Accessi vascolari: quali novità

(protesi, endoFAV ed altri devices)

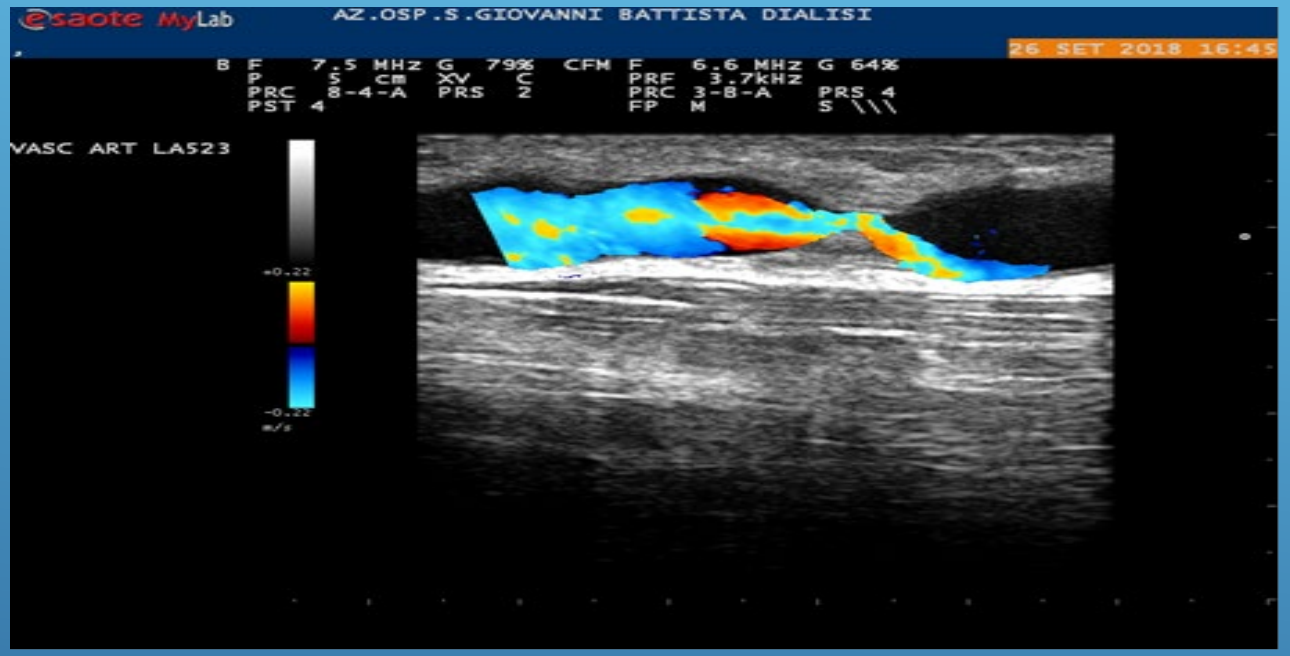
Dott. Gianluca LEONARDI
Direttore f.f. – ASL TO5 – S.C. Nefrologia e Dialisi – Ospedale Maggiore di Chieri

Riccione – 9/11 maggio 2022

N Engl J Med. 1966 Nov 17;275(20):1089-92.

Chronic hemodialysis using venipuncture and a surgically created arteriovenous fistula.

Brescia MJ, Cimino JE, Appel K, Hurwich BJ.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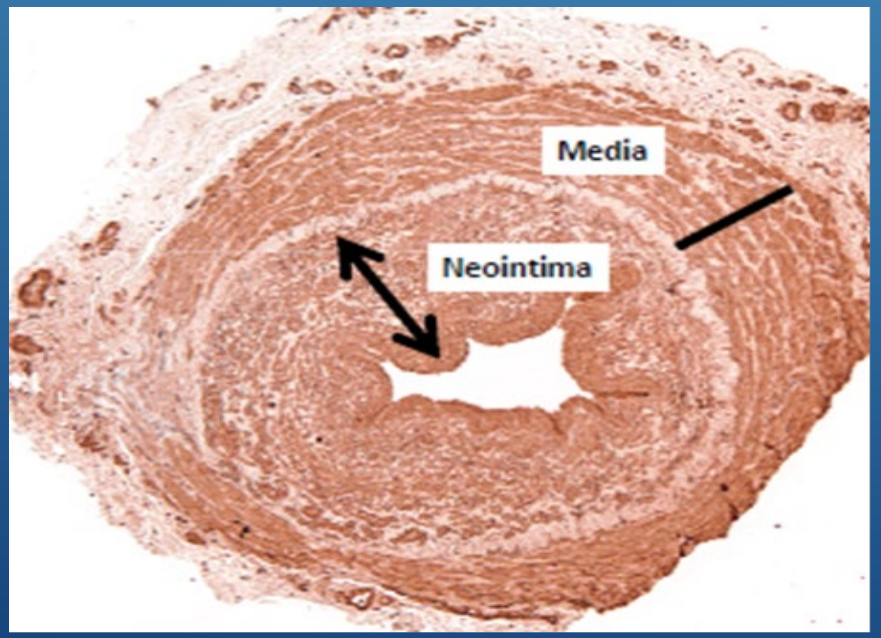
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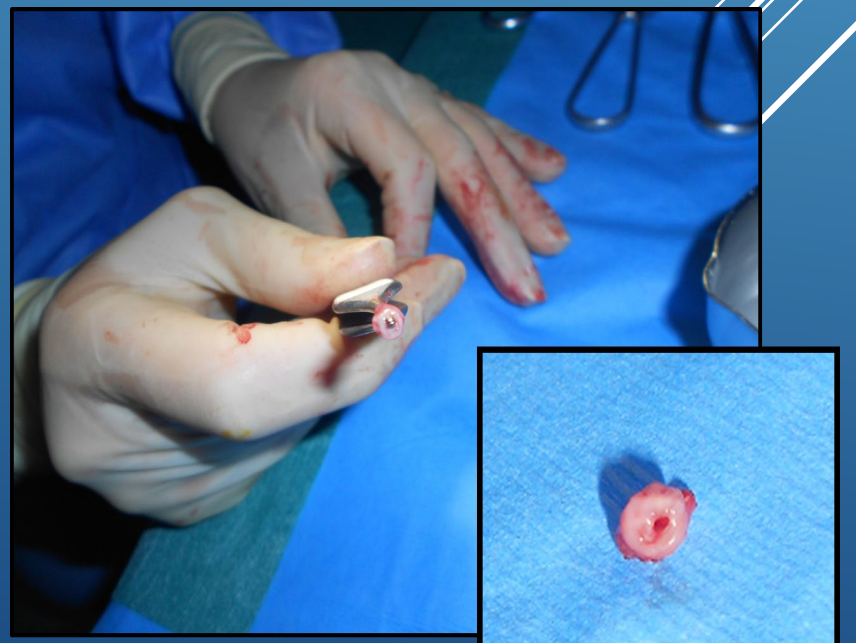
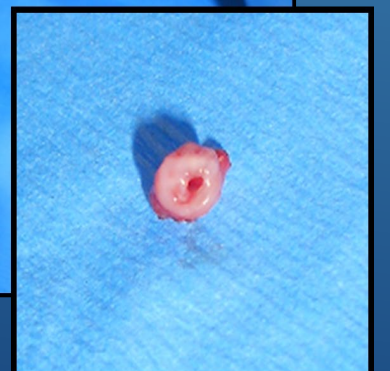
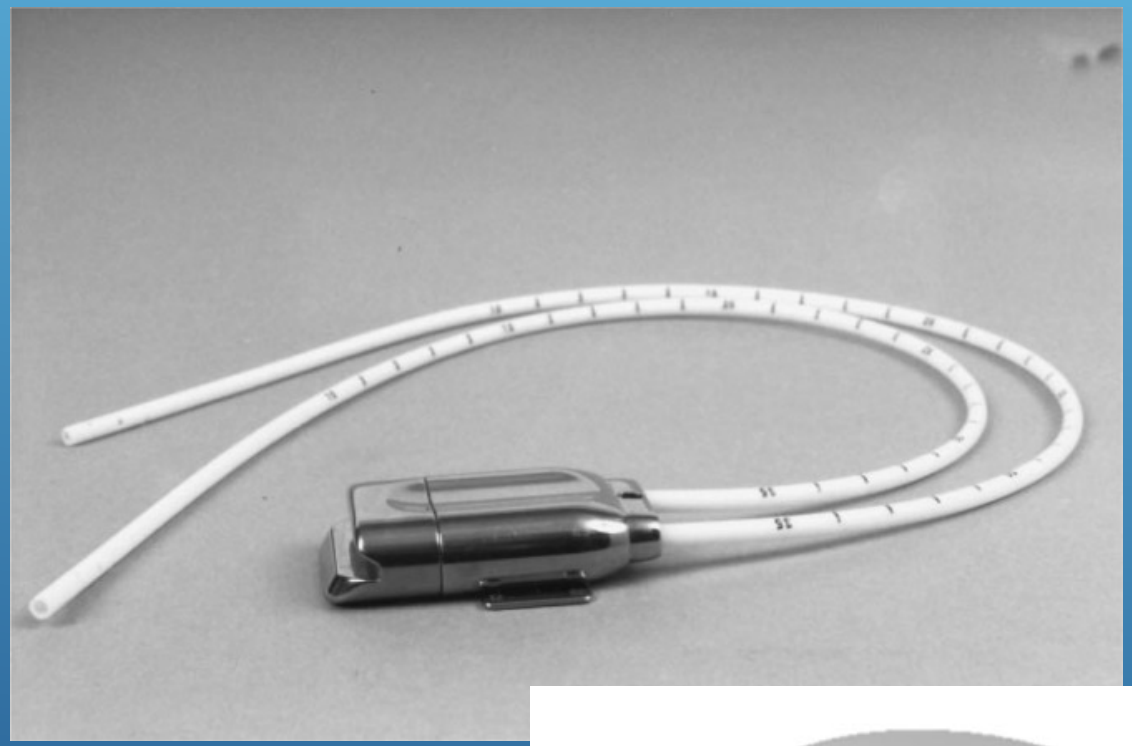
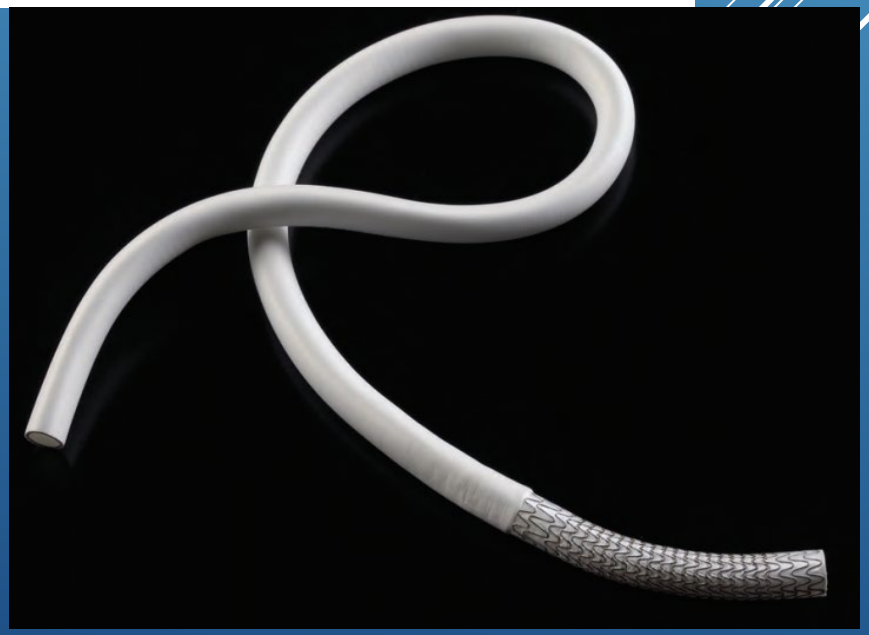
Neointima







ATRIUM



- FAV endovascolare
- VasQ
- Protesi (early cannulation, biologiche o biosintetiche)
- Stent e palloni medicati
- Hero
- Varie

- **FAV endovascolare**

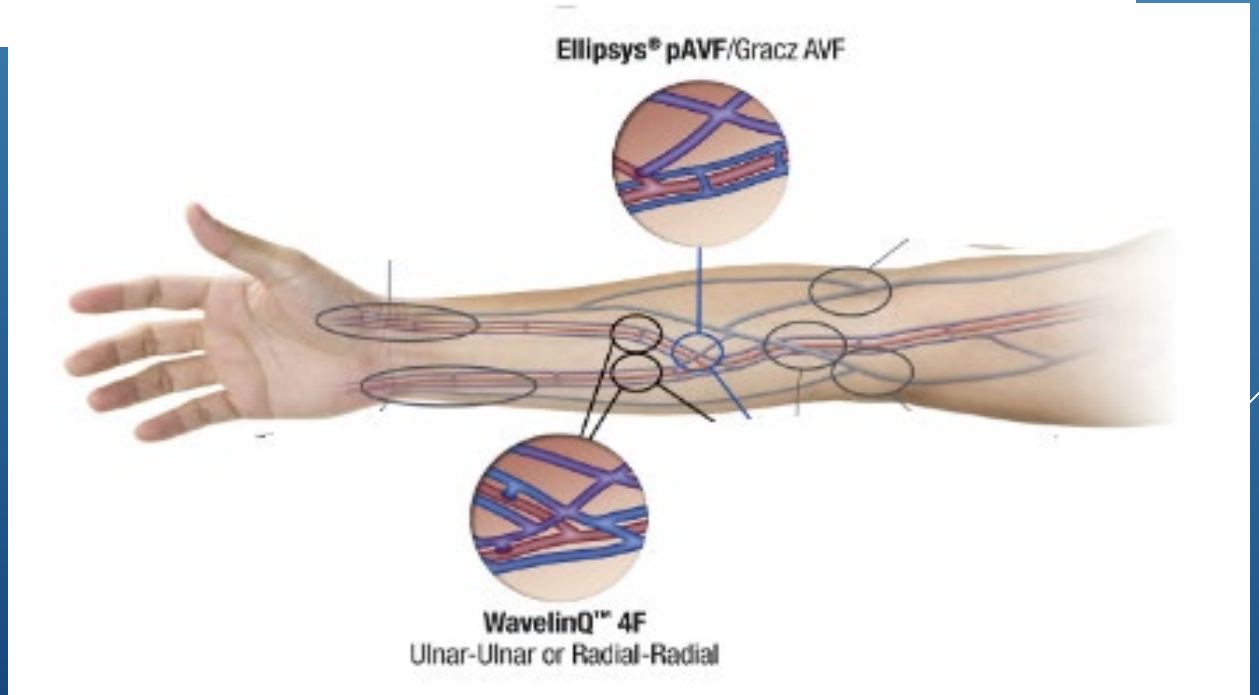
WavelinQ™ → dual catheter system
(ex EverlinQ) radiofrequenza
accoppiamento magnetico

Ellipsys™ → single catheter system
energia termica

- **FAV endovascolare**

- Vasi non idonei per una FAV distale chirurgica

- Vasi venosi superficiali da arterializzare di calibro >2.5mm e con decorso rettilineo (idonei ad incannulamento)



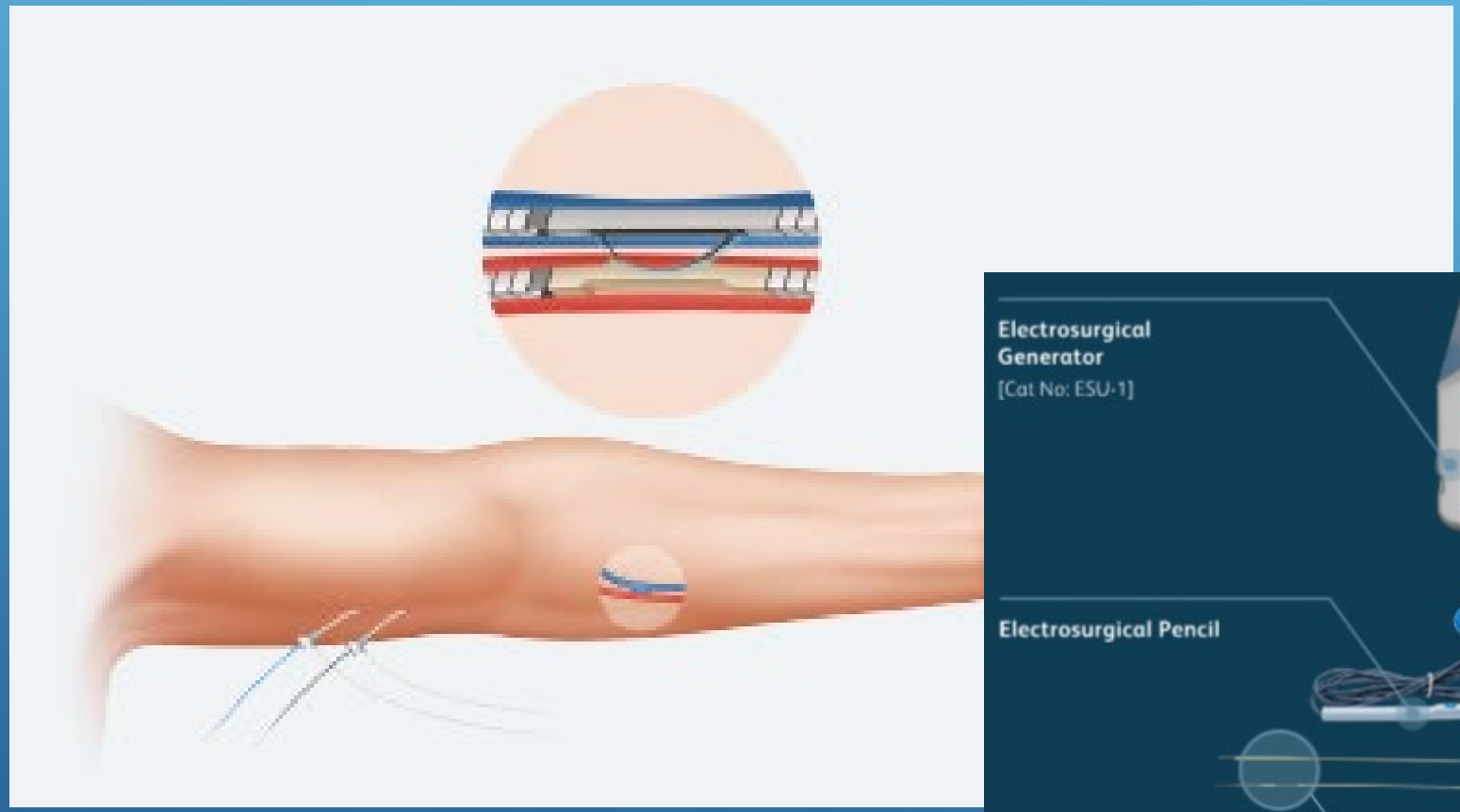
WavelinQ™

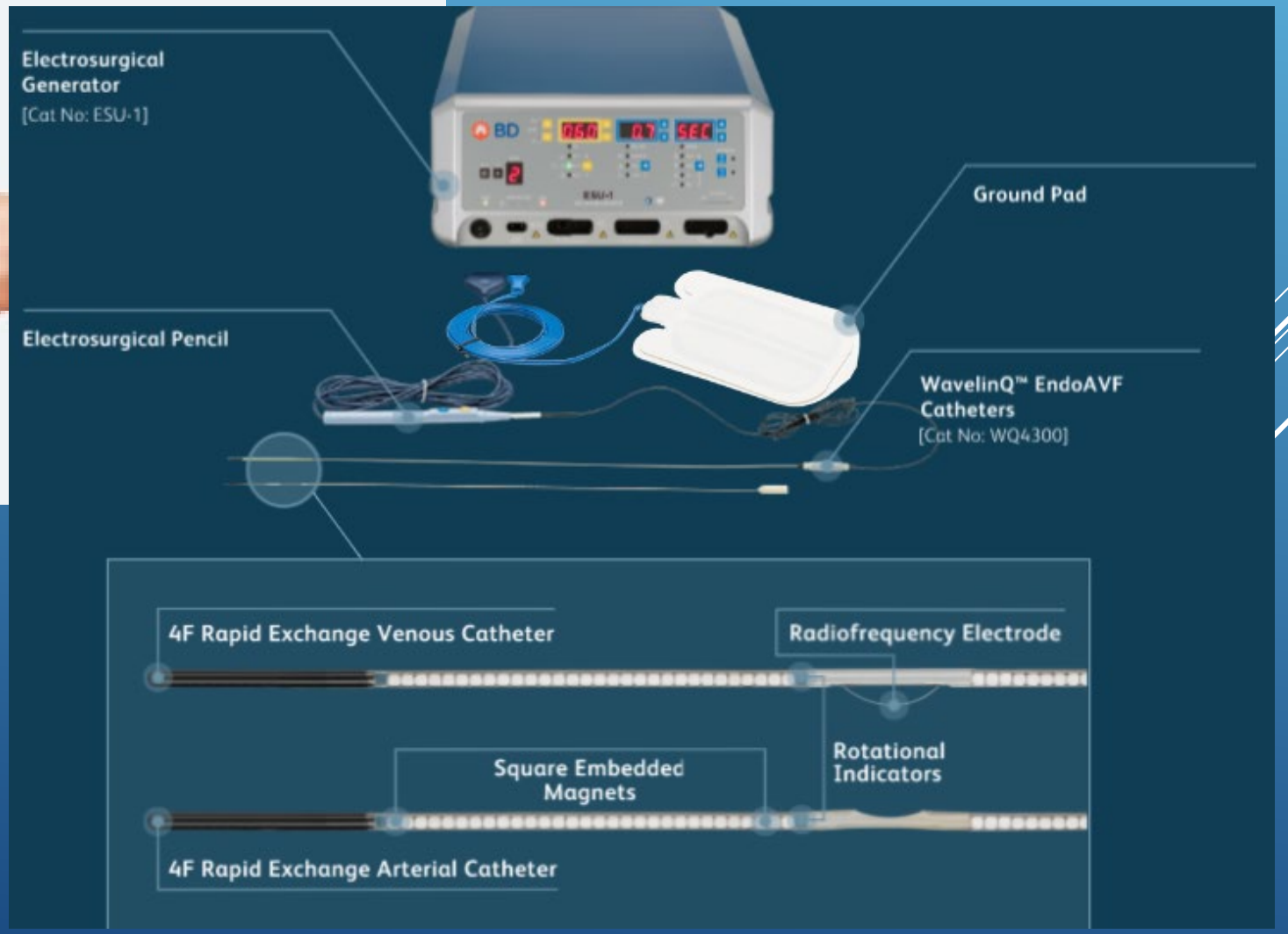
Arteria radiale e sua vena comitans
Arteria ulnare e sua arteria comitans

Guida ecografica e radioscopica

Controindicato se: Diametro dei vasi < 2.0 mm
Calcificazioni vascolari

Può essere necessaria embolizzazione della vena basilica




Electrosurgical Generator
[Cat No: ESU-1]
Ground Pad
Electrosurgical Pencil
WavelinQ™ EndoAVF Catheters
[Cat No: WQ4300]
4F Rapid Exchange Venous Catheter
Radiofrequency Electrode
Rotational Indicators
Square Embedded Magnets
4F Rapid Exchange Arterial Catheter

Arteria radiale prossimale e ramo venoso perforante

Ecoguidata

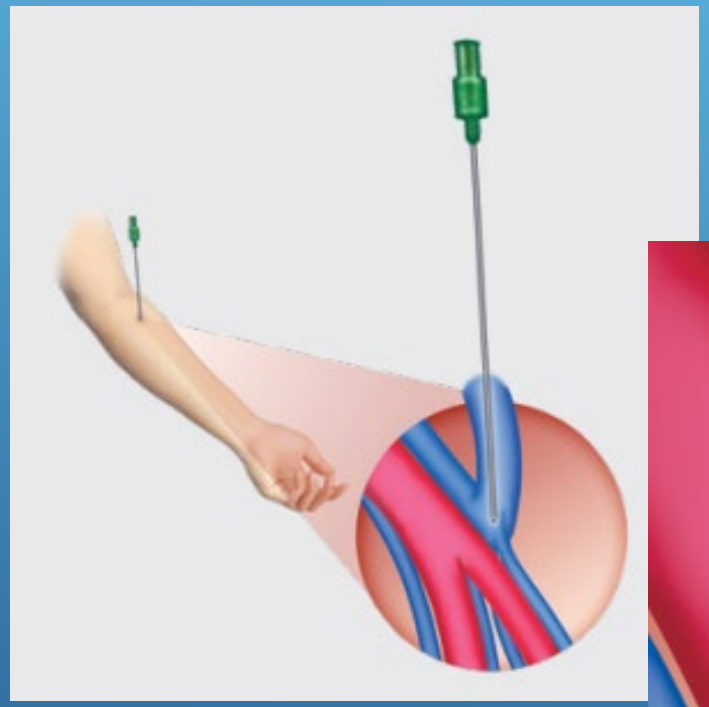
Controindicato se: Diametro dei vasi < 2.0mm
Distanza tra i vasi > 1.5mm
Calcificazioni vascolari

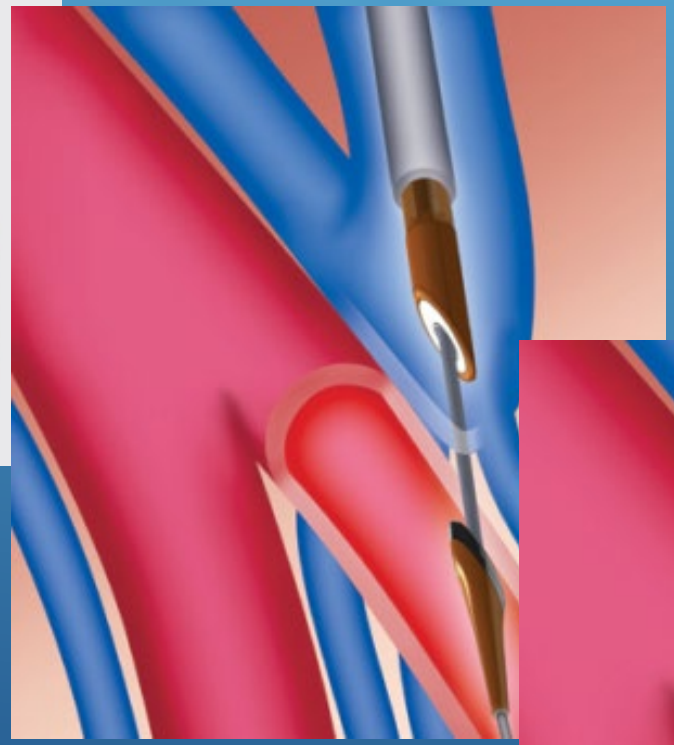
Necessaria PTA dell'anastomosi neoformata

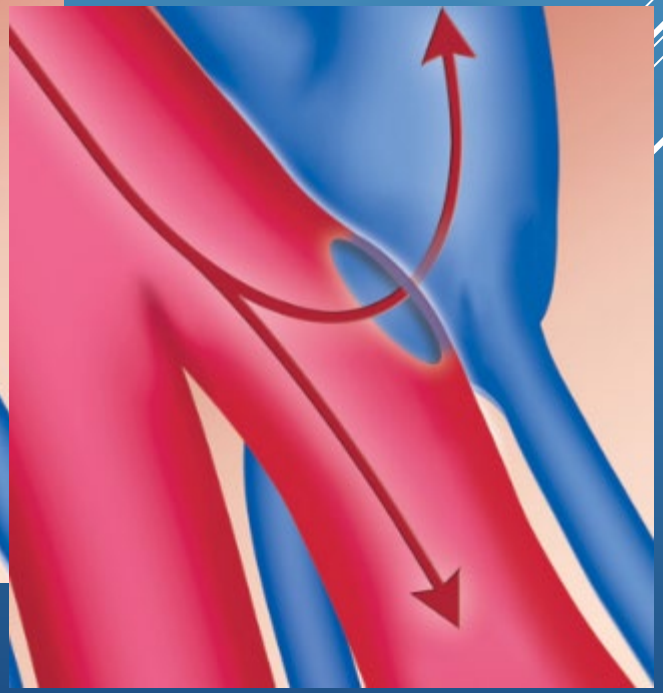
Nel 62% dei casi: embolizzazione di vasi collaterali

Ante

Ellipsys™







medtronic.com/ellipsys

AJKD

Review

New Devices and Technologies for Hemodialysis Vascular Access: A Review

Tushar J. Vachharajani, Jonathan J. Taliercio, and Evamaria Anvari

Am J Kidney Dis.
78(1):116-124. Published online May 6, 2021.

Assenza di cicatrice cutanea

Minore percezione della vena arterializzata

Thrill meno intenso (flussi minori)

Presenti numerosi siti venosi arterializzati che possono essere utilizzati

Può essere necessaria venipuntura ecoguidata

AJKD

Review

New Devices and Technologies for Hemodialysis Vascular Access: A Review

Tushar J. Vachharajani, Jonathan J. Taliercio, and Evamaria Anvari

Am J Kidney Dis. 78(1):116-124. Published online May 6, 2021.

WavelinQ System

87% (52/60paz): flusso 912cc/min, diametro medio vena efferente 5.2mm

Primary patency a 12 mesi: 69%
Seconday patency a 12 mesi: 84%

Reinterventi (embolizzazioni, PTA, superficializzazioni): 32%
Complicanze: rare (pseudoaneurismi arteria brachiale)

Ellipsys System

86% (92/107paz): flusso >500cc/min, diametro vena > 4mm

Secondary patency a 12 mesi: 93.4%

Reinterventi (embolizzazioni, PTA, superficializzazioni): 92.5%

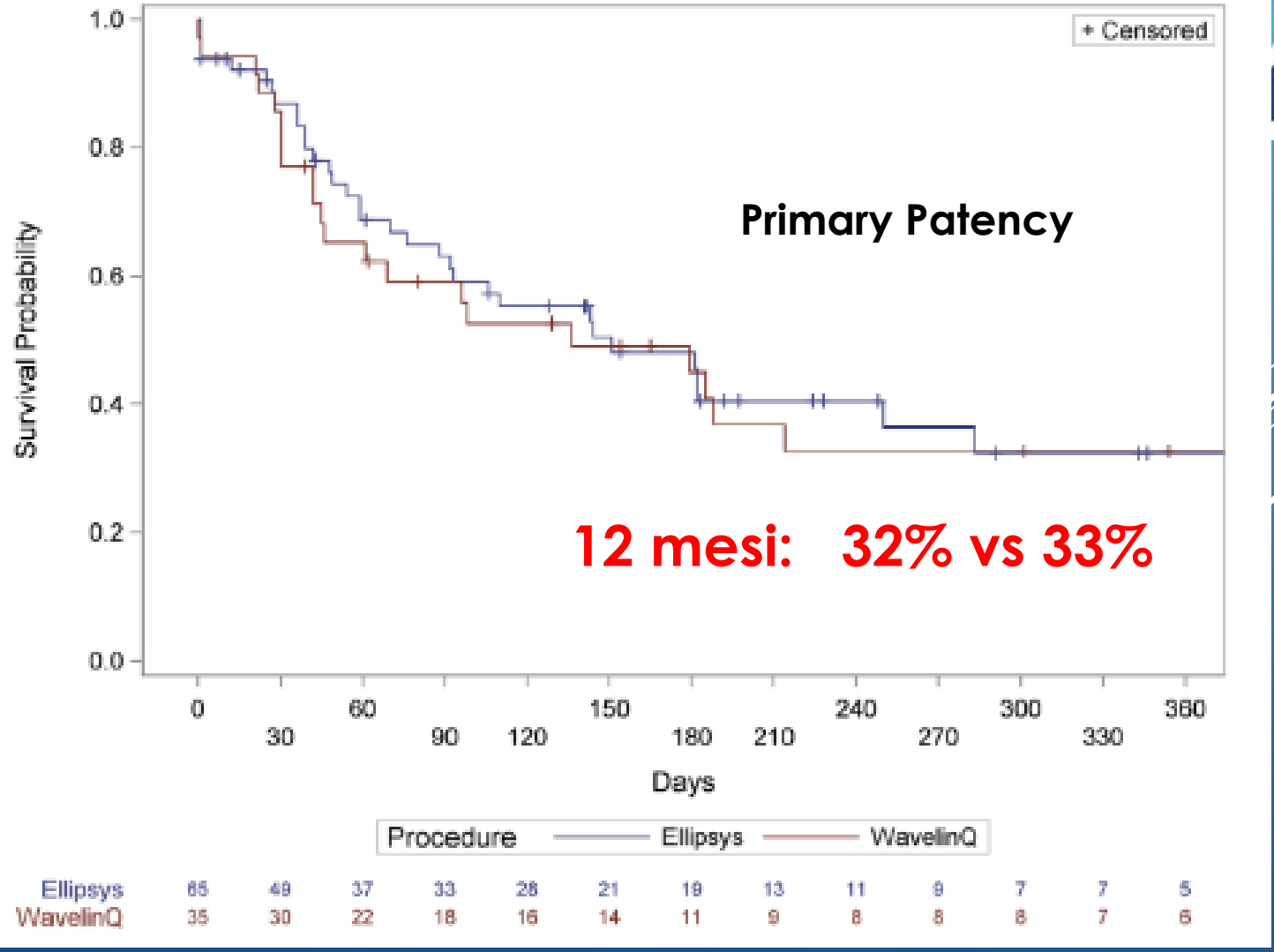
Complicanze: rare (ematoma, fallimento procedura)

J Vasc Interv Radiol 2020; 31:1365–1372

CLINICAL STUDY

Comparison of Outcomes
Arteriovenous Fistulae Cr
and V

Robert Shahverdyan, MD, Ge
Nasir Mushtaq, PhD, MBBS,
Peter R. Nelson, MD, MS, and V

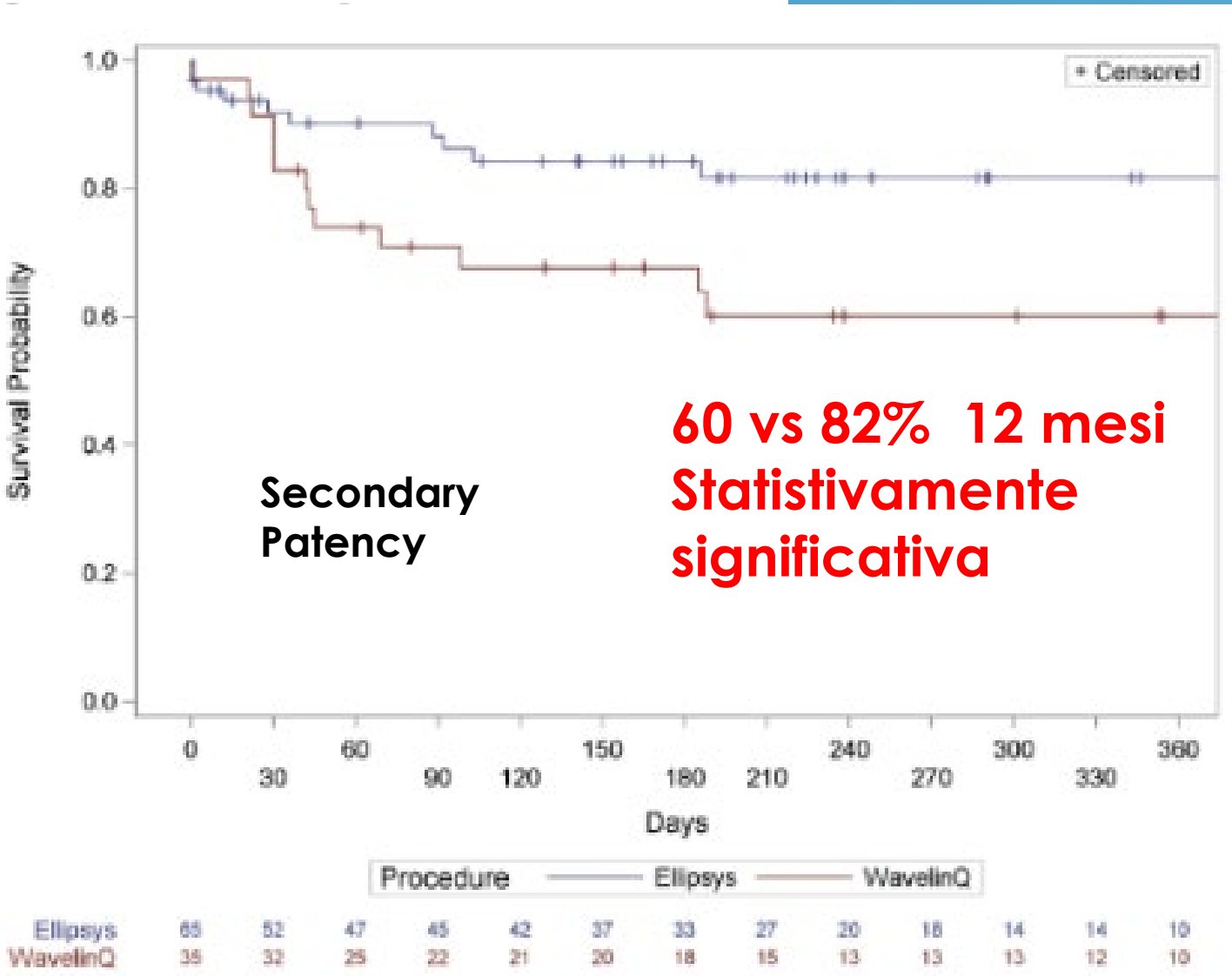


J Vasc Interv Radiol 2020; 31:1365–1372

CLINICAL STUDY

Comparison of
Arteriovenous I

Robert Shahve
Nasir Mushtac
Peter R. Nelson,



Secondary Patency

60 vs 82% 12 mesi
Statistivamente significativa

Variable	WavelinQ n (%)	Ellipsys n (%)	*P* Value[†]
Technical success			.3500
Yes	34 (97)	65 (100)	
No	1 (2.9)	0 (0)	
Anastomosis			<.0001
Proximal radial artery	22 (65)	64 (98)	
Proximal ulnar artery	11 (32)	0 (0)	
Brachial	1 (3)	1 (2)	
Outflow vein			.0012
Cephalic vein	8 (23)	14 (22)	
Basil vein	9 (26)	9 (14)	
Cephalic and basilic vein	11 (31)	41 (63)	
Brachial vein	7 (20)	1 (2)	
Procedure time, min*	63 (28-150)	14 (9-31)	<.0001
Contrast (n = 35), mL*	8 (2-22)	—	—
Ancillary procedure, primary embolization coil			<.0001
Yes	26 (74)	0 (0)	
No	9 (26)	65 (100)	
Primary angioplasty			
Yes	0 (0)	65 (65)	
No	35 (35)	0 (0)	
Follow-up, days*	188 (0-760)	183 (1-487)	.2980
AVF blood flow, mL/min *,‡			
Day 1 (n WavelinQ = 34; n Ellipsys = 65)	450 (85-1300)	460 (150-1400)	.6240
Day 2 (n WavelinQ = 28; n Ellipsys = 57)	640 (200-1450)	640 (180-1300)	.7646
Week 4 (n WavelinQ = 24; n Ellipsys = 47)	775 (150-2600)	780 (290-1300)	.8267
Months 2-3 (n WavelinQ = 19; n Ellipsys = 35)	840 (365-1700)	800 (280-1500)	.2142
Month 6 (n WavelinQ = 13; n Ellipsys = 22)	1000 (480-1600)	750 (70-1000)	.1156
Access failure			.0137
Yes	13 (37)	10 (15)	
No	22 (63)	55 (85)	
Maturation at 4 weeks			.1709
Yes[§]	19 (54)	41 (68)	
No	16 (46)	19 (32)	
AVF use in dialysis patients			.0711
Yes	14 (58)	31 (79)	
No	10 (42)	8 (21)	
Days to 1st use* (n WavelinQ = 13; n Ellipsys = 31)	90 (1-180)	60 (1-164)	.3676

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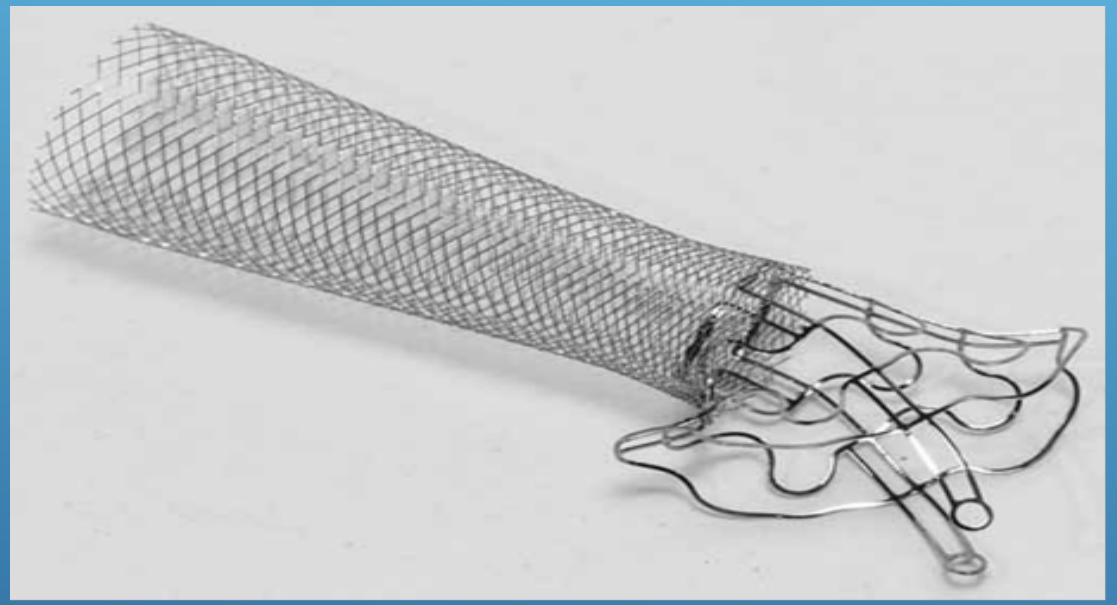
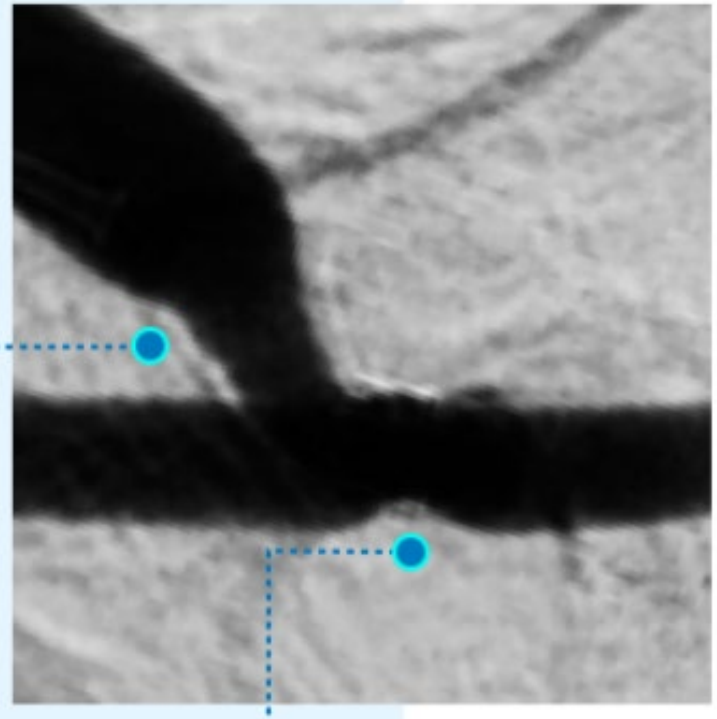
- Varie

- VasQ



VasQ™



http://www.laminatemedical.com/vasq

Venous Tapering

Smoothly transitions flow to the dilated fistula

A

De
tov

Arteriovenous fistula creation with VasQ™ device: A feasibility study to reveal hemodynamic implications

Michela Bozzetto, Luca Soliveri, Sofia Poloni, Paolo Brambilla, Diego Curtò, Giuseppina Carmela Condemi, Pietro Cefalì, Irene Spina, Alessandro Villa, Anna Caroli, Andrea Remuzzi

First Published April 22, 2022 | Research Article

https://doi.org/10.1177/11297298221087160

The Journal of Vascular Access

JVA
J Vasc Access 2016; 17 (3): 243-248
DOI: 10.5301/jva.5000527
Open Access

Risultati a 6 mesi:

- Primary patency 79%
- Tasso di fistole pervie e mature a fine studio 93% (14/15)
- Non eventi avversi correlati al device

Fistole prossimali omero cefaliche

Original Investigation

Risultati a 6 mesi:

- Non eventi avversi correlati al device
- No differenze in primary e secondary patency
- Functional patency nel gruppo trattato 100% (vs 56%)

Nikolaos Karydis, Paul Bevis, Timothy Beckitt, Daniel Silverberg, Moshe Halak, and Francis Calder

Implanted blood vessel external support device (VasQ™) for creation of hemodialysis arteriovenous fistula: A single-center experience

Gianluca Leonardi*, Marco Campagna*, Vincenzo Pellicanò, Cesare Guarena, Daniela Bergamo, Antonio Lavacca, Fabrizio Fop and Luigi Biancone

JVA | The Journal of Vascular Access

Volume: 22 issue: 4, page(s): 658-665
Article first published online: November 12, 2020; Issue published: July 1, 2021

Impianto: 100% senza problemi
10 FAV prossimali
10 FAV distali

Maturazione: 95% (19/20)

Table 3. Clinical and ultrasound AVFs assessments with VasQ device.

Clinical and ultrasound outcomes	Day-1 % (*n*)	1 month % (*n*)	6 months % (*n*)	12 months % (*n*)
Mean flow rate of patent fistulae (in brachial artery) (ml/min)	841 ± 176.8	1052 ± 224.6	1261 ± 490.3	1348 ± 477.1
Mean outflow vein diameter of patent fistulae (mm)	5.0 ± 1.0	5.9 ± 0.9	7.2 ± 1.6	7.9 ± 1.4

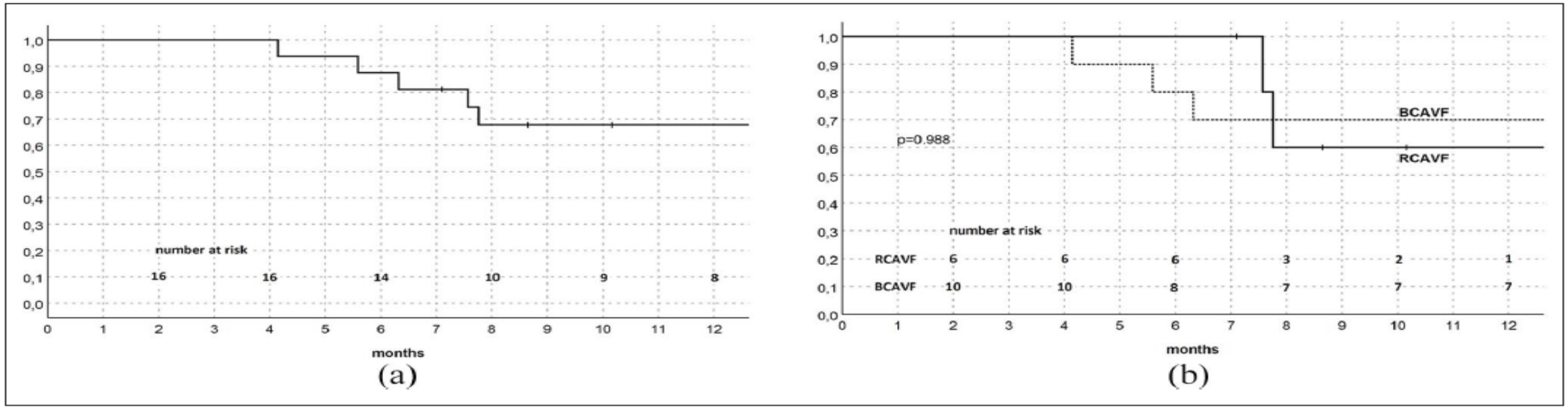


Figure 3. Primary patency. 3(a) all population; 3(b) population splitted by AVFs site

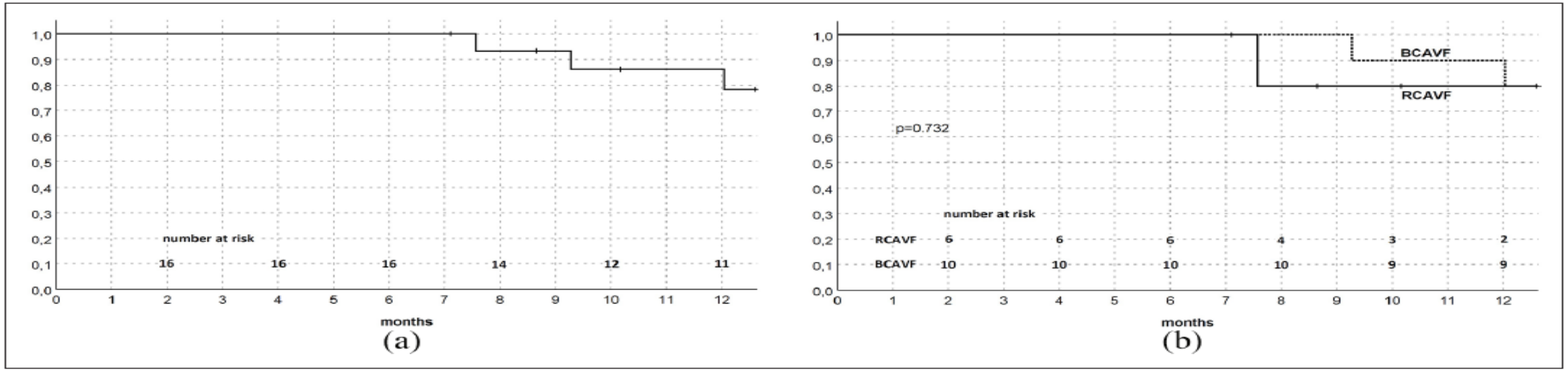
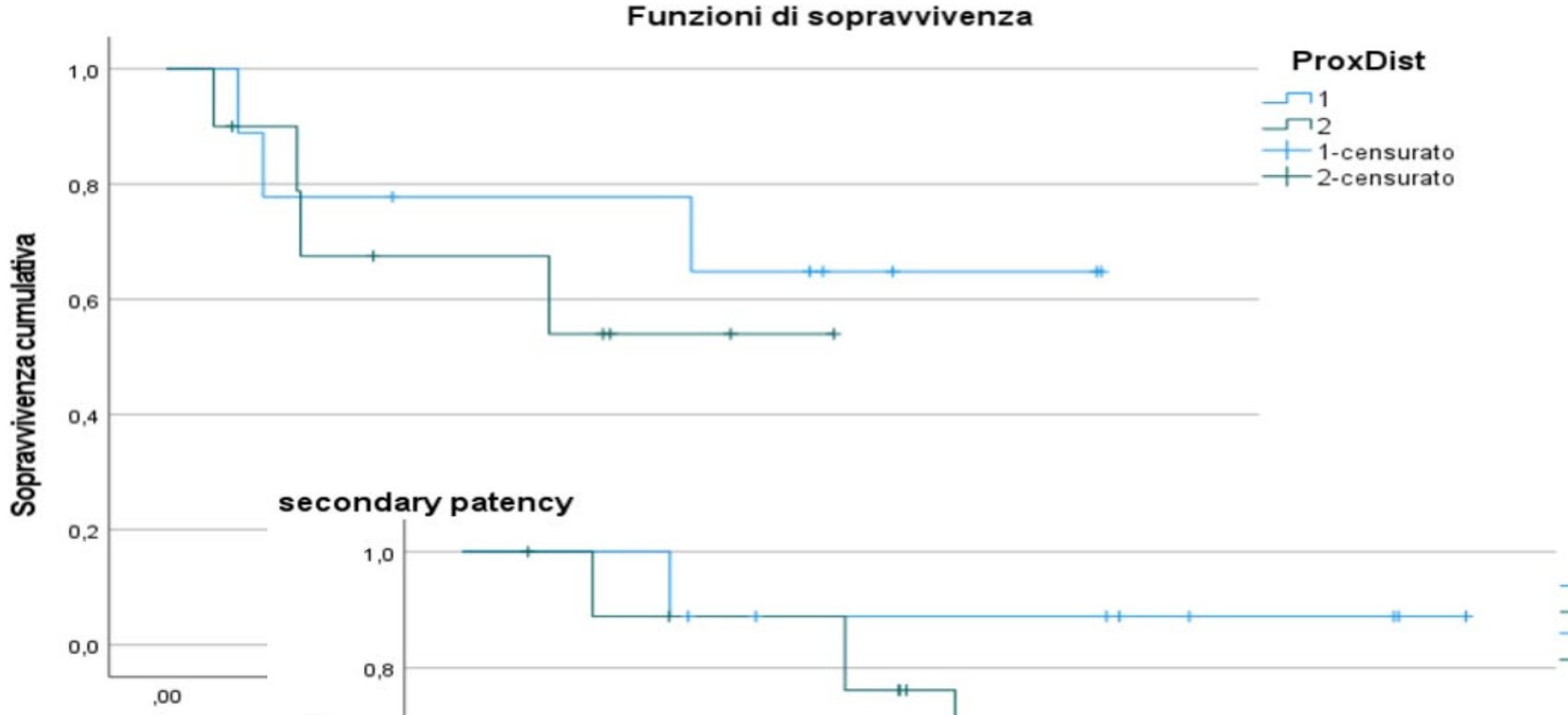
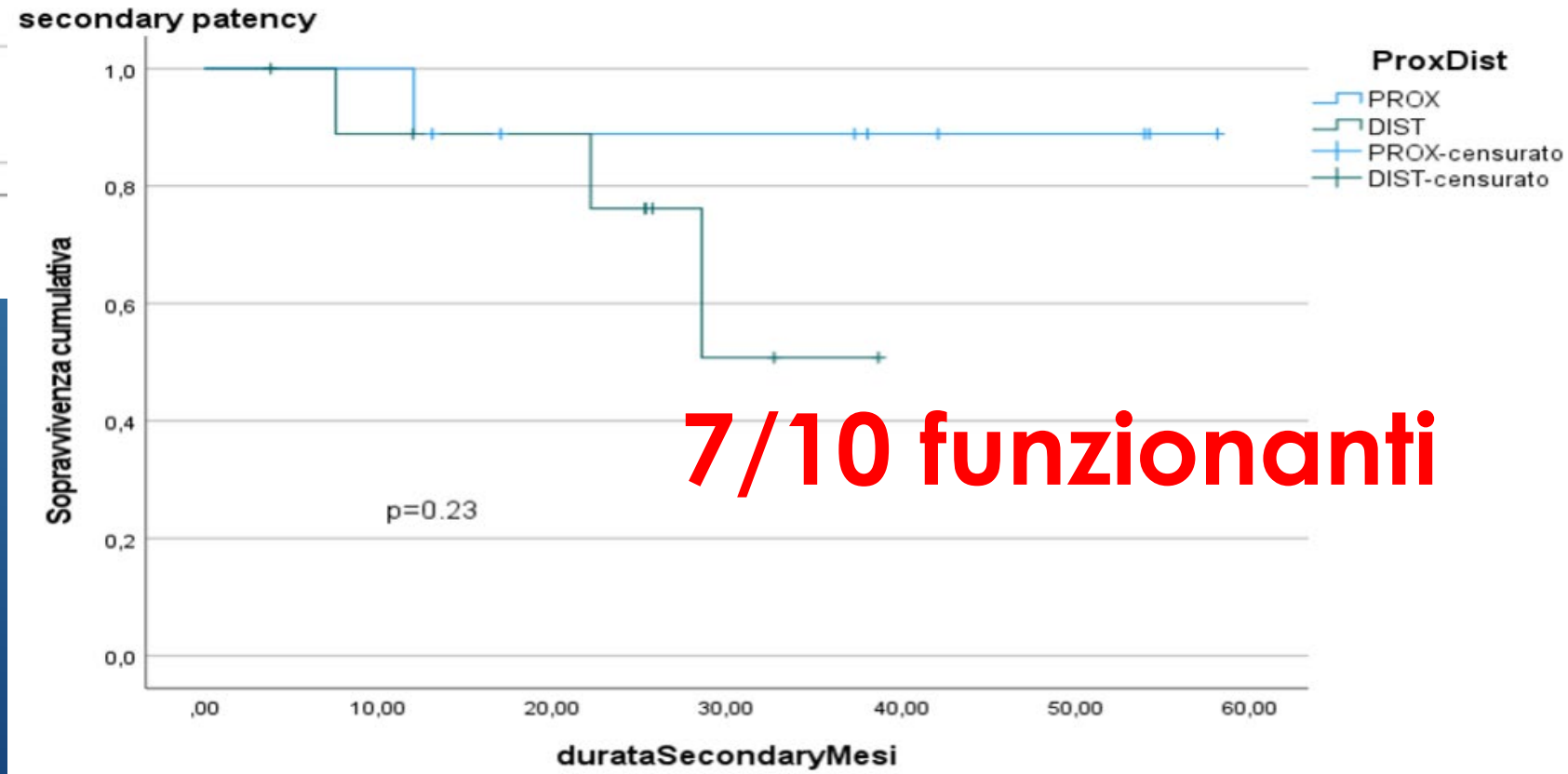
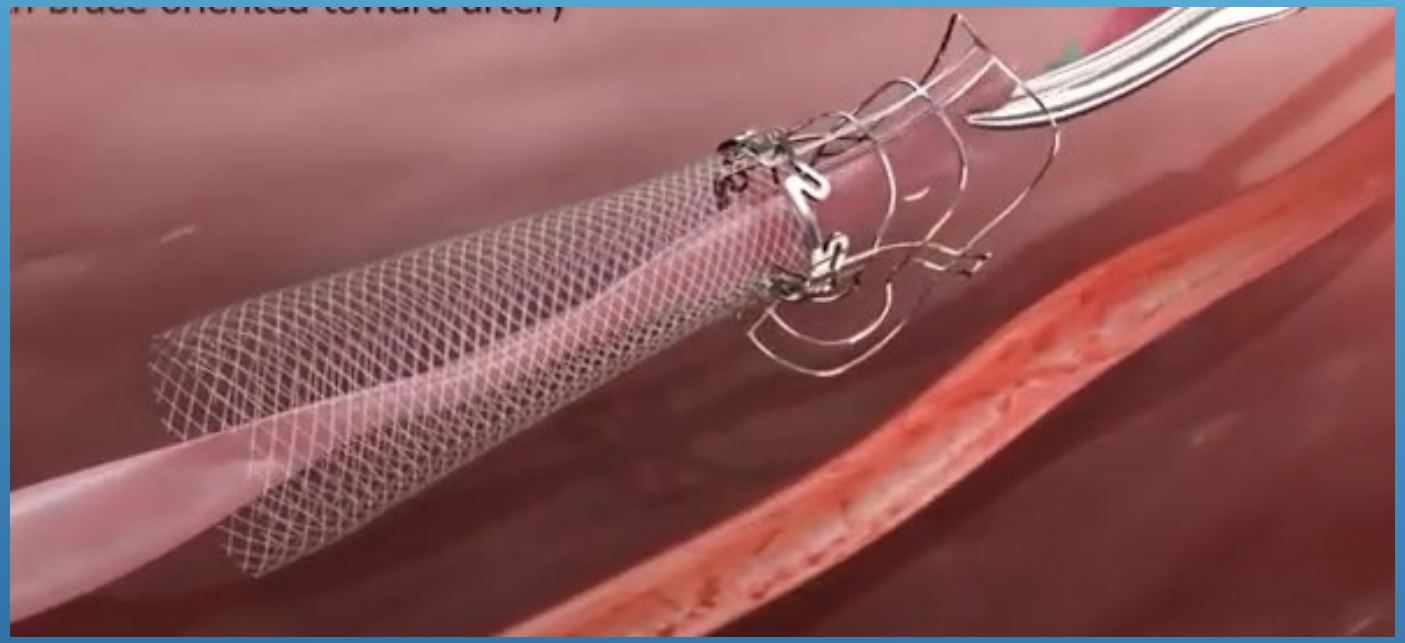


Figure 4. Secondary patency. 4(a) all population; 4(b) population splitted by AVF site





7/10 funzionanti



Non influenza la sede di venipuntura
Non problemi in caso di PTA intra dispositivo
Non pregiudica eventuale reintervento di prossimalizzazione

Journal of Vascular Surgery SVS Society for Vascular Surgery

CLINICAL RESEARCH STUDY VASCULAR ACCESS | VOLUME 75, ISSUE 1, P248-254, JANUARY 01, 2022

Multicenter European real-world utilization of VasQ anastomotic external support device for arteriovenous fistulae

Robert Shahverdyan, MD,[a] Paola Tabbi, MD,[b] *and* Gaspar Mestres, MD,[c] *Hamburg, Germany; Rome, Italy; and Barcelona, Spain*

Received: 14 December 2021 | Accepted: 21 February 2022

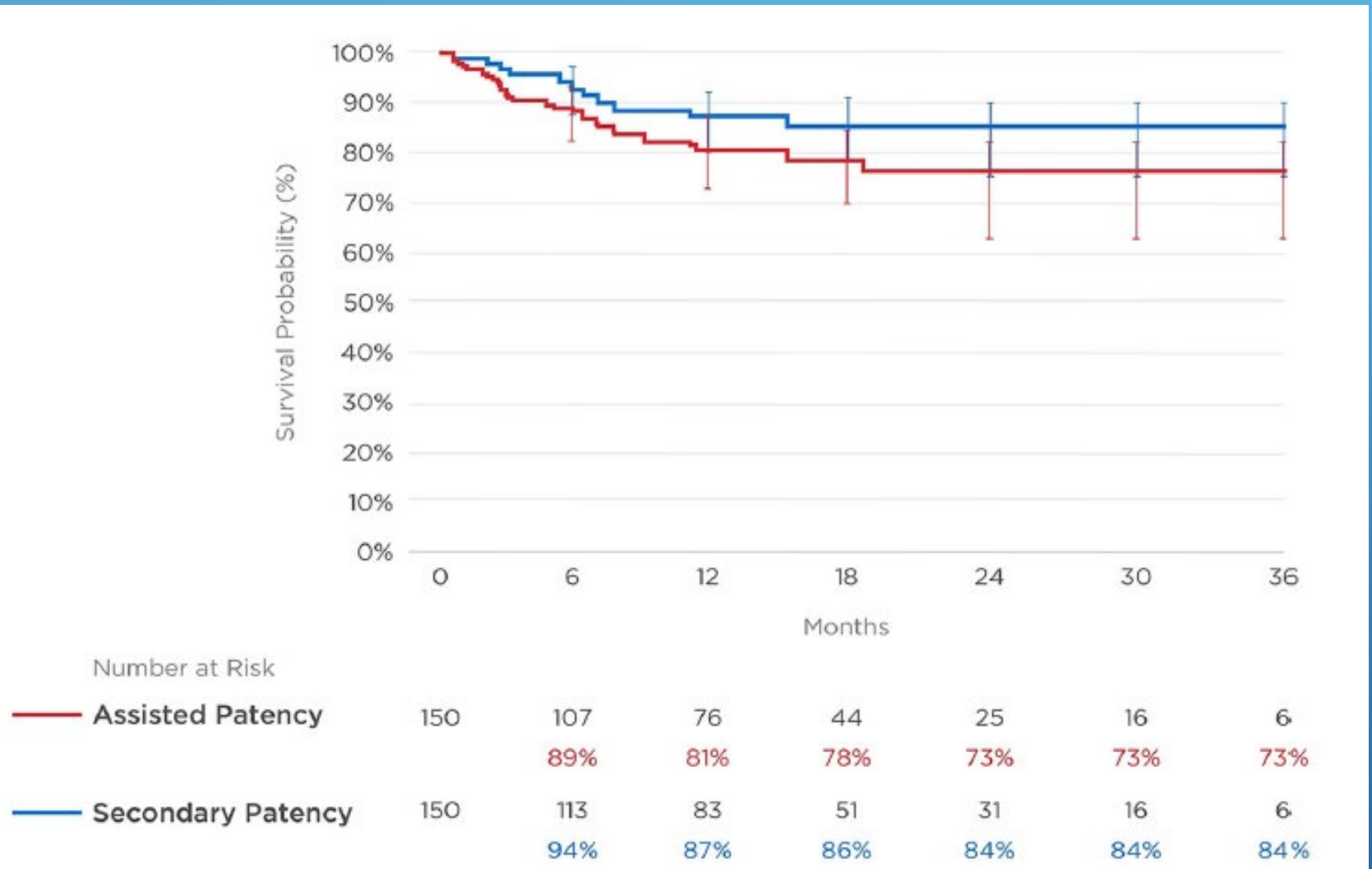
DOI: 10.1111/sdi.13065

Seminars in Dialysis WILEY

ORIGINAL ARTICLE

Achieving high maturation and cannulation rates of radial-cephalic arteriovenous fistulas with VasQ™ device

Robert Shahverdyan[1] | Dirk M. Hentschel[2]



Maturation (Qa > 500 ml/min, vein diameter ≥5 mm)	95%	142/150
Unassisted maturation	89%	133/150
Unassisted maturation within 4 weeks	86%	129/150
Successful cannulations in HD patients	90%	109/121[a]

Intervention		Success rate (postintervention patency ≥48 h)
Number of patients free from interventions *n*/*N* (%)	94/150 (63%)	
Time to first intervention to maintain patency, mean ± standard error	183 days ± 23 days	
Interventions per patient-years	102/185 patient-years (0.55)	
Total number of interventions	102	100/102 (98%)
1 intervention/patient	32/150 (21%)	30/32 (94%)
2 or more interventions/patient	24/150 (16%)	24/24 (100%)
Percutaneous angioplasty *n*/*N* (%)	86/102 (84%)	84/86 (98%)
Stent graft	2/86 (2%)	2/2 (100%)
Bare-metal stent	1/86 (1%)	1/1 (100%)
Hybrid (open thrombectomy and balloon angioplasty) *n*/*N* (%)	13/102 (13%)	13/13 (100%)
Open thrombectomy and patch angioplasty	3/102 (3%)	3/3 (100%)

A Multi-center Prospective Study to Evaluate the Safety and Effectiveness of the VasQ External Support for Arteriovenous Fistula

Prospective, multi-center, single-arm, open label, enrolling patients referred to surgical creation of new brachiocephalic fistula (144 arruolati)

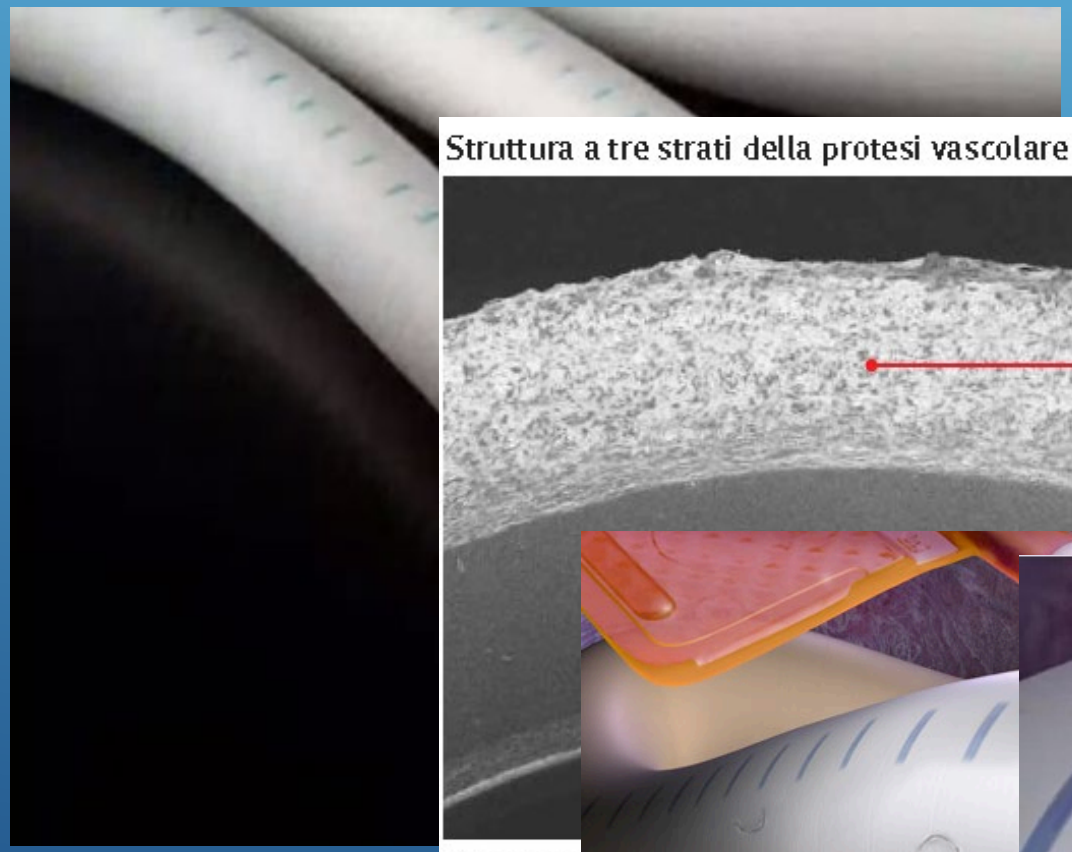
Supplementary study cohort: 15 patients will be prospectively enrolled which are referred to surgical creation of a new forearm arteriovenous fistula

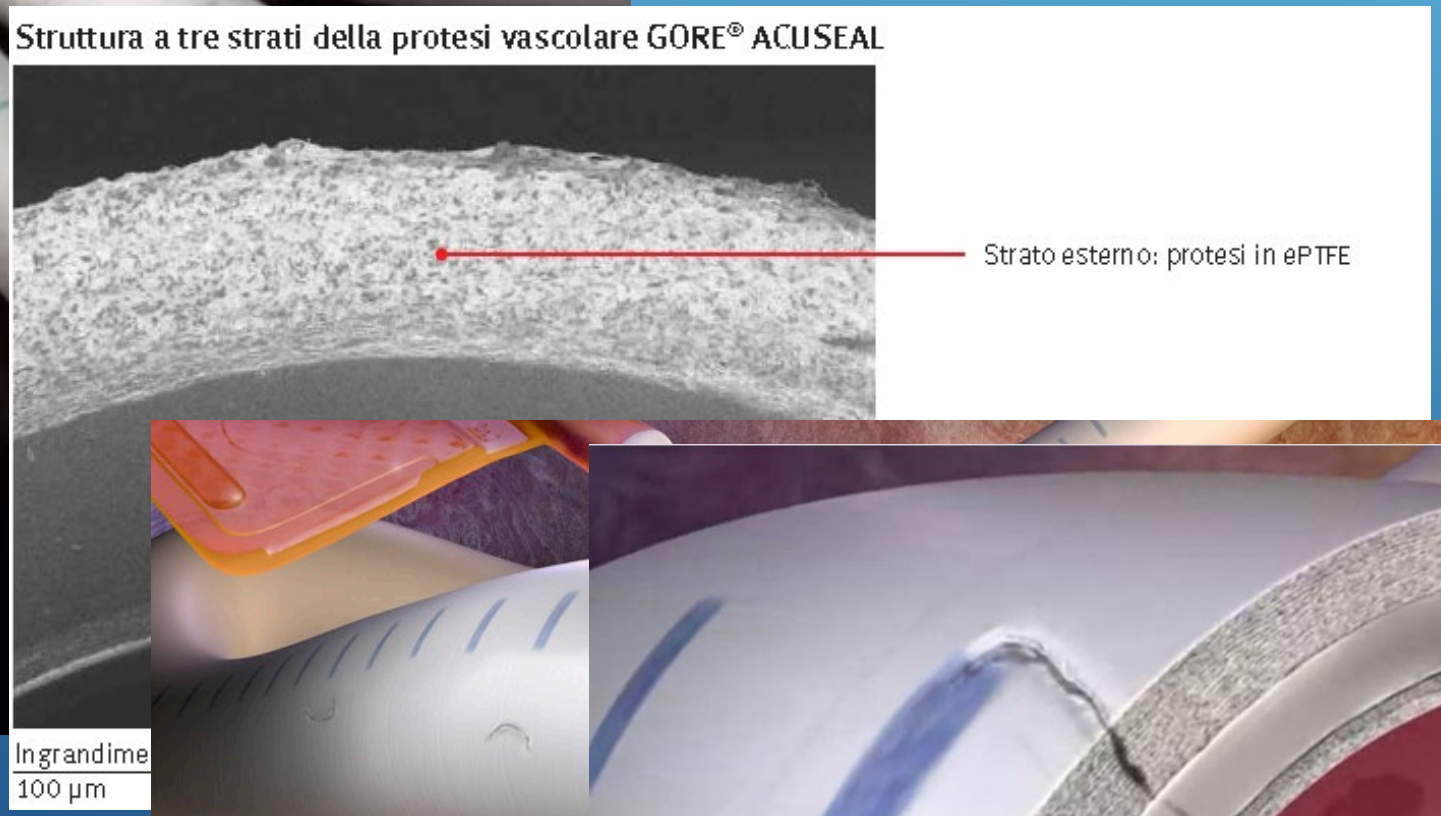
novembre 2017 → ottobre 2022

- FAV endovascolare
- VasQ
- Protesi (early cannulation, biologiche o biosintetiche)
- Stent e palloni medicati
- Hero
- Varie

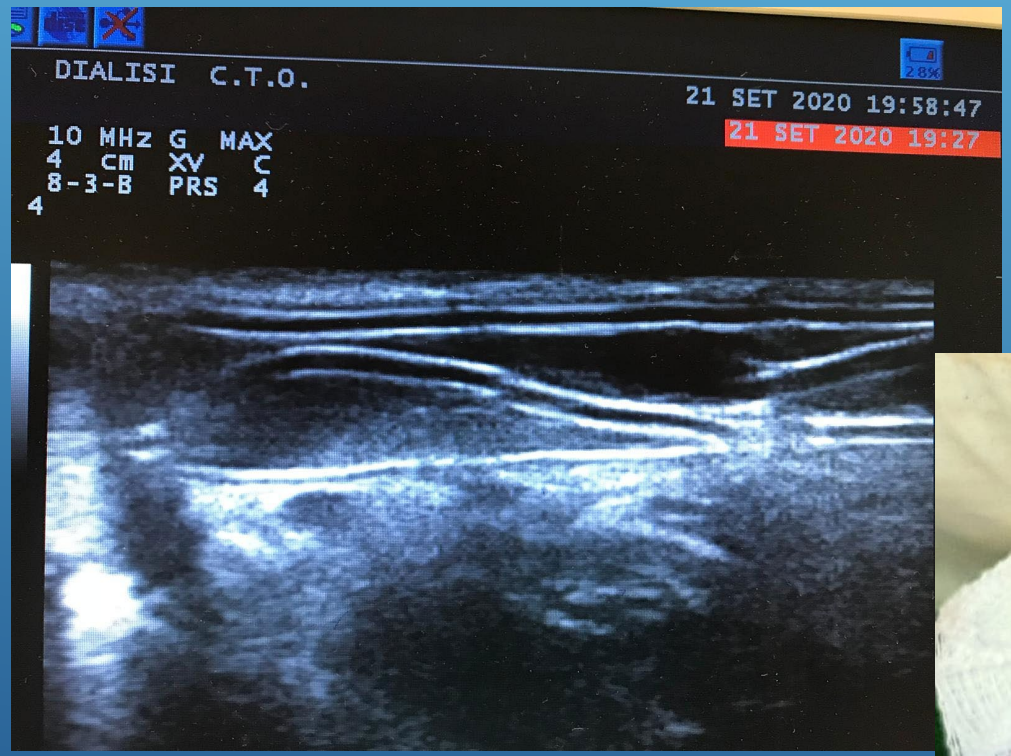
- Protesi (early cannulation, biologiche o biosintetiche)

Gore Acuseal





Gore Acuseal



J Vasc Access. 2021 Sep;22(5):840-844. doi: 10.1177/1129729820933396. Epub 2020 Jun 20.

Delamination of Acuseal early cannulation arteriovenous graft months after implantation

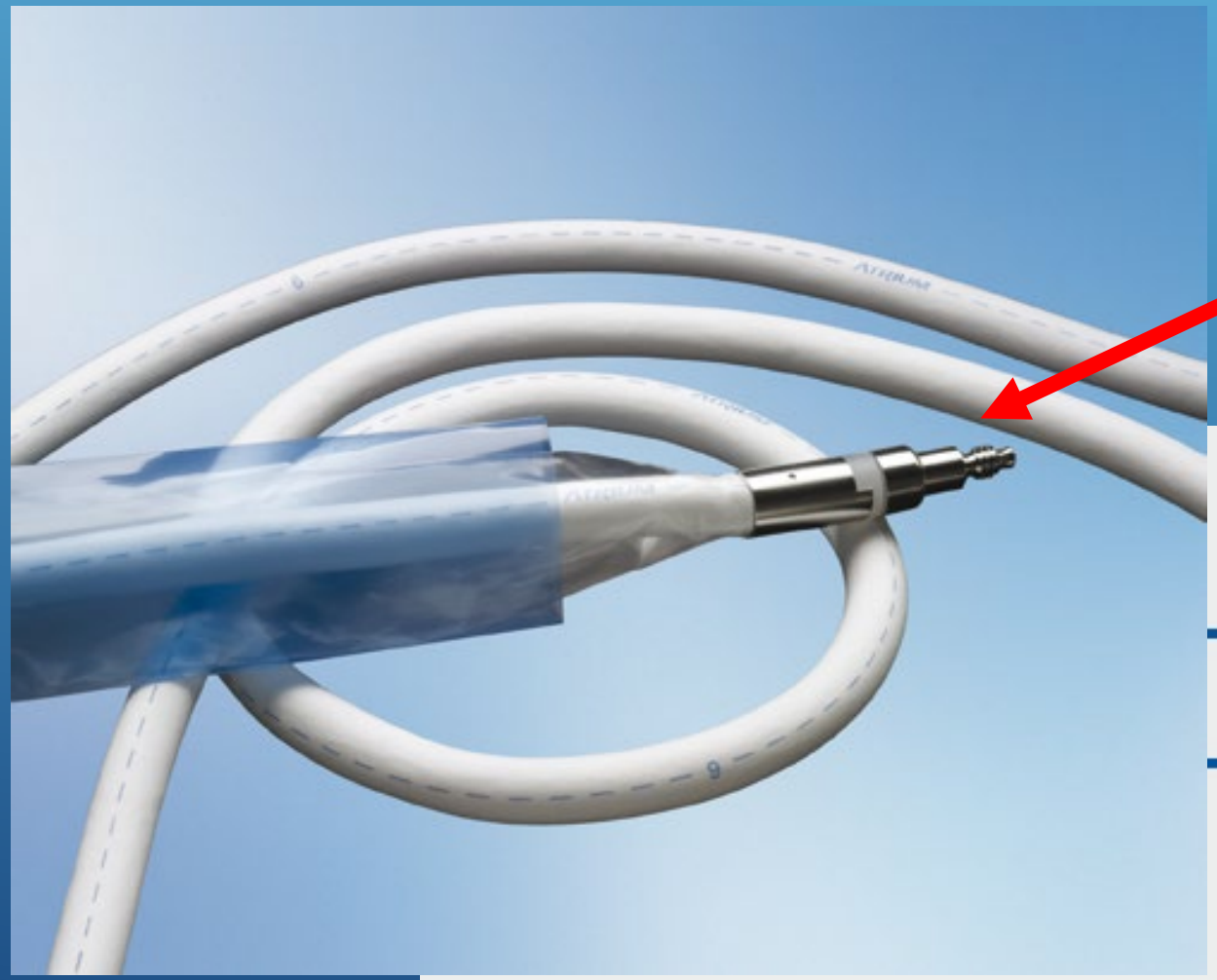
Kotaro Suemitsu [1], Tatsuya Shiraki [2], Masahito Miyamoto [3], Naru Sasagawa [3], Tomohiro Nakamura [4], Masaaki Izumi [1]

6/115 (5.1%) in 21 mesi

Per le prime due settimane:

- Utilizzare aghi 17 G
- Ridurre dose eparina
- Tamponamento per almeno 15 minuti anche se assenza di sanguinamento
- Flusso sangue ridotto (250cc/min)

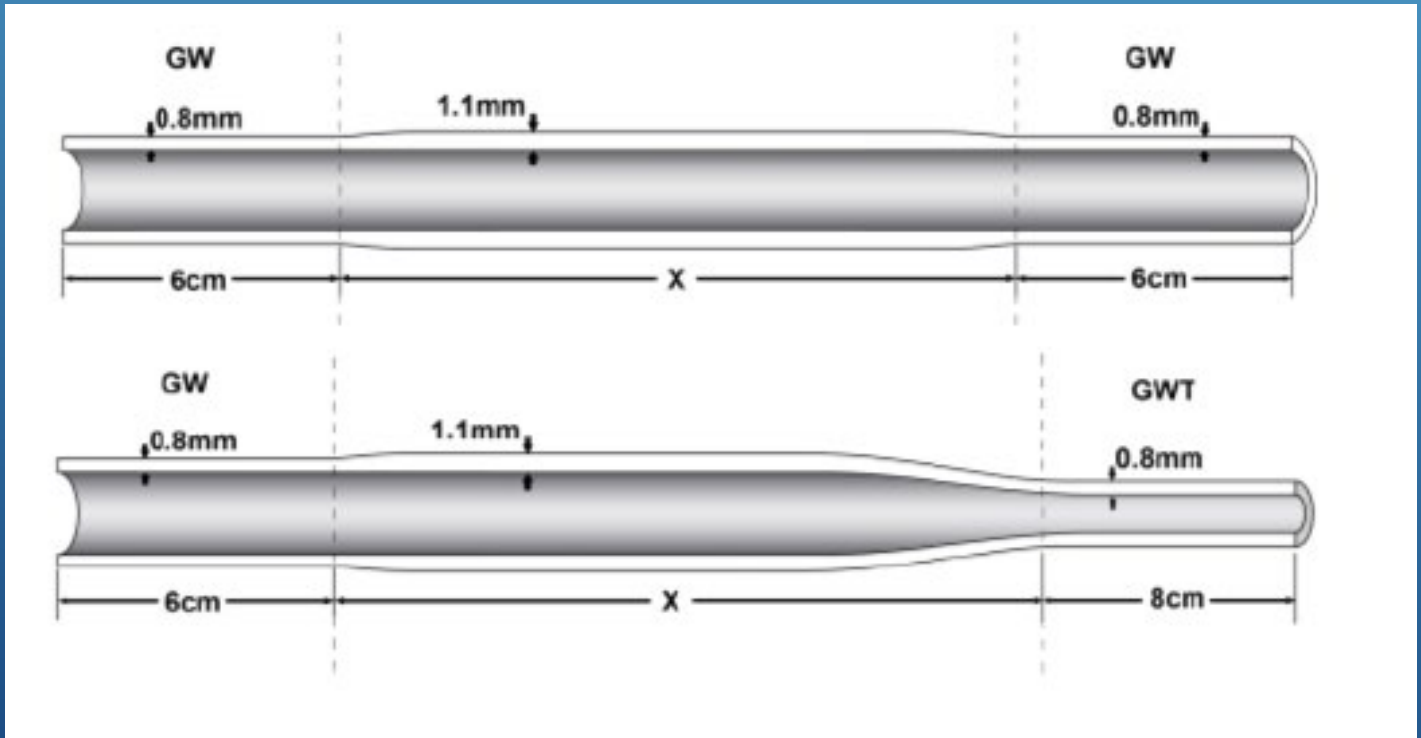
Flixene Atrium Getinge



Sistema Slider GDS

Small pore base layer, inner graft surface porosity of nominal 20um

Flixene Atrium Getinge



Graduated Wall

Graduated Wall Tapered

Early cannulation grafts for haemodialysis: An updated systematic review

Julien Al Shakarchi, Nicholas Inston

The Journal of Vascular Access

J Vasc Access. 2019 Mar;20(2):123-127. doi: 10.1177/1129729818776571. Epub 2018 May 30.

Trade Mark:	Flixene	Avflo	Acuseal	Vectra
1 anno primary patency	43.3%	58.2%	43.6%	63.7%
1 anno secondary patency	73.4%	79.2%	70.5%	85.8%

Protesi biologica

ProCol® Vascular Bioprosthesis

The Solution for AV Access

Artegraft® Collagen Vascular Graft*

For Functional Hemodialysis Access & Lower Extremity Bypass

*Approved for sale in the United States only

Pericardio bovino

Protesi semibiologica

Omniflow II: collagene ovino denaturato con glutaraldeide che incorpra un endoscheletro (rete in poliestere). In alcool etilico 50%

Viene vascolarizzato; necessario tunnellizzatore per evitare trazioni
Non PTA; non clampare ripetutamente; riempire di eparina

Non approvato dalla FDA

www.lemaitre.com

Protesi semibiologica

nephron Clinical Practice

Nephron Clin Pract 2009;113:c76–c80
DOI: 10.1159/000228538

Long-Term Favorable Results by Arteriovenous Graft with Omniflow II Prosthesis for Hemodialysis

Roberto Palumbo[a] Pasquale Niscola[b] Santo Calabria[c] Sabrina Fierimonte[c]
Monica Bevilacqua[a] Laura Scaramucci[b] Barbara Tolu[b] Paolo de Fabritiis[b]
Francesco Bondanini[d]

Outcome indicators	After 6 months	After 12 months	After 18 months	After 24 months
Primary patency	83	80	68	60
Aneurisms	0	0	0	0
Graft infections	0	0	0	0
Stenosis	8	10	12	12
Need for surgical reintervention	8	10	14	14
Secondary patency	92	83	78	75

38 impianti

Protesi semibiologica

Use of Biosynthetic Grafts (Omniflow II) for High Infection Risk Haemodialysis Vascular Access

Julien Al Shakarchi, Damian McGrogan, Philip J. Yates, Nicholas Inston

First Published April 9, 2015 | Research Article
https://doi.org/10.5301/jva.5000462
The Journal of Vascular Access

236 impianti in 4 studi

Primary patency a 12 mesi: 60.1%
Secondary patency a 12 mesi: 82.1%

Aneurysmal rate: 0-6.8%

Protesi a progettazione bioingegneristica

Obiettivi rispetto a protesi sintetiche

Più durature
Minor rischio infettivo
Non formazione di aneurismi
Non formazione di stenosi
Non immunizzanti

HUMACYTE®

Manufacturing Steps for Tissue Engineered Vessels
1
Cell type
Punch biopsy
Cells grown/ expanded under GMP conditions
Universal donor
2
Scaffold
Cells seeded onto synthetic or biologic scaffold
Vessel shaped mold or mandrel
3
Bio-reactor
Nutrients pulsating flow
Sampling port
Growth in standard conditions over weeks
Decellularization
4
Treatment with DNase + mild detergent
5
Final product: Decellularized construct for implantation

HUMACYTE®

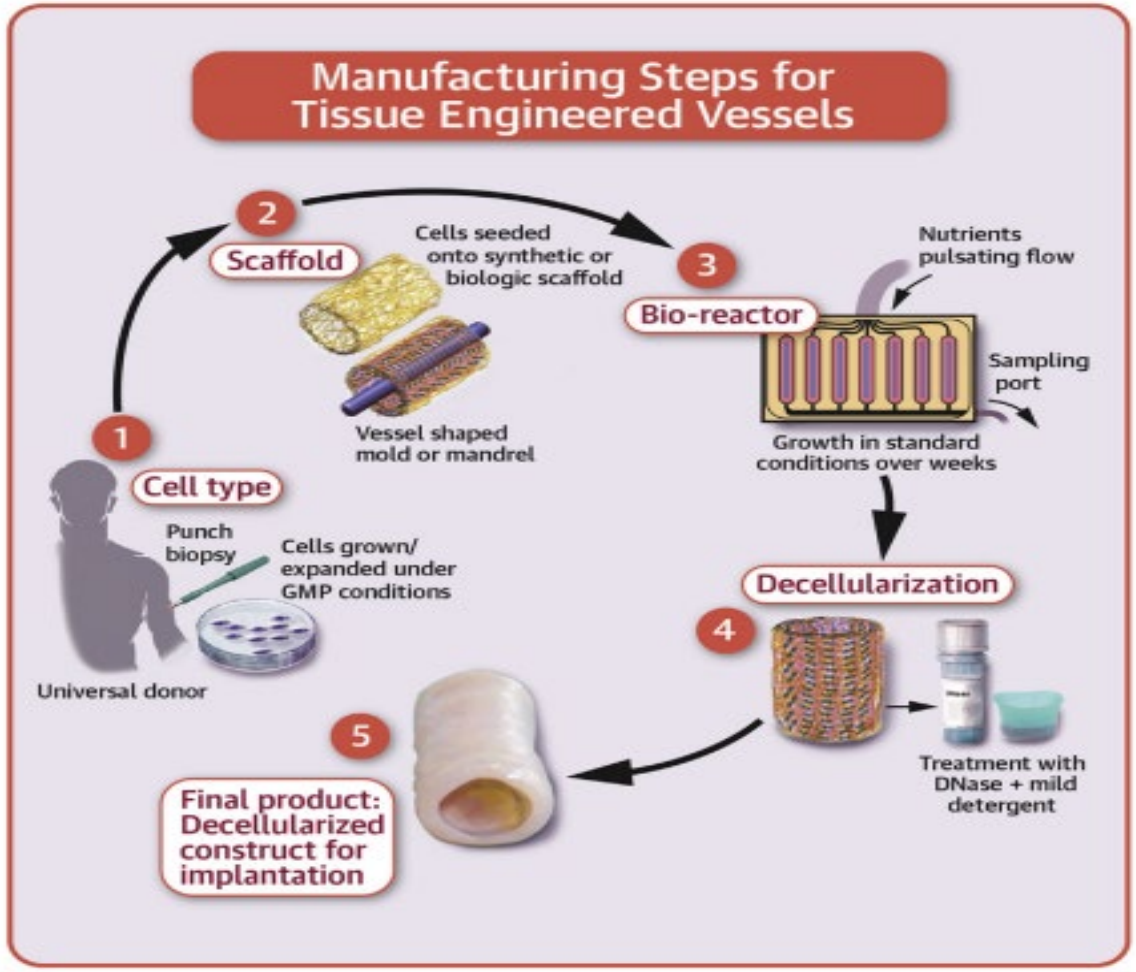
HAV: Human Acellular Vessel

coltura cellulare di donatore deceduto (cell muscolari lisce vasali)

semina in bioreattori su «scaffold» biodegradabili

flusso pulsatile del medium di nutrimento → orientamento fibre collagene, vtronectina, fibronectina

dopo 8 settimane decellularizzazione



HUMACYTE®

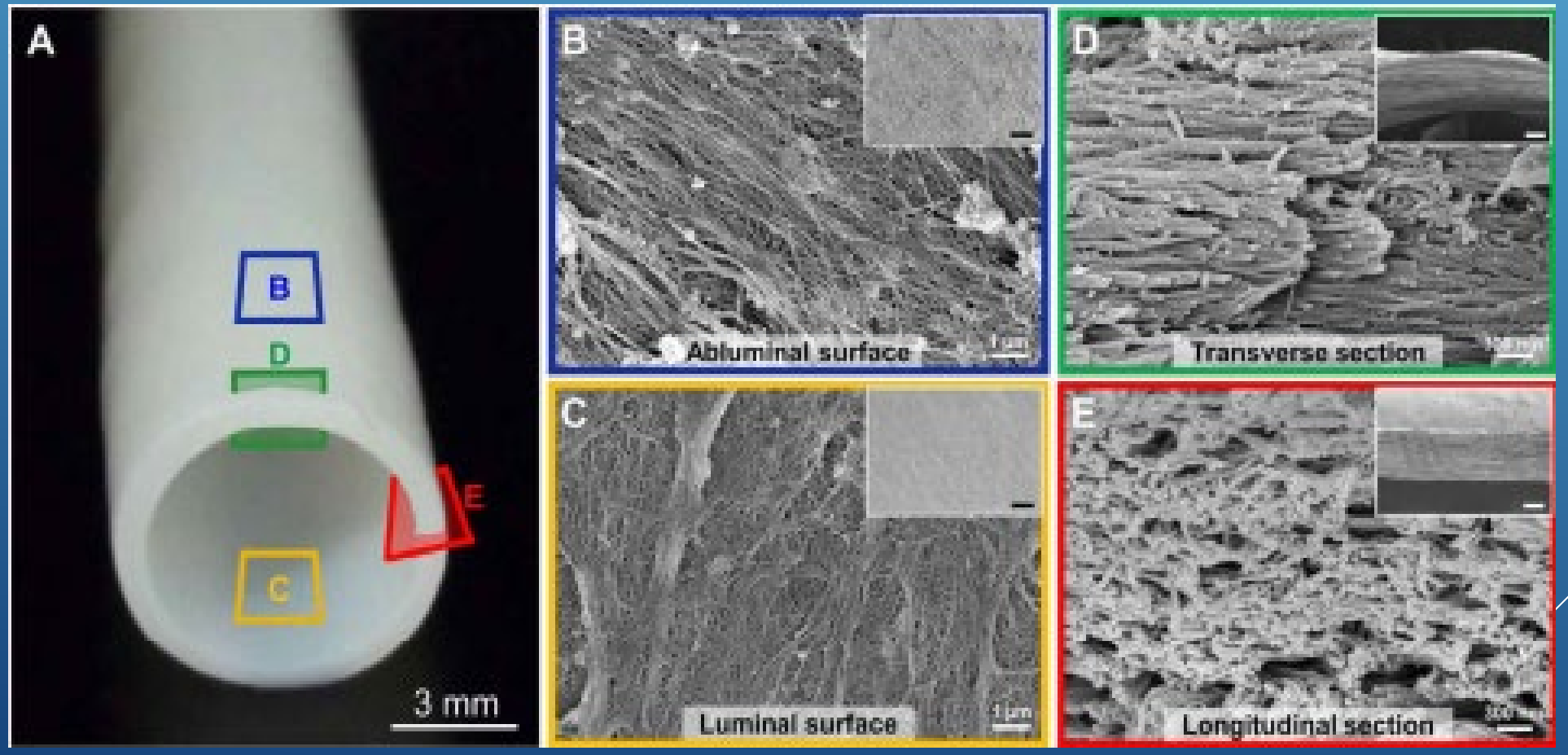
SCIENCE TRANSLATIONAL MEDICINE | RESEARCH ARTICLE

TISSUE ENGINEERING

Kirkton *et al.*, *Sci. Transl. Med.* **11**, eaau6934 (2019) 27 March 2019

Bioengineered human acellular vessels recellularize and evolve into living blood vessels after human implantation

Robert D. Kirkton[1], Maribel Santiago-Maysonet[1], Jeffrey H. Lawson[1,2], William E. Tente[1], Shannon L. M. Dahl[1], Laura E. Niklason[1,3], Heather L. Prichard[1]*



Ante

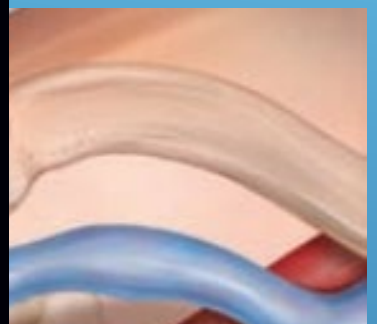
Su graft espiantati dopo uso: tessuto neoavventiziale, neoangiogenesi, presenza di cellule endoteliali dell'ospite (autoriparazione), assenza di cellule del sistema immunitario

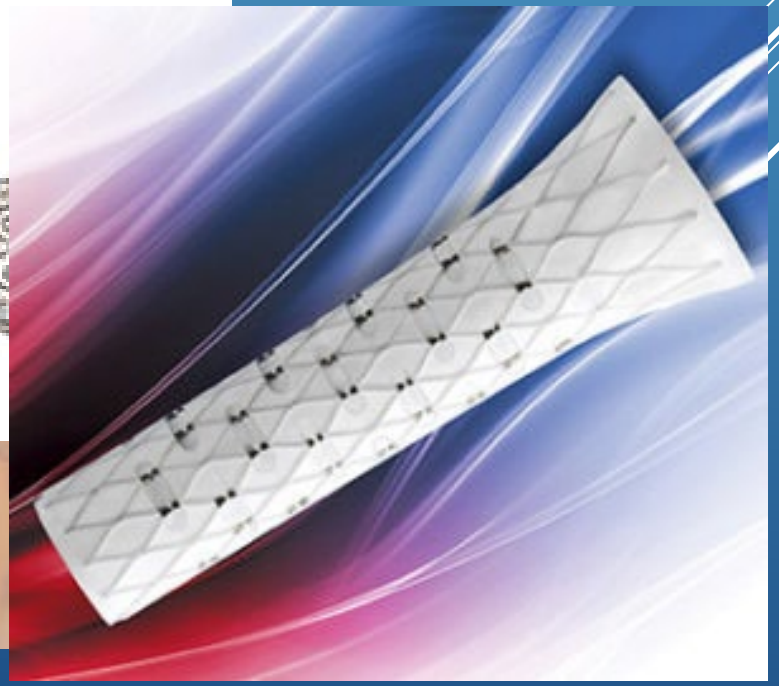
Studi di fase II e fase III (termine nel giugno 2024)

Primary patency a 12 mesi: 28%
Secondary patency a 12 mesi: 89%

- FAV endovascolare
- VasQ
- Protesi (early cannulation, biologiche o biosintetiche)
- Stent e palloni medicati
- Hero
- Varie

- Stent e palloni medicati
- Hero





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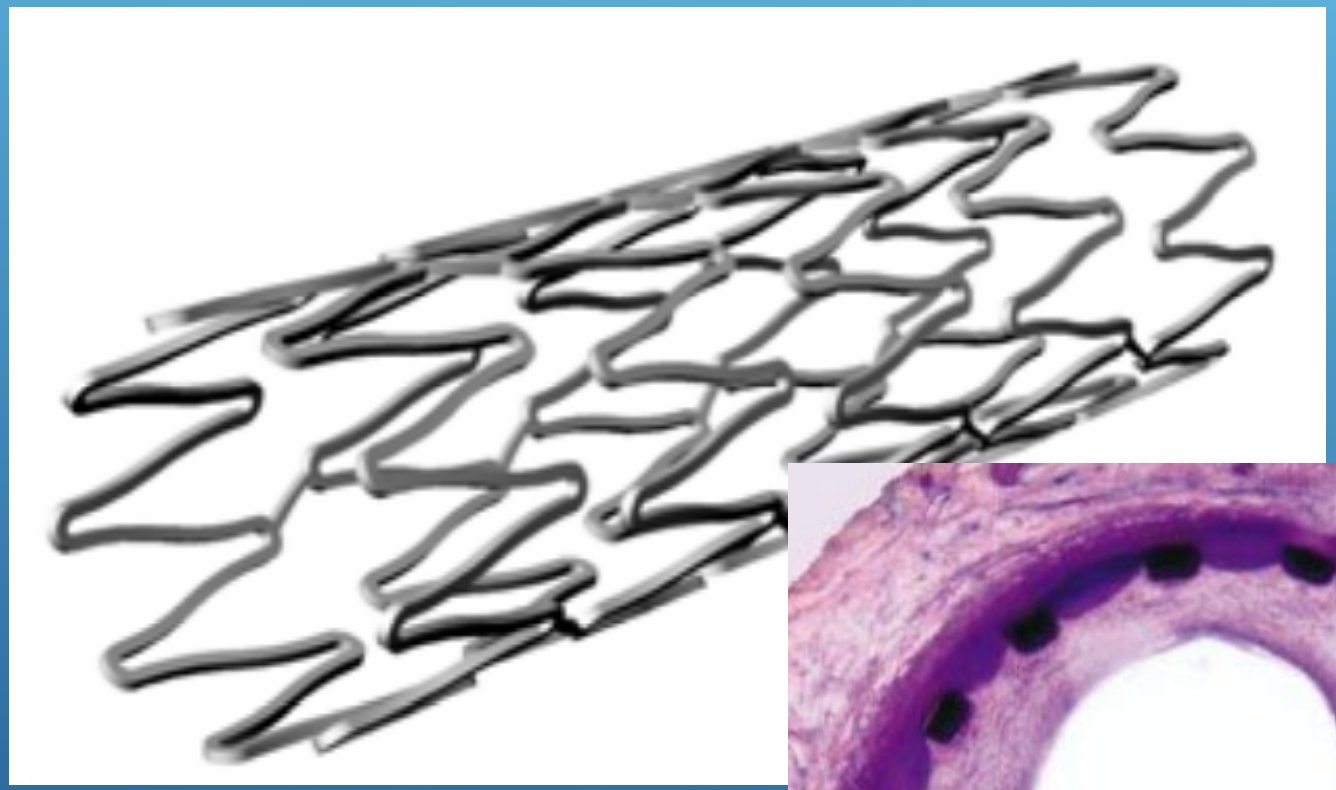
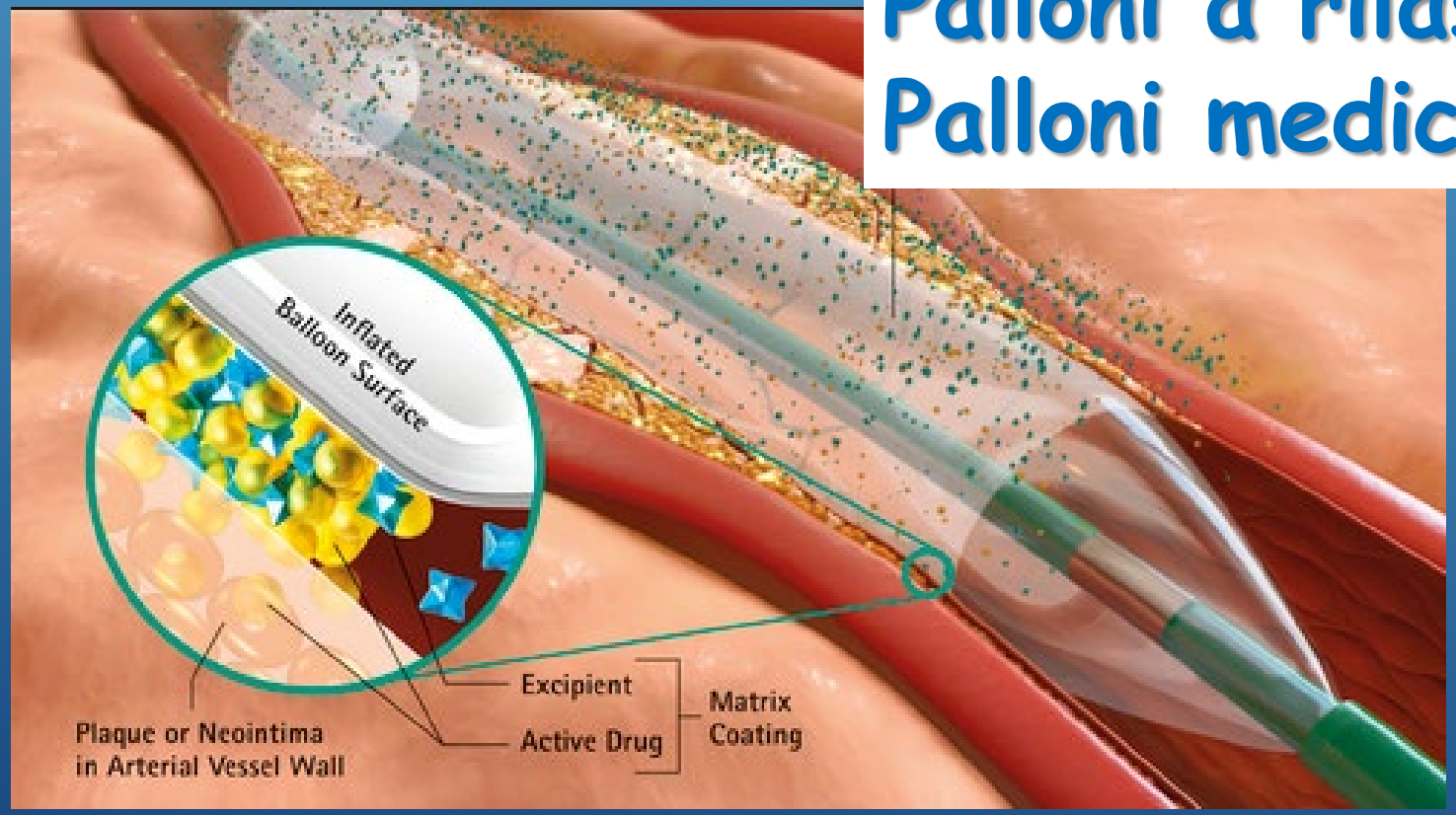
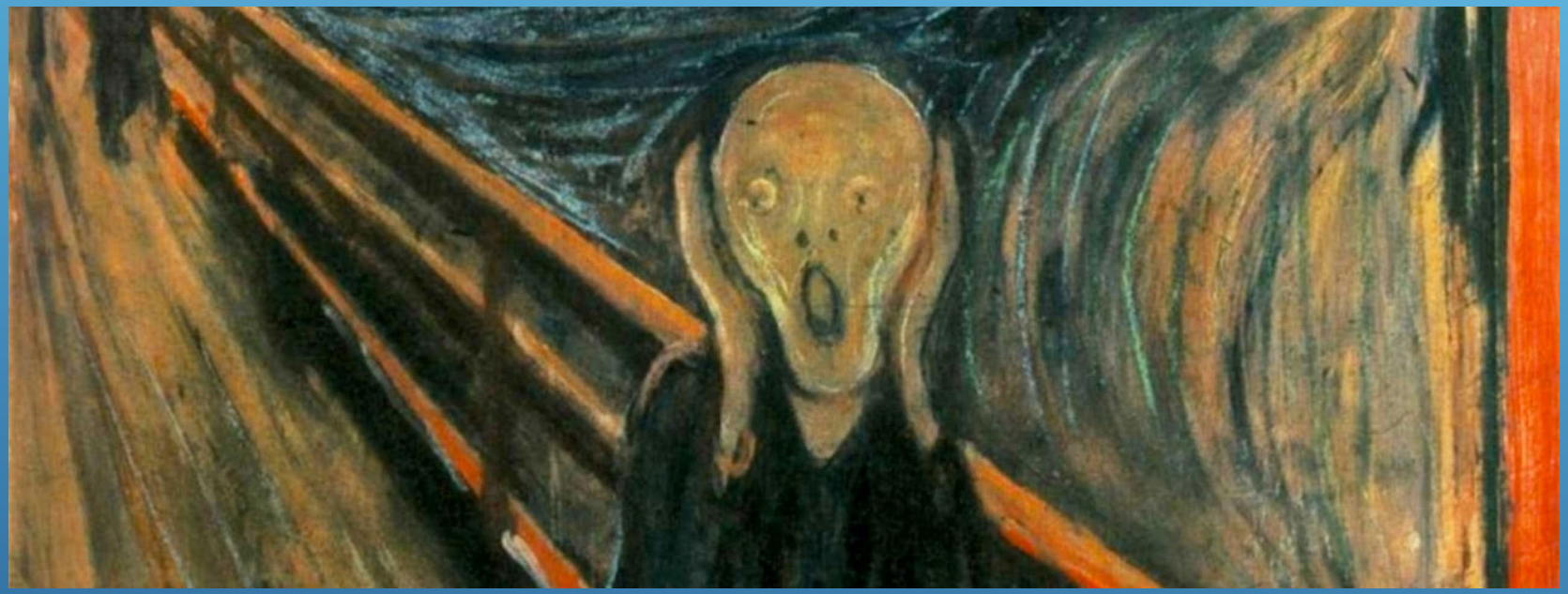
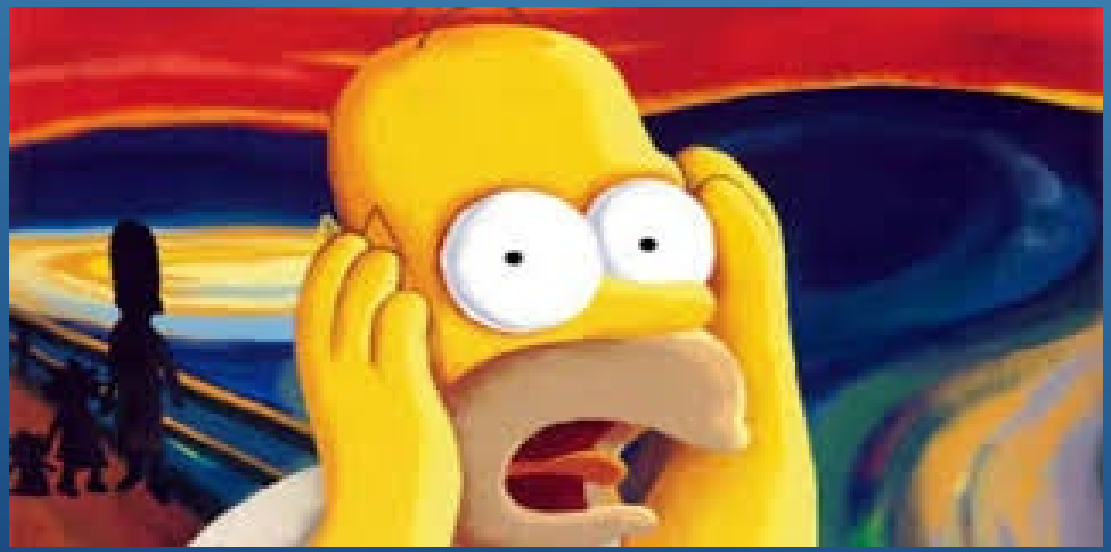


Ante

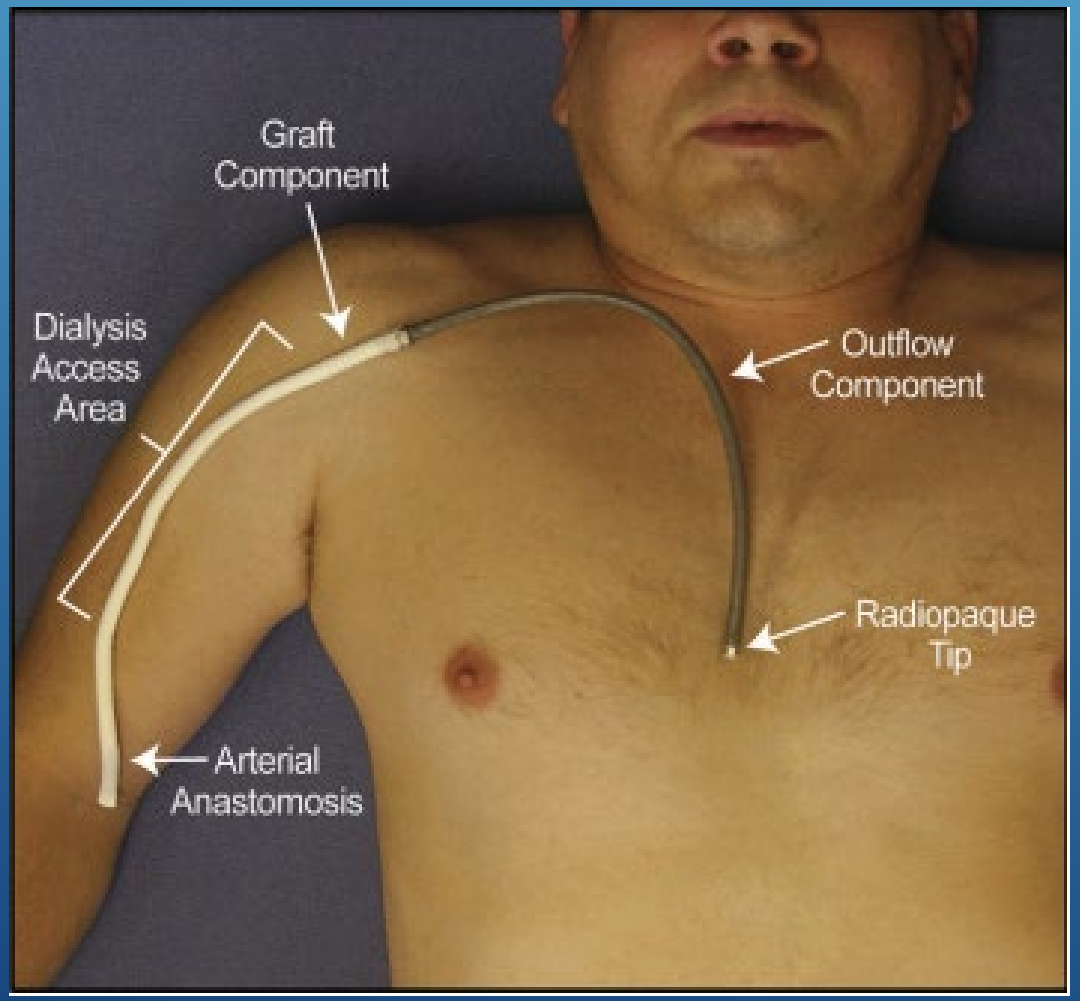
Drug Coated Balloon (DCB)
Drug Eluting Balloon (DEB)
Palloni a rilascio di farmaco
Palloni medicati



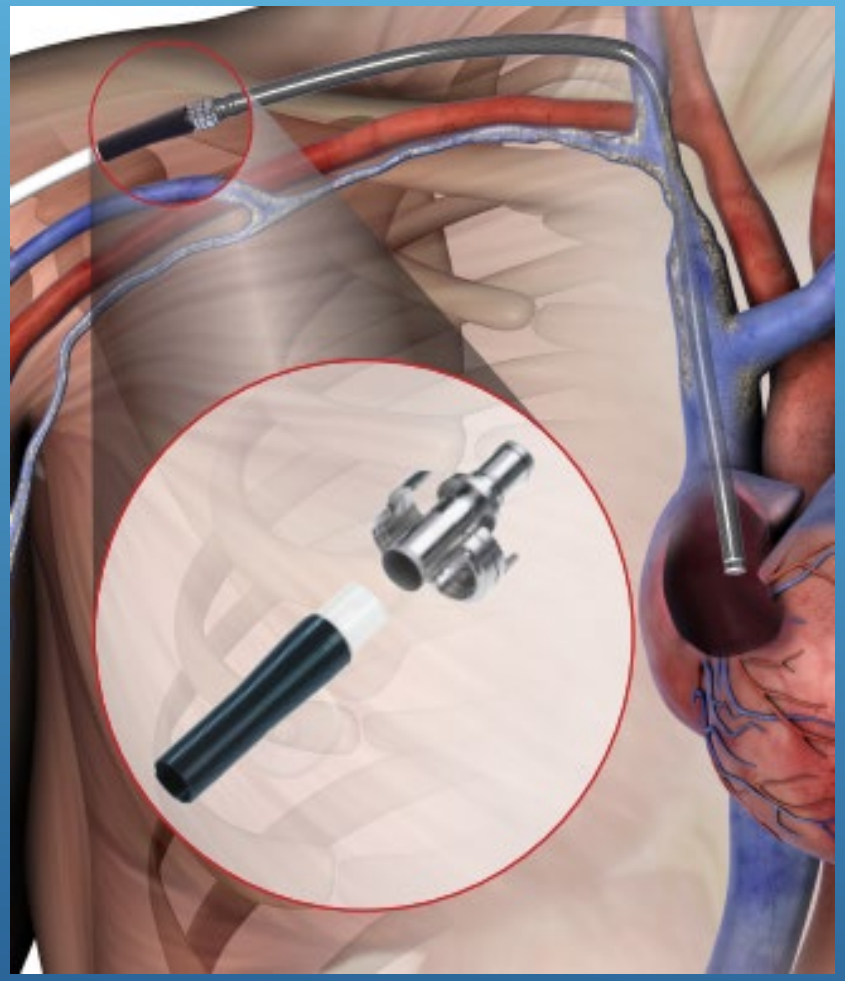


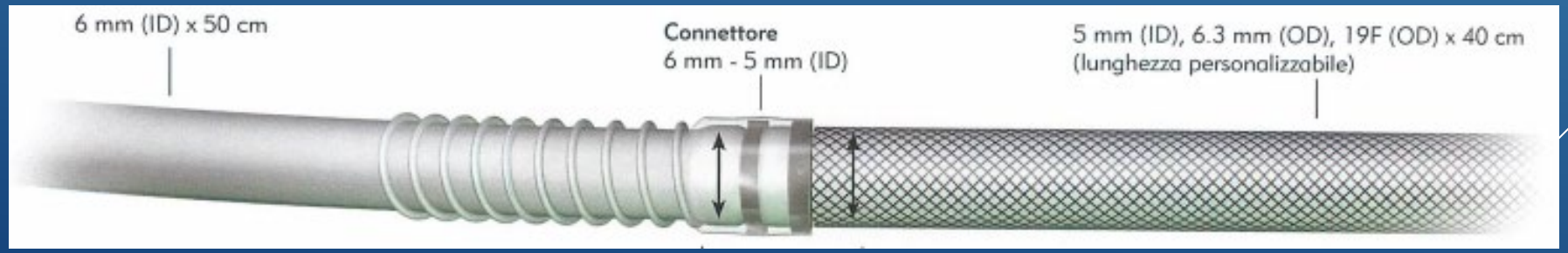


HE.R.O. graft:
Hemodialysis Reliable Outflow



La protesi HeRO bypassa
la stenosi venosa centrale
Riduzione della
dipendenza da
catetere




6 mm (ID) x 50 cm
Connettore
6 mm - 5 mm (ID)
5 mm (ID), 6.3 mm (OD), 19F (OD) x 40 cm
(lunghezza personalizzabile)

HE.R.O. graft:
Hemodialysis Reliable Outflow

Controindicato se diametro arteria brachiale < 3mm

Se PA sistolica < 100mmHg

Se infezione in atto

Se FE < 20%

Il paziente deve avere un'ostruzione di vaso venoso centrale

HE.R.O. graft:
Hemodialysis Reliable Outflow

Diametro interno 5mm

Diametro esterno 6.3mm (19F)

Lungo 40cm

Silicone radiopaco rinforzato da nitinolo

Estremità con marker radiopaco

Contents lists available at SciVerse ScienceDirect

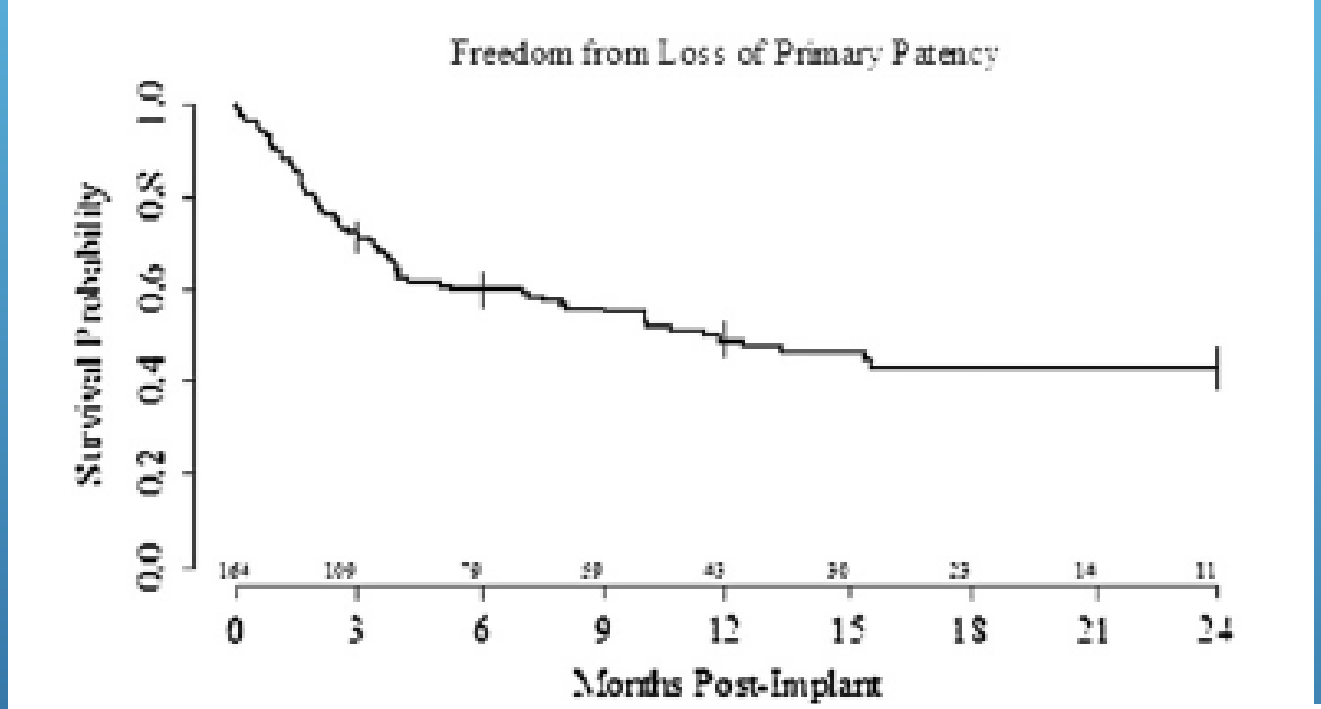
European Journal of Vascular and Endovascular Surgery

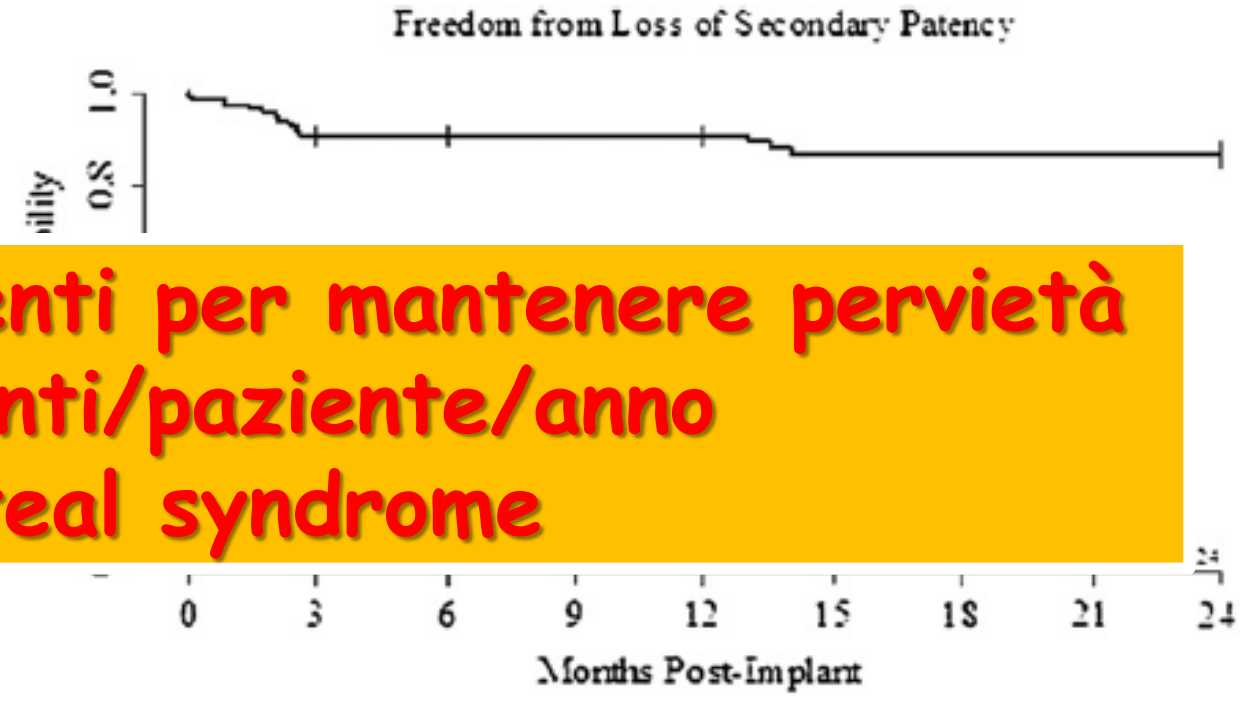
journal homepage: www.ejves.com

Multi-center Experience of 164 Consecutive Hemodialysis Reliable Outflow [HeRO] Graft Implants for Hemodialysis Treatment☆

S.M. Gage[a,*], H.E. Katzman[b], J.R. Ross[c], S.E. Hohmann[d], C.A. Sharpe[e], D.W. Butterly[f], J.H. Lawson[a,g]

Site	Primary patency[a] KM estimate [95% CI]	Secondary patency[b] KM estimate [95% CI]
Bamberg:		
6 Month	51.0% [34.9–65.1]	80.1% [65.1–89.8]
12 Month	40.8% [25.7–55.4]	80.1% [65.1–89.8]
24 Month	34.9% [20.5–49.8]	80.1% [65.1–89.8]
Baylor:		
6 Month	53.3% [31.7–70.9]	87.0% [64.8–95.6]
12 Month	47.4% [25.8–66.3]	87.0% [64.8–95.6]
24 Month	47.4% [25.8–66.3]	87.0% [64.8–95.6]
Duke:		
6 Month	62.0% [47.6–73.4]	98.1% [87.6–99.7]
12 Month	45.1% [29.9–59.2]	98.1% [87.6–99.7]
24 Month	38.7% [21.8–55.3]	85.5% [60.1–93.8]
Miami:		
6 Month	72.7% [54.1–84.8]	93.9%[77.9–98.4]
12 Month	67.9% [47.9–81.6]	93.9%[77.9–98.4]
24 Month	62.7% [41.6–77.9]	93.9%[77.9–98.4]





257 interventi per mantenere pervietà
1.5 interventi/paziente/anno
2 casi di steal syndrome

- FAV endovascolare
- VasQ
- Protesi (early cannulation, biologiche o biosintetiche)
- Stent e palloni medicati
- Hero
- Varie

- Varie

AV Guardian Vascular Access System

Creating the pocket for the device in the subcutaneous space

Device is placed on the deployment tool for insertion into the pocket

Inserting the device in the subcutaneous space using the deployment tool

Adjusting and checking that device in accurately in place using the markings as a guide, before suturing

3 sutures are are thrown across the device in the subcutaneous space, with the aid of the deployment tool.

Device is held in place in the subcutaneous space by the sutures. The sutures will be removed after device anchorage by fibrosis (about 3 weeks)

Incision is closed; implantation of device complete

Device site, after use for 3 months

Titanio
15mm x 5mm x 3 mm
RM compatibile
Completamente impiantabile sottocute

Original research article

JVA | The Journal of Vascular Access

Non-randomized safety and performance evaluation of the av-Guardian vascular access system

The Journal of Vascular Access
1–8
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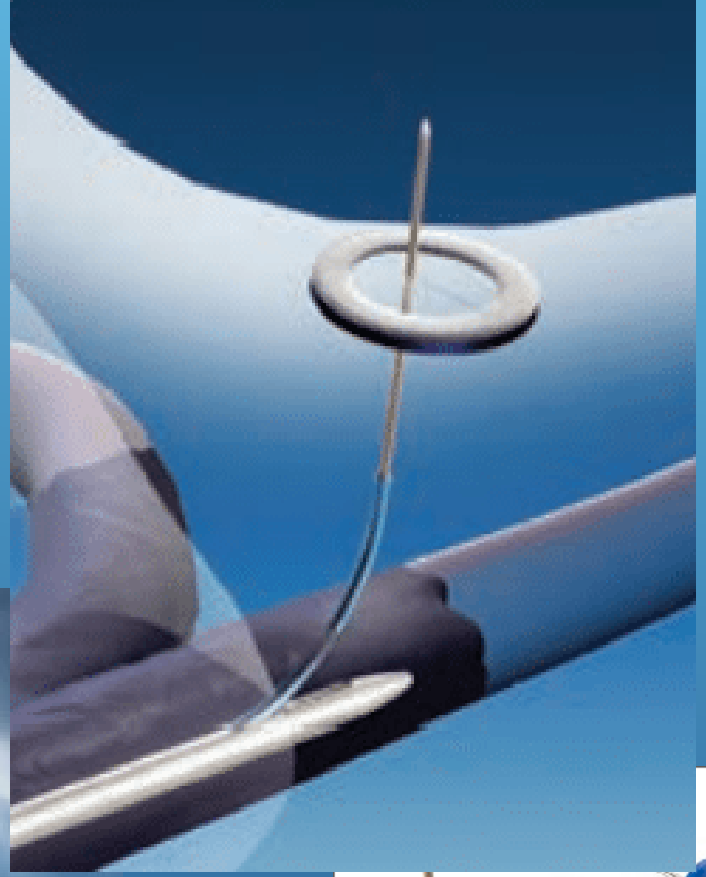
Chieh Suai Tan[1], Seck Guan Tan[2], Chi Leung Julian Wong[3], Bernard Wee[4], Weng Kin Wong[5], Edward Tieng Chek Choke[2], Ru Yu Tan[1], Peiyun Liu[1], Shervanthi Homer-Vanniasinkam[6,7,8], Titus Lau[5] and Lina Hui Lin Choong[1]

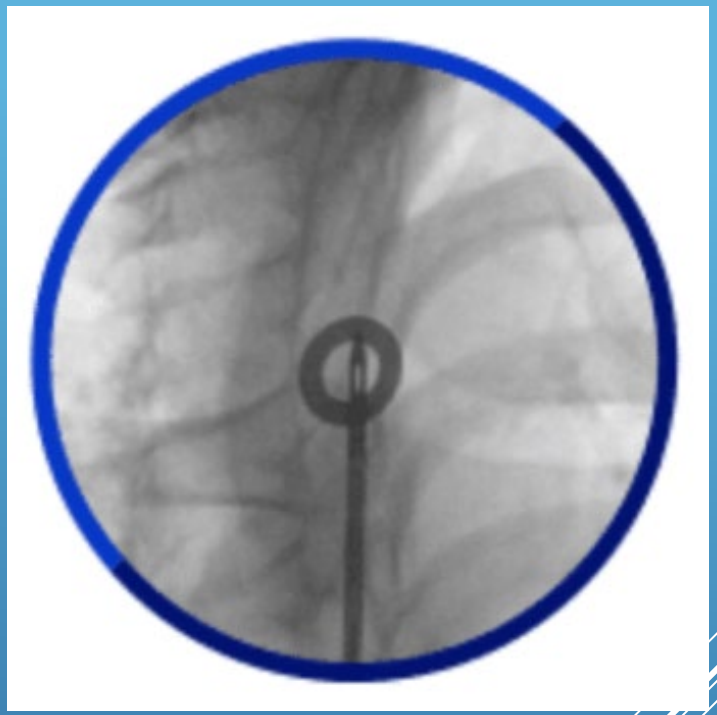
6 casi

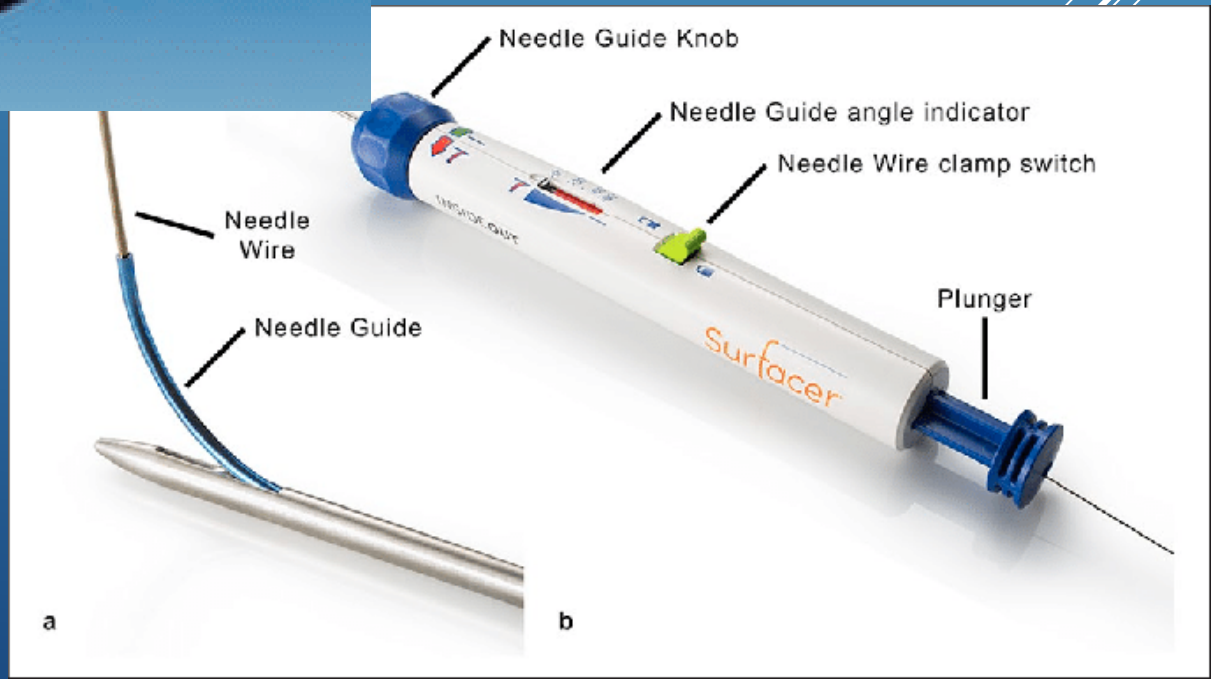
Primary outcomes	
Rate of successful hemodialysis sessions via avGD at each site over 3 months (n = 216)	
Arterial site, number of successful cannulation (%)	212/216 (98.1)
Venous site, number of successful cannulation (%)	204/216 (94.4)

Median number of dialysis sessions to first blunt needle puncture (range)	
Arterial site	15.5 (10–26)
Venous site	18.0 (11–26)

VWING™
Vascular Needle Guide






Needle Guide Knob
Needle Guide angle indicator
Needle Wire clamp switch
Needle Wire
Needle Guide
Plunger
Surfacer
a
b

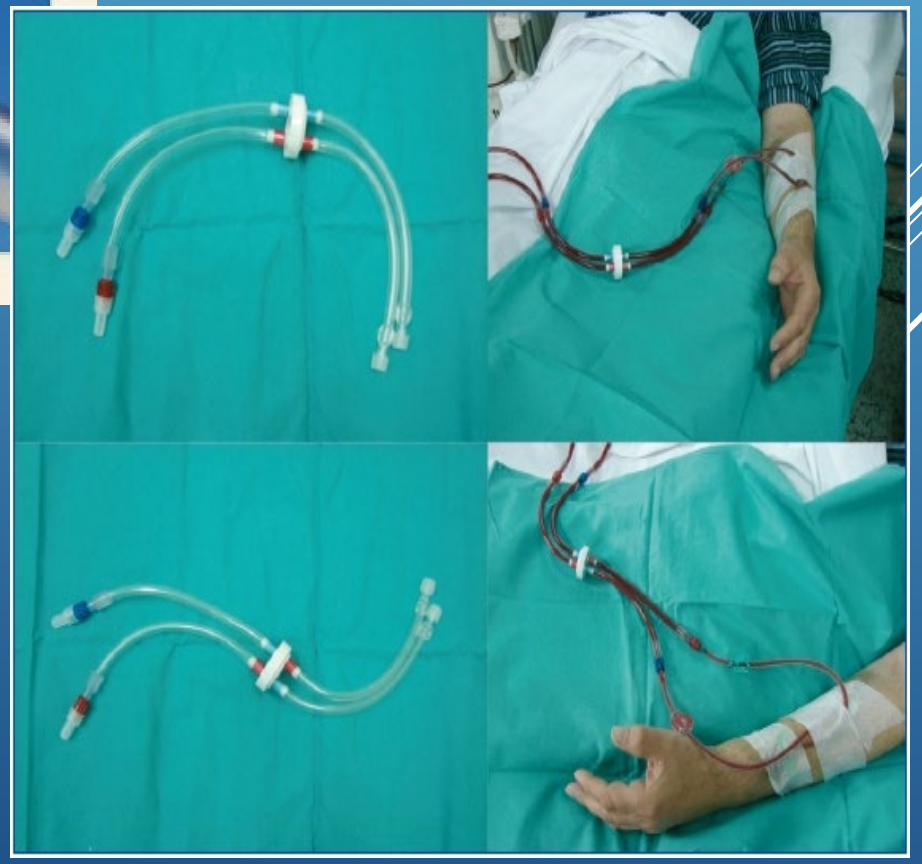
Use of the Surfacer® Inside-Out® Catheter Access System to Obtain Central Venous Access in Dialysis Patients With Thoracic Venous Obstructions: Single-Center Series

Noemi Galas, MD, Robert Shahverdyan, MD

First Published December 14, 2020 | Research
https://doi.org/10.1177/1538574420980604

Vascular and Endovascular Surgery

10 casi dal 2017 al 2020
7 posizionamento CVC
3 posizionamento di HeRO
67.2minuti (49-103)
Pazienti con media di 2.8 precedenti incannulamenti



Grazie per l'attenzione e buon proseguimento