# Does Vessel Prep Make a Difference?

## AVAFLEX Study 6 Month Results

**JOHN ROSS, MD**

**Medical Director, The Regional Medical Center**

**Orangeburg, SC**

16TH ANNUAL CiDA

Controversies in Dialysis Access

# Resistant Stenosis & Restenosis in AVF/AVG

## Problem:

- Failure of fistulas remains a significant issue and costs the healthcare system $2B annually[1]

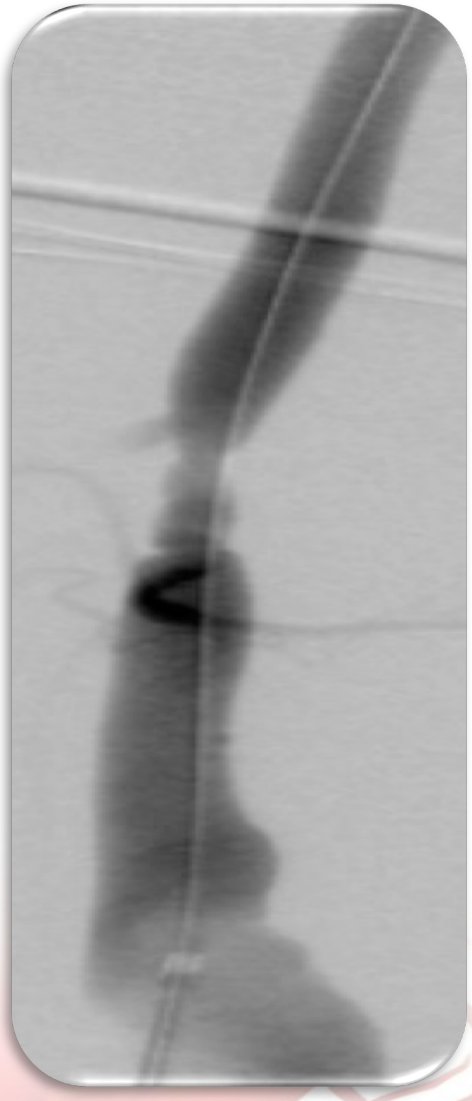
## Results: (Tretotola et al, JVIR, 2005):

- 55% of Lesions require pressures greater than 15 atm to efface the waist
- Primary patency AVF/AVG through 12 months: 48-80% 24 months: 50-80% (Holden CIRSE 2019)

1 USRDS: USRDS 2010 Annual Data Report: Atlas of Chronic KidneyDiseaseandEnd-StageRenalDiseaseintheUnitedStates, Bethesda, MD,National InstitutesofHealth,National Instituteof Diabetes and Digestive and Kidney Diseases, 2010

# Primary Patency of PTA in AV Access

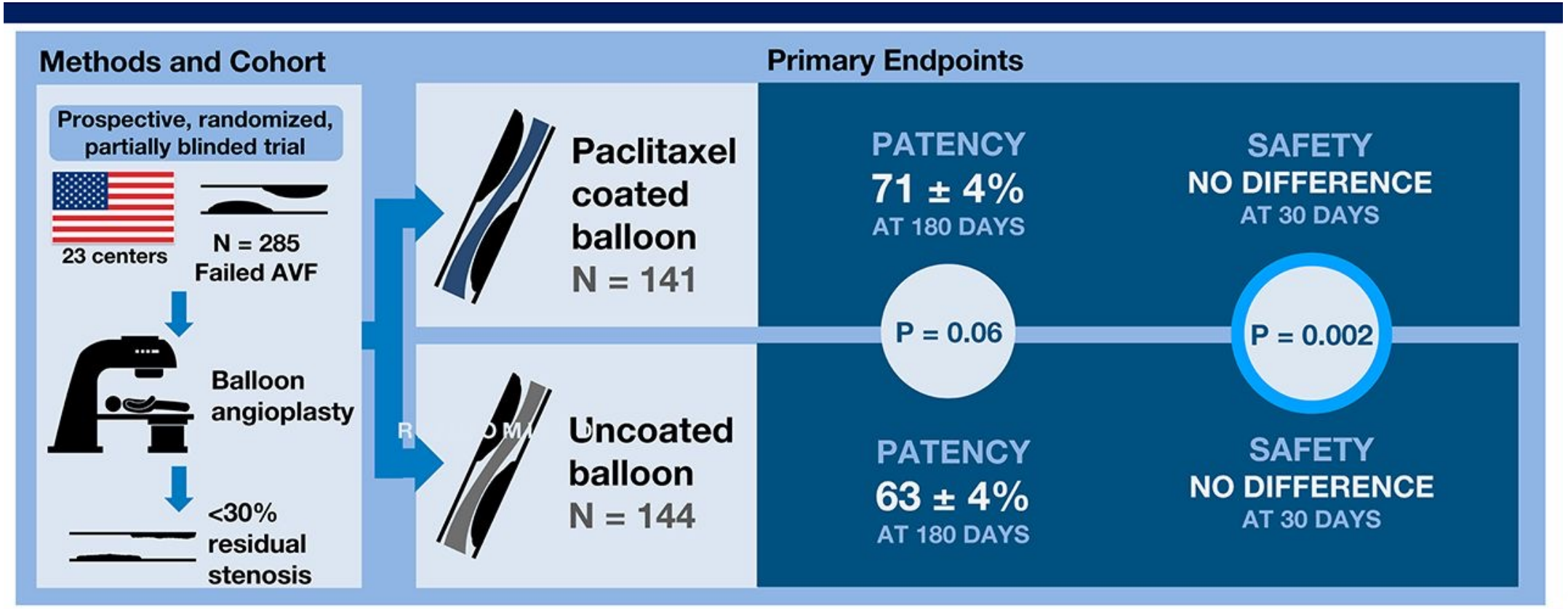
| Study Year | Primary Patency Reported Rates | | | Source |
|---|---|---|---|---|
| | 6 months | 12 months | 24 months | |
| **2000** | **67%** Forearm AVF | **51%** Forearm AVF | **37%** Forearm AVF | Turmel-Rodrigues et al. 2000, n=220 dysfunctional AVF |
| **2004** | **61%** After PTA in AVFs | **42%** After PTA in AVFs | **35%** After PTA in AVFs | Bountouris et al., 2014, n=159 PTA AVF's |



**Most other studies have reported similar primary patency rates of ~ 40–50 % at 1 year[1-3]**


1. Rajan DK, Bunston S. Dysfunctional autogenous hemodialysis fistulas: outcomes after angioplasty – are there clinical predictors of patency? Radiology. 2004;232:508–15.
2. Manninen HI, Kaukanen ET. Brachial arterial access: endovascular treatment of failing Brescia-Cimino hemodialysis fistulas – initial success and long-term results. Radiology. 2001;218:711–8.
3. Heye S, Maleux G. Factors influencing technical success and outcome of percutaneous balloon angioplasty in de novo native hemodialysis arteriovenous fistulas. Eur J Radiol. 2012;81:2298–303. doi: 10.1016/j.ejrad.2011.09.004.

# Lutonix DCB in AVF vs PTA




**Conclusions** Paclitaxel-coated balloon angioplasty did not meet the primary effectiveness endpoint at 180 days compared to conventional angioplasty. Both arms demonstrated equivalent safety.

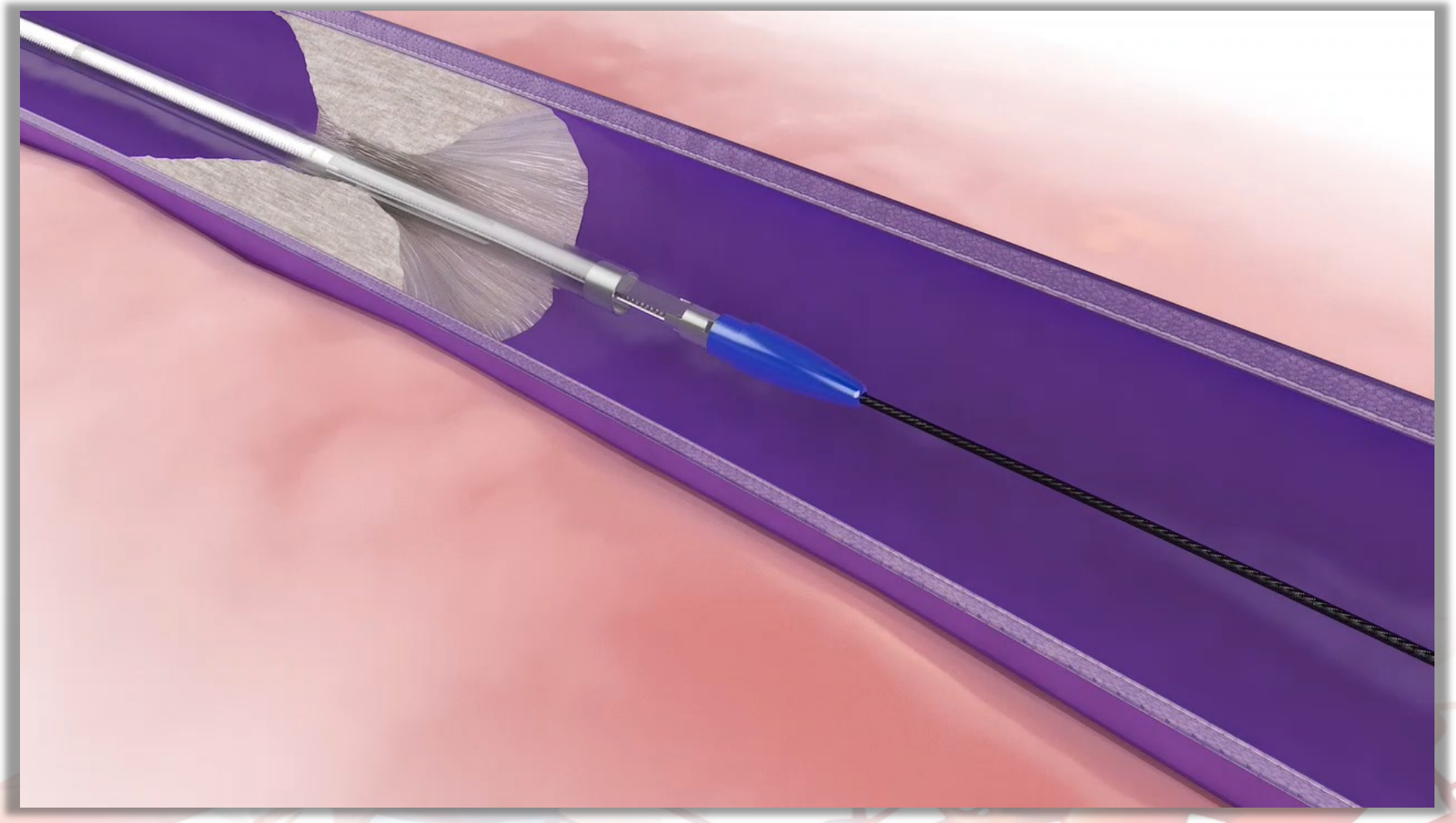
Scott Trerotola, Jeffrey Lawson, Prabir Roy-Chaudhury, and Theodore Saad, for the Lutonix AV Clinical Trial Investigators. ***Randomized Trial of Drug Coated Balloon Angioplasty in Failing AV Fistulas***. CJASN doi: 10.2215/CJN.14231217

Scott O. Trerotola et al. CJASN 2018;13:1215-1224

# Why Vessel Prep Prior to Angioplasty in AV Access?

- PTA has significant limitations:
  - Elastic recoil
  - Resistant hyperplasia – even with ultra high-pressure balloons
- Vessel prep along the entire length of stenosis:
  - Improves vessel compliance
  - Eliminates the need for high pressure balloons
  - Minimizes barotrauma that may extend primary patency or time to reintervention

# FLEX Vessel Prep™ System – AV



# FLEX Vessel Prep™ System - Dual MOA

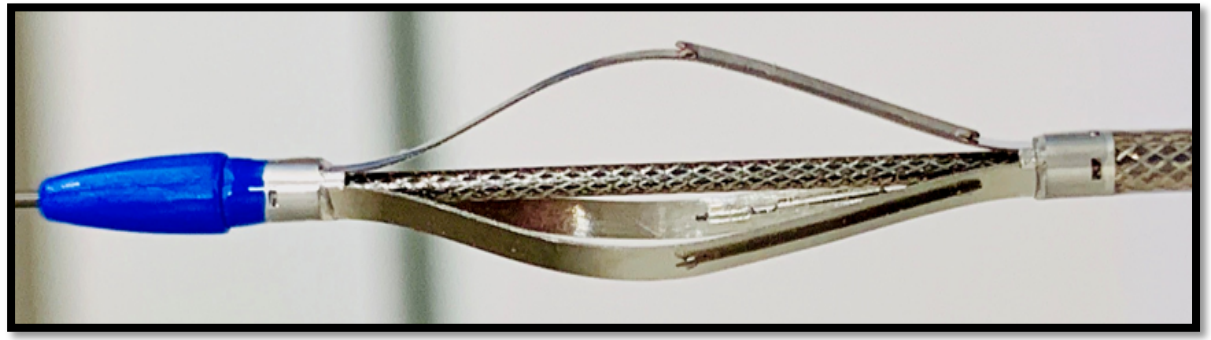
## Longitudinal Micro-incisions Combined With Radial Expansion Force

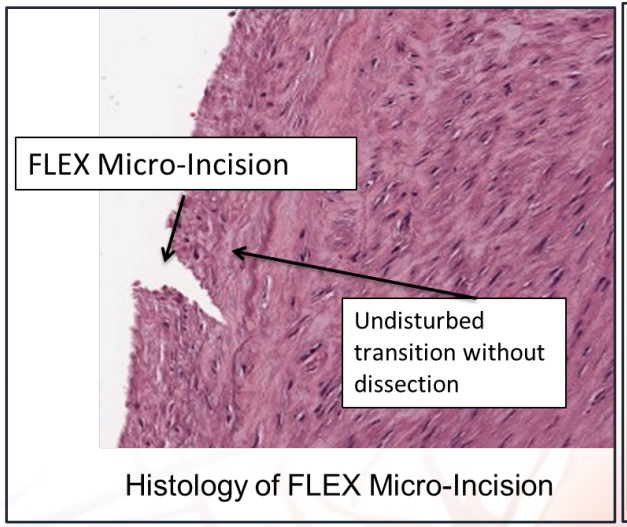
**Controlled, parallel micro-incisions**

**Radial expansion force**

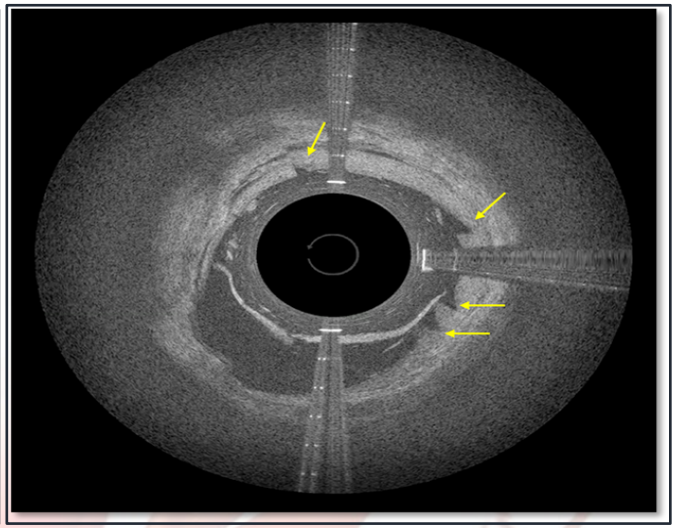
**3 protective "atherotome-mounted" skids**

- Proprietary depth control "flexes" to guide along the contour of the lesion






Histology of FLEX Micro-Incision

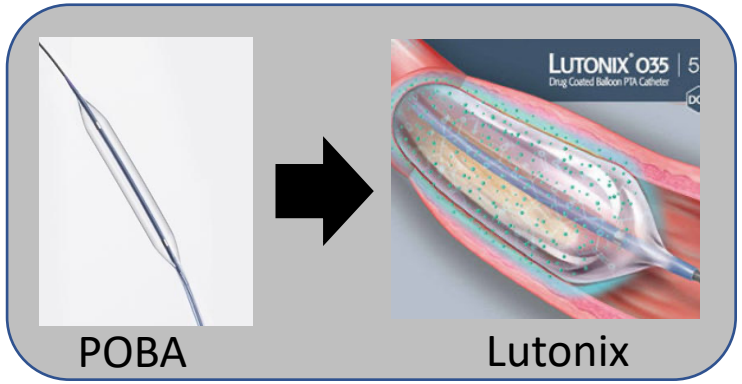


Optical Coherence Tomography of FLEX Micro-Incision

# DCB Studies In AVF/AVG

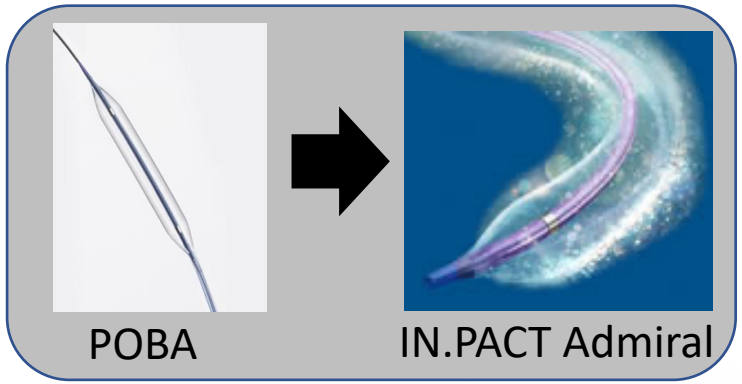
## Lutonix IDE Study:

- Multicenter
- Randomized
- Prospective



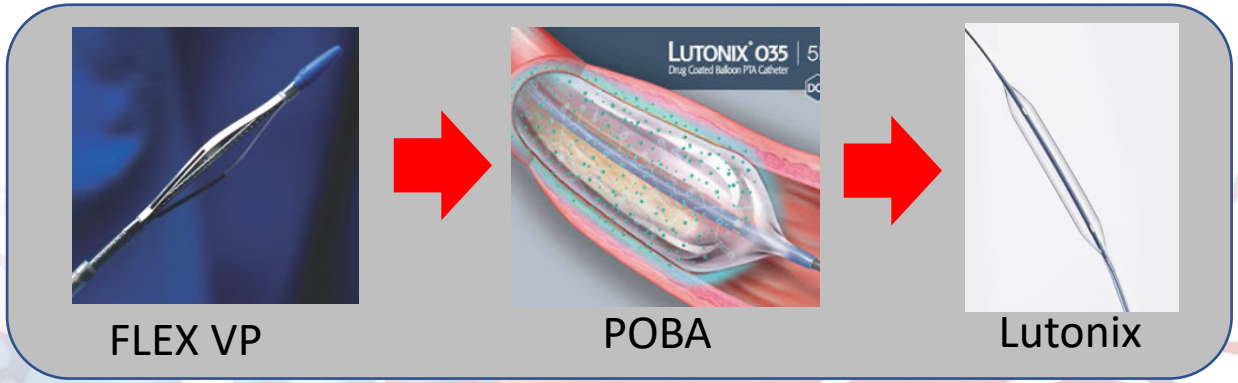

## IN.PACT AV Access IDE Study:

- Multicenter
- Randomized
- Prospective

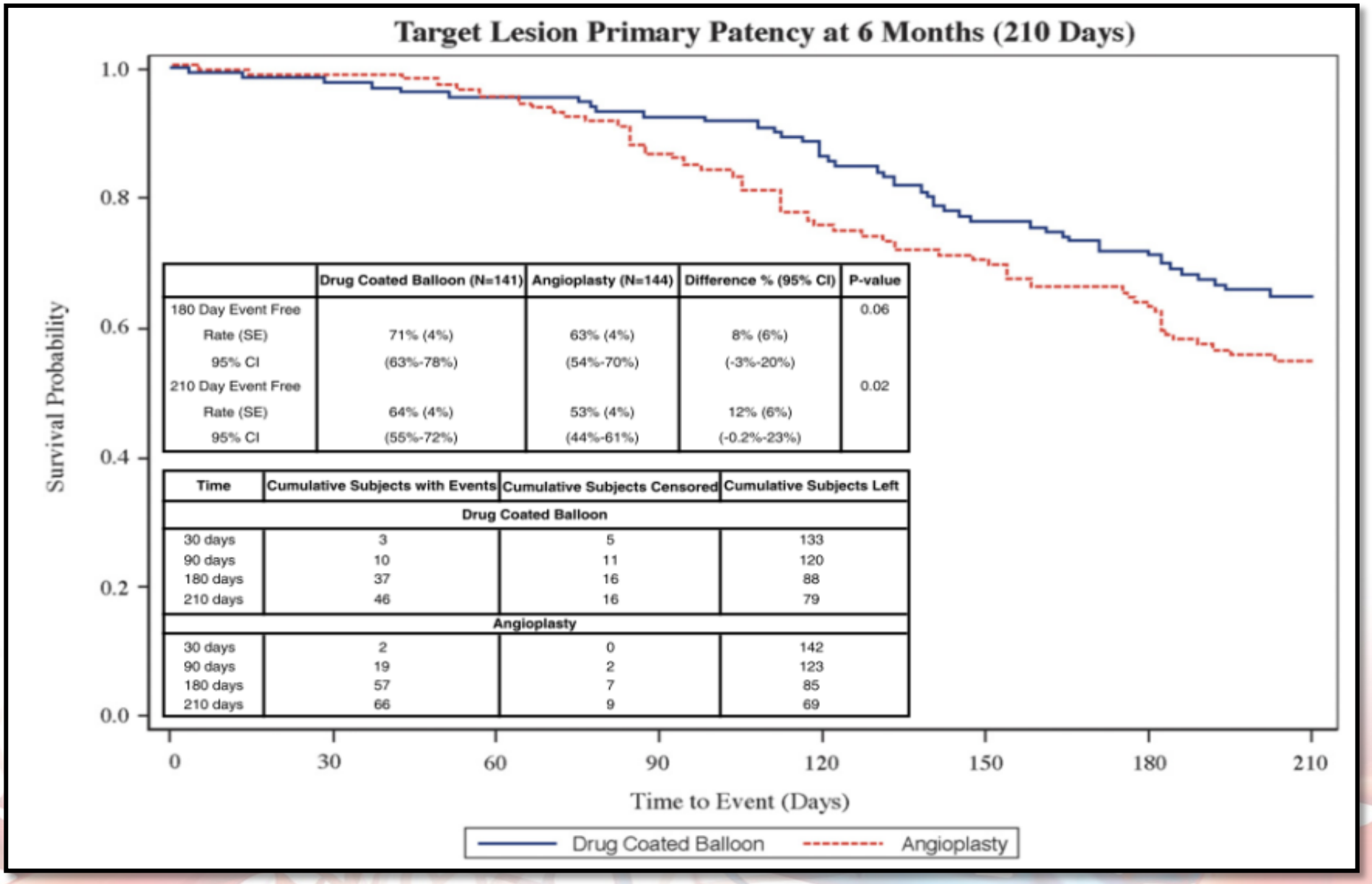



## AVAFLEX Study:

- Single Center
- Single Arm
- Prospective



# Lutonix AV IDE - 6 Month Data




| | Drug Coated Balloon (N=141) | Angioplasty (N=144) | Difference % (95% CI) | P-value |
|---|---|---|---|---|
| 180 Day Event Free | | | | 0.06 |
| Rate (SE) | 71% (4%) | 63% (4%) | 8% (6%) | |
| 95% CI | (63%-78%) | (54%-70%) | (-3%-20%) | |
| 210 Day Event Free | | | | 0.02 |
| Rate (SE) | 64% (4%) | 53% (4%) | 12% (6%) | |
| 95% CI | (55%-72%) | (44%-61%) | (-0.2%-23%) | |

| Time | Cumulative Subjects with Events | Cumulative Subjects Censored | Cumulative Subjects Left |
|---|---|---|---|
| **Drug Coated Balloon** | | | |
| 30 days | 3 | 5 | 133 |
| 90 days | 10 | 11 | 120 |
| 180 days | 37 | 16 | 88 |
| 210 days | 46 | 16 | 79 |
| **Angioplasty** | | | |
| 30 days | 2 | 0 | 142 |
| 90 days | 19 | 2 | 123 |
| 180 days | 57 | 7 | 85 |
| 210 days | 66 | 9 | 69 |

**6 Month Lutonix Target Lesion Patency: 71%**

Source: lutonixdcb.com/av-treatment

Trerotola SO, Lawson J, Roy-Chaudhury P, Saad TF, et al. Drug Coated Balloon Angioplasty in Failing AV Fistulas: A Randomized Controlled Trial. ClinJ Am SocNephrol2018;13:1215-1224.

# AVAFLEX Study

## FLEX - Drug Coated Balloon Dialysis ACCESS Stenosis Study

**Start Date:** May 2018

**Lead Investigator:** John Ross, MD, FACS

**Investigator Location:** **Dialysis Access Institute** Orangeburg, South Carolina

**Study Objective:** To evaluate the efficacy of the FLEX Vessel Prep™ System with a Drug Coated Balloon (DCB) in the maintenance of arteriovenous access

Similar Key Inclusion/Exclusion Criteria to Lutonix IDE Trial.

# AVAFLEX Demographics

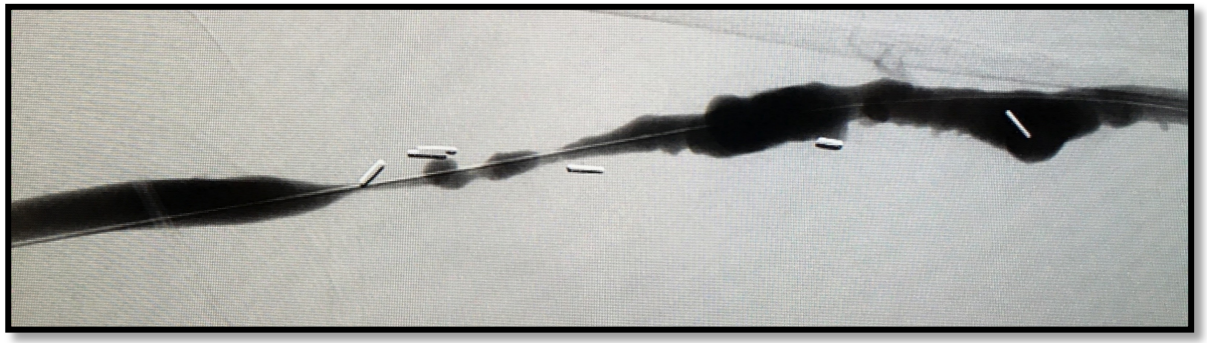
| Characteristic | Mean ± SD or n (%) (N=34) |
|---|---|
| Gender | |
| Female | 13 (38.2%) |
| Male | 21 (61.8%) |
| Age | 60.4 ± 11.0 |
| Smoker | 3 (8.8%) |
| Hypertension | 33 (97.1%) |
| CAD | 13 (38.2%) |
| Congestive HF | 14 (41.2%) |
| Diabetes | 17 (50.0%) |

| Characteristic | Mean ± SD or n (%) (N=34) |
|---|---|
| Type | |
| AVF | 31 (91.2%) |
| AVG | 3 (8.8%) |
| # Prior Intervention | |
| 0 | 12 (35.3%) |
| 1 | 6 (17.6%) |
| 2 | 8 (23.5%) |
| 3 | 2 (5.9%) |
| 4 | 1 (2.9%) |
| 5 | 1 (2.9%) |
| ≥6 | 4 (11.8%) |

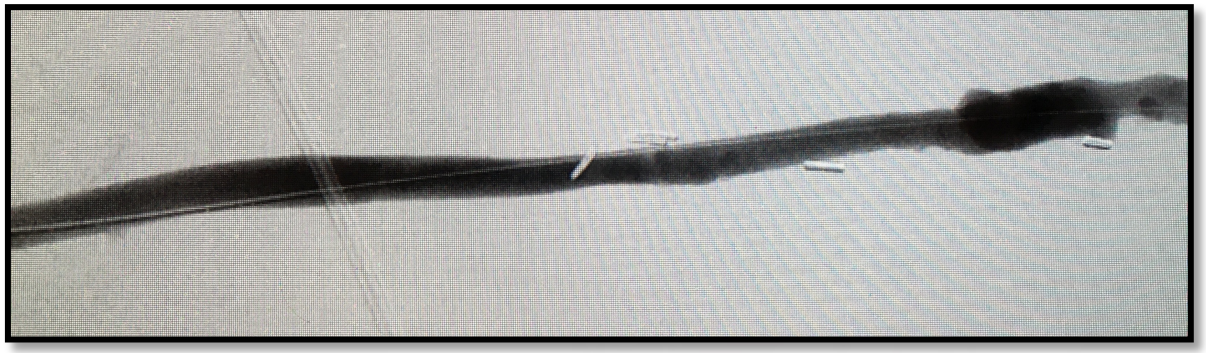
# AVAFLEX Procedural Characteristics

| Procedural Characteristics | |
|---|---|
| Target Vessel Diameter (mm) | 8.7 ± 1.1 |
| Target Lesion Length (cm) | 2.3 ± 2.6 |
| Cephalic Arch Lesion | 52.9% (18/34) |
| Pre-Stenosis | 79.9 ± 9.9 |
| Post FLEX Lumen Gain | 19.1 ±20.1 |
| Post Procedure Stenosis | 7.4 ± 6.6 |
| Device Success* | 100% (34/34) |

*Device Success is defined as the successful delivery to the target lesion, deployment of the treatment element, and retrieval at the index procedure.

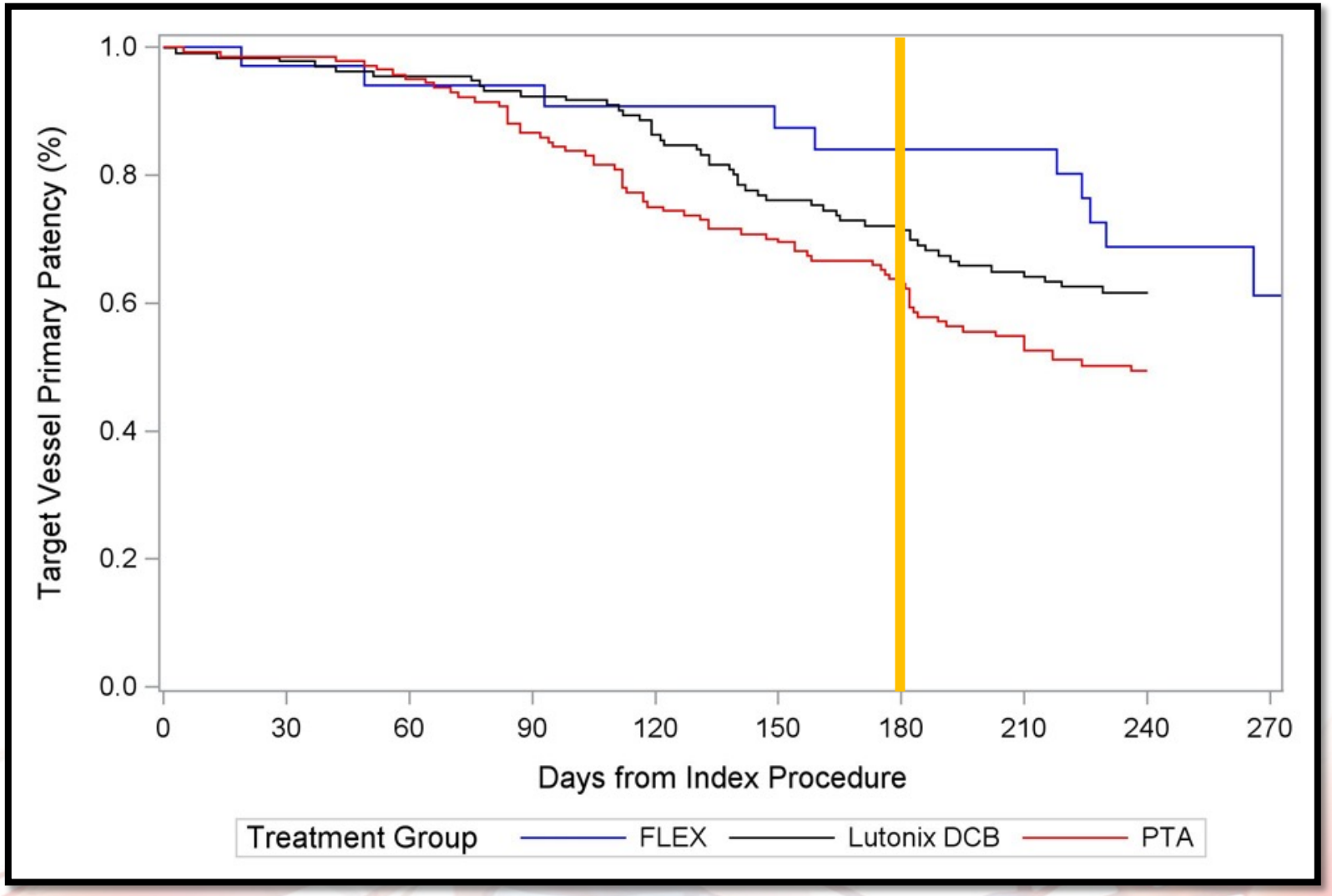


**Pre-Fistulagram**



**Post-FLEX + Lutonix DCB Fistulagram**

# 6 Month Target Lesion Patency



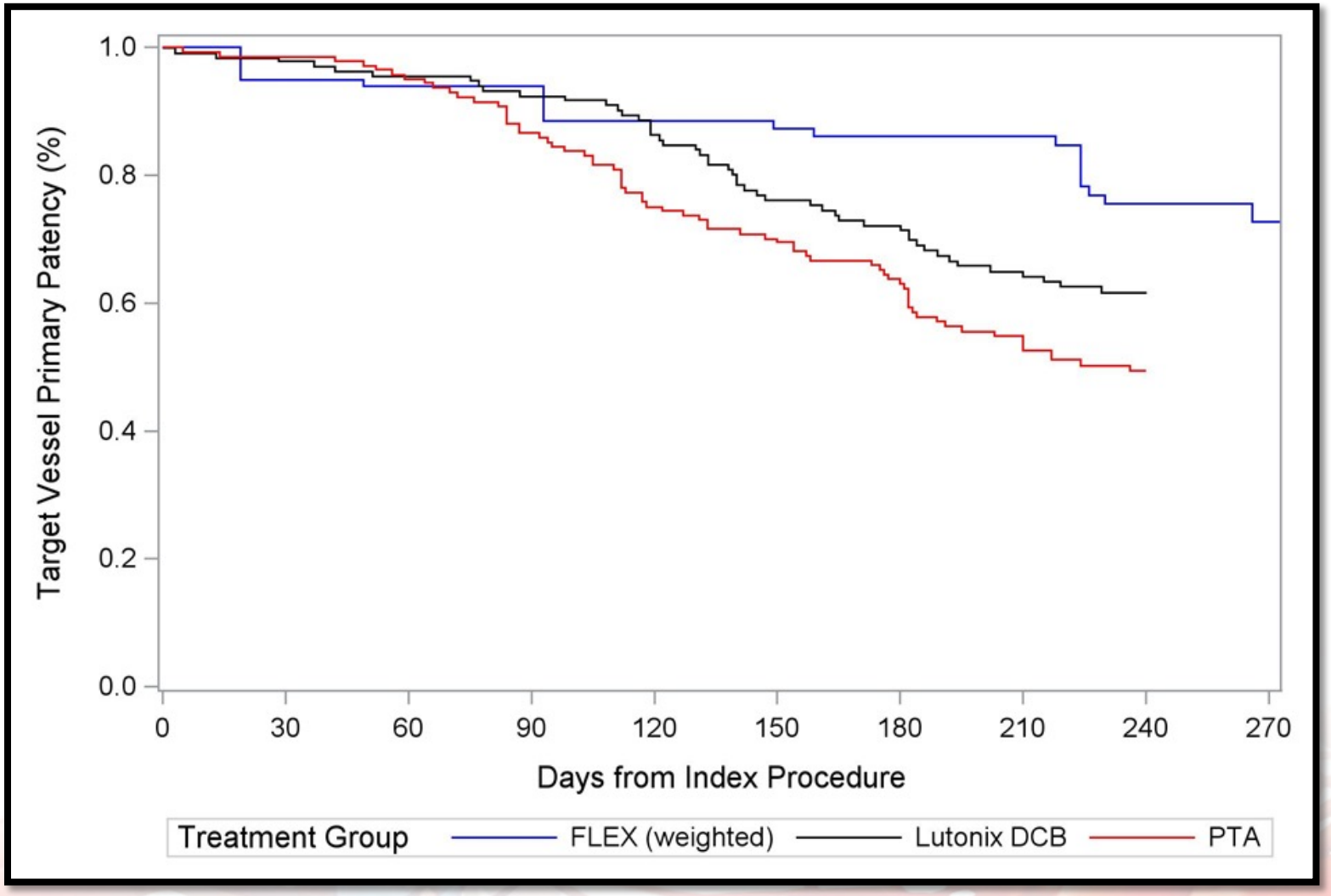

**AVAFLEX**
**(FLEX + Lutonix DCB)**
**Target Lesion Patency:**
**84.1%**

**Lutonix DCB**
**Target Lesion Patency:**
**71%**

**Lutonix POBA**
**Target Lesion Patency:**
**63%**

# AVAFLEX Data

## Re-Weighted per Lutonix Lesion Population




Time to target vessel re-intervention by device – FLEX re-weighted per Lutonix Lesion Location Population
Cephalic arch strata weighted 18.7% (versus original population percentage of 52.9%)
Other target vessels weighted 81.3% (versus original population percentage of 47.1%)

# Summary

AVAFLEX study demonstrates vessel prep with the FLEX Vessel Prep™ System improves 6 Month Target Lesion Patency prior to drug coated balloon or PTA.

AVAFLEX 6-Month Target Lesion Primary Patency is 84.1% (vs. 71% Lutonix AV IDE) with no procedural issues

In this challenging patient population, vessel prep has the potential to improve long-term patency due to:

- Reduced elastic recoil
- Improved ability to dilate in resistant hyperplastic stenoses
- Enhanced drug-uptake through micro-incisions

# FLEX-AV Registry

**Objective:** To document the endovascular intervention approaches and outcomes when the FLEX Vessel Prep™ System is utilized in a hospital per the institution's standard practice and at 6, 9, and 12 months following treatment.

**Hypothesis:** The FLEX VP System combined with Balloon Angioplasty will result in Anatomic Success of the index procedure and extend the period of target lesion primary patency as compared to balloon angioplasty alone as demonstrated with historic controls.

- **15-20 Registry Sites**
- **Western Institutional Review Board (WIRB) Approved**
- **Study initiation Start Date: September 2019**

**John Aruny MD.**
**Principal Investigator**
Dialysis Access Institute
Orangeburg, SC

# Thank You!