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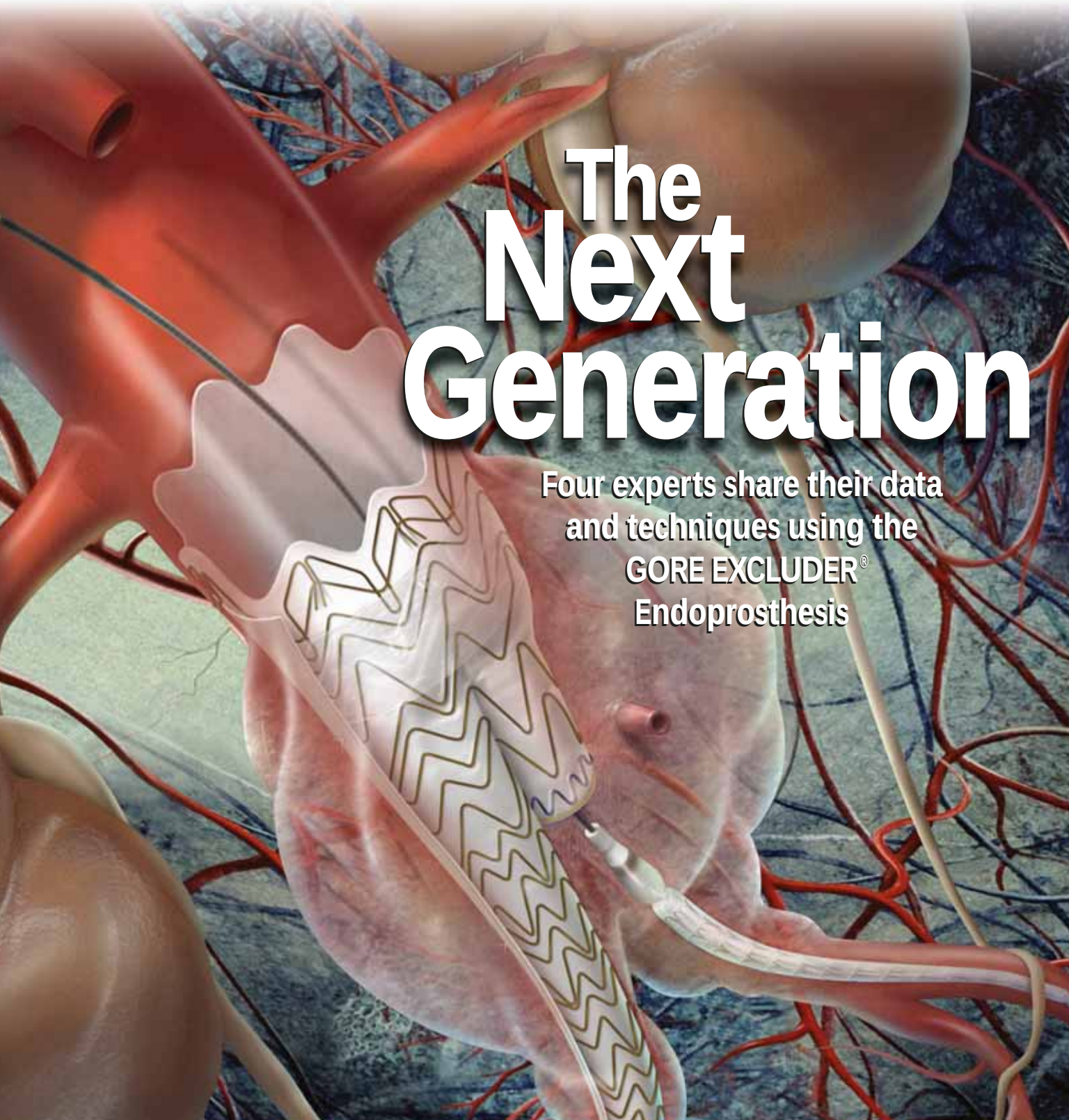


# The Next Generation

## Four experts share their data and techniques using the GORE EXCLUDER® Endoprosthesis

# Contents



# Long-Term Follow-Up With the GORE EXCLUDER® Endoprosthesis at the University of Pittsburgh Medical Center

## Does sac size influence clinical behavior?

BY ROBERT Y. RHEE, MD

Endovascular repair (EVAR) of abdominal aortic aneurysms (AAAs) has currently become the treatment of choice; the majority of the patients with AAA in the US are treated utilizing this technique. The revolution has resulted in the introduction and FDA approval of several commercial devices intended for the treatment of AAA disease. Three endografts, AneuRx (Medtronic/AVE, Santa Rosa, CA), EXCLUDER® (W. L. Gore & Associates, Flagstaff, AZ), and Zenith (Cook Incorporated, Bloomington, IN) are currently available for use.

The ultimate goal of AAA treatment is to prevent death and rupture. Many also consider freedom from AAA sac enlargement after treatment a significant secondary goal. In most cases, after an open AAA repair, the sac is closed tightly around the sewn graft and is essentially obliterated. However, the sac remains after EVAR. Because the sac is still present around the endograft after EVAR, the regression of AAA size was thought to be a marker for successful repair in most early series.[1] The shrinkage of the aneurysm around the endograft is presumed to indicate exclusion of the aneurysm from the circulation and decrease of systemic blood pressure within the sac. On the contrary, expansion of the sac implies persistent pressurization and incomplete exclusion of the AAA sac and has been suggested as an indication for intervention even in the absence of an endoleak.[2]

The therapeutic implications and long-term effects of such changes on the stability of AAA exclusion, however, are not entirely clear. Reduction in AAA size, although intuitively desirable, may itself lead to complications.[2,3] Such morphologic changes over time may alter mechanical forces acting

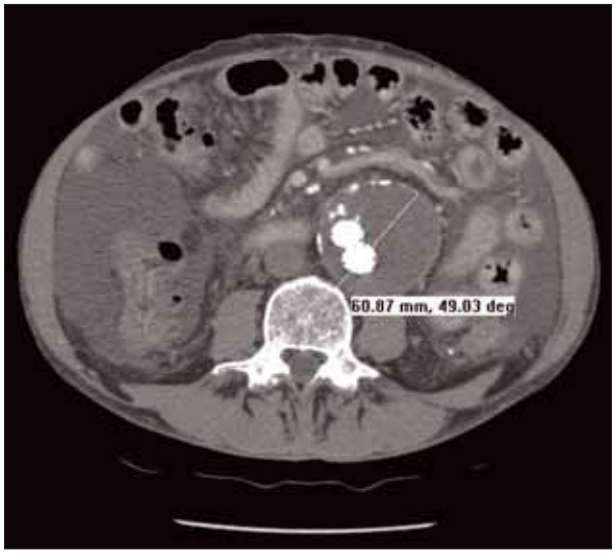



**Figure 1. Computed tomography (CT) of a patient with an implanted EXCLUDER endoprosthesis. Note the digital AAA sac measurement.**

**Figure 2. The EXCLUDER endoprosthesis.**

on the endograft, as suggested by the early experience with modular devices.

As mid- and long-term results are emerging, device-specific clinical outcomes with respect to frequency of endoleak, incidence of device migration, risk of limb thrombosis, and change in aneurysm sac size have been recognized. Each device has been associated with disparate long-term results. The initial reviews of our early endograft experience have suggested that the type of endograft was strongly correlated with the likelihood of sac regression.[4] While shrinkage of the aneurysm sac after EVAR may be desirable, a stable aneurysm has never been linked to any untoward effects.

The purpose of this article is to present the current long-term sac behavior data on the GORE EXCLUDER device at the University of Pittsburgh Medical Center with comparison to other endografts.

## UNIVERSITY OF PITTSBURGH MEDICAL CENTER EXPERIENCE

Since 1995, more than 1,200 endografts have been placed in patients at the University of Pittsburgh Medical Center. The majority of these patients were part of multiphase trials of devices prior to FDA approval. All data were collected prospectively and continue to be accrued according to trial and our institutional protocols. Several studies reviewing sac behavior were published by our group, including the recent review of the EXCLUDER bifurcated endoprosthesis.[1,4-6] This article concentrates on the sac behavior of the EXCLUDER device relative to some of the other available endografts.

All patients underwent rigid preoperative evaluations and follow-up protocols. Spiral computed tomography (CT) images with 2.5-mm collimations were the basis of our sac size analysis. The methodology used for measuring changes in dimension of the aneurysm was in accordance with the SVS reporting standards for endovascular aortic aneurysm repair. Sac size was recorded from CT scans at the initial postoperative, 1- and 2-year follow-up visits. The first postoperative CT obtained within 1 month of treatment was considered the baseline study. AAA size was defined as the minor axis on the largest axial cut of the aneurysm on the two-dimensional CT scan. The minor axis was chosen for reproducibility and to avoid overestimation of AAA size due to tortuosity of the aorta. A computer-aided, digital-measuring tool on a workstation or personal computer (Figure 1) was used to measure the sac size at each follow-up interval (Stentor, Stentor Inc., San Francisco, CA).

A change in AAA size of 5 mm between studies was considered clinically significant. The mean diameter, absolute and percent change, and percentage of patients with a change ≥ 5 mm were considered to be indicators of size regression and were compared at 1 and 2 years. Because patients exhibited an initial reduction in size followed by later enlargement, this phenomenon was referred to as re-expansion. The re-expansion was also considered significant at 5 mm above the smallest measured diameter during follow-up.

The presence or absence of endoleak was determined from CT scans with and without contrast enhancement. Patients with persistent endoleaks after 6 months of observation or with delayed-onset endoleaks underwent angiography and treatment. Those with sac expansion and no demonstrable endoleaks were followed with CT scans at closer 6-month intervals.

## CLINICAL RESULTS AND SAC BEHAVIOR

During the phase II, multicenter trial period from 1999 through 2002, 50 patients underwent EVAR with the EXCLUDER endograft at our institution. Since 1999, we have performed more than 300 endograft repairs with the

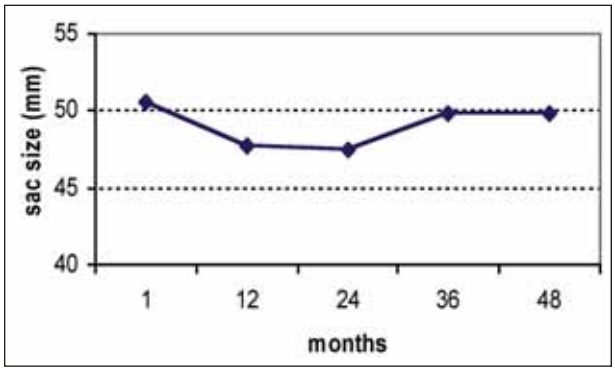



**Figure 3. The mean AAA sac diameter after treatment with the EXCLUDER endoprosthesis.**

EXCLUDER device (Figure 2), but for the purposes of this article, we will concentrate on this early group for long-term evaluation of sac behavior.

There were no perioperative or procedure-related deaths. One patient underwent immediate open conversion when a renal artery was inadvertently covered. There were no limb occlusions, aneurysm ruptures, graft migrations, or limb dislocations. One patient underwent an aortic cuff extender placement at 1 year to reinforce the severely angulated proximal attachment site. Three patients died of renal- and cardiac-related causes before reaching 6-month follow-up. One additional patient was lost to follow-up. The remaining 45 patients had at least 12 months of follow-up and form the basis for this review. Late deaths from unrelated causes occurred in seven patients during follow-up.

Mean AAA sac size at the 1- and 2-year follow-up was significantly reduced when compared to the reference scan. These differences were lost by the 3-year follow-up, suggesting delayed sac growth and re-expansion (Figure 3). With increasing follow-up, a larger proportion of patients displayed an expanding aneurysm sac compared to the baseline sac size. By 4 years, 37% of patients exhibited a significant enlargement of their aneurysm sacs, whereas only 21% showed a significant size reduction. All but one of the enlargements was delayed in onset for at least 3 years after implantation. One sac enlargement was detected at the 2-year follow-up examination. This is in contrast to sac regression, which was usually observed early and noted within 12 months in 13 patients. One patient was even noted to have a significant sac reduction at 1 month compared to the preoperative CT; there was continued shrinkage during the entire follow-up period.

The probability of freedom from sac enlargement as compared to the reference scan was 97% at 2 years, 86% at 3 years, and 57% at 4 years (Figure 4). This method of comparison, however, does not take into consideration those who re-expanded after initial sac regression because their last aneurysm size did not differ significantly from the reference value.

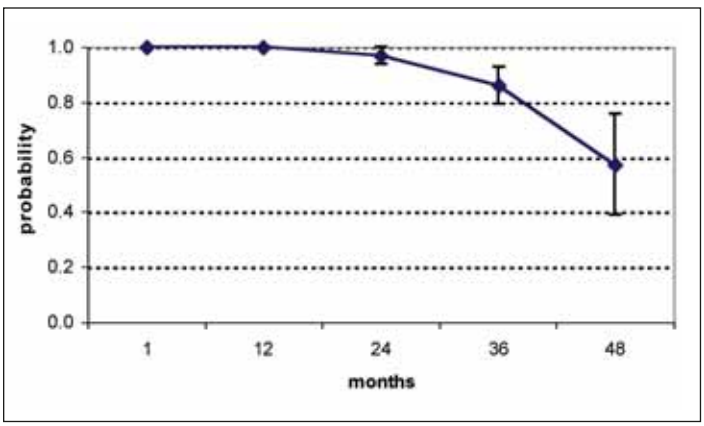



**Figure 4. The probability of freedom from sac enlargement as compared to the reference CT scan.**

**Long-Term Clinical Results of EVAR and Sac Morphology**

Because the primary goal in the treatment of AAA is to prevent aneurysm rupture and death, EVAR with the EXCLUDER endograft was a distinct clinical success. The recent attention on aneurysm sac shrinkage after treatment is unique to endovascular repair. However, some current reports are now showing that sac behavior even after open AAA repair is unpredictable.[7] Regression of AAA size implies exclusion of the aneurysm sac and is considered by many surgeons to be a marker for successful repair. Persistent aneurysm enlargement after EVAR has been suggested as an indication for intervention, even in the absence of perigraft flow. This concept has led to the Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery to include size reduction as a criterion for clinical success.[8] However, AAA regression may have deleterious consequences that have been well documented in the early experience with modular endografts. Many reports have shown that migration of endografts without active fixation, or limb occlusion in devices without support may occur as the aneurysm morphology changes.[2,3]

Aneurysm shrinkage has been reported to be greater with the Ancure (Guidant Corporation, Indianapolis, IN), Talent (Medtronic), and Zenith endografts, despite higher initial endoleak rates (Figure 5).[4,5] However, the long-term results of these grafts are comparable to other grafts, which do not exhibit similar sac regression, such as the GORE EXCLUDER device. Others have also reported that size changes in the presence of an endoleak are variable and unpredictable, and may also be endograft dependent. There are obviously many speculated explanations for the observed differences, but no concrete clinical evidence exists. The factors involved may be biomechanical or biological in nature. Earlier work from our institution indicated that endograft support was important.[4] This was suggested by the fact that AAA sac shrinkage was greater after repair with the unsupported Ancure than the fully supported EXCLUDER endograft. At first glance, this theory may appear less likely after this study because the Talent endograft is classified as fully supported and was associated with significant shrinkage. However, this is not entirely correct because the support of the Talent device is only intermittent with large gaps between some stented segments. Both the

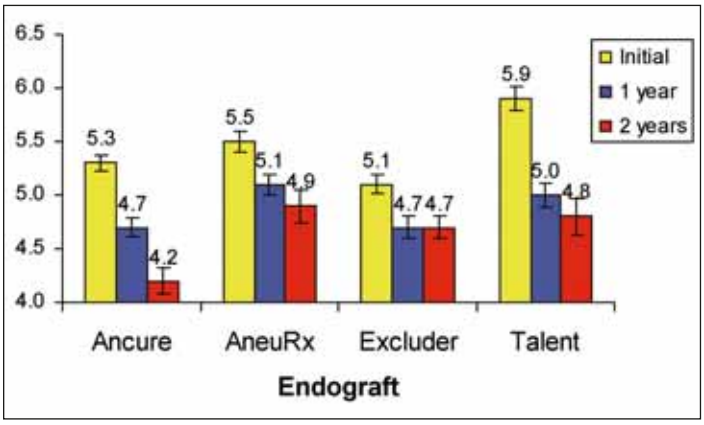
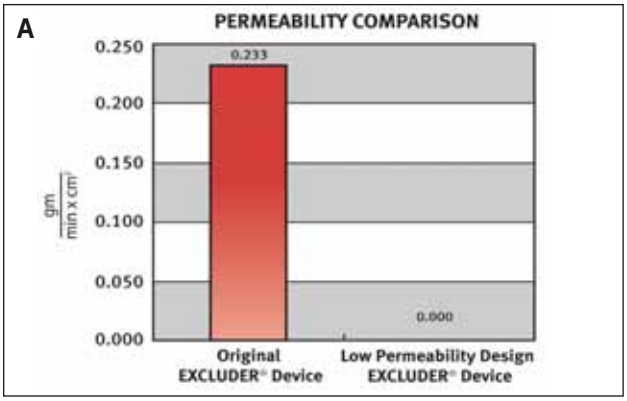



**Figure 5. Two-year sac size differences between various endografts, compared to the reference CT scan.**

AneuRx and EXCLUDER endografts have a more contiguous exoskeleton.

The influence of the exoskeleton may be in the transmission of pulsatile motion to the surrounding thrombus, expediting its resorption. The nature of the fabric, its thickness, and the presence or absence of microleaks may also strongly affect AAA regression. Microleaks at suture points between stent and fabric noted with other endografts have not been demonstrated with the EXCLUDER device, which relies on a bonded film to fix the components rather than manually placed sutures. Because AAA rupture after EVAR is a rare event, it is unlikely that minor size changes can reliably predict rupture. Although shrinkage of the sac may be reassuring, it does not necessarily indicate a complete exclusion because some patients may show regression in the presence of small endoleaks. Reduction in sac size is not universal, and many patients show no significant change over a long period of time, despite adequate exclusion by most methods of assessment. A stable sac is clinically benign and has even been considered desirable in the early endografting experience because it avoids inducing stresses on modular junctions with the changing geometry of a shrinking AAA. Concern during follow-up is usually elicited only by an enlarging sac because it has most often been associated with a significant endoleak and the anticipation of possible rupture. Although infrequent, an enlarging sac without a demonstrable endoleak has been reported on several occasions and has been blamed on "endotension," a state of increased pressure in the excluded sac. The incidence of such enlargement has been quite unusual, representing a small fraction of patients treated by EVAR. Nearly 40% of the patients treated with an EXCLUDER device had a significant enlargement compared to baseline diameter measurement by the fourth follow-up year. So far, this enlargement has not been associated with any untoward clinical events. Our only conversion to date involved a patient with a known endoleak from a set of lumbar arteries in the neck of the sac that could not be treated noninvasively.

Several theories have been proposed, including an active fibrinolytic state that may cause fluid accumulation into the sac. However, the absence of a similar behavior with other endografts in which clot absorption is also probably associated with a fibrinolytic state seems to favor a transgression of fluid through the fabric analogous to the subcutaneous implants of ePTFE in the periphery. Several open conversions in the US and Europe have indicated the presence of highly viscous fluid or gel in the sac without evidence of unrecognized endoleaks. This has been termed as a sac "hygroma" by Risberg.[9] Whether this represents an exudate of fluid through the graft material, or from another source,



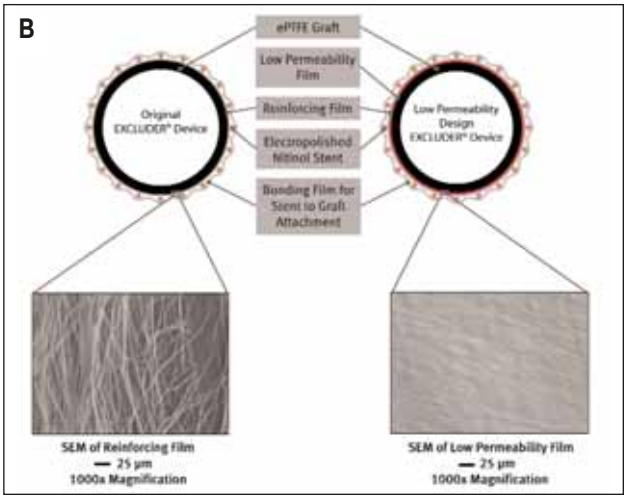




**Figure 6. The permeability and structure of the original EXCLUDER endoprosthesis compared to the new enhanced fabric design (A and B).**

remains to be determined. In a recent report by Dr. May's group, sac enlargement can occur even after open repair with PTFE grafts.[10] However, these patients exhibited a benign course despite persistent sac enlargement, leading the group to advocate conservative management for the patients who have expanding sacs after EVAR using an EXCLUDER graft. The recent modifications to the graft material (low-permeability layer) to reduce permeability should correct this pressing problem (Figure 6). Because this is the most likely theory for the observed sac behavior, this change will most likely resolve this issue.

## CONCLUSIONS

Despite the large number of patients exhibiting enlargement or re-expansion, the clinical results remain quite good at 4 years, with no migration, ruptures, disconnection of limbs, or occlusion. The excellent early results, as well as the good late clinical outcomes, continue to justify the use of this device. In addition, physical characteristics of the device, such as its low profile and flexibility, make it more suitable for certain anatomic situations than other available devices. This institutional report is obviously limited by its relatively small number of patients with 4-year follow-up, but the results mirror the national data. Until long-term behavior of this phenomenon is better understood, we recommend close follow-up of those patients with sac expansion at shorter intervals with CT and other adjunctive imaging modalities to identify and treat endoleaks, if present. Conversion to open repair should only be considered in the presence of an endoleak that is recalcitrant to catheter-based techniques. The new, enhanced EXCLUDER endograft with the low-permeability fabric should significantly stabilize the AAA sac in patients treated with the device ●

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1. Rhee RY, Eskandari M, Zajko A, et al. Long term fate of the aneurysmal sac following endoluminal exclusion of abdominal aortic aneurysms. J Vasc Surg. 2000;32:689-696.
2. Ouriel K, Clair DG, Greenberg RK, et al. Endovascular repair of abdominal aortic aneurysms: device-specific outcome. J Vasc Surg. 2003;37:991-998.
3. Sternbergh III WC, Conners III MS, Tonnessen BH, et al. Aortic aneurysm sac shrinkage after endovascular repair is device-dependent: a comparison of Zenith and AneuRx endografts. Ann Vasc Surg. 2003;17:49-53.
4. Rhee RY, Garvey L, Missig-Carroll N, et al. Does endograft support alter the rate of aneurysm sac shrinkage after endovascular repair? J Endovasc Ther. 2003;10:411.
5. Bertges DJ, Chow K, Wyers MC, et al. Abdominal aortic aneurysm size regression after endovascular repair is endograft dependent. J Vasc Surg. 2003;37:716-723.
6. Cho JS, Dillavou ED, Rhee RY, et al. Late abdominal aortic aneurysm enlargement after endovascular repair with the Excluder device. J Vasc Surg. 2004;39:1236-1241.
7. Williams GM. The management of massive ultra filtration distending the aneurysm sac after abdominal aortic aneurysm repair with a polytetrafluoroethylene aortobiiliac graft. J Vasc Surg. 1998;28:551-555.
8. Chaikof EL, Blankensteijn JD, Harris PL, et al. Ad Hoc Committee for Standardized Reporting Practices in Vascular Surgery of The Society for Vascular Surgery/American Association for Vascular Surgery. Reporting standards for endovascular aortic aneurysm repair. J Vasc Surg. 2002;35:1048-1060.
9. Risberg B, Delle M, Eriksson E, et al. Aneurysm sac hygroma: a cause of endotension. J Endovasc Ther. 2001;8:447-453.
10. Thoo CH, Bourke BM, May J. Symptomatic sac enlargement and rupture due to seroma after open abdominal aortic aneurysm repair with polytetrafluoroethylene graft: implications for endovascular repair and endotension J Vasc Surg. 2004;40:1089-1094.

# Percutaneous AAA Repair With the GORE EXCLUDER® Endoprosthesis

**This percutaneous EVAR technique using local anesthesia has resulted in shorter procedure times and fewer late access-related complications.**

BY JON S. MATSUMURA, MD, AND MARK D. MORASCH, MD

Endovascular aneurysm repair (EVAR) continues to be refined as patient selection, endovascular techniques, and devices improve. Completely percutaneous EVAR is now feasible at many institutions and has small but significant benefits compared to open cutdowns.[1-4] This technique requires familiarity with suture-mediated closure devices, and is facilitated by features of the EXCLUDER® device that permit relatively small introducer sheaths and predictably short procedure times.[5] This article details specific techniques, reviews procedural strategies, and summarizes the clinical benefits.

*"Completely percutaneous, EVAR is now feasible at many institutions and has small but significant benefits compared to open cutdowns."*

## PREOPERATIVE SELECTION

Thin-collimation CT with three-dimensional reconstruction provides the required information to determine anatomic suitability for percutaneous EVAR. This includes the length and diameter measurements for endograft selection, but also assessment of the iliofemoral access arteries. Specific attention is directed to iliofemoral artery size, tortuosity, calcification, and the specific location of the femoral bifurcation. Percutaneous access is now planned in all patients, but early in our experience, we avoided patients with small, calcified iliac arteries; previous femoral dissection; recent use of closure devices; and significant lymphadenopathy. These anatomic challenges require adjustments during the placement of the sheaths and closure devices so as to minimize the chance of conversion to open cutdown.

## PRECLOSE

Suture-mediated closure devices are available in a range of sizes, but for the EXCLUDER device, the sheath size required is 18 F on the ipsilateral and 12 F on the contralateral side. These are larger than the approved 10-F size, so the sutures are placed prior to enlarging the arteriotomy, and this "preclose" technique is an off-label use of the closure device. Specific devices for suture-mediated large vessel closure are under development.

## DETAILED TECHNIQUES

We began the percutaneous EVAR experience by using the suture-mediated closure devices on arteries that were fully exposed surgically. This step develops visual familiarization with the mechanism of the devices, anticipated problems, and the expected resistance during each of the deployment steps.

The skin is shaved immediately prior to the procedure and is prepared using standard techniques for a cutdown. The C-arm is completely draped, and an adhesive, antiseptic-impregnated drape is placed over the groin regions. Local anesthetic is infiltrated in the skin and the expected tract of the introducers.

It is essential that anterior puncture of the common femoral artery be performed and verified. Specifically,

**TABLE 1. COMPARISON OF PERCUTANEOUS ACCESS AND CUTDOWNS**

| | Cutdown (n=35) | Percutaneous (n=47) | *P* |
|---|---|---|---|
| Mean Anesthesia Time (mins) | 225 | 201 | .008 |
| Mean Procedure Time (mins) | 169 | 139 | .002 |
| General Anesthesia | 32% | 28% | .003 |
| Mean Hospital Length of Stay (days) | 1.89 | 1.49 | .411 |

high punctures are less likely to be hemostatic and low punctures may result in closure of the superficial femoral artery. Puncture may be guided with ultrasound or fluoroscopy. Puncture location is confirmed by sheath injection arteriography with an ipsilateral oblique view. The skin and subcutaneous tissue are stretched with a spreading motion of a clamp to allow the Prostar XL, 10-F (Abbott Medical Devices, Redwood City, CA) to be exchanged over a guidewire. Alternatively, a subcutaneous tract may be bluntly dissected with a small finger so that anterior arterial puncture can be confirmed by direct palpation. The current version of the Prostar XL is monorail and the guidewire can be removed to avoid enlarging the arteriotomy. Sometimes, this results in loss of retrograde selection of the infrarenal neck, and the guidewire also can be left in to avoid coiling of the distal end of the device in the aneurysm sac.

*"Different strategies are necessary depending on the experience of the team and availability of facilities for immediate open cutdown."*

After confirmation of arterial flow through the marker lumen, the barrel is aligned. The proper amount of tension is maintained on the shaft so the artery is not compressed; the needles are then deployed, thus placing the sutures adjacent to the arteriotomy only in the anterior arterial wall. If there is significant resistance to deploying the needles, a "backdown" maneuver may be performed, and the device can be readjusted or exchanged. The free ends of the sutures are tagged, slack is removed, and the end of the sutures are soaked with heparinized saline to prevent thrombus formation during the rest of the procedure.

Guidewire access is regained, and the larger sheath is then inserted. Occasionally, the infrarenal neck must be reselected, or a catheter must be used to exchange for a stiffer wire. At this point, a small dose of intravenous heparin may be given. If there is good flow in the external iliac artery around the sheath and the procedure is expected to be short, administration of systemic heparin may be avoided. The endograft main trunk is positioned and deployed, the contralateral leg hole (with gold ring) is cannulated, and the contralateral limb is deployed with maximum overlap. Radiographic markers on the EXCLUDER device and the simple deployment system facilitate rapid completion of the procedure. Sealing zones from just below the lowest renal artery to the origin of the hypogastric arteries are maximized with use of aortic and iliac extenders, as needed.

After completion arteriography is reviewed and found to be acceptable, the sutures are wiped of any thrombus, the sutures are tied with sliding knots, and the sheaths are removed. The sutures are trimmed as short as possible. Often, a brief period of compression is needed to stop suture hole bleeding. The small wound is closed with a single subcutaneous suture and a single subcuticular suture, with the knots buried.

## STRATEGIES

Different strategies are necessary depending on the experience of the team and availability of facilities for immediate open cutdown. The approach we use is to treat every endovascular repair with the percutaneous technique, and convert immediately to an open cutdown if there is an issue with bleeding, stenosis, or femoral artery injury. This is feasible because we have access to an excellent fixed imaging unit present in the operating room.

A second strategy is to select out cases in which percutaneous repair is likely to be uncomplicated and perform a cutdown on all potentially problematic femoral arteries; this alternative may be used when preferred imaging or the operating room environment are not present in the

same location. Approximately 70% of patients suitable for endovascular repair are candidates for predictably uncomplicated bilateral percutaneous closure.

*"Patients are able to ambulate immediately after the procedure and have short recovery times."*

Strategy also involves selection of the ipsilateral access site. The contralateral side of the EXCLUDER device requires only a 12-F sheath, and this site often may be managed with manual compression alone. Therefore, choosing to use the ipsilateral side can be altered if the access puncture site is not ideally placed. Specifically, if the first puncture is inadvertently placed low in the femoral artery, the entry needle can be withdrawn and the artery repunctured, or that side can be chosen and dilated for use with the 12-F sheath. The second puncture can then be more carefully identified with a small aortic injection so as to have an ideal placement for the larger ipsilateral sheath.

## RESULTS

Early in the experience, complications occurred related to operator error, periarterial scarring, and full anticoagulation. After mastering technical proficiency with the devices and absolutely insisting on anterior common femoral artery puncture, percutaneous repair under local anesthesia has become a routine option. Patients are able to ambulate immediately after the procedure and have short recovery times. No late pseudoaneurysm, stenosis, or infection has been identified in these patients.

Comparative data of the EXCLUDER device percutaneous experience have recently been published.[6] Forty-seven patients with bilateral percutaneous access were compared to 35 patients with femoral cutdown. There is a reduction in use of general anesthesia in the bilateral percutaneous group compared to the cutdown group. Furthermore, procedure time and anesthetic time are significantly shorter using the percutaneous technique (Table 1). When considering the strategy of attempted bilateral percutaneous access in all patients, intraoperative conversion to cutdown occurs in less than 15% of patients, and postoperative wound, femoral neuropathy, and vascular complications are significantly reduced compared to routine open cutdown.

Nevertheless, caution is warranted because substantial complications may occur. In the same way that they do for open cutdown, clinicians should monitor for arterial occlusion and bleeding not controlled by topical pressure. These are easily addressed when identified in the operating room suite. Late complications are rare, and the most formidable may be suture infection that often requires aggressive surgical treatment.

## SUMMARY

Randomized clinical trials have demonstrated superior short-term results with lower 30-day mortality rates with EVAR compared to open repair.[7,8] Percutaneous EVAR under local anesthesia is feasible in most patients. Elements of success include an appropriate strategy for arterial access, familiarity with the technical nuances of the closure system, and using the EXCLUDER endoprosthesis with a predictably short procedure time and smaller access sheaths. Comparative studies with the EXCLUDER device demonstrate significant benefits with the percutaneous strategy. Greater benefits are expected with newer closure devices and improved development of specific percutaneous techniques. ●

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1. Rachel ES, Bergamini TM, Kinney EV, et al. Percutaneous endovascular abdominal aortic aneurysm repair. Ann Vasc Surg. 2002;16:43-49.
2. Howell M, Villareal R, Krajcer Z. Percutaneous access and closure of femoral artery access sites associated with endoluminal repair of abdominal aortic aneurysms. J Endovasc Ther. 2001;8:68-74.
3. Traul DK, Clair DG, Gray B, et al. Percutaneous endovascular repair of infrarenal abdominal aortic aneurysms: a feasibility study. J Vasc Surg. 2000;32:770-776.
4. Kibbe MR, Evans ME, Morasch MD. Percutaneous repair of abdominal aortic aneurysms. In: Yao J, Pearce W, Matsumura J, eds. Trends in Vascular Surgery. Chicago, IL: Precept Press, 2003.
5. Matsumura JS, Brewster DC, Makaroun, MS, et al, for the Excluder Bifurcated Endoprosthesis Investigators. A multicenter controlled clinical trial of open versus endovascular treatment of abdominal aortic aneurysms. J Vasc Surg. 2003;37:262-276. Submitted.
6. Morasch MD, Kibbe MR, Evans ME, et al. Percutaneous repair of abdominal aortic aneurysms. J Vasc Surg. 2004;40:12-16.
7. Prinssen M, Verhoeven ELG, Buth J, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. J Vasc Surg. 2004;351:1607-1618.
8. EVAR Trial Participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomized controlled trial. Lancet. 2004;364:843-848.



## AAA Treatment in 2005:

# A Community Surgeon's Perspective

**A guide to AAA etiology, prevalence, diagnosis and screening options, and endovascular treatment candidacy.**

BY LAWRENCE D. WILLIAMS, MD

Cornerstone Surgery is part of a multidisciplinary practice called Cornerstone Health Care, located in High Point, North Carolina. Our practice has always been involved in traditional open vascular surgery, but during the last 10 years we have transitioned to endovascular techniques as they have been developed. For approximately 3 years, we have been involved in endovascular treatment of abdominal aortic aneurysms (AAAs). We have used many of the commercially available endografts. Since approval of the GORE EXCLUDER® device, we have primarily used this device for endovascular aneurysm repair. This article summarizes our approaches and experience.

## DEFINITION

An aneurysm is a localized dilatation of an artery with an increase in diameter of >1.5 times its greatest diameter. AAAs are localized dilatations of the abdominal aorta, most commonly encountered in the infrarenal portion.

The normal diameter of an artery depends on age, gender, and blood pressure. The mean size of the abdominal aorta in men is 21.4 mm. The mean size of the abdominal aorta in women is 18.7 mm. Using these beginning measurements helps to determine the diagnosis of early aneurysmal dilatation and begin routine surveillance.

## GENERAL FACTS

AAAs occur in approximately 5% to 7% of the population older than 60 years of age. As the population ages, the incidence is expected to increase. In the 1950s and 1960s, there were approximately 8.7 new aneurysms diagnosed per 100,000 patients. From the years 1971 to 1980, approximately 36.5 new aneurysms were diagnosed per 100,000 patients. The rise in diagnosis of AAAs will continue and is believed to be due to an increase in longevity, as well as improved diagnostic capabilities.

AAAs occur five times more frequently in males, and 3.5 times more frequently in white males versus African American males. In men, the process seems to begin in the early 50s and appears to peak in the 80s. In women, the process seems to be delayed to the early 60s. The incidence increases greatly in both men and women after the age of 60.

There are approximately 32,000 new AAAs diagnosed each year. There are an estimated 2 million undiagnosed AAAs in the US. More than 10,000 deaths are attributable to AAAs each year. This is approximately 1.2% of the total mortality in men older than 65 years of age and places AAAs as the ninth leading cause of death in older men. Approximately 40% of patients with ruptured AAAs die prior to presentation to the emergency department. Of the patients with ruptured AAAs that arrive alive to the emergency department, there is approximately 40% operative mortality.

Risk factors associated with AAAs include age, family history, male gender, smoking, known peripheral aneurysms (popliteal and/or femoral), coronary artery disease, hypertension, and atherosclerosis. There is some genetic susceptibility, with 20% having first-degree relatives diagnosed with AAAs, and male siblings appear to be at particular risk. The average growth rate of AAAs appears to be 2 mm to 4 mm per year.

## ETIOLOGY

Aneurysms associated with a multifactorial etiology. They appear to be predominately degenerative in nature. The aortic media appear to degrade by a protolytic process. There appears to be failure of the major structure proteins: elastin and collagen. Chronic adventitia and medial inflammatory infiltrates are found on histologic examination showing the inflammatory nature of these processes. Recent studies have focused on the roll of metalloproteinases, a group of zinc-dependent enzymes responsible for tissue remodeling.

Disease processes, such as dissections, cystic medial necrosis, and Ehlers-Danlos syndrome can cause aneurysms. Approximately 25% of AAAs are associated with atherosclerotic occlusive disease.

Histology and biochemical analysis of the aorta have shown altered levels of collagenasis, elastasis, and proteases at various levels. The elastin levels seem to decrease from the aortic arch to the bifurcation. There seems to be alteration in oxygen and nutrients to the arterial wall at different levels in the aorta; the infrarenal aorta appears to lack medial vaso vasorum. These elements contribute to the fact that AAAs are more commonly located in the infrarenal level.

Survey of the literature shows small aneurysms, less than 4 cm, do rupture but at a very low rate. We tell our patients that the annual risk for AAAs 5 cm to 6 cm is approximately 6.6%. The annual rupture rates of aneurysms greater than 7 cm is ≥20%. Steepness of the rupture curve increases dramatically after 6 cm. If an aneurysm grows at a more rapid rate than anticipated, within a 6-month to 12-month period, there is an increased risk of rupture.

## PRESENTATION

Seventy-five percent of asymptomatic AAAs may be detected during routine examination or unrelated radiological or surgical procedures. They may be associated with abdominal bruits on examination, and between 30% to 40% have associated popliteal artery aneurysms. Symptomatic presentations can include mild symptoms to hemodynamic collapse. There are a small number of patients who may present with arterial thrombosis or embolization. In our experience, aortic duodenal fistula and aortic enteric fistula are very rarely seen.

Physical diagnosis of aneurysms can be difficult because of the variety of patient shapes, cooperativeness, obesity, tortuosity of the aorta, and lumbar lordosis. During the examination, the examiner looks for associated vascular issues such as carotid occlusive disease, coronary artery disease, renal artery stenosis, peripheral vascular disease, and diabetes mellitus.

## IMAGING

Once an AAA is suspected, a confirmatory test is necessary. Many tests are available, such as plain radiographs, B-mode ultrasound, CT, MRA, and invasive arteriography. In our practice, we rely on ultrasound as a primary screening tool and confirm size and anatomy with CTA on either a 10-slice or 16-slice multidetector CT unit.

Abdominal ultrasound is a cost-effective and rapid method for confirming AAAs. Abdominal ultrasound is available in most clinical settings and does not expose the patient to radiation. Details of the vessel wall and associated plaque can be obtained, and measurements of the AAA in the transverses and AP dimensions are easily made. These measurements are usually accurate to within 3 mm to 5 mm of CT findings. Limitations to ultrasound include bowel gas, body habitus, and unreliability in defining relationships between the proximal extent of the abdominal aorta and the renal arteries.

Computed tomography, and in particular computed tomography arteriography (CTA) is the most accurate test to determine the size and location of AAAs. CTA is readily available at most institutions. The 3-D image of the aorta and the surrounding structures clearly help plan for both traditional open and endovascular repair. CTA eliminates the need for invasive angiography but requires intravenous contrast. This modality does require specialized training to reconstruct the images.

MRI is another useful modality. We primarily employ this in patients with renal insufficiency. It does give 3-D imaging and no radiation exposure; however, in our experience, the resolution is not as good as CTAs. Contraindications include patients with claustrophobia, pacemakers, and defibrillators.

Arteriograms are the least useful modality in our practice in working up aneurysms. They are invasive and are unable to accurately delineate AAAs due to thrombus lining the lumen. However, when we do have concerns about associated arterial occlusive disease, we perform abdominal aortic arteriography with runoff. If indicated, we will do selective studies of renal, mesenteric, and internal iliac arteries.

## TREATMENT

Once the confirmatory diagnosis of AAAs has occurred, we then move to the treatment phase. Treatment depends on the size of the aneurysm. It is our practice to monitor most AAAs that are <4 cm every 6 to 12 months, depending on the patient's history. If the AAA is between 4 cm and 5 cm, we will monitor or perform elective repair depending on whether the patient is a good risk, his life expectancy, and how rapidly the aneurysm has changed. Aneurysms between 5 cm and 6 cm are repaired, unless the patient is extremely high risk. All aneurysms >6 cm are repaired, unless unusual circumstances are present.

## CANDIDACY

Once we have elected to proceed with treatment, full cardiac and pulmonary risk assessment are performed. This typically includes EKG, echocardiograms for ejection fraction calculation, some form of stress testing, cardiology consult, pulmonary function test with or without arterial blood gas, and pulmonary consultation in selected cases. If patients are determined to be at good risk and have significant longevity, we tend to recommend traditional open surgery. However, we do offer them a choice between the traditional open sur-

gery and endovascular repair if they are anatomically candidates. The higher the risk a patient is and the less longevity curve he has, the more we suggest endovascular repair if anatomically appropriate. We have experienced an increase in patients desiring an endovascular approach. In all of our patients, we outline both traditional aortic and endovascular repair and make them aware which one we think would be indicated for their particular circumstance.

For endovascular repair, we quote a mortality of less than 1%. A 1- to 2-hour operative time, as well as a 12- to 24-hour monitored postoperative period and a 24- to 36-hour postoperative hospital stay, are also quoted. A 14-day postoperative recovery stay is routine, and we stress the need to monitor endoleaks for life. We inform patients of the difference between open and endovascular repair as it relates to primary 30-day mortality, secondary procedures, and secondary procedure mortality.

For traditional open surgery, we quote 3% to 5% morbidity and mortality. We discuss general anesthesia and the fact that the procedure takes 2 to 4 hours, depending if it is a straight tube graft versus an aortobifemoral bypass graft. A 1- to 2-day intensive care unit stay and a 7- to 10-day hospital stay, plus a 12-week recovery period after hospitalization, are also quoted. We present detailed information on complications such as death, pneumonia, myocardial infarction, groin infections, graft infections, colonic ischemia, renal failure, renal insufficiency, incision hernias, possible amputation of limbs, blue toe syndrome, impotence, retrograde ejaculations, parenthesis, lympoceles, and late graft enteric fistulas.

In general, we find that 70% of our patients are endovascular candidates. Initially, female patients were not as desirable as male patients because of access vessel size. However, with the lower-profile devices, such as the GORE EXCLUDER device, we have been able to treat many female patients using endovascular repair. During the last 3 years, approximately 70% of our patient population with aneurysms has been treated endovascularly. The particular issues we look for in determining the type of graft to be used are the ability to fit the graft to the local anatomy, access the AAA through the pelvic vessels, position the graft correctly, and the device track record in terms of endoleaks, aneurysm growth, and migration record.

## RESULTS

During the past 3 years, we have treated 113 patients with endografts. Approximately 77% were male and 23% were female. We have experienced two deaths within 30 days of the procedure: one due to a spinal stroke approximately 2 weeks after the procedure and one due to congestive heart failure in a dialysis-dependent, end-stage renal disease patient approximately 2.5 weeks after the procedure. We did have one death beyond 30 days resulting from a complication of sepsis secondary to a hip decubitus ulcer.

In our experience, we have had 11 patients with endoleaks, eight of which have resolved, two required catheter-based intervention, and one required explantation at the patient's request. We have had four patients with limb occlusion, all occurred early in our experience and were associated with the Ancure graft (Guidant Corporation, Indianapolis, IN) resulting in our use of routine stenting of the unsupported limbs. We also have experienced three conversions to open repair; two of these were during the deployment of the Ancure graft and one with the GORE EXCLUDER.

Since the introduction of the GORE EXCLUDER endograft to the market, we have come to use it as our primary endograft. In our experience with the GORE EXCLUDER device, we find its deliverability, tractability, and precision in placement to be superior in our hands compared to other grafts we have used. The positive hook fixation has resulted in no migrations. We clearly can treat a wider range of patients who have more difficult access vessels. Recently, we made the transition to percutaneous treatment with the GORE EXCLUDER device in selective patients. We have done 10 successful percutaneous deployments of the GORE EXCLUDER device. It is our belief that we can further reduce the already low groin complication rates with this technique.

There have been 68 patients treated with the GORE EXCLUDER device. In our experience with the EXCLUDER, we have had one death secondary to congestive heart failure in the previously mentioned dialysis patient. We have had one explant at the patient's request secondary to a persistent type II endoleak. All aneurysm sacs have stayed at their current level or have diminished in size, with approximately 34% of our patient population experiencing a decrease in aneurysm size. There have been no aneurysm ruptures, limb occlusions, graft infections, migrations, or peripheral embolizations. We have had successful deployment in all but one patient, which was previously mentioned, when the contralateral gate did not deploy in a calcified, small, distal infrarenal abdominal aorta.

We believe our community experience compared favorably with the formal studies done on the GORE EXCLUDER graft. Following our endovascular patients is a priority in our practice, so we can continue to evaluate the effectiveness of this treatment in achieving our primary objectives, which are preventing aneurysm rupture and death from rupture. ●

*Lawrence D. Williams, MD, is from Cornerstone Health Care, High Point, North Carolina. He has disclosed that he holds no financial interest in any product or manufacturer mentioned herein. Dr. Williams may be reached at (336) 802-2150; dale.williams@cornerstonehealthcare.com.*

# Offering New Treatment Options by Adopting EVAR

**Since the approval of endovascular AAA grafts, the University of Alabama at Birmingham has performed more than 500 cases and found that EVAR provides a larger patient population with a safe and effective alternative to open repair.**

BY WILLIAM D. JORDAN, JR, MD

Endovascular aortic aneurysm repair (EVAR) was first marketed in 1999 when both the AneuRx (Medtronic, Inc., Santa Rosa, CA) and Ancure (Guidant Corporation, Indianapolis, IN) devices received FDA approval. Since that time, there have been changes in the endovascular market, including the introduction of the GORE EXCLUDER® graft (W.L. Gore & Associates, Flagstaff, AZ) in November 2002 and the Zenith graft (Cook Incorporated, Bloomington, IL) in June 2003. Market approval had been based upon prospective phase II clinical trials that showed a 97% to 98% technical success and 2% mortality associated with EVAR—a substantial improvement from the accepted 5% mortality for open aneurysm repair. The vascular community was very welcoming of this new technology, and patients began to seek this minimally invasive approach for aneurysm repair.

However, soon thereafter, experts in the field expressed caution about this new procedure. Specifically, Ohki and Veith published a report in 2001 with an 8.5% death rate from an experience of 239 grafts over 9 years.[1] They suggested that endovascular repair of aneurysms should be performed with caution and restraint, particularly in those patients with good risk. Additionally, an editorial that appeared in the *British Journal of Surgery* suggested that endovascular treatment of abdominal aortic aneurysms (AAAs) is a "failed experiment," and the authors wondered why anyone would consent to such a procedure.[2] Evaluation of the European Registry (EuroStar) experience suggested a higher-than-expected mortality associated with these procedures.[3] As concern swept through the vascular community, both the AneuRx and Ancure devices required recalls or a substantial revision, and the Ancure device was ultimately withdrawn from the market in 2003. Additionally, industry continues to modify and improve these endografts, including modification of Cook's Zenith device by improving flexibility,

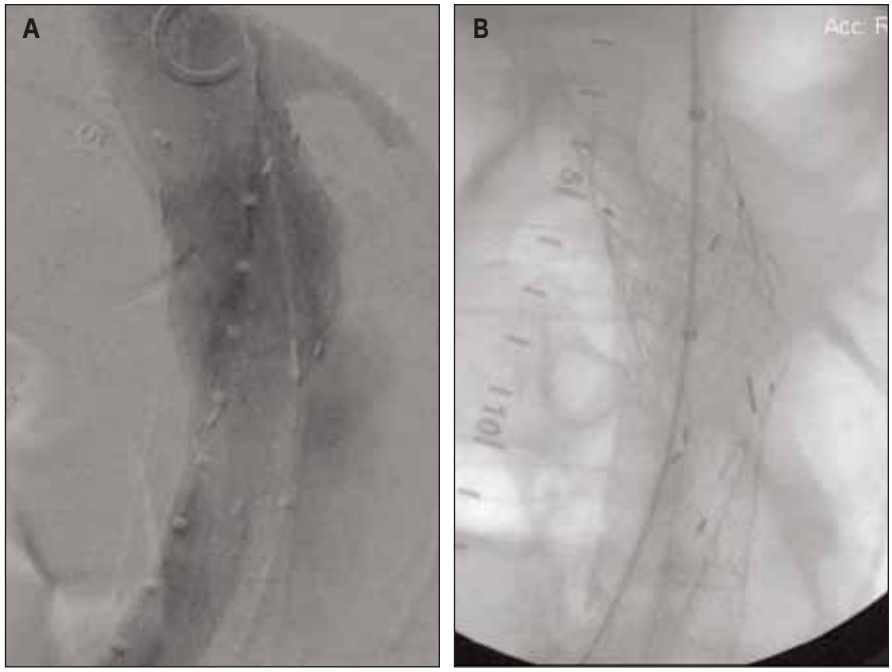


**Figure 1. A proximal type I endoleak sealed with a balloon-expandable transrenal stent.**

and also the GORE EXCLUDER device by reducing permeability of the graft material.

## UAB ENDOGRAFT EXPERIENCE

Although the first published report of endovascular grafting occurred in 1991,[4] there was extensive evaluation through FDA trials in the US through the mid-1990s. Although many institutions involved in clinical trials gained experience during that decade, most institutions were not introduced to EVAR until after the approval of these devices in 1999. Likewise, at the University of Alabama at Birmingham (UAB), we implanted only one custom-made graft prior to the 1999 approval, and did not begin application of EVAR until commercially made grafts became available in October 1999. Our experience expanded throughout 2000, leading to a near doubling of our aortic aneurysm case volume. Interestingly, open aneurysm repair has maintained at a relatively steady volume. Currently, we perform approximately 60% of our aortic reconstructions with EVAR. Considering that we were not involved in these initial clinical trials, our application of new technology was based upon the best surgical therapy when considering the patient's overall medical condition, our clinical expertise, and availability of endografts.

We then maintained a prospective clinical database that aided in constant clinical review of our endovascular grafting experience. Recent review found that we have placed more than 500 endografts, with a 99% success rate. We have had a total of four acute conversions.

### Results

After training with each commercially available graft, we have maintained a general enthusiasm for multiple graft types. When we reviewed our experience of 534 endografts, we found a relatively even distribution between the Ancure and AneuRx devices, with a subsequent utilization of both the EXCLUDER device and the Zenith device that have since become available. The perioperative mortality rate remains low at 2.1%, and the endoleak rate reflects a similar number when compared to the clinical trials. Six patients died during their hospitalization for the endograft procedure, including two who were treated for ruptured AAA. Additionally, five other patients died after discharge but before the 30-day follow-up assessment, although none of the deaths were attributed to aneurysm rupture. Four procedures required conversion to open repair related to angulated proximal neck, small iliac arteries, and technical reasons.

We recently compared the initial UAB experience by a review of the prospectively collected data in the first 2.5 years of our experience.[5] We evaluated more than 404 patients who had aortic reconstruction during a 28-month period. We specifically evaluated those who were considered to be low-risk based upon cardiac, pulmonary, and other physiologic parameters, to those who were considered high-risk. Of the 404 patients, 187 were classified as low-risk and 217 were classified as high-risk. The low-risk group had a mean aneurysm diameter of 5.5 cm, whereas the high-risk group had a mean diameter of 5.9 cm. Endovascular repair lead to a 7% complication rate, with no mortality in the low-risk group, and an 18% complication rate, including minor pulmonary and groin complications in the high-risk patients. In the open aneurysm reconstruction, there was a 28% complication rate in the low-risk group compared to a 41% complication rate in the high-risk group (Table 1).

We also found that patients who underwent endovascular repair had a substantially lower hospitalization time (median, 2 days) compared to those patients with an open aortic operation (median, 7 days). When we evaluated all of our patients, including emergencies, we found that the endovascular aneurysm repair had a 2.3% mortality rate compared to an 8% mortality rate with open reconstruction.

We also evaluated our specific experience with the GORE EXCLUDER graft. Since its introduction in November 2002, we have implanted more than 90 EXCLUDER endografts. Two patients have required con-

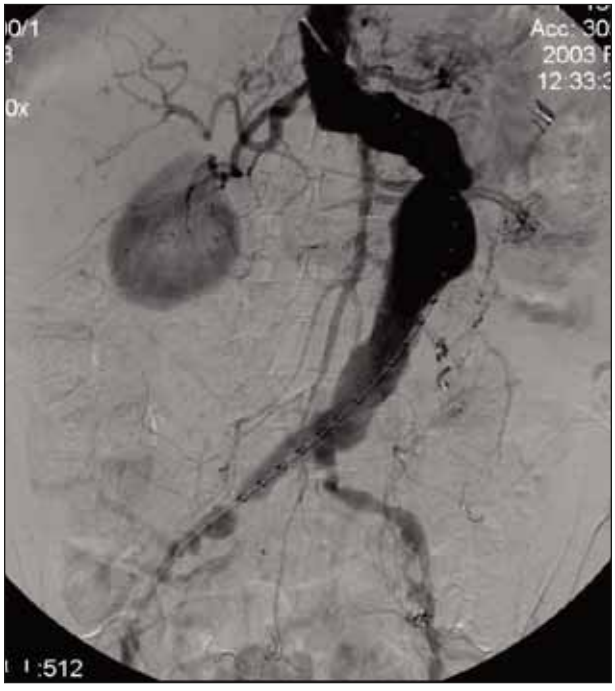


**Figure 2. An angulated proximal neck with severe iliac occlusive disease.**

**TABLE 1. MORBIDITY AFTER OPEN AND ENDOVASCULAR AAA REPAIR COMPARING LOW-RISK VS HIGH-RISK PATIENTS**

| | Low Risk (187) | | High Risk (217) | |
|---|---|---|---|---|
| | N | Systemic Complications | N | Systemic Complications |
| Open AAA (n=145) | 58 | 16 (27.6%) | 87 | 36 (41.4%) |
| Endo AAA (n=259) | 129 | 9 (7.0%) | 130 | 23 (17.7%) |

version; one had marginal proximal anatomy, and the second had a ruptured aortic aneurysm along with clinical instability before technical difficulties required conversion to an open procedure. Both of the patients survived and were discharged from the hospital. Our early clinical experience has shown an 8.9% endoleak rate and no 30-day mortalities. Follow-up for these patients has been limited because the graft has been implanted at our institution for only slightly more than 2 years.

Considering this early experience, we have identified only four patients with an increase in aneurysm diameter >5 mm, representing a 4.4% growth rate as imaged by CT scanning. After the acute conversions, there have been no delayed conversions in this early experience, and no secondary procedures have been required.

## WORKING OUTSIDE OF THE BOX

Based on review of our early clinical experience with EVAR over 5 years, we have applied this technology to marginal anatomic situations, particularly in patients who have high physiologic risks. These high-risk aortic patients can be treated with lower morbidity and mortality when utilizing a minimally invasive approach.

### Ruptured Aortic Aneurysms

Once a basic inventory has been established and EVAR experience is gained, we utilize EVAR for treating ruptured aortic aneurysms when possible. During the last 5 years, we have treated 10 patients with ruptured AAAs using EVAR. One patient required conversion and survived after a complicated course with ischemic colitis. Two other patients died, one after discharge on the 28th postoperative day and the other because of a gastrointestinal bleed during the index hospitalization on the 68th postoperative day. The total 30-day and hospital mortality for EVAR in ruptured AAAs was 20%.

### Hybrid Graft Type: Utilizing Multiple Parts

Because of our utilization of multiple graft types, we are also able to use hybrid grafts in patients who do not fit

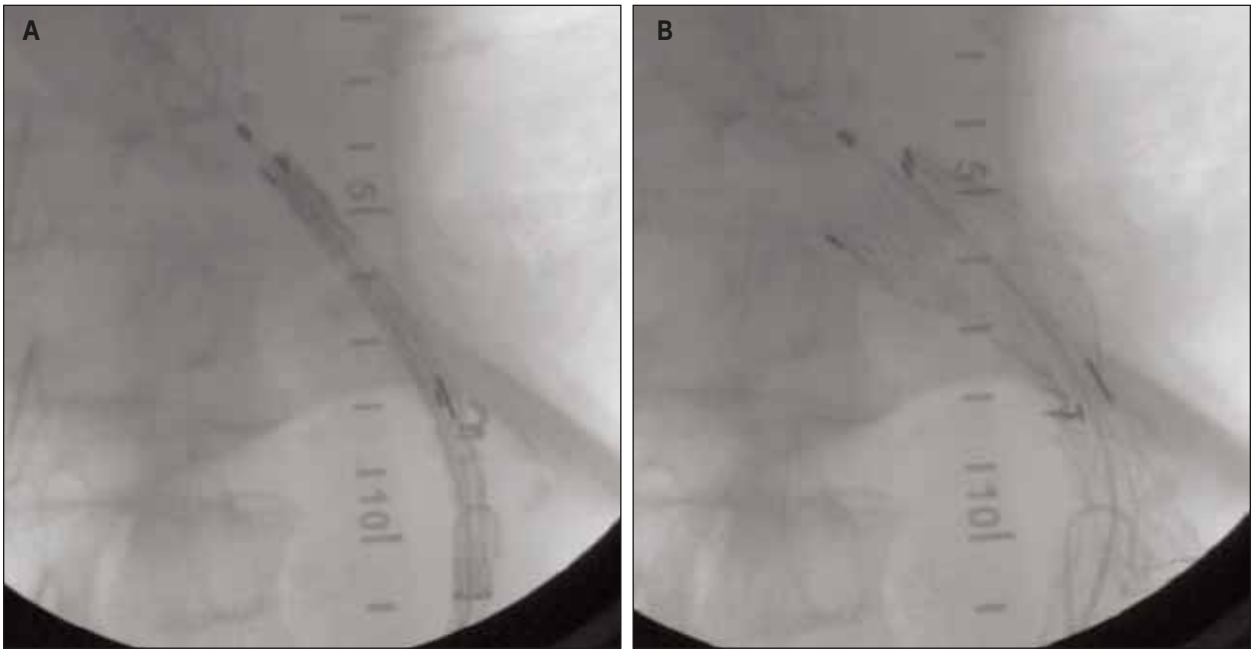


**Figure 3. Proximal deployment of EXCLUDER graft with wire withdrawn in angulated neck.**

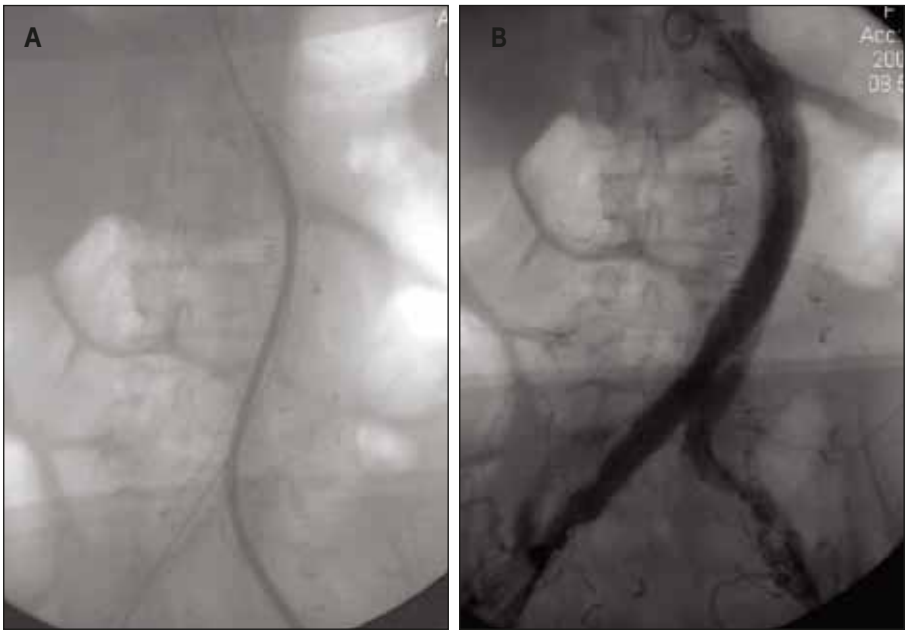


**Figure 4. An EXCLUDER endograft deployment is completed even in the case of severe iliac stenosis.**

specific anatomic criteria for one graft type. We would sometimes use an Ancure graft for its advantage of proximal fixation, and then AneuRx iliac cuffs for dilated iliac arteries to create a hybrid graft.[5] After necessity created a need of this type configuration, we then reviewed our early clinical experience.[5] This review found a similar clinical success (20% hybrid vs 28% standard morbidity) and endoleak rate (13% hybrid vs 15% standard) when compared to single graft type. After our initial experience with the hybrid endograft, we surveyed three other institutions that used the same concept. When we were able to accumulate and evaluate 90 patients who were treated with this technique, we found similar postoperative aneurysm behavior, with mean diameter decreasing from 6 cm to 4.7 cm over 12 months of surveillance.[6] Although not a pure hybrid graft, Figure 1 represents an example of a proximal type I endoleak that required a balloon-expandable stent (Palmaz 5010, Cordis Corporation, a Johnson & Johnson company, Miami, FL) across the renal artery origin to improve sealing at the proximal aspect.

### Angulated Proximal Necks

We have also been able to use these more flexible grafts in cases of angulated proximal necks. Due to the stiffness of some devices and unpredictably of deployment, EVAR was not initially used in necks with angulation >60 degrees. However, some patients with severe angulation had high physiologic risk that made EVAR advisable. For example, a 77-year-old woman with severe obstructive lung disease and coronary artery disease with class III angina had a 6.2-cm aneurysm. Angiography was performed to further evaluate her aortic aneurysm and iliac occlusive disease. She had an adequate infrarenal neck, but an 80-degree proximal aortic angle and severe iliac occlusive disease (Figure 2).

We elected to pursue EVAR because of her comorbidities. After sounding her iliac arteries with a 20-F Coons dilator (Cook), we were able to advance the sheath and EXCLUDER device into the infrarenal position. We first withdrew the stiff guidewire to allow the endograft to fit more evenly in the center flow line of the aorta (Figure 3). Deployment was completed without incident, and the contralateral gate was cannulated and deployed, with a good final result (Figure 4). Eighteen months later, the

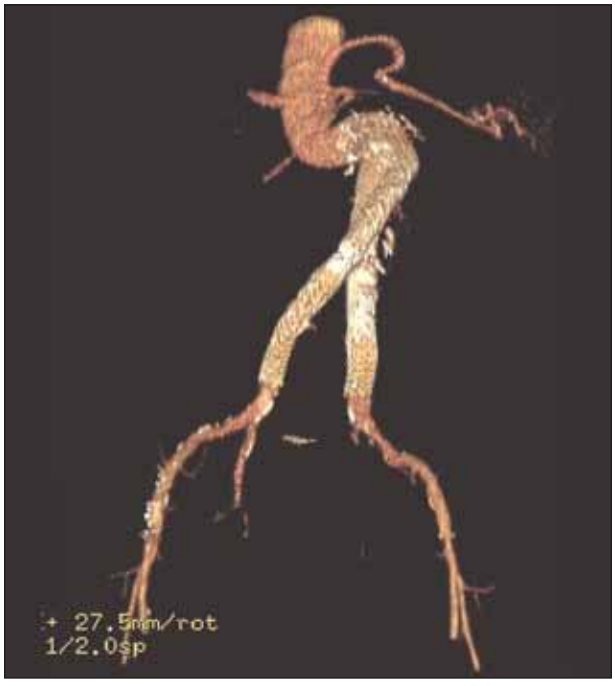


**Figure 5. An EXCLUDER device conforms well to a tortuous aorta.**

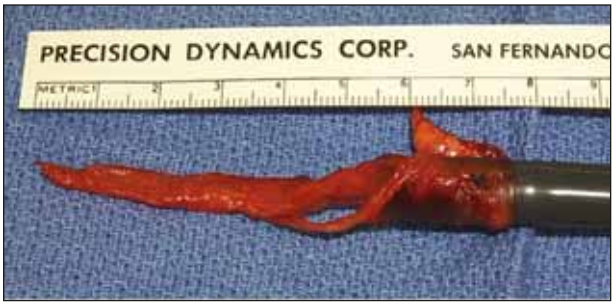


**Figure 6. An avulsed iliac artery after removal of a 22-F sheath for endograft deployment.**

aneurysm had decreased to 4.1 cm without endoleak. Deployment of the GORE EXCLUDER graft is done quickly and with appropriate seating in a satisfactory position that prevents endoleak, even in cases of tortuous proximal aortic neck (Figure 5).

Additionally, some patients have diseased iliacs that may be <7 mm, making endograft advancement difficult. We found that these patients can often be dilated with a combination of angioplasty and Dotter techniques using Coons dilators. Once these arteries are dilated, we are able to advance the endograft through the diseased iliac arteries, particularly with the aid of a sheath. However, even when large sheaths are required, complications including iliac perforation can occur (Figure 6). As more advances are made, these smaller, lower-profile devices have improved problems with iliac access anatomy that sometimes results in iliac perforation. Since we began using 18-F devices, we have not had iliac perforation.

## SUMMARY

In summary, the evolving world of aortic endografts has broadened the treatment of aortic aneurysms to a larger segment of our population. Experience with multiple endografts allows the opportunity for application of these devices and can expand an aortic aneurysm treatment beyond the good-risk patient. We found that patients who normally might be considered to be too high risk to undergo open aortic reconstruction are able to tolerate these procedures, which have reduced morbidity and mortality. Smaller devices that conform well to the aortic diameters and morphology have improved treatment using endovascular techniques. Further modifications likely will allow for more expansion in treatment for many complex vascular patients. ●

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1. Ohki T, Veith FJ, Shaw P, et al. Increasing incidence of midterm and long-term complications after endovascular graft repair of abdominal aortic aneurysms: a note of caution based on a 9-year experience. Ann Surg. 2001;234:323-334.
2. Collin J, Murie JA. Endovascular treatment of abdominal aortic aneurysm: a failed experiment. Br J Surg. 2001;88:1281-1282.
3. Buth J, Laheij RJ. Early complications and endoleaks after endovascular abdominal aortic aneurysm repair: report of a multicenter study. J Vasc Surg. 2000;31(1 Pt 1):134-146.
4. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg. 1991;5:491-499.
5. Jordan WD Jr, Alcocer F, Wirthlin DJ, et al. Abdominal aortic aneurysms in "high-risk" surgical patients: a comparison of open and endovascular repair. Ann Surg. 2003;237:623-629.
6. Jordan WD Jr, Naslund TJ, Adelman MA, et al. Endovascular abdominal aortic aneurysm repair in patients with challenging anatomy: the utility of the hybrid endograft. Vascular. 2004;12:106-113.