

# The Ovation Abdominal Stent Graft Creates a Patient-Specific EVAR Seal in a Variety of Anatomies

The Ovation® Abdominal Stent Graft System (Endologix) is delivered via a low-profile (14-F OD/12-F ID) catheter to treat abdominal aortic aneurysms (AAAs). The system has a trimodular design consisting of an aortic body and two iliac limbs. The Ovation Abdominal Stent Graft uniquely separates fixation and seal, with fixation achieved through suprarenal stent anchors and seal achieved through polymer-filled inflatable sealing rings, enabling the lowest-profile commercially approved AAA device on the US market by omitting metal structural support. Inadequate vascular access is an important consideration for patient exclusion from endovascular aneurysm repair (EVAR). Commercially available traditional stent grafts are typically 18- to 24-F OD to accommodate the mass of the ridged metal support structure. The low-profile, flexible technology of Ovation expands endovascular treatment to patients with small and tortuous iliac arteries as well as treating common EVAR anatomies, thus offering broad patient applicability for endovascular repair based on indications.

## DEPLOYMENT

The juxtarenal crown is deployed in distinct stages allowing for precise orientation of the graft to the patient prior to fixation. The mid-crown is deployed and the stiff wire is retracted; the relative distance between the graft and the wall of the vessel allow the graft to center within the aorta (Figure 1A). The radiopaque markers are positioned to the desired orientation in relation to the renal arteries before the device is fixated in place. This **sequential staged delivery of the juxtarenal crown facilitates more precise alignment to the anatomy of the individual patient** and

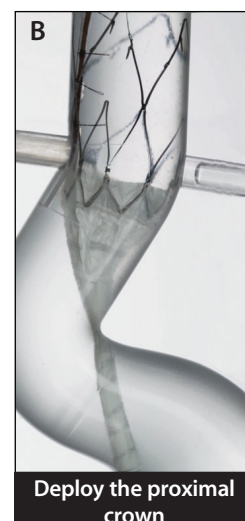
thus helps to avoid wire-biased graft deployment (Figure 1B).

Once fixated, the unfilled, flexible Ovation graft conforms to the patient's anatomy. When the fixated Ovation main body is injected with liquid polymer, the device forms a patient-specific, conforming seal (Figure 1C). This patient-specific treatment is a direct result of the polymer-enabled, flexible design of the Ovation Abdominal Stent Graft System.

Presented in this article are case studies in which Ovation was used as an EVAR solution in a range of anatomies. The first case study shared by Dr. Salem George of Baptist Hospital East is of a woman with challenging access vessels and a calcific aortic neck. The second case study, provided by Dr. Venkatesh Ramaiah of Arizona Heart Hospital, presents a challenging percutaneous EVAR (PEVAR) patient with a large AAA, angulated neck, and challenging access vessels.



Deploy the mid-crown



Deploy the proximal crown



Inject polymer to create patient-specific seal

Figure 1. Staged deployment of Ovation graft.\*

## CASE REPORT 1



# **EVAR TREATMENT OF A PATIENT WITH COMPLICATED ACCESS VESSELS AND CALCIFIED AORTIC NECK**

**By Salem M. George Jr, MD, FACS**  
Baptist Hospital East  
Louisville, Kentucky

## **CASE REPORT BACKGROUND**

A 68-year-old woman presented with a 50-mm infrarenal AAA. The infrarenal neck was calcified and narrow at an average of 16.6 mm in diameter (Figure 2A). The patient had narrow proximal iliac arteries of 4 mm and calcification (Figure 2B and 2C). The patient had comorbidities, including chronic obstructive pulmonary disease, hypertension, and coronary artery disease. The patient presented with an asymptomatic AAA that was increasing in diameter.

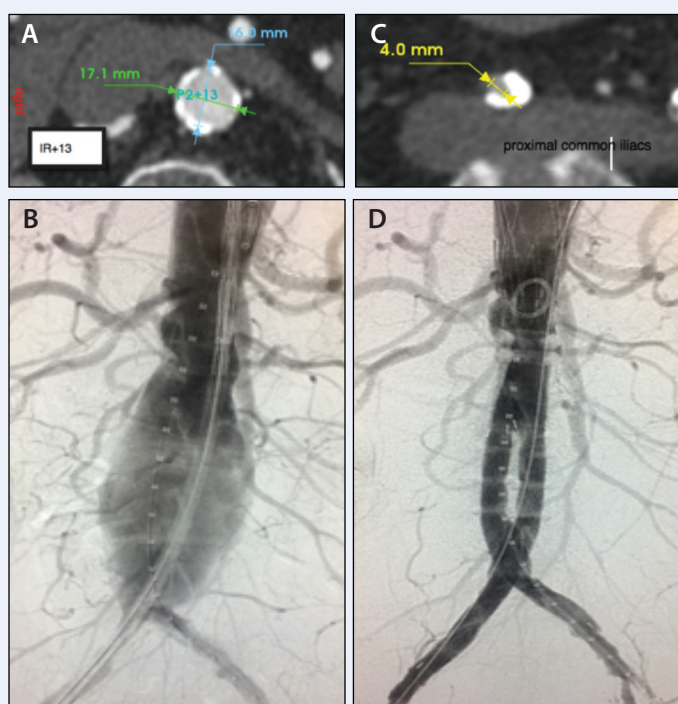
## **METHODS**

Due to the small 4-mm access vessels and prevalence of calcification, the patient was treated with the 12-F ID Ovation Abdominal Stent Graft System. Under general anesthesia, an Ovation iX graft was positioned with the sealing ring 13 mm below the inferior renal artery. The Ovation graft was filled with liquid polymer, which was ballooned 14 minutes after polymer mix to form a patient-specific seal and exclude the aneurysm from blood flow. The Ovation limbs were deployed into the iliac

arteries with ease and postdilated at the iliac junction. The patient was discharged on postoperative day 1.

## **RESULTS**

The procedure was successful and the completion angiogram showed isolation of the aneurysm (Figure 2D). There were no endoleaks and the access vessels were widely patent.



**Figure 2.** The narrow and calcified infrarenal neck (A). There were narrow access vessels in addition to the 50-mm aneurysm (B). The access vessels were also calcified (C). Completion angiogram (D).

## **DISCLOSURE**

**INDICATIONS FOR USE:** The Ovation® iX Abdominal Stent Graft System is indicated for treatment of patients with abdominal aortic aneurysms having the vascular morphology suitable for endovascular repair, including: adequate iliac/femoral access compatible with vascular access techniques (femoral cutdown or percutaneous), devices, and/or accessories; proximal aortic landing zone: with an inner wall diameter of no less than 16 mm and no greater than 30 mm at 13 mm below the inferior renal artery, and with an aortic angle of  $\leq 60$  degrees if proximal neck is  $\geq 10$  mm and  $\leq 45$  degrees if proximal neck is  $< 10$  mm; distal iliac landing zone: with a length of at least 10 mm, and with an inner wall diameter of no less than 8 mm and no greater than 25 mm.

Exercise particular care in difficult areas, such as areas of stenosis, intravascular thrombosis, or in calcified or tortuous vessels. Vessels that are significantly calcified, occlusive, tortuous or thrombus-lined may preclude placement of the device. Individual outcomes may vary, the results of this case study are not guaranteed in every case.

**CONTRAINDICATIONS:** The system is contraindicated for use in patients who have a condition that threatens to infect the graft and in patients with

known sensitivities or allergies to the device materials (including polytetrafluoroethylene [PTFE], polyethylene glycol [PEG]-based polymers, fluorinated ethylene propylene [FEP] or nitinol).

## **Rx only.**

Dr. Salem M. George, Jr is a paid consultant to Endologix.

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## CASE REPORT 2



### CHALLENGING PEVAR FOR A PATIENT WITH LARGE AAA AND ANGULATED NECK

By Venkatesh Ramaiah, MD, FACS

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Phoenix, Arizona

This case presents a 75-year-old man with a symptomatic large AAA measuring 73 X 76 mm, bilateral iliac aneurysms, and a highly angulated aortic neck with tortuous anatomy.

#### CASE REPORT BACKGROUND

The patient presented with abdominal, back, and flank pain. An abdominal CT scan, without contrast, was performed at our sister hospital, which showed a large AAA. The patient was subsequently transferred to Arizona Heart Hospital. A repeat CT scan with contrast (CTA) was performed to assess the infrarenal neck and the pelvic area. The scan showed a relatively short angulated infrarenal neck (Figure 3A). The patient had multiple comorbidities, including chronic obstructive pulmonary disease, coronary artery disease with a 30% narrowing of the mid-right coronary artery and the left anterior descending artery, aortic stenosis, and an ejection fraction of 50%. He was also a chronic tobacco user.

#### METHODS

Due to the angulated contour of the proximal neck, all other devices were considered and the Ovation iX Abdominal Stent Graft System was chosen to treat this patient due to its sealing technologies and conformance to the aorta. Under general anesthesia, utilizing a percutaneous technique, an Ovation iX graft was positioned and deployed with the sealing ring 13 mm below the left inferior renal artery (Figure 3B). The neck angulation between the celiac artery and 13 mm below the lowest left renal artery was 51.7 degrees, which is within the device's instructions for use (IFU). Due to the unique custom sealing properties of the Ovation iX polymer-based graft and because the patient was a nonoperative candidate, the Ovation iX device was selected. The Ovation iX graft was advanced with the radiopaque markers placed approximately 10 to 20 mm above the left renal artery. The Ovation iX graft was unsheathed and the mid crown was deployed. The relative distance between the markers of the graft

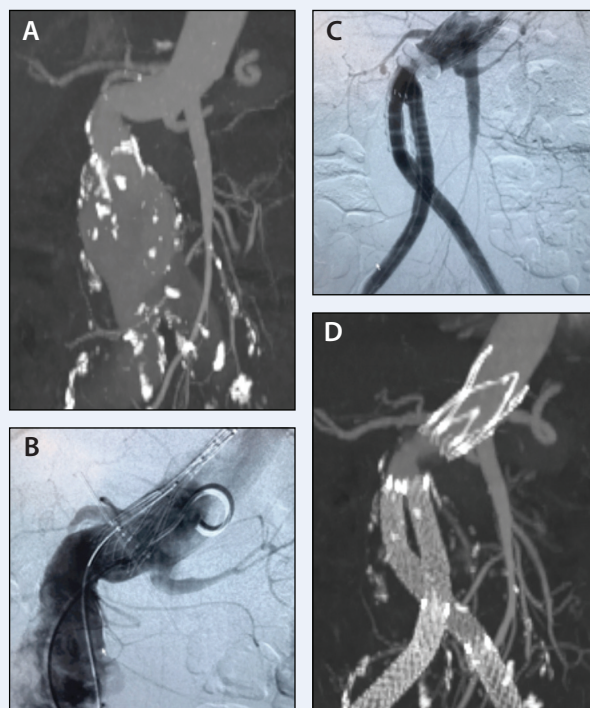


Figure 3. Preoperative imaging (A). The Ovation stent deployed, before polymer fill (B). Completion angiogram (C). Three-month follow-up (D).

and the wall were assessed, the stiff Lunderquist wire, within the delivery system, was retracted below the neck area, allowing the graft to center within the aorta. The radiopaque markers were positioned in the middle of the left renal artery ostium and the Ovation graft suprarenal stent was deployed, fixing the graft in place with precise alignment to the renal arteries. The unfilled Ovation iX graft conformed to the patient's anatomy and when filled with liquid polymer, it formed a patient-specific seal achieving proximal seal.

Because the limbs are not fully supported, they have a tendency to take the natural curve of the anatomy and contour to the morphology before the polymer eventually stiffens the limbs. The contralateral gate was cannulated in a retrograde fashion within 2 minutes of polymer fill. The appropriate length and diameter of contralateral limb was selected and when deployed, redundancy and foreshortening of the limb was utilized to allow the aortic body of the Ovation iX graft to conform to the shape of the aneurysmal aorta without tethering the

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aortic body to the iliac. Due to the need to extend to the external iliac, a second limb was selected and deployed in a similar fashion, allowing exclusion of the common iliac aneurysm without shifting the aortic body in the proximal neck.

At 14 minutes, the stiff Lunderquist wire was readvanced and the aortic body delivery system was demated and retrieved. The ipsilateral limbs were selected, advanced, and deployed in a similar fashion to the contralateral limbs, minimizing any tethering or tugging of the aortic body. This slack in the limbs allowed the graft to remain pliable within the flow lumen. The limbs were ballooned with bilateral 12 X 40 mm semicompliant balloons in a kissing fashion. This ballooning of the limbs was performed within 25 minutes of the graft body deployment. The patient was recovered in a PACU step-down unit and discharged within one postoperative day.

## RESULTS

The procedure was successful and the completion angiogram showed isolation of the aneurysm (Figure 3C). The 3-month follow-up CT showed complete exclusion of the AAA (Figure 3D). There were no endoleaks and the graft was widely patent throughout the aneurysmal curvature and the iliac vessels.

## CONCLUSIONS

This patient was a symptomatic, nonoperative candidate that was evaluated for PEVAR treatment. Due to the unique construction of the polymer-based modular-designed Ovation iX graft, with the graft's ability to provide custom seal without changing the morphology of the aortic neck or the aneurysm, I selected this device to treat this patient in a percutaneous endovascular manner. In my experience, the Ovation iX Abdominal Stent Graft System was the best-suited EVAR treatment option for this patient.

## DISCLOSURE

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## BENEFITS OF THE OVATION STENT GRAFT

By Matt Thompson, MD, FRCS  
CMO of Endologix

Over 15,000 patients worldwide have been treated with the Ovation Abdominal Stent Graft System, over 1,300 of which were treated in a controlled or real-world study. Clinical evidence at 30 days and through follow-up (to 5 years) reported low major adverse event rates, short length of hospital stay, low rates of rupture, conversions, and migration. In addition, study data

reported that patients treated with the Ovation system demonstrated stable neck diameter with no apparent ongoing aortic neck dilatation.<sup>1</sup> **The Ovation polymer-enabled sealing technology, staged deployment of the suprarenal fixation stent, together with a low-profile delivery system allows a larger proportion of patients with AAA to be treated on IFU in comparison to traditional EVAR grafts.**<sup>2</sup> The design of the Ovation graft might make it well suited for endovascular treatment of AAA patients with challenging access, and therefore make it particularly suitable for patient groups with narrow and tortuous iliac anatomy (eg, women).<sup>3</sup>

**TABLE 1. ANATOMIC VARIABLES OF PATIENTS IN THE LUCY STUDY DEMONSTRATING WOMEN'S SIGNIFICANTLY MORE COMPLEX DISTAL ANATOMY**

	♀	♂	P Value
Aortic neck diameter 13 mm below lowest renal artery	22 ± 3.6	23.1 ± 3.1	.01
Juxtarenal angle (degrees)	26.6 ± 19.2	18.3 ± 18.1	< .01
Proximal neck length (mm)	21.9 ± 9.6	23.9 ± 10.6	NS
Aortic aneurysm diameter (mm)	50.2 ± 6.1	53.7 ± 9.9	.01
Aortic bifurcation diameter (mm)	17.1 ± 5.3	20.2 ± 5.3	< .01
Left iliac minimum access diameter (mm)	6.5 ± 1.6	8.2 ± 2.2	< .01
Right iliac minimum access diameter (mm)	6.5 ± 1.3	8.1 ± 2.2	< .01

In a company-commissioned analysis of the access vessels of 43,000 patients in the M2S database, it was demonstrated that a greater proportion of patients could be treated with a lower-profile endograft. The limitations of the analysis of the M2S database are related to reporting delays and/or completeness of the data from each institution. In this core lab analysis, 58% of patients could be treated with the 14-F OD Ovation delivery system, compared to other endografts, which can treat 45% to 50% of patients.<sup>2</sup> Ovation has shown to be clinically effective and durable across the indicated patient anatomy population.<sup>1</sup>

Recent studies have demonstrated that women appear to have worse outcomes for AAA repair than men and are also undertreated.<sup>4</sup> Anatomical and demographic reasons for these differences may be related to smaller access vessels, more challenging proximal aortic anatomy and higher rates of comorbidities. With traditional, nonpolymer EVAR, only 34% of women<sup>4,5</sup> with AAA are eligible for on-label EVAR treatment as compared to 55% with the Ovation system.<sup>5</sup>

The Endologix Ovation LUCY<sup>3</sup> study (Evaluation of Females who are Underrepresented Candidates for Abdominal Aortic Aneurysm Repair), is a multicenter postmarket registry designed to explore clinical benefits associated with EVAR and the Ovation Abdominal Stent Graft Platform for treatment of AAA in women compared to men. It is the first-ever prospective study designed to evaluate EVAR in women, a population

**TABLE 2. 30-DAY RESULTS OF THE LUCY STUDY**

30-Day LUCY Results	Men N = 149	Women N = 76	P Value
Deployment success	99%	100%	NS
Length of stay (days)	1.7 ± 1.5	2.1 ± 2.4	NS
ICU admissions (n)	31 (21%)	17 (22%)	NS
30-day readmissions (n)	8 (5.3%)	3 (3.9%)	NS
Patients with one or more MAEs	2 (1.3%)	1 (1.3%)	NS
Type I endoleak	3 (2%)	0	NS
Type III endoleak	0	0	-
Secondary interventions	5 (3.3%)	2 (2.6%)	NS

that has historically been underrepresented in EVAR clinical trials. The LUCY study enrolled a total of 225 patients, including 76 women in the treatment group and 149 men in the control group (Table 1). The primary endpoint of 30-day major adverse events was adjudicated through a clinical events committee with longer-term data to be shared after the 1-year follow-up. Enrollment in 39 centers was completed on February 14, 2017, and results were presented in 2017 at both the VIVA and VEITH conferences. **The 30-day LUCY data<sup>6</sup> (Table 2) showed that in women, the ultra-low-profile (14-F) Ovation device resulted in:**

- **At least 28% greater EVAR eligibility for women with AAA**
- **1.3% major adverse events**
- **No deaths**
- **No proximal endoleaks**
- **No limb occlusion**
- **Low readmission rate of 3.9%**
- **100% deployment success**

Similarly, the Ovation EU postmarket registry (PMR) has shown durable results through 4 years, with a gender subanalysis that included 14% women. The EU PMR is an evaluation of real-world performance through a multicenter prospective study with 501 patients at 30 sites enrolled from May 2001 to December 2013, including the use of Ovation and Ovation Prime grafts.<sup>7</sup>

Data on the Ovation endograft indicate a durable graft design, one that works well for both men and women (Figure 4). The polymer-enabled sealing technology, unique staged deployment of the suprarenal fixation stent, and low-profile delivery system accommodate both traditional and challenging anatomies. Taken together, this suggests that the Ovation Abdominal Stent Graft might be well worth consideration as an endovascular solution for a wide range of patients with AAAs. ■

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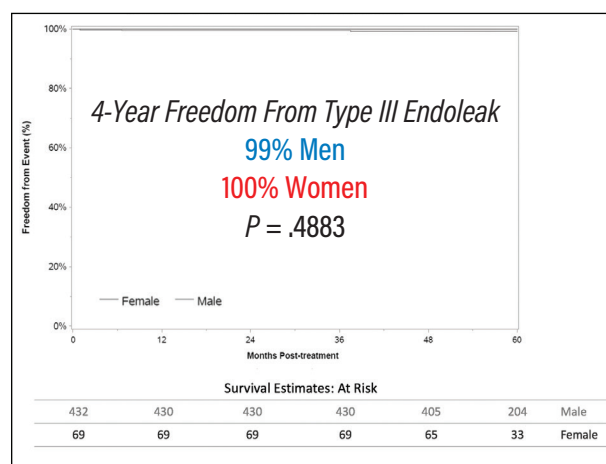
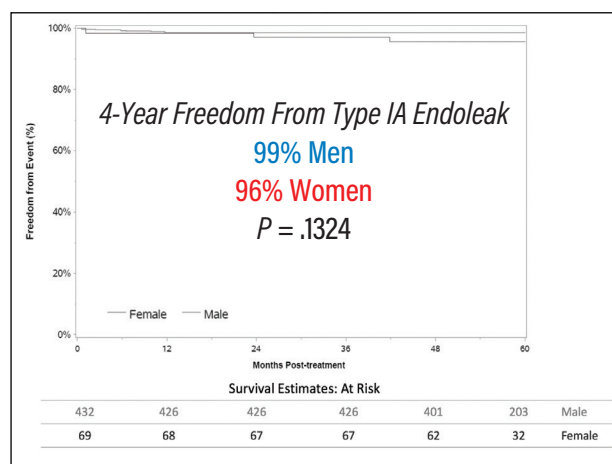
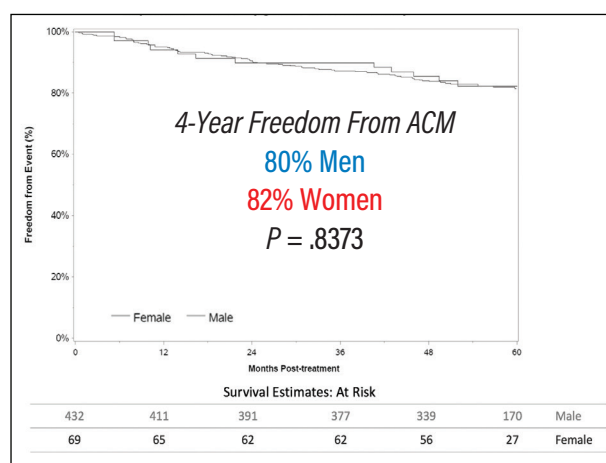


Figure 4. Gender subanalysis of EU postmarket registry: 4-year results.

1. 5-year IDE data as of August 2, 2016 on file with Endologix Clinical Affairs.

2. MM1873 Patient Applicability results from M2S database analysis.

3. MM1735 LUCY 30 day results, data as of May 1, 2017.

4. Ulug P, Sweeting MJ, von Allmen RS, et al. Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intact abdominal aortic aneurysm repair: systematic reviews with meta-analysis. Lancet. 2017;389:2482-2491.

5. 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.

6. Endologix reports positive clinical data from the Ovation LUCY study. <http://investor.endologix.com/releasedetail.cfm?releaseid=1028536>. Accessed February 28, 2018.

7. Data as of October 24, 2017 on file with Endologix Clinical group.

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