

FAV percutanée

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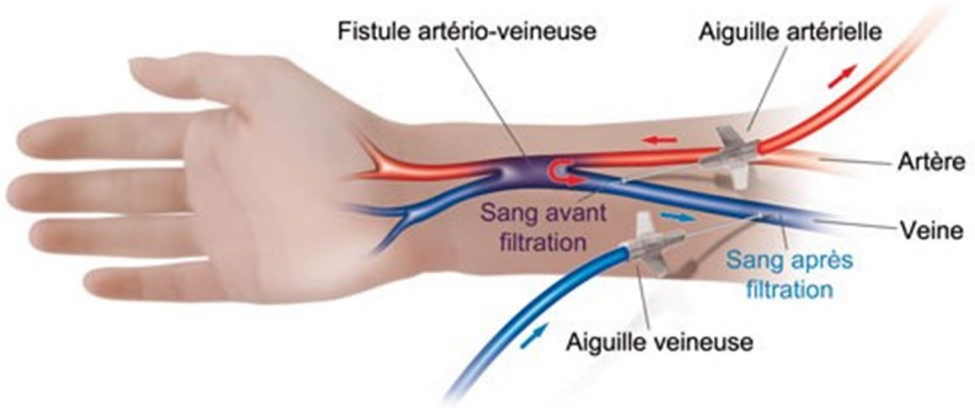
CHU – Hôpital François-Mitterrand – Dijon

AVF for hemodialysis access

- Goal: to obtain a superfical vein with sufficient flow in order to allow dialysis

- Surgical AVF
  → To connect a vein to a close artery (forearm or arm)
  → Part of the arterial flow diverted into the arterialized vein

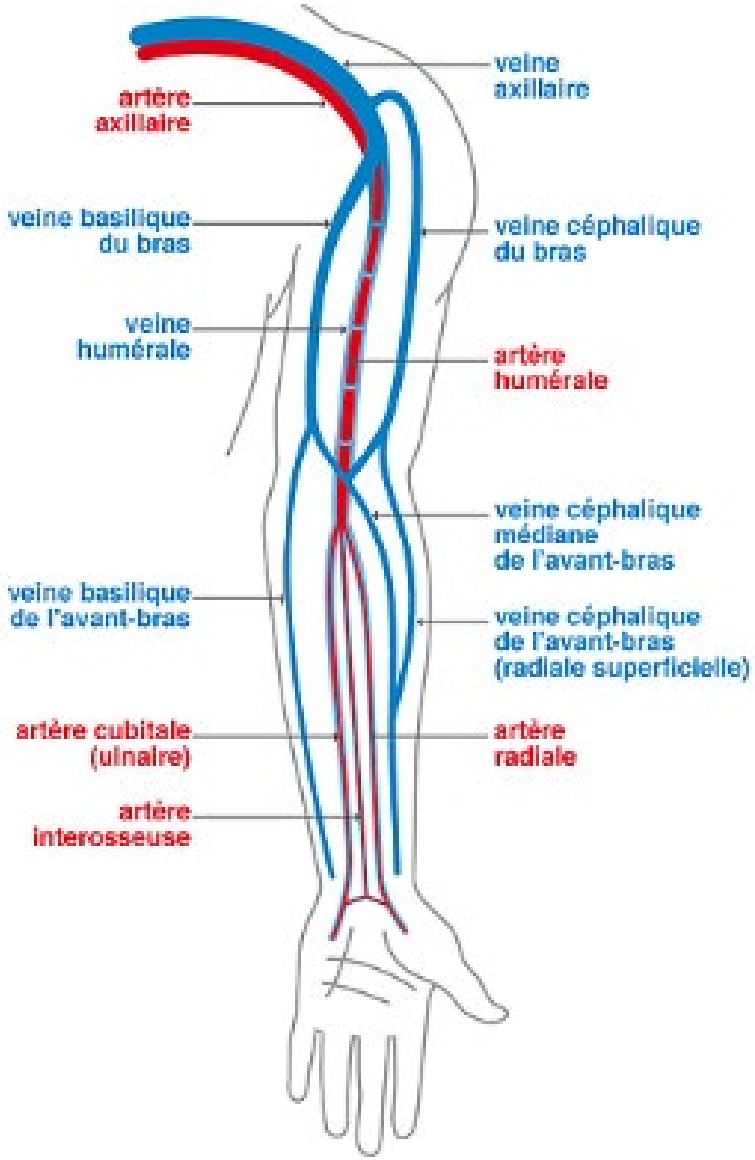
- Pressure increase + dilation → sufficient blood flow / facilitates puncture
  - *Flow at least 600 mL/min*
  - *Vein diameter at least 6 mm*
  - *Maximal depth 6 mm*



Rules and principles

- Distal radio-cephalic AVF
  - 1st choice +++
  - But impossible or at risk of lack of maturation in 30% of patients
    - Poor vascular condition, arterial calcifications, old patients, diabetic patients, polyvascular patients
- Humero-basilic ou humero-cephalic AVF
  - In 2 steps often times
  - Less good patency
  - Complications: steal syndrome, aneurysm
- Proximal radio-cephalic AVF ?

  → Creation with percutaneous technique



Pisoni RL et al. Am J Kidney Dis 2009
Rajan DK et al. J Vasc Interv Radiol 2015
Sidawy AN et al. J Vasc Surg 2002

WavelinQ™ 4 EndoFAV



Armboard



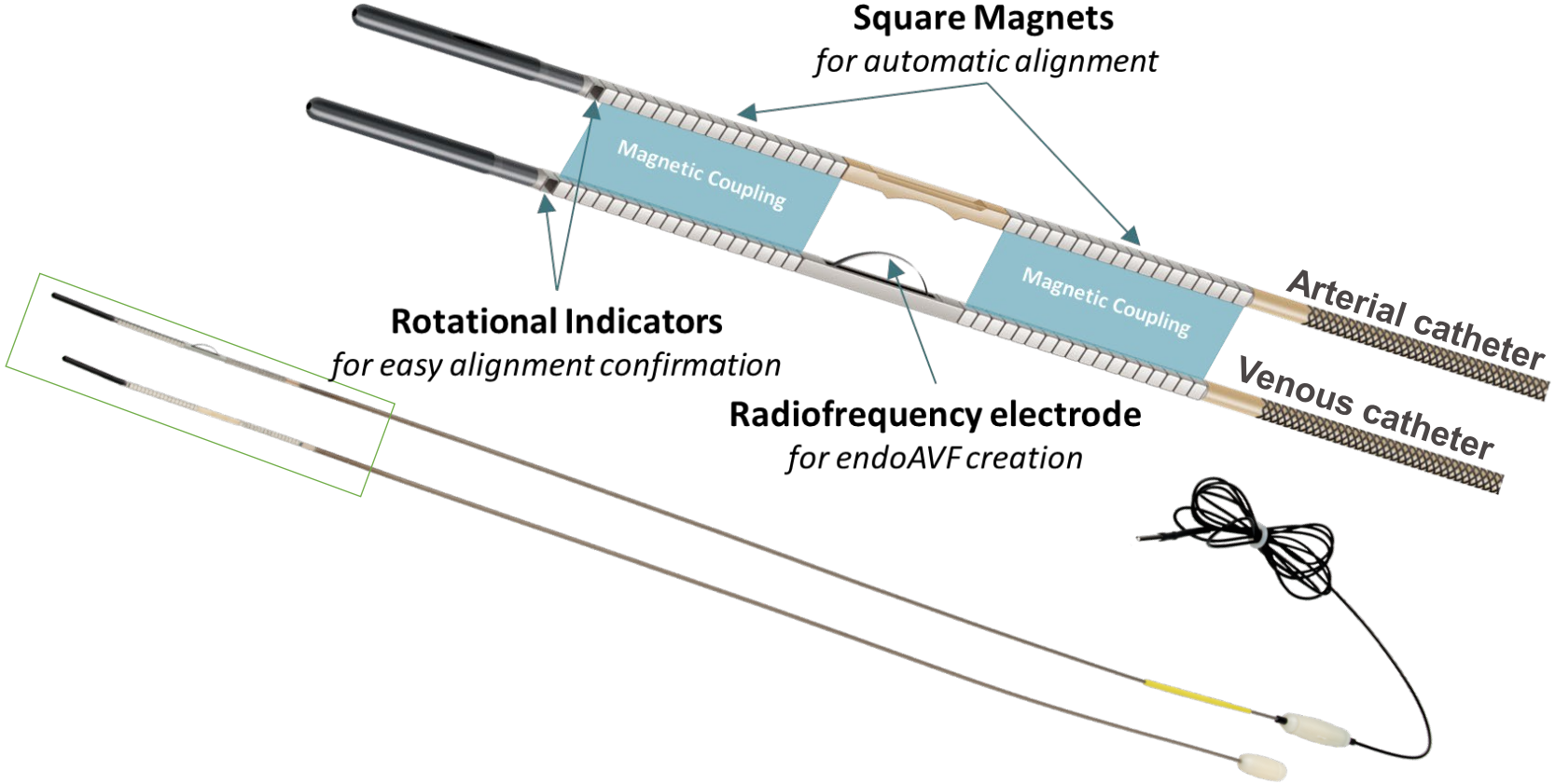
RF Generator

4 Fr Rapid Exchange Catheters
for vessel access and navigation

Square Magnets
for automatic alignment

Rotational Indicators
for easy alignment confirmation

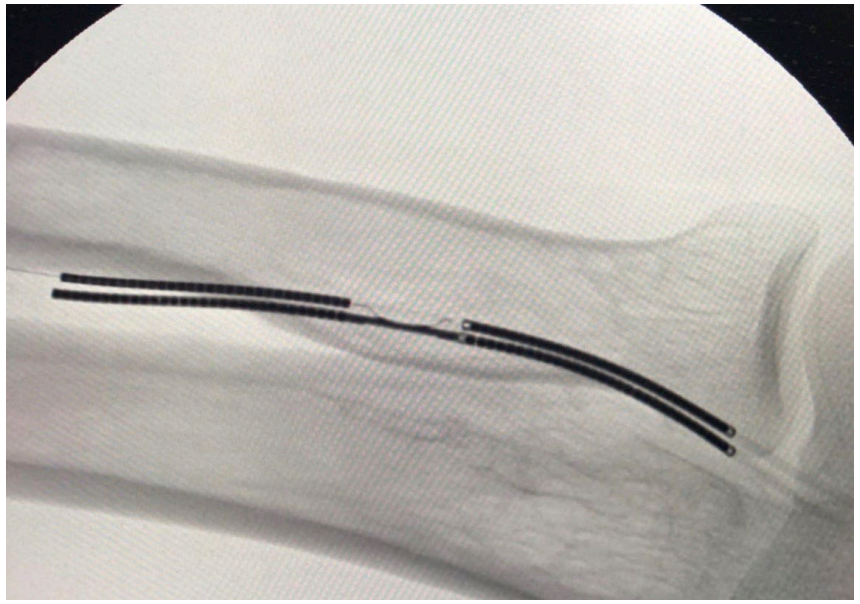
Radiofrequency electrode
for endoAVF creation

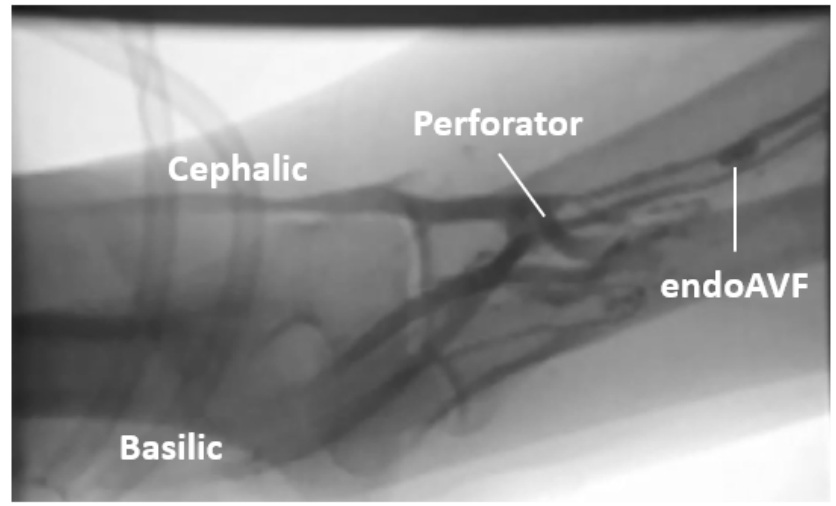


1. TVA Medical data on file. GLP Animal Studies.
2. Rajan et al. J Vasc Interv Radiol 2015; 26:484–490.
3. Yang et al. J Vasc Access 2017;28;18(Suppl. 2):8-14.
4. Lok et al. Am J Kidney Dis. 2017; 70(4): 486-497

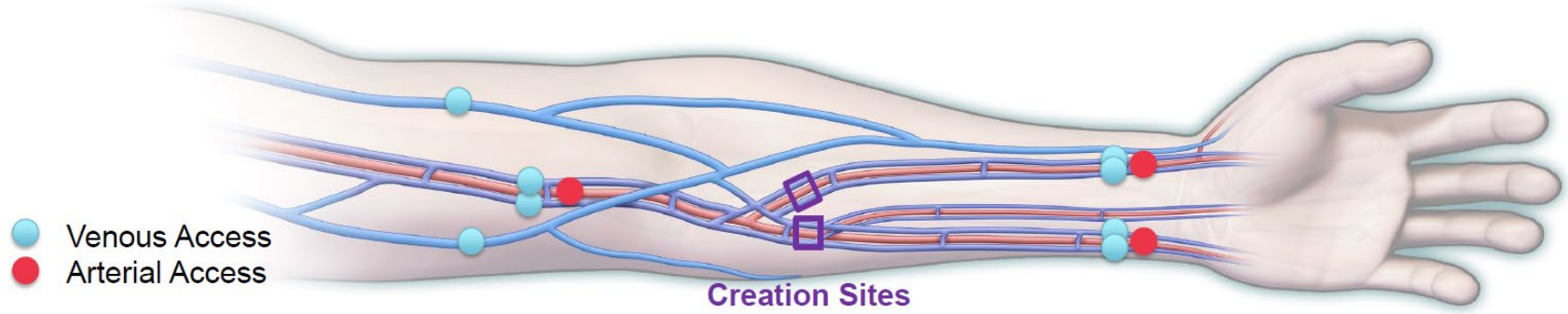
Alignment



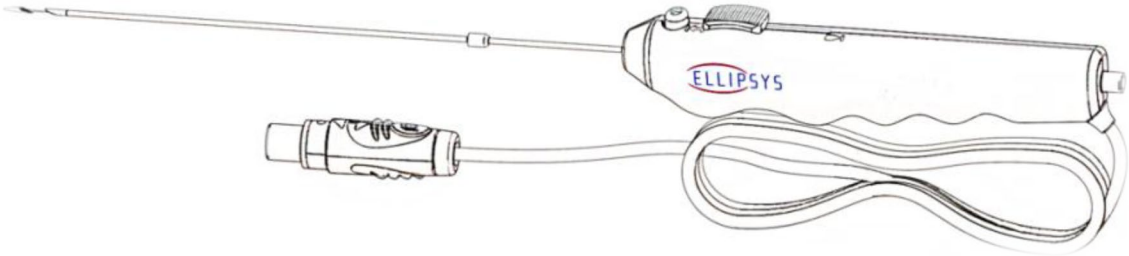



Perforator
Cephalic
endoAVF
Basilic



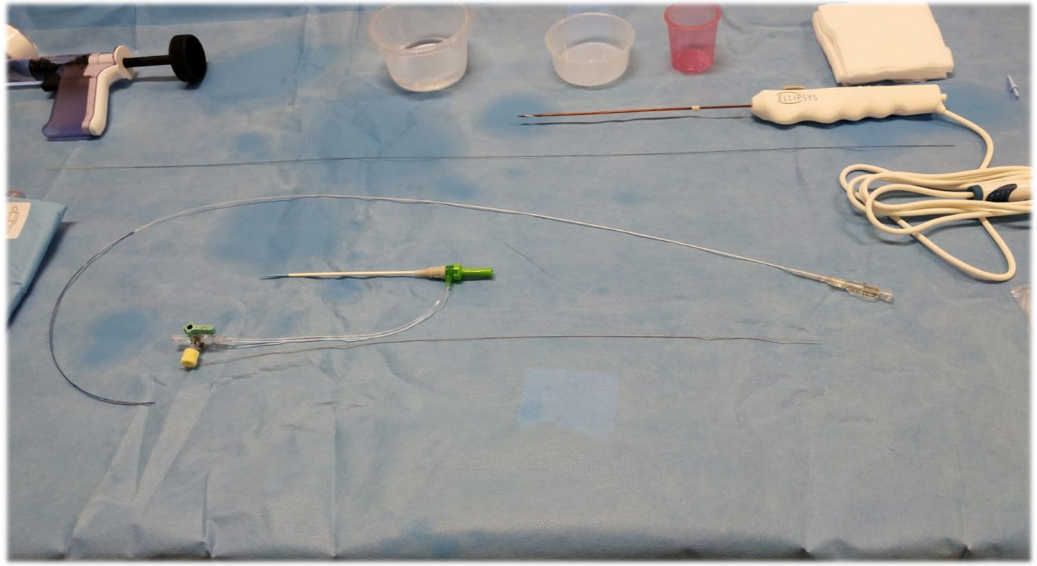

Venous Access
Arterial Access
Creation Sites





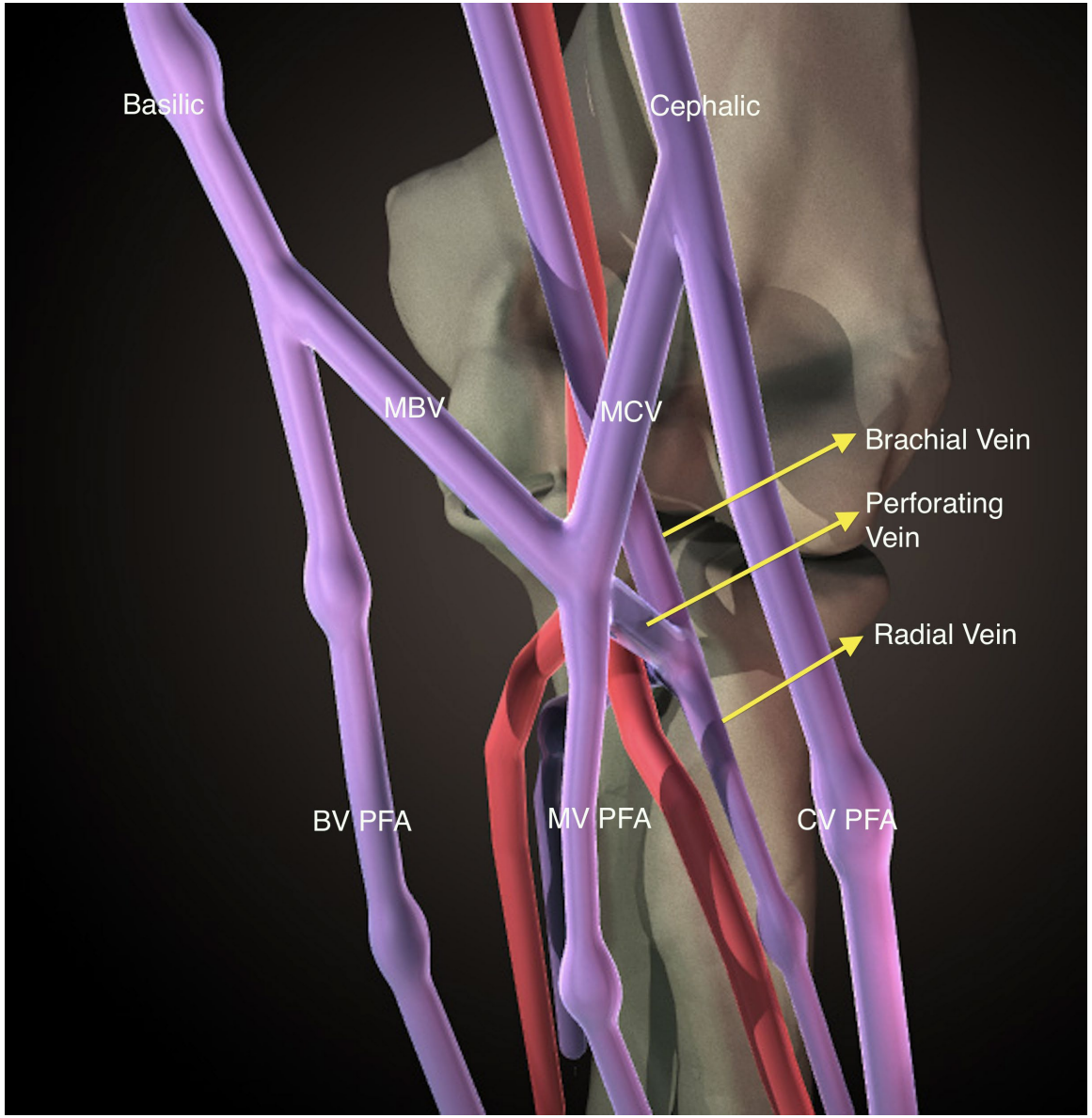
Thermal resistance anastomosis
Ellipsys vascular access system

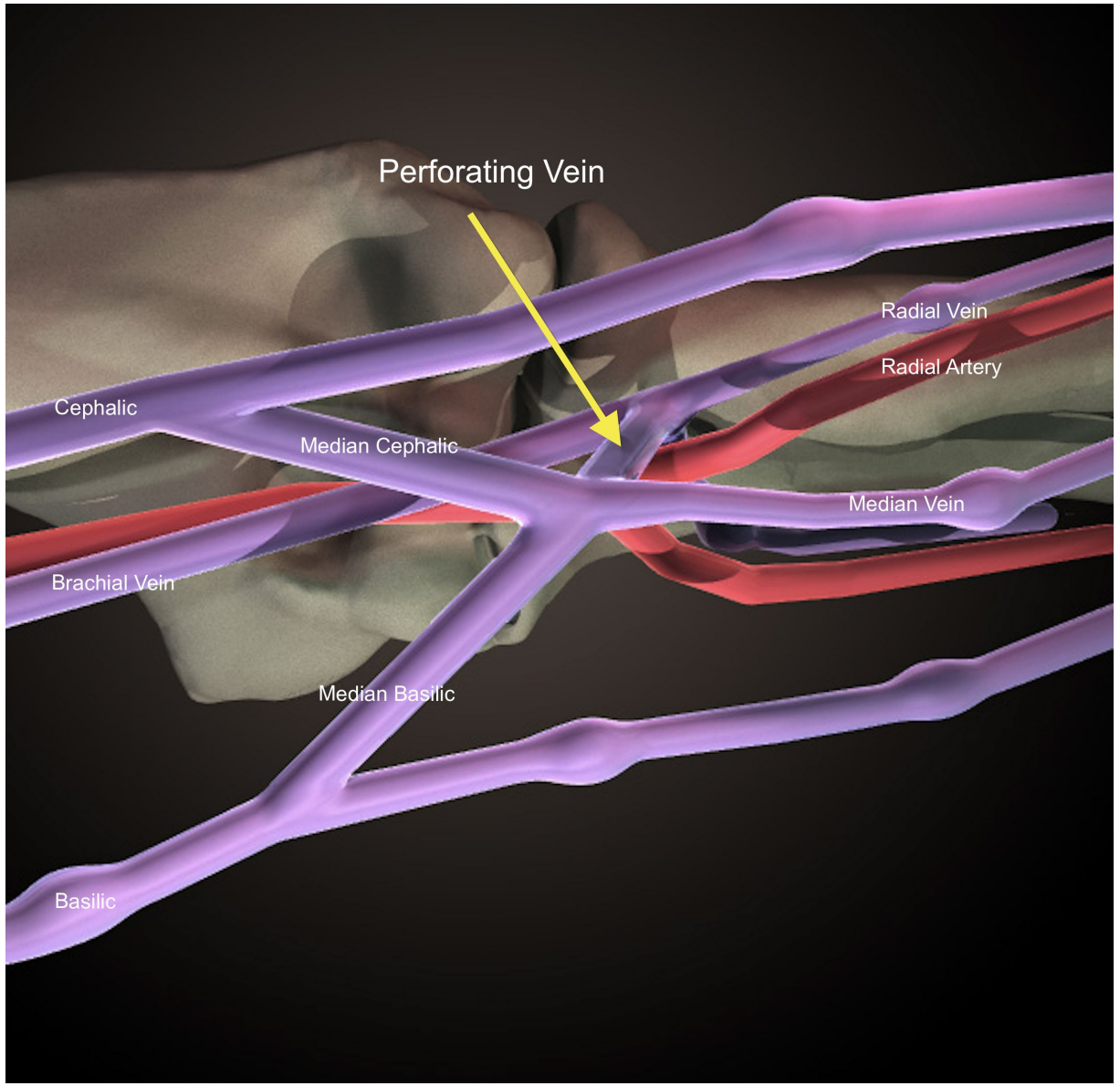




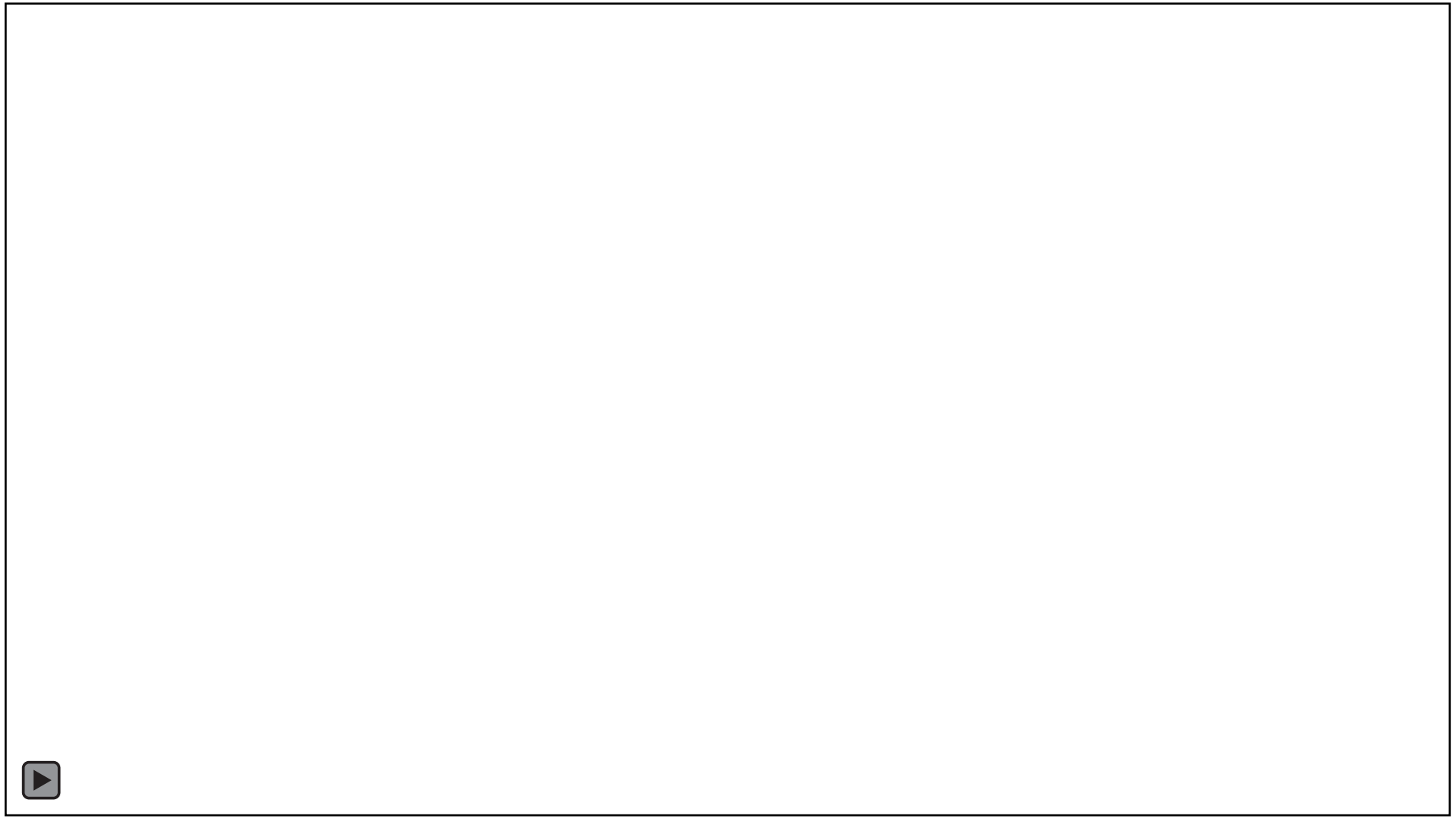


Anatomy

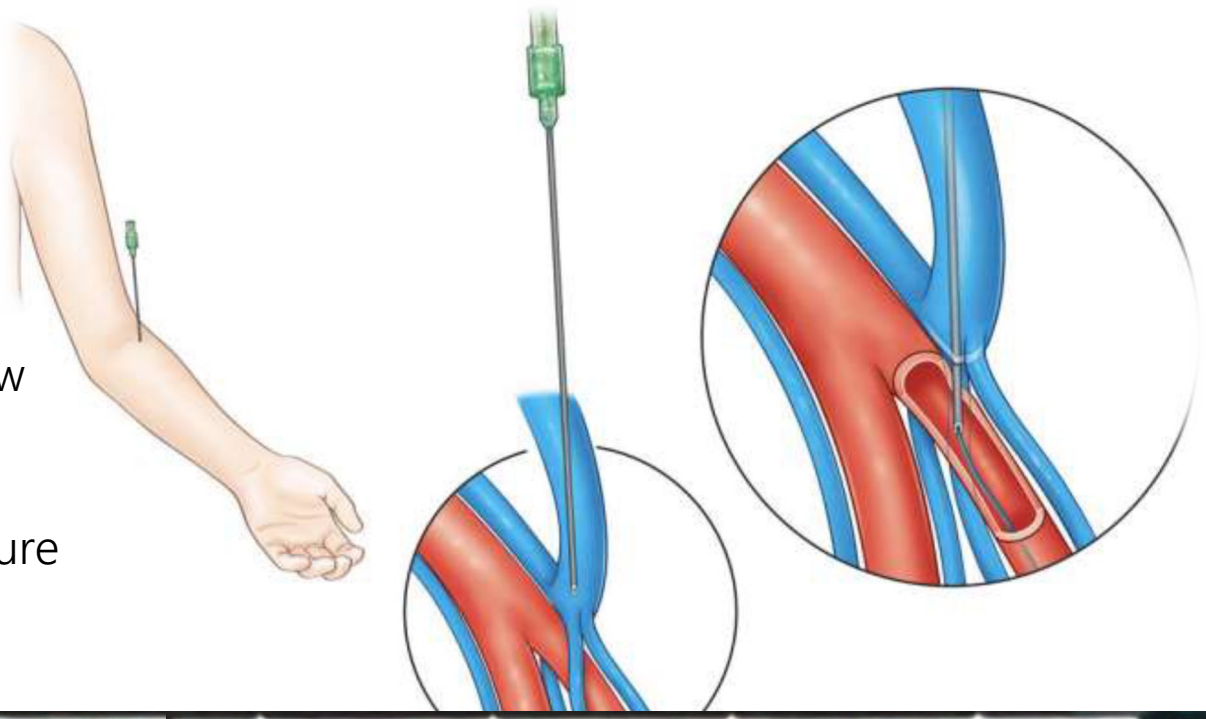

Basilic
Cephalic
MBV
MCV
Brachial Vein
Perforating Vein
Radial Vein
BV PFA
MV PFA
CV PFA

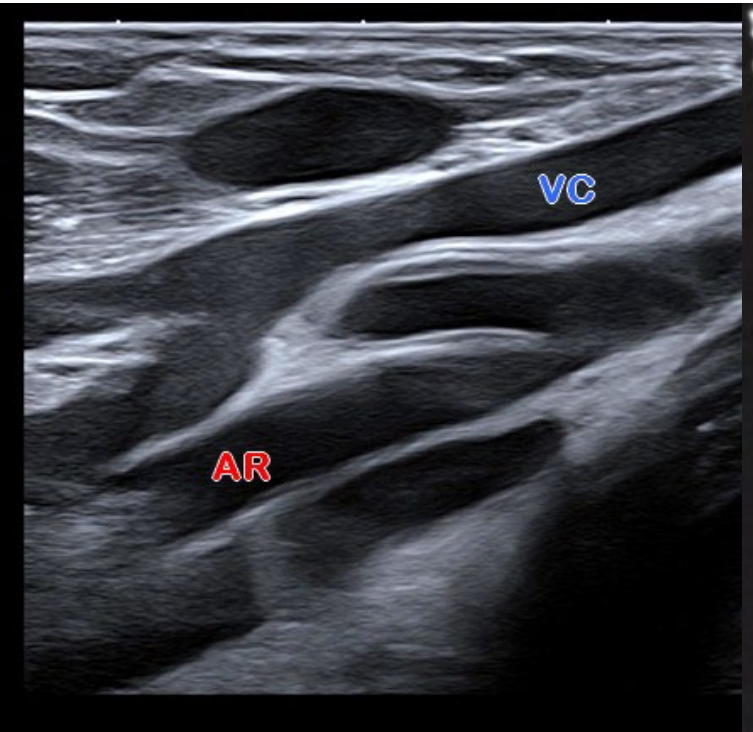

Perforating Vein
Radial Vein
Radial Artery
Cephalic
Median Cephalic
Median Vein
Brachial Vein
Median Basilic
Basilic

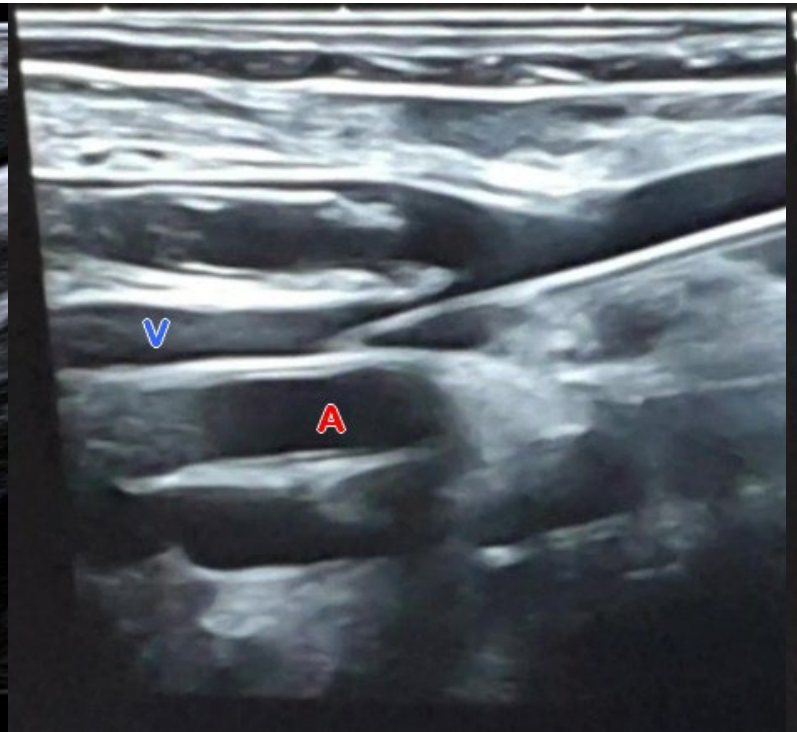
On video

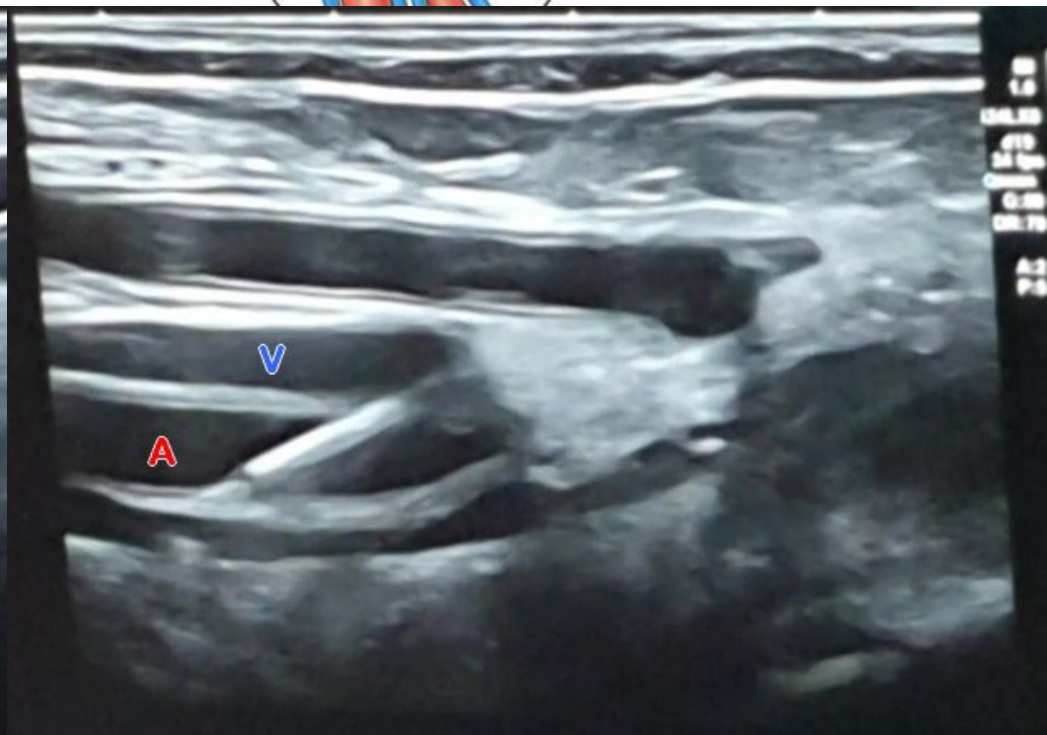


- Local anesthesia or axillary bloc (preferable)
  - Vasoplegia +++
- Puncture of the cephalic vein with a 20G needle at the elbow crease under US guidance
- Navigation into the MCV and perforating vein and puncture of the proximal radial artery

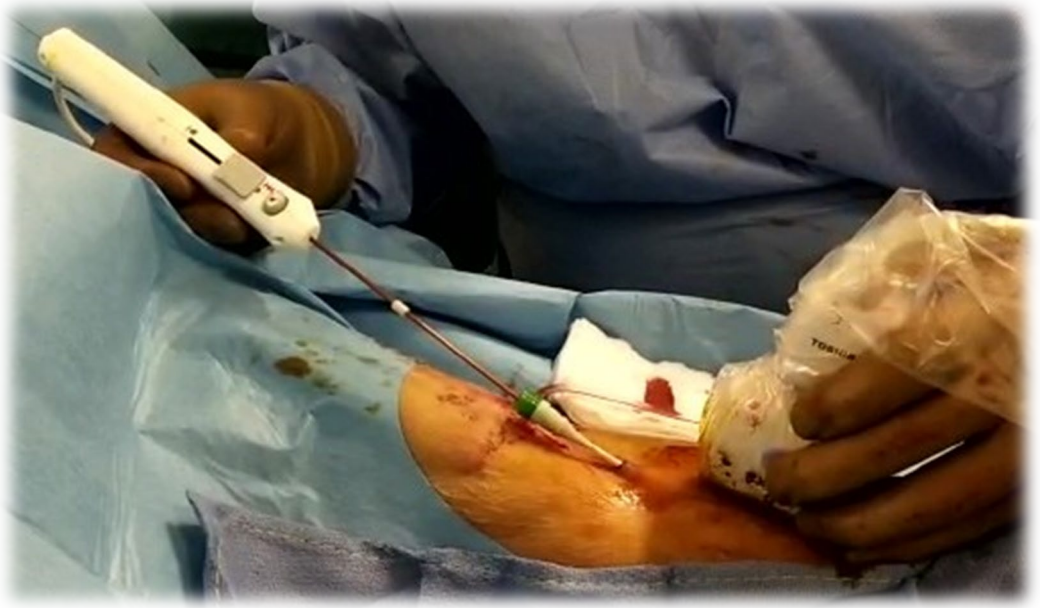




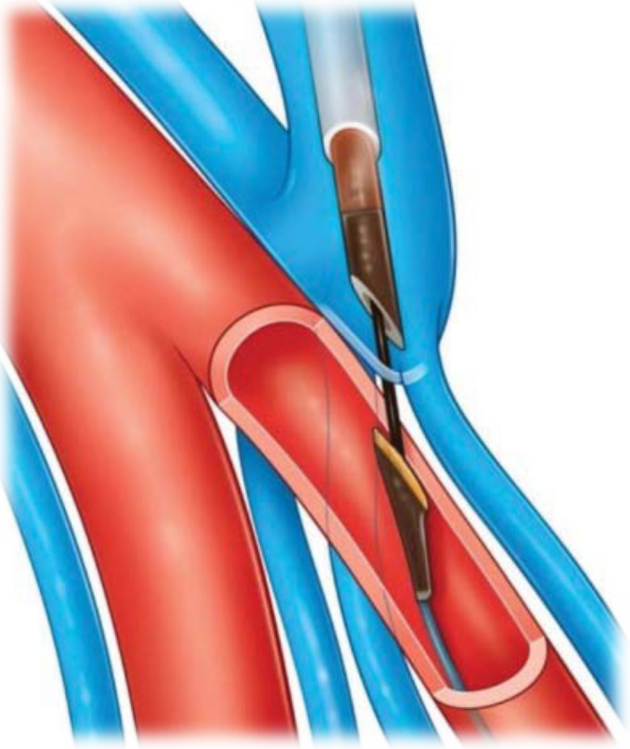


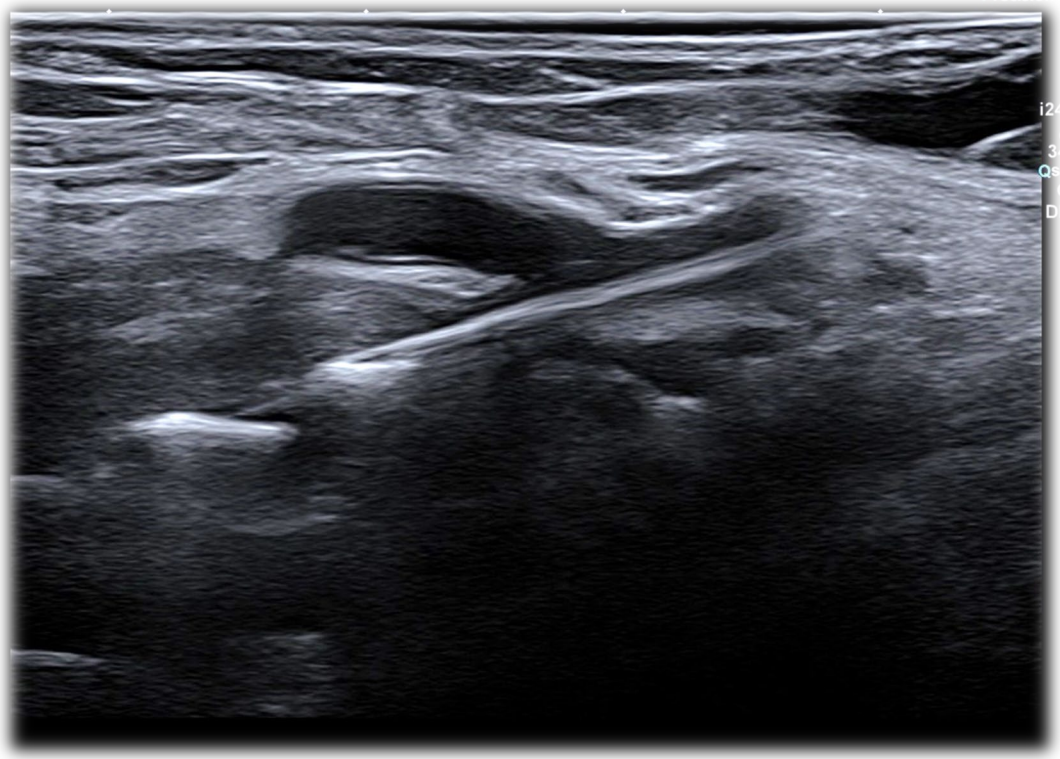


- Guidewire 0.014''
- Sheath 6-Fr
- Confection catheter inserted, hinged window in open position composed of 2 thermal components, deployed under US guidance
    - 1 arterial element and 1 venous element

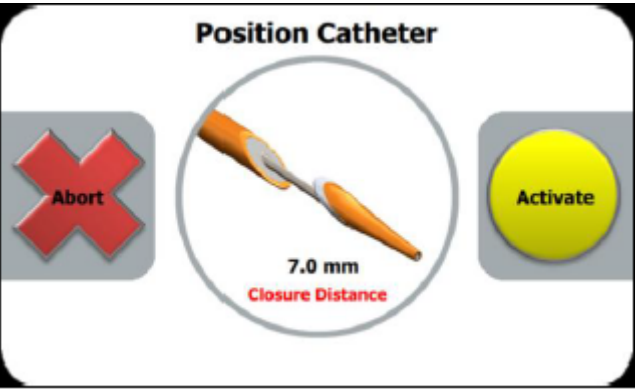


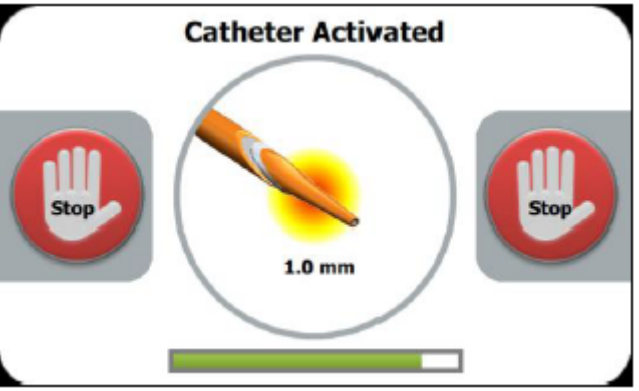






- The device is closed by bringing the arterial and venous walls together between the 2 components (< 1 mm)
  - → Thermal energy applied: cycle of several seconds
  - → Heat-sealed walls
  - → Anastomosis between artery and vein performed by thermofusion: AVF creation
  - → Jump to withdrawal





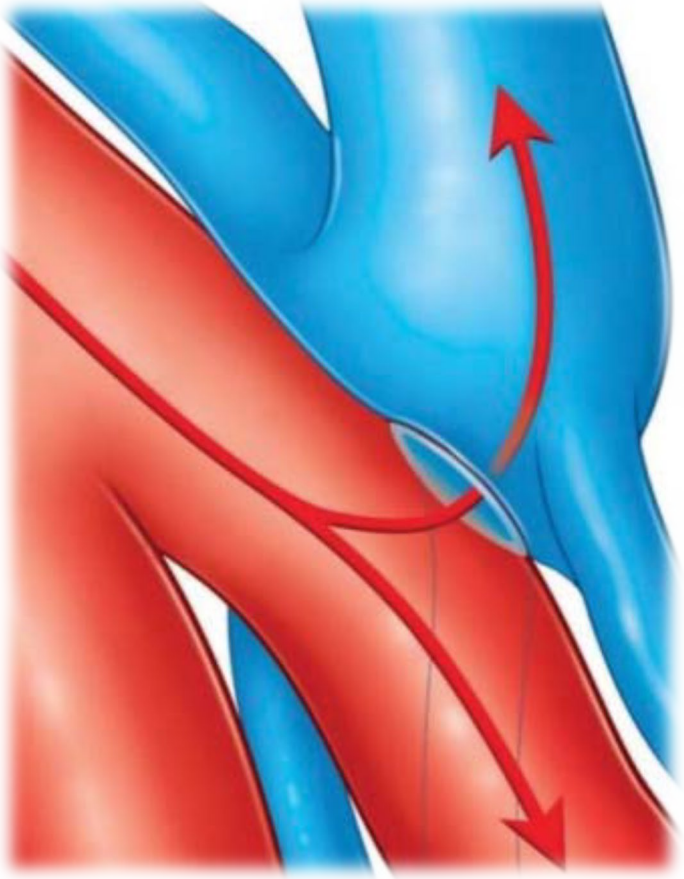


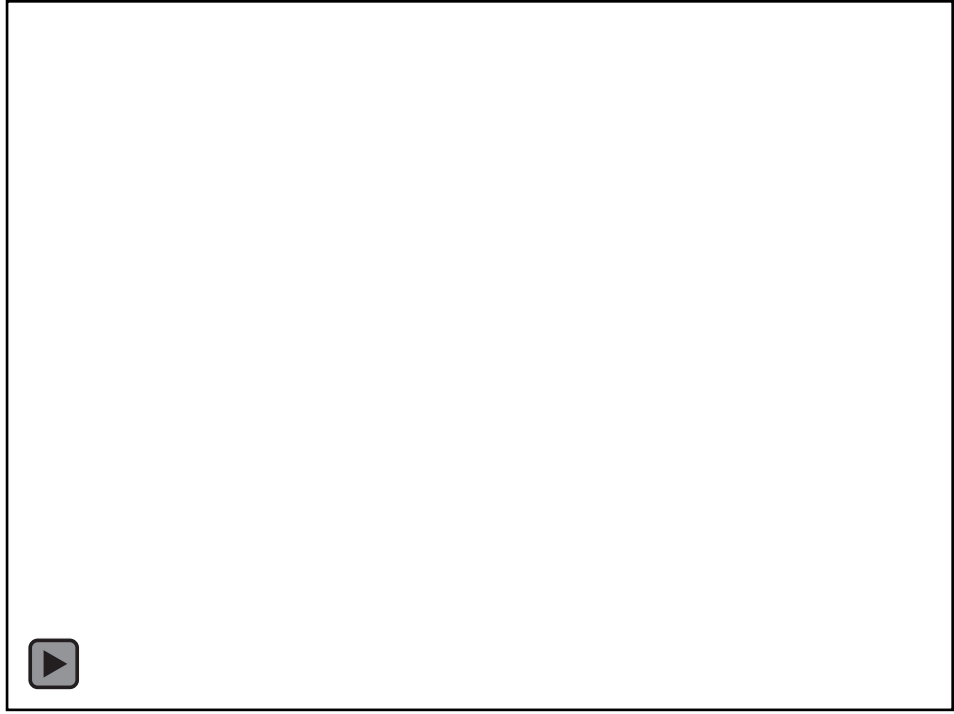
Technique modified by Dr Alexandros MALLIOS

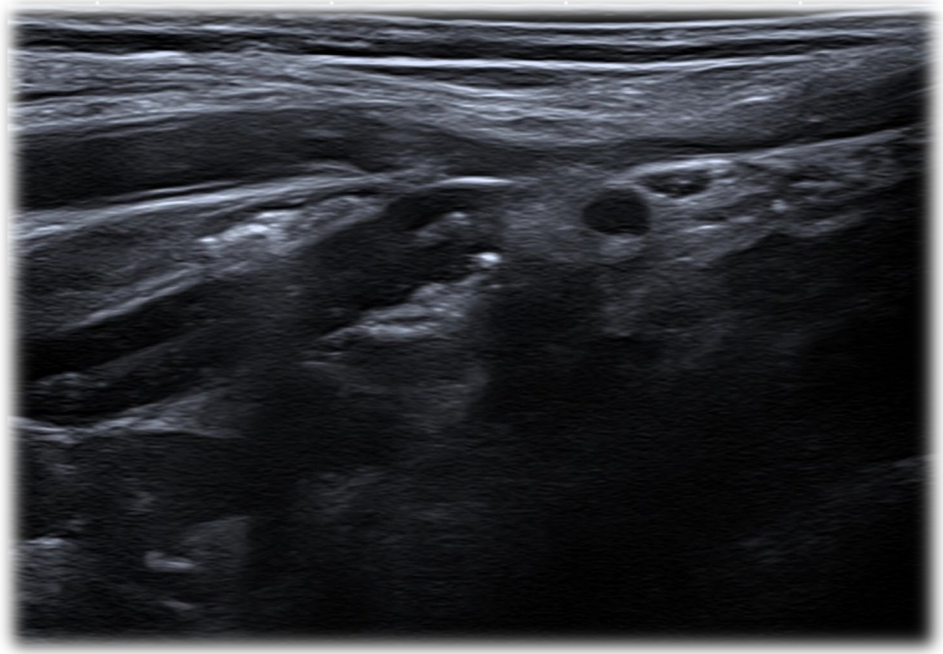
Balloon dilation: monorail 5 mm x 20 mm

→ Accelerated maturation of the FAV

→ Earlier use than with standard surgery

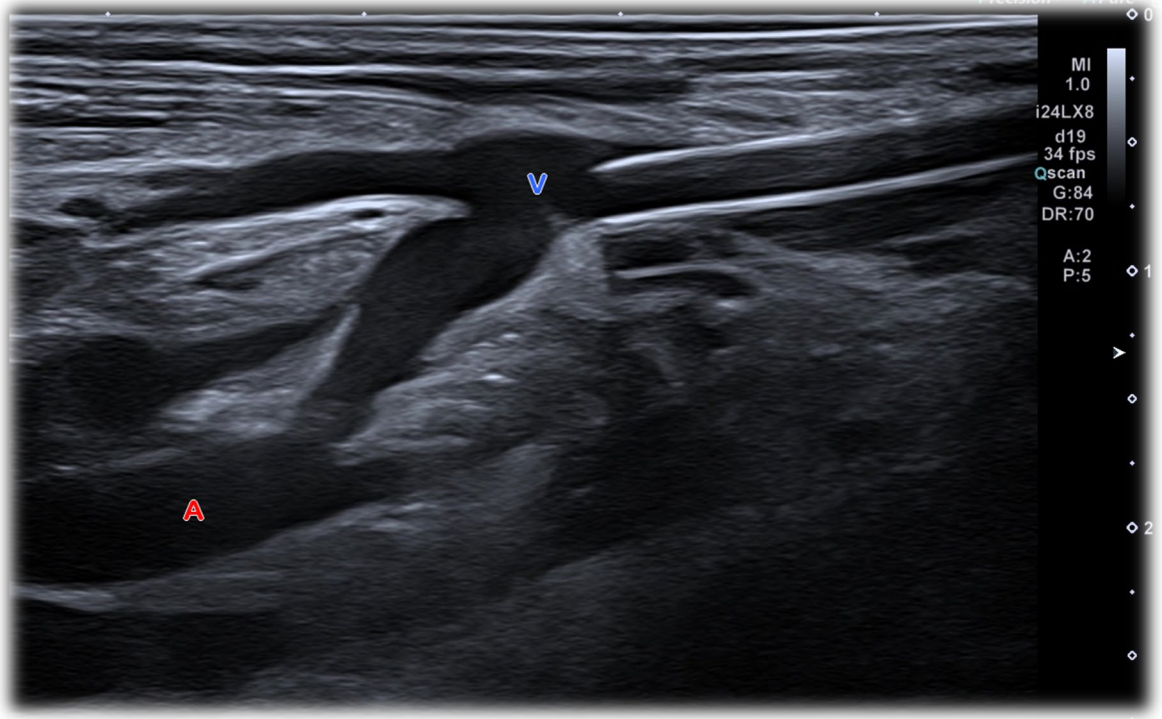


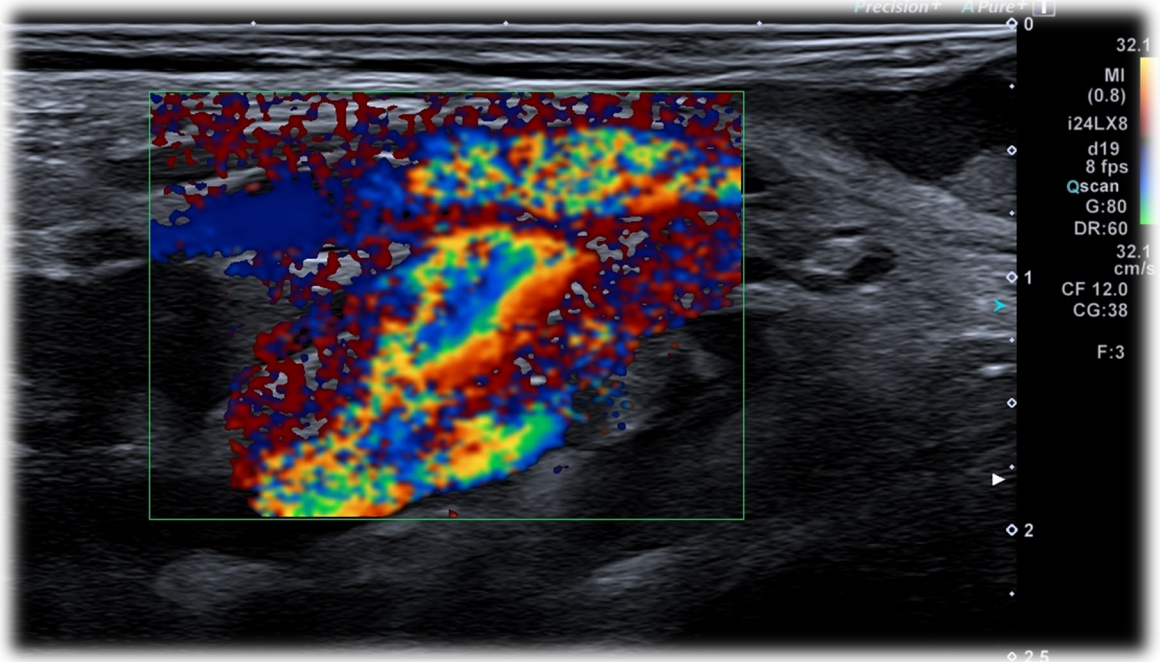




Final control







First series…

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

J Vasc Interv Radiol 2018; 29:149–158

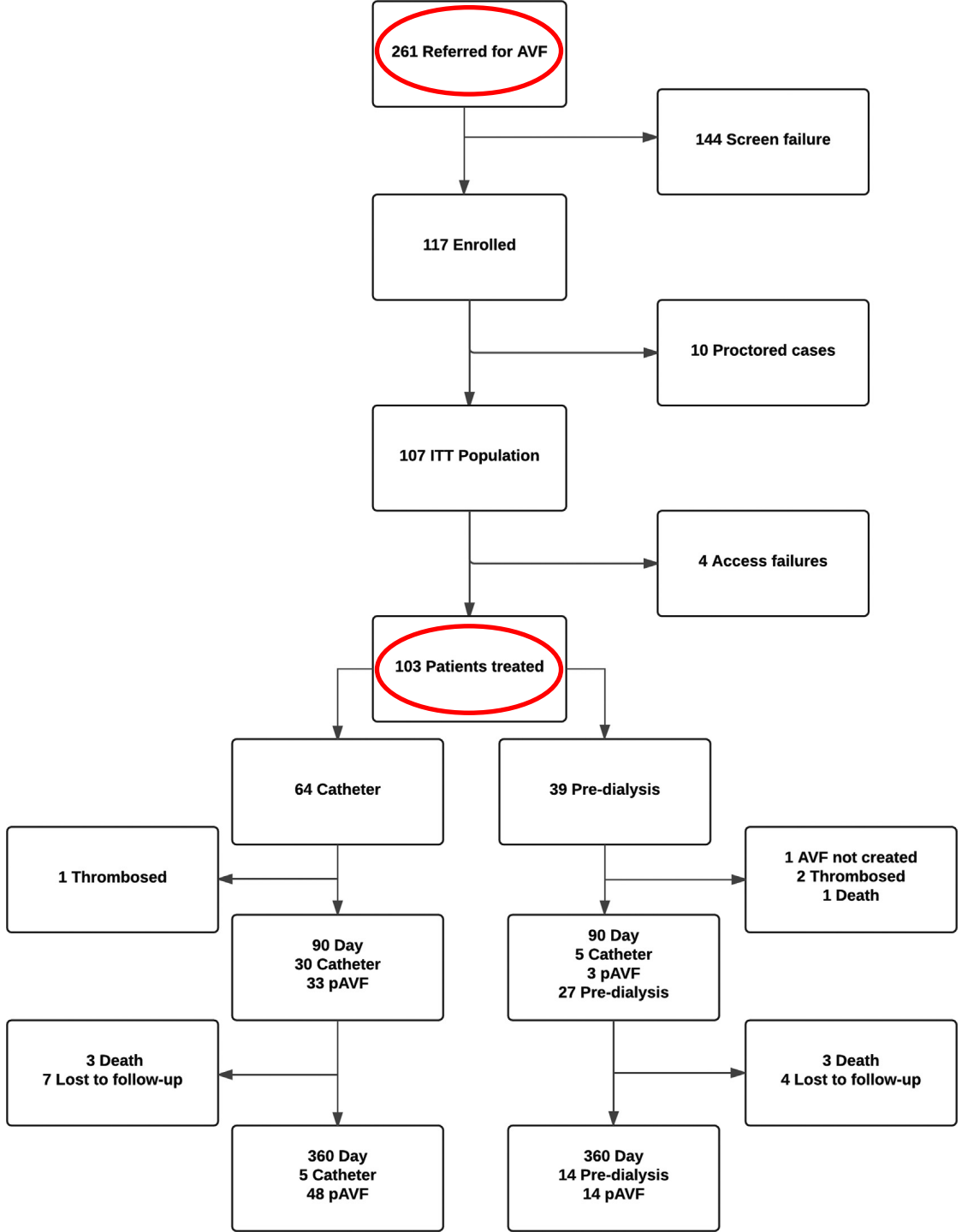


Table 3. Diameter and Flow

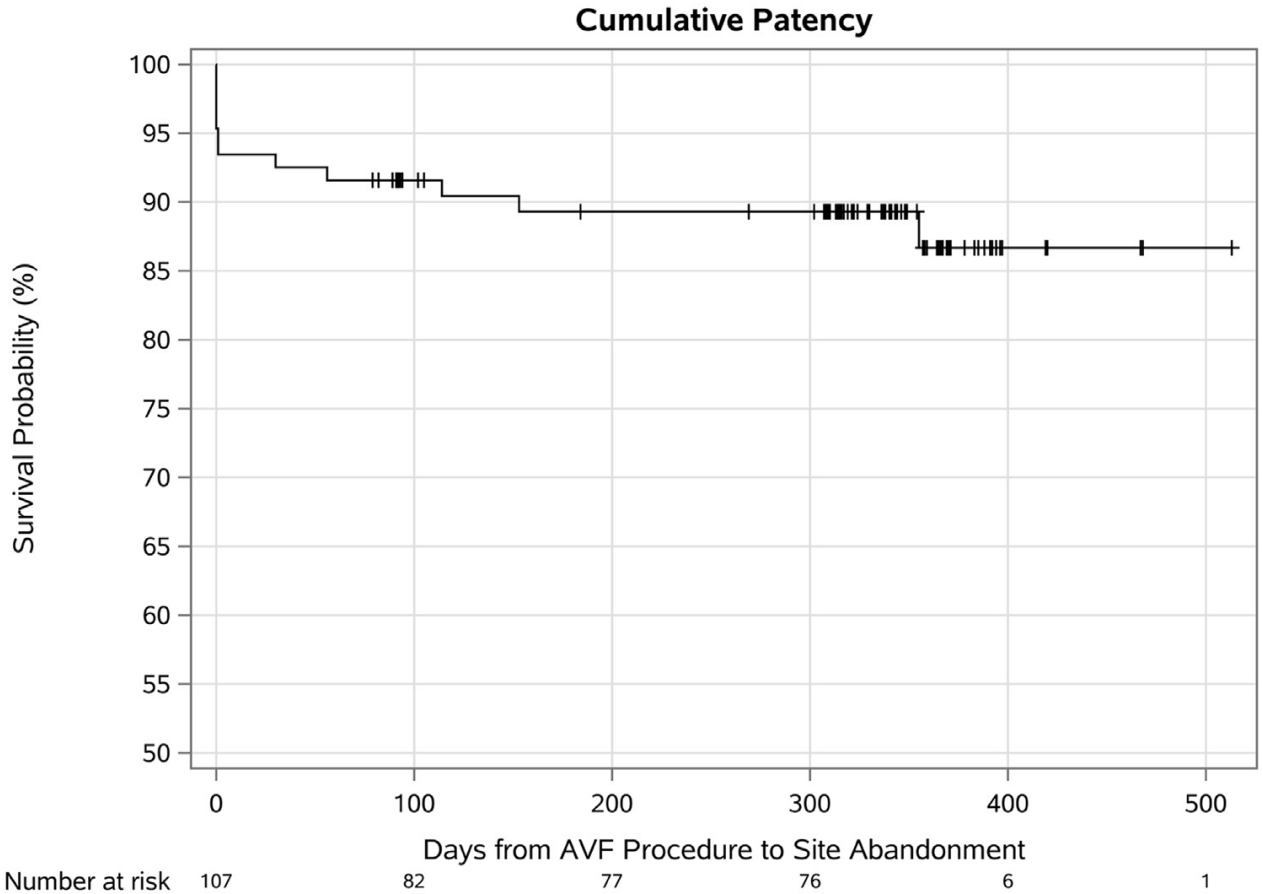
Measurement	Procedure	1 d	7 d	28 d	90 d	360 d
Number of patients	98	98	97	97	96	77
BA diameter, mm	5.0	5.0	5.1	5.2	5.5	5.9
Cephalic diameter, mm	4.4	4.6	4.8	5.4	6.6	8.5
Basilic diameter, mm	4.9	4.9	5.4	5.3	6.3	7.7
CSA, mm^2	2.9	3.0	3.5	4.8	6.2	8.8
BA flow, mL/min	330.4	335.1	422.7	606.0	931.5	1,089.7
Cephalic vein flow*, mL/min	123.9	150.3	174.1	366.7	631.9	891.8
Basilic vein flow*, mL/min	182.4	187.1	262.7	345.4	860.8	1,084.8

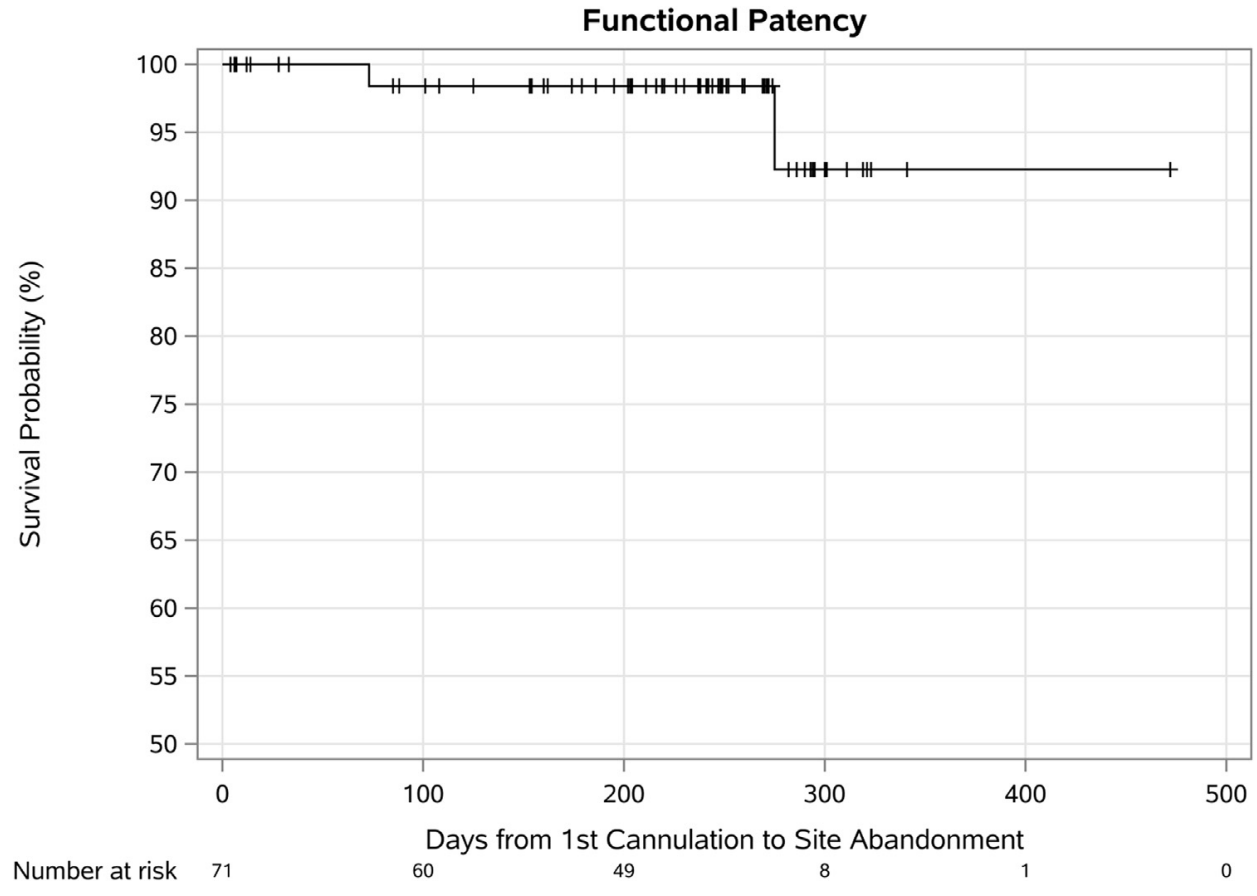
Table 4. Secondary Procedures

	Patients	Procedures	Days*
Total maturation	99	205	35.1 ± 35.0 (0–203)
PTA anastomosis	77	113	22.8 ± 21.2 (0–100)
Embolization deep	34	42	26.2 ± 21.9 (1–100)
Embolization branch	37	40	23.3 ± 16.9 (1–82)
Cubital	33	34	43.9 ± 46.3 (1–203)
Transposition	28	28	91.3 ± 45.4 (40–203)
Total maintenance	36	66	176.8 ± 97.6 (44–371)
PTA	28	51	182.6 ± 97.9 (44–369)
Embolization	10	10	97.0 ± 32.7 (50–154)
Stent	7	8	174.9 ± 111.5 (49–363)

Table 5. Fistula Complications

Complication	Number (%)*	Treatment
Anastomosis related		
Early thrombosis (< 30 d)	12 (11.7)	Declot 9, abandoned 3
Late thrombosis	3 (3.9)	Declot 2, abandoned 1
Anastomosis stenosis	22 (21.4)	Balloon dilation
Fistula related		
Fistula stenosis	16 (15.5)	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


Cumulative Patency
Survival Probability (%)
100
95
90
85
80
75
70
65
60
55
50
0
100
200
300
400
500
Days from AVF Procedure to Site Abandonment
Number at risk
107
82
77
76
6
1


Functional Patency
Survival Probability (%)
100
95
90
85
80
75
70
65
60
55
50
0
100
200
300
400
500
Days from 1st Cannulation to Site Abandonment
Number at risk
71
60
49
8
1
0

Our experience

- Retrospective study
- All patients who underwent US-guided anastomosis creation between the proximal radial artery and perforating vein in the proximal forearm
- With the Ellipsys® Vascular Access System (Medtronic)
- Between 2019 and 2023
- Percutaneous AVF was attempted ambulatory in 25 patients (16 men; mean age, 65.1±10.7 years; range, 49-85)
- Under locoregional anesthesia

Patient characteristics

Patient No.	Sex	Age, years	Ethnicity	Diabetes	Obesity*	Previous AVF	Catheter dialysis**
1	F	72	Caucasian	No	No	No	No
2	F	73	Caucasian	Yes	No	No	No
3	M	83	Caucasian	Yes	No	No	No
4	M	61	Caucasian	Yes	No	No	No
5	M	85	Caucasian	Yes	No	No	No
6	M	62	Caucasian	No	No	No	No
7	F	49	Arabic	No	No	No	No
8	M	63	Caucasian	Yes	No	No	No
9	M	76	Caucasian	No	No	No	No
10	M	64	Caucasian	No	No	No	No
11	M	72	Caucasian	No	No	No	No
12	F	54	Caucasian	Yes	Yes	No	No
13	M	61	Caucasian	No	No	No	No
14	F	77	Caucasian	Yes	Yes	No	Yes
15	M	57	Caucasian	No	No	No	Yes
16	F	52	African	Yes	Yes	No	No
17	M	81	Caucasian	No	No	No	No
18	M	70	Caucasian	No	No	No	Yes
19	M	55	Arabic	No	No	No	No
20	F	62	Caucasian	No	No	No	Yes
21	M	58	Caucasian	No	No	No	No
22	M	71	Caucasian	No	No	Yes	No
23	M	49	African	No	Yes	No	No
24	F	56	Caucasian	No	No	No	No
25	F	64	Caucasian	No	No	No	No

Procedural data

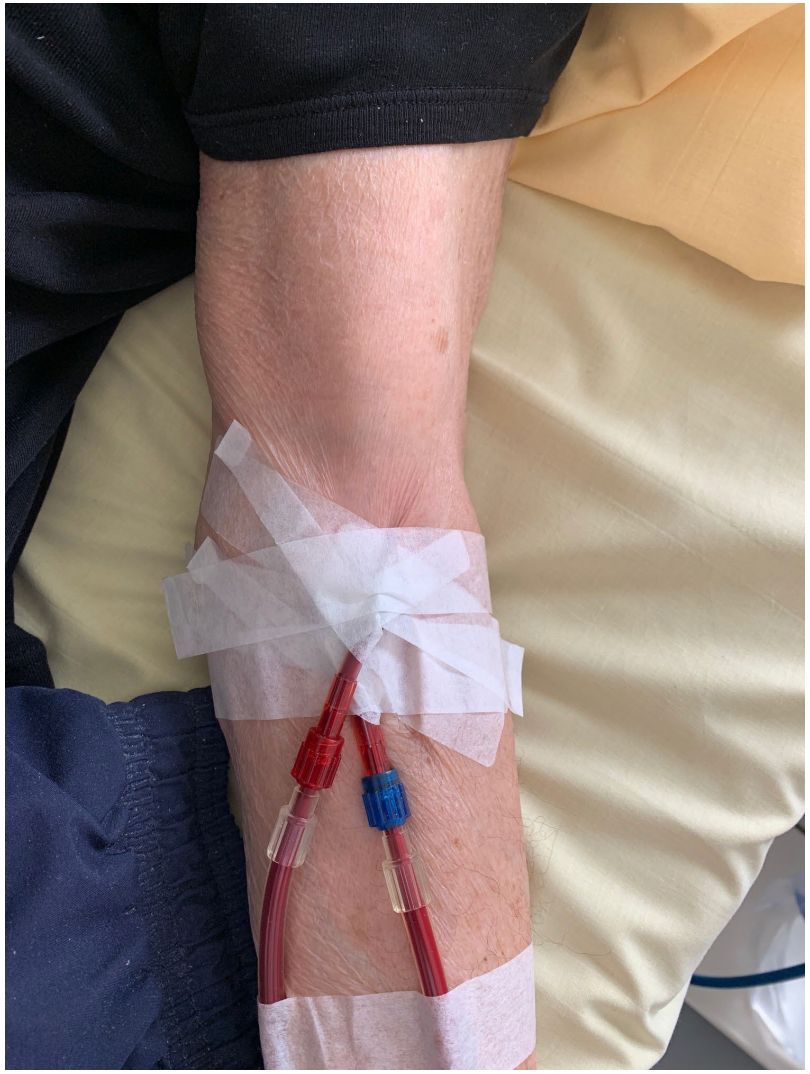
Patient No.	Localization of pAVF	Type of anesthesia	Use of contrast	Use of X-rays	Additional perprocedural action*
1	Right	Local	No	No	Anastomosis PTA + basilic vein ligation
2	Right	Local	No	No	Anastomosis PTA
3	Left	Local	No	No	Anastomosis PTA
4	Left	Regional	No	No	Anastomosis PTA
5	Left	Regional	No	No	Anastomosis PTA
6	Left	Regional	No	No	Anastomosis PTA
7	Left	Regional	No	No	Anastomosis PTA
8	Left	Regional	No	No	Anastomosis PTA
9	Left	Regional	No	No	Anastomosis PTA
10	Right	Regional	No	No	Anastomosis PTA
11	Left	Regional	No	No	Anastomosis PTA
12	Left	Regional	No	No	Anastomosis PTA
13	Left	Regional	No	No	Anastomosis PTA
14	Left	Regional	No	No	Anastomosis PTA
15	Left	Regional	No	No	Anastomosis PTA
16	Left	Regional	No	No	Anastomosis PTA
17	Right	Regional	No	No	Anastomosis PTA
18	Left	Regional	No	No	Anastomosis PTA
19	Left	Regional	No	No	Anastomosis PTA
20	Left	Regional	No	No	Anastomosis PTA
21	Left	Regional	No	No	Anastomosis PTA
22	Right	Regional	No	No	Anastomosis PTA
23	Left	Regional	No	No	Anastomosis PTA
24	Left	Regional	No	No	Anastomosis PTA
25	Left	Regional	No	No	Anastomosis PTA

Safety and short-term outcomes per patient

Patient No.	Technical success	Patency at follow-up	pAVF blood flow at 1 month*	pAVF blood flow at follow-up*	Follow-up, months	Reintervention at follow-up
1	Yes	Yes	580	940	56	Anastomosis PTA at 2.5 and 20 mo
2	Yes	Yes	560	700	53	No
3	Yes	Yes	490	1200	53	AnastomosisPTA/stenting + basilic vein embolization at 2.5 mo
4	Yes	Thrombosis	510	900	50	Surgical AVF° at 8 mo
5	Yes	Yes	650	1000	50	No
6	Yes	Yes	420	920	49	No
7	Yes	Yes	700	850	47	No but renal transplantation at 7 mo
8	Yes	Immature	210	220	47	Surgical AVF° at 4 mo
9	Yes	Immature	200	230	47	Surgical AVF° at 5 mo
10	Yes	Yes	500	830	43	No
11	Yes	Yes	580	750	40	No
12	Yes	Yes	810	1200	40	No
13	Yes	Yes	500	650	39	No
14	Yes	Yes	480	640	39	No
15	Yes	Yes	750	900	37	No
16	Yes	Yes	590	1100	37	No
17	Yes	Yes	460	880	37	No
18	Yes	Yes	780	880	35	No
19	Yes	Yes	810	910	34	No
20	Yes	Yes	670	750	30	No
21	Yes	Yes	550	800	29	No
22	Yes	Yes	490	800	28	Anastomosis PTA at 6 mo and superficialization
23	Yes	Yes	540	910	26	No
24	Yes	Yes	610	730	25	No
25	Yes	Yes	480	960	24	No

Overall outcomes in the study population

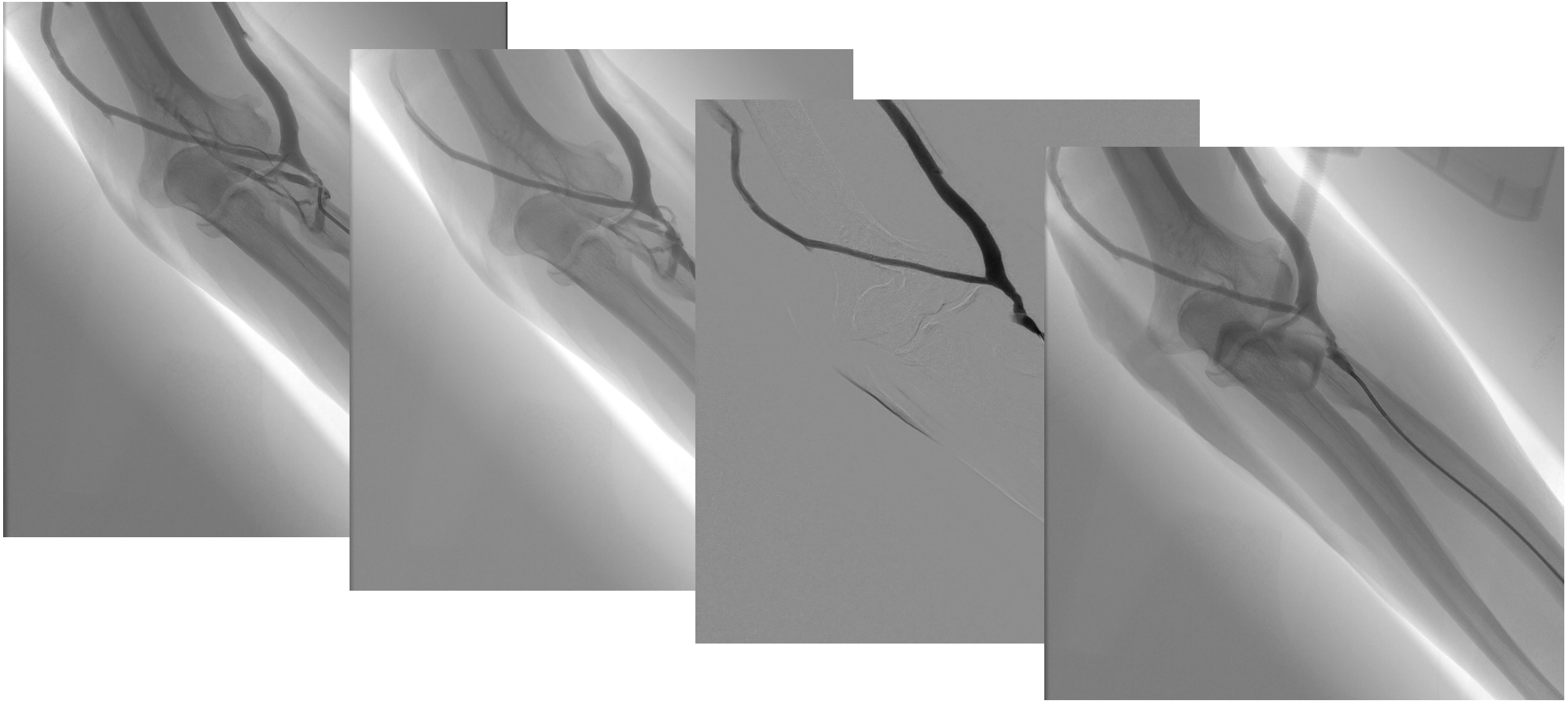
Variable	No. (% or range)
Technical success	25/25 (100)
Cumulative patency at mean follow-up	24/25 (96)
Average blood flow at mean follow-up (mL/min)	826 (220-1200)
Mean follow-up (months)	19.8 (4-36)
Reintervention during follow-up	6/25 (24)
Anastomosis PTA	2/25 (8)
Anastomosis PTA/stenting + basilic vein embolization	1/25 (4)
Surgical AVF confection	3/25 (12)
Outpatient procedure	25/25 (100)
Readmission within 30 days of pAVF	0/25 (0)
Adverse events within 30 days	0/25 (0)
Hematoma	0/25 (0)
Vessel dissection	0/25 (0)
Nerve damage	0/25 (0)
Infection	0/25 (0)
Thrombosis	0/25 (0)
Ischemia	0/25 (0)
Complications at mean follow-up	
Anastomosis related	6/25 (24)
Fistula related	0/25 (0)
Mean cannulation time (weeks)	5.9 (4-12)
Type of pAVF cannulation	
Normal	22/25 (88)
“Y”	3/25 (12)
One-month mortality rate	0/25 (0)
Overall survival at mean follow-up	23/25 (92)

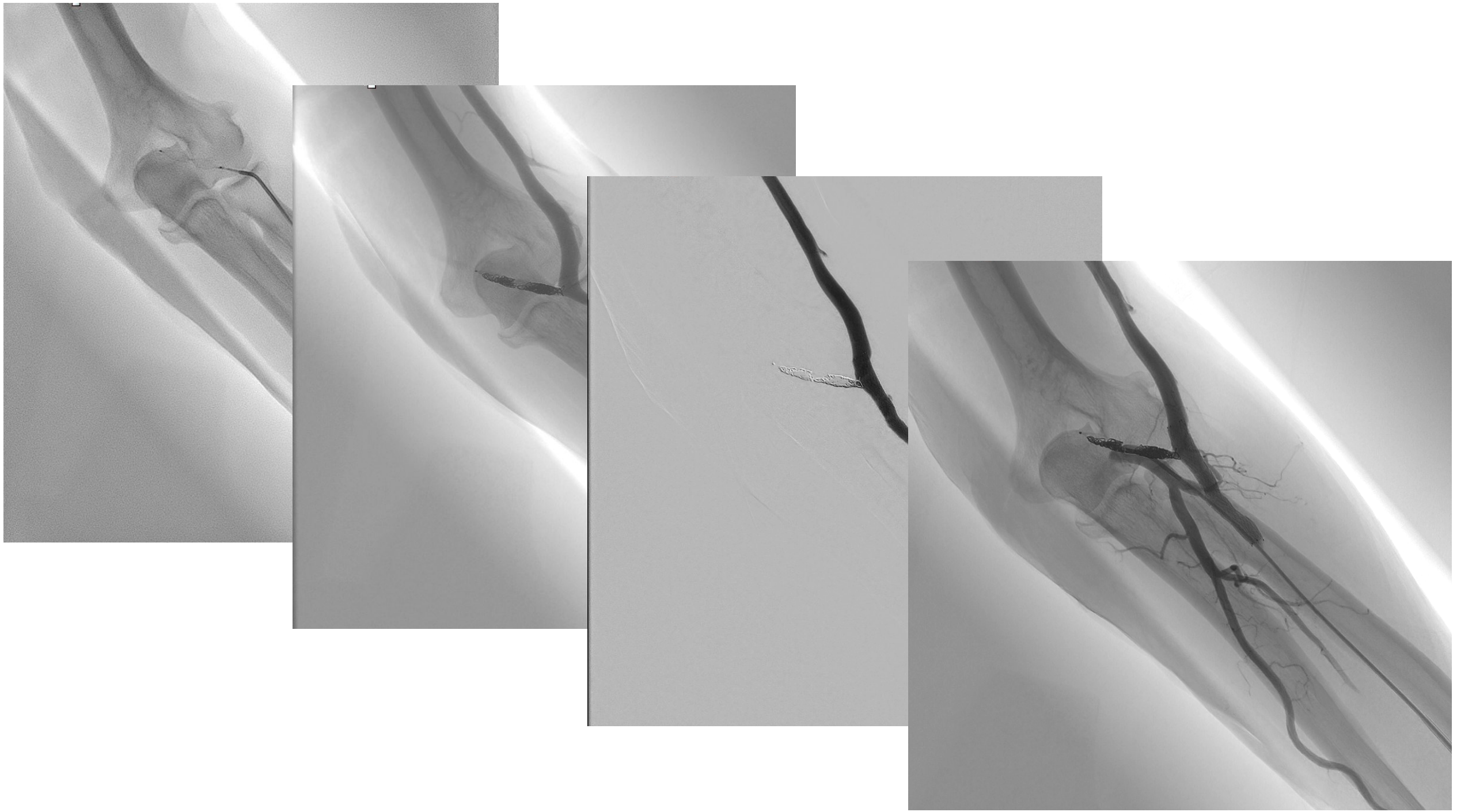






Mr R…82 yo





Largest series (Mallios et al. *J Vasc Surg 2020*)



- May 2017 – April 2019: 205 patients
- 99% technical success
- Mean follow-up 11 months (1-24 months)
- 65% primary patency
- 88% primary assisted patency
- 97% secondary patency

Midterm results of percutaneous arteriovenous fistula creation with the Ellipsys Vascular Access System, technical recommendations, and an algorithm for maintenance

Alexandros Mallios, MD,[a] Pierre Bourquelot, MD,[b] Gilbert Franco, MD,[c] Hadia Hebibi, MD,[d] Hortence Fonkoua, MD,[a] Mahmoud Allouache, MD,[a] Alessandro Costanzo, MD,[a] Romain de Blic, MD,[a] Ghazi Harika, MD,[a] Benoit Boura, MD,[a] *and* William C. Jennings, MD,[e] *Paris and Villejuif, France; and Tulsa, Okla*

- No serious adverse events
- Mean access flow: 874ml/min (brachial artery/range: 412-1254)
- No steal syndrome
- 7% superficialization (14 patients)
- Average maturation time: 4.3 weeks
- 10% - early cannulation (<2 weeks)

Conclusion



Percutaneous AVF creation with the Ellipsys® device is feasible, safe and efficient for giving prompt functional vascular access for hemodialysis



- Mini-invasive
- One-step confection
- Fast procedure (15-30 min)
- Outpatient procedure
- Low-pressure AVF
- AVF less unsightly
- Maturation & cannulation earlier
- Less complications: aneuvrysm, steal syndrome

- Patients satisfaction +++

- But specific education of nurses & nephrologists +++