

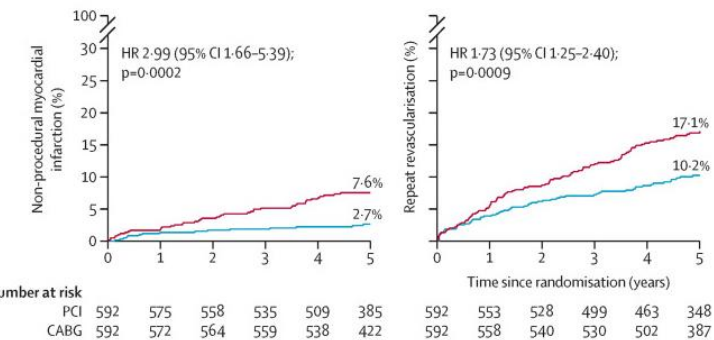
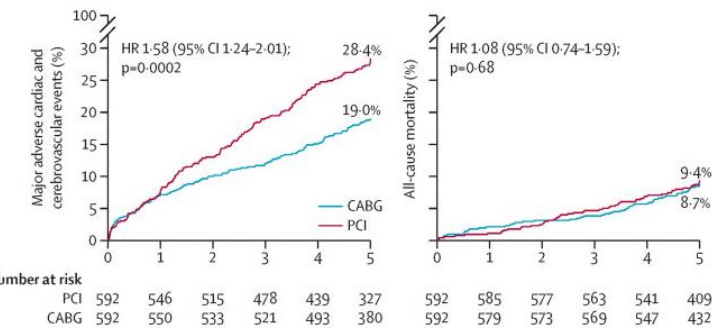
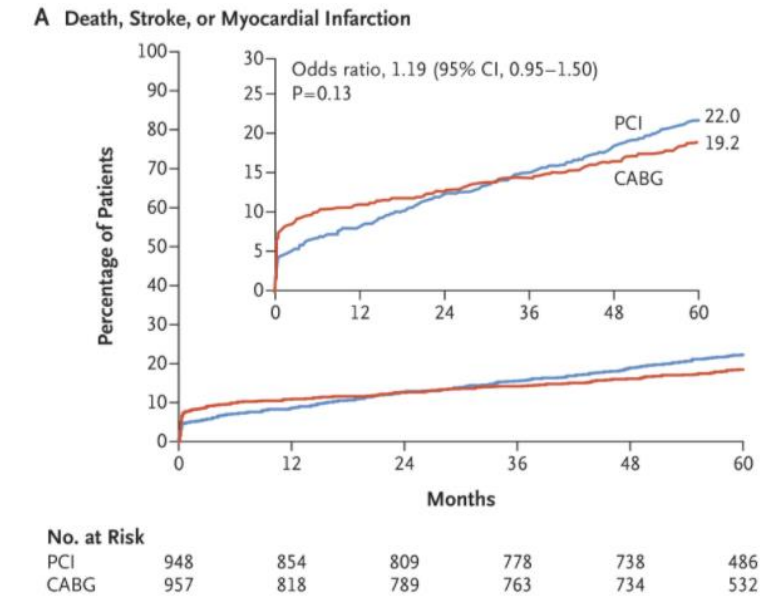
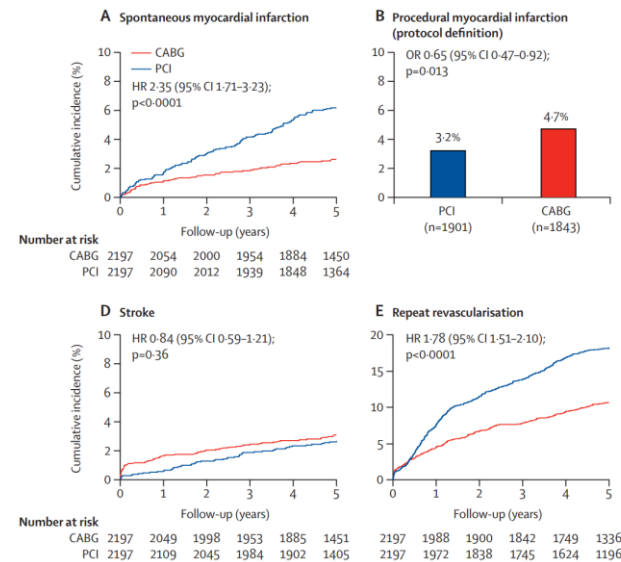
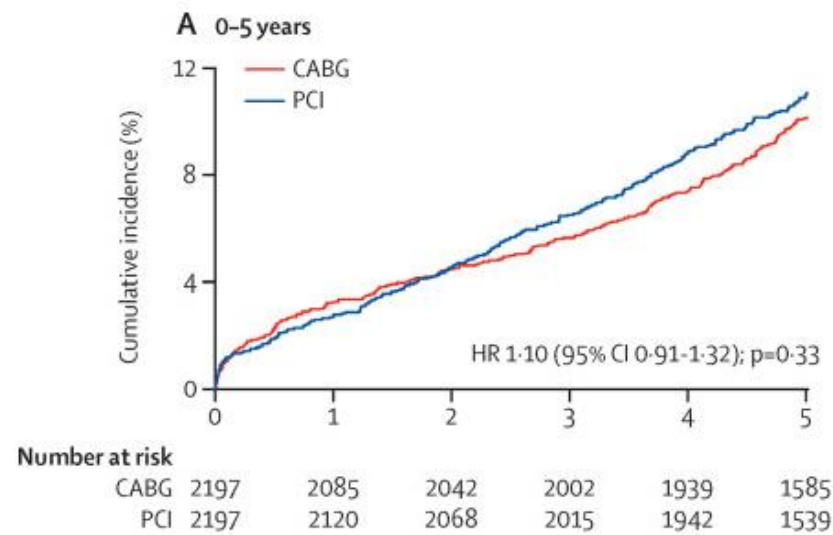
Strategies of IVUS-Guided Left Main PCI

SYNERGY MEGATRON™ BP Stent

SNUH Jeehoon Kang, MD

Issues in Left Main PCI

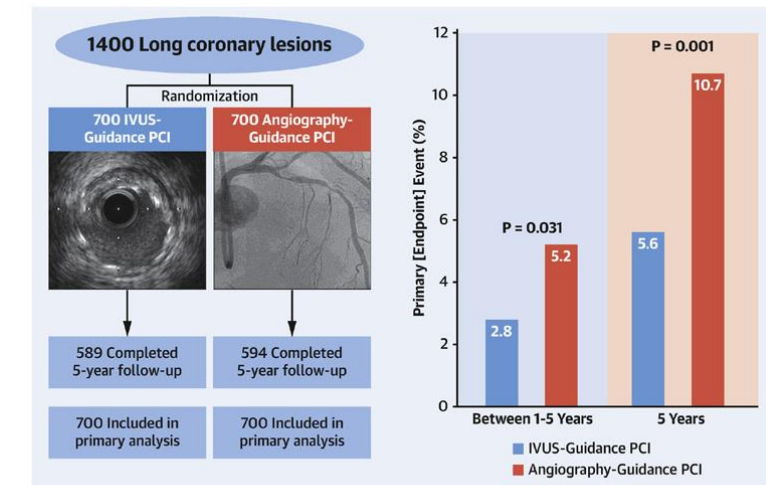
- Associated with a large extent myocardium
- Despite many RCTs and meta-analysis, we still do not know how to treat LM disease patients.
 - **EXCEL and NOBLE trial, and a IPD meta**



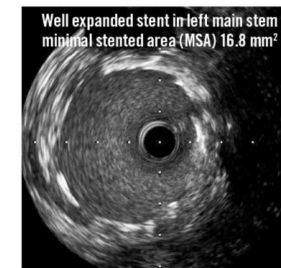
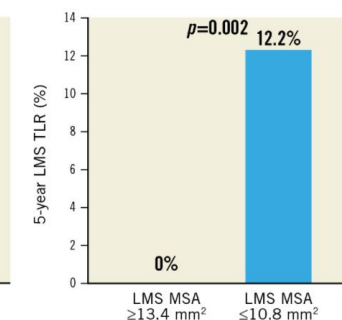
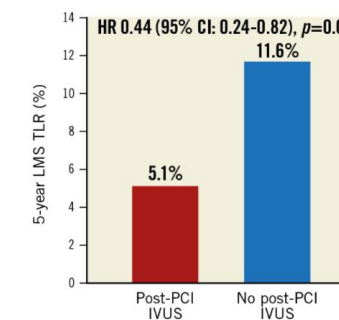
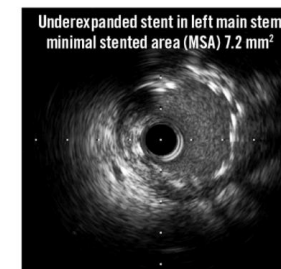
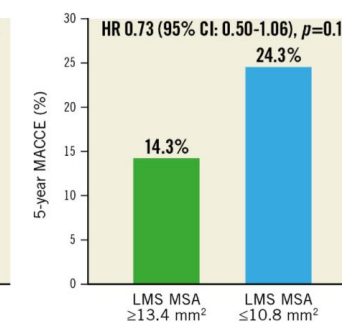
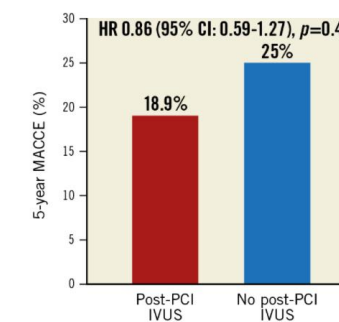
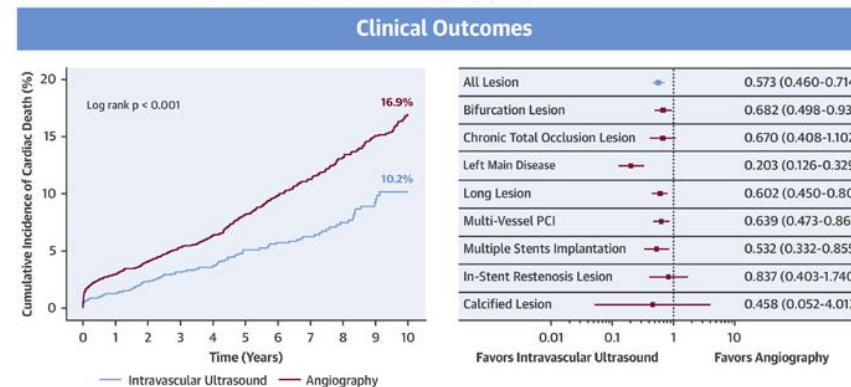
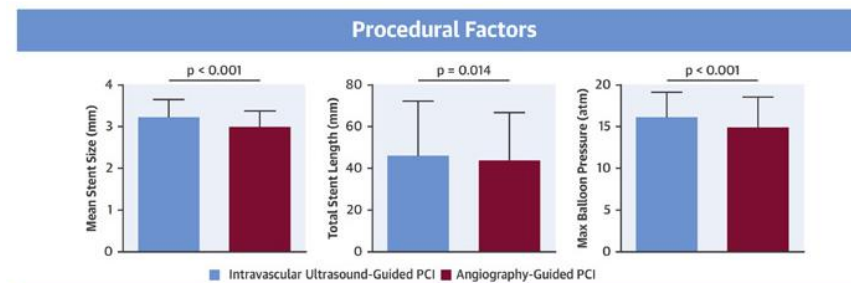
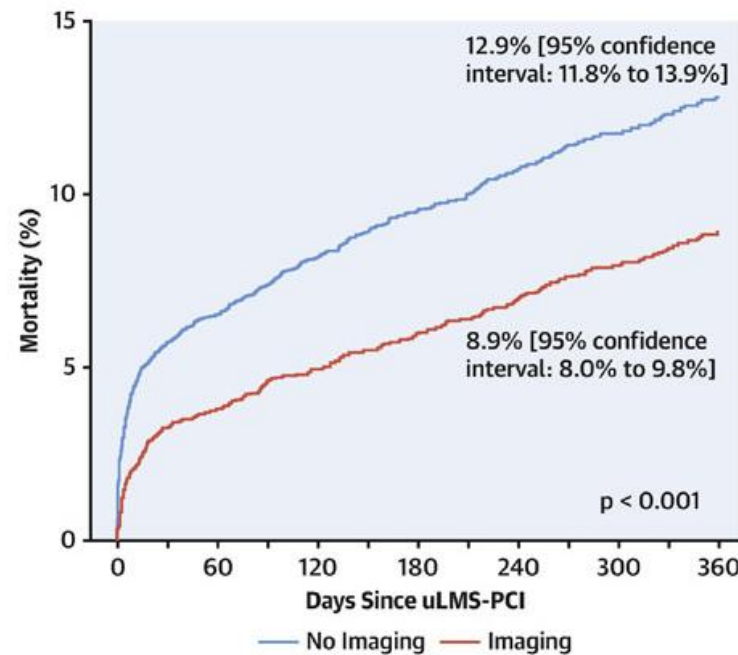
- *How can we perform Optimal LM Stent implantation?*

IVUS in Left Main PCI

- Previous trials have shown that Intravascular ultrasound (IVUS) guided-PCI improves clinical outcomes, compared to angiography guided PCI.



Hong, S.-J. et al. J Am Coll Cardiol Intv. 2020;13(1):62-71.

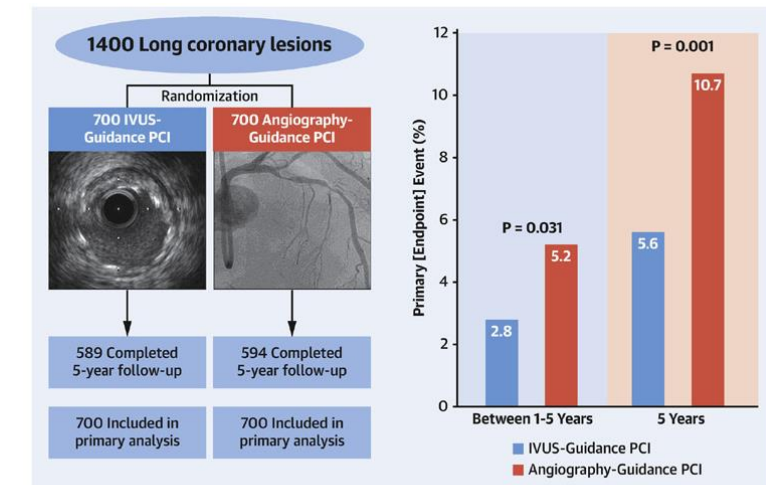


Kinnaird, T. et al. J Am Coll Cardiol Intv. 2020;13(3):346-57.

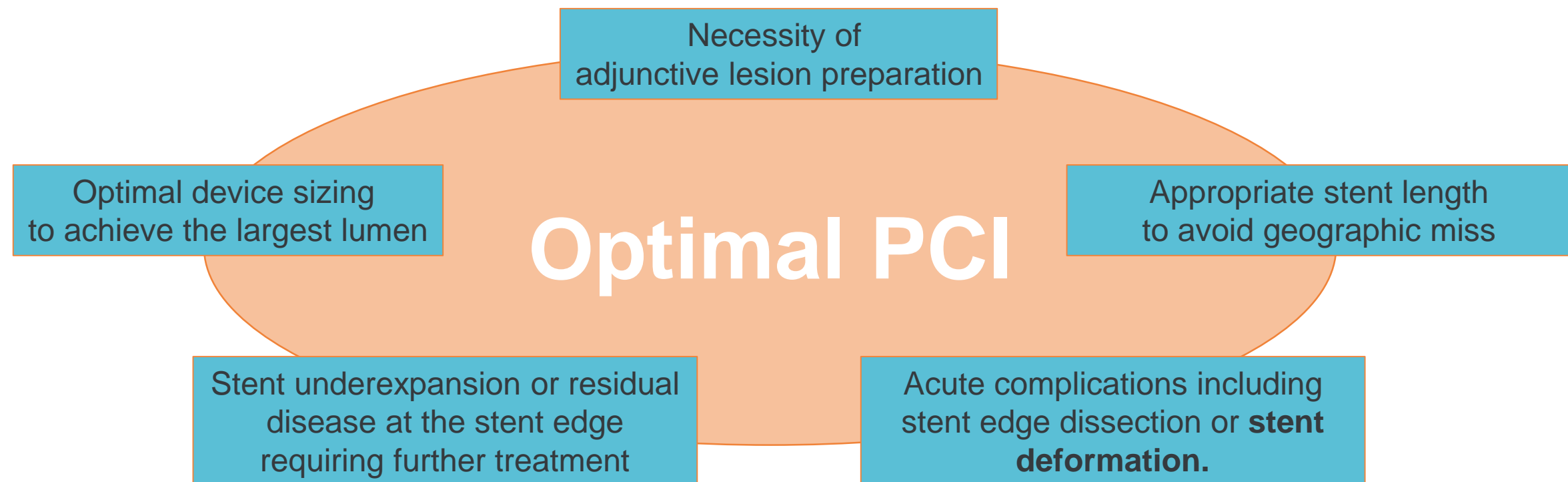
Choi, K.H. et al. J Am Coll Cardiol Intv. 2019;12(7):607-20.

IVUS in Left Main PCI

- Previous trials have shown that Intravascular ultrasound (IVUS) guided-PCI improves clinical outcomes, compared to angiography guided PCI.
- *What can be earned from IVUS evaluation ?*



Hong, S.-J. et al. J Am Coll Cardiol Intv. 2020;13(1):62-71.



Prevalence and Anatomical Features of Acute Longitudinal Stent Deformation: An Intravascular Ultrasound Study

Shinji Inaba,^{1,2} MD, Giora Weisz,^{1,2} MD, Nobuaki Kobayashi,^{1,2} MD, PHD, Shigeo Saito,^{1,2} MD, Tomotaka Dohi,^{1,2} MD, Liang Dong,^{1,2} MD, Lin Wang,^{1,2} MD, Joyce A. Moran,² CCRC, LeRoy E. Rabbani,^{1,2} MD, Manish A. Parikh,^{1,2} MD, Martin B. Leon,^{1,2} MD, Jeffrey W. Moses,^{1,2} MD, Gary S. Mintz,¹ MD, and Akiko Maehara,^{1,2*} MD

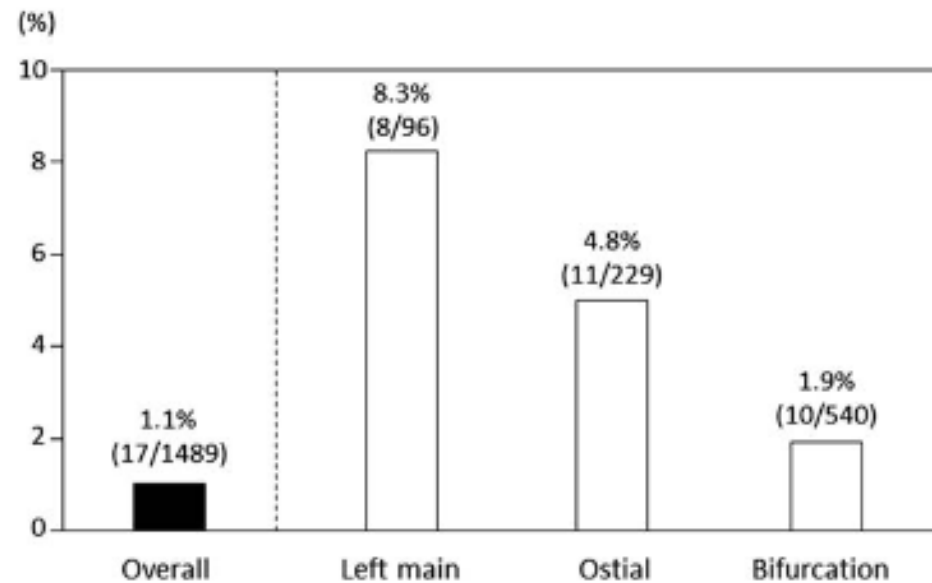
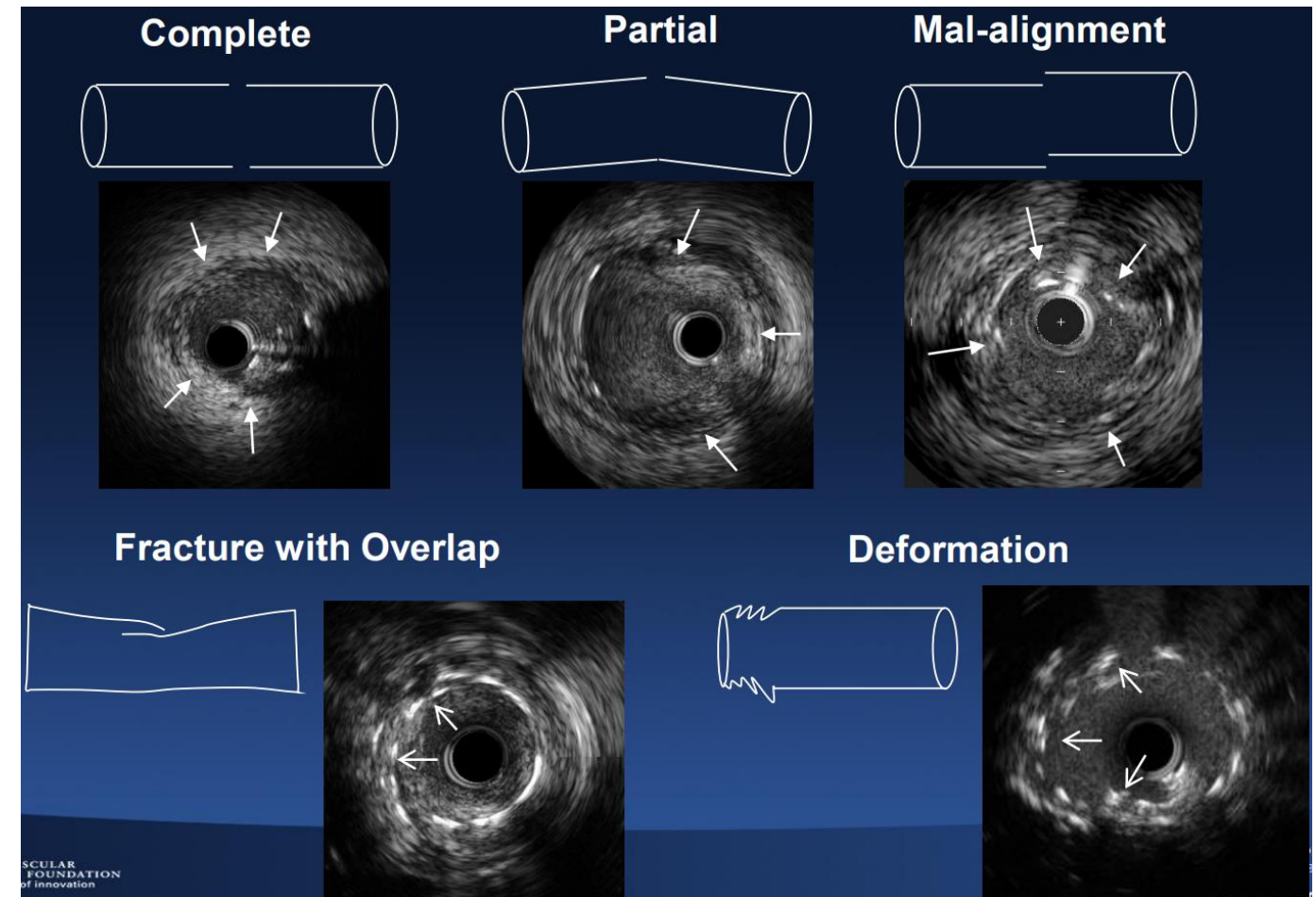


Fig. 1. Prevalence of deformation in according to lesion location. In the entire cohort there were 96 left main, 229 ostial, and 540 bifurcation lesions. Deformation was most frequently observed in the left main coronary artery.



SCULAR FOUNDATION of innovation

Predictors and Long-Term Clinical Outcome of Longitudinal Stent Deformation

Insights From Pooled Analysis of Korean Multicenter Drug-Eluting Stent Cohort

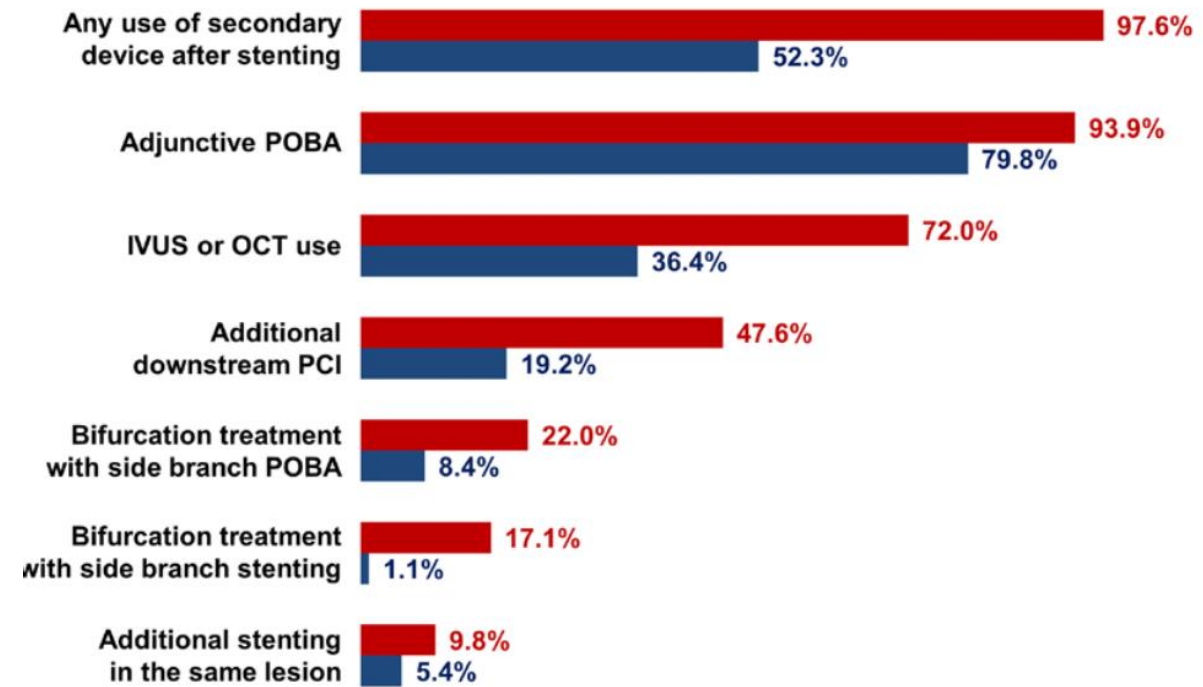
Tae-Min Rhee, MD; Kyung Woo Park, MD, PhD; Joo Myung Lee, MD, MPH, PhD; Michael S. Lee, MD; Ki-Hyun Jeon, MD; Hyun-Jae Kang, MD, PhD; Bon-Kwon Koo, MD, PhD; Jay Young Rhew, MD, PhD; Kwang Soo Cha, MD, PhD; Jang-Ho Bae, MD; Kyoo-Rok Han, MD; Si-Hoon Park, MD; Woo-Jung Park, MD, PhD; Seung-Woon Rha, MD; Seok-Kyu Oh, MD, PhD; Hyuck Moon Kwon, MD; Ki-Bae Seung, MD; Taehoon Ahn, MD, PhD; Sang-Hyun Kim, MD, PhD; Hyo-Soo Kim, MD, PhD

| | Odds Ratio (95% CI) | P Value |
|--|---------------------|---------|
| Lesion factors | | |
| Left main lesion | 3.272 (1.608–6.659) | 0.001 |
| Ostial lesion | 1.940 (1.072–3.514) | 0.029 |
| Stent-related factors | | |
| Peak-to-peak stent platform (vs offset peak-to-peak) | 1.520 (0.771–2.995) | 0.227 |
| Peak-to-valley stent platform (vs offset peak-to-peak) | 0.766 (0.438–1.342) | 0.352 |
| Procedural factors | | |
| Bifurcation treatment with SB stenting | 10.55 (5.372–20.72) | < 0.001 |
| Additional downstream PCI | 3.830 (2.384–6.154) | < 0.001 |
| IVUS or OCT use | 3.291 (1.992–5.438) | < 0.001 |
| Adjunctive POBA | 3.287 (1.268–8.523) | 0.014 |
| Bifurcation treatment with SB ballooning | 2.215 (1.243–3.944) | 0.007 |

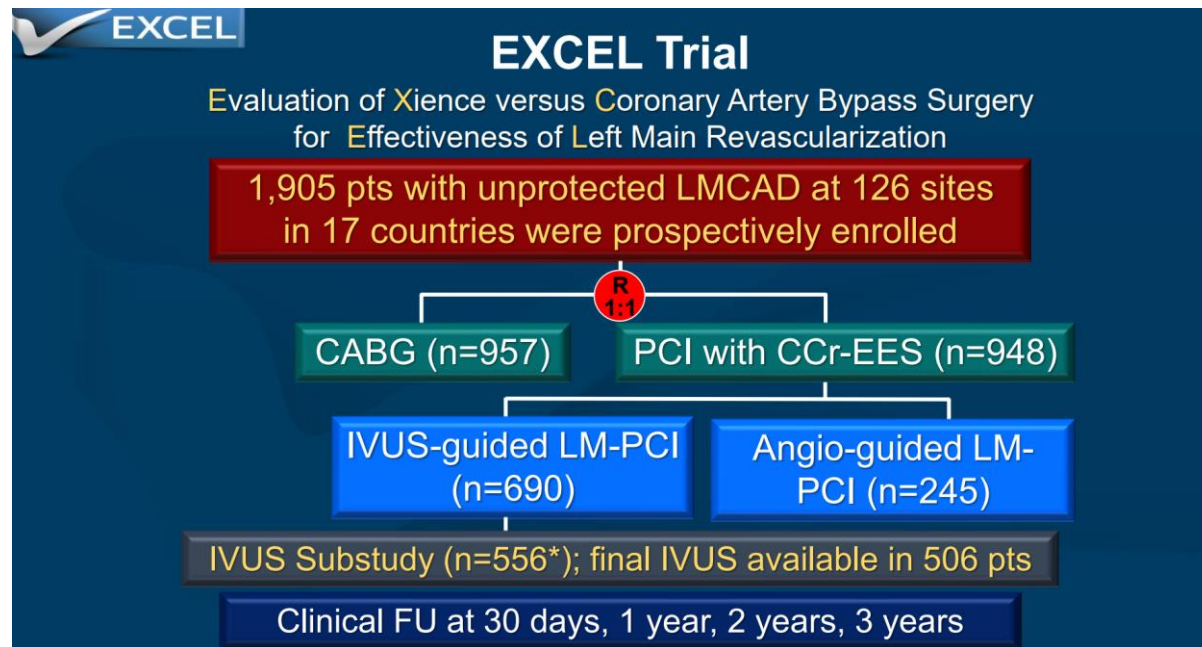
Lesion-related factors



Procedure-related factors

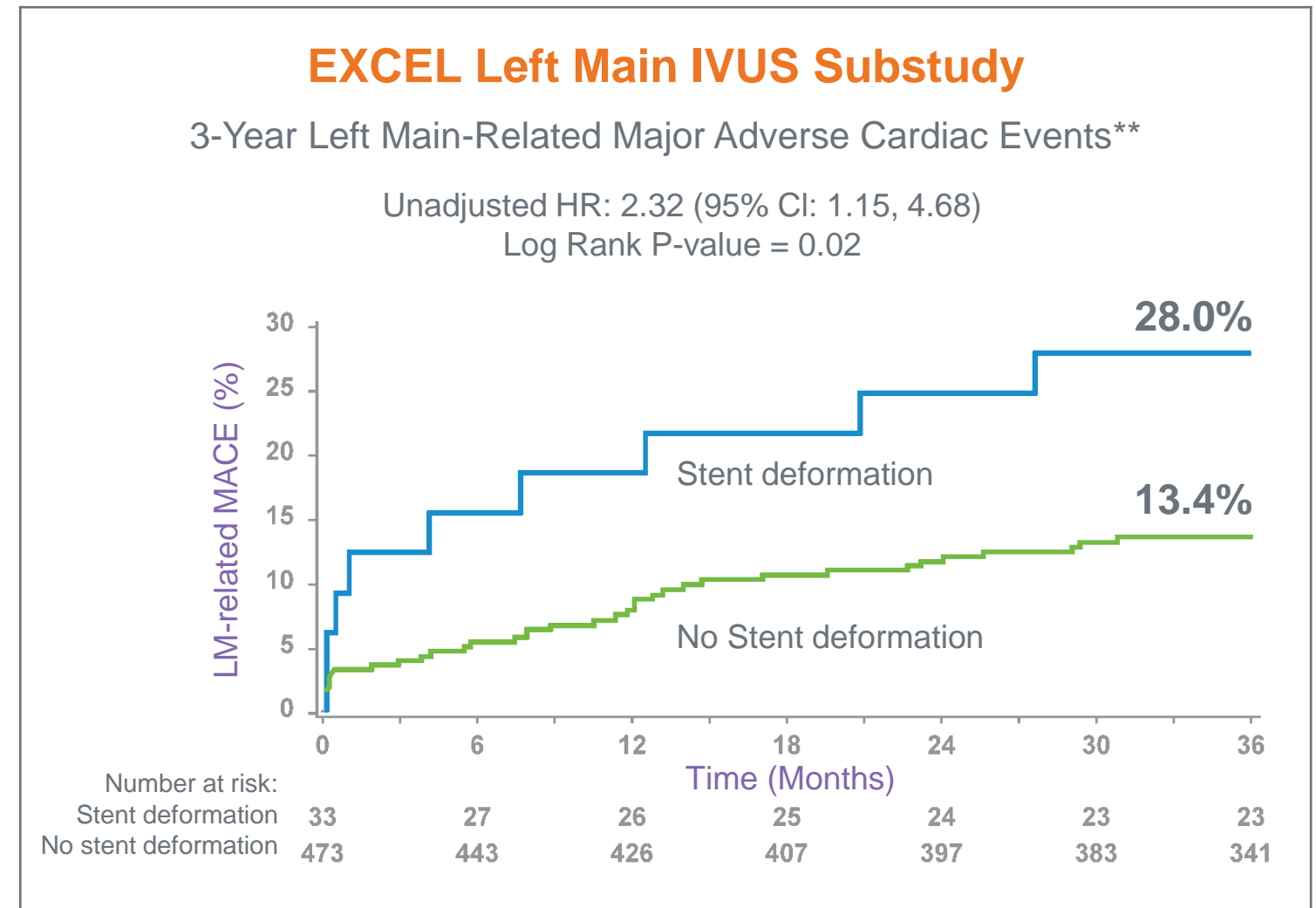


Significantly worse outcomes when stent strength is compromised



Acute stent deformation occurred in 6.5% of cases (35/506)¹

Statistically higher MACE rates when stent deformation occurred¹



1. Frequency and Impact of Acute Stent Deformation After PCI of Left Main Coronary Artery Disease: An EXCEL Trial Intravascular Ultrasound Substudy. CRF/Columbia University Medical Center. TCT 2017.

2. **MACE includes cardiac death, LM-related MI, LM-ischemia-driven TLR, LM-related def/prob ST.

Large Proximal Vessel Clinical Data

Significantly worse outcomes when stent strength is compromised

- Predictors of LM-related MACE (adjusted HR)

- Final IVUS Findings in the patients with vs without MACE

| | Adjusted Hazard Ratio (95% CI) | P-value |
|--------------------------------------|--------------------------------|-------------|
| Stent deformation | 2.25 (1.10, 4.63) | 0.03 |
| Acute coronary syndrome presentation | 0.55 (0.33, 0.93) | 0.03 |
| Male | 0.62 (0.37, 1.04) | 0.07 |
| LM distal bifurcation lesion | 2.12 (0.95, 4.72) | 0.07 |
| Diabetes mellitus | 1.49 (0.91, 2.45) | 0.12 |
| Baseline Syntax score (core lab) | 1.02 (0.99, 1.04) | 0.25 |
| Final IVUS LM MSA (mm ²) | 0.91 (0.82, 1.01) | 0.07 |

| Stent Deformation with MACE | Yes (n=9) | No (n=24) | P Value |
|--|------------------|------------------|---------|
| Minimum stent area in LM (mm ²) | 8.1 (7.1, 9.7) | 8.9 (7.3, 12.0) | 0.25 |
| Stent area at deformation (mm ²) | 8.6 (7.8, 9.5) | 10.0 (6.7, 12.7) | 0.75 |
| Lumen area at deformation (mm ²) | 12.2 (8.8, 17.2) | 10.3 (7.1, 13.5) | 0.44 |
| LM ostium fracture location | 89% (8/9) | 79% (19/24) | 0.52 |
| Floating stent in aorta | 33% (2/6) | 67% (16/24) | 0.14 |

The presence of Stent deformation itself is a risk factor, even if it is not associated with a smaller lumen area, or is not floating in the aorta !!

1. Frequency and Impact of Acute Stent Deformation After PCI of Left Main Coronary Artery Disease: An EXCEL Trial Intravascular Ultrasound Substudy. CRF/Columbia University Medical Center. TCT 2017.
 2. **MACE includes cardiac death, LM-related MI, LM-ischemia-driven TLR, LM-related def/prob ST.

How can the DES improve LSD?

Key features for an ideal LM stent

- 01 • **High Radial and Axial Strength**
 - Fibrotic lesions in the proximal position can be more resistant and require extra radial strength.
 - Maintaining stent integrity when adjunctive devices interact with the stent is critical, which requires extra axial strength.
- 02 • **Larger Overexpansion Range**
 - Ability to size to the distal vessel and overexpand with confidence
- 03 • **Optimized Scaffolding at Larger Diameters**
 - Reduce lumen loss due to tissue prolapse
- 04 • **Placement Accuracy**
 - Better visibility to aid in accurate stent placement

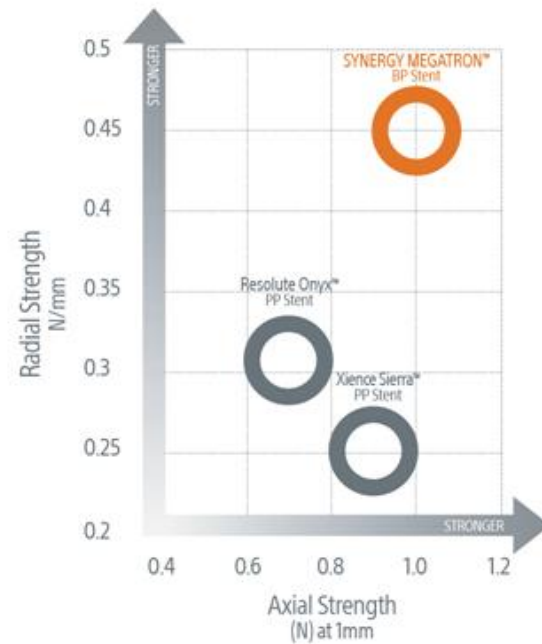
1. Image from Ng, Jaryl et al. "Over-expansion capacity and stent design model: An update with contemporary DES platforms." Int J Cardiol 221 (2016): 171-179. Figure 1A, page 173.

SYNERGY MEGATRON™ Key Features

Purpose Built for Large Proximal Vessels

Best-in-Class Axial & Radial Strength¹

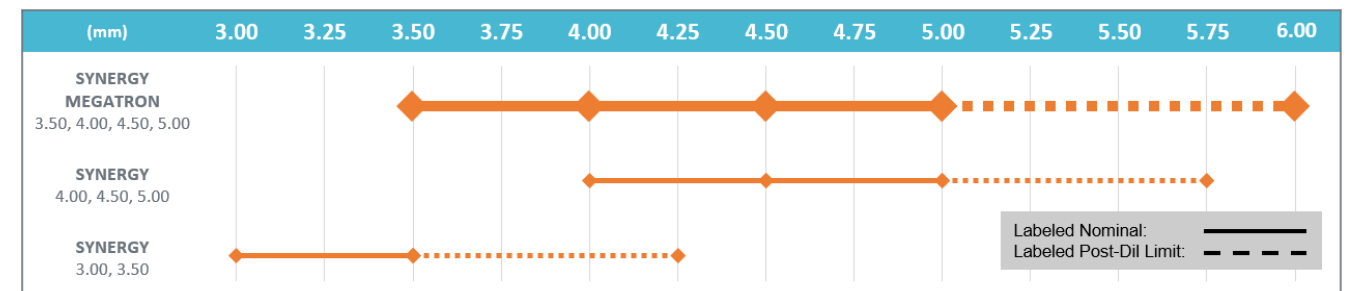
For Proximal, Fibrotic Lesions



Unmatched Overexpansion²

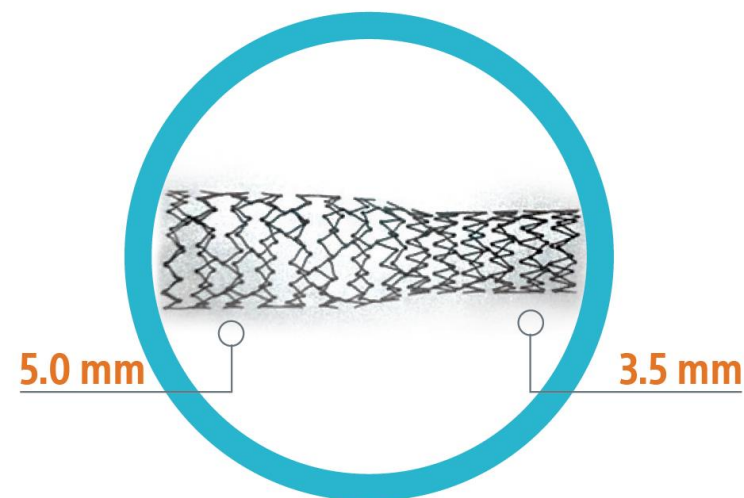
To Accommodate Wide Diameter Mismatch

One model (3.5-5.0mm) with overexpansion to 6.0 mm.³



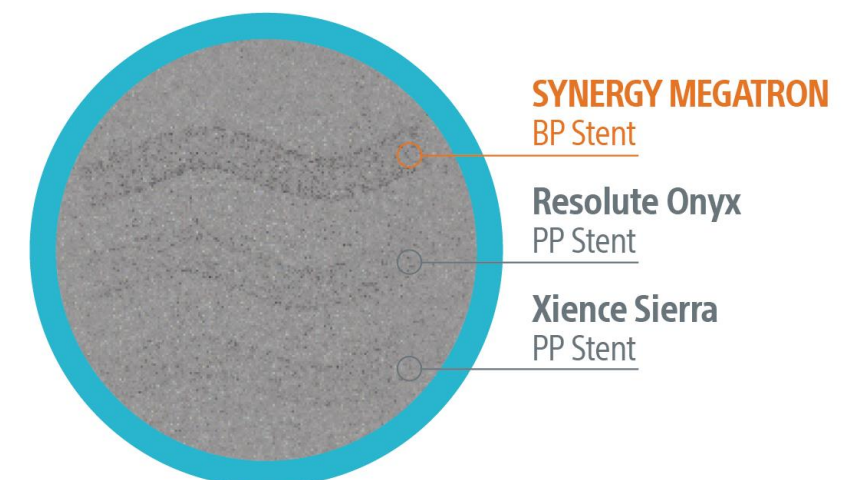
Uniform Lesion Scaffolding

To Maximize Lumen Gain



Maximum Visibility⁴

For Better Placement Accuracy



1. Based on bench test data comparing to largest nominal diameter – 4.0mm for Xience Sierra and 5.0mm for SYNERGY MEGATRON and Resolute Onyx. N=3 minimum. Data on file at BSC. 2. Compared to DFUs for SYNERGY, Xience Sierra, Orsiro and Resolute Onyx at 3.5mm overexpansion. 3.SYNERGY MEGATRON DFU. 4. Testing Completed by Boston Scientific data on file. Under 6.0mm copper phantom to simulate body mass. N=1. Bench test results may not necessarily be indicative of clinical performance.

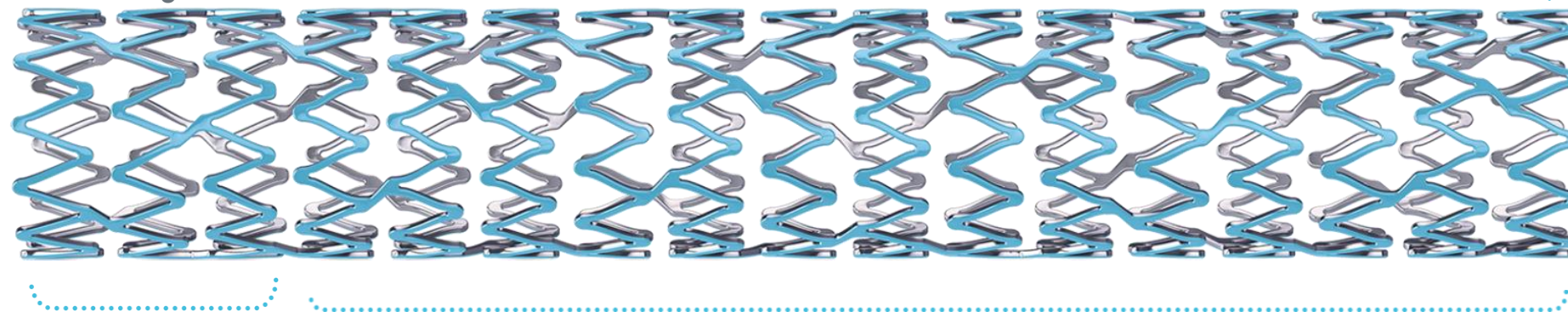
SYNERGY MEGATRON™ BP Stent

Purpose-Built Stent Architecture

Purpose-built stent architecture to maximize performance for large vessel stenting¹

12 Peak Design with Shorter Strut Length

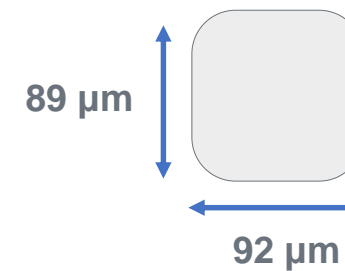
For Radial Strength, Unmatched Expansion and Uniform Vessel Scaffolding



Platinum Chromium (PtCr) Alloy

Specifically designed for coronary stents
For Visibility, Radial Strength, and Low Recoil

Optimized Strut Thickness and Width
For Maximum Visibility and Radial Strength

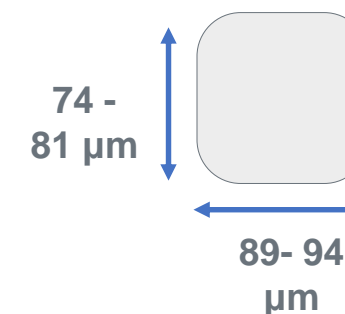


SYNERGY MEGATRON

4 Connectors on Proximal Two Segments

3 Connectors Throughout the Body For Exceptional Axial Strength

8(2.5mm)-10 Peak(4.0mm) Design with Strut Length



4-5 Connectors on Proximal Two Segments

2 Connectors Throughout the Body

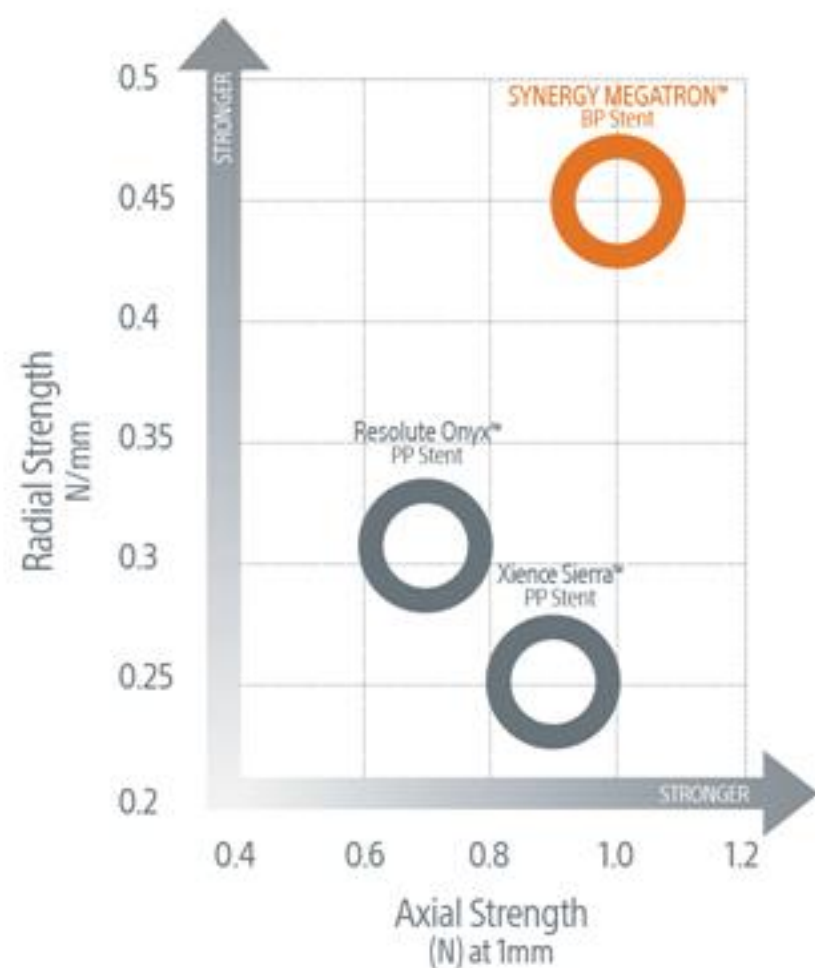
1. Design data on file at Boston Scientific Corporation.

SYNERGY MEGATRON™ BP Stent

Mega Strength, Optimal Healing, Low recoil.

SYNERGY MEGATRON Demonstrated Highest Overall Strength in bench testing¹

Overall Strength in Perspective¹



SYNERGY MEGATRON BP Stent

Focused strut bending

Wider Peak

2% Acute Lumen Loss¹

Xience Sierra™ PP Stent

Peak bending

Narrower Peak

4% Acute Lumen Loss¹

Resolute Onyx™ PP Stent

Peak bending

Continuous Wire

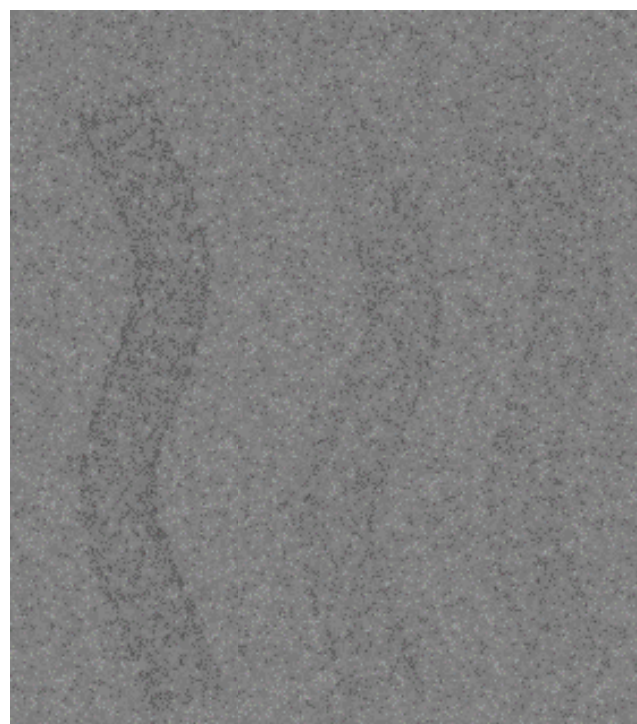
5% Acute Lumen Loss¹

Bench tests performed by Boston Scientific Corporation. Data on file. 1. Xience Sierra 4.0 mm, Resolute Onyx 5.0mm, SYNERGY MEGATRON 5.0mm – largest nominal size for each device. N=3 minimum. 2. N=3 minimum. Bench test results not necessarily indicative of clinical performance.

SYNERGY MEGATRON™ BP Stent

Maximum Visibility

Platinum Chromium Alloy Provides Maximum Visibility to Aid in Accurate Stent Placement¹



| | SYNERGY MEGATRON BP-DES | Resolute Onyx™ PP-DES | XIENCE Sierra™ PP-DES |
|------------------------|-------------------------|-----------------------|-----------------------|
| Alloy | PtCr | CoNi | CoCr |
| Strut Thickness | 0.0035" (89 μm) | 0.0032" (81 μm) | 0.0032" (81 μm) |



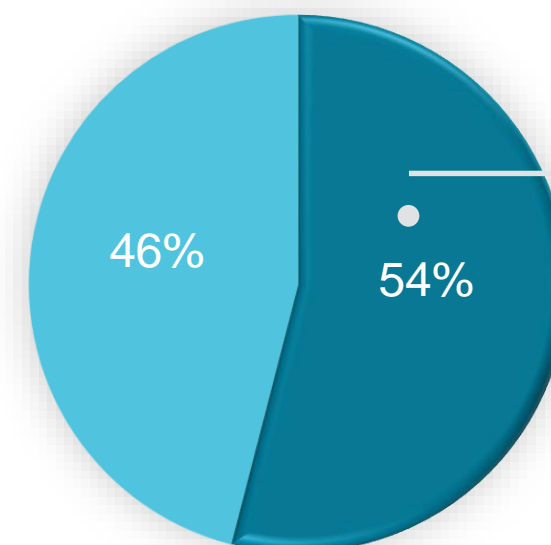
*"I'm very impressed at the visibility of MEGATRON ..."*²

– Dr. Margaret McEntegart,
Golden Jubilee National Hospital

Why Visibility is Important

One Study Showed:

Stent misplacement at the ostium occurs frequently and is associated with higher rates of restenosis and target lesion revascularization (TLR).³



True ostium was missed in **54%** of cases³

1. Testing Completed by Boston Scientific data on file. 3.5 mm stent products tested under 6.0mm copper phantom to simulate body mass. Bench test results may not necessarily be indicative of clinical performance. 2. SYNERGY MEGATRON image provided from Golden Jubilee Hospital. 3. "High Incidence of Inaccurate Stent Placement in the Treatment of Coronary Aorto-Ostial disease" : <https://www.invasivecardiology.com/articles/high-incidence-inaccurate-stent-placement-treatment-coronary-aorto-ostial-disease>

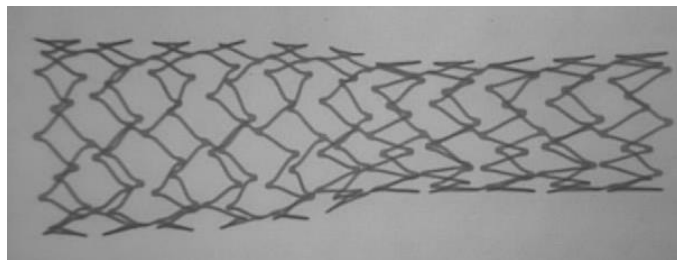
SYNERGY MEGATRON™ BP Stent

Uniform Lesion Scaffolding with a 12-Peak Design

Uniform lesion scaffolding to minimize tissue prolapse and maximize lumen gain¹

Stent pattern is maintained as its expanded

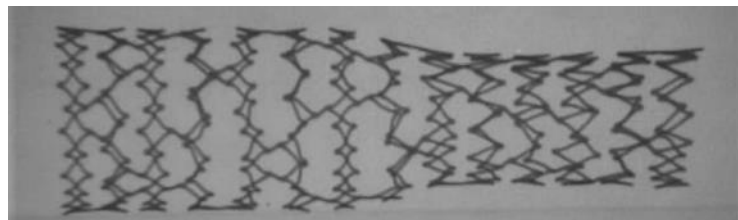
9-Peak Prototype DES



5.0 mm

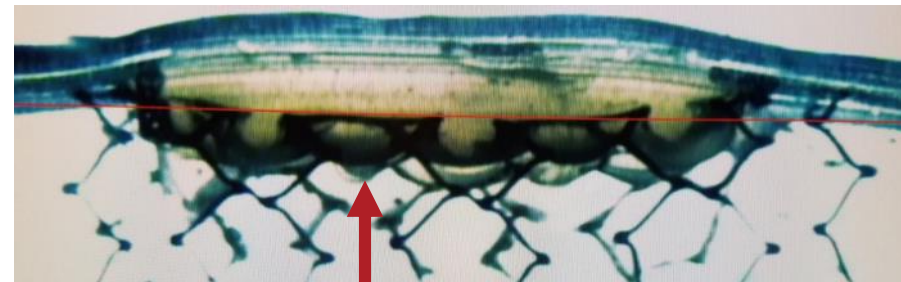
3.5 mm

SYNERGY MEGATRON 12-peak Design



Less tissue prolapse with a 12-peak design

9-Peak Prototype DES



Visible tissue prolapse ("pillowing")

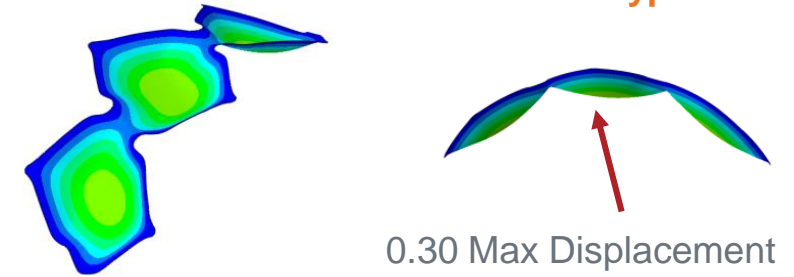
SYNERGY MEGATRON 12-peak Design



Minimal tissue prolapse (smoother edges)

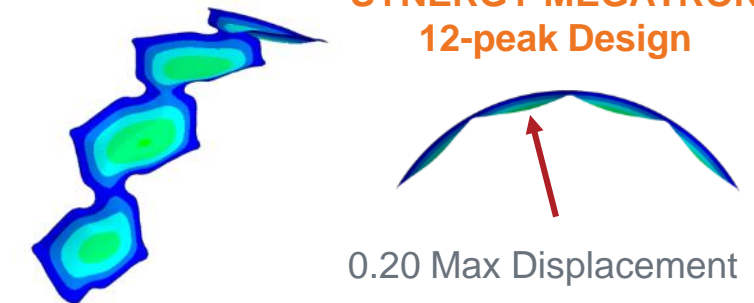
33% improvement in tissue prolapse which can lead to larger MLDs¹

9-Peak Prototype DES



0.30 Max Displacement

SYNERGY MEGATRON 12-peak Design



0.20 Max Displacement

1. Testing Completed by Boston Scientific data on file. Bench test and computational model results may not necessarily be indicative of clinical performance.

Studying DAPT with PCI with Synergy



Leading on Studying Short DAPT

Supporting well-constructed prospective Short DAPT clinical trials to study the SYNERGY™ BP Stent in various complex patient populations†

Indicated for High Bleeding Risk (HBR) patients.‡

The HBR indication is based on the data from the EVOLVE Short DAPT Trial



| | | | |
|--|---|--|--|
| <p>EVOLVE Short DAPT 3-month DAPT in HBR patients Region(s): US, Europe, Japan, Brazil</p> | <p>2,009 PATIENTS IDE Trial SYNERGY BP Stent</p> | | <p>Primary Endpoint Data Now Available</p> |
| <p>The SYNERGY BP Stent high bleeding risk (HBR) indication is supported by the EVOLVE Short DAPT Data</p> | | | |
| <p>Additional Short DAPT Trials</p> | | | |
| <p>SENIOR* 1-month DAPT in stable elderly patients 6-month DAPT in ACS elderly patients Region(s): Europe</p> | <p>1,200 PATIENTS SYNERGY BP Stent vs. REBEL™ BMS</p> | | <p>2-Year Data Now Available</p> |
| <p>IDEAL Left Main** 4-month DAPT in SYNERGY BP Stent LM cohort 12-month DAPT in Xience™ PP Stent LM cohort Region(s): France, Ireland, The Netherlands, Poland, UK</p> | <p>818 PATIENTS SYNERGY BP Stent vs. Xience PP Stent</p> | | <p>Primary Endpoint Data Now Available</p> |
| <p>ASET* 0-month DAPT in patients with chronic stable angina Region(s): Brazil</p> | <p>201 PATIENTS SYNERGY BP Stent</p> | | <p>Primary Endpoint Data Now Available</p> |
| <p>POEM* 1-month DAPT in HBR patients Region(s): Italy</p> | <p>443 PATIENTS SYNERGY BP Stent</p> | | <p>Primary Endpoint Data Now Available</p> |
| <p>SYNIVUS-DAPT* 1-month DAPT in HBR patients Region(s): US</p> | <p>100 PATIENTS SYNERGY BP Stent IVUS</p> | | <p>Ongoing Enrollment</p> |

* Investigator Sponsored Study. Boston Scientific is not responsible for the collection, analysis or reporting of the investigator-sponsored research output which is the sole responsibility of the investigators. Boston Scientific's involvement in investigator-sponsored research is limited to providing financial support for research that advances medical and scientific knowledge about our products.
† The safety and effectiveness of the SYNERGY BP Stent has not been established in patients with Left Main disease. Please review the SYNERGY DFU for full instructions on use. ‡ The HBR indication excludes the SYNERGY XD 48 mm stent.

EVOLVE Short DAPT Trial

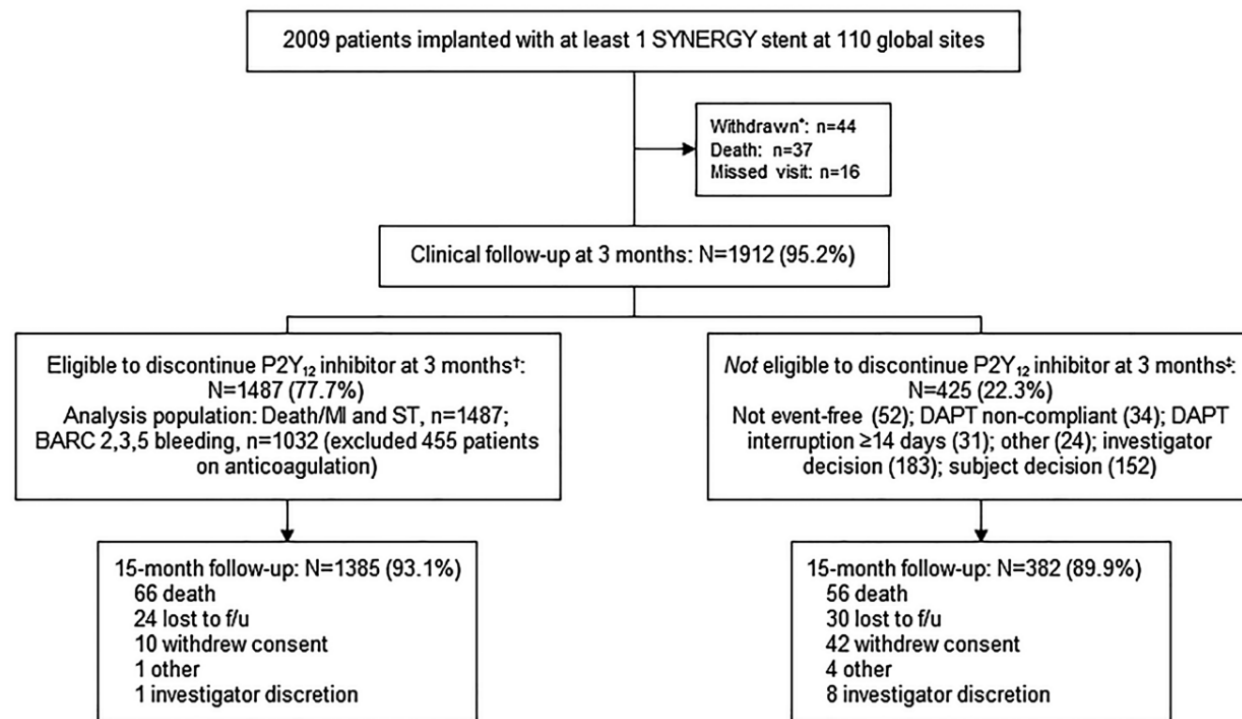
First U.S. Trial Data submitted to the FDA to get an HBR Indication

SYNERGY™ BP Stent can be safely used in conjunction with shortened DAPT in high bleeding risk (HBR) patients, based on the results of the EVOLVE Short DAPT Trial[§]

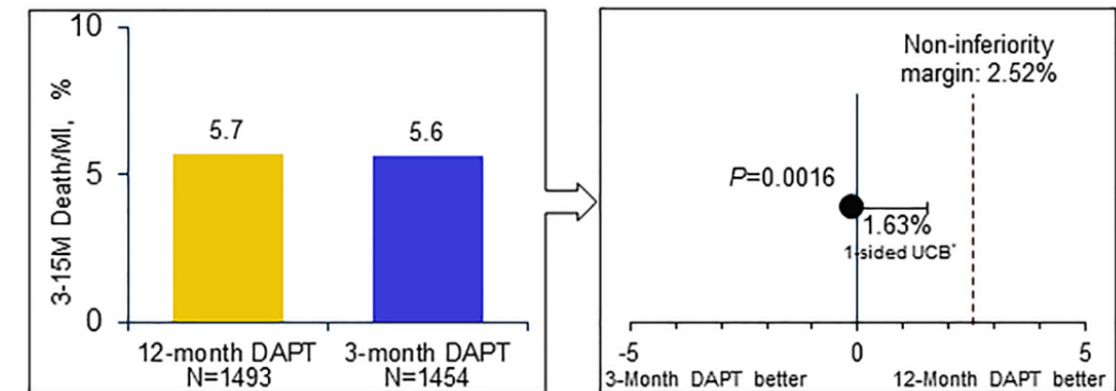
Primary Results of the EVOLVE Short DAPT Study

Evaluation of 3-Month Dual Antiplatelet Therapy in High Bleeding Risk Patients Treated With a Bioabsorbable Polymer-Coated Everolimus-Eluting Stent

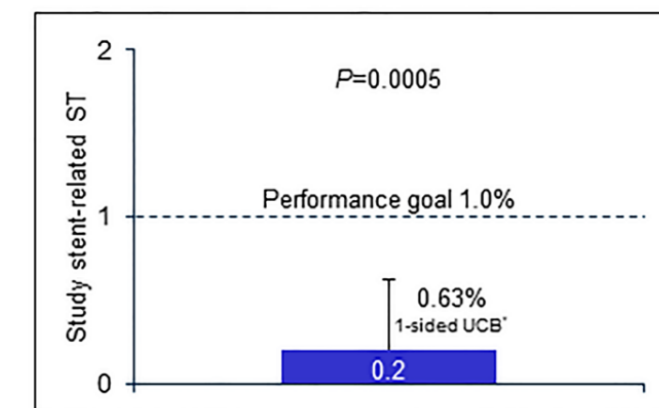
Ajay J. Kirtane[§], MD, SM; Robert Stoler, MD; Robert Feldman, MD; Franz-Josef Neumann, MD, PhD; Loukas Boutis, MD; Naeem Tahirkheli, MD; Ralph Toelg, MD; Islam Othman, MD; Bernardo Stein, MD; James W. Choi, MD; Stephan Windecker[§], MD; Robert W. Yeh[§], MD, MSC; Harold L. Dauerman, MD; Matthew J. Price, MD; Paul Underwood, MD; Dominic Allocco, MD; Ian Meredith, AM, MBBS, PhD; Dean J. Kereiakes[§], MD



A Death/MI between 3-15 months



B Study stent-related ST between 3-15 months



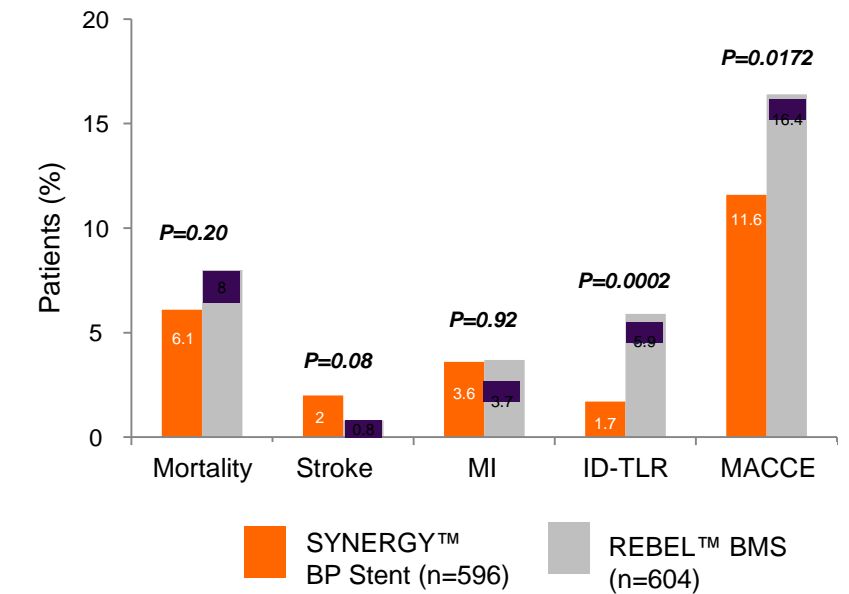
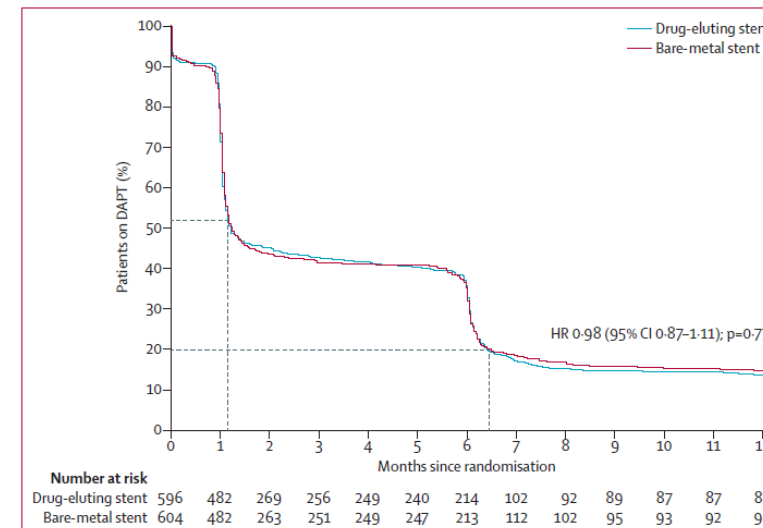
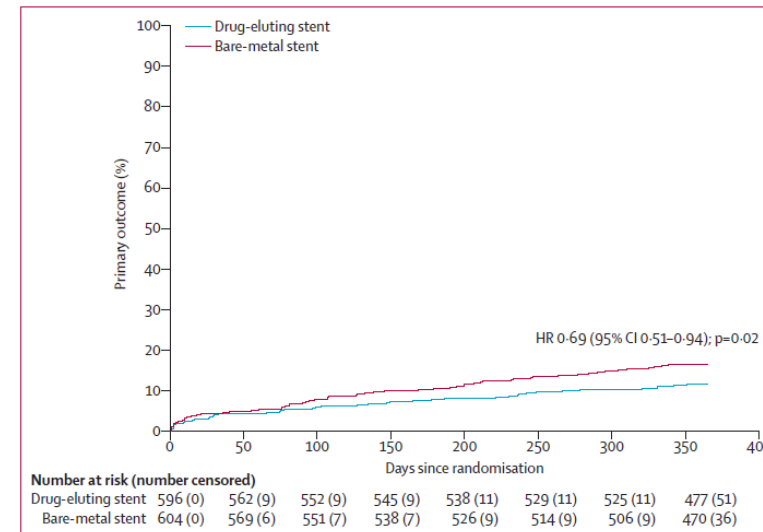
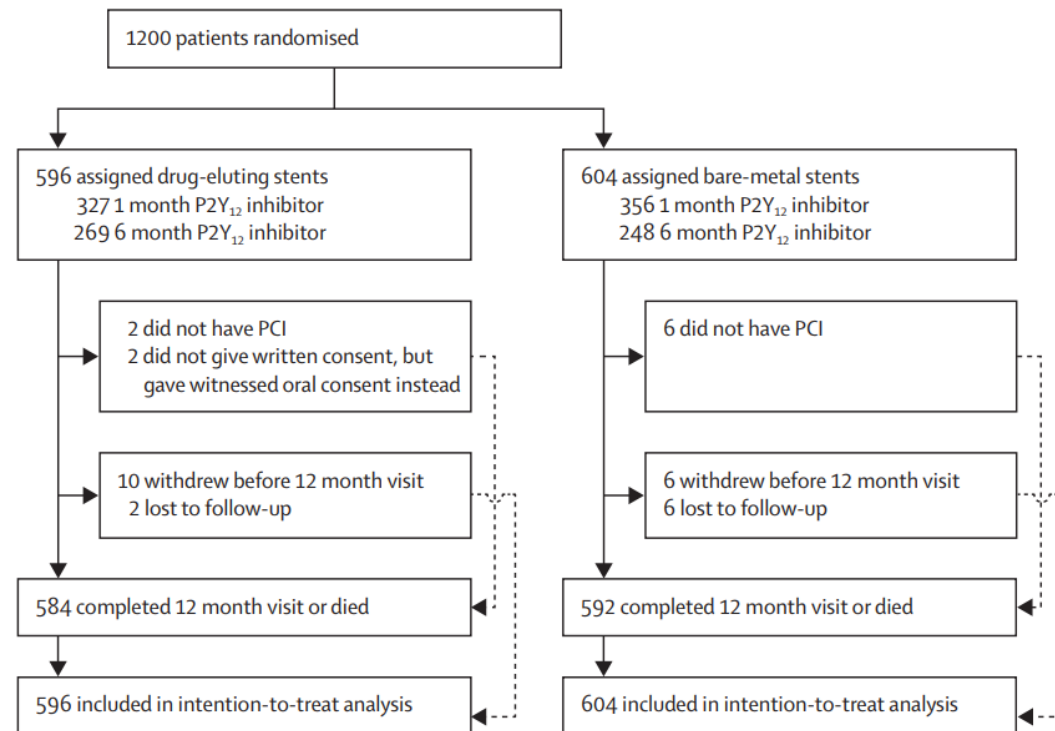
SENIOR Trial

1-Month DAPT in Elderly Patients

The SYNERGY™ BP Stent showed significantly lower MACCE** versus REBEL™ BMS at 1-year

Drug-eluting stents in elderly patients with coronary artery disease (SENIOR): a randomised single-blind trial

Olivier Varenne, Stéphane Cook, Georgios Sideris, Sasko Kedev, Thomas Cuisset, Didier Carrié, Thomas Hovasse, Philippe Garot, Rami El Mahmoud, Christian Spaulding, Gérard Helft, José F Diaz Fernandez, Salvatore Brugaletta, Eduardo Pinar-Bermudez, Josepa Mauri Ferre, Philippe Commeau, Emmanuel Teiger, Kris Bogaerts, Manel Sabate, Marie-Claude Morice, Peter R Sinnaeve, for the SENIOR investigators



A strategy of combination of a DES to reduce the risk of subsequent repeat revascularisations with a short BMS-like DAPT regimen to reduce the risk of bleeding event is an attractive option for elderly patients who have PCI.

POEM Trial

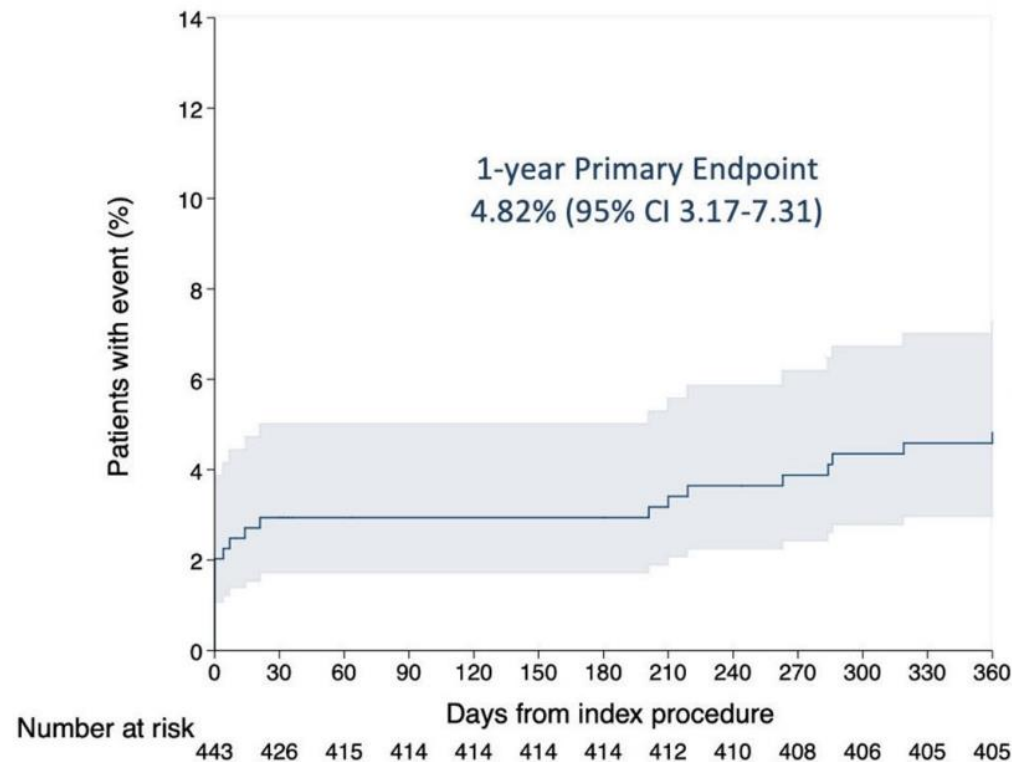
SYNERGY with 1-Month DAPT in HBR Patients

SYNERGY™ BP Stent demonstrated a low rate of ischemic and bleeding events in an all-comers HBR patient population

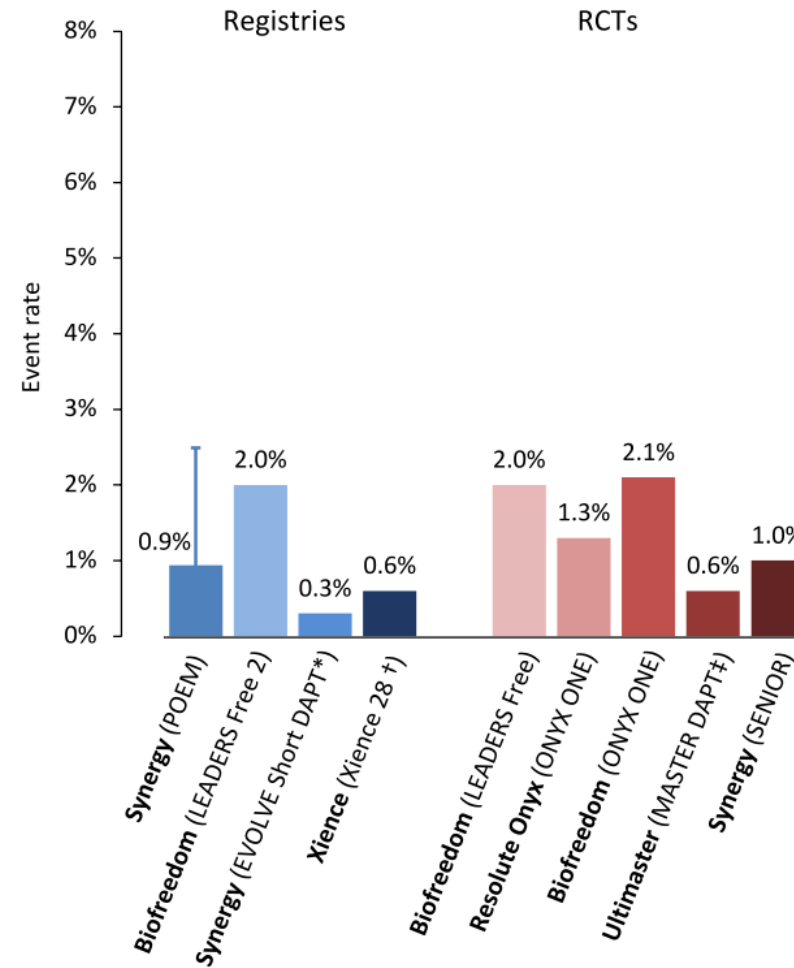
ORIGINAL RESEARCH

One-Month Dual Antiplatelet Therapy After Bioresorbable Polymer Everolimus-Eluting Stents in High Bleeding Risk Patients

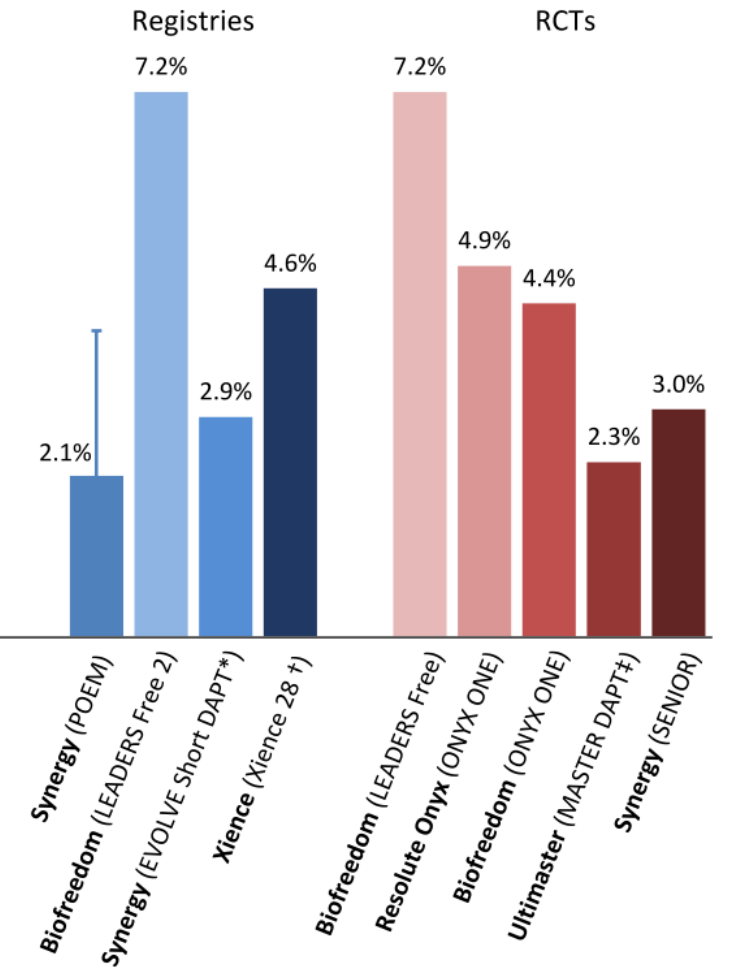
Carlo A. Pivato ¹, MD; Bernhard Reimers ², MD; Luca Testa ³, MD, PhD; Andrea Pacchioni ⁴, MD; Carlo Briguori ⁵, MD, PhD; Carmine Musto, MD, PhD; Giovanni Esposito ⁶, MD, PhD; Raffaele Piccolo, MD, PhD; Luigi Lucisano, MD; Leonardo De Luca ⁷, MD, PhD; Federico Conrotto, MD; Andrea De Marco, MSc; Anna Franzone, MD, PhD; Patrizia Presbitero, MD; Giuseppe Ferrante ⁸, MD, PhD; Gerolama Condorelli, MD, PhD; Valeria Paradies, MD; Gennaro Sardella, MD; Ciro Indolfi ⁹, MD; Gianluigi Condorelli ¹⁰, MD, PhD; Giulio G. Stefanini ¹¹, MD, PhD, MSc



DEFINITE/PROBABLE STENT THROMBOSIS



BARC TYPE 3-5 BLEEDING



SYNERGY™ BP Stent Clinical Research Program

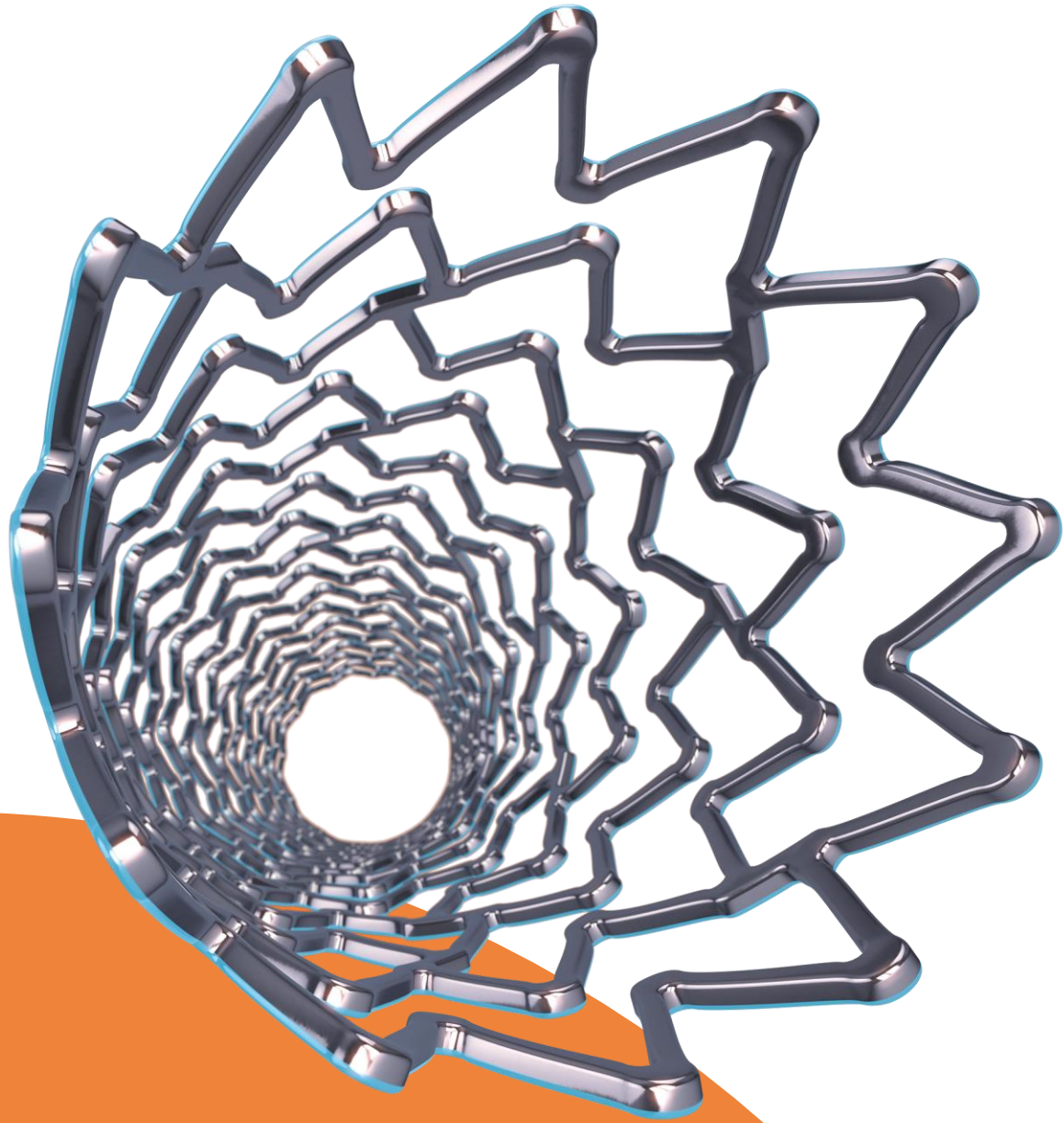
Robust Clinical Program Addressing the Full Spectrum of Cardiovascular Disease Complexity



| Boston Scientific Core Trials | Imaging / Healing | DAPT | Long Lesions | Diabetes | ACS | CTO | Bifurcation Lesions | Multi-vessel Disease |
|-------------------------------|-------------------|-------------------|--------------|------------|----------------|------------|---------------------|----------------------|
| EVOLVE | TIMELESS | SENIOR | SYNTAX II | BIO-RESORT | SENIOR | SYNTAX II | SYNTAX II | SYNTAX II |
| EVOLVE II | MOVES | EVOLVE Short DAPT | BIO-RESORT | SWEET | BIO-RESORT | CONSISTENT | SWEET | BIO-RESORT |
| EVOLVE China | TRANSFORM OCT | POEM | SWEET | SCAAR | SWEET | | BIO-RESORT | SWEET |
| EVOLVE Short DAPT | SORT OUT VIII | IDEAL Left Main | SCAAR | EVOLVE II | TRANSFORM OCT | | CELTIC | IDEAL Left Main |
| | GREEK | SYNIVUS | EVOLVE II | | SORT OUT VIII | | OCT/GSI | SORT OUT VIII |
| | PLATELET | | | | MULTISTARS AMI | | SCAAR | MULTISTARS AMI |
| | | | | | SCAAR | | | SCAAR |

- Boston Scientific Sponsored Trials
- Investigator-Sponsored Research*

* Boston Scientific is not responsible for the collection, analysis or reporting of the investigator-sponsored research output which is the sole responsibility of the investigators. Boston Scientific's involvement in investigator-sponsored research is limited to providing financial support for research that advances medical and scientific knowledge about our products.

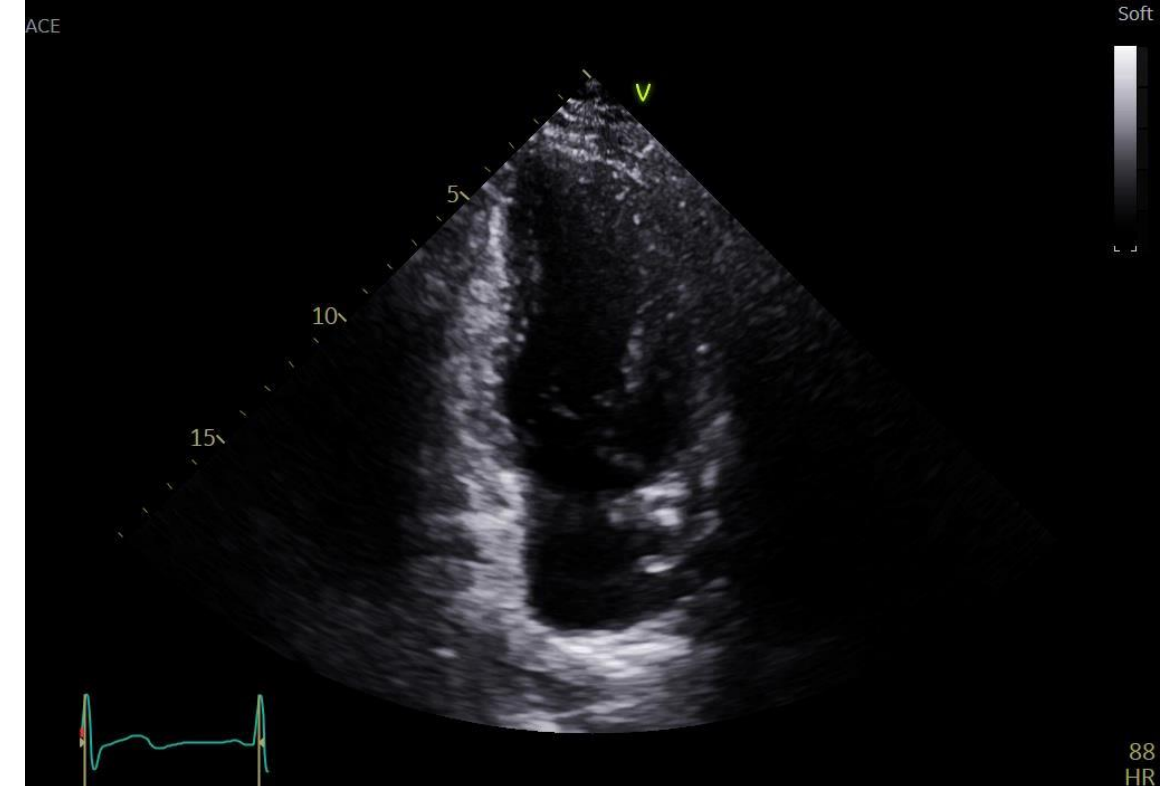
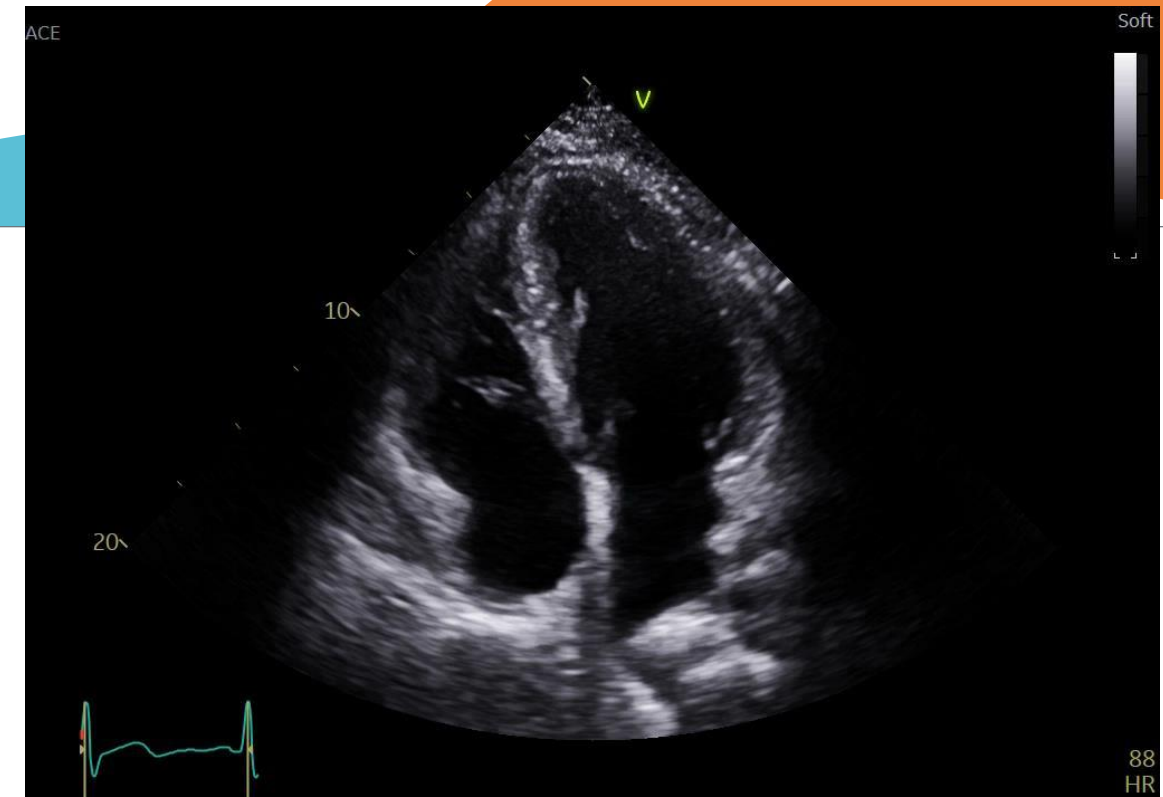
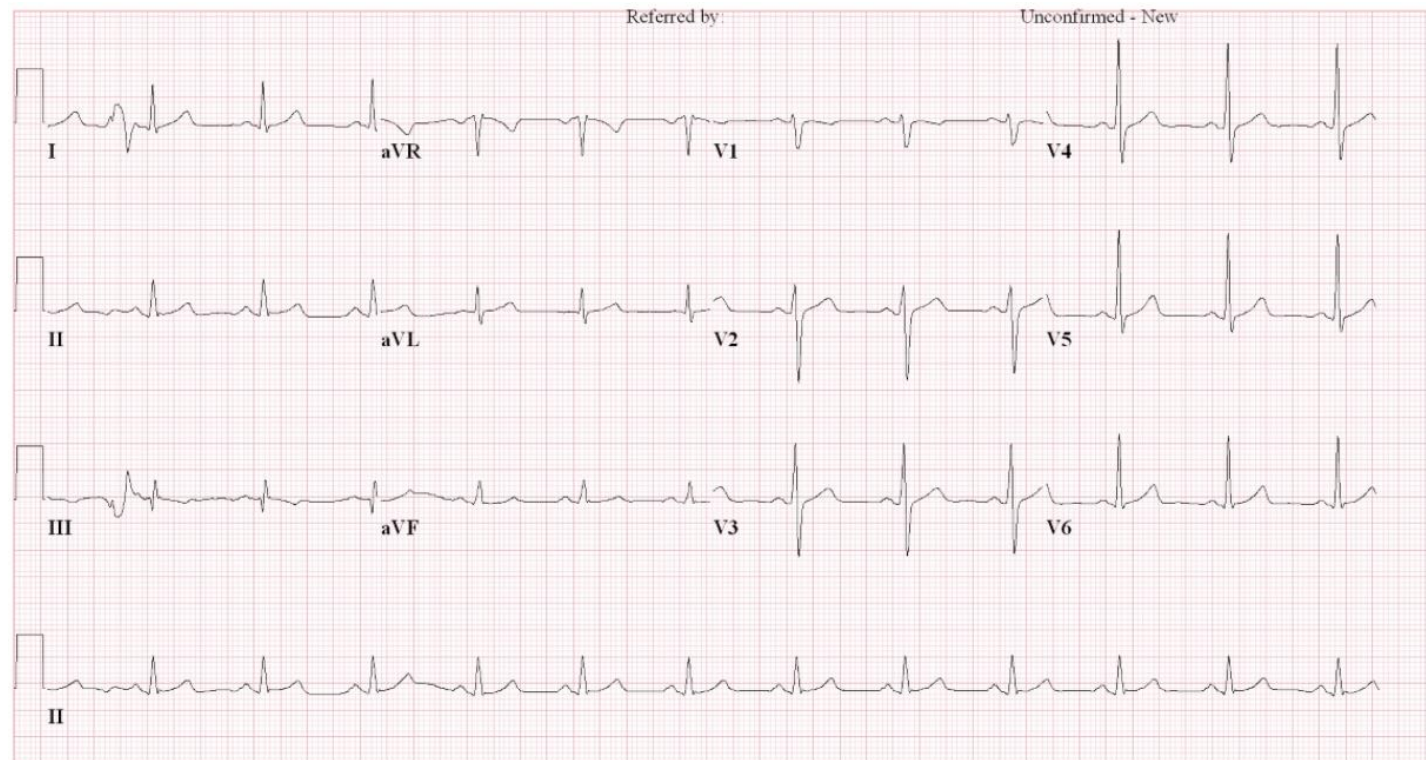


A Clinical Case

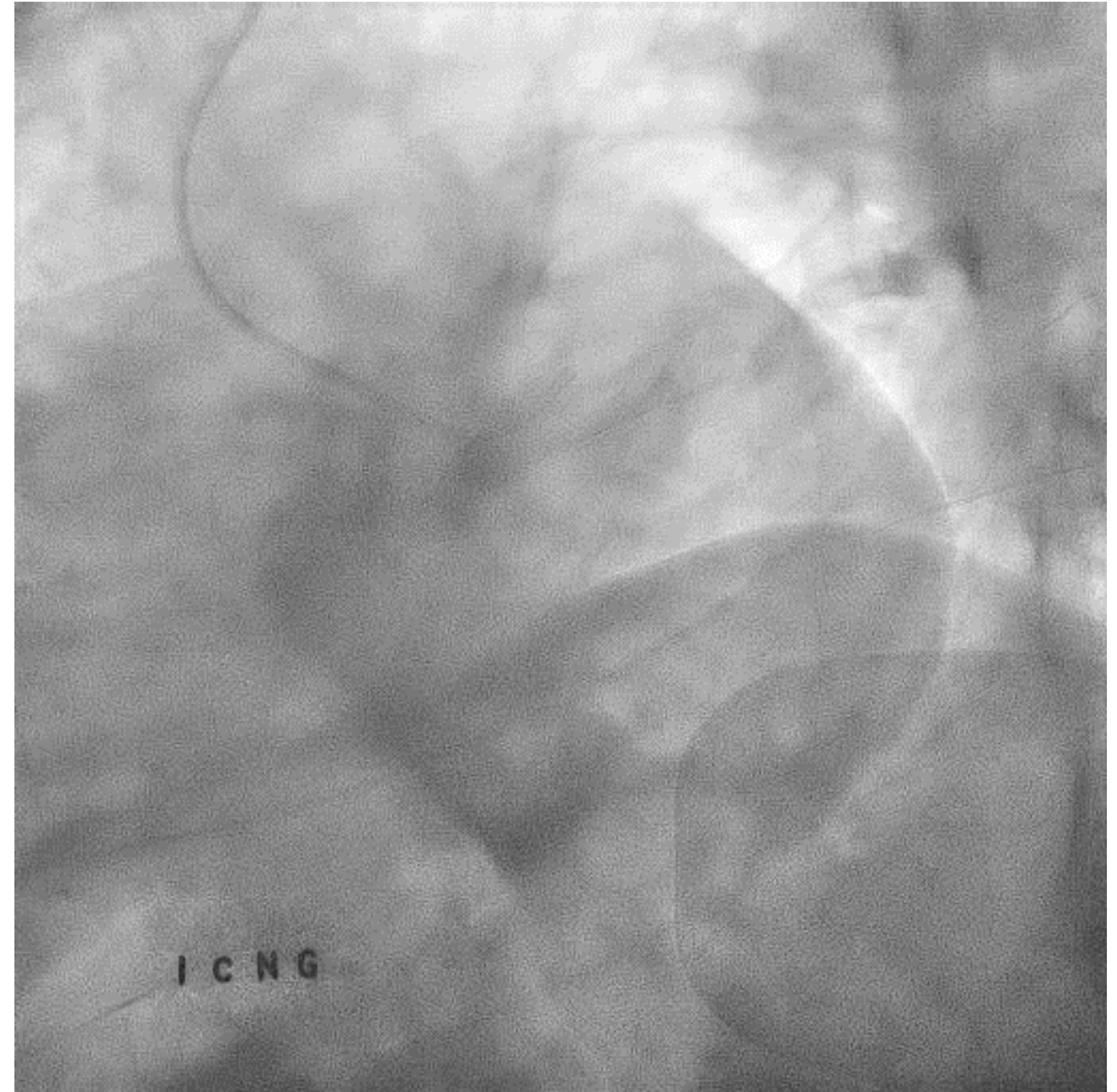
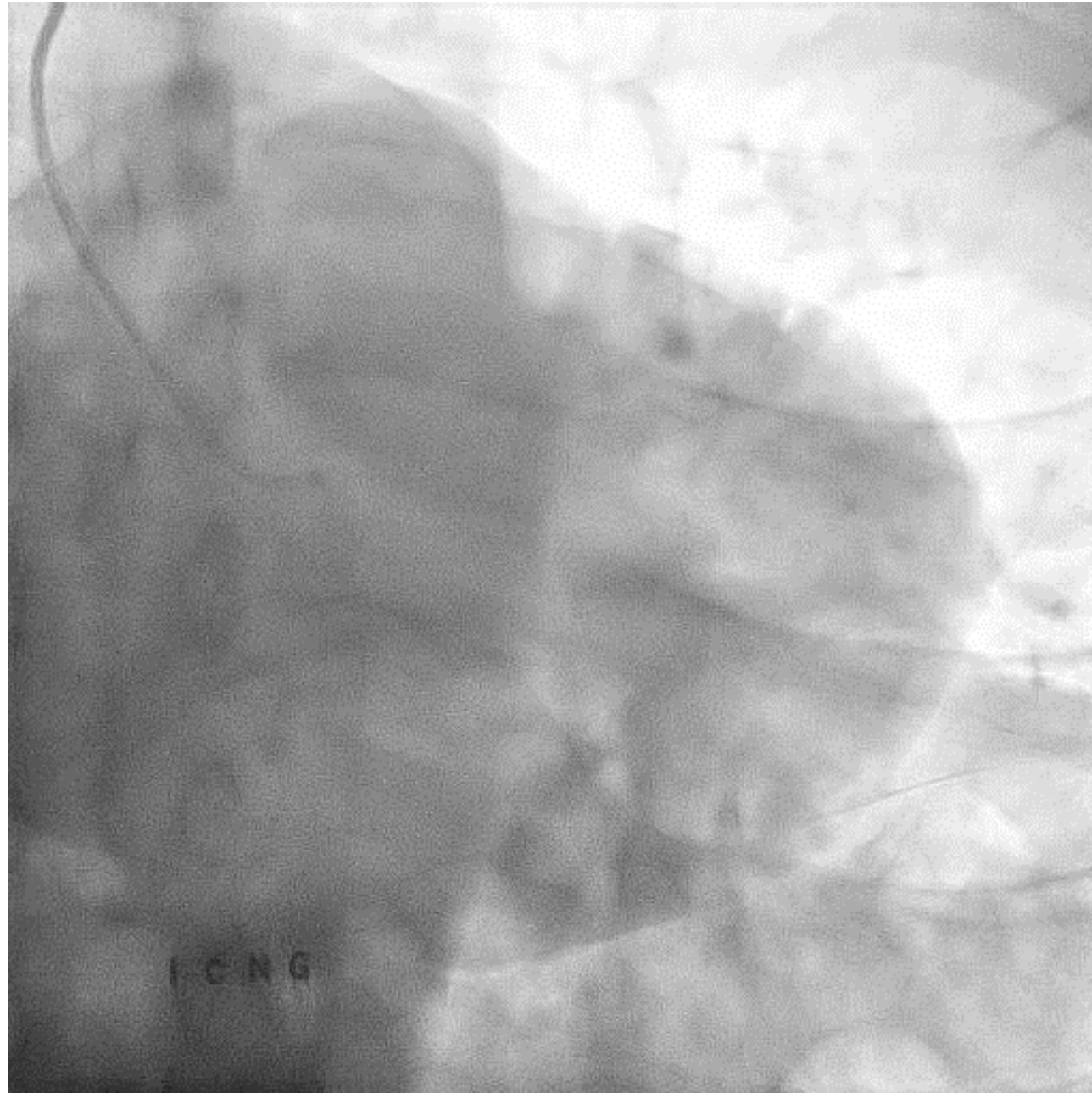
in which SYNERGY MEGATRON was helpful

Case Sharing

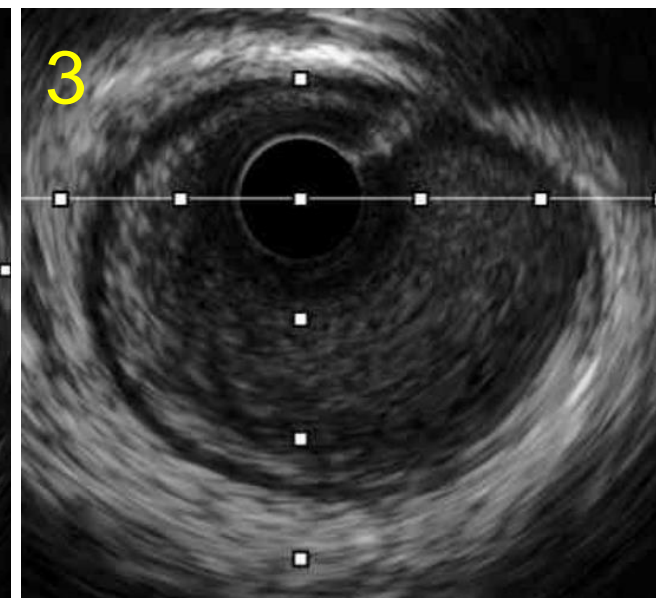
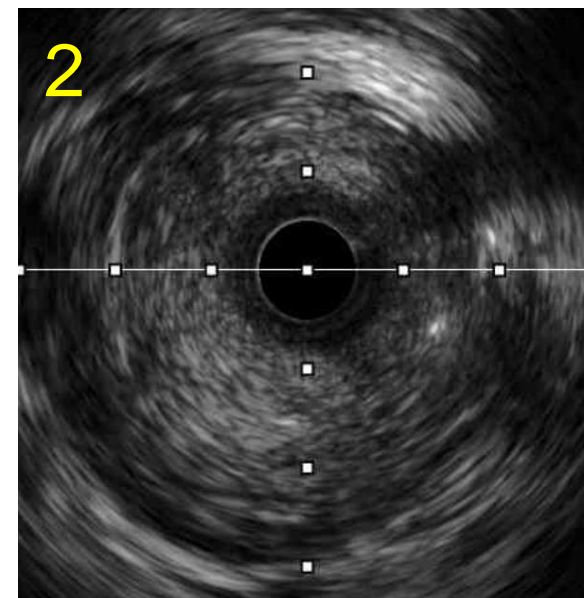
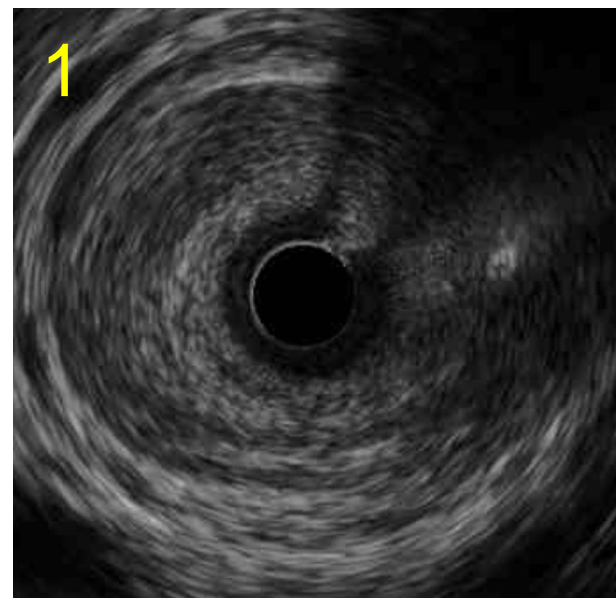
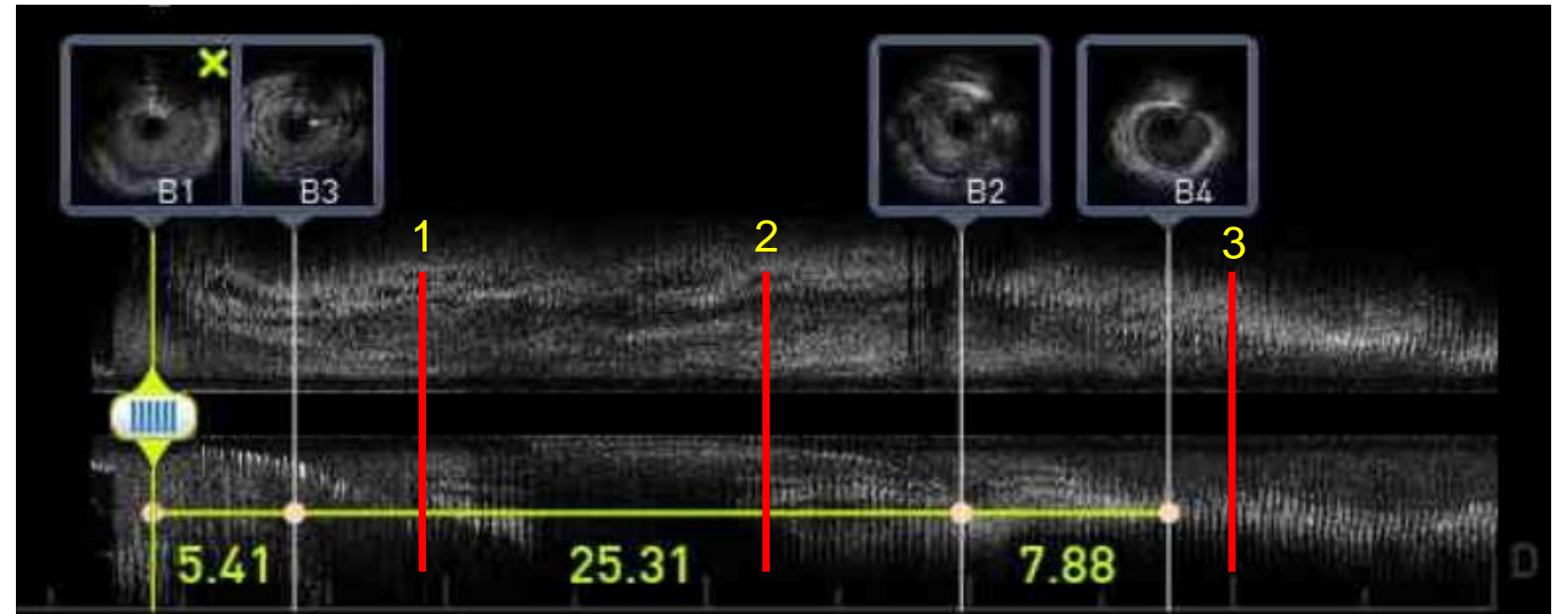
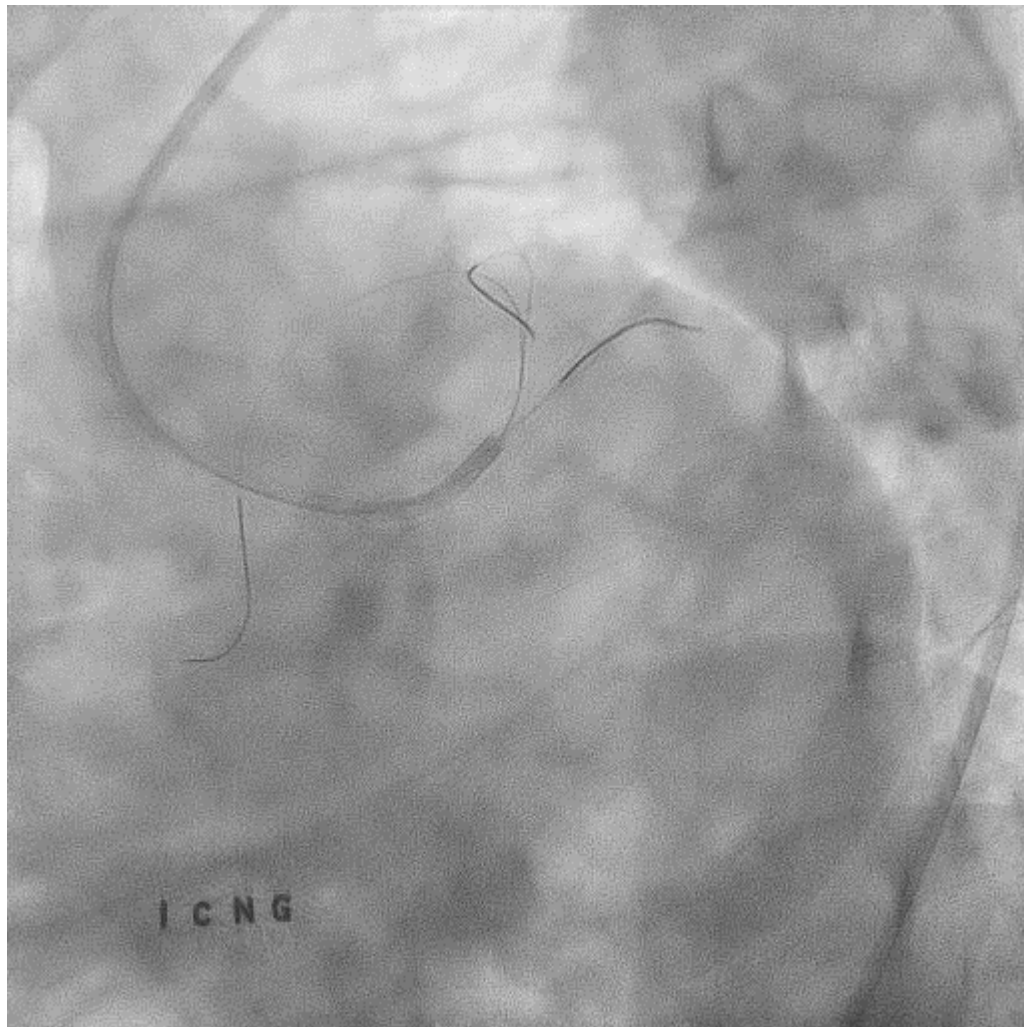
- 46/M
- Crescendo type chest discomfort, since 1MA
 - Previously healthy
 - Recent recovery from COVID-19



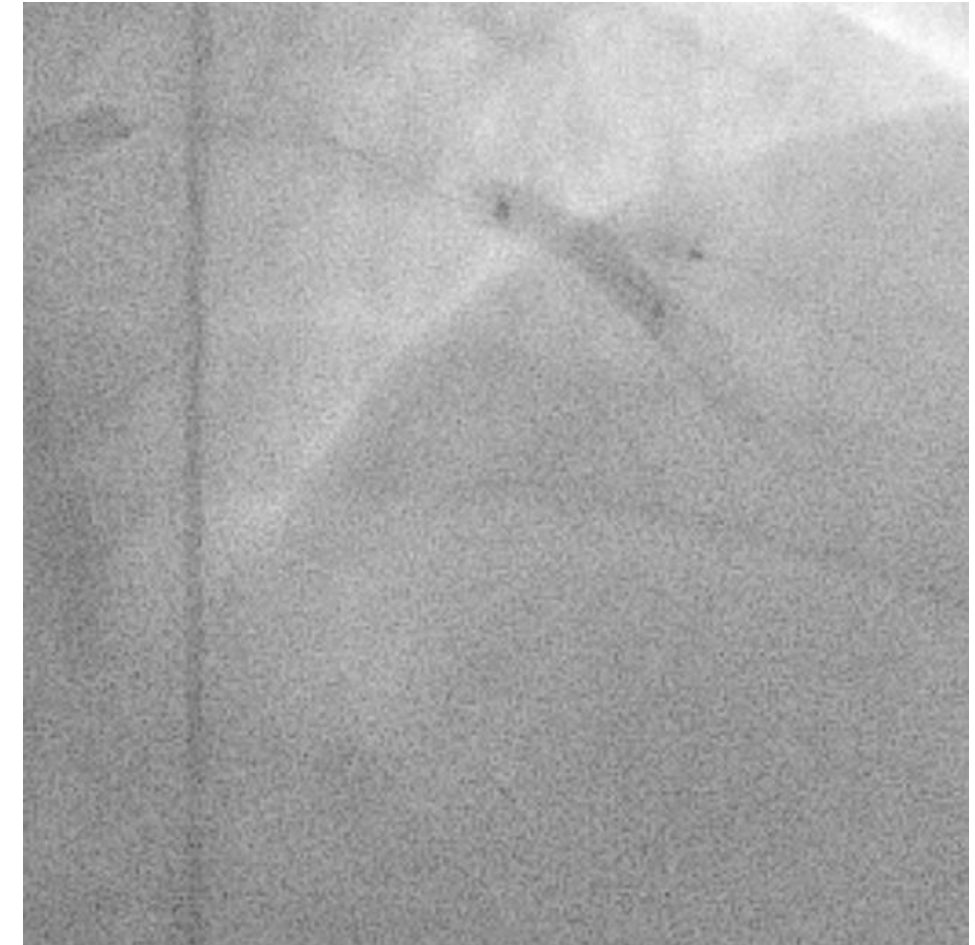
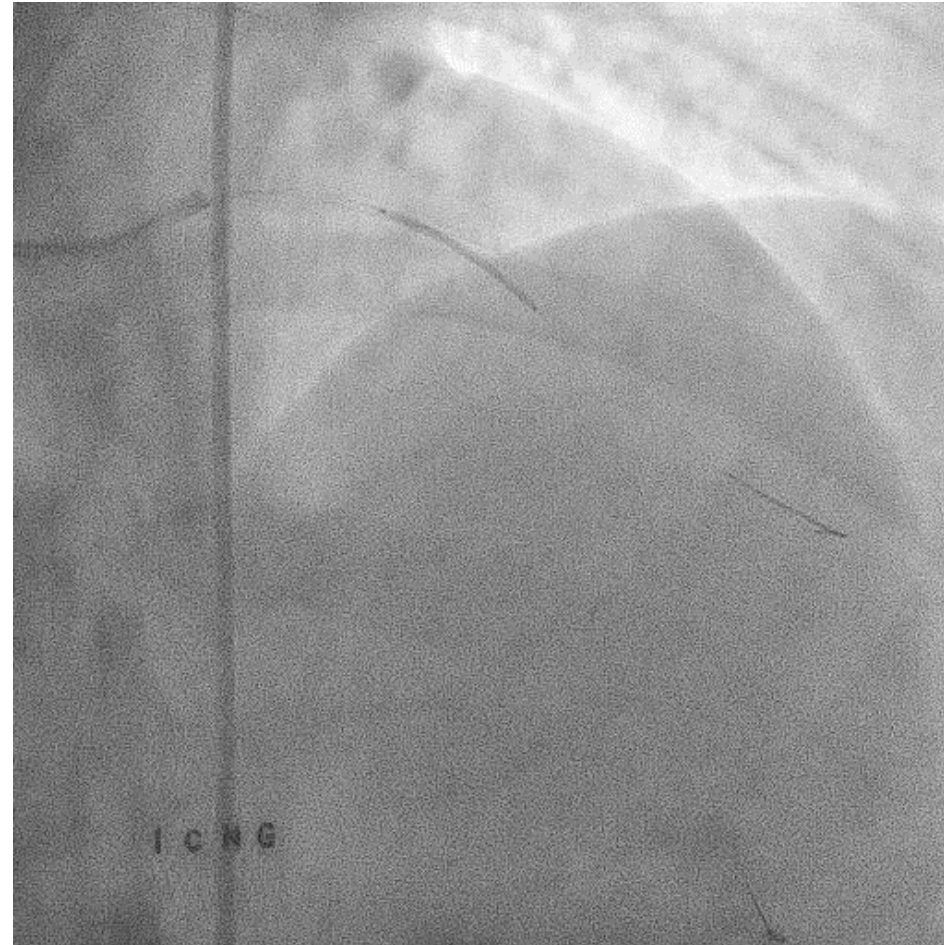
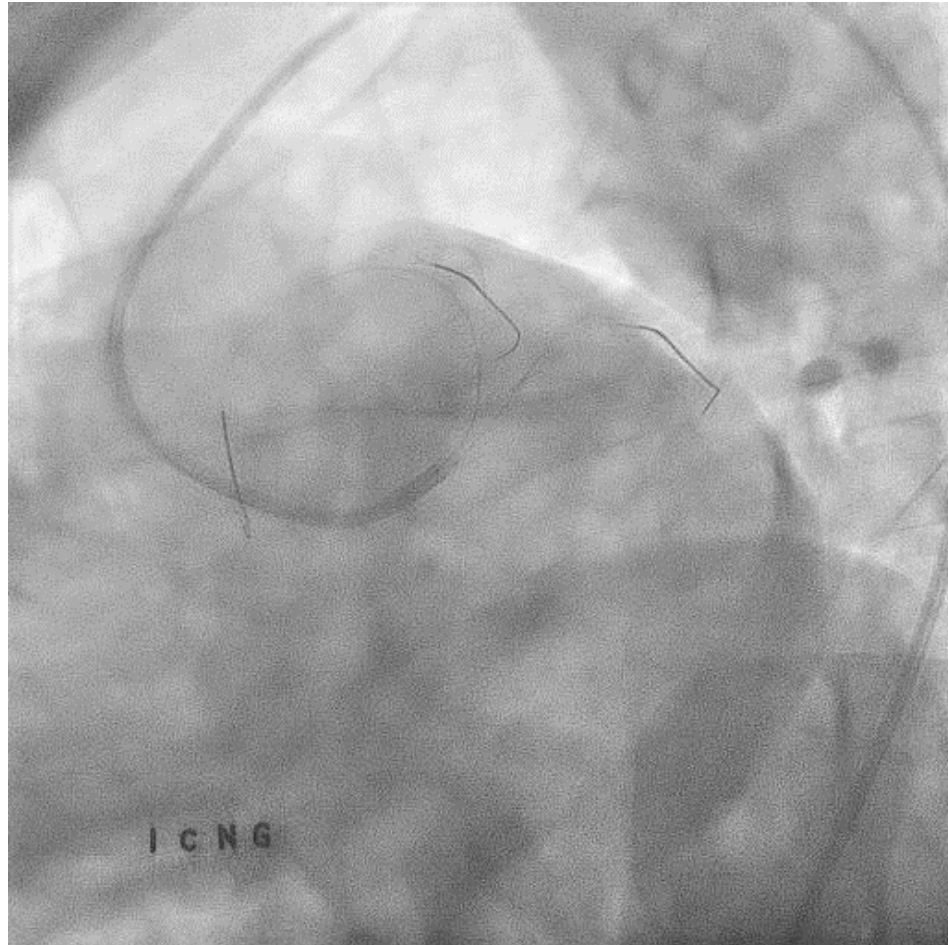
Case Sharing



Case Sharing



Case Sharing

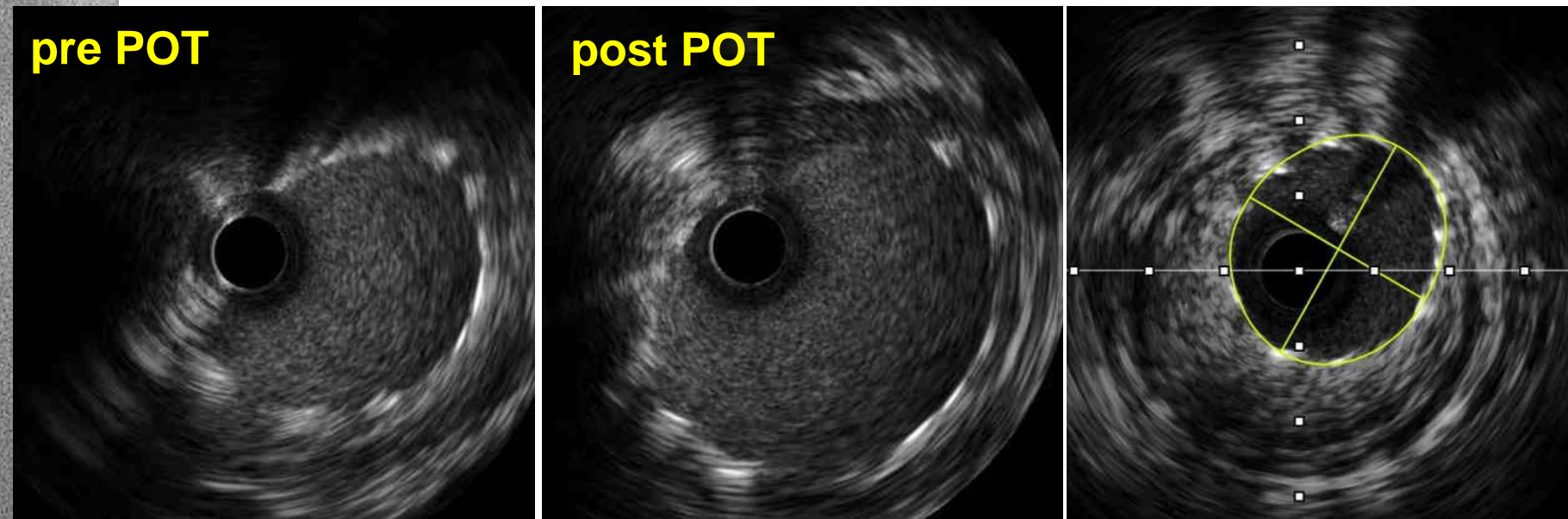
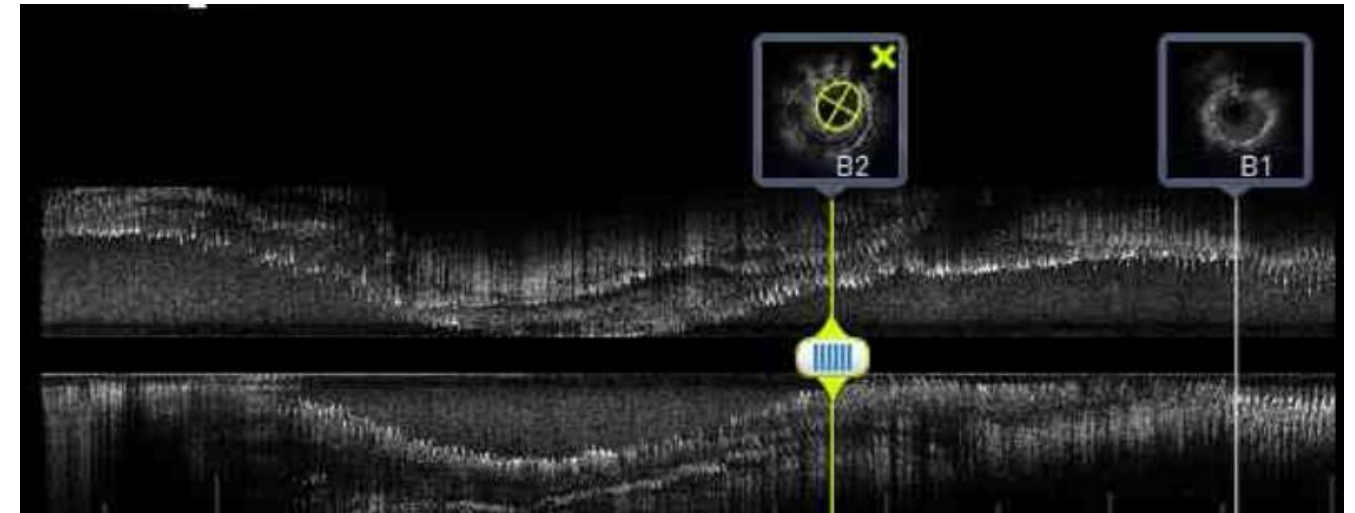


DEB angioplasty to RI with Sequent Please NEO 2.25x20mm
DES implantation to mLAD with Synergy Megatron 3.5x24mm
Kissing ballooning to LAD with 2.5x15mm
Dg with 2.0x15mm

Case Sharing

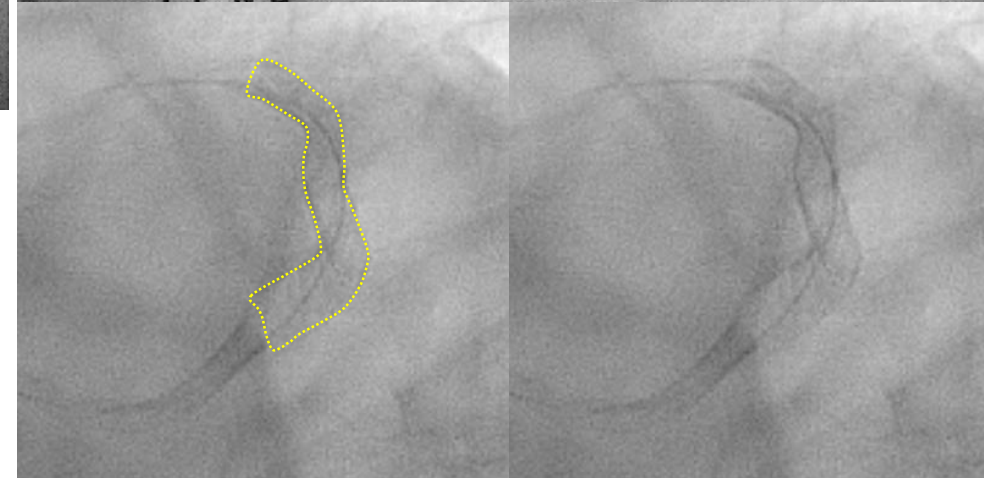
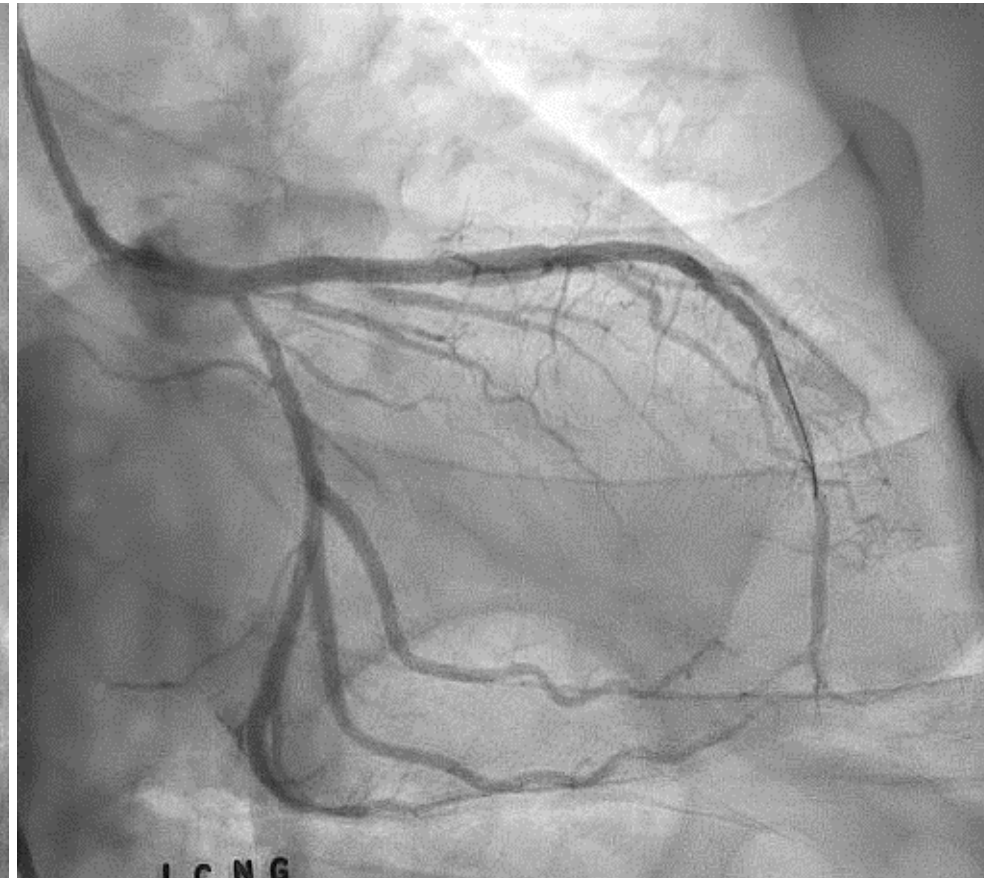
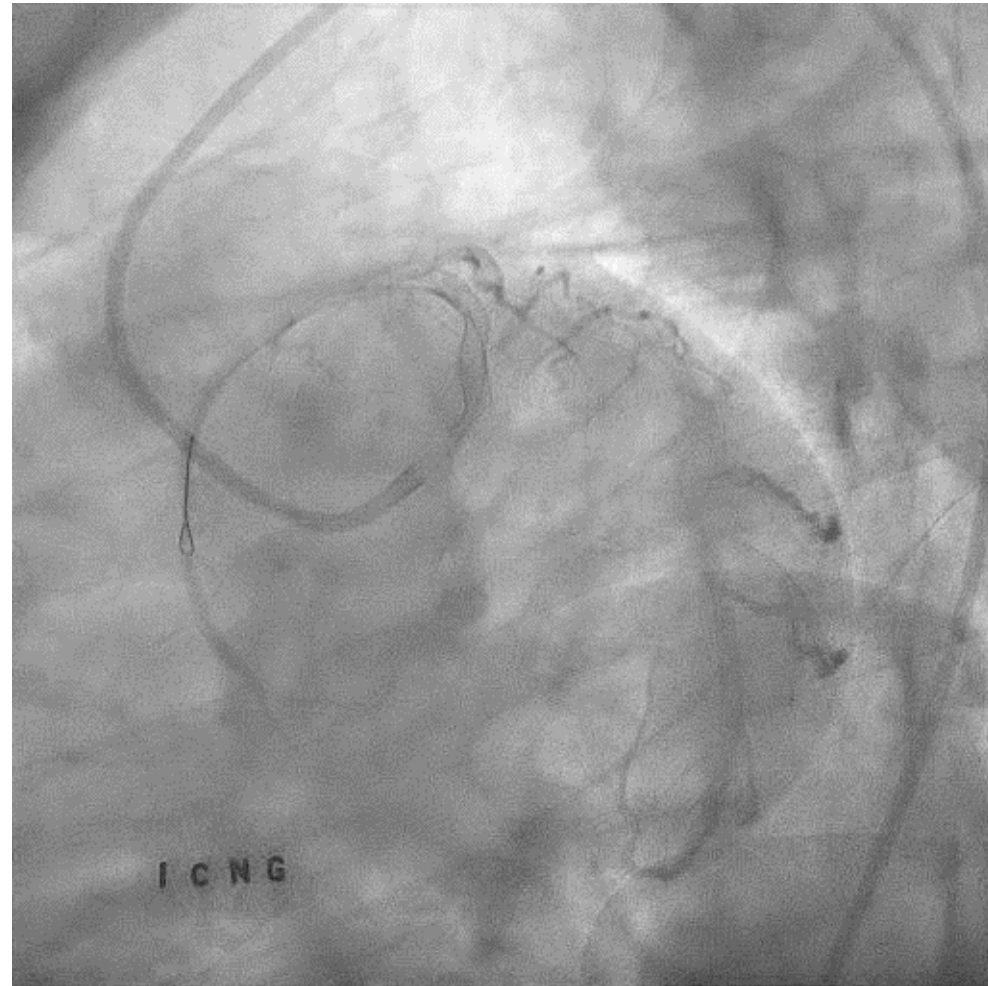
DES implantation to LM-pLAD with Synergy Megatron 4.0x24mm

→ POT to LM



ICNS

Case Sharing



**Successful PCI with 2 Synergy
Megatron stents**

FKB to LAD/Dg2 (rewiring)

Simple crossover to Dg1

POT to LM

IVUS to evaluate stent deformity

#1. Many efforts focus on PCI for Left Main disease.

- Intravascular imaging, including IVUS, has many merits in LM PCI.
- Especially, to evaluate any Stent deformity, which may be critical.

#2. Anatomic features of the Left Main disease require a DES with...

High Radial and Axial Strength, Larger Overexpansion Range,
Optimized Scaffolding, Visibility

#3. The Synergy Megatron Platform may be the best option for LM PCI !

Thank you for your attention

Any Questions are welcome to
medikang@gmail.com

