The advent of endovascular AAA repair (EVAR) roughly three decades ago was spurred by the growth of stent technology for the treatment of occlusive disease. Creative combinations of endovascular stent designs with surgical grafts by pioneers such as Volodos, Parodi, Lazarus, and others that followed, provided a path for minimally invasive treatment of aneurysmal disease. Early AAA stent graft designs emerged that employed self-expanding and balloon expandable stent structures to promote graft-to-aortic wall apposition (seal) and fixation. The early balloon expandable designs (e.g. Ancure, Lifepath) faced complexity, durability and profile challenges (exacerbated by the need to incorporate balloons within the delivery system for stent deployment). As such, despite their use of expansive radial force in proximity to aneurysmal disease for anchoring and sealing, self-expanding EVAR designs became the norm, and are still in routine use today.

This common self-expanding device architecture accepts inherent compromises: to enhance seal and fixation, the stent springs must push harder on the vascular walls (‘necks’) at the margins of the aneurysm - in stark contrast to the objective of “depressurization” that is the essence of the aneurysm therapy. In addition, to enhance durability, typically more spring and fabric material must be combined and compressed into a correspondingly larger delivery system - at odds with the motive of a less invasive therapy which propelled EVAR from the beginning.

A NEW APPROACH WITH POLYMER

A new approach to endograft design was needed to address these compromises in the pursuit of an effective, durable and less invasive therapy. The Ovation platform technology represented the first cardiovascular device application of a novel new ingredient: perioperative injection of a cross linking polymer. The Nellix platform also employs this approach, making Endologix the innovation leader in this regard. So why is Endologix, the most innovative aortic therapy company, leading the way with polymer-based technology?

There are three main benefits to the incorporation of cross-linking liquid polymer into endograft designs: conformability, stability, and profile.

In order to exclude blood pressure and flow from the aneurysm sac, an endograft must conform to the arterial wall adjacent to the aneurysm.
Self-expanding wire-fabric devices typically cannot conform well to highly irregular, diseased aneurysm necks, since their stent struts can have difficulty intimately following the contours of the surface. Using liquid polymer to inflate an endograft envelope (e.g. sealing ring or endobag) in apposition to the aortic wall mimics the process of injection molding (see Figure 1). This achieves high conformability as the device is molded in-situ to the specific patient anatomy to achieve a customized seal, even in cases with challenging neck morphology. Once this configuration is achieved, the polymer cross links to form a durable, ‘personalized’ prosthesis.

The bio-stable cross-linked polymer sealing structure maintains its size and shape over the long term. This provides a stable seal which not only excludes the aneurysm, but also the neck from exposure to blood pressure without exerting expansive radial force on the neck. Other EVAR devices use self-expanding sealing mechanisms which require oversizing in the aneurysm neck, and which therefore allow blood pressure to continue to act on the neck while also exerting outward radial stent force on the neck. Such forces on the neck can promote neck dilatation and potential late type 1 endoleak formation, in sharp contrast to the long term neck stability demonstrated by Ovation, as shown below in Figure 2. Longitudinal follow-up of Nellix patients has demonstrated a similar neck stability characteristic, as well.

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![Figure 1. Note the “impression mold” made by the proximal sealing ring after deployment in an in-vitro model over typeset letters “OVATION”](image)

**Figure 1.** Note the “impression mold” made by the proximal sealing ring after deployment in an in-vitro model over typeset letters “OVATION”

![Figure 2. Aortic neck dilatation over time](image)

**Figure 2.** Aortic neck dilatation over time

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3. Core Lab Data. Ovation Global Pivotal Trial
4. Neck dilation in proximal neck defined as growth >3 mm at 10 mm below renals, 13 mm below renals, and 15 mm below renals
The low profile delivery system of a polymer endograft includes a small inflation conduit which allows delivery to the device of low viscosity polymer, in whatever quantity required, over a short period of time. This avoids the need for larger delivery catheters typical of EVAR devices, which must deliver all of the material used to construct the device, all together at the same time. Figure 3 shows the relative delivery catheter sizes for FDA approved AAA endografts, as well as the approximate percentage of AAA patients with access vessels at least as large as the respective delivery catheters. Note the dramatic profile advantage of the Endologix Ovation system.

Well over 15,000 patients have been treated worldwide by Endologix polymer endograft technology, with over 1,000 of these patients being followed as part of closely monitored clinical studies. This clinical experience to date demonstrates excellent outcomes and patient benefits in a wide range of anatomies, and is the foundation for even more innovation to come.

CAUTION: The Nellix® EndoVascular Aneurysm sealing System is an investigational device. Limited by federal (or United States) law to investigational use only. Endologix products and associated components are not available in all countries or regions. Please contact your Endologix representative for details regarding product availability. Prior to use, refer to the “Instructions for Use” for complete and specific indications, contraindications, all warnings and precautions. Rx only. Nellix and Ovation are registered trademarks of Endologix, Inc. All other trademarks are the property of their respective owners. ©2016 Endologix Inc. All rights reserved. MM1524 Rev 01