



CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE  
**CONTROVERSIES & UPDATES  
IN VASCULAR SURGERY**

**JANUARY 25-27 2018**

**MARRIOTT RIVE GAUCHE & CONFERENCE CENTER**

**PARIS, FRANCE**

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**Ellipsys<sup>®</sup>**

Single Catheter Percutaneous  
Arteriovenous Fistula

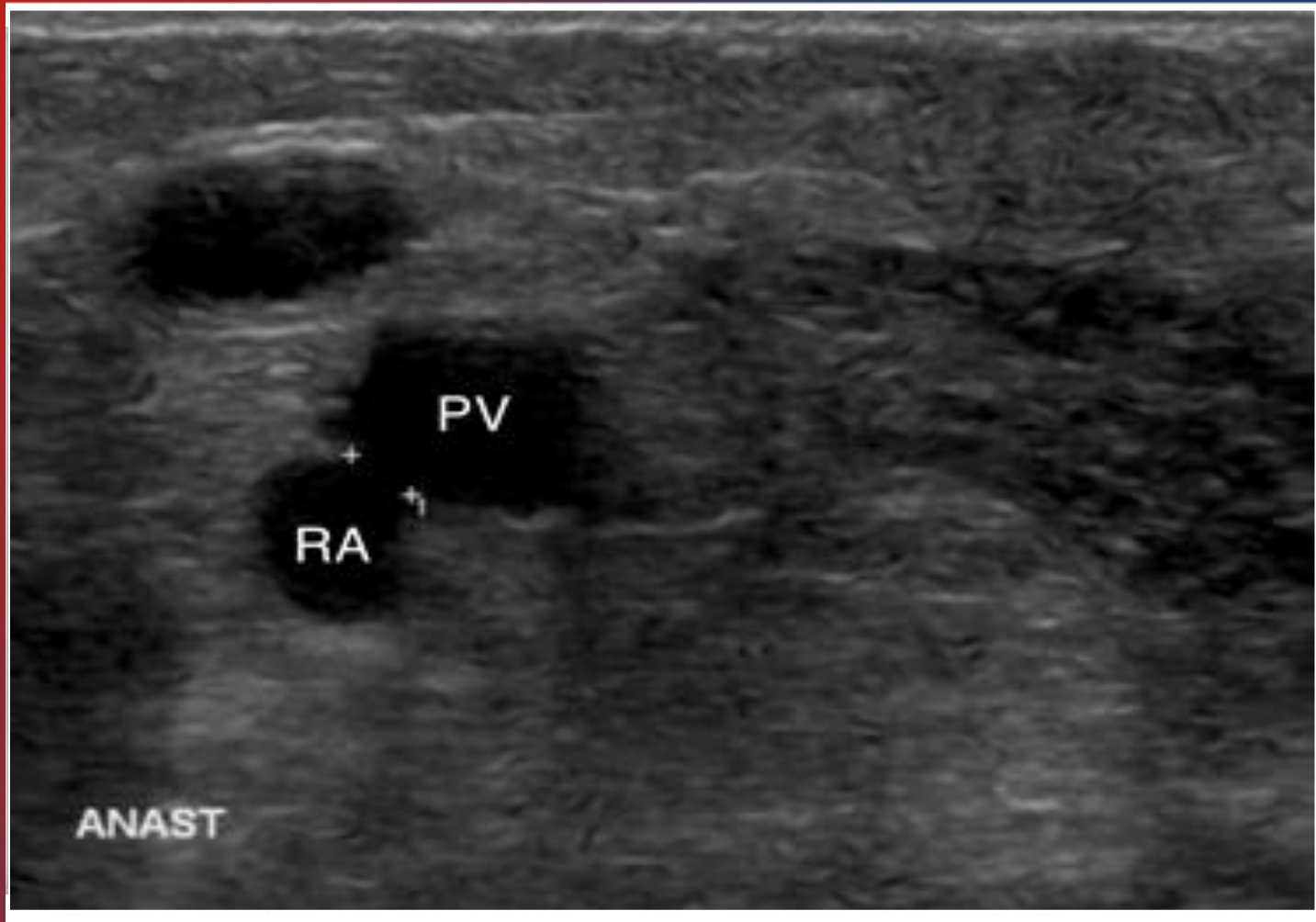
## Disclosure

Speaker name:

.....Jeffrey Hull.....

- I have the following potential conflicts of interest to report:
- Consulting
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

# *The Ellipsys<sup>®</sup> Anastomosis*



Brescia MJ, Cimino JE, et al. N Engl J Med 1966; 275:1089-92.

Cezo et. IEEE Trans Biomed Eng 2013; 60:2552-8.

# *Ellipsys® Catheter Design*

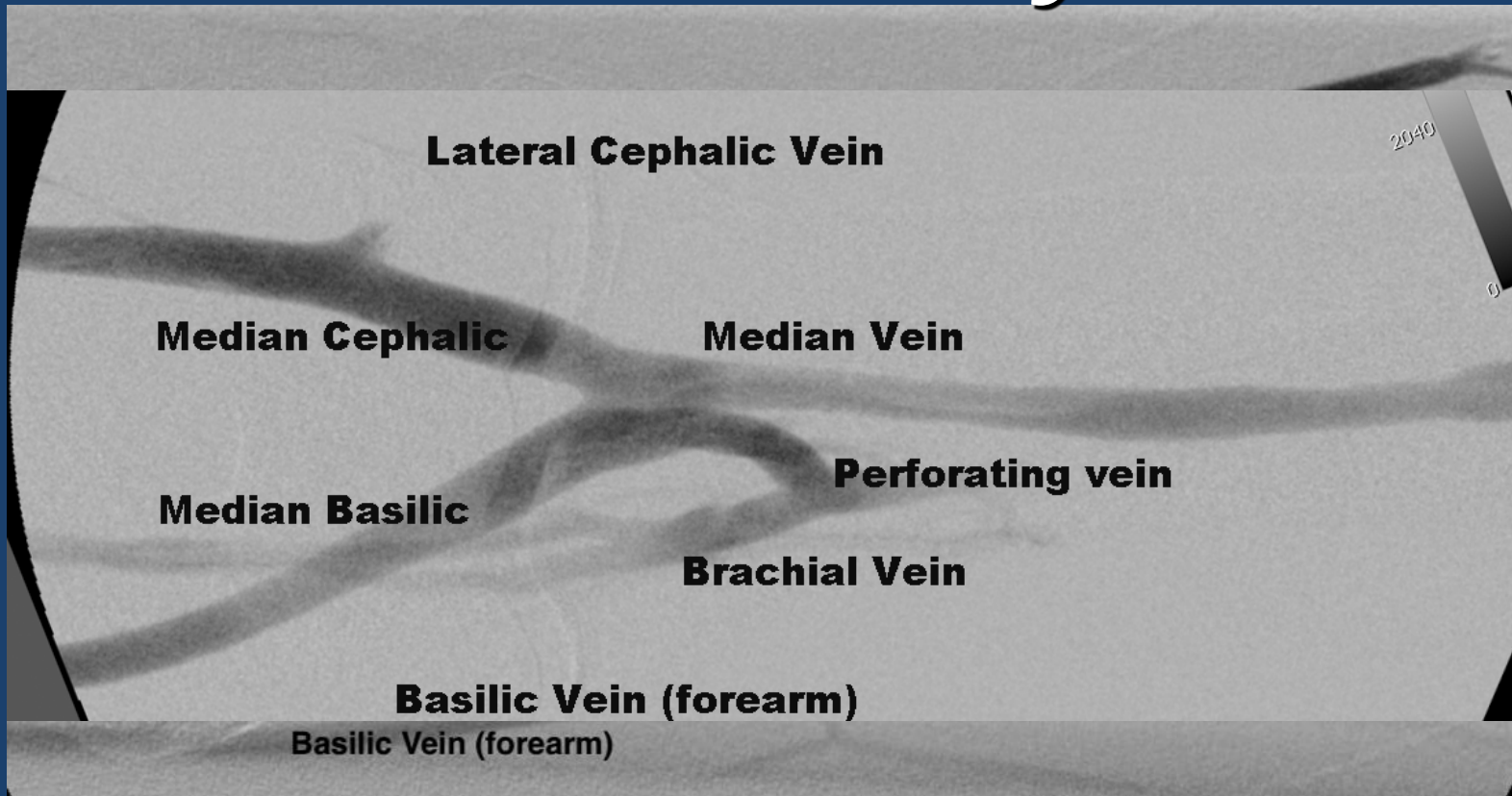


\* Hull JE, Elizondo-Riojas G, Bishop W, Voneida-Reyna YL. J Vasc Interv Radiol 2017; 28:380-7.

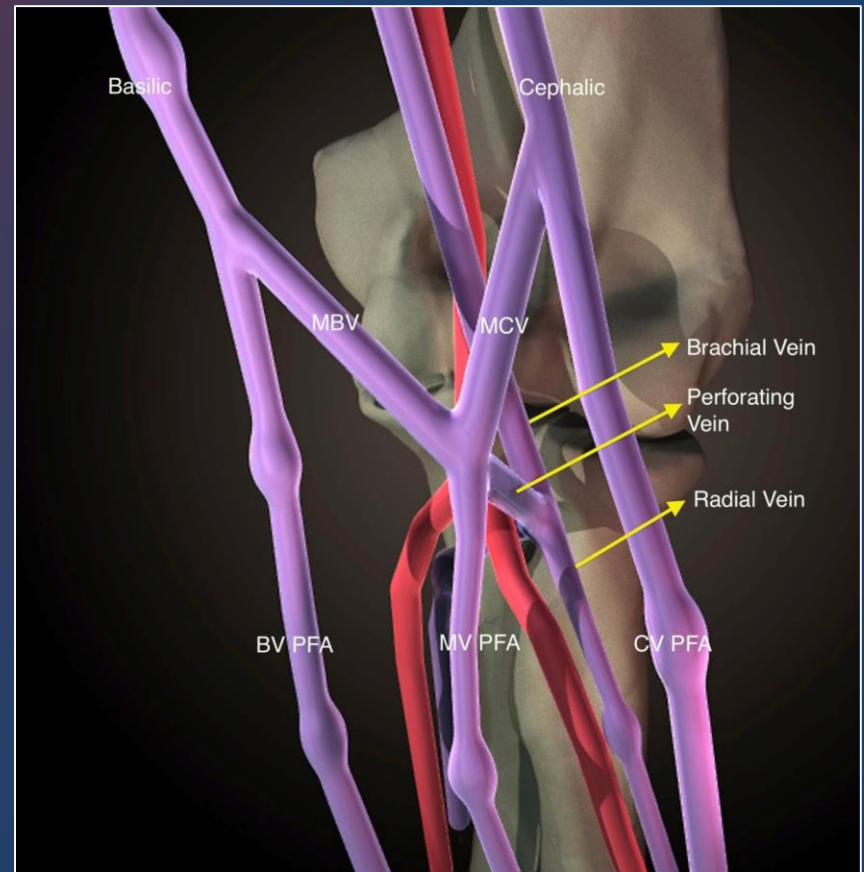
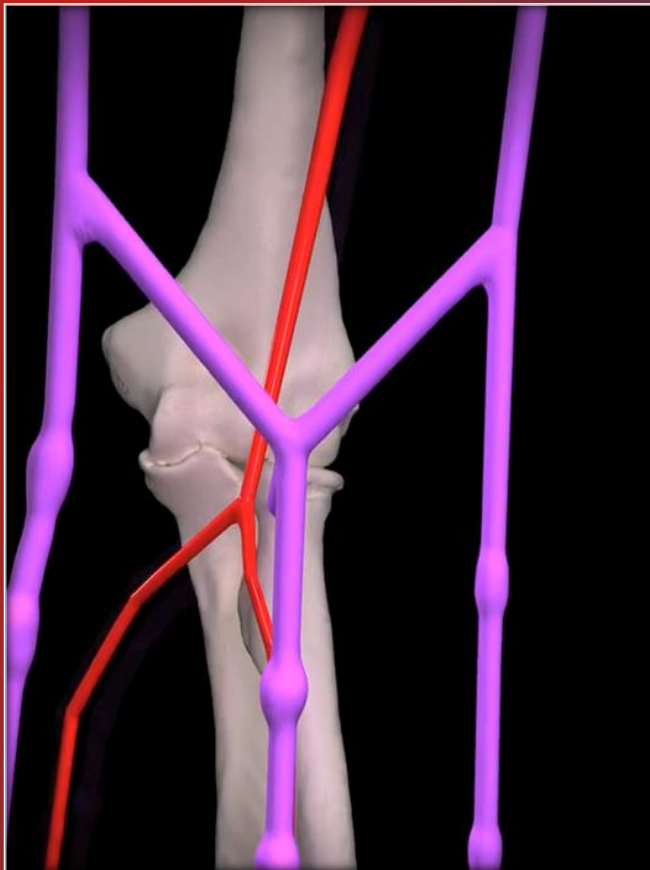
# *Proximal Radial Fistula*



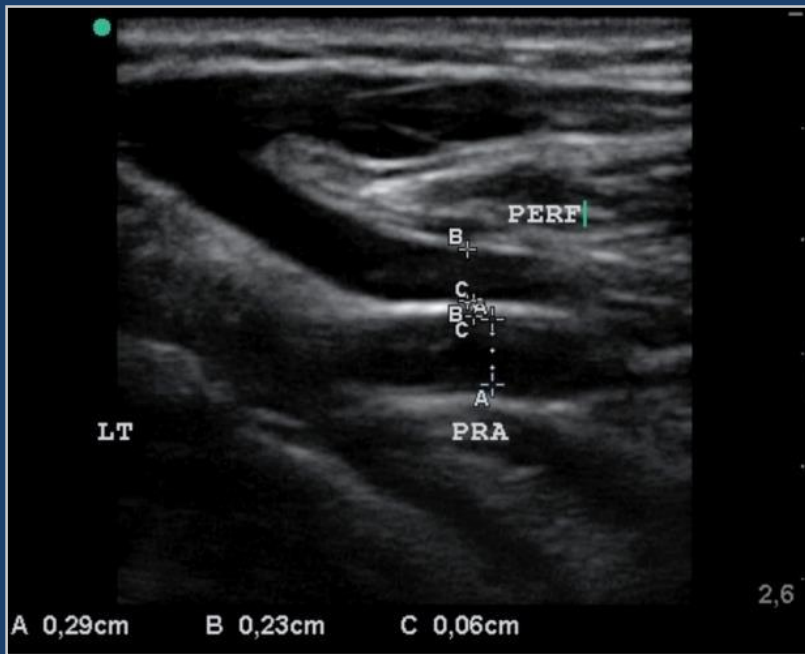
# Anatomy



# Antecubital Fossa



# Vein Mapping



- 88% (29/33) PV contacts PRA and was  $\geq 2.0$  mm

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



# *Ellipsys US Pivotal Trial*

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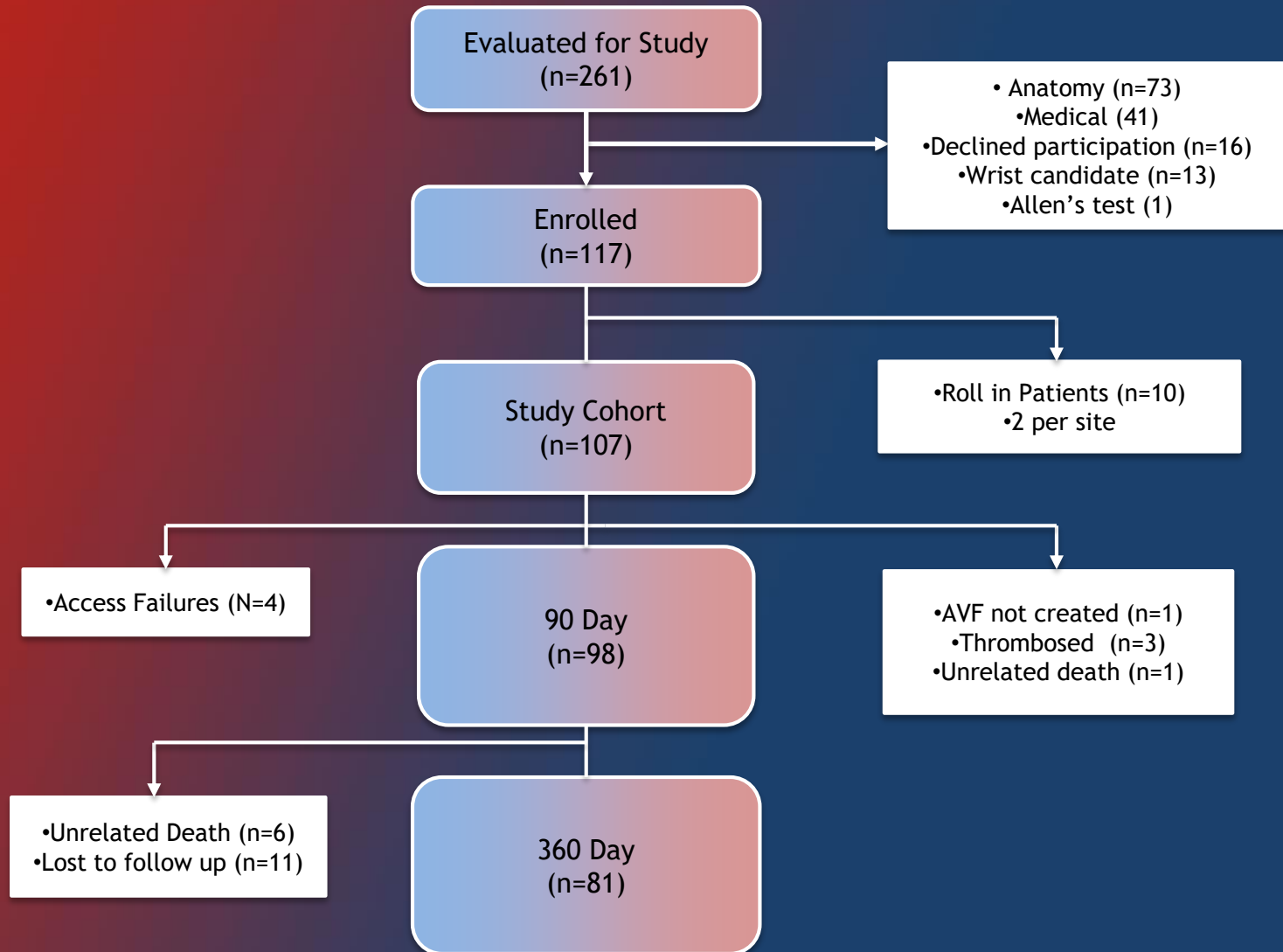
CLINICAL STUDY

## **The Pivotal Multicenter Trial of Ultrasound-Guided Percutaneous Arteriovenous Fistula Creation for Hemodialysis Access**

Jeffrey E. Hull, MD, William C. Jennings, MD, Randy I. Cooper, MD, Umar Waheed, MD, Matthew E. Schaefer, DO, and Rajeev Narayan, MD



# Patient Flow



# Patient Demographics

Characteristics	Value (%)
Race (White/Black/Asian/Other)	77 (74.8) / 21 (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 ± 12.0
BMI (Kg/m <sup>2</sup> )	31.21 ± 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)

# Procedural Characteristics

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

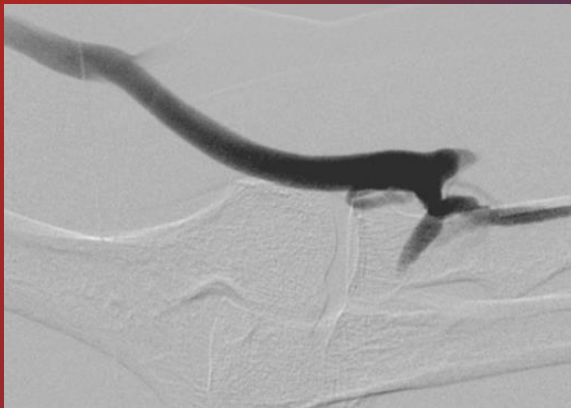
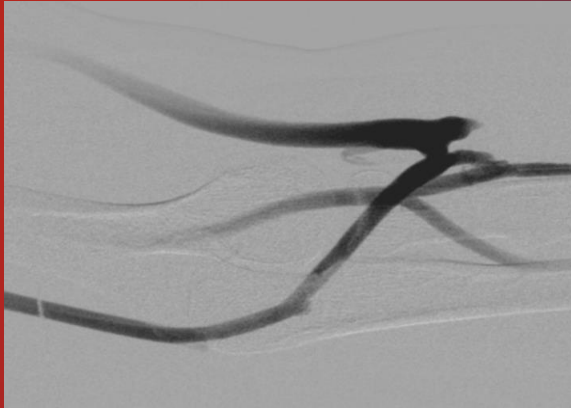
# Early Post Operative



- Intact anastomosis
- Mean flow 330 mL/min
- Multi-outflow
- Prepare for dialysis

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

# Maturation Procedures



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

- BA flow mean  $932 \pm 370$  mL/min

# *Endpoints*

- Primary endpoints:
  - Primary safety endpoint: Device related serious adverse events
    - None
  - Primary efficacy endpoint: BA flow  $\geq$  500 mL/min target vein  $\geq$  4 mm
    - 86% (92/107) vs. target goal  $>$  49% one sided binomial test ( $p < 0.0001$ )

# 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.JVIR In Press



# *Conclusion*

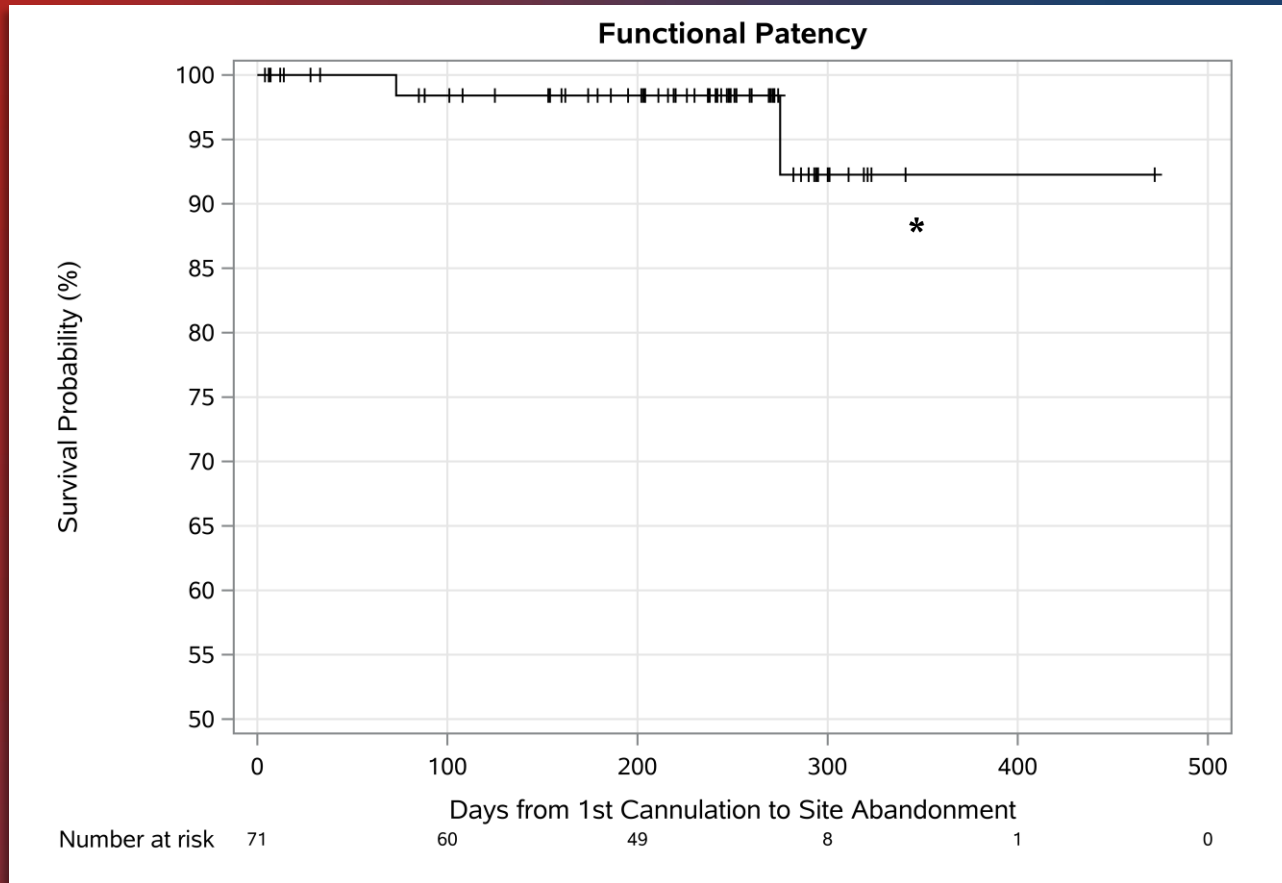
- Ellipsys Fistula
  - Safe and effective
  - A paradigm shift



# Maintenance Procedures

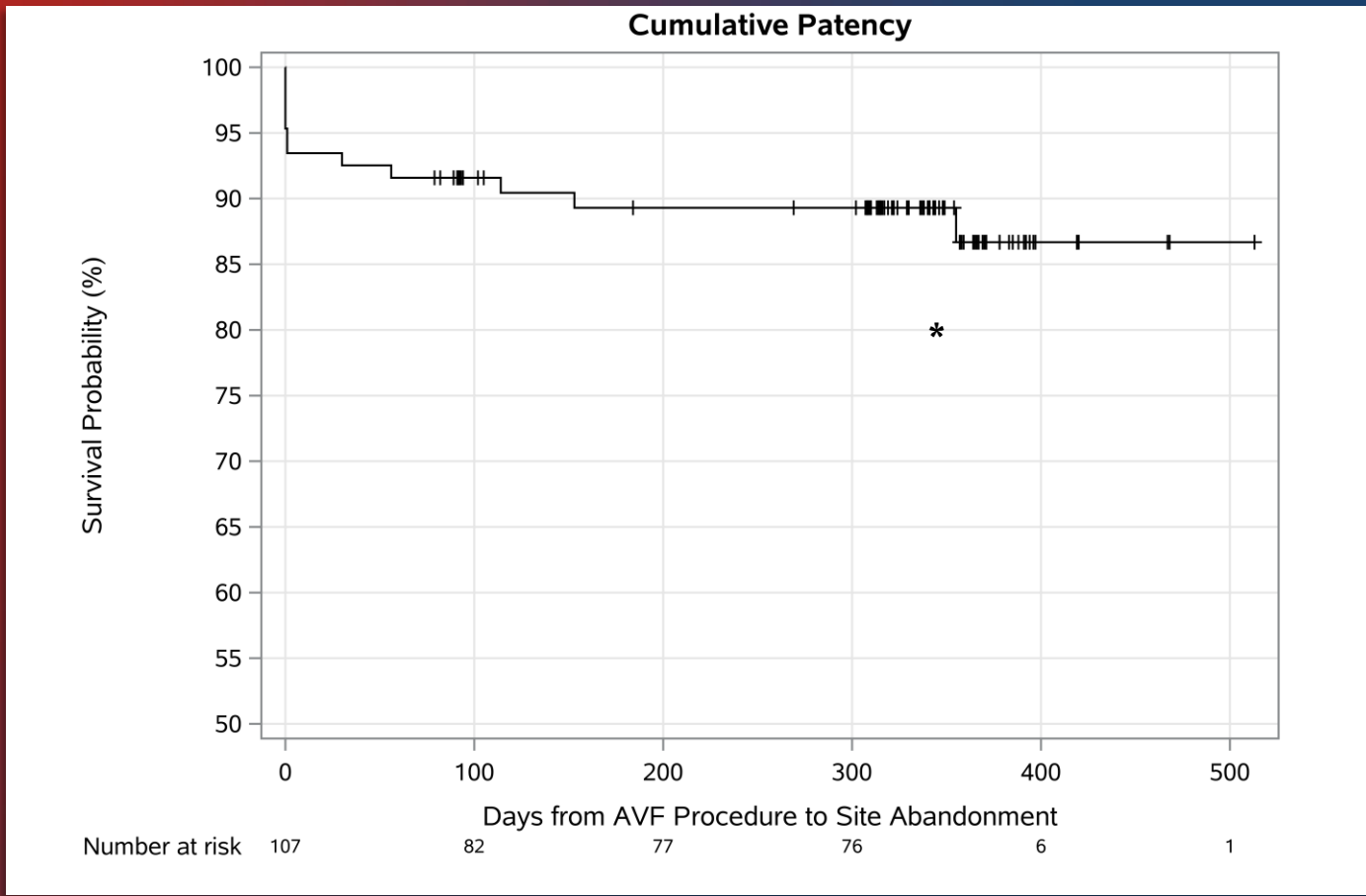
	Patients (%)	Procedures	Days
Total Maintenance	35 (36)	66	176.8 ± 97.6 (range 44 - 371)
PTA	28 (29)	51	182.6 ± 97.9 (range 44 - 369)
Embolization	10 (10)	10	97.0 ± 32.7 (range 50 - 154)
Stent	7 (7)	8	174.9 ± 111.5 (range 49 - 363)

# Functional Patency



\*Huijbregts HJ, Bots ML, Wittens CH, et al. Hemodialysis arteriovenous fistula patency revisited: results of a prospective, multicenter initiative. Clinical journal of the American Society of Nephrology : CJASN 2008; 3:714-9.

# Cumulative Patency

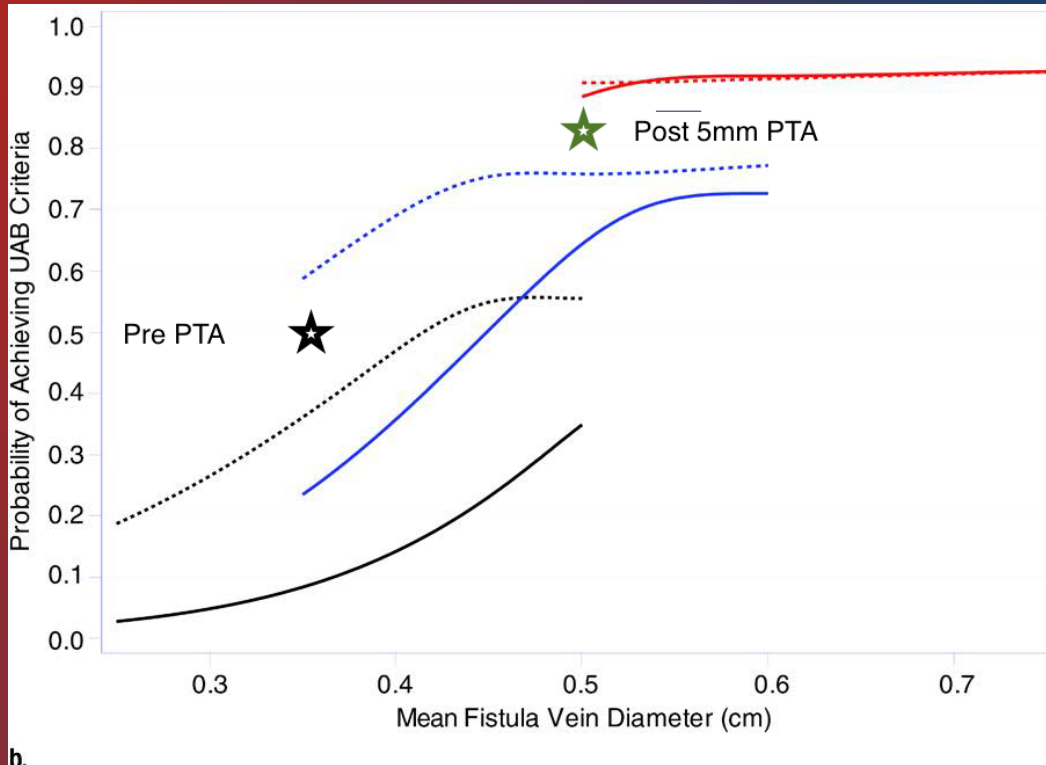


\*Wu CC, Jiang H, Cheng J, Zhao LF, Sheng KX, Chen JH. The outcome of the proximal radial artery arteriovenous fistula. *J Vasc Surg* 2015; 61:802-8.

# Fistula Related Events

	Patients (%)	Treatment
<b>Anastomosis</b>		
Early thrombosis (< 30 days)	12 (11.7)	Decлот 9, abandoned 3
Late thrombosis	3 (3.9)	Decлот 2, abandoned 1
<b>Fistula</b>		
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
<b>Other</b>		
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

# Rapid Maturation



Robbin ML, Greene T, Cheung AK, et al. Arteriovenous Fistula Development in the First 6 Weeks after Creation. *Radiology* 2016; 279:620-9.