FLEX Catheter: A Novel Device Facilitating in the Preparation of Vessels for Angioplasty.

Arne Schwindt, MD, Vascular Surgery, St. Franziskus Hospital, Muenster, Germany John Pigott, MD, Director Vascular and Endovascular Surgery, The Toledo Hospital, Promedica Healthcare Systems, Toledo, OH



Purpose: Early results of the FLEX Catheter® in real world data were evaluated.

Materials and Methods: The FLEX Catheter® is a 6 French, 0.18 guidewire compatible device, purposely engineered with 3 atherotomes to modify plaque with Dynamic Scoring® technology. It is rotationally controlled creating multiple linear scores, facilitating in the preparation of the vessel for angioplasty. The study examined 237 voluntarily provided case reports (51 operators in 32 hospital systems) with femoropopliteal lesions. The vessel was treated with the FLEX, followed by a drug coated balloon (DCB) or plain old balloon angioplasty (POBA).

Conclusion: The FLEX Catheter® safely treated femoropopliteal lesions with a high degree of technical success. There were no flow-limiting dissections and low balloon opening pressures suggest significant change in the vessel wall compliance after FLEX.

Accepted for Podium Presentation at LINC 2018



Data on File

Results	
Number of Cases:	237
In-stent Restenosis Cases	20
Moderate/Severe Calcification	51%
Average Lesion Length	136 mm (2 – 350)
Average Stenosis	92% (60 - 100)
Average Luminal Gain Post FLEX	24% (0 – 89)
Average Opening Balloon Inflation Pressure	4 atm (2 – 12)
Average Maximal Balloon Inflation Pressure	9 atm (4 – 18)
Residual Stenosis Post Treatment	9% (0 – 50%)
Flow-Limiting Dissections	0
Provisional Stent Use	19%
Technical Success	98.7%
Luminal Gain Achieved Post FLEX	234 Cases