



Protesi chirurgiche

Marco Franchin

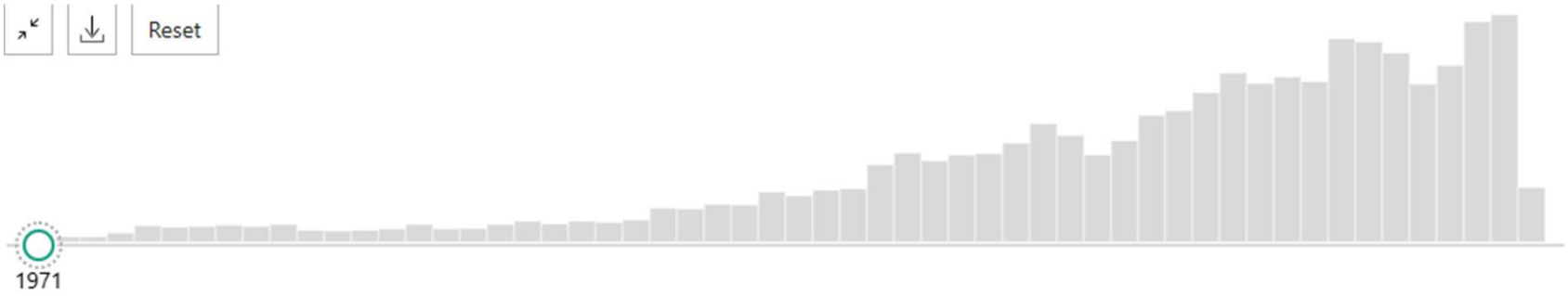
UOC Chirurgia Vascolare

ASST Sette Laghi - Varese

Access to blood vessels for hemodialysis: experience with 87 patients on chronic hemodialysis.

Haimov M, Singer A, Schupak E.

Surgery. 1971 Jun;69(6):884-9. PMID: 5578449.

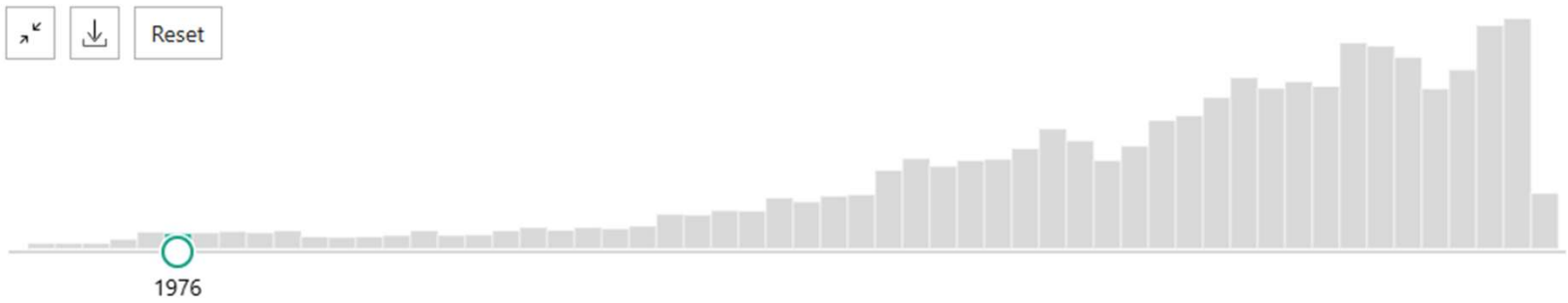


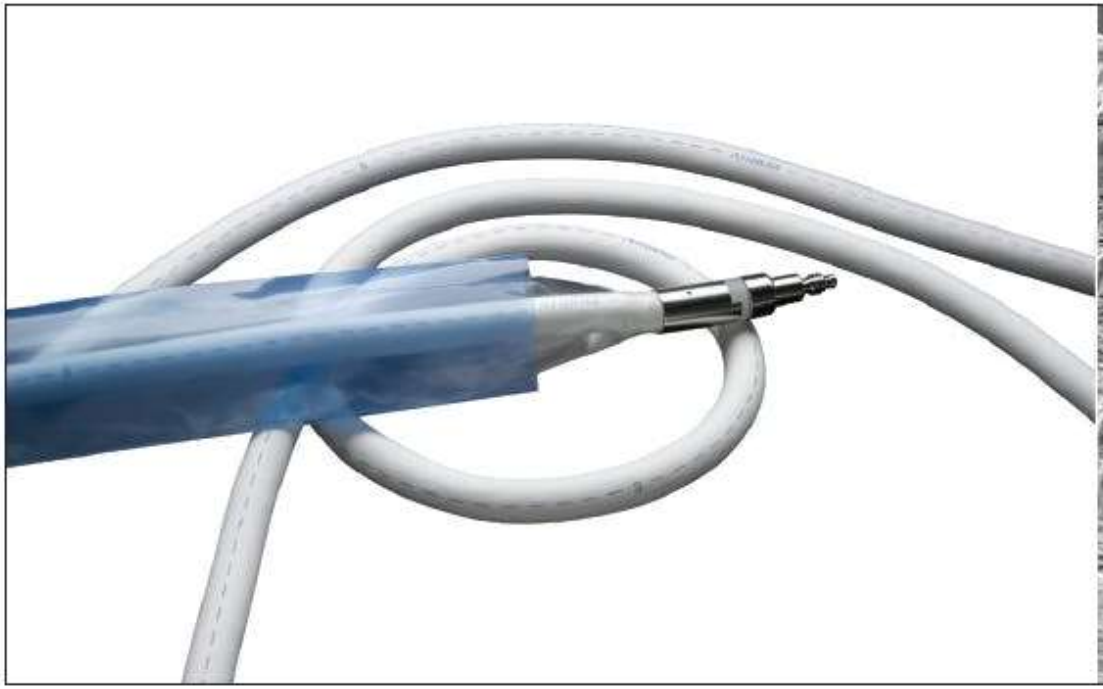
› Trans Am Soc Artif Intern Organs. 1976:22:382-7.

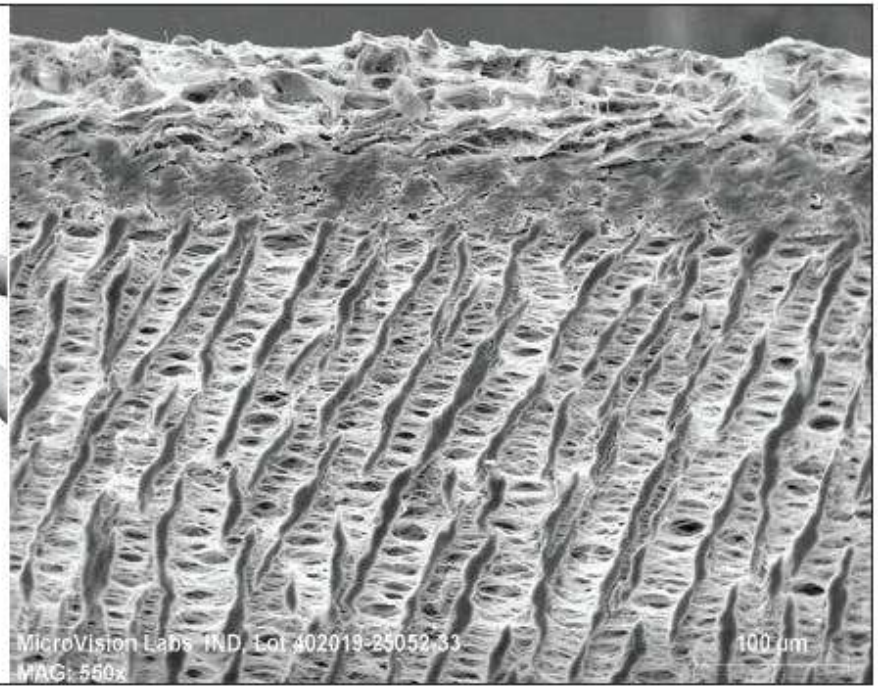
Expanded polytetrafluoroethylene (PTFE) subcutaneous arteriovenous conduit: an improved vascular access for chronic hemodialysis

L D Baker Jr, J M Johnson, D Goldfarb

PMID: 951854






MicroVision Labs IND Lot 402019-25052 33
MAG: 550x
100 µm

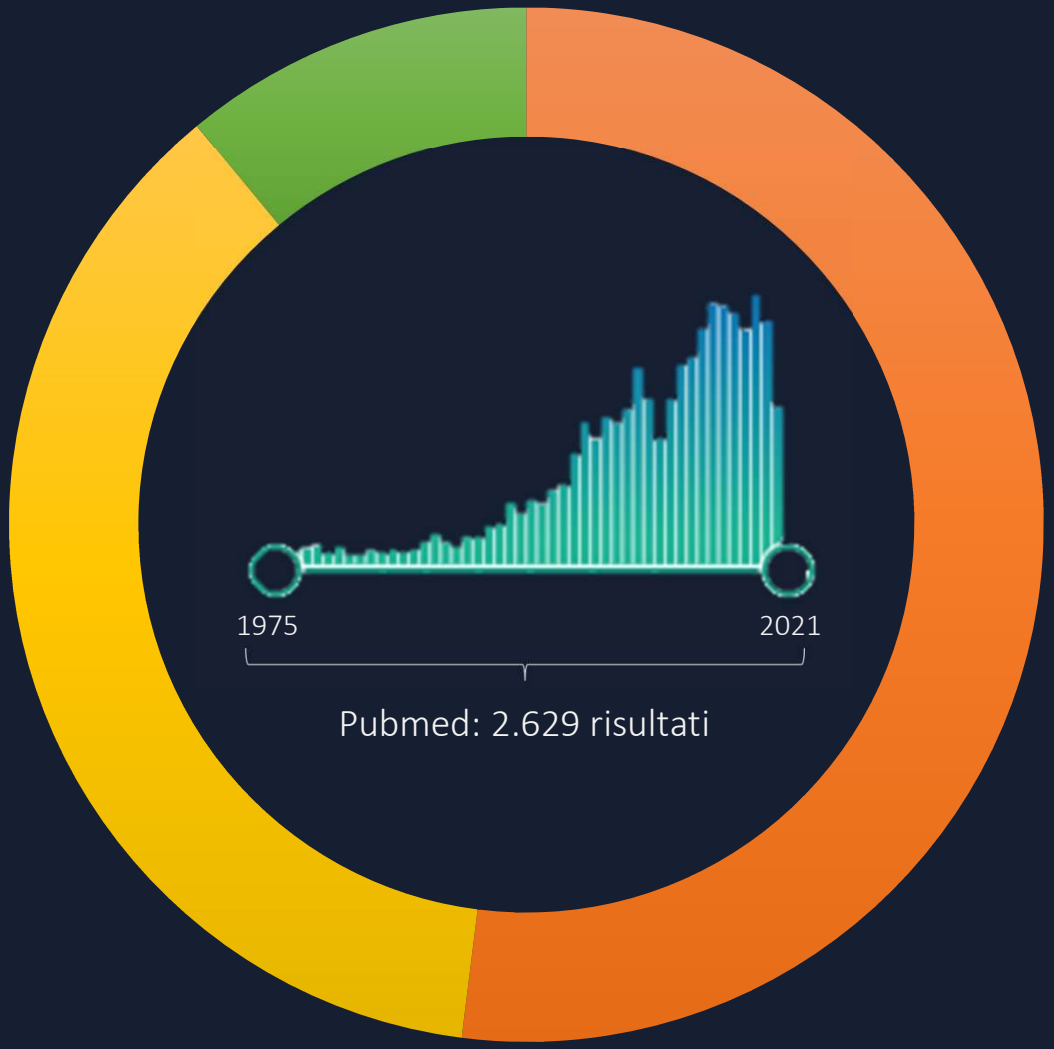


HABENT SUA FATA LIBELLI

Qual è il destino di un accesso vascolare protesico?

Fallimento degli AVG: principali topics della letteratura

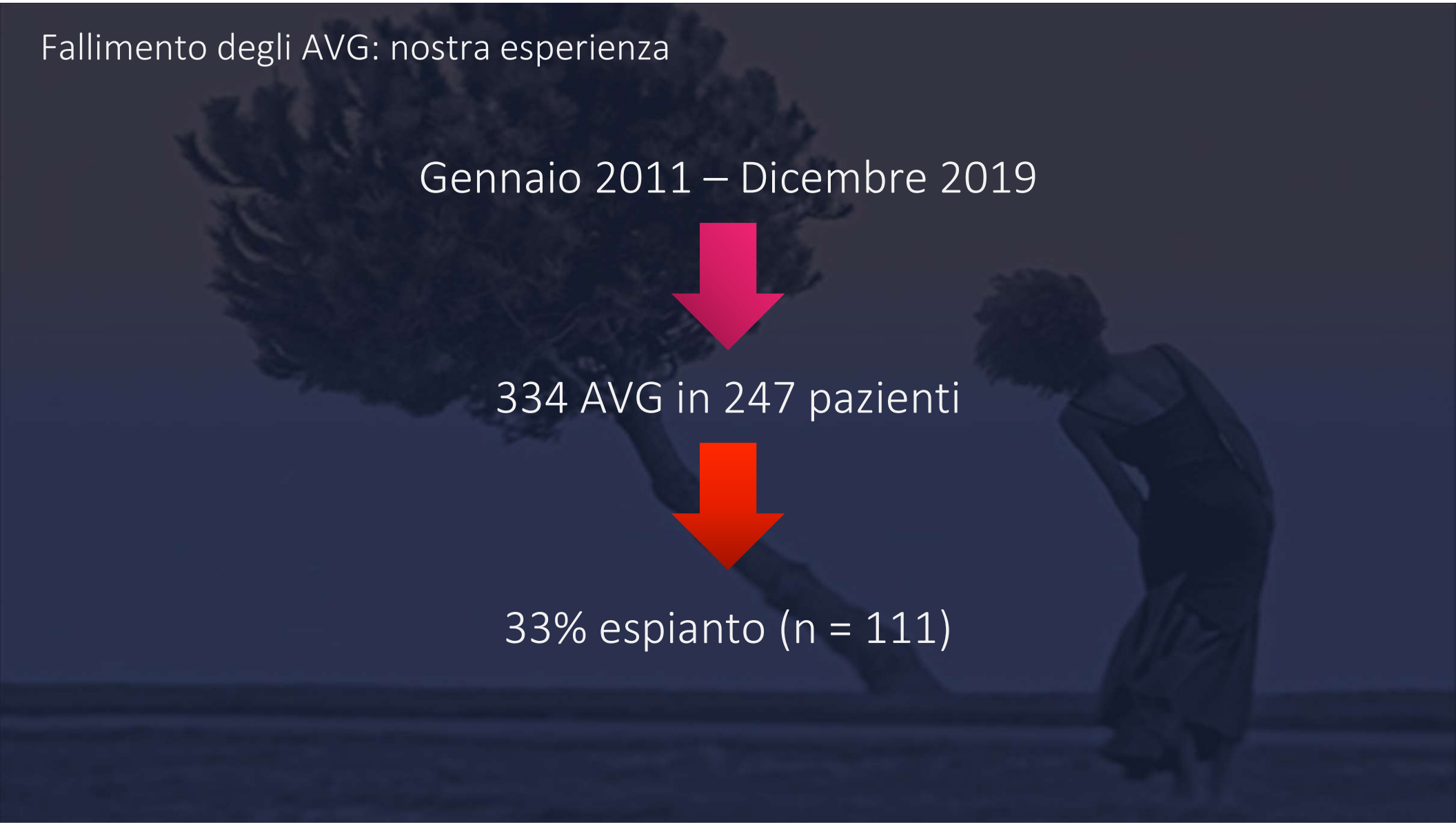
ALTRO
11%



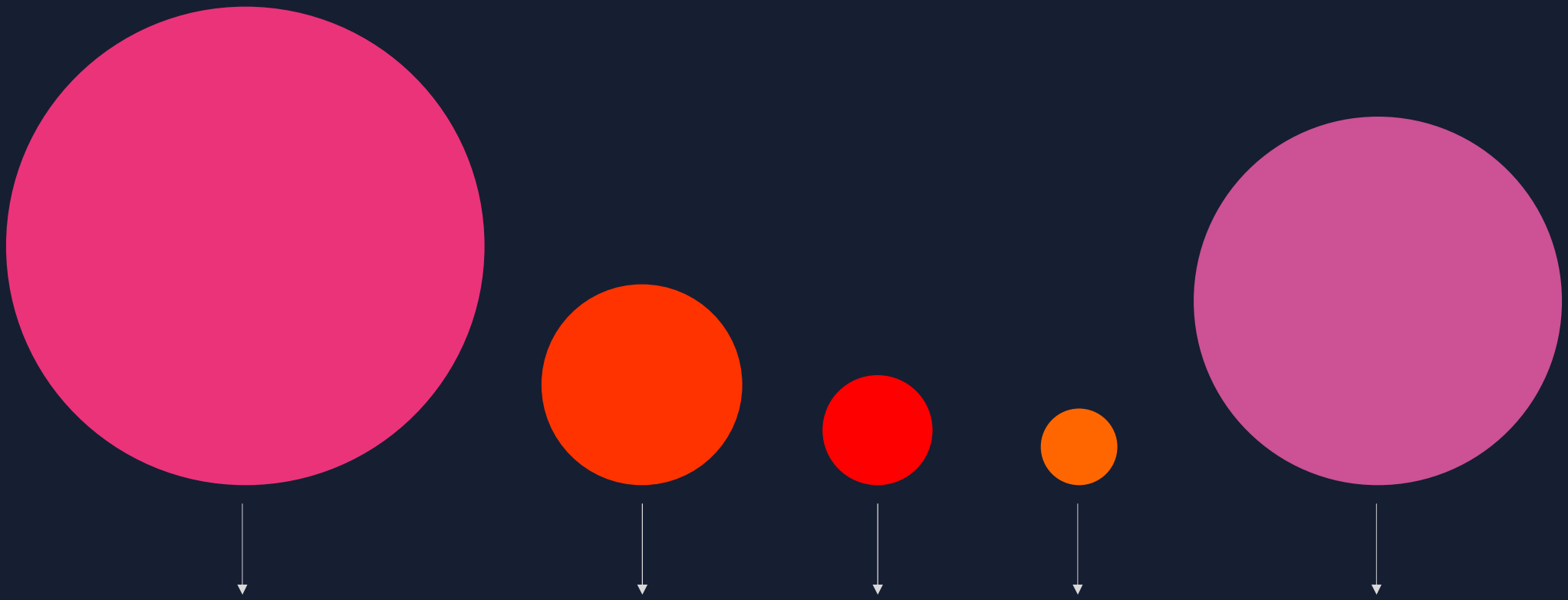
STENOSI
52%

INFEZIONI
37%

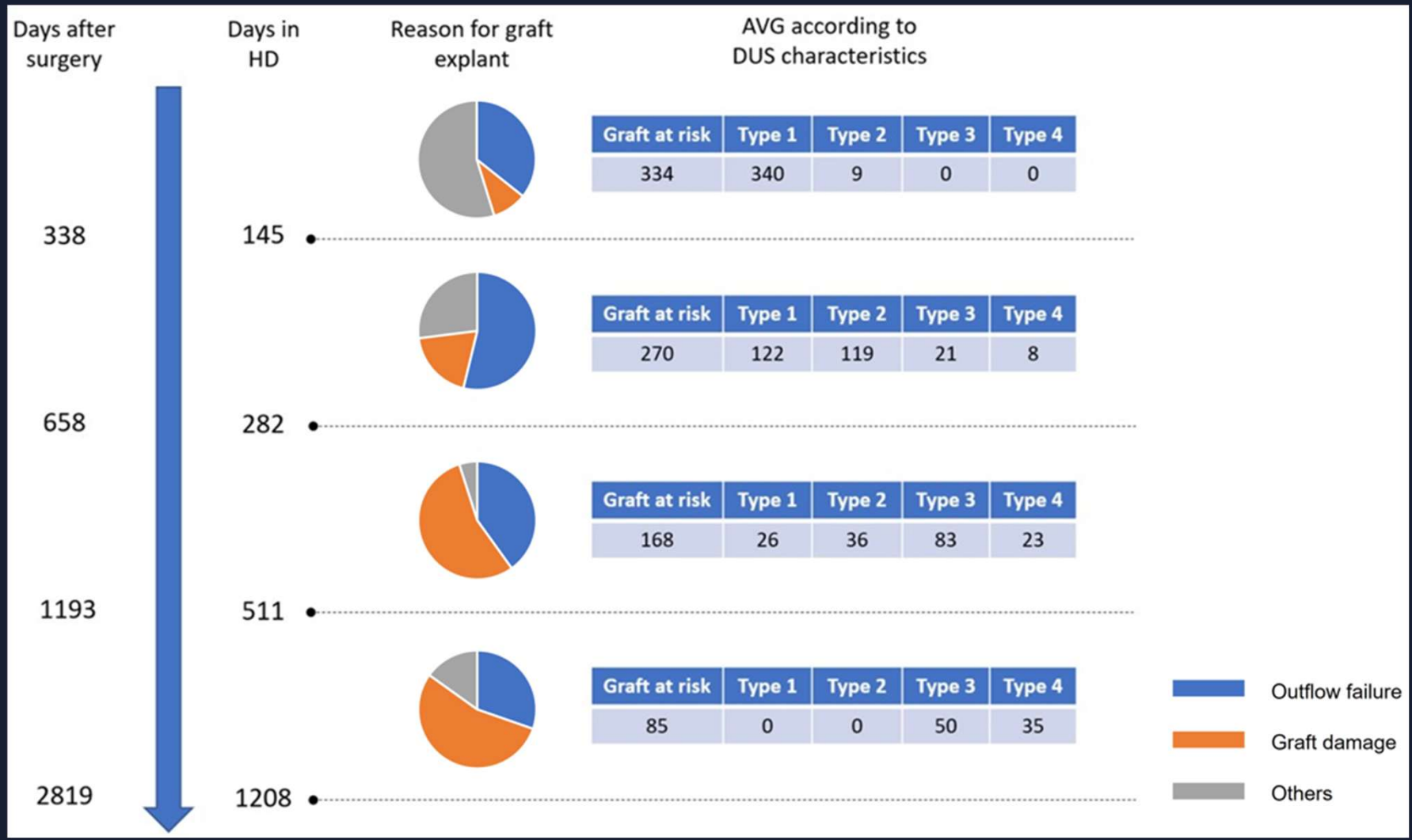
Fallimento degli AVG: nostra esperienza



Fallimento degli AVG: motivi




0
15
13
6
4
4
0
325
9
0
0
STENOSI
INFEZIONI
FURTO
TRAPIANTO
PSEUDOANEURIS...
DANNO
1
2
3
4
338 gg
14
3
1
3
0
5
122
119
21
8
658 gg
8
1
0
1
0
11
26
36
83
23
1194gg
6
1
0
2
0
13
0
0
82
59
2819 gg


Days after surgery
Days in HD
Reason for graft explant
AVG according to DUS characteristics
338
145
658
282
1193
511
2819
1208
Graft at risk | Type 1 | Type 2 | Type 3 | Type 4
334 | 340 | 9 | 0 | 0
Graft at risk | Type 1 | Type 2 | Type 3 | Type 4
270 | 122 | 119 | 21 | 8
Graft at risk | Type 1 | Type 2 | Type 3 | Type 4
168 | 26 | 36 | 83 | 23
Graft at risk | Type 1 | Type 2 | Type 3 | Type 4
85 | 0 | 0 | 50 | 35
Outflow failure
Graft damage
Others

Osservazioni preliminari

Il danno da cannulazione inizia ad essere evidente all'indagine ultrasonografica attorno al secondo anno *(560 cannulazioni)*

Il danno da cannulazione diventa una causa rilevante di fallimento dopo i 3 anni *(1.020 cannulazioni)*

Advertisement End

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https://doi.org/10.1177/11297298231205325

Sage Journals

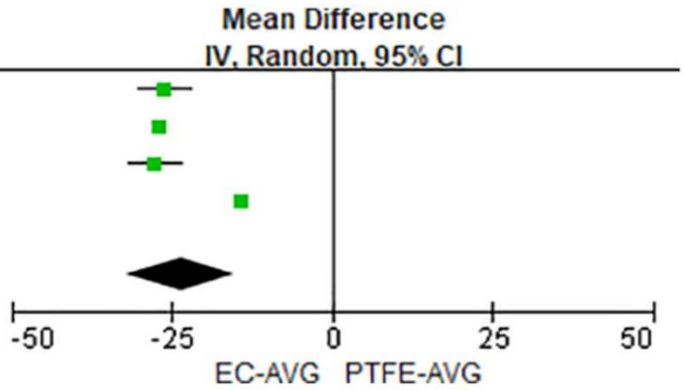
Reviews

Outcomes of early cannulation arteriovenous graft versus PTFE arteriovenous graft in hemodialysis patients: A meta-analysis and systematic review

Zhuotao Xiao [1,2], Joris I Rotmans [1], Krzysztof Letachowicz [3], Marco Franchin [4], and Mario D'Oria [5]

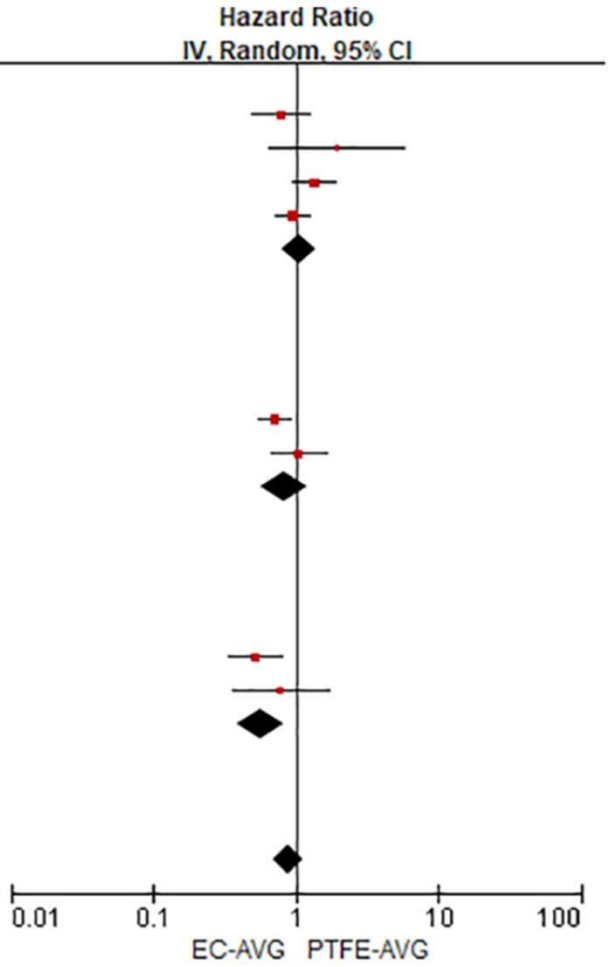
Study or Subgroup	EC-AVG Mean	EC-AVG SD	EC-AVG Total	PTFE-AVG Mean	PTFE-AVG SD	PTFE-AVG Total	Weight	Mean Difference IV, Random, 95% CI	Year
Wagner2017	8.8	13.7	62	34.9	15.7	148	24.2%	-26.10 [-30.35, -21.85]	2017
Kakisis2017	1.17	1.05	64	28	3.02	61	25.7%	-26.83 [-27.63, -26.03]	2017
He2021	6.5	10.5	143	34.2	23.9	161	24.3%	-27.70 [-31.77, -23.63]	2021
Tawfik2022	4.4	6	241	18.6	5.2	236	25.7%	-14.20 [-15.21, -13.19]	2022
Total (95% CI)			**510**			**606**	**100.0%**	**-23.62 [-32.03, -15.21]**	

Heterogeneity: Tau² = 71.34; Chi² = 381.26, df = 3 (P < 0.00001); I² = 99%
Test for overall effect: Z = 5.50 (P < 0.00001)



Primary patency

Study or Subgroup	log[Hazard Ratio]	SE	EC-AVG Total	PTFE-AVG Total	Weight	Hazard Ratio IV, Random, 95% CI	Year
4.2.1 Acuseal							
Wagner2017	-0.246	0.237	62	148	12.2%	0.78 [0.49, 1.24]	2017
Gerhardt2019	0.6684	0.5591	12	13	3.8%	1.95 [0.65, 5.84]	2019
He2021	0.30010459	0.176827	143	161	15.5%	1.35 [0.95, 1.91]	2021
Tawfik2022	-0.0444	0.1364	241	236	18.0%	0.96 [0.73, 1.25]	2022
Subtotal (95% CI)			**458**	**558**	**49.5%**	**1.06 [0.80, 1.41]**	
Heterogeneity: Tau² = 0.03; Chi² = 5.26, df = 3 (P = 0.15); I² = 43%							
Test for overall effect: Z = 0.43 (P = 0.67)							
4.2.2 Vectra							
Kakkos2011	-0.3369	0.13	239	125	18.4%	0.71 [0.55, 0.92]	2011
Kakisis2017	0.05612	0.22389	64	61	12.9%	1.06 [0.68, 1.64]	2017
Subtotal (95% CI)			**303**	**186**	**31.2%**	**0.83 [0.57, 1.21]**	
Heterogeneity: Tau² = 0.04; Chi² = 2.30, df = 1 (P = 0.13); I² = 57%							
Test for overall effect: Z = 0.95 (P = 0.34)							
4.2.3 Flixene							
Chiang2014	-0.6582	0.2256	78	65	12.8%	0.52 [0.33, 0.81]	2014
Scarritt2014	-0.2473	0.3989	45	19	6.5%	0.78 [0.36, 1.71]	2014
Subtotal (95% CI)			**123**	**84**	**19.3%**	**0.57 [0.39, 0.84]**	
Heterogeneity: Tau² = 0.00; Chi² = 0.80, df = 1 (P = 0.37); I² = 0%							
Test for overall effect: Z = 2.84 (P = 0.004)							
Total (95% CI)			**884**	**828**	**100.0%**	**0.89 [0.70, 1.12]**	
Heterogeneity: Tau² = 0.06; Chi² = 17.38, df = 7 (P = 0.02); I² = 60%							
Test for overall effect: Z = 1.01 (P = 0.31)							
Test for subgroup differences: Chi² = 6.50, df = 2 (P = 0.04), I² = 69.3%							

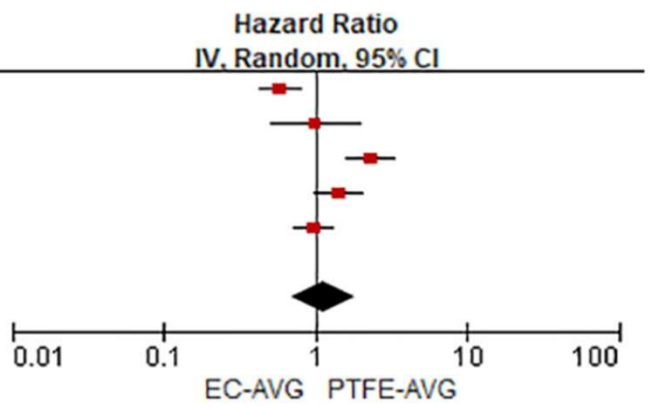


Primary assisted patency

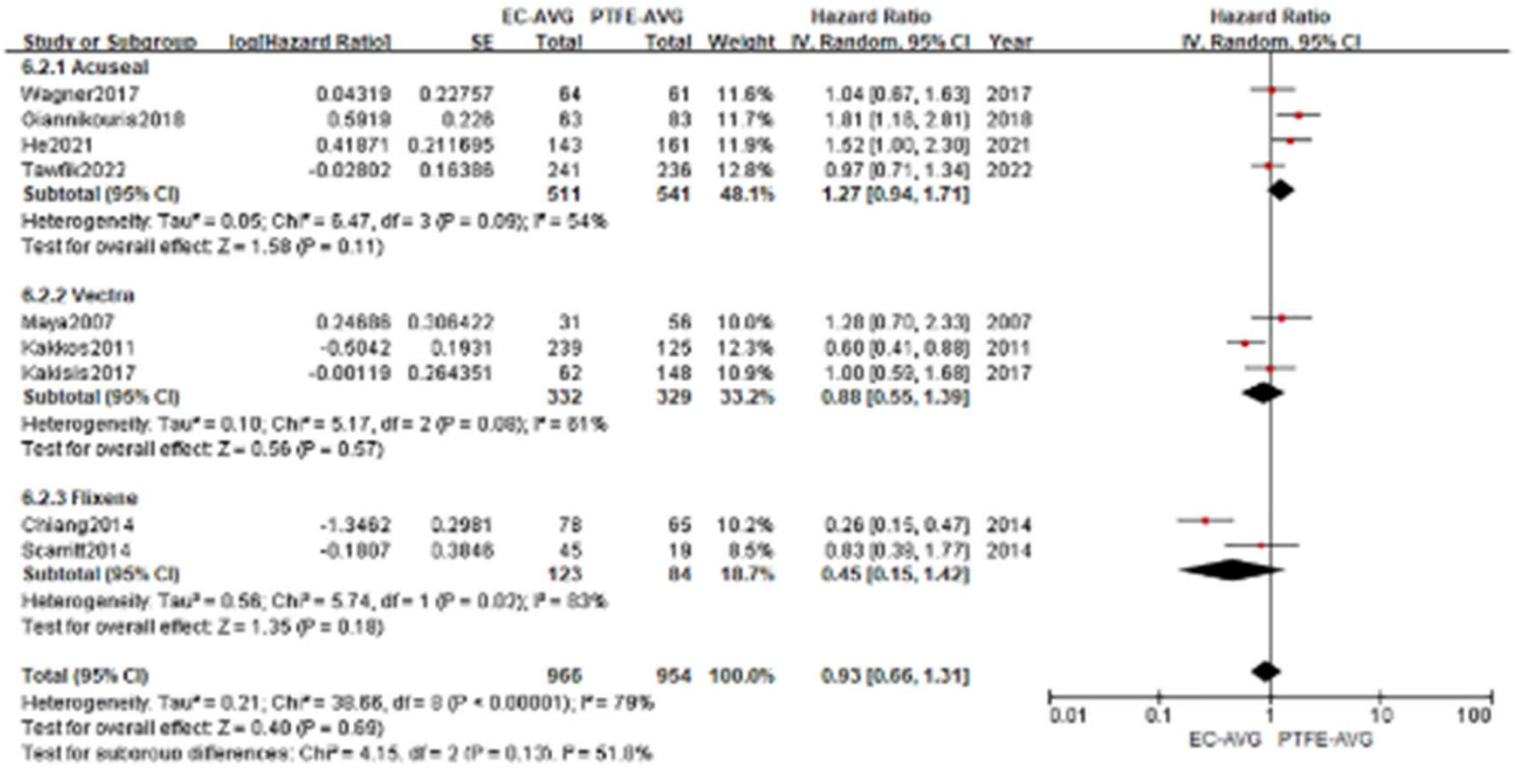
Study or Subgroup	log[Hazard Ratio]	SE	EC-AVG Total	PTFE-AVG Total	Weight	Hazard Ratio IV, Random, 95% CI	Year
Kakkos2011	-0.5386	0.1519	239	125	21.4%	0.58 [0.43, 0.79]	2011
Chiang2014	-0.00349	0.349242	45	19	15.9%	1.00 [0.50, 1.98]	2014
Giannikouris2018	0.8379	0.1891	63	83	20.5%	2.31 [1.60, 3.35]	2018
He2021	0.357674	0.186832	143	161	20.6%	1.43 [0.99, 2.06]	2021
Tawfik2022	-0.02674	0.14549	241	236	21.6%	0.97 [0.73, 1.29]	2022
Total (95% CI)			**731**	**624**	**100.0%**	**1.13 [0.70, 1.84]**	

Heterogeneity: $Tau^2 = 0.27$; $Chi^2 = 35.38$, $df = 4$ ($P < 0.00001$); $I^2 = 89\%$

Test for overall effect: $Z = 0.50$ ($P = 0.62$)



Secondary patency

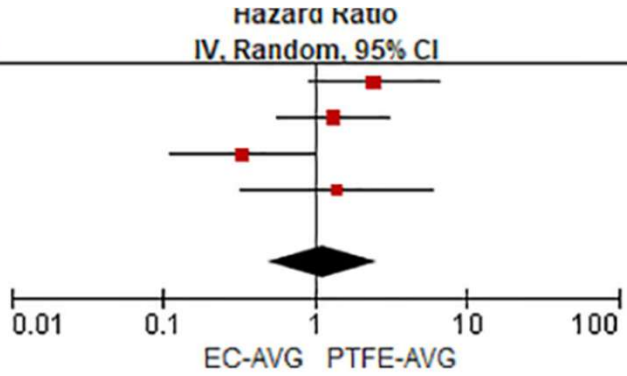


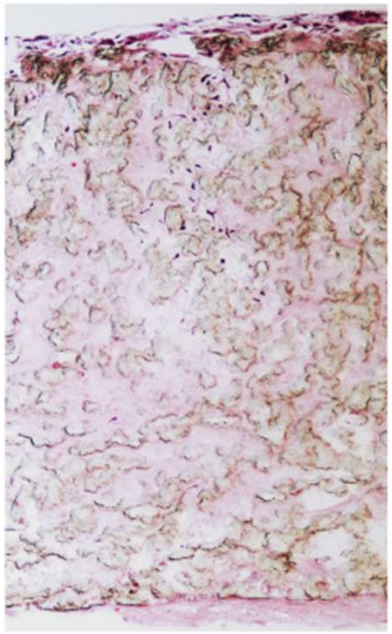
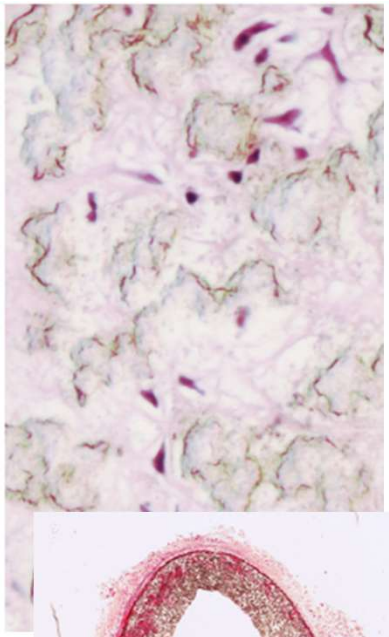
Infections

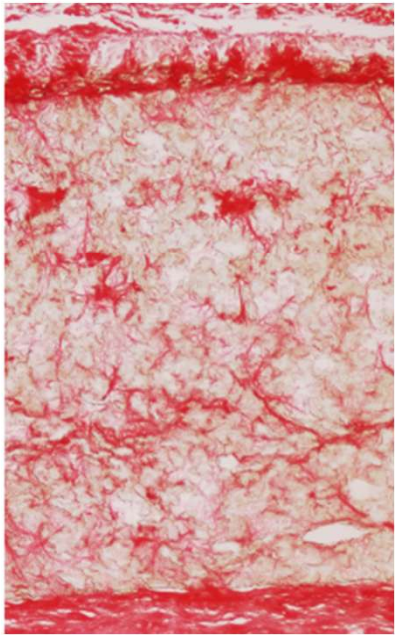
Study or Subgroup	log[Hazard Ratio]	SE	EC-AVG Total	PTFE-AVG Total	Weight	Hazard Ratio IV, Random, 95% CI	Year
Maya2007	0.887891	0.503228	31	56	26.9%	2.43 [0.91, 6.52]	2007
Kakkos2011	0.2872	0.4352	239	125	29.6%	1.33 [0.57, 3.13]	2011
Chiang2014	-1.1035	0.5567	45	19	24.8%	0.33 [0.11, 0.99]	2014
Kakisis2017	0.329	0.7413	64	61	18.7%	1.39 [0.33, 5.94]	2017
Total (95% CI)			**379**	**261**	**100.0%**	**1.12 [0.48, 2.58]**	

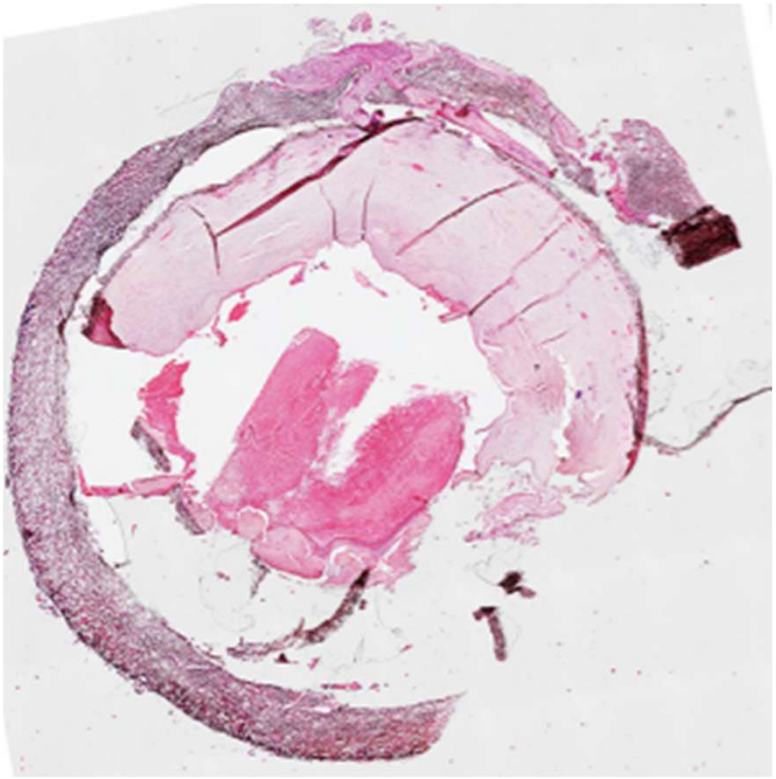
Heterogeneity: $Tau^2 = 0.43$; $Chi^2 = 7.38$, df = 3 (P = 0.06); $I^2 = 59\%$

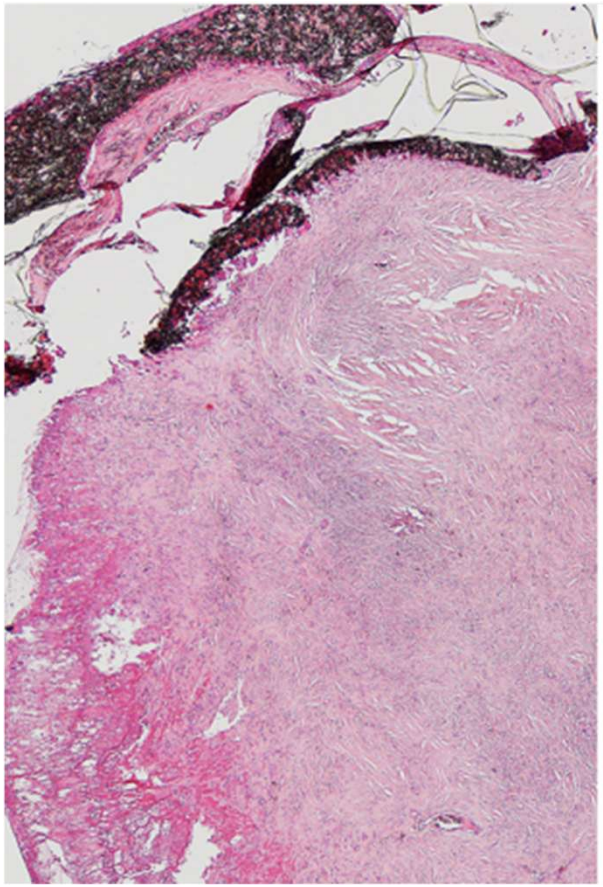
Test for overall effect: Z = 0.26 (P = 0.79)

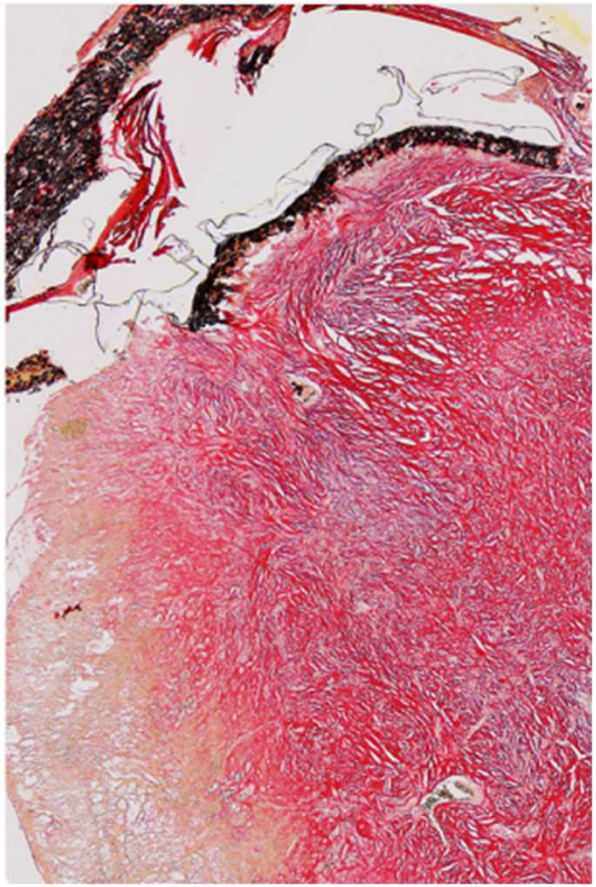


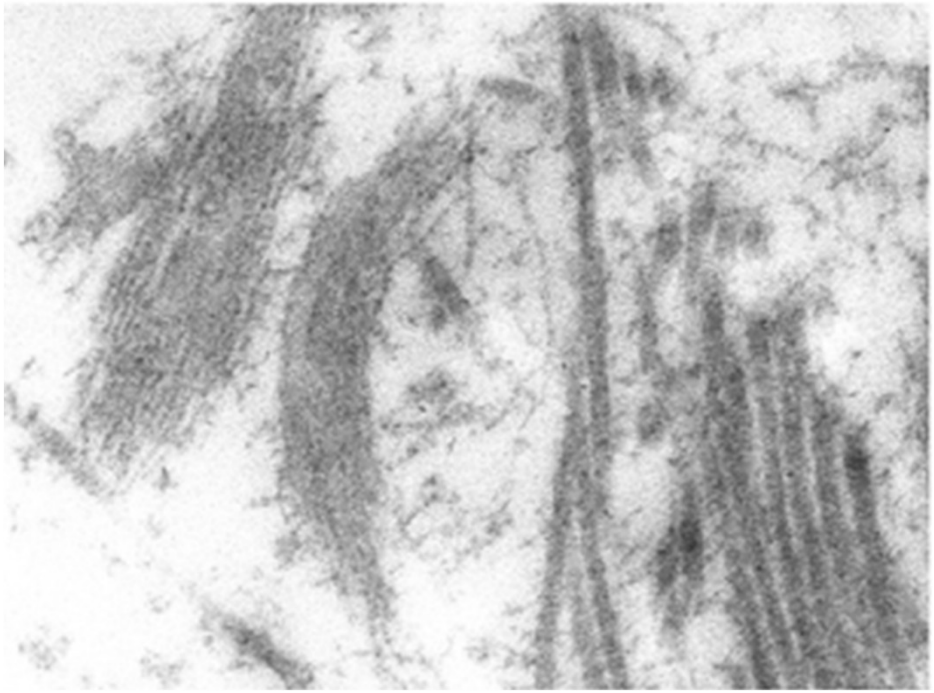




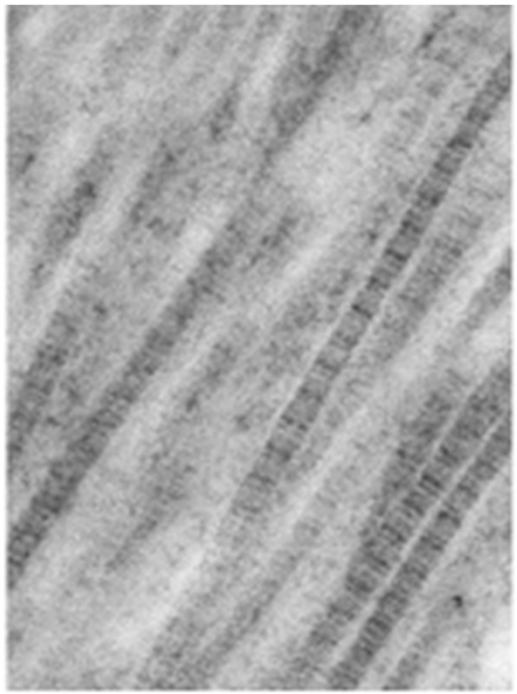




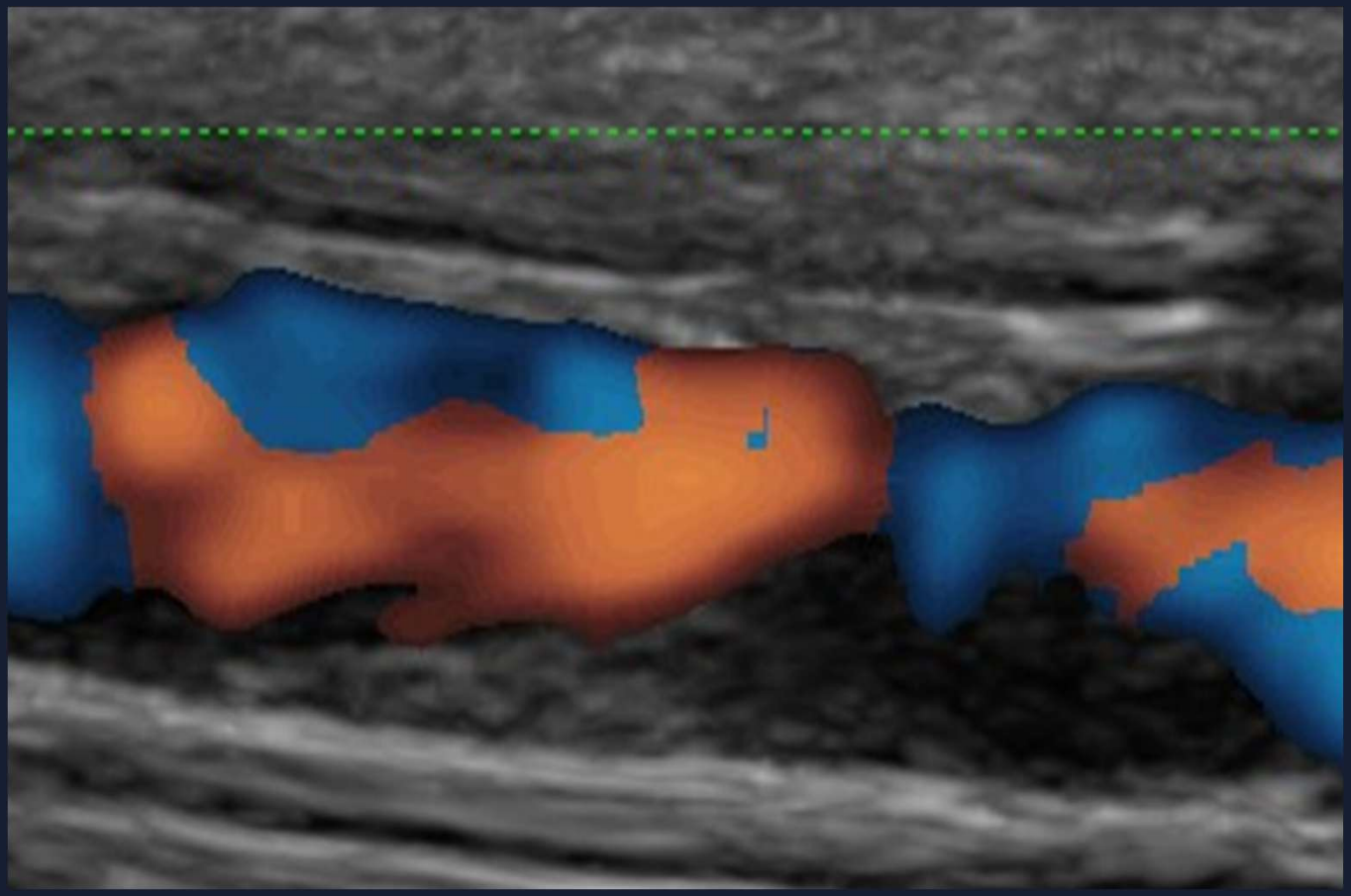


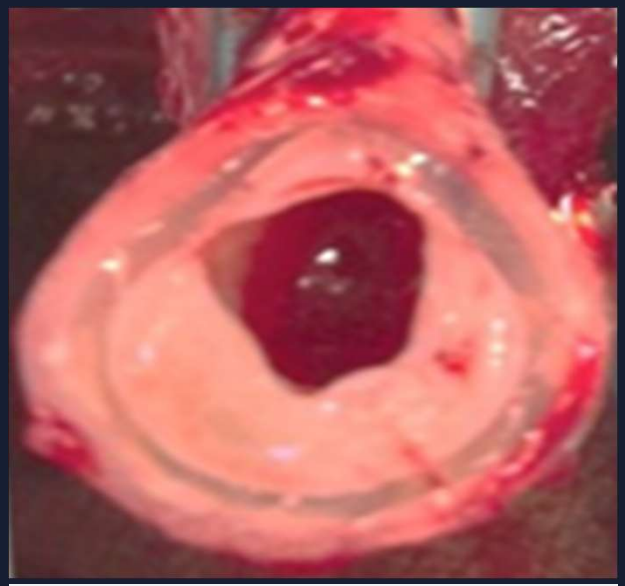






Confronto US – esame macroscopico e microscopico







Osservazioni preliminari

Il fallimento del graft non avviene per danno strutturale ma per il processo di integrazione con i tessuti dell'ospite

Final remarks

Il fallimento dell'accesso vascolare protesico è conseguenza di un processo di integrazione inizia con la prima puntura

E' un processo fatto di invasione/moltiplicazione cellulare seguito da produzione di matrice extracellulare

Il graft ha un destino segnato (fase 4)

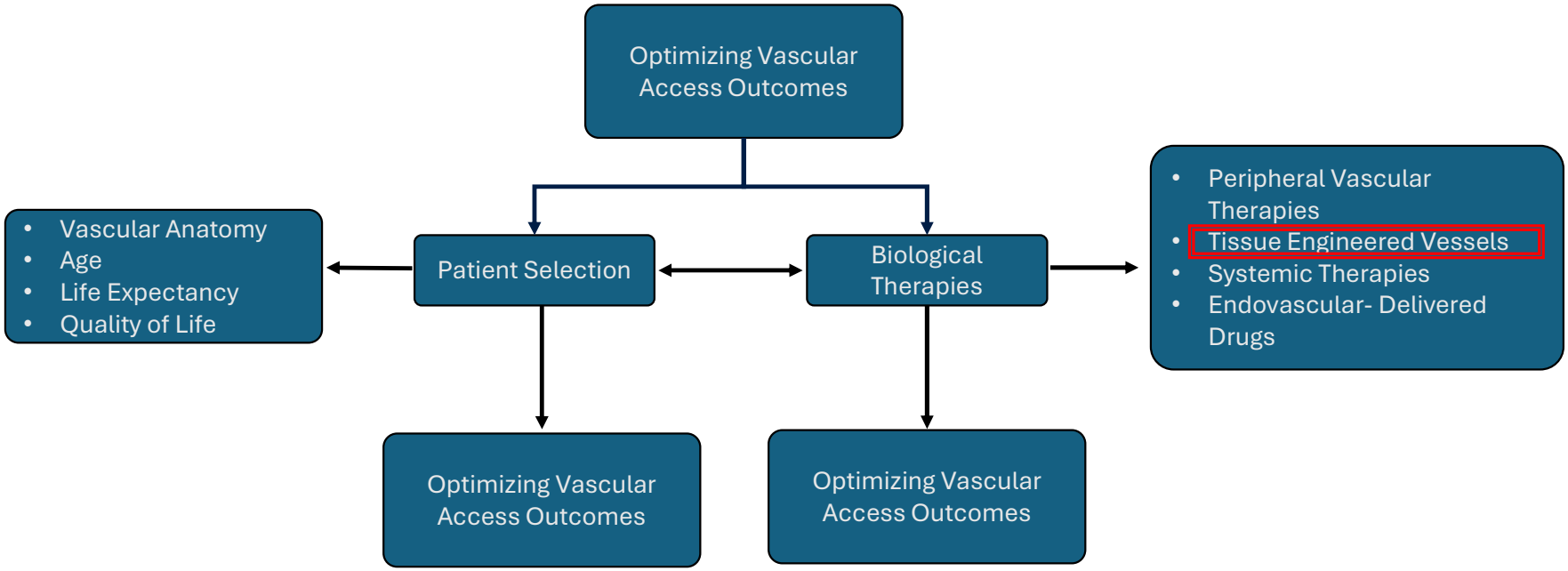
Impiego di device ad eluizione di farmaco antiproliferativo può avere un razionale in fase precoce (fase 2 – 3)

Possibile scenario



1. Prevedere la sostituzione dei graft a partire dai 3 anni

2. Sospendere i programmi di screening e di salvataggio delle fistole protesiche a partire dai 3 anni di vita



- *Arteriovenous conduits for hemodialysis: how to better modulate the pathophysiological vascular response to optimize vascular access durability*, Yan-Ting Shiu,1 * Joris I. Rotmans,2 * Wouter Jan Geelhoed,2 Daniel B. Pike,1 and Timmy Lee3,4 - Am J Physiol Renal Physiol


Silkothane®

Materials and methods: silk fibroin

- Selection of raw materials



Silk cocoons

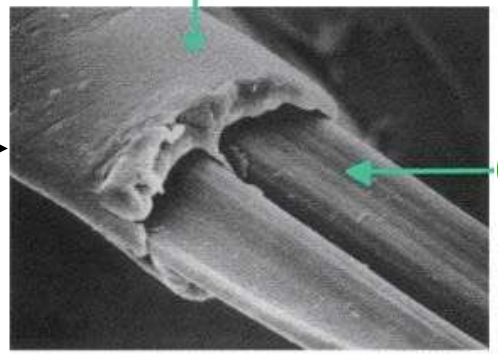


Degummed silk fibroin



Regenerated silk fibroin

Sericin



Fibroin

- **Biodegradable**
- **Bioactive**
- **Hemocompatible**
- **High tensile strength**

IDEAL VASCULAR ACCESS

SILKOTHANE® ARTERIOVENOUS GRAFT (SAG)



- ✓ Degradable
- ✓ Biocompatible
- ✓ Bioactive
- ✓ High tensile strength

SILKWORM FIBROIN



IN SITU TISSUE ENGINEERING



- ✓ Non-degradable
- ✓ Bioinert
- ✓ Implantable
- ✓ Highly elastic

POLYURETHANE (CARBOTHANE™)

- Graft manufacturing



SILK FIBROIN (SF)

in formic acid



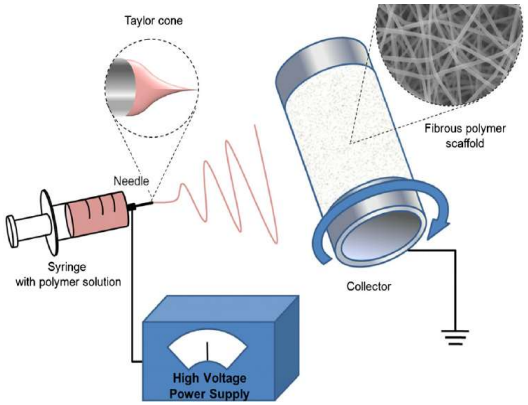
POLYURETHANE (PU)

in formic acid
+ dichloromethane



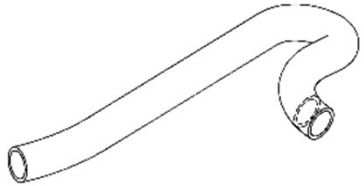
SILKOTHANE®

EU Registered Trademark



ELECTROSPINNING

EU Patented
US Patent pending



SILKOTHANE®

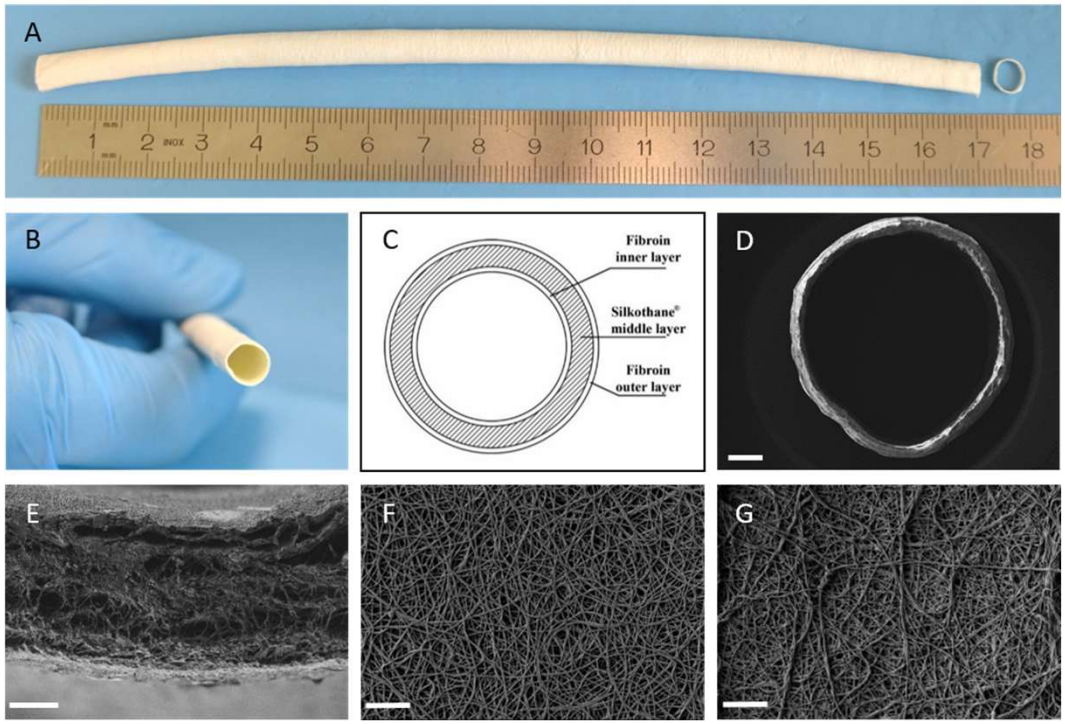
van Uden et al. J Biomed Mater Res B 2019

SILK FIBROIN
SILKOTHANE®
SILK FIBROIN

van Uden et al. Biomed Mater. 2019

- Graft manufacturing

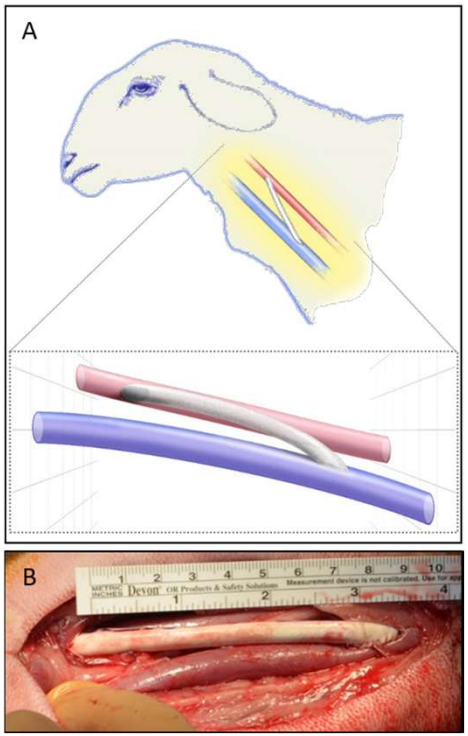
Riboldi et al., Adv Healtcare Mat 2020



- LENGTH ≈ 17cm
- INNER DIAMETER ≈ 5mm
- THICKNESS ≈ 350µm
- KEY FEATURES:
  - Compact wall and good cohesion between layers
  - Randomly oriented sub-micrometric fibers
- SCALE BARS:

  1 mm (D), 100 µm (E), 20 µm (F,G)

- *In vivo* testing

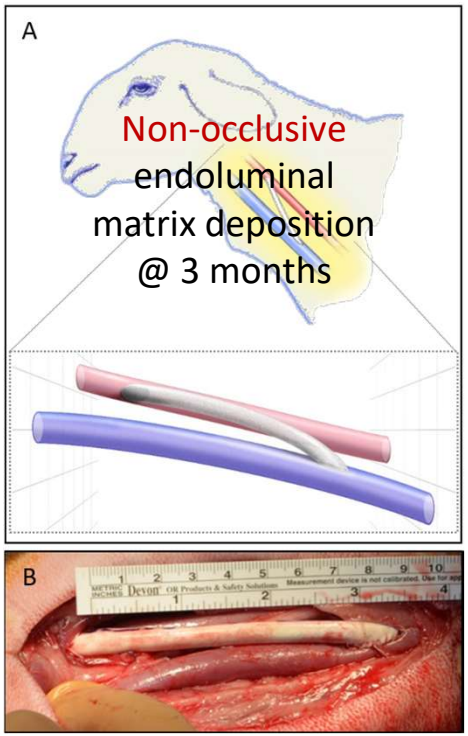


Riboldi et al., Adv Healtcare Mat 2020

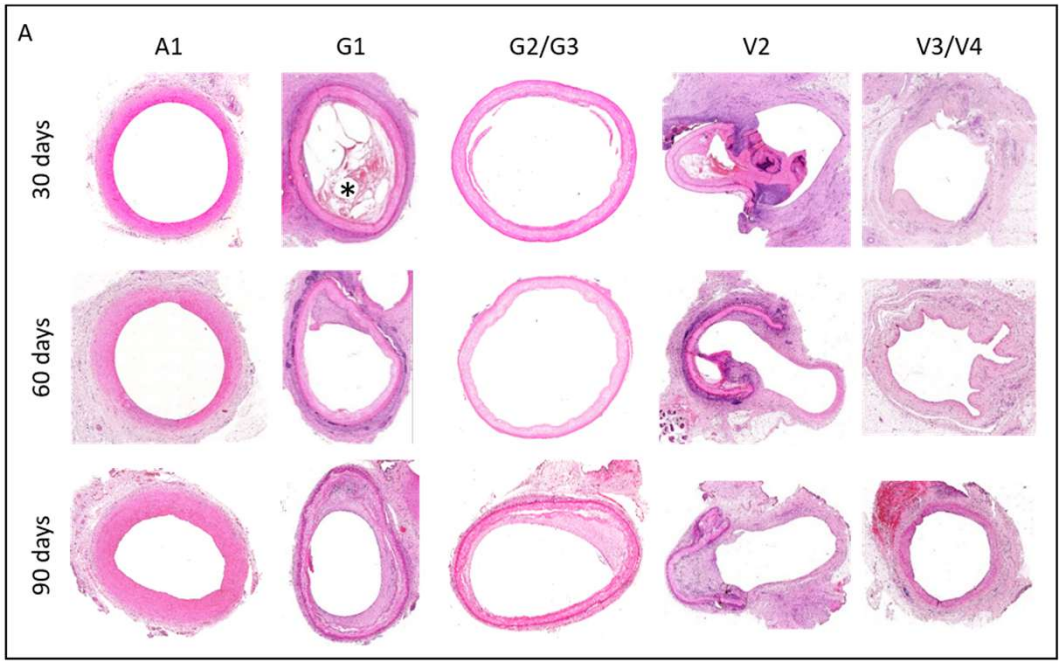
Auth. Italian Ministry of Health (DGSAF No. 0006623- P-08/03/2019)

- ANIMALS: 9 adult sheep
- CONFIGURATION: Ipsilateral carotid-jugular shunt
- IMPLANTED LENGTHS: 7.7 ± 1.7 cm
- ENDPOINTS: Patency and short-term remodeling
- TIME POINTS: 1, 2, 3 months (N = 3)
- FOLLOW UP: Echo-color Doppler every two weeks
- ANALYSES:
    - US Doppler measurements
    - Histology (H&E, Sirius Red, vWF)
    - Scanning Electron Microscopy (SEM)

- Histology and histomorphometry



Riboldi et al., Adv Healtcare Mat 2020



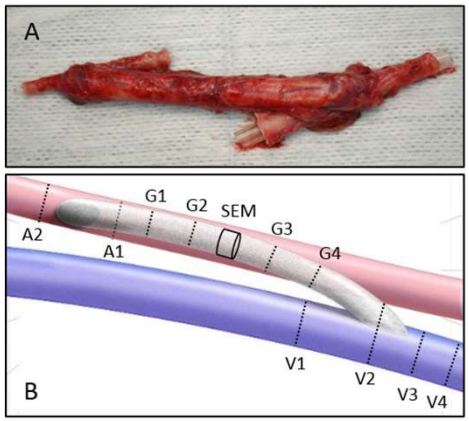
100%
patency rate
@ 3 months

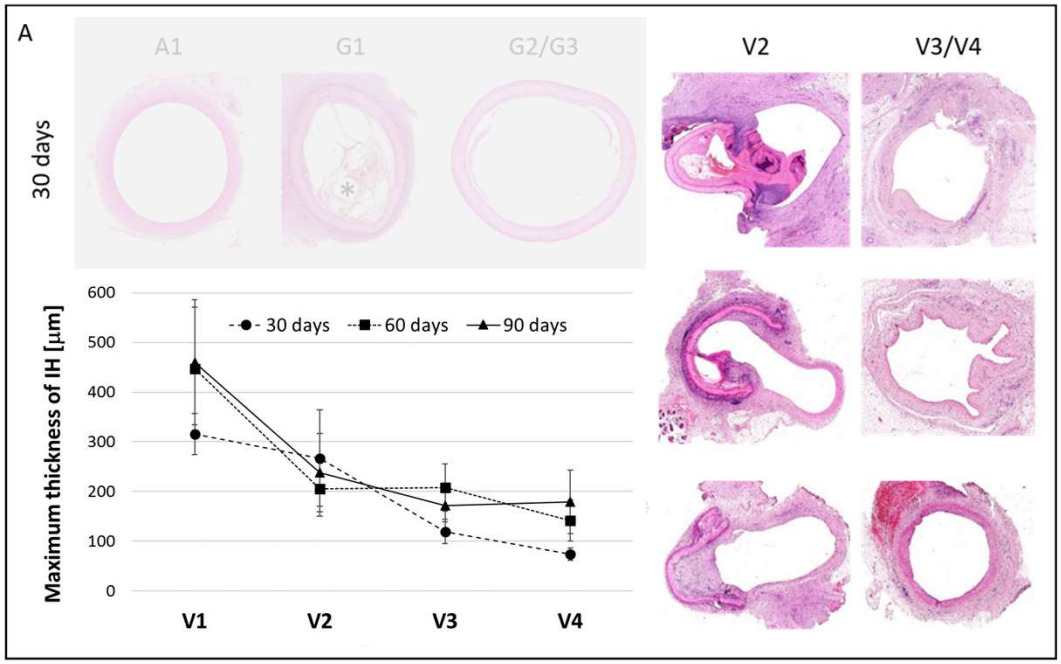
Neointimal
hyperplasia
stabilizing
over time
even at the
venous
anastomosis
V2

- Histology and histomorphometry

Riboldi et al., Adv Healtcare Mat 2020

Non-occlusive
endoluminal
matrix deposition
@ 3 months





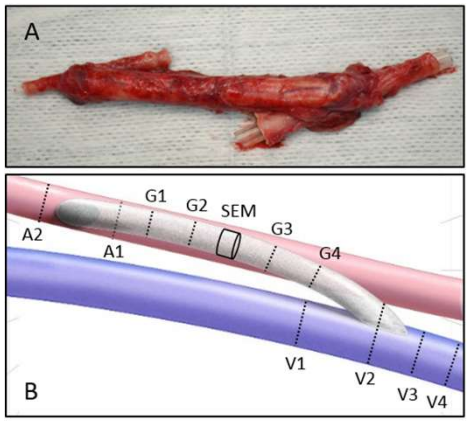
100%
patency rate
@ 3 months

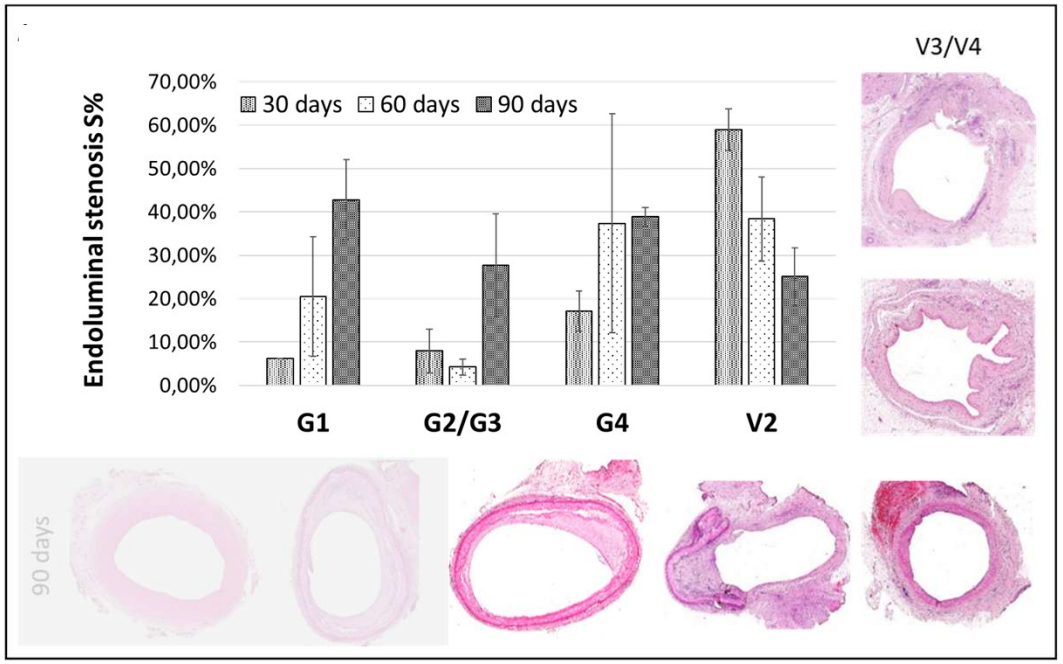
Intimal
thickening
chronicizes
on non-impairing
regime levels
(< 500µm in V2)

- Histology and histomorphometry

Riboldi et al., Adv Healtcare Mat 2020

Non-occlusive
endoluminal
matrix deposition
@ 3 months





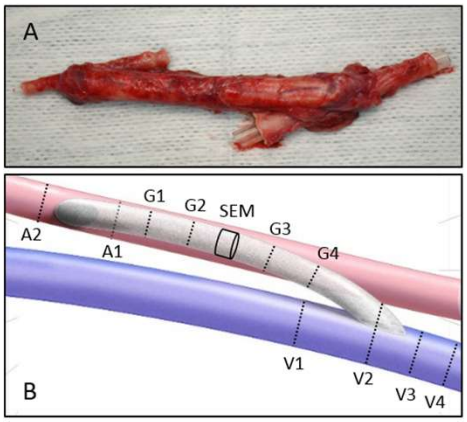
100%
patency rate
@ 3 months

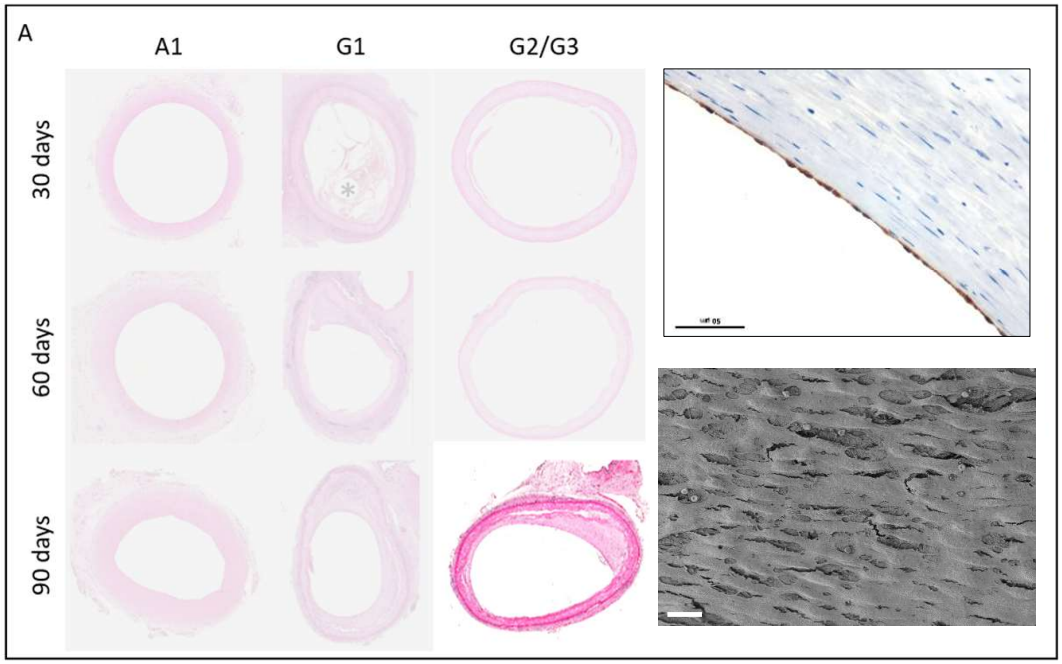
Endoluminal
stenosis with
tendency to
stabilize over
time below
impairing levels
(50%)

- Histology and histomorphometry

Riboldi et al., Adv Healtcare Mat 2020

Endothelization
@ 3 months @
mid-graft region





SCALE BAR:
50 µm

SCALE BAR:
20 µm