이대서울병원

Upcoming Future..

Myeong Su Kim

Clinical Assistant Professor
Department of Cardiovascular Surgery
Ewha Womans Universiry Seoul Hospital
Ewha Womans University Aorta & Vascular Hospital

EUMC SEOUL

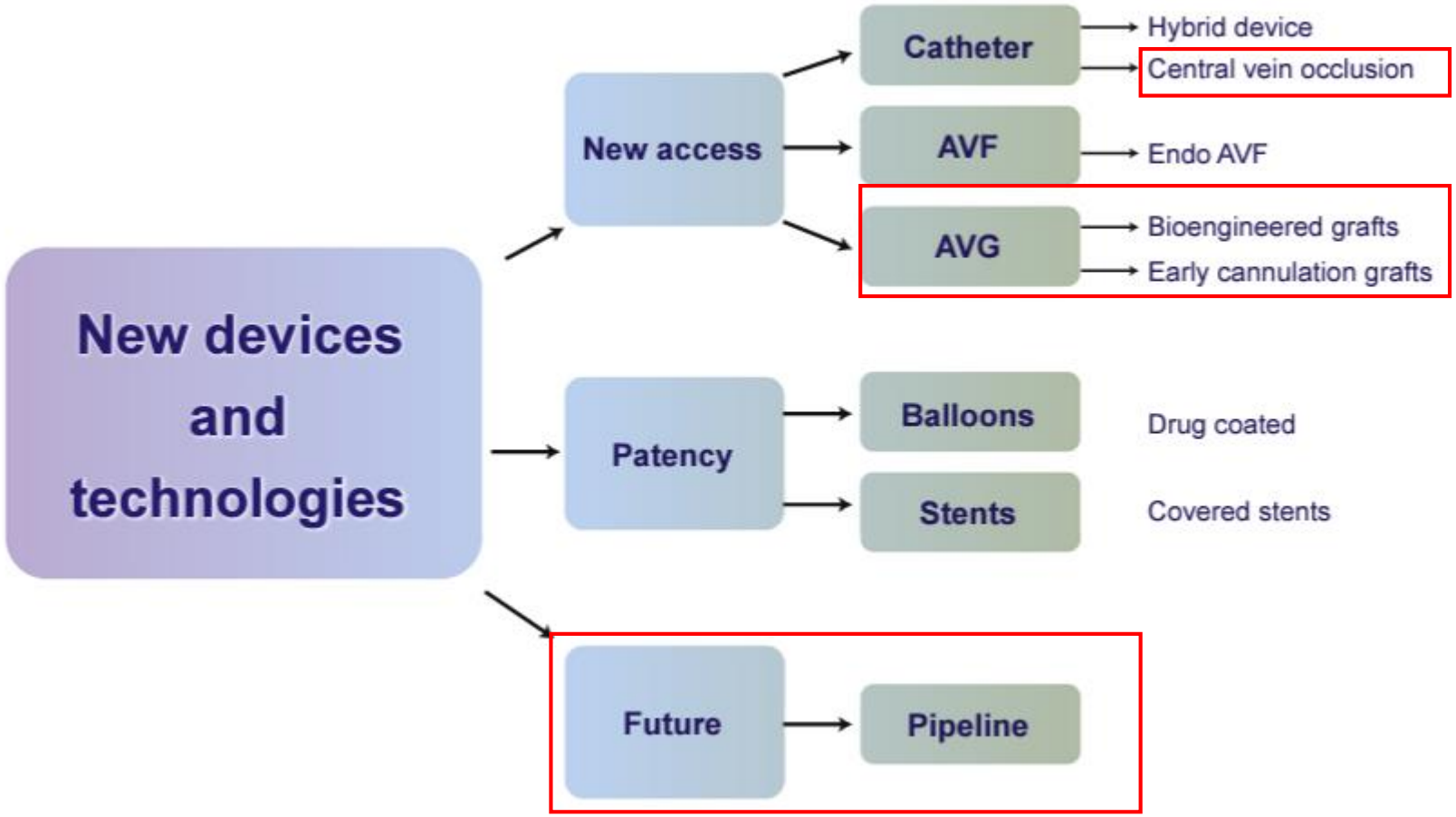
New Devices and New Technologies

AJKD

Review

New Devices and Technologies for Hemodialysis Vascular Access: A Review

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



New Access (Central vein occlusion)

From the Southern Association for Vascular Surgery

The inside-out technique for tunneled dialysis catheter placement with central venous occlusion

Brian M. Freeman, MD, Joseph S. Tingen, MD, David L. Cull, MD, *and* Christopher G. Carsten III, MD, *Greenville, SC*

Fig 1. Superior venacavogram before intervention.

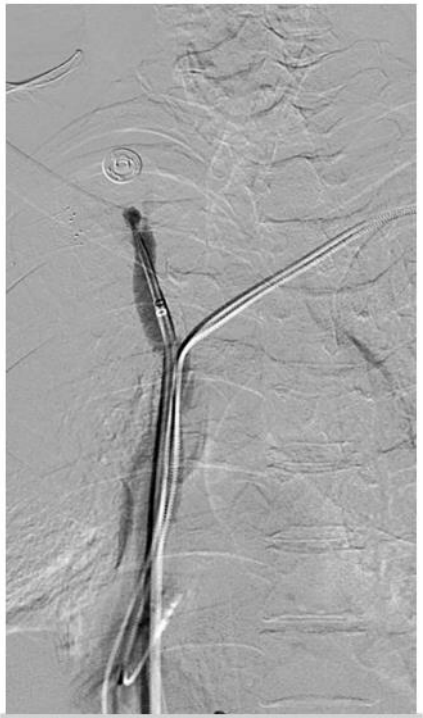


Fig 2. Contrast injection via SL1 catheter.

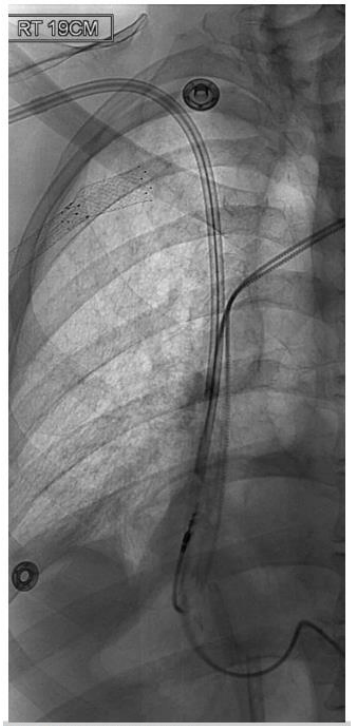


Fig 3. Tunneled catheter in place.

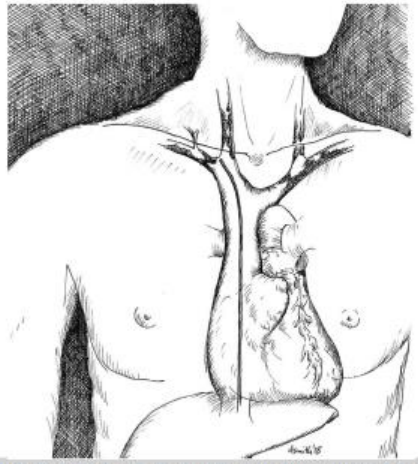
Table I. Patient characteristics (N = 8)

Characteristic	
Age, years, mean ± SD	59.8 ± 14.8
Male sex, No. (%)	3 (37.5)
No. of previous access	11.5 (6-36)
Time on dialysis, months	116 (60-231)

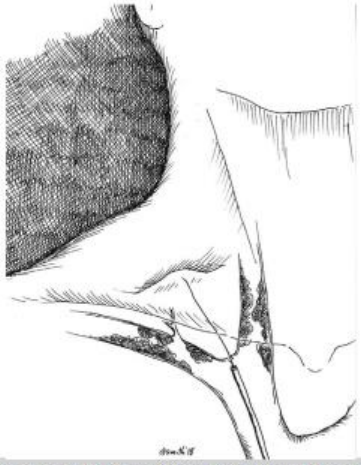
SD, Standard deviation.

Table II. Results

Results	
Technical success, No. (%)	8 (100.0)
Mean patency, days (range)	137 (8-467)
Procedural complications, No. (%)	0 (0.0)
Mean contrast volume, mL	40.9 (20-100)
Mean fluoroscopy time, minutes	15.1 (5.8-56.1)



Supplementary Fig 1. SL1 sheath in position before puncturing the vein with a 0.014 wire base.



Supplementary Fig 2. A 0.014 wire exiting the vein and tenting the skin before skin incision and wire retrieval.

New Access (Early Cannulation Grafts)

Check for updates

JVA
ISSN 1129-7298

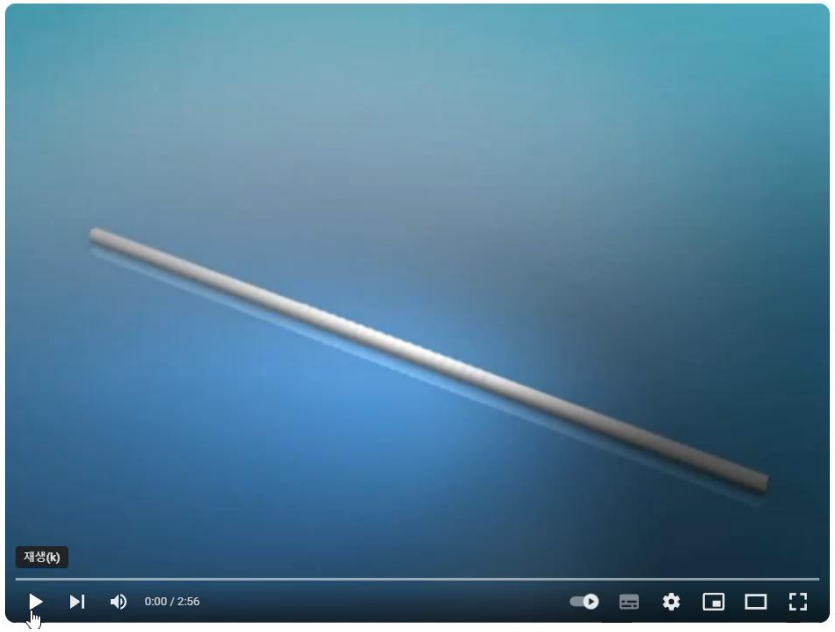
J Vasc Access 2015; 16 (6): 493-497
DOI: 10.5301/jva.5000412

ORIGINAL ARTICLE

Early cannulation grafts for haemodialysis: a systematic review

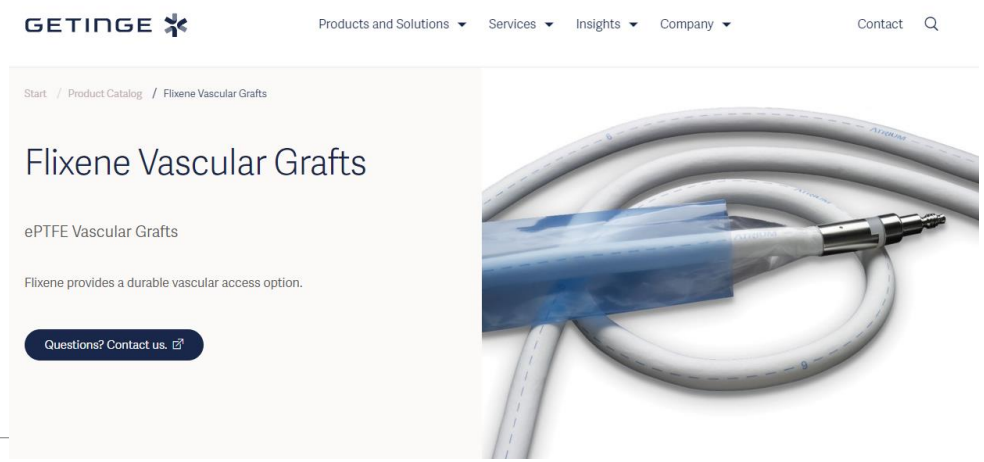
Julien Al Shakarchi[1,2], Graeme Houston[2,3], Nicholas Inston[1,2]

[1] Department of Renal Surgery, University Hospital Birmingham, Birmingham - UK
[2] ReDVA Research Consortium, Dundee - UK
[3] Medical Research Institute, University of Dundee, Dundee - UK



- Flixene [Getinge]
- AVflo [Nicast]
- Rapidax [Terumo Aortic]
- Vectra [Becton, Dickinson and Co.]
- Acuseal [W.L. Gore]

- Early cannulation grafts have a trilayer design incorporating an elastomeric “self-sealing” membrane that allows cannulation as early as 48-72 hours after the implantation.



New Access (Bioengineered grafts)

The International Journal of Artificial Organs
Volume 44, Issue 1, January 2021, Pages 3-16

https://doi.org/10.1177/0391398820922231

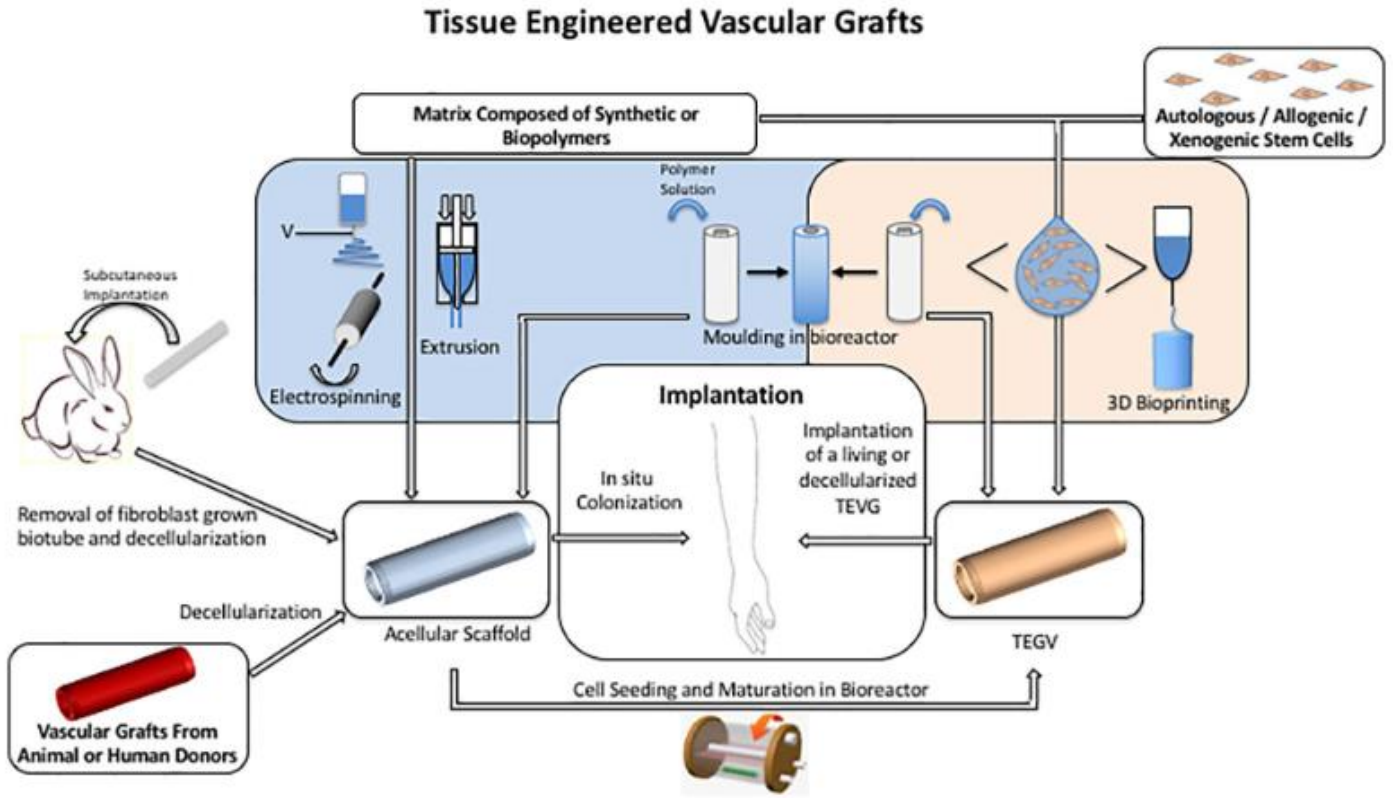
SAGE journals

Review - Apheresis, dialysis and liver support

Arteriovenous access in hemodialysis: A multidisciplinary perspective for future solutions

Bernd Stegmayr [1], Christian Willems[2], Thomas Groth [2,3], Albino Martins[4], Nuno M Neves[4], Khosrow Mottaghy[5], Andrea Remuzzi[6], and Beat Walpoth[7]

- expanded polytetrafluoroethylene (ePTFE)

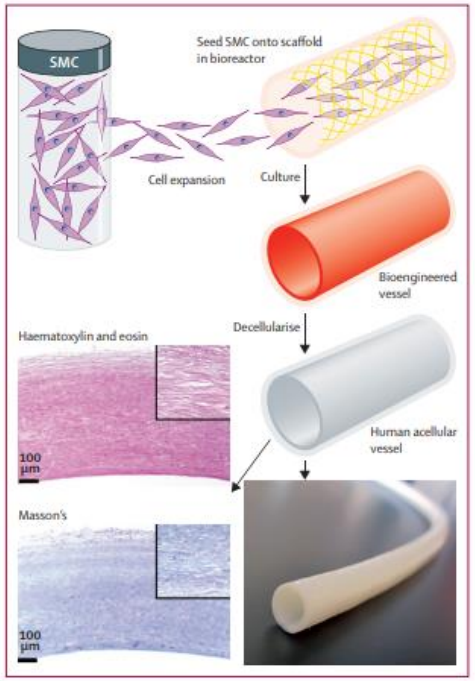


New Access (Bioengineered grafts)

Bioengineered human acellular vessels for dialysis access in patients with end-stage renal disease: two phase 2 single-arm trials

Jeffrey H Lawson, Marc H Glickman, Marek Ilzecki, Tomasz Jakimowicz, Andrzej Jaroszynski, Eric K Peden, Alison J Pilgrim, Heather L Prichard, Malgorzata Guziewicz, Stanisław Przywara, Jacek Szmidt, Jakub Turek, Wojciech Witkiewicz, Norbert Zapotoczny, Tomasz Zubilewicz, Laura E Niklason

Lancet 2016; 387: 2026–34



	Polish cohort (n=40)	US cohort (n=20)
Mean age (years; SD)	59 (10)	61 (8)
Mean duration of follow-up (months; SD)	18·5 (6·4)	10·0 (7·0)
≥6 months	39 (98%)	14 (70%)
≥12 months	36 (90%)	11 (55%)
≥18 months	23 (58%)	4 (20%)
≥24 months	9 (23%)	0
Men	22 (55%)	7 (35%)
Race		
White	40 (100%)	6 (30%)
African American	0	13 (65%)
Other	0	1 (5%)
Comorbidities		
Hypertension	34 (85%)	20 (100%)
Diabetes	15 (38%)	11 (55%)
Cardiovascular disease	13 (33%)	13 (65%)
Cerebrovascular disease	2 (5%)	8 (40%)
Peripheral arterial disease	5 (13%)	7 (35%)
Venous thromboembolic disease	3 (8%)	2 (10%)
Aspirin use	39 (98%)	17 (85%)
Mean number of previous dialysis accesses (SD)	3·6 (2·1)	3·6 (2·2)

Data are n (%) unless stated otherwise.

Table 1: Baseline characteristics

	Polish cohort (n=40)	US cohort (n=20)	
Adverse events	232	178	
Serious adverse events	91	64	
Deaths	1	3	
Withdrawals	1	2	
Transplantations	1	0	
Delayed haemostasis after dialysis	3	8	
Pseudoaneurysms	10 (in seven patients)	4 (in three patients)	
Aneurysm	0	0	
Steal syndrome requiring intervention	1	1	
Human acellular vessel abandonment	6	4	
Patency (%, 95% CI)			
Primary			
6 months	70% (53–82)	46% (23–67)	63%
12 months	33% (20–49)	13% (2–34)	28%
Primary assisted patency			
6 months	78% (61–88)	61% (35–79)	73%
12 months	41% (26–56)	31% (10–55)	38%
Secondary patency			
6 months	100% (100–100)	89% (64–97)	97%
12 months	95% (81–99)	76% (48–90)	89%
Interventions			
Total procedures	125	30	
Thrombectomy	98	18	
Angioplasty	36	19	
Revision	14	2	
Removal or ligation	0	2	
Interventions per patient-year	1·95	1·67	
Infections			
Haematoma or ePTFE infection	1	1	
Human acellular vessel infection	0	1	
Mean flow rate (mL per min; SD)			
Day 1	1544 (890)	705 (493)	
Week 12	1825 (1161)	1439 (861)	
Week 26	1627 (1077)	1387 (754)	
Month 9	1615 (978)	2030 (331)	
Month 12	1478 (950)	..	
Mean diameter (mm; SD)			
Day 15	5·83 (0·36)	6·49 (0·68)	
Week 12	5·84 (0·48)	6·82 (0·84)	
Week 26	5·90 (0·62)	7·99 (1·52)	
Month 9	6·10 (0·80)	8·63 (1·71)	
Month 12	6·41 (1·00)	..	

Data are n, or n (%) unless stated otherwise. ePTFE=expanded polytetrafluoroethylene.

Table 2: Clinical results

Fist Assist

Fist Assist®

The FACT Trial: Use of an Intermittent Pneumatic Compression Device to Promote Pre-Surgery Vein Dilation in Patients with Chronic Renal Failure to Decrease Catheter Complications and Increase AVF Placement

INTRODUCTION

AVF: Poor Results and High Costs

Small Veins: Poor AVF outcomes

Maturation Delays

Vein < 3 mm: **45%** Maturation

Vein > 4 mm: **65%** Maturation

Cephalic Vein >2 mm: **76%** Maturation

Increased Catheters: Complications

METHODS

Multicenter, Single-blinded Control Trial

Study procedures	Visit 1	Visit 2	Visit 3 (1 month)	Visit 4 (3 months)	Surgery	1 month post check	3 month post check	6 month post check
Medical history/ exam	X				X	X		
Informed consent	X							
Demographics	X							
Doppler measurements		X		X				
Device education		X						
Device compliance			X					
Adverse events			X					
Secondary endpoints						X	X	X

4 Hours Daily FOR 90 DAYS

Cephalic vein measurements at baseline and after 90 days

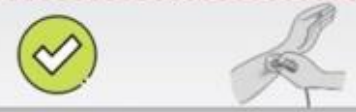
Use intermittent focal pneumatic device to enlarge arm veins

Endpoints: Arm vein dilation and percentage of veins over 2.5 mm with other secondary effective AVF endpoints

2.5 m/m Diameter

CONCLUSIONS

AVF Has Best Patency



AVF: less thrombosis, infection, stenosis, readmissions

Vein diameter helps AVF placement and maturation

Pneumatic compression: focal vein compression

FACT: Presurgery Vein dilation trial for AVF success

2.5 m/m

FACT Investigators:
Dr Mary Hammes, Dr. John Lucas, Dr. Sanjay Desai, Dr. Amit Mitra

FACT is supported by a grant from Fist Assist Devices, LLC from Silicon Valley, CA USA

Fist Assist

Study Design and Patient Cohort

FACT: Fist Assist Clinical Trial

FACT
@ University of Chicago
@Greenwood, MS
@Bangalore, India

FDA Clinical Data Trial – Approved April 2019-July 2021
50 patients, powered study, NSR study Vein dilation, safety, compliance, efficacy – Stage 4 ESRD

Primary Endpoint:
Difference in vein diameter before and after Fist Assist® use. Vein dilation in forearm, upper arm and perforator after 3 months

Secondary Endpoints:
i. ≥2.0 or ≥2.5 mm
ii. ≥3.5 mm
iii. % of successful AVF and % of catheters placed

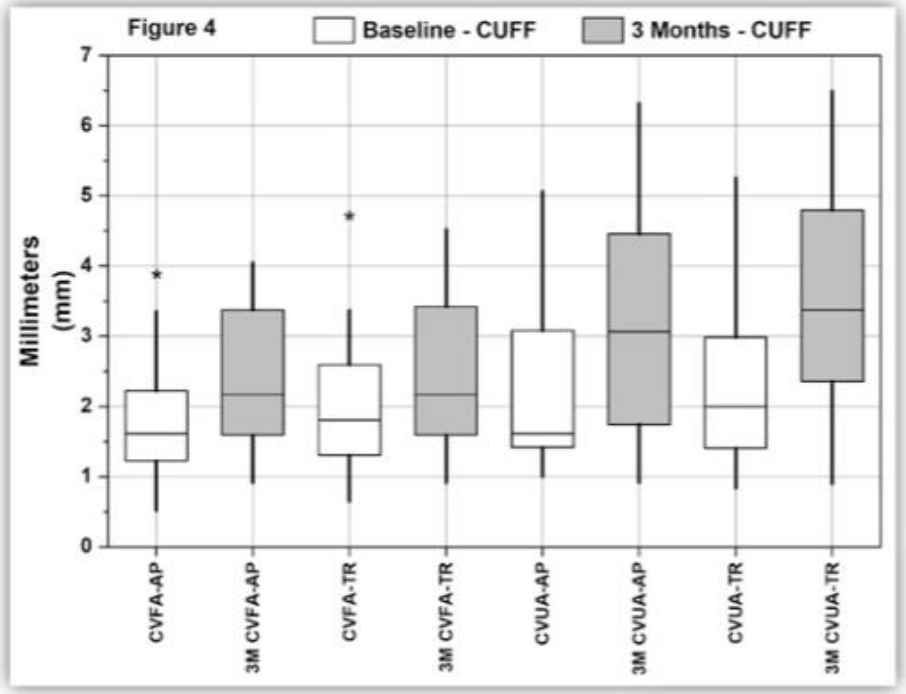
Greenwood Leflore Hospital
JVA The Journal of Vascular Access
AT THE FOREFRONT UChicago Medicine

Fist Assist®

Fist Assist

Key Findings

FACT Results on Cephalic Vein



Fist Assist®

Fist Assist

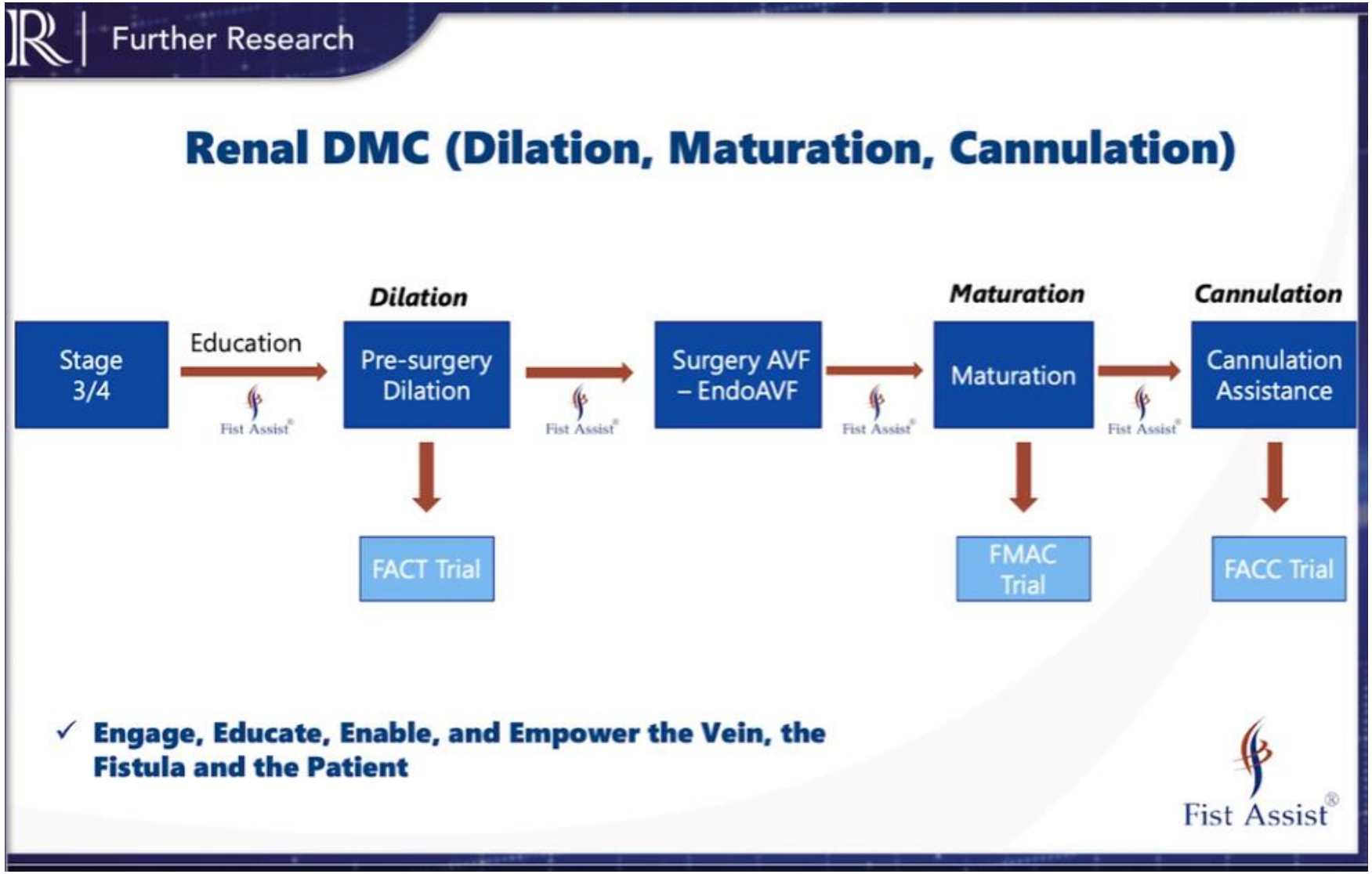
Key Findings

Fist Assist and endoAVF Placement

	Pre-Fist Assist Difference / % cent	Post Fist Assist Measurement	Range
Upper Arm- AP	2.2 mm	3.3 mm	1.1 mm / 50%
Upper Arm - TR	2.2 mm	3.5 mm	1.2 mm / 52%
Forearm - AP	1.8 mm	2.4 mm	0.6 mm / 33%
Forearm - TR	2 mm	2.5 mm	0.5 mm / 25%
Perforator - AP	2.7 mm	3.3 mm	0.6 mm / 26%
Perforator - TR	2.7 mm	3.3 mm	0.6 mm / 22%

- After Fist Assist, surgical fistula placement thresholds were reached of **2.5** mm for forearm and **3.5 mm** for upper arm
- ***46%*** of AP veins initially <2mm dilated to >2mm - *meeting the requirement in IFU for endoAVF*
- ***90%*** of perforator veins reached 3.0 mm or greater with a cuff: Endo AVF

Fist Assist


Further Research
Renal DMC (Dilation, Maturation, Cannulation)
Dilation
Maturation
Cannulation
Stage 3/4
Education
Fist Assist
Pre-surgery Dilation
Fist Assist
Surgery AVF – EndoAVF
Fist Assist
Maturation
Fist Assist
Cannulation Assistance
FACT Trial
FMAC Trial
FACC Trial
✓ Engage, Educate, Enable, and Empower the Vein, the Fistula and the Patient
Fist Assist®

Fist Assist

Nephrol Dial Transplant (2023) 38: 2330–2339
https://doi.org/10.1093/ndt/gfad040
Advance Access publication date 17 February 2023

Systematic review and meta-analysis of preoperative interventions to support the maturation of arteriovenous fistulae in patients with advanced kidney disease

Sivaramakrishnan Ramanarayanan[1,2], Shivani Sharma[2], Oscar Swift[1], Keith R. Laws[2], Hamza Umar[3] and Ken Farrington[1,2]

[1]Department of Renal Medicine, Lister Hospital, East and North Hertfordshire NHS Trust, Stevenage, UK, [2]School of Life and Medical Sciences, University of Hertfordshire, Hatfield, Hertfordshire, UK and [3]College of Medical and Dental Sciences, University of Birmingham, Birmingham, UK

Correspondence to: Sivaramakrishnan Ramanarayanan; E-mail: s.ramanarayanan@nhs.net

Systematic review and meta-analysis of pre-operative interventions to support the maturation of arteriovenous fistulae in patients with advanced kidney disease

Background

We aim to systematically review the evidence on safety and efficacy of various pre-operative interventions that have been tried to improve AVF maturation.

Methods

5 databases:
RCTs, non RCTs, case control and single arm cohort studies

Pre-operative interventions:
Exercise, drug, devices

Outcomes:
AVF maturation, primary failure, change in vessel calibre

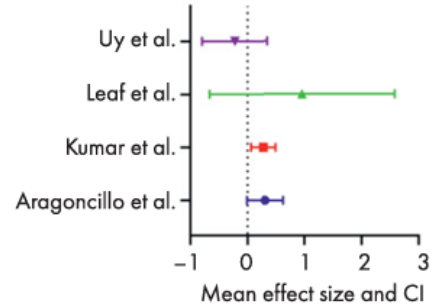
Results

Hand exercise
- 3 RCT, 3 non RCT
- 4 suitable for meta-analysis

Colecalciferol
- 1 RCT

Fist assist device
- 1 non RCT

Meta-analysis of hand exercise



Overall effect of pre-op hand exercise on cephalic vein calibre: 0.24 mm (CI 0.03–0.45 mm), P = 0.02

Conclusion

Hand exercise is effective in improving cephalic vein calibre. Well designed trials with hard outcomes and low risk of bias need to be conducted to assess efficacy of pre-op interventions on arteriovenous fistula maturation.

NEPHROLOGY DIALYSIS TRANSPLANTATION

Ramanarayanan, S., et al. NDT (2023)
@NDTSocial

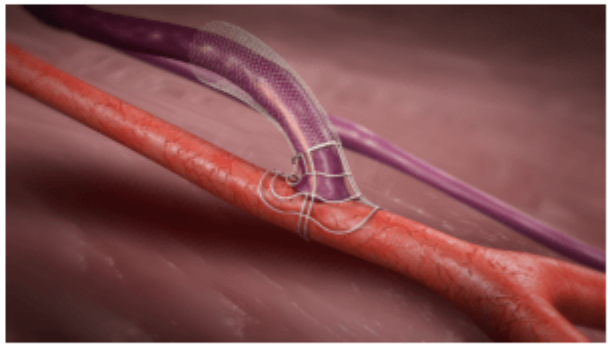
EUMC 이대서울병원 SEOUL

VasQ

VasQ AVF creation device receives FDA clearance

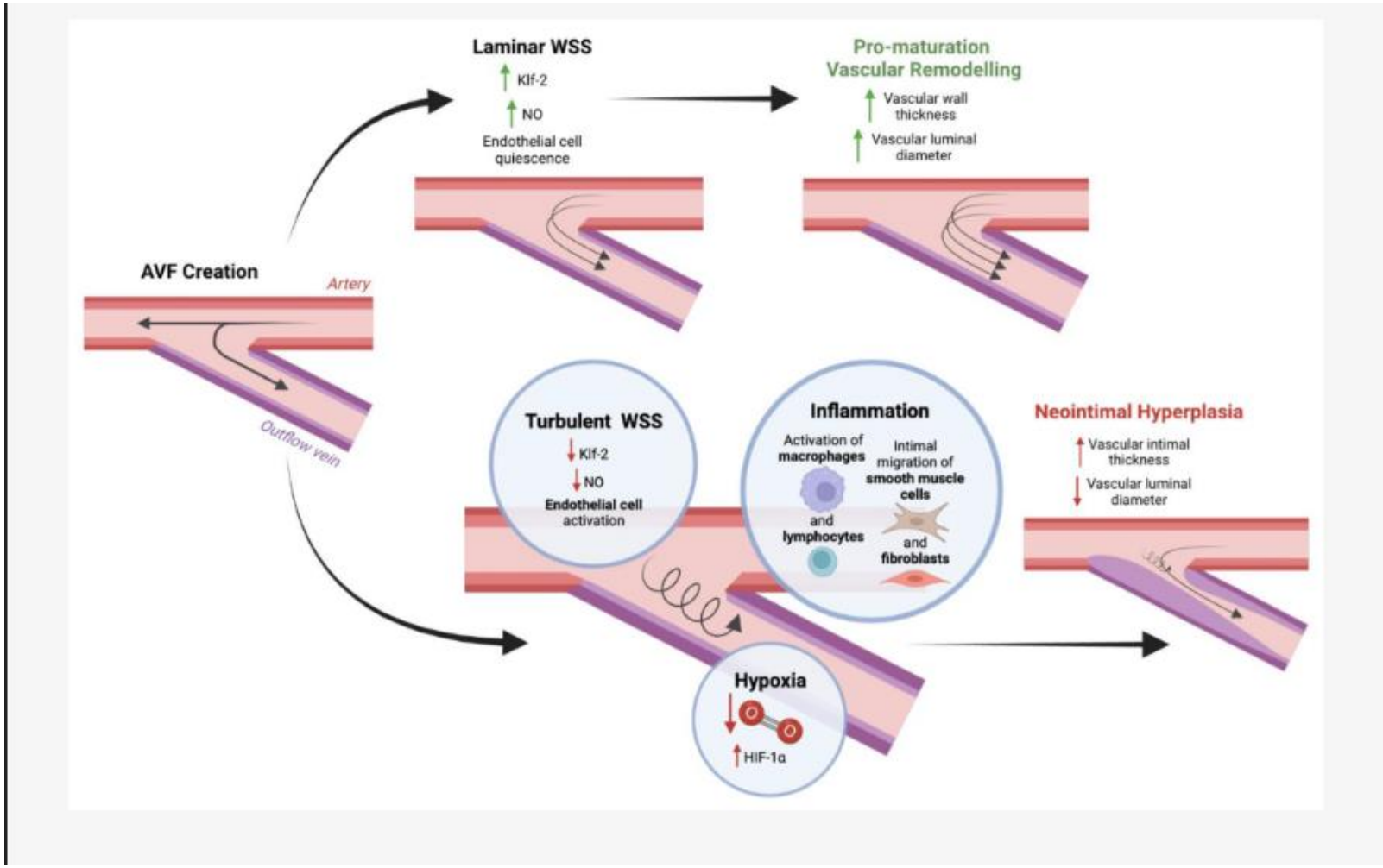
By **Bryan Kay** - 27th September 2023 2919

Laminate Medical Technologies has announced their flagship device, the VasQ external vascular support, has been cleared by the Food and Drug Administration (FDA) for use to create arteriovenous fistulas (AVFs) for dialysis access. The device, designated by the FDA as a breakthrough technology, was cleared based on a *de novo* review of the 144 patient VasQ U.S. pivotal study, as well as a track record of safety and effectiveness of use in multiple studies from outside the U.S.

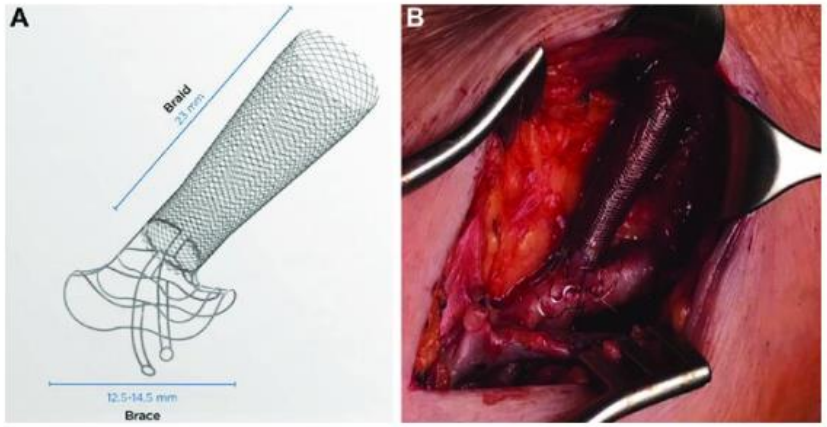


VasQ external vascular support

VasQ


Laminar WSS
Klf-2
NO
Endothelial cell quiescence
Pro-maturation
Vascular Remodelling
Vascular wall thickness
Vascular luminal diameter
AVF Creation
Artery
Outflow vein
Turbulent WSS
Klf-2
NO
Endothelial cell activation
Inflammation
Activation of macrophages
Intimal migration of smooth muscle cells
and lymphocytes
and fibroblasts
Neointimal Hyperplasia
Vascular intimal thickness
Vascular luminal diameter
Hypoxia
HIF-1α

VasQ



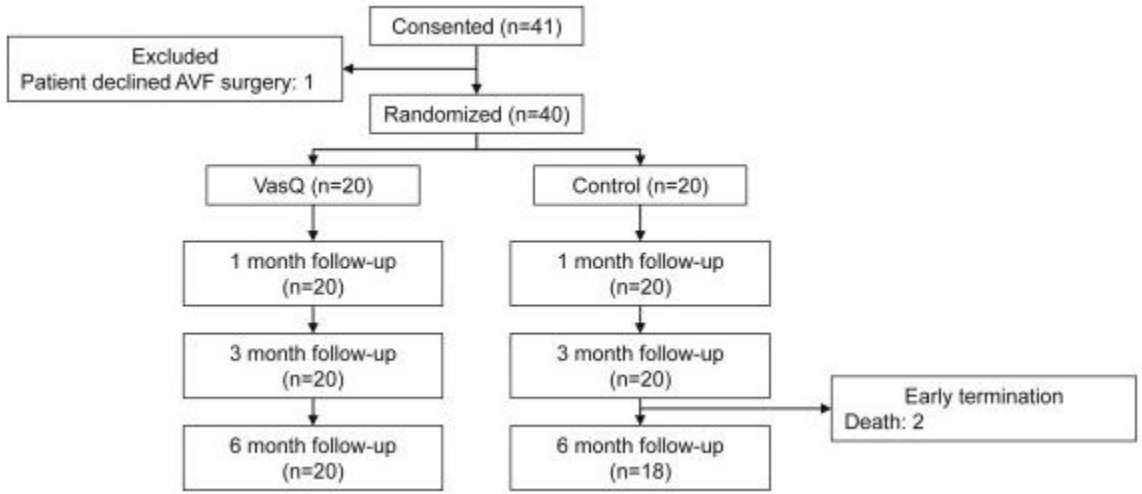
VasQ

FULL TEXT ARTICLE

An Implanted Blood Vessel Support Device for Arteriovenous Fistulas: A Randomized Controlled Trial

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

American Journal of Kidney Diseases, 2020-01-01, Volume 75, Issue 1, Pages 45-53, Copyright © 2019 The Authors



Outcome/Characteristic	Treatment	Control	*P*
Assisted maturation [a]			
1 mo	85% (17/20)	85% (17/20)	0.9
3 mo	85% (17/20)	80% (16/20)	0.9
Unassisted maturation [a]			
1 mo	80% (16/20)	80% (16/20)	0.9
3 mo	80% (16/20)	80% (16/20)	0.9
Functional patency [b]			
3 mo	90% (9/10)	45% (5/11)	0.06
6 mo	100% (14/14)	56% (5/9)	0.01
Cephalic vein volume flow, mL/min			
1 mo	1,259.06 ± 398.6	1,208.35 ± 543.2	0.8
3 mo	1,500.71 ± 518.9	1,113.5 ± 661.6	0.06
6 mo	1,393.7 ± 673.6	1,046.88 ± 625.5	0.1
Cephalic vein diameter, mm			
1 mo	6.94 ± 1.4	6.65 ± 1.3	0.5
3 mo	8.27 ± 1.3	6.69 ± 1.8	0.03
6 mo	9.6 ± 2.5	7.56 ± 2.7	0.03
AVF patency			
Primary patency at 6 mo	80% (16/20)	66% (12/18)	0.5
Secondary patency at 6 mo	85% (17/20)	77% (14/18)	0.6

Optiflow

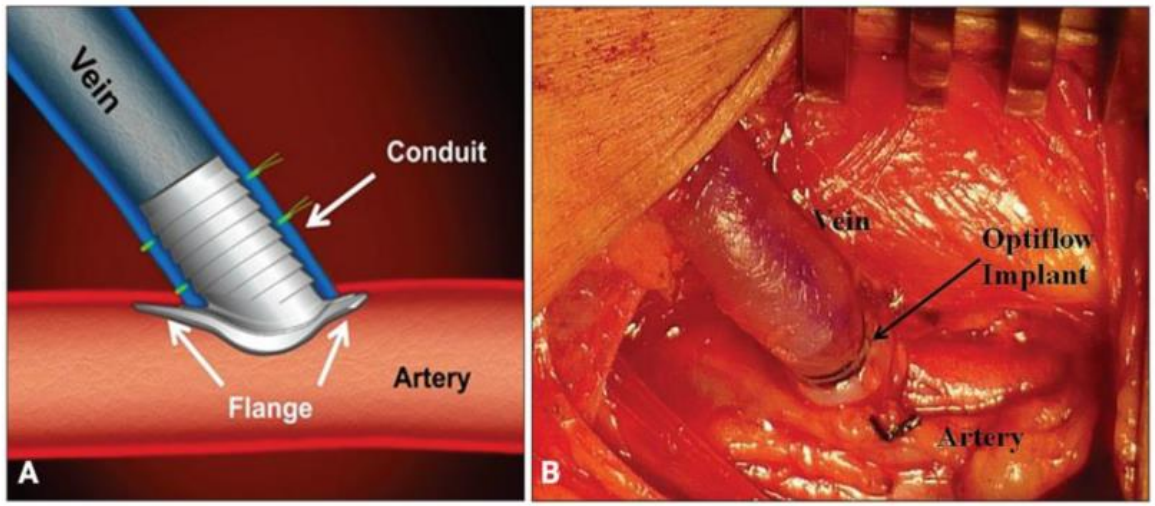
J Vasc Access 2013; 00 (00): 000-000
DOI: 10.5301/jva.5000169

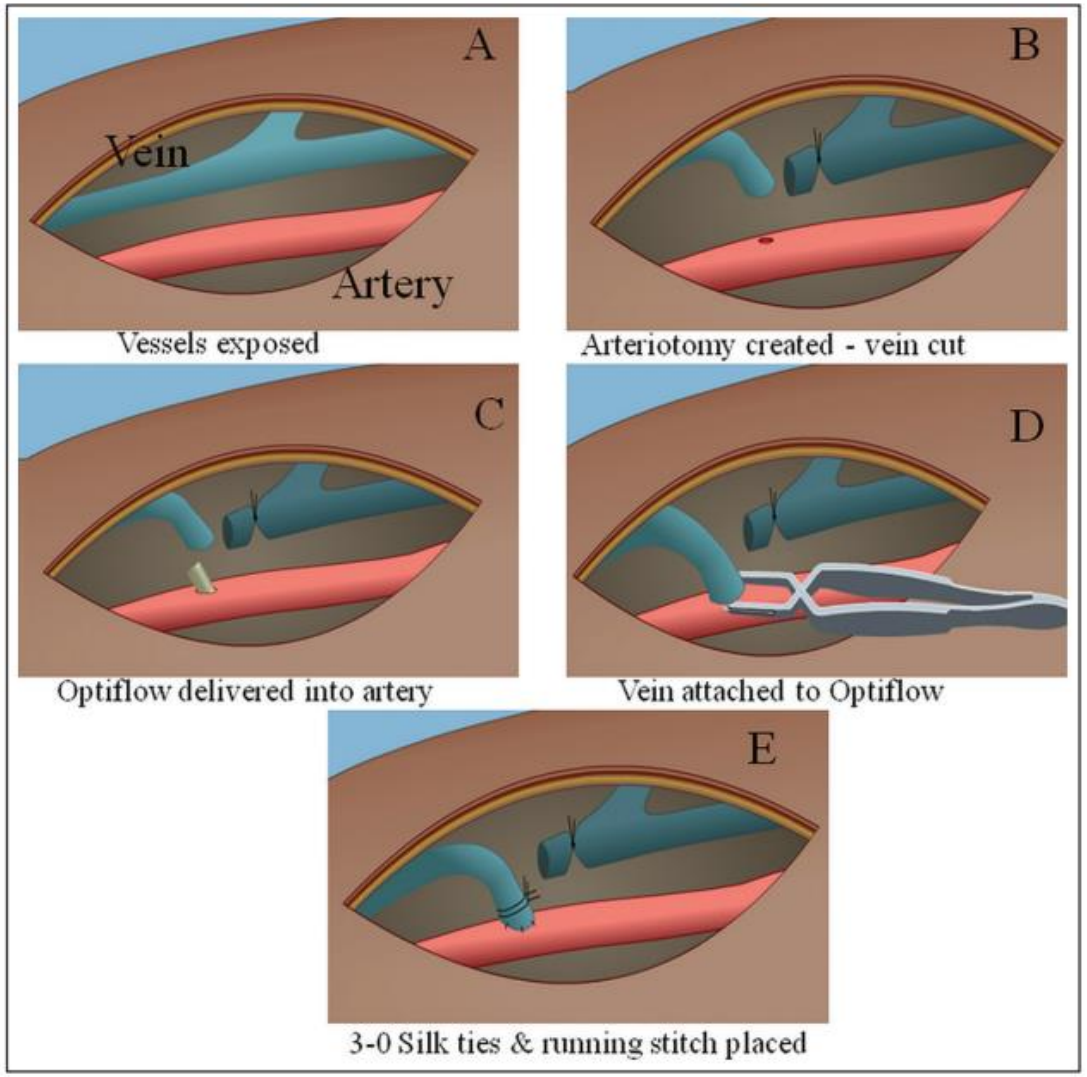
ORIGINAL ARTICLE

Arteriovenous fistula creation using the Optiflow™ vascular anastomotic connector: the OPEN (*O*ptiflow *P*at*E*ncy and Maturatio*N*) study

Eric Chemla[1], Afshin Tavakoli[2], Milind Nikam[3], Sandip Mitra[3], Tlou Malete[1], Jackie Evans[3], Prabir Roy-Chaudhury[4]

[1] Department of Transplantation, St George's Healthcare NHS Trust, London - UK
[2] Department of Transplantation, Manchester Royal Infirmary, Manchester - UK
[3] Department of Renal Medicine, Manchester Royal Infirmary, Manchester - UK
[4] Dialysis Vascular Access Research Group, Division of Nephrology, University of Cincinnati and Cincinnati VA Medical Center, Cincinnati - Ohio





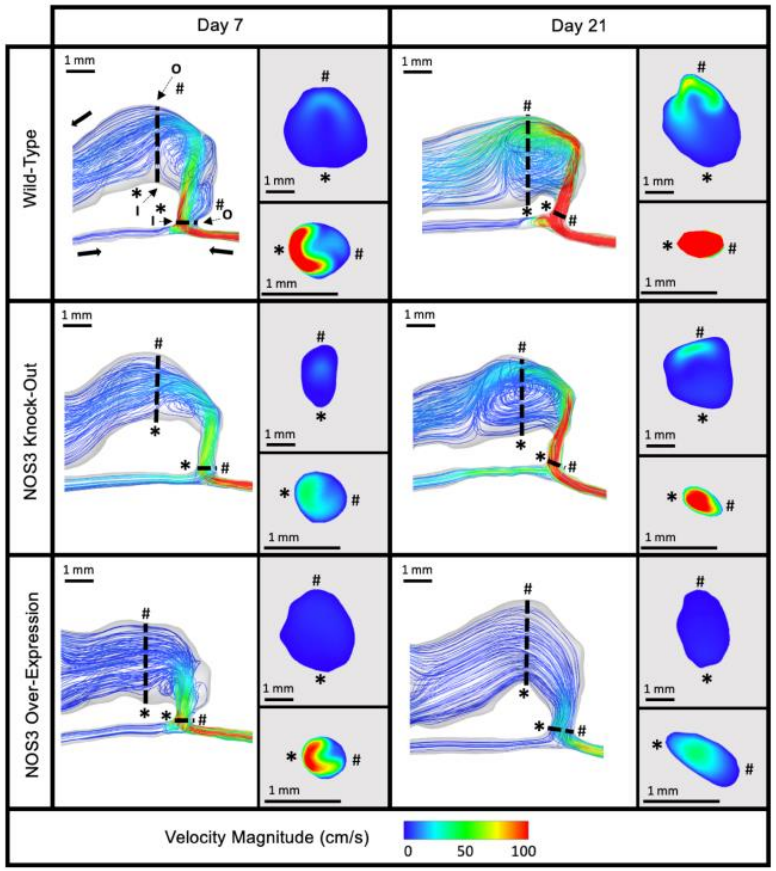
BioNanomatrix gel

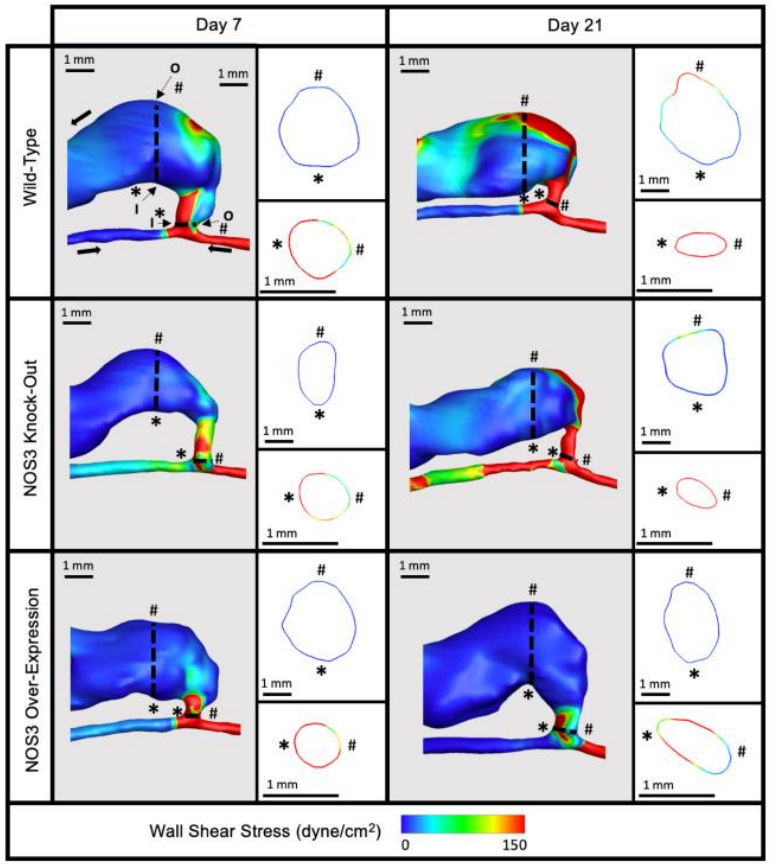
scientific reports

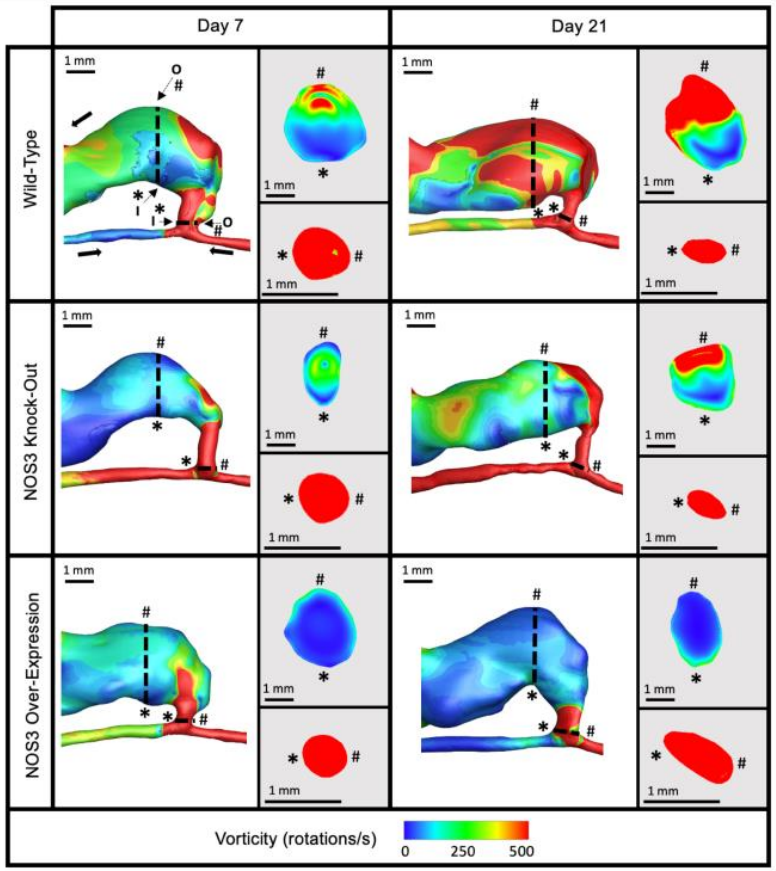
OPEN

Effects of endothelial nitric oxide synthase on mouse arteriovenous fistula hemodynamics

Shelly Baltazar[1,2], Hannah Northrup[2], Joshua Chang[2], Maheshika Somarathna[3], Tatyana Isayeva Waldrop[3], Timmy Lee[3,4] & Yan-Ting Shiu[2,5]✉





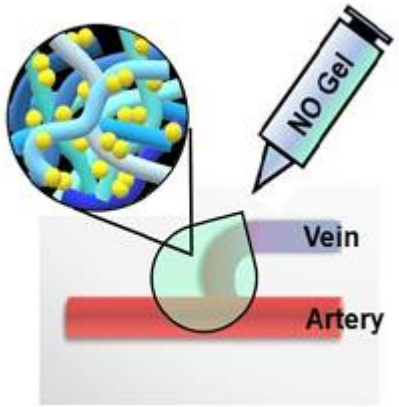


BioNanomatrix gel

Biomaterials
Volume 280, January 2022, 121254

Nitric oxide releasing nanomatrix gel treatment inhibits venous intimal hyperplasia and improves vascular remodeling in a rodent arteriovenous fistula

Maheshika Somarathna [a 1], Patrick TJ. Hwang [b c 1], Reid C. Millican [c], Grant C. Alexander [b c], Tatyana Isayeva-Waldrop [a], Jennifer A. Sherwood [c], Brigitta C. Brott [c d], Isabelle Falzon [e], Hannah Northrup [e], Yan-Ting Shiu [e f], Chris J. Stubben [g], John Totenhagen [h], Ho-Wook Jun [b c], Timmy Lee [a i]



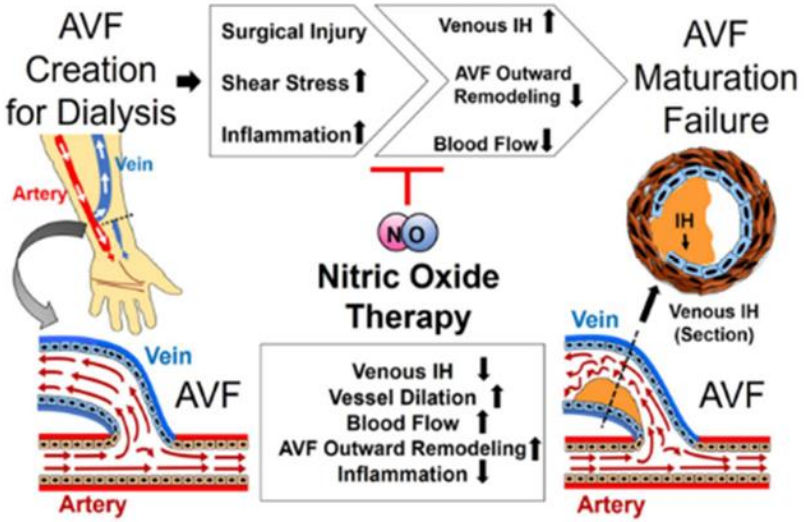
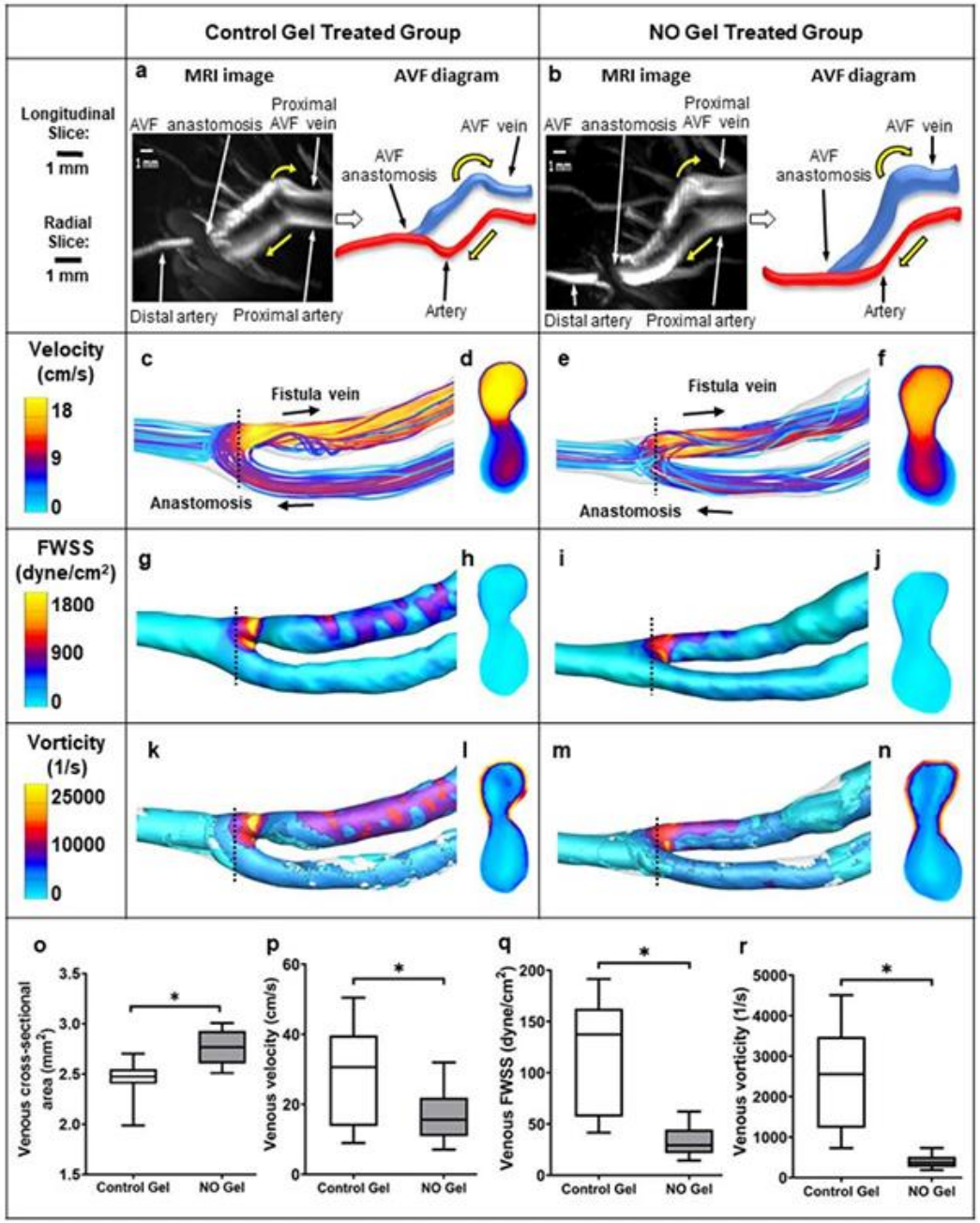


Fig. 1. AVF maturation failure and NO therapy. Progress of AVF maturation failure after AVF creation and potential application of NO therapy to improve AVF maturation process for hemodialysis. IH: Intimal hyperplasia.



Thank you for your attention!