

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

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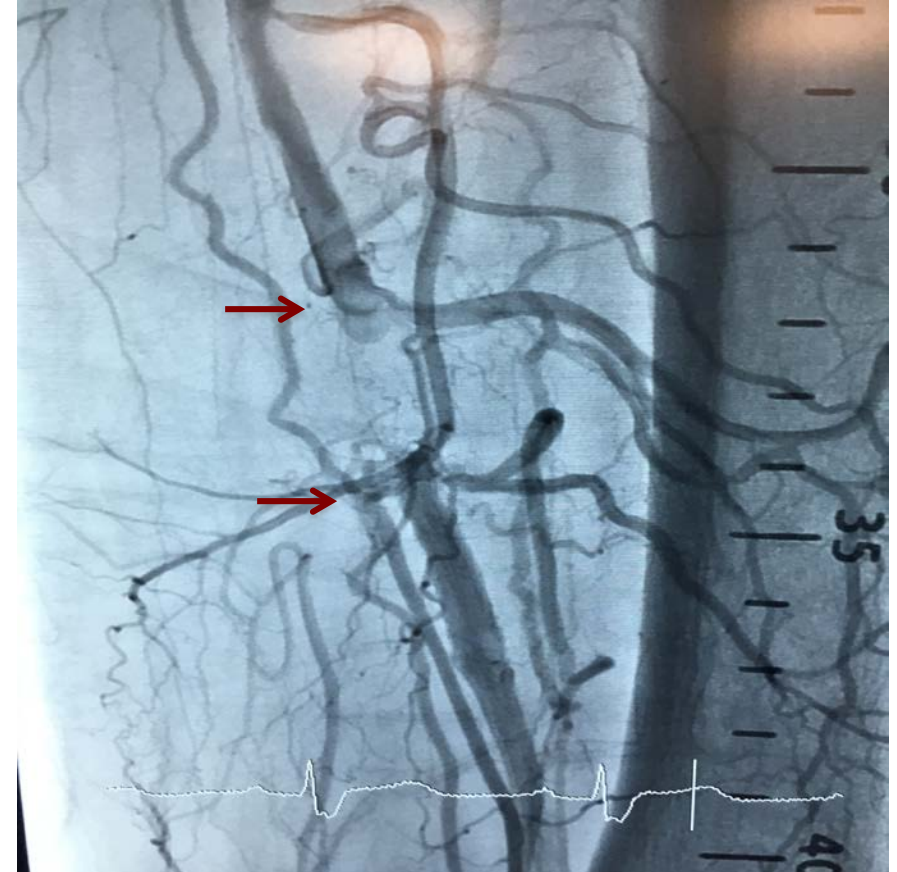
Disclosures

- Professor Thomas Zeller: I disclose the following types of financial relationships:
 - Honoraria:
 - Abbott Vascular, Angioslide, Bard Peripheral Vascular, Veryan, Biotronik, Boston Scientific Corp., Cook Medical, Cordis Corp., Covidien, Gore & Associates, Medtronic, Spectranetics, Straub Medical, TriReme, VIVA Physicians
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Background

Chronic Total Occlusions

- Increasingly Common
- Challenge to Treat
- Increased Risk
 - Calcium
 - Dissections
 - Perforations
 - Embolization
 - Poor Luminal Gain



Technology Overview

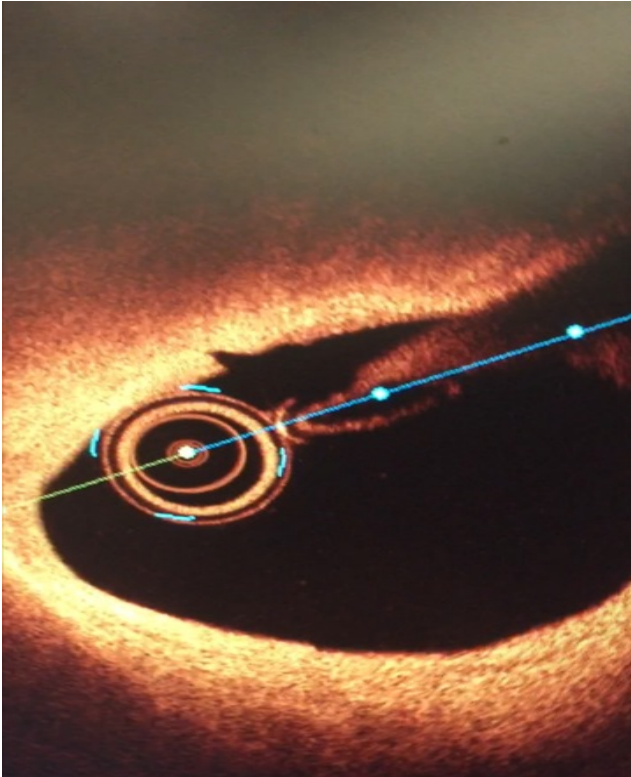
FLEX[®] Scoring Catheter

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



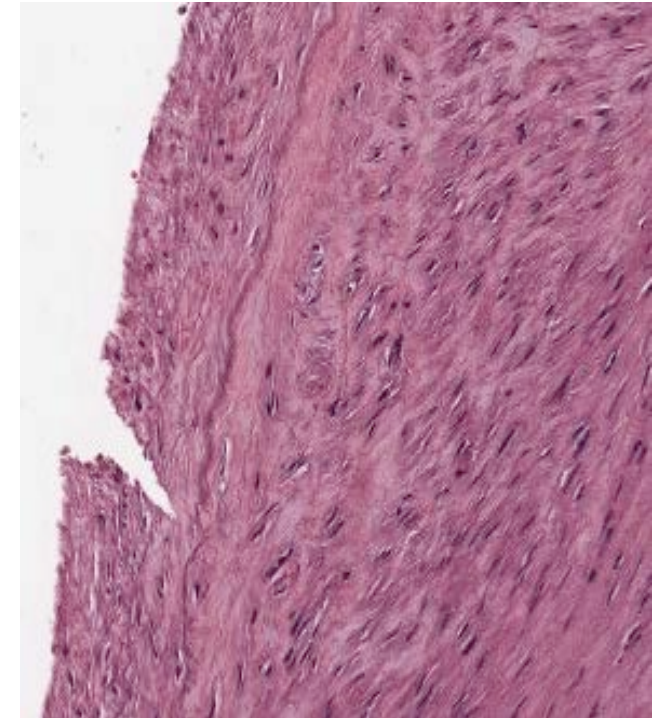
One Size Fits All
Single Insertion Pull-Back Technique

Mechanism Of Action



Dynamic Scoring® Technology

- Precise Longitudinal Micro-Incisions
- Atherotomes Interact with Vessel Surface: 1 atm
- Facilitates an Increase in Vessel Compliance
- Creates a Controlled Environment for Angioplasty
- Basket “Flexes” to Plaque Contour.



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Clinical Data

- Multi-Center Acute Data
- 24 Operators, 15 Hospital Systems
- December 2015 to September 2017
- Voluntarily Provided Case Reports
- Procedure:
 - Cross Occlusion → FLEX → Angioplasty
- 100 CTO Patients

LESION CHARACTERISTICS	DETAILS
Average Lesion Length (mm)	191
Lesion Length Range (mm)*	30 – 350
Moderate/ Severe Calcium	46%

*In Comparison to the MASCOT Trial: Average Lesion Length = <80 mm

Procedural Data

	Mean (Range)
Pre-Procedure Stenosis	100%
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%

*In Comparison to the MASCOT Trial: Provisional Stent Use = 42%

Case Studies

Case Study 1

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



PRE Angiogram

Case Study 1

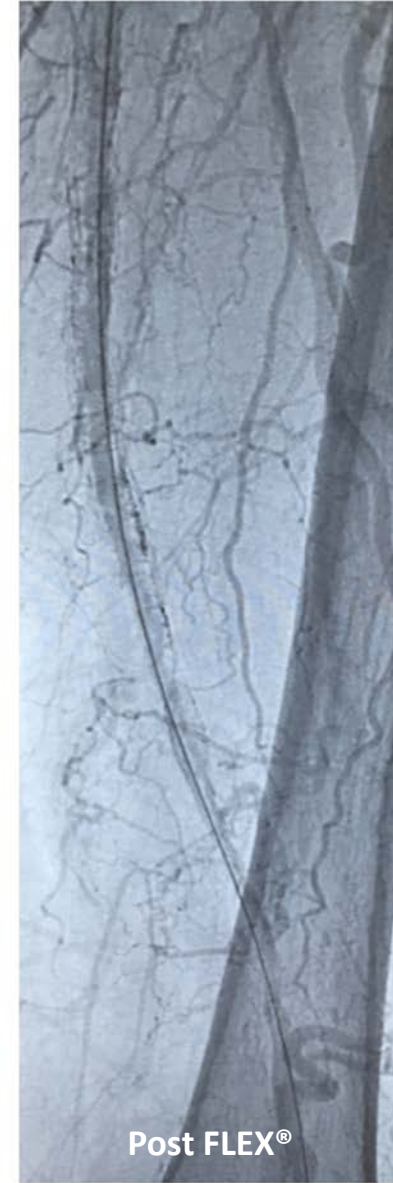
PROCEDURE RESULTS

DETAILS

Pre Stenosis	100%
Post FLEX Stenosis	60%
Luminal Gain Post FLEX	40%
Post DCB Stenosis	5%
DCB Opening Pressure	5 atm
Dissections	None



PRE Angiogram



Post FLEX®



Post DCB

Case Study 2

PROCEDURE INFORMATION

DETAILS

Lesion Location	Distal SFA
Lesion Length	120 mm
CTO Crossing Device	035 Glidewire and Support Catheter
Vessel Prep Device	FLEX Scoring Catheter®
DCB Treatment	4 x 120 (3 Minute Inflation)



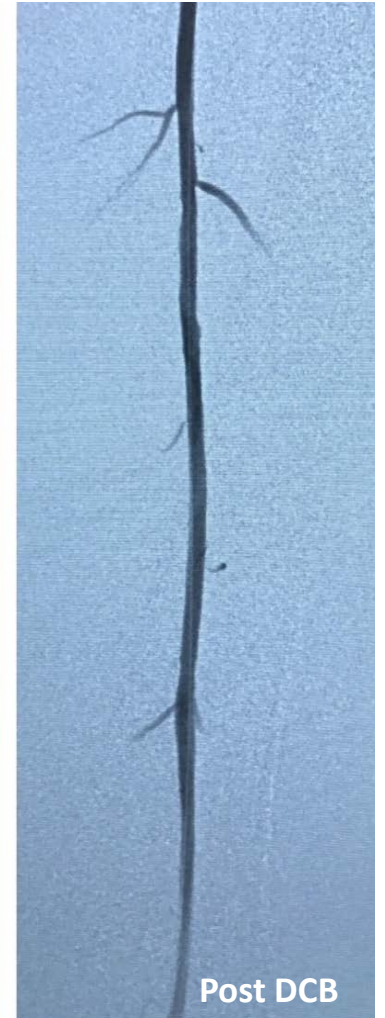
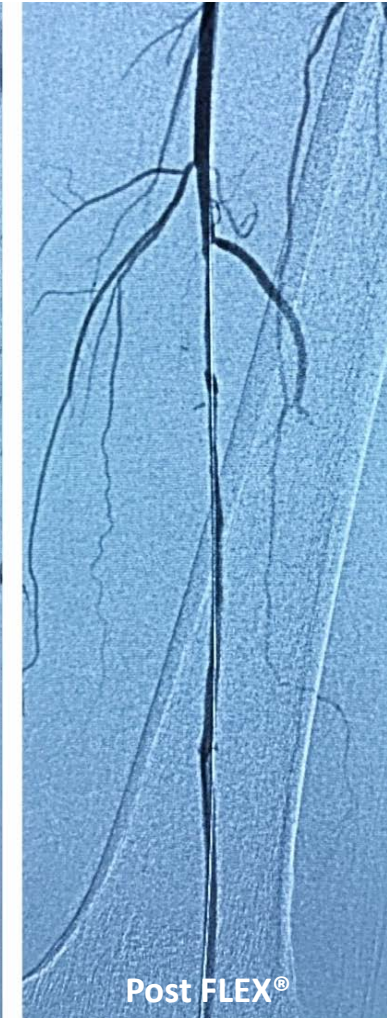
PRE Angiogram

Case Study 2

PROCEDURE RESULTS

DETAILS

Pre Stenosis	100%
Post FLEX Stenosis	70%
Luminal Gain Post FLEX	30%
Post DCB Stenosis	0%
DCB Opening Pressure	3 atm
Dissections	None



Conclusions

- High Degree of Technical Success in Achieving Consistent Luminal Gain Post FLEX.
- Low Opening Balloon Pressures Suggest Significant Improvement in Vessel Wall Compliance with FLEX.
- Recanalizes CTOs with Low Rates of Dissection.
- Low Provisional Stent Use in this Challenging Set of Long CTO Lesions.

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