

CLINICAL RESEARCH STUDIES

Secure fixation following EVAR with the Powerlink XL System in wide aortic necks: Results of a prospective, multicenter trial

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Purpose: Endovascular stent graft repair of abdominal aortic aneurysms (AAA) with the Endologix Powerlink System (Endologix, Inc, Irvine, Calif) has been shown to be a safe and effective alternative to open surgery in patients having an aortic neck diameter of up to 26 mm. We assessed the safety and effectiveness of AAA repair in patients with wide aortic necks (up to 32 mm in diameter) using the Powerlink XL System.

Methods: Between September 2005 and June 2008, a prospective, multicenter, pivotal US Food and Drug Administration trial of the Powerlink XL System for endovascular aneurysm repair was conducted at 13 centers. Using a sizing algorithm based on computed tomography scan (CT)-based measurements, a total of 78 patients (N = 60 [pivotal trial]; N = 18 [continued access]) presenting with AAA and an infrarenal aortic neck up to 32 mm in diameter received a bifurcated stent graft via anatomical fixation at the aortoiliac bifurcation and proximal sealing with a Powerlink XL infrarenal proximal extension stent graft. Postoperatively, results were assessed with contrast-enhanced CT scans and abdominal x-rays at one, six, and 12 months, with continued annual follow-up to five years.

Results: Predominantly male (91%), patients presented at a mean age of 73 ± 8.6 years with mean maximum aortic neck and AAA diameters of 31 ± 1.9 mm (range, 25 to 32 mm) and 5.7 ± 1.0 cm (range, 4.3 to 10 cm), respectively. Challenging infrarenal aortic neck anatomy, defined as the presence of severe thrombus and/or reverse taper, was present in 85% of patients. Technical success was achieved in 98.7% of patients, with one patient requiring femoral-femoral bypass intraoperatively. Aneurysm exclusion was achieved in 100% of patients over a mean procedure time of 129 ± 66 minutes. Patients were discharged at a mean of 2.2 days postoperatively. At the one-month CT scan, the independent core lab identified a Type II endoleak in 13 patients, distal Type I and Type II endoleak in one patient, and unknown endoleak in three patients. At 30 days, there were no deaths, conversions, ruptures, or migrations. Through one year follow-up, Type II endoleak predominated (9/10 patients with endoleak), with one proximal Type I and no Type III, IV, or unknown endoleak; no conversions, ruptures, or migrations have been observed. The one-year all-cause mortality rate was 6.4%, with 100% freedom from aneurysm-related mortality. Secondary procedures were performed within one year in five patients (6.4%) for treatment of proximal Type I endoleak (n = 2), proximal Type I/Type II endoleak (n = 1), and distal Type I endoleak (n = 2). Reduced or stable aneurysm sac diameter at one year is observed in 96% of patients.

Conclusions: The combination of an anatomically-fixed Powerlink bifurcated stent graft and a Powerlink XL infrarenal proximal extension appears safe and effectively excludes aneurysms in patients with wide aortic necks. These results suggest that fixation at the aortic bifurcation can provide secure fixation for patients with large diameter diseased proximal aortic necks. (J Vasc Surg 2009;50:979-86.)

In prospective, multicenter, controlled clinical trial experience with mid- to long-term follow-up, the Powerlink System (Endologix, Inc, Irvine, Calif) has been shown to be a safe and effective endovascular treatment option for patients with abdominal aortic aneurysms (AAA) and aortic

necks up to 26 mm in diameter.¹⁻⁵ To enable the treatment of patients with large aortic necks up to 32 mm in diameter, and to inhibit distal migration, an alternative approach coupling a Powerlink bifurcated stent graft placed at the aortic-iliac bifurcation and a large diameter Powerlink XL proximal extension placed to achieve proximal seal was developed. We report the mid-term results of the pivotal US Food and Drug Administration trial that was designed and conducted to evaluate this device and implant technique combination.

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METHODS

Trial design. A prospective, multicenter, single arm trial of the safety and efficacy of the Endologix Powerlink XL system was conducted at 13 centers (see [Appendix](#), online only) according to US Food and Drug Administration (FDA) regulations and guidelines. The Powerlink XL

device has been available in select international countries since 2002, and has been available in the United States under an investigational device exemption in the context of a pivotal US FDA trial with a continued access enrollment provision. The trial enrolled 60 patients between September 2005 and July 2007, with continuing follow-up for all patients. To gain additional experience with the device and implantation algorithm, an additional 18 patients were enrolled between August 2007 and June 2008 under an FDA-approved continued access provision. Available data for this group are limited to early outcomes; with continuing follow-up through five years. Each center obtained institutional review board approval for human investigation, and written informed consent was obtained from each patient. The primary study endpoint was the incidence of proximal Type I endoleak within one year. The target proportion for this study was 0.80, with null and alternative hypotheses given by $H_0: P \leq 0.80$ versus $H_1: P > 0.80$, where P is the proportion of patients with no proximal Type I endoleak at one year post-implant. Using a sample size of 50 patients, the smallest binomial parameter for which the upper tail contains 80% or more of the area is 0.922. To provide an allowance for patients who may be lost to follow-up, the sample size was increased to 60. Positive demonstration of the study hypothesis required analysis using the exact binomial distribution of the observed proportion of patients with no proximal Type I endoleak at one year post-treatment yielding a one-sided P -value less than .05. A sensitivity analysis was performed to impute a result if a patient was missing at one year, confirming the primary analysis results. The primary safety endpoint was the incidence of major adverse events (MAE) within one year. MAE was defined as all-cause mortality, aneurysm rupture, conversion to open repair, secondary procedure, coronary intervention, myocardial infarction, renal failure, respiratory failure, and stroke. Prospectively defined secondary endpoints include technical success, independent core laboratory evaluations of endoleak, device integrity, patency, and migration.

Device description and delivery. The Powerlink device consists of a unibody, self-expanding cobalt chromium alloy endoskeleton wire without sutures or welds. The graft, constructed from expanded polytetrafluoroethylene (ePTFE), resides outside the stent mechanism and is fully supported by the stent with proximal and distal attachment using polypropylene suture. Devices used in the trial (Fig 1) include Powerlink 28 mm infrarenal bifurcated devices with body lengths of 80 or 100 mm and limb lengths of 40 or 55 mm (total lengths of 120 to 155 mm), delivered with a 21 Fr coaxial delivery system, and the Powerlink XL 34 mm infrarenal proximal extension with length of 80 mm, delivered with a 22 Fr delivery system. Distal extensions were also available with diameters of 16 to 25 mm. The bifurcated device was delivered under fluoroscopic guidance through one surgically exposed femoral artery and percutaneous 9 Fr contralateral access. Bifurcated 21 Fr delivery system insertion, guidewire placement, heparin anticoagulation, and deployment steps have been previously de-



Fig 1. Powerlink 28 mm bifurcated graft with 34 mm Powerlink XL proximal extension cuff.

scribed and illustrated.⁶ Unique to this trial, the device was deployed such that the bifurcation of the stent graft was required to be placed at the level of the aortoiliac bifurcation. The delivery system was removed through the central lumen of the stent graft body and ipsilateral limb. The proximal aortic extension delivery system was then inserted over a 0.035" guidewire into the ipsilateral arteriotomy and through the central lumen of the bifurcated device into the proximal aorta. Under fluoroscopic guidance, the extension delivery system outer sheath was retracted, deploying the stent graft below the most caudal renal artery to achieve proximal seal. Balloon dilatation of attachment sites was performed if deemed necessary after completion arteriography.

Patient and device selection. Patients with nonruptured infrarenal aortoiliac aneurysms (Table I) underwent computed tomography (CT) scanning with three-dimensional reconstruction to assess for study inclusion. Scans were analyzed by the sites to determine anatomic suitability for enrollment and ultimately by the core laboratory (M2S, Inc, West Lebanon, NH) to determine baseline values for analysis. Preoperative catheter angiography was left to the discretion of the individual operator. Preoperative measurements of non-aneurysmal aortic neck diameter and distance from lowest renal artery to the aortic bifurcation and hypogastric arteries were performed to determine patient eligibility and bifurcated device options. When more than one choice of bifurcated device was available based on the sizing algorithm, physician discretion was used to determine the selection. While three patients had a neck diameter of 25 mm at the lowest renal, the more distal neck ranged from 30 to 32 mm and were considered appropriate for the trial. Even considering the variable proximal aortic neck diameters in reverse taper necks, the proximal cuff was selected to allow 10% to 20% oversizing of the proximal aortic cuff compared with the aortic diameter.

Table I. Study inclusion/exclusion criteria

<ul style="list-style-type: none"> ■ Proximal infrarenal aortic neck: <ul style="list-style-type: none"> - Length ≥ 15 mm - Diameter 23 to 32 mm - Angle to the AAA sac $\leq 60^\circ$ ■ AAA diameter ≥ 4.0 cm or rapidly growing ■ Iliac diameter ≥ 8 mm on ipsilateral side ■ Iliac seal zone ≥ 15 mm ■ Bilateral iliac angle to the aortic bifurcation $< 90^\circ$ ■ Distance from the most caudal renal artery to the aortic bifurcation (RTB) meets the sizing algorithm based on aortic neck diameter and length of bifurcated device body chosen: <table border="1" style="margin-left: 20px; width: 100%;"> <thead> <tr> <th>Neck diameter</th> <th>23 to 26 mm</th> <th>26 to 28 mm</th> <th>28 to 30 mm</th> <th>30 to 32 mm</th> </tr> </thead> <tbody> <tr> <td>RTB1[†]</td> <td>≥ 95 mm</td> <td>≥ 105 mm</td> <td>≥ 110 mm</td> <td>≥ 115 mm</td> </tr> <tr> <td>RTB2[‡]</td> <td>≥ 115 mm</td> <td>≥ 125 mm</td> <td>≥ 130 mm</td> <td>≥ 135 mm</td> </tr> </tbody> </table> ■ Preservation of at least one hypogastric artery ■ Dispensable inferior mesenteric artery ■ Serum creatinine level ≤ 1.7 mg/dL ■ No bleeding or connective tissue disorders ■ No contraindication to contrast media ■ Not pregnant ■ Life expectancy of at least two years ■ Provides written informed consent and is willing to comply with follow-up schedule 	Neck diameter	23 to 26 mm	26 to 28 mm	28 to 30 mm	30 to 32 mm	RTB1 [†]	≥ 95 mm	≥ 105 mm	≥ 110 mm	≥ 115 mm	RTB2 [‡]	≥ 115 mm	≥ 125 mm	≥ 130 mm	≥ 135 mm				
Neck diameter	23 to 26 mm	26 to 28 mm	28 to 30 mm	30 to 32 mm															
RTB1 [†]	≥ 95 mm	≥ 105 mm	≥ 110 mm	≥ 115 mm															
RTB2 [‡]	≥ 115 mm	≥ 125 mm	≥ 130 mm	≥ 135 mm															

[†]If bifurcated device with 80 mm body selected.

[‡]If bifurcated device with 100 mm body selected.

Anatomic definitions. Hostile aortic necks were defined as those having more than 3 mm of thrombus around 60% of the circumference of the proximal seal zone; less than 15 mm length of proximal landing zone; or a taper greater than 2 mm along the first 15 mm of proximal landing zone.

Follow-up evaluation. Patients underwent abdominal plain x-ray studies prior to hospital discharge. Protocol-specified continued follow-up is at one month, six months, one year, and annually to five years. At each visit, a physical exam including serum creatinine analysis, abdominal four-view x-ray studies (anteroposterior, lateral, left and right anterior oblique) and contrast-enhanced CT scans were conducted. Endoleak was defined as the presence of contrast material within the aneurysm sac but outside of the graft material. Migration was defined as >10 mm movement of the proximal end of the graft from the baseline scan relative to the lowest most renal artery. These studies were evaluated by each local site and independently by the central core laboratory.

Statistical analysis. Baseline and procedural continuous, ordinal, and categorical variables are presented descriptively. Early (within 30 days) and late major adverse events are presented descriptively. Kaplan-Meier survival estimates were used to analyze rates of mortality and major adverse events through the follow-up period at exact time points (ie, one year = 365 days). Analysis of the primary endpoint was conducted using the exact binomial distribution. Endoleak and aneurysm size data are presented descriptively. Changes in aneurysm size over time are analyzed with a paired *t* test. Statistical significance is considered for *P*-values less than .05. All statistical analyses were performed using SAS software version 8.2 or later (SAS Institute, Cary, NC).

Table II. Baseline demographics and comorbidities

Characteristic	Result
Male gender	71 (91%)
Age, years	73 \pm 8.6
Serum creatinine, mg/dL	1.2 \pm 0.4
Arrhythmia	20 (26%)
Cancer	23 (29%)
Cerebrovascular disease	17 (22%)
Coagulopathy	4 (5.1%)
Congestive heart failure	16 (21%)
Coronary artery disease	47 (60%)
COPD	33 (42%)
Diabetes	19 (24%)
Family history of AAA	10 (13%)
Gastrointestinal abnormality	32 (41%)
Hypertension	65 (83%)
Hypercholesterolemia	54 (69%)
Liver disease	3 (3.8%)
Peripheral arterial disease	27 (35%)
Prior abdominal surgery	32 (41%)
Prior myocardial infarction	21 (27%)
Prior CABG	22 (28%)
Prior PTCA/stent	45 (58%)
Renal failure	3 (3.8%)
Smoking (ever)	66 (85%)
Valvular disease	9 (12%)
Valve replacement	2 (2.6%)

Results reported as n (% of 78) or mean \pm standard deviation.

AAA, Abdominal aortic aneurysm; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; PTCA, percutaneous transluminal coronary angioplasty.

RESULTS

Enrollment and procedural outcomes. Patient demographic and baseline characteristics are shown in Table II. Similar to the originally reported Powerlink trial in

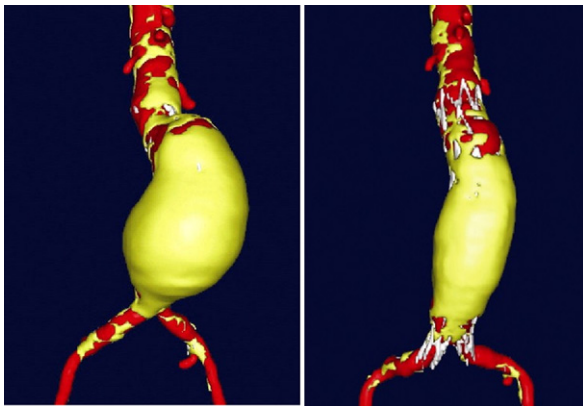


Fig 2. An example of a thrombus filled neck that was treated with shrinkage at 12 months.

patients with aortic necks up to 26 mm in diameter,¹ enrolled patients were primarily male (91%) at a mean age of 73 ± 8.6 years. Prevalent comorbidities included chronic obstructive pulmonary disease (COPD, 42%), coronary artery disease (60%), hypertension (83%), peripheral arterial disease (35%) and smoking history (85%). Median proximal non-aneurysmal neck diameter was 28 mm (proximal) and 31 mm (distal); median neck length and angulation to the aneurysm sac were 24 mm and 38° , respectively. Patients enrolled in this trial had a larger mean aneurysm sac diameter than patients enrolled in the original trial (5.7 ± 1.0 cm vs. 5.1 ± 0.7 cm, $P < .001$). Moreover, a substantial number of patients in this cohort were reported by the core lab with proximal neck characteristics that were considered challenging for endovascular repair.^{7,8} Severe neck thrombus was found in 41% (32/78) of enrolled patients (example shown in Fig 2). A reverse taper was found in 69% (54/78) of patients. Either feature was present in 85% of patients (66/78), while both were present in 26% of patients (20/78). In addition, a short proximal neck seal zone of 4 to 13 mm was present in 15 of 78 patients (19%). Five of these 15 patients had severe thrombus and nine of these had a reverse taper of 3 to 6 mm.

Per the Society for Vascular Surgery reporting standards,⁹ technical success was achieved in 98.7% of patients. Endovascular repairs were performed with the patient maintained under general anesthesia (62%), regional or epidural anesthesia (26%), or local anesthesia (12%). Each patient received one of four 28 mm bifurcated models, with implant at the aortoiliac bifurcation: 45 patients (58%) received an 80 mm body device, and 33 patients (42%) received a 100 mm body device. All patients received a proximal aortic extension, with 17 patients (22%) anatomically requiring a second extension. Distal extensions were used in 21 patients (27%).

Measures of clinical utility were consistent in this trial with those observed in the original Powerlink trial test group. During an average fluoroscopy time of 26 ± 18

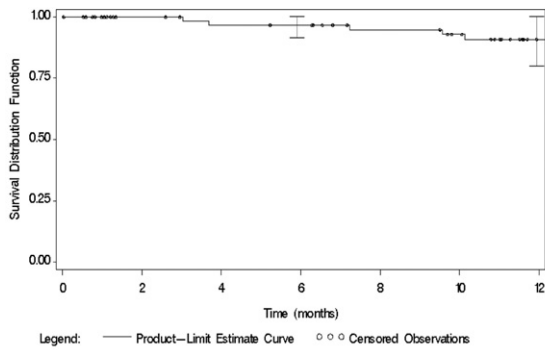
minutes, mean contrast usage was 126 ± 78 mL. Total procedure time averaged 129 ± 66 minutes, with mean estimated blood loss of 356 ± 299 mL. Patients were discharged from the hospital at a mean of 2.2 days (range, one to 18 days).

In one pivotal trial case, an inadvertent wire wrap leading to device limb damage necessitated femoral to femoral bypass to restore distal flow. Complications attributed to the procedure include hematoma development at the percutaneous access site resolved with drainage ($n = 1$), pseudoaneurysm development at the percutaneous access site resolved with thrombin injection ($n = 2$), femoral artery access vessel tear treated with endarterectomy and patch repair ($n = 2$), and external iliac dissection treated with angioplasty and stenting ($n = 1$).

The pivotal trial enrolled 60 test patients who have been followed for a median of 1.2 years. During the continued access phase, an additional 18 patients were enrolled and have been followed for a median of 0.3 years. One month follow-up data are available for all patients. Excluding five patients who died, two patients who withdrew voluntarily, two patients who suffered a stroke and were confined to long-term care facilities and did not undergo the scheduled CT imaging, one patient who refused the CT scan (but completed the clinical exam), and 17 continued access patients who are not yet eligible, one year follow-up data are available for 51 patients. Longer-term follow-up data are available over two years in 22 patients, and over three years in five patients.

Pivotal trial primary endpoint analysis. Within one year, two proximal Type I endoleaks were observed in the pivotal trial group, yielding a success rate of 96% ($P = .001$). In the first patient, who had a 7 mm reverse taper neck over the first 5 mm, no intraoperative endoleak was observed. A proximal Type I endoleak was reported by core lab at the one year visit, although the aneurysm sac did not significantly increase in size since the initial implant. The patient received an additional proximal extension on day 393, with resolution of the endoleak. In the second patient, intraoperative endoleak was observed and was treated with ballooning of the attachment point per the instructions for use, with apparent resolution of the endoleak. The patient was diagnosed with a proximal Type I endoleak after one year, although the aneurysm sac did not significantly increase in size since the initial implant. Treatment with a balloon-expandable Palmaz 5010 aortic stent on day 768 resolved the endoleak. This second failure was attributable to a thrombus filled, reverse taper neck and inadequate length to allow for full expansion of the proximal 34 mm cuff. Both initial failures were then attributed to diseased proximal aortic anatomy (thrombus-filled, highly angulated conical proximal aortic neck).

Mortality and major adverse events. Within 30 days, no patient death occurred. After 30 days and within one year, five (6.4%) patients died due to lung cancer ($n = 2$), multi-organ failure secondary to *C. difficile* colitis infection ($n = 1$), myocardial infarction ($n = 1$), and pneumonia ($n = 1$). None of these deaths was secondary to a proce-



Time	Number at Risk	Proportion Free from Mortality	95% Confidence Interval
1 Month	72	1.00	1.00, ---
6 Months	57	0.97	0.92, 1.00
1 Year	34	0.91	0.83, 0.99

Fig 3. Kaplan Meier Plot – freedom from all cause mortality.

dural event or to a device-related observation, and as such, none is considered aneurysm related. This one-year all-cause mortality rate (6.4%) is consistent with the all-cause mortality rate observed in test patients enrolled in the original Powerlink trial (6.7%). After one year and up to three years, six patient deaths were reported due to cancer (n = 2), congestive heart failure (n = 1), respiratory failure and sepsis secondary to COPD (n = 1), thrombocytopenia (n = 1), and stroke (n = 1). As illustrated in Fig 3, the Kaplan-Meier one-year estimate of freedom from all-cause mortality is 91%.

As detailed in Table III, three patients suffered a major adverse event (MAE) within 30 days post-procedure: respiratory failure secondary to pre-existing congestive heart failure (n = 1); renal failure secondary to pre-existing renal insufficiency attributed to contrast exposure (resolved following in-patient dialysis for two days), and secondary intervention for distal Type I endoleak (n = 1). No perioperative aneurysm rupture, conversion to open repair, coronary intervention, myocardial infarction, or stroke was observed. After 30 days and within one year, no aneurysm rupture, conversion to open repair, or coronary intervention has been reported. Late MAE included acute myocardial infarction treated medically (n = 1), renal failure (n = 3), respiratory failure secondary to lung cancer (n = 1), stroke (n = 2), and secondary intervention for Type II endoleak (n = 1 [with subsequent proximal Type I intervention during year 2]) or proximal Type I endoleak (n = 2). Mean serum creatinine level at one year was not significantly different than that measured preoperatively (1.18 ± 0.32 vs. 1.20 ± 0.36 , $P = .87$). Beyond one year, no aneurysm rupture, conversion to open repair, or coronary intervention occurred. During follow-up year 2, MAEs include coronary artery bypass grafting (n = 1), myocardial infarction treated medically (n = 1), and stroke (n = 1) in a patient who suffered a stroke during year 1. Mean serum creatinine level at two years remained stable (1.20 ± 0.28 vs. 1.20 ± 0.36 , $P = 1.00$). As illustrated in Fig 4, the

Kaplan-Meier one-year estimate of freedom from MAE is 79%.

Other treatment effectiveness measures

Aneurysm sac exclusion. The Core Laboratory assessed CT scans to determine the effectiveness of aneurysm sac exclusion, as measured by maximum diameter changes over time. Consistent with reporting standards, aneurysm sac diameter decrease or increase was defined as a change of >5 mm compared with baseline.⁹ A summary of the results through one year is presented in Table IV. In aggregate, 96% of patients had no growth in the aneurysm sac diameter (stable: 66%; significantly reduced: 30%). Two patients were identified with an increase in aneurysm sac diameter at one year and at two years. One patient was diagnosed with a Type II endoleak at the one and six month visits that resolved. A second patient was diagnosed with a Type II endoleak at one month, six months, and one year. No intervention has been required. Overall, mean aneurysm sac diameter was reduced at one year and two years compared with the baseline measurement (5.5 ± 0.9 cm vs. 5.7 ± 1.0 cm [$P = .21$] and 5.3 ± 1.0 cm vs. 5.7 ± 1.0 cm [$P = .09$], respectively). No migration (device movement >10 mm relative to the original implant location) has been observed. However, limited device movement of 5 mm at one year was identified in two patients who had thrombus-filled reverse taper necks that were <10 mm, neither of which has been observed with an MAE or an endoleak.

Device integrity. The Core Laboratory assessed abdominal x-rays and CT scans to evaluate device integrity, including stent fracture, stent graft patency, and limb occlusion. Throughout the follow-up period, no stent fractures or limb occlusions have been observed. Stent graft patency of 100% is observed at every follow-up timepoint.

Endoleak and secondary procedures. The Core Laboratory assessed CT scans to determine the presence of endoleak at each follow-up. Results are presented in Table V. The majority of endoleaks (27/31) are Type II. Moreover, there have been no Type III or Type IV endoleaks. Through current follow-up, a total of five patients have undergone a secondary procedure for endoleak of any type (Table VI). One secondary intervention was performed within 30 days, for an early secondary procedure rate of 1.3% (1/78). Attributed by the investigator to extreme tortuosity and narrowing at the native bifurcation, this patient was observed with kinking of the device within the stent graft limbs and at the level of the bifurcation, with associated distal Type I endoleak. On postoperative day seven, stenting and ballooning of the iliac vessels to the level of the aortic bifurcation and within the stent graft lumen was performed, resolving the kinking and endoleak. After 30 days and within one year, the secondary procedure rate was 5.1% (4/78). One patient with bilateral distal Type I endoleak received a limb extension (left iliac) and underwent angioplasty (right iliac) on postoperative day 51, successfully repairing the leaks. One patient diagnosed with Type II endoleak associated with both IMA and lumbar vessels underwent attempted embolization on days 176,

Table III. Major adverse events within one year*

<i>Event</i>	<i>Within 30 days [n/N (%)]</i>	<i>>30 days to one year [n/N (%)]</i>	<i>Total [n/N (%)]</i>
Patients with ≥ 1 event	3/78 (3.8%)	11/78 (14%)	13/78 (17%)
Mortality	0/78 (0.0%)	5/78 (6.4%)	5/78 (6.4%)
AAA rupture	0/78 (0.0%)	0/78 (0.0%)	0/78 (0.0%)
Conversion to open repair	0/78 (0.0%)	0/78 (0.0%)	0/78 (0.0%)
Coronary intervention	0/78 (0.0%)	0/78 (0.0%)	0/78 (0.0%)
Myocardial infarction	0/78 (0.0%)	1/78 (1.3%)	1/78 (1.3%)
Renal failure	1/78 (1.3%)	3/78 (3.8%)	4/78 (5.1%)
Respiratory failure	1/78 (1.3%)	1/78 (1.3%)	2/78 (2.6%)
Secondary procedure	1/78 (1.3%)	2/78 (2.6%) [†]	3/78 (3.8%)
Stroke	0/78 (0.0%)	2/78 (2.6%)	2/78 (2.6%)

Results shown as number of patients with event (% of total in group).

AAA, Abdominal aortic aneurysm.

*Defined as all-cause death, aneurysm rupture, conversion to open repair, coronary intervention, myocardial infarction, renal failure, respiratory failure, secondary procedure for proximal type I endoleak, and stroke.

[†]Includes one patient who underwent three interventions for Type II endoleak within one year and subsequent intervention for Type I proximal endoleak during follow-up year two.

Fig 4. Kaplan Meier Plot – freedom from major adverse events.

194, and 375 without resolution. This patient was later diagnosed during follow-up year two to have a proximal Type I endoleak, and received a balloon-expandable aortic stent on day 768, which resolved the endoleak.

DISCUSSION

A prospective clinical trial was conducted under an FDA-approved protocol to evaluate the safety and effectiveness of anatomical fixation using the Powerlink 28 mm bifurcated device with concomitant proximal sealing using the Powerlink XL 34 mm proximal extension in the treatment of abdominal aortic or aorto-iliac aneurysms (AAA). Notably, this is the first trial conducted using this distal fixation/proximal sealing technique. Additional data were gathered under a continued access provision of the protocol. Perioperatively, no mortality, aneurysm rupture, or conversion to open repair occurred. Procedural complications and major adverse events were limited. Through one year and currently available follow-up, no aneurysm-related

mortality, aneurysm rupture, or conversion to open repair has occurred. All-cause mortality is consistent with previous trial results. The overall major adverse event rate at 30 days and at one year was 3.8% (3/78) and 14% (11/78), respectively. These results compare favorably with corresponding rates observed in the original Powerlink trial (6.8% and 17%, respectively)¹ suggesting satisfactory utilization of the aortic bifurcation for fixation even with large proximal aortic necks. The main body graft resting on the aortic bifurcation can support the added mechanical forces of a larger (34 mm) cuff inside a standard size (28 mm) body.

Trial success was demonstrated with the prevention of proximal Type I endoleak at one year in more than 96% of the patients enrolled, leading to US FDA approval of this device and treatment algorithm in October 2008. Moreover, no migration has occurred and no renal artery infarct or occlusion has occurred as these aneurysms have begun to shrink over time. Outcomes of secondary endpoints such as clinical utility measures (ie, operative time, blood loss, hospital stay) and device related variables (ie, delivery success, aneurysm sac changes over time, and device integrity) provide supportive evidence as to the safety and effectiveness of this treatment algorithm for patients with aortic necks up to 32 mm in diameter.

The Powerlink system is unique among EVAR devices currently available in that the bifurcated stent graft is of a unibody design. Delivery is achieved through only one surgically exposed femoral artery for deployment, with a precannulated contralateral limb with guidewire compatible with percutaneous 9 Fr sheath placement. This design enables it to be used in patients with one small or diseased iliac access vessel, potentially broadening the population of patients that can be treated endovascularly. Within this trial population, the 16 mm bifurcated device limbs were placed within native vessels per the device design intent ranging in diameter from 10 mm to 14 mm. Patients with larger iliac vessels were treated with larger diameter limb extensions. The lack of limb thrombosis or occlusion serves to reinforce the validity of this device design.

Table IV. Aneurysm sac diameter results (Core Laboratory)

Time point	Decreased n/N (%)	Stabilized n/N (%)	No growth n/N (%)	Increased n/N (%)
One year	16/51 (31%)	33/51 (65%)	49/51 (96%)	2/51 (3.9%)
Two years	7/15 (47%)	6/15 (40%)	13/15 (87%)	2/15 (13%)

Decreased: >5 mm reduction; Stabilized: 5 mm or less change; Increased: >5 mm increase; No Growth = Decreased + Stabilized.

Table V. Endoleak results (Core Laboratory)

Any endoleak	Type I proximal	Type I distal	Type II	Type III	Type IV	Unknown
One month (N = 73) 17 (23%)	0 (0.0%)	1 (1.4%)	14 (19%)	0 (0.0%)	0 (0.0%)	3 (4.1%)
One year (N = 51) 10 (20%)	1 (2.0%)	1 (2.0%)	9 (18%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Two years (N = 15) 4 (27%)	0 (0.0%)	0 (0.0%)	4 (27%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table VI. Secondary procedures

Time point	Type I proximal endoleak [†] n/N (%)	Type I distal endoleak [‡] n/N (%)	Limb occlusion n/N (%)	Type II endoleak [§] n/N (%)
One month	0/78 (0.0%)	1/78 (1.3%)	0/78 (0.0%)	0/78 (0.0%)
Six months	1/75 (1.3%)	1/75 (1.3%)	0/75 (0.0%)	1/75 (1.3%)
One year	1/56 (1.8%)	0/56 (0.0%)	0/56 (0.0%)	1/56 (1.8%)
Two years	1/22 (4.5%)	0/22 (0.0%)	0/22 (0.0%)	0/22 (0.0%)

A total of five patients underwent one or more intervention.

[†]Three patients underwent successful intervention on days 66, 393 and 768, respectively.

[‡]Two patients underwent successful intervention on days seven and 51, respectively.

[§]One patient underwent three unsuccessful interventions on days 176, 194, and 375. This patient underwent a subsequent intervention during follow-up year two that successfully resolved a proximal Type I endoleak.

Placement of the bifurcated stent graft at the level of the aortic bifurcation enables fixation of the main device independently from sealing at the proximal neck and distal iliac seal zones. The core laboratory reported migration rate of 0% in this cohort provides substantial reinforcement for the mid-term durability of this approach. In their analysis of the original Powerlink trial in patients with aortic necks up to 26 mm in diameter, Wang et al⁵ identified a migration rate of 1.6% within one year, and 2.6% beyond one year through five years. Among all of these patients, two (1.0% of the cohort) required an intervention for endoleak. These authors determined that each of the eight migrations occurred in patients who did not receive the device via anatomical fixation. This finding has been echoed by Qu et al,¹⁰ wherein a Powerlink migration rate of 1.9% over a seven-year period was observed. Consistently, all of the migrations occurred in patients in whom the bifurcated devices were not placed at the aortic bifurcation, but still remains lower compared with rates between 9.5% and 17% reported for other endografts within four years.¹¹⁻¹³ To this end, some have focused efforts on improving proximal endograft fixation using mechanical means, including radial force, suprarenal fixation, or penetrating hooks and barbs; however, the problem remains. Others recognize that distal sealing is essential to ensuring the stability of stent graft

positioning over time.^{14,15} The absence of migration in this trial population is even more remarkable considering the prevalence of challenging anatomy in these patients having wide aortic necks. Suprarenal endograft fixation has been advocated as a potential means of treating patients with short aortic necks because in theory less infrarenal neck is required to generate an adequate seal.⁷ In addition, a thrombus-filled infrarenal aortic neck places patients undergoing endovascular repair with an infrarenal device requiring proximal fixation at increased risk for device migration and/or poor sealing.⁸ The presence of a conical or reverse conical aortic neck adds a further obstacle to achieving fixation and proximal seal. It is clear that use of more distal fixation by seating the bifurcated stent graft at the aortic bifurcation with concomitant sealing at distal and proximal zones effectively prevents migration. As evidenced in the results, this treatment algorithm was well tested in this trial enrolling patients with wide aortic necks and prevalent hostile proximal neck anatomical features that are recognized risk factors for migration. However, ultimately, longer term results will be required to assure the security of this fixation method.

The rate of secondary endovascular procedures for repair of Type I or Type II endoleak was 6.4%. Stent graft occlusion was not observed in this trial; this is in contrast to

a recent analysis of predictors for graft limb occlusion, citing a 7.2% event rate.¹⁶ The overall reintervention rate observed in this trial compares favorably with the one-year rates observed in the original Powerlink trial and trials of other devices (8.0% to 10%).^{1,11-13} Notably, although all patients in this trial received a bifurcated device and one or more proximal extensions, no Type III endoleaks were observed. Effective aneurysm exclusion at one year is further demonstrated by the lack of aneurysm growth in 96% of patients. Consistent with all other Powerlink trials, no stent or graft material fatigue or failure or Type IV endoleak has been observed.

CONCLUSIONS

The combination of an anatomically-fixed Powerlink bifurcated 28 mm stent graft and a Powerlink XL 34 mm proximal extension appears safe and effectively excludes aneurysms in patients with wide aortic necks. The requirement for only one surgically exposed femoral artery facilitates graft placement in patients with limited access routes. As in prior Powerlink trial reports, the graft and stent materials have been free from failure and fatigue. The absence of aneurysm-related death, conversion to open repair, and migration through one year in this pivotal trial underscore the significant clinical benefits of this endovascular treatment algorithm particularly in light of the prevalent hostile neck anatomy. Longer term follow-up will determine the durability of these results.

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Conception and design: WJ
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Appendix (online only)

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