The Genesis of the Ovation Prime™ Abdominal Stent Graft Platform

Employing requirements-driven design and physical principles to engineer a new generation of EVAR therapy.

BY MICHAEL V. CHOBOTOV, PHD

Endovascular aneurysm repair (EVAR) is a therapy that presents intense mechanical engineering challenges in addressing the needs of large numbers of patients worldwide. Primary among these challenges is optimizing the deployment of large, durable devices through constricted delivery paths. Once deployed, these devices must be capable of withstanding high pulsatile loads while sealing within a wide range of morphologies. The scale of these mechanical challenges, combined with the intrinsic complexity of the therapy, dictates that EVAR will be a progressive market receptive to technology advancements for years to come.

REQUIREMENTS-DRIVEN DESIGN: UNDERSTANDING THE TARGET

In setting out to address these challenges, TriVascular, Inc. (Santa Rosa, CA) employed a "first principles" approach. This began with the definition of end-user and functional requirements, free from the landscape of the incremental/iterative development of conventional device architectures and any preconceived notions of what could be delivered through a catheter. The concept of virtual modeling and physics-based simulations as an integral part of the development process seemed to be generally absent (or at best, minimally applied) in the medical device industry, where numerous build-test iterations, followed by preclinical and clinical testing cycles, prevailed. In contrast, many aerospace development programs extensively leverage such technologies, because no earth-bound test environments or facilities can faithfully replicate many of the end-use conditions, and the cost of a trial-and-error approach is prohibitive. An opportunity was apparent for EVAR in which traditional clinical validation could be supplemented through such an approach, such that many costly problems discovered in late-stage preclinical and clinical experience could be avoided. This could allow greater technological strides to be made in development while incurring less clinical and program risk.

Reconstructing the body's largest artery via the same small access paths employed for coronary artery interventions was akin to building a ship in a bottle or deploying large spacecraft antenna structures in geosynchronous orbit. How "minimally invasive" a therapy actually is, really does matter. Over time, various EVAR manufacturers could be expected to incrementally improve their devices' abilities to address the key challenges of seal, fixation, and durability. Thus, to make a significant impact on abdominal aortic aneurysm (AAA) therapy, a new device must not only provide robust best-in-class seal, fixation, and durability, but also meaningfully reduce the impact and risk to the patient receiving the device. The therapy must be cost-effectively applicable to more patients, as well.

The top-level requirements for EVAR endografts came into focus: (1) effectively seal flow and remove pressure from the diseased aneurysm, even when the aortic lumen at the aneurysm margins is diseased and/or irregular; (2) anchor securely in a wide range of anatomic conditions; (3) conform to irregular anatomy in pre- and postdeployed states and accommodate potential aortic remodeling in response to "deflation" of the aneurysm, given that aneurysms tend to reverse their previous course after exclusion by contracting both diametrically and longitudinally; and (4) the delivery of the device must allow for significantly less invasive

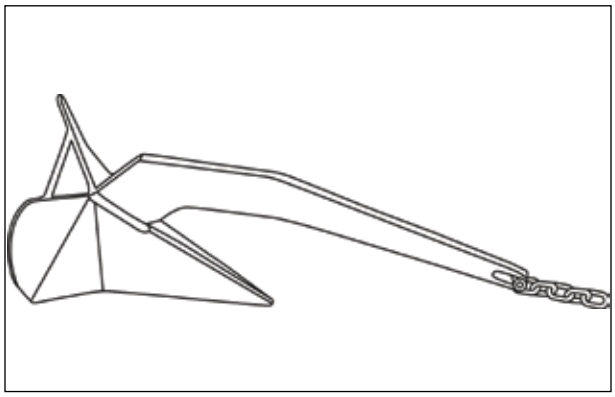

Figure 1. Plough anchor. A maritime anchor used to fix a vessel position by hooking into the seabed.

Figure 2. Close-up of an O-ring, one of the simplest yet most useful and robust sealing mechanisms ever developed.

access to the aneurysm in a simple and straightforward manner. Extensive interactions with physicians pioneering minimally invasive procedures and modalities confirmed these target requirements for a new endovascular approach to AAA.

APPLICATION OF FUNDAMENTAL PHYSICAL PRINCIPLES: THE RIGHT TOOLS FOR THE RIGHT JOBS

These seemingly disparate requirements and functions of an effective EVAR solution dictated the use of a corresponding segmentation by function, location, and time for the system architecture and its elements. To optimize performance, a seal is created that must only seal and not be burdened with the additional task of fixation, and a deployed anchor must only hold the implant securely in place and not be asked to do anything more. Furthermore, because these components can preferentially engage separate locations within the anatomy, they are not superimposed within the delivery catheter, and their constituents are not all delivered simultaneously. Consequently, ultra-low-profile delivery can be achieved without compromise. In contrast, other EVAR devices have aimed to both anchor and seal using stents combined with fabric, with neither optimized for their roles and each forced to compete for the same space within their delivery catheters.

Thus, the Ovation Prime stent graft (TriVascular, Inc.) employs a stent to engage tissue proximal to the site of the more diseased aneurysm, using integrally formed anchors. Such angled protrusions have long been used to hold onto irregular surfaces—consider the plough sea anchor (Figure 1) and also pitons used in rock climbing as well-proven examples. A progressive, staged delivery of the anchor is used to allow precise placement, particularly important in short-neck anatomies. Also, because annular, compliant rings (O-rings) are widely used in engineering applications for sealing fluid flow systems (e.g., hydraulic and pneumatic piping), such a venerable, ubiquitous component is ideally suited for sealing a device within the aorta (Figure 2).

To address the need to deliver this seal in a minimally invasive manner, and to adapt it to a variety of irregular lumens, an annular inflatable ring is cast in situ to form a custom molded O-ring seal at the margin of the aneurysm. This seal's conformability to irregular/diseased surfaces is illustrated by the "impression molds" shown in Figure 3. This ring is created by filling an annular envelope (integrally formed at the proximal end of the device) with a cross-linking polymer material in a liquid state, which subsequently solidifies to eliminate

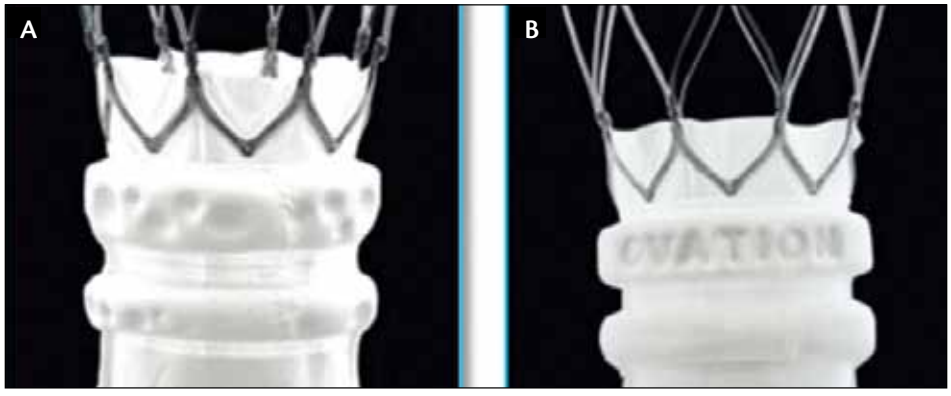

Figure 3. Ovation Prime's sealing rings after filling in an irregularly shaped cylinder (A) and a cylinder with "Ovation" lettering (B).

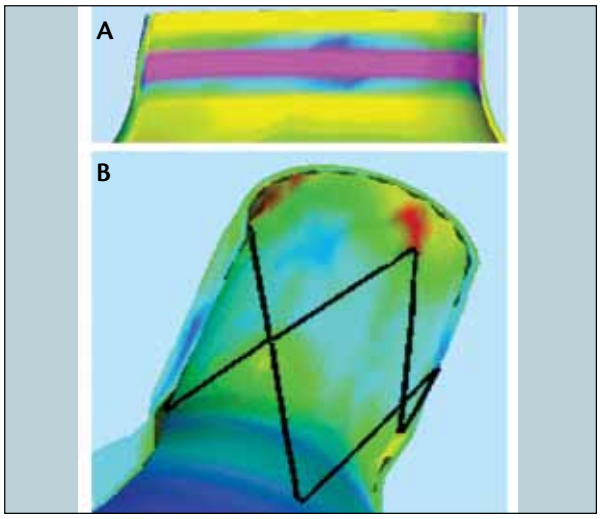

Figure 4. Finite element analysis (FEA) simulation showing uniform and continuous apposition (pink) of the Ovation sealing ring (A). Similar FEA simulation showing discontinuous points of apposition (red) with conventional wire and fabric structure (B).

the need to contain it in a fluid state under pressure over the long-term. Using a conduit within the delivery catheter to inject this structural material enables delivery of any amount of material that is required without affecting the delivery system profile or compromising durability. The cross-linking or "setting up" of this fill material contained within the sealing ring also provides for a nonexpansive apposition of the seal against the diseased aortic wall proximal to the aneurysm.

Because the underlying mechanism of aortic expansion in AAA stems from an imbalance between hemodynamic-pressure–induced wall stresses and degraded aortic wall mechanical integrity, it is intuitively desirable to avoid superimposing additional chronic outward radial force on the aorta, as is typically done with traditional self-expanding stent grafts (which have been associated with neck dilatation). Another benefit of the molded-sealing-ring approach is the uniformity of wall stress at its interface to the sealing zone, as the fluid encased in its compliant PTFE envelope achieves pressure equilibration prior to cross-linking (Figure 4A). In contrast, wire-fabric structures typical of other stent grafts can create highly irregular/nonuniform contact stress at their interface to the vessel wall, as depicted in Figure 4B.

While the Ovation Prime abdominal stent graft system can be described as a novel-architecture, new-generation EVAR solution, it applies well-understood and established engineering principles for fixation and sealing seen in a multitude of applications. We believe this will benefit large numbers of patients suffering from aortic disease worldwide. ■

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