Endovascular Proximal Forearm Fistula: Early Experience in Birmingham, England

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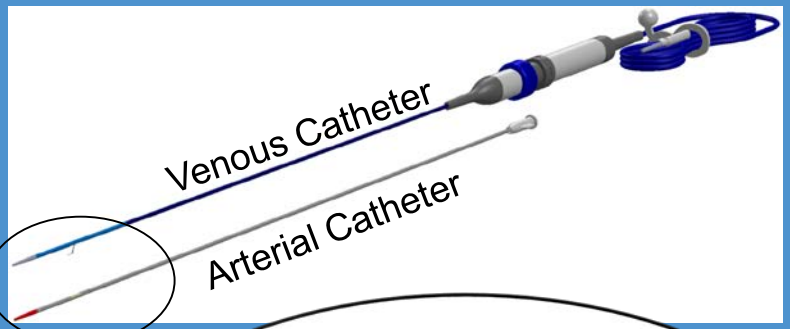
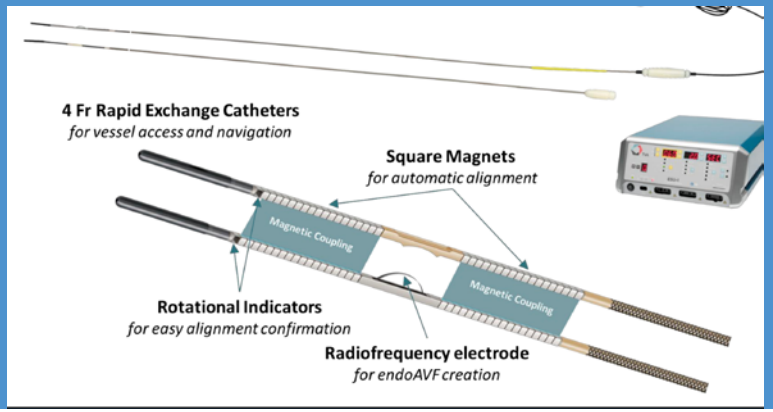
Disclosures

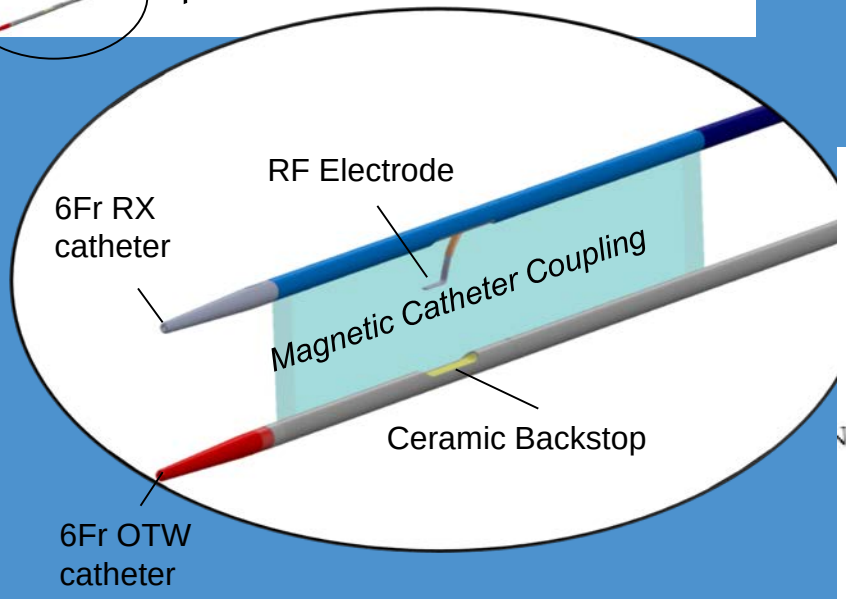
- I am UK CI for the everlinQ Post marketing UK study

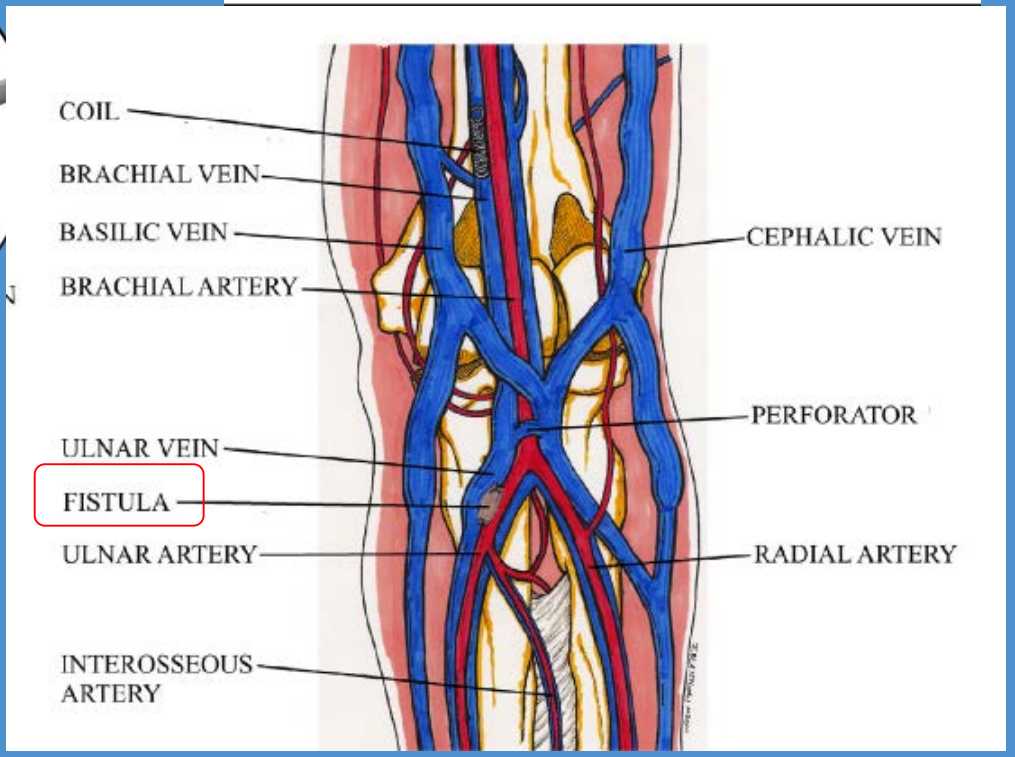
DISCLAIMER: U.S. audience: The everlinQ™ endoAVF System is not available for sale in the United States and is not cleared by the FDA. International audience: The everlinQ endoAVF System has been issued European CE Mark and Health Canada Medical Device License for the creation of an arteriovenous fistula for hemodialysis.

TVA everlinQ endoAVF System









Building Evidence for endoAVF

Single Center Study 6Fr

FLEX Study

Feasibility and safety of the everlinQ endoAVF system

Design

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

Key Outcomes

- 97% Technical success
- 96% Maturation
- 96% Patency @ 6 mo

Supported CE Mark

Completed in 2014

Expanded Population 6Fr

NEAT Study

Safety and effectiveness of the everlinQ endoAVF system

Design

- Multicenter, prospective in Canada, Australia and NZ
- 60 patients, single arm
- 1, 3, 6, & 12 month follow-up

Key Outcomes

- 98% procedure success
- Fewer procedures than surgery, (0.6 PPPY) to achieve and maintain comparable functional cannulation
- 91% maturation
- 83.5% secondary patency

Supports FDA *de novo* and US/EU Reimbursement

Completed in 2016

Next Generation Device 4Fr

EASE Study

Safety and efficacy of the everlinQ endoAVF System

Design

- Single center, multi-operator prospective study in Paraguay
- 32 patients
- 1, 3 & 6 month follow-up

Key Outcomes

- 97% procedure success
- 83% maturation @ 3 mo
- 71% 2-needle cannulation @ 6mo

Supports CE Mark and 4Fr 510(k) in US

Completed in 2017

Expanded Population

endoAVF EU Post-Market Study

"Real world" multi-center study designed to continue building clinical evidence with everlinQ endoAVF

Design

- Multicenter, prospective study
- ~120 patients, single arm
  - Up to 40 6Fr
  - Up to 80 4Fr
- 1, 3, 6, & 12 month follow-up
- 4Fr and 6Fr included

Enrolled by Q3 2018
Completion in Q3 2019

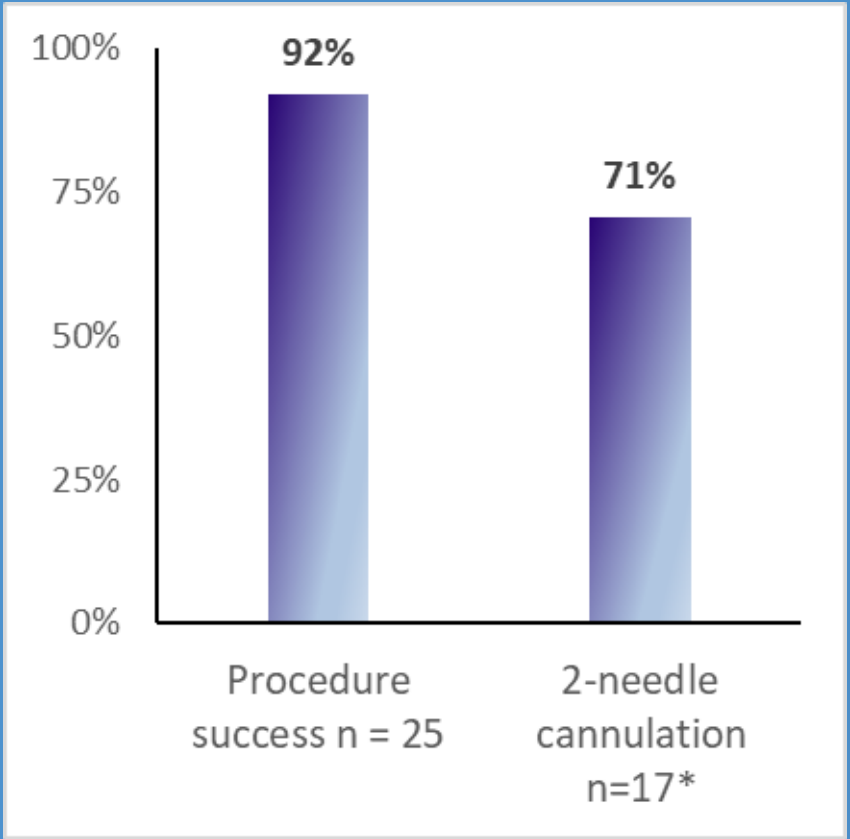
Supports 4Fr 510(k) in US & US/EU Reimbursement

Enrolling

Birmingham endoAVF patient demographics

Patient Characteristics	Birmingham
# of Cases to date	25
Pre-dialysis patients	48% (12/25)
Age (Mean, min.-max.)	58.0 (27-79)
Gender: male	84% (21/25)
BMI (Mean, min.-max.)	27.5 (18.9-35.5)
Diabetes	44% (11/25)
Previous AVF	32% (8/25)

Birmingham provisional results



* Excluding patients with successful endoAVF who were never on dialysis during study and 4 on-dialysis patients without 6 week follow-up

* 1 patient with 2 needle cannulation eventually had endoAVF abandonment

Clinical Outcomes	
Follow-up (Median, min-max)	141.2 days (0 – 391 days)
Adverse events	Bruising (x1 pt) Occlusion (x 2pt) Thrombosis (x 1pt previous Occlusion) – resulted in abandonment
Time to Cannulation (Median, min-max)	97 days* (41 - 169)
Interventions * Missing data for one patient	4 coil embolization 1 vein superficialization 2 thrombectomies

Case Study - Background

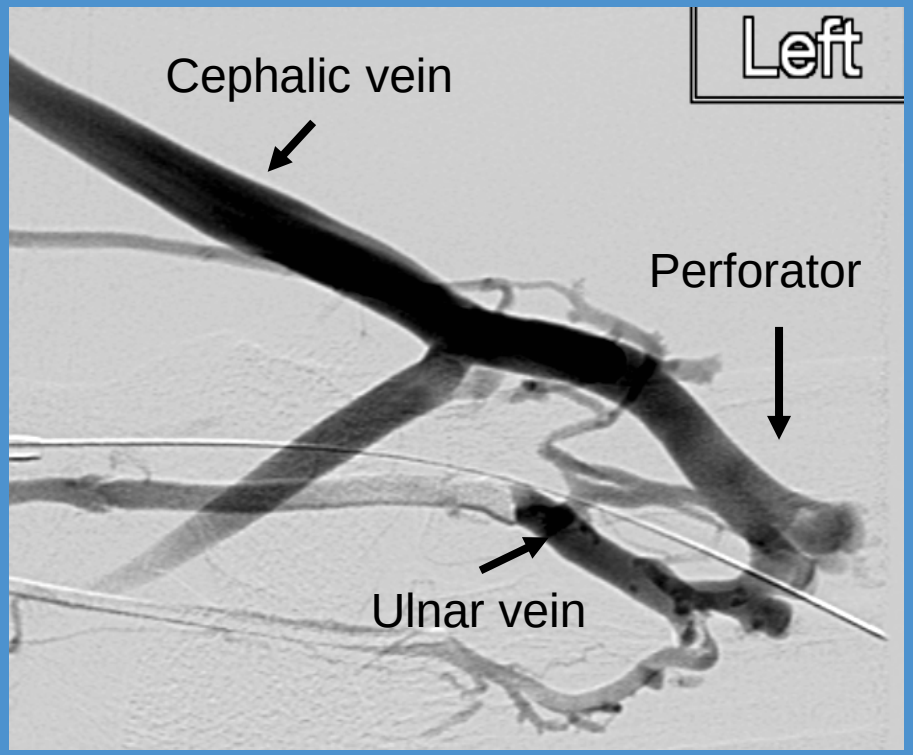
- 61 year old male dialysis patient
- 26.5 BMI

- Comorbidities
  - Type II diabetic
  - Hypertension

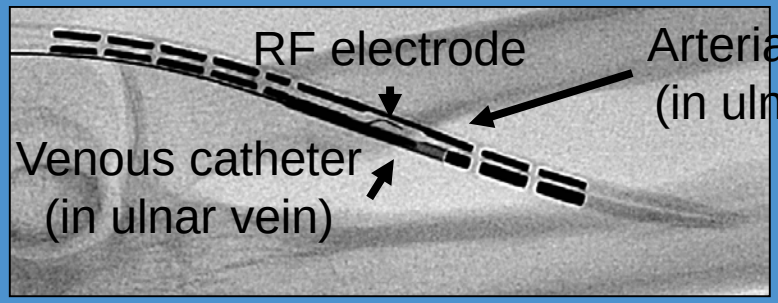
- No prior AVF or AVG (Currently has CVC)

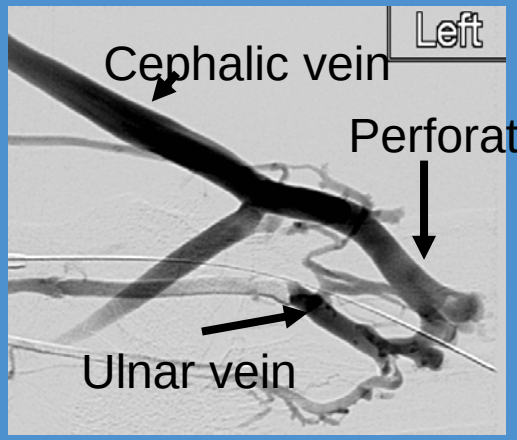
Case Study - Screening

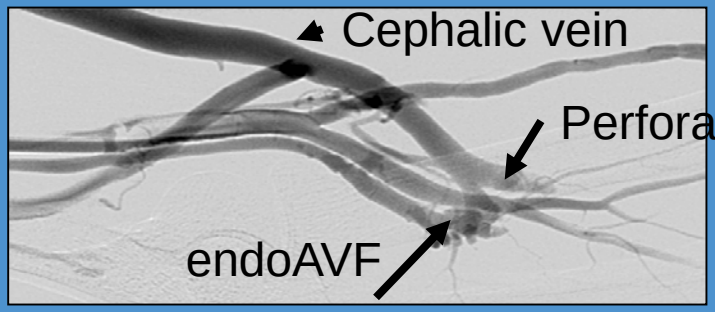
- Eligible for an endoAVF
  - ✓ Upper arm cephalic ≥2.5 mm
  - ✓ Patent perforator
  - ✓ Ulnar artery & vein ≥ 2.0 mm

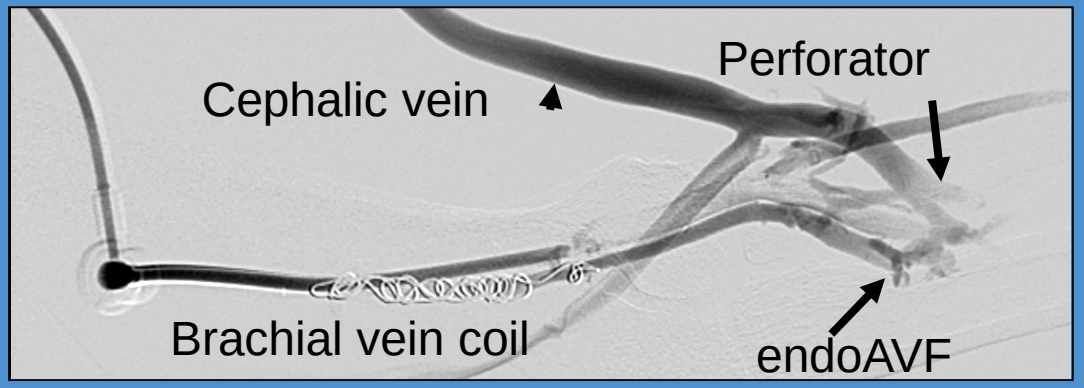


Case Study - Procedure





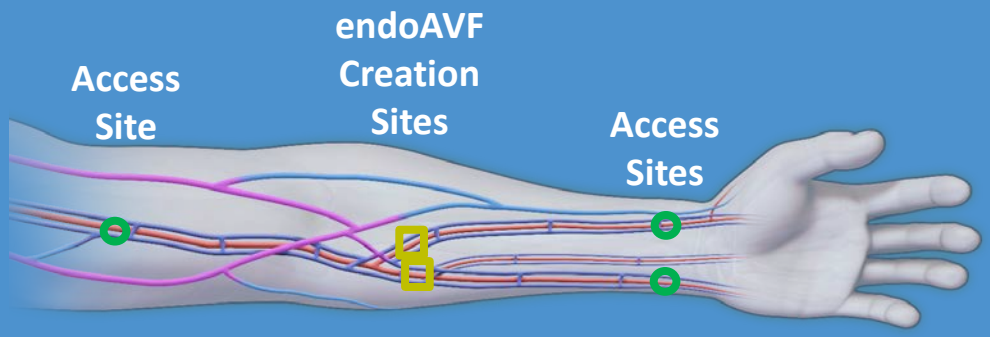


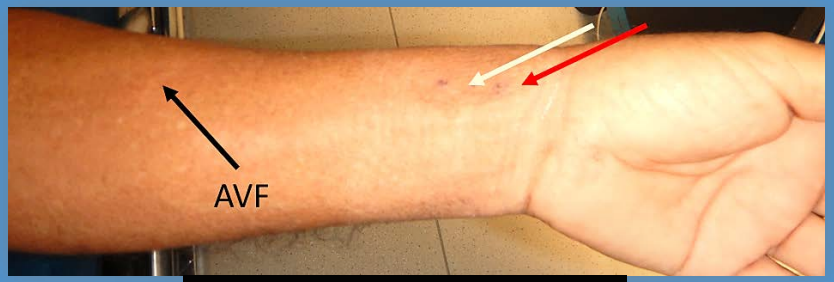


Case Study - Outcomes

- No interventions to mature
- Cannulated at day 70
- Achieved functional cannulation (2-needle cannulation for ≥2/3 dialysis sessions within 1 month)

New Access Options with 4F Device

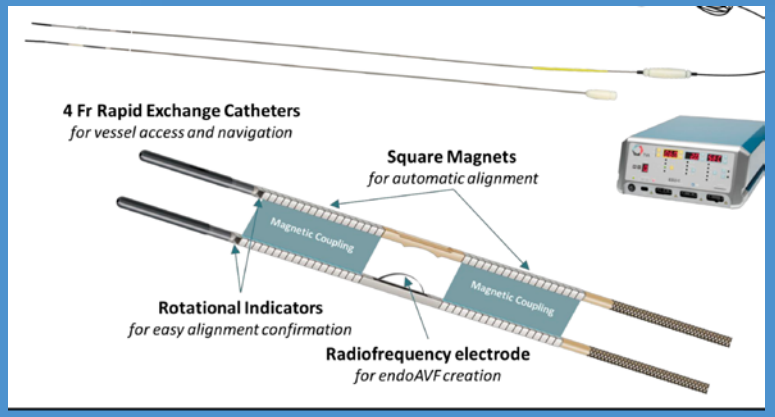




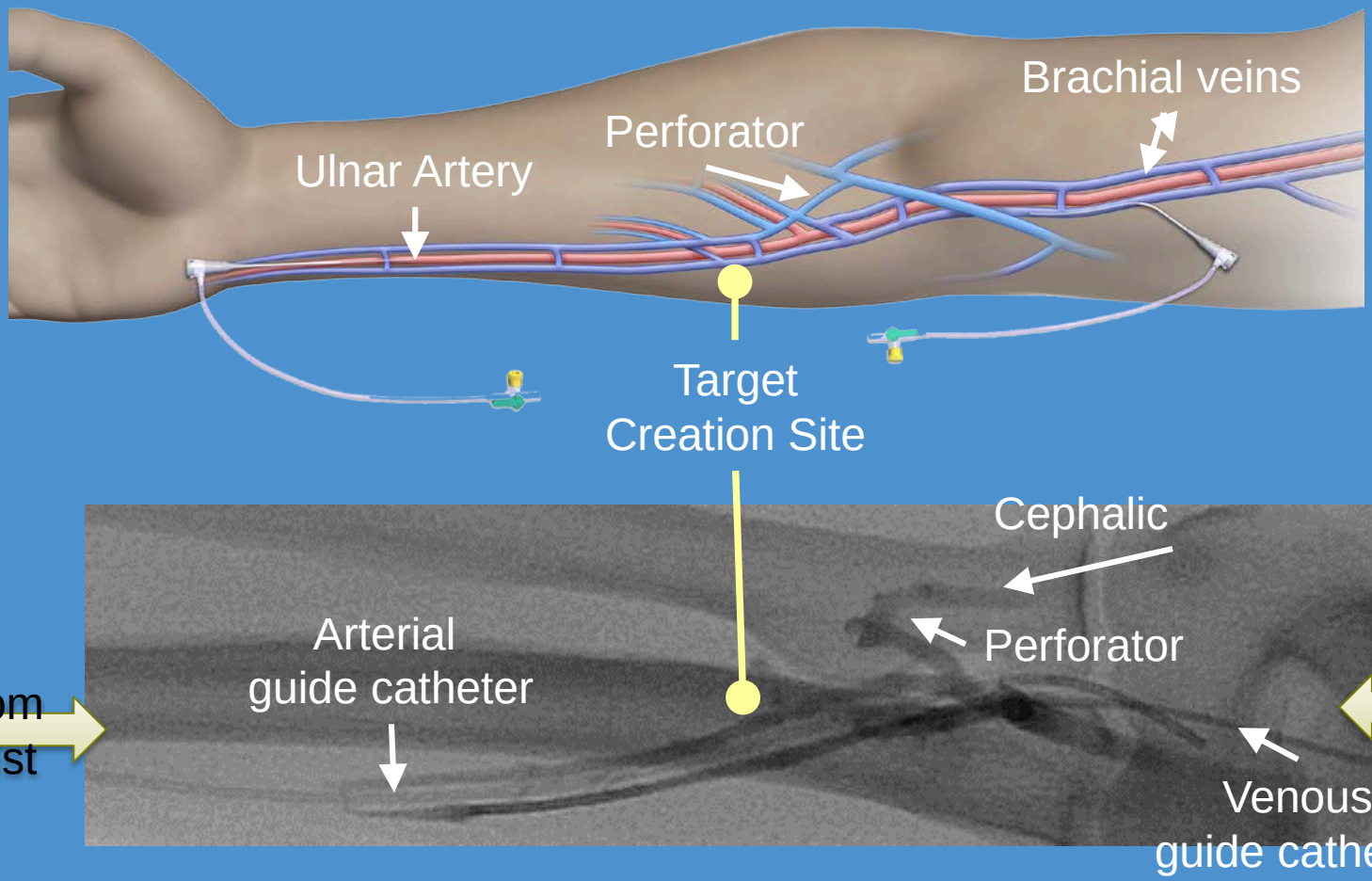
<24 hours post-procedure

4 Fr System

- *Adds additional creation sites for an endovascular fistula*
- *Enables wrist access or upper arm access*
- *Facilitates access site hemostasis*



Antiparallel Approach
Ulnar artery – Brachial vein access



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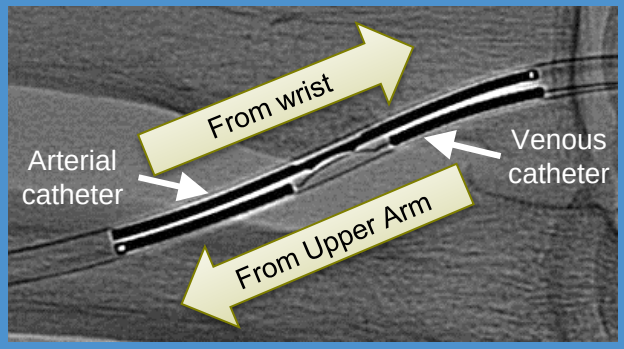

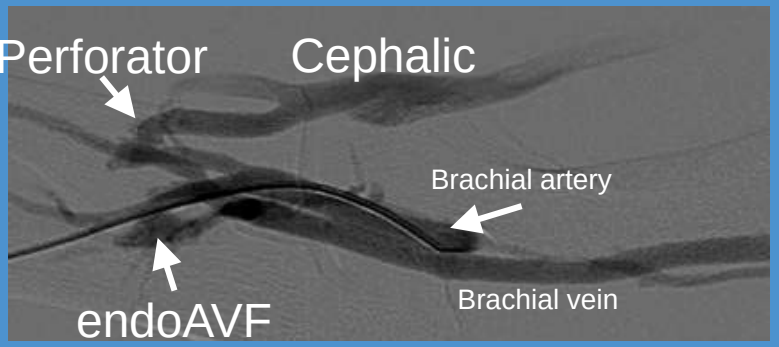

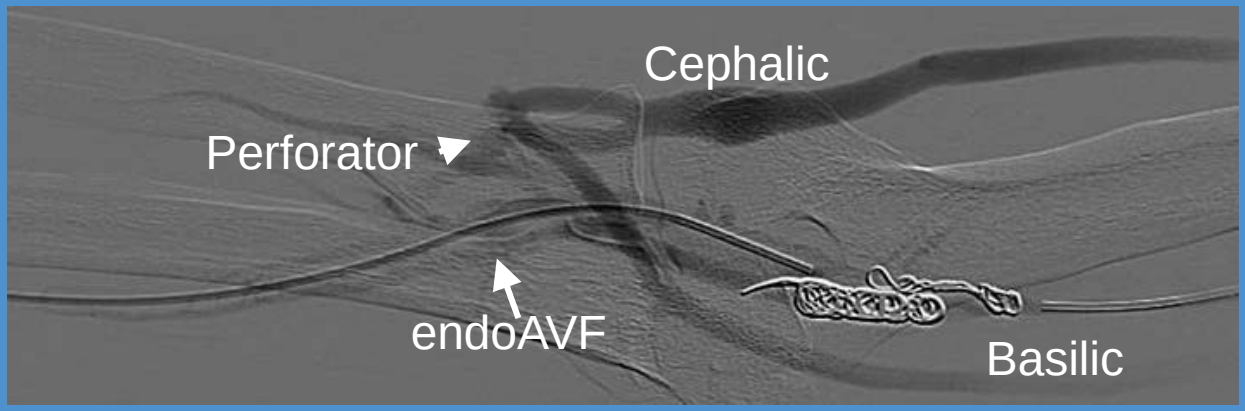

Summary

Multiple series already report the safe and effective application of the TVA device to create usable endoAVF

EU study is a real world study currently recruiting

Results: our study site so far demonstrate high rates of fistula usability with minimal need for interventions

4Fr System broadens options for access creation

Acknowledgments

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