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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:

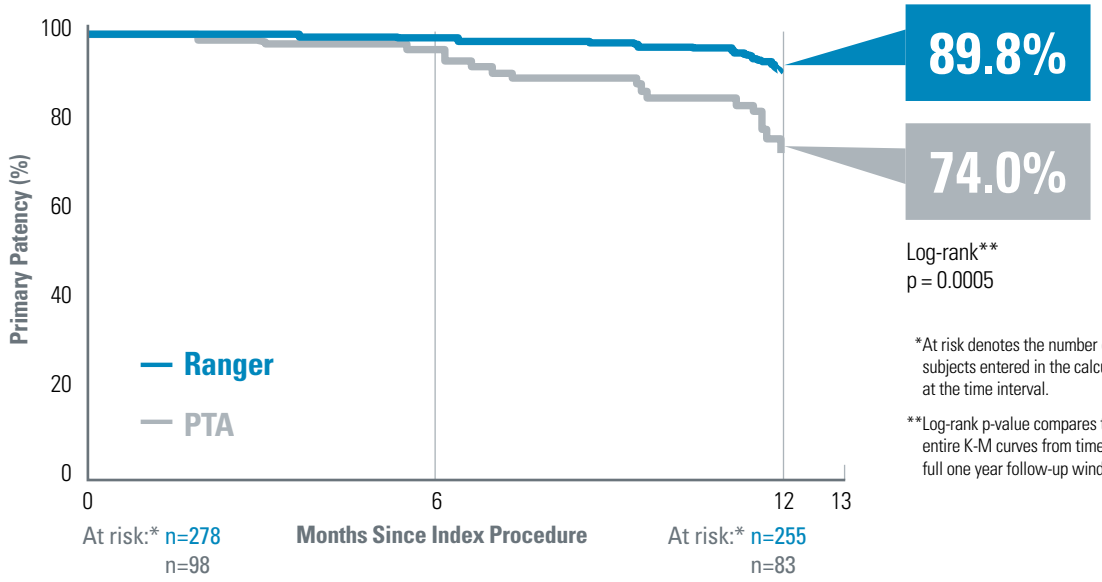
Prospective, multi-center, randomized controlled trial (3:1 Ranger DCB vs. standard PTA balloon). Follow up through 5 years.

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]



Log-rank**
p = 0.0005

*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:

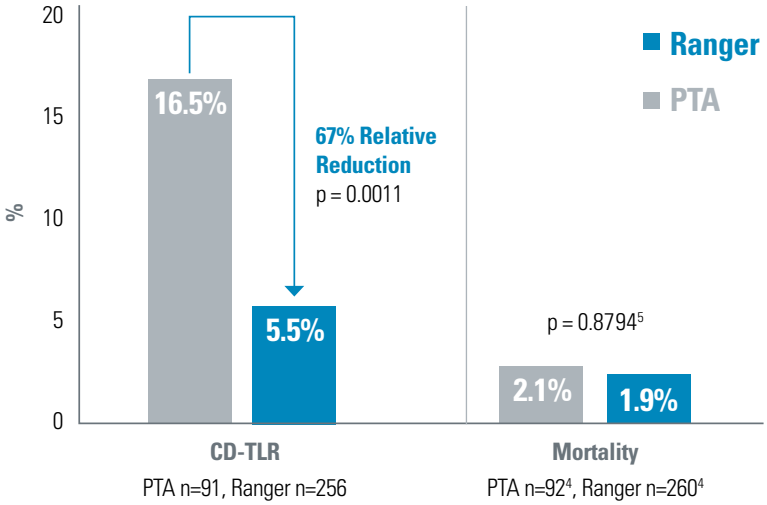
	RANGER	PTA	P-value
Primary Safety Endpoint (Freedom from MAE)	**94.1%** (241/256)	**83.5%** (76/91)	$P_{non\text{-}inferiority} < 0.0001$
Primary Effectiveness Endpoint (Binary Primary Patency)	**82.9%** (194/234)	**66.3%** (57/86)	0.0017

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]

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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.

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