# VasQ U.S. Post-Market Study Initial Results from an ASC

Dion Franga, MD

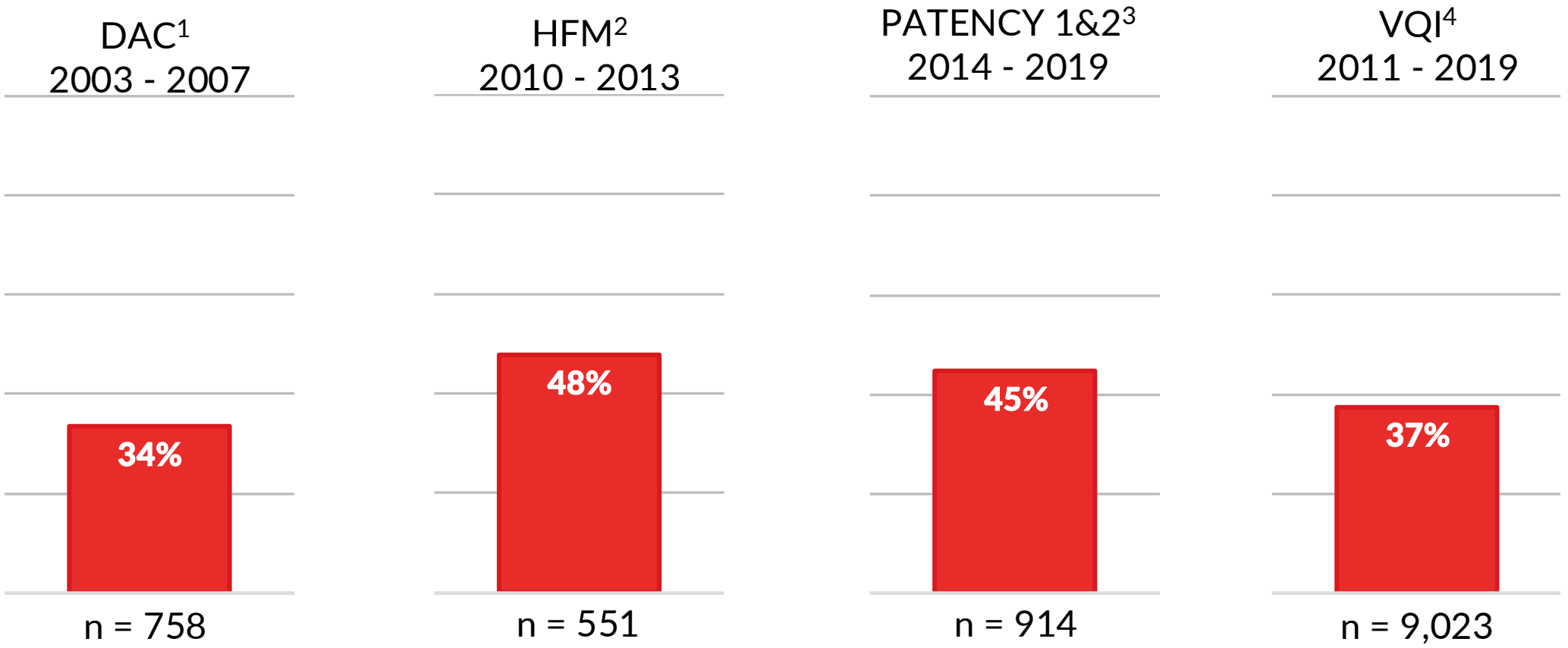
South Carolina Surgical, PA
Orangeburg, SC

Vascular Care of South Carolina
Columbia, SC

VASCULARCARE of South Carolina

# Have we Improved *Unassisted* Functional Success since DAC?

Six Month Unassisted Functional Success* from U.S. Studies




*Confirmed AVF use for dialysis via 2-needle cannulation without the need for maturation procedures

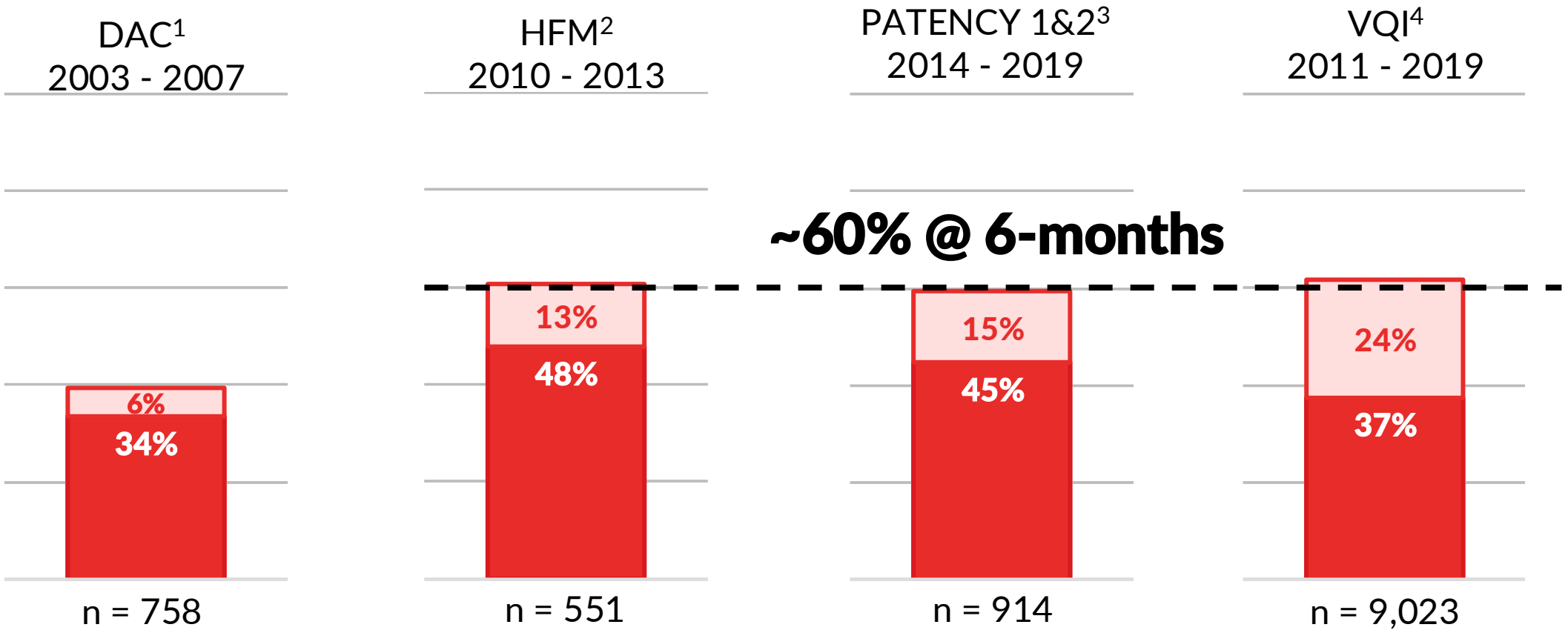

1. Dember et al. JAMA 2008;299(18):2164-2171
2. Allon, et al. Am J Kidney Dis 2018;71(5):677-689
3. Heindel et al. Annals of Surgery 2022 Aug 23;3(3):e199
4. Lopez et al. J Vasc Surg 2026 Jan 28:S0741-5214(26)00054-6.


Unassisted

VASCULARCARE of South Carolina

# Have we Improved *Assisted* Functional Success since DAC?

Six Month Assisted Functional Success* from U.S. Studies




*Confirmed AVF use for dialysis via 2-needle cannulation regardless of maturation procedures

Assisted
Unassisted


1. Dember et al. JAMA 2008;299(18):2164-2171
2. Allon, et al. Am J Kidney Dis 2018;71(5):677-689
3. Heindel et al. Annals of Surgery 2022 Aug 23;3(3):e199
4. Lopez et al. J Vasc Surg 2026 Jan 28:S0741-5214(26)00054-6.

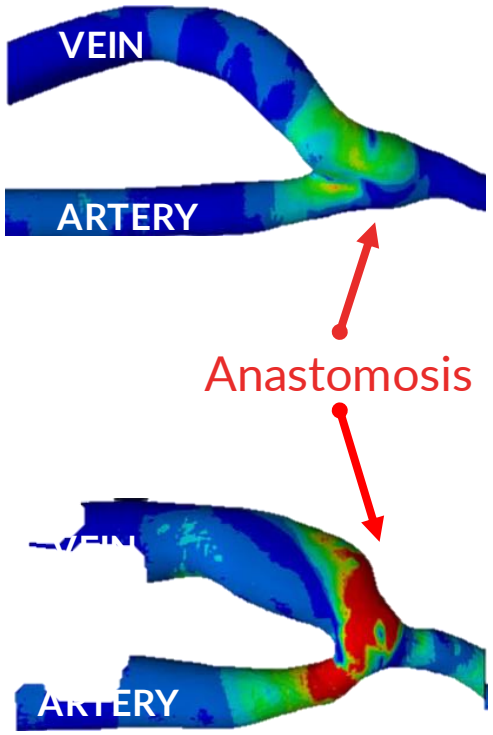

VASCULARCARE of South Carolina

# Unpredictability of Native AVF Creation

## Longitudinal MRI Geometric & Hemodynamic AVF Study[1]

### Fistula Creation

**Unsupported**

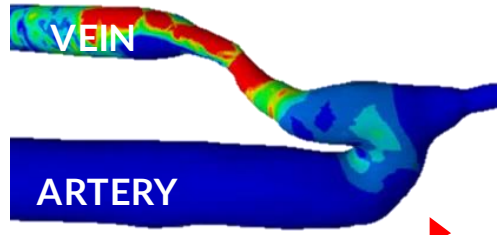



### Factors of Failure

- ✓ **Increased** wall tension [2]
- ✓ **Altered** configuration[1]
- ✓ **Unstable** flow prolfe[1]

### 1-year Post-Creation

**Stenotic**




**Aneurysmal**




Anastomosis

MRI-based flow models from Bozzetto 2022[2]

Time Average Wall Shear Stress (dyne/cm²)

0 500

1. Bozzetto et al. J Vasc Access 2022 (online ahead of print)
2. Owens et al. J Vasc Surg 2015;61(1):203–216

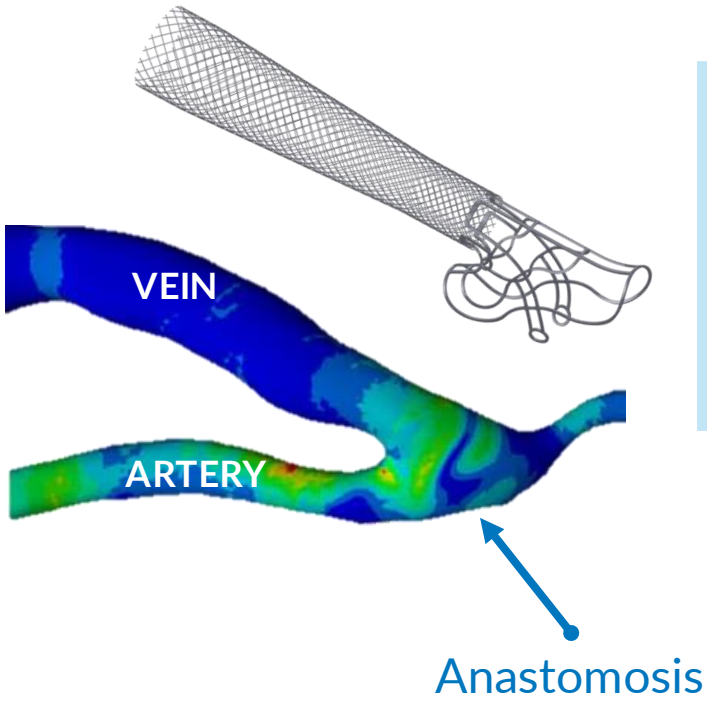
VASCULARCARE of South Carolina

# Extravascular Supported AVF Creation

## Longitudinal MRI Geometric & Hemodynamic AVF Study[1]

### Fistula Creation

VasQ™ Supported

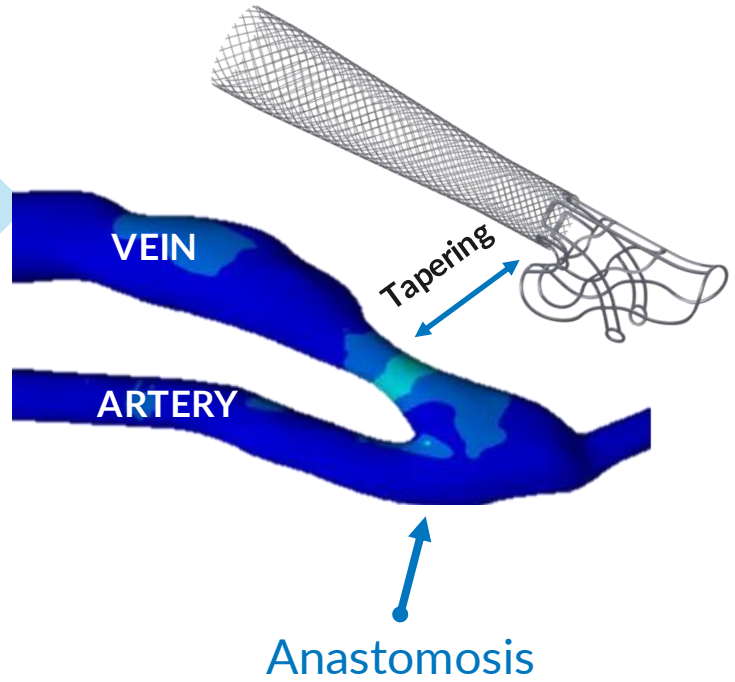



## Benefits of Support

- ✓ **Structural** reinforcement[2]
- ✓ **Retained** configuration[1]
- ✓ **More** stable flow[1]

### 1-year Post-Creation

**Open and Functional**




**MRI-based flow models from Bozzetto 2022[2]**

**Time Average Wall Shear Stress (dyne/cm²)**

0 — 500

1. Bozzetto et al. J Vasc Access 2022 (online ahead of print)
2. Owens et al. J Vasc Surg 2015;61(1):203–216

VASCULARCARE of South Carolina

# Extravascular Supported AVF Creation

## Implanted at Time of AVF Creation

### 1. Select VasQ Model Size



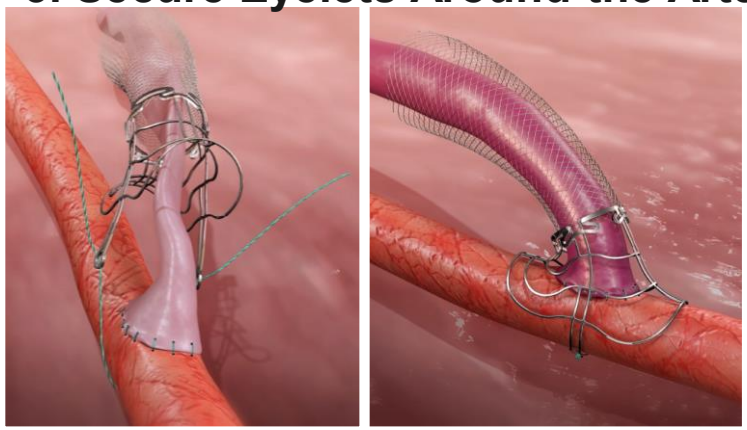

A disposable sizing tool gauges vessel diameter once surgically exposed to select one of six VasQ models

### 2. Slide Device Around Vein



VasQ is introduce with forceps and slide over the vein once dissected. VasQ is kept proximal under the skin flap while the anastomosis is created in the usual fashion.

### 3. Secure Eyelets Around the Artery



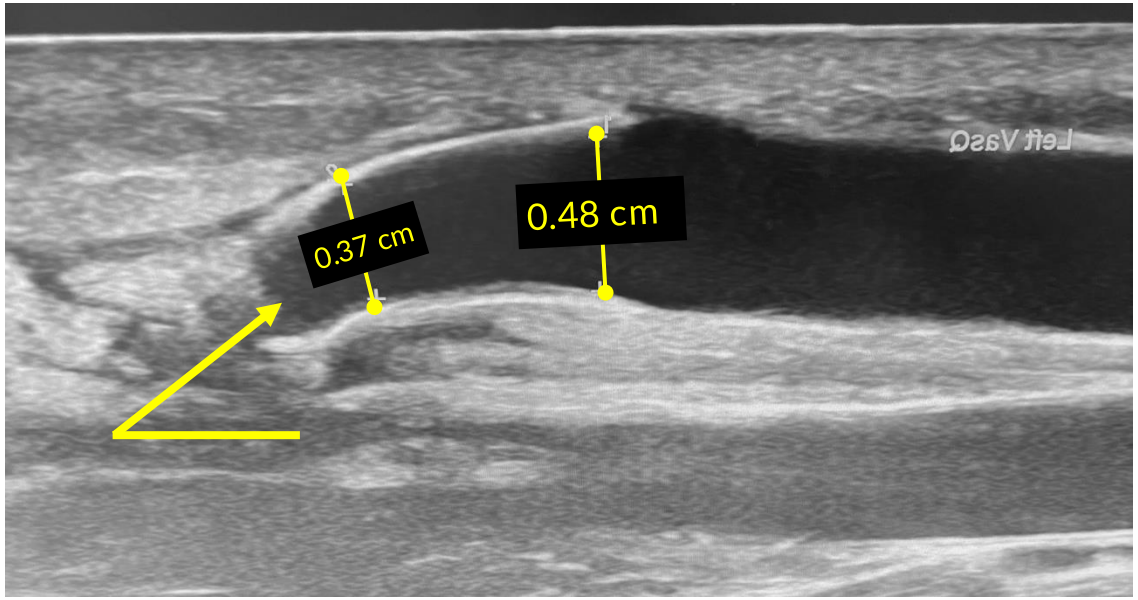
Once the anastomosis is created, slide VasQ into position over the artery. The eyelets wrap around the artery and are secured to each other with proline

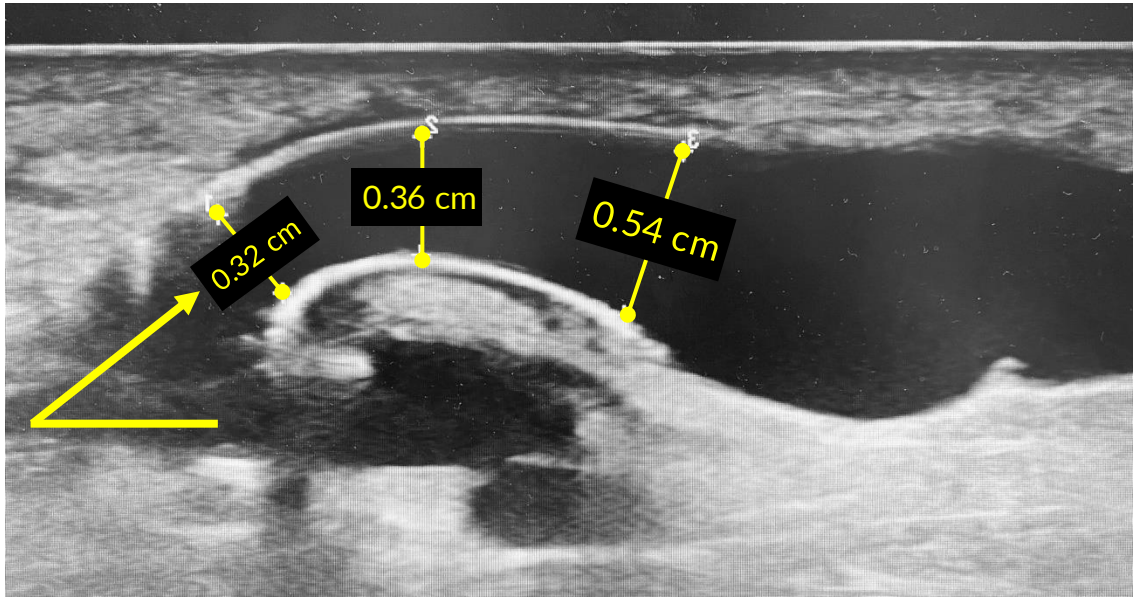
Hussain et al. JVS-Vascular Insights 2025;3:100205

VASCULARCARE of South Carolina

# Tapered Transition and Retained Anastomotic Configuration

Mature VasQ AVFs under ultrasound




**Tapered Transition**

From the level of the brace to the end of the braid

**Retained Anastomotic Configuration**

The brace holds the anastomotic configuration while the braid conforms to the natural position of the vein

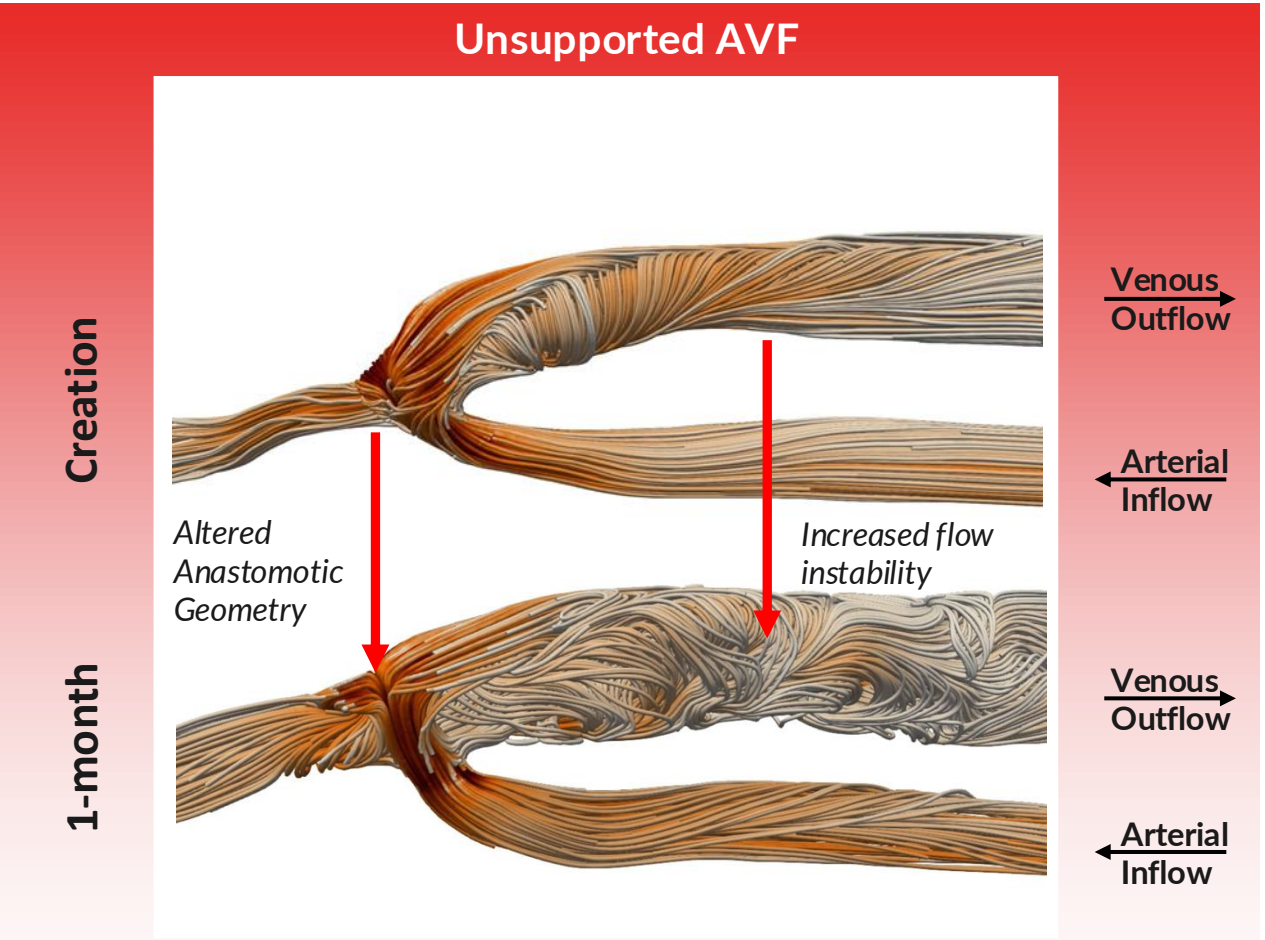
VASCULARCARE of South Carolina

Images courtesy of Robert Shahverdyan

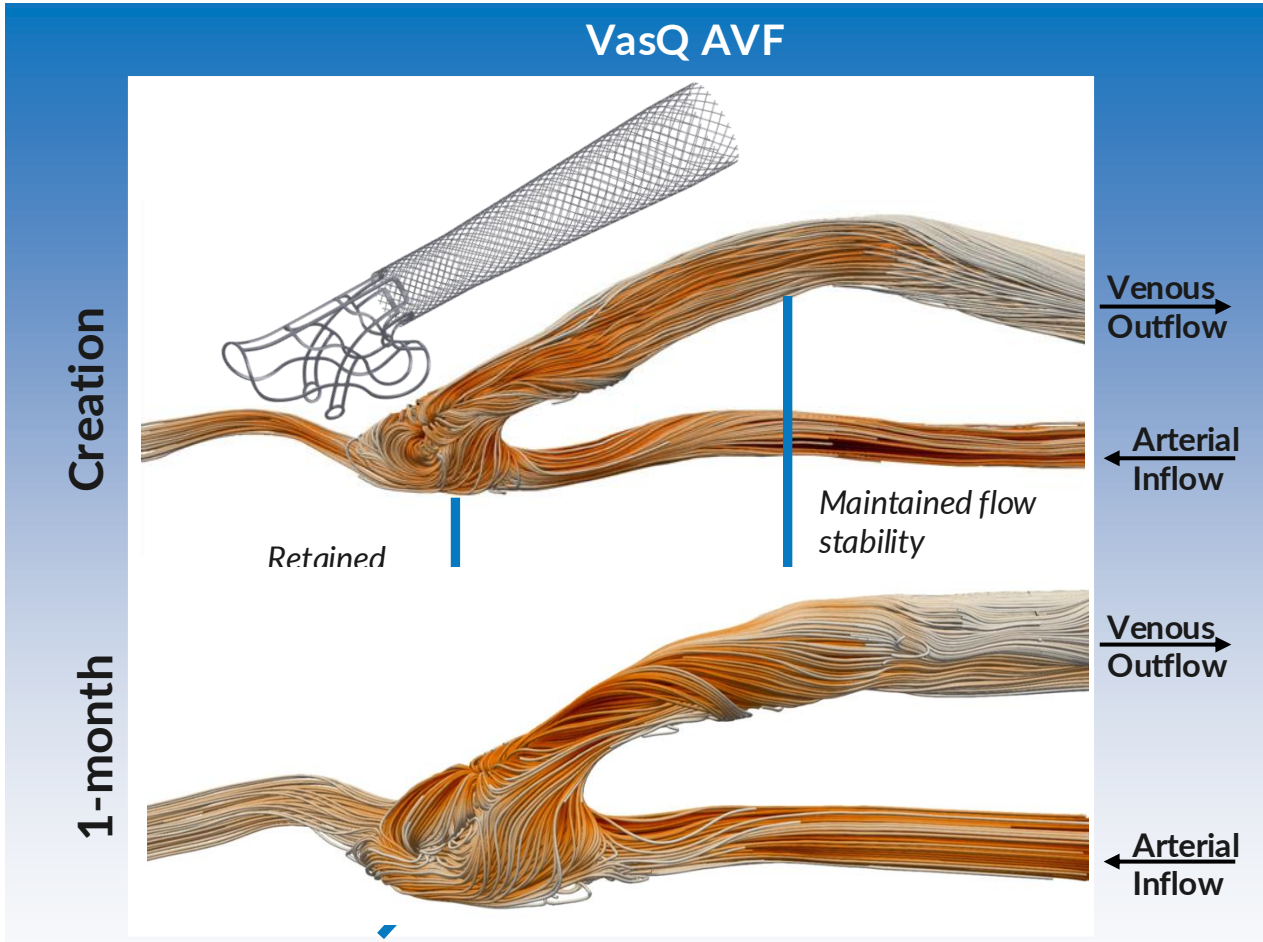
# VasQ Supports Maturation into Optimized Geometry for More Stable Flow

## CFD Analysis of Longitudinal MRIs from RCF Patients

### Unsupported AVF




### VasQ AVF



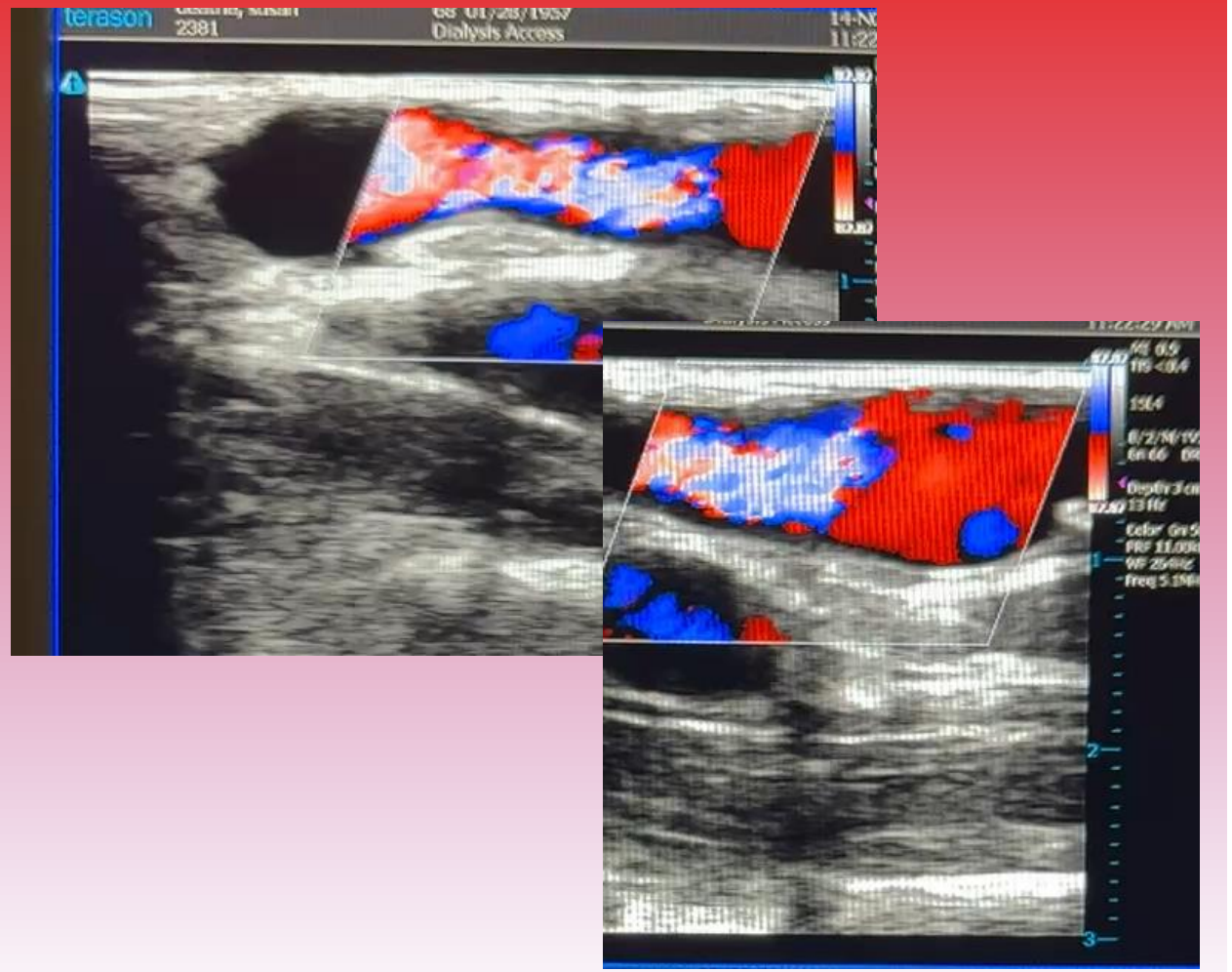

*Tapered transition of flow created by VasQ*

VASCULARCARE of South Carolina

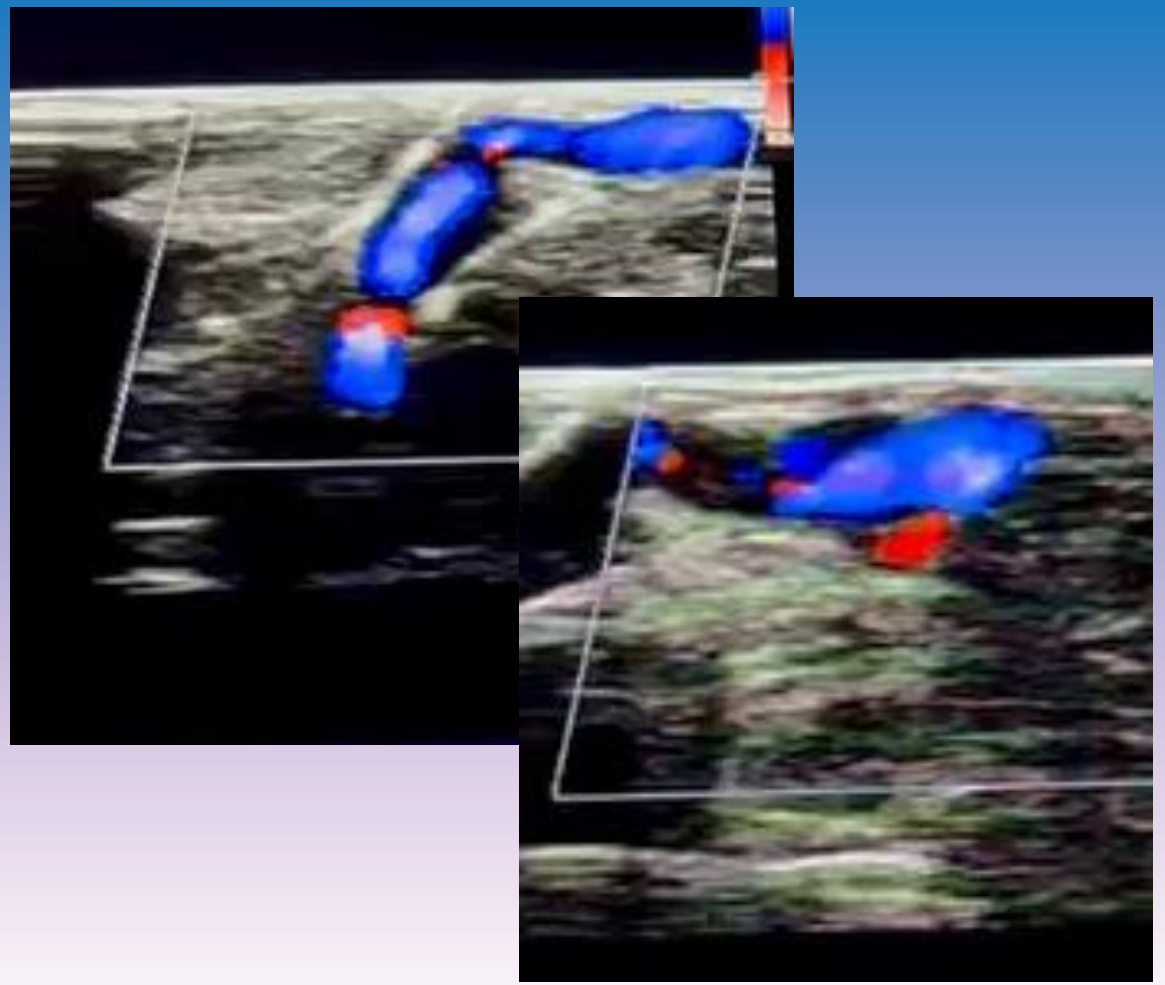
# VasQ Supports Maturation into Optimized Geometry for More Stable Flow

## Real World Examples of VasQ Impact on Geometry and Flow

### Unsupported Basilic AVF



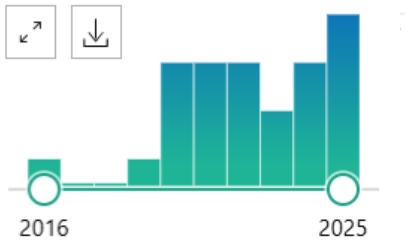

### VasQ Supported Basilic AVF at 1-year



VASCULARCARE of South Carolina

Videos courtesy of Dr. George Blessios

RESULTS BY YEAR




Associated data

ARTICLE TYPE

- Books and Documents
- Case Reports
- Clinical Trial
- Meta-Analysis
- Randomized Controlled Trial
- Review
- Systematic Review

See all article type filters

Additional filters +

Clear applied filters

Reset filters menu

1 Cite
Arteriovenous **fistula** creation with **VasQ**(TM) device: A feasibility study to reveal hemodynamic implications.
Bozzetto M, Soliveri L, Poloni S, Brambilla P, Curtò D, Condemi GC, Cefali P, Spina I, Villa A, Caroli A, Ramuzzi A.
J Vasc Access. 2024 Jan;25(1):60-70. doi: 10.1177/11297298221087160. Epub 2022 Apr 22.
PMID: 35451351 Free PMC article. Clinical Trial.
Increasing evidence suggests that the presence of turbulent-like flow may play a key role, therefore, to stabilize the flow in the venous segment, an external support device (**VasQ**(TM)) has been designed. The aim of this study was to provide preliminary evidence of **VasQ** ...
Open Access Sign In

2 Cite
Arteriovenous **fistula** construction with the **VasQ** external support device: a pilot study.
Chemla E, Velazquez CC, D'Abate F, Ramachandran V, Maytham G.
J Vasc Access. 2016 May 7;17(3):243-8. doi: 10.5301/jva.5000527. Epub 2016 Apr 14.
PMID: 27079670 Free article. Clinical Trial.
DESIGN, SETTING, PARTICIPANTS AND MEASUREMENTS: A single institution study of **VasQ** use was conducted with placement of the device in patients undergoing a brachiocephalic **fistula**, followed for 6 months. The **VasQ** was available in three sizes and was deployed e ...
Open Access Sign In

3 Cite
Implanted blood vessel external support device (**VasQ**) for creation of hemodialysis arteriovenous **fistula**: A single-center experience.
Leonardi G, Campagna M, Pellicanò V, Guarena C, Bergamo D, Lavacca A, Fop F, Biancone L.
J Vasc Access. 2021 Jul;22(4):658-665. doi: 10.1177/1129729820971533. Epub 2020 Nov 12.
PMID: 33183181
INTRODUCTION: the external support device **VasQ** is intended to promote arteriovenous **fistula** (AVF) maturation by maintaining the optimal anastomotic angle in order to minimize blood flow disturbances around the anastomotic area. The aim of the study is to assess effi ...
LitStream Sign In

4 Cite
**VasQ** U.S. pivotal study demonstrates the safety and effectiveness of an external vascular support for arteriovenous **fistula** creation.
Dillavou ED, Lucas JF, Woodside K, Burgess J, Farber A, Hentschel D, Ozaki CK.
J Vasc Surg. 2023 Nov;78(5):1302-1312.e3. doi: 10.1016/j.jvs.2023.07.054. Epub 2023 Jul 30.
PMID: 37527689 Free article.
Successful two-needle cannulation for patients that entered the study on dialysis was achieved in 88% of **VasQ** AVFs at a median of 56 days. Pre-dialysis patients who initiated dialysis during the study achieved two-needle cannulation in 81.6% **VasQ** AVFs. ...CONCLUSION ...
Open Access Sign In

5 Cite
Hemodynamic impact of **VASQ** device in vascular access creation.
Palumbo R, Dominijanni S, Centi A, D'Urso G, Tatangelo P, Floccari F, Smedile G, Niscola P, Londrino F, Di Daniele N.
J Vasc Access. 2022 Jan;23(1):105-108. doi: 10.1177/1129729820983153. Epub 2020 Dec 21.
PMID: 33349129
The aim of the study was to evaluate the impact on hemodynamic of the **VasQ** device in arteriovenous **fistulae** creation. METHODS: The analysis included patients who underwent to **fistula** creation with or without implantation of the **VasQ** device between May ...
LitStream Sign In

6 Cite
Initial single-center experience with a new external support device for the creation of the forearm native arteriovenous **fistula** for hemodialysis.
Benedetto F, Spinelli D, Derone G, Cutrupi A, Barilla D, Pipitò N.
J Vasc Access. 2022 Jul;23(4):524-531. doi: 10.1177/1129729821002570. Epub 2021 Mar 16.
PMID: 33726627
OBJECTIVE: To assess and compare the maturation rate of the native radiocephalic arteriovenous **fistula** (RC-AVF) created with and without a nitinol external support (**VasQ** Laminate Medical Technologies Ltd, Tel Aviv, Israel). ...At 1, 3, and 6 months, primary patency ...
LitStream Sign In

7 Cite
Singapore's experience on the **VasQ** anastomotic external support device to augment arteriovenous **fistula** maturation: Real world outcomes.
Lim X, Zhang L, Pan Y, Hong Q, Mak M, Chong LRC, Neo S, Tan GWL, Dharmaraj RB, Ng JJ, Chong SW, Ho P, Yong E.
J Vasc Access. 2025 Oct 3:11297298251377946. doi: 10.1177/11297298251377946. Online ahead of print.
PMID: 41039890
RESULTS: Out of the 118 AVFs created with the **VasQ** device, 57.6% were radiocephalic (RC) **fistulas**, 33.9% were brachiocephalic (BC) **fistulas** and 8.4% were brachiobasilic transposition (BVT) **fistulas**. The most common **VasQ** device size used in our p ...

8 Cite
Achieving high maturation and cannulation rates of radial-cephalic arteriovenous **fistulas** with **VasQ** device.
Shahverdyan R, Hentschel DM.
Semin Dial. 2023 Mar;36(2):147-154. doi: 10.1111/sdi.13065. Epub 2022 Mar 7.
PMID: 35258116
BACKGROUND: Hemodialysis is the predominant treatment modality for chronic kidney disease, with arteriovenous **fistula** (AVF) being considered to be the preferred type of long-term vascular access. Implantation of the external anastomotic **VasQ** support device during AV ...
Open Access Sign In

9 Cite
Multicenter European real-world utilization of **VasQ** anastomotic external support device for arteriovenous **fistulae**.
Shahverdyan R, Tabbì P, Mestres G.
J Vasc Surg. 2022 Jan;75(1):248-254. doi: 10.1016/j.jvs.2021.07.120. Epub 2021 Jul 24.
PMID: 34314835 Free article.
OBJECTIVE: To evaluate the outcomes of arteriovenous **fistulae** (AVF), created with **VasQ** external support device under standard clinical practice across three vascular access clinics. ...Primary failure, usability, patency, and intervention rates during the study peri ...
Open Access Sign In

10 Cite
Patency and functionality of radiocephalic arteriovenous **fistulas** with an external support device (**VasQ**): Real-world single-center experience.
Shahverdyan R, Meyer T, Matoussevitch V.
J Vasc Access. 2021 Mar;22(2):166-172. doi: 10.1177/1129729820904599. Epub 2020 Feb 6.
PMID: 32026749 Free PMC article.
BACKGROUND: The **VasQ**(TM) device was designed to improve the outcome of arteriovenous **fistulae** by optimizing the hemodynamics of the flow in the juxta-anastomotic region of the arteriovenous **fistulae** through tailored external support. The aim of the study was ...
Open Access Sign In

11 Cite
Efficacy and safety of implantable vascular support in the treatment of arteriovenous **fistula**: A single-arm meta-analyses.
Li X, Ma C, Li W, Li Y, Zhang M, Zhu P.
J Vasc Access. 2025 Mar;26(2):422-431. doi: 10.1177/11297298231223537. Epub 2024 Jan 10.
PMID: 38197230
BACKGROUND AND OBJECTIVES: **VasQ** (Laminate Medical Technologies, Israel) is an external support device for autologous arteriovenous **fistula** (AVF) designed to improve anastomotic blood flow and reduce neointimal hyperplasia. However, different studies have shown that ...
LitStream Sign In

12 Cite
Is the **VasQ** device useful in the maturation of native arteriovenous **fistulas**? A single-center experience.
Fontserè N, Mestres G, Yugueros X, Lozano V, Rodas LM, Burrel M, Maduell F.
Nefrologia (Engl Ed). 2024 Jan-Feb;44(1):109-111. doi: 10.1016/j.nefroe.2024.02.010. Epub 2024 Feb 28.
PMID: 38423836 Free article. No abstract available.
Open Access Sign In

13 Cite
An Implanted Blood Vessel Support Device for Arteriovenous **Fistulas**: A Randomized Controlled Trial.
Karydis N, Bevis P, Beckitt T, Silverberg D, Halak M, Calder F.
Am J Kidney Dis. 2020 Jan;75(1):45-53. doi: 10.1053/j.ajkd.2019.05.023. Epub 2019 Aug 22.
PMID: 31447072 Free article. Clinical Trial.
SETTINGS & PARTICIPANTS: 40 consecutive patients with kidney failure referred for creation of a brachiocephalic **fistula** in 4 vascular access centers in the United Kingdom and Israel. INTERVENTIONS: AVF surgical creation with placement of the **VasQ** implant (treatm ...
Open Access Sign In

14 Cite
Safety and efficacy of an innovative external support device for de novo arterio-venous **fistula** creation: a French bicentric experience.
Haugueł A, Finket L, De Blic R, Bonnet M, Michel C, Mallios A.
J Cardiovasc Surg (Torino). 2025 Feb;66(1):30-36. doi: 10.23736/S0021-9509.24.13124-2. Epub 2024 Nov 6.
PMID: 39501894 Free article.
BACKGROUND: The aim of this study was to evaluate the safety and efficacy of **VasQ**(TM), a permanent extravascular nitinol vascular support device, implanted around the anastomosis of de novo arteriovenous **fistulas** (AVF), in consecutive patients. ...**VasQ**(TM) ca ...
Download Only Sign In

15 Cite
Long-term outcomes of radiocephalic arteriovenous **fistulas** created in anatomical snuffbox or with **VasQ** external support device.
Shahverdyan R, Hussain MA.
J Vasc Surg. 2025 Jul;82(1):229-239. doi: 10.1016/j.jvs.2025.03.166. Epub 2025 Jun 4.
PMID: 40464722 Free article.
OBJECTIVE: This study evaluates the long-term outcomes of radiocephalic arteriovenous **fistulas** (RCAVFs) created in the anatomical snuffbox (SB-AVF) or with the **VasQ** external support device (ES-RCAVF). ...Moreover, **VasQ** significantly increased the probability ...
Open Access Sign In

16 Cite
Corrigendum to Patency and functionality of radiocephalic arteriovenous **fistulas** with an external support device (**VasQ**): Real-world single-center experience.
[No authors listed]
J Vasc Access. 2021 Sep;22(5):859-860. doi: 10.1177/11297298209366959. Epub 2020 Jun 11.
PMID: 32525720 Free PMC article. No abstract available.
LitStream Sign In

17 Cite
Prevailing insights into anastomotic angles of surgically created arteriovenous **fistulas**: a literature review.
Li X, Liu C, Hu H.
BMC Nephrol. 2025 May 22;26(1):252. doi: 10.1186/s12882-025-04182-4.
PMID: 40405071 Free PMC article. Review.
OBJECTIVE: An arteriovenous **fistula** (AVF) is the most common type of vascular access, given its low infection rate, few complications, good patency potential, and long service life. ...METHODS: This publication was intended to highlight the progress achieved with respect t ...
Open Access Sign In

18 Cite
DLP 3D printing of hyperelastic photocurable perivascular scaffolds enabling patient-specific vascular remodeling.
Zhang N, Lu Y, Li J, Xiao Z, Lyu Y, Liu Y, Wan J, Wang Z, Li X, Zhang H, Wang X, Li Q.
Acta Biomater. 2025 Sep 1;203:381-398. doi: 10.1016/j.actbio.2025.07.048. Epub 2025 Jul 23.
PMID: 40706782
Using this resin, we fabricated a dual-layered perivascular scaffold (BioShell) for arteriovenous **fistula** (AVF) intervention, that integrating mechanical support, hemodynamic optimization, and localized drug delivery. ...The initial burst release of TEMPOL scavenged reacti ...
Download Only Sign In

19 Cite
Implanted blood vessel external support device for the treatment of distal hypoperfusion ischemic syndrome in arteriovenous **fistulas** and high-frame-rate Vector Flow quality assessment.
Franchin M, Goddi A, Muscato P, Cervarolo MC, Piffaretti G, Tozzi M.
J Vasc Access. 2024 Mar;25(2):642-650. doi: 10.1177/11297298231151715. Epub 2023 Jan 27.
PMID: 36708038
INTRODUCTION: Distal hypoperfusion ischemic syndrome (DHIS) is a complication occurring after arteriovenous **fistula** (AVF) creation. Different surgical alternatives haves been proposed in case of severe DHIS. ...It consists of AVF remodeling using an external nitinol suppor ...
Open Access Sign In

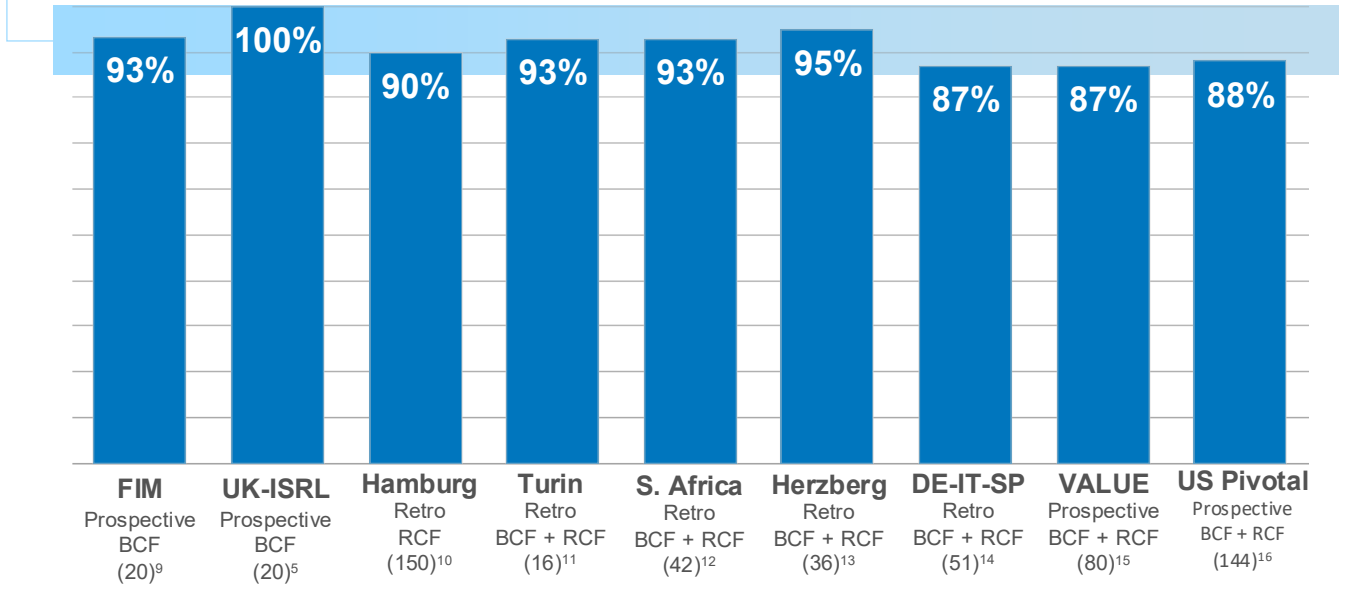
20 Cite
Comparative effectiveness of arteriovenous **fistulas** created with a nitinol extravascular support in patients with advanced kidney disease.
Lucas JF, Secemsky E, Song Y, Hussain MA, Hentschel D, Woodside KJ, Ozaki CK, Farber A, Dillavou E.
J Vasc Access. 2025 May 3:11297298251326967. doi: 10.1177/11297298251326967. Online ahead of print.
PMID: 40317219
BACKGROUND: Use of a nitinol extravascular support implanted during AVF (arteriovenous **fistula**) creation has been gaining traction due to its potential to improve functional success and reduce interventions; however, comparative effectiveness data with traditional unsuppor ...
LitStream Sign In

VASCULARCARE of South Carolina

# Overall Functional Success

VasQ™

**87% - 100%**




*Functional success was generally defined as confirmed use of the AVF to deliver dialysis


1. Karydis et al. Am J Kidney Dis 2019;75(1):45-53
2. Chemla et al. J Vasc Access 2016; 17(3):243-248
3. Shahverdyan et al. Seminars in Dialysis 2023;36(2):147-154
4. Leonardi et al. J Vasc Access 2020; 22(4):658-665
5. Publications in progress. Data on file with Laminate.
6. Swiecka, Zippel, Storck GMS 2021
7. Shahverdyan et al. J Vasc Access 2021;22(2):166-172
8. Karydis, Mallios, Mestres, Matoussevitch VAS 2021
9. Dillavou et al. J Vasc Surg 2023;78:1302-12


VASCULARCARE of South Carolina

# Post-Market VasQ RCT

Prospective, multicenter RCT evaluating the performance of VasQ for its intended use

- Open label trial enrolling 300 patients receiving end-to-side BCF or RCF
- Randomized into two arms (1:1 ratio)
  - Treatment group: **VasQ Extravascular Support**
  - Control group: **No extravascular support**
- 12-month follow-up post fistula creation
  - Primary endpoint: Time to Functional Success (3/4 sessions via 2-needle canulation over 28 days)
  - Additional endpoints: Patency, Reintervention Rates, CVC exposure
  - Safety: Access and Cannulation related complications

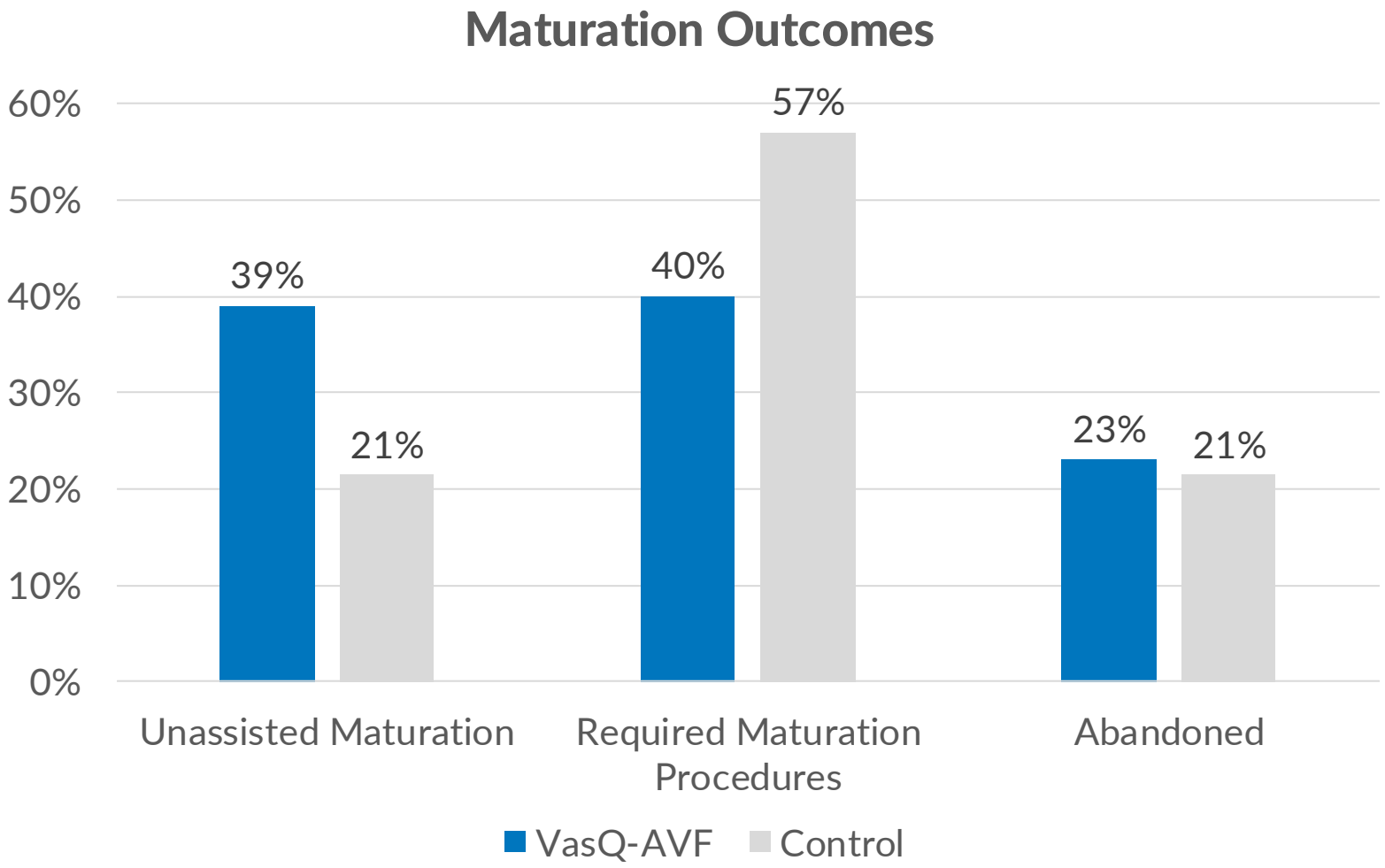
VASCULARCARE of South Carolina

# Columbia Enrollment

| | VasQ | Control | Total |
|---|---|---|---|
| | N (%) | N (%) | N (%) |
| Patients enrolled | 13 | 15 | 28 |
| Mean Follow-up Time | 8.2 mo | 8.8 mo | 8.5 mo |
| BCF | 8 (62%) | 9 (60%) | 17 (61%) |
| RCF | 5 (38%) | 6 (40%) | 11 (39%) |
| Pre-dialysis | 4 (31%) | 6 (40%) | 10 (36%) |
| Male | 9 (75%) | 11 (77%) | 20 (77%) |
| BMI-mean | 33.6 | 31.5 | 32.5 |
| Age-mean | 58 | 61 | 60 |
| Diabetic | 7 (58%) | 6 (43%) | 13 (50%) |

VASCULARCARE of South Carolina

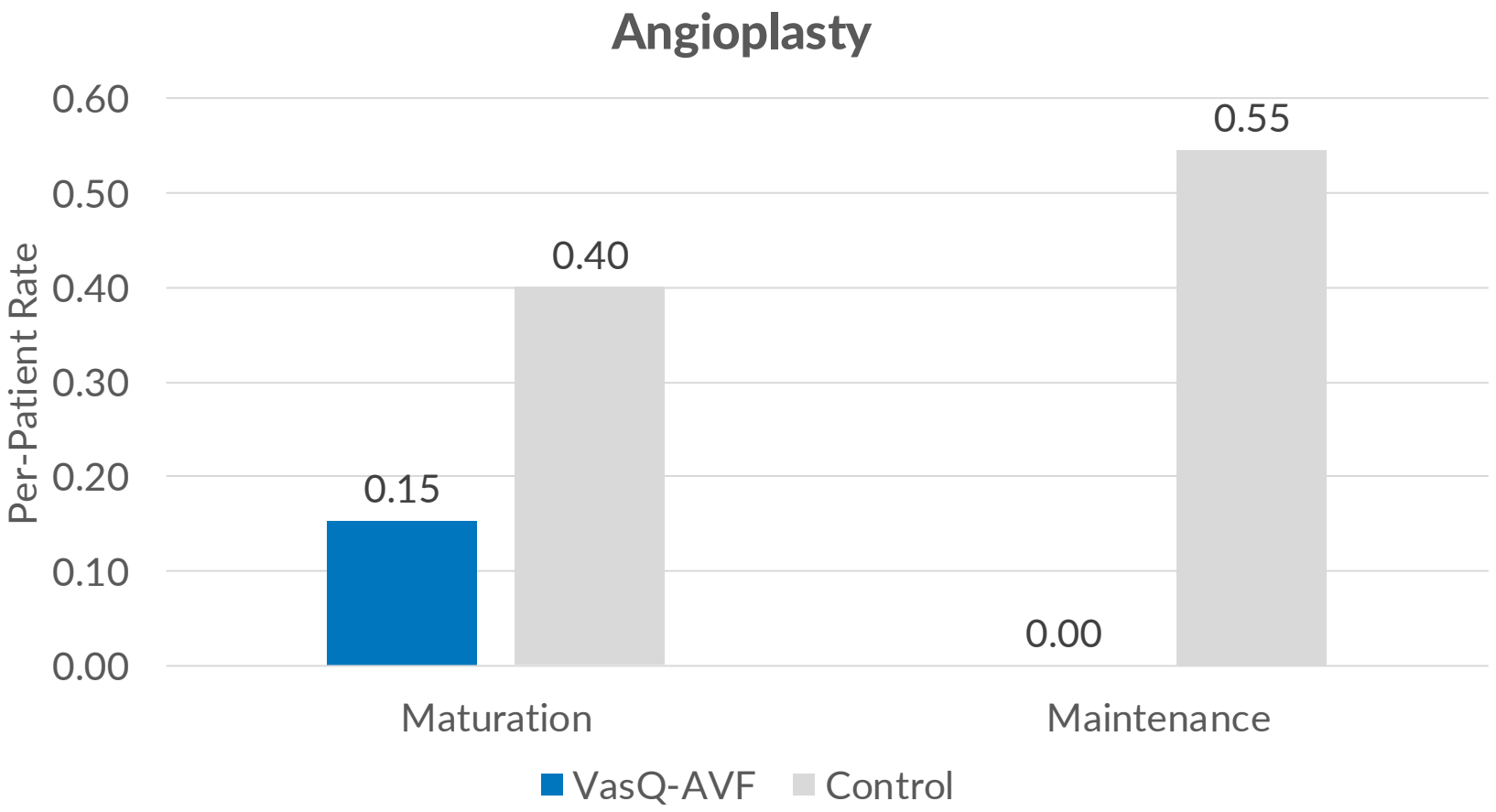
# Initial Outcomes




Note: 2 VasQ abandonments were BCFs using model #3, which may be too small for upper arm AVFs

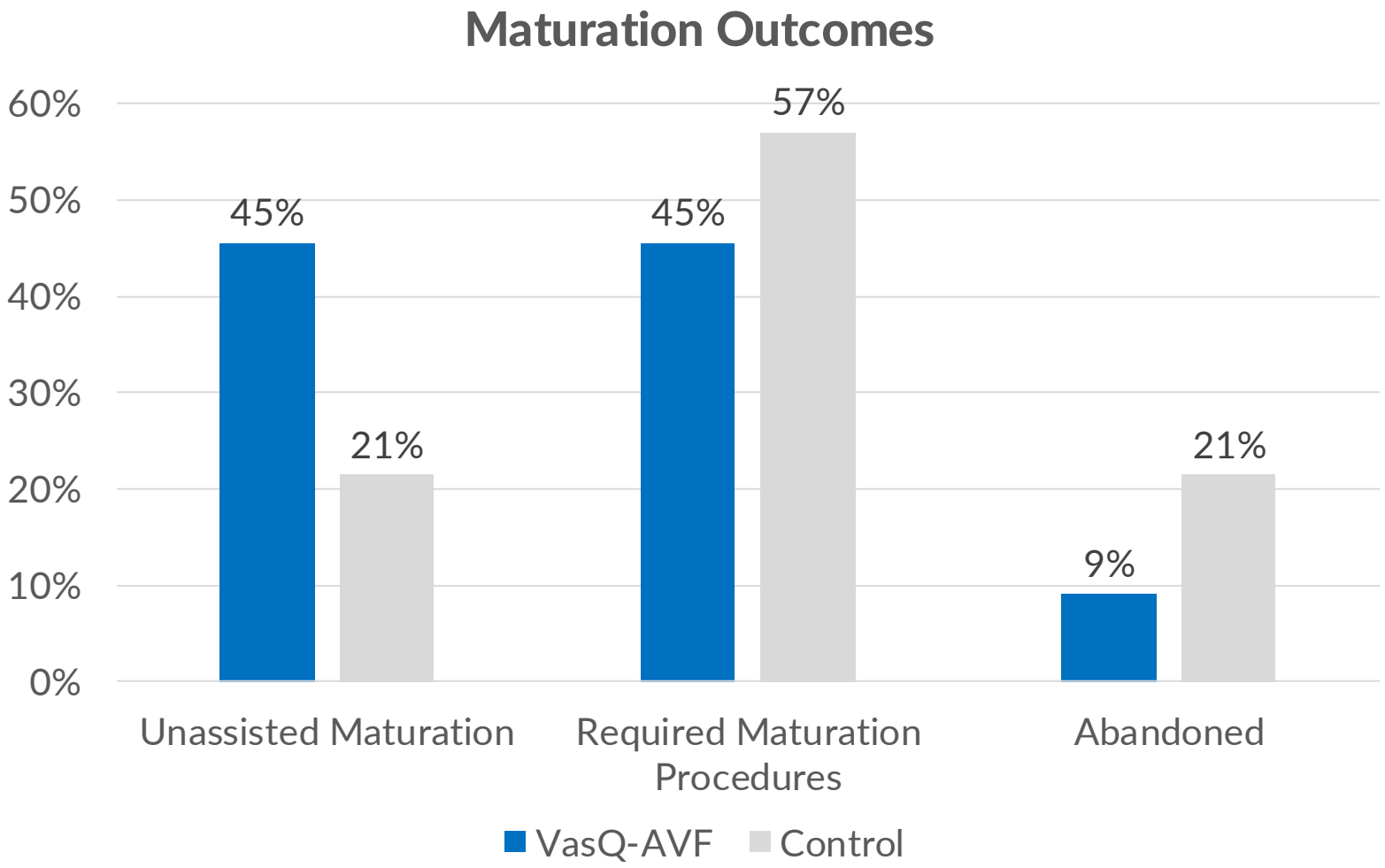
VASCULARCARE of South Carolina

# Initial Outcomes




VASCULARCARE of South Carolina

# Initial Outcomes




Excluding 2 BCF created with Model #3

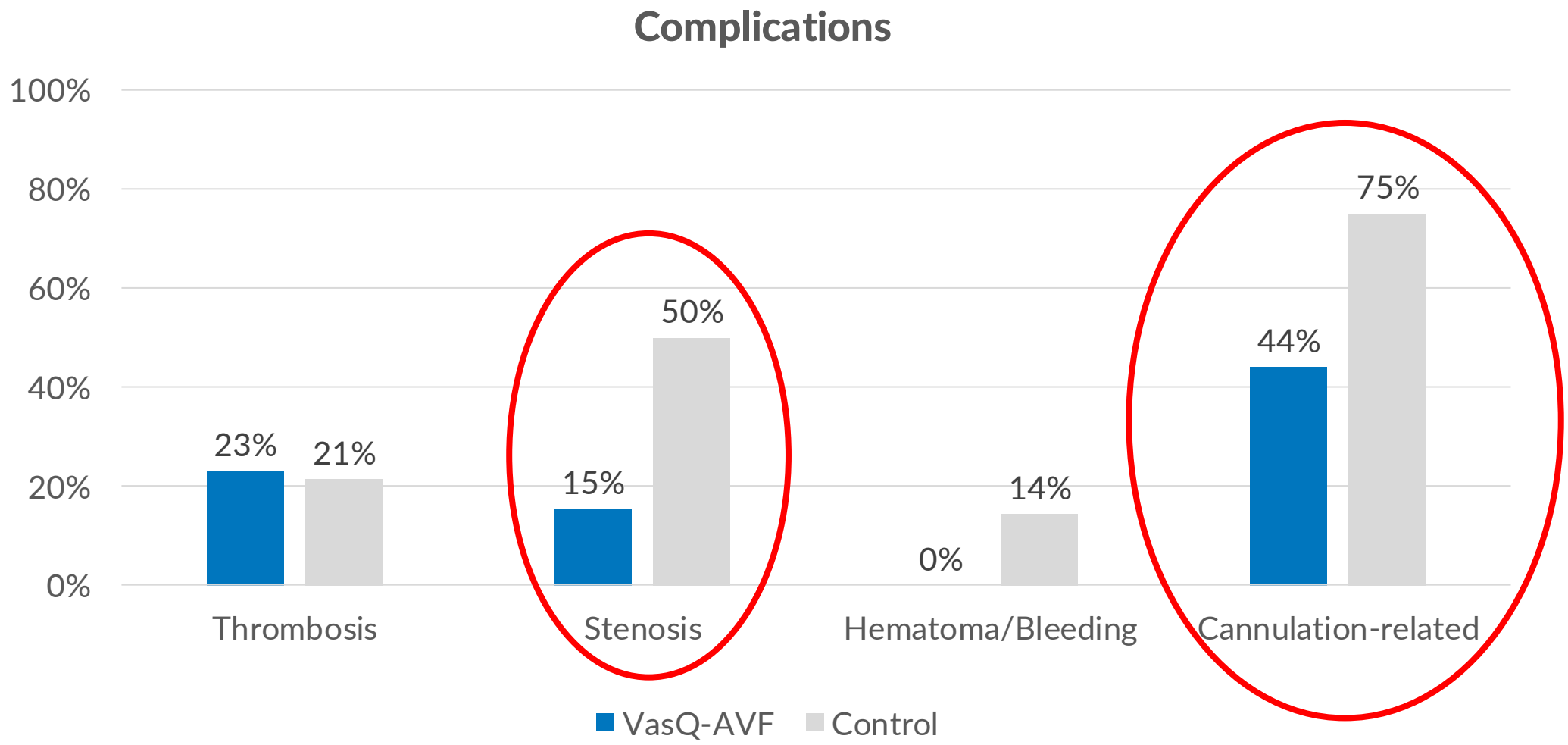
VASCULARCARE of South Carolina

# Maturation Intervention types

| | | VasQ | Control |
|---|---|---|---|
| **Total number of events** | | 6 | 11 |
| **Total number of patients** | | 5 | 9 |
| **# of events** | Side branch ligation | 1 | 1 |
| | Transposition | 1 | 1 |
| | PTA | 2 | 5 |
| | PTA + side branch ligation | --- | 1 |
| | Transposition + side branch ligation | --- | 1 |
| | Diagnostic fistulogram | 1 | 2 |
| | Diagnostic fistulogram + side branch ligation | 1 | --- |

VASCULARCARE of South Carolina

# Initial Outcomes




Note: 2 VasQ thrombosis were BCFs using model #3, which may be too small for upper arm AVFs

VASCULARCARE of South Carolina

# Conclusion

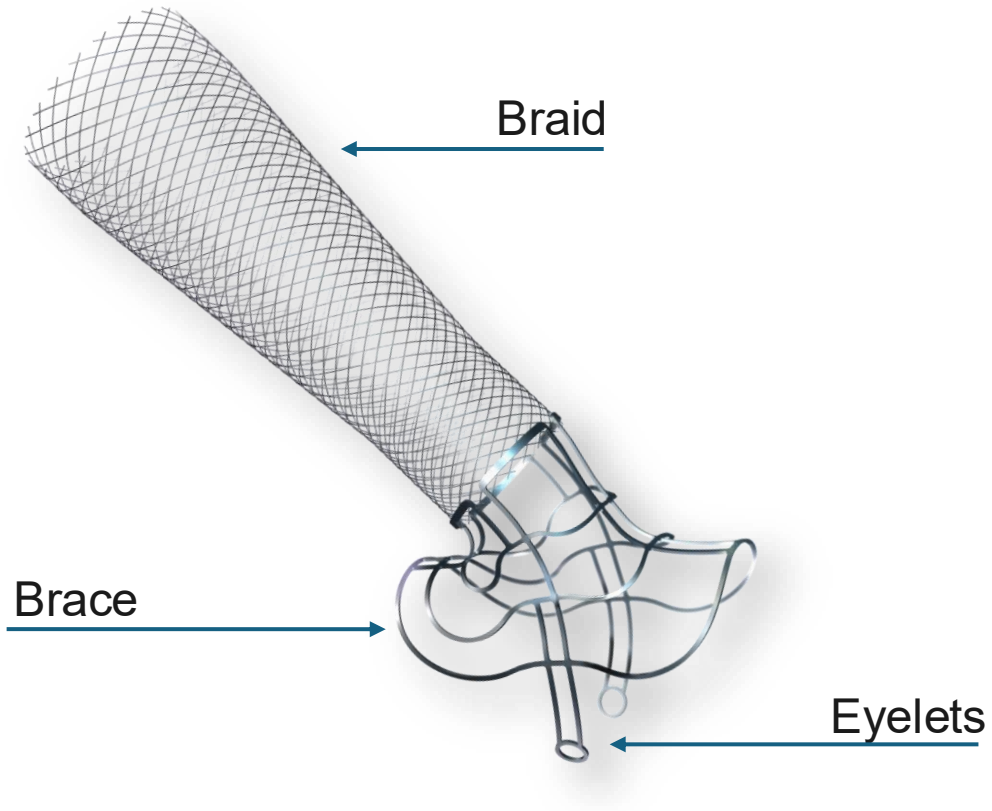
VasQ Extravascular Support . . .

- Improved my unassisted AVF maturation rate
- Reduced rates of stenosis and subsequent angioplasty
- Reduced complications due to cannulation such as infiltrations and “difficult to cannulate” referrals

**VasQ now adopted as part of my standard creation algorithm**

VASCULARCARE of South Carolina

# Anatomy of VasQ™




**FDA Approved Indication**

**VasQ is intended for use as an external support for upper extremity arteriovenous fistulas created for vascular access by means of vascular surgery.**

Refer to the Instructions for Use for contraindications, warnings and implantation steps at laminatemedical.com/eIFU

VASCULARCARE of South Carolina

# Back-up/Reference Slides

# Maintenance Intervention types

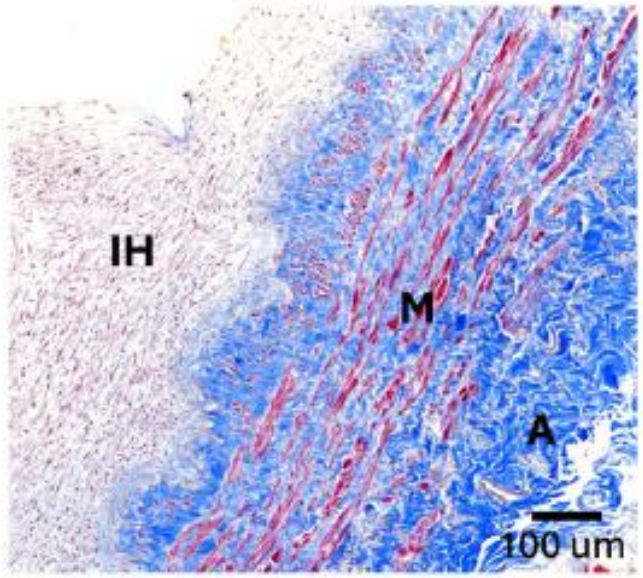
| | | VasQ | Control |
|---|---|---|---|
| **Total number of events** | | 4 | 11 |
| **Total number of patients** | | 3 | 7 |
| | PTA | --- | 5 |
| | PTA + Stent | --- | 1 |
| | Diagnostic fistulogram | 4 | 4 |
| | Diagnostic fistulogram + side branch ligation | --- | 1 |

VASCULARCARE of South Carolina

# Early Failure Linked to Inflammation from Excessive Wall Tension

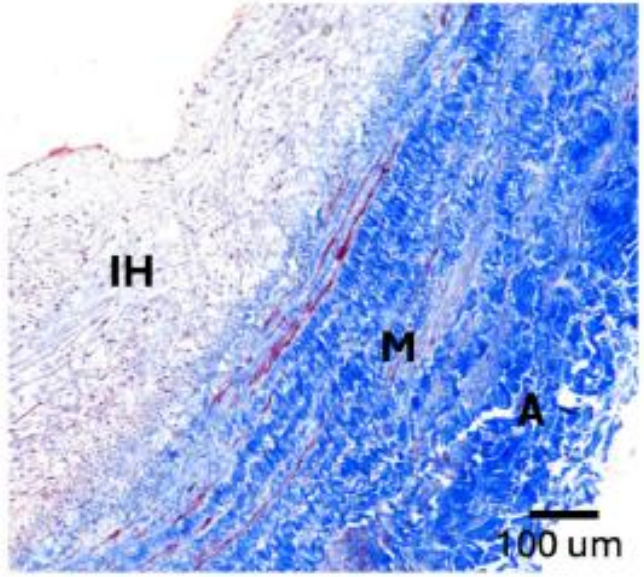
Histological study of samples taken from 2nd stage transpositions (n = 115)[1]

## Mature AVF




Blue = ExtraCellular Matrix
Red = Smooth Muscle Cells
IH = Intimal Hyperlasia
M = Medial Layer
A = Advential layer

## Failed AVF




**Features of Mature AVF**

- ✓ ***Preserved*** medial smooth muscle cell
- ✓ ***Moderate*** fibrosis
- ✓ Increased intimal hyperplasia

**Features of Failed AVF**

- ✓ ***Necrotic*** smooth muscle cell
- ✓ ***Significant*** fibrosis
- ✓ Increased intimal hyperplasia

1. Martinez et al. J Am Soc Nephrol. 2018;29:1030–1040.
2. Martinez et al. Kidney Int. 2026;109:160–177

VASCULARCARE of South Carolina