THE PERIPHERAL EVENT OF THE YEAR

A Comparative Review of the FLEX Vessel Prep™ System in the Treatment of Femoropopliteal Lesions of Differing Lengths.

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New Cardiovascular Horizons
CELEBRATING 20 YEARS
1999-2019

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Disclosures:

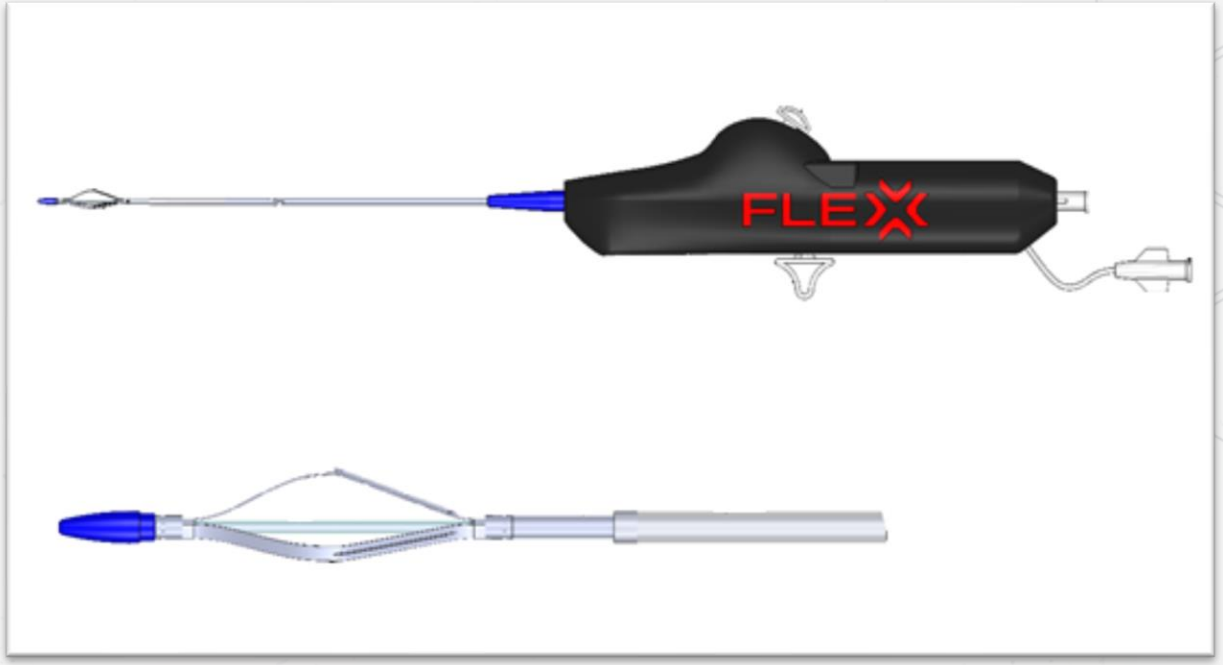
I have no conflicts of interest to disclose

FLEX Vessel Prep™ System

- **Creates an Optimal Environment for Angioplasty**
  - Improves Vessel Compliance

    -Lower Balloon Pressures for Lesion Effacement
  - Increases Luminal Gain
  - Facilitates Drug Distribution (preclinical testing underway)
  - Minimizes Adverse Events

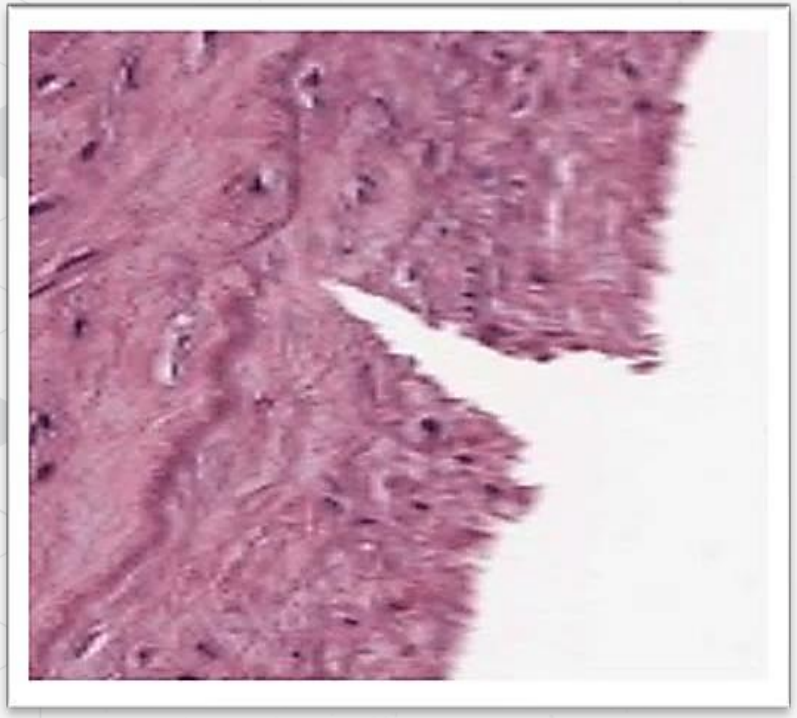
    -Dissections, Embolization, Perforations
  - Decreases the Need for Stenting

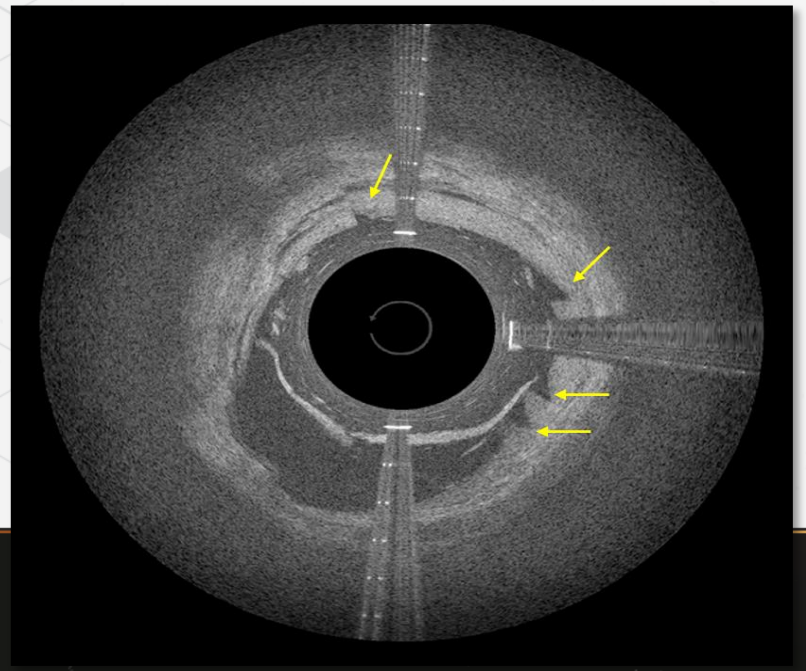


FLEX Vessel Prep™ System

Sheath Size	6 French
Wire Compatibility	.014 and .018
Catheter Length	40cm and 120cm
3 Atherotomes (Proximal)	0.01” in Height

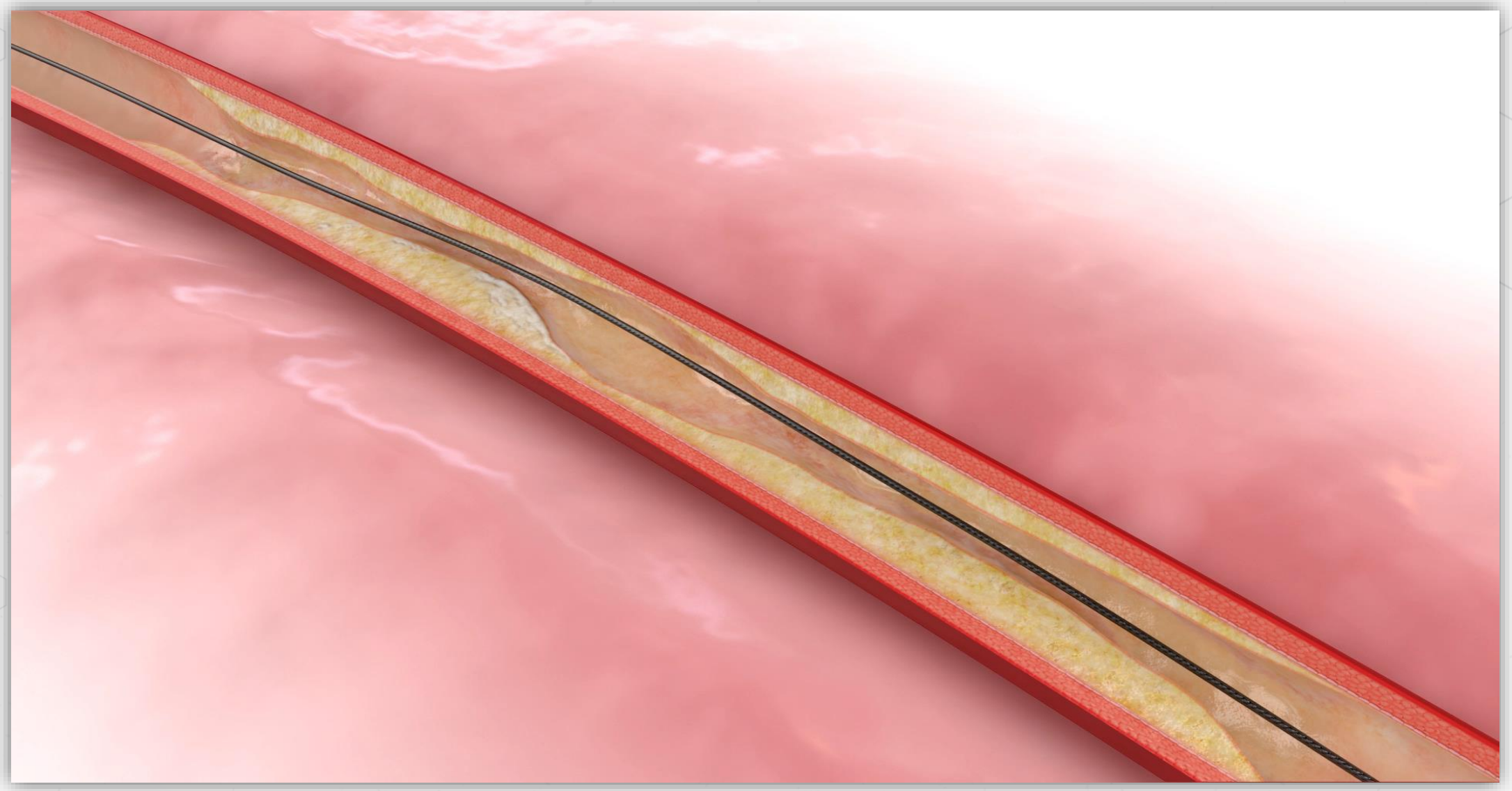
FDA Cleared Indication for Use: To facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae





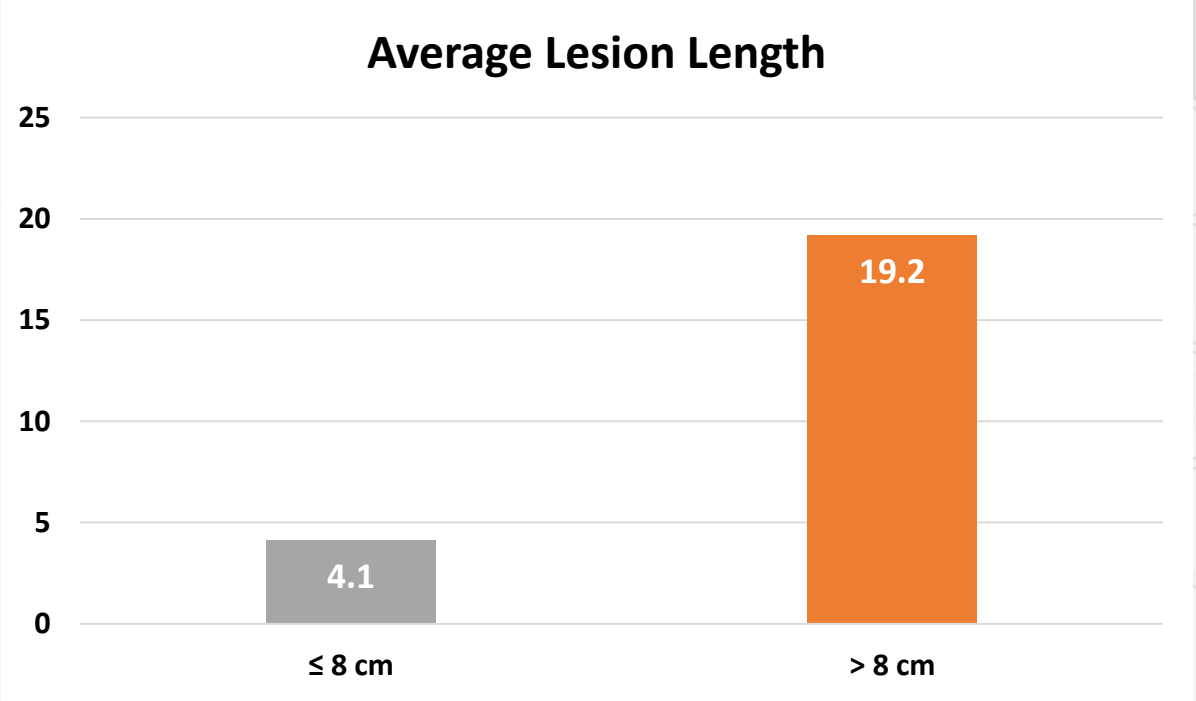
FLEX VP™ System Dual Mechanism of Action

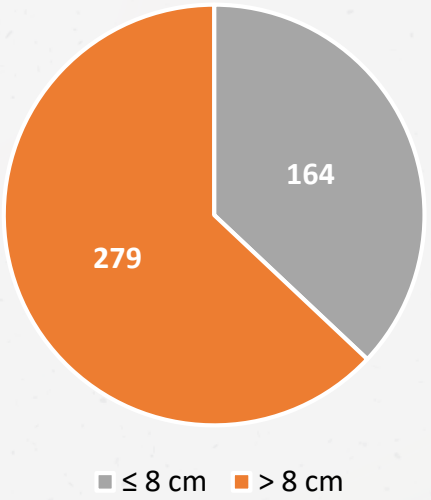
1. <u>Controlled</u> <u>Depth</u> Micro-Incisions
   - Atherotome Height 0.01”
   - Safely Creates Linear, Parallel Micro-Incisions in any lesion length (10 – 450 mm)
2. Predilates the Stenosis at ≈ 1 atm
   - Treatment Elements “Flex” to Follow the Vessel Wall Contour
   - One-Size-Fits-All Device



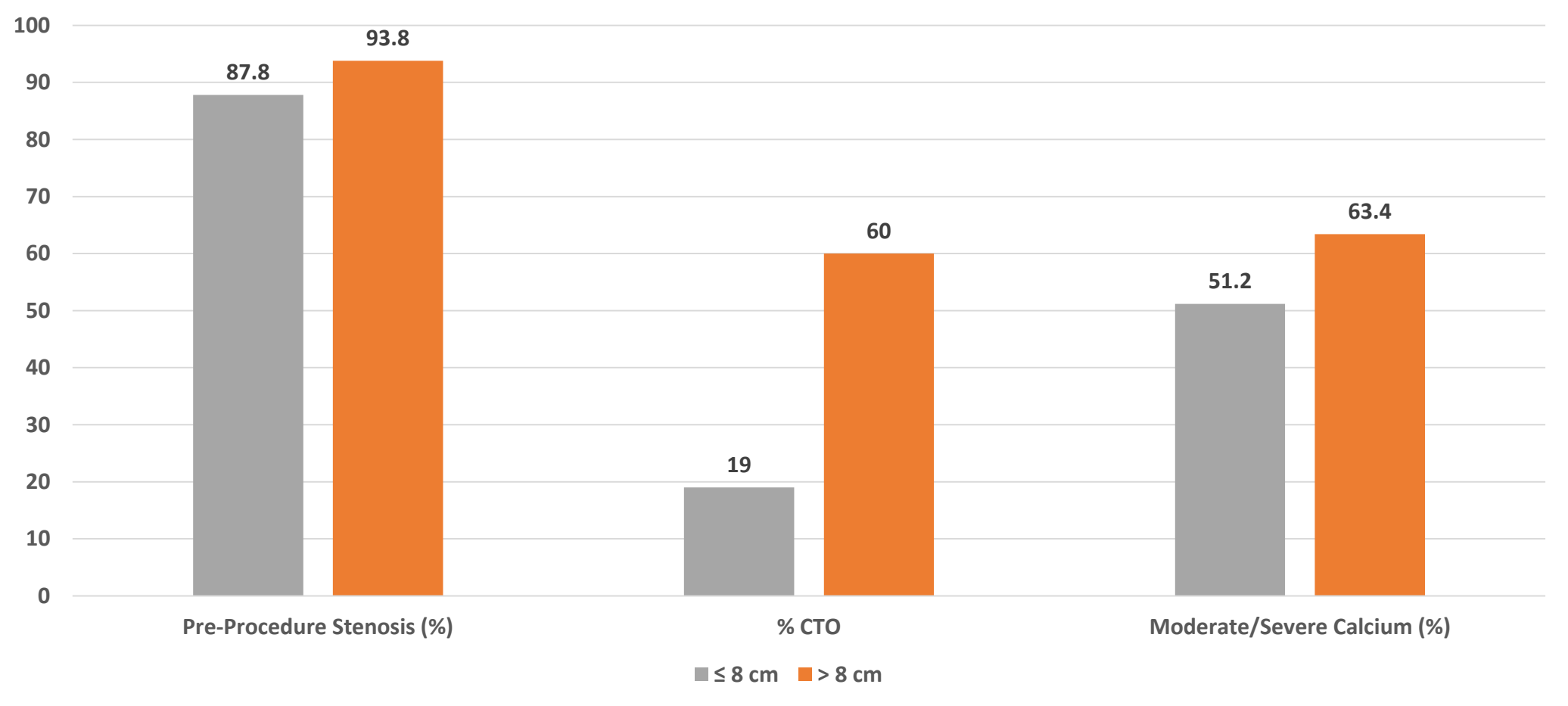
Clinical Data

- Real World Data
- 443 Femoropopliteal Cases Reported
- 104 Operators from 70 Health Systems
- Subsets by Lesion Length
  - Less than or Equal to 8 cm
  - Greater than 8 cm

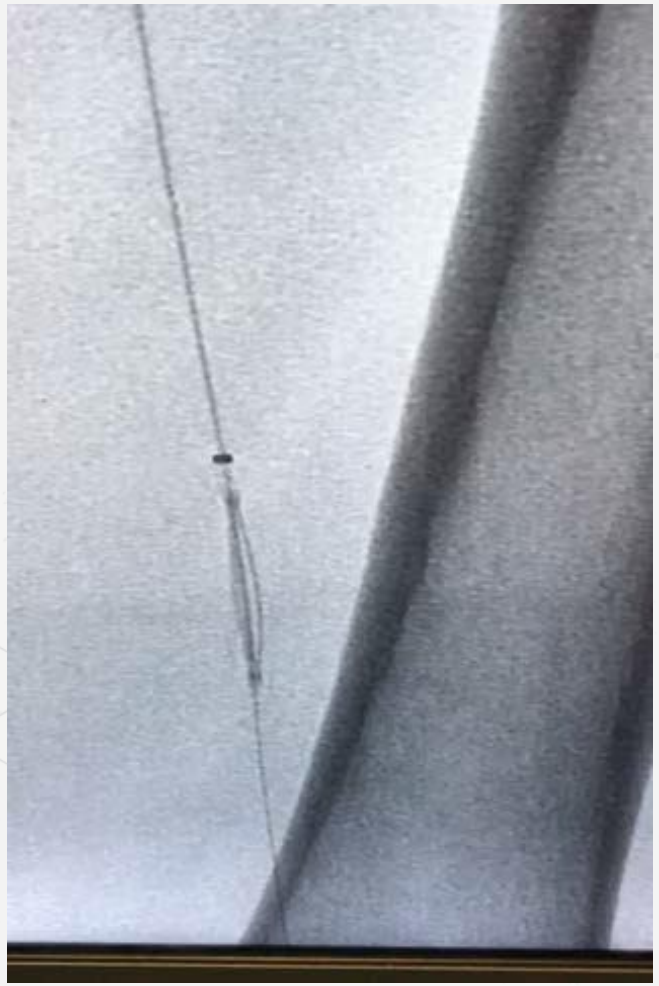




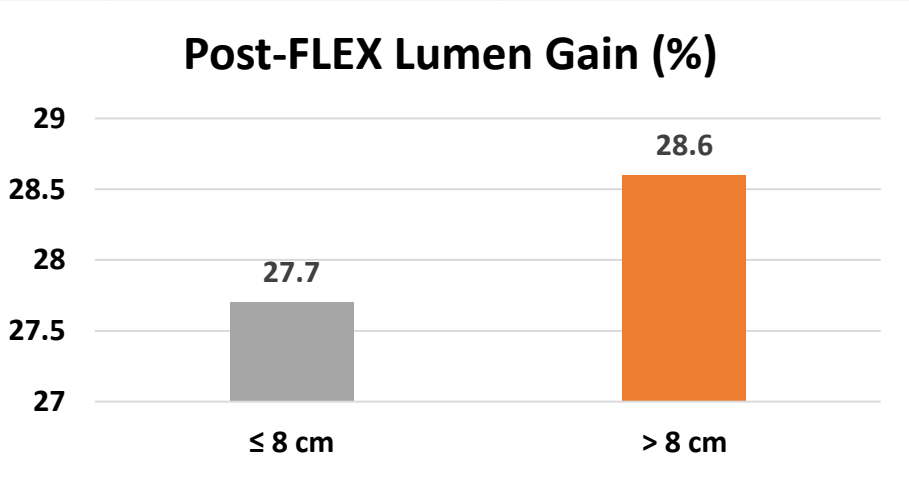
Procedural Data



FLEX Vessel Prep™ System

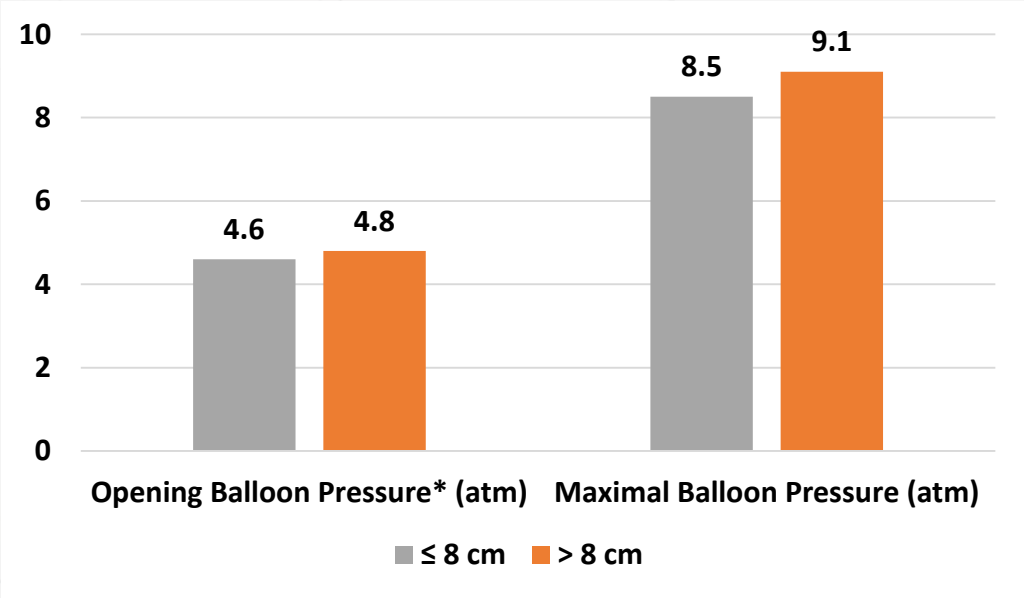


- Average Number of Retrograde Pullbacks: 3.4
- After each Pullback the System is Rotated 30°
- A Post FLEX Angiogram is Captured **Prior to Angioplasty** Evaluating Luminal Gain and Safety of the System.



Angioplasty Results

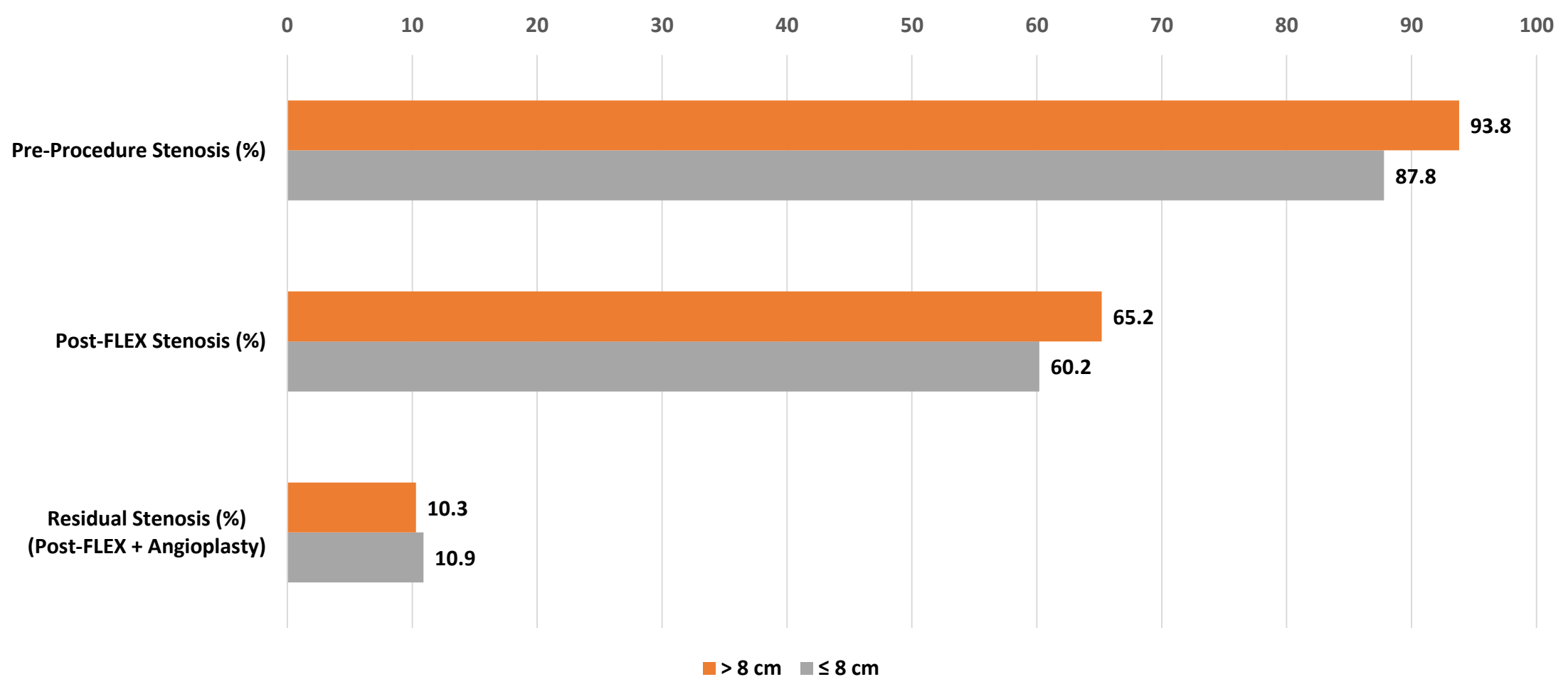
	≤ 8 cm	> 8 cm
DCB Use	78%	81.7%
Minor Dissection (Grade A or B)	4.27%	6.45%
Flow-Limiting Dissection	0%	0%
Emboli / Perforations	0%	0%



*Opening Balloon Pressure is the lowest pressure required to fully efface the lesion.

DCB at Operator's Discretion

Procedural Change in Stenosis



BEnefit of arterial preparation by LONGitudinal scoring before paclitaxel eluting balloon angioplasty of the superficial femoral and popliteal artery (The BELONG Study)

Presented at LINC 2019

Daniel Periard, MD, Rolf Engelberger, MD Fribourg cantonal hospital Fribourg, Switzerland

- 50 Interventions on SFA/Popliteal
- Follow up: 9 (1 to 22 months)
- The recanalization of long femoropopliteal stenosis/occlusions is achievable with FLEX VP™ System
  - Decreased stent implantation noted

Results	
Age (y)	71±13
Average Lesion Length (mm)	202±118
Mean Degree of Stenosis	88%
Occlusion	42%
Provisional Stent Use	9 (18.0%)
Technical Success	100%
Major amputation	0
Target Lesion Revascularization	4 (8%)

**Single-Center Feasibility Experience*

2-year experience using the FLEX VP™ System as a preparatory device for drug-coated balloon and/or balloon angioplasty

Presented at ISET 2019

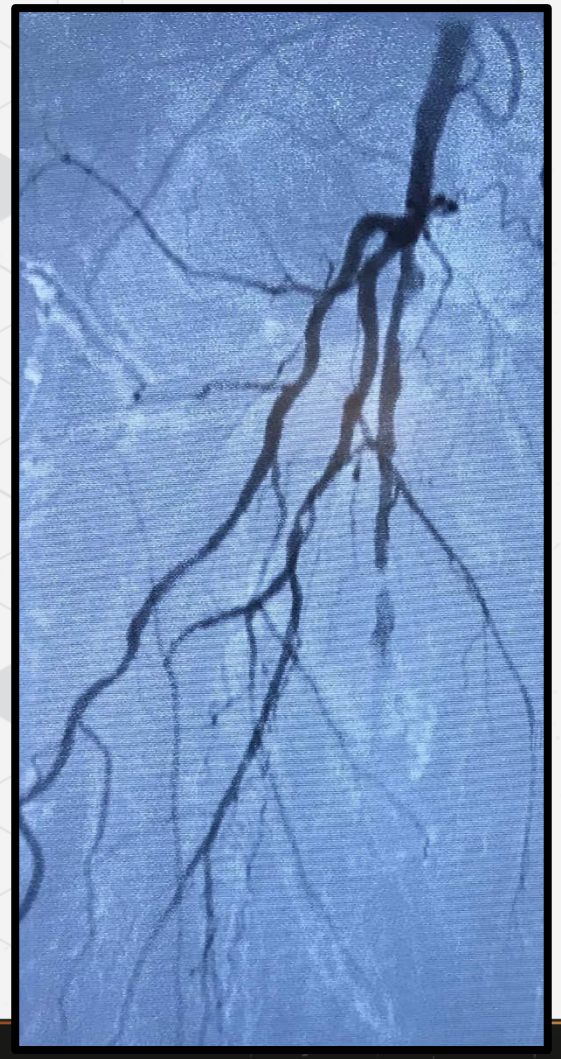
B. Oriowo, J. Abbas, F. Lurie, Jobst Vascular Institute, Toledo, Ohio

- 128 Lesions Treated
- No Flow-Limiting Dissections, Perforations, or Emboli
- The FLEX Vessel Preparation System Treats Complicated Femoropopliteal Lesions with a High Degree of Technical Success.

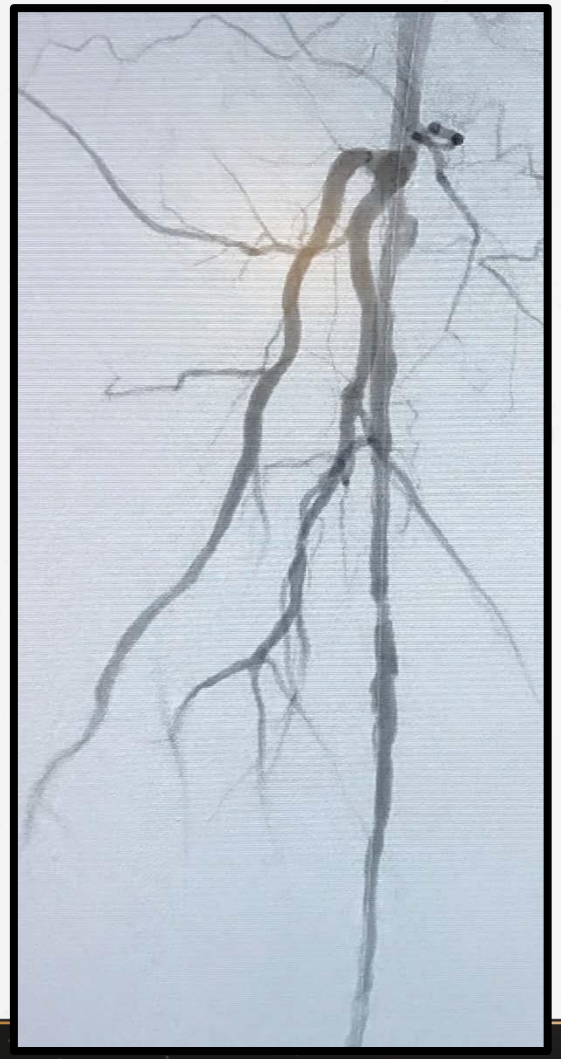
Average Lesion Length (mm)	245±102
Mean Degree of Stenosis	84±11%
Chronic Total Occlusions	31
Dissections (Non-Flow Limiting)	12%
Provisional Stent Use	12%
Technical Success	97%
Reinterventions	4%

**Retrospective, Single-Center*

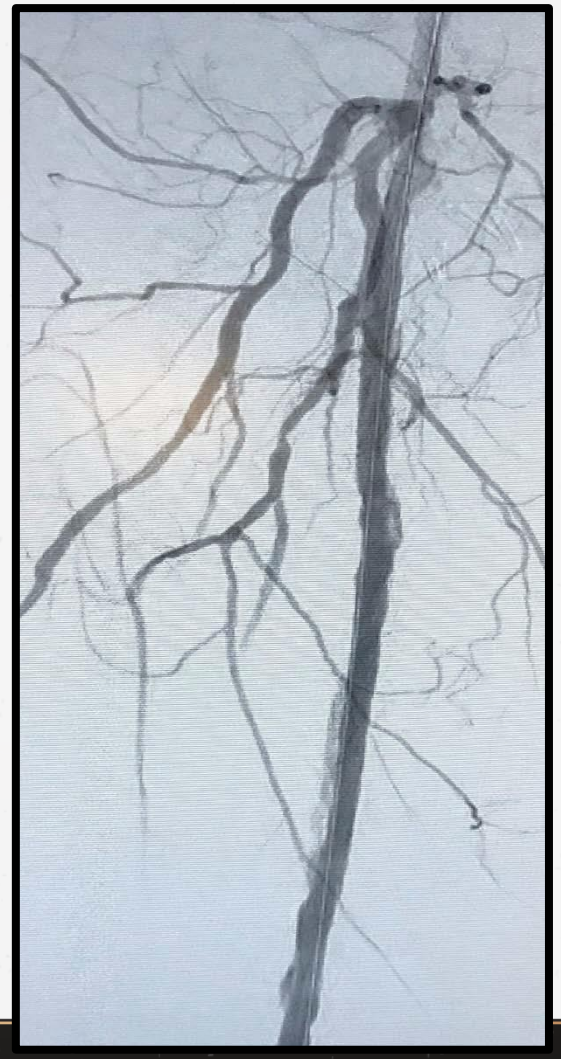
350 mm Calcified Lesion Treated



Pre-Procedure



Post FLEX



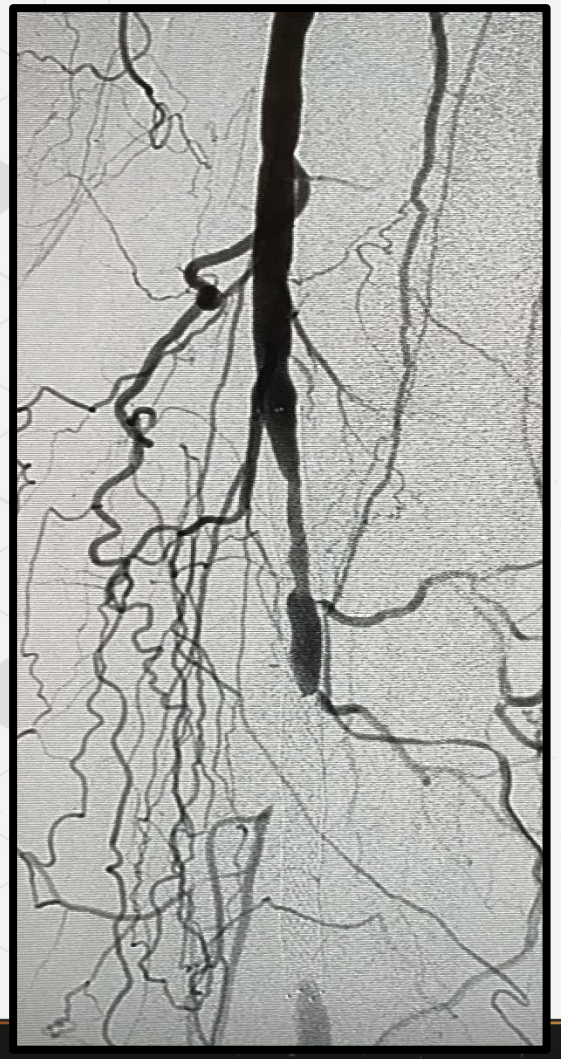
Post FLEX & DCB

Rutherford Class: 5
Lesion Length: 350 mm
Severe Calcium
Pre-Stenosis: 99%

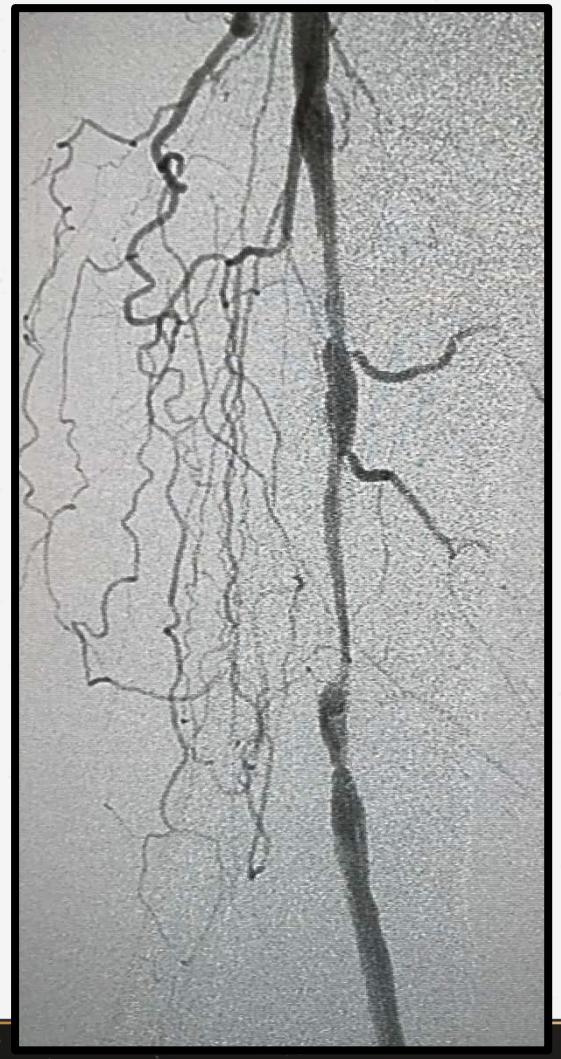
Vessel Prep: FLEX VP™ System
4 FLEX Passes
Post FLEX Stenosis: 40%

DCB Post FLEX
Opening Pressure: 4 atm
Residual Stenosis 10%

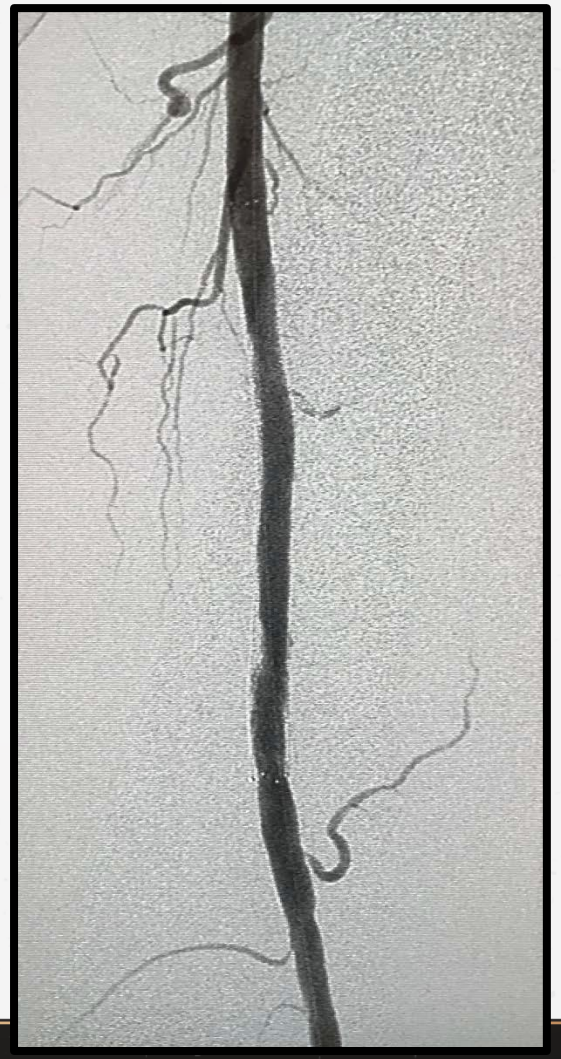
120 mm ISR CTO Treated



Pre-Procedure



Post FLEX



Post FLEX & DCB

Rutherford Class: 4
Lesion Length: 120 mm
Moderate Calcium
Pre-Stenosis: 100% / CTO (In-Stent Restenosis)

Vessel Prep: FLEX VP™ System
4 FLEX Passes
Post FLEX Stenosis: 75%

Treated with a DCB
Opening Pressure: 4 atm
Residual Stenosis 15%

Conclusions

- The FLEX Vessel Prep™ System was shown to safely and effectively facilitate angioplasty of femoral / popliteal stenosis of differing lengths.
- The 28% improvement in luminal gain achieved by the FLEX Vessel Prep™ System alone was consistent regardless of lesion length.
- Low opening balloon pressures (averaging 4.7 atm) suggest the FLEX Vessel Prep™ System positively improves vessel compliance.
- The FLEX Vessel Prep™ System creates an ideal environment for angioplasty of choice in femoropopliteal lesions of differing lengths.