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15 YEARS OF EXPERIENCE AND EVOLUTION

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Contents

The GREAT Registry

Lessons learned from real-world experience with the GORE® C3® Delivery System.

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All commercially available stent grafts perform generally well in a great variety of anatomies.[1] Nevertheless, there are still important differences in delivery systems and device designs, which call for tailor-made graft selection according to patients' specific anatomy and physicians' personal experiences.[2,3]

The GORE® EXCLUDER® Device (Gore & Associates, Flagstaff, AZ) is a third-generation device that has now been used for 15 years in more than 159,000 patients with proven safety, efficacy, and long-term durability.[4-8] Beneficial characteristics of the device include a low profile delivery catheter that is advantageous in narrow and tortuous iliac anatomies and a simple and rapid deployment mechanism.[6] A number of design improvements have been made over the years, with the most notable involving the addition of an expanded polytetrafluoroethylene layer to reduce porosity and serous fluid transmigration.[9,10]

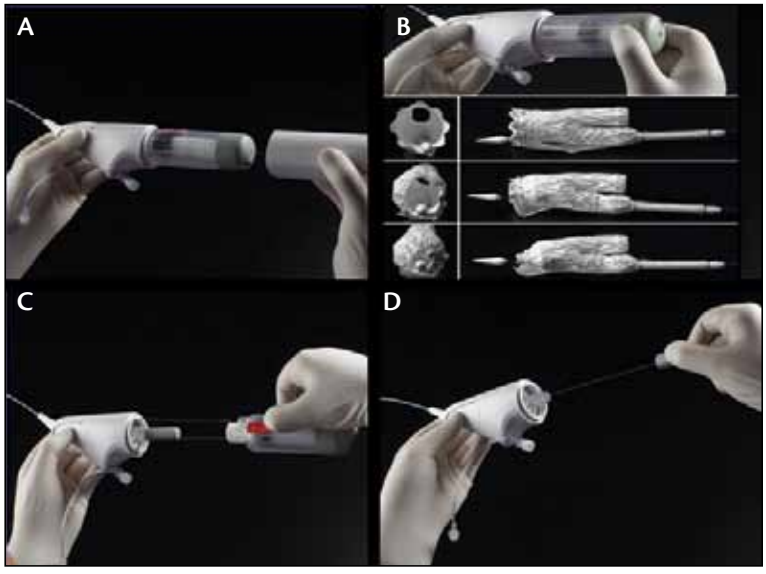

Figure 1. Deployment of the proximal trunk by pulling of the outer white deployment knob (A). Clockwise and counterclockwise rotation of the gray constraining dial enables proximal trunk reconstraining and reopening, respectively (B). The red safety lock is disengaged, and the transparent knob is pulled to remove the constraining loop (C). Full deployment with separate ipsilateral leg opening by pulling the gray deployment knob (D).

In 2010, Gore revised the GORE® EXCLUDER® Device delivery system to enable the user to achieve a more precise and controlled deployment. The GORE® C3® Delivery System allows the device to be repositioned twice before final deployment. The performance of the GORE® C3® Delivery System is currently being investigated in the Global Registry for Endovascular Aortic Treatment (GREAT). This article presents the options offered with the GORE® C3® Delivery System deployment mechanism and discusses the lessons learned from real-world experience as reflected in the preliminary outcomes of the GREAT registry.

GORE® C3® DELIVERY SYSTEM DEPLOYMENT MECHANISM

The deployment mechanism has been modified into a three-step sequence, which enables repositioning of the device up to two times prior to final release from the delivery catheter.[11] In the first step, the trunk and contralateral leg are opened (Figure 1A). A constraining loop around the proximal trunk of the graft enables recapturing and repositioning of the stent graft for both level and orientation (Figure 1B). The second step involves the removal of the reconstraining system after confirmation of correct positioning (Figure 1C). The third step involves the deployment of the ipsilateral leg (Figure 1D).

DEPLOYMENT OPTIONS

The concept of the GORE® C3® Delivery System enables readjustments of the GORE® EXCLUDER® Device for proximal level, orientation, and distal level of the ipsilateral leg. The main feature is the ability

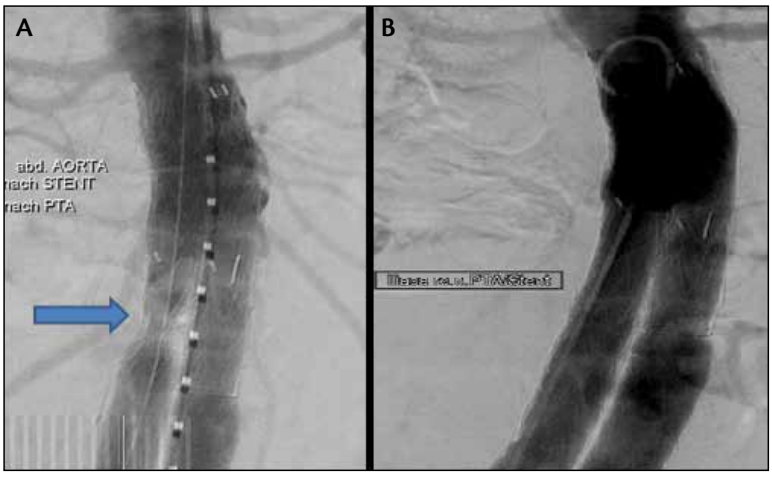

Figure 2. Twisting causing stenosis of the ipsilateral leg (arrow) after repeated aggressive reorientation maneuvers to facilitate contralateral gate cannulation (A). Successful treatment with a bare stent (B).

to reposition the device for the proximal level, enabling precise deployment with regard to the renal arteries. This can be advantageous both for inexperienced users (second and third chance for deployment at the correct level), but also for experienced users in more difficult proximal anatomies.

The deployment mechanism also offers the option for rotational readjustment. In cases of challenging contralateral gate cannulation, the proximal trunk can be reconstrained and the gate reoriented to a more convenient location for catheterization. The separate deployment of the ipsilateral leg allows for adaptation of the leg length. All this resulted in a deployment sequence in which all of the options can be used (without saying that one has to use all the options) (see Deployment Sequence sidebar).

THE GREAT REGISTRY

The GREAT registry was initiated in an attempt to identify global trends in device usage and to actively track long-term device performance and patient outcomes. GREAT aims to collect patient and device performance outcomes during treatment and throughout all posttreatment visits, including follow-up extending up to 10 years for patients treated with GORE® endovascular aortic products.

Commercial aortic endovascular products used in global markets (e.g., US, EU, Australia, Brazil, and China) are being evaluated with 10 years of follow-up in 5,000 patients from up to 300 sites worldwide. Data originating from both on-label and off-label use of the devices are collected through an internet-based system. Evaluated data consist of patient demographics and medical history, treatment indication, case planning and device used, operative details, and posttreatment follow-up to 10 years, including documentation of any serious adverse event. Additional data are also collected in case of modified device usage.

One of the modules of the GREAT registry collects and analyzes data regarding use of the GORE® C3® Delivery System in Europe. By the end of December 2012, 400 patients (86.8% men; mean age, 73.9 ± 7.8 years) from 13 European sites were enrolled in the registry by meeting the enrollment goal. Elective abdominal aortic aneurysm was the most common indication for treatment (94.5%) followed by common iliac artery aneurysm (3%), ruptured abdominal aortic aneurysm (1.5%), and other indications (1.1%). In 98.2% of the cases, device implantation was performed as a primary procedure, while the remaining cases concerned reinterventions after prior open- or endovascular aortic procedures. Challenging anatomy including short proximal neck (< 1.5 cm) and/or neck angulation > 60°, was present in 16.5% of the patients.

Operative mortality was 0%. Two patients (0.5%) required open conversion—one due to arterial rupture and the other due to stent graft deployment at the wrong position. Proximal trunk repositioning was performed in 47.6% of the cases, most frequently for level readjustment with regard to the renal arteries (79.5%) and less commonly (19.5%) for contralateral gate reorientation. Other less frequently reported reasons for repositioning included uncovering the renal arteries, intentional deployment above the renal arteries, intentionally twisting limbs for better position, and repositioning to facilitate renal chimney stent placement. The mean number of repositionings performed per case was 1.4 ± 0.7. One repositioning was required in 64.7%, two in 27.4%, three in 6.3%, and four in 1.6% of cases.* Exact positioning was achieved in 96.2% of patients, with 97.7% within 5 mm of the intended location. Unintentional use of proximal extender cuffs occurred in 4.5% of the patients.

Survival at 30 days was 99.5%. Two patients died—one of respiratory failure and the other due to cardiac failure. Type I endoleak within 30 days after the procedure was detected in one patient (0.25%). Device migration was not seen in any of the patients. A more extensive report and analysis of the GREAT registry outcomes with regard to the GORE® C3® Delivery System is beyond the scope of the present article.

*Per the Instructions for Use, do not constrain / reopen the trunk device more than two times during a procedure. Device and / or catheter damage may occur.

DEPLOYMENT SEQUENCE

1. Deployment of the proximal trunk after initial angiography
2. Cannulation of the contralateral leg with the option to reorient the device if needed
3. Angiographic control of the proximal position and the level and rotational repositioning, if required or desired (i.e., if catheterizing the contralateral leg in a ballerina position, it is possible to reorient the graft again in a more standard position)
4. Advance introducer sheath through contralateral leg hole
5. Removal of the proximal constraining loop
6. Deployment of the ipsilateral leg

LESSONS LEARNED FROM REAL-WORLD EXPERIENCE

The main reason for redesigning the GORE® EXCLUDER® Device deployment mechanism was to enable more accurate proximal deployment. This goal has been achieved with the GORE® C3® Delivery System. Current real-world outcomes suggest that repositioning for optimizing proximal landing is safe and feasible, with a more accurate deployment to start with. Occasionally, problems can arise, for example, in the case of low initial deployment in narrow or angulated neck anatomy with cumbersome upward repositioning of the device. This is partially due to the fact that there is only one proximal constraining loop, which reduces the proximal diameter of the device, but the rest of the distal stent graft remains unconstrained. In such cases, first deployment of the device as close as possible to the renals and then meticulous lower repositioning, as needed, should be considered.

Similarly, extensive or abusive rotational reorientation may cause a twist in the ipsilateral leg, requiring additional stenting for correction (Figure 2). Such a limb twist can easily be recognized during slow deployment under fluoroscopy and then corrected. Caution should also be observed not to lose proximal position during rotational repositioning, especially in narrow or angulated neck anatomy, as previously mentioned.

CONCLUSION

Early real-world experience shows that the GORE® C3® Delivery System offers important advantages in terms of device repositioning. Level and orientation repositioning can be useful. Additionally, the deployment system enables new alternative deployment sequences that should be considered in cases of difficult contralateral gate cannulation (reorientation) or relining after previous endovascular aortic repair. Not all of these options will be used in each and every patient, but physicians should be aware of these selections. The GORE® C3® Delivery System is safe, but abuse of the features may carry new risks in some situations. ■

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15-Year EVAR Update

Reflecting on the development of endovascular aneurysm repair and a look toward what's yet to come.

The first open surgical repair of an abdominal aortic aneurysm (AAA), which involved resection and replacement with a cadaver homograft, was performed by French physician Charles Dubost in Paris in March 1951. Surgery remained the only treatment technique for AAAs for nearly 40 years. The first clinical case of minimally invasive endovascular aneurysm repair (EVAR) was performed on September 7, 1990, by groundbreaking vascular surgeon Juan Parodi in Buenos Aires, Argentina.[1]

The story of EVAR since that time has been one of continuous development. The initial devices that Parodi developed and utilized consisted of a tube-shaped aorto-aortic graft sutured at each end to a balloon-expandable stent based on the design of radiologist Julio Palmaz. In 1994, this basic approach evolved into bifurcated devices resembling a pair of pants, which quickly became popular. From there, single-piece systems evolved into multicomponent devices of two, three, or even more segments. Today, there is a wide range of modular stent grafts available that includes multiple configurations and sizes of components to better suit various challenging anatomies.

Delivery systems have also progressed. Catheters that were initially rigid and bulky became narrower and much more flexible, allowing improved access in tortuous vessels. In addition, stent graft material and design have changed in various ways to improve conformability, reduce fracture, and minimize rates of device migration.

EVAR is now a commonly available option for a growing population of patients requiring treatment for AAAs. Some advantages of EVAR over traditional open surgery include shorter hospital stays, fewer postoperative complications, and greatly reduced recovery time; the treatment technique may also result in less operative blood loss. New devices with fenestrations and branches have increased the number of patients who are good candidates for EVAR, reducing the population of individuals who would otherwise be resigned to "watchful waiting" for their aneurysms. Recent research now demonstrates that EVAR offers reduced mortality rates compared with open repair.[2]

Endovascular Today spoke with three specialists who were instrumental in the birth and development of this life-saving treatment technique. Leaders in their field, Drs. Juan Parodi, Claudio Schönholz, and Michael Marin, took some time to recall and reflect on the early days of EVAR and commented on the present and future of this important procedure.

INSPIRATION

The development of EVAR was inspired by the needs of patients, specifically those with AAAs who were too high-risk to undergo traditional open surgical repair. "In 1976, I was a resident at the Cleveland Clinic, and we had two consecutive patients who had bad outcomes after AAA repair," said Parodi, who later worked at the University of Illinois before returning to the Instituto Cardiovascular de Buenos Aires in Argentina. "I thought to myself, 'If, in this high-quality hospital and with superb surgeons, the results of this operation are not always good, the cause should be inherent to the procedure, which is too traumatic for these old and debilitated patients."

Patients with AAAs are usually older, have coronary issues, renal insufficiency, lung issues, and perhaps even previous abdominal surgeries, which can lead to the condi-

> "The interest and drive were uniform across the world—we were all on the search for a less-invasive way to treat a complex disease in often very sick patients."
>
> *- Dr. Marin*

tion known as "hostile abdomen." All of these comorbidities make open surgery even more difficult and risky, if it remains an option at all for such patients.

Dr. Marin, a vascular surgeon based in the United States, echoed Parodi's sentiment. "The interest and drive were uniform across the world—we were all on the search for a less-invasive way to treat a complex disease in often very sick patients. Ultimately, we offered the new procedure first only to patients who had large aneurysms but who would not survive surgery."

Parodi had been learning the Seldinger technique from a radiology colleague, and he had become aware that most patients with aneurysms had large femoral arteries. "My initial idea was to use a big catheter guided by a guidewire," said Parodi. His vision was specific. "The catheter would contain a thin graft attached to a 'cage' of metal (with the graft sutured outside the cage). A stainless steel elastic wire forming a ring with a zigzag configuration would be compressed and then released (in a spring-loaded fashion) from the large catheter. Using fluoroscopy, the device could be deployed to cover the aneurysm." At this time, there were no such grafts available, meaning Parodi would have to design and construct the device himself. In time, he utilized this approach in numerous in vitro and canine trials, but not without difficulties.

EARLY CHALLENGES

Initially, the main goal of EVAR was to reinforce the aorta via an endoluminal approach. It was clear that a graft was needed, but as Schönholz noted, "the question was how to fix the graft to the inner lumen." Parodi had performed extensive animal research utilizing his homemade device, but migration was a true challenge, and the ability to keep the device fixed to the aortic neck remained elusive.

Parodi initially had to use nylon fabric instead of DACRON Material for the graft and a plastic tube as a sheath; this wireless solution proved to be less than ideal. "It was hard to advance the sheath into the aorta," he said, "because of the sharp edge on the plastic tube." Yet, another obstacle was the need to develop a device that was not too bulky but could still completely exclude the aneurysm upon deployment.

"It seems obvious now, 20 years later," said Schönholz, "but he needed something that could be small enough when introduced to navigate from the femoral to the iliac to the aorta and then be able to grow to a size to cover an aortic neck that is potentially 24 mm or larger in diameter."

ADVANCEMENTS AND ADAPTATIONS

In 1988, Parodi met Dr. Julio Palmaz at Georgetown University, where he was presenting animal research using the novel balloon-expandable stent that he had designed. The PALMAZ Stent for aortic valvuloplasty had a maximum diameter of 10 mm, which was not large enough to anchor a device within the abdominal aorta. However, the balloon-expandable stent held the potential for inspiration and experimentation. "I told him about my project," said Parodi. "Initially, he was not very excited, but he agreed to collaborate with me."

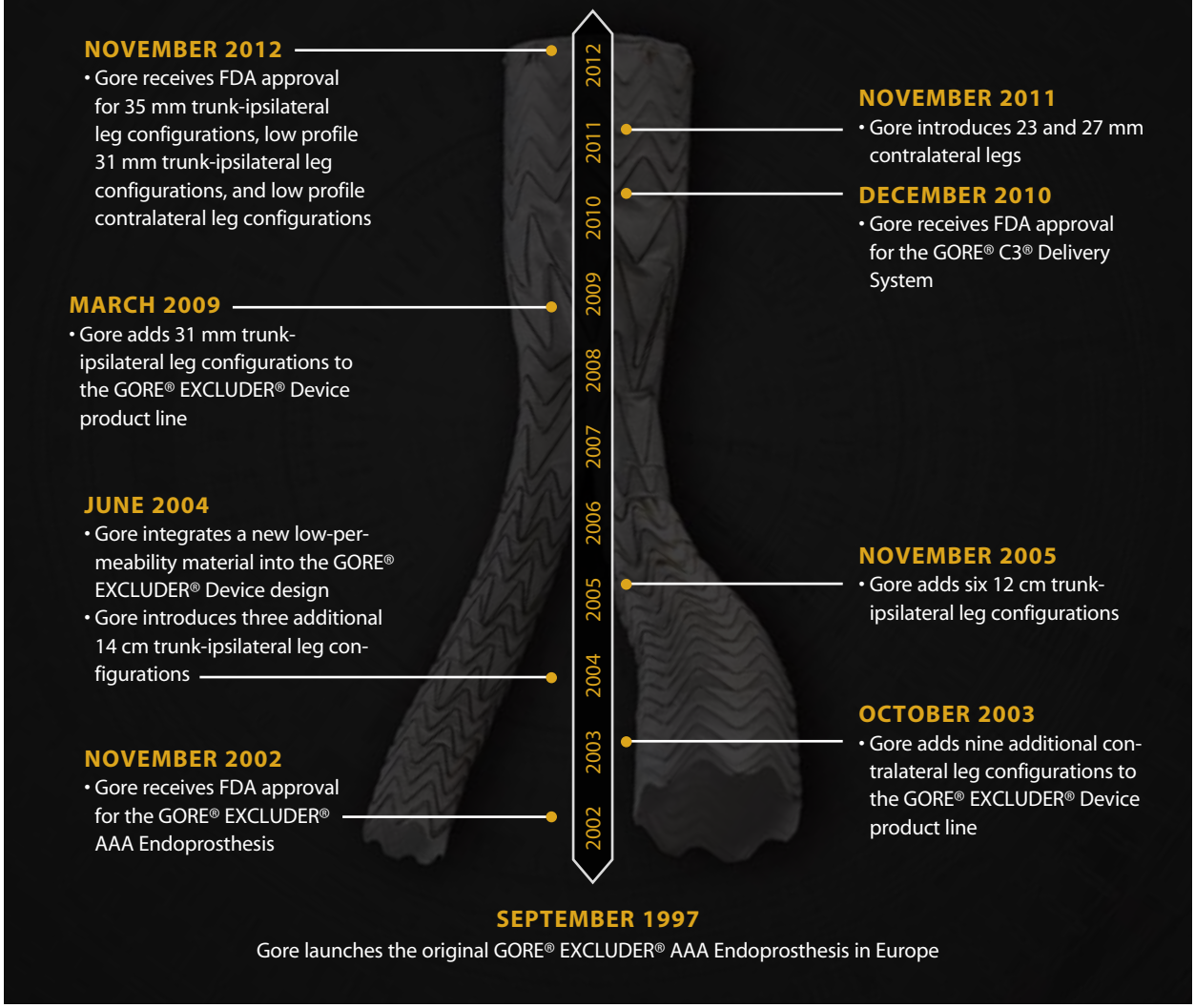
Back in Buenos Aires, Parodi took a sample of the PALMAZ Stent to bioengineer Hector D. Barone, who was able to reproduce a scaled-up version using electroerosion and electropolishing. "I then decided to replace the spring-loaded system with the balloon-expandable one," said Parodi. The new device incorporated a thin-walled DACRON Graft attached to the custom-made, upsized balloon-expandable stents. "The idea was to replace the vascular suture with the stent in both ends, and eventually in three ends, using an aortobi-iliac device (not yet developed at that time)," said Parodi.

It was time for EVAR to be put to the test. "After doing extensive in vitro and animal studies, we designed a device for patients," said Parodi. This set included a stiff guidewire, a TEFLON Sheath with a valve at the end, a valvuloplasty balloon, and an extra-large PALMAZ Stent that could be expanded up to 28 mm in diameter. "A nose cone was formed at the end of the sheath by inflating the protruding end of the balloon with a small amount of saline solution," Parodi explained. "The stent attached to the graft was compressed and applied over the balloon. Gold markers were sutured at the end of the graft." The sheath used in 1990 to perform that first-ever EVAR procedure in a patient measured a bulky 27 F, Schönholz recalled. "It was also very rigid and primitive," he said. But, most importantly, it worked.

On that day, Parodi and his colleagues performed two AAA procedures—the endovascular one as well as an open surgical repair in another patient. After the procedures were completed, Parodi invited Palmaz to have dinner with him at a nearby restaurant. When they returned to the hospital to check on their patients, the individual who had undergone EVAR was sitting up, enjoying his own dinner, and the surgical patient was still intubated.

15 YEARS OF EVOLUTION: THE *GORE® EXCLUDER®* DEVICE

The GORE® EXCLUDER® Device has been available in the US for more than a decade. Extensive clinical research and 15 years of commercial use since market release in Europe have proven its continuing success.



EVAR IN AMERICA

In 1992, Parodi, Schönholz, and Barone traveled to New York to meet with Marin and Dr. Frank Veith. They were coming together to perform the first EVAR in America, utilizing a handmade device that Parodi had brought from Argentina and carried with him in the airplane cabin.

"I want to make it very clear that Parodi was the one testing and proving the EVAR concept," Marin said. "He was able to visualize and come up with solutions to complex problems, and he was very generous with his knowledge. We had previously met in Milwaukee to discuss treatment possibilities for a patient of mine. When Parodi brought the device and performed the procedure in New York, that step initiated the whole process here. It became important to figure out how to continue to do these procedures."

From that point, Marin began to build his own devices, with modifications to make them easier to use. "I learned the techniques from Barone," he said. "Then I approached the US Food and Drug Administration (FDA) for an investigator-sponsored investigational device exemption study." His institution provided support, as well as room. "I set up a clean workspace environment in the hospital and sent the finished devices out to be gas sterilized. I built more than 200 devices," Marin said. "For each case, I would build two in order to have a backup."

"I had the honor of using the first GORE® EXCLUDER® Device in South America," Parodi said, "and it was very good from the beginning."

- Dr. Parodi

"The company does close follow-up of patients who receive the devices, and they are always looking for ways to improve their technology."

- Dr. Schönholz

A SOLID SOLUTION

In order for EVAR to become an accepted first-line therapy for even a select population of patients, certain technological milestones had to be met. "We needed the development of durable grafts that would not break down after implantation through wear and tear," said Marin. "It took an understanding of the bioengineering of the prostheses and knowledge of where forces were being applied." As clinicians began performing an increasing number of EVAR procedures, limitations became more apparent, and device manufacturers stepped up to create solutions.

The first-generation GORE® EXCLUDER® AAA Endoprosthesis (Gore & Associates, Flagstaff, AZ) received FDA approval in 2002. This device had been previously approved in Argentina. "I had the honor of using the first GORE® EXCLUDER® Device in South America," Parodi said, "and it was very good from the beginning."

In keeping with the company's reputation for responsiveness, Gore moved quickly when it was discovered that the original device could be improved. In Argentina, Schönholz was acting as a proctor for Gore at the time. "The company does close follow-up of patients who receive the devices, and they are always looking for ways to improve their technology. By 2004, clinicians had discovered that some patients treated with the device had aneurysms that were not shrinking; in fact, some were growing. These were not leaks—the substance in the sac was not blood, it was serous fluid. It was the result of selective permeation across the graft material."

This situation became referred to as "endotension," and Gore responded by adding a layer of low-permeability material to the graft. The second-generation GORE® EXCLUDER® Device effectively addressed the endotension problem. "The technology is now durable," said Schönholz. "We still see some patients with the first GORE® EXCLUDER® Device, and for those few that have a growing sac due to endotension, we reline those stent grafts with the newer-generation device."

Gore has since brought additional components onto the market every few years to expand the indications for their device, including new sizes for the stent graft main body and limbs. In 2010, the company released the GORE® C3® Delivery System. "We can now control how and where we deploy the device to the point that we can do a delivery, and if we don't like where it has landed, we can actually reconstrain and reposition the device," said Schönholz. According to Parodi, the GORE® C3® Delivery System is "magnificent."

THE FUTURE

It seems clear that EVAR procedures will only increase in frequency. With the number of FDA-approved devices and the variety of modular device iterations available, practitioners are less often finding that open surgery is necessarily the better option. "Almost always, the only reason I do open surgery now is if the patient's anatomy is not conducive to EVAR," said Marin, "and those cases are becoming fewer and fewer." The bottom line is that EVAR is less invasive and better tolerated by patients. "Of course, there are still some anatomic limitations," said Schönholz, "but even ruptured AAAs are being treated more and more by the endovascular approach." In Schönholz's group at MUSC, 80% of cases are treated with EVAR, "and this is not unique to just the United States—it is around the world. Many practitioners are using just EVAR whenever they can."

Manufacturers, including Gore, are supporting this global drive for increased access to EVAR. More complicated devices including features such as fenestrations and branches are being developed to address anatomic barriers. The phenomena of physicians using chimney grafts (also referred to as "snorkels") certainly points out yet another likely avenue for device companies to explore.[3] Ultimately, the future of EVAR technology will be decided by the ingenuity and creativity of physicians, biomedical engineers, and others who continue to work together to further refine this life-saving treatment technique. ■

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Feasibility and Utility of an Iliac Branch Endoprosthesis

Michael D. Dake, MD, shares his thoughts on challenging iliac artery anatomy and the potential for an off-the-shelf device that meets the inherent needs of these patients.

What are the current treatment options for patients with large common iliac artery aneurysms and no seal zone above the hypogastric artery?

Current treatment options include covering the origin of the hypogastric artery after preliminary coil embolization or a sandwich technique, which basically puts the branch into the hypogastric artery alongside the common iliac branch that extends down into the external iliac artery. In Europe and other parts of the world, there are integrated iliac branch systems designed for this approach, but in the US, none have been approved yet.

How do the disadvantages of covering the hypogastric artery manifest in patients?

In some patients with abdominal aortic aneurysms, one hypogastric artery may be occluded. In that case, preservation of the contralateral side is paramount. There is the risk of neurologic injury or impotence, as the hypogastric artery supplies the pelvic organs' pericollateral pathways. Oftentimes, when one side is occluded or you have a dominant hypogastric artery that is clearly contributing the bulk of the flow, I think preservation is a smart way to go.

Another possibility is claudication, especially in the gluteal or hip region where collateral flow in certain patients may not be as rich due to profunda disease or other causes. The flow may be adequate in other patients, so claudication would not occur, but there is no way to predict that. So again, I think as a general rule, the more you can preserve the hypogastric arteries, the better.

What are the advantages and disadvantages of the current options for treating these patients while preserving the flow you mentioned?

Option number one of just covering and embolizing the hypogastric artery does not preserve the flow; it treats the aneurysm, but you have to embolize the hypogastric artery so you don't get the transpelvic flow from the other side that would maintain patency and keep the common iliac artery pressurized. A sandwich technique is much more complicated and is clearly something that is not off-the-shelf. You're cobbling together off-the-shelf devices in an unapproved way to do this technique. Rather than having a device system that is designed for your needs, you are forced to cut and paste like an endovascular carpenter to achieve the best possible result.

When you place two devices within another (e.g., the snorkel or chimney technique), there is a possibility of endoleak from the gutters. You're placing the piece that is going down to the external iliac artery to preserve flow to the rest of the limb and the other piece into the hypogastric artery inside a common iliac stent. Those two pieces aren't always going to fit in a perfect geometric fashion.

What percentage of patients might benefit from an off-the-shelf iliac branch endoprosthesis?

Well, I'm not the market maven on this, but clearly I think that this comes up regularly in everyone's practice today. The availability of an off-the-shelf device is very attractive, benefitting around 10% to 20% of patients. ■

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Large Neck Aneurysm Treatability With Low Profile Grafts

Zvonimir Krajcer, MD, discusses the clinical value of low profile devices that do not sacrifice durability and performance.

How would you summarize the current unmet needs in endovascular aneurysm repair (EVAR) for patients with abdominal aortic aneurysms (AAAs)?

There are two areas where there is definitively a need for improvement. One area of importance is challenging infrarenal neck anatomy. This includes short, wide, angulated, tapered, calcified, or thrombus-laden infrarenal necks.

Another area there is a need for improvement is in patients with challenging access anatomy. This is related to narrowed, severely calcified, and tortuous iliac and common femoral arteries.

What would you say are the benefits of low profile delivery? What types of patients can benefit from this approach, and to roughly what percentage of the population does this apply?

Almost all of the companies that are currently involved in producing EVAR devices have a goal to reduce the profile of their delivery systems to accommodate patients with challenging access anatomy. Obviously, the purpose is to offer their products to a larger spectrum of patients and to reduce the incidence of vascular complications. Some of them have already significantly reduced the profile of these devices. For instance, the first-generation EVAR devices were 22 to 24 F in profile, and some even had a 27 F outer diameter profile. Until 2010, a great majority of EVAR devices were > 20 F in profile. Since 2010, some of the manufacturers now offer devices that are 16 F, or even 14 F, in profile. This advancement is particularly important when treating patients with severely diseased iliac arteries and when performing the procedures via percutaneous approach with local anesthesia.

What are some of the possible tradeoffs in making a current stent graft platform into a lower profile device?

Originally, the technology was not there, and compromises were made by some manufacturers to design lower profile devices. They found later that these devices frequently failed, and therefore, they are no longer available. More recently, several companies have made significant technological improvements in their products, and now they are producing third- or fourth-generation devices, which have resolved most of the concerns encountered with the first-generation products. Several issues that have plagued the first-generation devices, such as material fatigue, loss of structural integrity, high permeability, migration, modular component separation, and others, have been resolved.

To what degree can long-term data be applied from one iteration of a device platform to the next?

I think that is a question that should be addressed and seriously looked into by all current manufacturers of EVAR devices. In the United States, the FDA takes this issue very seriously, and based on our experience over the last 2 decades, several strict testing requirements are mandatory before the first-in-man procedure is performed or a clinical trial is initiated. I think that at the present time, due to these changes, there is definitively less risk involved for unexpected complications that might occur with the newer-generation devices than what was encountered with the older-generation endografts.

What would be the value of having the GORE® EXCLUDER® Device delivered via a lower profile without changing the durability of the graft?

We have been waiting very patiently for this improvement to happen. The previous-generation GORE®

EXCLUDER® Device (Gore & Associates, Flagstaff, AZ) required the use of 18 and 20 F sheaths. Iliac arteries are too narrow and too diseased to accommodate the use of 20 F sheaths, and this poses a serious problem. Obviously, if all GORE® EXCLUDER® Devices can be delivered via a smaller 18 F sheath, this would be a significant improvement. This was achieved with the latest-generation GORE® EXCLUDER® Device, without compromising the durability of the endograft. This lower profile device was designed with the intention in mind to lower the risk of vascular complications and to treat patients who have very narrow and diseased femoral and iliac arteries.

What future progress do you anticipate in low profile delivery from Gore in this platform?

I believe that in the near future, there will probably be an even lower profile expanded polytetrafluoroethylene endograft that will be as durable as the already well-tested current-generation GORE® EXCLUDER® Device.

What are the specific challenges that are posed by large neck aneurysms, both in the placement phase and down the road when you're looking at follow-up?

We have been using the GORE® EXCLUDER® Device for a long period of time—over a decade—and have had excellent long-term results, with an extremely low risk of complications, such as migration, type I or type III endoleaks, or thrombosis.

What was missing, until a few years ago, was the ability to make small adjustments during the positioning of the device and before the final deployment in the desired location. Accurate deployment of an endograft is particularly important in patients with challenging infrarenal neck anatomy. This was resolved with the introduction of the GORE® C3® Delivery System. This improvement allows the device to be repositioned if necessary and redeployed more accurately below the renal arteries, which is very important in patients with challenging infrarenal neck anatomy.

How does the availability of a 35 mm trunk graft affect your ability to match device to anatomy?

The latest development, the 35 mm GORE® EXCLUDER® Device trunk (and 36 mm cuff without any scallops on the top), is a great improvement that will expand the opportunities to treat patients with wide infrarenal necks and other challenging infrarenal neck anatomies that were not candidates for EVAR with previous-generation devices. Another significant achievement with this device is that it can be delivered through an 18 F sheath as any other GORE® EXCLUDER® Device. ■

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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 19–32 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation ≤ 60°; 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 for a complete description of all warnings, precautions, and adverse events. $\text{R}_{\text{X Only}}$

2004
June
Gore introduces a low permeability GORE® EXCLUDER® Device design and adds three 14 cm trunk-ipsilateral leg configurations

2005
November
Gore adds six 12 cm trunk-ipsilateral leg configurations

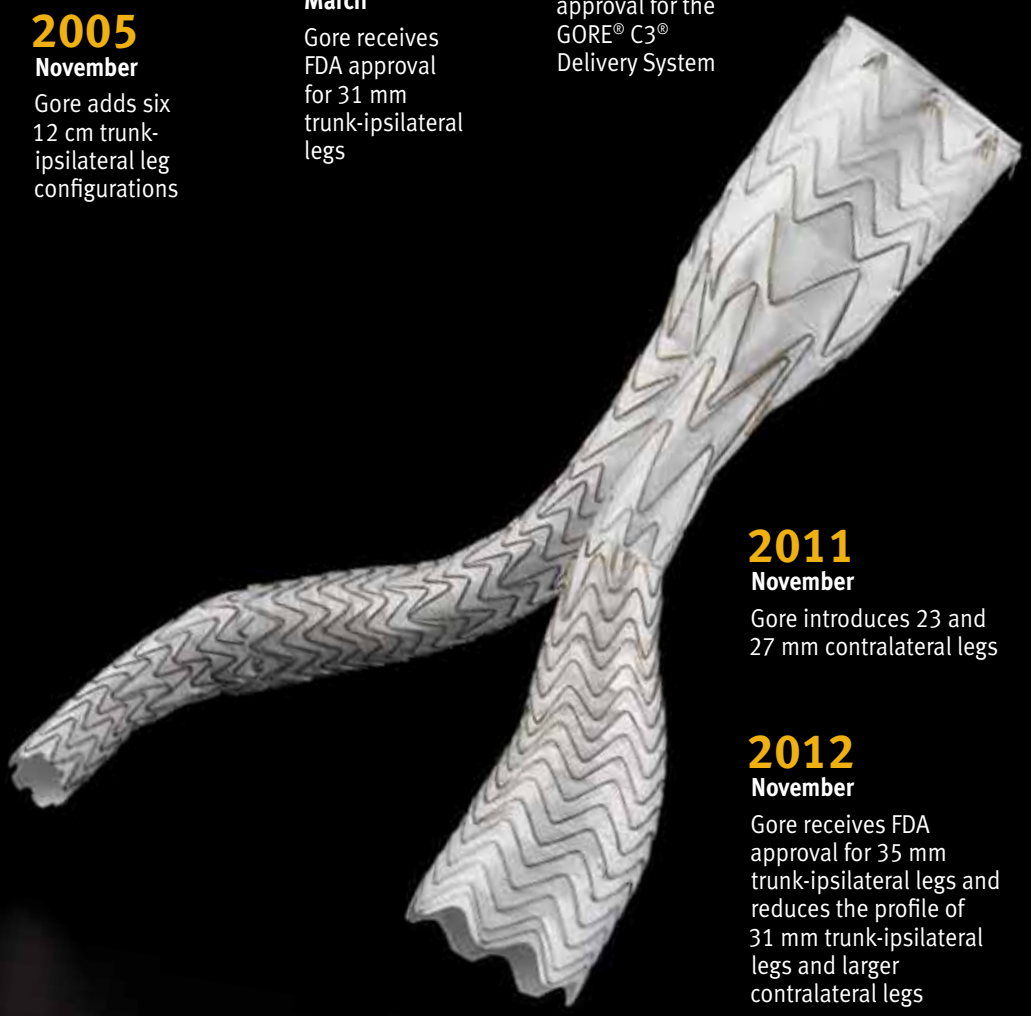
2009
March
Gore receives FDA approval for 31 mm trunk-ipsilateral legs

2010
December
Gore receives FDA approval for the GORE® C3® Delivery System

2003
October
Gore adds nine additional contralateral leg configurations

2002
November
Gore receives FDA approval for the GORE® EXCLUDER® AAA Endoprosthesis

1997
September
Gore launches the original GORE® EXCLUDER® AAA Endoprosthesis in Europe



2011
November
Gore introduces 23 and 27 mm contralateral legs

2012
November
Gore receives FDA approval for 35 mm trunk-ipsilateral legs and reduces the profile of 31 mm trunk-ipsilateral legs and larger contralateral legs

PERFORMANCE through experience

Celebrating 15 Years of Evolution

The GORE® EXCLUDER® Device has demonstrated impressive success in both clinical studies and commercial use.

GORE EXCLUDER®
AAA ENDOPROSTHESIS

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