Long-term behaviour of Nitinol stents in coronary arteries: two-year IVUS follow-up of the STENTYS stent

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Background

- The STENTYS stent has demonstrated very good apposition rates and could offer some advantages over balloon-expandable stents in certain complex situations, such as bifurcation lesions or STEMI patients

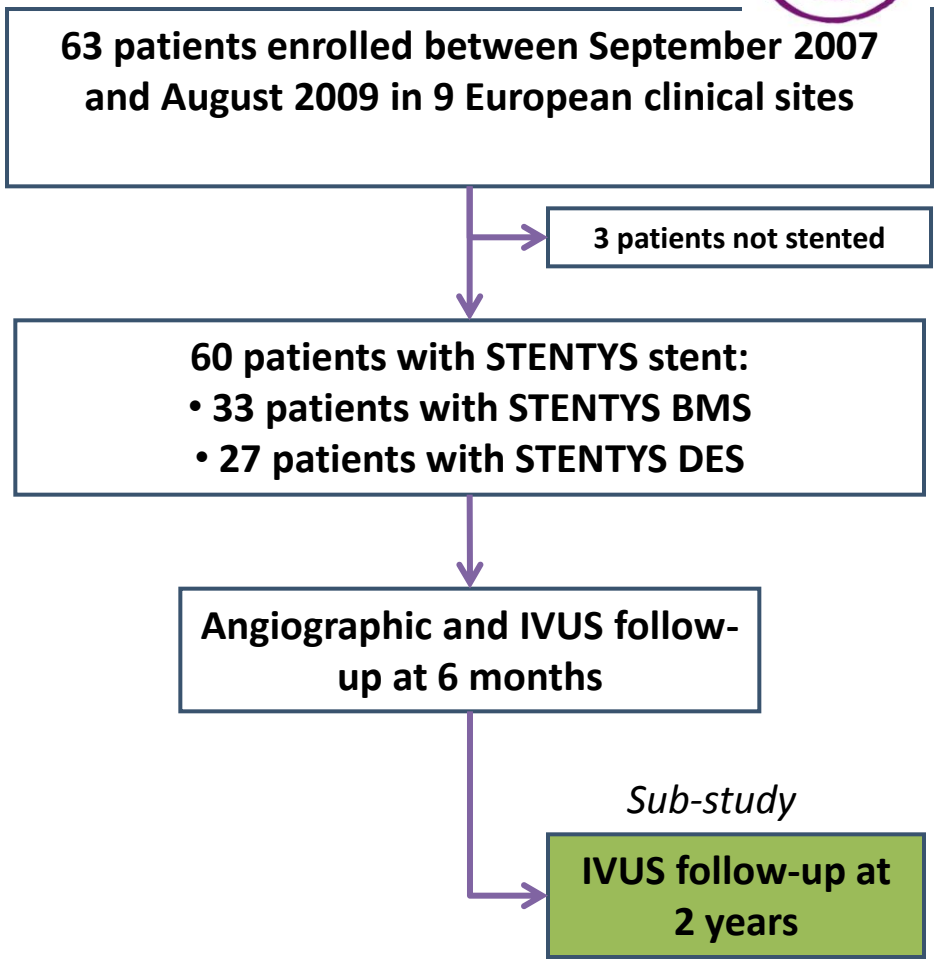
- By design, the STENTYS stent diameter is larger than vessel diameter, allowing for continuous adaptation to changes in vessel anatomy

- However, the LONG TERM effect of continued pressure on the vessel wall remains unknown:
  - Does the stent expansion reaches an equilibrium ?
  - Is there a long term impact on vessel patency ?
  - Is apposition preserved ?

OPEN I Study Design

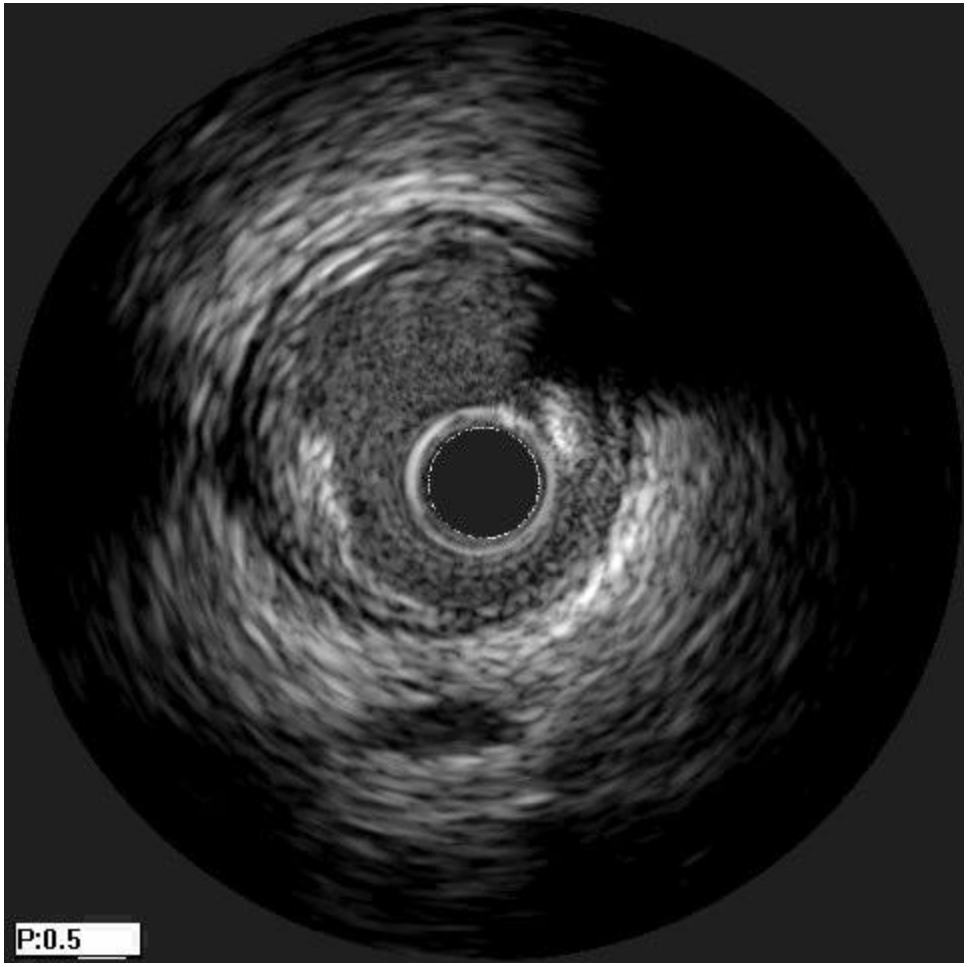
Design

- **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

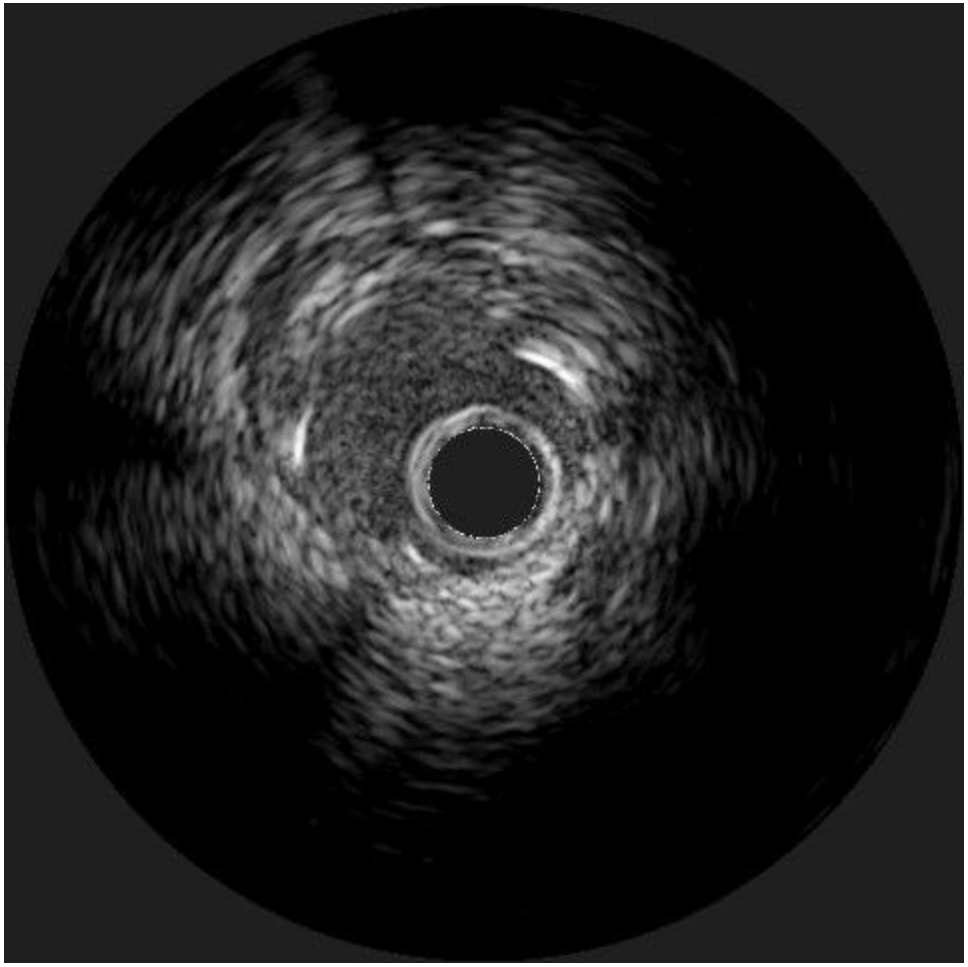


Case

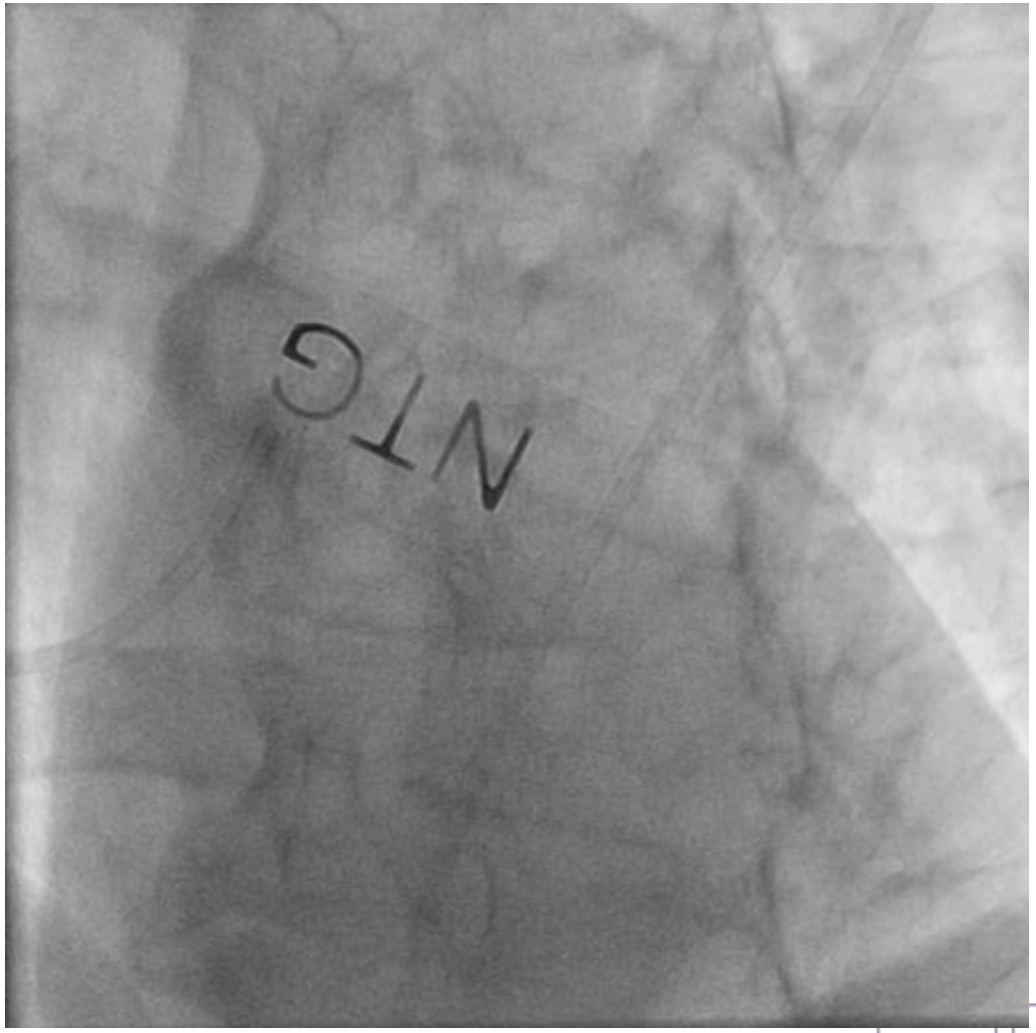
IVUS (MB)



IVUS (SB)



Follow up at 6 months



6 month QCA: Main Branch

	DES (n=25)	BMS (n=31)
In segment Restenosis*	1 (4%)	9 (29%)
Proximal MB	1 (4%)	4 (13%)
Distal MB	0 (0%)	7 (23%)
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: Side Branch

	STENTYS DES+BMS (n=56)
In segment Restenosis	9 (16%)
With SB balloon expandable stent (n=17)	1 (6%)
Without SB balloon expandable stent (n=39)	8 (21%)

Excellent result when "cross-over" to 2 stents

Cumulative 6 month MACE[1]

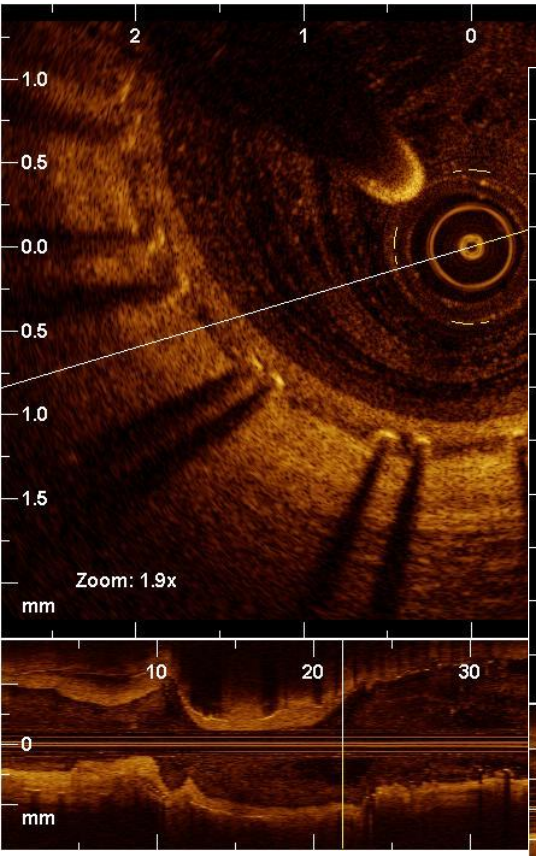
	DES (n=27)	BMS (n=33)
Cardiac Death	0	0
AMI		
Q-wave MI	0	0
Non Q-wave MI[2]	0	1
Clinically driven TLR	1	8
Total	**1 (3.7%)**	**9 (27.3%)**

[1] CEC adjudicated
[2] CK>2ULN & CK-MB>ULN

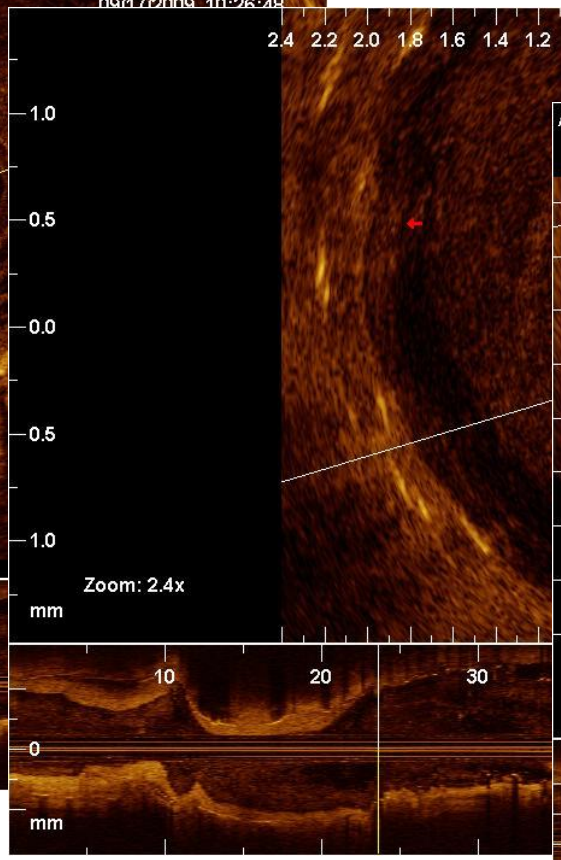
IVUS QA (matched): MB

	DES (n=19)		BMS (n=19)	
	Baseline	6 month	Baseline	6 month
Mean Reference Area (mm^2)	7.42 ± 3.19	7.95 ± 3.49	7.91 ± 2.78	7.31 ± 2.48
Mean Luminal Area (mm^2)	7.39 ± 1.99	8.58 ± 2.48	7.94 ± 1.39	8.91 ± 2.54
Minimum Luminal Area (mm^2)	5.10 ± 1.71	4.91 ± 2.15	5.74 ± 1.35	5.15 ± 1.99
Mean Stent Area (mm^2)	7.52 ± 1.86	12.32 ± 2.90	7.95 ± 1.40	11.56 ± 2.22
Incomplete Stent Apposition	4/22	2/22	0 /26	1/20

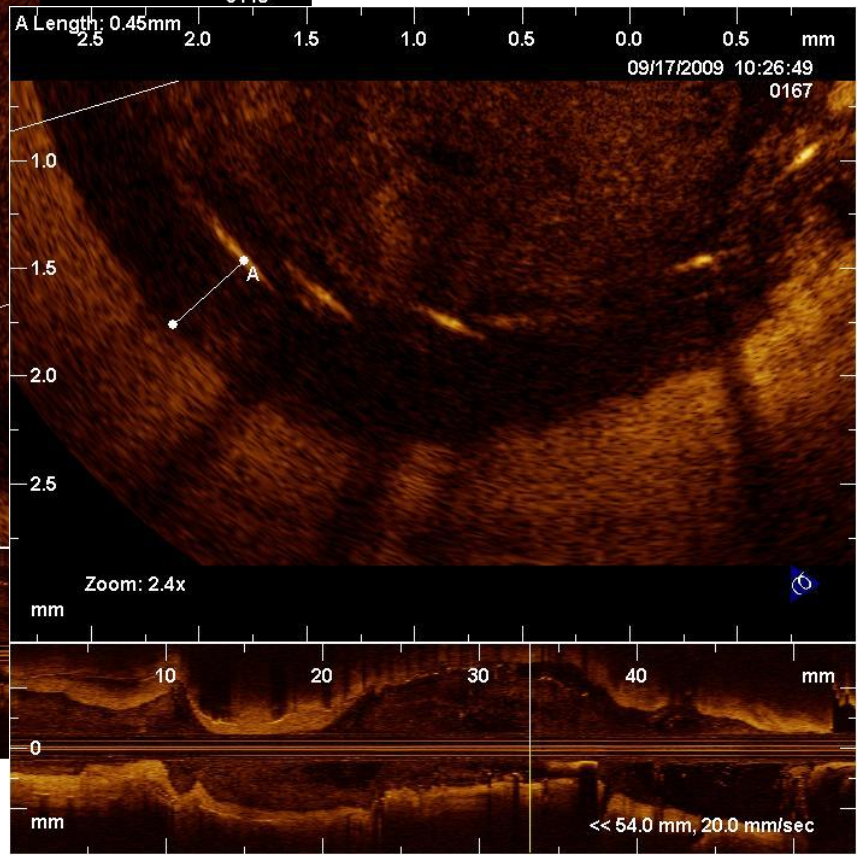
STENTYS DES vs Balloon Expandable DES: Apposition at 6 months



Distally: STENTYS well apposed



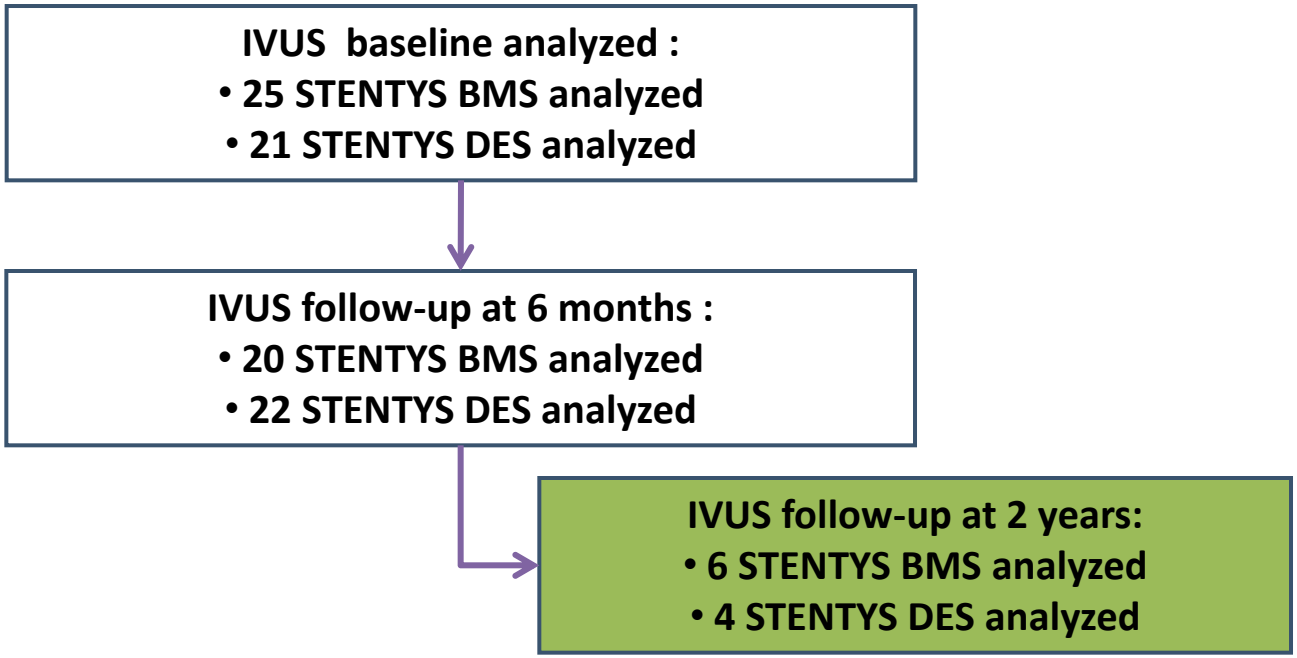
Overlapped region



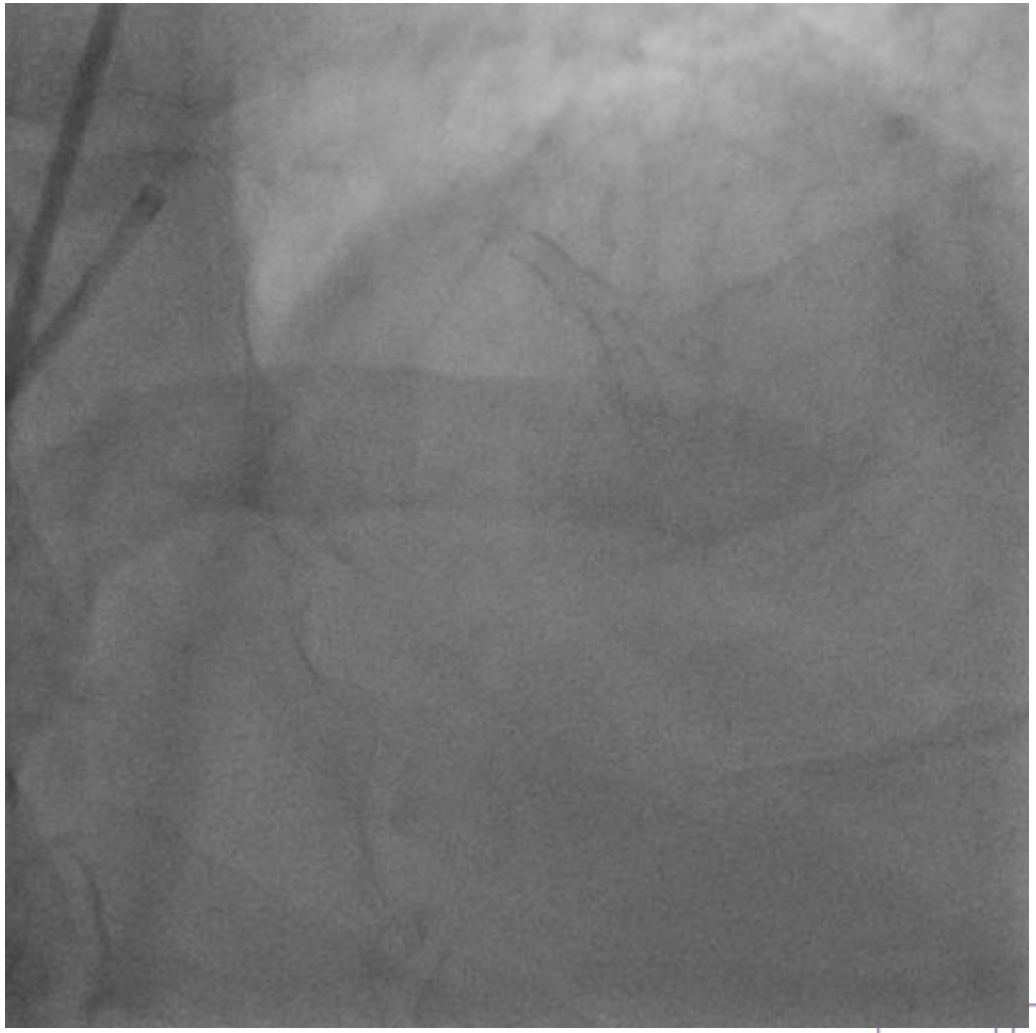
Proximally: Balloon-expandable DES malapposed

2 Year IVUS sub-study

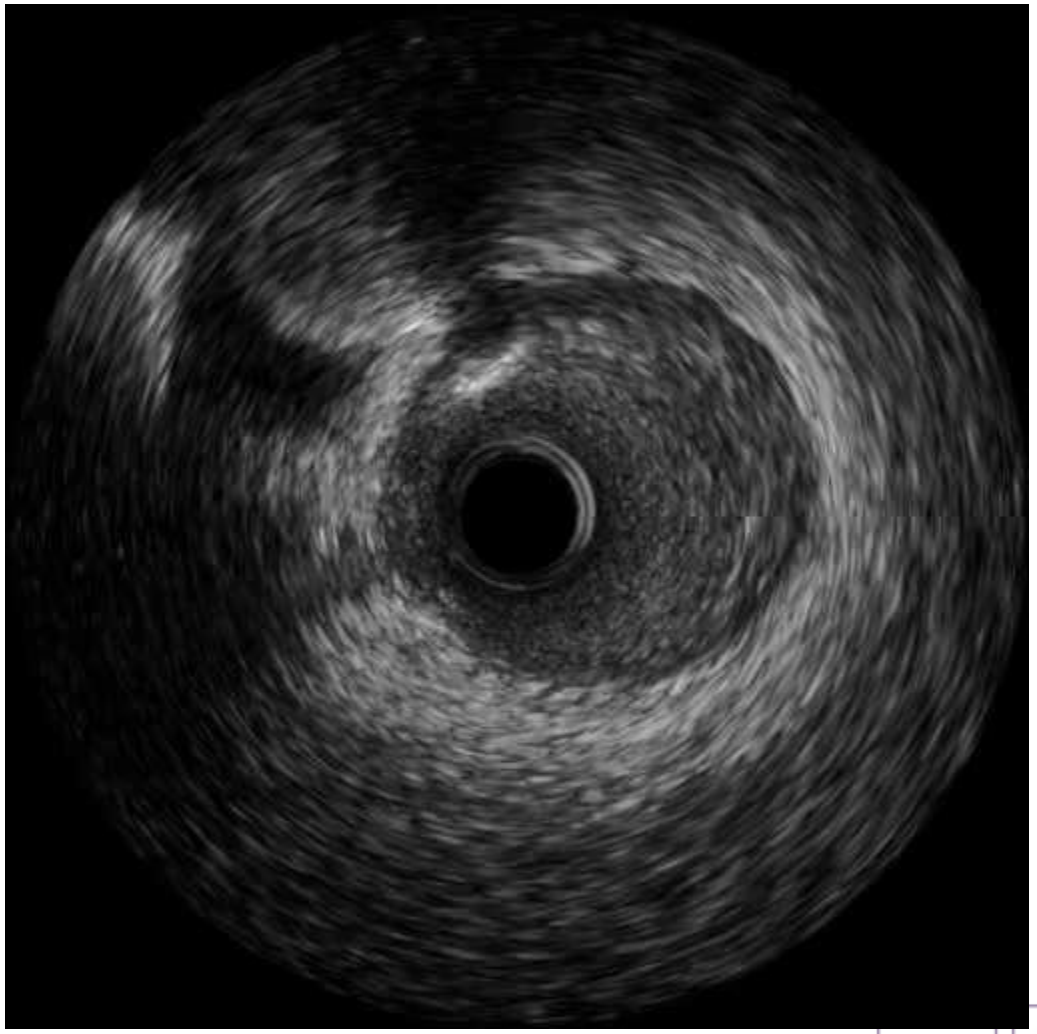
- Selection of 2 highest enrolling sites (65% of patients)
- Proposed additional 2 year invasive FU



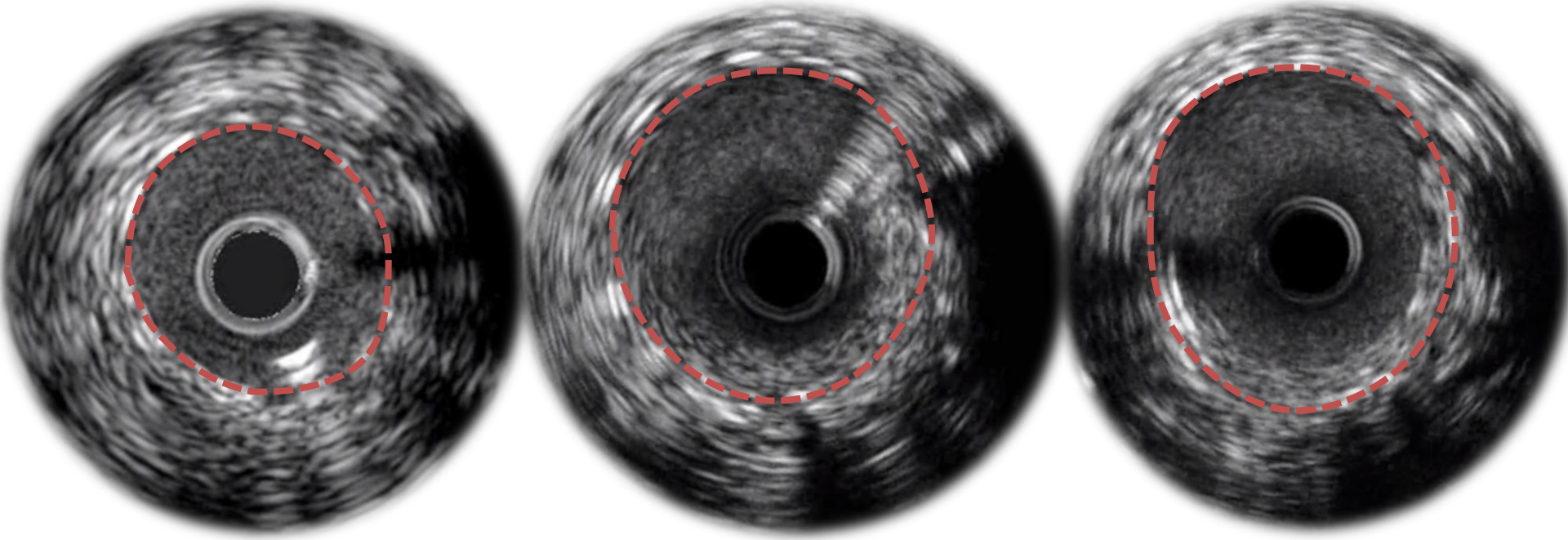
Follow up at 2 years



IVUS (MB)



Evolution over time



Baseline

6 months

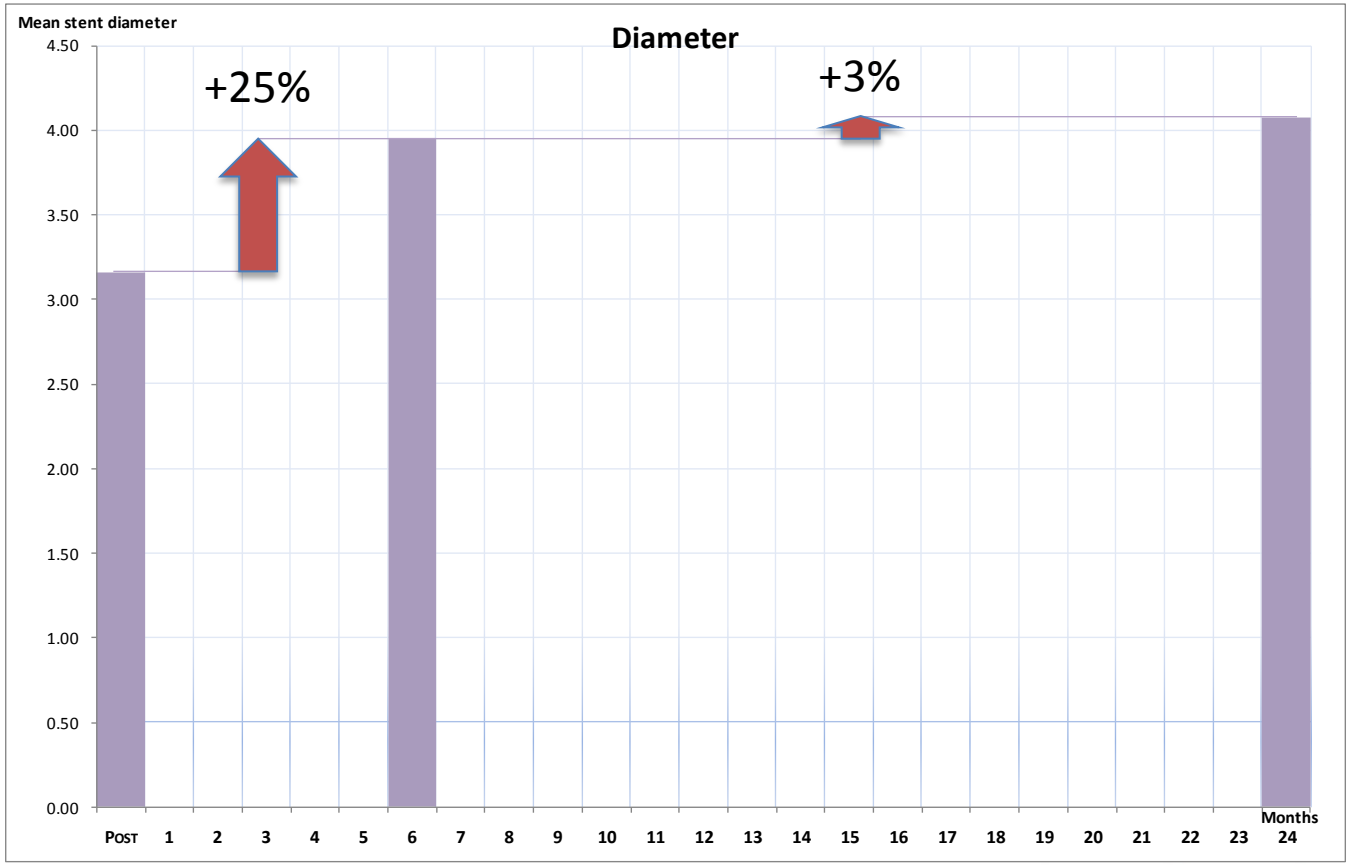
2 years

IVUS QA (unpaired): MB

	DES (n=4)			BMS (n=6)		
	Baseline	6 month	2 years	Baseline	6 month	2 years
Mean Reference Area (mm^2)	6.89 ±4.00	8.52 ±4.69	10.11 ±4.77	8.12 ±2.40	7.21 ±1.57	8.26 ±1.34
Mean Luminal Area (mm^2)	7.01 ±1.73	8.22 ±3.44	10.04 ±3.62	8.14 ±1.01	9.35 ±2.56	10.82 ±2.31
Minimum Luminal Area (mm^2)	5.55 ±1.77	5.46 ±2.50	6.53 ±2.33	5.37 ±1.14	5.58 ±1.70	6.46 ±2.08
Mean Stent Area (mm^2)	7.12 ±1.73	12.01 ±2.62	11.77 ±3.10	8.26 ±0.91	12.23 ±2.03	13.71 ±1.55
Neointima (mm^2)	0.09 ±0.18	3.79 ±1.58	1.73 ±1.64	0.12	2.88 ±0.99	2.91 ±1.66
Incomplete Stent Apposition	0	0	0	0	0	0

Long term expansion by IVUS

- Stabilization of stent expansion below unconstrained diameter (6.5mm)

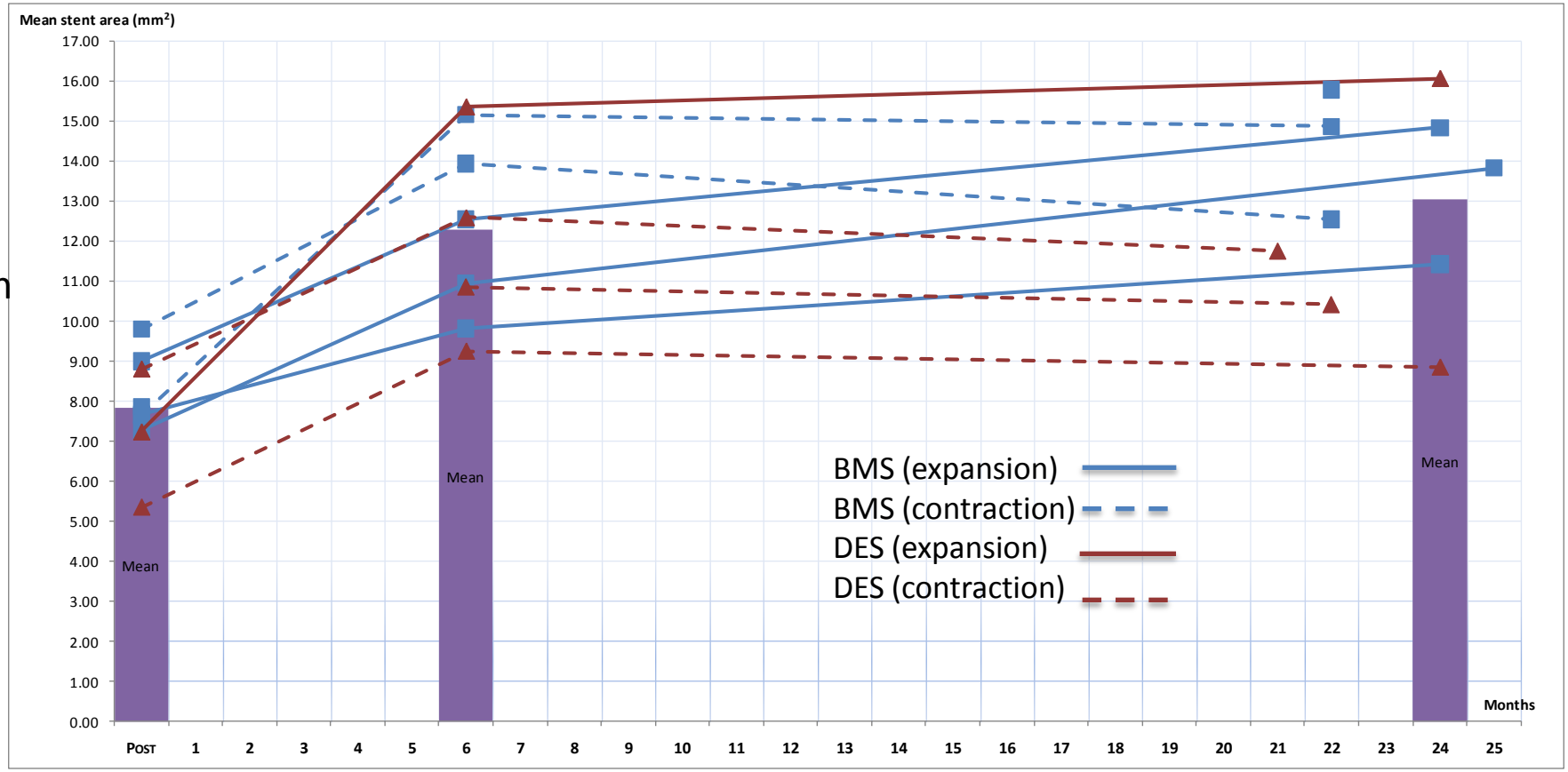


Mean stent diameter

Time

Long term expansion by IVUS

- In half of the cases, positive remodeling was higher than Chronic Outward Force, creating a reduction of mean stent area



Mean stent area

Time

Conclusions

The STENTYS platform:

- Is safe and feasible in complex lesions
- Delivers good outcome clinically, angiographically and by IVUS at 6 months
- Maintains good results at 2 years in a sub-group of patients:
  - Stabilization of stent expansion
  - Good lumen patency with stabilization of healing
  - Excellent apposition