The Evolution of Low-Profile Endograft Design

Are there tradeoffs being made for the improvements in these devices?

BY ROBERT M. BERSIN, MD, FSCAI, FACC

Tradeoffs between profile and performance have always been a significant issue for the design of implantable medical devices. This is a particularly important issue for endovascular aneurysm repair stent graft design, which, by nature, involves significant amounts of fabric and supporting material to treat large-vessel anatomy and yet needs to be inserted through the femoral artery. The benefits of lower-profile devices are obvious. Not only can more patients with smaller access vessels be treated without the need for conduit access or bypass graft surgery, but access site complications are lower the smaller the device, and more can be done percutaneously without the need for surgical arteriotomy for access.

Originally approved by the US Food and Drug Administration in 1999, the Ancure stent graft (Guidant Corporation), was a large, bulky, nonmodular device that required a large (25 F) and complicated delivery system. It was a challenge to implant even in relatively healthy iliac and femoral anatomy. There were later changes in how the device was delivered, but it was still a technically difficult process. The Ancure device was eventually removed from the market. In early experiences with commercially available devices, we learned that to reduce the profile, and therefore improve the safety of the implant procedure, stent grafts needed to be modular.

The AneuRx device (Medtronic, Inc., Minneapolis, MN) was the first modular design to separate the main flow divider from the contralateral endoleg, and in so doing, reduced the profile to 21 F. It was apparent that even at this size, however, access site complications were still a common cause of procedural morbidity. Soon thereafter, the Talent stent graft (Medtronic, Inc.), which was initially 23 to 24 F, underwent an evolution to a lower-profile device. Reduced access site complications and lower overall procedural mortality rates have been reported in a recent publication.[1-3] It became readily apparent that profile affected patient morbidity and mortality, independent of whether access was achieved surgically or percutaneously.

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After these early experiences, a movement began to develop lower-profile devices. The challenge became how to deliver the same amount of fabric and supporting frame in a progressively smaller delivery catheter. This required changes in the basic design and construction of the devices while not compromising the overall performance and durability of the device. The first efforts to do so fell into two basic categories. Either change the basic design and the materials used—a rad-

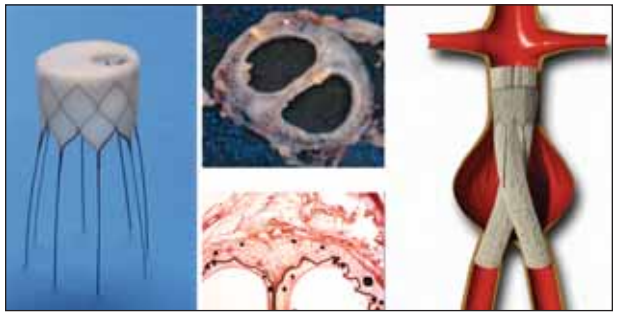

Figure 1. The original Cordis AAA device (Cordis Corporation, Bridgewater, NJ) incorporated a polyurethane sealing gasket in its three-piece design, which was intended to promote a biologic seal at the proximal attachment site.

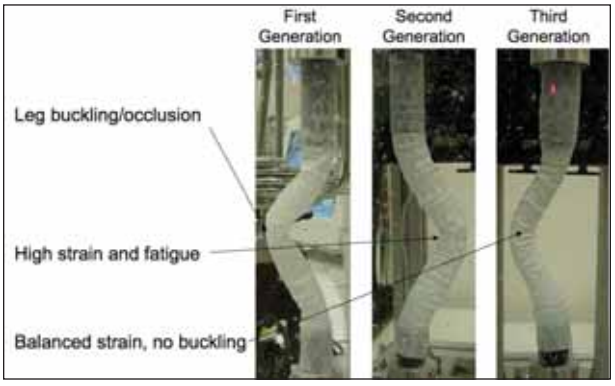

Figure 2. The evolution of endoleg design required re-engineering of the nitinol endoframes to accommodate the stress and compression forces to achieve lower profiles. Third-generation dual-taper design based on SMART stent optimized for fatigue life, balanced strain, and kink resistance.

ical change—or work with the same materials and re-engineer the device by making it increasingly modular and evolve the stent design to fit into smaller delivery catheters—an evolutionary change.

The first effort to dramatically lower the delivery profile was a Cordis device, which was initially implanted in patients in 1999. This device incorporated a three-piece design that included a proximal neck-sealing gasket made of polyurethane (bioseal) and two 13-F endolegs made of traditional nitinol and Dacron materials (Figure 1). In theory, the polyurethane sealing gasket would promote a fibrous tissue growth, which would afford a "biologic seal" at the proximal attachment site, eliminating any chance for proximal attachment site (type 1) endoleak, while at the same time supporting the endolegs. Two problems became apparent immediately. Because the sealing gasket relied on the polyurethane to support fibrous tissue growth, it was not mechanically robust. In fact, the design was made very conformable to fit into irregular shaped necks and avoid any leak paths. This conformability affected other elements of the implant in certain anatomical settings. For example, in high angulations, the bioseal was deformed easily by the relatively more robust endolegs, resulting in a few type I endoleaks.

The design of the first-generation nitinol endoleg endoframes achieved a lower profile by simply increasing the size of each stent cell to reduce the total number of cells circumferentially. However, to maintain columnar and radial strength with fewer cells, each cell had to be stronger, so the nitinol had to be stronger. This resulted in increased stiffness, which led to increased kinkability and torsion of the limbs in tortuous anatomy. The foam gasket was reinforced with retaining sutures to keep the foam from deforming, and the nitinol endoframes were redesigned several times, ultimately resembling large SMART stents (Cordis Corporation) (Figure 2).

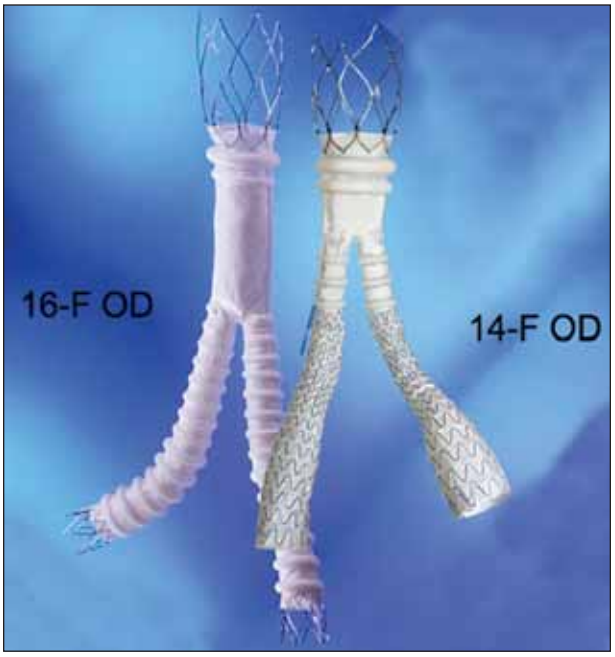

Figure 3. The TriVascular design (TriVascular, Inc., Santa Rosa, CA) evolved from a one-piece device supported entirely by an injectable polymer sleeve to a three-piece design that incorporated the injectable polymer sleeve only for the proximal sealing component. Enovus (left) and Ovation (right) endografts.

Although these design changes brought the modular components more into balance so that the endolegs no longer deformed the foam gasket, a third problem became apparent. The polyurethane foam, which had been demonstrated in animals to work very

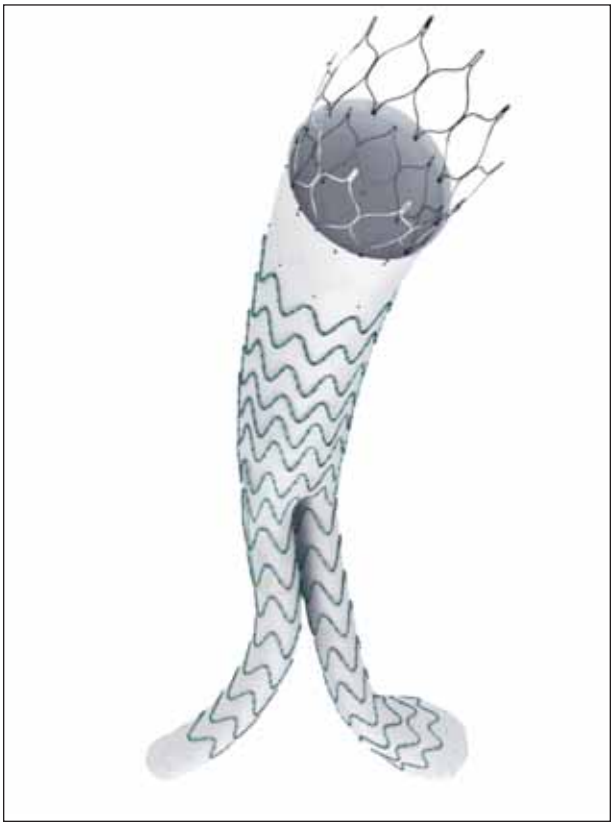

Figure 4. The Cook LP endograft (Cook Medical, Bloomington, IN) reduces the overall profile from 23 to 18 F without changing the basic configuration of the device.

Figure 5. The Cordis Incraft endograft incorporates traditional materials and a three-piece design to achieve a 14-F OD delivery system.

effectively to support fibrous tissue growth in the aortic position and had been demonstrated to do so in humans in many other tissues, did not provide the same effectiveness in the aorta in human implants. This meant that the biologic seal, which was critical to the long-term success of this design, did not occur consistently. Because the foam gasket was not mechanically robust and was not designed to provide a permanent mechanical seal, type I proximal attachment site endoleaks ensued, and the clinical development of this device was stopped. The lessons learned from this device are that the basic design must be able to afford a robust mechanical seal independent of the other attributes of the devices, and that the modular components must be in balance with each other so that force is distributed evenly.

The next effort to develop a low-profile device was the TriVascular endograft. This device also incorporated novel materials but initially was a unibody device. Instead of using traditional metallic stent frames to support the fabric of the endograft, this endograft incorporated a unique PTFE sleeve with channels for a biocompatible fill polymer as the endoframe for the device and used nitinol stents only for suprarenal and distal endoleg attachments. The PTFE sleeve also incorporated an injectable sealing ring at the proximal end, which assisted in achieving a proximal seal. Since the biocompatible polymer was injected into the sleeve after implantation of the device, a lower delivery profile of 16-F OD was achieved with a unibody device. The problem that ensued with this device in clinical trials was fracture of the suprarenal stent.

With the first-generation device, Enovus, the load created by anatomical flexing was concentrated across a small number of points, leading to a higher potential for fatigue and, in some cases, stent fracture. In the current-generation system, the Ovation, TriVascular addressed the issue by creating a design of more uniform strut width that achieves the goal of spreading stress-strain loads more evenly across the stent, thereby significantly improving the resistance to fatigue. By implementing these design alterations, TriVascular was able to preserve the unique sealing mechanism of the inflatable sealing rings and deliver a novel

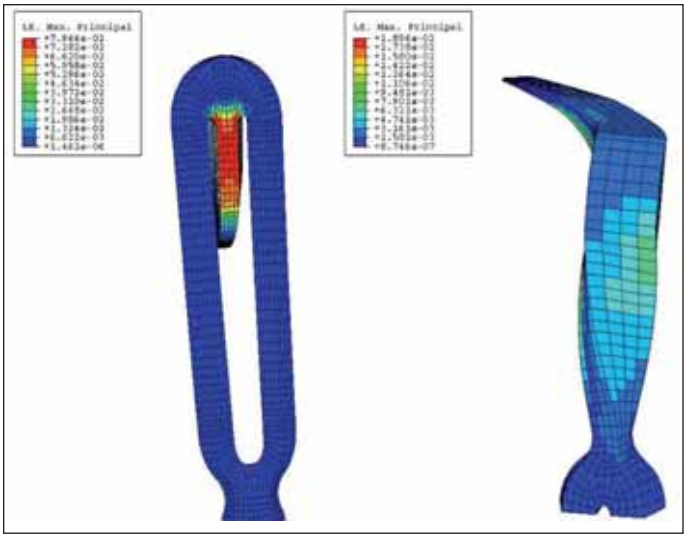

Figure 6. Hook stress fatigue analysis. Suprarenal stent hooks can be modeled for stress-strain durability using computer modeling as shown. Using this approach, hooks can be designed to be fracture-resistant while still affording excellent anchoring with high pullout forces.

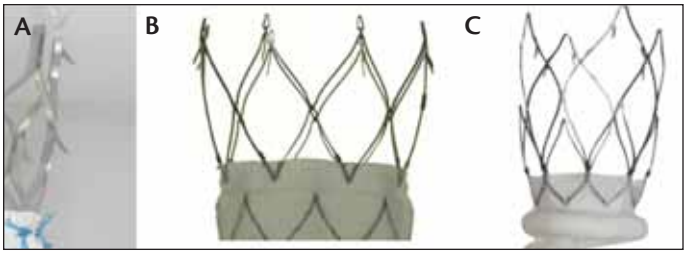

Figure 7. Next-generation suprarenal stents. The suprarenal stents have coevolved by all three manufacturers to be similar in design. All incorporate fewer nitinol crowns to achieve a lower profile and inferiorly angulated hooks for fixation. Zenith LP (A), Cordis Incraft (B), and TriVascular Ovation (C).

approach to endovascular aneurysm repair in a low-profile design. The other significant change to the Ovation device was that a three-piece modular design with two nitinol endolegs was adopted with a further reduction of profile from 16-F OD to 14-F OD (Figure 3). The lessons learned from this device development are similar to that of the initial Cordis device. When dissimilar materials are used, the physical forces exerted on each must be distributed in a way to keep the modular components in balance with each other, and that the best way to achieve a very low profile is to be increasingly modular, with a minimum of a three-piece design.

The two most recent efforts to achieve a lower profile have taken a different approach by engineering three-piece modular devices using traditional materials. The first is the Zenith LP device (Cook Medical), which is a three-piece device that achieved a lower profile by switching from a stainless steel endoframe to nitinol and by changing the basic design of the endoframe to individual stent rings with a broader sinusoidal pattern that reduce the number of stent crowns per circumference (Figure 4). The design of the suprarenal stent and fixation hooks was also changed, and the top cap was eliminated from the delivery system, which allowed for further reductions in overall profile from 23-F OD to 18-F OD as a result of these iterative changes.

The second is the Cordis Incraft AAA stent graft system, which is an entirely new endograft design that bears no relation to the initial Cordis device discussed earlier other than that it is a three-piece design (Figure 5). The Incraft includes the technologies and designs Cordis acquired from the TeraMed AAA device (also known as Fortron) in the design of its endolegs, but it has an entirely new bifurcated component. The challenges of designing components that can be more durable and fracture-resistant, while also providing the same migration resistance, pullout force, and conformability to neck angulation and irregular vessel contours, were formidable and required iterative design of each component over several years. The result was a suprarenal stent design whereby the number of crowns in the suprarenal stent was reduced to a minimum while the fixation hooks all take optimal inferior bend angles to minimize stress fatigue (Figure 6). Flexibility and columnar compression have also been improved by having the individual stent rings of the endoframe attached to the fabric without being attached to each other. The attachment of the stent rings to the fabric was also extensively studied and modified several times to minimize the wear forces of the attachments and reduce the metal-fabric interaction, which not only increased the durability of the fabric, but also reduced the profile.

DELIVERY

Another design feature of great significance is the delivery system used with each of the next-generation low-profile devices. To achieve the lowest profile, the delivery devices are designed to be sheathless using integrated delivery catheters without the need to insert a separately packaged sheath introducer. The

TriVascular Ovation and Cordis Incraft system both have 14-F OD integrated delivery catheters that can be inserted without an introducer sheath. The Cook Zenith LP utilizes a 16-F Flexor sheath with an outer diameter of 18 F. To improve deployment accuracy on angulated necks, all three devices incorporate a retention mechanism for the suprarenal stent to allow the first sealing stent to be deployed before the suprarenal stent is released (Figure 7). This minimizes the "tilt" of the bifurcate stent on angulated necks and allows the bifurcation to deploy at an angle that more closely approximates the orthogonal angle of the true vessel centerline.

CONCLUSION

In summary, the next generation of ultra-low-profile endografts has been designed and engineered with the goal of meeting or exceeding the performance characteristics of the current second-generation devices by becoming increasingly modular (three piece), reducing the number of stent crowns per circumference, and redesigning the stent-fabric interaction. In one instance, a lower profile is also achieved by the inclusion of a novel biopolymer fill that is injected after the device is implanted, eliminating the need for a metallic endoframe entirely. Thus far, these devices have achieved a lower profile of 14 F. In theory, the bench testing done to date would suggest that this has been accomplished without compromise of the types of anatomy that can be treated, or the flexibility, durability, or deployment accuracy of the devices, although much more clinical experience with the devices is needed to determine if the bench testing predicts their performance in patients. ■

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