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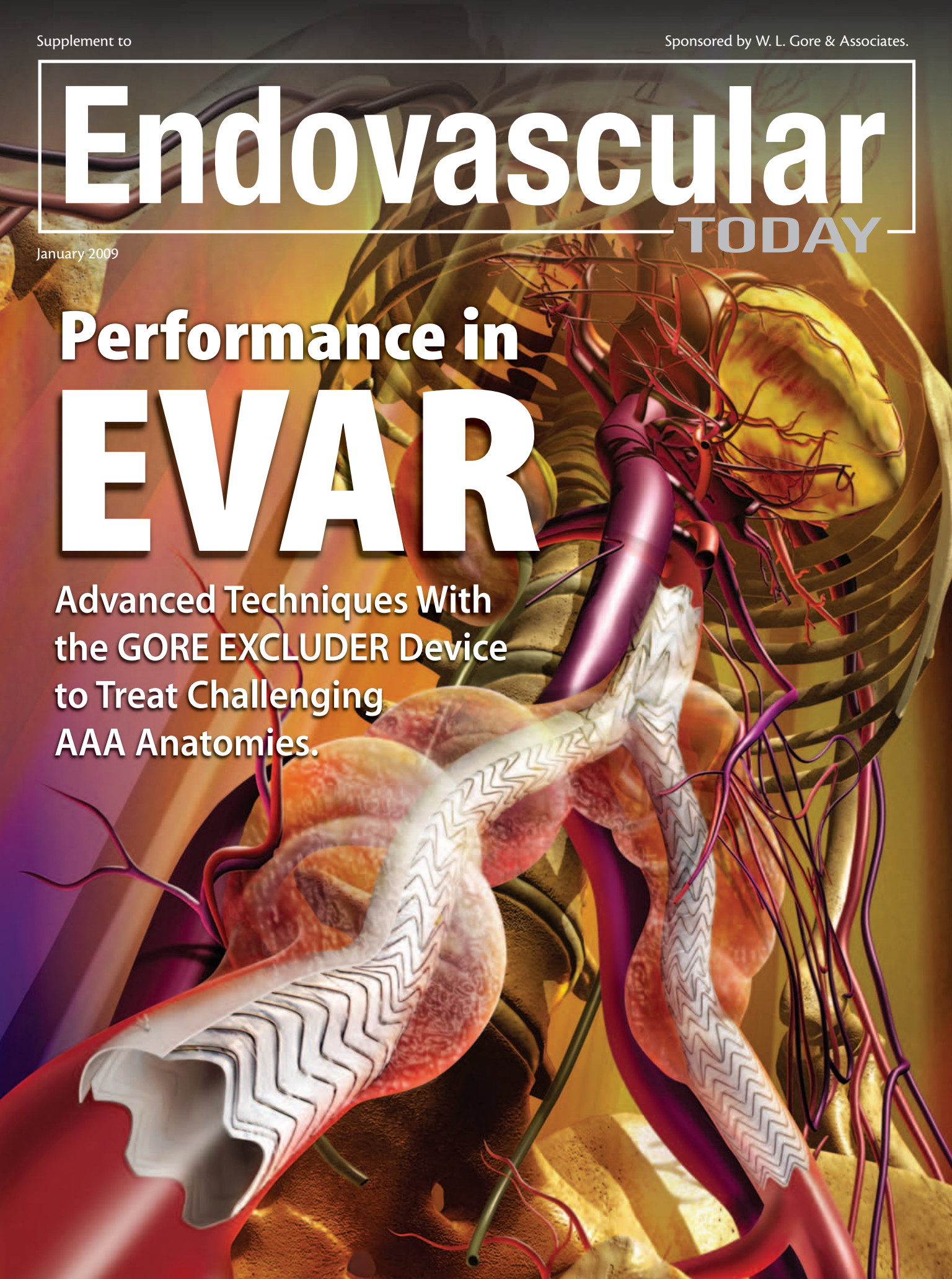
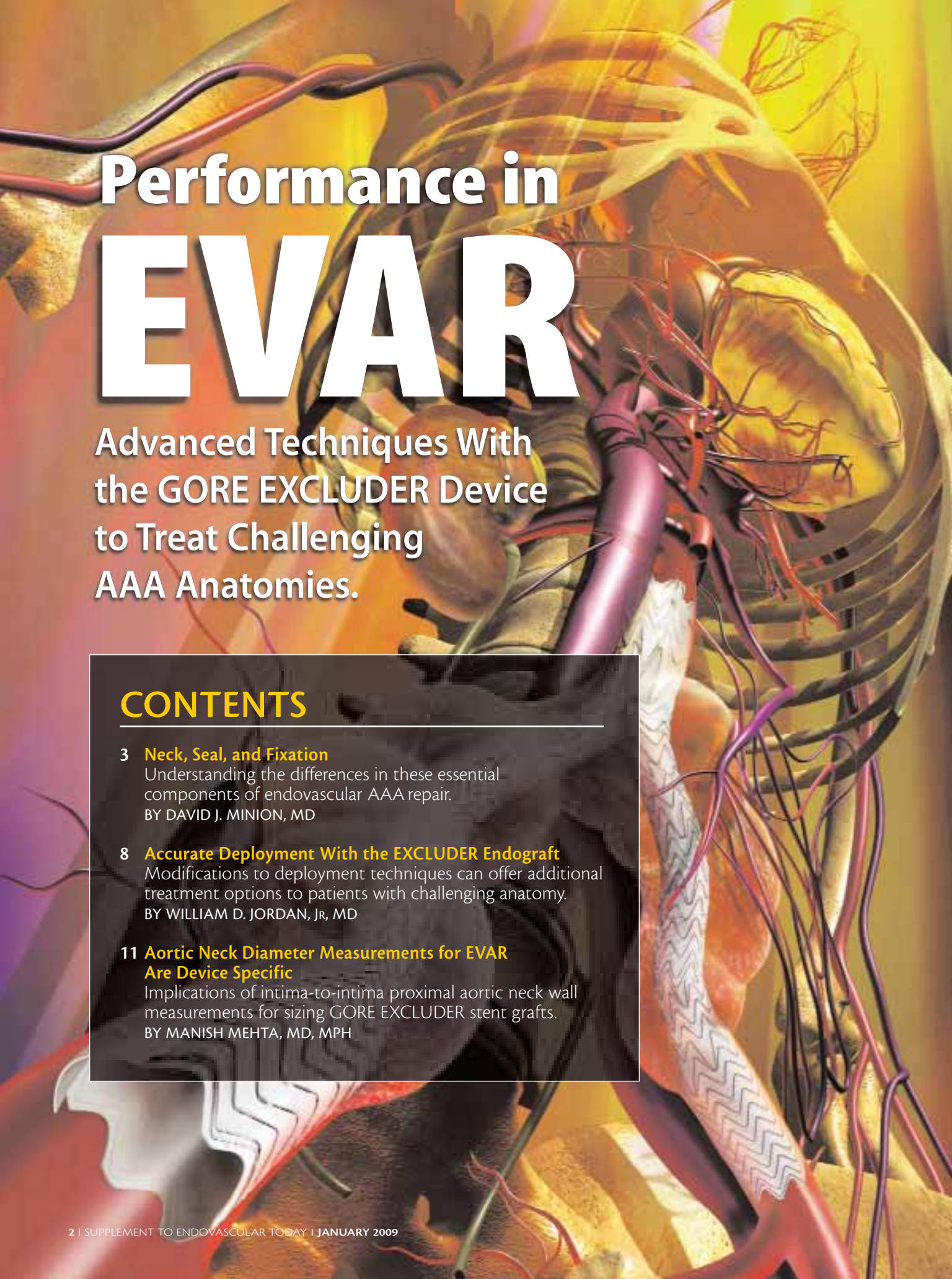
Performance in EVAR

Advanced Techniques With the GORE EXCLUDER Device to Treat Challenging AAA Anatomies.





Performance in EVAR

Advanced Techniques With the GORE EXCLUDER Device to Treat Challenging AAA Anatomies.

CONTENTS

Neck, Seal, and Fixation

Understanding the differences in these essential components of endovascular AAA repair.

BY DAVID J. MINION, MD

The proximal *neck* is by far the most critical technical challenge during endovascular aneurysm repair (EVAR). There are two basic requirements for success: *seal* and *fixation*. These two terms are often interchanged inappropriately, for they represent two distinct processes. *Seal* is the apposition of the outer surface of the endograft to the luminal surface of the aorta to exclude the aneurysm sac from systemic pressure. The amount of seal achieved is determined by the length of the proximal neck and the position of the endograft. *Fixation* is the counterforce that prevents migration of the endograft and helps maintain seal.

A proximal endoleak represents loss of seal, thereby allowing repressurization of the aneurysm sac and potential rupture. Although significant migration (failure of fixation) is often implicated in type I endoleaks, the two are not synonymous. In some patients, the infrarenal neck is of sufficient length or may even elongate after implantation[1] to maintain seal despite migration. More importantly, loss of seal can be due to factors other than migration. Factors such as excessive thrombus, calcification, or dilation of the proximal neck can most certainly lead to loss of apposition.

THERE IS NO SUBSTITUTE FOR SEAL

When dealing with challenging proximal neck anatomy, therefore, it is important to recognize that maximizing seal is the key to success. It has been suggested that suprarenal fixation can extend the applicability of EVAR to aneurysms with shorter necks. Conceptually, it is not clear why this should be so because suprarenal fixation does not increase seal. It simply changes the point of fixation. Fixation without seal will still result in endoleak (Figure 1). In fact, a critical review of the literature has shown that suprarenal fixation, in and of itself, has not extended the applicability of EVAR.

Early studies from developers of the Zenith endoprosthesis (Cook Medical, Bloomington, IN) found that the risk of endoleak was significantly higher in aneurysms with a proximal neck length >20 mm, and that risk increased for every millimeter of proximal neck length <20.[2] Adhering to the criteria of a proximal neck that was at least 20 mm in length, <28 mm in diameter, with less than 4 mm of contour change, and <30° of angulation

Figure 1. Late proximal endoleak due to loss of seal in a graft with transrenal fixation.

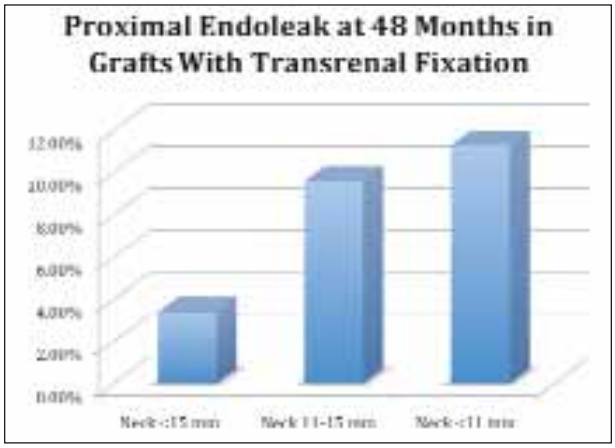


Figure 2. Data from the EUROSTAR collaborators demonstrating increased adverse outcomes when treating aneurysms with necks ≤15 mm using endografts with transrenal fixation (Zenith or Talent).

resulted in a low proximal endoleak rate of only 3.6%. If any of the criteria were breached, the proximal endoleak rate increased approximately fourfold to 14.8%.

Early studies from the principal investigators of the Talent endoprosthesis (Medtronic, Minneapolis, MN) similarly showed a greater than threefold increase in endoleaks in short-necked aneurysms (13%) compared to aneurysms with longer necks (4%).[3] However, because this did not reach statistical significance (*P*=.2), the investigators concluded that there was no difference in out-

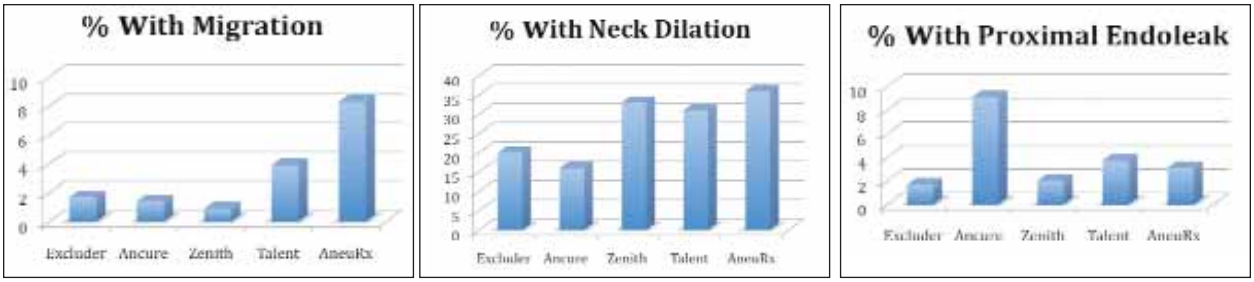


Figure 3. Comparative data from the EUROSTAR collaborators demonstrating that the EXCLUDER Device has a low incidence of both migration and proximal neck dilation, resulting in a very low incidence of late proximal endoleak.

Figure 4. The EXCLUDER Device is designed with a single spiraling wire (blue arrows) that runs the length of the graft and overlaps with the scalloped proximal sealing stent (red arrow) for stability and accuracy during deployment. Also note the anchors incorporated in the sealing stent for secure, active fixation.

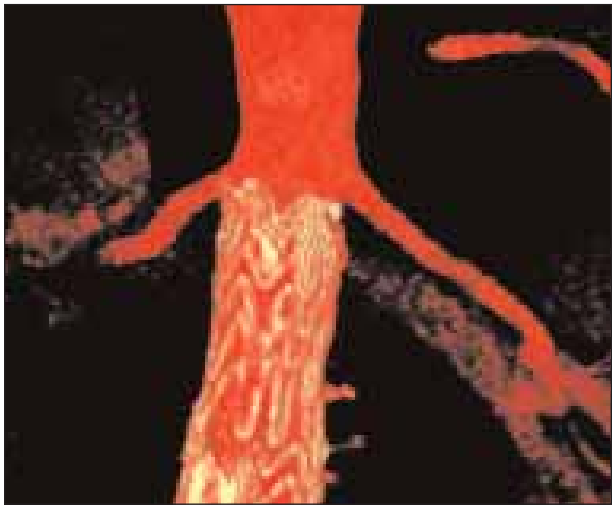


Figure 5. Proper alignment of the scallops of the GORE EXCLUDER Device can allow for an additional 4 mm of juxtarenal seal.

comes.

More recent data have demonstrated remarkably consistent but more robust numbers, suggesting that earlier studies lacking statistical significance were probably underpowered. In a report from the EUROSTAR collaborators, 3,499 patients who underwent EVAR with either the Talent or Zenith endograft were followed prospectively for adverse outcomes.[4] At midterm follow-up, the authors found that patients with an infrarenal neck length of >15 mm (n=2,822) had a 3.4% chance of developing a proximal endoleak. In contrast, patients with an infrarenal neck length of 11 to 15 mm (n=485) had a significantly higher rate of endoleak at 9.6% (hazard ratio, 1.98). Patients with a neck length of 10 mm or less (n=192) had an even higher endoleak rate at 11.3% (hazard ratio, 2.32) (Figure 2).

This is not to say that suprarenal fixation is ineffective. These data simply illustrate that suprarenal fixation has not succeeded in extending the applicability of EVAR to an infrarenal neck length <16 mm without increased risk of late failure. In other words, there is no substitute for seal.

SECURE FIXATION IS GRAFT DEPENDENT, NOT SITE DEPENDENT

Each endograft is designed with a specific mechanism for fixation. This mechanism can be active (ie, hooks or anchors) or passive (ie, frictional forces only). It can be infrarenal, transrenal, or distal. It is important to recognize these distinctions when interpreting studies evaluating migration. For example, Leurs and colleagues suggested that suprarenal fixation was associated with lower migration rates but increased neck dilation.[5] However, the infrarenal fixation group included endografts with both passive (eg, AneuRx, Medtronic) and active (eg, EXCLUDER Device, W. L. Gore & Associates, Flagstaff, AZ) fixation, with a wide variance in outcomes. Inexplicably, the suprarenal fixation group

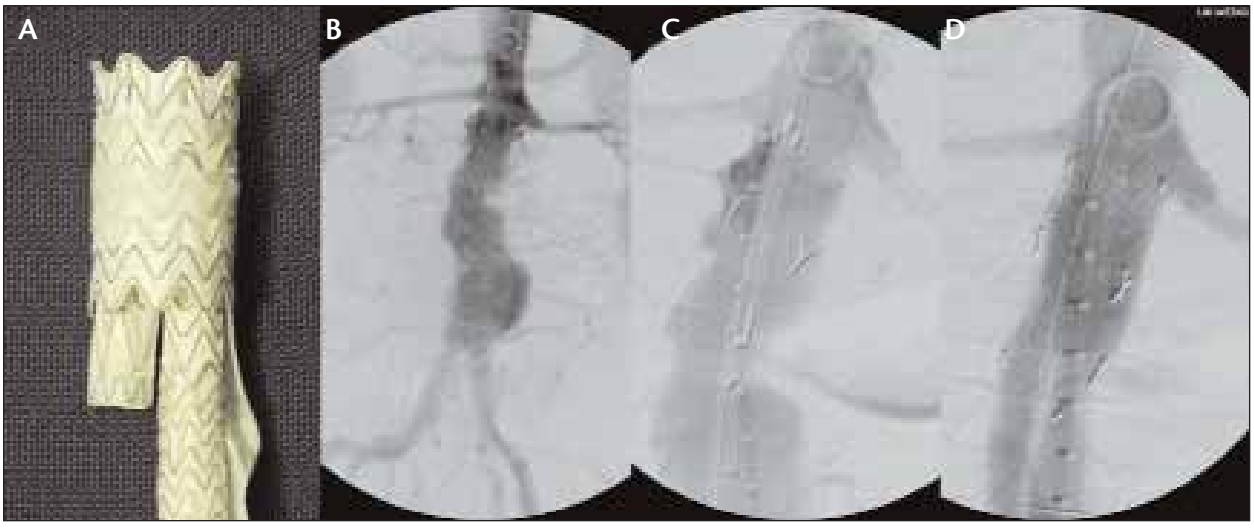


Figure 6. A predeployed cuff (kilt) can effectively extend the cylindrical portion of the main body of the GORE EXCLUDER Device to achieve additional seal in double-bubble or dumbbell-shaped anatomy (A). An example of an aneurysm with a short proximal neck, but a second seal zone well below the renal arteries (B). Preplacement of an aortic cuff to attain significant additional seal in the lower seal zone (C). The main body is then deployed using an using an Endowedge technique to align the scallops appropriately with the left renal artery to maximize seal in the proximal seal zone (D).

included endografts with active infrarenal fixation (eg, Ancure, Guidant Corporation; Indianapolis, IN). If the results are broken down in terms of the individual grafts, the EXCLUDER Device demonstrated a very low migration rate that was statistically comparable to other devices utilizing an active mechanism, such as the Zenith and Ancure. In addition, the EXCLUDER Device demonstrated a low neck dilation rate, resulting in the overall lowest rate of late endoleak (Figure 3).

TECHNICAL CONSIDERATIONS TO MAXIMIZING SEAL WITH THE EXCLUDER

Because secure fixation can be achieved in the intrarenal aorta, perhaps the largest impetus for the use of suprarenal fixation is that it can help stabilize an otherwise minimally supported proximal sealing stent, preventing excessive tilting during deployment. The EXCLUDER Device has a unique design utilizing a single spiraling coil throughout the main body that overlaps with the proximal sealing stent, providing stability during deployment and obviating the need for a bare suprarenal extension (Figure 4). This design also provides an unparalleled combination of flexibility, conformability, and columnar strength. These advantages, along with its simple deployment mechanism, facilitate the attainment of seal in patients with challenging proximal neck anatomy.

Conceptually, seal can be increased by either improving accuracy or finding additional seal zones. Magnification and correction for parallax are two essential and basic strategies for improved accuracy.[6] Because the deployment of the EXCLUDER Device is continuous, the correction for parallax must be calculated preoperatively from multiplanar reconstruction of CT scans. With regard to attaining additional seal, we have used numerous techniques with the EXCLUDER Device to achieve success in aneurysms with chal-

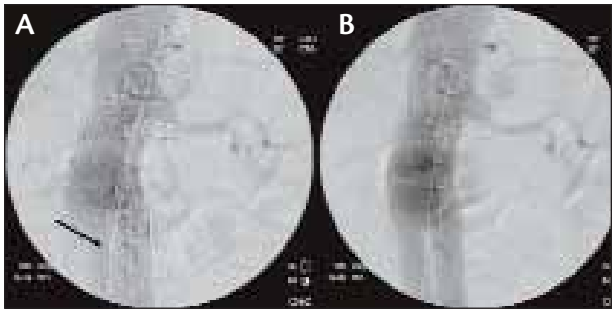


Figure 7. Proximal endoleak secondary to unfavorable graft tilt in an angulated proximal neck (A). Note the bend placed in the guidewire (arrow) in preparation for deployment of an extension cuff. The cuff deploys with more favorable tilt (perpendicular to the bent wire), achieving approximately 1 cm of additional seal along the outer curvature of the angulated aorta and sealing the endoleak (B).

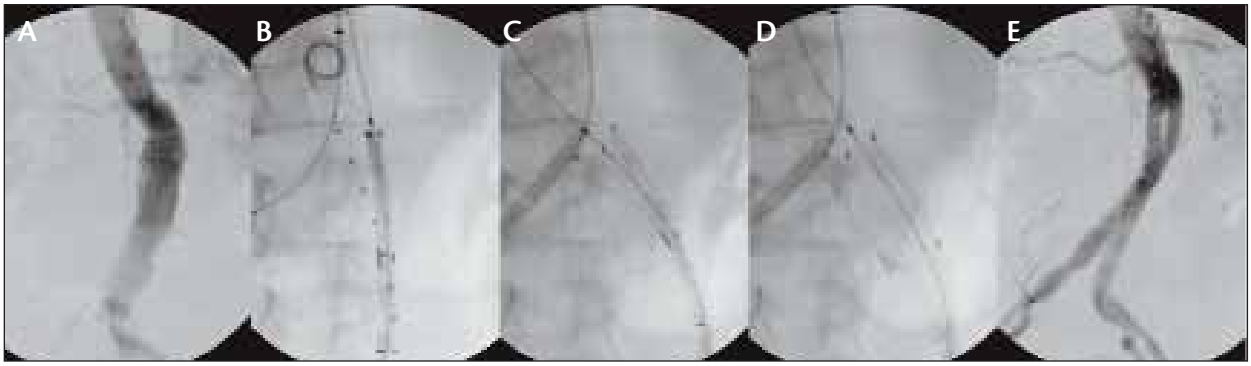


Figure 8. Preoperative aortogram of an aneurysm with a challenging proximal neck (A). If one were to use the natural path of the guidewire, the endograft would need to be deployed approximately 1 cm lower than the current position to avoid coverage of the right renal artery (B). Bowing of the guidewire alters the course to allow deployment with more favorable graft tilt. In addition, an Endowedge technique is used to gain 4 mm of additional seal along the inner curvature (C). The bow of the wire is adjusted slightly to avoid compromise to the left renal artery (D). Completion angiography revealing technical success (E).

lenging proximal neck anatomy, including alignment of scallops, predeployed cuffs (kilts), and manipulation of the wire to affect graft tilt.

ALIGNMENT OF SCALLOPS

The top 4 mm of the EXCLUDER Device are scalloped. Therefore, proper alignment of the scallops in relation to the lowest renal artery can attain an additional 4 mm of seal (Figure 5). Alignment is achieved through the use of a balloon placed in the renal artery from a brachial approach and is known as the *Endowedge technique*. This technique differs from suprarenal fixation in that it provides seal rather than fixation. Early experience with this strategy has been promising.[7] To date, we have used this technique on 25 patients, with follow-up ranging from 1 to 43 months. There have been no proximal endoleaks, significant sac growth, or aneurysm ruptures.

PREDEPLOYED CUFFS (KILTS)

In some cases, an aneurysm may have two proximal seal zones with a short, aneurysmal intervening segment. This anatomy is often referred to as *dumbbell-shaped* or *double-bubble* aneurysm. In these cases, we have deployed an aortic extension cuff first in the lower seal zone and then built up with a main body device (employing an Endowedge technique) to utilize all available proximal seal. We refer to this as the *kilt technique* because the predeployed cuff is positioned as a wrap around the two legs of the main body (Figure 6). The configuration effectively extends the cylindrical portion of the main body to nearly 5 cm to allow seal in the lower proximal seal zone. Additional kilts can extend this configuration even further.

MANIPULATION OF THE WIRE TO AFFECT GRAFT TILT

The tilt of the graft becomes an important factor in determining the amount of seal when there is either significant angulation of the proximal neck or asymmetry of the origins of the renal arteries. In the infrarenal aorta, angulation and elongation are part of the same process. Therefore, there is often adequate length for seal in angulated necks; it is simply a matter of manipulating the tilt of the graft to take advantage of the available length.

All current endografts deploy orthogonally to their shaft. Because the shaft follows the same path as the guidewire, the top of an endograft deploys perpendicular to the guidewire. Therefore, one can alter the tilt of a graft by altering the course of the guidewire. This can be very difficult in an endograft with a deployment mechanism that is designed with a long nosecone, such as those that rely on suprarenal fixation. The deployment catheter for the EXCLUDER Device, on the other hand, has a very short tip. Along with its flexible shaft and unique stent design, it is an ideal endograft for angulated anatomy.

The aortic cuffs for the EXCLUDER Device are particularly adept at sealing in tortuous anatomy. We have found that simply placing a bend in the guidewire can often alter graft tilt to a degree sufficient to achieve seal when using cuffs in these situations (Figure 7). This is likely related to the short length of the cuffs. From a technical standpoint, we prefer a Lunderquist wire (Cook Medical) and two bends, one infrarenal and one suprarenal, to facilitate this maneuver.

We have not been as satisfied with bending the wire to manipulate graft tilt during deployment of main body endoprosthesis. Again, this is likely due to the increased

length of the main body endoprosthesis, making it less susceptible to manipulation. In this situation, we have found better success with bowing of the wire. For this maneuver, we use an Amplatz Super Stiff wire (Cook Medical) snared via adjuvant brachial access to create a "body-floss" configuration. An assistant on each end of the wire then applies inward force to bow the wire while the graft is deployed (Figure 8). The technique requires a concerted effort from a three-person team, but it is extremely effective and allows for the intracorporeal adjustment of graft tilt. In these situations, we also have favored a short (12 cm) main body with planned ipsilateral iliac extension. There may be some benefit to placing the iliac extension with the wire bowed as well.

SUMMARY

Proximal seal is critical to success during EVAR. Suprarenal fixation does not increase seal and has not been shown to increase the applicability of EVAR to aneurysms with shorter necks without compromising results. Furthermore, there is no evidence to suggest that suprarenal fixation is more effective than active infrarenal fixation in the prevention of migration. The design of the GORE EXCLUDER Device ensures secure immediate fixation and facilitates the performance of technical maneuvers that maximize seal and may prove useful in aneurysms with challenging proximal neck anatomy. ■

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Accurate Deployment With the EXCLUDER Endograft

Modifications to deployment techniques can offer additional treatment options to patients with challenging anatomy.

BY WILLIAM D. JORDAN, JR, MD

Endovascular repair of abdominal aortic aneurysms (AAAs) has emerged as a widely accepted, minimally invasive approach to treating this life-threatening condition. Although four different types of endografts are commercially available to treat AAAs, each graft varies with regard to profile, fixation mechanism, graft material, deliverability, and deployment accuracy. The GORE EXCLUDER endograft (W. L. Gore & Associates, Flagstaff, AZ) offers the advantage of small sheath deliverability with accurate deployment, particularly in tortuous pararenal aortas or short proximal aortic necks. Most grafts can be deployed easily and accurately in normal anatomy with a straight segment of infrarenal aorta. The EXCLUDER graft offers the same accuracy without the additional step of unsheathing for deployment. Instead, a delivery sheath is first inserted with a well-matched dilator to secure a position for graft deliverability. After the graft is delivered, the sheath is withdrawn, but the graft is not immediately deployed. Instead, the graft can be repositioned after additional angiography confirms the origin of the renal arteries. Finally, the graft is deployed by pulling the deployment suture that secures it on the delivery catheter. The original design of the graft included a rapid pull of the suture for deployment; however, field experience and the natural curiosity of surgeons has led to the modification of this technique to further enhance the accuracy of deployment, particularly in irregular aortic necks that may be tortuous or short.

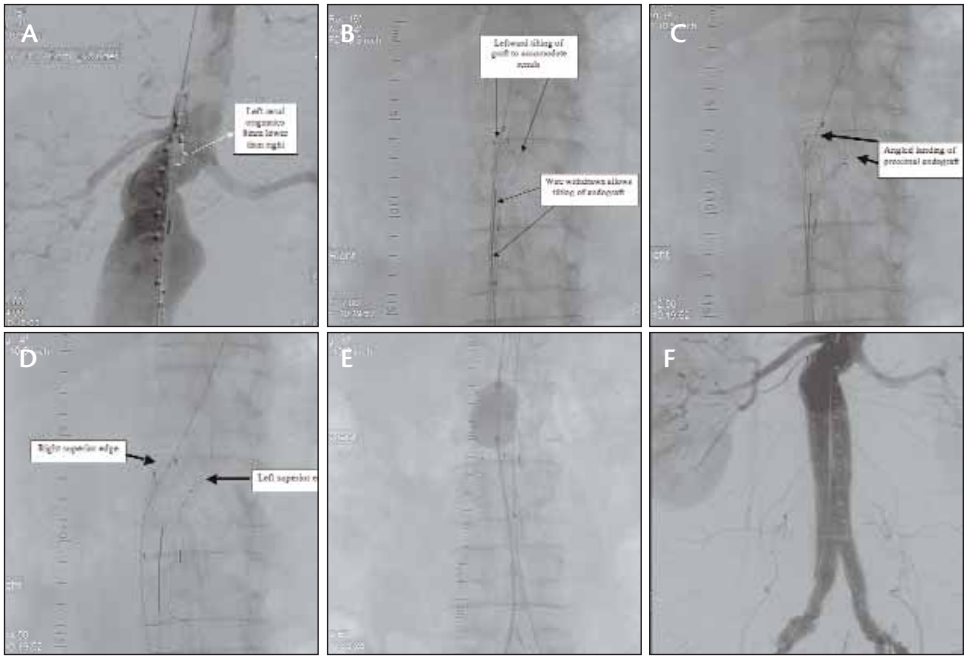

Figure 1. Tortuous proximal neck with the left renal origin lower than the right; the endograft is positioned in the centerline of the aorta accentuating the angle of the aortic neck (A). The stiff wire is withdrawn to allow the endograft to tilt toward the left wall of the aorta, and slow deployment is used to make fine accurate adjustments (B). The left edge of the endograft lands 8 mm lower than the right to compensate for the different levels of the renal origins (C). The completed proximal graft deployment reflects the angled anatomy below the renal arteries (D). Modeling of the proximal seal zone with a compliant balloon (E); the top of the endograft has conformed well to the proximal aortic wall with no endoleak (F).

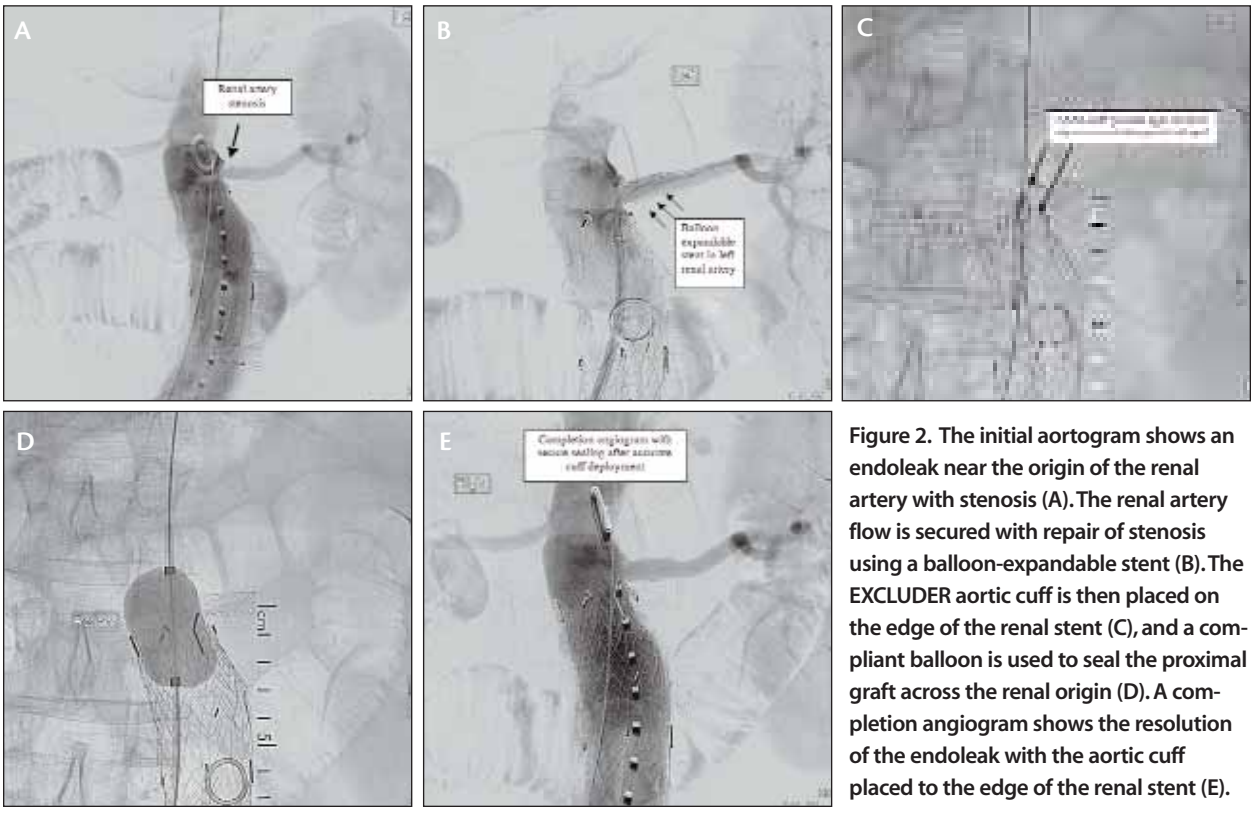

Figure 2. The initial aortogram shows an endoleak near the origin of the renal artery with stenosis (A). The renal artery flow is secured with repair of stenosis using a balloon-expandable stent (B). The EXCLUDER aortic cuff is then placed on the edge of the renal stent (C), and a compliant balloon is used to seal the proximal graft across the renal origin (D). A completion angiogram shows the resolution of the endoleak with the aortic cuff placed to the edge of the renal stent (E).

KEYS FOR ACCURATE GRAFT DEPLOYMENT

Most patients who are denied endovascular aneurysm repair have inadequate proximal aortic necks relative to short landing zones, tortuous anatomy, or large necks. Although large-diameter necks generally require a large-diameter graft, these other problems can often be solved by accurate deployment techniques. Again, most grafts can be accurately deployed in straight anatomy with healthy landing zones and easy access vessels. However, consider two difficult scenarios. First, if the seal zone below the renal arteries is short (<15 mm), the accuracy of deployment becomes especially critical. The graft must be placed as close as possible to the renal artery origins without impeding flow to the kidneys. Due to the occasional anterior angulation of the aorta just below the renal arteries, a cranial tilt of the fluoroscopy imaging unit is often required. Additionally, an oblique angle (usually left anterior oblique) is often required to better visualize the origin of the renal arteries that often do not originate in a perpendicular fashion of the straight axis of the aorta. Once the appropriate imaging angle has been ensured, the graft can be deployed in the position intended by the operator.

SLOW DEPLOYMENT

Although the traditional deployment for the EXCLUDER Device is a rapid pull of the suture, slow deployment techniques can be used to ensure accuracy and make fine adjustments as the graft flowers from the delivery catheter. The deployment suture can be slowly withdrawn at 1 to 2 seconds per click to slowly release the proximal end of the stent graft. As the graft slowly opens, fine adjustments can be made with subtle cranial and caudal movements by the operator. However, due to the downward orientation of the anchoring barbs on the proximal aspect of the endograft, cranial movement is safer in placing the graft on the edge of the renal orifice. That is to say, it is safer to initiate the slow deployment slightly distal to the renal ostia and then advance the graft cranially to place it at the more proximal location. Also, subtle rotation can be used to position the graft so that one side may land higher than the other during slow deployment. This rotation can be particularly helpful when rotating the serrated portion of the graft up to a renal stent or prepositioned balloon (see the Endowedge technique).

Next, the graft can be controlled relative to a tilt at the proximal sealing zone. The graft is mounted on the delivery catheter and creates a bias of the graft to the ipsilateral leg. If the aorta is oriented in a straight fashion with a healthy

long neck below the renals, these fine adjustments of the deployment technique are not needed. However, when the neck is short and the renal arteries may be originating at separate levels from the aorta, a tilted or slanted orientation may offer more seal zone for the graft (Figure 1A). When those renals are uneven, the graft should be oriented toward the higher renal with the contralateral limb oriented toward the lower renal. With slow deployment, the proximal portion of the graft will deploy approximately 2 to 4 mm lower on the opposite wall compared to the ipsilateral wall, where the main catheter is oriented on the aortic wall due to the stiff deployment wire (Figure 1B). If there is difficulty placing the endograft on the side of the higher renal artery because the stiff wire is causing the graft to "hug" the opposite aortic wall, the stiff wire can be withdrawn (while the graft remains in place) to be bent at 60° to 90° before reinsertion. This bent portion of the wire will then tend to push the graft on the opposite wall or in the orientation of the higher renal artery. Next, the slow deployment method is used to allow for the angled orientation of the proximal graft (Figure 1C and D). A compliant balloon can be used to seal the proximal end of the graft, even in a tortuous aorta, with a good final angiographic result (Figure 1E and F).

RENAL SUPPLEMENTATION WITH A RENAL STENT

At times, the short proximal neck requires accurate visualization of the renal ostia to maximize the seal zone. If there is renal artery stenosis present, placement of a renal stent prior to the graft deployment can improve visualization for accurate deployment. With a renal stent in place through the renal origin and some subtle protrusion into the aortic lumen (2–3 mm), the graft can be slowly deployed slightly inferior to the stent and then pushed slowly and cranially to buttress against the stent (stent motion can usually be detected). The scalloped edges on the proximal edge of the endograft can be oriented so that the stent rests in the valley portion of the proximal endograft. Considering the 3- to 4-mm variation between the peaks and valleys of the proximal endograft, this wedging can create more seal zone on the aortic wall next to the renal ostium. Additionally, if a stent is not needed, an angioplasty balloon can be inflated into the ostium of the renal artery, and the same slow deployment technique can be utilized to wedge the graft against the balloon. Even after main body deployment, an aortic cuff can be deployed with improved accuracy when renal adjuncts are added. Figure 2 demonstrates a proximal type 1 endoleak that was successfully treated with an aortic cuff. First, a balloon-expandable stent was used to treat a renal artery stenosis (Figure 2B). The cuff was then advanced and nudged against the stent to ensure complete seal distance up to the level of the renal arteries (Figure 2C). A compliant balloon placed across the renal artery origin was used to mold the aortic cuff just below the renal stent (Figure 2D), and a complete seal was achieved, with resolution of the endoleak (Figure 2E).

ADVANTAGES OF RECOVERABLE DEPLOYMENT WITH REPOSITIONING

Even in the most experienced hands, proximal graft deployment can sometimes be inaccurate. A proximal cuff is most often utilized to obtain complete seal if the deployment is distal to the renal arteries and an endoleak is present. If the graft is placed too proximally and renal artery occlusion occurs, additional maneuvers (distal repositioning, renal stenting, or renal bypass, etc.) are usually required. However, if the graft could be recaptured or constrained for repositioning, additional cuffs or extraordinary measures might not be required.

Specifically, if additional imaging can be done after an initial deployment but before firm sealing of the graft, the operator could then reposition the graft to seal at the desired position. Such adjustments offer an additional benefit when treating a challenging proximal neck. The adjunctive maneuvers, including securing the renal ostium with a balloon or stent, could be used if the proximal seal was marginal. Also, the operator could create a variable rotation for a tilted landing in a tortuous proximal neck to accommodate variable renal artery origins with a recoverable endograft.

CONCLUSION

Although the EXCLUDER endograft offers some distinct advantages with the sheath delivery system and the options of fast or slow deployment, further modifications of an endograft may offer more treatment options in patients with challenging anatomy. These listed deployment techniques can offer expanded treatment horizons for the difficult anatomic patient. More modifications of endografts may give the implanting surgeon better security for a long-term seal and patient protection from aneurysm rupture. ■

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Aortic Neck Diameter Measurements for EVAR Are Device Specific

Implications of intima-to-intima proximal aortic neck wall measurements for sizing GORE EXCLUDER stent grafts.

BY MANISH MEHTA, MD, MPH

To date, there are no standardized criteria for evaluating abdominal aortic neck morphology and performing accurate measurements during endovascular aneurysm repair (EVAR). Although CTA with and without 3D reconstruction with transverse, anterior-posterior, and centerline measurements are routinely used and are considered acceptable for preoperative planning, there remains a substantial interobserver variability with regard to aortic neck diameter measurements obtained by this method.[1] Adding to this complexity are findings demonstrating that progressive aortic neck expansion is often observed during mid-term and long-term follow-up after EVAR and can lead to type I endoleak from the proximal fixation site with, and sometimes without, stent graft migration, resulting in an increased need for secondary interventions. The natural history of aortic neck morphology and size remains poorly defined, and there are several factors that have been implicated in aortic neck dilatation and elongation, including aggressive stent graft oversizing at the time of implantation and the natural course of progressive aortic aneurysmal disease.[2-4]

When it comes to evaluating and sizing aortic neck diameters while planning for EVAR, measurements vary depending on the aortic neck wall thickness and whether they are calculated from aortic neck adventitia-to-adventitia (outer wall measurements) or intima-to-intima (inner wall measurements). Currently available FDA-approved stent grafts can be divided into two categories: (1) stent grafts that require aortic neck diameter measurements from intima-to-intima and (2) stent grafts that require aortic neck diameter measurements from adventitia-to-adventitia. The GORE EXCLUDER stent graft (W. L. Gore & Associates, Flagstaff, AZ) uses intima-to-intima inner wall measurements.

METHODS

To better understand the implications of inner wall measurements versus outer wall measurements, we conducted a study comparing the aortic neck diameter inner wall to aortic neck diameter outer wall measurements in patients who were treated as part of the pivotal trial (1999–2004) that led to the FDA approval of the GORE EXCLUDER stent graft. Prospectively collected CTA data, with axial and 3D reconstructions images (M2S, Lebanon, NH) from the EXCLUDER Device 1999 to 2004 pivotal trial, were analyzed retrospectively. Aortic neck diameters were measured from raw CTA data using a standardized approach. The aortic neck was defined as the nonaneurysmal cylindrical aorta beginning just distal to the lowermost renal artery and extending 15 mm caudal.

Figure 1. Variability between inner wall and outer wall measurements.

A standardized approach was defined, and the maximum aortic neck diameter was measured perpendicular to the centerline axis: (1) the first measurement was obtained at just below the lowermost renal artery; (2) the second measurement was obtained at 15 mm caudal to the first measurement; and (3) measurements were obtained at both locations from intima-to-intima (inner wall measurements) and from adventitia-to-adventitia (outer wall measurements) (Figure 1A and 1B). The size of the GORE EXCLUDER main body diameter (23 vs 26 vs 28.5 mm) was then compared to the inner wall and outer wall measurements. Statistical analysis was conducted using ANOVA, and $P<.05$ was considered significant.

TABLE 1. COMPARISON OF THE EXCLUDER STENT GRAFT MAIN BODY SIZE TO THE AORTIC NECK INNER WALL AND OUTER WALL MEASUREMENTS

N	EXCLUDER Stent Graft (Main Body)	Mean Inner-to-Inner Wall Diameter	SD	Mean Outer-to-Outer Wall Diameter	SD	*P* Value
61	23 mm	19.5 mm	1.17	23 mm	1.67	<.001
57	26 mm	21.5 mm	1.04	25.5 mm	1.65	<.001
53	28.5 mm	23.2 mm	1.62	26.8 mm	1.69	<.001

The mean difference between outer wall and inner wall aortic neck diameters in all patients was 3.83 mm (SD, 1.12 mm; P<.001).

FINDINGS

1. There is substantial variability in aortic neck inner wall and outer wall measurements. The mean difference in outer wall aortic diameter measurements versus inner wall aortic diameter measurements was 3.83 mm (standard deviation [SD], 1.12 mm; $P<.001$) (Table 1). This accounts for aortic wall thickness.

2. The mean difference across all aortic neck diameters was 3.83±1.12 mm and was not statistically different among the three groups of stent grafts (23 vs 26 vs 28.5 mm) (Figure 2).

3. Stent graft oversizing of 10% to 20% to accommodate the proximal aortic neck is considered acceptable when planning for EVAR, and when using the GORE EXCLUDER stent graft, oversizing should be based on the inner wall measurements and not the outer wall measurements. Our analysis of the CTA data would indicate that when inner wall intima-to-intima measurements were used, the mean GORE EXCLUDER device main body oversizing in the pivotal trial was approximately 17% (between the expected 10%–20%) and is the standard of care. However, the same CTA data, when analyzed for outer wall adventitia-to-adventitia measurements, indicate the mean GORE EXCLUDER device main body oversizing to be approximately 2%. These findings imply that if outer wall measurements are used during preoperative planning for the GORE EXCLUDER stent graft, the customary 10% to 20% oversizing might not be necessary.

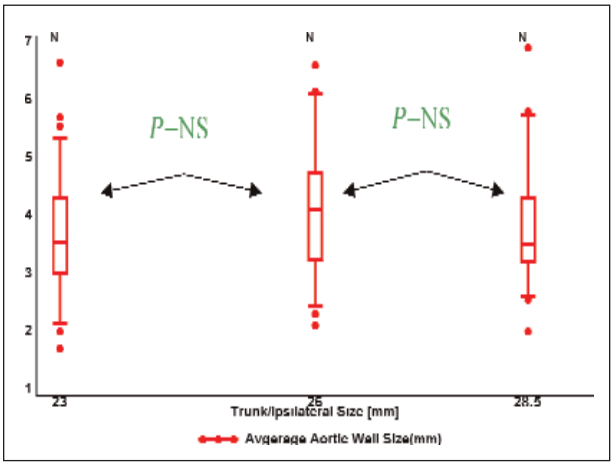

Figure 2. Mean difference between outer wall and inner wall aortic neck diameters was 3.83±1.12 mm, which was not statistically different among groups.

CONCLUSION

Based on these findings, the take-home message is simple. When planning to use the GORE EXCLUDER stent graft, the proximal aortic neck measurements and oversizing should be based on the inner wall intima-to-intima measurements and not the outer wall measurements. ■

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The GORE EXCLUDER® AAA Endoprosthesis goes where you want it — and stays where you put it. Comparisons of recent peer-reviewed publications regarding Endovascular Aneurysm Repair (EVAR) migration rates reinforce why leading physicians choose the GORE EXCLUDER® Device. For additional migration data, we invite you to review the *2008 Annual Clinical Update* at goremedical.com.

Migration Rates in Peer-Reviewed Studies

Device	Publications[1]	Total # of Patients	Average Migration[2]
GORE EXCLUDER® AAA Endoprosthesis	***J Endovasc Ther*** 2005;12(4):417-429 [808 patients; 1.24%] ***Ann Vasc Surg*** 2007;21(3):328-338 [428 patients; 0.23%] ***Vasc Endovasc Surg*** 2005;39(1):47-54 [211 patients; 0.95%] ***J Vasc Surg*** 2006;44(4):694-700 [72 patients; 0.0%] ***J Cardiovasc Surg*** 2004;45(4):293-300 [676 patients; 0.89%] ***J Vasc Surg*** 2007;45(5):885-890 [235 patients; 0.0%]	2,430	0.78%
Medtronic® TALENT Abdominal Stent Graft	***J Vasc Surg*** 2006;43(2):277-284 [165 patients; 4.24%] ***J Endovasc Ther*** 2002;9(5):652–664 [40 patients; 17.50%] ***J Vasc Interv Radiol*** 2006;17(6):973-977 [68 patients; 4.41%] ***J Vasc Surg*** 2004;40(6):1074-1082 [237 patients; 13.0%] ***J Endovasc Ther*** 2005;12(4):417-429 [1,579 patients; 3.0%]	2,089	4.55%
Cook® Medical ZENITH FLEX® AAA Endovascular Graft	***J Cardiovasc Surg*** 2008;49(3):311-316 [66 patients; 4.55%] ***J Vasc Surg*** 2005;42(3):392-401 [53 patients; 1.89%] ***J Endovasc Ther*** 2005;12(4):417-429 [1,988 patients; 0.80%] ***J Endovasc Ther*** 2007;14(2):115–121 [366 patients; 0.0%] ***J Endovasc Ther*** 2007;14(1):23–29 [67 patients; 1.49%] ***J Endovasc Ther*** 2007;14(5):625–629 [100 patients; 0.0%]	2,640	0.80%

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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 – 26 mm (US), 19 – 29 mm (outside the US) 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 GORE EXCLUDER® Extender Endoprostheses (Aortic and Iliac) 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:** There are no known contraindications for these devices. Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and adverse events. Products listed may not be available in all markets pending regulatory clearance. [1]Peer-reviewed studies with ≥ 40 patients with 12-month minimum follow-up. [2]Migration is defined as caudal movement ≥ 10 mm.

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GORE EXCLUDER® AAA ENDOPROSTHESIS

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