WavelinQ Endovascular AV Fistula Procedure

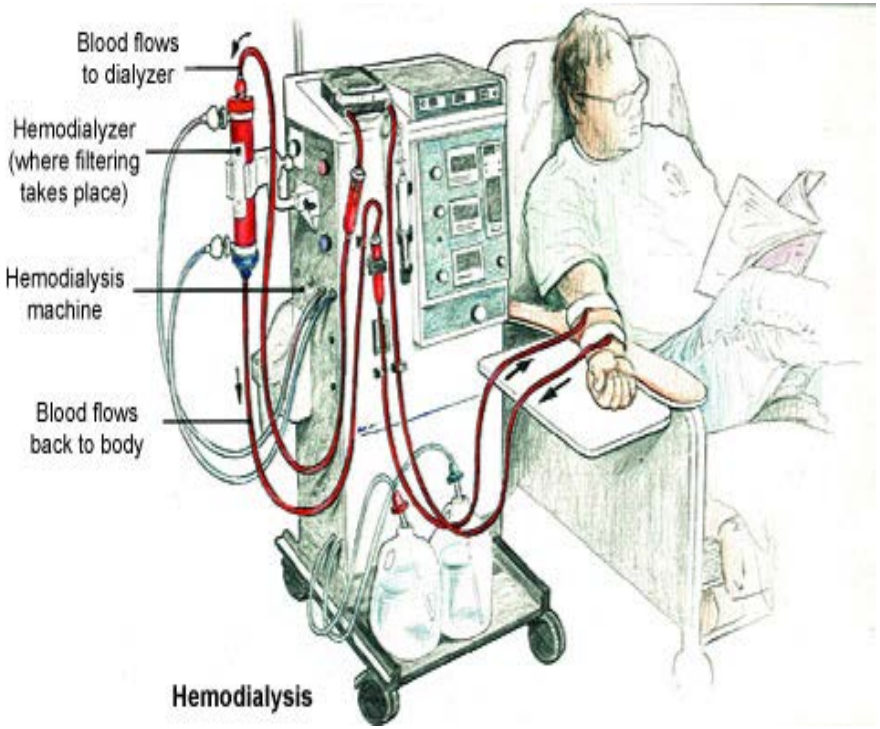
Presenter/Attendees

- Paul Kreienberg, MD
  - Vascular Surgeon, The Vascular Group, Albany NY
  - Program Director, Vascular Surgery Training Program, Albany Medical Center

- Ben Barclay, Director Reimbursement
- Michelle Machuca, Sr. Director Reimbursement
- Gail Daubert, Reed Smith

Hemodialysis for Kidney Failure

3-4 hours 3 times/week



Surgical AV Fistula

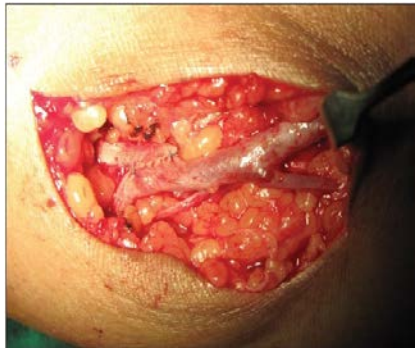
Open surgery in the arm to connect artery & vein, high volume surgery

Allows patient to connect to dialysis repeatedly

20-60% Failure[1,2]

2-3 repeat surgeries required[3-5]

Patient's lifeline, best option today



1 Al-Jaishi et al. AJKD 2014
2 Dember LM, Beck GJ, Allon M, et al. JAMA 2008; 299:2164–2171
3 Falk, A.M. J Vasc Interv Radiol 2006; 17:807–813.
4 Kimball, et al. Journal of Vascular Surgery. Vol 54, No 3. 2011
5 Yang, et al. JVA 2017

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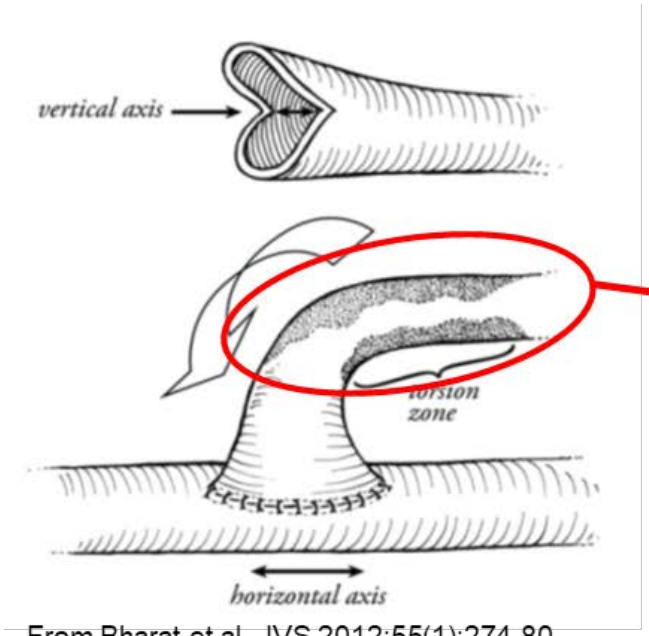
Surgical AV Fistulas – Gold Standard but …

Clinical Facts	
Primary failure rate[1-5]	20-60%
Mean maturation time[3,6]	4-9 months
Average re-interventions per pt-yr [1,7]	2-3
Occlusions (thrombosis)[5,8]	17-25%

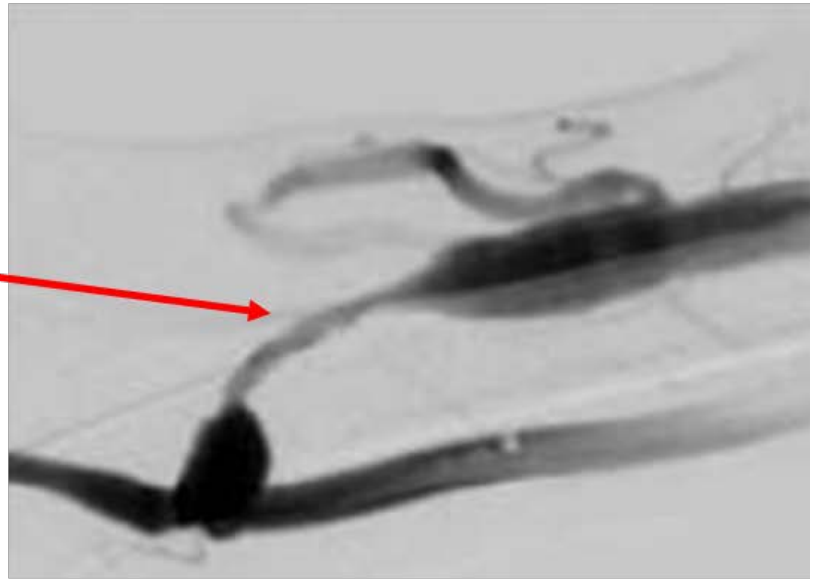
Reason for Innovation
Surgical technique consistency
Improve availability of AVF anatomical sites
Increase patient acceptance
Reduce cost of interventions & complications

1 Kimball, et al. Journal of Vascular Surgery. Vol 54, No 3. 2011
2 Peterson W., et al. Clin J Am Soc Nephrol. 2008 March; 3(2):437-441
3 Lee, T., et al. American Journal of Kidney Diseases, Vol 46, No 3 (September), 2005: pp. 501-508
4 Biuckians A, Scott EC, Meier GH, et al. J Vasc Surg 2008; 47:415–421
5 Dember LM, Beck GJ, Allon M, et al. JAMA 2008; 299:2164–2171
6 USRDS Annual report, 2017.
7 Falk, A.M. J Vasc Interv Radiol 2006; 17:807–813.
8 Stolic R. Med Princ Pract. 2012

Surgical manipulation of the vein is associated with fistula failure[1,2]



From Bharat et al. JVS 2012;55(1):274-80



27% to 68% reported juxta-anastomotic lesions as cause of failure[1]

Surgical manipulation of the vein is associated with neointimal hyperplasia and primary fistula failure[1,2]

1. Beathard ACKD 2009;16(5):339-51.
2. Roy-Chaudhury et al. JASN 2006;17:1112-27

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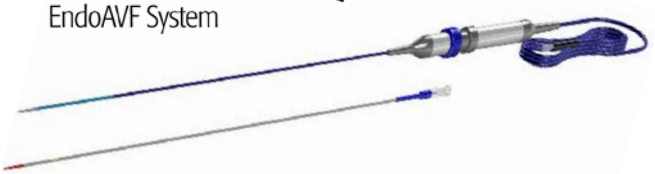
endoAVF Technologies

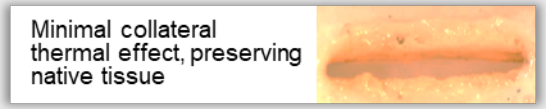
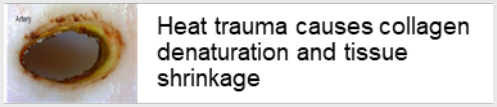
everlinQ

Rebranded to

WAVELINQ™
EndoAVF System



ELLIPSYS®

Device Design	**Two 6Fr flexible magnetic catheters**	**One 6 Fr catheter**
Mechanism of action	RF energy creates a channel with minimal heat or mechanical trauma 	Heat energy originally intended to shrink and close vessels 
Procedure	• Single-stage procedure • Requires fluoroscopy & ultrasound • Venous & arterial puncture • Coil embolization of brachial vein performed at time of endoAVF creation • Primary site of service outpatient, ASC	• Two-stage procedure, fistula day 1, angioplasty performed week 1-2 • Performed using ultrasound only • Venous puncture • Primary site of service in office-based lab
Outcomes[1,2]	• 98% technical success • 87% maturation • 0.46 interventions per pt-yr • 69% primary patency @ 1-year • 84% secondary patency @ 1-year	• 95% technical success • 86% maturation • 2.7 interventions per pt-yr • Primary patency: Not Reported – 2-stage procedure • Secondary patency: 86.7% @ 1-year

Lok, C. et al. Am J Kidney Dis. 2017; 70(4): 486-497
Hull, J. et al. J Vasc Interv Radiol 2018; 29:149–158

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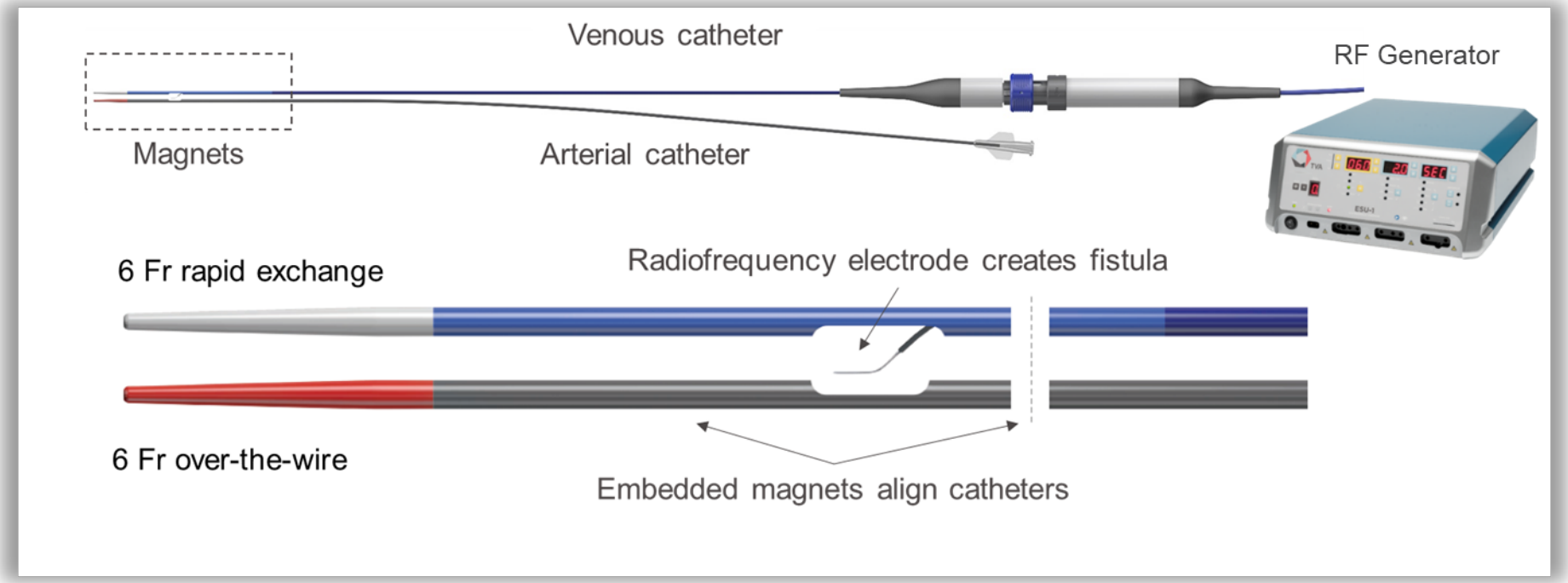
WavelinQ endoAVF System

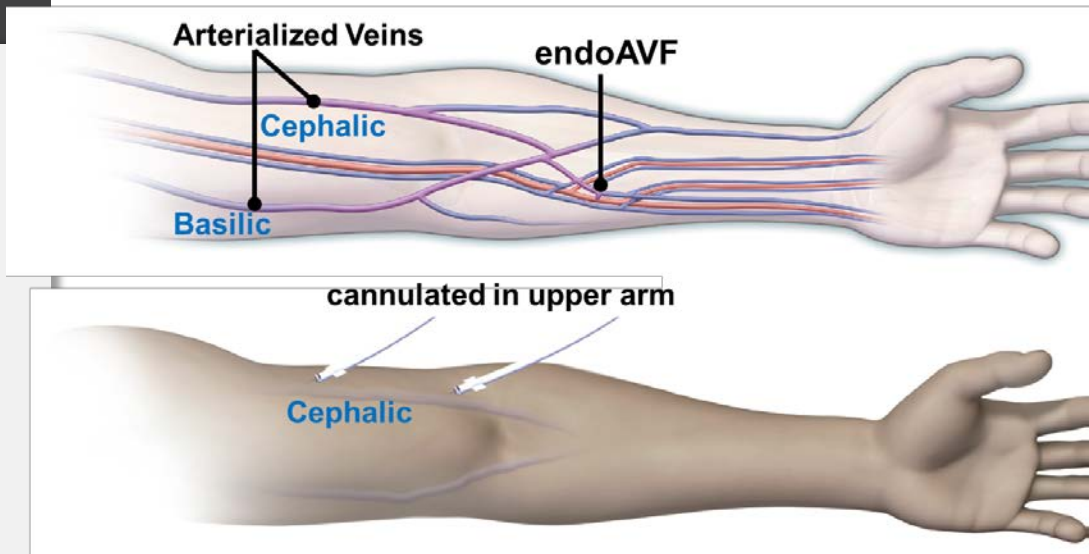
Dual catheter system utilizing RF energy to create an AV fistula without open surgery



WavelinQ endoAVF Expands Options for Hemodialysis Access

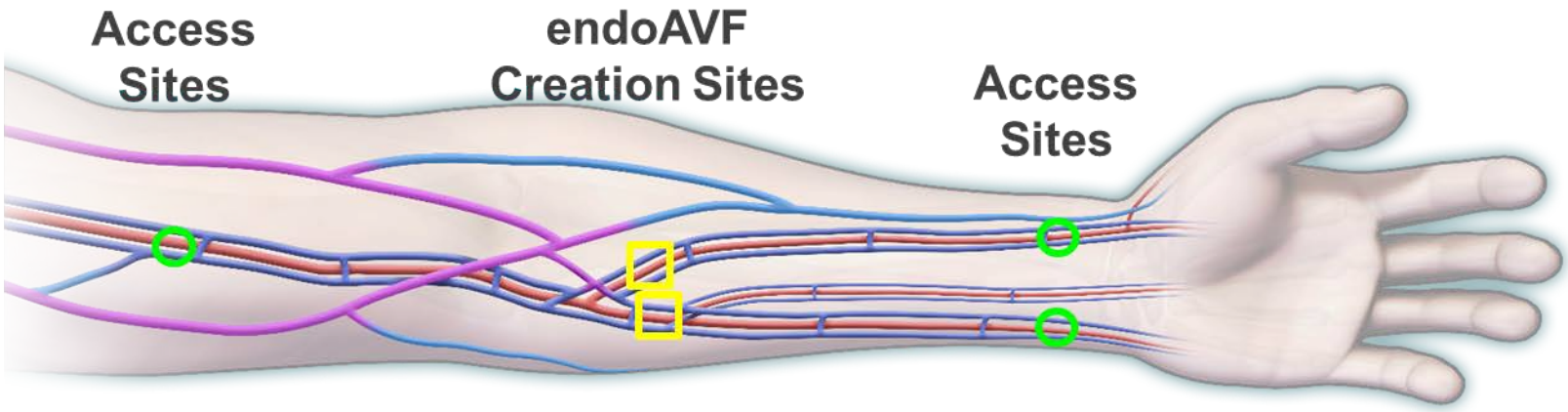
Benefits

- Creates a functioning AVF with minimal interventions needed to maintain patency[1,2]
- Avoids open surgery & scarring[2]
- Provides additional anatomic options for a fistula[1,3]



1.Lok. AJKD 2017
2.Yang. JVA 2017
3.J Am Soc Nephrol 2016; 27:31A.

WavelinQ EndoAVF Procedure



Arterial Procedural Access Vessels
- Brachial artery
- Radial artery at wrist
- Ulnar artery wrist

Venous Procedural Access Vessels
- Brachial vein
- Radial vein
- Ulnar vein

Fistula creation sites in proximal forearm
- Ulnar vein/ulnar artery
- Radial vein/radial artery

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Minimal Arm Disfigurement
Increased Patient Satisfaction

These case studies are shared as examples of potential outcome for a patient that has been treated using the everlinQ endoAVF System. Individual patient outcomes can and do vary based on the condition of the patient, severity of disease, extent of surgery, and response to treatment.

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Update slide re study Multiple Studies Support the Clinical Benefits of WavelinQ endoAVF

Pilot Study

FLEX Study

Feasibility and safety of using the everlinQ endoAVF system

Design

- Single-center, multi-operator, prospective study
- **33 patients**, 4 sequential cohorts
- 6 month follow-up

Completed in 2014

JVIR 2015; 26:484–490.

Expanded Population

NEAT Study

Safety and effectiveness of using the everlinQ endoAVF system

Design

- Multicenter, prospective in Canada, Australia and New Zealand
- **60 patients (+20 roll-in**),
- single arm
- 12 month follow-up

Completed in 2016

Am J Kidney Dis. 2017; 70(4): 486-497

Next Generation Device

EASE Study

Safety and efficacy of using the everlinQ *4* endoAVF (4 Fr) System

Design

- Single center prospective study
- **32 patients**
- 6 month follow-up

Completed 2017

Expanded Population

endoAVF Study
EU Post-Market Study

"Real world" multi-center study designed to continue building clinical evidence with everlinQ & everlinQ *4*

Design

- Multicenter, prospective study
- **120 patients**, single arm
- 12 month follow-up
- Includes radiocephalic AVF candidates

Enrolling

Post-Market US Study

CONNECT-AV Study

"Real world" multi-center study designed to collect US evidence with the everlinQ System

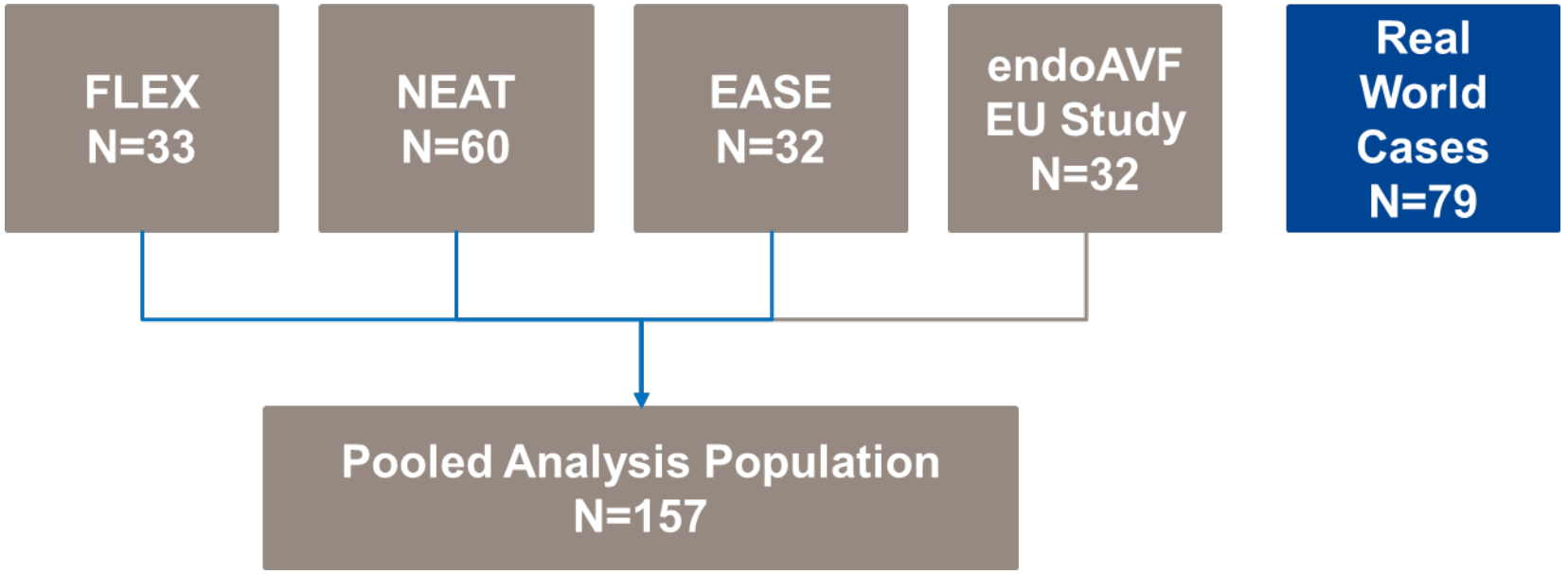
Design

- 30 centers in US, prospective study
- **200 - 300 patients**
- 12 month follow-up

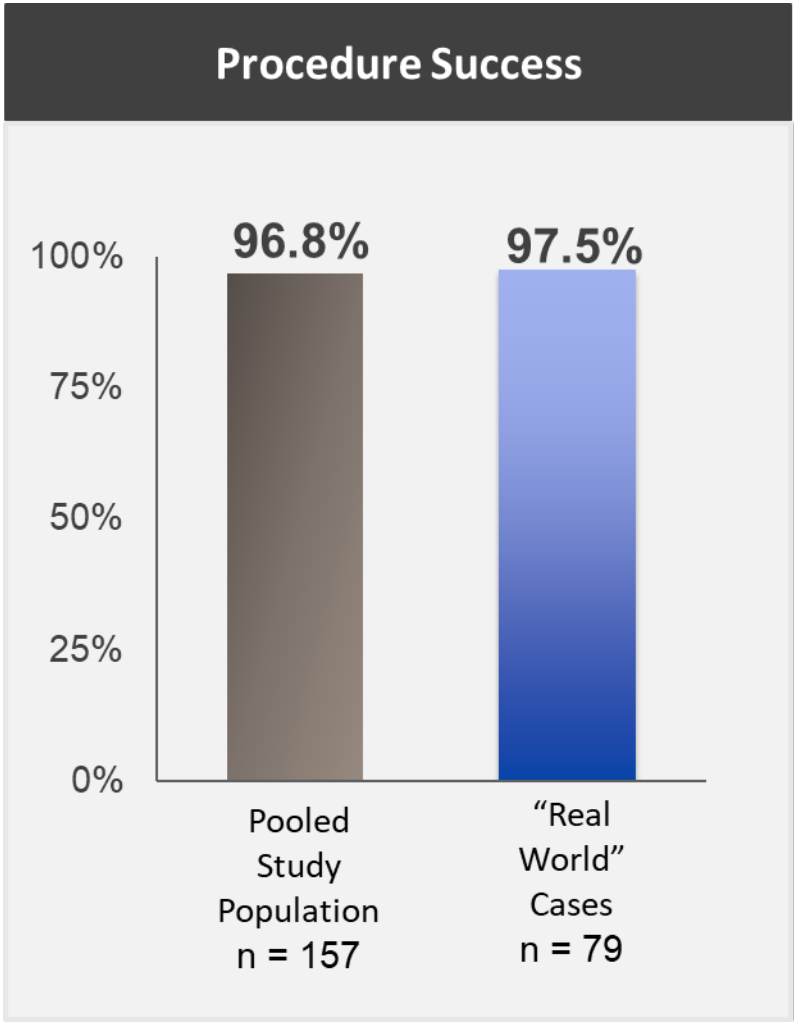
Starts Q1/Q2 2019

WavelinQ endoAVF Global Meta-Analysis

28 sites in Canada, Australia, Germany, UK, Netherlands, Paraguay, Switzerland

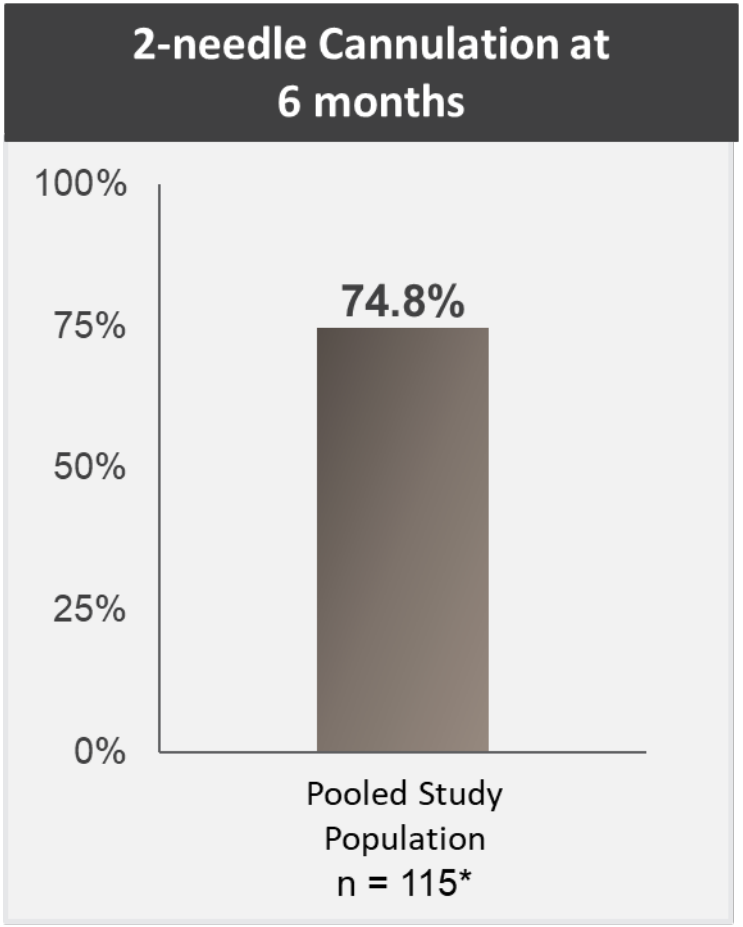


WavelinQ endoAVF Global Procedure Outcomes



Procedure Success: Successful endoAVF creation is confirmed via intra-procedural angiography or duplex ultrasound performed post-procedure

WavelinQ endoAVF Global Cannulation Outcomes

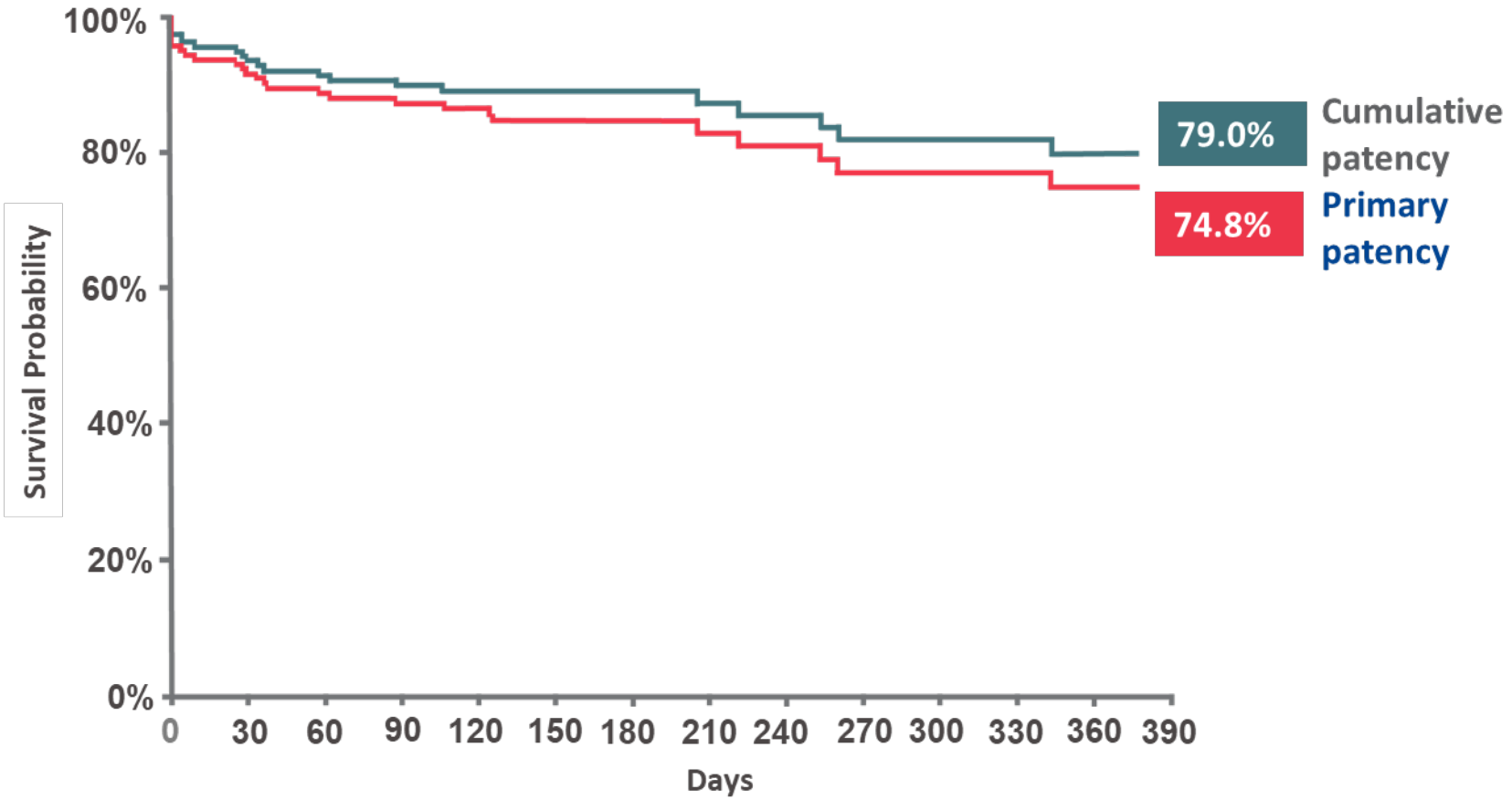


	Pooled Studies
Time to cannulation, months (median, range)	2.1 [1.6,3.2]

- Only 14.6% of predialysis patients initiated dialysis with a CVC
- Only 18.6% of patients on dialysis at enrollment were using a CVC at 12 months

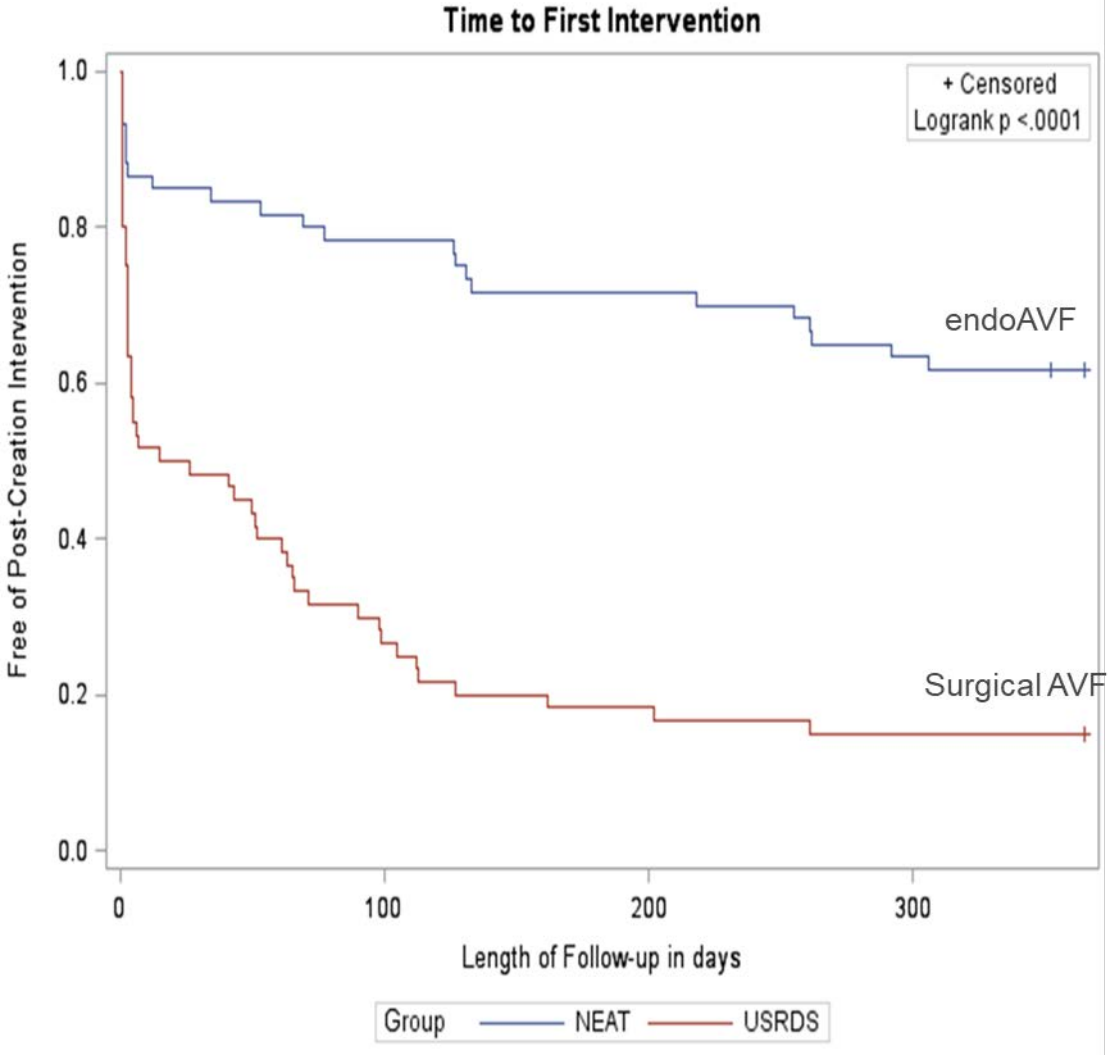
*Based on number of evaluable patients at 6 month time point. (ie, excludes deaths and patients lost to follow-up)

WavelinQ endoAVF Global Patencies



At Risk														
Primary	157	150	131	121	112	103	100	70	45	43	39	38	38	29
Cumulative	157	152	133	124	116	107	106	76	50	48	43	42	42	33

WavelinQ endoAVF vs. Surgical AVF



- 1 month after fistula created, 50% of surgical AVF patients need an additional intervention compared to only 15% with endoAVF[1]
- At 1 year, 85% of surgical AVF patients have had an additional intervention compared to only 38% of endoAVF patients[1]

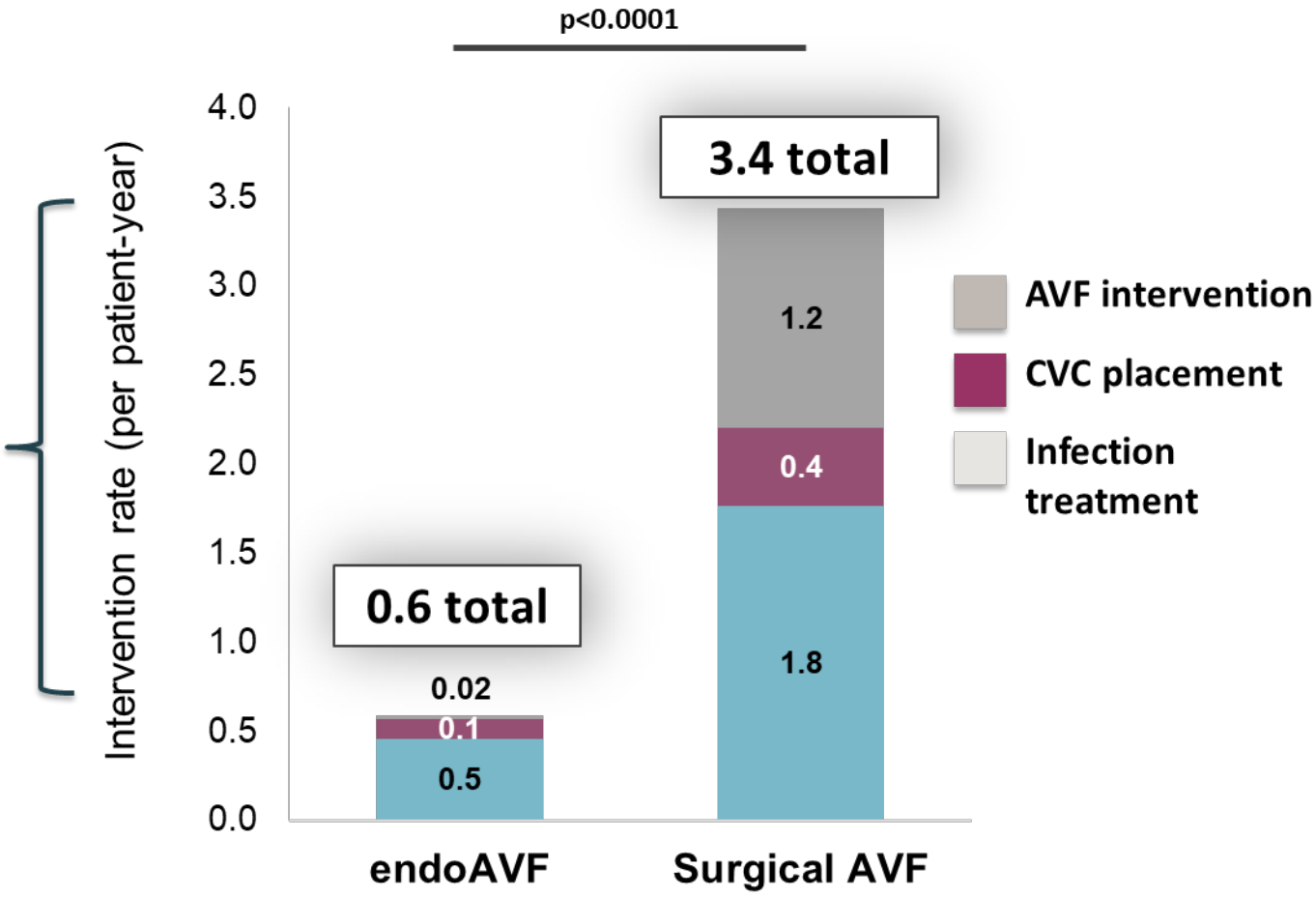
[1] Arnold, et al. Comparison of NEAT to a propensity-score matched surgical AVF cohort from US Renal Database System. JVIR 2018.

Fewer endoAVF patients need an intervention than patients with a surgical AVF

WavelinQ endoAVF vs Surgery: AVF Interventions

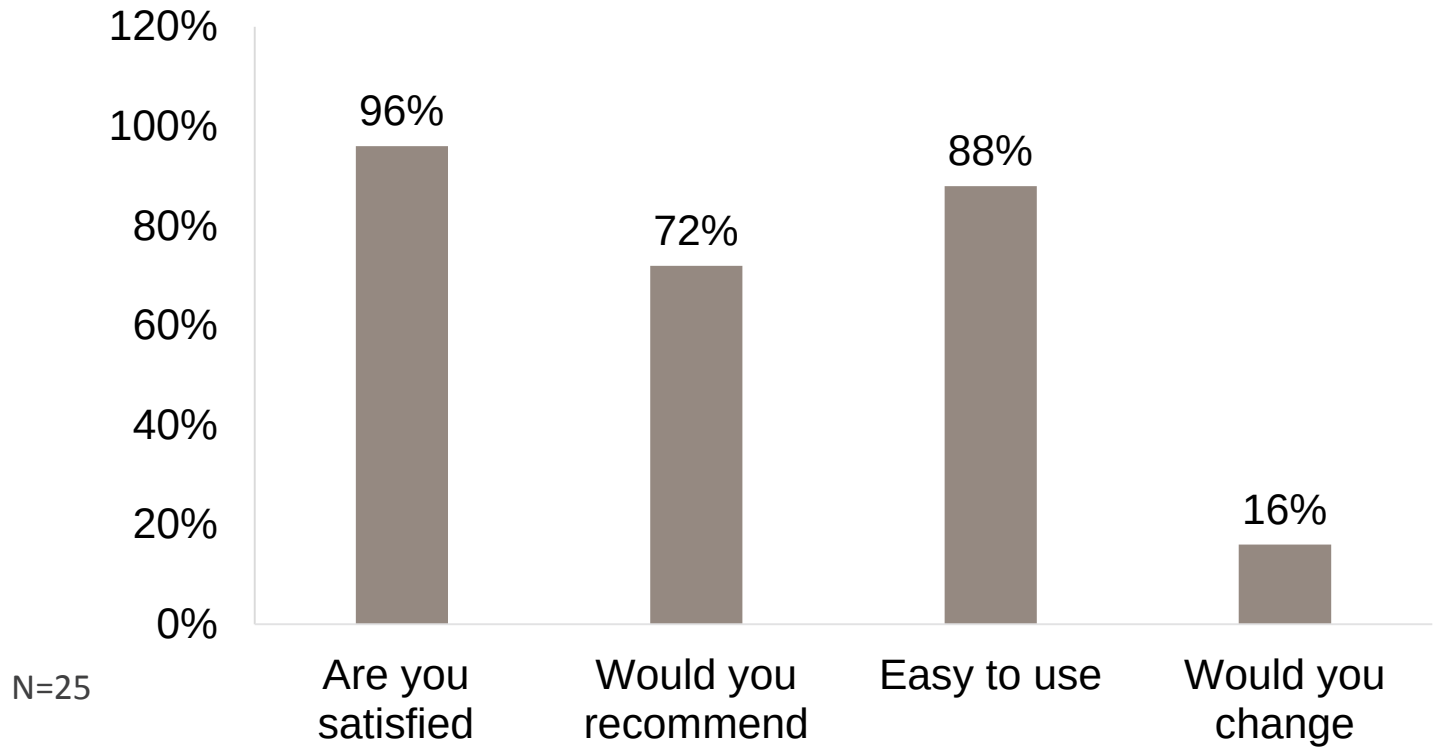
Propensity-score matched Medicare cohort of surgical AVF patients to NEAT endoAVF patients

~6X fewer post-creation interventions with everlinQ, resulting in substantial cost savings



Yang S, Arnold R, Lok C, Rajan D, Glickman M. J Vasc Access 2017; 18(Suppl. 2): 8 – 14.

Patient Satisfaction with WavelinQ endoAVF



Patients are satisfied with their endoAVF and would not change to another type of access

Lok, C. et al. Nephrology Dialysis Transplantation 32 (Supplement 3): iii329–iii343, 2017

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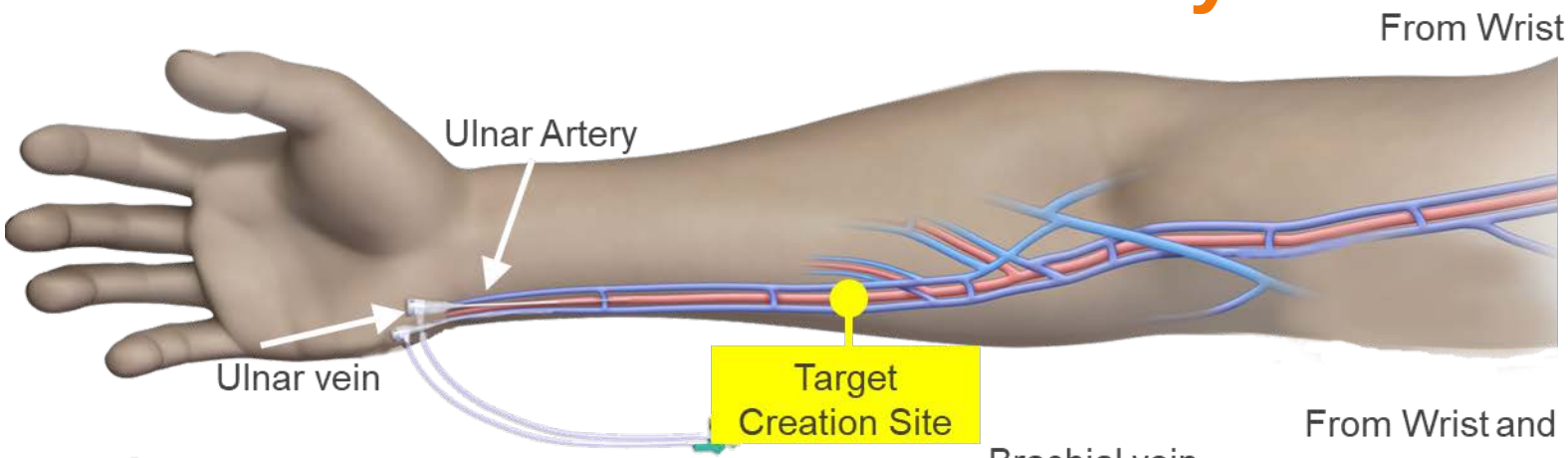
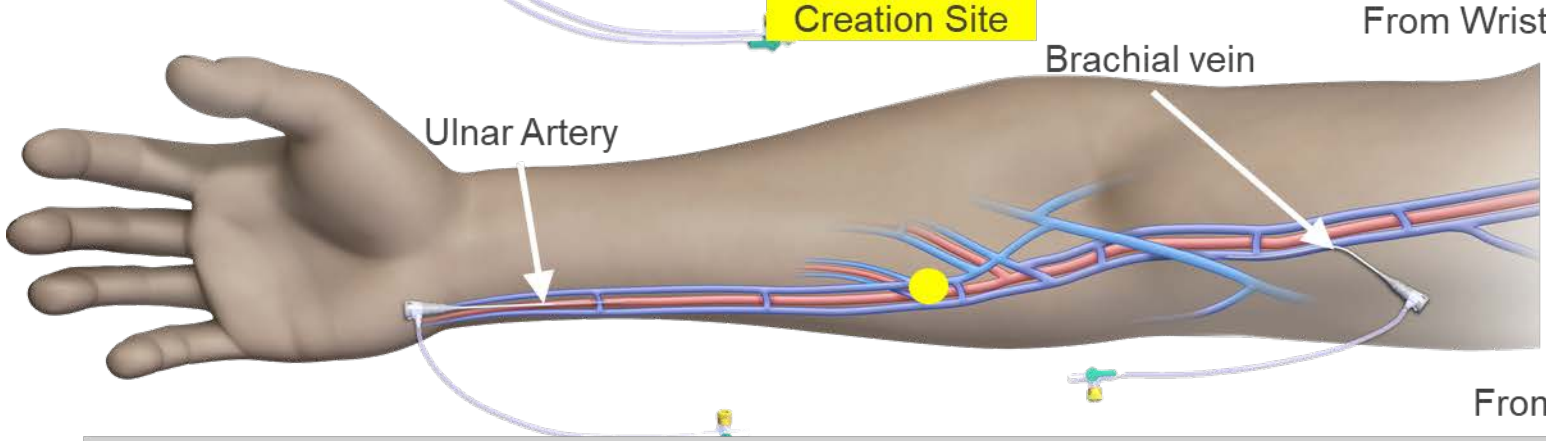
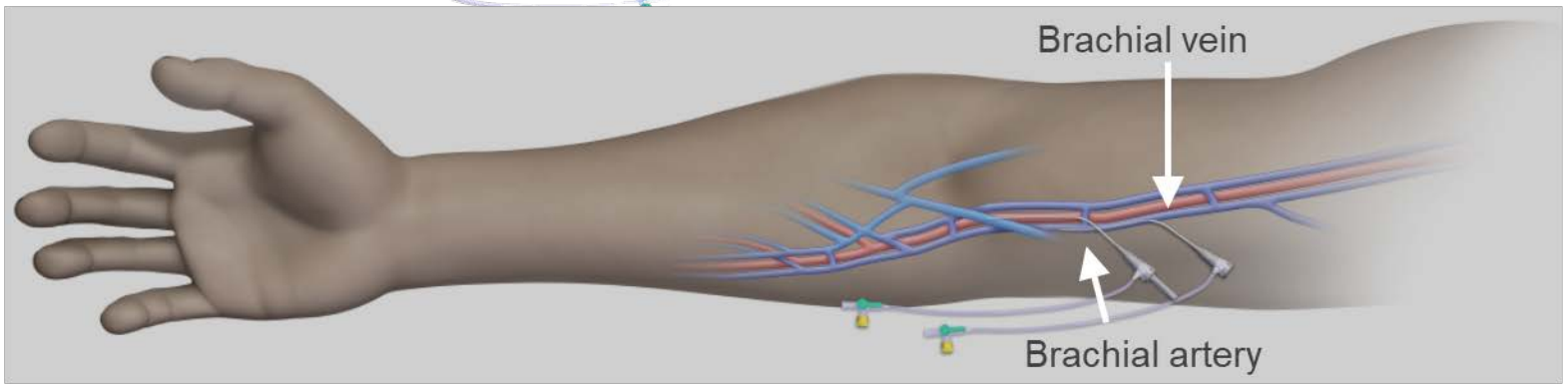
WavelinQ Harnesses Patient Driven Innovation

- Survey of 150 hemodialysis patients conducted by AAKP
- What matters most to patients:
  - Infection risk
  - Doctor recommendation
  - Durability of the access
  - Risk of needing another procedure (intervention)
  - Impact on daily activities
- Predictors for never receiving an AVF using multi-variate logistic regression:
  - Procedure invasiveness (odd ratio 3.95)
  - Durability of the vascular access (odd ratio 4.76)
- 86% of patients without an AVF would have been more likely to get an AVF if there was a less invasive option without open surgery

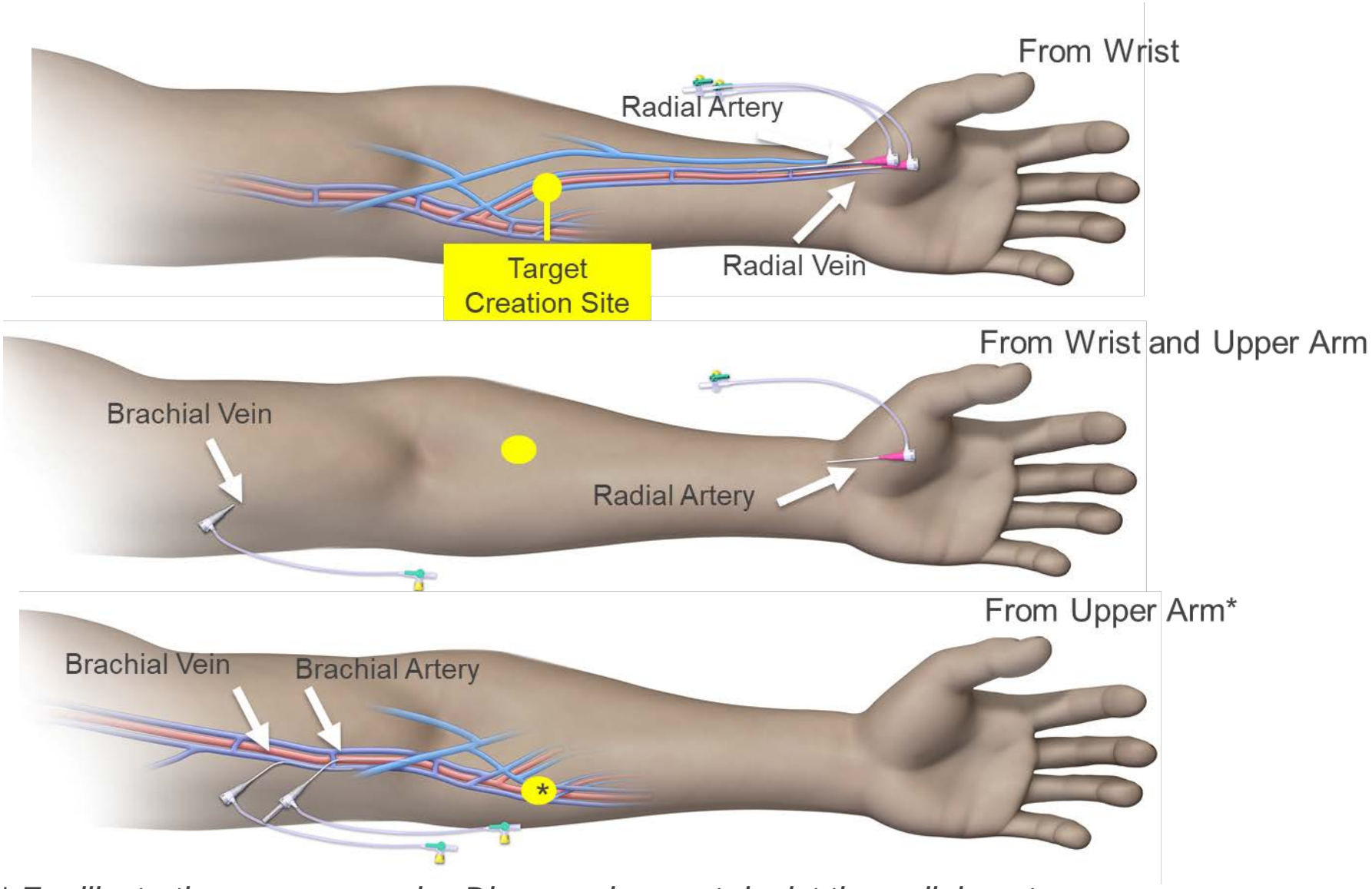
Procedure Access Options for Ulnar Vein to Ulnar Artery Fistula





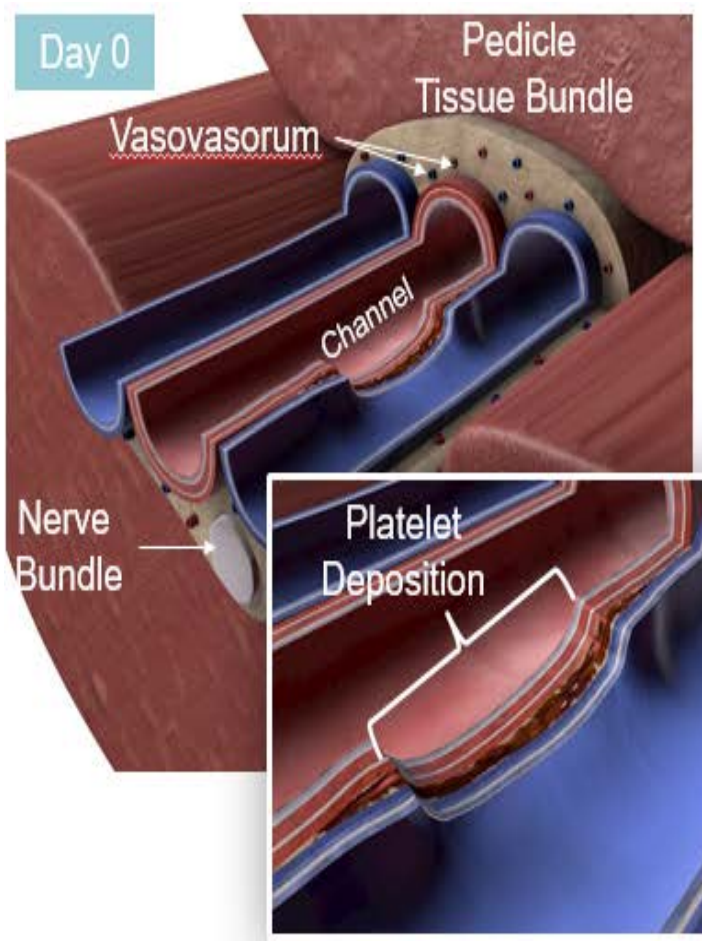


Procedure Access Options for Radial Vein to Radial Artery Fistula

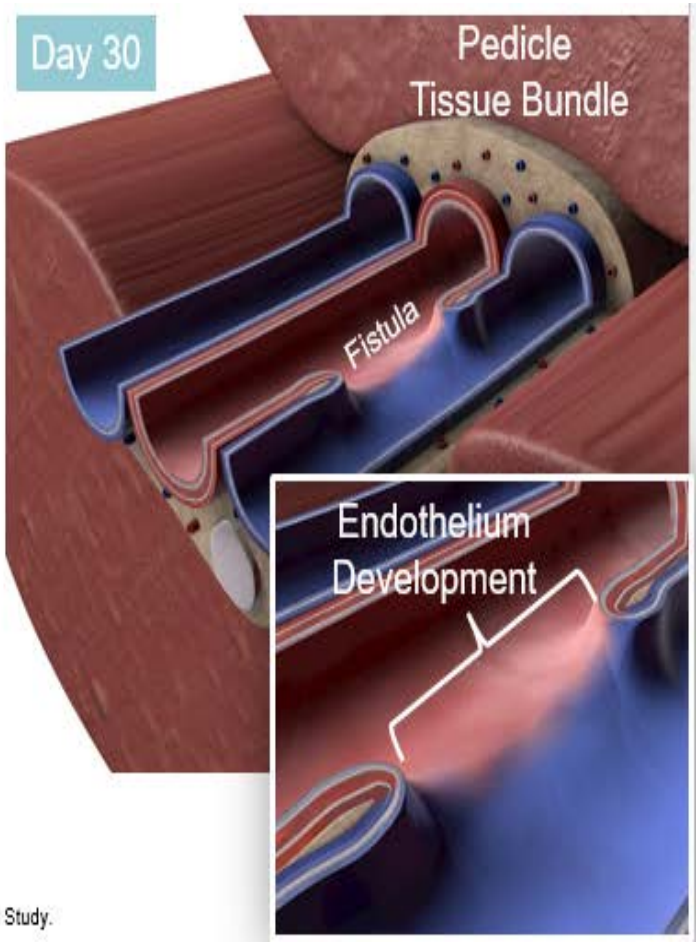


** For illustration purposes only. Diagram does not depict the radial anatomy*

Development of the endoAVF



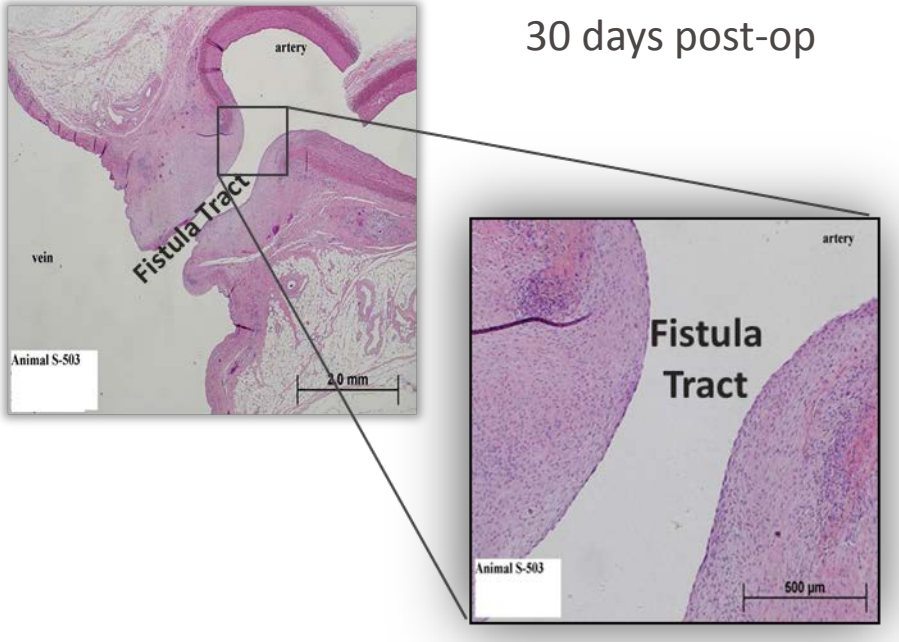
1. endoAVF develops from a channel cut through tissue
2. Blood follows path of least resistance from artery to vein
3. Initial platelet deposition leads to endothelium development over time (within 30 days)



TVA Medical Data on file. RR0055 GLP Animal Study.

Histology of the endoAVF

- Well-healed endoAVF tract with organized, mature fibrous remodeling
- Lining of endoAVF tract well covered in endothelial cells



30 days post-op

Image of an endoAVF at day 30 viewed from a dissected iliac artery of a sheep model.

TVA Medical Data on file. RR0055 GLP Animal Study.

endoAVF created with minimal vessel trauma

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Minimal Arm Disfigurement Increased Patient Satisfaction (2)

These case studies are shared as examples of potential outcome for a patient that has been treated using the everlinQ endoAVF System. Individual patient outcomes can and do vary based on the condition of the patient, severity of disease, extent of surgery, and response to treatment.

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Thank You