A New Concept in EVAR

Anatomical fixation with the Powerlink stent graft.

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Although endovascular aortic aneurysm repair (EVAR) of infrarenal abdominal aortic aneurysms (AAAs) has gained wide acceptance within the past 15 years,[1-3] some major complications in EVAR, such as distal migration of the device, which may result in proximal type I endoleak, still remain.[4] Therefore, endovascular stent grafts have undergone several generations of modification and evolution. Suprarenal/transrenal fixation with an uncovered stent is a typical design iteration with the goal of reducing distal migration.[5] Unfortunately, migration and the ensuing proximal type I endoleak still exist even with suprarenal/transrenal fixation.[6] The reason is obvious: downward displacement force caused by pulsatile aortic blood flow, but there are many causes responsible for the loss of proximal fixation. Theoretically, migration occurs when the device stabilization forces are less or weaker than the displacement forces. Although the forces are complex and cannot easily be defined with mathematical formulae, from a physical aspect, the fixation scheme plays an important role in the prevention of migration. Most of the devices pay much more attention to the proximal fixation modification, such as suprarenal struts and hooks,[6] but neglect other modifications that can potentially protect against downward displacement.

POWERLINK DEVICE

Mimicking the shape of the natural anatomy of the abdominal aorta, the Powerlink unibody bifurcated stent graft (Endologix, Inc., Irvine, CA) is uniquely designed to allow it to be implanted sitting on the anatomical abdominal aortic bifurcation (Figure 1). This design can theoretically provide support to counteract the downward force of pulsatile blood flow and possibly prevent distal migration. This fixation concept is referred to in our specialty as *anatomical fixation*. Of course, with the anatomical deployment and fixation, the blood flow remains more laminar and closely resembles that of the native aorta.

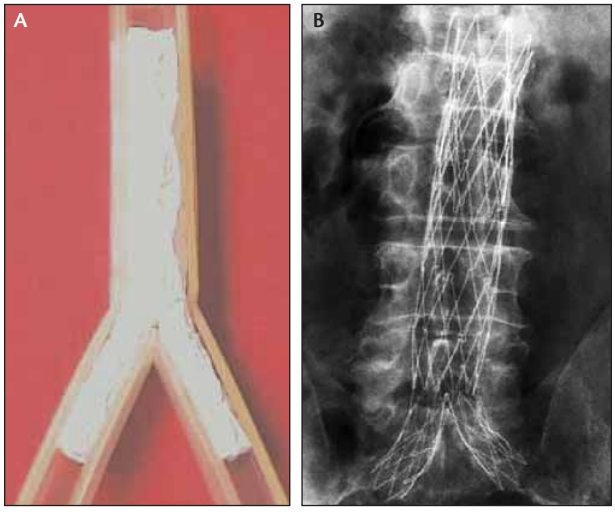

Figure 1. Model demonstration: Powerlink device sitting on the abdominal aortic bifurcation (A). Plain x-ray of implanted Powerlink device shows the endograft was implanted just on the abdominal aortic bifurcation (B).

DEPLOYMENT

Abiding by the concept of anatomical fixation, the deployment procedure is totally different from the other endografts. The bifurcation of the unibody device can be deployed sitting at or just above the native abdominal aortic bifurcation. If greater aortic length is needed, a proximal cuff is overlapped inside the long main body and implanted to just below the most distal renal artery. Based on these procedures, in the process of implantation of the main body, more attention is focused on the distance from the lowest renal artery to the aortic bifurcation than with other endografts. Because there are only two diameters (25 mm and 28 mm) of the main body and proximal cuffs suitable for the abdominal aorta,[7] it is easy to determine the size after aortography, and oversizing 10% to 20% of the aneurysm neck is recommended. Therefore, when com-

pared to the component modular endografts, the unibody Powerlink device is much simpler and easier in size determination and device implantation. Cuffs sized 34 mm are now available (outside the US) to treat necks up to 32 mm in diameter.

OUTCOMES

The outcomes were very good in the published midterm results of the multicenter trial of the Powerlink bifurcated system for EVAR,[7] with 97.9% technical success of implantation and only one case of proximal type I endoleak at 1-month CT follow-up. Most endoleaks were type II, and there were no type III and type IV endoleaks. As most recently reported at the Endovascular Congress on Endovascular Interventions in February 2006, there have been no graft material failures or wire fractures through 4-year follow-up.[8,9]

In our single-center experience, we had 297 cases of Powerlink implantation, and approximately one-third of them were implanted sitting on the aortic bifurcation with anatomic fixation. The others were implanted using infrarenal or transrenal fixation, and this may be another reason for the 4.4% type I endoleak. The most commonly used device size was 25 mm in diameter and 100 mm in length for the main body and 16 mm in diameter and 55 mm in length for the limb. The most commonly used size of the proximal cuff was 28 mm in diameter and 75 mm (infrarenal fixation) or 95 mm (suprarenal fixation) in length. The frequency of proximal cuffing was 42.1%. The average time for the total operation was 55 minutes, with 10 to 15 minutes used for the deployment. We had seven cases of distal migration in total, but all of the devices were not implanted sitting on the aortic bifurcation. There were no cases of distal migration observed in the patients receiving anatomic fixation. During the 1-month to 6-year follow-up, 13 cases (4.4%) experienced a proximal type I endoleak.

We put forward the new concept of anatomical fixation of a unibody stent graft, and we are aiming at protection against distal migration of a stent graft, which proves effective. Of course, there is a close relationship between distal migration and proximal type I endoleak. One important reason for secondary proximal type I endoleak is distal migration. Another important reason is insufficient fixation and sealing of the proximal anchoring zone of the stent graft, meaning that type I endoleak could still occur without distal migration. As with the improving experiences in EVAR, we greatly broadened the indications for EVAR such as a short neck (0.5-1.0 cm), angulated neck, calcified neck, and mural thrombus neck. We consider this may be one potential possible reason for 4.4% proximal type I endoleak. For proximal type I endoleak, we recommend suprarenal proximal cuff for further fixation and sealing, if it does not work, we implant a Palmaz stent in the neck for strengthening of radiant forces, which can achieve better fixation and sealing in the neck. For the 13 cases, nine were cured with suprarenal proximal cuff with or without Palmaz stent, three cases were incurable and are still under observation, and one case was converted because of persistent growing.

Hemodynamics also dramatically improve when the Powerlink device is used. With anatomical fixation, the bifurcation of the endograft sits on the native aortic bifurcation—the blood flow splits in a nearly normal anatomical position. Most endografts bifurcate much higher, therefore the blood hemodynamics change dramatically.

CONCLUSION

This new concept in EVAR (anatomical fixation) represented by the unibody bifurcated Powerlink device, provides substantial resistance to distal migration and low occurrence of proximal type I endoleak, improved blood hemodynamics through the graft due to the long main body, and simplifies the deployment procedures. ■

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