

A Comparative Review of the FLEX Scoring Catheter[®] in the Treatment of Femoropopliteal Lesions of Differing Lengths. Jason A. Yoho, MD, Heart and Vascular Institute of Texas, New Braunfels, TX Louis Lopez, MD, Allen County Cardiology, Saint Joseph Hospital, Fort Wayne, IN John Pigott, MD, Jobst Vascular Institute, Promedica Healthcare Systems, Toledo OH

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.

| Results | ≤ 8 cm N (%) / Mean (Range) | N (|
|----------------------------------|--------------------------------|-----|
| Number of Cases: | 122 | |
| Average Age: | 70 | |
| ISR: | 7 (6%) | |
| Average Lesion Length (cm): | 4.3 (0.2 – 8) | |
| *Opening Balloon Pressure (atm) | 4.3 (2 – 12) | |
| Maximal Balloon Pressure (atm) | 8.4 (4 – 20) | |
| Provisional Stent Usage: | 20 (16%) | |
| Minor Dissections (Grade: A, B): | 5 (4%) | |
| Flow-Limiting Dissections: | 0 (0%) | |
| Embolization / Perforations: | 0 (0%) | |
| | | |

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



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 \rightarrow Skids Apply a constant pressure (1 atm) Controlled depth micro-incisions (Atherotome Height 0.01") Rotationally controlled, provides the ability to create multiple scores

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







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%**





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