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

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**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.

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| Results | |
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| 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 |

Data on File