

Taking Advantage of Opportunities to Maximize Infrarenal Seal

Advantages and applicability of the GORE® C3® Delivery System.

BY ROBERT Y. RHEE, MD

Endovascular repair (EVAR) for abdominal aortic aneurysms (AAAs) has become the standard of care, with low perioperative morbidity and mortality.^{1,2} As physicians have become more skilled in the adaptation of this technology, the treatment range has been greatly extended to include patients with challenging anatomies. Central to successful EVAR in less-than-ideal anatomic situations is the precise placement of the device to maximize infrarenal seal. The use of a truly repositionable endograft is paramount both in teaching applications and in successful repair of challenging anatomy by maximizing deployment accuracy, potentially reducing procedure and fluoroscopy time, and providing cost savings in the form of reduced usage of additional components.

ADVANTAGES OF THE GORE® EXCLUDER® AAA ENDOPROSTHESIS AND GORE® C3® DELIVERY SYSTEM

The GORE EXCLUDER AAA Endoprosthesis featuring C3 Delivery System (Gore & Associates) was developed by the company in cooperation with experienced users. This system was borne out of a true clinical need for precise and adjustable deployment in less-than-ideal anatomic situations for EVAR that most clinicians face in today's modern aortic practices. With this unique deployment system, the operator can reposition the stent-graft to achieve optimal fixation and sealing within the limitations of the patient's hostile anatomy.³

Deployment with this system is a simple, three-step process, which includes the option

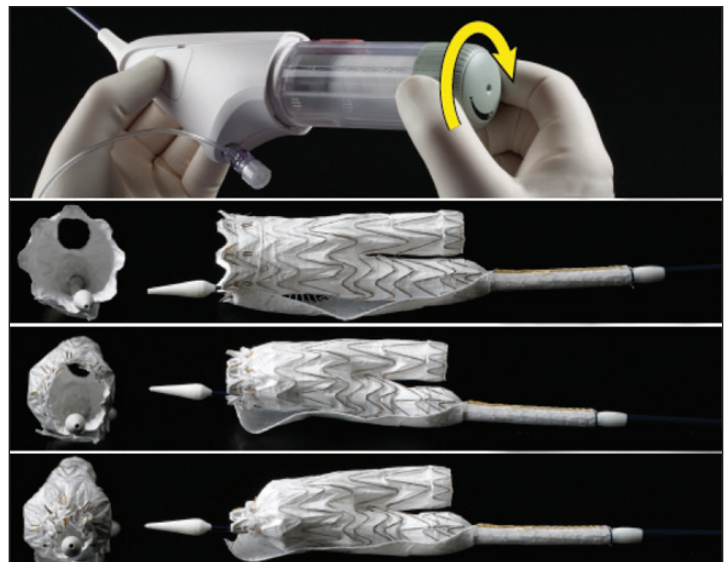


Figure 1. The system can be constrained to enable repositioning. Slowly constrain the proximal end, reposition the trunk, then slowly reopen to engage the proximal anchors.

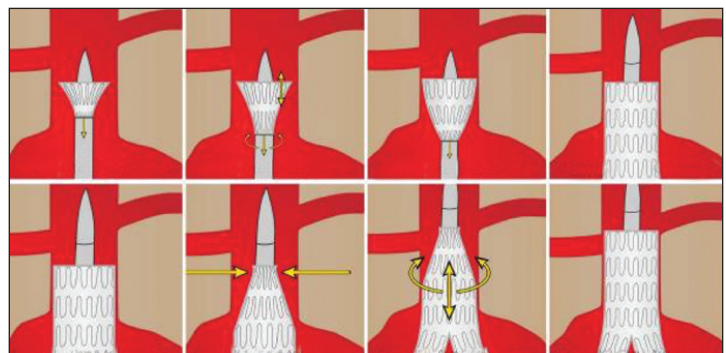


Figure 2. The system allows up to three opportunities to reposition for precise placement.



Figure 3. CTA of a patient with a short, angulated neck and an 8-cm AAA.

of reconstraining and repositioning the device (Figure 1). This allows for user-desired adjustments for both the level of the device for precise placement and orientation of the contralateral limb to ease gate cannulation. First, the body and contralateral limb of the device are opened. If desired, a constraining loop around the body of the graft allows for reconstraint of the device. After controlled positioning, the graft can then be unconstrained (Figure 2). These steps can be repeated up to two times. Once positioning is satisfactory, the constraining loop is removed, and the ipsilateral limb is opened to complete deployment.

CLINICAL CHALLENGES

Despite advancements in stent-graft technology, severely angulated or short necks (Figure 3) remain a significant challenge to successful endovascular treatment and are the most common reasons EVAR may not be a feasible option.^{4,5} As long as proper technique and optimized devices (e.g., hydrophilic sheaths and low-profile EVAR devices) are used, however, good outcomes are not impossible, and there are increasing

numbers of successful cases being reported with reasonable long-term outcomes.⁶⁻⁸

Short Necks

Although proximal neck lengths between 10 mm and 15 mm can be treated with most stent-grafts,^{8,9} a standardized neck length requirement for the best long-term results, regardless of the device used, still has yet to be determined. Depending on the device's design, the ideal length requirements vary. Stent-grafts that have active fixation with metal struts that penetrate the aorta tend to do well in short necks,^{10,11} although the quality of the neck (e.g., hostile neck features such as excessive thrombus or calcium, which can lead to poor outcomes) should be assessed, because the neck length is not the only determinant in accurate deployment or long-term success. Ideally, a stent-graft system's design should allow it to seal within 1 mm or less of the most distal renal artery and be able to take advantage of every millimeter of proximal neck for the greatest likelihood of long-term success (Figures 4–6).

Angulated Necks

The current-generation stent-grafts were mainly designed for straight-neck sealing zones. Most devices are not engineered to seal in necks > 60°. The indications do not consider concurrent hostile neck characteristics—including short necks < 15 mm, reverse taper of > 30%, or extensive thrombus or calcium—which reduce the likelihood of successful long- and short-term outcomes. As previously mentioned, the presence of more than one hostile neck characteristic further necessitates precise device placement to facilitate procedural success.

Tight Access

The GORE® DrySeal Sheath with hydrophilic coating has revolutionized difficult access issues because this sheath allows the operator to traverse almost any access environment. The sheath is designed to increase lubricity and minimize coating particulation to make for easier insertion and removal. The sheath's valve is pressurized to create a seal, which minimizes blood loss while still accommodating multiple wires and catheters. Gore has also reduced the device profile for the current-generation stent systems down to 16 Fr for stent-grafts up to 26 mm, so the 28.5 mm, 31 mm, and 35 mm grafts are the only sizes that need an 18 Fr delivery system.

Ease of Gate Cannulation

Another significant factor in EVAR is contralateral leg gate cannulation, especially in large, open sacs or where

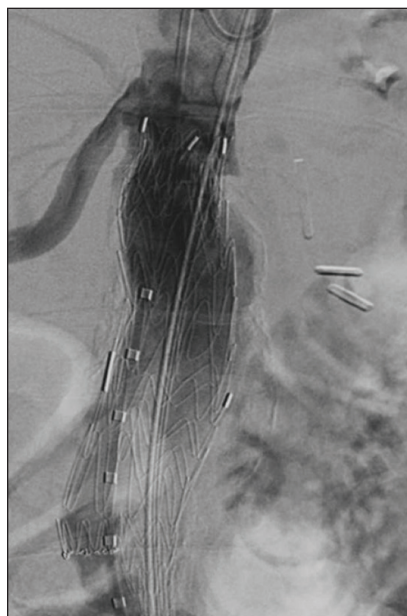


Figure 4. The GORE EXCLUDER AAA Endoprosthesis is initially deployed in a patient with an occluded left renal artery.

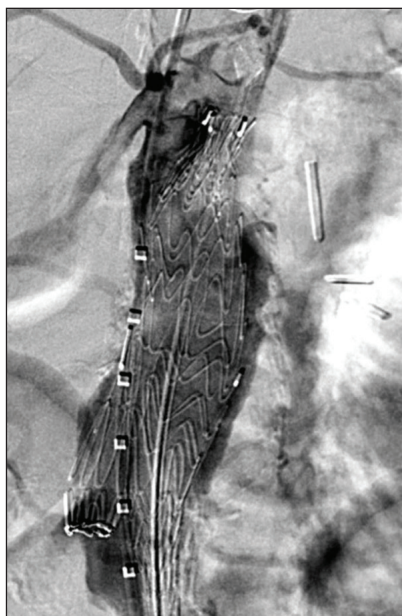


Figure 5. The Gore Excluder AAA Endoprosthesis is being repositioned and rotated to optimize the limited sealing zone of the infrarenal neck and to aid in cannulation because the contralateral gate is blocked by aortic plaque.



Figure 6. The GORE EXCLUDER AAA Endoprosthesis in final configuration.

there are aortic abnormalities such as lumen obstructions that can hinder cannulation (Figure 4). The ability to reposition the contralateral gate after initial deployment can significantly ease this process. The GORE C3 Delivery System makes these scenarios more navigable due to its ability to be reconstrained and repositioned to achieve an optimal proximal seal (Figure 5). This ease-of-use feature can also reduce procedure time, as well as fluoro time and exposure, which is beneficial to both the patient and physician.

Reduction in Aortic Extender Usage

Finally, the ability to maximize infrarenal seal with repositionability as desired can also have positive financial implications. The GORE EXCLUDER AAA Endoprosthesis featuring C3 Delivery system, can significantly reduce the need for proximal extension cuffs in patients with unfavorable aortic neck anatomy.¹² The Gore Global Registry for Endovascular Aortic Treatment (GREAT) was designed to evaluate real-world outcomes after treatment with aortic endovascular devices (the GORE EXCLUDER Device, GORE C3 Delivery System, GORE® TAG® Device, and Conformable GORE® TAG® Device)^{13,14} used in global markets and to identify the trends of on- and off-label use of the devices.

Data collected from the Gore GREAT registry have shown that the introduction of the GORE C3 Delivery System resulted in a > 50% reduction in aortic extender usage and a > 33% reduction in overall extender usage (including iliac extenders), as compared to use with the GORE® SIM-PULL Delivery System.¹⁵ Less unplanned extender usage is a clear benefit in both procedural time and from a case-cost standpoint.

GORE C3 DELIVERY SYSTEM IN A TEACHING APPLICATION

With EVAR becoming the standard of care for AAAs, it is important for fellows to be trained appropriately in this technique. Repositionable delivery provides an opportunity to teach this procedure, where suboptimal device placement is correctable without undue repercussions to patient safety. Gore also continues to work on profile reductions, such as with the new lower profile trunks, which provide benefits in patient inclusion and potentially reduced access complications.

The Gore C3 system allows the operator to confidently let the trainee deploy the stent-graft knowing the device can be repositioned. The system allows the trainee to perform the procedure without the irreversibility of other systems. Because of this fact, in

teaching environments, more difficult anatomies can be approached with the teaching aspect of this device always in the forefront.

CONCLUSION

The GORE C3 Delivery System is an optimal device, both to fellows and those new to EVAR and to the experienced physician facing a complex case with challenging anatomy. Experience thus far has shown that the system provides advantages with its repositionability in standard and complicated cases alike. ■

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Gore does not recommend treating patients with neck anatomy that does not comply with the following:

- *Infrarenal aortic neck treatment diameter range of 19 – 32 mm and a minimum aortic neck length of 15 mm*

- *Proximal aortic neck angulation $\leq 60^\circ$*
- *Please consult the Instructions for Use for complete indications, contraindications, warnings, and precautions.*

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