Vessel Preparation of Femoropopliteal Lesions Prior to Drug-Coated Balloon Angioplasty with the FLEX Dynamic Scoring Catheter

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Purpose

Vessel preparation (VP) prior to the implementation of drug-coated-balloons (DCB) is increasing in clinical importance. VP has the potential to improve acute results of DCB by decreasing dissections and limiting stenting. VP should also provide an optimal environment for drug-uptake potentially leading to improved long-term outcomes.

Methods

FLEX Dynamic Scoring Catheter, a non-balloon-based scoring device, was studied as a VP device prior to DCB. Retrospective review of 263 real-world cases (50 institutes, 74 physicians) was performed.

1) Pre-Procedure Evaluation Angiogram
Measure % Stenosis

2) Post FLEX Angiogram
(Vessel Preparation with the FLEX)
30° Rotation between Pull-Backs
Measure % Stenosis/ Luminal Gain

3) Post Procedure Angiogram
(Angioplasty and Capture Opening Balloon Pressure)
Measure % Stenosis / Luminal Gain

Pre-dilation using plain-old-balloon-angioplasty (POBA) was performed at the discretion of the operator. Dissection, luminal gain, and opening balloon pressures (lowest pressure required to fully efface the lesion) were the focus of this review.

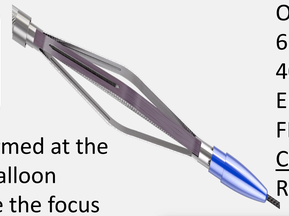
Vessel Characteristics	
Average Lesion Length	135 mm (2-410 mm)
Average Vessel Diameter	5.5 mm (2-8 mm)
Average Baseline Stenosis	91.7% (50-100%)
% CTO	45%

Results

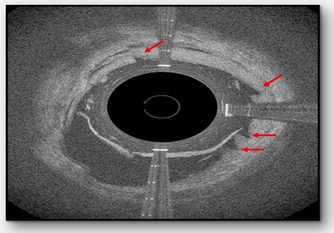
Post FLEX	
Average Number of FLEX Passes	4
Residual Stenosis	65.3%
Luminal Gain	26.6%
Adjunctive Therapy with DCB	
Average Opening Pressure	4.4 atm (2-12 atm)
Maximum Pressure	9 atm (3-15 atm)
Residual Stenosis	9.3% (0-40%)
Procedural Complications	
Grade A Dissections	1%
Grade B Dissections	4%

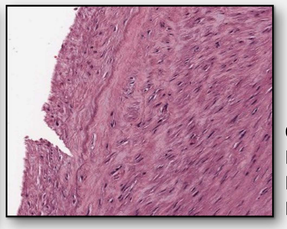
Bail-out stenting was not required.
No flow-limiting dissections, perforations, or emboli occurred.

Technology Overview



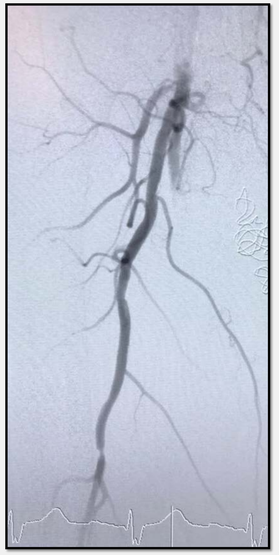
One-Size-Fits-All Device / 1 SKU Inventory
6 Fr / .014 and .018 Guidewire Compatible
40 cm and 120 cm Working Length
Engineered for continuous parallel micro-incisions by 3 Atherotomes
FLEX predilates the stenosis → Skids apply a constant pressure (1 atm)
Controlled depth micro-incisions (Atherotome Height 0.01")
Rotationally controlled, provides the ability to create multiple scores



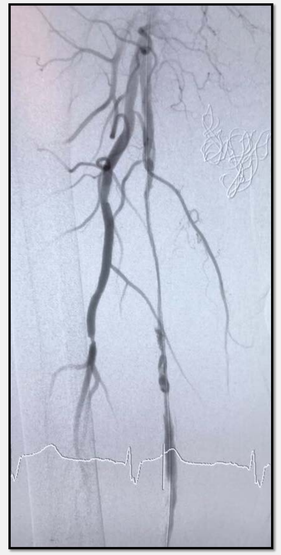


OCT Image (left) and Histology (right) of a Human Cadaver SFA FLEX Micro-Incision

Case Study



Vessel Diameter: 5 mm
Lesion Length: 250 mm
Calcification: Severe
Pre Stenosis: 100%



Post FLEX Recanalization
3 FLEX Passes
Post FLEX Alone
Luminal Gain: 30%

Final Result
Treated with a DCB
Inflation Time: 3 min
DCB Opening Pressure: 5 atm
Residual Stenosis: 5%

Conclusion

FLEX Dynamic Scoring Catheter is utilized by interventionalists as VP prior to DCB. A significant luminal gain was achieved. Observed adequate vessel compliance measured by low balloon opening pressures. Low rates of dissection were observed, suggesting VP can optimize results compared to angioplasty alone. Further studies are warranted to determine longer-term outcomes and demonstration of improving drug-uptake.