

Remodeling of AAA Morphology 5 Years After EVAR With The Endologix Endograft

Veith Symposium 2006
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Powerlink[®] System:

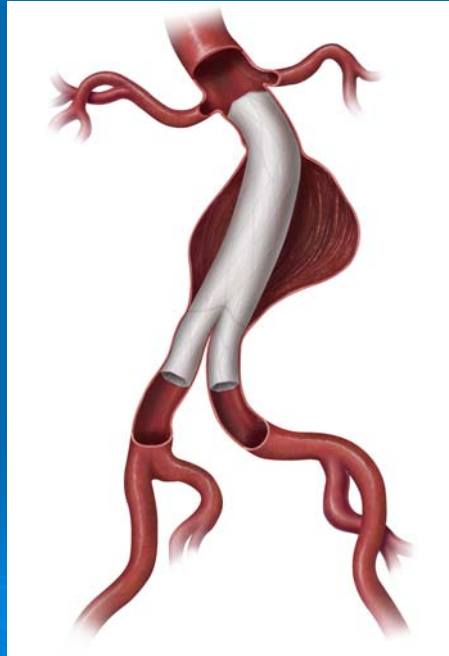
- Unibody-Bifurcated Design
- Long Main Body
- Low-Porosity Proprietary ePTFE Formulation
- Cobalt Chromium Alloy Stent
- Single-wire Main Body Construction
- Fully Supported



Anatomical Fixation

- Device implanted sitting on the anatomical aortic bifurcation
- Provides substantial resistance to distal migration
- Improved blood hemodynamics through the graft
- Simplifies deployment procedures

Raithel, et al. A New Concept in EVAR. *Endovascular Today*. 2006; 5:61-62.



Minimally Invasive Access

- 21 Fr Delivery System - Ipsilateral
 - No introducer sheath used
 - No upsizing of arteriotomy required
- 9 Fr Percutaneous Sheath - Contralateral

Powerlink® U.S. Pivotal Trial

➤ 192 patients enrolled between July 2000 and March 2003

➤ Eligibility Criteria

- Proximal Infrarenal Neck:
 - ≥15mm length
 - <60° angle
 - 26mm maximum diameter, 18mm minimum diameter
- AAA ≥4.0 cm diameter or rapidly growing AAA
- Iliac diameter ≥7mm on at least one side (for access)
- Dispensable inferior mesenteric artery
- Preservation of at least one hypogastric artery
- Iliac seal zone of ≥15mm length (≤18mm diameter)
- Aortic bifurcation diameter ≥18mm
- ≥18 years old
- Not pregnant
- Candidate for open AAA repair
- Serum creatinine ≤1.7mg/dL
- Willingness to comply with follow-up schedule
- No bleeding disorders
- Life expectancy >2 years
- No connective tissue disorders

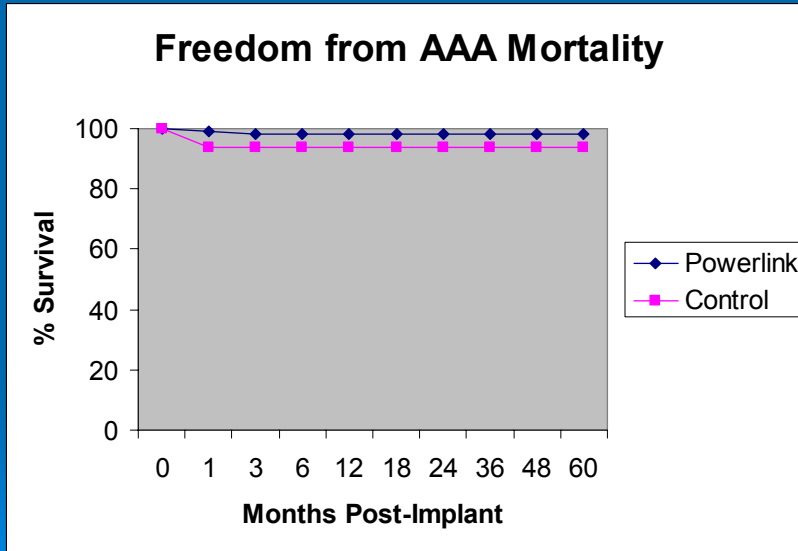
Summary of Significant Early Clinical Findings

	Powerlink	Control	P-value
➤ Age	73.2 ± 7.0	69.7 ± 7.9	<0.0008
➤ Successful Deployment	188/192 – 97.9%	N/A	N/A
➤ Patients with at least 1 Major† AE (0-30days)	13/192 - 6.8%	14/66 - 21.2%	<0.0020
➤ All Death ≤ 30 days	2*/192 - 1.0%	4/66 - 6.1%	< 0.0389
➤ Anesthesia Time (min)	185.1 ± 82.2	293.8 ± 111.5	<0.0001
➤ Procedure Time (min)	135.9 ± 65.9	222.3 ± 100.1	<0.0001
➤ Blood Loss (l)	0.34 ± 0.41	1.58 ± 1.6	<0.0001
➤ Days in ICU	0.78 ± 1.5	4.1 ± 8.4	<0.0001
➤ Days to Discharge	3.3 ± 3.4	9.5 ± 7.7	<0.0001

† Defined as death, MI, stroke, AAA rupture, conversion, secondary procedure, coronary intervention, renal failure, or respiratory failure

* Not device related

Carpenter JP, et al. Midterm results of the multicenter trial of the Powerlink bifurcated system for endovascular aortic aneurysm repair. *J Vasc Surg* 2004;40:849-59.



Secondary Procedures

(through 60 months*)

34 procedures in 26 patients

- Endoleak –23 (Cuffs, embolization, balloon dilatation)
 - Type II Endoleak –18
 - Type I Endoleak – 5
- Graft Limb Occlusion – 7
 - Embolectomy, Stent, PTA, or Lytic Therapy
- Native Artery Procedures – 3
- Migration - 1

* As of Sept. 2006

Conversion, Rupture

(through 60 months*)

- Surgical conversions – 4
 - Intraoperative – 3
 - @12 mo. – 1

- Aneurysm rupture – 0

* As of Sept. 2006

Patient Compliance at Follow Up*

	12 mo	24 mo	36 mo	48 mo	60 mo
Available Patients	175	159	149	110	46
Clinical Follow Up	152	151	113	101	44
	86.7%	95.0%	96.0%	91.8%	95.7%
Core Lab CTs	147	142	130	101	45
	84.0%	89.3%	87.3%	91.8%	97.8%

* As of Sept. 2006

Core Lab Analysis

Endoleaks (All Types, New and Persistent)[†]

	1 mo (N=123)	6 mo (N=119)	12 mo (N=147)	24 mo (N=142)	36 mo (N=130)	48 mo (N=101)	60 mo (N=45)
All Endoleaks	25	13	18	12	8	8	3
Type I	1	0	0	0	0	0	0
Type II	20	13	15	9	7	6	2
Type III	0	0	0	0	0	0	0
Type IV	0	0	0	0	0	0	0
Multiple	2	0	1	0	0	0	0
Indeterminate	2	0	2	3	1	2	1

[†]As of Sept. 2006

Core Lab Analysis

New Endoleaks [†]

	1 mo (N=123)	6 mo (N=119)	12 mo (N=147)	24 mo (N=142)	36 mo (N=130)	48 mo (N=101)	60 mo (N=45)
All Endoleaks	25	5	7	1	1	3	1
Type I	1	0	0	0	0	0	0
Type II	20	5	5	1	0	2	0
Type III	0	0	0	0	0	0	0
Type IV	0	0	0	0	0	0	0
Multiple	2	0	1	0	0	0	0
Indeterminate	2	0	1	0	1	1	1

[†]As of Sept. 2006

Sac Diameter Over Time†

Diameter (mm)	Pre-op (N=189)*	12 mo (N=147)	24 mo (N=142)	36 mo (N=130)	48 mo (N=101)	60 mo (N=45)
Mean (SD)	50.40 (6.98)	45.77 (7.94)	43.13 (9.01)	41.49 (9.35)	40.20 (9.66)	38.79 (9.27)
Minimum	37.30	30.20	27.00	26.80	27.10	27.30
Maximum	74.30	72.40	69.70	72.10	73.50	68.40

† As of Sept. 2006

* 192 patients enrolled, 3 patients' CT's lost before submission to core lab

Sac Volume Over Time†

Volume (cc)	Pre-op (N=187)*	12 mo (N=144)	24 mo (N=139)	36 mo (N=129)	48 mo (N=101)	60 mo (N=44)
Mean (SD)	135.4 (39.4)	124.6 (40.3)	119.1 (38.4)	115.3 (37.2)	111.0 (36.2)	114.4 (39.2)
Minimum	70.8	62.8	58.3	54.1	59.3	69.5
Maximum	270.5	292.4	293.9	279.2	262.4	277.9
Unevaluable**	2	3	3	1	0	1

† As of Sept. 2006

* 192 patients enrolled, 3 patients' CT's lost before submission to core lab

** Some CT scans are not evaluable for some parameters most often due to poor image quality, no contrast, CT's taken at greater than 3mm slices, etc.

Sac Diameter @ 60 months

Aneurysm Diameter	60 mo (N=45)
Decrease ($\geq 5\text{mm}$)	34 (75.6%)
No Change ($\pm < 5\text{mm}$)	9 (20%)
Increase ($\geq 5\text{mm}$)	2 (4.4%)*

* one patient identified with a Type II Endoleak

Morphology Change Sub-Analysis

Method

- Patients with paired data (both a 1-month and either a 2-year, 3-year, 4-year and 5-year follow-up CT) as of September 2006 were included in this analysis
- Current Analysis N = 95 pts.
- All CT's were analyzed by study core lab utilizing proprietary 3-D reconstruction software (*Medical Metrx Solutions, West Lebanon, NH*)

Analysis

- Mean max. sac diameter
- Mean sac volume
- Distance between distal renal and aortic bifurcation
- Δ in maximum sac angulation

- Sac angle calculation was determined from distal proximal neck to maximum inflection point in the sac to aortic bifurcation (180° = straight line through sac)

Overall Results

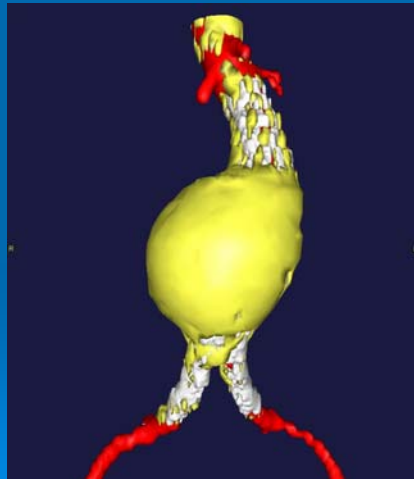
	1- Mo.	2-Yr.	3-Yr.	4-Yr.	5-Yr.
Mean Max. Sac Angle	143.4°	151.8 °	152.6°	153.5 °	155.6°
Mean Max. Sac Diameter	50.5 mm	43.1 mm	41.5 mm	40.2 mm	38.8 mm
Mean Aortic Volume	136.5 ml	119.1 ml	115.3ml	111.0 ml	114.4 ml
Mean Distance Between Distal Renal & Bifurcation	118.5 mm	121.0 mm	121.4 mm	122.1 mm	125.8 mm

Paired Results

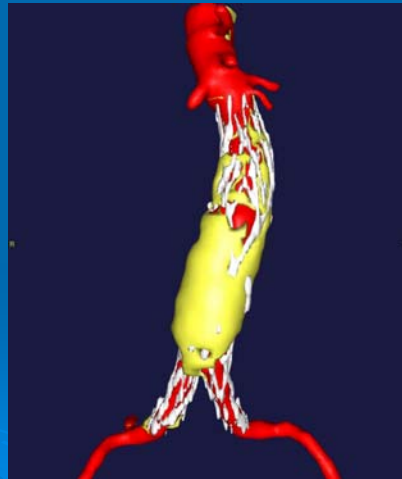
	1-Mo. - 2-Yr. (n=95)	1-Mo. - 3-Yr. (n=91)	1-Mo. - 4-Yr. (n=73)	1-Mo. - 5-Yr. (n=30)
% w/ Max. Sac Angle Becoming Straighter	78.9%	79.1%	75.3%	83.3%
Δ in Mean Max. Sac Angle Becoming Straighter	11.7°	12.7°	13.2°	12.8°
% w/ Max. Sac Angle Same or Becoming More Angled	21.1%	20.9%	24.7%	16.7%
Δ in Mean Max. Sac Angle Same or Becoming More Angled	-3.3°	-6.3°	-8.1°	-12°
Δ in Mean Length from Distal Renal to Bifurcation	2.2 mm	2.3 mm	2.7 mm	3.6 mm

Example: Pt. w/ 22.6° Straighter Sac Angle

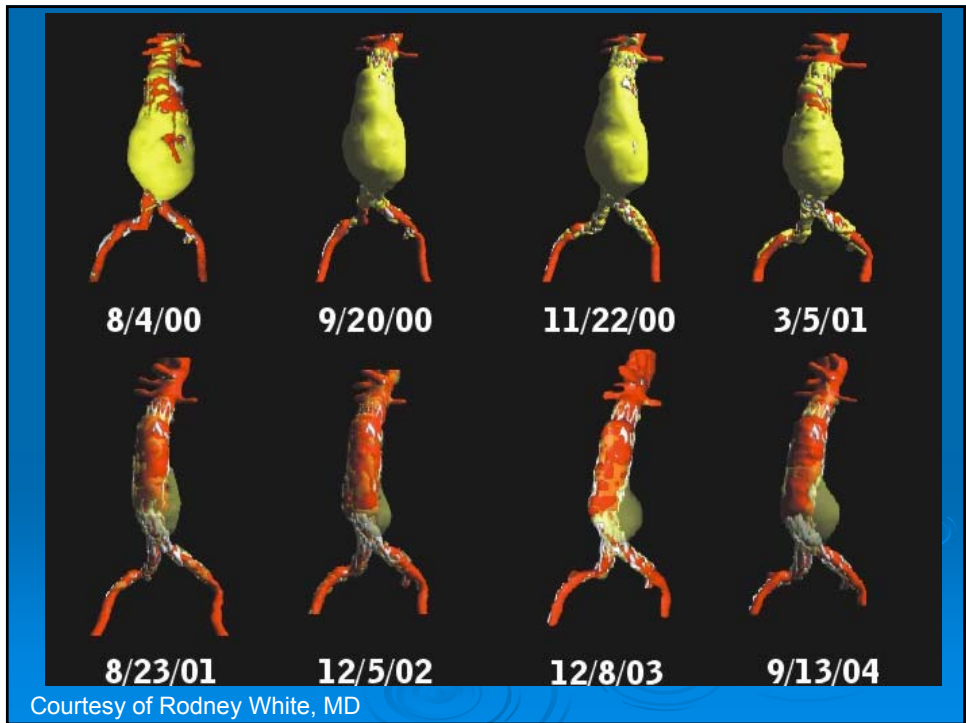
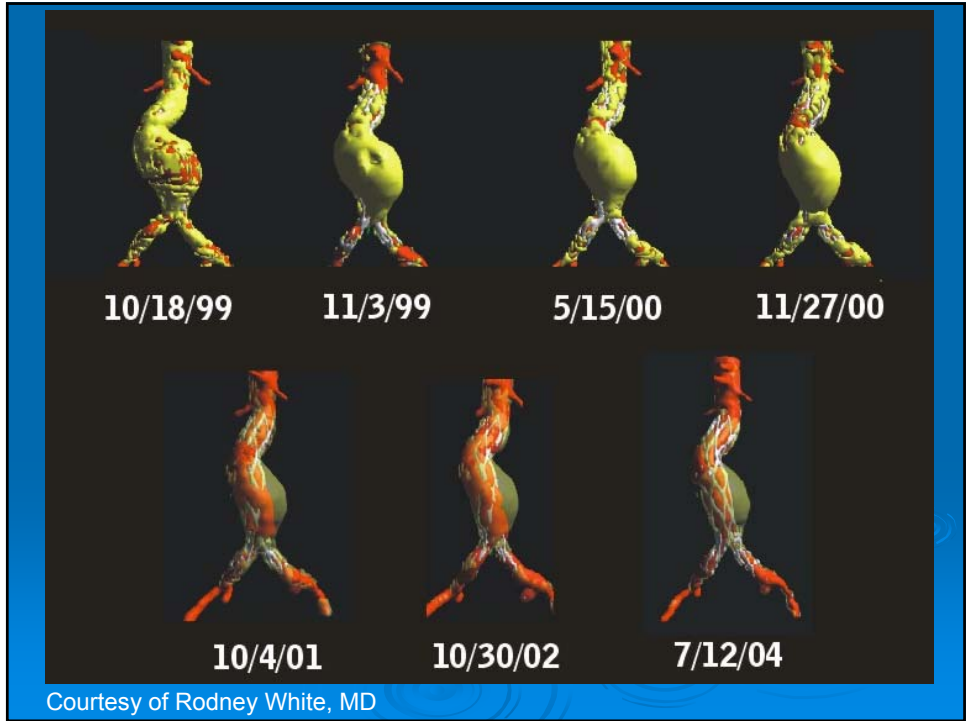
1 – Mth.

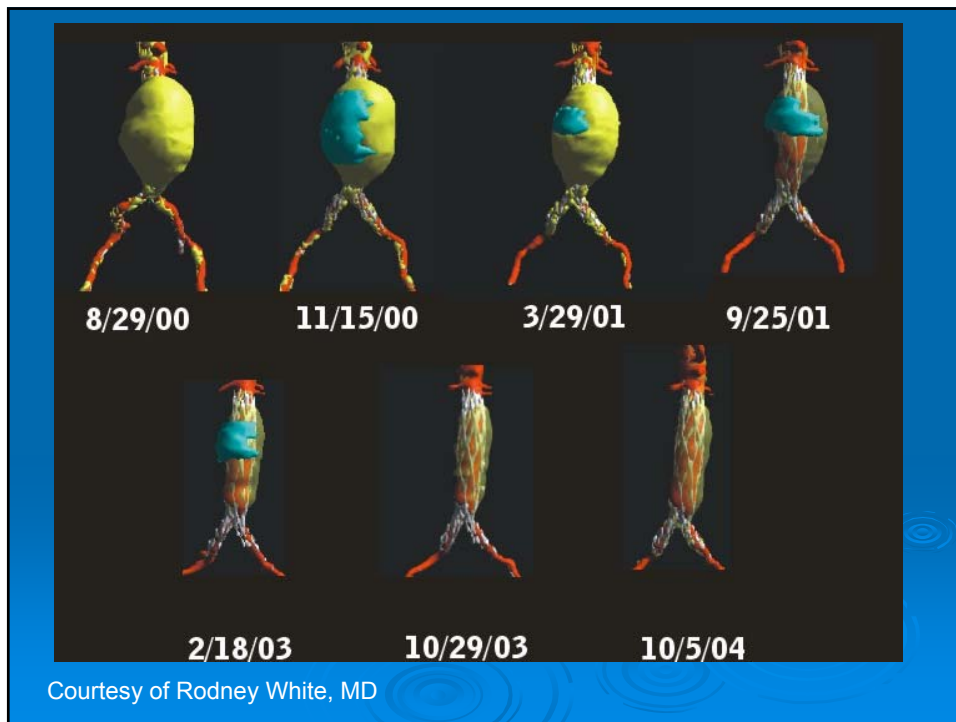


3 – Yr.



Courtesy of Rodney White, MD



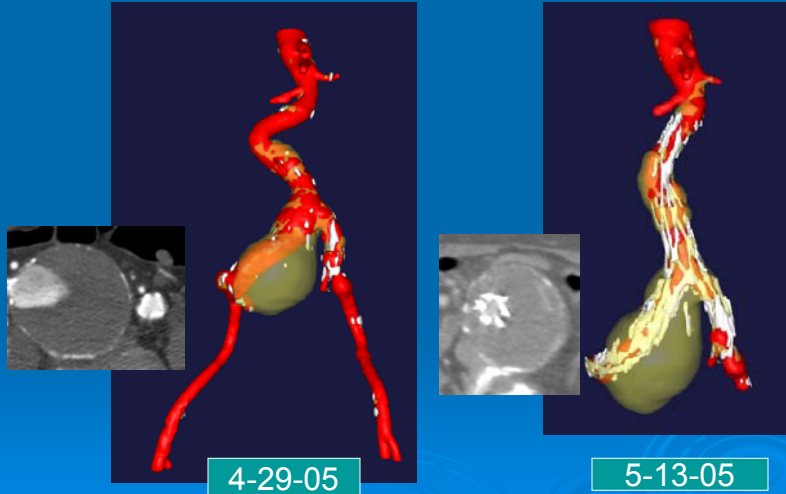


Differences in CT Assessment

- Graft material attached to stent only at proximal and distal ends
- Graft “balloons” off stent cage during cardiac cycle.
- Blood can flow outside of stent cage contained in ePTFE graft reducing stress on the stent cage

Courtesy of Rodney White, MD

Treatment of Challenging Anatomy



Courtesy of Rodney White, MD

Summary of Late Clinical Findings

- 97.9 % Freedom from AAA-Related Mortality @ 5 years with the Powerlink System
- No aneurysm ruptures
- Only 1 late conversion (@ 1 yr.)
- No ePTFE graft material failures @ 5 years
- No cobalt chromium stent graft failure or fatigue @ 5 years

Conclusions

- Simple implantation technique
- Minimally invasive access
- Anatomical Fixation for resistance to migration
- Low occurrence of secondary procedures
- Safe and effective protection from AAA rupture
- Low occurrence of Type II endoleaks
- Sac regression and improving morphology
- Proven durability