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Optimizing Limb Patency in EVAR

How improved EVAR technology and techniques are enabling successful outcomes in patients with complex anatomy.

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Although endovascular stent grafting has become the standard of care for abdominal aortic aneurysm (AAA) repair over the last decade, concerns related to long-term durability and late reintervention risk remain the Achilles' heel of endovascular aneurysm repair (EVAR). These risks are further magnified as vascular specialists continue to push the boundaries of EVAR by treating patients with increasingly hostile anatomies, oftentimes outside of Instructions for Use (IFU) guidelines.¹ Although device-related complications due to difficult proximal neck anatomy are frequently highlighted in the literature, therapeutic challenges related to maintenance of limb patency have received relatively little attention. Iliac limb occlusion, stenosis, kinking, and dislocation caused by narrow or stenotic iliac arteries, tortuous iliac vessels, or progressive aneurysmal degeneration are common complications of EVAR, with an incidence of 3% to 5%.²⁻⁵ In some cases, loss of limb patency can result in life-threatening ischemic symptoms, often necessitating urgent endovascular or surgical revascularization.^{6,7}

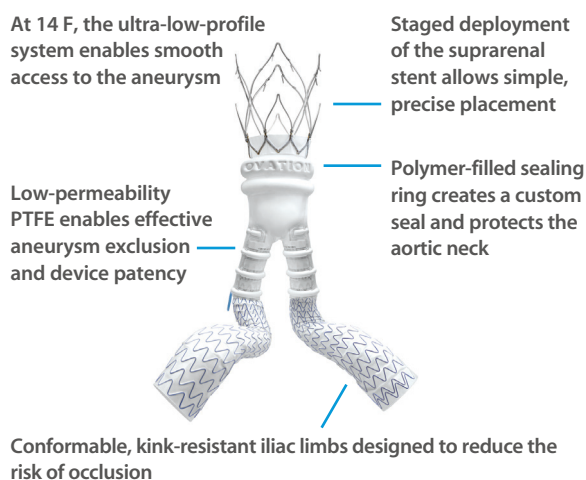
STEPS TOWARD FAVORABLE OUTCOMES

Careful patient selection, preoperative identification of adverse anatomy, and adherence to stent graft manufacturer sizing guidelines are crucial first steps to ensure favorable outcomes. Given the limited diameters and lengths of available iliac limbs, traditional anatomic boundaries of the distal landing zone must be re-evaluated. The presence of narrow tortuous iliac arteries and a distal aorta that is too narrow to accommodate both endolimbs is a major risk factor for limb kinking and thrombosis. Another contributing factor to limb occlusions is a distal landing zone in the external iliac artery (EIA). Although the common iliac artery (CIA) remains the preferred distal seal zone, the EIA becomes necessary when the CIA diameter exceeds manufacturer specifications or is aneurysmal more than 25 mm in diameter. While extension of the iliac

limbs into the EIA allows EVAR in patients who would otherwise be denied, this maneuver increases the risk of iliac limb occlusion by fivefold,⁸ potentially because of the smaller EIA diameter, use of smaller-diameter iliac limbs, and a higher likelihood of extrinsic compressive forces.

Several procedural steps should be considered to minimize thrombus formation. Technical errors are responsible for the majority of limb occlusions.⁹ Angioplasty of iliac stenosis before stent graft delivery may reduce the risk of occlusion. Care should be taken to avoid iatrogenic arterial injury during wire maneuvers or after long periods of iliac occlusion with large-bore sheaths, both of which may encourage limb thrombosis. Adjunctive bare-metal stenting has been proposed as a method to reduce the occlusion risk when limbs are deployed in narrow or tortuous anatomy.^{8,10} Finally, completion angiography should be performed after removal of stiff wires to inspect for limb kink and reduced outflow.

Figure 1. The Ovation Prime Abdominal Stent Graft



STENT GRAFT CHARACTERISTICS

Consideration of stent graft characteristics in relation to patient anatomy plays a crucial role in optimizing patient outcomes. In order to lower the risk of limb occlusion, it is mandatory that current-generation stent grafts incorporate several critical design features including an ultra-low-profile delivery system, a wide variety of limb lengths and diameters, excellent conformability, and kink-resistant iliac limbs. The Ovation® Prime abdominal stent graft (TriVascular, Inc.) (Figure 1) was designed to overcome the limitations of previous stent grafts by accommodating a broader range of aortoiliac anatomy. The Ovation Prime stent graft is characterized by a trimodular design with the aortic body delivered via a flexible, hydrophilic-coated, 14-F outer diameter (OD) catheter, the smallest profile of any currently commercially available stent graft. The aortic body is composed of a low-permeability PTFE graft and a suprarenal nitinol stent with integral anchors to achieve active fixation to the aortic wall. The aortic body contains a network of inflatable channels and sealing rings that are filled during deployment with a low-viscosity, radiopaque fill polymer that cures in situ to create a conformable seal to the aortic neck.

ILIAC LIMB PATENCY

The Ovation Prime iliac limbs are composed of highly flexible nitinol stents encapsulated in low-permeability PTFE that are packaged in an ultra-low-profile 13- to 14-F OD delivery system, which reduces the risk of iatrogenic vessel insult (Figure 2). The iliac limbs incorporate one continuous piece of nitinol wire that resists kinking and twisting, even in the most hostile iliac

Figure 2. The Ovation Prime Iliac Limb



anatomy. The nitinol wire is precisely engineered to lie on the PTFE to minimize kinking of the PTFE material between the stent structures. The stents are embedded between layers of PTFE, as opposed to sutured onto the graft material, contributing to a smooth luminal surface (Figure 1B). The lack of any indentations or grooves minimizes turbulent flow patterns. Radiopaque markers enable visualization of the appropriate iliac limb–aortic body overlap or iliac extension–iliac limb overlap during a catheter-based deployment. Stent radial force provides both fixation and sealing of the interface between the aortic body and each iliac limb, between

TABLE 1. COMPARISON OF ILIAC STENT GRAFT DEVICE FEATURES*

| | TriVascular Ovation Prime | Medtronic Endurant II | Gore Excluder C3 | Cook Zenith Flex | Endologix AFX | Lombard Aorfix |
|---------------------------------------|------------------------------|--------------------------|---------------------|---------------------|------------------|-------------------|
| Profile OD (main body) | 14–15 F | 18–20 F | 20 F | 21–23 F | 19 F | 22 F |
| Profile OD (limb) | 13–15 F | 14–16 F | 12–20-F ID | 14–16 F | 11 F | 20-F ID |
| Sheath required | No | No | Yes | Yes | Yes | No |
| Integrated sheath | No | No | No | Yes | Yes | No |
| Distal iliac diameter treatment range | 8–20 mm | 8–25 mm | 8–25 mm | 7.5–20 mm | 10–23 mm | 8–19 mm |
| Stent material | Nitinol | Nitinol | Nitinol | Stainless steel | Cobalt chromium | Nitinol |
| Graft material | PTFE | Multifilament polyester | ePTFE | Polyester | ePTFE | Polyester |

*Data from IFU and company marketing materials.

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TABLE 2. COMPARISON OF 1-YEAR LIMB OCCLUSION AND REINTERVENTION RATES*

| | TriVascular Ovation IDE | Medtronic Endurant IDE | Gore Excluder Combined IDE | Cook Zenith Flex IDE [†] | Endologix PowerLink IDE | Lombard Aorfix IDE |
|--|----------------------------|---------------------------|-------------------------------|--------------------------------------|-------------------------------|--------------------------|
| Patients enrolled | 161 | 150 | 565 | 200/100 | 192 | 218 |
| Limb occlusions [‡] | 1.2% | 2.7% | 0.4% | 0.5%/3% | 3.1% | 3.7% |
| Patients requiring reinterventions [‡] | 6.2% | 6.7% [§] | 11.5% | 11%/13% | 9.9% | 15.6% |

*Data rates pulled from IFU and Annual Clinical Updates.

[†]Values are for Cook Zenith standard-risk/high-risk patient cohorts.

[‡]Based on investigator-reported events.

[§]Defined as reintervention to treat a limb occlusion.

[¶]Includes reinterventions on day 0.¹¹

the iliac limb and iliac extension, and between the iliac limb/extension and its landing zone in the iliac artery. A comparison of the features of the Ovation Prime stent graft with other available stent grafts is shown in Table 1. All of these features may contribute to iliac limb patency in heavily calcified and tortuous iliac arteries.

Clinical study data on the Ovation stent graft confirm low limb occlusion rates in comparison to other stent grafts. For example, in the Ovation global pivotal study, rates of iliac limb occlusion and reintervention were 1.2% and 6.2%, respectively, through 1 year. Median 1-year event rates with other stent grafts were 3% for iliac limb occlusion (range, 0.4%–3.8%) and 11% for reintervention (range, 6.7%–16.2%) (Table 2). Similar favorable outcomes have been reported in the 501-patient European postmarket registry with the Ovation systems, with 1% iliac limb occlusion and 7% reintervention rates through 1 year. To date, more than 5,000 patients worldwide have been treated with the Ovation systems, many who were ineligible for EVAR with other stent grafts. The iliac occlusion incidence from the worldwide commercial experience is only 0.3%. In the author's experience, the Ovation endograft was utilized in many patients with small, calcified external iliac arteries down to 3.8 mm with no signs of limb occlusion. As external iliac arteries with small diameters have been associated with limb thrombosis, the engineering of the Ovation limbs may have some merit.

SUMMARY

Based on data from a global pivotal study, a European registry, and worldwide commercial experience, the Ovation Prime endograft is safe and effective in patients with AAAs, easily accommodates difficult anatomy not amenable to on-label treatment with other endografts, expands the eligible AAA patient pool, and optimizes iliac limb patency. ■

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