VANDERBILT HEALTH

WELCOME *To the*

2026 SYMPOSIUM

The VENOS-2 Early Feasibility Study: 1-year Outcomes of the Velocity® pAVF

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VASA Access Excellence.

INNOVATION
BEST ABSTRACTS SESSION 1

Disclosure:

Speaker name: **Robert Shahverdyan**

I have the following potential conflicts of interest to report:

X Consulting, honoraria and travel support: Becton Dickinson, Laminate medical, Xeltis, FLEX Vascular

X Speaker bureau: BrosMed medical, Cardionovum, Teleflex, Abbott Vascular, Getinge

X Advisory Board Member: Venova medical, FLEX Vascular

Endovascular AVFs? Again?









Stay put for 6 minutes!



Why a Percutaneous AVF?

Simplifies the access creation pathway

- Streamlines referral → evaluation → access creation

Reduces dependence on surgical scheduling

- Procedure can be performed by a broader group of trained physicians

Expands access to care

- Addresses workforce and geographic barriers

Increase Quality Dialysis Starts and Reduce Catheter Exposure

The Velocity

Ideal flow to support rapid maturation

- Fenestrated covered stent to create the AVF
- Avoids competitive deep venous flow (avoids deep vein embolization)

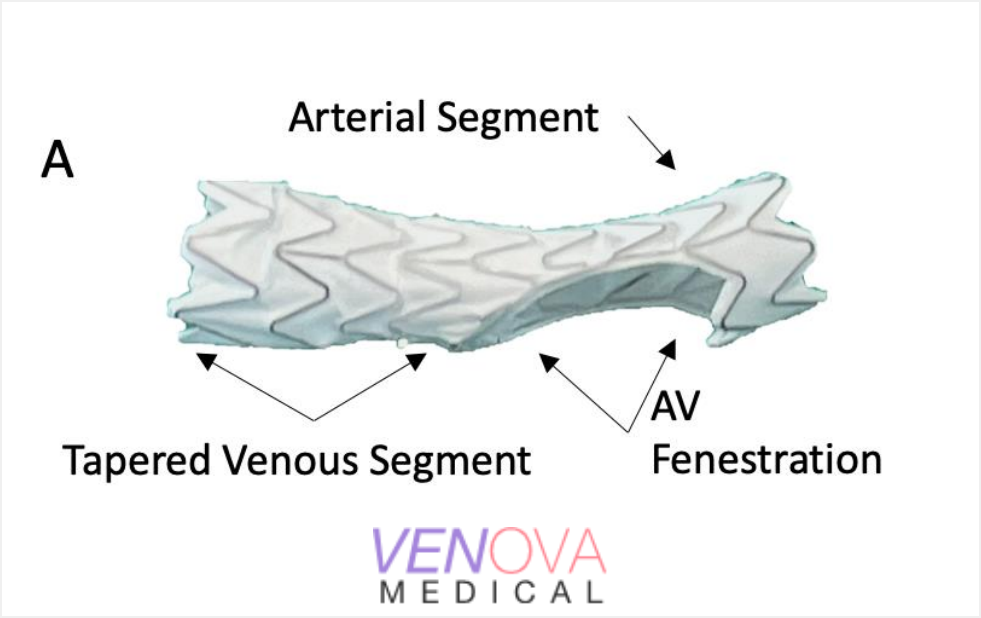
Creates a better AVF anastomosis

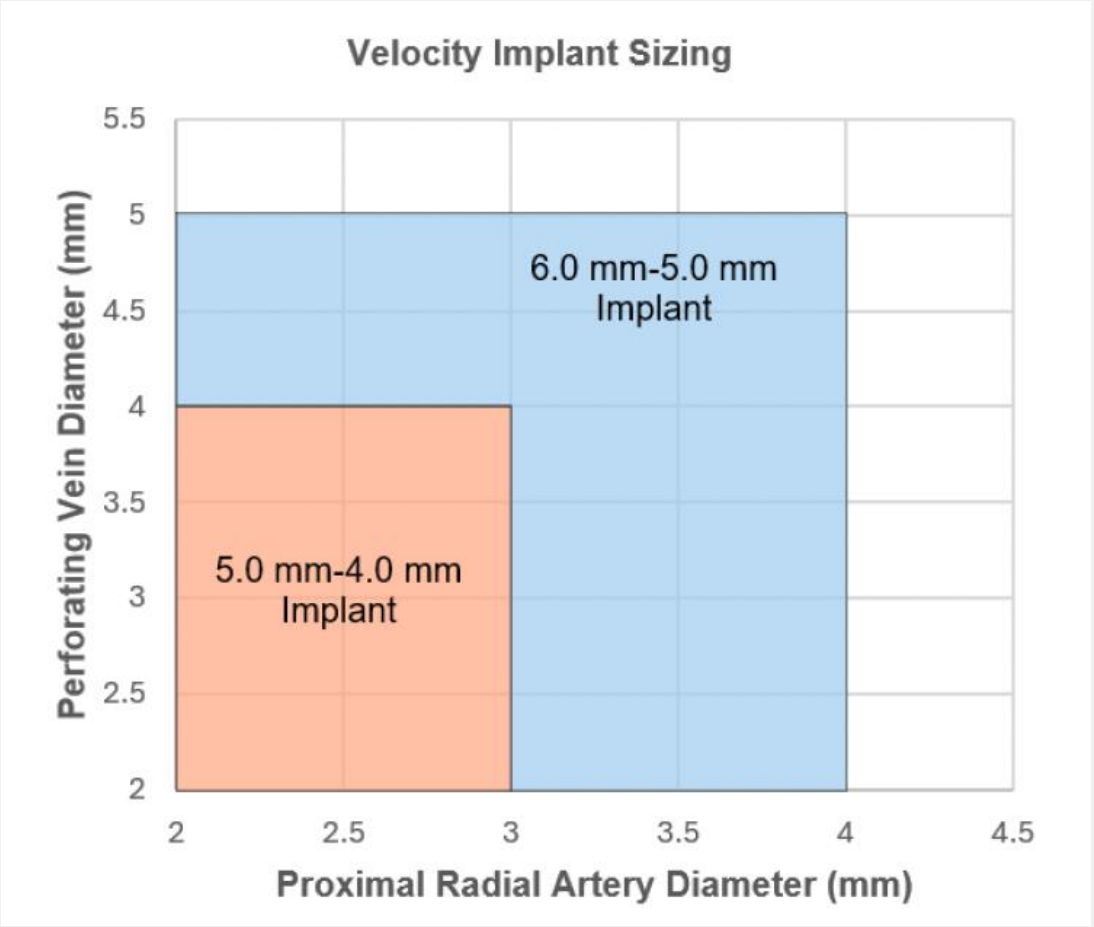
- Avoids anastomotic and perforating vein stenosis
- Absent surgical inflammation or thermal injury
- Fenestration limits excessive flow
- Average procedure time <20 minutes (VENOS-2)



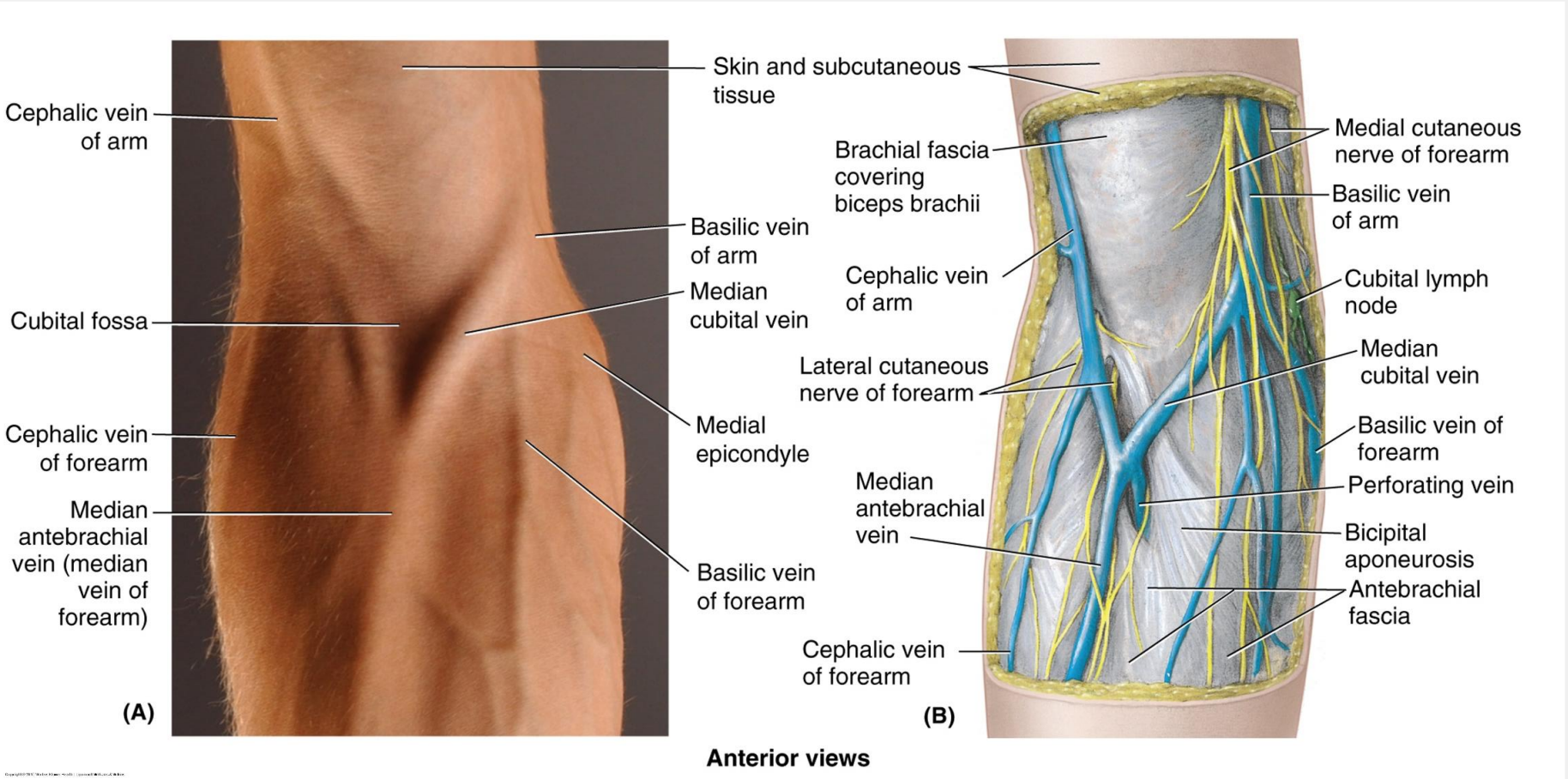
Velocity™ system





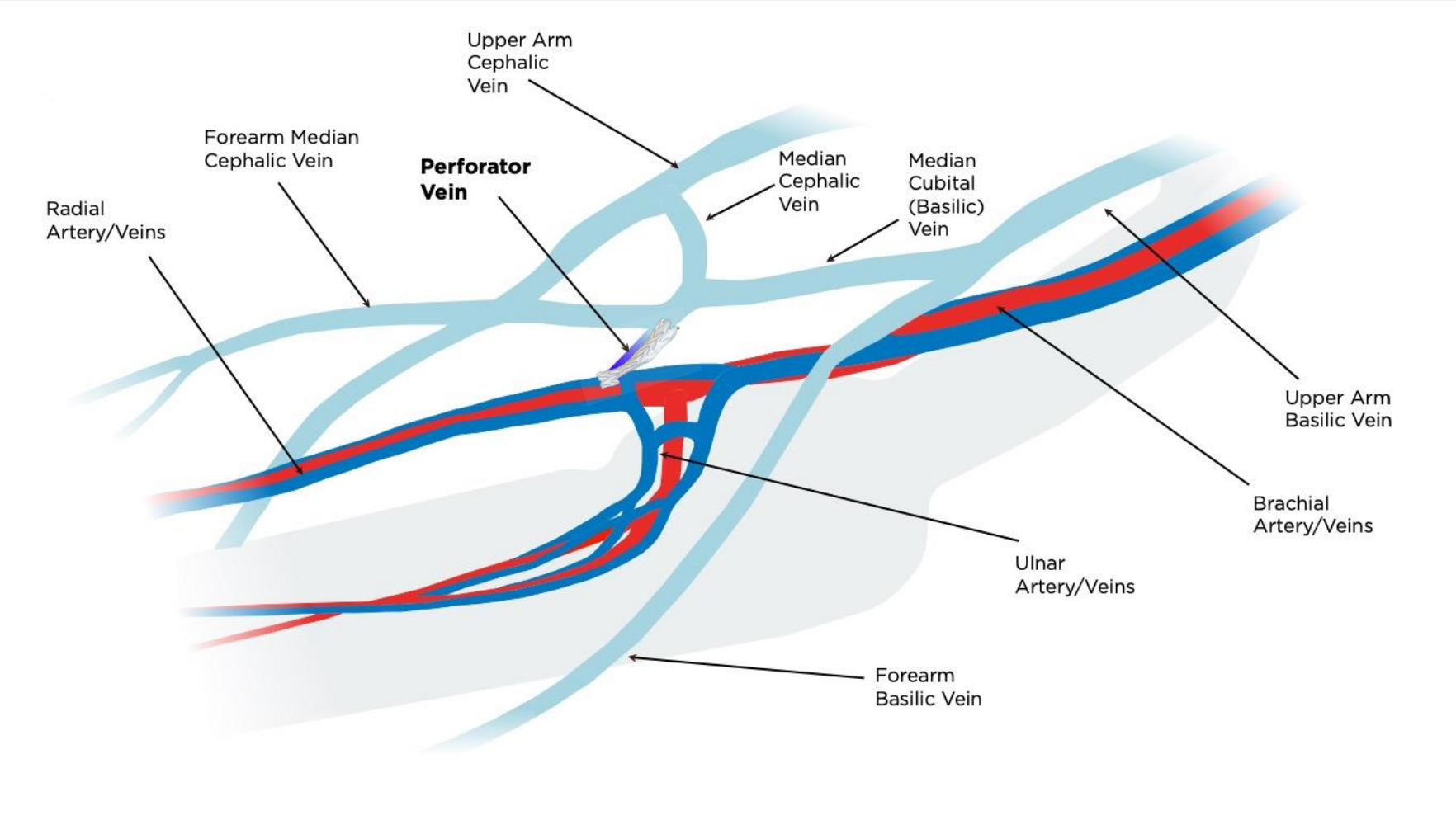


Perforator vein



2006 Moore & Dalley *COA*

The NextGen endoAVF



Modified from *Shahverdyan et al. JVA 2022,* DOI: 10.1177/11297298221141480
Novel classification of proximal forearm perforator vein in the planning and creation of percutaneous and surgical Gracz-type arteriovenous fistulae



- ✓ Animal study
- ✓ First In Human FIH (VENOS 1 trial)
- ✓ US Feasibility Study (VENOS 2 trial)
- ✓ US Pivotal Study (VENOS 3 trial)

Early Feasibility Study (FIH)

The VENOS – 1 Trial

Prospective, single-arm, single-center, open-label study Clinicaltrials.gov NCT 05757726

Indications for Use

- Proximal radial artery diameter ≥ 2.0 mm
- CPV diameter ≥ 2.5mm
- Distance from CPV to RA **< 3.0 mm**

Primary Endpoints

- Technical Success
- Serious Adverse Device Events
- Major Reintervention

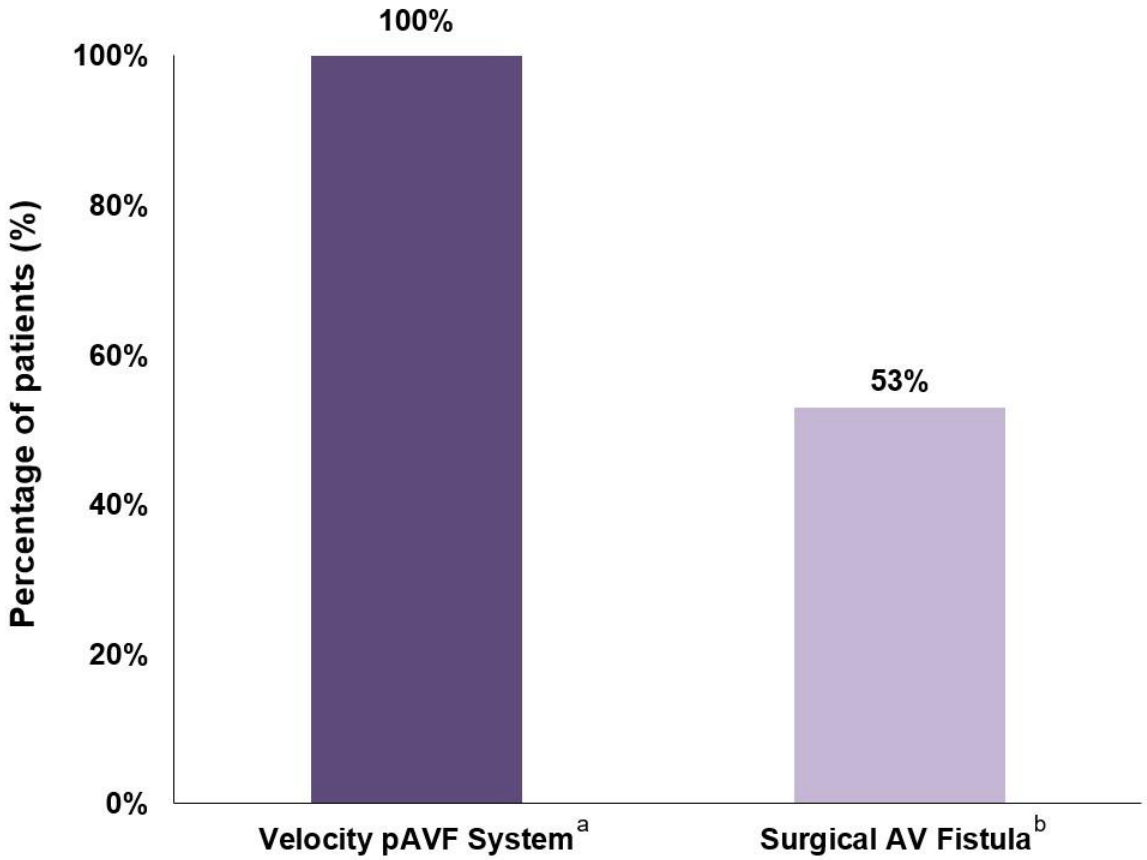
- Unassisted Maturation
- Functional Maturation
- Physiologic Maturation
- Cumulative Patency

Schedule of Assessment

- Clinical exam + Duplex ultrasound @ 2 wks, 6 wks, 3 mo, 6 mo & 1 year

Secondary Endpoints

Physiologic Maturation



[a] Based on results from VENOS-1 study

[b] Based on results from Hemodialysis Fistula Maturation (HFM) study. Huber TS, et al. JAMA Surg. 2021;156:1111-1118.

Definition

Arterial flow > 500 ml/min

+

Cephalic vein dia. > 5.0 mm

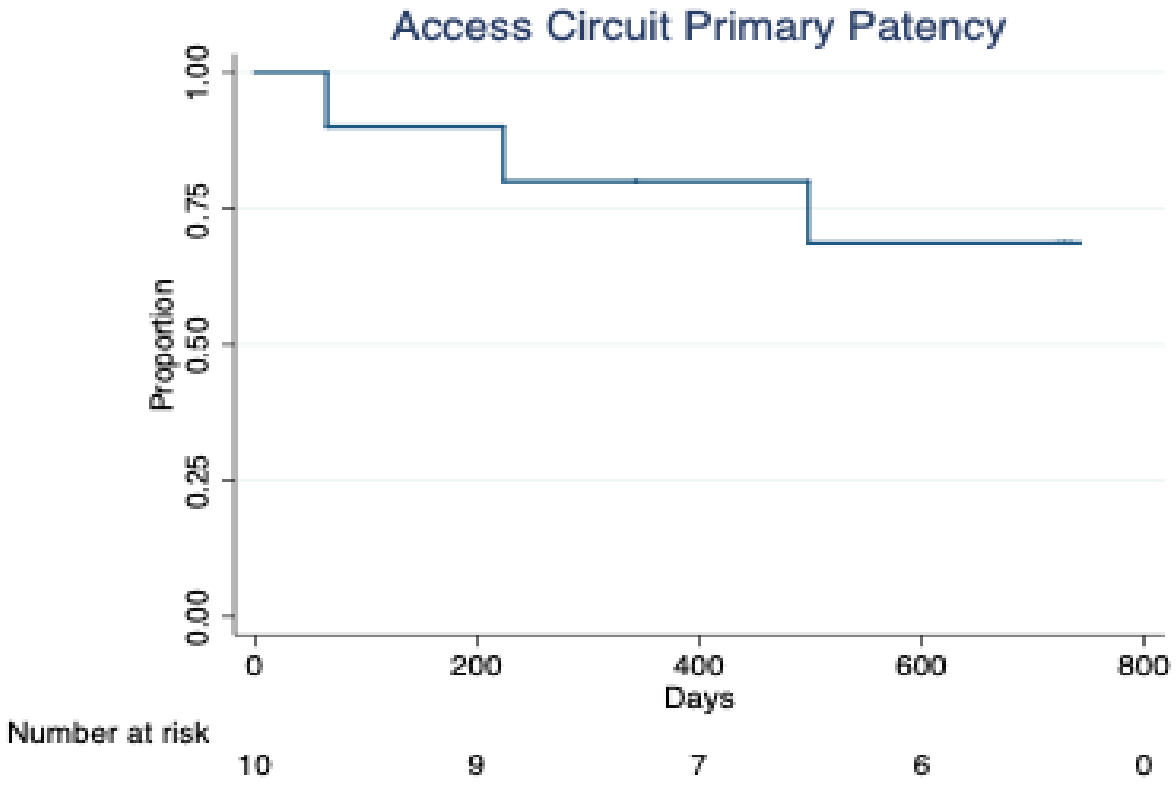
100% met criteria within 6 weeks

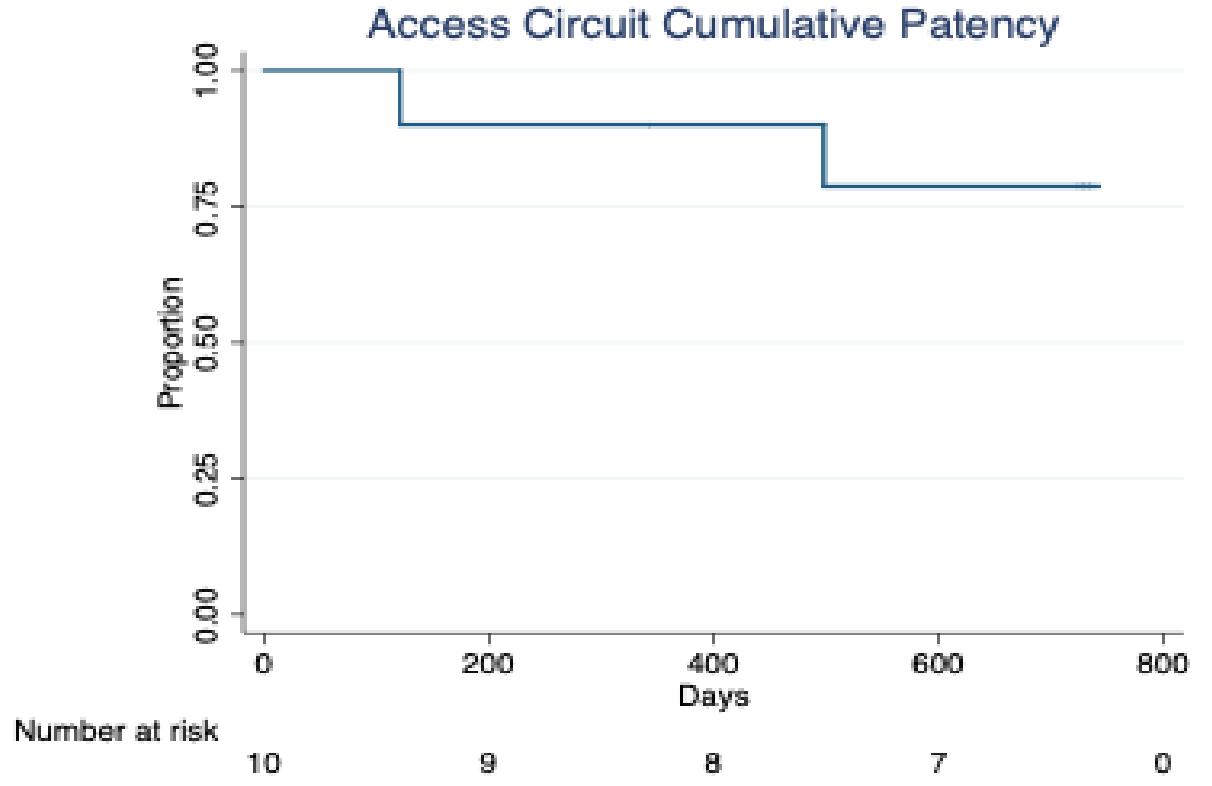
Ave 18 days to reach endpoint

No Reinterventions Needed to Reach Endpoint

J Am Soc Nephrol. 2018 Nov; 29(11): 2735–2744.

Access Circuit Patency





Publication

Clinical Trials

JOURNAL OF ENDOVASCULAR THERAPY

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Sage

A Novel Percutaneous Arteriovenous Fistula for Hemodialysis Access: One-Year Outcomes of the VENOS-I First-In-Human Trial

Robert Shahverdyan, MD[1], Dirk M. Hentschel, MD[2], Adrian Ebner, MD[3], Erik van der Burg, MSME[4], and Shant M. Vartanian, MD[4,5]

Abstract

Objectives: Starting patients on hemodialysis (HD) with an arteriovenous fistula (AVF) and minimizing catheter contact time are major unmet needs for end-stage renal disease (ESRD) patients. Percutaneous arteriovenous fistulas (pAVFs) could address these needs, but current devices often result in flow loss to the brachial vein, requiring reinterventions for target vein maturation and initial clinical use. This study evaluated the technical feasibility and safety of a novel implant-based pAVF, designed to replicate surgical AVF anatomy by directing flow exclusively into the superficial venous system of the upper arm. **Methods:** The VENOS-I trial (NCT05757726) is a prospective, single-arm, open-label early feasibility study. The primary effectiveness outcome was procedural success and primary safety outcome measures were serious adverse device events and major reinterventions at 6 weeks. Secondary outcomes included physiologic maturation, defined as brachial artery flow ≥500 mL/min and venous outflow diameter ≥5 mm, reintervention rate, and functional use. **Results:** Ten HD patients were enrolled and average follow-up was 15.9 months. Mean age was 45.1 years (range=27–61) and the mean body mass index was 24.3 kg/m^2 (SD±9.2). Procedural success was 100%, with no serious adverse events or major reinterventions at 6 weeks. At 6 weeks, median brachial artery flow was 977 ml/min (interquartile range [IQR]±300), and cephalic vein diameter increased to 6.3 mm (SD±1.0 mm). Physiologic maturation was achieved in all patients without reintervention, on average by day 18 (range=13–40). Four subjects underwent ligation of the median basilic vein after reaching unassisted physiologic maturation to facilitate 2-needle inline cannulation of the upper-arm cephalic vein. Two percutaneous reinterventions were needed to maintain or restore patency across 10 subjects in the first 12 months. Access circuit primary patency at 1 year was 80%. **Conclusion:** This first-in human study demonstrates that an implant-based technique is effective and safely creates an AVF for HD. By directing arterial flow into the superficial venous system, the device creates hemodynamic conditions that facilitate physiologic maturation without adjunctive procedures, an observation that will require confirmation in larger studies.

Clinical Impact

This first-in-human study demonstrates that an implant-based percutaneous arteriovenous fistula (AVF) can consistently achieve physiologic maturation without need for flow diversion from the deep venous system. Flow conditions in the superficial venous system drives maturation and creates physical exam findings in the cephalic vein needed for cannulation. This novel approach addresses limitations of earlier percutaneous arteriovenous fistula technologies by simplifying access creation and optimizing hemodynamics in the cannulation zone. Clinicians may benefit from expanded access options that reliably result in physiologic maturation and lowers procedural complexity, which together could reduce catheter exposure. If validated in larger studies, this technique has the potential to shift dialysis access practice by offering an additional access option that creates reliable maturation for initiating hemodialysis with an AVF.

U.S. Early Feasibility Study

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The VENOS – 2 Trial

- **Total Enrollment:** N=23
- Jan – April 2025
  - ESKD: N=14
  - CKD: N=9

Characteristic	
Age (yrs)	54.1
% Male	91%
Race	
Hispanic	52%
White	35%
Black	13%

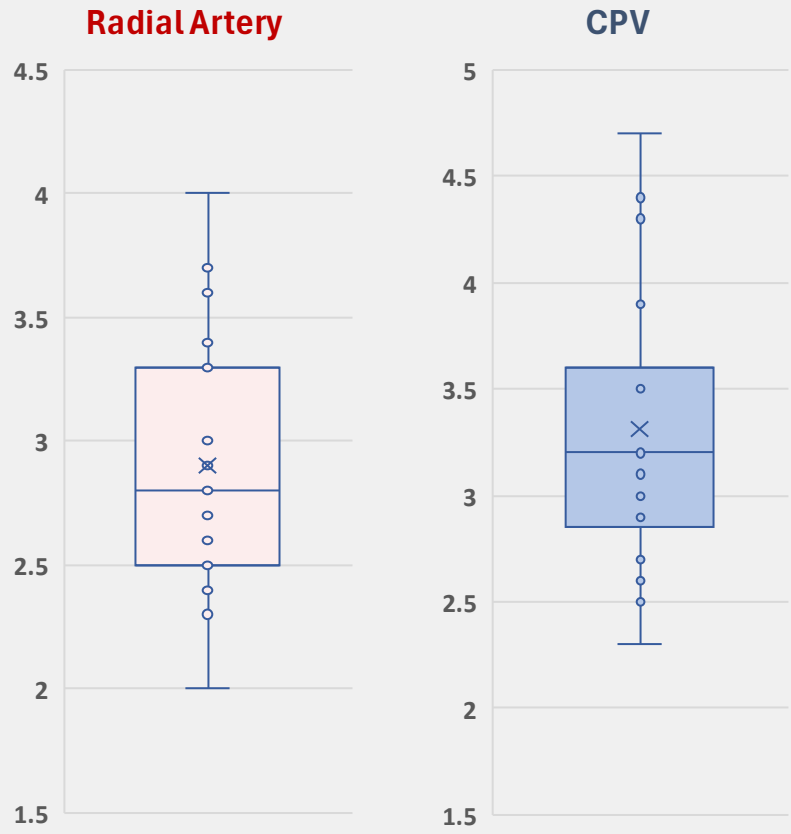
Characteristic	
Diabetes	65%
Hypertension	96%
Coronary Artery Disease	26%
Congestive Heart Failure	26%
Current Smoker	17%
End Stage Renal (on CVC)	70%
BMI	31.1

Single antiplatelet x 7 days

- 10 ASA 81 mg
- 12 Plavix 75 mg

Ave time on CVC: 7.8 months

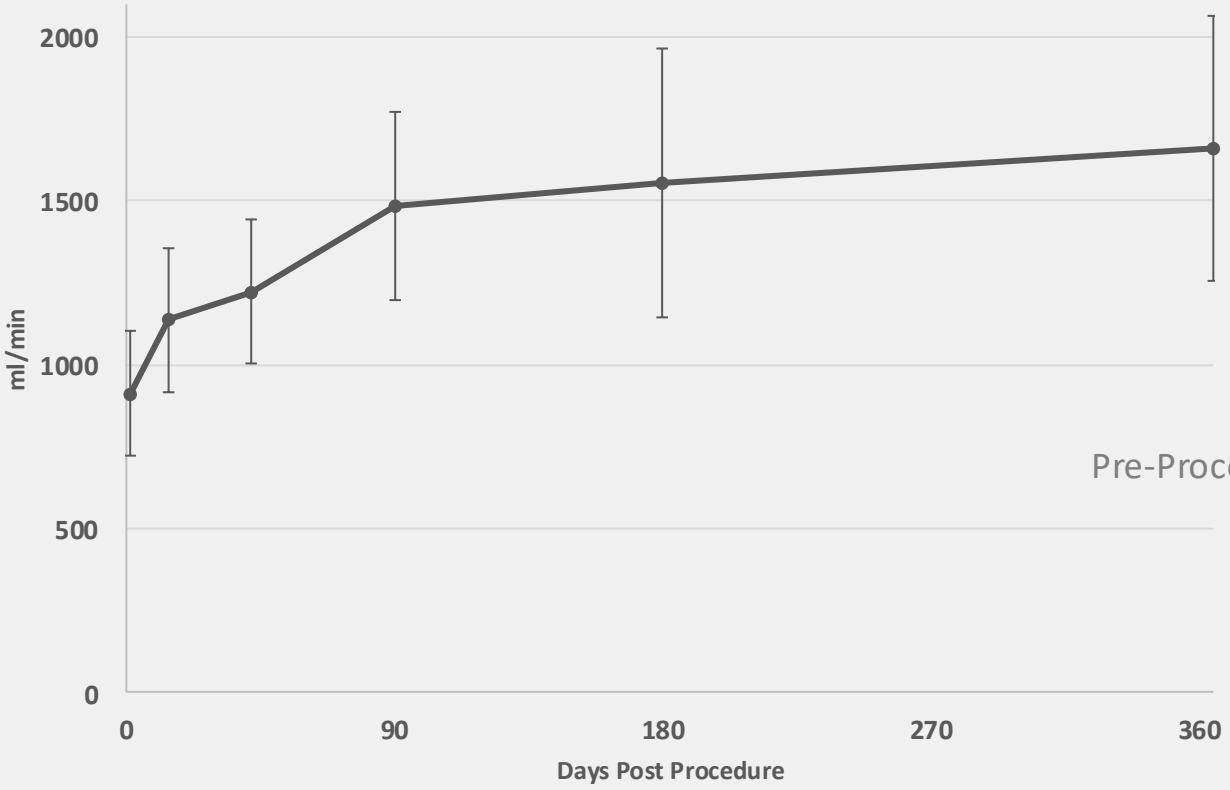
- **100% technical success**



Access Physiology

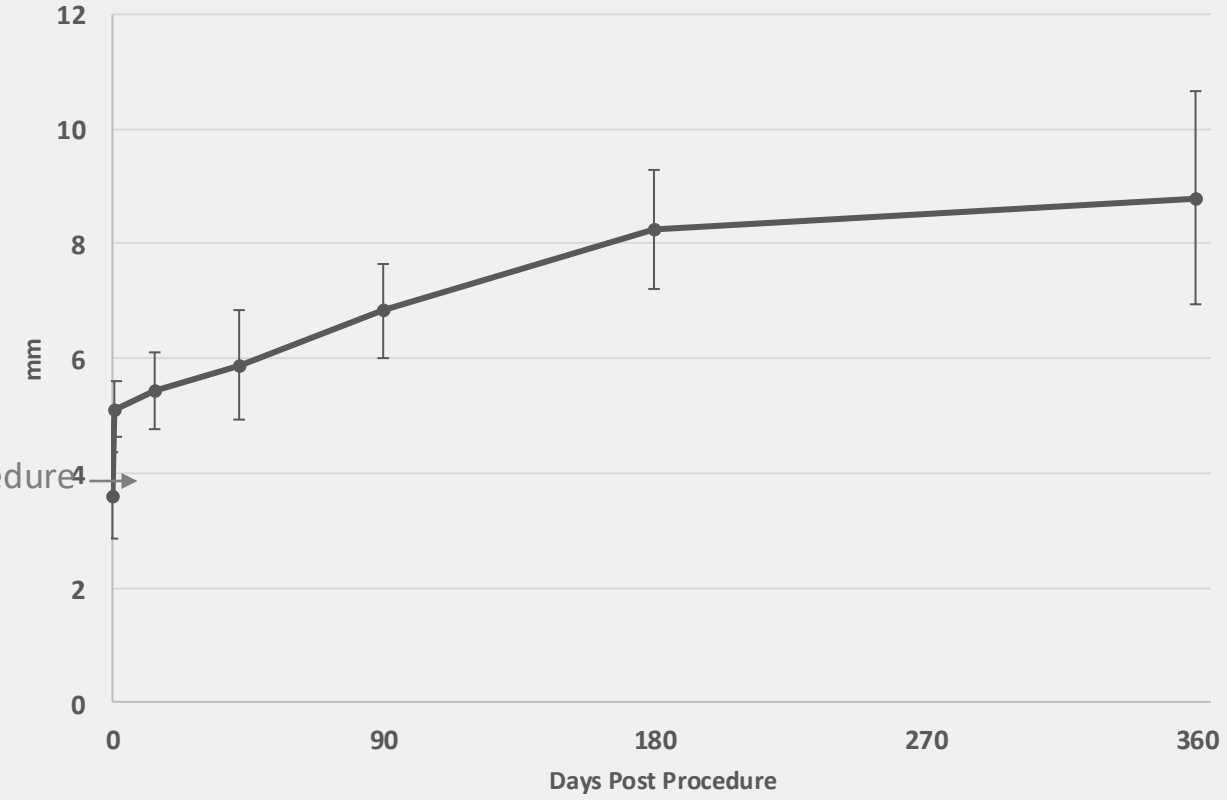
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Access Flow



N subjects	23	22	22	18

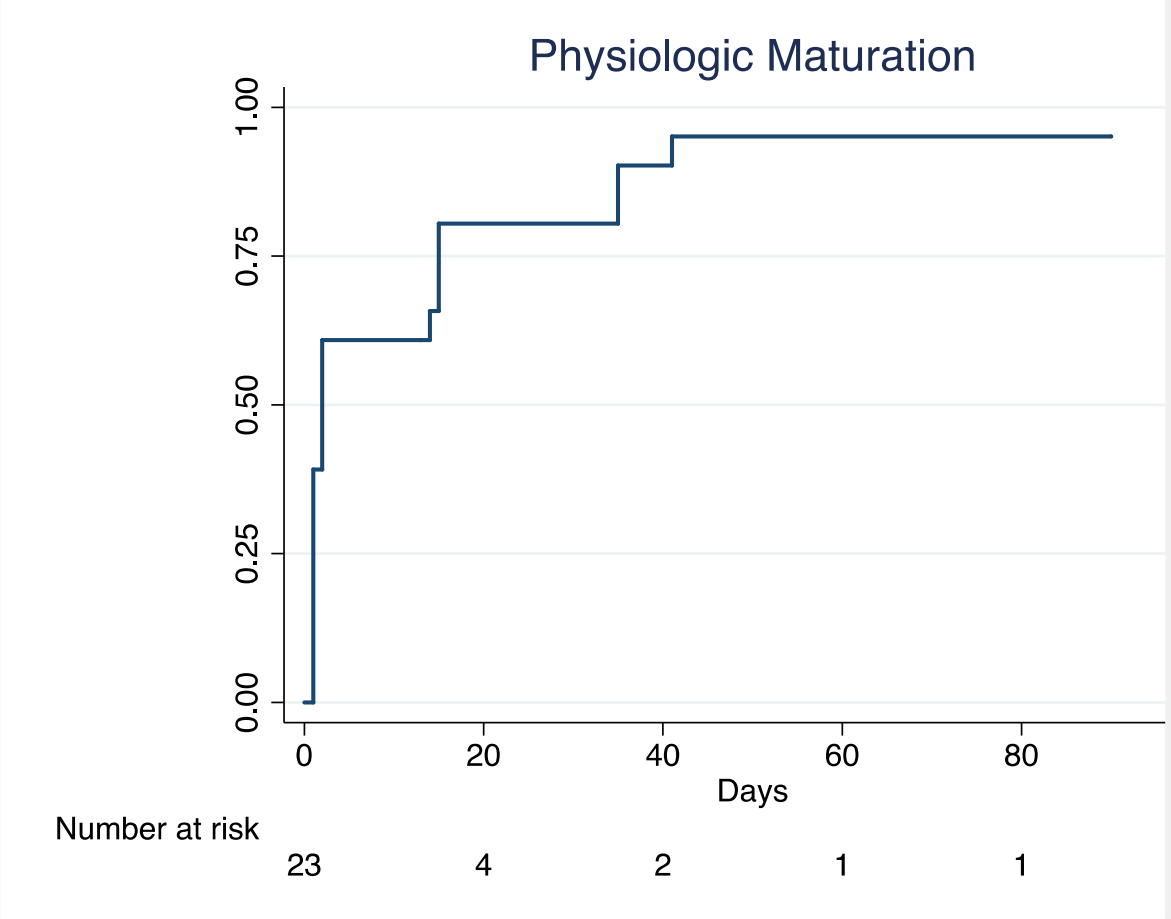
Cephalic Vien Diameter



N subjects	23	22	22	18

Physiologic Maturation

Flow > 500 mL/min and Diameter > 5.0 mm



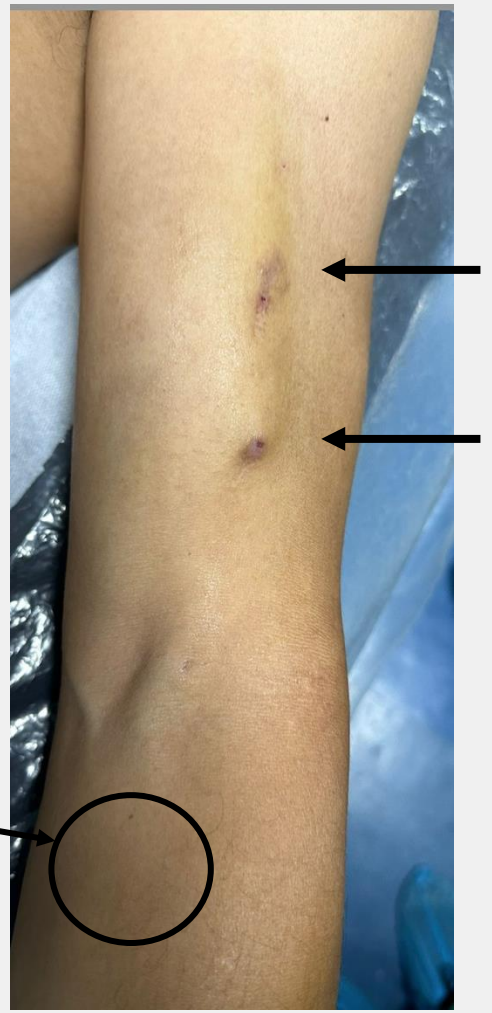
96% (22/23) reached endpoint by 6 weeks

Unassisted in 87% (20/23)

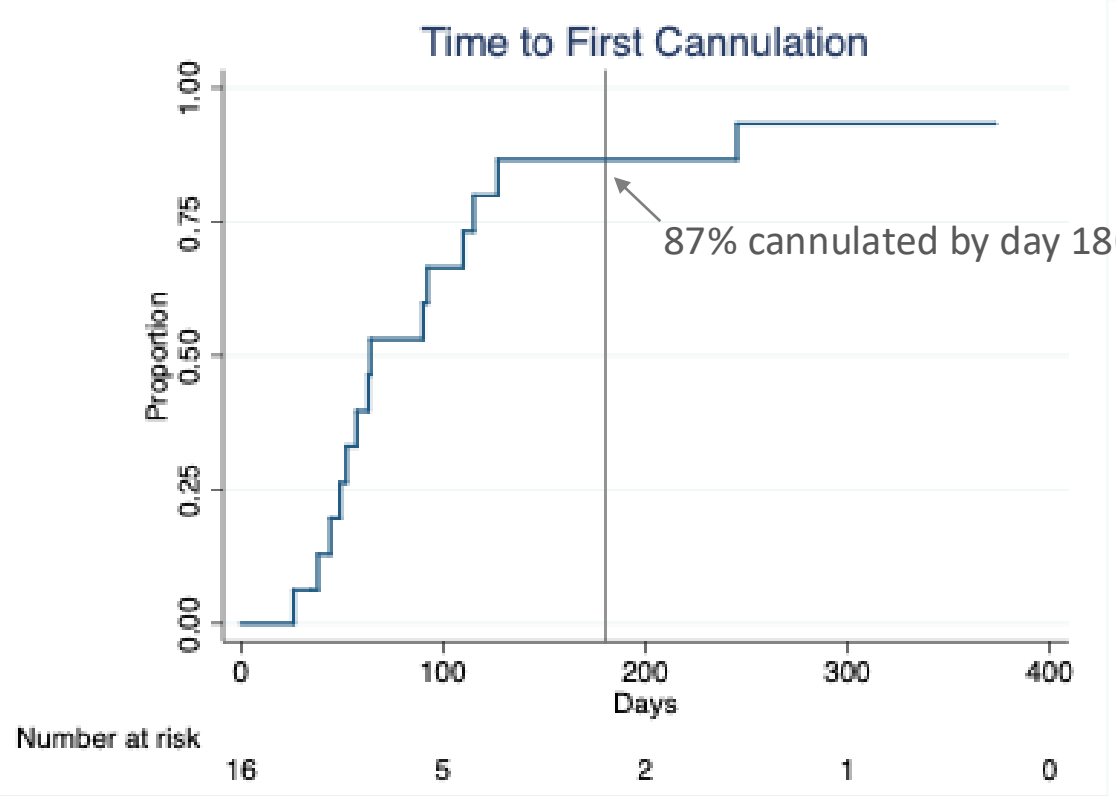
- No coil embolization of deep veins

Cannulation

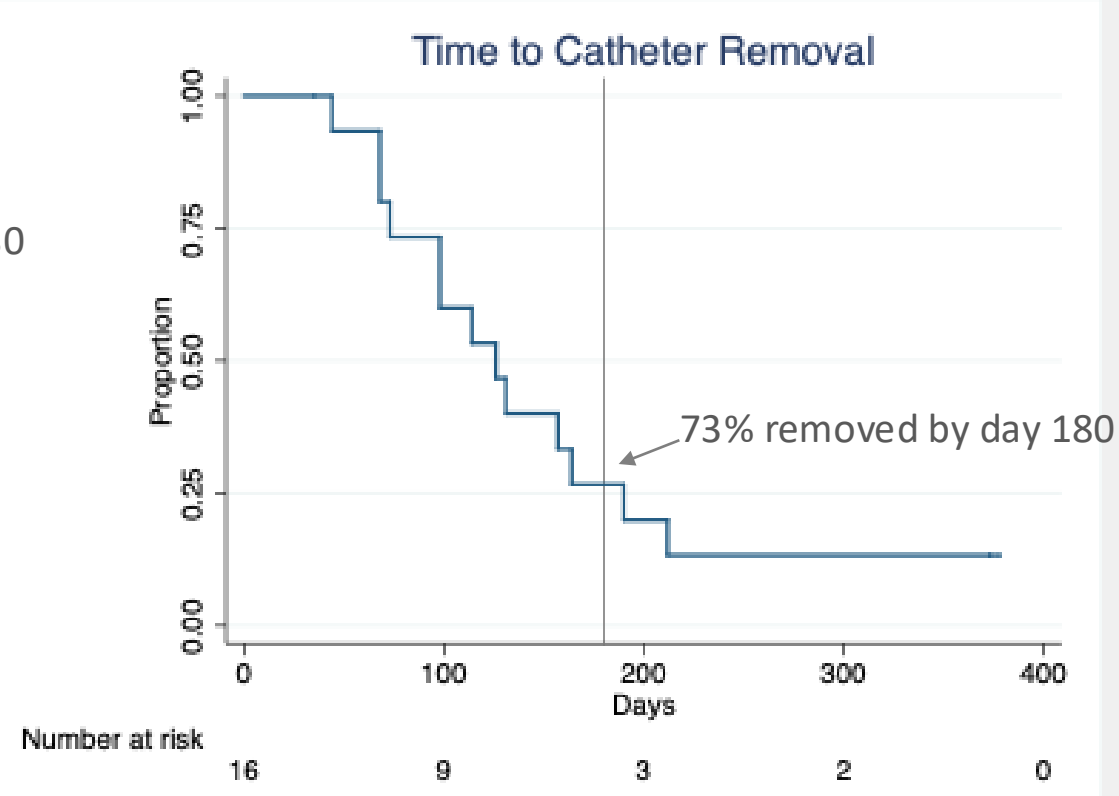




Functional Maturation (Usability)!!!



Median time to first 2-needle cannulation 63 d (IQR 49 – 110)

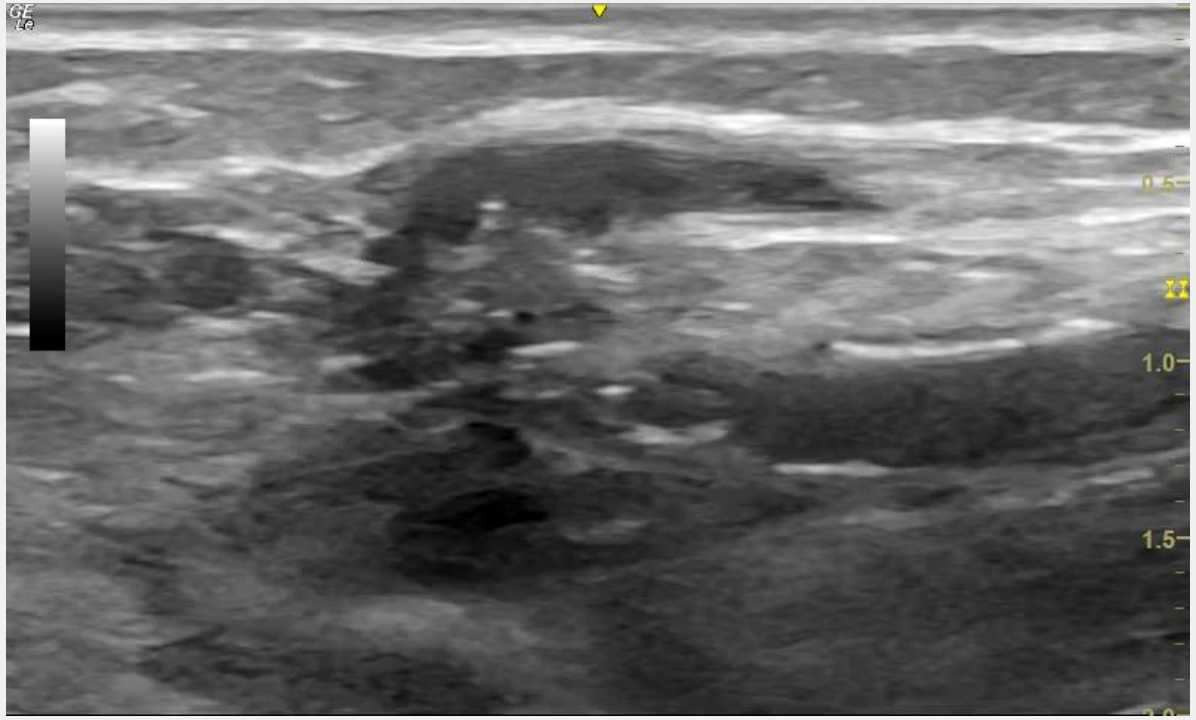


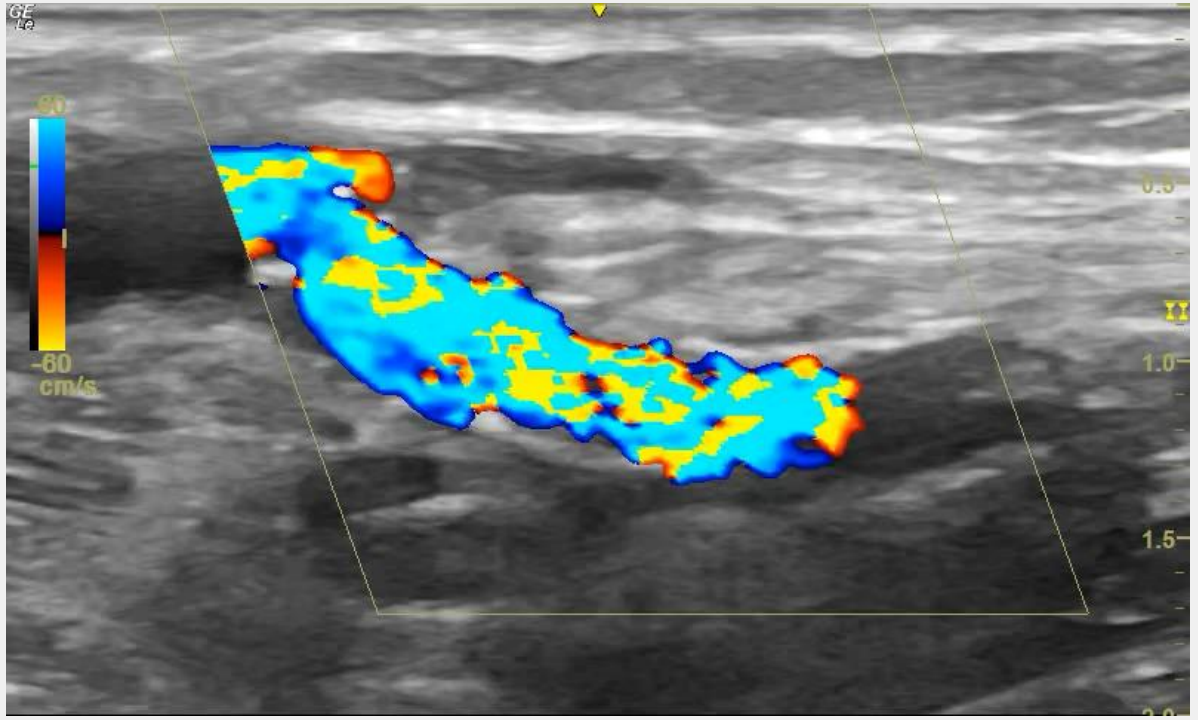
Median time to catheter removal 114 d (IQR 70 – 144)

- 16/23 patients entered the study catheter-dependent
- 4/7 CKD patients achieved a catheter-free dialysis start using the study AVF

U/S Imaging

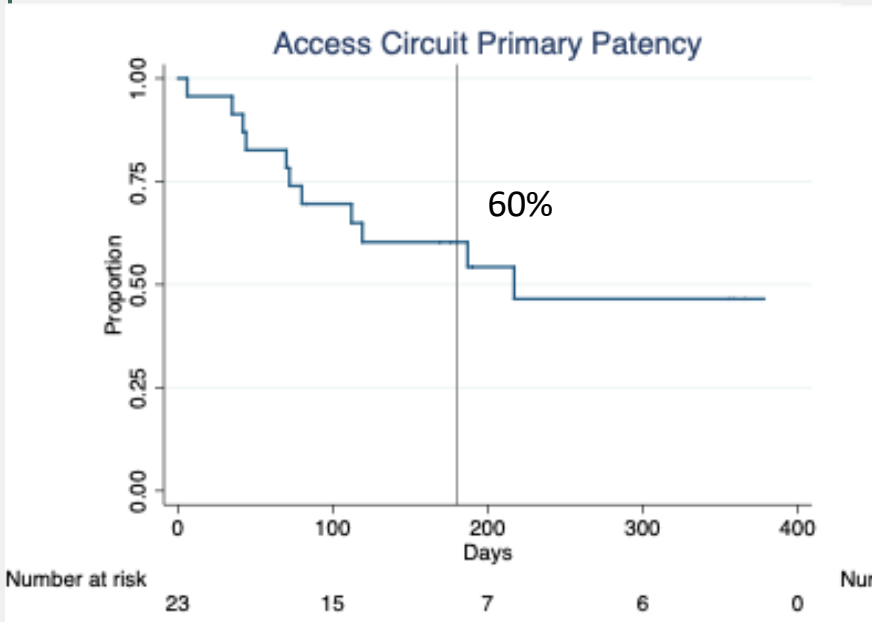
12-month ultrasound

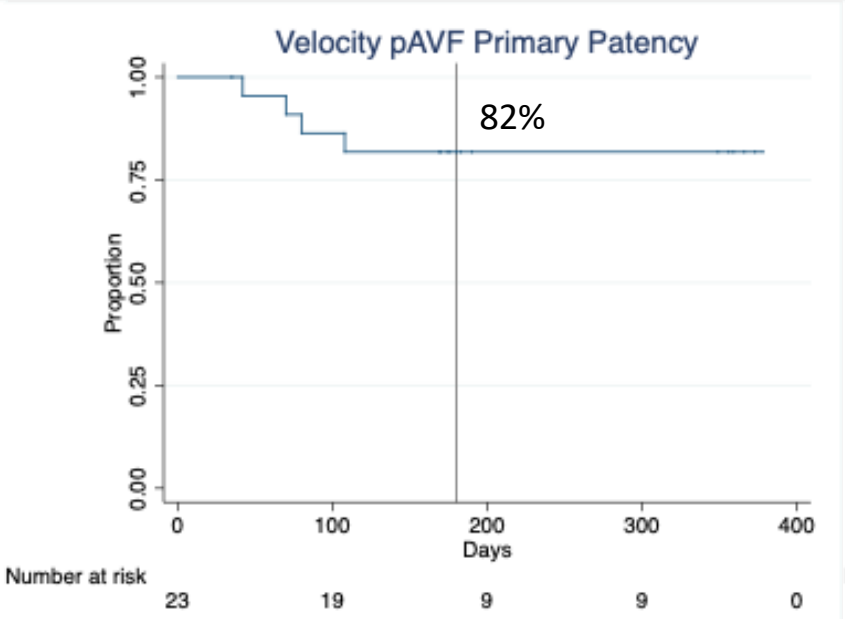


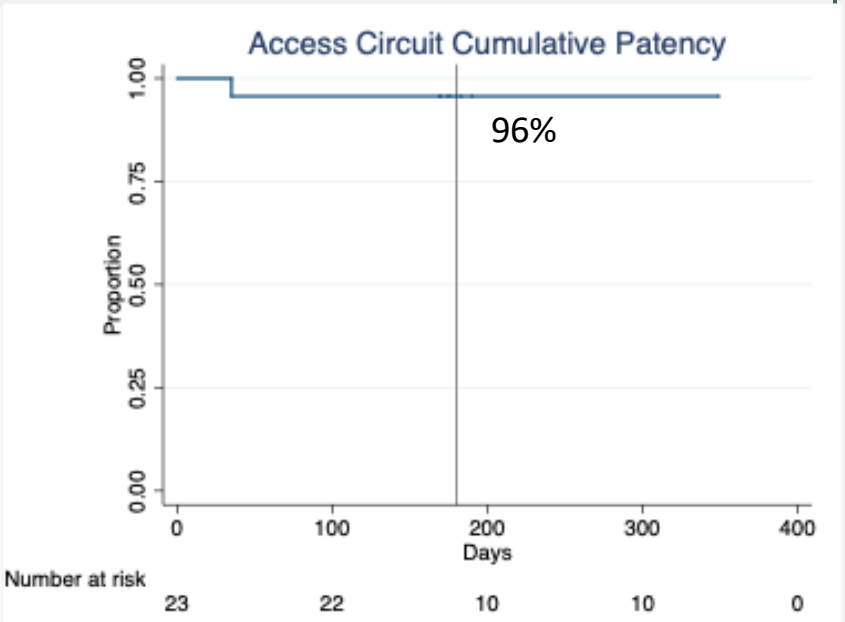


Reinterventions

- No coil embolization or reintervention aimed at brachial veins
- 11 subjects with median basilic vein ligation or embolization to direct basilic flow into the cephalic vein
- Two subjects incurred 36% of reinterventions, all related to cannulation zone and cephalic arch stenosis
- One subject with elective embolization of AVF to treat access related hand ischemia







U.S. Pivotal Trial – 2025

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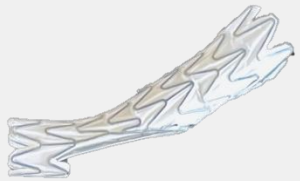
The VENOS – 3 Trial

126 subjects (39 enrolled)

14 sites across U.S.

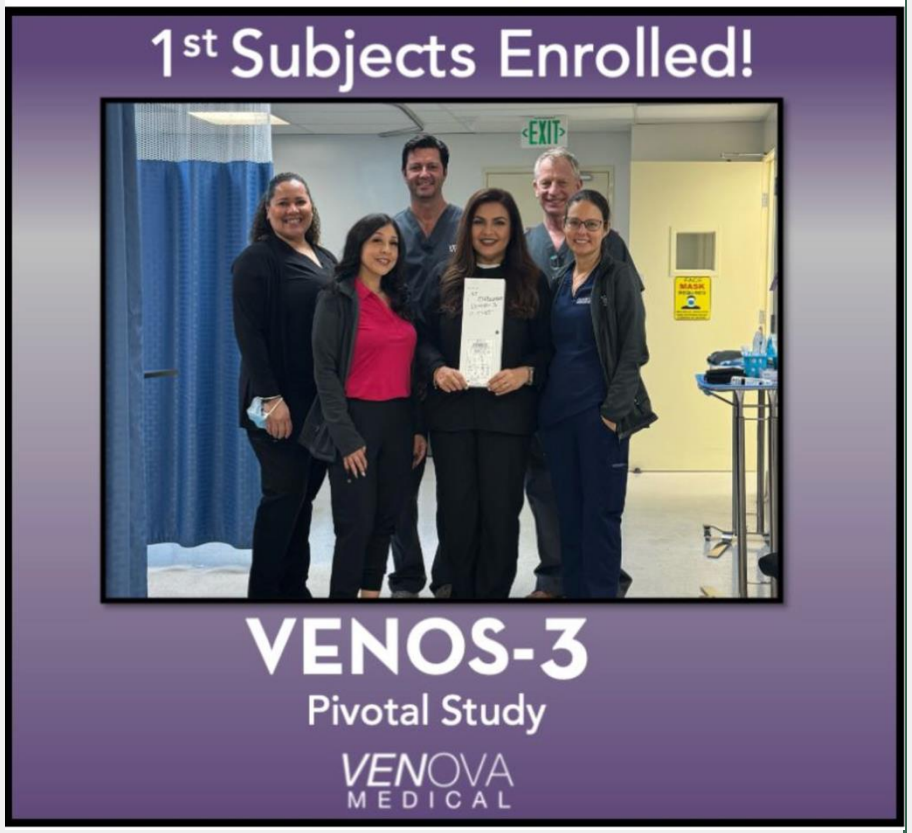
Enrolling started 10/2025





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1,544 followers
2d •

Congratulations to PI Dalia Dawoud, M.D. and the outstanding clinical research team at Apex Research of Riverside and Nephrology Associates Medical Group in Riverside, CA, on the successful initial enrollments in the VENOS-3 Pivotal Study of the Velocity pAVF System.
We're proud to partner with such a dedicated and talented group driving innovation in vascular access
research!
#pAVF #venovamedical #AVFistula #velocitypAVF #endoAVF #Venos #hemod



Velocity pAVF demonstrates

- Reliable maturation and cannulations
- Decreases TDC-contact in CKD patients
- No interventions targeting deep veins
- Most common reintervention was median basilic vein ligation

These findings to be further evaluated in the ongoing VENOS-3

multicenter pivotal trial in US

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Thank you!

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