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Anatomical Fixation in Challenging Aortic Anatomies

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Endovascular abdominal aortic aneurysm repair (EVAR) has been widely adopted as a less invasive alternative to open surgical repair. Initial-generation stent grafts were designed to mimic surgical bifurcated grafts with short main bodies and long modular limbs. These devices were developed to achieve fixation and seal at the infrarenal aortic neck using a combination of radial force, suprarenal stents, and/or penetrating hooks and barbs. Although device durability and clinical results have improved over time, the question remains: Is a short main body, proximal fixation device optimal for the treatment of a wide range of complex aortic anatomies? More recently, an alternative stent graft design with a fully supported, long main body having integrated limbs (Powerlink® System, Endologix, Inc., Irvine, CA) was developed to stabilize and exclude the aneurysm sac with a single-piece bifurcated device.[1] This design was believed to prevent the risk of component separation inherent in modular devices. In 2000, a multicenter, prospective clinical trial was initiated in the United States under a Food and Drug Administration (FDA) Investigational Device Exemption (IDE) to evaluate the safety and effectiveness of the Powerlink device. During the enrollment phase of the trial, investigators discovered the ability to securely fix the unibody device directly on the aortoiliac bifurcation and add an aortic extension to seal the infrarenal neck. This technique, termed *anatomical fixation* or "build from the bottom up," was believed to prevent device migration, a common failure mode of endovascular devices relying on both fixation and seal at the infrarenal aortic neck.[2-4]

Pivotal results from the original Powerlink trial were published[5] and led to FDA approval in 2004. Long-term results of this trial have also been published, highlighting the durability and positive outcomes with this device.[6,7] In evaluation of the trial results, a significant differential incidence of distal migration started to emerge among patients who received the device using traditional infrarenal fixation and those who received the device using the anatomical fixation technique.[5] Given these promising results, two additional FDA-approved IDE trials that prospectively applied the anatomical fixation technique in patients with wide aortic necks (the XL trial) and in patients using a suprarenal configuration (the Suprarenal trial) were conducted. Pivotal results for both trials[8,9] led to US FDA approval in 2008 and 2009, respectively. Clinical results from the XL and Suprarenal trials were recently presented[8,9] and demonstrated 0% migrations, 0% conversion to open repair, 0% ruptures, 0% aneurysm-related mortality, no stent fractures or graft material failures, and effective aneurysm sac exclusion. These results are particularly remarkable in light of the high prevalence of challenging anatomies, which included short, severely angled, thrombus-lined, and reverse-tapered aortic necks.

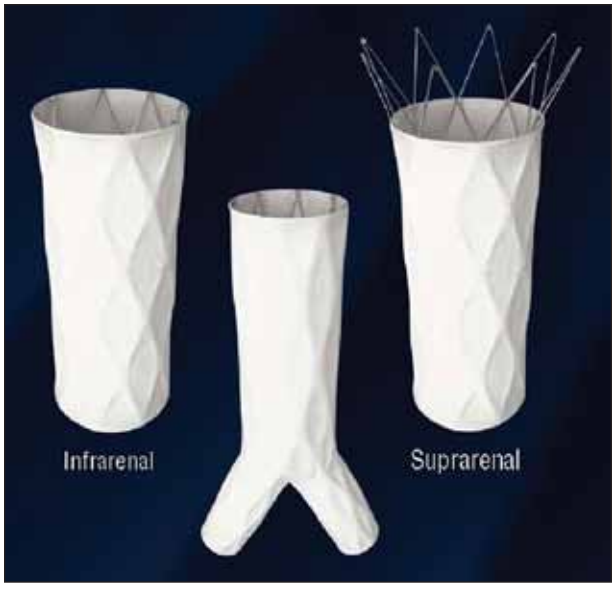

Figure 1. Powerlink stent grafts.

DEVICE DESCRIPTION AND DELIVERY

The Powerlink device consists of a unibody, self-expanding cobalt chromium alloy stent. The graft, con-

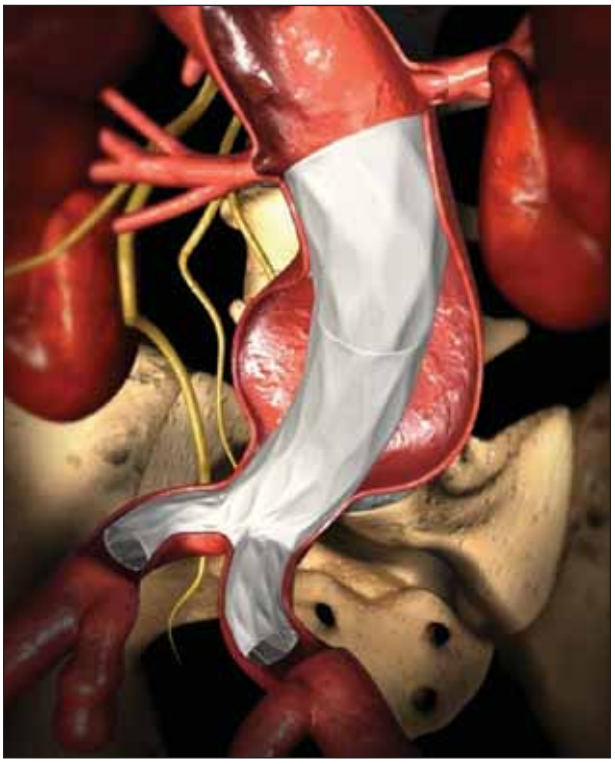

Figure 2. Powerlink stent graft implant configuration.

structed from high-density expanded polytetrafluoroethylene, is fully supported by the stent with proximal and distal attachment. The main body device (Figure 1) includes 25- and 28-mm diameters with total lengths of 120 to 155 mm. Aortic and distal extensions are available with diameters of 25 to 34 mm (infrarenal and suprarenal configuration) and 16 to 25 mm (distal limb).

The bifurcated device is delivered under fluoroscopic guidance through one surgically exposed femoral artery together with percutaneous 9-F contralateral access. Device insertion, guidewire placement, and deployment steps have been previously described and illustrated.[9] Unique to the anatomical fixation technique, the main body device is deployed directly on the aortoiliac bifurcation, and the delivery system is removed through the central lumen of the stent graft and ipsilateral limb. The aortic extension is then inserted over a 0.035-inch guidewire through the central lumen of the bifurcated device into the proximal aorta. Under fluoroscopic guidance, the aortic extension (infrarenal or suprarenal configuration) is deployed below the most caudal renal artery to achieve proximal seal (Figure 2).

In March 2009, a new delivery system (IntuiTrak, Endologix, Inc.) was introduced in the United States, simplifying device delivery and deployment through an integrated 19-F introducer sheath. The delivery system incorporates a precannulated contralateral limb and 9-F percutaneous contralateral access, thereby facilitating successful treatment of abdominal aortic aneurysm (AAA) patients with challenging anatomies.

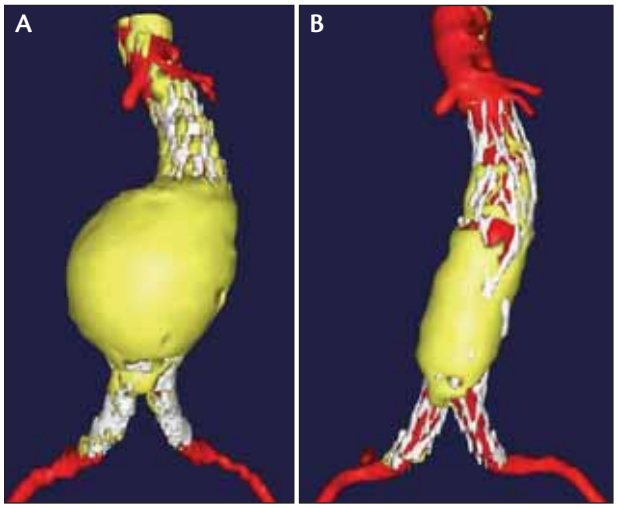

Figure 3. Positive remodeling after endograft implant. M2S reconstructions show a 50% sac diameter reduction (5.8 cm to 2.9 cm) and 23° sac straightening between 1 month (A) and 3 years (B).

DISCUSSION

The Powerlink System is unique among traditional modular proximal fixation devices in that the bifurcated stent graft has a fully supported, unibody design. Placement of the stent graft on the aortoiliac bifurcation provides anatomical fixation of the long main body device with the aortic extension providing seal at the infrarenal neck. The long main body device together with an aortic extension relines the entire infrarenal

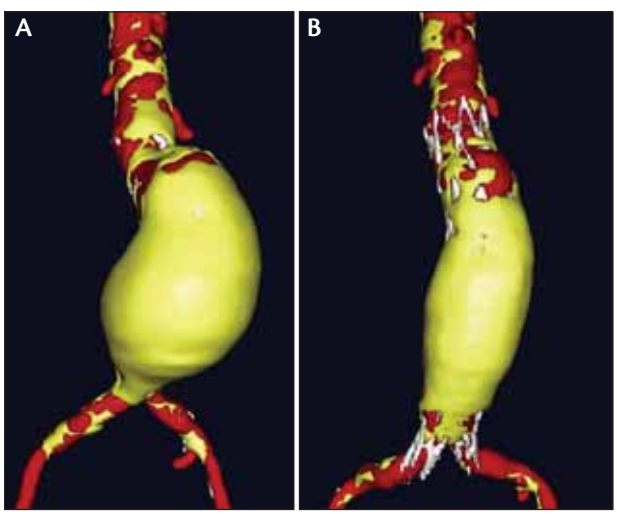

Figure 4. Treated reverse-taper aneurysm morphology. The core lab reconstructions demonstrate a 2.5-cm diameter reduction from baseline (A) to 2 years (B).

TABLE 1. ANATOMICAL FIXATION TREATMENT PATTERNS

Anatomy Challenge	Clinical Risks and Issues	Anatomical Fixation
Hostile neck		
Severely angled	Migration; placement accuracy; opposing angles	Device fixation at aortic bifurcation; controlled deployment of aortic extension provides accurate placement below the target renal arteries; infrarenal aortic extensions to treat aortas with opposing angles; endoskeleton stent design allows graft material to conform to the neck, improving seal.
Short	Migration; placement accuracy; seal	Device fixation at aortic bifurcation; controlled deployment of aortic extension provides accurate placement below the target renal arteries; endoskeleton stent design allows graft material to conform to the neck, improving seal.
Thrombus laden	Proximal fixation; seal	Device fixation from aortic bifurcation.
Reverse tapered	Migration; placement accuracy; seal	Device fixation at aortic bifurcation; controlled deployment of aortic extension provides accurate placement below the target renal arteries; endoskeleton stent design allows graft material to conform to the neck, improving seal.
Aneurysm and aorta characteristics		
Saccular	Gate cannulation; seal	Precannulated contralateral access; long main body maximizes seal zone.
Bilobe		
Narrow distal aorta	Gate cannulation; restricted distal flow	Precannulated contralateral access; long main body maximizes distal flow; eliminates constrained bilateral limbs in narrow aortic segment.
Infrarenal dissection	Patent false lumen; rupture risk	Long main body re-lines aortic luminal surface from renal arteries to bifurcation.
Femoral access		
Limited contralateral access	Delivery of stent graft/limbs	9-F percutaneous contralateral access; integrated introducer minimizes vessel re-entry and related complications.
Peripheral arterial disease	Crossover intervention approach after EVAR	Unibody design preserves native aortic orientation facilitating contralateral intervention.
Other		
Rupture	Gate cannulation; total procedure time to AAA exclusion	Precannulated contralateral access; rapid main body placement without angiogram; can stabilize patient with proximal occlusion balloon while placing neck extension.
Shaggy aorta	Gate cannulation; embolization	Precannulated contralateral access; long main body re-lines aortic surface from renal arteries to bifurcation.

aorta and provides support from the bifurcation all the way up to the renal arteries. In contrast to traditional modular proximal fixation devices with short bodies and long limbs, the Powerlink design matches the pre-aneurysmal shape of the infrarenal aorta and restores the original blood flow dynamics. This aortic-like design has proven to provide device stability, which leads to positive remodeling (Figure 3).

By building from the bottom up, the Powerlink System mitigates the risk of device migration and enables the effective treatment of a wide range of challenging anatomies including short, angulated, reverse-tapered (Figure 4), and thrombus-lined aortic necks. The precannulated contralateral limb also simplifies EVAR procedures in anatomies that are difficult to achieve gate cannulation with traditional modular devices. These anatomies include saccular or bilobed aneurysms and narrow distal aortas. Furthermore, by preserving the natural aortoiliac bifurcation, the Powerlink device enables future peripheral endovascular procedures in patients with peripheral arterial disease (Figure 5). Based on the promising clinical results

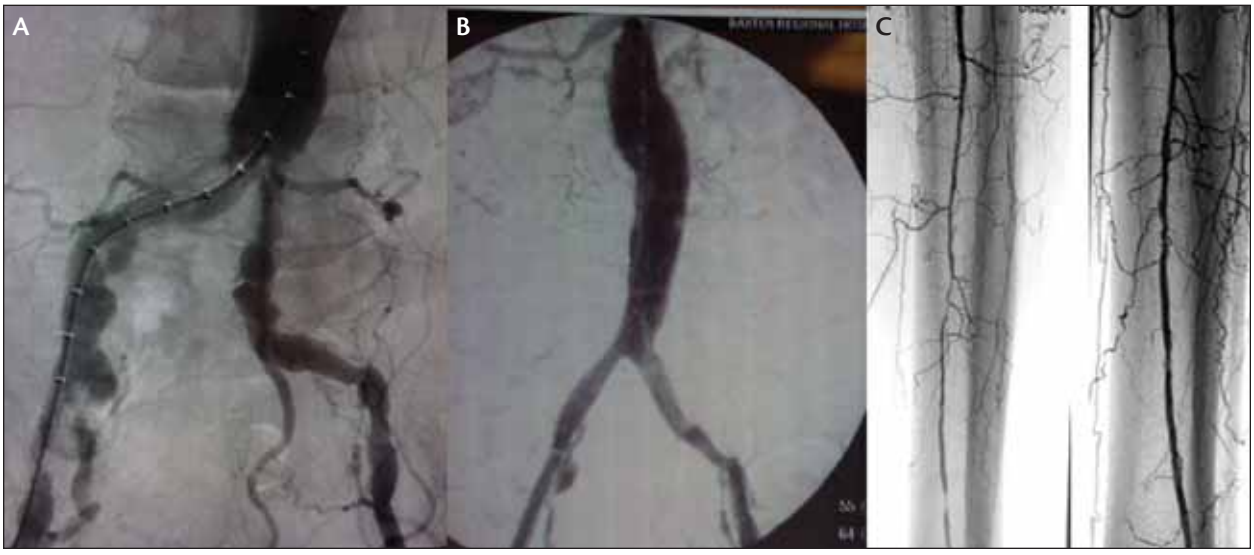

Figure 5. Preserved access with subsequent peripheral intervention. A patient with peripheral arterial occlusive disease (A) was preferentially treated with the anatomically fixed Powerlink stent graft (B) to preserve the aortoiliac bifurcation. Superficial femoral artery revascularization was completed 1 week after EVAR (C).

and the other unique design attributes of the device, Table 1 shows the aortic anatomies that are ideally suited for treatment using the Powerlink stent graft with the anatomical fixation technique.

CONCLUSION

The effectiveness of the Powerlink System and anatomical fixation has been validated in prospective, IDE multicenter clinical trials. The results of these studies together with the other unique design attributes of the device demonstrate the value of anatomical fixation in a wide range of challenging aortic anatomies. We believe that the Powerlink System offers compelling clinical advantages and represents an attractive alternative to traditional modular proximal fixation devices for the treatment of patients with AAAs. ■

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