The Next Generation of Aortic Endografts

Developing trends and new technologies.

BY DAVID H. DEATON, MD

The catheter-based approach to the repair of infrarenal abdominal aortic aneurysms was first attempted in the early 1990s by both individual clinicians with "homemade" devices and start-up commercial entities with technology specifically designed and manufactured for the task. From 1993 to 1999, endovascular aneurysm repair (EVAR) technologies were evaluated in preclinical animal models and human clinical trials throughout the world. In the US, two technologies with very different approaches to achieving graft-based exclusion of the infrarenal aorta were approved for clinical use by the FDA in 1999.

EVAR IN 2009: THE CURRENT STATE OF AFFAIRS

These two grafts were the Ancure (Guidant Corporation, Indianapolis, IN) and the AneuRx (Medtronic, Minneapolis, MN). Only one of these devices, the AneuRx, is still in use today, although both are still approved for use. In addition to these technologies, a variety of other approaches to EVAR have since been evaluated in clinical trials and approved for clinical use by the FDA in the US. As with their predecessors, these more recent grafts are all delivered with catheters and have stents and fabric coverings as their basic elements. Beyond those characteristics, the designs are quite variable with both modular and unibody bifurcated grafts, suprarenal and infrarenal fixation, polyester and polytetrafluoroethylene (PTFE) fabric, and a host of fixation techniques. The other approved grafts include the Excluder (W. L. Gore & Associates, Flagstaff, AZ), the Zenith (Cook Medical, Bloomington, IN), the Powerlink (Endologix, Inc., Irvine, CA), and the Talent (Medtronic).

EXPERIENCE WITH CURRENT ENDOGRAFTS

The first two endografts introduced to clinical use (Ancure and AneuRx) were markedly different in their approaches to endograft design. The Ancure graft was a conservative design that preserved most of the characteristics of an open surgical graft reconstruction by using a unibody bifurcated polyester graft without stent support except at the junction zones in the aorta and iliac arteries. Each of these junctions was constructed of a Z-stent as well as a series of hooks meant to penetrate the full thickness of the vessel and thus reproduce the graft fixation obtained with sutures in open surgery. The largest impediments to success with the Ancure graft included (1) a high degree of technical competence by the operator to plan and deliver an unsupported graft, (2) a significant requirement for the addition of stents to the iliac limbs in tortuous or stenotic anatomy, and (3) a large catheter system (27-F outer diameter [OD]) that resulted in more frequent iliac trauma and/or delivery failure. Despite these impediments, the Ancure graft has one of the best track records for long-term success if initially implanted successfully.[1] It is no longer available for clinical use as a result of Guidant withdrawing the graft from the market in 2003.

The AneuRx graft employed a more radical approach to endograft design by using (1) a modular endograft construction with a main body and long iliac limb augmented by secondary addition of the contralateral limb that "docked" into the main body, (2) a fully stented graft with stents sewn to the outside of a polyester graft, and (3) an approach to fixation that was based on radial force and column strength provided by the rigidity of the stents in the device. The AneuRx device enjoyed much quicker adoption upon the introduction of EVAR in to broad clinical use as a result of the much easier deployment that was the result of a fully stented design. In addition, the delivery catheter was slightly smaller than that required for Ancure. Although initial results with the AneuRx device were significantly better, long-term follow-up revealed a significantly higher rate of migration rendering the technology suitable only for relatively straightforward anatomy in which enough nonangulated proximal neck could be

engaged by the system to prevent future instability.[2]

Over time, the AneuRx device has been refined to be less rigid, and implantation techniques have been altered to augment fixation by using anatomical structures to prevent distal migration. This technique, broadly referred to as *anatomical fixation*, was recognized by others as a way to prevent migration in grafts that lacked the inherent characteristics necessary for effective long-term vascular fixation. In the case of AneuRx, the technique involved "building to the iliac bifurcation," or more simply deploying endograft components down to the bifurcation of the common iliac artery so that there could be no downward displacement of the iliac limbs and hopefully better support of the column supporting the proximal attachment of the device.

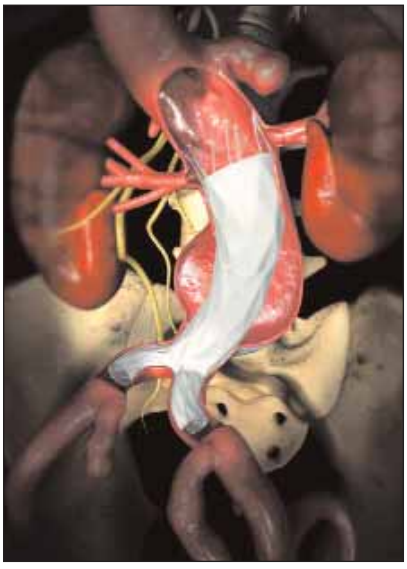

Figure 1. Endologix Powerlink graft employing "anatomical fixation" with graft bifurcation on native aortic bifurcation.

The next two devices introduced to the market were the Gore Excluder endograft and the Cook Zenith endograft. These grafts both incorporated some degree of hook or barb fixation to the aorta, reminiscent of the Ancure device and modular construction first seen in the AneuRx device. The Gore Excluder introduced PTFE as an endograft material. The original material proved to be permeable to serous fluid from the bloodstream and an impediment to aneurysm shrinkage.[3] It was altered by adding a low-porosity film to the graft construct. The Zenith endograft introduced the concept of two docking limb modularity and thus a more user-controlled approach to each attachment site (ie, aortic, ipsilateral iliac, and contralateral iliac). The Zenith was also the first graft in the US to use suprarenal attachment in the form of a large bare stent with multiple barbs that in effect "suspended" the rest of the endograft from its fixation point in the suprarenal aorta. Both of these technologies have achieved broad market acceptance with local patterns of adoption based largely on clinical support and industry relations with practitioners.

A more recent introduction to the US EVAR portfolio was the Endologix Powerlink graft, approved for clinical use in the US in 2004. This graft introduced a variety of unique aspects to EVAR technology. Like Ancure, it was a unibody graft that avoided the complications related to modular limb disjunction. Similar to the Excluder, the graft fabric was PTFE, but it had a different internodal composition. Like all endografts other than Ancure, it had a fully stented design, only the stent was on the inside of the graft material and only sewn to the graft at the top and bottom, allowing the graft material to "float away" from the stents in the aneurysmal segments of the anatomy and prevent stent-on-graft erosion, which had been documented in almost all other technologies. It did not incorporate any hook or barb fixation and migration was a risk in its early use. As experience with the graft progressed, the technique of anatomical fixation was used.[4] This technique is the deployment of the bifurcation of the main body onto the bifurcation of the aorta such that the graft is sitting on the aortic bifurcation (Figure 1).

The latest addition to the technologies available for clinical use in the US was the Medtronic Talent endograft, approved by the FDA in April 2008. This graft has been in clinical use almost as long as the Ancure and AneuRx grafts, but it had not been approved in the US because an approvable clinical trial had not been conducted. This graft is modular with a relatively stiff fully stented design. It uses suprarenal bare stents for fixation but no hooks or barbs.

DEFICIENCIES IN THE CURRENT GENERATION OF AORTIC ENDOGRAFTS

Although a remarkable degree of success has been achieved in reducing the mortality and morbidity of aortic aneurysm repair with the introduction of endovascular repair, there are significant deficiencies and limitations in essentially all of the current grafts. All of the grafts in clinical use have recognizable strengths and weaknesses that make them more or less useful in various clinical situations. It is for those reasons that most larger-volume EVAR centers utilize a wide variety of EVAR technology in their clinical practice. The hallmark of a highly evolved and perfected surgical procedure is the homogenous use of a single highly effective and broadly applicable technology and technique allowing increasing practitioner expertise and proficiency. It is clear that EVAR technology is far from that ideal, and the widely variant technologies and their differential applications are evidence for the clinical need to develop endovascular technologies that better reproduce the foundations of open surgical reconstruction that have such a remarkable degree of longevity and durability.

The weaknesses of the technologies available today and their consequences include:

(1) Deliverability: iliac trauma, inaccurate deployment

(2) Control: operator control of position, fixation, adjustments
(3) Fixation: migration
(4) Flexibility: aortic remodeling, cardiac cycle compliance
(5) Type II endoleak: late aneurysm growth
(6) Necessity of long-term follow-up
(7) Graft durability: stent/graft erosion, limb disjunction, stent fracture

DELIVERABILITY

Current endovascular grafts have delivery catheters that vary from roughly 21 to 26 F in OD or crossing profile. Care must be taken in understanding how manufacturers describe their devices, as many will state that they have an "18-F" device, but this is referring to an 18-F sheath that has an OD of approximately 21 F. Transfemoral delivery requires transit of the external iliac artery, which is rarely aneurysmal but is often stenotic, calcified, and tortuous. Any of these characteristics alone and particularly in combination can make the passage of the endograft delivery system impossible, requiring an open surgical graft or "conduit" to the more proximal iliac vasculature. This open procedure significantly diminishes the minimally invasive aspect of the procedure. Much of the mortality in early clinical trials with endografts was a result of overzealous attempts to transit a stenotic external iliac artery resulting in iliac rupture or avulsion.[5] Even when grafts could be pushed through difficult iliac anatomy, the manipulation, positioning, and accurate deployment of the graft were then frequently compromised. Future endografts will allow designs that have a crossing profile in the 14 to 16 F range without compromising the physical integrity of the endograft and its ability to withstand the aortic environment. These designs may well utilize a different approach to modularity; one that considers each function of the endograft separately and allows controlled delivery of each element separately.

CONTROL

Current endografts are all fully supported with stents. Fixation and "column" strength is often cited as the primary reason for this fully stented approach. Mentioned less often is the necessity of stent support to allow the graft to be deployed from a catheter. The rigidity of the graft system makes delivery systems easier to design and use as they mimic the deployment of many self-expanding stents that are utilized frequently in other endovascular procedures. This imposes significant constraints on the design of endografts and does not allow for significant design innovation—a short-term convenience with long-term liabilities. It also constrains the operator to a simple but poorly controlled and irreversible type of graft deployment. This violates an essential element of surgical creativity; namely the ability to precisely control technical elements and revise them during the procedure. The future of endografts will likely allow for design creativity and innovation that better suit the wide variety of anatomic features encountered in aortic aneurysmal pathology and also allow the operator to precisely position the endograft and adjust the position before committing to irreversible fixation of the endograft.

FIXATION

Most of the first endografts used in humans relied purely on the friction provided by radial force and the column strength of the stents to maintain proximal aortic neck fixation. The somewhat counterintuitive concept of using radial force in a dilating disease process was not discussed frequently, as initial results were good. This type of fixation depends on a variety of factors including but not limited to: (1) length of graft/aorta apposition, (2) neck angulation, (3) graft oversizing relative to aortic diameter, (4) neck shape, and (5) mural disease and wall integrity. As opposed to open surgical procedures in which the integrity of a suture is generally dependent on a single variable, full thickness penetration of the aorta to include the adventitia, endografts depended on a host of factors that were difficult if not impossible to characterize. For that and other reasons, grafts without any hook or anatomic fixation have had a significant incidence of late migration and aneurysm growth.[2] A significant incidence of late rupture and conversion to open surgical reconstruction occurs in the group of patients that experience proximal endograft migration.[6] The endografts introduced more recently into clinical use have all used either hooks to penetrate the aortic wall or some method of "sitting" the graft on a reliable vascular bifurcation to prevent migration. There has also been a variable use of suprarenal bare stents to augment fixation.

Although these methods have improved migration rates significantly, they have not reduced it to a value that would be considered equivalent to the very low figure of open aortic reconstruction proximal failure. Additionally, all of the hooks or barbs in current clinical use are made of a caliber and/or alloy that prevents their assessment after implantation. The inability to easily visualize and assess these vital fixation components during follow-up is hard to justify, and future endografts will likely incorporate fixation elements that are plainly visible on routine abdominal x-rays. Technologies that allow a more faithful reproduction of the time-tested method of open aortic reconstruction fixation (ie, robust transmural adventitial purchase) will allow endograft technology to shed its image of vulnerability to late migration and catastrophic failure. Additionally, any technology that liberates endografts

from the risk of aortic dilatation will further enhance the reliability of endograft technique.

FLEXIBILITY

The aortic environment is compliant during the cardiac cycle, and the anatomic configuration of the aortoiliac vessels changes over time in what is often described as "remodeling." Rigid prostheses are ill suited to respond to this environment, and most of the currently available endografts have been revised to be more flexible since their introduction. The evolution of open aortic reconstruction began with rigid prostheses and was almost abandoned as a result of the failure of rigid prostheses and homografts before suitable fabric prostheses were introduced.[7] The advent of modern cardiac-gated computed tomography and IVUS vividly illustrate the motion these grafts are subjected to during the cardiac cycle. Long-term follow-up of endografts amply demonstrates the significant remodeling that the aortoiliac segment goes through in response to effective aneurysm exclusion and the mechanical properties of the endograft. Current rigid prostheses are also compromised in situations in which the proximal neck or iliac vasculature is significantly angulated resulting in poor sealing, migration, graft/stent erosion and graft occlusion. The reproduction of flexible grafts that incorporate stents only to augment seal zones or iliac patency will allow tension-free endograft attachment proximally and distally and will allow the graft to accommodate the acute and chronic changes in aortic shape associated with the cardiac cycle and remodeling.

TYPE II ENDOLEAK

The very nature of endovascular grafting denies the operator the ability to ablate the small tributaries of the infrarenal aortic segment, namely the inferior mesenteric artery and segmental lumbar vessels. These vessels can be directly ligated in open reconstruction. Their maintenance of patency despite endograft exclusion of the aortic segment results type II endoleak in approximately 20% to 40% of patients treated. Although there is some evidence that the endografts with longer main bodies have a modest effect on type II leak reduction, none primarily address these vessels with a specific technology.[8] The ability to develop a technology that will directly address this problem will significantly alter the necessity for long-term follow-up in concert with improvements in graft fixation and flexibility. It would also significantly diminish the necessity of a considerable number of secondary procedures performed to address type II endoleak.

LONG-TERM FOLLOW-UP

As a result of the protocols developed for the initial human clinical trials for EVAR, yearly follow-up with a varying combination of plain x-ray, contrast-enhanced CT scan, and ultrasound has become a standard for clinical practice. This is not the clinical standard after open aortic reconstruction. Costly and potentially morbid imaging studies are a significant detriment to the cost-effectiveness and broad clinical acceptance of EVAR as a standard for aortic aneurysm therapy.[9] Technologies that can demonstrate a level of integrity and redundancy such that annual imaging studies are no longer needed will go a long way toward allowing EVAR to supersede open aortic reconstruction as the standard of care for all patients, irrespective of their comorbidities.

GRAFT DURABILITY

Early endografts demonstrated a disturbing vulnerability to physical wear in the aortic environment. These frailties included stent fractures, suture fractures, hook breakage, modular limb disjunction, and fabric disruption as a result of stent erosion.[10] Although there is a better appreciation for the rigors these grafts must withstand, there are still significant late failures in almost all of the categories enumerated previously. It is probably impossible to eliminate physical breakage, but the complexity and vulnerability of current endograft designs to these failure modalities can be significantly reduced. Minimizing the failure modalities and the reliance on nonvalidated techniques for long-term function would go a long way toward reducing the incidence in a number of the failure categories listed. Advancing modular designs to achieve a "functional unibody" such that modular pieces are firmly secured to each other will prevent the intracomponent migration that has been documented with essentially all modular devices. If the redundancy of the physical components of endografts to withstand the rigors of the aortic environment can be advanced to a level comparable to open surgical grafts and suture, the ability to surpass not only the acute outcome of open reconstruction but the chronic outcome as well will be a reality.

NEW TECHNOLOGIES AND CLINICAL TRIALS

Anaconda (Vascutek Ltd., a Terumo company, Renfrewshire, Scotland)

Current Phase of Development

- On market in the EU
- Phase I US trial complete
- Phase II US trial starting

Design Characteristics and Innovations

- Three-piece modular system
- Four pairs (eight) large proximal hooks visible on plain x-ray
- Reconstrainable and steerable proximal attachment

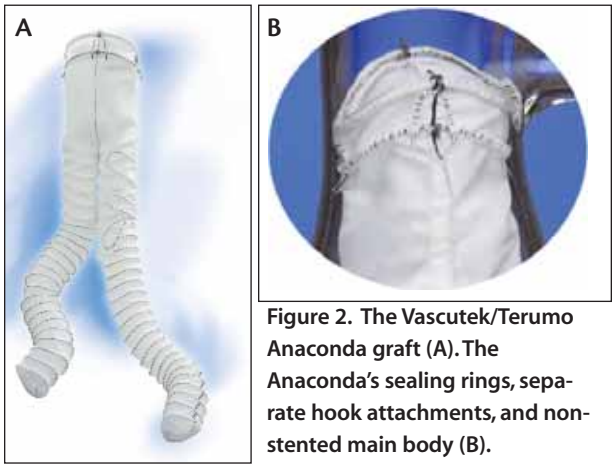

Figure 2. The Vascutek/Terumo Anaconda graft (A). The Anaconda's sealing rings, separate hook attachments, and nonstented main body (B).

- Unsupported main body
- Magnet-assisted contralateral cannulation
- Highly flexible iliac limbs with radial support only

Limiting Features
- Large graft delivery system: 20 and 22 F
- Complex delivery system
- Vulnerable to future aortic dilatation

The Anaconda graft incorporates a variety of features mentioned in the preceding sections (Figure 2). It is a three-piece modular device with robust hook aortic attachment. It has a unique sealing segment consisting of two slightly oval stents composed of wrapped wire rather than a single strut. The proximal deployment can be reconstrained and repositioned at the operator's discretion and can be angled or steered to accommodate neck angulation of renal anatomy. The main body of the device is without stent support, allowing the freedom to angulate the proximal attachment without inducing strain of the proximal or distal aspects of the endograft. The contralateral cannulation is assisted by a magnet in the main delivery system that is mated to a specially designed guidewire to both facilitate and confirm accurate cannulation. The iliac limbs are supported by individual radial stents and are therefore very conformable to tortuous anatomy and have no longitudinal rigidity.

Aorfix (Lombard Medical, Oxfordshire, England)
Current Phase of Development
- On market in the EU
- Phase II US trial in progress

Design Characteristics and Innovations
- Three-piece modular
- Four pairs (eight) proximal hooks
- Highly flexible main body; radial support only
- Highly flexible iliac limbs with radial support only

Limiting Features
- Large graft delivery system (22 F)
- Complex delivery system
- Vulnerable to future aortic dilatation

The Aorfix graft was designed to primarily address one of the most difficult features of proximal aortic neck pathology: angulation. It is a three-piece modular device with robust hook aortic attachment (Figure 3). The main body of the device has a unique radial stent support that provides patency but allows deployment in very angulated anatomy without strain. The iliac limbs are supported by individual radial stents and are therefore very conformable to tortuous anatomy and have no longitudinal rigidity.

Aptus Endovascular AAA Repair System (Aptus Endosystems, Sunnyvale, CA)
Current Phase of Development
- Phase I US trial complete
- Phase II US trial in progress
- CE mark in the EU expected Q2 2009

Figure 3. The Lombard Aorfix graft, with radial main body stent, proximal attachment, and separate hooks for mural attachment.

Design Characteristics and Innovations
- Independently delivered staple fixation
- Helical staple: increased holding, resists neck dilatation
- Low profile: 16- and 18-F OD
- Short proximal seal requirement: 12 mm
- Unsupported main body; flexibility
- Modular limbs physically lock to main body
- Iliac limbs: radial support, longitudinal flexibility

Limiting Features
- New technique of endograft fixation; learning curve

The Aptus endograft (Figure 4A) was designed specifically to be paired with an independent fixation system. This allows the graft to be constructed from a very robust polyester material while also fitting into a significantly smaller delivery catheter (ie, a 5-F size reduction over the smallest currently available). A

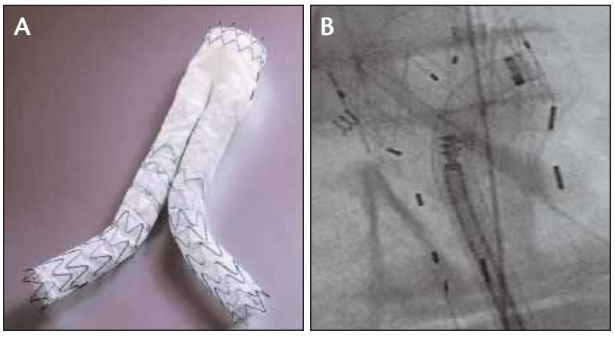

Figure 4. Aptus Endosystems endograft with short proximal sealing stent, nonstented main body, and two locking limbs (A). Aptus Endosystems steerable guide and staple applier in vivo (B).

short proximal sealing stent allows adaptation to highly tortuous anatomy and lessened dependence on aortic neck length. The main body of the device is without stent support, allowing the freedom to angulate the proximal attachment without inducing strain of the proximal or distal aspects of the endograft. The iliac limbs are supported by radial stents and are therefore very conformable to tortuous anatomy and have very little longitudinal rigidity. When deployed into the main body, the iliac limbs have a mechanism by which the proximal stent locks into folds of fabric on the exterior of the limbs, providing a strong physical barrier to limb disjunction. The independent fixation system consists of a steerable endoguide paired with an electronically controlled helical staple applier (Figure 4B).

The staples themselves are helical and designed to fully penetrate the aortic wall (Figure 5). Pull-out strength in a bench-top silastic model is as high as 20 newtons per staple. The helical staples allow the operator to control the degree and location of fixation and resist aortic dilatation. The staples can also be used to address focal sealing issues in much the same way sutures can be used to ablate defects in an open anastomosis. The primary strength of the Aptus system is the introduction of more control in both the design and the deployment of the endograft system by allowing the graft and fixation functions to be developed and deployed separately. This allows both the design engineer and clinical operator more possibilities and creativity to address the multitude of clinical variables encountered in aortoiliac pathology.

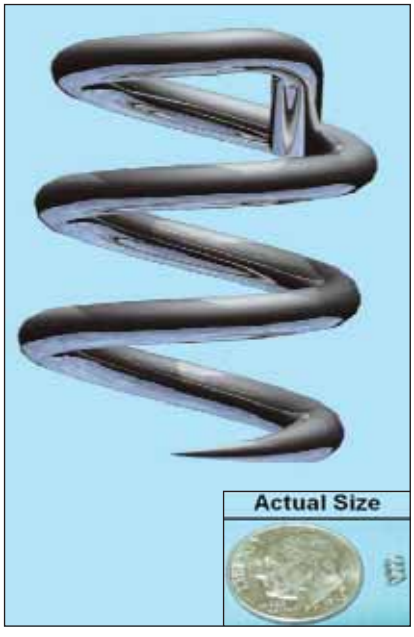

Figure 5. The Aptus Endosystems Endostaple.

Endurant (Medtronic)
Current Phase of Development
- On market in the EU
- Phase II US trial in progress

Design Characteristics and Innovations
- Three-piece modular
- Suprarenal stent with hook fixation
- More flexible main body and limbs
- Controlled release of proximal fixation
- Slightly lower-profile delivery: 18- and 20-F OD
- Designed to treat shorter and more angulated necks

Limiting Features
- Fixation incorporated into endograft
- Modular limbs with friction fit only
- Vulnerable to future aortic dilatation
- Visibility of hooks (nitinol) on plain x-ray unknown

The Endurant endograft represents a synthesis of the lessons learned throughout the last 10 to 15 years of endograft development. It is a three-piece modular device with good hook aortic attachment on a suprarenal stent (Figure 6). There is more control in the proximal deployment, allowing the operator to deploy the covered portion of the endograft before deploying the suprarenal stent and hooks. The body and limbs of the graft utilize a much more flexible stent design that allows for much more longitudinal flexibility and adaptation to tortuous anatomy. The graft delivery system is reduced by approximately 3 French sizes from the smallest prior endograft delivery system. Rather than introducing a fundamentally new technology to EVAR, the Endurant graft represents a refinement and distillation of technologies currently available but not previously within the same device.

Nellix Fillable Sac Anchoring Prosthesis (Nellix Endovascular, Palo Alto, CA)
Current Phase of Development
- Preclinical testing

Design Characteristics and Innovations
- Radically different approach to aneurysm exclusion

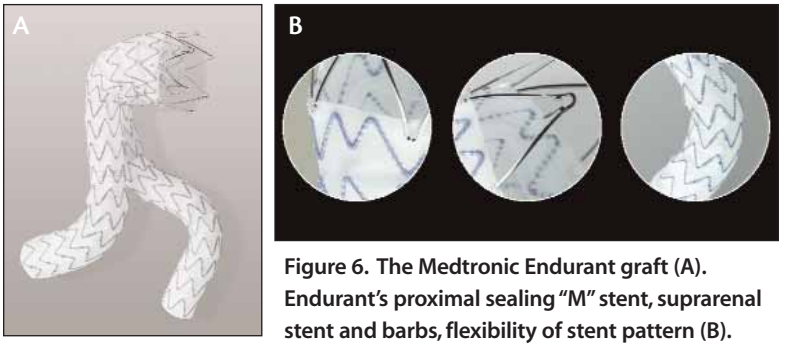

Figure 6. The Medtronic Endurant graft (A). Endurant's proximal sealing "M" stent, suprarenal stent and barbs, flexibility of stent pattern (B).

- Relies on filling sac with a polymer
- Presumably lower profile
- Should primarily address and ablate type II endoleak

Limiting Features
- No precedent for fundamental premise
- Unknown capability to respond to remodeling
- Unproven in either acute or chronic clinical model

Little is known of the technology being pursued by a new start-up, Nellix. What is known indicates that their technology will use the aneurysm sac itself to stabilize a conduit. A sac will be introduced into the aneurysm and filled with a polymer while maintaining a central conduit in the filled sac to allow for vascular patency. This is proposed to free the design from constraints of proximal neck attachment and stabilize the repair by utilizing the entire infrarenal aorta for fixation. Although successful preclinical animal models have been performed, there is no knowledge of successful human implementation. The large differences between preclinical aneurysm models and the actual human pathology with large thrombus burdens and degenerative mural pathology make this step of development critical to its proof-of-concept.

TriVascular2 (Santa Rosa, CA)

TriVascular introduced a low-profile (16-F OD) device that utilized a long suprarenal stent with robust hooks for fixation. This graft was augmented after initial introduction by the injection of a polymer, which filled circular sacs in the graft that were to provide proximal and distal sealing as well as radial support for iliac limb patency. It was also a unibody design and constructed of PTFE (Figure 7).

During the follow-up period of phase I, frequent proximal stent fractures were noted, and a number of grafts migrated. TriVascular had been acquired by Boston Scientific Corporation (Natick, MA) at that point in development, and a phase II trial had been initiated. All clinical trials stopped upon recognition of the scope of the stent fracture and graft migration problem. A redesign was initiated but was stopped when Boston Scientific elected to cease all further development work. Within the past year, the original founders of TriVascular have reacquired the assets and are continuing their redesign efforts in anticipation of reintroducing the technology into clinical trials.

Zenith (Cook Medical)

Cook has initiated several modifications to the original Zenith design. Most of these have been incremental changes to address deficiencies noted during market release with broader clinical use. The most notable of these developments has been their Flex design, which introduced broader spacing between the stents of the Zenith endograft. This design alteration also introduced some incremental changes to the delivery catheter handle to simplify deployment and control of endograft delivery.

More recently, a newer lower-profile design has been introduced into clinical trials. This design is called the Zenith AAA-LP (Figure 8). The delivery catheters for the new low-profile delivery system are 16 and 18 F inner diameter, which translates to roughly 19 and 21 F (OD or crossing profiles). In addition to the work on a newer low-

Figure 7. The original TriVascular graft, which is no longer in clinical investigation.

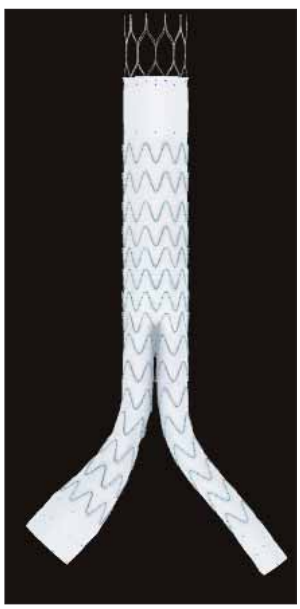

Figure 8. Cook Medical Zenith LP (low-profile) endograft, currently in clinical trials.

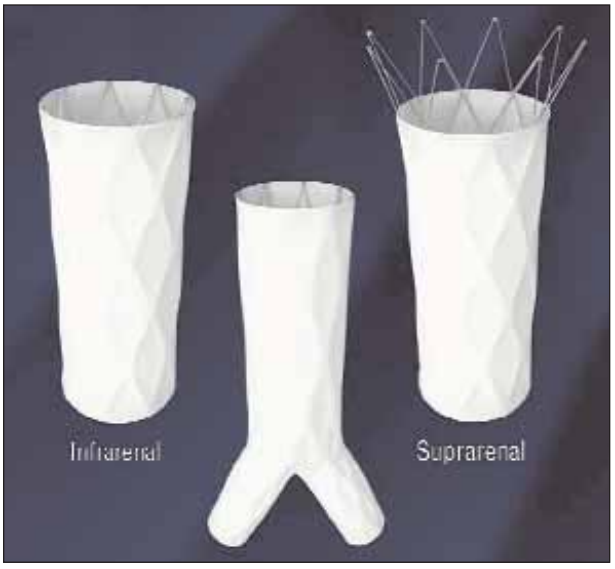

Figure 9. Endologix Powerlink's larger diameters and suprarenal stent design.

profile delivery system, there are ongoing trials for a fenestrated aortic endograft designed to allow covered graft deployment in the mesenteric segment of the abdominal aorta. There is also a trial for the Zenith Iliac Branch, which is a device that allows an endograft to be delivered to the external iliac artery while still maintaining patency of the internal iliac artery.

Powerlink (Endologix, Inc.)

Endologix has added incremental changes to the Powerlink system primarily by improving the delivery system with the introduction of its Visiflex delivery system and SurePass technology. More recently, a new delivery system was introduced as the IntuiTrak. In 2008, a broadened line of graft sizes was introduced (Figure 9), allowing treatment of aortic neck diameters as large as 32 mm and iliac arteries up to 23 mm. Also added was a line of proximal aortic cuffs that have a suprarenal bare stent.

Excluder (W. L. Gore & Associates)

The Excluder graft has not had any recent changes in its basic design or delivery system, but its portfolio of sizes is being expanded to include a 31-mm trunk. As mentioned previously, the primary alteration to the Excluder occurred in response to late aneurysm growth without endoleak documented in the initial pivotal trial. The graft was augmented with a low-porosity PTFE film to prevent what was perceived to be an exudate through the graft.[3] Long-term results with this new graft construct are not available, but the most current results will be included in the device's Annual Clinical Update. Another clinical trial was initiated to evaluate the 31-mm device, which has been modified somewhat from previous iterations.

CONCLUSION

The first 5 years of EVAR development have arguably transformed not just aortic aneurysm therapy but all peripheral vascular therapy, as endovascular techniques for the aorta, renal, carotid and lower extremity arterial circulation have witnessed explosive growth. Certainly, the field of vascular surgery is remarkably transformed compared to what it was prior to 1993, the year of the first commercial endograft deployment in the US. Although the acute results of infrarenal aortic aneurysm repair have been vastly improved, the long-term results are still a matter of heated controversy. The future of EVAR as the potential gold standard for aortic aneurysm therapy rests upon the vision and creativity of both surgeons and technology innovators to realize the potential of endovascular techniques. That potential will take the field of endovascular aortic reconstruction beyond the original paradigm of the "stent graft" toward a broader and more effective portfolio of techniques and devices that will define "endovascular aortic surgery." ■

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