REFORM trial clinical summary – **24 month results**[1]

Trial name:	REFORM
Company:	Cook Medical
Product:	Formula™ Renal Balloon-Expandable Stent
Lead investigator:	Dr. Robert Bersin, Seattle Cardiology and Swedish Medical Center
Trial design:	Prospective, single-arm study at seven investigative sites in U.S.
Patients enrolled:	100
Core lab adjudication:	Yes
General lesion requirement:	De novo or restenotic ostial lesions
Primary endpoint:	Primary patency at nine months
Secondary endpoints:	Target lesion revascularization (TLR) rate and changes in hypertension, renal function and blood pressure medication levels
Method:	Stenting following suboptimal angioplasty
Patient demographics:	
Age (years)	72 ± 10
Diabetes	43%
Hypertension	97%
Systolic blood pressure (mm Hg)	150 ± 21
eGFR (mL/min)	61 ± 29
Lesion characteristics:	
Lesion length (mm)	7.7 ± 3.6
Reference vessel diameter (mm)	5.3 ± 0.9
Diameter stenosis (preprocedure)	57 ± 14%
Moderate to severe calcification	37%

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	9 Months	24 Months
Major adverse events (TLRs only)*	2.2%	5.7%
Significant embolic events	0.0%	0.0%
Primary patency†	91.7%	–
Systolic blood pressure (mm Hg) – preprocedure = 150 ± 21	141 ± 21 ($P < 0.01$)	136 ± 20 ($P < 0.01$)
Patients with ≥ 10 mm Hg decrease in systolic blood pressure	45%	55%
Patients with decrease in **dosage** of blood pressure medications	30%	40%
Patients with decrease in **number** of blood pressure medications	23%	40%
Clinically meaningful improvement in renal function‡	11.9%	19.6%

* Per patient.

† Defined as freedom from TLR and < 60% stenosis by duplex ultrasound (peak systolic velocity < 225 cm/sec and renal aortic ratio ≤ 3.5) or angiography. Patency assessed at nine months only.

‡ Defined as ≥ 25% increase in eGFR or ≥ 0.5 mg/dL decrease in serum creatinine.

1. Bersin R. Results through 2-year follow-up from the REFORM clinical study. Presented at: EuroPCR; May 17-20, 2011; Paris, France.

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