TCTAP 2021 Virtual

The Future of PCI: Contemporary Optimal Indication, Technology, and Outlook

Prof. Robert A. Byrne

CVRI DUBLIN | RCSI | Mater Private

Dedication

In memory of Professor
David Foley PhD FESC

9.5.1961 – 16.1.2021

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Disclosure Statement | Robert A. Byrne

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

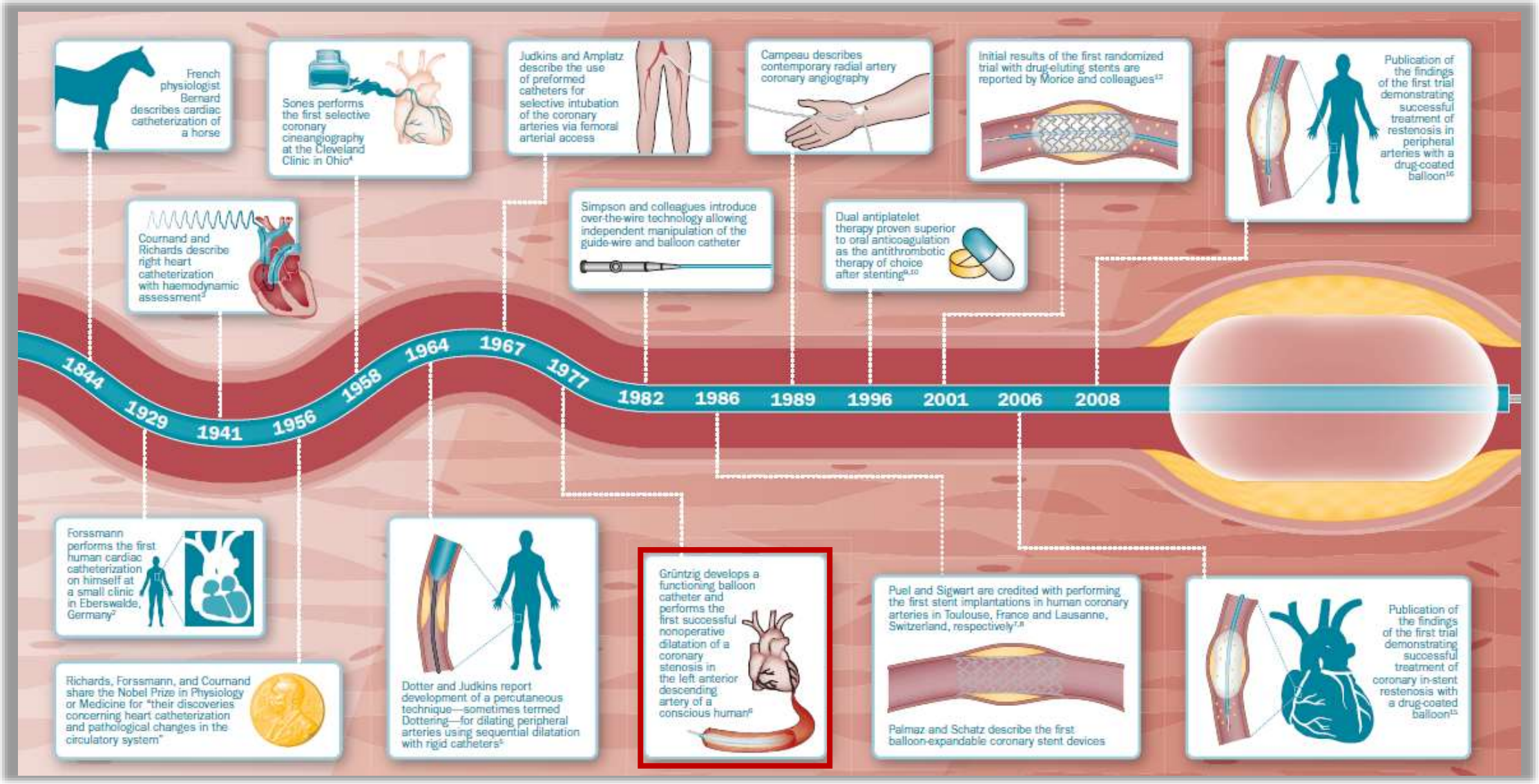
Affiliation/Financial Relationship	Company
Grant/Research Support	Celonova Biosciences* Abbott Vascular, Biosensors, Biotronik, Boston Scientific

RAB reports research funding to the institution of prior employment (*) from Celonova Biosciences and research or educational funding to the institution of current employment from Abbott Vascular, Biosensors, Biotronik and Boston Scientific

RAB has not received personal payments from any pharmaceutical company or device manufacturer

Agenda

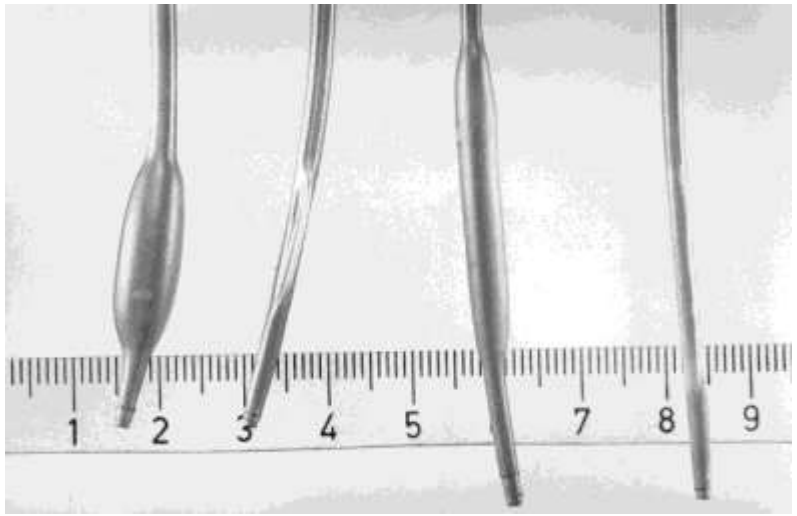
1. A Brief History of Catheter Intervention
2. DES as Breakthrough Technology and Remaining Unmet Need
3. New Roads | Leaving Nothing Behind
4. Advances in Lesion Preparation & Complex PCI
5. Contemporary Optimal Indication post ISCHEMIA



A brief history of catheter intervention

Byrne, Kastrati | Nat Rev Cardiol 2015

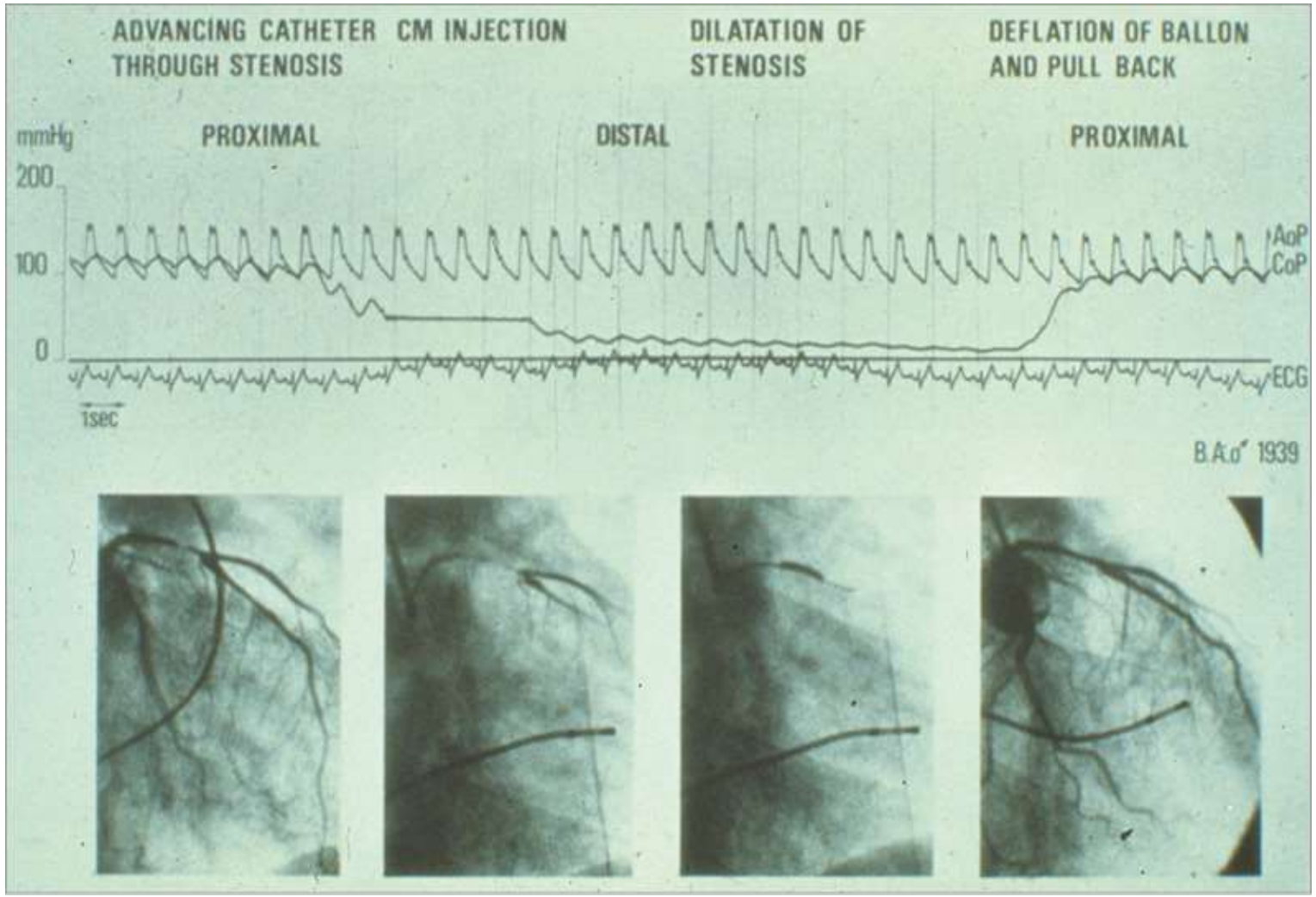
History of coronary angioplasty: first steps

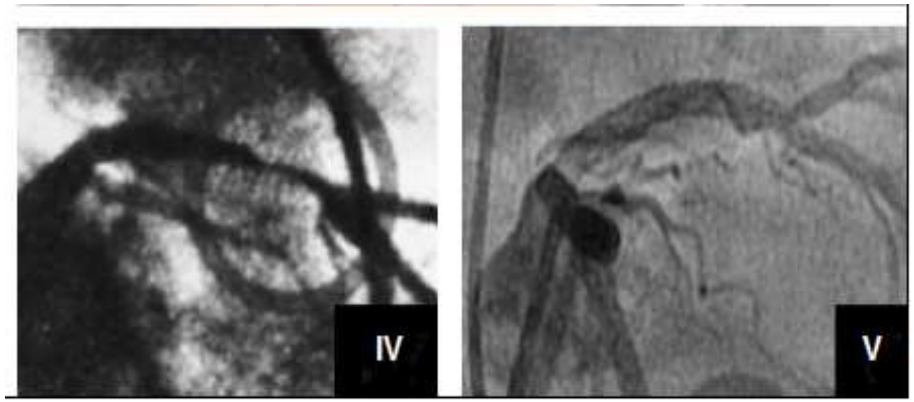


Byrne et al. | Lancet 2017; Meier | EuroIntervention 2017; Original photographs c/o M. Schlumpf

The first angioplasty case

Universitätsspital Zürich, Switzerland | September 16, 1977

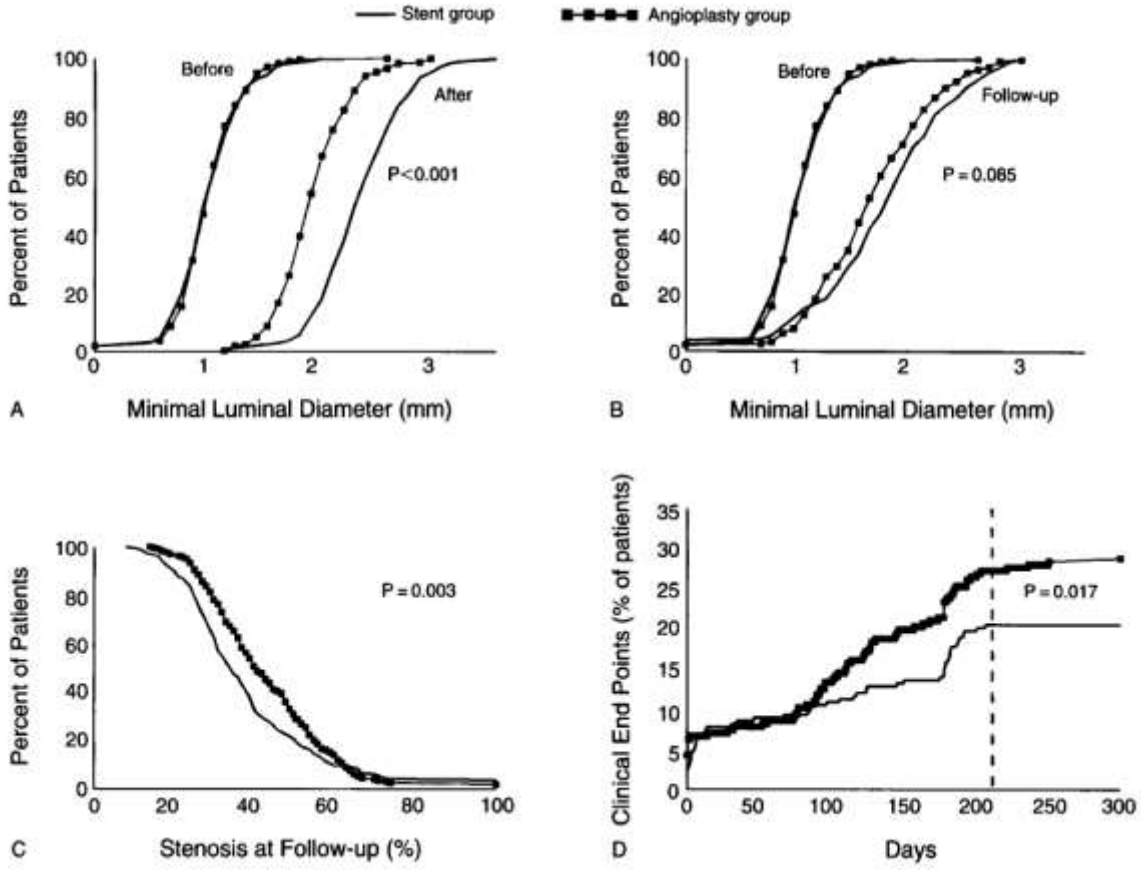




Meier | EuroIntervention 2017; Original photographs c/o M. Schlumpf

Pioneering of coronary stenting

Systematic stent implantation improved angiographic and clinical outcomes

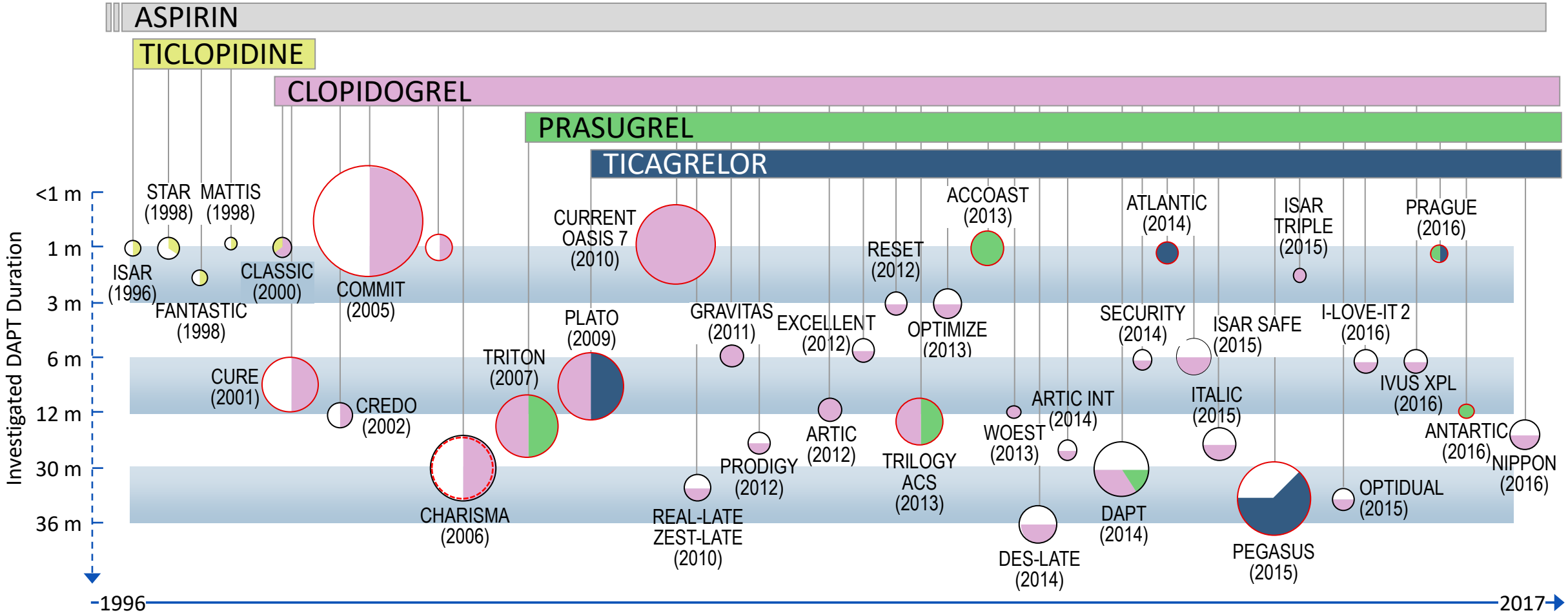


Sigwart/Puel March/April 1986

BENESTENT 1994

Sigwart et al. N Engl J Med 1987 | Puel et al. EuroIntervention 2009 | Serruys et al. N Engl J Med 1994

History of dual antiplatelet therapy (DAPT) in patients with coronary artery disease



Size of the circles denotes sample size

2 5 10 20 K pts

Perimeter of the circles denotes type of investigated population

- Mixed clinical presentation at the time of stent implantation
- Acute coronary syndrome at presentation
- DAPT initiated in patients with prior myocardia infarction
- DAPT for primary prevention

2017 ESC Focused Update on DAPT in Coronary Artery Disease, developed in collaboration with EACTS (European Heart Journal 2017 - doi:10.1093/eurheartj/ehx419)

Summary #1 | Introduction of stents and effective antiplatelet treatment were critical to ensure stable and reproducible results

Byrne, R.A. | TCTAP 2021 Virtual

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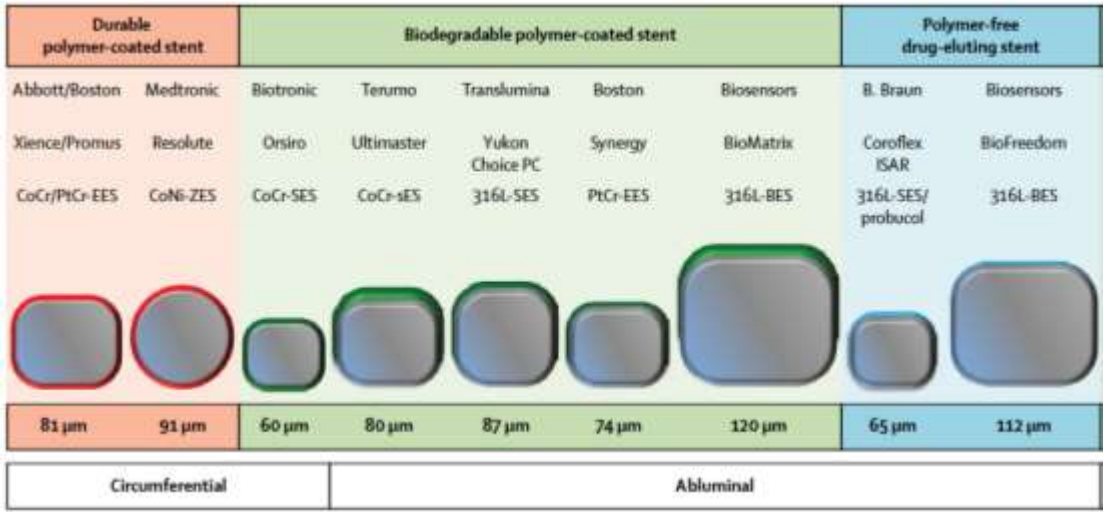
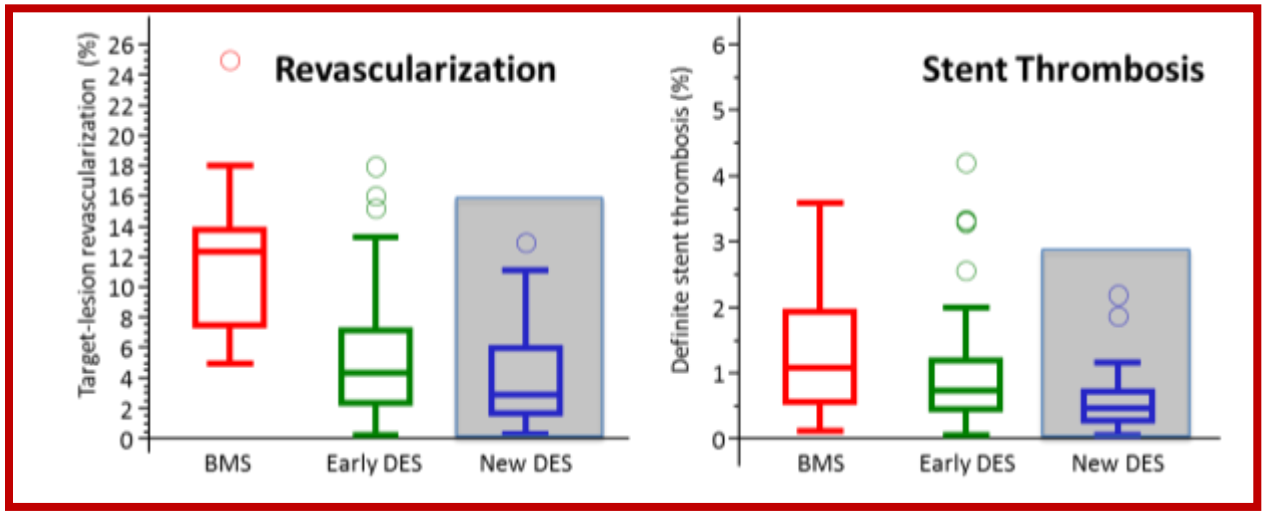
Drug-eluting stents: breakthrough technology



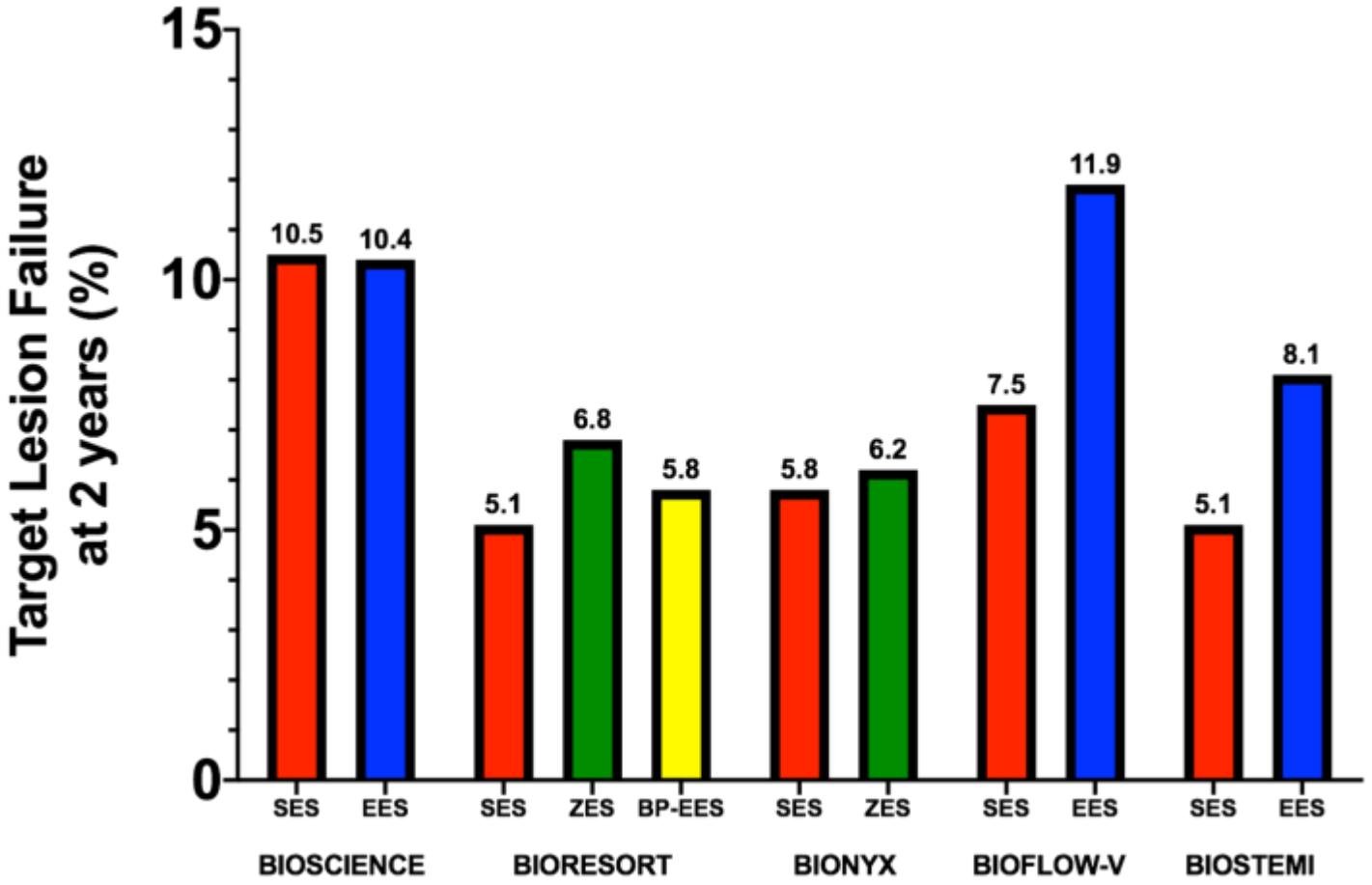


Recommendations	Class	Level
DES are recommended over BMS for any PCI irrespective of: • clinical presentation, • lesion type, • planned non-cardiac surgery, • anticipated duration of DAPT, • concomitant anticoagulant therapy.	I	A

Byrne, Stone, Ormiston, Kastrati | Lancet 2017; ESC Stent Task Force Report 2015

Biodegradable polymer vs durable polymer DES

"When choosing a stent from those widely-used and approved for clinical use in 2021 type of polymer coating is unlikely to represent the decisive factor in its own right"



Byrne, Coughlan | JACC Cardiovasc Interv in press; Byrne, Hanratty | Circulation in press

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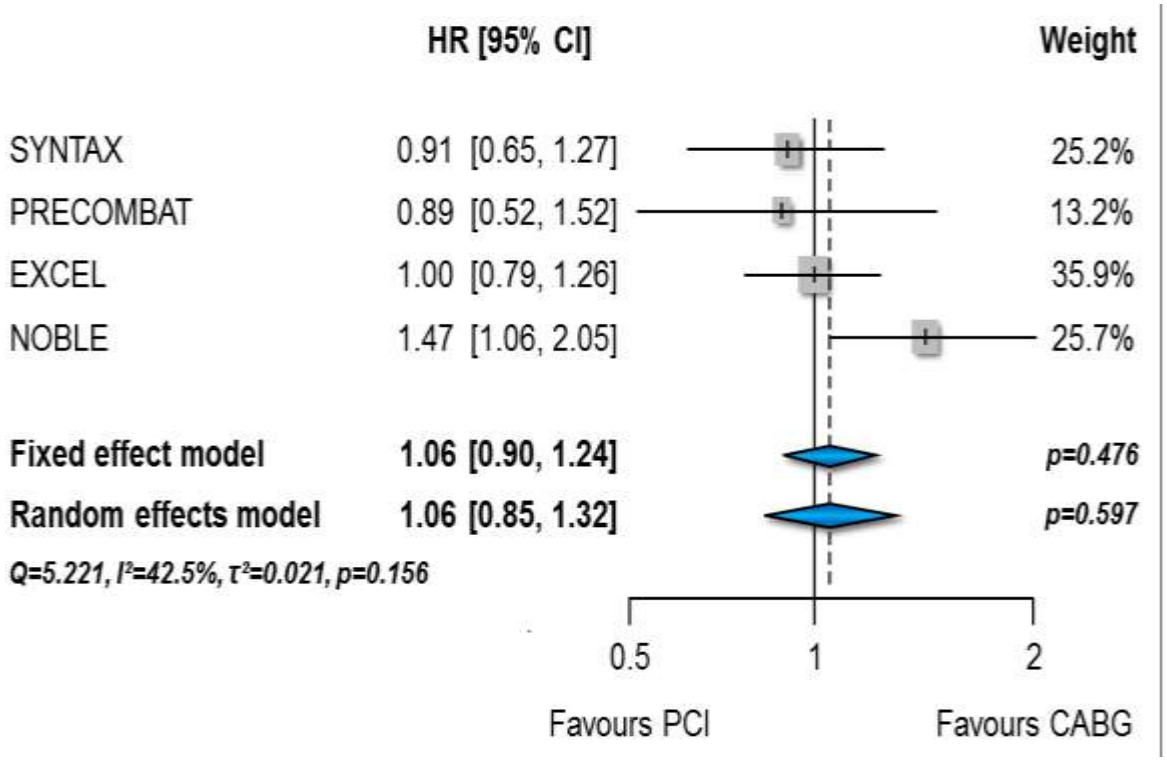
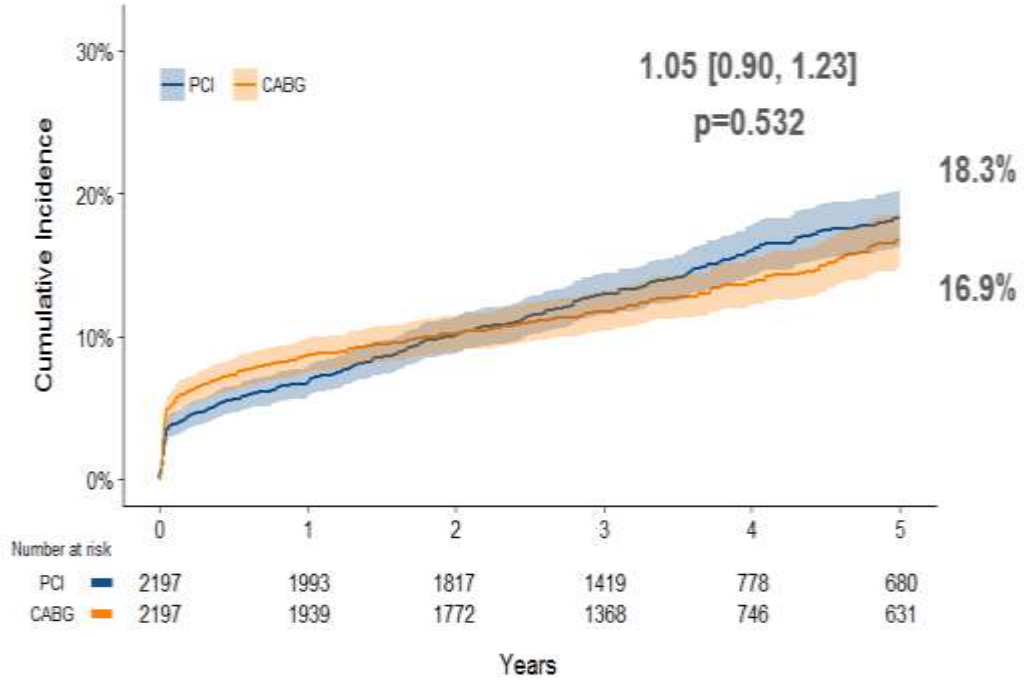
Stenting for left main stem disease

PCI vs CABG randomized trials with long-term follow-up

Composite of death, myocardial infarction or stroke



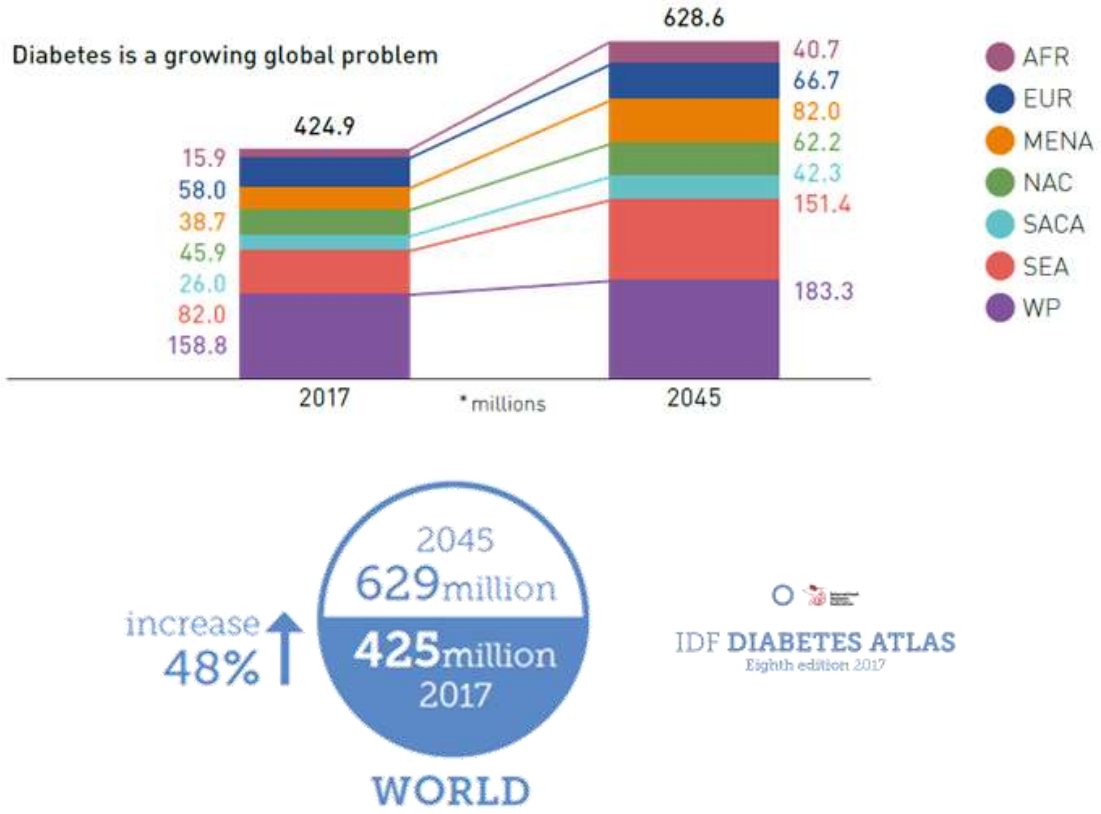


Giacoppo et al. | JAMA Cardiology 2017

Diabetes Mellitus and Percutaneous Coronary Intervention

The burden of DM continues to increase and DES performance still suboptimal

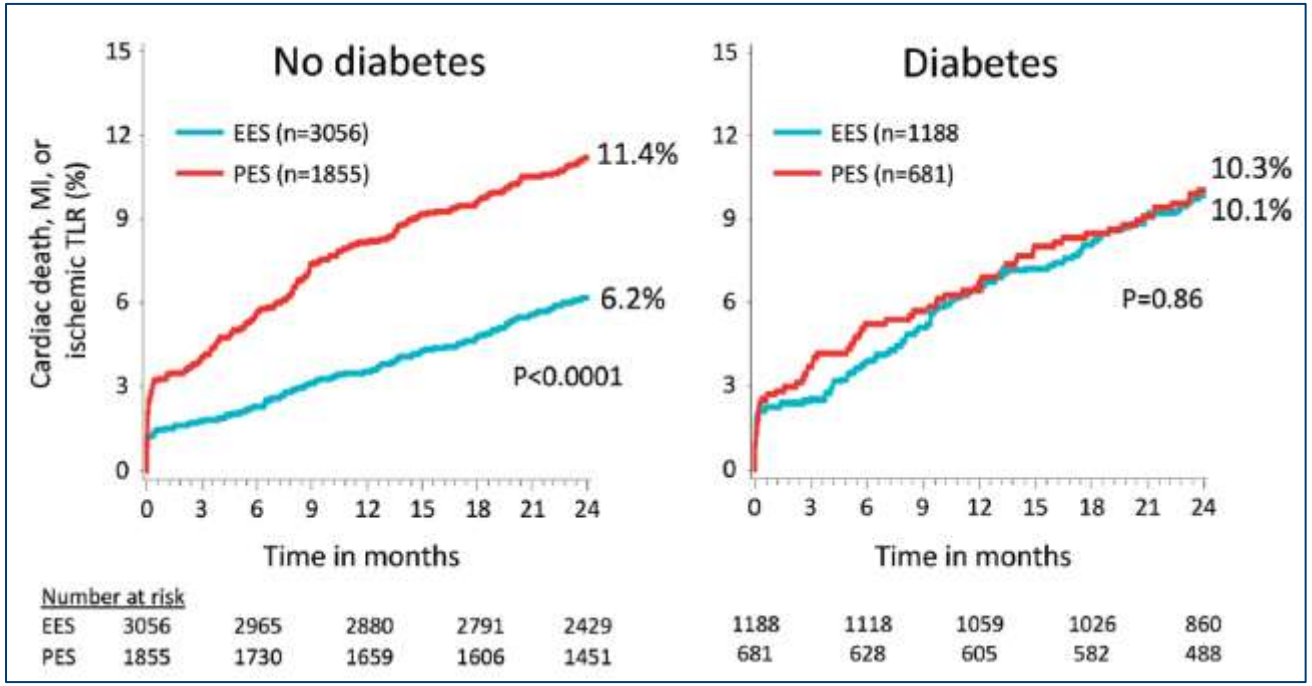
The growing problem of diabetes



DES performance in DM pts is still unsatisfactory

SPIRIT/ COMPARE pooled patient level analysis

(Spirit II, Spirit III, Spirit IV, Compare - 6789 pts)



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Circulation. 2011;124:893-900

Summary #2 | High-efficacy DES have facilitated expansion of PCI to more complex disease patterns…

Byrne, R.A. | TCTAP 2021 Virtual

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Summary #3 | …patients with diabetes continue to have unmet need and dedicated stents may have a role in the future

Byrne, R.A. | TCTAP 2021 Virtual

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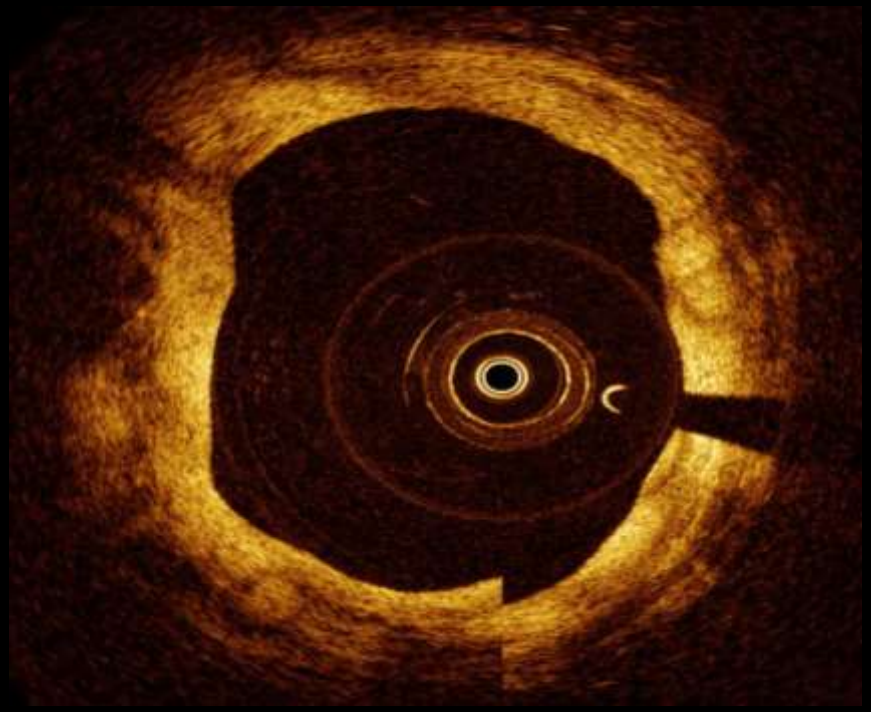
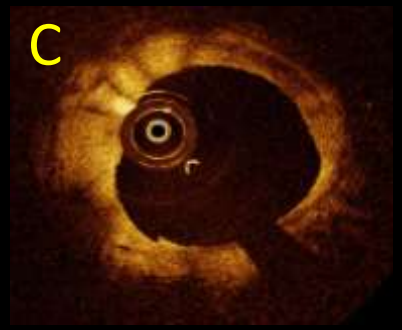
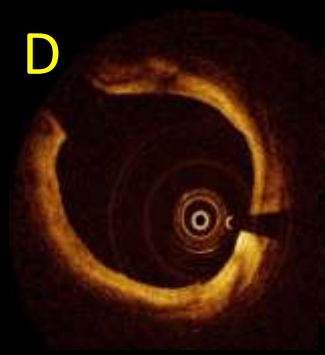
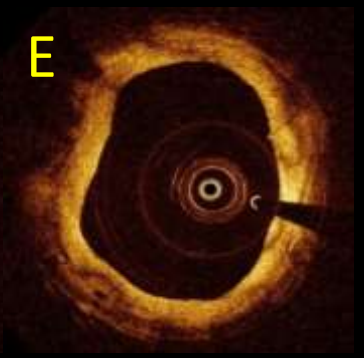
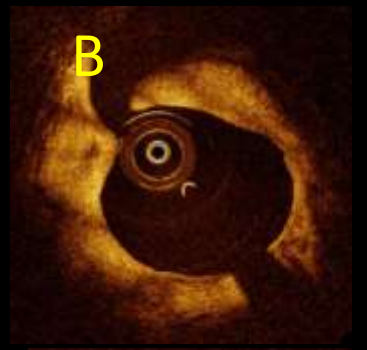
Bioresorbable scaffold (I-T) at 10-year FU

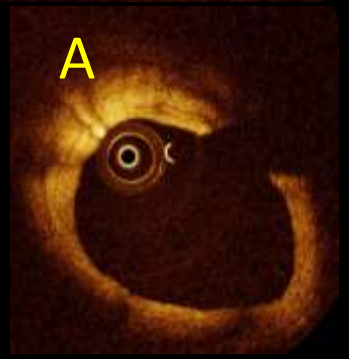


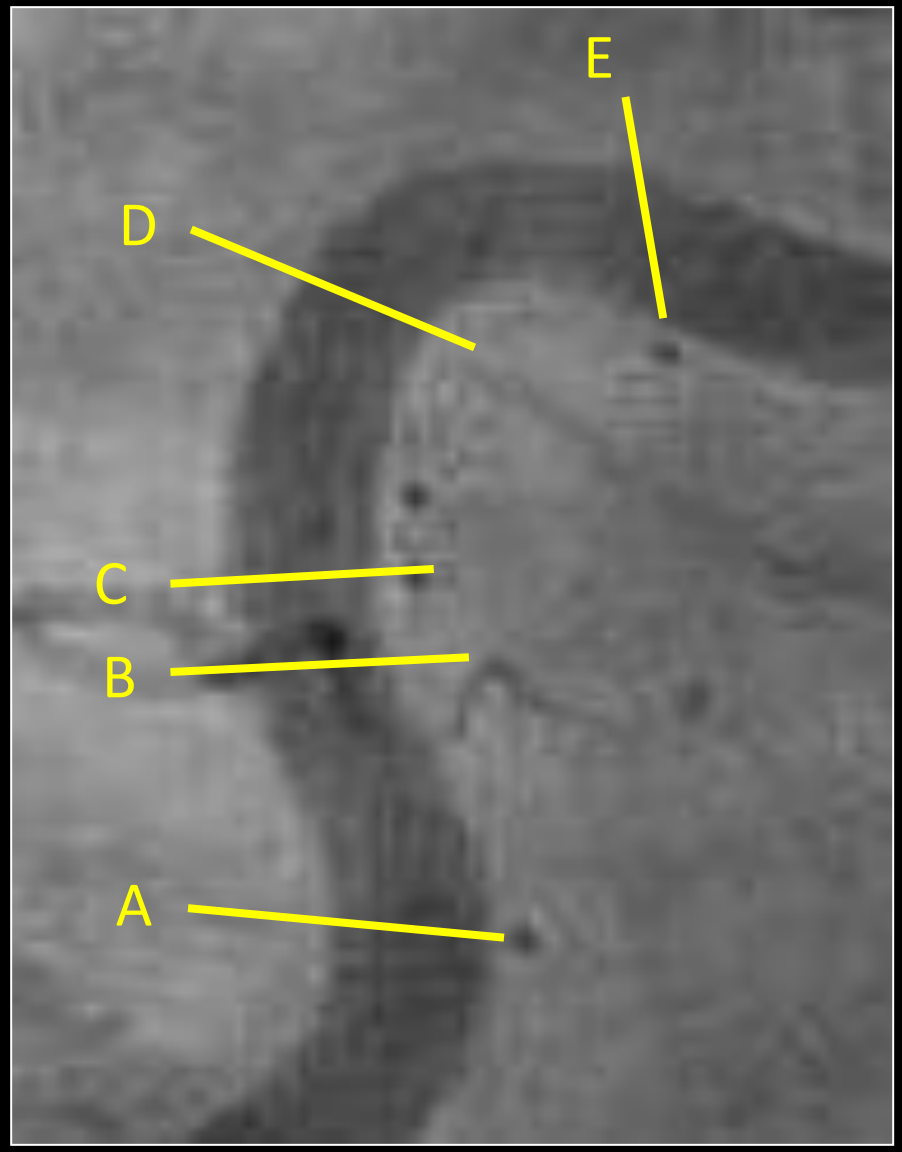




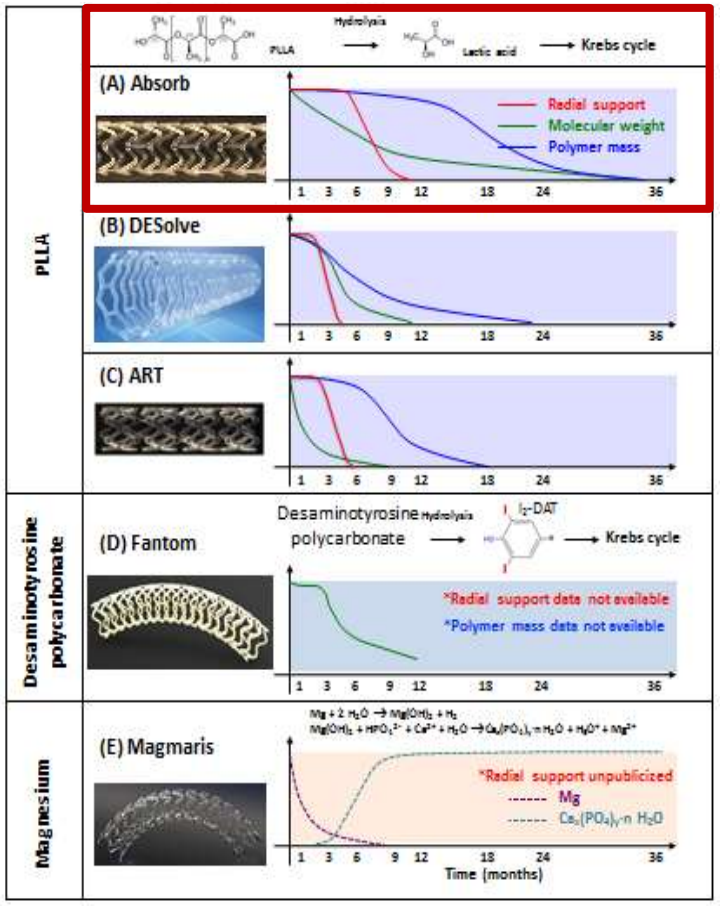








Bioresorbable scaffolds: work in progress



Target lesion failure

Trial	BVS Events	BVS Total	EES Events	EES Total	Odds Ratio [95% Confidence intervals]	Weight (fixed)	Weight (random)
ABSORB China	13	236	11	235	1.19 [0.52; 2.71]	6.0%	5.8%
ABSORB II	34	325	8	161	2.23 [1.01; 4.95]	5.5%	6.2%
ABSORB III	143	1296	53	671	1.45 [1.04; 2.01]	35.7%	36.2%
ABSORB Japan	23	258	7	128	1.69 [0.71; 4.05]	4.9%	5.2%
AIDA	91	899	78	894	1.18 [0.86; 1.62]	40.4%	39.1%
EVERBIO II	16	78	13	80	1.33 [0.59; 2.99]	5.9%	6.0%
TROFI II	3	95	3	96	1.01 [0.20; 5.14]	1.7%	1.5%
Fixed effect model	**323**	**3187**	**173**	**2265**	**1.36 [1.12; 1.66]**	**100.0%**	**--**
Random effects model					**1.35 [1.14; 1.61]**	**--**	**100.0%**

Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$, $p = 0.82$

0.1 0.2 0.5 1 2 5 10
BVS better EES better

Scaffold thrombosis (def/prob)

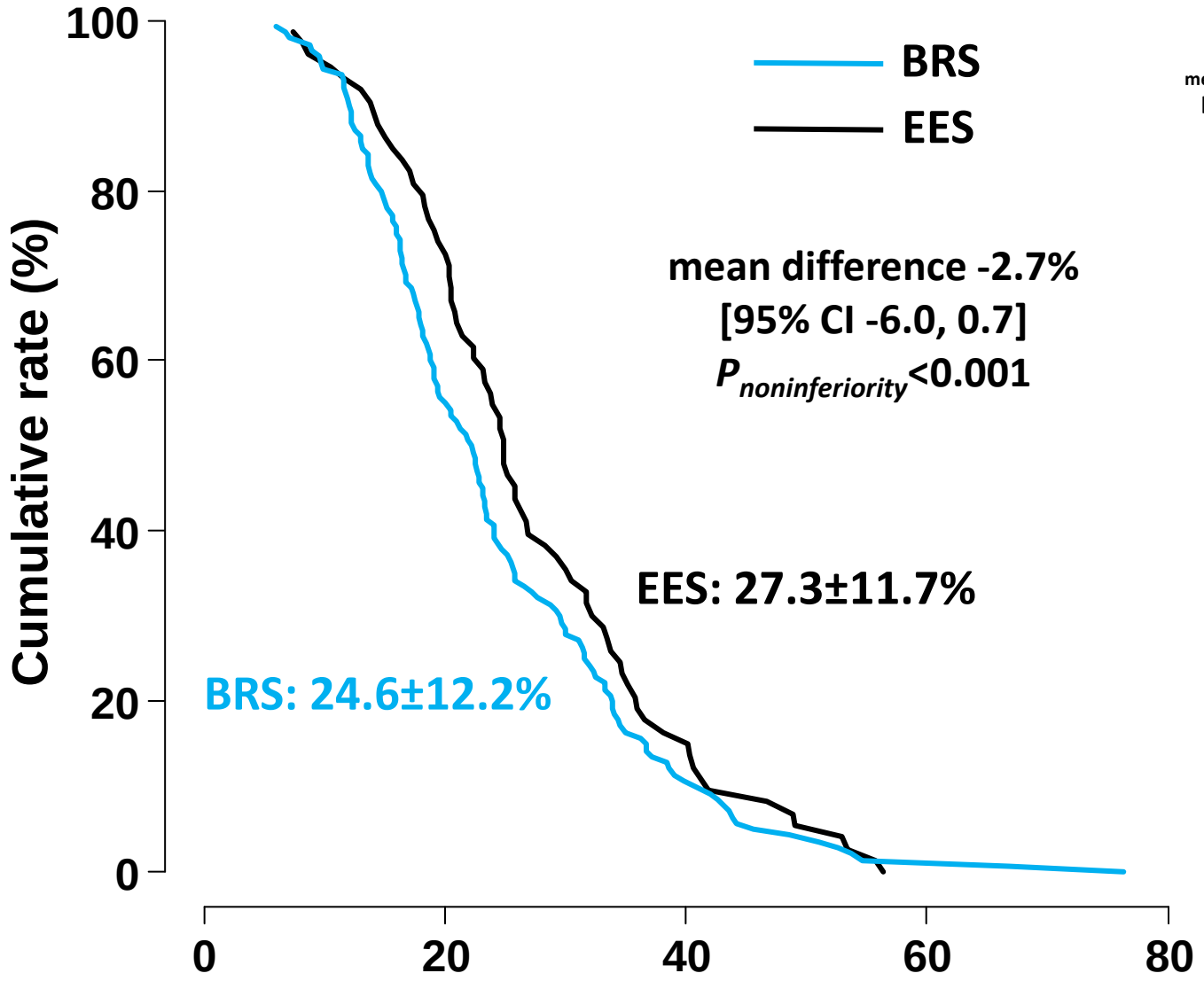
Trial	BVS Events	BVS Total	EES Events	EES Total	Odds Ratio [95% Confidence intervals]	Weight (fixed)	Weight (random)
ABSORB China	2	235	0	229	4.91 [0.23; 102.92]	2.6%	3.0%
ABSORB II	9	321	0	158	9.64 [0.56; 166.64]	3.3%	3.4%
ABSORB III	24	1296	5	671	2.51 [0.95; 6.62]	33.3%	29.5%
ABSORB Japan	9	258	2	128	2.28 [0.48; 10.70]	13.3%	11.6%
AIDA	31	899	8	894	3.96 [1.81; 8.65]	39.9%	45.1%
EVERBIO II	1	78	0	80	3.12 [0.13; 77.66]	2.5%	2.7%
TROFI II	2	95	1	96	2.04 [0.18; 22.92]	5.0%	4.7%
Fixed effect model	**78**	**3182**	**16**	**2256**	**3.35 [1.98; 5.66]**	**100.0%**	**--**
Random effects model					**3.24 [2.34; 4.50]**	**--**	**100.0%**

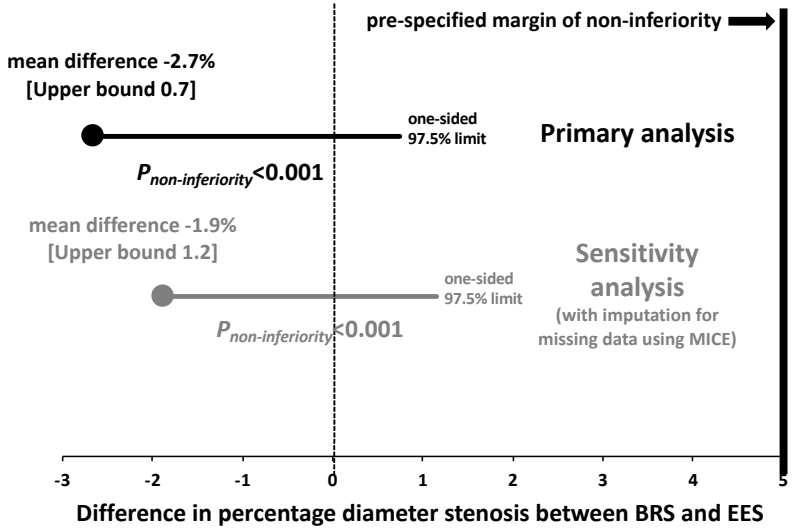
Heterogeneity: $I^2 = 0\%$, $\tau^2 = 0$, $p = 0.96$

0.1 0.2 0.5 1 2 5 10
BVS better EES better

Byrne et al., ESC-EAPCI Task Force on BRS | *Eur Heart J & EuroIntervention* 2017 online; Cassese et al. | *EuroIntervention* 2017 online

Acute MI as BRS Niche? | ISAR-ABSORB MI: 1° Endpoint



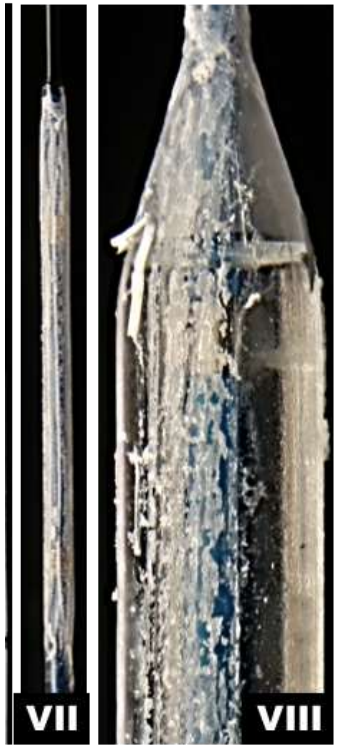


Byrne et al. | Eur Heart J 2019

Summary #4 | The concept of bioresorbable scaffold therapy remains valid and further iteration and clinical testing is warranted

Drug-Coated Balloon Angioplasty

Meticulous attention to angioplasty technique is critical



Byrne R.A. | Lancet 2017

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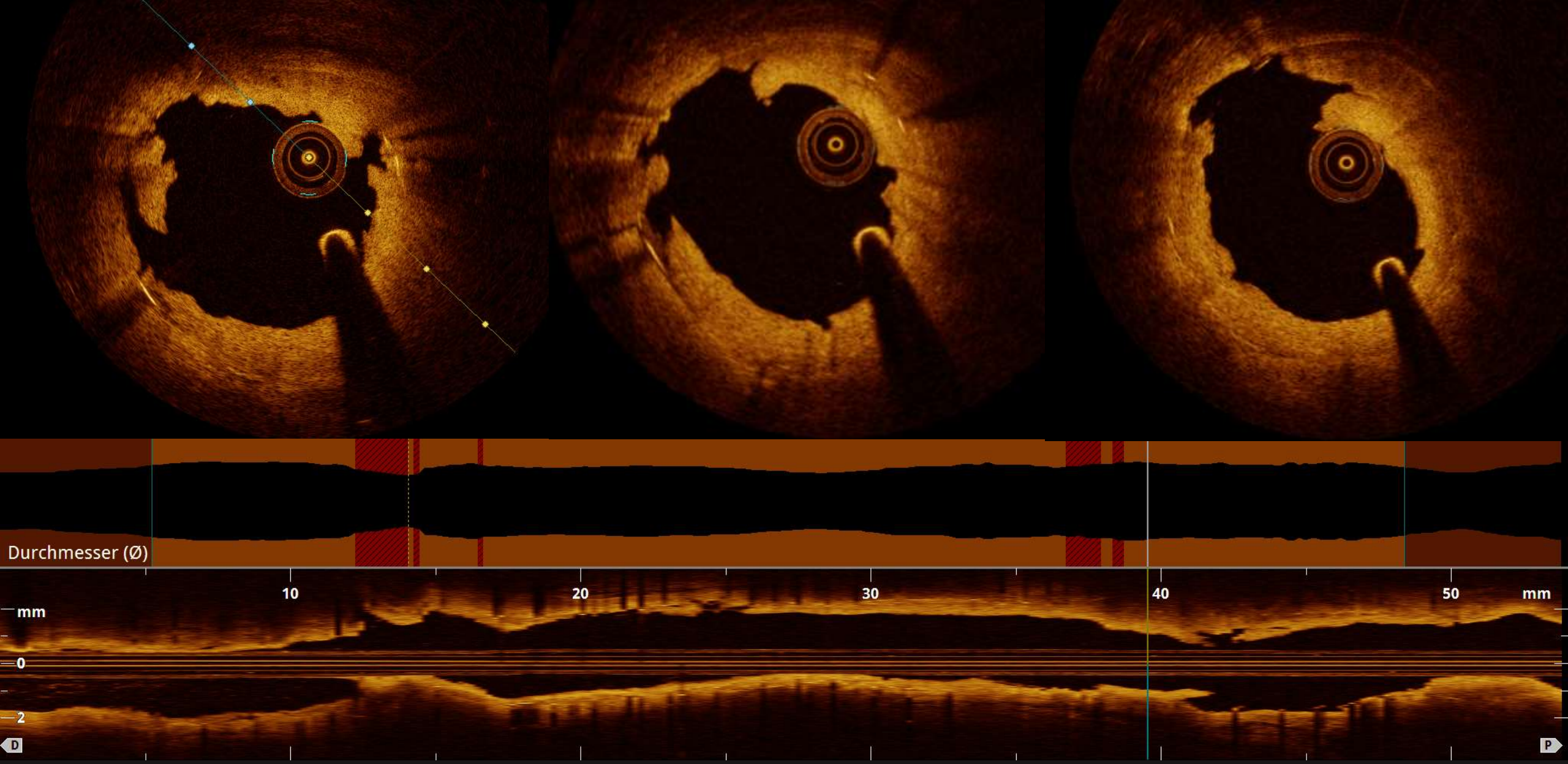

After DCB angioplasty accept a result that is not “stent-like“

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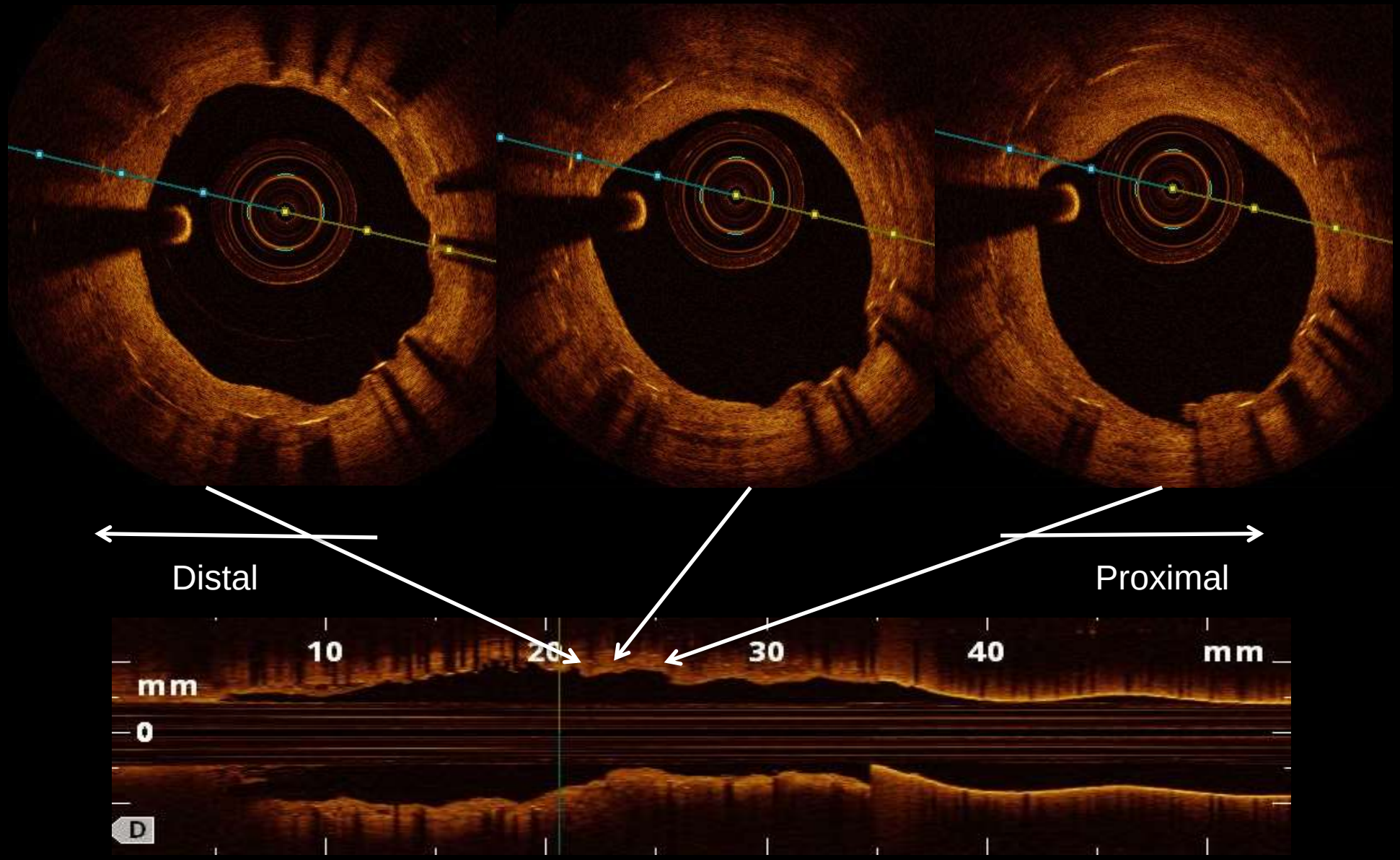
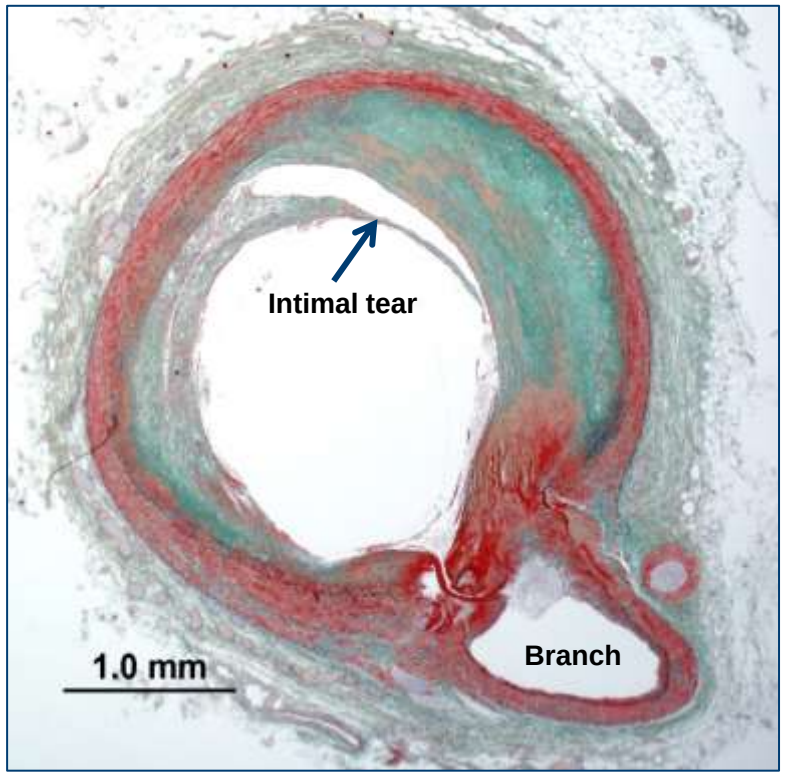
Optical coherence tomography (OCT) imaging (6-8 month FU)



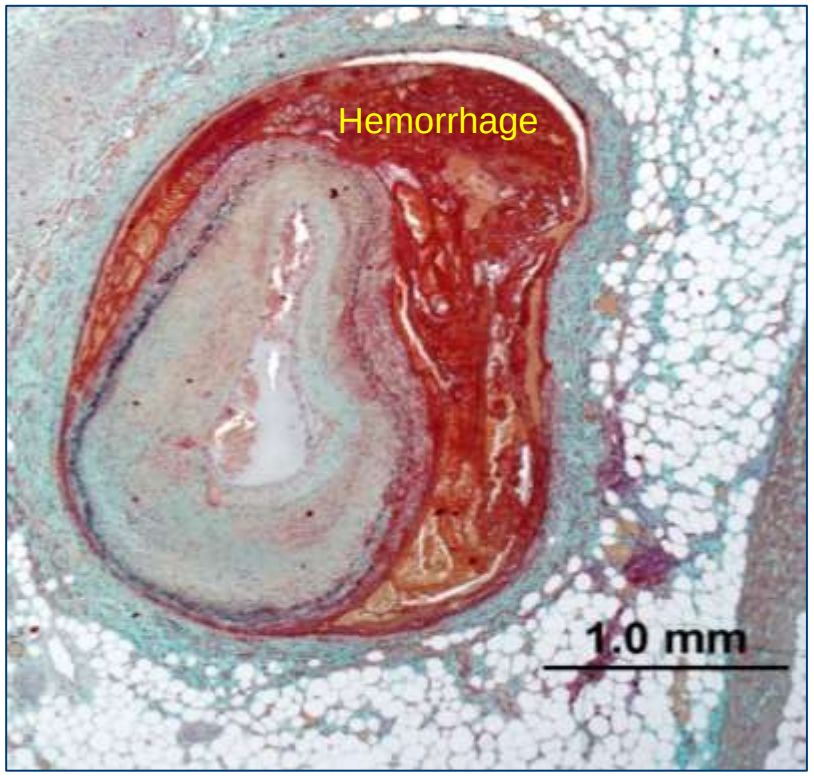
Dissections After Balloon Angioplasty

Drug-Coated Balloon Angioplasty for De Novo Stenosis

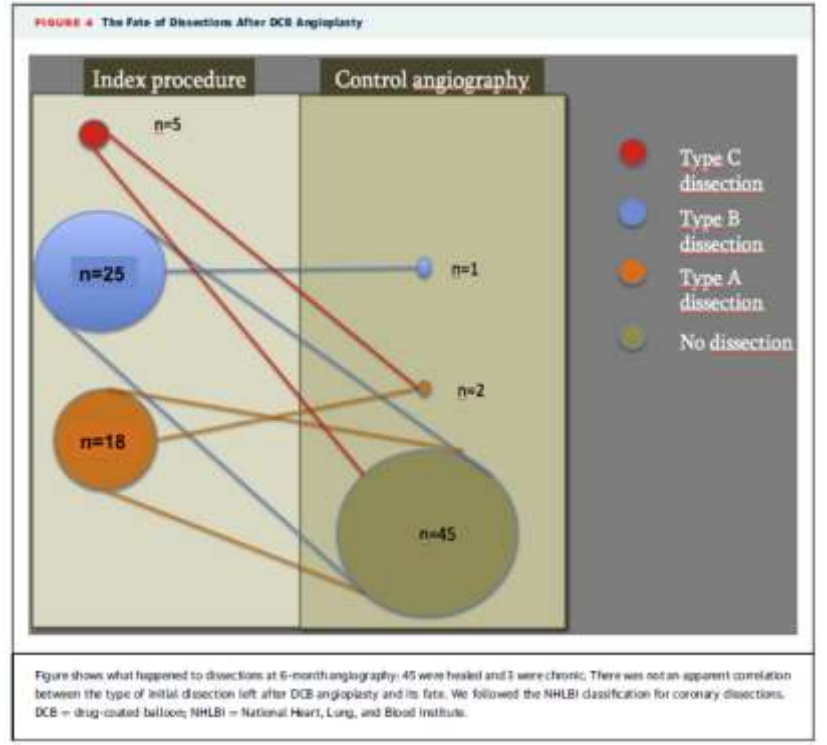
(A) Intimal tear



(B) Major medial dissection



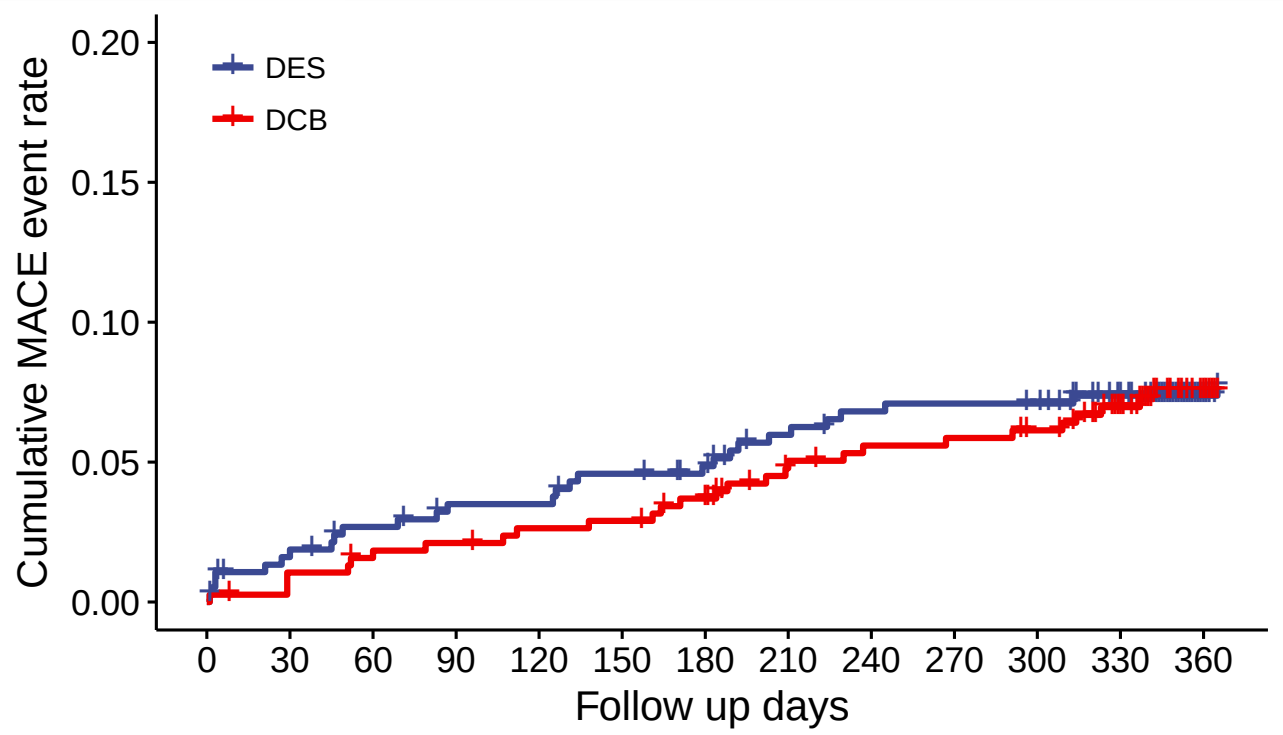
Fate of Dissections After DCB Angioplasty



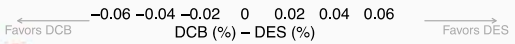
Byrne, Joner | JACC Interv 2016; Cortese et al. | JACC Interv 2016

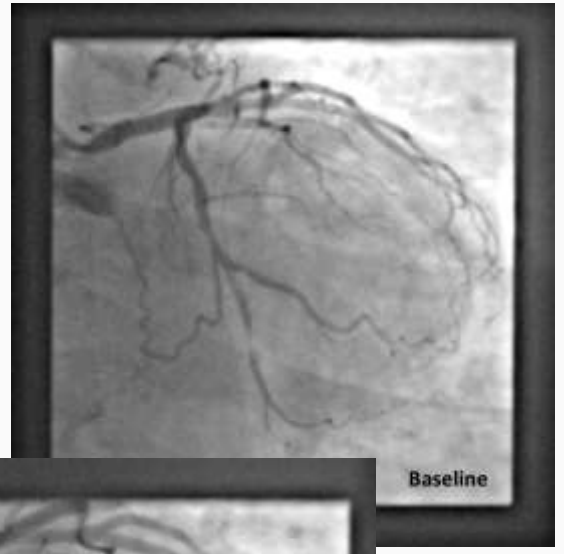
BASKET-SMALL 2: MACE (12 Months)

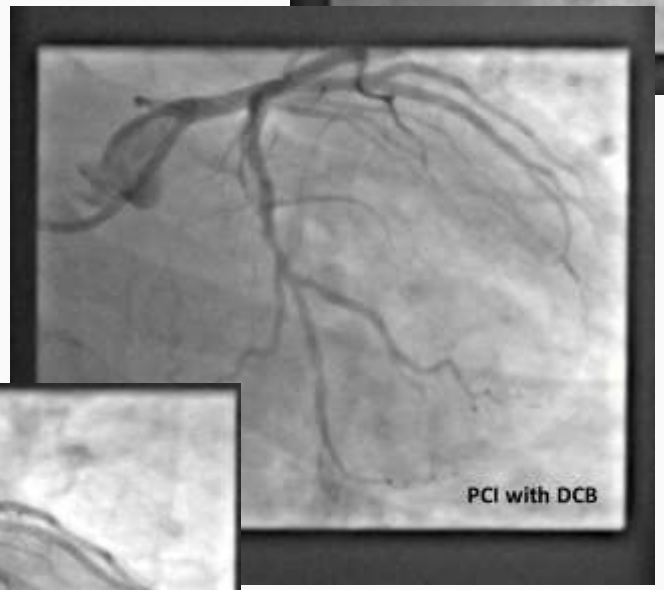
HR 0.97, 95% CI 0.58 to 1.64; p=0.9180



Set	Level	Events	Difference	CI	p
PPS	DES	27 / 359 (7.52%)			
	DCB	28 / 370 (7.57%)	0.0005	[−0.038, 0.039]	0.0217
FAS	DES	28 / 376 (7.45%)			
	DCB	28 / 382 (7.33%)	−0.0012	[−0.040, 0.037]	0.0152







ESC Congress Munich 2018

Raban et al. | Lancet 2018

Summary #5 | Drug-coated balloon therapy shows promise in de novo disease but further testing is required

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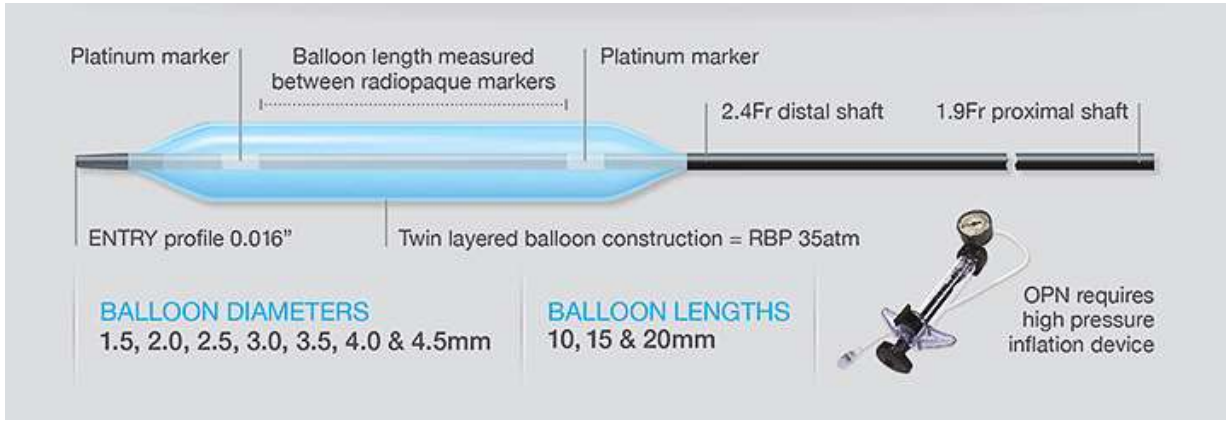
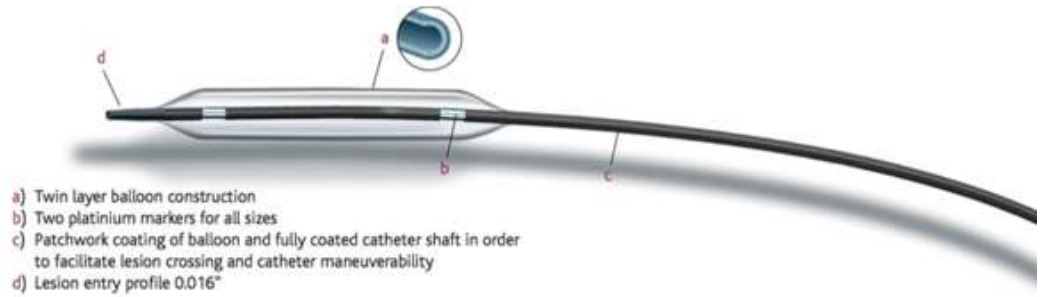
Super high pressure balloon angioplasty

OPN Balloon permits lesion dilation up to 55 bar





SIS MEDICAL DISTRIBUTION AG

Inflation Devices

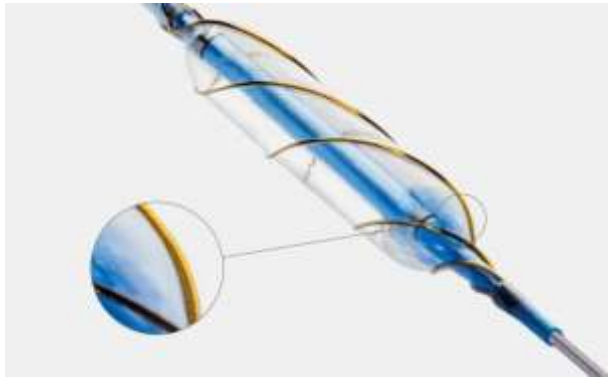
	SIS MEDICAL 40atm Inflation Device	SIS MEDICAL 55atm Inflation Device
Description	For standard and high pressure PTCA up to 40 atm	For super high pressure PTCA up to 55 atm
Ordering Information (REF)	96346	96463
Units per Pack	1	1
Technical Specifications		
Volume [ml, cc]	25	14
Manometer Resolution [atm]	2 (up to 20 atm), 5 (up to 40 atm)	1
Materials	Housing, plunger: Polycarbonate Other parts: plastics (glass fibre reinforced) and metal	

SIS MEDICAL

- www.sis-medical.com

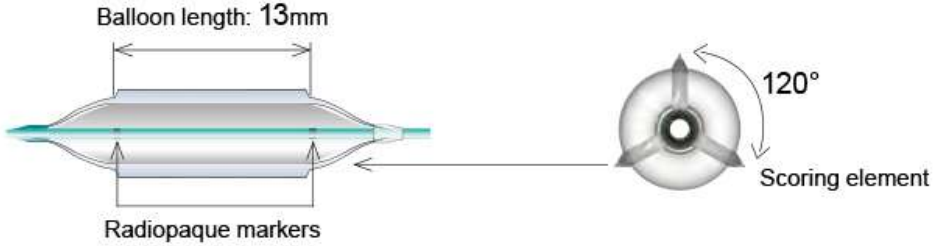
Lesion preparation: scoring balloon catheters

AngioSculpt



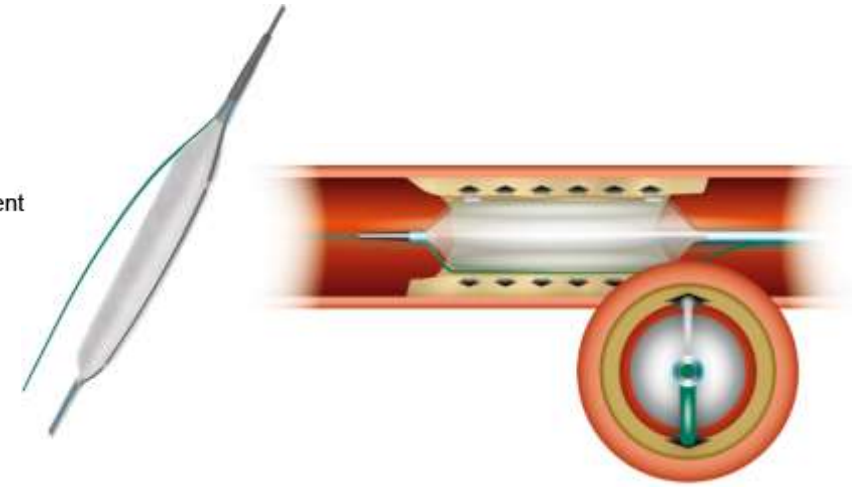
- ~0.005” rectangular scoring elements
- 3 nitinol spiral “scoring” wires
- Nitinol enhanced active deflation

NSE-Alpha



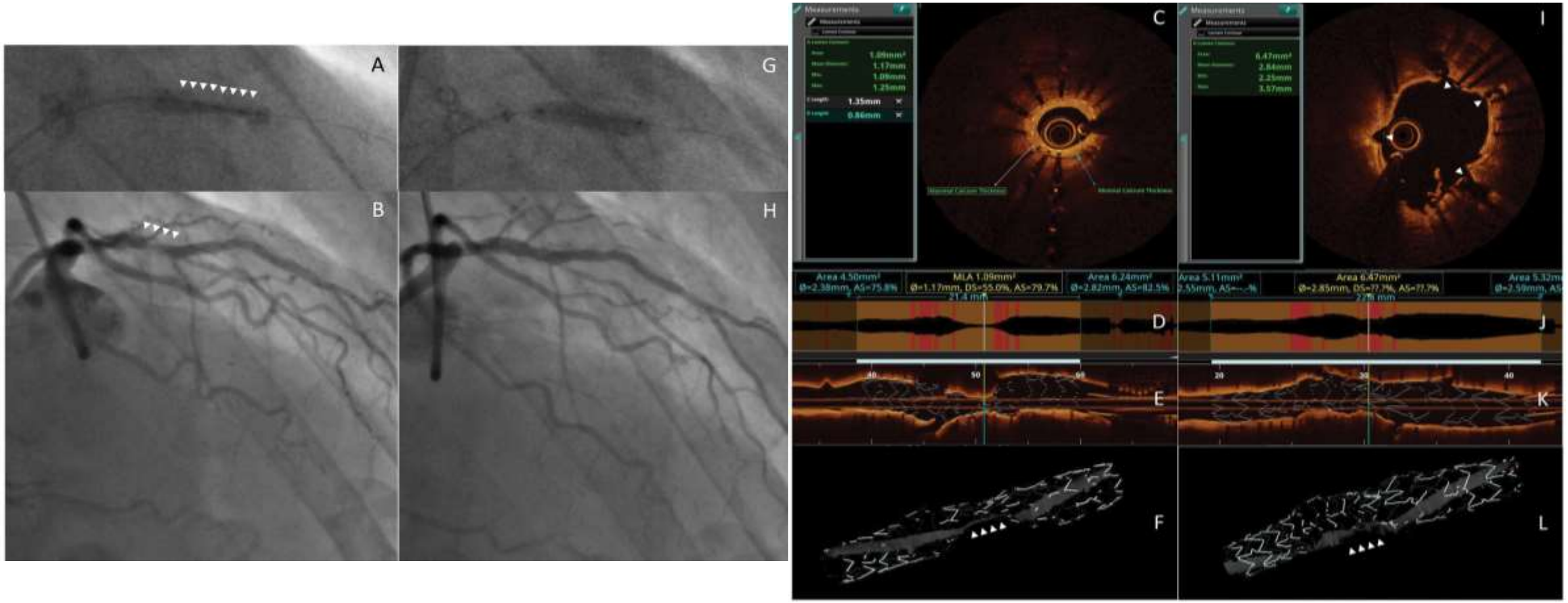
- 3 triangle- shaped non-slip scoring elements
- Rolled up balloon folding
- Resistant nylon material

Scoreflex



- 0.011” nitinol integral wire
- Crossing profile 0.030“
- Guide wire exit port 11mm from distal tip

Intravascular lithotripsy for calcified in-stent restenosis



Ali et al. | European Heart Journal 2020

Summary #6 | Improved tools for lesion preparation facilitate safer and more effective treatment of complex disease patterns

Byrne, R.A. | TCTAP 2021 Virtual

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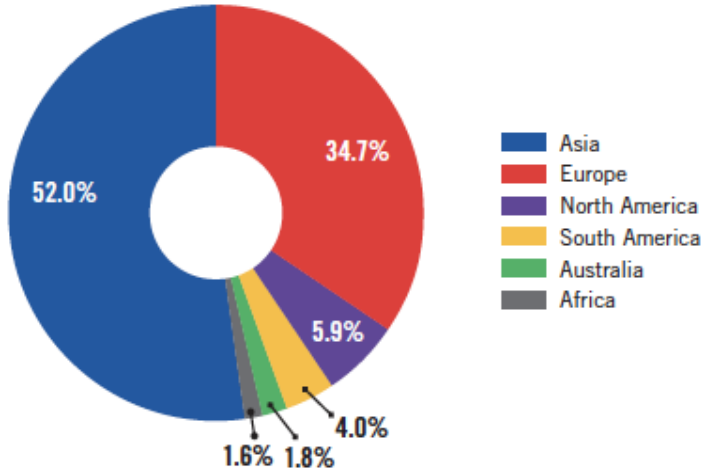
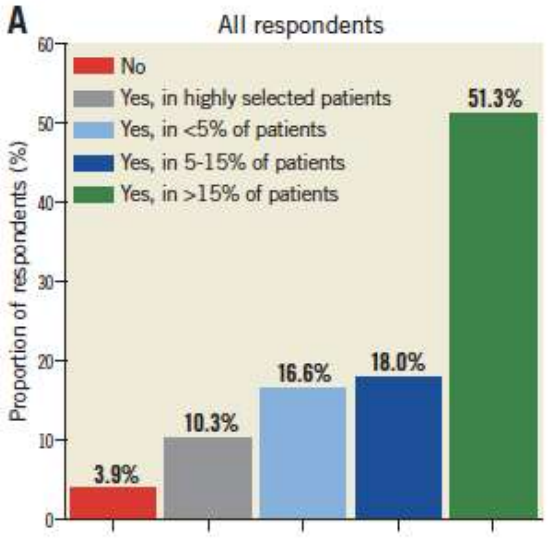
Results of EAPCI/CVIT Survey on Intravascular Imaging

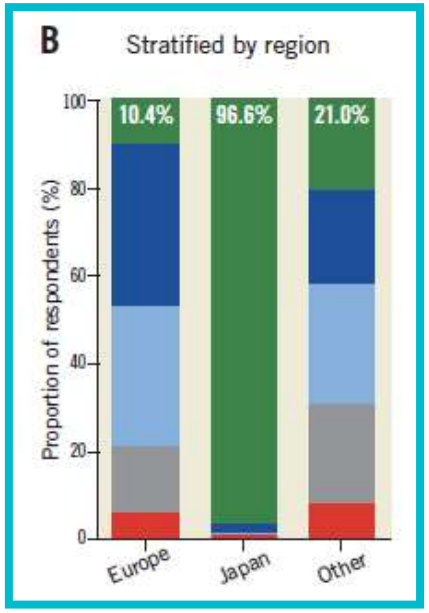
Current use of intracoronary imaging in interventional practice – Results of a European Association of Percutaneous Cardiovascular Interventions (EAPCI) and Japanese Association of Cardiovascular Interventions and Therapeutics (CVIT) Clinical Practice Survey

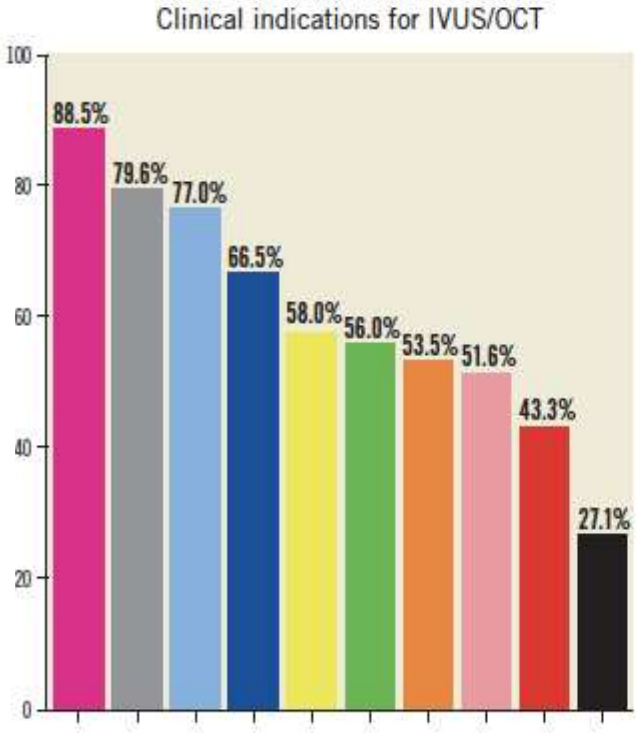
Konstantinos C. Koskinas[1]*, MD; Masato Nakamura[2], MD; Lorenz Räber[1], MD, PhD; Roisin Colleran[3], MD; Kazushige Kadota[4], MD; Davide Capodanno[5], MD, PhD; William Wijns[6], MD, PhD; Takashi Akasaka[7], MD; Marco Valgimigli[1], MD, PhD; Giulio Guagliumi[8], MD; Stephan Windecker[1], MD; Robert A. Byrne[3,9], MD, PhD

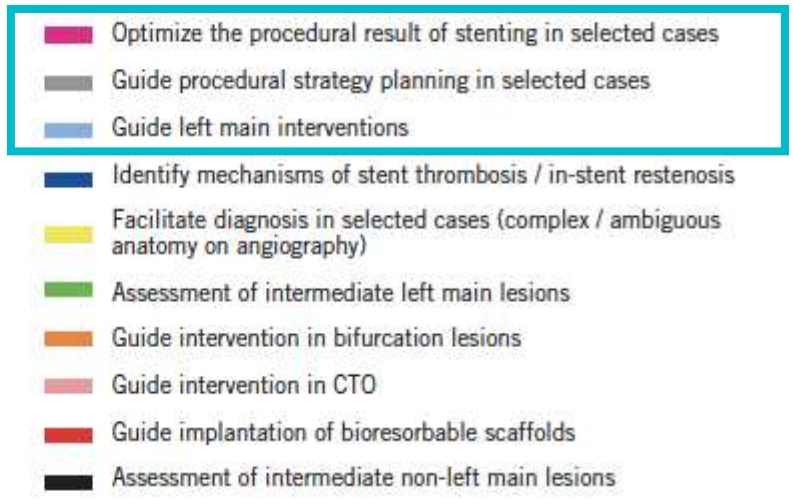
Sample cohort: 1,105 respondents (92% practising interventionists)









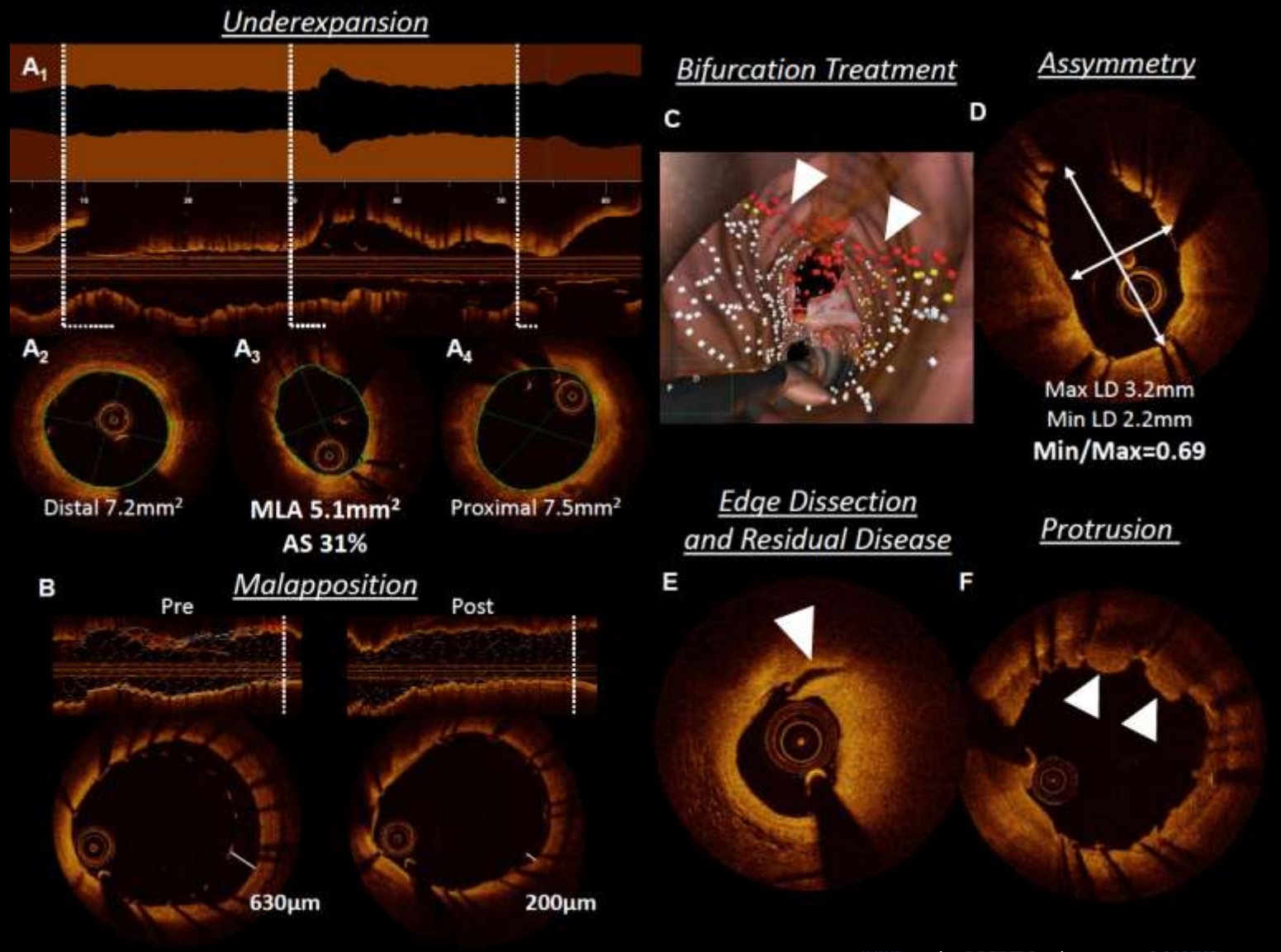


Koskinas et al. | EuroIntervention 2018 and Circ Journal 2018

PCI Optimization – actionable OCT findings

ILUMIEN I Study

- Clinically satisfactory stenting using angiographic guidance
- Additional stent optimization based on OCT in 25% of patients



Wijns et al. | ILUMIEN I | Eur Heart J 2015

Räber et al. | EAPCI consensus paper on intravascular imaging | submitted

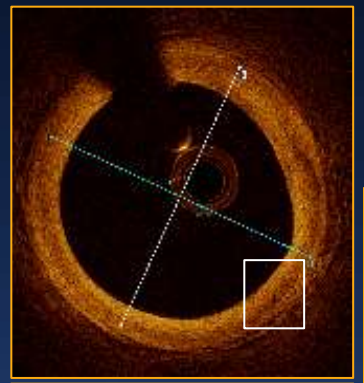
ILUMIEN IV | OCT Stent Sizing Algorithm

Pre-PCI OCT[1]

Measure the EEL at both proximal and distal reference segments, if possible.[2]

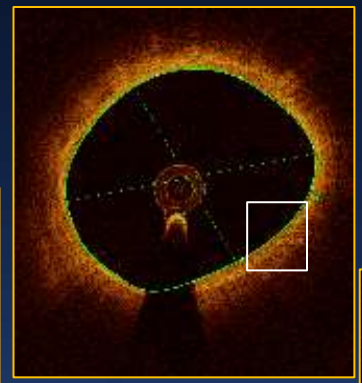
Can the EEL be identified at the distal reference segment to allow vessel diameter measurement?[3]

Yes



Stent diameter decided by OCT measurement of mean EEL to EEL diameter rounded down to nearest stent size[4]

No



Stent diameter decided by OCT measurement of mean lumen diameter rounded up to nearest stent size[4]

Stent length determined by OCT automation adjusted for Xience DES[5]

Summary #7 | Detailed automated algorithms to guide stent implantation may further improve outcomes with PCI

Byrne, R.A. | TCTAP 2021 Virtual

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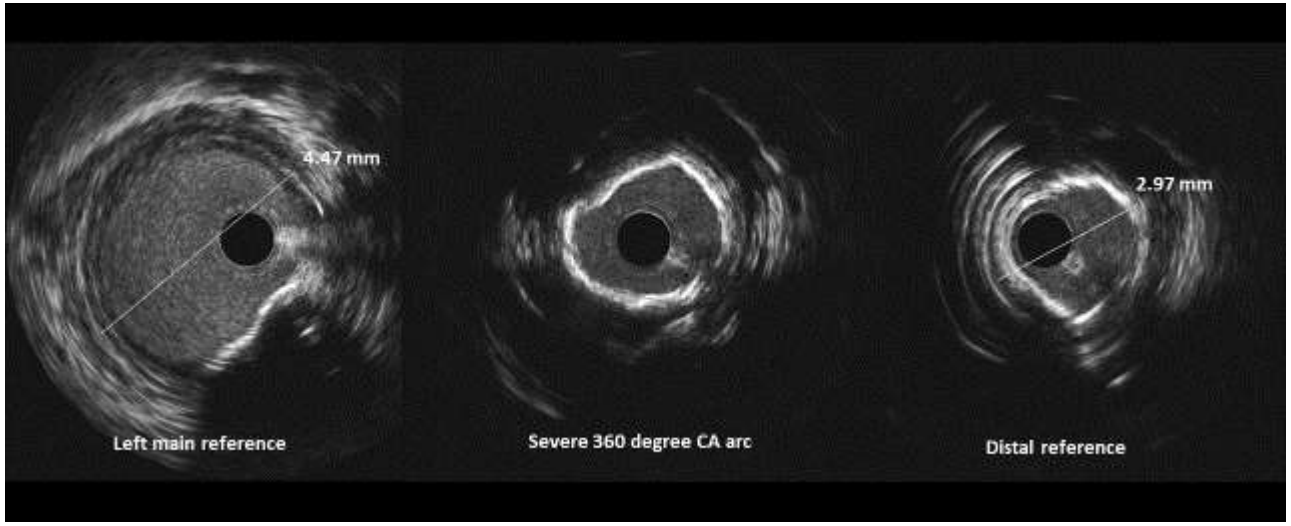
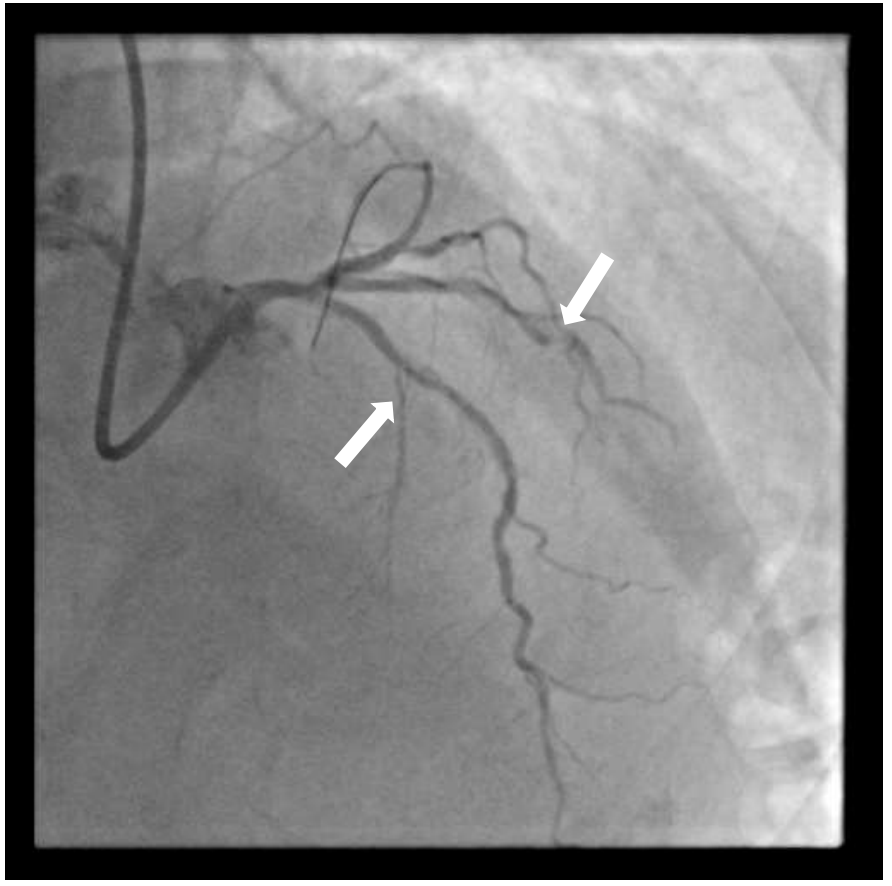
Case history (I)

72-year old male with stable angina (CCS II-III) & hs Troponin <14 pg/ml





New onset, typical angina pectoris since 07/20

Coronary angiography > severe calcific 3-VD with LMS# and preserved LV function

ISCHEMIA Trial data suggest risks/benefits of revascularization and modality of choice should be assessed offline incl. MDT

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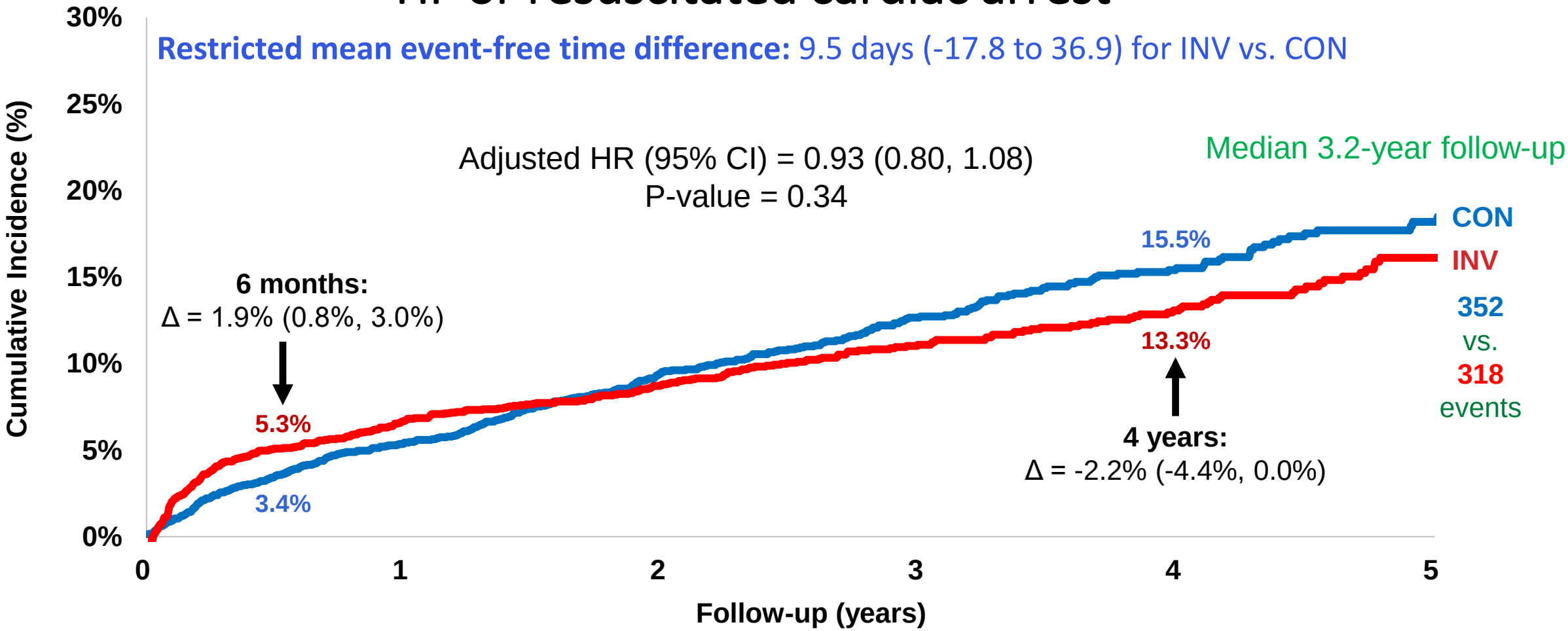
Primary Outcome: CV Death, MI, hospitalization for UA, HF or resuscitated cardiac arrest



No signal of differential mortality with either INV or CON approach

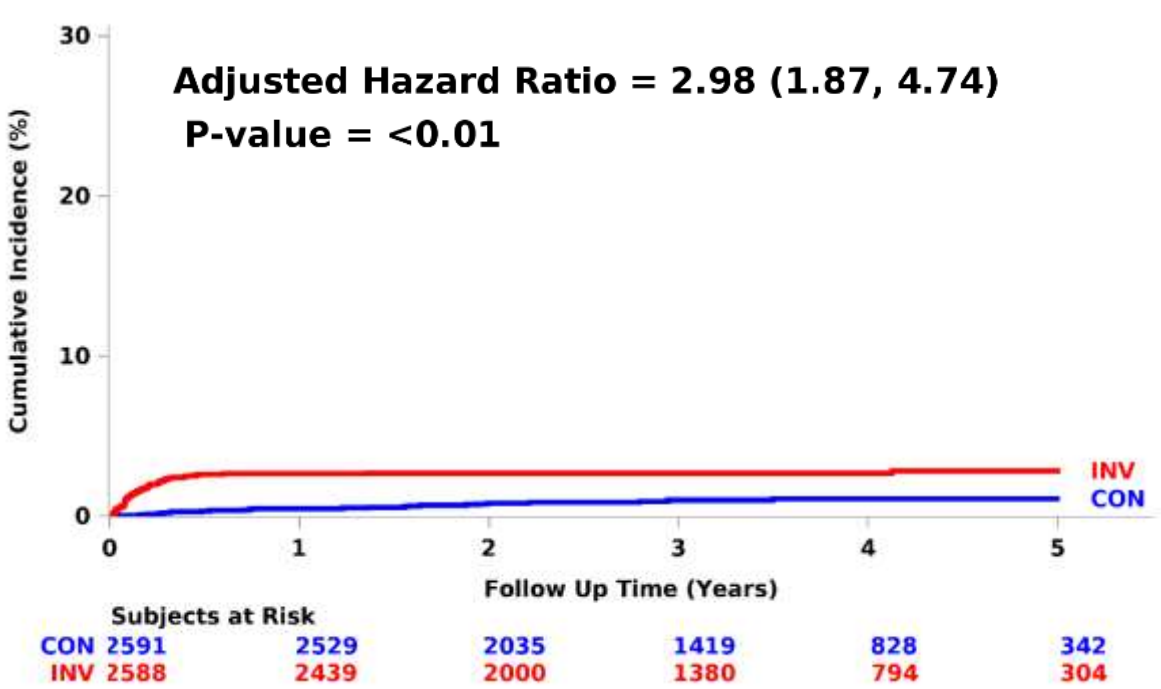
Maron DJ et al. N Engl J Med. 2020;382:1395-1407

ISCHEMIA

Myocardial Infarction

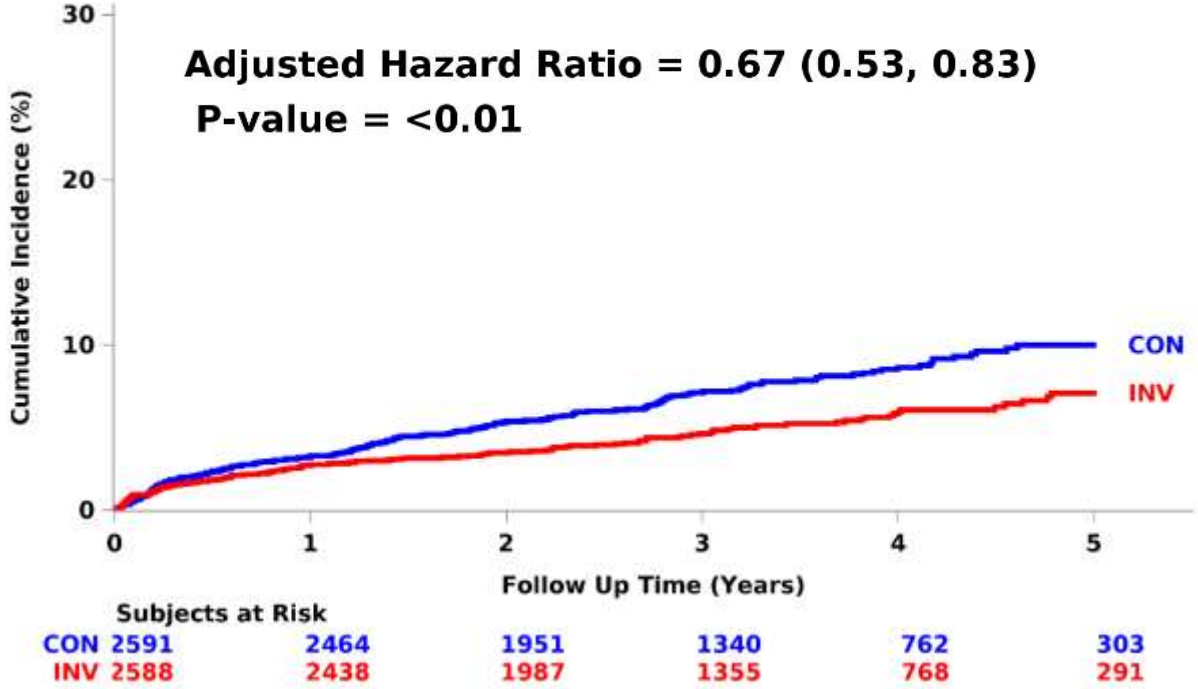
Procedural MI

Types 4a or 5 MI



Non-procedural MI

Types 1, 2, 4b, or 4c MI

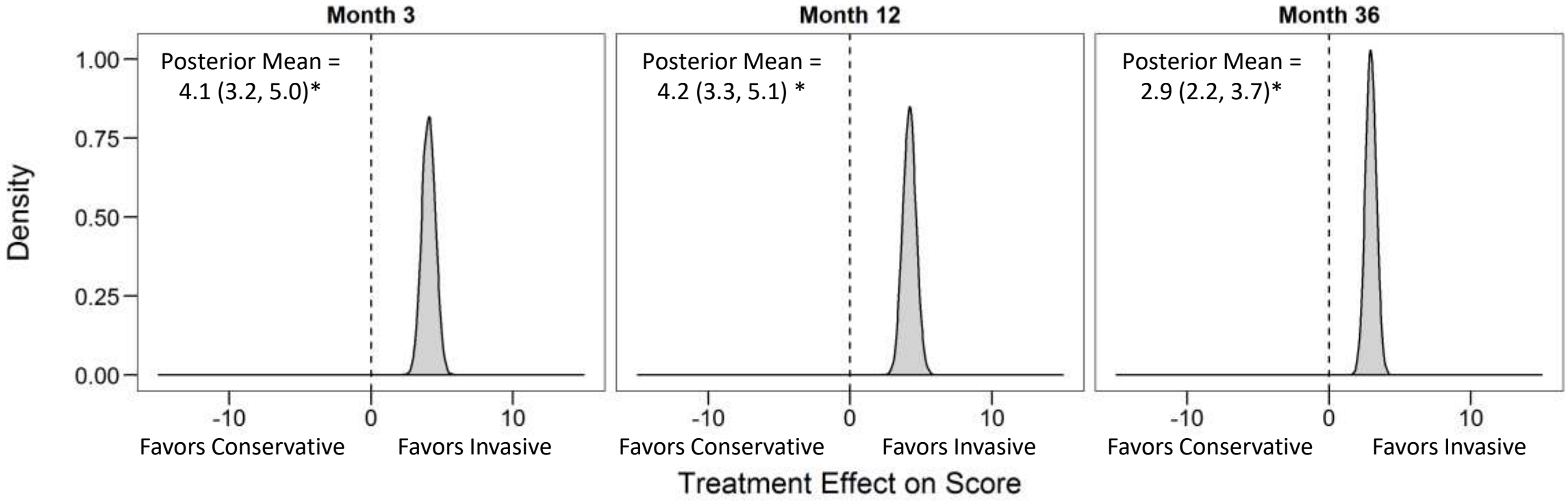


Maron DJ et al. N Engl J Med. 2020;382:1395-1407

ISCHEMIA

QOL Primary Outcome: Benefit of Invasive Rx on SAQ Summary Score

Typical Patient in ISCHEMIA



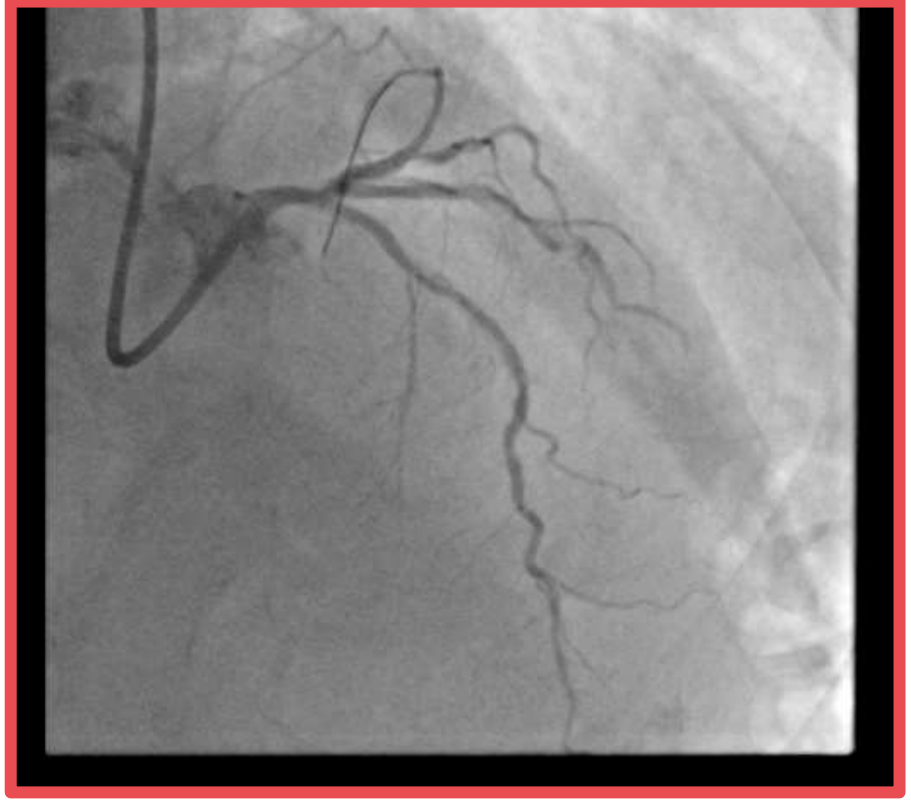
**95% Highest Posterior Density Interval*

Spertus JA et al. N Engl J Med. 2020;382:1408-1419

ISCHEMIA

Shared Decision Making (II)

OMT only



OMT + Revascularization

Following discussion at MDT and shared decision making appraoch a consensus was reached for OMT + PCI

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ISCHEMIA Trial: It Will Change My Practice

- The primary findings of ISCHEMIA provide a rationale for shared decision making between patient and physician with respect to initial management strategy based on:
  - Symptom burden and quality of life
  - Reduction in spontaneous myocardial infarction
  - Life expectancy of patient (in view of time dependency of risks)
  - Absence of signal of mortality difference between groups

- Ischaemia burden in isolation does not provided a good basis for decisions regarding revascularization

Summary #8 | Shared decision making for PCI should be on based on symptom burden, quality of life & risk of MI

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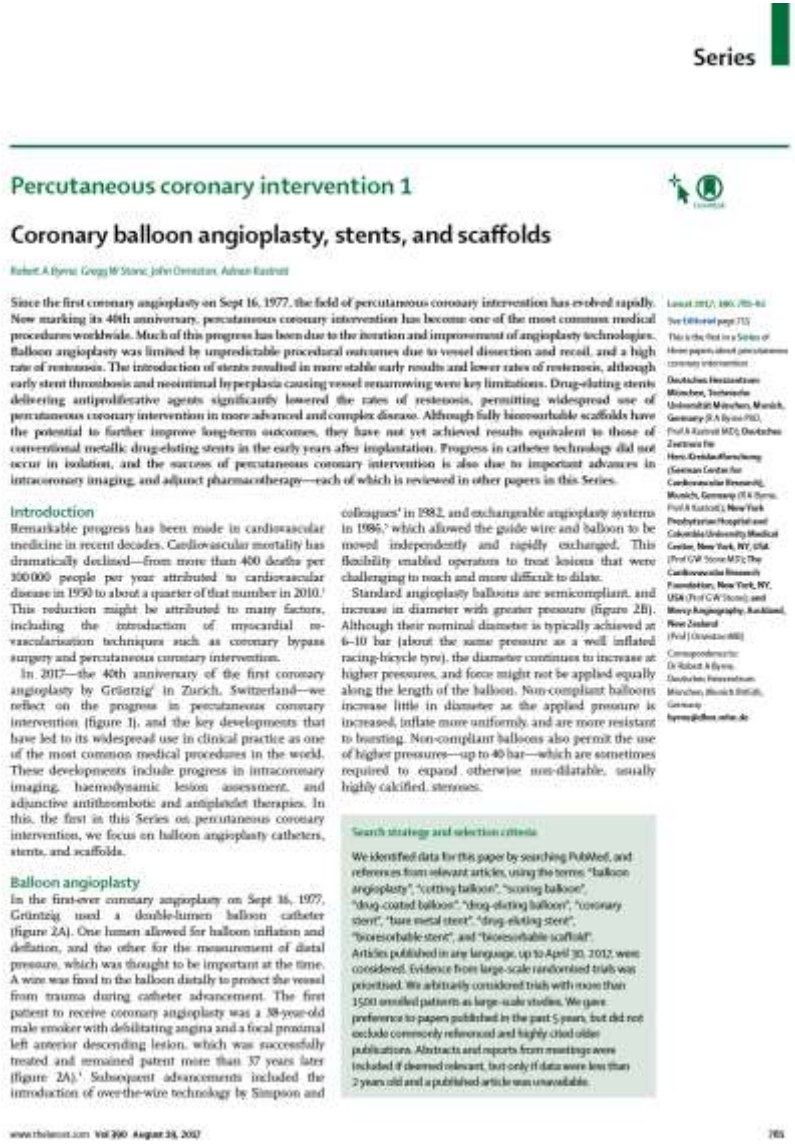
PCI: Contemporary Optimal Indication, Technology, & Outlook | Summary

- The introduction of stents and effective antiplatelet treatment were critical to ensure stable and reproducible results after PCI
- High-efficacy DES and better techniques for lesion preparation facilitated expansion of PCI to more complex disease patterns though areas of unmet clinical need persist e.g. in patient with diabetes mellitus
- The concept of bioresorbable scaffold therapy remains valid and further iteration and clinical testing is warranted
- Drug-coated balloon therapy shows promise in de novo disease but further clinical investiagtion is required
- Automated intravascular imaging and/or pressure wire algorithms to guide stent implantation may further improve outcomes with PCI
- Shared decision making for PCI should be on based on symptom burden, quality of life and future risk of spontaneous MI

Further reading…

Acknowledgements:
Maria Schlumpf



Series

Percutaneous coronary intervention 1

Coronary balloon angioplasty, stents, and scaffolds

Robert A Byrne, Gregg W Stone, John Ormiston, Adnan Kastrati

Since the first coronary angioplasty on Sept 16, 1977, the field of percutaneous coronary intervention has evolved rapidly. Now marking its 40th anniversary, percutaneous coronary intervention has become one of the most common medical procedures worldwide. Much of this progress has been due to the iteration and improvement of angioplasty technologies. Balloon angioplasty was limited by unpredictable procedural outcomes due to vessel dissection and recoil, and a high rate of restenosis. The introduction of stents resulted in more stable early results and lower rates of restenosis, although early stent thrombosis and neointimal hyperplasia causing vessel renarrowing were key limitations. Drug-eluting stents delivering antiproliferative agents significantly lowered the rates of restenosis, permitting widespread use of percutaneous coronary intervention in more advanced and complex disease. Although fully bioresorbable scaffolds have the potential to further improve long-term outcomes, they have not yet achieved results equivalent to those of conventional metallic drug-eluting stents in the early years after implantation. Progress in catheter technology did not occur in isolation, and the success of percutaneous coronary intervention is also due to important advances in intracoronary imaging, and adjunct pharmacotherapy—each of which is reviewed in other papers in this Series.

Deutsches Herzzentrum München, Technische Universität München, Munich, Germany (R A Byrne MD, Prof A Kastrati MD); Deutsches Zentrum für Herz-Kreislauf-Forschung (German Centre for Cardiovascular Research), Munich, Germany (R A Byrne, Prof A Kastrati); New York Presbyterian Hospital and Columbia University Medical Center, New York, NY, USA (Prof G W Stone MD); The Cardiovascular Research Foundation, New York, NY, USA (Prof G W Stone); and Mercy Angiography, Auckland, New Zealand (Prof J Ormiston MD)

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byrne@dhm.mhn.de

Lancet 2017; 390: 781–92
See Editorial page 713
This is the first in a Series of three papers about percutaneous coronary intervention

Introduction

Remarkable progress has been made in cardiovascular medicine in recent decades. Cardiovascular mortality has dramatically declined—from more than 400 deaths per 100 000 people per year attributed to cardiovascular disease in 1950 to about a quarter of that number in 2010.[1] This reduction might be attributed to many factors, including the introduction of myocardial revascularisation techniques such as coronary bypass surgery and percutaneous coronary intervention.

In 2017—the 40th anniversary of the first coronary angioplasty by Grüntzig[2] in Zurich, Switzerland—we reflect on the progress in percutaneous coronary intervention (figure 1), and the key developments that have led to its widespread use in clinical practice as one of the most common medical procedures in the world. These developments include progress in intracoronary imaging, haemodynamic lesion assessment, and adjunctive antithrombotic and antiplatelet therapies. In this, the first in this Series on percutaneous coronary intervention, we focus on balloon angioplasty catheters, stents, and scaffolds.

Balloon angioplasty

In the first-ever coronary angioplasty on Sept 16, 1977, Grüntzig used a double-lumen balloon catheter (figure 2A). One lumen allowed for balloon inflation and deflation, and the other for the measurement of distal pressure, which was thought to be important at the time. A wire was fixed to the balloon distally to protect the vessel from trauma during catheter advancement. The first patient to receive coronary angioplasty was a 38-year-old male smoker with debilitating angina and a focal proximal left anterior descending lesion, which was successfully treated and remained patent more than 37 years later (figure 2A).[3] Subsequent advancements included the introduction of over-the-wire technology by Simpson and colleagues[4] in 1982, and exchangeable angioplasty systems in 1986,[5] which allowed the guide wire and balloon to be moved independently and rapidly exchanged. This flexibility enabled operators to treat lesions that were challenging to reach and more difficult to dilate.

Standard angioplasty balloons are semicompliant, and increase in diameter with greater pressure (figure 2B). Although their nominal diameter is typically achieved at 6–10 bar (about the same pressure as a well inflated racing-bicycle tyre), the diameter continues to increase at higher pressures, and force might not be applied equally along the length of the balloon. Non-compliant balloons increase little in diameter as the applied pressure is increased, inflate more uniformly, and are more resistant to bursting. Non-compliant balloons also permit the use of higher pressures—up to 40 bar—which are sometimes required to expand otherwise non-dilatable, usually highly calcified, stenoses.

Search strategy and selection criteria

We identified data for this paper by searching PubMed, and references from relevant articles, using the terms "balloon angioplasty", "cutting balloon", "scoring balloon", "drug-coated balloon", "drug-eluting balloon", "coronary stent", "bare metal stent", "drug-eluting stent", "bioresorbable stent", and "bioresorbable scaffold". Articles published in any language, up to April 30, 2017, were considered. Evidence from large-scale randomised trials was prioritised. We arbitrarily considered trials with more than 1500 enrolled patients as large-scale studies. We gave preference to papers published in the past 5 years, but did not exclude commonly referenced and highly cited older publications. Abstracts and reports from meetings were included if deemed relevant, but only if data were less than 2 years old and a published article was unavailable.

Byrne, Stone, Ormiston, Kastrati | Lancet 2017

EuroIntervention 2017;13:10–12
DOI: 10.4244/EIJV13I1A2

40 YEARS OF ANGIOPLASTY | PCR

His master's art, Andreas Grüntzig's approach to performing and teaching coronary angioplasty

Bernhard Meier*, MD
University Hospital of Bern, Bern, Switzerland

This paper also includes supplementary data published online at: http://www.pcronline.com/eurointervention/13th_issue/2

Performing coronary angioplasty

Andreas Roland Grüntzig (1939–1985) was an accomplished clinician and an astute scientist. He was also a practical man endowed with dexterity, smartness, and common sense. For him, performing a catheter intervention in contrast to surgery was like playing the clarinet in contrast to playing the piano. It was easier but it still required talent and proper training to become a professional. Playing the piano means using all ten fingers at the same time and having 88 keys to choose from for every single finger, not to mention the simultaneous work on the foot pedals. A clarinet also requires the use of all ten fingers but each finger has just a single (exceptionally up to five) allotted function. Clarinet players may forgive my not mentioning the importance of the mouthpiece. The analogy is just to make a point. The cardiac surgeon works three-dimensionally with every stitch, every cut, and every suture having to meet quality requirements and representing his or her level of art. Performing a catheter intervention, on the other hand, only permits one to advance, retract, turn right, or turn left, one, two, or at the most three different instruments at a time. Yet, while the surgeon has a true three-dimensional field of vision, a catheter operator has to imagine the third dimension looking at a two-dimensional black and white picture. The surgeon approaches things directly and one millimetre (mm) of motion equals 1 mm of effect. The catheter operator has to account for a time delay of his motion and a five centimetre movement at his end of the catheter may well translate into no or just a very small movement at the other end of the catheter inside the patient. Video gaming may come close to what an operator experiences during catheter interventions. Grüntzig, living before the video game era, trained with catheters on the kitchen table and started performing his intervention in the leg where inaccuracy and imperfection were more forgivable and less dangerous.

While working in the leg, it was convenient to use a torquable guidewire with a J-tip to steer away from obstacles and to target the right direction in bifurcations. Grüntzig had to give that up when he turned to coronary angioplasty[2]. In the small catheter shaft required for coronary work, technology at the time did not allow a through lumen for a steerable guidewire and at the same time two additional lumina, one for balloon filling and one for distal pressure measurements. Fluoroscopy visibility at the time was so poor (**Figure 1**) that it was mandatory to guide the procedure by distal pressure measurements (**Figure 2**). Instead of a steerable guidewire, a short wire stub attached at the tip of the catheter had to be accepted as a compromise (**Figure 3**). The original balloon was quite compliant and ruptured at about 6 bar. Other than that, and in spite of the lack of steerability, this balloon could still be used nowadays for simple proximal lesions.

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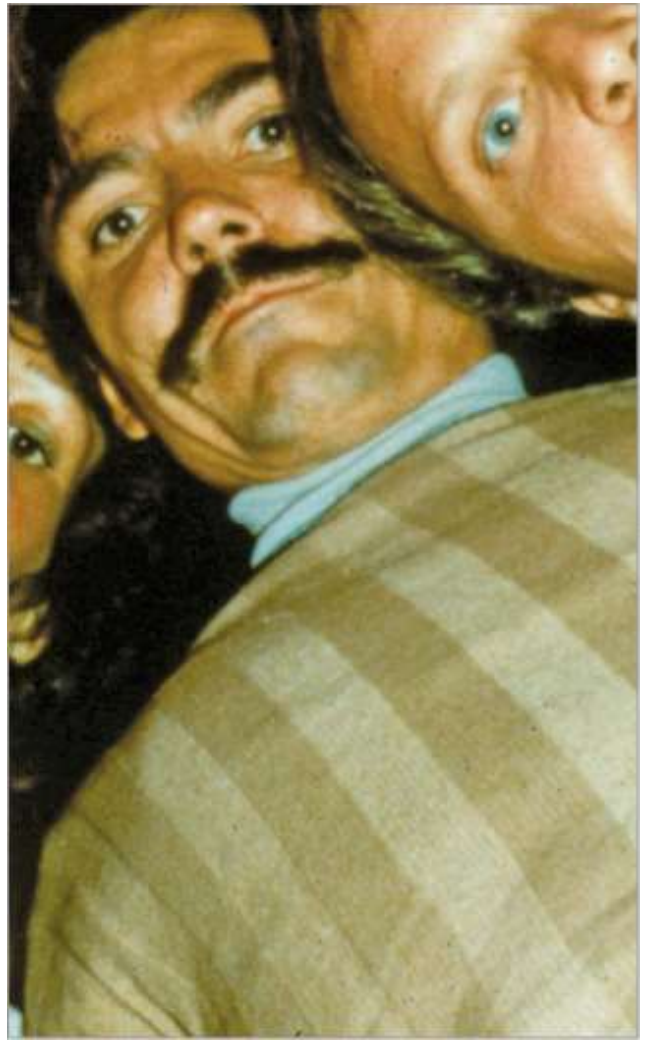
Meier | EuroIntervention 2017



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Thank You For Your Attention

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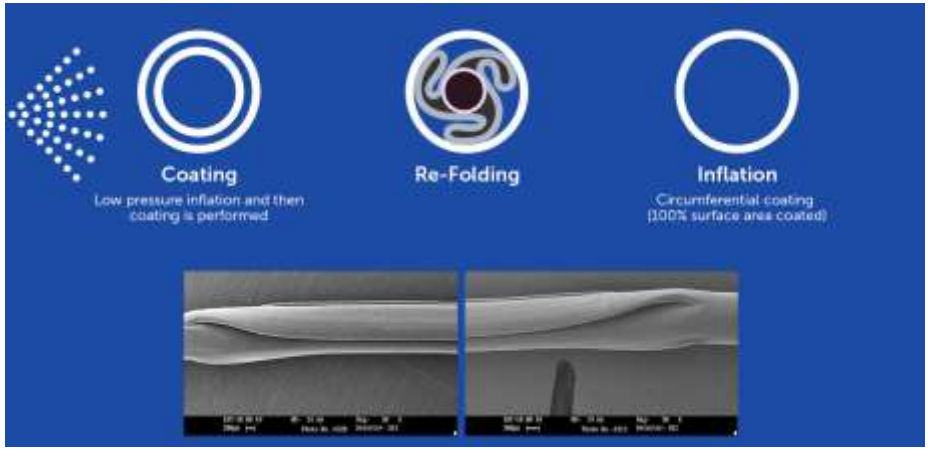
Update on LIMUS DCB Development

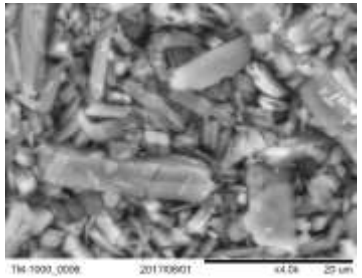
Further progress with sirolimus-coated balloon technology

Magic Touch folded SCB



SELUTION SLR SCB receives CE mark

Biolimus-A9-coated balloon enters clinical testing



SEB receives FDA breakthrough for CAD ISR + BTK

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Byrne, R.A. | TCT 2019

A Brief 40-Year History of PCI

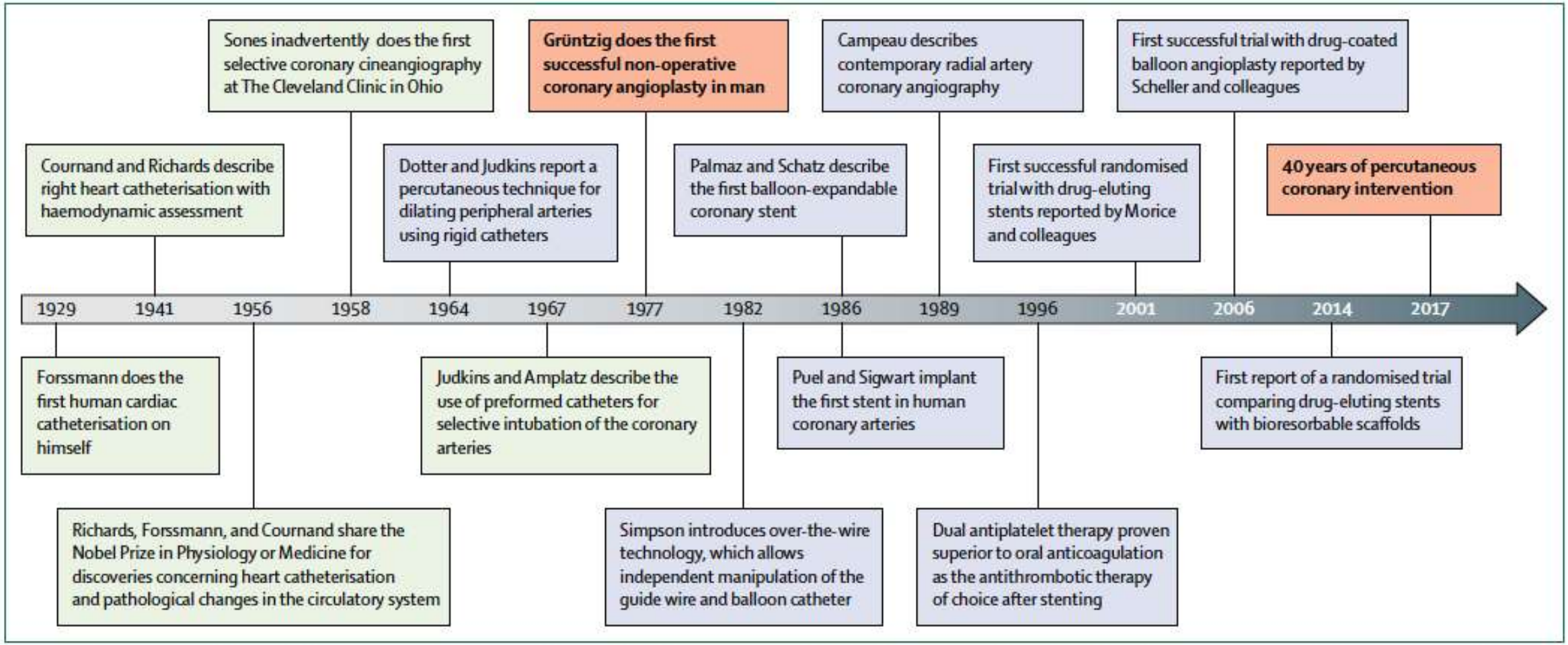
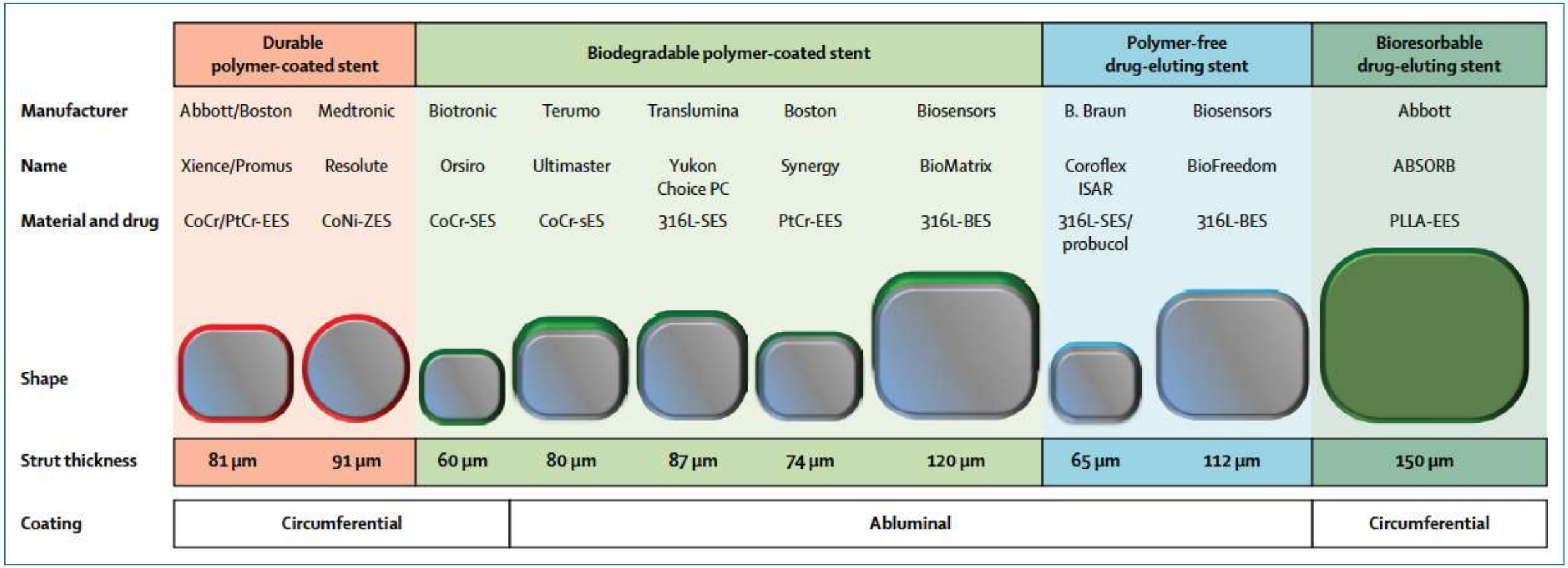


Figure 1: **Timeline of diagnostic cardiac catheterisation, coronary balloon angioplasty, stent, and scaffold implantation as contributors to improvements in freedom from cardiovascular death**
Developments in diagnostic catheterisation are shown in green, coronary angioplasty in red, and catheter therapeutics in blue. References to support milestones are provided in the appendix.

Byrne, Stone, Ormiston, Kastrati | Lancet 2017

Drug-eluting stents: breakthrough technology

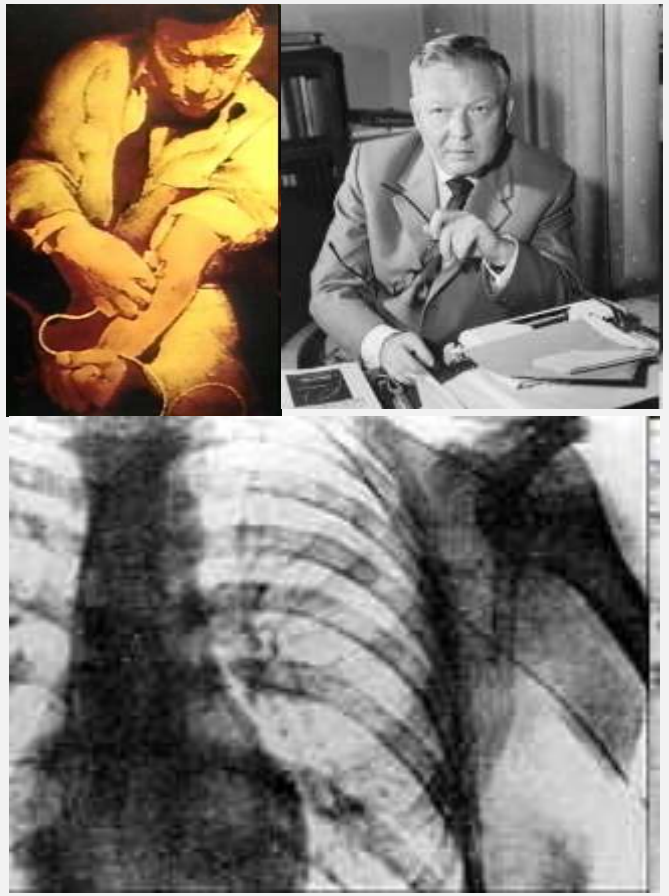
Selected devices with CE-mark approval and published large-sclae RCT data



Byrne, Stone, Ormiston, Kastrati | Lancet 2017

Standing on the shoulders of giants…

Forssmann | Feb. 1929



Sones | Oct 30, 1958

Dotter | Jan. 16, 1964

Byrne | 40 Years of Angioplasty: Remembering Patients and Pioneers | EuroIntervention 2017

2. Lesion preparation with cutting/scoring balloons improves efficacy

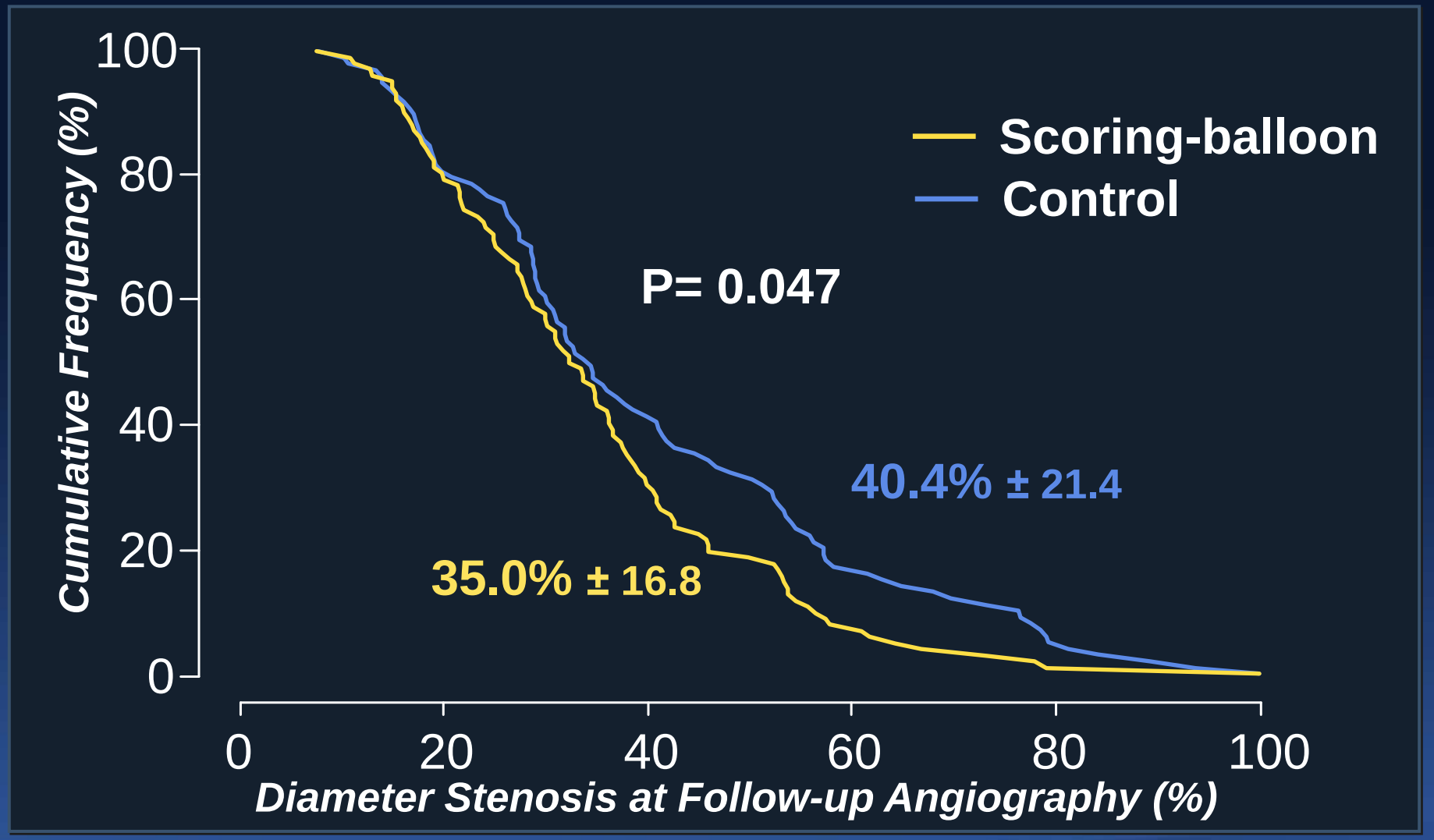
ISAR-DESIRE 4 Trial

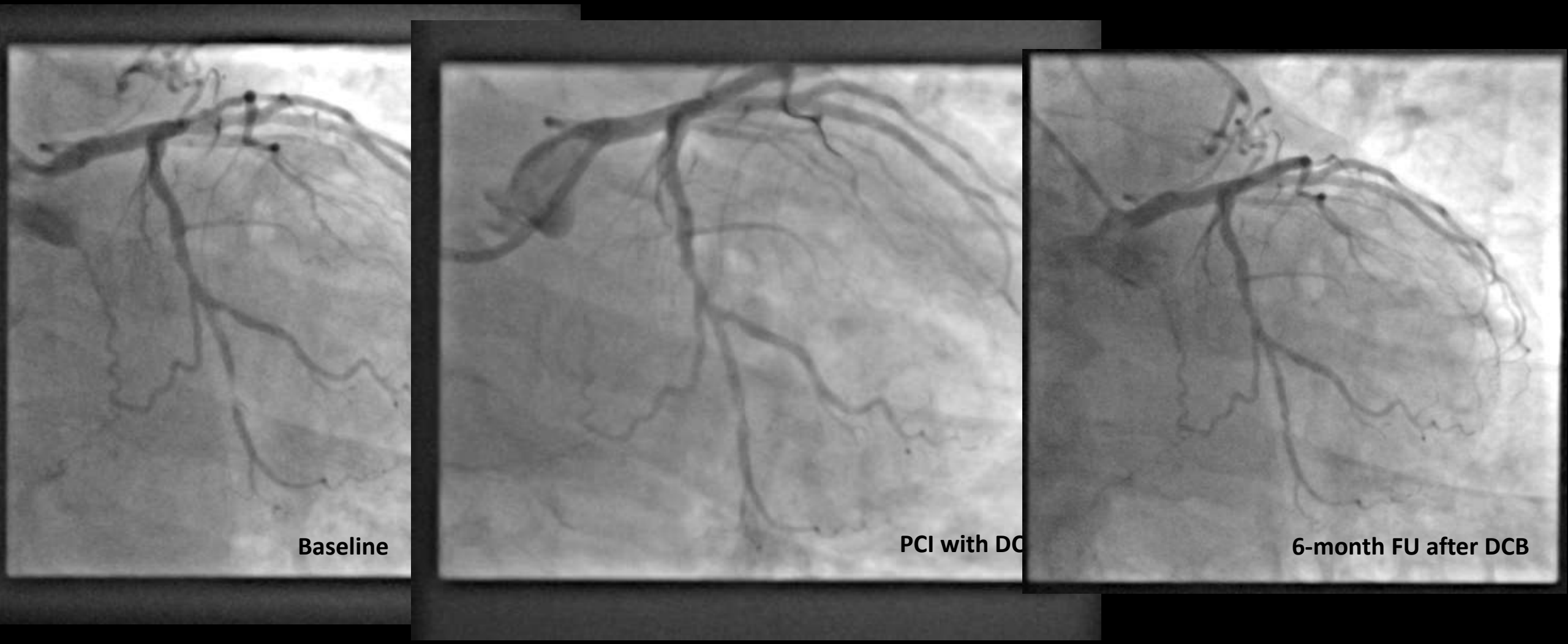
252 patients with DES-restenosis enrolled between June 2012 and December 2014 in 4 centers in Germany

- Scoring balloon plus paclitaxel-coated balloon (N=125)
- Standard balloon plus paclitaxel-coated balloon (N=127)

Angiographic follow-up at 6-8 months in 80.4% (N=203)*

Diameter Stenosis at Follow-up Angiography




Baseline
PCI with DC
6-month FU after DCB

ILUMIEN IV: OPTIMAL PCI

2556-3568 pts with high-risk clinical or angiographic features undergoing PCI at 125 centers in the US, Canada, Western Europe, and Asia-Pacific

HR clinical:
Diabetes
HR angio:
Troponin+ ACS culprit
Stent length ≥28 mm
2-stent bifurcation
Severe calcification
CTO
Diffuse/MF ISR

*ESRD not excluded

Randomize 1:1

OCT-guided* PCI (modified ILUMIEN III protocol)

Angiography-guided PCI

Final OCT (blinded in angiography arm)

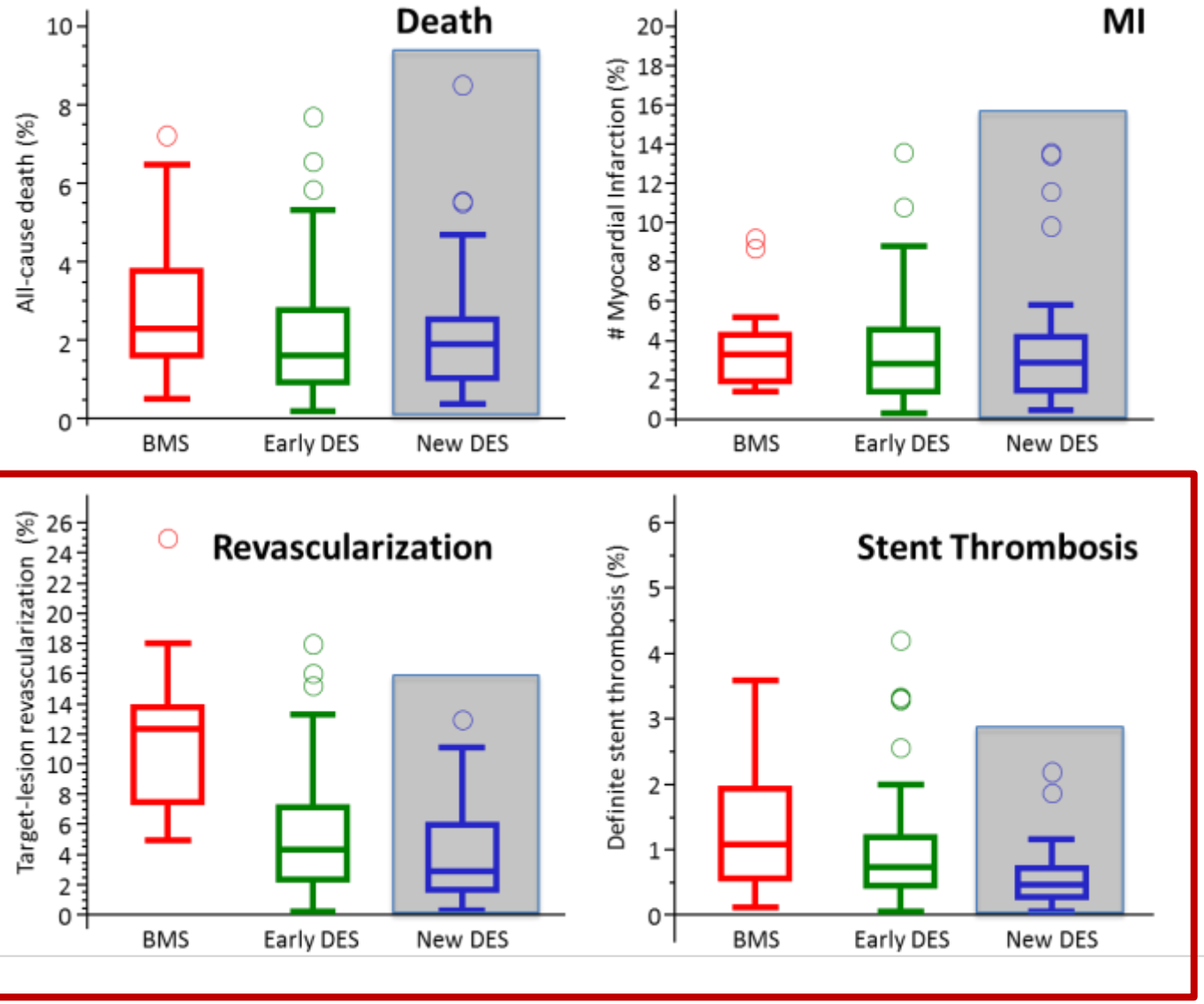
Follow-up: Minimum 1 year, maximum 2 years
Primary endpoints:
1) Minimal stent area (MSA) by OCT (powered for superiority)
2) Target vessel failure (event-driven, powered for superiority)
Principal Investigators: Ziad Ali and Ulf Landmesser
Study Chair: Gregg W. Stone

Cardiovascular Research Foundation

Sponsor: Abbott

Systematic review of 158 RCTs

ESC
European Society of Cardiology



Systematic review of 158 RCTs | ESC-EAPCI Stent Task Force | *Eur Heart J* 2015