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

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Purpose: Initial clinical results using the FLEX Scoring Catheter® (VentureMed Group, Toledo, Ohio) as a vessel preparation device to treat femoropopliteal chronic total occlusions were evaluated.

Materials and Methods: The Flex Scoring Catheter is a 6 French, 0.18 guidewire compatible device. The FLEX has 3 radially positioned, precision atherotomes that modify plaque during pull-back with Dynamic Scoring® technology. FLEX can be rotationally controlled, after each pull-back, to create multiple linear scores preparing the vessel for treatment. The present study analyzed voluntarily provided case reports (24 operators in 15 hospital systems) of 100 patients with femoropopliteal CTOs. After successfully crossing the CTO, the lesion was treated with the FLEX Scoring Catheter prior to angioplasty.

Conclusion: The FLEX catheter performed safely with a high degree of technical success. It is effective in recanalizing CTOs with low rates of vessel dissection. Provisional stent use is low and there were no flow limiting dissections. Low (sub-nominal) balloon opening pressures suggest significant change in vessel wall compliance after vessel prep with FLEX. The FLEX is utilized by interventionalists as a vessel preparation device, especially prior to drug coated balloon.

FLEX® SCORING CATHETER

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Data on File

Results	
Number of CTO Cases	100
Average Lesion Length	191 mm (30 – 350 mm)
Luminal Gain Post FLEX	31%
Residual Stenosis Post FLEX + Angioplasty	7.9%
Technical Success	99%
Pre-Dilation Needed for FLEX to Pass	1 Case
FLEX Allowed Recanalization of CTO Prior to Angioplasty	99%
Vessel Perforation Occurrences	0
Emboli Occurrences	0
No Dissections	96%
Minimal Dissections	4%
Provisional Stent Use	19%
Moderate / Severe Calcium	46%
DCB Used (at Operator's Discretion)	70%
Average Opening Balloon Inflation Pressure	4.1 atm (2 – 10 atm)
Average Maximal Balloon Inflation Pressure	9.4 atm (4 – 16 atm)