



AFE System Rapidly Dilates Ovine Cephalic Veins Before AVF Surgery and Enhances AVF Maturation

May 11, 2018



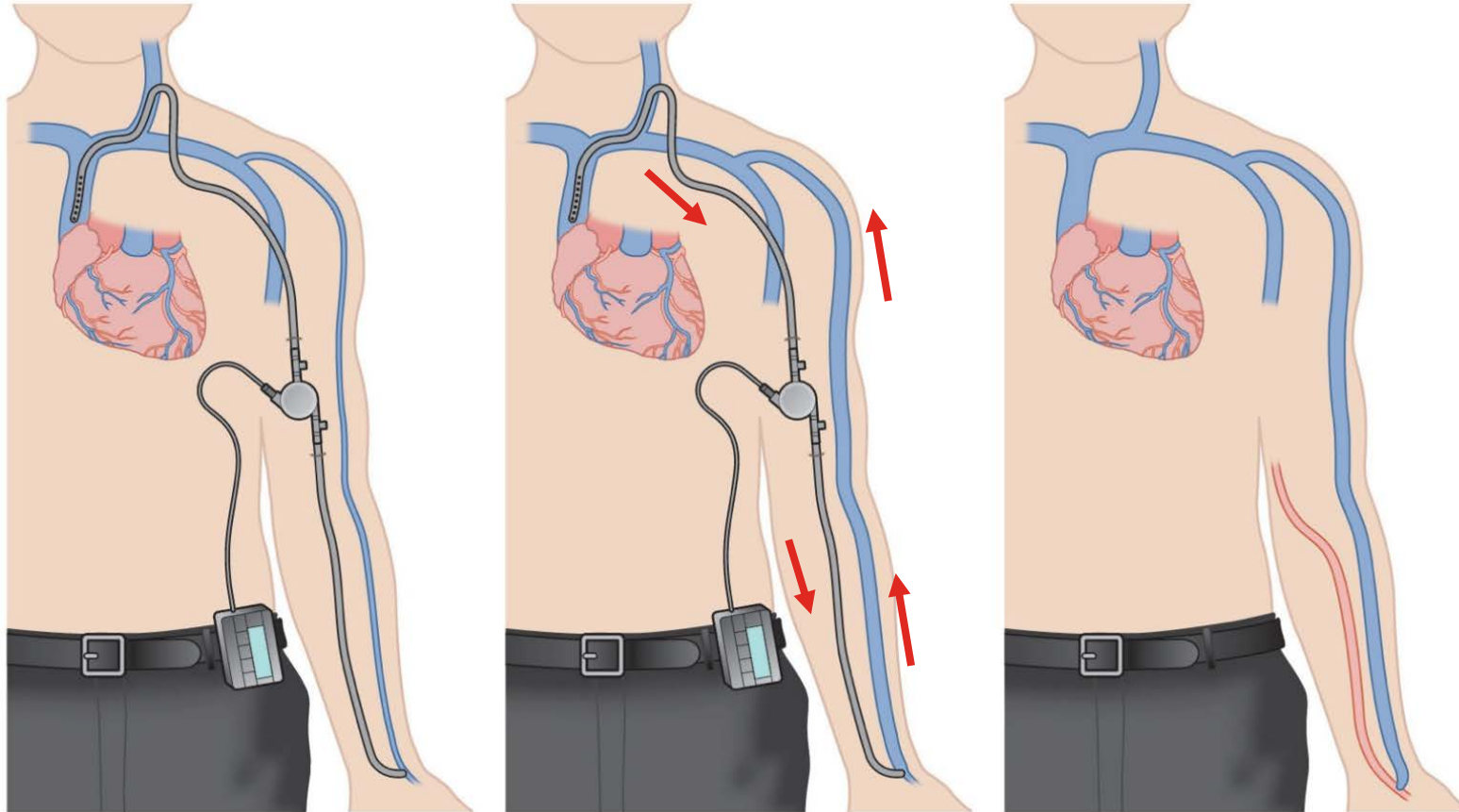
FlowForward
MEDICAL

Clinical Needs in Vascular Access

- Increase eligibility for AVF
- Increase AVF maturation success, especially forearm AVF and unassisted maturation
- Reduce time to AVF maturation and first successful use
- Prolong AVF primary and secondary patency
- Reduce catheter contact time

Routine availability of 6 – 8 mm diameter cephalic veins could help realize all these clinical needs

AFE System Dilates Veins Prior to AVF Surgery



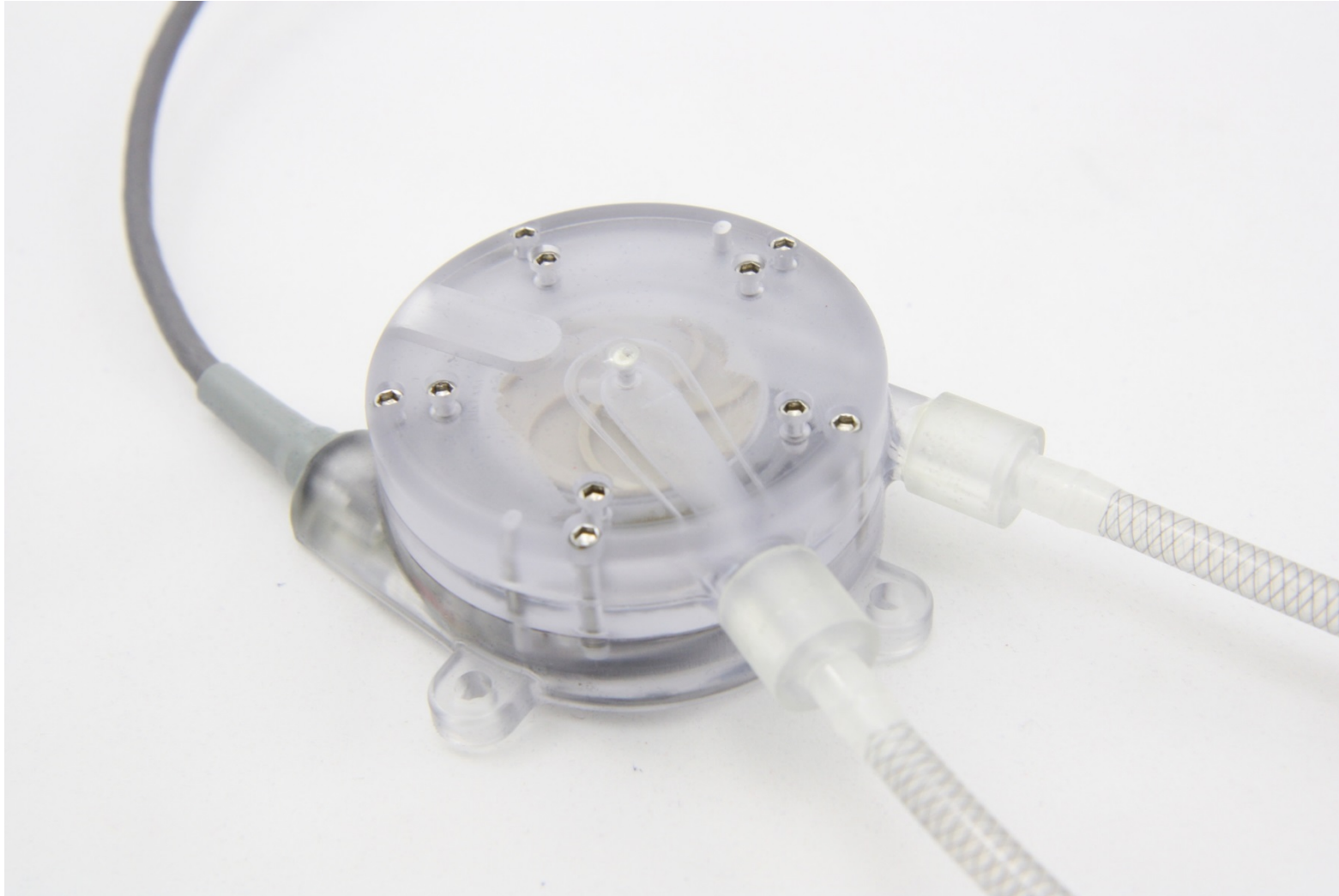
1 – 2 Weeks
of Treatment

Vein Dilated

AVF Created

Hypothesis:
Controlled increase
in wall shear stress
using non-pulsatile
blood flow delivered
to superficial veins
can induce rapid,
sustained vein
dilation

Blood Pump



AFE System Inflow Catheter

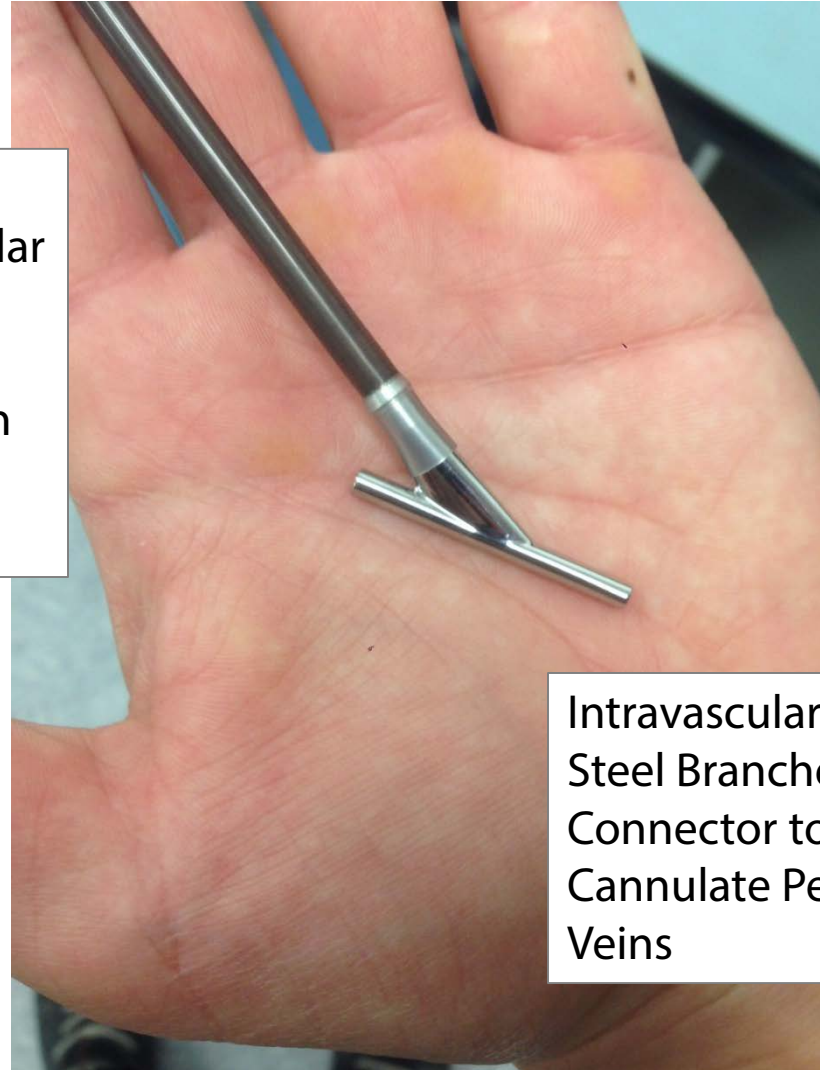


Extravascular Catheter Segment
with Nitinol Braid Support and
Heparin Coating

Intravascular Catheter Segment
with "Duckbill" Stainless Steel Tip
to Resist Thrombus Formation
and Nitinol Cage to Prevent
Suction

AFE System Outflow Catheter

Flexible and Kink
Resistant Extravascular
Catheter Segment
with Nitinol Coil
Support and Heparin
Coating

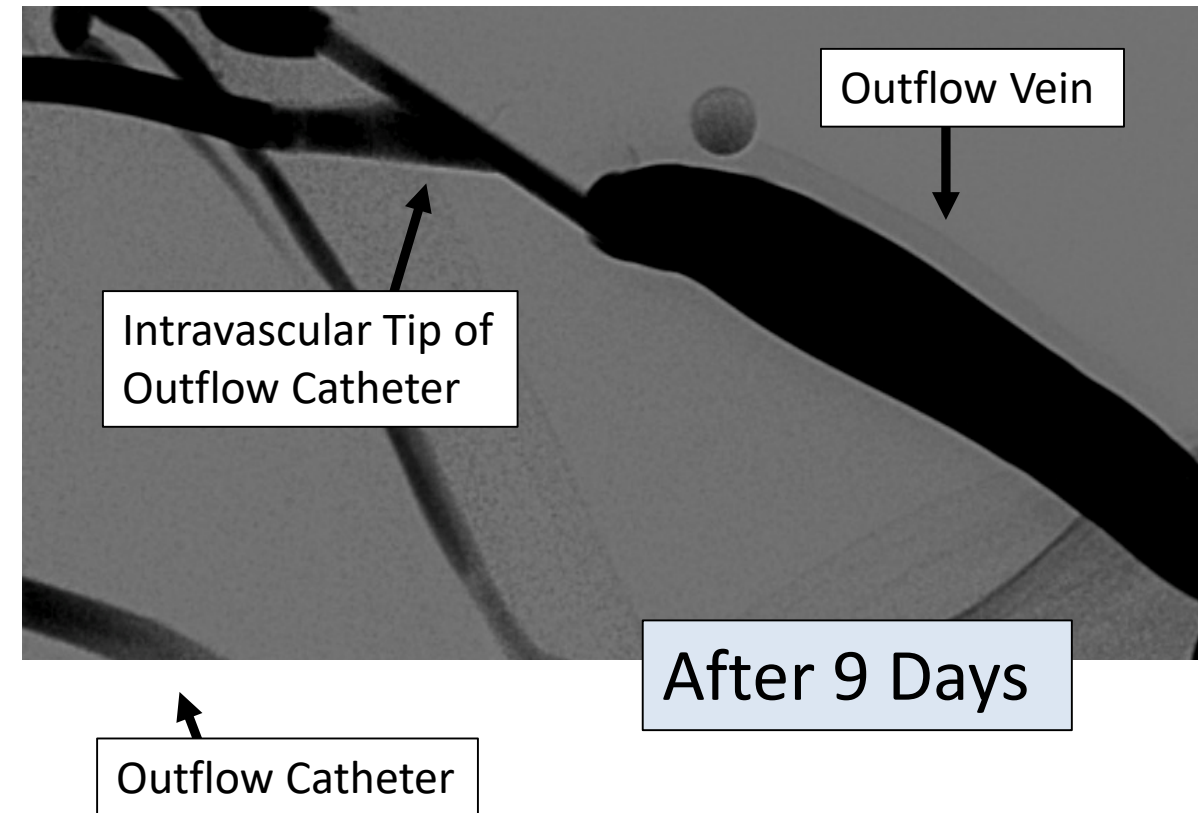
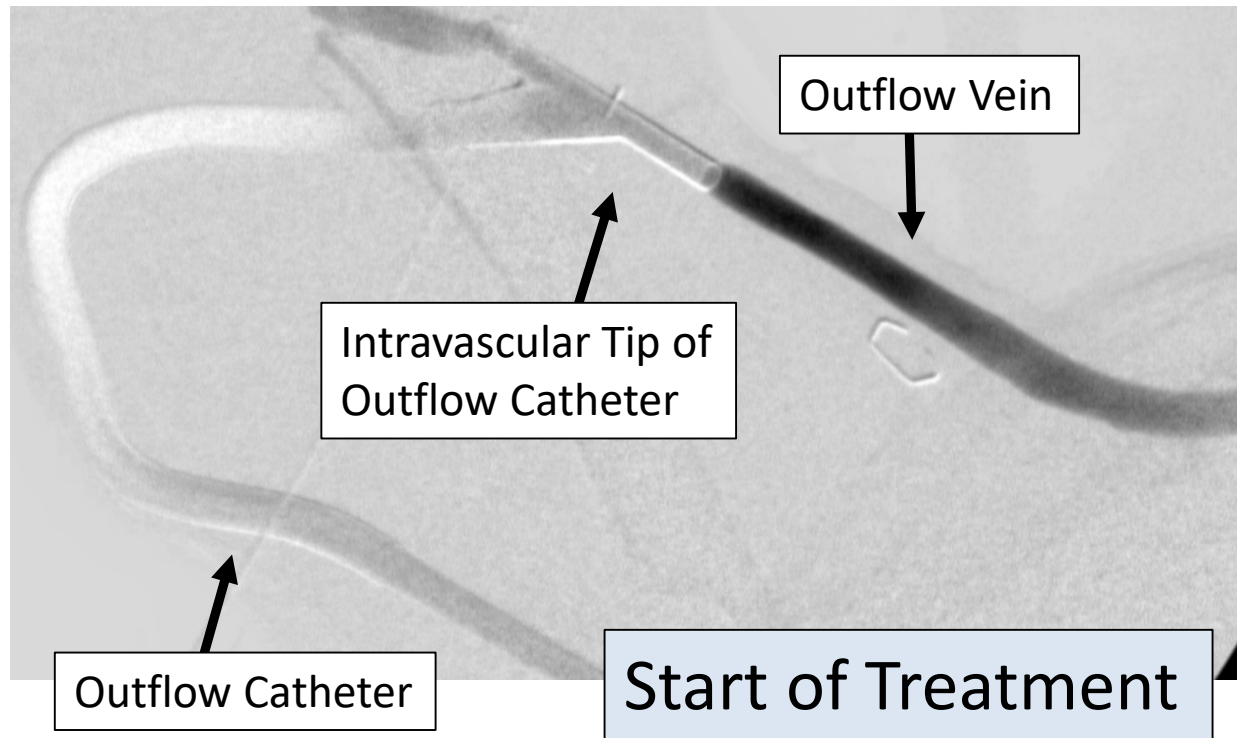


Intravascular Stainless
Steel Branched
Connector to
Cannulate Peripheral
Veins

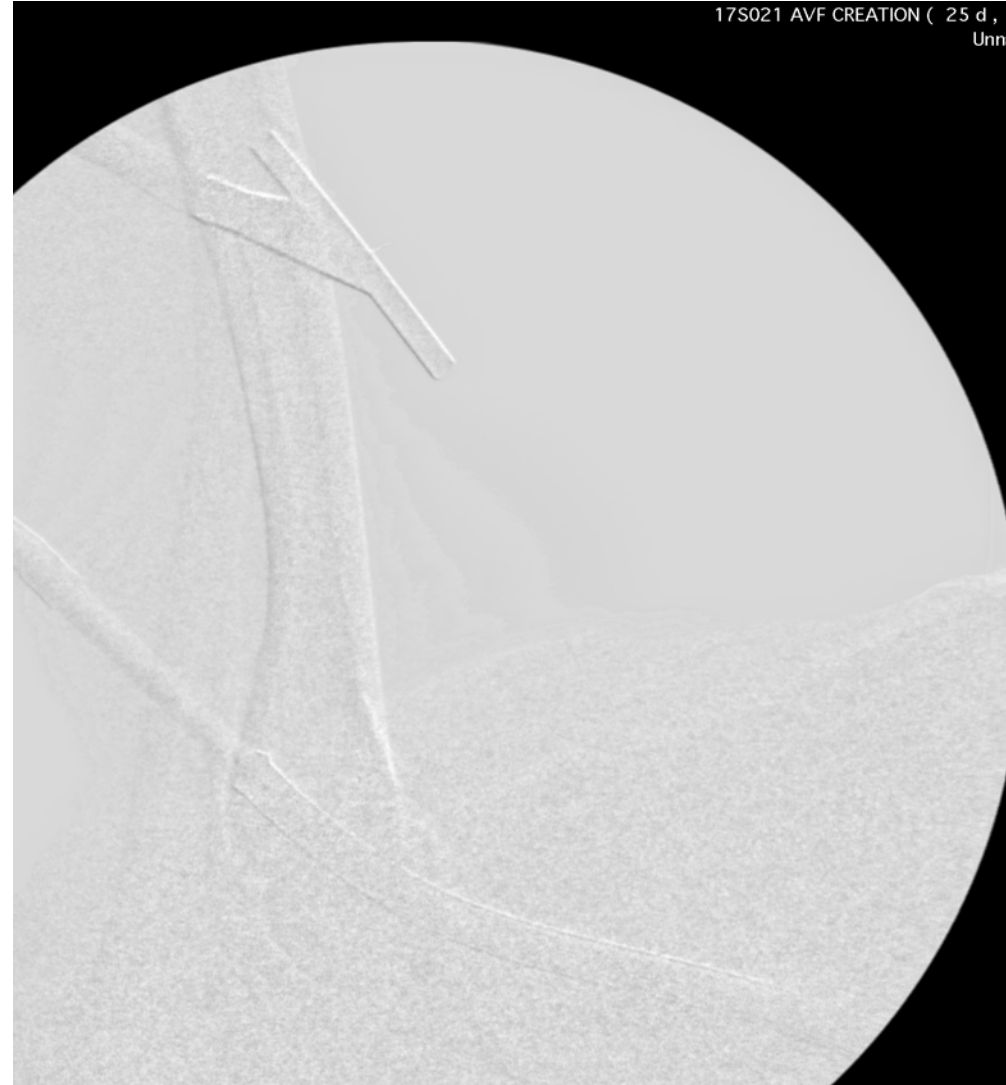
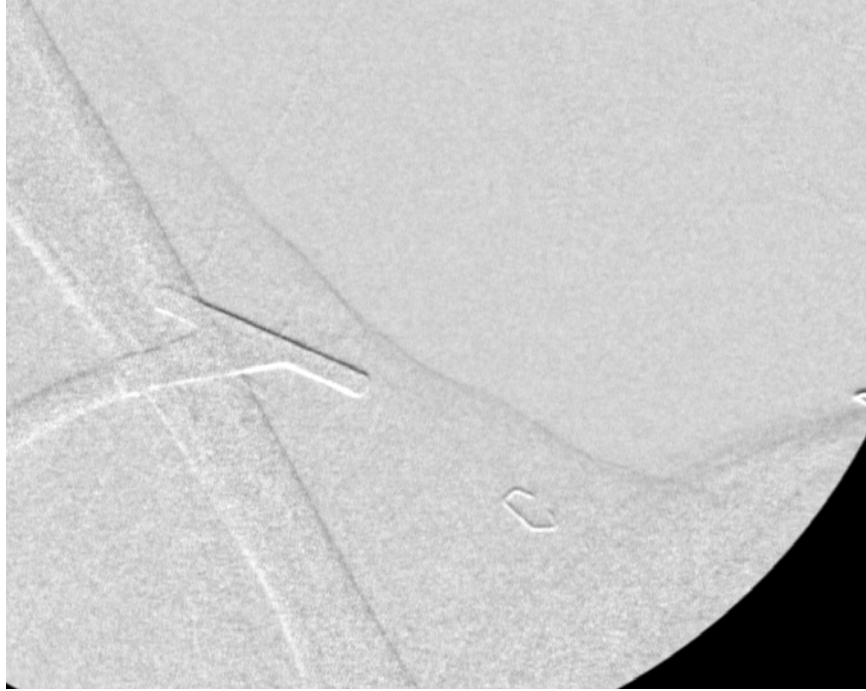
Sheep Model

- ▶ 50 – 60 kg adult sheep
- ▶ Create AVF using combined trunk of radial and median arteries and cephalic vein (forelimb) using veins treated with AFE System or untreated veins
- ▶ Weekly AVF ultrasound and angiography for 6 weeks
- ▶ Histopathology of AVFs after 6 weeks

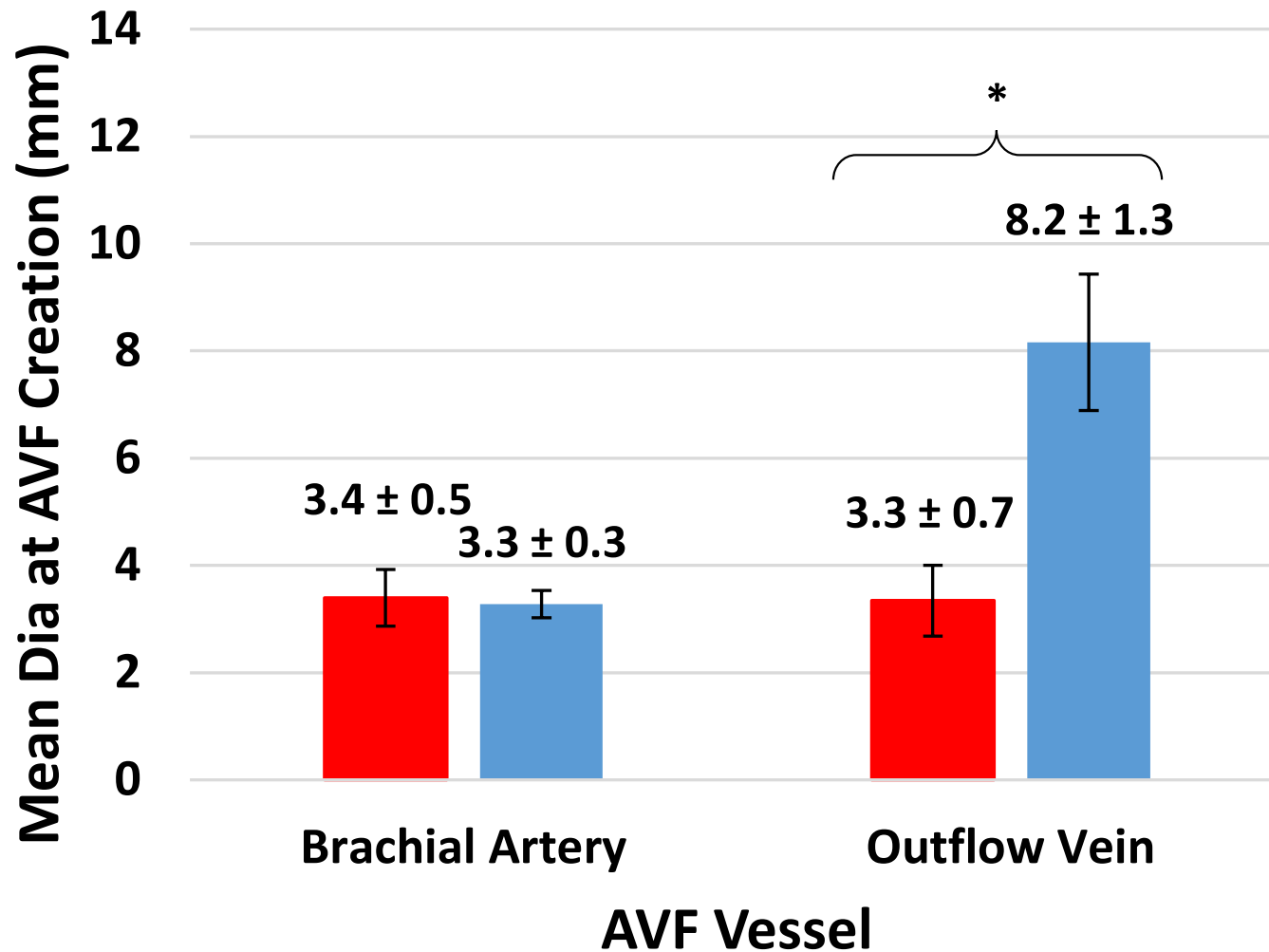
Rapid Outflow Vein Dilation During AFE System Treatment in Sheep



AVF Outflow Vein – Angiography



AVFs Made with Veins Pre-Treated with AFE System Have Larger Starting Vein Diameters



Outflow veins were significantly larger in AFE-assisted AVFs than in control AVFs at creation, as measured by angiography

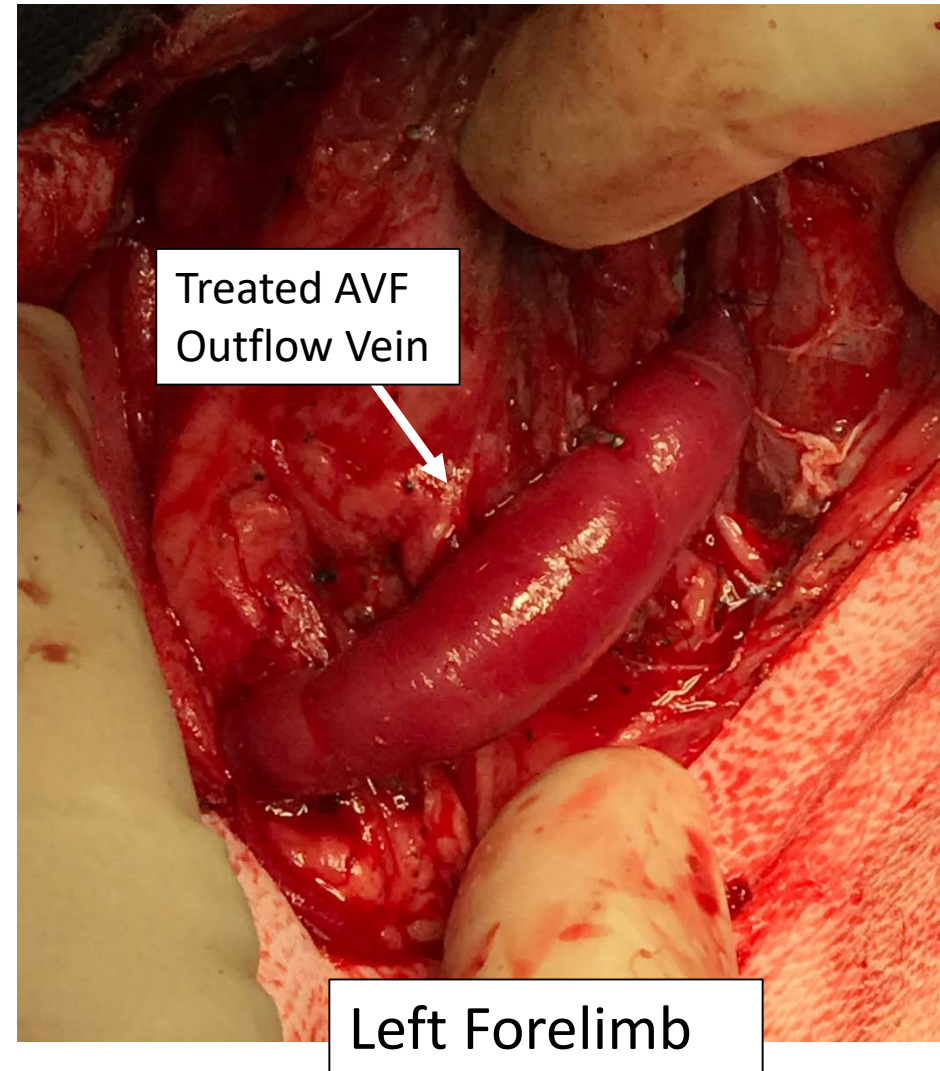
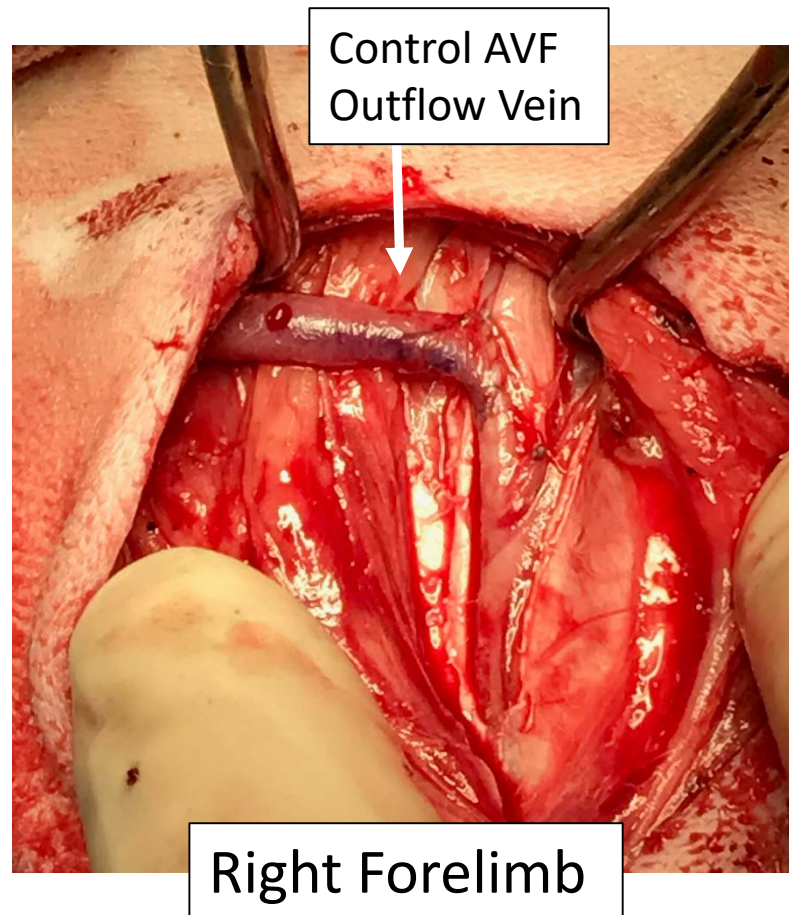
■ Control AVF (n=4)
■ AFE-Assisted AVF (n=3)

* p < .05

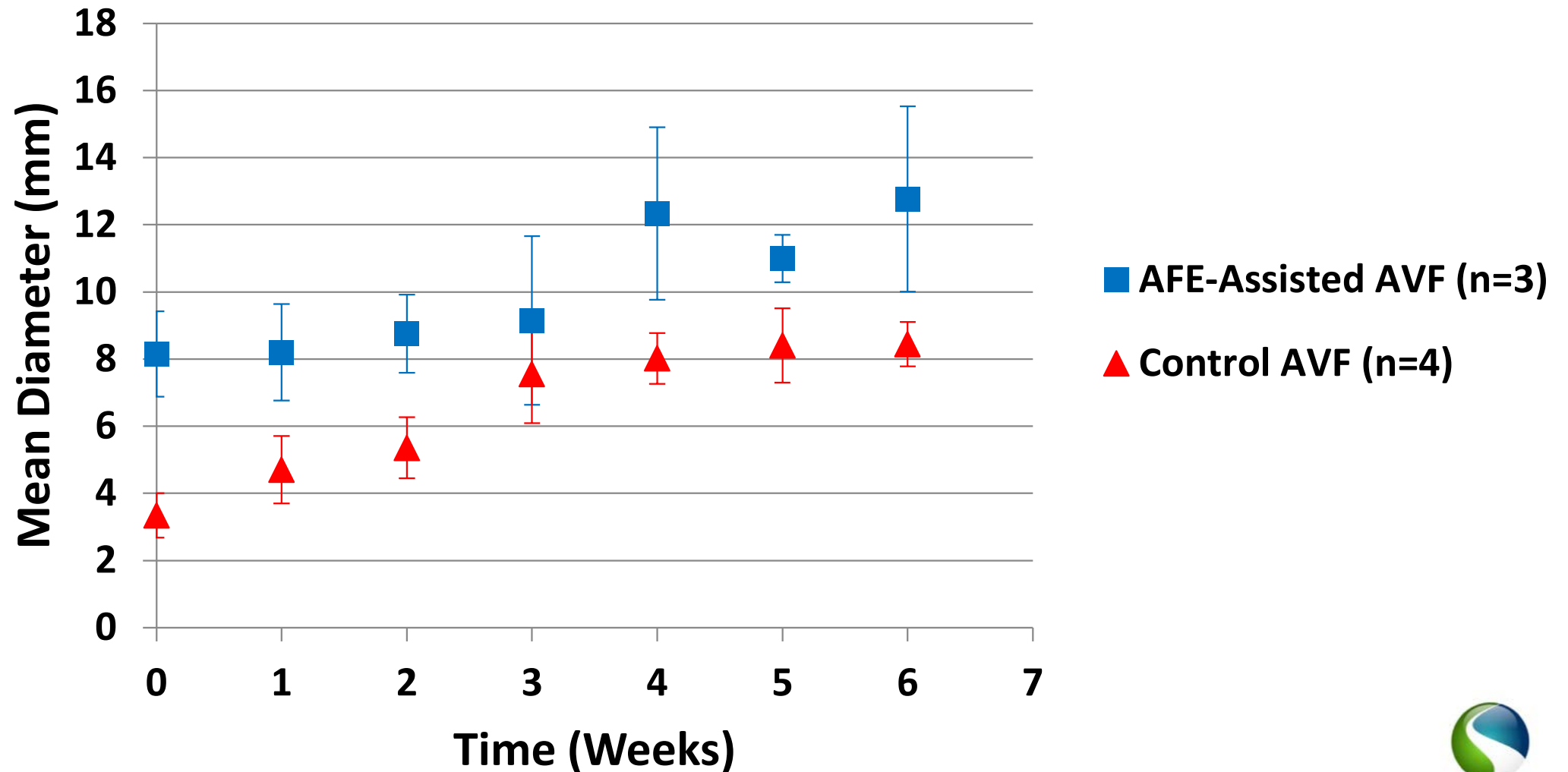


AVFs Made with Veins Pre-Treated with AFE System Have Larger Starting Vein Diameters

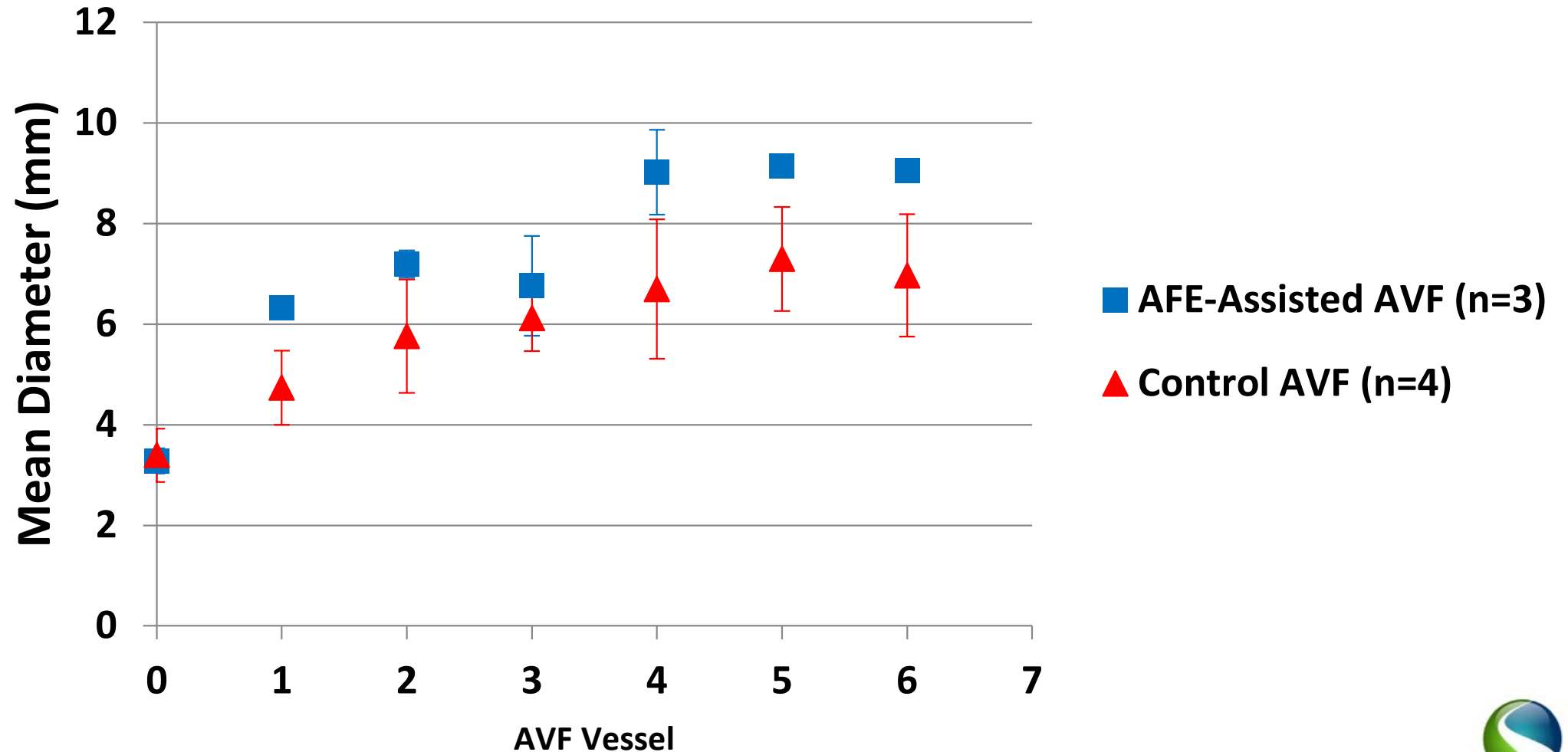
Animal 17S021



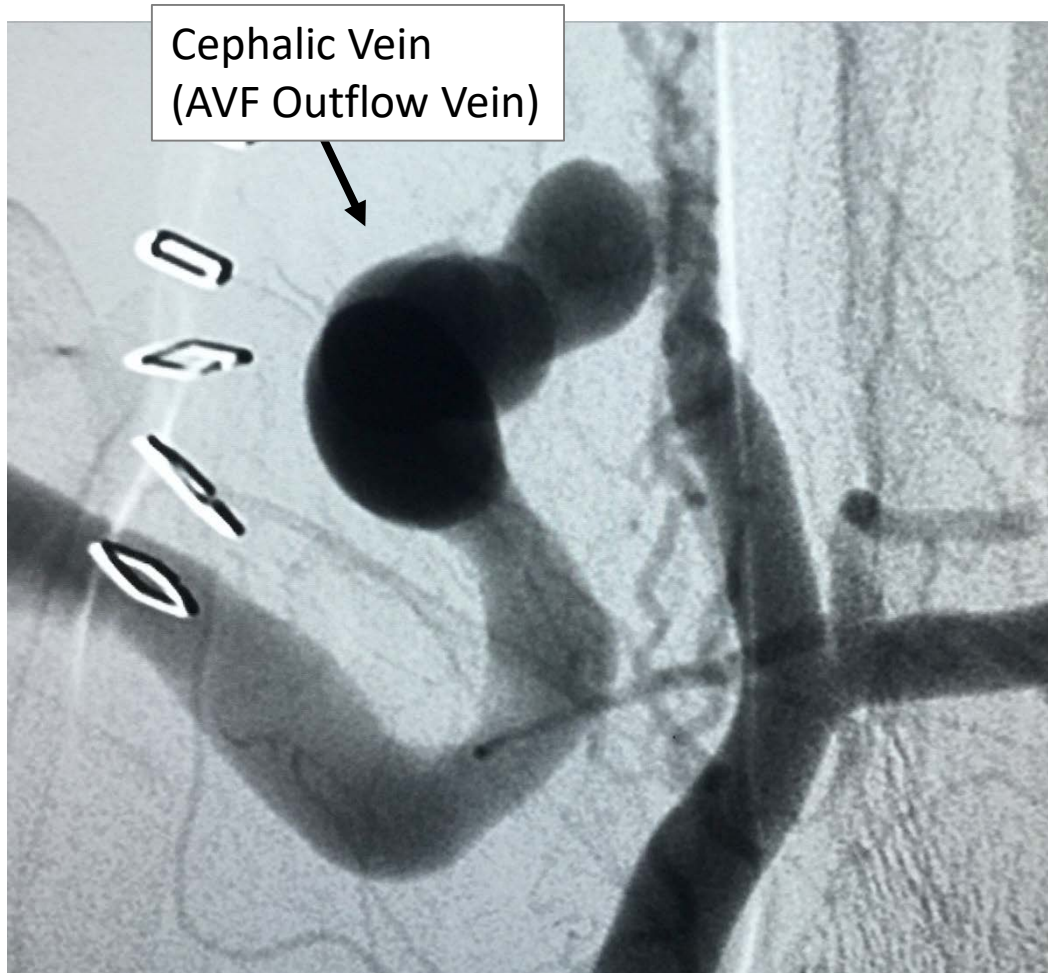
Ovine Forelimb AFE-Assisted vs. Control AVF Outflow Vein Mean Diameter



Ovine Forelimb AFE-Assisted vs. Control AVF Brachial Artery Mean Diameter



Increased AVF Vein Diameters at 1 Week with AFE System Pre-Treatment

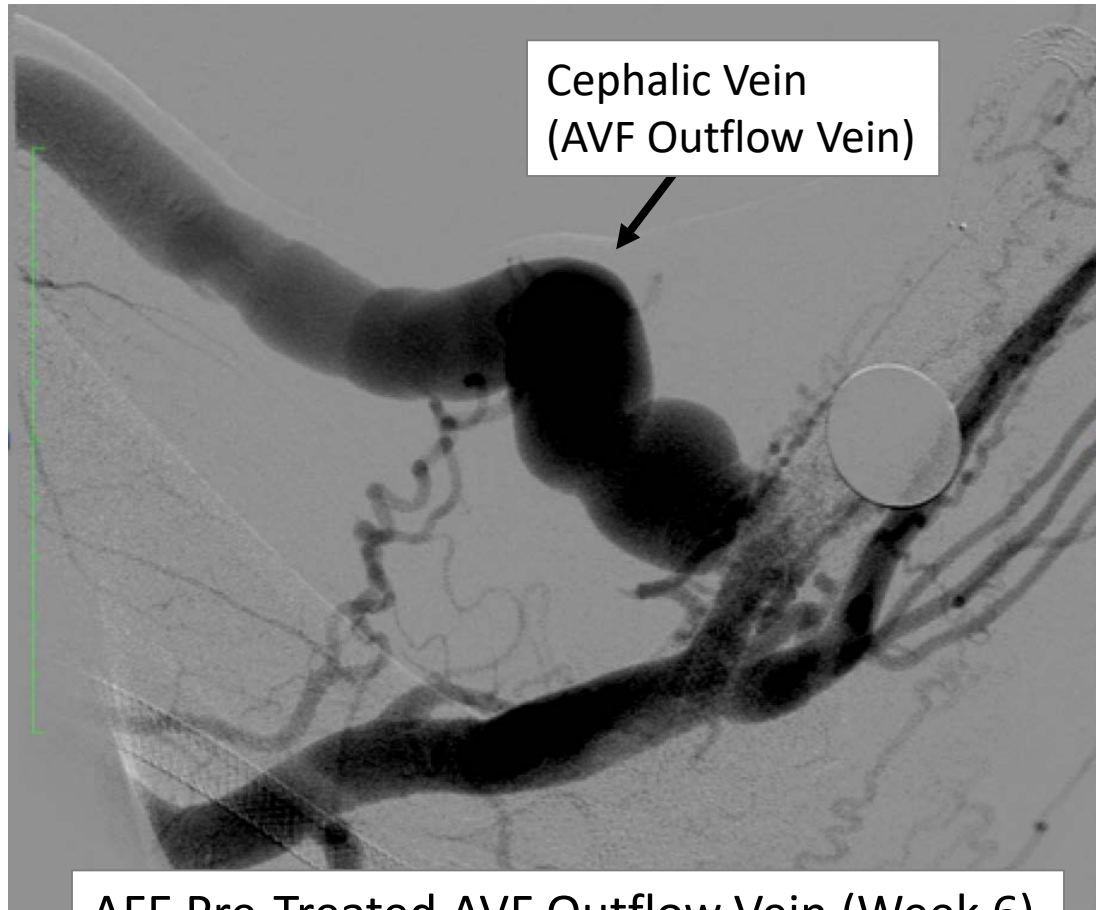


AFE Pre-Treated AVF Outflow Vein (Week 1)

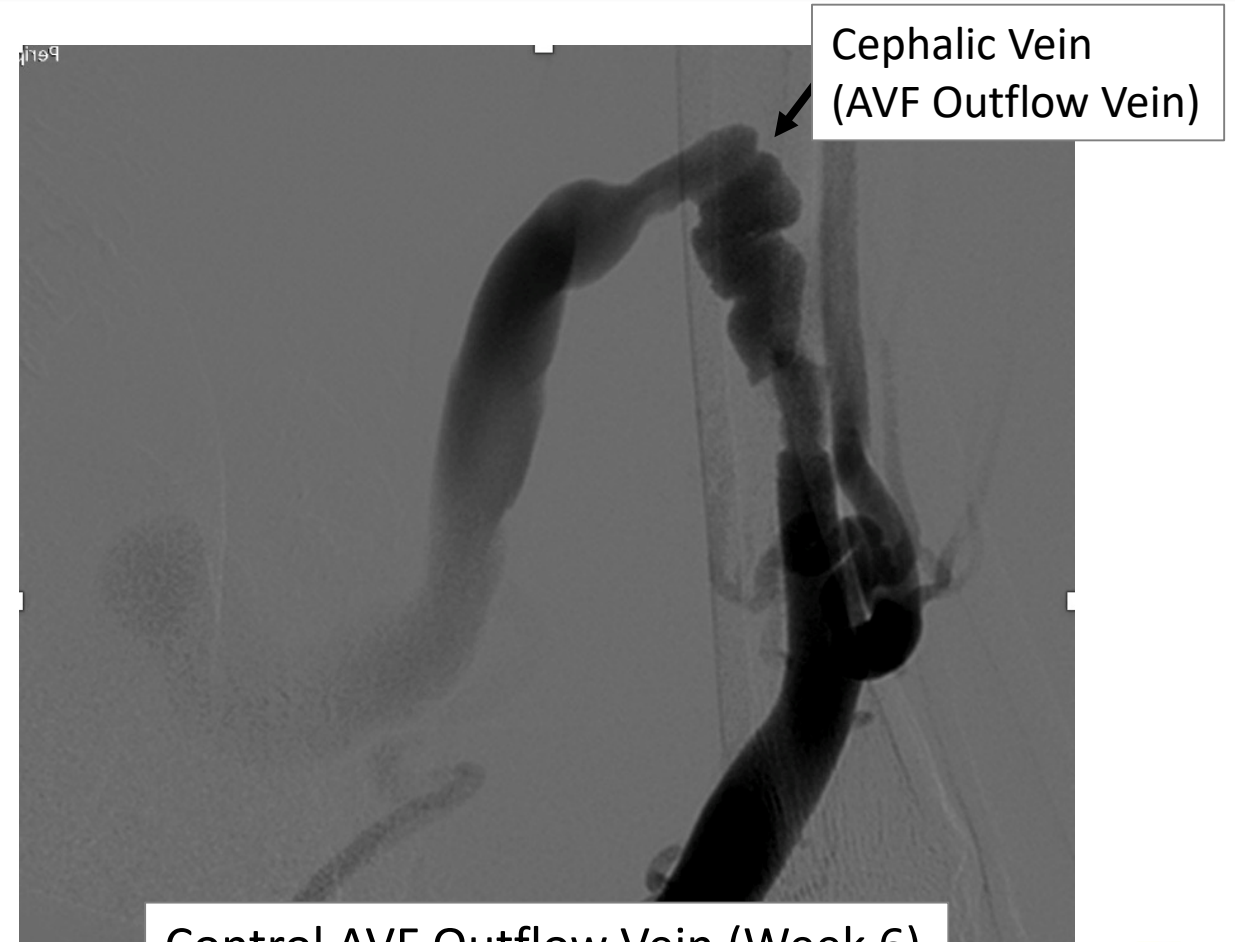


Control AVF Outflow Vein (Week 1)

Increased AVF Vein Diameters at 6 Weeks with AFE System Pre-Treatment



AFE Pre-Treated AVF Outflow Vein (Week 6)



Control AVF Outflow Vein (Week 6)

Summary

- ▶ Controlled increase in wall shear stress using non-pulsatile blood flow rapidly dilates ovine cephalic veins prior to AVF creation
- ▶ Making AVFs with dilated cephalic veins improves ovine AVF maturation
- ▶ Work supported by NIDDK SBIR Grant # 1R43DK105631-01
- ▶ A first-in-human clinical trial is planned for 2H 2018

Contact Us



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