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

Daniel Périard [1], Jean-Baptiste Dexpert [1], Rolf P. Engelberger [1], Daniel Hayoz [1], Eric A. Secemsky [2]

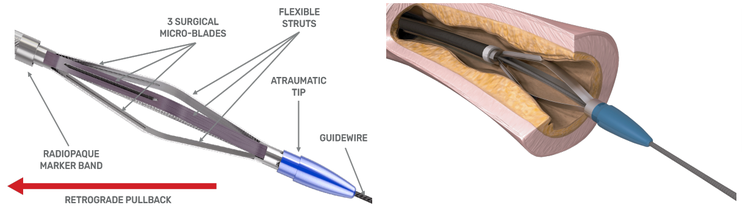
[1] HFR-Hôpital Cantonal Fribourg, Fribourg, Switzerland; [2] Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA

PURPOSE

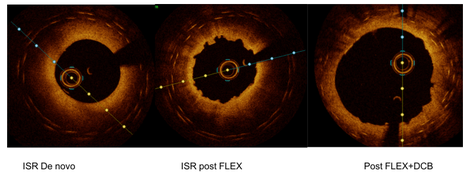
The purpose of this study was to assess the 12-month outcomes of subjects who underwent vessel preparation with FLEX VP prior to paclitaxel-coated DCB (PTx DCB)

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.



FLEX VP is FDA & CE Mark-cleared for Arterial Venous Fistulas and Arterial Venous Grafts as well as Peripheral Arterial Disease use. Images courtesy of VentureMed Group, Inc.



Optical coherence tomography demonstrating the uniformed, controlled micro-incisions created by the FLEX VP in an animal model of in-stent restenosis

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

Procedure:

Pre-Dilation CTO lesion → **FLEX VP** (4 passes) → **PTx DCB** (3 min hold) → Stent if Residual Stenosis ≥ 50%

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
Freedom from Clinically-Driven Target Lesion Revascularization	**97.5%** (39/40*)
Freedom from Target Lesion Restenosis (PSV>2.5)	**84.2%** (32/38**)
Freedom from Major Amputation	**100%** (40/40*)

Rutherford Class	% (number) at Baseline	% (number) at 12 months
0	0	**90.2%** (37/41)
1	0	**4.9%** (2/41)
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.**