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VISTA™ 2004

See Your Future From Here

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VISTA 2004: See Your Future From Here

The VISTA™ 2004 (Vascular Intervention Science, Technologies & Advances) meeting in Scottsdale, Arizona, gave vascular surgeons and other physicians specializing in endovascular interventions a first look at some of the most promising future advances in this rapidly evolving field.

Sponsored by Cook Incorporated (Bloomington, IN) as a medical education service, the VISTA meetings are designed to keep physicians aware of the very latest developments in interventional medicine from around the world. Featuring the world's foremost researchers and practitioners in interventional medicine discussing leading-edge endovascular technologies for treating vascular aneurysms and dissections, VISTA meetings are conducted in conjunction with major vascular medicine meetings and conferences. These research-focused meetings present invaluable techniques and data on next-generation technologies in interventional medicine. The articles in this supplement have been adapted from presentations given at VISTA 2004.

Fenestrated and Branch Aortic Stent Grafts

There is a role for fenestrated and branch aortic stent grafts in the treatment of difficult aortic aneurysms.

BY JOHN L. ANDERSON, FACS, FRACS

Aortic stent grafts have now been used in the treatment of aortic aneurysms for a period in excess of a decade. Many patients, however, may remain unsuitable for such techniques on the basis of nonfavorable aortic anatomy. Most commonly, this decision relates to the presence of a nonsuitable infrarenal aortic neck. Evidence has shown a higher incidence of type I proximal endoleak when established guidelines are disregarded, often leading to explantation of the stent and surgical conversion.

The introduction of fenestrated and branched stent grafts into clinical practice in 1997 has overcome many of the problems associated with an unsuitable proximal neck.[1,2] Such grafts allow use of the juxtarenal and transrenal segments of the aorta for proximal fixation and sealing. Appropriate placement of suitable fenestrations within the graft neck allows continued perfusion of renal and, where necessary, visceral vessels. To date, all treatments have been carried out with the Zenith (Cook Incorporated, Bloomington, IN) graft. The use of such devices is now wide-spread in Australia and has also been employed at several centers in Europe.

An increasing experience has led to relatively standard techniques of implantation with a significant degree of positive outcome. In particular, there has been a high incidence of success in relation to both target vessel revascularization and freedom from type I proximal endoleak.[1]

Improvements in graft design have expanded the clinical role of such devices, and many variations beyond simple fenestrations have now been employed to preserve targeted branch vessel perfusion. In some patients, this has included the use of branched aortic grafts (Figure 1A-C). To date, implanted vessels have included the renal, superior mesenteric, celiac, subclavian, and hypogastric arteries (Figure 2A-D).

GRAFT DESIGN AND DELIVERY

The key word in relation to design is *customization*—

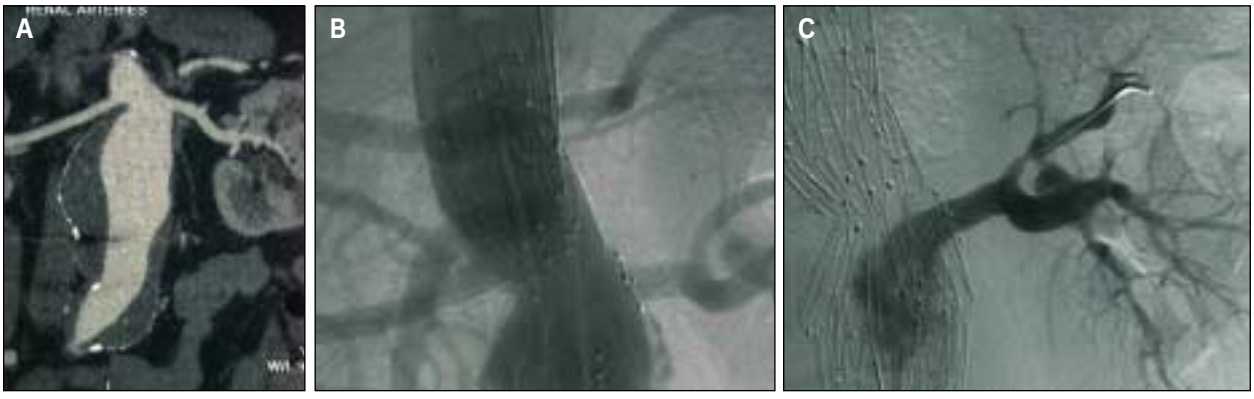

Figure 1. A 62-year-old man with ischemic heart disease, respiratory disease, and peripheral vascular disease presented with a large juxtarenal aortic aneurysm with an unfavorable neck due to length, shape, and angulation. Note that graft-to-wall contact is not possible in relation to the right renal artery (A). Treatment carried out with Zenith quadruple fenestrated graft. The vessels targeted for revascularization are the celiac, superior mesenteric artery, right renal, and left renal. Initial image after implantation shows an endoleak at the left renal (6 mm X 8 mm) fenestration (B). For the endoleak arising from the left renal artery, a Jomed (Beringen, Switzerland) stent graft was used (branched endograft) to achieve a satisfactory seal (C).

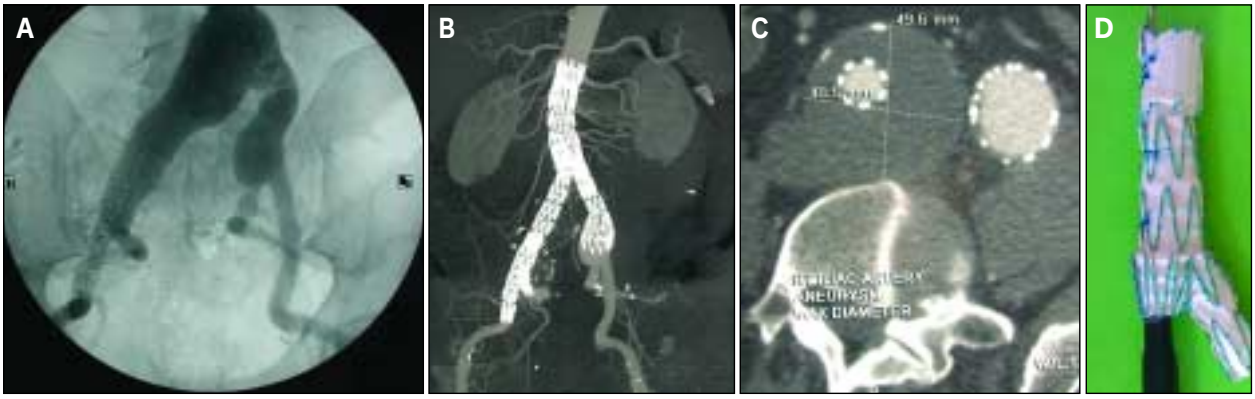

Figure 2. Angiography shows a large AAA along with a right common iliac artery aneurysm involving the hypogastric artery (A). A branched endograft was used to exclude the aneurysms while maintaining the hypogastric circulation (B). Follow-up CT scan shows complete exclusion of the right common iliac aneurysm with no endoleak (C). A branched endograft with a large flare for the contralateral limb was used in this case (D).

each graft being tailored for the individual patient. Such planning necessitates an adequate imaging work-up to fashion a graft that is both specific and accurate for the patient in question. This aside, the majority of grafts are more similar than dissimilar.

Initial grafts were bifurcated and modular in nature, in keeping with the majority of grafts used at that time in standard endoluminal repair. All current grafts are termed *composite*—the proximal graft component is tubular in nature and contains all of the fenestrations or branches. The use of a noncovered Gianturco proximal stent restrained by a cap, as in the standard Zenith, permits a controlled release of the graft from the delivery system, with subsequent accurate placement in relation to the renal and other vessels (Figure 3).

In essence, implantation of the fenestrated tube creates the ideal neck, allowing completion by placement of a bifurcated modular graft distal to the upper component.

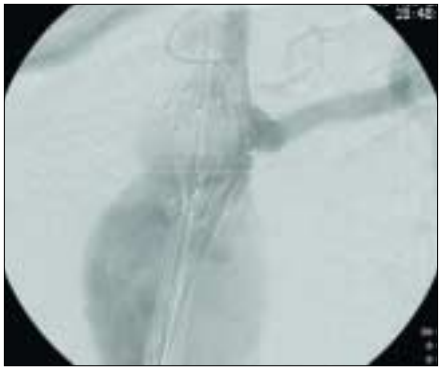

Figure 3. Partial release of the upper graft. Note the proximal cap remains in place. Graft rotation and longitudinal movement remains possible. Note the right renal fenestration markers are in a "diamond" configuration in keeping with the anterolateral position of the renal ostium. Markers for the left renal are largely tangential, in keeping with the 3-o'clock position of the renal orifice. This image was generated with 7 mL of contrast using a pressure injector.

FENESTRATION AND BRANCH TYPE

Fenestration types are classified as scallop, small fenestration, and large fenestration (Figure 4A-C). More recently, fenestrations have been improved by the incorporation of a nitinol circumferential ring that strengthens the edge, allowing for a more stable fixation when balloon-expandable stents are employed for accurate alignment of fenestration and vessel ostia.

Typically, small fenestrations, usually measuring 6 mm X 8 mm tend to be used for renal implantation and are always placed at the primary site of seal.

Large fenestrations are typically used for the superior mesenteric artery and celiac vessels and generally are not associated with the site of seal. If these vessels are relatively close to the renal arteries, it is easier to include them in the graft neck rather than to attempt their avoidance. The nature of the Gianturco stent has a large role in determining where fenestrations can be placed and also sets the transverse measurement of the fenestration.

To create a seal at the site of fenestration and vessel, it is paramount that there must be a secure contact between the fenestration and the vessel wall.

Balloon-expandable stents allowing extreme flaring of the luminal end are deployed to both align and fully open the area of fenestration-to-wall contact (Figure 5).

In cases in which fenestration-to-wall contact is not possible, use of a short branch may be indicated to span the gap. Any remaining gap between the branch and targeted vessel may be breached by a suitable covered stent (Figures 1B and 6).

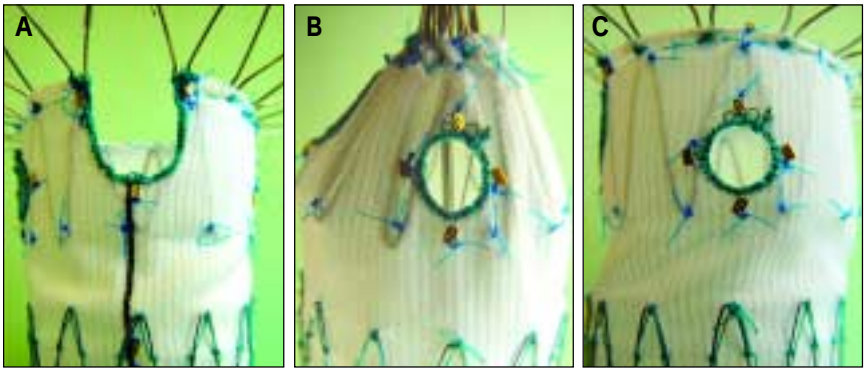

Figure 4. A scallop in the open position. Typically, this is used to provide continued perfusion of the celiac or superior mesenteric artery (A). A small fenestration in the proximal covered stent. At this stage, the proximal noncovered stent is contained within the proximal cap of the delivery system. This is the state in which the fenestration is catheterized during implantation (B). A small fenestration in the open position. Typically, this type of fenestration is used for renal artery perfusion (C).

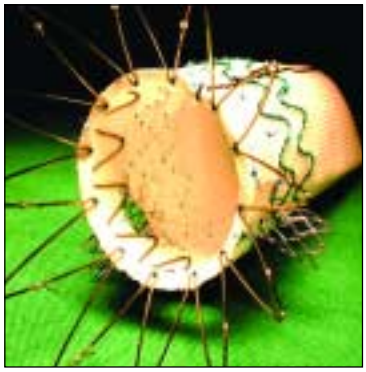

Figure 5. This image shows a bench model with the stents *in situ*. Note that the stents do not protrude into the lumen.

INDICATIONS FOR FENESTRATED AND BRANCHED GRAFTS

1. Unsuitable proximal neck.
2. Late or early failure of previous surgically implanted aortic graft (Figure 7A and B).
3. Early or late failure of previous endoluminal aortic graft.
4. Preservation of hypogastric artery flow.

DEPLOYMENT TECHNIQUE

To achieve accurate alignment of targeted vessels, adequate positioning both in a longitudinal and rotational aspect is mandatory. For this reason, additional graft markers are placed on the graft to achieve precise rotational positioning. All fenestrations have radiopaque markers positioned at the 12-, 3-, 6-, and 9-o'clock sites around the circumference of the fenestration.

When adequate alignment is achieved, controlled release of the graft is carried out. During release from the sheath, full expansion of the graft diameter is prevented by use of diameter-reducing ties held in place by an appropriate trigger wire. In this way, some adjustment or rotation is still possible after the graft is delivered from the sheath. The upper graft remains closed due to the presence of the distal cap, which restrains the upper noncovered stent.

Using a contralateral groin approach, the lumen of the composite component is catheterized from below.

Figure 6. Use of a short branch is indicated in cases in which wall contact is not possible.

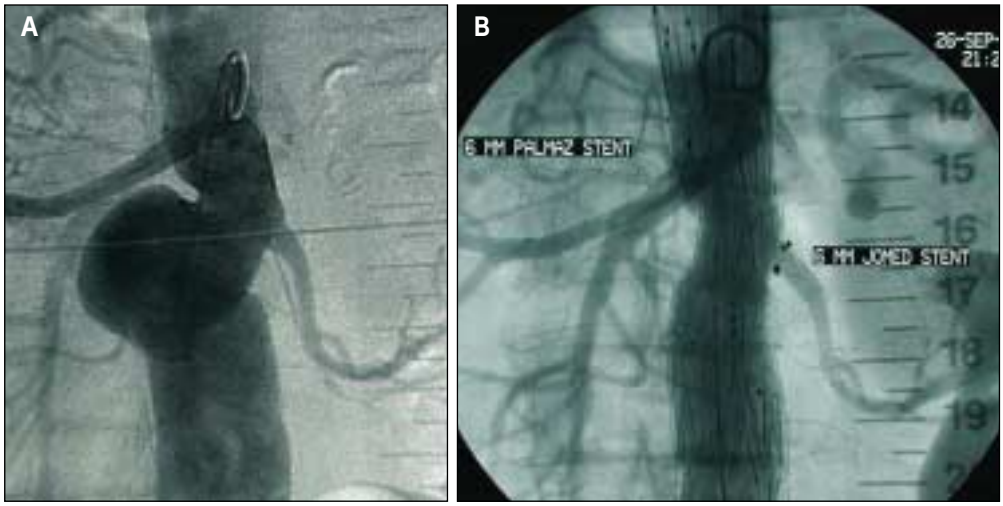

Figure 7. A false aneurysm noted 1 year after surgical repair for rupture. Wall contact with the renal artery on the left is not possible (A). Use of a body short branch with covered stent extension (Jomed) after angiography shows complete exclusion of the false aneurysm (B).

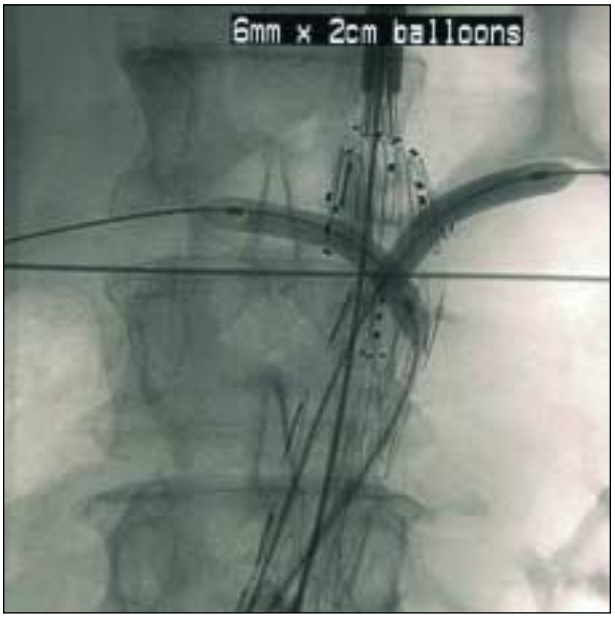

Figure 8. Balloons are placed in both renal vessels and inflated to a pressure of 2 to 4 atm prior to the release of the graft. With the balloons in place, the diameter-reducing tie and the proximal cap are released. With expansion of the graft, the fenestrations can only travel along the balloon rail onto the targeted vessel ostia, thereby creating a good alignment between the targeted vessel ostia and the fenestration.

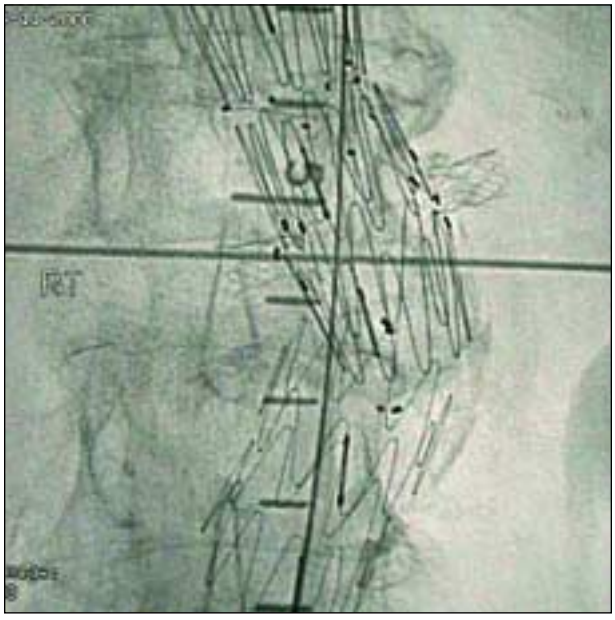

Figure 9. Graft-to-renal stenting using noncovered stents has been performed to maintain patency of the renal arteries.

Catheterization of the targeted vessels is then carried out from within the lumen of the graft. Appropriate angioplasty balloons are placed in the renal vessels to act as a balloon rail during release of both the diameter-reducing ties and the upper cap (Figure 8). In this way, with complete graft expansion, the fenestrations travel along the balloons to the vessel ostia. These balloons are then withdrawn leaving the guidewires in place. Graft-to-vessel stenting using noncovered stents is then carried out in relation to the targeted vessels. The stents are typically 18 to 20 mm in length and are placed two-thirds within the vessel and one-third within the aortic lumen (Figure 9). The stent diameter is sized to the target artery.

Flaring of the luminal component of the stent is then carried out to flatten it against the graft-aortic wall, allowing for subsequent recatheterization of the renal vessels at a later date should it become necessary. The procedure is completed with placement of the inferior bifurcated modular component.

RESULTS

To date, 50 patients have been treated by this technique. There have been no aneurysm-associated deaths and no conversions to open repair. One graft developed an endoleak at the fenestration site 1 year after implantation and was readily corrected by use of a balloon-expandable stent graft placed through the fenestration. Subsequent follow-up imaging has shown continued shrinkage of the aneurysm sac.

CONCLUSION

Fenestrated stent grafting of the abdominal aorta is an alternate to open surgical repair in the presence of an unsuitable proximal infrarenal aortic neck. It can be performed with safety and efficiency and may also be used to salvage later failure of previous open or endoluminal treatments of the aorta. The introduction of branched grafts has allowed treatment of aneurysms in which fenestration-to-wall contact has not been possible. Variations of these techniques have allowed preservation of hypogastric artery flow in suitable cases. ●

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This article has been adapted from Dr. Anderson's presentation at the VISTA Symposium in Scottsdale, Arizona.

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The Future of Branch Vessel AAA Endovascular Grafting

Previous anatomic limitations to endografting are becoming more flexible and forgiving, allowing for minimally invasive therapy independent of proximal neck anatomy.

BY ROY K. GREENBERG, MD

Anatomic exclusion criteria, such as short proximal neck lengths and inability to preserve hypogastric flow, have precluded endovascular repair in a significant percentage of patients. Furthermore, the treatment of thoracoabdominal and arch aneurysms with less-invasive approaches has the potential to dramatically diminish the morbidity associated with conventional therapy. These issues have been confronted by many innovators, and several methods of incorporating aortic branches have been described.

BACKGROUND

Fenestrated grafting was originally described by Browne et al,[1] followed by larger series reported by Anderson et al,[2] Stanley et al,[3] and Greenberg et al.[4,5] The technique is useful for patients with juxtarenal, and some pararenal, aneurysms that abut the visceral vessels but have a segment of normal perirenal aortic neck. The technique currently requires a customized design with a proximal tubular component that includes a number of fenestrations of a variety of sizes and configurations designed to incorporate the visceral segment, extending the fixation to the supraceliac aorta, and the sealing zone to the perirenal aorta. These devices are not intended to treat aneurysms that truly involve the aortic branches, but simply the aneurysms that approach them. The concept of sealing within the branch vessel as opposed to sealing within the aorta proper is fundamental to this distinction. Branch grafts seal within aortic branches, whereas fenestrated devices require sealing to occur within the aorta.

EARLY DESIGNS

Early experience with branched devices has been pioneered by Anderson et al,[2] Chuter,[6,7] and Marin. Although the technique employed by Anderson closely resembles fenestrated endovascular grafting, it requires an intact seal between a balloon-expandable stent graft and the fenestration itself. This is now accomplished by the addition of a nitinol ring designed to reinforce the fenestration and allow a balloon-expandable stent graft to expand, much like an hourglass, proximal and distal to the nitinol ring. Dr. Chuter's concept uses a primary device with a number of tubular columns that are then separately accessed and mated with another stent graft (balloon-expandable or self-expanding) that extends into the desired branches. We recently proposed the use of a third design that is based on the desire to have modular branch grafts, a tromboning overlap region with reliable access to the branch vessels utilizing a branch that wraps in a helical manner with a defined pitch around a base device. Although none of the techniques used today can be described as simple in nature, all have achieved technical success and continue to undergo early investigational studies.

CHALLENGES

There are several challenges that must be addressed when

Figure 1. Migration of an endovascular device is multifactorial. Although the risk of migration is primarily dependent upon the balance between the hemodynamic displacement forces and the strength of the device fixation system, there are several other components. For example, aortic degeneration in the region of the device fixation system, fixation system material fatigue, morphologic changes within the aneurysm sac resulting in increased angulation, and the closer the device proximity is to the aortic valve all increase the risk of device migration.

contemplating the extension of endovascular aneurysm repair into aortic branches. Fundamentally, the implants must be capable of excluding the aneurysm, preventing rupture, maintaining patent branches, and being deliverable. Furthermore, any migration of the main device would be considered unacceptable (because the branches may kink), and the multitude of modular joints would have to remain stable. Delivery systems by definition become more complex and require the involved interventionists not only to be proficient with endovascular grafting, but also the interventional management of the aortic branches, such as the renal, mesenteric, and carotid arteries. Finally, these challenges must be addressed, realizing that we still do not have an ideal infrarenal device. All of the available infrarenal endovascular prostheses are still plagued by late failures, migration, and the need for secondary procedures and intense follow-up.[8] Additionally, there are no well-studied, commercially available, small-vessel stent grafts.

The incorporation of additional branches (beyond the two common iliac arteries) into a given device will have implications to the global stability and function of that device beyond what is normally encountered after infrarenal aneurysm repair. Device stability within the aortic vasculature can be considered to be a balance between device-stabilizing forces (the fixation systems) and displacement forces. When the displacement forces exceed the stabilization forces, migration occurs. This is undesirable. Although migration is multifactorial (Figure 1),[9] it relates most closely to hemodynamic factors (the downward force of blood), fixation system durability (fatigue), morphologic aortic changes that alter the device configuration, and the proximity to the aortic valve.

Hemodynamic forces affect devices most significantly in the presence of cross-sectional area reductions or when significant amounts of blood flow are redirected away from the centerline of aortic flow. Both of these conditions are present in all branched graft designs and thus must be carefully considered when designing and implanting such devices. Ultimately, the fate of a prosthesis with displacement forces in excess of stabilization forces will be migration of the proximal fixation system, distal fixation system, or disruption of the modular joints (component separation).

Because of the complexity of device designs, as well as the inherent risk of branch complications, we elected to begin our studies with the internal iliac arteries. This arterial bed is easily accessed surgically if necessary, and many investigators have advocated occlusion of these branches.[10] The latter (internal iliac artery occlusion) would be the result of a failed branch graft. Conceptually, this technique involves a double bifurcation approach. The first bifurcation incorporates both common iliac arteries into the repair, whereas the second bifurcation relates to the internal iliac arteries. The additional redirection of blood flow from the lumen of the endoprosthesis into the internal iliac circulation will create additional hemodynamic forces that must be accounted for (Figure 2). These forces are most likely transmitted proximally to the modular joint between the components. If this joint remains stable, a portion of the forces is then transmitted to the proximal fixation system. For this reason, the joints and fixation systems must be capable of withstanding the calculated displacement forces.

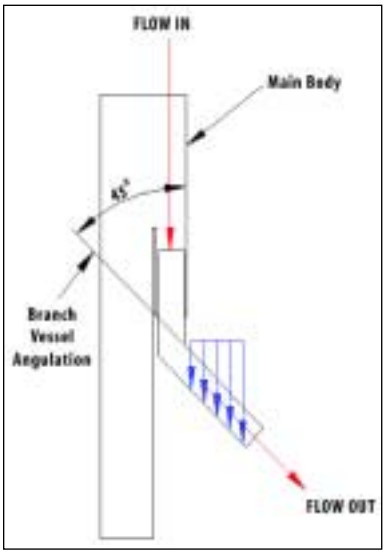

Figure 2. This diagram depicts a bifurcated endovascular graft with a single modular joint. The fundamental hemodynamic forces (red arrows) traverse the device. The displacement force on the device is dependent upon cross-section area reduction, as well as redirection of blood flow. The example depicted has an angulated limb that is joined in a modular fashion to the main device. The downward force on the modular limb (blue arrows) can strain the modular joint, or in the setting of a stable modular joint, be transmitted to the proximal fixation system. The greater the cross-sectional area reduction is and the more redirection of blood flow that occurs within a prosthesis, the greater the risk will be for either component separation or fixation system migration.

DESIGN ADVANCEMENTS

Component separation has been noted to occur with many devices; however, no specific analyzes have indicated why. In our experience, the vast majority of component separations have occurred after inadequate overlap between the device components and angulation, or after the placement of devices that were improperly sized (ie, the iliac limb joint resides within the mid or proximal aneurysm). In fact, using a mechanical testing apparatus, the pull-apart forces for each device's modular components can be tested in a pressurized setting at physiologic temperatures. It is abundantly clear that the greater the length of overlap, the greater the stability of the joint. However, limitations exist for each device in how much overlap can be safely achieved while still covering the distal aortoiliac circulation. Consequently, overlap

Figure 3. This diagram illustrates the helical wrap design for a branch-vessel device. The primary component has a limb that wraps around the tubular body at a given pitch such that it is appropriately oriented to the desired branch vessel. This is mated with a second stent graft (blue device) that can be tromboned into the helically wrapped limb and extend a variable distance into the desired branch.

lengths and modular joint designs will be critical to successful branch vessel endografting. In fact, using computational fluid dynamic modeling, displacement forces can be estimated and optimal designs theorized in a manner to minimize the generation of such forces and allow blood flow conditions to most closely approximate normal physiologic conditions. These techniques were employed during the development of the helical hypogastric device to define the pitch of the branch wrap and geometry of the branch orifice from the main portion of the prosthesis (Figure 3).

The device is designed to mate with a conventional Zenith device (Cook Incorporated, Bloomington, IN), and it is intended to be used when the preservation of pelvic blood flow is desirable. It is packaged with a catheter and wire preloaded through the branch to allow access from the contralateral femoral artery or a brachial approach for the introduction of the mating component. Preclinical testing has established that the joint strength of several mating stents is acceptable. Most frequently, this device has been employed in conjunction with a Viabahn graft (WL Gore & Associates, Flagstaff, AZ). The main device is inserted, oriented, and the proximal graft material is exposed. The preloaded access to the branch limb is utilized and a Balkin sheath (Cook) is placed within the branch. Steerable catheter guidewire combinations are used through the Balkin sheath to access the intended branch. Because the main device remains attached to the delivery system in a manner similar to the Zenith device, it may be repositioned longitudinally or rotated to properly access the branch vessel. Once access into the branch is established, the remainder of the main device is deployed, and the mating stent graft is deployed into the branch and overlap segment. The maintenance of a region of overlap allows for tromboning of the mating device such that position within the branch can be customized so as not to occlude early bifurcations. This method of placement is possible with conventional Zenith devices, as well as fenestrated endovascular devices (Figure 4).

SHORT HISTORY, BRIGHT FUTURE

It is interesting to consider the short history of endovascular grafting. What was initially considered a complex therapy to be reserved for a few patients who were incapable of

Figure 4. The helical branch is imaged after implantation into a hypogastric artery in a patient who presented with an aortic aneurysm in conjunction with bilateral common iliac aneurysms. The single white arrow depicts the artifact created by coils used to embolize one of the internal iliac arteries, whereas the double arrow denotes the patent hypogastric artery that was reconstructed with a Zenith device combined with a helical branch device in conjunction with a Viabahn device.

tolerating an open surgical repair has become commonplace therapy that is offered to most patients with acceptable anatomy—an amazing accomplishment. Despite the shortcomings of conventional devices, endovascular AAA repair has prospered and is now a critical part of our practices. The current anatomic contraindications are in a state of flux. As fenestrated repair is disseminated, the importance of the proximal neck length will no longer sway us away from a less-invasive approach. Similarly, the ability to maintain hypogastric flow will eliminate the need for an open approach for individuals with complex iliac aneurysms. Ultimately, branch vessel grafting in conjunction with other techniques used to address aortic pathology has the potential to relegate open aortic procedures historic while diminishing the invasiveness, morbidity, and hopefully the mortality associated with a devastating disease. ●

Roy K. Greenberg, MD, is Director of Endovascular Research, The Cleveland Clinic Foundation, Cleveland, Ohio. He had disclosed that he receives research funding from Cook and W.L. Gore; he receives consultant fees for speaking from Cook, and he receives royalties for patents licensed to Cook. Dr. Greenberg may be reached at (216) 445-5306; greenbr@ccf.org.

This article has been adapted from Dr. Greenberg's presentation at the VISTA Symposium in Scottsdale, Arizona.

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Ascending Thoracic Aortic Endovascular Grafting

An evolving technology may hold the solution to the difficulties involved in endovascular repair of this challenging region.

BY TIMOTHY A.M. CHUTER, MD, AND MICHAEL D. DAKE, MD

The ascending thoracic aorta is a challenging location for endovascular reconstruction. The aorta is wide and curved; the flow rate is high; and the downstream arteries include an organ, the brain, which has no tolerance for ischemia. Consequently, there has been only a handful of cases, despite the obvious advantages of avoiding open surgery.

Our first case was a very sick man with a pseudoaneurysm on the underside of the aortic arch. He also had severe cardiac and pulmonary disease, and the cardiac surgeons had declined to operate again on the grounds that his chance of survival was low. Unbranched endovascular exclusion of this area could not have been accomplished without occluding flow to all of the arch vessels.

As it happened, we had already been working on the development of a branched stent graft (Figure 1) for deployment in the aortic arch. We had a rubber model with a pulsatile perfusion pump hooked into its proximal and distal ends, as well as valved access to each of the arch vessels. It was a reasonably realistic version of normal anatomy because it was based on a regular CT scan.

THE DESIGN

We had several prototypes (Figure 2) that reflected our efforts in other areas of the arterial tree, in which the main aortic stent graft has little stumps for modular extensions to the branch vessels of the area. Version A did not work because the graft wanted to straighten, and the little stumps were crushed against the outer curvature of the outer aorta. Our next attempt (Version B) used a funnel-shaped arrangement to improve access to the stumps, and it actually worked for the first couple of stumps, but then the region became very crowded, and it was difficult to access the third stump. To get more space, we moved the stumps down inside a two-layered stent graft (Version C). The outer surface sealed with the ascending aorta, and the inner surface had multiple lumens to seal with the modular branches.

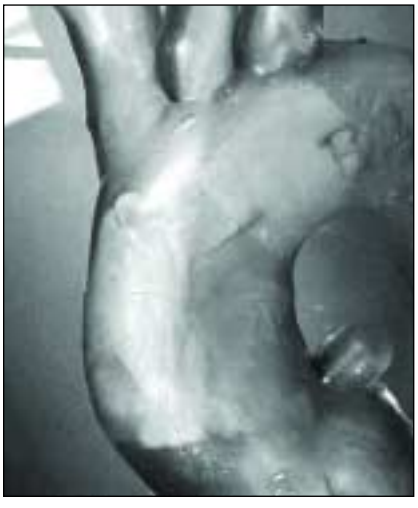

Figure 1. A reasonably realistic rubber version of normal aortic arch anatomy.

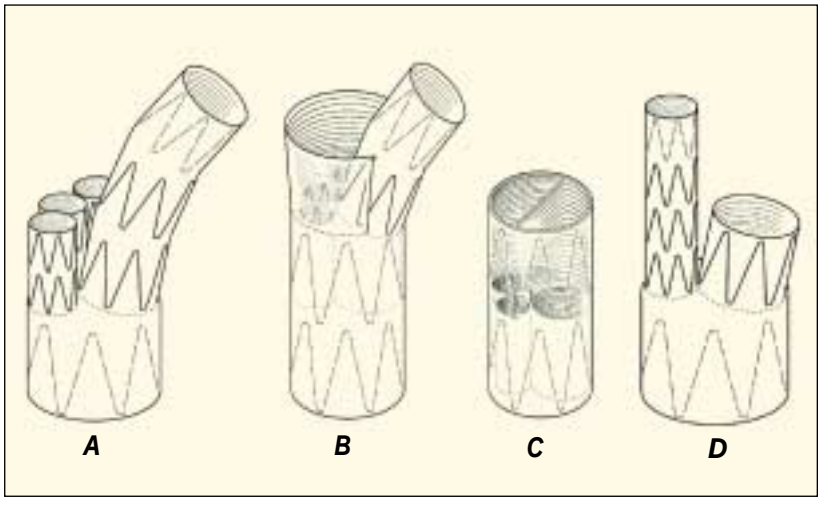

Figure 2. Prototypes of aortic arch stent grafts, Versions A through D.

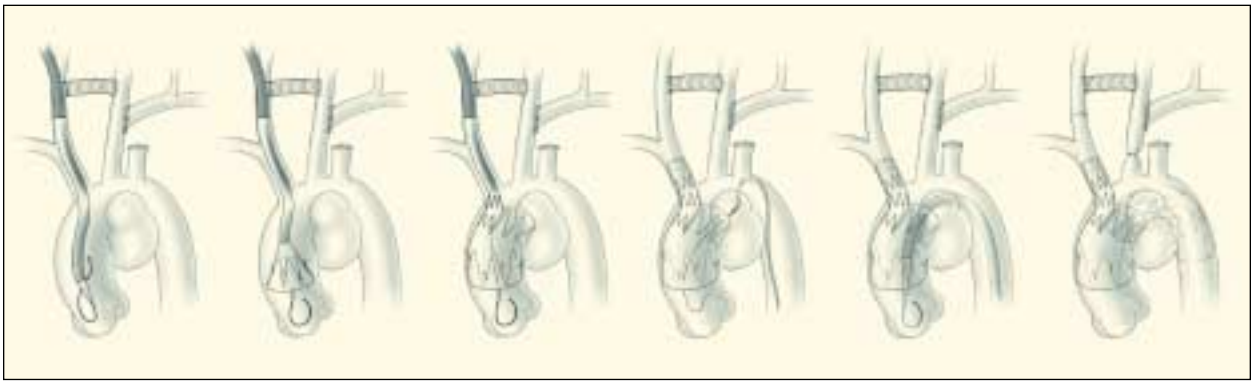

Figure 3. A schematic of the stent graft deployment procedure.

This version worked for all three branches, but it was complicated to make and too thick-walled. We concluded that we needed to come up with something more simple. To do so, we switched to a completely different approach. Our final prototype (Version D) was just like an upside down version of the original long-leg/short-leg abdominal aortic stent graft. This stent graft was inserted through the right carotid artery so the long leg would end up in the innominate artery, and the short, fat leg would end up in the aorta. The only additional endovascular component was a bridging component from the short, wide stump to the descending thoracic aorta.

Figure 4. Postoperative CT.

For clinical use, this system of stent grafts had to be combined with extra-anatomic bypasses to distribute innominate flow to the left side of the head and the left arm. Because the transcarotid route of insertion is relatively straight, the sheath was easy to insert over a short-tip dilator, and the stent graft was easy to rotate into the proper orientation. Stent graft deployment was accomplished by sheath withdrawal during a short period of adenosine-induced cardiac arrest, leaving the short limb in the innominate artery and the short, wide stump in the aorta. The short, wide stump then served as the proximal implantation site for a typical endovascular TAAA repair. The last step was to ligate the left subclavian artery and to prevent retrograde flow into the aorta (Figure 3).

ANTICIPATING POTENTIAL COMPLICATIONS

The patient in Figure 4 is approximately 8 months out from operation now, and he is back fixing cars. However, fluoroscopy shows the stent graft bouncing back and forth with every heart beat. It really is quite a mobile object, and its branch is subject to some fairly hefty hemodynamic forces, so you have to wonder about the durability of this approach. We have analyzed these forces using computational models to get a sense of how they affect stent graft movement and identify likely failure modes as the basis for future design changes.

AORTIC DISSECTION

We recognize that an aneurysm involving the aortic arch is a relatively rare disease. The most common disease of the ascending aorta is a type A dissection. When cardiac surgeons treat these dissections, they do so

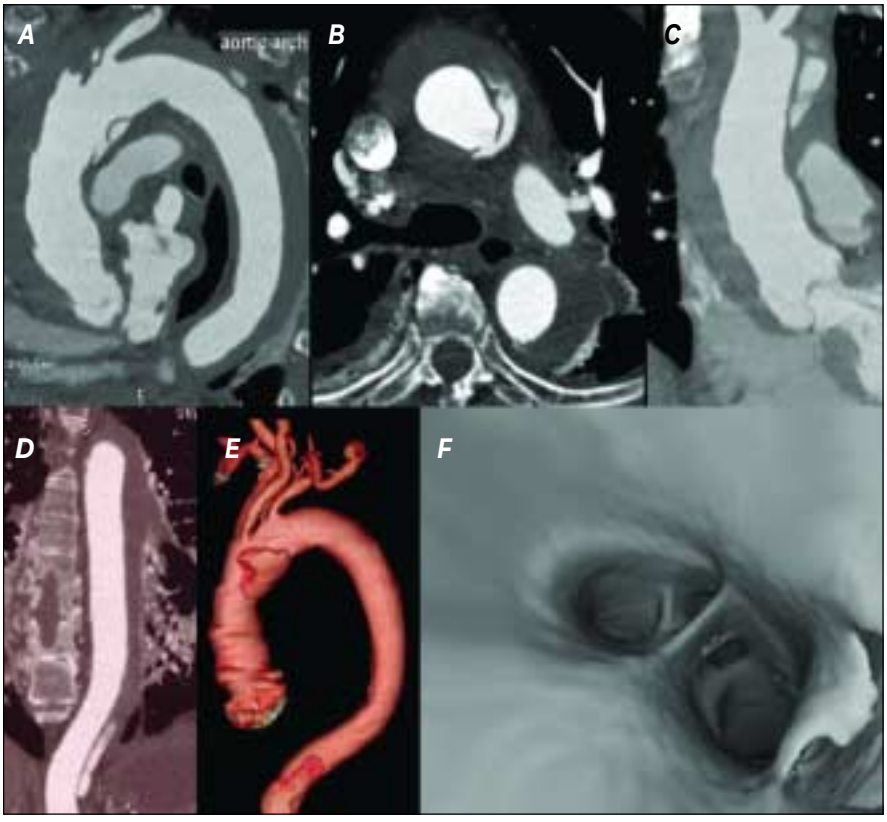

Figure 5. Three-dimensional CT reconstructions showing the location of a dissection, or pseudoaneurysm, just proximal to the origin of the innominate artery.

under hypothermic circulatory arrest. Even in the best hands, the mortality rates are reasonable, but the morbidity rates are high. Besides, I doubt anybody comes out of this procedure as smart as when they went in.

Obviously, if the dissection has already disrupted the aortic valve or compromised coronary flow, endovascular repair is not going to work. But, the stent graft is certainly capable of covering a hole in the intima. The endovascular technique might also play a role in treating some of the chronic complications of surgical repair, such as arch aneurysm.

In the case of type A dissection, a nonbranched reconstruction to the ascending aorta might be significantly easier and more stable.

The patient in Figure 5A through F presented to Stanford Medical Center with chest pain; CT scans showed the evolution from intramural hematoma to localized dissection. 3-D reconstructed CT scans demonstrated that the intimal tear was proximal to the take off of the arch vessels. The patient progressed rapidly, and her symptoms worsened. Using a femoral approach, the team at Stanford deployed a stent graft right on the sinotubular ridge, preserving flow to the left coronary. These reconstructions show that the placement was very precise and effective.

CONCLUSION

There is a risk of stroke with any endovascular procedure involving these segments of the proximal aorta. We need to keep the endovascular part of the intervention simple, quick, and clean. The question is: Do we have the necessary technology? I would respond with a qualified "Yes." The technology exists, but there are some obvious areas for improvement.

Simple bifurcated stent grafts can be combined with extra-anatomic reconstruction to treat aneurysms of the aortic arch. Even simpler unbranched stent grafts can be inserted into the ascending aorta to treat dissections. A low-profile stent graft and flexible delivery system would help, and Cook Incorporated (Bloomington, IN) is well along with development programs in both areas. In the meantime, transcarotid stent graft delivery allows access to the ascending aorta, but any sheath larger than 20 F blocks right carotid flow and requires either an extra-anatomic bypass or a system of connected sheaths to act as a shunt around the occlusion. Nevertheless, endovascular treatment offers enormous advantages over surgery under hypothermic circulatory arrest. I think endovascular treatment of the ascending aorta could well be the next big thing. ●

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This article has been adapted from Dr. Chuter's presentation at the VISTA Symposium in Scottsdale, Arizona.

Endovascular Iliac Bifurcation Grafting

Facing the challenge of an increasing number of patients with aortic aneurysms and difficult iliac and hypogastric anatomies, we designed this modification to an existing device.

BY WOLF J. STELTER, MD

We are currently seeing an increase in the number of patients presenting with both aortic aneurysms and enlarged iliac arteries. With the first generation of grafts, such patients were not operable because we did not have adequate iliac extensions. Previously, we treated patients with very large iliac arteries using a bell-bottom-shaped extension, but we were often not satisfied with the result (Figure 1). The alternative for excessively large or tortuous iliacs was to occlude the hypogastric and overstent the internal iliacs, proceeding straight through to the external iliac. Additionally, in our experience, patients who had occluded internal iliac arteries also presented with claudication. The few patients who did not have claudication were often sitting in a wheelchair due to heart failure. For these reasons, we attempted to find a means of preserving the hypogastric artery, if possible, and have designed a stent bifurcation that we believe could be easily introduced into the iliac bifurcation.

ACCOMMODATING THE ILIAC AND HYPOGASTRIC ANATOMIES

We had previously gained experience using a composite graft for aortic aneurysms; the distal part of this device has a little stump for the contralateral iliac artery. This component could be easily and successfully pulled into the iliac artery, so we figured we would do the same for the iliac bifurcation. In this example, the bifurcation in Figure 2A was pulled in a retrograde fashion into the hypogastric artery and opened. In Figure 2B, it is not yet fully opened; restriction ties keep the component from opening prematurely. Figure 3 shows the bifurcated stent graft pulled into the aortic bifurcation, after which the proximal stent graft was deployed at

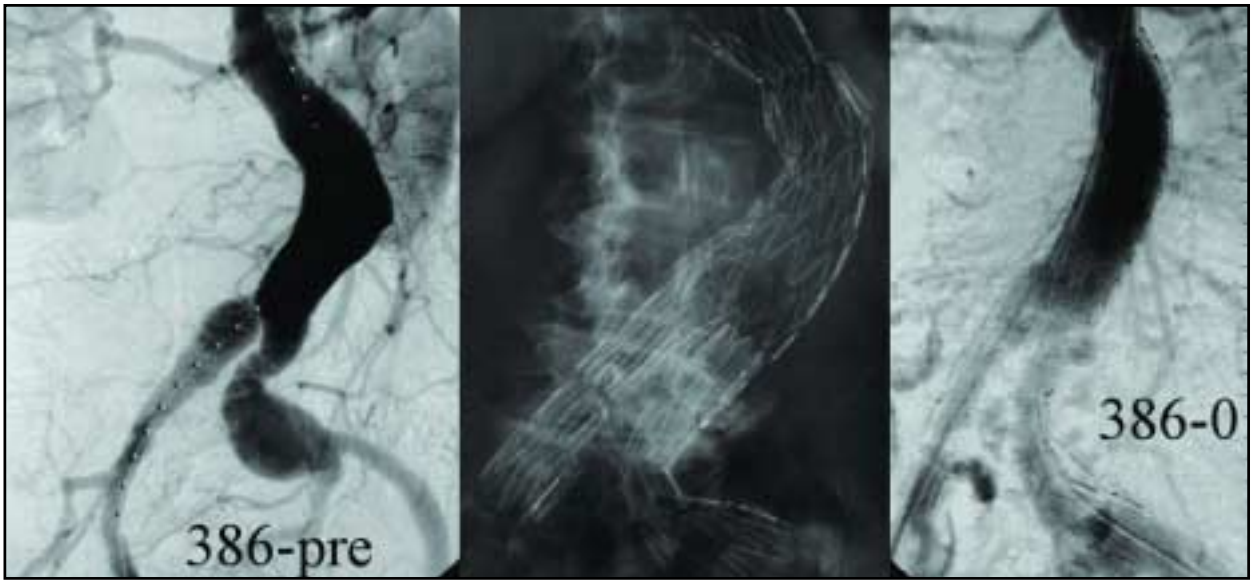

Figure 1. Treatment of large iliac arteries using a bell-bottom-shaped extension.

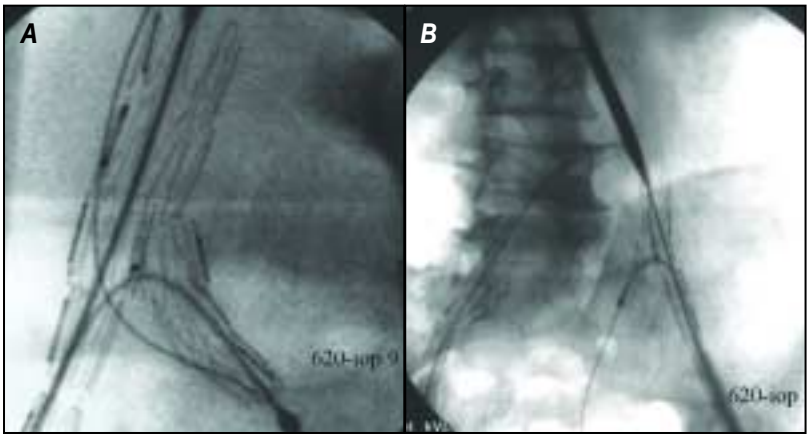

Figure 2. A bifurcation pulled in a retrograde fashion into the hypogastric and opened (A); the graft yet not fully opened (B). Restriction ties keep the component from opening prematurely.

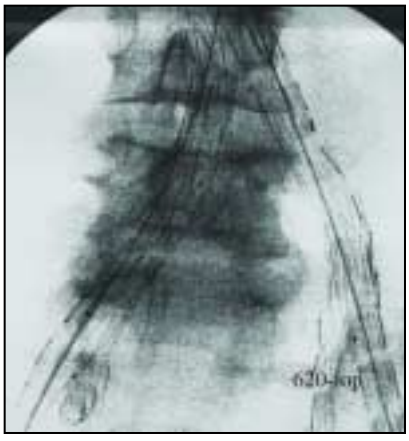

Figure 3. The bifurcated stent graft pulled into the aortic bifurcation, after which it was finally completed up to the renal arteries.

the level of the lowest renal artery. This device can also be used in conjunction with fenestrated grafts, as is illustrated in Figure 4. It is important to note that the examples are all nice iliac bifurcations with a relatively shallow angle.

DIFFICULTIES AND FAILURES

Our attempts with this design have not all been successful. In one case, we encountered a very tortuous iliac that could not be straightened by the wire and was not as easily manipulated. In cases during which we failed in this region, however, we simply pushed the graft up into the aortic sac. In another case, we successfully inserted two iliac bifurcations, but deployed the aortic segment much too high. The entire device had to be moved.

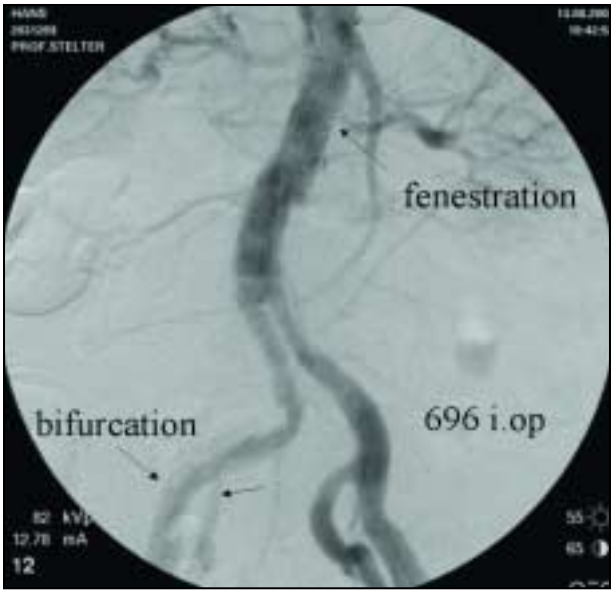

Figure 4. This device can also be used in conjunction with fenestrated grafts.

SUMMARY OF OUR EXPERIENCE

Twenty-seven iliac aneurysms in 21 patients resulted in eight hypogastric arteries becoming occluded. In two cases, the device did not work, and we had to convert the patients to surgery. These were young patients, and we wanted to avoid a femoral-femoral bypass, which should be a second choice for such situations. Only when the cases are not operable will we perform a femoral-femoral bypass. The conversion to surgery is not a satisfactory result. In the meantime, however, we have learned which patients are candidates for this bifurcation graft. Consequently, with better patient selection, I would predict approximately 80% to 90% success with this simple graft, which can be implanted in about 10 minutes. However, this is not satisfactory for all patients. In my opinion, use of a fixed sidearm is not the ideal solution, and modifications such as the modular bifurcation component described herein must be explored. ●

Wolf J. Stelter, MD, is from Frankfurt Hospital, Frankfurt, Germany. He has not disclosed a financial interest in any product or manufacturer mentioned herein. Dr. Stelter may be reached at Wolfstelter@gmy.de.

This article has been adapted from Dr. Stelter's presentation at the VISTA Symposium in Scottsdale, Arizona.

Descending Thoracic Endovascular Grafting Into 2005

A personal wish list for an ideal thoracic stent graft.

BY KRASSI IVANCEV, MD

Endovascular aneurysm repair (EVAR) using stent grafts for various conditions in the descending thoracic aorta is currently well accepted. However, the indications for EVAR are numerous and vary considerably, including focal lesions such as penetrating ulcers, traumatic transections, and limited atherosclerotic aneurysms, as well as extensive fusiform atherosclerotic aneurysms and type B dissections that may be complicated by acute perforation, end-organ ischemia, or a development of false-lumen aneurysms. Accordingly, the requirements of the stent grafts are also highly variable, as the stent grafts are placed in the straight portion of the descending aorta, or in the highly tortuous parts of the descending aorta, such as the aortic arch, or further in a compressed true lumen in a complicated type B dissection. All of these features, which are specific for the descending thoracic aorta and its lesions, impose requirements different from those used for stent grafts for EVAR of abdominal aortic aneurysms. This article provides a description of the various problems encountered during the use of thoracic stent grafts and suggestions for improvements of the stent graft design.

ACCESS DIFFICULTIES

Currently available thoracic stent grafts are delivered through 20-F to 24-F inner diameter introducer sheaths; this in turn implies that the outer diameter is even larger (adding an additional 2 F). Considering that 3 F is equivalent to 1 mm, introducer sheaths with outer diameters of 7 mm to 9 mm are occasionally too large to be passed through the pelvic arteries of patients without causing vessel injury.[1,2] The injuries may vary from dissection to the most dreaded one—a total disruption of the vessel. These large delivery systems are currently required for the delivery of the large thoracic stent grafts, which range in diameter from 34 mm to 44 mm. The risk for pelvic artery injury and disruption is highest in women because of the inherently smaller iliac arteries that may be calcified and stenotic. Specifically, this is true in acute situations of complicated type B dissections, when there is no time for elective planning. Otherwise, if necessary, large delivery systems can be deployed either from the common iliac artery, preferably on the left side, or from the distal abdominal aorta through a retroperitoneal approach.

To minimize the risk of injury to the pelvic arteries, it would be ideal to decrease the diameter of the delivery system to a maximum outer diameter of 22 F (7 mm). This may be achieved by decreasing the thickness of the graft fabric and metal components (the stents) of the

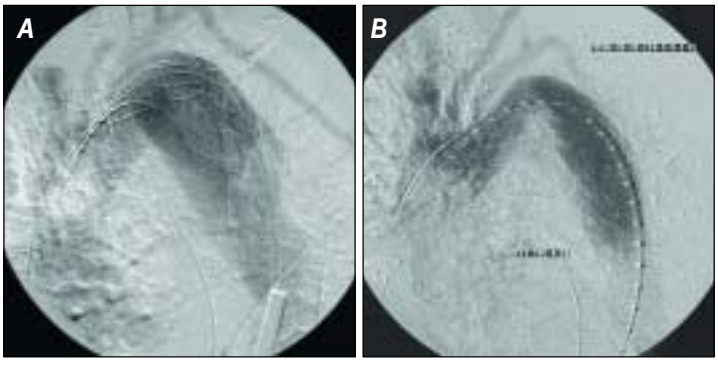

Figure 1. A 73-year-old man with type B dissection complicated by bowel ischemia. The arch is severely angulated, which has contributed to poor placement of the first stent graft, which has folded on itself (A). A second stent graft covers the origin of the left subclavian artery and partially the origin of the left common carotid artery. The primary entry is closed (B).

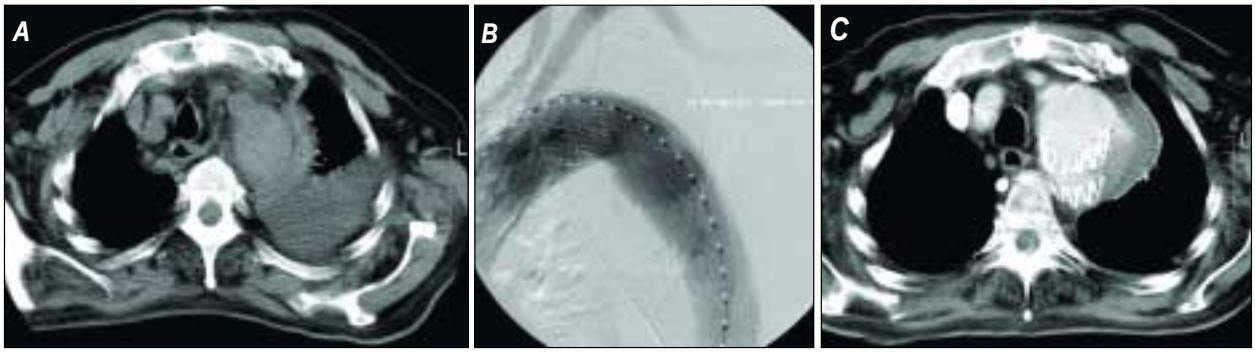

Figure 2. A 78-year-old man with type A dissection treated with open surgical repair 1 month earlier presents with contained rupture from a type B dissection (A). A stent graft placed immediately below the origin of the left subclavian artery closed the primary entry (B). Three months later, the stent graft caused erosion with recurrent contained rupture (C), which was fatal.

stent graft. However, by doing so, the stability of the stent graft, its fixation, and its durability may be jeopardized. Another approach would be to squeeze the stent graft to a maximum with an external "jacket," bringing the stent graft into the aorta and the aortic arch without the need for a protective delivery system. The use of an introducer would then be limited to gaining access into the femoral artery. The best example of such a technology that is currently available is the latest version of the Gore Excluder device (WL Gore & Associates, Flagstaff, AZ).

DEPLOYMENT DIFFICULTIES

It is extremely difficult to deploy a stent graft with a precision of less than 1 mm in the aortic arch. This may be explained by the tortuosity of the aortic arch, but also by the fact that current rigid stent graft delivery systems not only stretch the aortic arch but also tend to deliver the stent graft in the inner curve of the arch rather than along its centerline. This occurrence is further worsened if the stent graft is deployed by using a simple pull-back technique, without having the stent graft attached to a central carrier. There are several ways of addressing these difficulties. One is to decrease the blood pressure, thus minimizing the risk for dislodgment of the unsupported stent graft downstream. Another method is to partially deploy the stent graft and then make the stent graft conform to the longitudinal axis of the aortic arch by pushing in (ie, feeding) the stent graft and delivery system while deploying the stent graft by increments. Such a maneuver is difficult, however, and may produce unpredictable results, especially when a stent graft is going to be deployed across the left subclavian artery without covering the left common carotid artery (Figure 1).

To achieve such high precision, it may be advisable to have a control on the stent graft by attaching it to a central carrier and, in addition, control its expansion by a sequential release. During each of the steps of such a sequential release, the stent graft can be repositioned. Such a mechanism for partial release is already employed in fenestrated Zenith stent grafts (Cook Incorporated, Bloomington, IN) for abdominal aortic aneurysms.[3]

STENT GRAFT RIGIDITY/FLEXIBILITY

There are several reports of aortic wall injury caused by the currently commercially available stent grafts. The use of these may result in overt perforation or dissection.[4,5] The most likely cause for such an injury is excessive pressure by the metal frame of the stent graft against the aortic wall (eg, in the aortic arch), especially when only a thin intimal membrane separates the stent graft from the false lumen in a situation of type B dissection (Figure 2). This excessive pressure may be exaggerated by poor conformity of a rigid stent graft to the curve of the aortic arch, or by using uncovered stents, the eyelets of which are sharp points against the aortic wall, leading to subsequent injury.

An additional aspect to the importance of stent graft rigidity/flexibility is related to reported fractures of the metal frame of the stent grafts. The forces at work in the thoracic aorta are considerably higher than those in the abdominal aorta. This is particularly true in the aortic arch, or in any other curved portion of the thoracic aorta. In these locations, poor conformity of the stent graft to the tortuosity of the aorta enhances the stress forces to which the stent graft is exposed, with inevitable stent fractures as a consequence. Therefore, a highly flexible thoracic stent graft is strongly desirable. This may be achieved either by shortening the length of each stent element or by preshaping stent grafts to conform to the tortuosity of the aorta.

STENT GRAFT FIXATION

Due to the high displacement forces in the descending thoracic aorta, thoracic stent grafts are prone to migrate. This serious weakness of stent graft technology has been solved in the abdominal aorta by adding improved mechanical fixation to the stent grafts. This fixation is achieved through various shapes and numbers of barbs at the top of the stent graft or by adding a proximal uncovered stent, which acts as an anchor. Columnar strength (ie, semirigidity of the main body of the stent graft) has also been suggested as a contributing factor for improved stability of abdominal stent grafts. Of all these solutions, barbs can most easily be applied to thoracic stent grafts. However, as already mentioned, columnar strength or rigidity is a disadvantage in the thoracic descending aorta, and bare stents may cause wall injury, with erosion or dissections as a consequence. The situation in the thoracic aorta is further worsened by the fact that large fusiform atherosclerotic aneurysms form part of an extensive disease process, with severely degenerative changes in the aortic wall.[6] The implantation sites in these patients are therefore poor landing zones, where barbs alone may not be sufficient for durable stent graft fixation. Stent graft fixation may be improved by the use of endovascular stapling devices, or by adding external bands, through median sternotomy, at the level of the left subclavian artery or even through the pericardium around the distal descending thoracic aorta.

Currently, when stent grafts are used for extensive fusiform atherosclerotic aneurysms, it is recommended to place the stent graft as high up in the aortic arch as possible, even crossing the left subclavian artery, and as distally to a normal segment of the descending thoracic aorta at the level of the supraceliac portion as possible. Such extensive coverage decreases the risk for stent graft migration and has been shown not to be associated with an increased risk for spinal chord ischemia.[7-9] When multiple stent grafts are used in a similar situation, it is of utmost importance to allow for a maximum overlapping (more than 4 cm to 5 cm) of the stent grafts to prevent separation of the different components.

BRANCHED STENT GRAFTS

Covering the left subclavian artery is known to be generally well tolerated.[10] It is done to obtain a longer (ie, better) proximal fixation zone for the stent graft or to close a proximal entry in case of a type B dissection starting in the vicinity of the left subclavian artery. However, there are two major drawbacks with covering the left subclavian artery by the stent graft. One drawback is related to an anomaly that may occur, which includes the need for the left vertebral artery for the circulation in the posterior fossa, in which case, the left subclavian artery should not be covered by the stent graft. A similar situation occurs when there is a bypass from the left internal mammary artery to the coronary arteries.

The second drawback is the poor conformity of most of the currently available stent grafts due to their lack of flexibility in the aortic arch, especially when it is sharply angulated (Figure 1). Both of these weaknesses can be resolved by using a branch attached to the main stent graft and pulled into the left subclavian artery. Although this technique is theoretically easy to use due to the dual access to the aortic arch (ie, from the femoral artery for the main stent graft and the left brachial artery for the branch stent graft), there have been only a few reports in the literature.[11] The limitations are caused by the difficulties with orientation of the stent graft and its branch in the aortic arch and the risk for emboli due to excessive manipulation.

CONCLUSION

Thoracic stent grafts of the near future are anticipated to be delivered through a low-profile introducer (ie, no bigger than 20 F to 22 F outer diameter). It is highly advantageous to have a thoracic stent graft that is flexible enough to conform to the tortuosity of the descending thoracic aorta, with good mechanical fixation either through barbs or through the use of endostapling devices. A branch stent graft to the left subclavian artery is also highly desirable. Various types of stent grafts may be necessary to satisfy the different requirements for different indications. ●

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This article has been adapted from Dr. Ivancev's presentation at the VISTA Symposium in Scottsdale, Arizona.

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Remodeling With Advanced Materials

The use of advanced materials allows for remodeling of artificial venous valves.

BY DUSAN PAVCNIK, MD, PHD

At present, there are no widely accepted surgical or percutaneous treatment options for deep chronic venous insufficiency (DCVI). Patients with absent or incompetent venous valves and deep venous insufficiency syndrome can benefit greatly from implantation of artificial valves. Artificial venous valves made from either synthetic material or biomaterial should be low in profile, easy to place percutaneously, durable, stable, nonthrombogenic, and function properly to allow for free blood flow and prevent retrograde reflux.

Biological materials have potential advantages over synthetic materials as coverings for intravascular devices, which include rapid and complete endothelialization, absence of immunologic response, easier incorporation into the vessel wall, and high resistance to infection. Since 1999, we have been working on a bicuspid venous valve (BVV). The valve cusps are constructed of porcine small intestinal submucosa material (SIS) (Cook Biotech, West Lafayette, IN) that is legally marketed in the US as a surgical mesh to reinforce soft tissue. The SIS is sewn to the square stent valve frame. The SIS is slit on the diagonal axis to create the valve opening. SIS material has the capability to remodel or duplicate almost any tissue that it touches.[1]

In a study using sheep, 25 BVVs were placed into the jugular veins. Of the 25 placed valves, 22 were positioned with good axial orientation and self-expansion of the valve with centering of the BVV leaflets. Three valves (12%) were placed with a tilted orientation: 22 BVVs (88%) exhibited good function, whereas three BVVs (12%) had decreased function due to valve tilting. At 1 month, partial thrombosis was seen in one of the tilted valves (4%).[1] The SIS valves remodeled, as ingrowth of the host tissue transformed the valves into the body's own structure, incorporating them into the vein wall and therefore making them less likely to fail.[1,2] We found them very promising.

CASE REPORTS

Three patients with severe DCVI were treated with a BVV as part of a safety trial. The valves were implanted percutaneously by right internal jugular approach using

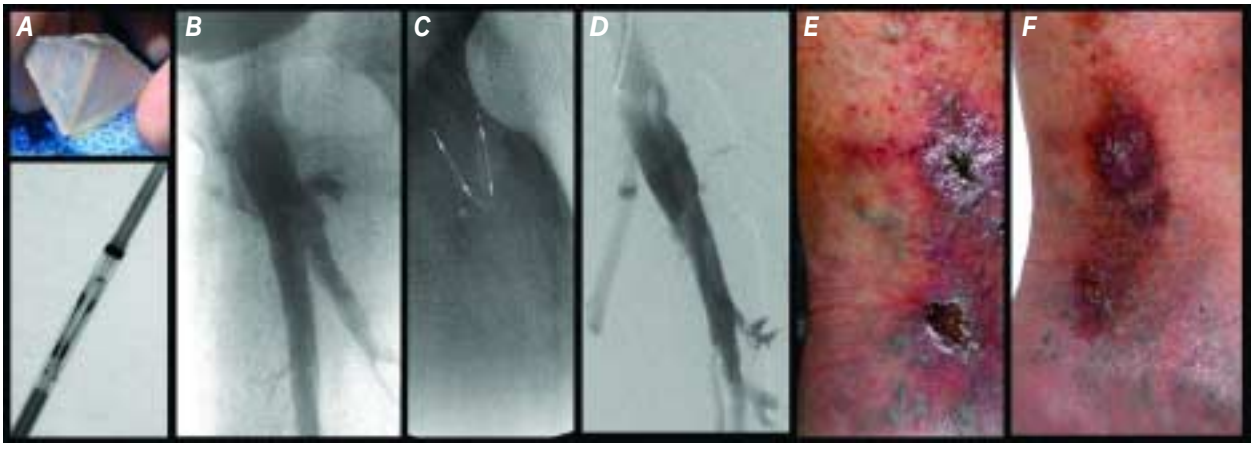

Figure 1. A 39-year-old man with postthrombotic syndrome who had severe venous claudication with an active venous ulcer. The square stent-based small intestinal submucosa valve (A). A descending venogram in the upright position shows severe reflux at the left common femoral vein, which extends into the profunda femoral vein and valveless femoral vein all the way into the calf (B). Valve placement (C). A follow-up descending venogram at 2 months demonstrates no spontaneous reflux through the valve into the femoral vein (D). Active ulcer before artificial valve placement (E). Healed ulcer at 1-month follow-up (F).

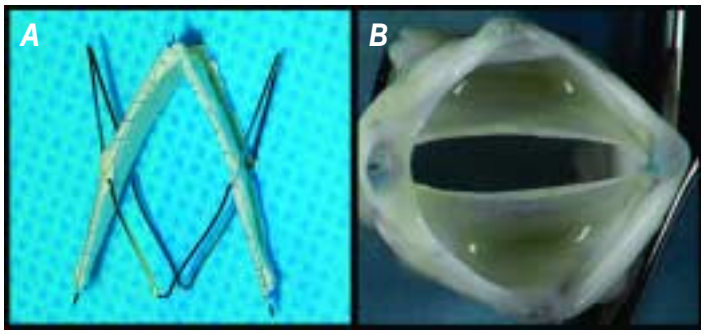

Figure 2. A second-generation venous valve. Nonrestricted lyophilized bicuspid venous valve with four barbs for a maximum vein diameter of 14 mm (A). A specimen shows smooth incorporation of the bioprosthetic valve into the vein wall in a sheep jugular vein at 6 weeks (B).

an over-the-wire 9-F delivery system. Descending venograms of the involved limb were done in the upright position. The proximal and distal femoral vein (FV) diameters were measured in two projections in the area of the intended vein implantation. The valves selected were 1 mm to 2 mm larger than the vein diameter. The BVVs were studied for function and stability in the upright position by injecting contrast medium above the BVV. Follow-up descending venograms were done at 2 months and duplex ultrasound was performed at 1, 3, 6, and 12 months.[3]

Patient No. 1

A 15-mm BVV was deployed in the proximal FV in a 38-year-old man with an active venous ulcer. Follow-up descending venograms at 2 months and duplex ultrasound at 1, 3, 6, and 12 months demonstrated no spontaneous reflux through the valve into the FV. The patient's active ulcer was found healed at 1 month after BVV implantation and did not recur at 1-year follow-up (Figure 1).

Patient No. 2

Placement of an 18-mm to 19-mm BVV was technically successful, but it was placed 8 mm to 10 mm lower than intended in the proximal FV. This resulted in an oversized BVV with significant valve leak. During the 1-year follow-up, the BVV stayed patent and did not cause any complications, but there was no change in the patient's clinical symptoms and disability scores.

Patient No. 3

The 11-mm BVV placed into the distal left FV resulted in approximately 30% valve tilting. Immediate follow-up venography showed good valve function with minimal leak. The patient showed immediate and 1-year clinical improvement, mainly a decrease of leg pain and edema.

The BVVs remained patent without thrombosis or other complications. Proper sizing and proper placement of the valves was critical to their function.

SECOND-GENERATION BIOPROSTHETIC VENOUS VALVE

To eliminate the occasional valve tilting, the second-generation BVV was developed. The new valve is a sturdier, second-generation version of a device invented at the Dotter Interventional Institute in collaboration with Cook Incorporated. The new valve solves the tilting issue. It now has two overlapping stents made from nitinol providing four extra points where the device contacts the inner wall of the vessel (Figure 2).

The second-generation double-stent valve design will always center correctly. We had no tilting during placement of the second-generation BVVs into the jugular veins in sheep. The valves exhibited good function in more than 92% of cases during the midterm follow-up. The new valve could be in clinical trials later this year.

CONCLUSION

A manufactured, percutaneously implantable, nonimmunogenic, and nonthrombogenic bioprosthetic venous valve that remains patent and competent over time is an attractive alternative to direct venous valvular reconstruction or transplantation. Our results and the potential for effective treatment with bioprosthetic venous valves warrants additional research in carefully selected patients and may lead to an effective, minimally invasive treatment for deep chronic venous insufficiency. ●

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The Q & A Session

The panel members respond to questions from the audience.

Q: To any members of the panel, with the branch endografts into the distal arteries, the iliac arteries, is perhaps the best way to go at them from the arm? Is that sensible or too difficult?

Timothy Chuter: We do it from the arm when the common iliac is too short. If the common iliac is short, it's hard to get up and over the trunk of the iliac device to come from the other side and place the extension. Under those circumstances, we come down from the arm, but I think coming from the other femoral is an easier option under most circumstances.

Wolf Stelter: I would say that we always keep the option open for a transbrachial approach, but we always try to cross over first.

Q: What I really mean is that when you already have an endograft in place, it's very difficult to go over through that sharp bifurcation and down.

Krassi Ivancev: There is no doubt that if you have the graft in place, then you have to go from the brachial. However, in tall patients, this means you have to use long sheaths to bring the stent graft all the way down. That's a disadvantage.

Roy Greenberg: In general, I think many of us prefer to place the hypogastric branch first, before the main body of the endograft is in place. That's why the length of the common iliac becomes important: you need a segment above your branch to allow you to mate with another device. This would make coming up from the contralateral side sometimes difficult in a short common iliac, but if you're doing this before you've placed your main bifurcated segment, then you don't have a steep angle to go through, and you can come from up and over.

John Anderson: The current system we're trying is a branch with a short limb for the internal iliac, and everything is packed in. You put it in, line it up as best you can in relation to your markers and the angiography, and then you pass a wire up the contralateral side. This device contains a snare that you put up, which then grabs the wire, at which point you're able to get a through-and-through wire. Then you can come down, catheterize from above, then put your extension stents through the short limb to bridge the gap to the internal iliac artery. I've only used one so far, and I don't know if anyone else has used them, but it worked very well in quite a difficult aortic bifurcation.

Q: I'd like to ask the vascular surgeons about their level of comfort. When we did carotid stenting, renal stenting, SFA stenting, or AAA, I always felt very comfortable because these were the lesions I was trained to treat and I always had the ability to fix them surgically. Now, when we're talking about ascending thoracic lesions, my question is, how comfortable are you doing it alone? Do you have a cardiac surgeon with you, and what are their feelings about the valve being taken away by percutaneous deployment? Is this like the cardiologists against the cardiac surgeons, and how comfortable are you doing something that you cannot bail out surgically?

John Anderson: I always work with a cardiothoracic surgeon in those circumstances.

Roy Greenberg: For us, the referrals generally come in depending on the time of day or week that they've arrived, so if the dissections are at night and the ruptured aneurysms are on the weekend, they're very happy to give them away. But, in all honesty, I think you're right. You have to work with them, and it's a good thing because they're your bail-out, too.

Timothy Chuter: I agree. Bring as many people to the party as you possibly can, at least in the early stages when things are unpredictable. Later on, if things get predictable, then you triage the cases according to the skills that are required. Right now we need a broad spectrum of skills because we don't know where it's going.

Q: All these high-tech, future-pipeline devices are very exciting, but if you have only ever used AneuRx for AAA, and then suddenly you want to convert to a Cook ascending stent graft, that is not a reasonable approach, is it? So, if one wants to get involved in this branch technology, and the ascending arch, the first thing we should do is get famil-

iar with the Cook Zenith AAA device; is that correct?

Timothy Chuter: You have hit the nail on the head and expressed the marketing position very well. I don't think anyone who is not familiar with the Zenith device should attempt to use a Zenith platform to jump to more difficult things. Those of us who are trying to persuade Cook to do these adventurous things, which perhaps are a bit of a niche market, have to make the case that there is sort of a knock-on effect, whereby you establish a broader market for the broader device.

John Anderson: I bluntly told Cook that this is the way to get people to use Zenith grafts, because if they want to advance, they need to have a good knowledge of the system. It took a little while but they seem to be listening now.

Roy Greenberg: I should relay a conversation that Wolf, Tim, and I were having about training; really, surgically fixing an aneurysm is a lot more complicated than putting an endograft in an aneurysm. The problem is that we didn't spend 7 years training to place an endograft in an aneurysm, and as the training paradigms change and the future of vascular surgery or interventional radiology or whatever you want to call it changes, I think that the people and the skills that are going to come to the table are going to change. Hopefully, that's where this technology will go.

Q: David Hartley is a pretty smart cookie, and he is responsible for much if not all of the development, but I never understood, David, why in the thoracic stent graft, you did not change the shape of the top end of it and make multiple, small, varied angles just to take in that curve, because when that graft goes in, there's always that bit hanging up on the convex side of the lower side of the arch, and it always looks wrong. Would smaller, narrower stents solve the problem? Would a V-shaped stent solve the problem?

David Hartley: We certainly tried asymmetrical stents and various other configurations. One of the problems is that we're wedded to stainless steel at the moment, but in looking at other materials, you probably need a more elastic material to be able to use shorter stents. If you make shorter stents with the technology we have now, they get a bit unstable and turn inside out, but be aware it's a problem we're looking into.

Q: Roy, we're always concerned about the overlap in the seal zones—the graft-to-graft seal zone in the modular device, and with the fenestration, the actual seal zone between the stent and the fenestration is really just a millimeter or so. Do you think that effectively extends the seal zone of the graft, and how do you think it will hold up over time?

Roy Greenberg: That's a good question, and in my own opinion, if you're perfect with the graft placement and you know your graft will never move, you really only need a millimeter or a point seal as long as there is no degeneration of the aorta after the placement of the graft. With the fenestrated graft, you have to make a decision regarding where your seal will actually be. Will it be directly below the renal arteries, or is there some segment of neck? And for a true fenestrated graft, you need some segment of neck that will seal. The fixation zone is where your fenestrated graft is coming up above the level of the SMA or the celiac, and you're adding renal stents and you're sure that the graft material is up above or at the level of the renals, because getting into the renal arteries is much greater than in a short proximal neck. As long as you're sure that you have some segment of neck below the renals, a fenestrated graft will probably work. If the aneurysm goes straight up to the renal arteries, or involves one of the renal arteries, even trying to get the graft into it may make you subject to some late failures. I think it would probably be more appropriate if John were to comment on this.

Q: As an add-on, what makes the fenestrated graft better than laying the graft right at the renals? What advantage are we getting from a fenestration?

John Anderson: The important thing is that you should stop focusing on the small segment of aorta that you may use to seal and think of where you're putting the covered stent. You're putting the covered stent in a parallel section of aorta, so the entire stent stays parallel and doesn't flare as it would if you were to place it at a short neck immediately above an aneurysm sac. So, the stent sits with its walls parallel, not pinched, and that's how you get your seal. You need some aorta below it unless you have the capability to use covered stents, which I believe you do not at the moment. It's the parallel nature of the struts of the covered stent that will actually give you the seal, and I think that is a more stable segment of aorta than the infrarenal segment because frequently you see thoracic and abdominal aneurysms that occur together or at different time points in the same patient, and the most stable segment of aorta is often the segment that contains the renal vessels. We've been doing this since 1997 and have had no aneurysm-related deaths, no open conversions, and no type I endoleaks.

Q: A lot of people talk about stroke in relation to the descending and thoracic aneurysm endografts, and I see a

lot of manipulation in the arch today. If you think that stroke is a big issue, do you think it's air embolism, hemodynamics, or adenosine arrest? Is it manipulation in the arch? If you think that stroke is an issue, what's the etiology?

Krassi Ivancev: Personally, I believe that it's manipulation in the arch. We're not using adenosine, and we're still seeing stroke in these patients, it is close to 1%, and it has to do with manipulation—how you place the stent graft, how precisely it can be placed, and if you're pushing it out. If you can minimize that manipulation by exact placement of the stent graft, I think that's the way to go.

Wolf Stelter: The wire scrubs on the ascending aorta much more than you would like for it to, so you're losing material.

Krassi Ivancev: Also, some say covering the subclavian artery is an innocuous procedure, but I do not agree. It depends very much on the supply of the arteries to the cerebellum, and that needs to be checked out by placing the stent graft, which is why we always investigate and are cautious about covering the subclavian.

Q: Sorry to be the devil's advocate, but David, about the materials used in the Zenith graft, if I look at some of the other grafts, they look very nice with their bonded nitinol and PTFE. What confidence, after a decade now of putting the grafts in, is there in stainless steel, prolene, and polyester in the long haul?

David Hartley: If you're talking about the current device, and I assume you are, that combination has been implanted and has ongoing patient follow-up longer than almost anything else on the market, so it's pretty good. I made the first grafts and then did some testing on them and I thought, OK, I hope they're putting these in fairly high-risk patients because I'd give it 3 years. But then the 5-year point came up, so I thought we'd give it 7, and now 10 years turns up, so I think that we can probably confidently look at 15. We have virtually never seen 5 years of follow-up evaluation of the graft material. We should look for something that is just as good, and stainless steel is also showing that it can withstand the test of time. Consequently, I'm much more confident than I was 10 years ago.

John Anderson: I can perhaps say something about the metallic component. Nitinol is the darling of the medical community at the moment. It has a much higher fracture rate than stainless steel because, as you're probably aware, nitinol can exist in two forms. One is austenitic, meaning that it's spring-like, which is the way we want it. The other is martensitic, and if you subject nitinol to stress and strain of a significant degree like you find in the thoracic aorta, it undergoes stress-induced martensitic formation and produces microfractures; this process is the cause of all nitinol stent failures.

Wolf Stelter: We have used all different kinds of grafts over the last 9 years, and we have seen a considerable number of stent fractures in all types of grafts, including the Zenith. When it occurs in the middle part of the graft because you have a kink or some stress, then in most cases, it has no significance, except if the stent were to puncture through the graft material and cause an endoleak. But the stents are outside, so this is not very frequent. However, if you have a stent fracture in the neck or landing zone, this situation would be much more serious. It indicates, nearly in all cases, that something is wrong with the landing zone, not with the graft. The landing zone may be dilating or otherwise problematic, causing the graft to fracture, after which it migrates.

David Hartley: There is just one other point that should be made. That is, the Zenith device, as is the case with all others, will fail in unusual and exceptional circumstances. One such circumstance is that we've seen just a small number of infrarenal necks that have simply collapsed, leaving the device sitting there hanging off the hooks. That's the same condition that applies when you put the device in a short neck—a 3-mm or 5-mm neck. You're taking all the strain, and it's not inconsiderable with the blood pounding on it, just suspending off of the hooks and off of the sutures. That isn't what it's designed for, and over a long period of time, that device like any other will fail. And if you put these devices in a dissected aneurysm, and you haven't sealed the primary leak, those are extraordinary circumstances that could cause failure in any graft.

Timothy Chuter: If you want to reduce your worry about long-term prospects or failure, one of my suggestions is not to put thoracic stent grafts in, because the thoracic aorta is often longer, angulated, wider, more compliant, and has higher flows. It has all of the nasty physiologic challenges that are going to break these stent grafts. You see these cases of failures all the time with multiple stent grafts, and that's not to say that those failures cannot be overcome through redesign, but it's much more challenging technology than what we use in the infrarenal aorta.

Q: With fenestration, is there any problem with migration?

John Anderson: No, as I've said before we've had no

device migration and no conversions. It's really going very well. We have not explanted any fenestrated grafts.

Wolf Stelter: I must say sometimes, yes, but we did not use stents at the beginning. We just used a fenestration, and out of 30 fenestrations, we had five occlusions of the renal artery. So somehow, the graft had probably moved, and therefore we now use, as John Anderson suggested, a stent to keep it in place. This solves the problem.

Moderator: One of the projects that we're working on right now is a range of stents with exactly this application.

SAC SHRINKAGE

Q: What are your expectations of AAA endovascular grafts with regard to sac shrinkage?

Krassi Ivancev: Sac shrinkage is anticipated to occur in approximately 70% of EVAR-treated AAAs after approximately 1 year. If there is no sac shrinkage after 2 years post-EVAR, we will perform intrasac pressure measurements in order to find out the pressure inside the aneurysm.

Roy Greenberg: This is dependent upon the device utilized, the presence of endoleak, and the patient's physiology. With the Zenith device, I expect the sac to shrink within 12 to 24 months. If this does not occur, I would be concerned.

Timothy Chuter: We perform endovascular aneurysm repair in the expectation that excluding the aneurysm from the circulation will protect it from arterial pressure, thereby preventing dilatation and rupture. We are not surprised to see continuing aneurysm dilatation in the presence of endoleak. The assumption is that continuing perfusion causes continuing pressurization. Our usual response is to identify and eliminate the source of the leak. Aneurysm dilatation in the absence of endoleak (endotension) is more puzzling, and more worrying. Clearly, the endovascular stent graft has failed to influence the natural history of the aneurysm, but we're not sure why, and we're not sure how to respond. For unclear reasons, this phenomenon is common with some stent grafts, the Excluder in particular, and rare with others, like the Zenith. According to the findings of the US multicenter study, aneurysm dilatation by more than 5 mm is seen in 23% of Excluder cases 3 years after implantation. Only half of these have an endoleak. The others are instances of endotension. Options include: continuing observation, treatment of any identifiable endoleak, conversion to open surgery, excluding the Excluder using another stent graft, and fenestrating the aneurysm to provide a route of egress for the seroma.

Q: Would complete sac shrinkage affect your follow-up?

Roy Greenberg: Absolutely, a relatively large number of patients have completely resolved their aneurysms after endovascular repair. In these circumstances, I alter the follow-up to include only duplex ultrasound and 4-view KUB on a yearly basis.

Timothy Chuter: Parodi has reported several cases in which stent graft migration and secondary type I endoleak led rapidly to rupture despite complete regression of the sac. Others have described an almost instantaneous return to preoperative aneurysm dimensions following the onset of secondary leakage. The only assurance of continuing freedom from risk of rupture is stable stent graft function, and the only thing that would justify a less rigorous surveillance program would be a track record of long-term durability. It would take long-term data showing low rates of complication or reintervention.

Krassi Ivancev: The follow-up in our patients after EVAR of AAA includes plain abdominal films at discharge, provided that EVAR has been completed without any problems, and then CT and plain films once a year. Complete sac shrinkage does not inhibit our yearly controls.

Q: How would you treat a patient who has aneurysm sac growth after an endovascular graft has been placed?

Timothy Chuter: In my practice, aneurysm dilatation signifies endoleak or infection. Aneurysm dilatation, in the presence of an endoleak, warrants angiographic localization and intervention.

Roy Greenberg: Again, this depends on the type of graft. Initially, it would depend upon whether there was a source for growth, such as an endoleak or suspected infection. If not, I would ensure the coverage extends from the renals to internal iliacs. Following that, if I believe there is a risk of rupture, and the patient is a candidate for open repair, I would proceed with that. If not, I would reline the device with an additional device, and move the fixation system to the next higher level (ie, if it is an infrarenal graft, move to suprarenal, if it's suprarenal, move to fenestrated, etc.).

Krassi Ivancev: If there is a hygroma, we will adopt CT follow-up every 6 months. If there is a high intrasac pressure, then we will look for a possible explanation, such as migration, separation of stent-graft components, thrombus-lined aneurysm neck, and possible undiscovered type II endoleaks. If the aneurysm sac continues to grow, then we will convert the patient to open surgery.

MIGRATION

Q: Can you compare and contrast your use of suprarenal versus infrarenal devices?

Krassi Ivancev: Suprarenal fixation in my opinion provides an improved fixation of the stent graft, thus minimizing the risk for migration. Out of approximately 280 Zenith stent grafts, we have seen only one patient with stent graft migration, and this was caused by an undersized stent graft placed in a thrombus-lined large neck. In a group of uni-iliac stent grafts without suprarenal fixation, comprising approximately 75 patients, migration of the stent graft occurred in approximately 45%.

Roy Greenberg: I mostly use suprarenal devices (the Zenith). I believe that the migration rate is lower, and the ability to deploy the device precisely at the renals is better. However, there are circumstances when I would alter this practice.

Q: Are you treating patients with endovascular grafts that have migrated? If so, what is your method of treatment?

Roy Greenberg: As I mentioned before—move to the next level of fixation. That is, if they are not candidates for open conversion, which is actually my treatment of choice.

Krassi Ivancev: If there is stent graft migration, we prefer to treat the patient with a proximal extension. The reason for this is often the fact that the patient is in the category of high operative risk and therefore would tolerate poorly a conversion to open surgery. If there is a poor aneurysm neck following stent graft migration, we will attempt to place a fenestrated stent graft. For us, the last option is to convert the patient to open surgery.

Timothy Chuter: Approximately 10% of our homemade devices migrated enough to cause secondary endoleak. Our preferred approach has been to implant a tapered aorto-uni-iliac stent graft to bridge the resulting gap.

ENDOLEAKS

Q: What is your method of treatment (if any) for type II endoleaks?

Roy Greenberg: If there is growth, I embolize using a transarterial puncture, usually in conjunction with cyanoacrylate glue.

Timothy Chuter: Having seen aneurysm rupture in a case of IMA-fed type II endoleak, we treat them all by transarterial embolization. But we treat the lumbar endoleaks only if the aneurysm dilates. Despite our failure to eliminate the endoleak in over half of these cases, none has ruptured in a series of more than 500 endovascular AAA repairs with up to 8 years of follow-up. Consequently, we are starting to wonder if we should be treating type II endoleaks at all. There are data from the EUROSTAR registry suggesting that type II endoleak is actually associated with a reduced risk of aneurysm rupture.

Krassi Ivancev: Type II endoleaks would be treated by translumbar puncture of the endoleak nidus itself, and then embolization with a combination of glue and lipiodol. Prior to that, pressure measurement is also performed in the thrombus and in the leak itself. This is performed if the type II endoleak persists at the 1-year follow-up or later.

Q: Are there any characteristics related to individual grafts that are more effective in preventing endoleaks?

Roy Greenberg: The incidence of endoleaks is graft dependent. There are a lot of misleading data that do not account for preoperative anatomic differences between devices, and these preoperative differences are critical when considering endoleak incidence. However, clearly endoleak incidence is device-dependent, and the effect a type II leak has on the sac is device-dependent.

Krassi Ivancev: I am not aware of any specific characteristics related to individual stent grafts with regard to preventing endoleaks. Rather, certain features minimize the risk for endoleaks. These include transrenal fixation, a sturdy graft fabric that is less prone to break with time, stents that are sutured on the outside of the graft material (thus, if a fracture should occur, the metal fragments would not perforate the fabric), and avoiding excessive oversizing of stent grafts (more than 15%-20%).

Timothy Chuter: Type II endoleak appears not to be related to stent graft design. Type III endoleak is becoming a rare event. So is primary type I endoleak, providing the individual anatomy falls within the performance limits of the device. The big differences between devices are in the rates of secondary type I endoleak, due to stent graft migration. The main factor is barb-mediated fixation. Devices, such as the Ancure, Zenith, and Excluder, rarely migrate. On the other hand, unbarbed devices, such as the Endologix, Talent, and AneuRx show alarming rates of late migration. This looming problem threatens to undermine the entire field. ●