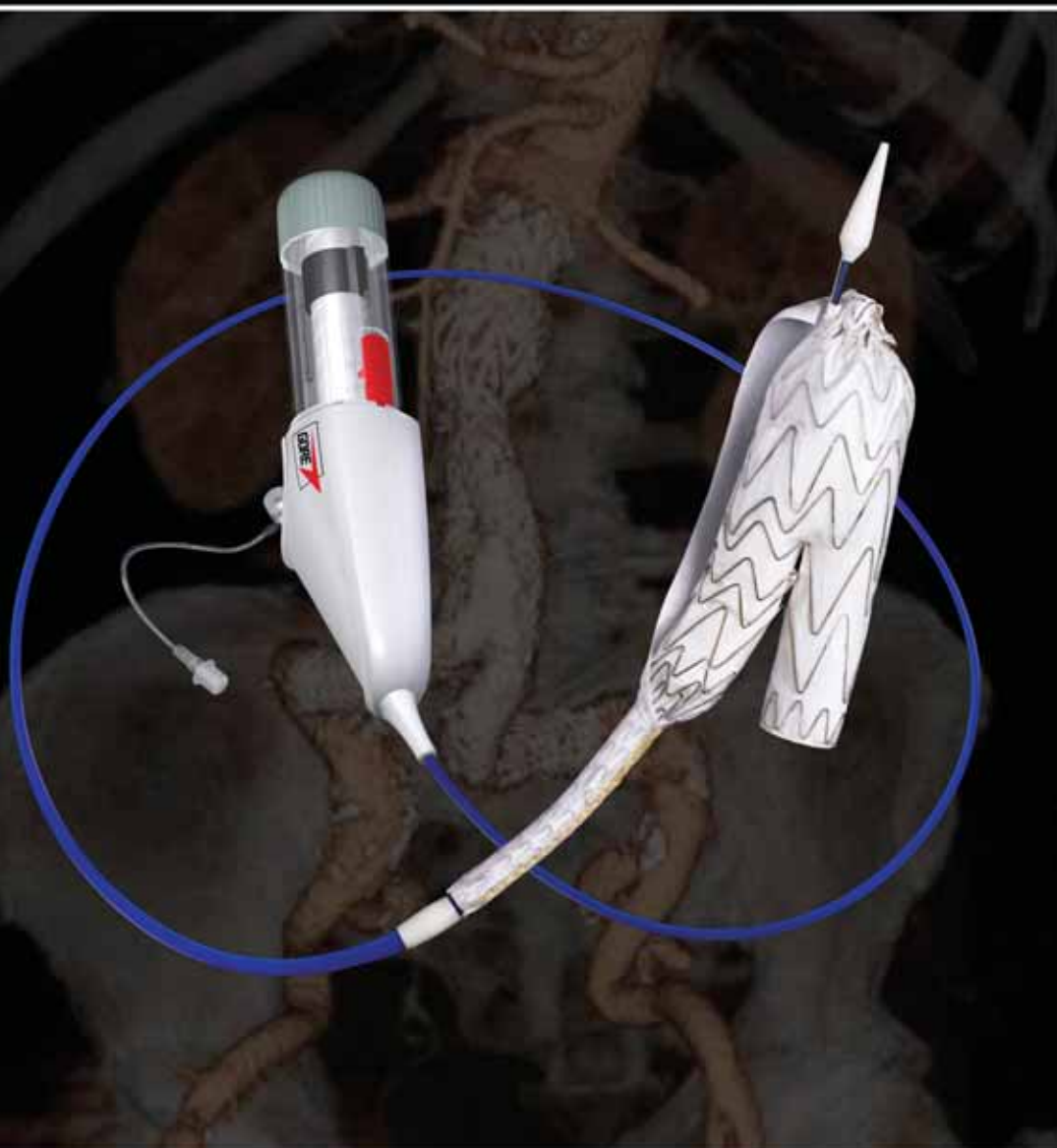


Endovascular

TODAY

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Repositioning Expectations for EVAR



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Repositioning the Future of EVAR

The first experiences with the new repositionable EXCLUDER stent graft.

BY ERIC VERHOEVEN, MD, PhD; ROLAND SIMMLER, MPH; AND MARK F. FILLINGER, MD

According to a report from the EUROSTAR registry collaborators, who studied endovascular repair of abdominal aortic aneurysms in Europe, all modern stent grafts perform reasonably well.¹ In their conclusion, the authors could not clearly identify one superior stent graft on the market. Instead, desirable characteristics and outcomes are dispersed among the varying stent grafts.² A comparison between third-generation devices is difficult because of the obvious clinical selection bias that is applicable to most large centers.³ However, the differences in device design and introduction systems allow for tailor-made graft selection that suit the patient's specific anatomy.⁴

The EXCLUDER Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ) is a third-generation device that has performed well. Numerous studies have demonstrated the efficacy, safety, and durability of this device.^{5,6} Strengths of the device include its original design, with a flexible, catheter-mounted delivery system and active infrarenal fixation. The limbs of the EXCLUDER Device are very flexible, are adaptable to most complex iliac anatomies, and have been implemented with great success for treating iliac aneurysms.⁷ Although there is literature documenting extremely accurate placement based on pre- and postoperative evaluation,⁸ accuracy of proximal deployment has been contested, and competing manufacturers have stressed that their system performs better in this regard. The microstructure of expanded polytetrafluoroethylene in the original device permitted selective permeability of serous fluid in a subset of patients,⁹ but with the addition of a nonpermeable, very thin, highly durable fluoropolymer layer, this endotension has been obsoleted.^{10,11}

DEPLOYMENT

The new C3 Delivery System (W. L. Gore & Associates) was developed by the company in cooperation with experienced users. The EXCLUDER Device itself remains unchanged, but deployment is now a three-step maneu-



Figure 1. The first deployment step opens the body of the graft and the contralateral limb.



Figure 2. A constraining wire allows for recapturing of the graft at the proximal end. The graft can now both be repositioned and reoriented.

ver, including the option of reconstraining and repositioning the device. Adjustments for both the level of the device and orientation of the contralateral limb can be executed. If the position is believed to be too high or too low with regard to the renal arteries, the device can be easily adjusted to reach the ideal final location. Similarly, reorientation of the contralateral gate is possible, which makes cannulation easier and less time consuming.

In the first step, the body and contralateral limb of the device are opened (Figure 1). A constraining loop around the body of the graft allows for recapture and easy repositioning, if desired (Figure 2). After controlled positioning, the graft can then be redeployed, and the position can be controlled with precision. If positioning is satisfactory, the constraining loop is removed, and the ipsilateral limb is opened. Similarly, if the gate orientation is not in the ideal location for catheter access, the proximal trunk can be reconstrained, and the limb can be repositioned to a more convenient location (Figure 3).

FIRST EXPERIENCE

The first five implants of the EXCLUDER Device featuring the new C3 Delivery System in humans occurred in Nürnberg, Germany on August 25, 2010. In subsequent days, other centers began using the graft throughout Europe. This device is also FDA approved.

The first cases using the device were chosen based on challenging patient anatomy that was identified as potentially benefiting from the device features. The first case involved a patient with a short and angulated aortic neck, so the graft had to be repositioned both for level (lower/distally) and orientation (more left anterior, contralateral limb landed right anterior). The final position was excellent and was confirmed on a postoperative computed tomography (CT) scan (Figure 4). In two additional cases, the graft was repositioned for level (higher/proximally). The fourth case involved a long aortic neck within a bulging aneurysm. It was anticipated that repositioning would be necessary for orientation, but cannulation occurred instantly, making repositioning unnecessary. In the fifth case, the proximal position was ideal after the initial deployment, and cannulation was uneventful. Therefore, no repositioning was required, and the graft opened completely.

In all five cases, the graft remained in position (immediately below the renal arteries). There were no proximal type I endoleaks seen on postoperative CT scans, and all renal arteries were fully patent.

DISCUSSION

The EXCLUDER Device has been used very successfully in a wide array of cases, but as with any device, improvements are possible.^{12,13} The current trend in most centers is for a larger percentage of patients to be treated with endovascular repair rather than open repair. As a natural result of this trend, clinicians gain increasing experience with more difficult anatomy and ask for device features that enhance performance in this challenging anatomy. The authors of this article have

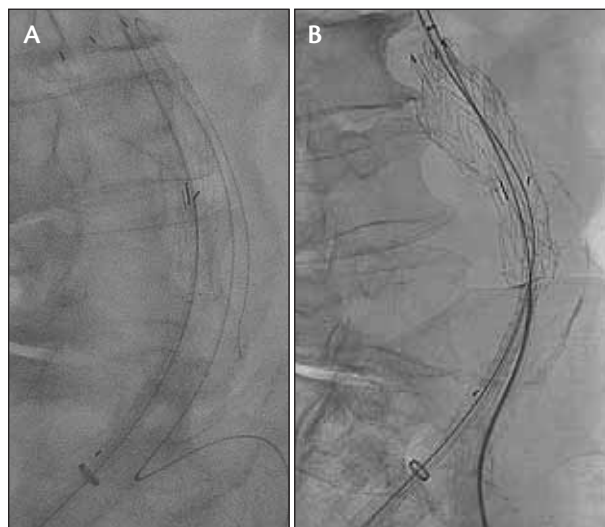


Figure 3. Position after initial deployment (A). Catheterization proved to be difficult due to left iliac artery angulation. Reorientation allowed for easier catheterization (B).



Figure 4. A postoperative CT scan showing the proximal position of the graft just below the renal arteries.

deployed a large number of original EXCLUDER Devices with a high degree of accuracy but certainly welcomed the idea of a repositionable device.^{6,8,14} With any endovascular device, as aortic neck angles become more angulated or the neck length becomes shorter, the allowable margin for error decreases. The ability to reconstrain and reposition the EXCLUDER Device gives clinicians the ability to achieve optimal device positioning in difficult cases without the fear that there is only one chance to get it right.

The ability to reposition the device after initial deployment should also be welcomed by clinicians who are relatively new to EVAR or those with limited experience using the EXCLUDER Device. The ease of repositioning decreases the risk of suboptimal device positioning during the short but finite learning curve of using a new device. Also important to newer users is that the repositioning feature does not add complication to the deployment sequence. Retaining ease of use was a key feature for those accustomed to earlier generations of the EXCLUDER Device.

Although the ability to reposition the device within the aortic neck is the most critical aspect of the new deployment design, the ability to reposition the contralateral limb gate can be quite useful as well. Access to the contralateral gate is rarely an issue in simple anatomy, and the position can be simulated and planned preoperatively.⁸ Nonetheless, any clinician with a large amount of experience has performed cases in which repositioning of the limb would have saved significant procedure time

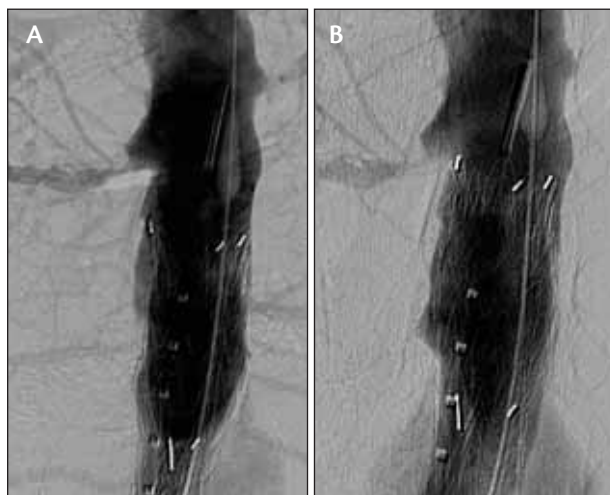


Figure 5. Intraoperative angiogram showing a proximal position that was too low after reorientation for cannulation in a dialysis patient with urine output (A). The graft was repositioned to land below the right renal artery (B).

and radiation dosage. Interestingly, in two cases with very tortuous iliac artery anatomy, we decided to use the EXCLUDER Device to its full extent (ie, to reorient the graft for catheterization before controlling the proximal position level). In both cases, reorientation was very useful in achieving catheterization, but the grafts equally needed proximal (higher) repositioning (Figure 5).

Finally, one further benefit from a repositionable delivery system may be cost savings. Although the percentage of EXCLUDER Device cases requiring aortic cuffs is low in our experience, any reduction in the use of cuffs will save on the cost of the component as well as the cost of the additional procedure time. Better device positioning on the first attempt should also decrease the number of balloon inflations in the neck, angiograms, or other interventions for suboptimal positioning and may decrease the need for subsequent reinterventions or additional imaging during follow-up. As previously mentioned, more rapid gate cannulation will contribute to time savings in a significant portion of cases. None of these aspects are trivial given the high cost of time in the operating room.

CONCLUSION

The new C3 Delivery System for the EXCLUDER Device enables easy positioning and repositioning, if necessary. In our first seven cases, the option to reposition the graft was used to adjust both the level and limb orientation with excellent results. This ability to reposition the device has obvious benefits, especially in cases with difficult anatomy. ■

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A Practical Look at EVAR Fixation

Ross Milner, MD, discusses the properties of fixation for endovascular abdominal aortic stent grafts, including their strengths and weaknesses and how the technology has evolved.

What are the properties of fixation for endovascular aneurysm repair (EVAR) devices, and how do they relate to sealing?

Dr. Milner: Fixation is designed to prevent distal migration of an endograft and can be accomplished by passive and active mechanisms. Generally speaking, passive fixation is provided via the radial force of the endograft, whereas active fixation is provided by such mechanisms as barbs and hooks, etc. The difference between fixation and sealing is commonly misunderstood. Fixation relates to migration but does not directly relate to sealing, which is accomplished via radial force in some approved devices. In the case of the EXCLUDER Device (W. L. Gore & Associates, Flagstaff, AZ), sealing is accomplished with both radial force and a sealant ring at the proximal end of the device, which is very useful in causing the device to stick to the inner wall of the aorta. The only correlation that exists between fixation and sealing is that poor fixation can result in migration of a device, which would then obviously affect sealing, but there is no direct correlation between the fixation properties of the various endografts and sealing.

How would you summarize the milestones in the evolution of fixation for EVAR devices from the first uses of the procedure through the current generations of devices?

Dr. Milner: The first two devices approved by the US Food and Drug Administration, Ancure (Abbott Vascular, Santa Clara, CA, formerly Guidant Corporation) and AneuRx (Medtronic, Inc., Minneapolis, MN), accomplished fixation by different means. The Ancure had active fixation with hooks, whereas the AneuRx relied on passive fixation alone. Both devices encountered difficulties. The Ancure device had delivery system malfunctions^{1,2} but excellent prevention of migration.³ The AneuRx device struggled with distal migration.⁴ This is especially true when treating challenging aortic neck anatomy.⁴

The next generation of devices included the Zenith device (Cook Medical, Bloomington, IN), which uses suprarenal fixation with barbs, the EXCLUDER Device, which uses infrarenal fixation with barbs, and the Powerlink device (Endologix, Inc., Irvine, CA) uses what they like to call “anatomical fixation” because the device is designed to sit on the iliac bifurcation. The Talent endograft (Medtronic, Inc.) is unique in that it uses passive suprarenal fixation.

There are currently no other endografts being marketed within the United States. One of the investigational devices, the Aptus endograft (Aptus Endosystems, Inc., Sunnyvale, CA), used staples to achieve fixation. The device had some issues regarding limb thrombosis, but that was not related to the staple fixation. I suspect that devices are evolving to incorporate the benefits of a combination of passive and active fixation mechanisms, but at present, the EXCLUDER Device is the only device that uses both passive and active fixation.

What are the possible risks associated with different types of fixation?

Dr. Milner: Any device is subject to fatigue. All devices have shown some element of fracture or fabric issues, and fixation has not been exempt from fatigue problems. All active fixation materials (stainless steel, nitinol, and cobalt-chromium alloy) have all shown fracture events and are still prone to this type of problem. It is not clear that fractures lead to significant device issues, such as migration, but this concern exists.⁵

In your practice, have you seen examples of when a particular type of fixation created issues?

Dr. Milner: I have seen a clinical trial device with suprarenal fixation develop a separation from the main body device. However, this did not lead to a migration event. When working in Europe, I did see an example in which oversizing of a passive fixation device led to aortic neck dilatation. I believe that we have seen less of that in recent years, and I don't know if that is because of device

improvements or if endovascular specialists have learned to do a better job of sizing devices for the anatomical measurements.

How does the type of fixation used by a device affect the delivery/deployment of various EVAR devices?

Dr. Milner: I think it does not significantly change the delivery/deployment of the device. For some devices, it adds one or two additional steps during the main body deployment. In addition, I always take great care in removing the main body device delivery system when a suprarenal fixation system has been deployed.

What are the proven benefits of different types of fixation? In short necks? In angulated necks?

Dr. Milner: I do not think there are data to support that different fixation means (ie, passive vs active, suprarenal vs infrarenal) allow for improved treatment in general or in short or angulated necks. This is based on the Instructions For Use (IFU) and my own clinical experience. Some specialists have assumed that devices with suprarenal fixation are better suited for treating shorter aortic necks, even though the devices' IFU were identical to that of other devices using infrarenal fixation. It may well be that those suprarenal devices are able to treat shorter necks but neither the clinical data nor the IFU have supported that conclusion. The Talent device differs slightly in that it is approved by the US Food and Drug Administration for a 10-mm aortic neck length.

I believe that the best option for treating challenging aortic necks is to use a debranching procedure, chimney/snorkel stent placement, or branched/fenestrated devices. All of these types of repair have been reported to be successful, but they have also had significant complications.⁶⁻⁸

Finally, open repair is still an appropriate option in physiologically suitable patients.

Are there misconceptions about the different types of fixation?

Dr. Milner: I think the main misconception is that suprarenal fixation allows the user to treat a shorter aortic neck. The suprarenal fixation devices can be deployed successfully in challenging anatomies, but I am always concerned about the durability of this approach.

What do you see as the short- and long-term future for fixation of EVAR devices?

Dr. Milner: In the short-term, the benefit of the new C3 Delivery System for the EXCLUDER Device (W. L. Gore & Associates) is that you can be exceptionally accurate in placing the device with active fixation because you will have the ability to deploy it and reposition it during the procedure. This device is available in Europe and recently FDA approved.

In the long-term, I think stent grafts will always need some amount of active fixation to prevent migration, and I do not think that improvements in fixation will change our ability to treat difficult anatomy. ■

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Achieving Limb Patency

How specific devices and techniques can help maximize outcomes.

BY VINCENT RIAMBAU, MD, PhD, AND GASPAR MESTRES, MD

Endovascular aneurysm repair (EVAR) has proven to be a safe and effective alternative to open aneurysm repair. Clearly, that is true in terms of early mortality and morbidity. However, long-term durability is marred by late complications, especially those requiring reintervention. Despite the fact that the majority of these reinterventions can be performed at low risk via an endovascular approach, the overall cost and need for surveillance limits the perceived advantage of the EVAR technique. After endoleak and device migration, limb thrombosis is the most common postoperative complication.^{1,2} Reported limb thrombosis prevalence ranges between 0.7% and 6.4%¹⁻⁴ and can occur immediately postoperative (up to 50% of limb thrombosis cases occur during the first postoperative month⁵) or months to years after surgery. The overall annual incidence rate is as high as 3.2%.⁶ These reported prevalence rates indicate a relationship between the technical selection of the endograft and the EVAR procedure itself.

Symptoms of lower extremity ischemia develop with graft limb occlusion. Actually, the first cause of leg ischemia after EVAR is limb thrombosis, not atheroembolization or thrombosis of runoff vessels.⁷ Clinical severity depends not only on graft occlusion but also the severity of other collateral flow loss, which is mainly due to external iliac graft extension and subsequent occlusion of the hypogastric artery. Presenting symptoms can range from mild to moderate claudication (31%), severe claudication (61%), or paresthesia and rest pain (8%).⁶ These symptoms may require additional interventions (including endovascular [thrombolysis and stenting] or direct surgical revascularization [thrombectomy, femorofemoral, or axillary-femoral bypass]),² which increase mortality, morbidity, rehospitalization, and overall cost.

CAUSES OF LIMB OCCLUSION

Identifying factors that have been attributed to increasing limb occlusion could assist in selecting the best graft and endovascular technique for each patient and their respective anatomy. This ideal selection also decreases complications and reinterventions, thus improving short- and long-term outcomes of EVAR. Factors that potentially predispose a patient to limb thrombosis are listed in the succeeding paragraphs.

Limb kinking has been identified as a major prothrombotic factor and is more frequent in areas of stenosis or narrow anatomies. The distal aortic neck or the aortic bifurcation should accommodate both limbs of a bifurcated endograft. If this area is not large enough, the limbs will be competing and ultimately constrained, likely causing limb thrombosis (Figure 1). Tortuous and angulated iliac arteries increase the risk of graft kinking and twisting,^{5,8-11} and subsequent limb thrombosis could occur. Some arterial kinking at the distal edge of the stent graft could promote late limb occlusion. Less often, extensive thrombus within the aneurysm sac can also prevent complete deployment of the endograft, promoting kinking, extrinsic graft compression, hemodynamic modification, and limb occlusion.⁶

Unsupported endograft devices have been associated with lower primary and assisted primary patency rates,^{5,8} which may be due to a higher risk of kinking and twisting in tortuous iliac anatomy.⁹ To avoid graft folding in unsupported grafts, adjunctive intraoperative insertion of additional bare-metal stents in narrowed or angulated limbs have been used, significantly increasing limb patency rates.¹⁰ A comparison of different types of graft supports is lacking.

Decreased arterial outflow is another main factor in limb occlusion. The use of small graft limb diameters (10 mm or less) and extension to the external iliac artery can be attrib-

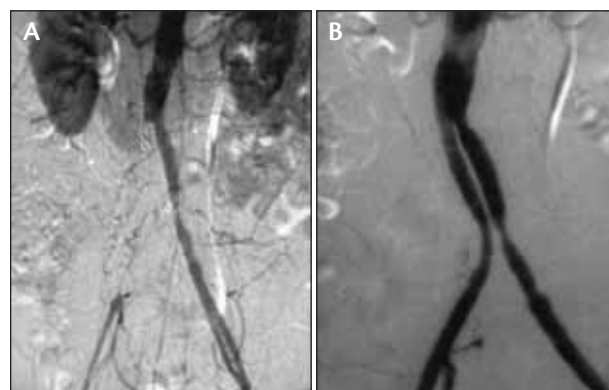


Figure 1. Right limb thrombosis due to a narrow distal neck 30 days after the procedure, which was treated with local thrombolysis, use of the AngioJet thrombectomy system (Medrad Interventional/Possis, Minneapolis, MN), and insertion of a bare-metal stent.

uted to decreased outflow. Also, underlying arterial occlusive disease and iliac angulation are both associated with a higher thrombosis rate.^{5,9} Smaller arterial diameters, arterial dissection,^{5,8,11} and irregularity of the endograft lumen from device overlap¹² are also correlated with lower patency rates. Aortomonoiliac grafts with femorofemoral bypass have been identified as having better patency rates than bifurcated grafts.^{8,13} This outcome is mostly likely related to hemodynamic factors, such as lack of flow divider issues, no limb competition in aortic bifurcation, and better outflow.

Migration and dislodgement of the endograft limb have also been proposed as a cause of limb thrombosis.⁹ Although they were stent supported, first-generation devices (ie, Stentor [formerly MinTec, the Bahamas] and Vanguard [Boston Scientific Corporation, Natick, MA]) were clearly associated with an elevated risk of limb thrombosis, mainly based on their high rate of migration, limb kinking, and disconnection.⁶

Stent graft material is also of significance. Expanded polytetrafluoroethylene grafts (ie, EXCLUDER Device [W. L. Gore & Associates, Flagstaff, AZ]) have been correlated to lower inflammatory response¹⁴ and better limb patency rates,⁶ but data are lacking in this area, and the role of other factors, such as particular graft support, are not well defined. The EXCLUDER Device has also been associated with lower kinking rates,⁶ probably due to its specific design, which is more flexible and fully supported by a nitinol stent.

Intragraft mural thrombus appears frequently in wide and long main bodies with small limbs and more often in polyester than expanded polytetrafluoroethylene grafts. A relationship between distal embolization and limb occlusion has been suggested. Polyester grafts and small limbs are associated with a higher limb occlusion risk. However, the clinical relevance of intragraft thrombus formation is not well defined, and the literature is not conclusive.^{15,16}

A lack of heparin administration is an unusual cause of early limb occlusion. Nevertheless, it should be pointed out as a clearly avoidable risk factor. Mechanical

obstruction of the outflow by large introducer sheaths is another easily avoidable cause of early limb occlusion and ischemia.

Other rare causes of limb occlusion have been reported, such as using microwave therapy or other physical warming waves for lumbar pain treatment. It has been well described that the metallic stent acts as an antenna, attracting heat energy and thereby causing blood coagulation inside the stent graft.¹⁷ There have been no clinical warnings associated with the use of magnetic resonance imaging techniques.

HOW TO AVOID LIMB THROMBOSIS

It seems easy to avoid limb occlusions once the causes are identified. Some recommendations will be dependent on device choice, and others will be particular to the technical aspects of the EVAR procedure itself.

First, regarding the device choice issue, we must take the morphological anatomy into account. For very narrow and calcified distal necks, it would be preferable to choose an endograft with an aortouni-iliac configuration. When the iliac anatomy is tortuous, a more flexible stent graft will fit better (Figure 2). For narrow iliac arteries or when the distal landing zone is targeted in external iliac arteries, a flexible and thinner material with high conformability and without infolding behavior would work best.

There are factors to be considered during the procedure, such as the use of heparin. Long periods of iliac occlusion by large sheaths should also be avoided. Be careful to avoid arterial dissections when introducing wires and introducing systems, and use extra overlapping lengths of the endograft in tortuous anatomies. Avoid placing the distal edge of the stent graft in an acute angle, as well as inducing any twisting during the limb deployment. For narrow distal necks or in acute aortoiliac angles, the intentional "cross leg" or "ballerina" position conforms better (Figure 3). Kissing-balloon techniques can be used in the case of limb competition in the distal aortic neck. Bare-metal stents are also useful if

(Continued on page 18)



Figure 2. X-ray image of 8-year follow-up control after implantation of an EXCLUDER Device. Intense left tortuosity; the distal end is in both external iliac arteries with excellent conformability of the stent graft.



Figure 3. Angiogram showing the "ballerina" position for narrow distal aortic necks.

The EXCLUDER-Centervasc Registry

A preliminary report from a 10-year efficacy and durability study on EVAR.

BY ARNO VON RISTOW, MD; BERNARDO MASSIÈRE, MD; AND ALBERTO VESCOVI, MD

The natural history of abdominal aortic aneurysms (AAAs) is well known. If left untreated, rupture and death is the expected outcome. Endovascular AAA repair (EVAR) was introduced by Parodi et al in 1990, primarily to treat high-risk patients, many of whom were unable to overcome the risks of open surgery.¹ After proving to be feasible in that decade, surgeons' worries were concentrated on the efficacy of the procedure, with special concern regarding the durability of the implanted devices and their ability to exclude AAAs.

Our experience with the GORE EXCLUDER Device (W. L. Gore & Associates, Flagstaff, AZ) began in December 1999. Through the end of 2010, 188 patients were treated at Centervasc (Rio de Janeiro, Brazil) with the EXCLUDER Device, with follow-up to 10 years. This is an independent prospective registry, and it has not been funded by either Gore or their distributor in Brazil. All endografts and hospital expenses have been paid for by either the patients themselves or by their health care supplier. All procedures have been performed under the supervision of the senior author, Dr. von Ristow.

INDICATIONS, PLANNING, AND METHOD OF TREATMENT

Indications for treatment were based on the presence of symptoms and size of the AAA, as internationally accepted. Preoperative workup included carotid and coronary noninvasive studies in all patients, and operative risk was assessed according to the American Society of Anesthesiology. In the first 6 years of this study, EVAR was indicated only for high-risk patients, with strict criteria. Later on, as confidence was acquired with the EXCLUDER Device, EVAR was progressively indicated for lower-risk patients.

Although always based in computed tomography (CT), imaging considerably improved during the study

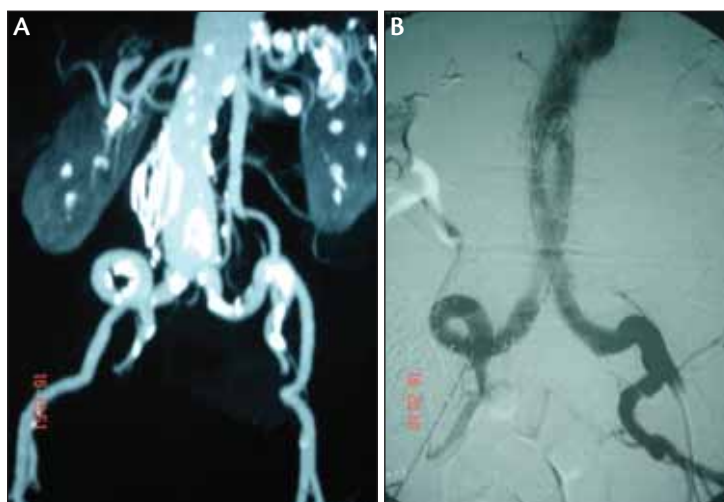


Figure 1. CTA reconstruction of a AAA with 360° coiling of the right external iliac artery and severe tortuosity of left common iliac artery (A). Intraoperative conclusion angiogram after successful EVAR with the EXCLUDER Device (B). The challenging anatomy of the iliac arteries was managed with introduction of the sheaths over extra-stiff guidewires.

period. Angiography with marked catheters played an important role in our early experience. Currently, multi-slice CT angiography (CTA) with multiplanar reconstructions has totally supplanted other methods.

The vascular surgery residents at Centervasc, assisted by senior staff members, performed all procedural planning. In this study, AAA cases with proximal necks of adequate length and an inner diameter ranging from 20 to 28 mm were enrolled. Thin thrombus at the neck, up to 25% of the circumference, was not considered to be a contraindication. Neck angle up to 60° was accepted. A diameter of at least 22 mm for the distal neck and a maximum of 18 mm for the iliac arteries was required, with a distal sealing zone of at least 10 mm.

The implantation was performed through surgical access to the femoral arteries. In the early cases, the EXCLUDER Device was released from its constraining covering using a quick deployment. With increased experience, release was performed slowly under full visual con-



Figure 2. Volume-rendering reconstruction of CTA of a patient treated in 2004 with bilateral bell-bottom EXCLUDER Device iliac limbs. In 2009, the iliac arteries have not enlarged, and both hypogastric arteries are patent.

trol. The techniques we employed have been published in the Brazilian literature and by Minion and Jordan, respectively.²⁻⁵

The device has been extensively used in cases of tortuous iliac arteries, often along with extra-stiff guidewires to straighten them (Figure 1). In Brazil, many patients have small stature. The ability to use the EXCLUDER Device with crossed limbs was applied to prevent undesired hypogastric occlusion. Ectatic common iliac arteries (up to 18 mm) were treated with bell-bottom limbs (Figure 2). We have given extreme attention to the preservation of at least one hypogastric artery. Aneurysms of both iliac arteries with involvement of the bifurcation were usually treated with unilateral hypogastric exclusion plus surgical hypogastric revascularization in this series. In sexually active men, bilateral hypogastric preservation was the rule (Figure 3). In eight cases of nondialytic renal insufficiency, EVAR was performed without the use of iodinated contrast media. Fluoroscopy and duplex scan were used to guide the implant in these cases.² Whenever the diameter of the femoral artery allowed the concomitant introduction of a 7-F sheath, with the 12-F sheath used to implant the EXCLUDER Device contralateral limb in place, we filled



Figure 3. EVAR with EXCLUDER Device in a patient with bilateral common iliac aneurysms. Late (6 years) CTA control of graft with bilateral polytetrafluoroethylene hypogastric artery revascularization.

the aneurysmal sac with fragmented gelfoam sponge to reduce the occurrence of type II endoleaks.

FOLLOW-UP

Patients were seen for follow-up consultations at 1, 6, and 12 months and yearly thereafter. Follow-up in the first 5 years of the study was based on physical examination and CT. Since 2005, our protocol has been based on an annual physical examination, duplex scan, and plain radiography of the abdomen and pelvis, complemented eventually by CTA.

Early (30-Day) Results

Technical success was achieved in all cases, with no operative death. Thirty-day mortality was 1.6% (three patients had blood dyscrasia, pulmonary embolism, and myocardial

TABLE 1. EARLY (30-DAY) RESULTS (N = 188)^a

Results	n	%
Technical success	188	100
Mortality	3	1.6
Conversion	0	0
Type I endoleak	1	0.5

^aCauses of early mortality: blood dyscrasia (1), pulmonary embolism (1), and myocardial infarction (1).



Figure 4. EXCLUDER Device stability in hostile anatomy: 2009 volume-rendering CTA image of an EXCLUDER Device implanted in 2002 within a 60° angulated neck.

infarction, respectively). One type IA endoleak was observed. There was no conversion to open surgery (Table 1).

Long-Term Results

One hundred eighty-five patients survived to 30 days and have undergone prospective follow-up (Table 2). One late migration in an angulated neck was observed, with development of a type IA endoleak, as well as one type IB endoleak due to enlargement of the iliac artery. Both endoleaks were treated by endovascular means—the type IA endoleak by transforming the bifurcation in a conical uni-iliac graft, with occlusion of the contralateral common iliac artery and femorofemoral crossover grafts. The type IB endoleak was treated with exclusion of the hypogastric artery with coils and implantation of an extension to the external iliac artery. Type II endoleaks were detected in nine patients (4.77%): two presented with spontaneous occlusions, two were treated by translumbar coiling, and five are under watchful observation, with no aneurysm growth. No structural failure (type III endoleak) has been observed.

We observed four patients (2.25%) that, after showing shrinkage of the sac, showed slow aneurysmal growth without a detectable endoleak, implying endotension. All of these patients underwent implantation before 2003. This occurrence is probably related to the expanded polytetrafluoroethylene permeability of the early device. To date, no sacs have enlarged to a size requiring further treatment.⁶

TABLE 2. LONG-TERM RESULTS: ADVERSE EVENTS (N = 185)

Results	n	%	Remarks
Endoleak IA	1	0.5	Migration, treated
Endoleak IB	1	0.5	Iliac enlargement, treated
Endoleak II	9	4.5	2 treated, 2 spontaneous occlusion, 5 under observation
Endoleak III	0	0	Structural defects have not been observed
Endoleak IV	0	0	None
Endoleak V (undetermined)	4	2	All under observation
Renal impairment	0	0	None
Limb kinking	0	0	None
Limb thrombosis	3	1.6	1 treated (thrombolysis)
Late migration	1	0.5	Treated (same case as type IA endoleak previously noted)
Infection	2	1	Tuberculosis psoriasis with endograft contamination
Secondary reinterventions of any kind	8	4	None
Late conversion	2	1	Both related to the infections previously noted

TABLE 3. ANEURYSM-RELATED DEATHS

Cause of Death	n	%	Remarks
Aneurysm rupture	0	0	None
Graft infection	2	1	All related to contamination of the graft by infection (<i>Mycobacterium tuberculosis</i> psoitis)

In this series, we have not observed late renal impairment related to the presence of the endograft. Thrombosis of limbs were rare (1.6%), and only one required treatment. No main graft thrombosis occurred. There was one case of graft infolding in the external iliac artery. It has been observed for 3 years without thrombosis of the limb. Late graft infection occurred in two cases (1.1%) and both were due to contamination of the graft by contiguous infection by *Mycobacterium tuberculosis* of the left psoas muscle in very debilitated octogenarians. Both patients did not survive extra-anatomical axillary bifemoral grafting plus endograft explantation, although this is not representative of the overall findings because these were the only two aneurysm-related deaths in the series (Table 3). Aside from these two cases, no late conversion was necessary. Integrity and long-term stability, even in hostile anatomy, has been the rule with the EXCLUDER Device. We have not observed barb fractures or other device integrity issues.

DISCUSSION

Results of the EXCLUDER Device for treating AAA have been widely published.⁶⁻⁸ Several improvements were made to the EXCLUDER Device during the study period. Most important is the incorporation of a new low-permeability interior layer while maintaining the same luminal and abluminal stent graft surfaces, the addition of a 31-mm main body size, and iliac extensions up to 20 mm in diameter. The development of techniques that allow gradual and precise proximal graft release expanded the application of this unique device, which to date remains the only one that is mounted on a catheter, a feature that allows its use in severe iliac angulations without kinking.

In this series, we did not observe late renal impairment, which has been reported with the use of grafts with suprarenal fixation.⁹ As well as efficacy, the durability of AAA exclusion has been a challenge to all grafts used for EVAR. Figure 4 shows an EXCLUDER Device that was implanted in a AAA with a 60° angulated neck and is perfectly stable 7 years after implantation. Long-term comparative outcomes after EVAR have been published, and all favor the EXCLUDER Device as an effective and durable device.¹⁰⁻¹⁴ This 10-year follow-up study confirms outstanding results, situating the EXCLUDER Device in a privileged standpoint.

CONCLUSION

After 188 EVAR procedures performed from 1999 to 2010 using the GORE EXCLUDER Device that were followed-up prospectively up to 10 years, we conclude that this device is durable and effective for the treatment of AAAs. ■

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The Role of Simulation in Aortic Endografting

How this tool can be used effectively to train the next generation of vascular clinicians.

BY ALAN B. LUMSDEN, MD; JEAN BISMUTH, MD; AND MICHAEL A. DONOVAN, BS

Endovascular training for vascular surgeons began in the mid 1990s, and at that time, the use of glass and plastic flow models was considered “state of the art.” The Society of Clinical Vascular Surgery, under the direction of Dr. Kim Hodgson, was first to run what were considered cutting-edge, hands-on courses using these models and portable C-arms to teach basic catheter and wire skills. Now considered rudimentary, these models served to educate a generation of vascular trainees. Supplemented by mini-fellowships and device-specific multiday courses, the endovascular transformation of vascular surgery had begun, and these modules all played an important role. Fast-forward 15 years, and one can reasonably ask the question, “Where are we now?” An increased number of devices, more complex devices, shortened resident work hours, and competition from multiple specialties are all factors that confound endovascular training. Endografts represent some of the most complex devices ever developed for the endovascular space, and with the emergence of branched vessels, they also represent significant training challenges. This article addresses the role of simulation for endograft training.

DEFINITION OF MEDICAL SIMULATION

Medical simulation is defined as “a person, device, or set of conditions that attempts to present (education and) evaluation problems authentically.” Multiple types of simulator exist, each with their particular role. The students or trainees are required to respond to the simulated problems as they would under natural circumstances. Frequently, the trainees receive performance feedback as if they were involved in a real situation.^{1,2} One elemental question remains: how much realism is actually necessary? Some of the common characteristics of most simulation technologies are:

- Cues and consequences that are very close to reality
- Ability to simulate complex situations
- Limitations in technology (eg, the endosimulator’s inability to learn, reliability of haptics)
- High costs

- Varying formats that can be either interactive or individualistic, inanimate (ie, anatomical model), or computer-based (ie, endosimulators).

The Agency for Healthcare Research and Quality report from 2007 essentially supports the effectiveness of simulation training “especially for psychomotor skills (eg, procedures) and communication skills.”³ However, this support is limited by data that are weak due to the small number of suitable trials and the lack of quantitative data.

SIMULATION AND AORTIC DISEASE

Interestingly, we now see a move back to the models and flow circuit-based simulation, albeit in a much more sophisticated environment compared to the models of 1995. This has been pioneered by a group of European surgeons working with the European Society for Vascular Surgery to create complex models that can be used for both endovascular training and for practicing and measuring technical capabilities for open aortic repair (Figure 1). Taught annually in Pontresina, Switzerland, students under the supervision of



Figure 1. Pontresina abdominal aortic training for open repair of an aortic aneurysm. A flow pump below the module provides pulsatile flow. Actual surgical retractors and instruments must be used. Aneurysms are replaceable, and assistance is necessary.

senior surgeons practice open aneurysm repair in a flow model environment. The European Board of Vascular Surgery has developed a validated method of testing vascular surgery skills that is now required for their board certification.⁴ No such program exists in the United States or in other parts of the world, although fledgling programs are beginning to quantitate the value of simulation in training.^{5,6} Introducing this type of training to the United States and to the international surgery community will help to standardize the workforce, increase the level of expertise among cardiovascular surgeons, and potentially shorten the learning curve for developing these skills. The American Board of Internal Medicine has developed Medical Knowledge Modules, which include interventional cardiology simulation. This is a pilot program in which simulation permits the candidate to accrue points toward maintenance of certification.

The Pontresina endovascular tower (Figure 2) permits groin puncture and device delivery into flowing glass models under video control (replacing C-arms) in a radiation-free environment. The real advantage of these towers is that actual stent grafts are delivered and deployed, providing the trainee with the tactile feedback associated with delivery of different types of devices. Also, adjustable pulsatile flow gives the model an even greater sense of realism.

One real challenge in the evolution of a true simulation experience for aortic endografts has been the disconnect between simulation companies and the device manufacturers. The device companies have long been uncertain about the real value in simulation and consequently have been reluctant to invest in the development of simulation modules. With fewer cash reserves, the simulation companies have not had the resources or desire to develop these simulated aortic environments alone. Both believe that hospitals should appreciate the potential role of simulation in credentialing and rec credentialing. But, to date, no matrices exist by which hospitals can use these expensive simulators to credential, refuse credentialing, or remove credentialing for physicians based on their performance in aortic simulation or in any other endovascular models.

This complex situation of who owns the simulator versus who owns the training module led to a bitter experience for our institution in which we leased and housed the simulator but were denied access to the most recently developed and



Figure 2. The endovascular tower has groin vessels that must be accessed using standard techniques. This is a radiation-free environment in which a C-arm is replaced by a mobile video camera that can be panned in a cranial-caudal direction or right and left anterior oblique direction to visualize devices tracked up through the transparent glass model.

most exciting modules. This led to a situation in which the standard modules were rapidly used and little additional value in the simulator was perceived. We learned that we needed continuously updated material of increasing complexity with built-in complications.

Consequently, it is only recently that aortic endograft simulation models have evolved. Medtronic, Inc. (Minneapolis, MN) first developed a thoracic simulation environment (Figure 3) in partnership with Medical Simulation Corporation (Denver, CO) for deployment of their Talent endograft. Interestingly, they also developed a dissection module, which would have been of immense value but was unavailable for United States physicians because this was an “off-label” indication for their device.

The absurdity of this is obvious. Module development is dependent on a device company that can only permit use of their module if it is in line with US Food and Drug Administration-approved indications for that device. Consequently, despite the fact that most physicians now believe that

stent grafting is the first-line intervention for complicated type B dissections, they were denied access (on regulatory grounds) to the one training system that could have benefited them and such patients.

W. L. Gore & Associates (Flagstaff, AZ) has partnered with Simbionix Ltd. (Cleveland, OH) to develop an abdominal aortic aneurysm simulation platform for the EXCLUDER Device (Figure 4). This was created in conjunction with coauthor Dr. Jean Bismuth. One potential advantage of the Simbionix platform is the ease of performing patient-specific simulation. Computed tomography (CT) scans in DICOM format can be loaded into the simulator to provide a “patient-like” simulation. Why the distinction? Basically, these simulation scenarios are created from a contrast-enhanced CT scan, whereas interventionists deploy devices using angiography. Not only do we deploy the devices using real-time angiography, but the device itself deforms the anatomy, and these device-tissue interactions are not yet modeled in simulation scenarios. Consequently, most simulation companies are not yet ready to claim the true fidelity of patient-specific scenarios. This claim may need a clinical trial approved by the US Food and Drug Administration to demonstrate true fidelity before it can be made. Nevertheless, we strongly believe that the capability of simulators to continuously modify the scenarios is an absolute



Figure 3. Dr. Denton Cooley evaluating the Medtronic module for placement of thoracic endografts (A). The simulator forces the physician to size the aneurysm and select the appropriate lengths and diameters of the devices to be deployed (B).

prerequisite to provide value in simulation. The real value is in simulating tomorrow's case today, provided the clinician is not lured into performing the procedure because of its ease of use in a simulation environment.

Although there is clearly a difference between angiographic guidance and CT guidance, those margins are becoming increasingly hard to distinguish. Modern hybrid rooms all permit the acquisition of CT scans using the image detector. Three-dimensional (3D) reconstruction and 3D overlay are increasingly being used as guidance systems (Figure 5). Consequently, the lines of distinction between CT angiography-based simulation and the intraprocedural imaging modality are rapidly being blurred.

Management of complications, especially device-specific complications and unusual clinical scenarios, is yet another mandatory component in simulation evolution. Indeed, rehearsing these seldom-experienced situations could be one of the most important assets of simulation.

METHODIST INSTITUTE FOR TECHNOLOGY AND EDUCATION

Depending on the ultimate goals of the individual training center, the infrastructure can clearly vary, but either way, a significant investment is necessary. Having perceived a huge void, a significant investment was made in the Methodist Institute for Technology and Education in Houston, Texas, which has trained more than 2,500 health care professionals across 16 different specialties since 2007. The mission of the training center at the Methodist Hospital is to serve as an educational resource for practicing health care professionals seeking to maintain excellent clinical skills and acquire new ones. Like many other training facilities, it is intended to improve patient safety through educational



Figure 4. Simbionix-based Gore module for deployment of the EXCLUDER abdominal aortic endograft. In this situation, the main body has been deployed. The operator must now catheterize the contralateral gate and deploy the contralateral limb.

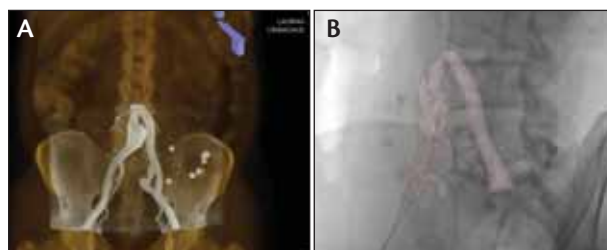


Figure 5. A 3D reconstruction of a rotational angiogram fused with an imported, previously acquired CT scan (A). The 3D overlay is then used to guide stent graft placement in the iliac aneurysm (B).

pursuits and conduct research on skills acquisition and technological development. The DeBakey Institute for Cardiovascular Education and Training has now been developed to support cardiovascular education, with a focus on aortic endografting. This will be launched within our extensive hands-on experience at the upcoming Total Endovascular Aorta II meeting in March 2011.

CONCLUSION

Given the quickly evolving world of endovascular therapeutics, it will be necessary for health care professionals to train on new devices and/or develop new techniques. Simulation is able to fill the education gap and likely improve physician confidence and patient outcomes. Although simulation for aortic endografting has lagged behind endovascular simulation in general, simulated environments for percutaneous aortic valves to thoracic endografts to abdominal aortic endografts are available. The expansion of simulated cases, the ability to develop patient-like modules, and the development of various simulated complications will greatly increase their utility. ■

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The GORE DrySeal Sheath

Hemostasis, ease of use, and the ability to introduce multiple devices through a single sheath represent a quantum leap in sheath technology.

BY ROBERT C. ALLEN, MD

Rarely does an introducer sheath truly stand out for its ability to improve vascular patient care, as for many years, the available sheath technologies had very comparable attributes and abilities. However, the GORE DrySeal Sheath (W. L. Gore & Associates, Flagstaff, AZ) is a unique exception, and it is elite among the class of large-bore introducer sheaths for a variety of reasons (Figure 1).

Paramount among these is the exceptional ability of the GORE DrySeal Sheath to adapt to a number of different devices and allow multiple exchanges while maintaining hemostasis despite the large caliber of the sheath. The sheath is pressurized to create a seal, and no manipulation is required on the part of the physician to maintain hemostasis.

The hemostasis allowed by this device decreases procedural blood loss and reduces the potential need for transfusion. Before I began using the GORE DrySeal Sheath, blood loss was a significant issue with other large-bore sheaths, with a frequent need for transfusion. With this sheath, I have found the need for transfusion to be very infrequent. It also helps to prevent blood loss complications such as hypotension throughout the case. Other sheaths that are used during the endovascular repair of abdominal aortic aneurysms (EVAR) and thoracic aortic aneurysms (TEVAR) have been aimed more at “hemoreduction” than hemostasis, and they continue to have issues during and between device exchanges. The compliant ePTFE film liner of the GORE DrySeal Valve has advanced beyond that with excellent results.

The GORE DrySeal Sheath is helpful in any type of aortic intervention, but its utility is particularly noted in challenging or complicated cases because of its ability to accommodate multiple catheters and wires through a single sheath. As a result, we can frequently avoid the need to create a separate access in the contralateral groin because everything can be done via one sheath.

In addition to providing excellent hemostasis, the sheath is easy to use, and its caliber and taper are well



Figure 1. GORE DrySeal Sheath.

suited for accessing difficult vessels. This facility, combined with the ability to introduce multiple devices through a single sheath, makes the GORE DrySeal Sheath less traumatic to the vessel, therefore decreasing patient morbidity from potential catastrophic sheath-related injuries. It has allowed me to take on more challenging cases, because with the myriad of other procedural conditions that require monitoring and attention, I can be confident that access will not be an issue.

In comparison to products that have been available in the past, the GORE DrySeal Sheath is a quantum leap in sheath technology. In my opinion, other large-bore sheaths do not compare. ■

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any kinking is suspected. It is best to obtain the completion angiogram at the end of the procedure without stiff wires in the patient and to explore femoral and distal pulses before leaving the operating room. Finally, advise patients about the use of warming waves.

CONCLUSION

Endograft limb occlusion is a serious complication of EVAR that leads to reintervention. The device and technical causes have been described throughout this article. Various tips and tricks should be considered to minimize adverse events and increase confidence in the EVAR technique. ■

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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 – 29 mm and a minimum aortic neck length of 15 mm; Proximal aortic neck angulation ≤ 60°; Iliac artery treatment diameter range of 8 – 18.5 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. 



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Repositioning

the future of EVAR



PERFORMANCE by design

FEATURING
C3
DELIVERY
SYSTEM

Repositioning = Control³

- 3 controlled deployments of the proven GORE® EXCLUDER® Device.
- 3 chances to maximize seal in the infrarenal aortic neck.
- 3 opportunities to rotate the stent-graft for precise orientation.

Reposition Your Expectations for EVAR

When facing a challenging infrarenal neck, don't settle for one 'controlled' deployment. Put yourself in the best position to succeed — put the confidence of the GORE® C3 Delivery System in your hands. And you will have not one, not two, but three opportunities to go beyond control — **and reposition the future of EVAR.**

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