Use of the FLEX Catheter as a New Arteriovenous Access Management Device.

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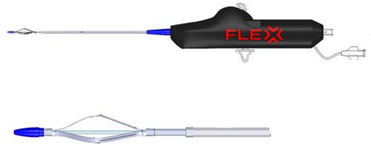
Purpose

End stage renal disease, treated by hemodialysis, affects over 2 million people worldwide. There is a growing clinical requirement for arteriovenous (AV) access management advancements that are cost-effective, reduce AV complications including thrombosis, and improve patient outcomes. The FLEX Catheter® (VentureMed Group, Toledo, Ohio) was evaluated in the treatment of AV access stenosis.

Technology Overview



Sheath Size 6 French

Wire Compatibility .014 and .018

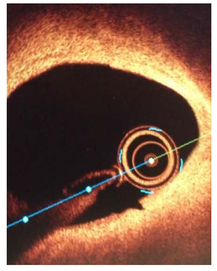
Catheter Length 40cm and 120cm

3 Atherotomes (Proximal) 0.01" in Height

FDA / CE Mark Indication Femoropopliteal and AVF/AVG

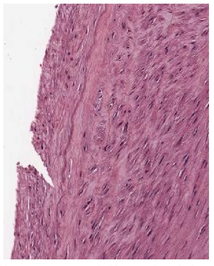
One Size Fits All
Single Insertion Pull-Back Technique

The Flex Catheter has 3 atherotomes that modify plaque during pull-back with **Dynamic Scoring® technology**. FLEX can be rotationally controlled to create multiple linear scores preparing the vessel for treatment.



OCT Image of Micro-Incision

- Precise Longitudinal Micro-Incisions
- Atherotomes Interact with Vessel Surface: 1 atm
- Facilitates an Increase in Vessel Compliance
- Creates a Controlled Environment for Angioplasty



Histology of Micro-Incision (Cadaveric Human SFA)

Methods

Voluntarily provided case reports (18 operators in 10 hospital systems) from 59 patients treated for AV access complications between January 2017 and October 2017 were analyzed. The lesions were treated with the FLEX Catheter followed by the administration of a drug coated balloon (DCB) or plain old balloon angioplasty (POBA). Luminal gain after treatment by the FLEX catheter was calculated, followed by subsequent opening balloon pressure, and the overall luminal gain achieved post-procedure.

Clinical Data	
Number of Cases	59
Average Age	63
Male	53% (n=31)
AVF	70% (n=41)
AVG	30% (n=18)
Average Lesion Length (mm)	33 (2 – 80)

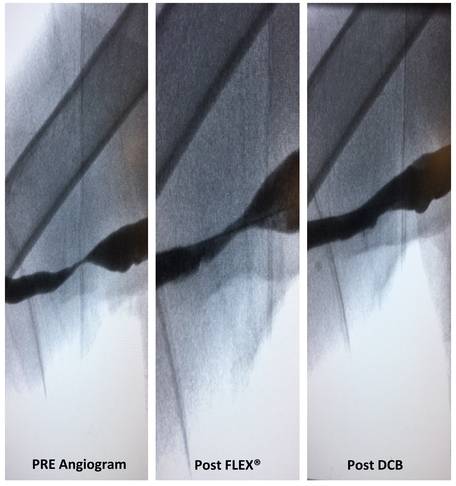
Results

Average Stenosis	83% (2 – 80)
Average Luminal Gain Post FLEX	25%
Average Opening Balloon Pressure (atm)	**6.5 (3 – 16)**
Average Maximal Balloon Pressure (atm)	12.1 (4 – 24)
Average Residual Stenosis	8.2% (0 – 40)
Most Common Balloon Diameter	8 mm (n= 26)
Patients Treated with DCB	11

The opening balloon pressure is defined as the pressure required for complete lesion effacement. The resulting balloon pressures were significantly lower than most AV access procedures. DCB or POBA was by operator's preference.

Case Study

PROCEDURE Details	
Lesion Location	AV Fistula
Lesion Length	20 mm
Vessel Prep Device	FLEX Catheter®
Number of FLEX Passes	3
DCB Treatment	7 x 40 (3 Minute Inflation)



PROCEDURE RESULTS	DETAILS
Pre Stenosis	95%
Post FLEX Stenosis	70%
Luminal Gain Post FLEX	30%
Post DCB Stenosis	10%
DCB Opening Pressure	6 atm

Conclusion

The growing occurrence of renal disease, and subsequent hemodialysis illustrates the need for advancements in arteriovenous access management. FLEX prior to angioplasty allows for significant luminal gain. Lesion effacement with angioplasty after FLEX occurs at sub-nominal pressures. Early experience with the FLEX catheter suggest it may offer benefits in the management of AV access, especially in the era of DCB. Further studies are warranted.