BASIC RESEARCH STUDIES

From the Eastern Vascular Society

Evaluation of pressure transmission and intra-aneurysmal contents after endovascular repair using the Trivascular Enovus expanded polytetrafluoroethylene stent graft in a canine model of abdominal aortic aneurysm

Robert L. Hynecek, MD, Mikel Sadek, MD, Brian G. DeRubertis, MD, Evan J. Ryer, MD, Jason Choi, BA, Steven Hsu, BA, K. Craig Kent, MD, and **Peter L. Faries, MD,** *New York, NY*

Objective: **Endotension has been defined as persistently increased pressure within the excluded sac of an abdominal aortic aneurysm (AAA) resulting in increasing aneurysm size after endovascular repair in the absence of endoleak. Devices that use expanded polytetrafluoroethylene (ePTFE) have been associated with the development of endotension and continued AAA enlargement. In this study, intra-aneurysmal pressure and aneurysm content were evaluated after endovascular repair with the Enovus ePTFE stent graft in a canine model.**

Methods: **Prosthetic ePTFE aneurysms, each containing a solid-state, strain-gauge pressure transducer, were implanted in the infrarenal aorta of 13 mongrel dogs (25-35 kg). A second pressure transducer was inserted into the native aorta for systemic arterial pressure measurement. The stent graft was then deployed to exclude the aneurysm via distal aortic access. Comparison was made among three distinct stent grafts: the Trivascular Enovus (nonporous ePTFE; four animals), the original Gore Excluder (porous ePTFE; five animals), and the Medtronic AneuRx (Dacron; four animals). Daily systemic and intra-AAA pressures were measured for 4 weeks. Intra-aneurysmal pressures were indexed to simultaneously measured systemic pressures. After 4 weeks, the aorta, the prosthetic aneurysm, and its contents were harvested, photographed, and processed for histologic investigation with hematoxylin and eosin and Masson trichrome staining.**

Results: **Within 24 hours after exclusion, the mean arterial pressure and pulse pressure within the AAA sac tapered to less than 20% of systemic pressure for all three stent graft types. Throughout the postoperative period, significantly lower indexed intra-aneurysmal pressures were present in the Enovus- and AneuRx-treated aneurysms as compared with those treated with the original Excluder stent graft (0.05 ± 0.04, 0.16 ± 0.06, and 0.06 ± 0.03 for the Enovus, Excluder, and AneuRx, respectively). Histologic analysis of the Enovus-treated aneurysms demonstrated intraluminal content characterized almost entirely by erythrocytes and infrequent white blood cells without the fibrin organization—characteristics of acute or chronic thrombus. This contrasted with the content of the Excluder-treated aneurysms, which contained poorly organized fibrin deposition suggestive of acute thrombus, and of the AneuRx-treated aneurysms, which demonstrated mature, well-organized collagenous connective tissue.**

Conclusions: **Exclusion of the AAA with the Enovus stent graft resulted in nearly complete elimination of intra-aneurysmal pressure in this model. Histologic analysis of the aneurysm content further suggested complete exclusion, including elimination of circulating clotting factors and fibroblasts responsible for thrombus formation and reorganization. Ultimately, clinical evaluation will be necessary to demonstrate the effectiveness of this stent graft in preventing the development of endotension. (J Vasc Surg 2007;46:1005-13.)**

From the Department of Surgery, New York Presbyterian Hospital, Weill Medical College of Cornell University, Columbia University College of Physicians and Surgeons.

Competition of interest: none.
Presented at the Eastern Vascular Society Annual Meeting, Washington, DC, Sep 28-30, 2006.
Supported by the American Vascular Association William J. von Liebig Award in conjunction with National Institute of Health grant K08HL073313-04.
Presented at the Twentieth Annual Conference of the Eastern Vascular Society, Washington, DC, September 2006.

Reprint requests: Peter L. Faries, MD, FACS, Chief of Vascular Surgery, Mount Sinai School of Medicine, 5 E 98th St, New York, NY 10029 (e-mail: plf2001@med.cornell.edu).

0741-5214/$32.00

doi:10.1016/j.jvs.2007.06.041

Clinical Relevance: **Endovascular aneurysm repair is an effective method for the treatment of abdominal aortic aneurysm (AAA) subjected to the unique complications of endoleak and endotension, the indirect pressurization of a sac in the absence of endoleak. In our model, AAA exclusion with the Enovus stent graft results in inhibition of fluid and serum transudation into the AAA sac, a corresponding prompt pressure decay profile, and near-complete elimination of intra-aneurysmal pressure. With the advent of implantable wireless pressure transducers, this research can be readily translated to the clinical setting. Future intraoperative and postoperative studies may help elucidate the clinical significance of pressure decay profiles in identifying successful AAA exclusion and monitoring for the development of endotension and its clinical sequelae.**

Although endovascular aneurysm repair (EVAR) is an effective method for the treatment of abdominal aortic aneurysm (AAA), a set of complications that are distinct from those encountered during open repair can compromise long-term outcome.[1-3] Endoleak, the direct communication of the systemic circulation with the excluded aneurysm sac, and endotension, the indirect pressurization of sac in the absence of endoleak, are complications specific to EVAR.[4,5] Attachment site endoleaks can be mitigated with careful preoperative planning, meticulous aneurysm measurement, and appropriate stent graft selection. Endotension, however, may be attributed in part to limitations in the graft material or in the stent-graft design.[4-8]

Graft material separates the intravascular space from the aneurysm sac to reduce the transmission of pressure to the aneurysm wall. The durability of the repair relies on biocompatible material suitable for use as a vascular graft. Expanded polytetrafluoroethylene (ePTFE) exhibits desirable characteristics as a vascular graft because it is biologically inert and can be used to construct low-profile endovascular devices. However, it has been postulated that the transfer of fluid blood components through the porous ePTFE graft can contribute to endotension in the absence of a documented endoleak and ultimately lead to pressurization and expansion of the aneurysm sac. Consequently, the occurrence of endotension in stent grafts constructed with porous ePTFE has led to the modification of these devices.[4,8-10] The recent introduction of a low-permeability ePTFE material may reduce the likelihood of this specific complication without compromising device profile or graft durability.[11,12]

In this study, characteristics and behavior of low-permeability ePTFE graft material were compared with those of porous ePTFE and Dacron stent grafts (DuPont, Wilmington, Del) by using a canine model. Intra-aneurysmal pressure and aneurysm sac contents were evaluated after EVAR with three distinct stent grafts. This model has been used to investigate implantable pressure sensors and type II endoleaks.[10,13-15] The aims of this study were to evaluate intra-aneurysmal pressure after exclusion with the Enovus stent graft, to characterize the intra-aneurysmal content and graft histologically, and to compare it with Food and Drug Administration–approved stent grafts.

METHODS

Overview. A canine model of AAA was used to analyze pressure transduction across graft material in three unique devices by measuring the pressure within prosthetic aneurysm sacs implanted as interposition grafts within the infrarenal canine aorta. Each animal was implanted with a prosthetic aneurysm sac and a single stent graft. Thirteen dogs were separated into three groups to evaluate the Enovus (Trivascular, San Diego, Calif; four animals), Excluder (WL Gore & Associates, Flagstaff, Ariz; five animals), and AneuRx (Medtronic, Minneapolis, Minn; four animals). All animals were treated in accordance with the *Guide for the Care and Use of Laboratory Animals.*[16]

Stent grafts. The stent grafts used in this study each incorporate unique design elements and materials within their construction. The Trivascular Enovus (Fig 1) uses barbed nitinol stents, which are isolated to the proximal and distal ends of the stent graft. The body of the graft is

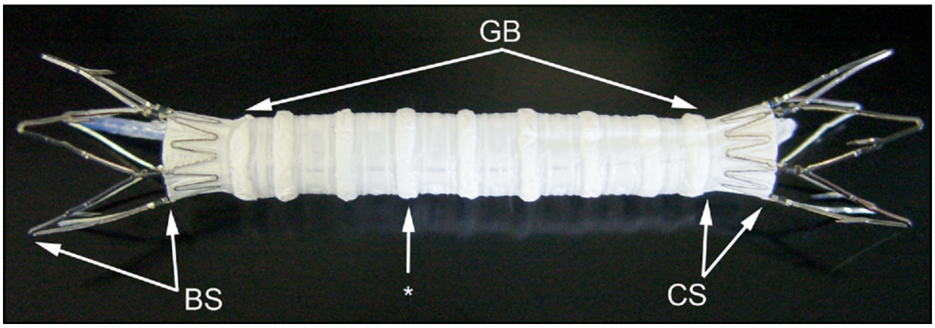

Fig 1. A photograph of a deployed Enovus stent graft highlights characteristics of its construction. The low-permeability expanded polytetrafluoroethylene graft body *(GB)* is bounded on either extremity by barbed nitinol bare stents *(BS)*, with a covered stent *(CS)* component located more proximally. A series of circular channels *(*)* are filled with epoxy during graft deployment.

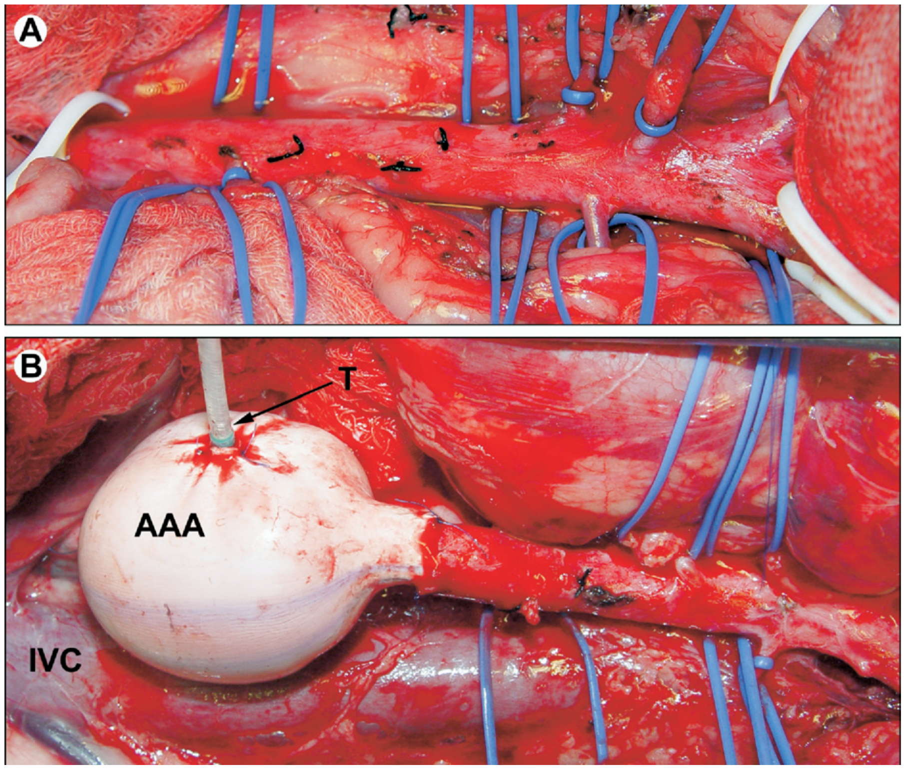

Fig 2. Intraoperative photographs are oriented with the proximal aorta on the left of the image. **A,** The infrarenal abdominal aorta is exposed from the renal arteries to the trifurcation. **B,** The prosthetic aneurysm *(AAA)* with an intraluminal transducer *(T)* is placed as an interposition graft in the infrarenal aorta. The inferior vena cava *(IVC)* is visible adjacent to the abdominal aorta.

free of metal and is composed of a flexible, hypdrophobic, and low-permeability ePTFE material. A series of ring-shaped cavities are incorporated into the body of the graft and are filled at the time of deployment with a radiopaque, three-component epoxy that solidifies to create a rigid scaffold. The covered portion is 6 cm, with a total length of 9 cm, and the lumen diameter is 10 mm. The remaining two grafts embrace a more traditional design, with graft material that extends along the entire length of the device. The first-generation Gore Excluder is composed of increased-permeability ePTFE. After this study, the Excluder was upgraded to include an ePTFE material that is laminated with a low-permeability film and an ePTFE-reinforcing film.[11] The outer diameter of the graft is 12 mm, with a length of 7 cm. The latest-generation Medtronic AneuRx uses a low-porosity polyethylene terephthalate (Dacron) fabric, which is hydrophilic and is rapidly incorporated into surrounding tissue. This graft also has an outer diameter of 12 mm, with a length of 5.5 cm.[17-19] All three graft types are inserted into the aorta through a 12F introducer sheath or delivery system.

AAA creation. Prosthetic implantable aneurysm sacs were created before surgery by using a single 10-cm-long segment of an 8-mm thin-walled PTFE vascular graft (Bard Medical, Covington, Ga). The 8-mm PTFE was dilated by using a 30-mm noncompliant angioplasty balloon to produce a final spherical aneurysm 30 mm in diameter. A solid-state pressure transducer was secured to the aneurysm wall with a 5-0 polypropylene suture before ethylene dioxide gas sterilization.

AAA implantation and AAA exclusion procedure. Dogs were loaded with 225 mg of clopidogrel before surgery. An intramuscular injection of tiletamine hydrochloride (2.2 mg/kg), zolazepam hydrochloride (2.2 mg/kg), xylazine hydrochloride (2.2 mg/kg), and atropine sulfate (0.2 mg/kg) was administered. The animals were intubated, and general anesthesia was maintained with inhaled isoflurane. A midline abdominal incision was made, and the viscera were displaced cranially to expose the retroperitoneum. The aorta was dissected circumferentially between the renal arteries and the aortic trifurcation (Fig 2). Infrarenal aortas measured 9 mm in diameter midway between the renal arteries and trifurcation. Intraoperative anticoagulation was maintained by using intravenous unfractionated heparin sodium (2000-U bolus followed by a 500 U/h infusion). The infrarenal aorta was exposed, clamped proximally and distally, and then transected. The prosthetic aneurysm was implanted by using a 5-0 proline suture to create each end-to-end anastomosis (Fig 2). Next, flow was re-established, and intraoperative angiography was

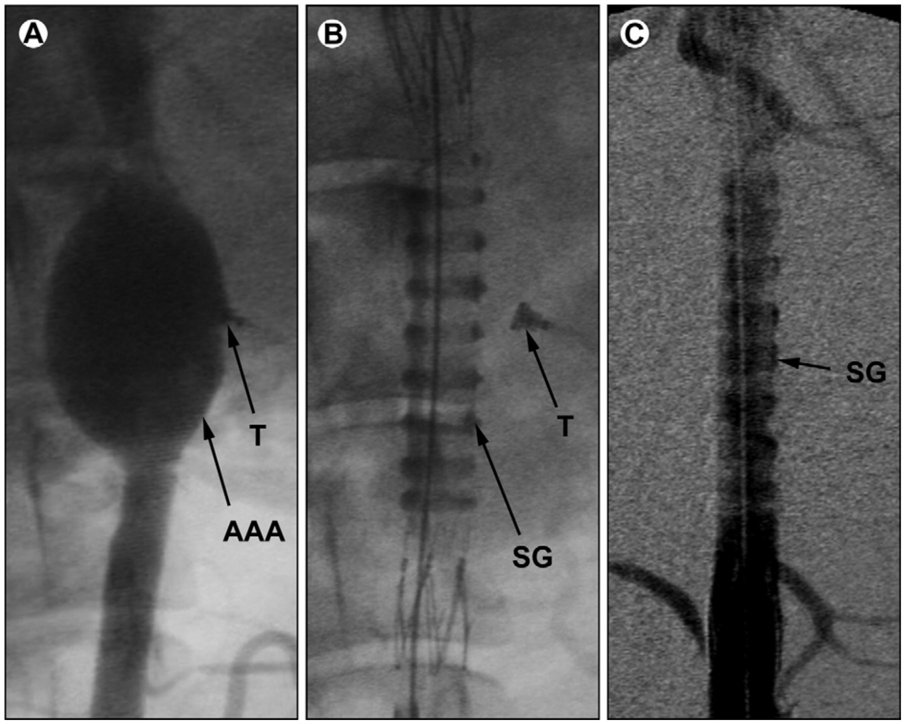

Fig 3. A, Intraoperative angiography illustrates the prosthetic aneurysm *(AAA)* and incorporated transducer *(T)*. **B,** Component epoxy can be visualized as radiopaque rings, which demarcate the body of the Enovus graft *(SG)* between the proximal and distal nitinol stents. **C,** Completion angiography confirms aneurysm exclusion and the absence of endoleak.

used to confirm the patency of the aneurysm sac (Fig 3). The stent graft was introduced through the native aorta distal to the AAA to allow appropriate space for a distal landing zone. The aneurysm was then excluded by deployment of the endograft, and completion angiography was performed to document successful exclusion. Finally, a second solid-state pressure transducer was introduced through the aortotomy and secured with 5-0 proline sutures. Cables from the systemic and intra-aneurysmal transducers were tunneled dorsolaterally through the abdominal wall and then subcutaneously to exit the skin at the interscapular space. The abdominal incision was closed in three layers, and the transducer interface was secured with absorbable suture.

Pressure sensor system. Two X6 series solid-state strain-gauge transducers (Konigsberg; Triton Technology Inc, San Diego, Calif) were implanted into each animal for the independent collection of systemic and aneurysm sac pressures. The sensors were secured within the lumen of the vessel and connected by a silicone-insulated cable to a skin-level interface. This interface was designed to allow ingrowth of dermis, to minimize infection, and to secure the interface for long-term follow-up monitoring. Each transducer had a designated compensation module, which was connected in tandem through a cable to a central processing unit for data collection.

Pressure collection. CA Recorder software (version 2.00; Data Integrated Scientific Systems, Dexter, Mich) was used to acquire all pressure data. Immediately after implantation of the prosthetic aneurysm sac, intraoperative pressure data collection commenced via the transducer implanted within the sac. Data collection continued throughout the duration of the procedure, and events pertaining to the deployment of the graft were documented and referenced to the pressure tracing. During the postoperative period, pressure data were collected from both sac and systemic transducers in each animal. Each sequence of data points was collected at intervals of 10 seconds for 5 minutes each day for 30 days. Data points collected during and after surgery included systolic blood pressure, diastolic blood pressure, mean arterial pressure (MAP), pulse pressure, and heart rate.

Radiographic confirmation of graft placement. Computed tomography (CT) angiography with general anesthesia was performed during the second postoperative week to confirm exclusion of the aneurysm sac from the arterial circulation. A localizer image was acquired, and the region of interest was identified. A 40-mL bolus of iohexol (300 mg/mL) contrast agent was injected intravenously at 3 mL/s immediately before imaging, and an image series was collected from the abdominal region of interest by using a Discovery ST CT scanner (General Electric, Piscataway, NJ).

Euthanasia and thrombus evaluation. After the completion of postoperative pressure data collection, each dog was killed by using a lethal injection of pentobarbital.

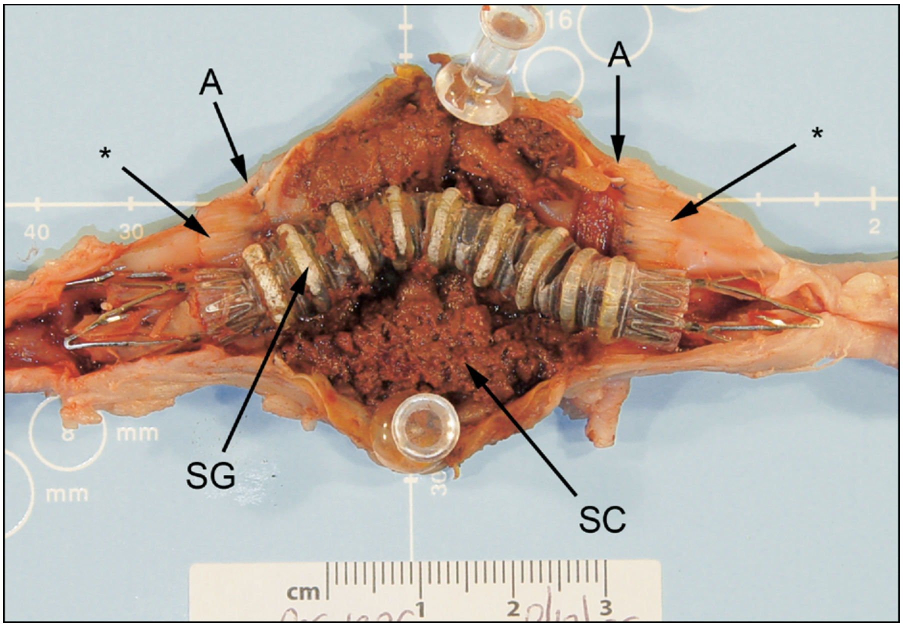

Fig 4. Once explanted, the prosthetic aneurysm sac was divided longitudinally, and the Enovus stent graft *(SG)* was separated from the aorta to evaluate aneurysm sac contents *(SC)* and aid in visualization of the graft. Suture lines reveal each end-to-end anastomosis *(A)* connecting the prosthetic aneurysm sac to the native aorta. Excellent apposition of the stent graft to the native arterial wall can be demonstrated by the impression left by the covered stent on the luminal surface of the aorta *(*)*.

The prosthetic aneurysm was excised, and the accompanying pressure transducers were carefully removed. The aneurysm was divided longitudinally, and the stent graft was removed from the lumen and inspected for integrity (Fig 4). Representative cross-sections of the aorta and aneurysm sac were collected and fixed in a 10% buffered formalin solution. Sections of the tissue samples were mounted and stained by using hematoxylin and eosin and Masson trichrome.

Statistical analysis. Unpaired Student t tests were performed by using SPSS version 15.0 for Windows (SPSS, Chicago, Ill). All values are represented as mean ± SD, and $P < .05$ was considered statistically significant.

RESULTS

Intraoperative pressure measurement. Continuous intraoperative pressure collection enabled the identification of pulse pressure elimination and the characterization of mean pressure decay within the excluded aneurysm sac (Fig 5). Pulse pressure exhibited an abrupt elimination of signal in all animal groups, and this coincided with the complete deployment of the endovascular stent graft. Fleeting intermittent pulse pressure signals appeared during the postexclusion period with no more than four episodes per animal, comprising 0.984% ± 0.891% of the total postdeployment intraoperative measurement time. In contrast to the pulse pressure, MAP measured from within the aneurysm sac initially persisted in each group and then subsequently dissipated. In the Enovus group, MAP decay commenced abruptly and had consistent dissipation characteristics in all animals tested. Pressure decay events were aligned so that the steepest slope and asymptote from each plot coincided. The regression analysis of aneurysm sac pressure decay followed the exponential function $P_t = P_o e^{-0.0271t}$, where t = time in seconds (Fig 6). The pressure half-life equaled 256 seconds, with a coefficient of determination (R^2) equal to 0.989 for the mean pressure decay interval of 20 minutes. Mean pressure dissipation plots in the Excluder and AneuRx animal groups were gradual, and the profiles were not as highly conserved as in the Enovus group.

Postoperative pressure measurement. Pressure data were collected from both sac and systemic transducers in each animal during the postoperative period. Indexed values were calculated by comparing each sac pressure measurement to the systemic pressure measurement, and the means of each group were compared. Indexed sac pressure from the Enovus group was significantly lower than sac pressure associated with the first-generation Excluder (Table; $P < .01$). No significant difference was found between indexed pressures in the Enovus and AneuRx groups (Table; $P = .08$). Additionally, in the three stent-graft groups, the AAA sac pressure decreased to the mean value represented in the Table within the first postoperative day. Each long-term pressure profile was horizontal for the duration of the 30-day postoperative period. Linear regression curves fitted to each plot confirmed no significant difference in slope between animal groups (not significant).

CT angiogram. Surveillance CT angiography demonstrated that each graft was patent, and no endoleaks were

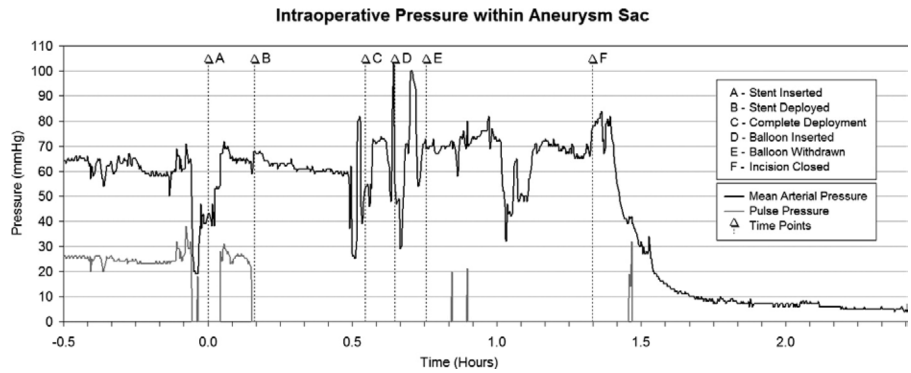

Fig 5. Mean arterial pressure (MAP; *black*) and pulse pressure *(gray)* tracings were collected during surgery from a transducer located in the aneurysm sac. After the insertion *(A)* and deployment *(B)* of the stent graft, pulse pressure was extinguished, but MAP persisted. Pulse pressure artifacts can be seen as intermittent spikes throughout the procedure. Epoxy was injected to solidify the stent between intervals *B* and *C*. Inconsistency in the MAP signal is evident during balloon fixation of the distal and proximal stents (*D* and *E*). An exponential MAP decay is apparent shortly after abdominal closure *(F)*.

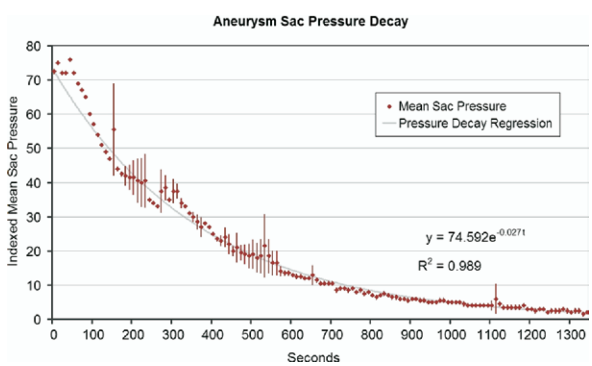

Fig 6. A highly conserved pattern of exponential mean arterial pressure decay was witnessed only in aneurysm sacs excluded with the Enovus stent graft. An exponential regression for the 20-minute mean pressure decay interval has a coefficient of determination (R^2) equal to 0.989.

detected within any AAA during the postoperative study period. Figure 7 represents a contrast-enhanced CT angiogram of an excluded AAA sac.

Histologic analysis. Postmortem evaluations consistently demonstrated that prosthetic aneurysms were well incorporated into the retroperitoneum and that dense fibrous connective tissue was adherent to the PTFE with no evidence of fluid collection outside of the aneurysm. Histologic evaluation also demonstrated notable differences within the aneurysm sacs in the three experimental groups. Within sacs excluded by the Enovus, the luminal contents were characterized almost entirely by erythrocytes, with few scattered white blood cells, occasional engorged hemosiderophages, rare amounts of eosinophilic fibrin, and numerous inflammatory cells (Fig 8). The lack of organization or lamination of sac contents suggested the absence of acute or chronic aneurysmal thrombus. Within prosthetic AAA sacs excluded with the Dacron AneuRx device, mature, trichrome-positive collagenous connective tissue densely covered the aneurysm and graft surfaces within the prosthetic AAA sac. Small blood vessels were visible within the organized focus of connective tissue. Granulation tissue was adjacent to the collagenous loci. Consistent with organized thrombus, abundant disorganized eosinophilic fibrin and abundant erythrocytes formed an acute thrombus adjacent to the collagenous and granulation tissue. Aneurysm sac contents in the Excluder group had an appearance analogous to an acute fibrin thrombus. Fibrin was arranged between the prosthetic aneurysm and the stent, and a few neovessels traversed the fibrin thrombus.

DISCUSSION

The prosthetic aneurysm model of AAA is a useful tool for the in vivo investigation of stent graft permeability and aneurysm sac pressure characteristics. The dilated segment of PTFE used in the creation of the prosthetic AAA provides an acceptable hemodynamic reproduction of an AAA. Reliable consistencies in aneurysm size, shape, and volume ensure the accurate measurement of pressure in fluid or thrombus from within the aneurysm sac during postoperative measurements.[13,20,21] Histologic phenomena observed within the AAA sac assist in the description of the interactions between the stent graft and circulating blood.[21]

The AneuRx and Excluder devices have been used extensively in clinical practice. Use of the Enovus stent graft has been limited to a phase I Food and Drug Administration trial, and it is the primary focus of this study. The Enovus has an outer diameter of 10 mm (11.1% oversized), and the AneuRx and Excluder devices are 12 mm in diameter (33.3% oversized). Distal stent graft migration is the most frequently cited complication in AAAs repaired with grafts oversized by greater than 30%.[22] There was no incidence of stent graft migration, endoleak, AAA rupture, or stent graft occlusion in this study. The most striking

Table. Pressure and histologic data

Group	*Stent graft*	*Material*	*Indexed mean pressure**	*Histologic findings*
I	Trivascular Enovus	ePTFE†	0.05 ± 0.04	No thrombus
II	Gore Excluder	ePTFE	0.16 ± 0.06	Acute thrombus
III	Medtronic AneuRx	Dacron	0.06 ± 0.03	Organized thrombus
I vs II‡	—	—	$P < .01$	—
I vs III	—	—	$P = .08$	—
II vs III	—	—	$P = .04$	—

ePTFE, Expanded polytetrafluoroethylene.
*Mean intra-aneurysmal pressure indexed to systemic mean arterial pressure represented with standard deviation.
†Trivascular Enovus uses low-permeability ePTFE.
‡Mean pressure comparison using unpaired Student *t* tests.

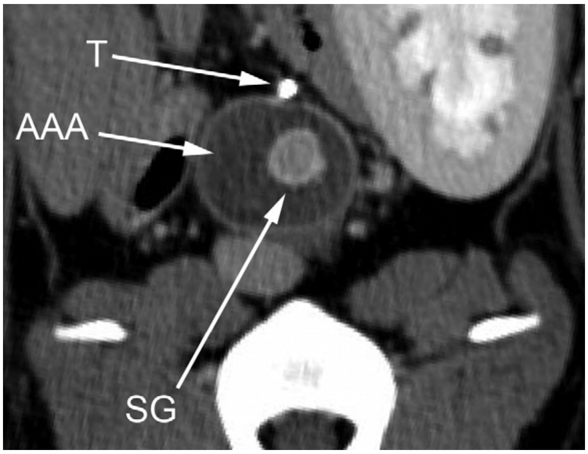

Fig 7. Surveillance computed tomographic angiograms were conducted during the postoperative period to evaluate stent-graft position and search for evidence of endoleak. A representative axial image demonstrates intravenous contrast within the stent graft *(SG)* without radiologic evidence of leak into the aneurysm sac *(AAA)*. Radiodensity ventral to the AAA represents the transducer cable *(T)*.

feature of the Enovus is the use of epoxy filling material to reinforce the flexible graft. The epoxy transforms a flexible graft into a rigid conduit through a low-profile delivery system. Permeability is unlikely to be affected by the epoxy filling material because it hardens into a widely fenestrated supportive structure. Rather, the reduced permeability of the Enovus at physiologic pressure gradients is conferred by the incorporation of additional coatings to the ePTFE graft material.[23,24]

Expanding AAA sacs without CT evidence of endoleak contain a gelatinous material likely composed of a plasma ultrafiltrate. This phenomenon, known as a *sac hygroma*, has been primarily described in AAAs excluded with ePTFE stent grafts and is a purported cause of endotension. Prosthetic aneurysm sacs explanted from dogs in this study did not contain hygromas. Each animal was investigated for a period that did not exceed 30 days; thus, the time for postoperative hygroma development may have been limited. With the Enovus graft, no evidence of transudation of serous components was detected, so hygroma formation in this group was unlikely.

The physical and functional characteristics of the graft materials are critical to understanding the potential for AAA sac hygroma formation and for subsequent endotension. Internodal distance and porosity represent the physical characteristics of the individual materials within the stent grafts. Expanded PTFE is typified by solid nodes of PTFE connected by tendrils that span the internodal space. The distance between the nodes (internodal distance) defines the porosity. Permeability is the functional characteristic classified by the ability of a material to transmit fluids and is a directly measured value. Water entry pressure, the pressure threshold that must be overcome to push water through a material, is an industry metric used for the permeability of ePTFE. The water entry pressures of the ePTFE devices used in this study are proprietary, thus requiring us to infer the degree of permeability by pressure decay curve analysis. Dacron can also be described by its porosity, but it is more accurately described by its permeability. Untreated Dacron grafts rely on fibrin deposition within the interstices of the fabric before an effective fluid barrier can be formed. The permeability of Dacron grafts used in this study[10] was 211 ± 26 mL · min^{-1} · cm^{-2}.

Immediately after the deployment of the Enovus graft, the pulse pressure was eliminated, and the mean pressure followed a precipitous decay. This finding is likely linked to the relative impermeability of the ePTFE material in the Enovus. In AAAs excluded with the AneuRx, sac pressure is maintained throughout the intraoperative period, and this agrees with the relatively high permeability of the Dacron graft. Measurements taken at the first postoperative day, however, demonstrate pressure elimination.

As described, the graft material within the Excluder has been improved to include a low-permeability film and a reinforcing film. At the time that this study was initiated, the original Gore Excluder graft was available but has since become unavailable. New clinical data regarding the performance of the modified Excluder have emerged, but no long-term studies evaluating the efficacy of the graft are available. AAA sac pressure characteristics across the new Excluder stent graft using an in vivo animal model have not yet been published.[11]

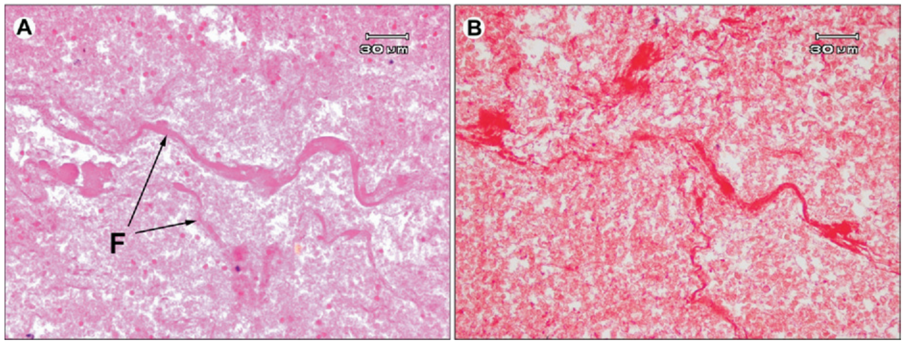

Fig 8. Photomicrographs of aneurysm sac contents were obtained 4 weeks after aneurysm exclusion with the Enovus stent graft. **A,** Hematoxylin and eosin (original magnification, 20×) demonstrates a preponderance of red blood cells with rare fibrillar material *(F)*. **B,** Masson trichrome stain (original magnification, 20×) of a similar section shows no mature collagen deposition within the field.

Endotension is a long-term problem. This study is based on the principle that the mechanism of endotension is pressurization of an AAA without evidence of endoleak. The transducers used in this experiment are sensitive and can detect abrupt changes or even slight trends in pressure over limited periods of time.[21] The capability to detect these changes in this model has provided a method to identify endotension before conventional imaging can identify changes in AAA diameter. The long-term consequences of endotension, however, are incompletely characterized. The breadth of this study has been intended to correlate sac pressure with graft performance and does not attempt to associate long-term sac pressurization with complications of EVAR. Repressurization of the AAA sac compromises fixation zones via continued expansion and distortion of the AAA.[25]

Complete elimination of pulse pressure was seen with all grafts investigated in this study. An intermittent pulse pressure signal was detected during surgery after graft deployment. These signals were likely artifactual and due to external manipulation of the excluded prosthetic aneurysm. Brisk decay of MAP was detectable only in the Enovus graft, thus suggesting immediate effective exclusion of the aneurysm sac from the systemic pressure. The material properties of the low-permeability ePTFE were likely responsible for the rapid elimination of sac pressure. The Enovus and AneuRx devices demonstrated equally effective long-term MAP elimination during the 30-day postoperative evaluation.

The exponential pressure decay with the Enovus stent graft is striking but may be dependent or codependent on the prosthetic aneurysm sac itself. The maintenance of sac pressure after exclusion is dependent on the materials that comprise the boundaries of the aneurysm sac. In this experiment, the stent graft and the prosthetic aneurysm provide those boundaries. The relative contribution of each of these materials to the profile of pressure dissipation is unknown. However, because the material properties of the prosthetic AAA remain constant among all three groups, the gradual decay of pressure detected in aneurysms excluded with the AneuRx and original Excluder stent grafts suggests that the difference between the grafts is related to the permeability of the stent graft material. The histologic differences in the aneurysmal sac clot burden further support this hypothesis. Histologic evidence of chronic and acute thrombus within the AAAs excluded by the AneuRx and Excluder grafts suggests ongoing perfusion and continued remodeling of the sac thrombus. The absence of thrombus in the Enovus group of animals suggests the immediate exclusion of the AAA after graft deployment, with no further AAA sac perfusion. With completion angiograms that rule out the presence of endoleaks, it is reasonable to conclude that the Enovus stent graft markedly reduces the transudation of permeable serum components, thus producing a favorable pressure decay curve and effectively eliminating endotension.

CONCLUSION

AAA exclusion with the Enovus stent graft resulted in a rapid and nearly complete elimination of intra-aneurysmal pressure in our model. The immediate elimination of pulse pressure with prompt decay of sac pressure, the low 30-day pressure measurement profile, and the paucity of fibrin clot within the excluded aneurysm sac support the hypothesis that the low-permeability ePTFE Enovus stent graft significantly inhibits the transudation of fluid and soluble serum components into the AAA sac. Ultimately, translation to clinical trials is needed to demonstrate the efficacy of low-permeability ePTFE stent grafts in preventing the development of endotension, aneurysm sac enlargement, and increased rupture risk after EVAR.

AUTHOR CONTRIBUTIONS

Conception and design: RLH, PLF
Analysis and interpretation: RLH, MS, BGD, EJR, JC, SH, PLF
Data collection: RLH, BGD, JC, SH, PLF
Writing the article: RLH, MS, PLF

Critical revision of the article: RLH, MS, BJD, EJR, JC, SH, PLF
Final approval of the article: RLH, MS, BJD, EJR, JC, SH, PLF
Statistical analysis: RLH, MS
Obtained funding: PLF
Overall responsibility: RLH, MS, PLF

REFERENCES

1. Bickerstaff LK, Hollier LH, Van Peenen HJ, Melton LJ III, Pairolero PC, Cherry KJ. Abdominal aortic aneurysms: the changing natural history. J Vasc Surg 1984;1:6-12.
2. May J, White GH, Harris JP. Complications of aortic endografting. J Cardiovasc Surg (Torino) 2005;46:359-69.
3. Parodi JC, Marin ML, Veith FJ. Transfemoral, endovascular stented graft repair of an abdominal aortic aneurysm. Arch Surg 1995;130: 549-52.
4. White GH, May J, Petrasek P, Waugh R, Stephen M, Harris J. Endotension: an explanation for continued AAA growth after successful endoluminal repair. J Endovasc Surg 1999;6:308-15.
5. White GH, Yu W, May J. Endoleak—a proposed new terminology to describe incomplete aneurysm exclusion by an endoluminal graft. J Endovasc Surg 1996;3:124-5.
6. Carpenter JP, Baum RA, Barker CF, Golden MA, Velazquez OC, Mitchell ME, et al. Durability of benefits of endovascular versus conventional abdominal aortic aneurysm repair. J Vasc Surg 2002; 35:222-8.
7. Chuter TA. Stent-graft design: the good, the bad and the ugly. Cardiovasc Surg 2002;10:7-13.
8. White GH. What are the causes of endotension? J Endovasc Ther 2001;8:454-6.
9. Risberg B, Delle M, Eriksson E, Klingenstierna H, Lonn L. Aneurysm sac hygroma: a cause of endotension. J Endovasc Ther 2001;8:447-53.
10. Trocciola SM, Dayal R, Chaer RA, Lin SC, DeRubertis B, Ryer EJ, et al. The development of endotension is associated with increased transmission of pressure and serous components in porous expanded polytetrafluoroethylene stent-grafts: characterization using a canine model. J Vasc Surg 2006;43:109-16.
11. Haider SE, Najjar SF, Cho JS, Rhee RY, Eskandari MK, Matsumura JS, et al. Sac behavior after aneurysm treatment with the Gore Excluder low-permeability aortic endoprosthesis: 12-month comparison to the original Excluder device. J Vasc Surg 2006;44:694-700.
12. Tanski W III, Fillinger M. Outcomes of original and low-permeability Gore Excluder endoprosthesis for endovascular abdominal aortic aneurysm repair. J Vasc Surg 2007;45:243-9.
13. Chaer RA, Trocciola S, DeRubertis B, Hynecek R, Xu Q, Lam R, et al. Evaluation of the accuracy of a wireless pressure sensor in a canine model of retrograde-collateral (type II) endoleak and correlation with histologic analysis. J Vasc Surg 2006;44:1306-13.
14. Mousa A, Dayal R, Bernheim J, Henderson P, Hollenbeck S, Trocciola S, et al. A canine model to study the significance and hemodynamics of type II endoleaks. J Surg Res 2005;123:275-83.
15. Rhee JY, Trocciola SM, Dayal R, Lin S, Chaer R, Kumar N, et al. Treatment of type II endoleaks with a novel polyurethane thrombogenic foam: induction of endoleak thrombosis and elimination of intra-aneurysmal pressure in the canine model. J Vasc Surg 2005;42: 321-8.
16. Institute of Laboratory Animal Resources, Commission on Life Sciences, National Research Council. Guide for the care and use of laboratory animals. Reissue ed. Washington (DC): National Academies Press; 1996.
17. Pacanowski JP, Stevens SL, Freeman MB, Dieter RS, Klosterman LA, Kirkpatrick SS, et al. Endotension distribution and the role of thrombus following endovascular AAA exclusion. J Endovasc Ther 2002;9: 639-51.
18. Dal Ponte DB, Berman SS, Patula V, Kleinert L, Williams SK. Abdominal aortic healing associated with a thin-walled Dacron-covered endovascular graft in a canine model. J Endovasc Ther 2002;9:333-43.
19. Ao PY, Hawthorne WJ, Vicaretti M, Fletcher JP. Development of intimal hyperplasia in six different vascular prostheses. Eur J Vasc Endovasc Surg 2000;20:241-9.
20. Dayal R, Mousa A, Bernheim J, Hollenbeck S, Henderson P, Prince M, et al. Characterization of retrograde collateral (type II) endoleak using a new canine model. J Vasc Surg 2004;40:985-94.
21. Faries PL, Sanchez LA, Marin ML, Parsons RE, Lyon RT, Oliveri S, et al. An experimental model for the acute and chronic evaluation of intra-aneurysmal pressure. J Endovasc Surg 1997;4:290-7.
22. Sternbergh WC III, Money SR, Greenberg RK, Chuter TA. Influence of endograft oversizing on device migration, endoleak, aneurysm shrinkage, and aortic neck dilation: results from the Zenith Multicenter Trial. J Vasc Surg 2004;39:20-6.
23. Faries PL, Dayal R, Lin S, Trociolla S, Rhee J, Craig Kent K. Endovascular stent graft selection for the treatment of abdominal aortic aneurysms. J Cardiovasc Surg (Torino) 2005;46:9-17.
24. Faries PL, Dayal R, Rhee J, Trocciola S, Kent KC. Stent graft treatment for abdominal aortic aneurysm repair: recent developments in therapy. Curr Opin Cardiol 2004;19:551-7.
25. Conners MS III, Sternbergh WC III, Carter G, Tonnessen BH, Yoselevitz M, Money SR. Endograft migration one to four years after endovascular abdominal aortic aneurysm repair with the AneuRx device: a cautionary note. J Vasc Surg 2002;36:476-84.

Submitted Apr 19, 2007; accepted Jun 20, 2007.