CARDIOVASCULAR INNOVATIONS 2018

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A TALE OF TWO LESIONS



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Patient Background

- 67 year old Male
- Hypertension
- History of smoking
- Rest pain
- Rutherford Class 3
- TASC II: C
- No previous interventions
- Pre-Procedure ABI: 0.18

Diagnostic

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Diagnostic

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Treatment to the Left SFA/POP



- 2 Lesions
- Moderate/Severe Calcification
- Lesion in the proximal SFA
 - Treated with a DCB only
- CTO in the POP
 - Vessel Diameter: 5 mm
 - Lesion Length: 60 mm
 - Lesion treated with the FLEX Dynamic Scoring Catheter and a DCB
- POBA was NOT used prior to DCB in either location.

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Vessel Preparation

FLEX Dynamic Scoring Catheter®

- 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

Early Clinical Results Utilizing the FLEX Scoring Catheter in 100 Femoropopliteal Chronic Total Occlusions. Presented at ISET January 2018

Thomas Zeller, MD, PhD, Universitaets-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen

- 24 operators in 15 hospital systems
- The FLEX is effective in recanalizing CTOs with low rates of vessel dissection.

Results			
Average Lesion Length (mm)	191		
Luminal Gain Post FLEX	31%		
DCB Use	70%		
Average Opening Balloon Pressure (atm)	4.1		
Residual Stenosis Post FLEX + Angioplasty	7.9%		
Provisional Stent Use	19%		
Moderate / Severe Calcium	46%		

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Real World Results of a Dynamic Scoring Device in Calcified Femoropopliteal Vessels Presented at CVC 2018

Frank Arko, MD, Director Endovascular Surgery, Sanger Heart and Vascular Institute, North Carolina

Results	None – Mild	Moderate - Severe
Number of Lesions	140	177
Average Lesion Length (mm)	110.5	145.6
Luminal Gain Post FLEX	24%	30%
DCB Use	78%	73%
Average Opening Balloon Pressure (atm)	4.5	4.6
Residual Stenosis Post FLEX + Angioplasty	9%	11.6%
Flow-Limiting Dissection	0%	0%
Emboli / Perforations	0%	0%
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83 operator, 55 health systems

- Low balloon opening pressures
- FLEX is Safe and Effective in Calcium

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- 3 passes with the FLEX Scoring Catheter
- 30° rotation between each pass
- FLEX achieved 60% luminal gain



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FL TRACK VASCULAR OPERATIVE DSA 7.5 Straight to DCB IN.PACT: 4x150 and 5x150

- Balloon fully effaced at 4 atm
- Balloon inflated to nominal
- Inflation held for 3 minutes
- Residual Stenosis: 10%

**No dissections, emboli, or perforations after FLEX + DCB



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Final Result

LAO: 1

GURECKY JEFFREY P

CTO in POP Treated with FLEX and IN.PACT No Dissections or Emboli



Proximal SFA Lesion Treated with IN.PACT only Non flow-limiting dissection occurred

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Final Result

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Conclusion

Without vessel prep, angioplasty resulted in a non-flow-limiting dissection.

Vessel Prep with the FLEX:

- CTO was successfully recanalized
- Luminal gain achieved
- Improved vessel compliance
 - Evident by the low balloon opening pressure
- No dissections
- No stents

Vessel preparation with the FLEX helps to avoids stents and dissections. FLEX + DCB saves time and radiation exposure

