The Conformable GORE® TAG® Thoracic Endoprosthesis

This new, compliant endograft is specifically designed to treat pathology in the aortic arch.

BY RACHEL E. CLOUGH, BSc, MRCS, AND PETER R. TAYLOR, MA, MChir, FRCS

The Conformable GORE® TAG® Thoracic Endoprosthesis is the latest thoracic stent graft from Gore & Associates (Flagstaff, AZ), specifically designed to conform to the geometry of the aortic arch.[1] Thoracic devices were initially developed from prototypes used in the infrarenal aorta.[2,3] It has long been recognized that thoracic devices perform well in the descending thoracic aorta but have difficulties accommodating to the anatomy of the aortic arch. This is especially true when the radius of the curvature of the arch is very tight. Rigid devices have even caused perforation in the arch.[4,5]

Stent grafts that do not conform to the contours of the aortic arch can sit above the inner curvature of the arch, forming a "bird's beak" on imaging. The length of the graft that is not in contact with the aorta is related to the risk of device collapse, which can result in sudden aortic occlusion and death. Device collapse is a problem that has been reported with all endografts used in the thoracic aortic arch.[6] Failure to comply with the arch anatomy may also increase the risk of type I endoleak. This continues to be a significant problem in endovascular arch procedures and, if untreated, may result in aortic rupture and death. There are very few devices that have been designed to adapt to the harsh environment of the aortic arch; the Conformable GORE® TAG® Endoprosthesis is one of the first compliant devices to be specifically designed for use in the arch.

TECHNICAL CONSIDERATIONS

The flared scallops at the proximal and distal ends of the GORE® TAG® Device (Gore & Associates) have been replaced by a partially uncovered stent proximally, which is straight, not flared, and has outward radial force consistent with the entire length of the device. The bare stent ranges from 3 to 6.5 mm in length, depending on 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 Conformable GORE® TAG® Device has no scallops or bare stents, and the material covers 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 has been added so that each circumference has nine apexes (the GORE® TAG® Device has eight), and this helps to distribute the load to increase bending fatigue life of the wire. When placed in a curved position, the device shows no tendency to straighten and continues to stay in its given conformation. This ability enables the device to adopt a stable position in the aortic arch after deployment. The reduction in length of the inner curvature is achieved by tele-

Figure 1. The Conformable GORE® TAG® Device telescopes onto itself to conform to the geometry of the aortic arch.

Labeled Diameter (mm)	Intended Aortic Diameter (mm)	Device Length (cm)	Device Profile (F)	Oversizing Range (%)	Bare Stent Length (mm)
21	16–19.5	10	18	8–31	3
26	19.5–24	10	20	8–33	4
28	22–26	10, 15	20	8–27	4
31	24–29	10, 15	22	7–29	4
34	27–32	10, 15, 20	22	6–26	5
37	29–34	10, 15, 20	24	9–28	5
40	31–37	10, 15, 20	24	8–29	6
45	34–42	10, 15, 20	24	7–32	6.5
26 X 21	19.5–24/ 16–19.5	10	20	8–33	4
31 X 26	24–29/ 19.5–24	10	22	7–33	4

Figure 2. Each Conformable GORE® TAG® Device now has an expanded oversizing range from 6% to 33%.

scoping consecutive segments in the inner radius of the device throughout its length (Figure 1).

The oversizing window has increased compared with the GORE® TAG® Device and now ranges from 6% to 33%, depending on the diameter and shape of the device (Figure 2). The smallest-diameter device 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. This small device will pass through an 18-F sheath. The increased oversizing windows compared with the GORE® TAG® Device mean that a patient who has a 31-mm-diameter aorta can be treated with three possible Conformable GORE® TAG® Devices, ranging from 34 mm through 37 to 40 mm. This is important because a patient could be treated with maximum oversizing using a 40-mm device, depending on the clinical need. Previously, this patient could only be treated with a 34-mm GORE® TAG® Device due to the relatively narrow oversizing windows of that device.

Two tapered devices are also available: a smaller one, which has a diameter of 26 mm at the proximal end decreasing to 21 mm distally, and a larger one that is 31 mm decreasing to 26 mm distally. These may be useful in treating patients with aneurysms that have a large size discrepancy in their proximal and distal landing zones. The largest device is a 45-mm-diameter device, which requires a 24-F sheath. The new GORE® DrySeal Sheath (Gore & Associates), with a saline-expandable silicone hemostatic valve, ensures complete hemostasis. This valve allows further catheters to be placed into the same sheath after the device has been introduced into the thoracic aorta, with no blood loss. Angiography can then be performed without the necessity of accessing either the contralateral femoral artery or the left brachial artery.

CASE REPORT

A 72-year-old man was being examined for hypertension, and a chest x-ray demonstrated a thoracic aneurysm. A computed tomography (CT) scan showed a 7.6-cm aneurysm starting just distal to the left subclavian artery and involving the entirety of the descending thoracic aorta to just above the diaphragm (Figure 3). A duplex scan of his carotid and vertebral arteries showed only minor disease, with 1% to 15% plaque affecting the origin of each internal carotid artery. The flow in both vertebral arteries was equal.

At a multidisciplinary meeting of vascular surgeons and interventional radiologists, it was decided that in order to gain an adequate length for the proximal landing zone, it would be necessary to cover the origin of the left subclavian artery. In view of the normal carotid and vertebral artery duplex scan, no preoperative revascularization of the left subclavian artery was performed.

The procedure was performed in a hybrid endovascular suite under an epidural anesthetic via a right common femoral arterial cutdown. Three Conformable GORE® TAG® Endoprosthesis were implanted in the descending thoracic aorta, starting distally and working proximally. The first 20-cm X 45-mm Conformable GORE® TAG® Endoprosthesis was placed just proximal to the celiac axis. The second 20-cm X 45-mm Conformable GORE® TAG® Endoprosthesis was placed proximal to this, with a 5-cm overlap between devices to ensure there would be no type III endoleak. Finally, a 15-cm X 45-mm Conformable GORE® TAG® Endoprosthesis was placed just distal to the left common carotid artery, deliberately covering the left subclavian artery. The device complied to the geometry of the aortic arch, with no bird's beak on the inner curvature (Figure 4).

The patient had no neurological complications and was discharged from the hospital after 48 hours. A follow-up CT scan performed at 3 months showed no evidence of an

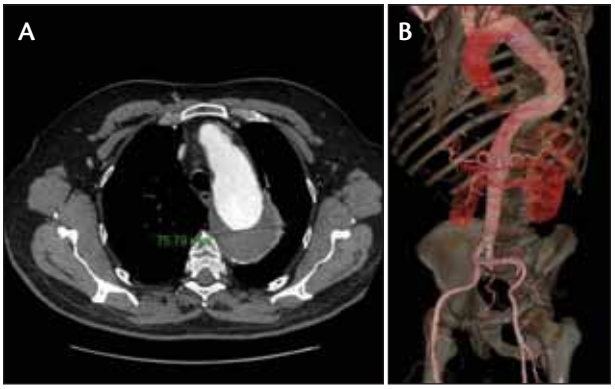

Figure 3. A CT scan showing a 7.6-cm aneurysm affecting the descending thoracic aorta (A). A volume-rendered image showing the relationship of the aneurysm to the arch vessels (B).

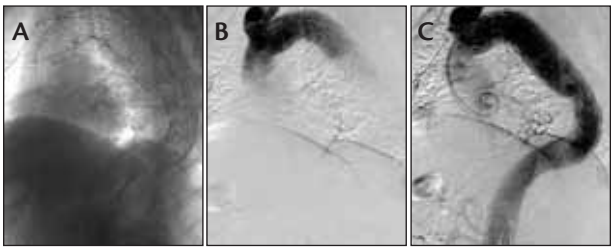

Figure 4. The proximal device conforms to the anatomy of the arch (A). Angiography shows no endoleak on the inner curvature of the aortic arch (B). Completion angiography shows no evidence of an endoleak (C).

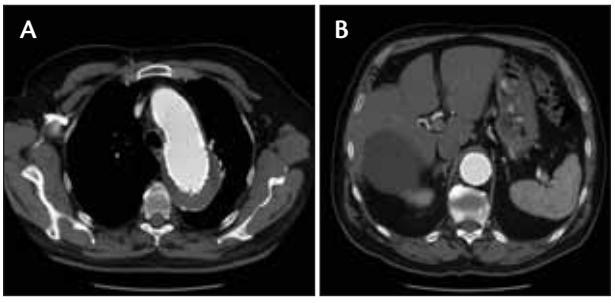

Figure 5. A CT scan at 3 months shows no evidence of an endoleak with sac shrinkage (A). A CT scan at 3 months shows an excellent result at the distal landing zone with no endoleak (B).

endoleak, and a sac that had shrunk to 6 cm (Figure 5). The patient continues to do well 1 year postprocedure.

EARLY CLINICAL RESULTS

The early results of a Gore-sponsored European registry of patients treated with the Conformable GORE® TAG® Endoprosthesis were presented at the CIRSE annual meeting in Munich, Germany in September 2011. Ninety-four patients had been treated with the device at five vascular centers in Germany, Italy, Sweden, and the United Kingdom. None of these cases were selected, and all patients were treated at the discretion of the primary operator in cases presenting to their units with pathology affecting the aortic arch. This registry represents real-world cases that were not carefully selected to produce a satisfactory outcome. These results can therefore be expected to translate to clinical practice when used by other medical practitioners with equivalent experience in dealing with thoracic cases.

The device was successfully placed in all patients, so the technical success rate was 100%. Conformability to the arch was expressed as the distance from the inner radius of the aortic arch to the proximal gold band, which marks the most proximal extent of the fabric. A distance of ≤ 2 mm was considered to show that the device had conformed to the arch anatomy; a distance of > 2 mm was considered to be nonconforming. The device conformed in 95% of patients. The accuracy of deployment was 99%, with one device moving proximally upon deployment. Three patients had a type I endoleak.

CONCLUSION

The Conformable GORE® TAG® Endoprosthesis represents a new development in compliant devices that are specifically designed for the aortic arch. In clinical use, it seems to conform to the arch in all but a few very challenging cases. The technical results are also very encouraging. The wider range of devices includes a device that can be used in young patients with small aortic diameters who have aortic arches with a tight radius of curvature. They also include tapered devices, which may allow patients with a significant size discrepancy in the aortic diameters of the proximal and distal landing zones to be treated. Clearly, although the registry results are encouraging, longer-term studies are required to prove the clinical usefulness of the Conformable GORE® TAG® Endoprosthesis. ■

Rachel E. Clough, BSc, MRCS, is a Clinical Training Fellow with the National Institute for Health Research Biomedical Research Centre at Guy's and St Thomas' NHS Foundation Trust and King's College London in London, United Kingdom. She has disclosed that she has no financial interests related to this article.

Peter R. Taylor, MA, MChir, FRCS, is Professor of Vascular Surgery, Department of Vascular Surgery, Guy's and St Thomas' NHS Foundation Trust and King's College London and King's Health Partners in London, United Kingdom. He has disclosed that he is a paid consultant for the Gore & Associates–sponsored ADSORB trial and has participated in the Conformable GORE® TAG® registry sponsored by Gore & Associates. Dr. Taylor may be reached at peter.taylor@gstt.nhs.uk.

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