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).

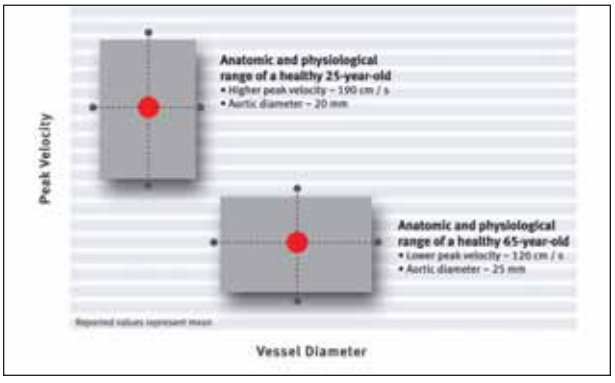

Figure 1. The device was designed and studied to treat multiple thoracic aortic pathologies including aneurysm, type B complicated dissection, and traumatic transaction.

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

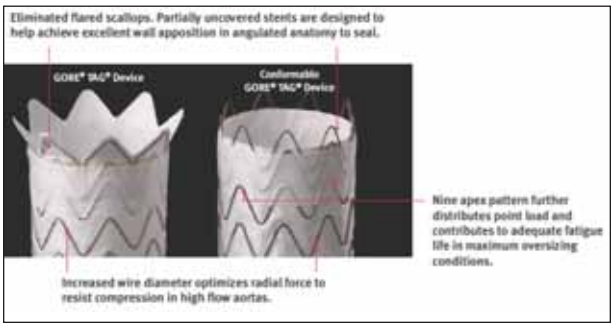

Figure 2. The device design capitalizes on the performance and durability of the original GORE® TAG® Device, yet incorporates several improvements to maximize clinical performance.

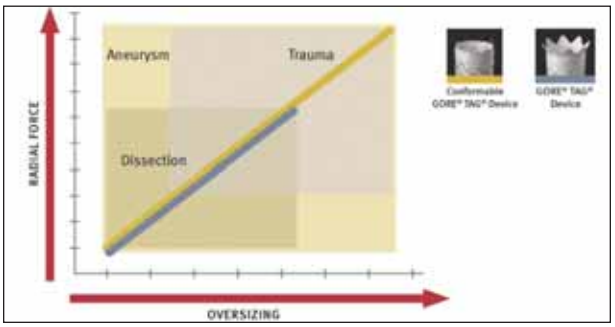

Figure 3. A broad oversizing window was incorporated into the device design to address treatment needs for multiple etiologies. The device is currently approved in the United States for exclusion of isolated lesions of the descending thoracic aorta.

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,

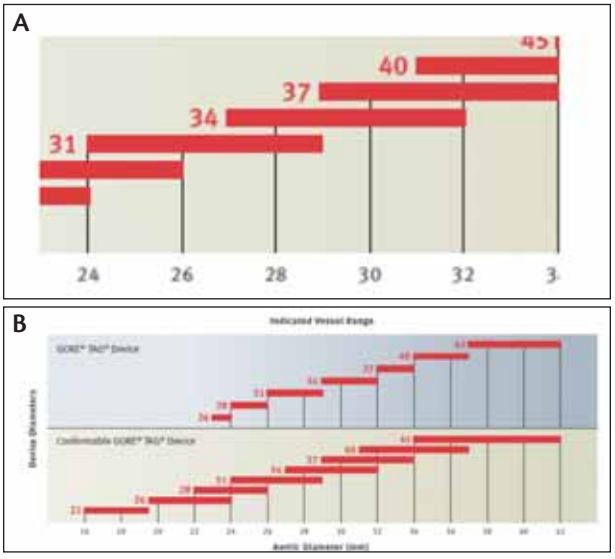

Figure 4. The expanded oversizing window for each device diameter provides more options for treatment by having overlapping oversizing windows and essentially allows the physician to choose the applied radial force by using the low or high end of the oversizing window (A). Note that a 29-mm vessel can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