Mass General Brigham

Initial Feasibility Study of SelfWrap-Assisted Arteriovenous Fistulas (SW-AVF) - A 54-Month Report

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Disclosures

Clinical Studies:

- Vascular Therapies (ACCESS-2 Trial)
- Humacyte (V-012 Trial)
- VenoStent (SAVE-FistulaS Trial)
- Voyager Biomedical (ACT II Trial)

Consulting/Advisory Board:

- BD-Bard, Humacyte, Laminate, Nephrodite, MeritMedial, Mozarc, Venova Medial, VenoStent

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Background

- AV access failure is commonly driven by **neointimal hyperplasia**
  - Manifests as **juxta-anastomotic stenosis**
  - Caused by **endothelial injury** and **disturbed hemodynamic flow**
    - Veins lack elasticity of artery to withstand high pressure and flow of arterial circulation (e.g. from AV access creation) without injury
- The **clinical** and **economic impact** is substantial:
  - Patients undergo **repeated procedures** & **prolonged CVC dependence** (causing infection/sepsis, adverse cardiovascular events, and mortality)
  - **>$3B** in direct Medicare spending annually related to AV access care

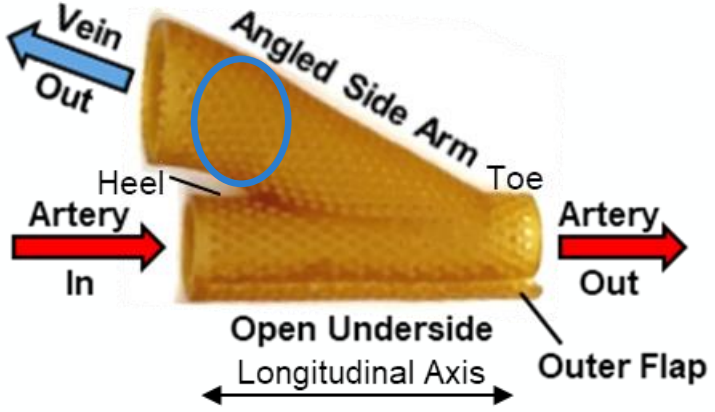
[a] Lee et al. JASN. 2019; 30(11): 2209–2218.
[b] Thamer et al. AJKD. 2018 Jul; 72(1): 10–18.

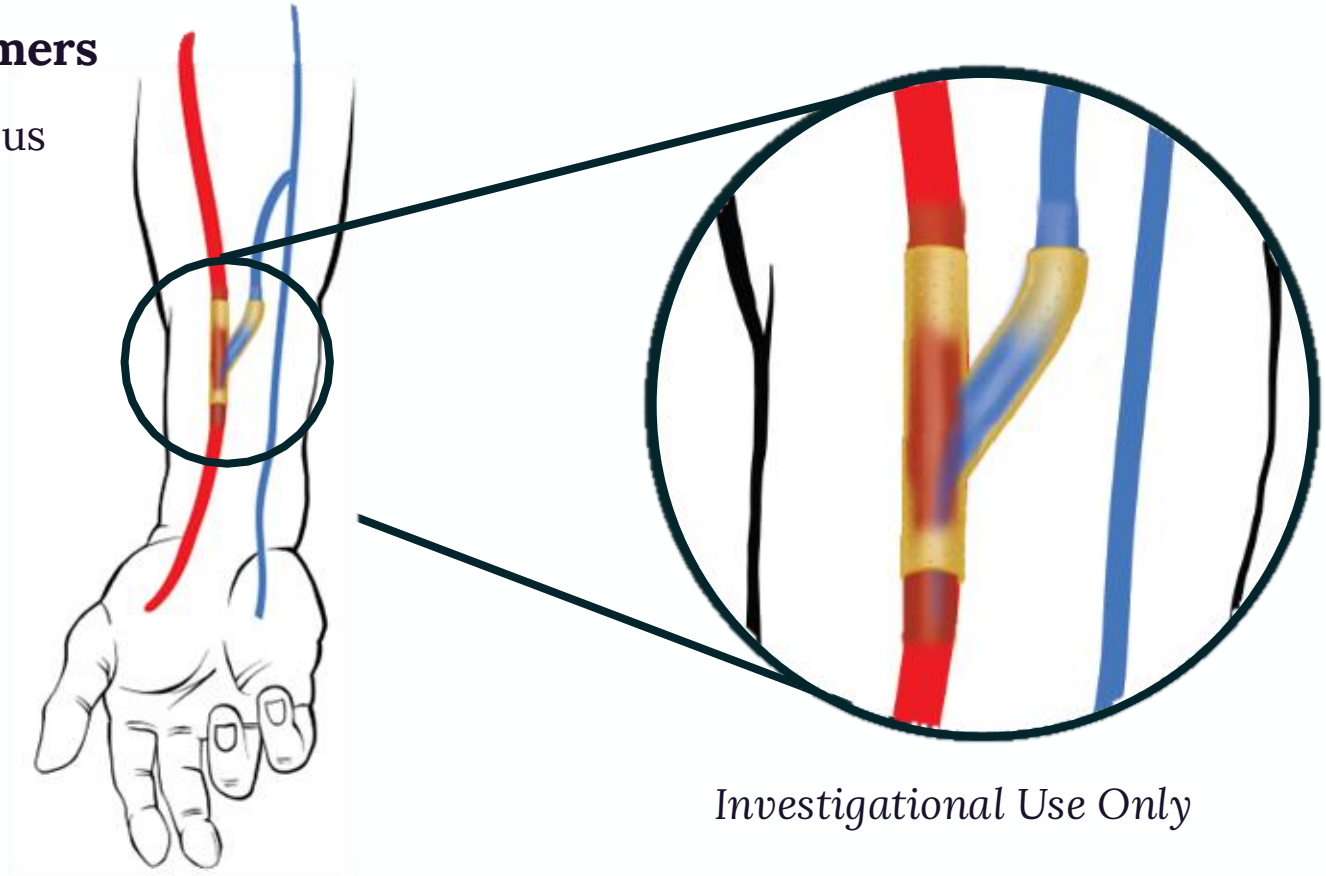
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SelfWrap® Bioabsorbable Perivascular Wrap – A Breakthrough Device

Vascular Wrap made of Bioabsorbable Polymers

- Provides mechanical support at arteriovenous fistula (AVF) anastomosis
- Regulates flow
- Promotes outward remodeling

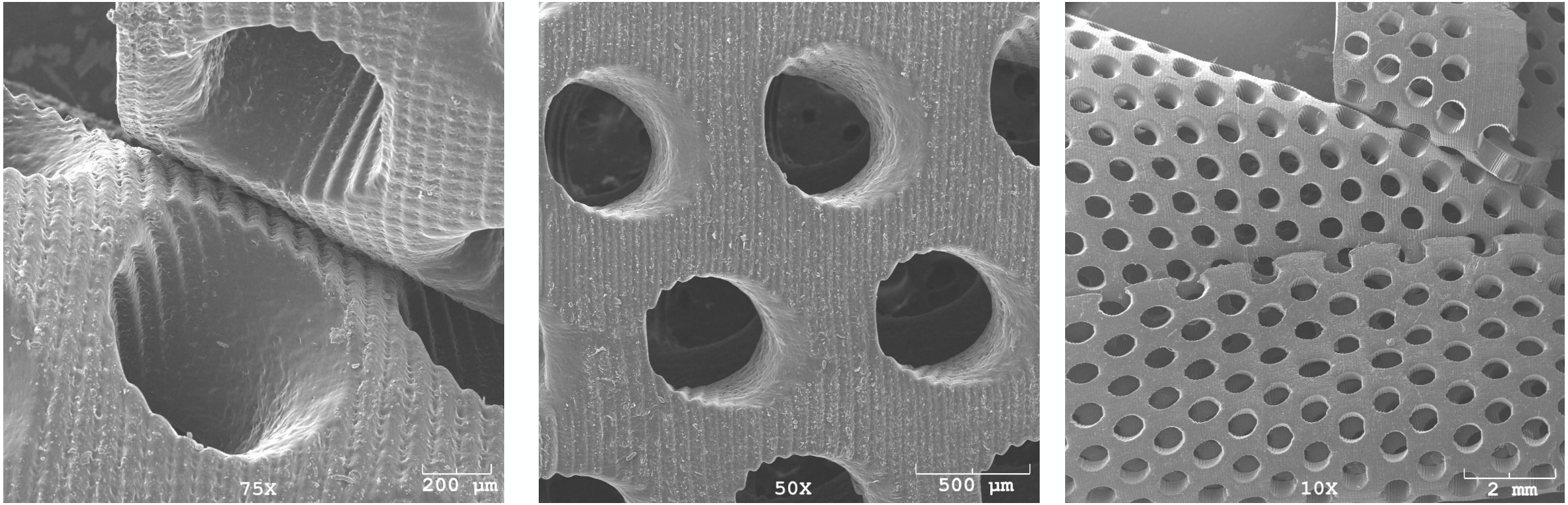




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3D-Printed, Slowly Absorbing, Macro-Porous Design



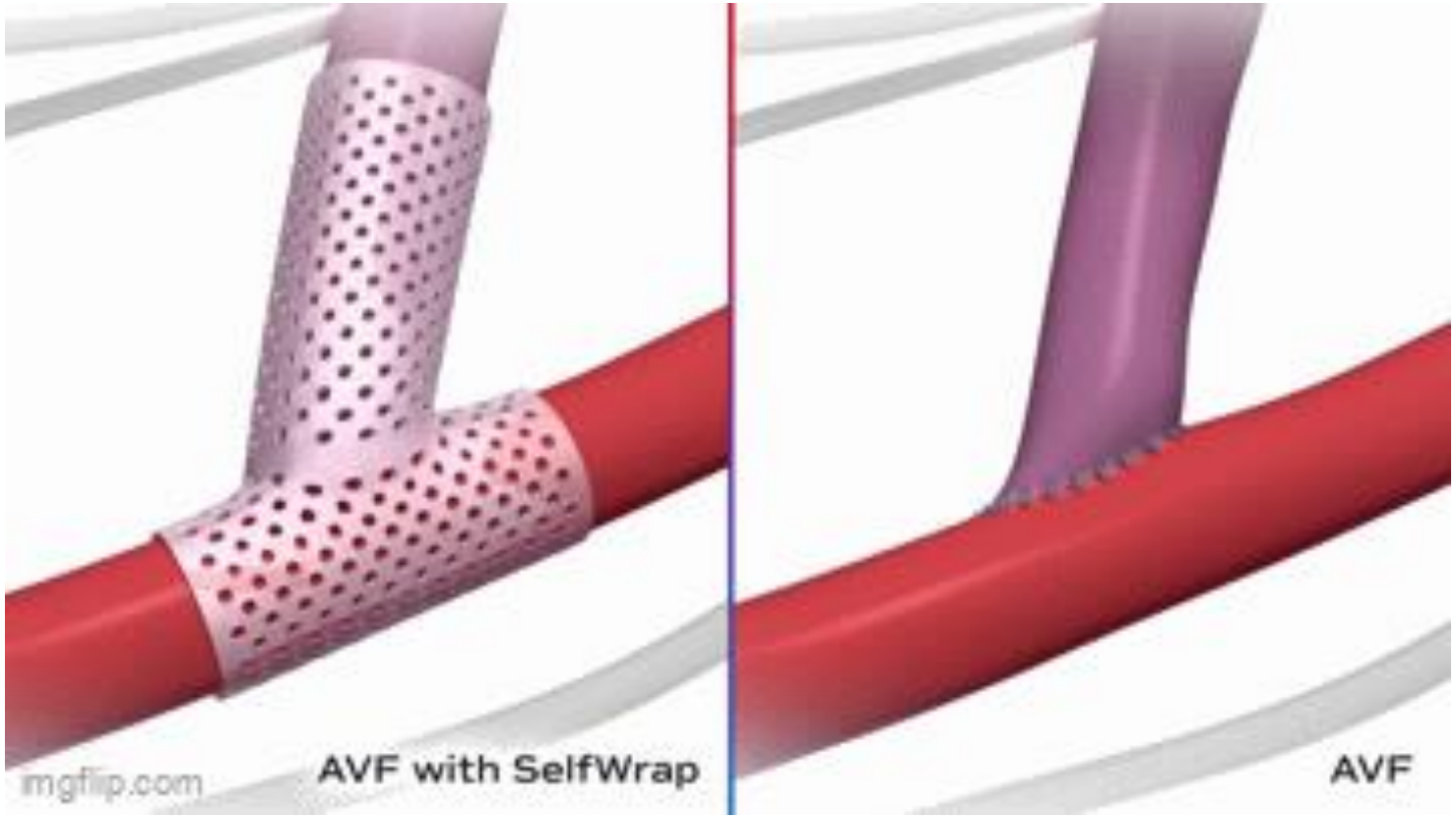
SEM images of layer-by-layer 3D printed devices

Porosity optimized in multiple animal models to **promote neovascularization** with minimal inflammatory response (hypothesized to **reduce neointimal hyperplasia**)

[c] Boire et al. J Biomed Mater Res A. 2021; 109(3): 272 – 288.
[d] Boire et al. Macromol Rapid Commun. 2016; 37(23): 1860 – 1880.

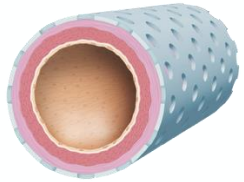
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SelfWrap: How it Works



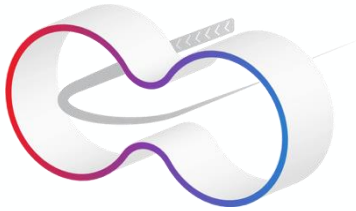
Biomimetic Mechanical Support

Trains vein to “behave” and “become” like an artery



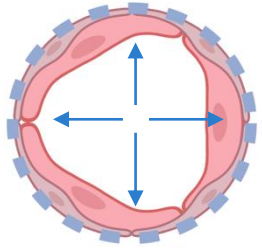
Regulated Flow

Results in less turbulence



Outward Growth

Vein wall remodels outward instead of inward

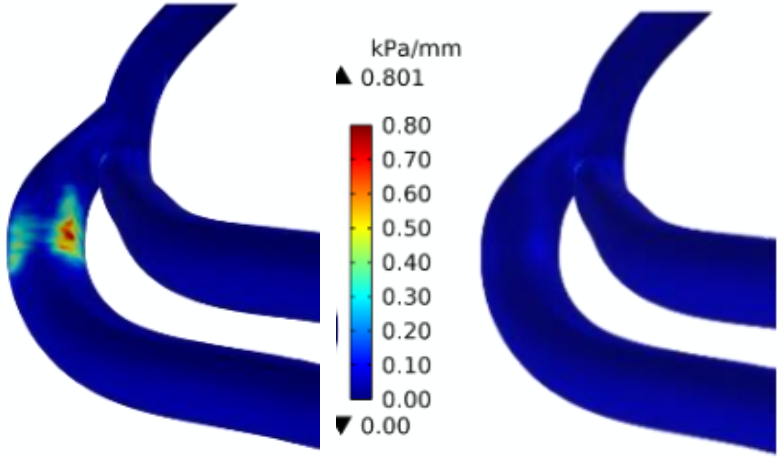


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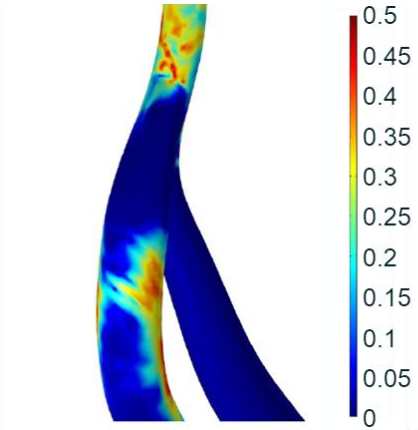
Mechanical Support Imparts Hemodynamic Benefits

Standard AVF **SelfWrap AVF**

Time-Averaged Wall Shear Stress Gradient (TAWSSG)



Oscillatory Shear Index (OSI)



Fluid-structure interaction computational fluid dynamic (FSI-CFD) modeling results demonstrate that SelfWrap:

- Modulates radial deformation and wall shear stress
- Reduces disturbed flow

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How SelfWrap is Implanted

1. Prior to anastomosis construction (and after vein mobilization), thread vein through SelfWrap



2. Prepare to suture vein to artery

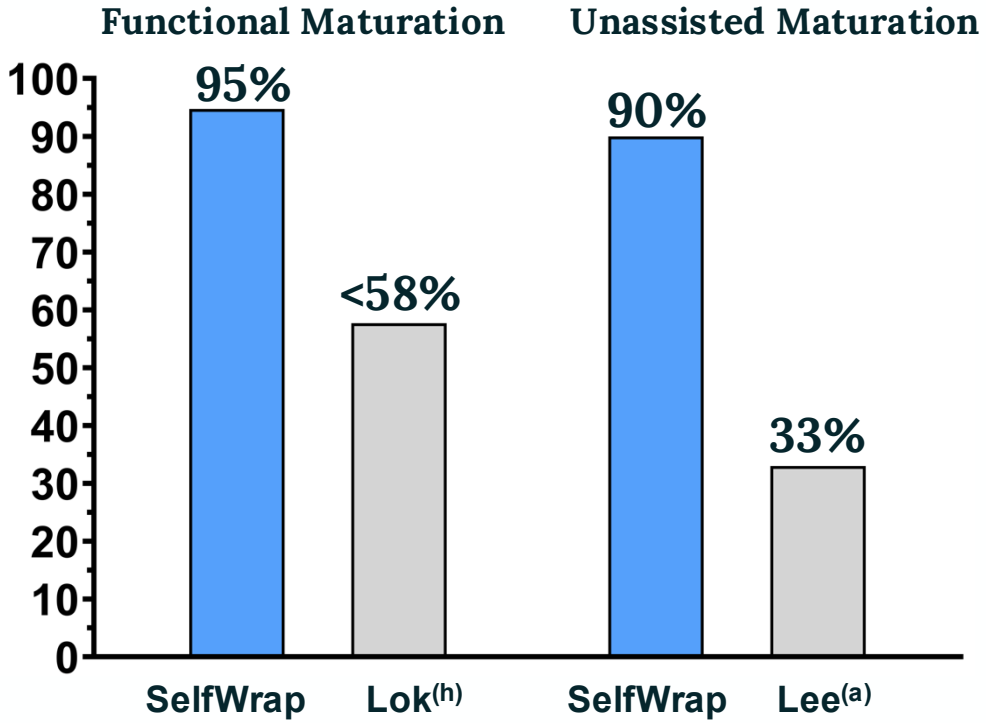
3. After constructing anastomosis, slide device down over AVF

4. With SelfWrap positioned around the AVF, close incision

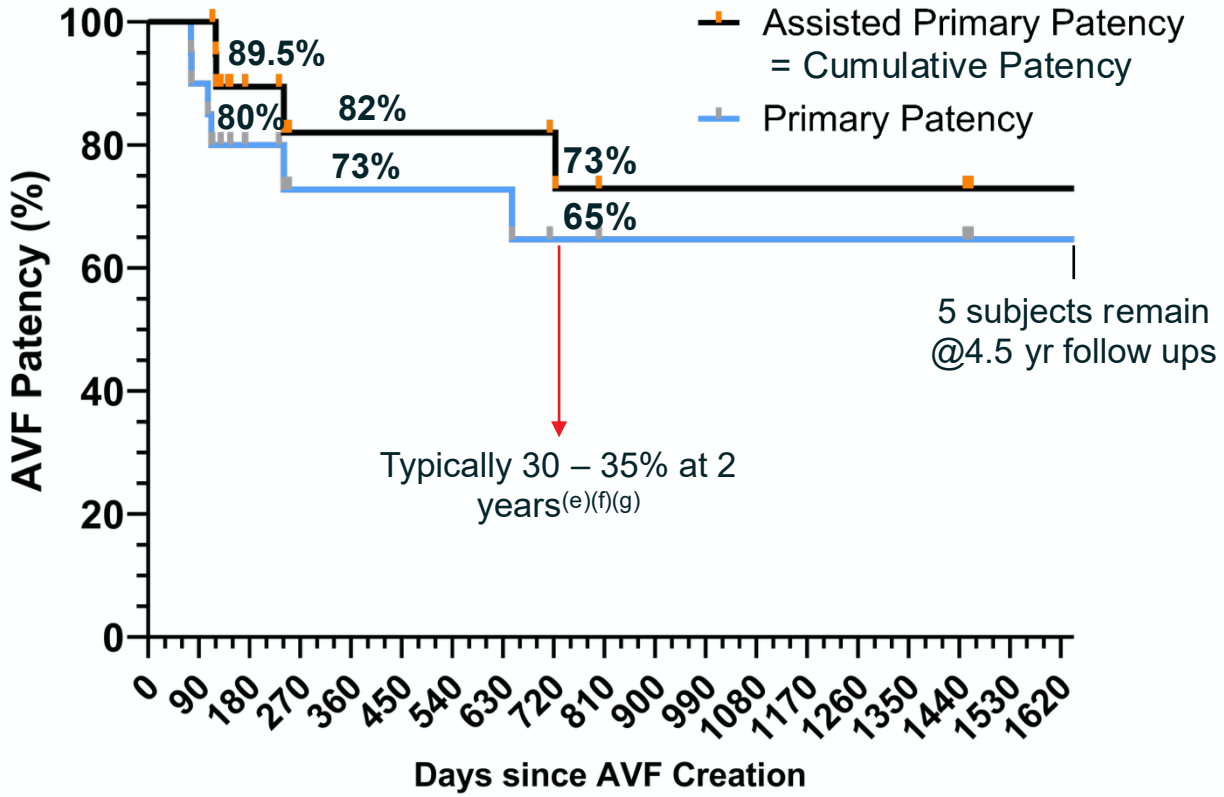
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High Maturation and Patency in SW-AVF Feasibility Study

N = 20, Single-center, Single-arm (75% Brachial-Based, 25% Radiocephalic) NCT05418816



Median Time to Cannulation: 59 days

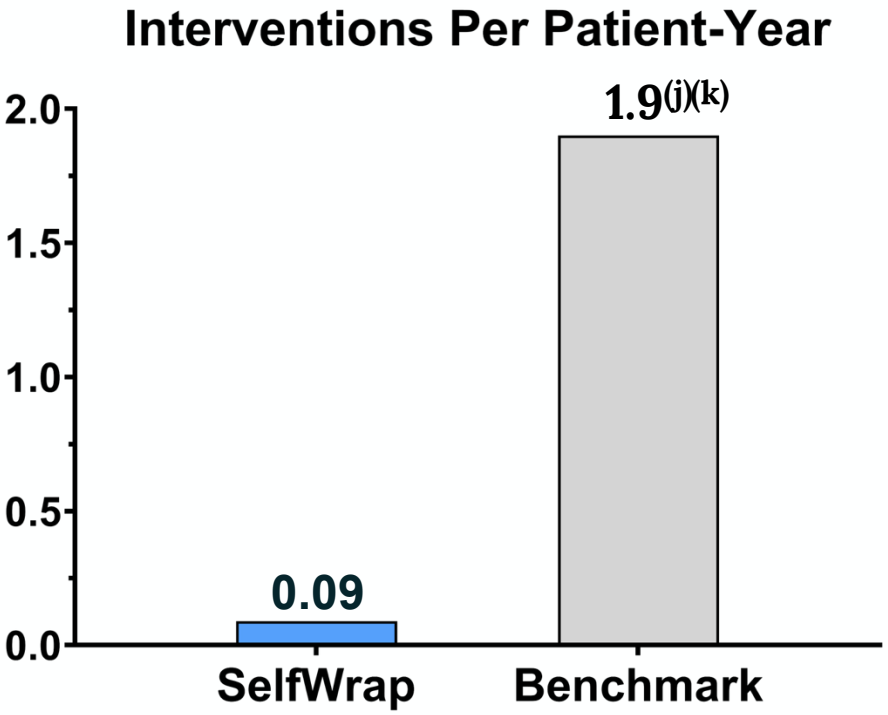


(h) Lok et al. J Am Soc Nephol. 2006; 17: 3204 - 3212.
(a) Lee et al. JASN. 2019; 39(11): 2209 – 2218.

(e) USRDS, 2021; (f) Al-Jaishi et al., 2014. AJKD. 63(3); (g) Peden et al., 2022. J Vasc Access. 23.

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Low Rate of Interventions with SelfWrap



- 4 Total Interventions
  - 3 PTA for juxta/anastomotic stenosis (2 for pre-/non-mature AVFs)
  - 1 surgical revision + stent for upper arm cephalic vein stenosis
- 0.09 interventions per patient year (PPY)
  - Compared to 1.9 interventions PPY for standard of care(j)(k)

Through > 4.5 years, no adverse events probably or definitely related to the device

(j) Litchfield et al. Endovascular Today. 2019; 18:64–66.
(k) Lok et al. JASN. 2019 Nov; 30(11):2040-2042.

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SAVE-FistulaS

Trial Update as of April 30th, 2026

SAVE-FistulaS RCT Design

Design:

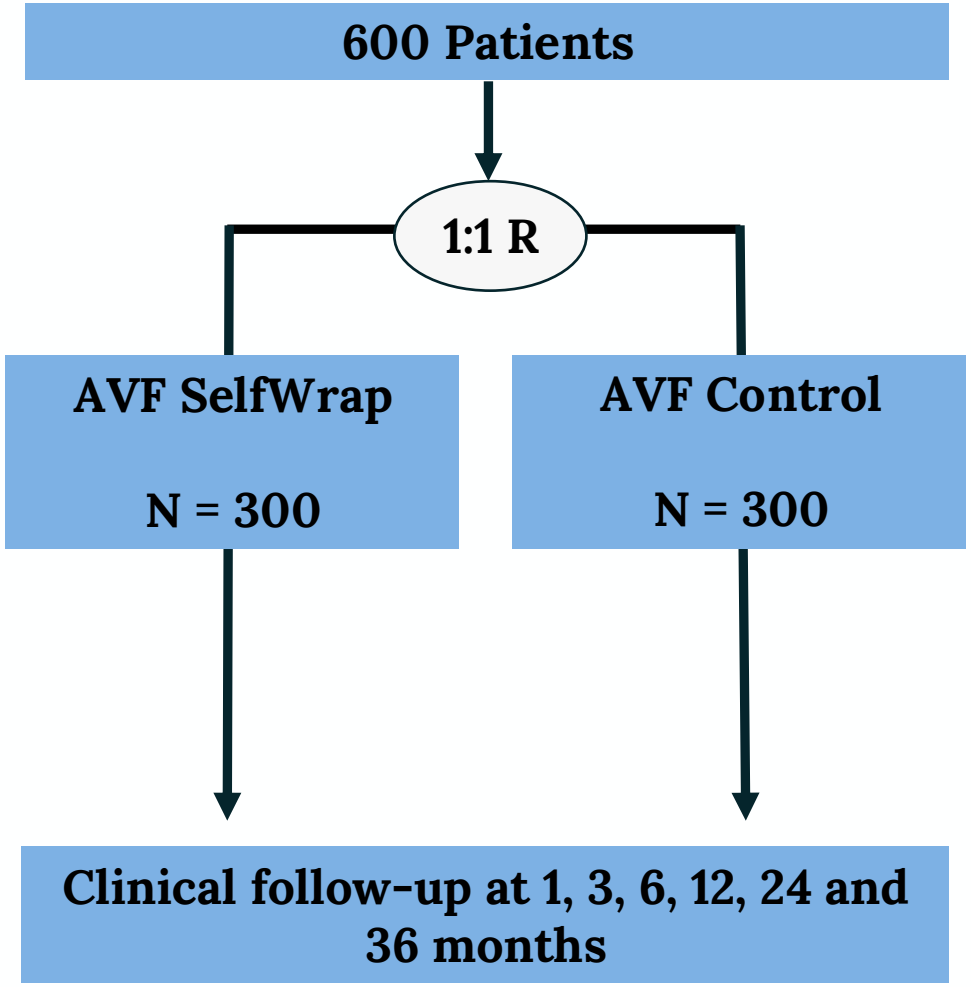
- Prospective, multi-center, 1:1 randomized, double-arm, single-blind study for CKD/ESKD patients undergoing AVF creation
- ~30 sites. NCT06001827. SAVE-FistulaS RCT

Patients:

- New cephalic-based AVF (≥ 1/3rd radiocephalic AVF)
- ≥ 2/3rd on hemodialysis at randomization

Primary Efficacy Endpoint:

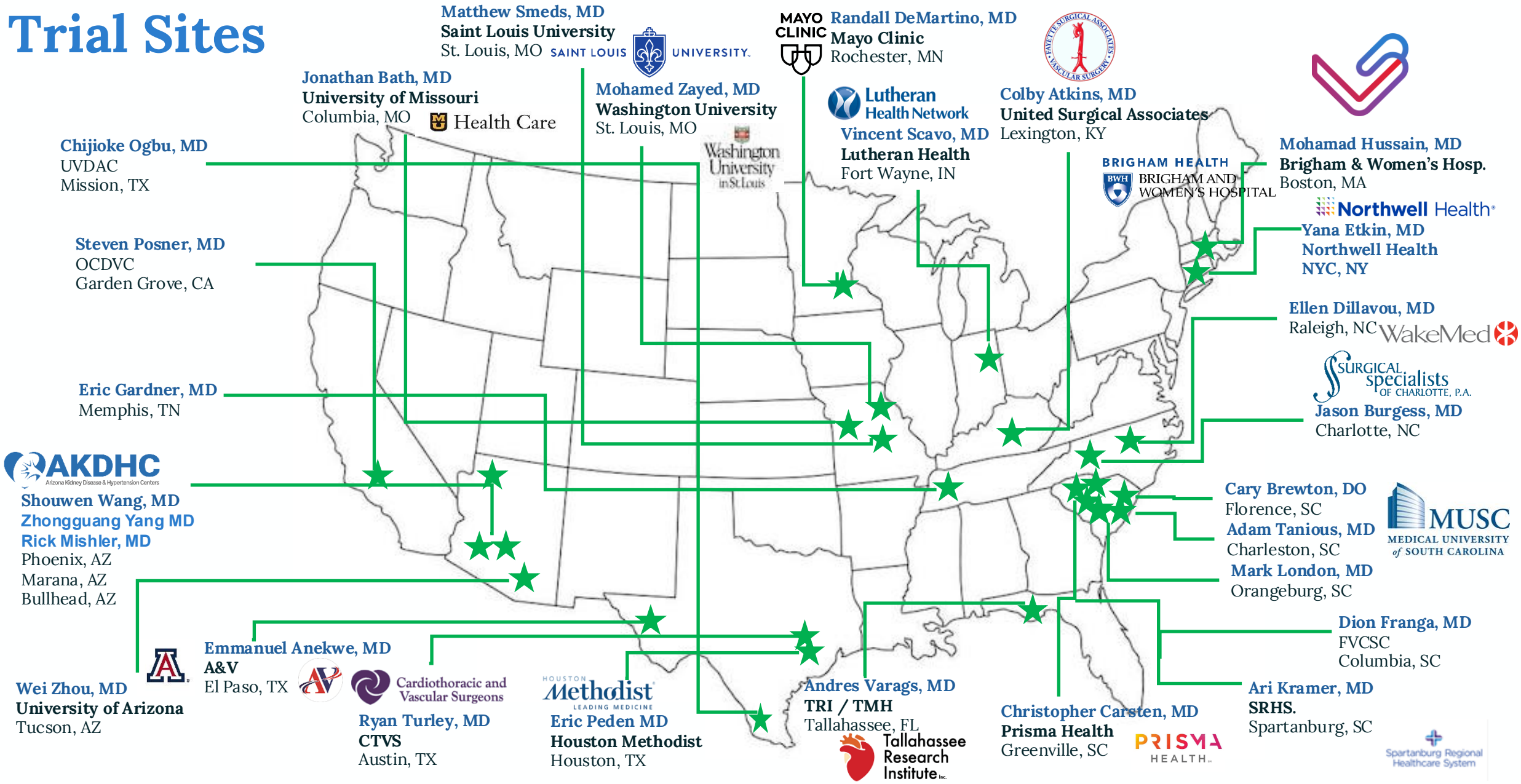
- Unassisted Maturation by **180 days**



NIH **Funded in part by NIH SBIR Phase II Award #2R44HL151025-02A1**

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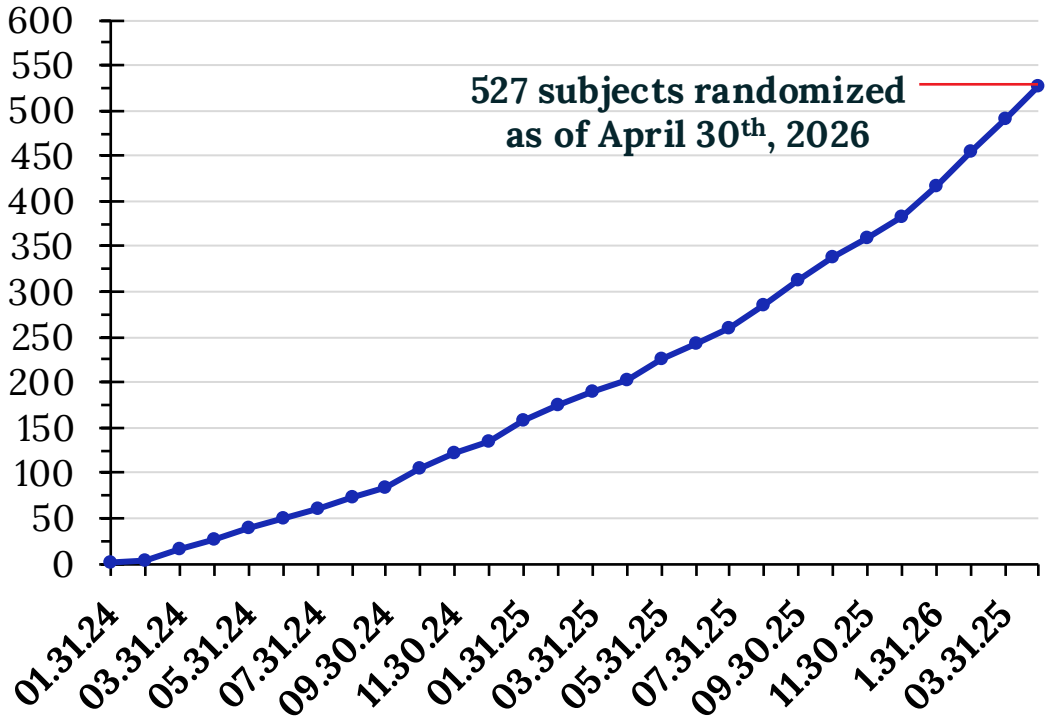
Trial Sites



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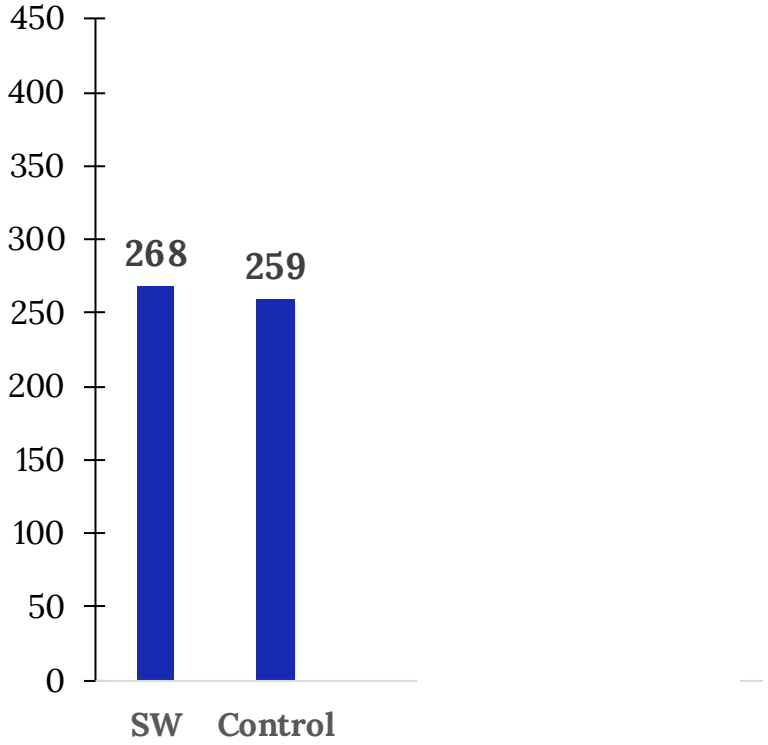
Enrollment Nearly Completed; No Concerning Safety

Cumulative Enrollment



Anticipated Enrollment Completion: *2026*

Baseline Characteristics



DSMB recommended the trial to continue w/o changes upon review of 350-subject safety data

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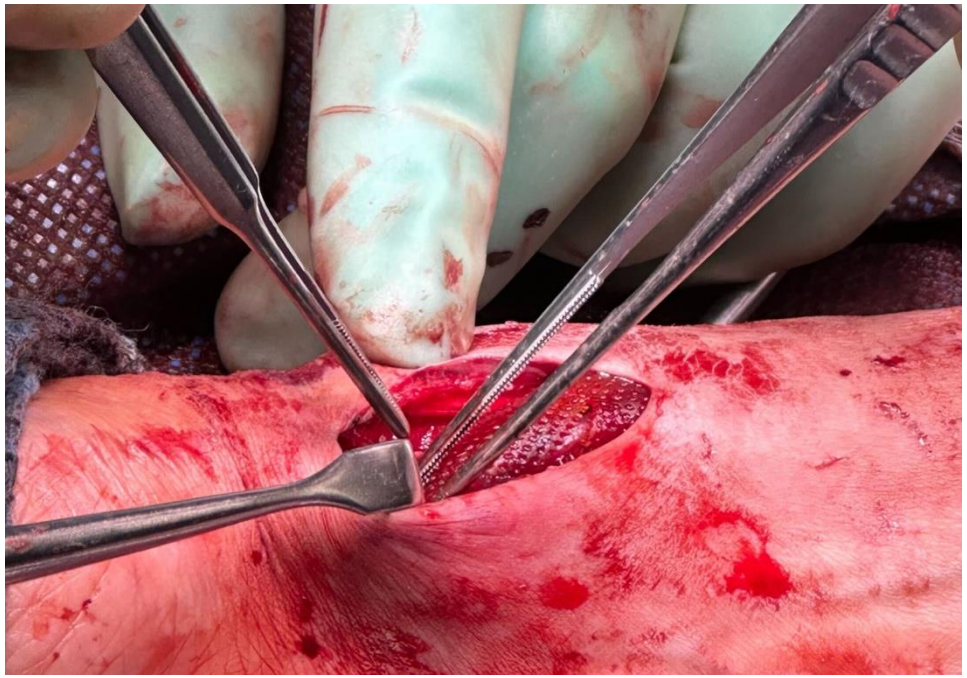
Summary

- **SelfWrap is a novel bioabsorbable technology to potentially improve AVF performance via:**
  - Artery-like mechanical support
  - Regulation of flow / shearstress
  - Limited neointimal proliferation and promotion of outward remodeling via neovascularization

- **Feasibility data demonstrates safety and early effectiveness of SelfWrap up to 4 years:**
  - High maturation and patency, with low intervention rates
  - No significant adverse events related to the device

- **SAVE-FistulaS is a large 600 patient RCT that is testing the safety & effectiveness of SelfWrap**
  - No safety issues upon 350-subject review by DSMB; Enrollment completion anticipated in 2026
  - Has the potential to positively impact care of CKD/ESKD patients requiring dialysis access

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THANK YOU!