FAV percutanées : états de lieux

Dr Denis HENROTEAUX



Percutaneous endovascular arteriovenous fistula: A systematic review and meta-analysis

Ji-Bo Sun[1†], Chun-Cheng Liu[2†], Xi Shen[1], Qin Chen[3], Cheng-Liang Xu[4] and Tian-Lei Cui[1*]

- 14 séries de cas, 5 études de cohorte
- Total = 1929 patients
- Pas de ≠ de succés de la procédure endoFAV/ chirurgicale FAV
- Pas de étude randomisée

Author, year	Design	Patients (p/s)	Device (p/s)	PT, min (p/s)	Age (p/s)	Male, *n* (p/s)	BMI, kg/m^2	DM, *n* (p/s)	HTN, *n* (p/s)
Mordhorst et al. (26)	RC	61/308	WavelinQ/S	55.0[a]/NR	64.0[a]/64.2	46/196	NR	36/186	50/286
Harika et al. (23)	RC	107/107	Ellipsys/S	NR	63.6 ± 15.41/63.5 ± 15.69[b]	66/65	27.2 ± 5.78/ 26.8 ± 5.95[b]	66/52	99/102
Osofsky et al. (25)	RC	24/62	Ellipsys/S	60 ± 40/56 ± 25 [b]	56.7 ± 22.6/62.5 ± 13.2[b]	12/32	28.8 ± 6.8/ 30.5 ± 6.7[b]	18/46	21/58
Shahverdyan et al. (24)	RC	89/69	Ellipsys/S	14.0/74.0[a]	66.0/67.9[a]	58/35	26.2/28.7[a]	32/33	NR
Inston et al. (22)	PC	30/40	WavelinQ/S	NR	57 ± 15 /54 ± 17[b]	25/29	NR	NR	NR
Berland et al. (21)	C	120/NR	WavelinQ/NR	NR	54.6 ± 15.9[b]/NR	97/NR	27.0 ± 6.6[b]/NR	NR	NR
Kitrou et al. (20)	C	30/NR	WavelinQ/NR	NR	55.3 ± 13.6[b]/NR	30/NR	NR	15/NR	21/NR
Zemela et al. (19)	C	32/NR	WavelinQ/NR	120.0[a]/NR	60.2[a]/NR	23/NR	32.5[a]/NR	21/NR	31/NR
Shahverdyan et al. (17)	C	100/NR	Ellipsys+ WavelinQ/NR	18.0[a]/NR	64.18 ± 14.18[b]/NR	69/NR	27.21 ± 6.70[b]/NR	37/NR	NR
Hull et al. (15)	C	62/NR	Ellipsys/NR	NR	64 ± 14[b]/NR	34/NR	30.7 ± 9.0[b]/NR	55/NR	57/NR
Beathard et al. (18)	C	105/NR	Ellipsys/NR	NR	56.2[a]/NR	77/NR	31.21[a]/NR	NR	NR
Mallios et al. (16)	C	232/NR	Ellipsys/NR	15.0[a]/NR	64[a]/NR	148/NR	NR	140/NR	NR
Berland et al. (14)	C	32/NR	WavelinQ/NR	NR	51 ± 13[b]/NR	31/NR	NR	17/NR	27/NR
HeBiBi et al. (13)	C	34/NR	Ellipsys/NR	NR	60.6[a]/NR	20/NR	NR	12/NR	33/NR
Mallios et al. (12)	C	34/NR	Ellipsys/NR	NR	64.0[a]/NR	22/NR	NR	21/NR	NR
Hull et al. (11)	C	107/NR	Ellipsys/NR	23.7 ± 11.3[b]/ NR	56.7 ± 12.0[b]/ NR	78/NR	31.18 ± 7.13[b]/ NR	69/NR	105/NR
Lok et al. (9)	C	80/NR	WavelinQ/NR	NR	60.1 ± 13.1[b]/NR	54/NR	28.1 ± 6.1[b]/NR	49/NR	73/NR
Hull et al. (10)	C	26/NR	Ellipsys/NR	18.4[a]/NR	45.5 ± 13.6[b]/NR	10/NR	26.7 ± 5.1[b]/NR	17/NR	24/NR
Rajan et al. (8)	C	33/NR	WavelinQ/NR	NR	51.0 ± 11.4[b]/NR	20/NR	24.3 ± 3.8[b]/NR	19/NR	NR

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Review Article on Endovascular and Surgical Interventions in the End Stage Renal Disease Population

Endovascular creation of hemodialysis arteriovenous fistulae: the current status and future perspective—a literature review

Xin Li, Shilpa N. Reddy, Timothy W. I. Clark, Ansar Z. Vance

FISTULES ENDOVASCULAIRES SÛRES ET EFFICACE

- Succés technique > 95%
- Bonne perméabilité cumulée
- Cannulation précoce possible pour certains patients

Table 2 Summary of endoAVF trial data

Study	Device	Follow-up duration	Primary patency rate	Cumulative patency rate	Intervention rate	Maturation rate	Dialysis rate
Rajan *et al.* (21)	6 Fr WavelinQ	6 months	–	96% at 6 months	0.6 per patient	96%	96%
Lok *et al.* (22)	6 Fr WavelinQ	12 months	69% at 1 year	84% at 1 year	0.46 per patient-year	87%	64%
Berland *et al.* (23)	4 Fr WavelinQ	180 days	83% at 6 months	87% at 6 months	0.21 per patient-year	91%	78%
Hull *et al.* (24)	Ellipsys	Up to 24 months	–	75% at 1 year	1.57 per patient-year	77% at 6 weeks	–
Hull *et al.* (25)	Ellipsys	12 months	–	87% at 1 year	2.7 per patient-year	86%	88%

endoAVF, endovascular creation of arteriovenous fistula.

Table 3 Summary of short- and mid-term endoAVF data

Study	Device	Primary patency rate	Cumulative patency rate	Intervention rate	Maturation rate	Dialysis rate
Short-term						
Mallios *et al.* (26)	Ellipsys	82%	92%	0.24 per patient	–	100%*
Hebibi *et al.* (27)	Ellipsys	–	–	0.53 per patient**	–	71%
Sultan *et al.* (28)	Ellipsys	83% at 6 weeks	–	0.73 per patient	47%	20%
Hull *et al.* (29)	Ellipsys	7% at 6 months	96% at 6 months	2.3 per patient**	93%	87%
Zemela *et al.* (30)	WavelinQ	–	88%	0.53 per patient	–	48%
Mid-term						
Mallios *et al.* (31)	Ellipsys	54% at 1 year	96% at 1 year	0.52 per patient**	–	–
Beathard *et al.* (32)	Ellipsys	–	91.6% at 2 years	–	98%	95%

*, all patients on catheter dialysis were successfully dialyzed via endoAVF; **, estimated from provided data. endoAVF, endovascular creation of arteriovenous fistula.



Cardiovasc Diagn Ther 2023

PUBLICATIONS INCLUANT ENDOAVF et AVF CHIRURGICAL

Auteur (année)	Etude	# participants	Commentaire clé
Ionston et al JVA (2020)	Etude rétrospective chirrurgie (RCAVF) vs WavelinQ endoAVF	30 WavelinQ 40 RCAVF	analyse comparative appariée de la FAV endo (Wavelinq) et FAV chirurgicale à l'avant-bras
Harika et al JVS (2021)	Etude rétrospective chirurgie vs Ellisys pFAV	107 Ellipsys 107 mix FAV	Comparaison de la FAV endo (Ellipsys) et FAV chirurgical bras et avant-bras
ShAhverdyan et al AJKD (2021)	Eude rétrospective FAV chirurgicale Gracz vs Ellipsys	89 Ellipsys 69 FAV Gracz	Comparaison de FAV endo (Ellipsys) et FAV chirurgical de Gracz chirurgicale
Osofsky et al Ann Vasc Surg (2021)	Etude rétrospective FAV chirurgicale vs Ellipsys	24 Ellipsys 62 FAV chirurgicales	Comparaison FAV endo et FAV chirurgical
Mordhorst et al JVC (2022)	Etude retrospesctive FAV chirurgicale vs FAV endo (EverlinQ)	61 EverlinQ 171 RCAVF 137 BCEVF	Comparaison des FAV Endo (Everlinq) non disponible depuis longtemps et FAV chirurgicale
Habib et al JVS (2023)	Etude rétrospective FAV chirurgicale vs pFAV	33 Ellipsys 18 WavelinQ 51 FAV chirurgicale	Comparaison des FAV endo (les 2) vs FAV chirurgicale

PUBLICATIONS INCLUANT ENDOAVF et AVF CHIRURGICAL

Table 4 Comparison studies between endoAVF and surgical AVF

Study	Type of EndoAVF	Type of surgical AVF	Primary patency rate°	Secondary patency rate°	Intervention rate°	Maturation rate°	Dialysis rate°
Inston *et al.* (37)	WavelinQ	RC AVF	65.5% *vs.* 53.4% at 6 months; 56.5% *vs.* 44% at 1 year	75.8% *vs.* 66.7% at 6 months; 69.5% *vs.* 57.6% at 1 year*	0.402 *vs.* 0.273 per patient-year	–	–**
Harika *et al.* (38)	Ellipsys	RC, BC, and BB AVF	61% *vs.* 86% at 1 year*; 55% *vs.* 52% at 2 years	91% *vs.* 90% at 12 months; 91% *vs.* 88% at 2 years	0.50 *vs.* 0.34 per patient at 1 year; 0.65 *vs.* 0.73 per patient at 2 years.	65% *vs.* 50% at 6 weeks*	–
Shahverdyan *et al.* (39)	Ellipsys	Gracz AVF	64% *vs.* 47% primary patency failure at 1 year	20% *vs* 12% secondary patency failure at 1 year	0.86 *vs.* 0.66 per patient-year	85% *vs.* 79% at 6 months	–***
Osofsky *et al.* (40)	Ellipsys	BC AVF	39% *vs.* 10% primary failure rate*	–	1.04 *vs.* 0.29 per patient*	52% *vs.* 87%*	–

*, findings with statistically significant difference, P<0.05; **, mean time to 2 needle cannulation was similar between the two groups; ***, time to 2 needle cannulation was similar between the two groups; °, EndoAVF versus surgical AVF. endoAVF, endovascular creation of arteriovenous fistula; RC, radiocephalic; BC, brachiocephalic; BB, brachiobasilic.

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Eur J Vasc & Endovasc Surg 2025

Long Term Results of a Comparative Study of Percutaneous and Surgically Created Proximal Forearm Arteriovenous Fistulae

Robert Shahverdyan [a,*], Tej I Mehta [b], Nicholas Inston [c], Klaus Konner [d], Shant Vartanian [e]

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[c] Renal Surgery and Transplantation, Queen Elizabeth Hospital Birmingham, Birmingham, UK
[d] Vascular Access Unit, University Hospital of Cologne, Cologne, Germany
[e] Department of Surgery, Division of Vascular and Endovascular Surgery, University of California, San Francisco, CA, USA

1ÉRE ÉTUDE COMPARATIVE D'EFFICACITÉ ENTRE LA FAV CHIRURGICALE PROXIMAL ET LES FAV PERCUTANÉE A LONG ET COURT TERME

- succès technique élevé pour FAVp et FAVs,
- taux de maturation significativement plus élevés pour Ellipsys
- taux de perméabilité primaire plus élevés pour les FAVs
- taux de perméabilité secondaire plus faibles pour les FAVp WavelinQ

	FAV chirurgicale	Ellipsys	WavelinQ
Succés technique	100%	100%	93%
Temps de la procédure	> 60 min	<15 min	>60 min
Maturation à 4 semaines	80%	79%	65%
Temps pour la canulation	73 jours	57 jours	98 jours
Débit élevé	10%	6%	14%
Syndrome de vol	Possible	Faible risque	Faible risque

J Vasc Intev Radiol 2024

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Study protocol for a French multicenter randomized controlled trial evaluating the medicoeconomic impact of Surgical vs Endovascular Arteriovenous Access Creation for Hemodialysis in End-stage Renal Disease (ENDO-FAV)

Caroline Caradu, MD, PhD,[a] Eric Ducasse, MD, PhD,[a] Edwin Ripoche, MD,[a] Audrey Cordon, MSc (Health Economics),[a] Antoine Bénard, MD, PhD,[a] *and* Alexandros Mallios, MD,[b] on behalf of the ENDO-FAV Collaborators, *Bordeaux and Paris, France*

Essai contrôlé randomisé multicentrique français

Evaluer la rentabilité des FAV endo versus chirurgicaleS

- critère d'évaluation principal : rapport coût-utilité
- critère d'évaluation secondaire : économie de la santé avec le coût total à 18 et 36 mois

ABSTRACT

Background: Vascular access is indispensable for performing hemodialysis in patients with end-stage renal disease. The Kidney Disease Outcome Quality Initiative and the French Health Authority advocate for native arteriovenous fistulas (AVFs) as a primary option owing to their association with lower morbidity, mortality, and enhanced quality of life. However, a significant proportion of AVFs fail to mature, and many require multiple re-interventions, increasing overall costs. To address these issues, endovascular techniques for AVF creation have been developed. These methods use energy-based technologies, avoiding vessel dissection and preserving perivascular tissues. Initial results are promising, but these devices are expensive, and the technical act of creating an endovenous fistula is not recorded in the coding of the common classification of medical procedures and, as such, cannot be reimbursed by health insurance in France. Although international studies suggest their effectiveness, no French studies have yet replicated or confirmed these findings in the local context, which would help to support a reimbursement request from health insurance.

Methods: This protocol represents the first French medicoeconomic study to compare the two available endovascular AVF creation devices (Ellipsys and WaveLinQ) with traditional open surgery. This multicenter, comparative clinical trial will randomize patients into two parallel groups: (1) endovascular AVF creation using either the WaveLinQ or Ellipsys device, and (2) surgical proximal AVF creation (brachiocephalic/brachiobasilic). Randomization will be balanced and stratified by center and dialysis timing. Follow-up assessments will occur at 1 week and 1, 3, 6, 12, and 18 months. The primary objective is to evaluate the cost effectiveness of endovascular AVF creation compared with open surgery from the perspective of the French health care system. The primary end point is the cost-utility ratio (cost per quality-adjusted life year gained) of endovascular AVF vs open surgery. Utility is assessed using the EQ-5D-5 L questionnaire, with costs derived from micro-costing and the National Health Data System. Secondary outcomes include health economics with total costs at 18 and 36 months, success rate of vascular access creation, AVF maturation and functionality, recirculation rates, early and late access failures, cannulation success, primary and secondary patency, reintervention rates, and adverse events. Based on a cost-utility threshold of €30,000 per quality-adjusted life year, cost difference estimates, and standard deviations from previous studies, anticipated sample size is 126 patients per group (endovascular and surgical), totaling 252 patients with approximately 142 patients for the Ellipsys device and 110 patients for WaveLinQ, based on the capacity of 7 centers using Ellipsys and 4 centers using WaveLinQ.

Conclusions: This multicenter randomized controlled trial will provide contemporary data on the clinical outcomes and prognoses for endovascular AVF techniques, potentially establishing endovascular methods as a viable and cost-effective alternative to traditional surgical AVF creation. (JVS-Vascular Insights 2025;3:100163.)

Keywords: Hemodialysis; Arteriovenous fistula; Endovascular; Restenosis; Cost effectiveness; Health economic evaluation

Eur J Vasc & Endovasc Surg 2025

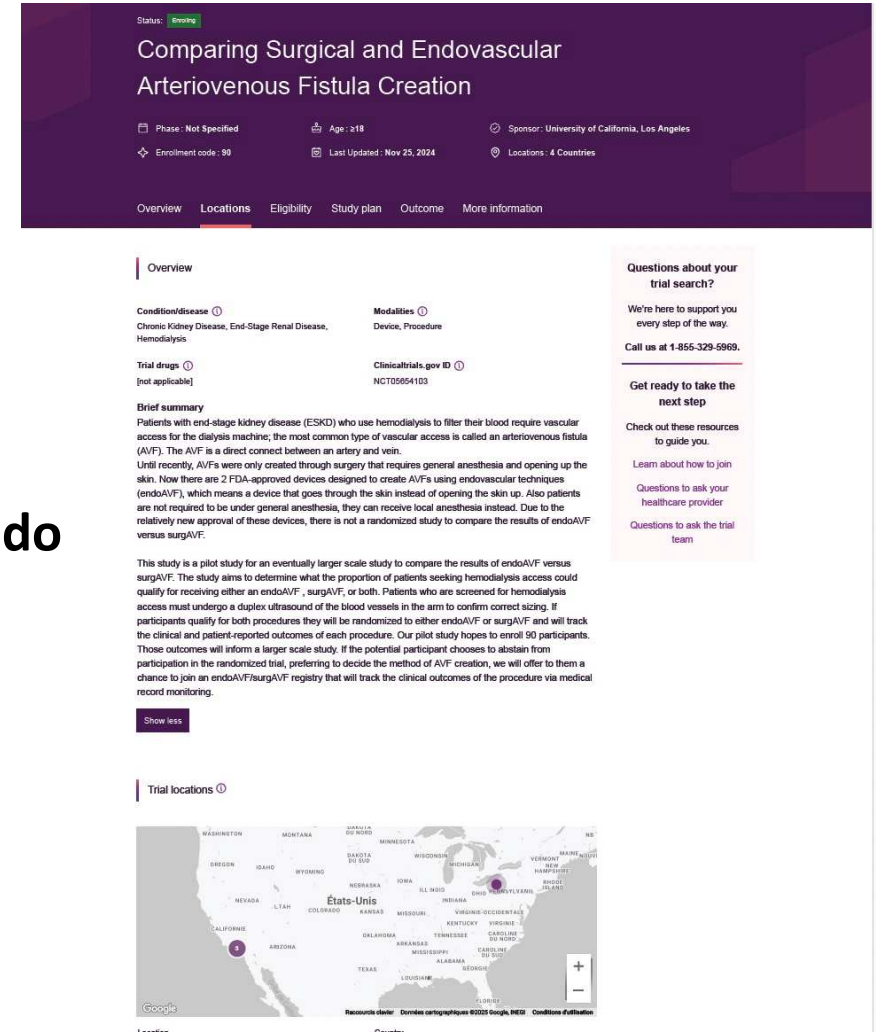


Essai contrôlé randomisé multicentrique US

Comparaison création FAV chirurgicale et FAV endo

- **90 ESKD patients**
- **Achévement 08/2026**

Clinical Trials.gov ID NCT05654103



Status: Enrolling

Comparing Surgical and Endovascular Arteriovenous Fistula Creation

Phase : Not Specified | Age : ≥18 | Sponsor : University of California, Los Angeles

Enrollment code : 90 | Last Updated : Nov 25, 2024 | Locations : 4 Countries

Overview | Locations | Eligibility | Study plan | Outcome | More information

Overview

Condition/disease
Chronic Kidney Disease, End-Stage Renal Disease, Hemodialysis

Modalities
Device, Procedure

Trial drugs
[not applicable]

Clinicaltrials.gov ID
NCT05654103

Brief summary
Patients with end-stage kidney disease (ESKD) who use hemodialysis to filter their blood require vascular access for the dialysis machine; the most common type of vascular access is called an arteriovenous fistula (AVF). The AVF is a direct connect between an artery and vein.
Until recently, AVFs were only created through surgery that requires general anesthesia and opening up the skin. Now there are 2 FDA-approved devices designed to create AVFs using endovascular techniques (endoAVF), which means a device that goes through the skin instead of opening the skin up. Also patients are not required to be under general anesthesia, they can receive local anesthesia instead. Due to the relatively new approval of these devices, there is not a randomized study to compare the results of endoAVF versus surgAVF.

This study is a pilot study for an eventually larger scale study to compare the results of endoAVF versus surgAVF. The study aims to determine what the proportion of patients seeking hemodialysis access could qualify for receiving either an endoAVF , surgAVF, or both. Patients who are screened for hemodialysis access must undergo a duplex ultrasound of the blood vessels in the arm to confirm correct sizing. If participants qualify for both procedures they will be randomized to either endoAVF or surgAVF and will track the clinical and patient-reported outcomes of each procedure. Our pilot study hopes to enroll 90 participants. Those outcomes will inform a larger scale study. If the potential participant chooses to abstain from participation in the randomized trial, preferring to decide the method of AVF creation, we will offer to them a chance to join an endoAVF/surgAVF registry that will track the clinical outcomes of the procedure via medical record monitoring.

Show less

Trial locations

Questions about your trial search?

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Learn about how to join

Questions to ask your healthcare provider

Questions to ask the trial team

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Étude post-commercialisation

Ellypsis Vascular Access System Post-Market Surveillance

- Multicentrique , observationnel , single arm, post-création
- 142 IRCT pts (>134 pts)
- Endpoint
  - Perméailité cumulée à 12 mois
  - Occlusion précoce
  - SAE

Post-market surveillance study of the Wavelinq system

- Multicentrique, observationel, single arm
- 99 IRCT pts (220 pts)
- Endpoint
  - Succés de canulation à 6 mis
  - Perméabilité 1aire à 6mois
  - Évènement indésirable grave à 30 j

Arrêt de la commercialisation

ELLYPSIS

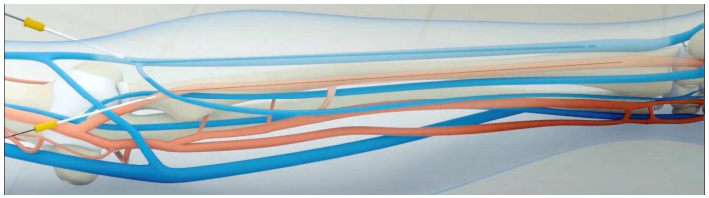


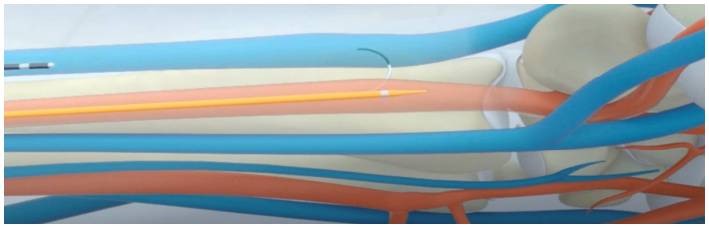


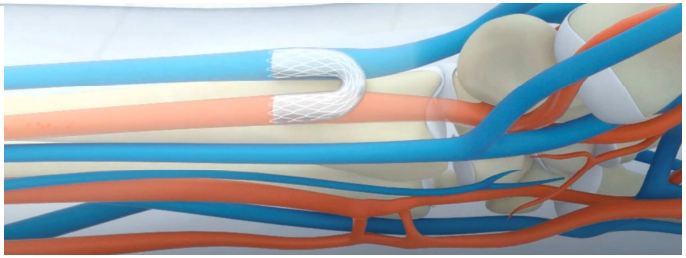
Pathfinder MEDICAL

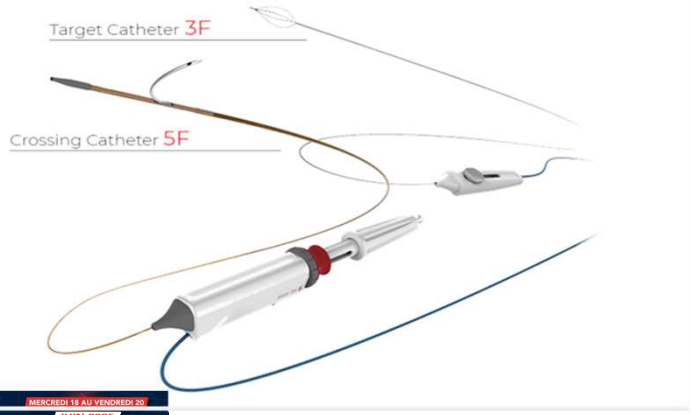
ePATH

- FAV à la tabatière anatomique
- Cathéter 5F guidage intuitif
- Technique de stenting
- Étude sur cadavre
- Étude FIH prévue pour fin 2025











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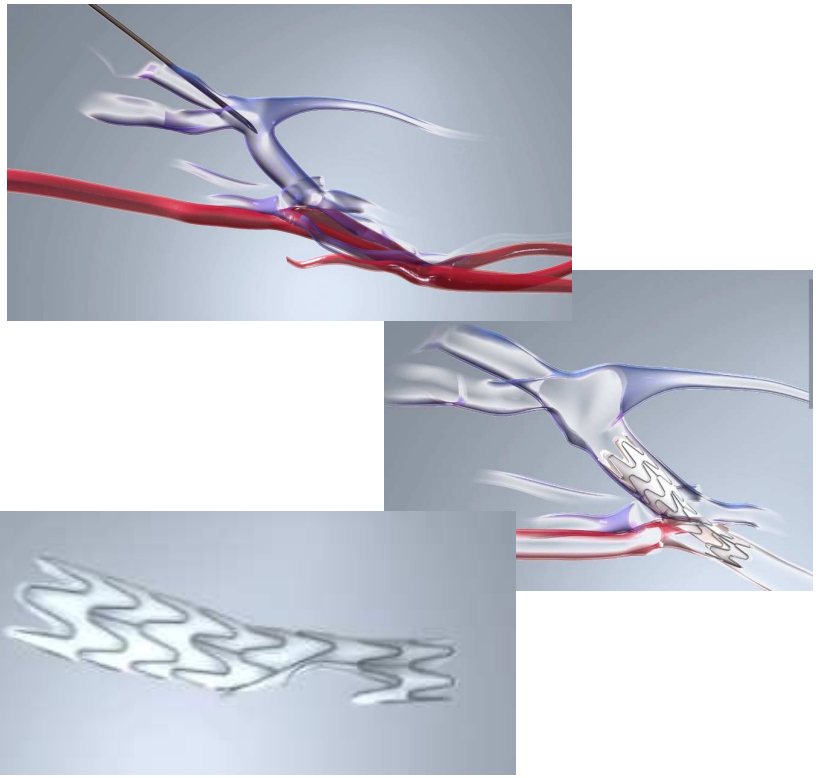
The Velocity™ Percutaneous Arterio-Venous Fistula System

- **Stent avec une géométrie optimale**
  - un seul poutflow
  - pas besoin d'une diversion du flux/embolisation
- **Moins de sténose anastomotique**
  - pas de trauma thermique , pas d'inflammation
  - endothelium « protégé » des turbulences
  - pas d'angioplastie
- **Utilisation faci**le (anesthésie locale/block)



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The Velocity™ Percutaneous Arterio-Venous Fistula System

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- **VENOS-1 Trial enrôlement fini en 10/2023**
  - 1er cohorte 10 patients suivi > 1 an
  - 2éme cohorte 17 patients suivi 12 mois (design adapté + 2d taille)
- Intervention
  - bloc axillaire
  - guidage uniquement échographique
  - double antiaggrégation plaquettaire

One-Year Outcomes of the VENOS-1 Trial: A Novel Percutaneous Arteriovenous Fistula for Hemodialysis Access

R. Shahverdyan[1], D. Hentschel[2], A. Ebner[3], E. van der Burg[4], S. Vartanian[5]; [1]Independent; [2]Brigham and Women's Hospital; [3]Italian Hospital Asuncion, Paraguay; [4]Venova Medical; [5]University of California, San Francisco



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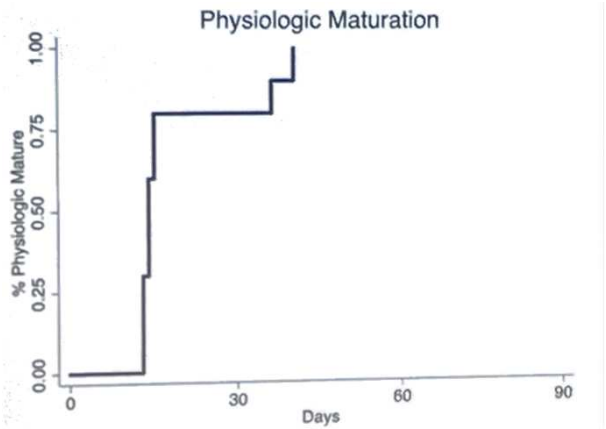


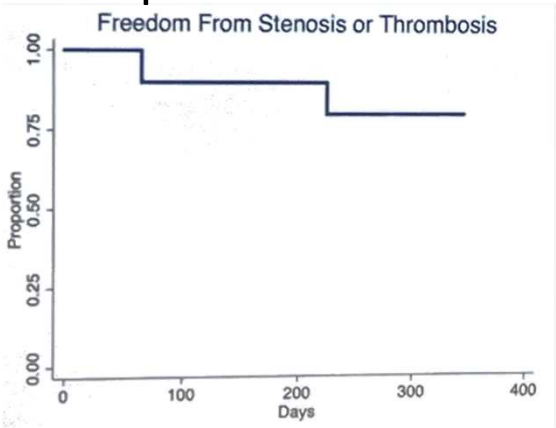
100% dans les 6 semaines (sans réintervention)

Critéres de maturation

- Flux artériel < 500 ml/min
- Calibre veine cephalique

Perméabilité primaire 80%

(2 interventions pour toute la cohorte)



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VENOS-2 Trial : étude préliminaire de faisabilité 01/2025

Merci pour votre attention



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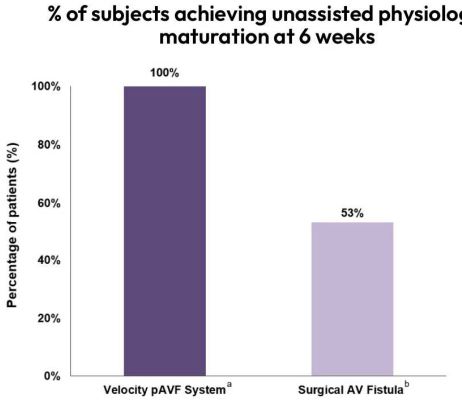
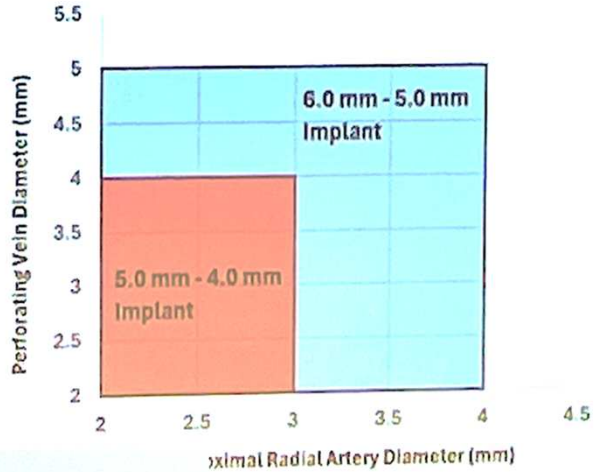
The VENOS-1 Clinical Study

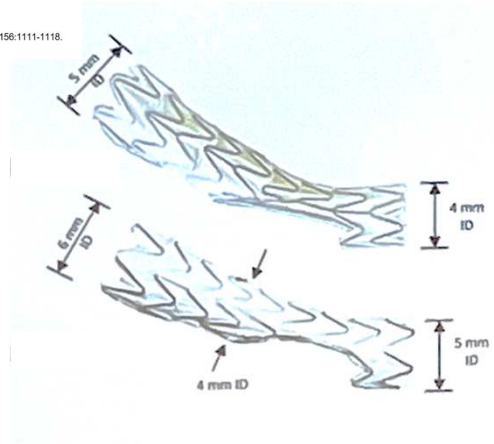
The VENOS-1 study is a first-in-human clinical study conducted outside the U.S., with patients followed for one year (NCT05757726). The results demonstrate the potential of our minimally invasive pAVF procedure:

- **100% Technical Success,** highlighting the reliability of our approach.
- **Rapid Maturation:** Using a common definition of maturation—a blood flow of 500 mL/min and a vein diameter of 5 mm—all subjects met this endpoint by 6 weeks. The bar graph on the right compares physiologic fistula maturation with the Velocity System to surgical creation of an AVF.



[a] Based on results from VENOS-1 study
[b] Based on results from Hemodialysis Fistula Maturation (HFM) study. Huber TS, et al. JAMA Surg. 2021;156:1111-1118.





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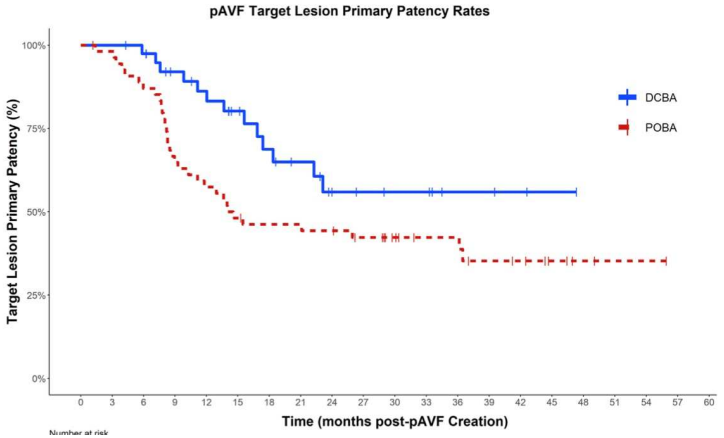
CLINICAL STUDY

Comparison of Outcomes of Drug-Coated Balloons versus Plain Balloons in Secondary Interventions on Percutaneous Arteriovenous Fistulae

Robert Shahverdyan, MD, Mark L. Lessne, MD, and Tej Ishaan Mehta, MD





- Étude rétrospective un seul centre
- 195 pts FAV percutanée
- Nécessité d'une angioplastie chez 95 pts (48,7%)
- Sténose juxta-anastomotique (75,5%)

Réintervention plus élevée pour ATL après la création d'une FAVp avec POBA comparé DCB. Mais durée de suivi POBA plus longue. Pas de différence de risque de perte de perméabilité entre la POBA et la DCBA.

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