Can Vessel Preparation Reduce the Need for High Pressure Balloon Angioplasty in Arteriovenous Access Treatment?

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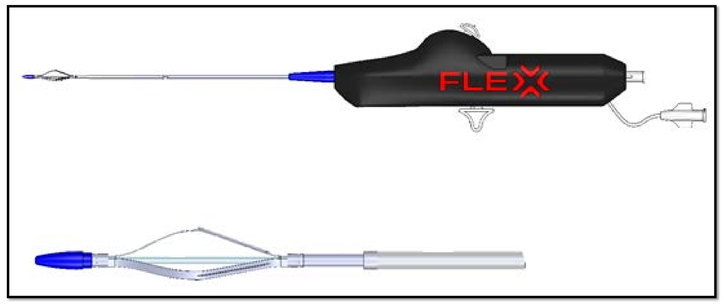
Objectives

A failing hemodialysis arteriovenous access is often a reoccurring and costly problem for many patients. The current standard of care is high pressure balloon angioplasty (POBA) to dilate the lesion. The high pressures can be painful for the patient, can cause venous rupture, and long-lasting results have remained elusive. Prepping the vessel with a novel scoring device could efface the stenoses at lower pressures and may lengthen the time to the next intervention.

FLEX® Scoring Catheter

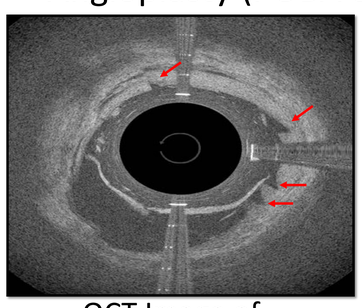
The dynamic scoring device evaluated is a 6 French, 0.018 guidewire compatible device, engineered with 3 atherotomes to modify stenoses during pull back. It can be rotationally controlled to provide multiple linear controlled-depth micro-incisions, facilitating in the preparation of the vessel for angioplasty.



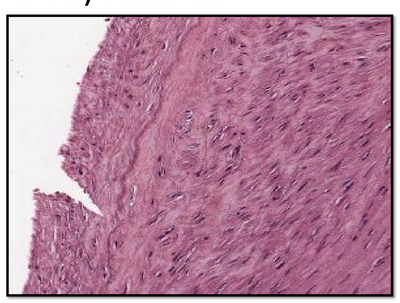
Sheath Size:	**6 French**
Wire Compatibility:	**.014 and .018**
Catheter Length:	**40cm and 120cm**
3 Atherotomes (Proximal):	**0.01” in Height**
FDA / CE Mark Indication:	**Facilitate Dilatation of Stenoses of Femoropopliteal and AV Access**

Dynamic Scoring® Technology

- Creates Precise Longitudinal Micro-Incisions
- Atherotomes Interact with the Vessel Surface at 1 atm.
- Facilitates improvement in Vessel Compliance
- Creates an Environment for Optimal Angioplasty (POBA or DCB) Results.



OCT Image of Micro-Incision



Cadaveric Human SFA

Methods

Acute, single operator, retrospective data from twenty-four patients were analyzed between May 2017 and September 2017. Each patient presented for an arteriovenous intervention due to either a pulsatile AV (4.2%), poor access (4.2%), inefficient dialysis (8.3%), or poor flow rate (83.3%). The mean age was 61 years old, with 75% of subjects being male.

Pre-Procedure Evaluation Fistulagram
Measure % Stenosis

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Vessel Preparation with the FLEX
30° Rotation between Pull-Backs
Post FLEX Fistulagram
Measure % Stenosis/ Luminal Gain

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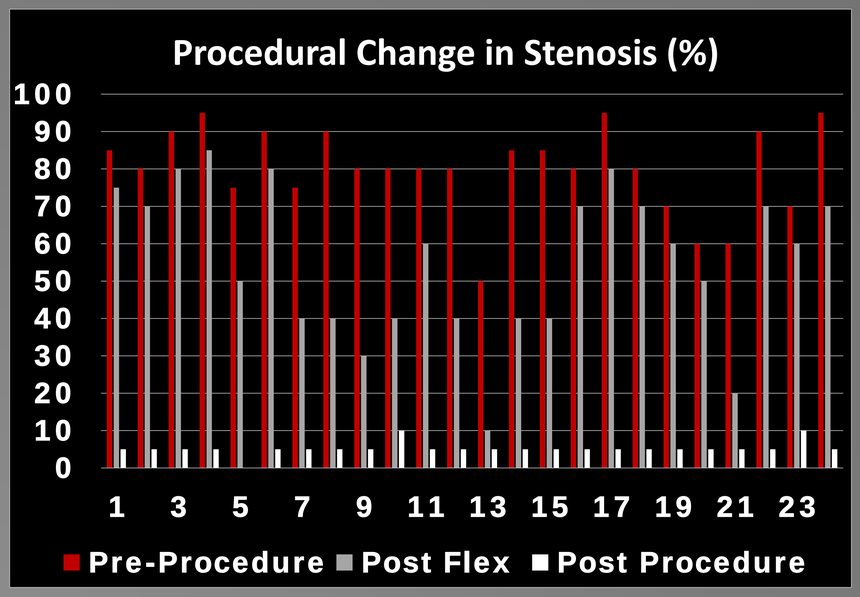
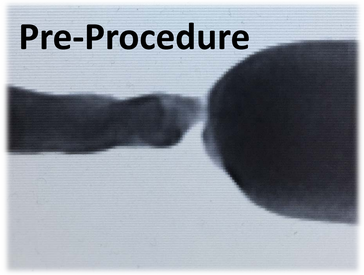
POBA Angioplasty
Opening Balloon Pressure
Post POBA Fistulagram
Measure % Stenosis / Luminal Gain

The reduction in stenosis was recorded after vessel preparation and after POBA. The opening pressure, defined as the lowest pressure required to obtain full lesion effacement, was recorded along with the maximal pressure.

Results	% (n) / Mean (Range)
AVF	67% (16)
AVG	33% (8)
Vessel Diameter (mm)	8.3 (6-10)
Lesion Length (mm)	36.3 (20-120)
Pre-Procedure Stenosis	80% (50-95)
Number of FLEX Pullbacks	3 (2-5)
Post FLEX Stenosis	55.4 (10-85)
Luminal Gain Achieved Post FLEX	24.6% (10-50)
POBA Balloon Size (mm)	8 (6-10)
Opening Balloon Pressure (atm)	8.1 (4-16)
Maximal Balloon Pressure (atm)	17 (9-24)
Residual Stenosis	5.2% (0-10)
Overall Luminal Gain	74.8% (45-90)



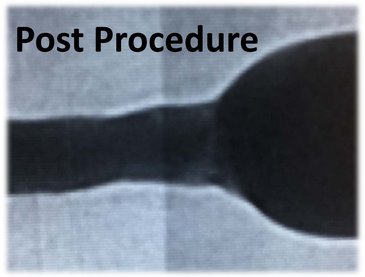
Case Study



Pre-Procedure Evaluation
AVF
Intervention Reason:
Poor Flow Rate
Lesion Length: 10 mm
Pre-Stenosis: 95%

Vessel Preparation
FLEX Passes: 5
Post FLEX Stenosis: 70%

POBA Angioplasty
Balloon Size: 7 mm
Opening Pressure: 4 atm
Maximal Pressure: 9 atm



Post Procedure
Residual Stenosis: 5%

Conclusion

Use of the FLEX prior to balloon angioplasty resulted in low balloon opening pressures.

Vessel preparation may decrease the need for expensive high pressure angioplasty balloons.

Further studies are warranted to investigate re-intervention rates and the time between interventions, especially as the FLEX creates an optimal environment for POBA or DCB .