

Implantation of Extraluminal Support Device During Arteriovenous Fistula Creation

September 13, 2022

Speakers

- Ellen Dillavou, MD, FACS, RPVI
Chief of Vascular Surgery at WakeMed Heart & Vascular
- Barb Peterson, President & CEO Emerson Consultants, Inc.

VasQ™ External Support Device for AV Fistula Creation

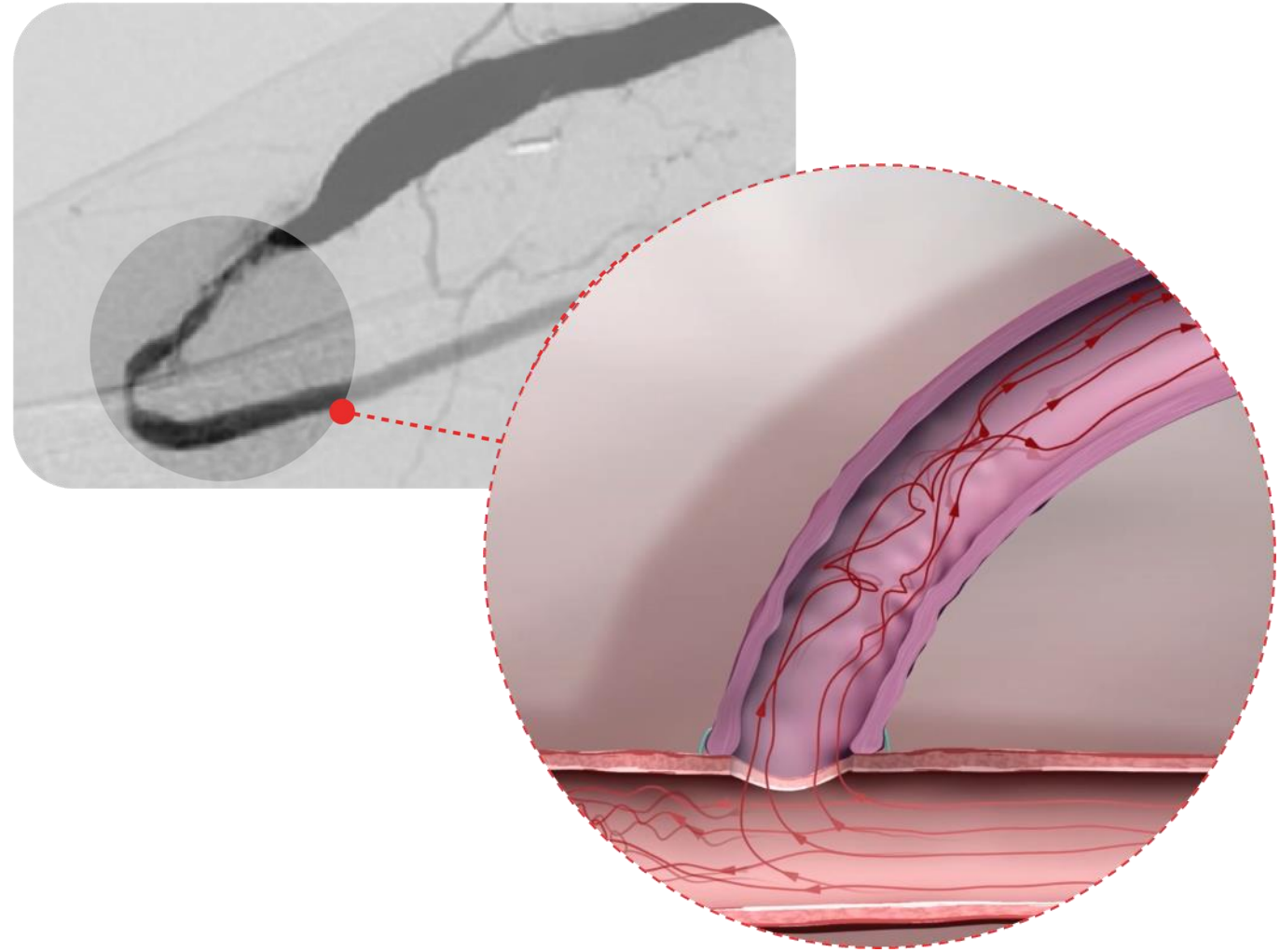
- The VasQ™ device was granted Breakthrough Device designation by the FDA in June 2020
- The VasQ™ IDE study enrollment was completed in February 2020
- The VasQ™ device is used during an AV Fistula creation procedure

VasQ™ External Support Device for AV Fistula Creation

- VasQ™ is a solution currently available that addresses both hemodynamic and mechanical stress to create more usable fistulas.
- The nitinol external support controls the remodeling at the anastomosis to promote outward wall thickening downstream for eventual use in hemodialysis.
- Implanted during AVF creation surgery, VasQ™ retains the optimal configuration of the anastomosis during the critical weeks of maturation post-surgery and beyond.

Biomechanical Mechanisms of Fistula Failure

Juxta-anastomotic Stenosis¹



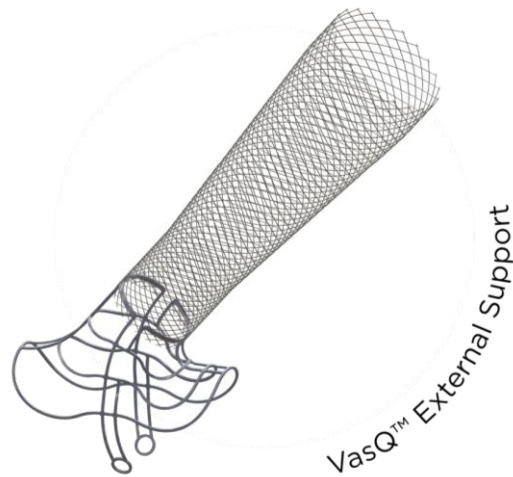
Biomechanical Factors for Stenosis

- ✓ **Increased wall tension** from vein mobilization²
- ✓ **Large areas of oscillatory wall shear stress** from flow instability³⁻⁵
- ✓ **Degradation of geometric configuration** post-surgery

1. Image courtesy of Swinnen et al. J Vasc Surg 2015;61:436-42
2. Owens et al. J Vasc Surg 2015;61(1):203-216
3. Bozzetto M et al. Ann Biomed Eng 2016 Aug;44(8):2388-2401
4. Ene-Iordache B & Remuzzi A. Nephrol Dial Transplant 2012;27:358-368

5. Davies PF. Nat Clin Pract Cardiovasc Med 2009;6:16-26
6. Taggart et al. J Cardiothorac Surg 2018;13(1):117
7. Hentschel & Bergner. ASN 2016 Abstract FR-Po720

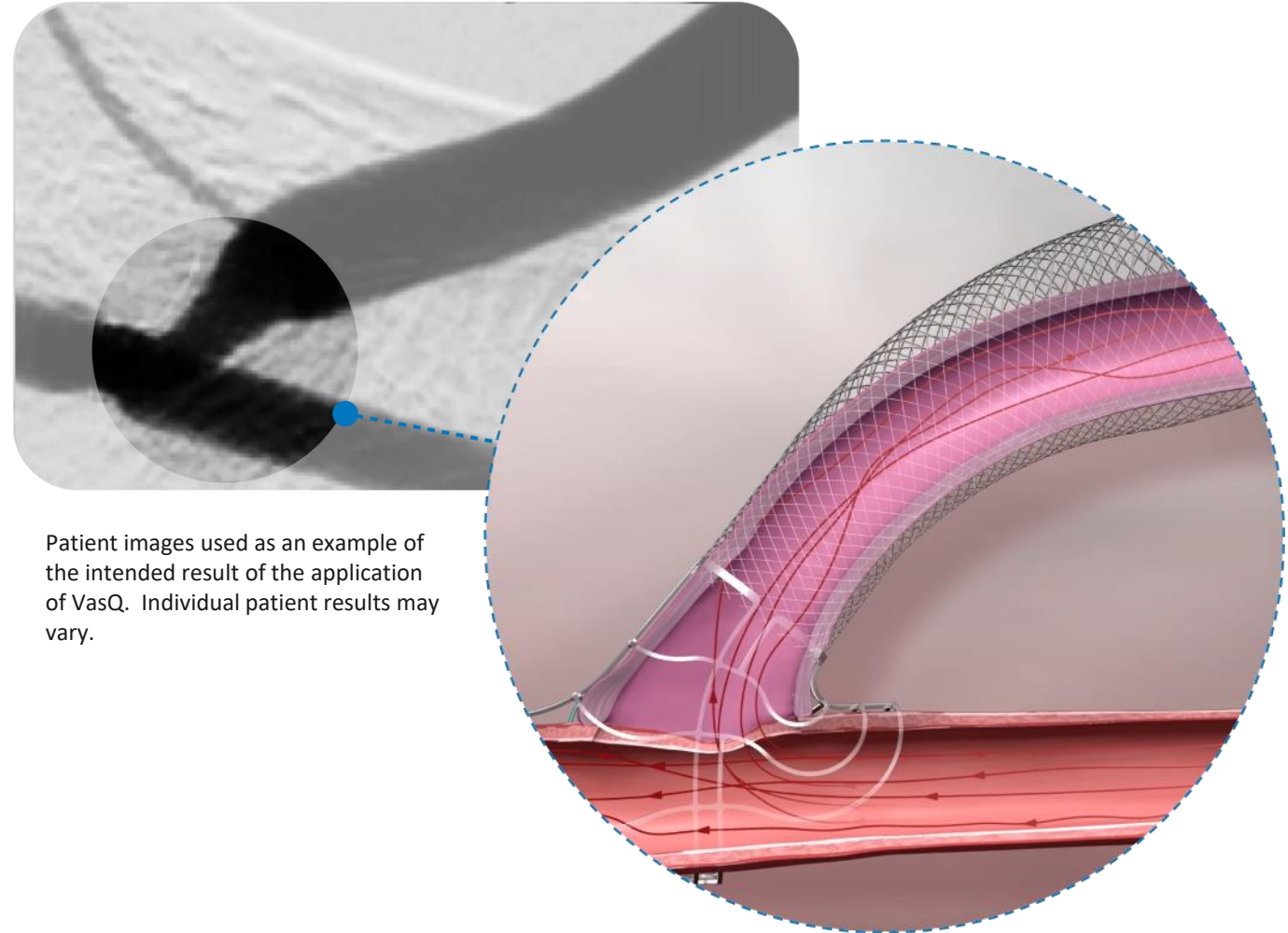
A Mechanical Solution for Biomechanical Mechanisms of Fistula Failure



Benefits of AVF External Support

- ✓ Structural reinforcement against increased wall tension^{2,6}
- ✓ Tapered transition of flow for a more stable flow profile⁷
- ✓ Retained anastomotic configuration post-surgery

VasQ™ Supported Mature AVF at 3 Month



Patient images used as an example of the intended result of the application of VasQ. Individual patient results may vary.

1. Image courtesy of Swinnen et al. J Vasc Surg 2015;61:436-42
2. Owens et al. J Vasc Surg 2015;61(1):203-216
3. Bozzetto M et al. Ann Biomed Eng 2016 Aug;44(8):2388-2401
4. Ene-Iordache B & Remuzzi A. Nephrol Dial Transplant 2012;27:358-368

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AVF Creation with VasQ™

1. Intraoperative Ultrasound



2. Expose Target Vessels



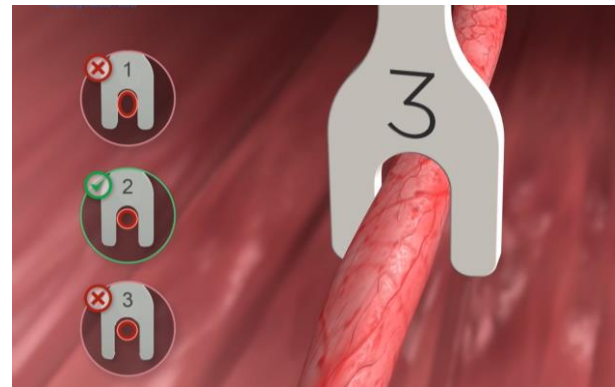
Size vessels with the Device Model Selection Tool (DMST)

*"The **DMST** was used to chose size **7B**"*

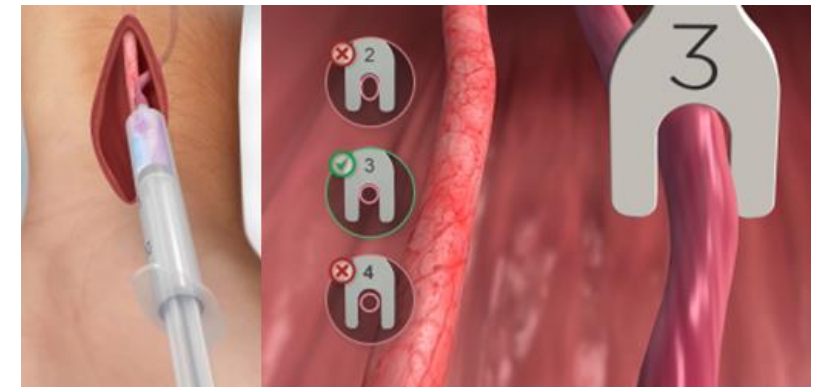
-or-

*"The artery and vein were **sized** with the **sizing tool** to choose **VasQ™ model 7B**"*

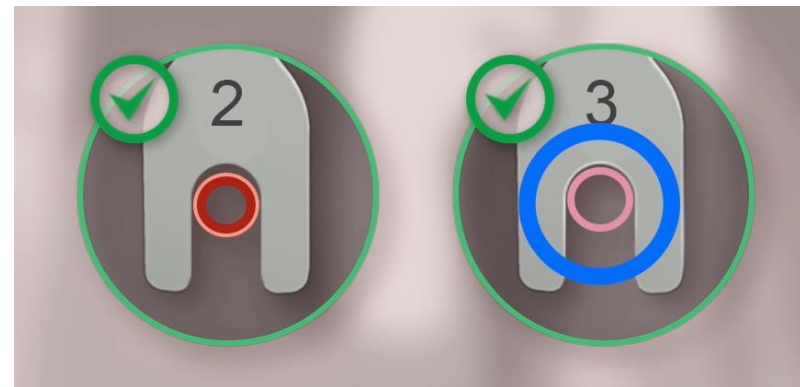
3. Measure Artery



4. Dilate and Measure Vein

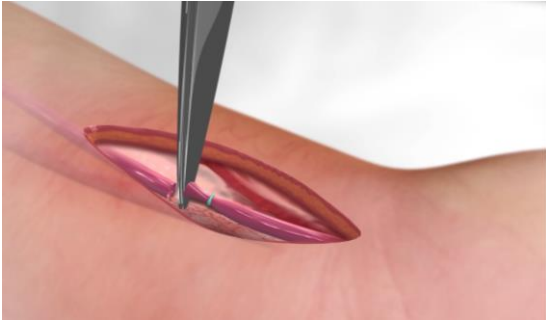


5. Select Larger Model

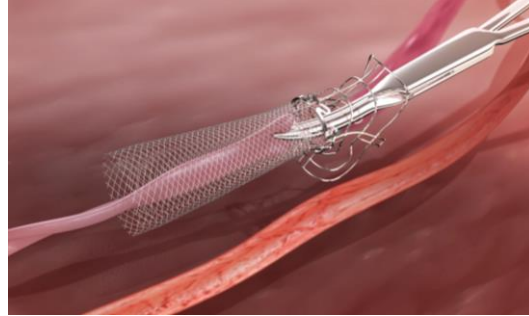


AVF Creation with VasQ™

6. Divide Vein



7. Load VasQ™ on Vein



"VasQ™ device 3 was loaded on to the cephalic vein"

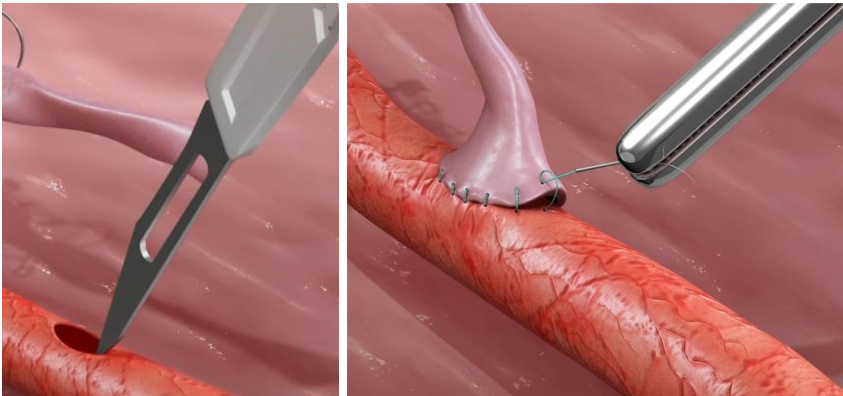
-or-

"A #3 VasQ™ device was placed over the vein and retracted"

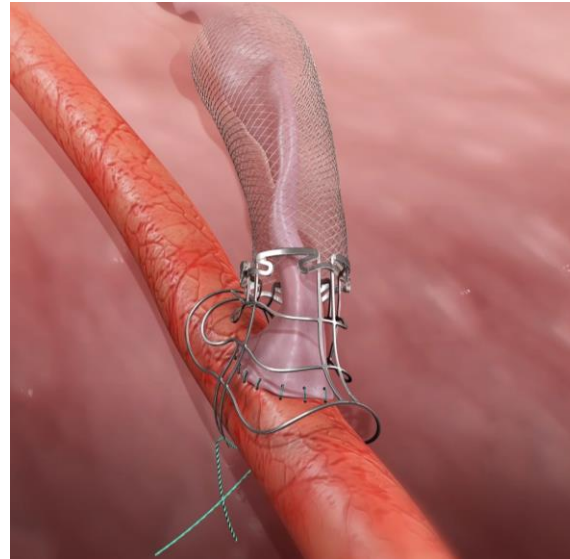
-or-

"The vein was then threaded through the VasQ™ device"

8. Arteriotomy & Anastomosis



9. Deploy & Secure VasQ



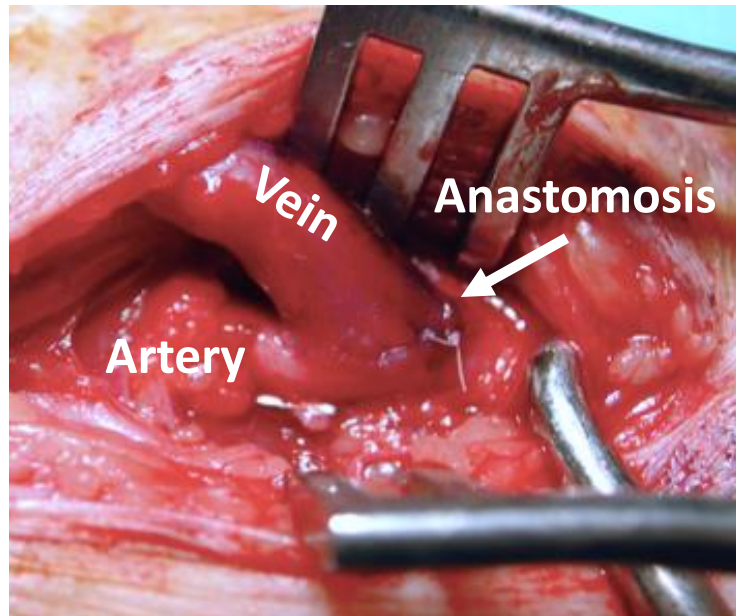
"The VasQ™ device was then cinched down over the artery and secured with a prolene stitch"

-or-

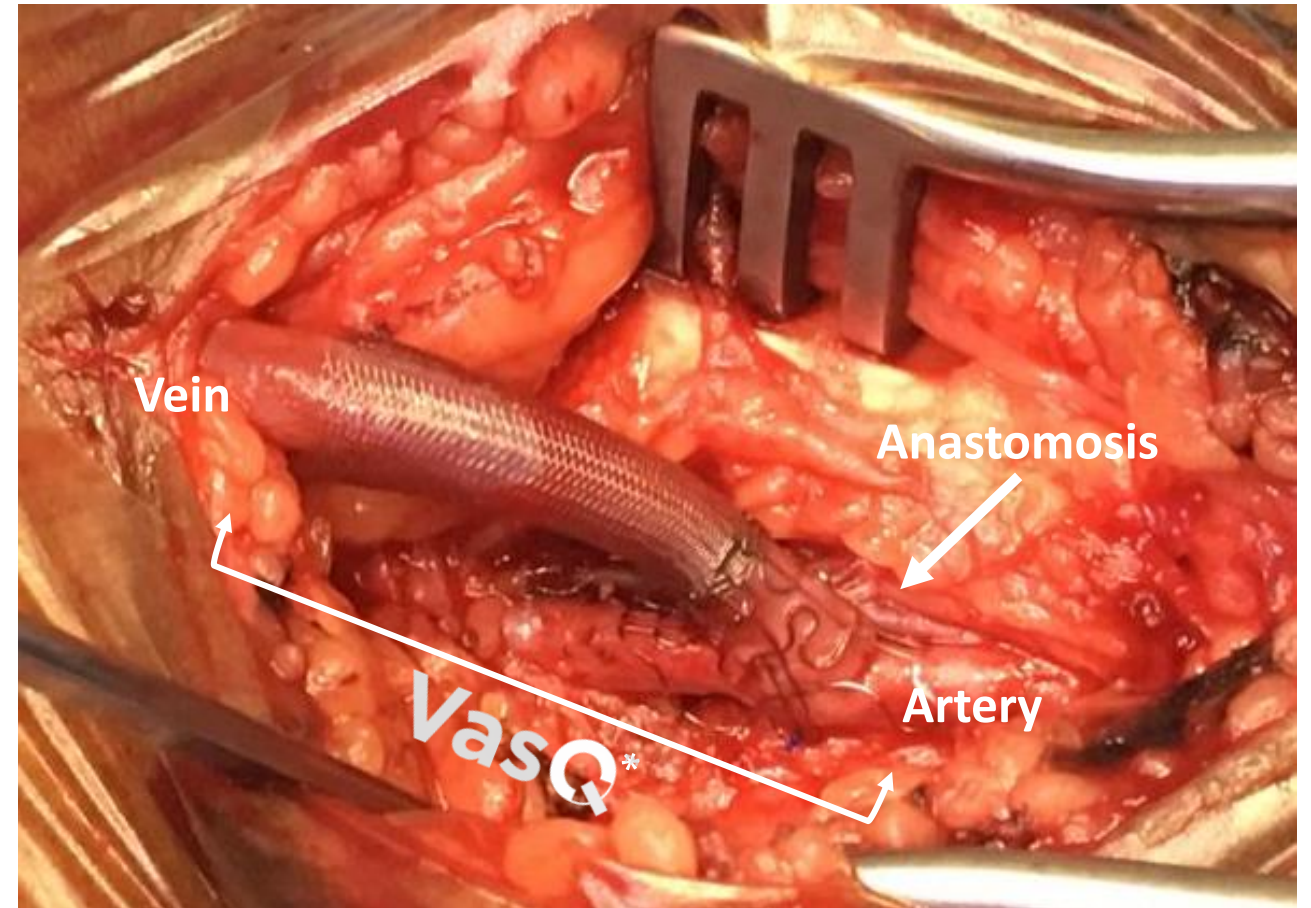
"VasQ™ device was pulled over the vein until it reached the anastomosis where it was secured under the artery"

Surgical Image Post-Creation

Standard AVF



AVF with VasQ™



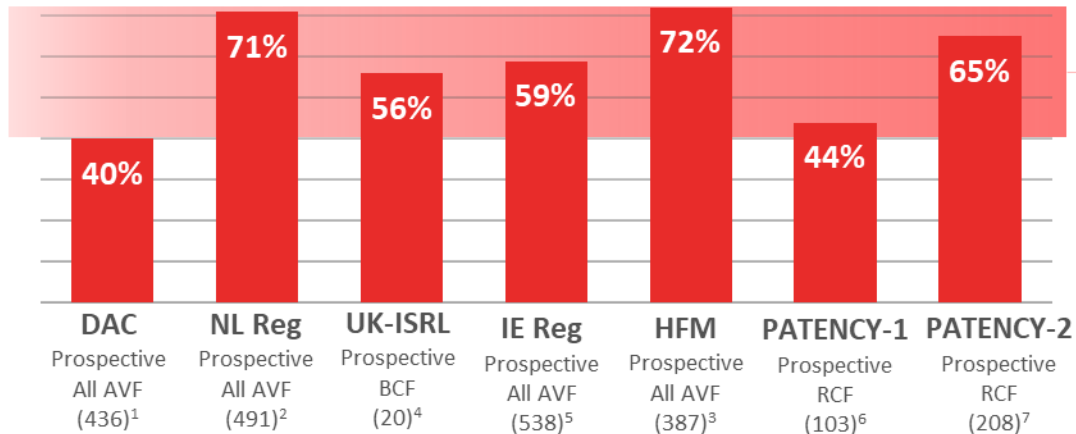
VasQ™ AVFs Demonstrate Consistently High Usability* Rates

Results from multiple studies evaluating usability of the VasQ™ AVFs

Standard AVF Usability

40% - 72%

n = 2,183 (7 studies)

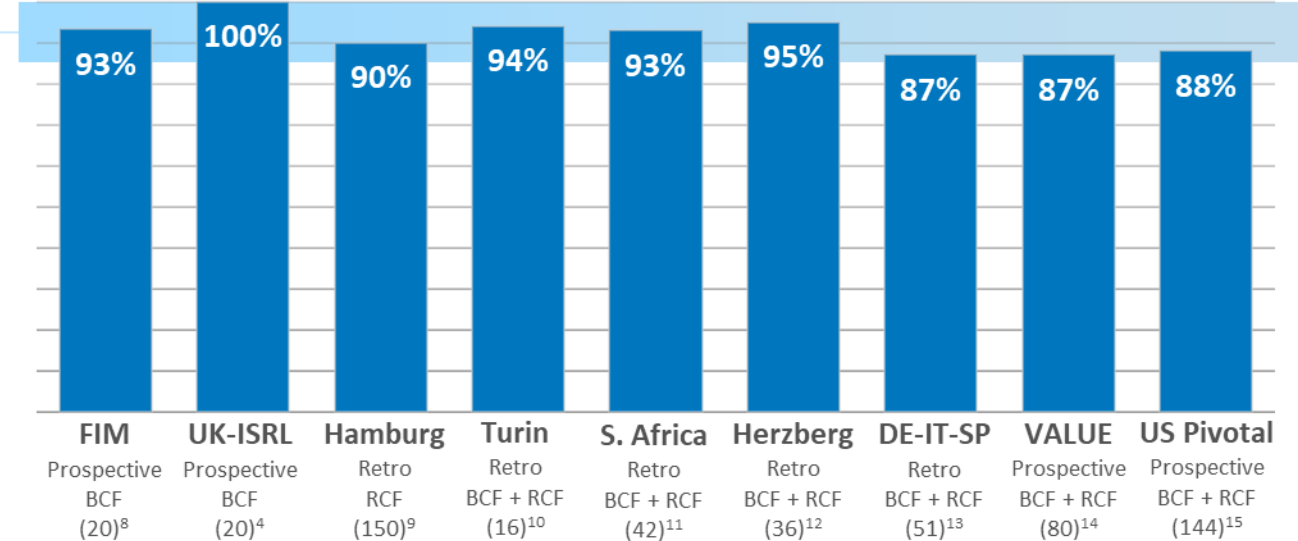


Study - Design (n)

VasQ™ AVF Usability*

87% - 100%

n = 559 (9 studies)



Study - Design (n)

** Usability was generally defined as confirmed use of the AVF to deliver dialysis although some studies required evidence of multiple uses*

1. Dember et al. JAMA 2008;299(18):2164-2171
2. Huijbregts et al. Clin J Am Soc Nephrol 2008;3:14-719
3. Allon, et al. Am J Kidney Dis 2018;71(5):677-689
4. Karydis et al. Am J Kidney Dis 2019;75(1):45-53
5. Masengu A, et al. Clin Kidney J. 2016 Feb;9(1):142-7
6. Bleyer et al. J Vasc Surg 2019;69:507-15

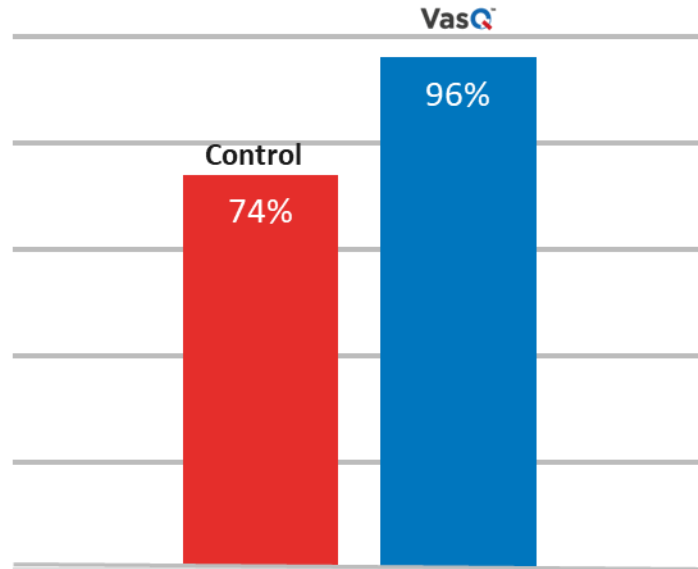
7. Peden et al. J Vasc Access 2021 (Online)
8. Chemla et al. J Vasc Access 2016; 17(3):243-248
9. Shahverdyan et al. Seminars in Dialysis 2022 (Online)
10. Leonardi et al. J Vasc Access 2020 (Online)
11. Publications in progress. Data on file with Laminate.
12. Swiecka, Zippel, Storck GMS 2021

13. Shahverdyan et al. J Vasc Surg 2021 (Online)
14. Karydis, Mallios, Mestres, Matoussevitch VAS 2021
15. Dillavou, Ozaki, Hentschel, Lucas VIETH 2021

VasQ™ AVFs Consistently Outperforms Usability Controls

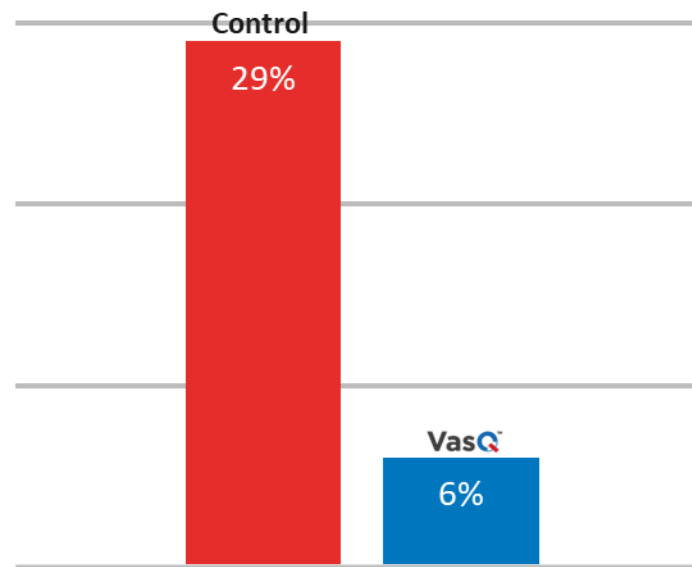
Key results from the three controlled studies reporting AVF usability metrics

Maturation at 1-month (P = .044)



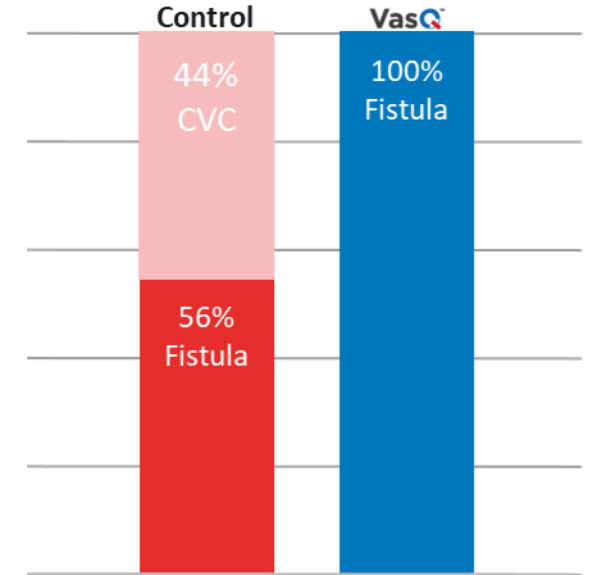
Benedetto¹
24 Control v 25 VasQ RCF

Primary Failure at 3-month (P = .025)



Shahverdyan²
17 Control v 33 VasQ RCF

AVF Usability at 6-month (P = .01)



Karydis³
20 Control v 20 VasQ BCF

Maturation was defined as an AVF with flow rate ≥ 500 ml/min and a vein diameter ≥ 5 mm or a successful fistula use with two-needle cannulation

Primary failure was defined as an access that cannot be used by the third month following creation per ESVS Guidelines

AVF Usability was defined as successful 2-needle cannulation of patent fistulas for two-thirds or more of all dialysis runs for 1 month

1. Benedetto et al. J Vasc Access 2021 (Online)
2. Shahverdyan et al. J Vasc Access 2021;22(2):166-172
3. Karydis et al. Am J Kidney Dis 2019;75(1):45-53

Conclusions from Data

- ❖ VasQ™ implantation is a unique procedure designed to provide external vascular support for fistulas
- ❖ VasQ™ creates a more stable flow profile and reinforces against excessive wall tension associated with fistula failure
- ❖ VasQ™ AVF have demonstrated consistently higher rates of AVF usability vs standard of care in multiple studies around the world