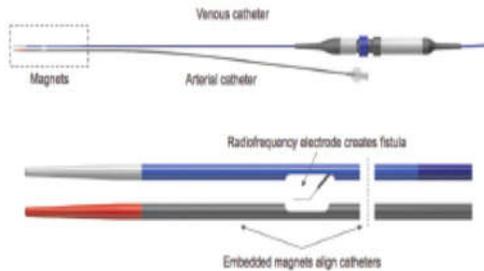


# Et les FAV percutanées, où en sommes-nous ?

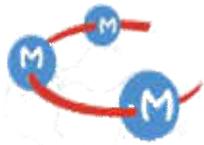


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SFAV Ajaccio 2022

# Conflit d'intérêt

- Pas de conflit concernant ce sujet

## Ellipsys

(Avenu Medical acquis par Medtronic)

Marquage CE



Résistance thermique  
+ pression  
+ échoguidage

Ponction : veine céphalique

Fistule: art. radiale proximale, v. communicante

→ Multi-outflow

## « Percutaneous Less Invasive AV Fistula for Vascular Access in ESRD »

*J Vasc Interv Radiol 2018;29:148-59*

**107 patients**

*Succès technique : 95%*

93 % ont eu  $\geq 1$  procédure secondaire  
(total de 205 procédures)

**Taux de maturation à 3 mois : 86%**

**Perméabilité primaire à 12 mois non rapportée**

**Complications majeures (78 sur 42 patients) :**

*12 thromboses précoces, 3 abandons*

*3 thromboses tardives, 1 abandon*

*1 ischémie*

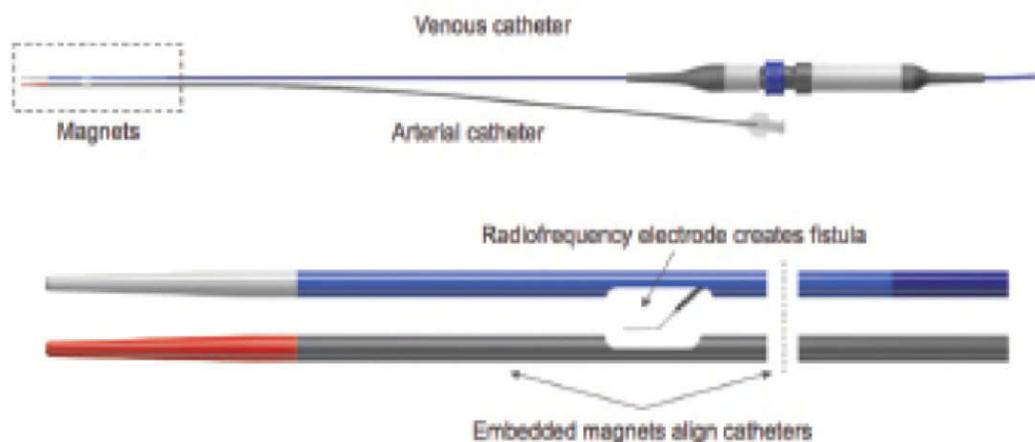
*Inclus les intervention d'angioplastie pour sténose*

# Everling

(TVA Medical acquis par BD Bard)

Marquage CE

1<sup>ère</sup> version 6F



Radiofréquence + fluoroscopie

Ponction : art. et v. brachiale

Fistule: art. et v. ulnaire

→ Multi-outflow

Etude NEAT (Australia, Canada, N-Zeland)

*Am J Kidney Dis* 2017;70:486-97

**60 patients**

*Succès technique : 98%*

*Maturation à 3 mois : 87%*

**Utilisation à 12 mois : 64%**

*(vs. USRDS : 65%)*

**Perméabilité primaire à 6 mois : 69%**

*(vs. Al-Jaishi AJKD 2014 : 65%)*

**Complications majeures : 8%**

*1 thrombose précoce*

*2 abandons*

*3 lésions de l'artère brachiale*

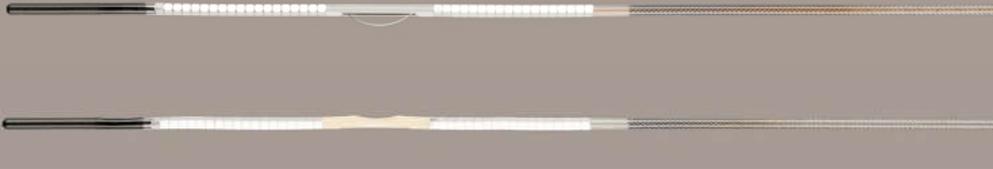
*1 ischémie*

## Wavelinq 4F

(TVA Medical acquis par BD Bard)

Marquage CE

Version actuelle 4F



Radiofréquence + fluoroscopie

Fistule: art. et v. ulnaire ++

→ Multi-outflow

### Etude EASE (Paraguay)

Ann Vasc Surg 2019

**32 patients**

Succès technique: 100%

temps moyen de maturation : 49days

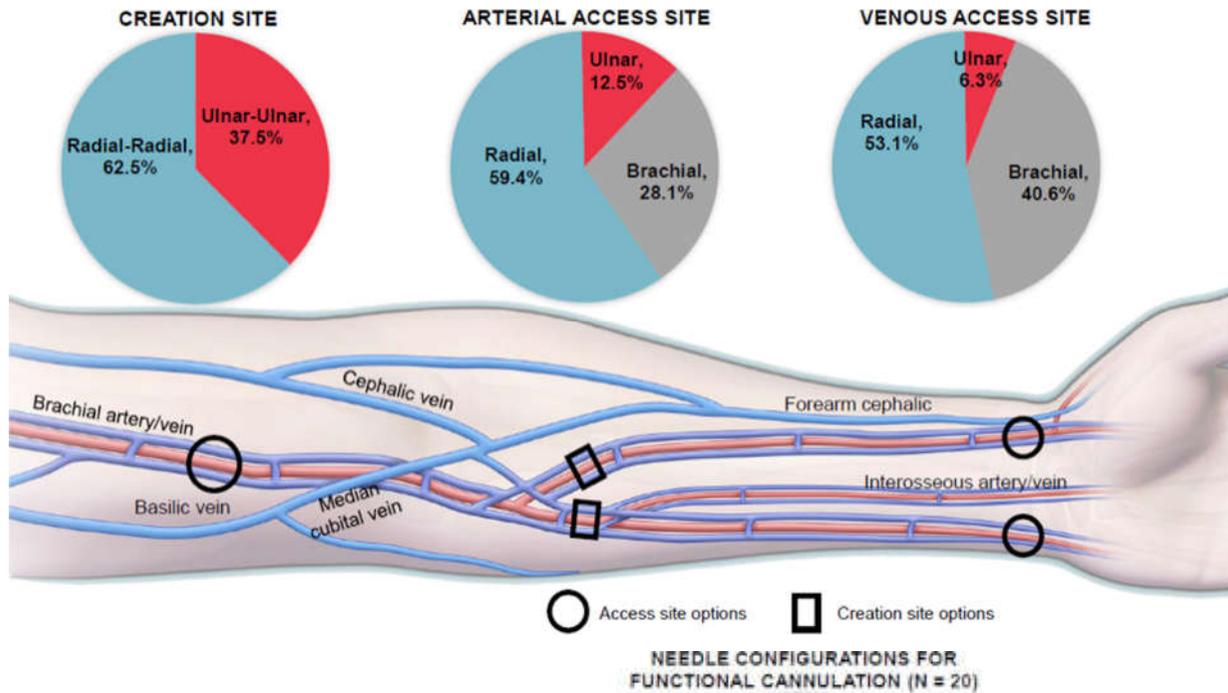
**Maturation à 6 mois : 72%**

**Perméabilité primaire à 6 mois: 83%**

**Complications per-procédure: 3%**

1 perforation par le guide

# Wavelinq 4F

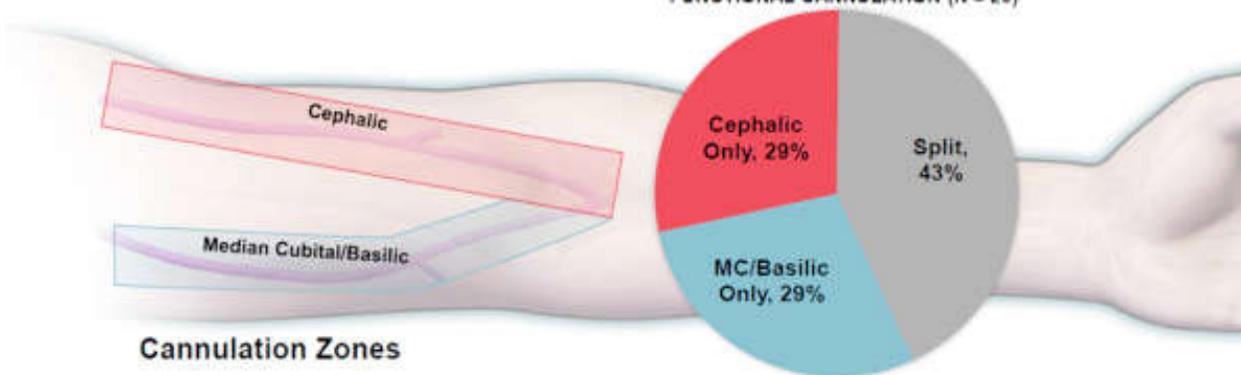


**Etude EASE (Paraguay)**  
*Ann Vasc Surg 2019*

**38% FAV ulnaire**  
**68% FAV radiale**

**72% ponction artérielle distale**  
**60% ponction veineuse distale**

**Cannulation en Y : 43%**





Courtesy Pr Coscas

## Premières publications

1st author (Year)	Device	Patients	Prospective	Multi-center	Comparative	Randomized
Rajan (2015)	Everling	33	YES	NO	NO	NO
Lok (2017)	Everling	60	YES	YES	NO	NO
Radosa (2017)	Everling	8	NO	NO	NO	NO
Hull (2017)	Ellipsys	26	YES	NO	NO	NO
Hull (2018)	Ellipsys	107	YES	YES	NO	NO
Mallios (2018)	Ellipsys	34	NO	NO	NO	NO
Berland (2019)	Wavelinq 4F	32	YES	NO	NO	NO

## Premières publications

1st author (Year)	Device	Patients	Technical success	Maturation @3 months	Patency @ 12 months
Rajan (2015)	Everling	33	97	96	
Lok (2017)	Everling	60	98	87	84
Radosa (2017)	Everling	8	100	86	
Hull (2017)	Ellipsys	26	88		75
Hull (2018)	Ellipsys	107	95	86	87
Mallios (2018)	Ellipsys	34	97	97	
Berland (2019)	Wavelinq4F	32	100	91	

## Procédures secondaires avant maturation

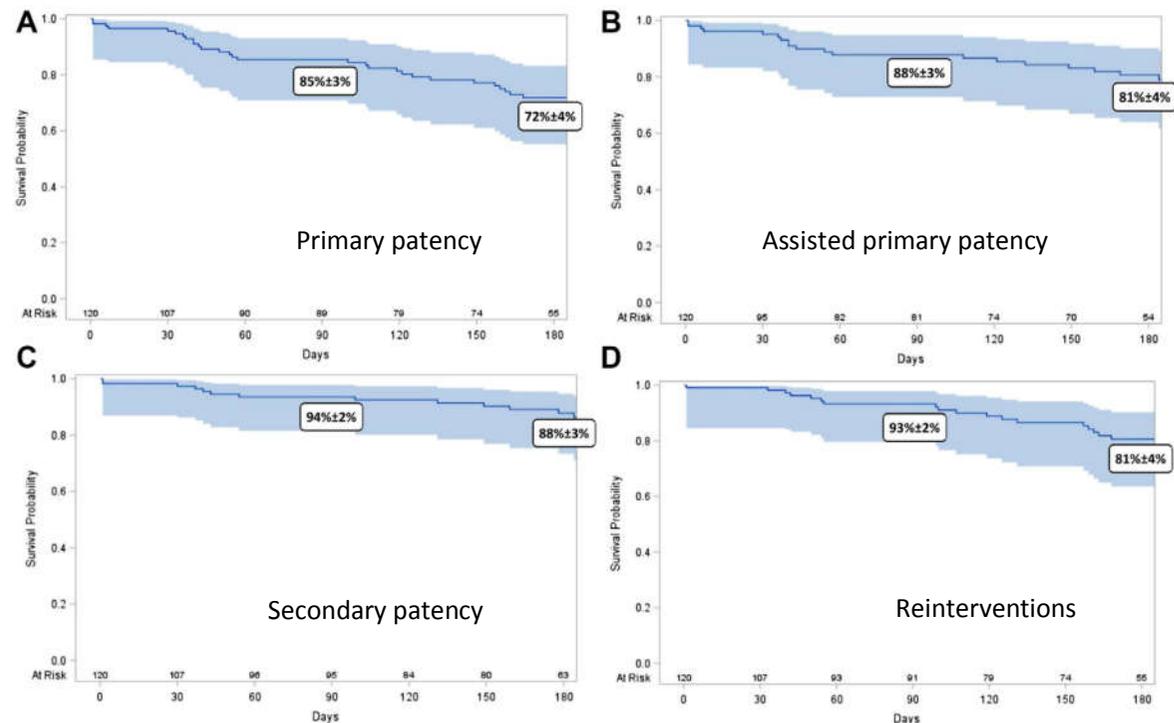
	EverlinQ Lok 2017	Ellipsys Hull 2018	Ellipsys Hebibi 2019
<b><i>Number of Patients</i></b>	<b>60</b>	<b>107</b>	<b>34</b>
Transposition	5 (8%)	28 (26%)	2 (6%)
Brachial vein embolization	5 (8%)	34 (32%)	0
Ulnar vein embolization	0	33 (30%)	0
Ulnar vein ligation	0	33 (31%)	1 (3%)
Angioplasty	2 (3%)	77 (72%)	12 (35%)
Thrombectomy	2% + 11%	9% + 2%	6%
Surgical AVF	ND	4%	6%

# Percutaneous arteriovenous fistula creation with the 4F WavelinQ EndoAVF System

Todd Berland, MD,<sup>a</sup> Jason Clement, MD,<sup>b</sup> Nicholas Inston, MD,<sup>c</sup> Paul Kreienberg, MD,<sup>d</sup> and Kenneth Ouriel, MD,<sup>e</sup> on Behalf of the WavelinQ 4 French Investigators, *New York and Albany, NY; British Columbia, Canada; and Birmingham, UK*

Characteristic	Value
N = 120	
<b>Sex</b>	
Male	97/120 (80.8)
Female	23/120 (19.2)
<b>Dialysis status</b>	
Enrolled on dialysis	82/120 (68.3)
Started dialysis during study	17/120 (14.2)
Not on dialysis through follow-up	21/120 (17.5)
<b>Age, years</b>	
	54.6 ± 15.9
	55 (range, 21-88)
	Interquartile range, 46-66
<b>Geography</b>	
Canada	14/120 (11.7)
Germany	8/120 (6.7)
Paraguay	56/120 (46.7)
UK	42/120 (35.0)
<b>Race<sup>a</sup></b>	
Asian	15/63 (23.8)
Black	5/63 (7.9)
Caucasian	39/63 (61.9)
Indian	4/63 (6.3)
Not specified	57/120 (47.5)
<b>Ethnicity</b>	
Not Hispanic or Latino	64/120 (53.3)
Hispanic or Latino	56/120 (46.7)
<b>BMI</b>	
	27.0 ± 6.6
	25.0 (range, 16.7-57.8)
	Interquartile range, 23.4-29.3

BMI, Body mass index.  
Values are number/total (%) unless otherwise specified.  
<sup>a</sup>Denominator excludes those in whom race was not specified.



*Berland et al. for the WavelinQ 4 French Investigators; J Vasc Surg 2022*

Characteristic	Participants
Arterial access site	
Wrist	105/120 (87.5)
Radial artery	27/120 (22.5)
Ulnar artery	78/120 (65.0)
Brachial artery	15/120 (12.5)
Venous access site	
Wrist	47/120 (39.2)
Radial vein	21/120 (17.5)
Ulnar vein	26/120 (21.7)
Upper arm	73/120 (60.8)
Brachial vein	67/120 (55.8)
Cephalic vein	6/120 (5.0)
Ulnar-ulnar	92/120 (76.7)
Radial-radial	28/120 (23.3)
Target artery diameter, mm	3.6 ± 0.8 3.7 (range, 1.3-5.8) Interquartile range, 3.1-4.0
Target vein diameter, mm	2.9 ± 0.6 2.8 (range, 1.8-4.9) Interquartile range, 2.4- 3.4
Procedure time, minutes	84 ± 62 74 (range, 4-390) Interquartile range, 47-101
Procedural success	
Yes	116/120 (96.7)
No	4/120 (3.3)
Arterial closure	
Manual pressure	14/120 (11.7)
Closure device	106/120 (88.3)
Adequate flow to hand	115/115 (100.0)
Brachial artery flow (mL/min) <sup>a</sup>	1337 ± 665 1198 (range, 71-2914) Interquartile range, 927-1747

Values are number/total (%) unless otherwise noted.  
<sup>a</sup>Flows were measured on duplex ultrasound and the value is the maximum flow through 6 months follow-up period.

**Table III.** All adverse events

Type of adverse event	Events	Patients with ≥1 event, No. (%)
All adverse events	71	58 (48.3)
Occlusions and stenoses	43	38 (31.7)
Wound infection	5	5 (4.2)
Bleeding and hematoma	5	5 (4.2)
Death	5	5 (4.2)
Pseudoaneurysm	4	4 (3.3)
Distant infection	3	2 (1.7)
Cardiac complications	2	2 (1.7)
Allergic reaction	1	1 (0.8)
Poor flow	1	1 (0.8)
Arm edema	1	1 (0.8)
Steal	1	1 (0.8)

**Table IV.** Reinterventions

Type of reintervention	Reinterventions	Patients with ≥1 reintervention	Reinterventions per patient-year
Reinterventions for maturation	13	13/120 (10.8%)	0.28
Superficialization	8	8/120 (6.7%)	0.17
Coiling	5	5/120 (4.2%)	0.11
Ligation of tributaries	0	0/120 (0.0%)	0.00
Reinterventions for maintenance	13	11/120 (9.2%)	0.28
PTA	9	8/120 (6.7%)	0.19
Stenting	1	1/120 (0.8%)	0.02
Thrombolysis	0	0/120 (0.0%)	0.00
Thrombectomy	3	2/120 (1.7%)	0.06
Any reintervention <sup>a</sup>	26	23/120 (19.2%)	0.55

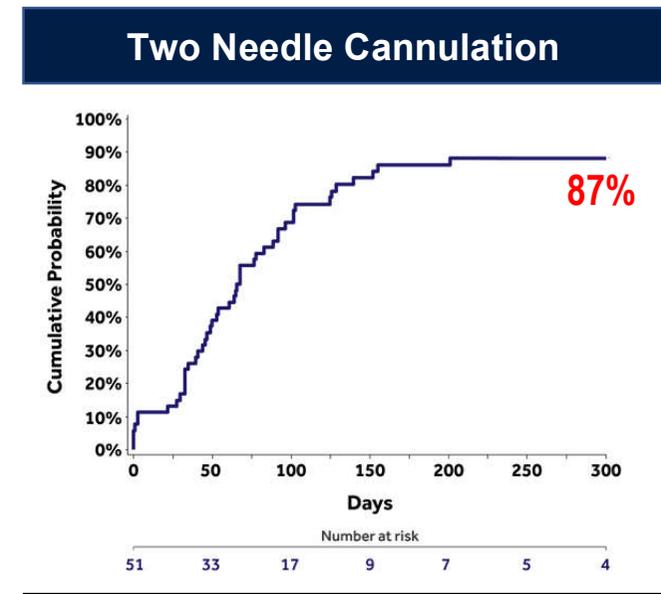
PTA, Percutaneous transluminal angioplasty.  
<sup>a</sup>Reinterventions for either maturation or maintenance. The number of patients with "any reintervention" is greater than the sum of patients with "reinterventions for maturation" and "reinterventions for maintenance" since one patient had reinterventions for both maturation and maintenance.

*Berland et al. for the Wavelinq 4 French Investigators; J Vasc Surg 2022*

# Ellipsys Registre *post-market* - 2020

Outcomes	Ellipsys AVF
# Patients	60
Candidates for Ellipsys	63% (60/95)
Mean Procedure Time	19.5 ± 11.3 min (range, 7–70 min)
Maturation (target vein flow 500 mL/min and diameter 5 mm)	93% (56/60)
Mean Time to Maturation	40.4 ± 4.3 days
2 Needle Cannulation	87% (47 of 54)
Target Vein for Dialysis	
Cephalic	70% (42/60)
Basilic	22% (13/60)
Brachial	8% (5/60)

Secondary Procedures
Balloon Dilatation <b>62%</b>
Brachial Vein Embolization <b>32%</b>
Banding Cubital Vein <b>30%</b>
Transposition/ Superficialization <b>30%</b>



Hull et al. J Vasc Interv Radiol 2020

# Ellipsys Série rétrospective française - 2020

## Percutaneous Arteriovenous Fistula (pAVF) Creation with the Ellipsys Vascular Access System

Single-center retrospective cohort study 234 patients underwent pAVF creation

### Results

99% Technical Success  
No Procedure Related Adverse Events  
Average Follow Up: 252 days

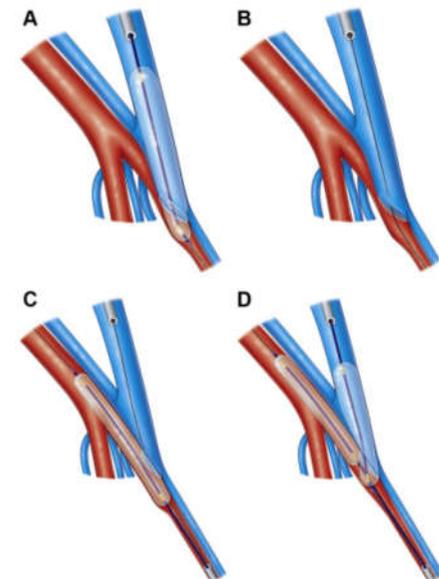
Patencies at 1 year

54%	Primary
85%	Primary Assisted
96%	Secondary



24 Superficialisations (10%)

94 patients (40%) : angioplastie secondaire de l'anastomose et de la v. perforante



# Les études disponibles montrent :

- **Que la FAV percutanée :**
  - **est faisable**
  - **est sûre... dans les mains entraînées et chez les patients sélectionnés**
- **Mais, la FAV percutanée:**
  - **peut nécessiter de nombreuses réinterventions avant d'être utilisable**
  - **peut nécessiter un changement de pratique en salle de dialyse**

**Il manque toujours une étude comparative et randomisée pour déterminer la place de ces techniques en éliminant un maximum de biais.**

# Perspectives : quelle place pour la FAV percutanée ?

1. Nécessité d'une étude prospective comparative randomisée justifiant de la place de la FAV créée par voie percutanée dans l'algorithme de création
2. Incluant une étude médico-économique pour justifier le surcoût lié au dispositif

**MERCI**