Can Vessel Preparation Improve Endovascular Intervention Outcomes in Arteriovenous Access? A Single Operator Retrospective Review

Allen Lazenby, MD, East Alabama Medical Center, Opelika, Alabama

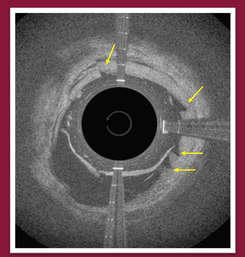
eamc east alabama medical center

Purpose

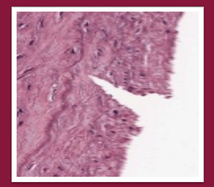
A patent vascular access is vital to patients undergoing dialysis therapy. The primary reason for access failure is the development of a stenosis. The current standard of care is a balloon angioplasty (POBA) or high pressure balloons. Vessel preparation in conjunction with balloon angioplasty may improve acute outcomes and prolong the life of the access.

Technology Overview

The FLEX Vessel Preparation System
Engineered for continuous parallel micro-incisions
6 Fr compatible
40 cm working length
Atherotome Height 0.01”
Controlled depth micro-incisions



OCT Image (left) and Histology (right) of a Human Cadaver SFA FLEX Micro-Incision



Materials and Methods

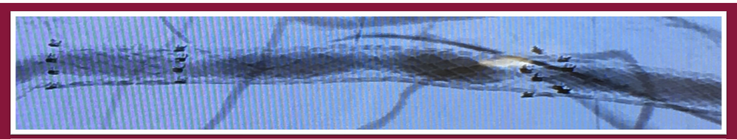
Single-center, single-operator review of acute data captured between March 2018 and October 2018. Reduction in stenosis was recorded after vessel preparation and after angioplasty. A second point of interest was the balloon inflation pressures. Opening pressure (lowest pressure required to obtain full lesion effacement) was recorded to determine change in vessel compliance.

Endovascular intervention performed due to poor flowrate (83%), inefficient dialysis (6%), or high venous pressure (4%).

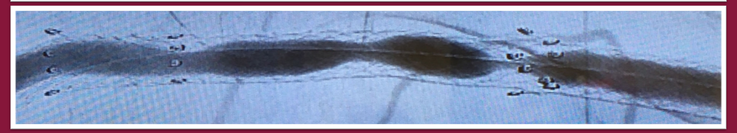
Each lesion was prepped by the FLEX Vessel Preparation System (VentureMed Group, Toledo, Ohio).

Angioplasty with POBA or a combination of POBA and a drug-coated balloon (DCB) at the operator’s discretion.

Case Study



Vessel diameter: 7 mm
Pre-Stenosis: 95%



Post-FLEX Recanalization
6 Passes with FLEX
Post-FLEX Stenosis: 70%

POBA+DCB
Inflation Time: 2 min
Opening Pressure: 12 atm

Results

Number of Patients	80
Thrombosed Access	10%
Mean Age	64 years (33-85)
Average Vessel Diameter	7 mm (5-10)
Average Lesion Length	99 mm (3-200)
Average Baseline Stenosis	82% (50-100)
Average Number of Pullbacks	5
Average Stenosis Post FLEX	59%
Average Luminal Gain (with FLEX exclusively)	23%
POBA	33.8%
POBA + DCB	66.2%
Average POBA Opening Pressure	9.83 atm
Average POBA Maximal Pressure	12.42 atm
Average DCB Opening Pressure	8.65 atm
Average DCB Maximal Pressure	11.49 atm
Average Stenosis Post Treatment	5.45%
Adverse Events	0

Conclusion

Preliminary data suggests that vessel preparation has a positive effect on the acute results. Using the FLEX System prior to POBA or DCB decreases inflation pressures required for lesion effacement. While luminal gain is demonstrated, further studies are warranted regarding other parameters such as time to next intervention.