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Endovascular TODAY

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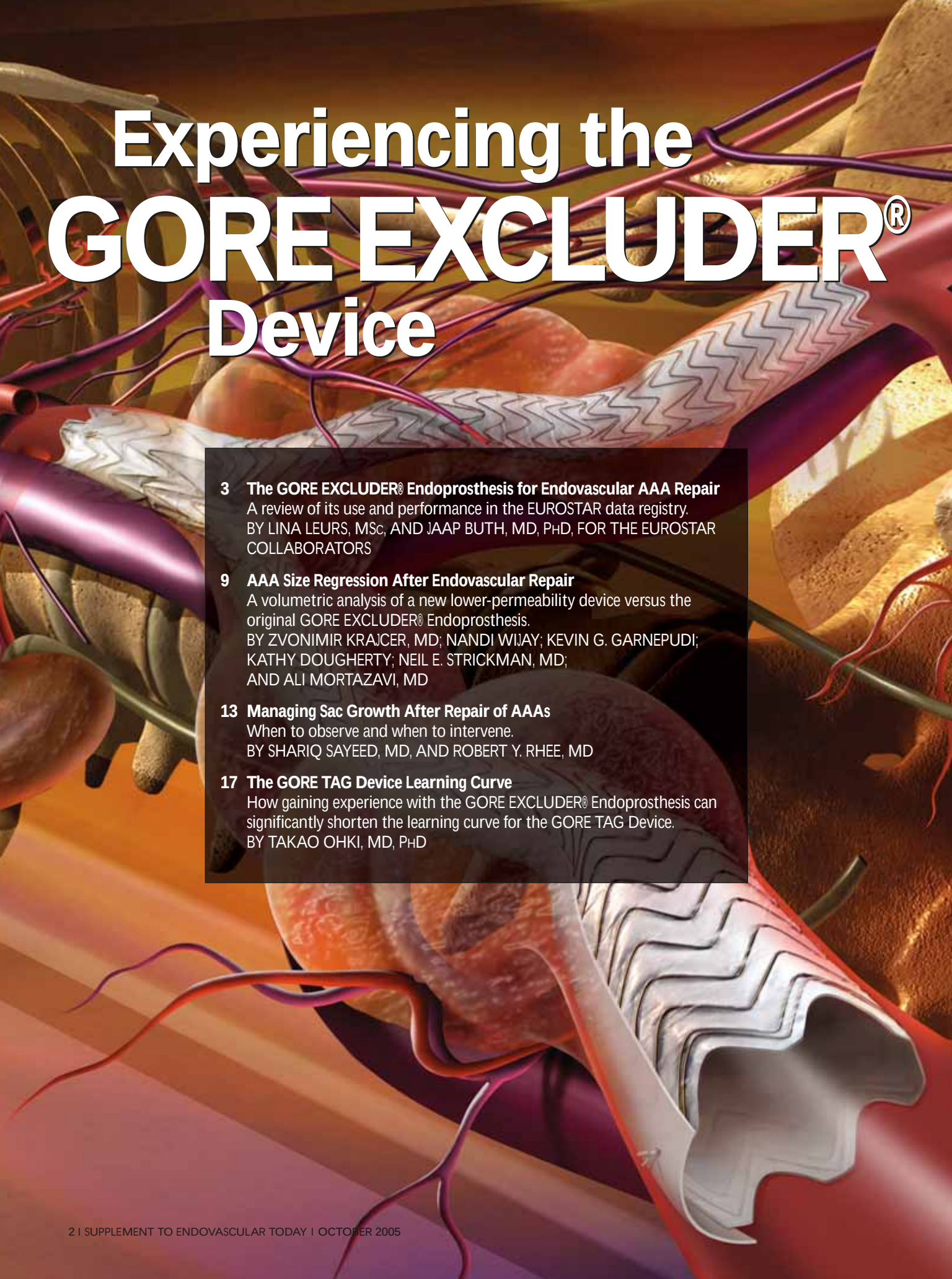
Experiencing the GORE EXCLUDER® Device

Observations, data, and analysis in the successful treatment of AAAs.

Experiencing the GORE EXCLUDER® Device



The GORE EXCLUDER® Endoprosthesis for Endovascular AAA Repair

A review of its use and performance in the EUROSTAR data registry.

BY LINA LEURS, MSc, AND JAAP BUTH, MD, PhD, FOR THE EUROSTAR COLLABORATORS

Endovascular repair of abdominal aortic aneurysms (AAAs) was introduced by Juan Parodi in 1990.[1] After the early experience with a variety of prototype stent grafts, many commercial devices have come into use during the last decade. Although some of the earlier manufactured endografts have been withdrawn because of device failure, a number of other devices have proven to be efficacious and remained in use for several years now. The EUROSTAR Registry is a project that started in 1996 as a voluntary pan-European multicenter registry for data collection and assessment of stent graft treatment for aortic aneurysm repair.

The devices that are currently included in the registry are the AneuRx (Medtronic, Santa Rosa, CA), EXCLUDER (W. L. Gore & Associates, Flagstaff, AZ), Fortron (Cordis, a Johnson & Johnson company, Miami, FL), Talent (Medtronic), and Zenith (Cook Incorporated, Bloomington, IN). Withdrawn devices that are no longer in use include EVT/Ancure (Guidant Corporation, Indianapolis, IN), Lifepath (Edwards Lifescience, Irvine, CA), Stentor (MinTec, Bahamas), and Vanguard (Boston Scientific Corporation, Natick, MA). Recently, a comprehensive EUROSTAR analysis of the mid- and long-term outcomes of the different stent grafts, including withdrawn devices, was published to compare the weaknesses and strengths of the different makes.[2] The conclusion of this assessment was that no clearly superior stent graft could be identified. Desirable characteristics and outcomes were dispersed among the different stent grafts. This report was also performed on the basis of EUROSTAR data. However, this assessment differs from the previous communication in that only current devices were considered. In this analysis, the GORE EXCLUDER Endoprosthesis is compared to the other current stent graft systems.

METHODS

Between July 1999 and July 2000, 801 patients underwent endovascular abdominal aortic aneurysm repair (EVAR) with the GORE EXCLUDER Endoprosthesis (EXCLUDER group). The procedures were performed in 25 centers. Procedures with stent grafts of other brands

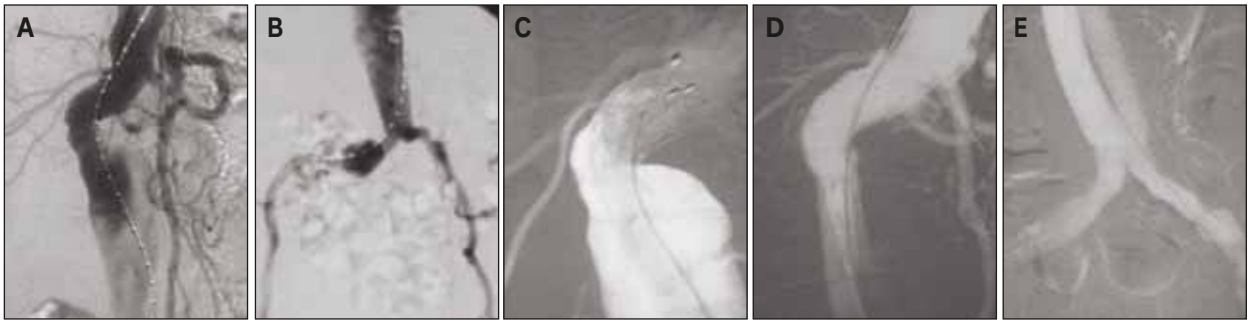


Figure 1. Angiogram of an AAA with an angulated neck (A,B); during and after proximal deployment of the GORE EXCLUDER Device. Note the adaptability of the stent graft (C,D). Image after complete deployment of the stent graft (E).

were performed in 136 centers (other device group). Baseline and follow-up data were prospectively entered by participating centers into the database. After 2003, data entry was primarily via a Web site (www.eurostar-online.org), which is hosted by KIKA-medical® (Nancy, France). The protocol of the EUROSTAR registry and standardized variables of patients, risk factors, and aortoiliac morphologic details have been described previously.[3-5] Briefly, there is no outside audit of source data in participating centers, or a core laboratory for the evaluation of radiographic studies. All data are checked on logic and consistency by data managers and algorithms of the automated data entry system.

The GORE EXCLUDER Endoprosthesis is a modular endovascular system composed of one trunk-ipsilateral leg piece and one contralateral leg piece. Additional aortic and iliac artery extension cuffs are available in similar sizes as the aortic and iliac endograft components, respectively. Each stent graft is made of expanded polytetrafluoroethylene (ePTFE) graft material bonded to the inside of a nitinol exoskeleton with a PTFE film. Each device comes on a delivery catheter, which may be introduced over a .035-inch guidewire through an 18-F (for the major endograft component) and a 12-F sheath (for the contralateral iliac leg). Deployment of the device follows after pulling a deployment line, allowing rapid self-expansion of the stent graft (Figure 1).

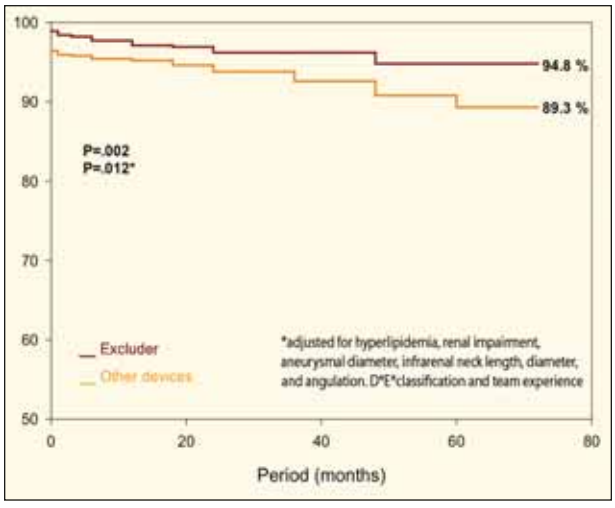


Figure 2. Freedom from major adverse events (aneurysm-related death, conversion, or rupture).

Differences in findings between study groups were assessed by X^2-tests for discrete variables and by Wilcoxon rank sum test for continuous variables. Time-dependent outcomes (after the first postoperative month) were subjected to regression analysis, with adjustment for relevant factors. All statistical analyses were performed with SAS Statistical Software (version 6.12, SAS Institute, Inc., Cary, NC).

TABLE 1. PREPROCEDURAL PATIENT CHARACTERISTICS

	EXCLUDER Device N=801 (14%)		Other Devices N=4,922 (86%)		*P* Value
	n	*(%)*	*n*	*(%)*	
Age at Operation (mean [SD])	72.3	(7.7)	72.4	(7.6)	NS
Male Gender	743	(92.8)	4,632	(94.1)	NS
ASA ≥ 3	383	(47.8)	2,398	(48.7)	NS
Unfit for Open Surgery*	198	(24.7)	1,271	(25.8)	
SVS – ISCVS risk factors					
Hyperlipemia	410	(51.2)	2,091	(42.5)	<.0001
Cardiac events/disease	465	(58.1)	2,938	(59.7)	NS
Renal function impairment	120	(15)	944	(19.2)	.0046
Pulmonary disease	351	(43.8)	2,050	(41.7)	NS
Team Experience (30 cases/year)	84	(10.5)	671	(13.6)	.0147

*As indicated by the managing physician.

TABLE 2. MORPHOLOGY OF THE AORTOILIAC SEGMENT

	EXCLUDER Device N=801 (14%)		Other Devices N=4,922 (86%)		*P* Value
	n	*(%)*	*n*	*(%)*	
Measurements					
Neck diameter (mean [SD])	22.6	(2.5)	24.1	(3.2)	<.0001
AAA diameter (mean [SD])	57	(10.4)	59.0	(11.1)	<.0001
Neck length (mean [SD])	28.5	(11.6)	26.9	(12)	<.0001
Severe Angulation					
Neck	214	(26.7)	1,074	(21.8)	.0021
Aneurysm	93	(11.6)	552	(11.2)	NS
R iliac artery	260	(32.5)	1,545	(31.4)	NS
L iliac artery	290	(36.2)	1,798	(36.5)	NS
D*E* classification of iliac artery#	87	(10.9)	688	(14)	.0168

D to E indicates the EUROSTAR classification with progressive aneurysmatic involvement of the iliac arteries.[3]

RESULTS

Eight hundred one patients were recorded in the EXCLUDER group and 4,922 patients were recorded in the other device group. Analyses determined minimal differences in 24 baseline characteristics that were compared between the two patient groups. A comparison of some preprocedural variables is presented in Table 1. Aortoiliac anatomic assessment demonstrated somewhat more favorable characteristics in the EXCLUDER group, in that a smaller neck diameter, a smaller maximum aneurysm diameter, and a larger neck length were observed in this group (Table 2). In contrast, the neck was more frequently severely angulated in the EXCLUDER group, indicating more complex vascular anatomy.

Procedural and 30-Day Details

The volume of blood loss, the duration of the procedure, and the admission time were significantly less in patients who received a GORE EXCLUDER Endoprosthesis, indicating a smoother procedure (Table 3). Procedural and 30-day details involved a lower perioperative mortality in the EXCLUDER group than in other devices (1.4% vs 3.4%; Table 4). The incidence of device-related complications with introduction and deployment in the EXCLUDER group was half of the incidence in the other device group (Table 4). Endoleaks at completion angiography, irrespective of the type of endoleak, were less frequent in the EXCLUDER group.

Outcome at Follow-Up

The follow-up periods were comparable in the two study groups (19 and 20 months in the EXCLUDER and other device groups, respectively). Type II endoleaks were more frequently observed in the EXCLUDER group. The

TABLE 3. OPERATIVE DETAILS AND HOSPITAL STAY

	EXCLUDER Device N=801		Other Devices N=4,922		*P* Value
	n	*(%)*	*n*	*(%)*	
Blood Loss (mL, mean [SD])	418	(532)	628	(833)	<.0001
Duration of the Procedure (minutes, mean [SD])	113	(47)	132	(58)	<.0001
Length of Hospital Stay (days, mean [SD])	4.1	(4)	6	(8)	<.0001

incidences of stenoses and thromboses of device limbs in the EXCLUDER group were only one-third of the incidence in the other device group (Table 5). Migration of the stent graft was less frequent in patients treated with the GORE EXCLUDER Device. However, when migration of the proximal device extremity was singled out, the statistical difference disappeared because of the small patient numbers.

Aneurysm growth and shrinkage were similar in the two study groups. It is of note that the threshold for aneurysm change as used in the EUROSTAR is greater (8 mm) than in most other studies (5 mm) to allow for an inherently larger interobserver variability. The infrarenal neck demonstrated significantly less frequent dilatation (greater than 4 mm) in the EXCLUDER group than in the other devices group.

No statistical differences were observed in conversion to open repair, post-EVAR rupture, all-cause death, and aneurysm-related death (Table 6). However, when major adverse events during follow-up, consisting of aneurysm-related death, conversion, and rupture were combined, the composite rate was significantly lower in the EXCLUDER group (Figure 2).

DISCUSSION

Comparison of clinical outcome with the use of various endovascular devices is difficult because of inherent differences in selection criteria for patients in whom a specific

TABLE 4. EARLY (30-DAY) COMPLICATIONS

	EXCLUDER Device N=801		Other Devices N=4,922		OR* (95% CI)	*P* Value*
	n	*(%)*	*n*	*(%)*		
Endoleak						
Type I to III	19	(2.4)	305	(6.2)	0.42 (0.26 – 0.67)	.0003
Type II	57	(7.1)	528	(10.7)	0.61 (0.45 – 0.81)	.0008
Complications Intraoperatively						
Device-related complications†	18	(2.3)	250	(5.1)	0.42 (0.26 – 0.70)	.0008
Failure to complete procedure††	5	(0.6)	75	(1.5)	0.48 (0.19 – 1.20)	NS
Arterial complications	22	(2.8)	183	(3.7)	0.75 (0.47 – 1.20)	NS
Complications From Operation to Discharge						
Systemic complications#	57	(7.1)	585	(11.9)	0.60 (0.45 – 0.80)	.0005
Procedure and device related$	8	(1)	147	(3)	0.38 (0.18 – 0.79)	.0089
Access site and lower-limb complications	43	(5.4)	320	(6.5)	0.84 (0.60 – 1.18)	NS
Early Death	11	(1.4)	166	(3.4)	0.49 (0.26 – 0.93)	.0278
Early Conversion to Open Surgery	2	(0.3)	54	(1.1)	0.27 (0.07 – 1.13)	NS
Early Rupture	-		2	(0.04)	-	NS

*Adjusted for hyperlipidemia, renal impairment, aneurysmal diameter, infrarenal neck length, diameter, and angulation, D*E*classification and team experience.[3]

†Differences consisted of difficulties with device placement, dissection of the access artery and limb disconnection or occlusion.

‡Procedures aborted or converted to open surgery.

#Differences consisted of cardiac, pulmonary and bowel complications.

$Differences consisted of limb thrombosis, transfemoral and extra-anatomic interventions.

TABLE 5. COMPLICATIONS DURING FOLLOW-UP

Major Complication	EXCLUDER Device N=790		Other Devices N=4,740		HR* (95% CI)	*P* Value*
	n	*(%)*	*n*	*(%)*		
Findings at Assessment						
Type I to III endoleak	57	(7.2)	407	(8.6)	1.00 (0.75 – 1.33)	NS
Type II endoleak	139	(17.6)	578	(12.2)	1.50 (1.24 – 1.83)	<.0001
Stenosis/thrombosis	10	(1.3)	172	(3.6)	0.40 (0.21 – 0.76)	.005
Graft migration	7	(0.9)	121	(2.6)	0.40 (0.18 – 0.92)	.0318
Proximal migration	5	(0.6)	88	(1.9)	0.47 (0.19 – 1.17)	NS
Secondary Intervention	39	(4.9)	337	(7.1)	0.73 (0.52 – 1.03)	NS (.08)
Transfemoral	30	(3.8)	246	(5.2)	0.76 (0.51 – 1.14)	NS
Transabdominal	8	(1)	64	(1.4)	0.94 (0.44 – 2.00)	NS
Extra-anatomic	5	(0.6)	55	(1.2)	0.59 (0.24 – 1.51)	NS
Neck Dilatation ≥ 4 mm†	152	(10.3)	1,326	(33)	0.76 (0.64 – 0.90)	.0016
AAA Growth ≥ 8 mm‡	54	(6.8)	313	(6.6)	1.02 (0.75 – 1.28)	NS
AAA Shrinkage ≥ 8 mm‡	293	(37.1)	1,928	(40.7)	0.94 (0.81 – 1.09)	NS

*Adjusted for hyperlipidemia, renal impairment, aneurysmal diameter, infrarenal neck length, diameter, and angulation, D*E*classification and team experience.[3]

†n=642 for the EXCLUDER group, n=4,024 for the group of the other stent graft brands.

‡n=713 for the EXCLUDER group, n=4,487 for the group of the other stent graft brands.

device is considered. These differences are associated with device characteristics. For instance, some devices can be used in large-diameter necks. The GORE EXCLUDER Endoprosthesis aims for the regular neck size, which is reflected by the observed smaller mean neck diameter in this study. Moreover, the GORE EXCLUDER Device has a rapid deployment mechanism with a pull wire, and this may cause some users to prefer to use it in patients with sufficient neck length rather than short necks. This assumption seems confirmed by longer necks in the EXCLUDER group.

Device adaptability to angulation may differ between available stent grafts due to the structure, dimensions, and material of the stent frame and the fabric covering. The construction of the GORE EXCLUDER Endoprosthesis provides an extensive adaptability to neck angulation, and this was in agreement with the high proportion of patients with angulated necks that were treated in this group.

Finally, a flexible, small-caliber delivery system combined with a simple and reliable expansion mode may explain the low incidence of early device-related complications. A lower incidence of early systemic complications, including first-month death, which was noted in the EXCLUDER category, often reflects a patient category with lower medical risk. However, the recorded general health indicators, including ASA class, unfitness for open procedure, and cardiac risk class were similar in the two study groups. An exception was the incidence of renal impairment, which was higher in the other device group.

Results During Mid-Term Follow-Up

The number of type I and III endoleaks combined was observed with a similar frequency during follow-up in the study groups. The reason why a higher incidence of type II endoleaks occurred in the EXCLUDER group can only be speculated on (ie, PAOD, ABI >.87, thrombogenic differences, wall properties of the stent graft).

Concern has been expressed in previous publications that the shrinkage rate of EXCLUDER Device-treated aneurysms may be less pronounced and less frequent than in other devices.[6-8] The higher incidence of type II

TABLE 6. MAJOR ADVERSE EVENTS OVERALL (EARLY AND LATE)

Major Complication	EXCLUDER Device N=801 (14%)		Other Devices N=4,922 (86%)		HR* (95% CI)	*P* Value*
	n	*(%)*	*n*	*(%)*		
Death	60	(7.5)	596	(12.1)	0.78 (0.59 – 1.02)	NS (.07)
AAA-related death	16	(2)	202	(4.1)	0.61 (0.37 – 1.03)	NS (.07)
Conversion	9	(1.1)	113	(2.3)	0.61 (0.31 – 1.22)	NS
Rupture	2	(0.3)	25	(0.5)	0.73 (0.16 – 3.23)	NS

*Adjusted for hyperlipidemia, renal impairment, aneurysmal diameter, infrarenal neck length, diameter, and angulation, D*E*classification and team experience.[3]

endoleaks in the present EXCLUDER group may be a possible explanation for this finding. However, in the present series, no difference in aneurysm growth or shrinkage was observed. This may be because of the larger threshold (8 mm instead of the more commonly used 5 mm) to indicate growth or shrinking. The greater threshold is used by EUROSTAR to allow for a greater interobserver variability.

W. L. Gore & Associates has responded to the concerns that some of the aneurysm expansions were not clearly caused by endoleaks, but perhaps by microleaks of the ePTFE fabric. Modifications were made in the endograft material to reduce the permeability. In this analysis, none of the two observed cases with ruptures was associated with non–endoleak-related sac growth. One patient experienced aneurysm rupture after 12 months of follow-up without aneurysm expansion or endoleak. The cause of the rupture could not be determined. The second patient had a rupture of his aneurysm after 2 years associated with a known but untreated type I endoleak.

Dilatation of the proximal neck is a predisposing factor for proximal device migration.[9] Neck dilatation had a lower incidence in the EXCLUDER group. This finding may explain the low device migration rate compared to other stent grafts. However, patient numbers with migration were quite small and lack statistical significance.

CONCLUSION

The GORE EXCLUDER Endoprosthesis represents a stent graft of the most recent generation. Its low-profile delivery system and simple deployment mechanism account for a low incidence of procedure-related intraoperative and postoperative complications. A significantly lower combined major event rate represented a satisfactory late outcome. ✯

Lina Leurs, MSc, is an epidemiologist working at the EUROSTAR Data Registry Center, Department of Surgery, Catharina Hospital, Eindhoven, The Netherlands. She has disclosed that she holds no financial interest in any product or manufacturer mentioned herein. Ms. Leurs may be reached at +31 40 2397 163; eurostar@iea.nl.

Jaap Buth, MD, PhD, is the Executive Director of the EUROSTAR Data Registry Center, Department of Surgery, Catharina Hospital, Eindhoven, The Netherlands. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Buth may be reached at +31 40 2397 163; jaap.buth@cze.nl.

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AAA Size Regression After Endovascular Repair

A volumetric analysis of a new lower-permeability device versus the original GORE EXCLUDER® Endoprosthesis.

BY ZVONIMIR KRAJCER, MD; NANDI WIJAY; KEVIN G. GARNEPUDI; KATHY DOUGHERTY; NEIL E. STRICKMAN, MD; AND ALI MORTAZAVI, MD

Endovascular exclusion of abdominal aortic aneurysms (AAAs) has clearly shown to decrease operative morbidity, patient discomfort, length of hospital stay, the need for intensive care monitoring, blood loss, and the time needed to return to normal activities.[1-4] The popularity of endovascular aneurysm repair (EVAR) has resulted in FDA approval of several stent graft devices, of which four remain commercially available in the US (AneuRx, Medtronic/AVE, Santa Rosa, CA; EXCLUDER, W. L. Gore & Associates, Flagstaff, AZ; Zenith, Cook Incorporated, Bloomington, IN; and PowerLink, Endologix, Inc., Irvine, CA).

As mid- and long-term results emerge, device-specific clinical success and outcomes remain under investigation. Clinical success after EVAR is defined as complete absence of endoleak (type I, II, III, or IV), absence of aneurysm rupture, open surgical conversion, and absence of aneurysm expansion.[5]

It has been previously stated that the effectiveness of the AAA exclusion is correlated to decrease in aneurysmal sac volume.[1] It has also been documented that in certain instances after successful deployment of a stent graft, patients still experience an increase in aneurysmal sac volume unrelated to an endoleak.[2,6,7] This phenomenon is due to endotension.[7] In addition, the increase in endotension has resulted in the rupture of aneurysms after EVAR in previous clinical trails.[4,5]

Previous researchers have shown that, in some instances, a viscous fluid known as hygroma is found to be present in permeable stent grafts.[8] During *in vitro* studies, it has also been shown that the type of the material of the stent graft has a direct correlation on the likelihood of plasma permeability.[3] In July 2004, Gore released an updated version of the EXCLUDER device to reduce graft permeability and prevent the probability of hygroma formation (Figure 1).

Several recent reports have shown that change in aneurysm size after EVAR is device specific.[8,9] Aneurysm shrinkage has been reported to be more pronounced with thicker endograft materials than with more permeable materials. The long-term follow-up data have revealed higher rates of shrinkage for the Ancure (Guidant Corporation, Indianapolis, IN) than for the AneuRx and the GORE EXCLUDER Endoprosthesis.[9] Specifically, the GORE EXCLUDER Device has been associated with aneurysm sac expansion in the absence of endoleak.[10] Several mechanisms have been suggested, including a local fibrinolytic state and transgression of fluid through the thin polytetrafluoroethyl-

Figure 1. The GORE EXCLUDER bifurcated stent graft system.

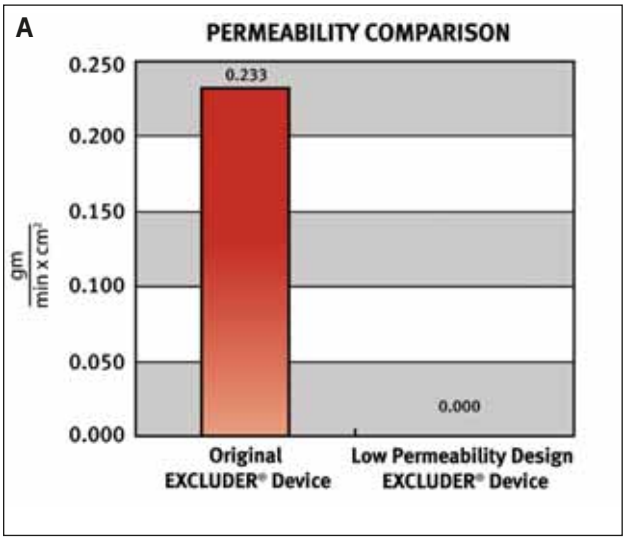
TABLE 1. MAXIMUM AORTIC ANEURYSM DIAMETER AND AORTIC ANEURYSM VOLUME BEFORE AND 1 YEAR AFTER EXCLUSION WITH THE GORE EXCLUDER DEVICE

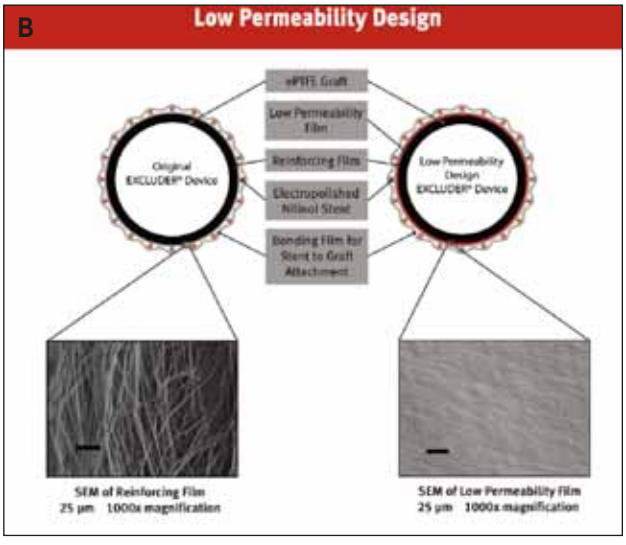
	Original N=34	Low Permeability N=15	*P* Value
Baseline mean AAA diameter (mm)	53.8 ± 10.6	56.4 ± 12.7	NS
Mean AAA diameter at 12 months (mm)	50.7 ± 6.8	50.15 ± 7.3	NS
Baseline mean AAA volume (mL)	175.7 ± 106.1	135.3 ± 65.3	NS
Mean AAA volume at 12 months (mL)	183.24 ± 113.7	121.5 ± 45.3	< .03
Mean change in AAA volume (mL)	7.54 ± 0.62	-13.8 ± -0.73	= .001

ene graft material. Risberg et al[11] have documented a presence of aneurysm sac hygroma at the time of open repair. Absence of endoleak with aneurysm sac expansion implies incomplete exclusion and systemic pressurization or endotension. Endotension, however, and its significance on long-term outcome remain unclear and therefore treatment is controversial.

THE STUDY

In an effort to resolve this problem, in June 2004, Gore modified material of the EXCLUDER Device to reduce its permeability (Figure 2 A,B). This was done with the intention to alleviate the problem of aneurysm sac enlargement. Recent evaluation at the Texas Heart Institute of the original and new low-permeability design EXCLUDER Devices





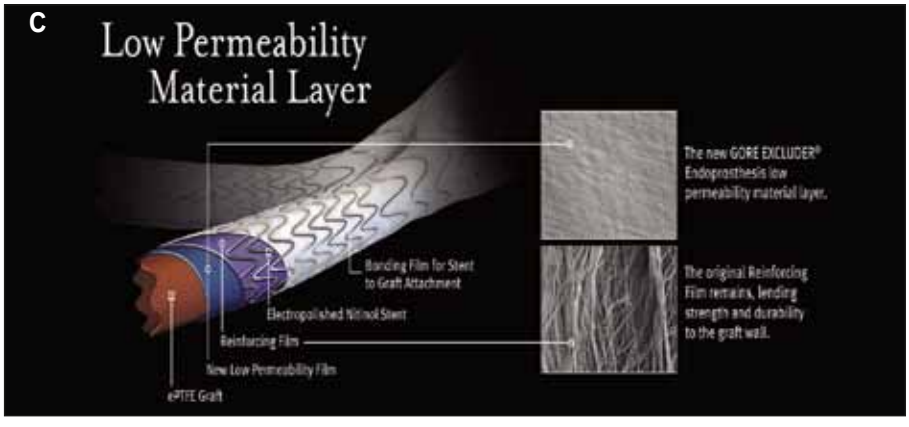


Figure 2. The permeability and structure of the original GORE EXCLUDER Endoprosthesis compared to the new enhanced fabric design (A). A schematic of the new low-permeability design (B). The new lower-permeability graft design to reduce the potential of serous fluid movement through the graft wall (C).

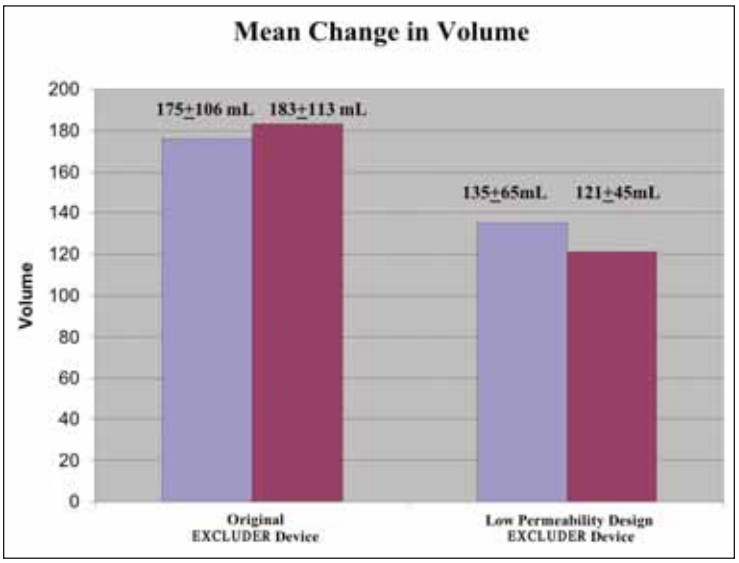


Figure 3. The bar graph shows the baseline AAA volume (blue) and the volume 1 year later (purple).

revealed interesting and encouraging findings.

From November 2002 through June 2004, 101 consecutive patients (group 1) underwent endoluminal AAA repair at our institution with the original GORE EXCLUDER Endoprosthesis. In July 2004, the improved and lower-permeability stent graft material was available at our institution. From July 2004 until June 2005, 125 consecutive patients (group 2) underwent EVAR with the updated system.

Patients returned for follow-up CT scan at 30 days, 6 months, and annually thereafter. The presence or absence of endoleak was determined by CT scans with and without contrast. Patients with persistent branch flow endoleaks at 6-month observation underwent angiography and, when feasible, coil embolization of the culprit branch vessels.

Only the patients with baseline and 1-year follow-up CT scans that were performed at our institution, who showed no evidence of type I to III endoleaks, were included in this study. group 1 comprised 34 patients and group 2 comprised 15 patients.

Image Processing, Measurement Methods, and Statistical Analysis

CT scans were performed on HiSpeed Advantage RP or Lightspeed VCT (General Electric, Milwaukee, WI) equipment, using standard acquisition protocols. Postprocessing CT data included multiplanar and three-dimensional reconstructions. Reformatted CT slices orthogonal to the center of blood flow in the aorta and the iliac arteries were measured. The volume within the aortic wall, including thrombus, the blood flow lumen, calcification, and the stent graft was obtained using the volume measurements with Vitrea 2 software (Vital Images, Minneapolis, MN). For each data point, changes in diameter and volume were determined and compared to corresponding baseline measurements. Diameter and volume changes greater than or equal to 5 mm and 10%, respectively, were considered significant.

Results

From the data collected at our institution, it is evident that the low-permeability design of the GORE EXCLUDER Endoprosthesis is significantly more effective in preventing aneurysm maximal enlargement when compared to the original design (Table 1). The long-term follow-up revealed that the patients with the new stent graft design had a greater decrease in aneurysm volume than the patients with the original design (Figure 3). This preliminary information in a limit-

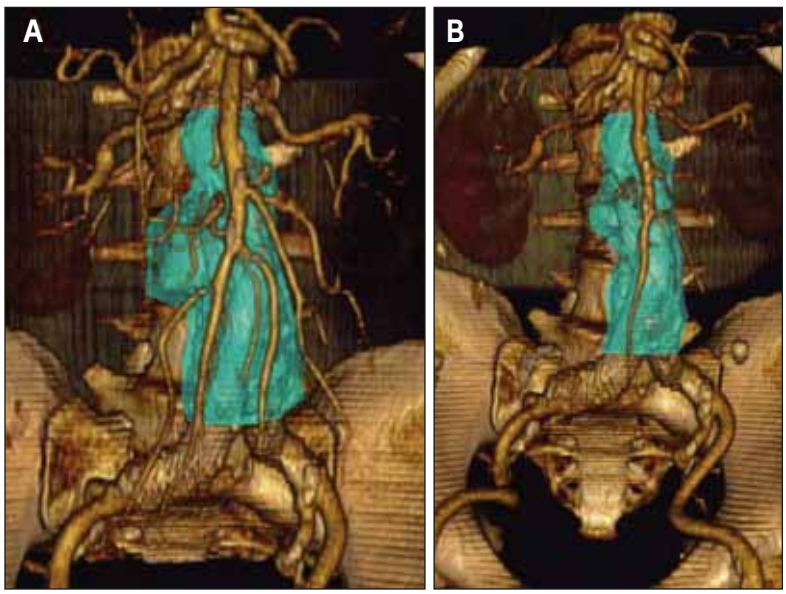


Figure 4. Baseline volume measurements prior to endovascular exclusion with a GORE EXCLUDER Endoprosthesis (A). Volume measurements 1 year later in the same patient (B).

ed number of patients suggests that the new expanded polytetrafluoroethylene material is less permeable to fluids than the old material (Figure 4 A,B), and therefore reduces the occurrence of hygroma and endotension after AAA exclusion.

Note that although the maximum diameter of the aneurysm in patients with the old type of stent graft decreased, their overall volume of the aneurysmal sac increased. In accordance to previous researchers, our observations revealed that the maximum diameter measurements are not a valid parameter for detecting aneurysmal sac enlargement after endografting.[1] Although these preliminary data are encouraging, further studies in a larger number of patients with longer follow-up are needed to determine the long-term benefits of the new-generation GORE EXCLUDER Endoprosthesis in preventing AAA enlargement after endoluminal repair. ✯

Zvonimir Krajcer, MD, is Co-Director of Peripheral Vascular Disease Service, Texas Heart Institute, St. Luke's Episcopal Hospital, Houston, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Krajcer may be reached at (713) 790-9401; ZvonkoMD@aol.com.

Nandi Wijay is a student in a pre-med program at the University of Texas, Houston, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Kevin G. Garnepudi is a student in a pre-med program at Tulane University, New Orleans, Louisiana. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Kathy Dougherty is Clinical Coordinator, Peripheral Vascular Program, Texas Heart Institute, St. Luke's Episcopal Hospital, Houston, Texas. She has disclosed that she holds no financial interest in any product or manufacturer mentioned herein.

Neil E. Strickman, MD, is a cardiologist with St. Luke's Episcopal Hospital, Houston, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

Ali Mortazavi, MD, is a cardiologist with the Texas Heart Institute, St. Luke's Episcopal Hospital, Houston, Texas. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein.

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Managing Sac Growth After Repair of AAAs

When to observe and when to intervene.

BY SHARIQ SAYEED, MD, AND ROBERT Y. RHEE, MD

Since Parodi et al[1] reported their initial experience with endovascular repair of abdominal aortic aneurysms (AAAs), endovascular exclusion of aneurysmal disease has become the treatment of choice. The enthusiasm for this minimally invasive treatment is driven primarily because of its shorter hospital stay, decreased anesthetic risk, and reduced recovery period compared to conventional open AAA repair. However, the primary goal of endovascular aneurysm repair (EVAR), to prevent death from aneurysm rupture, is the same as open repair. Worldwide interest in EVAR has spurred closer scrutiny and ongoing surveillance of EVAR patients' results than had been previously reported for patients after traditional open repair. As true long-term results become available, unique problems related to EVAR such as device integrity, iliac limb occlusion, migration, and endoleak are being more frequently described.[2] Additionally, enlargement of the aneurysm sac has also been described as a potential shortcoming of EVAR.

THE PROBLEM OF THE AAA SAC

Reduction in the size of the aneurysm sac is considered a sign of successful endograft repair by many vascular surgeons.[3] Shrinkage of the aneurysm sac is presumed to imply exclusion of the aneurysm from the circulation and subsequent decrease of systemic blood pressure within the sac. Sac expansion, conversely, implies persistent pressurization and incomplete exclusion of the sac. Failure to totally exclude the aneurysm from continued flow and pressurization is defined as an endoleak and remains a significant limitation of endoluminal repair. A widely accepted classification for endoleaks differentiates endoleaks into categories depending on the origin of flow into the aneurysm sac.[4-6] If an endoleak is visualized, but the source cannot be determined despite thorough imaging modalities, the endoleak is categorized as an endoleak of undefined origin. Even in the absence of any discernable endoleak, the aneurysm sac may continue to enlarge and is referred to as endotension.[7,8]

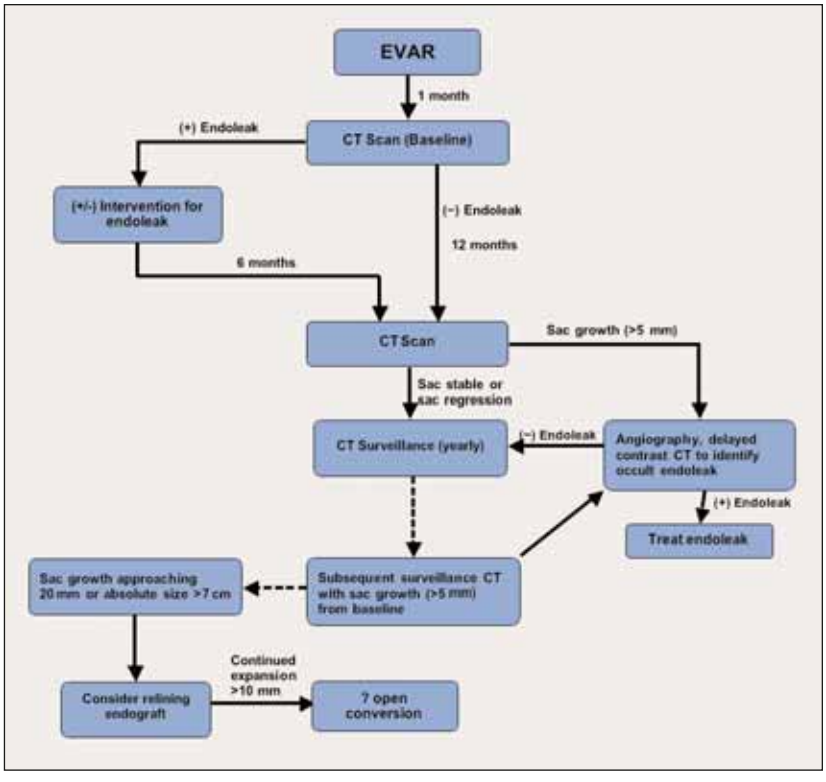

Figure 1. Algorithm for sac enlargement surveillance and treatment. Note this algorithm applies to patients who have sac enlargement without evidence of endoleak.

What Happens When the AAA Sac Continues to Enlarge?

The significance of endotension and related aneurysm sac growth remains unclear, and its treatment thus far remains a topic of controversy.[9] Several mechanisms for sac enlargement without endoleak have been postulated. One common explanation for persistent pressurization of an AAA sac includes the presence of a "low flow" endoleak that is below the limits of detection by current imaging modalities. Other hypotheses for endotension involve the transmission of pressure through thrombus at or around the ends of attachment zones of the prosthesis.[10]

Still another explanation for aneurysm sac enlargement in the absence of an endoleak is theorized to be secondary to intrasac fluid accumulation. This has been termed "sac hygroma,"[11] and may involve the activation of coagulation and fibrinolytic cascades via several inflammatory mediators. The result is a highly viscous gelatinous fluid in the aneurysm sac. An alternative theory involves the direct transmission of fluid through the graft wall.[8] This transmission has been hypothesized as occurring secondary to graft porosity or even possibly microleaks via suture points between graft fabric and stent scaffolding. Nonetheless, whatever the cause of endotension, the end result is potential sac growth.

Clinical Significance of Sac Enlargement Without Evidence of Endoleak

Opinions differ widely on the clinical significance of sac enlargement in the absence of any discernable endoleak. This phenomenon is infrequent, and most reported cases of sac enlargement are concurrent with endoleaks. Sac enlargement has been found in 20% of patients with type I or III endoleak, in 10% of patients with type II endoleak, and in only 1% to 5% of patients with no endoleak.[12,13] Nonetheless, these incidences of endotension increase the risk of aneurysm rupture. However, some investigators believe that aneurysm enlargement after EVAR may not be associated with an increased risk of aneurysm rupture.[14] Yet, other investigators assume that sac size regression is the only indication for aortic stent graft success.[15] Aneurysm rupture, however, has been reported in aneurysms that have decreased in size as well.[15,16]

The risk of aneurysm rupture is hypothesized to depend primarily on the size of the aneurysm, the pressure within the sac, and the force applied to the aneurysm wall.[17] Rupture in the presence of little or no intrasac flow may not result in massive hemorrhage and eventual patient death. A study comparing the clinical scenarios and outcomes of patients with a ruptured AAA after EVAR versus ruptures occurring *de novo* revealed that those patients with a rupture after EVAR were unlikely to present with hypotension and had a markedly lower 30-day mortality rate (0% vs 43%) compared to those with *de novo* ruptures.[18] In addition, most reported cases of secondary open surgical conversion for sac enlargement describe a lack of any visible endoleak or intrasac flow upon opening of the aneurysm sac. The fact remains, however, that continued expansion of the sac can result in dilation of the infrarenal neck or iliac arteries and presumably endanger the integrity of proximal or distal graft attachment zones.

Treatment Recommendations for EVAR Patients Based on Sac Size

There are several therapeutic options for treating an enlarging aneurysm sac in the absence of endoleak. Because the incidences of sac growth after EVAR without endoleak have been infrequent, the literature on possible treatments has been limited to a few case reports and small case series. Nevertheless, some of the described treatment options include close observation, surgical conversion, or sac fenestration.

One treatment option is to simply observe these patients. Supporters of this management decision rely on data showing that sac enlargement, without evidence of type I endoleak or evidence of insecure fixation, has not been shown to be a predictor of rupture.[14] Because aneurysm ruptures have been reported in patients with decreasing, increasing, and stable sizes after endovascular repair, factors other than aneurysm size changes may be primary determinants of aneurysm rupture.[17] Patients undergoing simple observation, however, do require close surveillance with frequent imaging.

Another option is secondary surgical conversion. There have been several case series that recommend open surgical repair for sac enlargements.[19,20] Proponents of this option submit that endotension may result from a missed endoleak that continues to transmit systemic pressure to the aneurysm sac, and thus the risk for rupture is inherent to growth of the sac.[19] A recent consensus meeting was held to survey key issues dealing with endoleaks and endotension,[21] and they concluded that an expanding AAA after EVAR without evidence of endoleak should be repaired surgically or with a new endograft. It should, however, be mentioned that these consensus statements were based on opinion, and many of the consensus statements had only 15 of the 26 experts agreeing on various topics. A summary of clinical series of secondary surgical conversion from 1997 to 2002 revealed a mean perioperative mortality of 23%.[20] Thus,

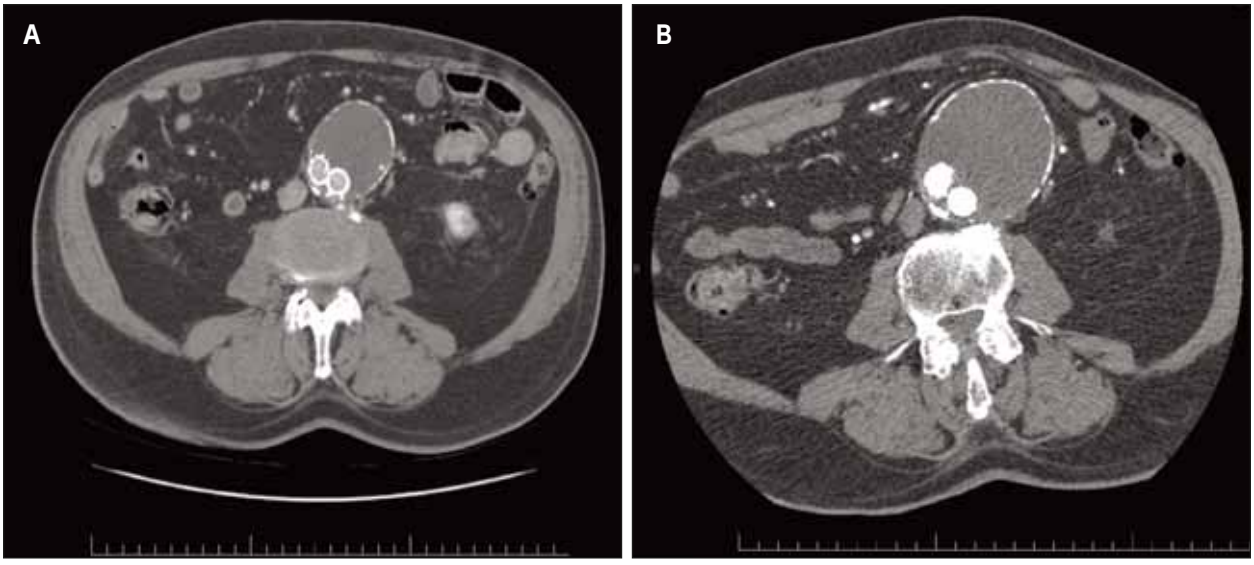

Figure 2. CT scans of patient demonstrating marked increase in sac size from 6 cm to 7.6 cm. Despite further imaging modalities, no endoleak was found. Given the unexplained sac increase, this patient underwent relining of the endograft with two GORE EXCLUDER® (W. L. Gore & Associates, Inc., Flagstaff, AZ) contralateral leg endoprostheses.

the risk of death or severe complication of open surgical intervention may be greater than the risk of close observation.

Another interesting option is laparoscopic fenestration of the aneurysm. The aorta is exposed with a transabdominal, left retrocolic approach.[22,23] The inferior mesenteric artery and lumbar arteries can be clipped and transected if necessary. Subsequently, the aorta is fenestrated and fluid and thrombus are removed from the AAA sac. The fenestration orifice is then closed tightly to prevent possible back bleeding from a persistent feeding vessel. Outcomes of this technique have yet to be summarized; however, in a case series using fenestration for treatment of enlarging sacs, there was a high reoccurrence rate with this technique.[24]

THE UNIVERSITY OF PITTSBURGH APPROACH

Since 1995, more than 1,200 aortic endografts have been placed at the University of Pittsburgh Medical Center. Since 1999, we have performed more than 300 endograft repairs with the GORE EXCLUDER Endoprosthesis. In a long-term surveillance subgroup of approximately 50 patients, we reported a sac enlargement (>5 mm) at 4 years of 37%.[25] So far, this enlargement has not been associated with any known untoward clinical events. At 4-year follow-up, we have had no graft migrations, ruptures, or limb disconnections in this subgroup. Despite the high percentages of sac growth, very few have grown to an alarming degree.

Careful postoperative surveillance is the accepted standard of care after EVAR. Published recommendations for surveillance after EVAR without endoleak suggest screening at 1, 6, and 12 months postoperatively, and then yearly thereafter.[26] Duplex ultrasound and contrast CT are the most important tools for recognizing and following endoleaks or sac growth. At the University of Pittsburgh, all of our EVAR recipients receive a baseline CT at 1 month and then yearly after the procedure (Figure 1). Individuals with an endoleak on their baseline CT will either have endoleak intervention or observation (based on the endoleak). These patients will subsequently receive a CT scan at 6 months to re-evaluate their endoleak.

Individuals with a stable or regressing sac undergo imaging yearly. At this time, there are no established criteria for length of surveillance or criteria for reduction in frequency of surveillance imaging, thus we typically image our patients yearly. For those patients with sac enlargement (>5 mm) without evidence of endoleak on CT, we perform ultrasound and angiography to verify lack of endoleak. If there is no evidence of endoleak, we observe these patients yearly. For patients with sac growth that approaches 20 mm from their baseline CT or expansion to an absolute size of 7 cm, we suggest intervention (either endovascular relining or open conversion) (Figure 2). Much like the findings of Mehta et al, our few open conversions have revealed sac contents

that were gelatinous and yellow in nature, suggesting that graft porosity may play a role in these patients.[27] For patients who require relining, we suggest placing bilateral GORE EXCLUDER contralateral leg endoprostheses (new permeability design), which extend from the previous graft's limb-trunk junction to the native iliac artery, if possible. Only in those patients with very short necks do we recommend the placement of an aortic extension cuff inside the proximal trunk. We believe that most of the transudation of the fluid occurs through the iliac limbs within the AAA sac; therefore, if the main body is mostly within the proximal neck, it is not necessary to reline this region. Finally, for patients who continue to have sac growth despite relining, we suggest open conversion. At this time, only four patients have needed relining, and none have required open conversion. Further research is required into the etiologies, pathophysiologies, and long-term clinical significances of sac enlargement. Treatment is yet undefined and remains challenging, but with long-term follow-up, clues to solving this diagnostic and treatment dilemma should emerge. ✯

Shariq Sayeed, MD, is a Vascular and Endovascular Fellow, from the University of Pittsburgh Medical Center Division of Vascular Surgery, Pittsburgh, Pennsylvania. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Sayeed may be reached at (412) 464-7387; sayeeds@upmc.edu.

Robert Y. Rhee, MD, is Associate Professor of Surgery at the University of Pittsburgh Medical Center Division of Vascular Surgery, Pittsburgh, Pennsylvania. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Rhee may be reached at (412) 623-3333; Rheery@upmc.edu.

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The GORE TAG Device Learning Curve

How gaining experience with the GORE EXCLUDER® Endoprosthesis can significantly shorten the learning curve for the GORE TAG Device.

BY TAKAO OHKI, MD, PHD

The long-awaited GORE TAG Thoracic Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ) for descending thoracic aortic aneurysm repair was approved by the FDA on March 23, 2005. The benefit of any minimally invasive therapy can be measured by the difference in the invasiveness and its associated risks between the standard surgical therapy and the proposed new therapy. In this regard, laparoscopic herniorrhaphy has almost no value in the majority of patients, not because the new therapy was invasive, but because the standard therapy with mesh repair was a very benign procedure and also had an excellent long-term outcome. The acute benefit of endografting for abdominal aortic aneurysms (AAAs) was much more evident, and this has been proven by two randomized trials.[1,2] In this regard, the GORE TAG Device provides the biggest benefit among all endovascular procedures because the invasiveness associated with open thoracotomy, aortic cross-clamping, visceral ischemia, and blood loss was poorly tolerated by many patients who have thoracic aortic pathology. These patients were often elderly, sick, and had severe cardiopulmonary comorbidities.

With the introduction of any new procedure or device, physician training becomes an important issue. The idea behind training and credentialing is to minimize the physicians' learning curve and to ensure that the risk to the patient is kept to a minimum. There are a number of ways to do this, including participation in a society-sponsored training program, industry-sponsored program, and mini-fellowships. In addition, gaining experience in similar procedures or similar devices that are less risky is a reasonable step. For example, it would be unwise to use a self-expanding stent or a rapid exchange system for the first time in the carotid territory. For this reason, both the Guidant (Indianapolis, IN) and the Cordis (a Johnson & Johnson company, Miami, FL) carotid training programs are evaluating and selecting physicians to be trained based on their prior experience with these devices—there is no disagreement with this approach.

Thoracic aortic stenting is another groundbreaking, novel procedure and therefore requires a significant amount of training. Shortening the learning curve to minimize patient risk is an important task for both physicians and manufacturers. Participation in the Gore-sponsored, 1.5-day training program is mandated by the FDA. However, there are also other ways to minimize patient risk. In my experience, familiarity with the GORE EXCLUDER Endoprosthesis has helped significantly with the use of the GORE TAG Device. This article describes some of the similarities between the two devices and the rationale to gain familiarity with the GORE EXCLUDER Device prior to using the GORE TAG Device.

Figure 1. The GORE EXCLUDER Endoprosthesis and the GORE TAG Device. Both systems are constructed from expanded PTFE and a nitinol stent. The resemblance is clear.

Figure 2. The GORE EXCLUDER Endoprosthesis and the GORE TAG Device prior to deployment. Both devices are constrained by a PTFE wrap and can be deployed by pulling the deployment line.

SIMILARITY IN DESIGN OF THE EXCLUDER AND TAG DEVICES

Both the GORE EXCLUDER Endoprosthesis and the GORE TAG Device are made from expanded PTFE combined with a temperature-dependent nitinol stent (Figure 1). Both are constrained by a PTFE sleeve so that they can be delivered through a small sheath (Figure 2). A rip cord style deployment line is used to deploy both stents. Device appearance to the naked eye, as well as fluoroscopic images, clearly show the similarity in device design (Figure 3).

PREPARATION AND DELIVERY OF THE DEVICE

Device preparation is often overlooked. However, poor preparation of devices can lead to significant complications. Both systems require flushing of the sideport in order to exchange the air with saline. Also, a sheath is required for introduction of the endograft, which is unique to Gore endografts. The inner dilator is removed, and the endografts are then introduced through the sheath. Because both systems utilize a non-sheathed deployment system, it is not necessary to introduce the sheath all the way into the proximal landing zone.

HOW THE DEVICE REACTS DURING INTRODUCTION

The flexibility and the torquability of the two devices are very similar. Both have balloon catheter-like flexibility and can negotiate tortuous anatomy incredibly well. There is no other device, either for AAAs or thoracic aortic aneurysms, that has this level of flexibility. Experience with the GORE EXCLUDER Device has given me a good sense of what the GORE TAG Device can do in a challenging situation.

DEPLOYMENT MECHANISM

The deployment mechanisms of the GORE EXCLUDER Endoprosthesis and the GORE TAG Device are very unique and differ radically from other endografts. The key in deploying the GORE EXCLUDER Device accurately includes pulling the deployment line rapidly and aligning the C-arm perpendicular to the aortic neck in cases in which there is an anterior-posterior angulation. The former is somewhat counterintuitive for experienced operators who are not familiar with Gore stent grafts because all other endografts are deployed slowly. As long as these two requirements are accomplished, and as long as the selected size of the GORE EXCLUDER Device is appropriate for the target neck, it deploys extremely accurately.

Early in my experience with the GORE EXCLUDER Endoprosthesis, occasionally I did not pull the deployment line as fast as I should have. Slow deployment will give the aortic flow a chance to push down the endograft and may result in too low a deployment. The key to deploying the GORE TAG Device accurately at the target site is exactly the same as it is for the GORE EXCLUDER Device. It is of paramount importance to hold the catheter stable while pulling the deployment line. Any downward movement of the catheter during this step will lead to caudal migration of the endograft. It is highly recommended that one operator holds the catheter in position while the other pulls the deployment line rapidly (Figure 4). Gaining experience with

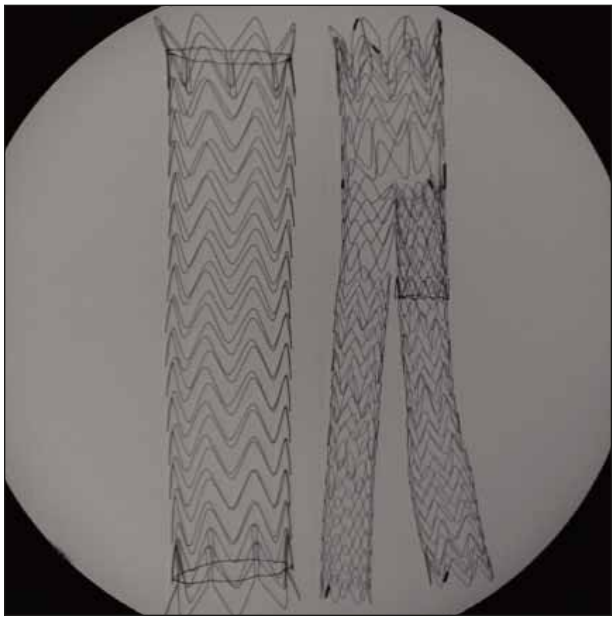

Figure 3. Fluoroscopic images of the GORE EXCLUDER Endoprosthesis and the GORE TAG Device. Fluoroscopic images also resemble each other.

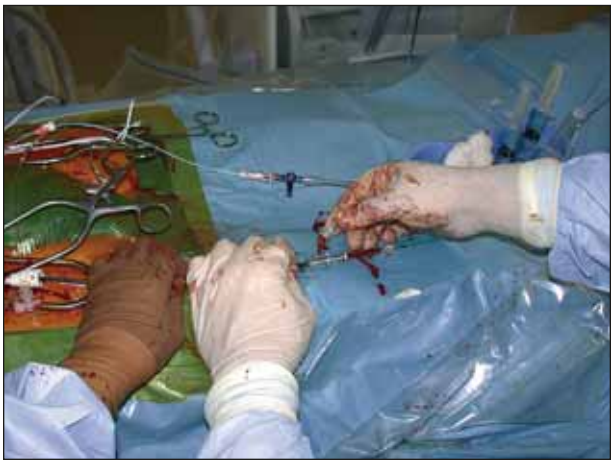

Figure 4. Two-person deployment technique used for both the GORE TAG Device and the GORE EXCLUDER Endoprosthesis.

the GORE EXCLUDER Endoprosthesis has tremendous value in deploying the GORE TAG Device accurately.

INTERPRETATION OF THE COMPLETION ANGIOGRAM

Both the GORE EXCLUDER Endoprosthesis and the GORE TAG Device utilize an ePTFE graft that has a very low porosity. Due to this low porous nature, I have never encountered a type IV endoleak. Interpreting the completion angiogram can sometimes be difficult, especially when there is an endoleak. One needs to determine the origin and the significance of the endoleak. If one is using an endograft other than that made of ePTFE, type IV endoleak should be listed as one of the differentials. Familiarity in interpreting completion angiograms of the GORE EXCLUDER Endoprosthesis will certainly help with TAG Device procedures.

CONCLUSIONS

Thoracic stenting probably carries a higher risk of adverse events than abdominal endovascular aneurysm repair (EVAR). For example, the risk of stroke has been reported at 3% for the TAG Device US pivotal trial, and it was 6% for the Medtronic VALOR trial (Santa Rosa, CA).[3,4] Although TAG Device results are acceptably low compared to that of surgical repair, they are certainly higher than what we expect after abdominal EVAR. Also, the mortality and morbidity rates after acute surgical conversion are expected to be substantially higher compared to abdominal EVAR. Therefore, it appears to be reasonable to gain experience with the GORE EXCLUDER Device in a less-risky setting before undertaking thoracic stenting with the GORE TAG Device. It is analogous to becoming familiar with how the Dynalink stent (Guidant), Wallstent (Boston Scientific Corporation, Natick, MA), or the Precise stent (Cordis) behaves in the periphery before using each sister device (Acculink [Guidant], Carotid Wallstent [Boston Scientific], Precise stent [Cordis]) in the carotid artery.

I have used the GORE EXCLUDER Device extensively for the treatment of AAAs, and this experience has helped me in shortening the learning curve associated with the GORE TAG Device. For those who wish to utilize the GORE TAG Device but have not used the GORE EXCLUDER Endoprosthesis, I believe it is reasonable to first gain experience with the GORE EXCLUDER Endoprosthesis for AAAs. ✯

Takao Ohki, MD, PhD, is Professor and Chief, Division of Vascular and Endovascular Surgery, Montefiore Medical Center, Albert Einstein College of Medicine, New York, New York. He is a consultant for CardioMEMS, Aptus Inc, Gore Carotid program, GE, and Cordis. Dr. Ohki may be reached at (718) 920-4707; takohki@msn.com.

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