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RANGER™ SFA Trial

12-month results presented at Charing Cross 2017

Objective

To prove the superior performance of the Ranger™ paclitaxel-coated PTA balloon catheter (Boston Scientific) for angioplasty for femoropopliteal artery lesions when compared to non-coated balloons.

Trial Design

Prospective, multicenter, randomized, controlled trial (2:1 Ranger DCB vs. non-drug-coated balloon). Follow up through 3 years.

Key Enrollment Criteria

- Rutherford 2, 3 or 4
- Stenotic, restenotic or occlusive lesions (≥70% stenosis) in the native non-stented SFA/PPA
- No prior treatment with drug coated balloons or drug-eluting stents in the treated limb
- Lesion length ≥20 mm and ≤150 mm

Key Baseline Lesion Characteristics#

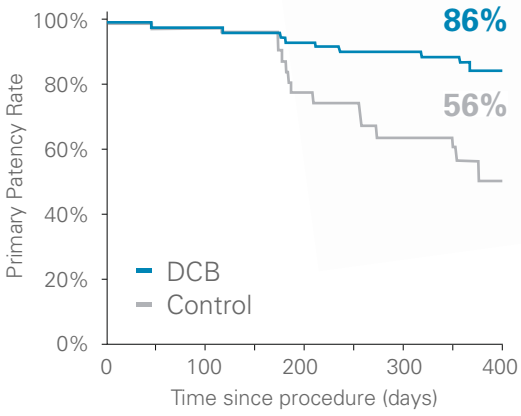
#core lab adjudicated

	PTA (34)	Ranger DCB (71)
Target Lesion Length (mm)	60 ± 48	68 ± 46
Reference Vessel Diameter (mm)	4.5 ± 0.83	5 ± 0.89
Percent Diameter Stenosis (%)	82 ± 18	85 ± 15
Total Occlusions (%)	34	34

12 Month Outcome

Patency

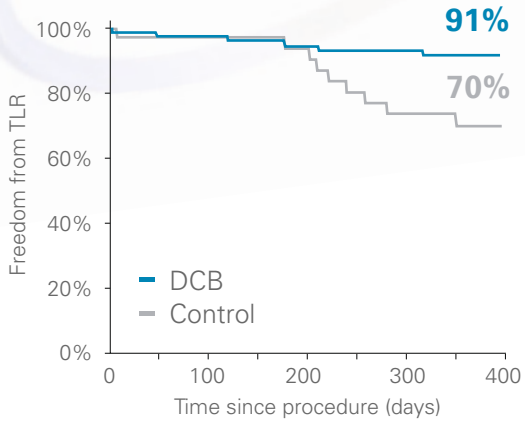
- Ranger achieved an 86% primary patency at 12 months (patent by DUS and without reintervention)
- Ranger demonstrated primary patency superior* to PTA



*p=<0.001 log rank test , Kaplan-Meier Analysis

Freedom from TLR

- Ranger achieved a 91% Freedom from TLR at 12 months
- Ranger demonstrated Freedom from TLR superior* to PTA



*p=0.010 log rank test, Kaplan-Meier Analysis

Presented by Prof. Scheinert, Charing Cross - 2017

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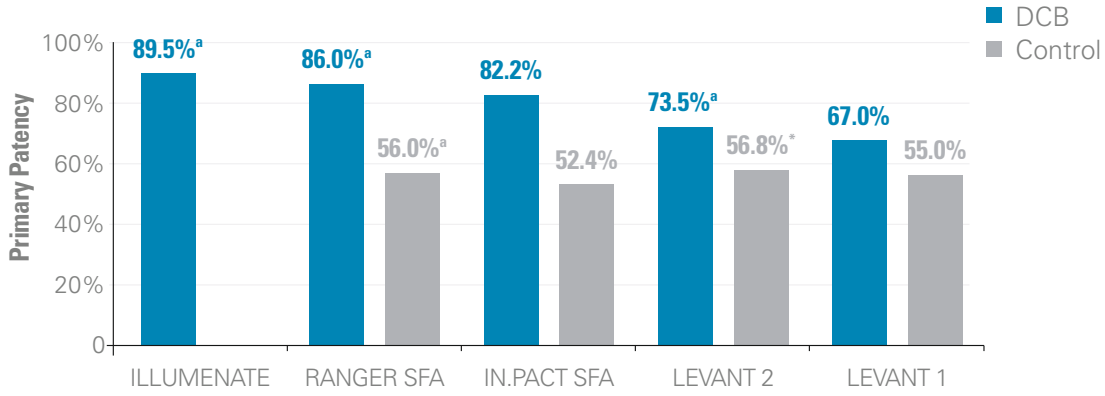
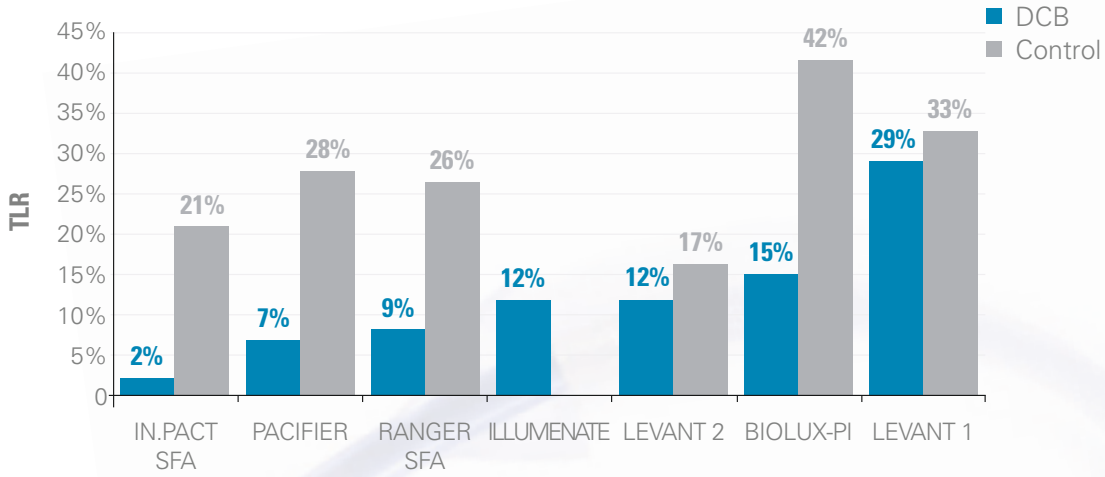
Primary Patency at 12 months from DCB trials of the SFA

[a]KM Estimates



LEVANT 2 - Rosenfield K, et al. N Engl J Med. 2015 9;373(2):145-53., ILLUMENATE - Schroeder H, et al. Catheter Cardiovasc Interv. 2015;86(2):278-86., LEVANT 1 - Scheinert D, et al. JACC Cardiovasc Interv. 2014;7(1):10-19., IN.PACT SFA - Tepe G, et al. Circulation. 2014 pii: CIRCULATIONAHA.114.011004.

TLR at 12 months from DCB trials of the SFA



BIOLUX-PI - Scheinert D, et al. J Endovasc Ther 2015; 22(1): 14-21., LEVANT 2 - Rosenfield K, et al. N Engl J Med. 2015 9;373(2):145-53., PACIFIER - Werk M, et al. Circ Cardiovasc Interv. 2012;5(6):831-840., ILLUMENATE - Schroeder H, et al. Catheter Cardiovasc Interv. 2015;86(2):278-86., LEVANT 1 - Scheinert D, et al. JACC Cardiovasc Interv. 2014;7(1):10-19., IN.PACT SFA - Tepe G, et al. Circulation. 2014 pii: CIRCULATIONAHA.114.011004.

Patient Outcomes

Rutherford score

- 84% of Ranger subjects had no or mild symptoms - Rutherford category 0 or 1
- Compared to baseline, Ranger and PTA groups both showed improvement in Rutherford score and ABI

Conclusions

- Greater patency rate at 12 months for Ranger DCB than Control (86% vs 56%)
- Freedom from TLR greater for Ranger DCB than Control at 12 months (91% vs 70%)
- Patients treated with Ranger DCB demonstrated significant improvements in symptoms and hemodynamics at 12 months
  - Symptomatic improvement generally similar to Control but with ~1/3 as many revascularizations

Ranger™ Paclitaxel Coated PTA Balloon Catheter is manufactured by Hemoteq AG and distributed by Boston Scientific Corporation.
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