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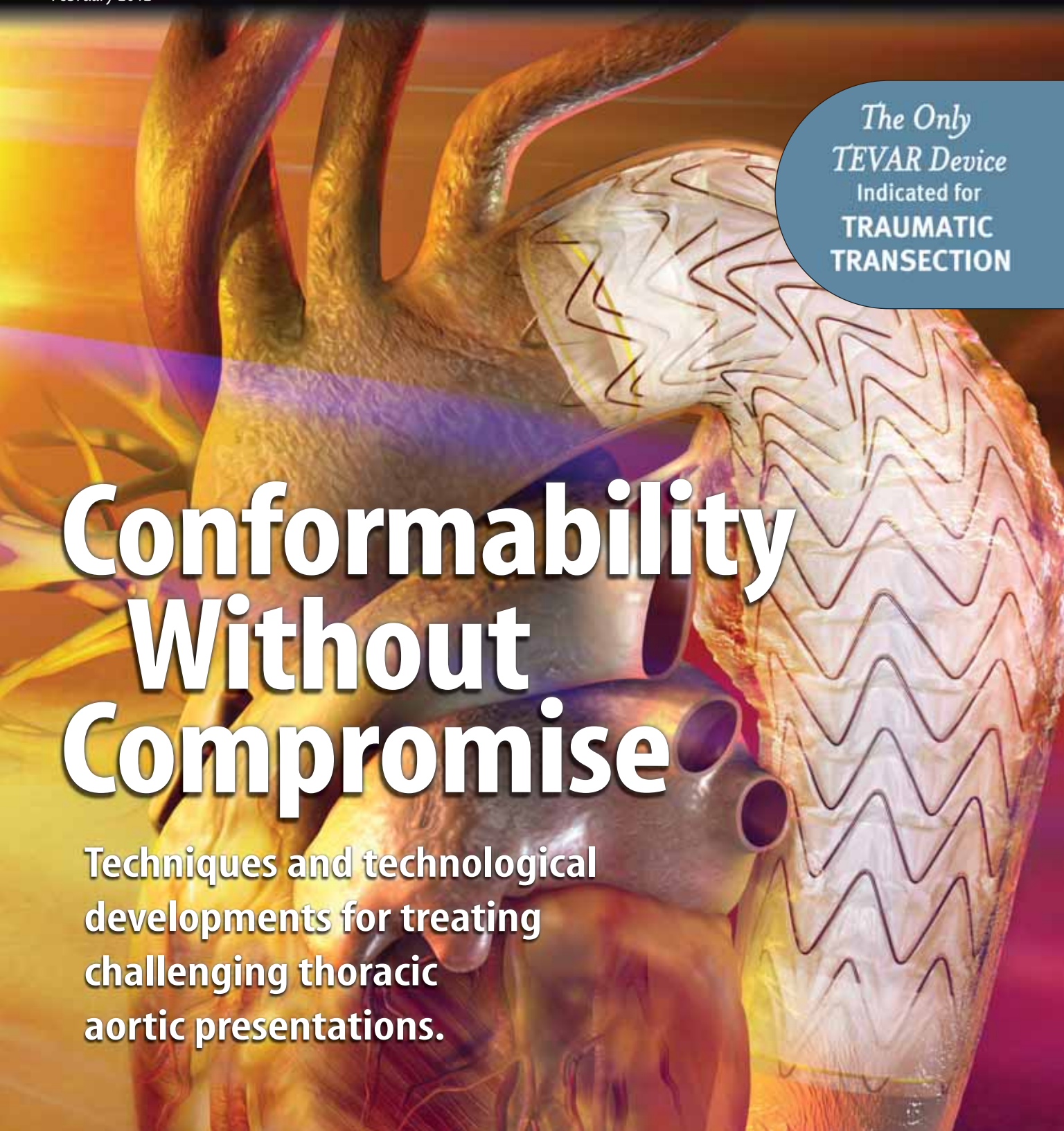
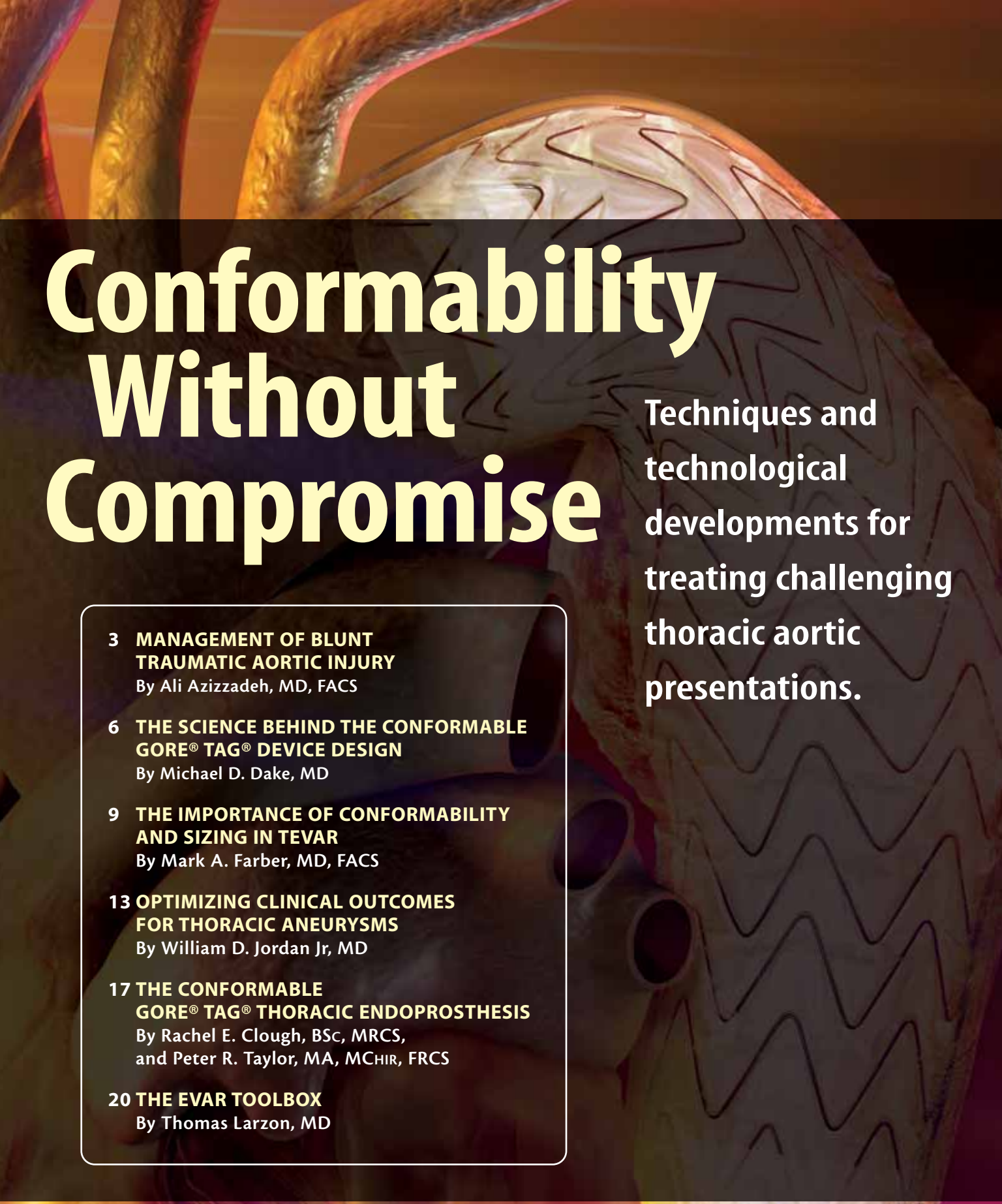


Conformability Without Compromise

Techniques and technological developments for treating challenging thoracic aortic presentations.



Conformability Without Compromise

Techniques and technological developments for treating challenging thoracic aortic presentations.

Management of Blunt Traumatic Aortic Injury

How to best utilize TEVAR to treat this challenging presentation.

BY ALI AZIZZADEH, MD, FACS

Traumatic aortic injury (TAI) is the second most common cause of death after blunt trauma among patients with major traumatic injuries.[1] The mechanism of injury is likely related to a complex combination of both the relative motion of the structures within the thorax and local loading of the tissues, either as a result of the anatomy or the nature of the impact.[2] In the aorta, the greatest strain occurs at the isthmus.[3,4] In 1958, Parmley et al reported an 85% prehospital mortality rate in patients with TAI.[5] Traditional open repair has been associated with high morbidity and mortality rates,[6] and therefore, thoracic endovascular aortic repair (TEVAR) has rapidly been adopted for treatment of TAI. Several meta-analyses have documented significantly improved outcomes with TEVAR compared to open repair.[7-9] This article provides a brief summary regarding the use of TEVAR for the treatment of TAI.

DIAGNOSIS AND MANAGEMENT

TAI includes a spectrum of aortic lesions that range from intimal tears to free ruptures. Diagnosis is often suspected based on the mechanism of injury. External signs of severe chest impact, such as seat belt marks, may be present. Abnormalities seen on plain chest x-ray include widened mediastinum, indistinct aortic knob, apical cap, left pleural effusion, first or second rib fractures, tracheal deviation, and depressed left bronchus. Computed tomographic angiography (CTA) is often diagnostic.[10] In a small subset of patients, additional imaging, such as angiography or intravascular ultrasound (IVUS), may be required if CTA results are equivocal.

In a recent retrospective study, my colleagues and I found that in patients who have an equivocal CTA, IVUS was better than angiography in diagnosing TAI.[11] Of the 7,961 patients who were admitted to our emergency center, 2,153 (27%) underwent CTA study. The results were interpreted as negative (2,128 patients [26.7%]), positive (14 patients [0.18%]), or equivocal (11 patients [0.14%]). All patients with positive or equivocal results underwent angiography and IVUS. Angiography results were twice as likely to be equivocal compared to IVUS (5% vs 2.5%). TAI lesions that do not cause an abnormality in the contour of the aortic wall (grade I and some grade II) are inherently difficult to see on angiography. As a result, we recommend the use of IVUS in patients who are undergoing angiography for equivocal CTA.

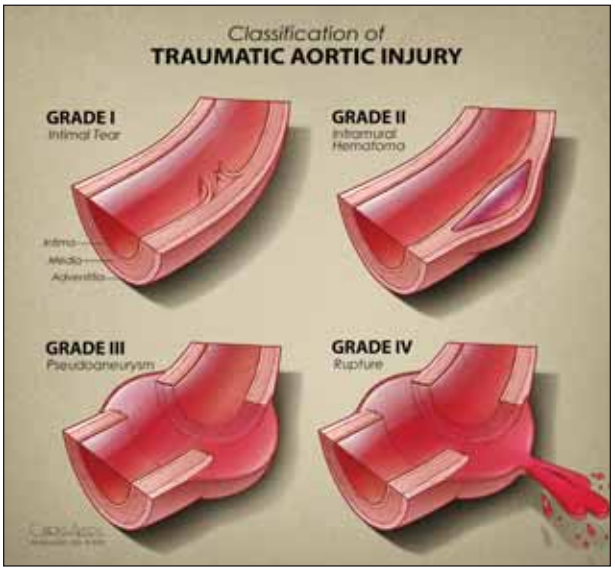


Figure 1. Classification of TAI.

Based on imaging, TAI is classified into intimal tears (grade I), intramural hematoma (grade II), pseudoaneurysm (grade III), and rupture (grade IV) (Figure 1).[12] Initial management includes resuscitation, blood pressure control, and treatment of associated injuries. Patients with grade I injuries can be managed with medical therapy (antiimpulse control). A repeat CTA study can be performed in 6 weeks. In our experience, most grade I injuries heal with medical therapy.[11,12] Patients with injuries grades II to IV require repair. The Conformable GORE® TAG® Thoracic Endoprosthesis (Gore & Associates, Flagstaff, AZ) is currently the only TEVAR device approved by the US Food and Drug Administration to treat traumatic transections.

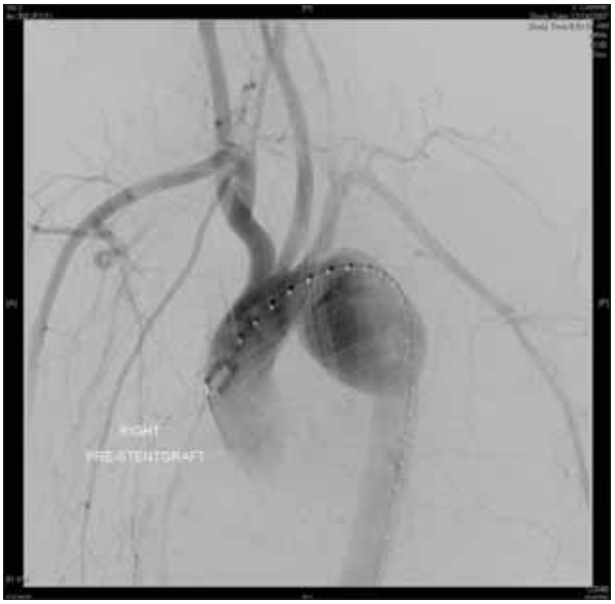


Figure 2. Diagnostic aortography of a patient with a grade III TAI.

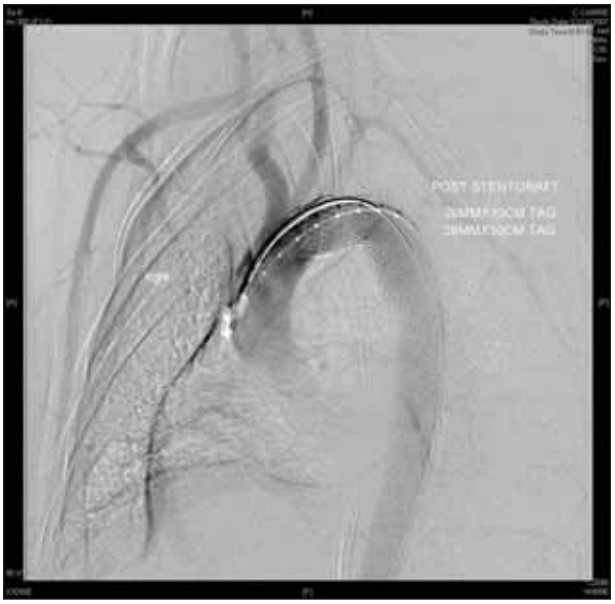


Figure 3. Completion aortography showing successful exclusion of grade III TAI.

The suitability of a patient for endovascular repair is based on aortic diameter according to the manufacturer's sizing recommendations for thoracic devices, as well as the location of the injury.

TEVAR

Endovascular procedures may be performed under local or general anesthesia in an operating room that is supplied with imaging equipment. The abdomen and bilateral groins are prepped in standard fashion. Single femoral access is achieved using an open or percutaneous technique. We select the more suitable femoral/iliac access side based on CTA imaging. Then, arch aortography is performed to identify the location of the injury. The cerebrovascular anatomy is also evaluated based on arch angiography, especially if left subclavian artery coverage is planned. IVUS is used selectively in cases where angiography is equivocal. The patient is then anticoagulated with heparin. A smaller dose than the standard weight-based protocol can be used in patients with severe multiorgan injury, especially those who have intracranial hemorrhage. The thoracic device(s) is selected based on CT images according to the manufacturer's sizing recommendations.

Measurements are made based on two-dimensional thin-cut axial CT scans with intravenous contrast. The device(s) is delivered over a stiff wire. We deliver the imaging catheter through the same sheath using a buddy wire technique after the device is in place. The ability to simultaneously use more than one device through a single sheath while maintaining hemostatsis is one of the advantages of the GORE® DrySeal Sheath (Gore & Associates). The device is then deployed using the standard technique without any pharmacological adjunct. We cover the subclavian artery as needed to obtain a proximal landing zone or gain better apposition with the lesser curvature of the aortic arch and maintain a policy of selective delayed subclavian artery revascularization. We selectively perform postdeployment balloon angioplasty in cases of incomplete apposition of the graft at the proximal landing zone or proximal type I endoleak. Heparin is reversed with protamine. Diagnostic and completion angiography of a patient with a grade III TAI are shown in Figures 2 and 3. A 2-year follow-up CTA shows successful exclusion of the pseudoaneurysm in Figure 4.

SVS CLINICAL PRACTICE GUIDELINES

The Society for Vascular Surgery (SVS) pursued development of clinical practice guidelines for the use of TEVAR in managing TAI.[13] In addition to conducting a systematic review and meta-analysis of the literature, the SVS selected a panel of experts to arrive at a consensus regarding a number of unresolved or controversial issues. In the review, which included 7,768 patients from 139 studies, the mortality rate was significantly lower in patients who underwent endovascular repair, followed by open repair and nonoperative management (9%, 19%, and 46%, respectively; $P < .01$). With regard to issues that were not specifically addressed by the meta-analysis, the majority opinions of the committee suggested the following:

- **Timing of TEVAR in a stable patient.** The committee suggested urgent repair (< 24 hours) in the absence of other serious concomitant injuries or repair immediately after other injuries have been treated, but at the latest, prior to hospital discharge.

Figure 4. Two-year follow-up CTA showing successful repair of the TAI.

- **Management of minimal aortic injuries.** The committee suggested expectant management with serial imaging for grade I injuries and repair for injuries grades II to IV.
- **Type of repair in young patients.** The committee suggested endovascular repair regardless of age, if anatomically suitable.
- **Management of the left subclavian artery.** The committee suggested selective revascularization.
- **Systemic heparinization.** The committee suggested routine heparinization, but at a lower dose than in elective TEVAR.
- **Spinal drainage.** The committee did not suggest routine spinal drainage.
- **Choice of anesthesia.** The committee suggested general anesthesia.
- **Femoral access technique.** The committee suggested open femoral exposure.

RESULTS

Experience with the use of TEVAR for management of TAI is rapidly accumulating. In a modern meta-analysis of published literature, Tang et al analyzed 33 articles reporting 699 procedures (TEVAR = 370; open repair = 329).[8] They found significantly lower rates of mortality (7.6% vs 15.2%; $P = .0076$), paraplegia (0% vs 5.6%; $P < .0001$), and stroke (0.85% vs 5.3%; $P = .0028$) in patients who underwent TEVAR compared to open repair.

COMPLICATIONS

Current data suggest that in comparison to open repair, TEVAR may reduce early death, paraplegia, renal insufficiency, transfusions, reoperation for bleeding, cardiac complications, pneumonia, and length of hospital stay.[14] However, the risk of complications associated with endovascular repair, such as device migration, endoleak, device malfunction, retrograde dissection, and access vessel rupture, are still present. Device collapse is a complication that is primarily reported after TEVAR for TAI. In a study of 60 patients with device collapse, 39 (65%) had been treated for TAI.[15] Excessive device oversizing and a small radius of curvature of the aortic arch were found to be the causative factors. To date, there have been no reported device compressions with the Conformable GORE® TAG® Thoracic Endoprosthesis.

CONCLUSION

The current body of evidence supports the preferential use of TEVAR compared to open repair for patients with TAI. Meticulous case planning can help avoid some of the reported complications. The next generation of thoracic aortic devices is expected to make this technology applicable to a wider range of patients. ■

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The Science Behind the Conformable GORE® TAG® Device Design

Rigorous design and testing enable this technology to treat a greater range of thoracic aortic pathologies.

BY MICHAEL D. DAKE, MD

The GORE® TAG® Endoprosthesis (Gore & Associates, Flagstaff, AZ) has been proven to be a safe and effective choice for the treatment of patients with thoracic aortic aneurysms (TAAs) involving the descending thoracic aorta. While developing an extensive record of clinical experience for this application, the need to address additional thoracic pathologies was increasingly recognized. Gore engineers closely monitored the clinical data and worked to define a new design space for the next-generation device that would address the emergence of extended clinical needs. Based on these data, the design input requirements were established to create specifications for the next-generation GORE® TAG® Device, the Conformable GORE® TAG® Thoracic Endoprosthesis (Gore & Associates).

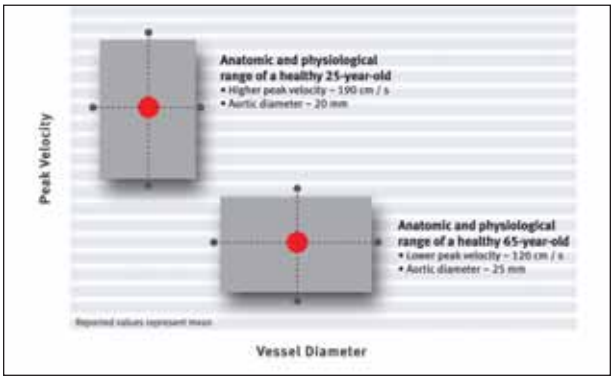

Figure 1. The device was designed and studied to treat multiple thoracic aortic pathologies including aneurysm, type B complicated dissection, and traumatic transaction.

DESIGN

The Conformable GORE® TAG® Device maintains the design attributes and clinical performance of the commercially available GORE® TAG® Device while expanding the capability of the device to treat a larger population of patients with different thoracic aortic lesions and complex anatomies. The challenge was to design a single product line to safely and effectively treat multiple thoracic aortic pathologies including aneurysm, type B complicated dissection, and traumatic transection (Figure 1). Detailed investigations into the specific needs of each of these different treatment indications were translated into engineering design inputs and were given to the engineering design team.

In addition to the prerequisite that the next-generation device meet all of the same proven design standards and functional requirements of the GORE® TAG® Device, additional performance goals were given to the design team including: the capability of treating smaller thoracic aortas as small as 16 mm, expanded oversizing windows, treatment of markedly tapered thoracic aortas, enhanced device conformability, and greater resistance to device compression. It was clear that these inputs could not simply be addressed independently but must be considered collectively to achieve the optimal design. It was also evident that to meet all of the design requirements, the development of the new design would need to take into account more than just a single design consideration such as radial force or conformability. Awareness of all the functional characteristics that influence device performance was critical. Everything needed to be collectively considered to achieve the optimal design.

In the end, the design of the Conformable GORE® TAG® Device incorporated changes to the commercially available GORE® TAG® Device to meet the design requirements (Figure 2). The stent design maintains the helical sinusoidal pattern, but the flares were removed and replaced with a partially uncovered stent on the proximal

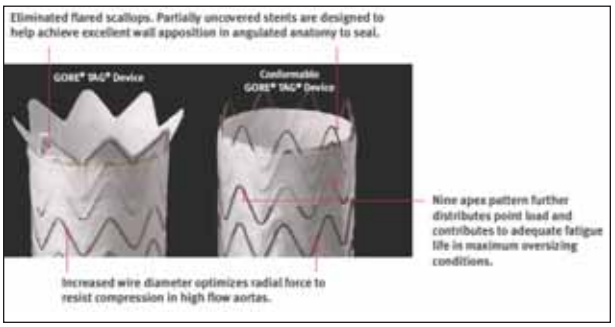

Figure 2. The device design capitalizes on the performance and durability of the original GORE® TAG® Device, yet incorporates several improvements to maximize clinical performance.

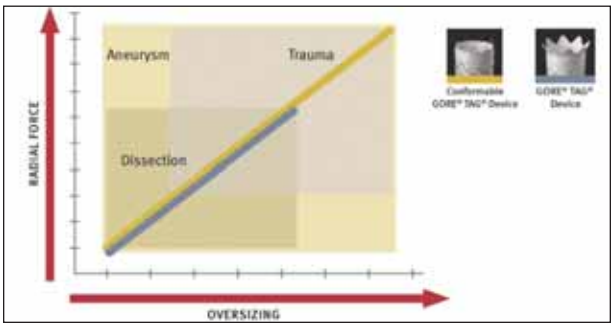

Figure 3. A broad oversizing window was incorporated into the device design to address treatment needs for multiple etiologies. The device is currently approved in the United States for exclusion of isolated lesions of the descending thoracic aorta.

end. The partially uncovered stent was added to minimize blood velocity pressure on the inner curve of the device while still providing sufficient radial force for fixation and seal. Iterations of the stent design, including changes to the stent wire diameter, apex height, apex angle, apex radius, and helical pitch, were created and tested to optimize conformability, radial force, compression resistance, and fatigue resistance.

The graft material of the Conformable GORE® TAG® Device was also optimized to assist in device conformability while maintaining the same inner luminal and outer surface, impermeability, and sufficient longitudinal strength to allow for accurate deployment and migration resistance. Familiar GORE® TAG® Device features including the sealing cuffs on the proximal and distal ends of the device and the circumferential gold markers around the proximal and distal ends of the graft were incorporated into the design.

TESTING

Because the Conformable GORE® TAG® Device was being designed to address clinical requirements that had not previously been applied to thoracic endografts, it was necessary to completely understand the demands of the design specifications. For example, it is obvious that in patients with traumatic aortic injury or transection, the characteristic associated anatomy and physiology are vastly different than those typically observed in patients with traditional degenerative aneurysms of the descending thoracic aorta.

Careful planning and development of test fixtures and test parameters that take into account these important etiological differences were critical early in the design process to optimize performance of the next-generation thoracic endograft. New simulated-use tests were developed to challenge prototypes in expected environments. Anatomical models were made to challenge device conformability. Literature review and patient data collection from volunteers provided valuable details that were used to develop a correlation between aortic diameter and aortic velocity. It was shown that as aortic diameter decreases, aortic blood velocity increases. Because smaller-diameter aortas are generally associated with younger patients, these parameters were of particular interest in the creation of the simulated traumatic transaction test. These parameters became critical to the design of the device because high blood velocity can lead to high dynamic pressure on a perpendicular surface, such as a nonapposed endograft on the lesser (inner) curve of the thoracic aortic arch. By understanding the clinical environment and user needs early in the project, design iterations could more efficiently and effectively be evaluated throughout the entire project.

Additionally, the newly designed device was required to undergo the same simulated use testing and pass the performance standards that are applied to the commercially available GORE® TAG® Device. These tests collectively evaluate the deployment reliability attributes of the device, including deployment accuracy, sealing, acute migration, and delivery.

In addition to the battery of preclinical testing to evaluate deployment reliability, the newly designed device was subjected to the same durability testing as the commercially available GORE® TAG® Device. The modifications to the device design and additional applications for intended use presented new challenges and resulted in enhanced levels of expected device performance in these commonly accepted tests.

OVERSIZING AND RADIAL FORCE

The Conformable GORE® TAG® Device is designed to offer an expanded oversizing window for each device diameter to provide physicians and patients with more options to treat a particular aortic caliber by having overlapping oversizing windows for devices within the product offering grid. This design requirement allows a device to be selected based on the level of outward radial force that it would transmit to the aortic wall. Thus,

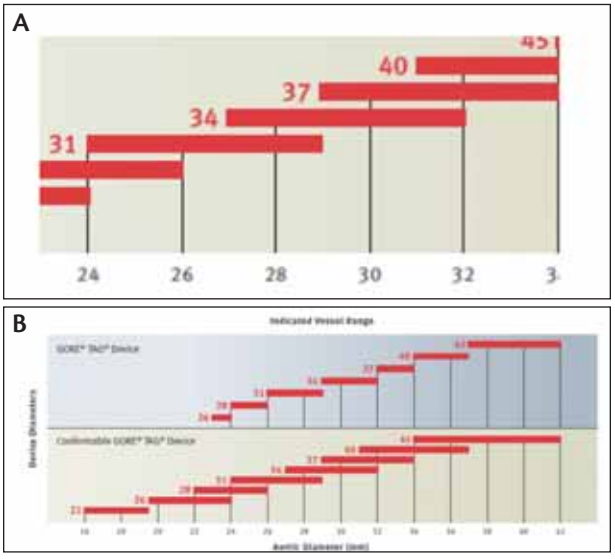

Figure 4. The expanded oversizing window for each device diameter provides more options for treatment by having overlapping oversizing windows and essentially allows the physician to choose the applied radial force by using the low or high end of the oversizing window (A). Note that a 29-mm vessel can be treated with a 31-, 34-, or 37-mm device (B).

physicians may select the desired relative level of outward force applied, based on considerations of the underlying pathology (eg, aneurysm, dissection, traumatic injury, etc.). By specifying that a given device needs to operate with higher radial outward force than previously required, the device has to be able to withstand pulsatile loading conditions in a high-material-stress environment. The stent frame geometry was optimized to operate throughout the expanded range of these new loading conditions.

Entering into the design project for the next-generation device, it was known that outward radial force was an important design factor that contributes to the compression resistance of any device design. However, radial force needed to be factored within the context of the overall device design to provide the best solution for increased conformability and compression resistance. It was also known that in some applications, minimal radial force is more desirable while still maintaining the conformability of the device design. By increasing the oversizing windows for each device diameter and allowing the windows to overlap, devices can be selected based on the intended application. The Conformable GORE® TAG® Device can be appropriately oversized between 6% to 33%, depending on the device diameter. For example, for an aortic diameter of 29 mm, a device diameter of 31 mm (7% oversizing), 34 mm (17% oversizing), or 37 mm (28% oversizing) may be selected. In a 29-mm aorta, the 34-mm device provides 67% of the radial force as that of the 37-mm device, and the 31-mm device provides 26% of the radial force. By allowing these treatment options, individual patients can receive custom treatment with a device that is tailored to the specific needs of the etiology involved (Figures 3 and 4).

DEPLOYMENT

Previous modifications to the GORE® TAG® Device delivery catheter continue to offer enhanced performance of the deployment system. The leading olive-shaped tip of the delivery catheter continues to provide a flexible soft tip to enhance trackability and delivery to the target landing zone. Additionally, the transition of the leading olive-shaped tip and the constrained endoprosthesis are stiff enough to allow for a smooth transition between the device and the catheter. This minimizes interaction between the device and the aortic wall during device delivery. A radiopaque marker was added on the leading olive-shaped tip, providing increased visibility during delivery and catheter retraction.

CONCLUSION

The Conformable GORE® TAG® Endoprosthesis was designed for application in a wide range of thoracic aortic diseases and injuries. Because the device was specifically developed to include treatments that were not previously considered, engineers were required to look beyond the scope of what was currently available. Special attention was directed to ensuring that the correct testing conditions were established to enhance device performance and durability. The Conformable GORE® TAG® Device is a next-generation endoprosthesis that was developed to address an expanded spectrum of thoracic aortic applications and is based on an established record of proven long-term safety and clinical performance benefits. ■

Michael D. Dake, MD, is Thelma and Henry Doelger Professor (III), Department of Cardiothoracic Surgery, Stanford University School of Medicine and Falk Cardiovascular Research Center in Stanford, California. He has disclosed that he is a paid consultant to Gore & Associates. Dr. Dake may be reached at mddake@stanford.edu.

The Importance of Conformability and Sizing in TEVAR

Achieving effective outcomes in trauma patients with blunt aortic injury.

BY MARK A. FARBER, MD, FACS

The management of patients who suffer blunt aortic injury (BAI) has drastically changed since the approval of stent grafts to treat aortic disease. At most major trauma centers, thoracic endovascular aortic repair (TEVAR) has now become the treatment of choice.[1] With the recent approval of the Conformable GORE® TAG® Device (Gore & Associates, Flagstaff, AZ) for isolated lesions, BAI is now an on-label treatment option for patients. Although these devices were originally designed for treating aneurysmal disease, they have found success in treating BAI.[2] However, distinct differences exist between these two patient populations. Based on clinical trial data from the United States,[3-5] the average age of patients who are treated with TEVAR for thoracic aortic aneurysms is 71 years. In comparison, the average patient age is 40 years in 100 patients treated at the University of North Carolina during the past 20 years who presented with a traumatic aortic injury.

As individuals age, not only does the aorta enlarge, but the radius of curvature also increases. Whether this is the result of increases in aortic stiffness or a natural process is difficult to determine. It does, however, have a significant impact on device performance in the proximal thoracic aorta. Despite the overwhelming acceptance of TEVAR for treating BAI, when planning these procedures, there are certain aspects to be aware of, which are crucial to achieving successful outcomes; most notably, these are device sizing and conformability.

SUPPORTING DATA FOR BAI TREATMENT WITH TEVAR

Numerous studies have been published showing a decrease in operative mortality, hospital mortality, and morbidity rates by employing TEVAR in patients with BAI.[6,7] Although spinal cord ischemia has been reported after TEVAR, it is exceedingly rare, and published data suggest that it occurs less frequently compared to open repair. Recent meta-analysis indicated that complications of paraplegia and stroke are also reduced with TEVAR.[7]

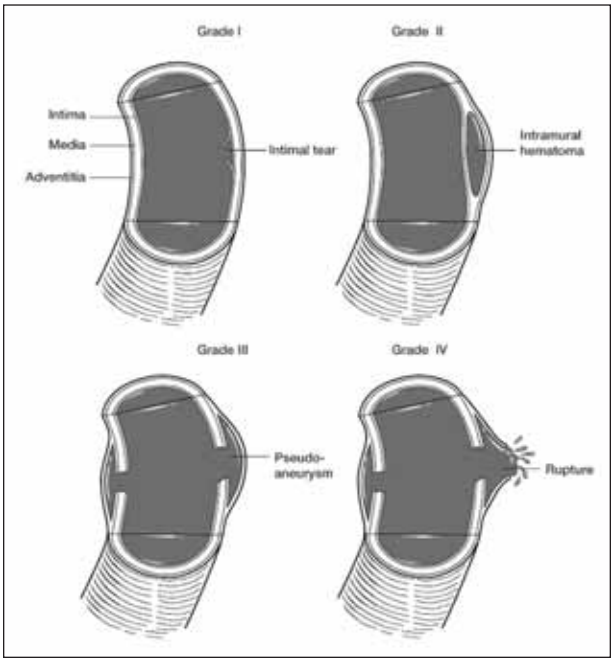

Figure 1. Grading classification for BAI.

There is evidence that not all BAIs require repair. Using the grading system described by Azizzadeh et al,[8] minimal aortic injures involving intimal defects (classified as grade I) (Figure 1) are unlikely to result in rupture or pseudo-aneurysm development, and therefore, conservative management with observation and blood pressure control is warranted. For severe injuries (grades III–IV), repair is advocated to prevent rupture and

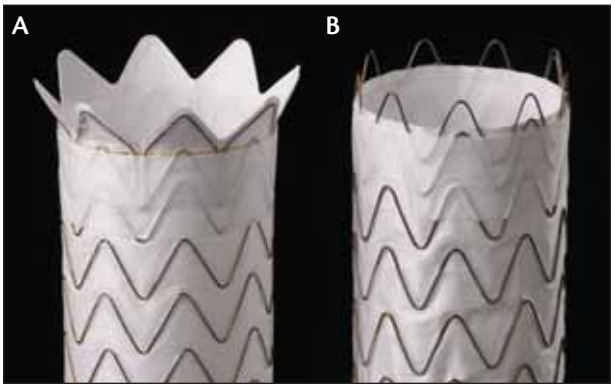

Figure 2. The original GORE® TAG® Device (A) and the new Conformable GORE® TAG® Device (B) (Gore & Associates).

pseudoaneurysm formation. Before the advent of stent grafts, some practitioners employed the technique of delayed repair in patients with intramural hematomas (grade II injuries). By doing so, the patients were able to recover from concomitant injuries, such as lung and cardiac contusions, enabling improved results with operative repair of their aortic injury. This has been less of a concern when endovascular repair is performed because few, if any, patients have contraindications to repair, as single-lung ventilation, cardiopulmonary bypass, and heparin are not required. In addition, cardiac stress is minimized with an endovascular approach.

SIZING

Once repair has been deemed necessary, critical planning is required to achieve favorable results. Axial imaging alone should be avoided, as it can lead to inaccurate diameter determination due to tortuosity and angulation. Imaging inspection using three-dimensional (3D) planning software is essential. The thoracic aorta can be very tortuous and the radius of curvature severe, especially in young patients. As such, 3D planning software can easily create orthogonal diameters throughout the treatment region. By inspecting the proximal and distal aspects of the treatment region, the aortic diameter can be measured. For most injuries, this involves the distal aortic arch region just distal to the left common carotid artery extending caudally for approximately 10 cm. In some cases, the left subclavian artery can be spared when the injury occurs more distally. However, critical evaluation of the aortic arch curvature should be undertaken.

Despite critical orthogonal inspection, diameter measurements using this method can still be inaccurate. Trauma patients with severe hypovolemia can experience aortic contraction, and the diameter can be underestimated by as much as 5% to 40%.[9,10] This can result in potential problems because undersized devices can exhibit a type I endoleak, persistent lesion perfusion, and bleeding. Oversizing the device would help minimize this risk; however, excessive oversizing can also

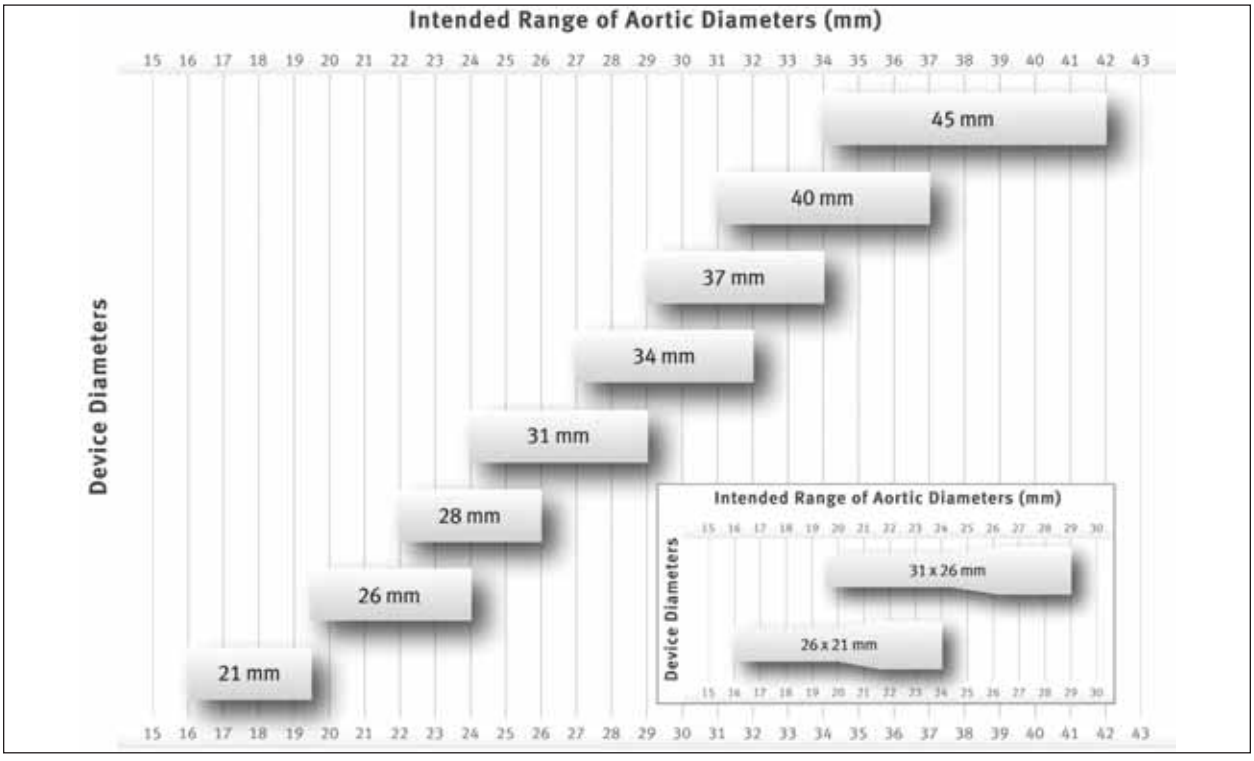

Figure 3. Conformable GORE® TAG® Device oversizing chart.

lead to significant problems inherent to each individual device.

Device compression is a rare occurrence, but it has significant implications when it occurs. A study by the American Association for the Surgery of Trauma reports an incidence of 0.8%, whereas a recent study showed a 0.4% incidence with use of the GORE® TAG® Device.[11] Device compression has been shown in various studies to be associated with graft oversizing, which is more likely to occur with small aortic lumens.[12] However, it may also be related to a lack of aortic arch conformability. This is a potentially dangerous complication that, if not remedied, can result in acute device failure, which is associated with significant morbidity and mortality from aortic occlusion.

Avoiding this recognized complication can often be accomplished by utilizing intravascular ultrasound during the procedure in transection patients. One must keep in mind, however, that intravascular ultrasound generally underestimates the aortic diameter measurements by 2 to 3 mm compared to computed tomography. This technique can help further define the true diameter, because generally, the patients have undergone fluid resuscitation between the imaging study and the procedure.

Additional information can also be gained using the intravascular ultrasound catheter, including the exact location of the injury and the extent of the injury into the proximal aspect of the aorta. However, added procedural time is one drawback to using this technique.

CONFORMABILITY

As previously mentioned, the radius of aortic curvature is smaller in patients with BAI. This is potentially problematic for devices that are designed to mimic the stiffness of older patients with thoracic aneurysms. As such, their conformability is not ideal along the lesser curvature of the arch. This can potentially result in proximal endoleaks, especially in patients with traumatic injury because the injury is typically located at the ligamentum arteriosum on the inner curvature of the arch where the seal length is less due to the aforementioned device malapposition.

When coupled with the increased aortic impulse in young patients, a lack of proximal conformability can also result in the development of aortic pseudocoarctation from compression of the device. Although malapposition to the inner aortic curve has occurred with numerous devices, it rarely results in significant hemodynamic compromise in patients with degenerative thoracic aortic aneurysms because of the reduced aortic impulse in elderly patients and the greater aortic curvature. The degree to which conformability occurs is also related to the position of the device within the curvature of the arch.

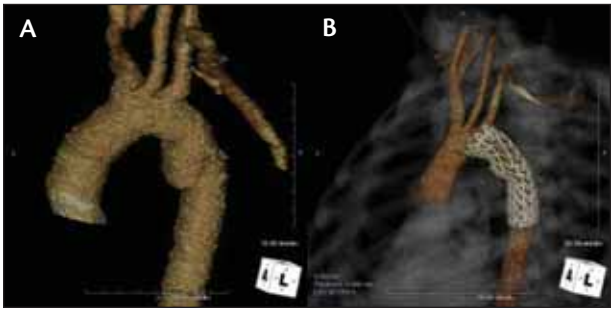

Figure 4. Aortic transection in a patient with a small radius of curvature (A). Aortic transection repair with the Conformable GORE® TAG® Device (B). Note the degree of conformability.

Inspection of the anticipated device location in relation to the arch curvature using 3D imaging can also reveal potential conformability problems, and alterations in deployment position are often made based on this information. Recognition of this problem and careful planning of the procedure can help minimize this potential complication with TEVAR for BAI.

Both device collapse and conformability are not always predictable occurrences and as such, cannot always be avoided. They can, however, be treated when they occur. Reported success in correcting these complications includes the placement of a second device in a more favorable position or placement of a Palmaz stent (Cordis Corporation, Bridgewater, NJ) at the proximal aspect of the device.[13] Both of these solutions involve added procedural costs and procedural time and are also not without potential complications themselves. If proximal treatment extension is required into zone 1 of the aorta, then extra-anatomic bypass may be required to ensure adequate cerebral perfusion.

FUTURE DIRECTIONS

Gore has redesigned their GORE® TAG® Device to help avoid the problems of sizing and conformability. The modified polytetrafluoroethylene graft and stent-to-graft attachment configuration adds increased conformability while maintaining its original characteristics of device profile and ease of delivery (Figure 2). Modifications to the stent, including an increased wire diameter and additional apex to the circumference, have also allowed for increased oversizing windows (Figure 3), permitting significantly wider treatment ranges for any given device diameter. Whereas the previous iteration of the device generally yielded one device size for a specific diameter, there are now as many as three different sizes available for a specific aortic inner diameter.

Targeting the upper limit of the oversizing range is generally used in the treatment of older patients with

aneurysmal disease to maximize radial force in the proximal and distal sealing regions. In contrast, patients with dissections and transections generally require less resistance to migration, and device sizing is based on matching diameters appropriately. Choosing the best device diameter is often difficult and governed by the location of the implant in conjunction with the degree of aortic constriction from hypovolemia. In severely curved regions, increased oversizing aids in inner curvature apposition, so long as it is within the appropriate size range for the device. Determining the appropriate size to compensate for hypovolemia and curvature is often based on experience.

Gore & Associates recognized that aortic diameters vary significantly in patients with transections and has designed tapered versions of their device to appropriately manage patients so that distal device oversizing does not occur. The proximal and distal device diameters vary by 5 mm, which allows for improved accommodation to the true aortic diameter in patients with non-aneurysmal disease.

Early results with the Conformable GORE® TAG® Device appear to mimic prior outcomes in patients with thoracic aortic aneurysms, and the US Food and Drug Administration has approved it for use in aneurysmal disease and, more recently, other isolated lesions, including aortic transection (not including dissections). The device is also being studied in aortic dissection. Early experience with the device shows that it conforms extremely well to the aortic arch (Figure 4). Whether the clinical trial data support its use in this additional pathology is yet to be determined; however, given previous experience with thoracic aortic aneurysms and aortic transection, many of us are optimistic.

CONCLUSION

Current data suggest that the endovascular treatment of BAI results in improved outcomes. There are, however, procedure-specific complications that can occur. Proper planning is required to avoid errors in device oversizing and conformability, using centerline software algorithms. Recognition of these issues, in addition to next-generation devices designed to mitigate these problems, should only improve on the impressive results being reported with the expansion of endovascular technology for treating BAI. ■

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Optimizing Clinical Outcomes for Thoracic Aneurysms

The variability of treatment diameters with the new Conformable GORE® TAG® Device offers improved management for a wide variety of patients.

BY WILLIAM D. JORDAN JR, MD

Since receiving US Food and Drug Administration (FDA) approval in 2005, endovascular repair of thoracic aortic aneurysms (TEVAR) has experienced a dramatic increase in clinical application to a wide variety of pathologies. Although the initial trial and application of this technology was intended for degenerative aneurysm disease, the commercial availability created an opportunity for clinicians to use the GORE® TAG® Device (Gore & Associates, Flagstaff, AZ) in areas beyond aneurysm disease. Specifically, the GORE® TAG® Device has been used for occlusive disease (such as aortic coarctation), aortic dissection, and traumatic aortic disruption—most of which are clinical scenarios that were not listed in the instructions for use until the recent indication for isolated lesions (not including dissections). According to a recent report of 10,288 patients who underwent endovascular repair of infrarenal abdominal aortic aneurysms, 31% to 58% underwent a procedure in which the endograft was used in an anatomical situation that was not within the manufacturers' instruction for use.[1]

After commercialization, thoracic endografting has suffered a similar fate but the large-scale details of this practice are not as thoroughly studied from an anatomic perspective.[2] As a result of this broadened real-world application, new failure modes for TEVAR were identified. Specifically, proximal device compression has been seen in small aortas when an oversized graft is used.

Additionally, the large-diameter thoracic endografts have created problems related to delivery of the prosthesis through small or diseased iliac arteries. By analyzing some of these failure modes, the designing engineers gained valuable information to design a better endograft. The Conformable GORE® TAG® Thoracic Endoprosthesis (Gore & Associates) has been developed to leverage these lessons learned to create a better graft for standard and difficult anatomic situations.

Figure 1. Tortuous access vessels and a patent femoral graft make access for TEVAR challenging.

Figure 2. The Conformable GORE® TAG® Device in a tortuous proximal aorta.

TRACKABILITY

The Conformable GORE® TAG® Device is designed to provide more trackability through tortuous iliac vessels and, ultimately, to land in healthy or nondiseased aortic arches. The single larger-diameter nitinol wire is wound

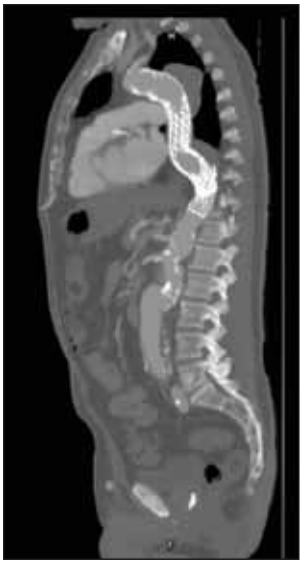

Figure 3. Sagittal view of the Conformable GORE® TAG® Device in the descending thoracic aorta.

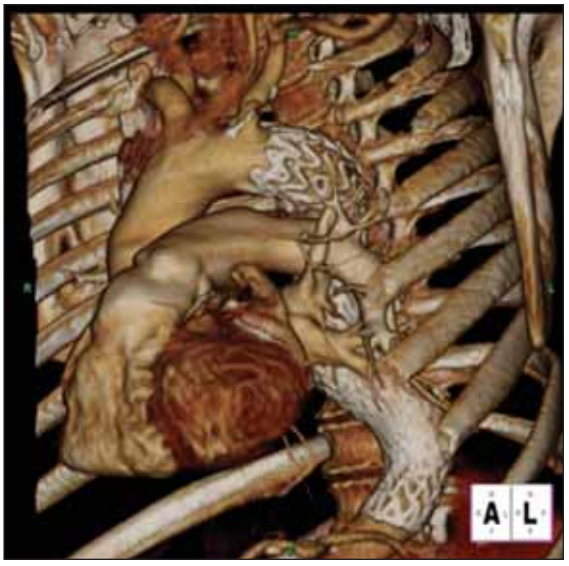

Figure 4. Three-dimensional reconstruction of the Conformable GORE® TAG® Device in a tortuous aorta.

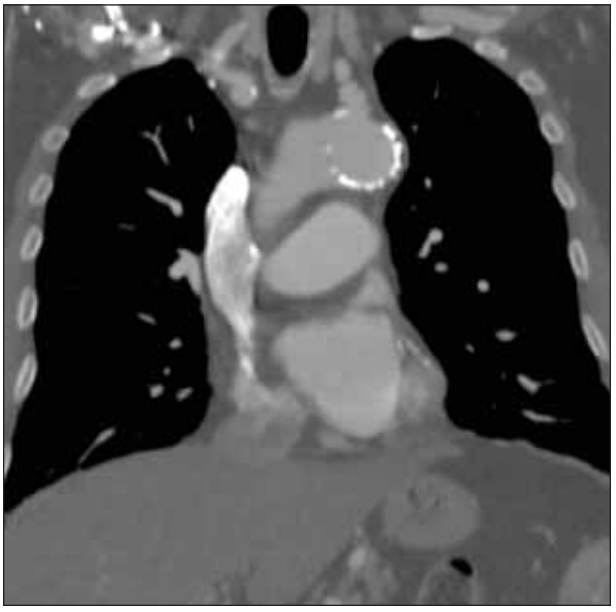

Figure 5. Proximal Conformable GORE® TAG® Device conforming to the inner aortic radius at the subclavian origin.

with an additional apex that creates increased structural integrity to avoid collapse yet allow trackability through diseased iliacs. For example, the device was used in a patient who had one occluded iliac system, with severe tortuosity of the contralateral patent iliac. The patient was an 83-year-old man who first suffered a ruptured abdominal aortic aneurysm 14 years earlier and was successfully treated with open repair. He also required a femoral-to-femoral bypass for right leg ischemia. However, this was further complicated by a prolonged hospital course and recovery after discharge. When it was discovered that he had a thoracic aneurysm, he promptly sought treatment but with a less-invasive approach. His preoperative computed tomography scan showed the infrarenal Dacron tube graft with a 4-cm paraanastomic aneurysm at his renal arteries and a patent femoral graft (Figure 1). Additionally, the thoracic aorta was rather tortuous above and below the aneurysmal segment, yet the Conformable GORE® TAG® Device tracked, treated, and sealed this aneurysm without complication (Figures 2 through 4).

CONFORMABILITY

When the first GORE® TAG® Device prosthesis was used for treating aneurysm disease, the results were consistent with findings from the original clinical trial, which provided the safety and efficacy data that led to FDA approval and subsequent commercial availability in March 2005. As is typical in the medical community, an approved device is commonly used in clinical circumstances that do not match the exact tested clinical environment that is outlined in the clinical trial that gained FDA approval based on the specific instructions for use.[3]

As reports of these various clinical scenarios became available, we learned of potential failure modes when the original GORE® TAG® Device was used in relatively small aortas with a very acute aortic arch, particularly in the face of acute traumatic aortic injury. These patients sometimes suffered compression of the proximal endograft when oversizing was > 30 % of the normal aortic diameter. After further analysis and evaluation of these failure modes, the new Conformable GORE® TAG® Device provides greater variability of treatment diameters, with improved compression resistance, particularly in the proximal aortic segment near the left subclavian artery. Figure 5 shows a sagittal image of the Conformable GORE® TAG® Device in a proximal aorta as it closely conforms to the inner radius of the arch (Figure 6).

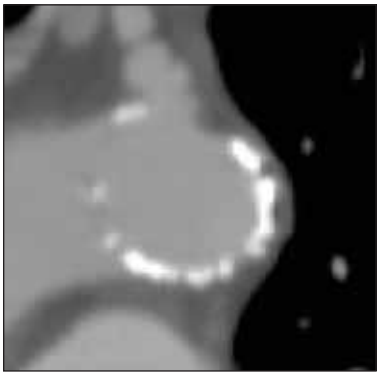

Figure 6. Magnified view of the Conformable GORE® TAG® Device attached to the inner curve of a tortuous proximal aorta.

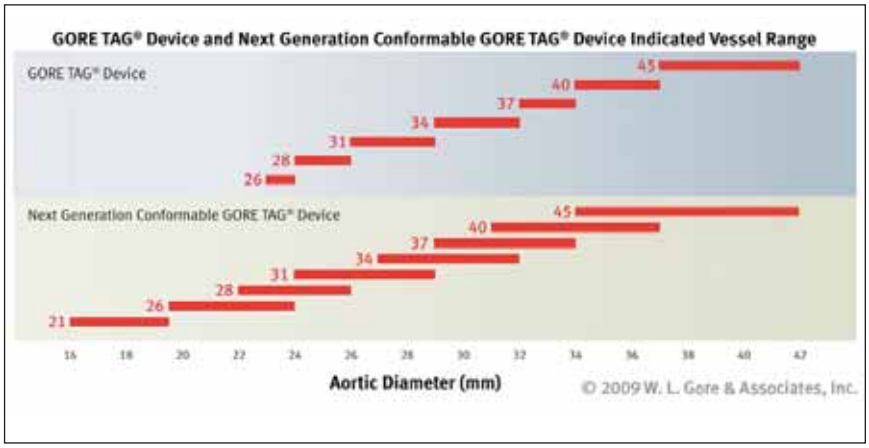

Figure 7. A comparison of the indicated vessel diameters between the original GORE® TAG® Device and the new Conformable GORE® TAG® Device.

With better attachment on the inner radius of the aortic arch, fewer pieces and adjunctive maneuvers are required to maintain clinical success. Also, the catastrophic and potentially life-threatening problem of proximal endograft collapse has not been reported as this endograft has been applied in clinical trials and after early release in the United States and Europe.

VERSATILITY

An additional challenge of treating thoracic aortic disease includes optimizing graft diameters in a diseased aorta that commonly has great variations in diameter between the proximal and distal landing zones. Interventionists commonly found it necessary to use shorter endograft pieces with a stepwise increase in diameter to reach the appropriate proximal diameter. Not uncommonly, this clinical scenario may require four endografts to achieve a good clinical result. The Conformable GORE® TAG® Device provides a wider range of treatment diameters for each endograft size to allow wider applicability in different aortic diameters. In effect, this variability provides a "tapered graft" approach when treating patients with variable diameters of the proximal and distal landing zones. Figure 7 shows the treatment diameters for this new graft along with the corresponding intended treatment diameters for the original GORE® TAG® Device.

We recently treated a 70-year-old man with hypertension, hyperlipidemia, prior history of smoking, and a previous stroke, who had a 6-mm increase of a thoracic aneurysm to 6.3 cm during a 6-month surveillance period. His proximal and distal landing zone diameters were 31 mm proximally and 26 mm distally (Figures 8 and 9).

The Conformable GORE® TAG® Device with the broader range of treatment diameters allows for this patient to be treated with a single 34-mm X 20-cm Conformable GORE® TAG® Device with good clinical result. Not only does this simplicity translate to an easier treatment but also a reduced device cost, as two devices are no longer needed. As the financial pressures of the current endovascular practice creates pressure to limit costs for treating these patients, we look for opportunities to reduce cost yet still maintain a high standard of treatment with the latest technologic advances. Most clinicians welcome the variability of treatment diameters and are afforded fewer restrictions in choosing a graft for a clinical application. The measurements during the planning phase of the procedure do not require the precision that may be needed with a less-flexible endograft. Additionally, if continued budget restrictions limit the resources available to maintain an in-hospital inventory to treat patients, fewer grafts are needed to provide treatment for a variety of patients. After a recent review of GORE® TAG® Device use at our own hospital, we identified 66 patients who were treated with 120 GORE® TAG® Endografts. With reconsideration of the sizing, these same 66 patients would have required 21% fewer (95) pieces, representing a substantial cost savings.

EARLY TRIAL RESULTS FOR THE CONFORMABLE GORE® TAG® DEVICE

After these design changes were incorporated and approved, the premarket approval clinical trial was initiated in October 2009. Fifty-one patients were enrolled from multiple clinical sites within 1 year, with 15 patients added as part of the continued access arm for a total of 66 patients followed. The early results showed 98.5% survival (one multisystem failure mortality). At 30 days, with 46 CTs available, there were two minor proximal type I endoleaks (4.3%), with no endograft migration, compres-

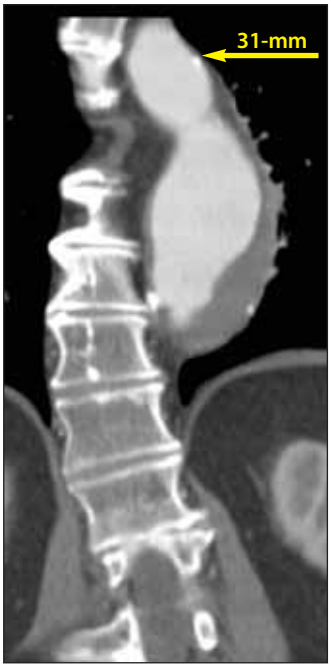

Figure 8. The patient's 31-mm proximal landing zone.

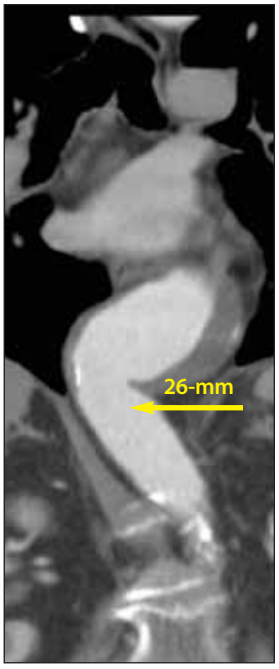

Figure 9. The patient's 26-mm distal landing zone.

sion, graft failure, rupture, or stent fracture. None of these endoleaks had significant aneurysm filling, and most of these were related to grafts that were placed proximal to the aortic arch near the subclavian origin. Each patient required an average of 1.7 endografts for treatment, but the landing zone diameters were noted to have a mean difference of 3.4 mm, which allowed the patients to be treated with a device that could adapt across a wider range of diameters.[4]

CONCLUSION

TEVAR has been explored for 2 decades in the United States, but the first approved thoracic aortic endograft was introduced to the general medical community in 2005. In 6 short years, there have been lessons learned that provided important clinical feedback to the manufacturing companies. The engineers then processed these concerns, examined the successes, and produced a new, improved product that has now completed a premarket approval clinical trial. The results of this trial have led to the approval of the Conformable GORE® TAG® Device. This new endograft provides the aortic clinician reassurance that they can gain a new and improved product in relatively short order to treat patients with challenging clinical situations. ■

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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

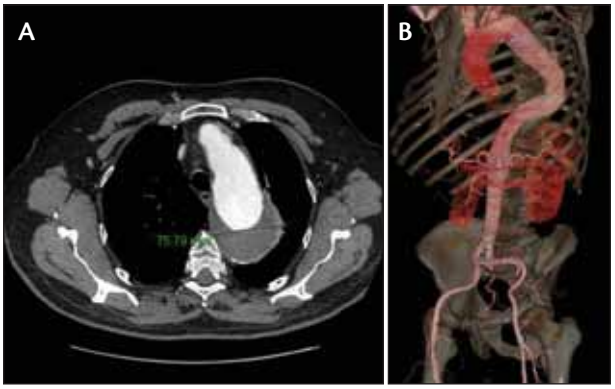

Figure 3. A CT scan showing a 7.6-cm aneurysm affecting the descending thoracic aorta (A). A volume-rendered image showing the relationship of the aneurysm to the arch vessels (B).

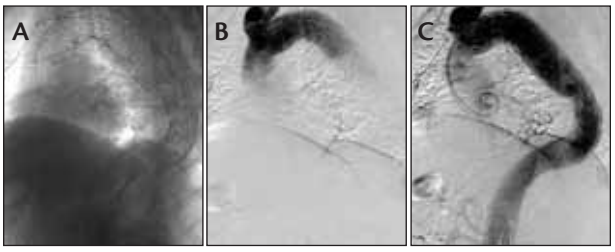

Figure 4. The proximal device conforms to the anatomy of the arch (A). Angiography shows no endoleak on the inner curvature of the aortic arch (B). Completion angiography shows no evidence of an endoleak (C).

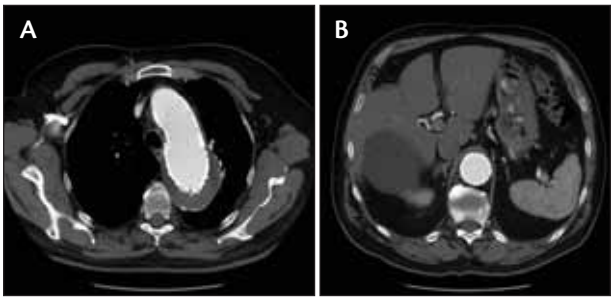

Figure 5. A CT scan at 3 months shows no evidence of an endoleak with sac shrinkage (A). A CT scan at 3 months shows an excellent result at the distal landing zone with no endoleak (B).

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. ■

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The EVAR Toolbox

A wide range of accessories is essential for the best technical results.

BY THOMAS LARZON, MD

Endovascular repair of the aorta has become a widely accepted treatment modality since its introduction in the early 1990s. As endovascular indications and treatment options have expanded, it is clear that having a wide range of available accessories is essential for achieving optimal results.

CATHETERS

Not only are catheters used as guiding accessories and as a component in the Seldinger technique, but they can also be of high value as indicators for branch vessels. In the treatment of thoracoabdominal aortic aneurysms, when four vessels are normally planned to be branched with stent grafts, it is especially important that all efforts are made to reduce the amount of contrast administered. A simple method we use is to hook a catheter (eg, a universal flush catheter) at the origin of the branch vessel. Another method is to place a 4-F catheter into the target vessel. This will facilitate placement of the aortic component and make it easier to obtain access to the target vessel whether the fenestrated or branched technique is used.

BALLOONS

The GORE® Tri-Lobe Balloon (Gore & Associates, Flagstaff, AZ) is especially valuable in the thoracic arch.

Figure 1. The GORE® Tri-Lobe Balloon consists of three separate balloons and comes in two different sizes, both in 18-F introducer systems.

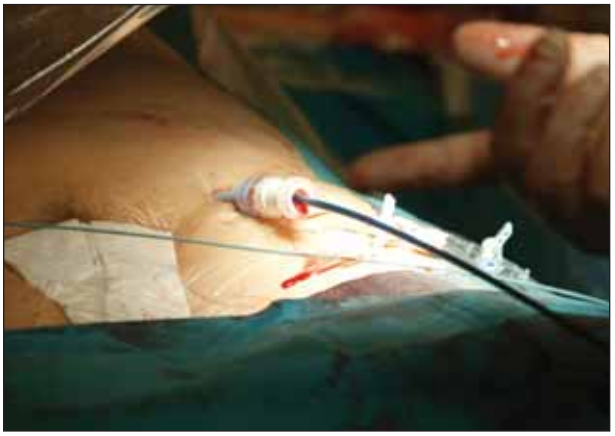

Figure 2. Minimal leaking of blood through the GORE® DrySeal Sheath (Gore & Associates) after routine endovascular aneurysm repair.

For example, we have used the GORE® Tri-Lobe Balloon to mimic a stent in assessing endoleaks. The normal use of elastic aortic balloons is for expanding implanted stent grafts to achieve better alignment against the arterial wall. In the thoracic portion of the aorta, the use of aortic balloons requires more restrictions because there is a risk of balloon and endoprosthesis migration. Also, to decrease the cardiac load, induced hypotension or super pacing might be necessary. The GORE® Tri-Lobe Balloon Catheter is an exception, with its ability to maintain up to 80% of blood flow through the system while it is inflated. The system consists of three different balloons. When the system is inflated through its single port, three separate balloons expand rapidly, uniformly, and simultaneously, and in between the balloons, a significant amount of blood can pass through (Figure 1). The GORE® Tri-Lobe Balloon is very versatile, does not need an introducer to prevent it from distal migration, and can be used in various situations.

If a type I endoleak is revealed on completion angiography, the balloon can be inflated inside the device. If the endoleak then disappears, this will indicate that a bare stent for alignment purposes would be of benefit. On the other hand, if the endoleak still exists, this is an indication that proximal extension with fabrics could be of value.

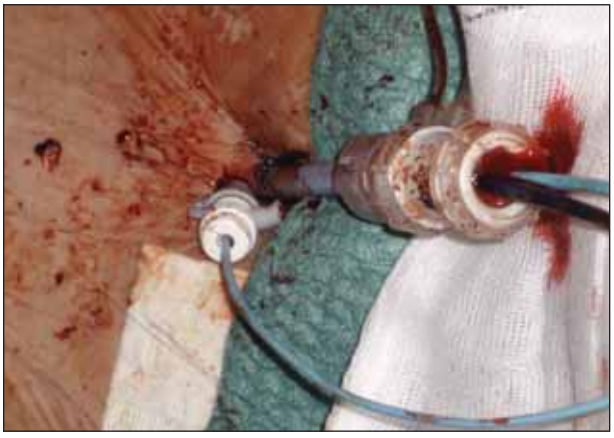

Figure 3. The GORE® DrySeal Sheath can accommodate more than one catheter without leaking a significant amount of blood.

INTRODUCERS

Percutaneous access for endovascular aneurysm repair has continued to gain popularity. It is faster and possibly less traumatic than open access and has the potential to significantly decrease procedural blood loss. Yet, a limiting factor associated with introducers has been the occurrence of blood leaking through the valve. However, the new GORE® DrySeal Sheath has the ability to provide true hemostasis (Figure 2). The sheath is pressurized with a 2.5-mL valve-inflation syringe to create a seal, and no further manipulation is required to maintain hemostasis. The sheath is helpful in any type of aortic intervention, with the ability to accommodate many catheters and guidewires (Figure 3), making it especially valuable in challenging endovascular aneurysm repair and thoracic endovascular aneurysm repair cases or in thoracoabdominal aneurysms in which access for multiple wires and catheter access is essential. As a result, we can frequently avoid multiple accesses in the same groin in these complicated cases and avoid repeated catheterization, as well as a less-traumatic approach to the iliac artery.

CONCLUSION

Standard accessories, such as catheters, balloons, and introducers, can be used in many different situations. In fact, they represent an important part of the toolbox needed to assist with endovascular repairs that are beyond the more standardized procedures, as they can be used to facilitate the orientation of stent grafts to achieve access to target vessels, to determine a strategy of endoleak treatment, and to minimize blood loss in a percutaneous case. ■

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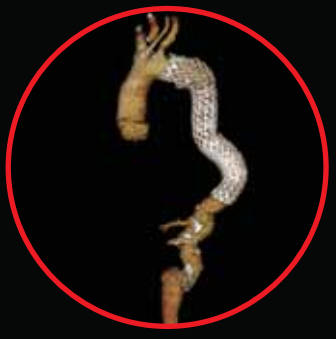

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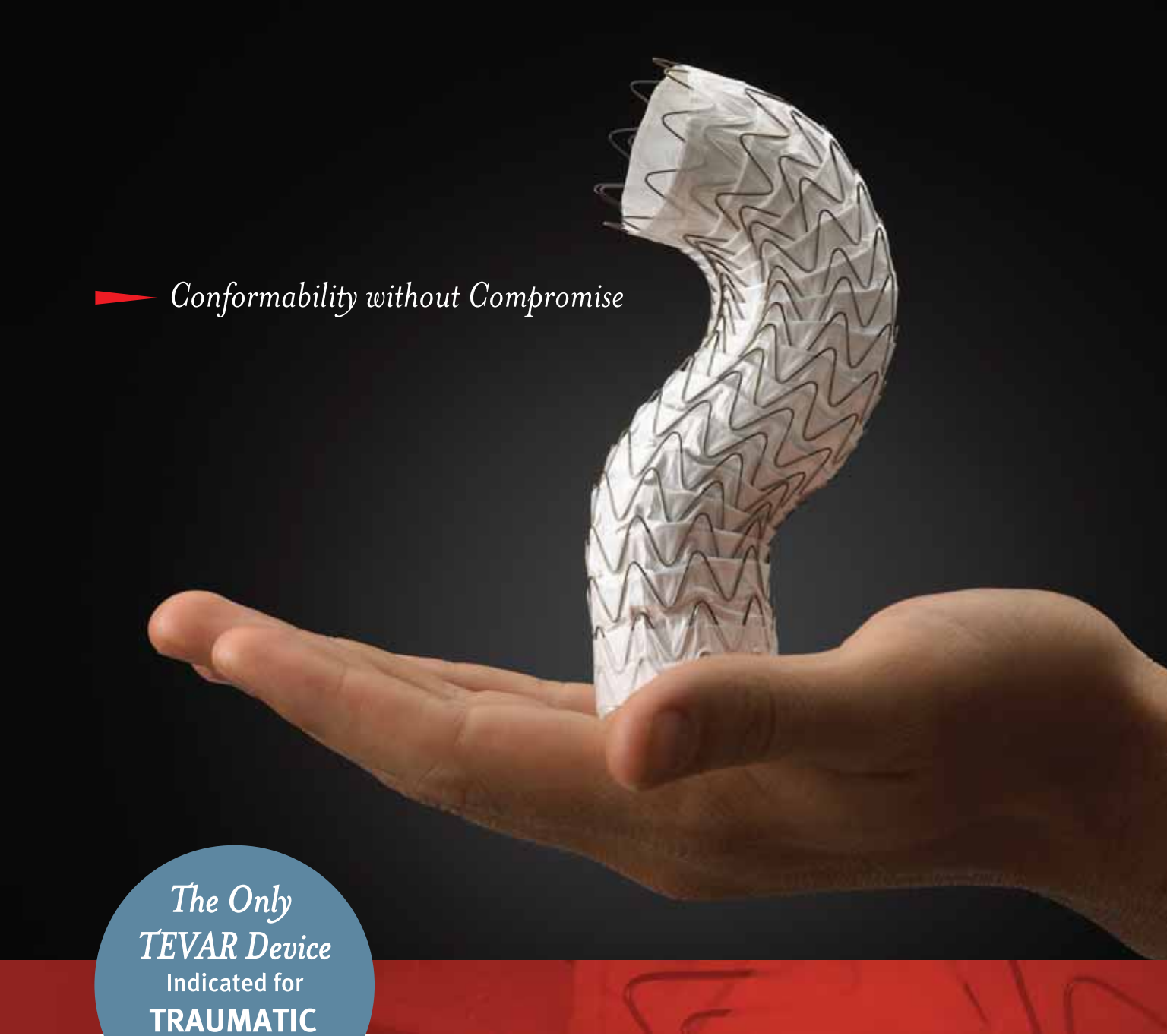

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INDICATIONS FOR USE: The GORE® TAG® Thoracic Endoprosthesis is intended for endovascular repair of isolated lesions (not including dissections) of the descending thoracic aorta, in patients who have appropriate anatomy including: Adequate iliac/femoral 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 for a complete description of all warnings, precautions and adverse events. ℞ Only

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