

Improving Procedural Predictability in EVAR

New TriVascular Ovation iX™ Delivery System adds integrated sheath and an additional option for gate cannulation.

BY STEVE HENAO, MD, FACS, FACC

Continued advancements in endovascular aneurysm repair (EVAR) technology, combined with greater operator experience, have resulted in more effective treatment options that are less likely to cause morbidity for patients with abdominal aortic aneurysms (AAAs). Vascular specialists are increasingly managing more complex aneurysms with endovascular techniques. Although EVAR for complex aneurysms remains a less invasive procedure than open surgical repair, these cases are associated with greater procedural complexity, longer procedure times, higher complication rates, and greater radiation exposure to patients and operators compared to straightforward cases.^{1,2}

OVATION® SYSTEM IMPROVES AND EXPANDS EVAR

Availability of the Ovation stent graft (TriVascular, Inc.) in the United States in 2011 marked a significant advancement in the evolution of EVAR by offering an on-label, less invasive treatment option to patients across a wider range of challenging anatomies, from simple to complex and in both men and women.³

The Ovation abdominal stent graft was designed to address many of the limitations of first-generation EVAR devices and expand patient applicability. As part of the trimodular implant, the aortic body is composed of low-permeability polytetrafluoroethylene (PTFE) and a suprarenal nitinol stent for active fixation in healthy tissue. Narrow and tortuous access vessels are easily traversed by the flexible, hydrophilic-coated, 12-F delivery system with an integrated sheath, the smallest profile of any currently commercially available stent graft.

Aneurysm seal is achieved in both straightforward and challenging proximal aortic neck anatomies (ie, short, reverse

taper, and/or calcified) via a novel O-ring design. By inserting a low-viscosity, radiopaque fill polymer into inflatable channels within the aortic body, physicians effectively create a customized seal in situ. As would be expected, this innovative sealing mechanism has implications for how we think about the shape and length of sealing zones with this EVAR system.

The longitudinal sealing mechanism employed by covered, oversized self-expanding stents relies on a length of parallel wall (generally 15 mm) over which sufficient fabric can be pushed against the vessel to achieve a seal. By contrast, the Ovation system's customized O-ring seal creates a circumferential fit at the level of the polymer-filled ring and thus does not require parallel walls to obtain a seal. In the engineering world, this type of O-ring seal is widely used and is considered the gold standard for sealing in fluid flow systems. In addition, the controlled, low-pressure injection of the polymer causes the sealing ring to conform around irregularities caused by disease or native anatomy. In the aorta, the resulting O-ring seal produces

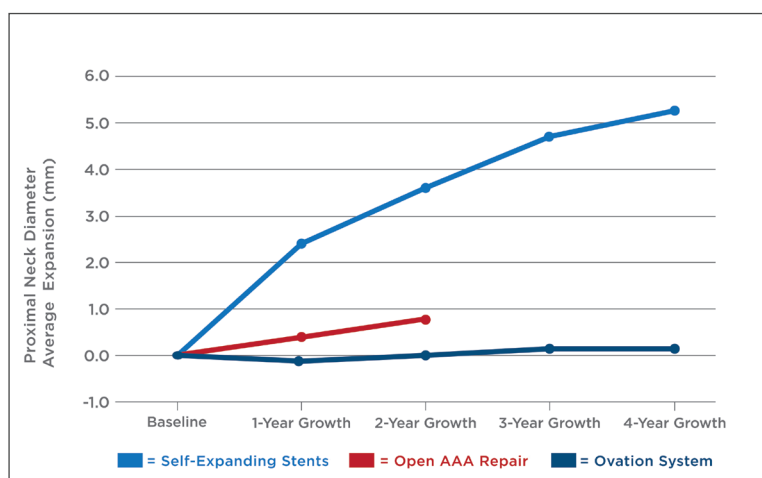


Figure 1. The sealing ring of the Ovation system insulates the neck from blood pressure, resulting in stable neck diameters.

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TABLE 1. GLOBAL OVATION PIVOTAL TRIAL EXPERIENCE*

Technical Success†					All N = 161
Defined as successful delivery and deployment of one aortic body and two iliac limbs					
Safety‡	0–30 Days	31–365 Days	366–730 Days	731–1,095 Days	1,096–1,460 Days
Major adverse events	2.5%	3.8%	—	—	—
Device-related major adverse events	0%	0%	—	—	—
Rupture	0%	0%	0%	0%	0%
Conversion to open repair	0%	0%	0%	0%	0%
Effectiveness§	30 Days	1 Year	2 Years	3 Years	4 Years
Type I and III endoleaks	0%	0%	0%	0%	0%
Migration	Baseline	0%	0%	0%	0%

*Data as of July 31, 2015.
†Technical success based on investigator reports.
‡Major adverse events and device-related major adverse events based on clinical events committee adjudicated data. Rupture and conversion to open repair based on investigator reports.
§Endoleaks and migration rates based on core lab data (M2S).

an additional benefit of exerting no outward force on the vessel wall and insulating the neck from blood pressure, resulting in stable neck diameters (Figure 1).⁴⁻⁶

With its low profile and insulating sealing mechanism, the Ovation stent graft is designed to be a workhorse system that can offer compelling benefits to all patients with AAA disease. Without a conventional aortic neck length requirement, the system is also well suited to treat short and hostile neck anatomies. Completing the implanted system, PTFE-covered, wire-wound nitinol limbs reduce vessel occlusion and maintain patency.⁷

Highly encouraging midterm (4-year) results from the Ovation Global Pivotal Trial in both challenging and straightforward anatomies appear to confirm that the Ovation system provides durable and clinically meaningful treatment benefits in patients with AAAs (Table 1).

Through 4 years, no type I or III endoleaks or migrations were identified, and freedom from AAA-related mortality through 4 years was 99.4%.

INNOVATING FOR EFFICIENCY: OVATION iX™

TriVascular, Inc. has been committed to continuous device improvements to reduce procedure times and improve predictability and safety in the operating room. The most recent of these improvements is the Ovation iX system. Building upon the strength of the Ovation and Ovation Prime® iliac technology, the Ovation iX iliac stent graft was developed to improve physician ease of use and expand patient applicability.

The Ovation iX system received premarket approval (PMA-S) from the US Food and Drug Administration earlier this year. Ovation iX stands for integrated exchange;

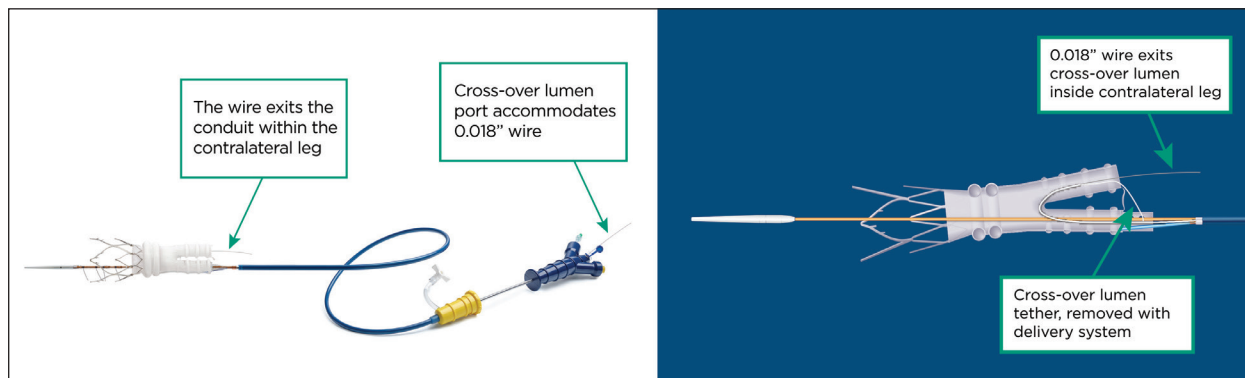


Figure 2. The Ovation iX delivery system offers an on-demand alternative to retrograde cannulation via a built-in crossover lumen.

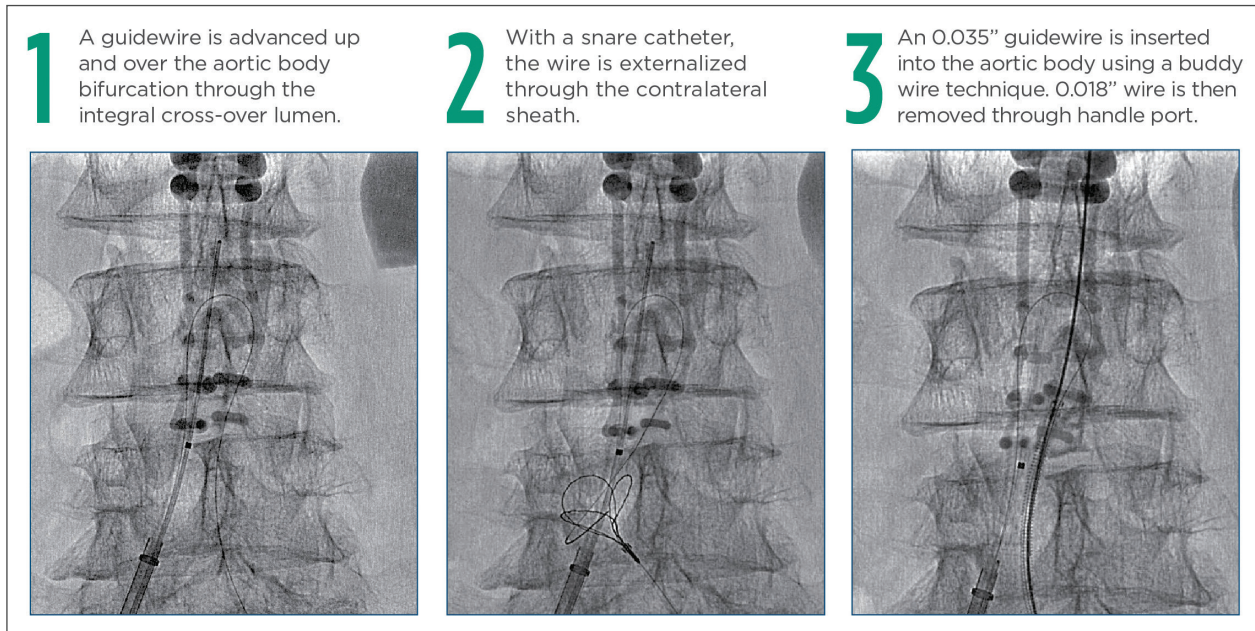


Figure 3. Use of the crossover lumen under fluoroscopy.

the delivery system allows the inner catheter to be withdrawn through the sheath, leaving behind an integral 12-F introducer sheath. Designed to minimize vessel trauma and reduce procedural steps, the integral sheath allows for the introduction of ancillary devices without necessitating a sheath exchange (Figure 2).

Retrograde cannulation of the contralateral limb has posed a common procedural challenge during EVAR and is often the rate-limiting step that requires the most wire and catheter skill, particularly in treating the growing number of patients with complex aortoiliac anatomy. The Ovation iX aortic body provides a new procedural option

designed for easier and more predictable contralateral gate access. A built-in PTFE lumen traverses the ipsilateral leg and crosses over into the contralateral leg. The conduit is compatible with a 0.018-inch guidewire, inserted through a new port in the handle. This wire is snared on the contralateral side, and a 0.035-inch guidewire is inserted into the aortic body using a buddy wire technique (Figure 3). The crossover lumen is entirely withdrawn with the delivery system after placement of the contralateral limb. This new capability may improve procedural efficiency by reducing ancillary devices required for challenging retrograde cannulations and precluding the need for bra-

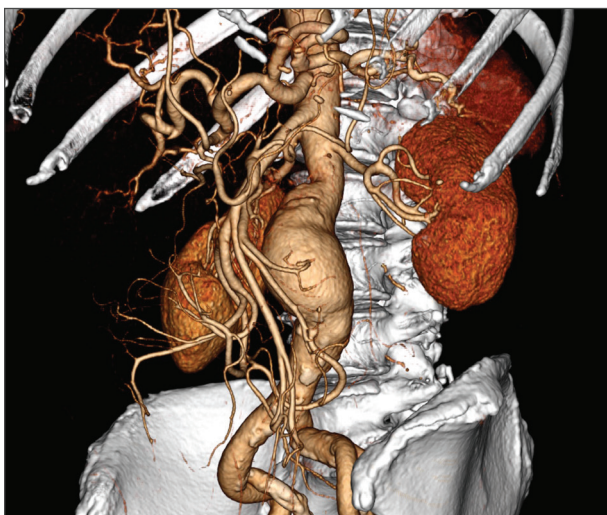


Figure 4. Initial CT showing AAA.



Figure 5. Pretreatment CT showing AAA.

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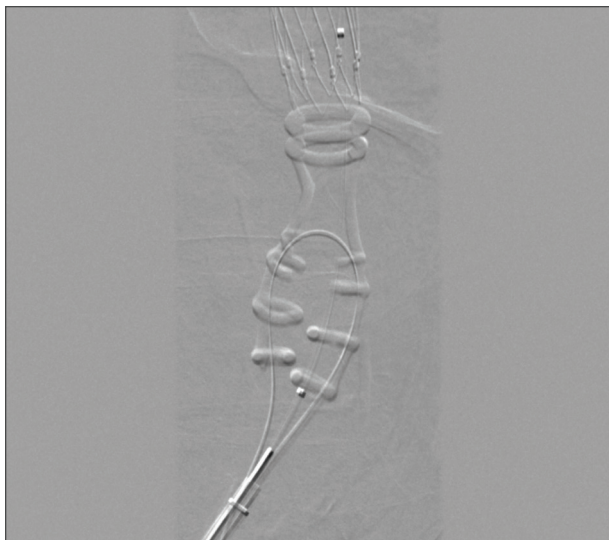


Figure 6. Fluoroscopic image showing the 0.018-inch guide-wire through the crossover lumen.

chial or radial access. These enhancements are anticipated to result in shorter procedure times and lower operating room costs without sacrificing patient safety or durable aneurysmal exclusion.

HEART HOSPITAL OF NEW MEXICO EXPERIENCE

From late August through early October 2015, 23 patients were treated with the Ovation iX system at the Heart Hospital of New Mexico (Albuquerque, New Mexico) with excellent results. In this early experience, the system improvements have resulted in an average device time of 28 minutes with the Ovation iX system. Figures 4 through 8 show use of the Ovation iX system and success-

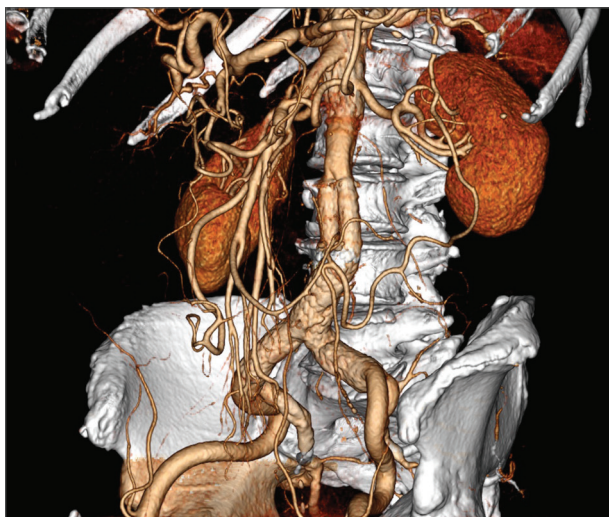


Figure 8. Follow-up CT showing successful exclusion of the AAA.



Figure 7. Follow-up CT showing the deployment of the Ovation iX system.

ful exclusion in a patient with an AAA from pretreatment to follow-up.

The nature of the crossover lumen allows for retrograde cannulation without interference when that option is preferable, which is the majority of our cases. When particularly challenging anatomy complicates retrograde cannulation, the crossover lumen presents an option to gain access to the contralateral gate without unnecessarily extending procedure time. In our center, any gate cannulation requiring more than 1 to 2 minutes is now easily engaged using the built-in crossover lumen in the Ovation iX system. Knowing we have multiple options in the new system gives us confidence in our EVAR planning and scheduling cases can be completed in a controlled and predictable manner with resulting benefits for the patient, operator, and staff. In fact, based on early device experience, some operators have indicated their intention to preferentially use the crossover lumen in Ovation iX procedures. ■

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1. Monastiriotis S, Comito M, Labropoulos N. Radiation exposure in endovascular repair of abdominal and thoracic aortic aneurysms. *Vasc Surg*. 2015;62:753-761.
2. Sailer AM, Schurink GW, de Haan MW, et al. Occupational radiation exposure during endovascular aortic repair. *Cardiovasc Intervent Radiol*. 2015;38:827-832.
3. Krajcer Z. TriVascular Ovation: its role in solving current endograft deficiencies. *J Cardiovasc Surg (Torino)*. 2015;56:325-329.
4. Monahan TS, Chuter TA, Reilly LM. Long-term follow-up of neck expansion after endovascular aortic aneurysm repair. *J Vasc Surg*. 2010;52:303-307.
5. Rodway AD, Powell JT, Brown LC, Greenhalgh RM. Do abdominal aortic aneurysm necks increase in size faster after endovascular than open repair? *Eur J Vasc Endovasc Surg*. 2008;35:685-693.
6. Ovation Global Pivotal Trial, core lab evaluation. Data as of July 31, 2015. Presented at the 13th annual Vascular Interventional Advances (VIVA) conference; November 2-5, 2015; Las Vegas, Nevada.
7. Mehta M, Valdés FE, Nolte T, et al. One-year outcomes from an international study of the Ovation Abdominal Stent Graft System for endovascular aneurysm repair. *J Vasc Surg*. 2014;59:65-73.