SYNERGY Stent:
Korean Experience with Case Presentation

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Evolution of DES Technology

First Gen

Durable Polymer Stents

	Cypher	TAXUS Express	TAXUS Liberte
Strut Thickness	140 µm	132 µm	96 µm
Coat Thickness	7µm / side	16µm/side	14µm/side

Bioabsorbable Polymer Stents

	Biomatrix	Nobori
Strut Thickness	120 µm	125 µm
Coat Thickness	10 µm	20 µm

Second Gen

	Resolute Integrity	Xience Xpedition	Promus PREMIER
Strut Thickness	89 µm	81 µm	81 µm
Coat Thickness	6µm / side	8µm / side	8µm / side

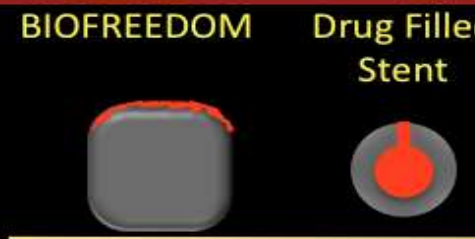
	Firehawk	Synergy	Ultimaster
Strut Thickness	86µm	74µm	80µm
Coat Thickness	10 µm	4 µm	14 µm

First Generation Future Technologies

Fully Bioresorbable Stents

	BVS	ELIXIR DESolve	DREAMS II
Strut Thickness	150 µm	150 µm	150 µm
Coat Thickness	3 µm / side	<3 µm / side	8 µm / side

Polymer Free Stents



	BIOFREEDOM	Drug Filled Stent
Strut Thickness	112	86
Coat Thickness	NA	NA

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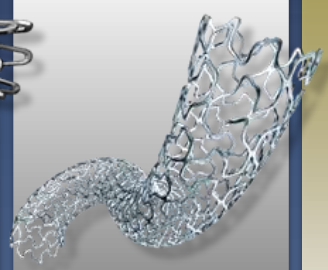
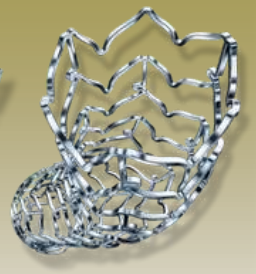
Advance of Stent Design

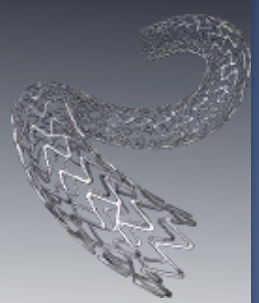
2004
TAXUS™ Express²™ Stent System



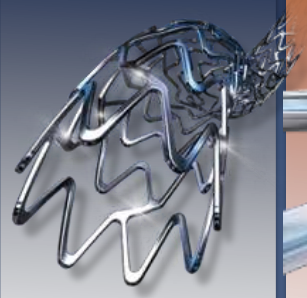
2008
TAXUS™ Liberté™ Stent System



2008
PROMUS™ Stent System



2011
ION™ and PROMUS Element™ Plus Stent Systems



2013
Promus PREMIER™ Stent System

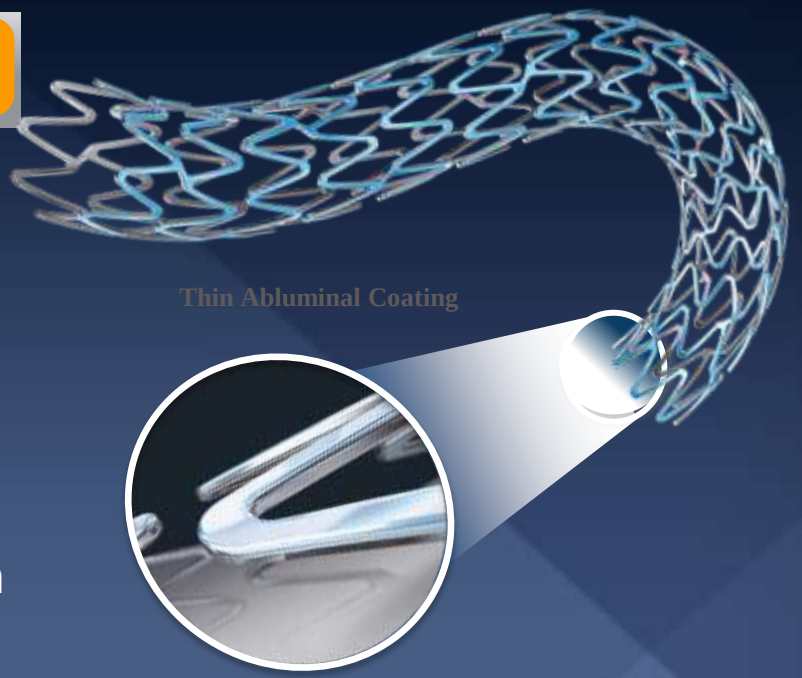
2015
SYNERGY™ Stent System

SYNERGY™ Everolimus-Eluting Stent

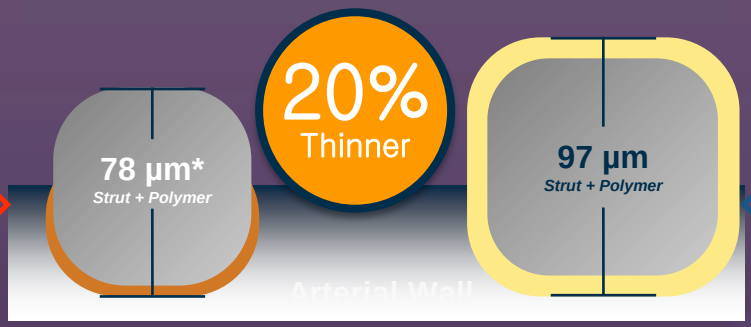
Product Summary

Synchrony™ Bioabsorbable Coating

- Polymer is gone when no longer needed, shortly after completion of drug elution at 3 months
- Applied to the abluminal side of the stent, designed for optimal healing
- **Providing *Suppression* of neointimal growth at the arterial wall & *Promotion* of healing inside the lumen**



SYNERGY Stent
Abluminal PLGA Bioabsorbable Polymer

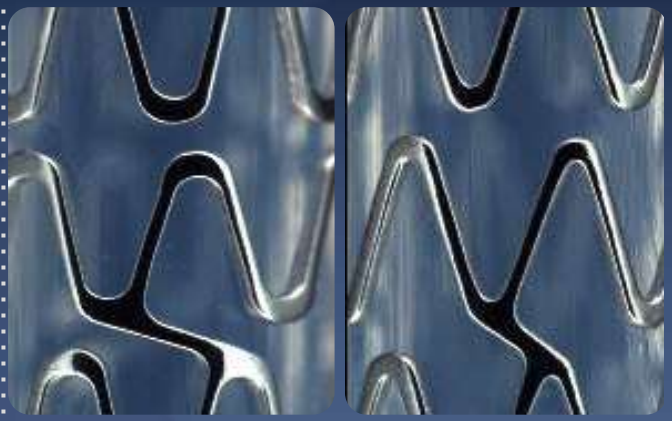


Promus PREMIER™ Stent
Conformal PVDF Permanent Polymer

SYNERGY™ Stent Enhanced Platform

Strength and Flexibility Where It Matters

Connector Angle Comparison



Promus PREMIER™ Stent

SYNERGY Stent

Strut thickness, peak radius and connector angles designed ***to improve crimping profile and deliverability over Promus PREMIER Stent***

Customized Stent Architecture

Additional connectors on proximal two segments

Robust proximal end for *increased axial strength*[1]

2 connectors throughout body

Overall design maintains *flexibility and conformability*[2]

SYNERGY™ Stent

Stent Design + PtCr Alloy Combine for Greater Radial Strength

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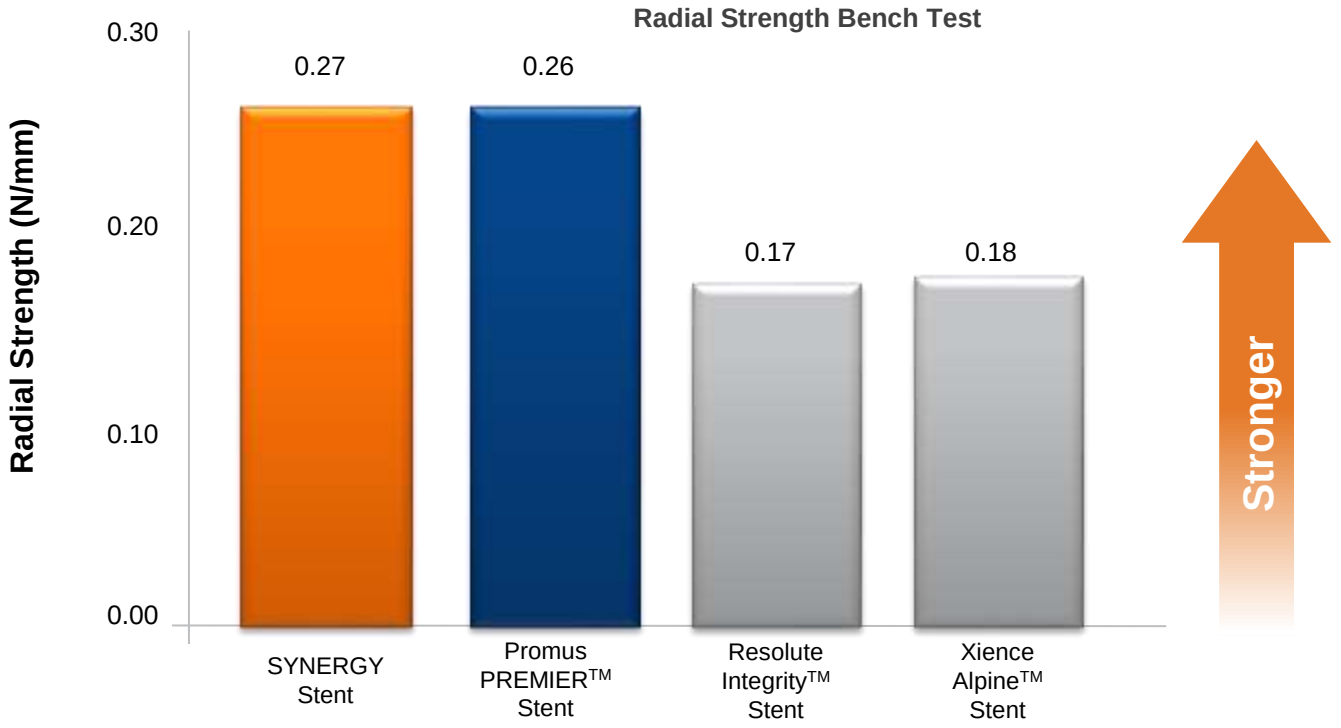
Unmatched Radial Strength



Radial Strength: Amount of radial force required to reduce the diameter of a deployed stent by 15%

Bench testing performed by Boston Scientific Corporation. Data on file at Boston Scientific. All stents 2.50 mm; SYNERGY n = 5,Promus PREMIER n = 15, Resolute Integrity n = 3, and Xience Alpine n = 3. Bench test results not necessarily indicative of clinical performance.

SYNERGY™ Stent

Engineered to minimize recoil

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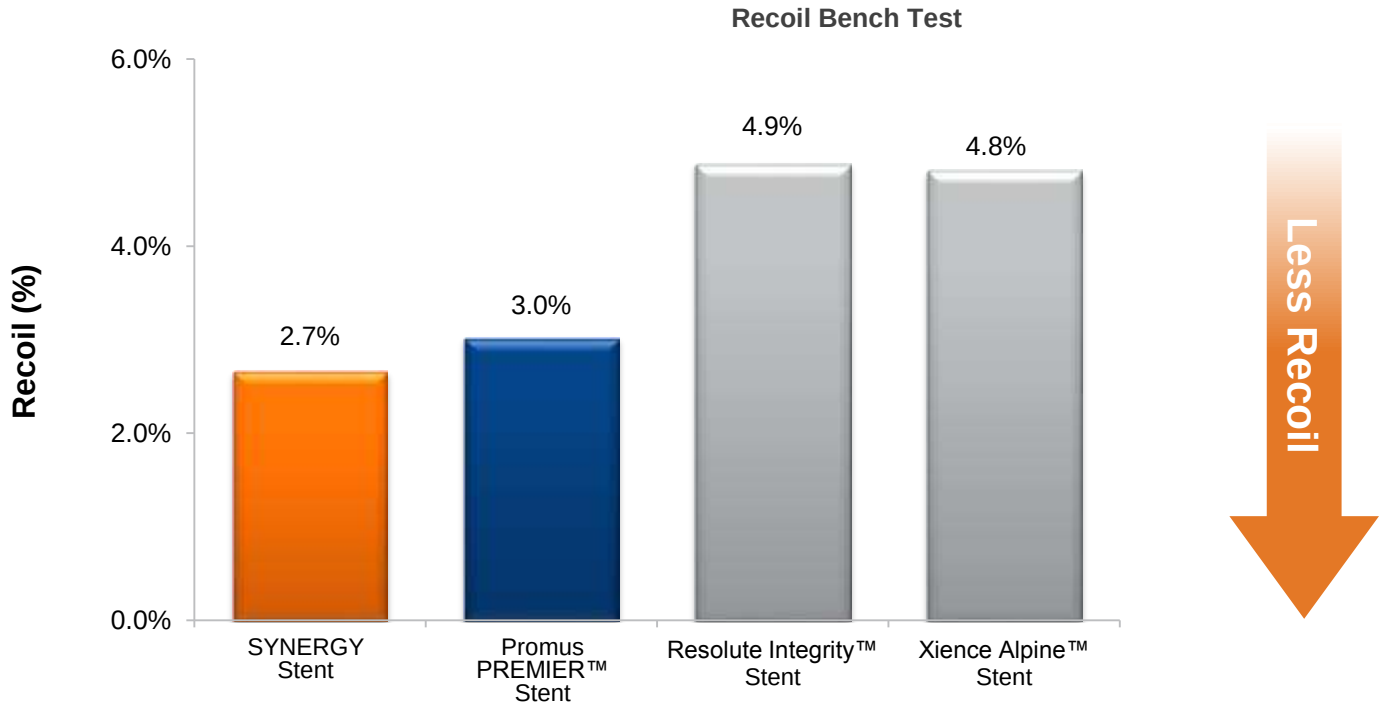
Exceptionally Low Recoil



Stent Recoil: Amount the stent diameter reduces after deflation and removal of balloon

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Bench testing performed by Boston Scientific Corporation. Data on file at Boston Scientific. All stents 2.50 mm; SYNERGY n = 15,Promus PREMIER n = 15, Resolute Integrity n = 3, and Xience Alpine n = 3. Bench test results not necessarily indicative of clinical performance.

SYNERGY™ Stent

Customized Connector Design for Improved Conformability

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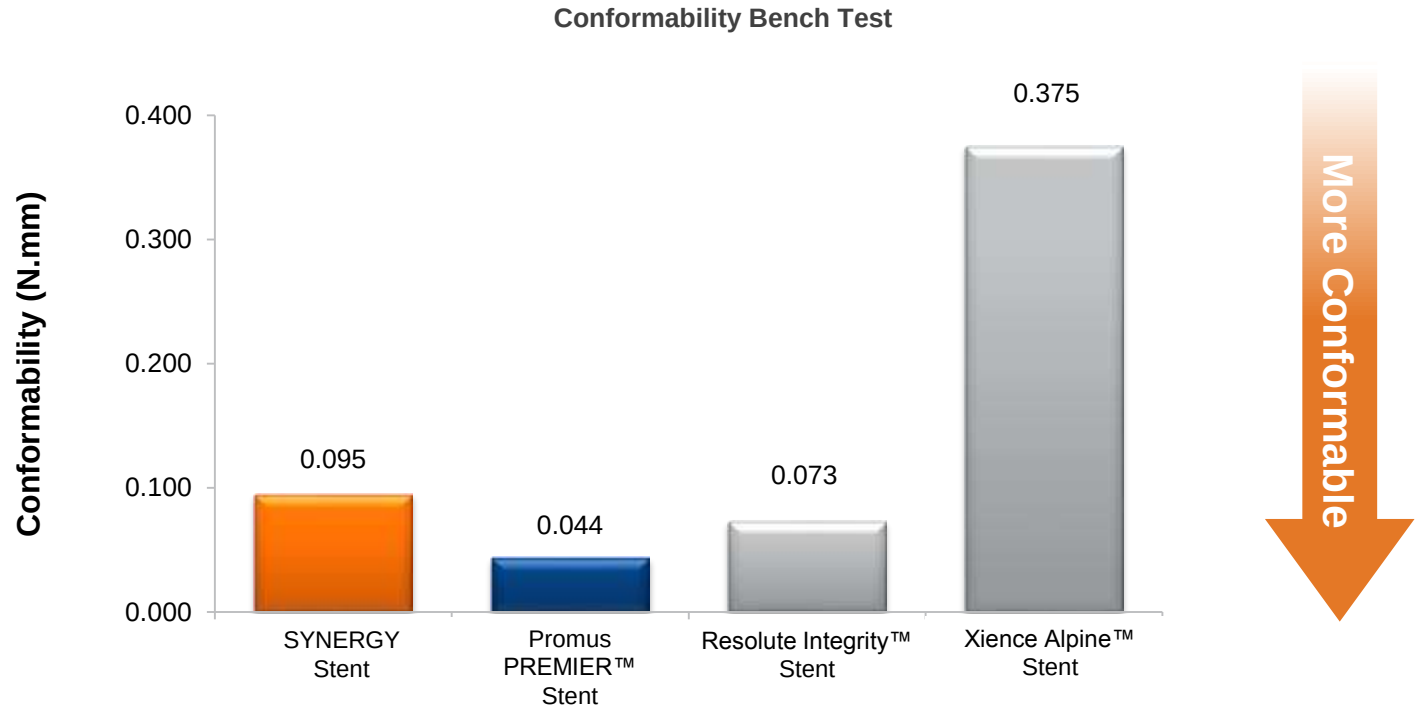
Excellent Conformability



Conformability: The amount of torque required to bend the stent to a specific curvature

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Bench testing performed by Boston Scientific Corporation. Data on file at Boston Scientific. All stents 2.50 mm; SYNERGY n = 5, Promus PREMIER n = 15, Resolute Integrity n = 3, and Xience Alpine n = 3. Bench test results not necessarily indicative of clinical performance.

SYNERGY™ Stent Clinical Program

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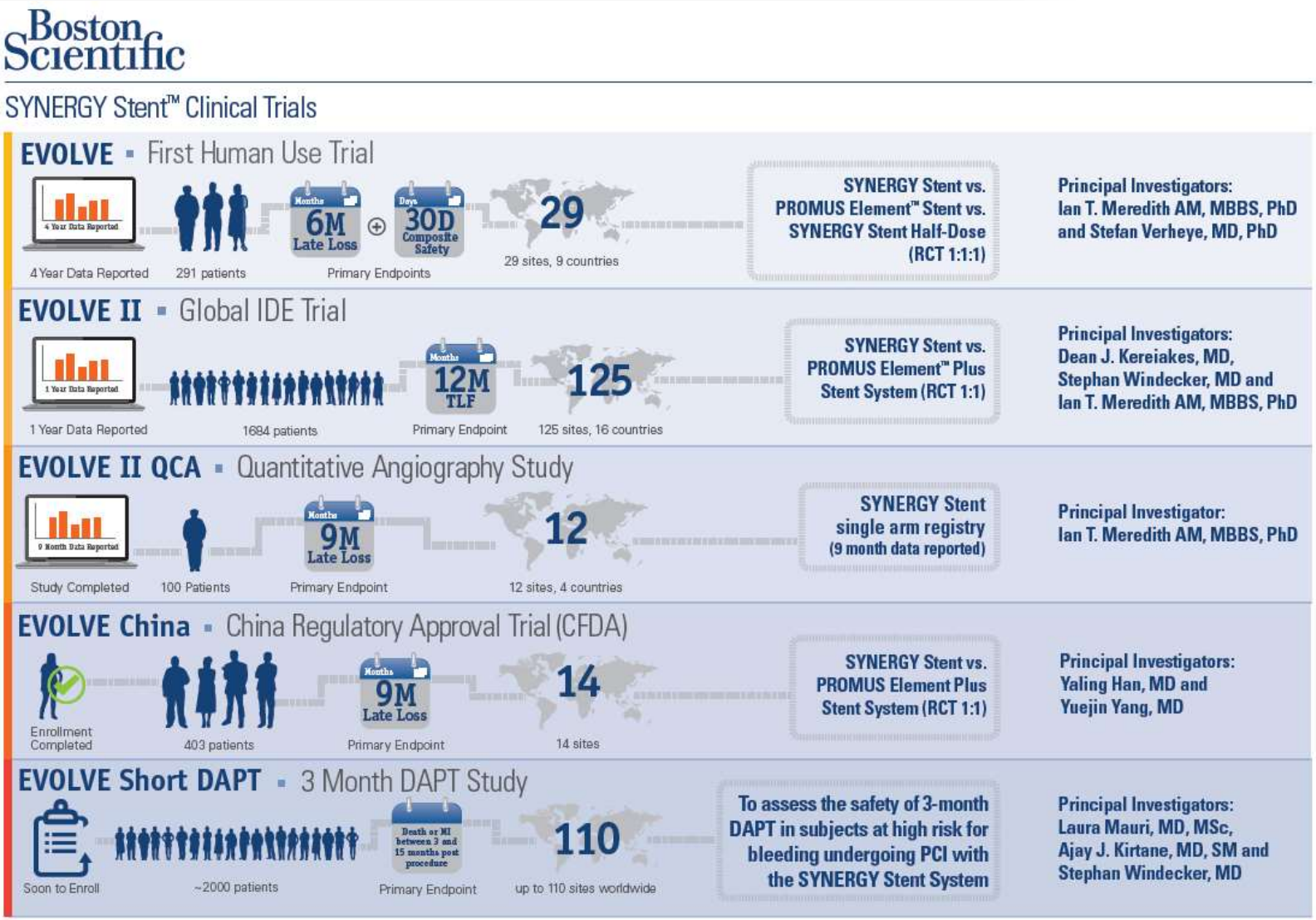

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EVOLVE II Clinical Trial Design

First Successful U.S. Pivotal Trial of a Bioabsorbable Polymer Technology

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Most complex patient population ever studied in a U.S. Pivotal Trial

Patients with ≤3 native coronary artery lesions in ≤2 major epicardial vessels; lesion length ≤34 mm, RVD ≥2.25 mm ≤4.0, %DS> 50 <100 (excluded LM disease, SVG, CTO, ISR or recent STEMI)

Randomized Cohort (RCT)

125 global sites

PROMUS Element™ Plus Stent System
n = 838

SYNERGY™ Stent
n = 846

RCT Design

Multicenter noninferiority trial

Pivotal, single-blind, 1:1 randomization

Primary Endpoint: TLF (CD, TV-MI, or TLR) at 12 months

Follow-up through 5 years

Diabetes Substudy

Single-arm Diabetes Study
n = 203

SYNERGY Cohort EVOLVE II RCT
n = 263

EVOLVE II Diabetes Substudy Design

Consecutive, multicentre, single-arm, non-randomised

1° Endpoint: TLF at 12 mo

PK Substudy

SYNERGY Stent
n = 21

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10

Kereiakes et al. The EVOLVE II Trial. Circ Cardiovasc Interv. 2015.
EVOLVE II DM Substudy. Presented by Stephan Windecker, MD at PCR 2015.wing the index procedure.
Per protocol, patients were treated with one of the following P2Y12 inhibitors (clopidogrel, ticlopidine, prasugrel, or ticagrelor) for at least 6 months follo

EVOLVE II Clinical Trial

1-Year Results

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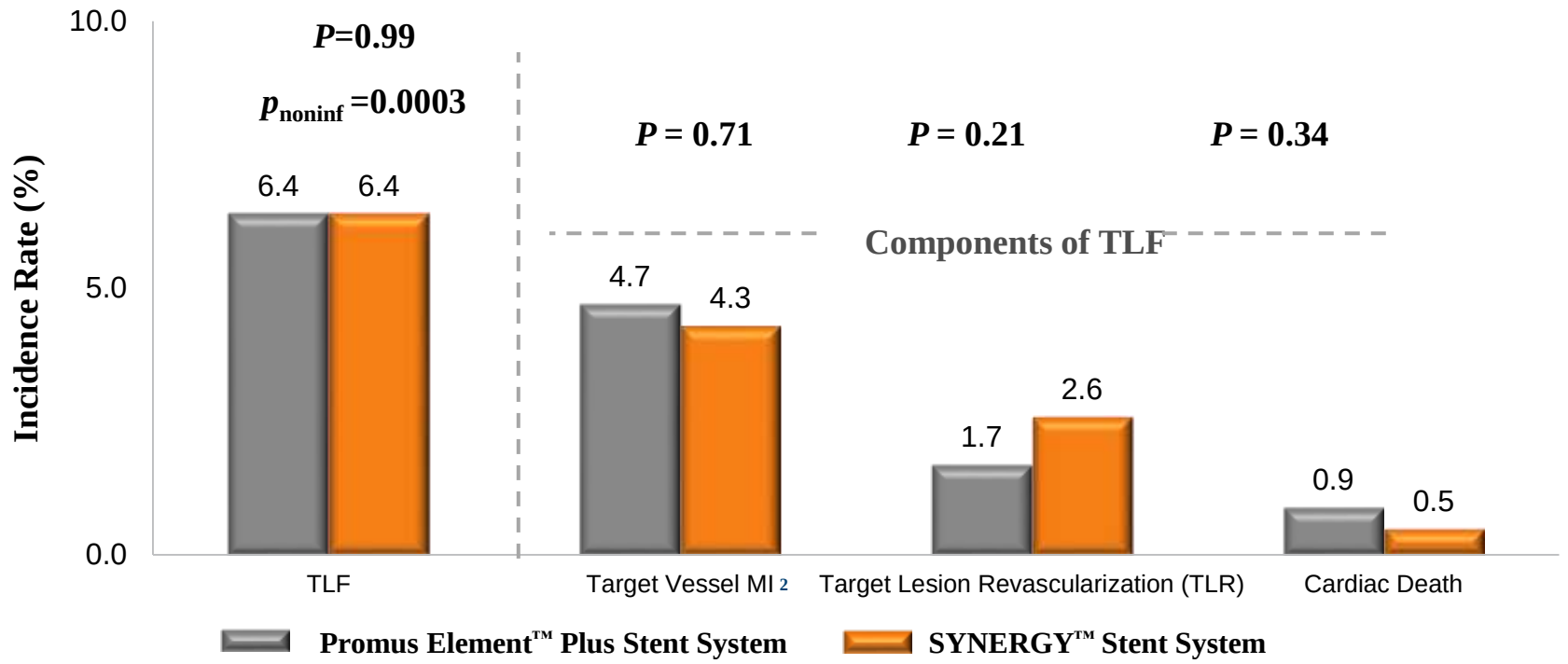
Primary Endpoint of Target Lesion Failure[1] (TLF) Met



IC-338001-AE FEB2016 11

Kereiakes et al. The EVOLVE II Trial. Circ Cardiovasc Interv. 2015. 1684 patients were randomized 1:1 to SYNERGY or PROMUS Element Plus Stent Systems. Graph shows TLF Per Protocol (PP) and MI, TLR, CD shown for the Intent-to-Treat (ITT) population. ITT TLF for SYNERGY Stent = 6.7%. and for PROMUS Element Stent = 6.4% respectively (p=0.0005 for non-inferiority).

1 TLF: ischemia-driven TLR, MI related to the target vessel, or any cardiac death. The study primary endpoint was the rate of 12-month TLF by both intent-to-treat and per-protocol analyses.

2 Per protocol spontaneous MI is defined as rise and/or fall of cardiac biomarkers with ≥1 value >99th percentile of the URL + evidence of myocardial ischemia. Peri-PCI Mi is defined as ≥1 of the following: i) biomarker elevations within 48 hours of PCI (based on CK-MB >3X URL), ii) new pathological Q waves, or iii) autopsy evidence of acute MI

EVOLVE II Clinical Trial

Exceptionally Low Stent Thrombosis

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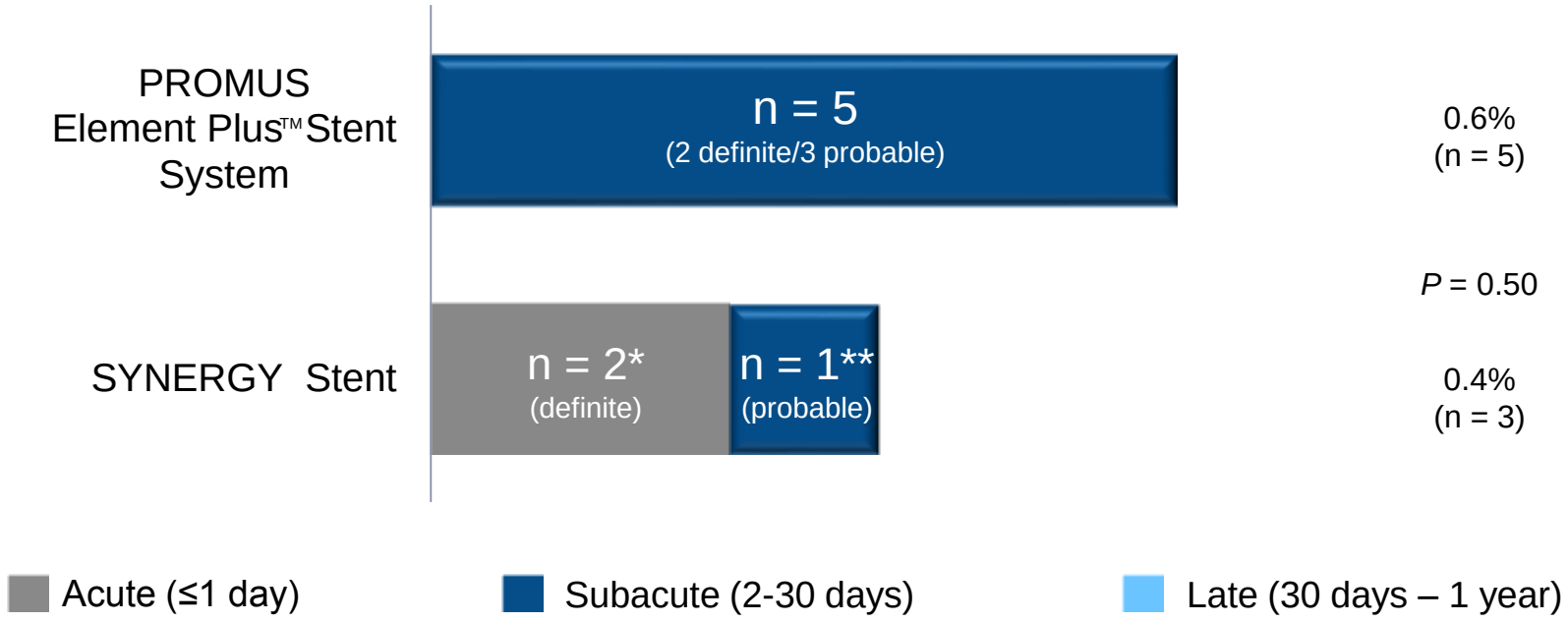
ZERO definite ST events in SYNERGY™ arm after 24 hours

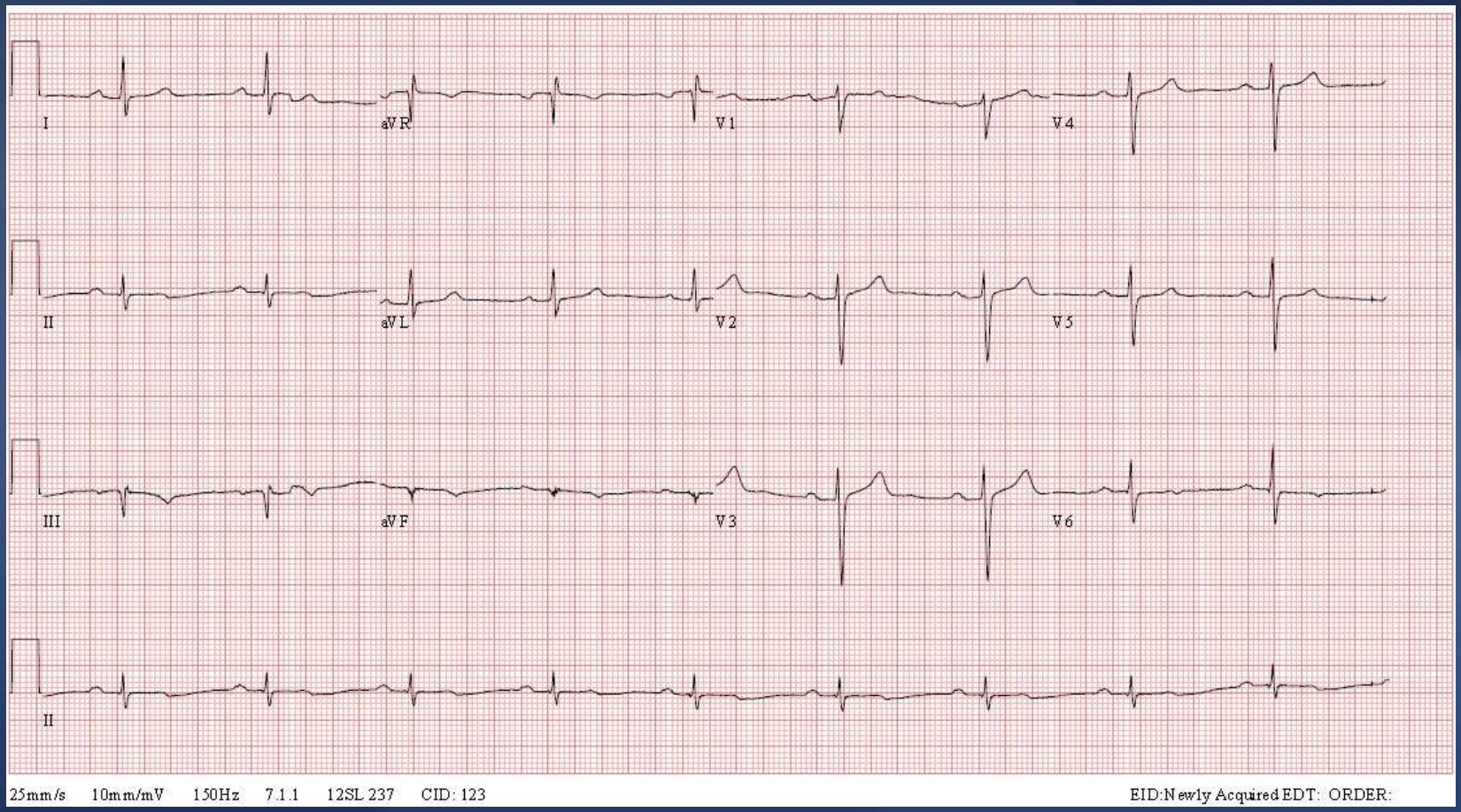


IC-338001-AE FEB2016 12

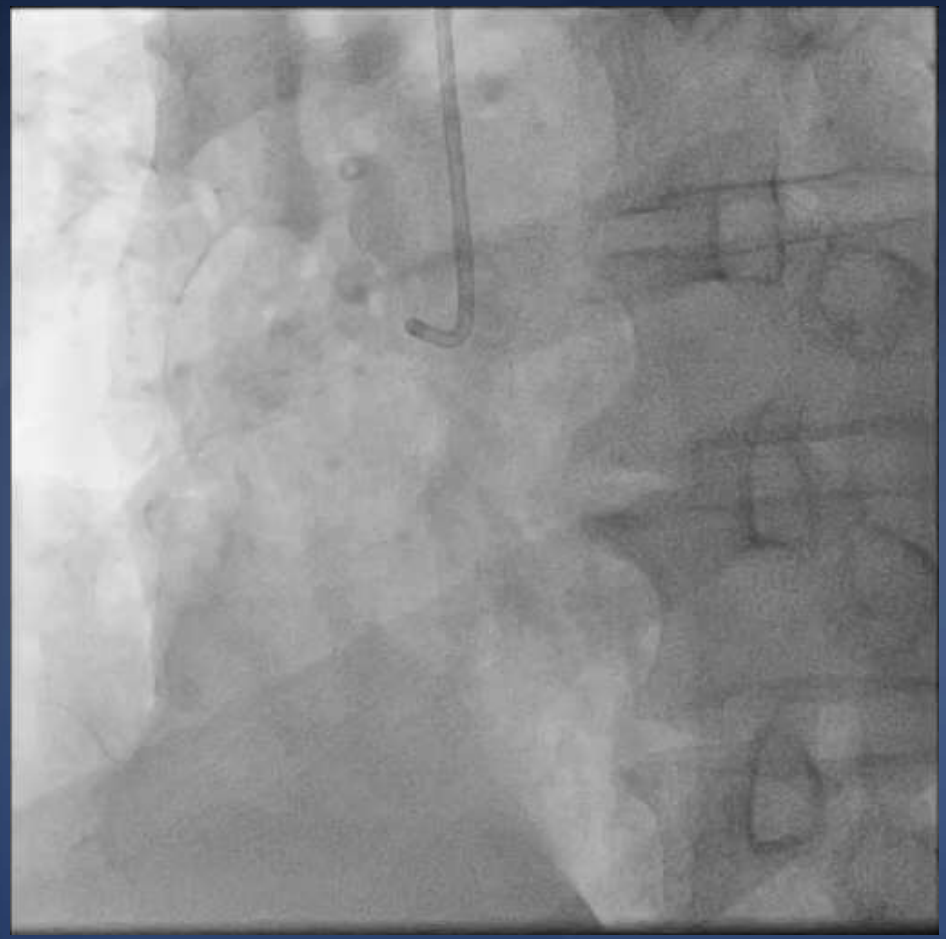
Kereiakes et al. The EVOLVE II Trial. Circ Cardiovasc Interv. 2015.
*One of the SYNERGY acute ST events involved a patient who was not treated with pre-procedural aspirin
*^Occurred on day 6. ST rates were equivalent when analyzed in an intent-to-treat or per protocol manner.

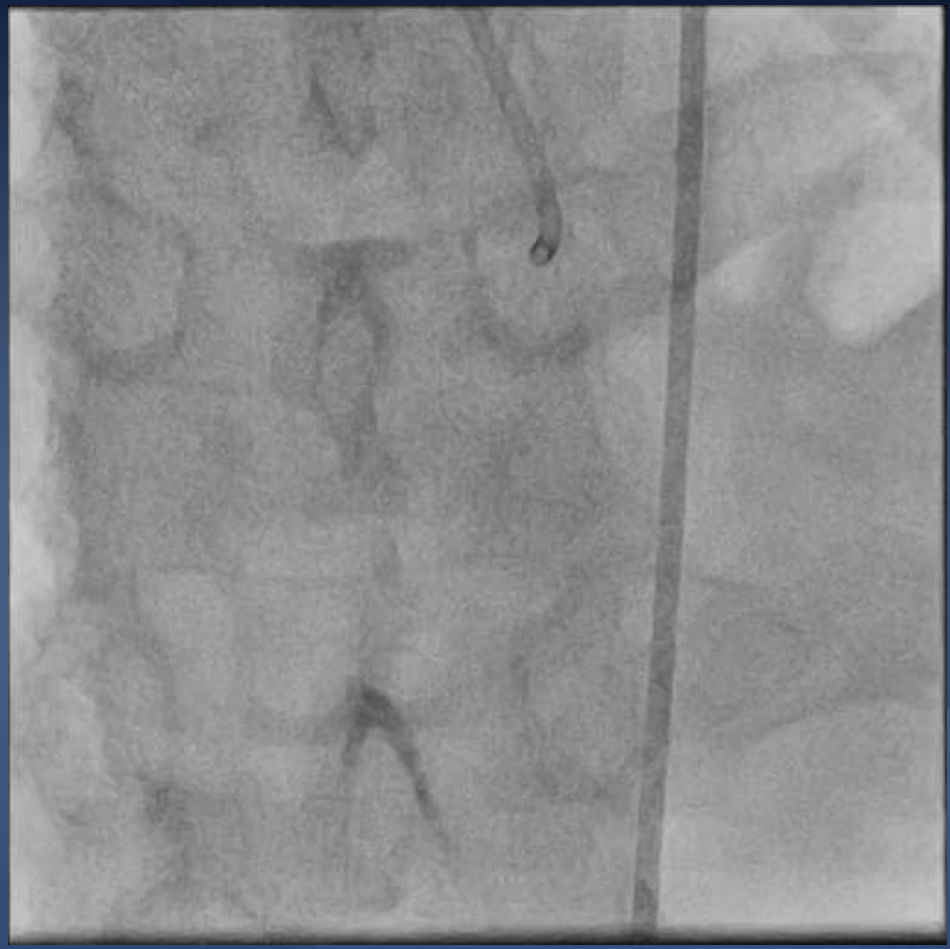
Our SYNERGY experience

- M/58
- Clinical presentation; NSTEMI
- No history of DM, HTN, hyperlipidemia, smoking
- Echo; EF 68%, basal inferoposterior wall hypokinesia.

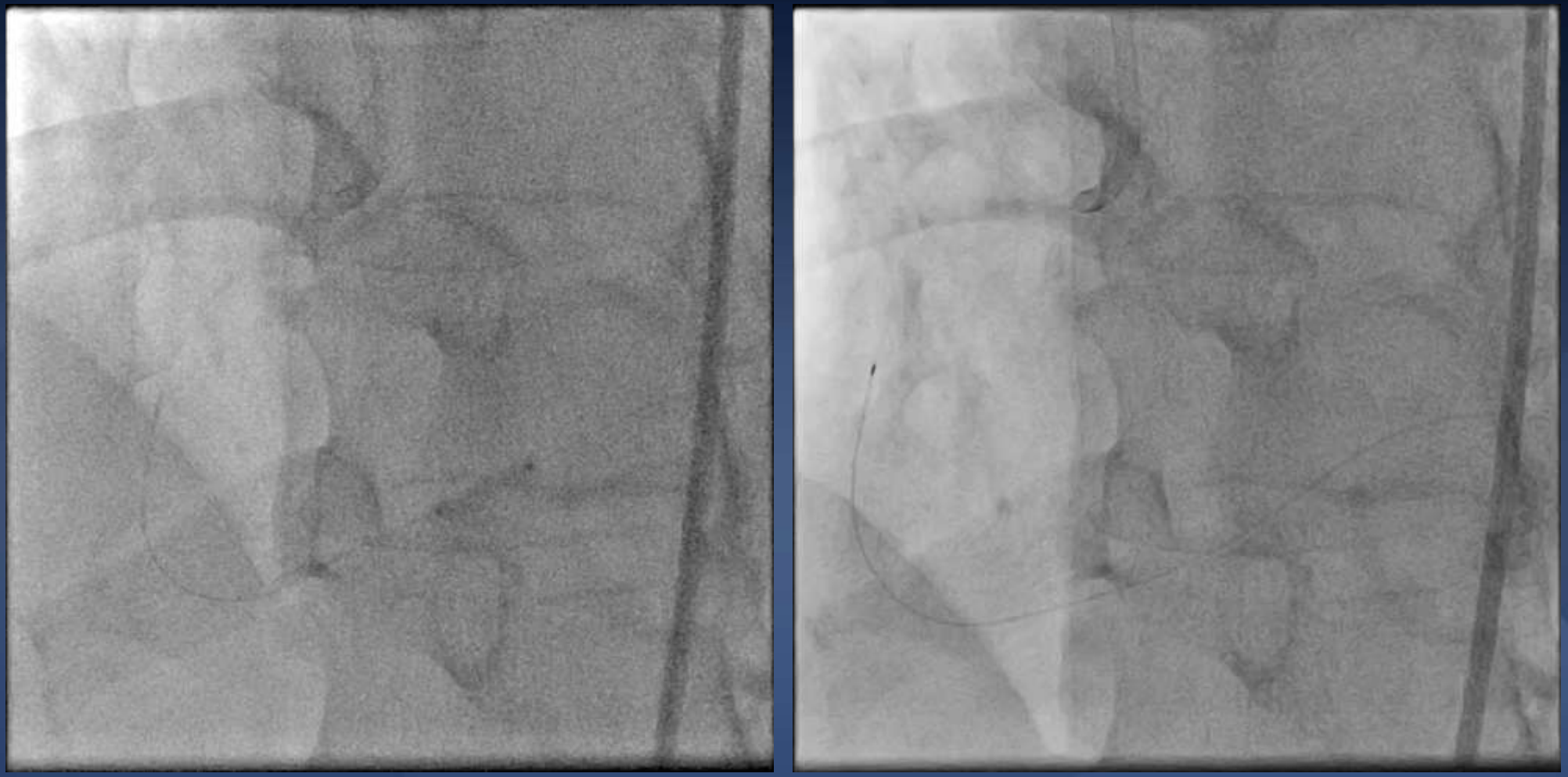


Baseline CAG



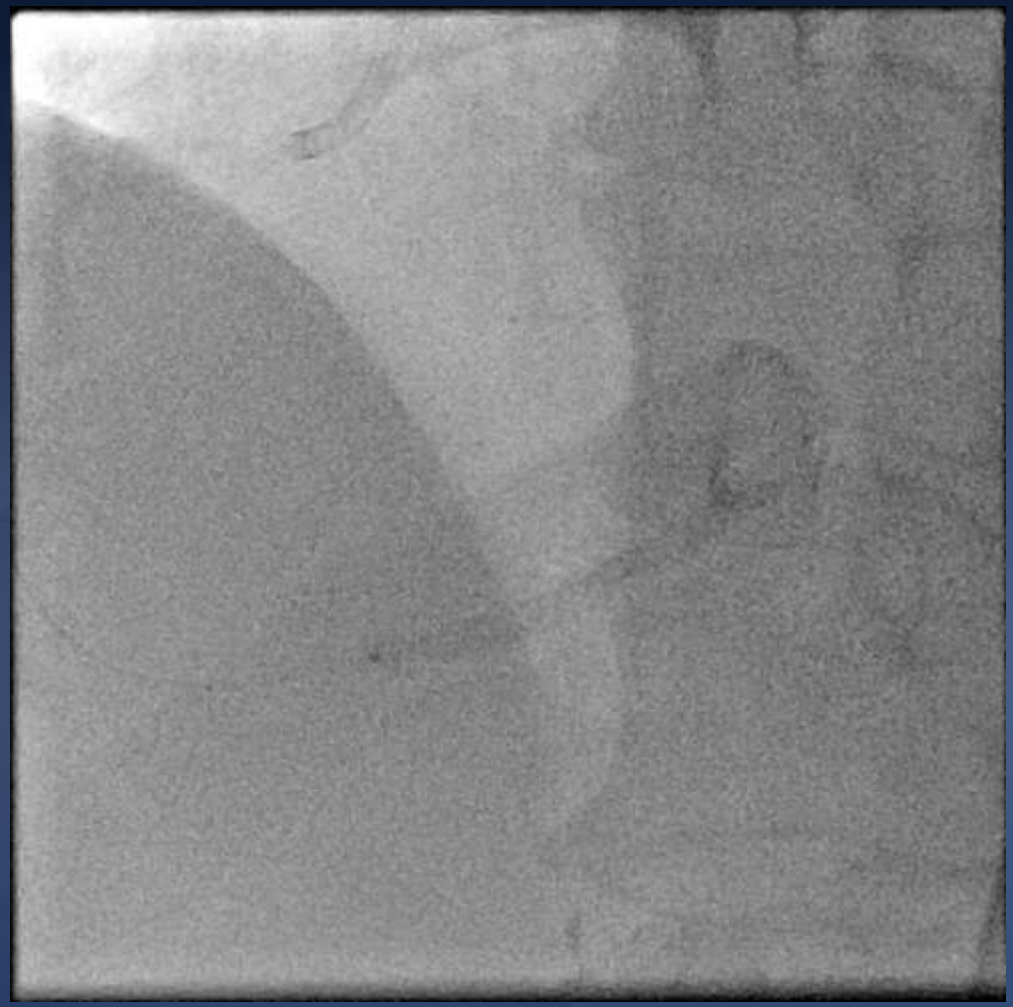


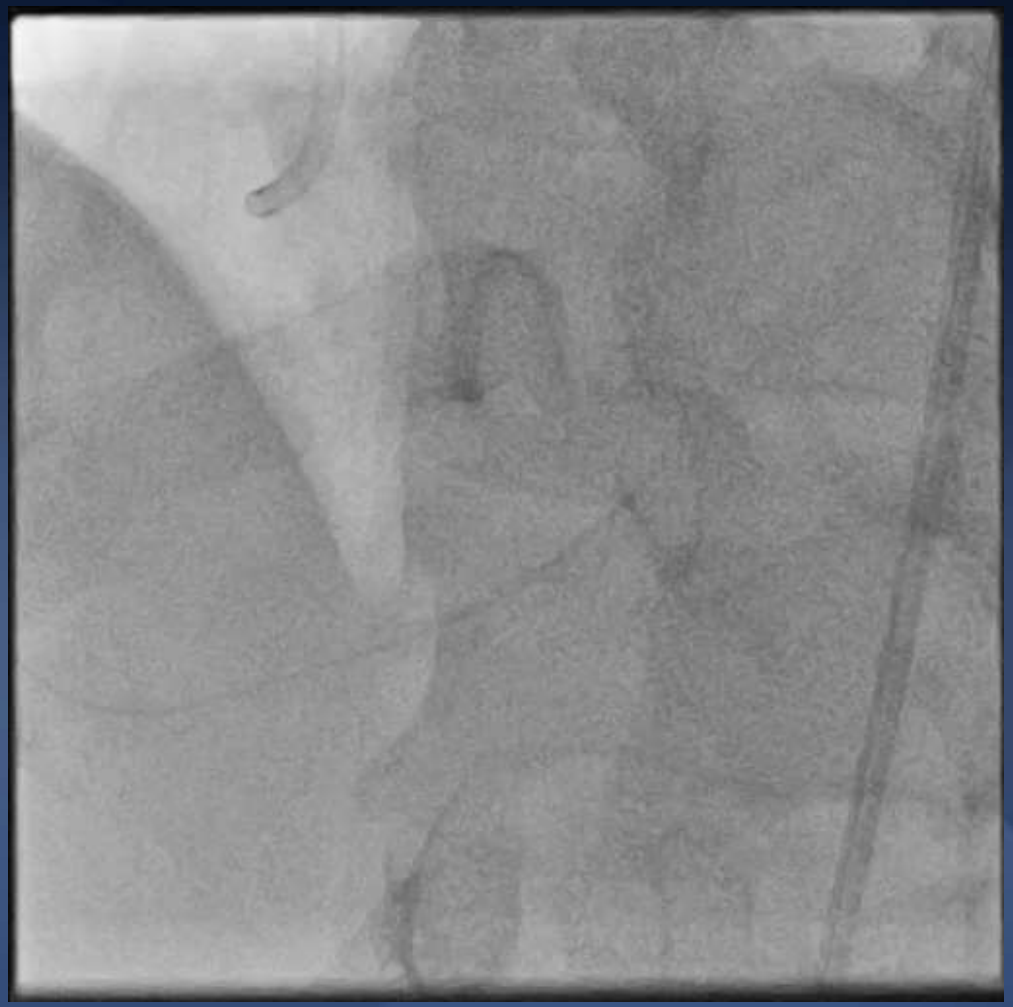
Pre-balloon dilation



Everest 2.5x15 mm

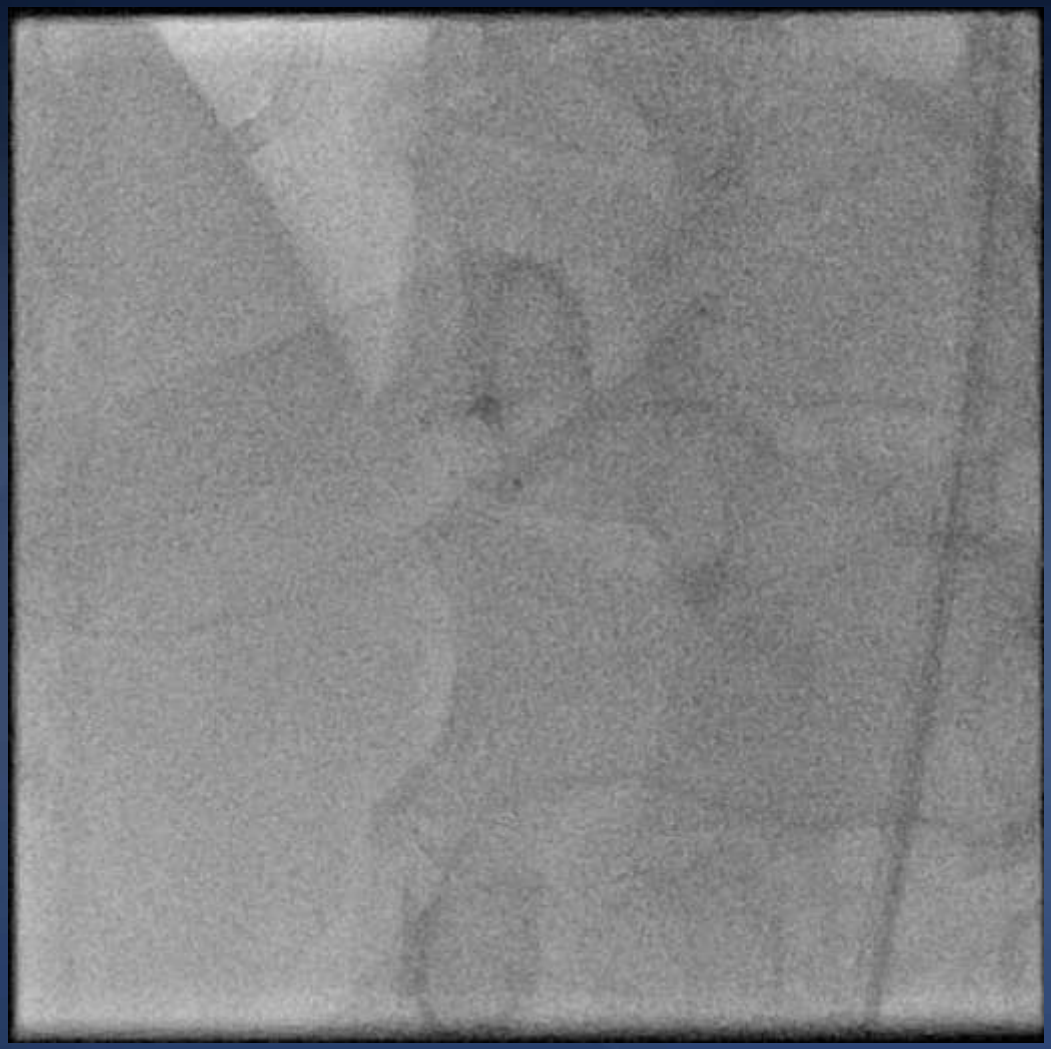
SYNERGY stent

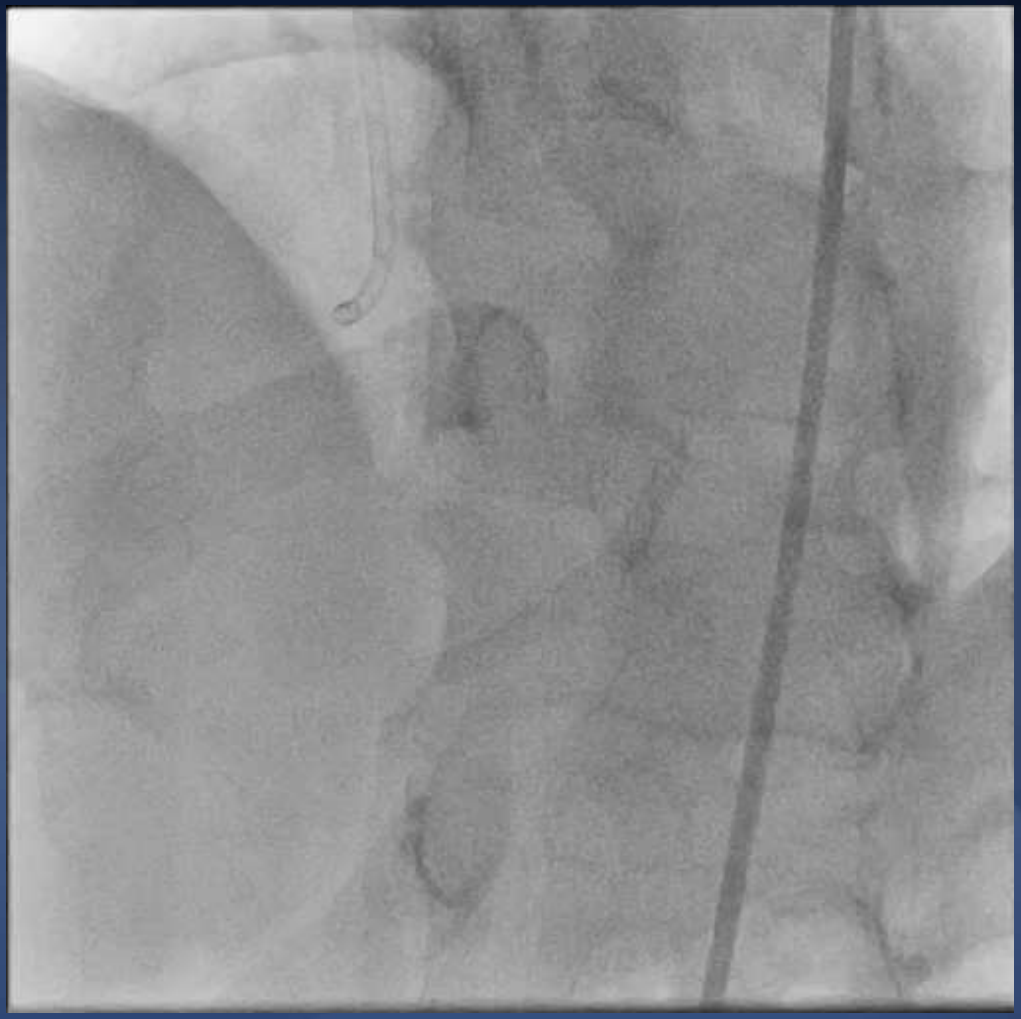




SYNERGY 3.0x38 mm

HP balloon and Final Results





Empira NC 3.0x20 mm

SYNERGY stent

- The SYNERGY has thinner stent strut, bioabsorbable polymer, well-documented drug/release kinetics, good visibility and enhanced platforms ensuring better flexibility and deliverability.
- This newer DES platform might be be more applicable for diverse complex lesions.
- However, long-term safety and efficacy should be addressed in the real-world practice.

IRIS-DES Registry

Design

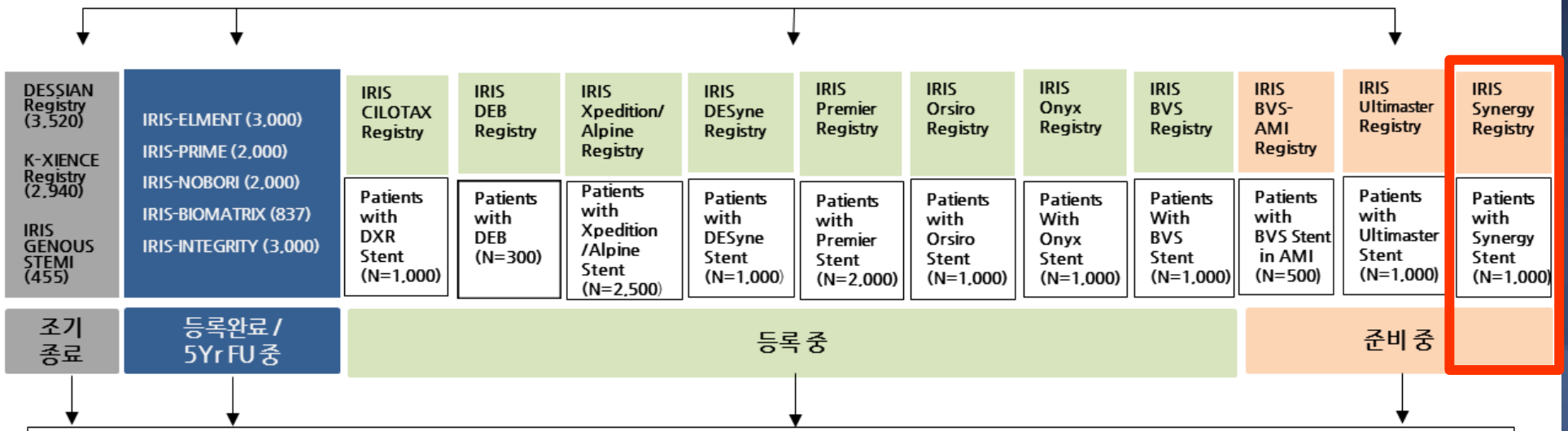
- DESIGN: An unrestricted, multicenter, prospective cohort
- OBJECTIVE: To compare the safety and efficacy of the second- or newer-generation DES and the first-generation DES in everyday clinical practice,
- PRINCIPAL INVESTIGATOR
  Seung-Jung Park, MD, PhD, Asan Medical Center, Seoul, Korea

Evaluation of Effectiveness and Safety of the First, Second, and New Drug-Eluting Stents in Routine Clinical Practice;

IRIS-DES Registry

Consecutive PCI patients receiving New DES without a mixture of other DES

Prospective Enrollment



Clinical follow-up at 1-, 6-, and 12-months, and annually up to 5 years

***Primary end point: Composite of Death, MI, and TVR at 12-months**

Comparative Effectiveness Research (CER) of Various DES

- Enrollment and at least 2-year clinical follow-up was completed for Cypher, Xience, Genous, Promus element, Xience prime, Nobori, Biomatrix, and Resolute intergrity; analysis results are expected in the summer of 2016.
- The IRIS-SYNERGY registry is actively ongoing, and comparative data will be available in the near future.