

Mid-term outcome of CERAB for aorto-iliac occlusive disease

Michel Reijnen
Rijnstate Arnhem
The Netherlands



Disclosure

Speaker name:

Michel Reijnen

I have the following potential conflicts of interest to report:

- Consulting
 - Employment in industry
 - Stockholder of a healthcare company
 - Owner of a healthcare company
 - Other(s); Research funding
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- I do not have any potential conflict of interest

Lesions of the aortic bifurcation and Kissing Stents



- Wide range in patency results of kissing stents, usually inferior compared to isolated stents in iliac artery or the aorta
- Patency affected by geometry:
 - **Radial mismatch**; aortic lumen dead space around the protruding segment of the stents
 - Differences in **stent conformation**
 - The **overlap of the free proximal stent ends**
 - Re-circulation, turbulence and stasis
 - Mesenchymal tissue, thrombus and intimal hyperplasia





Covered Endovascular Reconstruction of the Aortic Bifurcation - CERAB



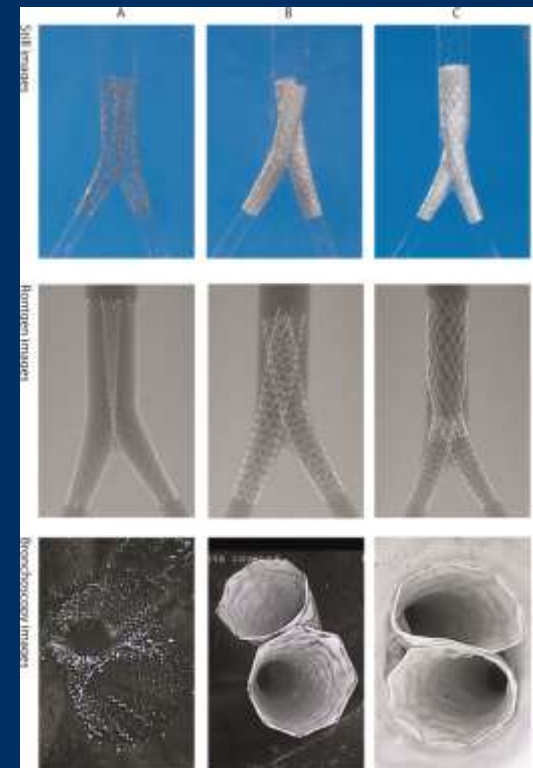
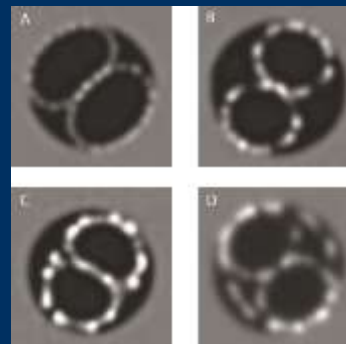
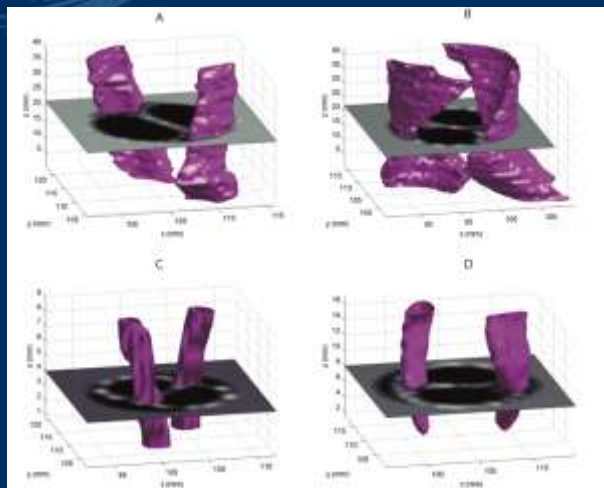


CERAB

Stent geometry

CERAB related to:

- Lowest radial mismatch
- High conformation ratio ('double-D' configuration)





CERAB

Laser Particle Image Velocimetry



CERAB and BM kissing stents; Mostly laminar flow throughout the cardiac cycle



BM Kissing stents; turbulence and recirculation at phases B and C



Clinical results of CERAB

Midterm outcome

- February 2009 – July 2016
- 130 elective patients, two centers
- Age 61 (36-81) years, 69 male
- Chimney procedures excluded
- Previous aorto-iliac intervention in 41 %



Rutherford classification:

- 1 (n=1) 0.8%
- 2 (n=0) 0.0%
- 3 (n=84) 66.1%
- 4 (n=22) 17.3%
- 5 (n=18) 14.2%
- 6 (n=2) 1.6%

TASC -II classification:

- B n=7 (5.4%)
- C n=7 (5.4%)
- D n=116 (89.2%)



Clinical results of CERAB

Midterm outcome

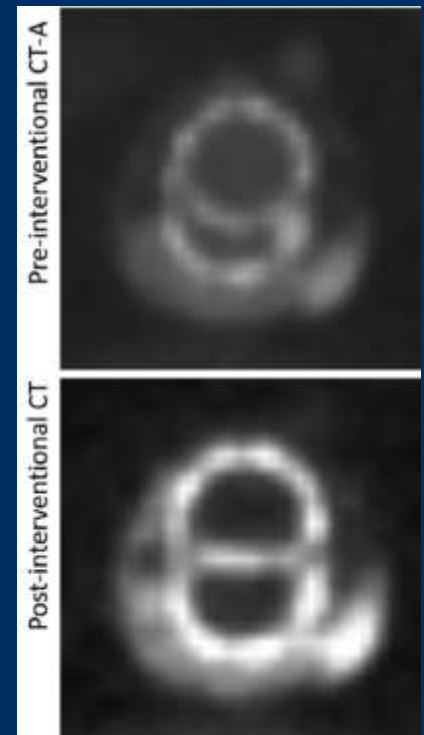
Age, years, mean (range)	61 (36-81)	
	No.	%
Men	69	53
Risk factors		
Current smoking	100	78
Diabetes mellitus	46	35
Hypertension	96	74
Hyperlipidemia	121	93
Cardiac disease	61	47
Pulmonary disease	51	39
Carotid disease	26	20
Renal disease	25	19
ASA category		
1	0	0
2	73	57
3	50	39
4	6	5

Outflow vessels (open; stenosis; occluded)	Right, %	Left, %
EIA	59; 30; 11	67; 22; 10
Internal iliac artery	66; 21; 14	61; 22; 17
Common femoral artery	71; 26; 3	76; 22; 2
SFA	67; 29; 5	66; 27; 7
Deep femoral artery	91; 8; 18	90; 10; 0



Clinical results of CERAB *complications*

	No.	Severity/comments
Procedural, major		
Dissection	6	All resolved with endovascular repair in the same procedure (PBA or stenting), no influence on health
Bleeding	2	One led to resuscitation after cardiac arrest during the procedure
Rupture	2	All resolved in the same procedure with endovascular repair, no influence on health
Dislocation of stent	1	Migration of the CERAB body, correction unsuccessful; however, CERAB completed
Stent deformation	1	Treated with PBA
Thrombus formation	2	All treated in the same procedure (thrombectomy), no influence on health
Postprocedural, major		
Stent deformation	3	Recovery after reintervention; stent collapse (one limb crushing the other limb), PBA in two cases, aortobifemoral graft in one case
Pneumonia	2	Leading to death in one case; second case, same patient as MOF case
Thrombosis	2	Recovery after intervention; one thrombectomy and one thrombolysis treatment
CFA occlusion related to closure device	1	Recovery after intervention; removal of the closure device
MOF	1	ICU stay with complete recovery; patient died 6 months postoperatively
Acute renal insufficiency	1	Permanent impairment requiring dialysis; patient died 4 months postoperatively

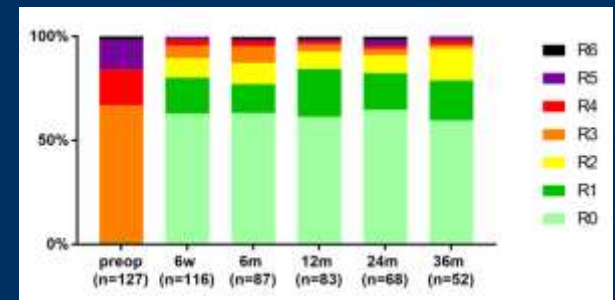
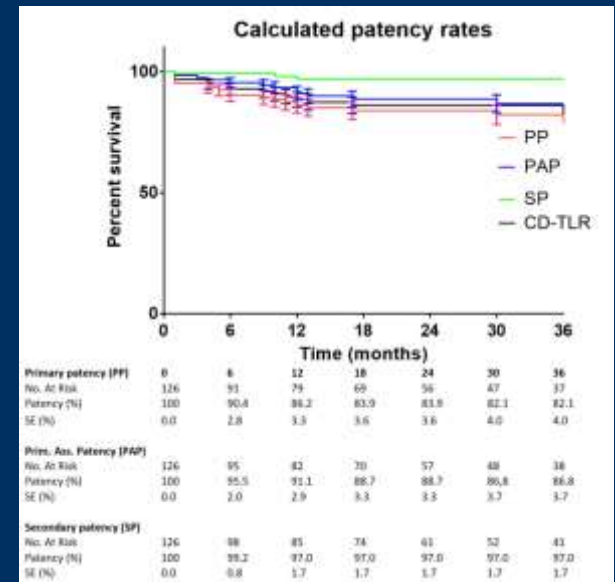




Clinical results of CERAB

Midterm outcome

- Median follow-up 24 months
- Total primary patency
 - 12 months 91%
 - 24 months 89%
 - 36 months 87%
- Secondary patency
 - 12 months 97%
 - 24 months 97%
 - 36 months 97%
- Clinical improvement at 36 months 96%
- Limb salvage rate at 36 months 97%





Clinical results of CERAB

Previous treatment

Previous treatment of AIOD

- Surgical reconstruction of the aortoiliac segment (n=7);
Five aorto-bi-iliac, one ileo-femoral and one femoro-femoral crossover bypass
- Endovascular intervention (N=46, 35%)
 - 46% PTA of the common iliac artery (in 17% kissing balloons)
 - 37% were PTA with stenting of the common iliac artery (31% KS)

	Yes (n = 46), %	No (n = 80), %
One-year follow-up		
Primary patency	80	88
Primary assisted patency	91	97
Secondary patency	98	98
Three-year follow-up		
Primary patency	76	85
Primary assisted patency	83	88
Secondary patency	94	98



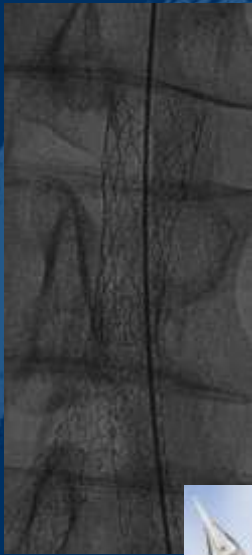
Balloon expandable covered stents

- Issues with availability of large diameter Advanta V12
- Alternative BE covered stents

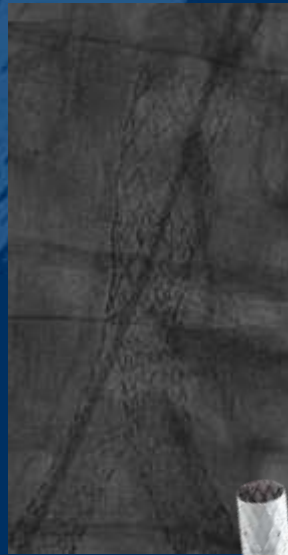
	Atrium Maquet V12	Bard Lifestream	Bentley BeGraft	Gore Viabahn BX
				
Stent material	316L Stainless steel	316L Stainless steel	CoCr (L605)	Stainless steel
Graft material	ePTFE	ePTFE	ePTFE	ePTFE with Heparin surface
Porosity	100 -120 μm	10-40 μm	102 \pm 25 μm	N/A
Graft design	Completely encapsulated	2 Layers, sandwich	Single stent, external cover	Internal cover
Stent diameters (mm)	RX: 5, 6, 7 OTW: 5, 6, 7, 8, 9, 10 LD: 12, 14, 16	5, 6, 7, 8, 9, 10, 12	SV: 5, 6 MV: 7, 8 LV: 9, 10	5, 6, 7, 8, 9, 10
Stent lengths (mm)	RX: 16, 21, 24 OTW: 16, 22, 38, 59 LD: 29, 41, 61	5-8 ϕ : 16, 26, 37, 58 9-12 ϕ : 38, 58	SV: 18, 22, 28, 38, 58 MV: 18, 23, 27, 37, 57 LV: 27, 37, 57	5-7 ϕ : 15, 19, 39, 59 8-10 ϕ : 39, 59
Strut Dimensions (Strut Width x Strut thickness)	N/A	N/A	0.135 x 0.145 mm (SV) 0.145 x 0.145 mm (MV) 0.165 x 0.145 mm (LV)	N/A
Catheter length (cm)	80 and 140	80 and 135	75 and 120	80 and 135



CERAB with different aortic stents



AdvantaV12™



Lifestream™



CP Stent™



BeGraft™



Conclusions

- Endovascular treatment of AIOD is an established treatment modality, also for complex disease
- The CERAB configuration is related to good outcomes up to three years, but issues with availability of the LD Atrium V12 stent
- Alternatives are available and the choice will mainly depend on availability, personal preference and costs
- Further studies are indicated to assess the outcome of alternative balloon-expandable covered stents

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