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° 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°–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 al[1] 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.

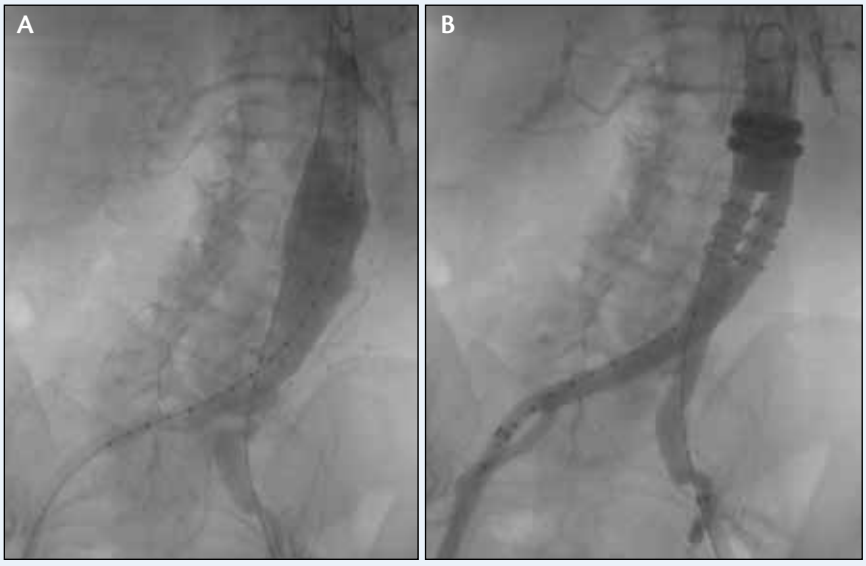

Figure 2. Initial angiogram (A) and final angiogram (B).

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).

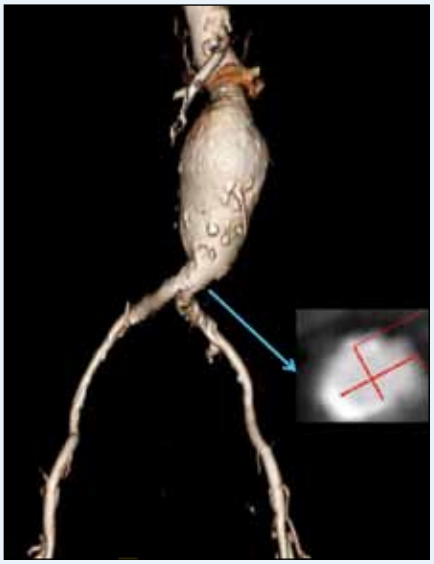

Figure 1. Preoperative three-dimensional reconstruction.

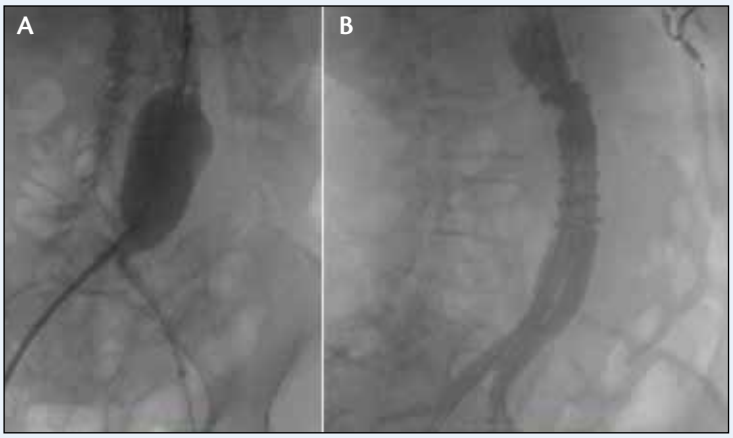

Figure 2. Initial angiogram (A) and final angiogram (B).

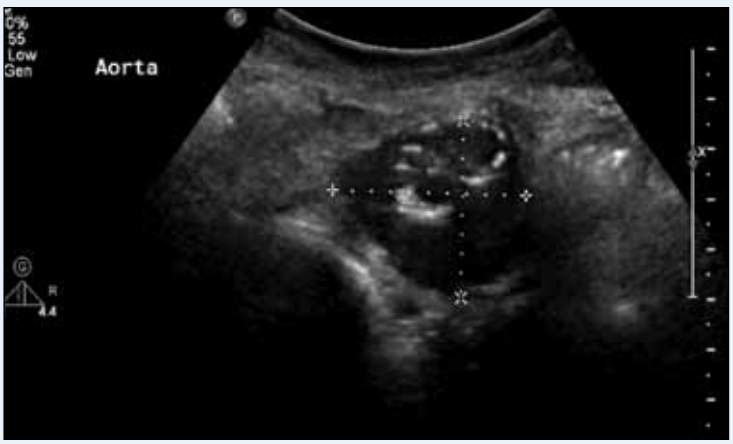

Figure 3. Ultrasound imaging at 1 year.

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, Kracjer 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.
19. 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, Bergoeing 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.