First time data release:
COMPARE-Pilot RCT:
2-year results of a randomized comparison of RANGER DCB vs. IN.PACT DCB in complex SFA lesions

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Disclosure

Dierk Scheinert, MD

Advisory Board /Consultant:

Abbott, Biotronik, Boston Scientific, Cook Medical, Cordis, CR Bard, Gardia Medical/Allium, Medtronic, TriReme Medical, Trivascular, Upstream Peripheral Technologies

Study objective

To compare two different Paclitaxel coated balloons (with different coatings and different paclitaxel dose density) in the treatment of high grade stenotic or occluded lesions in SFA and/or PPA in PAD patients with Rutherford class 2-4

Investigational device:

Ranger™ Paclitaxel Coated PTA Balloon Catheter

(Paclitaxel dose 2ug/mm2)

Control device:

IN.PACT™ Admiral or IN.PACT™ Pacific Drug Eluting Balloon

(Paclitaxel dose 3.5ug/mm2)

Study Set-up

- Investigator Initiated Trial (IIT)
- Principal Investigator: Prof. Dierk Scheinert
- Study sponsor: University of Leipzig
- Funded through a research grant of Boston Scientific

- Independent monitoring with 100% source data verification
- Independent corelab for angio and duplex
- Clinical events committee

Study Design

- Prospective, multicenter, randomized trial
- Randomization 1:1
- Phase 1: Pilot Study (150 patients)
- Phase 2: Extension (414 patients) for testing of a formal non-inferiority hypothesis
- Stratification according to lesion length
- Follow-up clinical visits at 6, 12, 24 months

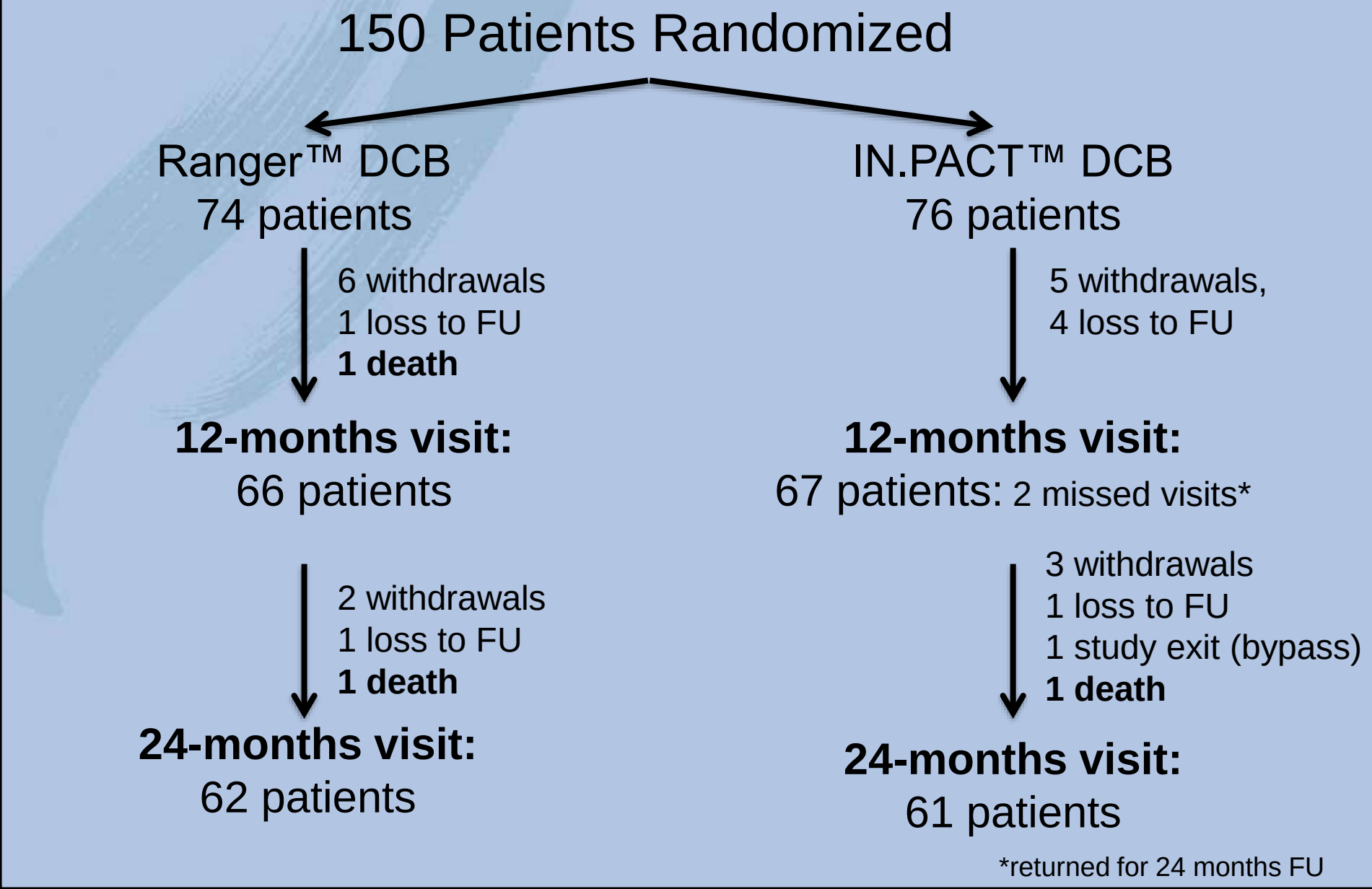
- Protocol pre-specified analysis of the first 150 patients (COMPARE Pilot) after 12 and 24 months of follow-up
  -> **24 months results presented today**

Study Sites COMPARE Pilot (n=15)

Key In- and Exclusion criteria

- Symptomatic PAD Rutherford 2-4
- Stenosis (>70%) or occlusion of the SFA or proximal popliteal artery
- De-novo or restenotic lesions (no ISR)
- No severe calcification
- Lesion length up to 30 cm
- At least one patent BTK outflow vessel to the foot

Compare Pilot: Patient flow diagram



Baseline Demographics of first 150pts

	RANGER DCB (n=74)	**IN.PACT DCB (n=76)**	p-value
Age, y	68.6±9.2	68.9±9.5	0.5
Male gender	44 (60%)	53 (70%)	0.2
Weight, kg	77.9±15.8	79.1±14.7	0.6
Prior myocardial infarction	11 (15%)	5 (7%)	0.2
Coronary artery disease	21 (29%)	21 (28%)	0.9
Cerebrovascular disease	12 (16%)	8 (11%)	0.3
Hyperlipidemia	50 (68%)	57 (75%)	0.3
Hypertension	65 (88%)	68 (90%)	0.8
Renal Insufficiency	12 (16%)	14 (18%)	0.6
Smoking			0.4
Current	32 (43%)	38 (50%)	
Previous	27 (37%)	20 (26%)	
Diabetes mellitus	25 (34%)	28 (37%)	0.7
Claudication (RC 2-3)	69 (93%)	71 (94%)	0.6
Critical limb ischemia (RC 4)	5 (7%)	5 (6%)	

Data are given as mean±SD or number (%).

Lesion Characteristics* of first 150pts

	RANGER DCB (n=74)	IN.PACT DCB (n=76)	p-value
Target lesion length, mm	117.4±100.4	122.3±91.2	0.8
Diameter stenosis, %	82.7±17.5	84.2±18.2	0.6
Reference vessel diameter, mm	4.9±0.6	5.0±0.8	0.3
Minimal vessel diameter, mm	0.8±0.9	0.8±1.0	0.9
Total occlusion	29 (39.2%)	34 (44.7%)	0.5
Total occlusion length, mm	110.9±95.1	94.8±87.9	0.5
Prox. popliteal involvement	14 (18.9%)	11 (14.5%)	0.2
Lesion calcification			0.7
None	8 (11.1%)	8 (10.7%)	0.7
Mild	21 (29.2%)	18 (24%)	
Moderate	1 (1.4%)	0 (0%)	
Moderately severe	25 (34.7%)	33 (44%)	
Severe	17 (23.6%)	16 (21.3%)	
0-1 patent run off vessels	20 (26.9%)	25 (32.9%)	0.6

* Per angiographic core lab assessment.
Data are given as mean±SD or number (%).

Procedural Outcomes* of first 150pts

	RANGER DCB (n=74)	IN.PACT DCB (n=76)	p-value
Bailout stent placement	19 (25.7%)	17 (22.4%)	0.6
MVD postprocedure, mm	3.6±0.6	3.7±0.8	0.6
Diameter stenosis postprocedure, %	25.8±11.6	26.0±14.6	0.9
Residual stenosis > 30%	26 (35.1)	29 (38.2)	0.7
Dissection	70 (92.1%)	70 (94.6%)	0.7
Type A/B, n (%)	54 (77.1%)	44 (62.8)	0.1
Type C-F, n (%)	16 (22.9%)	26 (37.2%)	
Complications			
Embolic event	2 (2.7%)	1 (1.3%)	
AV-Fistel (local)	5 (6.8%)	5 (6.6%)	
Target Vessel Perforation	1 (1.4%)	1 (1.3%)	

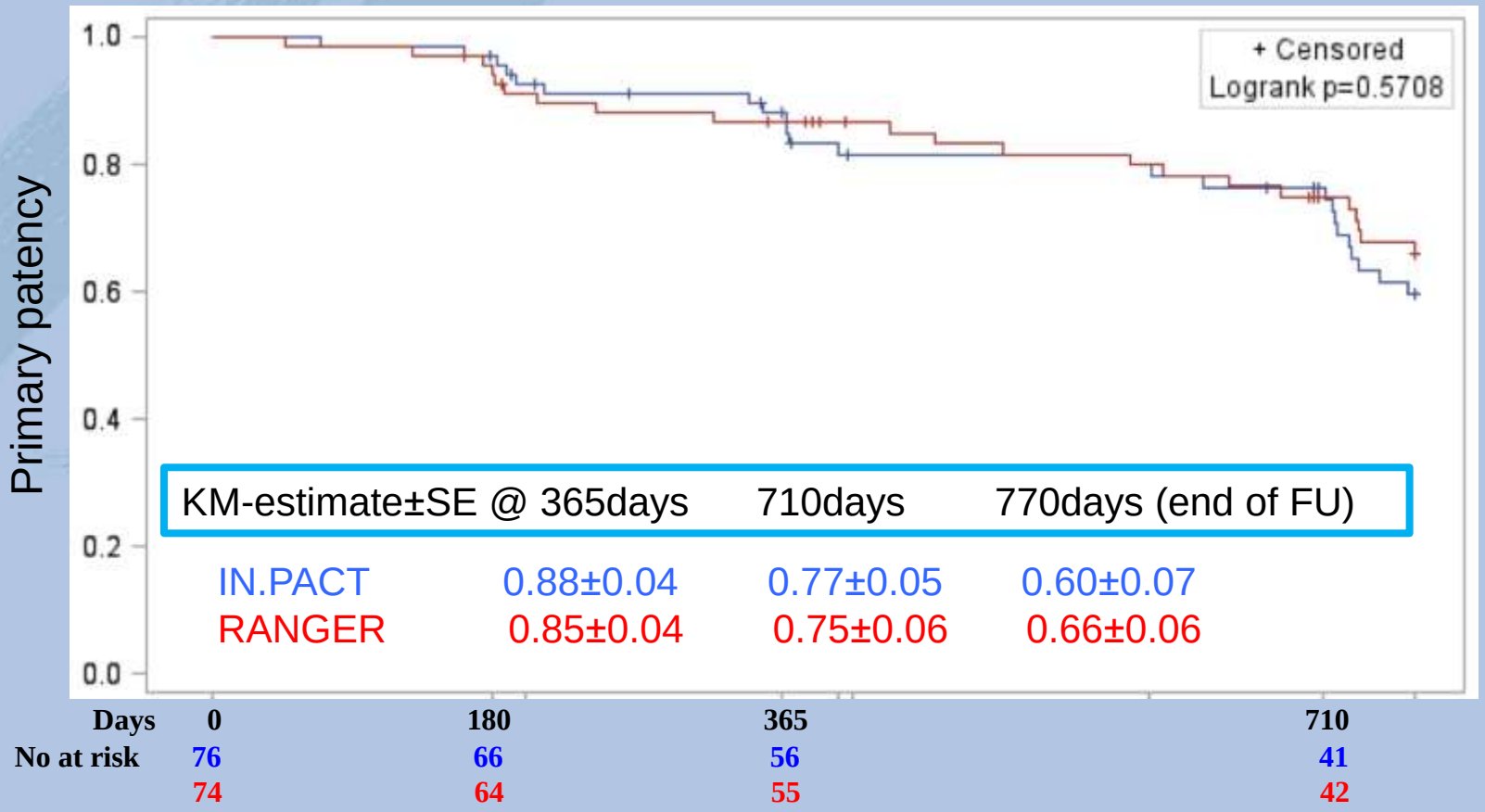
* Per angiographic core lab assessment.
Data are given as mean±SD or number (%).

Safety - Mortality

- First 150 patients cohort: **3 deaths in 2 years**
  (1 In.Pact, 2 Ranger)
  Reasons of death:
  - pancreatic cancer
  - cardiac decompensation
  - enterococcal septicemia

- Full cohort of 414 patients: **7 deaths so far**
  (3 In.Pact, 4 Ranger)
  Further reasons of death:
  - cardiac decompensation
  - polytrauma
  - respiratory failure/exacerbated COPD
  - multi organ failure

Compare Pilot study (150 patients): Primary patency through 24 months



For KM-estimates, the study end was harmonized to 770 days for all events censored ≥710 days.

Summary

- Head-to-head comparison of Ranger™ DCB vs. IN.PACT™ DCB in femoropopliteal interventions.
- Complex real world lesion subset with lesion length ~12cm and proportion of CTO`s ~40%.
- Excellent efficacy at 2 years of both tested DCB in the Compare Pilot study comprising 150 randomized patients.
- Similar primary patency of the low-dose Ranger™ DCB compared to the Inpact™ DCB during the 2 year surveillance period.
- Recruitment of full study cohort (414 patients) completed; will be presented at LINC 2020.

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