2-Year Experience Using the FLEX Vessel Preparation System prior to Drug-Coated Balloon and/or Balloon Angioplasty

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Study Design

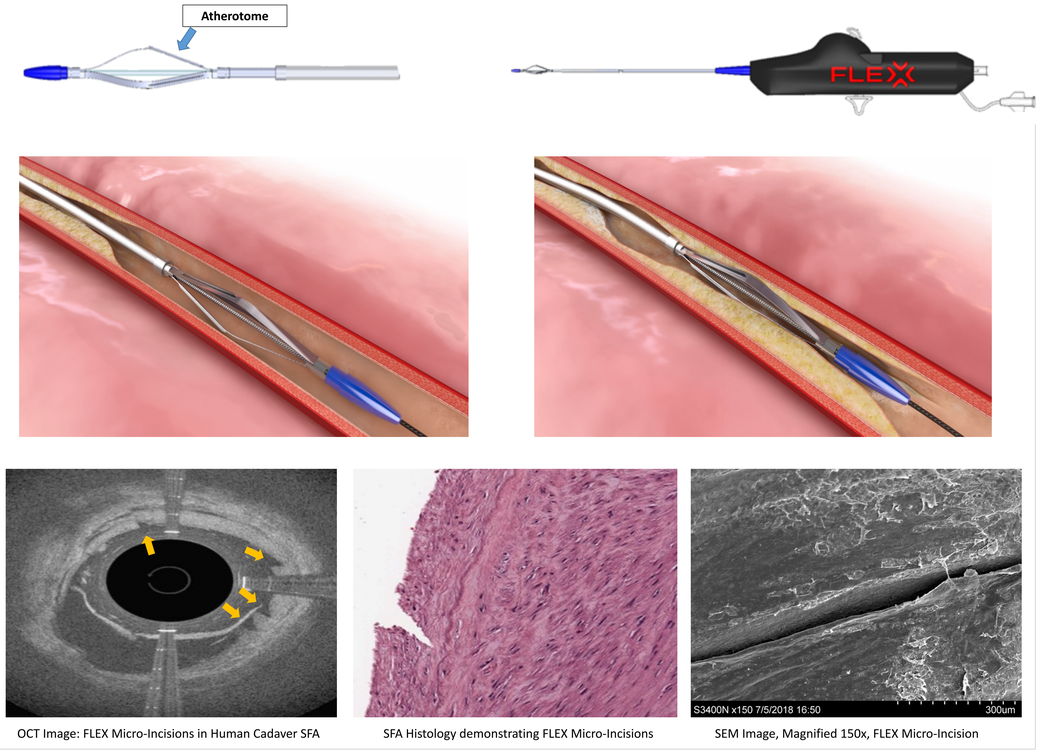
2-year sequential case-series study with 6-month follow up

Population

All patients in whom the FLEX Vessel Preparation System was used prior to drug-coated balloon (DCB) and/or balloon angioplasty (POBA)

FLEXCatheter®	
Sheath Size	6 French
Wire Compatibility	.014 and .018
Catheter Length	40cm and 120cm
3 Atherotomes (Proximal)	0.01” in Height
FDA / CE Mark Indication	Facilitate Dilatation of Stenoses of Femoropopliteal and AVF/AVG

- Creates Precise Longitudinal Micro-Incisions
  - Along Any Length Lesion (10 – 450 mm)
- Controlled Depth Micro-Incisions
  - Atherotome Height 0.01”
- Scoring Elements “Flex” to Follow the Vessel Wall Contour during Retrograde Pull-back
- Predilates the Stenosis at 1 atm
- Creates a Controlled Environment for Angioplasty

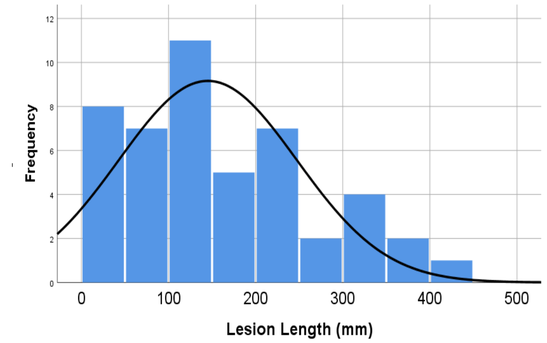


OCT Image: FLEX Micro-Incisions in Human Cadaver SFA

SFA Histology demonstrating FLEX Micro-Incisions

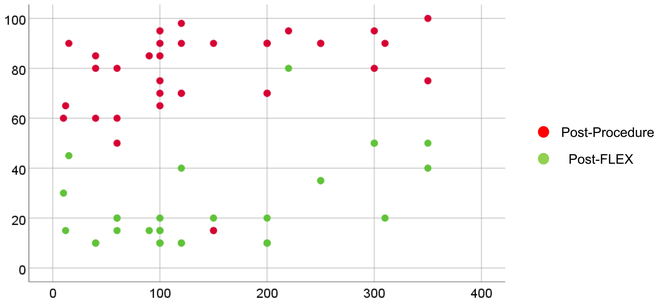
SEM Image, Magnified 150x, FLEX Micro-Incision

Lesion Characteristics	
Number of Lesions Treated	128
Chronic Total Occlusions	31
Average Pre-Stenosis (M%± SD)	84 ± 11
Average Lesion Length (M mm± SD)	245 ± 102
Moderate / Severe Calcification (%) (PACSS score ≥ 2)	55%



Patient Demographics	
Number of Patients	123
Male sex (%)	59
Diabetes (%)	51
Smokers (%)	84

Luminal Gain and Lesion Length



	Mean (SD)
Pre-Existing Stenosis (%)	92 (11)
Post FLEX Stenosis (%)	70 (16)
Post FLEX Luminal Gain (%)	22 (16)
DCB Use (%)	80
Opening Balloon Pressure (atm)	5 (1)
Maximal Balloon Pressure (atm)	9 (3)

TECHNICAL	
Technical Success	97%
Vessel Perforation Occurrences	0
Distal Emboli	0
Minimal Vessel Dissection	12% (n=17)
Flow-Limiting Dissection	0
Stent Use	12% (n=17)
Average Luminal Gain Post Procedure	78%
6 Month Re-Intervention Rate	4%

Conclusions

- **The FLEX System Safely Treats Complicated Femoropopliteal Lesions with a High Degree of Technical Success.**
- **Successfully Achieves Luminal Gain Post FLEX Without Flow-Limiting Dissection, or Emboli.**
- **Low Opening Balloon Pressures (≤ 5 atm) Suggest Significant Improvement in Vessel Wall Compliance Post FLEX.**
- **Lower Dissection Rate After FLEX use Lowers the Necessity of Stenting.**
- **Re-Intervention Rate at 6 Months was 4%.**

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