

# Endovascular TODAY

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## REAL REPOSITIONING BENEFITS



Are new opportunities  
to improve device position  
delivering EVAR success  
in the real world?

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delivering EVAR success in the real world?**

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# Clinical Impact of Repositionable EVAR Delivery

A panel of five expert EVAR practitioners discusses how the GORE® C3 Delivery System has changed their techniques and practices.

## PANEL



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**A slow or controlled deployment technique has been described in regard to both the GORE® SIM-PULL Delivery System's (Gore & Associates, Flagstaff, AZ) deployment and many competitors' deployment systems. How does repositioning differ between these options?**

**Dr. Katzen:** Repositioning is really very different than the slow deployment systems and techniques that many operators employ. The GORE® C3 Delivery System's (Gore & Associates) ability to reconstrain the proximal part of the implant makes this device a game-changer. In fact, I don't see the two techniques as being directly related. Many operators use slow deployment as a way to get a more predictable location of the implant. But the reconstrainable or repositionable device is really orders of magnitude better.

**Dr. Peterson:** Even with slow deployment, the orientation or how a device opens up and behaves within the aorta is somewhat unpredictable. Repositioning offers a much more reliable and accurate deployment option, especially when dealing with angulated proximal necks.

**Dr. Paludetto:** With the competitors' systems we can only move the device before fully opening the proximal part (the first covered stent). Sometimes, after the device is opened, it does not accommodate to the anatomy as we had wished. The big difference is that the GORE® C3 Delivery System's deployment is the only one that makes it possible to fully open the device at the proximal neck in order to see how the device will be accommodated in the aortic wall. If the device won't accommodate as planned,



we can close the proximal part and push up, pull down, and/or rotate the device to achieve the optimal position.

**Dr. Becquemin:** I would add that the ability to reposition gives a feeling of safety and is a great improvement.

**How would you describe the transition or learning curve in adopting the GORE® C3 Delivery System for you, your partners, and trainees?**

**Dr. Katzen:** Even if you've never used a GORE® EXCLUDER® Device (Gore & Associates) before, the GORE® C3 Delivery System is extremely simple to use. If you have used it before, I think you'll be very appreciative of the retained simplicity and the control the handle provides.

**Dr. Peterson:** Exactly. A lot of physicians really were attracted to the GORE® EXCLUDER® Device because of its simplicity. One concern with this new delivery was that the simplicity would be lost, but it certainly isn't. It's the same turn-and-pull motion, but now it's in triplicate, with the added benefit of being able to reposition if you don't like the initial device positioning.

The transition hasn't been an issue for me or for our general surgery residents and vascular fellows. In fact, using the new repositionable delivery system seems to increase some physicians' confidence in being aggressive, and therefore more accurate, on initial deployment.

Learning any new stent graft system seems intimidating at first. Once you get your hands on this device, however, it becomes evident that there is a very small learning curve needed to adapt to the new delivery system.

**Dr. Bachoo:** I also think it's been relatively straightforward, because I was familiar with the GORE® EXCLUDER® Device. The main learning challenge is really to identify the best use of repositioning (eg, whether you are repositioning up or down to the renal artery). It took about 10 to 12 cases for me to fully understand the utility of the repositioning. It isn't in the delivery process, but it has more to do with the expanded ways that you can now use and reposition it.

**Dr. Paludetto:** For us, the new system seems familiar. The steps are simple to understand. We've had no trouble.

**How did the GORE® C3 Delivery System meet your expectations? Did it work as expected, or did it surprise you in some way?**

**Dr. Katzen:** I think many of us weren't sure what to expect with the new delivery system. But, having used it, the GORE® C3 Delivery System really works exactly as

expected—it's very easy to deploy, reconstrain, and rotate and move the implant up and down to get fine levels of precision in deployment.

**Dr. Paludetto:** It achieved even more than we expected. We were surprised by the ability to easily close and change the device's position. We performed our first case with an extremely challenging anatomy, and it was only possible because the delivery system can close and change position.

**Dr. Peterson:** I'd say that the thing that surprised me most is that I was expecting it to be a little bit more difficult and complicated, but really it was quite easy to pick up the deployment and reconstraining sequence. As we became more familiar with the steps, how the device acted, and its characteristics, we have been able to get creative and tackle more difficult proximal neck anatomy, perhaps shorter or angulated necks. Ideally, the device's repositioning aspect is going to allow us to treat more patients who have challenging proximal neck anatomy.

We were also pleasantly surprised by the GORE® C3 Delivery System's ability to aid in parallax correction and gain additional seal. An example of this was a case we performed today. We used a straight anteroposterior projection, and when we deployed the device at the renal arteries, we noticed that the gold markers at the top of the device didn't line up very well. When we put the image intensifier in the appropriate cranial orientation, however, we were able to reconstrain the device and gain an additional 5 mm of seal.

**Dr. Bachoo:** It certainly met our expectations, but we were also surprised by the trackability of the GORE® C3 Delivery System, which was very significant. What I mean is, during vertical repositioning, a small movement of the hand was described equally on the x-ray machine in terms of position of the graft. So, a small movement of the hand produced an equally small movement of the graft; there was no need to be very forceful. I was also surprised by how reliable the whole process is, in that the various steps of repositioning are very smooth as you transition between deployment and repositioning.

**What is your favorite aspect or benefit of the GORE® C3 Delivery System and why?**

**Dr. Peterson:** My favorite aspect of the device is that it really allows you to be aggressive on your initial deployment. Whereas before, we would always be concerned about encroaching upon the renal artery orifices, now we can be very aggressive because we know that we

can reposition and move the device down a little bit if needed.

**Dr. Bachoo:** I think the biggest benefit of the GORE® C3 Delivery System is its ability to handle challenging anatomy. With this system, we are now able to take on short, angled necks, and we're also able to approach tortuous iliac anatomy with confidence. These are things we couldn't do as confidently before we had the GORE® C3 Delivery System, so it's quite easy for me to say that taking on more difficult anatomy is a clear outcome of using the new device.

**Dr. Becquemin:** The device can help to catheterize the contralateral limb, thanks to the ability to rotate the main body and bring the graft down closer to the ostium of the iliac artery.

**Dr. Katzen:** I think the strongest aspect of the new delivery system is the predictability of where the proximal part of the implant is going to wind up. In the previous iteration, we pulled the string and guessed a little bit about where the proximal part of the implant would land. It almost always landed where you expected it to, but you really didn't feel that you knew for sure. All guesswork has now been removed with the new deployment system.

**Dr. Paludetto:** For me, the strongest benefit is the possibility to fully open and then close the proximal part of the device, which makes it possible to change the position. This feature allows me to confirm position and see how the device accommodates the aortic wall.

**Most physicians use a variety of devices to treat their AAA patients. When selecting an EVAR device, physicians typically choose one based on the strengths of the device as a match for the anatomy of the individual patient. For which patients have you selected the GORE® EXCLUDER® Device with SIM-PULL Delivery System in the past, and how has the addition of the GORE® C3 Delivery System changed your selection process?**

**Dr. Peterson:** The new device certainly has broadened the range of patients I would treat with the GORE® EXCLUDER® Device. The ideal candidates for the traditional GORE® SIM-PULL Delivery System were often patients with favorable proximal necks and small or heavily calcified or really tortuous iliac arteries. Now, many more patients will benefit from the addition of the repositionable GORE® C3 Delivery System. We can

treat not only patients with difficult iliac anatomy, but also those with the most difficult proximal aortic necks; characteristics of these situations would be a reverse tapered neck, a neck with a lot of thrombus or heavy calcification, or extremely angulated proximal aortic necks.

**Dr. Bachoo:** Exactly. In the past, the GORE® SIM-PULL Delivery System was often used for more ideal anatomy. Now, the GORE® C3 Delivery System is used routinely without reference to the actual anatomy, whether shorter necks, angulated necks, or tortuous iliac arteries. We use it for all comers, basically.

**Dr. Paludetto:** I agree. There were limits to using the GORE® EXCLUDER® Device in patients with short, tortuous, and angled necks. With the GORE® C3 Delivery System, we can now treat more challenging necks.

**Dr. Katzen:** Yes, in the past, I think some physicians would use a suprarenal device to get a better feeling of control during deployment. The new reconstrainable delivery system allows the operator to more accurately position the fabric at the lowest level of the ostium without requiring suprarenal stents.

**Dr. Becquemin:** It's true; we can treat more challenging cases than ever before.

**Many physicians hoped that the GORE® C3 Delivery System would increase their deployment accuracy, limiting the need for aortic extender cuffs. How would you describe your experience in this regard?**

**Dr. Bachoo:** First of all, I would agree that the final deployment accuracy is greatly improved, and that's a result of repositioning. The role of the cuffs has changed completely. Aortic extender cuffs were previously used as a second step or salvage intervention for migration. Currently, we use extender cuffs in a planned fashion and in difficult angled necks.

**Dr. Paludetto:** I agree. In most past cases, if we needed to use extender cuffs, it was because the device wasn't accommodated in the way we had hoped. Usually, the extender cuffs were used to make corrections. With this new and secure system, extender cuff use will certainly decrease.

**Dr. Peterson:** This is interesting; we just presented data at the Annual Winter Meeting of the Peripheral Vascular Surgery Society. We looked at our experience

in treating patients with unfavorable proximal aortic neck anatomy and have clearly seen a significant reduction in our aortic extension cuff usage. Despite the slightly higher cost of the GORE® C3 Delivery System, a cost analysis showed that it doesn't take many cases to realize the cost savings for a hospital. On average, in patients with unfavorable neck anatomy, we had to do fewer than eight cases using the GORE® C3 Delivery System to really see a cost benefit because we are not using as many aortic extension cuffs.

**Are there things that you are able to do technique-wise with the GORE® C3 Delivery System that either were impossible previously, or were much more difficult?**

**Dr. Peterson:** I think gate cannulation has certainly been made easier, especially when the aneurysm is very large or when, say, there is an hourglass-shaped aneurysm and the contralateral gate is going to open up in the narrowest portion of the aorta. Another classically difficult gate cannulation situation happens when there is a short distance between the lowest renal artery and the aortic bifurcation.

The GORE® C3 Delivery System makes those situations easier to deal with. Not only can the device be reconstrained and repositioned to achieve an optimal proximal seal, but it can also be reconstrained with the idea that the gate can be moved to cannulate more effectively. As you know, the GORE® EXCLUDER® Device hasn't changed, so the complete gold ring on the contralateral gate remains unchanged. Combine that with the repositionable aspect of the GORE® C3 Delivery System, and gate cannulation is now that much easier.

**Dr. Bachoo:** As I mentioned earlier, we can now address many anatomic presentations with the GORE® C3 Delivery System.

**Dr. Paludetto:** Certainly. With the GORE® C3 Delivery System, treating short and angulated necks, as well as performing contralateral leg catheterizations, becomes easier because you can move and find the best position. With other systems, repositioning is impossible. The GORE® C3 Delivery System makes it possible to treat highly complex aneurysms and emergent cases.

**Dr. Becquemin:** Yes, I've also been able to more easily manage emergent AAAs with this device.

**People have come up with different analogies to describe the benefits of repositionability—a rewind button, an insurance policy, etc. What analogy works best to describe its impact on your practice, and why?**

**Dr. Becquemin:** I would call it a second chance, that is there if needed.

**Dr. Bachoo:** I would say it is like an insurance policy.

**Dr. Paludetto:** Yes, "insurance policy" is a good way to describe the GORE® C3 Delivery System. It seems like it can help predict the future, because this system enables us to deploy the top of the device and see how it will be positioned on the aortic wall. If it is not properly positioned, we have the assurance that we can come back, close, relocate, and reopen the device in order to more effectively exclude the aneurysm.

**Dr. Katzen:** If I had to pick a phrase, I'd simply say proximal deployment—precise proximal deployment.

**Dr. Peterson:** I like all of those descriptions, but I kind of think of the repositionable aspect of the GORE® C3 Delivery System as a guardian angel sitting on my shoulder that is ready to help out in difficult situations. ■

# Case Study: Repositioning the GORE<sup>®</sup> EXCLUDER<sup>®</sup> Device Featuring C3 Delivery System

Proper placement is achieved in a challenging neck without the need for extension cuffs.

**BY JEAN BISMUTH, MD**

**T**he GORE<sup>®</sup> C3 Delivery System (Gore & Associates, Flagstaff, AZ) further strengthens the GORE<sup>®</sup> EXCLUDER<sup>®</sup> Device (Gore & Associates), an aortic stent graft that has long been an exceptionally reliable device. Using this delivery system, the user has the option to partially deploy (specifically bringing the device to full diameter from the top to the contralateral gate), constrain, and reposition the device, which is a clear advantage if the device has been positioned inappropriately relative to either the landing zone or gate position. This capability has the potential to prevent renal ischemia due to coverage of the renal arteries, to reduce the need to use cuffs for low deployment, and to reduce prolonged irradiation and operative times due to difficult gate cannulation. Although renal artery coverage is not common and is usually discovered immediately intraprocedurally, Gabrielli and colleagues<sup>1</sup> reported an incidence of 0.9%. Rates may be higher, as this is generally poorly documented in the literature.

Verhoeven et al<sup>2</sup> found that they used the repositionable ability of the GORE<sup>®</sup> EXCLUDER<sup>®</sup> Device featuring C3 Delivery System in 72% of their cases to achieve better positioning or facilitate cannulation. Additionally, they did not use any proximal cuffs.

The ability to reposition would ideally suit challenging abdominal aortic aneurysm (AAA) cases because it allows for cannulation and ideal positioning to rapidly exclude the aneurysm.

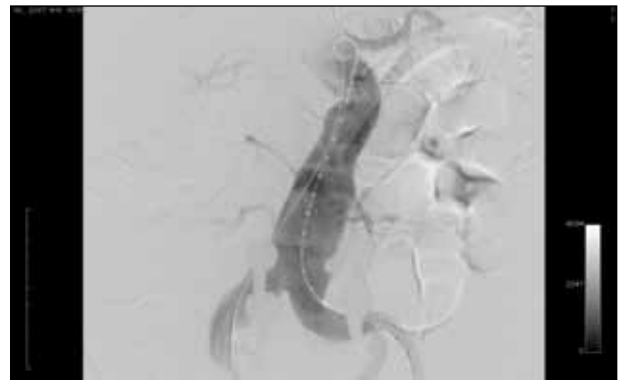


Figure 1. Initial angiography showing an angulated neck.



Figure 2. Poor initial positioning of the stent graft (A) despite placement at the level of the lowest renal artery (B).



**Figure 3.** The device is constrained prior to repositioning (A) and moved proximally to a more ideal position (B).



**Figure 4.** Completion aortography confirms adequate graft positioning, aneurysm exclusion, and no appreciable endoleaks.

## CASE REPORT

A 64-year-old man presented to the emergency department with a symptomatic AAA. His medical history included hypertension, chronic obstructive pulmonary disease, three previous myocardial infarctions, and prostate cancer. On computed tomography, he was found to have a nonruptured AAA measuring 5.6 cm. The patient was evaluated by cross-sectional imaging, which identified a nonruptured AAA and adequate access

vessels, but a significantly angulated neck. We believed that the angulated neck could render appropriate device placement challenging and, therefore, would benefit from the unique repositionable feature of the GORE® EXCLUDER® Device featuring C3 Delivery System.

Bilateral groin cutdowns were performed, and wire access was obtained. Initial angiography (Figure 1) identified the angulated neck as well as better positioning by crossing the limbs of the device. We delivered the main body via the right femoral artery as we believed that this would likely allow for better positioning with the angulated neck. Initial device positioning was poor (Figure 2A) despite having placed the device at the level of the lowest renal artery (Figure 2B). This poor device position, if unchanged, would likely lead to a significant type I endoleak with need for additional cuffs. We constrained the graft (Figure 3A) and moved the device proximally into a better position (Figure 3B). After we deployed the limbs and ballooned the device, completion aortography showed adequate positioning of the graft with exclusion of the aneurysm and no appreciable endoleaks (Figure 4).

After the procedure, the patient's abdominal pain was completely relieved, and he was discharged after 2 days without any further issues. On 6-month follow-up, the patient had no complications, and the stent graft remained in a good position without endoleaks.

## CONCLUSION

This case illustrates the ability to reposition the GORE® EXCLUDER® Device and achieve a more effective exclusion of the AAA without the need to place additional aortic cuffs. This fundamentally changes the way we think about performing endovascular aneurysm repair, as we cannot always predict how a graft will behave in challenging anatomy. Having the opportunity to modify positioning can both be less costly (as in this case, by avoiding the need for additional devices) and also accelerate cases, thereby avoiding prolonged operative times and reducing radiation and contrast usage. ■

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1. Gabrielli L, Baudo A, Molinari A, Domanin M. Early complications in endovascular treatment of abdominal aortic aneurysm. *Acta Chir Belg*. 2004;104:519-526.
2. Verhoeven EL, Oikonomou K, Möhner B, et al; European C3 Global Registry Participants. First experience with the new repositionable C3 Excluder stent graft. *J Cardiovasc Surg (Torino)*. 2011;52:637-642.



# EVAR in a High-Volume, Multisurgeon Practice

The GORE® EXCLUDER® Device's unique features and proven durability make it an indispensable part of our EVAR armamentarium.

**BY JIM G. MELTON, DO; LENNY D. STUBBS, MD; AND KOUSTA I. FOTEH, MD**

In the last 20 years, the treatment of abdominal aortic aneurysms has been revolutionized by endovascular repair. To date, there have been seven endografts approved by the US Food and Drug Administration for commercial use. Our group has had experience with many of these devices. Clinical outcomes, ease-of-use, and cost concerns have driven our practice to the preferential use of the GORE® EXCLUDER® Device (Gore & Associates, Flagstaff, AZ). In the past 5 years, we have performed 748 endovascular aneurysm repairs (EVAR) procedures using the GORE® EXCLUDER® Device as our primary graft for both complex and straightforward aneurysm repair.

## EFFICIENT PROCEDURAL TIMES

The Vascular Institute at Oklahoma Heart Hospital is a comprehensive peripheral vascular program located in Oklahoma City, Oklahoma. It is one of the most active vascular surgery specialty groups in the region, dedicated to providing the highest levels of patient care using the most current technologies for the treatment of vascular disease. Minimized procedural times and component usage are important to a successful private practice. The elegance and simplicity of the GORE® EXCLUDER® Device facilitate a reduction in procedure times, thereby improving operative efficiency and minimizing anesthesia times.

Extensive case planning and surgical team training have allowed us to achieve an average procedure time of approximately 40 minutes from incision to closure of the skin. Short operative times play a crucial role in our ability to successfully treat challenging aortic aneurysm pathologies via an endovascular approach. Additionally, the ability to treat patients with a minimal number of components greatly simplifies case planning and procedural complexity. In the majority of our cases, the GORE® EXCLUDER® Device requires only two pieces for complete aneurysm exclusion. In the event that an extension is required to promote seal, it can be delivered and deployed accurately and rapidly.

## DEVICE SEAL, MIGRATION, AND PATENCY

In our broad experience, we have seen very few intraoperative proximal or distal type I endoleaks. In the

case of delayed or small blush type I leaks, we adopt a “wait-to-treat” approach and find that the majority resolve before the patient’s scheduled 30-day follow-up computed tomography, resulting in a very low rate of secondary intervention. This is consistent with large, multicenter registry data, as well as randomized controlled trials in which the GORE® EXCLUDER® Device has been shown to be associated with statistically significant lower reintervention rates compared to all other endografts.<sup>1,2</sup>

One significant issue among many early endografts has been failed fixation. Endograft migration has led to catastrophic complications, including aneurysm rupture and conversion to open surgical repair.

Manufacturers and physicians have made claims that devices with suprarenal fixation have inherent superior fixation and a lower incidence of graft migration. These assumptions, largely based on first-generation device performance, have been refuted through various trials and clinical studies. More accurately, devices that rely solely on radial force and graft wall/aorta contact are devices that struggle with migration.

A review of published literature establishes the durability and effectiveness of infrarenal active fixation with the GORE® EXCLUDER® Device.<sup>2-8</sup> This infrarenal fixation avoids the clinical risks associated with suprarenal stents, both in terms of renal function and endograft delivery. A recent review has indicated that suprarenal fixation poses an increased risk of renal injury.<sup>9</sup> Several reports of suprarenal delivery system failures have shown that the added stent row and its delivery/release mechanism increases procedural complexity. Additionally, a taller, rigid suprarenal stent can actually work against graft seal by holding it away from the aortic wall, especially in angulated anatomies. The highly flexible GORE® EXCLUDER® Device with shorter stents and infrarenal fixation constantly conforms to challenging anatomy, thus promoting seal.

We simply do not see migration of the GORE® EXCLUDER® Device when used within the instructions for use, and we do not believe that suprarenal fixation offers

any advantage, even in the treatment of complex proximal neck anatomy. Our results have been superior in both migration resistance and seal as compared to the published results of suprarenal devices.

## LIMB PERFORMANCE

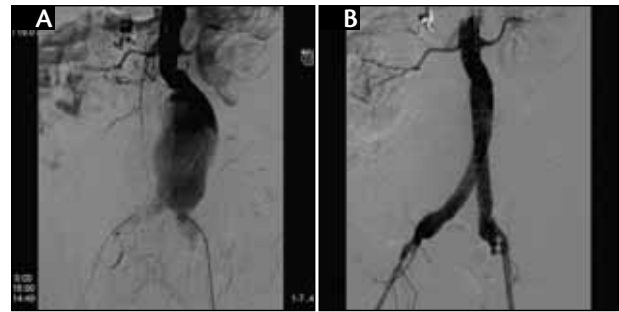
Limb thrombosis/kinking of the EVT device (Endovascular Technologies, Inc., a subsidiary of Guidant Corporation) led to the incorporation of supported stents within endograft limbs. It was believed that supported limbs were essential to optimal clinical performance. Since the EVT graft, different stent features have been incorporated to try to obtain flexibility, as well as longitudinal and radial support. Some device limbs have individual rings or even spiral stents but leave regions of unsupported graft that can bunch into the graft lumen in angulated anatomy. Others have longitudinal wires to provide longitudinal support for delivery accuracy and to limit graft accordioning; however, these wires limit device flexibility.

The sutureless, nested stents and polytetrafluoroethylene material of the GORE® EXCLUDER® Device limbs provide full radial and longitudinal support without sacrificing device flexibility. Clinical results have demonstrated the superiority of the GORE® EXCLUDER® Device limbs in clinical performance. In our 748 patients treated with the GORE® EXCLUDER® Device, we have experienced just one limb occlusion, which was a result of placing a bifurcated graft within a flow lumen that only measured 14 mm in diameter. The GORE® EXCLUDER® Device limbs are the most kink- and occlusion-resistant limbs of the currently available devices.<sup>2,10-13</sup>

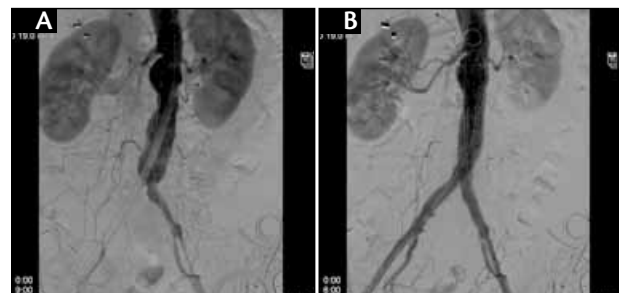
## CONTROL AND PRECISION OF DELIVERY

The addition of the GORE® C3 Delivery System (Gore & Associates) has further enhanced our ability to treat patients with complex aortic neck anatomy (Figure 1). The ability to reposition the graft after device deployment, when the proximal half of the graft is in complete contact with the aortic wall, has allowed us to be more aggressive when placing the graft as close to the renal ostium as possible. The majority of our deployments are done with sufficient accuracy so that we do not have to reposition the graft, but the GORE® C3 Delivery System provides security against any miscalculation or anatomical complexity.

One of the unique features of the GORE® C3 Delivery System is that it accommodates different modes of device release from the catheter. As published by Alterman et al, Minion et al, and Krajcer et al, the constraining sleeve deployment allows the graft to fall away from the catheter to more easily accommodate angulated anatomy.<sup>14-16</sup> After constraining the device to the catheter upon initial deployment, the graft is released from the catheter in a concentric fashion. Whether using the original GORE® SIM-PULL



**Figure 1.** Angiography highlighting an angulated aortic neck (A). Precise placement of the main body was performed utilizing the GORE® C3 Delivery System. Completion arteriography shows no endoleak and a good seal (B). Note that the left hypogastric artery was coil embolized, and a limb extension was placed. The right hypogastric artery was preserved.



**Figure 2.** Challenging iliac access and a short conical aortic neck (A). Completion angiography showing successful endograft repair.

Delivery System (Gore & Associates) or GORE® C3 Delivery System, operators can use the unique deployment attributes to their advantage, which is very accommodating for physicians within the same group who may have different preferences for treating different patients.<sup>17</sup>

## ACCESS

When access is difficult because of small or tortuous iliac arteries, the on-catheter flexibility of the device enables device tracking (Figure 2). Our practice is to attempt different techniques that will allow endovascular repair without the use of a standard iliac conduit unless necessary. More often than not, the introducer dilator/sheath can be navigated through the vessels so that safe and accurate deployment can occur. However, adjunctive maneuvers are sometimes required. When using larger sheaths (18 or 20 F), gentle balloon angioplasty of the iliac arteries allows enough room so that the dilator/sheath can be placed. When balloon angioplasty is not effective, we have utilized a 7- or 8-mm GORE® VIABAHN® Stent (Gore & Associates) as an “endoconduit” to aid in delivery.<sup>15</sup> We have rarely encountered perforations of the iliac artery or other traumatic injuries. Additionally, using a delivery sheath for access allows

for one sheath introduction that protects the femoral artery from iatrogenic injury during the subsequent catheter, device, and balloon exchanges.

### TOTALLY PERCUTANEOUS EVAR

Although the majority of our EVAR procedures are performed through standard bilateral common femoral cutdowns, we sometimes perform them via a totally percutaneous approach utilizing closure devices in patients with suitable anatomy. Unsuccessful closure with a closure device does require patients to undergo open repair of the femoral artery, but we have not encountered any problems with the GORE® EXCLUDER® Device when attempting percutaneous EVAR. This is consistent with the US Food and Drug Administration trial of the GORE® EXCLUDER® Device, which was the first EVAR approval study in the United States to incorporate this technique.<sup>16</sup>

### DURABILITY

EVAR clinical trial results have called into question the long-term benefit of endovascular repair because of problems related to endograft durability and endograft revision. It is possible that this is, in part, a result of the endografts selected. Studies have reported device failures related to migration, patency, and endoleak. As manufacturers have worked to lower the profile of their devices, fabrics used have become thinner and thinner.

Reports of graft fatigue of newly released endografts have already been published.<sup>17</sup> This has also shown clinical relevance in type IV endoleaks and aneurysm sac pulse pressure.<sup>18,19</sup> In these publications, the GORE® EXCLUDER® Device was shown to have a more durable response. This is most likely due to the unique construction of the graft. The GORE® EXCLUDER® Device is the only endograft that does not rely on sutures to tie the graft to the stent. Gore uses a sutureless construction to bond the stent with ePTFE film to create a single, seamless laminate abrasion-resistant graft. The durability of this construction has been confirmed through many long-term clinical studies as well as our personal experience.<sup>20-22</sup> Extensive case planning, clinical support, and device design have minimized complications and provided our patients with an excellent long-term repair.

### CURRENT LIMITATIONS

Product line extensions have been added to the GORE® EXCLUDER® Device line to augment the number of patients who can be treated with this device. Most recently, larger limbs extended treatment to patients with iliacs as large as 25 mm. Still, there remains a small subset of patients who cannot be treated due to anatomical restrictions, such as patients with aortic necks > 29 mm in diameter. We look forward to this summer's anticipated release of the larger GORE® EXCLUDER® Device trunk, designed to treat inner

aortic diameters up to 32 mm, as well as projects to lower the portfolio's profile.

### CONCLUSION

Treatment of straightforward and challenging anatomy with the GORE® EXCLUDER® Device is technically feasible and clinically effective. Device performance and ease-of-use have made it the standard of care for EVAR in our facility. It has proven to be a durable and reliable endograft and has enabled us to treat a wide variety of patients and pathologies. ■

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1. Brown LC, Greenhalgh RM, Powell JT, Thompson SG; EVAR Trial Participants. Use of baseline factors to predict complications and reinterventions after endovascular repair of abdominal aortic aneurysm. *Br J Surg*. 2010;97:1207-1217.
2. van Marrewijk CJ, Leurs LJ, Vallabhaneni SR, et al; EUROSTAR collaborators. Risk-adjusted outcome analysis of endovascular abdominal aortic aneurysm repair in a large population: how do stent-grafts compare? *J Endovasc Ther*. 2005;12:417-429.
3. Kibbe MR, Matsumura JS; Excluder Investigators. The Gore Excluder US multi-center trial: analysis of adverse events at 2 years. *Sem Vasc Surg*. 2003;16:144-150.
4. Peterson BG, Matsumura JS, Brewster DC, Makaroun MS; Excluder Bifurcated Endoprosthesis Investigators. Five-year report of a multicenter controlled clinical trial of open versus endovascular treatment of abdominal aortic aneurysms. *J Vasc Surg*. 2007;45:885-890.
5. Haider SE, Najjar SF, Cho JS, et al. Sac behavior after aneurysm treatment with the Gore Excluder low-permeability aortic endoprosthesis: 12-month comparison to the original Excluder device. *J Vasc Surg*. 2006;44:694-700.
6. Currin JA, Fillingim MF, Naslund TC, Rubin BG; for the Excluder Bifurcated Endoprosthesis Investigators. Clinical trial results of a modified gore excluder endograft: comparison with open repair and original device design. *Ann Vasc Surg*. 2007;21:328-338.
7. Dillavou ED, Muluk S, Makaroun MS. Is neck dilatation after endovascular aneurysm repair graft dependent? Results of 4 US Phase II trials. *Vasc Endovasc Surg*. 2005;39:47-54.
8. Leurs LJ, Hobo R, Buth J; EUROSTAR Collaborators. The multicenter experience with a third-generation endovascular device for abdominal aortic aneurysm repair. A report from the EUROSTAR database. *J Cardiovasc Surg*. 2004;45:293-300.
9. Noorani A, Walsh SR, Boyle JR. Long-term effects of EVAR. Suprarenal versus infrarenal fixation. *J Cardiovasc Surg (Torino)*. 2011;52:199-203.
10. Hingorani AP, Ascher E, Marks N, et al. Iatrogenic injuries of the common femoral artery (CFA) and external iliac artery (EIA) during endograft placement: an underdiagnosed entity. *J Vasc Surg*. 2009;50:505-509; discussion 509.
11. Bos WT, Tielliu IF, Van Den Dungen JJ, et al. Results of endovascular abdominal aortic aneurysm repair with selective use of the Gore Excluder. *J Cardiovasc Surg*. 2009;50:159-164.
12. Mendonça CT, de Carvalho CA, Weingartner J, et al. Endovascular treatment of abdominal aortic aneurysms in high-surgical-risk patients using commercially available stent-grafts. *J Endovasc Ther*. 2010;17:89-94.
13. Maleux G, Koolen M, Heye S, Nevelsteen A. Limb occlusion after endovascular repair of abdominal aortic aneurysms with supported endografts. *J Vasc Interv Radiol*. 2008;19:1409-1412.
14. Alterman DM, Stevens SL. The excluder aortic endograft. *Perspect Vasc Surg Endovasc Ther*. 2008;20:136-148; discussion 149-157.
15. Peterson BG, Matsumura JS. Internal endoconduit: an innovative technique to address unfavorable iliac artery anatomy encountered during thoracic endovascular aortic repair. *J Vasc Surg*. 2008;47:441-445.
16. Matsumura JS, Katzen BT, Hollier LH, Dake MD. Update on the bifurcated EXCLUDER endoprosthesis: phase I results. *J Vasc Surg*. 2001;33:150-153.
17. Aboultitim I, Gouicem D, Kobeiter H, et al. Early type III endoleak with an Endurant endograft. *J Vasc Surg*. 2010;52:1665-1667.
18. Baum RA, Stavropoulos SW, Fairman RM, Carpenter JP. Endoleaks after endovascular repair of abdominal aortic aneurysms. *J Vasc Interv Radiol*. 2003;14:1111-1117.
19. Shrikhande G, Khan S, Hussain H, et al. Significance of initial aortic aneurysm pressure sensor readings varies with aortic endograft design. *World J Surg*. 2010;34:2969-2972.
20. Kim YI, Chung JW, Kim HB. Placement of Endovascular Stent across the Branching Arteries: Long-term Serial Evaluation of Stent-tissue Responses Overlaying the Arterial Orifices in an Experimental Study. *Cardiovasc Intervent Radiol*. [published online ahead of print August 9, 2011]
21. van Marrewijk CJ, Leurs LJ, Vallabhaneni SR, et al. Risk-adjusted outcome analysis of endovascular abdominal aortic aneurysm repair in a large population: how do stent-grafts compare? *J Endovasc Ther*. 2005;12:417-429.
22. Peterson BG, Matsumura JS, Brewster DC, et al. Five-year report of a multicenter controlled clinical trial of open versus endovascular treatment of abdominal aortic aneurysms [published online ahead of print March 28, 2007]. *J Vasc Surg*. 2007;45:885-890.

# My Kit for Emergent EVAR

Treating acute symptomatic AAA using the GORE® EXCLUDER® Device featuring C3 Delivery System.

**BY MANISH MEHTA, MD, MPH**

**T**oday, the proportion of emergent/acute symptomatic abdominal aortic aneurysm (AAA) patients being treated by endovascular means is steadily increasing, and ample evidence exists regarding the safety and efficacy of these procedures in academic tertiary medical centers as well as community hospitals.<sup>1-3</sup> Most well-established centers performing emergent aortic procedures have developed strategies that facilitate a seamless transition of the patient from the emergency department to the operating room for endovascular aneurysm repair (EVAR). Although the standardization of any approach will vary from one institution to another, the fundamentals are simple in that success depends on the early diagnosis of emergent AAA, the ability to have an expeditious computed tomography scan to evaluate the aortoiliac morphology, and quick transition of the patient from the emergency department to the operating room, which is equipped to perform endovascular as well as open surgical repair under these emergent circumstances.<sup>4</sup>

Over the past decade, The Vascular Group in Albany, New York has treated nearly 400 cases of acute symptomatic abdominal and thoracic aortic aneurysms, approximately 50% of which underwent emergent EVAR. Through this evolution, in our experience, we have noticed an increasing percentage of patients with acute aortic emergencies being treated by endovascular means. Today, more than 75% of patients with acute symptomatic AAAs undergo EVAR, whereas in 2002, only 15% underwent EVAR.

In addition to the standardized triage approach that enables a seamless transition of patients from the emergency department to the operating room, we have also evolved to using a few of the standard tools (wires, catheters, snares, sheaths, occlusion balloons,

stents, covered stents, and stent grafts). Frankly, there is no single kit for emergent AAA treatment that would necessarily be better than another. However, please see Table 1 for a list of tools that we routinely use, as we have found their simplicity to improve our ability to treat the vast majority of patients with emergent AAAs.

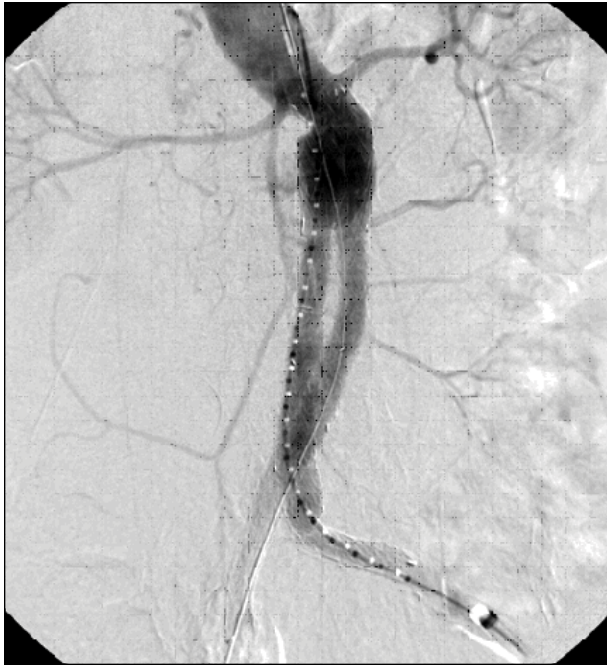
## **THE GORE® EXCLUDER® DEVICE FEATURING C3 DELIVERY SYSTEM**

Currently available stent grafts with or without suprarenal fixation have their pros and cons for accommodating complex aortoiliac morphology, which is well beyond the scope of this discussion. In our experience of treating emergent AAAs, we have used all “off-the-shelf” stent grafts approved by the US Food and Drug Administration and would recommend that surgeons/interventionists have access to stent grafts with suprarenal as well as infrarenal fixation to have the greatest flexibility during these procedures. Particularly under emergent circumstances, the device with which the physician is most comfortable should be used. In our practice, we have most commonly used the GORE® EXCLUDER® Device featuring C3 Delivery System (Gore & Associates, Flagstaff, AZ). This system provides clinicians with the ability to deploy and then reposition the endoprosthesis prior to final release from the delivery catheter. There have not been any changes to the materials; the device is still constructed of an expanded polytetrafluoroethylene bifurcated graft with an outer self-expanding nitinol support structure. There have also been no changes to the profile of the device. The main difference between the GORE® C3 Delivery System and the original delivery system is that there are now three distinctive steps for deploying the trunk-ipsilateral endoprosthesis.



**TABLE 1. MY KIT FOR TREATING EMERGENT AAA**

Product Name	Manufacturer	Size(s)
<b>Wires</b>		
Bentson wire	Various	0.035 inch/150 cm
Angled Glidewire	Terumo Interventional Systems, Inc. (Somerset, NJ)	0.035 inch/150 cm
Meier wire	Boston Scientific Corporation (Natick, MA)	0.035 inch/185 cm
Lunderquist wire	Cook Medical (Bloomington, IN)	0.035 inch/260 cm
Spartacore wire	Abbott Vascular (Santa Clara, CA)	0.014 inch/190 cm
<b>Catheters</b>		
Straight flush catheter	Various	5 F/70 cm
Bernstein catheter	Various	5 F/65 cm
Omni Flush catheter	AngioDynamics, Inc. (Latham, NY)	4 F/70 cm
Sos Omni Selective catheter (#1, #3)	AngioDynamics, Inc.	5 F/80 cm
<b>Snares</b>		
GooseNeck snare	Covidien (Mansfield, MA)	6 F/25 mm/120 cm
<b>Sheaths</b>		
Check-Flo Performer introducer sheath	Cook Medical	12 F/30 cm, 18 F/30 cm, 22 F/25 cm
GORE® DrySeal Sheath	Gore & Associates	12 F/28 cm, 20 F/28 cm, 22 F/28 cm, 24 F/28 cm
<b>Occlusion Balloons</b>		
Q50	Gore & Associates	Introduced through a 12-F sheath
Reliant 46	Medtronic, Inc. (Minneapolis, MN)	Introduced through a 12-F sheath
<b>Balloons Used for Palmaz Stent Placement<sup>a</sup></b>		
Maxi LD	Cordis Corporation (Bridgeport, NJ)	22 mm–4 cm/80 cm, 25 mm–4 cm/80 cm
<b>Stents</b>		
Balloon-expandable and self-expanding stents to treat visceral and iliac arteries	Various	Various
Palmaz stents 3910, 4910	Cordis Corporation	NA
GORE® VIABAHN® Stent	Gore & Associates	5–8 mm/2.5 cm, 5–8 mm, 5 cm
<b>Stent Grafts<sup>b</sup></b>		
GORE® EXCLUDER® Device featuring C3 Delivery System	Gore & Associates	23 X 14.5 X 14 cm, 28 X 14.5 X 14 cm, 31 X 14.5 X 13 cm
<p><sup>a</sup>A Palmaz stent is initially mounted onto the appropriately sized Maxi LD balloon, delivered through an 18-F sheath up to the aortic neck and deployed. The Maxi LD balloon is deflated and removed, and the occlusion balloon is used to mold the Palmaz stent to the aortic neck.</p> <p><sup>b</sup>We would always recommend using the stent grafts with which the physician is most comfortable, particularly during emergent circumstances. The most commonly used stent graft during emergent EVAR in our practice has been the GORE® EXCLUDER® Device, now with the GORE® C3 Delivery System. A variety of iliac limbs accommodate most iliac arteries ranging in length from 7–14 cm and 8–25 mm in diameter.</p> <p>Abbreviations: NA, not available.</p>		



Completion angiography.

The deployment controls of the GORE® C3 Delivery System are housed in the device handle, which is ergonomically designed, is easy to maneuver, has great trackability similar to the original device, and allows for one-to-one rotation during device positioning.

The GORE® C3 Delivery System deployment of the main body up to the contralateral gate is similar to the original GORE® SIM-PULL Delivery System (Gore & Associates) and requires turning the outermost handle 90° counterclockwise and pulling a deployment cord. Once the first stage is deployed, the x-ray intensifier can be repositioned to adjust for parallax. The top of the stent graft main body can then be constrained by turning the gray knob on the back of the GORE® C3 Delivery System handle clockwise. This allows the proximal barbs to fully disengage from the aortic wall, enabling the stent graft to be advanced or pulled down as needed.

The constrained stent graft can also be rotated to align the contralateral gate with the catheter used for gate cannulation, easing the cannulation process. Subsequently, the constrained device can be advanced up to the lowermost renal artery. Once in position, the gray knob is turned counterclockwise to once again deploy the proximal end of the stent graft and engage

the proximal barbs into the aortic neck for active fixation in a very controlled manner.

The second stage of the GORE® C3 Delivery System handle is then turned 90° counterclockwise and pulled to release the constraining mechanism. Finally, the third stage and innermost knob is turned 90° counterclockwise and pulled to release the constrained ipsilateral stent graft limb. The delivery catheter is then retracted over the wire.

## RECENT ALBANY VASCULAR GROUP EXPERIENCE

At Albany Medical Center, during the past year, 14 patients underwent EVAR for emergent AAAs using the GORE® EXCLUDER® Device featuring C3 Delivery System, and we have found the additional distinctive features of the new system to be valuable in treating a wide range of complex, acute symptomatic AAAs.

The expected succession of new technology includes improvements in techniques that enable us to further explore new and often undiscovered boundaries. When it comes to managing patients with emergent AAA, subtle improvements in both techniques and technology can have a significantly favorable effect on patient's outcomes. ■

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1. Mehta M. Endovascular repair of ruptured abdominal aortic aneurysms: The Albany Vascular Group Approach. *J Vasc Surg.* 2010;52:1706-1712.
2. Dgorova N, Giacomelli J, Greco G, et al. National outcomes of treatment of ruptured AAA: comparison of open versus endovascular repair. *J Vasc Surg.* 2008;48:1092-1100.
3. Starnes BW, Anderson CA, Ronsaville JA, et al. Totally percutaneous aortic aneurysm repair: experience and prudence. *J Vasc Surg.* 2006;43:270-276.
4. Mehta M, Taggart J, Darling RC III, et al. Establishing a protocol for endovascular treatment of ruptured abdominal aortic aneurysms: outcomes of a prospective analysis. *J Vasc Surg.* 2006;44:1-8.

# A Model for Industry-Supported Physician Education

An expert panel of physicians discusses the state of industry-supported education today, including Gore's Medical Mastery Series of educational programs.

## PANEL



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**Although some industry-supported activities have recently come under increased scrutiny, it still seems to be an area that is widely perceived as providing value to physicians and their patients. What are your thoughts on the value of industry participation and financial support of physician education activities, and what do you think the future holds?**

**Dr. Verhoeven:** This is not a black and white issue—this is a gray area. You know the argument: without industry cooperation, we wouldn't be where we are, but obviously, there are inherent risks of cooperation with industry that are mostly financially inflicted. It's clear that increased scrutiny is required, but there must be some latitude to do

things. It is most important that we are open about industry participation, that we declare what we do, and that financial advantages are clearly stated and probably should not go to physicians directly.

**Dr. Benenati:** I think that regulatory policies will continue to require more stringent rules on what industry and physicians can do regarding educational activities. I agree that it is very important that physicians openly disclose all of their relationships. One of the problems in the past was that there were conflicts of interest that were not disclosed. This lack of disclosure leads to biased presentations and, ultimately, can result in physicians performing procedures

to receive incentives that may benefit a company at the expense of a patient.

I believe industry can continue to support education with full disclosure and with minimal bias. The use of unrestricted grants is a valuable way to be sure that there is support from industry without influence on speakers or CME content. There are many educational opportunities that are procedure-specific or device-specific, and industry support is critical to the necessary training and dissemination of information.

**Dr. Lee:** These activities allow the rollout of new knowledge and new technology. Although many people have become very experienced with endovascular techniques, there is always room for improvement. As clinicians, we're pleased that everyone has partnered together to come up with better and safer devices and techniques. To introduce new technologies to the experienced users, however, emphasis should be put on educational events.

It is often more convenient when these educational events are tied into meetings that we're already attending. Partnering with national or regional societies is an appropriate way to present new technology and education given the current climate of conflict of interest for many academic faculty. Many device companies have supported the Society for Clinical Vascular Surgery and the Society for Vascular Surgery meetings, as well as the regional societies to inform physicians of new products, have tabletop demos, and introduce simulation.

I also think that by industry partnering and supporting a meeting, it often improves the attendance and viability of the smaller societies. It is clear in 2012 that there are a lot of meetings for vascular specialists to attend, and time spent away often means revenue loss from a clinical standpoint. The more we're able to augment meetings with alternate forms of education, the better. I know that industry partners have been very thoughtful, proactive, and supportive of those types of venues.

These educational activities are also good for the fellows and residents. With the introduction of vascular residencies now (the 5-year programs in addition to the 2-year fellowships), we will see a doubling or tripling of the number of vascular trainees that are attending meetings in the next several years. A great way for industry to interact is to help introduce some of the new technology and utilize simulation to help teach the more novice users rather than just the seasoned clinicians.

**Dr. Dubenec:** The value of industry-supported activities is important. In the right setting, they can provide physicians with an opportunity to update their knowledge to improve their skills and to discuss ideas in an open forum. Without

the help of industry-supported education, we may miss an enormous tool that helps to facilitate communication among physicians all over the world.

What we need to consider is that the physician's relationship with industry remains professional and ethical. Open disclosure is important to identify our relationships with industry to our colleagues so as to minimize bias and maintain our clinical independence.

Industry-sponsored education should be used as a tool to provide education updates and opportunity for discussion to further advance our clinical practice that, in the end, will benefit our patients.

### **What types of industry-supported educational events have the most impact on advancing endovascular medicine? Why?**

**Dr. Dubenec:** There are different kinds of educational events, and they are all important in their own ways. There are the local forums where surgeons meet to discuss a certain topic, such as journal clubs, site visits to other centers of excellence where you see how different groups are employing new techniques and tools, and major scientific meetings. Each type of event can have something special to offer. What is important is that when we attend, we learn something new.

**Dr. Lee:** Sessions with thought leaders discussing the pros and cons of different approaches are very educational. I think attendees, particularly trainees and community physicians, need to hear different opinions and approaches. When a company brings out lecturers who debate the utility of a device or technique in an honest and open way, it highlights the merits of a particular technology. Although many are focused on endovascular procedures, and patients are clamoring for them, I think that we cannot forget or ignore the fact that we must set up the appropriate clinical studies to prove that the endovascular approaches can be and are as safe as the traditional approaches.

**Dr. Verhoeven:** Well, we cooperate with companies that give or sell us stent grafts, and sometimes they come here to do demos. This is clearly a very appreciated educational event for the younger doctors. I think the same goes for support to go to conferences, but they must be appropriate. The support must be to go to a conference and to learn something. For example, in Bavaria, Germany, every 3 months we have a Gore evening where there is one speaker on a legitimate educational topic and then a dinner where the clinical discussion is continued. I think that is fairly acceptable. We all like to be in a nice room, we all like to have a good dinner, but it should be balanced with educational value.



**Dr. Benenati:** It's important to remember that support for specialty society meetings is necessary for them to exist. These meetings have strong scientific content and are the primary way that many physicians receive their CME.

**In what ways can industry support fellows' education that differ from how it supports other physicians' ongoing education?**

**Dr. Lee:** Having been involved in a lot of educational sessions and meetings over the years as a participant and faculty member, I believe it is good to spark some sort of competitiveness among the trainees. Surgeons by their nature are competitive, and so trainees may respond favorably in an educational forum if you make the experience some sort of a competition, perhaps prizes for the best research project, the best anastomosis, the best deployment of a device. I think those are all ways to get young people excited about education. In the most idealistic world, we would all want to learn because it's important for our patients, but sometimes, adding a little bit of fun to education can make for a more enjoyable experience for the trainee.

**Dr. Verhoeven:** To me, the more an event is about supporting younger people, fellows, and new physicians, and the less it is about helping the big guys to go somewhere, the better it is. I think bringing young physicians to congresses is even more important compared to opportunities for the experienced physicians. With Gore or with Cook, we had a fellows' meeting every year where it was really an invitation for fellows only to spend a day or two with a few experienced leaders in the field.

As another example, in Canada, I attended a fellows' dinner during an official board meeting. I had a very interesting two hours there with six fellows who were able to ask questions, and a company supported that event. I think that went very well, and the fellows were happy to have a more private opportunity to talk.

**Dr. Benenati:** Fellows and trainees also seem to value the ability to have hands-on opportunities. Many times, when a new technology is introduced into a program or laboratory, the attending physicians need to gain experience, and so the fellows are not able to work with the devices. It may be intimidating sometimes for fellows to ask questions with attending physicians and more experienced staff present. Focused time for fellows allows them to learn about new devices and get their hands on the devices, and it gives them the opportunity to ask questions that they may not have been comfortable asking in a larger setting.

**Dr. Dubenec:** The support that industry provides to fellows can be very beneficial. Fellows really need as much

exposure to as many surgical techniques during their training as possible. Industry can support younger fellows with first-hand exposure to products. It's only when you understand the product and its areas of application that you can use and hopefully gain some mastery with it. Workshops, overseas fellowships, and local meetings are all important educational tools that provide in-depth knowledge in a short period of time. I remember gaining experience and confidence through such workshops and know it only improved my endovascular skills.

**Are there any specific educational tools that industry can help to provide that bring value to clinicians?**

**Dr. Dubenec:** I really enjoy those area-wide forums for the more advanced clinicians where there is a lot of open discussion. They're the ones that I like the most because you can hear about interesting cases that are difficult and may be pushing technological boundaries and challenging the skill level and skill sets of a lot of people. Once you get a different perspective on those sorts of cases and you see a whole variety of them, you take back a huge amount of knowledge that you might not see, even over a 12-month period.

**Dr. Benenati:** To me, small-group training sessions on specific topics are extremely valuable. The use of models as tools is helpful. I agree with Dr. Dubenec that using previously performed cases is an outstanding way to demonstrate points relating to technique.

**Dr. Lee:** I think tabletop demos are very good for fellows, residents, and even junior attendings. These days, as the trainees are learning, we don't often have an opportunity for them to deploy and practice with devices. At a meeting, a demo is a nice way to break the ice with the trainees. Industry has the resources to be able to provide basic education and introduction to the different devices.

I would caution against the typical didactic lectures that simply describe how great a certain device is. Rather than a commercial of the wonderful devices coming down the pipeline, I think lectures should be more about the disease process and how the technology may potentially be applied to help your patients with those diseases.

**What has been your most enjoyable/rewarding experience as an instructor for an industry-sponsored educational event? Why?**

**Dr. Dubenec:** The most rewarding experience for me has been to act as a guide for some of the fellows coming through. It is sometimes difficult to discuss questions in certain settings, even if it is with a mentor. These forums are very different from learning at work. They allow you to have an opportunity to sit down with trainees in a comfortable

environment away from other commitments and support them. It's nice knowing that when they leave, they have a better understanding of the topic and that they have had a chance to ask other questions that may have interested them.

**Dr. Lee:** I enjoy meeting the trainees coming up through the ranks. I believe educational events at meetings can be an opportunity for faculty and trainees to have one-on-one time with mentors who aren't their immediate attendings. It definitely makes a difference in the future when looking for a job, getting a recommendation, or trying to sit on a committee for a society.

I've personally become pretty well acquainted with many trainees across the country through such educational events. The vascular community, as we all know, is a very small group of physicians, so networking and making those connections with people not only at my own institution has been professionally and socially satisfying for me.

**Dr. Benenati:** I personally learn each time I teach, so the most rewarding experiences for me are getting to know attendees at courses and sharing experiences. A wealth of information and insight can be gained from listening to the experience of others. Trying to help solve problems or learning creative ways to solve problems is a common occurrence during these kinds of discussions. Making friends and developing relationships is also a very rewarding consequence of participating in these events.

### As a clinician and an educator, how would you describe Gore and its Medical Mastery Series of programs?

**Dr. Lee:** In the 15 years that I've been both a surgical trainee and a faculty member and have been interested in surgical education, Gore has gone above and beyond their desire to partner with educators to provide training. I think education is one of the company's core missions, and I respect them for that.

Over the past 5 years, having been involved with educational events at many meetings, I think one can get a pretty well-rounded technical introduction/education in vascular prostheses, suturing, endografts, imaging, and clinical trials. These programs often provide education without making it seem like a marketing ploy. The Medical Mastery Series highlights talks that are more about diseases and better ways to treat them, rather than actually selling the device.

**Dr. Benenati:** The Gore Medical Mastery Series is actually a fantastic opportunity to learn about more advanced techniques for treating AAAs. The small size of the course allows for discussion and interaction that cannot occur in larger

meetings. The ability for registrants to bring their own cases ensures that specific issues and concerns that endovascular physicians have can be fully addressed. The multispecialty makeup of the courses allows for cross-pollination of ideas and techniques. Having the programs in different cities around the United States makes it easy for physicians to attend, and the compact program maximizes the efficiency of the meeting so that time away is kept to a minimum.

**Dr. Dubenec:** Gore's focus on ongoing education and clinical support is, in my mind, one of their best qualities. To provide support and education to clinicians helps one to get the most out of that product and learn how it can be used to its maximal benefit. The Medical Mastery Series is an excellent tool that allows this. These forums are extremely open in terms of Gore not only discussing their own products, but they also discuss other products and how they may be used in different situations. Gore is focused on clinical outcomes, which should be our first priority.

**Dr. Verhoeven:** This is interesting because I've talked to a few people about this only 2 days ago. I think Gore is a special company because they have a very positive attitude. They are not afraid of being supportive, and they are playing by the rules, which is very important. It's very balanced, it's very open, and it's a very good group. ■

## GORE® EXCLUDER® AAA Endoprosthesis

**INDICATIONS FOR USE:** Trunk-Ipsilateral Leg Endoprosthesis and Contralateral Leg Endoprosthesis Components. The GORE® EXCLUDER® AAA Endoprosthesis is intended to exclude the aneurysm from the blood circulation in patients diagnosed with infrarenal abdominal aortic aneurysm (AAA) disease and who have appropriate anatomy as described below: Adequate iliac / femoral access; Infrarenal aortic neck treatment diameter range of 19–29 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation  $\leq 60^\circ$ ; Iliac artery treatment diameter range of 8–25 mm and iliac distal vessel seal zone length of at least 10 mm. **Aortic Extender Endoprosthesis and Iliac Extender Endoprosthesis Components.** The Aortic and Iliac Extender Endoprostheses are intended to be used after deployment of the GORE® EXCLUDER® AAA Endoprosthesis. These extensions are intended to be used when additional length and / or sealing for aneurysmal exclusion is desired. **CONTRAINDICATIONS:** The GORE® EXCLUDER® AAA Endoprosthesis is contraindicated in patients with known sensitivities or allergies to the device materials and patients with a systemic infection who may be at increased risk of endovascular graft infection. 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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# Great Legs

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## PERFORMANCE through data

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A PubMed® search of all EVAR literature from 2001 through 2010 generated 12 peer-reviewed publications<sup>1</sup> that report on limb patency and / or limb kinking for EVAR devices and met basic criteria for inclusion in this literature review. The inclusion criteria for these publications was a minimum of 40 patients and follow-up of greater than one year.

GORE® EXCLUDER® AAA Endoprosthesis legs provide the flexibility and long-term conformability that have been shown to maintain patency in more challenging patient anatomies. A unique combination of advanced sinusoidal stent design, ultra smooth ePTFE graft material, and sutureless attachment between the two enables these legs to flex in challenging / tortuous vessels.

Legs crossed or uncrossed — with GORE® EXCLUDER® AAA Endoprosthesis you choose the best option for your procedure and your patient.

<sup>1</sup> For the complete list of references, please visit [www.goremedical.com/AAAgreatlegs](http://www.goremedical.com/AAAgreatlegs)



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