New Stent Technologies: Clinical Applications of Evidence-Based Medicine

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Do We Really Need a Next Generation of DES?

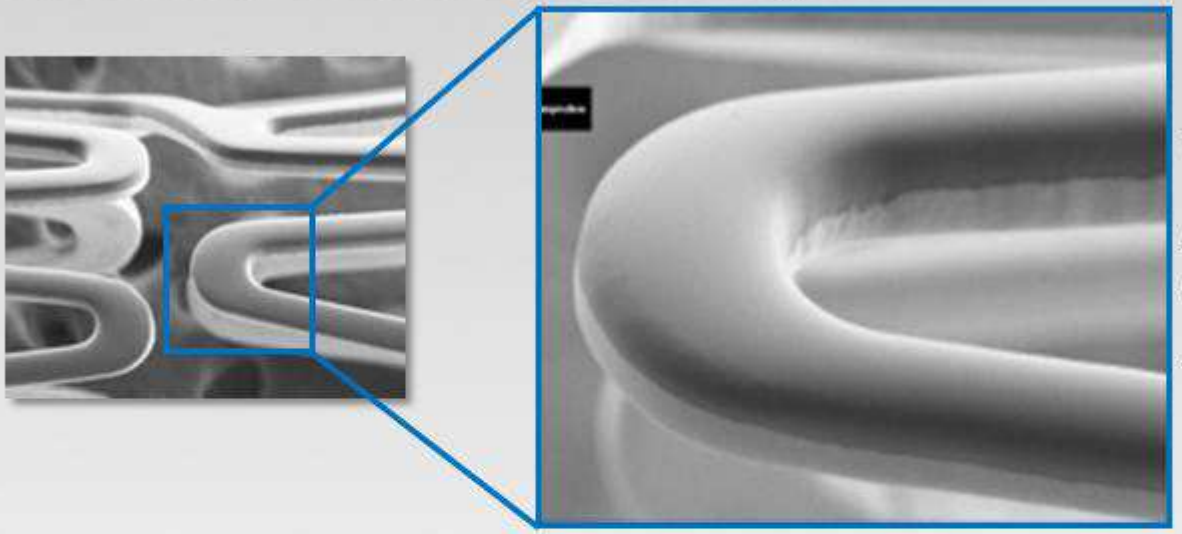
Current second-generation stents have low MACE rates

- But are associated with polymer hypersensitivity reactions, occasional strut fractures, longitudinal deformation, malapposition, aneurysms, late loss, late-late loss, abnormal vasomotion
- Early and late stent thrombosis remain issues

Will bioabsorbable polymers or stents address these issues?

SYNERGY Stent

Abluminal Bioabsorbable Polymer



Bioabsorbable polymer (PLGA)

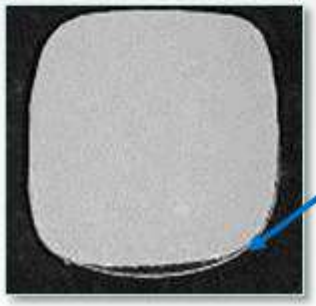
Applied only to the abluminal surface (rollcoat)

Thin strut (0.0029") PtCr Stent

Durable permanent polymer + drug 360° around stent

Current Durable Polymer

Abluminal Bioabsorbable Polymer



PLGA bioabsorbable polymer + everolimus on abluminal side of stent

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Data presented by Meredith IT. TCT 2011.

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EVOLVE Study Design

Patients with *de novo* native coronary lesions
≤ 28 mm in length, RVD ≥ 2.25 mm ≤ 3.5, %DS > 50
(excluded LM disease, CTO, AMI, or recent MI)

↓

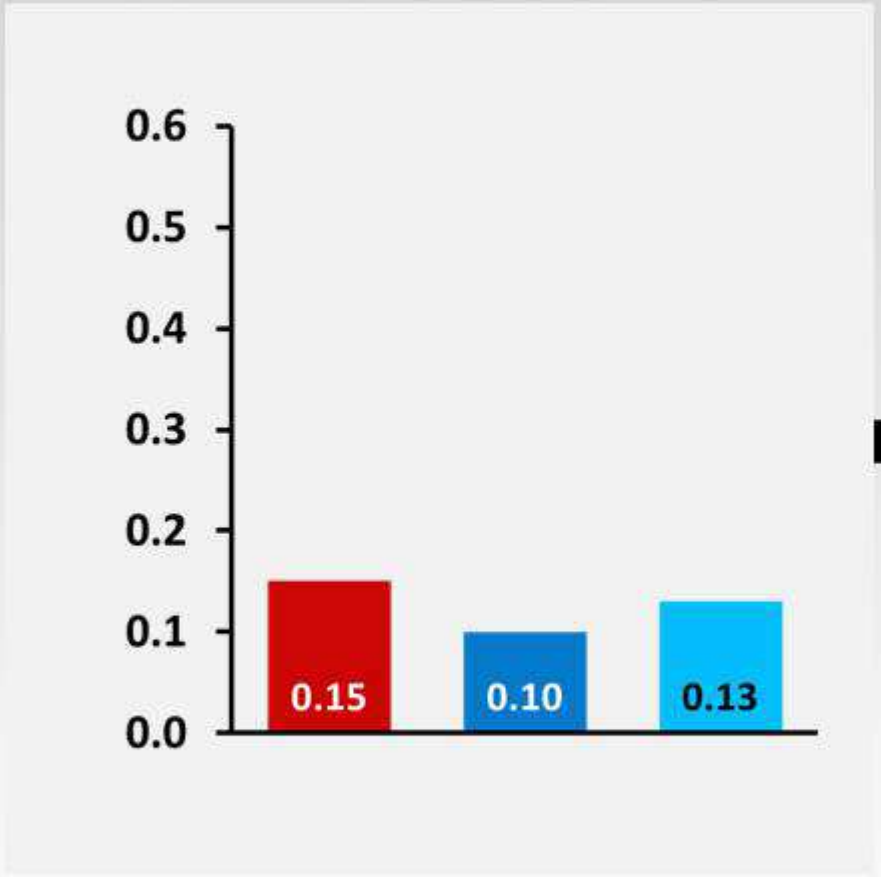
Randomized 1:1:1 at 29 sites
(EU, Australia, New Zealand)

PROMUS Element	SYNERGY	SYNERGY ½ Dose
n = 98	n = 94	n = 99

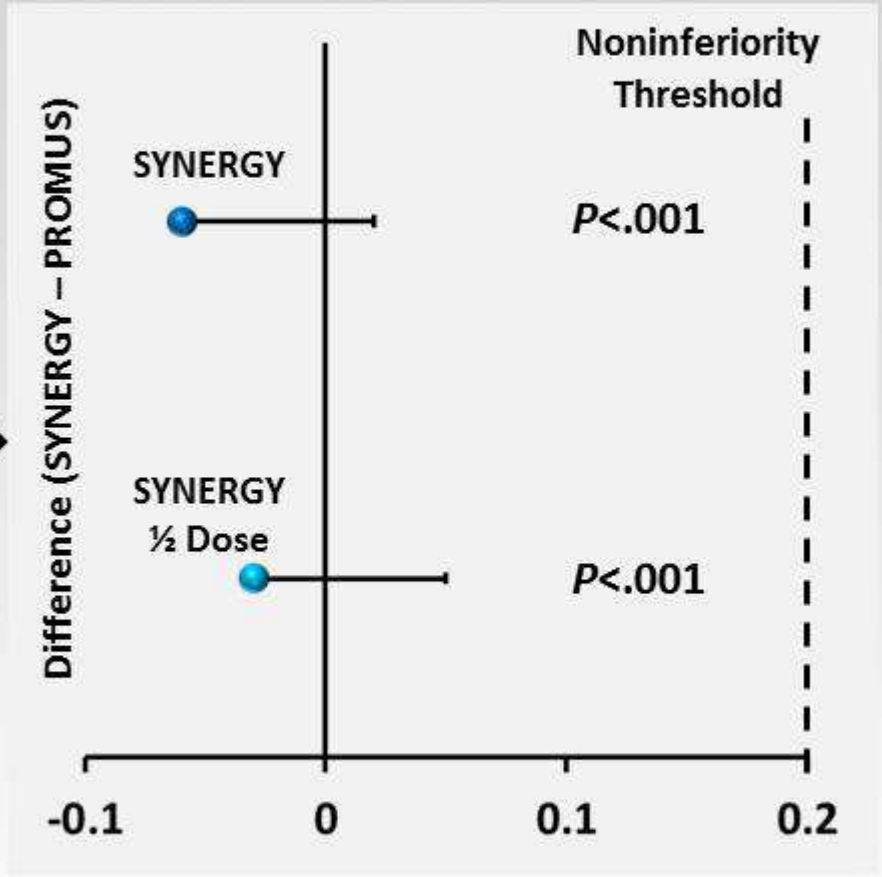
Single-blind, noninferiority design
Primary Clinical Endpoint: TLF (TV-CD, TV-MI, or TLR) at 30 days
Primary Angiographic Endpoint: In-stent late loss at 6 months

EVOLVE: Late Loss at 6 Months

Late Loss at 6 Months



Difference and 95.2% UCB



Intent-to-treat; **P* values for superiority comparison

UCB = upper confidence bound

EVOLVE: Angiographic Outcomes at 6 Months

In-stent values	PROMUS Element N = 98	SYNERGY N = 94	*P* Value	SYNERGY ½ Dose N = 99	*P* Value
Minimum lumen diameter	2.29 ± 0.50	2.41 ± 0.42	0.08	2.45 ± 0.44	.02
Late loss	0.15 ± 0.34	0.10 ± 0.25	0.19	0.13 ± 0.26	.56
Diameter stenosis	8.95 ± 14.97	6.59 ± 9.90	0.18	7.27 ± 9.47	.34
Binary restenosis	3.2%	0.0%	0.25	0.0%	.25

Assessed by QCA
Values are mm or percent
Intent-to-treat; *P* values are vs PROMUS Element