

Endovascular TODAY

September 2014

PROTECT THE NECK

The Ovation Prime® sealing ring preserves the aortic neck with an innovative, less-invasive, clinically proven solution for the broadest range of AAA anatomies.

Contents

3 RETHINK THE NECK

How the Ovation Prime® System is revolutionizing the way we approach EVAR.

By Manish Mehta, MD, MPH

7 PRESERVING THE AORTIC NECK

Why the O-ring sealing technology of the Ovation Prime® System does not contribute to aortic neck dilatation.

By Sean P. Lyden, MD

9 REAL-WORLD EXPERIENCE

What we have learned thus far from the midterm results of the European OVATION® Post-Market Registry.

By Dierk Scheinert, MD

12 THE WORKHORSE SYSTEM

Versatility of the Ovation Prime® System in challenging and straightforward anatomies.

By Venkatesh G. Ramaiah, MD, FACS; Syed M. Hussain, MD; Jennifer L. Ash, MD;

Ayman Jamal, MD; Ravi Hasanadka, MD; and Thomas King, DO

16 THE LEAST-INVASIVE APPROACH

Transitioning to a fast-track EVAR protocol.

By Brant W. Ullery, MD, and Jason T. Lee, MD

Rethink the Neck

How the Ovation Prime® System is revolutionizing the way we approach EVAR.

BY MANISH MEHTA, MD, MPH

The widespread adoption of endovascular aneurysm repair (EVAR) over the last decade represents a major therapeutic advancement in the treatment of aortic aneurysms. In abdominal aortic aneurysm (AAA) patients with suitable aorto-iliac anatomy, EVAR has been consistently shown to improve perioperative outcomes in comparison to surgical AAA excision with graft interposition.^{1,2} Even as third- and fourth-generation stent grafts have recently been introduced, endograft technology continues to evolve in a constant effort to address and overcome ongoing therapeutic challenges such as expanding patient eligibility, reducing perioperative complications, and improving long-term graft durability in the presence of progressive aneurysmal disease.

IMPORTANCE OF PROXIMAL NECK ANATOMY IN EVAR

Unquestionably, the most important factor in ensuring a durable repair with a conventional stent graft is the anatomy of the proximal aortic neck. The Characterization of Human Aortic Anatomy Project found that nearly 35% of men and 60% of women remain ineligible for EVAR solely based on anatomical requirements.³ Additionally, inadequate aortic neck length was a main driver of EVAR ineligibility, with neck lengths < 10 mm identified in more than one

in four patients. Few satisfactory treatment options exist for these patients and are mainly limited to open surgical repair in suitable patients, fenestrated and branched endografts at select centers, off-label EVAR, or “watchful waiting,” none of which are ideal solutions.

Even in patients who qualify for EVAR, short aortic necks remain the greatest limitation to achieving adequate proximal seal and durable aneurysm exclusion. Numerous studies have demonstrated that patients with short proximal necks are at significantly higher risk for device-related complications. In a study of 3,500 patients from the EUROSTAR registry, patients with aortic necks < 10 mm had a fourfold greater risk of proximal endoleak through 30 days of follow-up compared to those with necks > 15 mm.⁴

AbuRahma and colleagues⁵ identified proximal endoleaks in approximately 50% of patients with aortic neck lengths < 10 mm at a mean of 2 years of follow-up. In a follow-up study by this group in patients with hostile or favorable neck anatomy, short neck length not only increased the risk for early proximal endoleak and reintervention, but was also a stronger predictor of complications than most other features of a “hostile neck,” such as a highly angulated neck and calcification.⁶ Clearly, a short proximal neck portends an unfavorable outcome in many patients when using traditional endografts.

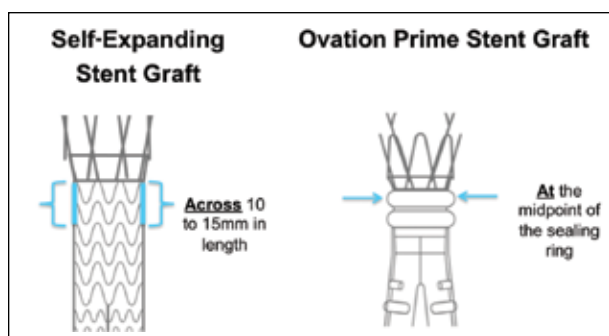


Figure 1. Self-expanding stent grafts require a longitudinal seal (parallel walls) across a minimum 10- or 15-mm length. The Ovation Prime stent graft provides a circumferential seal at the midpoint of the O-ring.

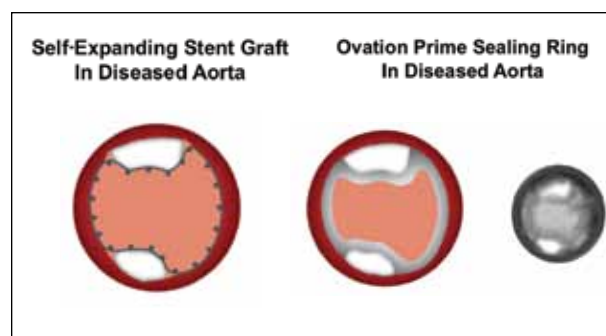


Figure 2. Self-expanding stent grafts may not conform to an irregular luminal surface. The Ovation Prime O-ring molds and conforms to irregular luminal surface, creating a customized seal.

WHY DO TRADITIONAL ENDOGRAFTS PERFORM POORLY IN SHORT NECKS?

Traditional wire and fabric stent grafts (Figure 1) require 10 to 15 mm of nonaneurysmal, relatively cylindrical proximal neck to adequately seal the aneurysm sac from chronic circulatory pressures. In long, straight, cylindrical necks with minimal thrombus and calcification, most stent grafts perform similarly well. These devices achieve seal by oversizing the stent by approximately 10% to 20% in relation to the aortic diameter in hopes that the chronic radial force exerted against the aortic wall will circumferentially prevent blood from repressurizing the aneurysm sac.

Unfortunately, as we have learned over the years, the design of stent and graft combination has several limitations. First, the radial force exerted by endografts varies considerably depending on endograft characteristics and the degree of oversizing in relation to the aorta. Therefore, it is difficult to reliably predict the robustness of the seal from patient to patient. Second, when hostile necks are encountered, stent graft performance declines significantly because of their inability to fully conform to an irregular luminal surface (Figure 2), creating discontinuous points of apposition. Third, proximal necks of any length tend to enlarge after EVAR to approximate the nominal diameter of the stent graft (Figure 3A). The influence of chronic radial forces with traditional stent grafts on progressive neck dilatation and increased risk of device complications is well-documented.^{7,8}

THE SCIENCE BEHIND THE SEAL

The Ovation Prime system (TriVascular, Inc.) is a revolutionary endograft that challenges conventional wisdom by redefining the concept of aortic neck length with a sealing mechanism that is completely different from other stent grafts. For over 100 years, O-rings have been used in commercial applications to seal water and air within defined spaces. This concept was carried over to the sealing mechanism of the Ovation Prime stent graft. The Ovation Prime system utilizes an innovative, polymer-filled sealing ring that is cast in situ at the margin of the aneurysm. The ring is created by filling the proximal sealing channels with a polymer material in a liquid state, which quickly solidifies, forming a watertight bond against the aortic wall at a specific location. Unlike other available stent grafts, this gasket-like seal conforms to irregular anatomies, including reverse-tapered necks or those with extensive thrombus and/or calcification.

Additionally, the Ovation Prime O-ring seal provides uniform, nonexpansive, continuous wall apposition that insulates the aortic neck from circulatory pressures and minimizes the risk of progressive aortic neck dilatation (Figure 3B). This is in sharp contrast to traditional wire

and fabric stent grafts that have discontinuous points of apposition in irregular or tapered anatomies, which expose the aortic neck to chronic systemic pressures.

RETHINKING THE REQUIREMENT FOR NECK LENGTH

The Ovation Prime sealing ring technology has undergone extensive biomechanical testing that demonstrated a durable seal.⁹ Furthermore, based on excellent short- and midterm clinical outcomes reported to date,¹⁰⁻¹³ the US Food and Drug Administration recently approved a modification to the indication for use statement for the Ovation and Ovation Prime systems that clarifies the unique anatomical considerations for patient selection. This makes the Ovation and Ovation Prime systems the only stent graft approved by the US Food and Drug Administration for EVAR not restricted by the conventional measurement¹⁴ of aortic neck length in its labeling (requiring minimum length of parallel walls). The clarified indication states that the Ovation systems may be used when the inner wall diameter is no less than 16 mm and no greater

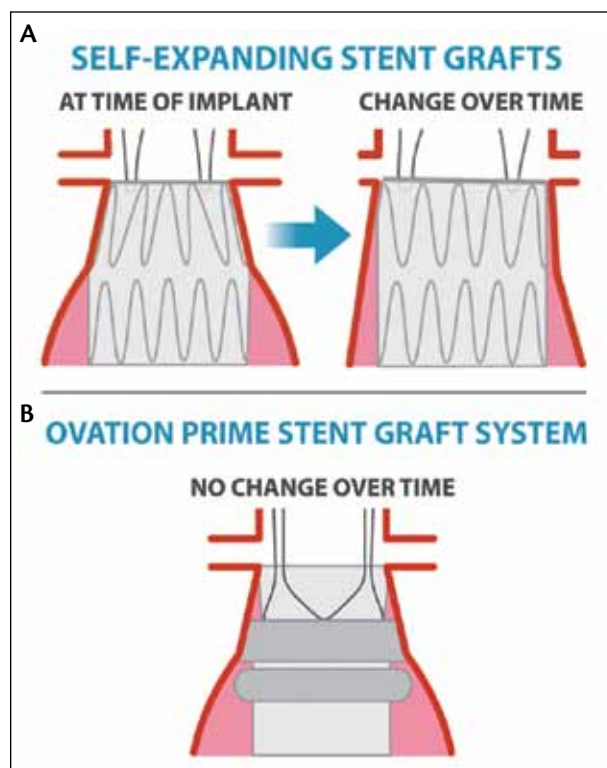


Figure 3. Chronic outward force from a self-expanding stent, combined with blood pressure, can result in neck dilatation and may compromise seal (A).¹⁵⁻¹⁷ Ovation Prime sealing ring creates no chronic outward force and insulates the neck from blood pressure, resulting in no neck dilatation* (B).

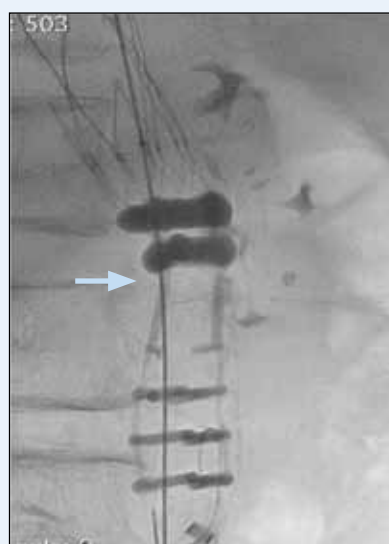
*Results as of July 26, 2013, based on Core lab data from Ovation study.

CASE STUDY

A 76-year-old man presented with lower extremity thromboembolism and underwent successful endovascular thromboembolism. On workup, CT angiography indicated a 5.5-cm AAA with a neck that had significant angulation and thrombus. When planning the EVAR procedure, an Ovation Prime stent graft was selected due to its low profile and unique properties that allow the stent graft to have suprarenal fixation and an infrarenal O-ring seal zone that conforms to the angulated aortic neck, even with severe thrombus.



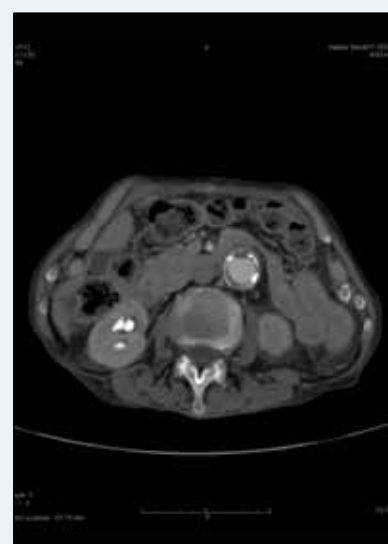
1. Aortic neck with severe angulation and thrombus.



2. Ovation main-body O-ring (lateral view). The slow and precise inflation of the O-rings allows conformation to the severe angulation and thrombus.



3. Completion angiogram indicating complete aneurysm exclusion, with no endoleak. The O-rings self-adjusted to conform to the aortic neck, even with significant angulation and thrombus.



4. Postoperative CTA.

than 30 mm at 13 mm below the inferior renal artery. Neck length is only considered in assessing angulation: patients with a proximal neck length of < 10 mm are indicated with an aortic angle of $\leq 45^\circ$; otherwise, angles up to 60° are indicated.

OVATION GLOBAL PIVOTAL TRIAL RESULTS

In the Ovation Global Pivotal Trial, 161 patients were electively treated with the Ovation® stent graft for AAA, including 65 patients who were not eligible for EVAR with other commercially available stent grafts. Of those 65 patients, 26 patients had an aortic neck length of < 10

mm. Interestingly, compared to the total study population, a very short neck did not increase the risk for device-related complications (Table 1).

LOOKING AHEAD

The innovative sealing ring technology in the Ovation Prime stent graft serves as the gold standard for other stent graft manufacturers to emulate. This revolutionary design has advanced EVAR with the Ovation Prime system well beyond the incremental improvements typically seen with next-generation stent graft modifications. With impressive pivotal trial clinical results

TABLE 1. DATA FROM THE OVATION® GLOBAL PIVOTAL TRIAL AS OF JANUARY 30, 2014

| Studied Outcomes | Full Cohort | | | Short-Neck Subgroup (< 10 mm) | | |
|--|---------------------|-----------------------|------------------------|-------------------------------|----------------------|-----------------------|
| Safety | 0–30 d (n = 161) | 31–365 d (n = 159) | 366–730 d (n = 154) | 0–30 d (n = 26) | 31–365 d (n = 26) | 366–730 d (n = 25) |
| Freedom from major adverse events | 97.5% | 96.2% | – | 100% | 96.2% | – |
| Freedom from device-related major adverse events | 100% | 100% | – | 100% | 100% | – |
| Freedom from rupture | 100% | 100% | 100% | 100% | 100% | 100% |
| Freedom from conversion | 100% | 100% | 100% | 100% | 100% | 100% |
| Effectiveness | 30 d | 1 y | 2 y | 30 d | 1 y | 2 y |
| Freedom from type I and III endoleaks | 100% (n = 153) | 100% (n = 143) | 100% (n = 120) | 100% (n = 25) | 100% (n = 22) | 100% (n = 17) |
| Freedom from device migration | Baseline | 100% (n = 150) | 100% (n = 132) | Baseline | 100% (n = 24) | 100% (n = 19) |

reported out to 2 years and more than 4,500 patients treated worldwide, the Ovation Prime system sets the standard for EVAR excellence. ■

Manish Mehta, MD, MPH, is with The Vascular Group, PLLC in Albany, New York. He has disclosed that he was the National Principal Investigator for the Ovation Pivotal Trial and a consultant to TriVascular. Dr. Mehta may be reached at (518) 262-5640; mehtam@albanyvascular.com.

1. Jackson RS, Chang DC, Freischlag JA. Comparison of long-term survival after open vs endovascular repair of intact abdominal aortic aneurysm among Medicare beneficiaries. *JAMA*. 2012;307:1621–1628.
2. Lovegrove RE, Javid M, Magee TR, Galland RB. A meta-analysis of 21,178 patients undergoing open or endovascular repair of abdominal aortic aneurysm. *Br J Surg*. 2008;95:677–684.
3. Morrison T, Fillinger M, Meyer C, et al. Gender disparities in endovascular treatment options for infrarenal abdominal aortic aneurysms. <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM359044.pdf>. Published June 25, 2013. Accessed June 20, 2014.
4. Leurs LJ, Kievit J, Dagnelie PC, et al. Influence of infrarenal neck length on outcome of endovascular abdominal aortic aneurysm repair. *J Endovasc Ther*. 2006;13:640–648.
5. AbuRahma AF, Campbell J, Stone PA, et al. The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients. *J Vasc Surg*. 2009;50:738–748.
6. Aburahma AF, Campbell JE, Mousa AY, et al. Clinical outcomes for hostile versus favorable aortic neck

- anatomy in endovascular aortic aneurysm repair using modular devices. *J Vasc Surg*. 2011;54:13–21.
7. Monahan TS, Chuter TA, Reilly LM, et al. Long-term follow-up of neck expansion after endovascular aortic aneurysm repair. *J Vasc Surg*. 2010;52:303–307.
8. Dillavou ED, Muluk S, Makaroun MS. Is neck dilatation after endovascular aneurysm repair graft dependent? Results of 4 US Phase II trials. *Vasc Endovasc Surg*. 2005;39:47–54.
9. US Food and Drug Administration. TriVascular, Inc. Ovation abdominal stent graft system. Summary of Safety and Effectiveness Data (SSED). http://www.accessdata.fda.gov/cdrh_docs/pdf12/P120006b.pdf. Accessed September 5, 2014.
10. Nano G, Mazzaccaro D, Stegher S, et al. Early experience with Ovation endograft system in abdominal aortic disease. *J Cardiothorac Surg*. 2014;9:48.
11. Irace L, Venosi S, Gattuso R, et al. Initial single-site experience with the Ovation abdominal stent-graft system in patients with challenging aortoiliac anatomy [published online ahead of print January 16, 2014]. *J Cardiovasc Surg (Torino)*.
12. Mangialardi N, Ronchey S, Kasemi H, et al. Percutaneous endovascular aneurysm repair with the ultra-low profile Ovation abdominal stent-graft system. *J Cardiovasc Surg (Torino)*. 2013;54:581–587.
13. Mehta M, Valdes 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 e61–63.
14. Sweet MP, Fillinger MF, Morrison TM, Abel D. The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair. *J Vasc Surg*. 2011;54:931–937.
15. Cao P, Verzini F, Parlani G, et al. Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts. *J Vasc Surg*. 2003;37:1200–1205.
16. Dillavou ED, Muluk S, Makaroun MS. Is neck dilatation after endovascular aneurysm repair graft dependent? Results of 4 US Phase II trials. *Vasc Endovasc Surg*. 2005;39:47–54.
17. Li Z, Kleinstreuer C. Analysis of biomechanical factors affecting stent-graft migration in an abdominal aortic aneurysm model. *J Biomechanics*. 2006;39:2264–2273.

Preserving the Aortic Neck

Why the O-ring sealing technology of the Ovation Prime® System does not contribute to aortic neck dilatation.

BY SEAN P. LYDEN, MD

Most of you have probably never heard of an O-ring, but they make everyday life possible, as they are used in engines, pumps, pipelines, autoclaves, compressors, reactors, hydraulics, HVAC (heating, ventilation, and air conditioning), and aerospace uses. As you can see, O-rings are one of the most common seals used in machine design because they are inexpensive, easy to make, reliable, and have simple mounting requirements.

O-RING MECHANISM OF ACTION

An O-ring is a torus, or a doughnut-shaped object, generally made from an elastomer designed to be seated in a groove and compressed between two or more parts, creating a seal at the interface (Figure 1). The O-ring may be used in static applications or in dynamic applications where there is relative motion between the parts and the O-ring. Dynamic examples include rotating pump shafts and hydraulic cylinder pistons.¹ The amazing quality of an O-ring is that it can seal tens of thousands of pounds per square inch of pressure.

Now, how does the O-ring apply in the context of vascular surgery? The two main challenges in endovascular aneurysm repair are fixation and sealing.² For devices with-

out suprarenal stents, fixation and sealing occur at the same level. Devices with suprarenal stents use the paravisceral segment of the aorta to enhance fixation. Sealing for most endovascular aneurysm repair devices approved by the US Food and Drug Administration (FDA) is achieved via radial force from (nitinol or stainless steel) stents pushing fabric (either polyester or polytetrafluoroethylene) against the aneurysm wall. The exception is the Ovation Prime stent graft (TriVascular, Inc.), which uses an O-ring for seal (Figure 2).

O-RING SEALING WITH THE OVATION PRIME DEVICE

The TriVascular Ovation Prime device gained FDA approval based on data from a prospective, multicenter, single-arm trial in which 161 patients were treated.³ The Ovation Prime device is unique in that the fixation and sealing mechanisms are separated. The device uses a suprarenal nitinol stent with integral anchors for active fixation. To achieve seal, a polymer fills an O-ring that, once cured, does not exert chronic outward force on the aortic wall. The midpoint of the primary sealing O-ring is located 13 mm below the top of the fabric on the Ovation Prime device. A secondary sealing ring is located 20 mm below the top of the fabric.



Figure 1. A basic O-ring design.



Figure 2. The Ovation Prime stent graft with sealing O-ring.

The prospective, multicenter, single-arm trial utilized an independent imaging core laboratory (M2S, Inc.). The imaging core lab analyzed all CT scans and radiographs in that study. Measurements were obtained by the core laboratory at 15 mm below the lowest renal artery. The 15-mm measurement should approximate the location of the sealing O-ring. The core lab data noted a 0.18-mm decrease (-0.55 to 0.18 mm; 95% confidence interval) in mean diameter at 15 mm below the lowest renal arteries at 24 months after placement (data on file at TriVascular, Inc.). The lack of significant neck dilation at 15 mm below the lowest renal artery at 24 months supports the concept that the aorta is not subjected to chronic outward force applied to the aorta at the sealing location. The regression of aortic diameter and lack of proximal endoleaks found in the multicenter trial, as well as a single-center trial, also support the concept of durability of an O-ring seal in the aorta.^{3,4}

The lack of neck dilation at 24 months due to the Ovation Prime sealing ring is likely due to its unique design. Unlike the Ovation Prime device, all prior FDA-approved endovascular abdominal aneurysm devices use self-expanding stents that perform the combined function of fixation and sealing in the aortic neck. Endovascular aneurysm repair devices without active fixation rely on chronic outward force generated by the Z-stent design to hold it in place. The type of self-expanding stent metal used (nitinol vs stainless steel), thickness of the metal, height of the strut, strut design, and amount of oversizing all have an impact on the amount of chronic outward force generated. These factors affect the force required to displace a stent graft from its fixation on the aortic wall.⁵

Several studies have noted neck dilatation with self-expanding stent grafts.⁶⁻¹⁰ In many cases, the aortic neck dilates to a diameter approaching the device diameter.¹¹ The growth of the aortic neck can upset the delicate balance that a self-expanding stent graft needs to maintain fixation.¹² The continued expansion in proximal neck diameter raises concern for the risk of developing late migration and/or proximal endoleak. To date, self-expanding stent grafts have demonstrated neck enlargement and thus confer this limitation.⁶⁻¹² The addition of active fixation with hooks and/or barbs or screws has been shown to increase the pull-

out force required to displace a device.¹³⁻¹⁵ The additional methods of active fixation employed by some devices could explain the lack of device migration seen clinically when aortic neck growth occurs.¹¹

CONCLUSION

Aortic neck dilation occurs with endovascular aneurysm repair using self-expanding stent grafts. The Ovation Prime device does not use self-expanding stents for sealing and therefore does not put chronic outward force on the aorta. The separation of fixation from sealing with the Ovation Prime device has proven durability throughout this follow-up period.

Sean P. Lyden, MD, is Associate Professor of Surgery, Department of Vascular Surgery, Cleveland Clinic College of Medicine at Case Western Reserve University, Cleveland Clinic Foundation in Cleveland, Ohio. He has disclosed that he is a Scientific Advisory Board member and consultant to TriVascular, Inc. Dr. Lyden may be reached at (216) 444-3581; lydens@ccf.org.

1. O-rings: a definition. Parker Seals website. <http://www.greatlakesrubber.com/definon.html>. Accessed September 2, 2014.
2. Greenberg RK. Abdominal aortic endografting: fixation and sealing. *J Am Coll Surg*. 2002;194(1 suppl):S79-87.
3. Mehta M, Valdes 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 e1-3.
4. Carrafiello G, Ierardi A, Piffaretti G, et al. Treatment of abdominal aortic aneurysm with a new type of polymer-filled low profile device. *Int J Surg*. 2013;11(suppl 1):S24-29.
5. Andrews SM, Anson AW, Greenhalgh RM, Nott DM. In vitro evaluation of endovascular stents to assess suitability for endovascular graft fixation. *Eur J Vasc Endovasc Surg*. 1995;9:403-407.
6. Cao P, Verzini F, Parlani G, et al. Predictive factors and clinical consequences of proximal aortic neck dilatation in 230 patients undergoing abdominal aorta aneurysm repair with self-expandable stent-grafts. *J Vasc Surg*. 2003;37:1200-1205.
7. Sternbergh WC 3rd, 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;39:20-26.
8. Tonnesen BH, Sternbergh WC 3rd, Money SR. Late problems at the proximal aortic neck: migration and dilation. *Semin Vasc Surg*. 2004;17:288-293.
9. Sampaio SM, Panneton JM, Mozes G, et al. Aortic neck dilation after endovascular abdominal aortic aneurysm repair: should oversizing be blamed? *Ann Vasc Surg*. 2006;20:338-345.
10. Monahan TS, Chuter TA, Reilly LM, et al. Long-term follow-up of neck expansion after endovascular aortic aneurysm repair. *J Vasc Surg*. 2010;52:303-307.
11. Arthurs ZM, Lyden SP, Rajani RR. Long-term outcomes of Palmaz stent placement for intraoperative type Ia endoleak during endovascular aneurysm repair. *Ann Vasc Surg*. 2011;25:120-126.
12. Connors MS 3rd, Sternbergh WC 3rd, Carter G, et al. Endograft migration one to four years after endovascular abdominal aortic aneurysm repair with the AneuRx device: a cautionary note. *J Vasc Surg*. 2002;36:476-484.
13. Resch T, Malina M, Lindblad B, et al. The impact of stent design on proximal stent-graft fixation in the abdominal aorta: an experimental study. *Eur J Vasc Endovasc Surg*. 2000;20:190-195.
14. Malina M, Lindblad B, Ivancev K, et al. Endovascular AAA exclusion: will stents with hooks and barbs prevent stent-graft migration? *J Endovasc Surg*. 1998;5:310-317.
15. Melas N, Saratzis A, Saratzis N, et al. Aortic and iliac fixation of seven endografts for abdominal-aortic aneurysm repair in an experimental model using human cadaveric aortas. *Eur J Vasc Endovasc Surg*. 2010;40:429-435.

Real-World Experience

What we have learned thus far from the midterm results of the European OVATION® Post-Market Registry.

BY DIERK SCHEINERT, MD

Although endovascular aneurysm repair (EVAR) has now become the treatment of choice for patients with abdominal aortic aneurysms (AAAs), we continue to witness tremendous advances in EVAR technology with smaller-caliber and more flexible delivery systems, improved sealing technologies, and expanded size offerings, all in an effort to expand the eligible patient population and improve long-term treatment durability. Still, a considerable opportunity for EVAR innovation remains, as a substantial proportion of AAA patients remains ineligible for treatment with an endograft due to their anatomical characteristics.¹ Additionally, durable aneurysmal exclusion remains an elusive therapeutic goal, with higher reintervention rates with EVAR compared to open surgical repair.²

The Ovation and Ovation Prime® stent graft systems (TriVascular, Inc.) were specifically designed to overcome and address the main limitations of traditional EVAR stent grafts by providing low-profile access using a 14-F (outer diameter) delivery system, active suprarenal fixation, and a durable O-ring sealing mechanism that provides a custom, gasket-like fit even in short, tortuous, or irregular aortic necks without exerting chronic radial force on the aortic wall. The Ovation device has been commercially available in Europe since receiving CE Mark approval in August 2010 and in the United States since US Food and Drug Administration approval in October 2012, which was in part based on the impressive results from the Ovation Global Pivotal Trial.³ The Ovation Prime stent graft system has been commercially available in Europe since June 2012 and in the United States since December 2012. In the global pivotal trial, 161 patients were electively treated with the Ovation stent graft for AAA, including 65 patients who were not eligible for EVAR with other commercially available stent grafts. During 1-year follow-up, there were no technical failures, AAA ruptures, conversions to open surgery, migrations, or type I/III endoleaks. Freedom from AAA-related mortality was 99.4%, and AAA enlargement was identified in

only two patients (1.3%). The 2-year data from this study were recently presented and look equally impressive.

Human clinical trials are fundamental to the medical device development process. Clinical trials of endovascular devices are generally conducted at experienced centers in highly selected patients in an effort to minimize the impact of confounding factors on study outcomes. Although the internal validity of clinical trials increases when strict controls on patient selection, surgical technique, and user experience are implemented, external validity usually suffers. Put simply, the outcomes reported in clinical trials are oftentimes not generalizable to patients treated in routine clinical practice.

In order to demonstrate that clinical trial results with the Ovation system were representative of the outcomes in patients treated in a real-world setting, the OVATION registry was initiated. The OVATION Post-Market Registry is a postmarket study of the Ovation and Ovation Prime stent grafts conducted at 30 European centers, many with no prior experience with the device. This article summarizes our experience thus far using the Ovation stent grafts in the OVATION registry, outside the rigorous constraints of a traditional clinical trial.

THE OVATION REGISTRY: STUDY DESIGN AND MAIN OUTCOMES

Patients enrolled in this prospective, single-arm, post-market study were anatomically suitable for the Ovation stent graft based on the indication for use statements. All patients underwent CT angiography of the abdomen and pelvis to confirm anatomic suitability for the Ovation or Ovation Prime endografts. Follow-up imaging and procedures were performed in accordance with routine clinical practice at each site and will continue for 5 years.

Between May 2011 and December 2013, 501 consecutive patients were enrolled at 30 European centers. Most patients (86%) were men, and the mean age was 73 years. As a whole, these patients presented with very challenging anatomy: 42% had narrow (< 7 mm) access

vessels, 21% had short (< 15 mm) proximal necks, and moderate/severe neck calcium and thrombus were observed in approximately 50% of patients. Bilateral percutaneous access was performed in 39% of patients, and 63% of patients underwent general anesthesia. Patients were treated with the Ovation (n = 264) or Ovation Prime (n = 235) stent graft. Procedural blood loss was minimal (median, 100 mL), and technical success was 99.6%.

Follow-up in this study is ongoing, with more than 50% of patients with 1-year data available. Radiographic findings include 0.9% AAA enlargement, 0.4% type I endoleak, 0.4% type III endoleak, 0% migration, and 0% limb occlusion. Through 1 year, there has been one (0.2%) AAA rupture (contained) and one (0.2%) surgical conversion; 6.4% of patients have undergone secondary procedures. Only 0.3% AAA-related secondary procedures have been reported in the 2-year follow-up window (366–730 days). Interestingly, neither female sex nor complex aortic anatomy increased the risk for device-related complications.

THE LEIPZIG OVATION REGISTRY EXPERIENCE

At our center, Park Hospital in Leipzig, we enrolled 41 consecutive patients in the OVATION registry between December 2011 and December 2013. The mean patient age was 72.3 years, with most (88%) patients being men. Overall, the registry patients presented with very challenging anatomy: 40% had narrow (< 7 mm) access vessels, which was similar to the population of the OVATION registry. In contrast, the patients at our

center had much more hostile neck anatomy than in the registry, with more than 50% of the patients presenting with a short (< 15 mm) proximal neck. Totally percutaneous access was achieved in 97.6% of patients, and 97.6% of patients did not require general anesthesia. Patients were treated with the Ovation (n = 13) or Ovation Prime (n = 28) stent graft. Procedural blood loss was minimal (median, 100 mL), and technical success was 100%.

Follow-up at our center in this study is ongoing, with more than 56% of patients with 1-year data available. Radiographic findings at 1 year include no AAA enlargement, no type I/III endoleak, no migration, and no limb occlusion. Through 1 year, there have been no AAA ruptures and no surgical conversions, and only two patients have undergone secondary procedures. One of the procedures was for treatment of a persistent type Ia endoleak at 1-month follow-up, which was resolved with coils, and one for treatment of a type II endoleak, which was treated with coils and thrombin injection.

In order to further highlight the clinical utility of the Ovation systems, we have selected a case from the registry that was treated at our center.

CASE STUDY: OVATION REGISTRY

A 78-year-old man with renal failure and a tumor was followed for his expanding infrarenal AAA, which measured 42 mm (Figure 1A). He was referred to our clinic for evaluation. His CT scan revealed an infrarenal AAA with a small-diameter aortic neck (average, 21 mm) at

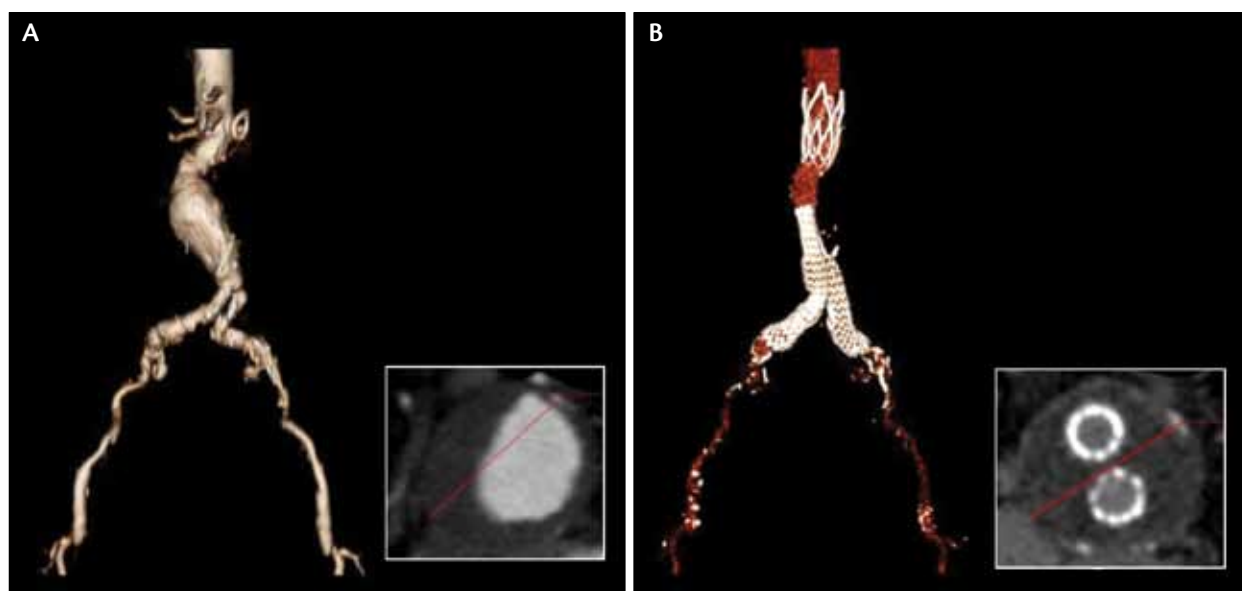


Figure 1. Preoperative imaging of a AAA measuring 42 mm (A). Follow-up imaging showing successful aneurysm exclusion and AAA shrinkage to 37.6 mm (B).

the location of the sealing ring, 13 mm below the lowest renal artery. The distal common iliac arteries were 15 mm on the right and 13.3 mm on the left. There was significant tortuosity noted in both of the iliac arteries. The juxtarenal neck angulation was moderate, at approximately 43°. The native aortic bifurcation was narrow, with a minimum diameter of 18 mm.

This was our second consecutive patient treated in the OVATION registry. We chose a 26-mm Ovation stent graft and the right side as the primary access site because it was slightly less tortuous than the left. The patient was placed under local anesthesia, and under ultrasound guidance, bilateral percutaneous access was achieved. Two Perclose ProGlide or Prostar sutures (Abbott Vascular) were placed on each side. The main body was deployed, followed by the introduction of the radiopaque, low-viscosity, biocompatible polymer into the sealing rings. Next, the contralateral limb and ipsilateral limb were deployed. Completion angiography confirmed excellent endograft placement, exclusion of the AAA, and no endoleaks.

After discharge, the patient was followed up at 1 month, 6 months, 1 year, and 2 years. The most recent CT scan showed excellent graft placement, patent renal and bilateral internal iliac arteries, and a shrinking aneurysm sac (now down to 37.6 mm), with no evidence of any endoleaks (Figure 1B).

DISCUSSION

The midterm results from the OVATION registry demonstrated that EVAR using the Ovation and Ovation Prime stent grafts effectively treat patients with complex aortic anatomies in a real-world setting. Longer-term data from this registry will be required to confirm the durability of these midterm outcomes. Based on our personal experience with the Ovation systems, it has become a routine part of our treatment protocol for AAA due to its ability to treat a broad range of aortic anatomies with similarly impressive results. ■

Dierk Scheinert, MD, is Director, Center of Vascular Medicine, Angiology & Vascular Surgery at Park Krankenhaus in Leipzig, Germany. He has disclosed that he is the Principal Investigator for the OVATION Post-Market Registry and is a consultant to TriVascular, Inc. Prof. Scheinert may be reached at dierk.scheinert@park-krankenhaus-leipzig.de.

1. Morrison T, Fillingim M, Meyer C, et al. Gender disparities in endovascular treatment options for infrarenal abdominal aortic aneurysms 2013; <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM359044.pdf>. Published June 25, 2013. Accessed June 17, 2014.
2. Stather PW, Sidloff D, Dattani N, et al. Systematic review and meta-analysis of the early and late outcomes of open and endovascular repair of abdominal aortic aneurysm. *Br J Surg*. 2013;100:863-872.
3. Mehta M, Valdes 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 e61-63.

The Workhorse System

Versatility of the Ovation Prime® System in challenging and straightforward anatomies.

BY VENKATESH G. RAMAIAH, MD, FACS; SYED M. HUSSAIN, MD; JENNIFER L. ASH, MD; AYMAN JAMAL, MD; RAVI HASANADKA, MD; AND THOMAS KING, DO

The basic premise of aortic stent grafting involves introduction of a stent graft that is constrained on a delivery catheter through the femoral arteries, advancement of the catheter to the area of the aneurysm, and deployment of the stent graft within a cylindrical aortic neck to seal the aneurysm from chronic systemic pressures in order to reduce rupture risk. Unfortunately, this oversimplified description does not account for the many anatomic challenges encountered by the vascular specialist during an endovascular aneurysm repair (EVAR) procedure.

In the decade following US Food and Drug Administration (FDA) approval of the first stent graft for EVAR, a variety of stent grafts were introduced with comparable anatomic requirements for use. Typical guidelines included neck length ≥ 10 to 15 mm, neck diameter of 18 to 32 mm, angulation $< 45^\circ$ to 60° , and access vessels > 6 to 7 mm in diameter. Although these requirements were adequate to execute clinical trials for the purposes of regulatory approval, these criteria excluded many abdominal aortic aneurysm (AAA) patients in need of intervention (Table 1).

Given the complex anatomies of typical patients with AAA disease, achieving minimally traumatic vascular access and durable seal with commercially available stent grafts across a wide range of anatomies remains an elusive therapeutic goal. Over the last several years, many stent graft manufacturers have introduced next-generation devices intended to address the therapeutic gap in patients with small-diameter access vessels and challenging aortic neck anatomy. However, recent advancements in EVAR have been incremental at best, and many patients in need of EVAR continue to be denied treatment due to anatomic constraints. The

Ovation Prime stent graft system (TriVascular, Inc.) was specifically developed to significantly expand patient eligibility for EVAR by identifying, addressing, and overcoming the major barriers to EVAR today—namely, access, fixation, and seal—for long-term, durable results.

ACCESS

The Ovation Prime stent graft is delivered via a 14-F outer-diameter delivery system, which is a comparably much smaller profile than the typical 18- to 22-F delivery systems used with other stent grafts. This lower profile is achieved by adding polymer material over time, thereby minimizing the region of fabric and metal overlap within the catheter. The advantages of a lower-profile delivery system are obvious. More than 50% of women and nearly 20% of men with AAAs present with bilateral iliac diameters of < 6 mm,¹ and these patients would be denied EVAR with other stent grafts based solely on inadequate access. In contrast, at least four out of five of these patients could be treated with the Ovation Prime system. Additionally, the ultra-low-profile delivery system facilitates percutaneous access. A growing body of evidence shows that totally percutaneous vascular access results in higher technical success rates, less blood loss, fewer complications, and shorter hospital stays compared to surgical cutdown.²⁻⁹

When comparing outcomes in patients who underwent bilateral percutaneous access ($n = 69$) or surgical cutdown ($n = 92$) in the global pivotal trial of the Ovation® stent graft,¹⁰ anesthesia (149 vs 191 minutes) and procedure (98

TABLE 1. TYPICAL ANATOMICAL CHARACTERISTICS AS COMPARED TO CONVENTIONAL STENT GRAFT INDICATION STATEMENTS*

| Parameter | Typical IFU Range | Typical Male Patient | Typical Female Patient |
|----------------------------|---------------------------|--|--|
| Neck length, mm | > 10 –15 | 16 (9–27) | 12 (6–20) |
| Neck diameter, mm | 18–32 | 23 (21–26) | 21 (19–24) |
| Neck angulation | $< 45^\circ$ – 60° | 36° (26° – 47°) | 45° (34° – 58°) |
| Access vessel diameter, mm | > 6 –7 | 7 (4.8–9.2) | 5.6 (3.8–7.4) |

*Data from Sweet et al¹ and Morrison et al.¹¹ Values are median or mean (interquartile range). Abbreviation: IFU, instructions for use.

vs 118 minutes) times were shorter; hospital stays were shorter (1 vs 2 days); the 30-day major adverse event rate was lower (1.4% vs 3.3%); and treatment success at 1 year was higher (100% vs 98.9%). The Ovation Prime system is approved by the FDA for use via percutaneous access, which has become our preferred access method. Based on these access-related advantages alone, the Ovation Prime system is well positioned to broaden EVAR eligibility and improve perioperative outcomes.

FIXATION

The Ovation Prime system employs a suprarenal stent to engage healthy tissue proximal to the site of the more diseased aneurysm using integrally formed anchors. This allows for reliable fixation in the most stable part of the aorta. Anchoring into healthy tissue area increases pullout forces and may prevent migration. In the global pivotal trial, there were no reported migrations at the 1- and 2-year follow-up intervals. The Ovation Prime stent graft is delivered via a progressive, staged delivery. The first stage releases the mid-crown, which centers and aligns the suprarenal stent and graft in the lumen. Eight radiopaque markers allow for an orthogonal view to be achieved, enabling precise placement. Once positioned, the second stage releases the proximal crown with integral anchors, which are deployed radially, with no longitudinal displacement. This ability allows for controlled deployment and precise placement, especially in short-neck anatomies.

SEAL

The Ovation Prime stent graft utilizes an O-ring sealing mechanism that is a truly game-changing innovation. The O-rings create a custom seal by injection of a low-viscosity polymer that conforms to the aortic wall without exerting chronic radial force and insulating the aortic neck from circulation. These effects are particularly beneficial in the presence of irregular anatomies resulting from calcification, thrombus, or reverse taper. This is in sharp contrast to

conventional, self-expanding wire and fabric grafts that seal by exerting outward radial force against the luminal surface. The implications for this novel sealing mechanism are tremendous in maintaining a durable seal, preventing neck dilatation, and minimizing risk for late complications such as endoleak or migration.

GLOBAL EXPERIENCE WITH OVATION AND OVATION PRIME SYSTEMS

The pivotal trial of the Ovation stent graft system demonstrated excellent safety and device effectiveness through 1 year.¹⁰ Based on recent reports, the 2-year data are similarly impressive, with no type I or III endoleaks, migration, AAA rupture, or surgical conversion. These impressive patient outcomes are not confined to the clinical trial setting alone. The ongoing OVATION Post-Market Registry has enrolled more than 500 patients with similarly promising outcomes. To date, the Ovation and Ovation Prime systems have been implanted in more than 4,500 patients worldwide. A summary of published reports on the clinical experience with the Ovation and Ovation Prime systems is shown in Table 2.

ARIZONA HEART HOSPITAL AND CHAMPAIGN-URBANA EXPERIENCES WITH OVATION PRIME SYSTEM SINCE FDA APPROVAL

After the much-anticipated FDA approval of the Ovation Prime stent graft system in late 2012, we quickly incorporated this device into our practice as our go-to stent graft in patients who could not be treated with EVAR otherwise. This early experience mainly included patients with small-caliber access vessels and short aortic necks. However, with continued experience, we quickly realized that the Ovation Prime system was well-suited for challenging and straightforward anatomies alike.

Our combined commercial experience with the Ovation Prime system includes 156 cases with an average follow-up

TABLE 2. SUMMARY OF PUBLISHED REPORTS ON THE CLINICAL EXPERIENCE WITH THE OVATION AND OVATION PRIME SYSTEMS

| Study | N | Follow-Up (mo) | Late Type I Endoleak % (No. of Patients) | Late Type III Endoleak (%) | Migration (%) | Enlargement % (No. of Patients) | AAA Rupture (%) |
|---------------------------------|------------|----------------|--|----------------------------|---------------|---------------------------------|-----------------|
| Carrafiello et al ¹² | 33 | 19 | 0 | 0 | 0 | 0 | 0 |
| Irace et al ¹³ | 14 | 5 | 0 | 0 | 0 | 0 | 0 |
| Mangialardi et al ¹⁴ | 35 | 10 | 3 (1) | 0 | 0 | 0 | 0 |
| Mehta et al ¹¹ | 161 | 12 | 0 | 0 | 0 | 1 (1) | 0 |
| Nano et al ¹⁵ | 37 | 10 | 0 | 0 | 0 | 0 | 0 |
| Valdés et al ¹⁶ | 10 | 12 | 0 | 0 | 0 | 0 | 0 |
| Total | 290 | 12 | 0.3 (1) | 0 | 0 | 0.3 (1) | 0 |

CASE STUDY 1: CHAMPAIGN-URBANA

An 84-year-old woman with a history of diabetes, chronic obstructive pulmonary disease, and hypertension presented with a AAA and challenging anatomy. She had a short (< 10 mm), wide, reverse-tapered neck; significant thrombus in the proximal seal zone; significant tortuosity in the left common iliac artery; and a narrow distal aorta (Figures 1 and 2A). The patient was first referred to another hospital for fenestrated AAA endograft placement; however, she and her family sought a second opinion at our institution.

Completion angiography confirmed excellent endograft placement, exclusion of the AAA, and no endoleaks (Figure 2B). After discharge, the patient was followed-up at 1 month, 6 months, and 1 year. The most recent CT scan showed excellent endograft placement with no evidence of any endoleaks or sac enlargement.



Figure 1. Preoperative three-dimensional reconstruction.

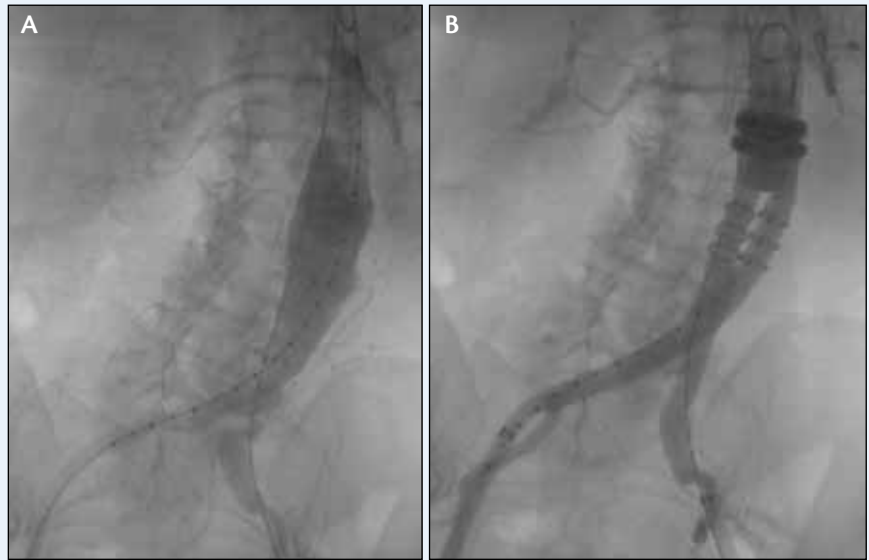


Figure 2. Initial angiogram (A) and final angiogram (B).

of 8.5 months (range, 1–19 months). Most patients (78%) were men, and the mean age was 74.5 years. As a whole, these patients presented with very challenging anatomy: 41% had narrow (< 7 mm) access vessels, 39% had short (< 15 mm) proximal necks, and moderate/severe neck calcium and thrombus was observed in approximately half of all patients. Totally percutaneous access was achieved in 66% of patients, with the majority undergoing general anesthesia. Procedural blood loss was minimal (mean, 82 mL).

The overall mean hospital stay was 1.9 days, with only three patients with severe comorbidities being admitted to the intensive care unit (unrelated to the procedure). In this combined series, we have experienced no technical failures. There were seven intraoperative type Ia endoleaks. Four patients were successfully treated with Palmaz stent (Cordis Corporation) placement, one with coiling; one case resolved before the 30-day follow-up, and another patient was treated with extension of the proximal landing zone.

Over a mean 8.5-month follow-up period, there have been no late type I, III, or IV endoleaks; no migrations; no AAA enlargements; and no limb occlusions. For patients at 1-year

follow-up, there have been no AAA ruptures, no surgical conversions, no secondary interventions, and no migrations. ■

Venkatesh G. Ramaiah, MD, FACS, is a vascular surgeon at the Arizona Heart Institute and Hospital in Phoenix, Arizona. He is Director of Research at the Arizona Heart Institute and Medical Director of the Arizona Heart Hospital. He has disclosed that he is a consultant to TriVascular and National Principal Co-Investigator of the LIFE study.

Syed M. Hussain, MD, is Chairman, Vascular/Endovascular Surgery, Christie Clinic; and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Champaign, Illinois. He has disclosed that he is a consultant to TriVascular and National Principal Investigator of the Ovation and Ovation Prime postapproval study. Dr. Hussain may be reached at msyhussain@yahoo.com.

Jennifer L. Ash, MD, is with the Vascular/Endovascular Surgery Department, Christie Clinic; and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Champaign, Illinois. She disclosed that she is a consultant to TriVascular.

Ayman Jamal, MD, is a consultant interventional cardiologist at the Arizona Heart Institute and Hospital in Phoenix, Arizona.

CASE STUDY 2: ARIZONA HEART HOSPITAL

A 78-year-old woman with a history of severe coronary artery disease, coronary artery bypass grafting, diabetes, hypertension, and severe chronic obstructive pulmonary disease with at-home oxygen presented with a 5.6-cm AAA. She had a patent inferior mesenteric artery and a narrow distal aorta with circumferential calcium (Figure 1).

The patient was placed under general anesthesia, bilateral percutaneous access was achieved, and two Perclose ProGlide closure devices (Abbott Vascular) were placed on each side. Completion angiography confirmed excellent endograft placement, exclusion of the AAA, and no endoleaks (Figure 2).

After discharge, the patient was followed-up at 1 month, 6 months, and 1 year. The most recent ultrasound scan showed a shrinking aneurysm sac (now down to 3.8 cm), with no evidence of any late-term endoleaks (Figure 3).



Figure 1. Preoperative three-dimensional reconstruction.

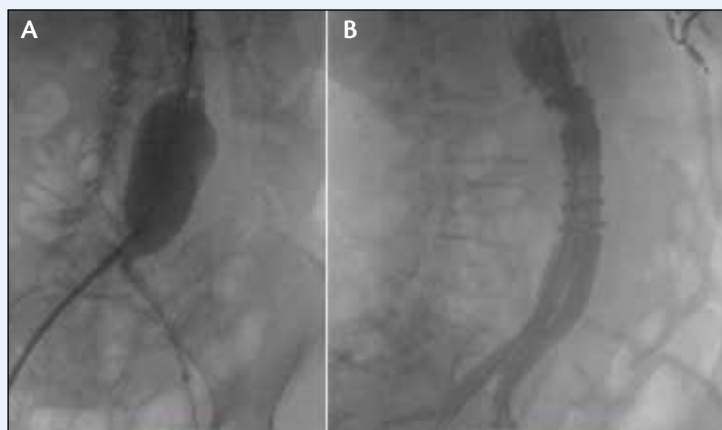


Figure 2. Initial angiogram (A) and final angiogram (B).



Figure 3. Ultrasound imaging at 1 year.

He has disclosed that he is a consultant to TriVascular.

Ravi Hasanadka, MD, is with the Vascular/Endovascular Surgery Department, Christie Clinic, and Assistant Clinical Professor of Surgery, University of Illinois College of Medicine in Champaign, Illinois. He stated that he has no financial interests related to this article.

Thomas King, DO, is an attending vascular surgeon at CGH Hospital in Sterling, Illinois. He stated that he has no financial interests related to this article.

1. Sweet MP, Fillinger MF, Morrison TM, Abel D. The influence of gender and aortic aneurysm size on eligibility for endovascular abdominal aortic aneurysm repair. *J Vasc Surg.* 2011;54:931-937.
2. Haulon S, Hassen Khodja R, et al. A systematic literature review of the efficacy and safety of the Prostar XL device for the closure of large femoral arterial access sites in patients undergoing percutaneous endovascular aortic procedures. *Eur J Vasc Endovasc Surg.* 2011;41:201-213.
3. Al-Khatib WK, Zayed MA, Harris EJ, et al. Selective use of percutaneous endovascular aneurysm repair in women leads to fewer groin complications. *Ann Vasc Surg.* 2012;26:476-482.
4. Jaffan AA, Prince EA, Hampson CO, Murphy TP. The preclose technique in percutaneous endovascular aortic repair: a systematic literature review and meta-analysis. *Cardiovasc Intervent Radiol.* 2013;36:567-577.

5. Krajcer Z, Strickman N, Mortazavi A, Dougherty K. Single-center experience of percutaneous abdominal aortic aneurysm repair with local anesthesia and conscious sedation: technique and results. *J Cardiovasc Surg (Torino).* 2012;53:695-706.
6. Bensley RP, Hurks R, Huang Z, et al. Ultrasound-guided percutaneous endovascular aneurysm repair success is predicted by access vessel diameter. *J Vasc Surg.* 2012;55:1554-1561.
7. Nelson PR, Krajcer Z, Kansal N, et al. A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). *J Vasc Surg.* 2014;59:1181-1193.
8. Krajcer Z, Matos JM. Totally percutaneous endovascular abdominal aortic aneurysm repair: 30-day results from the independent access-site closure study of the PEVAR trial. *Tex Heart Inst J.* 2013;40:560-561.
9. Krajcer Z, Nelson P, Bianchi C, et al. Percutaneous endovascular abdominal aortic aneurysm repair: methods and initial outcomes from the first prospective, multicenter trial. *J Cardiovasc Surg (Torino).* 2011;52:651-659.
10. Mehta M, Valdes 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.e1-3.
11. Morison T, Fillinger M, Meyer C, et al. Gender disparities in endovascular treatment options for infrarenal abdominal aortic aneurysms 2013. <http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM359044.pdf>. Published June 25, 2013. Accessed June 18, 2014.
12. Carrafiello G, Ierardi A, Piffaretti G, et al. Treatment of abdominal aortic aneurysm with a new type of polymer-filled low profile device. *Int J Surg.* 2013;11(suppl 1):S24-29.
13. Irace L, Venosi S, Gattuso R, et al. Initial single-site experience with the Ovation abdominal stent-graft system in patients with challenging aortoiliac anatomy [published online ahead of print January 16, 2014]. *J Cardiovasc Surg (Torino).*
14. Mangialardi N, Ronchey S, Kasemi H, et al. Percutaneous endovascular aneurysm repair with the ultra-low profile Ovation abdominal stent-graft system. *J Cardiovasc Surg (Torino).* 2013;54:581-587.
15. Nano G, Mazzaccaro D, Stegher S, et al. Early experience with Ovation endograft system in abdominal aortic disease. *J Cardiothorac Surg.* 2014;9:48.
16. Valdés F, Mertens R, Bergoing M, et al. Endovascular repair of abdominal aortic aneurysm: comparative results of a pilot study using the Ovation prosthesis. *Rev Med Chil.* 2011;30:42-46.

The Least-Invasive Approach

Transitioning to a fast-track EVAR protocol.

BY BRANT W. ULLERY, MD, AND JASON T. LEE, MD

Since its introduction in 1991, endovascular aneurysm repair (EVAR) has been shown in multiple randomized controlled trials to be associated with reduced early morbidity and mortality and equivalent long-term clinical outcomes compared with conventional open surgery.^{1,2} Although up to 50% of patients with abdominal aortic aneurysms (AAAs) have been historically considered anatomically unsuitable for standard EVAR, the combination of technological advancement and increased surgeon experience has allowed many of these initial anatomic constraints to be overcome, including those related to hostile proximal aortic neck anatomy and inadequate access site vessels. This extension of EVAR technology to a wider cohort of patients with challenging anatomy has been complemented by more recent procedural and engineering refinements aimed at further minimizing morbidity and enhancing cost effectiveness while preserving patient safety.

INCREASING UTILIZATION OF PEVAR

The widespread use of percutaneous EVAR (PEVAR) and the increasingly smaller profiles of currently available devices have served as the foundation for an even less-invasive, modern-day EVAR procedure. In observational reports of PEVAR and standard femoral exposure EVAR, benefits attributed to PEVAR included shorter procedure times, reduced need for general anesthesia, lower complication rates, fewer wound complications, and shorter hospital stays.^{3,4} Nelson and colleagues⁴ conducted the only multicenter, randomized controlled trial of PEVAR versus open femoral exposure for EVAR and demonstrated that PEVAR can be performed safely with > 90% technical success and a low incidence of access site–related complications. The study demonstrated significantly shorter times to hemostasis (10 vs 23 minutes) and procedural completion (107 vs 141 minutes) using the Perclose ProGlide closure device (Abbott Vascular) in a “preclose” technique. Additionally, favorable trends were noted with regard to procedural blood loss, groin pain, time to ambulation, and overall quality of life among those undergoing PEVAR. Successful PEVAR may also increase operator confidence by avoiding routine

The widespread use of PEVAR and the increasingly smaller profiles of currently available devices have served as the foundation for an even less-invasive, modern-day EVAR procedure.

general anesthesia or postoperative intensive care unit admissions and, in some centers, even routine admission at all.

REDUCING LENGTH OF HOSPITAL STAY AFTER EVAR

EVAR is associated with higher overall costs relative to open repair mainly as a result of up-front, device-related costs and, to a lesser extent, the accrual of long-term costs associated with more intensive imaging surveillance and the increased need for secondary procedures.^{5,6} Although the adoption of less-aggressive postoperative imaging surveillance protocols and ultrasound-based (vs CT angiography) surveillance by many institutions is expected to yield some long-term improvement in the cost efficiency of EVAR, recent attention has focused on reducing hospital length of stay as a primary strategy to minimize the overall cost of EVAR, particularly given that devices represent a fixed cost that often remains outside immediate control of the implanting physician. In the European study by Al-Zhuir and colleagues,⁷ an increase in short-stay EVAR procedures (1 day vs >1 day) from 30% to 45% in the first and second half of a 21-month study period resulted in an overall cost reduction of nearly £2,000 per patient.

In an even more aggressive attempt at reducing length of stay, Lachat and colleagues⁸ recently reported the first series of outpatient EVARs involving a cohort of 100 consecutive patients. Inclusion criteria for outpatient EVAR in their series included asymptomatic AAAs, the ability

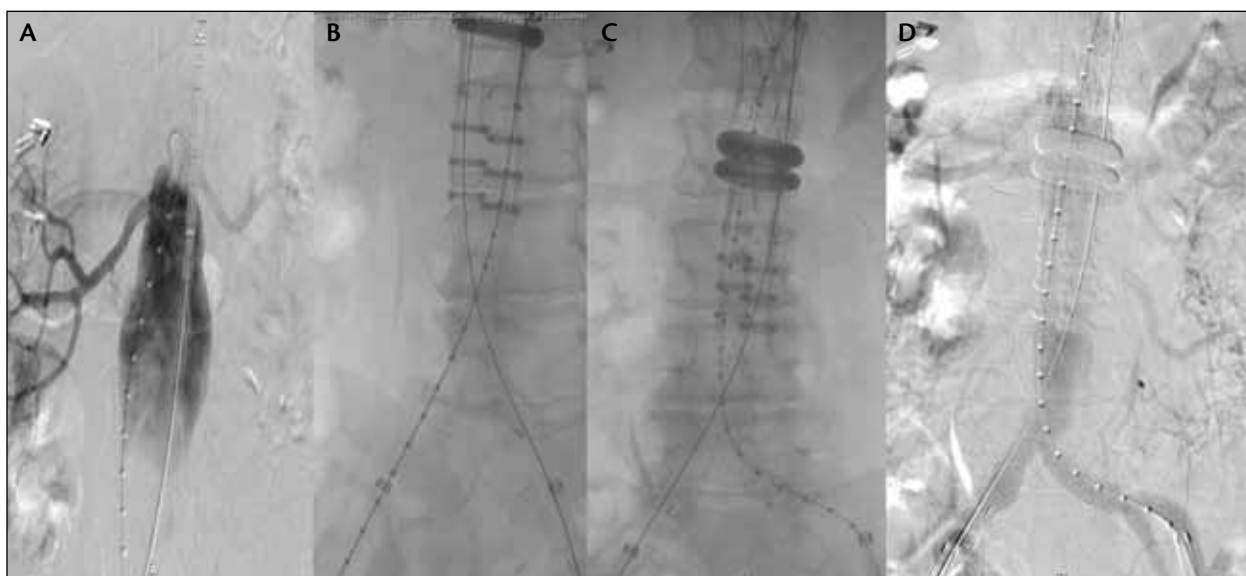


Figure 1. Intraprocedural images during EVAR with the Ovation Prime® System. Initial aortogram (A), cannulation of the contralateral gate and placement of iliac limbs (B, C), and completion aortogram (D).

to provide informed consent, technically uncomplicated EVAR procedures with an operative time of < 4 hours, adult observer assistance at home for the first 24 hours, and travel time to the hospital of < 1 hour if readmission was required. Per protocol, EVAR was generally performed under local anesthesia and with percutaneous access. Patients were discharged home after 4 to 6 hours of observation and checked the following morning and on the fifth postoperative day in the outpatient clinic.

Clinical results demonstrated 30-day mortality and readmission rates for this cohort of 0% and 4%, respectively, with all readmissions secondary to access vessel complications (stenosis, $n = 2$; pseudoaneurysm, $n = 2$). Renal function remained stable in all patients, and none of the outpatients developed any infections or perioperative delirium following same-day discharge. Satisfaction surveys performed on the fifth postoperative day and repeated at 3-month follow-up showed that 97% of the patients in the cohort would undergo outpatient EVAR again and recommend it to others. Moreover, financial analysis revealed significant cost savings in nursing fees, ward costs, management costs, and total costs in a cohort of 42 matched contemporary patients treated with a standard stent graft (21 outpatient EVARs vs 21 inpatient EVARs). The authors concluded that elective outpatient EVAR can be performed safely, provided that specific criteria are fulfilled and special precautions are taken.

Earlier this year, Dosluoglu and colleagues⁹ also reported outpatient EVAR to be safe and feasible in a select group of patients undergoing elective procedures.

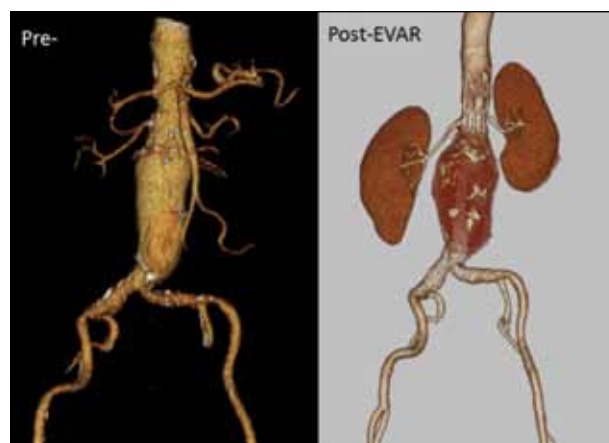


Figure 2. Pre- and postoperative CT angiography of a AAA after endovascular treatment using the Ovation Prime System.

The authors discussed the option of same-day discharge at the time of the preoperative clinical visit for patients with favorable anatomy, normal renal function, void of high-risk medical conditions, good functional capacity, and who had someone to stay with them the night of surgery. Patients opting for same-day discharge were permitted to do so following a 6-hour observational period if the physician had no concerns regarding the repair, closure, or postoperative clinical status.

Of the 64 elective EVARs performed over the 21-month study period, 84% were performed totally percutaneously, and 81% utilized general anesthesia. One-third of patients ($n = 21$) were discharged on the same day, whereas the remaining patients were dis-

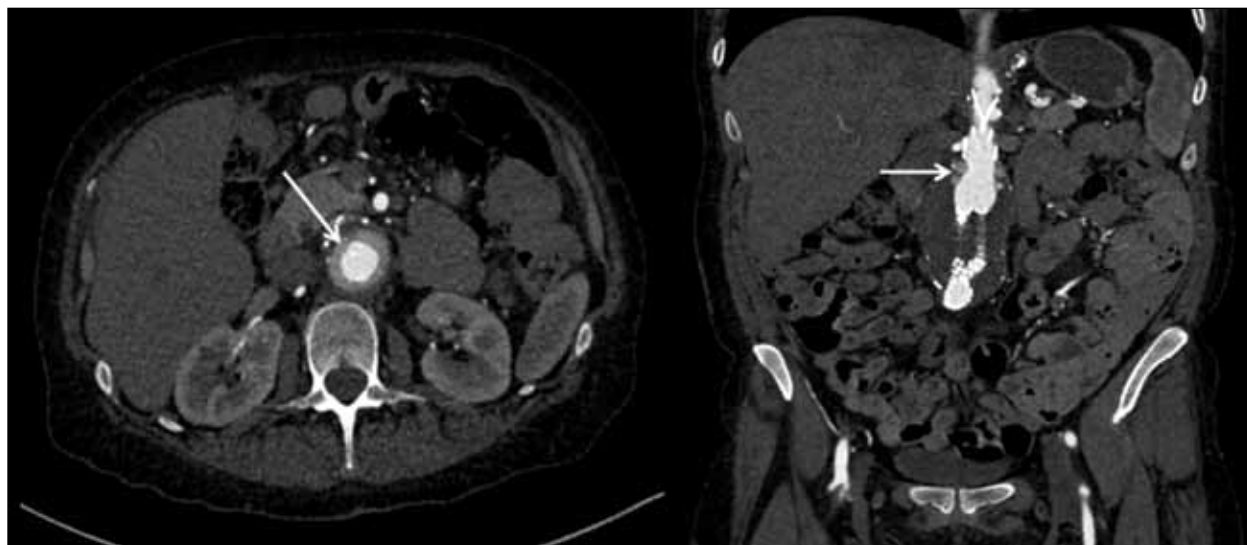


Figure 3. Routine postoperative CT angiography showing sealing rings of the Ovation Prime System.

charged on either postoperative day 1 ($n = 23$; 36%) or postoperative day 2 to 6 ($n = 20$; 31%) due to significant baseline comorbid status, transportation issues, patient preference, urinary retention, femoral cutdown, or baseline chronic renal insufficiency requiring peri-procedural hydration. The only unplanned readmission occurred in the same-day discharge group because of severe postimplantation syndrome. No patients developed renal failure or any infectious complications. At a mean follow-up of 8.3 months, aneurysm-related mortality was 0%.

CLINICAL DATA WITH THE OVATION® STENT GRAFT

These early favorable clinical experiences demonstrate the viability of fast-tracking appropriate EVAR patients, and such efforts are likely to gain considerable momentum with the development of increasingly low-profile, highly versatile stent grafts. The Ovation Prime Stent Graft (TriVascular, Inc.) represents one of the most recent US Food and Drug Administration–approved devices and was specifically developed to accommodate a broader range of complex aortoiliac neck anatomy and difficult iliofemoral access vessels with a low-profile 14-F outer-diameter delivery system and a proximal aortic neck seal mechanism designed to conform to complex proximal infrarenal aortic neck morphology (Figures 1 through 3).

In a recent, prospective, multicenter trial, the Ovation® Stent Graft demonstrated excellent safety and effectiveness in the treatment of 161 patients with AAAs, particularly in the subgroup of patients with short aortic necks and small-caliber, heavily calcified

access vessels.¹⁰ Bilateral percutaneous access was performed in 43% of cases, with 34% of cases completed using locoregional anesthesia or conscious sedation. No stent graft migration or type I, III, or IV endoleaks were observed. At 1 year, AAA-related and all-cause mortality were 0.6% and 2.5%, respectively, along with an overall treatment success rate of 99.3%. Even in the 40% of patients with challenging anatomy (defined as access vessel < 6 mm in diameter and/or proximal neck length < 10 mm), the Ovation® Stent Graft yielded 100% technical success and 97% freedom from major adverse events through 1 year.

STANFORD EXPERIENCE WITH THE OVATION PRIME STENT GRAFT

Our experience with the Ovation Prime Stent Graft began after its US Food and Drug Administration approval in late 2012. Since this time, we have successfully implanted > 30 endografts. Technical success has been 100%, with the majority (91%) of these cases performed using bilateral percutaneous femoral access. We have not experienced any significant type I, III, or IV endoleaks, and there have been no limb occlusions or secondary interventions to date. Length of hospital stay has ranged from 1 to 2 days. Over time, and with increasing familiarity with the device and delivery system, we have found the Ovation Prime Stent Graft to be particularly useful for patients with challenging aortic anatomy and difficult access site vessels. Less trauma to the access site, increasing accommodation of the iliac vessels for smaller-profile devices, and relative ease of deployment contribute overall to the less-invasive approach that likely will have theoretical clinical benefits.

We recently performed successful percutaneous EVAR

STANFORD CRITERIA FOR FAST-TRACK EVAR

Preoperative Criteria

- Functionally independent, performing all activities of daily living
- Social support with someone available to stay with the patient for the first 24 hours postprocedure
- Absence of significant baseline comorbidities (unstable angina, congestive heart failure, severe chronic obstructive pulmonary disease)
- Normal renal function
- Favorable aortic anatomy (no angulated iliac or aortic portions or significant thrombus)

Periprocedural Criteria

- Uncomplicated PEVAR with a procedural duration < 2 hours
- Uneventful 4-hour observation period following the procedure
- Able to tolerate a regular oral diet
- Pain controlled with oral analgesics

using the Ovation Prime Stent Graft in two nonagenarians under local anesthesia only, with both patients being discharged approximately 12 hours postprocedure with minimal discomfort and the ability to return to full activities of daily living that day. One of the procedures was performed with routine cath lab nursing staff under monitored sedation, much like performing bilateral iliac stents in an outpatient setting, further amplifying the cost savings by avoiding anesthesia issues completely. Although these are only anecdotal reports, most experienced EVAR enthusiasts understand the challenges of treating patients in their 90s and that avoiding any time of anesthetic or access complication is paramount to long-term benefit when treating patients at advanced age.¹¹ More rigorous and controlled trials will be necessary to truly understand the benefits and potential disadvantages of such an approach. At Stanford, we are currently developing a fast-track EVAR protocol using the criteria noted in the *Stanford Criteria for Fast-Track EVAR* sidebar.

LIFE STUDY: LEAST INVASIVE FAST-TRACK EVAR

Due to single-center reports and surgeon interest in fast-tracking patients, there is now industry support to study these efforts to determine its place in modern EVAR practice. The Ovation Prime System represents the first device to explore the safety and feasibility of EVAR using a systematic, less-invasive protocol.

The company recently launched the LIFE study, a prospective, consecutively enrolling, nonrandomized, multicenter, postmarket registry to evaluate the clinical and cost benefits of the low-profile Ovation Prime System when used as part of a fast-track EVAR protocol featuring bilateral percutaneous access, no general anesthesia, no postoperative intensive care unit admission, and next-day discharge. The primary endpoint will be determined by evaluating the proportion of patients who experience a major adverse event within 30 days of the procedure and will be compared to a performance goal based on the previous Ovation Global Pivotal Trial. A host of secondary endpoints will also assist in demonstrating the benefits to the patient, physician, and hospital through improved clinical outcomes and reductions in health care system costs as compared to historical control data.

CONCLUSION

In summary, EVAR continues to evolve into an increasingly safe, less-invasive, and efficacious therapeutic alternative to open AAA repair. Led by the low-profile 14-F Ovation Prime Stent Graft, the trend toward lower-profile devices has enabled the transition toward a fast-track EVAR protocol characterized by routine percutaneous access and the potential to avoid general anesthesia. Results of the LIFE study will significantly contribute to the existing literature in the near future and add momentum to the inevitable transition toward a fast-track, next-day-discharge EVAR protocol. ■

Brant W. Ullery, MD, is with the Division of Vascular Surgery, Stanford University in Stanford, California. He stated that he has no financial interests related to this article.

Jason T. Lee, MD, is with the Division of Vascular Surgery, Stanford University in Stanford, California. He has disclosed that he receives clinical trial support from Cook Medical, Medtronic, Inc., TriVascular, Inc., and W.L. Gore & Associates, but receives no direct financial support from any of the companies. Dr. Lee may be reached at jtleee@stanford.edu.

1. Lederle FA, Freischlag JA, Kyriakides TC. Outcomes following endovascular versus open abdominal aortic aneurysm repair. *JAMA*. 2009;302:1535-1542.
2. United Kingdom EVAR Trial Investigators, Greenhalgh RM, Brown LC, et al. Endovascular versus open repair of abdominal aortic aneurysms. *N Engl J Med*. 2010;362:1863-1871.
3. Malkawi AH, Hinchliffe RJ, Holt PJ, et al. Percutaneous access for endovascular aneurysm repair: a systematic review. *Eur J Vasc Endovasc Surg*. 2010;39:676-782.
4. Nelson PR, Kracjer Z, Kansal N. A multicenter, randomized, controlled trial of totally percutaneous access versus open femoral exposure for endovascular aortic aneurysm repair (the PEVAR trial). *J Vasc Surg*. 2014;59:1181-1193.
5. Dryjski M, O'Brien-Jr MS, Hassett J. Hospital costs for endovascular and open repair of abdominal aortic aneurysms. *J Am Coll Surg*. 2003;197:64-70.
6. Angle N, Dorafshar AH, Moore WS, et al. Open versus endovascular repair of abdominal aortic aneurysms: what does each really cost? *Ann Vasc Surg*. 2004;18:612-618.
7. Al-Zhuir N, Wong J, Nammuni I, et al. Selection, thirty day outcome and costs for short stay endovascular aortic aneurysm repair (SEVAR). *Eur J Vasc Endovasc Surg*. 2012;43:662-665.
8. Lachat ML, Pecoraro F, Mayer D, et al. Outpatient endovascular aortic aneurysm repair. *Ann Surg*. 2013;258:754-759.
9. Dosluoglu HH, Lall P, Blochle R, et al. Ambulatory percutaneous endovascular abdominal aortic aneurysm repair. *J Vasc Surg*. 2014;59:58-64.
10. Mehta M, Valdes 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.
11. Lee GK, Ullery BW, Lee JT. Elective EVAR in nonagenarians is safe in carefully selected patients [published online ahead of print April 3, 2014]. *Ann Vasc Surg*. doi: 10.1016/j.avsg.2014.03.026.

