

*VasQ- External support
device for A-V fistula*

Disclosures

Medical consultant Laminate

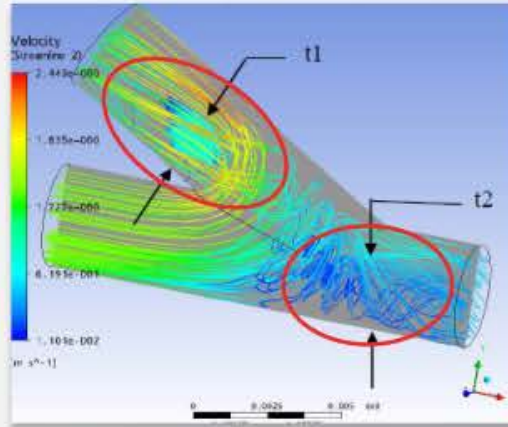
Center participant in US trial

AVF – the Gold Standard that Requires Improvement



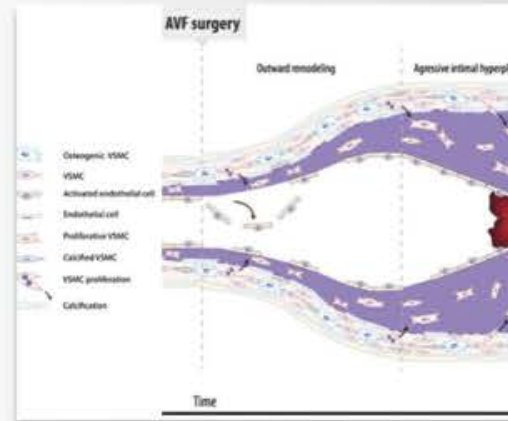
Lee, Timmy. et al., "Comparison of survival of upper arm arteriovenous fistulas and grafts after failed forearm fistula." Journal of the American Society of Nephrology 18.6 (2007): 1936-1941. Dember, Laura M., et al. "Effect of clopidogrel on early failure of arteriovenous fistulas for hemodialysis: a randomized controlled trial." Jama 299.18 (2008): 2164-2171.

Peri-Anastomotic Hemodynamics Triggers Intimal Hyperplasia



Hemodynamic changes

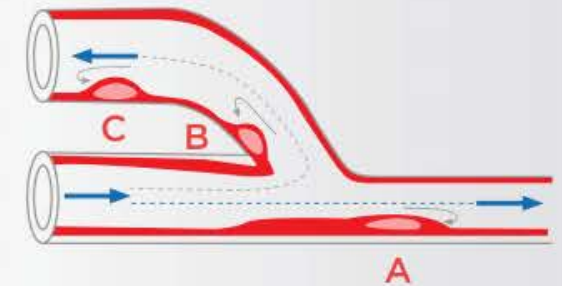
- › Turbulent/Multidirectional blood flow
- › Low vein wall shear stress



Nephrol Dial Transplant.
2013;28(5):1085-1092

Cellular & clinical effect

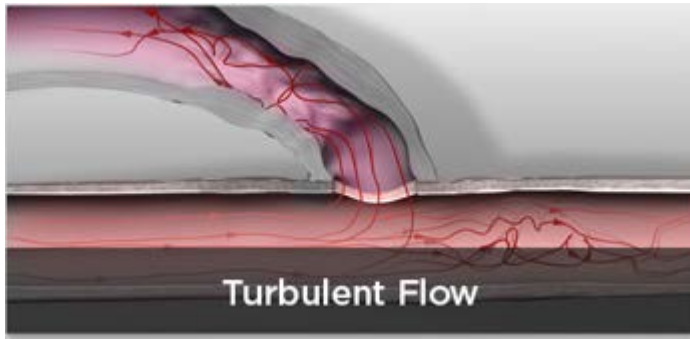
- › Endothelial cells activation
- › Expression of pro inflammatory and pro-coagulant stimulants



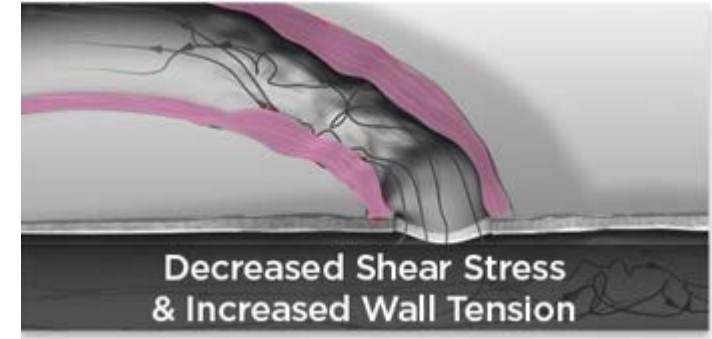
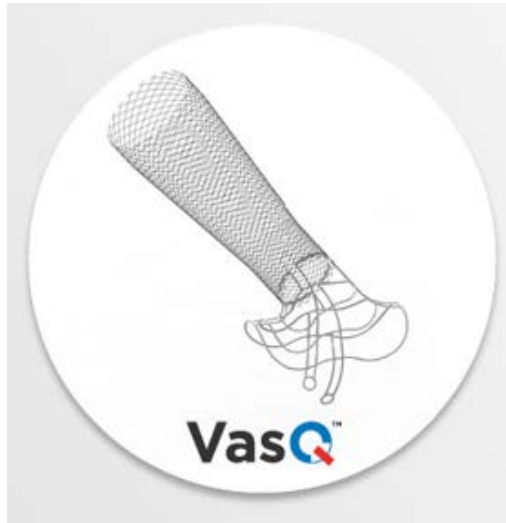
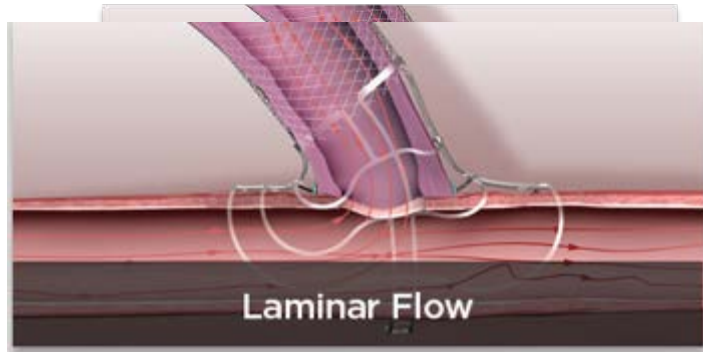
Stenosis develop at specific sites within an AVF

- A Heel of the artery
- B Inner wall of the swing segment
- C Inner wall of the proximal vein where the vein straightens out

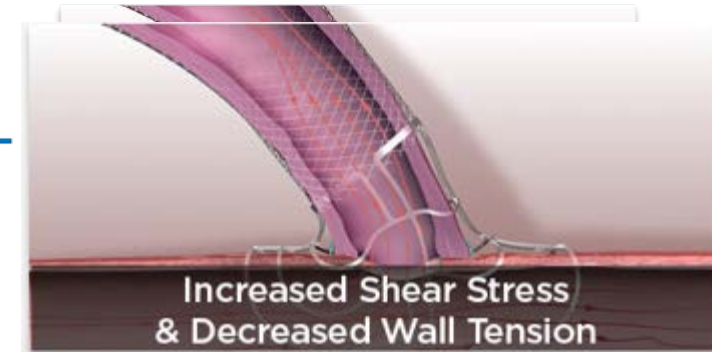
Theoretic Approach



- ✓ Geometrical configuration – Controlled
- ✓ Angle & radius of curvature - Optimized

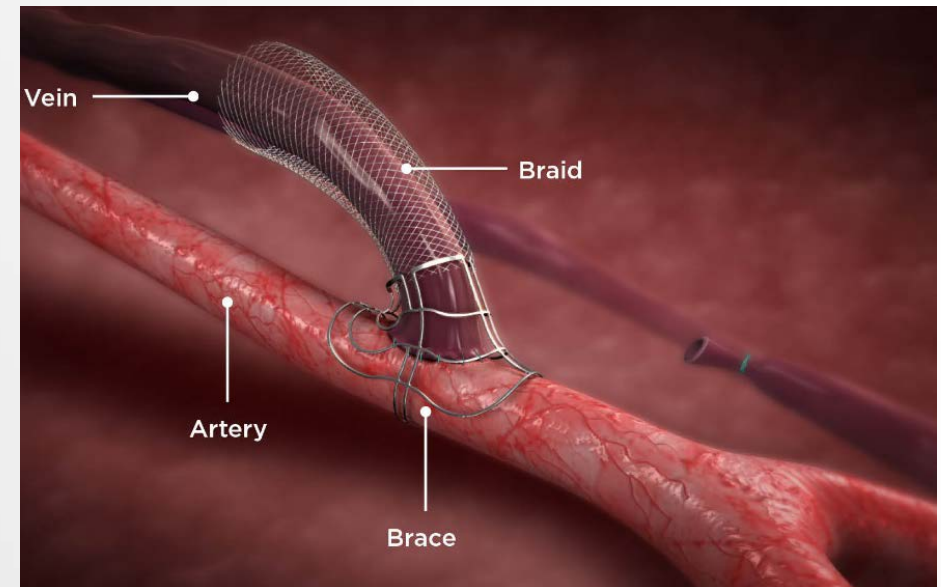
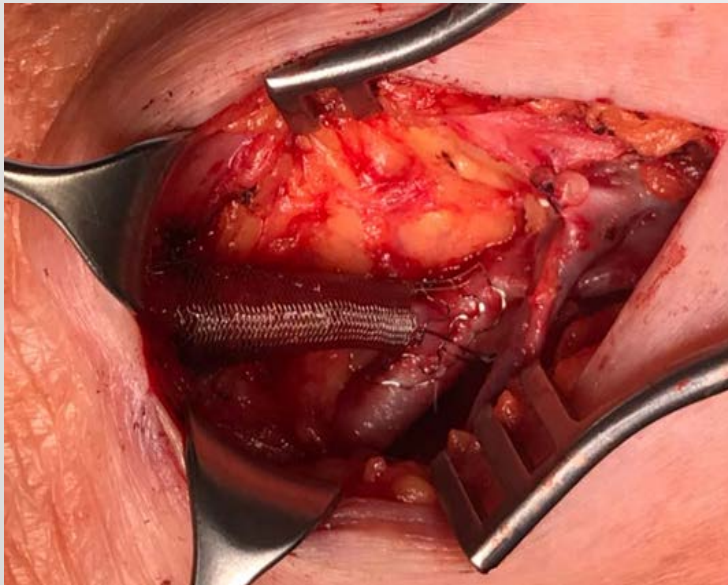


- ✓ Vein dilatation - Controlled

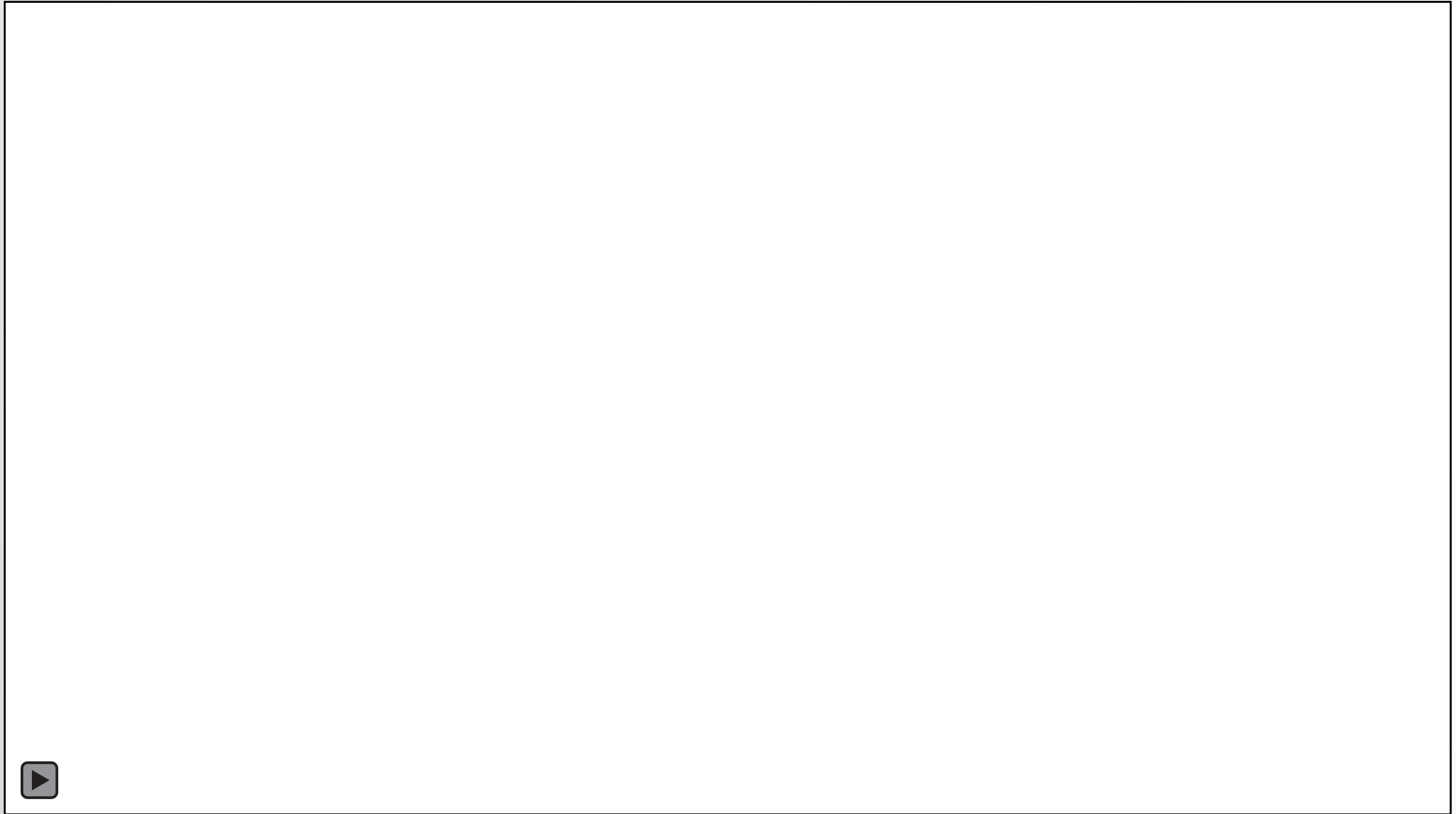


VasQ™ Device

- > Seamless Integration with the standard AVF procedure
- > Completely external (no blood contact)
- > Crush and kink resistant



Implantation Demonstration



The VasQ Clinical Study

- › Multi-National
- › Randomized Controlled Study
- › 40 Patients (20 Device, 20 Control)
- › 6 Month Follow-up

End points:

- › Safety
- › Usability
- › Maturation success
- › Primary patency



St. Georges Hospital, **London**
Guy's and St. Thomas, **London**
Southmead Hospital, **Bristol**

Sheba Medical Center, **Israel**

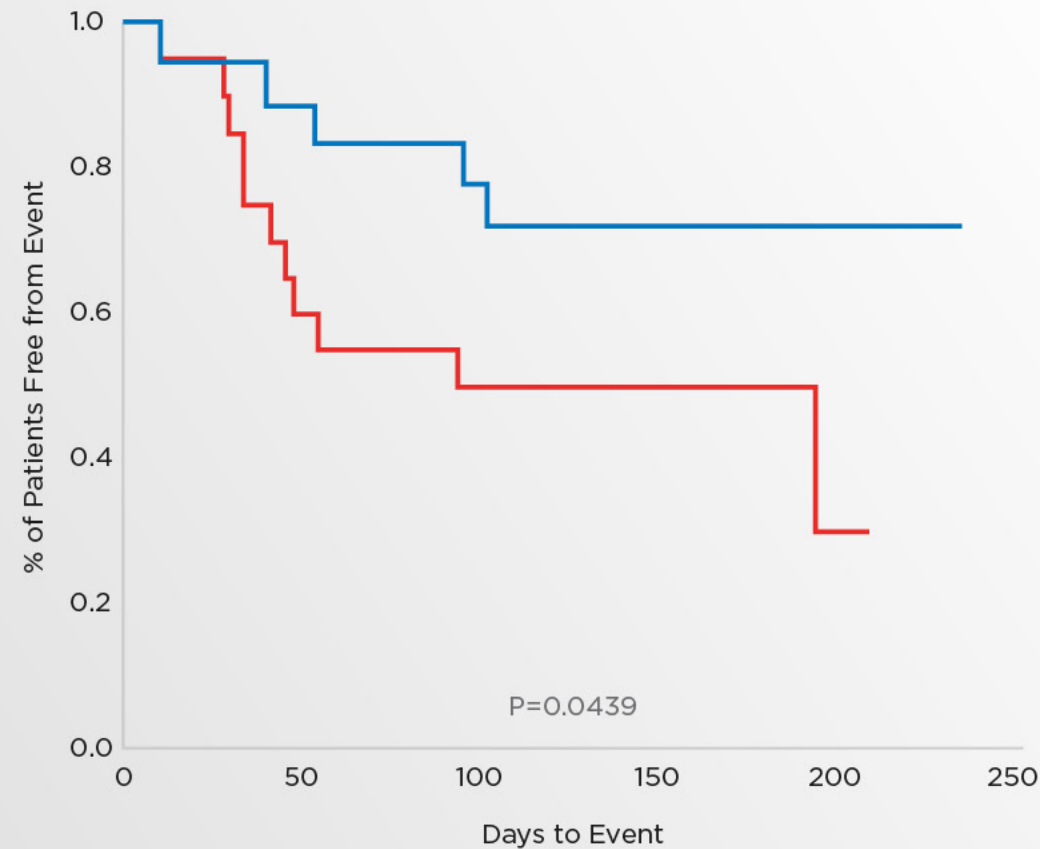
Patient Population

- › Patients with CKD on or expecting to initiate hemodialysis
- › Referred for surgical creation of a Brachiocephalic fistula
- › Target Artery/Vein diameter $> 3\text{mm}$
- › Target vein depth $< 8\text{ mm}$

Demographics

	Treatment (n=20)	Control (n=20)
Age	61.8±12.6	70±11.8
Gender (Male) [% (n)]	70% (14)	65% (13)
BMI	31.3±7.24	29.4±7.4
Diabetes [% (n)]	65% (13)	60% (12)
Hypertension [% (n)]	95% (19)	90% (18)
Hemodialysis status [% (n)]		
Not initiated	40% (8)	55% (11)
Initiated	60% (12)	45% (9)

Greater Freedom from Stenosis & Occlusion

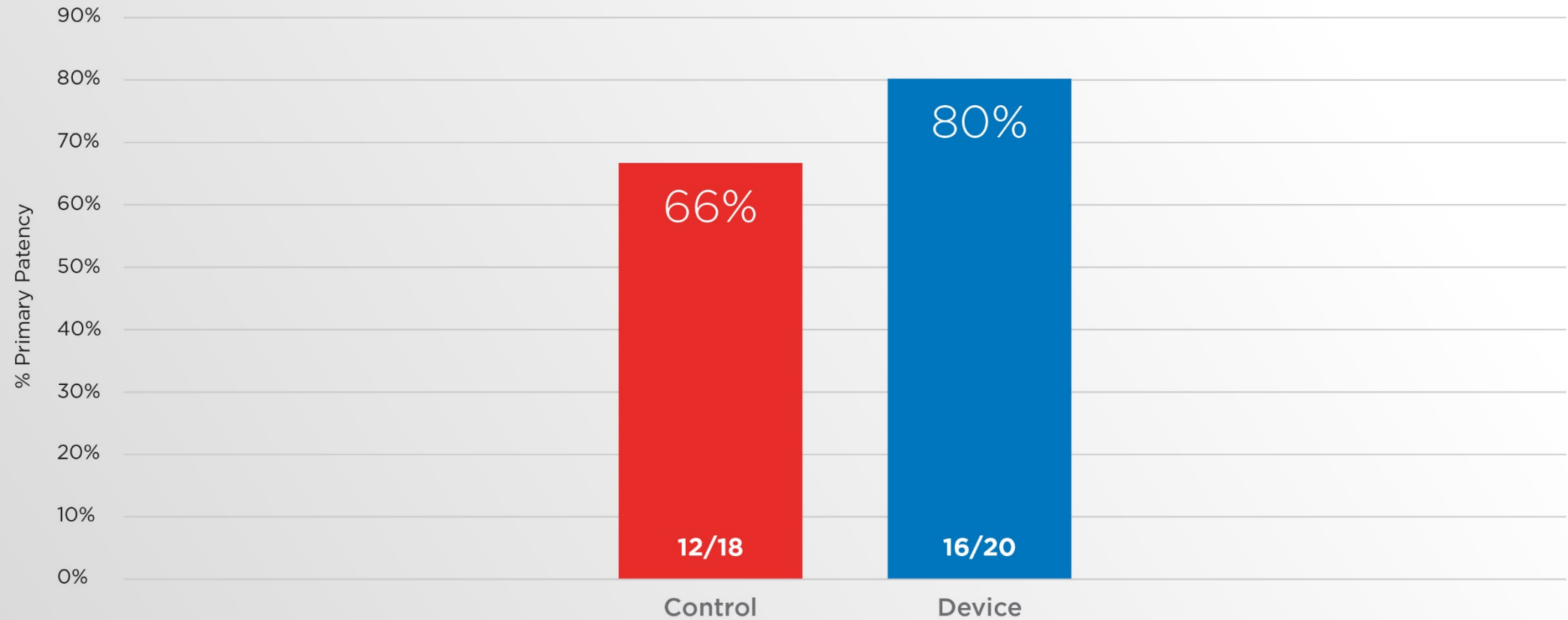


* Excluding early failures occurred within 72 hours of AVF surgery

**Stenosis= Luminal reduction $\geq 50\%$ anywhere within the access circuit

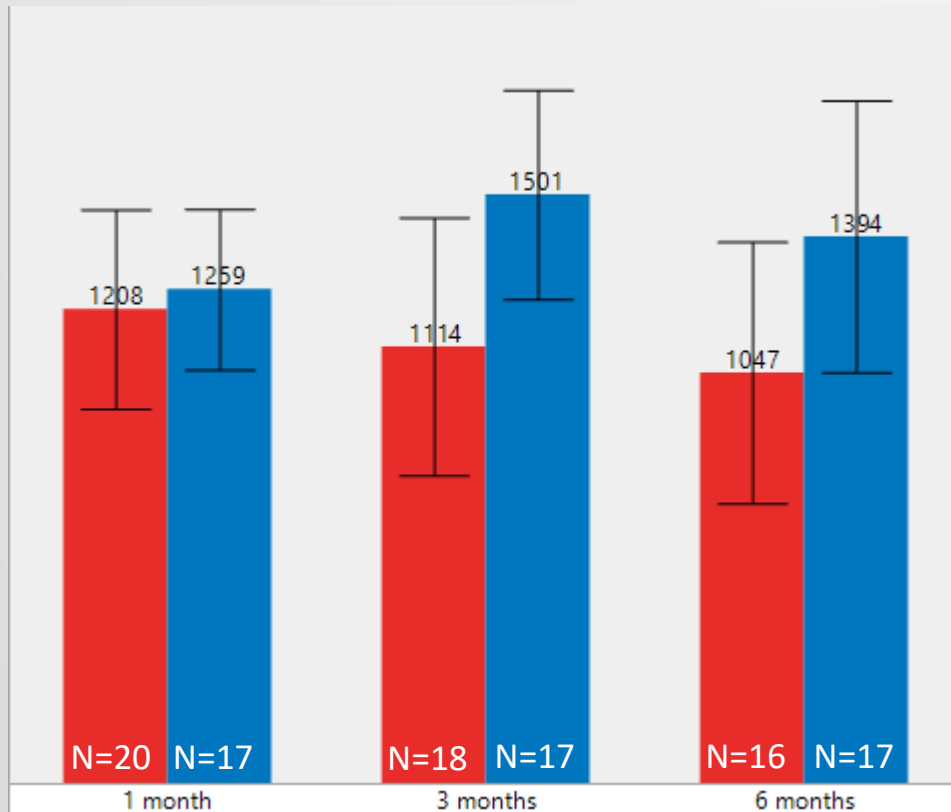
● Control ● Device

Primary Patency 6 months

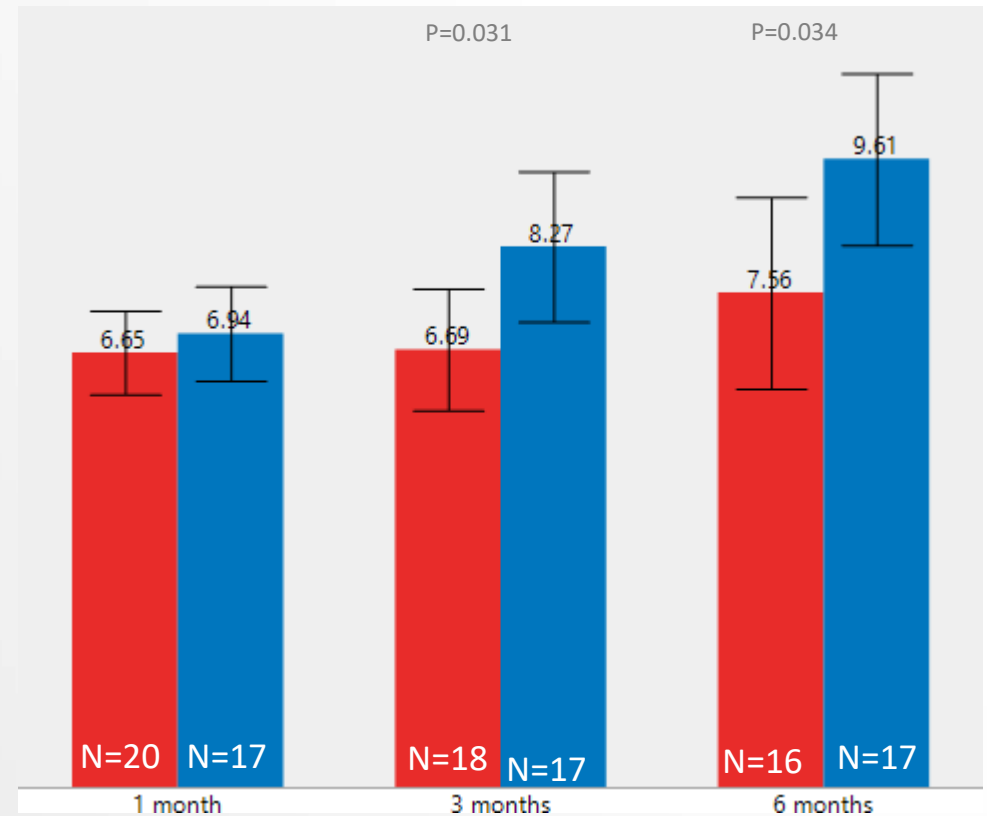


Fistula outflow and lumen diameter

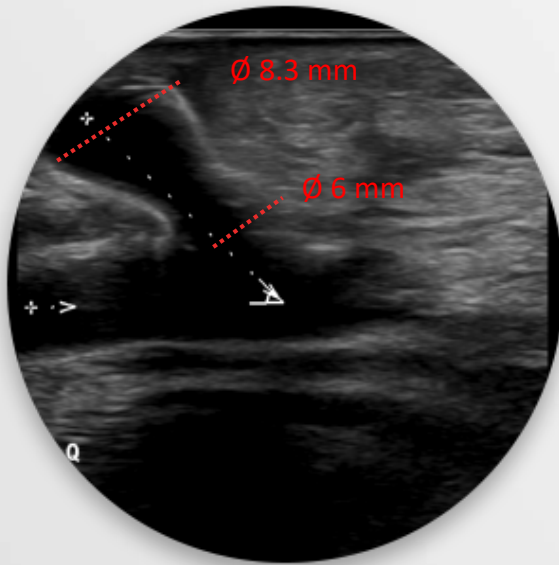
Blood Flow (mL/min)



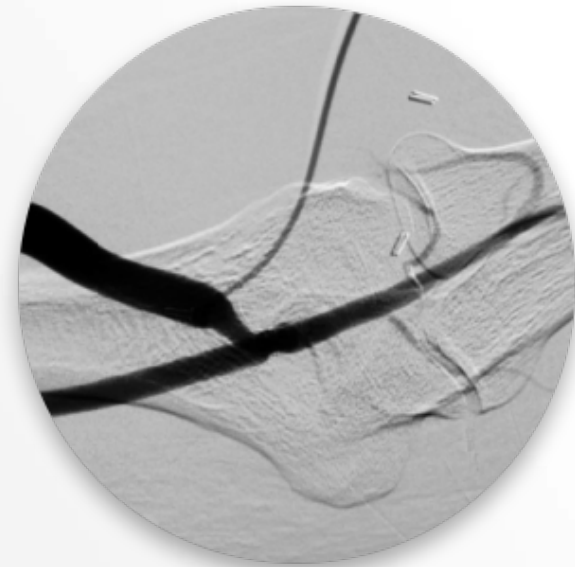
Vein Internal lumen diameter (mm)



● Control ● Device CI=95%

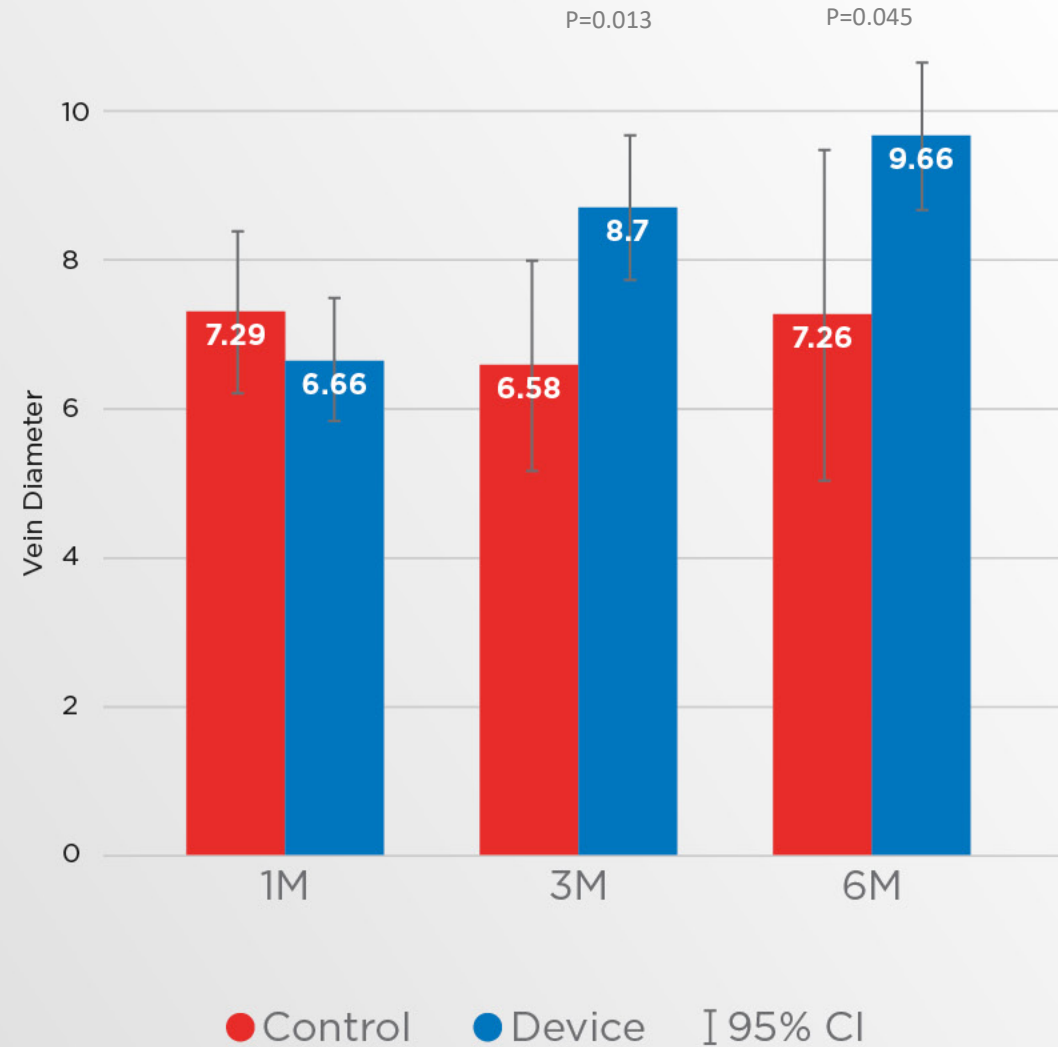


1 Month US

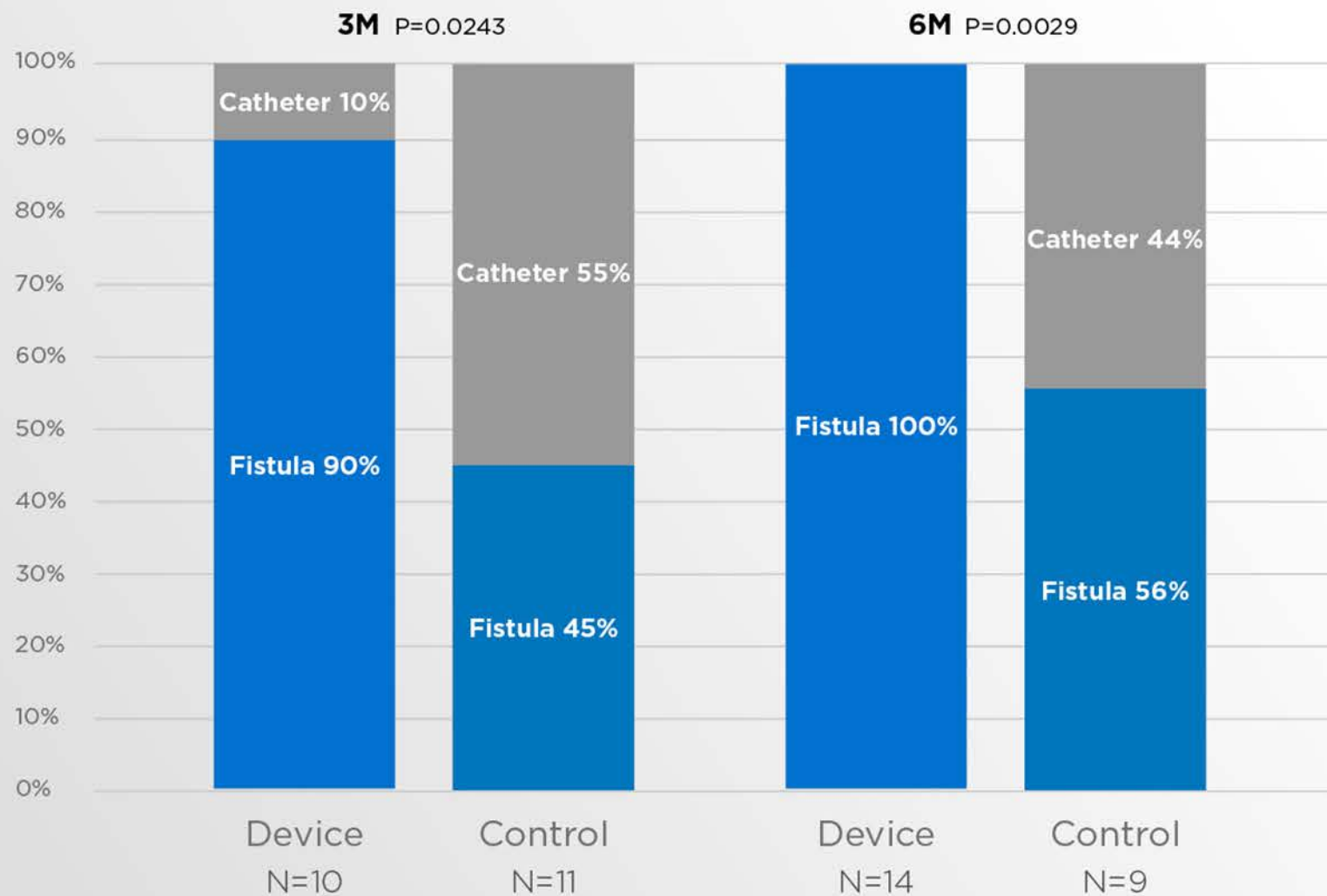


3 Months Angio

Vein Diameter in Patients on Active HD



Favorable Functional Maturation in **VasQ**™ Implanted Patients



*Patients on active dialysis

Factors associated with likelihood of using the fistula for hemodialysis 3 months post surgery

Logistic regression

Univariate Logistic Regression

Variable	Odds Ratio	95% Confidence Interval	P Value
Treatment group (Device vs Control)	23	2.58 to 204.6	0.0049
Diameter (per 1mm increase)	2.73	1.3 to 5.73	0.0077
Flow (≥ 600 vs < 600)	8.85	1.34 to 58.34	0.023
Gender (Male/Female)	3.75	0.89 to 15.6	0.069
HTN (Yes vs No)	3.2	0.18 to 55.9	0.425
Age (≥ 65 vs < 65)	0.68	0.16 to 2.79	0.599
Race (Black vs White)	1.78	0.18 to 17.2	0.61
BMI (per 1 Kg/m ²)	0.985	0.92 to 1.04	0.648

Multivariate Logistic Regression

Variable	Odds Ratio	95% Confidence Interval	P Value
Diameter (per 1mm increase)	2.56	1.08 to 6.08	0.0328
Treatment group (Device/Control)	14.3	1.28 to 159.4	0.0304
Flow (≥ 600 vs < 600)	4.3	0.009 to 1992	0.64

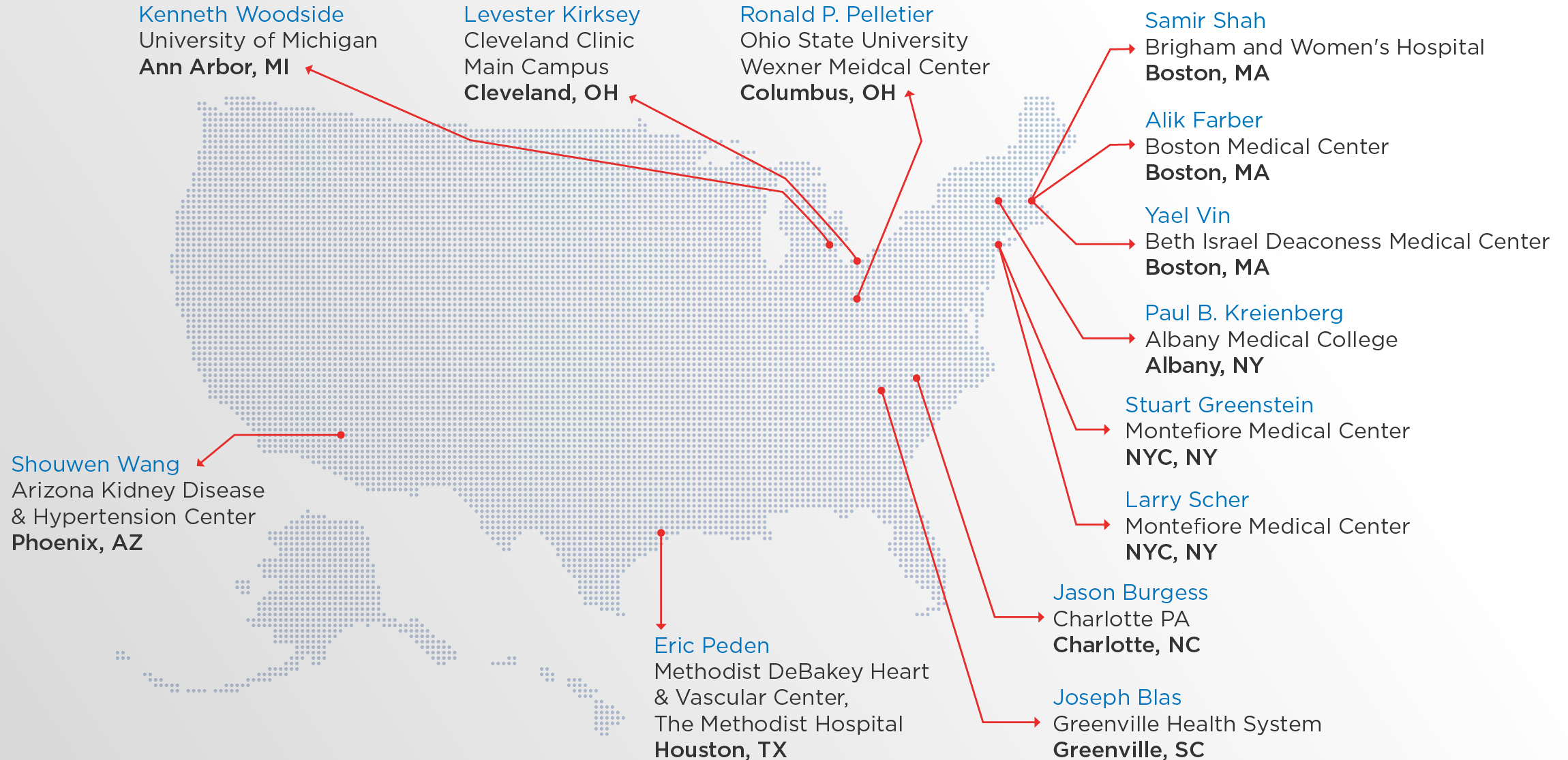
VasQ US Study

(NCT03242343)

Study design- Prospective, multi-center, single-arm, open label, enrolling patients referred to surgical creation of new brachiocephalic fistula (BCF).

- Primary endpoint- Primary patency 6 months post AVF creation
- Sample size- 129 patients
- Follow up- 24 months (visits at 1, 3, 6, 12 and 24 months), all study visits include:
- Doppler US and Clinical examination of the study fistula

US Study Centers



VasQ US study status

- All 13 centers are open for patient recruitment
- First patient enrolled on January 2018
- To date 25 patients implanted by 10 different surgeons in 9 centers
- 16 patients attended 1 month follow up
- No device related AE's were noted

