I was almost in denial accepting the truth that there was a medical issue without a perfect solution. But, lo and behold, he said that there was a study that may address my issues.

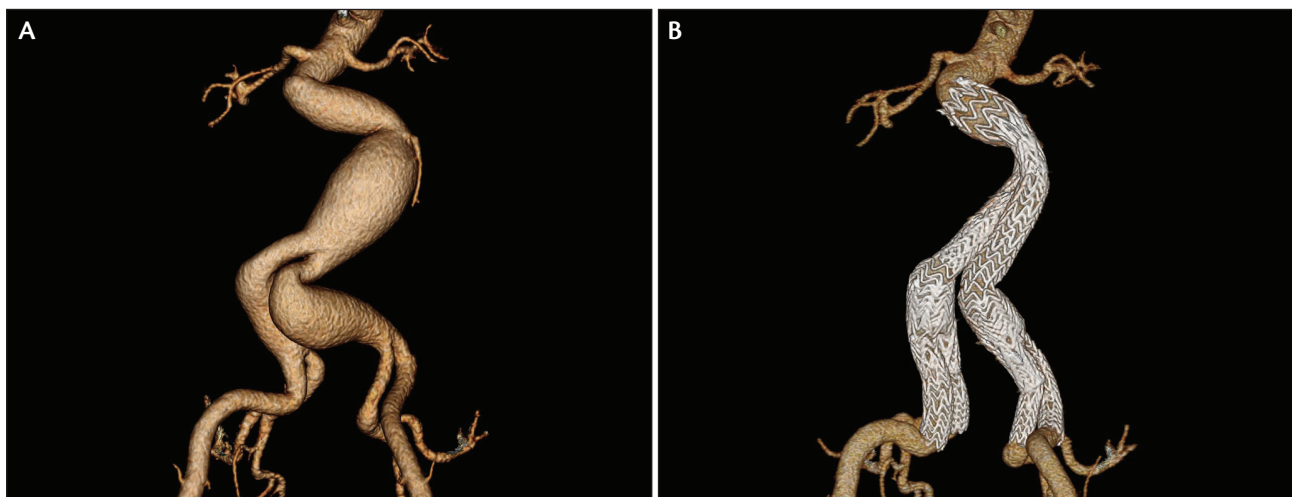


Figure 1. Pre-implant (A) and 1-year follow-up (B). Courtesy of Sharif Ellozy, MD, and Darren Schneider, MD, New York Presbyterian/Weill Cornell Medical Center; New York, New York.

When I met with Dr. Ellozy, he walked me through my condition and how the bifurcated iliac stents could address my specific diagnosis. Melissa and I looked at each other, and we immediately knew that we were in the right place, and we were extremely fortunate to have all of the elements—a great hospital, a great doctor, and a procedure that appeared to be a solution.

What was recovery like? How long before you could resume normal activity?

Mr. Grieco: I was diagnosed in January of 2015 and had the procedure in February of 2015. By March I was starting to cycle a little bit and starting to get on the treadmill to walk a little bit. By the end of March, Melissa and I went out to Tucson, Arizona, and that week I cycled 300 miles.

All of 2015 was a rebuilding year, and I was so grateful that I could still cycle and still run long distance without having any pain or discomfort—that was just incredible.

Before my diagnosis, we had set out to do several IRONMAN® triathlons the year that I had the surgery. I put that in the back of my mind and assumed that may not happen. Once I started to cycle again, I realized that I could still participate in the triathlons. I couldn't race them, but I could certainly show up and complete them. So that's what we did—we

completed four IRONMAN® races the year (Figure 2) that I had the surgery, which is an incredible amount of training and racing even for someone who didn't go through the surgery.

What is your lifestyle like now?

Mr. Grieco: This year, my goal was to try to get back to 100%, and my wife and I just completed a race this past November, and we qualified for the half IRONMAN® world championship in our respective age groups, which will take place next August 2017 in Penticton, Canada.

Dr. Ellozy, how did Mr. Grieco's age and lifestyle factor into your treatment decision?

Dr. Ellozy: John came in to my office with a picture of himself on a bike, and he had angles calculated, the

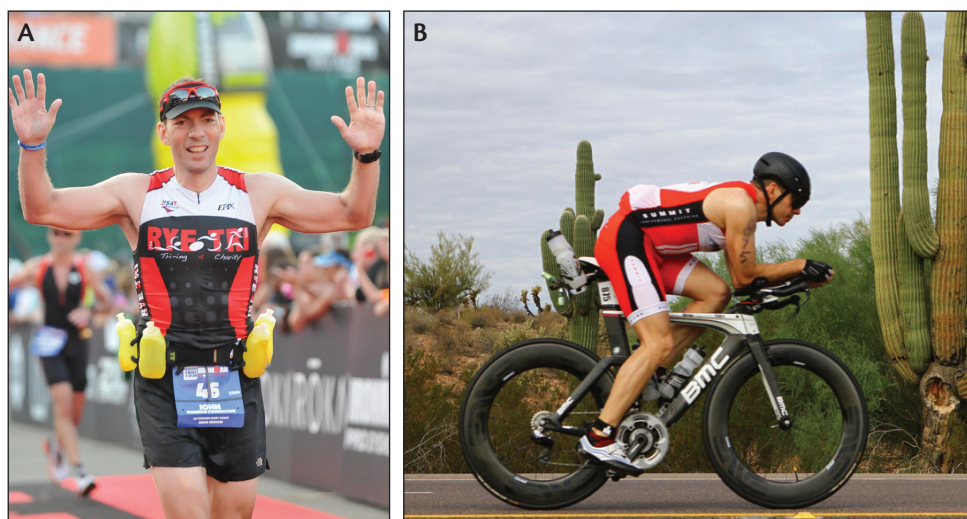


Figure 2. Each year, John Grieco participates in several triathlons across the country. He competed in the July 2015 IRONMAN® Lake Placid 5 months after surgery (A) and the November 2015 IRONMAN® Arizona 9 months after surgery (B). Images courtesy of John Grieco.

position that he'd be sitting in, asking if it would be stressful for the device. There were a lot of considerations that I hadn't run into with my typical AAA patients before then because most of them are not triathletes.

He is not a typical patient because he's much younger and healthier, and his anatomy was a little more tortuous than most aneurysms. There is always a certain amount of patient input into therapeutic choices, and when we met, I offered the possibility of open surgical repair. Listening to what was important to him, however, I thought that enrollment in the trial would be a good solution for his problem.

What influenced your decision to choose this device?

Dr. Ellozy: We had a couple of options. To pursue an endovascular approach, we could do embolization and extensions to the external iliac arteries, but then we would lose the benefits of pelvic perfusion. We had access to two iliac branch devices in two different clinical trials, but only the GORE EXCLUDER Iliac Branch Device was allowing for bilateral repair, and there is about a 20% incidence of buttock claudication in unilateral embolization.

There are off-label uses such as a sandwich technique, but when there is a device that's designed for this, I think you're much more likely to get a durable result than if you have an off-label use of a device or a modification of a device.

What concerns did you have as the treating physician about long-term outcomes, based on the data that exists?

Dr. Ellozy: Durability is going to be a concern in any patient, but especially for the younger patients. For a patient who is athletic, you may put the device under more strain than someone who doesn't have such an active lifestyle, but there's no real way to test for that. These devices are put through lifecycle testing to see if they will endure, but at some point, you have to make a decision based on judgment and experience.

Although this was an investigational device, it was based on the same platform as the GORE® EXCLUDER® Device, which has been time-tested, and the iliac branch device is

essentially a smaller GORE EXCLUDER Device. The system is a little different to allow for tracking the internal iliac component to it, but we know that it performs well and it's durable, so that gave me more comfort than if it had been a totally new platform.

What was unique about this case?

Dr. Ellozy: There are some patients who are endurance athletes and develop iliac aneurysms, but it didn't really look like that because there was an aortic component as well. Similarly, a connective tissue disorder is always a concern, but it wasn't that either. This was more tortuous than most aneurysms. When aneurysms dilate, they get longer, but this got a lot longer (Figure 1A).

The iliac component was well within the instructions for use (IFU), but the aortic component also had to be within the IFU for the GORE EXCLUDER Device, and there was more tortuosity there. There was a significant angle at the level of the renal arteries, but a straighter portion just proximal to the first bend where the device would land nicely. We believed that there was a normal segment beyond the first bend, and that wouldn't fit within the IFU. That had some implications in terms of where it was okay to deploy the device.

What is the plan for long-term follow-up?

Dr. Ellozy: We will continue to do CT scans according to the clinical trial protocol. This is an MR-compatible device, so ultimately my goal is to use MR or ultrasound surveillance so that we don't have to use any radiation. The 1-month, 6-month, and 1-year (Figure 1B) surveillance were CT scans. In an older patient, the implication of repeat CT scans is less because of the potential for oncogenesis. In a younger patient, if you can avoid the radiation, it's better. Once a year is not a lot, but we only do what's necessary for surveillance.

As surgeons, you always think about the outcomes and you always anticipate managing complications. I think with this device, if there are failures in the future, it is a little easier to handle than with some of the other devices.

As physicians we are always concerned about surveillance and making sure that the repair is intact, even more so on a young, active patient, but so far we are good, and 2-year follow-up is coming soon. ■

Imaging Considerations for Every Endovascular Aortic Branch Program

With increasing case complexity, proper protocol is crucial.

BY GUSTAVO S. ODERICH, MD, AND GIULIANO SANDRI, MD

Endovascular aneurism repair (EVAR) has been widely accepted as the first treatment option for patients with aortic aneurysms.¹⁻⁵ Prospective studies have shown that EVAR reduces mortality and morbidity compared with open surgical repair.¹⁻³ During the past decade, advancements in endovascular technology have focused on expanding the indications of EVAR to patients with complex aneurysms involving the arch, thoracoabdominal aorta, and iliac bifurcation. Total endovascular repair with branch vessel incorporation has been possible by using fenestrated, branched, and parallel stent grafts. Clinical experience from large tertiary centers has shown that these procedures can be performed with high technical success (> 95%) and with mortality in the range of 1%-5% for pararenal and 4%-10% for thoracoabdominal aortic aneurysms.⁶⁻¹² Corresponding with these advancements, there have been significant improvements in imaging capabilities to facilitate pre-procedure planning, device implantation, and immediate assessment of the repair.



Figure 1. Large display monitor with computed tomography angiography fusion using GE® Discovery IGS 740 during deployment of a GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis*. The yellow line marks the contour of the aorta and renal-mesenteric arteries, which are also identified by colored rings. Note: the image is digital zoom and not a magnification view.

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

SCOPE OF THE PROBLEM

EVAR has been traditionally performed with 2D fluoroscopy using C-arm mobile imaging units. Though procedures can be performed in many patients, significant disadvantages are lower x-ray tube output, potential for x-ray tube overheating, and greater radiation exposure to the patient and personnel. Image quality is also compromised, and in some cases, it may not be adequate. Coupled with the increasing demand for complex endovascular procedures, there is raised awareness about the deleterious effects of radiation exposure. El-Sayed and colleagues reported acute DNA damage to operators and patients during standard and complex EVAR. Although the study did not show direct evidence of stochastic effects (e.g., increased risk of cancer), one can extrapolate that repeated exposure to radiation may result in clinical sequelae.¹³

Radiation exposure can be significantly reduced during EVAR depending on the type of hybrid operating room (OR), imaging equipment, and availability of advanced applications such as computed tomography angiography (CTA) fusion or cone-beam computed tomography (CBCT).^{14,15} The dose area product (DAP), measured in Gy.cm², is the product of absorbed radiation dose, or air kerma (AK), measured in Gy or mGy, by the exposed area. The DAP is directly linked to stochastic effects. Although there is a wide variation in DAP for standard and complex EVAR procedures, newer hybrid ORs have decreased radiation exposure for complex EVAR (Table 1). For example, in some studies with standard EVAR the median DAP was measured as high as 276 Gy.cm² per case, whereas in others the DAP was as low as 43 Gy.cm² per case for complex EVAR performed using most advanced imaging units.

HYBRID-ROOM CONCEPT

Hybrid ORs combine optimal imaging with the ideal environment to perform complex open and endovascular operations. These rooms are equipped with modern fixed imaging units that have several advantages such as stronger x-ray tube power (preventing overheating), flat panel detectors (optimizing imaging quality), and

TABLE 1. SELECTED REFERENCES FOR DOSIMETRIC DATA FOLLOWING STANDARD AND COMPLEX EVAR

Author(s)	Year	n	Procedure (subgroup)	Fluoroscopy Time (min)	Median DAP (Gy.cm ²)
Geijjer et al ¹⁶	2005	24	EVAR	21.4 (7.4–78.9)*	60.1 (16.6–195)*
Weiss et al ¹⁷	2008	12	EVAR	20.6 (12.6–34.2) [†]	151.7 (52.1–245.4) [†]
Weerakkody et al ¹⁸	2008	96	EVAR	21 (16–31)	–
Kalef-Ezra et al ¹⁹	2009	62	EVAR	18 (4.3–75)*	37.4 (9–139)*
Kuhelj et al ²⁰	2010	172	EVAR	17 (2.9–97.8)*	153 (35–700)*
Jones et al ²¹	2010	320	EVAR	29.4 ± 23.3 [§]	46.9 ± 28.4 [§]
Panuccio et al ²²	2011	18	BEVAR (extent II–III)	140.7 ± 64.4 [§]	1,005.7 ± 627.8 [§]
		29	BEVAR (extent IV)	81.9 ± 45.8 [§]	642.5 ± 311.6 [§]
Fossaceca et al ²³	2012	153	EVAR	–	78 (27–370)
Howells et al ²⁴	2012	630	EVAR	18 (2.4–161)	173 (109–3,343)*
		53	BEVAR/FEVAR	58 (6.7–212)*	320.6 (172.1–2,133.2)
Maurel et al ²⁵	2012	188	EVAR	9.36 (1.76–67.1)*	30 (4.3–280)*
		54	FEVAR	27.2 (2.1–69.1)*	72.8 (11.0–290.0)*
		20	BEVAR	42.98 (2.38–95.5)*	159.5 (29.8–777.0)*
Peach et al ²⁶	2012	57	EVAR (non-operator controlled)	20.0 (4.8–49.3)*	69 (19.1–950)*
		65	EVAR (operator-controlled)	16.2 (3.1–51.1)*	49 (12.5–133)*
Walsh et al ²⁷	2012	111	EVAR	18.5 [‡]	85.8 [‡]
Tacher et al ¹⁵	2013	9	BEVAR/FEVAR (2D)	82 ± 46 [§]	1,188 ± 1,067 [§]
		14	BEVAR/FEVAR (3D)	42 ± 22 [§]	984 ± 581 [§]
		14	BEVAR/FEVAR (fusion)	80 ± 36 [‡]	656 ± 457 [‡]
Patel et al ²⁸	2013	26	EVAR	19.5 (14.4–31.5)	97.3 (55.4–167.9)
Blaszak et al ²⁹	2014	266	EVAR (men)	–	271 (37–1,760) [†]
		31	EVAR (women)	–	276 (64–625) [†]
Hertault et al ¹⁴	2014	44	EVAR	10.6 (9.1–14.7)	12.2 (8.7–19.9)
		18	FEVAR	30.7 (20.2–40.5)	43.7 (24.7–57.5)
		20	BEVAR	39.5 (34.8–51.6)	47.4 (37.2–108.2)

Abbreviations: 2D, two-dimensional; 3D, three-dimensional; BEVAR, branched endovascular aortic repair; DAP, dose area product; FEVAR, fenestrated endovascular aortic repair.

*Median (range); [†]Mean (range); [‡]Mean; [§]Mean ± SD. Note: Values are given as mean interquartile range unless otherwise indicated.

customizable protocols to regulate radiation dose levels. Several features such as CTA fusion, CBCT, larger detector panels, digital zoom, and low-dose protocols further reduce the radiation exposure to a patient and an operator.

NOVEL IMAGING APPLICATIONS

CTA Fusion

Fusion imaging using the 3D model is displayed on a large display monitor along with live fluoroscopic imaging (Figure 1). This is used as a 3D “roadmap” to help guide implantation of branched stent grafts by identifying anatomical landmarks without performing repeat 2D angiography (Figure 2). The CTA 3D model

and fluoroscopic image are both registered by aligning the two datasets with each other. The 3D model can be obtained from intraoperative, contrast-enhanced CBCT (e.g., CBCT fusion), but this technique has disadvantages since it requires additional radiation exposure, contrast, and is more time consuming. Alternatively, fusion can be created from pre-operative CTA or magnetic resonance angiography (MRA) datasets. CTA fusion has a more efficient workflow and minimizes radiation by avoiding the need to perform CBCT. During the fusion registration workflow, the bone sub-volume from CTA is aligned with two orthogonal fluoroscopic shots using bone landmarks such as the iliac crest and vertebral bodies. Fusion registration workflow can be easily performed by

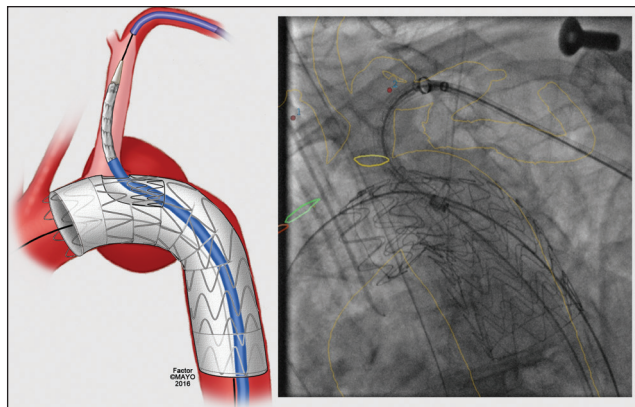


Figure 2. Computed tomography angiography fusion imaging shows vessel outline and origins of the left subclavian (yellow ring) and common carotid arteries (green ring) during deployment of the GORE® TAG® Thoracic Branch Endoprosthesis* to treat distal aortic arch aneurysm. Avoiding repeat angiography markedly reduces contrast use. Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved.

the operator using tableside control and is fast, adding minimal or no radiation exposure.

There is increasing evidence on the benefit of fusion imaging to facilitate standard and complex EVAR.^{14,15} Prior reports have shown significant reduction in total dose of contrast media compared with procedures performed with conventional fluoroscopy.^{30,31} Hertault et al and Dias et al^{14,30} have shown noticeable decline in radiation dose since adoption of CTA fusion.

Cone-Beam Computed Tomography

Complex EVAR has been plagued by high reintervention rates with secondary stent graft-related complications in up to 34% of patients. In some reports, early reinterventions (< 30 days) are required in 10% of patients to treat proximal endoleaks from attachment sites or severe side branch kinks, accounting for nearly half of all reinterventions (Figure 3).^{6,9,11,12} The most common problems are endoleaks from sealing zones or compression of side stents. If not recognized, these problems may lead to devastating complications such as stent occlusion or aneurysm rupture.

Traditionally, the immediate assessment of the repair has been done by 2D angiography. However, this may not adequately demonstrate structural problems such as kinks or compression of side branch stents. CBCT with and/or without contrast enhancement using high definition imaging can be obtained through 3D rotation. Multiplanar reconstructions of the CBCT images allow immediate assessment of the repair including location of stent grafts in relation to target vessels, configuration of side branches (Figure 4), patency of iliac limbs, and

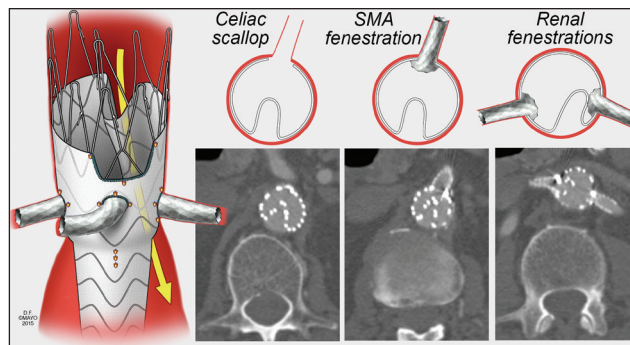


Figure 3. Illustration of a patient who was found to have an in-folded aortic fenestrated stent graft on postoperative computed tomography (CT) angiography. The patient required an early reintervention, which may have been avoided by immediate assessment with cone-beam CT. Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved.

presence of endoleaks. These technical complications can be recognized and immediately revised at the time of the initial procedure (Figures 5 and 6), avoiding potential risk of complications and decreasing the need for secondary reinterventions. Schulz and colleagues recently reported a comparison of contrast-enhanced CBCT (ceCBCT) with digital subtraction angiography (DSA) and post-procedure CTA.³² In that study, ceCBCT detected more endoleaks (36%) than DSA (16%) and CTA (22%), prompting intraoperative interventions in 7% of patients.

MAYO CLINIC WORKFLOW

All patients undergoing complex EVAR receive preoperative CTA of the chest, abdomen, and pelvis. This is the most important imaging modality to plan EVAR. Its utility relies on the accurate assessment of etiology, extent of disease, involvement of side branches, adequacy

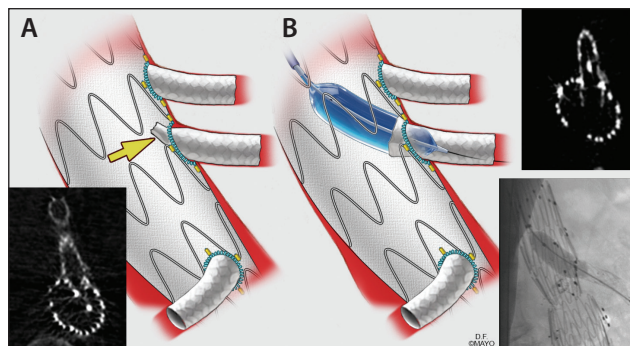


Figure 4. Completion cone-beam CT (CBCT) shows compression of the superior mesenteric artery bridging stent (A, yellow arrow). This was immediately revised by balloon angioplasty (B) with resolution of the compression on repeat CBCT. Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved.

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

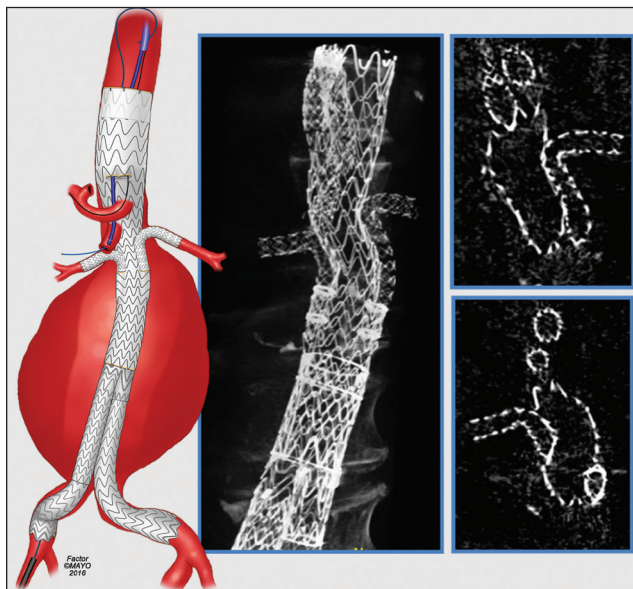


Figure 5. Completion cone-beam CT in a patient treated with a GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis stent graft shows stent architecture and absence of kinks within the retrograde renal stents. Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved.

of access vessels, and presence of extravascular diseases that might affect treatment selection and approach. Before the procedure, meticulous planning is reviewed on the GE Advantage Workstation (AW) using the EVAR Assist planning tool. The 3D reconstruction obtained from the preoperative CTA is carefully analyzed for access routes, measurements of lengths, clock positions, and angles of origin for the renal-mesenteric arteries. Colored rings mark the location of each target vessel during preparation of CTA fusion (Figure 1). Ideal angles of parallax view are also stored during the planning phase, allowing the gantry to be positioned at the proper angle during the procedure. Automatic positioning capability contributes to minimizing fluoroscopy time and prevents the need to perform unnecessary DSA runs. Sizing and planning can be done weeks before the procedure and are fully integrated into the imaging unit on the day of the operation.

All complex EVAR cases are currently performed in a dedicated hybrid endovascular room with the latest generation GE® DISCOVERY IGS 740 angiography system. This imaging has a 40 X 40 cm flat panel detector, EVAR Assist software, CTA fusion, and high-definition CBCT. The initial registration process is done using pre-operative CTA, which is fused with two orthogonal views, either anterior-posterior (AP) and lateral or right anterior oblique and left anterior oblique. The CTA bone sub-volume is aligned with the bone landmarks from two fluoroscopic projections. After arterial access

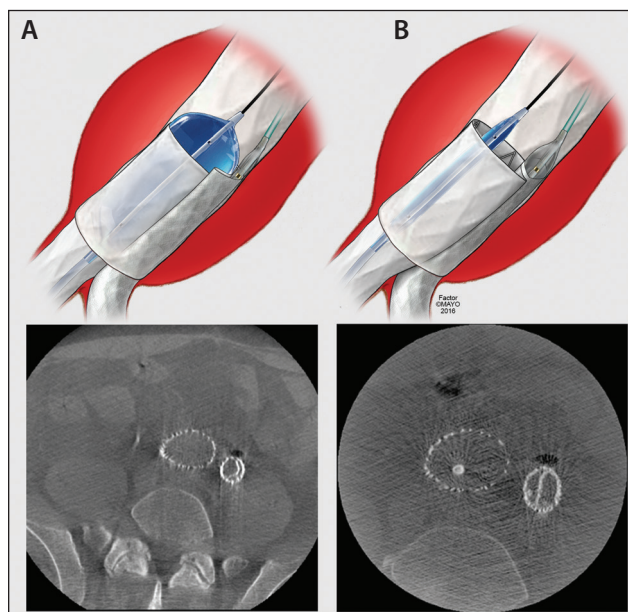


Figure 6. Intraoperative cone-beam CT was used in this patient who was treated with an aortic stent graft and parallel iliac stent grafts. Note compression of the internal iliac bridging stent (A). This was immediately revised by placement of balloon-expandable stents to achieve perfect "D" configuration (B). Used with permission of Mayo Foundation for Medical Education and Research. All rights reserved.

is established, the 3D CTA vessel model is realigned by selective catheterization of one of the renal arteries with limited angiography or by DSA using injection of 7 ml of contrast medium at 30 ml/sec. The use of iodinated contrast is minimized throughout the procedure

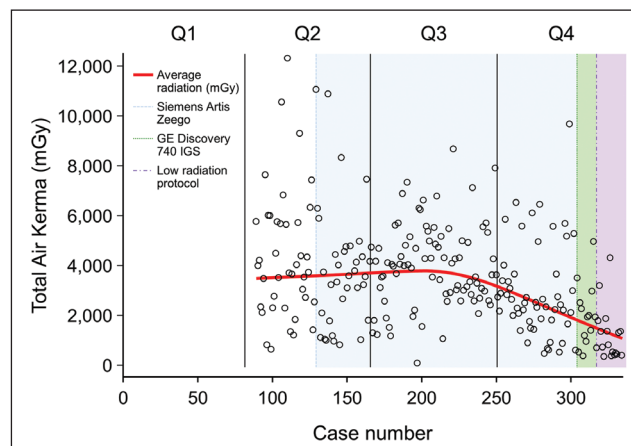


Figure 7. Radiation dose (dots and red line) in 340 consecutive patients treated by fenestrated and branched stent grafts. Radiation dose was recorded after the first quartile of experience (Q1). Note: Marked reduction in radiation exposure after 250 cases. The lowest radiation levels were achieved using the GE® Discovery IGS 740 unit with low-radiation protocol (green and purple panels).

TABLE 2. TECHNICAL TIPS TO MINIMIZE RADIATION DOSE DURING STANDARD AND COMPLEX EVAR

Technical Tip	Comments
Shielding	Lead aprons, thyroid shield, lead goggles, tableside glass shields, and skirts
Tube Position	Avoid lateral and oblique projections
Continuous Monitoring Exposure	Modern fluoroscopy systems display fluoroscopy time, DAP, and cumulative AK; staff exposure should be monitored with active dosimeters that provide direct display of accumulated dose; longitudinal dose analysis should be collected and reviewed on regular basis
Flat Panel Detectors	High level radiographic performance with limited geometric distortion and high uniformity
Pulse Mode	7.5 images per second reduce number of produced images by 90% compared with continuous mode (30 images per second)
Auto Exposing Settings	X-ray exposure is automatically adjusted in real time to deliver constant image quality at lowest dose
Low Dose Setting	Low frame rate and detail settings
Time on Pedal	Pedal control by senior operator with limited time on pedal at all times
Fluoroscopic Mode	Digital subtraction angiography should be avoided and instead high quality fluoroscopic loops should be used to analyze target vessels before and after stenting
Collimation	Reduction of field of view using vertical, horizontal, and iris collimation to focus on the area of interest
Digital Zoom	Digital zoom is applied instead of increased field of view whenever possible
Limit Angulations	Gantry position > 30° oblique or > 15° cranial increases staff exposure to scattered radiation and deteriorate image quality; angled and lateral views should be minimized and used only for short intervals
Imaging Chain Geometry	The detector should be placed as close to the patient as possible
CTA Fusion	Onlay anatomical correlation with 2D fluoroscopy
CBCT	Immediate assessment of technical problems and endoleaks

Abbreviations: 2D, two-dimensional; AK, air kerma; CTA, computed tomography angiography; CBCT, cone-beam computed tomography; DAP, dose area product.

using CTA fusion to identify the target vessels. Once the vessels are located, small hand injections (3 ml of contrast in 7 ml of saline) with fluoro loops are stored for confirmation. We avoid DSA acquisitions to minimize radiation. Once the stent graft has been implanted, CBCT is done with and without contrast-enhancement to assess stent architecture and endoleaks. If there is a significant technical problem, this is immediately revised.

Radiation protection is critical when performing these procedures by following the “as low as reasonably achievable” (ALARA) principle, which aims to use the lowest radiation exposure to complete the procedure. To follow the ALARA principle, several technical tips (Table 2) have been implemented as part of a low dose protocol. The protocol is customized with reduced fluoro frame rate (7.5 fps) with low detail. The fluoroscopic pedal is controlled by the most senior operating surgeon and DSA acquisitions are avoided whenever possible. Increased magnification is avoided by using the digital zoom feature. Gantry angulations are limited to < 30° anterior oblique views and imaging is collimated with

digital zooming, instead of magnified views. Proper shielding is used to minimize scattered radiation, including protective garments, eye protection, lead hats, and protective surgical drapes.

CLINICAL RESULTS

Our results have continued to evolve and reflect significant time investment from the physician on planning, performing, and refining the procedure. It is no surprise that for complex EVAR there is a steep learning curve, and increasing clinical experience has been associated with improvements in operative mortality and morbidity. We have recently reviewed our experience with 334 consecutive patients treated by complex EVAR. Operative mortality was 2% for the entire cohort, but declined from 6% in the first quartile to 0% in the last two quartiles of experience. Similarly, we have noted a significant reduction in radiation dose (Figures 7 and 8) since the installation of the latest generation of GE Discovery IGS 740 hybrid endovascular room and adaptation to our low dose protocol. The reduced dose

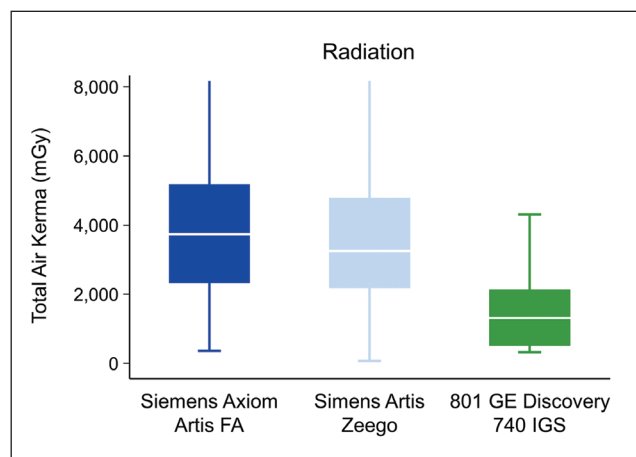


Figure 8. Radiation dose by specific type of imaging unit in patients treated by fenestrated branched stent grafts. The bar marks median and 95% confidence interval, whereas the line marks minimum and maximum value.

in radiation exposure is explained by the use of CTA fusion with fluoroscopic registration (as opposed to initial CBCT) fusion, digital zoom with collimation (as opposed to larger magnification), and fluoro loops (as opposed to DSA acquisitions).

CONCLUSION

Complex EVAR has been increasingly utilized to treat aortic aneurysms involving the aortic arch, thoracoabdominal aorta, and iliac bifurcation. It is important that centers performing these types of procedures are prepared to adapt to the technical demands of newer devices to treat complex anatomy and have advanced imaging tools available. There are several advantages of latest generation hybrid operating rooms, notably the combination of the ideal surgical environment with optimal imaging and advanced applications to minimize radiation exposure, use of contrast media, and need for secondary interventions. ■

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Tested by Time

The story of the evolution of endovascular aneurysm repair and the GORE® EXCLUDER® Device.

BY MICHAEL M. McNALLY, MD, AND SCOTT L. STEVENS, MD

The repair of abdominal aortic aneurysms (AAA) has parallels in the history of clockmaking which began more than 5,000 years ago with the creation of the Egyptian obelisk sun clock in 3500 BC. Based on humankind's needs and empowered by advances in technology, the clock evolved dramatically over time. Similarly, fueled by competitive market pressure and based upon applied technical knowledge, the repair of AAA progressed relentlessly, but over a much shorter period. Open surgical repair of AAA was first described by French physician Charles Dubost in 1951. His work set the standard until 1986 when Nickolay Volodos first described aortic stent graft repair of a post-traumatic descending thoracic aortic aneurysm. Shortly thereafter, in 1991, the more well-known Juan Parodi, MD, published his first endovascular aneurysm repair (EVAR) manuscript.¹ Despite EVAR having a history from the 1990s—a very short timescale when compared with thousands of years of clockmaking—both reflect a pattern of systems moving up-market by responding to the pressure of unanswered needs.

Indeed, EVAR has surged and now dominates the market. For most patients with acceptable anatomy, it has disrupted open surgical repair as the new gold standard. Over time, outcome data have demonstrated that EVAR offers tremendous morbidity and mortality benefits in the perioperative period. The trade-off, however, seems to be dealing with long-term aneurysm concerns and commitment to ongoing device imaging and management. The long-term durability of EVAR has been established, and EVAR outcomes continue to improve. Currently, several endografts have received Food and Drug Administration (FDA) approval, with more in development or under clinical evaluation. To date, most of these have offered very strong outcomes and have excellent track records for safety and efficacy. However, it has become clearer that differences in device delivery and design provide certain advantages that may favor one anatomical milieu over another. The goal of this article is to describe the history and evolution of the GORE® EXCLUDER® AAA Endoprosthesis, a product whose development draws analogy to the field of clockmaking.

DISRUPTIVE INNOVATION, MECHANICAL CLOCKS, AND THE FIRST-GENERATION GORE EXCLUDER DEVICE

Because of the imperfect function of sundials and second-century water clocks, mechanical clocks were introduced in the 10th century. Similarly, the first



Figure 1. GORE® EXCLUDER® AAA Endoprosthesis: a modular system including a bifurcated trunk-ipsilateral component, contralateral leg component, and optional iliac and aortic extender components.

endovascular repairs centered on a solution for the imperfect outcomes associated with open AAA repair in patients with poor physiology. The early endovascular approach was limited to physician-made devices using graft material sutured to available stents. Those early homemade endovascular devices, like early mechanical clocks, were clunky and poorly efficacious. As described by the Harvard School of Business's Clayton Christensen in his book *The Innovator's Dilemma*,² this phase of inadequacy is typical and even required of all disrupting technologies. Since first described by Dr. Parodi a quarter-century prior, numerous commercial endograft devices are now in use and in various phases of evaluation. These devices have undergone aggressive iterations as new needs are identified based on growing clinical experience and lessons learned with older models.

The GORE EXCLUDER Device has undergone several refinements since its original release in Europe in 1997. The original GORE EXCLUDER Device was used from 1997 to 1999, where it was then modified and in use until 2004. It received FDA approval for commercial distribution in the United States in 2002. In 2004, the low-permeability GORE EXCLUDER Device was introduced and remains in use today.

The device is a modular system consisting of a bifurcated main body with a single docking limb and assorted contralateral limbs, with optional iliac and proximal extenders (Figure 1). The proximal portion of the main body is covered with paired nitinol anchors for infrarenal fixation. The proximal edge is identifiable by

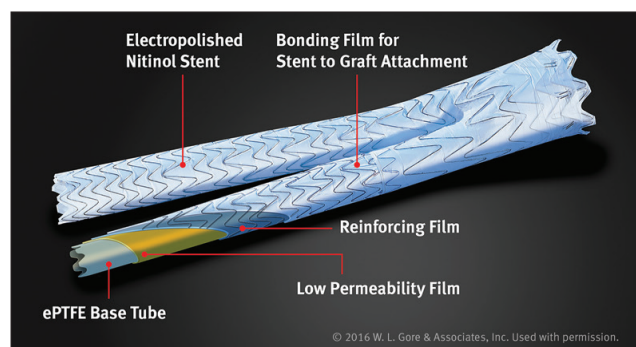


Figure 2. GORE® EXCLUDER® AAA Endoprosthesis: the graft is comprised of an ePTFE base tube on the luminal side, a low-permeability film in the middle, and a reinforcing film on the outside. An electropolished nitinol stent is attached to the graft by bonding film.

gold markers designed to be placed immediately below the most inferior renal artery. The endograft is a multilayer expanded polytetrafluoroethylene (ePTFE) construction supported by a nitinol stent frame. The endograft material is bonded to the nitinol frame and thus has no suture holes in the material. The device is constrained onto the catheter using an ePTFE sleeve. The delivery system is flexible and tracks well with tortuous iliac vessels. The low profile of the delivery system is advantageous for patients with small access vessels, and thus makes it suitable for a percutaneous approach, as well. Its rotational orientation is facilitated by varied-length markers on the ipsilateral and contralateral graft sides.

The 2004 low-permeability GORE EXCLUDER Device was engineered to address endotension. This iteration was prompted after a rising rate of aneurysm expansion in the absence of demonstrable endoleak and was noted with the first-generation GORE EXCLUDER Devices. The low-permeability endograft incorporates an additional ePTFE film layer that decreases the overall graft permeability and reduces fluid flow across the graft material (Figure 2). This low-permeability solution has been effective and durable. In fact, the low-permeability construct has been so successful that it continues as the foundation for current GORE EXCLUDER Devices and has been the only substantive change to the construct. Based, in part, on the improved performance of the low-permeability endograft with very low rates of endotension and sac expansion, it has been suggested that if an aneurysm is stable or has reduced in size at the 12-month CT scan, it could safely be followed with a clinical and ultrasound evaluation.³ This relaxed surveillance protocol represents significant advantages for patients. Although serial CT imaging has the benefit of enhanced information compared with an ultrasound or a plain radiograph, the financial burden, cumulative radiation exposure, cancer risk, and potential renal impairment from repeated dye loads are important concerns.

ADVANCING INNOVATION: THE GORE® C3® DELIVERY SYSTEM

Whether building clocks or repairing aortic aneurysms, advancement requires careful observation to pinpoint market needs and guide innovation. Early mechanical clocks became more accurate when their design changed from heavy weights to spring power to a pendulum concept design. Comparable to this trend, the accuracy of EVAR was advanced with the GORE C3 Delivery System (introduced in 2010) for the device. The GORE C3 Delivery System allows more precise and controlled deployment with three advantages over its predecessor and other endografts on the market. First, the delivery system supports users in readjusting the stent graft for proximal-level orientation for precise infrarenal artery deployment (which is advantageous for training inexperienced users, as well as experienced users confronted with difficult proximal anatomy). Second, the deployment mechanism offers rotational adjustment, which facilitates gate reorientation in challenging gate cannulation. Finally, a separate deployment of the ipsilateral limb of the bifurcated trunk component allows for the device to remain on the catheter for improved control throughout the deployment process.⁴⁻⁶

Responding to the demand for larger proximal aortic and distal iliac landing zones, Gore & Associates has frequently brought additional components into the market. These new components have expanded our EVAR reach and increased the GORE EXCLUDER Device applicability for treating aortic aneurysms of different sizes and anatomies.

DURABILITY AND EFFICACY

In his publication *Competing Against Luck: The Story of Innovation and Customer Choice*,⁷ Christensen describes his “Job to Be Done” theory. This theory requires the question “What needs to be designed, developed, and delivered so that it does the job well?” It also requires that the solution be incorporated into the enterprises’ operations and capabilities to “nail the job” consistently. The GORE EXCLUDER Device, now in its second generation, has “nailed the job” consistently. It has been used for 19 years with proven safety, efficacy, and long-term durability in more than 250,000 patients. Two important design improvements have been noted: low permeability and the GORE C3 Delivery System. These enhancements, along with a flexible, low-profile delivery catheter and simple deployment mechanism, have led the GORE EXCLUDER Device to become the United States market leader for EVAR devices and the worldwide leader for most implants of any single-device design.

Based on the company-sponsored trials and registries shown on clinicaltrials.gov, the GORE EXCLUDER Device is the most studied of all currently available endografts.

The Low Permeability Post Approval Study (2005-2006) reported a 100% freedom from aneurysm mortality and < 1% type I or type III endoleak during a 2-year follow-up period. The Global Registry for Endovascular Aortic Therapy (GREAT) was established to identify global trends in device usage and to track long-term device performance and patient outcomes. During GREAT's ongoing study, 2,970 patients implanted with a GORE EXCLUDER Device for treatment of an AAA have been enrolled with a 1.3% type I endoleak rate, a 0.2% type III endoleak rate, a 0% migration rate, and 99.1% freedom from aneurysm mortality. This data is based on reported serious adverse events in GREAT. Finally, the newest addition to the GORE EXCLUDER Device family is the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE). The IBE trial, with 63 total patients enrolled from 2013–2015, demonstrated a 0% type I and type III endoleak rate, 0% migration, and 100% freedom from aneurysm mortality.³

Several independent studies demonstrate the durability of the GORE EXCLUDER Device for AAA repair. Goncalves et al reported 144 GORE EXCLUDER patients with treated AAA from 2000-2007, with median follow-up of 5 years, had a low rate of AAA-related mortality or rupture (2.8%), up to 11 years postimplant, and an overall life expectancy after EVAR at 6.8 years.⁸ Maleux et al detailed that 121 AAA patients treated with the GORE EXCLUDER Device between 1998 and 2010 near 5-year (4.98 years) follow-up had an estimated intervention-free survival after 5 and 10 years at 90% and 77.7%, respectively, with no aneurysm rupture during follow-up.⁹ In a 2014 study, Pratesi et al reported on a large, retrospective, nonindustry-sponsored, multisite Italian registry of more than 800 patients with implanted GORE EXCLUDER Devices. Their results included a freedom from all causes of death estimated to be 97.9% at 1 year, 93.4% at 3 years, and 88.5% at 5 years. Aneurysm-related mortality was 1.6%, and freedom from reintervention at 1, 3, and 5 years of follow-up were 98.6%, 94.6%, and 86.5%, respectively. Overall low rates for mortality, migration, reintervention, and limb thrombosis were described in this recent large multicenter study.^{10,11}

ATOMIC CLOCKS AND THE FUTURE OF THE GORE EXCLUDER DEVICE

The past 100 years of clockmaking are analogous to the past 5 years of EVAR with the GORE EXCLUDER Device. The longstanding traditional grandfather clocks were phased out by quartz clocks, which have been phased out by atomic clocks. The piezoelectric properties of quartz revolutionized the clockmaking industry by eliminating gear-based design and allowing for mass-base distribution. The stability and reliability of atomic clocks have since surpassed quartz. For atomic clocks, the cesium atom's natural frequency redefined the internationally recognized unit of time: the second. The days of measuring time to

the nearest quarter hour are long over, as modern market pressures demand more precision in timekeeping.¹²

Precision deployment highlights the future of the GORE EXCLUDER Device platform. The days of hypogastric artery embolization and stent graft coverage have been replaced with the IBE. Preservation of internal iliac artery flow decreases the risk of spinal cord ischemia, impotence, and gluteal/hip claudication. The GORE® EXCLUDER® Conformable AAA Endoprosthesis* (Figure 3) delivery system has been designed to provide angulation control of the proximal endograft and to give physicians the option to bend the device to achieve placement orthogonal to the aortic lumen in short and hostile proximal aortic landing zones. The GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis* (TAMBE) (Figure 4) will aim to treat thoracoabdominal aortic aneurysms involving the visceral branch vessels. Clinical trials are planned for both devices.



Figure 3. GORE® EXCLUDER® Conformable AAA Endoprosthesis.



Figure 4. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.

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

CONCLUSION

The evolution of the GORE EXCLUDER Device for EVAR is comparable to the history of clockmaking, both of which have exhibited disruptive and sustaining design innovation. Numerous independent studies positively demonstrate the durability of this device. Extreme competitive pressures in the EVAR field will require continued improvements and result in better therapy for our patients with aortic aneurysms. As with modern clockwork design, the GORE EXCLUDER Device design, which is based on improved precision, will lead the next generation of endovascular aortic aneurysm treatment.

In this arena, it is all about outcomes. Cumulative data delineated in this manuscript demonstrate very low perioperative morbidity and mortality and excellent protection from aneurysm-related complications with Gore aortic endografts. Superior ease of use, excellent trackability, and rare failure modes characterize the GORE EXCLUDER Device. By addressing the market pressures of clinical demands with aortic endografting, Gore has become a market leader, developing endografts that continue to offer unique advantages. ■

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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.

BY MICHAEL D. DAKE, MD, AND HIMANSHU J. PATEL, MD

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 1999¹ 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.

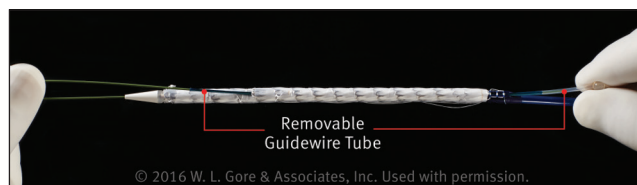


Figure 2. Distal end of the aortic component delivery system with a removable guidewire tube to facilitate guidewire passage through the internal portal. The device is advanced in the aorta over the guidewire exiting the end hole and the second wire placed within the target branch artery.

(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).

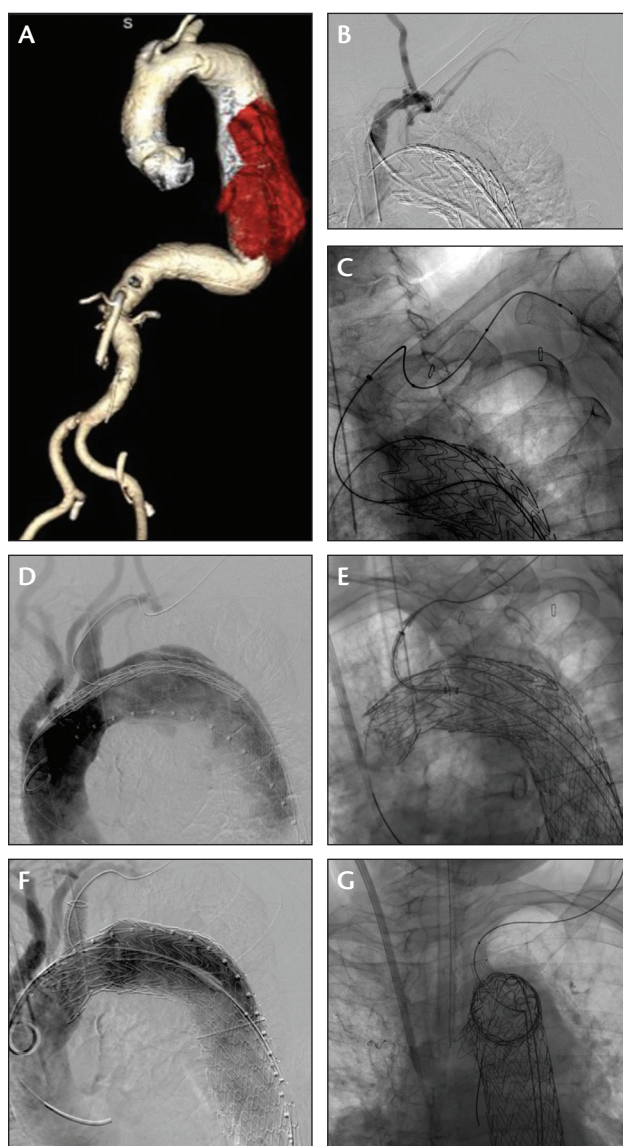


Figure 3. Procedural images depicting deployment of the GORE® TAG® Thoracic Branch Endoprosthesis.

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. ■

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Evolving Endovascular Treatment of Type B Dissection

Two leading centers weigh in on current practice.

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How has your dissection practice evolved with availability of endovascular devices and expanding experience?

Drs. Knowles & Farber, University of North Carolina at Chapel Hill (UNC): Over the last 10 years, the landscape in the management of aortic pathology has changed significantly. Unlike in the infrarenal aorta, devices for the treatment of thoracic pathology have to deal with more complex anatomy and encompass more diverse etiologies including aortic aneurysms, traumatic injuries, penetrating atherosclerotic ulcers, and dissections. The combination of endovascular device proliferation, experience with endovascular aortic surgery, and the improvement of device performance has provided vascular specialists with endovascular options for the management of patients with both complicated and uncomplicated Type B dissections. Improvement in various aspects of endovascular devices include improvements in

fixation, delivery sheath profile reduction, precision with proximal deployment, and conformability within the arch. Furthermore, the use of intravascular ultrasound has allowed for improved safety and efficacy during these procedures by adding information regarding lumen size, septal movement, and confirmation of presence within true lumen. In addition, our increasing understanding of aortic Type B dissections has allowed us to identify patients who are at higher risk for complications or aneurysmal degeneration over time. All these improvements have allowed us to treat more patients with improved outcomes.

Drs. Crawford & Taylor, University of Maryland (UMD): Endovascular technology has allowed interventionists worldwide the opportunity to treat patients whom would have been managed medically in years past. We see and manage all patients with aortic dissection in our

comprehensive aortic center, a multidisciplinary unit with cardiac, vascular, and antihypertensive experts. This has expanded the availability of options. The advent of thoracic endovascular aneurysm repair (TEVAR) has given us the option to be more aggressive in treating all pathologies related to dissection. There is no question that for acute complicated dissection, TEVAR is the preferred method. With increasing experience, the option to treat uncomplicated and chronic dissections with endovascular methods is also gaining favor, as is the idea that because of its excellent safety profile, other pathologies, such as penetrating ulcers and intramural hematomas, should be treated more aggressively when encountered. Our personal experience has evolved in this manner. We have clearly moved from a more traditional approach of “treat complicated cases only” to a posture where we are able to recognize additional factors that push us to intervene sooner.

How does your center ensure efficient flow from diagnosis to treatment of dissections?

Drs. Crawford & Taylor, UMD: We work closely with regional emergency departments across the mid-Atlantic region and have a 24-hour, 365-day call center. Our outreach program is very active in terms of education about dissection. First, we mounted an extensive campaign that started in our emergency department to educate practitioners about the signs and symptoms of aortic dissections. We followed this up with guidelines about the type of imaging modalities that are required for the appropriate diagnosis of the condition. The University of Maryland Medical System is comprised of more than a dozen hospitals coordinated through a central command system (called Express Care). This system permits any hospital in the system access to specialists at our flagship hospital where patients with diagnosed or suspected dissections can be transferred and treated. We advanced our message throughout all the system area hospitals using this structure. The goal is to have outside practitioners think about acute aortic emergencies in patients who they are treating, when appropriate. Members of the Center for Aortic Disease regularly lecture at all hospitals about the need to transfer dissections promptly and to refer chronic patients to our specialized clinic. We have newsletters, a strong website presence, and education campaigns using public radio. We attack this problem in multiple ways.

Drs. Knowles & Farber, UNC: The University of North Carolina Hospital System encompasses a large area in the Southeast United States. The use of an aortic network allows for local or regional education of available aortic pathologies treatment options, facilitates the transfer for acute aortic syndromes, and the referral of nonurgent patients. All dissections are referrals to the vascular surgery service, and all patients are managed by the vascular surgery aortic

team unless they are isolated to the ascending aorta. This management strategy uses a multidisciplinary approach, including intensive care unit intensivists and consultative services for the management of these patients to assist in the management of hypertension and the sequelae of aortic dissections. Diagnosis is primarily through computerized tomographic angiography (CTA) imaging. Repeat imaging is necessary when symptoms do not resolve after appropriate therapy. Surgical (endovascular) repair is typically based on complications related to the Type B dissection, or patients with uncomplicated Type B dissection who are at significant risk for subsequent aneurysmal degeneration or the development of complications. Furthermore, good communication with the patient's outpatient primary care provider for the appropriate medical management is prudent for the avoidance of sequelae related to the Type B dissection and hypertension.

What are the characteristics of dissection patients you treat early with endovascular or surgical intervention?

Drs. Knowles & Farber, UNC: Patients generally fall into three categories: complicated, high risk/uncomplicated, and low risk/uncomplicated. With respect to complicated patients, we initiate early repair for patients with persistent hypertension and/or pain despite best medical management, signs of malperfusion (limb ischemia, visceral ischemia, spinal ischemia), or findings suggestive of rupture or impending rupture. Due to the risk of retrograde Type A dissection, early intervention is only performed for these complicated patients who did not improve with medical management and not for uncomplicated patients.¹ Uncomplicated patients with high-risk morphologic and anatomic characteristics are typically treated during the subacute period (8-12 weeks). These patients have specific predictive prognostic indicators of growth and progression.

Patients deemed to be low risk/uncomplicated are monitored with best medical management and serial imaging with CTA. If there is growth or progression, surgical repair is then considered. We feel strongly that treatment of uncomplicated aortic Type B dissections should occur in patients with these specific predictive prognostic indicators to avoid proximal or distal aneurysmal degeneration or extension of the dissection, as it potentially complicates subsequent repair and increases the morbidity and mortality. A thoracic endograft can typically be placed to cover the proximal entry tear and cause depressurization or thrombosis of the false lumen, and avoid further sequelae from the dissection. Earlier repair can avoid extension into the brachiocephalic vessels proximally or into the visceral vessels distally (Figure 1). If this were to occur, the need for brachiocephalic vessel debranching or visceral vessel branched/fenestrated devices adds to the complexity, morbidity, and mortality of these repairs.

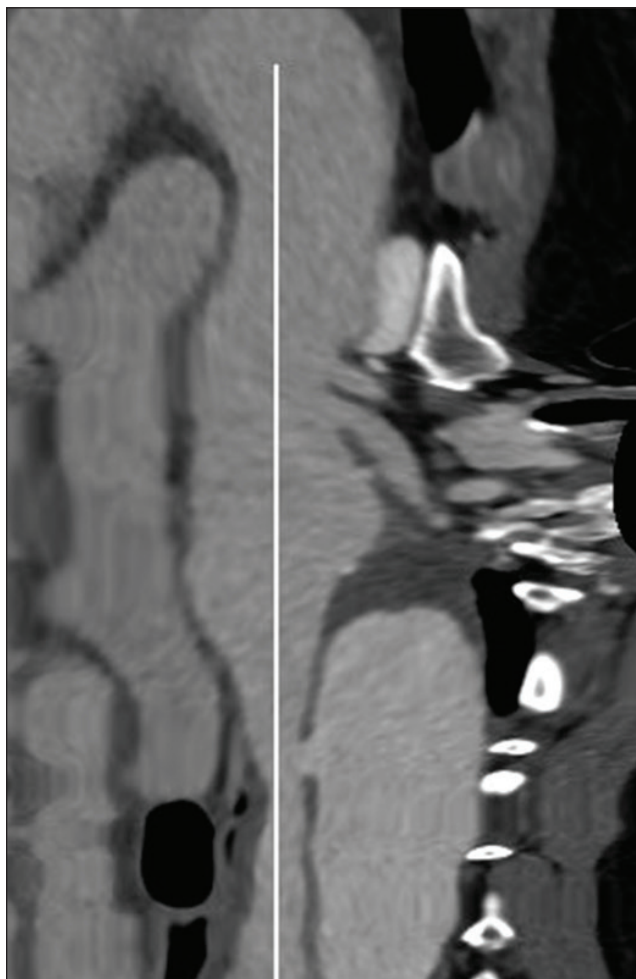


Figure 1. Centerline imaging on Type B aortic dissection with large proximal entry tear and retrograde aneurysm degeneration involving the origin of the left subclavian artery.

Drs. Crawford & Taylor, UMD: The patients we treat early are those who have the following life-threatening features: malperfusion of a limb, spinal cord, intestines, or kidney; rupture; or expansion. Pain and refractory hypertension are no longer considered soft indications. In our experience, these are harbingers of early, continued growth and rupture. Therefore, we treat early in the acute phase if we are concerned that a patient's life or limb is at risk. Consideration to delay is made when the patient has significant coronary disease that must be addressed first or if they have no signs of brain activity. It is safe to say that our approach is an endovascular first approach. Any patient who shows any signs of complications or anatomical features that are worrisome—for example a severely collapsed true lumen feeding mesenteric vessels—is treated early. This is the advantage of the availability of an endovascular approach.

There is another group of patients in whom a preponderance of anatomical and physiological factors (e.g., false lumen configuration, size, aortic size, tear diameter, location of tear, age, location of largest diameter), which

have been discussed in the literature, has prompted earlier treatment. This is a very important area of research. The short answer is that we tend to “cool off” these patients and extend them as much as we can into a subacute period that can range from a few days to a few weeks before treatment. We feel this is an optimal approach that avoids additional complications such as retrograde or antegrade extensions of the dissections, and/or conversion to a complicated pathology. We base this not just on anecdotal data, but also on our own experience in the treatment of patients with similar aortic pathologies (i.e., transections). In this group of patients, delay of treatment when possible decreases the incidence of complication and prevents exacerbations of concurrent pathologies such as head trauma. The benefits of waiting for the acute inflammatory phase to die down is something that has also been seen in the treatment of other acute conditions in orthopedics and general surgery. As the specific indications for earlier treatment of uncomplicated dissections become more well accepted, the issue of the timing will also have to be examined.

How do you define or identify high risk/uncomplicated patients?

Drs. Knowles & Farber, UNC: Uncomplicated dissection patients who have high-risk characteristics are offered repair. Growth > 5 mm during the acute phase (in the first 30 days) is believed to be high risk and should mandate repair between 8 and 12 weeks. In addition, a total aortic size of 55 mm in the chronic phase including the false and true lumen requires repair.² Patients with a large total lumen > 45 mm at 3 months are particularly at risk for further degeneration.³⁻⁵ An enlarged false lumen size measured from the aortic wall perpendicular to the septum > 22 mm,⁶ false lumen thrombus formation,^{7,8} and entry tear size ≥ 10 mm^{9,10} also has been shown to cause degeneration and should prompt repair between 8 and 12 weeks. Type IIIB dissection with extension distal to the left subclavian artery and patients with appropriate landing zones should undergo repair, as proximal and distal degeneration over time could lead to a more complicated repair. True lumen shape can influence the need for repair,^{9,10} such as high-risk patients having completely encircled thrombus. At our institution, 8 to 12 weeks is considered the optimal timing for the endovascular repair of patients with uncomplicated dissections. This timing avoids the early risk of retrograde Type A dissection, but decreases the risk of degeneration and the need for more complicated repair.

Drs. Crawford & Taylor, UMD: We define high-risk, uncomplicated patients as those who have one or more of the following features: total aorta > 4.4 cm, false lumen > 2.2 cm, true lumen ≤ 1 cm, primary entry tear > 1 cm. Young patients, patients with suitable anatomy (e.g., good proximal landing, reasonable chance of distal seal, all vessels coming off true lumen, good access), large total aortic diameter at

presentation, largest diameter at the proximal descending thoracic aorta, or large tear with no outflow are considered for earlier intervention. Just as important, the ability of a patient to have appropriate follow-up and adherence to blood pressure medication regimens is also a factor. The idea of “maximal medical management” is only as good as the adherence to said regimen. There are many patients in whom a reasonable blood pressure goal is hard to achieve despite best efforts from the practitioners and patients. In this group, an early intervention might be protective of a major catastrophe. Finally, we consider when patients have more than one risk factor, or even three. This definitely tips the scale for us in terms of early treatment and is also supported in the literature.

We want to get the patient out of the early “inflammatory phase” of the disease process into a subacute phase. This can take up to 2 weeks. For other reasons, we might treat the patient before they leave the hospital, in which case we allow at least a few days to a week for this process. The optimal timing is still a hot debate topic, but the idea of a cool down period is becoming well accepted.

What are the benefits and risks of stenting a dissection patient? Do the benefits and risks vary by dissection subtype?

Drs. Knowles & Farber, UNC: In our experience, procedural complications and reintervention rates differ between complicated and uncomplicated patients. The risk of stroke, paraplegia, and retrograde Type A dissection all increase with acute complicated repair, especially in the early setting (< 14 days). Morbidity and mortality may be high in patients with acute Type B dissections, with mortality rates in excess of 10% when complications occur.¹¹ We recommend delayed repair of uncomplicated Type B dissections for this reason. This delayed timing decreases the risk of complications without impacting the ability of the aorta to remodel. In addition, dissections involving the visceral aorta are likely to need additional adjunctive procedures, which increases the risk of complications. We allow approximately 3 months to pass in uncomplicated patients to decrease the complications that are associated in the acute phase. Short-term outcomes favor TEVAR compared with open repair with a low mortality rate of 3.2% and a paraplegia rate of 0.4%.¹²⁻¹⁴ There is no extensive long-term data currently available, but we hope that on-going and future studies will provide better guidance on uncomplicated patient management. Some data suggests that in uncomplicated patients, aortic specific survival is improved beyond 5 years in patients who undergo endovascular management compared with those who undergo best medical management.⁹ Long-term outcomes after TEVAR for dissection are related to successful thrombosis of the false lumen and aortic remodeling. Outcomes do appear to be improved in patients with a Type IIIA dissection due to improved complete thrombosis in this group.¹⁵

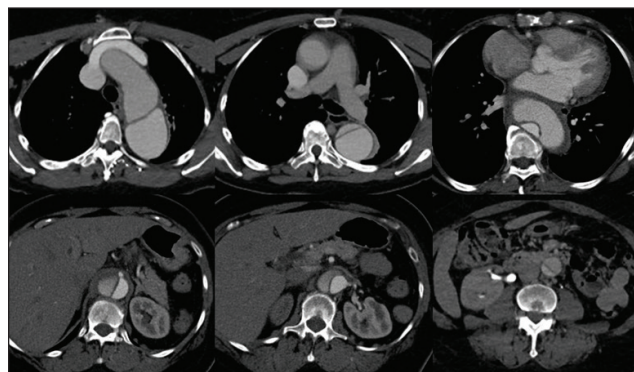


Figure 2. Chronic Type B aortic dissection extending from a tear just distal to the left subclavian artery down into the iliac vessels. Aneurysmal degeneration measuring 6.2 cm (false and true lumen) identified in the proximal descending thoracic artery.

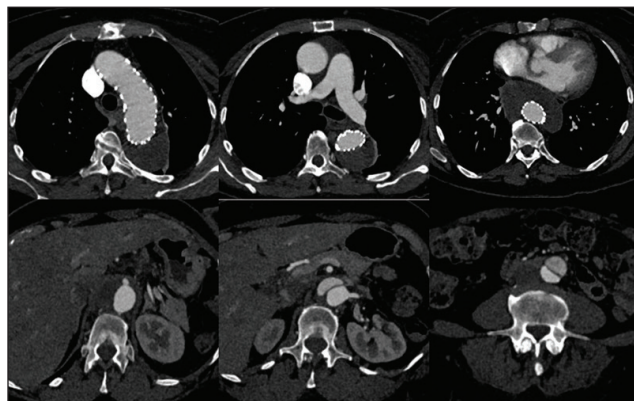


Figure 3. Chronic Type B aortic dissection after repair with a Conformable GORE® TAG® Thoracic Device from the left subclavian to the level of the celiac artery, with complete thrombosis of the false lumen behind the graft. Serial imaging with computerized tomographic angiography will continue to assess for any growth after repair in the thoracic aorta, and in the visceral and infrarenal aorta to ensure degeneration does not occur.

The risk of not intervening in uncomplicated Type B dissections includes the concern that medical management will not be optimal. However, even with best medical management, the dissection can potentially extend either proximally and/or distally, and aneurysm degeneration can occur which will make any repair more difficult. Furthermore, as the dissection propagates, further septal tears can develop that complicates thrombosis of the false lumen with subsequent intervention. A repair prior to the development of propagation that involves a simple endograft to cover a proximal tear will likely depressurize or cause thrombosis of the false lumen and minimize any further sequelae (Figures 2 and 3). With the delay in management, proximal extension of the dissection with aneurysmal changes make brachiocephalic vessel involvement a higher likelihood, which will require a branched endograft, extrathoracic debranching, or

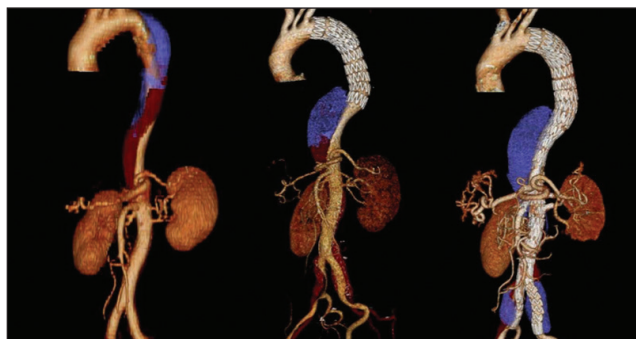


Figure 4. Acute Type B dissection extending to the common iliac vessels. The patient was initially treated for the acute dissection, but developed dilation in the visceral segment. The patient then underwent repair with a 5-vessel custom-made device with excellent result.

debranching from the ascending aorta. The risk to the patient is subsequently much higher with more invasive proximal intervention. The dissection can also propagate distally and develop aneurysmal degeneration into the visceral vessels. This will require fenestrated/branched devices for management of these patients which further increases the risk to the patient (Figure 4).

Drs. Crawford & Taylor, UMD: The benefits of stenting a dissection patient is that the aorta is stabilized. The true lumen expands while flow in the false lumen decreases. The goal is to achieve thrombosis of the false lumen.

In our experience, procedural complications and reintervention rates do not differ between complicated or uncomplicated patients. In general, we prefer to wait if possible until a subacute phase. We believe the risk of retrograde Type A dissection decreases as the acute injury and inflammation phase of a Type B aortic dissection passes. In our hands, we have not seen a flurry of procedural complications related to acute patients. The balance is far in favor of endovascular treatment. We see occasional extensions of dissections in acute patients, however, they are rare. For uncomplicated patients, any complication is important. Practitioners must be very vigilant of their own results when embarking on the endovascular treatment of uncomplicated dissections. A major complication rate of < 2% is a requirement in order to advance a practice centered on these patients. For chronic patients, continued perfusion of the false lumen is the major obstacle we encounter. We have begun to proactively use techniques (e.g., Knickerbocker, coil embolization) to promote false lumen thrombosis. As devices that can treat the visceral segment become commercially available (e.g., distal bare stents, GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis [TAMBE]*), I think this problem might be better tackled. Nonetheless, we are very happy with our ability to treat chronic thoracic dissections using TEVAR.

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

Acute dissections do very well. Our own results show a < 5% major complication rate (paraplegia and death) for this group, with excellent remodeling data. The uncomplicated group treated in the subacute phase does as good or better than the acute group and we attempt to push all patients into this timeframe when possible. Chronic patients have even fewer major complications, but with the caveat of some needing reinterventions for continued aneurysmal growth of the aorta.

The risks of not treating an uncomplicated patient are further expansion of the aorta and late aortic death. Untreated Type B aortic dissection can carry a mortality risk of 40% to 50% at 5 years. Good results can be obtained in patients who respond and adhere to blood pressure control regimens. At the Center for Aortic Disease in Maryland, we have a specialist solely dedicated to treat hypertension in our dissection patients. Follow-up is available and intense. However, compliance is strictly patient dependent, and without it, the best regimen will fail. We have seen a higher than expected proportion of patients back with early complications when treated conservatively. Large rapid growth and extension of the dissection are the most common modes of failure we observe. More importantly, in patients with focal aortic pathologies (intramural hematomas, penetrating ulcers, and chronic pseudoaneurysms) treated conservatively, we see a high failure rate (rupture, readmission for pain, conversion to full dissection). Because of this, we have become very aggressive in this patient population and we tend to treat a high proportion of asymptomatic patients with these pathologies.

What are the trade-offs between early and late treatment?

Drs. Knowles & Farber, UNC: The timing of management for Type B aortic dissections is a balance between the risks of early treatment including retrograde Type A dissection and the risk over time of further degeneration or development of worsening symptoms.¹ Wire manipulation in an early acute aortic syndrome can place the patient at risk for complications. The greatest risk in these patients is within the first few days, and decreases after 2 weeks. The longer the aorta has time to “cool down,” the less likely these complications are to occur. The early timing of repair must also be taken into consideration when assessing the ability to control the patient’s hypertension or improvement of any other symptoms such as limb, visceral, spinal cord ischemia, or rapid enlargement of an aneurysm. The patient should undergo serial imaging, and should undergo imaging with any change in status. Beyond 90 days the risk is unlikely to decrease any further. However, with more extensive delay, the risk of proximal and distal extension of disease with the requirement for a more invasive procedure goes up. This is especially true in patients with high-risk characteristics.

Drs. Crawford & Taylor, UMD: Our approach is guided by how the patient is doing clinically. We don't use days but rather clinical features to guide whether we treat a dissection or not. We look at this in a simpler way at our institution. Complicated and impending catastrophes get treated right away. High-risk uncomplicated patients with poor follow-up or evidence of in-hospital progression (we tend to rescan patients with high-risk features before considering discharge), get treated during index admission. Uncomplicated patients who are reliable and stabilize, or have high-risk features we treat between 2 weeks and 1 month. Otherwise, patients go into our chronic dissection pathway.

How does your center prepare to prevent potential complications such as stroke, paraplegia, and retrograde Type A aortic dissection?

Drs. Crawford & Taylor, UMD: There is a multidisciplinary approach to preventing these complications. For stroke prevention and prevention of retrograde Type A dissection, careful procedural practices are probably the most important. We use caution in the number of times we cross the arch of the aorta with a wire. Stiff wires are exchanged via a catheter and the tips of the wires are carefully monitored. We perform a transesophageal echocardiograph at the end of every case to access the ascending aorta and confirm there is not a retrograde Type A dissection. Clean wire and anticoagulation management are paramount for this issue. For paraplegia management, awareness of the problem is important. At the University of Maryland, we have a liberal spinal drain policy whereby more than 90% of our patients are treated with a spinal drain, especially for any case that requires a piece that is > 15 cm in length or if they have high-risk features (previous abdominal aortic aneurysm repair, aorto-iliac occlusive disease, coverage of T10 area and chronic renal failure) that place them at increased risk of spinal cord injury. Never is a spinal drain more needed than when we decide not to put it in in the first place. We also use neuromonitoring in every case. Post-procedure, all patients are extubated in order to make the neurological examination easier to perform. This we consider is a very important point. We have trained intensive care unit staff who can recognize spinal cord complications, which responds immediately with blood pressure management, additional drainage, and pharmacologic interventions.

Drs. Knowles & Farber, UNC: Our group carefully reviews each case to identify the timing of potential treatment. This is the first step in the avoidance of potential complications. If the patient has a complicated Type B dissection, and early treatment cannot be avoided, care and attention to detail during the procedure is prudent. Intravascular ultrasound and centerline reconstructive imaging should be used to assist in the appropriate sizing of endografts and for the identification of the true lumen. It is critically important to ensure the

leading edge of the prosthesis is in undissected aorta. Careful wire management skills and catheter exchanges can decrease the chance of a retrograde Type A dissection and stroke. Patients with brachiocephalic vessel involvement should undergo CTA imaging of the neck and head to assess collateral circulation and how repair will impact circulation. This imaging of the head and neck also assists in the evaluation of the need to revascularize the left subclavian artery if involved. We feel strongly about revascularization of the left subclavian artery in dissection cases, as typically a large amount of the thoracic aorta requires coverage with an endograft, or develops false lumen thrombosis, and the risk of spinal cord ischemia is higher with coverage of the left subclavian artery. The aggressive use of spinal cord drainage in these patients can decrease the risk of paraplegia, however it is rarely used in emergent malperfusion scenarios when it would result in a significant treatment delay.

What is your practice in dissection patient care and monitoring pre- and post-treatment?

Drs. Knowles & Farber, UNC: Patients with aortic dissections should be managed by physicians in facilities that have the infrastructure to handle the potential complications. Due to familiarity throughout the facility, the more dissections treated at an institution the better the outcomes. The use of spinal drainage should be considered in patients at risk for spinal cord ischemia, and depending on the facility can either be placed preprocedurally or expectantly. Protocols should be in place for emergent placement of a spinal cord drain if you elect to expectantly place them when symptoms arise. The ability to have expedited placement of these catheters needs to be able to occur 24 hours a day, 7 days a week. Any changes in the motor or sensory exam after TEVAR require rapid placement of a spinal cord drain if not already present with removal of cerebrospinal fluid and elevation of the mean arterial pressure > 80 mmHg. Up to approximately 30% of patients with dissection can exhibit ischemia to the spine, lower extremities, or viscera and care must be taken to identify and treat these patients.^{16,17} Patients undergo serial imaging with CTA to follow dissections before and after treatment. Serial imaging examinations should examine the chest/abdomen/pelvis as a whole, as well as an attention to portions of the aorta that did not have coverage of a stent graft, to check for progressive aneurysmal degeneration. Any changes in symptoms should necessitate a new CTA for further evaluation.

Drs. Crawford & Taylor, UMD: All our Type B aortic patients, whether treated with a stent graft or managed medically, are followed in a comprehensive aortic center. Our follow-up consists of a 2-week visit for wound checks and a CTA within 1 month. We add a 3-month scan in order to recognize early aneurysmal degeneration. This is followed by a 6-month and 1-year scan. A dedicated blood pressure

specialist concurrently sees patients and some are plugged into a transitional care program to monitor adherence to blood pressure control regimens. We view this as a lifelong disease state that requires lifelong surveillance. ■

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GORE® EXCLUDER® AAA Endoprosthesis

INDICATIONS FOR USE: Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac / femoral access; Infrarenal aortic neck treatment diameter range of 19–32 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation $\leq 60^\circ$; Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE® EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® AAA Endoprosthesis is contraindicated in patients with known sensitivities or allergies to the device materials and patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions, and adverse events. **Rx Only**

Conformable GORE® TAG® Thoracic Endoprosthesis

INDICATIONS FOR USE IN THE US: The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of all lesions of the descending thoracic aorta, including: Isolated lesions in patients who have appropriate anatomy, including: adequate iliac / femoral access, aortic inner diameter in the range of 16–42 mm, ≥ 20 mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac / femoral access, ≥ 20 mm landing zone proximal to the primary entry tear, proximal extent of the landing zone must not be dissected, diameter at proximal extent of proximal landing zone in the range of 16–42 mm. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients who have a condition that threatens to infect the graft. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions, and adverse events.

INDICATIONS FOR USE UNDER CE MARK: The GORE® TAG® Thoracic Endoprosthesis is indicated for endovascular repair of the descending thoracic aorta. **CONTRAINDICATIONS:** Patients with known sensitivities or allergies to the device materials; patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions, and adverse events. **Rx Only**

GORE® EXCLUDER® Iliac Branch Endoprosthesis

INDICATIONS FOR USE IN THE US: The GORE® EXCLUDER® Iliac Branch Endoprosthesis is indicated for use with the GORE® EXCLUDER® AAA Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: adequate iliac / femoral access; minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; external iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm; internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm; adequate length from the lowest major renal artery to the internal iliac artery to accommodate the total endoprosthesis length, calculated by adding the minimum lengths of required components, taking into account appropriate overlaps between components. **Trunk-Ipsilateral Leg Endoprosthesis Components:** The Trunk-Ipsilateral Leg Endoprosthesis is intended to provide proximal seal and fixation for the endovascular repair of the aneurysm. For more information on the Trunk-Ipsilateral Leg Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions for Use. **Contralateral Leg Endoprosthesis Components:** The Contralateral Leg Endoprosthesis is intended to bridge the GORE® EXCLUDER® Trunk-Ipsilateral Leg Component to the GORE® EXCLUDER® Iliac Branch Endoprosthesis. Additionally, the Contralateral Leg Endoprosthesis is intended to be used for distal extension of the Iliac Branch Component in the external iliac artery. The Iliac Branch Component can treat external iliac artery diameters up to 13.5 mm. This ability to extend the Iliac Branch Component distally with any Contralateral Leg Endoprosthesis expands the external iliac artery treatment range up to 25 mm. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions for Use. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components:** The Aortic and Iliac Extender Endoprostheses can be used after deployment of the GORE® EXCLUDER® Iliac Branch and AAA Endoprostheses. These extensions are used when additional length and / or sealing for aneurysmal exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions for Use*. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials. All components of the GORE® EXCLUDER® Iliac Branch Endoprosthesis and the GORE® EXCLUDER® AAA Endoprosthesis contain ePTFE, FEP, nitinol (nickel-titanium alloy), and gold. Patients with a systemic infection who may be at increased risk of endovascular graft infection. **Rx Only**

INDICATIONS FOR USE UNDER CE MARK: Iliac Branch and Internal Iliac Components. The GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE) is intended to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy, including: Adequate iliac / femoral access; Minimum common iliac diameter of 17 mm at the proximal implantation zone of the IBE; External iliac artery treatment diameter range of 6.5 – 25 mm and seal zone length of at least 10 mm; Internal iliac artery treatment diameter range of 6.5 – 13.5 mm and seal zone length of at least 10 mm. **Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Components.** The Trunk-Ipsilateral Leg and Contralateral Leg Endoprostheses are intended to provide proximal seal and fixation to the GORE® EXCLUDER® Iliac Branch Endoprosthesis following deployment of the GORE® EXCLUDER® Iliac Branch Endoprosthesis. For more information on the Trunk-Ipsilateral Leg and Contralateral Leg Endoprosthesis Component indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis Instructions for Use. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses can be used after deployment of the GORE® EXCLUDER® Iliac Branch and AAA Endoprostheses. These extensions are used when additional length and / or sealing for aneurysmal exclusion is desired. For more information on Aortic Extender and Iliac Extender indications for use and deployment, see the GORE® EXCLUDER® AAA Endoprosthesis *Instructions for Use*. **CONTRAINDICATIONS:** The GORE® EXCLUDER® Iliac Branch Endoprosthesis is contraindicated in: Patients with known sensitivities or allergies to the device materials, and patients with a systemic infection who may be at increased risk of endovascular graft infection. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions, and adverse events. **Rx Only**

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Devices Distributed

Trust is Earned

over
250,000
Patients Treated



For the past **20 years**, through clinical trials, registries, and site-reported use, the GORE® EXCLUDER® AAA Endoprosthesis and the GORE® TAG® Device family have **proven** to be safe, effective, and durable, earning the trust of physicians **worldwide**. As the U.S. **market leader**, we will continue to deliver solutions that you can count on for your EVAR and TEVAR patients.

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