

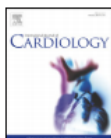
2-Year Experience using FLEX Catheter as a Preparatory Device for Drug-Coated Balloon and/or Balloon Angioplasty

Fedor Lurie, PhD, RPVI, FSVS

Faculty Disclosures

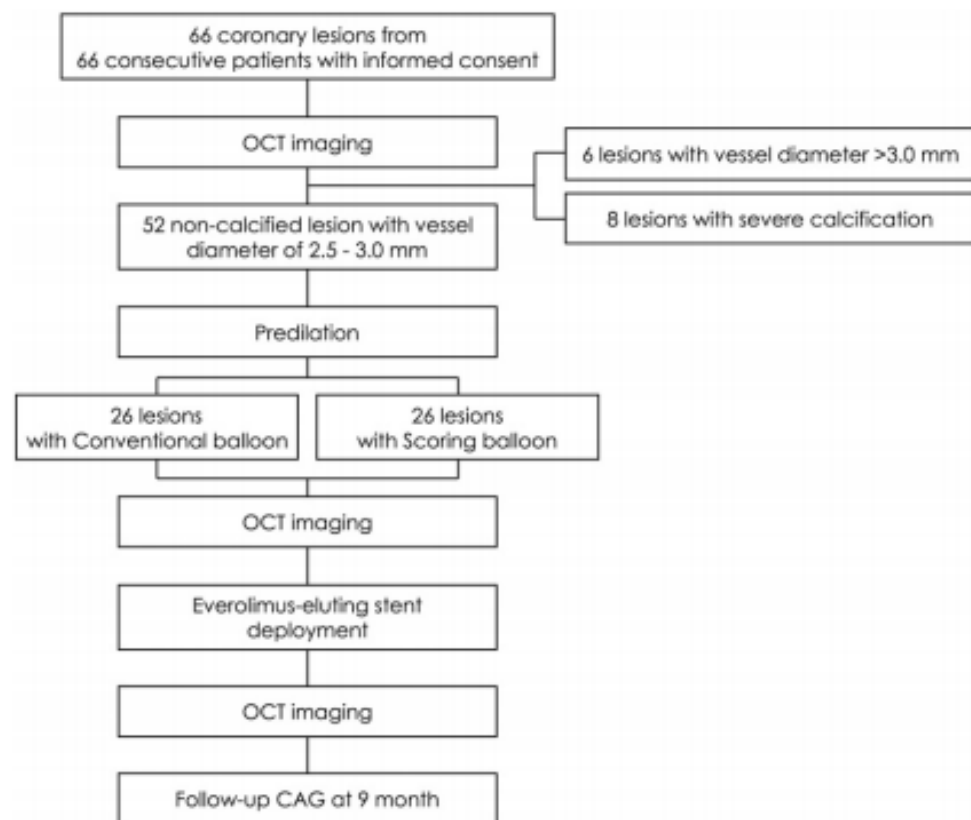
Fedor Lurie, PhD: has nothing to disclose.

*Brand names are included in this presentation for participant clarification purposes only.
No product promotion should be inferred.*

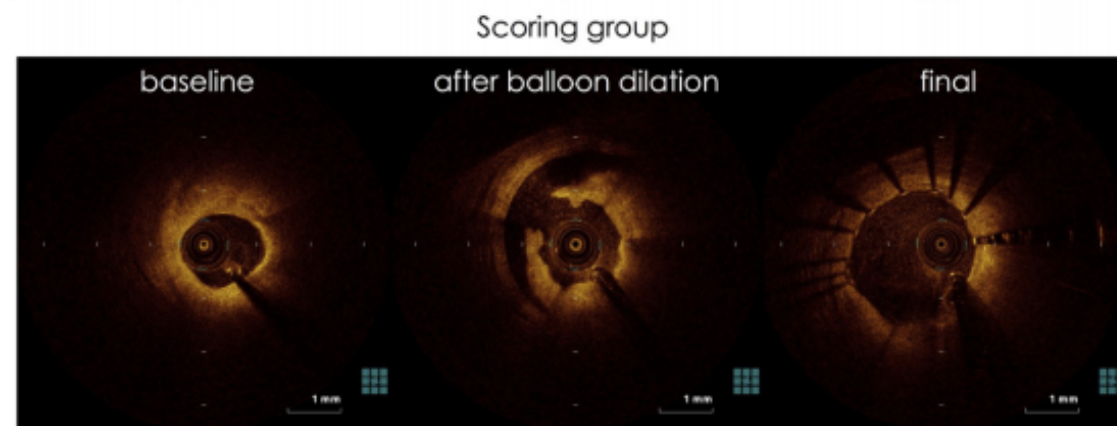
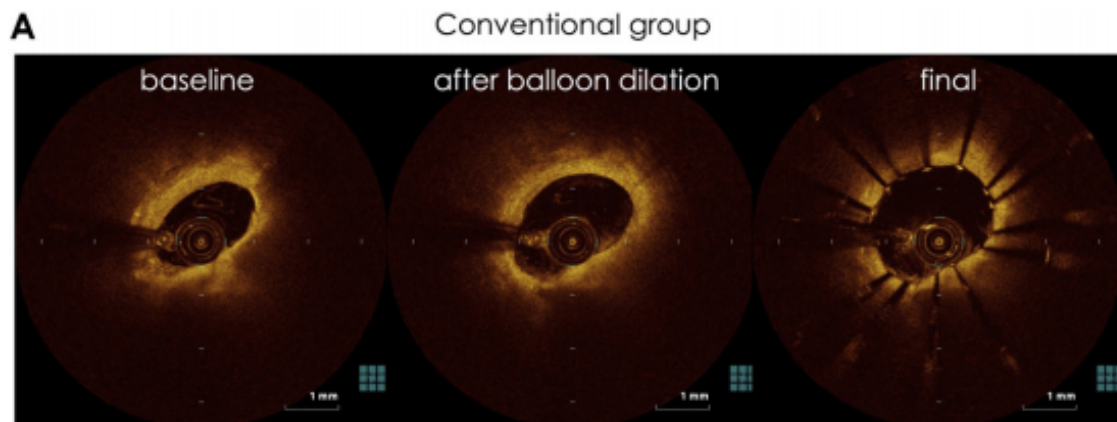


Intimal disruption affects drug-eluting cobalt-chromium stent expansion: A randomized trial comparing scoring and conventional balloon predilation☆☆☆

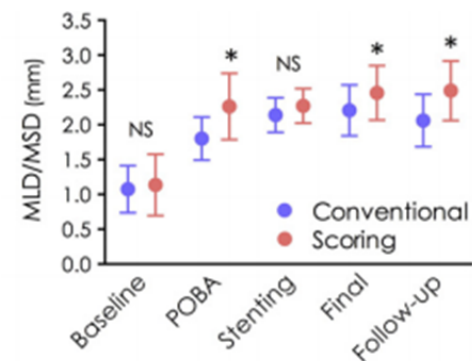
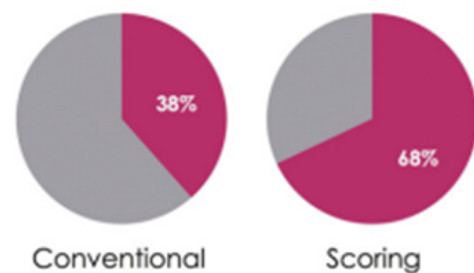
Kentaro Jujo^{a,b,*}, Katsumi Saito^b, Issei Ishida^b, Ahsung Kim^b, Yuki Suzuki^b, Yuho Furuki^b, Taisuke Ouchi^b, Yasuhiro Ishii^c, Haruki Sekiguchi^d, Junichi Yamaguchi^a, Hiroshi Ogawa^a, Nobuhisa Hagiwara^a



A



Intimal disruption



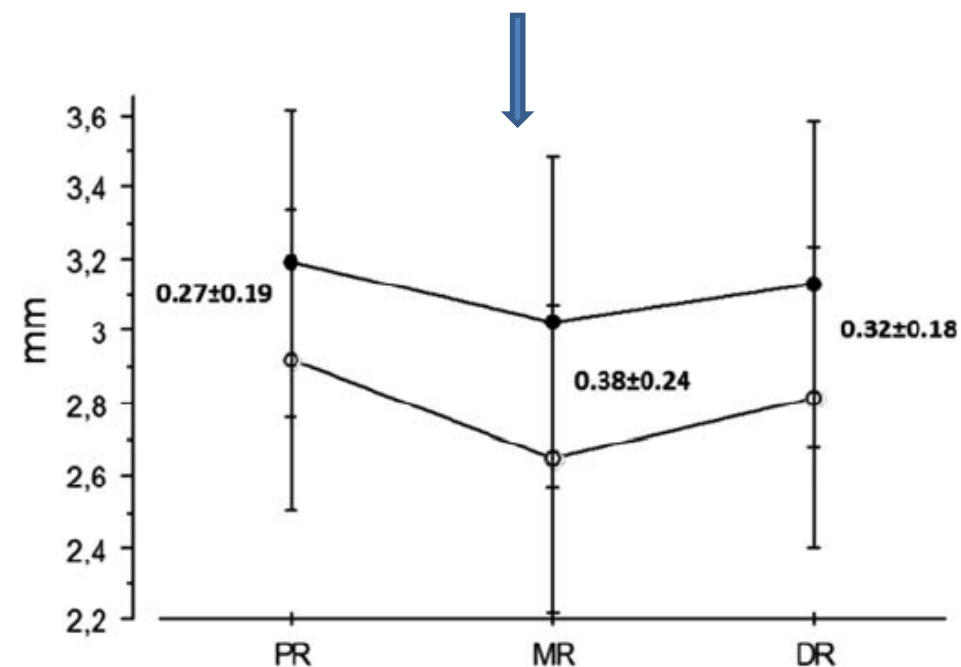
Does Optimal Lesion Preparation Reduce the Amount of Acute Recoil of the Absorbe BVS? Insights from a Real-World Population

Gian Battista Danzi,^{1*} MD, Marco Sesana,² MD, Mario Arieti,² MD, Giuliano Villa,² MD, Sergio Rutigliano,² MD, Alessandro Aprile,² MD, Annamaria Nicolino,¹ MD, Shahram Moshiri,¹ MD, and Renato Valenti,³ MD

Factors Predicting Acute Percent Recoil

Multiple regression analysis of the population as a whole identified BVS use ($\beta = 0.477$; $P < 0.001$), a small reference vessel diameter ($\beta = 0.229$; $P = 0.003$), and a residual stenosis of $\geq 20\%$ after pre-dilatation as predictors of acute percent recoil ($\beta = 0.142$; $P = 0.03$). A separate regression analysis of the BVS group showed that a small reference vessel diameter ($\beta = 0.334$; $P = 0.002$) and a residual lesion of $\geq 20\%$ after predilatation ($\beta = 0.217$; $P = 0.027$) were independent predictors. The regression analysis of the EES group did not reveal any significant predictors related to acute recoil.

Acute recoil is higher in the area of calcification



Absolute recoil PR vs MR; $P < 0.001$

Absolute recoil PR vs DR; $P = 0.008$

Absolute recoil MR vs DR; $P = 0.007$

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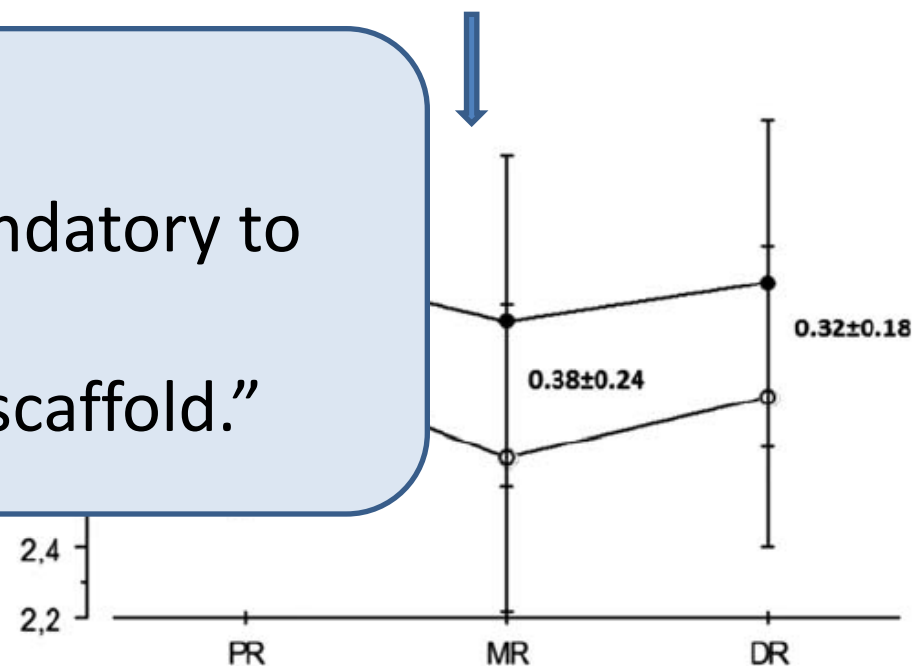
Acute recoil is higher in the area of calcification

CONCLUSIONS: “optimal lesion preparation seems to be mandatory to maximize the mechanical properties of the scaffold.”

Factor

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Absolute recoil PR vs MR; $P < 0.001$
 Absolute recoil PR vs DR; $P = 0.008$
 Absolute recoil MR vs DR; $P = 0.007$

Directional Atherectomy Followed by a Paclitaxel-Coated Balloon to Inhibit Restenosis and Maintain Vessel Patency

Twelve-Month Results of the DEFINITIVE AR Study

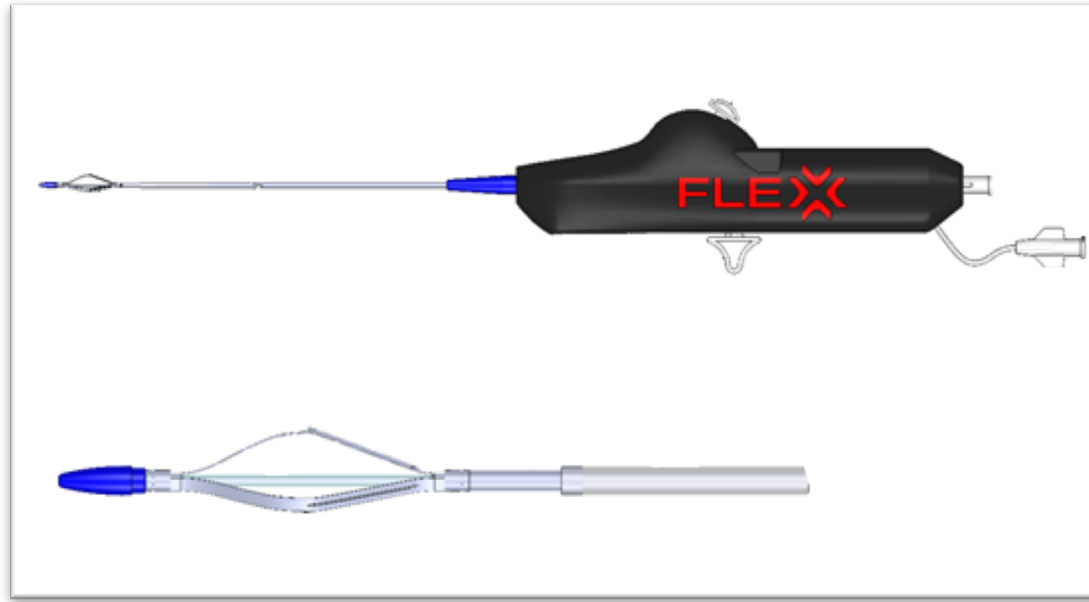
Thomas Zeller, MD; Ralf Langhoff, MD; Krishna J. Rocha-Singh, MD; Michael R. Jaff, DO;
Erwin Blessing, MD; Beatrice Amann-Vesti, MD; Marek Krzanowski, MD; Patrick Peeters, MD;
Dierk Scheinert, MD; Giovanni Torsello, MD; Sebastian Sixt, MD; Gunnar Tepe, MD;
on behalf of the DEFINITIVE AR Investigators

Circ Cardiovasc Interv. 2017 Sep;10(9). pii: e004848.

Table 4. Procedural Complications

	Nonrandomized	Randomized		
Complication	DA+DCB	DA+DCB	DCB Only	<i>P</i> Value*
Arterial perforation	0% (0/19)	4.2% (2/48)	0% (0/54)	0.22
Arteriovenous fistula	0% (0/19)	6.3% (3/48)	11.1% (6/54)	0.49
Dissection—grade C/D or greater	0% (0/19)	2.1% (1/48)	18.5% (10/54)	0.009
Distal embolism (clinically significant)	5.3% (1/19)	4.2% (2/48)	0% (0/54)	0.22
Distal embolism (not clinically significant)	0% (0/19)	2.1% (1/48)	0% (0/54)	0.47
Aneurysm	0% (0/19)	0% (0/48)	0% (0/54)	...
Pseudoaneurysm	5.3% (1/19)	6.3% (3/48)	0% (0/54)	0.10
Total†	5.3% (1/19) [2]	22.9% (11/48) [12]	25.9% (14/54) [16]	0.82

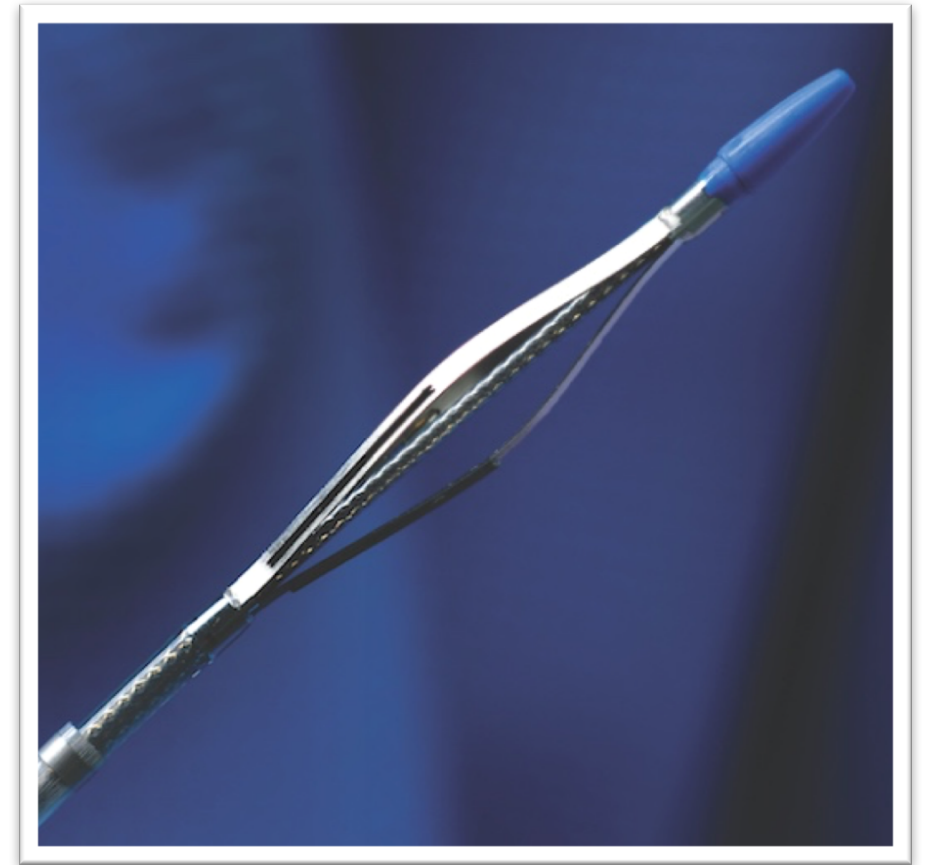
FLEX[®] Vessel Preparation System



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

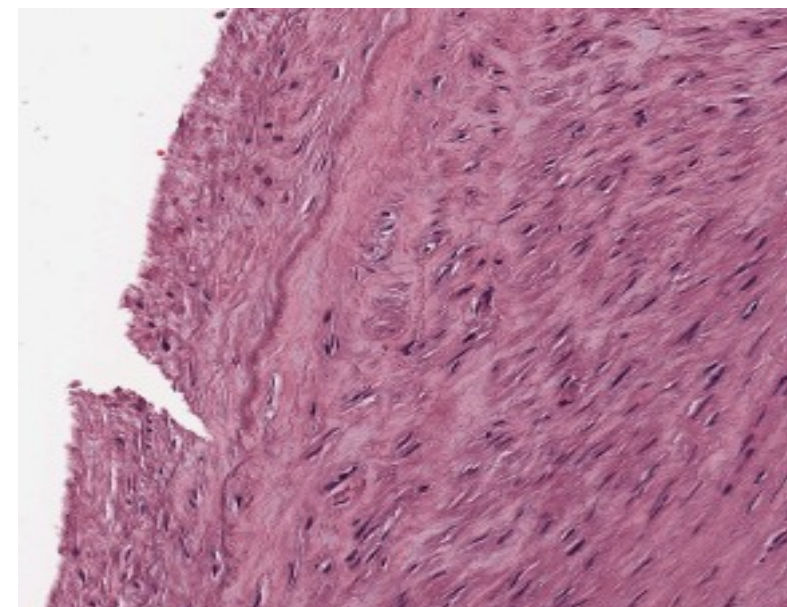
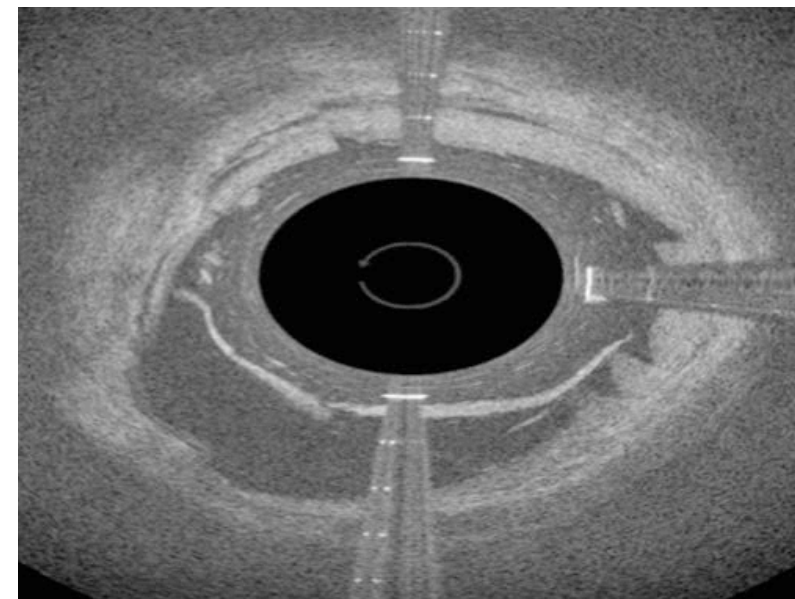
The FLEX System

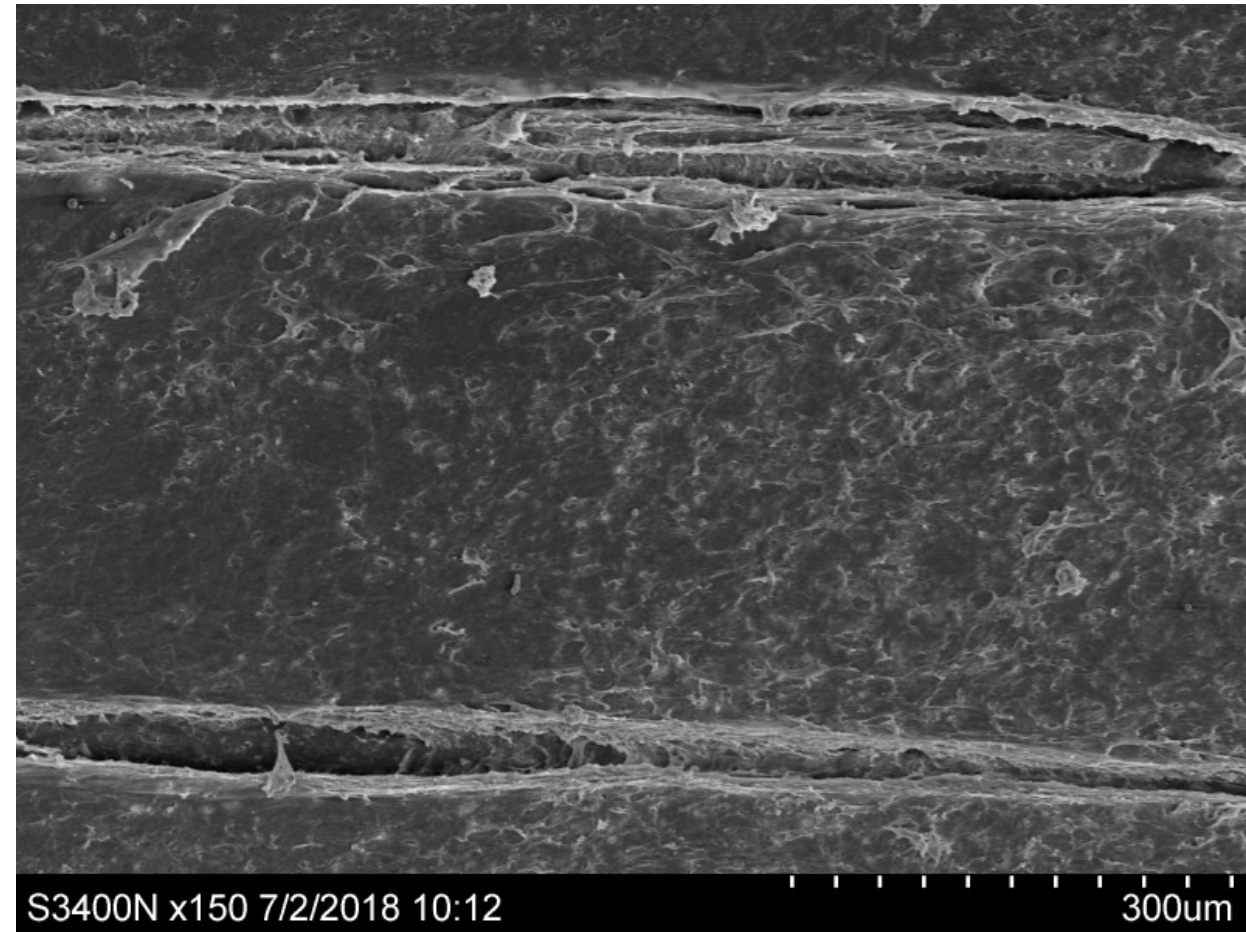
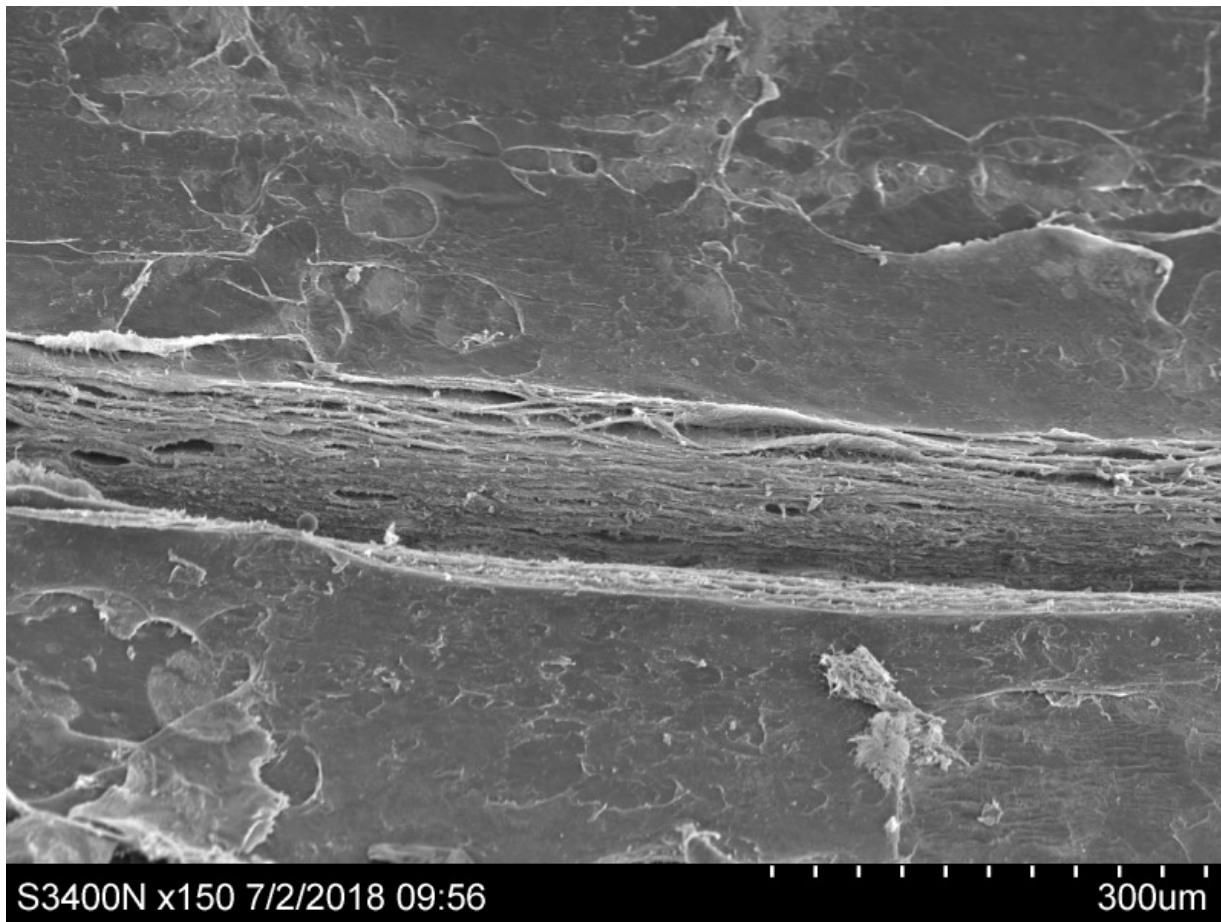
- 3 Skid Plates with a Proximal Atherotome
- Controlled Depth Micro-Incision
- Basket Expands by a Actuation Button
- Retrograde Pull-Back
- Rotation Control
- A One Size Fits All Device.



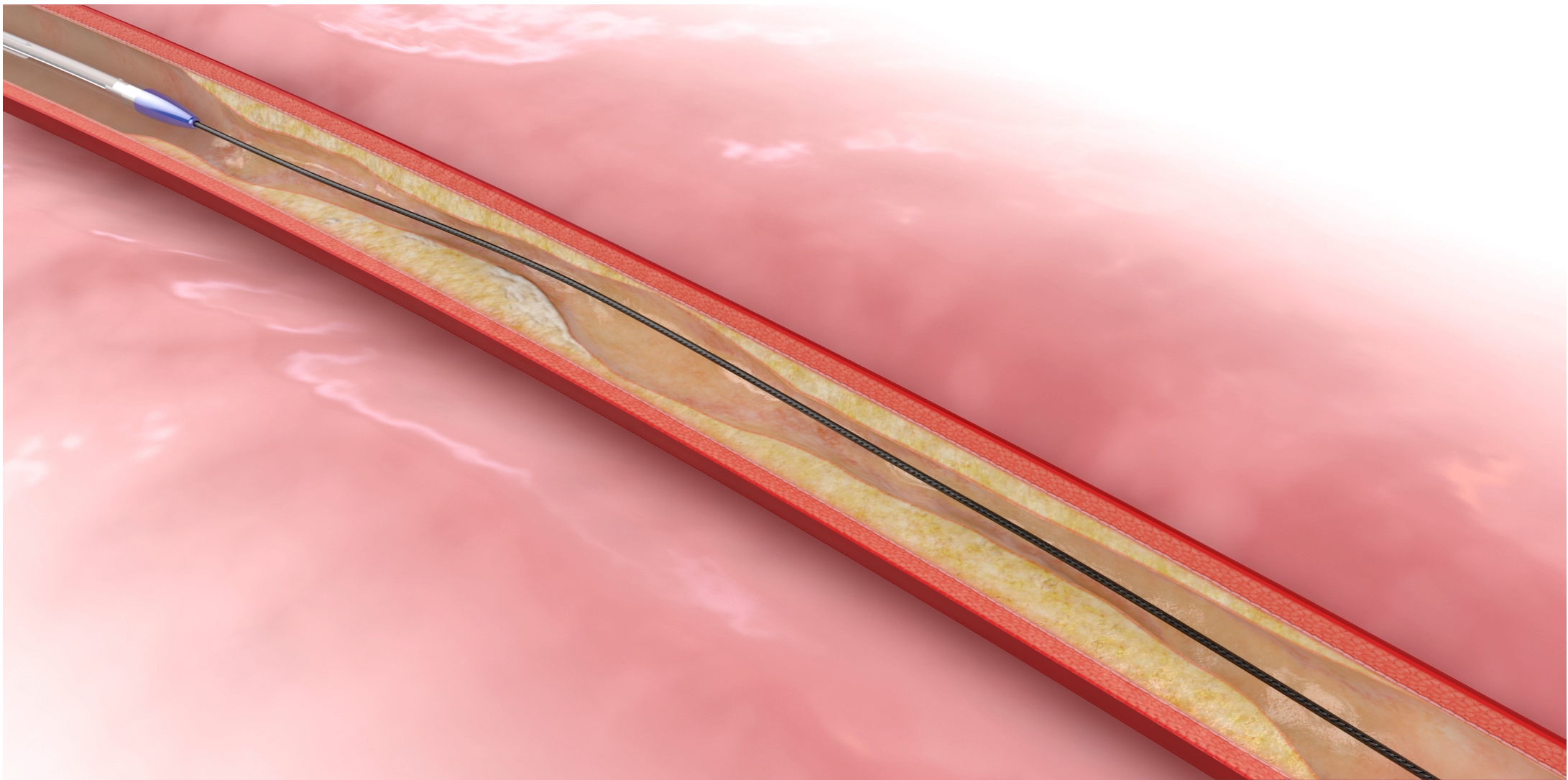
Mechanism Of Action

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





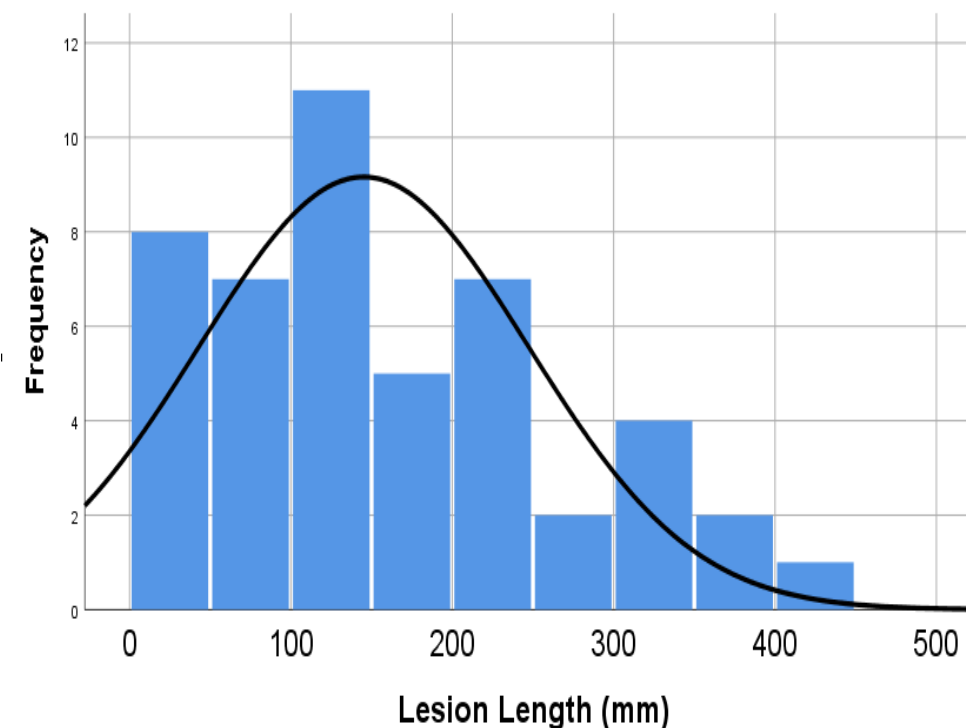




Study design: 2-year sequential case-series study with 6-month follow up
Population: all patients in whom the FLEX System was used as a preparatory device for a drug-coated balloon (DCB) and/or balloon angioplasty (POBA).

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%

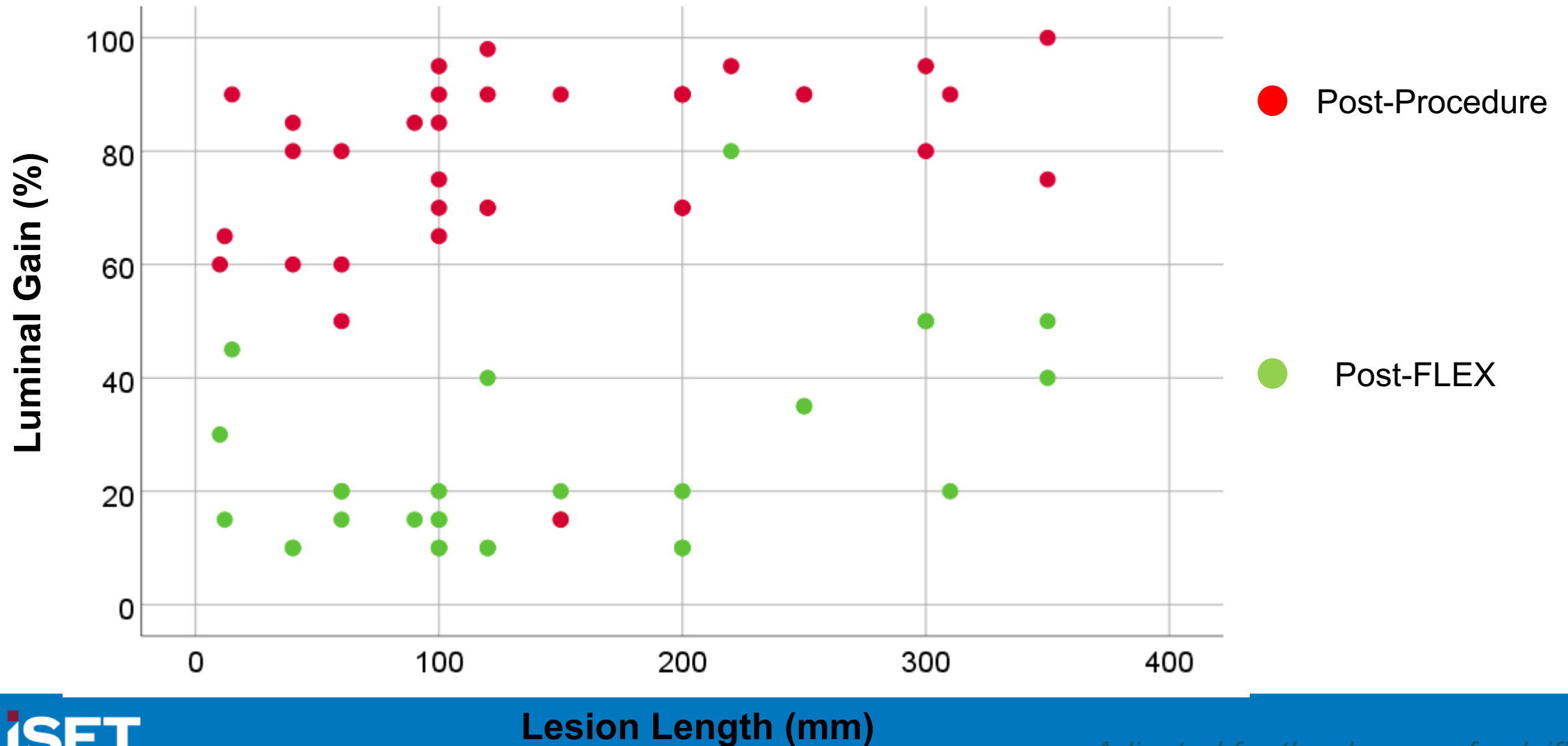
Patient Demographics	
Number of Patients	123
Male sex (%)	59
Diabetes (%)	51
Smokers (%)	84



Periprocedural outcomes

	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)

Luminal Gain and Lesion Length



RESULTS

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%
CLINICAL (6 Month Follow-Up)	
ABI improvement (increase > 0.15)	61%
Re-interventions	4%

Conclusions

- The FLEX Vessel Preparation System 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 with FLEX use.
- Lower Dissection Rate After FLEX use Lowers the Necessity of Stenting.

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