

# Endovascular **TODAY**

September 2012

## ADVANCING **THORACIC CARE**

Exploring the versatility  
of the Conformable GORE®  
TAG® Device in challenging  
thoracic anatomies.

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Gore has raised the bar for aortic stent grafts designed to treat the thoracic aorta. Building on 15 years of proven technology with the GORE® TAG® Thoracic Endoprosthesis, Gore introduced its next-generation stent graft with a series of clinical trials designed to support safety and efficacy across multiple etiologies. Originally approved for treating aneurysms of the descending thoracic aorta in August 2011, the expanded indication for isolated lesions was granted in January 2012 based on the Conformable Gore® TAG® Traumatic Transection Study (08-02), specifically designed to assess device performance in traumatic transections.

The Conformable GORE® TAG® Thoracic Endoprosthesis was specifically designed to conform to the aorta in multiple etiologies and anatomies. As the device was developed, the concept of “radial fit” was introduced—incorporating many of the design features. For example, the device has a unique oversizing range capability of 6% to 33%, allowing physicians to effectively choose the amount of radial force, which is consistent throughout the entire device length, that best fits the specific patient etiology. This sizing range also provides the potential economic advantage of treating tapered aortas with up to an 8-mm proximal-to-distal variance with a single straight Conformable GORE® TAG®

Device. Completing the concept of radial fit is the availability of the broadest treatment range of any thoracic device, treating patients with aortas between 16 and 42 mm in diameter.

In this supplement, two articles outline how the new Conformable GORE® TAG® Thoracic Endoprosthesis advances thoracic aortic therapy. In the first article, Alan Lumsden, MD, and Jean Bismuth, MD, further define the concept of “radial fit” and how advanced imaging technology can help detect some of the benefits afforded by device design improvements in the clinical setting. Then, as the national principal investigators of the Conformable GORE® TAG® Device thoracic aneurysm (TAG 08-03) and traumatic transaction (TAG 08-02) studies, William Jordan, MD, and Mark Farber, MD, define “isolated lesions of the descending thoracic aorta.” This indication-for-use statement is not a traditional clinical term and has evolved to adapt to current technology and thoracic treatment paradigms.

Finally, a series of case reports from around the world show how the Conformable GORE® TAG® Device is used to treat blunt aortic injuries, aneurysms, and isolated lesions of the descending thoracic aorta.

Please consult your Gore clinical sales specialist for further discussion of the supplement content.

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# What Exactly Is Radial Fit?

Adaptable technology is crucial in accommodating a variety of patient needs.

BY ALAN LUMSDEN, MD, AND JEAN BISMUTH, MD

**T**his article introduces the concept of radial fit—the optimization of force and conformability of a device in a disease- and anatomy-specific manner. Ideally, we would like to see a device about the entire circumference of the aorta with enough radial force to provide a seal without adversely affecting the vessel wall with excessive force. In maintaining these elements, the device should be able to conform to non-uniform circumferential anatomies and a variety of longitudinal aortic shapes and be usable in a range of aortic pathologies with variable vessel wall characteristics. A device is only able to appose the wall along its entire surface if it has features that permit adaptability.

## RADIAL FIT: EXPANDED OVERSIZING RANGE

A key example of a device's adaptability is the expanded oversizing range of the Conformable GORE® TAG® Device (Gore & Associates), which can accommodate a larger treatment range with a single device.

In preoperative planning, computed tomographic angiography is the most commonly used modality. As we gain significant experience in cardiac (dynamic) magnetic resonance imaging (MRI) and electrocardiography-gated computed tomography, we realize that there can be up to 27.5% variation between systolic and diastolic aortic diameters.<sup>1</sup> It is difficult to calculate the most appropriate fit in preoperative imaging, where dimensions are measured during diastole. In this case, radial fit is the ability of a stent graft to manage a range of diameters without losing radial apposition. Table 1 shows the expanded treatment range of the Conformable GORE® TAG® Device, which can accommodate a potential difference between systolic and diastolic in aortic diameters of up to 8 mm. These expanded treatment ranges are also important when considering tapered aortas, traumatic disruptions in younger patients, and aortic coarctation, in which a difference of up to 9.5 mm between the proximal and distal diameters can be accommodated with a tapered device.

## RADIAL FIT: CONFORMABILITY

In preoperative measurements, we tend to identify tortuosity and sharp angulations at the arch or diaphragm as cautionary landing zones, generally trying to move that landing zone into straighter segments. Proper radial fit improves conformability so that the device is able to seal in territory that was previously hostile because of tortuosity, including difficult landing zones distal to the left subclavian artery. There, radial fit has the potential of avoiding a significant percentage of left carotid-subclavian bypasses, which have become fairly standard when coverage of the left subclavian artery is required.

There are several engineering elements that contribute to the radial fit of the device. This includes outward radial force (amount of force the device applies to the vessel wall due to oversizing), minimum bend radius

**TABLE 1. MAXIMUM TREATMENT RANGE FOR THE CONFORMABLE GORE® TAG® DEVICE**

Device Diameter (mm)	Aortic Diameter (mm)	Difference Between Upper and Lower Treatment Range (mm)
21	16–19.5	3.5
26	19.5–24	4.5
28	22–26	4
31	24–29	5
34	27–32	5
37	29–34	5
40	31–37	6
45	34–42	8
26 X 21	19.5–24/16–19.5	8
31 X 26	24–29/19.5–24	9.5



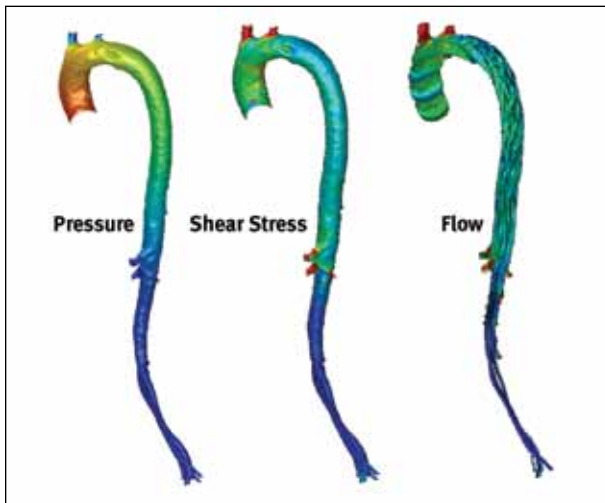


Figure 1. Computational fluid dynamics (CFD) of a healthy aorta demonstrating pressure, shear stress, and spiral flow patterns in the thoracic aorta. Image provided courtesy of Christof Karmonik, PhD.

(device flexibility without kinking), and spring-back force (amount of force the device exerts on the aortic wall due to device straightening). Engineers use these terms to study devices in a preclinical setting to predict device behavior when implanted in patients. In reality, the engineering inputs have not affected device selection, because this level of detailed patient-specific measurement is not currently available in humans. We have been interested in using dynamic MRI to evaluate many of these parameters on a patient-specific basis for device deployment in the thoracic aorta. Dynamic MRI provides anatomic and physiologic data acquired in four-dimensional mode. With the addition of patient-specific computational fluid dynamics, we can solve the flow conditions in which the devices are being

deployed (Figure 1). Cardiac MRI techniques, which include four-dimensional flow, are completely unique and allow an evaluation of flow directional changes and vessel wall interactions. There is some evidence that changes in spiral flow with increased eccentric flow vectors and consequent elevated shear stress have a link to aortic aneurysm development.<sup>2</sup> There is also an indication that decreased spiral flow patterns are linked to increased atheromatous disease in the carotids, as well as coronary artery disease at all ages.<sup>3,4</sup> In light of these findings, we submit that radial fit is extremely important, particularly as clinicians continue to push the envelope and bring aortic endografts into more proximal segments of the aortic arch. Poorly apposed endografts are more likely to cause flow disturbance with ensuing elevated shear stress and potential clinical consequences, such as stent collapse and fracture.<sup>5</sup> Currently, we evaluate all our aortic endografts with these techniques, including computational fluid dynamics, in an effort to understand the effects of flow on the grafts and how devices promote conformational changes of the aorta versus stents that conform to the patient's anatomy.

### RADIAL FIT: RADIAL FORCE

The early results of a regulatory study originally published in 2005 led to the US Food and Drug Administration's approval of the GORE® TAG® Device as the first stent graft approved for the repair of descending aortic aneurysms of the thoracic aorta.<sup>6</sup> Since then, the Conformable GORE® TAG® Device, along with multiple other devices, have undergone numerous modifications to address some of the issues initially encountered—bird-beaking, collapse, and stent fatigue with fracture. Radial fit potentially addresses many of these issues by giving the interventionist an opportunity to dictate the

radial force of the endograft, tailoring it to a specific pathology or anatomy. For example, a patient with a 29-mm aorta can be treated with three different Conformable GORE® TAG® Devices (31, 34, and 37 mm) that will provide different amounts of radial force (Figure 2).

### RADIAL FIT IN THE CLINICAL SETTING

The need for pathology-specific grafts that increase conformability and trackability was well noted in a recent European position state-

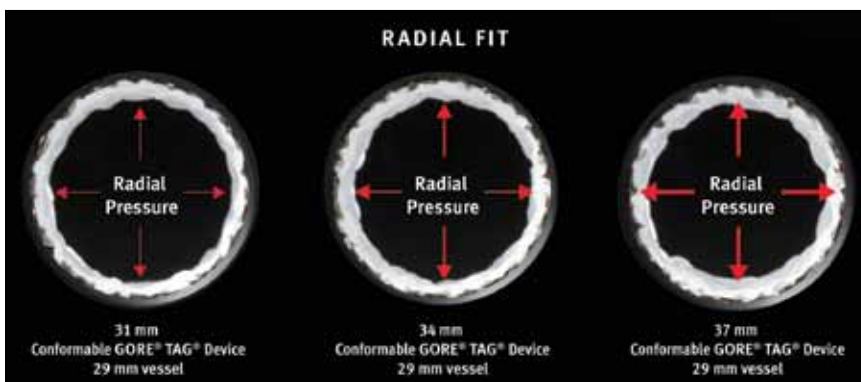


Figure 2. The 31-mm, 34-mm, and 37-mm Conformable GORE® TAG® Devices in a 29-mm-diameter mock vessel, demonstrating radial fit with the radial force increasing (shown with red arrows) with device diameter.

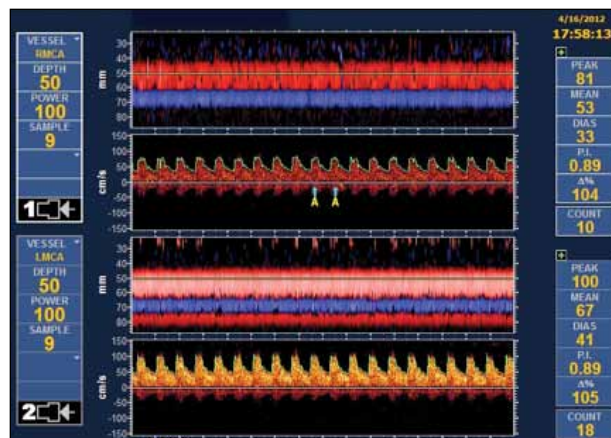


Figure 3. TCD showing minimal microembolic signal during deployment of the Conformable GORE® TAG® Device. Image provided courtesy of Zsolt Garami, MD.

ment on TEVAR.<sup>7</sup> In modern endovascular aortic repair, pathologies encountered include degenerative aortic disease (aneurysm, penetrating ulcer), aortic dissection, intramural hematoma, aortic trauma, and coarctation. In each pathological process, the aortic wall will behave differently upon being manipulated by endovascular devices, and therefore, a clinician must be able to identify a disadvantaged aortic wall and dictate the most appropriate radial force.

The risk of stroke can also be affected by proper radial fit. Stroke is a consequential complication of TEVAR and still persists at a rate of 4.3% to 5.8%.<sup>8,9</sup> By using transcranial Doppler (TCD) monitoring during all our TEVAR procedures, we found that there was a significant association between the total number of microemboli and postopera-

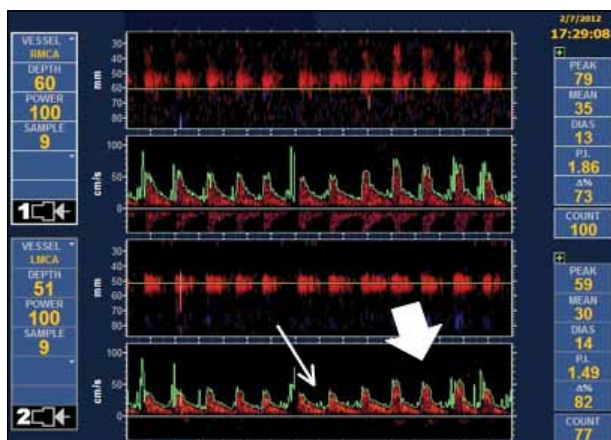


Figure 5. TCD demonstrating significant hemodynamic cerebral changes secondary to ballooning of aortic endograft with depression of Doppler waveform (narrow arrow) with compensatory vasodilation (wide arrow). Image provided courtesy of Zsolt Garami, MD.

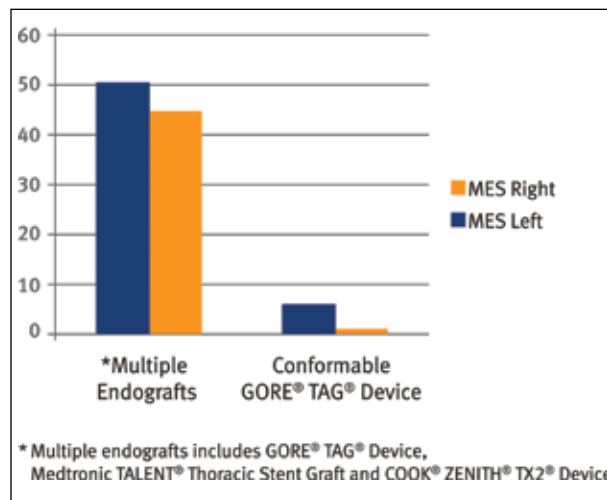


Figure 4. Total number of microembolic signals (MES) identified by transcranial Doppler (TCD) measured in the middle cerebral artery during TEVAR. Ballooning was only performed with one of the Conformable GORE® TAG® Devices.

tive stroke, transient ischemic attack, and death.<sup>10</sup> TCD monitoring's objective is to estimate which devices and steps of the procedure provoke the most microembolization. This information implores changes in the approach toward stent grafting: How can certain parts of the procedure, or the actual device choice, be modified to limit the degree of microembolization and ensuing stroke? One of the most common issues with the early generation of thoracic devices was "bird-beaking," a process that exerts a degree of deformation to the aorta.<sup>11,12</sup> The ideal condition is to devise an endograft that conforms to the vessel and does not deform the aorta. The Conformable GORE® TAG® Device does exactly that, as it affords better wall apposition and low spring-back force.

In our analysis of the TEVAR procedure, device deployment generated the greatest number of microemboli. We have noted that the microemboli count has been greatly reduced when using the Conformable GORE® TAG® Device (Figures 3 and 4). This observation is inherently intuitive when one considers the potential adverse impact that a non-conformable stent could have on the vessel. With a conformable stent, forces are naturally distributed more evenly on the entire stent-to-wall interface, displaying an ideal radial fit of the stent. Because radial fit is maintained across greater degrees of oversizing, the clinician gains significant control in how he or she chooses a stent based on the ideal radial force desired. Furthermore, we have identified a major modification in the way a majority of procedures are performed in our practice. Proper radial fit may obviate the need for post-delivery ballooning in cases

(Continued on page 8)

# Intricacies of Isolated Lesions

With technological developments comes new focus on isolated lesions, but what exactly are they?

**BY WILLIAM JORDAN, MD, AND MARK FARBER, MD, FACS**

In January 2012, the US Food and Drug Administration (FDA) approved the redesigned Conformable GORE® TAG® Device (Gore & Associates, Flagstaff, AZ) for the treatment of isolated lesions of the descending thoracic aorta. This new indication adds to the already approved indication of aneurysmal disease. However, the new indication may be somewhat confusing to many vascular specialists because the term “isolated lesion” has not been clearly defined.

As improved axial imaging techniques replace traditional modalities such as angiography for evaluation of the thoracic aorta, aortic specialists have recognized subtler pathologies involving the wall of the aorta. No longer are only the terms *aneurysm*, *transection*, and *dissection* used to describe the pathologic process that afflicts the area. Additional terms, such as *penetrating atherosclerotic ulcer*, *intramural hematoma*, *intimal disruption*, *focal dissection*, and *isolated injuries*, have been identified. Although these lesions can occur in other regions of the aorta, they are often limited to the descending thoracic aorta.

## DEFINING ISOLATED LESIONS

If normal aortic sections exist above and below a concerning lesion, allowing for endovascular treatment distal to the left common carotid artery and proximal to the celiac artery, then the term “isolated lesion of the descending thoracic aorta” can be used to describe the lesion. This broader term expresses the many different disease processes that the vascular specialist may encounter and creates an environment in which endovascular treatment is appropriate. It should be noted that extensive pathologies, such as dissections, are generally excluded from the definition given the typical extent of disease and pathologic implications. Instead, for the Conformable GORE® TAG® Device, the FDA has considered the multitude of pathologies that have been tested in clinical trials and sees endovascular treatment as safe and appropriate when the disease is limited to the descending aorta.

Defining “indications for use” based on pathology limited to an anatomic location condition is a more practical approach to endovascular therapy.

## CONCLUSION

This approach to defining “indications for use” based on pathology limited to an anatomic location condition is a more practical approach to endovascular therapy than the previously restrictive method based on specific pathologies. The multiple studies on endovascular thoracic aortic disease gave the FDA an overview of the common problems seen by vascular specialists and led to the approval of the broader indication for use of the



Figure 1. Sagittal view of a blunt aortic injury.





Figure 2. Axial view of the blunt aortic injury.



Figure 3. Postoperative (TEVAR) imaging follow-up of the BAI treated with the Conformable GORE® TAG® Device.

Conformable GORE® TAG® Device. Continued collaborative efforts with the FDA in clinical trials and the pursuit of device approval will likely bring additional alternative therapies to patients. ■

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where the device is appropriately apposed to the aortic wall. Ballooning is a process that can produce significant embolization, as well as cerebral flow changes (Figure 5).<sup>10</sup>

## CONCLUSION

Endovascular management is only as successful as the devices we implant. Therein lies the paradox—for years, we have implanted devices that were not designed for all thoracic applications. Therefore, it only requires an occasional twist of fate for devices to show signs of failure, requiring further intervention. Imaging modalities such as TCD and MRI have allowed us to ascertain that positive changes can come with device improvements, such as those of the Conformable GORE® TAG® Device. Learning from incidents and clinical observations over a longer period of time will establish whether these encouraging outcomes will be maintained. ■

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# TEVAR for Blunt Aortic Injury

Have newer devices made a difference?

BY BENJAMIN W. STARNES, MD

## CASE REPORT

In July 2010, a 17-year-old boy was airlifted to Harborview Medical Center in Seattle with traumatic transection of his thoracic aorta, often referred to as *blunt aortic injury* (BAI). The patient was cliff jumping with friends in Idaho from a 50-foot-tall ridge into still water below; he struck the water with his chest and complained of immediate, excruciating chest and back pain. His mother took him to a nearby hospital facility, where a computed tomography (CT) scan was performed (Figure 1). Upon presentation at Harborview, he was taken to the operating room and underwent thoracic endovascular repair with a device that is specifically designed to treat these types of injuries, the Conformable GORE® TAG® Device (Gore & Associates) (Figure 2). The surgery was performed as part of the Conformable GORE® TAG® Device Traumatic Transection Study (08-02) after his surgeons received approval for “emergency use” due to the fact that the patient was excluded from the study, as he was a minor.

Patients with BAI are typically young and have anatomic considerations that make conventional endovascular repair a challenge. Small and differential aortic diameters, steep “Gothic” arch configurations, and small-diameter access vessels are common in this patient population. Two-year follow-up CT scanning of this patient demonstrated a perfect result, with good apposition of the graft, no migration or in-folding, and more importantly, no adverse clinical events (Figure 3).

## THE PROBLEM

During the past decade, there has been a shift toward endovascular repair of patients with BAIs. Multiple series with short- and mid-term follow-up suggest that thoracic endovascular aortic repair (TEVAR) is a viable alternative to open repair for traumatic aortic injuries.

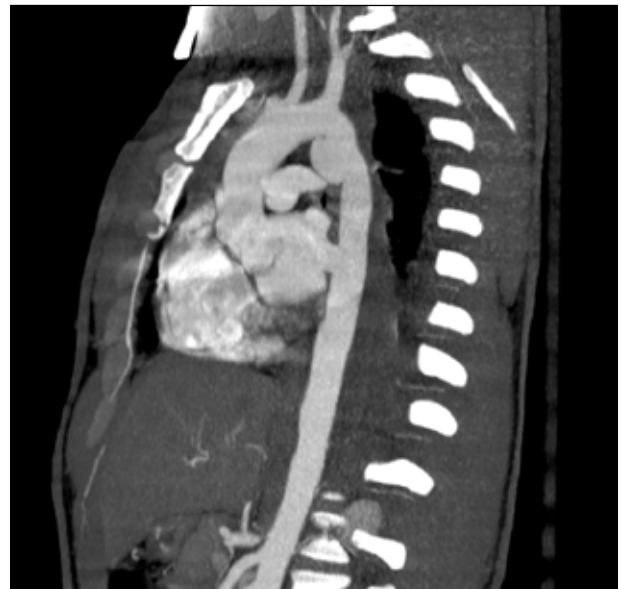


Figure 1. Sagittal CT imaging shows the BAI in the typical location just distal to the left subclavian artery. Notice the “Gothic” or steep arch configuration and size discrepancy between the aortic diameter at the level of the left common carotid artery (21 mm) and the descending thoracic aorta (18 mm).

Several studies have demonstrated reduced mortality and paraplegia rates with endovascular repair of BAI compared with open repair.<sup>1</sup> Recent clinical practice guidelines endorsed by the Society for Vascular Surgery suggest that endovascular repair of traumatic thoracic aortic injuries should be performed preferentially over open surgical repair or non-operative management.<sup>2</sup> Paraplegia resulting from compromise to the collateral circulation of the spinal cord is reported in open repair of traumatic aortic disruptions but has been conspicuously absent in multiple meta-analyses in which TEVAR for blunt thoracic aortic injury (BTAI) has been stud-



**Figure 2.** The Conformable GORE® TAG® Device was approved in January 2012 to treat patients presenting with traumatic BTAI.

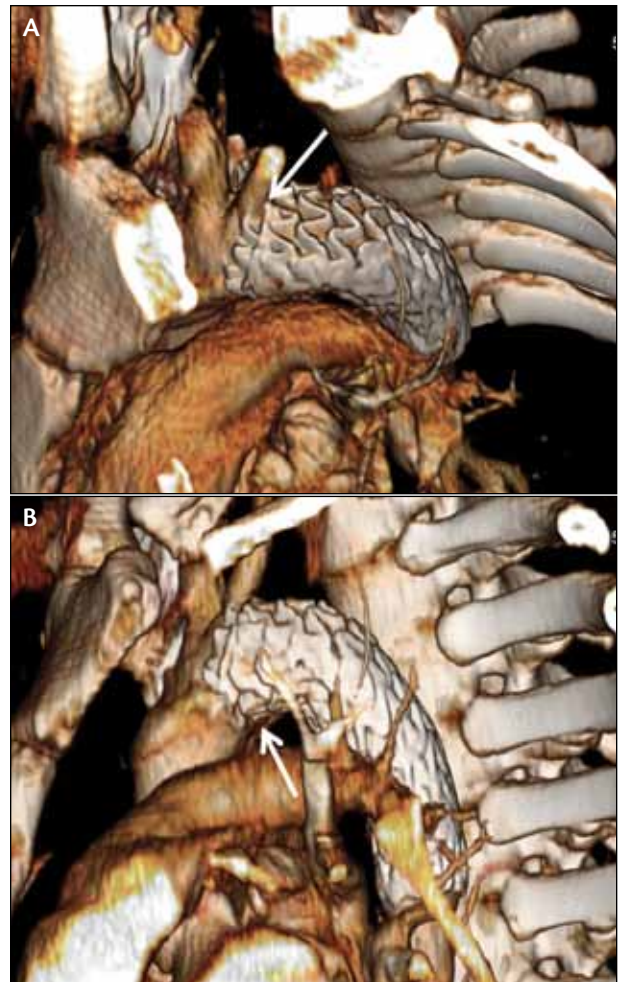
ied.<sup>3</sup> The only device that is currently approved by the US Food and Drug Administration to treat BAI is the Conformable GORE® TAG® Device, which was approved for this indication in January 2012.

Until recently, physicians were forced to use stent grafts that were originally designed to treat aneurysmal disease in the young patient population. Graft oversizing in small aortas can lead to device compression (Figure 4). Graft collapse can also occur due to a lack of apposition of the proximal stent graft along the inner curvature of the aortic arch. The recent release of the Conformable GORE® TAG® Device addresses the aortic size issue and allows for successful treatment of patients with aortic diameters as small as 16 mm.

### THE SOLUTION

Repair is dictated by the type of injury, and the timing of repair depends on the patient's associated injuries. Intimal tears (< 10 mm) heal with non-operative management. The University of Washington clinical treatment guidelines for BAI are as follows:<sup>4</sup>

- All patients with radiographic evidence of BAI should undergo anti-impulse therapy with beta-blockade, if tolerated, coupled with antiplatelet therapy (81 mg of aspirin).
- Observation alone with interval follow-up CT angiography within 30 days is appropriate for all intimal tears < 10 mm.
- Selective management of large intimal flaps (> 10 mm) is appropriate, with repeat imaging within 7 days to assess for progression. Evidence of progression should be managed, when possible, with endovascular repair.
- All patients with an aortic external contour abnormality on CT angiography should be considered for

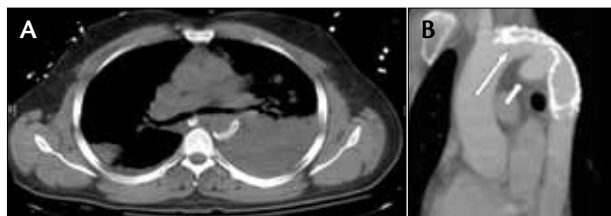


**Figure 3.** Two-year follow-up CT imaging. Note the precise deployment and lack of migration with the proximal end of the device just distal to the left common carotid artery (arrow) (A). Note the impressive apposition of the graft to the lesser curvature of the arch (arrow) (B).

semielective (< 1 week) endovascular repair if there is a high likelihood of survival from other associated injuries. These patients should be monitored with CT imaging as follows: 1 month, 6 months, 1 year, and every other year thereafter. Patients with hypotension on presentation and an aortic arch hematoma > 15 mm should be repaired with endovascular methods on a more urgent basis.

• Intentional left subclavian artery coverage without revascularization is well tolerated in the majority of patients with BAI.

• Patients with traumatic brain injuries and aortic external contour abnormalities should be considered for earlier repair if a deliberate increase in the mean arterial pressure is deemed to be beneficial for the patient.



**Figure 4.** Endovascular stent graft collapse 5 days after successful endovascular repair of a BAI. The long arrow shows the collapsed stent, and the short arrow shows the persistent pseudoaneurysm (B).

The short- and medium-term results of TEVAR for BTAI are encouraging, but the impact of aortic growth on graft anatomy in the long-term is not known. It has been shown that the proximal thoracic aorta dilates minimally after endovascular repair of BTAI, with the segment just distal to the left subclavian artery expanding at a slightly greater rate.<sup>2</sup> The trauma population tends to be young and is expected to live for decades following a successful repair. The concern for graft migration as aortic remodeling occurs with growth remains

valid, and adherence to a long-term follow-up protocol is imperative.

## CONCLUSION

Newer devices have definitely made a difference in the management options for BAI. Conformable devices with compression resistance offer a potentially permanent solution to this life-threatening situation. ■

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# Endovascular Stenting of Blunt Thoracic Aortic Transection Using the Conformable GORE® TAG® Device

Challenging anatomy has become more feasible to navigate.

BY MO HAMADY, MD, FRCR; ELIKA KASHEF, MD, FRCR; AND MIKE JENKINS, MD, FRCS

**B**lunt thoracic injury is a lethal condition that is treated with an endovascular stent graft as first-line management. Stent technology is continuously evolving to provide better minimally invasive treatment. The Conformable GORE® TAG® Device (Gore & Associates) is the latest addition to the armamentarium of stent technology, with a special design to cope with challenging anatomy.

Traumatic aortic transection (TAT) is a serious injury that is associated with high mortality and is considered to be the second most common cause of death in trauma patients.<sup>1,2</sup> Open surgical repair of TAT used to be the standard form of management. With the advent of endovascular techniques, growing experience, and continuous development of graft technology, thoracic endovascular aortic repair (TEVAR) has become the first-line management of blunt thoracic injury, with good short- and mid-term results in many centers. We report a case of multiple injuries and aortic transection treated with the new Conformable GORE® TAG® Device.

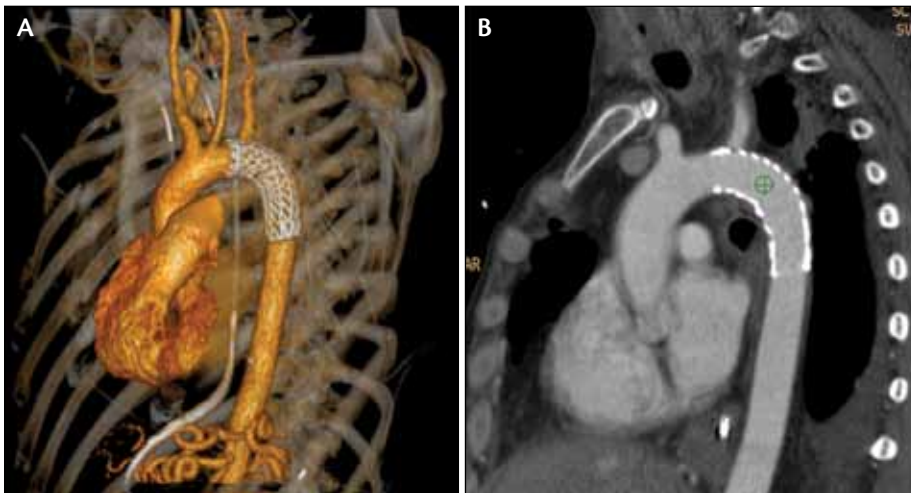
## CASE REPORT

A 47-year-old man was transferred to our level 1 trauma center following a car accident. He sustained multiple injuries to the chest, abdomen, and head. On



Figure 1. Oblique sagittal CT angiography shows pseudoaneurysm formation 6 mm distal to the left subclavian artery.

arrival, he was a 6 on the Glasgow Coma Scale and was hemodynamically unstable. The patient was intubated, and life-support resuscitation was provided. A total-body computed tomography (CT) scan revealed a brain



**Figure 2.** Oblique volume-rendering CT angiography and oblique maximum-intensity projection, showing good alignment of the stent graft (A) and complete exclusion of the injured aorta (B).

contusion to the right occipital lobe with no intra-axial or extra-axial hematoma, 60% right-sided pneumothorax with flail chest secondary to fractures of right-side ribs 3 through 6, and grade 3 aortic transection (Figure 1). A right-sided chest drain was inserted.

The multidisciplinary trauma team decided to transfer the patient to the hybrid interventional suite for endovascular repair of his aortic injury. The aortic measurements were a 24-mm proximal landing zone, a 23-mm distal landing zone, and a 6-mm distance between the transected area and the origin of the left subclavian artery. Cut-down was performed in the right groin, and a GORE® DrySeal Sheath (Gore & Associates) was inserted into the right iliac artery.

Percutaneous access for a diagnostic catheter was achieved in the left common femoral artery. Under controlled hypotension, a Conformable GORE® TAG® Device stent graft (26 mm X 26 mm X 10 cm) was deployed across the origin of the left subclavian artery. Completion angiography and CT angiography performed on day 3 showed good conformation to the aortic arch, with complete exclusion of the transected segment of the aorta and no endoleak (Figure 2). The patient was then transferred to the intensive care unit for initial recovery. Five days later, he was transferred to a neurology rehabilitation center and discharged to home 5 weeks later with good functional recovery.

## DISCUSSION

Traumatic aortic transection (TAT) is a life-threatening condition, associated with a 90% mortality rate.<sup>3</sup> The majority of patients die on the accident scene. Of

those who make it to the hospital, there is a 50% risk of mortality in the first 24 hours if the patient receives no intervention.<sup>4</sup> Furthermore, delayed aortic rupture has been reported in a significant proportion of patients.<sup>5</sup> The aortic injury is classified into four grades: grade 1 (intimal injury), grade 2 (intramural hematoma), grade 3 (pseudoaneurysm) and grade 4 (aortic rupture).<sup>6</sup> Intervention is needed for grades 2 to 4, while conservative treatment is reserved for grade 1.

Open surgical repair with high thoracotomy, aortic cross-clamping, single-lung ventilation, and systemic heparinization has been the standard treatment. However, the open approach is associated with a reported mortality rate of 24% and a significant paraplegia rate of 13%.<sup>7</sup> In addition, the usual polytrauma nature of those patients frequently precludes the use of systemic anticoagulation and single-lung perfusion.

The advent of TEVAR, with its less-invasive approach, is now the preferred method of treatment for anatomically suitable patients in most level 1 trauma centers. Several single- and multicenter studies demonstrate the safety and effectiveness of TEVAR in TAT patients. Ehrlich et al<sup>8</sup> reported on 41 patients treated with TEVAR, achieving 100% technical success. The in-hospital mortality and paraplegia rates in this series were 2.4% and 0%, respectively. In another series of 48 patients with 10 years of follow-up, the initial technical success rate was 100%. The 30-day mortality and procedure-related complication rates were 8.3% and 2.1%, respectively.<sup>9</sup>

In a meta-analysis of 699 patients with blunt aortic transection treated with TEVAR or open surgery, endovascular treatment showed significantly better results in the main outcomes of mortality, paraplegia, and stroke.<sup>10</sup>

Despite the outcomes favoring TEVAR in polytrauma patients, certain limitations and concerns remain unresolved. Wider usage of this technology is hindered by a lack of suitable device sizes for young patients with small aortic diameters, poor conformability of stiff devices in acutely angulated arches, stent failure, large

device profiles, and a lack of long-term durability data.

Stent collapse, although rare, can be a serious complication of stent grafts. Excessive oversizing and tight arch angulation in young patients with healthy aortas have been implicated in this type of stent failure.<sup>11</sup>

The new Conformable GORE® TAG® Device is designed to address some of the issues associated with challenging anatomy. The top end of the new device has nine uncovered apices, an increased diameter of the nitinol wire, and multilayer expanded polytetrafluoroethylene reinforcement. Those changes in design result in improved radial force, point-load distribution, and conformability against the inner curve of the aorta. The Conformable GORE® TAG® Device also allows more generous oversizing (6% to 33%) to treat aortas as small as 16 mm. It is available in a wide range of sizes (21–45 mm) in both straight and tapered designs. However, the device profile remains relatively large (18–24 F), which needs particular attention during access planning. The device has been approved by the US Food and Drug Administration for the treatment of isolated lesions of the descending thoracic aorta, which includes thoracic aneurysm and aortic transection.<sup>12,13</sup>

## CONCLUSION

In this case, the Conformable GORE® TAG® Device stent graft was used to treat traumatic aortic transection in a critically injured patient who had challenging anatomy and provided a good technical and clinical outcome. However, further data are needed to establish its mid- and long-term durability. ■

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# Conformable GORE® TAG® Device Exclusion of Severe Descending Thoracic Aortic Traumatic Injury

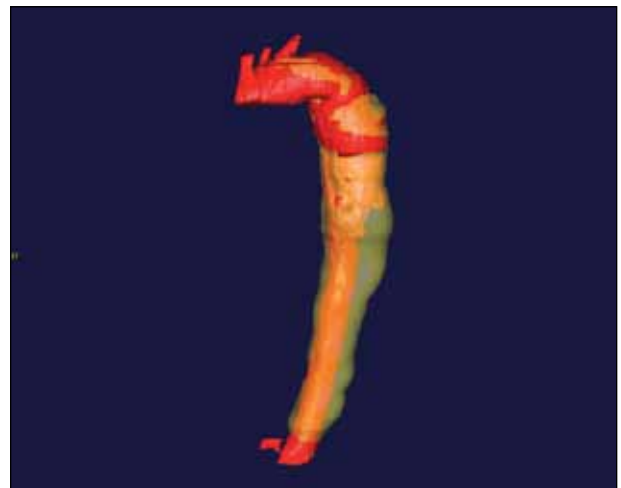
The utility of a new FDA-approved indication.

**BY RODNEY A. WHITE, MD; CHRISTOPHER MARROCCO, MD; GEORGE KOPCHOK, BS; IRWIN WALOT, MD; AND CARLOS E. DONAYRE, MD**

**T**raumatic aortic injury carries significant morbidity and mortality. Complete aortic transection is often fatal in the field, with few patients surviving the immediate injury or transport period. Partial transection and aortic disruption also carry a significant mortality rate and pose a management dilemma, as these are almost uniformly compounded by concomitant traumatic injuries associated with rapid deceleration and impact. Anticoagulation during the time of aortic repair may carry an increased risk of hemorrhage in the multitrauma victim, especially when there is associated closed head or spinal injury. In the following case, we present a young multitrauma patient who was successfully managed using the Conformable GORE® TAG® Device (Gore & Associates) thoracic endoluminal prosthesis without the use of systemic heparinization.

## CASE REPORT

A 47-year-old woman was injured as a pedestrian who sustained the head-on impact of an automobile, which was estimated to be traveling at approximately 60 miles per hour. She had severe traumatic injuries, including a cervical spine fracture, multiple pelvic bone fractures, bilateral femoral fractures, left femoral neck fracture, left patella fracture, left fibular head fracture, pulmonary contusion, and no pulse in the left lower extremity below the groin. In addition, a computed tomography (CT) scan of her chest showed severe descending thoracic aortic traumatic injury (Figure 1).



**Figure 1.** A CT scan showing severe descending thoracic aortic disruption.

After rapid assessment and prioritization of surgical interventions, the patient and her family were consulted regarding the severity of her multiple injuries and the urgency to intervene to prevent life-threatening hemorrhage from the descending thoracic aortic injury. After discussing the options of open descending thoracic repair compared to placement of the recently approved Conformable GORE® TAG® Device for this indication, the patient and her family opted for endovascular repair.

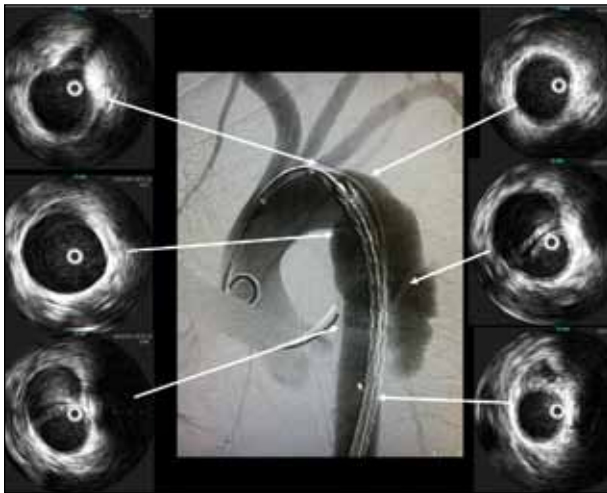


Figure 2. Angiogram of the descending thoracic aorta before device deployment, with corresponding IVUS images at the landing zones and along the length of the traumatic injury.

### TREATMENT

The left femoral artery was exposed through an oblique incision. After achieving access and passing a starter wire, the thoracic aorta was interrogated with intravascular ultrasound, and the length of injury and landing zones were identified. The CT, angiographic, and intravascular ultrasound findings were consistent with the aortic disruption being approximately 3 cm distal to the takeoff of the left subclavian artery. The diameter of the aorta distal to the left subclavian measured 25 mm. There was evidence of extensive disruption of the tapered aorta over approximately 100 mm



Figure 3. Angiography of the descending thoracic aorta after endograft deployment.

in length from the initial entry site. To expediently place the device without heparin due to the risk of hemorrhage from other traumatic injuries, the device and an angiographic catheter were introduced through a GORE® DrySeal Sheath (Gore & Associates), and the landing zones were confirmed with angiography (Figure 2). A Conformable GORE® TAG® Device (28 mm X 28 mm X 15 cm) was deployed distal to the left subclavian artery without difficulty. After deployment of the device (Figure 3), it was apparent that the length of the aortic disruption had been covered by the device, with the



Figure 4. A CT scan 4 days after device deployment, showing near-complete exclusion of the lesion, with a large hematoma surrounding the device.

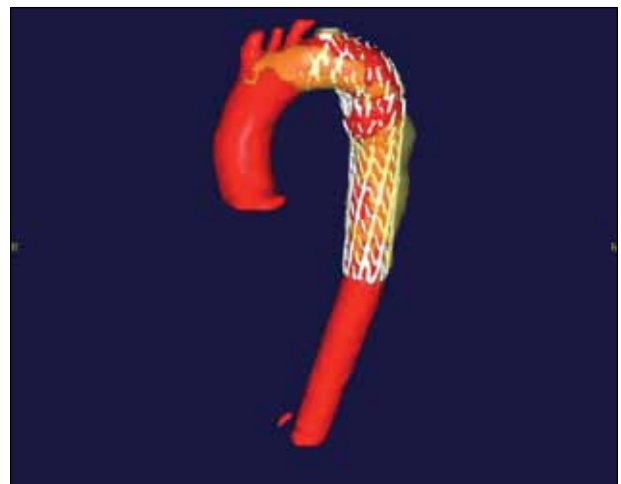


Figure 5. A CT scan 6 weeks after the procedure, showing nearly complete resolution of the descending thoracic aortic injury with aortic remodeling.

left subclavian artery remaining patent.

Before completing the procedure, catheter embolectomy of the left lower extremity was performed; completion angiography showed patency of the femoral and lower extremity arteries without injury. Throughout the procedure, the infusion sheaths in the femoral artery were flushed with heparin to help prevent local thrombosis. Thrombectomy was performed using 2,000 units of heparin to achieve patency while minimizing potential hemorrhagic complications.

A CT scan 4 days post-deployment showed complete coverage of the lesion, with a large hematoma surrounding the device (Figure 4). The patient was subsequently transferred to a rehabilitation facility where a follow-up CT was achieved at 6 weeks, which showed near-complete resolution of the injury, with conformity of the device to the aortic anatomy (Figure 5).

## CONCLUSION

This case demonstrates the potential for endoluminal graft exclusion of descending thoracic aortic traumatic disruptions using the newly approved Conformable GORE® TAG® Device. The extent of aortic disruption in this patient clearly exemplifies the advance that endoluminal exclusion of traumatic injuries has provided for severely injured patients while avoiding the concomitant morbidity, mortality, and potential delays associated with open thoracoabdominal repair. The series of images from this patient also show the aortic remodeling that occurred during the post-deployment period with near-complete resolution by 6 weeks.

Rapid deployment of the device without systemic heparin can be accomplished in severely injured patients if the procedure can be completed expedi-

tiously. In this case, the total time from skin incision to completion of device deployment was 20 minutes. ■

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# Technical Considerations in the Use of TEVAR in Young Patients With Aortic Aneurysms

Dynamic features of the Conformable GORE® TAG® Device can provide unique advantages in the young patient.

BY JEHANGIR J. APPOO, MDCM

**E**ndovascular aortic repair has been successful in the treatment of thoracic aortic aneurysms. However, the vast majority of these patients are elderly. Young patients pose specific anatomic challenges, as well as long-term durability issues, when endovascular prostheses are used.

## CASE REPORT

A 37-year-old woman presented with cough and cold-like symptoms. The patient had a documented medical history of Crohn's disease, a 20-pack-per-year cigarette smoking history, and a motor vehicle accident at age 11. A chest x-ray revealed an enlarged thoracic aortic shadow, and the patient underwent fine-cut computed tomography (CT) angiography of the chest (Figure 1). The CT scan revealed a fusiform descending thoracic aortic aneurysm with a maximal diameter of 5.8 cm, which was more than twice the diameter of the aorta above and below the aneurysm.

The etiology of the aneurysm was unclear. There was no definite intimal flap or pseudoaneurysm to confirm that this was secondary to a localized dissection or a blunt traumatic aortic injury that was incurred at the time of the motor vehicle accident 26 years ago. No interval imaging was available for comparison. Hypertensive or atherosclerotic disease seemed even less likely, given that she was normotensive, and there was no degenerative or atherosclerotic disease evident in the rest of the thoracic or abdominal aorta.

Intervention was deemed to be appropriate to prevent aortic rupture. It was believed that the patient could undergo either endovascular or open repair via a thora-

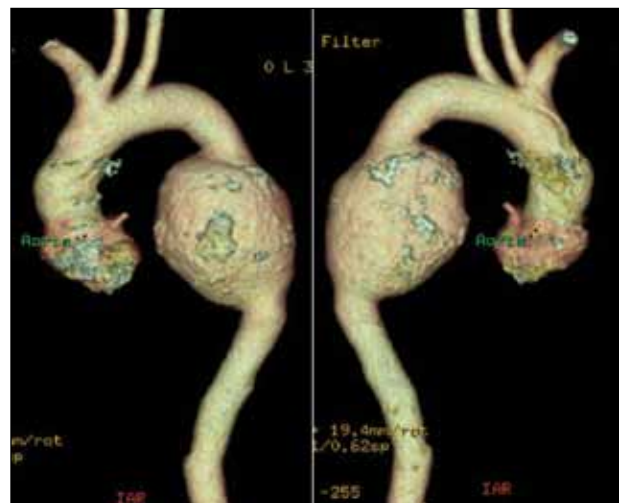


Figure 1. Volume-rendered three-dimensional CT reconstruction showing a large descending thoracic aortic aneurysm distal to the left subclavian artery.

cotomy. After discussing the risks and benefits of both options, an endovascular approach was selected.

Detailed CT analysis revealed a proximal landing zone diameter 3 cm distal to the left subclavian artery of 20 mm (Figure 2). The distal landing zone was only 16 mm in diameter. Estimated total length of coverage needed was 12 to 14 cm.

## PROCEDURE

The procedure was performed under general anesthesia in the operating room with intraoperative



**Figure 2.** Sagittal reconstruction of a CT angiogram, showing the small diameter of the proximal and distal landing zones.

transesophageal echocardiographic guidance and fluoroscopy. We decided preoperatively not to insert a spinal cord drain, but instead, to wake the patient up on the operating room table, assess her neurological status, and be ready to insert a cerebrospinal fluid drain if needed.

The right femoral artery was accessed via a 1.5-inch transverse groin incision, 5,000 units of intravenous heparin was administered, and a 20-F GORE® DrySeal Sheath (Gore & Associates)

was placed. Under fluoroscopic guidance, a 26-mm X 26-mm X 10-cm Conformable GORE® TAG® Device (Gore & Associates) was advanced over a Lunderquist Extra-Stiff wire (Cook Medical, Bloomington, IN) and deployed 2 cm distal to the left subclavian artery (Figure 3). The second device was a tapered, 26-mm X 21-mm X 10-cm Conformable GORE® TAG® Device, which was inserted distally, providing 5 cm of overlap coverage between the two stent grafts. Completion angiography (Figure 4) was performed, and the femoral artery was repaired with interrupted PROLENE® Sutures. The patient was extubated on the operating table and was neurologically intact. A postoperative CT scan revealed exclusion of the aneurysm sac with no endoleak (Figure 5). The patient was discharged home 3 days later.

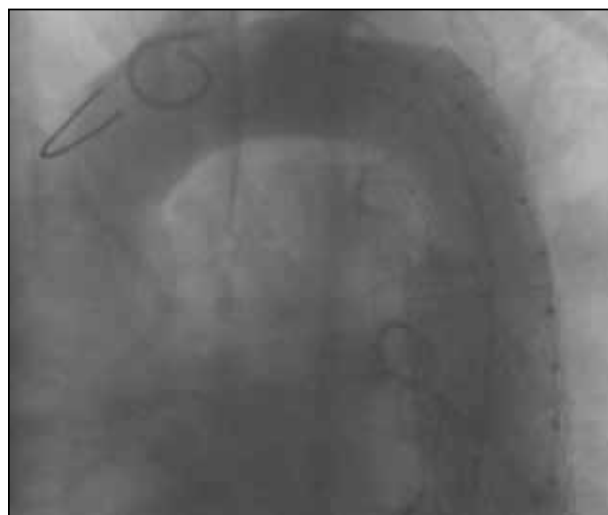
### ANATOMIC CHALLENGES OF YOUNG PATIENTS

In young patients, landing zone sites can often have a small diameter. This patient's 16-mm distal landing zone would traditionally be a contraindication to endovascular repair. However, the expanded sizing indications of the Conformable GORE® TAG® Device accommodate a 16-mm aorta with a 21-mm device, resulting in 31% oversizing. In young patients, a long-lasting durable repair is of consequence. The long-term outcome of thoracic endovascular aortic repair

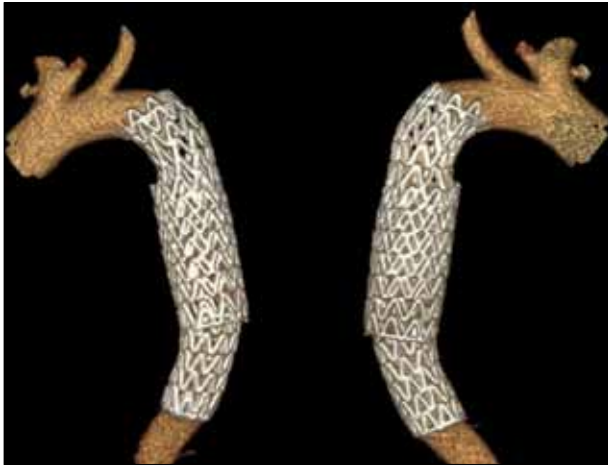


**Figure 3.** Intraoperative angiography of the Conformable GORE® TAG® Device in place but not deployed. The aneurysm can be seen enhancing with contrast.

(TEVAR) beyond 10 years is not yet defined. The “normal” non-diseased aortic diameter is known to increase over time. There is a risk of delayed endoleak formation as the device fails to remain opposed to the expanding aorta. In this case, the 31% oversizing of the distal landing zone should, theoretically, be able to maintain wall apposition over time.



**Figure 4.** Intraoperative angiography after deployment of the Conformable GORE® TAG® Device, showing exclusion of the aneurysm sac.



**Figure 5.** The three-dimensional volume-rendered CT image post-Conformable GORE® TAG® Device insertion reveals exclusion of the aneurysm sac, no endoleak, and a well-positioned thoracic endovascular device.

A tapered graft is also useful in young patients who have uniform tapering of the non-diseased segment of their thoracic aorta. The tapered Conformable GORE® TAG® Device graft allows for accommodation of proximal and distal landing zone diameters.

When treating young patients, physicians have to be aware of the future ramifications of the endovascular prosthesis. Apart from the fact that patients with thoracic aortic endografts are likely to require lifelong surveillance imaging, there are many other reasons that a patient might require magnetic resonance imaging (MRI) during the next 3, 4, or 5 decades. With the Conformable GORE® TAG® Device being MRI compatible, the patient will not be exposed to annual radiation from surveillance CT scans. In addition, endovascular treatment does not result in a contraindication to MRI for neurologic, orthopedic, cardiac, or other reasons.

### OPEN SURGERY VERSUS ENDOVASCULAR REPAIR

Both open and endovascular repair techniques are performed in the cardiac surgery operating room by a

multidisciplinary team trained in both open and endovascular surgery, allowing for fair assessment of the risks and benefits associated with each approach. The advantages of an open operation would be a more known/understood long-term result. Endovascular surgery has been shown to have a lower risk of spinal cord ischemia and mortality and a similar risk of stroke versus open surgery for descending thoracic aortic aneurysms.<sup>1</sup> Other advantages of TEVAR include less pain, cosmesis, and quicker recovery—all of which were important to the young woman in this case. The procedure was also planned in such a way that TEVAR would not unnecessarily complicate future open repair, should the patient require surgical graft revision. As the graft was not encroaching on the arch, the descending thoracic aorta could be clamped distal to the left subclavian artery and resected via a thoracotomy if necessitated by infection or delayed graft failure.

### FOLLOW-UP

Our patient was a busy mother of three children and returned to full-time employment 1 week postoperatively. She was very grateful to avoid a thoracotomy incision. A follow-up CT scan at 6 months revealed no evidence of complications. Going forward, annual follow-up will be performed via MRI.

### CONCLUSION

The diameter range, oversizing ability, presence of tapered grafts, and MRI compatibility of the Conformable GORE® TAG® Device provides unique solutions to some of the challenges of treating thoracic aortic aneurysms in young patients. ■

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# Endovascular Repair of a Traumatic Aortic Tear With the Conformable GORE® TAG® Device

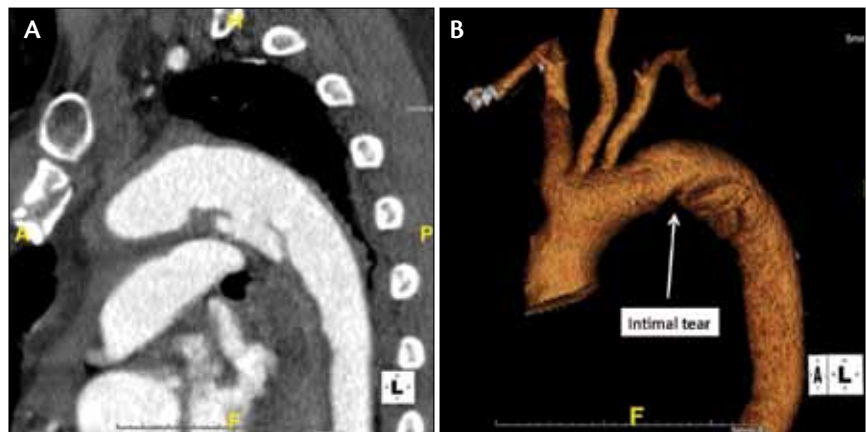
This complex problem has seen improved mortality rates thanks to refined technology.

**BY JUAN CARLOS JIMENEZ, MD, FACS; SHARON C. KIANG, MD; AND WILLIAM J. QUINONES-BALDRICH, MD**

Improvements in technology continue to expand the indications for endovascular repair of traumatic thoracic aortic pathology. We present the following case, which utilized the newer-generation Conformable GORE® TAG® Device (Gore & Associates) for successful endovascular treatment of a complex traumatic aortic tear.

## CASE REPORT

The patient was a 74-year-old man who sustained a 25-foot fall and presented to the emergency department as a critical trauma patient. Upon presentation, he was hemodynamically stable, with a heart rate ranging between 100 to 110 bpm and a blood pressure of 118/78. A computed tomography (CT) scan of his chest demonstrated a traumatic aortic tear involving the arch distal to the left subclavian artery origin (Figure 1). An intramural dissection and mediastinal hematoma were also pres-



Figures 1. CT with sagittal view showing the location of the intimal defect (A). Three-dimensional reconstruction shows the location of the intimal defect (B).

ent. Multiple associated injuries included right-sided rib fractures of ribs 5 through 11, bilateral pulmonary contusions, a right psoas muscle hematoma, multiple serosal bowel injuries, a right adrenal hematoma, a left open tibial fracture, multiple transverse process fractures, and a left sacral fracture.

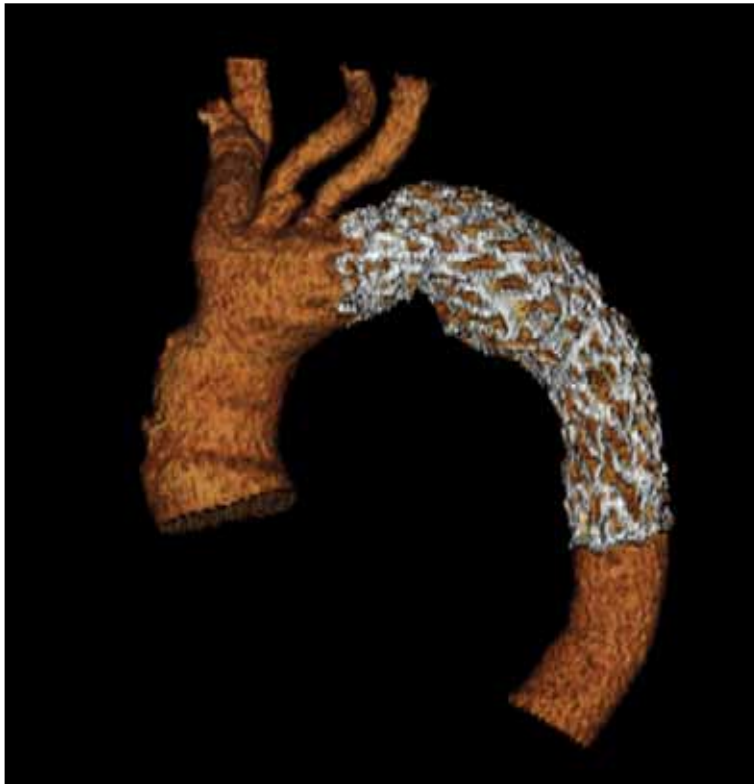
The patient was immediately taken to the operating



room for endovascular thoracic repair. We began with an ultrasound-guided puncture of the right common femoral artery. Due to the patient's multiple concomitant injuries, it was decided not to administer systemic heparin. Percutaneous arterial access was achieved using the preclose technique, and two PROGLIDE Sutures (Abbott Vascular, Santa Clara, CA) were placed. The right common femoral artery was predilated with 9- and 14-F sheaths, respectively, over a BENTSON Guidewire (Cook Medical, Bloomington, IN). A Lunderquist Extra-Stiff wire (Cook Medical) was exchanged and advanced to the descending thoracic aorta, and a 24-F GORE® DrySeal Sheath (Gore & Associates) was advanced to this level. A Bentsen "buddy" wire was placed through the sheath, and a marker pigtail catheter was advanced to the ascending aorta.

Aortography confirmed the presence of the traumatic aortic dissection approximately 3 cm distal to the subclavian artery origin. We loaded a 37-mm X 37-mm X 15-cm Conformable GORE® TAG® Device over the Lunderquist wire and positioned the partially uncovered stent portion of the graft immediately distal to the subclavian artery takeoff. The graft was deployed at this level, and completion angiography showed successful coverage of the aortic tear without evidence of endoleak or extravasation and continued patency of the arch vessels. The total time between pre- and post-deployment angiography was 17 minutes. The volume of iodinated contrast administered for the thoracic repair was 60 mL.

Upon completion of the endovascular repair, exploratory laparotomy was performed for hemoperitoneum and associated serosal bowel injuries. The patient also underwent subsequent angiographic embolization the next day for continued retroperitoneal bleeding from a lumbar artery and open repair of his open tibial fracture. After stabilization of his multiple traumatic injuries, the patient had a prolonged hospital course that was complicated by acute respiratory distress syndrome. He was extubated on postoperative day 14 and discharged to a rehabilitation facility. One month postoperatively, a follow-up CT of the chest demonstrated no evidence of aortic dissection or endoleak, and there was no evidence of stent graft migration (Figure 2).



**Figure 2.** Postoperative CT at 1 month follow-up shows successful repair of the traumatic aortic tear with continued patency of the great vessels and no evidence of endoleak or stent migration.

## DISCUSSION

Aortic injury after blunt trauma is associated with extremely high morbidity and mortality; up to 80% of patients with this injury are thought to die prior to arrival at a hospital.<sup>1</sup> It most frequently occurs after sudden deceleration and focal disruption at the level of aortic fixation to the chest wall. In a contemporary series by Canaud and colleagues, the mortality rates after open repair in these patients was 11.4% compared with 2.5% after endovascular repair.<sup>2</sup> A recent review of 100 consecutive patients treated with stent grafts following blunt traumatic thoracic aortic injury demonstrated an in-hospital mortality rate of 12%.<sup>3</sup> Endovascular repair was also associated with lower operative times, estimated blood loss, and intraoperative blood transfusions compared with open repair. In addition, endovascular repair is associated with decreased postoperative pneumonia, shorter length of hospital stay, and a decreased incidence of paraplegia.<sup>4</sup>

Several key technical points regarding endovascular repair of traumatic aortic injuries should be emphasized. The severe blunt chest trauma associated with aortic tears frequently causes multiple associated inju-

ries, which may be present in multiple body cavities and extremities.<sup>5</sup> Thus, rapid evaluation of CT images and measurements should be performed as the patient is being prepped for surgery. Intravascular ultrasound may be used to measure aortic landing zone diameters and locate the precise location of the intimal defect in patients who are unable to be imaged with CT scans. Our 17-minute case duration demonstrates that the Conformable GORE® TAG® Device can be optimally positioned and rapidly deployed following arch angiography. Short operative times are essential to reduce thrombotic complications because systemic anticoagulation is frequently contraindicated in patients following severe blunt trauma.<sup>6</sup> Because these patients frequently have multiple concomitant injuries that also require operative or interventional repair after stent graft placement, delays in treatment of the thoracic aortic injury due to long operative times may lead to poor outcomes.

The development of newer, more flexible stent grafts, such as the Conformable GORE® TAG® Device, has allowed for improved circumferential aortic wall apposition in patients with tortuous anatomy over a wider range of aortic diameters. Traditionally, many patients with traumatic aortic injuries are younger and have relatively smaller-diameter aortas compared to the aneurysmal aortas that the stent grafts were originally designed to accommodate. The newer-generation Conformable GORE® TAG® Device can be used to treat aortas of 16 to 42 mm, and modifications, which add to its conformability, include increased wire diameter for higher radial force and optimized expanded polytetrafluoroethylene graft material for increased flexibility. Additionally, use of the GORE® DrySeal Sheath allowed us to perform the operation using unilateral femoral artery access with the use of a “buddy” wire, pigtail catheter, and stent graft through a single sheath.

## CONCLUSION

In summary, endovascular repair of blunt traumatic aortic injuries has improved mortality rates and perioperative morbidity for this complex problem. Further refinement of existing commercial devices will likely continue to improve patient outcomes and allow for successful treatment in a wider range of anatomic variants and clinical scenarios. ■

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## Conformable GORE® TAG® Thoracic Endoprosthesis

**INDICATIONS FOR USE:** The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of isolated lesions (not including dissections) of the descending thoracic aorta, in patients who have appropriate anatomy including: Adequate iliac/femoral access; Aortic inner diameter in the range of 16 - 42 mm; ≥20 mm non-aneurysmal aorta proximal and distal to the lesion. **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. Rx Only



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