

BENEFIT OF LONGITUDINAL MICRO-INCISIONS PRIOR TO PACLITAXEL-COATED BALLOON ANGIOLPLASTY (BELONG Study):12-MONTH RESULTS

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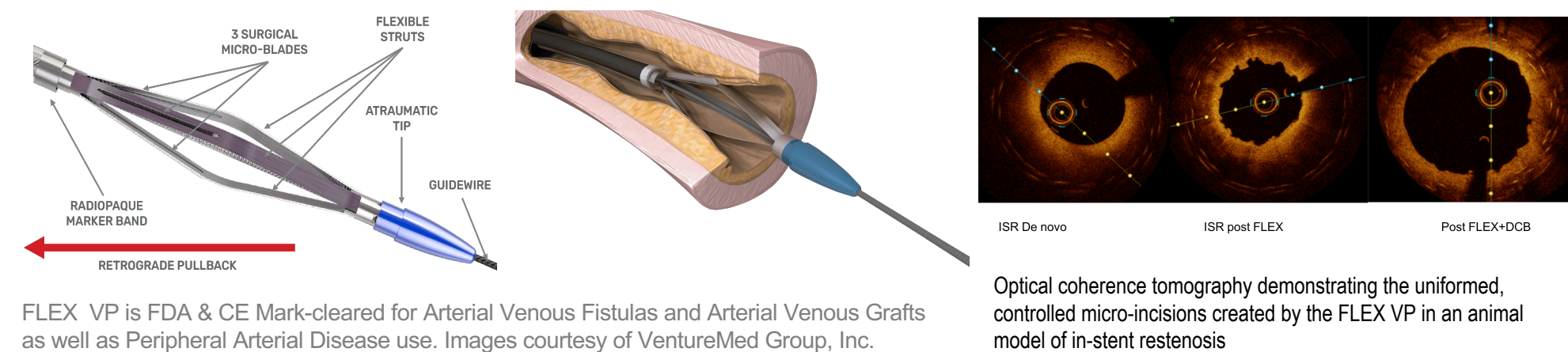
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PURPOSE

The purpose of this study was to assess the 12-month outcomes of subjects who underwent vessel preparation with FLEX VP prior to paclitaxel-coated DCB (PTx DCB)

FLEX VESSEL PREP™ SYSTEM (FLEX VP™)

FLEX VP™ creates longitudinal, controlled-depth micro-incisions that modify the plaque to release the circumferential tension of fibrous and calcific stenoses and provide lumen gain that prepares the vessel for final therapy.

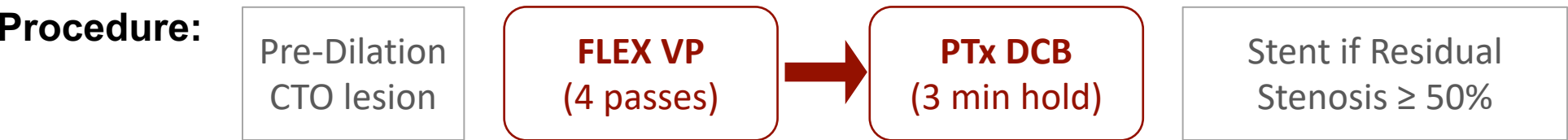


THE BELONG STUDY

Study Design: Single-center, single arm prospective study

Study Population: Patients with symptomatic lower extremity peripheral artery disease and a Rutherford Class of 2-5 with 70% or more de novo, restenotic, or in-stent stenosis of the superficial femoral (SFA) or popliteal (PA) arteries

Study Follow-up: 3- and 12-months post-procedure



Analysis: coreLab Black Forest (GmbH)

RESULTS

- Forty-one (41) patients with average age of 70 years (range 43 – 94 years); 46.5% female
- 100% procedural success with no perforation, no serious adverse events, and no flow-limiting embolization

Lesion Location	SFA 86% (37/43) Popliteal 14% (6/43)
Lesion Length, mm (range)	117.6 mm (9.8 – 290.7)
Avg. Stenosis, % (range)	81.8% (40-100)
Avg. Residual Stenosis post FLEX VP, % (range)	62.8% (20.9 - 90.3)
Avg. Residual Stenosis post DCB, % (range)	33.6% (10.7 - 67.56)
Total Occlusion, n (%)	28.3%
Total Occlusion Length, mm, avg. (range)	86 mm (9.6 - 271.6)
Stent Placement (if residual stenosis > 50%)	41.8 % (18/43) (Stented Lesions with PACSS Score ≥ 3 = 16/18)

CLINICAL EFFICACY	% (number) at 12 months	Rutherford Class	% (number) at Baseline	% (number) at 12 months
Freedom from Clinically-Driven Target Lesion Revascularization	97.5% (39/40*)	0	0	90.2% (37/41)
Freedom from Target Lesion Restenosis (PSV>2.5)	84.2% (32/38**)	1	0	4.9% (2/41)
Freedom from Major Amputation	100% (40/40*)	2	58.5% (24/41)	4.9% (2/41)
		3	26.8% (11/41)	0
		4	4.9% (2/41)	0
		5	9.8% (4/41)	0
		ABI	0.71	0.93

* One patient had a non-procedure related death prior to 12 months with no intervention prior to death **Duplex measurement (PSV) in 38 patients; 2 patients follow-up

CONCLUSION

The promising long-term clinical outcomes and considerable Rutherford class improvement at 12-months without complications suggest that **vessel-preparation with micro-incisions may enhance DCB therapy in treating long, complex, and calcified lesions.**