

The Powerlink AAA Stent-graft: Durability

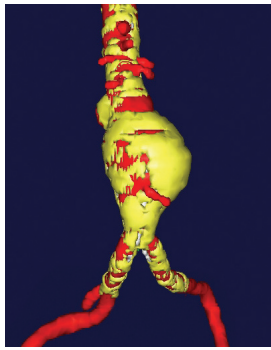


Figure 1. Pre-op

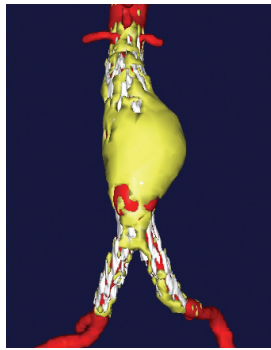


Figure 2. One Year

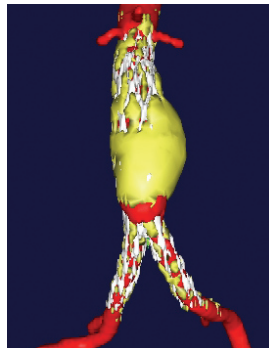


Figure 3. Two Year

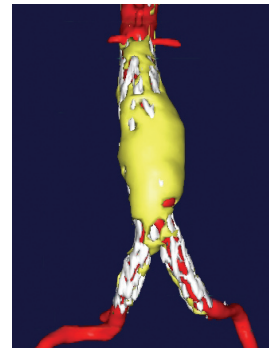


Figure 4. Three Year

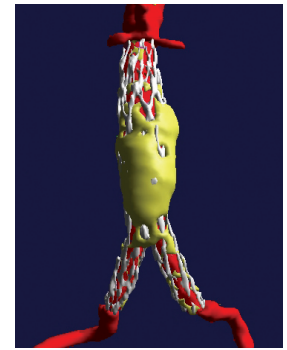


Figure 5. Four Year

CASE REPORT

A pivotal multicenter trial of the Powerlink device was performed in patients with infrarenal abdominal aortic aneurysm. The trial included both test patients receiving the Powerlink and concurrent surgical controls. A total of 258 patients (192 test and 66 control) were enrolled. FDA approval was received on October 29, 2004. The Powerlink is a unibody bifurcated endograft for repair of AAA. Its stented endoskeleton is self-expanding chromium cobalt alloy and is covered with a proprietary ePTFE fabric. The Powerlink is surgically implanted through one surgically exposed femoral artery and a contralateral 9 French puncture.

We report on four year follow up of a patient who was enrolled in the pivotal trial. MMS (Medical Metrx Solutions) is the core lab for the clinical trial. MMS offers the service of 3D reconstruction based on spiral CT scans.

The patient is a 68 year old male who was diagnosed with an abdominal aortic aneurysm. Pre-op measurements show a proximal infrarenal aortic neck diameter of 23 mm and a maximum aneurysm diameter of 57 mm. The proximal neck sealzone length measured by CT and IVUS is 20 mm. The right and left common iliac arteries are 11 mm in diameter. The renal to aortic bifurcation length is 108 mm and the renal to hypogastric length is 160 mm. (Figure 1)

Table 1

Time Period	Pre-op	One Year	Two Year	Three Year	Four Year
Maximum AAA Diameter	57.0 mm	46.8 mm	41.6 mm	37.8 mm	35.4 mm
Aneurysm Volume	142.6 ml	117.2 ml	102.8 ml	106.8 ml	95.3 ml

METHOD

A 28-16-155BL stent-graft was chosen based on the patient's pre-op measurements. The stent-graft proximal diameter is 28 mm, the limb diameter is 16 mm and the total stent-graft length is 155 mm. The patient's renal to aortic bifurcation length is 108 mm. The main body of the selected Powerlink is 100 mm. A 28-28-55L infrarenal proximal cuff was placed to add length to the stent-graft. The cuff is 28 mm in diameter and 55 mm in length.

RESULTS

The Powerlink AAA stent-graft was successfully implanted. Patient follow up includes CT scans and MMS reconstructions through four years. One, two, three and four year MMS images are shown in Figures 2, 3, 4 and 5. The data is shown in Table 1.

CONCLUSION

The patient data obtained through four years shows continuing reduction in maximum AAA diameter and AAA volume. The data is an example of a type of classical remodeling seen in some patients with Powerlink implants. The Powerlink appears to have a positive effect on aneurysm morphology demonstrated by decreased aneurysm diameter and volume. The long main body and column strength of the Powerlink may contribute to the findings. No migration, graft related endoleak or wire fracture have been identified during patient follow up. Durability and classical remodeling look to be benefits of the Powerlink AAA stent-graft.



**The Powerlink System:
Dependability of Outcome... Durability of Design.**