BRS: Should be the prime time now (NO) ! should be ultimate future (YES) !!

DR. ASHOK SETH

FRCP (LOND, EDIN, IREL), FACC, FESC, MSCAI, FCSI, DSc., D.Litt.

CHAIRMAN - FORTIS ESCORTS HEART INSTITUTE

NEW DELHI, INDIA

FOUNDER TRUSTEE – Heart Valve Foundation of India and Course Director "INDIA VALVES"

DIRECTOR - Interventional Cardiology Foundation of India and "INDIA LIVE"

MEMBER - Medical council of India and Academic Sub committee

PRESIDENT ELECT – Asian Pacific Society of Interventional Cardiology

PAST PRESIDENT - Cardiological Society of India

PAST VICE PRESIDENT - Asia Pacific Society of Cardiology

I , Dr. Ashok Seth

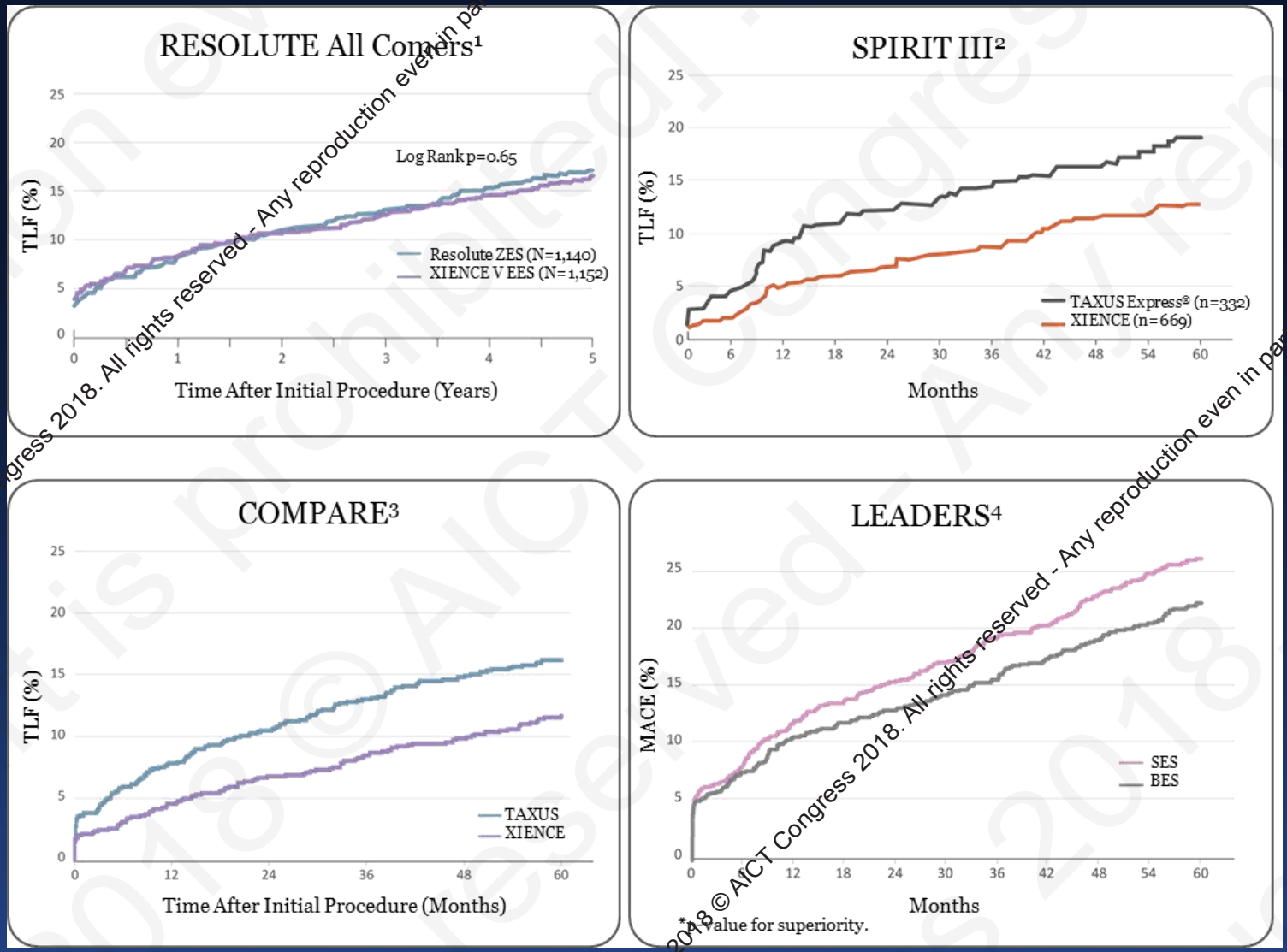
- I have the following potential conflicts of interest to report:
  - Scientific Advisor: Meril Life Sciences
  - Principal Investigator: Myval-1 Study, MeRes-1 Study
  - Consultant/Speaker's Bureau: Medtronic, Boston Scientific, Abbott Vascular
  - Member, BRS Global Advisory Board: Abbott Vascular

Fortis Escorts HEART INSTITUTE

Do we REALLY NEED a BRS ??

LONG-TERM COMPLICATIONS OF PERMANENT STENTS

Ongoing Annual Accrual of Events with Permanent DES



*¹Windecker S. RESOLUTE All Comers 5-Year. EuroPCR 2014. / ²Gada H et al. SPIRIT III 5-year. JACC Cardiovasc Interv. 2013;6:1263-1266. / ³Smits P.C. et al. COMPARE 5-Year. J AM Coll Cardiol Cardiovasc Interv. 2015; *: 1157-1165. / ⁴Serruys PW. LEADERS 5-Year. TCT 2012.*

Growing Challenges of DES In-stent Restenosis (ISR)

In the U.S., there are approximately 900,000 PCIs / year[1]

1.4% ISR per year = 12,600 ISRs per year and growing

After an ISR, ISR "relapses" occur in the same lesion at a rate of 20% to 66%[2,3]

Although not widespread, there are a growing number of ISR patients who have 3 layers of stents that are being referred for BRACHYTHERAPY (I.C. beta-radiation)

1. DeFrances CJ, Lucas CA, Vuie VC, Golosinskiy A. 2006 National Hospital Discharge Survey. Hyattsville, MD: National Center for Health Statistics; 2008. 2. Meliga, E. et al. New drug-eluting stent implantation for recalcitrant in-stent restenosis treated with drug-eluting stents. the Stent-in-Stent Cube (SIS³) registry. J Invasive Cardiol 2011;23:365–368. 3. Latib et al. JACC Cardiovasc Interv. 2011 Feb;4(2):155-64.

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BRS addresses an UNMET CLINICAL NEED

Rationale

*Vessel scaffolding is only needed transiently**

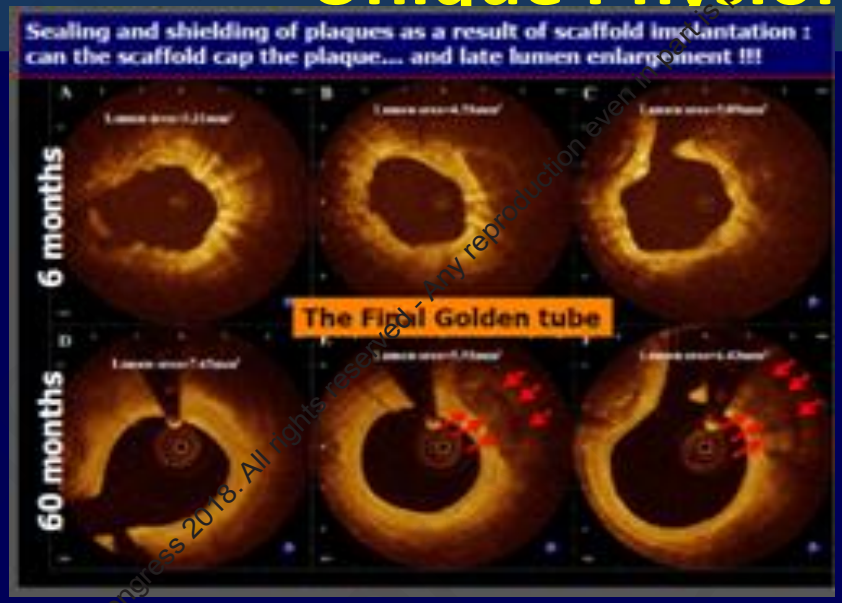
Vision

Improve Long Term Outcomes for Patients by Leaving No STENT Behind[1]

Potential Benefits

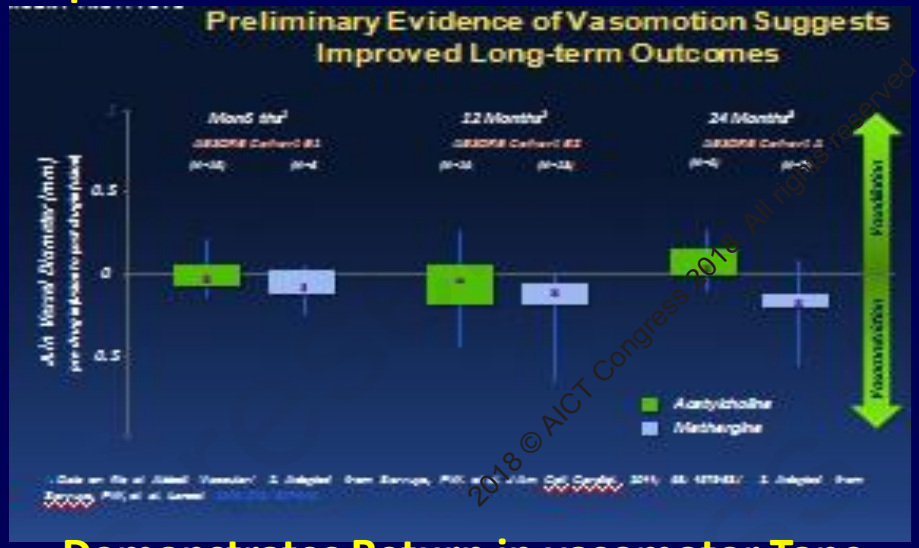
- *Restore the vessel to a more natural state, capable of natural vascular function*
- *Eliminate chronic sources of vessel irritation and inflammation*
- *Vessels remain free for future treatment options*
- *Reduce the need for prolonged DAPT[2]*
- *Allow for use of non-invasive imaging techniques (CCTA)*
- *Improve patient quality of life*

Do WE Really NEED BRS ??
Unique Physiological Advantages



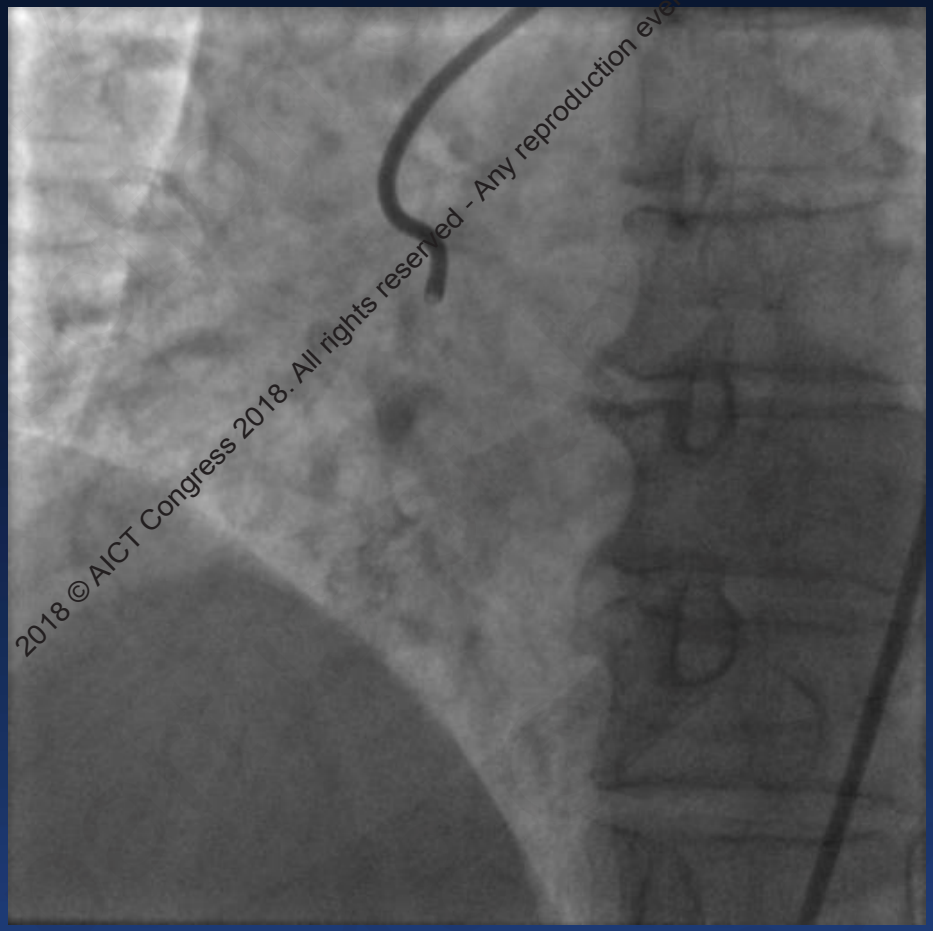
Demonstrates Resorption

Demonstrates Uncaging and Late lumen Gain



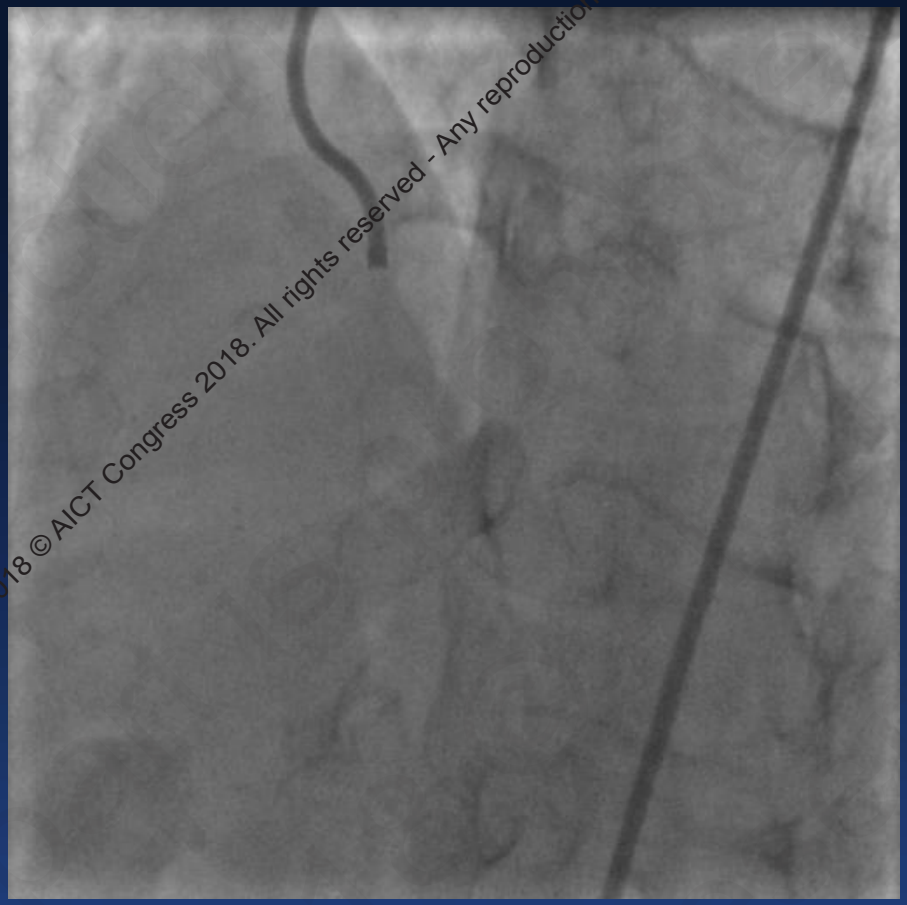
Demonstrates Return in vasomotor Tone

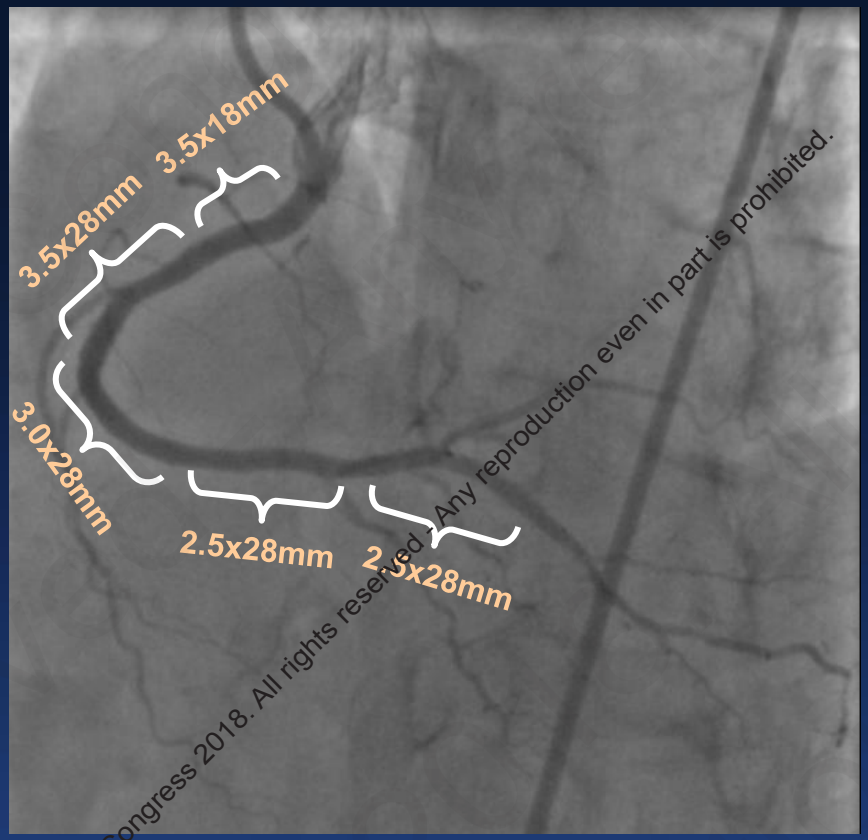
48 YR M Anamalous RCA CTO



A

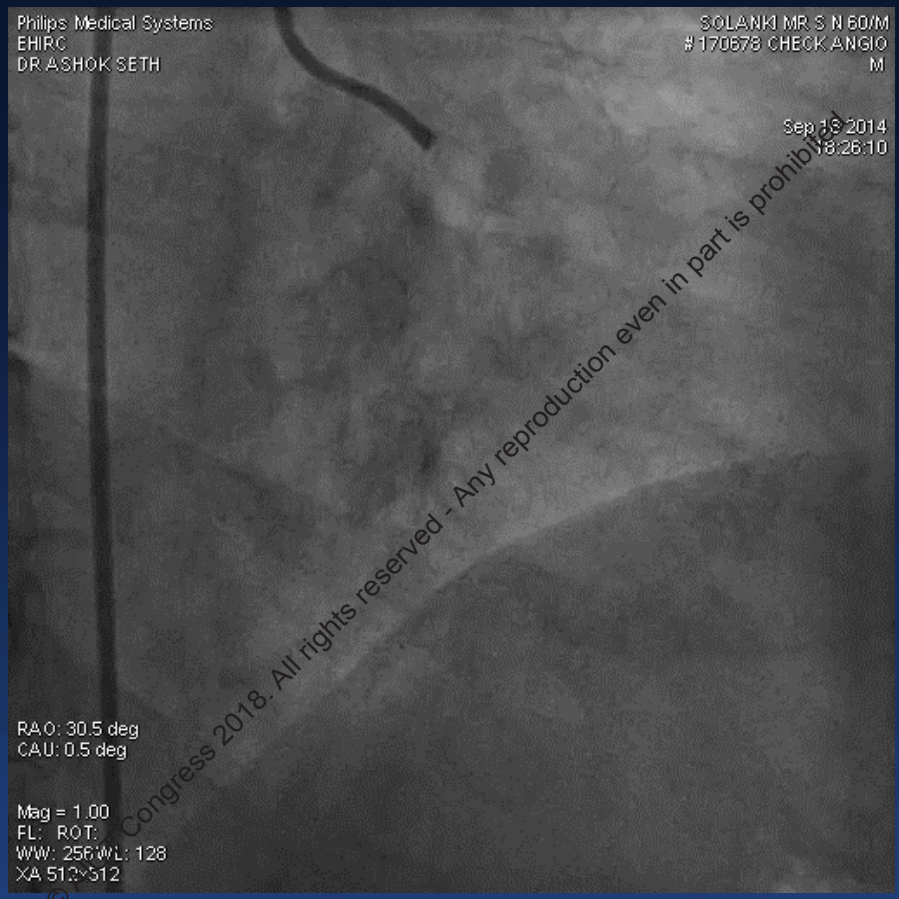
Final Result
5 A-BVS , 12.5 cm of Coverage
FULL PLASTIC JACKET





3-years follow up
ENDOLUMINAL RECONSTRUCTION

abc



abc

DO WE REALLY NEED BRS ???

I BELIEVE IT IS WORTH IT !!

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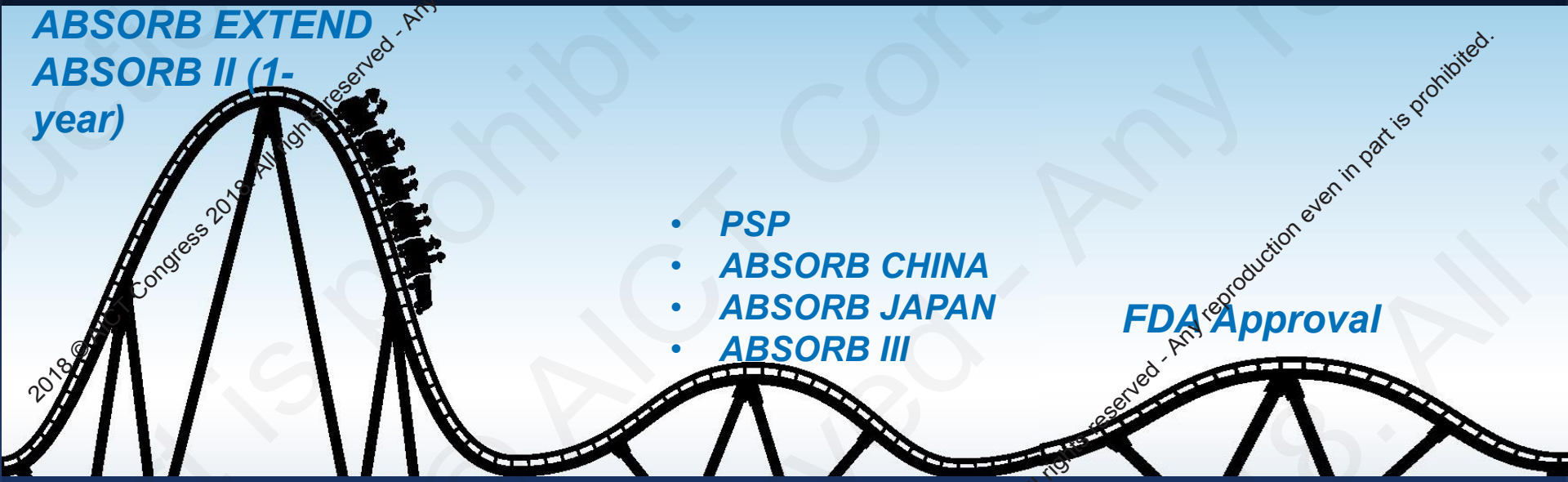
BVS a Roller Coaster Ride



ABSORB EXTEND
ABSORB II (1-year)

- PSP
- ABSORB CHINA
- ABSORB JAPAN
- ABSORB III

FDA Approval

GHOST EU

ABSORB II (3-years)

- ABSORB III (2-
- FDA Advisory
- European

Annals of Internal Medicine®

LATEST ISSUES CHANNELS CME/MOC IN THE CLINIC JOURNAL CLUB WEB EXCLUSIVES AUTHOR INFO

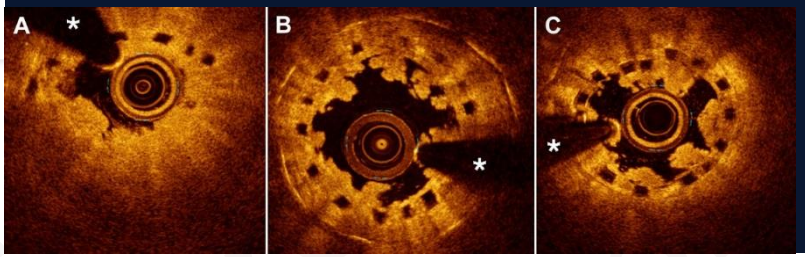
REVIEWS | 17 OCTOBER 2017

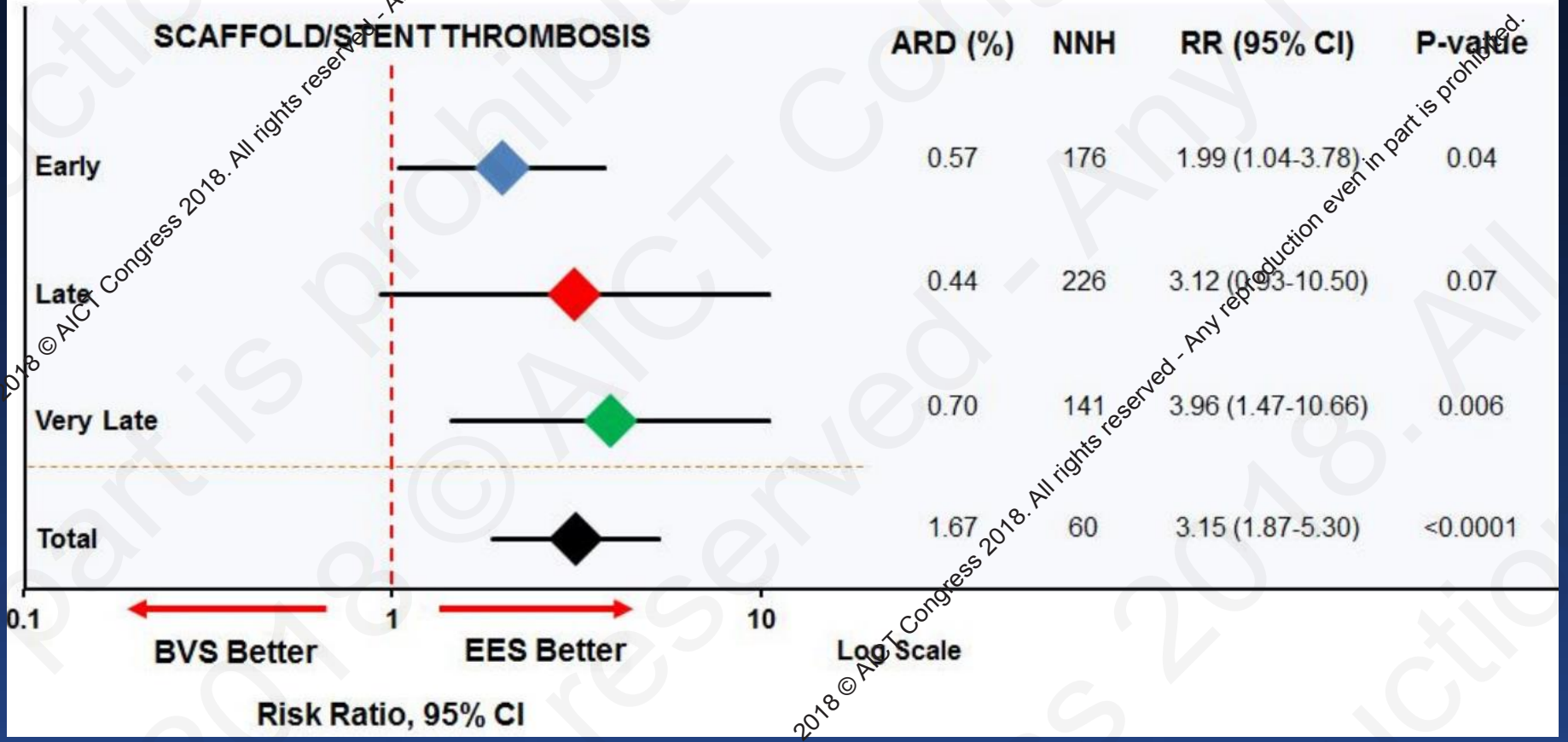
Mid- and Long-Term Outcome Comparisons of Everolimus-Eluting Bioresorbable Scaffolds Versus Everolimus-Eluting Metallic Stents: A Systematic Review and Meta-Analysis

Xin-Lin Zhang, MD (*); Qing-Qing Zhu, MD (*); Li-Na Kang, MD (*); Jian-Ling Li, MD; Biao Xu, MD, PhD

Article, Author, and Disclosure Information

Eligible for CME Point of Care Learn More





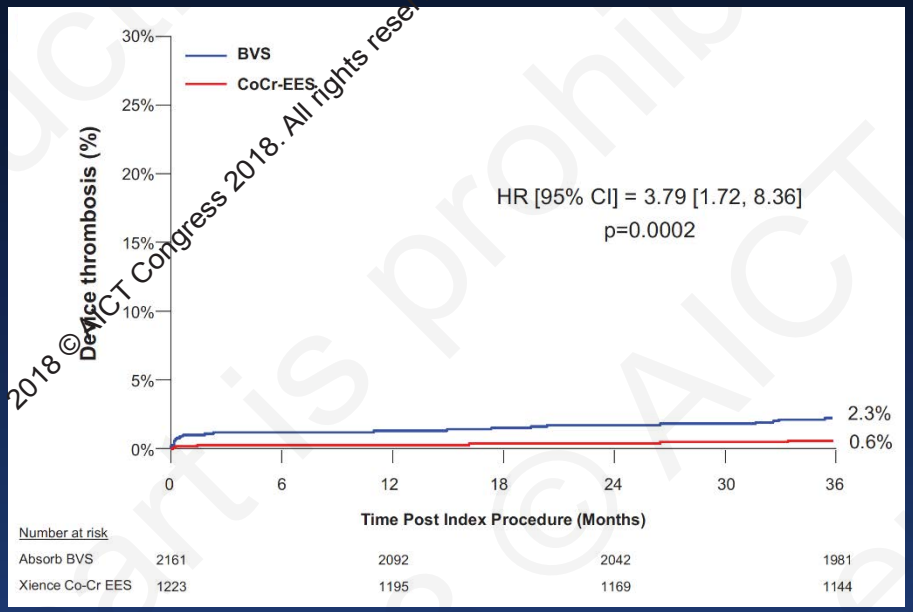
3-Year Outcomes With Absorb BVS, but Xience Performed Exceptionally Well !!

Ali Z et al. *Circulation* 2017, ahead of print

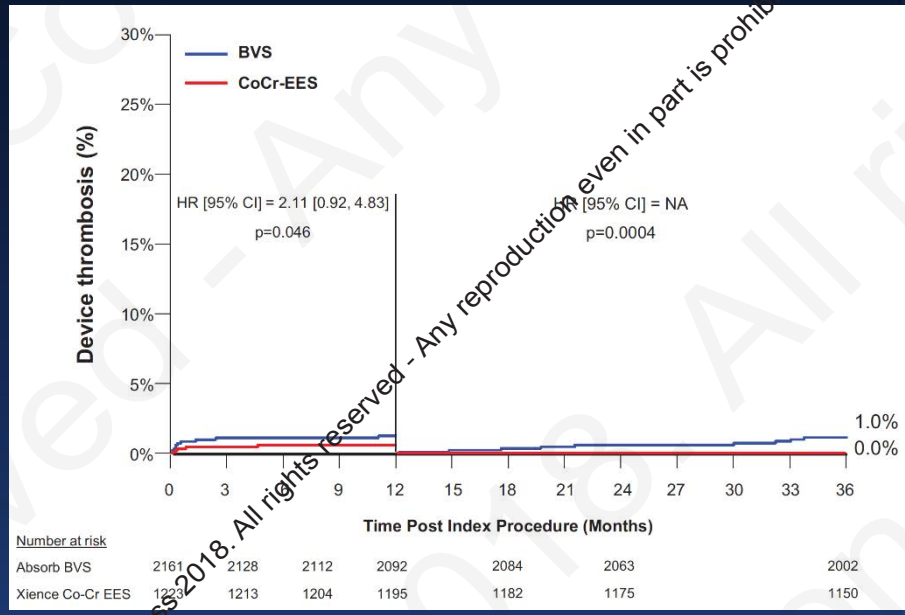
IPD of ABSORB II, III, China and Japan Trials (N=3389)

Device Thrombosis

Through 3 years



Landmark @1 Year



Safety

Home > Safety > MedWatch The FDA Safety Information and Adverse Event Reporting Program > Safety Information > Safety Alerts for Human Med

Absorb GT1 Bioresorbable Vascular Scaffo (BVS) by Abbott Vascular: Letter to Health Providers - FDA Investigating Increased R Major Adverse Cardiac Events

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

[Posted 03/18/2017]

AUDIENCE: Cardiology, Surgery, Risk Manager

ISSUE: The FDA is informing health care providers treating patients with Absorb GT1 Scaffold (BVS) that there is an increased rate of major adverse cardiac events obser BVS, when compared to patients treated with the approved metallic XIENCE

The FDA's initial review of two-year data from the BVS pivot

News Conferences Slides & M

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THE TIMES OF INDIA

PAGES 36 | CAPITAL | INVITATION PRICE ₹4.50; ₹7.00 WITH ET, OR ₹8.50 WITH NAVBHARAT TI

Govt issues alert on dissolvable stents

...ive years after the launch of ... bio-resorbable stents in India, Union health authorities on Monday asked patients and doctors to report any problem with them. P15

Centre issues medical 'alert' on bio-resorbable stents

Asks Patients, Docs To Report On Problem

Malathy.Iyer@timesgroup.com

Mumbai: Almost five years after the launch of the revolutionary bio-resorbable stents in India, Union health authorities on Monday issued a medical alert cautioning patients and doctors and asking them to report any problems.

The Central Drugs Standard Control Organisation (CDSCO)'s note posted on its website cited "safety concerns" as the reason...

SAFETY CONCERNS'

- Bio-resorbable stents were introduced in India in Mumbai in December 2012 by Abbott
- They were considered path-breaking as they dissolve in about three years, leaving no foreign metal behind
- From April 1, EU allowed only restrictive sale of such stents till a review in 2018
- Indian CDSCO has cited elevated rate of 'adverse cardiac events'

review in 2018. "After the manufacturer brought the EU decision to our notice, we decided to inform our doctors, distributors and patients about the concerns," said the official, adding that the ... hasn't placed any restriction so far. The bio-resorbable stents were considered a path-breaking invention in the ... as these dissolve in ... years after implantation, leaving no foreign metal ... drug-eluting ... metal ...

... public hospital doctor. Delhi-based cardiologist Dr Ashok Seth, who has used a maximum number of bio-resorbable stents in India, said the implantation technique and choice of patients (with ... arteries that aren't small and narrow) are of prime importance. "We have ... cases ... success ... choose ... patients ... he said.

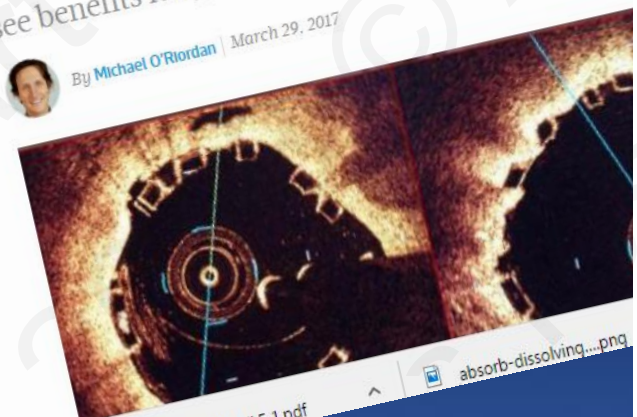
tctMD/the heart beat

NEWS | INTERVENTIONAL

Scaffold Thrombosis Concerns With Absorb BVS Echoed in AIDA Trial

Rates of definite stent thrombosis were fivefold hig... the newer technology, but some experts are still h... see benefits long-term.

By Michael O'Riordan | March 29, 2017



absorb-dissolving....png

BLOG HOME ANGIOPLASTY.ORG HOME THE ACTIVATED PATIENT NEWS CENTER

The Voice in the Ear

Stent Blog by Burt Cohen

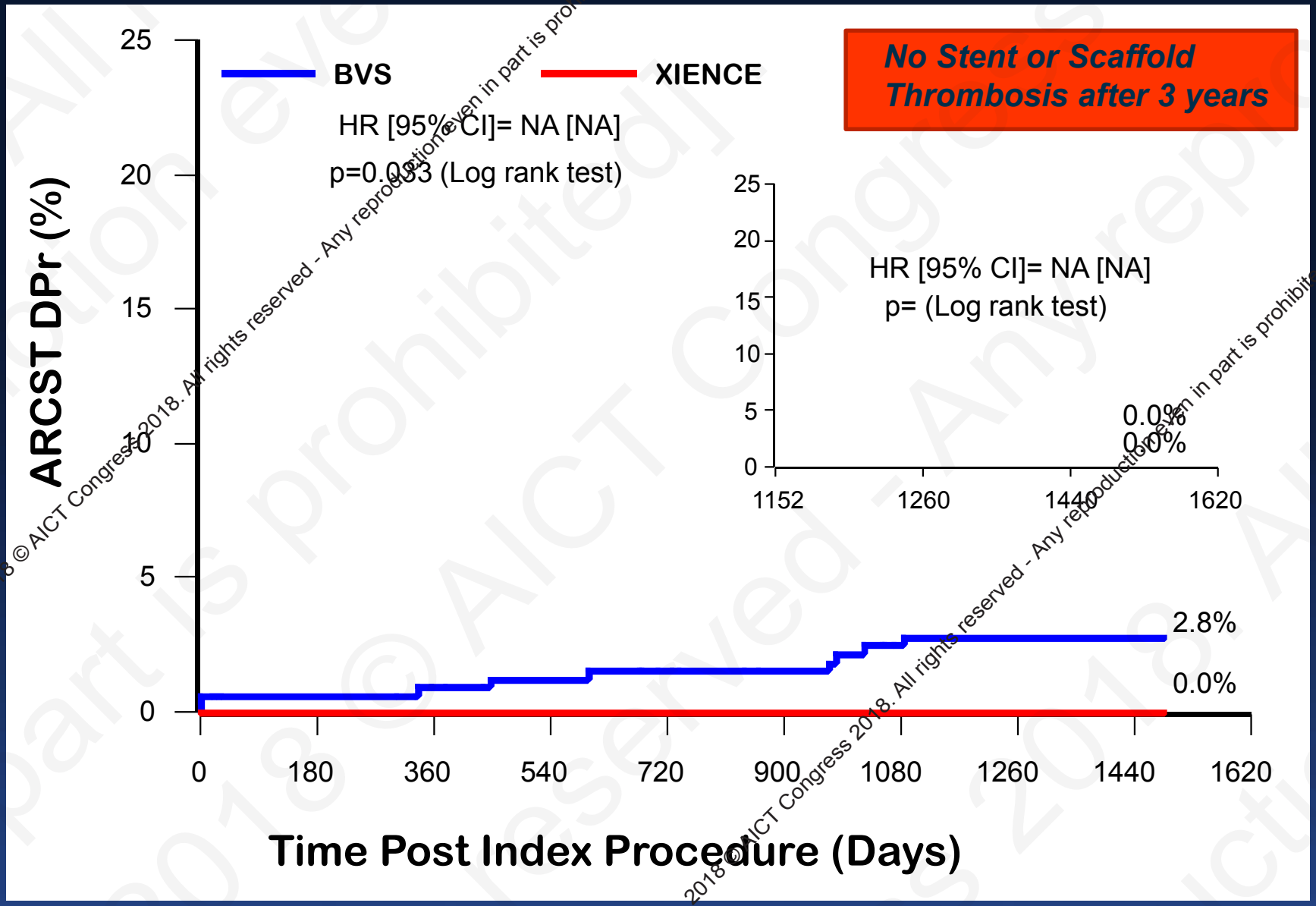
Status of the "Disappearing Stent" in Europe: It's Complicated!

2

Last night news began circulating on Twitter that Abbott's Absorb BVS (Bioresorbable Vascular Scaffold) was being withdrawn from the European market. This information was prompted by several physicians posting on Twitter a March 31 "Urgent Field Safety Notice/Physician Advisory" letter from Abbott addressed to "Valued Abbott Vascular Customer."

Abbott Vascular voluntarily stops commercial sales of ABSORB BVS in September 2017

ABSORB II , 4 YEAR DATA (HOPE) !!



* Serruys et al TCT 2017

It is a NEW DEVICE
And therefore has a
LEARNING CURVE

tion and Cardiovascular Interventions 00:00–00 (2014)

Editorial Comment

Bioresorbable Scaffold: "Looking at the 'Real World' through a Plastic Tube"

Ashok Seth,[1]* FRCP, FACC, FSCAI, FESC, FCSI, DSC, DLITT, **and Vijay Kumar,**[2] MD, DNB
[1]Fortis Escorts Heart Institute, New Delhi, India
[2]Interventional Cardiology, Fortis Escorts Heart Institute, New Delhi, India

Requires
Meticulous
ATTENTION TO
IMPLANTATION
TECNIQUES
including HP POST
DiL and result
Optimization

lar, Santa
lesions.
Use of
associated
suboptimal de
sultant risk of
polymer coating
and resultant incr
by rotational atherectomy (RA), cutting or scoring balloon has helped to overcome these complications [2]. Basavarajaiah et al. have demonstrated the value of vessel bed preparation and lesion modification by RA or scoring balloon to achieve optimal results with large

Fortis Escorts HEART INSTITUTE

LIMITATIONS of 1st GEN BRS

.. is a Drug Eluting Device which differs from a 3 rd Gen Metallic Drug Eluting Stent !!

Unfavourable Device Charecteristics

- *Larger Profile , Thick Struts*
- *Limited sizes, lengths*
- *Limited expansion properties*

Challenging Procedural Charecteristics

- *Gradual inflations*
- *More difficult to recross with wires, balloon, stents through scaffold*
- *Poor trackability in calcified tortuous artery*
- *Minimal Overlap / Poor visibility*
- *Recoil in some lesions*

UNIQUE FAILURE MODES : ACUTE / SUBACUTE AND LATE SCFFOLD THROMBOSIS

JACC: CARDIOVASCULAR INTERVENTIONS
© 2017 PUBLISHED BY ELSEVIER ON BEHALF OF THE
AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

VOL. 10, NO. 18, 2017
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2017.06.067

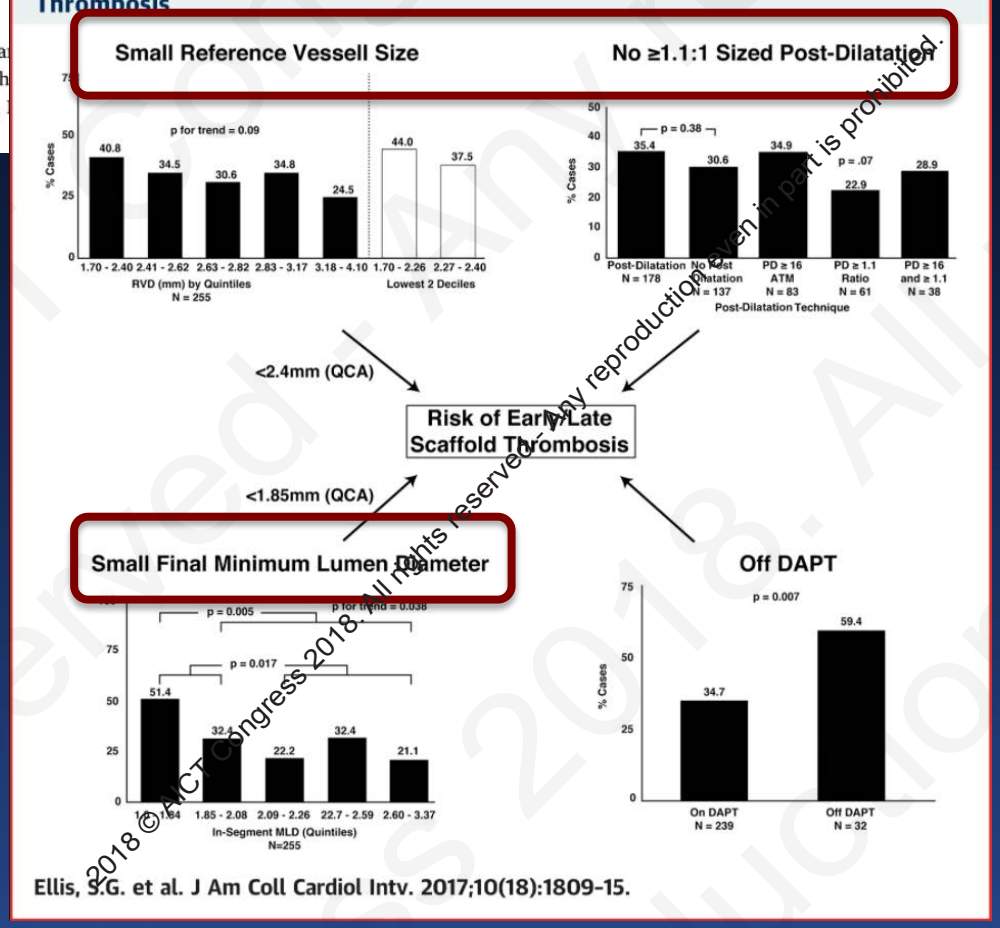
FOCUS ON BIORESORBABLE VASCULAR SCAFFOLDS

Clinical, Angiographic, and Procedural Correlates of Acute, Subacute, and Late Absorb Scaffold Thrombosis

Stephen G. Ellis, MD,[a] Giuseppe Steffenino, MD,[b] Dean J. Kereiakes, MD,[c] Gregg W. Stone, MD,[d] R.J. va
Alexandre Abizaid, MD,[f] Holger Nef, MD,[g] Bernardo Cortese, MD,[h] Luca Testa, MD,[i] Maurizio Menich
Corrado Tamburino, MD,[k] Tommaso Gori, MD, PhD,[l] Takeshi Kimura, MD,[m] Patrick W. Serruys, MD,
Salvatore Brugaletta, MD, PhD,[o] Manel Sabaté, MD, PhD,[o] Run-Lin Gao, MD[p]

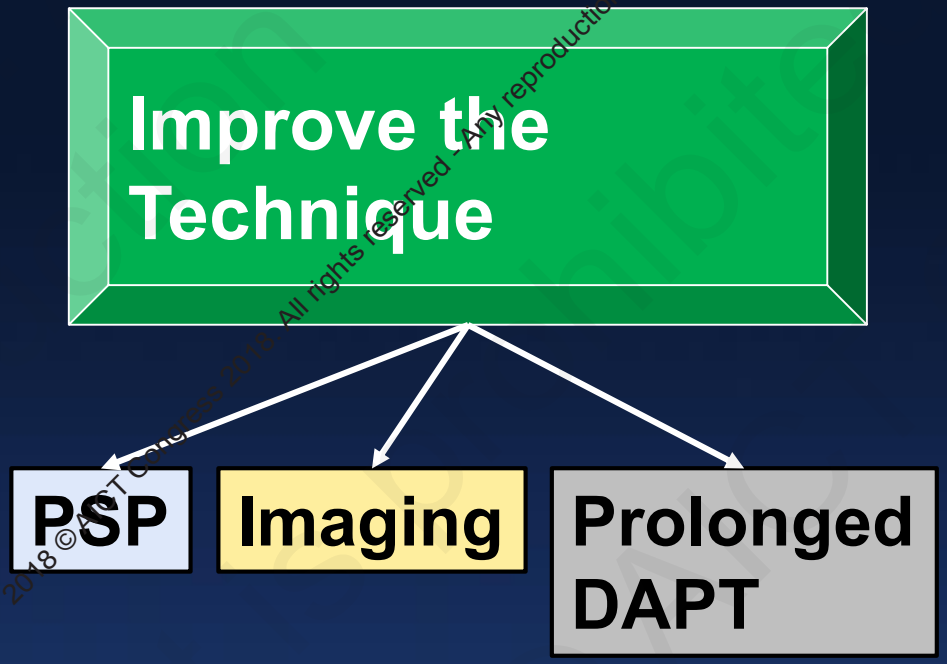
✓**8,771** consecutively treated patients,
✓**105 patients (1.2%)** had scaffold thrombosis within 1 year of implantation.
✓They were matched 2:1 with controls selected randomly from non thrombosis patient

CENTRAL ILLUSTRATION: Principal Risk Factors for Absorb Scaffold Thrombosis



Ellis, S.G. et al. J Am Coll Cardiol Intv. 2017;10(18):1809-15.

How to Improve BRS Outcomes Prior to Their Complete Bioresorption



EuroIntervention 2015;11:131-135

EDITORIAL

BRS in complex lesions: massaging (and messaging) the right pressure points

Ashok Seth*, FIACP, FACC, FESC, D.Sc; Vijay Kumar, MD, DNB (Cardiology); Vishal Rastogi, MD, DM (Cardiology)

Fortis Escorts Heart Institute, New Delhi, India

- **'DÉJÀ VU' of 20-Years ago** when we first learnt to safely put a thick strut metal stent into coronary arteries using **HIGH PRESSURE DIL.**
- A-BVS in its current form (156 µm thick strut) is like 1 st GEN Metal Stent
- It therefore requires **back to the Basics** set of 'tips and tricks' for complex lesion anatomies, which includes **'HIGH PRESSURE DIL'.**

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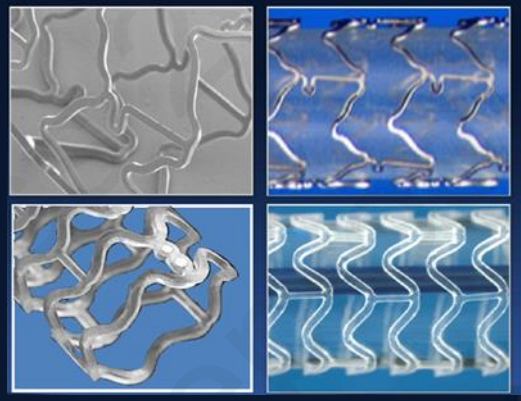
PSP

BVS SPECIFIC IMPLANTATION TECNIQUE



Comparable results to best in class DES can be achieved with optimal implantation technique

P PREPARE THE LESION

OBJECTIVE

- *Prepare lesion to receive scaffold*
- *Facilitate delivery*
- *Enable full expansion of pre-dilatation balloon to facilitate full scaffold expansion*

S SIZE APPROPRIATELY

OBJECTIVE

- *Accurately size the vessel*
- *Select appropriate scaffold for "best fit"*

P POST-DILATE

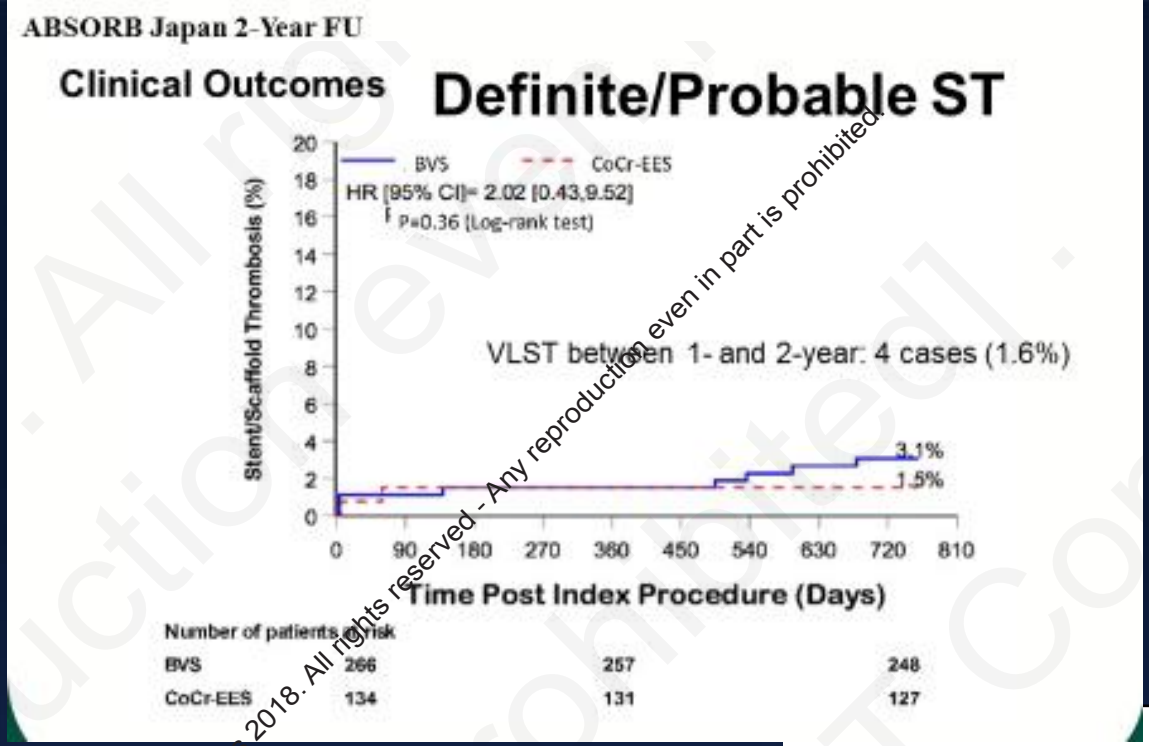
OBJECTIVE

- *Achieve <10% final residual stenosis*
- *Ensure full strut apposition*

Wright, RS, et al., Circulation. 2011; 123: 2022-2060. / Wijns, W, et al., European Heart Journal. 2010; 31: 2501-2555. / Levine, GN, et al., Circulation. 2011; 124: 2574-2651. / Steg, PG, et al., European Heart Journal. 2012; 33: 2569-2619. / O'Gara, PT, et al., Circulation. 2013; 127: 529-555.

2016 : VLScT: A NEW ANIMAL

ABSORB II (3 Years VLScT Rates)

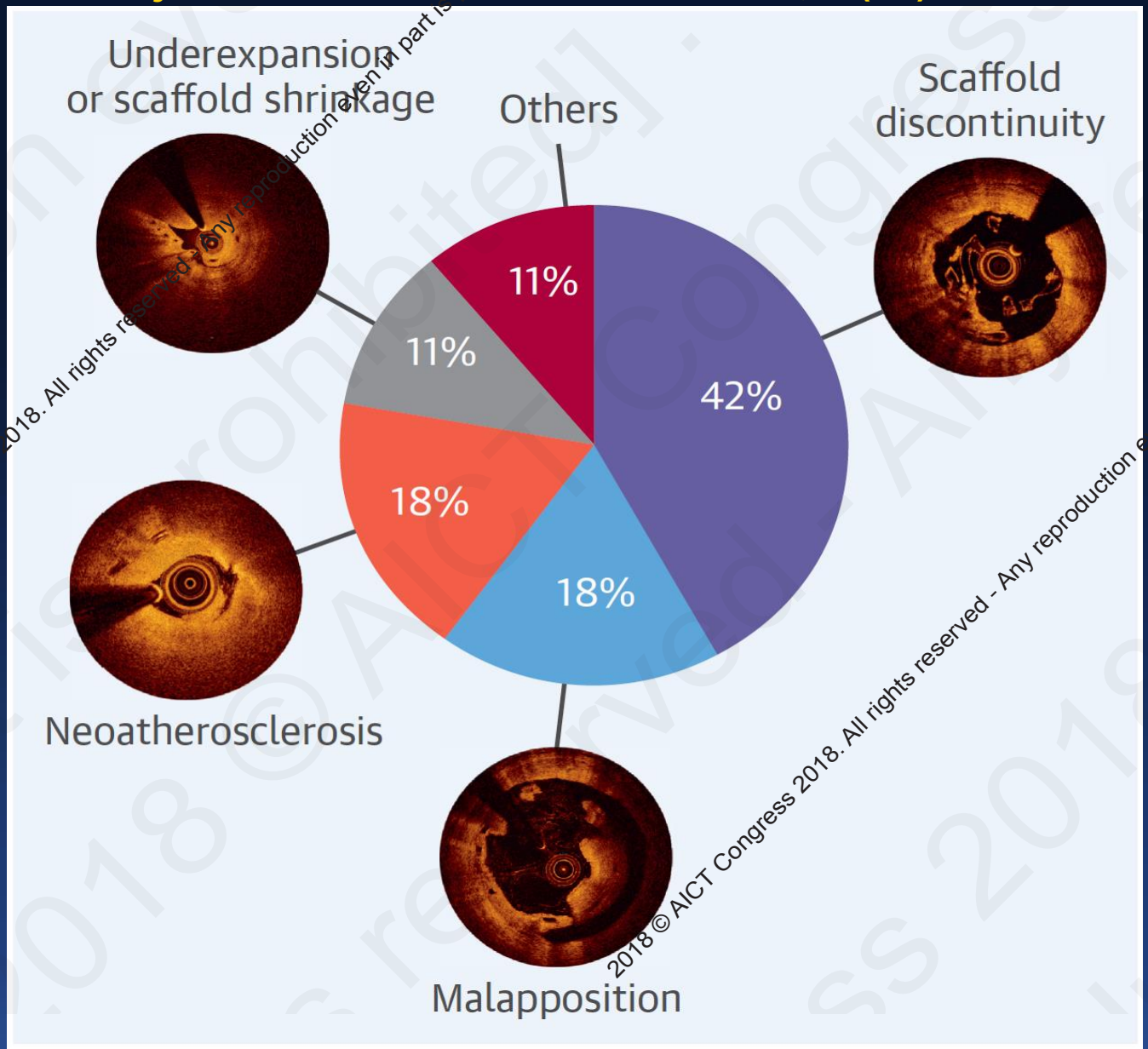


ABSORB JAPAN (2 years VLSc T rates)

	Absorb 335 patients	Xience 166 patients	p valuVLScT e
Definite	**2·5% (8)**	**0·0% (0)**	**0·06**
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·0% (0)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19
Definite or probable	**2·8%(9)**	**0·0% (0)**	**0·03**
Acute (0–1 day)	0·3% (1)	0·0% (0)	1·0
Sub-acute (2–30 days)	0·3% (1)	0·0% (0)	1·0
Late (31–365 days)	0·3% (1)	0·0% (0)	1·0
Very late (>365 days)	1·8% (6)	0·0% (0)	0·19

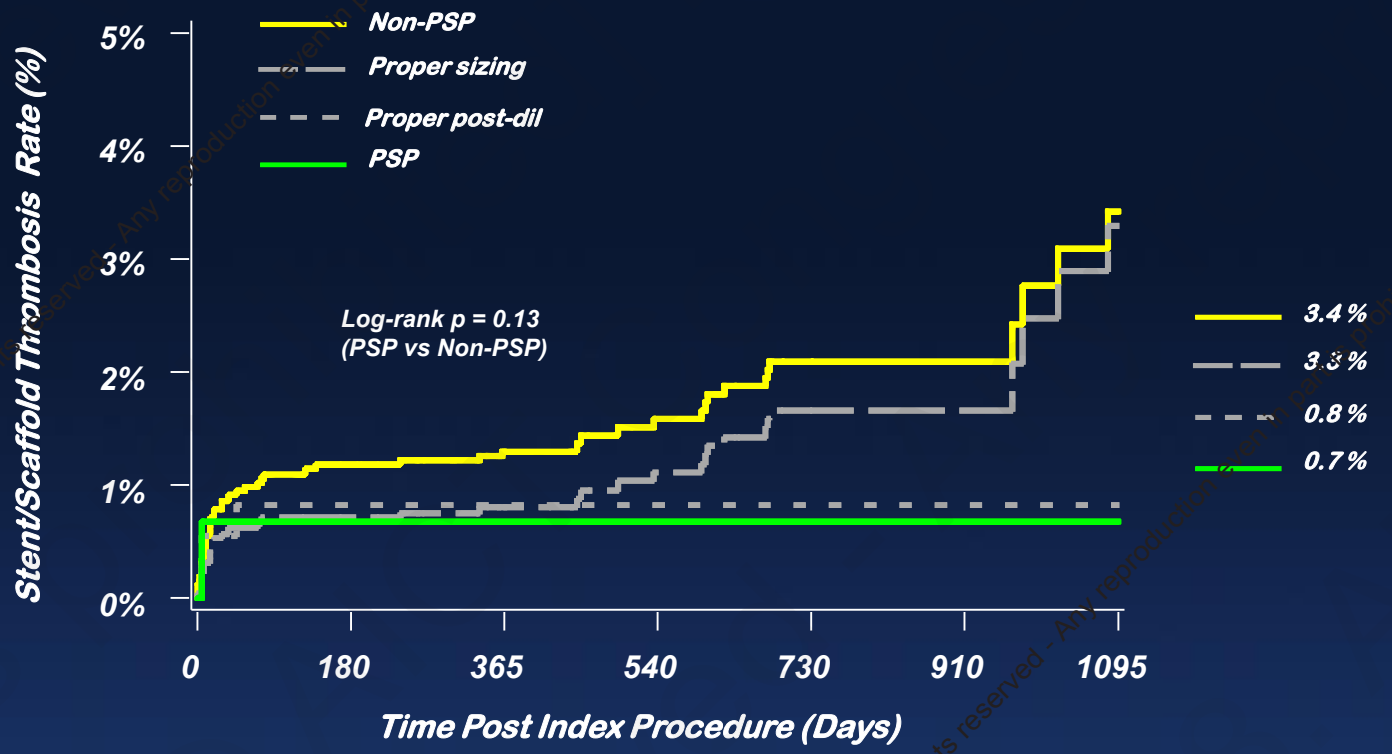
Very Late Scaffold Thrombosis: Underlying Causes

Yamaji K. et al. *J Am Coll Cardiol*. 2017;70(19):2330–44



Bioresorbable Vascular Scaffolds – Optimal PCI

Impact of Individual Components of PSP ON ST



	0	365	730	1095
Non-PSP	2549	2483	1354	291
Proper Sizing	2261	2211	1247	238
Proper post-dil	365	357	227	26
PSP	297	290	192	21

0-365 days population: A-EXTEND, A-II, A-Japan, A-China, A-III
366-730 days population: A-EXTEND, A-II, A-Japan, A-China
731-1095 days population: A-II

Ellis, S., ABSORB Trials PSP Analysis, TCT 2016

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IJCA-26643; No of Pages 5

International Journal of Cardiology xxx (2018) xxx–xxx

Contents lists available at ScienceDirect

International Journal of Cardiology

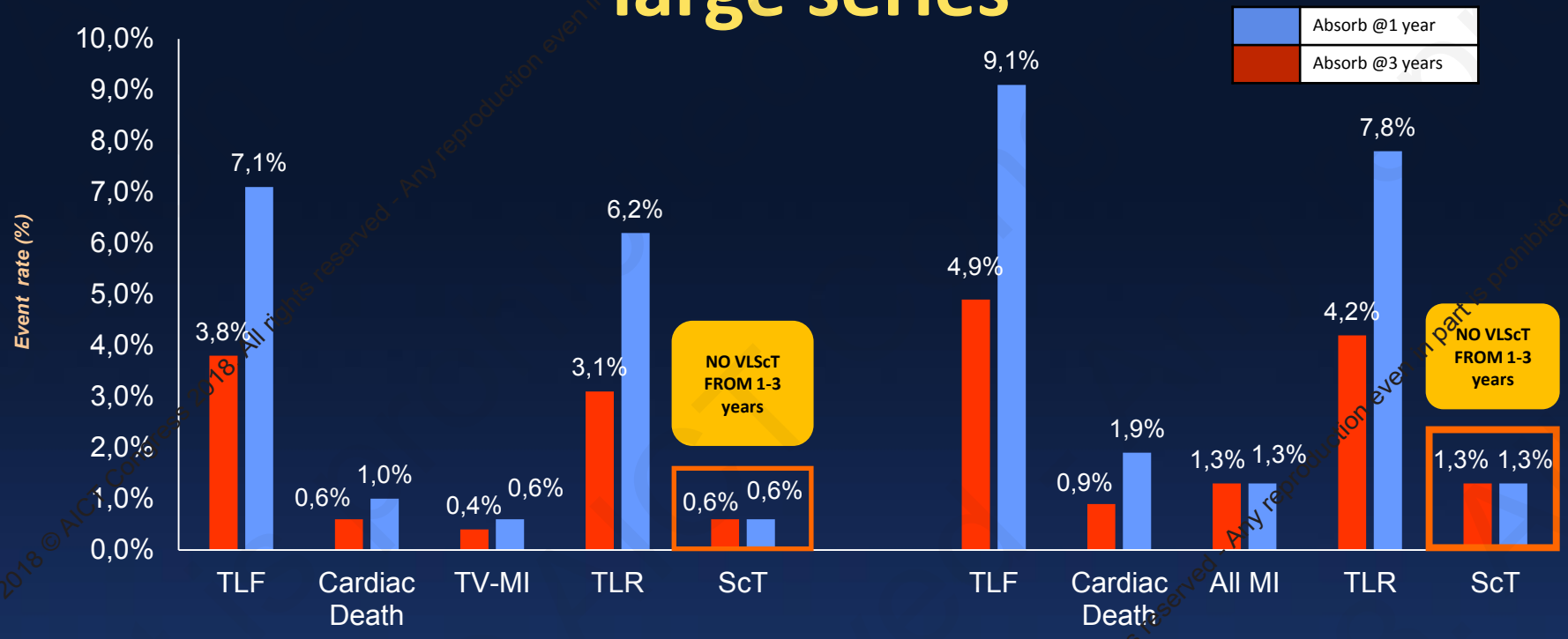
journal homepage: www.elsevier.com/locate/ijcard

Long-term follow-up of BVS from a prospective multicenter registry: Impact of a dedicated implantation technique on clinical outcomes

Damiano Regazzoli [a,1], Azeem Latib [a,b,*,1], Babu Ezhumalai [c], Akihito Tanaka [a], Pier Pasquale Leone [a], Sara Khan [c], Vijay Kumar [c], Vishal Rastogi [c], Marco Bruno Ancona [a], Antonio Mangieri [a], Francesco Giannini [a,b], Satoru Mitomo [a], Ashok Seth [c], Antonio Colombo [a,b]

[a] Unit of Cardiovascular Interventions, IRCCS San Raffaele Scientific Institute, Milan, Italy
[b] Unit of Cardiovascular Interventions, EMO-GVM Centro Cuore Columbus, Milan, Italy
[c] Unit of Cardiovascular Interventions, Fortis Escorts Heart Institute, New Delhi, India

Long term (3 yr) follow up (99%) in large series



BVS MILAN/DELHI

480 patients
Regazzoli D., EuroPCR 2017

44.4mm (average scaffold length per lesion)
73.9% (B2/C lesions)
28.3% (% of bifurcations)

**Regazzoli D., EuroPCR 2017*

GHOST FERRAROTTO**

319 patients (mean Follow-up @ 906 ± 265 days)
Tamburino, C., CRT 2017

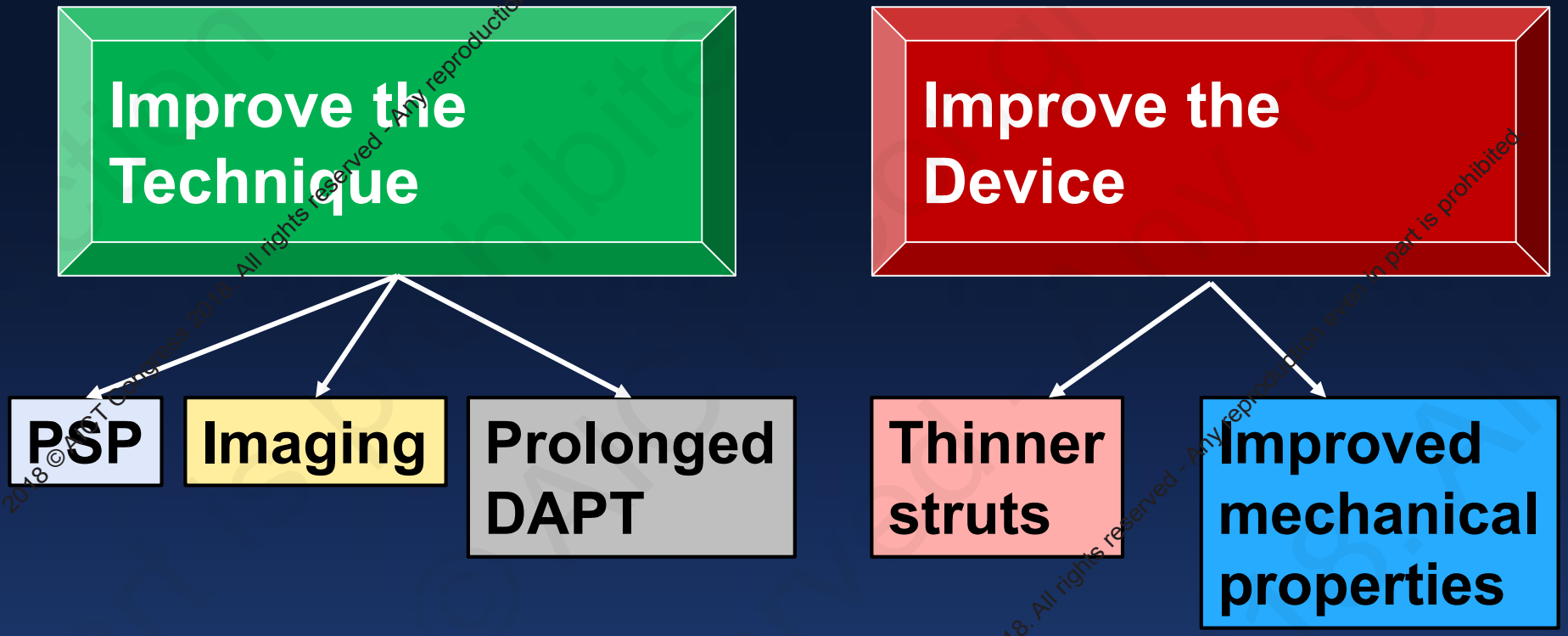
21.2mm (average scaffold length per lesion)
13.5% (lesion length > 34mm)
51.2% (B2/C lesions)
49.5% (ACS patients)

Tamburino C., CRT 2017

1 st Gen BRS Effective but Not Safe ,Hence Failed

- Thick strut NEW DEVICE with special implantation characteristics and a which took time to understand and master.
- Difficult to use in complex real world lesion setting
- Enthusiasm overtook the trials , trials did not use Dedicated implantation Technique
- Comparator “Xience “was just too Good

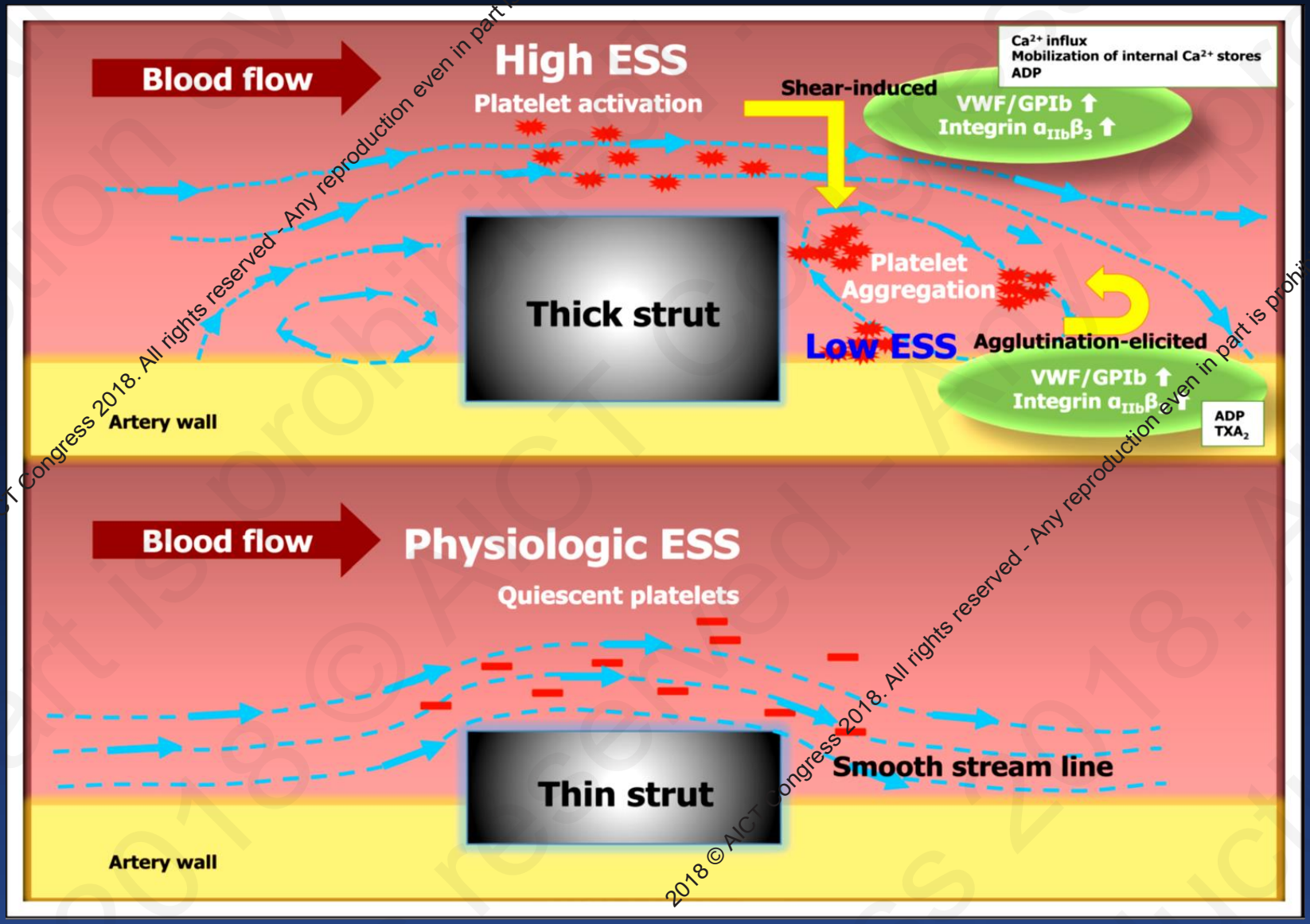
How to Improve BRS Outcomes Prior to Their Complete Bioresorption



Ideal Bioresorbable Scaffold

1. Comparable radial strength to metallic stents, without compromising flexibility.
2. Strut thickness and scaffold geometry of the best-in-class metallic stents.
3. The integrity and strength of a polymer scaffold, during the remodelling phase of the arterial wall (normally 6 months post implantation).
4. Flexibility and ease of implantation that is comparable to metallic stents
5. No polymer degradation until the stent is fully encapsulated in the intimal layer of the arterial wall, with full reabsorption taking place within 24 months, “leaving nothing behind”.
6. No degradation of the polymer during the preuse storage phase, and properties that allow the BRSs to be stored at room temperature.
7. Cost comparability to drug eluting stents (DESs).
8. A wide portfolio of diameters and lengths comparable to metallic stents).

Strut thickness and platelet activation



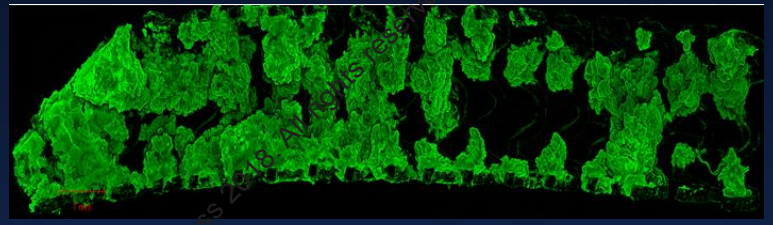
Sotomi Y et al, Circ Res. 2017; 120: 1341-1352

Strut Thickness in Perspective: BRS vs. New-generation DES

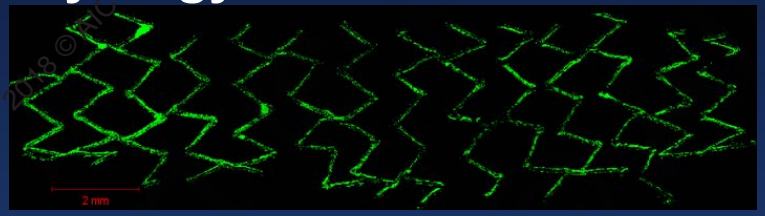
In vivo Thrombogenicity

Joner M, Presented at EuroPCR 2014

Absorb

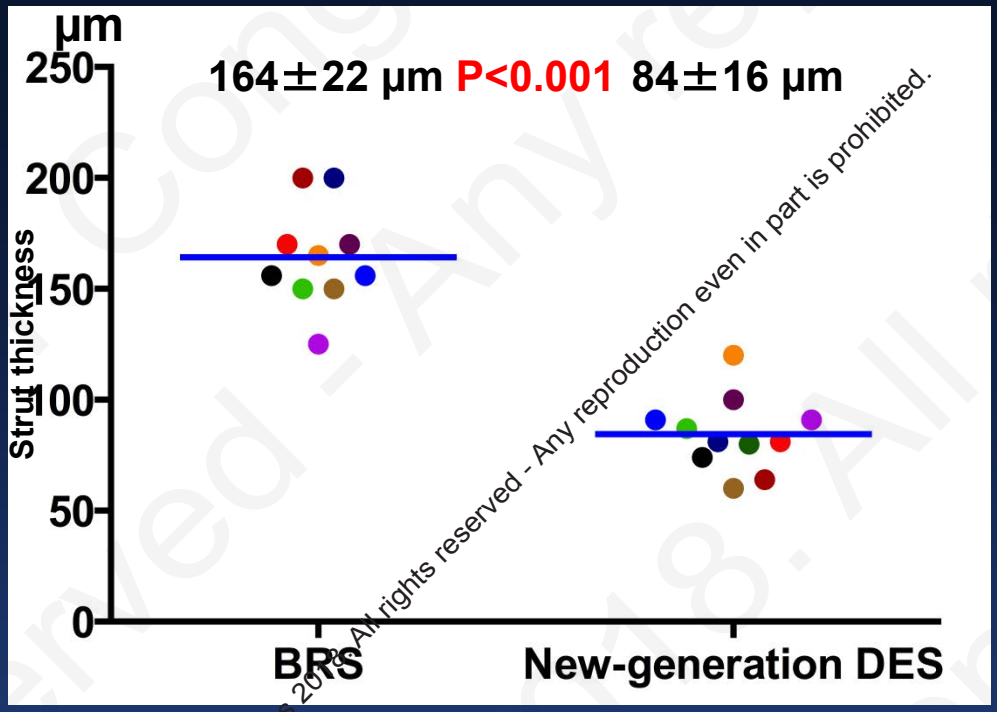


Synergy



Thrombus formation assessed by immunofluorescence staining for platelet marker CD61 after 1 hour in ex-vivo pig AV shunt model

Strut Thickness in Perspective



AMS-1 (155 µm), DREAMS-1 (125 µm), DREAMS-2 (150 µm), Igaki-Tamai (170 µm), BVS-1 (156 µm), BVS 1.1 (156 µm), DESolve (150 µm), REVA (200 µm), ART 18AY (170 µm), Ideal BTI (64 µm)

Biomatrix (120 µm), Endeavor (91 µm), Yukon PC (87 µm), Xience (81 µm), Resolute (91 µm), Synergy (74 µm), Orsiro (60 µm), DESyne (81 µm), Combo (100 µm), Mistent (64 µm), Ultimaster (80 µm)

Thin strut scaffold VS thick strut scaffold vs mDES

***thrombus formation** of everolimus-eluting Xience stent (81µm), with BVS (157µm) and thin-strut BRS (ArterioSorb BRS, 95µm) (3.0mm size, n=3 per group) deployed in an in-vitro coronary model*

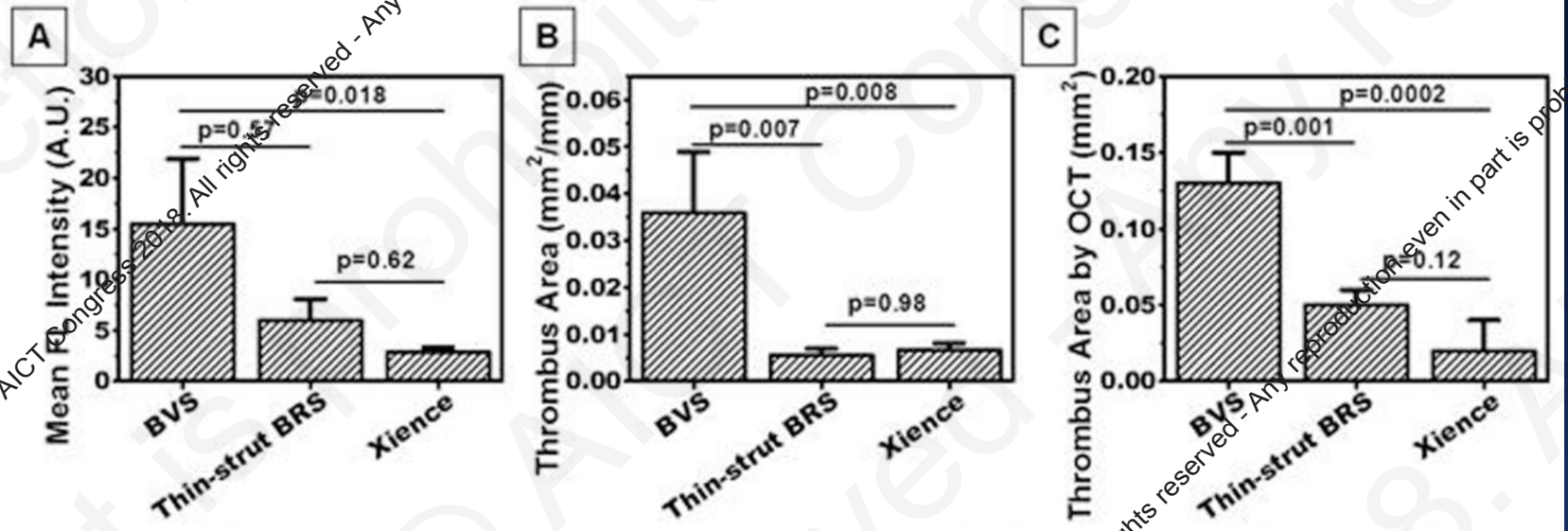


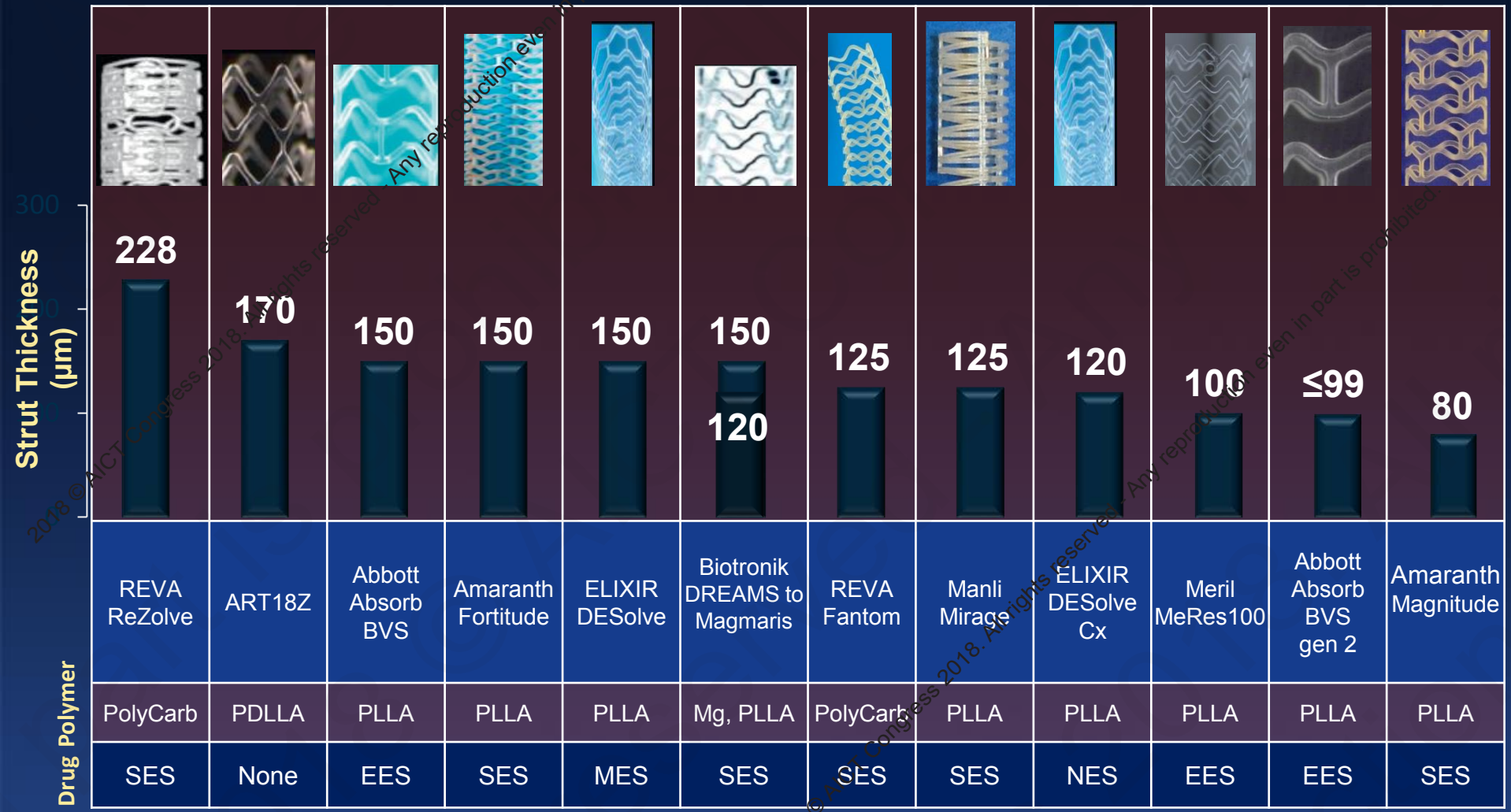
Figure 1: Mean immunofluorescence intensity (A) and thrombus area (B) quantified on immunofluorescence images of the samples. (C): Mean cross-sectional thrombus area was quantified from OCT pullback analysis of samples.

Journal of the American College of Cardiology
Volume 70, Issue 18, Supplement, 31 October 2017, Pages B58–B59

Bioresorbable Scaffolds: Rapidly thinning

1st Generation BRS

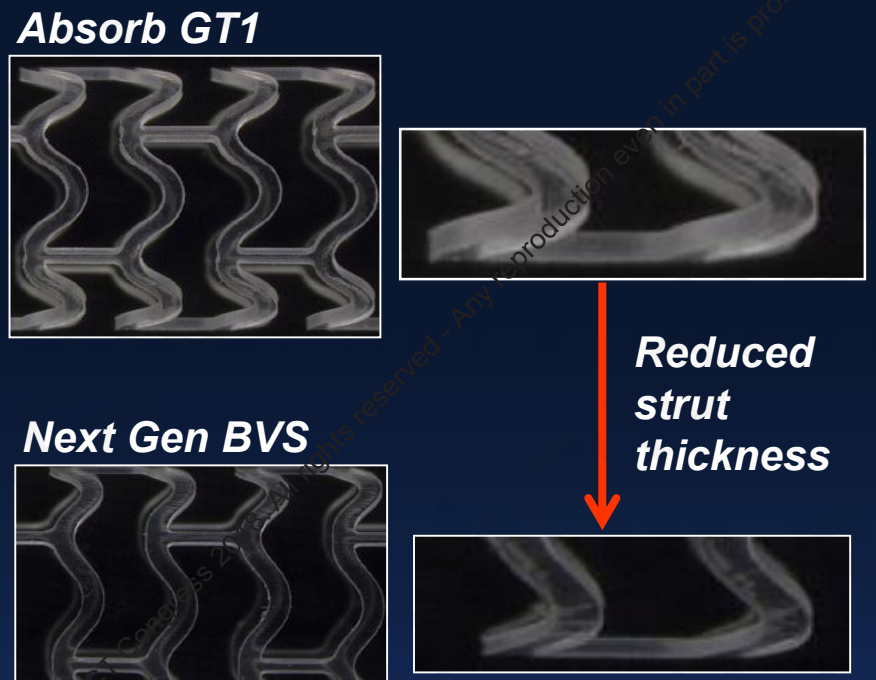
2nd Generation BRS



	REVA ReZolve	ART18Z	Abbott Absorb BVS	Amaranth Fortitude	ELIXIR DESolve	Biotronik DREAMS to Magmaris	REVA Fantom	Manli Mirage	ELIXIR DESolve Cx	Meril MeRes100	Abbott Absorb BVS gen 2	Amaranth Magnitude
Drug Polymer	PolyCarb	PDLLA	PLLA	PLLA	PLLA	Mg, PLLA	PolyCarb	PLLA	PLLA	PLLA	PLLA	PLLA
	SES	None	EES	SES	MES	SES	SES	SES	NES	EES	EES	SES

SES = sirolimus-eluting scaffold, EES = everoliumus-eluting scaffold
MES=myolimus-eluting scaffold, NES = novolimus-eluting scaffold

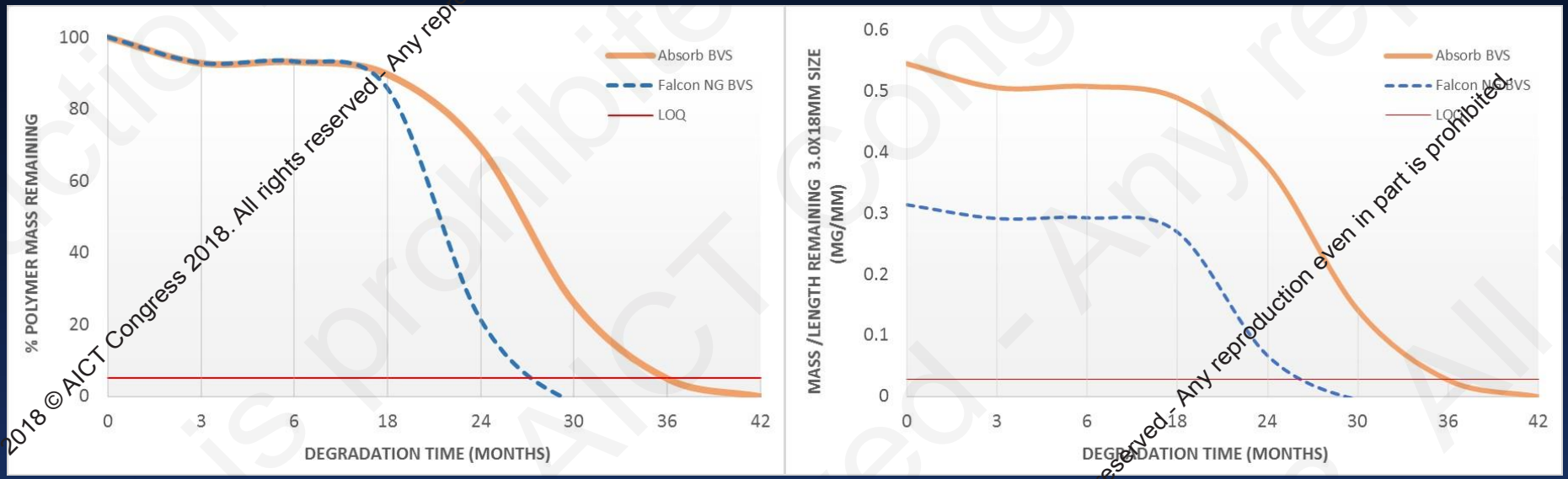
Next Generation Absorb Scaffold



- Thinner struts: ~98 microns all sizes
- Expanded range of diameters and lengths
- Larger expansion limit: ≥0.75mm over nominal
- Broader pressure working range: ¼ size at least 16 atm
- Shorter resorption time
- Unchanged:
  - Drug content & elution rate
  - Pattern & footprint
  - Radial strength
  - Scaffold retention

Data on file at Abbott Vascular

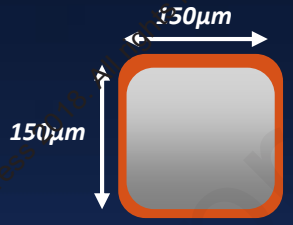
Resorption Kinetics Unchanged
But thinner scaffold resorbs sooner

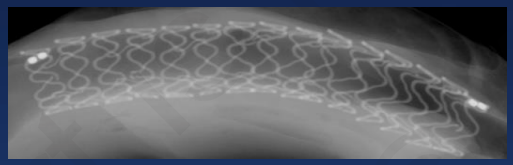


Data on file at Abbott Vascular. Graphs show theoretical depiction of long-term Falcon behavior based on known Absorb results

DREAMS-2G (MAGMARIS)
Sirolimus Eluting Mg Scaffold

Sirolimus + PLLA (BIOlute)



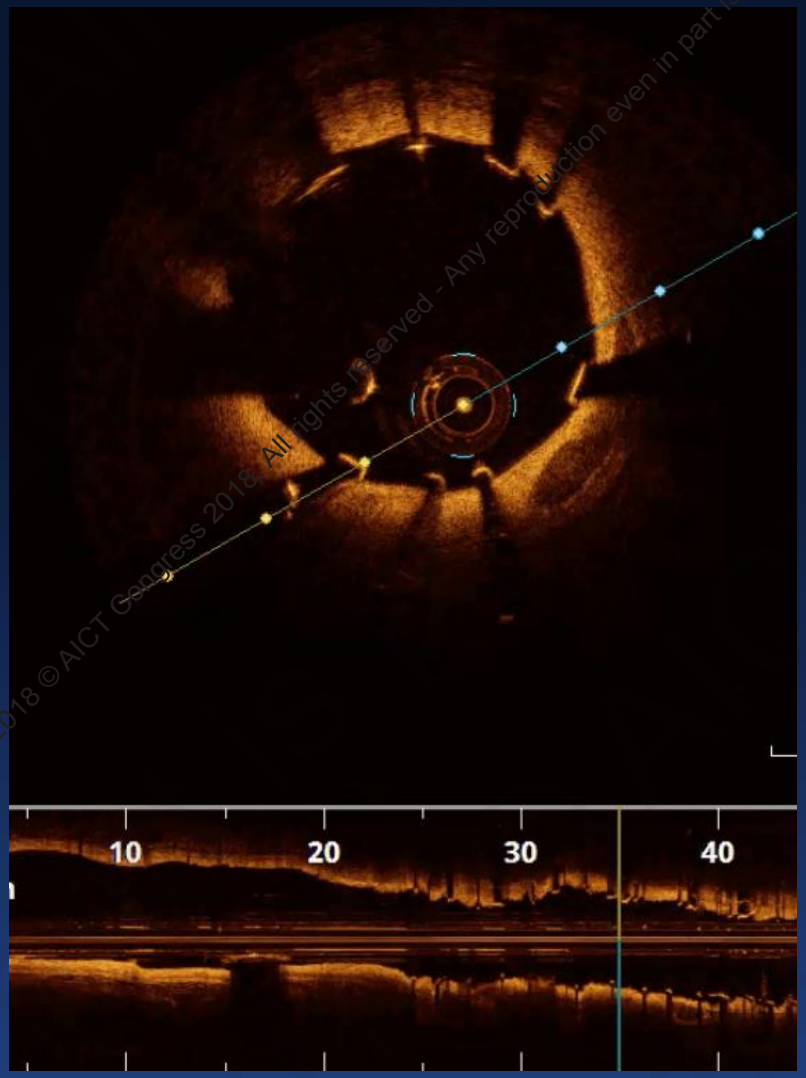


90-Day Faxitron, porcine explant

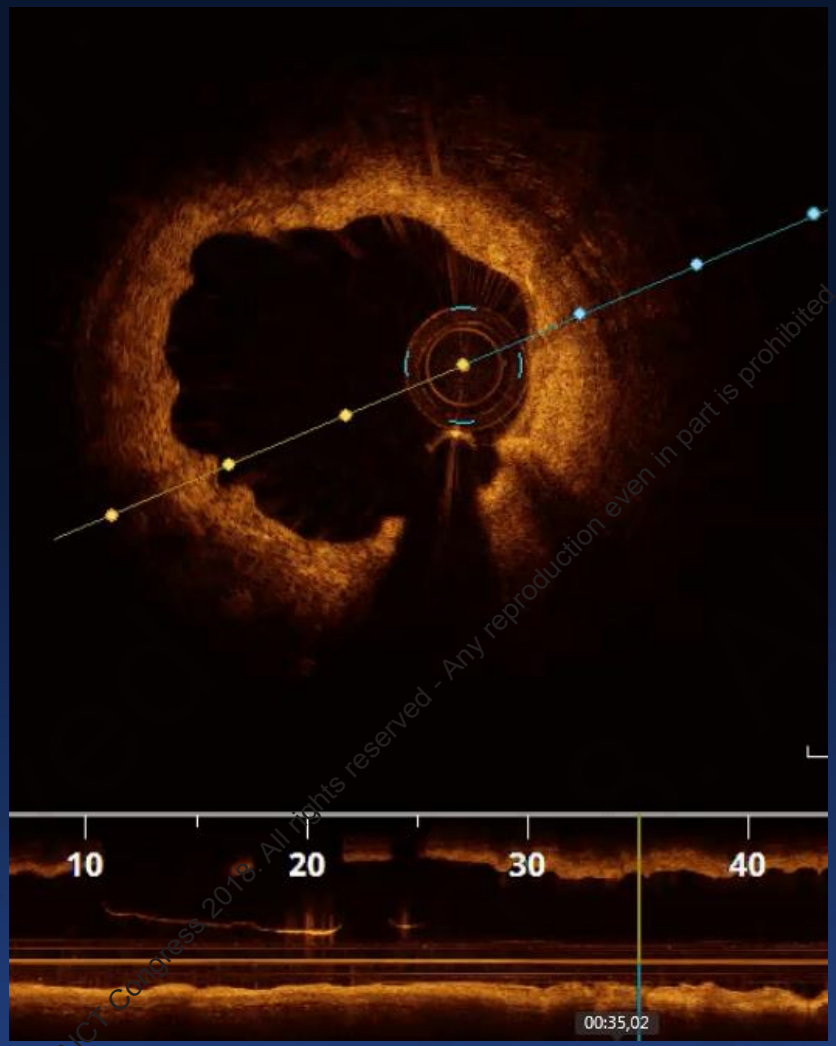
- 6-crown 2-link design,
- 150µm strut thickness
- 150µm strut width
- Optimized scaffold design for
  - Higher bending flexibility
  - Higher acute radial force
  - Slower absorption rate: 95% at 12 months
- Sirolimus drug elution & PLLA (ORSIRO BIOlute coating)
- Tantalum radiopaque markers
- Gained CE mark in June 2016

Haude et al, EuroIntervention 2017

Magmaris resorption on OCT



Immediately after implantation:
struts are well apposed to the vessel wall

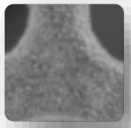


9 months Magnesium resorption continues,
endothelialization progresses

MeRes100 (developed in INDIA)

Sirolimus Eluting Bioresorbable Vascular Scaffold

100 micron strut thickness



Hybrid cell design

Closed cell

Open cell

Scaffold backbone PLLA
100 µm strut thickness

Drug coat of PDLLA +
Sirolimus 1.25 µg/mm²

High radial strength, 22.30 N

24% scaffold to artery ratio

Low recoil, 1.23%

Couplets of tri-axial
RO markers at either end

Estimated degradation
in 2-3 years

Optimal side
branch access

MeRes-1 : simultaneous publication on line ahead of print

EuroIntervention, 16 th May 2017

CLINICAL RESEARCH
CORONARY INTERVENTIONS

euro PCR 2017 LATE BREAKING TRIALS

First-in-human evaluation of a novel poly-L-lactide based sirolimus-eluting bioresorbable vascular scaffold for the treatment of de novo native coronary artery lesions: MeRes-1 trial

Ashok Seth[1]*, FRCP, D.Sc; Yoshinobu Onuma[2,3], MD, PhD; Ricardo Costa[4], MD, PhD; Praveen Chandra[5], MD, DM; Vinay K. Bahl[6], MD, DM; Cholenahally N. Manjunath[7], MD, DM; Ajaykumar U. Mahajan[8], MD, DM; Viveka Kumar[9], MD, DM; Parvin K. Goel[10], MD, DM; Gurpreet S. Wander[11], MD, DM; Mathew S. Kalarickal,[12], MD, DM; Upendra Kaul[13], MD, DM; V.K. Ajit Kumar[14], MD, DM; Pratap C. Rath[15], MD, DM; Vijay Irehan[16], MD, DM; Gunasekaran Sengottuvelu[12], MD, DM; Sundeep Mishra[6], MD, DM; Alexandre Abizaid[4], MD, PhD; Patrick W. Serruys[17], MD, PhD

The authors' affiliations can be found in the Appendix paragraph.

GUEST EDITOR: Davide Capodanno, MD, PhD; *Cardio-Thoracic-Vascular Department, Ferrarotto Hospital, University of Catania, Catania, Italy*

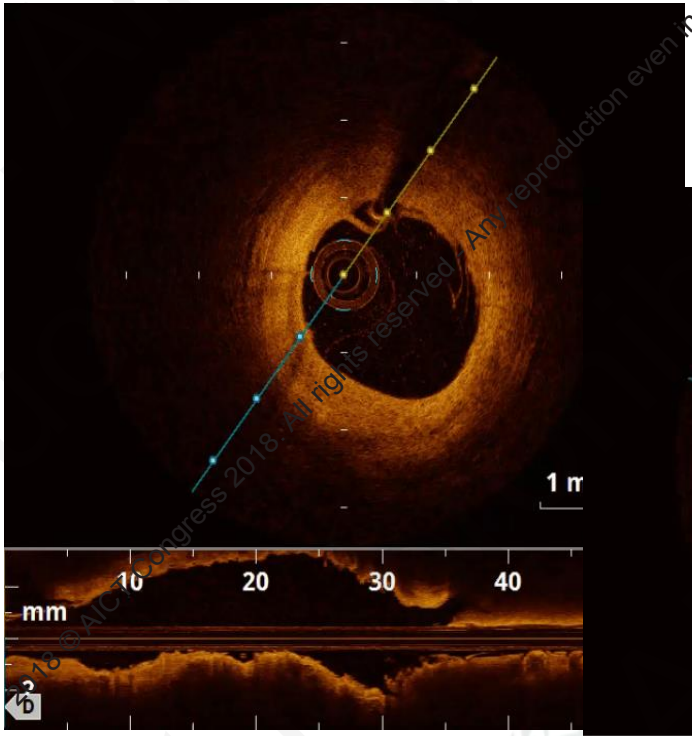
EuroIntervention 2017;13-online publish-ahead-of-print May 2017

Conclusion

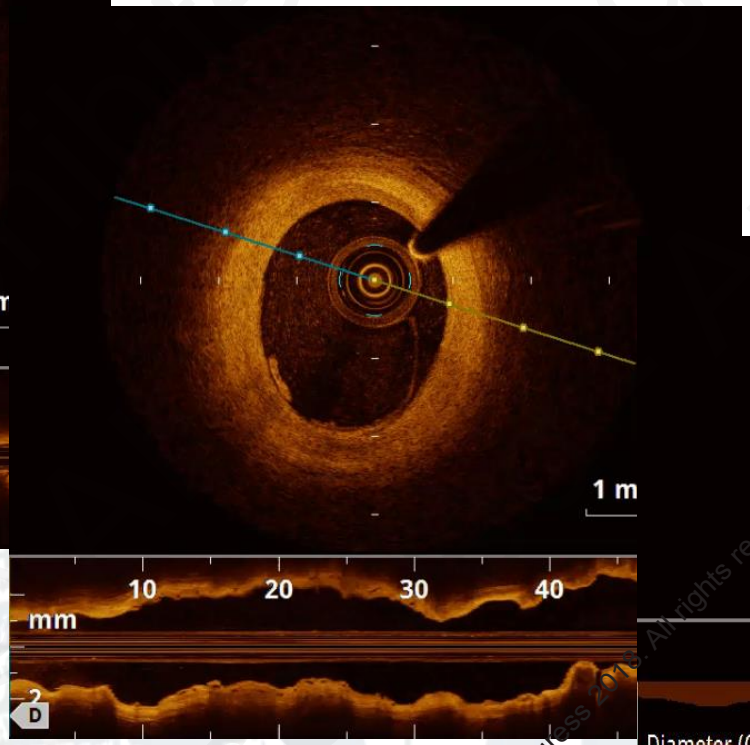
- MeRes-1 trial for the first in human evaluation of the thinner strut 2nd generation scaffold : MeRes100 – BRS demonstrated high acute success, **very low MACE (0.93% ,** 1 ID-TLR) and **no Scaffold Thrombosis** up to 2 -year follow-up.
- **Multimodality Vascular Imaging** are consistent in demonstrating **high efficacy** of MeRes100 – BRS up to 1 year
  - **QCA** at 6 Months: Low late lumen loss (0.15 ± 0.23 mm)
  - **OCT** at 6 Months: Virtually complete strut coverage (99.3%)
  - **IVUS** at 6 months: Sustained mean flow area and very low %VO (2.53%)
  - **CTA** at 1 year: Low mean area stenosis 11.33 ± 26.57%

Case Example

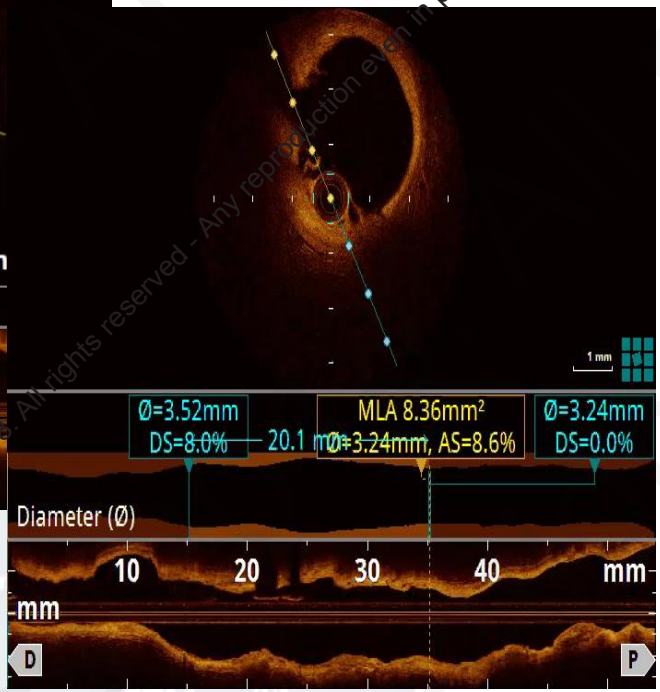
Baseline OCT



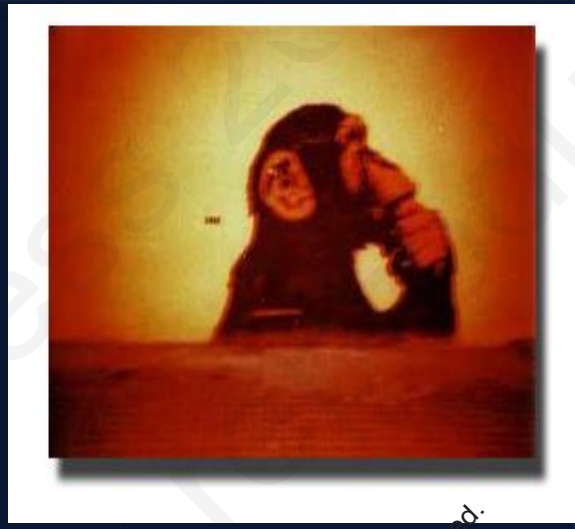
6-months FU



2-years FU



POINTS TO PONDER , next 5 years??



- BRS would need to show superiority at 5-7 years , would it be possible from current trials and how long would it take ?? ?
- Would the data act as a surrogate for 2 nd Gen BRS ??
- Will companies be able to justify the R&D costs in the current healthcare environment ??

Fortis Escorts
HEART INSTITUTE

CONCLUSION

There was unfortunate Demise of BVS : because of short and long term safety concerns :

-BRS a different device to mDES and required scaffold specific techniques to improve its safety which got understood over time

- BVS was voluntarily discontinued by the manufacturer before its potential benefits could be demonstrated and therefore still remain hypothetical

Fortis Escorts HEART INSTITUTE

..CONCLUSION …5 yrs

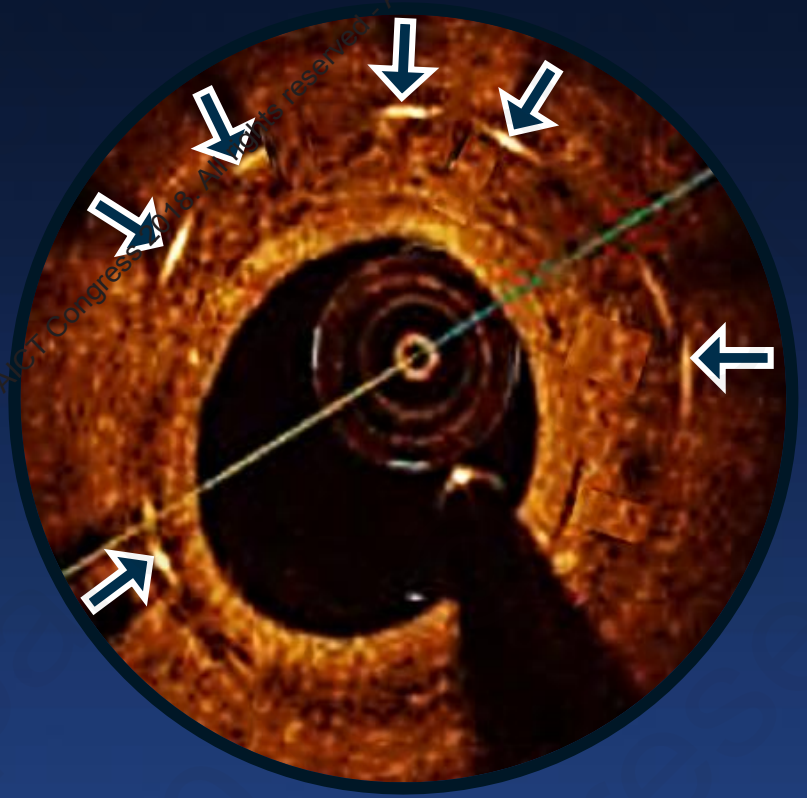
Long Term follow up of nearly 6000 pts in the 5 randomized controlled ABSORB trials would shed more light towards the potential for longterm benefits of BRS over mDES

Second Gen BRS with Thinner Struts and more DES like user friendly features especially with good implantation technique could overcome the pitfalls of 1st Gen BRS

AND FINALLY…… !!!

THE UNMET NEED STILL REMAINS and I REMAIN CAUTIOUSLY OPTIMISTIC THAT BRS IS THE FUTURE !!!

Metallic DES[1]



Absorb-Treated Artery[2]

1. Atherosclerosis 2014;237:23e29
2. Image courtesy of S Windecker, ABSORB Cohort B 5 Yrs