

*Do We Need a Dedicated
Bifurcation Stent in our Practice
or is this a Niche Device?*

Eberhard Grube MD, FACC, FSCAI

*University Hospital, Dept of Medicine II, Bonn, Germany
Stanford University, Palo Alto, California, USA*

Eberhard Grube, MD

Physician Name

Company/Relationship

Eberhard Grube, MD

Medtronic, CoreValve: C, SB, AB, OF
Direct Flow: C, SB, AB
Mitralign: AB, SB, E
Boston Scientific: C, SB, AB
Biosensors: E, SB, C, AB
Kona: AB, E
Abbott Vascular: AB
InSeal Medical: AB, E,
Valtech: E, SB,
Claret: SB
Keystone: AB
Shockwave: E, AB

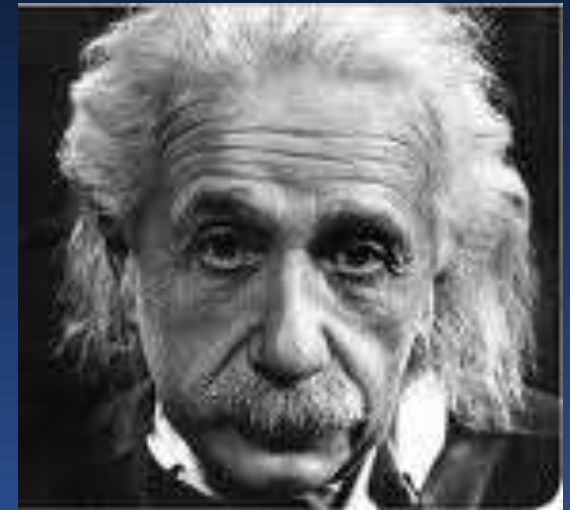
Key

G – Grant and or Research Support E – Equity Interests S – Salary, AB – Advisory Board
C – Consulting fees, Honoraria R – Royalty Income I – Intellectual Property Rights
SB – Speaker's Bureau O – Ownership OF – Other Financial Benefits

Bifurcation Stenting

“Make everything as simple as possible, but not simpler”

When it comes to treating bifurcation lesions.....



Studies support a provisional approach

Results from the Nordic I Trial¹

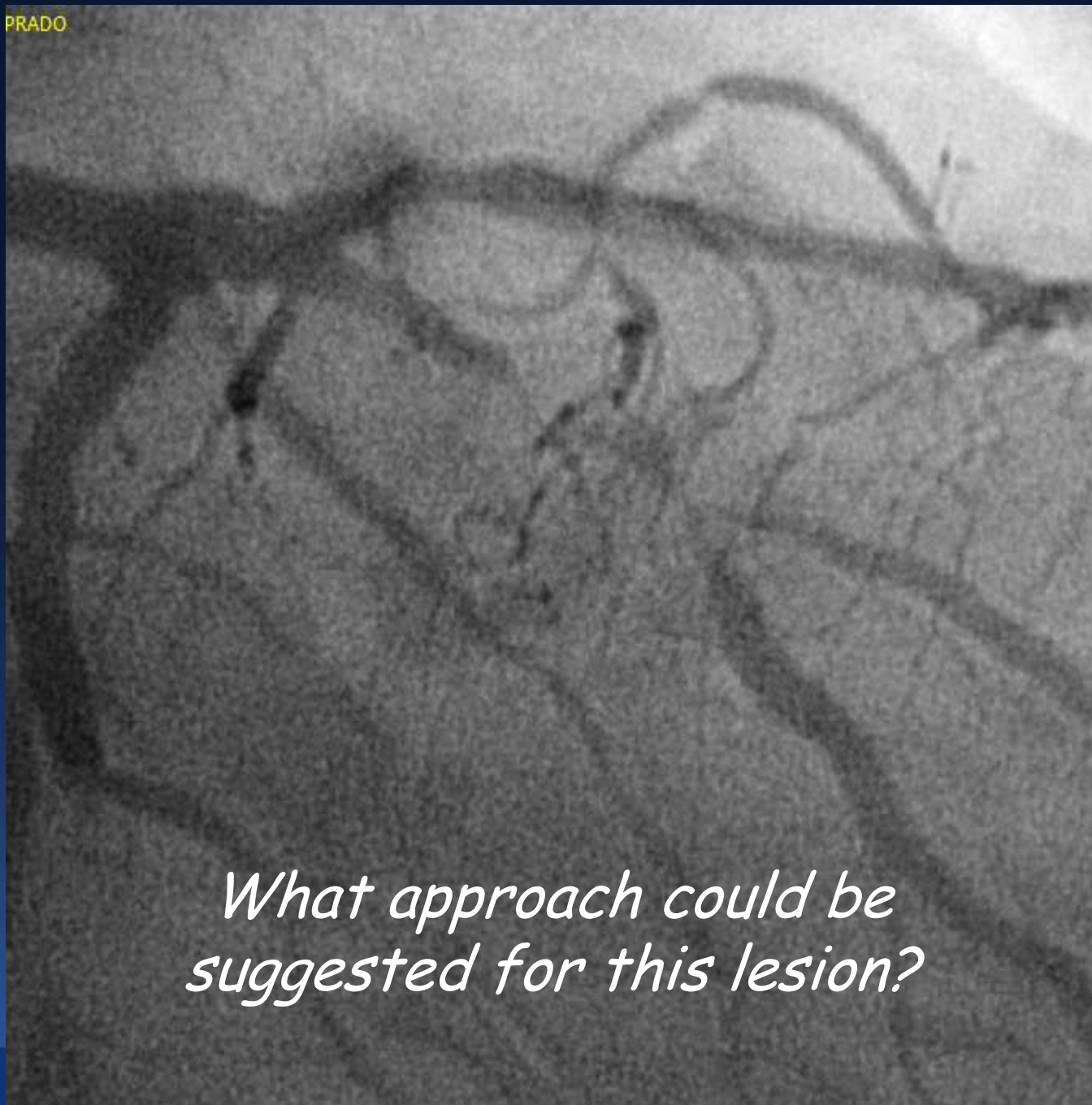
- Randomised: simple (MB) vs complex (MB+SB) bifurcation stenting
- N=413 (28 Scandinavian sites), SES
- MACE at 6 months: 2.9% vs 3.4% (NS)
- Restenosis at 8 months: 5.3% vs 5.1% (NS)
- No benefit with 2 stent strategy

Studies support a provisional approach

Results from the BBC One Trial¹

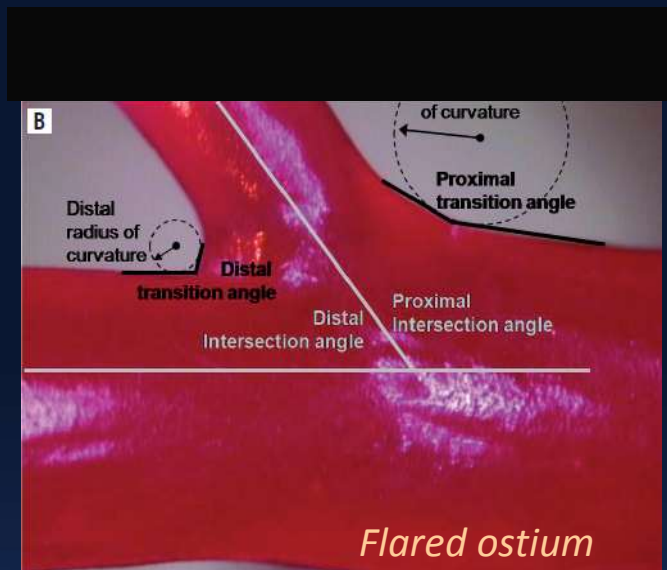
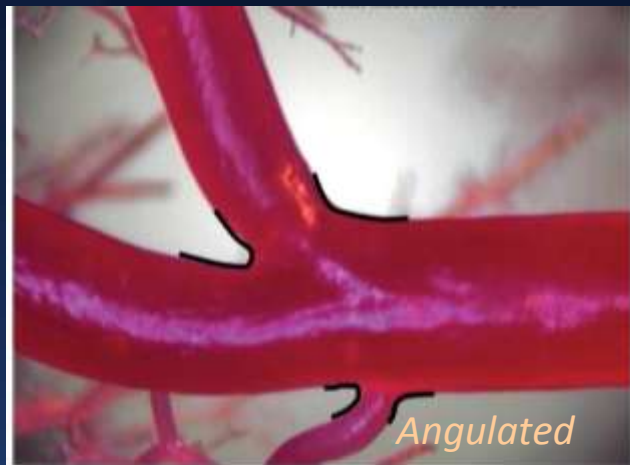
- Randomised: simple single stent (with provisional SB stenting) vs complex stenting (2 stents) strategy
- N=500, PES
- In-hospital MACE: 2.0% vs 8.0%
- Death, MI, TVF at 9 months: 8.0% vs 15.2%
- Fewer adverse events with simple strategy

1. British Bifurcation Coronary Study presented by Dr David Hildick-Smith at TCT 2008.



What approach could be suggested for this lesion?

What is the basic anatomy



Complexity :

- Variation in Ostium Ovality
- Variation in Sidebranch take off angle.
- Variation in Vessel Geometry as per "Murrays Law"
- Variation in Stenosis location (Medina Classification)

It is therefore extremely difficult to design a single device to accommodate this variation, except.....

...if we had a provisional Device which could:

1. Reduce complexity

- *sized to the vessel proximally and distally*
- *enable side-branch access*

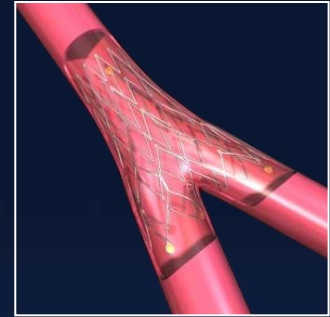
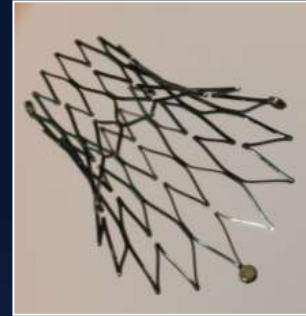
2. Improve safety

- *less metal*
- *better apposition*

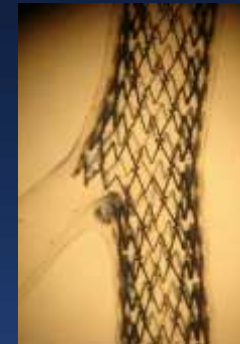
✓ *Self-Expansion*
✓ *Provisional*

Dedicated Bifurcation Stents

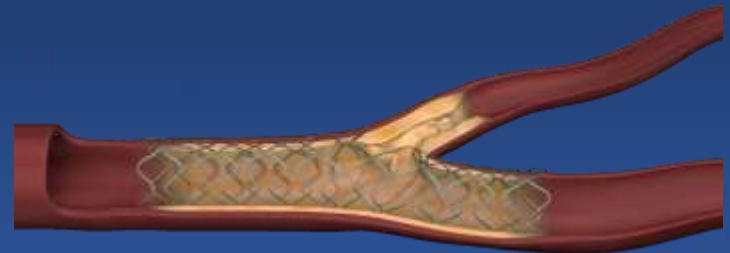
- *AXXESS Stent*



- *Stentys Stent*



- *Triton Stent*



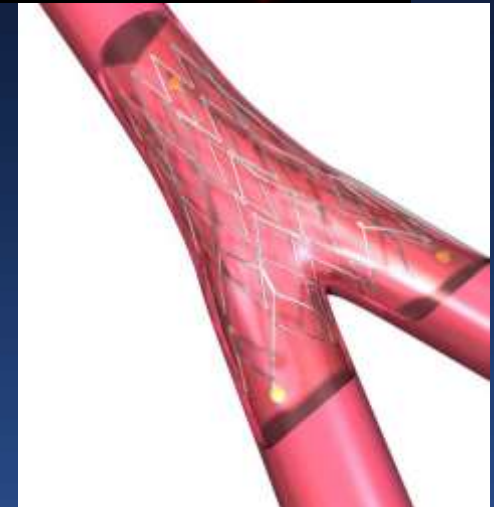
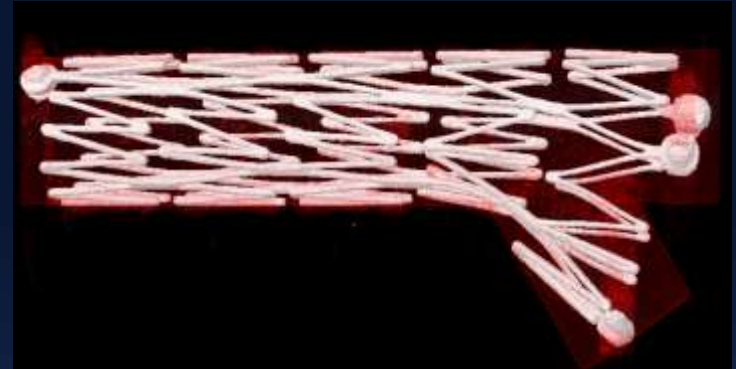
Agenda

- *Do we benefit from a dedicated stent when treating bifurcations?*
- *Understand the use and mechanism of the self-expanding dedicated AXXESS stent*
 - *What they can do, when to use them, and why?*
- *Master how to use the Axxess stent in complex anatomies*
- *Use OCT imaging to learn about stent strut behaviour at the carina, both post-procedure and at follow-up compared with “culotte” technique*

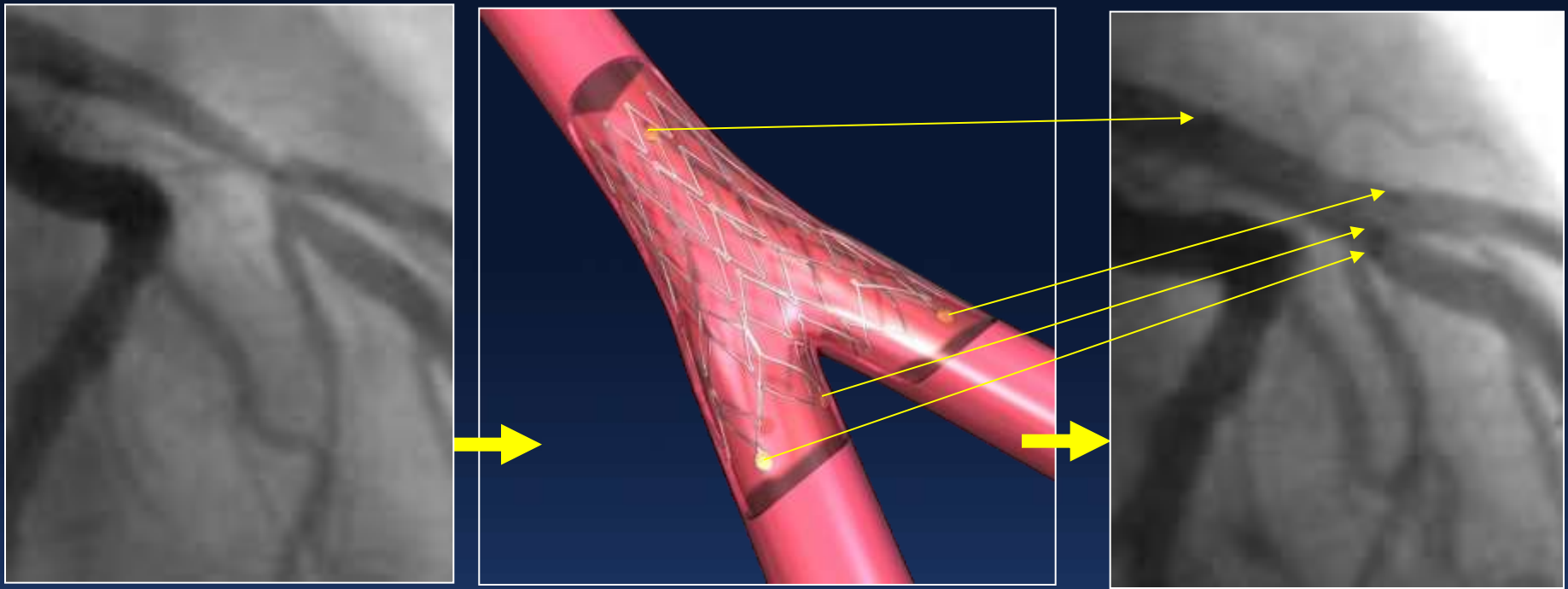
Biosensors Axxess™

Dedicated Bifurcation Stent

- Conical shape 3 and 3.5 mm diam and 11 & 14 mm length
- Self-expanding nitinol
- Elutes Biolimus A9 from an abluminal resorbable PLA polymer
- Delivers over single wire (*no wrap or wire bias issues*)
- *SB protected*
- 7 or 8F guide



Goal: Expand Both Vessels



- Cover the proximal lesion segment
- Cover the ostium of the side branch and distal parent vessel without
- Compromising access to the side branch
- This is accomplished if 2 markers are in 1 branch and 1 is in the other
- Provide a convenient placement marker for additional distal stents

The Rationale

- Atheroma and intimal hyperplasia do not occur at carina
- With many stenting techniques it is the non-endothelialized carinal struts that are associated with thrombus
- Biosensors Axxess stent (dotted black line) pushes atheroma away from flow divider and leaves no drug-eluting struts near the carina



Flow divider



Flow divider

Axxess™ Clinical Program

AXXESS **N=43**

- *France & Germany*
- *Pilot study using bare metal stent Axxess™ Platform*
- *In-segment restenosis at 6 months*
- *6 month follow-up available, study completed*

AXXESS **PLUS** **N=139**

- *Europe, Brazil and New Zealand*
- *FIM Safety and performance evaluation of Axxess™ DES*
- *Axxess cone stent in-stent late loss at 6 months*
- *5 year follow-up available, study completed*

DIVERGE **N=302**

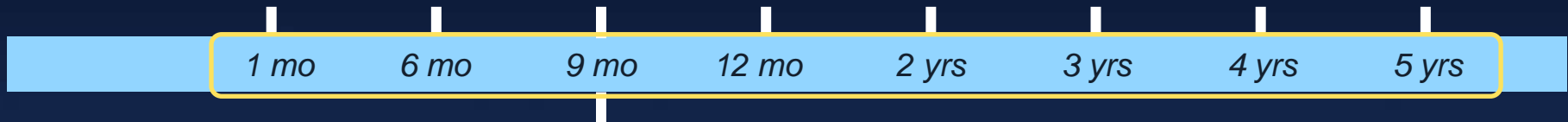
- *Europe, Australia and New Zealand*
- *Evaluated best practices from AXXESS PLUS*
- *MACE at 9 months*
- *3 year follow-up available, follow-up planned up to 5 years*

DIVERGE Trial Design

Prospective, single-arm, multi-center trial
Any bifurcation with: significant SB's ≥ 2.25 mm;
PV-SB angulation $< 70^\circ$
PI: S. Verheye

302 patients
14 clinical sites
Europe, Australia and NZ

Clinical FU



Angio / IVUS FU

1° Endpoint:

MACE* at 9 months

Key 2° Endpoints:

MACE* at 30 days, 6, 9 and 12 months and 2, 3, 4 and 5 yrs
death, cardiac death, MI (Q-wave and non Q-Wave), id-TLR, id-TVR and
stent thrombosis at 30 days, 6, 9 and 12 months and 2, 3, 4 and 5 yrs
Angiographic: In-stent restenosis and late loss at 9 months

*MACE = composite of all death, MI and ischemia-driven TLR

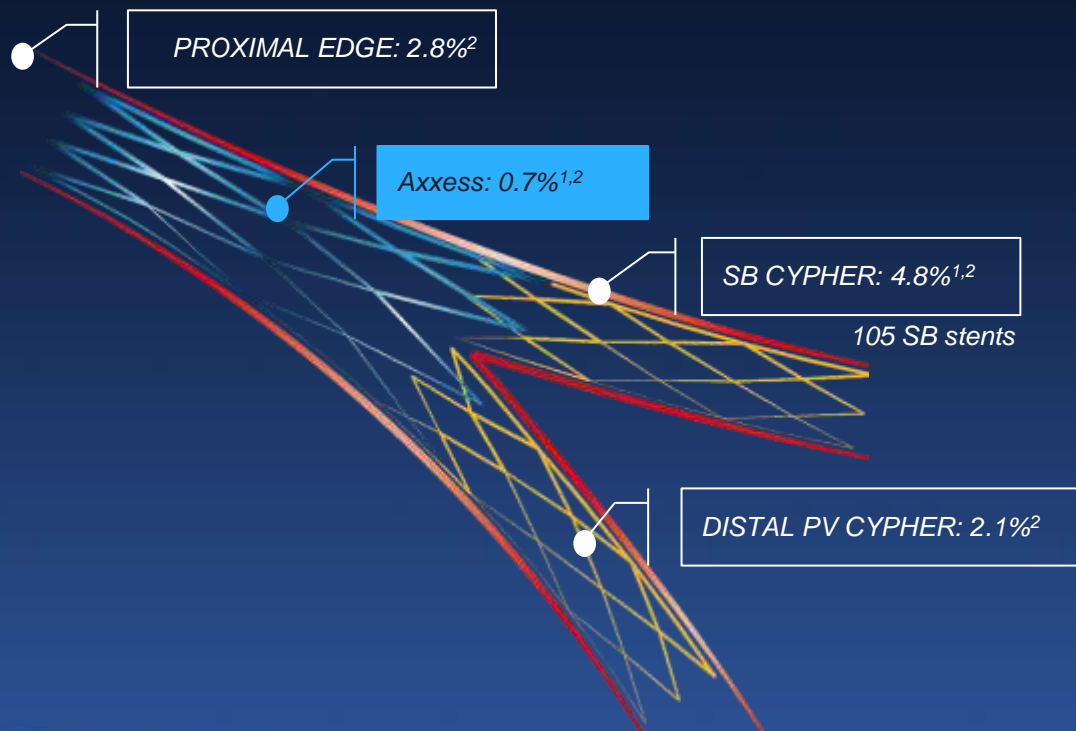
DAPT recommended:

12 months

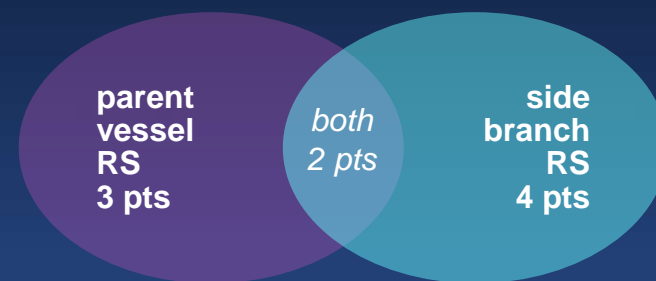
9-month Restenosis

VERY LOW RESTENOSIS RATE IN BIFURCATION LESIONS

LOCATION ANALYSIS

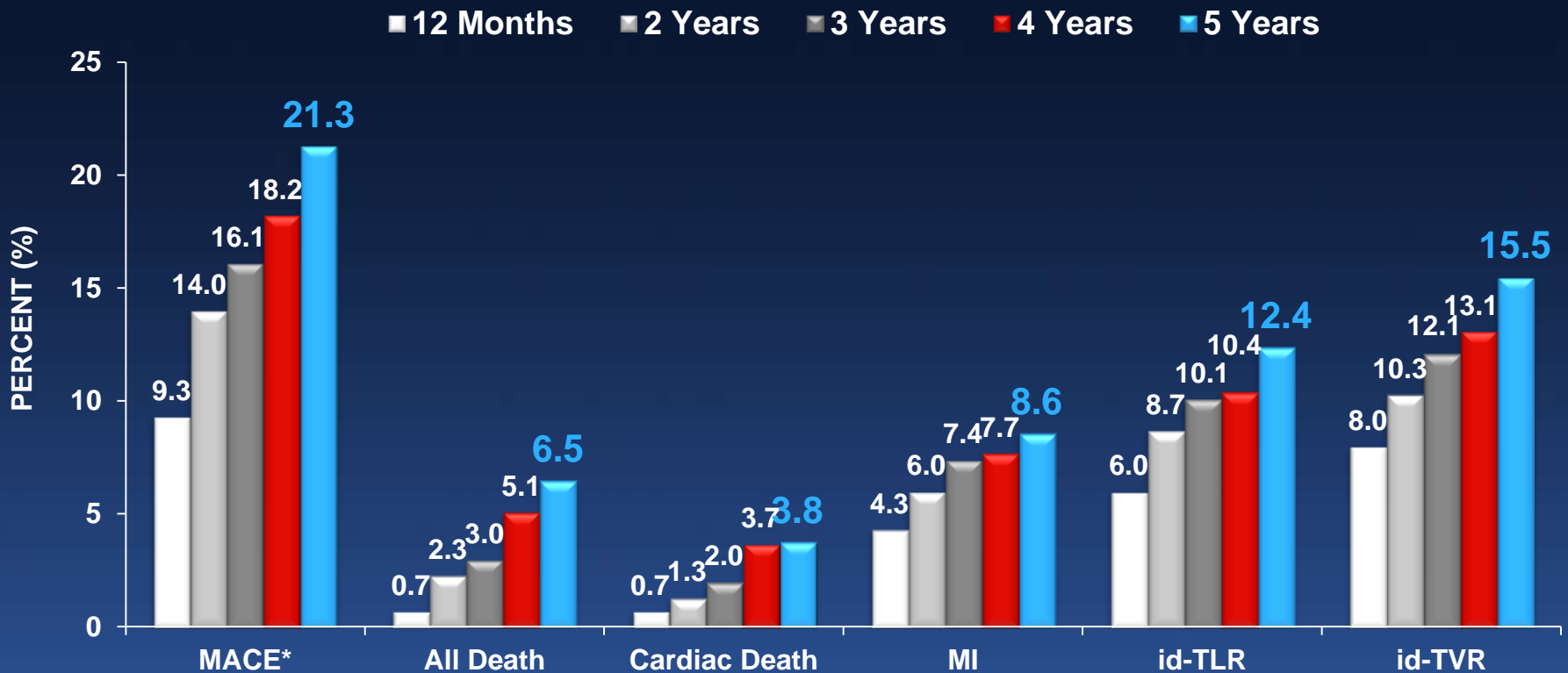


Any in-segment bifurcation restenosis:
6.4% (9/140 at 9 months)



5-year Clinical Outcomes

Primary endpoint, its components, and cardiac events



11203-000-EN-Rev.01

Stent Thrombosis up to 5 Years

N = 302	ARC*		
	DEFINITE	PROBABLE	POSSIBLE
ACUTE (in hospital)	0%	0%	0%
SUBACUTE (30 Days)	0.7% (2)	0%	0%
LATE	0.3% (1)	0%	0%
VERY LATE (1 YEAR – 5 Years)	1.7% (5)	0.7% (2)	2.1% (6)

11203-000-EN-Rev.01

Axxess PLUS & DIVERGE Pooled Analysis

Presented by STEFAN VERHEYE at EuroPCR 2014

On Behalf of the DIVERGE and AXXESS PLUS Investigators

AXXESS PLUS and DIVERGE Pooled Data

Prospective, Single-arm,
Multi-center registries

400 patients
Europe, South America,
Australia & NZ

Pooling of 5 year clinical data, FU: 93.8%

1° Endpoint: MACE at 5 years defined as a composite of all death, MI and ischemia-driven TLR

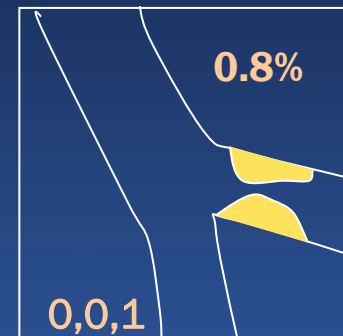
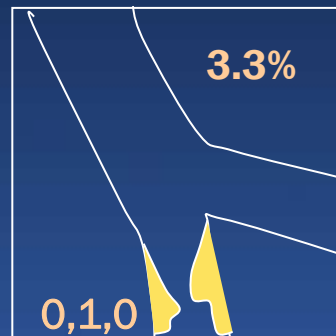
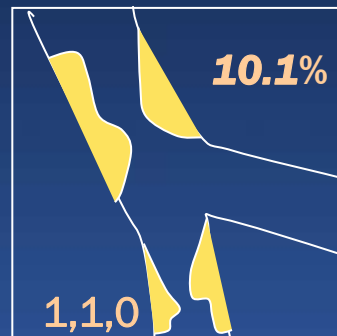
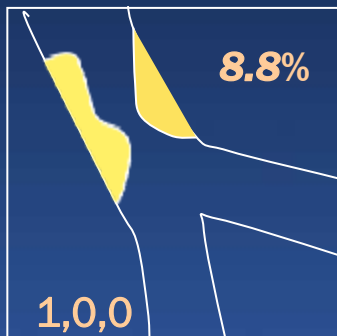
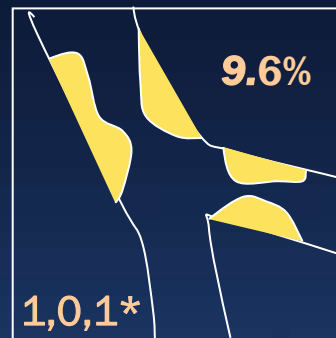
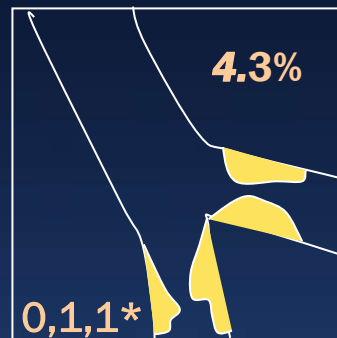
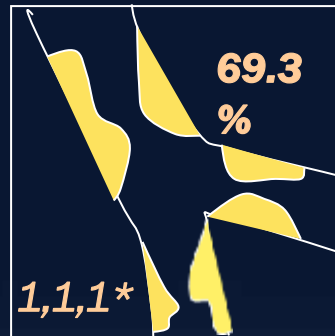
	AXXESS PLUS	DIVERGE	POOLED ANALYSIS
Enrollment	139	302	
Excluded patients*			
Patients receiving additional stents other than Cypher**	32	0	
Patients with LM lesions	6	0	
Patients who did not receive an Axxess stent	2	4	
Available for analysis	102	298	400

* Some patients were excluded for more than one reason

** Other stents: Taxus (11), BMS (3) or straight Axxess (18)
Verheye S., oral abstract presentation, EuroPCR 2014

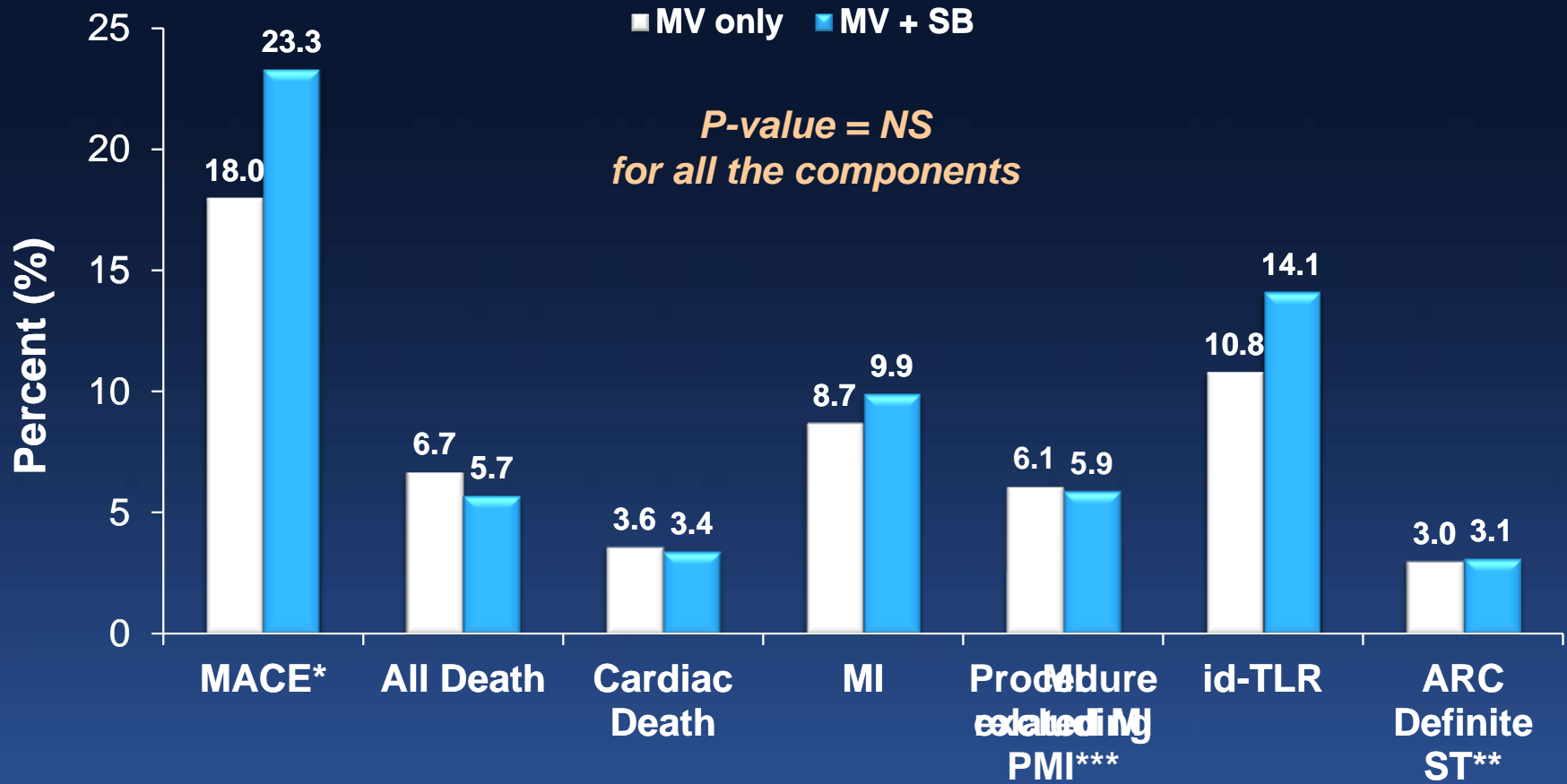
Medina Class All Patients

77.2%
True Bifurcation*



5-year Adjusted Clinical Outcomes KM Estimates (Pooled Data)

Primary endpoint, its components, and cardiac events

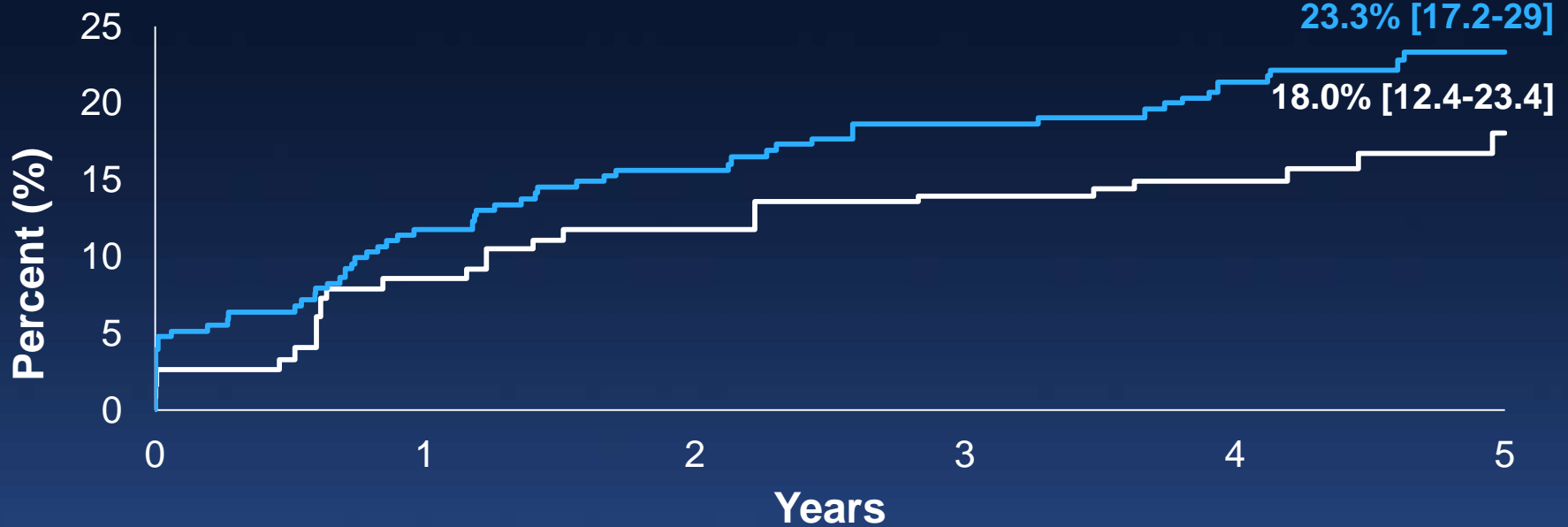


* MACE: a composite of all Death, MI, id-TLR and ARC defined ST
 ** Stent thrombosis defined by ARC (Cutlip D. et al., Circulation, 2007)
 *** PMI: Periprocedural MI

Adjusted MACE* Rates at 5 Years

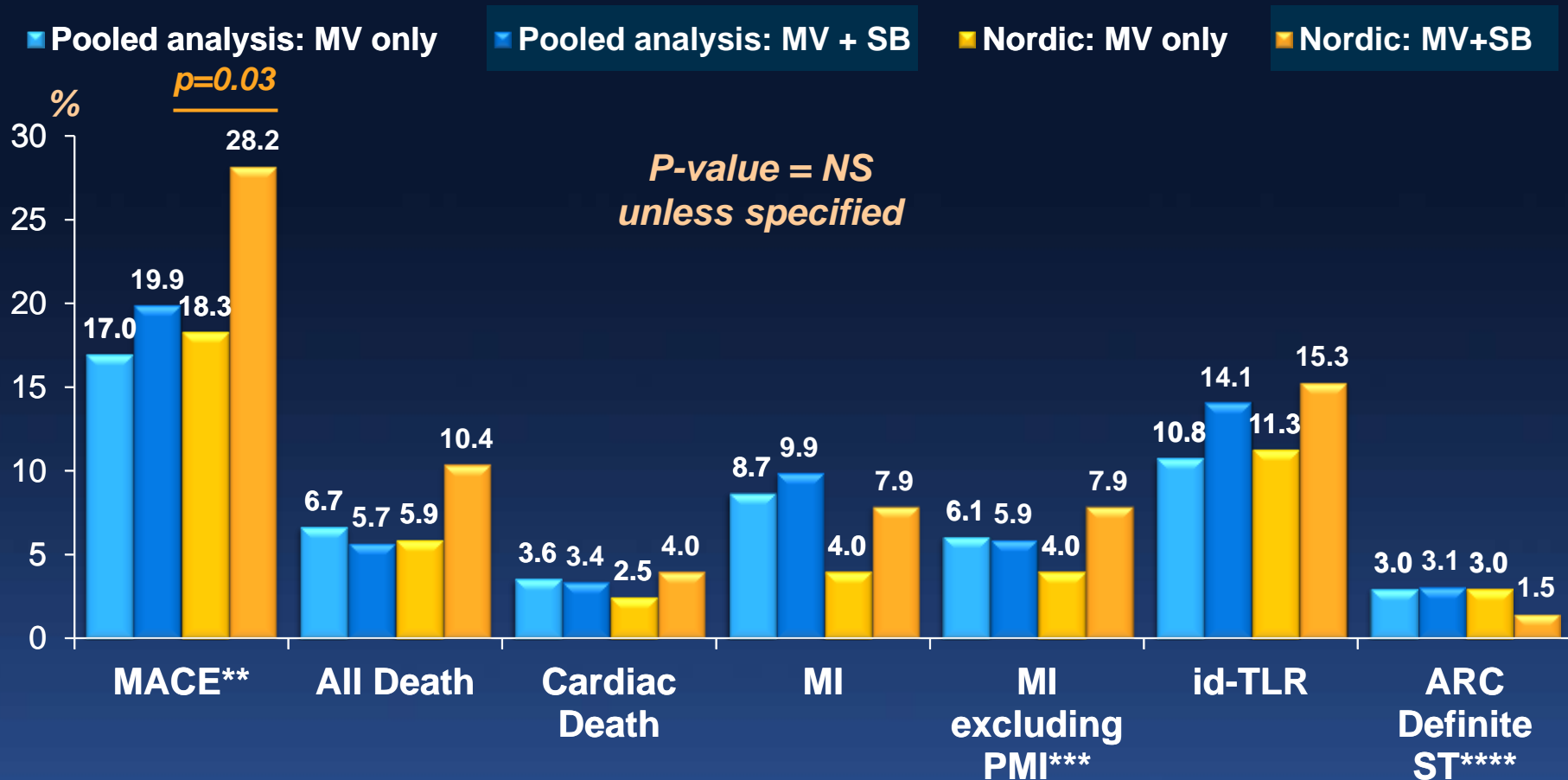
— MV only — MV+SB

p-value**=0.16



Years	0	1	2	3	4	5
Numbers at risk	136	127	121	118	116	38
	264	227	214	207	199	87

Comparison with the 5-year Follow-up of the Nordic Bifurcation Study*



* Maeng M. et al., J Am Coll Cardiol. 2013; 62(1):30-34

** MACE: composite of all death, MI (excluding peri-procedural MIs) and id-TLR; *** PMI : Periprocedural MI

**** Stent thrombosis defined by ARC (Cutlip D. et al., Circulation, 2007)

This comparison is for descriptive purposes only

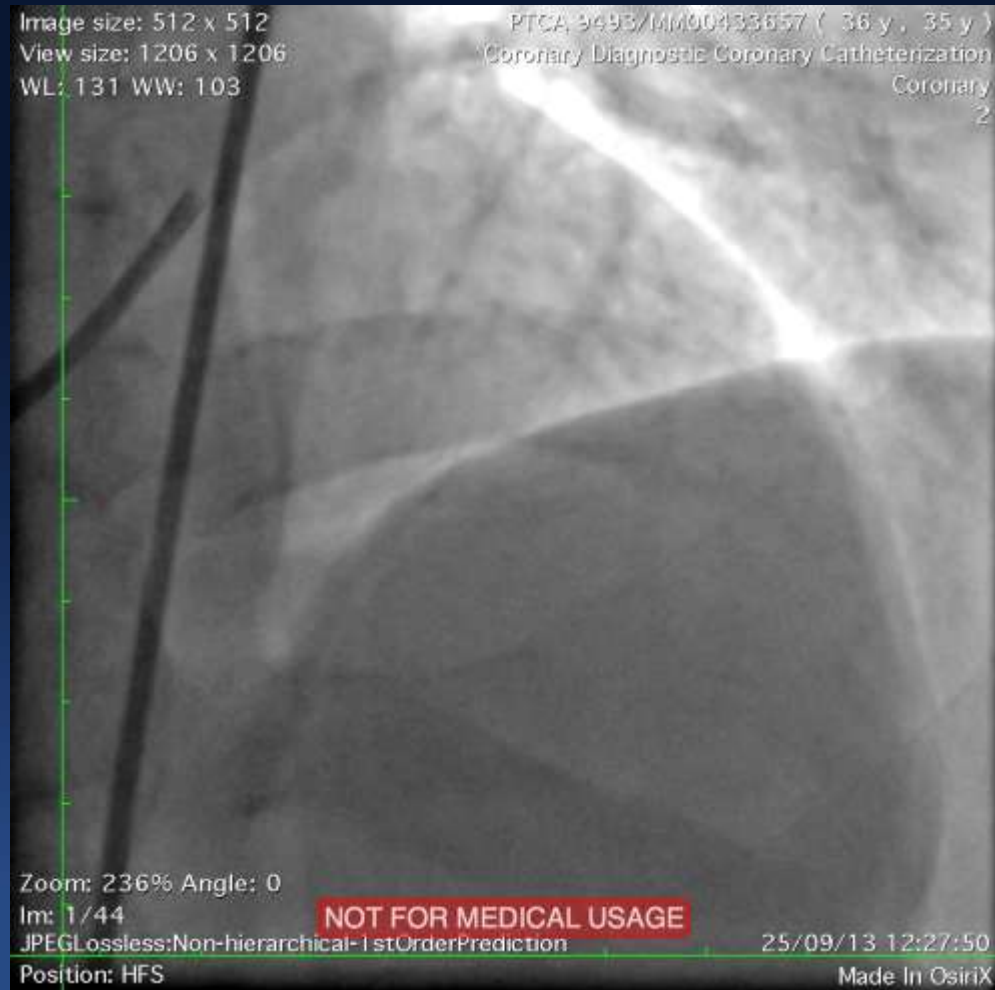
Conclusions

- The pooled analysis of the DIVERGE and AXXESS PLUS trials confirmed the safety and efficacy of the Axxess Biolimus A9-eluting stent up to 5 years.
- In a complex patient population with 77% true bifurcations treated, the use of the Axxess stent resulted in a pooled analysis in low equivalent 5-year event rates both in the MV group and MV+SB group.
- Using the Axxess stent including SB stenting did not result in higher adverse events: overall death, MI, ST.
- The Axxess stent is the only dedicated bifurcation drug-eluting stent that has data out to 5 years in a large number of patients.
- This pooled analysis supports the hypothesis that Axxess, the dedicated bifurcation stent has the potential to outperform provisional stenting in clinical events when being combined with newer generation DES.

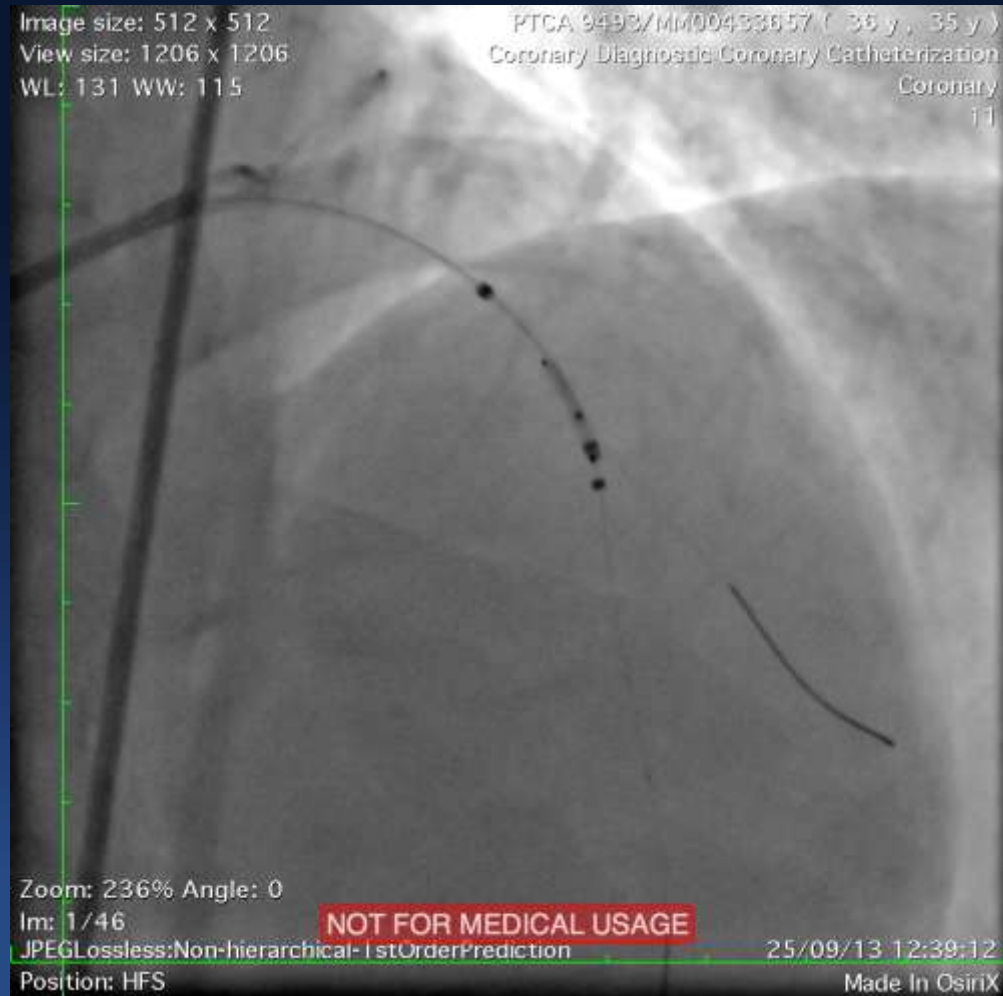
Case example

(AXXESS Stent in LAD/D1)

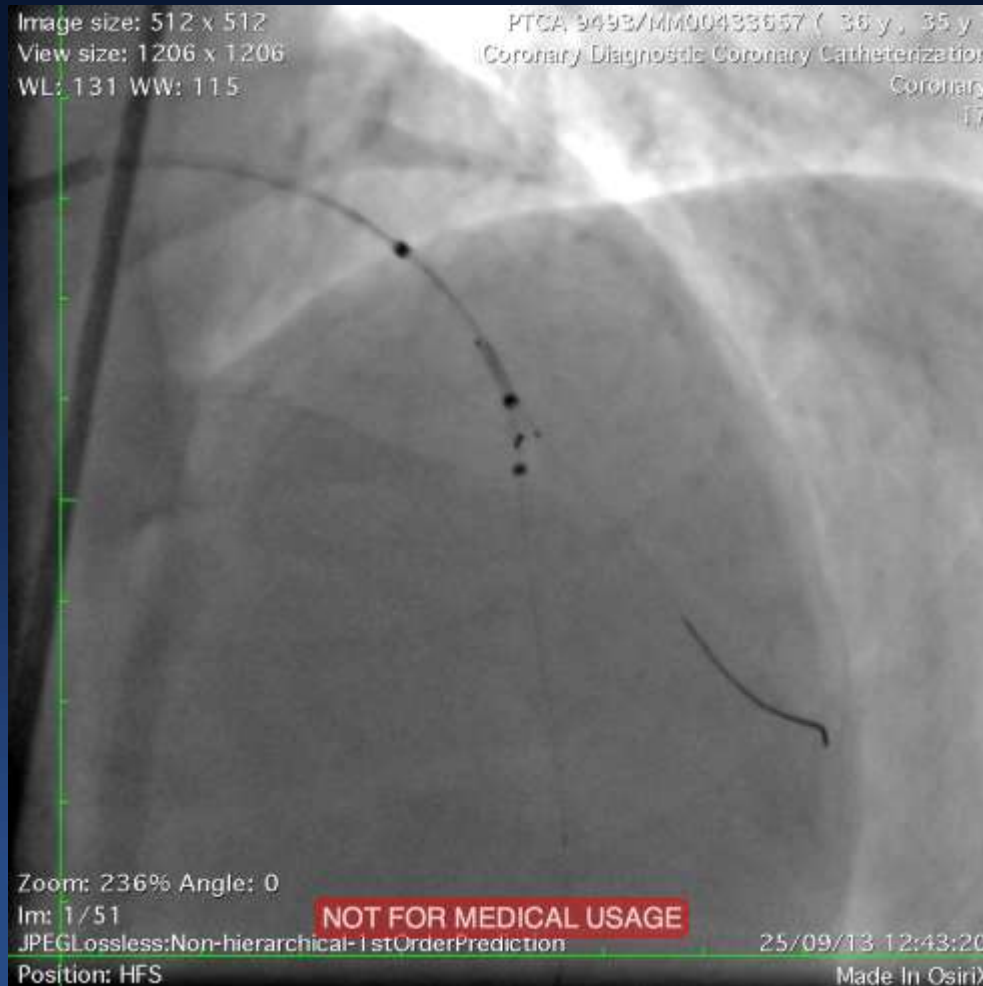
LAD/D1 Bifurcation Lesion



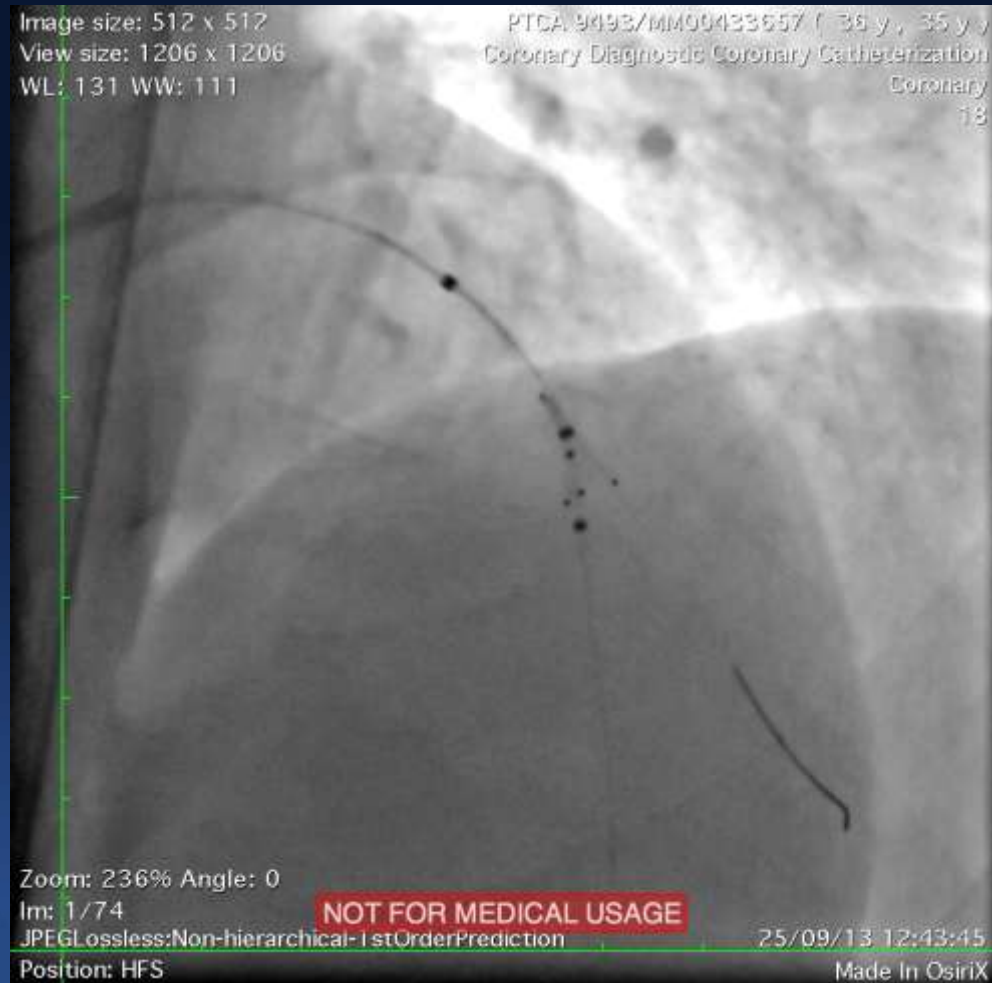
AXXESS Stent advanced



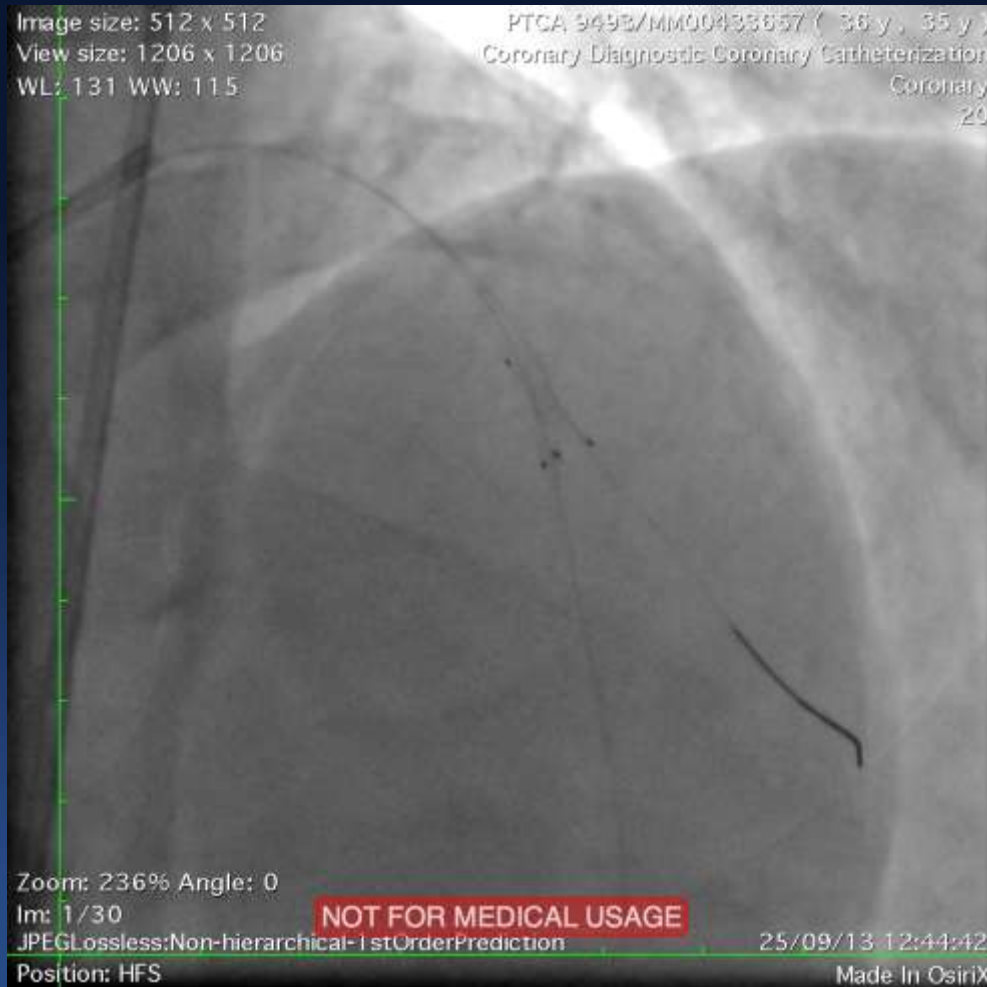
AXXESS Stent partially deployed



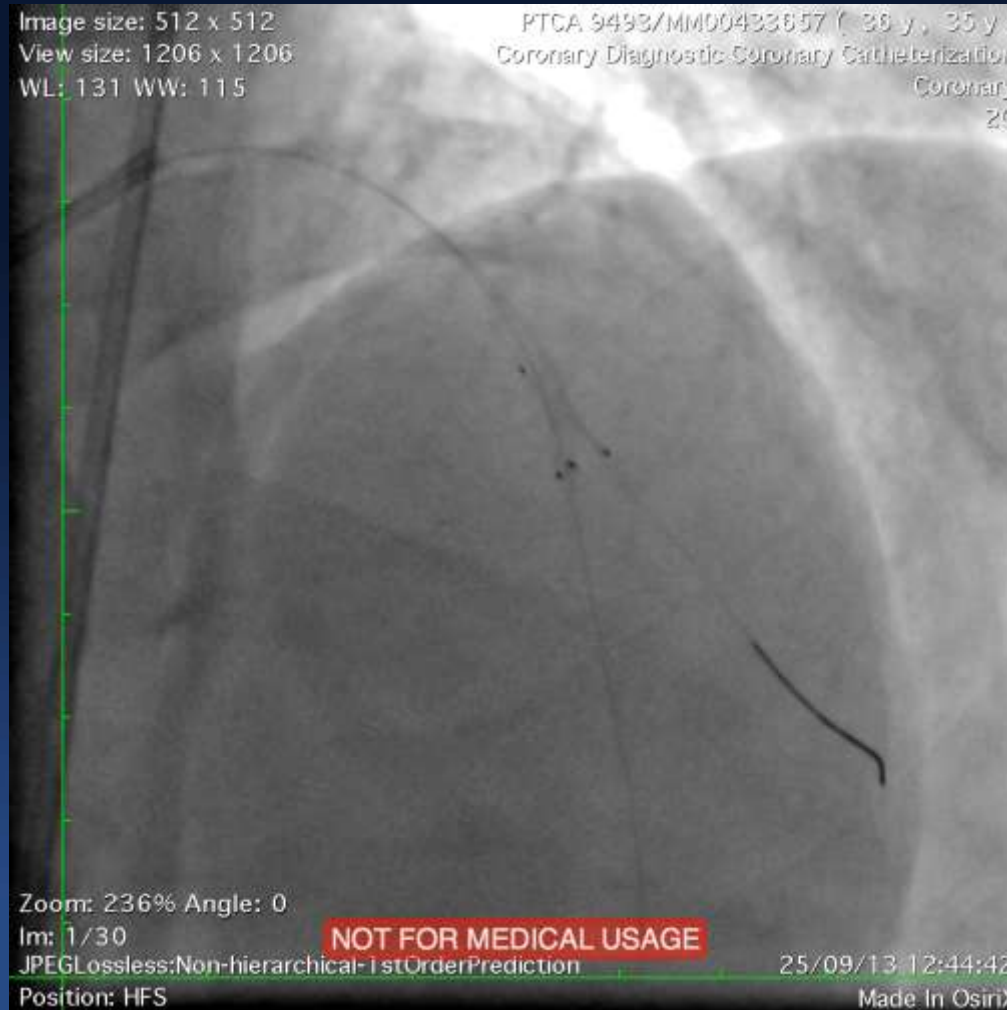
AXXESS Stent partially deployed (reaching into LAD and D1)



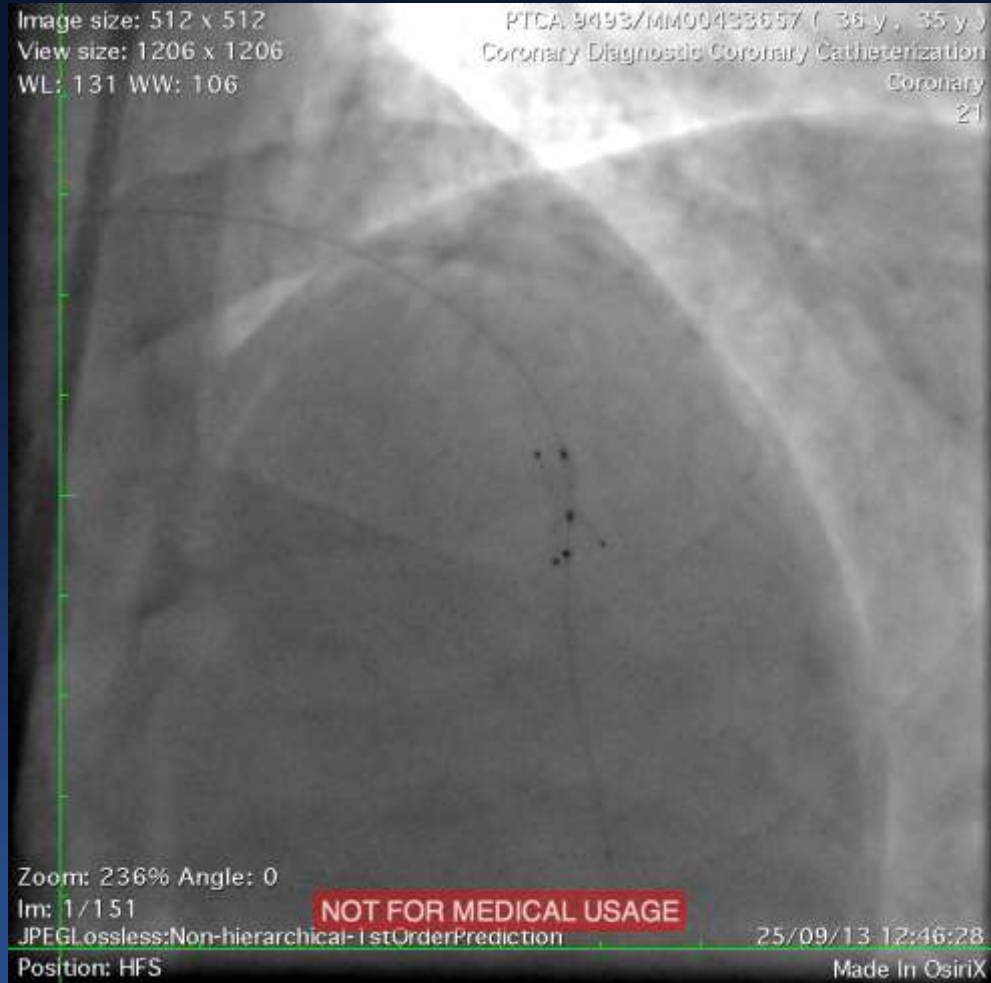
AXXESS Stent fully deployed (reaching into LAD and D1)



AXXESS Stent deployed (Control)

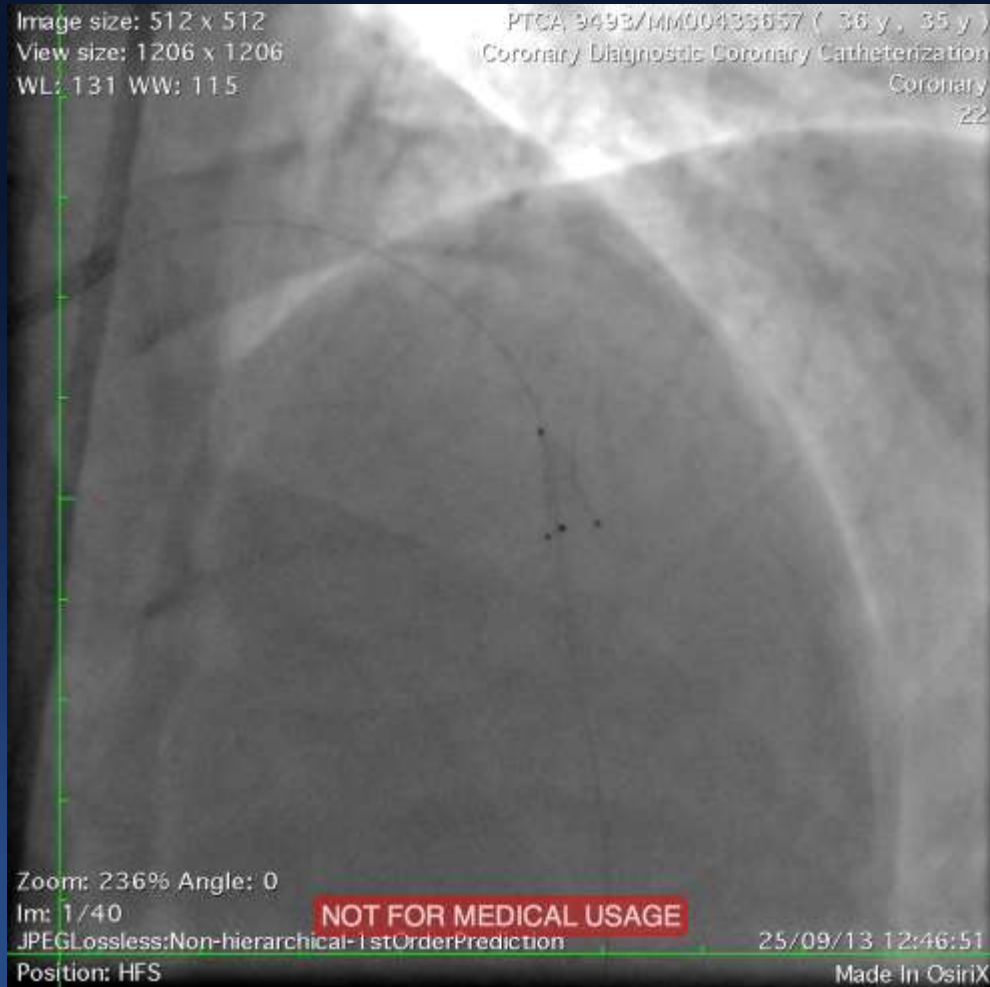


AXXESS Stent fully deployed (Postdilatation)



AXXESS Stent Final Result

(distal markers reaching down into LAD and D1 and covering the carina)



In Conclusion:

Do I need a Dedicated Bifurcation Stent in My Practice?

- Definitely: Medina 1-0-0
- Medina 1-0-1. Medina 1-1-1 and a viable SB that feeds a large territory?
- Young Patients that need possibly future interventions?
- With Axxess, I no longer strategise my patients for Culotte, DK Crush, V or any other technique.
 - Immediate Term: It's faster & reduces radiation
 - Mid to Long term: Lower ST & ISR
- Yes I still perform Provisional Stenting, with POT & if compromised SB, I will perform TAP

*Thank You for Your Kind
Attention*