A Comparative Review of the FLEX Catheter® in the Treatment of Femoropopliteal Lesions of Differing Lengths.

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Category: Peripheral Artery Disease

Background: Treatment of femoropopliteal lesions, especially those longer than 8 cm, can be complex potentially requiring multiple devices for a successful intervention. The need for innovative improvements in treatment options for long lesions is imperative. Early clinical results of the FLEX Catheter (VentureMed Group, Toledo, Ohio) in real world patients were retrospectively reviewed by lesion length subsets to determine the feasibility and safety of the device.

Methods: The FLEX Catheter was engineered to create continuous and controlled depth longitudinal micro-incisions along the length of the lesion, prepping the vessel for angioplasty. The FLEX is a one-size-fits-all device that utilizes an expandable basket equipped with 3 atherotomes that follows the contour of the vessel wall. Voluntarily provided case reports from 326 real world patients (85 operators in 54 hospital systems) were analyzed. Lesions were pre-treated with the FLEX, followed by a drug coated balloon (DCB) or plain old balloon angioplasty (POBA), at operator's discretion. Angiograms were performed pre-procedure, post FLEX, and post procedure to visually measure stenosis.

Results: The data was separated into subsets by lesion length; (1) less than or equal to 8 cm and (2) longer than 8 cm (See Table 1). In (1) the average lesion length was 4.3 cm (0.2 – 8 cm) and 18.6 cm (8.5 – 41 cm) in (2). The pre-existing average stenosis for the 8 cm or less subset was 88.7%, and 93.8% for the latter. Sixty percent of the longer lesions were chronic total occlusions (CTO). Technical success, defined as lesion (stenosis or CTO) crossing and luminal gain post FLEX, was 99% overall. Luminal gain post treatment with the FLEX averaged 26.7% for the shorter subset, and 26.8% in the longer. The opening balloon pressure (lowest pressure allowing complete lesion effacement) was 4.3 and 4.4 atm respectively. Residual stenosis at the completion of the procedure was 10.2% for (1) and 9.6% for (2). Provisional stent use was low, and no flow-limiting dissections, perforations, or embolization occurred.

Conclusions: The FLEX Catheter performed with a high rate of technical success in real world lesions. The luminal gain achieved, by the FLEX alone, was consistent regardless of lesion length. Low opening balloon pressures suggest the pre-treatment of the vessel by the FLEX positively improved vessel compliance. There were no flow-limiting dissections or emboli, and a low rate of provisional stents (19% overall) after angioplasty. The FLEX is a viable option to interventionalists in the treatment of femoropopliteal lesions of differing lengths.

Table 1: Summary of Femoropopliteal Lesion Data

	Less Than or Equal to 8 cm N (%) or Mean (Range)	More than 8 cm N (%) or Mean (Range)
Number of Cases:	122	204

Average Age:	70	72
ISR:	7 (6%)	19 (9%)
Average Lesion Length (cm):	4.3 (0.2 – 8)	18.6 (8.5 – 41)
Chronic Total Occlusions	25 (20%)	122 (60%)
Pre-Stenosis (%):	88.7 (60 - 100)	93.8 (50 – 100)
Post FLEX Stenosis (%):	62 (5 – 90)	67 (10– 100)
Luminal Gain Post FLEX (%):	26.7 (0 – 95)	26.8 (0 – 85)
Opening Balloon Pressure (atm)	4.3 (2 – 12)	4 .4 (2 – 12)
Maximal Balloon Pressure (atm)	8.4 (4 – 20)	9.4 (3 – 18)
DCB Use:	90 (73%)	151 (74%)
Provisional Stent Usage:	20 (16%)	42 (21%)
Minor Dissections (Grade: A, B):	5 (4%)	12 (6%)
Flow-Limiting Dissections:	0 (0%)	0 (0%)
Moderate / Severe Calcium:	62 (51%)	113 (55%)
Residual Stenosis (%):	10.2 (0 – 50)	9.6 (0 – 60)
Luminal Gain Post Procedure (%):	78 (40 – 100)	84 (25 – 100)
Technical Success	121 (99%)	202 (99%)