Supplement to

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Endovascular TODAY

October 2010

What keeps an AAA endovascular graft from migrating?

What features do physicians value in migration resistance for AAA endovascular grafts?

Also includes:

What keeps an AAA endovascular graft from migrating?

What features do physicians value in migration resistance for AAA endovascular grafts?

Also includes:

Treating Ruptured Abdominal Aortic Aneurysms
Setting up your practice for an endovascular approach.
Benjamin W. Starnes, MD, FACS

Preliminary Experience with the Zenith® TX2® with Pro-Form® in the Aortic Arch
Prof. Ralf Kolvenbach, MD, PhD, FEVS

In Your Opinion...

What are the top three device attributes of an endovascular stent graft that prevent migration and/or endoleak?

"I believe the three most important device-related features to prevent migration are: (1) active proximal fixation in the form of barbs to help the graft resist the physiologic force of the aortic blood flow; (2) a long main body with a low bifurcation to improve the columnar strength of the graft, once again to deal with the hemodynamic force of the blood flow in the aorta; and (3) flexibility within the graft to conform to tortuous anatomy and maintain a seal."

DR. MATTHEW LONGO
University of Nebraska Medical Center
Omaha VA
Omaha, NE

"For me, there are three key things that influence my decision on which endograft to choose and implant. The first is the accuracy and precision of device deployment. If a device is deployed and lands where it is intended to, then the chances of migration or an endoleak are much lower. Moreover, less additional devices are then needed to prevent a future leak or device migration. The second important property of a device is its method of active fixation. In my experience, grafts that have barbs or hooks tend to migrate less, which further reduces the number of endoleaks. Finally, a device's radial force is crucial. Grafts that have strong radial forces associated with them tend to fall or migrate less. In addition, they require less additional stents. In general, the fewer additional devices or maneuvers that are required to treat a patient, the better both the short- and long-term results will be."

DR. MICHAEL WILDERMAN
Hackensack University Medical Center
Hackensack, NJ

"Active fixation, appropriate neck apposition and seal, and extensive size options to accommodate aorta and iliac anatomy."

DR. LUIS SANCHEZ
Washington University, Barnes-Jewish Hospital
St. Louis, MO

"One, that the graft can be deployed accurately and predictably. This is especially true in cases of a short and/or suboptimal neck. Maximizing the seal zone is of critical importance in these cases; (2) active fixation of any kind will increase the displacement force necessary to dislodge the graft; and (3) the ability to handle neck angulations and conform to the neck. This will maximize apposition of the graft."

DR. EVAN LIPSITZ
Montefiore Medical Center
Albert Einstein College of Medicine
Bronx, NY

"I believe the most important factors contributing to migration and endoleaks is first and foremost patient selection. In some cases, even though the proximal neck may meet the upper limit of the size recommended by the IFU, the pararenal aorta is not healthy and will continue to grow, leading to future migration and failure. Columnar strength is another factor, hence the importance of covering the aorta from the renal arteries to the hypogastric arteries. Proximal stent radial force and active fixation are device attributes creating a seal and reducing the risk of migration."

DR. ALI SHAHRIARI
Methodist Hospital
Indiana Heart Hospital
Indianapolis, IN

"From a seal standpoint, I think the three major attributes are conformability to the neck, good radial strength to the graft at the seal zones, and the use of a long graft body to maximize apposition and even cover more lumbars. From a fixation standpoint, I think using the aortic bifurcation for anatomic support is the most physiologic option and has other added benefits. Positive fixation and suprarenal fixation are also worthwhile in appropriate anatomies."

DR. MATT JUNG
Baptist East Hospital
Louisville, KY

"At first, we thought the most critical factors were appropriate graft sizing and radial force from the stent graft. However, from our experience over the years, we now know that those are not the only factors to prevent graft migra-

tion and type I endoleaks. Active proximal fixation is absolutely crucial to ensure the graft remains in place. Finally, columnar strength prevents proximal and distal graft retraction that could result in migration and subsequent endoleak. Combining active fixation, radial force, and columnar strength provides us the best combination for success."

DR. NABEEL RANA AND DR. SYED HUSSAIN
Heartcare Midwest
Peoria, IL

"Barbed top stent, radial strength of top stent, and controlled accurate deployment."

DR. CHERRIE ABRAHAM
Jewish General Hospital
McGill University
Montreal, Quebec, Canada

"Active fixation (eg, barbs), suprarenal fixation, and stent graft to aortic wall apposition."

DR. GUSTAVO ODERICH
Mayo Clinic
Rochester, MN

"Barbs, radial force, and correct oversizing."

DR. MARCELO FERREIRA
SITE Group
Rio de Janeiro, Brazil

"In answering this question, it is critical to distinguish these two events (ie, migration and endoleaks) as separate but related failure modes of an endograft. Graft designs that don't consider these separately, in my opinion, have more limited applicability than those that consider them as separate design factors.

As such, active fixation is a significant factor in limiting migration. Active fixation is provided by hooks or barbs that embed in the wall of the aorta preventing graft movement. All grafts have an element of active fixation provided by the radial force of the proximal stent, but this is limited to the degree and length of apposition to the aortic wall. The shorter and/or more abnormal (thrombus, calcification, angulation) the neck, the more tenuous the fixation provided by friction alone and thus the benefit of active fixation with hooks/barbs. By design, active fixation should maintain graft position even as the patient's posture and therefore aortic axial shape changes with time.

Passive fixation is defined by physical factors such as the columnar strength of the graft often augmented by extending limbs to the iliac bifurcations. Another manner in which passive fixation prevents movement is by a uni-body, bifurcated design that seats the graft bifurcation on the aortic bifurcation, thereby eliminating any possibility of movement.

Preventing endoleak requires sealing of the graft to the arterial wall at the proximal and distal attachment sites. The exact length of apposition needed to provide complete seal is ill defined. However, the condition of the seal zone will certainly influence this event. Thrombus and calcification will both impact the ability of the graft to juxtapose to the arterial wall and therefore increase the length needed to achieve seal. Graft material designs that stimulate an inflammatory response to promote some level of graft incorporation will also encourage seal. Dacron is far more proinflammatory than polytetrafluoroethylene and may therefore provide an advantage in achieving seal and preventing endoleaks."

DR. SCOTT S. BERMAN
Tucson Vascular Specialists
Tucson, AZ

"Proper graft-to-aorta match, proximal fixation capabilities, and graft conformity to the aorta post-balloon angioplasty."

DR. EDWIN DUNCAN
East Texas Medical Center
Tyler, TX

"Patient selection, active fixation, and appropriate oversizing."

DR. BENJAMIN W. STARNES
University of Washington
Seattle, WA

"First, anatomic patient selection is key. The anatomy must be suitable for endovascular grafting, including a diameter that permits adequate oversizing, a proximal neck that does not have significant laminated mural thrombus, and absence of a reverse-taper configuration. Second, active suprarenal fixation dramatically reduces the chance of graft migration. Finally, well-controlled deployment mechanisms (such as that associated with the Zenith delivery catheter) permit highly accurate placement of the main body device at the intended location, which allows the surgeon to maximize fixation/contact in the proximal neck of the aorta."

DR. STEVEN MERRELL
Intermountain Medical Center
Salt Lake City, UT ■

Treating Ruptured Abdominal Aortic Aneurysms

Setting up your practice for an endovascular approach.

BY BENJAMIN W. STARNES, MD, FACS

Endovascular methods have recently led to dramatic reductions in mortality associated with patients presenting with a ruptured abdominal aortic aneurysm (rAAA). In 1991 at our institution, the mortality rate for this aortic catastrophe was 70%.[1] A recent analysis of this same population of patients demonstrated a mortality rate of 57.8% for patients undergoing open repair of an rAAA. In 2007, we implemented a protocol for managing rAAA patients with a preference for endovascular aneurysm repair (EVAR) when feasible.[2]

THE HARBORVIEW EXAMPLE

Harborview Medical Center in Seattle, Washington, is a level-1 trauma center serving a five-state region representing 25% of the landmass of the United States and nearly 15 million people. Approximately 30 to 50 rAAAs are seen and treated annually. In 2007, an endovascular protocol was established to manage this seriously moribund patient population in a timely and efficient manner. Our protocol at Harborview was adopted from that of the Albany Group (Figure 1).[3] During our study period over 7 years, 187 patients with rAAAs presented to our institution. Before implementation of the algorithm, 131 patients with rAAAs presented and 128 were treated with open repair. The 30-day mortality rate was 57.8%. After implementation of the protocol, 56 patients with rAAAs were managed. Twenty-seven patients (48%) underwent successful EVAR, and 24 patients (43%) underwent open repair. Five patients (9%) underwent comfort care only. In the postprotocol period, five patients in the EVAR group (18.5%) and 13 patients in the open group (54.2%) died during the follow-up period for an overall 30-day mortality rate of 35.3% (P = .008 vs 57.8% preprotocol). After implementation of a structured protocol for managing rAAAs, there was a relative risk reduction in 30-day mortality of 35% compared to the time before implementation of the protocol (95% confidence interval [CI], 14%–51%) corresponding to an absolute risk reduction of 22.5% (95% CI, 6.8%–38.2%). A review of the most recent 12-month experience with this protocol at Harborview has revealed a mortality rate of only 6% for any patient presenting with an rAAA (unpublished data). This is truly a transformational event in the history of vascular intervention.

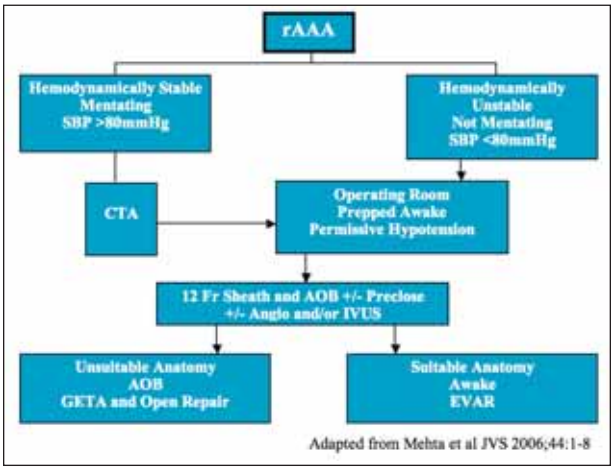


Figure 1. Pathway for patients presenting with rAAA.

At Harborview, we use the rAAA protocol with continuing success and have performed EVAR for rupture in nearly 100 patients. Currently, 80% to 90% of patients presenting to Harborview with rAAAs are treated using an EVAR approach. We foresee the gradual diminishment in the use of open rAAA surgical repair except when patients present with anatomical features ruling out the rEVAR option.

BUILDING YOUR CENTER

It is the author's opinion that certain select centers should seek to build a program for managing rAAAs

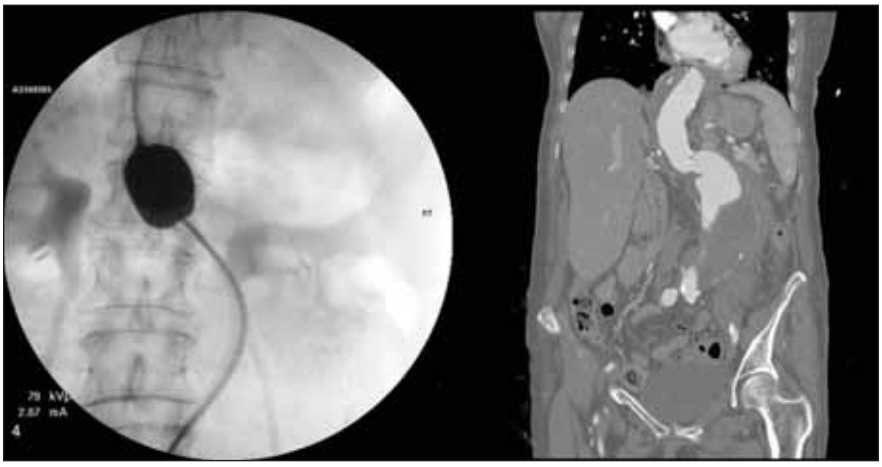


Figure 2. Aortic occlusion balloon for an rAAA in a patient unsuitable for endovascular repair.

using an endovascular approach. The creation of an endovascular ruptured aneurysm protocol requires several key requisites for success (Table 1). If a provider is practicing in a hospital that performs only a few of these procedures per year, that provider should be cautious in applying endovascular techniques for the management of rAAAs except in extremely permissive circumstances. In addition, these procedures must be done in an environment where the default operative pathway is conversion to a traditional open procedure. Therefore, a traditional operating room (OR) with endovascular capability or a hybrid endovascular/OR suite remain the best options.

Institutional requirements include the infrastructure to admit patients with rAAAs into an OR quickly. This requires an emergency department (ED) that can rapidly assess and appropriately resuscitate patients and perform CTA when needed within minutes. Also required are quick turn-around times for transferring a patient from the ED into the OR. This often requires repeated rehearsal on the part of the ED staff, radiology and angiography staff, and OR personnel. Key personnel familiar with endovascular techniques need to be available around the clock. At Harborview, a "rupture room" is maintained after hours and on weekends and is reserved only for incoming patients with ruptured aneurysms. This room has a C-arm, power injector, imaging table, and endovascular inventory in the room and ready for use.

One of the advantages of an "all-endo" approach is the ability to sneak into the aorta with the patient awake and place an aortic occlusion balloon above the renal arteries using solely percutaneous techniques (Figure 2). This can be done under local anesthesia (and often no anesthesia) and helps maintain the patient's physiologic state (permissive hypotension). Once the aortic occlusion balloon is in place, the anesthesiology team can then choose a method of anesthesia with an emphasis on keeping the patient awake. We have elected to keep patients awake during EVAR procedures for rAAAs using local anesthesia with sedation only. Morbidly obese patients present challenges with conventional imaging, and it has been our practice to electively intubate these patients once an aortic occlusion balloon has been placed.

TABLE 1. REQUIREMENTS FOR A SUCCESSFUL ENDOVASCULAR rAAA PROGRAM

- Infrastructure
- Appropriate staffing
- Anesthesia provider "buy-in"
- Imaging equipment
- Endovascular inventory
- Endovascular skill set
- Expert postoperative care

ASSEMBLING THE STAFF

A fully trained staff is essential for a successful endovascular rAAA program. One of the biggest obstacles to establishing a rAAA program is disrupting the status quo and changing the mindset of providers who care for patients with rAAAs. Different specialties are defined by different "comfort zones." In managing rAAAs, the comfort zone of a surgeon is to be in an OR, and the comfort zone for an anesthesia provider is to have a patient intubated and under general anesthesia. It only takes a few successful cases to convince an anesthesiologist that keeping a patient with a blood pressure of 80 mm Hg hypotensive and awake for rAAA repair can be life-saving. Our anesthesiologists have moved toward being very gentle with administrating sedatives during insertion of the Foley catheter and placement of IVs, central lines, and an arterial line.

The unfortunate tendency when a patient becomes a little agitated is to reach for whatever anesthetic agent is handy and plow the patient with sedatives. This is exactly what not to do because the patient loses all protective measures, including abdominal wall muscular tone and may become rapidly hypotensive, necessitating urgent intubation and sometimes a rush to convert to open

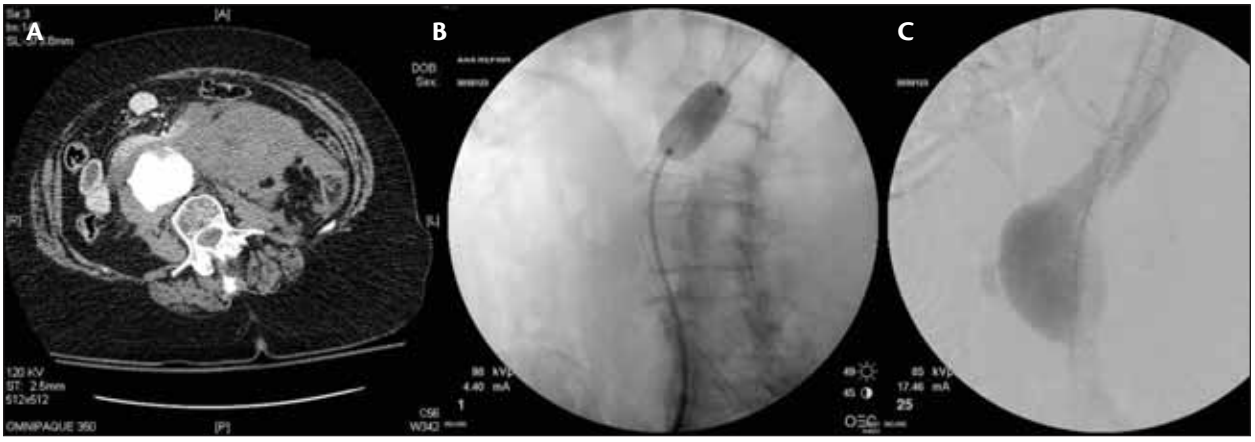


Figure 3. Successful endovascular repair of a ruptured infrarenal aortic aneurysm in an 82-year-old woman awake under local anesthesia. Axial CT image of the large ruptured aneurysm (A). Remote aortic balloon occlusion (B). Aortic stent graft in position before deployment; the aortic balloon has been removed. Note the active extravasation of contrast along the anterior wall of the aneurysm (C).

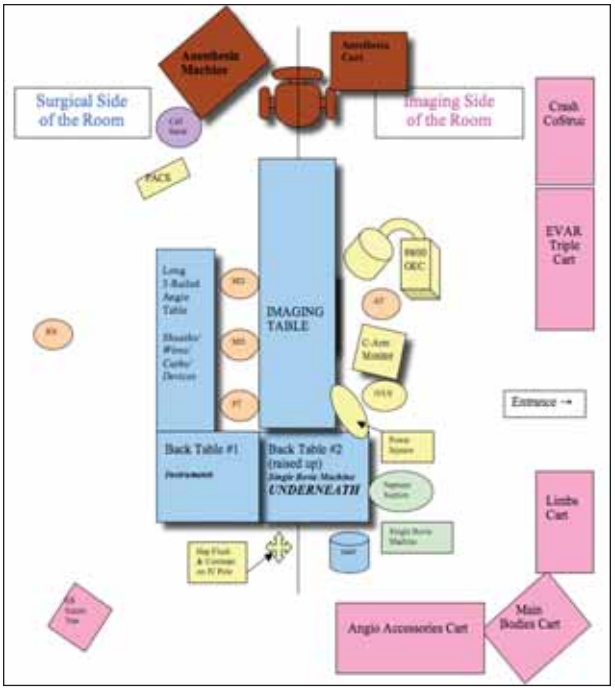


Figure 4. The rupture room setup.

repair (the comfort zone of the nervous endovascular surgeon). Gentle application of anesthetics only until the aortic occlusion balloon is in place is all that is required.

A full complement of endovascular skills is paramount for managing these patients. If certain staff members are uncomfortable with an endovascular approach, those who are comfortable should be immediately available if the patient is a candidate for endovascular repair. These procedures must be done rapidly. It is the author's opinion that if it normally takes a provider more than 1 hour to perform a standard EVAR under elective conditions, that provider should not be managing patients with rAAAs. One of the most time-consuming aspects of any EVAR can be cannulation of the contralateral gate with a guidewire. Preoperative selection of the graft components and delivery site to best allow for rapid gate cannulation will potentially lead to improved outcomes. A protocol should be considered so that in an rAAA setting, if it takes more than 10 minutes to cannulate the contralateral gate, consideration must be given to converting to an aorto-uni-iliac construct. Prolonged EVAR times and gate cannulation times may ultimately directly correlate with the onset of abdominal compartment syndrome and lead to an increase in subsequent morbidity and mortality.

Figure 3 demonstrates a successful repair of an rAAA in which the graft was implanted within 27 minutes of access. Optional and potentially more advantageous approaches to patients with rAAAs involve the use of suture-mediated closure devices for closure of large-bore sheath sites, which saves both time and the potential morbidity for bilateral groin incisions.[4]

IMAGING SELECTION

Many modern hospitals have built hybrid ORs and modern imaging suites into their existing ORs. If this room is empty when an rAAA case arrives, the patient will ultimately benefit. However, this scenario is not often realistic, and the default in an emergency situation is to use portable imaging and an imaging table in whatever room is available at the time. In the not-too-distant future, flat-panel rotational detectors and portable C-arms with superb imaging will be available for managing

COOK MEDICAL

Zenith®
ENDOVASCULAR GRAFTS

AAA Device Technology Leader

Precision proven

Five-Year AAA Clinical Data[1,2]

0%	migration
0%	limb separation
0%	graft material rupture
0%	stent fracture
75.7%	aneurysm shrinkage
95.7%	free from aneurysm growth
92.5%	free from endoleaks
97.8%	free from conversion
98.6%	limb patency
98.9%	free from AAA-related mortality
99.5%	deployment success
99.7%	free from rupture

To learn more about our results, please visit www.cookmedical.com/ai and download the Zenith® AAA Endovascular Graft Clinical Update.

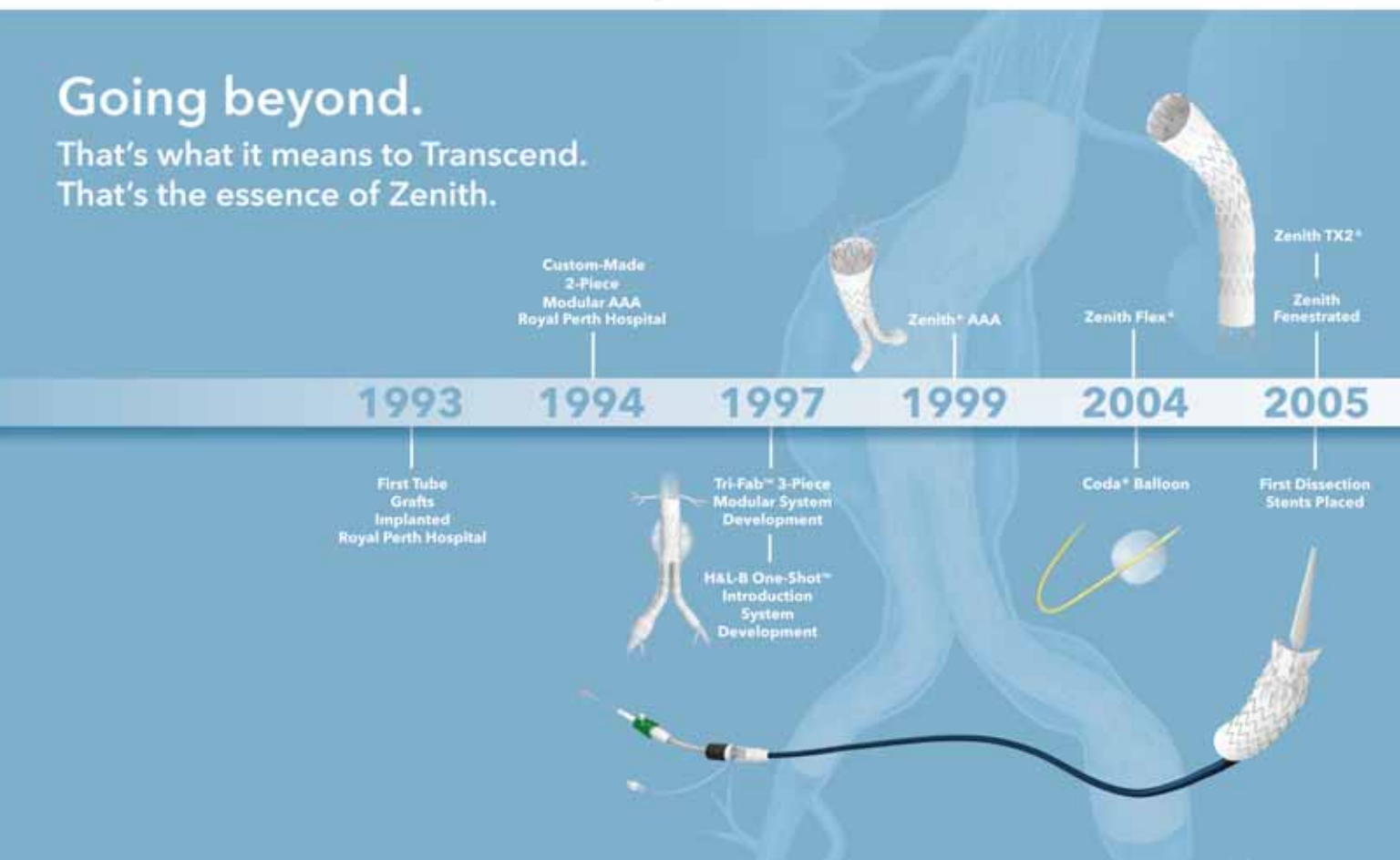
[1]Standard risk patients.
[2]Data on file.

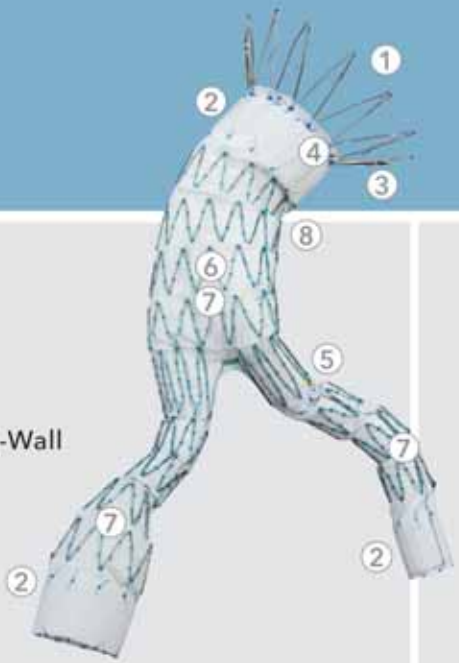
Precision delivery

1. Integrated Introduction Sheath
   1997
2. Dilator Tip
   1997
3. Trigger-Wire Release
   1997
4. Captor® Hemostatic Valve
   2004
5. Radiopaque Band
   2004
6. Hydrophilic Coating
   2004
7. Flexor® Introducer Sheath
   2004
8. Gripper
   2008

Going beyond.

That's what it means to Transcend.
That's the essence of Zenith.





Precision design

1. Suprarenal Fixation
   1993
2. Proximal/Distal Graft-to-Wall Apposition
   1993
3. ARC™ Technology
   1995
4. Staggered Barbs
   1997
5. Proximal Gold Markers
   1997
6. Gold Check Marker on Main Body
   1997
7. Woven Polyester
   1997
8. Three-Piece System
   1997
9. Flex Main Body Design
   2001

ARC TECHNOLOGY™

ARC Technology at a glance...

ACTIVE FIXATION

Our anchoring barbs have the angle, staggered configuration and beveled tip that make them the industry standard for design and migration resistance.

RADIAL FORCE

The self-expanding z-stents provide continuous radial force, added stability and optimal graft-to-vessel apposition.

COLUMNAR STRENGTH

The long main-body design mimics natural anatomy and features a time-tested balance of length, stiffness and flexibility.

2006

- Zenith Renu®
- Zenith TX2 with Z-Trak Plus™
- Bifurcated Iliac Side Branch
- 1,000th Zenith Fenestrated Implanted
- Zenith AAA Japan First to Market

2007

- Zenith Flex AAA 36 mm
- Lunderquist® Wire Guide Enhancements
- Custom-Made Ascending Aortic Device
- Helical Branch

2008

- AAA Low Profile First Clinical Use
- Zenith TX2 U.S. Introduction
- Zenith Flex AAA with Z-Trak™
- Zenith Flex Legs with Z-Trak
- 1,000th Zenith Branch Iliac Graft Implanted

2009

- Zenith Flex Legs Enhancements
- Dissection Endovascular System Clinical Study
- Zenith TX2 with Pro-Form®
- Indy OTW™ Vascular Retriever

2010

- Zenith Dissection Endovascular System Type B
- Zenith LP AAA
- Zenith Fenestrated U.S. Clinical Study
- Zenith Iliac Branch U.S. Clinical Study

2011

- Spiral-Z™ Legs AAA

2012

- Ascending Aorta Developments
- Arch Branch Developments
- Zenith TX2 LP TAA Early Clinical Experience

2013

Global Timeline – Not all products are approved in all markets.

rAAAs. Intravascular ultrasound is an incredibly useful tool for intraoperative imaging and sizing if the patient did not have a CTA before presentation. A power injector is crucial for appropriate imaging of the aorta using standard flush aortography. The only factor that is different from standard equipment available for elective EVAR is blood preservation and suction equipment. At Harborview, the Cell Saver (Haemonetic Corp., Braintree, MA) and Stryker Neptune suction machines (Stryker Corp., Kalamazoo, MI) are maintained in the rupture room. If at any time a procedure needs to be converted or a decompressive laparotomy needs to be done at the end of the procedure, these machines are critical for preservation and proper blood collection. Our standard rupture room setup is depicted in Figure 4.

INVENTORY

Placing the properly sized graft into the patient requires a full complement of inventory (Figure 5). Also required is a stock of common catheters, guidewires, and sheaths just as for standard elective EVAR procedures. This inventory should be kept as simple as possible. At Harborview, we have separated the equipment required for an aortic occlusion balloon set for rapid opening at the beginning of the procedure (Table 2). Whatever graft is utilized, once the sizing measurements have been made, whether intraoperatively or in the ED when the patient arrives from an outside hospital with a CTA on transferable electronic media, the graft components should be chosen, opened, and flushed for immediate delivery when needed. In the most common scenario at Harborview, the grafts are opened and prepared before the patient is prepped.

TABLE 2. COMPONENTS OF AN AORTIC OCCLUSION BALLOON SET

- Access needle
- 0.035-inch, 150-cm Bentson starter wire (Cook Medical, Bloomington, IN)
- 45-cm, 12-F sheath (Cook Medical)
- 32-mm Coda Balloon Catheter (Cook Medical)
- 0.035-inch, 260-cm Amplatz wire (Cook Medical)
- Contrast 50-mL bottle
- 65-cm Kumpe catheter (Cook Medical)
- 30-mL syringe
- Three-way stopcock
- 10-F Prostar device (optional) (Abbott Vascular, Santa Clara, CA)

Figure 5. Dr. Manne Andersson selecting a graft for a patient from the Harborview inventory.

POSTOPERATIVE CARE

Patients with ruptured aneurysms have unique physiologic conditions and require a tailored approach to postoperative management. Surgeons realize that success is not defined only by a successful operation but by the comprehensive management of the patient before, during, and mostly after the operation. Expert intensive care unit management is essential for establishing a successful endovascular rAAA program, and implementation of that program requires a multitude of factors for ultimate success.

CONCLUSION

Creating a seamless endovascular rAAA program can be challenging but will most assuredly have an impact on mortality versus historical institutional controls undergoing open repair. As technology improves, hopefully so will mortality rates for this deadly condition. ■

Benjamin W. Starnes, MD, FACS, is Chief, Division of Vascular Surgery, University of Washington, and Chief, Vascular and Endovascular Surgery, Harborview Medical Center, in Seattle, Washington. He has disclosed that he is a consultant to Cook Medical and Abbott Vascular. Dr. Starnes may be reached at starnes@u.washington.edu; (206) 731-3370.

1. Johansen K, Kohler TR, Nicholls SC, et al. Ruptured abdominal aortic aneurysm: the Harborview experience. J Vasc Surg. 1991;13:240-245;discussion 245-247.
2. Starnes BW, Quiroga E, Hutter C, et al. Management of ruptured aortic abdominal aneurysm in the endovascular era. J Vasc Surg. 2010;51:9-18.
3. Mehta M, Taggert J, Darling RC III, et al. Establishing a protocol for endovascular treatment of ruptured abdominal aortic aneurysms: outcomes of a prospective analysis. J Vasc Surg. 2006;44:1-8.
4. Starnes BW, Andersen CA, Ronsivalle JA, et al. Totally percutaneous aortic aneurysm repair: experience and prudence. J Vasc Surg. 2006;43:270-276.

The Zenith TX2 With Pro-Form in the Aortic Arch

Preliminary experience with this new technology in complex anatomy.

BY PROF. RALF KOLVENBACH, MD, PHD, FEVS

Endovascular stent grafting has emerged as a therapeutic option for thoracic aortic aneurysms (TAAs), dissections, and trauma.[1] Despite expanding indications for treating proximal lesions in the aortic arch with stent grafts, technical and anatomic difficulties persist caused by the inflexible structure of most tubular stent grafts and their inability to conform to the curvature of the aortic arch.

In an earlier effort to address this technical challenge, the Malmö Group[2] chose to use the existing Zenith TX2 TAA Endovascular Graft (Cook Medical, Bloomington, IN) and modify it to permit in situ bending. The Zenith TX2 already features a trifold configuration of its proximal end that allows continuous blood flow around the graft during deployment, preventing the windsock effect (Figure 1). It was modified by affixing an additional slipknot and trigger wire to the proximal end, which caused controlled shortening of the inner curvature of the TX2 after deployment (Figure 2). As with the TX2's successor, the Zenith TX2 TAA Endovascular Graft with Pro-Form, this controlled shortening caused the first two proximal stents to overlap, resulting in greater conformability and improved wall apposition without the gap at the inner curvature of the aortic arch (bird's beak effect) (Figures 3 and 4).

Figure 1. Trifold configuration of the proximal end of the Pro-Form graft.

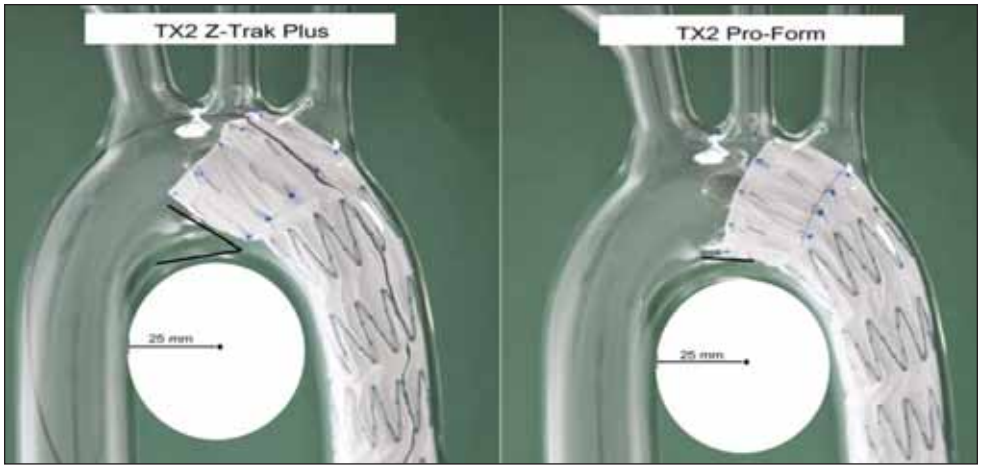


Figure 2. Differences in controlled deployment.

EXPERIENCE WITH MODIFIED TX2

The following summarizes cases in which we used the new TX2 with Pro-Form graft (modified TX2) in increasingly difficult anatomy with favorable results. Thoracic endovascular aortic repair (TEVAR) within the aortic arch zones 0 through 2 is especially demanding due to the supra-aortic vessels and the Gothic (angular) arch configuration common to the zone. In such cases, open surgery to treat aneurysms and dissections is still associated with considerable morbidity, with a mortality rate up to 17% and a neurologic complication rate up to 12%. These percentages are partly related to the necessity of cardiopulmonary bypass. If this necessity exists, TEVAR can be performed in combination with debranching or even less

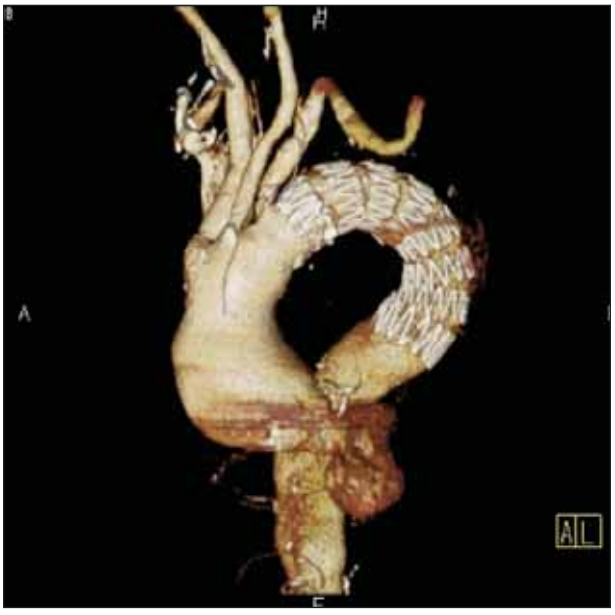


Figure 3. Optimal conformity of the stent graft in the aortic arch.

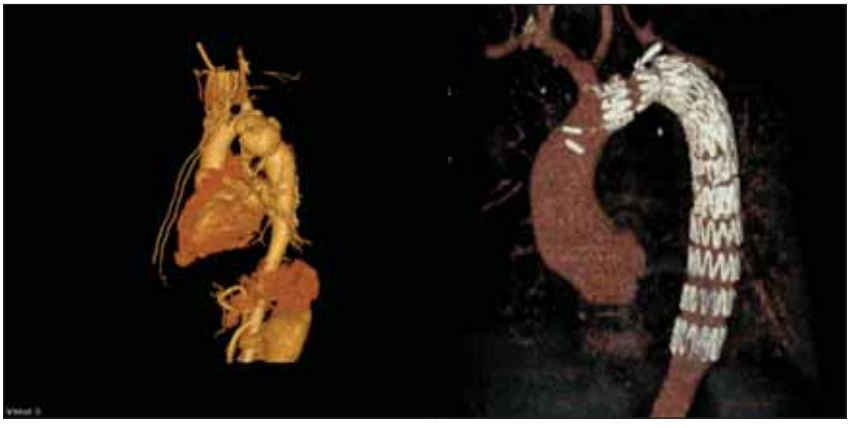


Figure 4. Deployment of a Pro-Form graft after partial debranching.

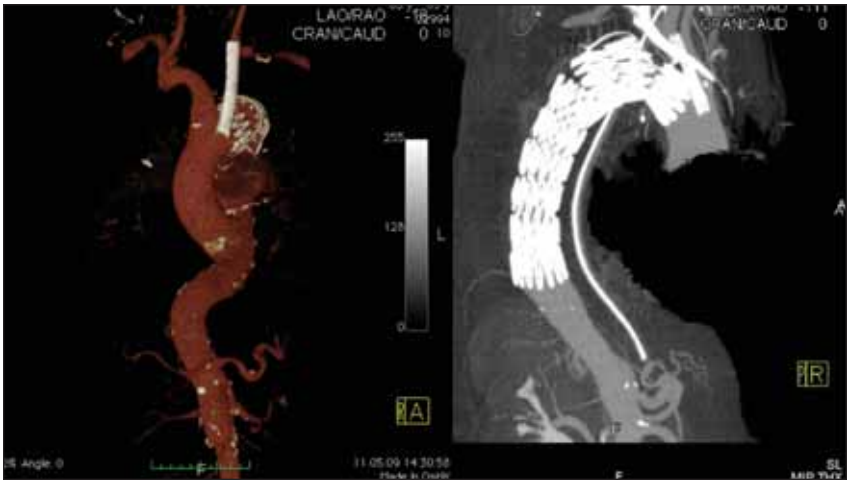


Figure 5. A Chimney graft in the left common carotid artery.

invasively with branched grafts (parallel grafts if branch devices are not available) (Figure 5).

To increase prevention of type I endoleaks in aortic arch zone 0-2, a proximal landing zone of at least 2 cm is required for ideal conformability to the inner curvature. The more proximally the graft is deployed, the larger the diameter of the graft required. Additionally, diameter alterations must be taken into account due to the cardiac cycle and changes during systole and diastole. Deployment of the stent graft in the ascending aorta often requires a transvalvular wire and graft manipulations (in cooperation with cardiologists), plus intraoperative transesophageal ultrasounds and inflow occlusions (Figure 6).

We have performed 26 endovascular procedures within the proximal aortic landing zone of areas 0 through 2 during the last 2 years. In 12 cases, stent grafts were deployed in the ascending aorta, with pathologies treated involving true and false aneurysms, as well as type A and type B dissections. The majority of patients were unfit for open surgery. Cases of ascending aneurysms were discussed with cardiac surgeons before stenting. Figure 7 shows a 42-mm TX2 with Pro-Form stent graft in an emergency case with pending rupture, after aortocoronary bypass and aortic valve replacement. Total supra-aortic debranching was performed in combination with a retrograde parallel graft and placement of an occluder device into the innominate artery.[3]

We had one type I endoleak in an aneurysm involving zone 1. Treatment required an extension of the proximal landing zone with a Pro-Form graft to the ascending aorta. Chimney grafts were deployed if necessary in the left common carotid artery, as well as the innominate trunk, with good midterm results and patency. The Pro-Form graft permitted excellent adaptation to the inner curvature in all cases. It was particularly important in ascending cases because of the regularly curved configuration of the ascending aorta distal to the sinotubular junction.

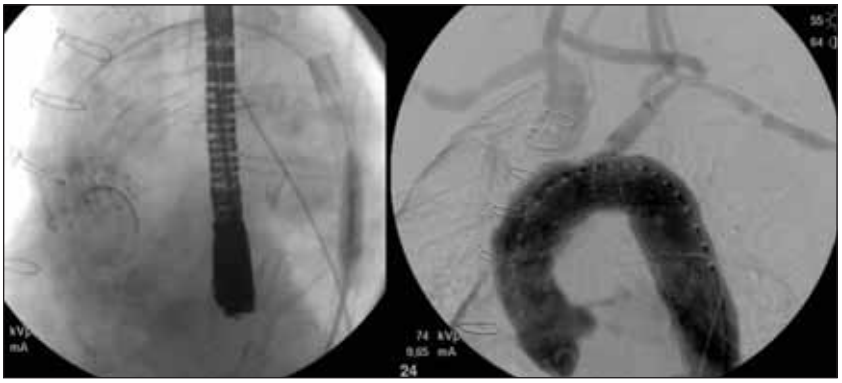


Figure 6. A Pro-Form 42-mm graft in the ascending aorta after debranching of the supra-aortic vessels.

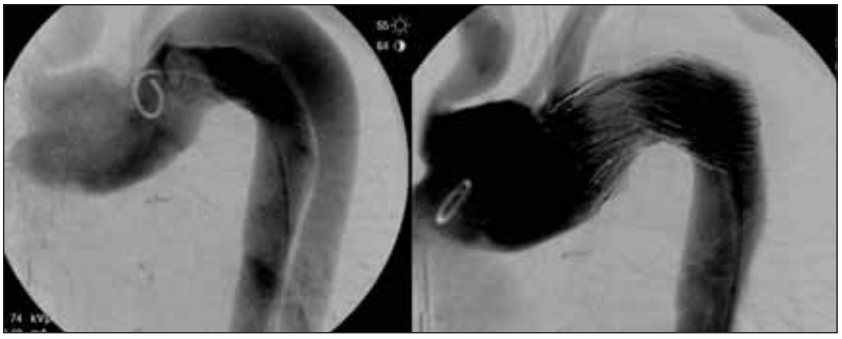


Figure 7. Optimal conformity of the Pro-Form graft in a type B dissection.

Figure 8. A Pro-Form graft occluding a proximal entry tear (A). A Cook 46-mm dissection graft deployed to remodel a dissected aorta (B).

TYPE A AND B DISSECTIONS

Type A and type B dissections are a completely separate disease entity. Stent grafting with the Pro-Form graft was offered in cases in which the aortic sinus and the aortic valve were not included in the dissection; patients requiring open surgery with a valve-bearing conduit were excluded. In cases with massive thrombus material or severe calcification of the aortic arch, extracorporeal bypass and clamping of the carotid arteries was performed to prevent dislodgment during wire and graft manipulations. In some patients with type B dissections, in addition to sealing the proximal entry tear, the Zenith Dissection Endovascular Stent (Cook Medical) was added to the deployment of the Pro-Form graft, which permitted remodeling of the dissected descending aorta.

The Pro-Form graft has barbs at its proximal end, yet intimal damage from the barbs has never been shown in any of our cases (Figures 7 and 8). The barbs are always positioned in a normal landing zone of a nondissected aorta. We believe this is one reason why graft migration has not been observed in these cases, although all grafts were deployed in an area where high velocity with significant turbulence could easily cause forward movement of the stent graft.

CONCLUSION

Our current series shows the clinical feasibility and safety of in situ bending of thoracic stent grafts. A better proximal apposition of the device at the inner curvature of the aortic arch was achieved in all cases, possibly preventing early and late stent graft complications. In the future, off-the-shelf solutions will be required to meet challenges in the ascending aorta and the aortic arch, including devices with larger diameters, as well as branched grafts and/or premanufactured fenestrations to treat a larger variety of patients.[4] ■

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Panel Discussion

Physicians discuss stent graft sizing and selection, as well as their hopes for future technology.

When sizing an endovascular stent graft, do you prefer measuring inner wall to inner wall or outer wall to outer wall? Why?

Dr. Cheng: I do not use a strict rule but take a measurement based on what I think would best suit the aorta. Most of the time this is a value between the inner wall to outer wall. I do not think this is particularly important, because I make final adjustments to the required graft size based on the pathology and anatomy of the neck; for favorable, long necks I tend to oversize the graft less, whereas for difficult necks I oversize more. This decision would make the relatively small difference between inner and outer wall irrelevant.

Dr. Illig: I guess it's not really what I prefer but rather what the grafts are designed for. I always measure outer wall to outer wall, simply because that is how the grafts are engineered. The sizing algorithms are designed for this, and when using this technique (along with good patient selection), we essentially never see proximal type I endoleaks.

Dr. Verhagen: Definitely outer wall to outer wall. The adventitia is responsible for the majority of the strength of the wall—a vascular graft is never sewn to the intima in open surgery. Besides that, thrombus is not a firm structure to secure a graft in. Furthermore, the worst thing that can happen is undersizing a graft, especially when hooks or barbs are present because that cannot be corrected endovascularly.

What unmet clinical needs do you have that can be met with future technology?

Dr. Cheng: Referring to endografts, a lower-profile, larger-diameter thoracic device with a more accurate deployment. A practical device for the aortic arch with preservation of the branches is also very much called for.

Dr. Illig: The obvious need is for a graft (or graft system) that allows safe and straightforward treatment of branches. The obvious application at this point is to be able to deal with juxtarenal and paravisceral aneurysms and aneurysms that involve the hypogastric bifurcation. I would estimate that about 75% of all aneurysms can be treated with endovascular devices right now; these two improvements (both of which are in clinical trials) may increase this percentage to 90%. The next step is being able to treat true thoracoabdominal aneurysms, and the final frontier will be the ability to treat arch and even valve/coronary/ascending aorta pathology.

Dr. Verhagen: Stent grafts with smaller introduction sheaths, especially for thoracic pathology.

The whole concept of fenestrated and branched endografts is beautiful, but it's still far too complex, time consuming, and expensive.

Thoracic endovascular aneurysm repair (TEVAR) for acute and chronic dissections is still in its infancy.

Future technology should enable us to change the follow-up scheme for EVAR/TEVAR patients back to the original follow-up after open repair.

What is your current method of treatment for type B aortic dissection?

Dr. Cheng: For uncomplicated acute type B dissection, the majority of patients are treated medically. For complicated dissection, thoracic endografting to cover the primary tear with appropriate branch revascularization. We rarely use distal bare stents.

Dr. Illig: We are fairly aggressive in considering endografting for acute dissection. Although prospective randomized data do not show benefit at 2 years for TEVAR in this setting, the risk of future thoracoabdominal aneurysm degeneration and the mortality of their repair are formidable and must be kept in mind. The Investigation of Stent Grafts in Aortic Dissection (INSTEAD) trial (prospective randomized) and numerous other series consistently show an improved rate of false lumen thrombosis and reduced overall aortic size after endovascular treatment of acute dissection, which in turn strongly suggests a reduced rate of thoracoabdominal aneurysm degeneration. Exactly analogous to chronic venous disease after deep vein thrombosis, vascular surgeons see the late effects of medically treated dissection. After a few 8-hour operations

with poor outcomes, the prospect of doing something at the time of the original insult in order to reduce the need for eventual thoracoabdominal aneurysm repair several years down the line becomes very appealing.

Dr. Verhagen: Acute: conservative treatment (optimal medical therapy) unless complicated. Then TEVAR for covering the entry tear, possibly followed by stenting of compromised side branches

Chronic: open repair in case of aneurysmal dilatation of the aorta as no one has ever shown me any proof that stent grafting of chronic dissections actually solves the clinical problem. Other complications in chronic dissections are so rare that a customized solution should be followed.

What device features do you consider most important when choosing an endovascular stent graft?

Dr. Cheng: For the abdominal aorta, I consider a wide choice of lengths (and diameters) and the ability of fine adjustments during deployment (both of the top and of the iliac extensions) to be of paramount importance, because this will enable very accurate landing of the graft in patients with short necks and short iliacs. For the thoracic aorta, a low-profile device with a flexible graft to negotiate complex arches and a stable delivery mechanism.

Dr. Illig: I very strongly believe that the three most critical things needed for successful stent grafting of aortic aneurysms are active proximal fixation, controlled release, and modularity. Active fixation ensures that the graft will stay where it is put, essentially forever. We have never seen a graft with this feature migrate and have fixed many, many grafts without this fixture that have migrated. Controlled release, along with active proximal fixation, allows us to treat aneurysms with very short or disadvantaged necks; we can put the upper lip of fabric within a millimeter or so of where we want it (even safely overlapping a slight bit of the renal artery, if needed) and then "hang" the graft right there. Finally, modularity offers the key to the future. At present, its benefit is allowing "off-the-shelf" components to be used to treat exactly what is needed on both sides (rather than settling for the closest available premade device on one [or both] sides), but in the future this seems to us the best bet for being able to treat branches.

Another important feature, structurally, would seem to be a graft that functions in tension rather than compression (ie, one that "hangs" from the top rather than one that needs to support itself from the bottom). As these grafts are made of fabric and need a degree of flexibility to cope with conformational changes in the aorta, they will not function well in compression. In turn, grafts that are stiff enough to function in compression may not behave well because the shape of the aorta changes over time.

Dr. Verhagen: Accurate deployment, conformability of the graft, size of introduction system, durability.

How do long-term follow-up data affect your decision-making when selecting your endovascular stent graft of choice?

Dr. Cheng: Not much, as most grafts in our market are matured third-generation devices with good track records. I would rank graft performance during implantation over long-term results because the latter are determined by patient selection and operator skills.

Dr. Illig: Long-term behavior is obviously the whole point. Financial issues are important to keep in mind, but ultimately the need to treat a patient with the device that has the best chance of long-term success overwhelms any other factor. Factors applicable only at the point of implantation (eg, ease of delivery, number of steps required, and time needed for the procedure) should play no role in graft selection unless long-term success can be ensured.

Dr. Verhagen: Of course, durability is extremely important, possibly the most important characteristic of an endograft. The ones with real long-term data are either not available anymore, or have (sometimes theoretical) disadvantages over newer grafts. Due to the rapid changes in technology, no long-term data are available for most current endografts. Therefore, unfortunately, long-term data can only affect us minimally in our decision-making when selecting an endograft of choice. ■

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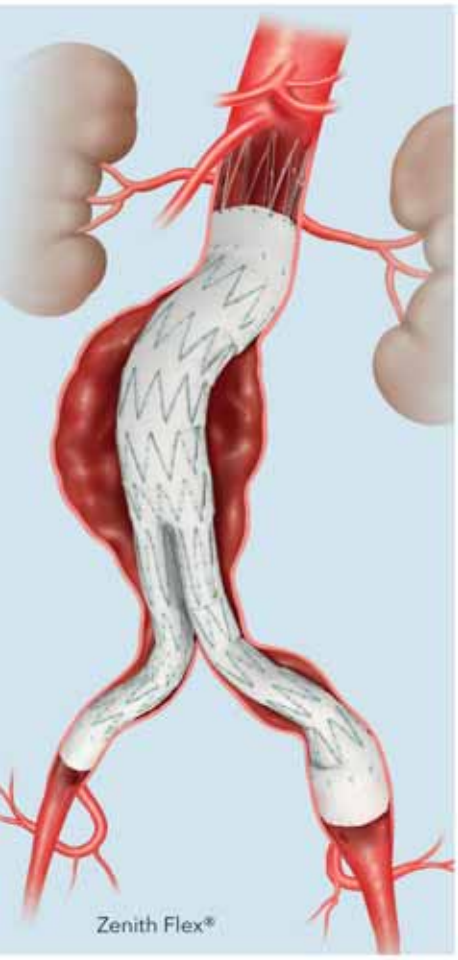

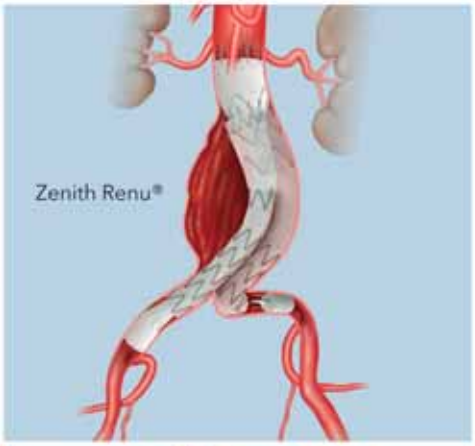

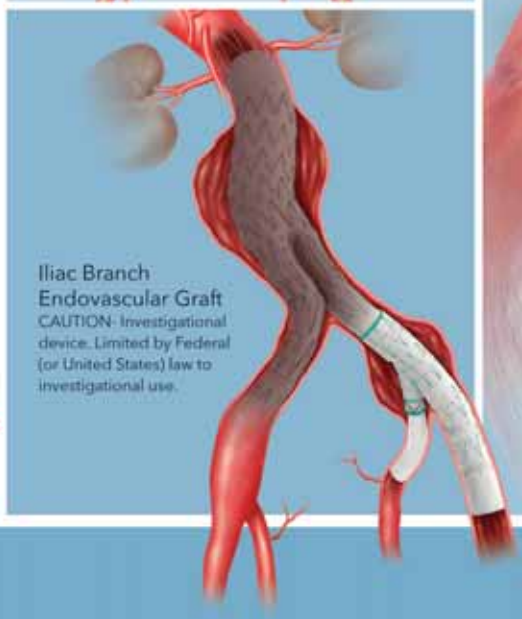

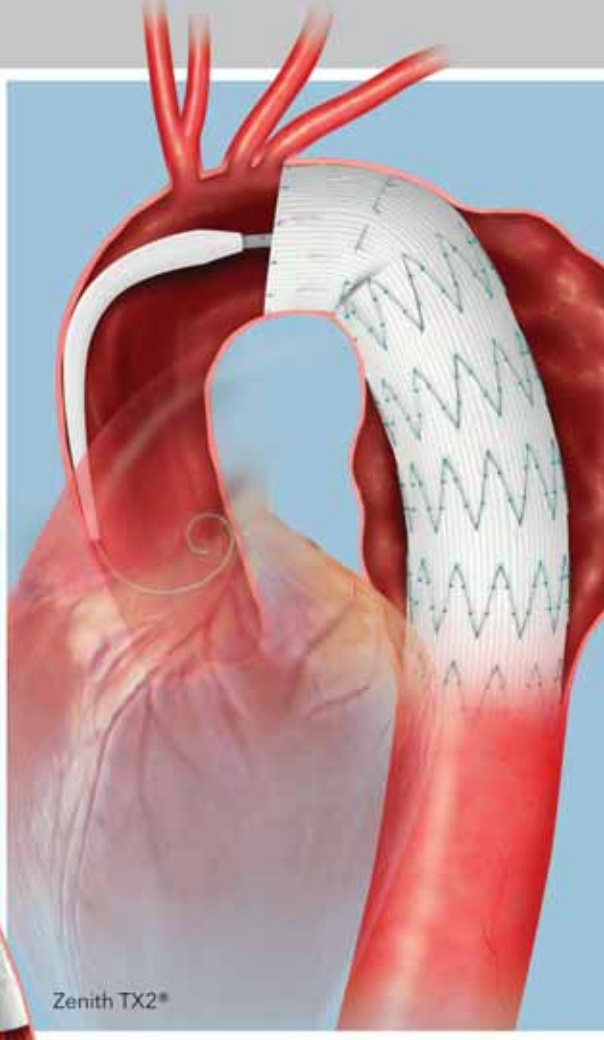

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