

Vein predilation with AFE system

2019 VASA Hands-On Practicum, May 10-11th, Houston, Texas

Presented by:

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Disclosures

**Speaker is a scientific and
medical advisor to
Flow Forward Medical
No monetary support for
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Is there a preferred location to create AVF that meets the dialysis need?

Functional AVF

- Sustain adequate dialysis
- Easily accessible
- Low complication rates
- Prolonged patency

Forearm radio-cephalic location seems to have an Anatomic and physiologic advantages to meet the needs

- Easily accessible in upper extremity, forearm
- Medium size artery provides 400 -500ml/min flow
- Long cannulation segment with multiple outflow near elbow
- Built in safety with collateral flow from Ulnar
- Lower chances to develop high flow & related complication



International comparisons

Characteristic	Japan	Europe/ANZ	United states
AVF placement	88%	87%	75%
Forearm (DOPPS1)	93% (93%)	77% (60%)	32% (70%)
Upper arm (DOPPS 1)	7% (7%)	23% (40%)	68% (30%)
Time to cannulate	10 days	46 days	82 days
Facility variation	90-100% (IQR)	53-78% (IQR)	25-47% (IQR)
Successful use	89%	76%	77%
AVG placement	12%	13%	25%
Successful use AVG	89%	78%	83%
Median flow rates	200mL/min	300mL/min	400mL/min

Pisoni RL et.al. Am J Kid Dis 2017;71:469-478



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Why Radiocephalic AVF is less prevalent?

- Poor maturation rates
- Longer maturation time
- Needs few interventions
- Increasing catheter dependency

Smaller vein caliber

What could be a game changer for radiocephalic AVF?

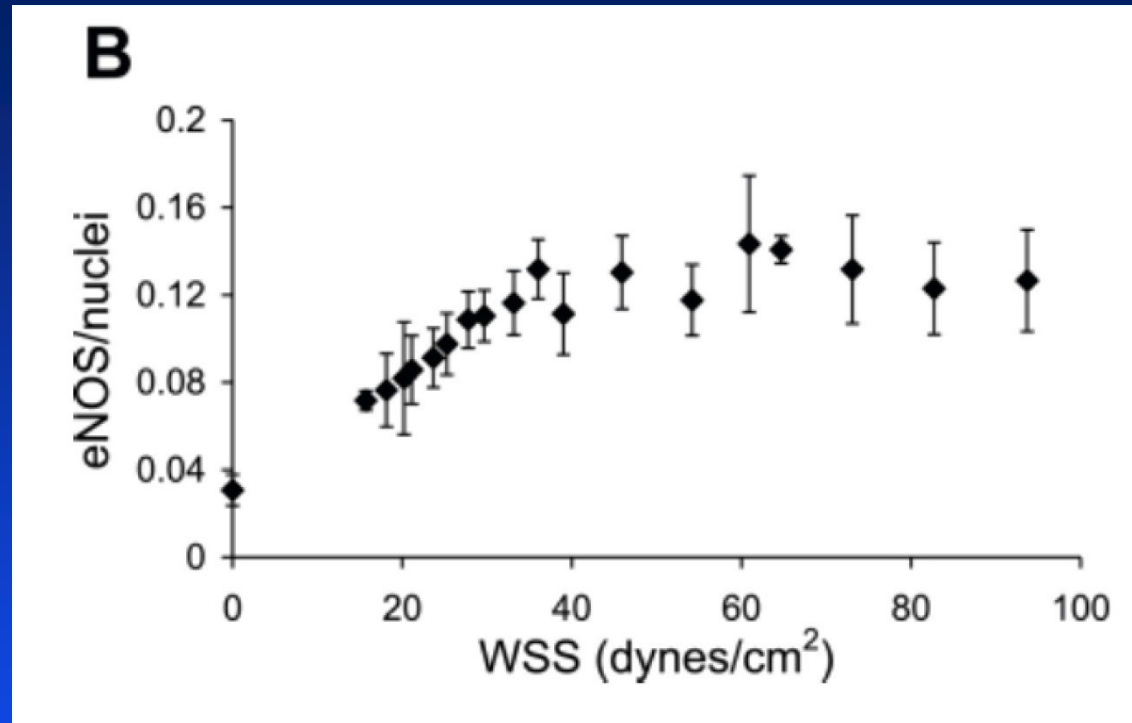
- **Increased rates of AVF maturation**
- **Shorter time to maturation & use**
- **Prolong AVF primary & secondary patency**
- **Decreased need for interventions**
- **Reduction in catheter use**

**Routine availability of 6 – 8 mm diameter veins
tend to provide an easier surgical target
a faster and more reliable maturation**



Hypothesis

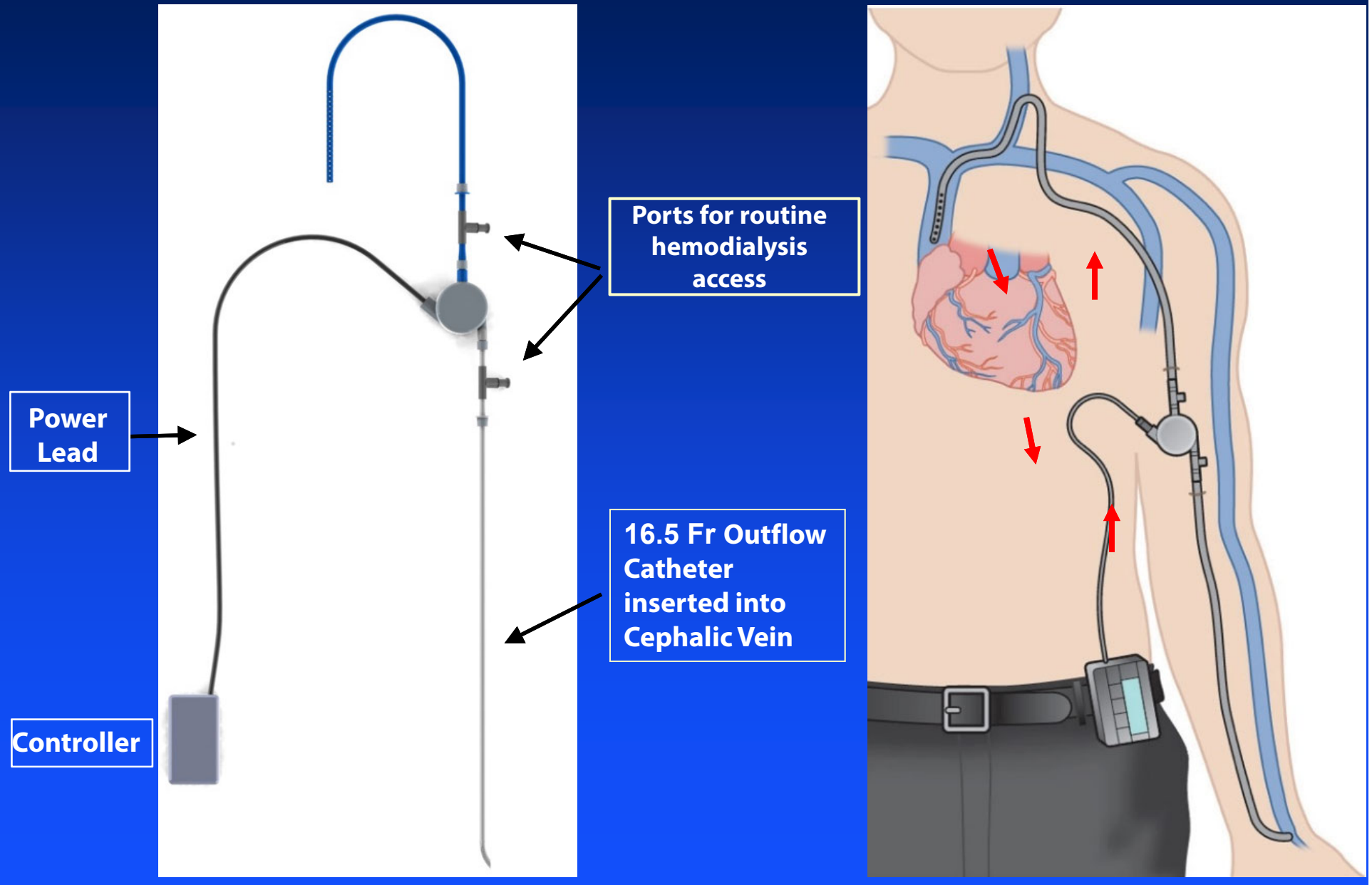
Controlled increase in wall shear stress to around 4 Pa using graduated, non-pulsatile blood flow delivered to superficial veins can induce rapid, stenosis-free vein dilation



- Metaxa *et al*, Am J Physiol Heart Circ Physiol. Aug 2008; 295(2): H736–H742



AFE System Concept



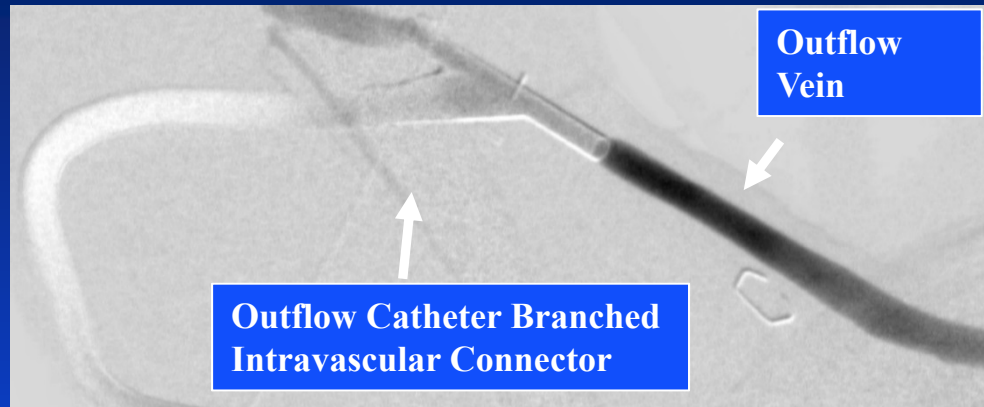
Ovine Study

Method

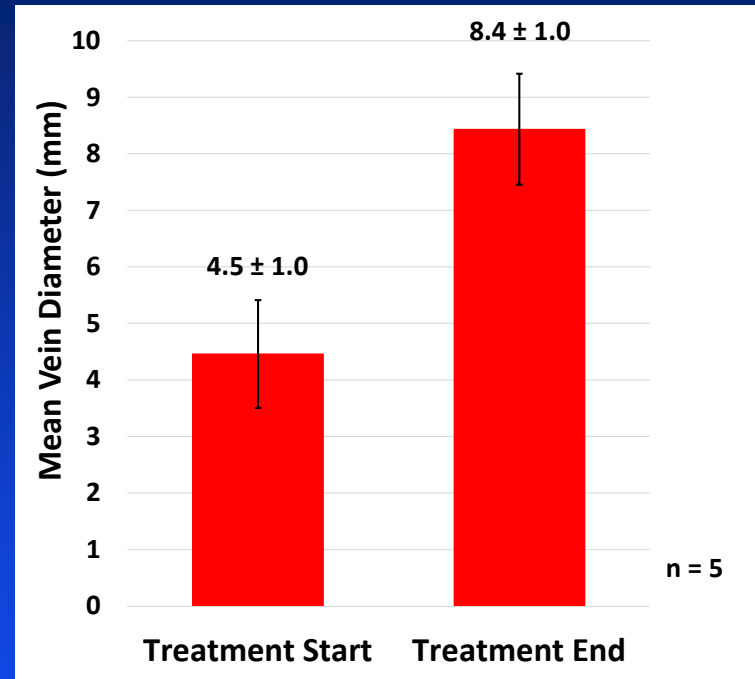
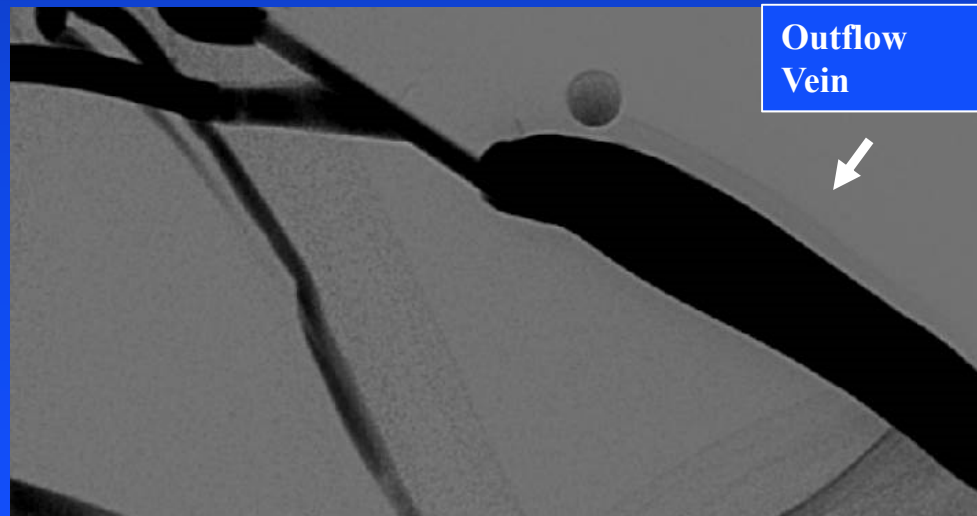
- 5 sheep weighing 54 – 68 kg
- Heparin coated centrifugal pump and catheters, rack-mounted controller
- Inflow from SVC via external jugular access
- Outflow to cephalic vein
- 7 – 11 days of treatment
- Forelimb AVF created using treated cephalic vein to combined trunk of radial and median arteries
- Followed 6 weeks with weekly US and angiography
- 2 control sheep with bilateral forelimb AVF created using same vessels but with untreated veins

Ovine Study Results: Treatment Effect on Vein Diameter

Start

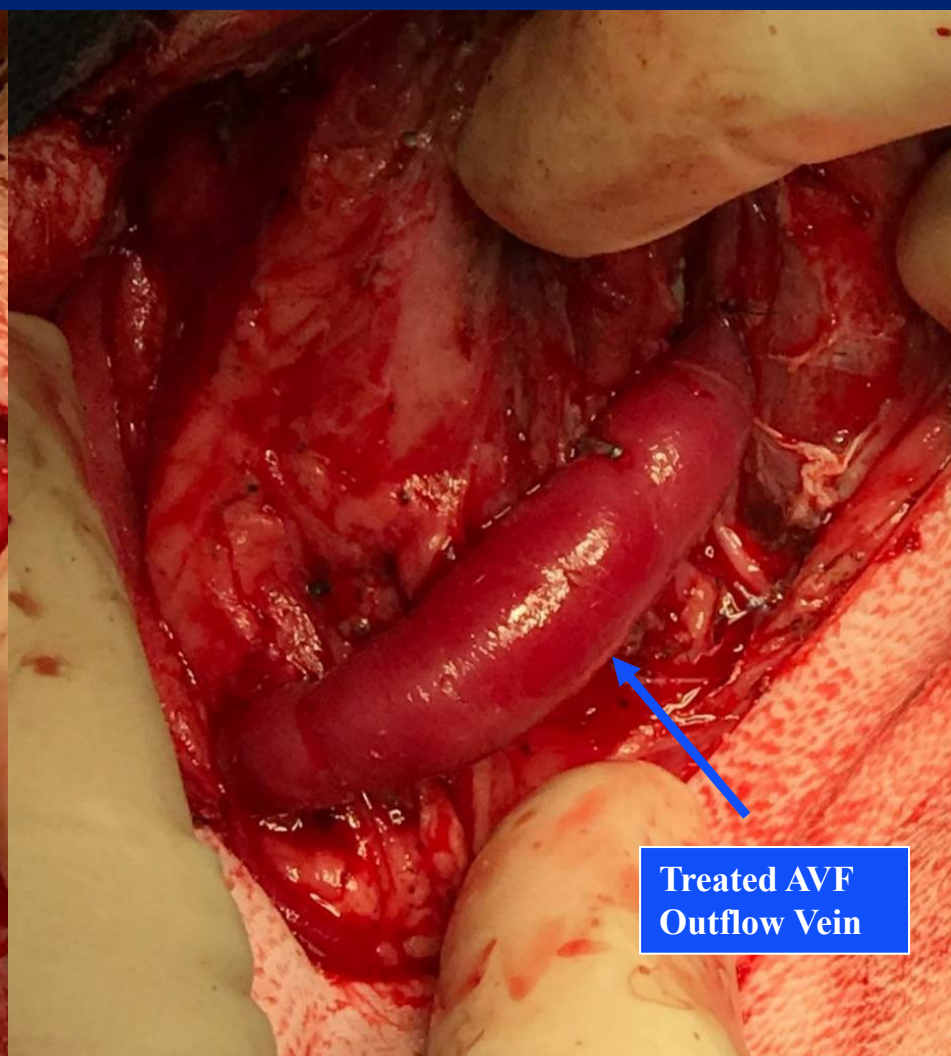
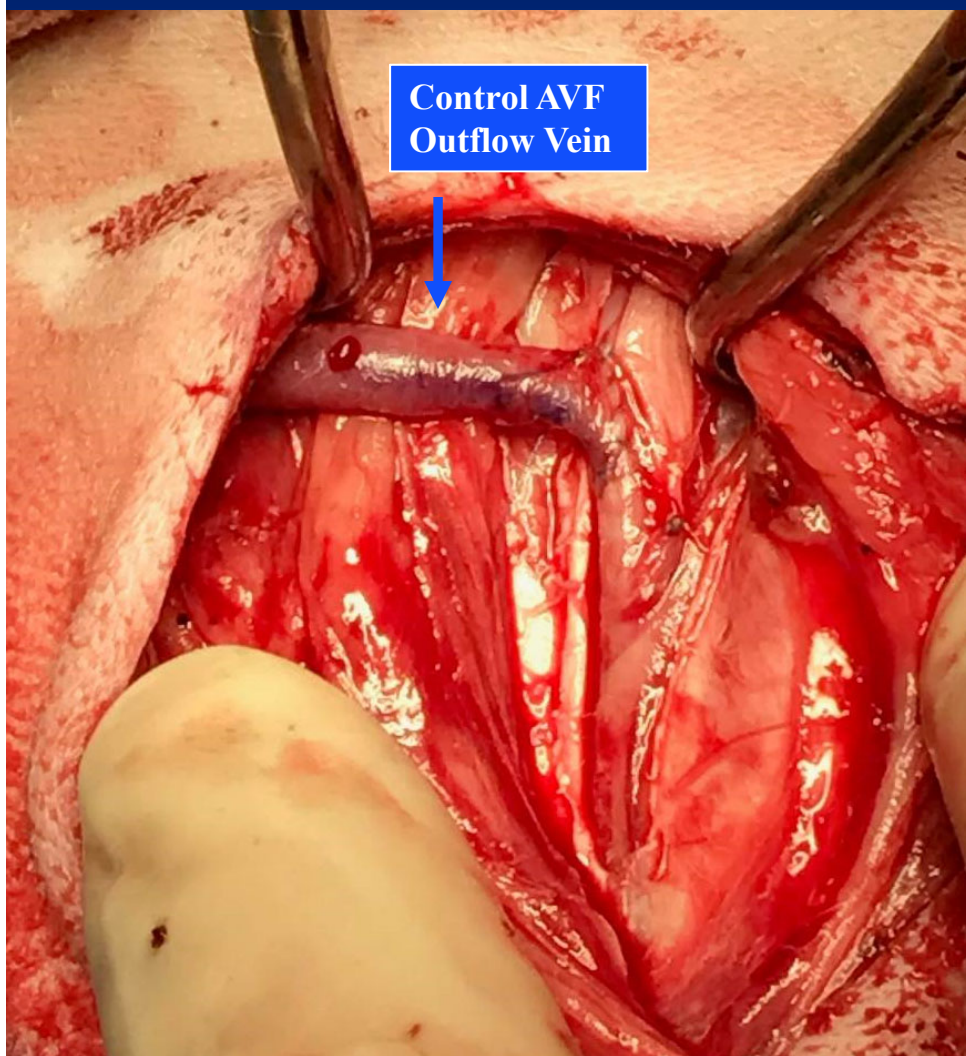


Day 9

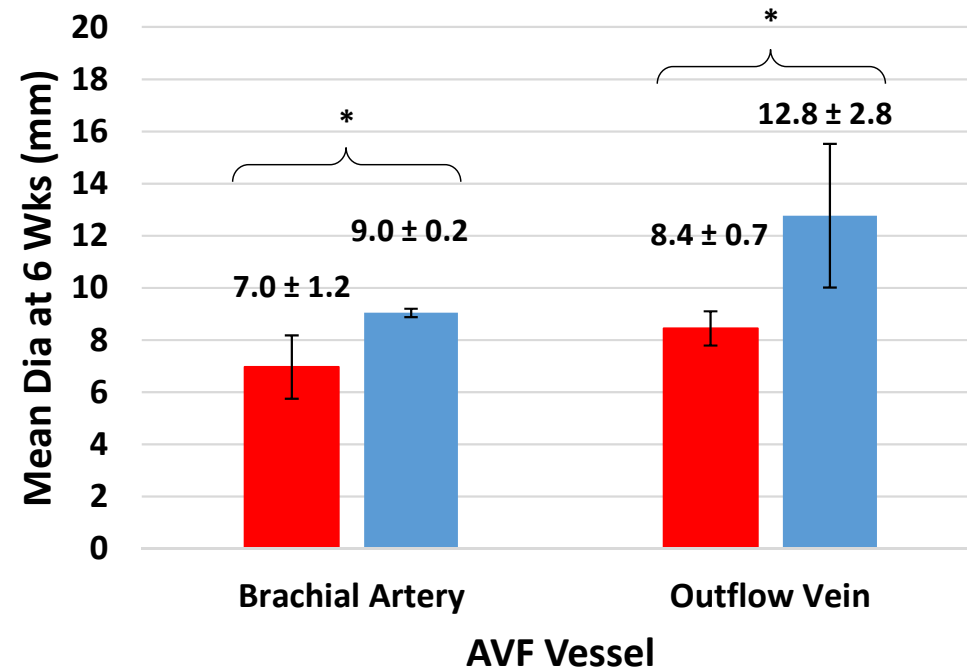
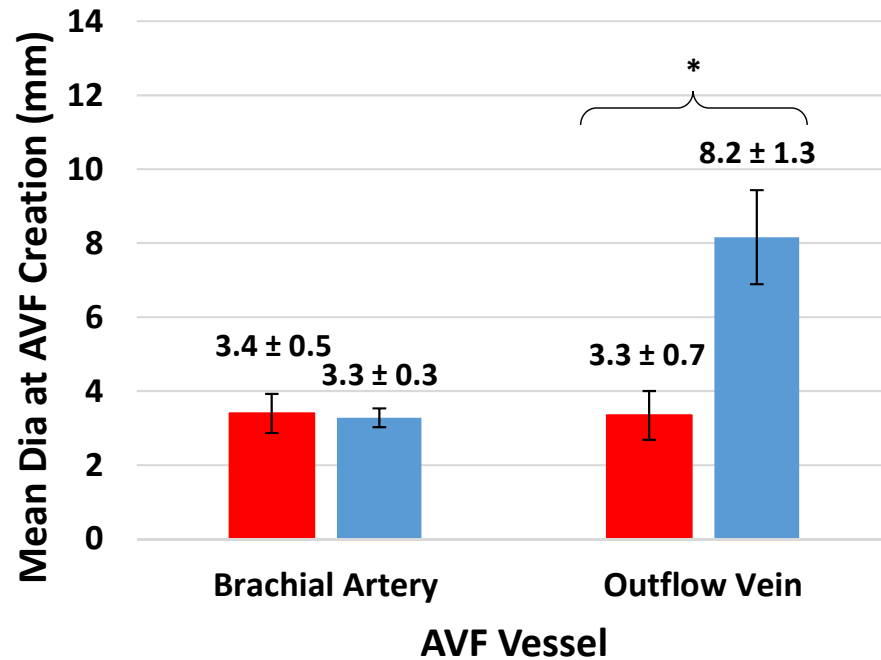


87% increase in cephalic vein diameter over 6 - 11 days

Intraoperative AVF Outflow Vein Diameter



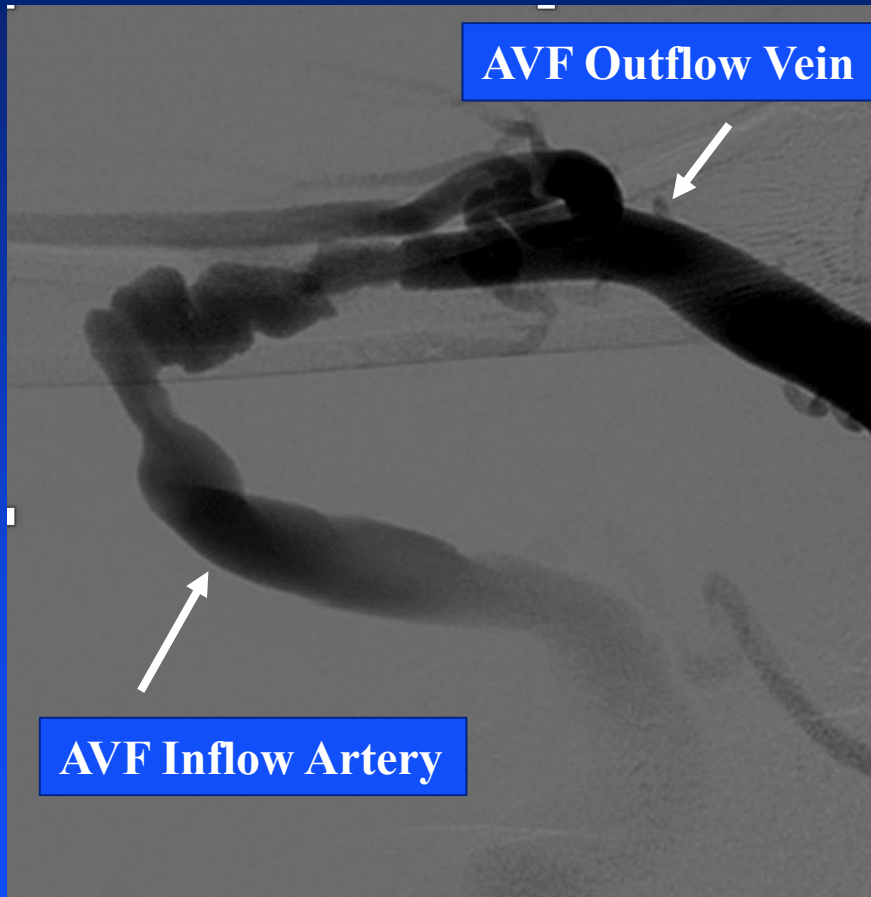
Ovine Study Results: Treatment Effect on AVF Maturation



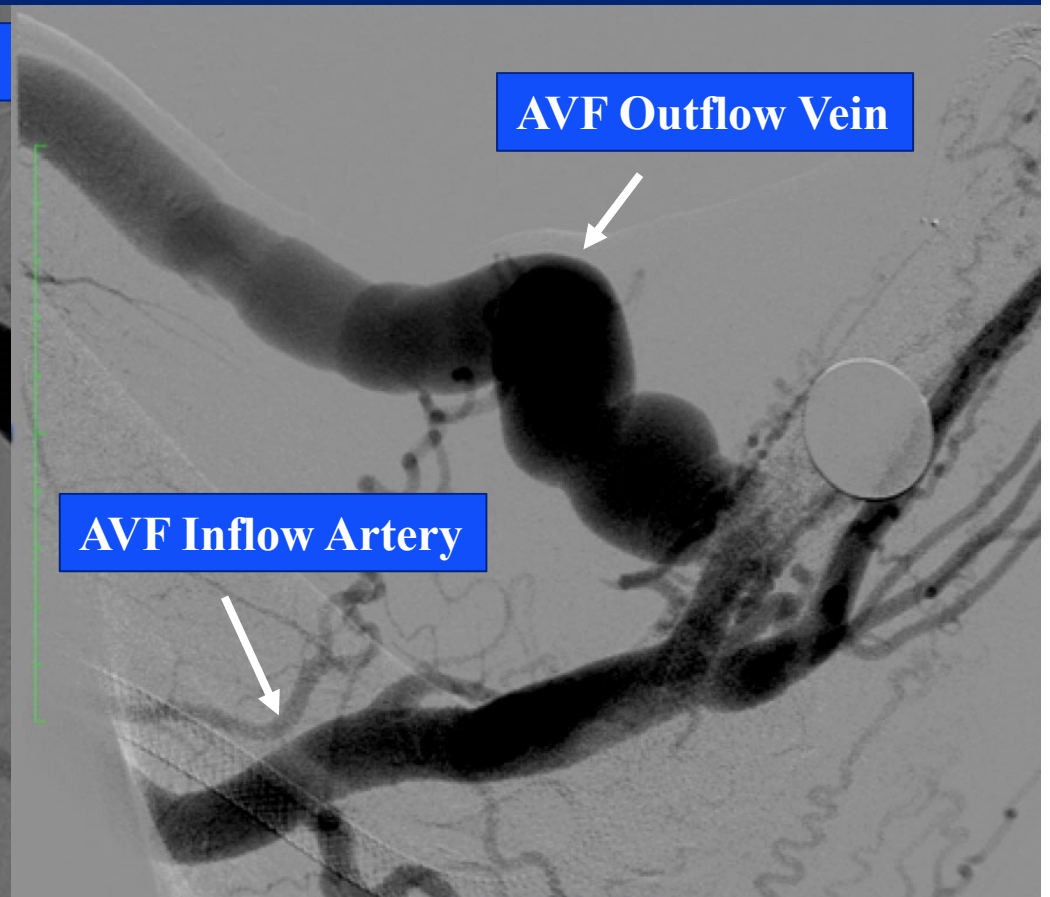
- Initial AVF outflow vein > 2X larger in treated animals

- Brachial artery diameter 28% larger at 6 wks
- Cephalic vein diameter 58% larger at 6 wks
- Greater AVF blood flow

AVF Angiography After 6 Weeks of Maturation



Control AVF



AFE Pre-Treated AVF

Ovine Study Conclusions

- ▶ **Controlled increase in wall shear stress using graduated increase in non-pulsatile blood flow produces rapid, stenosis-free dilation of ovine cephalic veins**
- ▶ **Making AVFs with AFE System-treated ovine cephalic veins results in improved AVF maturation (larger artery and vein diameters and increased blood flow) compared to AVFs made with untreated veins**
- ▶ **This study suggests AFE System treatment is a viable method to obtain larger veins in the forearm and upper arm suitable for AVF creation in ESRD patients and could potentially improve AVF maturation and use rates, reduce time to AVF maturation, reduce AVF procedure, prolong AVF primary and secondary patency, and reduce the use of catheters**

Future steps

First in Human Clinical Trial



- ▶ Trial scheduled to start in Q3 2019
- ▶ Planning to carry out the trial at Sanatorio Italiano Hospital in Asunción, Paraguay
- ▶ The government of Paraguay generally pays for routine hemodialysis for citizens but does not pay for vascular access surgery

First in Human Clinical Trial

- ▶ 10 subjects
- ▶ Cephalic vein diameter ≥ 2.5 mm and < 4 mm
- ▶ Radial artery diameter > 2 mm
- ▶ AFE System treatment of forearm cephalic vein for 10 days
- ▶ Serial ultrasound of AFE System outflow vein diameter and flow during treatment
- ▶ Venography of cephalic vein before and after AFE System treatment
- ▶ AVF created after 10 day treatment
- ▶ Serial ultrasound of AVF outflow vein diameter and blood flow after AVF creation
- ▶ Primary clinical endpoints
 - Safety and absolute change in AFE System outflow cephalic vein diameter from baseline to end of treatment period
- ▶ Selected secondary clinical endpoints
 - AVF outflow cephalic vein diameter and blood flow prior to treatment and 2, 4, 6, 8, and 28 weeks after study enrollment

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