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 aortoiliac 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 colleagues[5] 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.

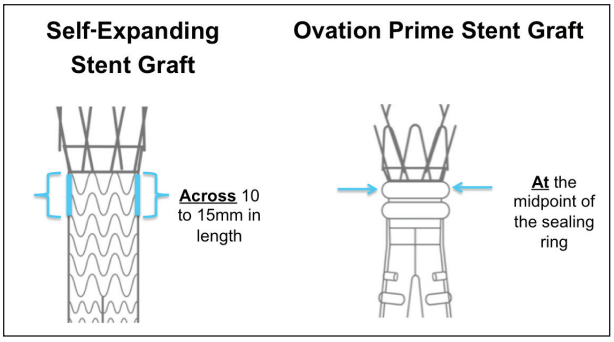


Figure 1. Self-expanding stent grafts require a longitudinal seal (parallel walls) across a minimum 10- or 15-mm length. The Ovation Prime stent graft provides a circumferential seal at the midpoint of the O-ring.

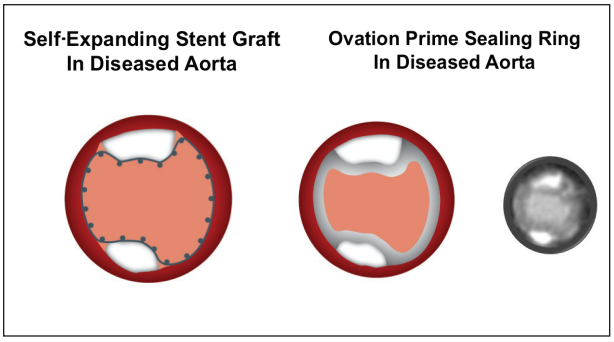


Figure 2. Self-expanding stent grafts may not conform to an irregular luminal surface. The Ovation Prime O-ring molds and conforms to irregular luminal surface, creating a customized seal.

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 measurement[14] 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

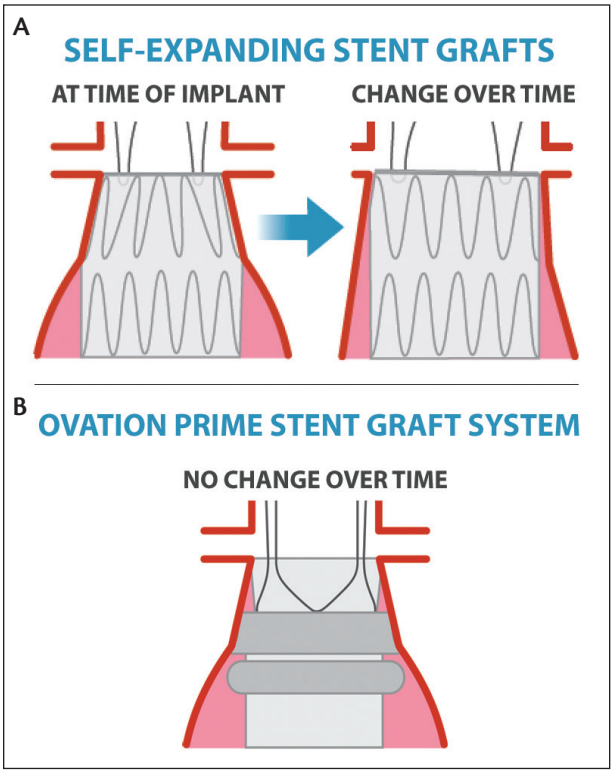
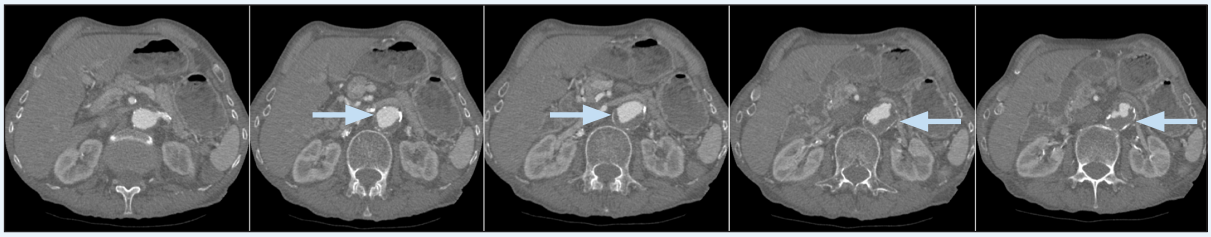


Figure 3. Chronic outward force from a self-expanding stent, combined with blood pressure, can result in neck dilatation and may compromise seal (A).[15-17] Ovation Prime sealing ring creates no chronic outward force and insulates the neck from blood pressure, resulting in no neck dilatation* (B).

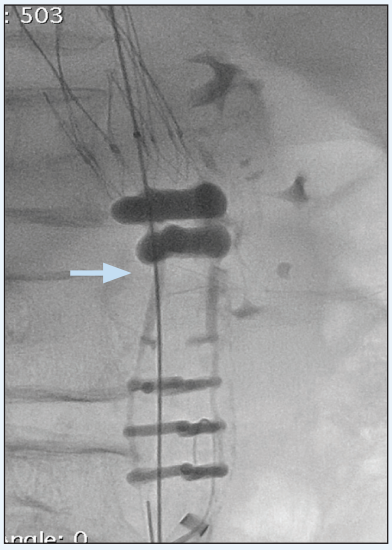
*Results as of July 26, 2013, based on Core lab data from Ovation study.

CASE STUDY

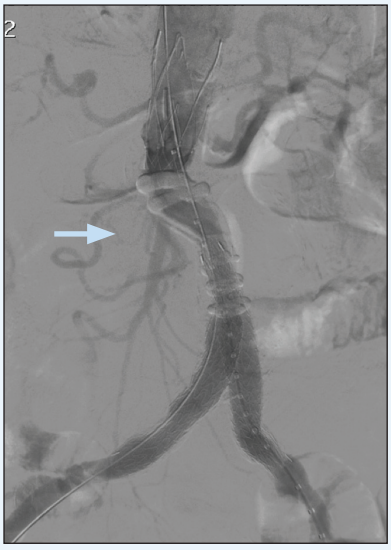
A 76-year-old man presented with lower extremity thromboembolism and underwent successful endovascular thromboembolectomy. On workup, CT angiography indicated a 5.5-cm AAA with a neck that had significant angulation and thrombus. When planning the EVAR procedure, an Ovation Prime stent graft was selected 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.



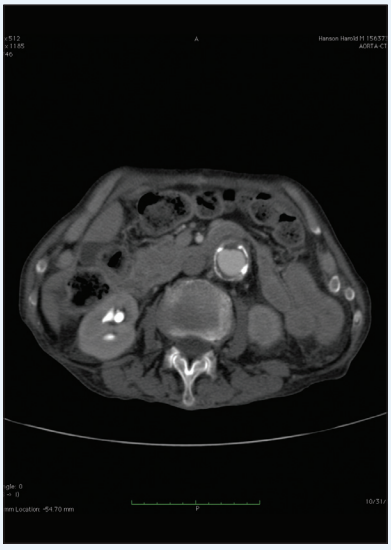
1. Aortic neck with severe angulation and thrombus.



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 ≤ 45°; 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. ■

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