



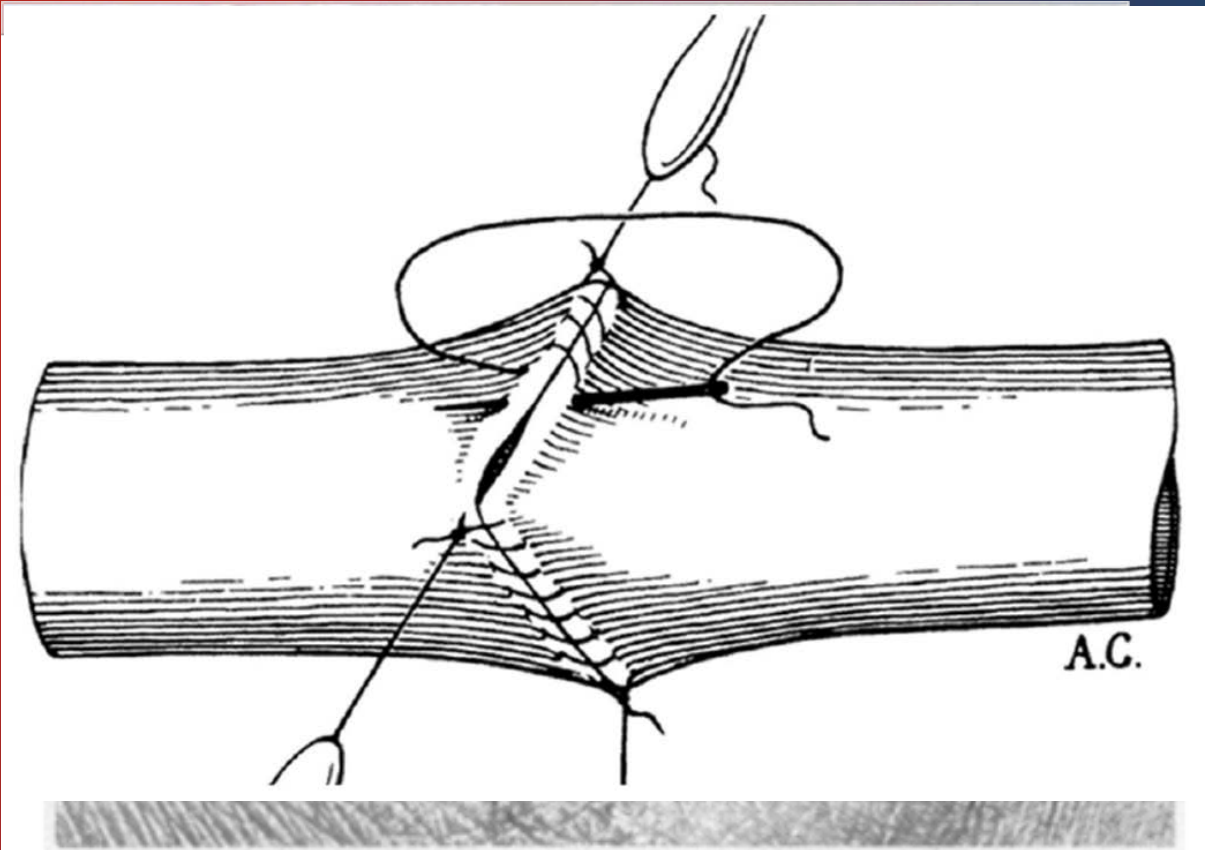
Update on the Ellipsys® EndoAVF

Jeffrey Hull MD

Disclosures

- Avenu Medical : Stockholder, consultant
- Medtronic: Investigator IN-PACT trial

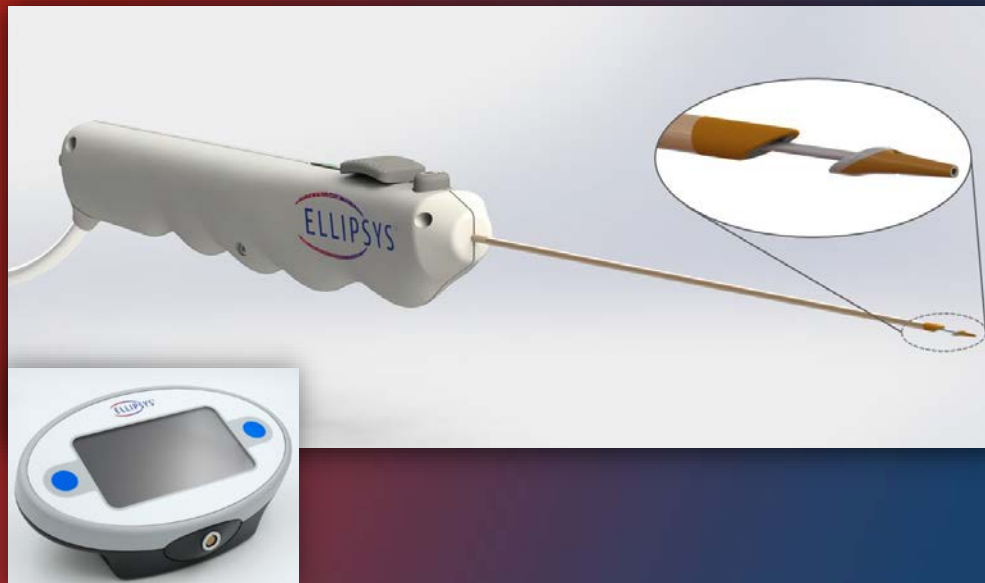
Anastomosis



Tissue Fused
Side-to-Side
3.5-9 mm²
Radial

- Carrel A. Lyon Medical 1902; 98:859-64.
- Brescia, Cimino, et al. N Engl J Med 1966; 275:1089-92.
- Hull et al. J Vasc Interv Radiol 2017; 28:380-7.
- Jennings et al. J Vasc Surg 2018; 67:244-53.

Ellipsys® Catheter Design



- Single Catheter
- Venous Access
- Over-the-Wire
- Tissue Fusion

* Hull et al. Thermal resistance anastomosis device for the percutaneous creation of arteriovenous fistulae for hemodialysis. J Vasc Interv Radiol 2017; 28(3):380-7.

The Ellipsys® Anastomosis

CLINICAL STUDY

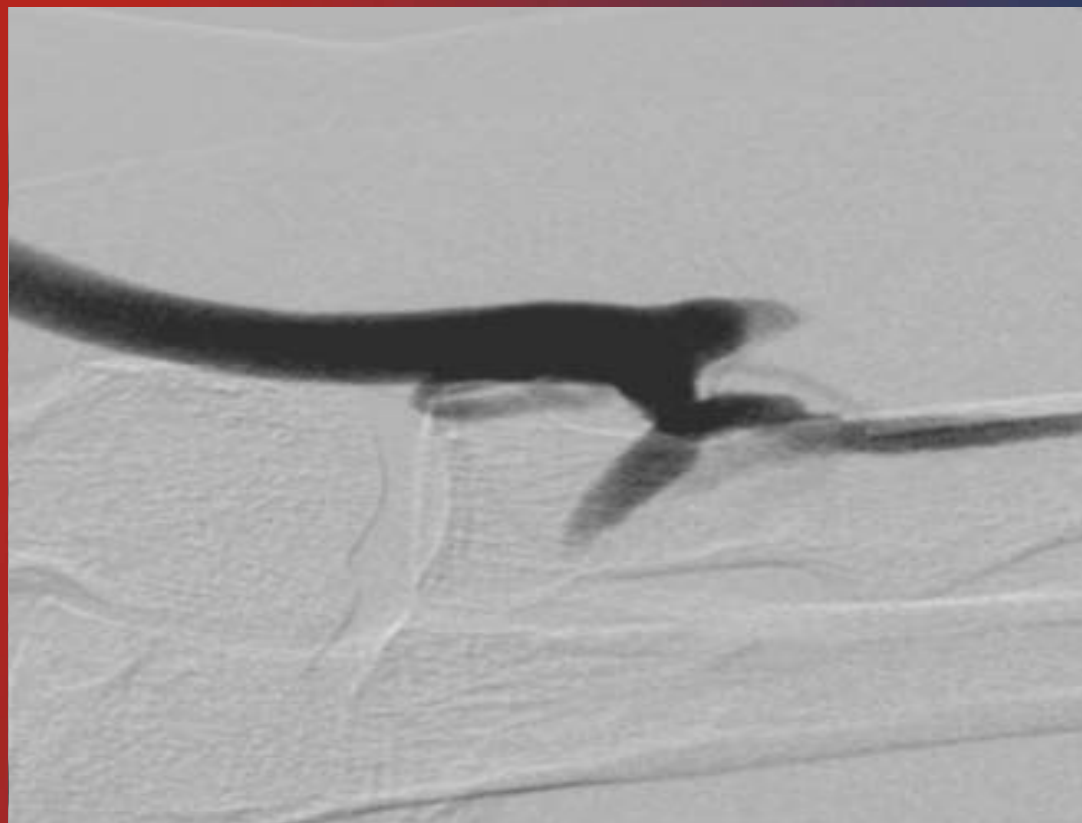


Thermal Resistance Anastomosis Device for the Percutaneous Creation of Arteriovenous Fistulae for Hemodialysis

Jeffrey E. Hull, MD, Guillermo Elizondo-Riojas, MD,
Wendy Bishop, BHSc, RVT, and Yesenia L. Voneida-Reyna, MD

ANAST

Ellipsys® US Pivotal Trial



- IR and IN
- Office
- Community
Dialysis
- Two-Stage
- Single Vein
Outflow

J Vasc Interv Radiol. 2018;29(2):149-58

Proximal Radial Fistula



Primary Endpoints: 90 Days

- Safety: device related serious adverse events
 - None
- Efficacy: BA flow volume ≥ 500 mL/min, Vein 4 mm vs. target goal $> 49\%$
 - 86% (92/107) one sided binomial test ($p < 0.0001$)

12 Month Results

Ellipsys®



Cumulative Patency 87%‡
Functional Patency 92%‡

Surgery



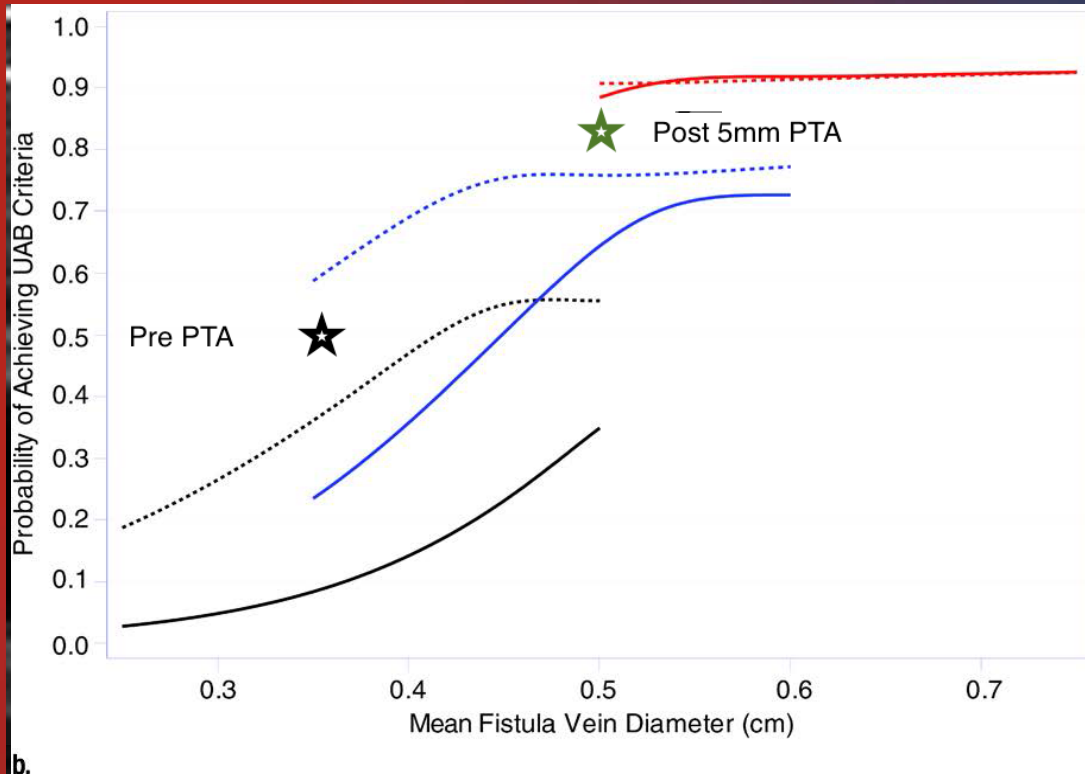
Cumulative Patency 80%*
Functional Patency 88%^

*Wu CC et al J Vasc Surg 2015; 61:802-8.

^Huijbregts HJ, et al. Clinical journal of the American Society of Nephrology : CJASN 2008; 3:714-9.

‡Hull et al. J Vasc Interv Radiol. 2018;29(2):149-58

Lessons Learned



- Treat Spasm
- Maturation
- T1 Flow and Diameter

Robbin ML, et al. Radiology 2016; 279:620-9

Paris Study

Early results of percutaneous arteriovenous fistula creation with the Ellipsys Vascular Access System

Alexandros Mallios, MD,^a William C. Jennings, MD,^b Benoit Boura, MD,^a Alessandro Costanzo, MD,^a Pierre Bourquelot, MD,^c and Myriam Combes, MD, MBA,^a *Paris, France; and Tulsa, Okla*

- Combined anastomosis + maturation
- Multi-Outflow avoid transposition
- Early cannulation
- High patient acceptance

J Vasc Surg: 2018

Paris Data

- May 2017 – April 2018
- 83 Patients
- 99% Technical Success
- 94% Cumulative Patency
- Mean Follow-up 5 Months (1-11mos)

Paris Data

- No Serious Adverse Events
- 20% Patients Required Additional Procedures
- 2 Superficializations
- All AVFs Used or Usable at 4-6 Weeks

Cannulation



Europe



USA

Future Directions

- Change the fistula paradigm
 - High failure rate: 30-60%¹
 - Time to two-needle cannulation mean: 136 days²
 - 80% initiate dialysis with a catheter³

1. Al-Jaishi AA, Oliver MJ, Thomas SM, et al. Am J Kidney Dis 2014; 63:464-78.

2. 2016 USRDS annual data report.

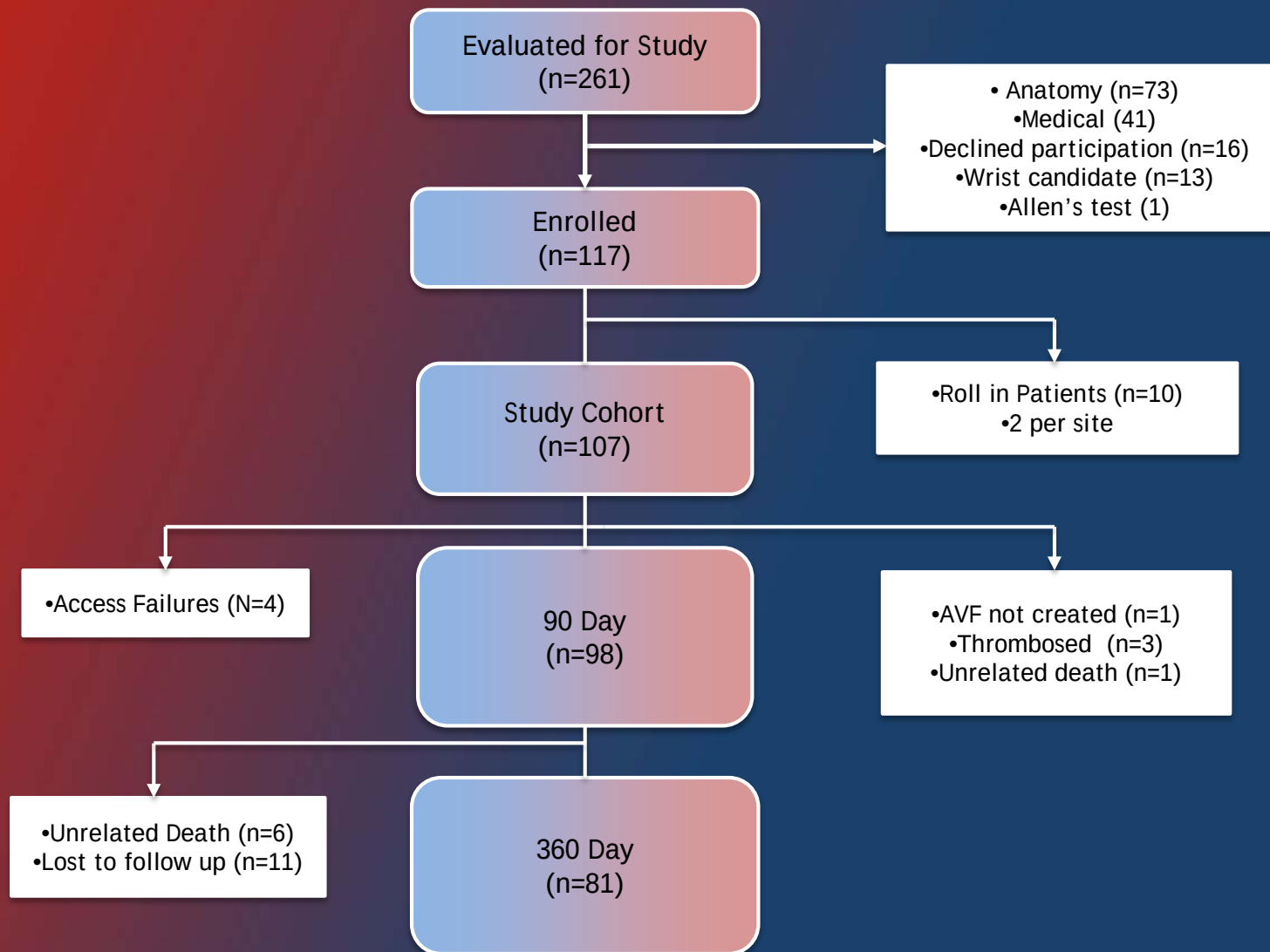
3. Chan KE, et al: Clinical journal of the American Society of Nephrology : CJASN 2011; 6:2642-9.

Thank you!

Patient Demographics

Characteristics	Value (%)
Race (White/Black/Asian/Other)	77 (74.8) / 2 (20.4) / 2 (1.9) / 3 (2.9)
Ethnicity (Hispanic/Not Hispanic)	37 (35.9) / 65 (63.1)
Sex (M/F)	76 / 27
Age	56.6 $\pm$ 12.0
BMI (Kg/m ²)	31.21 $\pm$ 7.20
Obesity	52 (50)
Type 1 diabetes	5 (4.9)
Type II diabetes	63 (61.2)
Hypertension	101 (98.1)
Catheter dialysis at time of procedure	64 (62.1)

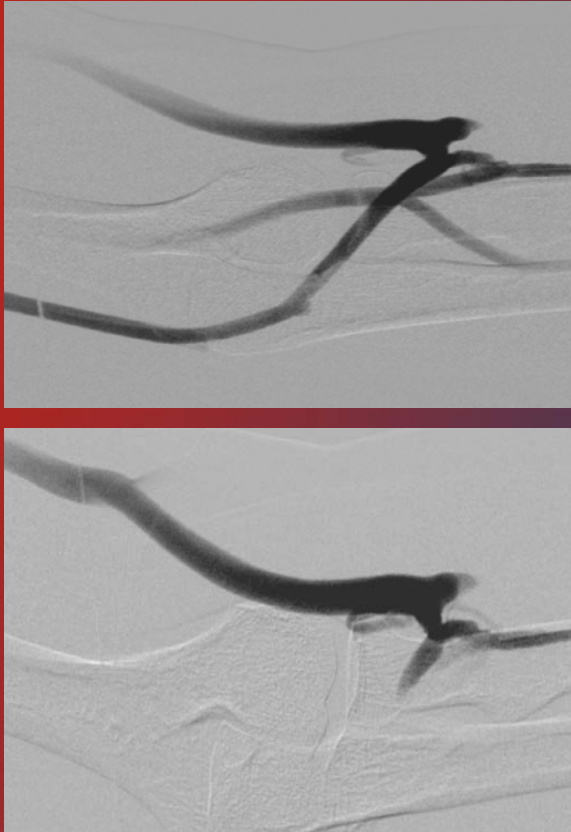
Patient Flow



Procedural Characteristics

Characteristic	Value
Technical success	95% (102/107)
PRA diameter	3.1 $\pm$ 0.6 mm (range 2.0 – 4.6)
Perforating vein diameter	3.5 $\pm$ 0.9 mm (range 2.0 – 7.2)
Procedure time	23.7 $\pm$ 11.3 min (range 8-66)
Target vein cephalic / basilic / other	74% / 24% / 3%

Two Stage Procedure



- BA flow mean 334 mL/min

Procedure	Patients (%)
PTA proximal fistula	77 (72)
Embolization deep	34 (32)
Embolization branch	37 (35)
Cubital vein ligation	33 (31)
Transposition	28 (26)

- BA flow mean 932 mL/min

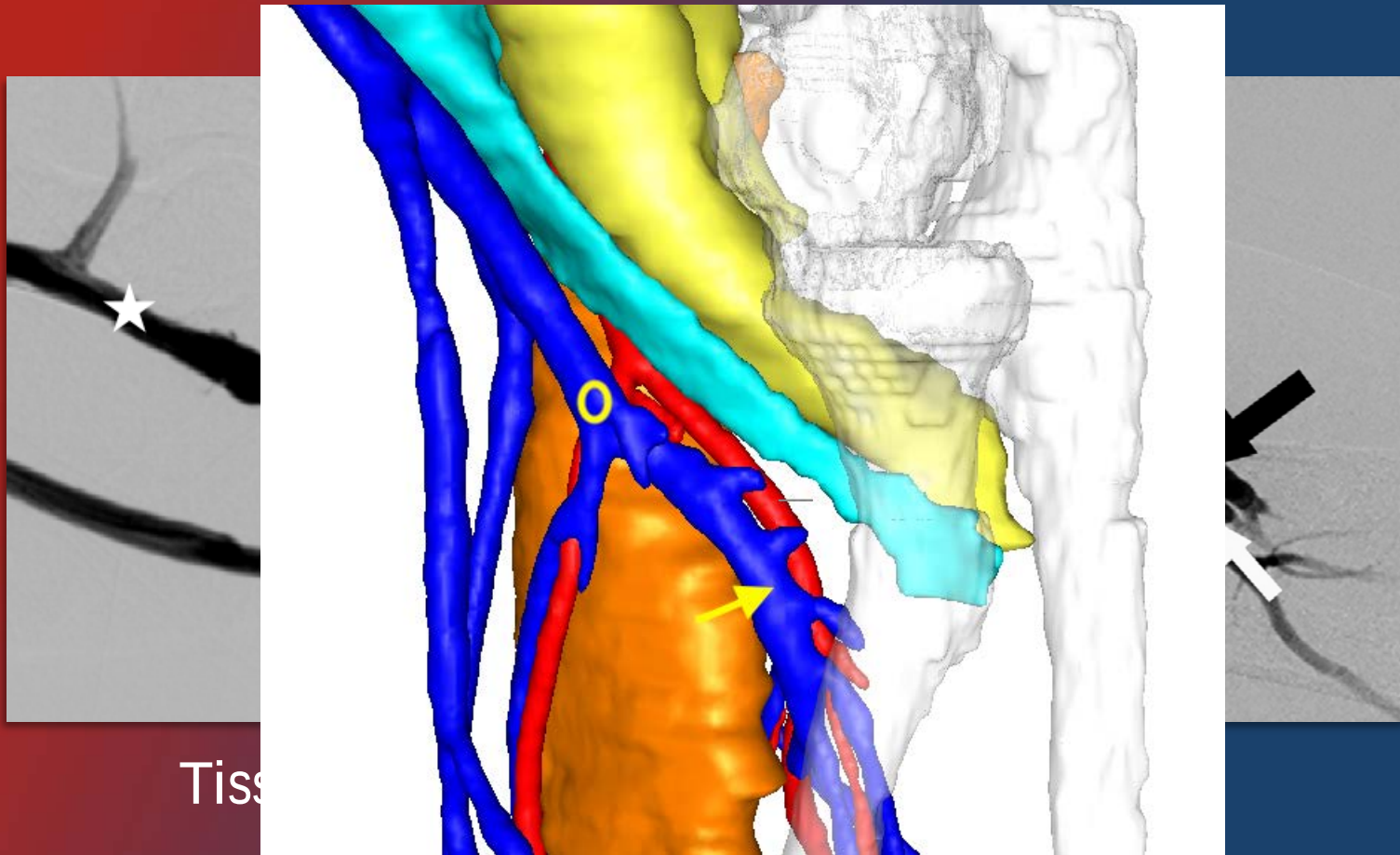
Proximal Radial Artery Fistula



- Day 1 flow 334 mL/min
- Prepare for dialysis at community dialysis center

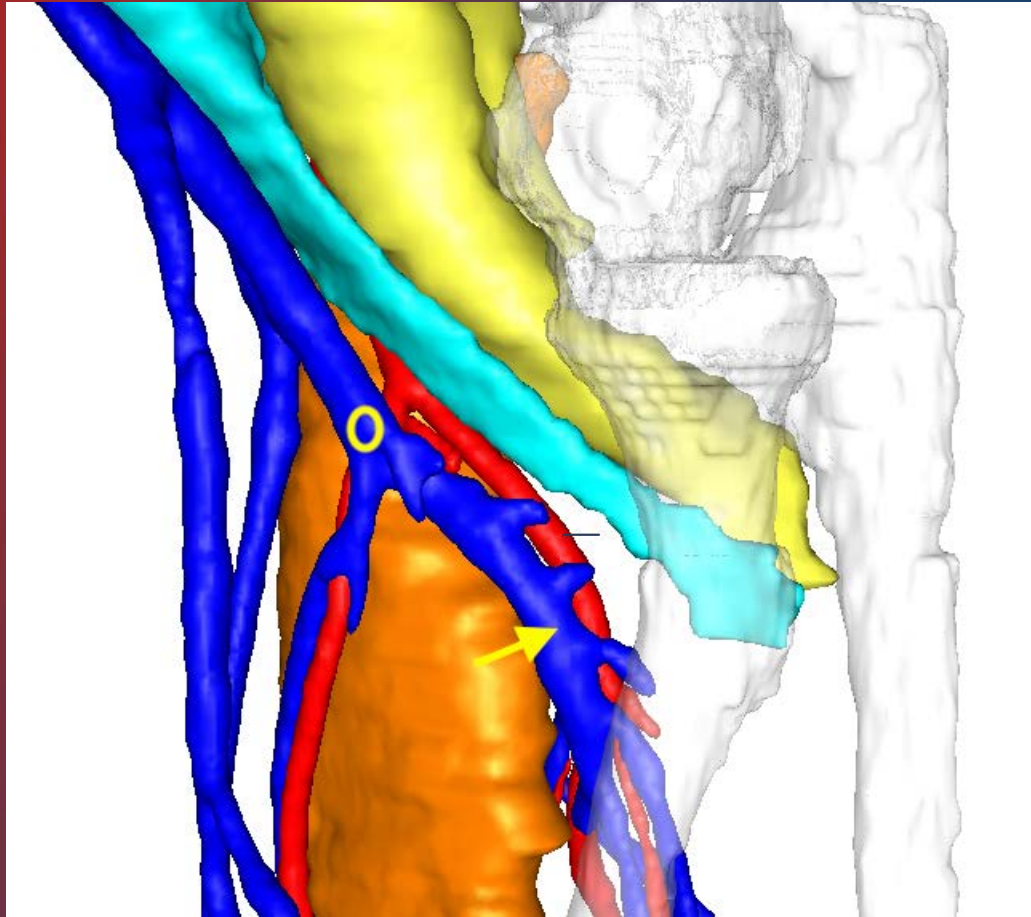
*Jennings WC, Mallios A, Mushtaq N. Proximal radial artery arteriovenous fistula for hemodialysis vascular access. J Vasc Surg 2017.

Percutaneous Fistulae



*Rajan DK, Ebner A, Desai SB, Rios JM, Cohn WE. Percutaneous creation of an arteriovenous fistula for hemodialysis access. J Vasc Interv Radiol 2015; 26:484-90.

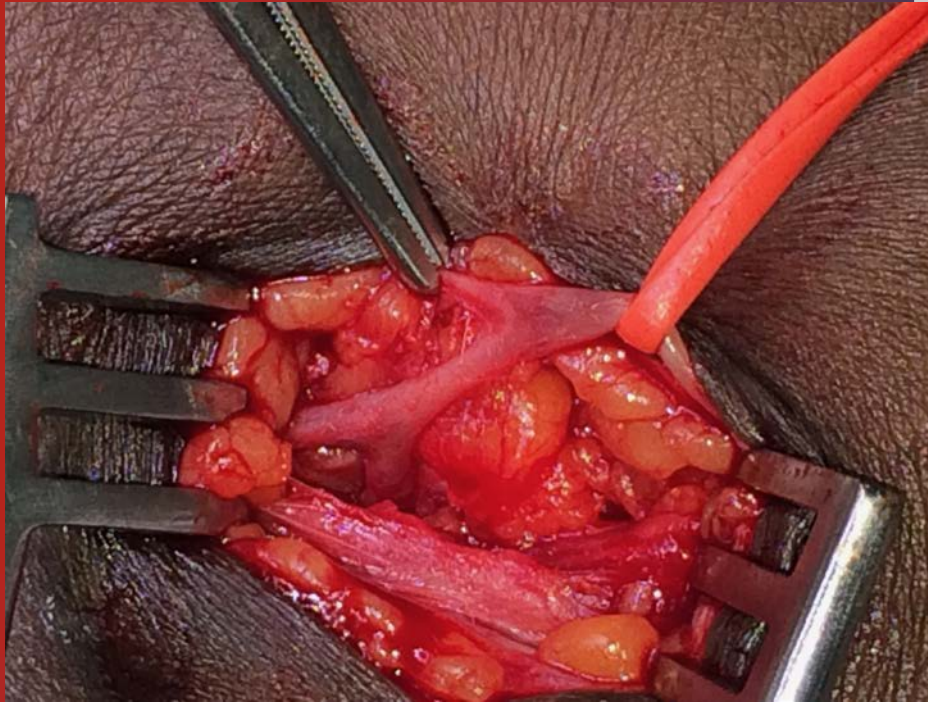
Percutaneous Fistulae



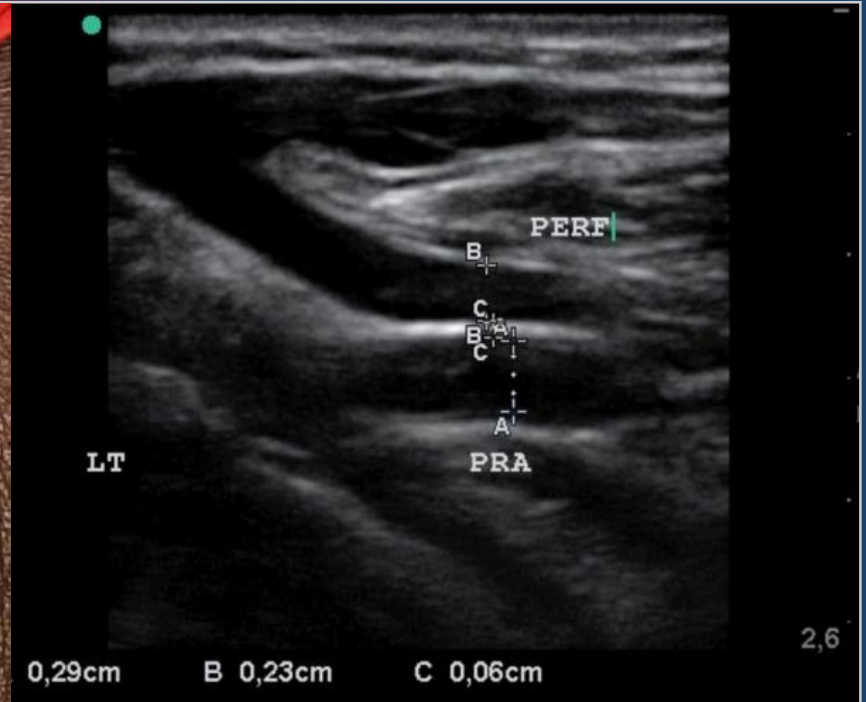
The Ellipsys® Procedure



Replace Dissection



Vessels dissected



Vessels in-situ

Jennings WC. Creating arteriovenous fistulas in 132 consecutive patients: exploiting the proximal radial artery arteriovenous fistula: reliable, safe, and simple forearm and upper arm hemodialysis access. Arch Surg 2006; 141:27-32; discussion

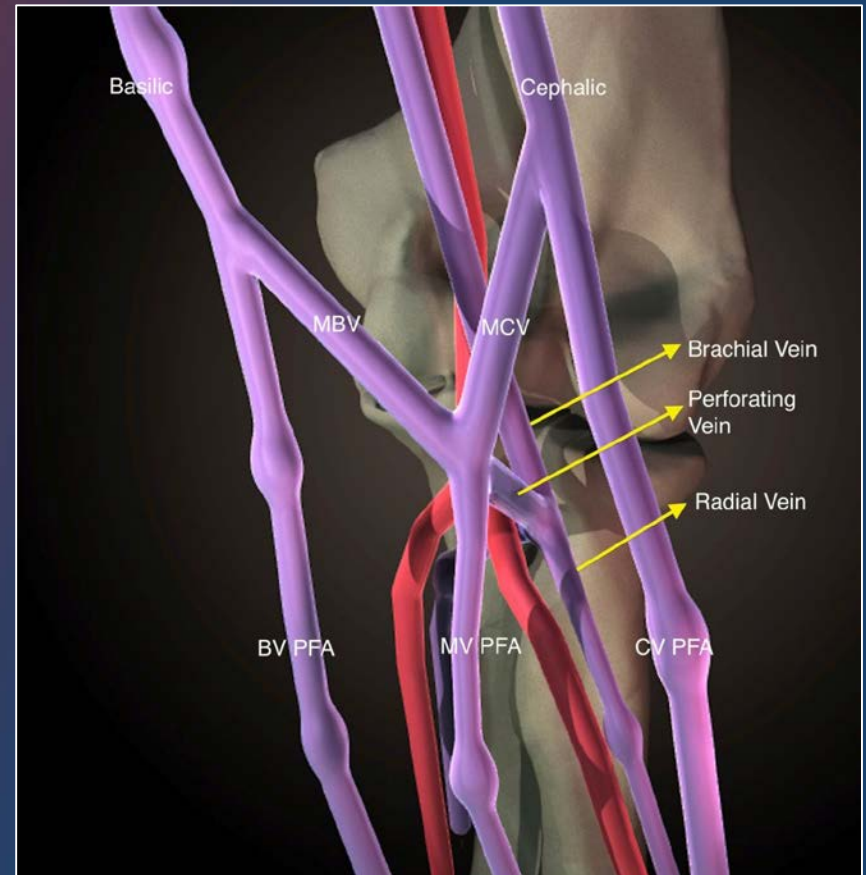
Maintenance Procedures

	Patients (%)	Procedures	Days
Total Maintenance	35 (36)	66	176.8 $\pm$ 97.6 (range 44 - 371)
PTA	28 (29)	51	182.6 $\pm$ 97.9 (range 44 - 369)
Embolization	10 (10)	10	97.0 $\pm$ 32.7 (range 50 - 154)
Stent	7 (7)	8	174.9 $\pm$ 111.5 (range 49 - 363)

Fistula Related Events

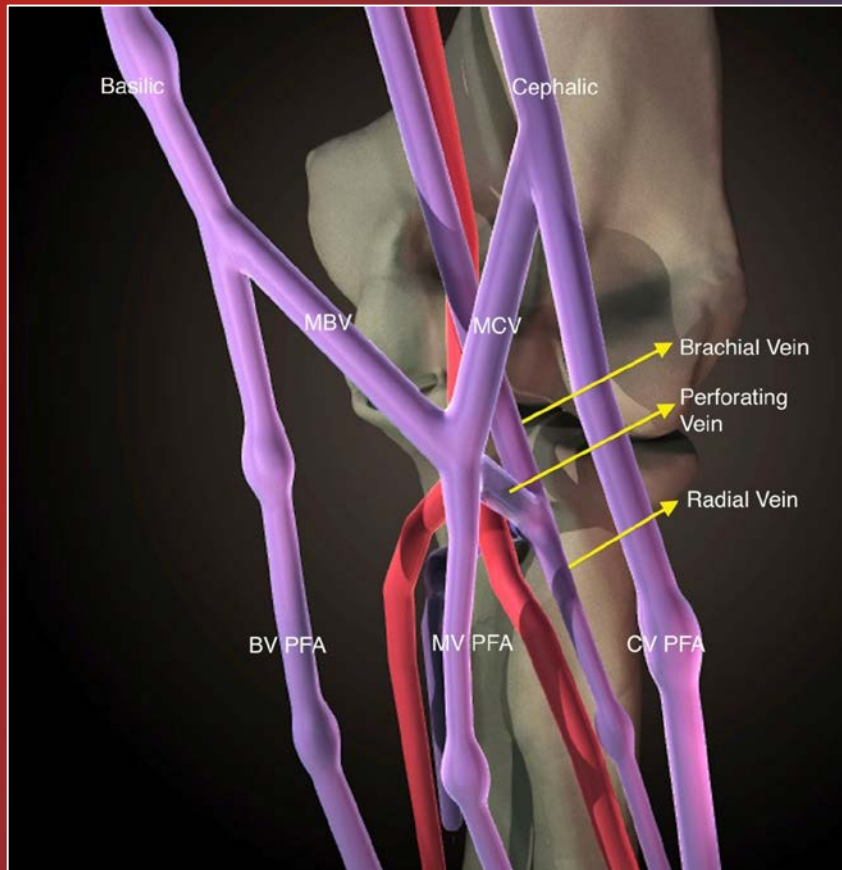
	Patients (%)	Treatment
Anastomosis		
Early thrombosis (< 30 days)	12 (11.7)	Declot 9, abandoned 3
Late thrombosis	3 (3.9)	Declot 2, abandoned 1
Fistula		
Proximal stenosis	22 (21.4)	Balloon dilation
Fistula Stenosis	17 (16.5)	Balloon dilation
Central stenosis	4 (3.9)	Balloon dilation or stent
Cephalic arch stenosis	4 (3.9)	Balloon dilation or stent
Difficult cannulation	7 (6.8)	Balloon dilation or surgical elevation
Cannulation injury	13 (12.6)	Medical and endovascular management
Steal syndrome	1 (1.0)	Ligation of second anastomosis
Venous hypertension	3 (2.9)	2 endovascular, 1 ligation
Other		
Coil migration	1 (1.0)	Migrated to lung, asymptomatic
Vein rupture	1 (1.0)	During transposition treated with stent
Neuropathy	1 (1.0)	Transient day 7 to day 30
Epistaxis	1 (1.0)	Discontinued aspirin and clopidogrel
Infection	1 (1.0)	Jump graft and defibrillator lead removed

Antecubital Fossa

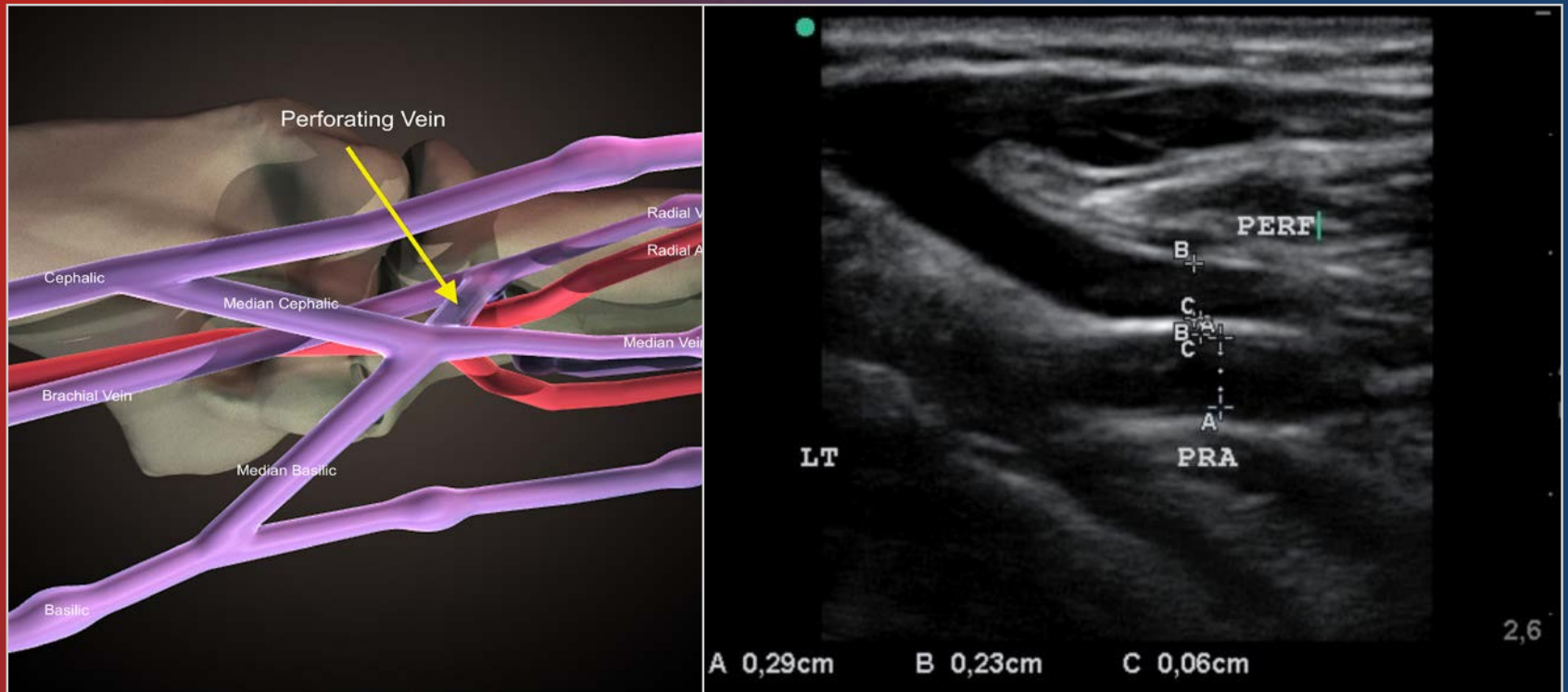


Hull JE, Kinsey EN, Bishop WL. Mapping of the snuffbox and cubital vessels for percutaneous Arterial Venous Fistula (pAVF) in dialysis patients. J Vasc Access. 2013;14(3):245-51.

The Anatomy Antecubital Fossa



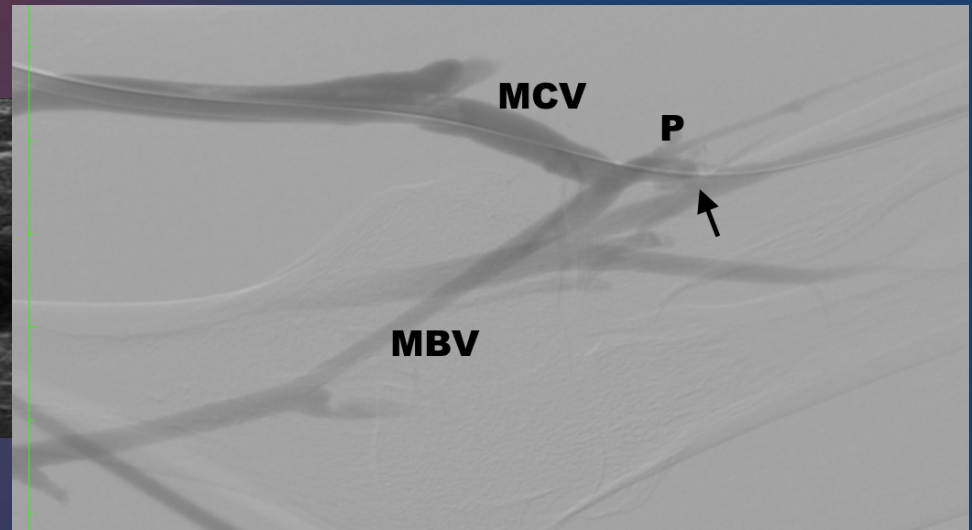
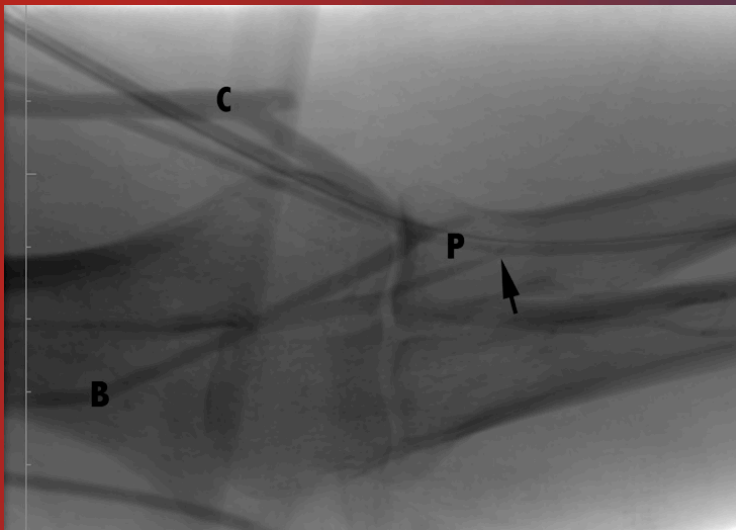
Proximal Radial Artery Perforating Vein



- 88% (29/33) PV contacts PRA and was ≥ 2.0 mm

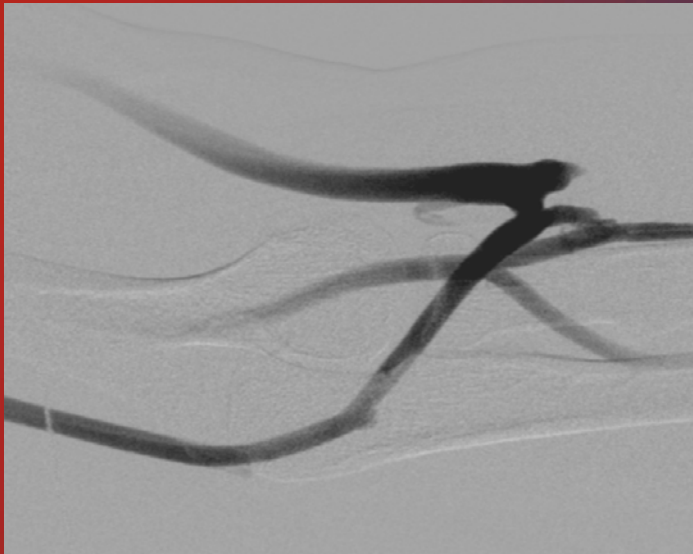
Hull JE, Kinsey EN, Bishop WL. J Vasc Access 2013; 14:245-51.

Multi-Outflow Fistula Balloon Dilation

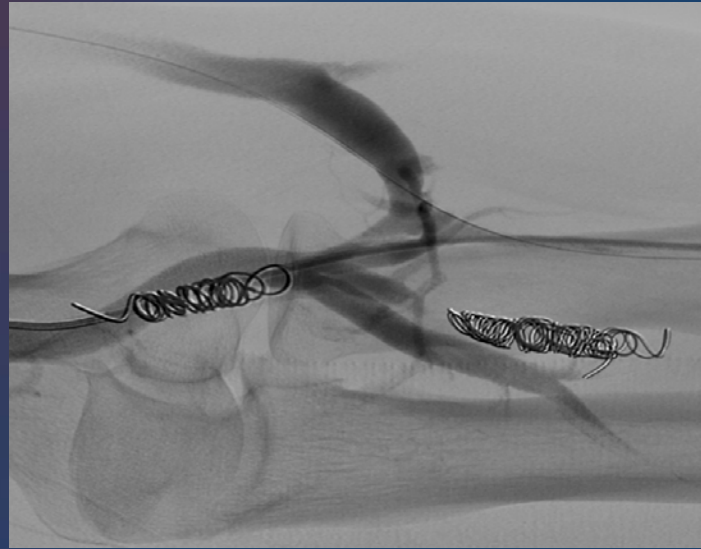
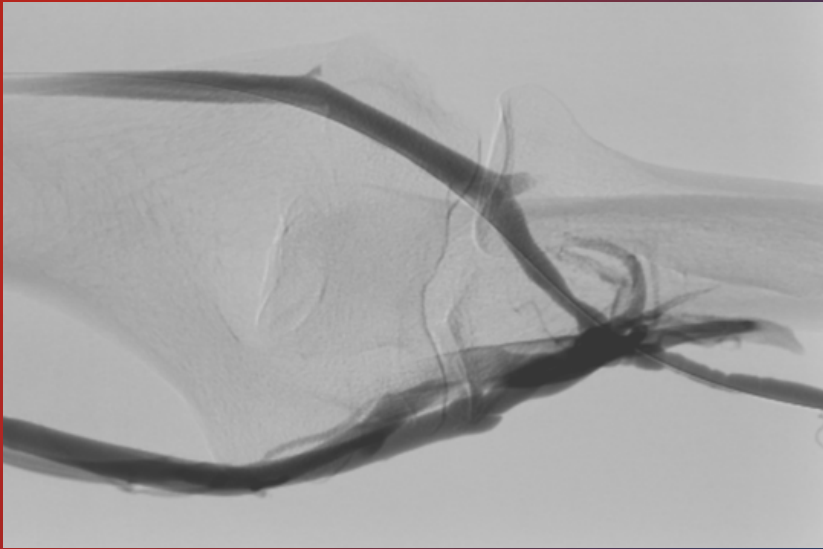


* Hull et al. Thermal resistance anastomosis device for the percutaneous creation of arteriovenous fistulae for hemodialysis. JVIR 2015; on line, article in press.

Multi-Outflow Fistula



Multi-Outflow Fistula Balloon Dilation Deep Embolization



Ellipsys® 18 Months on Dialysis



Ellipsys® Patients on Dialysis



Pt. #1 @
6 mos



Pt. #2 @
12 mos



Pt. #3 @
18 mos

