

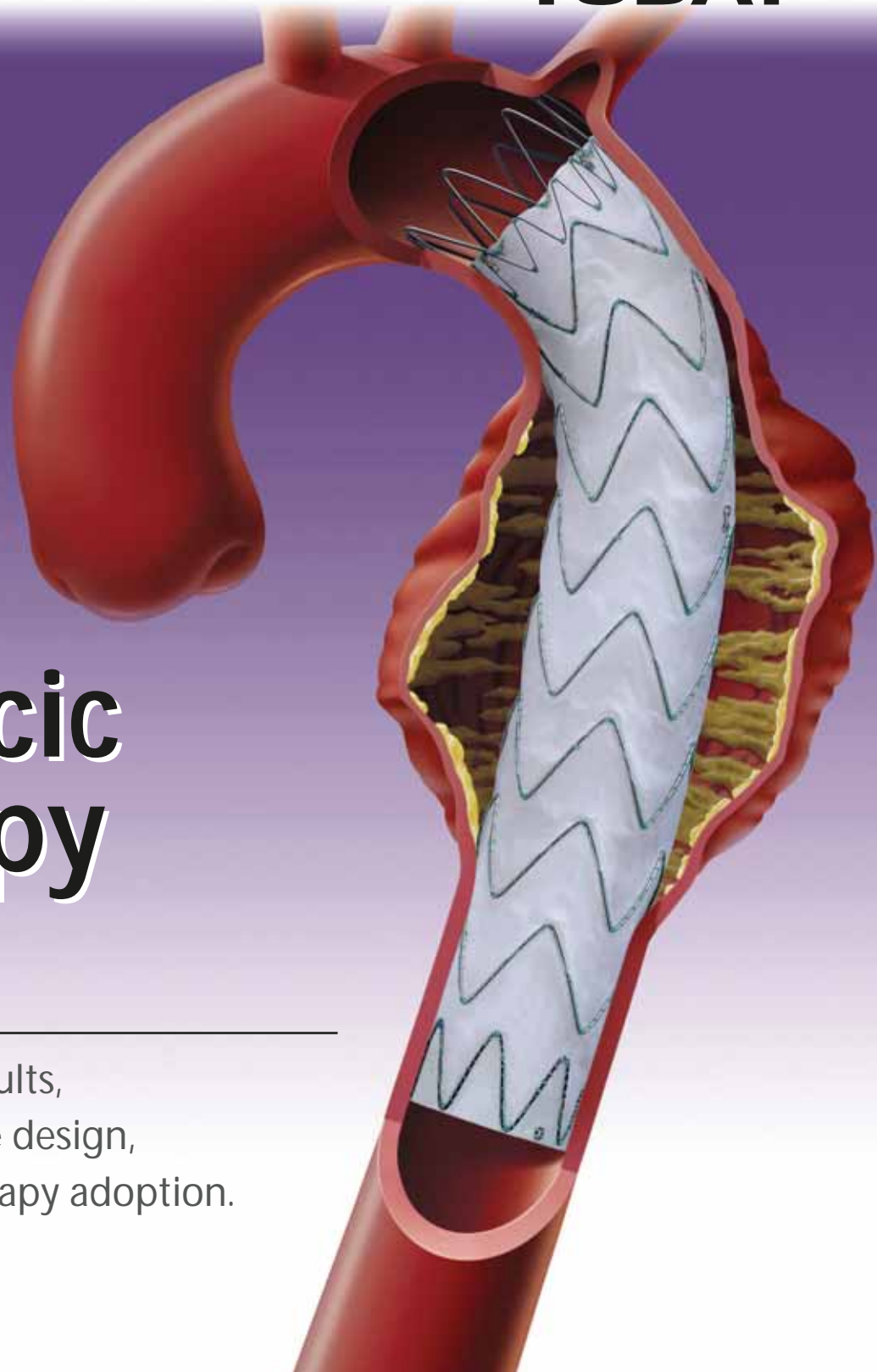
Supplement to

Endovascular TODAY

November 2005

Thoracic Therapy 2006

Emerging trial results,
progress in device design,
and trends in therapy adoption.



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During the past several years, numerous trials in the US and abroad have been conducted to determine the safety and efficacy of endovascular alternatives to open surgical repair of the descending thoracic aorta. Due to the relatively high potential for serious complications and deleterious impacts on quality of life associated with traditional surgery, even in expert hands, clinicians worldwide agree that there is clearly a need for a less-invasive approach. The results from trials comparing endovascular to surgical procedures have shown favorable results in procedure-related complications, outcomes, and in the patients' ability to more quickly return to the lifestyle they enjoyed prior to the procedure.

Another benefit of these studies is that they have given industry the opportunity to improve upon device design, resulting in even better patient outcomes. The physicians involved have also learned a great deal about the thoracic anatomy and the optimal use of today's endovascular device designs. In this supplement to *Endovascular Today*, four of these early pioneers discuss some of the challenges posed by this unique anatomy, how devices such as the Talent Thoracic Stent System (Medtronic, Inc., Santa Rosa, CA) have been designed to handle them, updated trial results, and current issues in endovascular thoracic practice development.

W. Anthony Lee, MD, provides an overview of the hurdles presented by thoracic aortic pathologies such as patient demographics, hemodynamics of the thoracic aorta, the tortuosity of the thoracoabdominal aorta, and

the proximity of the pathologies to the great vessels and mesenteric arteries. He discusses vascular access and right brachial access in this tortuous anatomy, as well as ideal guidewire positioning, arch imaging, and how to achieve an optimal proximal landing.

Ronald M. Fairman, MD, follows with a look at the next generation of thoracic aortic stent grafts. He delineates the improvements made to the Talent Thoracic Stent Graft System, such as a redesigned balloonless delivery system. The need for a thoracic device to conform to the aortic arch and the inherently tortuous atherosclerotic thoracic aorta has been addressed in the Xcelerant delivery system and modified for the Valiant device. The delivery system and stent graft changes culminating in the Valiant design will allow more precise placement of endografts and possible reduction of deployment-related complications.

Christoph A. Nienaber, MD, discusses the design of the INSTEAD Trial, begun in February 2002 and includes 136 consecutive patients to be followed over a 2-year period. INSTEAD is the first randomized trial investigating the role of endoluminal treatment of uncomplicated type B aortic dissection and the 24-month outcomes of endoluminal treatment versus conservative therapy. Availability of final results is expected in 2006.

H. Edward Garrett, Jr, MD, argues that opportunities to master endovascular techniques must be seized in order to assure the future health of the specialty of cardiothoracic surgery. He discusses the future of thoracic endografting and provides advice on why and how to start your practice. ●

An anatomical illustration of the thoracic aorta, showing a cross-section of the vessel wall and the placement of a stent graft. The stent graft is a white, zig-zagging mesh structure that is inserted into the aorta, covering a section of the vessel wall. The illustration is set against a purple background.

CONTENTS

- 4 Endografting of the Thoracic Aorta**
Expert advice regarding tips for success.
By W. ANTHONY LEE, MD
- 8 Medtronic Talent and Valiant Devices**
Moving toward the next generation of
thoracic aortic stent grafts.
By RONALD M. FAIRMAN, MD
- 11 The INSTEAD Trial**
The first randomized trial investigating
the role of endoluminal treatment of
uncomplicated type B aortic dissection.
By CHRISTOPH A. NIENABER, MD
- 13 Getting Started With
Thoracic Endografting**
A cardiac surgeon's perspective on
starting your practice.
By H. EDWARD GARRETT, JR, MD

Endografting of the Thoracic Aorta

Expert advice regarding tips for success.

By W. ANTHONY LEE, MD

Endovascular treatment of thoracic aortic pathologies, when compared to endovascular repair of abdominal aortic aneurysms, poses some similar and different technical challenges. These challenges are related to patient demographics, hemodynamics of the thoracic aorta, the tortuosity of the thoracoabdominal aorta, and the proximity of the pathologies to the great vessels and mesenteric arteries. In general, the “easiest” endovascular thoracic aortic repair can be much easier than the most straightforward endovascular abdominal aortic aneurysm repair, but the “hardest” thoracic case can be significantly more difficult than the most difficult abdominal case, and can be fraught with life-threatening pitfalls.

Unlike the case of abdominal aortic aneurysms in which there is a 4:1 male to female ratio, there is a relatively greater proportion of females with thoracic aortic aneurysms as compared to males (approximating a 50:50 ratio). The hemodynamic conditions of the thoracic aorta, especially near the arch, cannot be underestimated. The pulsatility and the increased blood flow can result in significant inertial drag and loss of positional control from sheer mass and any wind-sock effect throughout the cardiac cycle. The arch is also subject to displacement that is dependent on the respiratory cycle that is most evident on deep inspiration.

Thoracic aortic aneurysms can often present with significant aortic tortuosity (Figures 1 and 2). Tortuosity occurs in multiple locations such that the mechanical forces required for catheter and device navigation are compounded at each tandem twist and turn. Typically, the two

most common areas of tortuosity occur just proximal to the diaphragm and in the apex of the arch. Because the thoracic aorta is fixed proximally by the great vessels and distally by the diaphragm, elongation as a physiologic response to chronic hypertension is accommodated by the aorta bending onto itself. Finally, the branch vessels and the ability to properly image the adjacent landing zones delimit the extent of coverage of any aortic endovascular device. In the thoracic aorta, these branch vessels are the left common

carotid artery (or the innominate artery in cases of a bovine arch) and the celiac artery. Once again, the tortuosity of the thoracic aorta near these vessels can make optimal visualization of the landing zones challenging because the proper gantry angles may be severe in both the lateral and craniocaudal directions.

VASCULAR ACCESS

Thoracic stent grafts are significantly larger than abdominal aortic devices, resulting in larger delivery catheter systems in the range of 22-F to 27-F outer diameter profiles, which would require roughly 8-mm to 9-mm external iliac and common femoral arteries. Because there is a relatively greater proportion of females in this cohort, the need for adjunctive access-related procedures, such as iliac conduits, is increased. In the W. L. Gore & Associates (Flagstaff, AZ) Pivotal Trial for the recently FDA-approved TAG thoracic stent graft, 15% (21 patients of 140) required an iliac conduit, whereas in the University of Florida experience, iliac access was used in one third of the cases. Access-related issues represent the most common reason for



Figure 1. Note the significant tortuosity of the iliac arteries and the compound turns in the thoracic aorta.



Figure 2. Preoperative (A) and postoperative (B) angiography shows successful placement of the Talent stent graft (Medtronic, Santa Rosa, CA) in a thoracic aneurysm.

technical failure and serious life-threatening vascular complications. Furthermore, certain endograft systems do not use a single-pass introducer sheath, or have intrinsic sheaths that allow other devices to pass through them. Multiple passages of these large-diameter devices in diseased iliac arteries can result in significant iliac injuries. Construction of an iliac conduit has been previously described.¹ Briefly, the pelvic retroperitoneum is entered through a modified Gibson incision, and the iliac bifurcation is exposed. A 10-mm Dacron graft is sewn end-to-side to the distal common iliac artery with the heel ending in the external iliac artery (Figure 3A). The distal end of the graft is anatomically tunneled below the inguinal ligament and is brought out through a separate transverse stab incision positioned directly over the common femoral artery (Figure 3B). The

end of the graft is clamped, and the graft is distended under arterial pressure and punctured like an artery. Clamping the distal end and puncturing the graft itself (3 cm to 4 cm beyond the exit site of the stab incision) obviates any need to use cumbersome Rummel tourniquets or any other hemostatic adjuncts because the graft material forms a tight seal around the delivery catheter. At the conclusion of the procedure, the conduit can be transected at the level of the femoral artery and converted into an iliofemoral bypass, or it can be oversewn and buried with a large marking metallic clip within the deep subcutaneous tissue just below the inguinal ligament. In either instance, the conduit is accessible if a secondary procedure is required. The general rule of thumb is that if one even thinks about using an iliac conduit, one should do it.

RIGHT BRACHIAL ACCESS

One can never have too many vascular access sites when performing a complex endovascular thoracic aortic repair. Although the majority of brachial access for percutaneous procedures is performed from the left brachial artery, the left subclavian artery may be covered to gain additional proximal landing zone in up to 25% of cases. Therefore, for thoracic endografting, right brachial access is preferred. The risk of neurologic complications incurred from crossing the right carotid artery is minimal. The brachial artery is punctured just at the level of the humeral condyle or usually about 1 cm above the elbow crease, and a 5-F sheath is inserted. A pigtail catheter is placed and positioned in the mid-ascending aorta. In my opinion, this technique is critical when performing stent graft repairs of Stanford type B dissections, extremely tortuous arches, or unusual aneurysm

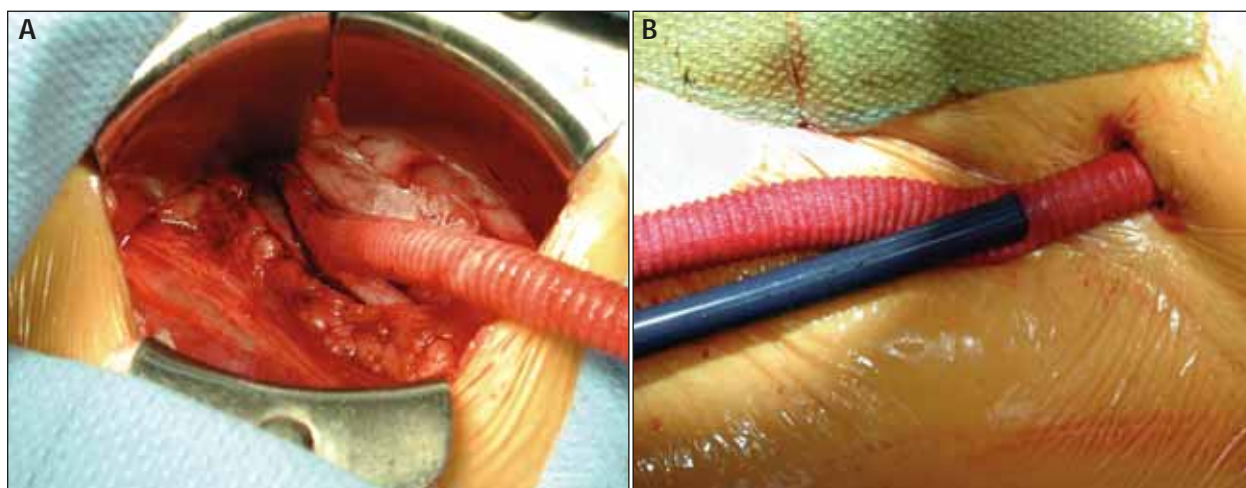


Figure 3. A 10-mm Dacron iliac conduit through a lower-quadrant retroperitoneal exposure anastomosed to the distal right common iliac artery (A). The distal end of the conduit is brought out through a separate stab incision below the inguinal ligament and directly over the femoral artery so that it can be readily converted to an iliofemoral bypass, if necessary (B).

morphologies with significant distortions of the arch. Manipulations of the stent graft can inadvertently dislodge an angiographic catheter inserted from the groin in a difficult arch jeopardizing repeated imaging at critical points during the procedure.

IMAGING OF THE ARCH

Many thoracic aortic pathologies occur either proximally near the arch, distally near the celiac artery, or both. Proper imaging is critical to optimally visualize the maximum length of the landing zone so as to leave no useable neck uncovered. This is not trivial because of the significant tortuosity that can occur in this area. In the nondiseased state, the arch takes almost a directly posterior course. A 30° to 40° left anterior oblique projection is usually sufficient to “open” up the arch to allow visualization of the great vessels. Although with three-dimensional reconstructions the optimal angle may be determined, this may not be readily achievable given the rotational limitations of the C-arm and patient positioning. In practice, the most expedient method of determining the optimal C-arm angle is to rotate the image intensifier under “live” fluoroscopy and watch the widening of the ascending-descending thoracic wire or catheter and stop at the point of maximum width. This, however, does not take into account any craniocaudal rotations that may be required to image the takeoff of the carotid or subclavian arteries. In critical situations, multiple runs may be needed to obtain the necessary projection.



Figure 4. Note that the floppy portion of superstiff primary guidewire is recurved against the aortic valve resulting in the TAG device to appose the outer curve. Note also, the use of an angiographic catheter from the right brachial artery.

PRIMARY GUIDEWIRE POSITIONING

One of the most difficult aspects of thoracic stent graft positioning is predicting the deployment angle of the leading edge of the stent graft against the outer curve. This is critical in cases involving a short neck. Delivery systems that allow partial deployment (“flowering”) of the proximal segment and retraction of the entire delivery apparatus can overcome this problem, although a limitation is the ability to hold the stent graft in position while the remainder of the device is deployed, and also by the extent of the device that can be deployed to sufficiently tubularize the stent graft while still maintaining an ability to retract it. For single-step deployment systems, such as the TAG device, proper positioning of the primary stiff guidewire is critical. This is performed by allowing the floppy portion of the guidewire to recurve off the aortic valve, enabling the operator to push up against the wire (Figure 4) and forcing the guidewire to appose the outer curve. When the TAG device is positioned with the guidewire in this position, the leading edge can be precisely placed, and deployment will reliably land the device in this position.

TORTUOUS AORTA

The thoracic aorta can be very tortuous, especially just above the diaphragm and near the arch. Like any aortic endograft procedure, stiff guidewire support is critical in negotiating tortuosity, but on occasion, a simple stiff wire is not sufficient. The extra-stiff guidewires that are available



Figure 5. Note that a 75-cm, 24-F Cook Keller-Timmerman sheath (Cook Incorporated, Bloomington, IN) has been advanced proximally to two of the three major bends in the distal thoracic aorta allowing easier passage of the device.



Figure 6. The proximal 1 cm of the device has lifted off the inner curve of the arch due to the tight radius of curvature.

include the Amplatz Superstiff (Boston Scientific, Natick, MA), Meier (Boston Scientific), and the Lunderquist ES (Cook Incorporated, Bloomington, IN) (and more recently, a preshaped curve for the arch). Currently, there is no endograft delivery catheter that has perfectly uniform stiffness. Although some are better than others, all the delivery catheters have an intrinsic flexion point at the transition between the leading segment where the device is loaded and the remainder of the shaft, which can adversely impact trackability of the device. In the presence of a 90° curve or greater, the delivery catheter will buckle at this flexion point such that any additional force applied to the delivery catheter will simply cause it to buckle further without advancing the delivery catheter. Some ways to aid in this situation involves use of a stiff “buddy” wire introduced from the contralateral groin to further straighten the tortuosity, use of a long (65 cm to 75 cm) introducer sheath that may track better along the wire and advance the leading edge beyond the point of maximum angle (Figure 5), and lastly the “body-floss” technique. In the body-floss technique, the primary femoral guidewire is snared from the right brachial approach such that a trans-femoral-brachial “rail” is established. This represents the ultimate form of wire support because the application of traction from both ends enables almost any device to track through even the most tortuous anatomies. The only technical note that should be exercised is that a short (60-cm) 6-F guide catheter should be introduced from the brachial sheath (ie, after the wire has been snared) and advanced over the wire and beyond the origin

of the innominate artery. This is done to avoid a “cheese cutter” effect of a bare wire against the orificial edge of the thoracic aorta possibly resulting in a dissection.

OPTIMAL PROXIMAL LANDING

There is no currently available device, either FDA-approved or undergoing clinical trials, that is sufficiently conformable such that it will coapt circumferentially around sharp angles and the apex of most arches. Although most of the devices will coapt nicely to the outer curve of the angle, the side of the graft that is opposite the lesser curve will frequently lift away from the aortic wall. The reasons for this are twofold: first, the inner curve's radius of curvature is tighter than the outer curve, and second, a straight tubular object is essentially being fit into a curved one. Especially in the proximal thoracic aorta, this malcoaptation can be seen as lifting off of the device with each pulsation leading to a significant type I endoleak. This has implications in preoperative planning because in proximal pathologies, determining the adequacy of the proximal landing zone actually depends on the length of the inner curve as opposed to the “center-path length.” Similar to the infrarenal neck, the tighter the radius of curvature is, the longer the neck should be. In situations where one has the luxury of a long (>3 cm) proximal neck, it is more advantageous not to use the entirety of the uninvolved aorta if it means that the device will drape over the apex of the curve. Instead, if one intends to land the device proximal to the curve, it should be positioned well beyond the curve and conversely, if one has sufficient length, one should land the device distal to the curve on the “down-slope” of the apex to avoid the malapposition (Figure 6).

CONCLUSION

Endografting of the thoracic aorta can challenge the most skilled endovascular specialist. Although most procedures can be conducted in a safe and straightforward manner, difficult anatomies will bring to bare the entire gamut of catheter and guidewire techniques. Adequate and detailed preoperative case selection and preparation remain keys to success. ●

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1. Abu-Ghaida AM, Clari DG, Greenberg RK, et al. Broadening the applicability of endovascular aneurysm repair: the use of iliac conduits. *J Vasc Surg.* 2002;36:111-117.

Medtronic Talent and Valiant Devices

Moving toward the next generation of thoracic aortic stent grafts.

BY RONALD M. FAIRMAN, MD

With the recent completion of enrollment in the three arms of the VALOR trial (Evaluation of the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aortic Aneurysms), Medtronic (Santa Rosa, CA) is preparing to introduce into US clinical trials their next-generation thoracic aortic endovascular stent graft, called the Valiant device. This technology was introduced in Europe through a limited-market release program in the spring of 2005. The Talent Thoracic Stent Graft System evaluated in the VALOR trial has been used extensively outside the US for many years. In addition, physicians have gained considerable experience with the Talent Thoracic Stent Graft since the feasibility phase I high-risk trial was performed in the US in 1998. The evolution of the Talent Thoracic Stent Graft to the Valiant design is a result of accumulated feedback from thousands of implants worldwide. Medtronic engineers have enhanced both the delivery system as well as the stent graft itself, creating a product that promises to be vastly superior to the original Talent Thoracic Stent Graft. The original Talent Thoracic Stent Graft was the first endovascular device available to treat thoracic aortic pathology when we began our thoracic endovascular program at the Hospital of the University of Pennsylvania in 1998. The customization features of that first-generation Talent thoracic device presented us with our first opportunity to offer novel endovascular options to patients who were being managed with "watchful waiting." The preliminary outcomes in our first 50 patients using the early Talent design were largely extraordinary. Minor changes to that original Talent device culminated in the Talent Thoracic Stent Graft System used in the VALOR trial (Figure 1).

SYSTEM COMPOSITION

The system is composed of a preloaded stent graft and the CoilTrac TDS delivery

system. For the purposes of the VALOR trial, the delivery system was redesigned to a balloonless system with a longer push rod. This change was made based on previous clinical trial experiences. Elimination of the integral balloon served to reduce the potential for kinking and thereby reducing the deployment forces. The implanted Talent endoprosthesis is composed of a polyester graft fabric sewn to a self-expanding nitinol wire frame. The design concept is modular and, although the Talent Stent Graft has been viewed as a customized device, only catalog sizes were available in the VALOR trial. Proximal and distal stent graft diameters range from 22 mm to 46 mm, and the total covered length of the device ranges from 112 mm to 116 mm. Bare spring (proximal device diameter <24 mm) and Freeflo (proximal device diameter >24 mm) configurations are available proximally, which indicate a terminating spring without fabric coverage. Bare spring configurations are also available distally. Both proximal and distal bare spring configurations allow for crossing the great vessels of the arch and the celiac artery respectively. An accessory Reliant stent graft balloon, packaged separately, is intended for use after stent graft deployment to facilitate modeling of the covered springs and to remove fabric pleats from the graft material.

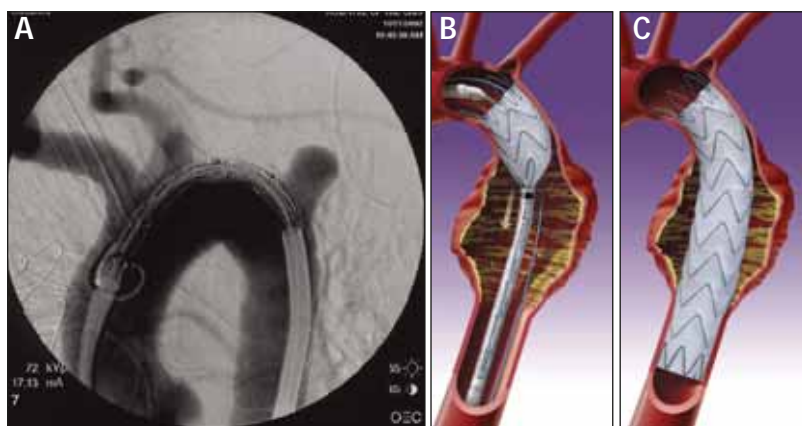


Figure 1. The Talent Thoracic Stent Graft System. Images B and C indicate deployment of the device.

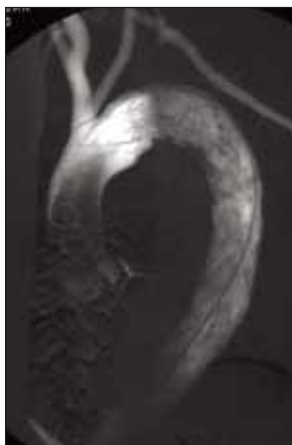


Figure 2. The Talent proximal bare springs crossing bovine arch anatomy.

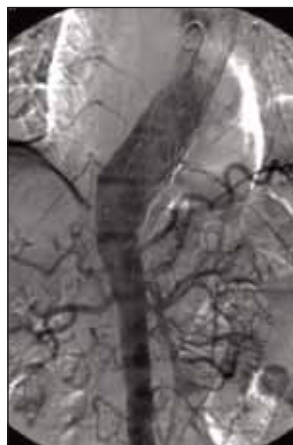


Figure 3. Current Talent design with connecting bar did not conform to the tortuous distal thoracic aorta.

THE VALOR TRIAL

The VALOR trial is a prospective, multicenter, nonrandomized evaluation of the safety (rate of all cause mortality) and efficacy (successful aneurysm treatment at 1 year) of the Talent Thoracic Stent Graft System when used in patients with thoracic aortic aneurysms (test arm). The test arm consists of patients diagnosed with thoracic aortic aneurysms who are considered candidates for open surgical repair and who are at low- to moderate-risk based on SVS/ISCVS criteria.

Additionally, two observational treatment group registries were conducted to record descriptive information that may serve as the basis for future clinical investigations. The registry and high-risk arms include patients diagnosed with dissections, traumatic injury, pseudoaneurysms, and aneurysms without a distinct proximal or distal aneurysm neck of ≥ 20 mm.

Although there were 40 active sites in the VALOR trial, eight sites in the US trial enrolled 57% of the test group patients and 66% of the high-risk/registry arm. At the time of this trial, thoracic stent grafting was performed largely in a handful of centers. Most of the pathology treated throughout all arms of the trial consisted of fusiform or saccular aneurysms; in the high-risk arms, this pathology was present in 76% of the patients enrolled. The demographics revealed that 40% of the patients enrolled were female, a percentage not dissimilar from the phase II multicenter trial of the Gore TAG thoracic endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ). Because a greater percentage of women have thoracic aneurysms compared to abdominal aortic aneurysmal disease, issues of iliac access assume critical importance. In the VALOR trial, surgically placed conduits were necessary in upward of 15% of patients, demonstrating the need for delivery systems smaller than 22 F to 24 F. The bare spring or Freeflo proximal design (as well as

the availability of stent graft devices with diameters as large as 46 mm) opened the door to endovascular thoracic aortic options for a broader range of patients in the VALOR trial compared to any other industry-sponsored thoracic device trial (Figure 2). Due to device sizing constraints based on thoracic aortic anatomy, 35% of the patients treated with the Talent Stent Graft in the high-risk arm of VALOR could not be treated with any other industry-sponsored device. The preliminary results of the high-risk arm were presented in June 2005 at the Vascular Annual Meeting in Chicago.

LESSONS LEARNED

The Talent thoracic experience has resulted in a number of consistent observations that are relevant not only to the Talent device, but to all endovascular therapies in the thoracic aorta. Although rigid stent grafts can function well in the abdominal aorta, thoracic devices need to conform to the aortic arch and the inherently tortuous atherosclerotic thoracic aorta (Figure 3). Although one can accurately deploy a Talent thoracic device in the proximal descending thoracic aorta, controlled deployment in an angulated arch or in an area of marked tortuosity is difficult. These issues are addressed with the Xcelerant delivery system, which has been available to physicians in the US for the AneuRx AAA stent graft and has been modified for the Valiant device (Figure 4). Although the new thoracic version of the delivery system is the same French size as that used for Talent, it allows for controlled ratcheted precise deployment. Stabilization of the delivery system when deploying in the arch is fundamentally important to prevent embolic stroke. To optimize ease and accuracy of deployment as well as conformability, the long connecting bar of the Talent device has been removed in the Valiant, whereas columnar support has been optimized through stent spacing and the exoskeleton. The removal of the connecting bar has eliminated the need to orient the device *in vivo* and results in improved flexibility. The proximal uncov-



Figure 4. The Xcelerant delivery system.

TABLE 1. COMPARISON OF TALENT AND VALIANT DESIGNS

Product Features	Talent	Valiant
Diameters Available	22-46 mm	24-46 mm
Graft Material	LPS (monofilament polyester)	Same
Suture	5-0 Braided Polyester	Same
Body Spring	5-Peak (.020-inch wire)	Same
Stent Material	Chemical Etched Nitinol	Same
Delivery System	CoilTrac TDS	Xcelerant
Maximum Total Length	130 mm	227 mm
Body Spring Attachment	Inside Graft Material	Outside Graft Material
Connecting Bar	Yes	No
Proximal End Configurations	Bare Spring (5-Peak/.020-inch wire) Open Web (5-Peak/.020-inch wire)	Bare Spring (8-Peak/.021-inch wire) Closed Web (8-Peak/.021-inch wire)
Distal End Configurations	Closed Web (5-Peak/.020-inch wire) Bare Spring (5-Peak/.020-inch wire) Open Web (5-Peak/.020-inch wire)	Closed Web (8-Peak/.021-inch wire) Bare Spring (8-Peak/.021-inch wire)
Proximal Radiopaque Markers	Two figure-of-eight platinum/iridium alloy	Four-figure-of-eight platinum/iridium alloy
Distal Radiopaque Markers	Two figure-of-eight platinum/iridium alloy	Two-"zero" platinum/iridium alloy
Sterilization Method	Ethylene oxide	E-Beam

ered bare spring has been increased from five to eight peaks, distributing the force of the spring over more apices. Additionally, the proximal stents have been inset into the fabric. Experience to date has shown that this change results in more stable deployment and may prevent the rare instances of asymmetric flowering of the device observed when deploying in an angulated arch (Figure 5).

Furthermore, longer stent grafts are particularly desirable when treating most pathology in the thoracic aorta. The great majority of thoracic aortic conditions require stent graft coverage of up to 200 mm. Although shorter stent grafts are fine for treating focal disease processes, such as penetrating ulcers, transections, or saccular aneurysms, in most instances we are treating fusiform longer segments of disease. Longer endografts result in less modular junctions and fewer passes of large delivery systems through small diseased iliac arteries, which can result in life-threatening iliac artery avulsions.

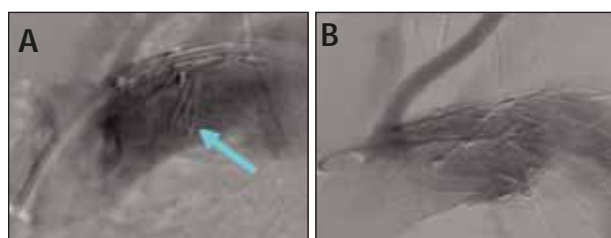


Figure 5. Rare instance of asymmetric flowering of the proximal bare spring (A). Final result after minor repositioning (B).

The difficulty of identifying proximal and distal aspects of modular components once inserted is a consistent observation. The new Valiant device has distinct "figure-of-eight" radiopaque markers proximally and "zero" markers distally that provide enhanced visibility and result in more precise overlap at modular junctions. The Talent and Valiant devices are compared side by side in Table 1.

CONCLUSION

Although the preliminary outcomes of the VALOR high-risk arm using the Talent Thoracic Stent Graft System are encouraging and reveal high procedural success in the setting of low operative mortality, stroke incidence, and paraplegia rates, enhancements in stent graft design are evolving. The delivery system and stent graft changes culminating in the Valiant design will allow more precise placement of endografts and should further reduce deployment-related complications.

The VALOR test arm is now in the follow-up phase, and the PMA will be filed with the FDA in the early summer of 2006. Medtronic is currently finalizing a US clinical trial protocol using the Valiant Stent Graft System for FDA submission. ●

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The INSTEAD Trial

The first randomized trial investigating the role of endoluminal treatment of uncomplicated type B aortic dissection.

By CHRISTOPH A. NIENABER, MD

Eighty-five percent of patients with chronic type B aortic dissection who are treated with aggressive antihypertensive treatment survive their initial hospital stay. The long-term outlook for these patients is an estimated 50% mortality at 5 years and late expansion of the false lumen in about 25% of this group at 4 years (Figure 1). Recent data from the International Registry of Aortic Dissection, which showed an increased use of stent grafts in type B aortic dissection and 1-year mortality <5% after stent graft placement (unpublished data), prompted the investigators of the INSTEAD trial to compare the outcomes of patients with type B aortic dissection subjected to interventional thoracic stent grafting combined with tailored antihypertensive treatment to those with tailored antihypertensive treatment alone. The randomized INSTEAD trial is the first to investigate the role of endoluminal treatment of patients with uncomplicated type B aortic dissection, as well as the 24-month outcomes of endoluminal treatment versus conservative therapy. The trial began in February 2002 and will include 136 consecutive patients to be followed over a 2-year period. By May 2005, all patients (N=136) were enrolled; final results are expected to become available in 2006.

PURPOSE

The INSTEAD trial addresses the issue of stent grafting in uncomplicated type B dissection. It does not focus on the enrollment of patients at high risk in whom endovascular strategies have shown benefit. Another criterion for exclusion is spontaneous false lumen thrombosis occurring within the initial 14 days of index dissection because it infers a superior prognosis. Additionally, patients with type B aortic dissection and spontaneous false lumen thrombosis are excluded because accurately determining the role of stent

graft treatment in reconstruction and healing of the dissection is difficult to achieve. False lumen patency is documented at baseline by reporting false lumen flow using either MRI, CT, or transesophageal echocardiography. Randomization occurs for all eligible patients after exclusion criteria are determined.

TREATMENT ARMS

Patients are randomized to one of two treatment arms: endovascular stent graft placement with tailored antihypertensive treatment or tailored antihypertensive treatment alone. Patients randomized to endovascular treatment will receive a Medtronic Talent Stent Graft System (Medtronic, Santa Rosa, CA) customized to their anatomical specifications. Implementation of the device is done either in the catheterization laboratory, the angiographic suite, or an operating theater with appropriate imaging equipment to enable fluoroscopic guidance.

The thoracic stent graft treatment requires sealing of the proximal entry tears by placing the endograft within the true lumen across the entry tear. Stent graft coverage of the entry site interrupts both proximal communications and flow to the false lumen and causes depressurization of the false lumen and reconstruction of the true channel (Figure 2). Stent-induced aortic remodeling occurs when

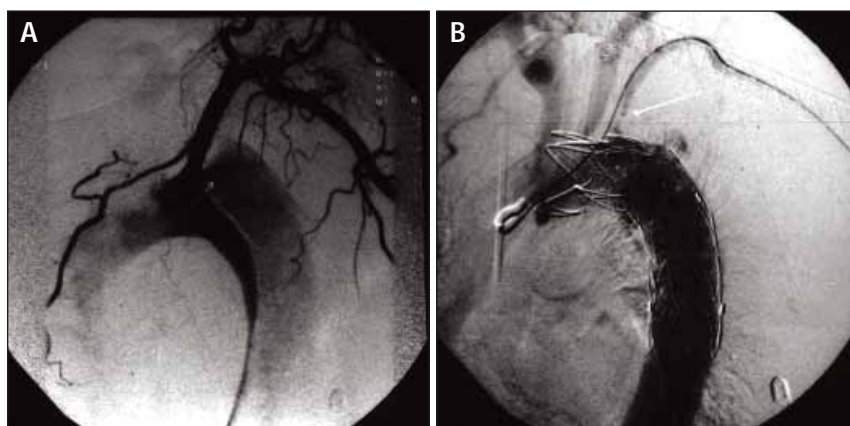


Figure 1. Thoracic aorta with imminent rupture of type B dissection (A), treated successfully with the Medtronic Talent Thoracic stent graft (B).

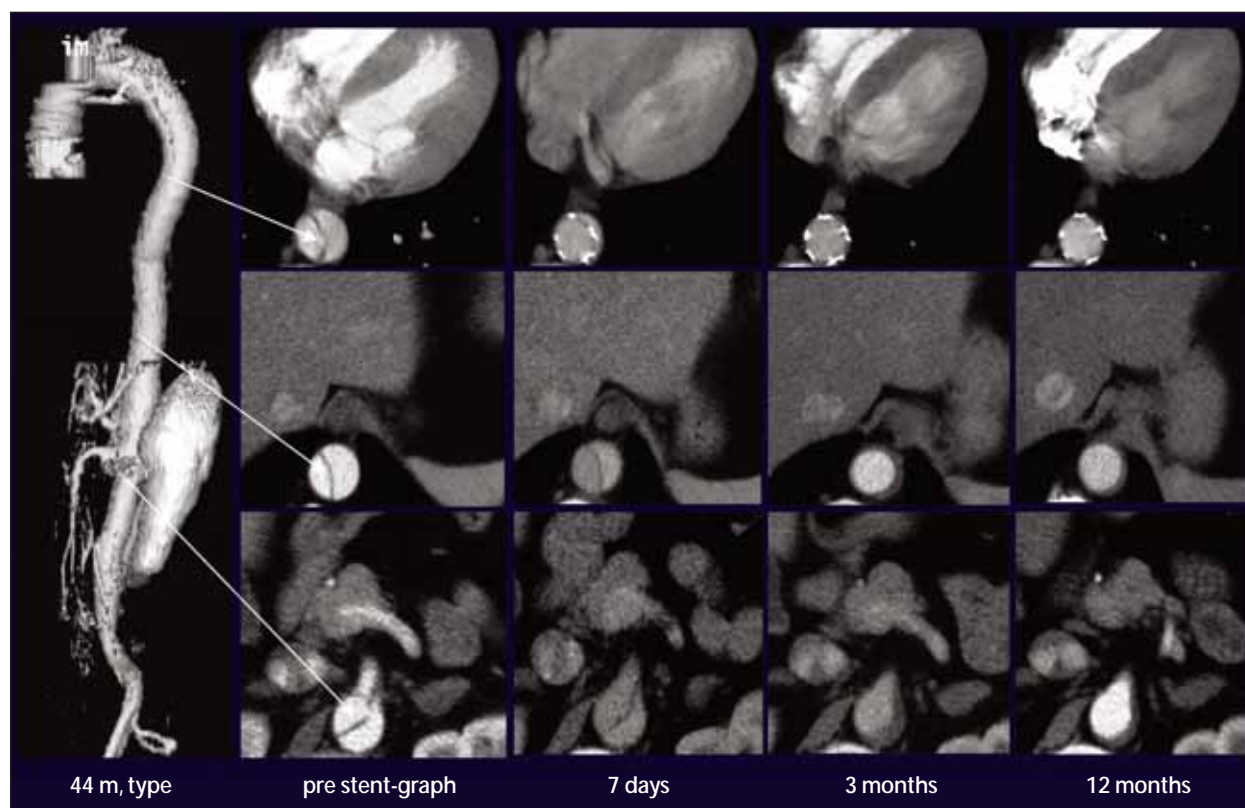


Figure 2. CT scans show aortic remodeling and thrombosis of the false lumen after use of the Medtronic Talent Thoracic stent graft.

proximal thrombosis of the false lumen supports repositioning of the dissection lamella, progressive caudal thrombosis, and fibrosis of the false lumen.

Mortality is related to expansion of the false lumen and formation of a thoracic aneurysm with inherent rupture risk, or to retrograde progression of dissection with involvement of the proximal aorta with even higher mortality. Surgery for type B aortic dissection has a 14% to 76% risk of irreversible spinal cord injury or postoperative mortality. Endovascular treatment techniques are appealing because they may have potential for fewer complications and improved outcomes of type B aortic dissection considering promising preliminary results of both elective and emergency endoluminal treatments of this aortic dissection.

FOLLOW-UP

After randomization, all study patients are scheduled for 3-, 12-, and 24-month follow-up visits at which time clinical and imaging evaluation and completion of the short form 12 questionnaire, adverse events, patient discontinuation, assessment of thrombosis of the false lumen, changes in aortic diameter, and complications or crossovers are documented.

ENDPOINTS

The primary endpoint is all-cause mortality, whereas the secondary endpoints are thrombosis of the false lumen, cardiovascular morbidity, degree of aortic expansion, quality of life as determined from the short form 12 questionnaire, length of hospital stay, and quantitative assessment of single combination antihypertensive drug therapy. The maximum window of opportunity is considered to be the 52-week upper limit from onset of dissection for aortic plasticity because the lamella may become too rigid late in chronic dissection to allow for stent-induced aortic remodeling. Kaplan-Meier life table analysis showed a 5.1% risk of death at 12 months in the stent-graft treated group versus a historic mortality rate of 27.5% with conventional therapy. Additional secondary endpoints such as conversion to open or endovascular repair, or significant expansion of aortic diameter over time are investigated. Further evaluations include successful aortic remodeling, length of hospital stay, and quality of life. ●

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Getting Started With Thoracic Endografting

A cardiac surgeon's perspective on starting your practice.

BY H. EDWARD GARRETT, JR, MD

The medical and surgical treatment of disease is constantly evolving. Cardiothoracic surgeons have witnessed this evolution in the treatment of coronary artery disease with the advent of off-pump bypass surgery and coated coronary stents. Treatment of thoracic aortic pathology is experiencing the same kind of change.

WHY START?

Endovascular repair of thoracic aortic pathology began as an extension of endovascular abdominal aortic aneurysm (AAA) repair, but may offer more advantages to the patient. Although thoracic aortic aneurysms (TAAs) are less common than AAAs, the detection of thoracic aortic pathology is increasing, possibly due to an increased prevalence, the aging population, and the increased access of patients to sophisticated radiographic imaging.¹ The natural history of TAAs is progressive enlargement and rupture; more than 70% of untreated patients die within 5 years.² Surgical mortality for endovascular repair of thoracic aortic disease is 5% compared to 15% for open repair in selected patients.^{3,4} In addition, it is reasonable to assume that a large number of patients with thoracic aortic pathology who have been denied open surgical treatment because of their comorbidities would be candidates for less-invasive endovascular repair. It is conceivable that 50% of thoracic aortic pathology remains untreated by traditional means because of unacceptable morbidity and mortality rates. In a retrospective study by Brandt et al, endovascular repair was associated with a lower 30-day mortality rate and comparable morbidity in older patients with significant comorbidities compared to open surgery.⁵

Aortic endografting is a possible solution for a wide range of pathologic entities. Besides degenerative fusiform aneurysms, aortic endografting is applicable for treating saccular aneurysms, penetrating ulcers, intramural hematomas, aortobronchial fistulas, traumatic disruptions, other pseudoaneurysms, atheroemboli originating from the thoracic aorta, and some cases of acute and chronic aortic dissection (Figures 1, 2).

All physicians are challenged to master new information and learn new procedures that were developed after their residency. For cardiothoracic surgeons, the motivation to learn endovascular techniques encompasses more than aortic endografting. Future treatment of cardiac valvular disease may include an endovascular solution. Confirming the technical adequacy of coronary graft anastomoses requires endovascular skills. Hybrid procedures combining open and endovascular techniques might offer advantages for the treatment of both aortic and coronary pathology. Coronary artery stenting of the right and circumflex coronaries has been combined with minimally invasive and robotic internal thoracic artery to left anterior descending bypass. Extra-anatomic bypass of the arch branches has allowed more aggressive endovascular coverage of the aortic arch. Technological improvements may allow fenestrated grafts to cover the entire aortic arch with selective preservation of the arch branches.

HOW TO START?

How, then, do cardiac thoracic surgeons begin to learn endovascular techniques? The first requirement is a true



Figure 1. A 68-year-old man with saccular pseudoaneurysm at the site of previous open thoracic aortic repair (A). CTA after endovascular placement of thoracic stent graft and coil embolization confirms resolving pseudoaneurysm (B).

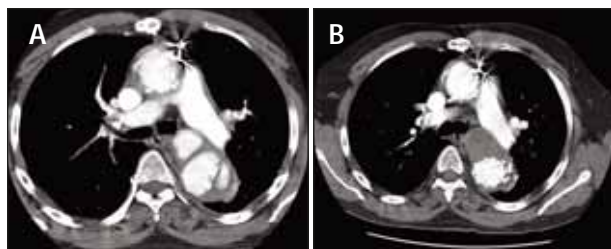


Figure 2. A 63-year-old man with chronic type B thoracic aortic dissection status post open repair of ascending and transverse aortic arch dissection. Preoperative CT shows two false lumens (A). CTA after endovascular placement of thoracic stent graft confirms thrombosis of false lumens (B).

commitment on the part of the thoracic surgeon. It is not reasonable to think that the endovascular interventionist can master an isolated procedure without understanding all aspects of endovascular techniques. When working around the aortic arch, a variety of guidewires and catheters may be necessary, depending on the patient's individual anatomy. Vascular access may be necessary through the femoral, iliac, brachial, or axillary vessels. It may also be helpful to snare a guidewire or perform a "body floss" maneuver to negotiate a tortuous aorta. Coil embolization may be indicated to eliminate the left subclavian artery as a source of endoleak. The endovascular specialist must know all of the available tools and understand their advantages and limitations to deal with the variations of human anatomy.

Time must be dedicated to attain the knowledge of new equipment, the appropriate applications, and new plans for dealing with complications. A new body of knowledge must be assimilated. It may be necessary to work on a simulator or animal model before proceeding in the clinical arena. The bottom line: quality of care cannot be compromised.

Opportunities to master endovascular techniques are varied. Mini-fellowships have been offered at facilities (eg, The Arizona Heart Institute) with sufficient volume and expertise to offer postgraduate training, requiring a time commitment of several months. Following the lead of the vascular surgeons, the Society of Thoracic Surgery plans to develop a directory of available opportunities. Groups of surgeons may choose to support a partner during a mini-fellowship who then can return to the practice as the designated endovascular specialist to mentor other members of the group.

Surgeons may choose to partner with other endovascular specialists who currently have endovascular privileges. The thoracic surgeon may have a bargaining position, such as referral of patients with thoracic aortic disease in exchange for participation in the procedure. The surgeon can provide

open arterial access for a nonsurgical interventionist, and thereby participate in the endovascular portion of the procedure.

Another option for gaining experience with endovascular techniques is to begin with simple procedures, such as central venous cannulation and insertion of pacemakers. In some settings, endovascular management of thrombosed dialysis grafts offers a low-risk introduction to the use of guidewires and catheters. Vanderbilt University has installed an endovascular suite in the operating room for the routine performance of completion cardiac catheterization after coronary artery bypass. Beginning with this type of endovascular procedure allows the surgeon to develop endovascular skills.

Industry is very willing to invest time and money in training surgeons who are committed to mastering endovascular skills through workshops and small group mentoring arrangements. Proctors are also available to assist with cases early in one's experience, particularly in the areas of thoracic and abdominal aortic endografting and carotid stenting.

In the long run, thoracic surgical residencies must provide sufficient training to allow future generations of graduating surgeons to be proficient endovascular specialists capable of obtaining appropriate hospital privileges. This ability will restore interest in the field among prospective students and will open tremendous opportunities in the job market.

CONCLUSION

Although some endovascular procedures are challenging, they are certainly not mysterious. A surgeon who can master the technical intricacies of cardiothoracic surgery can also master endovascular intervention with the appropriate investment of time and commitment. The future health of the specialty of cardiothoracic surgery may depend on its response to this new challenge. ●

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