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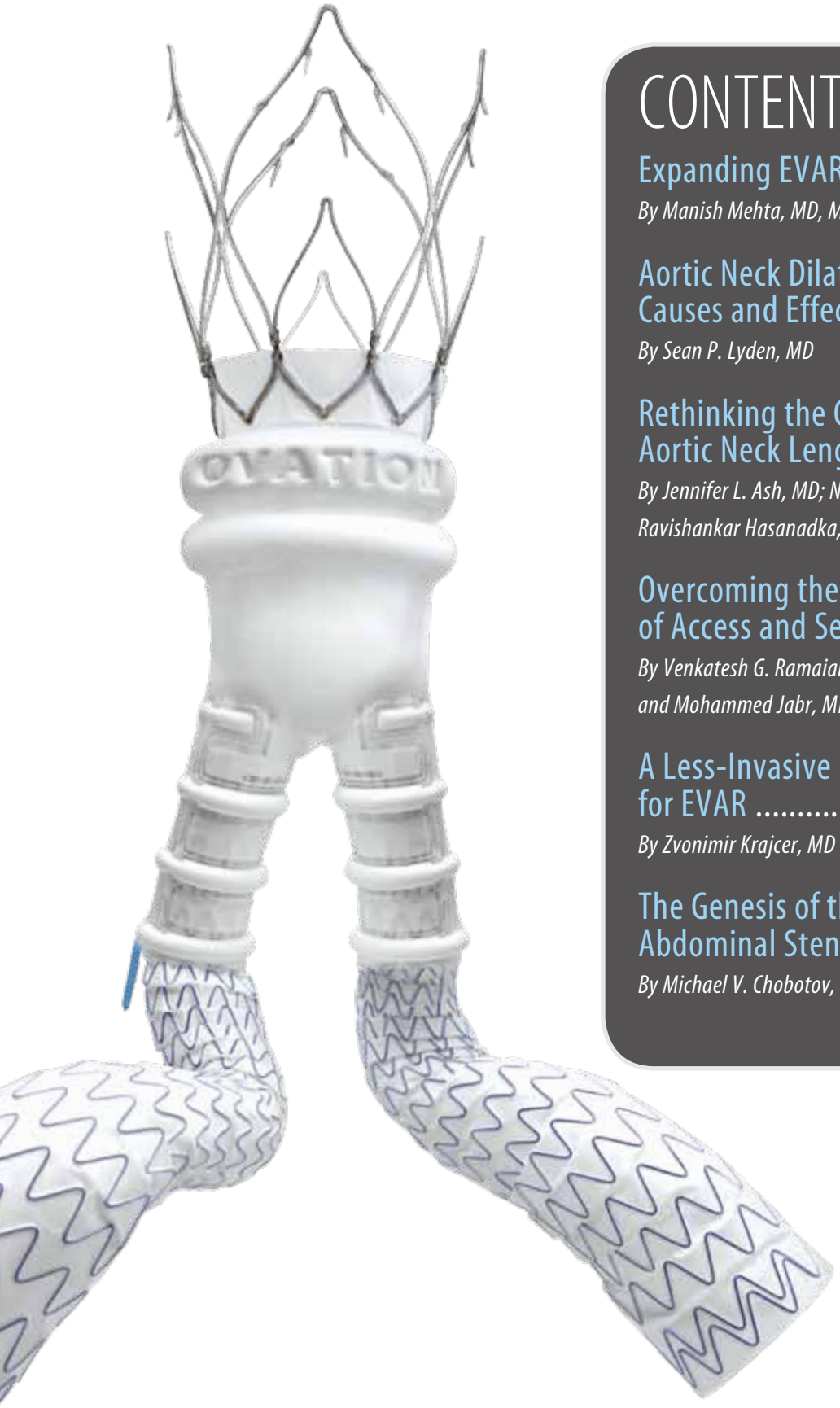
EXPANDING EVAR SAFELY

How a truly low-profile system with novel sealing technology is advancing EVAR.



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Expanding EVAR Safely

With worldwide experience and promising outcomes of the global clinical trial, it is clear the next-generation Ovation™ endograft will accommodate a wider range of AAA patients with difficult anatomy.

BY MANISH MEHTA, MD, MPH

Over the past decade, endovascular aneurysm repair (EVAR) has replaced open surgical repair at many centers as the treatment of choice for abdominal aortic aneurysms (AAAs), particularly in patients at high surgical risk. Despite the availability of six FDA-approved devices in the United States, the utility of EVAR is limited due to challenging anatomical characteristics.[1-6] Earlier studies have shown that up to 50% of patients who are considered for EVAR are ultimately denied treatment due to challenging aortoiliac anatomy such as short and complex proximal aortic necks and narrow access vessels.[7-13] Our own experience of treating approximately 3,500 AAAs over the past decade indicates that only 65% were eligible for EVAR.[14] The next generation of emerging stent grafts are evolving to accommodate difficult anatomies without sacrificing durability.

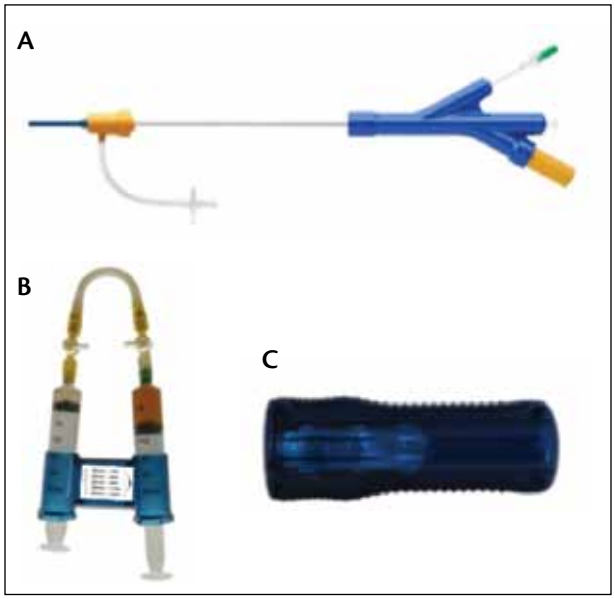

Figure 1. The Ovation Prime™ abdominal stent graft system (TriVascular, Inc.) includes a 14-F OD delivery catheter (A), fill polymer kit (B), and auto injector (C).

THE OVATION ABDOMINAL STENT GRAFT SYSTEM

The Ovation abdominal stent graft system (TriVascular, Inc., Santa Rosa, CA) utilizes a trimodular design with the aortic body delivered via a flexible, hydrophilic-coated, 14-F outer diameter (OD) catheter (Figure 1). The aortic body is composed of a low-permeability polytetrafluoroethylene graft and a suprarenal nitinol stent with integral anchors to achieve active fixation to the aortic wall. The aortic body contains a network of inflatable channels and sealing rings that are filled during deployment with a low-viscosity, nonembolic, radiopaque fill polymer that cures in situ to create a conformable seal to the aortic neck. The Ovation iliac limbs are comprised of highly flexible nitinol stents encapsulated in low-permeability polytetrafluoroethylene that are packaged in an ultra-low-profile 13- to 14-F OD delivery system (Figure 2). The distinguishing features of the Ovation stent graft include the smallest delivery system profile of any currently commercially available stent graft and the polymer-based sealing rings that provide a unique customized fit for each patient, including those with irregular and angulated aortic neck anatomies.

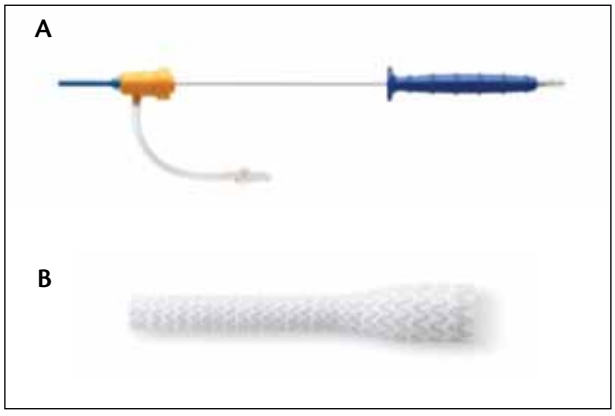

Figure 2. The Ovation Prime 13- to 14-F OD iliac limb delivery catheter (A) and flared iliac limb (B).

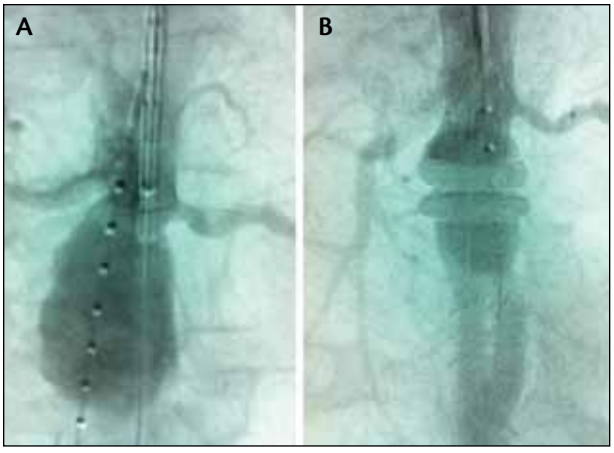

Figure 3. A preoperative angiogram shows the aneurysm (A), and a postoperative angiogram (B) demonstrates successful aneurysm exclusion with the Ovation abdominal stent graft system.

THE OVATION GLOBAL CLINICAL TRIAL

The Ovation global clinical trial enrolled 161 patients at 36 sites in the United States, Germany, and Chile. Key anatomical criteria included proximal neck length ≥ 7 mm and diameter between 16 and 30 mm; aortic neck angulation ≤ 60º (≤ 45º if proximal neck length < 10 mm); distal seal zone length ≥ 10 mm and diameter between 8 and 20 mm; and AAA diameter ≥ 5 cm, 1.5 times adjacent nonaneurysmal aorta, or expansion ≥ 0.5 cm in the preceding 6 months. Importantly, challenging aortoiliac anatomy, defined as proximal aortic neck length < 10 mm and/or minimum access vessel diameter < 6 mm, was identified in 63 patients (39%) enrolled in the study.

The primary safety endpoint in the study, major adverse event rate at 30 days, was 2.5% with 0% Device Related Major Adverse Events. Treatment success, defined as technical success and freedom from AAA enlargement, type I and IV endoleaks, rupture, or conversion to open repair, was 99.3% at 1 year, with a single AAA enlargement > 5 mm reported at 1 year based on core lab (M2S, West Lebanon, NH) review of CT imaging. The investigator did not report an enlargement, but reported a type II endoleak.

The 1-year safety outcomes included a 6.2% major adverse event rate, 0.6% AAA-related mortality, and 1.9% all-cause mortality. The imaging core laboratory reported no type I, III, or IV endoleaks or stent graft migration. There were no AAA ruptures or conversions to open surgical repair, and AAA-related secondary procedures were performed in only 10 patients (6.2%) through 1 year.

It is of great interest in this study that outcomes in patients with challenging aortoiliac anatomy were impressive. In the subgroup of patients with neck length < 10 mm (Figure 3) or access vessels < 6 mm in diameter (Figure 4), there were no reports of type I or III endoleak, AAA enlargement, migration, rupture, or conversion.

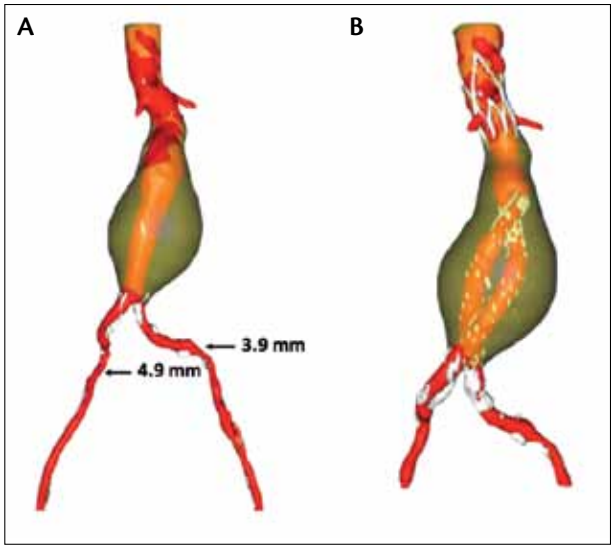

Figure 4. A CT reconstruction showing the aneurysm preoperatively (A) and successful aneurysm exclusion (B) with the Ovation abdominal stent graft system in a patient with challenging anatomy. Aortoiliac characteristics include a proximal neck length of 7 mm with thrombus and access vessel diameters of 3.9 mm (left) and 4.9 mm (right).

DISCUSSION

Stent graft technology continues to evolve at a rapid pace in order to safely expand EVAR accessibility. The Ovation endograft is a next-generation stent graft that significantly improves upon the limitations of earlier-generation devices. Historically, the most common reason for EVAR ineligibility was related to access, and therefore women have derived less benefit from EVAR when compared to men.[14] Now, with the low-profile delivery catheter of the Ovation stent graft, approximately 90% of men and 70% of women with AAA have access vessel diameters amenable to endovascular repair.[15,16] Another distinct advantage of the Ovation graft is that it is the only stent graft approved to treat proximal necks shorter than 10 mm; this feature alone might increase EVAR eligibility by about 10%.[15]

The Ovation aortic body is delivered via a 14-F OD delivery catheter, and the sealing rings are filled with polymer in situ. The noteworthy features include a shift in EVAR technology that utilizes the delivery system to truly uncouple the stages of stent graft fixation and seal during the procedure. This staged deployment allows for the Ovation stent graft aortic body to be packaged within a 14-F OD delivery system. The polymer-filled ring network conforms to the patient's aortic neck, creating an uninterrupted concentric seal reminiscent of O-ring or gasket-like seals that have long been considered the gold standard in other sealing applications. Further, the polymer-filled O-rings do not exert the kind of chronic outward force on the aorta that is seen with other stent graft systems that employ oversized, self-expanding stents to achieve seal in proximal aortic necks.

In the 161-patient prospective IDE study, we observed no migration, no type I or III endoleak, and no AAA rupture with the Ovation device through 1 year. To date, more than 2,500 patients worldwide have been treated with the Ovation device, many of whom were ineligible for EVAR with other stent grafts. Based on this worldwide experience and on the promising outcomes of the international clinical trial, we can conclude that the next-generation Ovation endograft is safe and effective in patients with AAA, accommodates a wider range of difficult anatomy not amenable to on-label treatment with other endografts, and expands the eligible AAA patient pool. ■

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Aortic Neck Dilatation: Causes and Effects

A look at the mechanisms of aortic neck dilatation and how they can be overcome with new technology.

BY SEAN P. LYDEN, MD

When endovascular aneurysm repair (EVAR) began in the 1990s, very little was known about device design and durability. Physicians, engineers, and companies raced to create devices to mimic open surgical repair, simply replacing the aortic suture line with stents to achieve fixation. A minority of senior vascular surgeons embraced the technology, whereas most questioned the entire concept, believing that EVAR was destined for failure.

The biggest concern was the durability of the device to stay in place and seal off the aneurysm. Clinical experience with open repair noted an infrequent need for late surgical revisions.[1] Contrary to the belief that open repair was a forever fix, in 1997, Illig and colleagues reviewed the fate of the proximal cuff after open aortic repairs and noted that one-third of patients experience significant dilatation over time. They suggested that this dilatation could prove to be the Achilles' heel for EVAR.[2] The concern regarding neck dilatation was partially validated in a 2000 study. Wever and colleagues noted dilatation of the proximal neck by 15.5% at 12 months in patients undergoing EVAR.[3] The reason for the dilatation could not be correlated with the graft diameter or amount of graft oversizing, and concern for late failure of EVAR remained.

Aortic growth leading to failure of the distal aortic seal zone was confirmed and publicized with the failure of the EVT/Ancure graft (formerly Guidant Corporation straight tube graft).[4] This led to better understanding of what a seal zone should look like and abandoning the concept of sealing in the distal infrarenal aorta. After this point, seal zones for EVAR would always be proximal in the aorta next to the renal arteries and distal in a normal iliac artery. The midterm results from several different device trials for EVAR with bifurcated endografts eventually proved success with EVAR, with outcomes as good as open surgical repair.[5-9] Multiple variations exist between devices to achieve fixation and sealing, with no one method proving superior.[10] To date, reports for patients treated within the instructions for use (IFU) in the pivotal trials have not found loss of proximal fixation and migration to be a frequent problem. However, several devices did change the IFU to recommend treatment of longer and less-angulated necks.

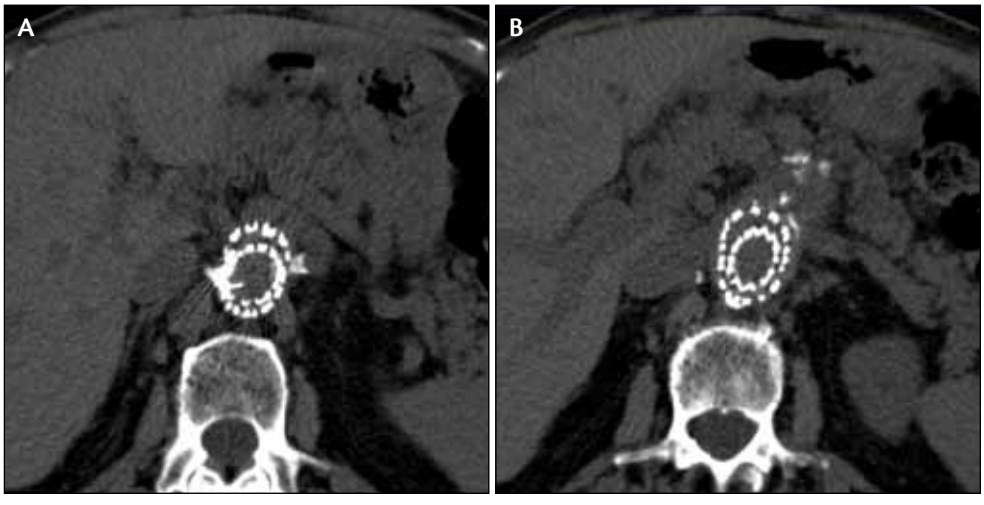

Figure 1. Dilatation in aortic neck diameter at the level of renal arteries (A) and 10 mm distal (B) at follow-up with a self-expanding stent graft, which was treated with a giant balloon-expandable stent to achieve sealing. The inner balloon-expandable stent stays at the same diameter while the self-expanding stent graft has enlarged the aortic neck seal zone.

Figure 2. The Ovation Prime™ device (TriVascular, Inc., Santa Rosa, CA) and polymer injection to fill the sealing rings.

RESEARCH FINDINGS AND CREATING BETTER TOOLS

Single-center studies have suggested that neck dilatation could be an issue and that excessive device oversizing could be the force leading to growth and eventual migration.[11-14,15] Balloon-expandable stents have commonly been used to achieve sealing when treating neck anatomy outside of the IFU. We recently followed up the long-term results of usage of giant balloon-expandable stents to achieve sealing in proximal type IA endoleaks at the Cleveland Clinic, finding no late endoleaks or migration. An interesting side finding was the lack of diameter change in the balloon-expandable stent but progressive dilatation of the aortic neck to within 1 mm of the device diameter of the EVAR self-expanding stent grafts, suggesting a possible causal connection between oversizing with self-expanding stent grafts and neck dilatation in our series (Figure 1).[16]

Another study, which evaluated the long-term results of the Zenith® device (Cook Medical, Bloomington, IN), also noted that neck dilatation was associated with the device.[17] The continued expansion in proximal neck diameter does raise concern for the risk of developing late migration and/or proximal endoleak. To date, all self-expanding stent grafts have demonstrated neck enlargement and thus have this limitation.

Balloon-expandable stents do not place continued outward force on the aortic wall and may be an alternative for long-term fixation and sealing. The use of balloon-expandable stents for creating fixation and sealing in EVAR was used with the Lifepath device (Edwards Lifesciences Corporation, Irving, CA; note, this device did not progress to FDA approval) and the MEGS device (Montefiore Endovascular Graft System). Interestingly, experience with these devices noted no dilatation of the aortic neck with the MEGS device and significantly less dilatation with the Lifepath device compared to devices utilizing self-expanding stents.[18,19] These data lead us to question the generally accepted notion that oversizing the EVAR device by a minimum of 10% to 15% with self-expanding devices is always the best option.

NEW OPTIONS

Clearly, devices that do not place chronic outward force on the aorta may have some merit. The Ovation Prime device was recently approved by the FDA and is the first FDA-approved device that does not use self-expanding stents to achieve proximal sealing.[20] This device uses a polymer to fill a sealing ring that, once

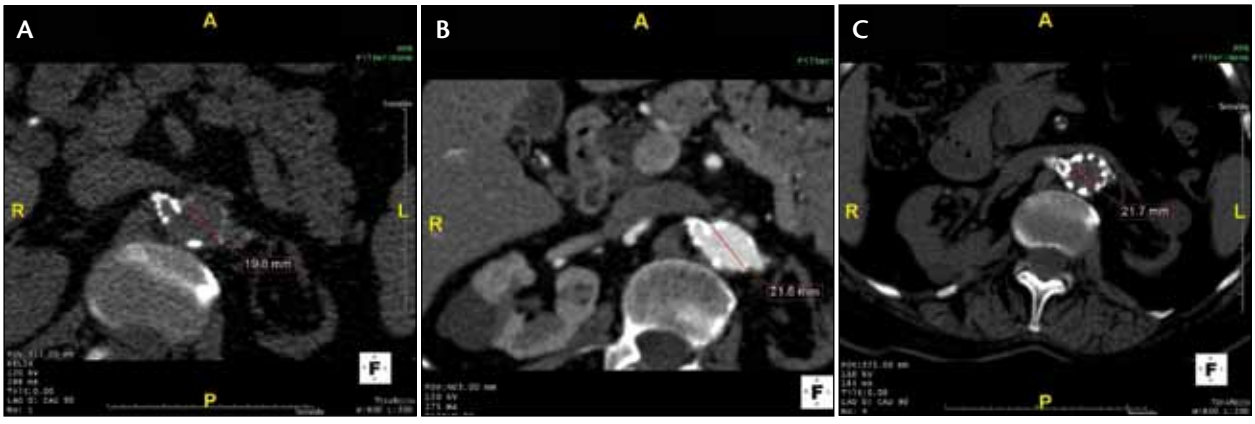

Figure 3. A proximal neck diameter of 19.8 mm in a small aneurysm in 2008 (A). An intimal neck diameter of 21.6 mm prior to EVAR in November 2011 (B). A proximal neck diameter 21.7 mm 18 months after EVAR in May 2013 (C).

cured, does not exert outward force on the aortic wall (Figure 2).

To date, 12-month data presented with the premarket approval application for the Ovation device have shown durability of the seal zone without migration or proximal endoleak in all patients. The aortic proximal neck diameters have been stable. This further suggests that an EVAR device that does not exert force against the wall may actually protect from growth of the aorta. The regression of aortic diameter when successful sealing is achieved supports this concept. Although late outcome data to prove this concept are still not available, in my own clinical experience with TriVascular EVAR devices, I have not seen aortic neck growth with either the first-generation unibody device or the current device iteration (Figure 3).

CONCLUSION

Aortic neck dilatation is seen with both open and endovascular repairs. Current concepts regarding the reason for this phenomenon remain poorly understood. Clearly, in some patients, this could be due to progression of the pathophysiologic changes in the vessel wall biology, leading to continued aneurysmal degeneration of the aorta. The influence of EVAR on this phenomenon is surely different for devices that exert continued outward force on the aortic wall versus those that do not. The amount of proximal device oversizing with self-expanding devices influences this phenomenon, and more is not always better. New innovative ways to achieve fixation and sealing may improve late outcomes with EVAR by protecting the aortic wall from pressure and growth. ■

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Rethinking the Concept of Aortic Neck Length

Will the concept of proximal aortic neck length become obsolete as aortic endograft designs incorporate new sealing technologies?

BY JENNIFER L. ASH, MD; NABEEL R. RANA, MD; RAVISHANKAR HASANADKA, MD; AND SYED M. HUSSAIN, MD

Juan Parodi placed the first endovascular stent graft for the purpose of treating abdominal aortic aneurysm (AAA) in 1990. The procedure employed an intraluminal, balloon-expandable, stent-anchored, Dacron prosthetic graft inserted via retrograde cannulation of the common femoral artery. The device created friction seals, which fixed the ends of the graft to the vessel wall. This excluded the aneurysm from circulation and allowed normal blood flow through the graft lumen.[1] In a follow-up article published in 1995,[2] Parodi described five limitations of the initial procedure, based on a population of 57 patients who were treated between 1990 and 1994: (1) preoperative measurements of the involved arteries and lesions, (2) arterial access challenges, (3) the absence of a distal aortic cuff or distal seal zone within the aorta, (4) stent migration (primarily due to incomplete stent deployment within the aneurysm neck), and (5) microembolization. The concept of progressive proximal neck dilatation was not described, and in fact, the authors stated that in their experience, the distal aortic cuff became shorter and tended to disappear, whereas the proximal aortic neck became shorter and elongated, thereby creating added tortuosity.[2]

In 2008, Rodway et al studied two groups of patients: those who had undergone open AAA repair and those who had undergone endovascular AAA repair. Their results demonstrated a statistically significant increase in proximal aortic neck diameter in the endovascular repair group versus the open repair group at 2 years.[3] Malas et al was the first group to describe the lack of aortic neck dilatation noted in those patients who underwent AAA repair employing a balloon-expandable stent graft design.[4] In 2007, Dalainas et al reported similar results when they assessed self-expanding versus balloon-expandable stents in the abdominal aorta. Two hundred forty-two patients were studied; 27.5% of the patients treated with self-expanding stent grafts demonstrated aortic neck dilatation versus 7.1% of the patients treated with balloon-expandable stent grafts.[5]

FIXATION AND SEAL

The aortic neck is generally defined in clinical studies as the longitudinal distance between the first transverse CT slice directly distal to the lowermost renal artery (D1) and the first transverse CT slice (D2) that shows at least a 10% larger outer aortic wall diameter versus the diameter measured directly below the lowermost renal artery (Figure 1). Hemodynamic forces tend to pull both ends of the stent graft into the aneurysm; however, the term "stent graft migration" typically refers to an unstable proximal attachment that results in caudal migration of the stent graft. The forces on the stent graft increase with the degree of angulation, the diameter of the trunk, and the pressure gradient across the walls of the stent graft.[6]

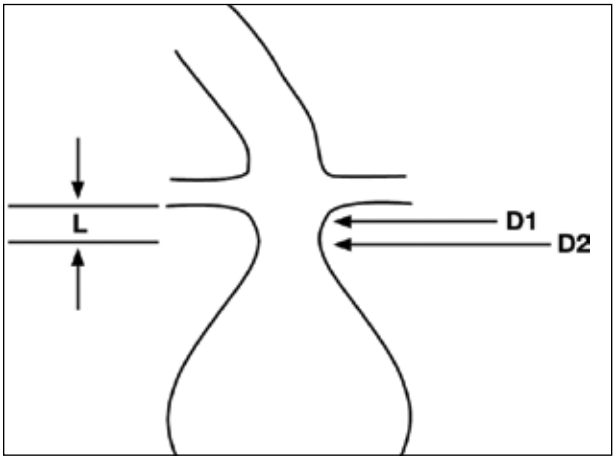

Figure 1. Neck length defined by L, where D1 is diameter at lowest renal and D2 is first diameter showing growth of 10% over D1.

A comparison of two devices, AneuRx® (Medtronic, Inc., Minneapolis, MN) and Ancure® (formerly Guidant Corporation), both of which lack suprarenal stents, showed a higher incidence of migration with the unbarbed AneuRx device when compared to the barbed Ancure. Another comparison of two devices, Talent™ (Medtronic, Inc.) and Zenith® (Cook Medical, Bloomington, IN), both of which have suprarenal stents, showed a higher incidence of migration with the unbarbed Talent device when compared to the barbed Zenith device. A similar set of comparisons showed that the suprarenal stent also contributed to a reduced incidence of migration. Neither the stiffness (column strength) of the stent graft nor its incorporation into the wall of the aorta seemed to play much of a role in stabilizing the stent graft position. The result is a sixfold difference in migration rates between the AneuRx and Zenith stent grafts. Kaplan-Meier analysis of data from the AneuRx clinical trial showed migration in 19% of subjects at 3 years, although individual centers have reported much higher rates. Clearly, fixation with hooks or barbs improves the performance of aortic stent grafts in terms of migration.[7-14]

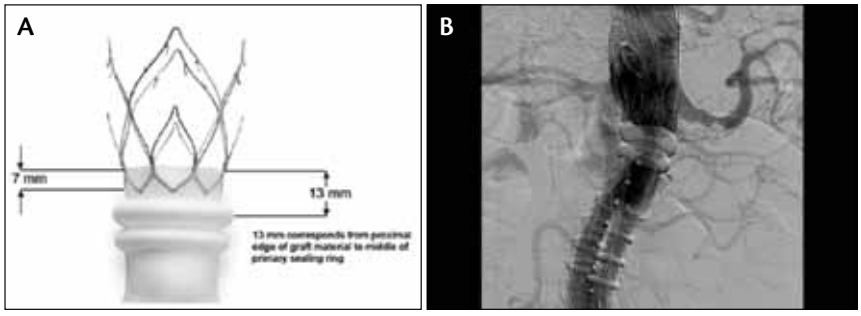

Figure 2. The Ovation Prime™ stent graft (TriVascular, Inc., Santa Rosa, CA) showing the middle of the sealing ring at 13 mm below the top of the fabric (A). The Ovation Prime stent graft under fluoroscopy with gasket-like seal achieved in the sealing ring and conventional wire and fabric seal above (B). The top of the graft material is identified by markers.

Mohan et al found that the risk of type I endoleaks was significantly increased with device oversizing of < 10%. Using a model derived from these clinical data, they predicted a reduced type I endoleak rate with 10% to 20% device oversizing.[15] Using this information, the anatomic seal zone can be defined as an aortic segment of sufficient infrarenal length that exhibits relatively parallel walls without significant calcification or mural thrombus in which a self-expanding stent graft can, by force, maintain contact between the endograft fabric and the aortic wall through interval points of contact.

However, Conners et al found an association of > 20% device oversizing with late aortic neck dilatation and subsequent endograft migration. In this study, there was a significant relationship between the degree of endograft oversizing and subsequent aortic neck dilatation.[16] The endograft's radial force is used to create wall friction, creating stability and seal of the endograft within the aorta. This radial force exerts a constant outward pressure on the aortic wall. Over time, this constant outward force may exhaust the elastic recoil of the degenerating aortic wall and result in enlargement of the aneurysm neck. As the aneurysm neck dilates, the endograft approaches its maximal diameter. This in turn translates into a reduction in outward force and, ultimately, a reduction in the friction that maintains the endograft's position and seal. Therefore, excessive oversizing (> 20%) may expose the aneurysm neck to a higher radial force generated by the large endograft. This may accelerate the phenomenon of aneurysm neck dilatation.[16]

IMPLICATION OF NEW SEALING METHODS

Limitations in current endograft design have spurred interest in new endograft designs and sealing methods. One such design (the Nellix® endovascular aneurysm sealing system, Endologix, Inc., Irvine, CA) consists of dual balloon-expandable endoframes surrounded by polymer-filled endobags, which obliterate the aneurysm sac and maintain endograft position. Nellix is designed to completely fill and seal the aortic aneurysm sac with the aim of preventing device migration and endoleak and therefore potentially reducing the need for secondary procedures. The following are among the anatomical requirements for patients to be enrolled in the clinical investigations: nonaneurysmal aortic neck length of ≥ 10 mm, nonaneurysmal aortic neck diameter of 18 to 32 mm, maximum aortic blood flow lumen diameter of ≤ 60 mm, and common iliac artery diameter of 8 to 35 mm.[17]

An additional novel design is the Ovation Prime abdominal stent graft system, which employs a sealing ring at the infrarenal aortic sealing zone. The Ovation Prime abdominal stent graft system is trimodular, consisting of a 14-F outer diameter aortic body and two iliac limbs—the smallest profile of any currently commercially available stent graft. The Ovation Prime system is designed to accommodate a broader range of anatomy by addressing the two most important issues in endovascular aneurysm repair: access and seal.

The Ovation Prime stent graft's sealing ring is a doughnut- or torus-shaped O-ring. O-rings are typically used to prevent the passing of air or fluid between two surfaces. They provide a simple, precise, and reliable seal in a variety of applications and function by introducing a calculated mechanical stress between the O-ring itself and

the surface that the ring is in contact with. As long as the pressure of the fluid (in this case, blood) being "excluded" does not exceed the contact stress of the O-ring, leaking cannot occur. For this reason, an O-ring can easily seal at high pressures. As long as the infrarenal abdominal aortic diameter at 13-mm below the lowest renal artery (the site of the most proximal sealing ring) is measured as a treatable diameter, the O-ring design is designed to provide an adequate seal (Figure 2). This design application calls into question the current and most widely accepted definition of proximal aortic neck length that incorporates both length and diameter.

In the Ovation™ global pivotal study, short neck length was not a predictor of graft failure related to fixation or seal. The main inclusion criteria of the study were proximal aortic neck length ≥ 7 mm, inner-wall diameter between 16 to 30 mm, and iliac inner-wall diameter between 8 and 20 mm. Despite relatively broad inclusion criteria, results of the study were positive, as technical success was achieved in 100% of cases. The 30-day major adverse event rate, the primary safety endpoint of the study, was 2.5% (4/161). AAA-related and all-cause mortality rates were 0.6% and 2.5%, respectively, through 1 year. No migrations, AAA ruptures, or conversions to open surgery were reported.

Of the 161 patients enrolled, 39% (63 patients) presented with challenging anatomical characteristics, including a minimum access vessel of < 6 mm, aortic neck length < 10 mm, or both. No major adverse events were observed in this group at 30 days, and treatment success was achieved in all 63 patients at 1 year.

These new technologies call into question not only the definition of aortic neck, but also the concept of aneurysmal progression at the untreated aortic segment. If the argument holds true that aneurysmal progression is the result of self-expanding stent graft design along with oversizing, then perhaps a new design that alters the manner by which an endograft seals will address the dilemma of "aneurysmal disease progression" by altering the forces exerted at this aortic segment.

CONCLUSION

The treatment of AAAs changed dramatically with the introduction of the endovascular stent graft by Parodi in the early 1990s. Since that time, endograft design has continued to evolve and change, resulting in the most common and widely accepted aortic endograft design utilized today, that being a covered, self-expanding stent graft design. The endograft revolution has been accompanied by the use of currently available endografts in less than ideal circumstances. By pushing the limits of currently available technologies in challenging and hostile anatomies, the incidence of endoleak, aneurysm expansion, secondary intervention, and endograft failure has become a widely recognized downfall of the therapy as its limits are pushed.

New endograft designs are utilizing novel ways of achieving a proximal seal endeavor to overcome current anatomic limitations, thereby providing an endovascular treatment option for a broader patient population. These designs bring into question the definition of the aortic neck and also the concept of aneurysmal disease progression in the untreated abdominal aorta. Future trial results, long-term outcomes, and device applications will likely continue to push the limits of current indications and anatomies considered suitable for endovascular aortic aneurysm repair. ■

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Overcoming the Challenges of Access and Seal

The Arizona Heart experience with the Ovation Prime™ stent graft system.

BY VENKATESH G. RAMAIAH, MD, FACS; AYMAN JAMAL, MD; AND MOHAMMED JABR, MD

There have been significant advances in the devices used for the endovascular treatment of infrarenal abdominal aortic aneurysms (AAAs) since Dr. Parodi's first description in 1990. Currently, there are eight infrarenal devices approved by the US Food and Drug Administration to treat AAAs. Conventional wire scaffolded infrarenal endografts appear to have reached their technological plateau, and it is apparent that there is little room for any substantial or meaningful improvements to be made to these grafts.

Devices have tackled migration issues with suprarenal fixation, active fixation, and anatomical fixation. They attempt to continue to improve the profile of the devices, although this may have a limiting factor or involve unappealing trade offs. As the metal and the graft materials used in the construction of these devices thin out, they lose some of the radial force needed in the sealing zones. To accommodate the current challenges of hostile necks and access issues, any new technology would need to embrace an innovative "out-of-the-box thinking" philosophy.

The Ovation™ stent graft system (TriVascular, Inc., Santa Rosa, CA) received premarket approval from the US Food and Drug Administration for the treatment of infrarenal AAA in October 2012, and the Ovation Prime stent graft system received subsequent premarket approval in December 2012, which improved upon the delivery system attributes to further enhance ease of use. This novel graft is an ultra-low-profile, modular endovascular graft characterized by a 14-F–outer diameter (4.7-mm) delivery system catheter, which makes it the lowest-profile commercially available system for EVAR. The Ovation Prime graft employs an active suprarenal fixation component and innovative polymer-filled proximal rings that allow sealing in short (≥ 7 mm) proximal necks. Unlike conventional wire and fabric grafts that employ an oversized self-expanding stent to push fabric against the arterial wall to achieve seal, the Ovation Prime graft employs customizable O-rings, which are filled at low pressure (1 atm), to achieve

CASE 1

An 82-year-old woman with a history of breast cancer and hypothyroidism presented to us with an enlarging infrarenal AAA, which was 4.6 X 5 cm at the time of surgery (Figure 1). After informed consent was obtained, the patient was taken to the operating room for percutaneous endoluminal exclusion of her aneurysm. After mapping and sizing the aneurysm with intravascular ultrasound and angiography, we elected to use the Ovation Prime 34-mm–inner diameter main body (Figure 2). On the ipsilateral side, an 18- X 140-mm Ovation Prime right limb was used with an 18- X 45-mm extension. A 16- X 140-mm Ovation Prime limb was used on the contralateral side. The femoral arteries were repaired using a ProGlide® closure device (Abbott Vascular, Santa Clara, CA).

Figure 1. Preoperative CT imaging.

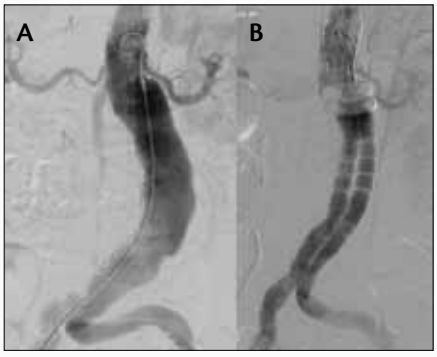

Figure 2. Predeployment (A) and post-deployment angiograms (B).

CASE 2

An 80-year-old man with a history of coronary artery disease, carotid artery stenosis, and peripheral vascular disease presented with an asymptomatic 5.1-cm infrarenal AAA. Based on the results of intravascular ultrasound and angiographic imaging, we decided to place an Ovation Prime 34-mm-diameter aortic body with a 16- X 120-mm contralateral limb and a 16- X 140-mm ipsilateral limb (Figure 3).

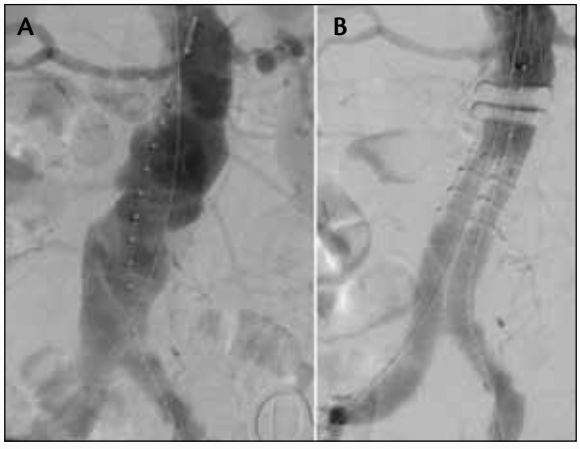

Figure 3. Predeployment (A) and postdeployment angiograms (B).

seal. Although this gasket-like seal is novel in the context of EVAR devices, O-rings are the gold standard in applications that require sealing liquid or gas flow in all other applications. By resolving the challenge of delivering an O-ring seal through a catheter, TriVascular has created many interesting possibilities for sealing in complex anatomies with the Ovation Prime graft. Furthermore, by adjusting the shape, size, and location of the sealing rings in future iterations, the platform has tremendous room for enhancement relative to infrarenal applications and beyond.

Arizona Heart Institute (Phoenix, AZ) has historically been an early adopter of innovative technology, participates in multiple trials and postmarket surveillance studies, and has developed or been a part of the development of some of the endografts currently approved for use.

With its low profile (14-F outer diameter) and novel sealing technology, the Ovation Prime endograft was designed to overcome the challenges of access and seal. In this article, we present three cases to illustrate our experience with the device in challenging anatomies, as well as a brief preliminary synopsis of our 6-month experience.

ARIZONA HEART PRELIMINARY EXPERIENCE WITH THE OVATION PRIME ENDOGRAFT

Our experience with the Ovation Prime stent graft began on February 8, 2013. Within a 6-month period, we

CASE 3

An 87-year-old woman with a history of smoking, chronic obstructive pulmonary disease, cerebrovascular accident, and hyperlipidemia presented with abdominal pain and an 8-cm infrarenal AAA. Small, calcified iliacs and a tortuous proximal neck made this a challenging case. We evaluated the aneurysm via intravascular ultrasound and angiography and then decided to use the Ovation Prime 26-mm-diameter aortic body with bilateral 12- X 120-mm iliac limbs (Figures 4 and 5). The femoral arteries were repaired using ProGlide closure devices that had been placed in a "preclose" fashion.

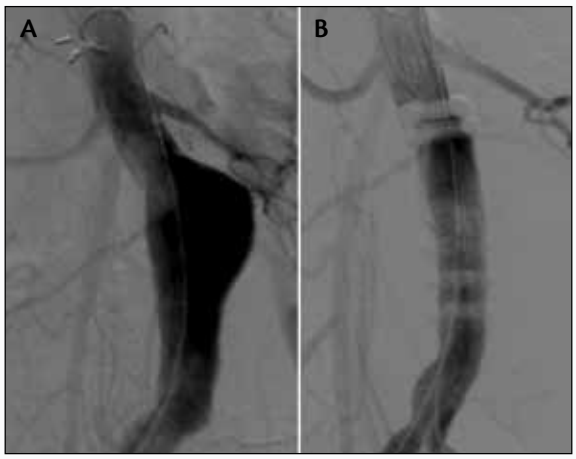

Figure 4. Predeployment (A) and postdeployment angiograms (B).

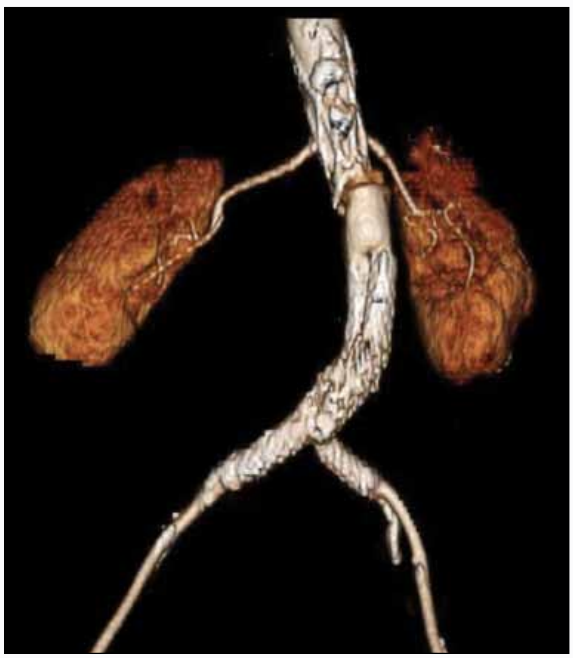

Figure 5. A 30-day CT scan showing visible sealing rings due to remaining contrast in the polymer.

have implanted more than 30 grafts, with a 100% technical success rate; 90% of the procedures have been performed via bilateral percutaneous access. The four procedures that were performed via femoral cutdown were done so due to the patients' body habitus and/or severe femoral artery calcification. One of the four patients preoperatively presented with a chronically occluded external iliac artery that was crossed and stented at the time of implantation of the Ovation Prime stent graft. We have observed one groin complication, a pseudoaneurysm, that was resolved using an ultrasound-guided injection of thrombin.

We have experienced three perioperative type IA endoleaks in three extremely challenging cases. All of the endoleaks were treated and resolved at the time of initial implantation. Two of these endoleaks were resolved by placing a Palmaz® stent (Cordis Corporation, Bridgewater, NJ), and one was resolved by placing coils in the proximal sealing zone between the proximal and distal sealing rings. We have not observed any significant type II endoleaks nor type III, IV, or V endoleaks. There have been zero limb occlusions and zero secondary procedures to date. The average length of hospital stay has been 1.5 days.

DISCUSSION

Although improvements have been made to the commercially available traditional wire and fabric endovascular infrarenal AAA endografts, the concept of manipulating or molding the endograft after insertion makes this innovative technology very exciting and presents opportunities for future iterations. The three case examples in this article illustrate the promise of this novel technology in challenging anatomies. Its ability to enable treatment of the most difficult anatomies is what initially led us to use the device. We have since adopted it as our primary option for endovascular aneurysm repair due in large part to its ease of use and accuracy of deployment, which we have found to be best in class among available endografts. With its ultra-low profile, the Ovation Prime system also facilitates easier closure after implantation via percutaneous access, which has become our preferred treatment method since incorporating this device into our practice. ■

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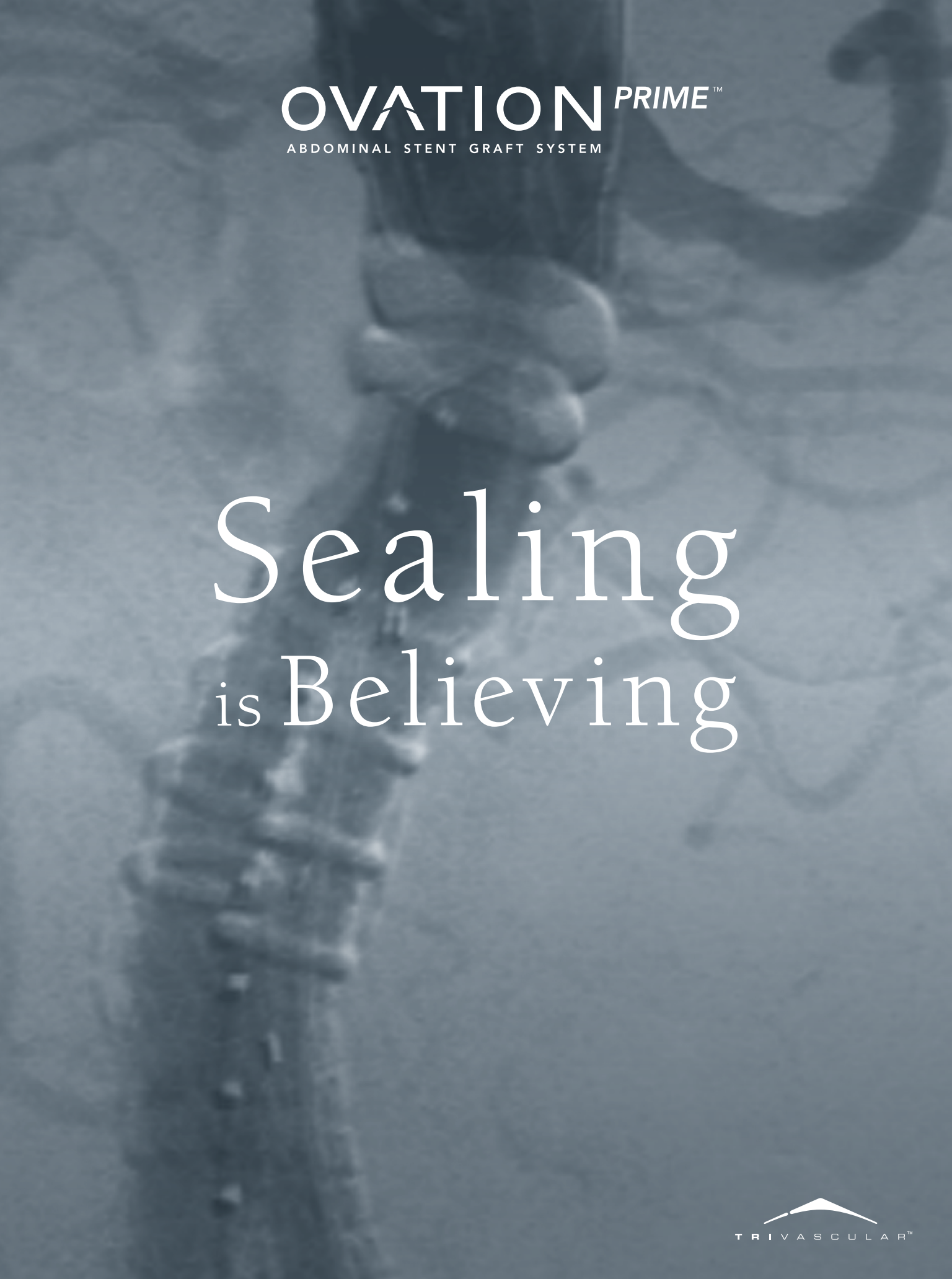
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Sealing
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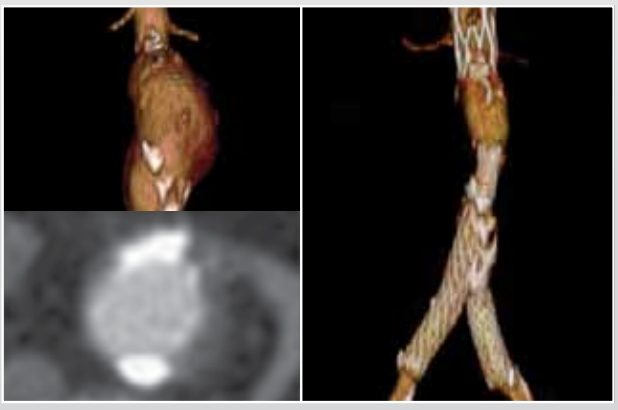
SEAL WITH **CONFIDENCE**

Polymer-filled sealing rings conform and seal in even the toughest anatomies.

0% Type I Endoleaks and 0% Migration at two years in the Ovation™ global pivotal study.
(Results as of January 30, 2013 based on Core Lab Data from Ovation Study.)

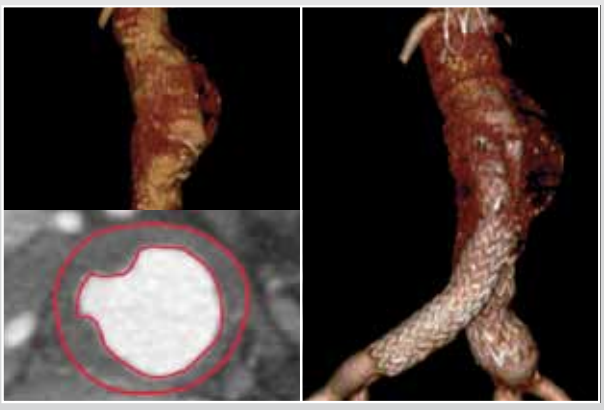
HEAVY CALCIFICATION

PRE-OPERATIVE **TWO YEAR FOLLOW-UP**



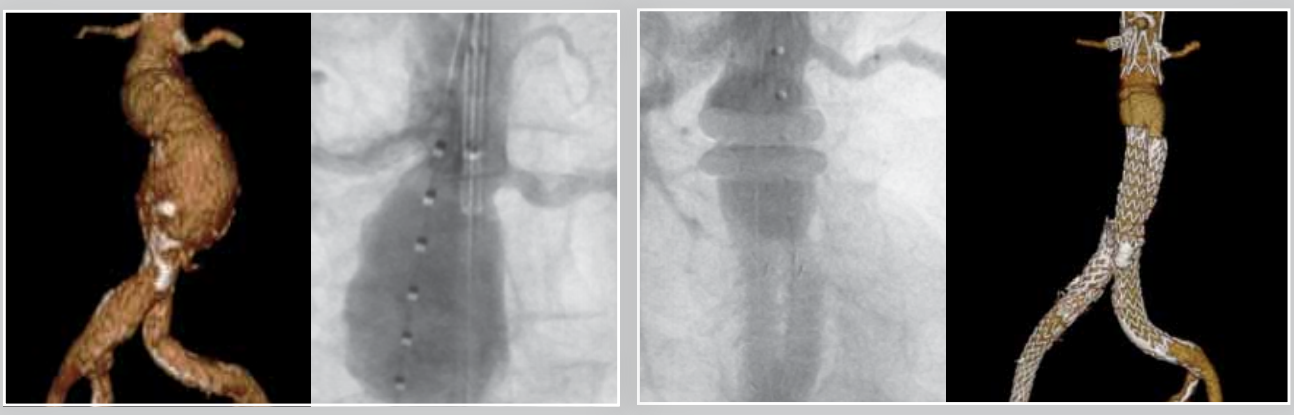
SIGNIFICANT THROMBUS

PRE-OPERATIVE **ONE YEAR FOLLOW-UP**



REVERSE-TAPERED NECKS AS SHORT AS 7MM IN LENGTH

PRE-OPERATIVE **PRE-DEPLOYMENT ANGIOGRAM** **FINAL ANGIOGRAM** **TWO YEAR FOLLOW-UP**



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INDICATIONS FOR USE: The TriVascular Ovation Prime Abdominal Stent Graft System is indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including: adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories; non-aneurysmal proximal aortic neck: with a length of at least 7 mm proximal to the aneurysm, with an inner wall diameter of no less than 16 mm and no greater than 30 mm and with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm; adequate distal iliac landing zone: with a length of at least 10 mm, and with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

CONTRAINDICATIONS: The TriVascular Ovation Prime Abdominal Stent Graft System is contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol). Also consider the information in Section 4 Warnings and Precautions of the system's Instructions for Use. Refer to Instructions for Use at TriVascular.com for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

CE marked. Please refer to current Ovation Prime Instructions for Use.
830-0158-01 rA

TRIVASCULAR™

A Less-Invasive Protocol for EVAR

Can lower-profile endografts improve the safety and efficiency of EVAR?

BY ZVONIMIR KRAJCER, MD

Despite the well-accepted safety and effectiveness of endovascular aneurysm repair (EVAR) for the treatment of abdominal aortic aneurysm (AAA), the prevention of access-related morbidity continues to pose a significant challenge. Traditional bilateral femoral artery cutdown and surgical closure increases groin complication risks, especially in patients with small-caliber, severely calcified, or tortuous access vessels.[1] Although first-generation EVAR devices were 22- to 27-F outer diameter (OD) in profile, newer-generation endografts incorporate even lower-profile delivery systems that, in some cases, enable totally percutaneous EVAR (PEVAR).

PEVAR was first tried at our institution in 1998, and results were reported in 1999.[2] In early single-center PEVAR reports, the success rates varied significantly and were less than optimal. The question remained, will the smaller-profile devices lead to improved PEVAR results? More recently, single-center publications revealed that as the EVAR device profile decreased and the experience increased, the success rate has increased to 96%.[3] Starnes et al reported that the success rate for patients treated with a sheath size > 20 F was 78% compared to 98.4% for patients treated with a sheath size ≤ 18 F.[3] In another meta-analysis, Georgiadis et al reported that the risk of conversion to cutdown during PEVAR increased by 78% with sheath sizes that were 20 F or greater.[4] Of the endografts that are commercially available today, the Ovation Prime™ abdominal stent graft (TriVascular, Inc., Santa Rosa, CA) offers the lowest delivery system profile (14-F OD) and should be ideally suited for PEVAR (Figure 1).

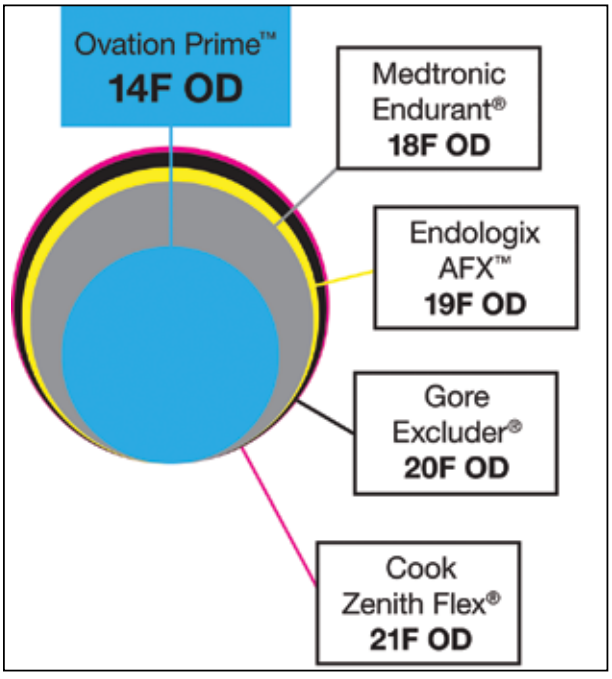

Figure 1. Outside sheath and/or device diameter of the Ovation Prime graft and other currently commercially available endografts in the United States. Note that the lowest-profile device is the Ovation Prime endograft.

THE ADVANTAGES OF PEVAR

Although single-center PEVAR reports have shown significant potential benefits to patients, physicians, and hospitals, the access-related complications (such as excessive procedural blood loss) still remain as a concern for certain patients. Several factors, including body mass index, operator experience, and femoral artery calcification, are known to influence success rates; however, the most consistent predictor of technical success is sheath diameter.[3,4] Recent studies have confirmed that smaller sheath diameters are associated with higher technical success rates and a lower risk of conversion to surgical cutdown.[3-5] Based on these findings, the 14-F Ovation Prime stent graft might be better suited for PEVAR compared to other stent grafts that have delivery system profiles ranging from 18 to 21 F.

One of the often-overlooked advantages is the use of local anesthesia during PEVAR. This affords numerous potential advantages to the patient and the physician alike. From the patient's perspective, PEVAR results in less postoperative discomfort, lowers the groin morbidity risk, allows treatment of challenging access anatomy, and enables treatment of those with significant comorbidities who are not suitable candidates for general anesthesia. From the physicians' and payors' perspectives, patient care is deliv-

TABLE 1. RESULTS OF THE OVATION™ PIVOTAL TRIAL		
	Femoral Cutdown	**Percutaneous Access**
Major adverse events at 30 d	3.3% (3/92)	1.4% (1/69)
Treatment success at 1 y	98.9% (91/92)	100% (69/69)
Anesthesia time (mean)	191 min	149 min
Procedure time (mean)	118 min	98 min
Hospitalization time (median)	2 d	1 d

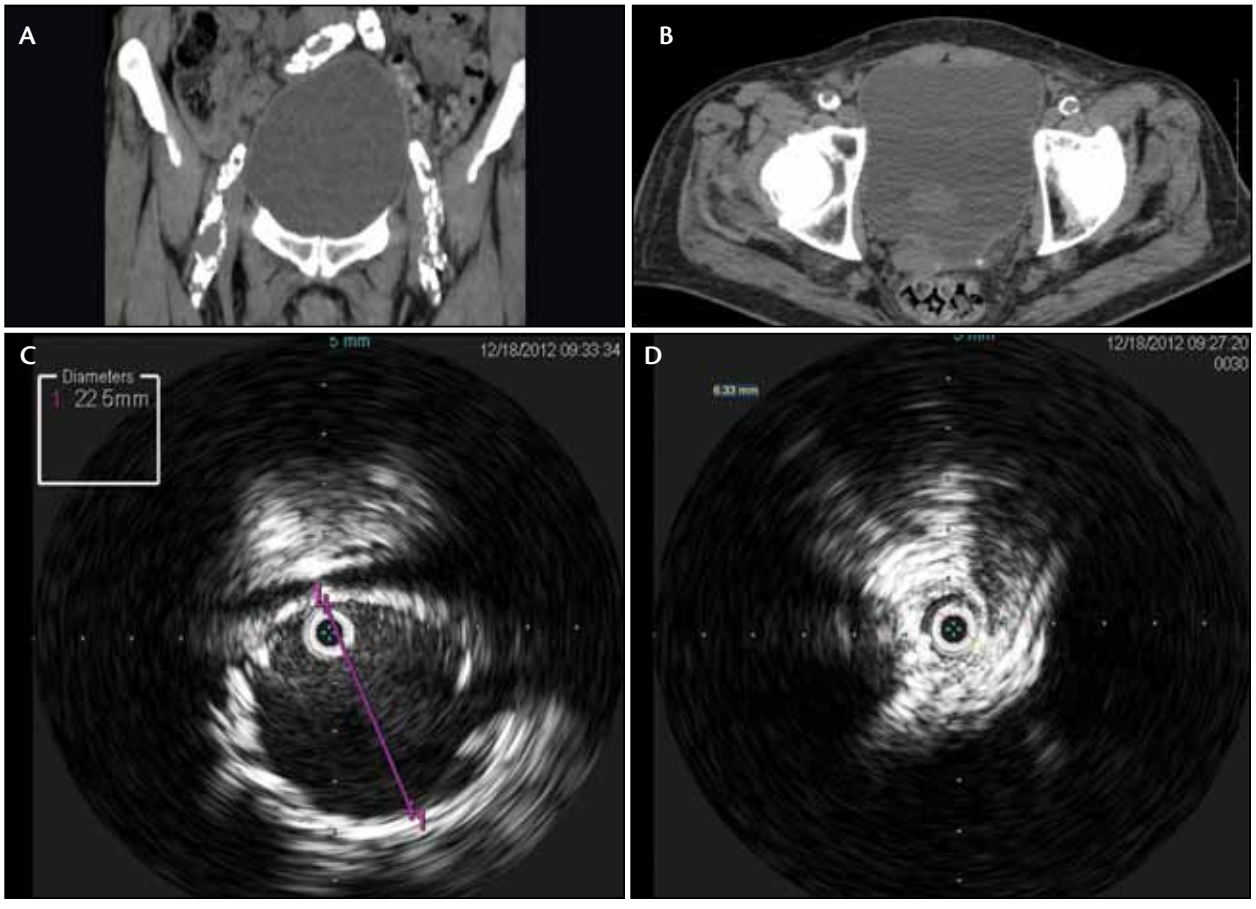

Figure 2. The maximum image projection CT of the femoral and iliac arteries reveals severe calcifications (A). A CT slice image at the access sites reveals circumferential calcification of the left common femoral artery and near-circumferential calcification of the right common femoral artery (B). The intravascular ultrasound image reveals the infrarenal aortic neck diameter to be 22.5 mm (C). The intravascular ultrasound image reveals circumferential calcification of the left common iliac artery that measured 6.3 mm in maximal diameter (D).

ered more cost effectively because general anesthesia is not required, procedure and operating room times are shorter, and hospital stays are also shorter. With the recent emphasis on reducing health care costs without sacrificing patient outcomes, the adoption of PEVAR with the Ovation Prime endograft has great potential to safely expand the eligible EVAR population with less patient morbidity and expense (Figure 1).

CLINICAL DATA ON PEVAR WITH THE OVATION DEVICE

Of course, rigorous evaluation in clinical trials is required to confirm the potential benefits and risks of each particular endograft. The recent Ovation global clinical study provides compelling evidence for the benefits of less-invasive PEVAR protocols using an ultra-low-profile delivery system. This clinical trial enrolled 161 patients with AAA; 69 underwent

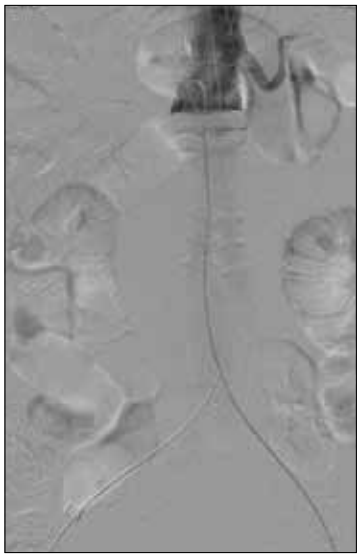

Figure 3. Completion angiographic image obtained with 5 mL of contrast reveals satisfactory positioning of the Ovation Prime endograft and no evidence of endoleak.

PEVAR, and 92 had traditional femoral cutdown. The access method was left to the discretion of the investigators. Short-term outcomes in PEVAR-treated patients showed some benefit when compared to those treated with cutdown, including greater treatment success; shorter anesthesia, procedure, and hospitalization times; and lower major adverse event rates through 30 days (Table 1).[6]

Outcomes with PEVAR using the Ovation device confirm the encouraging results seen with the 19-F OD AFX™ device (Endologix, Inc., Irvine, CA) in the Endologix PEVAR study.[5]

CASE EXAMPLE

Our experience using the Ovation Prime stent graft confirms the benefits observed in recent series. The following is a representative case that exemplifies the benefits of this device. An 87-year-old man with a rapidly enlarging AAA and comorbid conditions (coronary artery disease, angina, chronic obstructive pulmonary disease, intermittent claudication, and chronic renal failure) was referred for EVAR. We decided to perform PEVAR with the Ovation Prime stent graft in order to avoid complications with general anesthesia. The patient's right and left iliac arteries were severely calcified and showed significant narrowing, but his access sites were deemed to be appropriate for percutaneous access (Figure 2).

The procedure was performed under local anesthesia and conscious sedation, and we employed the PEVAR technique using the ProGlide® suture-mediated closure system (Abbott Vascular, Santa Clara, CA) for right and left femoral artery repair. Because of the patient's renal functional impairment, the procedure was performed with intravascular ultrasound guidance (Visions® PV .035 digital IVUS catheter, Volcano Corporation, San Diego, CA), and no contrast was used until completion angiography was performed (Figure 3). There were no complications, and completion angiography demonstrated complete exclusion of the AAA. The patient was discharged 24 hours later. Noncontrast CT at 1-month follow-up demonstrated AAA shrinkage with no reported complications (Figure 4). Notably, this patient was considered high risk for EVAR due to access vessel anatomy and multiple comorbidities.

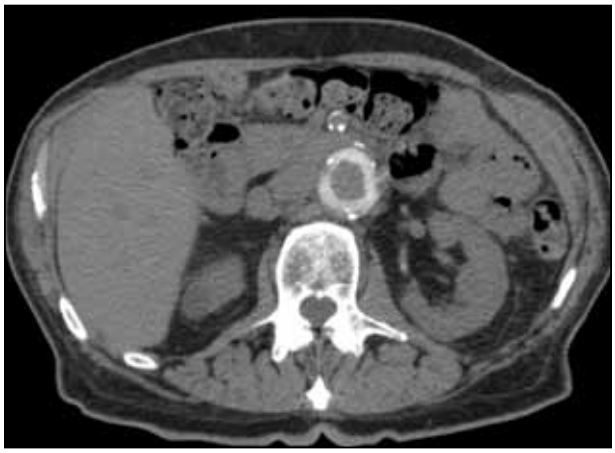

Figure 4. A noncontrast CT image reveals the Ovation Prime seal ring in the infrarenal neck at 1-month follow-up.

ENABLING LESS-INVASIVE EVAR PROTOCOLS

Minimally invasive EVAR protocols, including PEVAR under local anesthesia, are appealing to hospitals, patients, and physicians. In the United States in particular, a variety of factors are likely to accelerate the adoption of less-invasive EVAR protocols, including: (1) the increased focus on the cost of health care delivery, (2) increased patient awareness of and preference for treatment options that reduce recovery times, and (3) the availability of lower-profile devices, such as the 14-F OD Ovation Prime abdominal stent graft. The convergence of these factors is likely to create an environment that rewards hospitals and physicians that are equipped to adopt less-invasive and less-expensive AAA treatment modalities that reduce anesthesia use and length of stay.

Evidence to date with the Ovation Prime stent graft suggests that these treatment modalities are feasible and safe in well-selected patients. ■

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The Genesis of the Ovation Prime™ Abdominal Stent Graft Platform

Employing requirements-driven design and physical principles to engineer a new generation of EVAR therapy.

BY MICHAEL V. CHOBOTOV, PHD

Endovascular aneurysm repair (EVAR) is a therapy that presents intense mechanical engineering challenges in addressing the needs of large numbers of patients worldwide. Primary among these challenges is optimizing the deployment of large, durable devices through constricted delivery paths. Once deployed, these devices must be capable of withstanding high pulsatile loads while sealing within a wide range of morphologies. The scale of these mechanical challenges, combined with the intrinsic complexity of the therapy, dictates that EVAR will be a progressive market receptive to technology advancements for years to come.

REQUIREMENTS-DRIVEN DESIGN: UNDERSTANDING THE TARGET

In setting out to address these challenges, TriVascular, Inc. (Santa Rosa, CA) employed a "first principles" approach. This began with the definition of end-user and functional requirements, free from the landscape of the incremental/iterative development of conventional device architectures and any preconceived notions of what could be delivered through a catheter. The concept of virtual modeling and physics-based simulations as an integral part of the development process seemed to be generally absent (or at best, minimally applied) in the medical device industry, where numerous build-test iterations, followed by preclinical and clinical testing cycles, prevailed. In contrast, many aerospace development programs extensively leverage such technologies, because no earth-bound test environments or facilities can faithfully replicate many of the end-use conditions, and the cost of a trial-and-error approach is prohibitive. An opportunity was apparent for EVAR in which traditional clinical validation could be supplemented through such an approach, such that many costly problems discovered in late-stage preclinical and clinical experience could be avoided. This could allow greater technological strides to be made in development while incurring less clinical and program risk.

Reconstructing the body's largest artery via the same small access paths employed for coronary artery interventions was akin to building a ship in a bottle or deploying large spacecraft antenna structures in geosynchronous orbit. How "minimally invasive" a therapy actually is, really does matter. Over time, various EVAR manufacturers could be expected to incrementally improve their devices' abilities to address the key challenges of seal, fixation, and durability. Thus, to make a significant impact on abdominal aortic aneurysm (AAA) therapy, a new device must not only provide robust best-in-class seal, fixation, and durability, but also meaningfully reduce the impact and risk to the patient receiving the device. The therapy must be cost-effectively applicable to more patients, as well.

The top-level requirements for EVAR endografts came into focus: (1) effectively seal flow and remove pressure from the diseased aneurysm, even when the aortic lumen at the aneurysm margins is diseased and/or irregular; (2) anchor securely in a wide range of anatomic conditions; (3) conform to irregular anatomy in pre- and postdeployed states and accommodate potential aortic remodeling in response to "deflation" of the aneurysm, given that aneurysms tend to reverse their previous course after exclusion by contracting both diametrically and longitudinally; and (4) the delivery of the device must allow for significantly less invasive

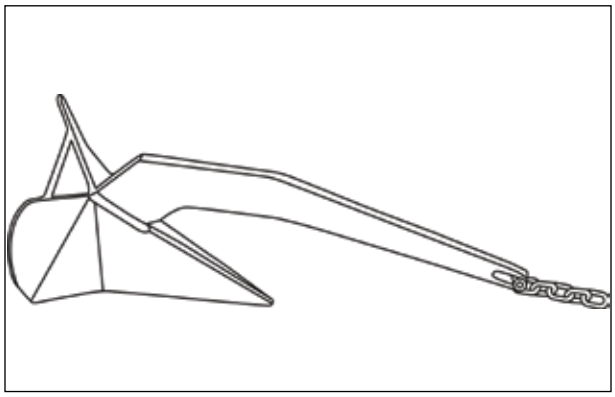

Figure 1. Plough anchor. A maritime anchor used to fix a vessel position by hooking into the seabed.

Figure 2. Close-up of an O-ring, one of the simplest yet most useful and robust sealing mechanisms ever developed.

access to the aneurysm in a simple and straightforward manner. Extensive interactions with physicians pioneering minimally invasive procedures and modalities confirmed these target requirements for a new endovascular approach to AAA.

APPLICATION OF FUNDAMENTAL PHYSICAL PRINCIPLES: THE RIGHT TOOLS FOR THE RIGHT JOBS

These seemingly disparate requirements and functions of an effective EVAR solution dictated the use of a corresponding segmentation by function, location, and time for the system architecture and its elements. To optimize performance, a seal is created that must only seal and not be burdened with the additional task of fixation, and a deployed anchor must only hold the implant securely in place and not be asked to do anything more. Furthermore, because these components can preferentially engage separate locations within the anatomy, they are not superimposed within the delivery catheter, and their constituents are not all delivered simultaneously. Consequently, ultra-low-profile delivery can be achieved without compromise. In contrast, other EVAR devices have aimed to both anchor and seal using stents combined with fabric, with neither optimized for their roles and each forced to compete for the same space within their delivery catheters.

Thus, the Ovation Prime stent graft (TriVascular, Inc.) employs a stent to engage tissue proximal to the site of the more diseased aneurysm, using integrally formed anchors. Such angled protrusions have long been used to hold onto irregular surfaces—consider the plough sea anchor (Figure 1) and also pitons used in rock climbing as well-proven examples. A progressive, staged delivery of the anchor is used to allow precise placement, particularly important in short-neck anatomies. Also, because annular, compliant rings (O-rings) are widely used in engineering applications for sealing fluid flow systems (e.g., hydraulic and pneumatic piping), such a venerable, ubiquitous component is ideally suited for sealing a device within the aorta (Figure 2).

To address the need to deliver this seal in a minimally invasive manner, and to adapt it to a variety of irregular lumens, an annular inflatable ring is cast in situ to form a custom molded O-ring seal at the margin of the aneurysm. This seal's conformability to irregular/diseased surfaces is illustrated by the "impression molds" shown in Figure 3. This ring is created by filling an annular envelope (integrally formed at the proximal end of the device) with a cross-linking polymer material in a liquid state, which subsequently solidifies to eliminate

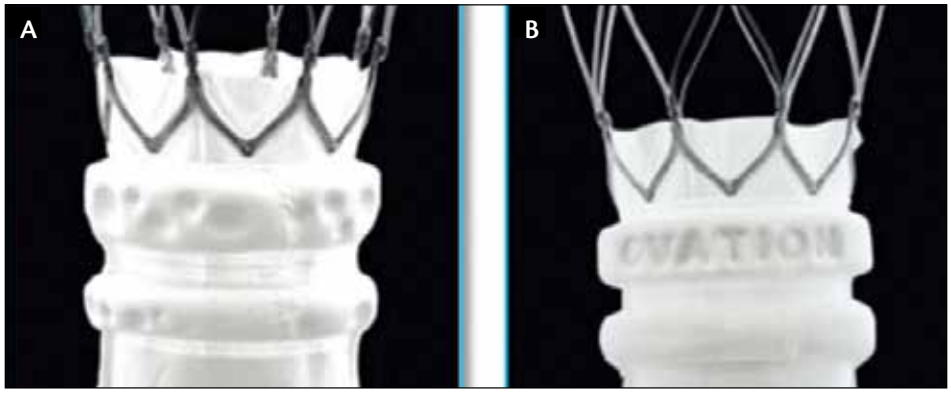

Figure 3. Ovation Prime's sealing rings after filling in an irregularly shaped cylinder (A) and a cylinder with "Ovation" lettering (B).

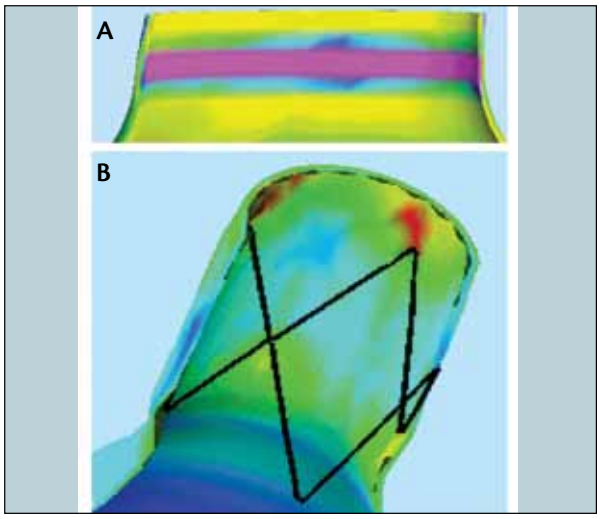

Figure 4. Finite element analysis (FEA) simulation showing uniform and continuous apposition (pink) of the Ovation sealing ring (A). Similar FEA simulation showing discontinuous points of apposition (red) with conventional wire and fabric structure (B).

the need to contain it in a fluid state under pressure over the long-term. Using a conduit within the delivery catheter to inject this structural material enables delivery of any amount of material that is required without affecting the delivery system profile or compromising durability. The cross-linking or "setting up" of this fill material contained within the sealing ring also provides for a nonexpansive apposition of the seal against the diseased aortic wall proximal to the aneurysm.

Because the underlying mechanism of aortic expansion in AAA stems from an imbalance between hemodynamic-pressure–induced wall stresses and degraded aortic wall mechanical integrity, it is intuitively desirable to avoid superimposing additional chronic outward radial force on the aorta, as is typically done with traditional self-expanding stent grafts (which have been associated with neck dilatation). Another benefit of the molded-sealing-ring approach is the uniformity of wall stress at its interface to the sealing zone, as the fluid encased in its compliant PTFE envelope achieves pressure equilibration prior to cross-linking (Figure 4A). In contrast, wire-fabric structures typical of other stent grafts can create highly irregular/nonuniform contact stress at their interface to the vessel wall, as depicted in Figure 4B.

While the Ovation Prime abdominal stent graft system can be described as a novel-architecture, new-generation EVAR solution, it applies well-understood and established engineering principles for fixation and sealing seen in a multitude of applications. We believe this will benefit large numbers of patients suffering from aortic disease worldwide. ■

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INDICATIONS FOR USE:
The TriVascular Ovation Prime Abdominal Stent Graft System is indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including: adequate iliac/femoral access compatible with vascular access techniques, devices, and/or accessories; non-aneurysmal proximal aortic neck: with a length of at least 7 mm proximal to the aneurysm, with an inner wall diameter of no less than 16 mm and no greater than 30 mm, and with an aortic angle of ≤ 60 degrees if proximal neck is ≥ 10 mm and ≤ 45 degrees if proximal neck is < 10 mm; adequate distal iliac landing zone: with a length of at least 10 mm, and with an inner wall diameter of no less than 8 mm and no greater than 20 mm.

CONTRAINDICATIONS:
The TriVascular Ovation Prime Abdominal Stent Graft System is contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol). Also consider the information in Section 4 Warnings and Precautions of the system's Instructions for Use. Refer to Instructions for Use at TriVascular.com for more information concerning Indications, Contraindications, Warnings and Precautions, and Adverse Events.

CAUTION:
Federal (USA) law restricts this device to sale by or on the order of a physician.


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