

Background: Early clinical results of the FLEX Catheter (VentureMed Group, Toledo, Ohio) in real world patients were retrospectively reviewed by lesion length subsets. Safety and acute procedural results were evaluated.

Methods: Voluntarily provided case reports from 326 real world patients (85 operators in 54 hospital systems) were analyzed.

1) Pre-Procedure Evaluation Angiogram
Measure % Stenosis

2) Post FLEX Angiogram
(Vessel Preparation with the FLEX)
30° Rotation between Pull-Backs
Measure % Stenosis/ Luminal Gain

3) Post Procedure Angiogram
(Angioplasty and Capture Opening
Balloon Pressure)
Measure % Stenosis / Luminal Gain

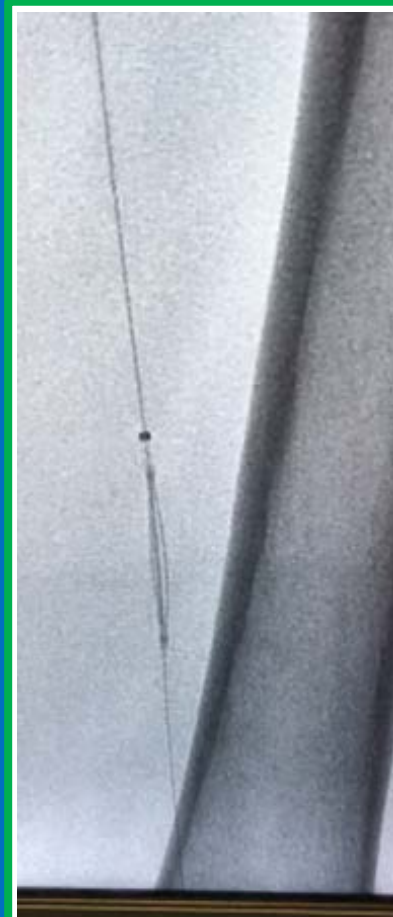
Lesions were treated post FLEX with a drug coated balloon (DCB) or plain old balloon angioplasty (POBA), at operator's discretion.

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.

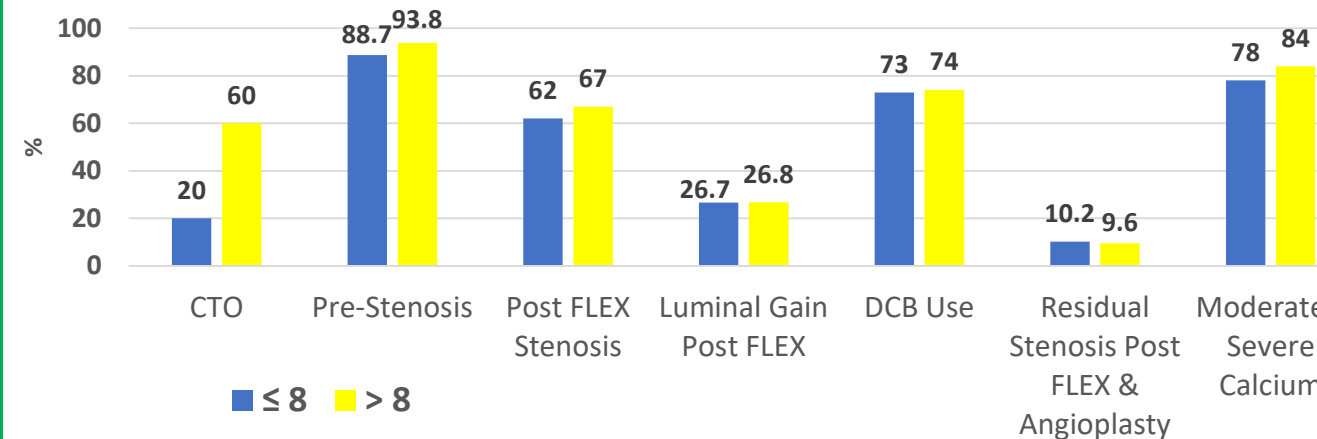
The FLEX is a viable option to interventionalists in the treatment of femoropopliteal lesions of differing lengths.



Retrograde pull-back of the FLEX Catheter in a high-grade stenosis.

Results	≤ 8 cm N (%) / Mean (Range)	> 8 cm N (%) / Mean (Range)
Number of Cases:	122	204
Average Age:	70	72
ISR:	7 (6%)	19 (9%)
Average Lesion Length (cm):	4.3 (0.2 – 8)	18.6 (8.5 – 41)
*Opening Balloon Pressure (atm)	4.3 (2 – 12)	4.4 (2 – 12)
Maximal Balloon Pressure (atm)	8.4 (4 – 20)	9.4 (3 – 18)
Provisional Stent Usage:	20 (16%)	42 (21%)
Minor Dissections (Grade: A, B):	5 (4%)	12 (6%)
Flow-Limiting Dissections:	0 (0%)	0 (0%)
Embolization / Perforations:	0 (0%)	0 (0%)

*Opening Pressure: the lowest pressure required to achieve full lesion effacement



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

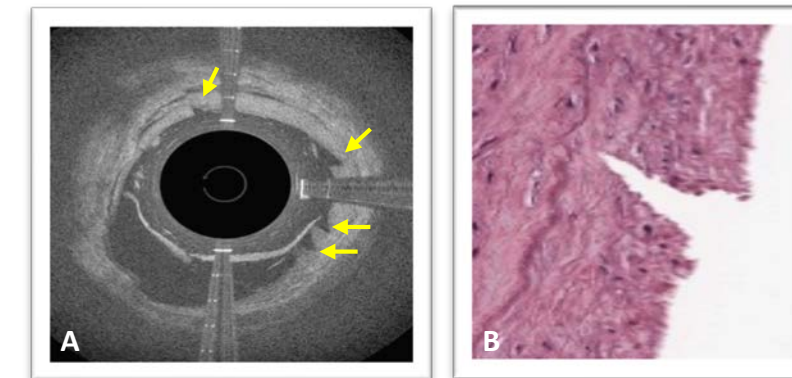
Post FLEX Recanalization:
5 FLEX Passes
Post FLEX Stenosis: 40%

Final Result:
Treated Post FLEX & DCB
Opening Pressure: 4 atm
Residual Stenosis: 10%



FLEX Scoring Catheter

One-Size-Fits-All Device / 1 SKU Inventory
6 Fr / .014 and .018 Guidewire Compatible
40 cm and 120 cm Working Length
Engineered for continuous parallel micro-incisions by 3 Atherotomes
FLEX predilates the stenosis → Skids Apply a constant pressure (1 atm)
Controlled depth micro-incisions (Atherotome Height 0.01")
Rotationally controlled, provides the ability to create multiple scores



A) OCT Image of Micro-Incisions
B) Histology of a Cadaveric Human SFA of a micro-incision