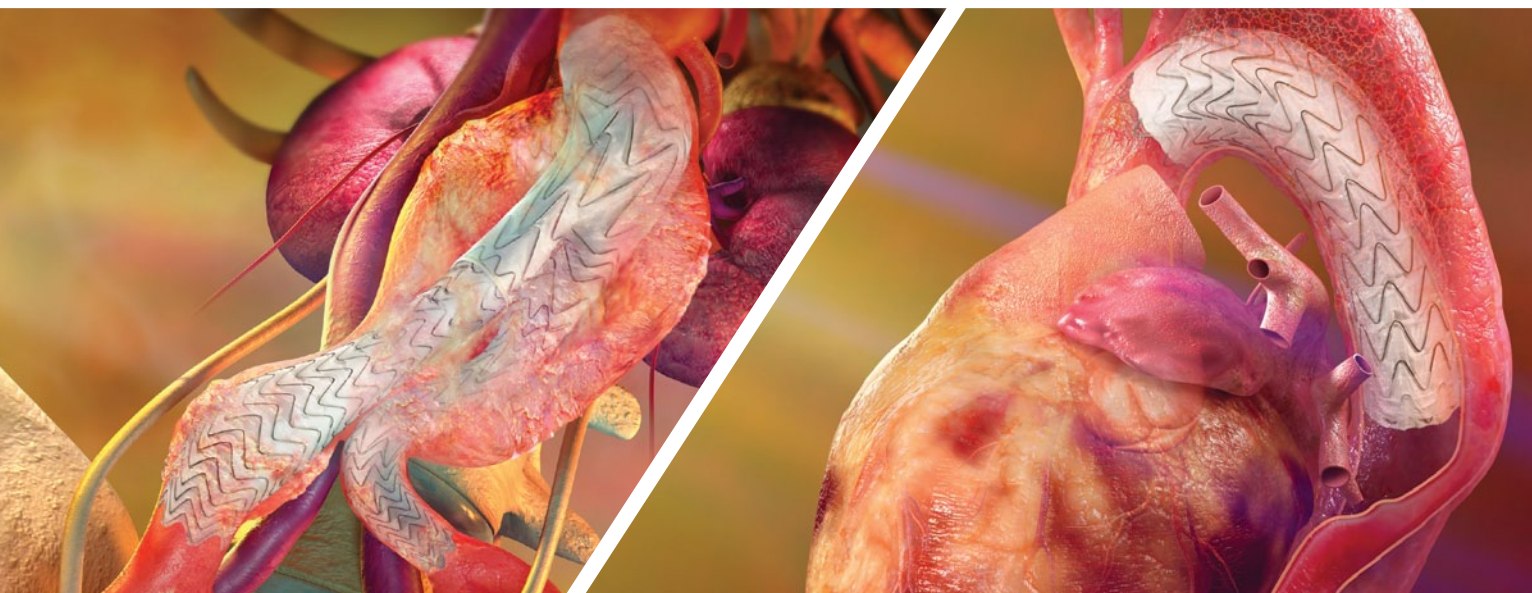


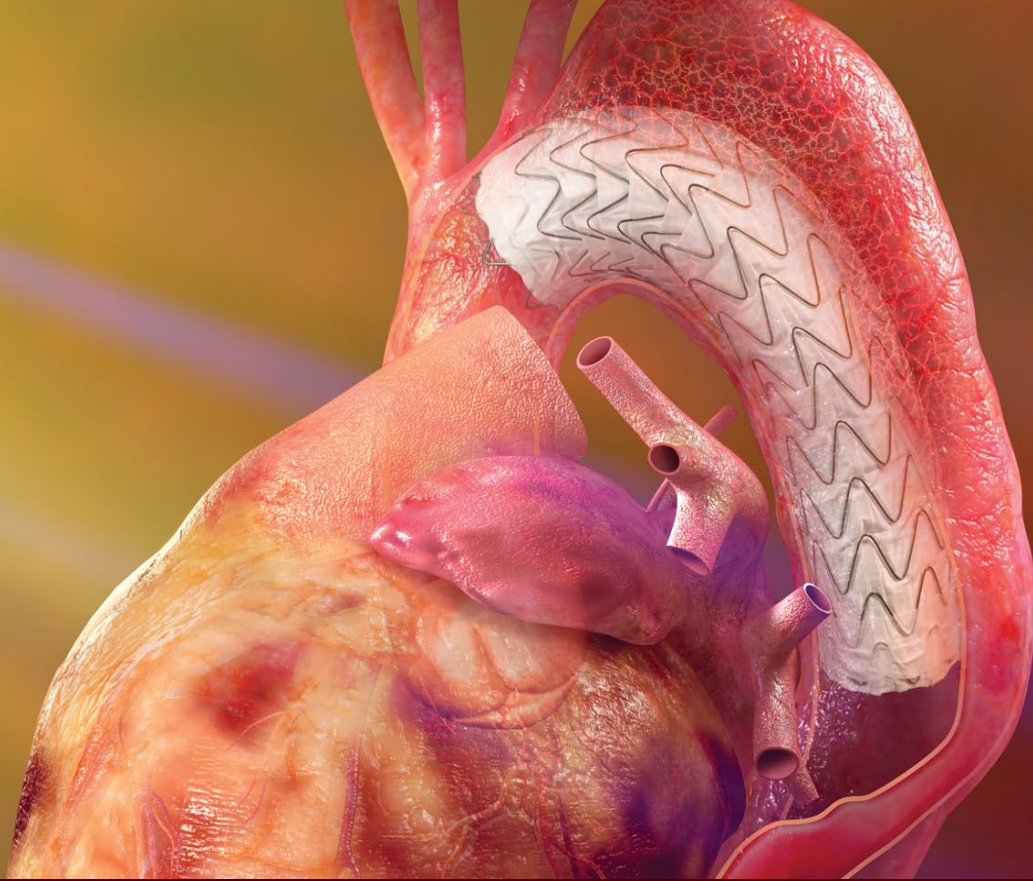
# Endovascular TODAY

February 2014

## PROVEN PERFORMANCE ACROSS INDICATIONS



Utility of the Gore thoracic and abdominal  
suite in challenging anatomies.



# Proven Performance Across Indications

Utility of the Gore thoracic and abdominal suite in challenging anatomies.



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# The Gore Global Registry for Endovascular Aortic Treatment (GREAT)

Real-world experience in Brazil and worldwide with the GORE® EXCLUDER® AAA Endoprosthesis, GORE® C3® Delivery System, GORE® TAG® Thoracic Endoprosthesis, and Conformable GORE® TAG® Thoracic Endoprosthesis.

BY PIERRE GALVAGNI SILVEIRA, MD, PhD; GUILHERME BARBOSA LIMA, MD; RAFAEL NARCISO FRANKLIN, MD; CRISTIANO BORTOLUZZI, MD; AND GILBERTO DO NASCIMENTO GALEGO, MD, PhD

At 8,514,877 km<sup>2</sup> and with 203,429,773 people, Brazil is the largest country in South America. Eighty-seven percent of its population lives in urban areas, with a life expectancy of 68.97 and 76.27 years for men and women, respectively. According to the Brazilian Ministry of Health (DATASUS), cardiovascular diseases account for 31.5% of all deaths, the highest mortality rate for cardiovascular diseases in the Americas, representing 286 deaths per 100,000 inhabitants per year; the United States has 179 deaths per 100,000 per year. These rates are at epidemic proportions, becoming an emerging concern and a priority for the Brazilian Ministry of Health.<sup>1</sup>

The prevalence of aortic aneurysm disease in Brazil is similar to that in the occidental world, affecting 5% of men over age 65. In 2012, approximately 10,000 patients were treated for aortic aneurysms, and less than 50% underwent endovascular techniques.<sup>1</sup>

Recent studies have shown that approximately 65% of all abdominal aortic aneurysm repairs in the United States were performed through endovascular techniques, while in Europe, the average is 40%.<sup>2</sup> Due to new advances and technologies, the trend has been a rise in endovascular aneurysm repair (EVAR) coming closer to being the first choice for aneurysm repair.

The GORE EXCLUDER Device and GORE TAG Device (Gore & Associates, Flagstaff, AZ) have been commercially available for more than 15 years and 13 years in Brazil with more than 750 GORE EXCLUDER Devices featuring C3 Delivery System and 3,500 GORE TAG Devices and Conformable GORE TAG Devices implanted through 2012.<sup>3,4</sup>

The Gore Global Registry for Endovascular Aortic Treatment (GREAT) was designed to evaluate real-world

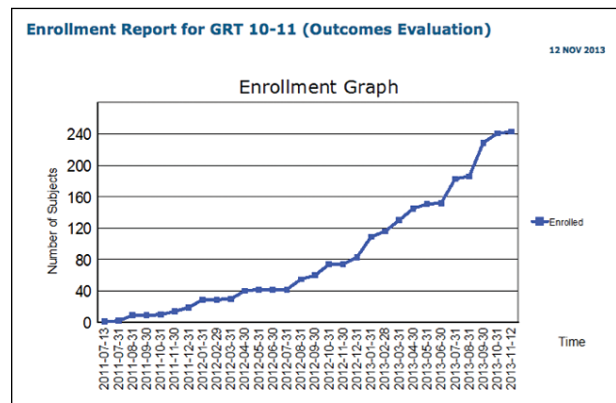


Figure 1. Gore GREAT registry–Brazil enrollment, as of November 2013.

outcomes after treatment with aortic endovascular products (GORE EXCLUDER Device, GORE C3 Delivery System, GORE TAG Device, and Conformable GORE TAG Device) used in global markets (United States, Europe, Australia, and Brazil) and to identify the trends of on-label and off-label use of the devices. In order to reach this goal, the Internet-based registry will collect data from 10 years of follow-up on 5,000 patients from up to 300 sites worldwide.<sup>5</sup>

This is the first time that Brazil has participated in a global, multicenter registry for aortic stent-grafts.

## THE GREAT REGISTRY IN BRAZIL

Ten institutions located in seven states were selected for the Gore GREAT registry–Brazil. Recruitment of consecutive patients began in July 2011. The Gore

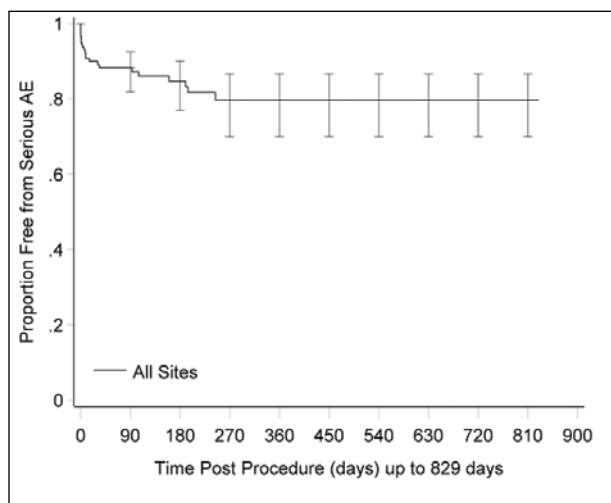


Figure 2. The Kaplan-Meier curve for freedom from serious adverse events.

GREAT-Brazil enrollment target was 300 patients by the end of 2013. In November 2013, we stood at 243 patients (Figure 1).

Within the 243 patients enrolled so far, 80.4% were men, 75% were white, and the mean age was 68.9 years old (median 70; range, 42–87). Primary pathology indicating treatment was abdominal aortic aneurysm (61.8%), followed by descending thoracic aortic aneurysm (16.9%), common iliac aneurysm (11.2%), thoracoabdominal aneurysm (5.1%), type B uncompli-

cated dissection (4.5%), and others. Eighty-three percent of the GORE TAG Thoracic Endoprostheses were used outside the instructions for use (IFU), as were 55% of the placed Conformable GORE TAG Thoracic Endoprostheses, and 47.3% of the deployed GORE EXCLUDER AAA Endoprostheses. Cases treated with GORE EXCLUDER AAA Endoprostheses were challenging in 17.1% (proximal neck length < 1.5 cm and/or those with infrarenal neck angle > 60°).

Among the procedures, 91% were primary endovascular repair, 5.1% were reintervention after open repair, and 3.9% were reintervention after endovascular repair. Cutdown was performed in 95.6% of the cases, and percutaneous access was performed in 15% of the cases. Procedural survival rate was 100%, and mean hospital stay was 7.8 days (median 4; range, 1–82).

The 30-day mortality rate was 3.9%. Stroke/transient ischemic attack (considered serious adverse events), paraplegia/paraparesis, reinterventions, conversion to open repair, and device-related reinterventions are outlined in Table 1. The Kaplan-Meier curve for freedom from serious adverse events is shown in Figure 2.

**THE GORE GREAT REGISTRY WORLDWIDE**

Among enrolled patients worldwide (N = 909 at data export in November 2013), 83.2% were men, and the mean age was 72.3 years. The majority of treatment indication was abdominal aortic aneurysm (79.4%), followed by descending thoracic aortic aneurysm (6.4%),

**TABLE 1. GORE GREAT REGISTRY—BRAZIL**

Key Outcomes Since Initial Procedure Across Analysis Windows						
	Procedure	1 Month	6 Months	1 Year	2 Years	Total (Procedure–2 Years)
All Reinterventions <sup>1</sup>	0 (0%)	4 (3.1%)	2 (2.0%)	0 (0%)	0 (0%)	6 (3.3%)
Device-Related Reinterventions <sup>1</sup>	0 (0%)	2 (1.6%)	2 (2.0%)	0 (0%)	0 (0%)	4 (2.2%)
Number of Subjects With Any Follow-Up and/or Event <sup>2</sup>	180	127	101	44	4	180
Subjects With Any Event Below	2 (1.1%)	8 (6.3%)	6 (5.9%)	0 (0%)	0 (0%)	16 (8.9%)
Mortality	0 (0%)	5 (3.9%)	4 (4.0%)	0 (0%)	0 (0%)	9 (5.0%)
Stroke/TIA <sup>3</sup>	1 (0.6%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	2 (1.1%)
Paraplegia/Paraparesis/Spinal Cord Ischemia <sup>3</sup>	1 (0.6%)	1 (0.8%)	0 (0%)	0 (0%)	0 (0%)	2 (1.1%)

*Analysis time window definitions: Procedure (0 day), 1 Month (1–59 days), 6 Months (60–240 days), 1 Year (241–545 days), 2 Years (546–910 days), 3 Years (911–1,276 days), 4 Years (1,277–1,641 days), 5 Years (1,642–2,006 days), 6 Years (2,007–2,371 days), 7 Years (2,372–2,736 days), 8 Years (2,737–3,101 days), 9 Years (3,102–3,466 days), 10 Years (3,467–3,831 days)*

<sup>1</sup> 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.  
<sup>2</sup> Subjects are counted in the denominator if either had any reported date of contact ≥ start of window and/or reported event in the window; all subjects with initial procedure date are counted in Procedure and Total windows.  
<sup>3</sup> Only those considered serious adverse events.

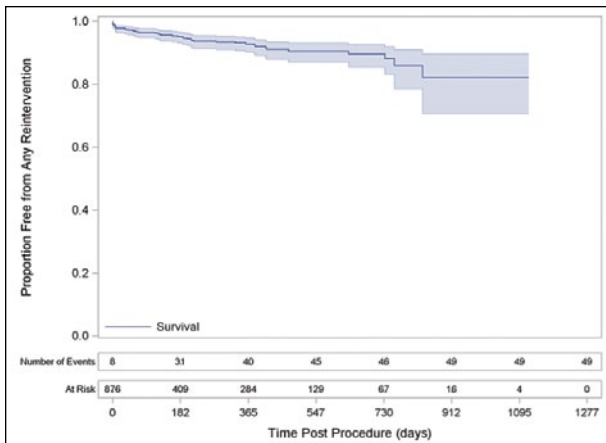


Figure 3. Kaplan-Meier curves for patients free from any reinterventions. The shading represents the confidence intervals.

and common iliac aneurysm (6.2%). Other treatment indications were found in 2% of the cases and included abdominal aneurysm rupture, aortic dissection, internal iliac aneurysm, and others. For abdominal aneurysm, only a GORE EXCLUDER Device was placed in 99% of the cases; in the remaining cases, a GORE EXCLUDER Device and GORE TAG Device were used. For descending thoracic aortic aneurysm, only a GORE EXCLUDER Device was placed in 1% of the cases, a GORE TAG Device was placed in 94.7%, and a GORE EXCLUDER Device and GORE TAG Device were placed in 3% of the cases. Finally, for common iliac aneurysms, only a GORE EXCLUDER Device was placed in 96% of the procedures. The GORE TAG Thoracic Endoprosthesis was used outside the IFU in 76.5% of the cases that it was placed; the Conformable GORE TAG Thoracic Endoprosthesis, in 54.5%; and the GORE EXCLUDER AAA Endoprosthesis, in 49.4%.

The procedures were performed as primary treatment in 95.1% of the cases, whereas the remaining were reinterventions after previous endovascular or open surgical repair. Percutaneous access was performed in 33.4%; cutdown was used in 75.6% of the cases. There was no perioperative death. Endoleak rates after the procedure were 0.2% for type IA, 0.1% for type IB, and 0% for type III. At 1 year, rates were 0% for type IA, 0% for type IB, and 0% for type III. At 2 years, rates were 0% for type IA, 0.8% for IB, and 0% for type III. No migration or fracture of the device was identified through 2 years of follow-up.

Kaplan-Meier curves for patients free from any reinterventions and patients free from device-related reintervention are as shown in Figure 3 and Figure 4, respectively. Any reinterventions were defined as any invasive or minimally invasive measure related to the initial aortic procedure performed at any time following the initial procedure. Device-related reinterventions were defined

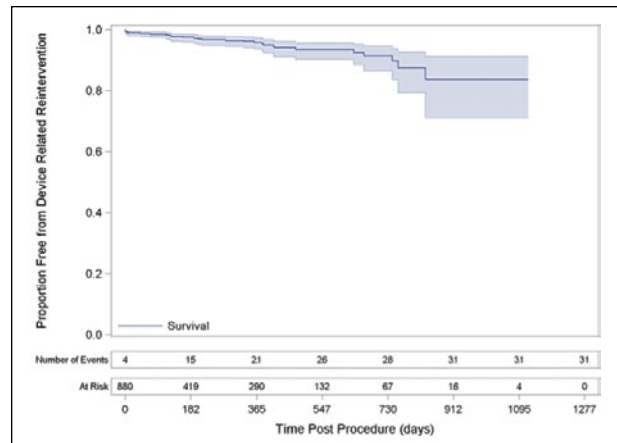


Figure 4. Kaplan-Meier curves for patients free from device-related reintervention. The shading represents the confidence intervals.

as 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.

### CONCERNS

Endovascular approaches for aortic disease repair have been used extensively in recent years. Even though published patient outcomes and device performance confirmed good results, these procedures were mainly performed in high-volume centers and do not disclose the real-world reality. Furthermore, despite the fact that procedural success could match these data, it is crucial to compare long-term outcomes. Bearing in mind this possible imparity, the Gore GREAT registry may have a distinctive role because it is able to evaluate worldwide outcomes and is also capable of comparing real-world experience with high-volume center results, including 10-year follow-up.

Regarding the Gore GREAT registry–Brazil, concerns about the reliability of patient information were raised because it is the first time Brazil is participating in a global, multicenter registry with aortic stent-grafts. However, we cannot lose sight of the fact that Brazil is the largest country in South America, representing a significant portion of the global stent-graft market and with great growth potential, and it is therefore an important section of the real-world results. Moreover, being part of a worldwide trial is the most efficient method of learning and training research centers to achieve levels of excellence. This feature becomes even more important when we realize that the real-world results will only be truly reliable when the enrollment of patients is equal to the proportion of procedures performed worldwide; even if this is unlikely to happen, we need to keep moving in this direction.

Concerning the Gore aortic endovascular devices, we must remember that an essential aspect of endovascular

procedures is the accuracy of the device deployment. The redesigned GORE EXCLUDER Endoprosthesis featuring C3 Delivery System allows repositioning of the stent-graft, ensuring higher precision on the endograft placement.<sup>6,7</sup> The newer design of the Conformable GORE TAG Device allows a better accommodation in the aortic arch, especially with tight aortic arches and smaller aortic diameter, decreasing endoleak rates.<sup>8</sup> Such improvements in endovascular devices are leading us to their widespread application and oftentimes with off-label use. This is a great feature for many patients, but it can also induce problems and complications. To date in Brazil and worldwide, outcomes show that the GORE EXCLUDER Device and Conformable GORE TAG Device are safe and effective, presenting low rates of serious adverse events and reintervention when we analyze the Kaplan-Meier free-from-device-related-reintervention curve (Figure 4). Nevertheless, even with documented favorable outcomes, surgeons should be aware that troubles could arise, especially when the devices are used outside the IFU.

## CONCLUSION

Initial Gore GREAT registry results demonstrate that Gore aortic endovascular devices are secure and offer advantages, particularly with the GORE C3 Delivery System, which allows device repositioning, and the Conformable GORE TAG Device, which permits better accommodation to the aortic arch. Such improvements in device technology have clearly increased off-label use as surgeons become more confident with endovascular procedures. Although this is lifesaving for many patients, it may cause problems and complications, therefore endovascular devices should not be misused.

Despite the criticism against registry studies regarding possible bias and lack of methodological rigor, the snapshot gained gives us a true landscape of EVAR and TEVAR results in the real world. A 10-year follow-up

registry, such as the Gore GREAT registry, will provide important real-world data from across the globe. ■

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# Conformability in Aortic Type B Dissection

Clinical experience with the Conformable GORE® TAG® Thoracic Endoprosthesis.

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HENDRIK VON TENGG-KOBLIGK, MD; MORITZ S. BISCHOFF, MD

According to an International Registry of Acute Aortic Dissections (IRAD) update and the interdisciplinary expert consensus document on management of type B aortic dissection, patients with acute (first 2 weeks), complicated dissections have a 17.5% to 28.6% risk for early mortality after open surgery, 10.2% after thoracic aortic endovascular repair (TEVAR), and up to 6.4% under best medical treatment.<sup>1,2</sup> There were limited data for the treatments of subacute dissections (2 to 6 weeks after onset), with 2.8% mortality after TEVAR and 6.6% in chronic type B dissections. Within the last group of chronic type B dissection, there is increasing evidence with the recently published INSTEAD 5-year results showing a benefit of TEVAR for all end points between 2 and 5 years, with improved 5-year aorta-specific survival and delayed disease progression. The authors concluded that in stable type B dissections with suitable anatomy, preemptive TEVAR should be considered to improve late outcomes.<sup>3</sup>

Therefore, aortic dissections are increasingly treated with endovascular therapy as first-line management. Until recently, endovascular therapists were forced to use stent-grafts that were originally designed to treat aneurysmal disease in descending pathology. Type I endoleak, retrograde dissection, and graft collapse occurred due to a lack of apposition of the proximal stent-graft along the inner curvature of the aortic arch.<sup>4</sup> The Conformable GORE TAG Endoprosthesis (Gore & Associates, Flagstaff, AZ), launched in 2010, is the latest addition to the armamentarium of stent technology, with a special design to cope with challenging anatomies such as aortic dissections. The Conformable GORE TAG Device addresses the issue of conformability and allows for successful treatment of patients with excellent technical and clinical results.

Improvements in technology continue to expand the indications for endovascular repair of aortic arch pathologies. In this article, we present two cases, in which we used the newer generation Conformable GORE TAG Endoprosthesis for successful endovascular treatment of complicated aortic type B dissection and discuss the importance of conformability of stent-grafts while treating these challenging arch and descending aortic anatomies.

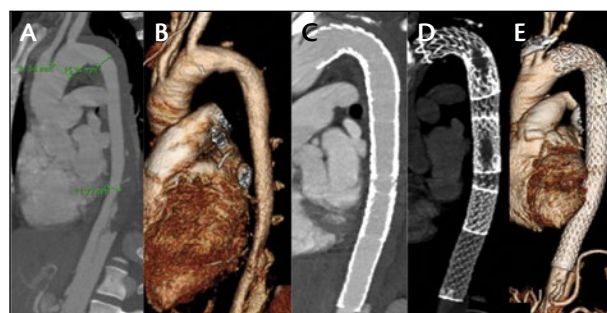


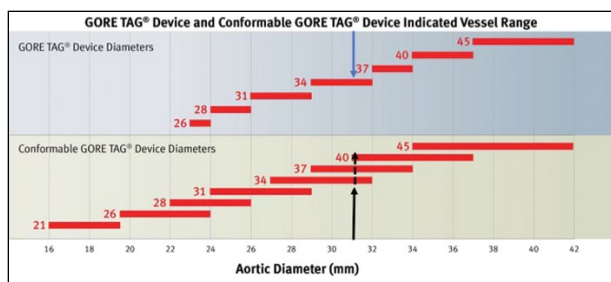
Figure 1. Preoperative CT scan of the gothic arch with proximal intramural hematoma, aortic wall bleedings, and distal dissection (A,B). The remodeled aorta after implantation of four Conformable GORE TAG Devices (C-E).

## CASE 1

A 45-year-old woman (log EuroSCORE 7.06) with a history of untreated arterial hypertension was admitted with a primary episode of chest pain. She reported a 15-minute transient period of paraparesis 2 hours before hospital referral. Contrast-enhanced computed tomography (CT) angiography revealed an acute uncomplicated type B aortic dissection at the time of admission in the emergency room. The CT scan showed intramural hematoma and isolated aortic wall bleeding in the proximal descending aorta and a dissected membrane in the thoracoabdominal aortic segment. The patient continued suffering from refractory chest pain and hypertensive episodes under a four-medication intravenous antihypertensive therapy, including  $\beta$ -blockade. A repeated CT-scan showed ongoing and additional intramural aortic bleeding, enlargement of overall aortic diameters at all aortic levels, and developed left-sided pleural effusion. TEVAR was indicated.

Morphological challenges included small access iliac arteries of 5 to 6 mm, a gothic arch (type 3), a hypoplastic right vertebral artery, a zone 3 proximal landing, a long intended treatment length of 290 mm (for coverage of the entire descending aorta) and a significant taper between the proximal (24 mm) and distal landing zones (12 mm) (Figure 1A and 1B). The implantation strategy included cerebrospinal fluid drainage, general anesthesia, left subcla-





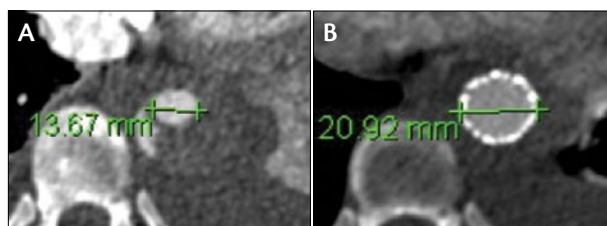
**Figure 2.** The sizing chart shows oversized windows from the former GORE TAG Device (above, grey) and the Conformable GORE TAG Device (below, green). For example, selecting a GORE TAG Device for an aortic diameter of 31 mm results in a 34-mm device (blue arrow), whereas with the Conformable GORE TAG Device, the users can choose a 34-, 37-, or 40-mm device diameter (black arrow).

vian artery transposition, right transfemoral access, transesophageal echocardiogram-guided stent-graft positioning and controlled deployment under rapid pacing. To treat all multiple-level bleeding and to remodel the dissected descending aorta, four Conformable GORE TAG Devices were selected according to the instructions for use sizing guidelines (Figure 2), employing tapering configurations to stay within a 10% oversizing window. The procedure was uneventful and completed as planned. The postoperative CT scan showed total remodeling and high conformability in the arch (Figure 1C–1E, Figure 3). The patient was discharged on day 7 without neurological adverse events.

## CASE 2

A 61-year-old man was admitted with a complicated subacute type B aortic dissection after conservative treatment in a referring hospital. He suffered from claudication due to true lumen compression of a dissected common iliac artery and was treated with a self-expanding stent. On the primary CT scan, there was a large primary entry and several thoracic distal tears causing true lumen compression (Figure 4). Due to ongoing hypertension despite triple intravenous antihypertensive medication and early expansion of the false lumen seen on a control CT scan on day 14, the patient was scheduled for TEVAR. A carotid-subclavian bypass graft was inserted and two Conformable GORE TAG Devices (40-mm X 20-cm and 40-mm X 15-cm) were implanted.

After placement of the first proximal stent-graft, an intraoperative angiogram showed a persisting true lumen compression of the visceral aortic segment. With the deployment of a second device covering the distal thoracic reentries, the true lumen of the abdominal aorta partially hemodynamically remodeled, with hemodynamic improvement of the distal outflow (Figure 4A and 4B). A bare stent was implanted in the dissected left renal artery (Figure 4C). The patient was discharged on the seventh postoperative day.



**Figure 3.** Axial views on the preoperative CT scan show true lumen compression (A). The postoperative CT angiogram showed at the same aortic level an expanded aortic lumen after implantation of a 21-mm Conformable GORE TAG Device (B).

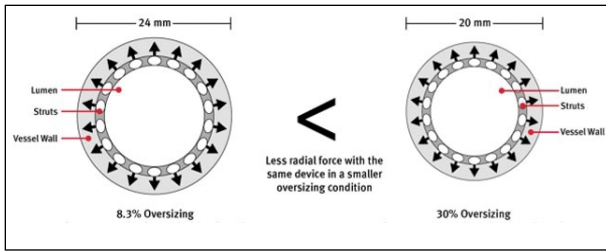


**Figure 4.** The intraoperative digital subtraction angiogram showed permanent true lumen compression of the infrarenal aorta after implantation of the first Conformable GORE TAG Device (A) and partial remodeling with optimized perfusion after the second device (B). Simultaneous renal stenting may be necessary in impaired renal inflow (C).

## DISCUSSION

The Conformable GORE TAG Device is the company's latest thoracic stent-graft and was specifically designed to conform to the geometry of the aortic arch.<sup>1</sup> Commercially available thoracic devices were initially derived from prototypes used years before in the infrarenal aorta.<sup>5,6</sup> In the early beginnings of TEVAR, thoracic devices performed well in the descending thoracic aorta, but experienced difficulties accommodating to the challenging anatomy of the aortic arch, especially in those morphologies in which the radius of the arch's curvature was very tight, or a so called *gothic arch*. Rigid devices have caused perforations in the arch and have been implicated in the conversion of type B to type A aortic dissections with disastrous consequences.<sup>7,8</sup> Stent-grafts that do not conform to the contours of the aortic arch can extend into the lumen at the inner curvature of the arch, forming a bird beak on imaging.

The length of the graft that is not in contact with the aorta is related to a certain risk of device collapse. This phenomenon can cause hypertension, sudden aortic occlusion, or even death. Traditional device collapse is a problem that has been reported in the past with all stent-grafts used in the thoracic aortic arch.<sup>9</sup> Failure to comply with the arch anatomy has been investigated in animal models<sup>10</sup> and in clinical settings, and it may increase the

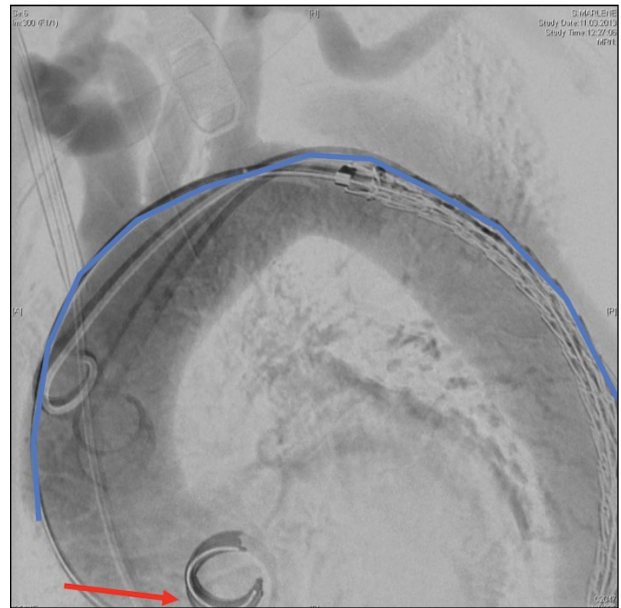


**Figure 5. The association of radial force and oversizing according to device diameter.**

risk of type I endoleak. This continues to be a significant problem in endovascular arch procedures and, when untreated, may result in treatment failure.

The Conformable GORE TAG Device is one of the first compliant devices to be specifically designed for the arch. Features include flared scallops at the proximal and distal end of the device that have been replaced by a small, proximal, partially uncovered stent that is consistent in diameter and outward force as the rest of the device. The partially uncovered stents range from 3 to 6.5 mm in length depending upon the diameter of the device. The most proximal part of the fabric that covers the device is marked with a gold band, which is easily visible under fluoroscopy. Distally, the device has no scallops, with the graft material covering the stent right up to the end of the device, which is also marked with a gold ring. The diameter of the nitinol wire is increased to optimize the radial force. The nitinol is a single piece of wire that continues in a spiral throughout the length of the device. An extra apex was added so that each circumference has nine apices, compared to eight in the original GORE TAG Device; this helps to distribute the point load. When placed in a curved position, the device shows no tendency to straighten and stays in its given conformation, enabling a stable position in the aortic arch after deployment with minimal spring-back force exerted on the anatomy. The reduction in length of the inner curvature is achieved by telescoping consecutive segments in the inner radius of the device throughout its length.

Compared with the original GORE TAG Device, the oversizing window was increased and now ranges from 6% to 33% depending on the diameter and shape of the device (Figure 2). The smallest device diameter is 21 mm, which is intended for use in aortic diameters ranging from 16 to 19.5 mm. This can be used to safely treat young patients with small aortic dimensions who present with traumatic aortic transection. This small device passes through an 18-F sheath. The increased oversizing windows allow a patient with a 31-mm diameter aorta to be treated with three possible Conformable GORE TAG Devices: 34 mm, 37 mm, and 40 mm. This is important as a patient with a dissection could be treated with minimal oversizing using a 34-mm device, whereas a



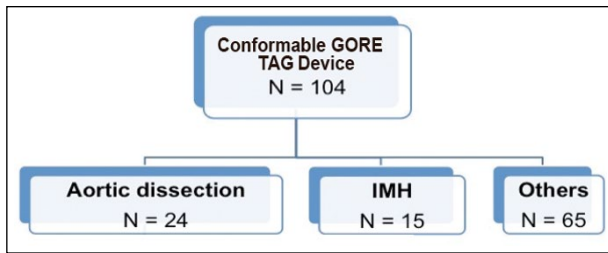
**Figure 6. During placement of the Conformable GORE TAG Device, appositioning on the outer curvature (blue line) over a double curved stiff wire in the ascending aorta (red arrow) is mandatory and ensures accurate device deployment.**

patient with an aneurysm could be treated safely with a 40-mm device. Previously, this patient anatomy could only be treated with a 34-mm GORE TAG Device due to the relatively narrow oversizing windows of that device (Figure 2).

Two tapered devices are also available: a smaller diameter of 26 mm at the proximal end decreasing to 21 mm distally, and a larger 31-mm diameter that decreases to 26 mm distally. These may be useful in treating patients with large size discrepancies in the proximal and distal landing zones.

### THE CONCEPT OF CONFORMABILITY

The Conformable GORE TAG Device achieves conformability with a combination of radial force (ie, the amount of force the device applies to the vessel wall due to oversizing) (Figure 5), device flexibility (minimum bend radius), and spring-back force (amount of force the device exerts on the aortic wall due to device straightening). Ideally, users like to see a device appose the entire circumference of the aorta with enough radial force to provide a seal without adversely affecting the vessel wall with excessive force. This is especially necessary in fragile aortic wall conditions such as acute dissections or traumatic transections. A device is only able to appose the wall along its entire surface if it has features that permit adaptability within the aorta. The Conformable GORE TAG Endoprosthesis is a key example of a device's adaptability with an expanded oversizing range that can accommodate a larger treatment range of pathologies with a single device (Figure 2).



**Figure 7.** Flow chart of the single center experience at the University Hospital of Heidelberg, Germany; 104 patients were treated with the Conformable GORE TAG Device from October 2009 to October 2013.

There are several reasons the Conformable GORE TAG Device is our preferred device in patients with aortic dissections:

1. The radial fit of the Conformable GORE TAG Device manages a range of diameters without losing radial apposition. In each pathological process, the aortic wall behaves differently upon manipulation with endovascular devices, so the most appropriate radial force needs careful consideration.
2. The expanded treatment ranges are also important when considering tapered aortic anatomy in acute settings (such as Case 1) or in chronic dissections where the dissection membrane is fixed, and closing entry tears is the primary goal, rather than complete aortic remodeling.
3. Radial fit improves conformability for sealing in territories that were previously considered hostile because of tortuosity, including difficult landing zones, such as zone 2 proximal to the left subclavian artery.
4. Precise and accurate placement is achieved using a double curved stiff wire in the ascending aorta and stabilizing the device on the outer curve by maintaining forward pressure on the wire during deployment (Figure 6).
5. The device has now been approved by the US Food and Drug Administration for all lesions of the descending thoracic aorta, including thoracic aneurysm, aortic transection, and all type B aortic dissections.
6. Our technical results and consequently the clinical results with the Conformable GORE TAG Device in more than 100 patients are very encouraging (Figure 7).

## CONCLUSION

Treatment and endovascular repair of aortic dissection remains challenging. The question of which patients benefit most<sup>11</sup> is addressed by randomized trials such as INSTEAD and ADSORB.<sup>3,12</sup> The question of which device to use remains to be answered by the user, who must choose the most appropriate device for his patient. The Conformable GORE TAG Device, along with multiple

other devices, underwent numerous design modifications in order to address the morphological demands of the aortic arch. Endovascular management is only as successful as the devices we implant. The two cases reported here demonstrate the concept of conformability of the Conformable GORE TAG Device. Moreover, the conformability of the Conformable GORE TAG Device allows for the use of the device in a disease- and anatomy-specific manner, which is very important for dissections. These refinements of existing commercial devices will most likely continue to improve patient outcomes. However, further data are needed to establish mid- and long-term durability and whether these encouraging outcomes will be maintained.

The Conformable GORE TAG Device represents a new development resulting in compliant devices that are specifically designed for the aortic arch and is, at least in our hands, very useful, effective, and our first choice in the treatment of acute, subacute, and chronic dissections. ■

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# Device Selection and Case Planning for the Treatment of Type B Dissections With the Conformable GORE® TAG® Thoracic Endoprosthesis

What to know regarding stent-graft sizing and patient selection for successful endovascular management.

BY MARTYN KNOWLES, MD; M. SHADMAN BAIG, MD; AND CARLOS H. TIMARAN, MD

In recent years, the field of endovascular surgery has revolutionized the treatment of patients with acute and chronic type B dissections. Acute type B dissections are associated with significant morbidity and mortality related to complications that occur due to visceral malperfusion, paraplegia, limb ischemia, and retrograde dissection due to the unruly extension of the dissection flap. Thoracic stent-grafting has, in recent years, been utilized for the management of acute and complicated type B dissections with favorable results in comparison to open repair. Additionally, the INSTEAD XL trial has shown that thoracic stenting can improve outcomes in uncomplicated chronic type B dissections. Recently, the US Food and Drug Administration (FDA) approved the Conformable GORE TAG Endoprosthesis (Gore & Associates, Flagstaff, AZ) for use in aortic dissections—the first stent-graft to receive this approval. Device sizing and careful planning with consideration of patient-specific anatomy, dissection extent, need for brachiocephalic artery coverage, and location of tears all have to be taken into consideration for a successful repair.

## BACKGROUND

A type B dissection is an intimal tear that develops distal to the left subclavian artery. Conversely, a primary intimal tear in the ascending aorta defines a type A dissection, which is a surgical emergency requiring ascending arch replacement. Type B dissections are broken into acute (< 2 weeks duration) and chronic. Patients with acute aortic dissection usually complain of excruciating, sharp chest or abdominal pain that is tearing in nature. Typically aided by

severe hypertension, these dissections spread distally. Acute type B dissections may be complicated by either rupture or malperfusion of the spinal cord, lower extremities, or visceral vessels. Malperfusion typically occurs when the dissection flap shears off and occludes the origin of the involved vessels or, less frequently, when compression of the true lumen compromises flow. Morbidity and mortality may be high in patients with acute type B dissections, with mortality rates in excess of 10% when complications occur.<sup>1</sup> In general, type B dissections are initially treated medically with anti-impulse hypertensive therapy and vasodilators. Operative management is reserved for complicated cases and usually involves exclusion of the primary entry tear and any aneurysmal degeneration with a stent-graft, which frequently requires coverage of the left subclavian artery.

The complicated type B dissection is an intricate, complex management problem that is patient specific. No two patients have the same location of the primary tear, proximity to the brachiocephalic vessels, aneurysmal degeneration, pattern of involvement of the visceral aorta, distal extension into the iliac arteries, or risk of spinal cord ischemia. Good cross-sectional imaging and 3D reconstructions are imperative for case planning. Emergent treatment is geared toward reopening a compressed true lumen and reestablishing flow to an underperfused branch vessel. Spinal cord ischemia, visceral malperfusion, and lower extremity ischemia are all surgical emergencies secondary to occluded, compressed, or thrombosed vessels. Aneurysmal degeneration and rupture make up the other component of complicated type B dissections requiring rapid intervention, typically by exclusion

with a stent-graft and covering the proximal entry tear. Careful examination of the renal vessels and the quantitative evaluation of renal perfusion and excretion should be followed for severe decline that mandates intervention.

Uncomplicated, chronic type B dissections have traditionally been treated with medical therapy. The INSTEAD trial evaluated best medical therapy compared to endovascular stenting for the management of patients with uncomplicated type B dissections, and at 2 years found no significant difference in mortality.<sup>2</sup> However, in extending the patient follow-up to 5 years, a significant improvement in patient aorta-specific survival was noted and delayed disease progression in the stenting group.<sup>3</sup> The pendulum appears to be swinging toward more aggressive endovascular management of this aortic pathology once stabilized from the initial presentation, unless urgent repair is required for complications.

### **FDA APPROVAL OF THE CONFORMABLE GORE TAG DEVICE FOR MANAGEMENT OF AORTIC DISSECTIONS**

The GORE TAG Thoracic Endoprosthesis was the first thoracic device on the market specifically for descending thoracic aneurysms approved by the FDA in 2005. It was further expanded to include lesions such as transections, penetrating atherosclerotic ulcers, and intramural hematomas. Since the introduction of thoracic stent-grafts, use in dissections has been off label. In September 2013, the FDA extended approval for a dissection indication. The GORE TAG Endoprosthesis has been vetted in the treatment of thoracic disease and the FDA felt that, given the diversity of descending thoracic pathology, a broad approval without individualized studies addressing each pathology was warranted. Given the approval, plans for postapproval studies evaluating the Conformable GORE TAG Endoprosthesis use in acute and chronic dissections are commencing.

### **ANATOMIC AND DISSECTION-SPECIFIC KEYS TO SUCCESSFUL ENDOVASCULAR MANAGEMENT**

Initial management of a patient with an acute dissection or complicated chronic dissection is the lowering of the blood pressure via intravenous  $\beta$ -blockade and vasodilators. Symptom relief typically follows a reduction in blood pressure, however, it can lag several hours behind. Axial imaging of the entire aorta is imperative with fine cuts (1 mm), and 3D reconstruction ability is highly recommended. Careful identification of aneurysmal degeneration, location of the primary intimal tear—especially in regard to the left subclavian artery, presence and location of secondary tears, involvement and flow to the visceral vessels, ability to define true and false lumen, and distal extent and involvement of the iliac vessels are all imperative in case planning. Pressurization within the false lumen from the intimal tear can compress and cause thrombosis of branch

vessels, causing malperfusion of the legs, viscera, or spinal cord. Question of retrograde dissection or presence of a type A dissection should prompt further workup with a gated computed tomography (CT) scan of the chest or transesophageal echocardiogram.

The mainstay of endovascular therapy for the treatment of a type B dissection is to cover the proximal intimal tear. Due to the typical location of the proximal tear in close proximity to the left subclavian artery, intentional coverage of the vessel is often required. This, in theory, blocks the entry of flow into the false lumen, denying any further propagation of the dissection. Angiography is used to confirm improvement of flow to the vessels affected by malperfusion. If the placement of the thoracic stent does not improve the malperfusion, adjunctive measures are taken. Further stenting down to just above the celiac artery is indicated if there remains significant true lumen compression. If the true lumen appears patent and malperfusion of branch or visceral vessels remains, stenting or fenestration might be required.

Careful identification of true and false lumen, location, and number of fenestrations allows the surgeon to plan for arterial access location. A wire should be carefully advanced up into the aortic arch. Intravascular ultrasound (IVUS) use is highly recommended to identify position within the true lumen, location of tears, accurate determination of the flaccidity of the septum, and size of the true lumen for stent-graft sizing. IVUS allows avoidance of the misplacement of a stent within the false lumen, or identification of the wire traversing the tears incorrectly.

The Conformable GORE TAG Endoprosthesis does not have active fixation, which is a benefit in treating aortic dissection. Active fixation could potentially increase the risk of retrograde dissection and tearing of the fragile aorta. Coverage of the proximal tear typically involves the coverage of the left subclavian artery due to the usual proximity of the tear to the vessel. Careful consideration must be given to spinal cord perfusion with either spinal drain placement or extrathoracic revascularization. In the absence of aneurysmal degeneration, excessive stent-graft oversizing is not required, and most practitioners do not feel a full 2 cm of proximal fixation is needed. While staying within the instructions for use, most practitioners would tend to pick the smaller stent size. In the presence of aneurysmal degeneration, a full 2 cm of proximal fixation is recommended, and traditional sizing of stent-grafts is typical.

In acute dissections, where the septum is thin and mobile, sizing typically involves sizing the entire aorta (true and false lumen together) to achieve complete obliteration of the false lumen. In chronic dissections, where it is more likely that the septum is fixed, sizing must further take into account the size of the lumen to stent, with the understanding that the stent might compress the false lumen but not to the extent it does in an acute dissection.

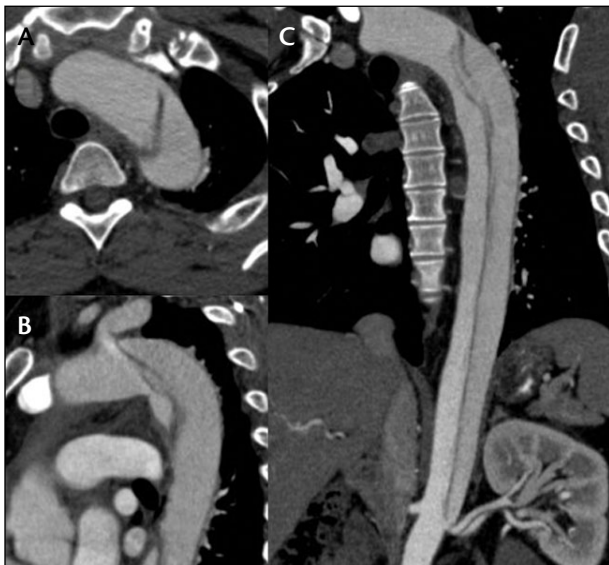


Figure 1. CT angiogram showing a type B dissection from the origin of the left subclavian artery with proximal entry tear abutting the origin of the vessel (A, B). Additionally, the dissection extends to the left renal artery with no further fenestrations (C).

### CASE 1: ACUTE DISSECTION

A 52-year-old man with a history of hypertension presented to the emergency room with a 5-day history of chest pain and severe hypertension (systolic blood pressure > 200 mm Hg). A CT angiogram confirmed a type B dissection. He was admitted to the intensive care unit and placed on intravenous  $\beta$ -blockade and vasodilators, and his systolic blood pressure was kept below 110 and heart rate, below 70. He had palpable pulses throughout and no abdominal pain. His creatinine level was 1 mg/dL. Over the next 48 hours, his chest pain was only slightly improved, his creatinine increased to 1.5 mg/dL and required higher doses of intravenous blood pressure medication. Repeat imaging revealed an increase in size of the proximal descending thoracic aorta by 9 mm. Immediate intervention was felt to be required.

Case planning was accomplished using 3D reconstruction with the AQUARIUS® iNTUITION Viewer (Aquarius, TeraRecon, Foster City, CA). The dissection flap and aneurysmal degeneration started right at the left subclavian artery that had a size of 43 mm, with maximal aneurysm dimensions of 48 mm (39 mm 2 days prior). The diameter just distal to the left subclavian artery was 38 mm. The distance down to the celiac artery was 292 mm and tapered down to 27 mm (Figure 1). The dissection extended down involving the celiac artery with both true and false lumen flow, whereas the superior mesenteric artery and the renal vessels originated off the true lumen (Figure 2). The dissection stopped at the origin of the left renal artery with a distal fenestration noted. Endovascular management involved planned coverage of the proximal tear, requiring

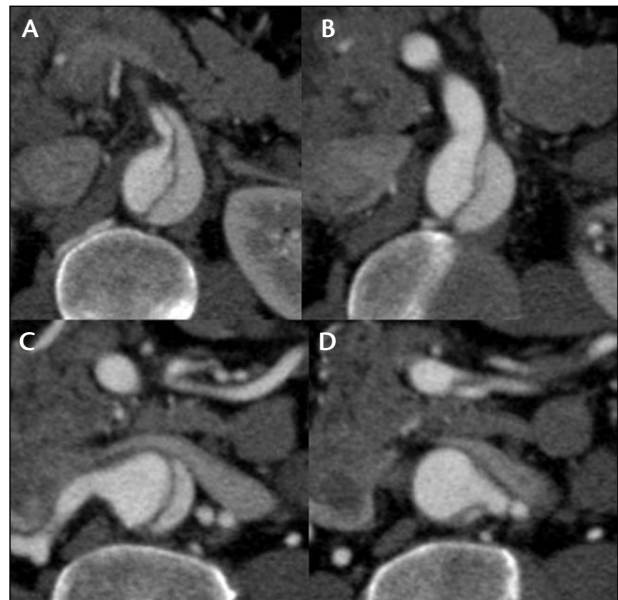


Figure 2. Axial images from a CT angiogram showing the visceral vessel involvement. There is true and false lumen involvement of the celiac artery (A). The superior mesenteric artery (B) and right (C) and left renal (D) vessels originate only in the true lumen, and the dissection ends at the left renal artery with a fenestration.

coverage of the left subclavian artery with coverage down to the celiac artery. Coverage all the way to the celiac was chosen due to aneurysmal degeneration and acute change in size of the descending thoracic aorta. The plan for left subclavian revascularization was decided upon because of the length of aortic coverage and the diminutive size of the contralateral vertebral artery, and this was performed initially. After wire access into the aortic arch was accomplished, IVUS was used to confirm diameters and ensure accurate location within the true lumen. As per the instructions for use, the choice of either a 40- or 45-mm Conformable GORE TAG Device was reasonable; however, due to the aneurysmal degeneration, the larger size was chosen. A 45-mm X 15-cm Conformable GORE TAG Device was placed proximally covering the left subclavian artery (Figure 3). A 34-mm X 15-cm Conformable GORE TAG Device was then deployed just above the celiac artery building up, and another 45-mm X 15-cm graft was used to bridge the two grafts.

The postprocedural course was unremarkable. The patient had no complaints of any further chest or back pain. His creatinine level remained stable and then dropped back to baseline. CT angiogram prior to discharge revealed adequate position of the stent-graft, primary tear coverage, and no extension of the dissection. On postoperative day 3, the patient was doing well on oral antihypertensive medication. Thirty-day postoperative CT angiogram revealed exclusion of the primary tear with aortic remodeling and false lumen thrombosis behind the stent (Figures 4 and 5).

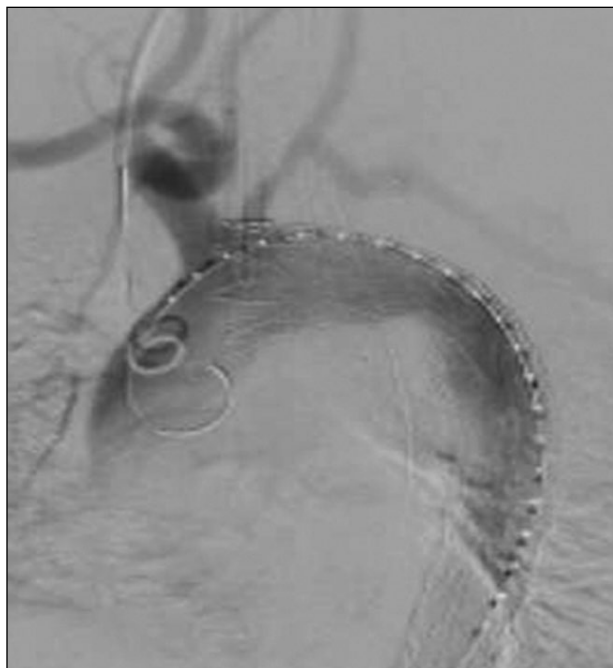


Figure 3. Intraoperative aortogram showing the placement of the Conformable GORE TAG Device with planned coverage of the left subclavian artery with excellent apposition and no bird beaking.

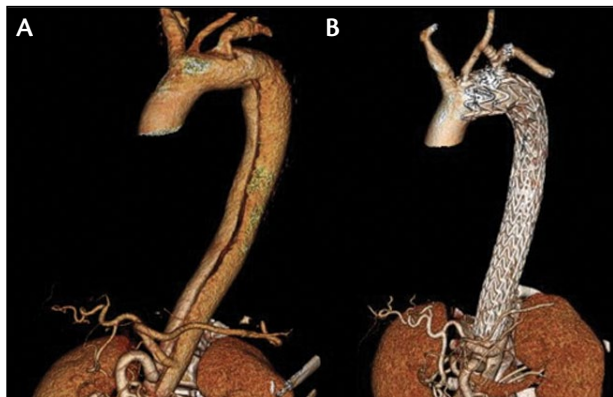


Figure 5. Pre- (A) and postprocedure (B) 3D reconstructions showing coverage of the left subclavian artery with stent coverage to above the celiac artery. A carotid-subclavian bypass supplies the left subclavian artery.

## CASE 2: CHRONIC DISSECTION

A 57-year-old woman with a history of hypertension, autoimmune hepatitis, and a known type B dissection presented to the hospital with sharp back pain. She was followed at an outside hospital for a type B dissection down to the level of the renal arteries. She underwent a CT angiogram that revealed progression of the dissection down to the iliac bifurcation. She was admitted and placed on intravenous  $\beta$ -blockade with a reduction in her blood pressure and resolution of her pain. Over the next few days, the patient had difficulties transitioning to oral anti-hypertensive medications. The decision was made to treat her.



Figure 4. A CT angiogram 1 month after the procedure shows complete remodeling and thrombosis of the false lumen of the entire covered portion. Flow still remains in the visceral segment via a distal fenestration at the level of the left renal artery.

The CT angiogram with reconstructions revealed an aortic diameter at the left subclavian artery of 25 mm and a proximal entry tear 54 mm distally, where the true lumen was 24 mm X 16 mm, and the total aortic diameter was 30 mm. The dissection compressed the true lumen throughout the descending thoracic aorta for a total distance of 231 mm (Figure 6). All the visceral vessels appeared to come from the true lumen, which was fairly compressed through the paravisceral segment. IVUS was performed through the left femoral access, after wire access was navigated into the aortic arch, confirming the location within the true lumen. Additionally, IVUS confirmed an aortic diameter of 24 to 26 mm at the level of the left subclavian artery and true lumen diameter in the descending thoracic aorta of 19 mm. After performing an aortogram and identifying the left subclavian artery, a 31-mm X 15-cm

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\* Conformable GORE® TAG® Device was approved in US for DTA aneurysms in 2011.

Refer to page 23 of this journal for prescribing information.

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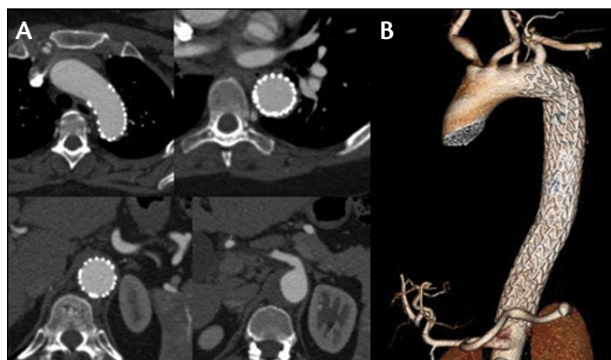


THORACIC  
ENDOPROSTHESIS





**Figure 6.** Axial cuts from a CT angiogram showing the extent of the dissection from just beyond the left subclavian artery (A) through the descending thoracic aorta (B, C), and just above the celiac artery (D).



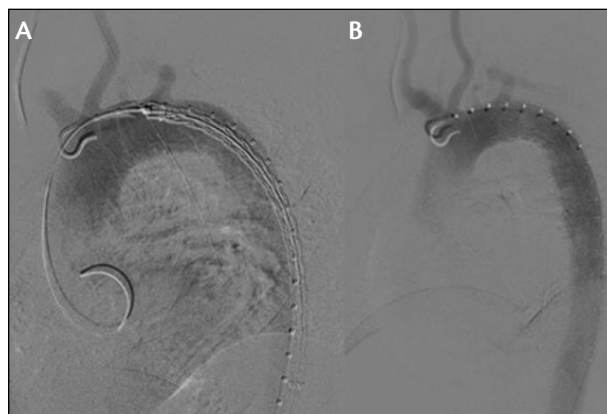
**Figure 8.** Axial images (A) and 3D reconstruction (B) from a 6-month repeat CT angiogram showing excellent stent apposition, true lumen expansion, and complete aortic remodeling and false lumen thrombosis.

Conformable GORE TAG Device was placed (Figure 7), with another 31-mm X 15-cm Conformable GORE TAG Device used to land just above the celiac artery. IVUS was used to confirm good stent apposition and no infolding and identified slight true lumen expansion.

The patient did well postoperatively and was discharged to home after 2 days. A repeat CT angiogram was obtained at 1 and 6 months showing full expansion of the true lumen, with complete aortic remodeling and false lumen thrombosis (Figure 8).

## SUMMARY

Endovascular management of type B dissections appears to be the treatment of choice for acute, complicated, and select uncomplicated dissections. Immediate



**Figure 7.** An aortogram confirming the location of the left subclavian artery (A), followed by graft deployment with excellent positioning at the left subclavian artery (B).

and lasting aorta-specific morbidity and disease progression are improved with thoracic stent-grafting. Careful patient-specific evaluation of preoperative imaging identifies potential pitfalls such as entry tear proximity to the left subclavian artery, aneurysmal degeneration, and true lumen size, which aids in successful placement of a well-sized stent-graft that covers the entry tear and causes false lumen thrombosis and remodeling. The Conformable GORE TAG Device is ideally suited for dissection pathology and should be the first-line therapy for repair. ■

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# Hypogastric Preservation With the GORE® EXCLUDER® Iliac Branch Endoprosthesis\*

How the potential technical benefits of the device may help navigate tortuous anatomy.

BY PIERGIORGIO CAO, MD, FRCS, AND CIRO FERRER, MD

**D**ilatation of one or both common iliac arteries (CIAs) is a major anatomic challenge of endovascular aneurysm repair (EVAR) and is estimated to occur in 20% to 40% of EVAR patients.<sup>1-3</sup> Ectatic or aneurysmal CIAs are often anatomically inadequate for effective distal seal and fixation, which can ultimately compromise the effectiveness and viability of the EVAR procedure. One option for CIA repair is hypogastric occlusion followed by endograft extension into the external iliac artery. However, hypogastric occlusion can lead to ischemic complications, commonly resulting in buttock claudication in up to 50% of patients,<sup>4</sup> sexual dysfunction in up to 40% of patients,<sup>4</sup> and more rarely can result in severe morbidity and mortality caused by bowel or spinal ischaemia.<sup>5</sup> Bifurcated iliac side branch devices represent a valid alternative technique to preserve pelvic blood flow while providing adequate distal seal and fixation with EVAR. Experience with the COOK® ZENITH® Iliac Branch Device (Cook Medical, Bloomington, IN) showed that this technique is feasible and safe, with promising results.<sup>6</sup>

## DEVICE AND DEPLOYMENT

The recently introduced GORE EXCLUDER Iliac Branch Endoprosthesis<sup>7</sup> (Gore & Associates, Flagstaff, AZ) is based on the design of the GORE EXCLUDER Abdominal Aortic Aneurysm (AAA) Endoprosthesis. The major design differences in the GORE EXCLUDER Iliac Branch Endoprosthesis compared to the AAA device center around alterations in device dimensions (overall length and distal iliac limb diameters) for suitability within the iliac artery anatomy. There are certain morphological characteristics required of the native arteries, the most important of which is the minimum diameter of the CIA, and the procedure should be completed using the standard GORE EXCLUDER Device for the abdominal aorta. There are several advantageous design aspects of the device. The first is that the GORE

EXCLUDER Iliac Branch Endoprosthesis is compatible with a 16-F introducer sheath, which is intended to allow for improved vessel access. The second is that the device design is based on the current GORE EXCLUDER AAA Device, which has high conformability in the limbs to offer good adaptation even in tortuous iliac arteries, avoiding flow-limiting kinking.

Furthermore, several features represent important technical innovation in the deployment of the GORE EXCLUDER Iliac Branch Endoprosthesis. This device is designed to offer repositionability using a simple, two-stage deployment mechanism via a nested deployment knob. The outer deployment knob initiates deployment of the GORE EXCLUDER Iliac Branch Endoprosthesis to the level of the internal iliac artery (IIA) gate, similar to how deployment of the GORE EXCLUDER AAA Endoprosthesis featuring C3 Delivery System initiates deployment to the device's contralateral gate. At this point, if the IIA gate is deployed slightly higher than the intended final position, then the GORE EXCLUDER Iliac Branch Endoprosthesis can be rotated up to 90° in either direction to facilitate access to the hypogastric artery, and gently moved distally as needed for optimal alignment with the IIA ostium. The inner deployment knob initiates deployment of the IIA leg, completing the deployment of the device as a final step.

The second novel technical feature of the GORE EXCLUDER Iliac Branch Endoprosthesis is the removable guidewire tube, which is intended to provide a small channel within the constrained device for the introduction of a second guidewire to precannulate the IIA gate. This guidewire is a bifemoral, up-and-over through wire, captured via a snare catheter from the contralateral groin and is established before the introduction of the device. The GORE EXCLUDER Iliac Branch Endoprosthesis is guided through the introducer sheath over both the aortic wire and the through wire. The intended purpose of this, aside from precan-

nulating the side branch channel, is to easily advance the contralateral introducer sheath into the device gate, which can facilitate catheterization of the IIA and provide stability to the contralateral sheath for delivering the internal iliac component.

Finally, the third important characteristic is the internal iliac component, which is a dedicated, self-expanding stent-graft for the hypogastric artery that is based on the design of GORE EXCLUDER Device iliac legs. With maintenance of the through wire, it is not necessary for the sheath to go inside the hypogastric artery, but it is instead stabilized inside the side branch of the device.

### FIRST EXPERIENCE

Two of the first three implants of the GORE EXCLUDER Iliac Branch Endoprosthesis in Europe occurred in Rome, Italy on November 4, 2013. In subsequent days, other centers began using the graft throughout Europe. This device is undergoing a clinical trial in the United States.

Patients identified as having challenging anatomy that could potentially benefit from the device design and features were chosen for these first cases. The first case involved a patient with a straight stent-graft in the infrarenal aorta (previously implanted at a different hospital), and a 39-mm CIA aneurysm. The procedure was performed with a percutaneous approach. The IIA take-off angle was quite steep, and the repositionability of the device aided in hypogastric artery cannulation. Postprocedure computed tomography (CT) scans showed good blood flow through both the external and internal legs of the stent-graft. The second case involved bilateral, saccular CIA aneurysms as well as a saccular aneurysm in the aorta.

Again using percutaneous access, we elected to place the GORE EXCLUDER Iliac Branch Endoprosthesis in both CIAs in a bilateral configuration. The completion angiogram showed excellent flow in all iliac branch vessels, with both sides accommodating the GORE EXCLUDER Iliac Branch Endoprosthesis. The follow-up CT at 1 week showed the same. In both cases, there were no proximal or distal type I endoleaks seen on postoperative CT scans, and all branch vessels were fully patent.

### DISCUSSION

Iliac side branch devices can be considered the first endovascular option in patients with aortoiliac aneurysm

and suitable anatomy. The major disadvantage of this technique is the technical feasibility related to anatomical requirements. In our experience with the Cook platform, the majority of technical failures were related to severe vessel tortuosity or iliac anatomies not totally fulfilling the criteria for application. The presence of small or tortuous EIA or the concurrence of large IIA were the main negative predictors of outcome.<sup>6</sup> In our initial experience, the GORE EXCLUDER Iliac Branch Endoprosthesis may be an optimal endovascular option in this scenario. The stent-graft appeared to conform well to accommodate the difficult anatomies experienced in these first cases. We found the deployment to be intuitive and easy, aided by the ability to precannulate the IIA gate and stabilize the contralateral introducer sheath with the bifemoral through wire. The ability to reposition the GORE EXCLUDER Iliac Branch Endoprosthesis is designed to provide clinicians with the ability to realign the device for easier hypogastric cannulation, which may reduce operative time and achieve optimal device positioning. Further data on the GORE EXCLUDER Iliac Branch Endoprosthesis performance will be collected as part of the post-market GREAT registry in Europe. The device is also in clinical study in the United States. With EVAR becoming the common, preferred option over open surgical repair, technological improvements such as those offered with the GORE EXCLUDER Iliac Branch Endoprosthesis are needed to continue expanding the treatment options and performance in the face of difficult anatomy. ■

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# Challenges of EVAR in Highly Angulated and Short Infrarenal Neck Anatomies

This difficult clinical presentation remains one of the few roadblocks to a higher standard of success with endovascular repair.

BY ROBERT Y. RHEE, MD

Endovascular repair of abdominal aortic aneurysm (EVAR) has evolved to become the treatment of choice for patients with infrarenal aortic aneurysms (AAAs). It has become very clear within the last 10 years that the currently available stent-grafts are used in challenging aortic neck situations throughout the world.<sup>1-6</sup>

EVAR, when utilized within the instructions for use, is extremely effective in preventing aneurysm-related death, rupture, and AAA sac expansion in the long term. Recent studies, however, have revealed that even patients with hostile anatomy can benefit from EVAR when performed at experienced centers.<sup>3-5,7</sup> Currently, hostile neck anatomy is the only absolute deterrent to successful infrarenal EVAR. With the introduction of hydrophilic introducer sheaths from most manufacturers and lowered device profiles in the latest EVAR system generations, iliac access problems have become less of an issue.

An angulated neck  $> 60^\circ$  and/or a neck length  $< 15$  mm remain the two most common reasons why a vascular specialist might not be able to offer EVAR.<sup>3,4</sup> This is particularly true if both factors are present in the same patient. Reports of successful treatment of patients with isolated short infrarenal necks (10–15 mm) are increasing in the literature.<sup>5,7,8</sup> EVAR is also possible in severely angulated necks ( $> 60^\circ$ ), provided the neck length is adequate to maintain stent-graft neck wall apposition (Figure 1). However, when one or more of the hostile neck factors are present, the challenge becomes intensified and demands extreme precision in order to deliver the stent-graft into the exact position that would allow it to remain effective in the long run. It becomes increasingly important to take advantage of every millimeter of the infrarenal sealing zone when multiple hostile neck features are present.

Although many of these patients with hostile necks can be managed with fenestrated or branched stent-graft systems, recent reports reveal that fenestrated EVAR (FEVAR) with the currently available systems have



Figure 1. A severely angulated neck with multiple left renal arteries. An example of a hostile proximal sealing zone.

significantly higher risk than standard EVAR.<sup>9</sup> Thus, infrarenal EVAR remains the gold standard for most patients with AAA disease, even with hostile necks.

## THE HIGHLY ANGULATED NECK

The current stent-graft systems were designed primarily as straight neck sealing zone systems. Although some of the systems are “more flexible” than others, most of the current devices were not engineered to seal in necks  $> 60^\circ$ . Even if the US Food and Drug Administration indication states  $> 60^\circ$ , other concurrent hostile neck attributes were not taken into account for these situations, such as a short ( $< 15$  mm), reverse taper of  $> 30\%$ , extensive thrombus or calcifications, etc. When the proximal sealing zone displays

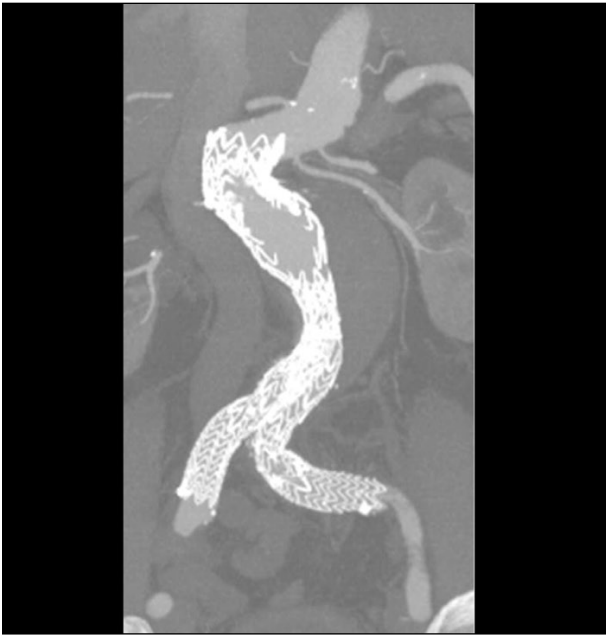


Figure 2. The same patient as in Figure 1, after placing an infrarenal stent-graft system with a proximal cuff extension. Note the bird beaking of the stent-graft on the inner curve.



Figure 3. A suprarenal fixation stent-graft system placed into an angulated short neck. Note the lack of apposition of the fixation system on the inner curve.

multiple hostile factors, the probability of successful short- and long-term outcome diminishes significantly. The following is an overview of maximizing outcomes in select patients with one or more hostile neck features.

## DEPLOYMENT ACCURACY

### Flexibility

The main challenge in treating patients with hostile necks lies in accurately positioning the stent-graft to maximize its inherent ability to conform to the neck and form an adequate sealing for proper AAA exclusion. This is particularly true for a severely angulated neck. Although it is true that most stent-grafts “bend” more readily in one direction versus another outside the body, this inherent property of the system is usually not possible in real-life clinical situations within the confines of a severely angulated neck. This is related to multiple factors, including the tortuosity of the iliac system as well as the actual bending properties of the stent-graft itself. When significant tortuosity exists in the access vessels, the stent-graft cannot bend proximally without creating tension in the infrarenal sealing zone. This ultimately contributes to the inability of the stent-graft to conform to the native anatomy, and it can create zones of separation in the proximal neck with bird beaking (Figure 2) and loss of fixation apposition to the aortic wall (Figure 3). The challenge is to create a stent-graft system with almost independent flexibility in the limbs compared to the proximal main body zones.

### Deliverability

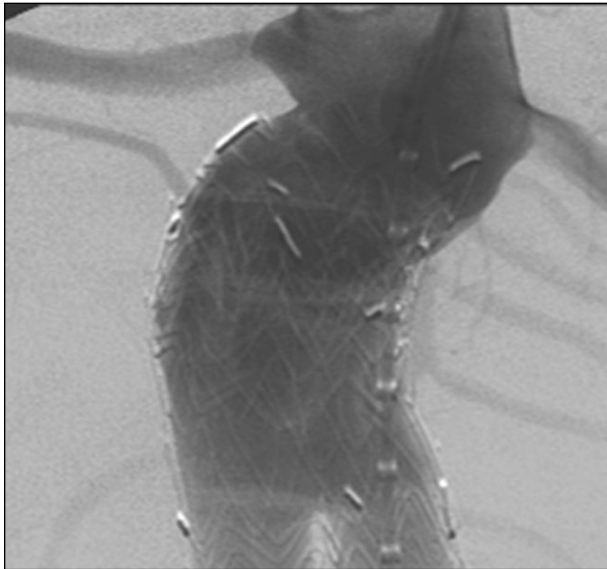
Most current stent-graft systems exhibit significantly improved flexibility in the proximal main body segment.

However, it is still challenging to deploy the stent-graft precisely to conform to every millimeter of the proximal neck. When these modern stent-graft systems are manually deployed and manipulated ex vivo, the flexibility is often more than adequate. The challenge is to achieve this conformity in vivo within the proximal neck of the patient. Initial fixation to the aortic wall is crucial in achieving the correct position during deployment as well as in maintaining the position in the long term. Without active penetrating fixation, it is virtually impossible to maintain the flexed state within the neck in the short or long term. It also appears that there is no difference between infra- and transrenal fixation for achieving this process.

### Adjustments

Except for the GORE EXCLUDER AAA Endoprosthesis featuring C3 Delivery System (Gore & Associates, Flagstaff, AZ), all current systems disallow adjustment to the position of the proximal stent-graft after the initial deployment. Therefore, the operator essentially has only one chance to achieve success in sealing.<sup>10</sup> Proximal extension with extension cuffs is never ideal because the main stent-graft system is compromised from the very beginning because of its malposition. There are exceptions with the GORE EXCLUDER Device when there is extreme angulation that is long enough to reticulate with cuffs.<sup>11</sup> This technique can often create a bend that is not possible to achieve when only the stent-graft main body is used (Figure 4). In general, however, utilization of an aortic proximal extender is failure of the device to deploy precisely just distal to the renal arteries.

A repositionable system allows the operator to try one



**Figure 4.** Reticulation technique with aortic cuffs to overcome severe angulation.

configuration initially and then several other attempts to ensure adequate sealing in the infrarenal aorta. This ability clearly allows greater success in the physician's ability to deploy the stent-graft in the ideal position, especially in challenging neck situations. Even with repositionability, the severity of the angulation may simply not allow the stent-graft to conform exactly to the correct angle of the neck. Therefore, a second, postdeployment adjustment system, which allows the operator to actually bend the proximal stent-graft to fit the patient's neck more closely, is necessary. The current COOK® ZENITH® TX2 TAA Endovascular Graft with PRO-FORM® system (Cook Medical, Bloomington, IN) is an example of a system that allows the stent-graft to bend after partial proximal deployment in order to maximize the sealing in a highly angulated proximal descending thoracic aorta. A similar ability is needed for the abdominal EVAR system for highly angulated necks.

### THE SHORT NECK

Proximal necks < 15 mm and > 10 mm can be treated successfully with most modern stent-graft systems with excellent results.<sup>7,8</sup> The actual length of neck required for best long-term success is yet to be determined because it is clearly different for different types of stent-grafts. When active fixation with metal struts that penetrate the aorta is incorporated into the stent-graft design, the performance of these stent-grafts in relatively short necks (provided that there are no other significant hostile neck features) is satisfactory.<sup>12,13</sup> The quality of the neck should also be taken into consideration. Clearly, the presence of excessive thrombus or calcium can contribute to poor outcomes. The absolute length of the infrarenal neck is not the only determinant of accurate deployment or long-term success. For example, EVAR

performed in a patient with a 10-mm, straight, uniform diameter neck is more likely to be successful than a diseased, conical-shaped, thrombus-laden neck that is 15 mm. The ideal stent-graft system should again be able to take advantage of every millimeter of the proximal neck by its deliverability attributes. If the stent-graft cannot seal within 1 mm or less in these short neck situations, the likelihood of long-term success diminishes markedly.

### SUMMARY

Successful EVAR in severely angulated and short necks is possible and can produce satisfactory long-term outcomes with good patient selection. The challenges in the treatment of highly angulated and short necks lie in being able to utilize the entire proximal seal zone. Stent-graft deliverability is the key to meeting that challenge. It is a prerequisite that the EVAR stent-graft system is flexible and compliant enough to adhere to the patient's anatomy. However, it is not enough to have a flexible system. The interventionist must be able to deliver the system accurately and precisely to seal along the entirety of the proximal infrarenal neck. ■

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*Gore does not recommend treating patients with neck anatomy that does not comply with the following:*

- Infrarenal aortic neck treatment diameter range of 19 – 32 mm and a minimum aortic neck length of 15 mm
- Proximal aortic neck angulation ≤ 60°

*Please consult the Instructions for Use for complete indications, contraindications, warnings, and precautions.*

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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](http://goremedical.com) for a complete description of all warnings, precautions, and adverse events.  $\mathbb{R}_x$  Only

## GORE® EXCLUDER® Iliac Branch Endoprosthesis

**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](http://goremedical.com) for a complete description of all warnings, precautions, and adverse events.  $\mathbb{R}_x$  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,  $\geq 20$  mm non-aneurysmal aorta proximal and distal to the lesion; Type B dissections in patients who have appropriate anatomy, including: adequate iliac / femoral access,  $\geq 20$  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](http://goremedical.com) for a complete description of all warnings, precautions, and adverse events.  $\mathbb{R}_x$  Only

**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](http://goremedical.com) for a complete description of all warnings, precautions, and adverse events.  $\mathbb{R}_x$  Only

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