

# Conformability in Aortic Type B Dissection

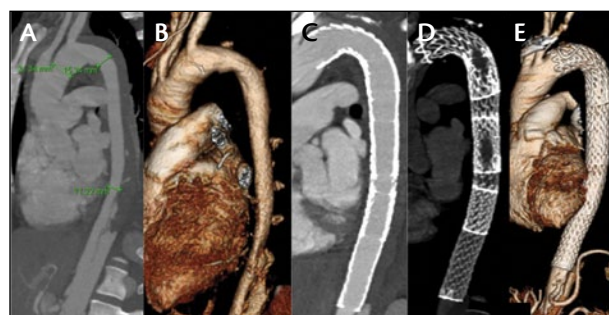
Clinical experience with the Conformable GORE® TAG® Thoracic Endoprosthesis.

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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.

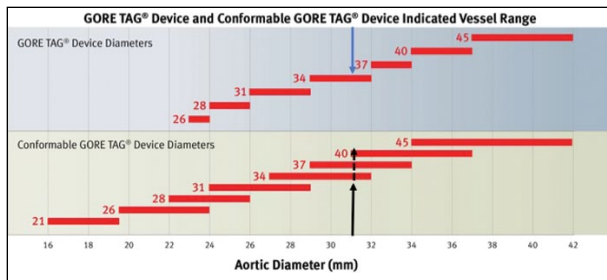


**Figure 1.** Preoperative CT scan of the gothic arch with proximal intramural hematoma, aortic wall bleedings, and distal dissection (A,B). The remodeled aorta after implantation of four Conformable GORE TAG Devices (C-E).

## 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-



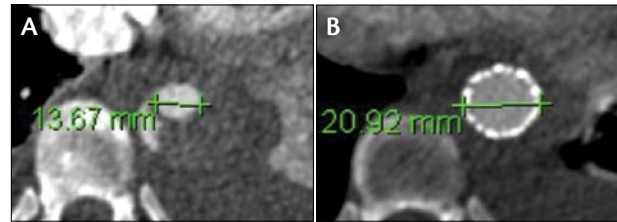
**Figure 2.** The sizing chart shows oversizing windows from the former GORE TAG Device (above, grey) and the Conformable GORE TAG Device (below, green). For example, selecting a GORE TAG Device for an aortic diameter of 31 mm results in a 34-mm device (blue arrow), whereas with the Conformable GORE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

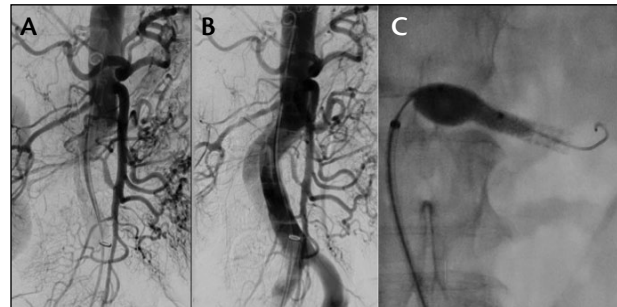
## CASE 2

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).

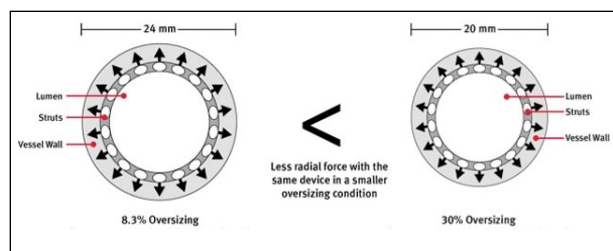


**Figure 4.** The intraoperative digital subtraction angiogram showed permanent true lumen compression of the infrarenal aorta after implantation of the first Conformable GORE TAG Device (A) and partial remodeling with optimized perfusion after the second device (B). Simultaneous renal stenting may be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

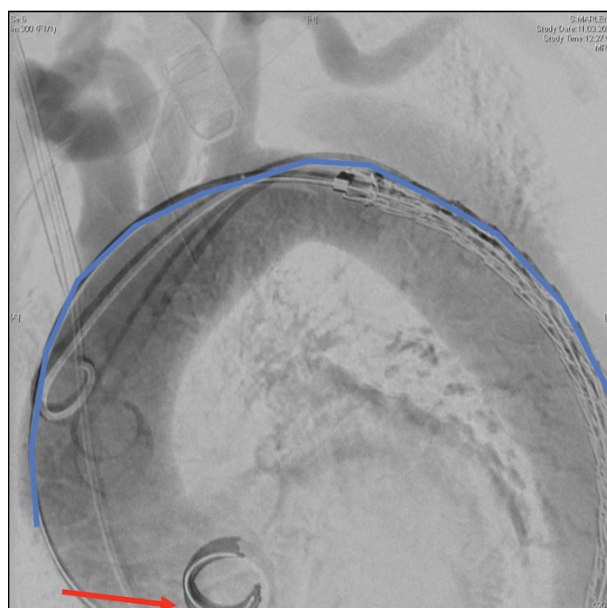


**Figure 5.** The association of radial force and oversizing according to device diameter.

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.

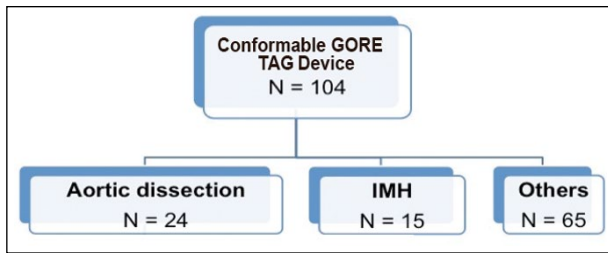
patient with an aneurysm could be treated safely with a 40-mm device. Previously, this patient anatomy could only be treated with a 34-mm GORE TAG Device due to the relatively narrow oversizing windows of that device (Figure 2).

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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