Advances in Distal Migration of Endografts

Innovative techniques to prevent endograft migration and type I endoleak.

BY ZVONIMIR KRAJCER, MD, FACC, AND MAAZ GHOURI, MD, MRCS

ndovascular aneurysm repair (EVAR) is an attractive alternative to an open surgical approach in treating abdominal aortic aneurysms (AAAs). Despite favorable outcomes immediately after EVAR, postprocedural complications continue to be a problem. These complications include endoleak, modular component separation, material fatigue, stent or hook fractures, aneurysm enlargement or migration, and rupture.¹

EVAR results are strongly influenced by preprocedural planning, the experience of the operator, the technique employed, and the type and generation of the endograft. The predictors of endograft failure have been delineated in previous studies. ^{1,2} The EUROSTAR registry studies have revealed that the most common predictors of endograft failure are angulated and/or short infrarenal necks, large infrarenal neck diameter, large maximal AAA diameter, and complex iliac artery anatomy. ¹⁻⁵

One of the major challenges facing physicians during and after EVAR is the potential for migration of the endograft, which has a reported incidence of 9% to 45%.^{1,3} Stent graft migration is usually defined as device movement of >10 mm or movement ≤10 mm resulting in secondary interventions.^{2,6}

First-generation endografts have a higher propensity of progressive neck dilatation, distal migration, modular separation, thrombosis, and loss of integrity.¹⁻⁵ Significant progress has been made in recent years with second- and third-generation devices.

On the basis of their mode of fixation to the aortic wall, EVAR devices can be generally divided into active-and passive-fixation endografts. Both types of devices use radial force to form a seal. The passive-fixation devices only use radial force for fixation, whereas active-fixation devices have adjunctive hooks or barbs. Unfortunately, all of the commercially available devices have shown the risk of migration, but this problem has been more pronounced with passive-fixation devices. Suboptimal prostheses flexibility and wall shear stress have been implicated as the primary factors responsible for distal migration, separation of modular components, and disruption of endograft components.

Some of the active fixation devices, such as the Zenith (Cook Medical, Bloomington, IN), offer a mode of suprarenal fixation with barbs and some, such as the Excluder (W. L. Gore & Associates, Flagstaff, AZ), offer infrarenal fixation with barbs. The Powerlink endograft (Endologix, Inc., Irvine, CA) offers anatomical fixation on the aortic bifurcation to prevent distal migration.

TECHNIQUES USED TO PREVENT ENDOGRAFT MIGRATION WITH CURRENT-GENERATION ENDOGRAFTS

The key to success in preventing stent graft migration depends on patient selection, anatomy of the infrarenal neck, deployment technique and quality, and design of the stent graft itself. To prevent endograft migration using Powerlink, the investigators have used the anatomical fixation technique (Figure 1A). This technique utilizes the





Figure 1. The anatomic fixation technique is shown using a Powerlink stent graft during endovascular AAA repair. This bifurcated device has a suprarenal fixation and rests on the aortoiliac bifurcation, which prevents distal migration of the endograft (A). Different components of the Powerlink stent graft, which can be used for additional aortic extension (B).

principle of deploying the endograft so that the bifurcated component rests on the aortoiliac bifurcation, which supports the endograft and prevents distal migration. An additional aortic extension is then used, if necessary, providing generous overlap between two components to extend the endograft to the infrarenal neck (Figure 1B). Another fixation technique was described by Raithel et al,⁹ in which the Powerlink stent graft was used in conjunction with the balloon-expandable Palmaz XL stent (Cordis Corporation, Warren, NJ). The Palmaz XL stent is used in the infrarenal aortic neck after the Powerlink stent

graft is deployed to expand the endograft in complex infrarenal neck anatomy. The preliminary report from their study reveals encouraging midterm results in preventing type I endoleak, as well as distal migration in patients with challenging infrarenal neck anatomy.

Several techniques have detailed the use of the Excluder endograft to prevent type I endoleak and distal migration in patients with severe infrarenal neck angulation and very short infrarenal necks. The technique of using the Palmaz XL stent before deployment of the

Excluder endograft in patients with irregular, angulated, or short infrarenal necks, has been shown to offer a reliable mode of fixation (Figure 2). However, use of the Palmaz XL stent after deployment of the Excluder has also been successful in preventing type I endoleak and distal migration.

CURRENT INVESTIGATIONS AND FUTURE DEVELOPMENTS TO PREVENT DISTAL MIGRATION OF ENDOGRAFTS

To address the issues of problematic infrarenal neck

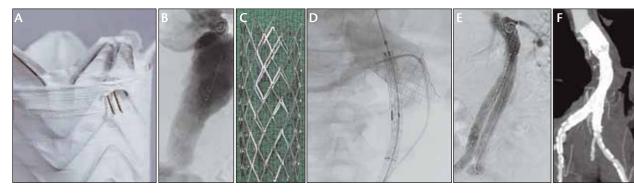


Figure 2. The Excluder stent graft showing the eight pairs of anchors that fixate the device to the infrarenal aorta (A). Angiographic image of the abdominal aorta of a patient with AAA reveals a short and angulated infrarenal aortic neck (B). 4010 Palmaz XL stent after expansion with a 25-mm diameter and a 40-mm Maxi LD balloon (C). Angiographic image of the abdominal aorta after deployment of a Palmaz XL stent and before deployment of an Excluder stent graft (D). Abdominal aortic angiogram of the same patient as in Figure 2D reveals satisfactory position of the Excluder stent graft without evidence of endoleak (E). Computerized tomographic image with three-dimensional reconstruction at 6-month follow-up reveals no evidence of migration of the Excluder stent graft or of endoleak (F).

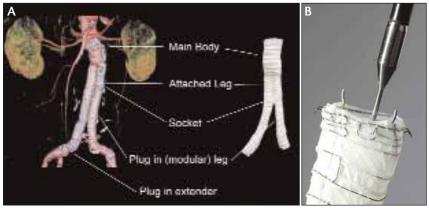


Figure 3. Three-dimensional computerized tomographic scan image of a patient with angulated infrarenal aortic neck after endoluminal AAA repair (left) with an Aorfix stent graft (right) (A). A partially deployed Aorfix stent graft shows the clips used for anchoring the device to the infrarenal aorta (B).

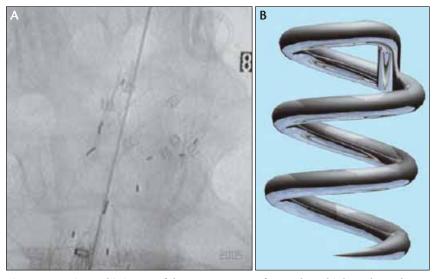


Figure 4. Angiographic image of the Aptus stent graft reveals multiple endostaples below the renal arteries (A). The Aptus Endostaple used for proximal fixation of the Aptus stent graft (B).

anatomy and the risk of distal migration, several manufacturers have put an emphasis on increasing endograft flexibility. They also offer active fixation to the aortic wall with the use of hooks, barbs, or clips that are an integral part of the device or that can be deployed after the device is already in place. The Aorfix (Lombard Medical Technologies Inc., Wellesley Hills, MA) (Figure 3) and the Aptus endograft (Aptus Endosystems Inc., Sunnyvale, CA) (Figure 4) are currently undergoing clinical trials in the US. Both devices are made of polyester material and are partially supported by a nitinol stent frame.

The Aptus endograft (Aptus Endosystems, Inc.) is a

three-piece device with a main body and two fully supported limbs. It is a partially supported stent graft that consists of a woven polyester material and an infrarenal balloon-expandable nitinol stent that attaches the stent graft in the desired location (Figure 4A). The principles used in preventing graft migration in the Aptus endograft are presence of a stable and supportive endograft and the use of endostaples, which provide transmural graft fixation and sealing.

The Aptus endograft has circumferential strength with resistance for longitudinal tear or abrasions. The endograft is deployed into the aneurysmal sac in a controlled fashion followed by endostaple application in a circumferential manner using an endostaple applier. The endostaples measure 4 X 3 mm (Figure 4B).

Lombard Medical also offers an EndoRefix device consisting of a 16-F delivery catheter that delivers the nitinol clips. The clips are then used to staple the infrarenal portion of stent graft to the aortic wall (Figure 3B). The EndoRefix clips can be used in patients with distal migration of a previously placed endograft or in a patient with a potential risk of migration with a newly

placed endograft. This device was undergoing evaluation in the US clinical trial; however, the trial was recently temporarily suspended due to financial constraints. Only patients with polyester stent grafts are candidates for the use of EndoRefix clips. The EndoRefix clips should not be used with polytetrafluoroethylene grafts because there is a risk of tearing the graft material. Lombard Medical also offers an Aorfix endograft that has the same clips incorporated in the endograft (Figure 3B). Aorfix is also undergoing a pivotal FDA trial in the US, known as PYTHAGORAS, for both normal and complex anatomies (0°–90°).

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CONCLUSION

Significant progress has been made in recent years to prevent distal migration using second- and third-generation devices. Preliminary results of EVAR using the described innovative techniques in patients with challenging infrarenal neck anatomy reveal encouraging procedural and intermediate-term results in preventing distal migration. Caution must be exercised by less experienced interventionists using these techniques because there is a higher incidence of complications and need for secondary procedures. It is essential to keep close surveillance of patients with complex infrarenal neck anatomy that undergo EVAR. It is clear that future improvements in device design, such as mechanisms of attachment, are forthcoming and will further simplify and improve the results of EVAR.

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