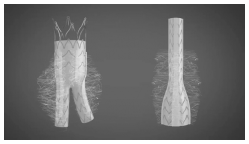
VEITH SYMPOSIUM
Connecting The Vascular Community

A RCT Shows The Advantages Of IMA And Lumbar Embolization

The Next Generation Of EVAR Endografts Must Prevent Endoleaks: How Can It Be Done !



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Disclosure

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Speaker name:

Dominique Fabre

I have the following potential conflicts of interest to report:

Consulting for Affluent Medical

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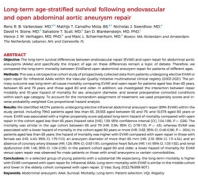
Endoleak is a long term factor of mortality!



Long-term age-stratified survival following endovascular and open abdominal aortic aneurysm repair

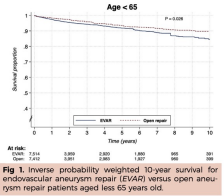


Fig 1. Inverse probability weighted 10-year survival for endovascular aneurysm repair (*EVAR*) versus open aneurysm repair patients aged less 65 years old.

Varkevisser JVS 2022

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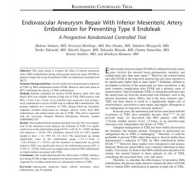
Endovascular Aneurysm Repair With Selective IMA embolization:

Prospective RCT

- 2 groups:
- EVAR + IMA EMBOLIZATION
  vs
- EVAR



Endovascular Aneurysm Repair With Inferior Mesenteric Artery Embolization for Preventing Type II Endoleak
A Prospective Randomized Controlled Trial

Endovascular Aneurysm Repair With IMA Embolization for Preventing Type II EL: A Prospective RCT. Samura M, Morikage N, Otsuka R, Mizoguchi T, Takeuchi Y, Nagase T, Harada T, Yamashita O, Suehiro K, Hamano K. Ann Surg. 2020

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Clinical outcomes

TABLE 5. Clinical Outcomes in the Per-protocol Analysis

Variables	Embolization (n = 46)	Nonembolization (n = 51)	P	ARR (95% CI)	NNT (95% CI)
Follow-up periods, mo	23.8 ± 10.9	23.2 ± 11.0	0.76		
Presence of T2EL	10 (21.7%)	24 (47.1%)	0.009	25.3% (8.4%–41.0%)	3.9 (2.4–15.6)
Source of T2EL (% in T2EL presence)					
IMA	0	3 (12.5%)			
LAs	11 (100%)	12 (50.0%)			
IMA + LAs	0	6 (25.0%)			
Others (MSA, LAs + MSA or ARA)	0	3 (12.5%)			
Aneurysmal diameter change, mm	−4.3 ± 7.5	−2.9 ± 8.7	0.021		
Aneurysmal growth ≥2 mm related to T2EL	1 (2.2%)	9 (17.6%)	0.017	15.5% (3.8%–16.9%)	6.5 (5.3–27.6)
Source of T2EL (% in related to T2EL)					
IMA, IMA + LAs	0	8 (88.9%)			
Others	1 (100%)	1 (22.2%)			
Secondary intervention	1 (2.2%)	5 (2.0%)	1.00		
Related to T2EL	0	0			

ARA indicates accessory renal artery; ARR, absolute risk reduction; CI, confidence interval; IMA, inferior mesenteric artery; LA, lumbar artery; MSA, medial sacral artery; NNT, number needed to treat; T2EL, type II endoleak.

the incidence of T2EL is lower in the embolization group number needed to treat = 4.1
The aneurysmal sac shrunk significantly more in the embolization group (5.7 vs 2.8mm; P = 0.037), and
the incidence of aneurysmal sac growth related to T2EL was significantly lower in the embolization group

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TABLE 2. Operative Variables

Variables	Embolization (n = 53)	Nonembolization (n = 53)	P
Operation time, min	214 ± 106	174 ± 68	0.031
Embolization time, min	14.5 ± 13.7	–	
Successful embolization	47 (88.7%)	–	
Embolization source			
Vascular plug (% success)	36 (76.6%)	–	
Fluoroscopy time, min	72.8 ± 48.4	49.4 ± 32.5	0.008
Contrast agent, mL	60.5 ± 29.6	44.7 ± 24.5	0.007
Type of stent-graft			0.40
Aorfix	2 (3.8%)	2 (3.8%)	
AFX	0 (0%)	1 (1.9%)	
Excluder	18 (34.0%)	24 (45.3%)	
Endurant	27 (50.9%)	24 (45.3%)	
Zenith	6 (11.3%)	2 (3.8%)	
Embolization of the IIAs			0.87
Unilateral	8 (15.1%)	10 (18.9%)	
Bilateral	6 (11.3%)	6 (11.3%)	
Cost (Japanese yen)	2,101,609 ± 667,138	1,969,201 ± 551,192	0.31

IIA indicates internal iliac artery.

IMA embo is 40 minutes longer

The fluoroscopic time is significantly longer

the amount of contrast is more important

Samura M, Morikage N, Otsuka R, Mizoguchi T, Takeuchi Y, Nagase T, Harada T, Yamashita O, Suehiro K, Hamano K. Ann Surg. 2020

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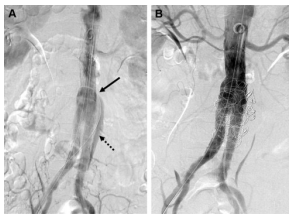
PRT EVAR with or without Sac Embolization

RANDOMISED CONTROLLED TRIAL

Prospective, Randomised Two Centre Study of Endovascular Repair of Abdominal Aortic Aneurysm With or Without Sac Embolisation



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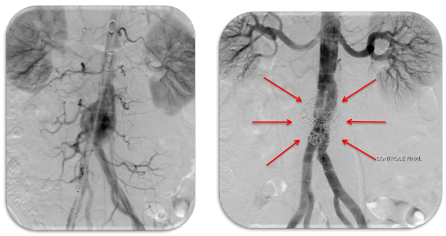
At risk patients!



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- Freedom from type II endoleak and reinterventions

P=0.003

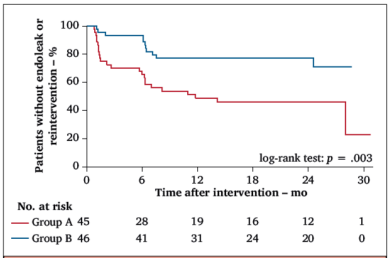

Figure 3. Cumulative Kaplan–Meier estimate of freedom from type II endoleak and re-interventions for patients with endovascular aneurysm repair without (group A) or with sac embolisation with coils (group B).

Looking at thoses results, a novel innovative patented endograft with thrombogenic fibers was developed
that ensures a complete sac thrombosis and promotes sac shrinkage

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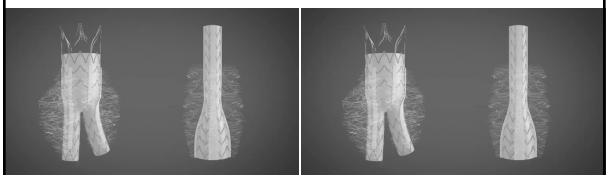
The Concept: Kardiozis fibers!



Integrate into one a low profile device and the thrombogenic fibers of the coils, eliminating the metal support of the coils

- Without impacting any feature/performance of the EVAR device
- Without changing the standard EVAR procedure in any aspect, including duration
- Without increasing costs in a significant way
- Without adding risks

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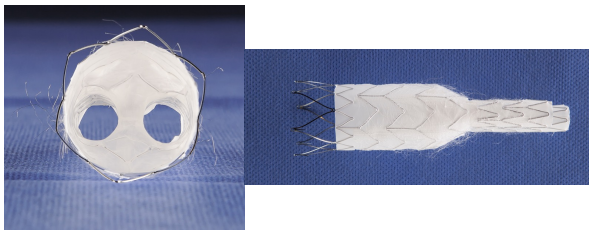

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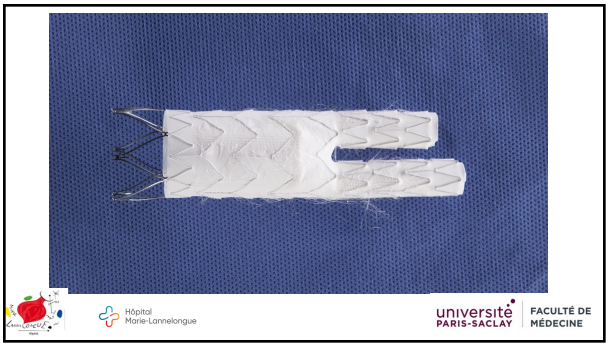
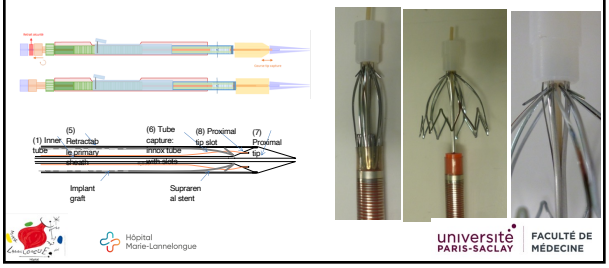


Patented delivery system / 14 fr



Thrombogenic fibers

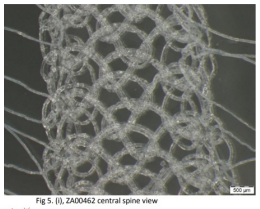


Fig 5. (i), ZA00462 central spine view

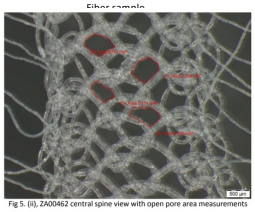


Fig 5. (ii), ZA00462 central spine view with open pore area measurements

Fiber strips

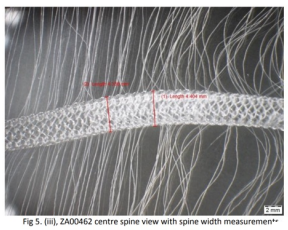
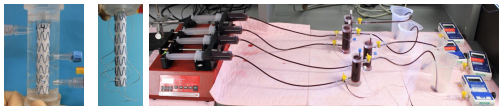


Fig 5. (iii), ZA00462 centre spine view with spine width measuremen**

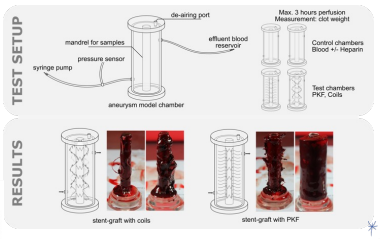
Proof of Concept: we have done an in vitro test Study to compare thoses fibers with coils



Test Chamber *Implant + Coils* *Test Setup*

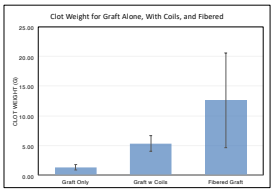
*In-vitro Assessments of **Clot** Elicitation by Thrombogenic Fibers vs. Embolization Coils.*
Fabre D
ASAIO J. 2022

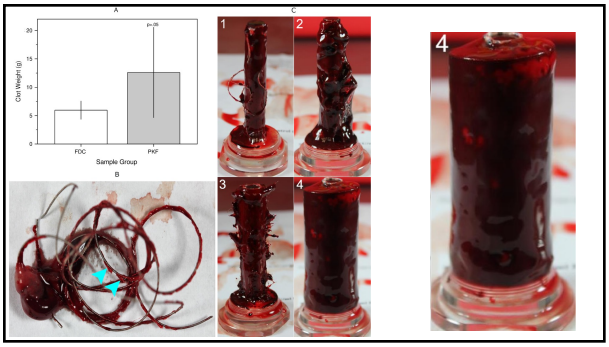
In-vitro assessments of clot elicitation by thrombogenic fibers vs. embolization coils

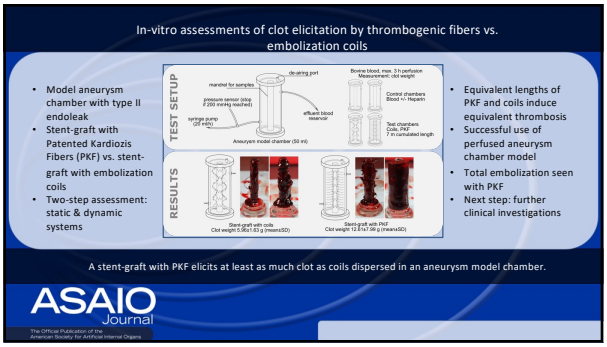


Results: Our fibers do it better!

The thrombogenic KARDIOZIS fibers display at least the same embolization properties of EVAR with coils (both significantly better than "naked" EVAR)

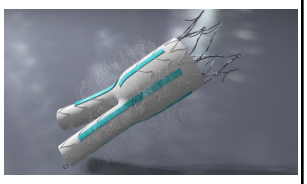






Conclusions

- We need a new generation of endograft
- This technology can do better in a simple way
- The strips of fibers could be also fixed on the external part of all grafts



Take home message

1/ Endoleak is not always visible
2/ it is the weakpoint of EVAR
3/ it is simple to ignore it
but it is a proven silent killer
5/You have now a solution!