

The Powerlink AAA Stent-graft: Classical Remodeling

CASE REPORT

A pivotal multicenter trial of the Powerlink device was performed in patients with infrarenal abdominal aortic aneurysms. 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 and is covered with an ePTFE fabric. The Powerlink is surgically implanted through one surgically exposed femoral artery and a contralateral 9 French puncture.

We report on three 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 an 82 year old male who was diagnosed with an abdominal aortic aneurysm. Pre-op measurements show a proximal infrarenal aortic neck diameter of 22 mm, a maximum aneurysm diameter of 52.6 mm, a proximal neck sealzone length of 33.5 mm with mild thrombus and an aortic neck angle of 38.1 degrees. The length from the renals to the aortic bifurcation is 121 mm. The right common iliac diameter is 14 mm and the left common iliac diameter is 11.1 mm. The length from the aortic bifurcation to the right hypogastric artery is 50.8 mm and the length from the aortic bifurcation to the left hypogastric artery is 47.3 mm. There is severe plaque and mild tortuosity noted on the right and left common iliac arteries. The access vessels measure 6.1 mm on the right external iliac and 6.7 mm on the left external iliac. An accessory renal is noted on the pre-op CT scan. (Figure 1)

METHOD

A 25 x 16 x 155BL stent-graft was chosen based on the

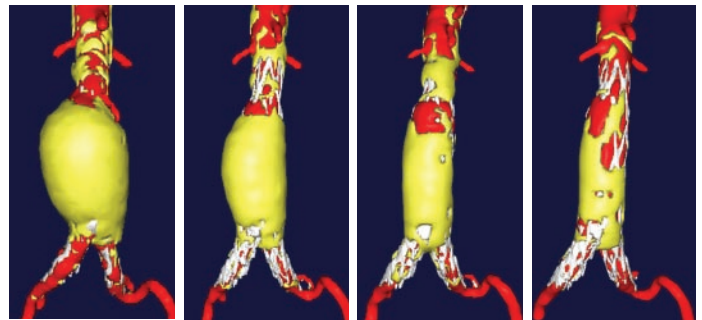


Figure 1. Pre-op Figure 2. One Year Figure 3. Two Year Figure 4. Three Year

patient's pre-op measurements. The stent-graft proximal diameter is 25 mm, the limb diameter is 16 mm and the total stent-graft length is 155 mm. The patient's renal to aortic bifurcation distance is 121 mm. The main body of the selected Powerlink is 100 mm. The Powerlink was placed at the lowest renal artery and no additional components were required to achieve fixation.

RESULTS

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

CONCLUSION

The patient data obtained through three 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 Powerlink may contribute to the findings. No migration, graft related endoleak, wire fracture or graft defect have been identified during patient follow up. Durability and classical remodeling are benefits of the Powerlink AAA stent-graft.

Table 1

Time Period	Pre-op	One Year	Two Year	Three Year
Maximum AAA Diameter	52.6 mm	42.5 mm	30.4 mm	27.5 mm
Aneurysm Volume	149.6 ml	104.6 ml	87.9 ml	81.1 ml



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