



Powerlink stent-graft
Preliminary results of the
French trial

Marseille	Pr Branchereau/Pr Magnan	9
St Etienne	Pr Favre	9
Reims	Pr Clement	8
Toulouse	Dr Giraud	8
Lomme	Pr Puppinck	7
Lyon	Pr Chevalier	5
Grenoble	Pr Magne	4
Clermont-Ferrand	Pr Ribal	4
St Denis	Dr Sebbag	4
Montpellier	Pr Mary	2
Marseille	Dr Jausseran	1
Angers	Pr Enon	1
Paris	Pr Kieffer/Pr Benhamou	1
Toulouse	Pr Rousseau	1

Powerlink French Trial Design

Centers	14
Beginning of trial	June 2000
Last procedure	July 2001
Patients per center	4.42 (1- 9)

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Inclusion criteria

AAA

diameter	> 50 mm
growth	> 10 mm/year
diameter	> 2x aortic Ø at renal a. level

Proximal neck

diameter	≥ 22 mm and ≤ 26 mm
length	≥ 15 mm
angle	$< 45^\circ$
thrombus	< 50 % circumference

Powerlink French Trial Inclusion criteria

Aorta

Length	> 80 mm
Ø distal aorta	≥ 22 mm

Iliac arteries

Landing zone	length	20 mm
	Ø	11 - 15 mm
Access (ext. il. a.)	Ø	≥ 7 mm
Preservation of one internal iliac artery		

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Exclusion criteria

- ✓ Patient unfit for open surgery
- ✓ Patient unable to give informed consent
- ✓ Complicated AAA
- ✓ False aneurysm
- ✓ Age < 18 years
- ✓ Life expectancy < 24 months
- ✓ Coagulation disorders
- ✓ Dialysis
- ✓ Bilateral occlusion of IIA and patent AMI
- ✓ Infectious disease

Powerlink French Trial Patients

Included patients **64**

Mean age **70 years (56-90)**

Mean AAA Ø **55 mm (44-76)**

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Patients - Risk factors

HTA	39	61 %
Coronary disease	33	52 %
Respiratory insufficiency	16	25 %
LVEF < 40 %	3	4.7 %
Creat. > 150 micromoles/l	3	4.7 %
Hostile abdomen	11	17 %

ASA 1 and 2	55 %
ASA 3	42 %
ASA 4	3 %

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Patients - AAA morphology

Diameter

Proximal neck	23 mm	(22-26)
Right iliac neck	13 mm	(11-15)
Left iliac neck	13 mm	(11-15)

Length

Proximal neck	29 mm	(15-66)
Aorta	115 mm	(90-140)
RCIA	52 mm	(20-80)
LCIA	55 mm	(20-93)

Powerlink French Trial Patients - AAA morphology

Aortic length

< 100 mm	6	9.4%
≥ 100 et < 120 mm	43	67.2%
≥ 120 mm	15	23.4%

Aortic body length of stent-graft: 80 or 100 mm

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Patients - AAA morphology

Angle proximal neck/AAA

Mean angle 16.3° (0-45)

$\geq 30^\circ$ 19 patients

Powerlink French Trial Stent-graft

Body length	100 mm	52
	80 mm	12
Diameter	25 mm	31
	28 mm	33
25 x 16 x 135		8
28 x 16 x 135		4
25 x 16 x 155		23
28 x 16 x 155		29

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Stent-graft

Aortic cuff **24 37%**

scheduled 7

unscheduled 17

Iliac extension **8 12%**

scheduled 6

unscheduled 2

Powerlink French Trial Procedure

N = 64

Proctors 100 % of cases

Anesthesia general 60 epidural 4

Procedure duration 116 mn (55 - 240)

Fluoro time 19 mn (4 - 65)

Contrast load 170 ml(60 - 400)

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Intraoperative complications

Proximal leak (palmaz stent)	1
Iliac dissection	2
CIA Kinking + stenosis	1
CFA dissection	1
IIA coverage	3

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Postoperative course

	N	days
ICU stay	8	1.1
SCCU stay	23	1.6
Total length of stay	64	6 (2-26)

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Postoperative complications (1 month)

Death	0
Conversion	0
Resolutive ischemic colitis	1
Groin hematoma	1
Stent-graft limb occlusion	1

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Postoperative results (1 month)

Postoperative CT scan	64
Type I Endoleak	0
Type II Endoleak	2

Powerlink French Trial Follow-up

At discharge, 3 m, 6 m, 12 m, 18 m, 24 m...

Clinical examination

Serum creatinine

Abdominal X-Ray

CT-scan

Duplex scan

Powerlink French Trial Follow-up

Mean follow-up 10.4 months (2-20)

Lost to follow-up 0

Deaths 2 at 2 and 4 months
(bladder carcinoma/stroke)

Conversion 0

Secondary procedure 0

Rupture 0

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3-month CT-scan follow-up

CT-scan (1 death, 1 stroke)		62
Type I Endoleak	0	
Type II Endoleak (primary)	1	
Type II Endoleak (secondary)	1	
AAA diameter		
Stable	53	85%
Decrease > 5 mm	9	15%
Increase > 5 mm	0	

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6-month CT-scan follow-up

CT-scan		62*
Type I Endoleak	0	
Type II Endoleak (primary)	1	
Type II Endoleak (secondary)	2	
AAA diameter		
Stable	41	66%
Decrease > 5 mm	21	34%
Increase > 5 mm	0	

*2 deaths

Conclusion

Preliminary results are good.

There was no major intraoperative complication nor early conversion.

The rate of type II endoleaks (6%) is low.

The trial is progressing and in July 2002 all patients will have one-year follow-up.

I address a call for close follow-up to all the investigators.