

A Comparative Review of the FLEX Catheter® in the Vessel Preparation of Femoropopliteal Lesions of Differing Lengths

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19th Annual Conference

2018
May 30 - June 01

THE PERIPHERAL EVENT OF THE YEAR

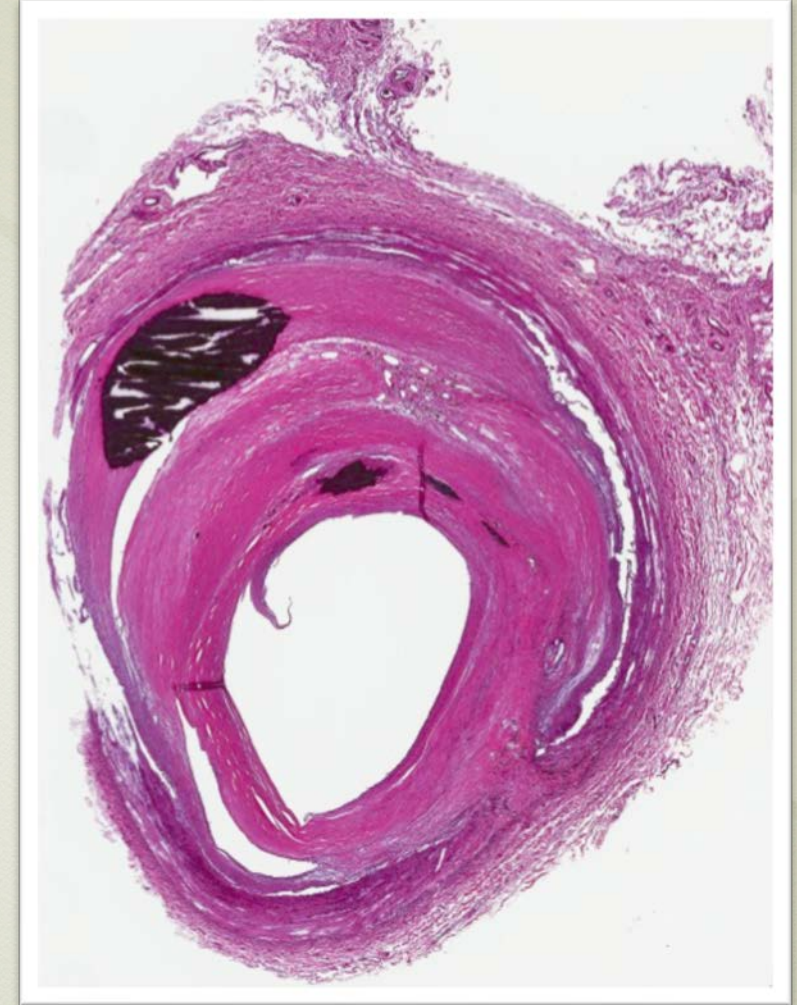


Disclosures

I have nothing to disclose.

Purpose of Vessel Preparation

- Creates an Optimal Environment for Angioplasty
- Improves Vessel Compliance
 - Lower Balloon Pressures for Lesion Effacement
- Increases Luminal Gain
- Facilitates Drug Distribution
- Minimize Adverse Events
 - Dissections, Embolization, Perforations
- Decreases the Need for Stenting



Calcified Atherosclerotic
Cadaver SFA Lesion

FLEX Dynamic Scoring Catheter™



Sheath Size

6 French

Wire Compatibility

.014 and .018

Catheter Length

40cm and 120cm

3 Atherotomes (Proximal)

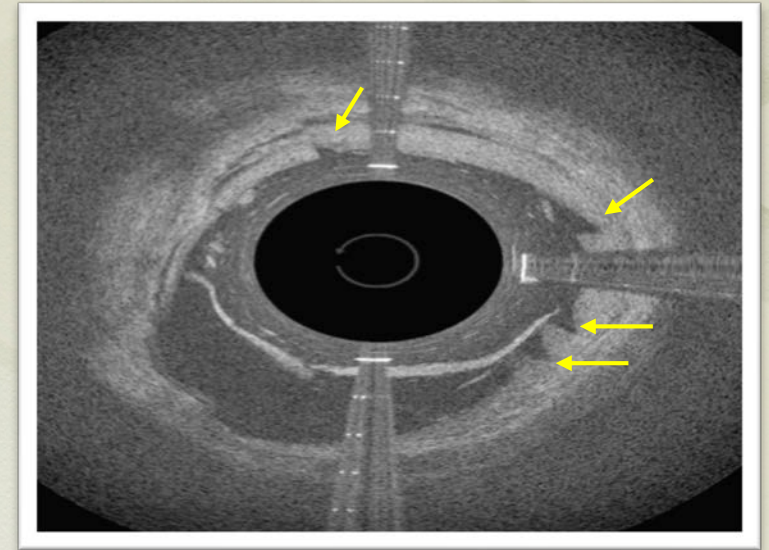
0.01" in Height

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

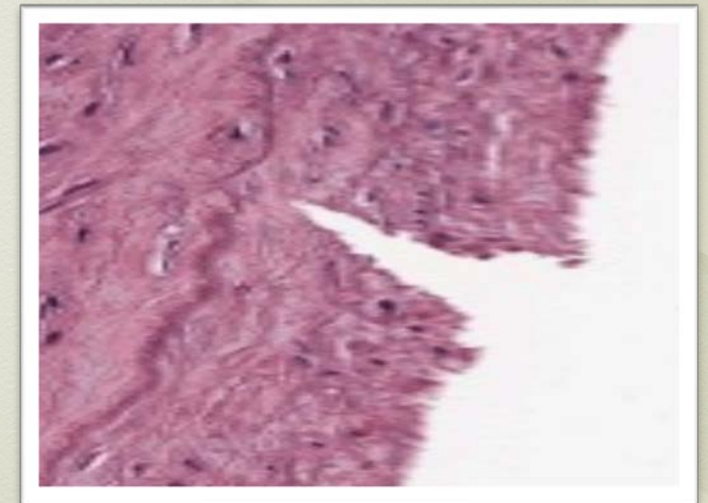
NCVH 2018

FLEX[®] Mechanism of Action

- One-Size-Fits-All Device
- Creates Precise Longitudinal Micro-Incisions
 - Along Any Length Lesion (10 – 450 mm)
- Controlled Depth Micro-Incisions
 - Atherotome Height 0.01"
- Scoring Elements “Flex” to Follow the Vessel Wall Contour
- Predilates the Stenosis at 1 atm
- Creates a Controlled Environment for Angioplasty



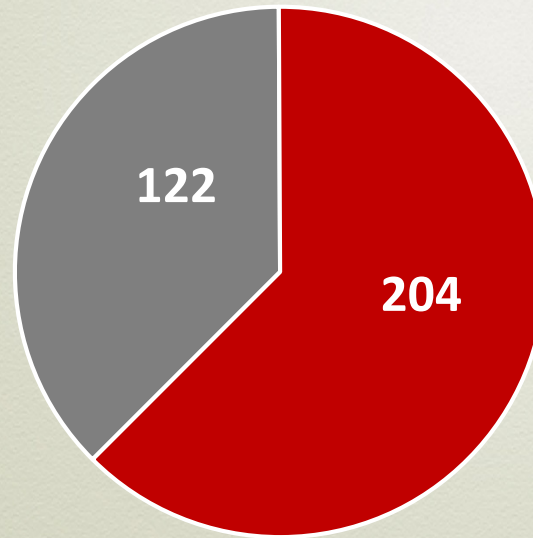
OCT Image of FLEX Micro-Incisions



Histology of Micro-Incision
(Cadaveric Human SFA)

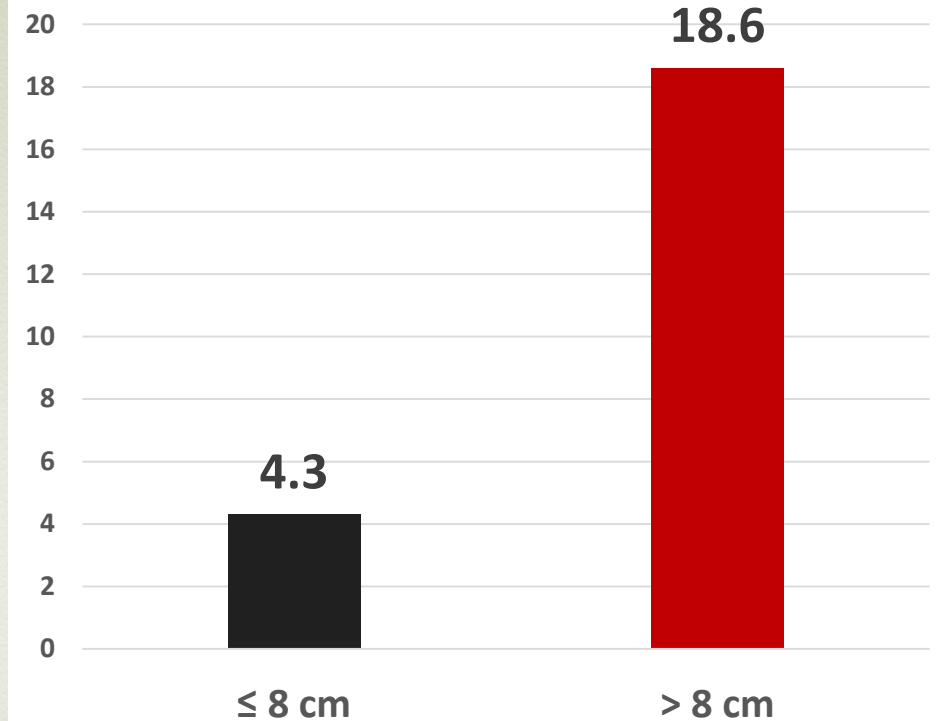
Clinical Data

- Real World Data
- 326 Femoropopliteal Cases Reported
- 85 Operators from 54 Health Systems
- Subsets by Lesion Length
 - Less than or Equal to 8 cm
 - Greater than 8 cm

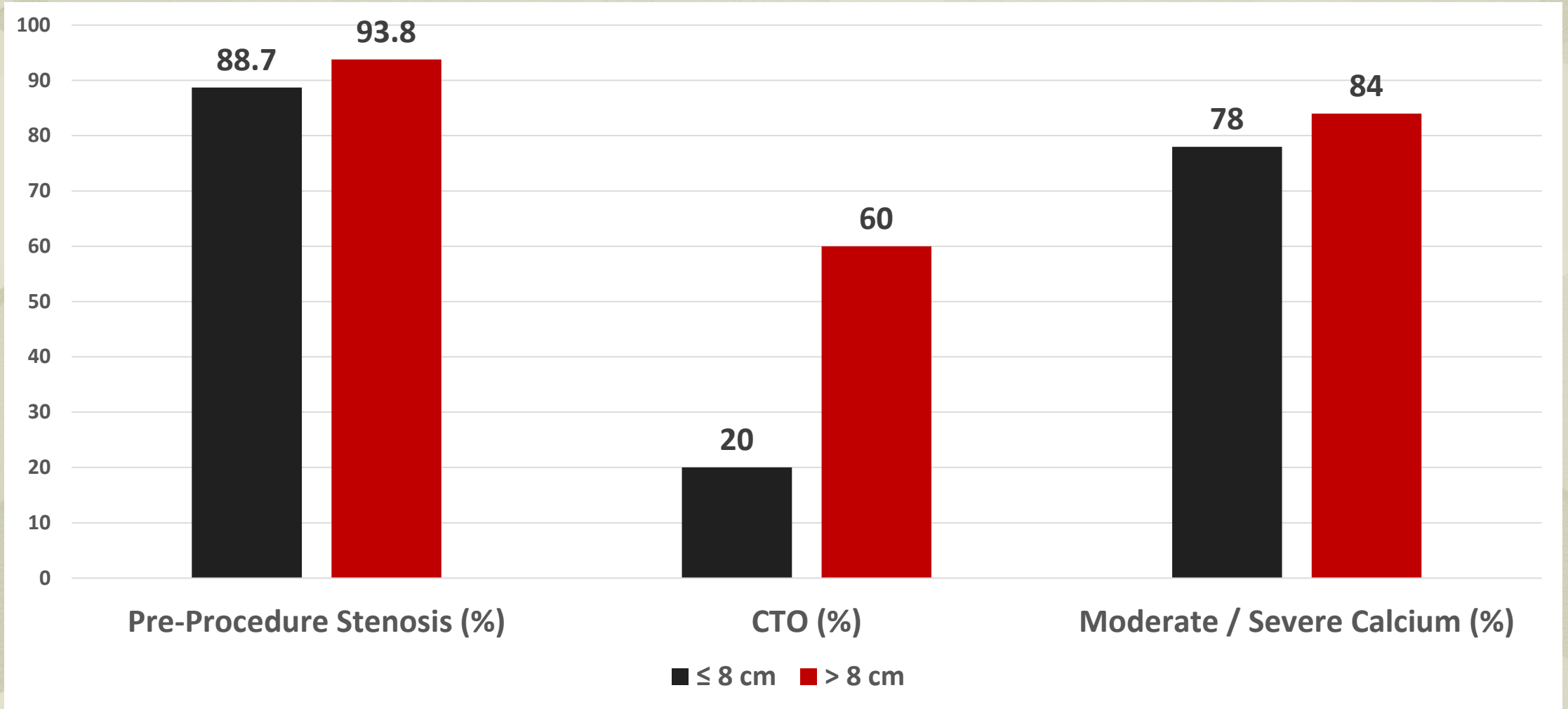


■ ≤ 8 cm ■ > 8 cm

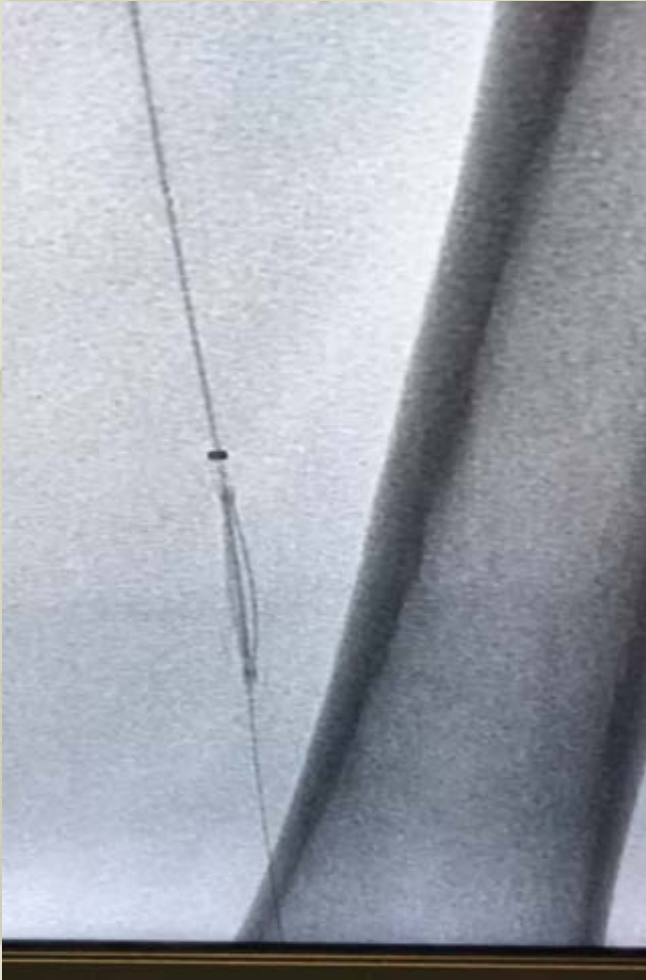
Average Lesion Length



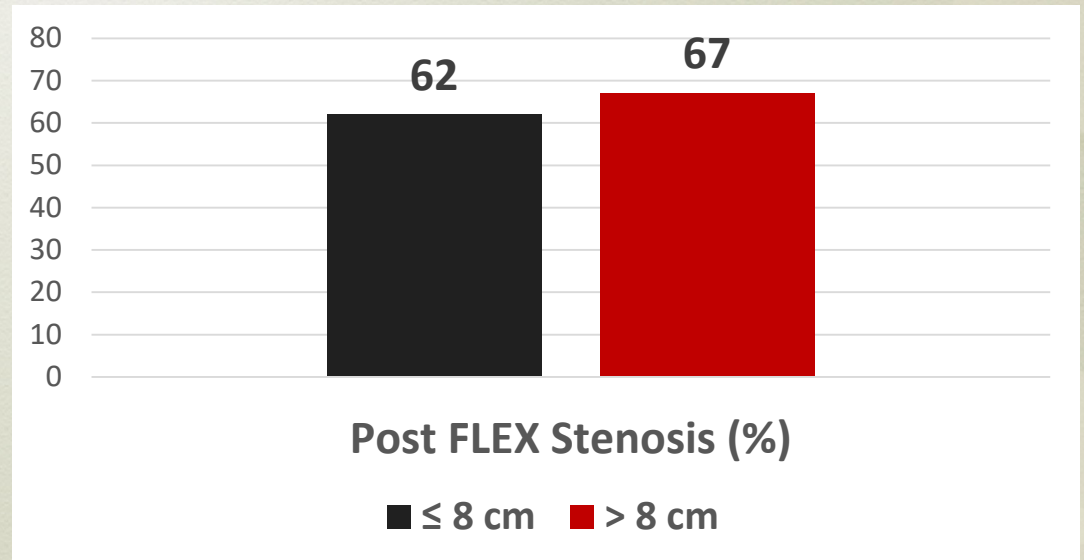
Procedural Data



Vessel Preparation By the FLEX Catheter

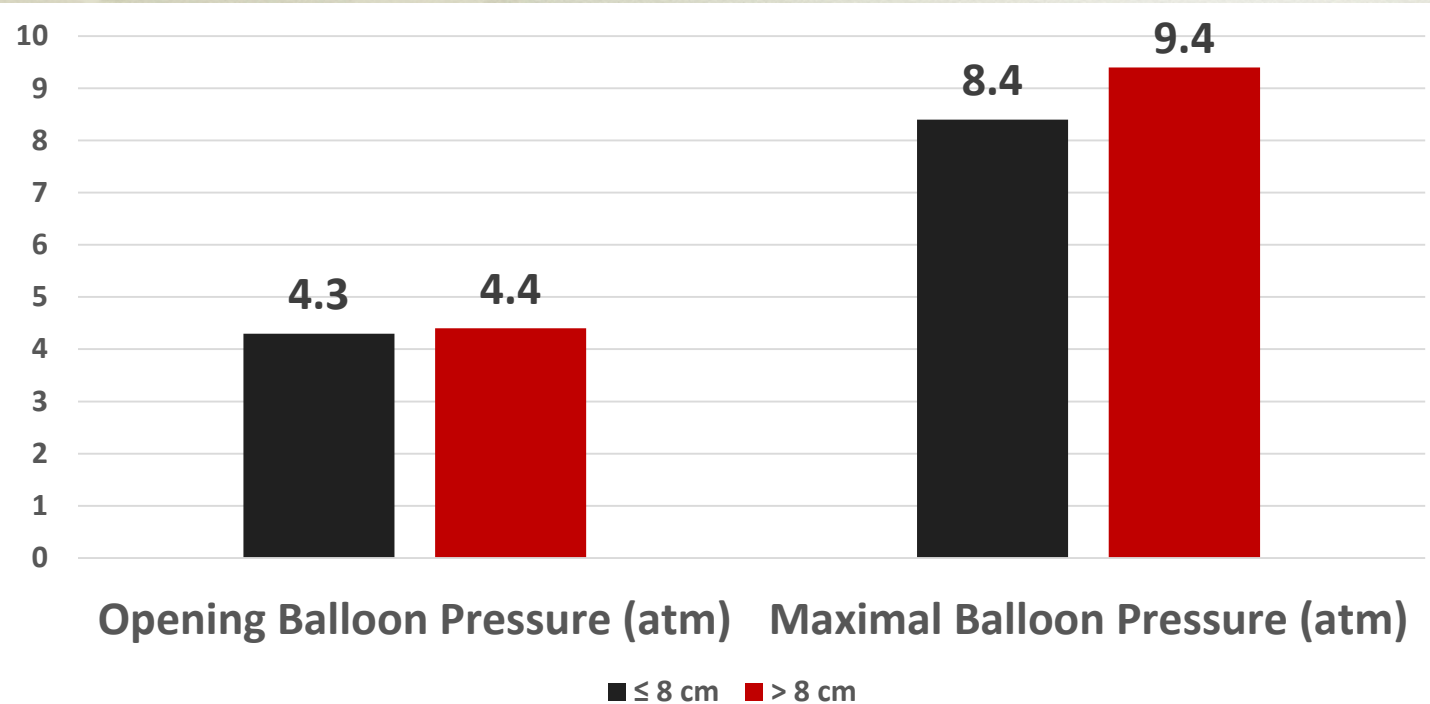


- Average Number of Retrograde Pullbacks: 3.6
- Between Pullbacks the Device is Rotated 30°
- A Post FLEX Angiogram is Captured Prior to Angioplasty Evaluating Luminal Gain and Safety of the Device.



Angioplasty Results

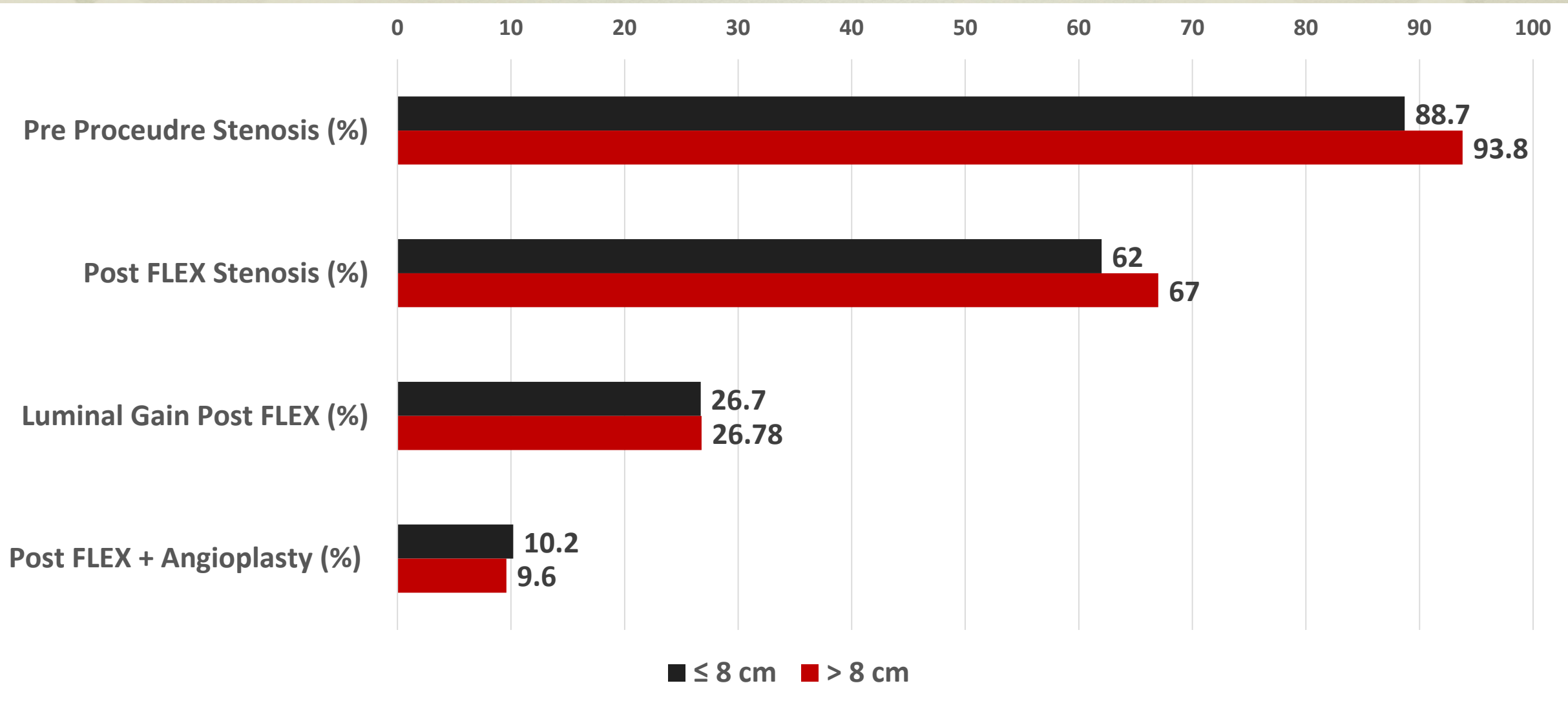
	≤ 8 cm	> 8 cm
DCB Use	73%	74%
Minor Dissection	4%	6%
Flow-Limiting Dissection	0%	0%
Emboli / Perforations	0%	0%



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

DCB at Operator's Discretion

Procedural Change in Stenosis



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 Catheter
4 FLEX Passes
Post FLEX Stenosis: 40%

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

Real World Results of a Dynamic Scoring Device in Calcified Femoropopliteal Vessels.

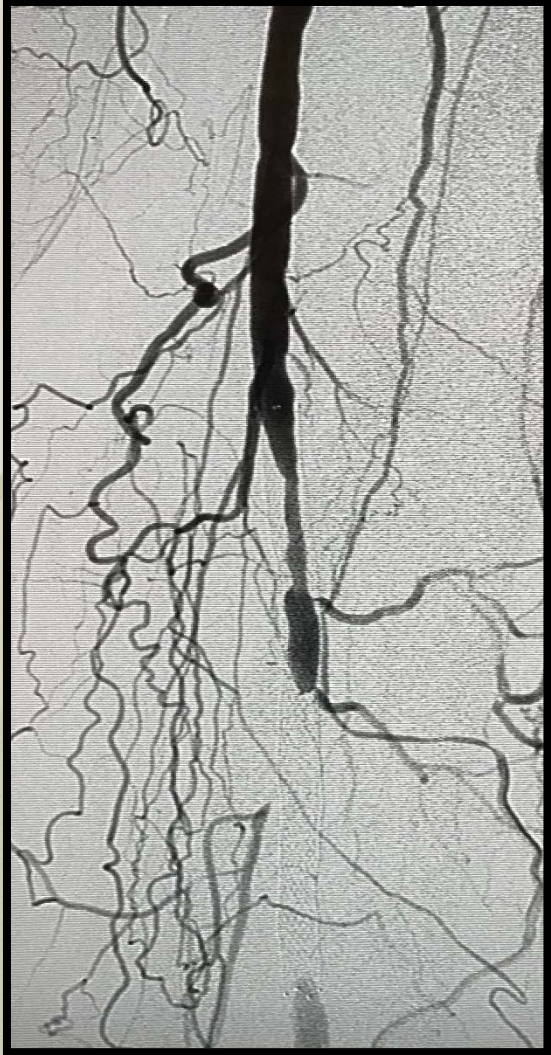
Presented at Charing Cross April 2018

Frank Arko, MD Director, Sanger Heart and Vascular Institute, Charlotte, North Carolina, United States

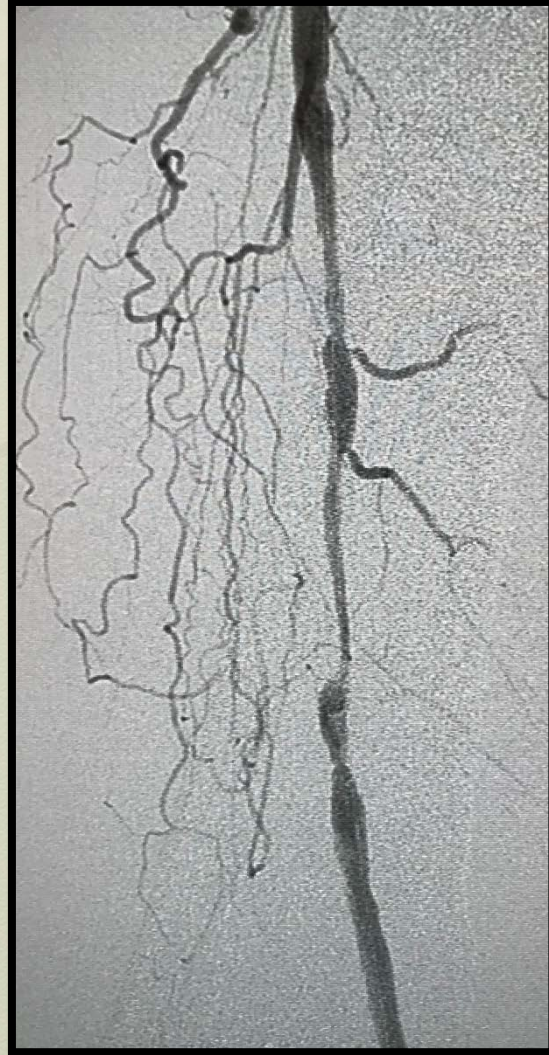
- Evaluating results from 237 case reports varying degrees of calcification.
- 51 operators in 32 hospital systems.
- Acute results revealed significant luminal gain with the device (Avg 25%).
- Dissection rates were low.
- Significant change in vessel wall compliance is suggested by the low balloon opening pressures observed.

Results	None – Mild	Moderate – Severe
Number of Cases	115	122
Lesion Length (mm)	130	142
Pre-Stenosis (%)	90 (60 – 100)	93 (60 – 100)
Luminal Gain Post FLEX (%)	23 (0 – 80)	26 (0 – 89)
DCB Use (%)	75	72
Opening Pressure (atm)	4 (2 – 12)	4 (2 – 8)
Minor Dissection (%)	4	8
Flow-Limiting Dissection (%)	0	0

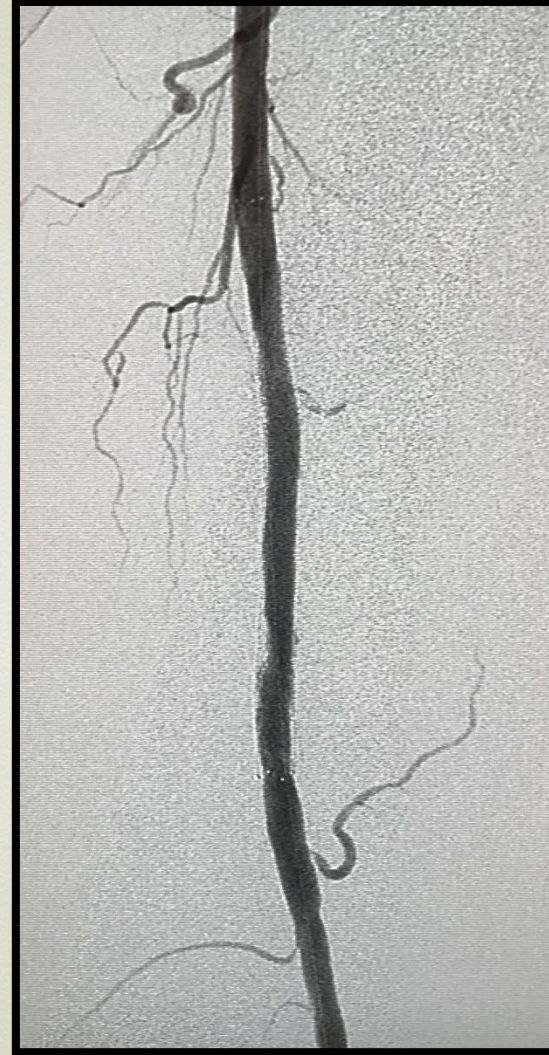
120 mm CTO Treated



Pre-Procedure



Post FLEX



Post FLEX & DCB

Rutherford Class: 4
Lesion Length: 120 mm
Moderate Calcium
Pre-Stenosis: 100% / CTO

Vessel Prep: FLEX Catheter
4 FLEX Passes
Post FLEX Stenosis: 75%

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

Early Clinical Results Utilizing the FLEX Scoring Catheter in 100 Femoropopliteal Chronic Total Occlusions.

Presented at ISET January 2018

Thomas Zeller, MD, PhD, Universitaets-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen

- Clinical results using the FLEX Scoring Catheter as a vessel preparation device to treat femoropopliteal CTOs.
- 24 operators in 15 hospital systems
- 31% Luminal gain from the FLEX alone.
- The FLEX is effective in recanalizing CTOs with low rates of vessel dissection.

Results	
Number of CTO Case	100
Average Lesion Length (mm)	191 (30 – 350)
Luminal Gain Post FLEX	31%
Residual Stenosis Post FLEX + Angioplasty	7.9%
Provisional Stent Use	19%
Moderate / Severe Calcium	46%
Average Opening Balloon Pressure (atm)	4.1 (2 – 10)

Conclusions

- The FLEX Catheter was shown to safely and effectively facilitate angioplasty of femoral / popliteal stenosis of differing lengths.
- The 27% improvement in luminal gain achieved by the FLEX alone was consistent regardless of lesion length.
- Low opening balloon pressures (averaging 4.3 atm) suggest the FLEX positively improves vessel compliance.
- The FLEX is a treatment option for femoropopliteal lesions of differing lengths