12-month results of vascular mimetic implants in the CFA

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Disclosures

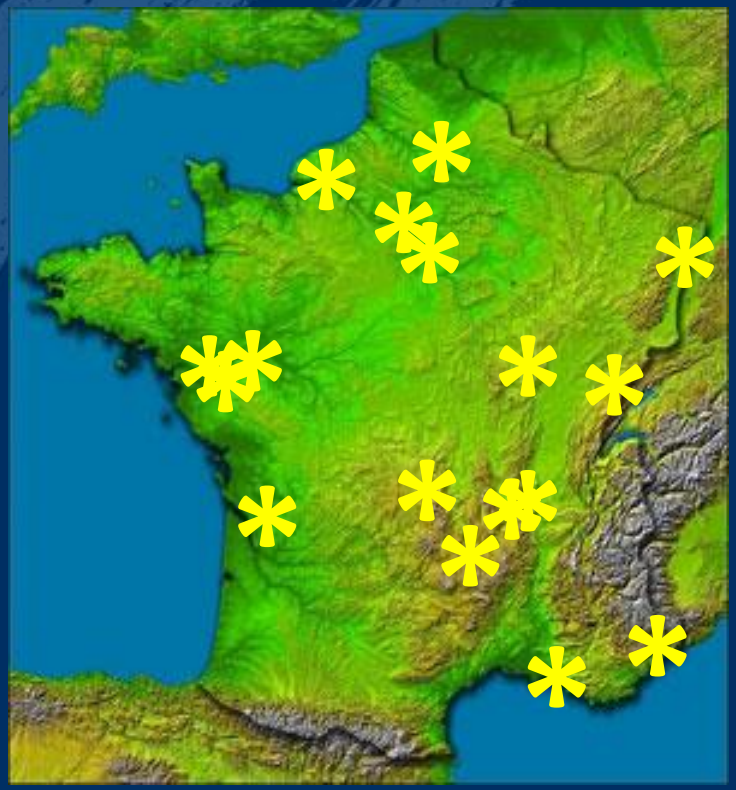
Y. Gouëffic reports:

- **Research funding** from Bard, Biotronik, Medtronic, Terumo, WL Gore

- **Personal fees and grants** from Abbott, Bard, Biotronik, Boston Scientic, Medtronic, Terumo, Vygon, WL Gore (medical advisory board, educational course, speaking)

TECCO trial

French multicenter randomized trial comparing surgery versus stenting for the treatment of CFA atherosclerotic lesion *(From 2011 to 2015)*



TECCO trial, NCT01353651
Sponsor Nantes University Hospital
PHRC 2010 DGOS 20-03

17 centers : CHU de Nantes (N°1), CHU de Amiens (N°2), CHU Besançon (N°3), CHU de Strasbourg (N°4), CHU de Dijon (N°5), CHU de Clermont-Ferrand (N°6), CHU de Nice (N°7), CHU de Marseille (La Timone) (N°8), CHU de Bordeaux (N°9), CHU de Lyon (N°10), CHU de St Etienne (N°11), CHU de Rouen (N°12), Clinque du Tonkin (N°13), Nouvelles Cliniques Nantaises (N°14), Clinique St Augustin (N°15), HEGP (N°16),) Hopital Henri Mondor (N°17)

TECCO randomized clinical trial, NCT01353651
Gouëffic, JACC Interv, 2017

Stenting or Surgery for De Novo Common Femoral Artery Stenosis

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JACC: CARDIOVASCULAR INTERVENTIONS CME/MOC

Modified intent to treat analysis

	Surgery (n=61)	Stenting (n=56)	p
Morbid-mortality rate @ 1 month, n (%)	16 (26)	7 (12.5)	0.05

Per protocol analysis

	Surgery (n=58)	Stenting (n=47)	p
Morbid-mortality rate @ 1 month, n (%)	16 (26)	3 (6.4)	0.005

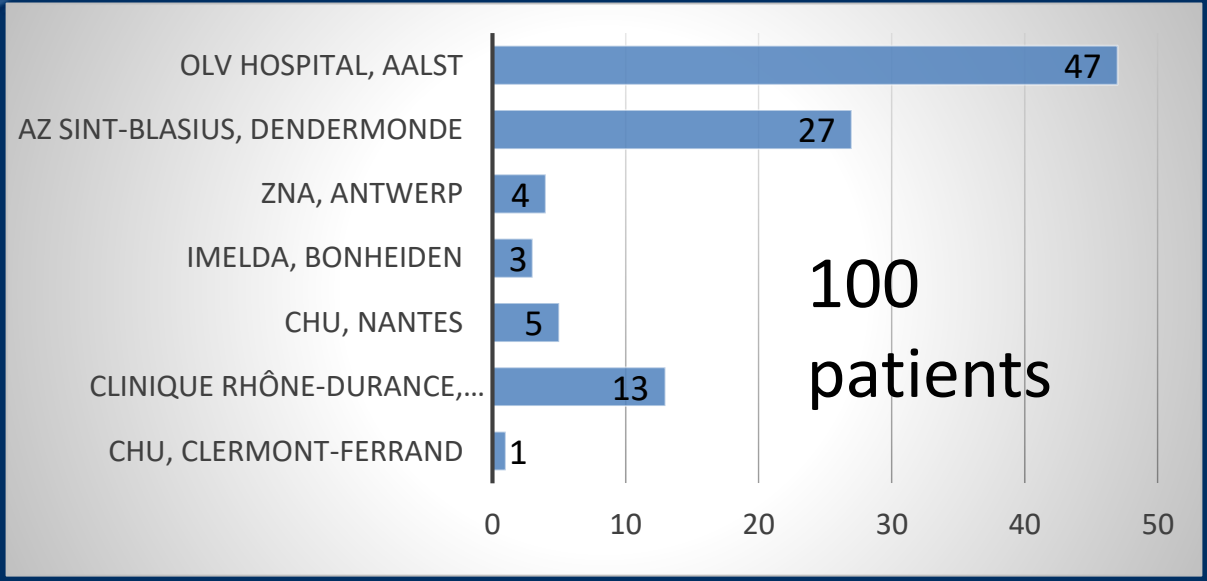
Gouëffic, JACC Interv, 2017

Supera® stent (Abbott)

Interwoven mimetic and self expandable stent

VMI-CFA trial

Prospective, multicenter, single arm trial to evaluate the Supera Peripheral Vascular Mimetic Implant Device (Abbott Vascular) for symptomatic (RB 2-4) CFA disease treatment



VMI-CFA trial: endpoints

- **Primary endpoint**

✓ ***Efficacy endpoint*** *: Primary patency @12 months (DUS PSVR<2.5 - Core lab adjudicated*) in CFA with noreintervention*

✓ ***Safety endpoint*** *: Periprocedural adverse events up to 30 days post procedure, as defined per ISO 14155:2011 (TLR, death, amputation)*

**EuroImaging Srl, Rome, Italy*

VMI-CFA trial: In/ex. criteria

In. criteria

RB 2-4 classification

De novo/post POBA lesions

Stenosis >50%/occlusions

Patent DFA

Good SFA run off

Ex. critieria

RB 5-6 classification

In-stent lesions CFA

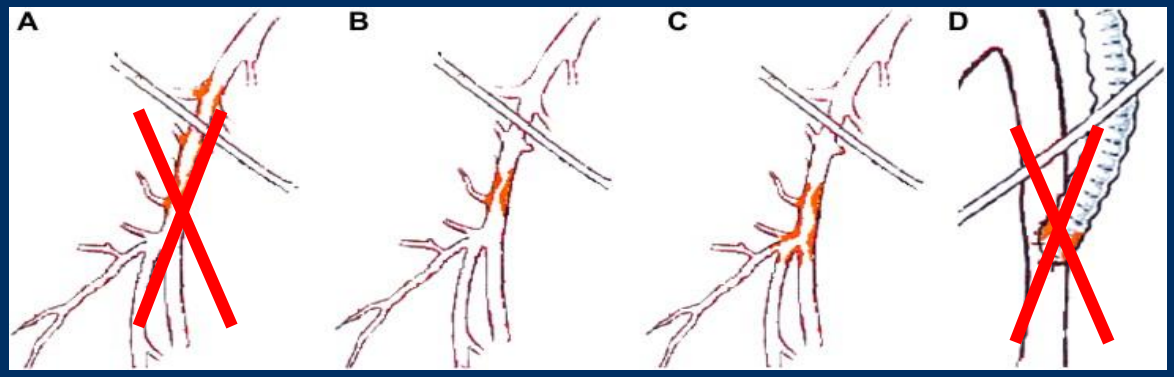
Previous surgery CFA

Occluded DFA/SFA

Non treatable inflow lesion

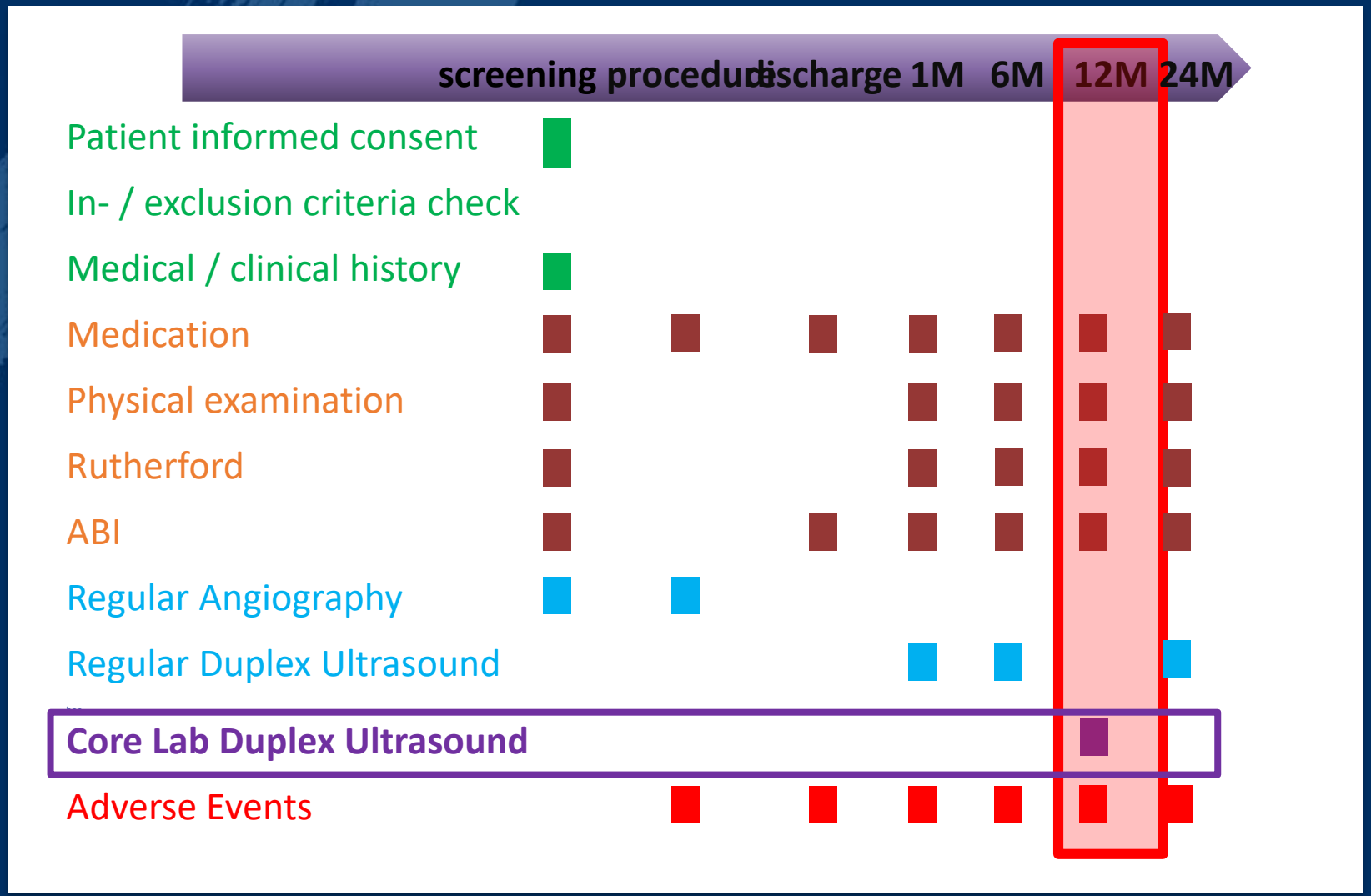
Thrombus

Debulking, DE technologies…



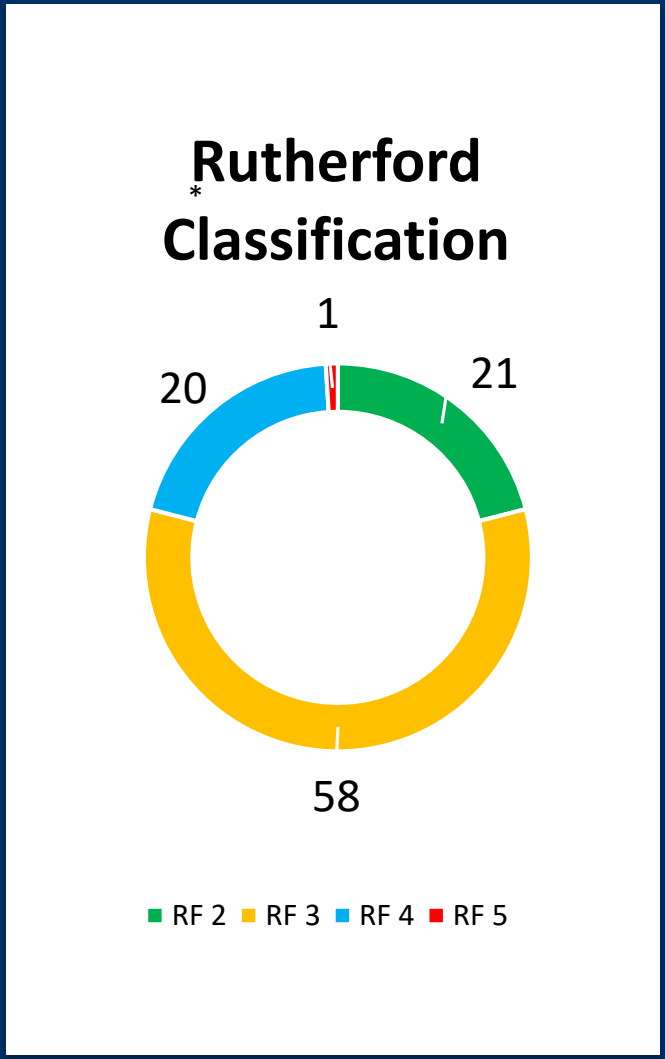
Azéma L. et al. EJVEVS, 41, 6 : June 2011 ; 787-793

VMI-CFA trial: timeline



VMI-CFA trial: demographics

	N = 100 out of 100
Male (%)	81 (81%)
Age (min-max ± SD)	72.72 (46.87 – 95.76 ± 8.59)
Nicotine (%)	29 (29%)
Hypertension (%)	78 (78%)
Diabetes (%)	35 (35%)
Renal insufficiency (%)	14 (14%)
Hypercholesterolemia (%)	62 (62%)
Obesity (%)	25 (25%)
Claudicant	79 (79%)
CLI patient	21 (21%)



* Protocol deviation

VMI-CFA trial: lesions

	N = 100 out of 100
Lesion length (min-max ± SD)	44.17mm (15mm – 80mm ± 15,67)
Ref vessel diameter (min-max ± SD)	7.29mm (5mm – 9mm ± 0,93mm)
Degree of stenosis (min-max ± SD)	82,6% (60% - 100% ± 10,65%)
Occlusion (%)	11 (11%)
Calcified lesion (%)	82 (82%)
Azéma classification B (%)	52%
Azéma classification C (%)	47%

* Data from 1 patient is missing

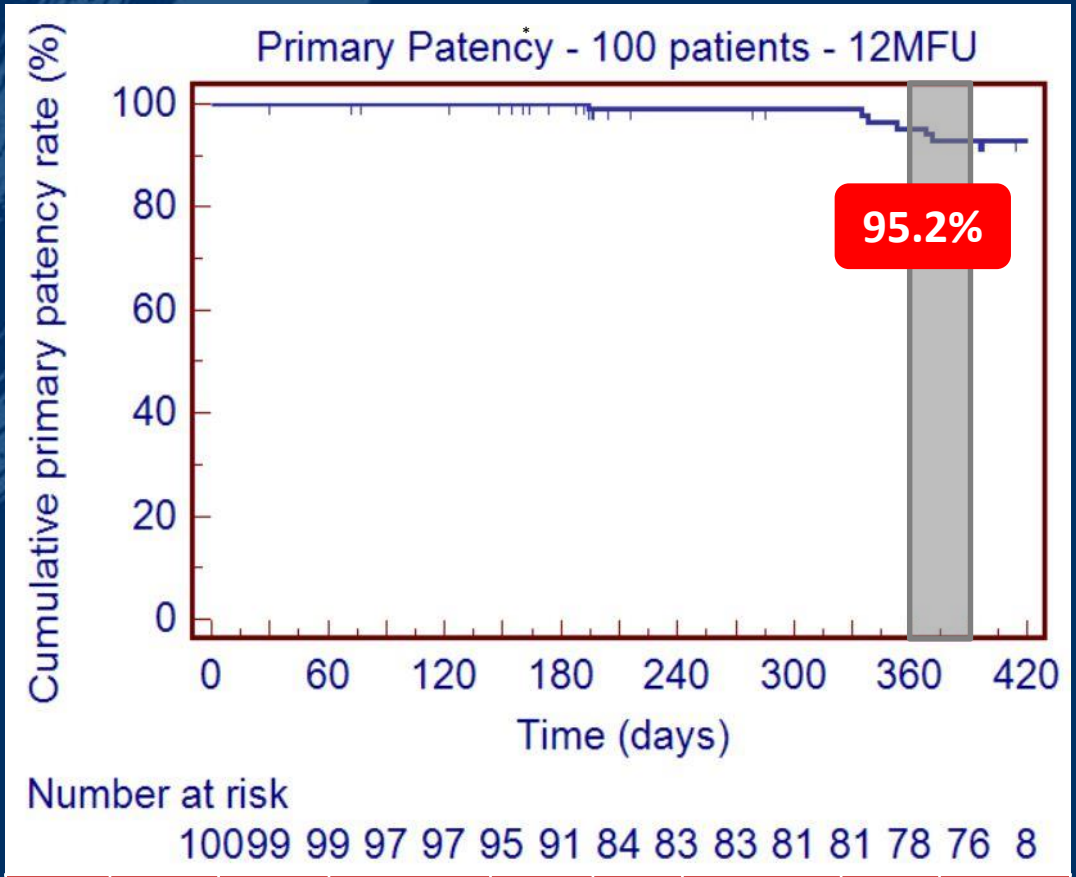
VMI-CFA trial: Procedure

	N = 100 out of 100
Procedure time (min-max ± SD)	55,68min (15min – 150min ± 29,59min)
Scopy time (min-max ± SD)	14,64min (4min – 55min ± 9,93min)
Contrast (min-max ± SD)	82,54ml (10ml – 353ml ± 75,08ml)
Femoral access (%)	92 (92%)
Cross-over performed (%)	82 (89,13%)
Inflow lesion (%)	23 (23%)
Outflow lesion (%)	62 (62%)

	N = 100 out of 100
Technical success	100%

	N = 100 out of 100
Predilatation performed (%)	100 (100%)
Diameter predilatation balloon (min-max ± SD)	7,19mm (3mm – 9mm ± 1,22mm)
Length predilatation balloon (min-max ± SD)	50,53mm (20mm – 200mm ± 31,65mm)
# supera used	102
1 stent received (%)	98 (98%)
2 stents received (%)	2 (2%)
Diameter stent (min-max ± SD)	6,48mm (5mm – 8mm ± 0,79mm)
Length stent (min-max ± SD)	49,02mm (20mm – 100mm ± 16,32mm)
Postdilatation performed (%)	83 (83%)
Diameter postdilatation balloon (min-max ± SD)	7,43mm (5mm – 10mm ± 1,06mm)
Length postdilatation balloon (min-max ± SD)	50mm (20mm – 200mm ± 25,79mm)

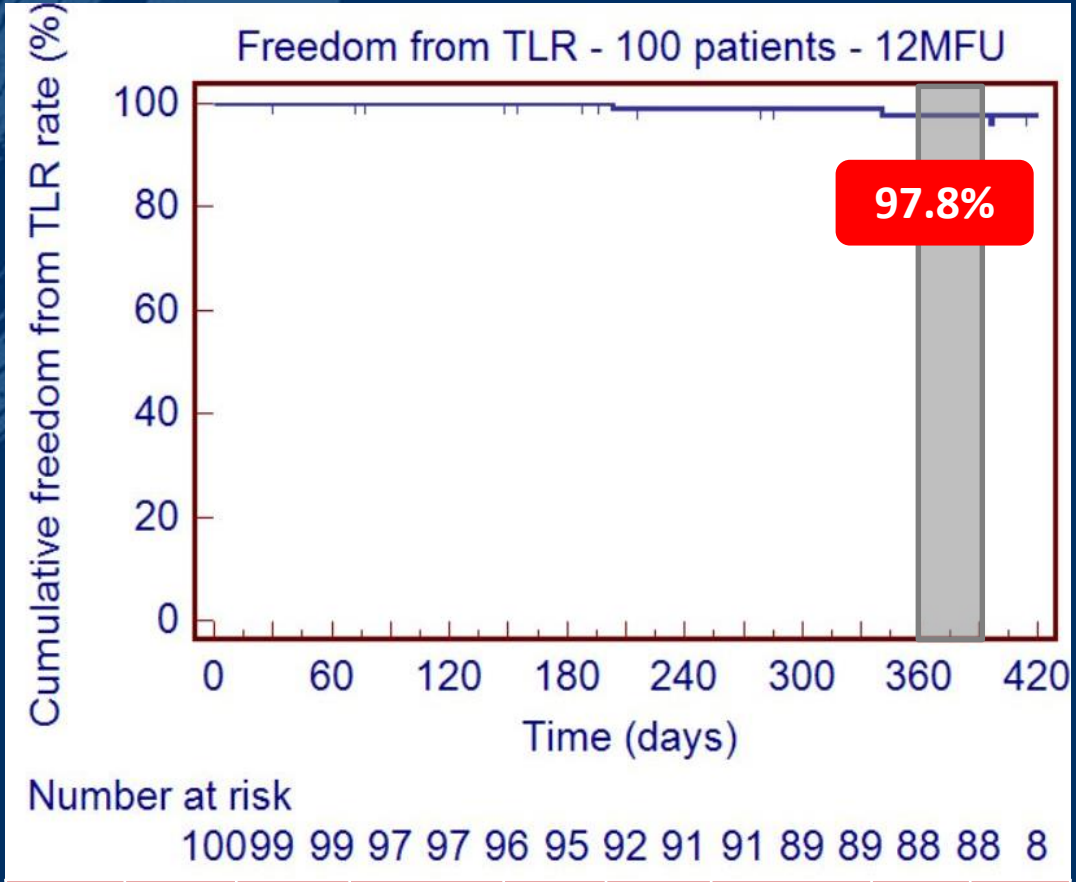
VMI-CFA trial: 1 year results



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	99		91	84		78	76
%	100	100		100	98,9		95,2	92,8

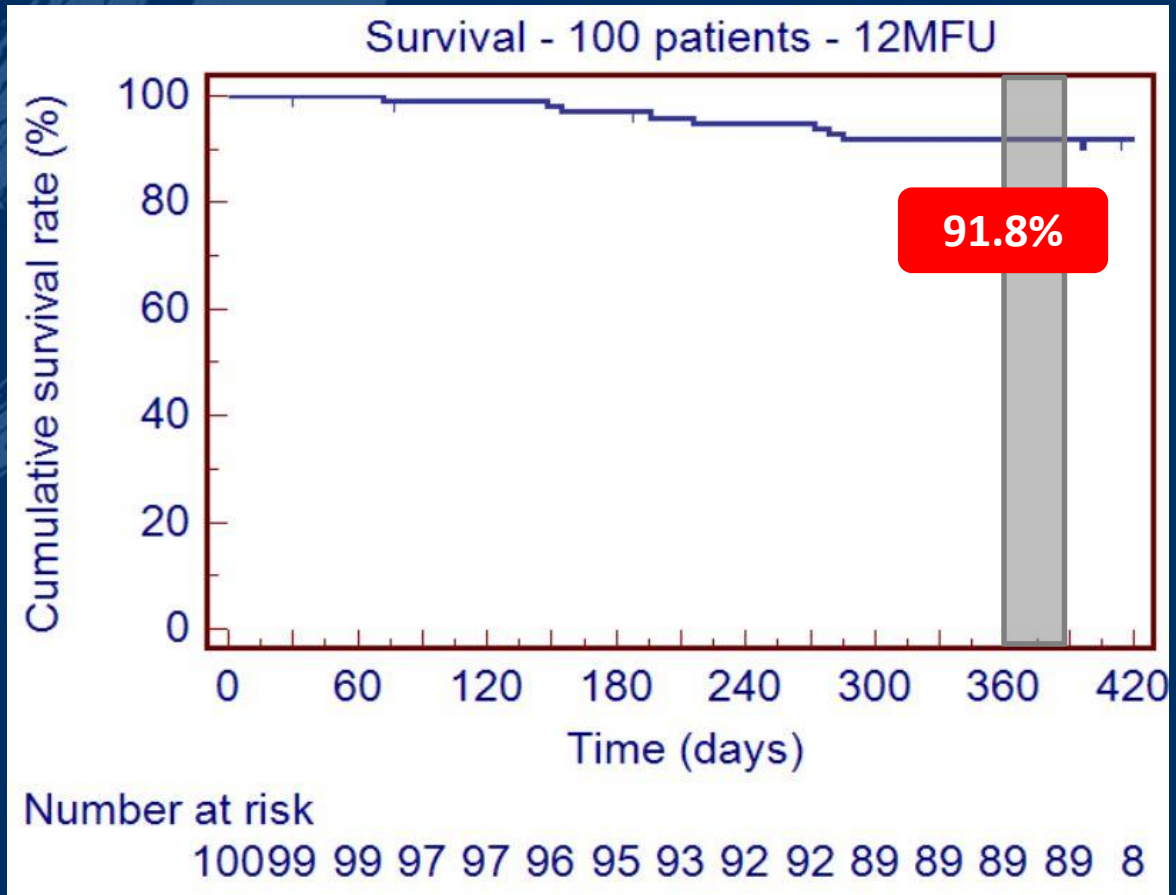
* Freedom from > 50% restenosis as indicated by DUS PSV-ratio <2,5 in the target lesion – **CORE-LAB VERIFIED**

VMI-CFA trial: 1 year results



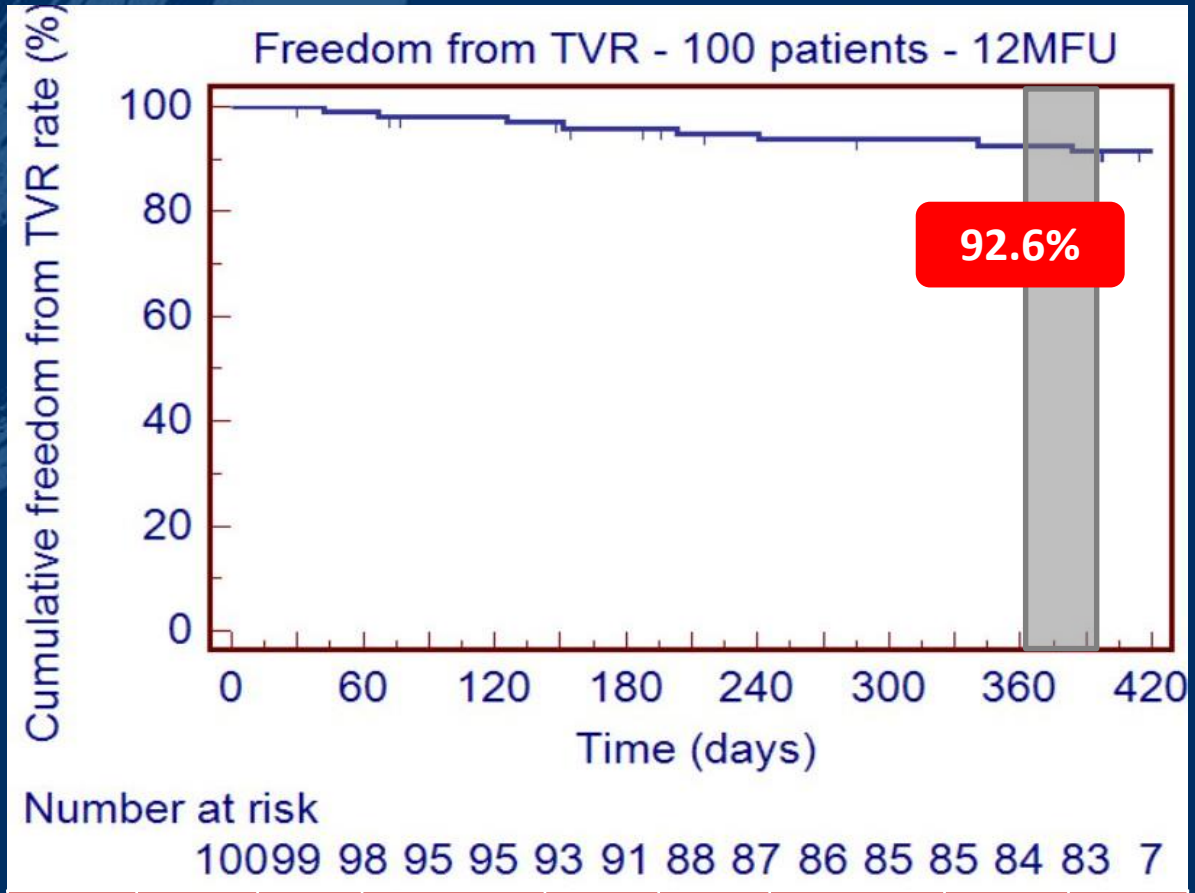
time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	99		95	92		88	88
%	100	100		100	98,9		97,8	97,8

VMI-CFA trial: 1 year results



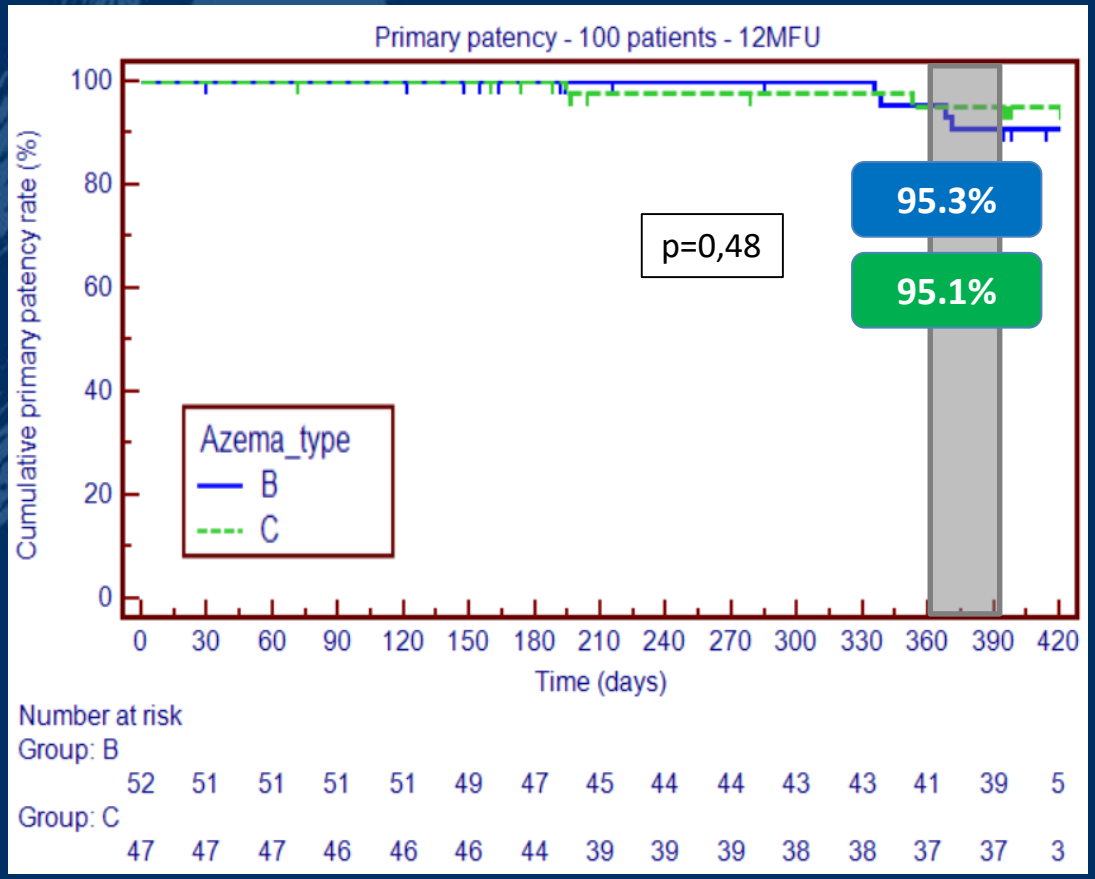
time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	99		95	93		89	89
%	100	100		96,9	95,9		91,8	91,8

VMI-CFA trial: 1 year results



time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
at risk	100	99		91	88		84	83
%	100	100		95,9	94,8		92,6	91,5

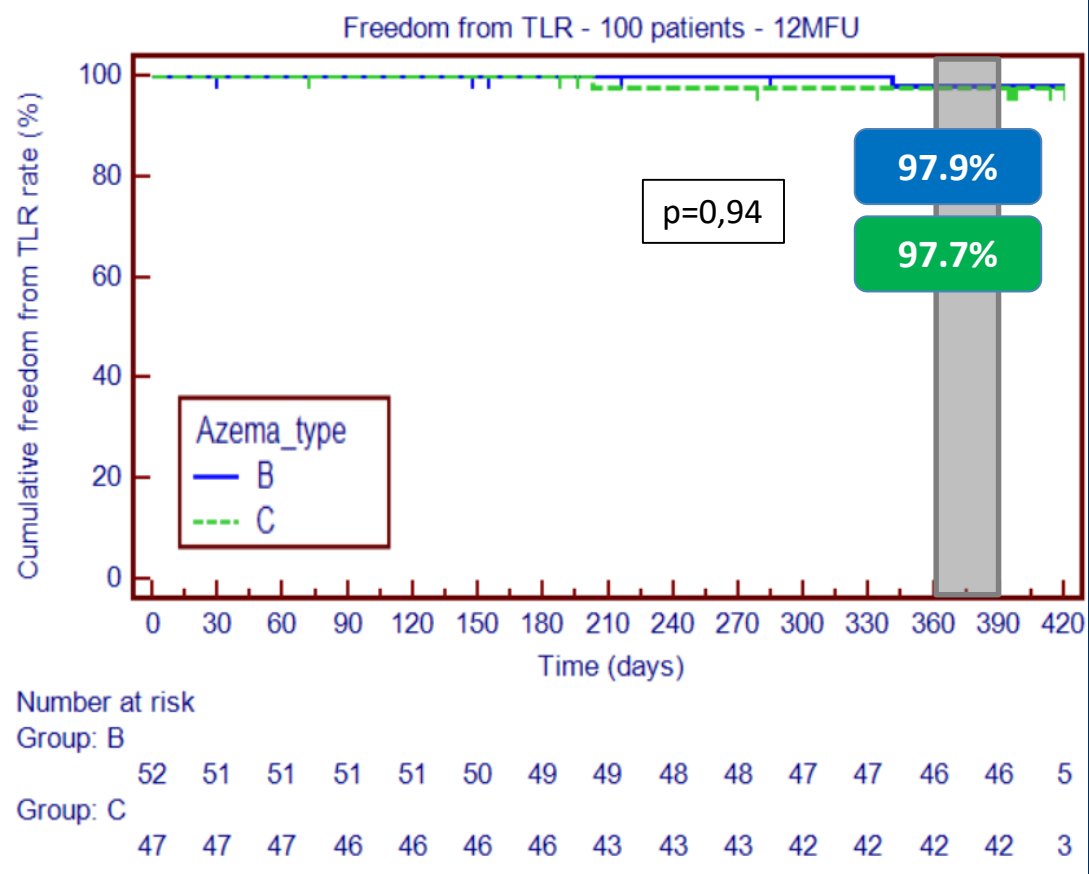
VMI-CFA trial: 1 year results



	time	baseline	1MFU		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
Azema B	at risk	52	51		47	45		41	39
	%	100%	100 %		100%	100%		95,3%	90,7%
Azema C	at risk	47	47		44	39		37	37
	%	100%	100 %		100%	83,7%		95,1%	95,1%

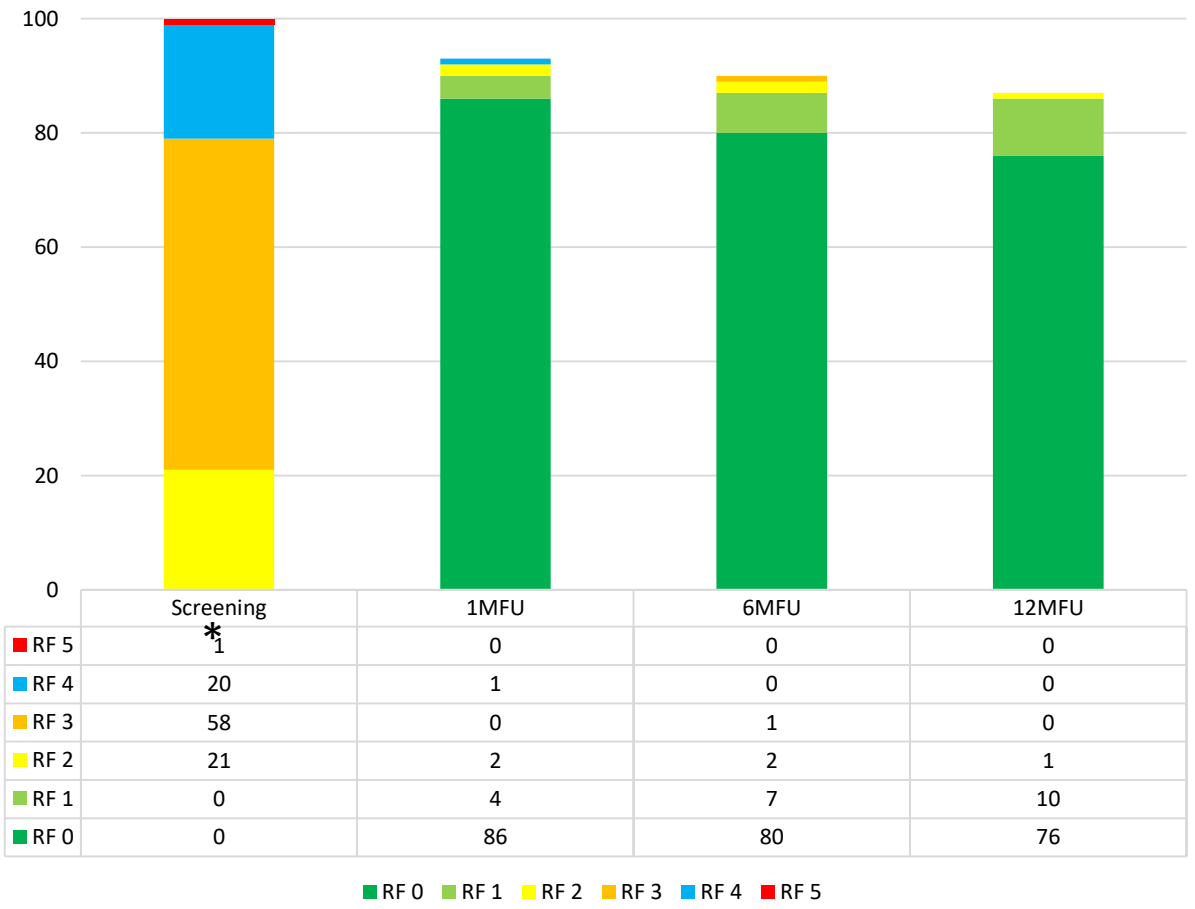
* Freedom from > 50% restenosis as indicated by DUS PSV-ratio <2,5 in the target lesion – **CORE-LAB VERIFIED**

VMI-CFA trial: 1 year results



	time	baseline	1MFU (30 days)		6MFU (180 days)	6MFU (210 days)		12MFU (365 days)	12MFU (395 days)
Azema B	at risk	52	51		49	49		46	46
	%	100%	100%		100%	100%		97,9%	97,9%
Azema C	at risk	47	47		46	43		42	42
	%	100%	100%		100%	97,7%		97,7%	97,7%

VMI-CFA trial: clinical outcome



	Screening	1MFU	6MFU	12MFU
RF 5	1*	0	0	0
RF 4	20	1	0	0
RF 3	58	0	1	0
RF 2	21	2	2	1
RF 1	0	4	7	10
RF 0	0	86	80	76

* Protocol deviation

VMI-CFA trial: safety outcomes

Primary safety endpoint	30 days	6 months	12 months
Device or procedure related death (n)	0	0	0
CD-TLR (n)	0	1	2
Target limb major amputation (n)	0	0	0

Conclusion

- In 2019, CFA stenting appears as an alternative to open surgery
- Newer generation of devices, like the high crush resistant, repuncturable Supera stent, are facilitating this endo-approach
- With this particular device, the VMI-CFA trial shows excellent 1 year results
- A longer follow-up (up to 24 months planned) and a head to head RCT Supera versus endarterectomy seems to be a logical sequence to clarify definitively the CFA-treatment discussion

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