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

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Purpose: Results of a dynamic scoring device in calcified femoropopliteal vessels 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 present study examined 237 voluntarily provided case reports (51 operators in 32 hospital systems) with femoropopliteal lesions. Initially, the vessel was treated with the dynamic scoring device followed by a drug coated balloon (DCB) or plain old balloon angioplasty (POBA). Study case report forms were classified by calcification severity: none to mild and moderate to severe, as per operator visual estimation and assessment.

Conclusion: A high degree of technical success was achieved with the evaluated dynamic scoring device. Acute results revealed significant luminal gain with the device. The provisional stent use and dissection rates were low. Significant change in vessel wall compliance is suggested by the low balloon opening pressures observed. The device achieved acceptable results in vessels with none to mild calcification, as well as moderate to severe. Further studies are warranted.

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FLEX SCORING CATHETER

Data on File

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)
Residual Stenosis (%)	8 (0 – 30)	10 (0 – 50)
DCB Use (%)	75	72
Opening Pressure (atm)	4 (2 – 12)	4 (2 – 8)
Maximal Pressure (atm)	10 (4 – 16)	9 (4 – 18)
No Dissections (%)	96	92
Flow Limiting Dissection (%)	0	0
Provisional Stenting (%)	19	19
Technical Success (%)	98.7	