HOT TOPICS IN CARDIOLOGIA 2024

27 e 28 Novembre

Università degli studi di Napoli Parthenope
Villa Doria D'Angri - Via F. Petrarca 80,
Napoli

Presidente del congresso: Dr. Ciro Mauro

VIII SESSIONE: SINDROME CORONARICA CRONICA

Lettura magistrale

Guida ad una corretta scelta dello stent medicato

Prof Giuseppe M Sangiorgi

Responsabile UOS Emodinamica – Policlinico «Tor Vergata», Roma

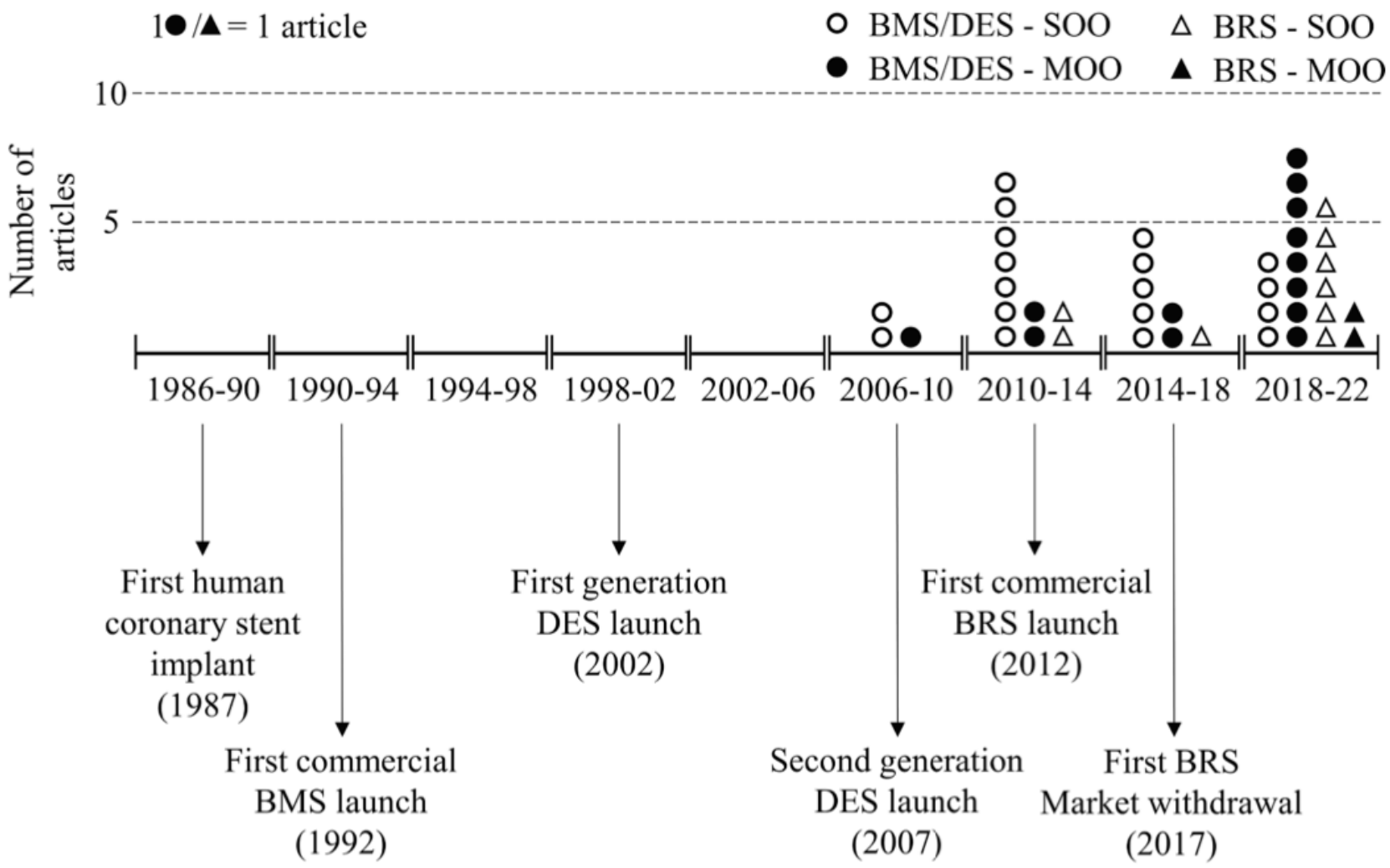
Prof Associato di Cardiologia – Dipartimento di Biomedicina e Prevenzione
Università degli Studi di Roma «Tor Vergata»

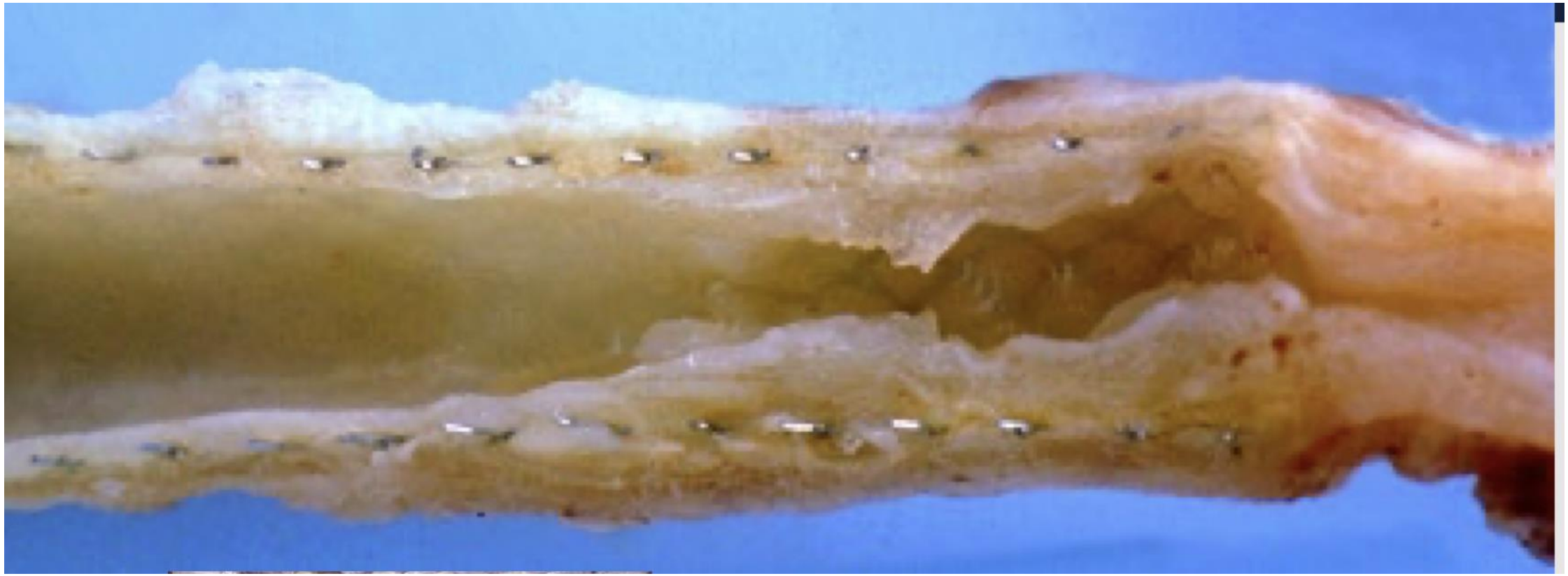
Ciascuno chiama
idee chiare quelle
che sono allo stesso
grado di confusione
delle proprie.
Marcel Proust

Index

- Coronary stents: a long journey
- What to know about stent structure
- Beyond conventional stents: the future is now

Coronary stents: the story





Restenosis after BMS: 20-50%

From BMS to DES

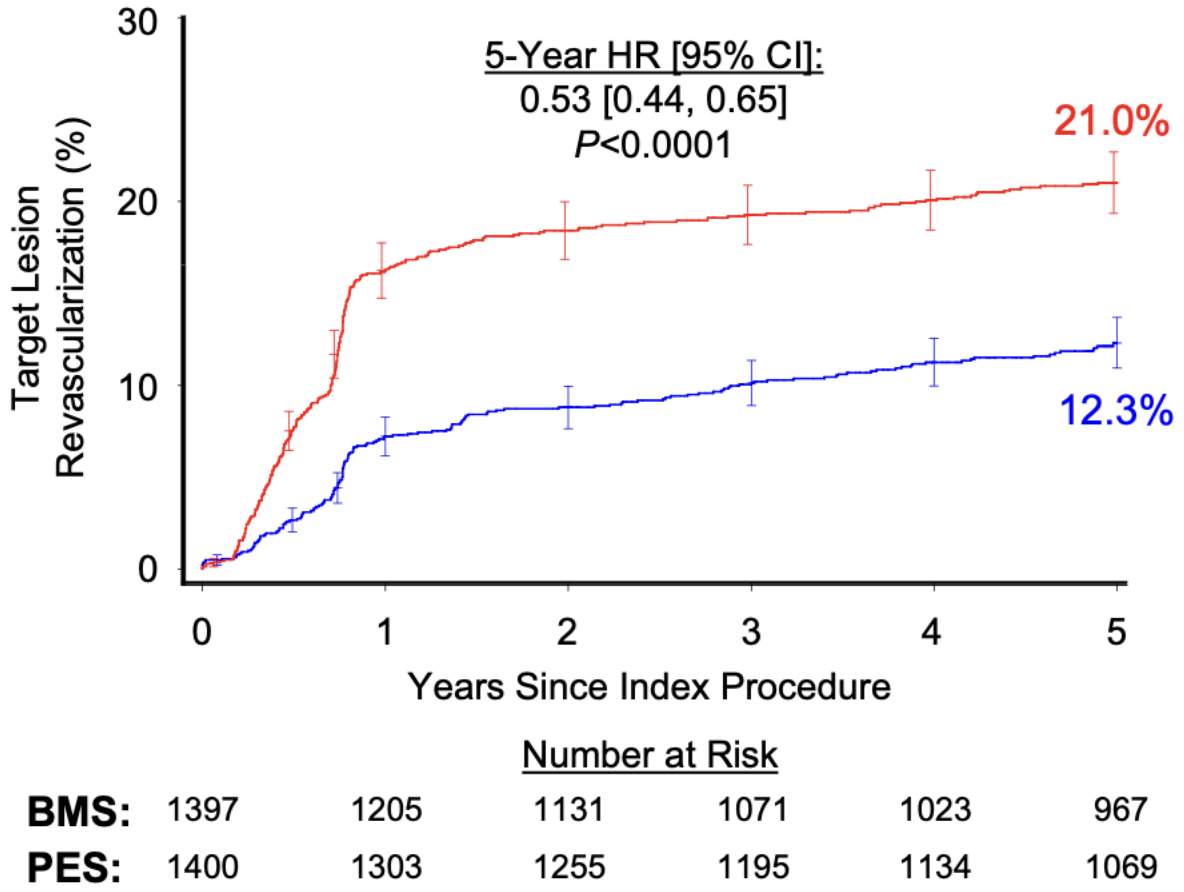
CLINICAL RESEARCH

Long-Term Safety and Efficacy of Paclitaxel-Eluting Stents

Final 5-Year Analysis From the TAXUS Clinical Trial Program

Gregg W. Stone, MD,*† Stephen G. Ellis, MD,‡ Antonio Colombo, MD,§ Eberhard Grube, MD,‖ Jeffrey J. Popma, MD,¶ Takahiro Uchida, MD, PHD,# Jill S. Bleuit, PHD,# Keith D. Dawkins, MD,# Mary E. Russell, MD, PHD#

New York, New York; Cleveland, Ohio; Milan, Italy; Essen, Germany; and Boston and Natick, Massachusetts



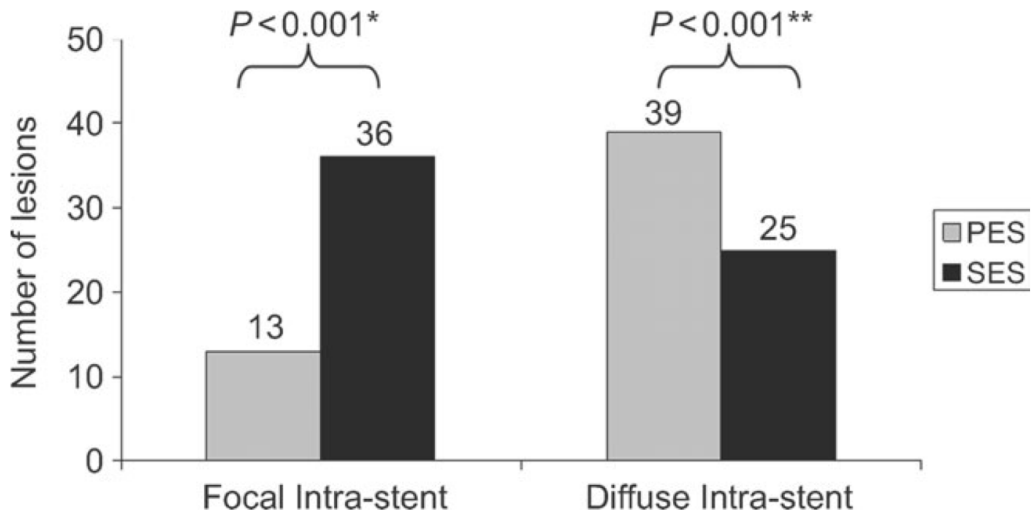
JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 4, NO. 5, 2011
MAY 2011:530–42

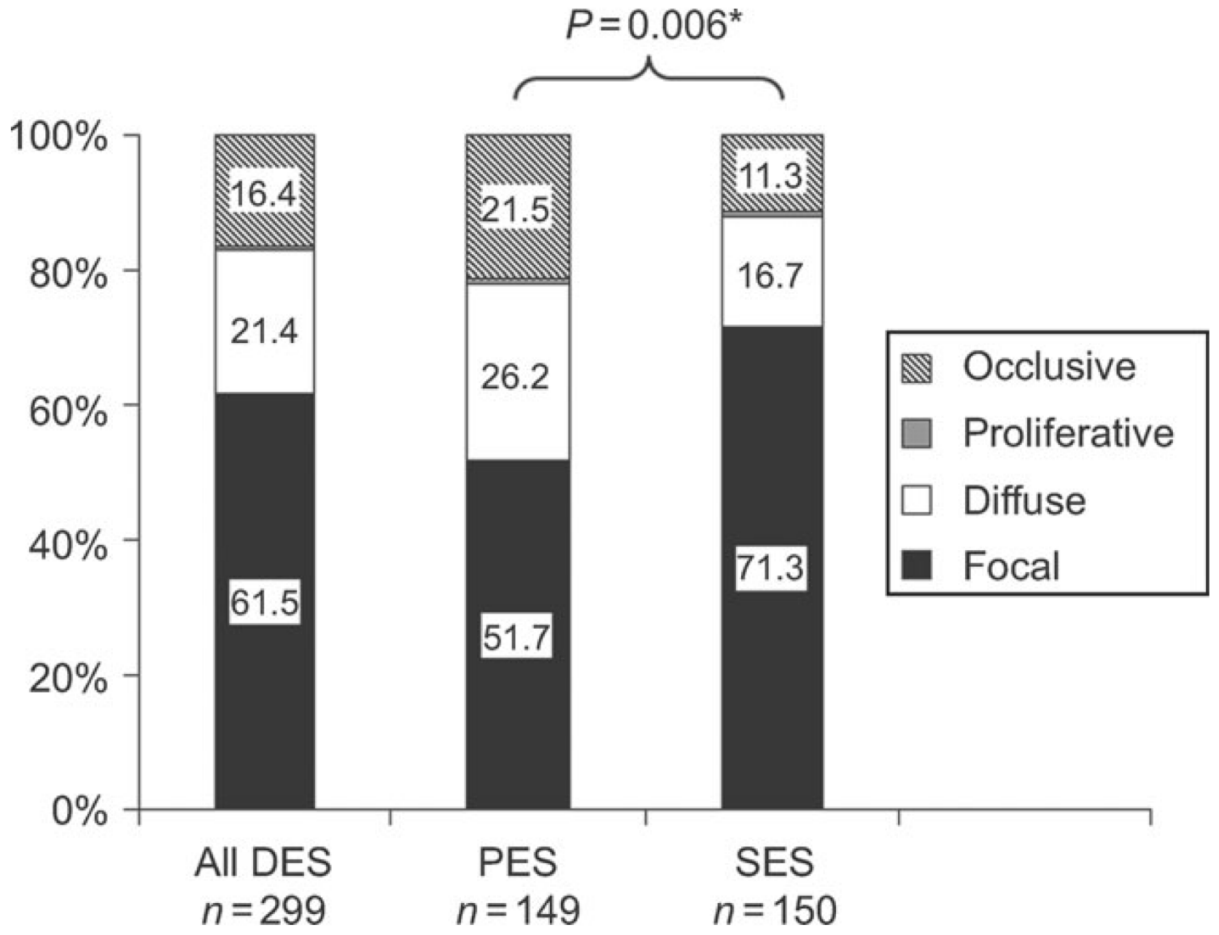
European Heart Journal (2006) 27, 2330–2337
doi:10.1093/eurheartj/ehl229

Patterns of restenosis after drug-eluting stent implantation: insights from a contemporary and comparative analysis of sirolimus- and paclitaxel-eluting stents

Simon J. Corbett[1], John Cosgrave[1], Gloria Melzi[1,2], Rade Babic[1], Giuseppe G.L. Biondi-Zoccai[4], Cosmo Godino[2], Nuccia Morici[2], Flavio Airoldi[1,2], Iassen Michev[1,2], Matteo Montorfano[1,2], Giuseppe M. Sangiorgi[1,2], Erminio Bonizzoni[3], and Antonio Colombo[1,2*]

[1]*EMO Centro Cuore Columbus, 48 Via M. Buonarroti, 20145 Milan, Italy;* [2]*San Raffaele Scientific Institute, Milan, Italy;* [3]*Institute of Medical Statistics and Biometry, Milan, Italy; and* [4]*Abano Terme Hospital, Abano Terme, Italy*





Focal restenosis remains the most common pattern with SES. In contrast, just under half of restenosis in PES is the more severe non-focal pattern. Paradoxically, the majority of focal restenosis occurs at the proximal stent margin for both platforms

Neuroimaging Clin N Am. 2007 August ; 17(3): 285–vii. doi:10.1016/j.nic.2007.03.006.

Pathology of Atherosclerosis and Stenting

Frank D. Kolodgie, PhD, **Gaku Nakazawa, MD**, **Giuseppe Sangiorgi, MD**, **Elena Ladich, MD**, **Allen P. Burke, MD**, and **Renu Virmani, MD**
CVPath Institute, Inc., 19 Firstfield Road, Gaithersburg, MD 20878, Giuseppe Sangiorgi, Emo Centro Cuore Columbus, via buonarroti 48, 20145 Milan, tel.+39.02.4812920

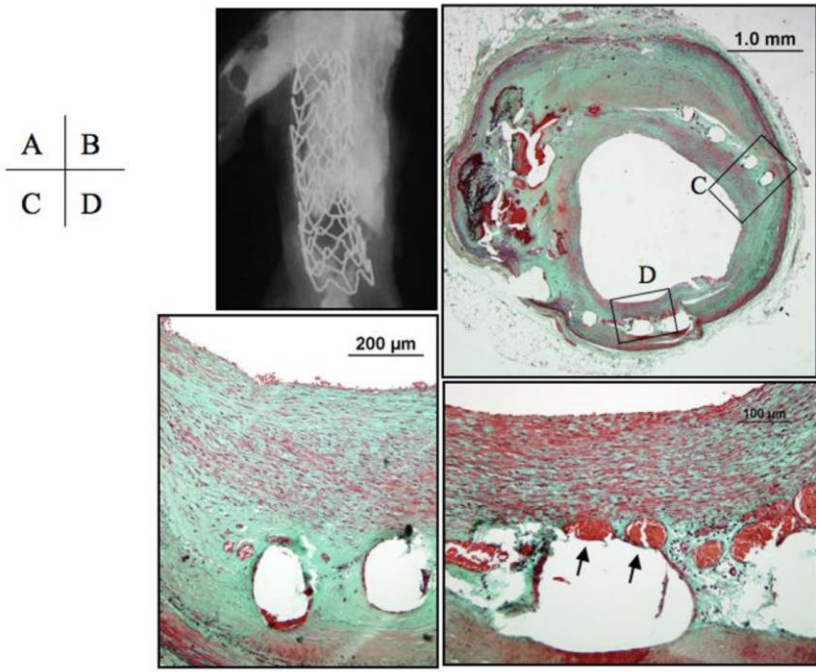


Figure 6. Bare metal stent in coronary artery at 7 months after implantation

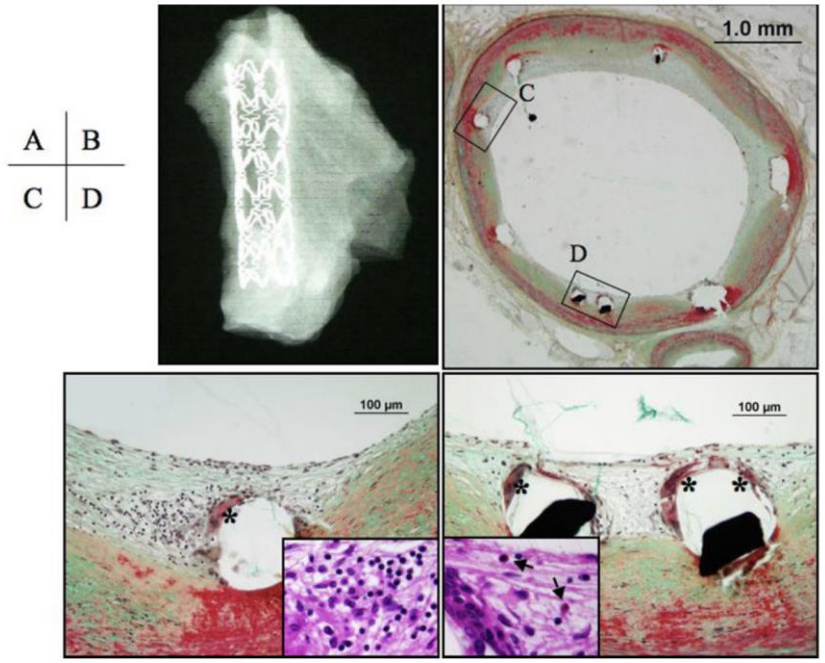


Figure 7. Drug-eluting coronary Cypher™ stent at 4 months after implantation

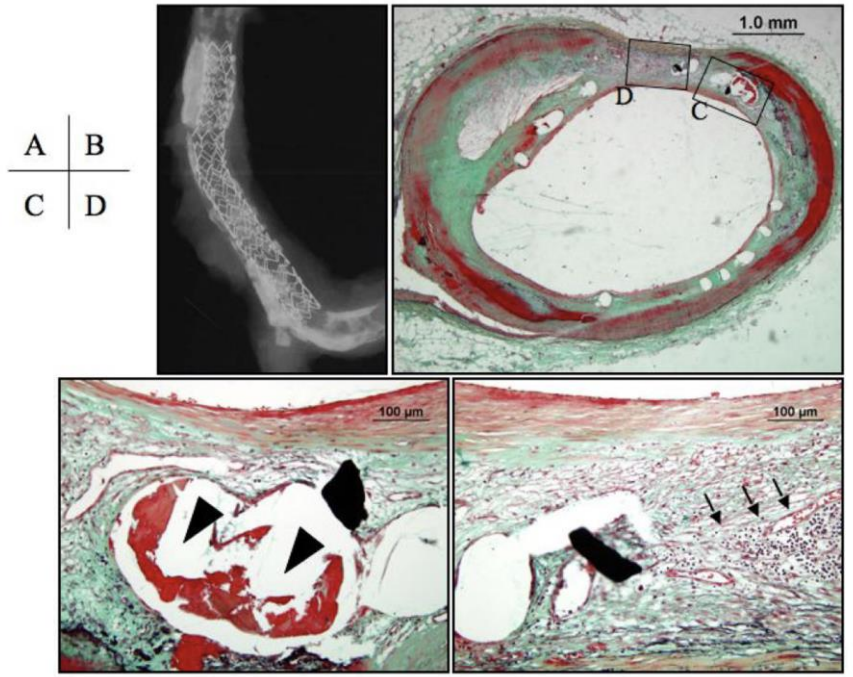
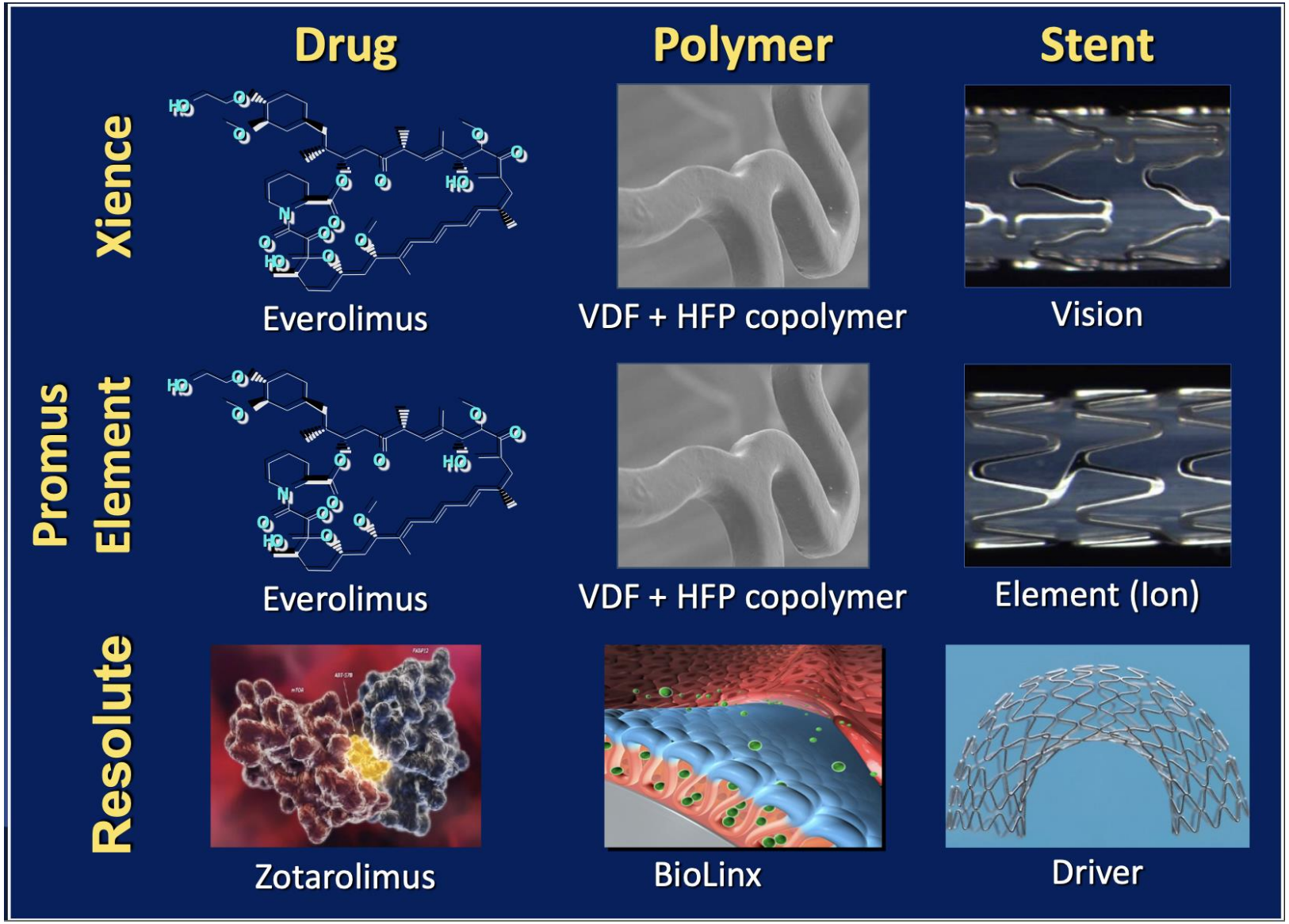
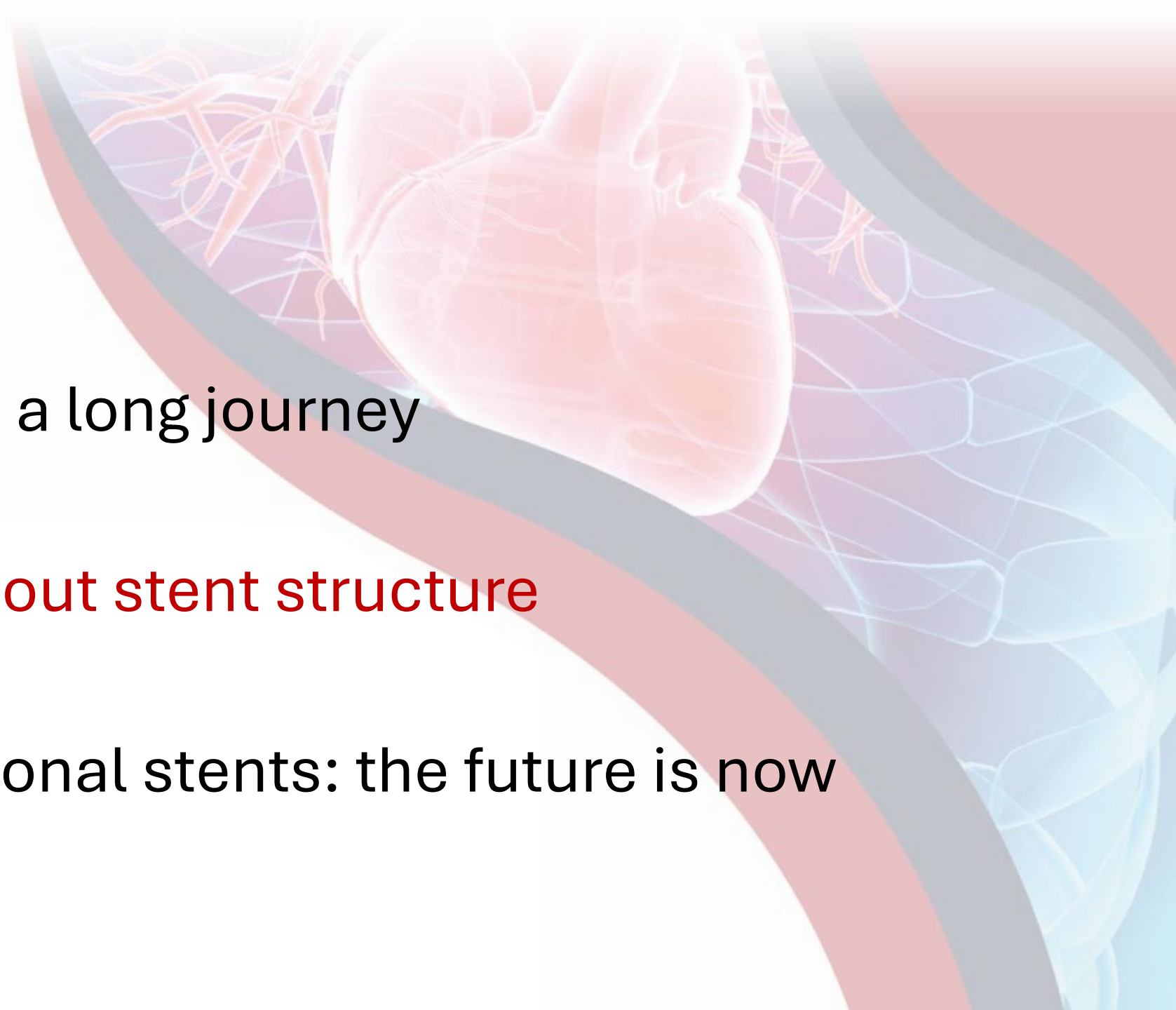


Figure 8. Drug-eluting coronary Taxus™ stent at 7 months after implantation

2° generation DES to overcome the limitations



Index



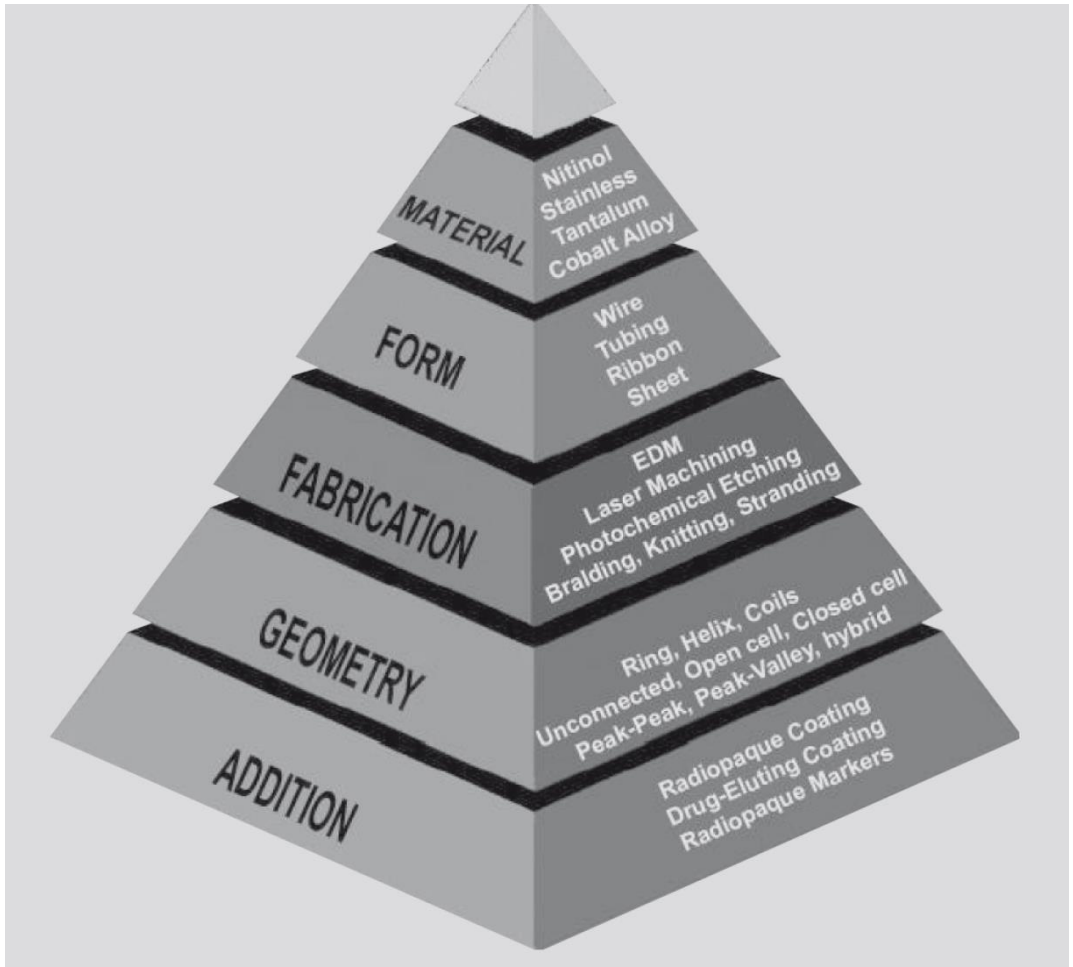
- Coronary stents: a long journey
- What to know about stent structure
- Beyond conventional stents: the future is now

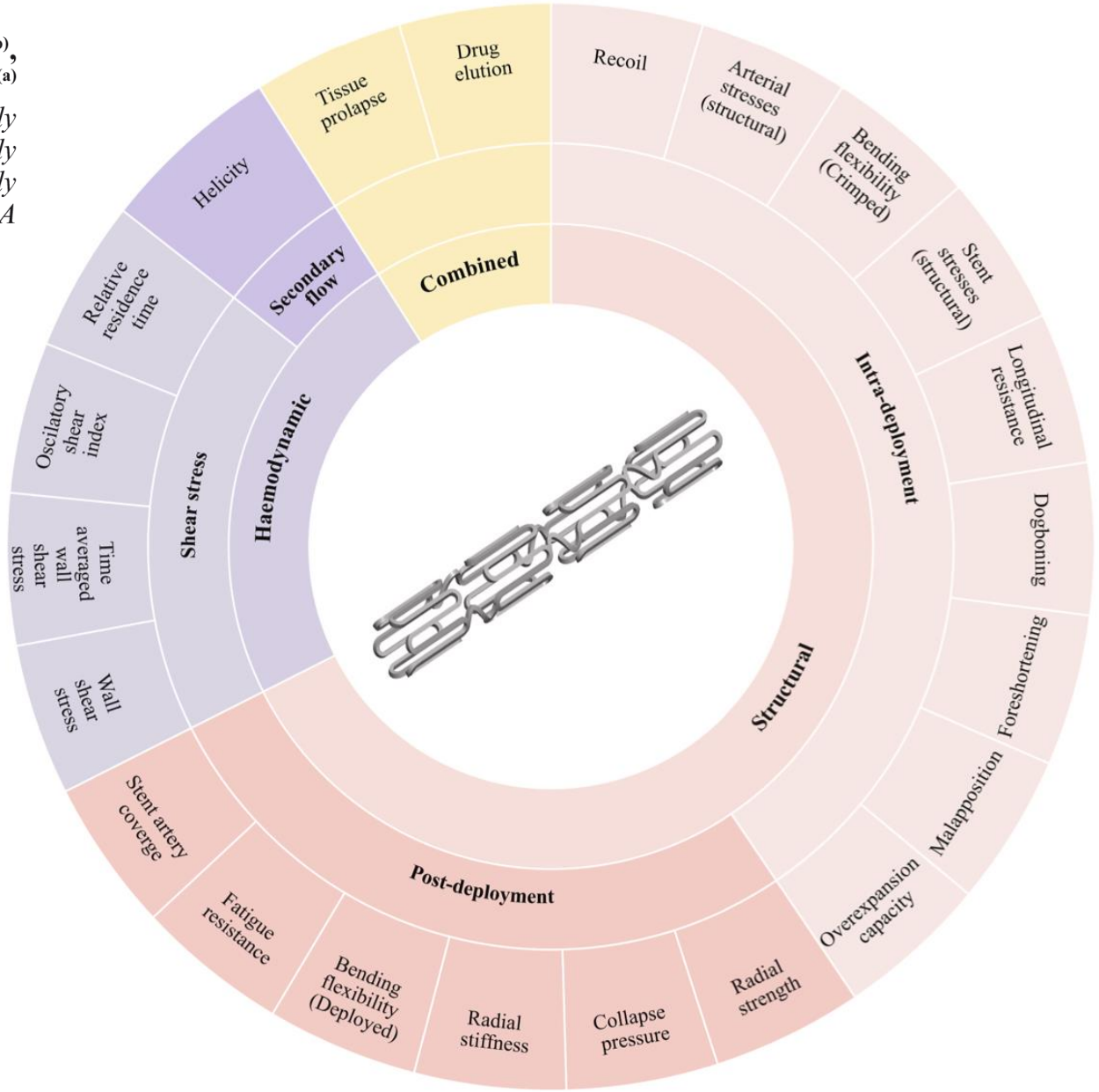
Engineering aspects of stents design and their translation into clinical practice

ANN IST SUPER SANITÀ 2007 | VOL. 43, NO. 1: 89-100

Giuseppe Sangiorgi[a], Gloria Melzi[a], Pierfrancesco Agostoni[a], Clarissa Cola[b], Fabrizio Clementi[b], Paolo Romitelli[c], Renu Birmani[d] and Antonio Colombo[a]

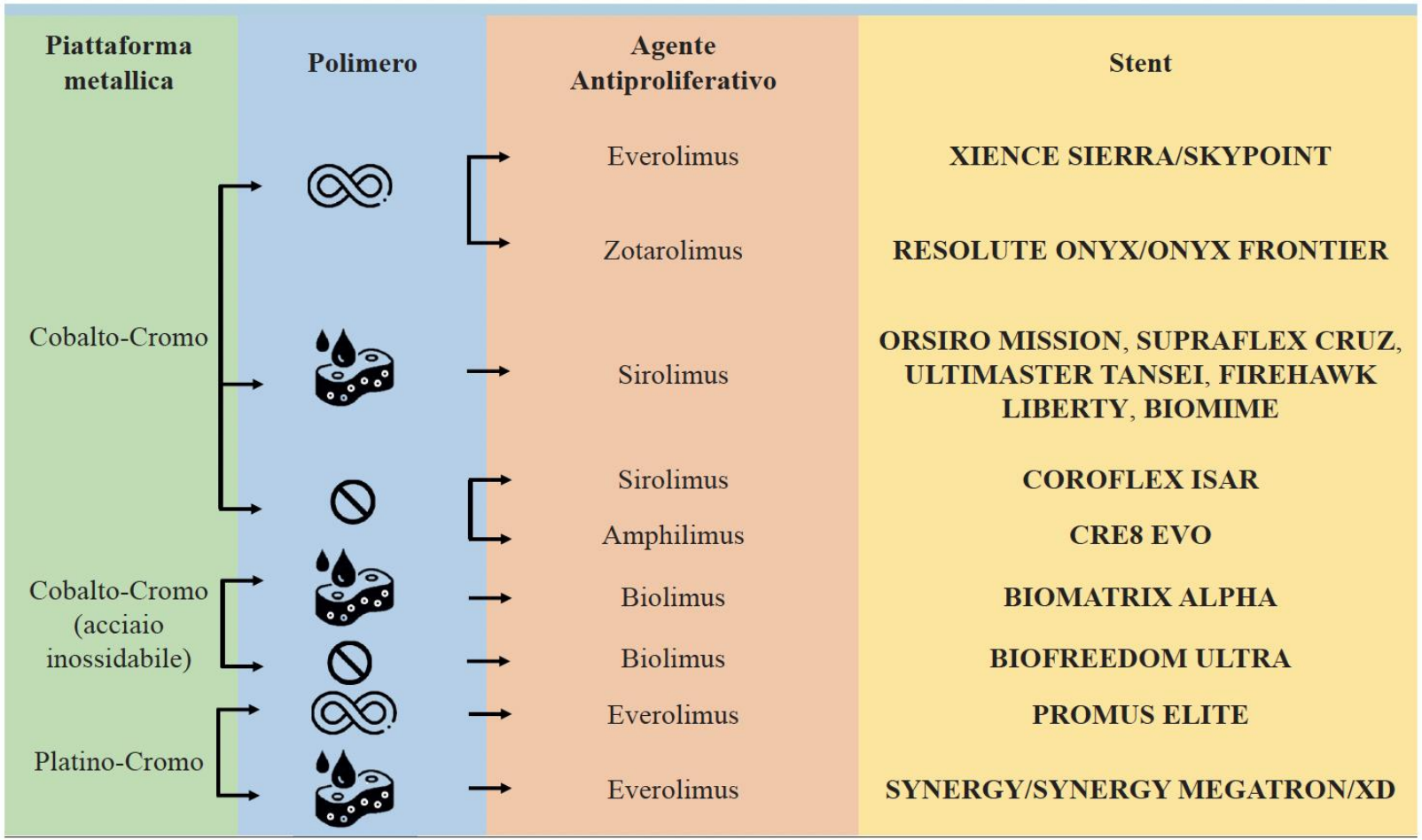
[a] Unità Operativa di Emodinamica, Ospedale San Raffaele, Milan, Italy
[b] Dipartimento di Cardiologia, Università di Roma Tor Vergata, Rome, Italy
[c] Divisione Vascolare, Medtronic Italia, Milan, Italy
[d] CVPath Gaithersburg, Maryland, USA





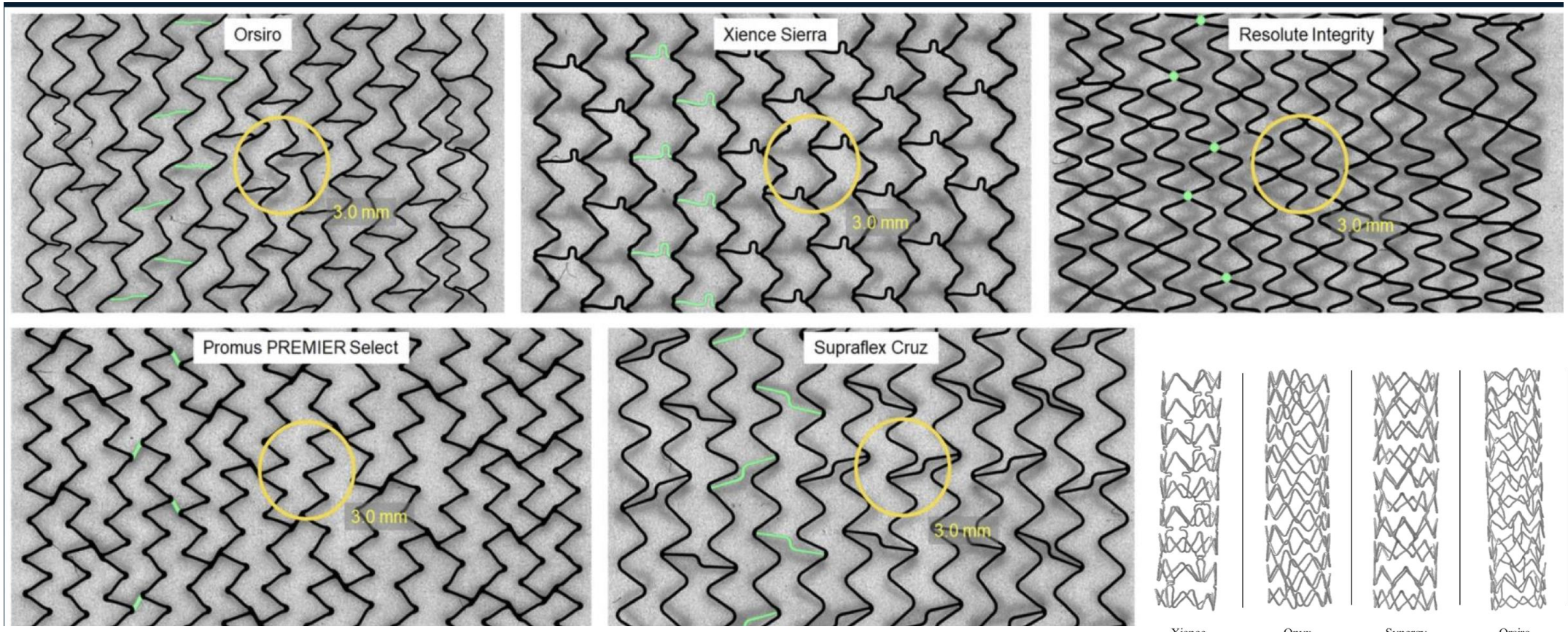
Coronary stent: what to consider?

- Architecture
- Strut thickness
- Polymer
- Expansion capability



G Ital Cardiol 2024

Architecture



Strut thickness

Thinner	Thicker
Increased flexibility	Higher radial force
Easier delivery	Larger strut coverage
Conformability	More plaque containment
Quicker endothelialization	Less recoil
Less side-branch coverage	More symmetrical expansion

POLIMERO FISSO

Xience Xpedition/Sierra/Skypoint (Abbott Medical Italia Srl)

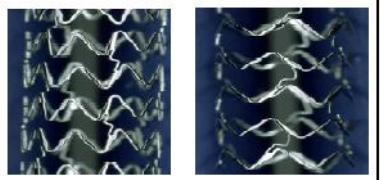
Promus Elite (Boston Scientific SpA)

Resolute Onyx/Onyx Frontier (Medtronic Italia SpA)

SENZA POLIMERO

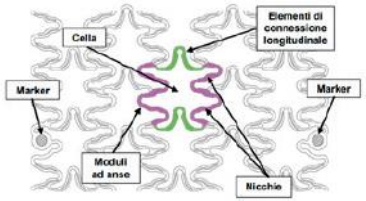
Biofreedom Ultra (Acilia HS Srl)

Corofles Isar NEO (B. Braun Milano SpA)



S L

Cre8 EVO (Cis SpA)

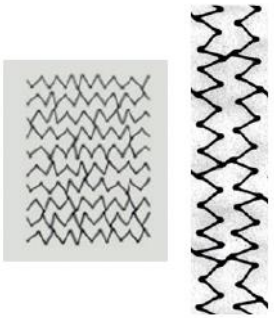


POLIMERO RIASSORBIBILE

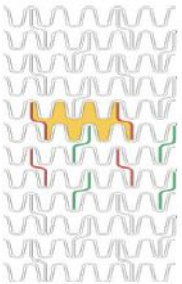
Biomatrix Alpha (Acilia HS Srl)

Orsiro Mission (Biotronik Italia SpA)

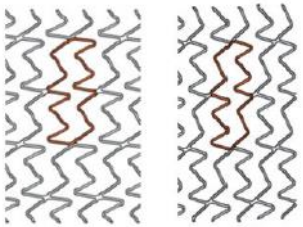
Synergy/Synergy Megatron/XD (Boston Scientific SpA)



Supraflex Cruz (Eukon Srl)

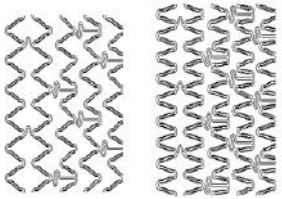


Ultimaster Tansei (Terumo Corp.)



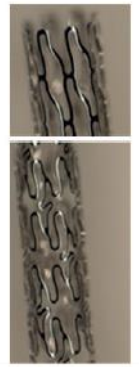
S L

Firehawk Liberty (Microport CRM Srl)



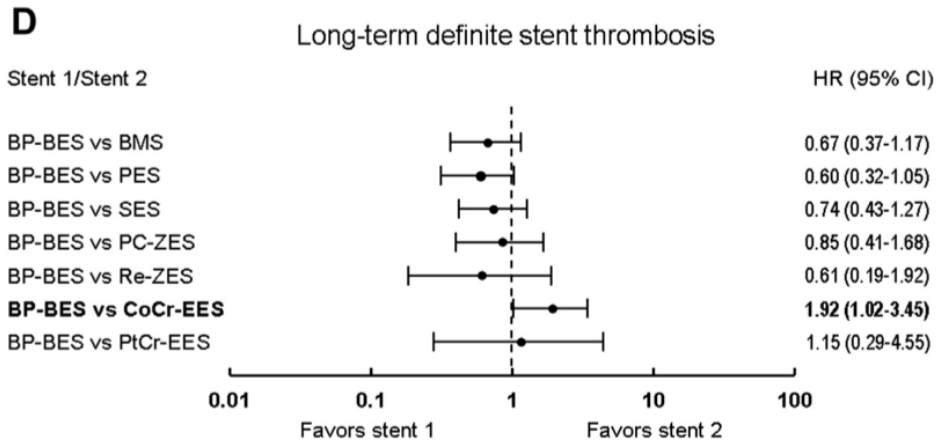
S, M L

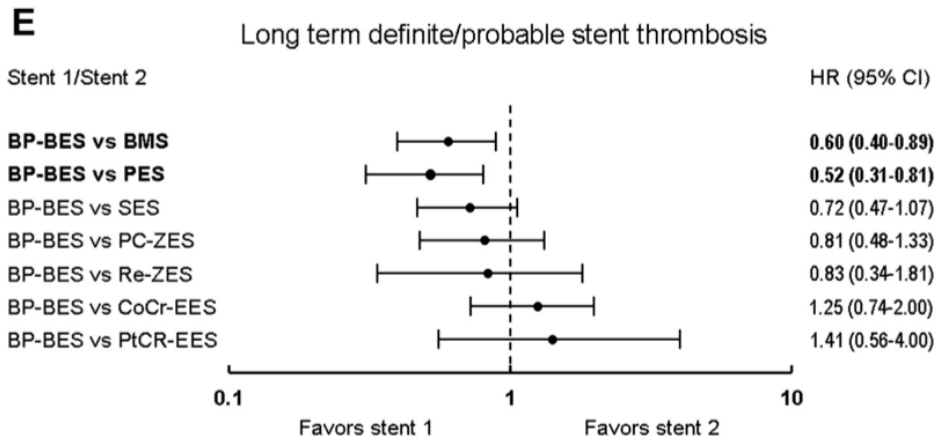
Biomime (Sintec Srl)

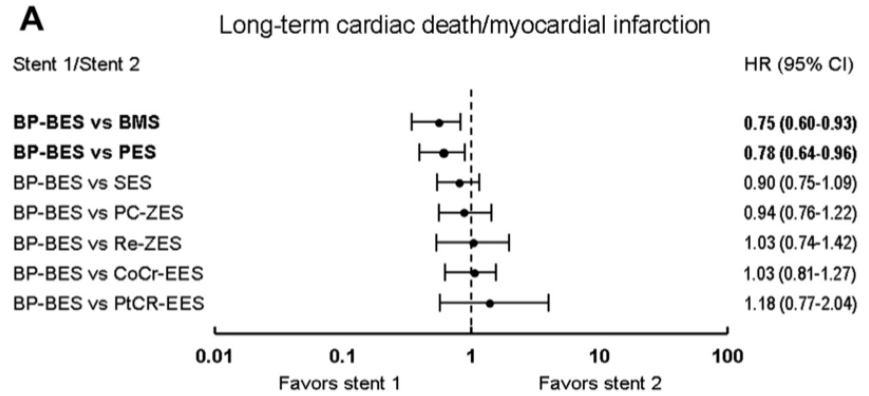


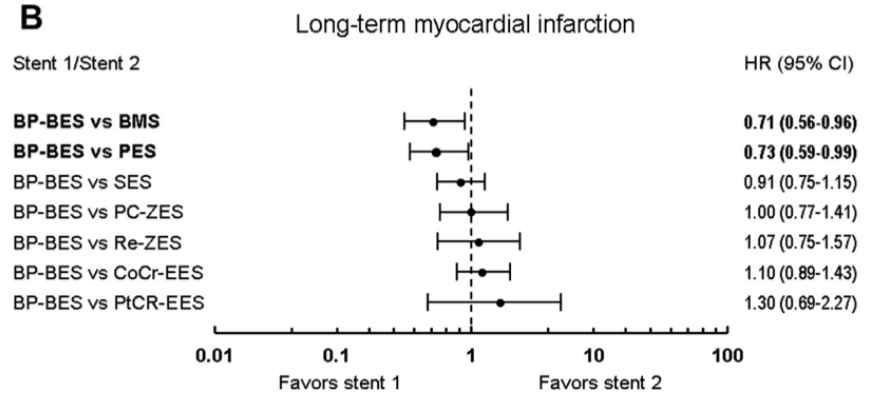
Biodegradable vs Durable Polymer

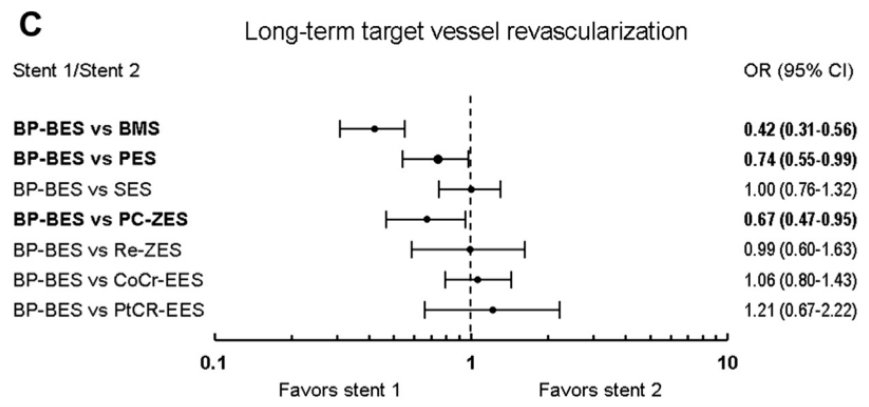
Bioabsorbable Polymer-BES were associated with superior clinical outcomes compared with BMS and 1st-generation DES and similar rates of cardiac death/MI, MI, and TVR compared with second-generation DP-DES but higher rates of def nite ST than CoCr-EES.











Palmerini et al. JACC 2014

Is polymer-free a real benefit?

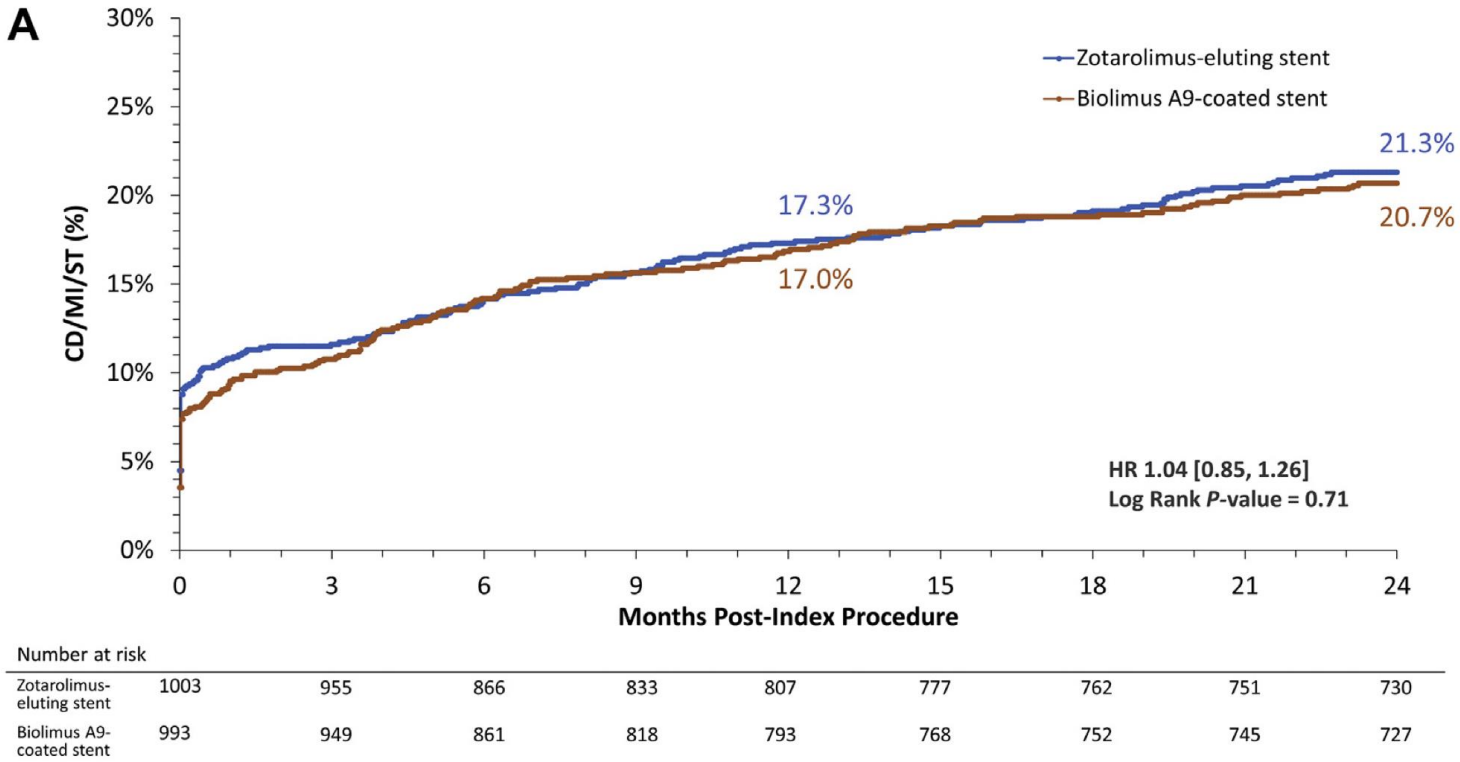
ONYX ONE at 2-y

BioFreedom vs ONYX

1,996 HBR patients

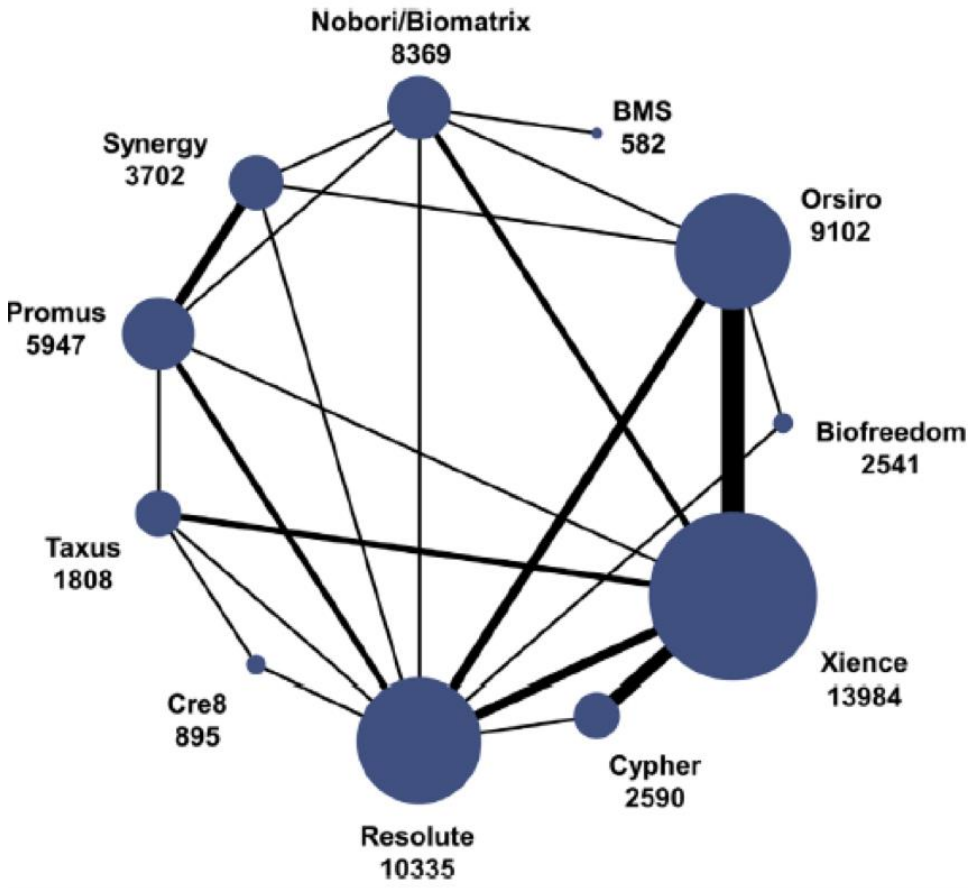
1-month DAPT

Cardiac death, MI or ST



So, what is the best platform?

TLF with current DES

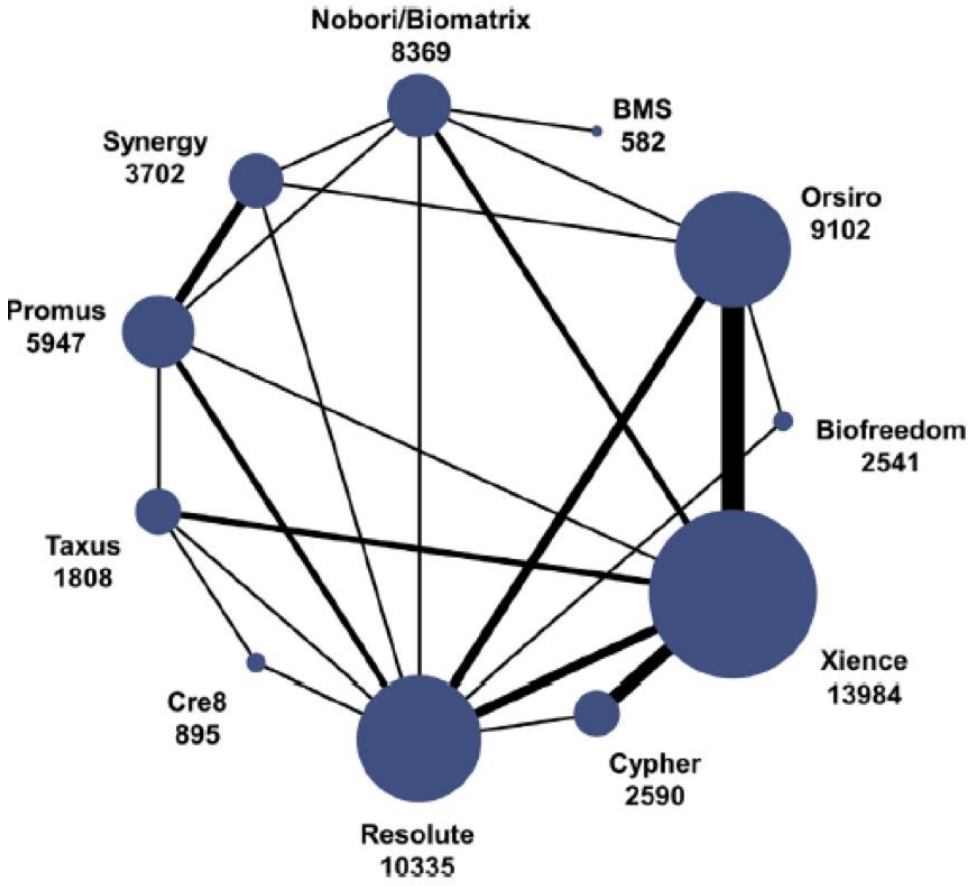


4 Most Common DES:
Orsiro, XIENCE, Nobori/BioMatrix, and Resolute

1-year TLF	OR (95% CI)	P
Orsiro vs.		
- Xience	0.84 (0.71–0.98)	0.03
- Resolute	0.81 (0.68–0.95)	0.01
- Nobori/Biomatrix	0.81 (0.67–0.98)	0.03
Xience vs.		
- Resolute	0.96 (0.83–1.12)	0.63
- Nobori/Biomatrix	0.97 (0.82–1.15)	0.72
Resolute vs.		
- Nobori/Biomatrix	1.01 (0.84–1.20)	0.95
Median 50-months TLF	**OR (95% CI)**	**P**
Orsiro vs.		
- Xience	0.93 (0.80-1.07)	0.29
- Resolute	0.89 (0.76-1.05)	0.18
- Nobori/Biomatrix	0.85 (0.72-1.01)	0.06
Xience vs.		
- Resolute	0.67 (0.84-1.10)	0.54
- Nobori/Biomatrix	0.92 (0.81-1.05)	0.22
Resolute vs.		
- Nobori/Biomatrix	0.96 (0.82-1.12)	0.57

Taglieri N et al. JACC Interv 2020;13:2868–78

ST with current DES



Taglieri N et al. JACC Interv 2020;13:2868–78

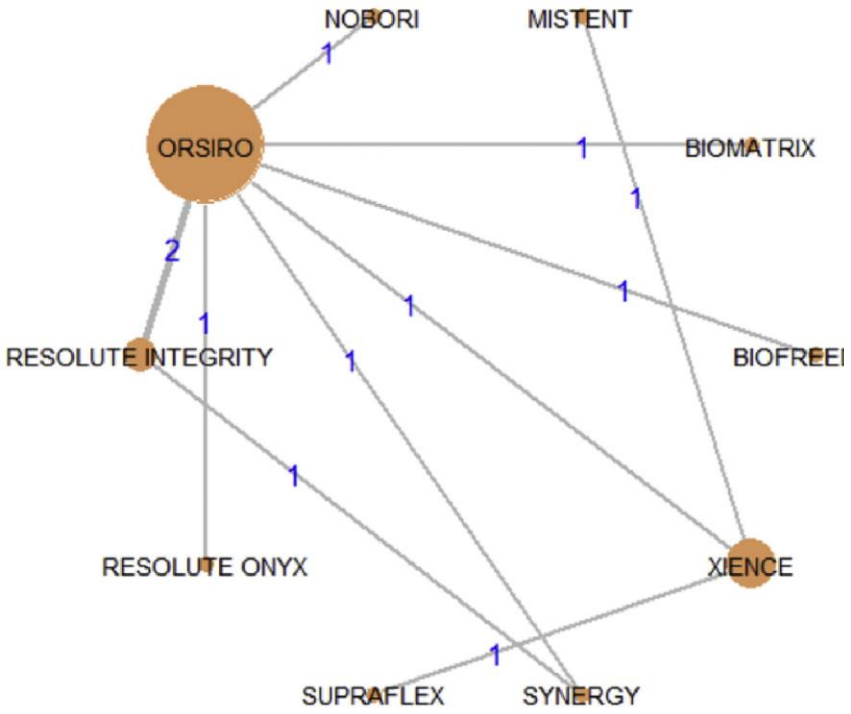
4 Most Common DES:

Orsiro, XIENCE, Nobori/BioMatrix, and Resolute

1-year ST (def/prob)	OR (95% CI)	P
Orsiro vs.		
- Xience	0.99 (0.71–1.38)	0.95
- Resolute	0.83 (0.54–1.27)	0.39
- Nobori/Biomatrix	0.77 (0.52–1.16)	0.21
Xience vs.		
- Resolute	0.83 (0.57–1.22)	0.35
- Nobori/Biomatrix	0.78 (0.58–1.12)	0.18
Resolute vs.		
- Nobori/Biomatrix	0.94 (0.62–1.43)	0.76
Median 50-months ST	**OR (95% CI)**	**P**
Orsiro vs.		
- Xience	0.79 (0.60–1.05)	0.10
- Resolute	0.66 (0.45–0.99)	0.04
- Nobori/Biomatrix	0.72 (0.51–1.03)	0.07
Xience vs.		
- Resolute	0.84 (0.60–1.18)	0.32
- Nobori/Biomatrix	0.92 (0.69–1.22)	0.55
Resolute vs.		
- Nobori/Biomatrix	1.09 (0.74–1.59)	0.90

Comparison Among Ultra-Thin Coronary Stents: A Network Meta-Analysis

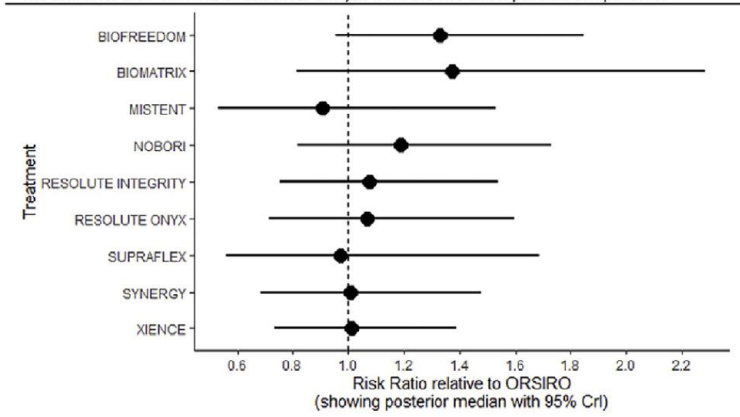
Giorgio Marengo, MD[a], Francesco Bruno, MD[a], Luca Scudeler, MD[a], Federica Savoca, MD[a], Daniela Zugna, PhD[b], Elena Isaevska, PhD[b], Thomas Pilgrim, MD [c], Lisette Okkels Jensen, PhD[d], Ovidio De Filippo, MD[a,*], Lorenzo Richiardi, PhD[b], Gaetano Maria De Ferrari, MD[a], and Fabrizio D'Ascenzo, MD, PhD[a]

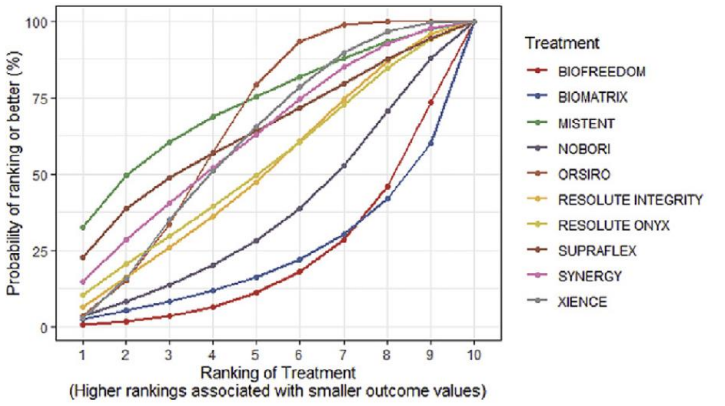


PRIMARY ENDPOINT: TARGET LESION FAILURE (TLF)

	EES	ZES		SES			EES	BES		BES
	XIENCE	RES.INTEGRITY	RES.ONYX	MISTENT	ORSIRO	SUPRAFLEX	SYNERGY	BIOMATRIX	NOBORI	BIOFREEDOM
XIENCE				0.88 (0.58, 1.33)	0.98 (0.71, 1.35)	0.94 (0.60, 1.47)				
RES.INTEGRITY	0.97 (0.58, 1.51)				0.90 (0.63, 1.29)		0.93 (0.63, 1.35)			
RES.ONYX	0.98 (0.56, 1.58)	1.05 (0.59, 1.73)			0.92 (0.61, 1.37)					
MISTENT	1.14 (0.74, 1.69)	1.25 (0.63, 2.25)	1.25 (0.61, 2.28)							
ORSIRO	1.02 (0.73, 1.39)	1.09 (0.75, 1.54)	1.09 (0.72, 1.60)	0.94 (0.53, 1.53)			1.04 (0.70, 1.54)	1.43 (0.85, 2.39)	1.31 (0.90, 1.90)	**1.80 (1.30, 2.51)**
SUPRAFLEX	1.07 (0.67, 1.64)	1.17 (0.58, 2.15)	1.17 (0.56, 2.18)	0.98 (0.51, 1.72)	1.07 (0.59, 1.78)					
SYNERGY	1.04 (0.61, 1.64)	1.09 (0.73, 1.57)	1.11 (0.61, 1.84)	0.95 (0.47, 1.71)	1.01 (0.68, 1.46)	1.02 (0.49, 1.87)				
BIOMATRIX	0.77 (0.40, 1.34)	0.83 (0.42, 1.49)	0.82 (0.41, 1.50)	0.71 (0.32, 1.38)	0.75 (0.44, 1.22)	0.76 (0.33, 1.48)	0.77 (0.39, 1.40)			
NOBORI	0.88 (0.52, 1.39)	0.94 (0.54, 1.52)	0.94 (0.52, 1.55)	0.81 (0.40, 1.45)	0.86 (0.58, 1.22)	0.87 (0.42, 1.60)	0.88 (0.50, 1.44)	1.22 (0.61, 2.17)		
BIOFREEDOM	0.78 (0.48, 1.20)	0.84 (0.50, 1.32)	0.84 (0.48, 1.35)	0.72 (0.37, 1.27)	0.76 (0.54, 1.05)	0.77 (0,38, 1.39)	0.78 (0.45, 1.26)	1.09 (0.56, 1.90)	0,92 (0.54, 1.47)	

The upper right triangle gives the RRs from the direct pairwise comparisons. The lower left triangle gives the RRs and the 95% credible intervals from the network meta-analysis. Row names indicate the reference stent.
*The estimates are from fixed effects meta-analysis from the two direct pairwise comparisons.





At 1-year follow-up, no significant differences were noted for TLF among these ultrathin DES

Do we need a PCI revolution?
DES have limitations

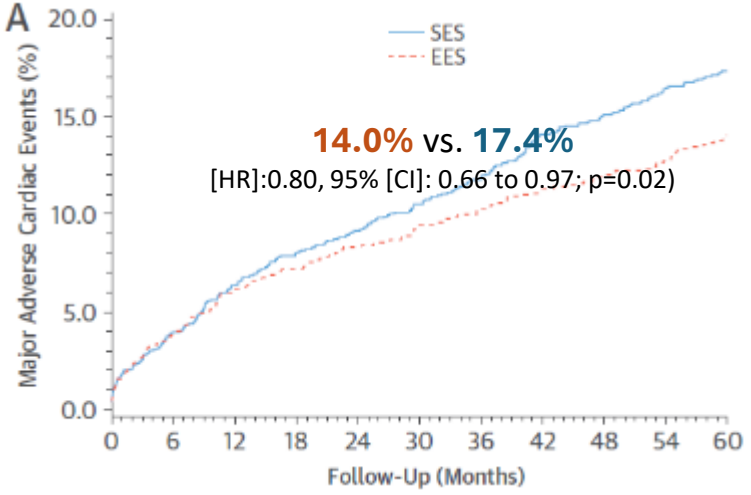
Level I evidence consistently indicates an unceasing 2-3% annual event rate through 5 – 10 years

SORT OUT [1]

~3% p/y thr. 5 years

Jensen et al. JACC 2016

N=2771, RCT of SES vs. EES

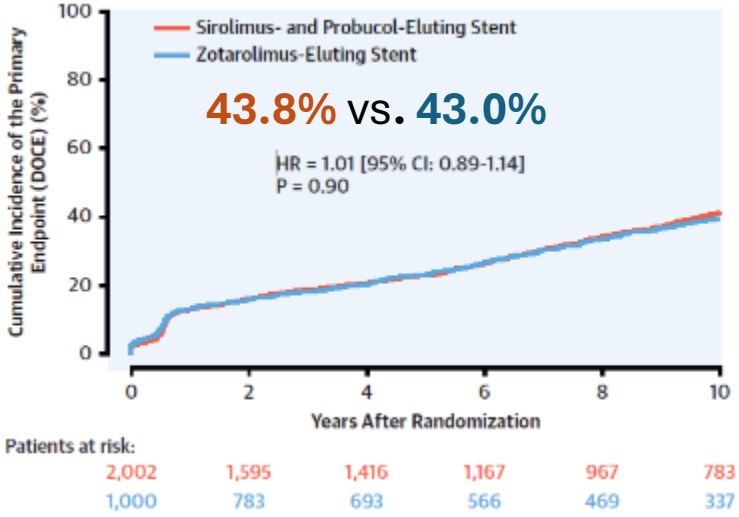


ISAR-TEST-5 [2]

~2% p/y thr. 10 years

Kufner et a. JACC 2020

N=3000, RCT of Resolute vs. Coroflex



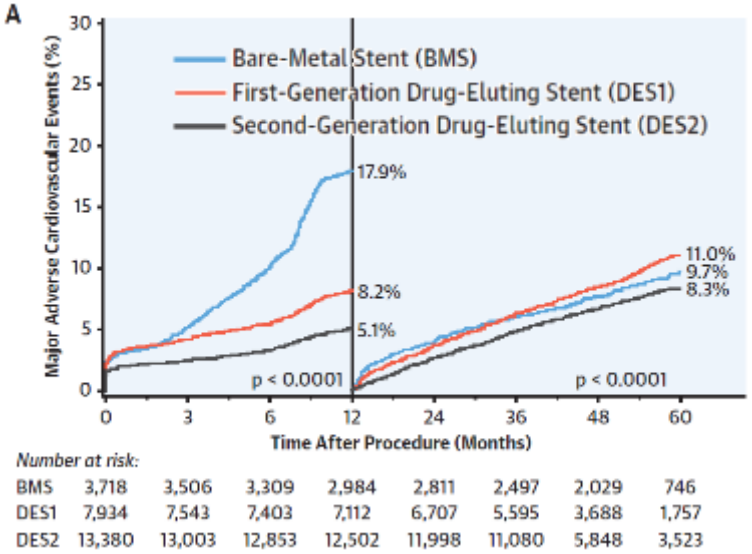
Primary endpoint: composite of cardiac death, TV-MI or TLR (device-oriented composite endpoint [DOCE]) at 10 years

Meta-analysis [3]

~2% p/y thr. 5 years

Madhavan et al. JACC 2020

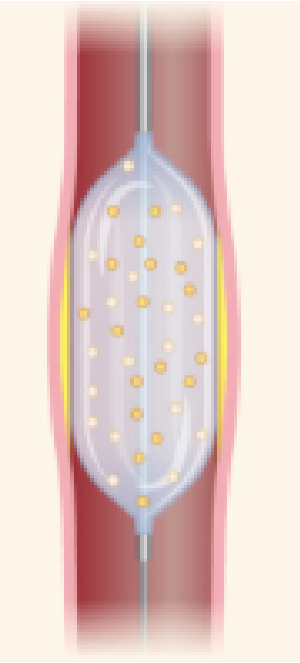
25032 Patients (19 RCT)



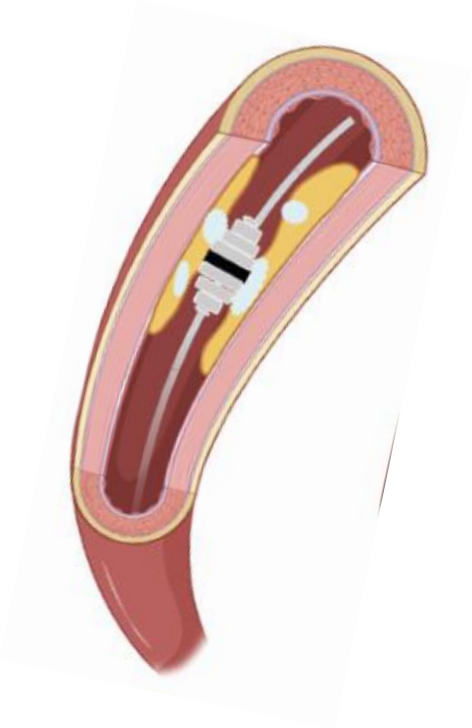
1. Jensen LO, Thayssen P, Christiansen EH, Maeng M, Ravkilde J, Hansen KN, Hansen HS, Krusell L, Kaltoft A, Tilsted HH, Berencsi K, Junker A, Lassen JF; SORT OUT IV Investigators. Safety and Efficacy of Everolimus- Versus Sirolimus-Eluting Stents: 5-Year Results From SORT OUT IV. J Am Coll Cardiol. 2016 Feb 23;67(7):751-62. doi: 10.1016/j.jacc.2015.11.051. PMID: 26892409.
2. Kufner S, Ernst M, Cassese S, Joner M, Mayer K, Colleran R, Koppara T, Xhepa E, Koch T, Wiebe J, Ibrahim T, Fusaro M, Laugwitz KL, Schunkert H, Kastrati A, Byrne RA; ISAR-TEST-5 Investigators. 10-Year Outcomes From a Randomized Trial of Polymer-Free Versus Durable Polymer Drug-Eluting Coronary Stents. J Am Coll Cardiol. 2020 Jul 14;76(2):146-158. doi: 10.1016/j.jacc.2020.05.026. PMID: 32646563.
3. Madhavan MV, Kirtane AJ, Redfors B, Généreux P, Ben-Yehuda O, Palmerini T, Benedetto U, Biondi-Zoccai G, Smits PC, von Birgelen C, Mehran R, McAndrew T, Serruys PW, Leon MB, Pocock SJ, Stone GW. Stent-Related Adverse Events >1 Year After Percutaneous Coronary Intervention. J Am Coll Cardiol. 2020 Feb 18;75(6):590-604. doi: 10.1016/j.jacc.2019.11.058. PMID: 32057373.

«How» is more important that «Which»

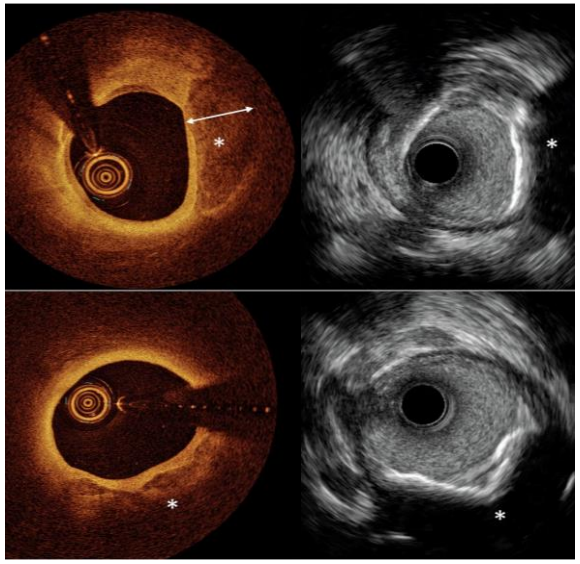
Lesion preparation and post-PCI optimization



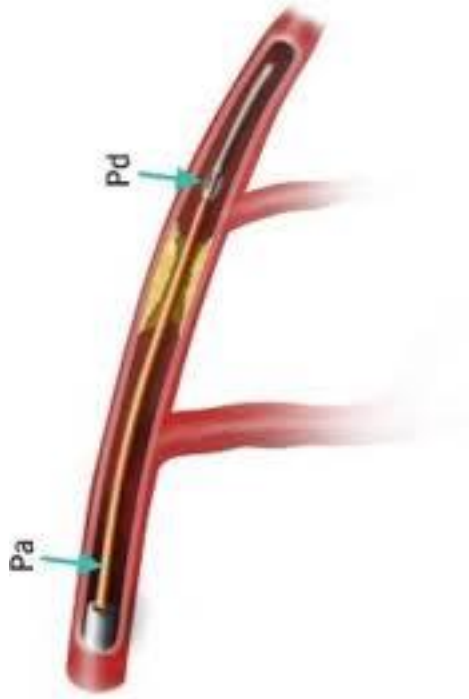
Plaque debulking/modification



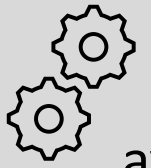
Intravascular imaging



Intravascular physiology



Rationale for PCI revolution: 2 Perspectives



Mechanistic:

avoid stent-related issues

- Avoid chronic inflammation
- Maintain physiological vasomotion, pulsatility and allow for uneventful positive remodeling
- Avoid stent fractures and ISR treatment burden

Clinical:

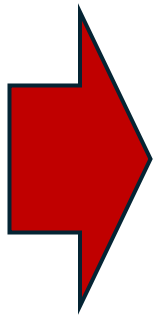
improve outcomes

through the long run

- Interrupt DES observed, lifelong, 2-3% MACE annual cadence
- Reduce DAPT regimen and associated burden
- Leave future options fully open

What are the outocome to be pursued in the technological advancement of stents?

- Limitate/eliminate early and late stent thrombosis
- Reduce dipendendy on long term DAPT
- Improve longlife outcomes after PCI



- Thin struts
- Bioadsorbable polymer
- Eliminate the polymer
- Eliminate the stent

DCB

Bioresorbable scaffold

Bioadaptors

DES with antithrombotic

Appetite comes with eating

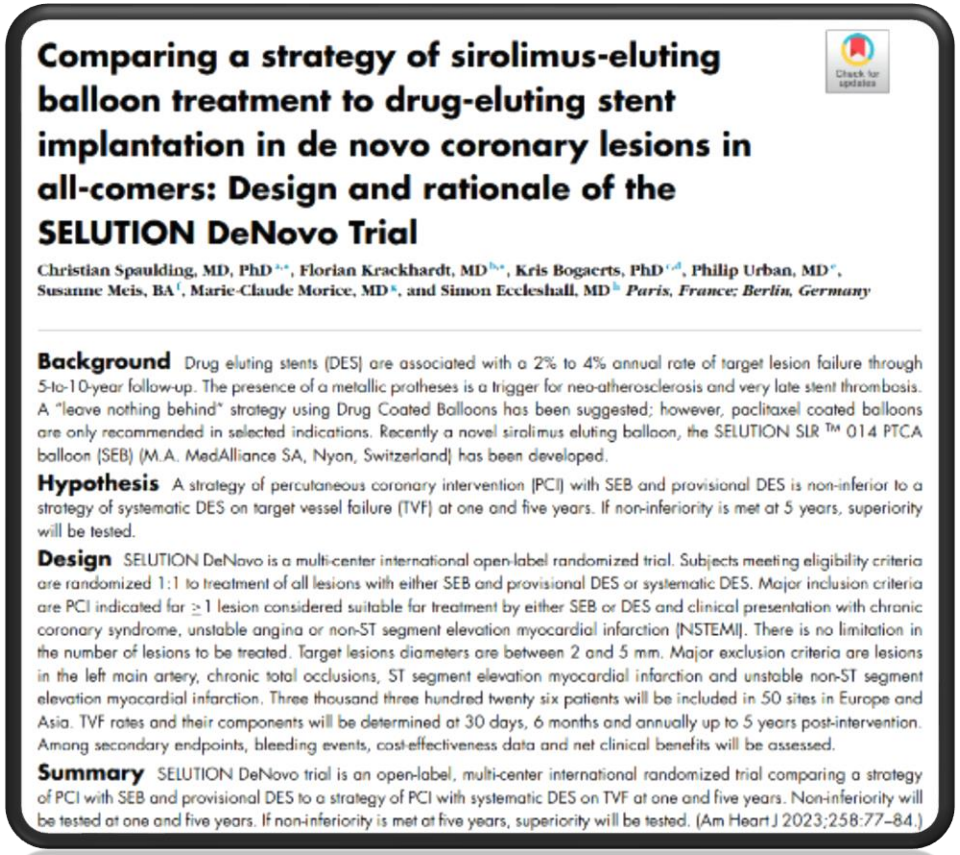
Encouraging Data trigger continuous evolution of DCB Technologies

New DCBs entering the race to best match 4 DCB Design Goals

Manufacturer	DCB	Drug
Cordis	SELUTION SLR	Sirolimus
Concept Medical	MAGIC TOUCH	Sirolimus
B|BRAUN	SEQUENT SCB	Sirolimus
Orchestra BioMed	VIRTUE	Sirolimus
Medtronic	PREVAIL	Paclitaxel
B|BRAUN	SEQUENT PLEASE NEO	Paclitaxel
Boston Scientific	AGENT	Paclitaxel
BIOTRONIK	PANTERA LUX	Paclitaxel
CARDIONOVUM	RESTORE	Paclitaxel
BIOSENSORS INTERNATIONAL	BIOLIMUS A9	Paclitaxel
translumina LIMITLESS POSSIBILITIES	PROTÉGÉ / NC	Paclitaxel
ANT	SIRPLUX DUO	Paclitaxel + Sirolimus
AR Baltic Medical	EMPEROR	Paclitaxel + Dextran

1. **Coating Durability**
   drug adherence on balloon surface during transit
2. **Rapid and Efficient Tissue Transfer**
   rapid and enhanced tissue absorption upon balloon inflation
3. **Sustained Tissue Retention**
   sustained release, tissue persistence at therapeutic levels
4. **Homogeneous in-Tissue Distribution**
   no drug concentration peaks and vacancies

SELUTION DeNovo RCT ClinicalTrials.gov ID NCT04859985



Comparing a strategy of sirolimus-eluting balloon treatment to drug-eluting stent implantation in de novo coronary lesions in all-comers: Design and rationale of the SELUTION DeNovo Trial

Christian Spaulding, MD, PhD [a,*], Florian Krackhardt, MD [b,*], Kris Bogaerts, PhD [c,d], Philip Urban, MD [e], Susanne Meis, BA [f], Marie-Claude Morice, MD [g], and Simon Eccleshall, MD [h] *Paris, France; Berlin, Germany*

Background Drug eluting stents (DES) are associated with a 2% to 4% annual rate of target lesion failure through 5-to-10-year follow-up. The presence of a metallic protheses is a trigger for neo-atherosclerosis and very late stent thrombosis. A "leave nothing behind" strategy using Drug Coated Balloons has been suggested; however, paclitaxel coated balloons are only recommended in selected indications. Recently a novel sirolimus eluting balloon, the SELUTION SLR ™ 014 PTCA balloon (SEB) (M.A. MedAlliance SA, Nyon, Switzerland) has been developed.

Hypothesis A strategy of percutaneous coronary intervention (PCI) with SEB and provisional DES is non-inferior to a strategy of systematic DES on target vessel failure (TVF) at one and five years. If non-inferiority is met at 5 years, superiority will be tested.

Design SELUTION DeNovo is a multi-center international open-label randomized trial. Subjects meeting eligibility criteria are randomized 1:1 to treatment of all lesions with either SEB and provisional DES or systematic DES. Major inclusion criteria are PCI indicated for ≥1 lesion considered suitable for treatment by either SEB or DES and clinical presentation with chronic coronary syndrome, unstable angina or non-ST segment elevation myocardial infarction (NSTEMI). There is no limitation in the number of lesions to be treated. Target lesions diameters are between 2 and 5 mm. Major exclusion criteria are lesions in the left main artery, chronic total occlusions, ST segment elevation myocardial infarction and unstable non-ST segment elevation myocardial infarction. Three thousand three hundred twenty six patients will be included in 50 sites in Europe and Asia. TVF rates and their components will be determined at 30 days, 6 months and annually up to 5 years post-intervention. Among secondary endpoints, bleeding events, cost-effectiveness data and net clinical benefits will be assessed.

Summary SELUTION DeNovo trial is an open-label, multi-center international randomized trial comparing a strategy of PCI with SEB and provisional DES to a strategy of PCI with systematic DES on TVF at one and five years. Non-inferiority will be tested at one and five years. If non-inferiority is met at five years, superiority will be tested. (Am Heart J 2023;258:77–84.)

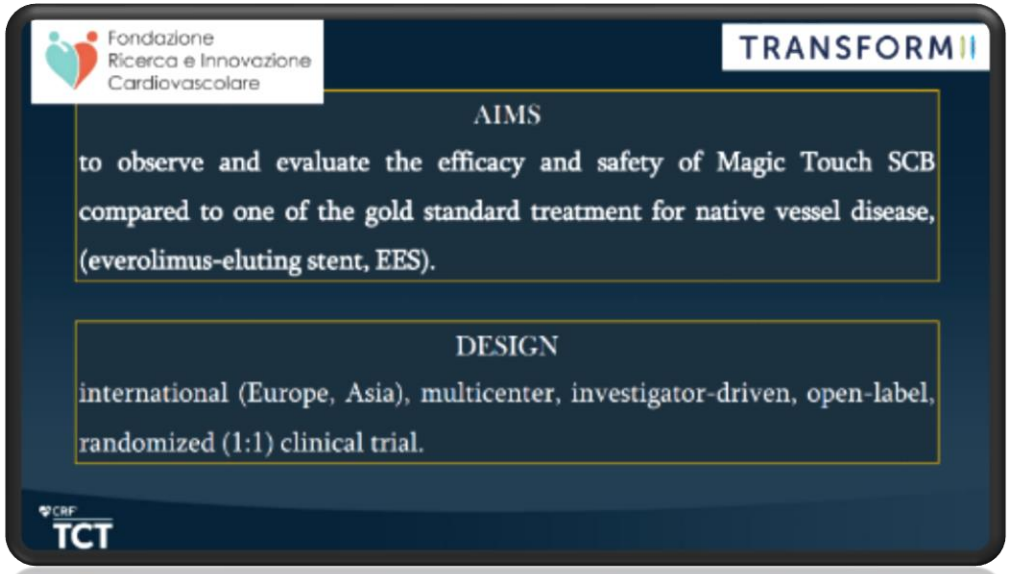
SELUTION vs. DES - Strategy Trial

- RCT, N=3326 @ ~50 Sites in EU and Asia
- DEB vs. DES Strategy Trial with randomization prior to vessel preparation
- de-novo, RVD 2.0-5.0 mm, any lesion length
- Primary Efficacy Endpoint: TVF @ 1 and 5 years
- Statistical Hypothesis: NI @ 1-year; NI + SUP. @ 5 years

PIs: Simon Eccleshall, Christian Spaulding

Spaulding C, Krackhardt F, Bogaerts K, Urban P, Meis S, Morice MC, Eccleshall S. Comparing a strategy of sirolimus-eluting balloon treatment to drug-eluting stent implantation in de novo coronary lesions in all-comers: Design and rationale of the SELUTION DeNovo Trial. Am Heart J. 2023 Apr;258:77-84. doi: 10.1016/j.ahj.2023.01.007. Epub 2023 Jan 13. PMID: 36642225.

TRANSFORM II RCT ClinicalTrials.gov ID NCT04893291



B.Cortese – TCT 2022

MAGIC TOUCH vs. EES Trial

- RCT, N=1820 @ ~25 Sites in EU and Asia
- DEB vs. DES Trial with randomization post vessel preparation
- de-novo, RVD 2.0-3.5 mm, lesion length up to 50 mm
- Primary Efficacy Endpoint: TLF @ 1 year

PIs: Bernardo Cortese

Why Magnesium Resorbable Scaffolds?

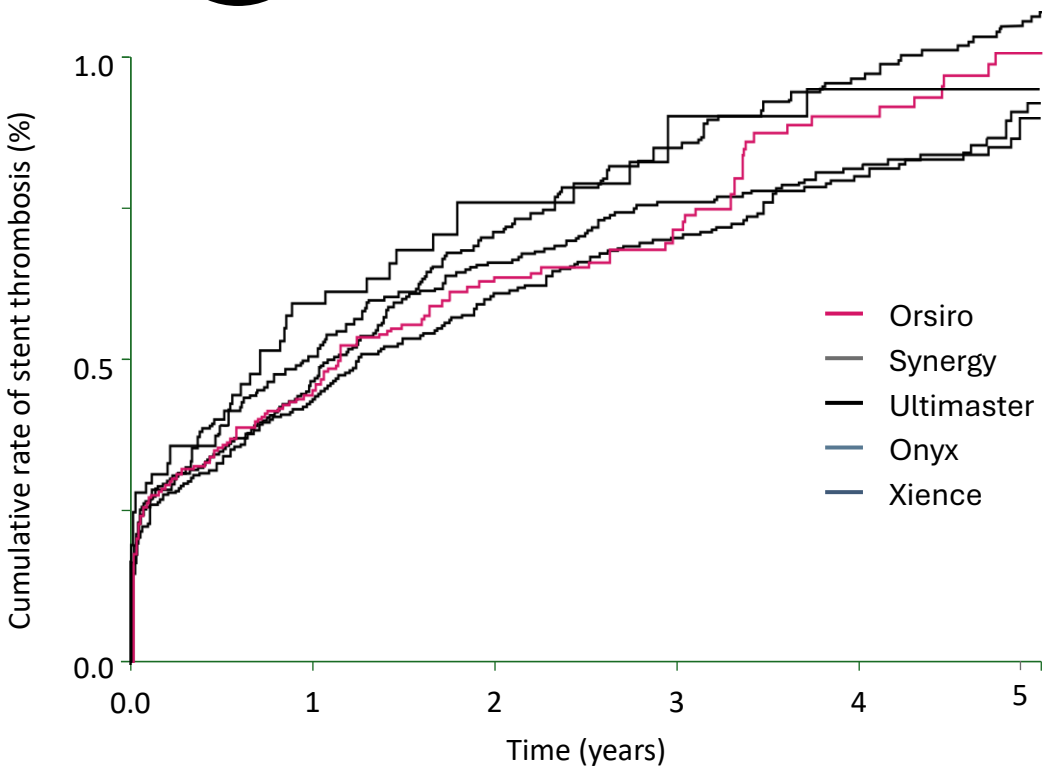
- The vision of scaffolds is to reduce long-term events of DES

- **After resorption:**
  - Restoration of vessel anatomy
  - Restoration of vasomotion

Reduced late clinical events compared to permanent stent implants:

- Low thrombogenicity and events of scaffold thrombosis
- Lowers the risk of neoatherosclerosis
- No permanent implant
  (CT and MRI compatibility)

Modern 2nd generation DES demonstrate an increase of clinical events over time[1]



1. Stent reports - SWEDEHEART (uu.se); 2007 – Sep 2020; Most used stents, implanted >1000 times in Sweden.

Freesolve

New generation **Resorbable Magnesium Scaffold**

Thin struts[6]

99 µm
150 µm
ø 2.5 mm

117 µm
150 µm
ø 3.0/3.5 mm

147 µm
150 µm
ø 4.0 mm

NEW BIOmag®
Magnesium Alloy

Optimal vessel support

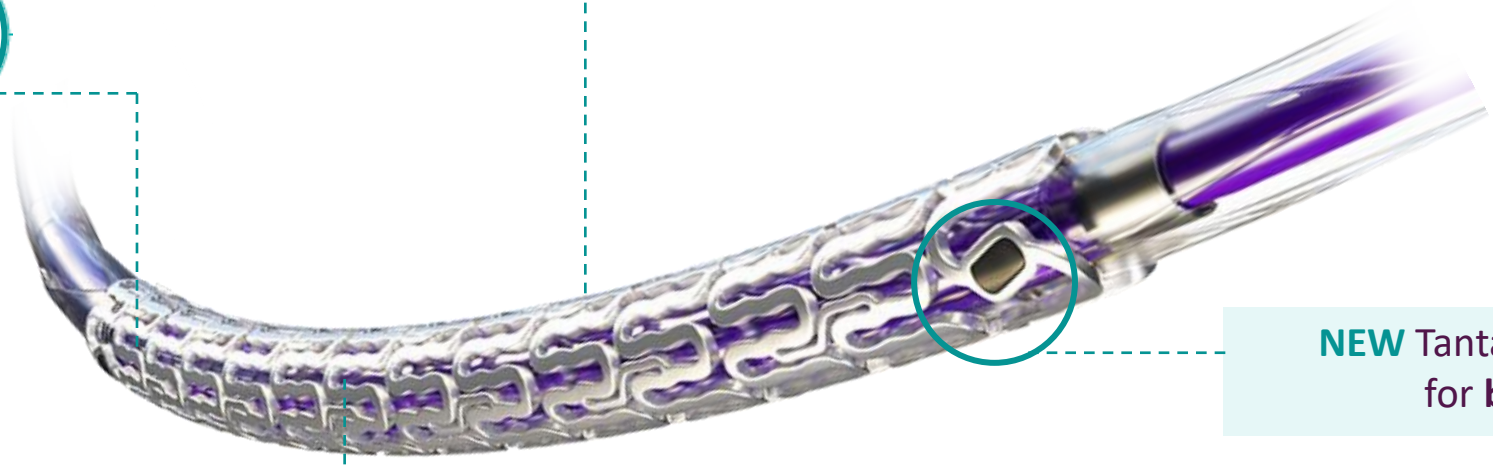
Predictable, homogenous resorption process[7]

BIOmag®

BIOmag® backbone
A strong Magnesium alloy[6]

BIOlute® coating

BIOmag® core
A strong[6], uniform shape[7]



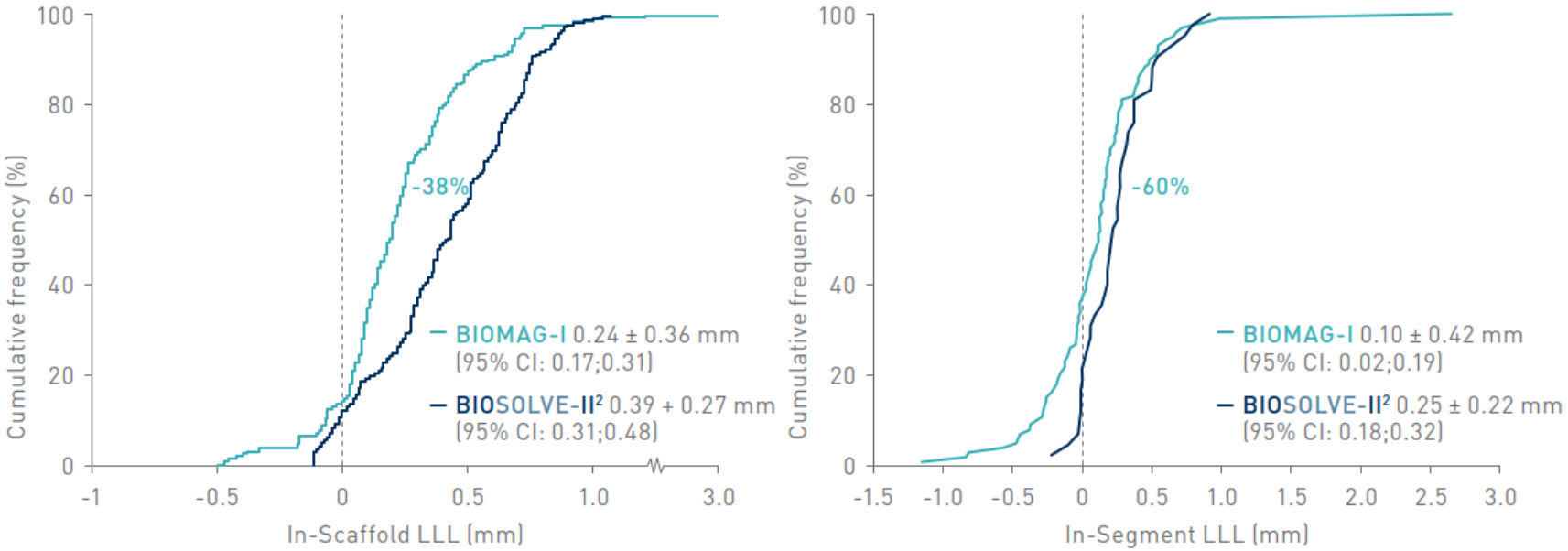
NEW Tantalum marker concept for better visibility

NEW Size matrix

Diameter: 2.5, 3.0, 3.5, 4.0 mm
Lenght: 13, 18, 22, 26, 30 mm

BIOMAG-I First-in-man study - Results at 12-months

In scaffold Late Lumen Loss at 12[1] months follow up



Freesolve demonstrates **reduced angiographic in scaffold and in segment Late Lumen Loss (LLL)** compared to the predecessor device DREAMS 2G

Clinical Endpoints

12 Months

116 patients

2.6% TLF*

0.0% Definite/probable Scaffold Thrombosis

* composite of cardiac death, target vessel myocardial infarction, clinically driven target lesion revascularization;

1. Haude, M "1-Year Clinical Outcomes of the new resorbable Magnesium scaffold DREAMS 3G, from the first in-human BIOMAG-I study" presented at EuroPCR May 2023; 2. Haude M, et al., Sustained safety and performance of the second-generation drug-eluting absorbable metal scaffold in patients with de novo coronary lesions: 12-month clinical results and angiographic findings of the BIOSOLVE-II first-in-man trial. Eur Heart J 2016;37:2701-2709. 3. Byrne RA, et al., Report of a European Society of Cardiology-European Association of Percutaneous Cardiovascular Interventions task force on the evaluation of coronary stents in Europe: executive summary. Eur Heart J 2015;36:2608-262.

TLF (1° EP) and MACE @ 12-month FU

IT-MASTERS Registry

FU completed in 303/359 (85%) patients at 12-month FU

Outcome	1-Month	6-Month	12-Month
TLF	0 (-)	7* (**2.3%**) (0,6%; 4%)	14 (**4.3%**) (2%; 6,6%)
Cardiac Death	0 (-)	0 (-)	0 (-)
Scaffold Thrombosis (ST)	0 (-)	2 (**0.7%**) (0%; 1.6%)	2 (**0.7%**) (0%; 1.6%)
Spontaneous Myocardial Infarction	0 (-)	3 (**1.0%**) (0%; 2.1%)	4 (**1.3%**) (0%; 2.6%)
TLR (due to ST=2 and Scaffold ISR=11)	0 (-)	7 (**2.0%**) (0%; 3.6%)	13* (**4.0%**) (1.8%; 6.2%)
CABG	0 (-)	1 (**0.3%**) (0%; 1%)	1 (**0.3%**) (0%; 1%)

Data are shown as number of events and Kaplan-Meier estimates (%) at 1, 6, 12 months with 95% Confidence Interval
Note: the analyses are based on the first 303 patients enrolled with 1-year Follow Up complete

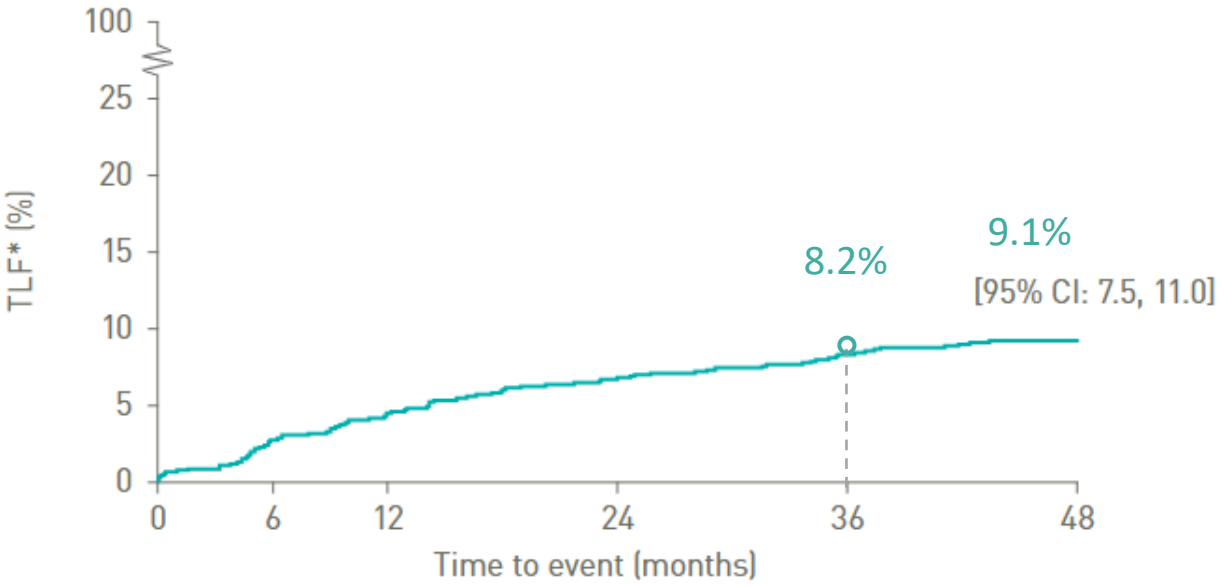
Data from EuroPCR 2024

BIOSOLVE-IV - Cohort 1 – 1075 patients

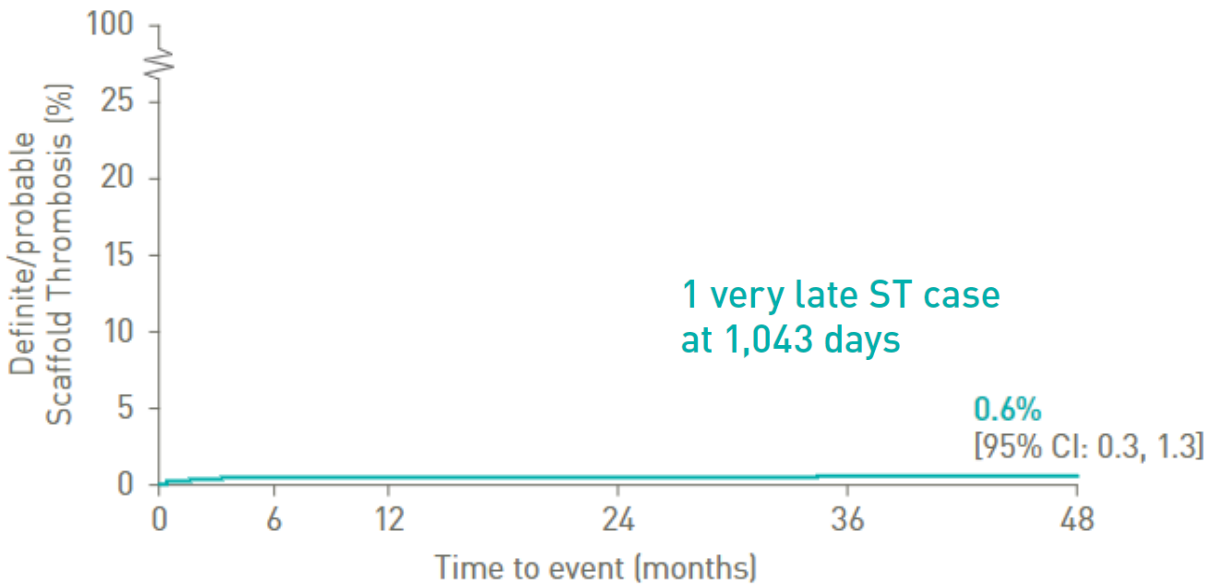
Outcomes at 48-month Follow Up

BIOSOLVE-IV

Target Lesion Failure



Def./Prob. ST up to 48 months



Magmaris TLF results are comparable with contemporary DES results

TLF of contemporary DES[2,3] up to 36 months

BIORESORT[2] TLF						BIOFLOW-V[3] TLF			
SES n = 1,169		EES n = 1,172		ZES n = 1,173		SES n = 884		DP EES n = 450	
77	6.7%	86	7.5%	96	8.3%	70	8.2%	59	13.6%

0.5% def./prob. ST at 24 months

0.6%§ def./prob. ST at 48 months

*4 out of 6 scaffold thrombosis at 24-months cases had early antiplatelet or anticoagulant interruption after procedure

Magmaris

Resorbable Magnesium Scaffold

Magnesium Alloy:
3 Months Scaffolding Time

150µm x 150µm struts

12 Months
Resorption time

Two tantalum markers at each end

Diameter: 3.0, 3.5 mm
Lenght: 15, 20, 25 mm

New Technology GOALS

Improve mechanical properties

Reduce strut thickness

Maintain Resorption time

Improve Radiopacity

Improve Size Portfolio

Freesolve™

Resorbable Magnesium Scaffold

New BIOMAG Mg Alloy

Optimal vessel support > 3 months

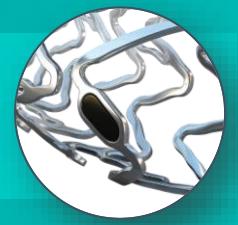
Thin Struts

Ø 2.5	Ø 3.0, 3.5	Ø 4.0
99 µm	117 µm	147 µm

12 Months
Resorption time

New Markers

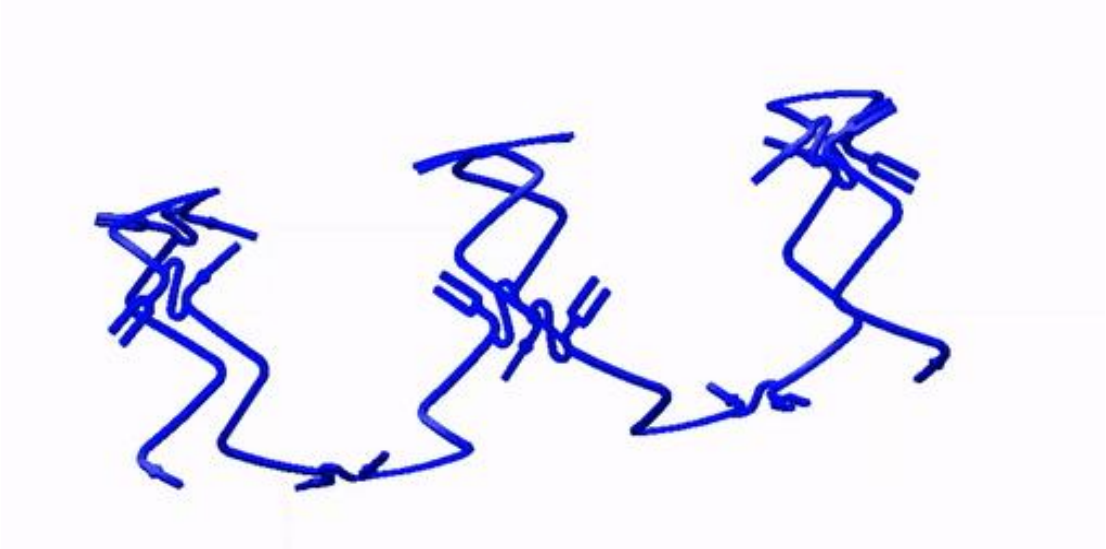
One oval Tantalum marker at each end



New Sizes

Diameter: **2.5, 3.0, 3.5, 4.0 mm**
Lenght: **13, 18, 22, 26, 30 mm**

DynamiX Bioadaptor Novel Design and Unique Mechanism of Action



- Three helical sinusoidal strands (CoCr 71µm) are temporary locked and held by bioresorbable polymer
- They unlock after 6 months following polymer resorption

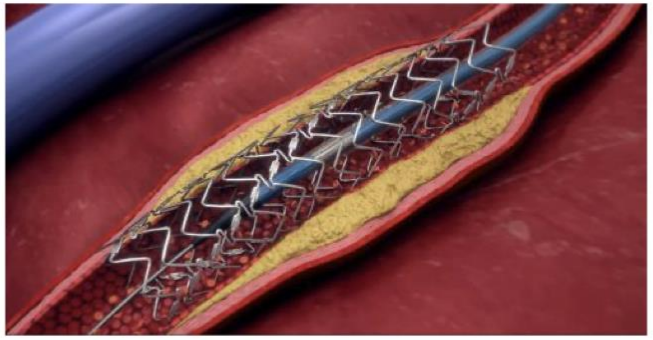
Mechanism of action and function:

- **Locked** to establish flow lumen
- **Unlock and separate** to maintain flow lumen
- **Dynamic adaptive support after unlocking and separating** to restore hemodynamic modulation

Bioadaptor (DynamX, Elixir Medical, CA) is a novel technology designed to *restore hemodynamic modulation of the vessel.*

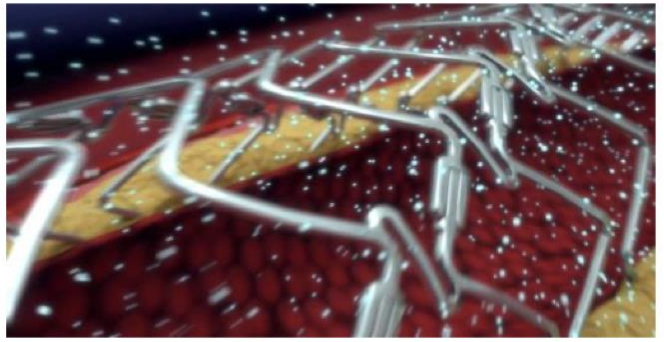
0 – 6 months

after 6 months



1. Locked:
Establish Flow Lumen

Restore flow and achieve high acute gain and low residual %DS[1,2]



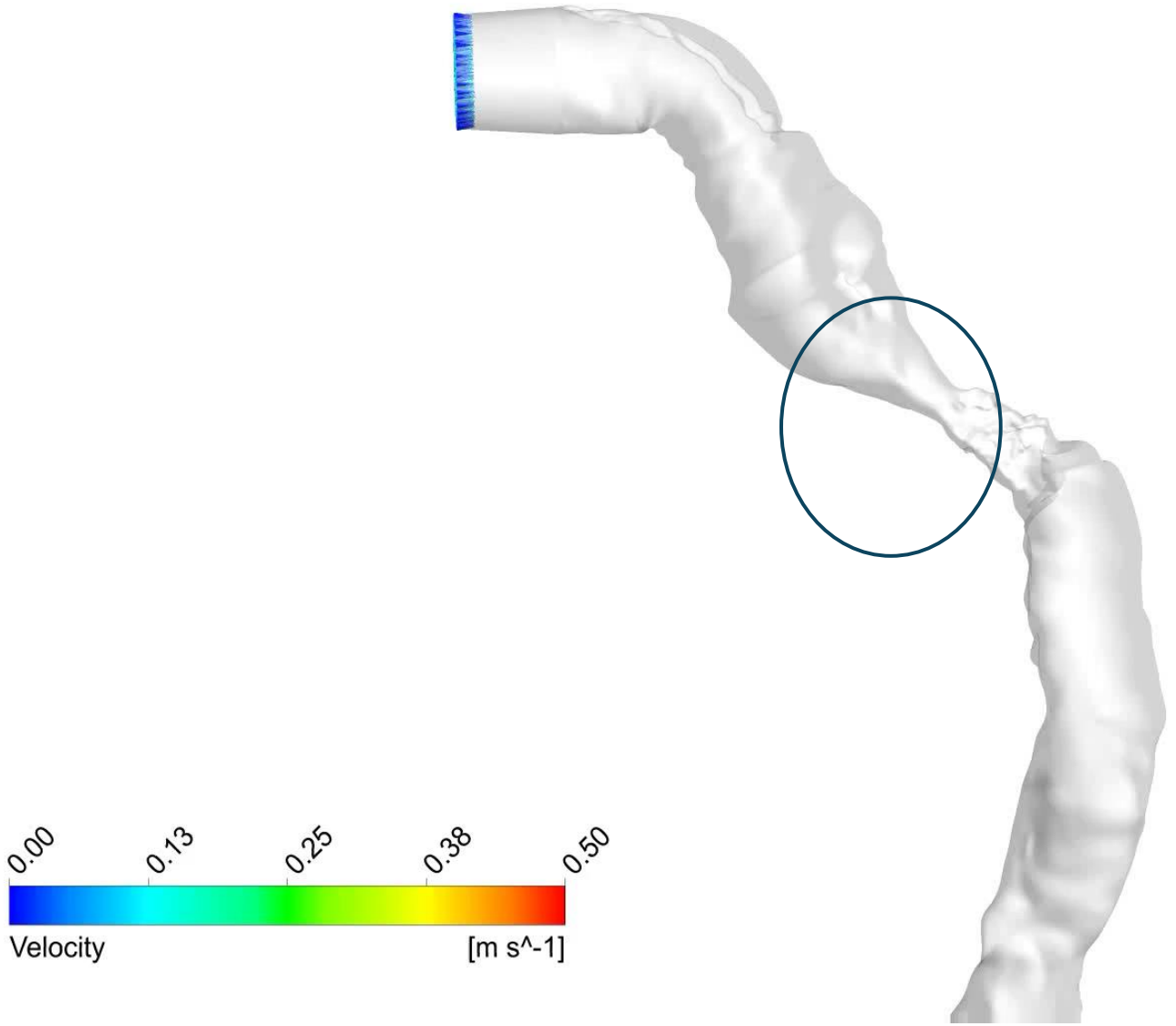
2. Unlocked:
Maintain Flow Lumen

Restore adaptive remodeling and maintain low %DS[1,2]

3. Dynamic Support:
Restore Hemodynamic Modulation

Restore pulsatility, compliance, adaptive coronary flow[1-3]

Computational Model for Dynamix Regarding Flow Restoration



Russo G. and Sangiorgi G.

BIOADAPTOR RCT - Trial Design

N=445 in 34 centers

50% patients enrolled in Germany, Belgium and New Zealand; 50% patients enrolled in Japan

DynamX Bioadaptor (n=223)

1:1

Resolute Onyx DES (n=222)

Imaging subgroups at Baseline and 12M: QCA (N=50), IVUS (N=50), OCT (N=10)

Imaging subgroups at Baseline and 12M: QCA (N=50), IVUS (N=50), OCT (N=10)

1-Year Primary Endpoint (ITT): TLF (non-inferiority), clinical follow-up to 5 years;
Secondary Endpoints: %DS, pulsatility by QCA/IVUS/OCT, TVF; **Subgroup Analysis:** LAD, LL (≥23mm), SV (≤2.75mm)

2-Year Clinical Follow-up (Per Protocol Population)

Follow-up Completion: 99% (434/440)

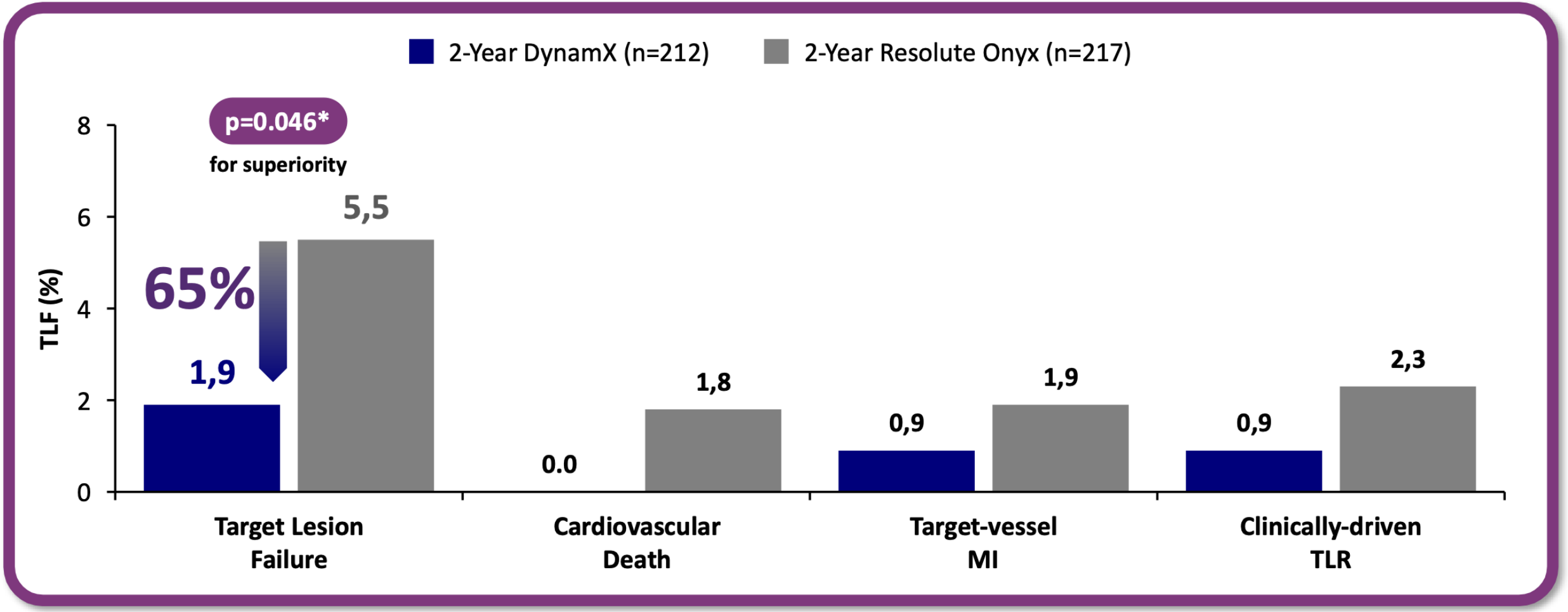
Per Protocol (PP) Population Analysis at 2 Years:

- 3 subjects excluded due to non-de novo lesion (ISR in prior BVS implant)
- 2 subjects excluded due to cross-over randomization error

Subjects who did not complete 2-year follow-up:

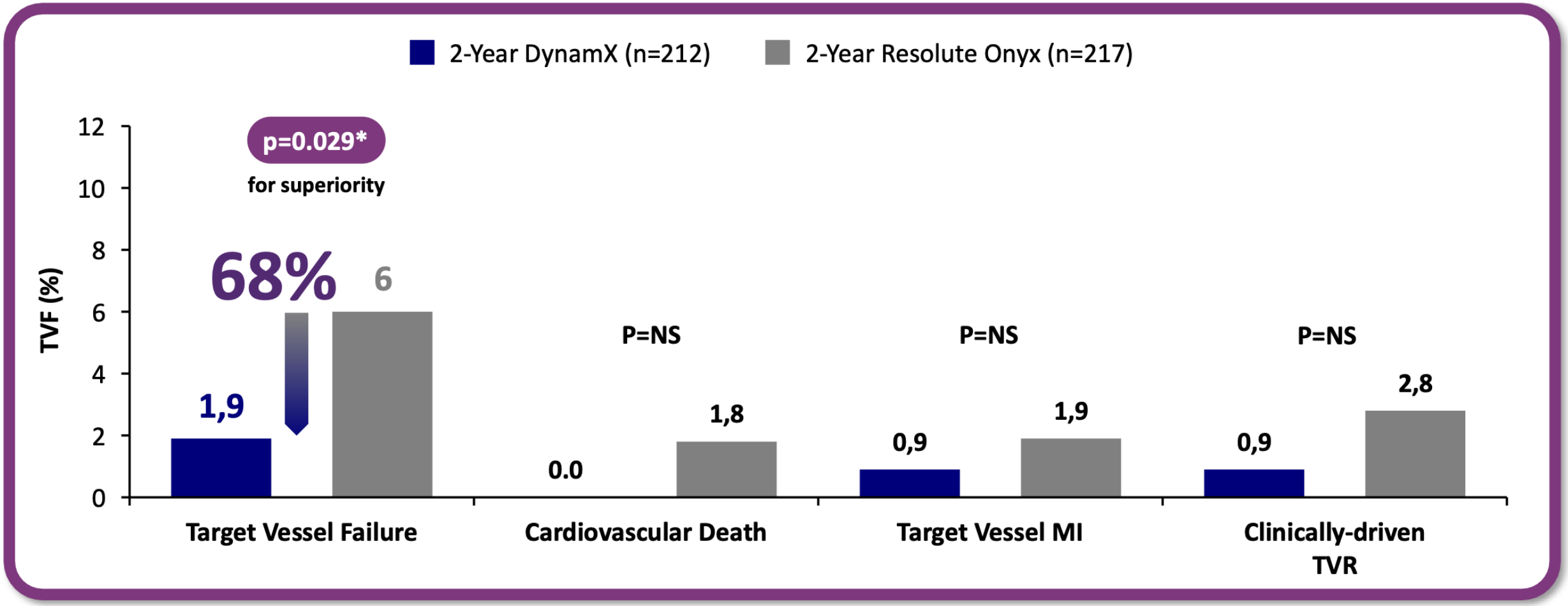
- 2 subject withdrawals
- 4 subjects missed 2-Year visits

Significant TLF Reduction Driven by Lower CVD, TVMI, TLR



*Chi-square test. Per Protocol Population

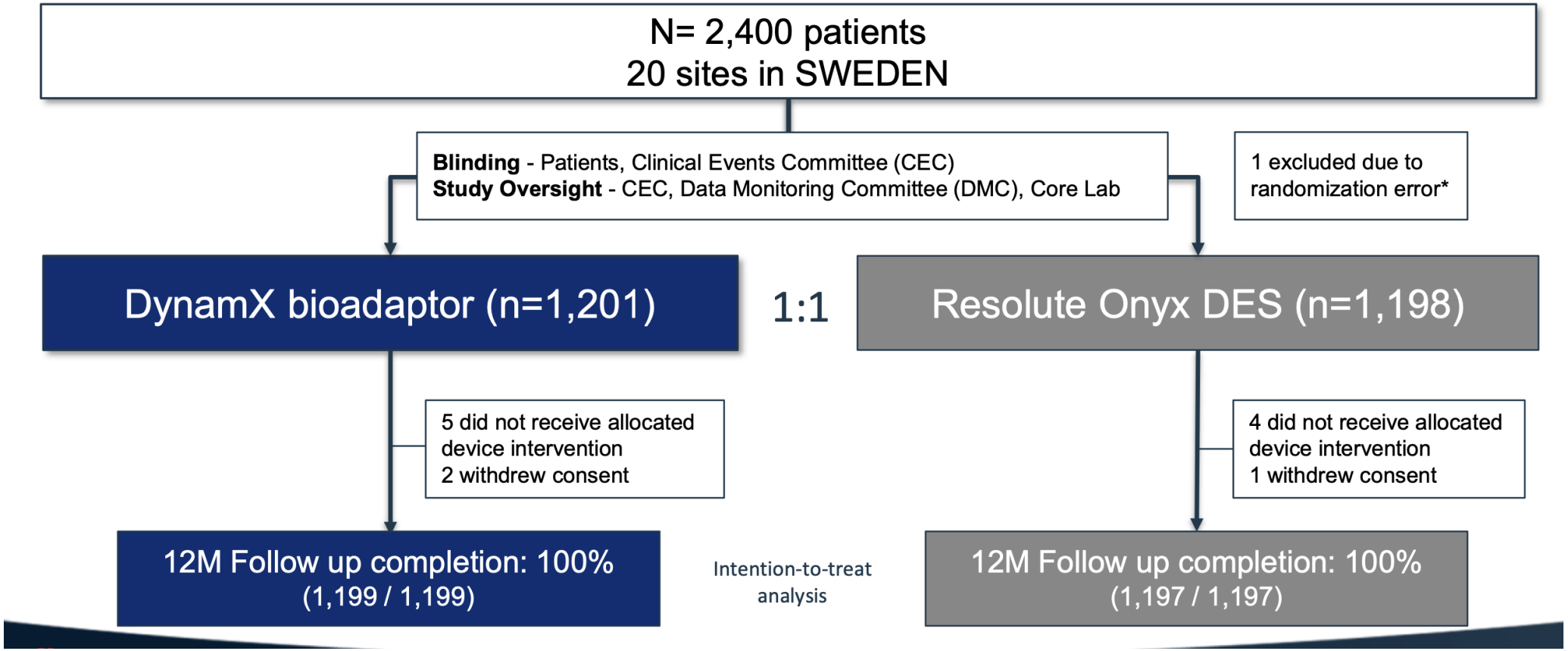
Significant Reduction in TVF at 2 Years



*Chi-square test. Per Protocol Population

Bioadaptor implant versus contemporary drug-eluting stent in percutaneous coronary interventions in Sweden (INFINITY-SWEDEHEART): a single-blind, non-inferiority, registry-based, randomised controlled trial

12-M Follow up completion: 100%



Lancet 2024; 404: 1750–59

Target Lesion Failure at 12 Months

INFINITY-SWEDEHEART

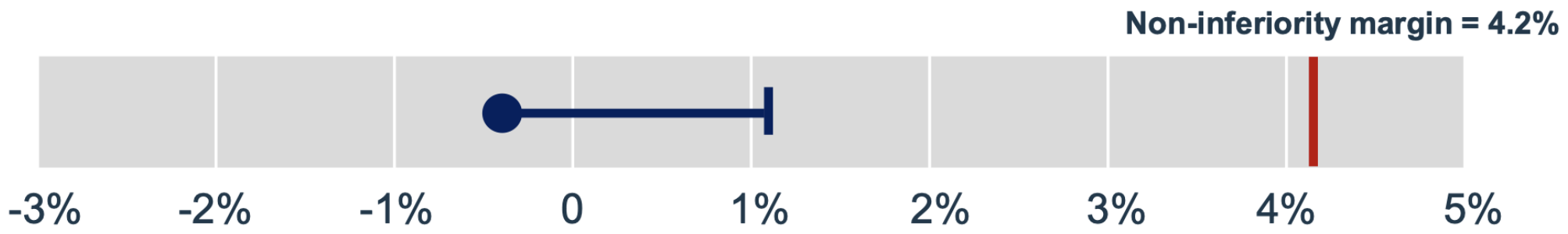
Primary Non-Inferiority Endpoint Met

DynamX
(N=1,189)
2.35%

p-value <0.0001

Difference: - 0.41%
[-1.94%, 1.11%]

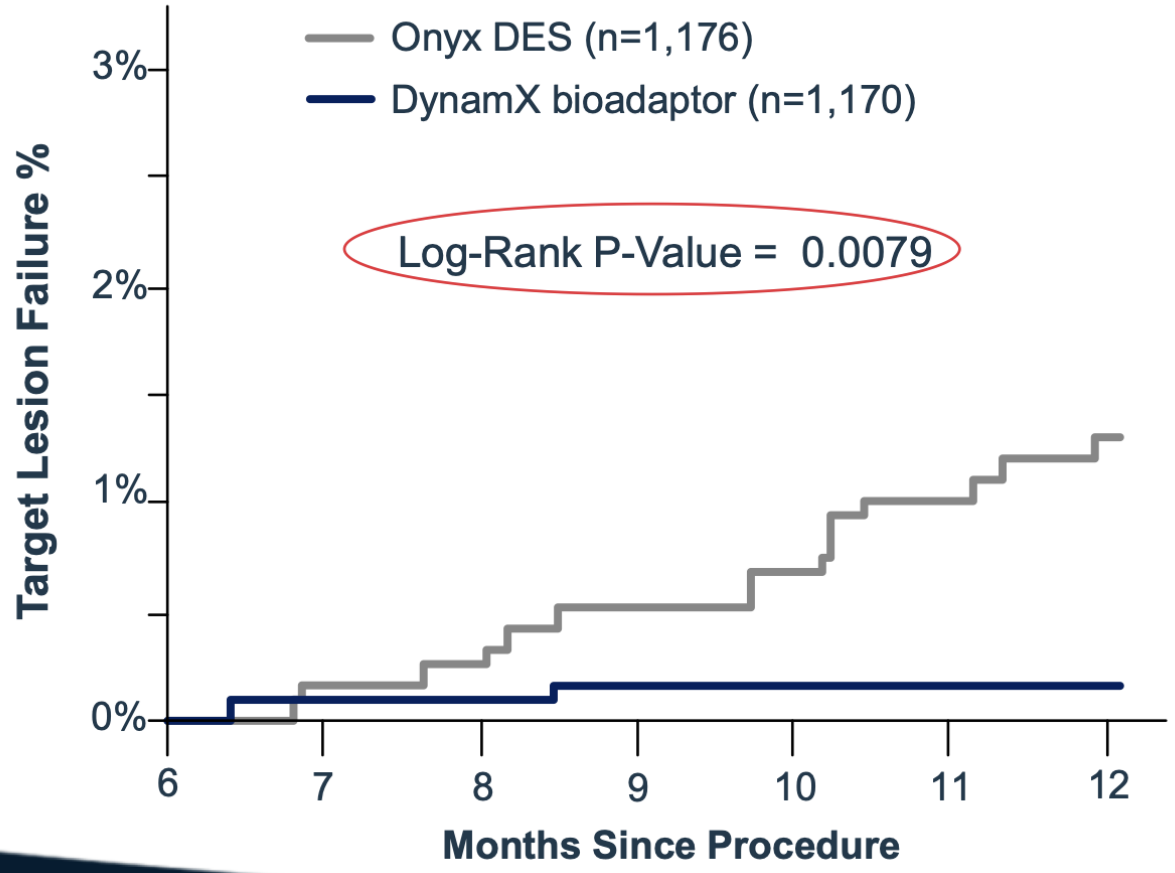
Onyx DES
(N=1,192)
2.77%



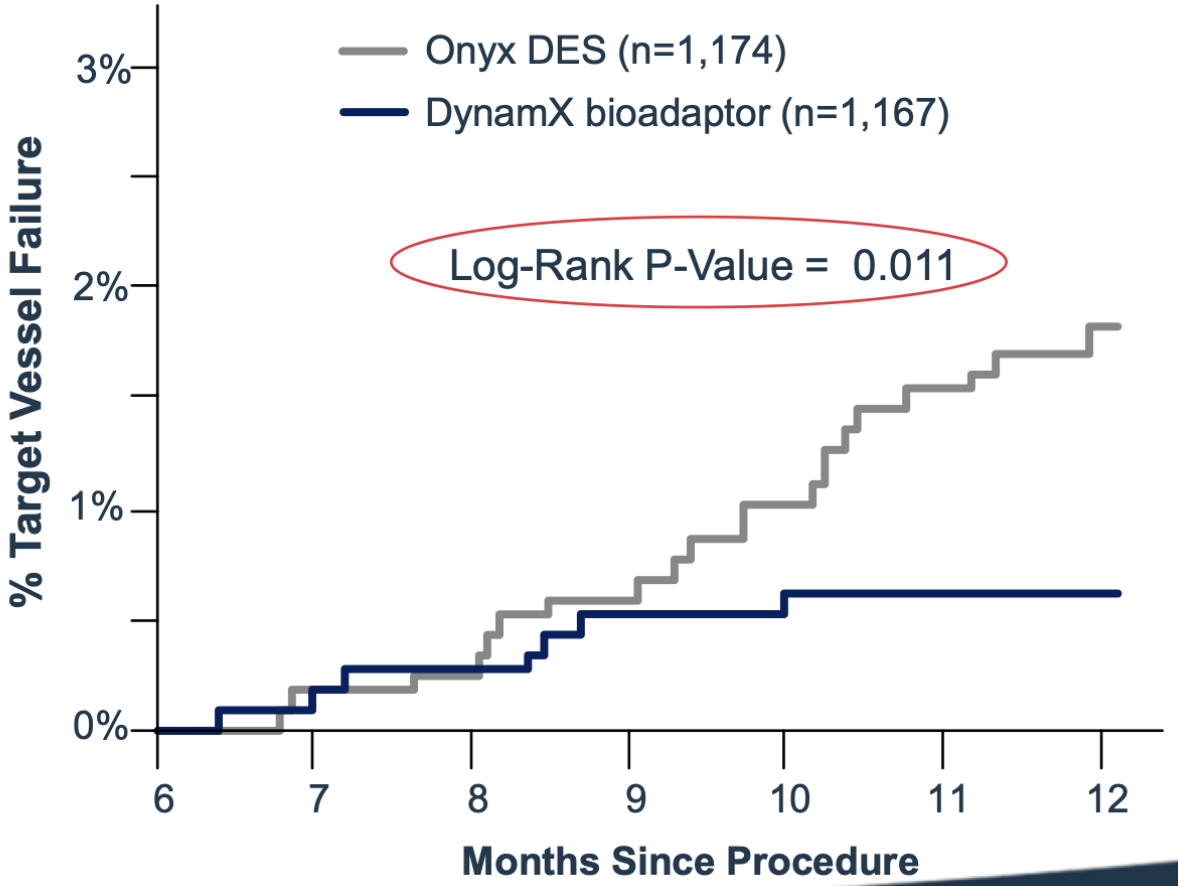
Powered Secondary Endpoints, 6-12 Mos

Significant Reduction and Plateau in TLF and TVF After 6 Mos

#1: TLF, Landmarked at 6 Months

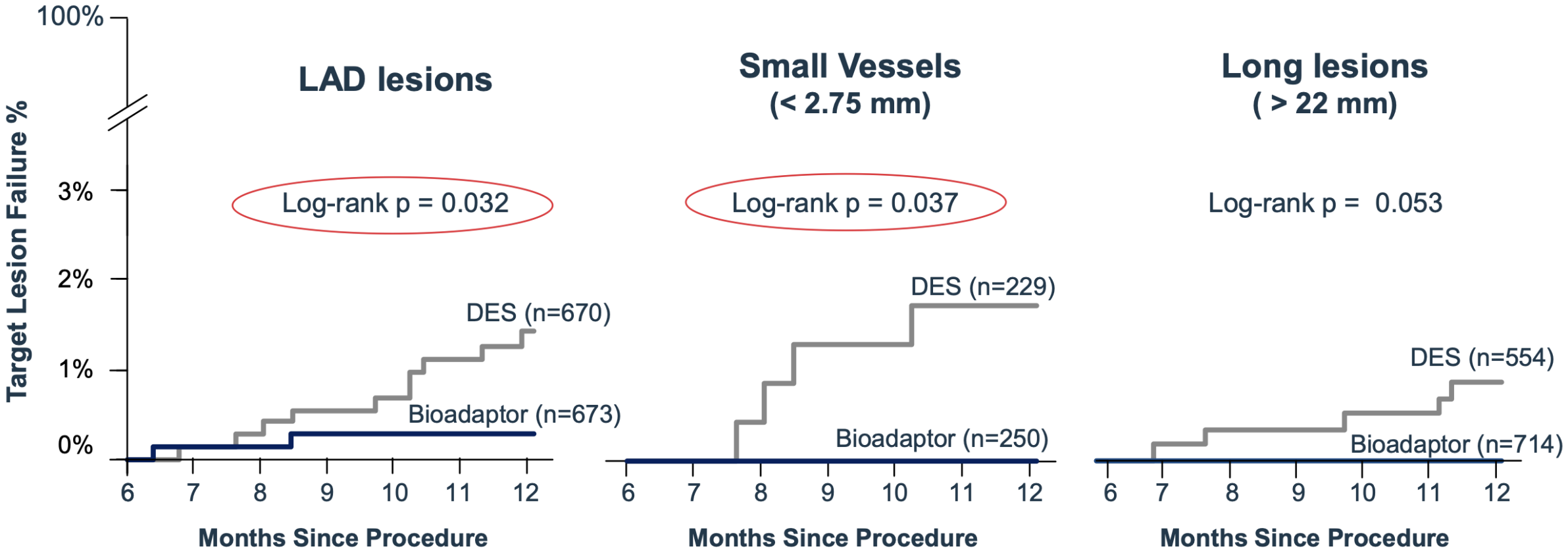


#2: TVF, Landmarked at 6 Months

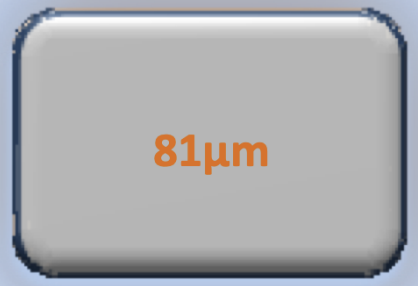


TLF in High-Risk Lesions, 6-12 Mos

Significant Reduction and Sustained Treatment Effect



A novel triple drug (TRx) eluting coronary stent system eluting Sirolimus along with two anticoagulants at the site of the implant is designed to deliver site-specific antithrombotic therapy



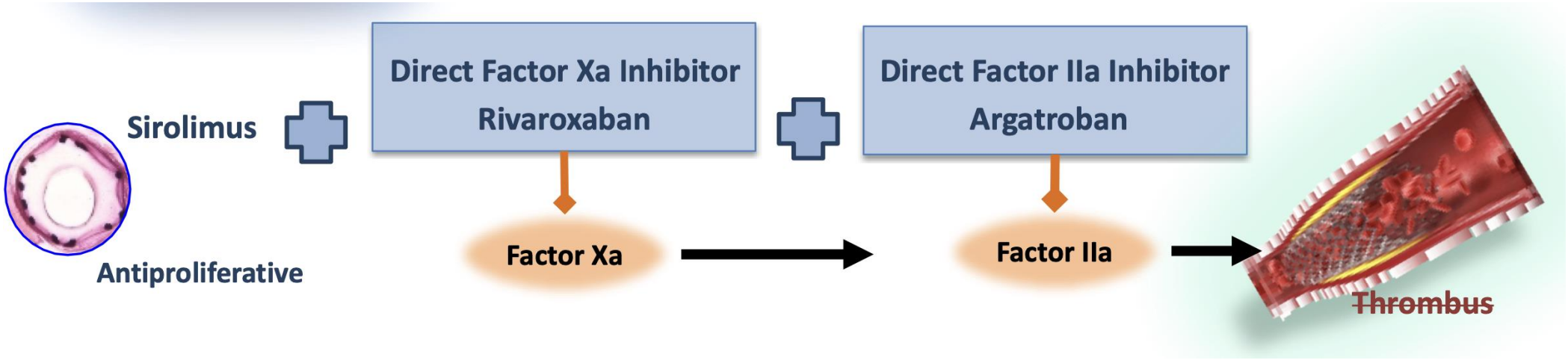
Platform

Thin struts

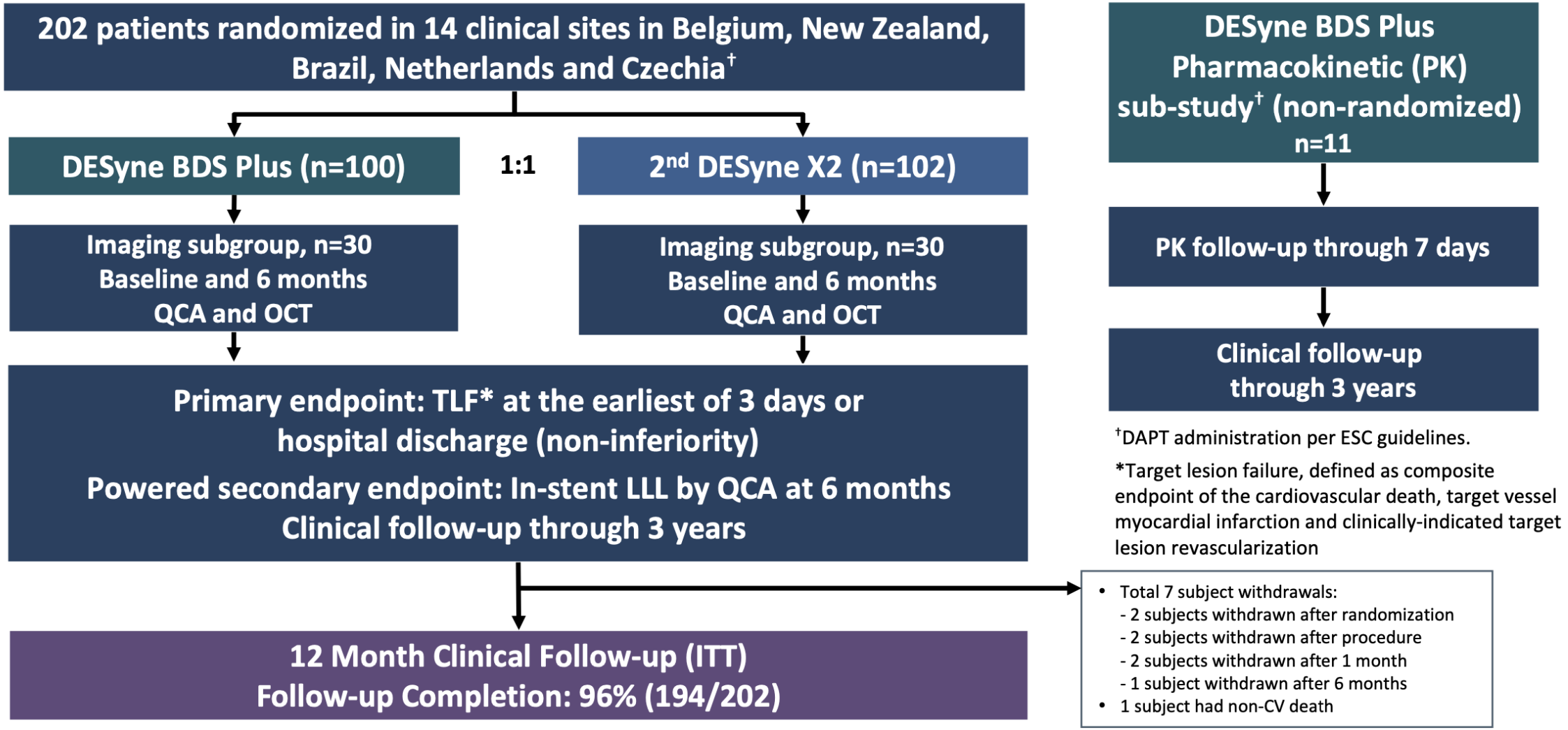
Bioabsorbable Polymer

Drugs:

Sirolimus (7µg/mm) – 4 weeks
Argatroban (8µg/mm) – 6 months
Rivaroxaban (8µg/mm) – 6 months



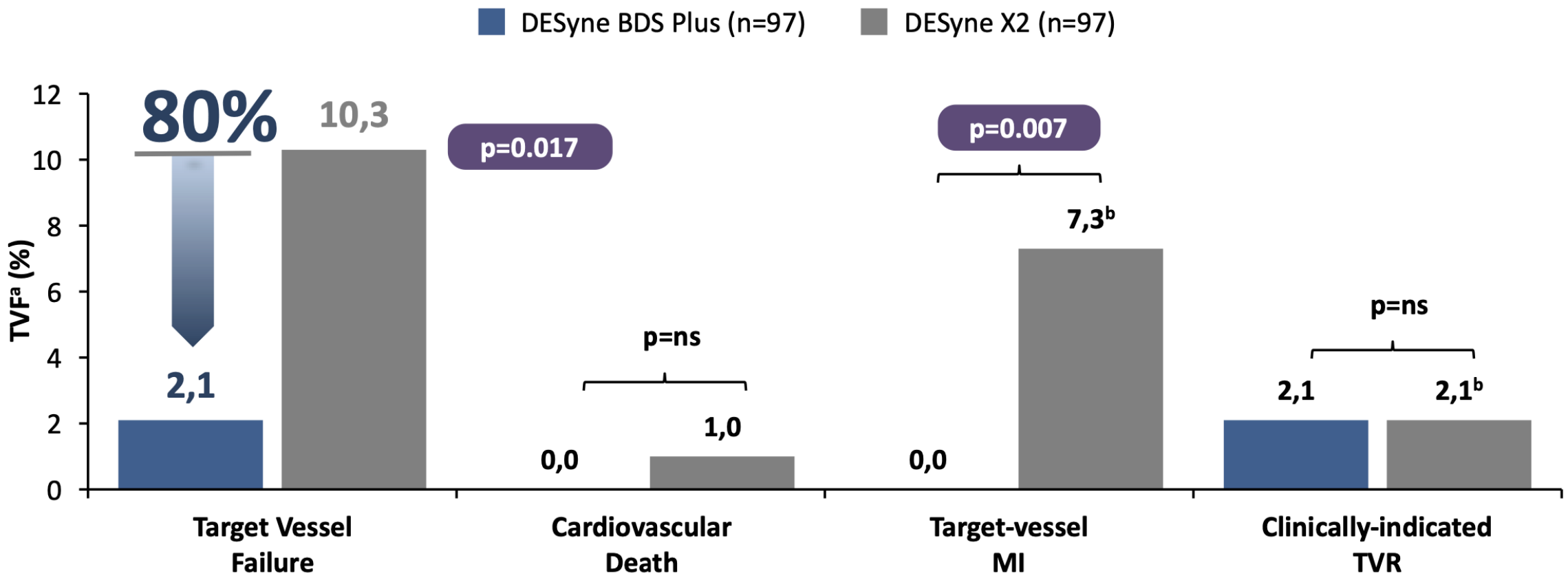
DESyne BDS Plus RCT Trial Design



†DAPT administration per ESC guidelines.

*Target lesion failure, defined as composite endpoint of the cardiovascular death, target vessel myocardial infarction and clinically-indicated target lesion revascularization

12-Month Outcomes Demonstrate Significantly Lower TVF with DESyne BDS Plus



Values are event rate. TVF, Target vessel failure. [a]Composite endpoint of the CV death, TV-MI and CI-TVR. [b]Event rate based on 96 subjects.

Conclusions

- Most of the currently used stents have excellent outcomes, in all lesions.
- PCI outcome has more to do with lesion preparation and medical therapy (OMT – anti-cholesterol and anti-platelet therapy) rather than stent type.
- In the future, we will be treating some patients with combination of stent and DEB : long diabetic LADs with diffuse disease… CTOs. Clinical outcomes data is forthcoming.
- Trials will be about **treatment strategy** and no longer stent A versus stent B.