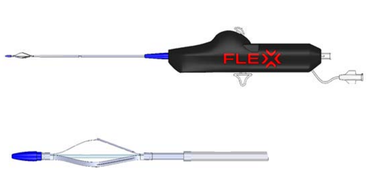
Early Clinical Results Utilizing the FLEX Catheter in 100 Femoropopliteal Chronic Total Occlusions.

Thomas Zeller, MD, PhD, Universitaets-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen,
Louis Lopez, MD, Director, Cardiac Catherterization Lab, Allen County Cardiology, Saint Joseph Hospital, Fort Wayne, IN,
John Pigott, MD, Director Vascular and Endovascular Surgery, The Toledo Hospital, Promedica Healthcare Systems, Toledo, OH

Purpose

Current methods in the treatment of chronic total occlusions (CTO) present numerous clinical and technical limitations. There is strong unmet need for treatment methods that are cost-effective and lead to improved patient outcomes. Initial clinical results using the FLEX Catheter® (VentureMed Group, Toledo, Ohio) as a vessel preparation device to treat femoropopliteal chronic total occlusions were evaluated.

Technology Overview



Sheath Size 6 French

Wire Compatibility .014 and .018

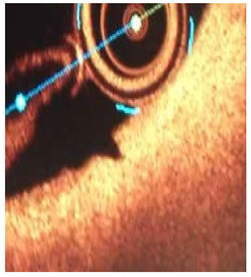
Catheter Length 40cm and 120cm

3 Atherotomes (Proximal) 0.01" in Height

FDA / CE Mark Indication Femoropopliteal and AVF/AVG

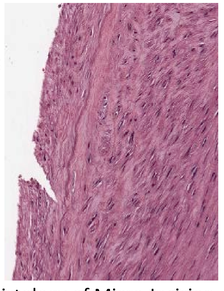
One Size Fits All
Single Insertion Pull-Back Technique

The Flex Catheter has 3 atherotomes that modify plaque during pull-back with **Dynamic Scoring® technology**. FLEX can be rotationally controlled to create multiple linear scores preparing the vessel for treatment.



OCT Image of Micro-Incision

- Precise Longitudinal Micro-Incisions
- Atherotomes (Proximal) Interact with Vessel Surface: 1 atm
- Facilitates an Increase in Vessel Compliance
- Creates a Controlled Environment for Angioplasty



Histology of Micro-Incision (Cadaveric Human SFA)

Methods

This study analyzed voluntarily provided case reports of 100 patients presenting between December 2015 and September 2017 with femoropopliteal CTOs. After successfully crossing the CTO, the lesion was treated with the FLEX Catheter prior to angioplasty. Luminal gain after administration of the FLEX and post-procedure were calculated, as well as the average opening and maximal balloon pressures.

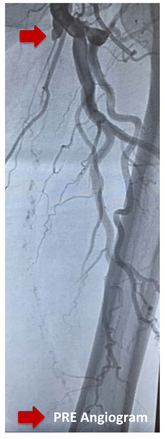
Procedure Data	Mean (Range)
Lesion Length (mm)	191 (30-350)
Moderate / Severe Calcium	46%
Post FLEX Stenosis	69% (20 – 100)
Post FLEX Luminal Gain	31% (0 – 80)
Opening Balloon Pressure (atm)	4.1 (2 – 10)
Maximal Balloon Pressure (atm)	9.4 (4 – 16)
Post Procedure Residual Stenosis	7.9% (0 – 50)
DCB Use (Per Operator Preference)	70%

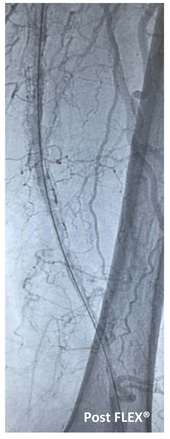
Results

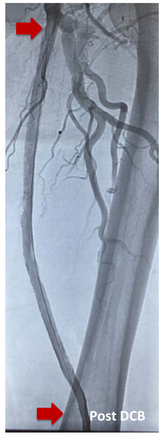
Technical Success	99%
Cases Requiring Pre-Dilatation to Pass FLEX	1
FLEX Recanalized CTO Prior to Angioplasty	99%
Vessel Perforation Occurrences	0
Emboli Occurrences	0
No Dissections	96%
Minimal Dissections	4%
Flow-Limiting Dissections	0%
Provisional Stent Use	19%
Average Luminal Gain Post Procedure	92.1%

Case Study VMG38

PROCEDURE DETAILS	
Lesion Location	Entire Left SFA
Lesion Length	300 mm
CTO Crossing Device	035 Glidewire and Support Cather
Vessel Prep Device	FLEX Catheter®
POBA Treatment	5 x 200 (2 Minute Inflation)
DCB Treatment	6 x 150 (3 Minute Inflation)







RESULTS	
Pre Stenosis	100%
Post FLEX Stenosis	60%
Luminal Gain Post FLEX	40%
Post DCB Stenosis	5%
DCB Opening Pressure	5 atm
Provisional Stenting	0
Dissections	0
Perforations	0

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.