Standard EVAR for the 10-mm Neck

A comprehensive strategy composed of the essential experience and technology needed to achieve satisfactory outcomes when treating short-necked aneurysms.

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The preferred therapeutic options for infrarenal abdominal aortic aneurysms (AAAs) with short proximal landing zones are open surgical repair or endovascular treatment with custom-made fenestrated stent grafts (Figure 1).[1,2] However, significant comorbidities frequently limit the role of open surgical repair, and the use of custom-made fenestrated devices is restricted by morphological criteria and delays in availability related to the complexity of manufacturing. "Off-the-shelf" fenestrated and branched solutions are still under development, and evidence on their long-term durability is lacking.

Standard endovascular aneurysm repair (EVAR) is sometimes the only option for patients deemed unfit for open repair and when custom-made fenestrated devices are not feasible. EVAR should only be performed after robust consideration of the pros and cons of using a device outside of the manufacturer's instructions for use (IFU). The incidence of type IA endoleak, migration, and reintervention are higher when EVAR is extended beyond the IFU.[3] Despite this, immediate recognition and intervention can result in short- and midterm outcomes not dissimilar to EVAR with favorable morphology.[4,5] However, long-term outcomes remain undefined. A comprehensive strategy that utilizes advanced endovascular experience and technology is essential to achieve a satisfactory outcome following standard EVAR for short-necked aneurysms.

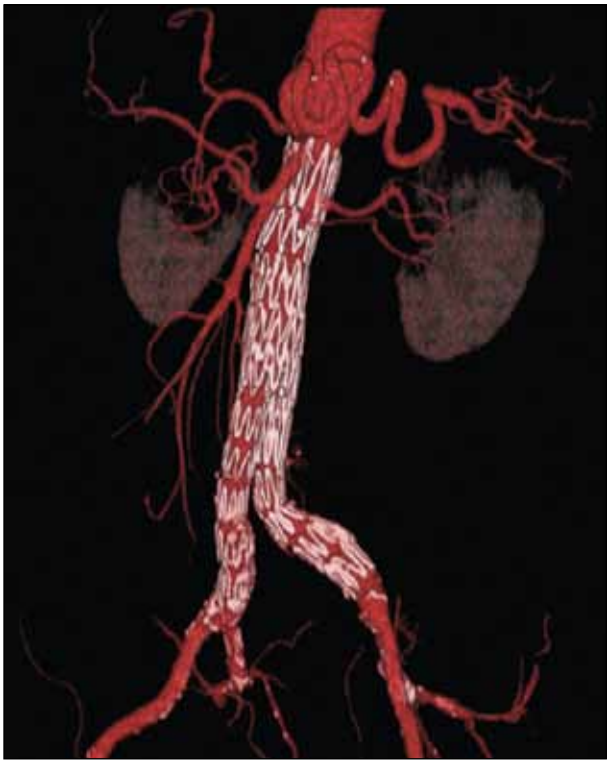

Figure 1. Completion imaging after fenestrated stent graft deployment (3D reconstruction).

DEVICE SELECTION

Selecting an appropriate device is essential in maintaining a successful and durable outcome. Despite significant improvements in first-generation stent graft designs, no ideal device exists for short-neck aneurysms. Selection of a particular stent is influenced not only by the presence of a short proximal neck, but also on device familiarity, availability, and other adverse anatomical features such as neck angulation and access vessels. As a rule, it is not possible to consider one parameter of aortic morphology in isolation. All parameters of the proximal neck need to be integrated to form an estimate of relative risk. Experience with a

number of devices is advisable to enable knowledgeable device selection. Suboptimal device deployment due to inexperience with a particular device is equally important in terms of procedural outcome.[6,7]

Most EVAR devices have formal regulatory approval for use in aneurysms with a 15-mm minimum proximal neck length. More recently, devices have been approved for use in shorter neck lengths. The latest-generation Endurant device (Medtronic, Inc., Minneapolis, MN) has gained approval for use in aneurysms with a minimum proximal neck length of 10 mm (Case 1). The combination of a shorter body length, "M-shaped" configuration of nitinol stents, and improved active fixation provides potentially greater conformability and resistance to migration in shorter proximal neck lengths.[8]

Early outcomes using the Endurant device in aneurysms with a mean proximal length of 10.6 mm show satisfactory results, with no type IA endoleak detected at 30 days.[9] Longer-term data are being collected prospectively within the ENGAGE registry. It should be noted that other morphological criteria are incorporated into the IFU for the Endurant device, including the absence of excessive intraluminal thrombus, calcification, infrarenal angulation < 60°, and a maximal neck diameter of 32 mm.

The IFU for the Zenith Flex device (Cook Medical, Bloomington, IN) includes a minimum neck length of 15 mm. However, substantial long-term data, the availability of large graft diameters, suprarenal bare-metal stents, and a delivery system that facilitates precise deployment have increased confidence levels in using the device for treating aneurysms with challenging morphology.[10] A 5-year follow-up of EVAR using the Zenith device showed a similar incidence of endoleak and reintervention in aneurysms with a short neck (5–15 mm) to those with a neck length in excess of 15 mm.[11] Worse outcomes were associated with a combination of adverse features, such as excessive angulation and short neck length.

Adequate proximal fixation is essential in maintaining a circumferential seal and reducing caudal migration. Incomplete apposition and migration are associated with an increased incidence of type IA endoleak and subsequent rupture. Although active fixation appears to be superior to radial force in preventing graft migration, the level of fixation relative to the renal arteries is contentious.[12] Advocates of suprarenal fixation highlight the importance of fixation to a segment of the aortic wall that is "normal" and less likely to undergo aneurysmal dilatation. Others prefer the conformability of devices that employ infrarenal fixation, such as the Excluder device (Gore & Associates, Flagstaff, AZ). Better apposition in angulated necks and the increased difficulty in cases of device explantation are other reasons cited in support of devices with infrarenal fixation.[13] So far, there is no strong evidence to suggest a significant difference in outcomes between devices that utilize infrarenal versus

CASE 1. TREATING A 10-MM NECK WITH THE ENDURANT DEVICE

A 65-year-old man presented with a 6.5-cm AAA with a short (10 mm) proximal neck. He was deemed to be unsuitable for open repair due to evidence of cardiac ischemia on a stress echocardiogram. Precase planning consisted of 3D CT reconstruction software (3mensio Medical Imaging BV, Bilthoven, The Netherlands) (Figure 1). A standard EVAR procedure was performed using the Endurant device. It was deployed close to the origins of the renal arteries, with satisfactory postprocedural imaging (Figure 2).

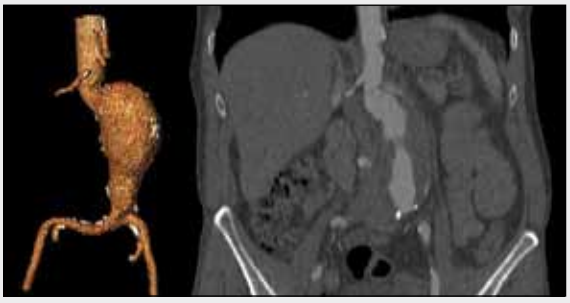

Figure 1. CT images and 3D reconstruction showing a short-necked 6.5-cm AAA.

Figure 2. Completion imaging after an Endurant device was deployed in a short-necked aneurysm (3D reconstruction).

CASE 2. USE OF A PROXIMAL CUFF TO TREAT A SHORT-NECKED ANEURYSM

A 74-year-old woman underwent EVAR for a 5.6-cm AAA with a 10-mm angulated, proximal neck. A 32-mm Endurant device was placed despite a native proximal neck diameter of only 23 mm. Surveillance by Duplex ultrasound at 6 months indicated a 9-mm sac expansion. Although no obvious endoleak was demonstrated on CTA, the main body was positioned low (Figure 1). A 32-mm Endurant proximal extension cuff was placed to improve stent graft apposition (Figure 2). Reintervention follow-up was satisfactory, with no further sac expansion.

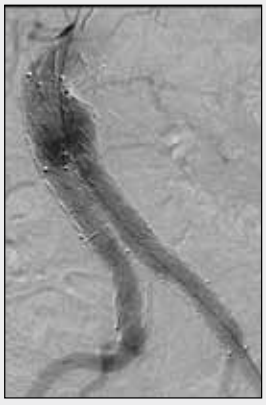

Figure 1. Low device placement.

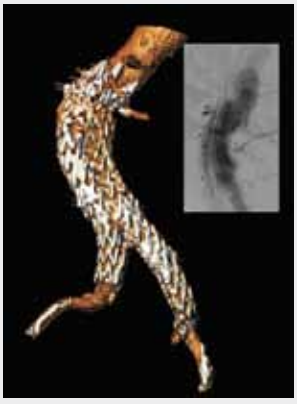

Figure 2. Imaging after proximal cuff insertion.

suprarenal fixation in AAAs with short necks.[12]

Novel fixation mechanisms may provide an enhanced proximal seal in the face of hostile neck morphology. The Ovation device (TriVascular, Inc., Santa Rosa, CA) has conformable, polymer, inflatable rings and has been developed for short-necked aneurysms.[14] The AFX stent (Endologix, Inc., Irvine, CA) "sits" on the aortic bifurcation to prevent migration and has shown encouraging results, including a proportion of patients with short-necked aneurysms.[15] The Nellix device (Endologix, Inc.) incorporates a polymer-filled sac to fill and seal the aneurysm. Satisfactory early results have been demonstrated in aneurysms with adverse neck anatomy.[16] Further clinical studies with these devices are awaited with interest.

Some interventionists have advocated the chimney technique to gain a seal in short proximal necks by positioning renal stents alongside conventional EVAR devices.[17] This technique is more expensive and complex than standard EVAR but cheaper than custom-made devices, and it employs a standard range of endovascular components. There is a risk of stent fracture and the inherent tendency of an endoleak to occur through the gutter between the components.[17] Long-term results are lacking, and durability may be a concern.

> Off-the-shelf solutions are being developed to address some of the shortcomings of custom-made stent grafts, but off-the-shelf devices share similar concerns over long-term durability.

Off-the-shelf solutions are being developed to address some of the shortcomings of custom-made stent grafts. The Pivot fenestrated stent graft (Cook Medical) comprises a 15-mm "domed" fenestration, which enables cannulation of the branch in proximity to the outer circumference of the fenestration.[18] This configuration should allow the treatment of a significant proportion of juxtarenal aneurysms with a small range of device components. Off-the-shelf devices share similar concerns over long-term durability, in particular, relating to the resultant strain and lack of conformity from the mismatch between the stent graft components and aneurysm/branch morphology. These concerns demand the collection of robust mid-to-long-term data.

PERIOPERATIVE IMAGING

High-quality imaging and detailed planning are essential when treating aneurysms with challenging neck morphology. Spiral multidetector CT angiography (CTA) is currently the gold standard for preoperative planning.[19] Case planning with the aid of post-CTA image processing (3D centerline reconstruction) has been found to be more accurate and reproducible than other imaging modalities.[20,21] However, in severely angulated proximal aortic necks, centerline length measurements tend to overestimate neck length.[22]

Poor intraoperative imaging can lead to suboptimal device positioning and an increased likelihood of endoleak, caudal migration, and iatrogenic coverage of visceral branches. Modern hybrid theater suites with either fixed or mobile imaging units and tableside controls provide high-resolution images and an expanded field of view. Contemporary fluoroscopy units with on-table biplane digital subtraction angiography provide improved definition of vessels and proximal device markers at reduced contrast and radiation loads.[23] A larger field of view provides the ability to see a longer proportion of the stent during important maneuvers such as stent graft advancement and deployment, which results in fewer changes of table or C-arm configuration and better spatial awareness.

For optimal visualization of the proximal neck region, the C-arm craniocaudal and lateral position needs to be perpendicular to the longitudinal axis of the neck at the level of deployment. Although C-arm positioning can be anticipated during planning, device insertion often alters neck morphology. Orientation should be adjusted after stent introduction and prior to deployment. Once the optimal position is achieved, the table and C-arm configuration is locked, and slow and controlled device deployment is commenced under magnified projection.[13] Also, main body insertion should be performed from the side that offers better alignment with the proximal neck angulation to help maintain the position during deployment.

A minimum of two postdeployment angiography views is essential to assess satisfactory device position and the presence of endoleak. Imaging adjuncts such as rotational angiography have been shown to increase the detection rate of immediate endoleak and reduce the incidence of early reintervention, with no significant increase in screening duration or radiation dose.[24]

ADJUNCTS TO EVAR

Despite careful planning and device selection, adjunctive procedures may be required to gain a satisfactory proximal seal. Type IA endoleak is the most common cause for reintervention following EVAR.[25] Poor apposition between the graft and the native aortic neck wall increases the potential for endoleak, migration, and rupture.[26] Despite the fact that immediate type IA endoleaks are more common in short-necked aneurysms, immediate recognition and primary intervention can result in satisfactory outcomes.[5] Low deployment or caudal migration can usually be treated by placement of a proximal extension cuff as demonstrated in Case 2.[27]

Ancillary Grafts

The Zenith Renu AAA ancillary graft (Cook Medical) has transrenal fixation and a proximal sealing zone and is also effective in dealing with caudal migration and endoleak associated with adverse neck morphology.[28] Limitations of the use of this adjunct relate to a maximum proximal neck diameter of 32 mm, an infrarenal angle < 60°, and a suprarenal angle < 45°.

Occlusion Molding Balloons

If the device position appears satisfactory, initial treatment of the endoleak is performed by molding the proximal main body with a compliant balloon (eg, Coda [Cook Medical] or Reliant [Medtronic, Inc., Minneapolis, MN]) to improve apposition (Figure 2). Caution is required in the presence of intraluminal thrombus, and balloon occlusion of the renal arteries can prevent embolization. Similarly, during stent deployment in short-necked aneurysms, renal cannulation can assist in accurate deployment of the main body immediately below the ostium of the lower renal artery.

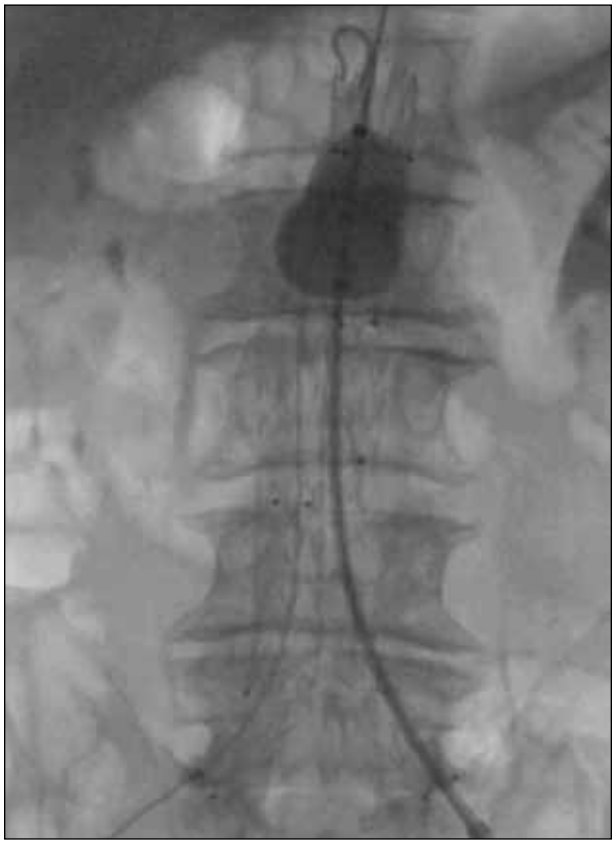

Figure 2. Balloon molding at the proximal landing zone.

Balloon-Expandable Stents

Deployment of a balloon-expandable stent (Palmaz, Cordis Corporation, Bridgewater, NJ) across the junction between the stent graft and the proximal neck/suprarenal aorta has been shown to be effective in treating early and delayed type IA endoleaks (Figure 3).[29] Clinical effectiveness seems to be maintained on mid- and long-term follow-up despite morphological alterations to these stents over time.[27,30] Balloon-expandable stent placement increases the radial force of the proximal stent graft and enhances resistance to migration. Some advocate deployment of balloon-expandable stents in adverse neck morphology, even in the absence of endoleak.[31] Prophylactic placement has to be balanced against the additional cost, increased difficulty of future access to adjacent visceral branches, and the potential for aortic trauma during deployment.

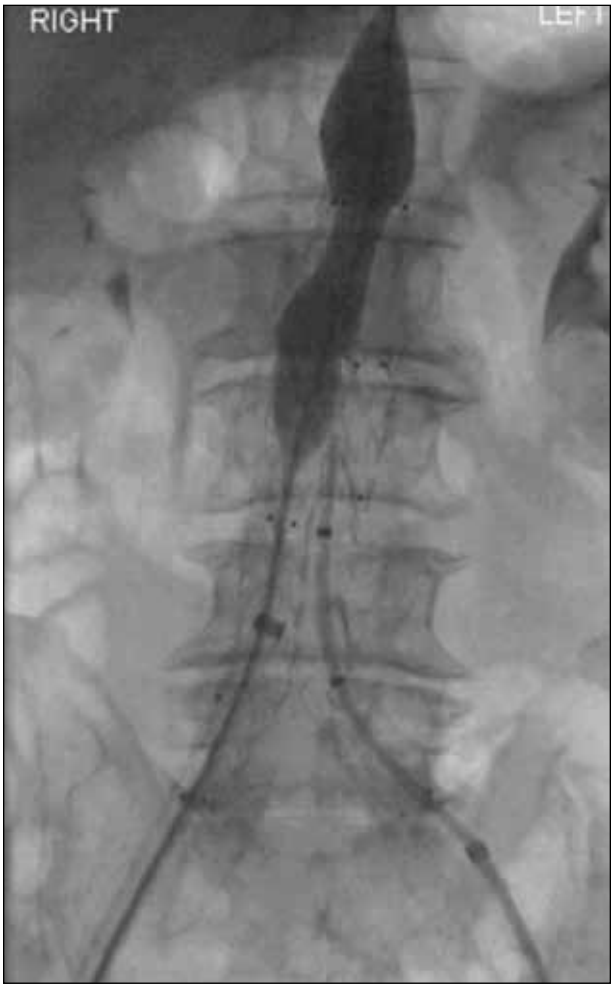

Figure 3. Palmaz stent deployment

Endograft Sealing and Fixation Systems

Despite improved stent design, considerably less force is required to induce movement of the devices compared to the sutured prosthesis used in open repair. Endoanchors such as the Heli-FX aortic securement system (Aptus Endosystems, Inc., Sunnyvale, CA) and EndoRefix (Lombard Medical Technologies, Oxfordshire, UK) have been utilized as primary or secondary measures to increase fixation strength and reduce caudal migration by the transmural application of a helical (Heli-FX) or "seagull-shaped" (EndoRefix) endoanchor that traverses (and fixes) both the stent graft and aortic wall.[32,33] In theory, this maintains the apposition between the native aorta and the stent graft fabric and limits neck expansion up to the diameter of the deployed stent graft. Ease of use with the electronically controlled application and shorter additional procedural time requirements have increased the popularity of these devices. Endoanchor use in EVAR for AAAs with adverse proximal neck features has shown satisfactory short-term results, but there is currently little evidence for routine clinical use.[32,34]

POSTOPERATIVE SURVEILLANCE

The majority of current recommendations for surveillance have been derived from trial data in the early experience of EVAR. Contemporary practice differs in terms of the devices used and in the complexity of the aneurysms treated.[3] Current surveillance strategies vary worldwide and between institutions in the same country.[35] Regional specialist societies have provided some evidence-based guidance in an effort to standardize follow-up.[36,37]

The late results of the EVAR-1 trial have demonstrated that lifelong surveillance—and reintervention for surveillance-detected problems—are essential. Most late aortic ruptures occurred in patients who have had a complicated course during treatment or surveillance.[26] Despite this, some have questioned the efficiency of a standard routine surveillance program for all patients because many patients requiring reintervention present with clinical symptoms.[38] Furthermore, advanced age, hostile morphology, and intraoperative adjunctive procedures have been identified as factors associated with an increased incidence of adverse events and reintervention.[3,38,39] It may be that different strategies need to be employed for different patient groups. Patients with adverse morphology may require more intensive surveillance than those with straightforward anatomy. In our institution, a proactive surveillance strategy has led to an increase in reintervention rates but resulted in a very low incidence of rupture, despite a significant proportion of devices deployed outside the IFU.[25]

CONCLUSION

Open repair is associated with increased perioperative mortality and morbidity rates compared with EVAR.[40] However, the presence of adverse morphological features, including a short proximal neck, often exclude patients from undergoing EVAR.[25,41] Although data on the midterm durability of EVAR with fenestrated stent grafts are satisfactory, custom-made stent grafts incur a significant cost and delay compared to standard devices. Morphological constraints predominantly relating to the orientation of branches, neck angulation, and access difficulties further limit the utilization of custom-made devices.

Standard EVAR is occasionally the only viable therapeutic option in a group of patients deemed unfit for open surgical repair and unsuitable for fenestrated devices. Along with increased experience, progressive improvement of stent graft technology (including endovascular adjuncts) has been an important factor in extending EVAR to a greater proportion of patients. Stent graft use

outside the IFU has increased but may have a detrimental effect on long-term outcomes.

In experienced, high-volume units, standard EVAR for treating aneurysms with short proximal necks can be performed with acceptable results. Careful planning, appropriate device selection, high-quality intraoperative imaging, and advanced endovascular skills are essential for a successful primary outcome. Despite this, there will be a higher incidence of endoleak, migration, and sac expansion. An intensive postprocedure surveillance strategy is needed to enable early detection and timely reintervention to maintain a low incidence of post-EVAR rupture. ■

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