

# **Are self-expanding DES safer than balloon-expandable DES?**

## **Long-term results of the Stentys DES and BMS**

Stefan Verheye, MD, PhD  
Antwerp Cardiovascular Institute  
ZNA Middelheim, Antwerp, Belgium  
On behalf of the OPEN I investigators



# Background

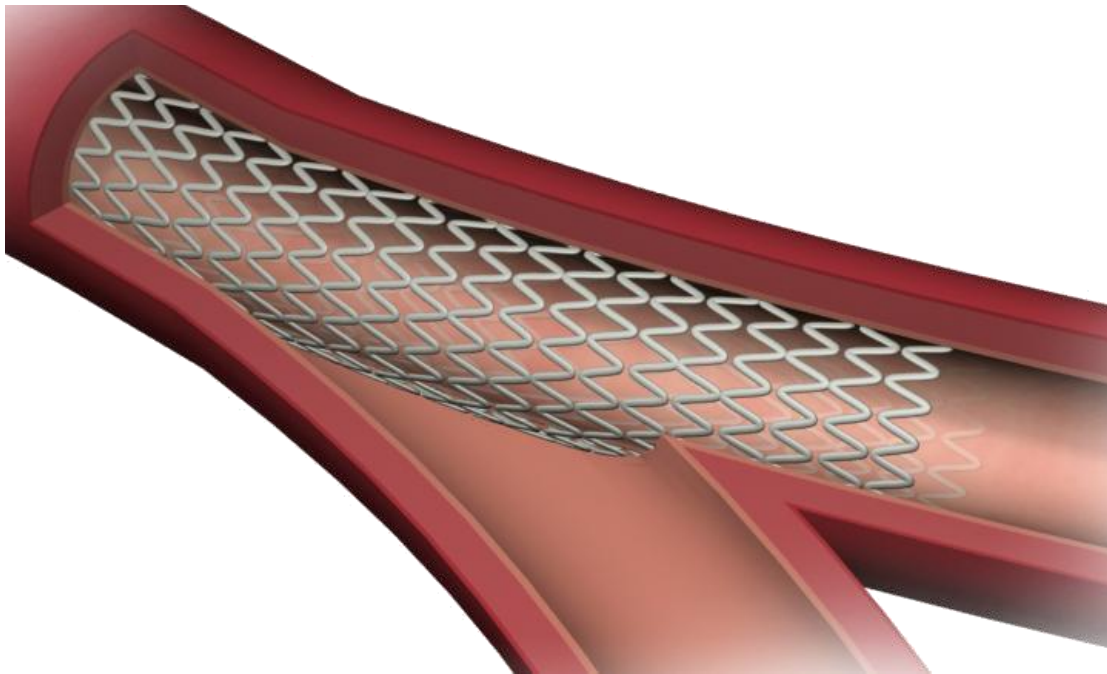
- Bifurcation lesions remain complex lesions to treat
  - Lower procedural success
  - Higher restenosis rate
- Shortcomings of balloon expandable DES in complex interventions like bifurcations
  - Large metallic burden
  - Mechanical distortion of stent struts at the carina
  - Double wire technique, wire wrap
  - Late acquired malapposition
- Need for simple stent technology that leaves access to side branch with low metallic burden and without stent distortion

# Stentys Stent : Procedure

# Consistent strategy

“Enhanced” provisional technique with multiple options:

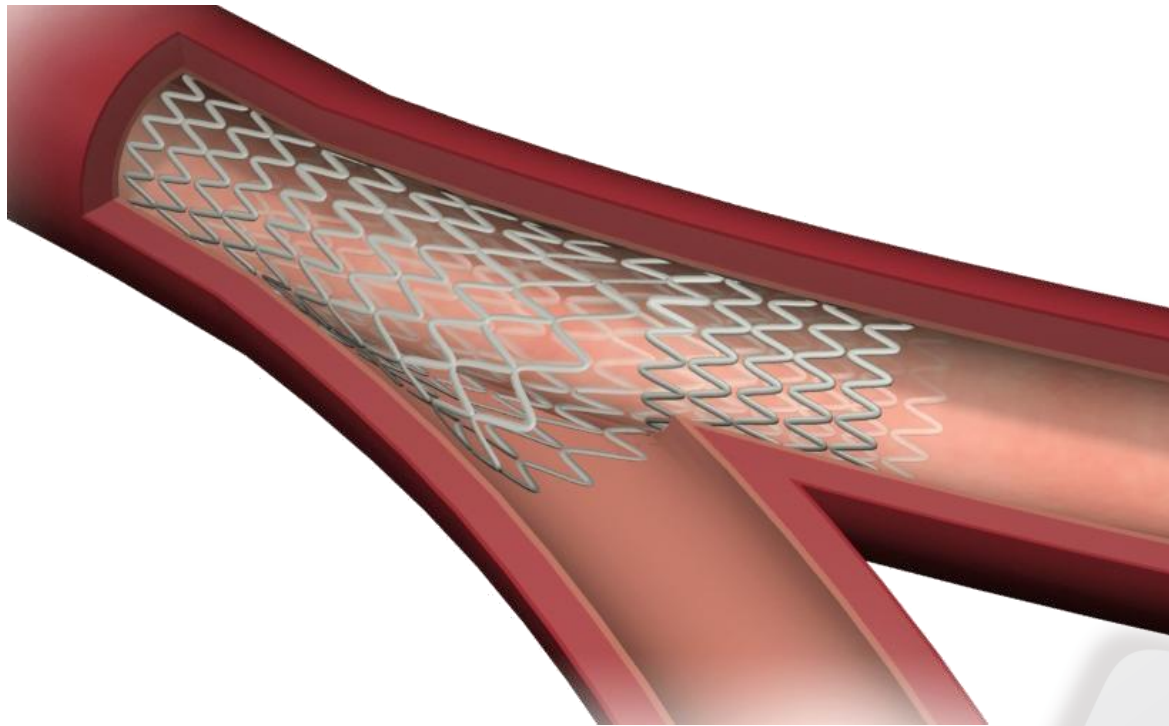
1. Main Branch stenting only



# Consistent strategy

“Enhanced” provisional technique with multiple options:

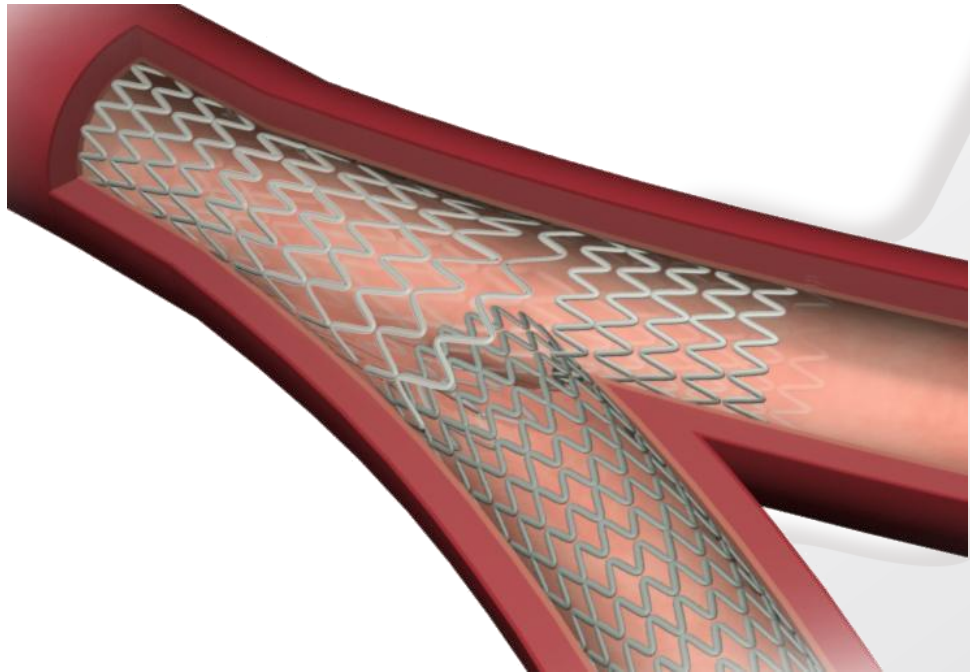
1. Main Branch stenting only
2. Main Branch stenting + disconnection



# Consistent strategy

“Enhanced” provisional technique with multiple options:

1. Main Branch stenting only
2. Main Branch stenting + disconnection
3. Main Branch stenting + disconnection + T-stenting with no gap



# OPEN I Design

## Design

- **DESIGN:** Prospective, non-randomized, single-arm, multi-center study
- **OBJECTIVE:** To evaluate the safety and feasibility of the Stentys DES and BMS in bifurcated lesions
- **ENDPOINTS:**  
Procedural success  
MACE @ 30 days and 6 months
- Events adjudicated by CEC
- Independent monitoring: Medpass
- Core lab: Cardialysis

63 patients enrolled between September 2007 and August 2009 in 9 European clinical sites

3 patients not stented

60 patients with Stentys stent:  
• 33 patients with Stentys BMS  
• 27 patients with Stentys DES

Clinical follow-up  
at 30 days

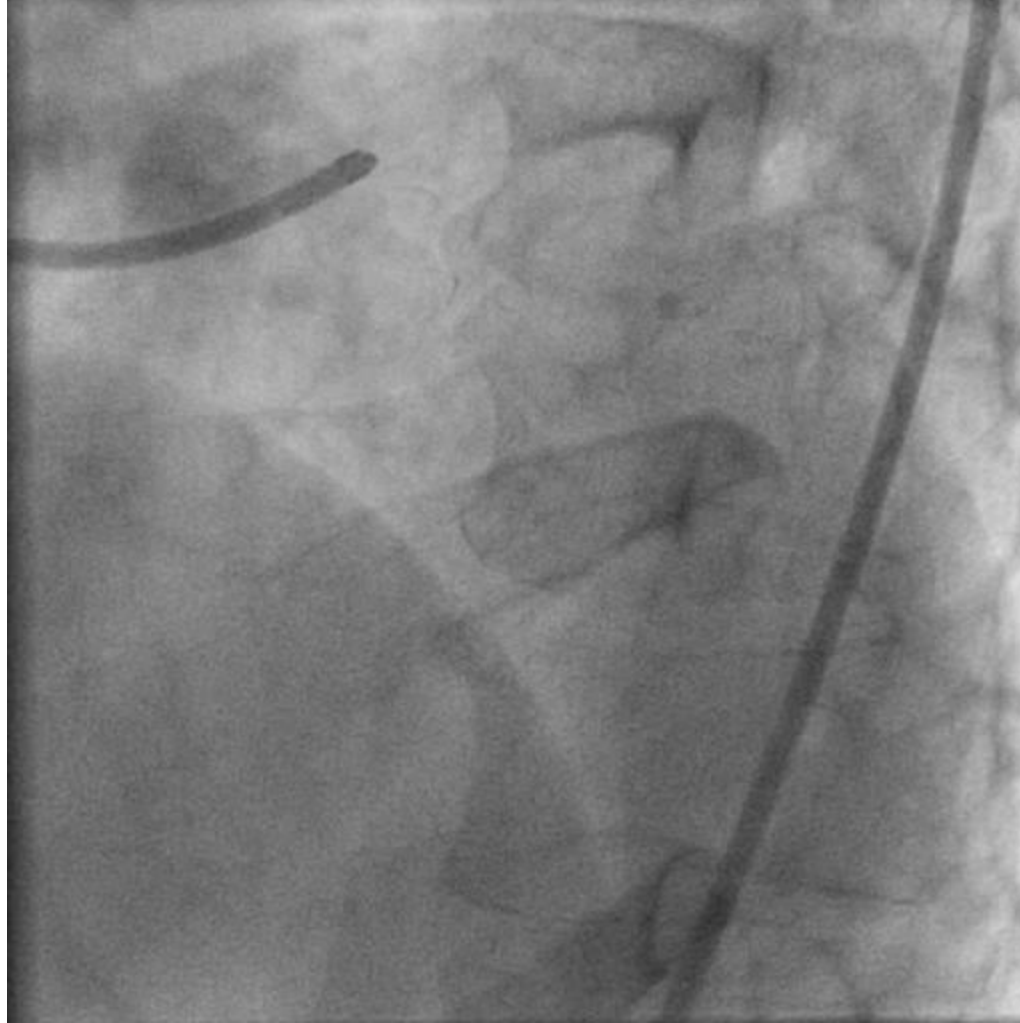
Clinical follow-up  
at 3 months

Angiographic  
and IVUS follow-up  
at 6 months

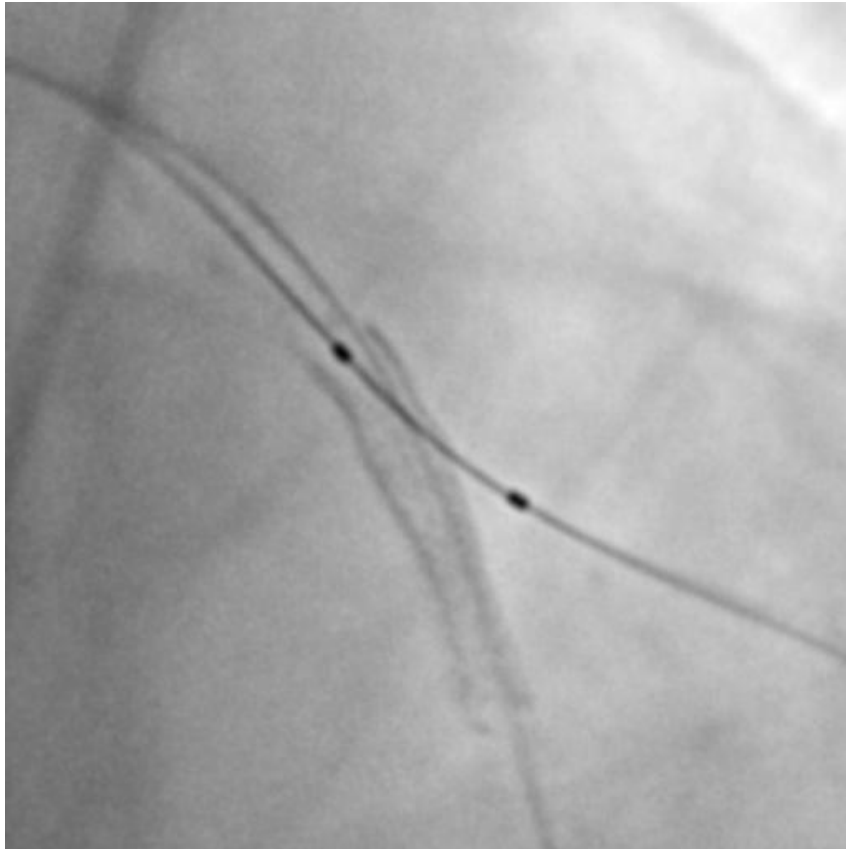
# Participating sites

Site	Investigator
Antwerp	S. Verheye
Rotterdam	R.J Van Geuns/P. Serruys
Trier	K. Hauptmann
Hamburg	J. Schofer
Siegburg	E. Grube
Bad Oeynhausen	M. Wiemer
Berlin	B. Witzenbichler
Leicester	J. Kovac/A. Gershlick
Massy	T. Lefèvre

# Case



# Stent Boost



# Follow up at 6 months



# Demographics

	DES (n=27)	BMS (n=33)	p
Age (years)	64	63	NS
Male	82%	88%	NS
Diabetes	11%	0%	NS
Hypertension	56%	64%	NS
Hypercholesterol.	85%	58%	<0.05
Former smoker	32%	54%	NS
Prior MI	46%	30%	NS
Prior PCI	37%	45%	NS
Prior CABG	7.4%	0%	NS

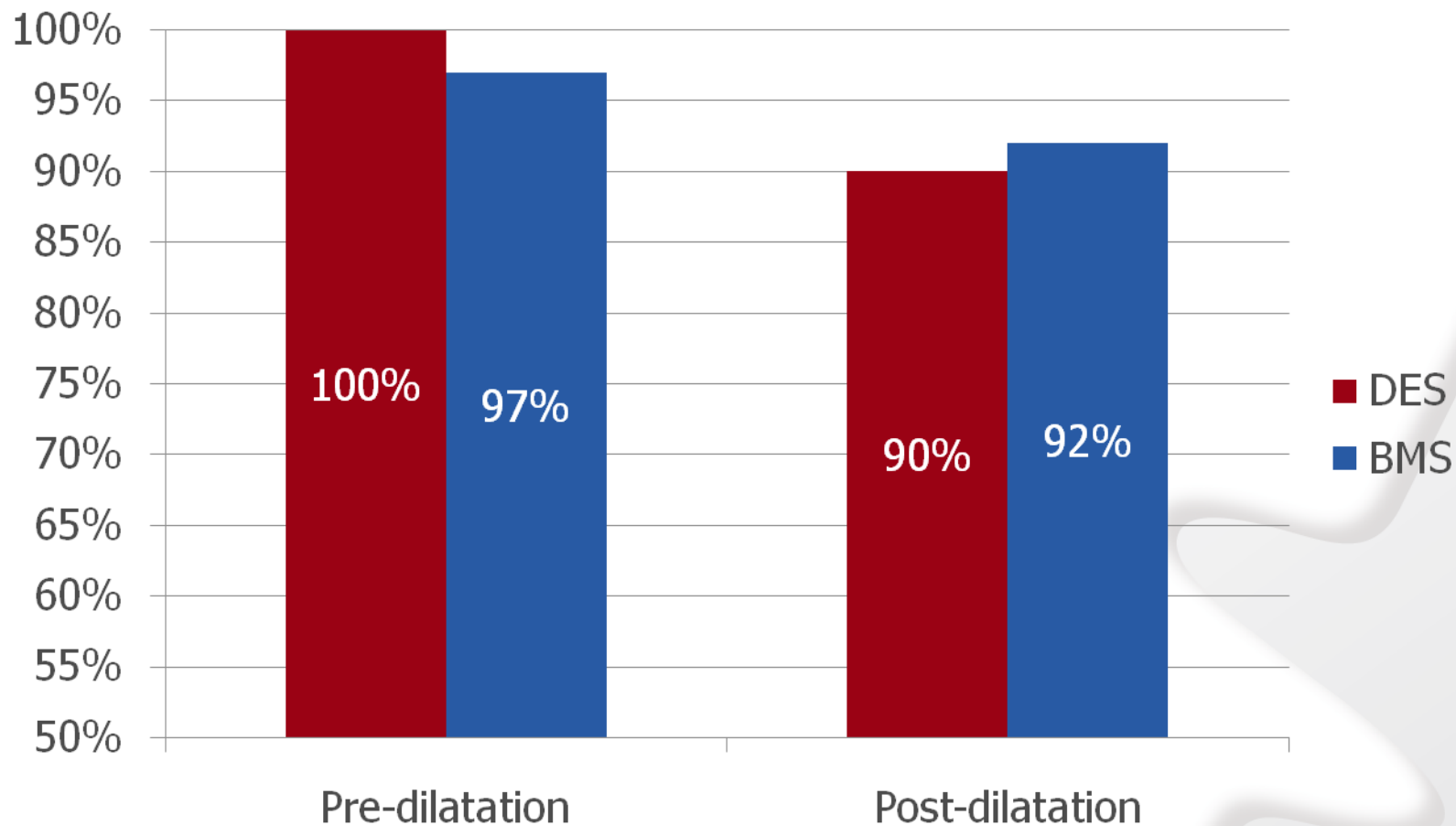
# Baseline QCA (n=56)

	DES (n=24)	BMS (n=32)
<b>Main Branch</b>		
RVD <b>Proximal</b> (mm)	2.89 ± 0.61	2.69 ± 0.50
RVD <b>Distal</b> (mm)	2.27 ± 0.39	2.40 ± 0.39
MLD (mm)	1.14 ± 0.26	1.25 ± 0.41
LAD Location	81%	82%
<b>Side Branch</b>		
Reference Diameter (mm)	2.10 ± 0.45	2.16 ± 0.45
MLD (mm)	1.50 ± 0.57	1.66 ± 0.50

# Procedure outcome

	DES	BMS
Procedural success	27/29 (93%)	33/34 (97%)
Additional Side Branch stents	4	13
<b>Final mean DS (%)</b>		
Main Branch	19.0%	10.3%
Side Branch	24.5%	17.2%

# Pre- and post-dilatation (n=60)



# 6 month QCA Results: MB

	DES	BMS
	n=25	n=31
In segment Restenosis*	1 (4%)	9 (29%)
Proximal MB	1 (4%)	4 (13%)
Distal MB	0 (0%)	7 (23%)
	n=25	n=30
In stent Late Loss (mm)		
Proximal MB	0.39 ± 0.62	0.83 ± 0.65
Distal MB	0.40 ± 0.50	0.85 ± 0.63

*\*Not mutually exclusive*

# 6 month QCA Results: SB

	DES	BMS
Restenosis	4 16% n=25	5 16% n=31
With SB Stent	0 0% n=4	1 8% - n=13
Without SB stent	4 19% n=21	4 22% - n=18

- Excellent result when “cross-over” to 2 stents

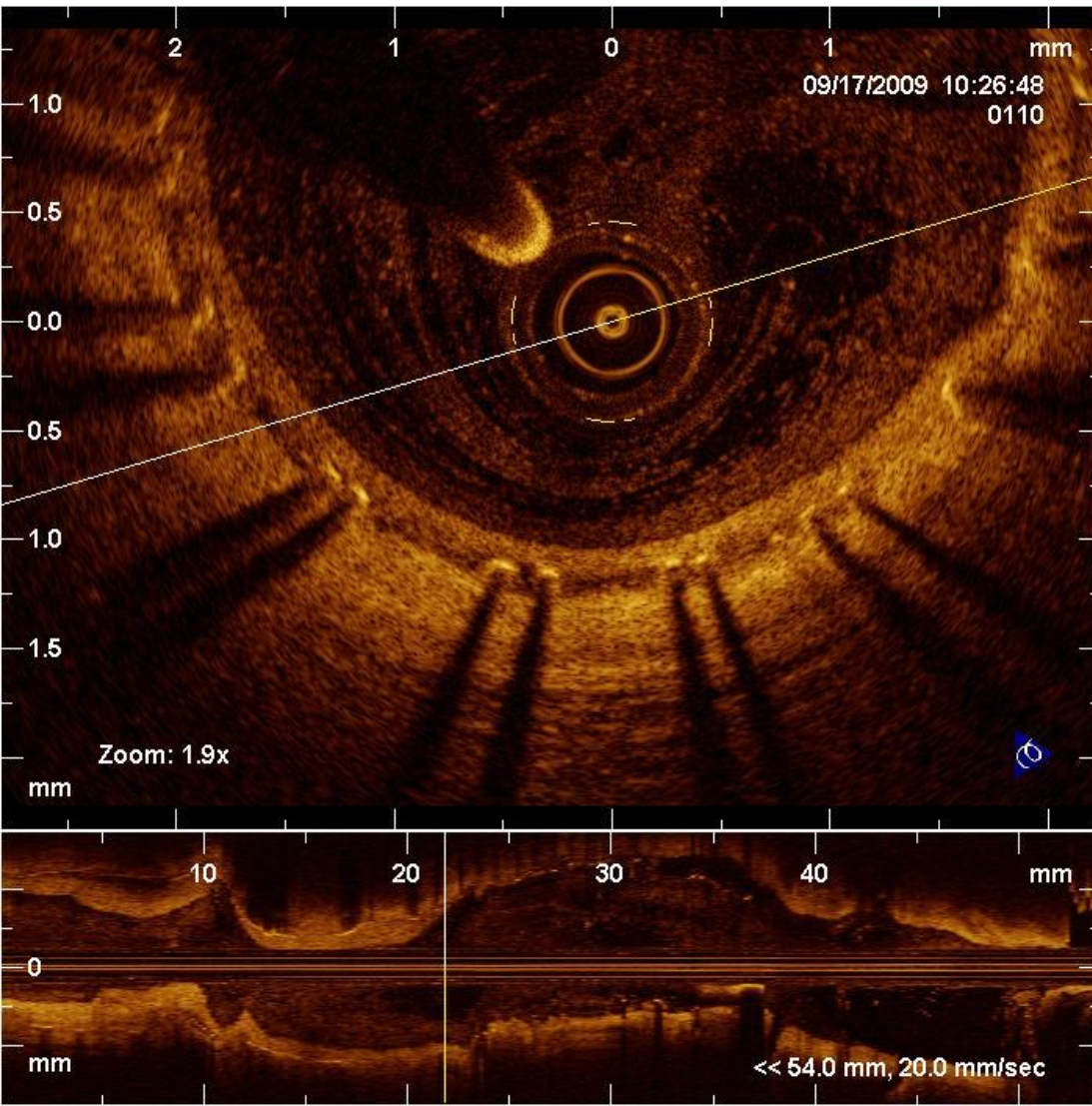
# Cumulative 6 month MACE<sup>1</sup>

	DES (n=27)	BMS (n=33)
Cardiac Death	0	0
AMI		
Q-wave MI	0	0
Non Q-wave MI <sup>2</sup>	0	1
Clinically driven TLR	1	8
<b>Total</b>	<b>1 (3.7%)</b>	<b>9 (27.3%)</b>

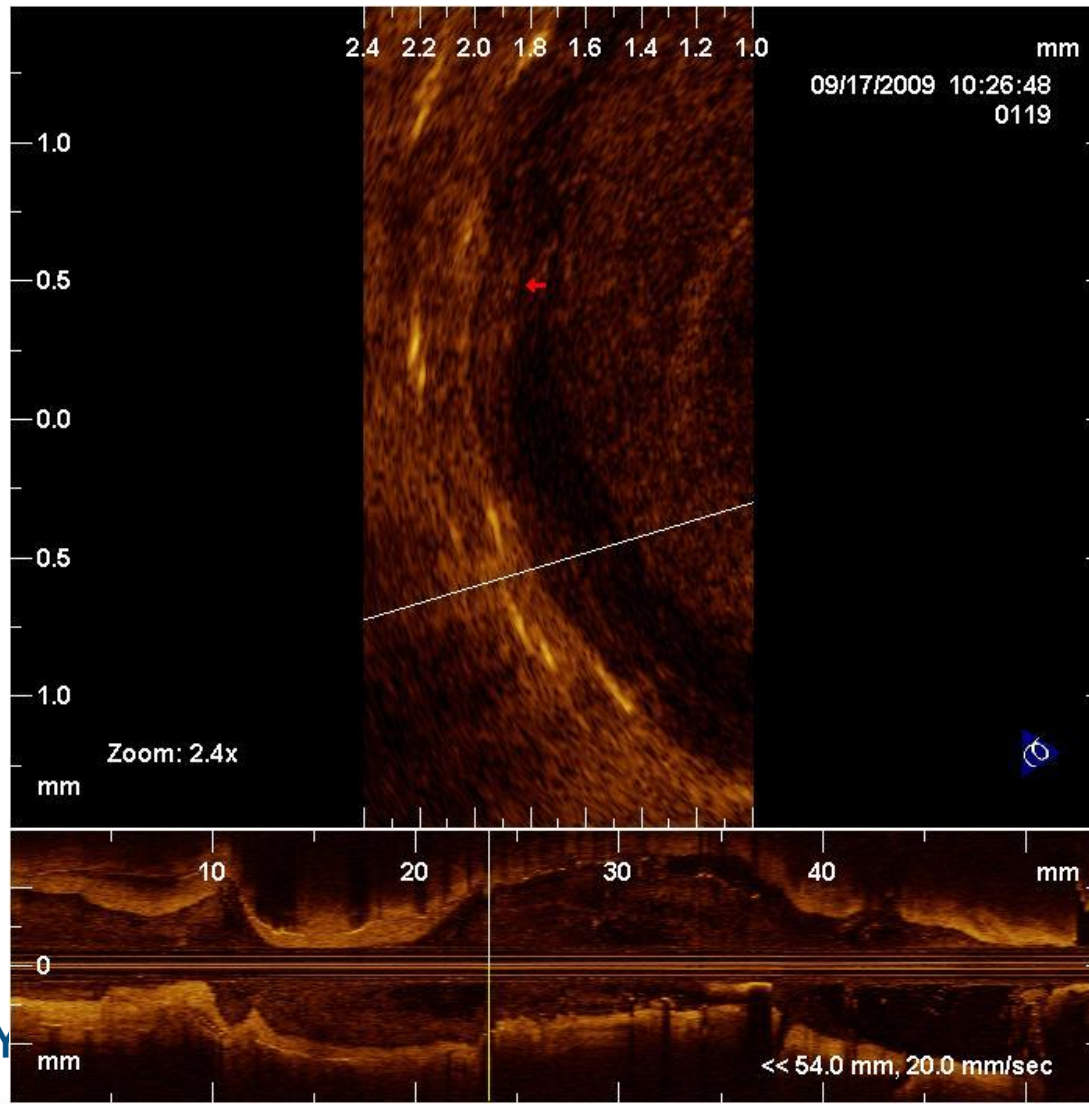
<sup>1</sup> CEC adjudicated

<sup>2</sup> CK>2ULN & CK-MB>ULN

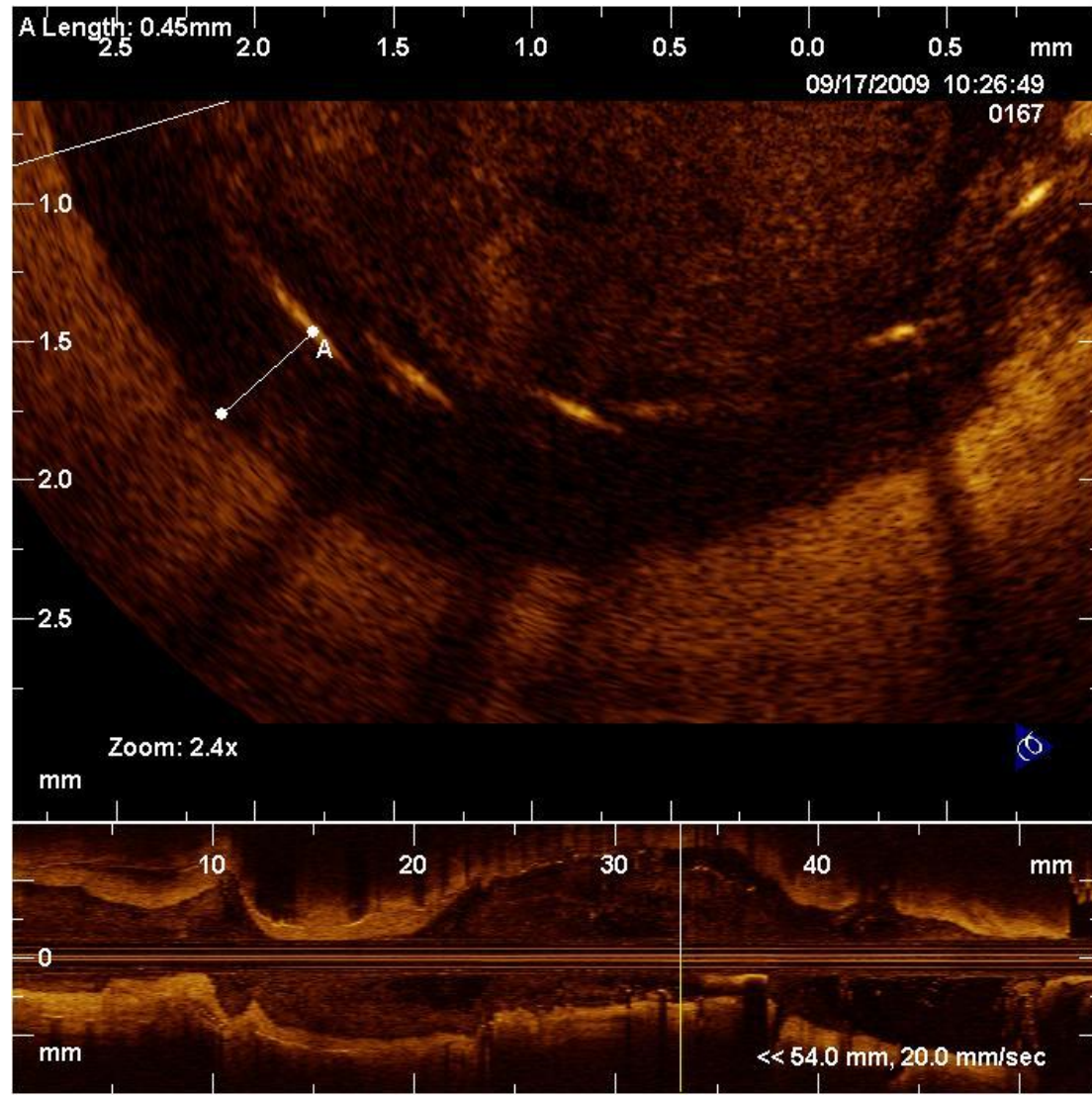
# Stentys vs Taxus Apposition at 6 months



# Stentys vs Taxus Apposition at 6 months



# Stentys vs Taxus Apposition at 6 months



# Conclusions

## The Stentys platform

- Is safe and feasible in complex lesions
- Delivers very good outcome both clinically and angiographically
- Could eliminate late acquired stent malapposition
- Provides side branch access and allows provisional treatment of branch vessels with excellent “cross-over”