VentureMed®

FLEX™ VESSEL PREP

# FLEX First AV Registry 6-month Results

# Study Overview

- **Objective**: Assess safety and efficacy of the FLEX Vessel Prep (VP) System in combination with standard PTA.
- **Design**: Multi-center observational registry with 130 subjects.
- Sites:  4 sites
- **Population**: Hemodialysis patients with AVF/AVG presenting with vascular access dysfunction.
- **Follow-Up**: 1, 6, and 12-month follow-up visits.

# Study Endpoints

- **Primary Endpoint**: Target Lesion Primary Patency (TLPP) at 6 months, freedom from CD-TLR or access thrombosis.
- **Primary Safety Endpoint**: Freedom from Serious Adverse Events (SAEs) through 1 month.
- **Secondary Endpoints**: Anatomic success, procedural success, clinical success, and circuit patency at 6 and 12 months.

# Inclusion Criteria

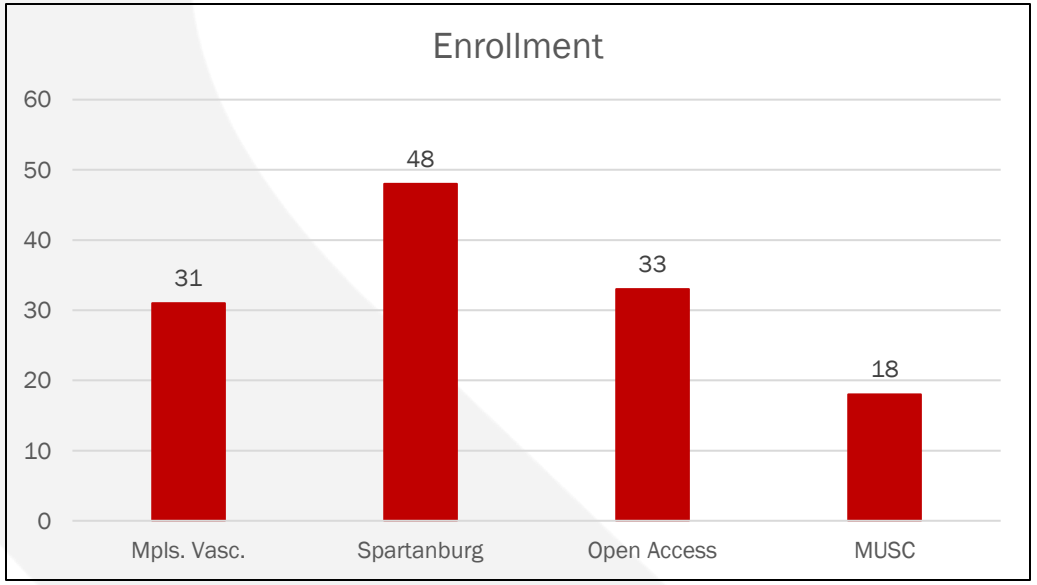
1. Subject is ≥18 years of age.
2. Subject is currently scheduled to undergo an endovascular intervention of arteriovenous fistula or graft due to clinical and hemodynamic abnormalities meeting the KDOQI Guidelines for AV access dysfunction:
   - Elevated venous pressure during hemodialysis,
   - Abnormal physical findings, and
   - Unexplained decrease in delivered dialysis dose.
3. Subject has a reasonable expectation of remaining on hemodialysis for ≥12 months.
4. Subject is legally competent, informed of the study, voluntarily agrees to participate, and signs the informed consent form.
5. Subject understands the study and is willing and able to comply with the follow-up requirements.

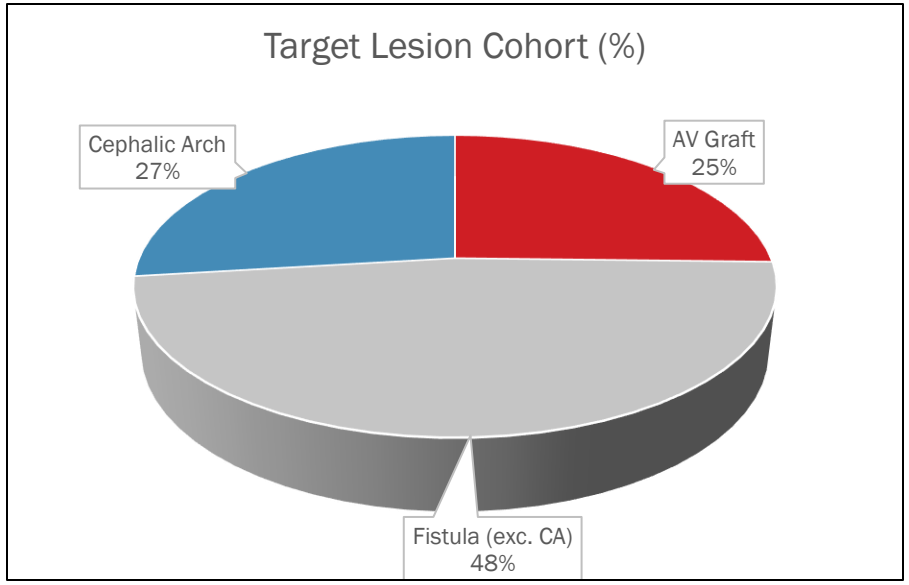
# Exclusion Criteria

1. Subject has a known or suspected systemic infection.
2. Subject has a known or suspected infection of the hemodialysis graft.
3. Subject has an untreatable allergy to radiographic contrast material.
4. In the opinion of the operating physician, the subject's hemodialysis access is unsuitable for endovascular treatment.

# Overview of Enrollments

- 130 patients enrolled
- Number of target lesion treated = 130
- Total number of lesions treated = 176
- 35% of patients had secondary lesions
- 4 clinical sites



# Patient Demographics & Stratification

- Demographics:  Gender, race, and lesion location analysis.
- Stratification: AV Graft, AV Fistula with Cephalic Arch Stenosis, African American, Female.
- Enrollment Goals:
  - ✓ 35% Black/African American
  - ✓ 30% Female
  - ✓ 20% AV Graft,
  - ✓ 20% Cephalic Arch Stenosis

# Patient Demographics

FLEX First Registry

| Variable | 130 Subjects |
|---|---|
| Age (years) | 66.4 ± 12.1 (130)<br>27.0 - 87.0 |
| Gender | |
| Female | 48/130 (37%) |
| Male | 82/130 (63%) |
| Race | |
| American Indian or Alaska Native | 1/130 (0.8%) |
| Pacific Islander | 1/130 (0.8%) |
| Not Reported/Other | 6/130 (4.6% |
| Asian | 2/130 (1.5%) |
| Black or African American | 78/130 (60.0%) |
| White | 42/130 (32.3%) |
| Smoking History | |
| Current | 11/130 (8.5%) |
| Never | 77/130 (59.2%) |
| Past | 42/130 (32.3%) |

Original Registry

| Variable | 114 Subjects |
|---|---|
| Age (years) | 63.3 ± 12.7 (114)<br>31.0-88.0 |
| Gender | |
| Female | 61/114 (53.5%) |
| Male | 53/114 (46.5%) |
| Race | |
| American Indian or Alaska Native | 2/114 (1.8%) |
| Asian | 1/114 (0.9%) |
| Black or African American | 75/114 (65.8%) |
| White | 36/114 (31.6%) |
| Smoking History | |
| Current | 17/114 (14.9%) |
| Never | 60/114 (52.6%) |
| Past | 37/114 (32.5%) |

# Medical History

FLEX First Registry

| Variable | 130 Subjects |
|---|---|
| Diabetes | 84/130 (65%) |
| Hypertension | 124/130 (95%) |
| Congestive Heart Failure | 38/130 (29%) |
| Prior AV Access Interventions (count) | 4.2 ± 4.1 (127)<br>0.0-26.0 |
| Years since AV Access Creation (years) | 3.7 ± 3.9 (130)<br>0.0 - 29.0 |
| Years since Started Hemodialysis (years) | 3.3 ± 3.8 (130)<br>0.0 -29.0 |
| Days since last dialysis (days) | 1.3 ± 0.7 (130)<br>0.0-5.0 |

Original Registry

| Variable | 114 Subjects |
|---|---|
| Diabetes | 71/114 (62.3%) |
| Hypertension | 105/114 (92.1%) |
| Congestive Heart Failure | 44/114 (38.6%) |
| Prior AV Access Interventions (count) | 4.9 ± 5.8 (104)<br>0.0-29.0 |
| Years since AV Access Creation (years) | 3.1 ± 2.6 (114)<br>0.1-13.9 |
| Years since Started Hemodialysis (years) | 4.7 ± 4.0 (114)<br>0.1-19.3 |
| Days since last dialysis (days) | 2.3 ± 11.1 (113)<br>0.0-119.0 |

# Access Characteristics

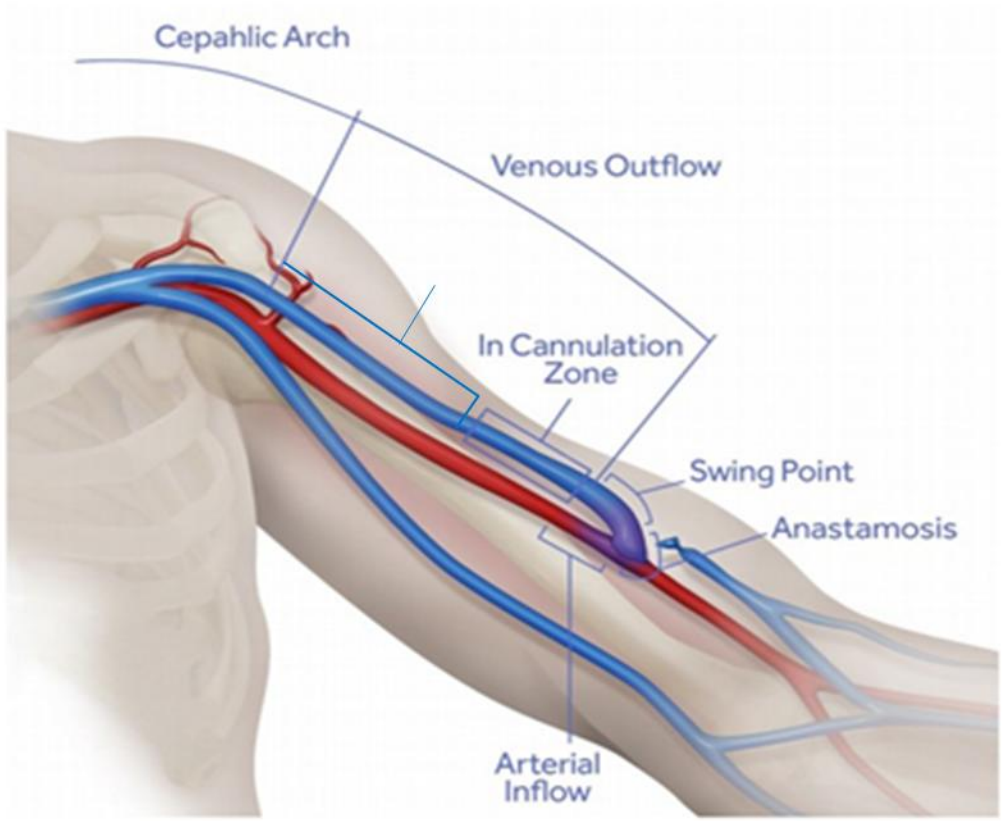
| Variable | 130 Subjects |
|---|---|
| **Fistula Type** | |
| Arteriovenous Fistula | 97/130 (75%) |
| Arteriovenous Graft | 33/130 (25%) |
| **Location** | |
| Forearm | 22 (17%) |
| Upper Arm | 108 (83%) |

| Access Sites- Detailed | 130 Subjects |
|---|---|
| Brachial-Basilic Fistula | 27/130 (23.7%) |
| Brachial-Cephalic Fistula | 48/130 (32.5%) |
| Radial-Cephalic Vein Fistula | 22/130 (2.6%) |
| Radial-Cephalic Graft | 1/130 (0.8%) |
| Radial-Basilic Graft | 2/130 (1.5%) |
| Brachial-Basilic Graft | 18/130 (13.8%) |
| Loop Graft | 2/130 (1.5%) |
| Graft, other | 10/130 (7.7%) |

# Lesion Characteristics

| Variable | 130 Subjects |
|---|---|
| **Target Vessel Diameter (mm)** | 8.1 ± 1.1 (130) |
| **Number of Lesions** | |
| 1 | 84/130 (64.6%) |
| 2 | 39/130 (30%) |
| 3 | 6/130 (4.6%) |
| 4 | 1/130 (0.8%) |
| **Target Lesion Location** | |
| Anastomosis | 8/130 (6.2%) |
| Cannulation Zone (Up to 1st large collateral vein) | 18/130 (13.8%) |
| Cephalic Arch | 35/130 (26.9%) |
| Inflow (2 cm from Anastomosis) | 1/130 (0.8%) |
| Outflow (Above Cannulation Zone) | 29/130 (22.3%) |
| Swing Segment | 8/130 (6.2%) |
| Other | 31/130 (23.8%) |
| **Target Lesion Length (mm)** | 29 ± 21 (130) |
| **Target Lesion Pre-Procedure Stenosis (%)** | 75.4 ± 14.6 (130) |

Original Registry
Target Vessel Diameter = 7.8 mm




Original Registry
Target Lesion length= 21 mm
Pre-procedure stenosis = 75.2

# Procedure Characteristics

| Variable | 130 Subjects |
|---|---|
| Technical Success | 100% |
| Target Lesion FLEX passes (count) | 4.8 ± 0.9 (130)<br>3.0-6.0 |
| Target Lesion Post PTA Stenosis (%) | 15.3 ± 16.0 (130)<br>0.0-95.0 |
| No. of balloon Used | |
| 1 | 114/130 (87.7%) |
| 2 | 14/130 (10.8%) |
| 3 | 2/130 (1.5%) |

| Variable | 130 Subjects |
|---|---|
| Largest PTA Diameter (mm) | 8.5 ± 5.5<br>5.0 - 10.0 |
| Largest PTA Length (mm) | 52.4 ± 19.0 (114)<br>6.0 - 100.0 |
| Maximum Pressure (atm) | 19.5 ± 4.3<br>8.0 - 32.0 |
| Maximum Effacement Pressure (atm) | 10 ± 5.9 |

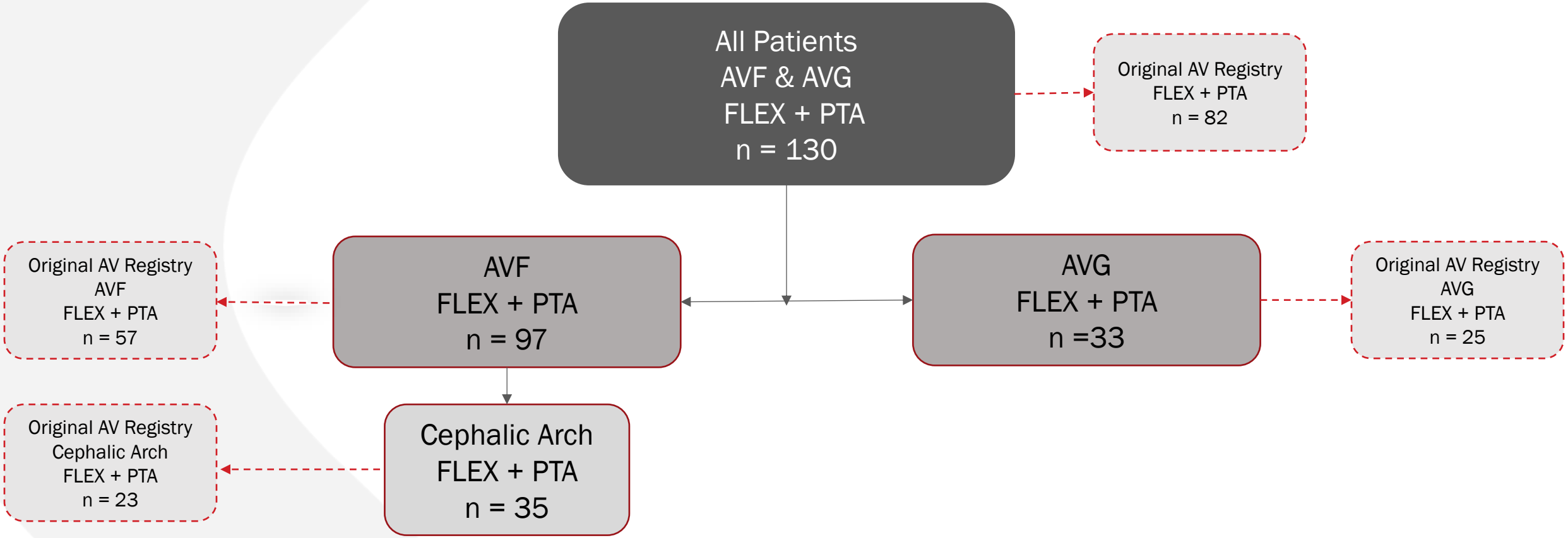
**Original AV Registry**

- FLEX Passes = 5.1
- Max Pressure = 15.2 Atm
- Max Effacement = 9.5 Atm

# Primary Efficacy Results

- 129/130 target lesions were considered for the Kaplan-Meier estimate
  - 1 subject did not contribute to any follow-up analysis
- Patients analyzed in following cohorts
  - All
  - AVFs
  - AVGs
  - Cephalic Arch target lesions
- Statistical Analysis
  - Freedom from Clinically Driven TLR estimation via Kaplan-Meier analysis at 6-months (180 days)

# Patient Cohorts



# Primary Safety Results

- **Primary Safety Endpoint**: Freedom from Serious Adverse Events (SAEs) through 1 month.

  NO (0%) Serious Adverse Events Reported through 1 month FU

- Procedure Complications

| Classification | Reported Complication | Number | Reported Cause | Treatment | % | JVIR Quality Improvement Guideline[1] Thresholds |
|---|---|---|---|---|---|---|
| Major | None | 0 | N/A | N/A | 0% | 2% (AVF) 7% (AVG) |
| Minor | Dissection | 1 | Angioplasty | 1 – Stent Graft | 0.8% | 8% (AVF) 4% (AVG) |

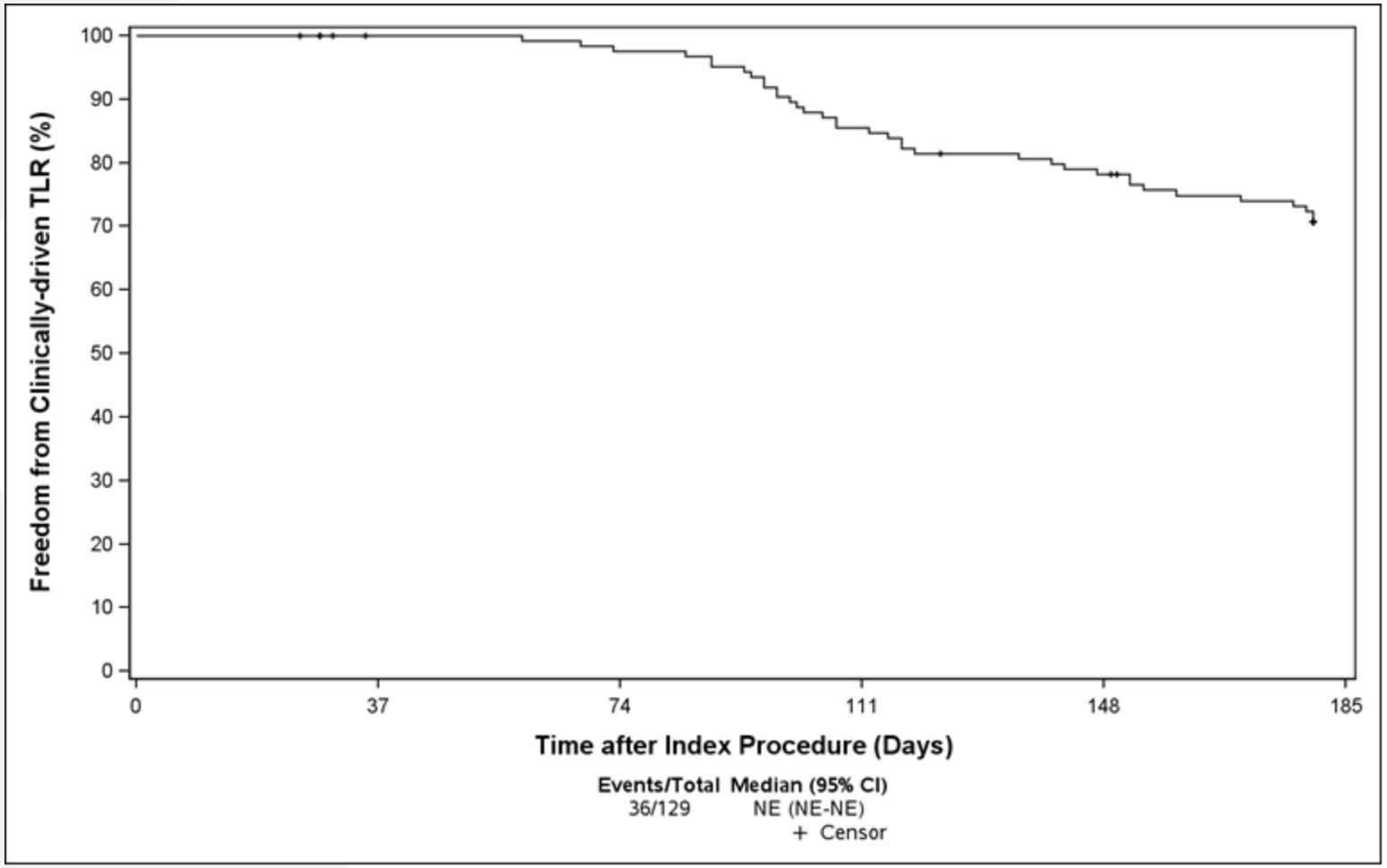
**Original AV Study**

- No (0) SAE/Major Complications
- 5 Minor Complication (rate = 4.3%)
  - 4 Dissections
  - 1 Balloon Burst

# 6-month Primary Efficacy – Target Lesion Primary Patency FLEX + PTA

| Cohort | TLPP<br>FLEX First AV Registry<br>FLEX + PTA | N |
|---|---|---|
| ALL | 70.7% | 129 |
| AVF's | 75.6% | 97 |
| AVG's | 55.2% | 32 |
| Cephalic Arch | 76.3% | 35 |

# Kaplan-Meier Curve – All Patients
# Freedom from Clinically-driven TLR through 6 Months



# 6-month Primary Efficacy – Target Lesion Primary Patency FLEX + PTA

| Cohort | TLPP FLEX First AV Registry FLEX + PTA | N | | TLPP FLEX AV Registry FLEX + PTA Only[1] | N | TLPP Historical PTA[1] |
|---|---|---|---|---|---|---|
| ALL | 70.7% | 129 | | 63.7% | 82 | 8 – 34% |
| AVF's | 75.6% | 97 | | 70.6% | 57 | 21% – 55% |
| AVG's | 55.2% | 32 | | 46.6% | 25 | 5.7% – 24.2% |
| Cephalic Arch | 76.3% | 35 | | 69.3% | 23 | 8% – 51.6% |

[1]Aruny et al, Longitudinal microincision creation prior to balloon angioplasty for treatment of arteriovenous access dysfunction in a real-world patient population: 6-month cohort analysis. *Hemodialysis International*. 2023

# Additional Endpoints – Anatomic, Clinical & Procedural Success

| Additional Endpoints -- Anatomic Success | |
|---|---|
| Anatomic Success[1] | 125/130 (96.2%) |
| The anatomic success will be described as the percent of subjects achieving a percentage of stenosis post-procedure of 30% or less per visual assessment of angiographic images. | |

| Additional Endpoints -- Clinical Success | |
|---|---|
| Clinical Success[1] | 129/130 (99.2%) |
| [1]Clinical success will be summarized as the percent of subjects resuming normal dialysis for at least one session | |

1 patient exited study 1 day after procedure – clotted access (pt. 4-024)

| Additional Endpoints -- Procedural Success | |
|---|---|
| Procedural Success[1] | 124/130 (95.4%) |
| [1]Procedural success will be calculated using the percent of subjects who achieve a composite of anatomic and clinical success. | |

# Additional Endpoints – Technical Success, Circuit Patency & Access Secondary Patency

| Additional Endpoints -- Technical Success | |
|---|---|
| Technical Success[1] | 130/130 (100.0%) |
| [1]Technical success of the device will be described as the percent of subjects who have the FLEX VP System successfully delivered, deployed, and retrieved at and to the Target Lesion during the index procedure. | |

| Table 7.2.6 Additional Endpoints -- Circuit Primary Patency | |
|---|---|
| Circuit Primary Patency through 6-months | 70/130 (53.8%) |
| Circuit Primary Patency will be assessed by the percent of subjects who are free from re-intervention or vascular thrombosis in the vascular access circuit through 6-months post-procedure. | |

Original AV Registry
Circuit Patency = 54.1%

| Table 7.2.7 Additional Endpoints -- Access Secondary Patency | |
|---|---|
| Access Secondary Patency through 6-months | 127/130 (97.7%) |
| Access Secondary Patency is described as the percent of subjects free from abandonment of the vascular access circuit through 6-months. | |

| Additional Endpoints -- Number of Stents Used | |
|---|---|
| Total Number of Stents Used | 1 |

# Summary

- Highly complex, “Real World” patient population … again
- No (0%) Serious Adverse Events
- Sub-20 ATM MAX Balloon Pressures required (15.5 & 19.5)
- Even more impressive 6-mo patency results than Original AV Registry
  - Highlighted by 76% Cephalic Arch patency at 6-mos