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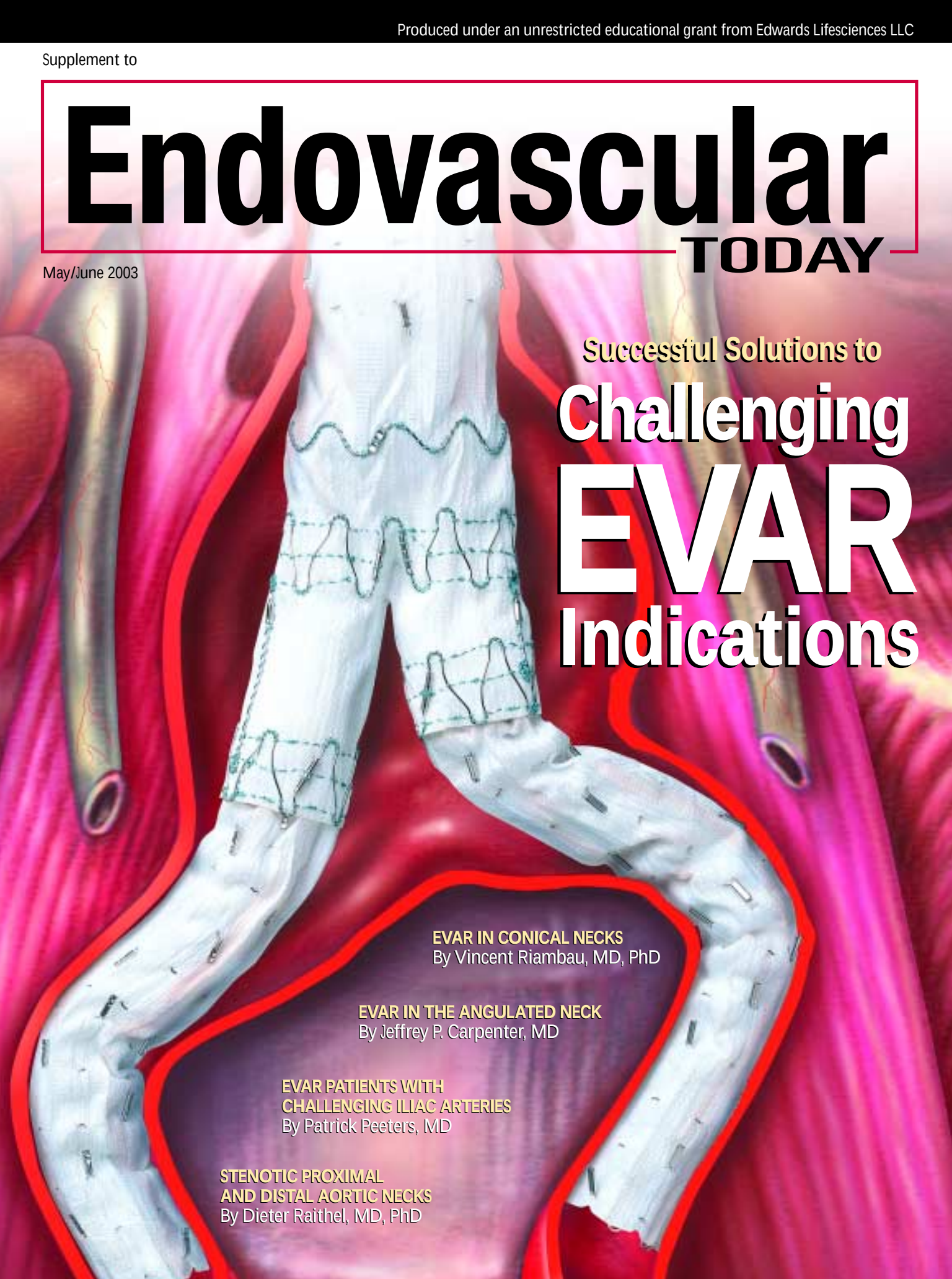

Successful Solutions to Challenging EVAR Indications

Successful Solutions to

Challenging EVAR Indications

Today's endovascular specialist encounters a variety of challenging situations when evaluating and treating AAA patients. Assessing endovascular treatment for patients with challenging anatomy poses a particular difficulty, as we must understand the complexities of the procedure and performance characteristics of the selected endovascular graft.

Edwards Lifesciences LLC (Irvine, CA) developed the Edwards Lifepath AAA Graft System to address specific challenges of endovascular repair. Edwards sponsored a session at the 2003 Charing Cross International Symposium in London, during which Drs. Jeffrey Carpenter, Vincent Riambau, Dieter Raithel, and Patrick Peeters presented information and personal experiences with the Lifepath AAA Graft System in challenging EVAR procedures.

This educational supplement to *Endovascular Today* includes detailed articles that address specific EVAR challenges: Dr. Carpenter describes the challenges of managing angulated aortic necks; Dr. Riambau discusses endovascular treatment for patients with conical necks; Professor Raithel writes on the unique challenges of planning endovascular repair for patients with stenotic aortic necks; and Dr. Peeters addresses EVAR in patients with challenging iliac arteries.

This supplement is designed to assist endovascular specialists when considering treatment for AAA patients with challenging anatomy and morphology.

CONTENTS

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EVAR IN THE ANGULATED NECK

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STENOTIC PROXIMAL AND DISTAL AORTIC NECKS

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EVAR in the Angulated Neck

Patients with angulated aortic necks pose special challenges when presenting for AAA repair.

BY JEFFREY P. CARPENTER, MD

As aneurysms expand, they do so not only in diameter, but also in length. The latter type of growth introduces angulation and tortuosity. Accordingly, it has been well described in the literature that angulation is encountered more frequently in larger aneurysms.[1,2] The prevalence of neck angulation is determined by its definition. Most patients with AAA exhibit some degree of angulation. In a University of Pennsylvania study[3] of 307 patients presenting for AAA repair, 103 (34%) were deemed anatomically unsuitable for endovascular aneurysm repair (EVAR). Neck angulation greater than 60º was the reason for exclusion in 14 (4.6%) patients. Stanley et al[4] reported an incidence of neck angle greater than 30º in 25% of patients with EVAR.

Figure 1. An EVAR device dislodged from proximal neck with resultant type I endoleak.

"Use of flexible sheaths that can traverse the angulated segment prior to device introduction has proved to be a successful strategy in this condition."

Significant aortic neck angulation is considered to be a relative (or to some interventionalists, an absolute) contraindication to EVAR. This warning is not unfounded, because aortic neck angulation presents challenges to all aspects of endovascular grafting.

WIRE PASSAGE

Initially, neck angulation may render wire passage difficult. This situation is almost always overcome by the interventionalist's use of curved angiographic catheters and hydrophilic, steerable guidewires. Once initial access is achieved, neck angulation presents further difficulties in device passage. Although stiff wires may be able to overcome tortuosity in the iliac arteries and the aortic neck to some extent, the aorta is resistant to deformation by the use of stiff wires alone. The relatively rigid devices and delivery systems do not readily negotiate the crooked path through the neck. Use of flexible sheaths that can traverse the angulated segment prior to device introduction has proved to be a successful strategy in this condition.

Sometimes, brachial-femoral access is required to adequately overcome tortuosity.[5] In this maneuver, the interventionalist places a single guidewire from the brachial (usually left) approach and retrieves the wire from a femoral artery. The interventionalist protects the subcla-

vian artery by placing an angiographic catheter to avoid "cheese knifing" through the artery when applying traction to the wire from both ends. This strategy can provide efficient straightening and a smooth path for the device to follow through tortuous vessels. The additional tactics necessary to successfully arrive at the angulated neck may be expected to significantly increase the morbidity of the procedure.[1]

DELIVERY DIFFICULTIES

After the interventionalist has successfully introduced the delivery system, EVAR device deployment may be hampered by neck angulation. Device delivery may be impossible due to friction from kinks introduced by the angulation. Neck angulation may also cause device malpositioning for a number of reasons. The transition from the graft's position within the delivery system to the aortic neck may involve a significant realignment that is not easily foreseen. In addition, the presence of the delivery system significantly alters the angulated neck's geometry, making the final neck geometry after device placement somewhat unpredictable.

Location of Renal Arteries

The location of the renal arteries will change with the introduction of rigid wires and delivery systems into the angulated neck. The interventionalist must make frequent contrast material injections during device deployment to guide the delivery. The angulation will cause the delivery system to assume a place on the aortic wall, rather than in the center of the aortic stream, which may result in an unstable, canted graft position. Because of this risk of misplacement, longer lengths of aortic neck are necessary in patients with significant neck angulation to achieve an adequate seal and to account for the uncertainties of placement. As the angulation increases, so too does the length of neck required for an adequate seal.

"As the angulation increases, so too does the length of neck required for an adequate seal."

Flexibility Issues

Although the device may be successfully deployed, endograft-related challenges still persist. There is a limit to the flexibility of sealing stents. Either the graft must conform to the aorta, or the aorta to the graft. Forces will not be uniformly distributed throughout the stents in the angulated portions, thereby introducing strain and the risk of early material fatigue. This scenario creates a setup for device failure over time.

THE PITFALLS OF EVAR SUCCESS

Successful EVAR is marked by AAA sac shrinkage. This reduction may introduce even greater tortuosity and angulation, accentuating the forces on the proximal attachment zone as time passes. The conformational change may dislodge the graft from the neck resulting in a type I endoleak (Figure 1), just as it may lead to component separation (type III endoleak). Several investigators have warned that aortic neck angulation is associated with the development of type I proximal attachment endoleaks.[2,6-9] Migration is also more likely to occur in patients with neck angulation because of the unequal and asymmetric forces acting on the graft.[9] In addition, late rupture in the setting of neck angulation with resultant endoleak has been reported.[2] Remedial procedures, such as additional cuff or stent placement, can be extremely difficult to perform in these patients.

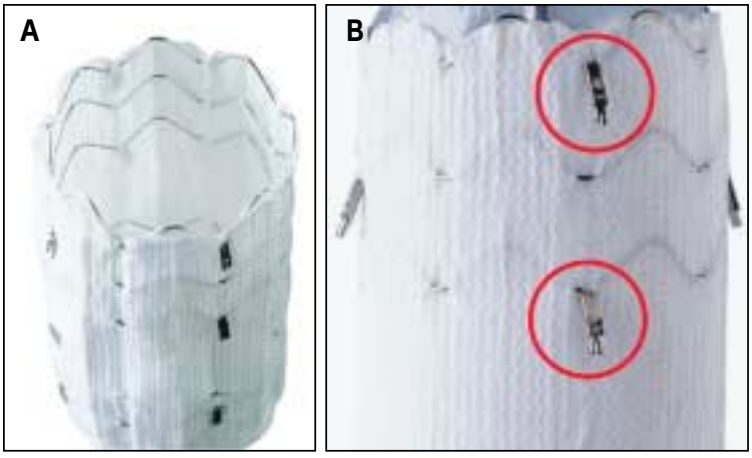

Figure 2. The Lifepath AAA Graft System's (Edwards Lifesciences LLC, Irvine, CA) circular wireforms are independent of each other for greater flexibility and interwoven through the graft material for optimal graft-to-vessel wall interface (A). Fixation crimps in the top three wireforms of the Lifepath AAA Graft System increase friction and add to stent graft stability already provided by radial force (B).

TREATMENT STRATEGY

Patients with significant aortic neck angulation should be considered to have a

relative anatomic contraindication to EVAR. Most endograft manufacturers have deemed this condition as an anatomic exclusion to the use of their device. If the patient is unsuitable for open AAA repair, several technical tips should be kept in mind to achieve a successful EVAR outcome.

Seal

Seal and fixation should be considered separately. Seal is achieved chiefly by the radial force of the endograft. Only grafts with high radial force should be trusted in this situation. As previously stated, the longer the angulated neck is, the more likely the interventionalist is to achieve an adequate seal. The short angulated neck is the most hazardous anatomical configuration.

Fixation

The ability of an endograft to resist migration is called fixation. This ability can be a function of the graft's radial force and is supplemented by the use of metal hooks, barbs, or crimps that affix the graft to the aortic wall. The interventionalist can extend the fixation mechanism into the suprarenal segment of the aorta with bare metal stents, which may provide additional fixation security. In the setting of severe angulation, however, this maneuver can be the source of additional strain in the device and may distort the position of the endograft, particularly if the angulation reverses in the suprarenal segment. The safety of suprarenal fixation and its long-term effect on the kidneys remains unclear.

Corrective Procedures

Self-expanding grafts may fail to seal when placed in angulated necks. The metal skeleton, composed of interlocking straight pieces, often cannot conform adequately to the curved aortic surface, resulting in an inadequate seal. Remedial procedures for this situation usually involve a supplemental aortic cuff deployed within the previously placed endograft. This strategy helps to increase the overall radial force of the endograft in the seal zone of the aortic neck. Alternatively, the interventionalist can deploy a balloon-expandable stent with high radial force within the endograft, which will force the sealing fabric and endograft skeleton to more tightly conform to the aortic wall.[7] Both of these remedial procedures result in significant straightening of the aortic neck.

THE LIFEPATH SYSTEM

The Edwards Lifepath AAA Graft System is well suited to the challenges of the patient with an angulated neck.

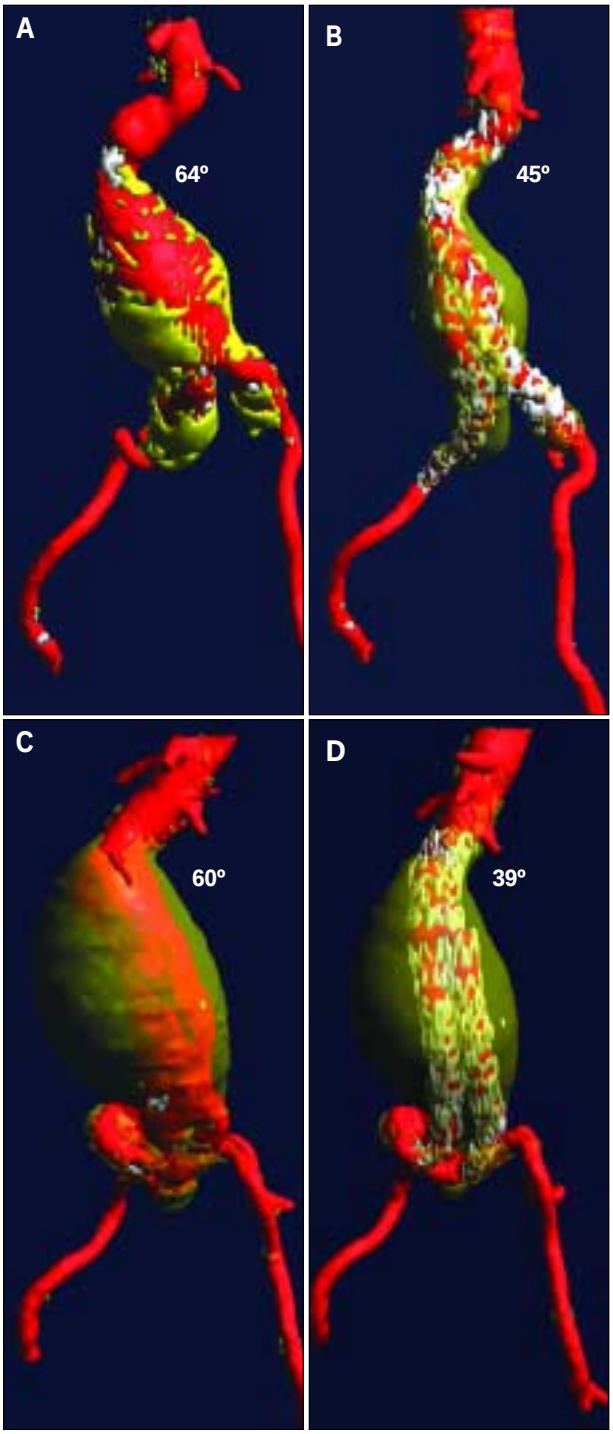

Figure 3. Prior to endovascular repair, proximal neck angulation of 64° is demonstrated with 3-D CT scan reconstruction (Preview System, Medical Media Systems, West Lebanon, NH) (A). Neck angulation was reduced to 45° at 6 months after implantation of the Lifepath AAA Graft System (B). A second example of neck angulation reduction (60° to 39°) (C,D).

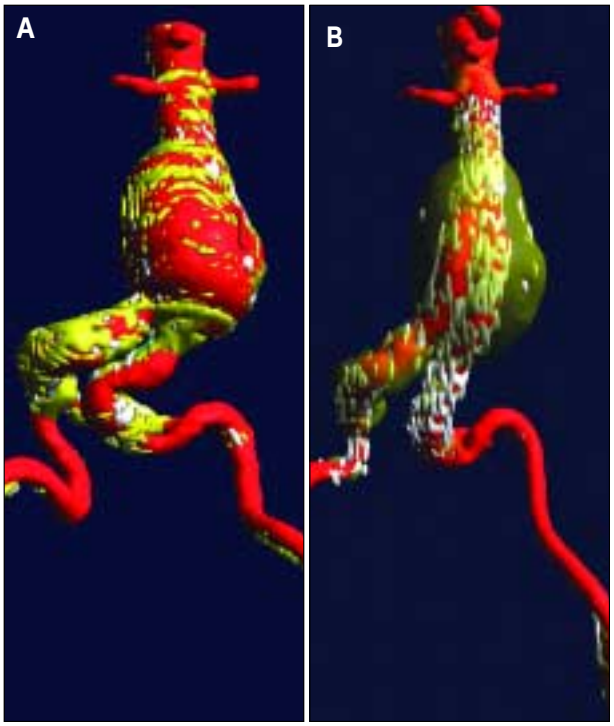

Figure 4. Prior to endovascular repair, iliac arteries demonstrate substantial tortuosity as seen on this 3-D reconstruction (A). Iliac artery remodeling seen at 6 months after implantation of the Lifepath AAA Graft System, again demonstrating recontouring effect (B).

The system is delivered via introducer sheaths, which allow for initial placement of the flexible sheath system over a stiff guidewire and introduction of the device only after the more flexible sheath has already negotiated the twists and turns. The device is balloon-expandable, allowing precise placement in the neck with the ability to make fine adjustments during deployment as the angles change. As the balloon is slowly expanded, the neck molds, or recontours, and the interventionalist can alter the device position as the balloon is inflated. The very high radial force of the balloon expanded endograft wireforms provides a strong seal.

The concentric circular orientation of the wireforms is ideal for curved surfaces, providing serial "gaskets" interrupted by flexible fabric (Figure 2A), rather than an inflexible metallic skeleton that may not conform to angulation. Fixation is ensured both by the radial force of the proximal internal wireforms and the external metal "crimps," which penetrate into the aortic wall (Figure 2B). Significant straightening of the angulated neck occurs when the Lifepath device is deployed. This "recontouring" effect remains even after the initial device placement (Figure 3A-D). Use of the Lifepath System directional catheter simplifies contralateral limb cannulation, which can be challenging in the presence of angulation. The modular components allow for easy length adjustment *in situ*, which can be difficult to predict in tortuous anatomy.

After deployment, the combination of independent wireforms and radial force make the balloon-expandable limbs of the Lifepath System highly resistant to the kinking and thrombosis that can occur after EVAR as a result of long-term morphologic changes. In addition, the recontouring effect that is seen with the Lifepath System in the proximal neck is also demonstrated in the iliac limbs. The balloon expandable limbs are highly resistant to kinking and thrombosis with long-term changes in conformation after EVAR (Figures 4A,B).

CONCLUSION

Angulation provides challenges to all aspects of the EVAR procedure, which should be avoided in patients with angulated aortic necks when these patients are medically fit for open repair. Successful EVAR in angulated necks requires longer neck lengths and is facilitated by the use of endografts with high radial force and supplemental fixation elements. ■

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EVAR in Conical Necks

When treating a patient with a conical neck, consider using a device that can be gradually deployed and repositioned.

BY VINCENT RIAMBAU, MD, PHD

Researchers tend to differ greatly in their opinions regarding the definition of a conical neck (Table 1).[1-6] Overall, estimates of conical neck prevalence range from 18% to 24% in AAA patients who have received endovascular grafts.[2,3,6] Whereas some researchers consider the presence of a conical neck to be a contraindication to endovascular AAA repair,[3-5,7-9] others treat conical neck patients with endovascular repair, yet consider these patients at increased risk for postprocedural complications (eg, proximal endoleak, stent graft migration).[2,3,8,10] In contrast, Albertini et al[6] concluded that neck angulation, not the conical nature of the neck, had the most significant association with proximal endoleak and graft migration. Furthermore, Mohan et al[11] reviewed EUROSTAR database information and demonstrated that the shape of the aorta was not associated with the occurrence of an endoleak, and that patients with shorter proximal necks actually had a higher risk of endoleak.

At the Institute of Cardiovascular Diseases in Barcelona (ICDB), where the Stanley definition for conical necks is used (Table 1), approximately 10% of all AAA patients present with a conical neck. These patients are not routinely rejected for endovascular AAA repair due to the conical neck; however, they are rejected if their neck is very short (< 10 mm) and/or if the neck contains thrombus in more than 30% of its circumference. Until recently, all of these patients were treated with suprarenal fixation, self-expanding stent grafts. Graft migration complications in several patients, however, have led to the consideration of an infrarenal fixation, balloon-expandable device.

In the following case report of a typical conical neck patient treated with an infrarenal fixation, balloon-expandable device, the endovascular specialist was able to achieve a favorable short-term outcome after deploying the Edwards Lifepath AAA Graft System (Edwards Lifesciences LLC, Irvine, CA).

CASE REPORT

A 71-year-old, white male with chronic obstructive pulmonary disease, hypertension, and a history of smoking was referred for treatment of an infrarenal AAA (45 mm in diameter), with right and left iliac artery aneurysms (30 and 40 mm, respectively). Although the infrarenal AAA was relatively small and may not have required immediate repair, large, bilateral iliac aneurysms were growing at an

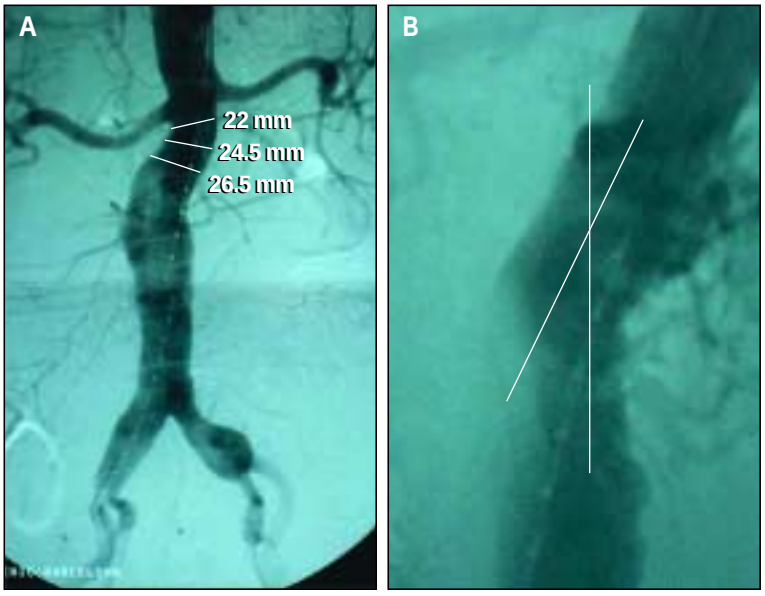

Figure 1. In this preoperative angiogram, the AP view showed a conical neck (A). The proximal diameter was 22 mm, and the distal diameter was 26.5 mm. The lateral view demonstrated a slight anteroposterior angulation (B).

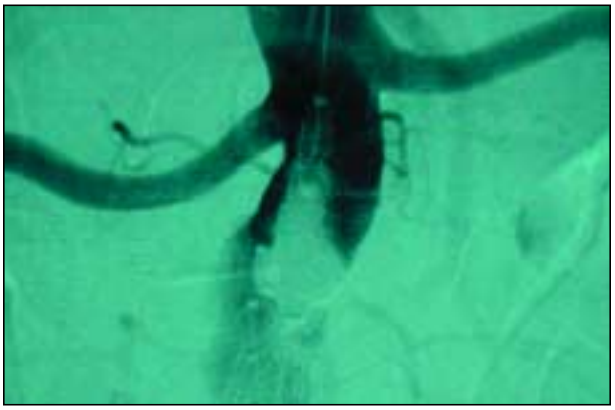

Figure 2. This intraoperative angiogram showed a slow, controlled expansion of the balloon, which allows gradual dilation of the narrower portion of the infrarenal neck and approximation to the landing zone.

aggressive pace. These aneurysms were causing lower abdominal pain, which validated the physician's decision to intervene. Because of the patient's compromised pulmonary status, the endovascular specialist decided to perform endovascular repair.

THE ISSUE OF OVERSIZING

When selecting an endovascular device for the patient with a conical neck, the interventionalist must take into consideration the amount of oversizing recommended by the manufacturer. Because oversizing is based on the largest measured diameter, in a conical neck this could mean stretching the narrower portion of the neck beyond a size that may be considered reasonable. Some researchers have noted that oversizing may increase stent graft apposition to the aortic wall, thereby enhancing fixation and possibly providing a margin of safety if dilation of the neck occurs at follow-up; however, it has been implicated in folding or wrinkling of graft fabric, which can cause endoleaks.[12,13] May et al[9] have suggested that self-expanding endograft oversizing contributes to future neck dilation. Although self-expanding devices are typically oversized by approximately 20%, Edwards Lifesciences recommends oversizing the balloon-expandable Lifepath AAA Graft System by 10% to 15% of the inner diameter of the aortic wall. This recommendation is consistent with the experimental findings of Chaufour et al.[14] In this study with cadaveric aortas, the author concludes that overdilatation of the aorta by 2 mm at pressures under 2 atm allows safe deployment, even in the presence of severe atheroma, and that rupture of the aorta is unlikely with overdilatation up to 6 mm, especially in less calcified vessels.[14]

The patient's infrarenal neck was conical in shape (Figure 1), with a 22-mm proximal neck diameter just below the renal arteries (PD1) and a 26.5-mm proximal neck diameter 15 to 20 mm below the renal arteries (PD2). The infrarenal neck measured 20 mm in length. The concern with this 20% diameter gradient (from PD1 to PD2) was in device sizing. If a self-expanding device were used to seal the larger PD2, a 31-mm or 32-mm device would have been chosen. This choice would mean that the PD1 would then be abruptly oversized by approximately 41%. In this case, the specialist selected a 27-mm, balloon-expandable device instead, which represented a 23% oversizing of PD1 and a 2% oversizing of PD2.

Both internal iliac arteries on this patient originated within the iliac aneurysm sacs. Because there have been no severe complications experienced to date at ICDB in 24 patients who have had both internal iliacs occluded (supported by similar experiences of other researchers),[14,15] the surgeon decided to proceed with bilateral hypogastric embolization. The patient underwent staged procedures performed 3 weeks apart to embolize the hypogastric arteries before undergoing endovascular AAA repair, which took place the day after the second embolization procedure.

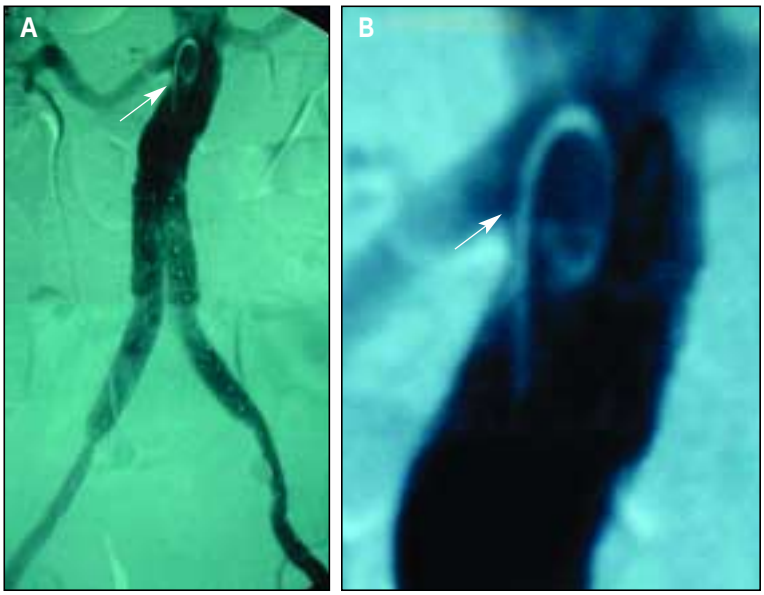

Figure 3. Immediate postoperative angiography revealed a precisely positioned endograft with no endoleak (A). The magnification shows the position of proximal wireforms very close to the lowest renal artery (arrows) (B).

THE PROCEDURE

Because the patient in this case was at risk of proximal neck damage or rupture, the surgeon used slow, staged balloon inflation during deployment of the Lifepath System's main graft body. This procedure enabled the proximal neck to dilate gradually and safely, while allowing the team to gauge the reaction of the narrower segment of the neck to the balloon dilatation (Figure 2).

Immediate postoperative angiography revealed a precisely positioned endograft with no endoleak (Figure 3). One-month CT scans showed complete exclusion of all aneurysms, no evidence of proximal neck recoil, no evidence of endoleak, and no graft migration (Figure 4A). The device had conformed well to the patient's tortuous anatomy; no signs of kinking in the limbs or main body were evident.

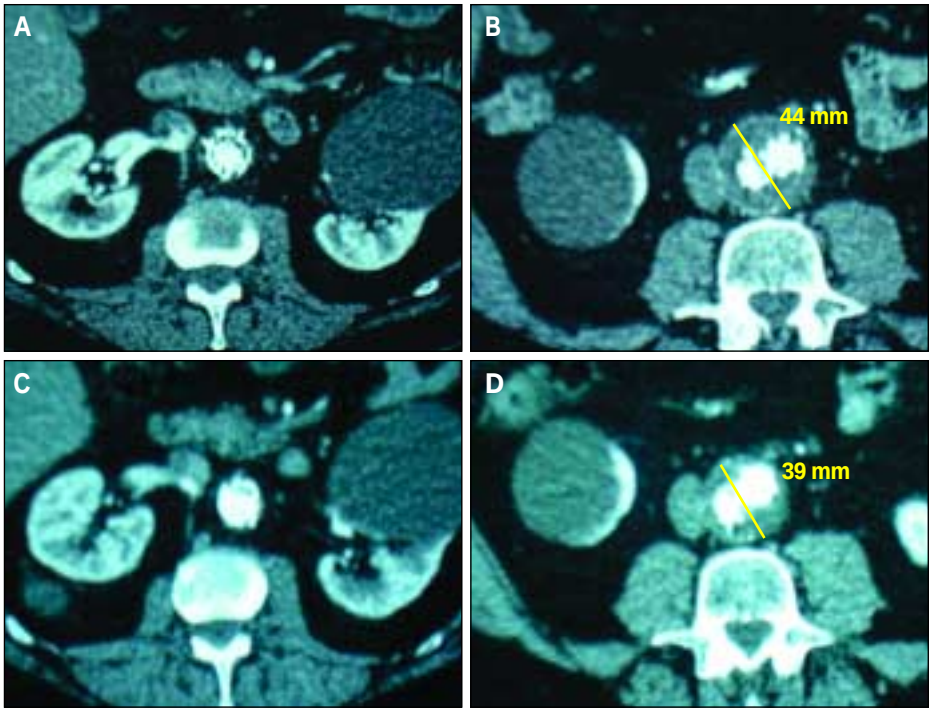

Figure 4. The 1-month postoperative CT scan showed complete exclusion of all aneurysms, no evidence of proximal neck recoil, and no graft migration (A,B). Six-month postoperative CT scan showed no complications, the same wireform on the neck, and a reduction in sac diameter (C,D).

At the patient's 6-month follow-up visit, no adverse events were registered; there was no endoleak, no device migration, and the AAA sac diameter was reduced (Figure 4B). In the immediate postoperative period, the hoop strength of the wireforms appeared to recontour the conical neck on x-ray (Figure 5A). Moreover, the postoperative

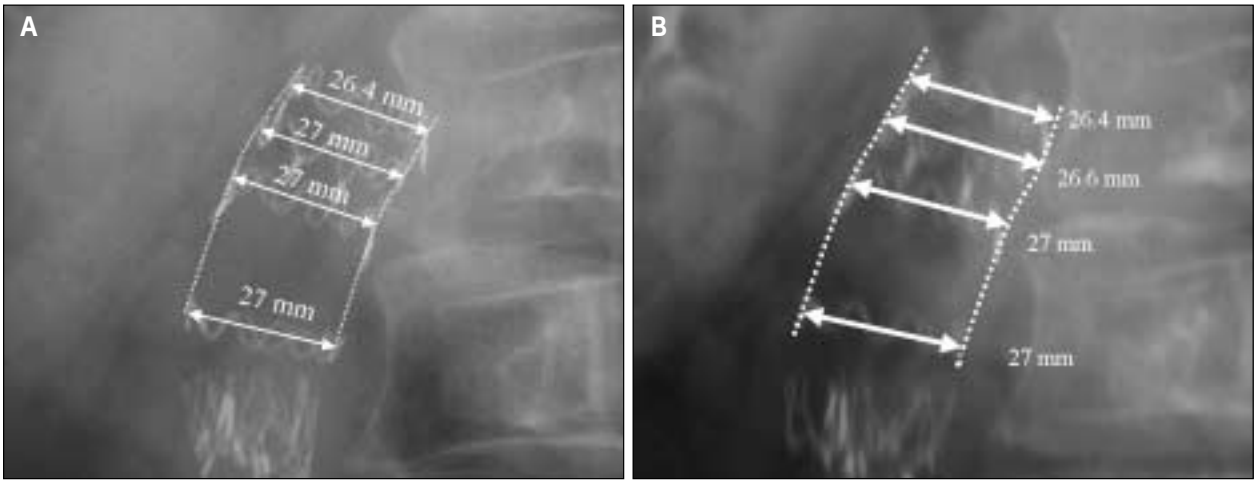

Figure 5. The 2-day postoperative plain x-ray with measurements clearly demonstrated a recontouring of the infrarenal neck (A). The 6-month postoperative plain x-ray with measurements showed maintenance of the recontouring effect exhibited in Figure 5A (B).

TABLE 1. VARIOUS DEFINITIONS OF A CONICAL NECK

AUTHOR	DEFINITION
Blum et al[1]	Cone-shaped, divergent walls (from proximal to distal)
Dias et al[2]	Increase in proximal neck diameter >2 mm for each cm of length
Stanley et al[3]	"Diameter progressively increases between the renal arteries and the sac" with a proximal neck contour change >3 mm
Chuter et al[4]	Change in proximal neck diameter of >5 mm from proximal to distal
Beebe et al[5]	Cone-shaped or tapered proximal neck that enlarges distally to >120% of the uppermost infrarenal diameter
Albertini et al[6]	"Neck coefficient" calculated using the following formula (D=diameter): Arctangent ([D3-D1]/[neck length]) X 180/pi (If the absolute value of the neck coefficient was >10, it was defined as conical or inverted conical; aortic neck configurations were defined as straight, conical, inverted conical, hourglass, or barrel types.)

dimensions remained unchanged at the 6-month x-ray examination, illustrating the maintenance of this recontouring effect (Figure 5B).

DISCUSSION

The specialist's decision to use an infrarenal fixation, balloon-expandable device in a patient with a conical neck is based on the belief that balloon-expandable stents have the ability to recontour the treated vessel. This recontouring is most likely related to the radial force generated by the balloon and maintained by the wireform structure. In contrast, self-expanding wireforms are typically less rigid and possess less hoop strength, thus they may not generate the radial force required to "reshape" a conical neck. Ten percent to 15% oversizing recommendations are also more ideally suited to the patient with a conical neck because the risk of unreasonably oversizing the narrower neck segment is reduced. Moreover, according to the Chaufour et al study,[14] this reshaping technique should be avoided in heavily calcified necks that need more than 2 mm of oversizing.

SUMMARY

Endovascular specialists should consider expanding the use of the Lifepath System to include appropriately selected AAA patients with conical necks, largely because of the device's apparent ability to recontour the conical infrarenal neck. The device can be gradually deployed and repositioned, if necessary, during placement. In addition, the oversizing recommendation for the Lifepath System is conservative and, when combined with slow and controlled expansion of the device in the narrower portion of the infrarenal neck, can yield a greater measure of confidence for the operator. ■

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Challenging EVAR Indications

Stenotic Proximal and Distal Aortic Necks

Patients with stenotic proximal and distal aortic necks present unique challenges in treatment planning.

BY **DIETER RAITHEL, MD, PHD**

There are numerous anatomic and morphologic variations in patients with AAAs, which present challenges to the clinician who wishes to perform endovascular AAA repair (EVAR), not the least of which are stenotic proximal and/or distal aortic necks. Prevention of complications such as endoleaks, graft migration, and graft thrombosis and/or occlusion after EVAR, depends largely on careful patient and device selection and accurate deployment technique.[1-6]

Patient anatomy and morphology are the primary determinants of whether a patient is a candidate for EVAR. Aortic stenoses do not typically present in isolation; there is concomitant calcification, thrombus, and/or angulation of the stenotic area. For example, patients with common iliac artery aneurysms often have a stenotic aortoiliac bifurcation resulting from calcium or thrombus at the origin of the common iliac artery.

A narrowed proximal or distal aortic neck puts the patient at increased risk for graft thrombosis and occlusion after deployment. The stenotic area often dictates that the selected stent graft size be smaller than would typically be chosen for a nonstenotic neck, and a smaller device diameter increases the tendency for stent graft body or limb occlusions. Focal lesions, especially in the presence of angulation, are particularly prone to graft kinking with subsequent thrombosis or occlusion after graft deployment.[4-8]

Each of these morphologic factors requires special consideration in procedure planning for the EVAR patient.

MANAGING THE EVAR PATIENT WITH A STENOTIC AORTIC NECK

Careful patient selection is mandatory in cases of stenotic aortic neck and must be based on morphologic

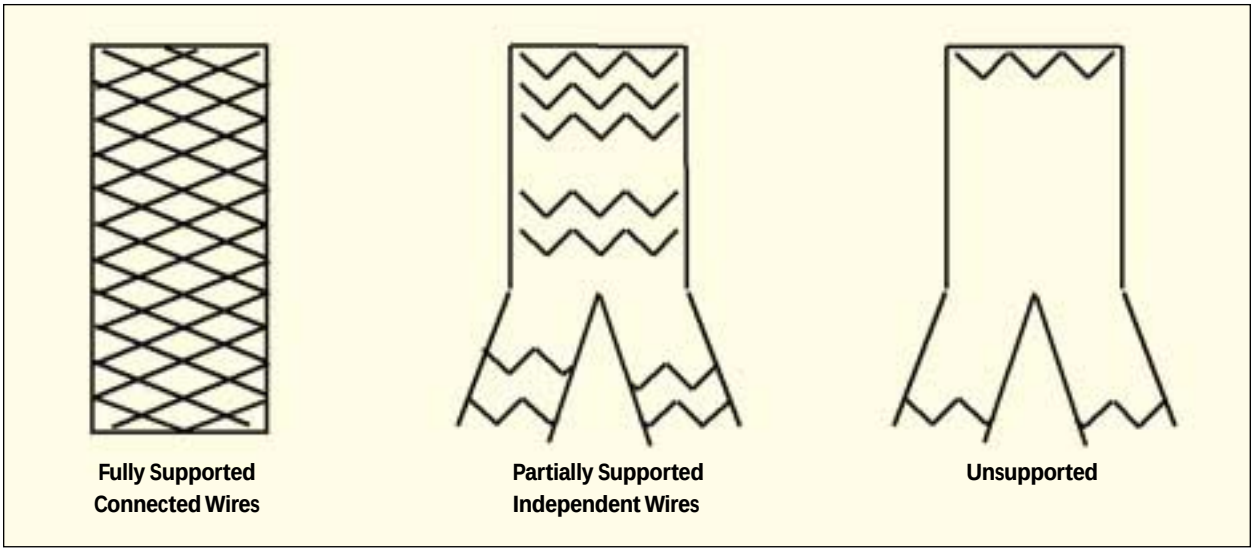

Figure 1. Different designs for EVAR stent grafts.

analysis of preoperative imaging studies. The preoperative imaging in our clinic includes a spiral CT with 3-mm cuts, and angiography with calibrated catheters.

During patient measurement and device sizing, it is necessary to consider that if the stent graft is excessively oversized, a degree of graft infolding may occur. This can create flow channels, around which blood can still communicate with the aneurysm sac or be a potential site of decreased flow.[5] Conversely, if the device is sized too narrowly, it may fit the stenotic portion of the artery but be undersized for the rest of the seal zone, predisposing the device to endoleak and migration. Therefore, device sizing must take into consideration:

- the diameter gradient between nonstenotic and stenotic areas to assess whether the device size required to seal the nonstenotic portion is unreasonably larger than the stenotic portion;
- the morphology of the stenotic portion; and
- the presence of angulation.

Generally, oversizing of the stent graft in a healthy vessel segment should not exceed 5 mm, after which point there is a greater risk of dissection and rupture. In an atherosclerotic vessel, oversizing should typically not exceed 3 mm to 4 mm because the risk of plaque fracture (with intact adventitia but disrupted intima) beyond this point is increased. Also, dilating beyond 6 mm increases the risk of vessel rupture. Heavily calcified lesions are typically resistant to dilation, and oversizing should not exceed 3 mm because the plaques can fracture fairly easily and the risk of rupture is relatively high.[9]

The presence of large thrombi in lesions creates an unstable surface for stent-graft fixation. These patients may not be suitable candidates for EVAR if thrombus is present in more than 50% of the seal zone surface. The presence of calcium and thrombus within an angulated vessel segment creates the additional problem of obtaining good conformance of the stent graft to the curvature of the vessel.

"Partially supported grafts provide both the metal support and the flexibility required"

STENT GRAFT DESIGN

With stenotic regions, the hypothesis is that, even if initially dilated, the lesion will attempt to resume its original configuration after device deployment (recoil), causing restenosis and possibly occlusion. For this reason, the type of device selected must consider the following (Figure 1):

- Unsupported grafts are not recommended, because they have no metallic framework with which to resist this recoil effect;[10]
- Supported grafts provide the metal framework required to provide resistance to compressive or recoil forces exerted by the vessel/lesion on the device:
  - Fully supported grafts (interconnected metal framework throughout the device length) provide the metal support required but lack the flexibility needed to adapt to primary angulation, as well as to the morphologic changes that occur over time; and
  - Partially supported grafts (metal framework throughout the length of the device but independent wireforms) provide both the metal support and the flexibility required. This is the preferred design, particularly for patients with stenotic aortic necks.

DEPLOYMENT MECHANISM

Another important consideration is the mechanism of stent graft deployment. Stenotic arteries exert compressive forces on the stent graft, resulting in postdeployment graft diameters that can be significantly narrower

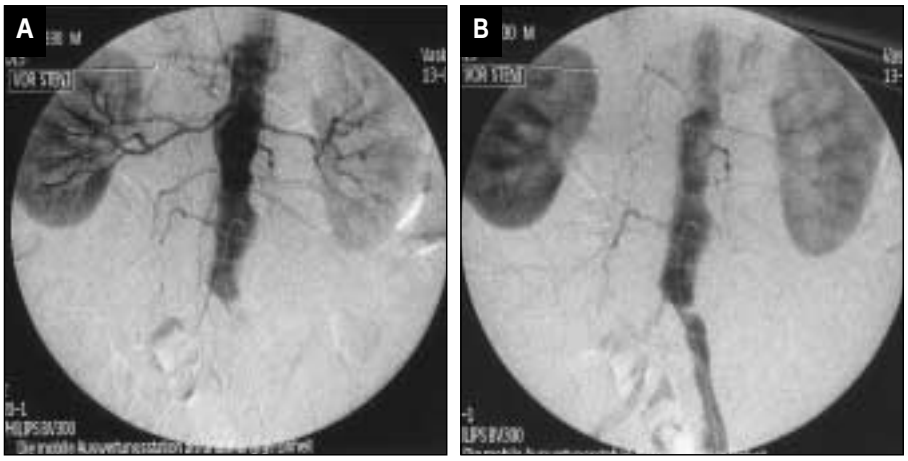

Figure 2. An angiogram obtained before deployment shows stenosis just proximal to a 5-cm infrarenal AAA.

than the limbs of the implanted graft.[7,8] The risk of graft occlusion related to compression-induced thrombosis is, therefore, increased. Self-expandable devices do not have the necessary radial force to efficiently dilate a stenotic lesion in the initial deployment. Consequently, balloon expansion of the lesion is typically required before and/or after device deployment. Additionally, they do not have sufficient hoop strength to resist postdilatation lesion recoil.

Balloon-expandable devices are preferred because they provide an ideal combination of high radial force for dilatation during balloon deployment, and hoop strength after deployment to resist recoil, thus stabilizing the lesion.

"Because both iliac limbs of the Lifepath System are balloon expandable, simultaneous dilatation and stent grafting of the lesion are possible."

THE LIFEPATH AAA GRAFT SYSTEM

The Edwards Lifepath AAA Graft System (Edwards Lifesciences LLC, Irvine, CA) is the optimal graft for patients with stenotic proximal and distal aortic necks.

The introducer sheath is hydrophilic-coated and highly flexible, characteristics which, in my experience, enable it to navigate through stenotic, calcific, and tortuous regions.

The graft has partially supported, concentric wireforms interwoven through conventional, standard thickness woven polyester fabric. The wireform configuration ensures a high degree of device flexibility. The graft is fixated to the aortic wall by a combination of friction fit and anchorage by extended wireforms (hooks). Because it is balloon-expandable, the device has a very high radial force and hoop strength, both of which are required to provide an optimal seal while simultaneously resisting recoil pressures exerted on the device by stenotic lesions.

In a stenotic distal aortic neck, the preferred deployment approach is the kissing-balloon technique. Because both iliac limbs of the Lifepath System are balloon expandable, simultaneous dilatation and stent grafting of the lesion are possible. Even in tight aortoiliac regions, the hoop strength of the balloon-expandable system resists recoil and helps keep the distal sac open.

CASE REPORT

The patient was a 72-year-old, white man with multiple risk factors (coronary heart disease, cerebral vascular insufficiency) with a 5-cm infrarenal AAA (Figure 2A,B). He had a stenotic proximal neck measuring 23 mm in diameter just below the renal arteries and 16 mm just above the aneurysmal sac (Figure 3A,B), a stenotic and calcific distal aortic neck measuring 14 mm in diameter, and stenotic iliac arteries with significant calcification (Figure 4).

Dilatation of the stenotic iliacs with a balloon catheter was performed prior to EVAR with implantation of the Lifepath System. The main body diameter was 25 mm; 2-mm oversizing in the proximal portion of the aorta was within the standard range, whereas the 7-mm oversizing

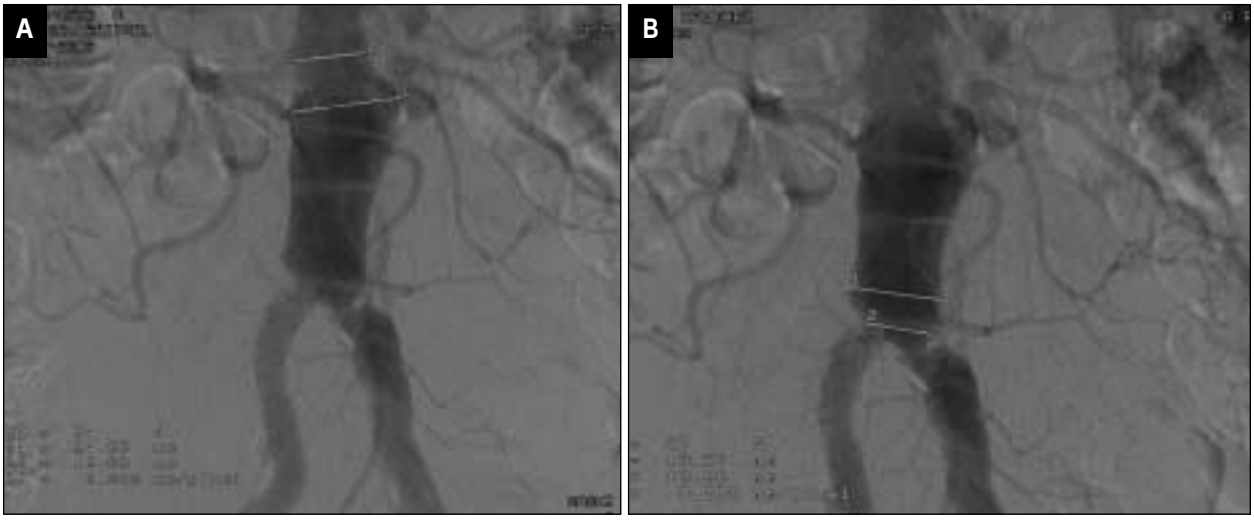

Figure 3. Preoperative measurements show stenotic areas of the proximal aorta (A) and the distal aorta and iliacs (B).

in the distal portion of the proximal neck was justifiable because the 16-mm segment was very short and much of the lumen narrowing seen was due to thrombus. There was only minor calcification.

Two 16-mm iliac grafts were used on the two stenotic iliacs. Completion angiography showed optimal perfusion of both renal and iliac arteries, without evidence of endoleak (Figure 4).

At the 6-month follow-up, the peripheral pulses were perfectly palpable. The Duplex ultrasound showed no endoleak and optimal perfusion of both iliac limbs.

SUMMARY

Patients with stenotic proximal and distal aortic necks present unique challenges in treatment planning for EVAR. There are particular considerations for device selection and sizing in this group of patients that must be taken into account to achieve the goal of aneurysm sac exclusion. At the Klinikum Sud in Nuremberg, Germany, my experience includes approximately 850 endovascular stent graft implantations over 8 years. Based on these experiences, I have developed some general guidelines for device selection and sizing for patients with stenotic aortic necks.

The decision about optimal device sizing is dependent on the patient anatomy and morphology, as assessed with 3-mm spiral CT scan and calibrated angiography. Healthy vessel segments can be oversized up to 5 mm; beyond this point, there is an increased risk of dissection and rupture.

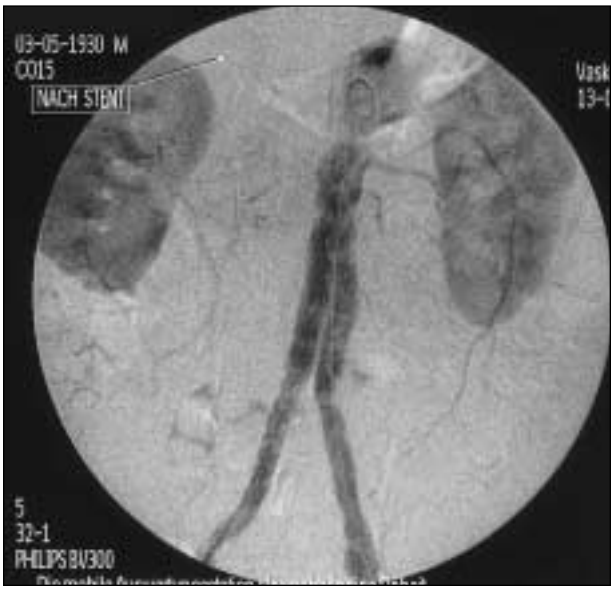

Figure 4. An angiogram obtained after deployment shows stenotic iliac arteries with significant calcification.

Atherosclerotic vessels without heavy calcification or thrombus can be oversized by 3 mm to 4 mm, after which point the risk of plaque fracture with intimal tearing increases.

Heavily calcified lesions can be oversized up to 3 mm, after which point the risk of plaque fracture and rupture increases in this potentially unstable morphology.

Angulated, stenotic lesions with extensive calcium and/or thrombus may not be suitable candidates for EVAR. If the patients are approved for EVAR, adjunctive measures (such as predilation or additional ballooning of the iliacs after deployment of the graft) may be required to adequately dilate this lesion, for example in nonlesion-supported grafts, and ensure device conformability.

The ideal wireform structure is partially supported, providing the high degree of device flexibility required to adapt to angulations and morphologic changes over time.

Balloon-expandable devices are preferred because they provide an ideal combination of high radial force for dilatation during balloon deployment, and hoop strength after deployment to resist recoil, thus stabilizing the lesion. In addition, this type of device delivery enables simultaneous lesion dilatation and stenting, and utilization of the kissing-balloon technique for limb deployment. ■

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EVAR Patients with Challenging Iliac Arteries

The Edwards Lifepath AAA Graft System may facilitate EVAR in these patients.

BY PATRICK PEETERS, MD; MARC BOSIERS, MD; JÜRGEN VERBIST, MD; AND KOEN DELOOSE, MD

The importance of the iliac anatomy during endovascular aneurysm repair (EVAR) cannot be underestimated. The success of EVAR depends in large part on the adequacy of iliofemoral access and the morphology of the iliac arteries, both of which determine the deliverability of the stent graft components and the ability to maintain a fluid-tight seal zone.[1]

As is frequently recognized, approximately 40% to 50% of patients currently presenting with AAA are candidates for EVAR.[2] The statuses of the proximal neck and iliac anatomy are two primary considerations in the decision to treat via endovascular repair. Schumacher et al[3] stated that the presence of diseased iliac arteries might reduce the total number of EVAR candidates to 40%. In a series of 307 AAA patients, Carpenter et al[4] diagnosed iliacs of insufficient size in 48 patients (16%), iliac aneurysms involving the hypogastric arteries in 22 patients (7%), and tortuous iliac arteries in 10 patients (3%), all resulting in exclusion for EVAR. It has been shown that even in those patients who have been accepted for EVAR, nearly 47% will require additional procedural steps specifically related to the iliac arteries.[5]

Careful preprocedural screening can obviously help identify potential difficulties during EVAR, but current imaging modalities are somewhat imprecise and qualitative at best. Arteriography, most commonly performed in the anteroposterior projection, underestimates the exact degree of stenosis, and even with the use of calibrated measurement catheters, an accurate length cannot be measured reliably. Although contrast-enhanced CT scans, ideally in 2-mm slices, enable acceptable diameter measurements in nontortuous anatomy, they have limited value in precise visualization. Because precise quantification of tortuosity is impossible, obtaining accurate diameter and length measurements in tortuous anatomy is difficult. Additionally, because of volume averaging, the exact amount of stenosis is difficult to estimate. However, CT-scan imaging may be useful in displaying the amount of calcification, which can also be diagnosed by plain abdominal x-ray in both oblique projections.[6]

The use of three-dimensional imaging enables both qualitative and quantitative patient assessment. Using contrast-enhanced spiral CT scans, the Preview System (Medical Media Systems, West Lebanon, NH) reconstructs flat CT scan images into three-dimensional images. All diameter and length measurements are made using the centerline blood flow, preventing the inaccuracies typically encountered when using the perpendicular slices of CT scans. Vessel tortuosities and the presence of calcium and thrombus are readily visible. "Virtual

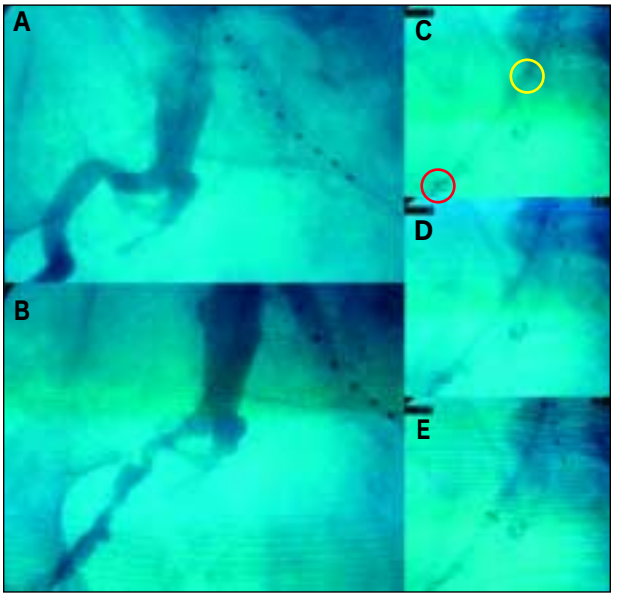

Figure 1. A tortuous iliac artery is crossed with a guidewire (A,B). The Lifepath System dilator/sheath assembly is advanced through the tortuous iliac artery (distal dilator shown in *red circle*; distal introducer sheath shown in *yellow circle*) (C). The dilator is advanced further ahead of the sheath to facilitate eventual sheath passage (D). The dilator/sheath has successfully and safely passed the tortuosity (E).

sheaths" can be inserted to test for proper anatomical and dimensional fit prior to the procedure. Thus, use of the Preview System in preoperative assessment and planning has the potential to prevent complications related to unanticipated iliac problems.

"...even in those patients who have been accepted for EVAR, nearly 47% will require additional procedural steps specifically related to the iliac arteries."

STRATEGIES FOR MANAGING ILIAC ARTERY CHALLENGES

Iliac artery challenges can manifest themselves in different ways during EVAR. Small vessels, calcified stenoses, aneurysms, and tortuosities at the iliac region often make endograft placement far more laborious than in EVAR cases with normal iliac vasculature.

Small iliac arteries are typical for female patients. Because the external iliac artery has to accommodate introducer sheath profiles varying between 18F to 22F, the minimal external iliac diameter of a patient suitable for EVAR should be at least 7 mm (depending on device selected). Approximately 8% of the total population, primarily women, present with smaller external iliac diameters.[7] Attempts can be made to predilate with the Edwards Lifepath AAA Graft System's long tapered dilator. Its hydrophilic coating is necessary to navigate in these tight vessels (Figure 1). In our personal experience, the presence of small-diameter external iliac arteries is a contraindication for EVAR because endovascular treatment attempts may result in arterial dissection, avulsion, or rupture. These patients should be referred for open surgical repair.

In calcified, stenotic iliac arteries, preprocedural definition of both degree of calcification, as diagnosed by plain abdominal x-ray, CT scan, or IVUS, and minimal lumen diameter, are mandatory. No endovascular intervention should be performed on patients presenting with either heavily calcified iliac vessels or concentric calcification of the aortic bifurcation, which cannot be broken by simple predilation, unless the physician is willing to implant an monoaortoiliac device. If the minimal lumen diameter of the iliac arteries appears to preclude easy insertion of the device's introducer system, but EVAR remains the most suitable treatment option for a given patient, there are several methods to consider for gaining access.

Ordinarily, the first option is simple predilation of the vessel with a dilator. The Lifepath System shows excellent crossability in this type of lesion due to its extra-long, hydrophilic-coated dilator, which enables predilation by advancing the dilator ahead of the introducer system. Our experience shows that additional preprocedural percutaneous transluminal angiography (PTA) is seldom necessary to allow Lifepath dilator/sheath passage. After the dilator/sheath crosses the lesion, all system components are subsequently passed through the introducer, protecting the grafts while crossing the stenotic area. Because the Lifepath System is balloon expandable, the simultaneous PTA of stenotic lesions during graft deployment will prevent any postprocedural flow obstruction. Another means of bypassing these difficult access vessels is the use of different types of iliac conduits, as suggested by Abu-Ghaida et al.[8]

Another frequently encountered problem when performing EVAR is the presence of combined abdominal

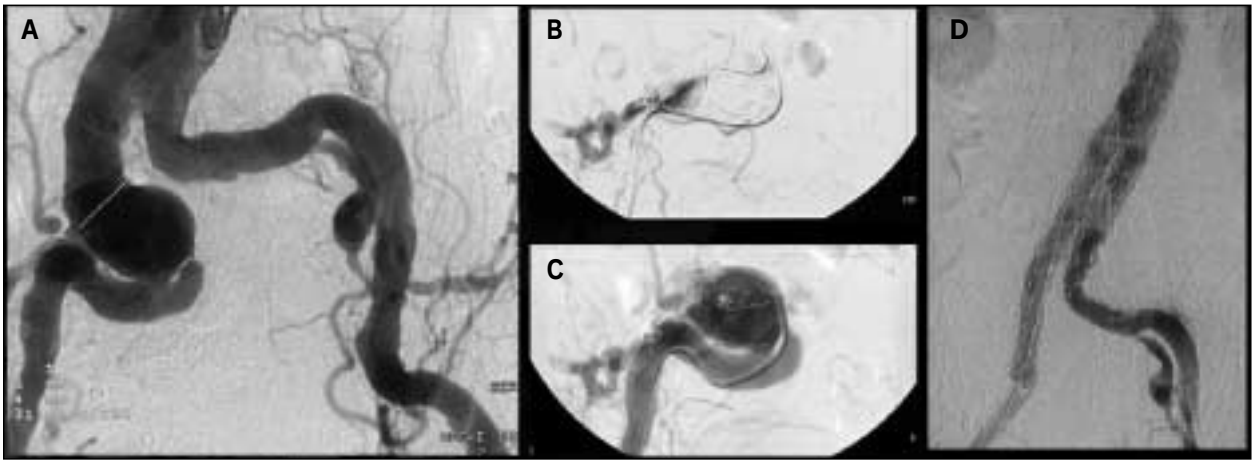

Figure 2. A typical iliac aneurysm involving the right hypogastric artery (A). Coiling of the right hypogastric artery (B,C). Complete exclusion of the AAA with the Lifepath System covering the right hypogastric artery (D).

Figure 3. Kinking of an endograft caused by a tortuous iliac artery.

and iliac aneurysmal disease. Twenty percent of all patients presenting with AAAs are diagnosed to have an additional iliac aneurysm.[9] A maximal distal seal-zone diameter of at least 2 mm smaller than the largest limb graft available is a threshold for optimal hemostatic sealing and graft fixation.[10] In iliac aneurysms that do not extend into the hypogastric arteries, there is often only a very small working area available as a landing zone, making precise placement of the limb grafts essential. The opportunity to acquire angiograms through the side port of the Lifepath graft delivery system just prior to deployment of the endograft aids in this mandatory precise positioning. If the largest diameter limb graft available is not sufficient to secure proper sealing and fixation, the use of aortic or flared cuffs—the so-called *bell-bottom technique*[11,12]—can offer an alternative to exclusion of the iliac aneurysm by actually using part of the aneurysmal area as a seal zone. Because it is questionable whether an aneurysmal area can actually be an effective seal zone, a more frequently used solution is the extension of the limb graft over the hypogastric artery into an external iliac artery zone with sufficient diameter. In these cases, preprocedural occlusion of the hypogastric by coiling with Gianturco (Cook Incorporated, Bloomington, IN) stainless-steel coils, implantation of an Amplatz Spider obstructing device (ev3, Inc., Plymouth, MN), or occlusion with detachable balloons, are considered to prevent occurrence of type II endoleaks,[13,14] which can cause high sac pressurization and consequently increase the risk of aneurysm rupture (Figure 2). Our experience has shown that one hypogastric artery can be sacrificed without causing pelvic or spinal ischemia if the remaining hypogastric is not diseased. If iliac aneurysmal size necessitates covering both hypogastric arteries, the need to revascularize them to prevent ischemic symptoms of the pelvis and spinal circulation remains in question. In addition to providing surgical collaterals by relocation[15] or iliac conduits,[13,16] natural collaterals can also be formed by staged coiling within a timeframe of 3 to 4 weeks. Although it is acknowledged that the presence of combined iliac and abdominal aneurysmal disease makes EVAR more difficult and laborious, its presence does not necessarily cause less-satisfactory midterm results.[17]

Tortuous iliac arteries can complicate both vascular access and graft-to-artery wall apposition. Tortuosity in and of itself is problematic, but when it occurs in conjunction with a small-diameter vessel, calcification, thrombus, and/or stenosis, an increasingly challenging situation arises. With the use of a superstiff guidewire and an introducer system, both of which can navigate the tortuosity, the tortuosity can usually be straightened enough to enable safe device delivery.[18,19]

Figure 4. A patient presented with AAA with tortuous iliac arteries (A). Postprocedural imaging of the Lifepath System excluded AAA demonstrated slight recontouring of iliac angle and graft adaptation to the tortuosity (B,C).

If stiff wires cannot sufficiently stretch the vessel, the body-floss technique, a brachial-femoral wire offering more firm support, can be administered to facilitate stretching and device delivery.[18-20] When using either technique, vessel recoil must be anticipated as the vessel tries to resume its original shape. This recoil can increase the pressure on the graft during deployment, causing malpositioning. It can also result in graft kinking after deployment or affect the seal zones and overlap zones of the device, potentially causing limb dislocation (Figure 3).

The design of the Lifepath System facilitates endovascular AAA exclusion in patients with tortuous access vessels in several ways. The delivery system is highly flexible, permitting navigation through substantial tortuosity. Once the tortuosity is traversed, all graft components remain covered within the sheath until the time of deployment, protecting the endograft from the vessel wall. Furthermore, the hoop strength of the balloon-expandable system and the iliac graft flexibility attributed to the partially supported wireform structure prevents device recoil and kinking that can occur after EVAR device delivery in patients with tortuous iliac arteries (Figure 4).

SUMMARY

Challenging iliac artery anatomy can seriously complicate endovascular AAA repair. Despite careful preprocedural imaging, not every challenge can be anticipated. There are several effective methods for dealing with these challenges, with documented favorable clinical outcomes. The Edwards Lifepath AAA Graft System facilitates implantation in diverse and challenging iliac arteries. The introducer system is hydrophilic-coated and highly flexible, enabling it to easily navigate tortuous vessels. The extra-long dilator enables advancement ahead of the sheath for predilation of narrow or stenotic vessels.

After dilator removal, the sheath remains firm enough to straighten the tortuous vessel, preventing kinking by recoil pressure of the tortuous vessel and allowing precise graft positioning. Once deployed, the hoop strength provided by the balloon-expandable, independent, wireforms slightly recontours the vessel and minimizes the degree of vessel angulation while maintaining a patent lumen, even in a highly tortuous position. The highly flexible nature of the iliac grafts enables adaptation to the anatomy as it changes, minimizing the risk of pullout or limb dislocation. ■

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