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RANGER II SFA PIVOTAL TRIAL
12-MONTH FULL COHORT RESULTS

Presented by Marianne Brodmann, MD at LINC 2020

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

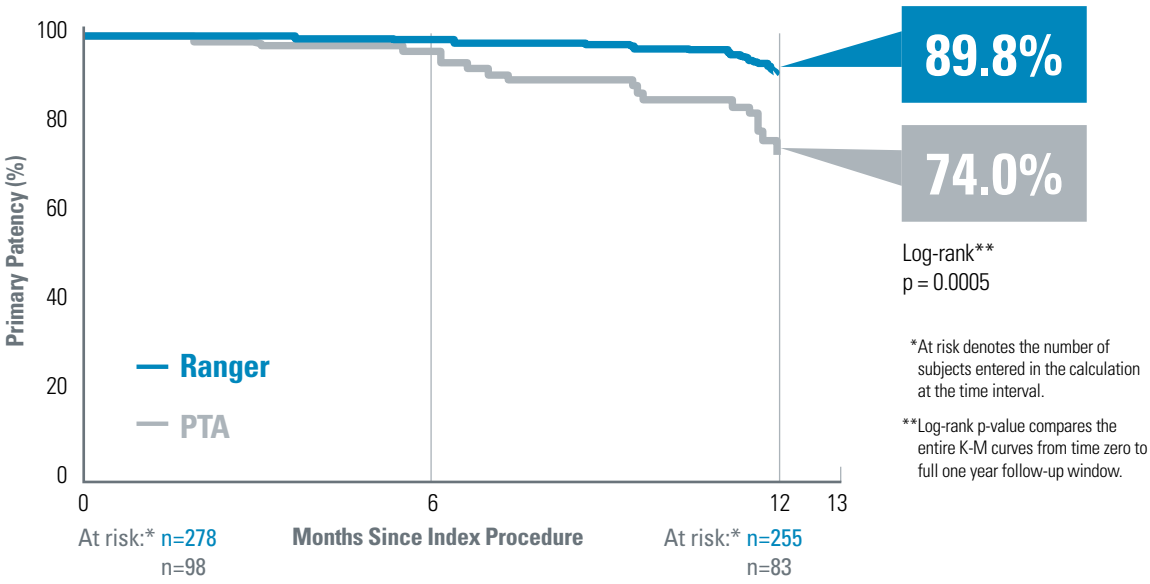
TRIAL DESIGN:
Prospective, multi-center, randomized controlled trial (3:1 Ranger DCB vs. standard PTA balloon). Follow up through 5 years.

KEY BASELINE CHARACTERISTICS	Ranger DCB *(n=278)*	PTA *(n=98)*
Age (year)	70.6	69.1
Smoker (current/previous)	85.3%	84.7%
Current Diabetes Mellitus	42.4%	43.9%
Target Lesion Length (mm)[1]	82.5	79.9
Calcium: PACSS Grade 3/4[2]	47.8%	62.2%

1. Core lab. 2. PACSS Grade 3/4 may be considered similar to moderate/severe calcification.

OUTCOMES:

12-MONTH PRIMARY PATENCY RATES K-M ESTIMATE[3]



*At risk denotes the number of subjects entered in the calculation at the time interval.

**Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up window.

RESULTS:

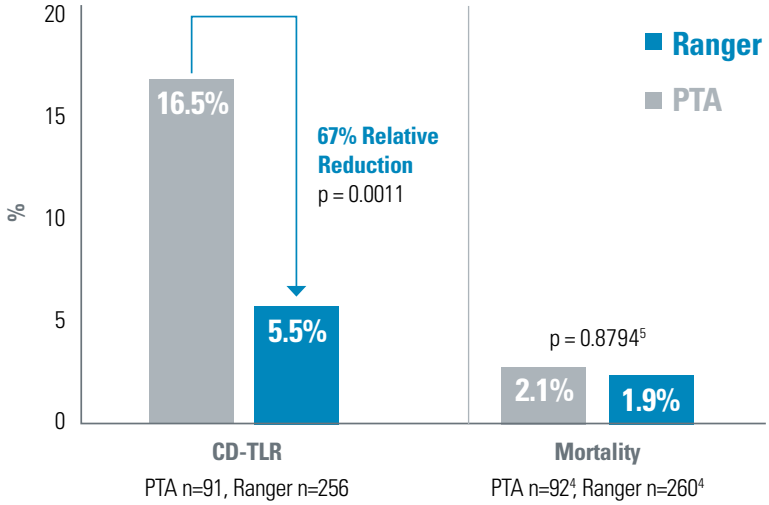
	RANGER	PTA	P-value
Primary Safety Endpoint (Freedom from MAE)	**94.1%** (241/256)	**83.5%** (76/91)	$P_{non\text{-}inferiority} < 0.0001$
Primary Effectiveness Endpoint (Binary Primary Patency)	**82.9%** (194/234)	**66.3%** (57/86)	0.0017

OUTCOMES ONE-YEAR FULL-COHORT RESULTS

CD-TLR & Mortality

Compared to PTA, Ranger demonstrated:

- Significantly lower TLR
- No difference in mortality



RANGER PK SUBSTUDY

Study Method:

- Protocol required blood draws: Baseline, 10 minutes, 30 minutes, 1, 3, 6, 24 or 48 hours, 7 days and 30 days after last Ranger DCB treatment and removal
- All 12 patients received Ranger DCB
- Average number of DCBs used per patient: 1.75

154 mm

Average Lesion Length

At 1 hour 11 of 12 patients

did not have measurable levels[6] of paclitaxel in the blood stream.[7]

3. Kaplan-Meier Estimate: Primary patency as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) is ≤ 2.4 at the 12-month follow-up visit, in the absence of clinically-driven TLR or bypass of the target lesion.
4. At risk denotes the number of subjects entered in the calculation at the time interval.
5. Log-rank p-value compares the entire K-M curves from time zero to full one year follow-up.
6. Measurable level is 1.0 ng/ml.
7. Paclitaxel in the blood stream was below measurable levels at 3 hours in all 12 patients.

"RANGER™ Paclitaxel-Coated PTA Balloon Catheter is distributed by Boston Scientific. The legal manufacturer is Hemoteq AG, Adenauerstrasse 15, 52146 Wurselen (Germany).

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France."

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