WELCOME *To the*

2026 SYMPOSIUM

FLEX FIRST AV Registry:

12-Month Outcomes of Kinetic Endovascular Micro-Incision Creation (KEMIC) for Hemodialysis Access

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Disclosure Statement

Research Support

Financial support for conducting clinical research in vascular access interventions

Speaker Bureau

Medtronic

Scientific Advisory Boards

Medtronic (Global AV Therapies), Flex Vascular, Sonavex (Chairman CEC), Venostent

Industry Relationships

Medtronic, Flex Vascular, Venostent, Sonavex, Mozarc Medical, DaVita PSN

The Problem: Vascular Access Failure

$23,759

Annual cost gap per patient: AVF nonuse vs. maintained patency (Thamer et al. AJKD 2018)

End-stage renal disease **patients depend on functioning vascular access** for life-sustaining hemodialysis.

2–3/yr

Average interventions per HD patient

Access failure drives repeated interventions, hospitalizations, catheter dependence, and increased mortality.

624 hrs

Annual hours on dialysis per ESRD patient

The average **HD patient undergoes 2–3 access interventions per year** — each carrying procedural risk, patient burden, and system cost.

Current Standard of Care: Unmet Needs

- Current AV Access procedural standard of care limits consistent outcomes
- Significant cost burden associated with current AV Access maintenance
- Delivering consistent patient care in AV Access could lower overall costs

*The **FLEX FIRST AV Registries** were designed to address the current standard of AV Access care.*

Study Design: FLEX FIRST AV Registry

Parameter	Detail
Registry ID	NCT05616104
Design	Prospective, multicenter, all-comers registry
Centers	4 US sites (HOPD and ASC)
Enrollment	130 patients — no exclusions for prior stents, DCB, or grafts
Device	FLEX Vessel Prep (KEMIC mechanism) + standard PTA
Primary Endpoint	6-month target lesion primary patency (TLPP)
Extended Follow-up	12-month TLPP, safety, reintervention rates
Key Feature	Real-world, all-comers — AVFs, AVGs, cephalic arch, prior interventions

Patient Demographics & Lesion Characteristics

Patient Population
N=130 patients, 176 lesions
Mean age: 66.4 years
Diabetes: 84/130 (64.6%)
Hypertension: 124/130 (95.4%)
Prior interventions: mean count: 4.2 +- 4.1
All-comers: no exclusion for prior stents, DCB, or grafts

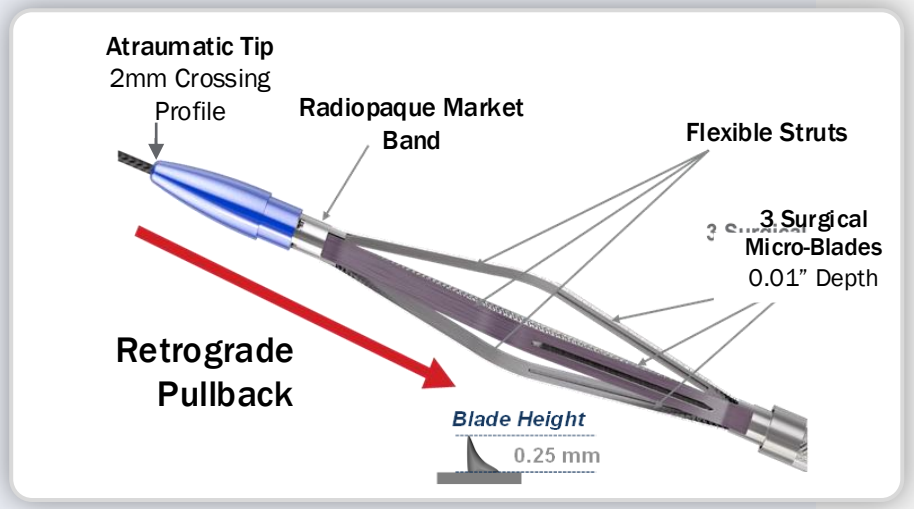
Lesion Profile
AVF lesions: 97/130 (75%)
AVG lesions: 33/130 (25%)
Cephalic arch: 35/130 (26.9%)
Mean lesion length: 29 ± 21 mm
Mean stenosis: 75.4% + - 14.6
Multiple lesions treated: 39/130 (30%)

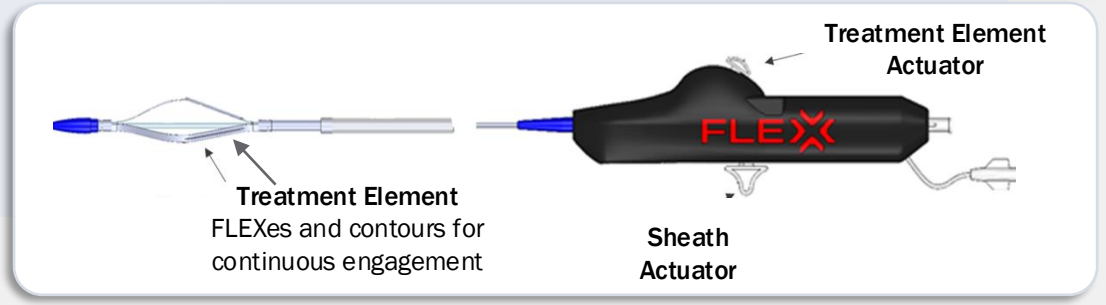
*This is a **real-world** registry. All-comers included.*

FLEX Vessel Prep: Mechanism of Action

Kinetic endovascular micro-incision creation (KEMIC) technology to create controlled, precise micro-incisions to consistently modify obstructive stenosis and plaque.

- ***No* Implant:** *No stent or covered prosthesis left*
- ***No* Balloon:** *Controlled, precise vessel prep*
- ***One* Device:** *Simple addition to existing PTA workflow*

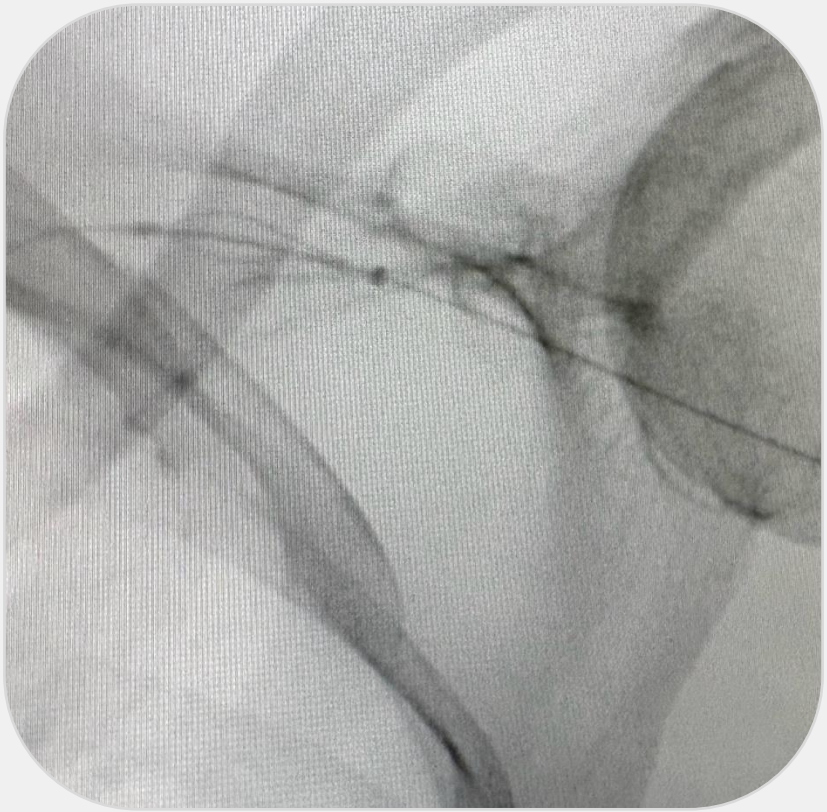




Representative Case



PRE-FLEX



FLEX VESSEL PREP



POST-FLEX

12-Month Primary Safety Results vs Recent Published Data

0%

Serious Adverse Events

Through 30-day follow-up
(0/130 patients)

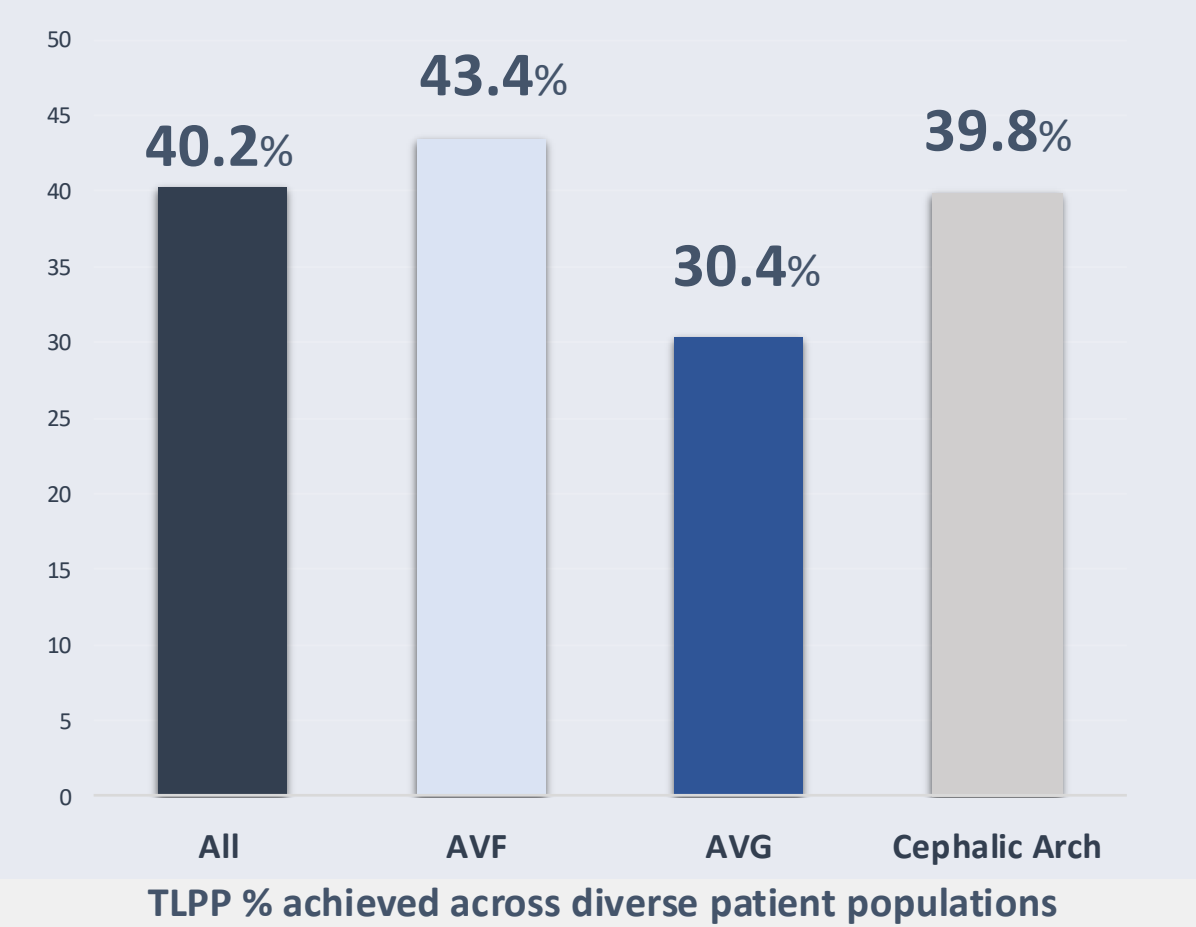
Single minor dissection: **0.8%**

vs. Published RCT 30-Day SAE Rates

FLEX FIRST AV	**0.0%**
Published PTA Arms	**2.0 – 7.0%**
Published DCB Arms	**2.0 – 4.4%**
Published Stent Graft Arms	**1.5 – 5.0%**

*The safety case is unambiguous. **Below** every JVIR threshold. **Below** every published RCT arm.*

12-Month Primary Efficacy Results



TLPP % achieved across diverse patient populations

Intent-to-Treat Analysis Patient Cohorts for Subgroup Analysis (FLEX + PTA)

Patient Subgroup		*N*
All	Complete study population	**130**
AVF	Arteriovenous fistula subgroup	**97**
AVG	Arteriovenous graft subgroup	**32***
CA	Cephalic arch lesion subgroup	**35**

These cohorts enable comparative analysis of outcomes across different access types and lesion locations.

* One patient did not complete the procedure and thus not counted via Kaplan-Meier analysis.

Cephalic Arch — Where FLEX Separates

The highest-failure lesion in vascular access — and where mechanical prep changes the math

39.8%

FLEX FIRST AV Cephalic Arch TLPP at 12 Months

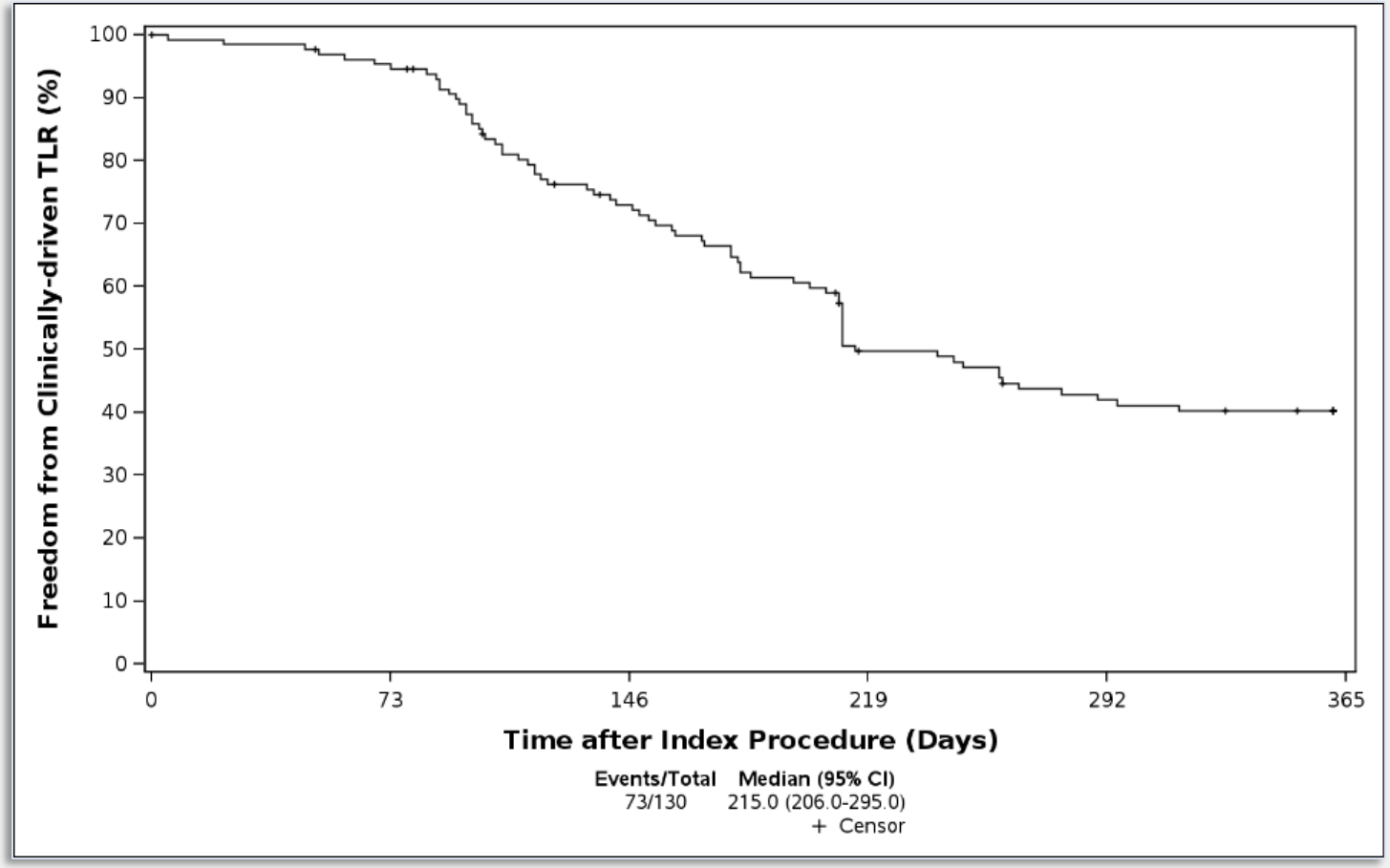
N = 35

Historical Context

0 – 23% 12-month TLPP with standard PTA alone (D'Cruz et al. JVA 2018)

Nearly **2× the best historical PTA benchmark**.
No drug. No implant. No stent to fracture or migrate.

Freedom from Clinically Driven TLR



The Kaplan-Meier analysis provides time-to-event data that illustrates the durability of the FLEX Vessel Prep System combined with PTA. The relatively flat slope of the curve in the later follow-up period suggests potential for continued patency beyond the 6-month timepoint.

Key Findings

- **40%+ freedom** from CD-TLR at 12 months
- Most failures occurred within the **first 6 months**
- **Curve stabilizes** in the second half — suggesting durable benefit
- **Consistent** across AVF and AVG subgroups

Secondary Patency — Preserving Access

Every saved access = one less catheter, one less infection risk, one more future option

Cohort	N	6 Month	12 Month	Historical PTA 12m
All Patients	129	96.9%	**91.5%**	—
AVF	97	95.9%	88.7%	85–95%
AVG	32	**100%**	**100%**	75–90%
Cephalic Arch	35	94.3%	88.6%	70–85%

Strong Secondary Patency esp. in AVG's & Cephalic Arch

Reintervention Reduction

1

Fewer intervention per patient per year

Before FLEX	**~2.5/yr**
With FLEX	**~1.5/yr**

Derived from 12-Mos FLEX FIRST Registry data |

What Does One Fewer Intervention Mean?

If every US hemodialysis access patient experienced one fewer intervention per year:

325,000
fewer interventions
(AV Access Patients / Yr.)

$1.6–2.6B
in system savings
($5 – 8K per intervention)

Zero
additional risk

The economic case writes itself:
reduce procedures, reduce risk, reduce cost.

Source: USRDS 2024 Annual Data Report. PubMed 39396752

Conclusions

Primary endpoint at 6 months was substantially achieved
Published in JVS (Kramer et al., 2025)

12-month data confirms durability
Strong overall, AVG, and cephalic arch performance

Zero serious adverse events
130 patients, 4 centers, all comers, 12 months

One fewer intervention per patient per year
Reduction from ~2.5 to ~1.5 — across all sites

A real-world, all-comers registry
No exclusions for prior stents, DCB, or grafts

FROM MY PRACTICE

The data confirms what I see every day.

I have access to every product at any price point.

90–95% of my interventions begin with FLEX.

I don't climb the escalation ladder with near the frequency I did in my twenty years as an access surgeon.

My days are quicker. My schedule is predictable. My patients stay out of the hospital.

Questions

References & Endpoint Definitions

References

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Endpoint Definitions

TLPP
Freedom from clinically-driven target lesion revascularization (CD-TLR) or access thrombosis

Technical Success
Successful device delivery, deployment, and retrieval

Anatomic Success
Post-procedure stenosis ≤30% per visual assessment

Secondary Patency
Freedom from abandonment of the vascular access circuit