Can Vessel Preparation Minimize Residual Stenosis and Improve Outcomes?

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Purpose of Vessel Preparation

Creates an optimal environment for angioplasty:

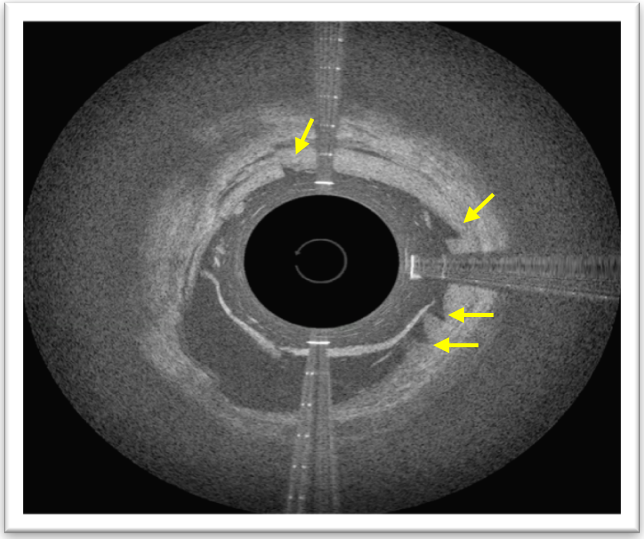
- Improves vessel compliance
  - Lower balloon pressures required for lesion effacement
- Increases luminal gain
- Facilitates drug distribution
- Minimize adverse events
  - Dissections, embolization, perforations
- Decreases the need for stenting

FLEX Vessel Preparation System

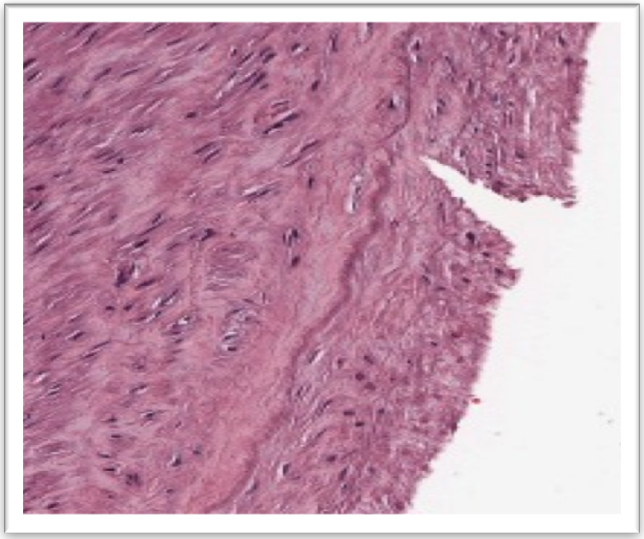
Sheath Size	6 French
Wire Compatibility	.014 and .018
Catheter Length	40cm and 120cm
3 Atherotomes (Proximal)	0.01” in Height

CE Mark / FDA Indication for Use: To facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae

The FLEX System



OCT Image of Micro-Incision

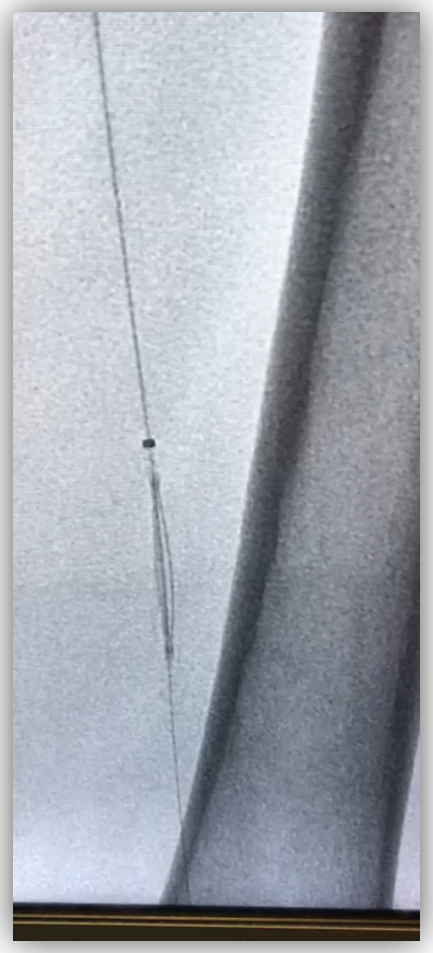


Histology of Micro-Incision

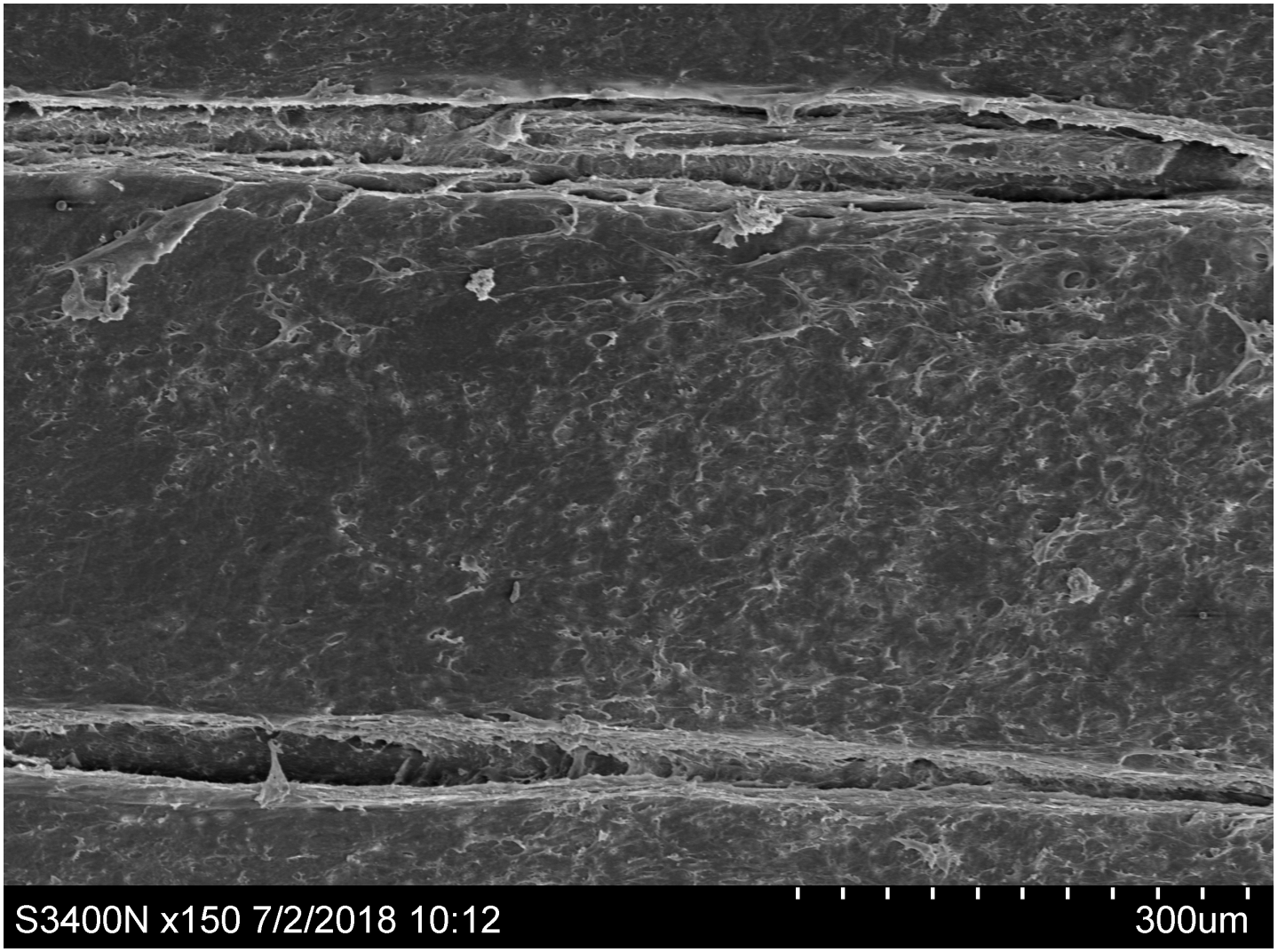
- 3 Proximal Atherotomes Mounted on Skids
- Controlled Depth Micro-Incision
- Retrograde Pull-Back
- Rotation Control (1:1 torque)
- A One Size Fits All

Mechanism of Action

- Precise longitudinal micro-incisions
- Skid surface area prevents perforation
- Atherotomes interact with vessel surface at 1 atm
- Creates a controlled environment for angioplasty
- Basket “flexes” to plaque contour



Parallel FLEX Micro-Incisions



Human cadaver SFA, SEM Image magnified 150x

Acute Real-World Data

- 457 Patients treated
- 66 Institutions, 100 Physicians

Definitions:

Procedural Success: Residual Stenosis ≤ 30%

Opening Balloon Pressure: Lowest pressure required to fully efface the lesion.

- Average Age: 71 years old
- Average Lesion Length: 13.7 cm
- Chronic Total Occlusions: 44%
- Average Baseline Stenosis: 92%

Vessel Preparation by the FLEX

- Angiogram is Captured Prior to Angioplasty Evaluating Luminal Gain and Safety of the FLEX.

Post FLEX Alone:

Average Luminal Gain: 29.5%

Pre-Procedure **Post FLEX**

Procedural Results

- DCB utilized in 73% of cases
- Average Opening Balloon Pressure: 4.5 atm

Grade A Dissections	4.6%
Grade B Dissections	1.3%
Flow-Limiting Dissection	0%
Perforation	0%
Embolization	0%

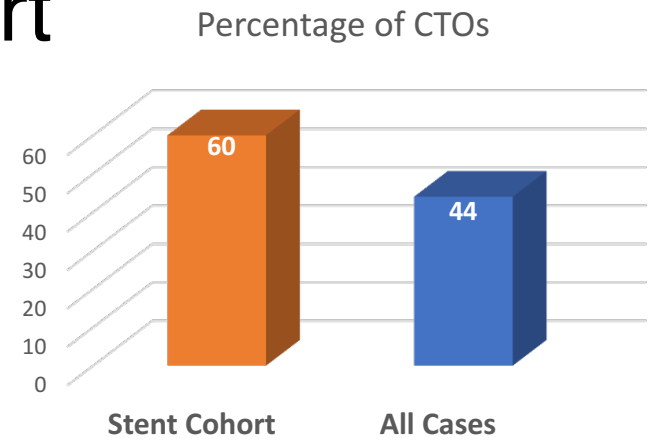
- No Bail-Out Stenting Required
- Provisional Stent Use: 21.7%
- Average Residual Stenosis: 10%

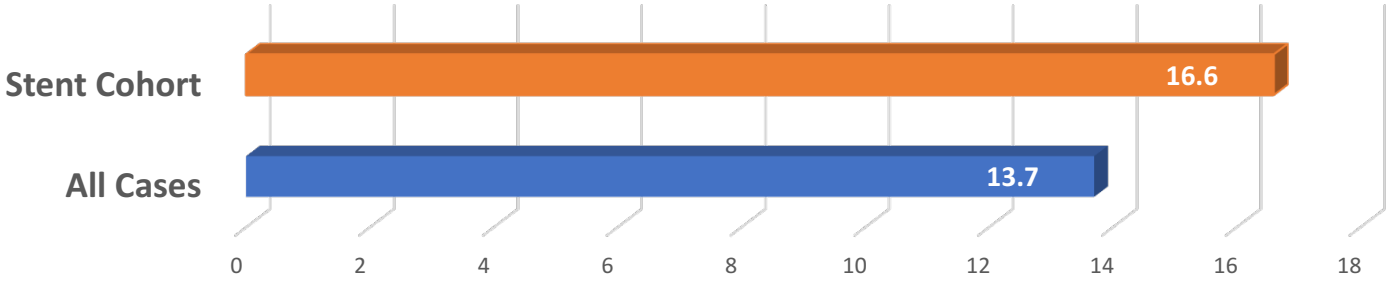
- Procedural Success: 97.2%

Post FLEX & DCB

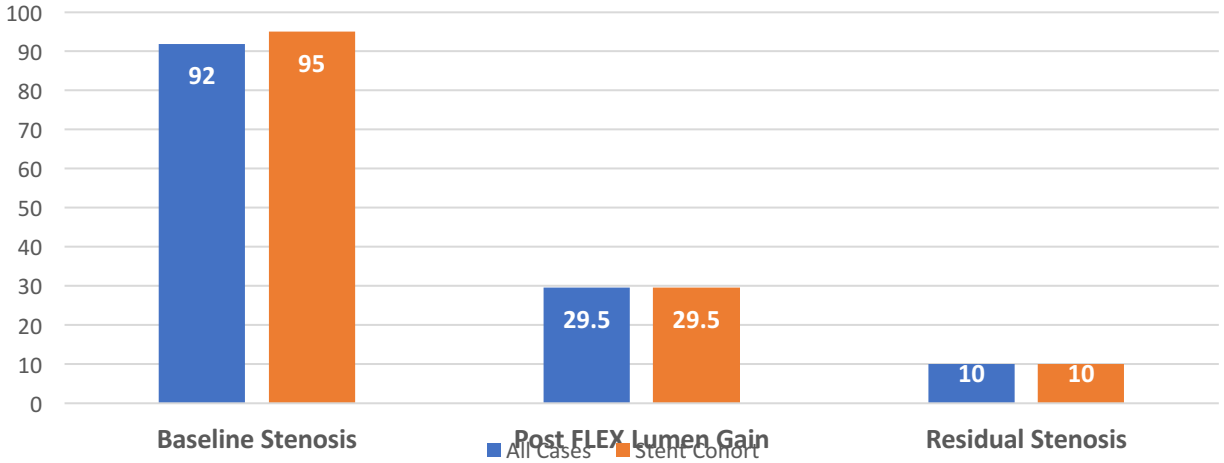
Stent Cohort

- No Flow-Limiting Dissections
- All Provisional
- Increased Average Lesion Length (cm)
- Higher percentage of CTOs





- No Change to FLEX Luminal Gain or Residual Stenosis



Conclusion

- Vessel preparation with the FLEX System achieved a high rate of procedural success. ¾ cases used DCB post FLEX.
- Low opening balloon pressures suggest improvement in vessel wall compliance with use of the FLEX. Low dissection rate with no flow-limiting dissections.
- All stenting was provisional; longer lesions and CTOs tended towards stenting.
- Further studies are warranted on the long-term benefits.