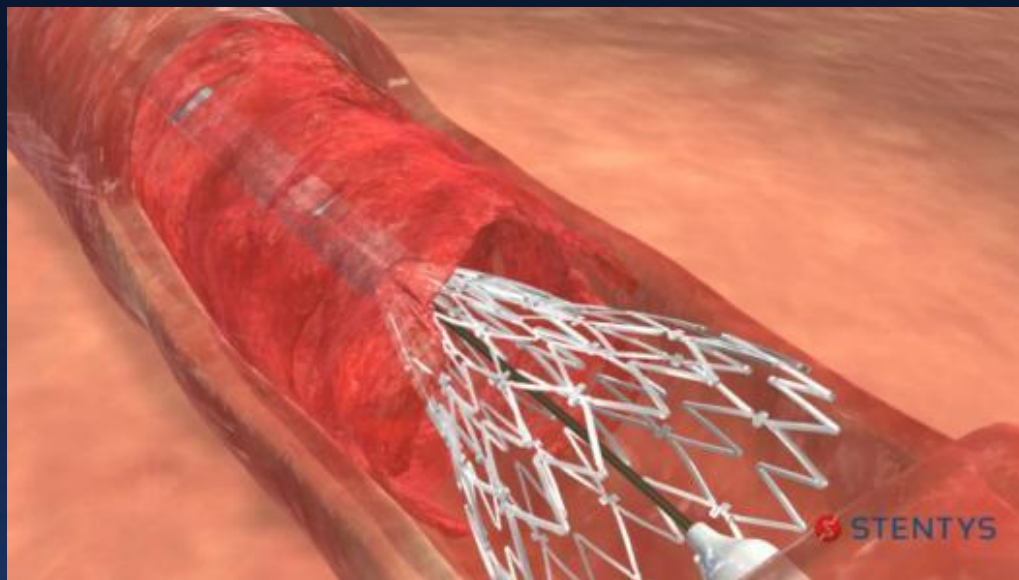


APPOSITION I & II

One-Year Clinical Results in STEMI



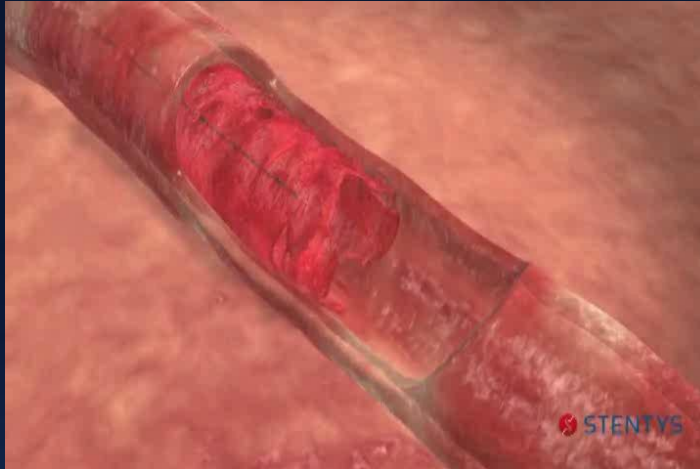
Sander IJsselmuiden, MD, PhD

Albert Schweitzer Hospital, Dordrecht

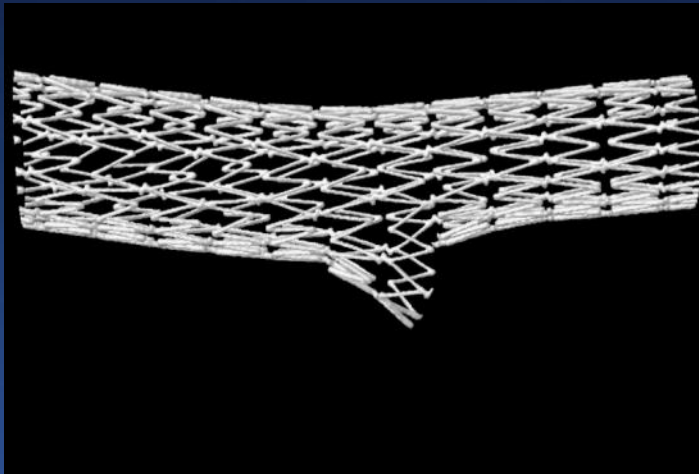
The Netherlands

On behalf of the APPOSITION investigators

Self-expanding stent



- 6F compatible
- Nitinol
- Z-shaped struts with interconnections



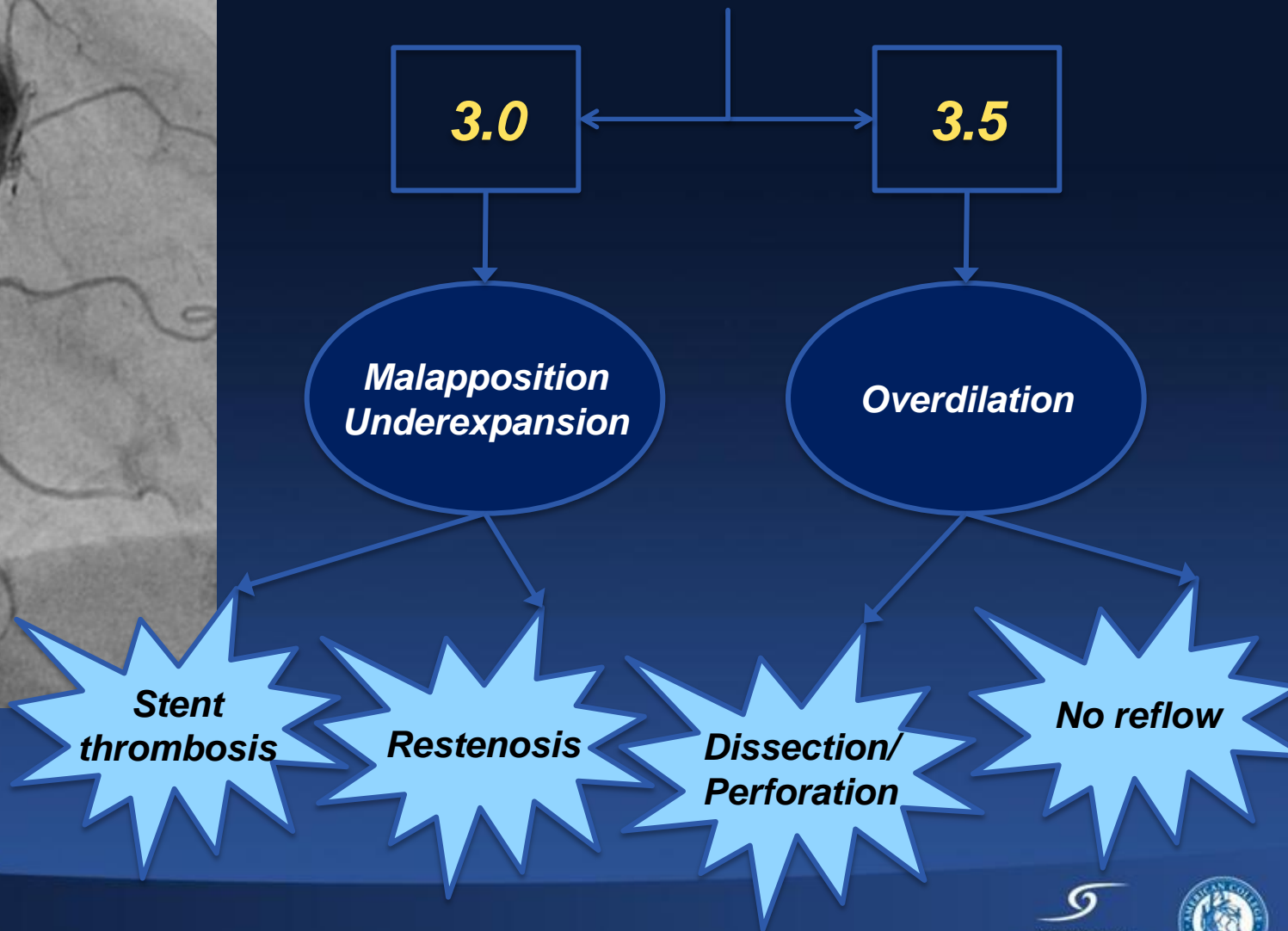
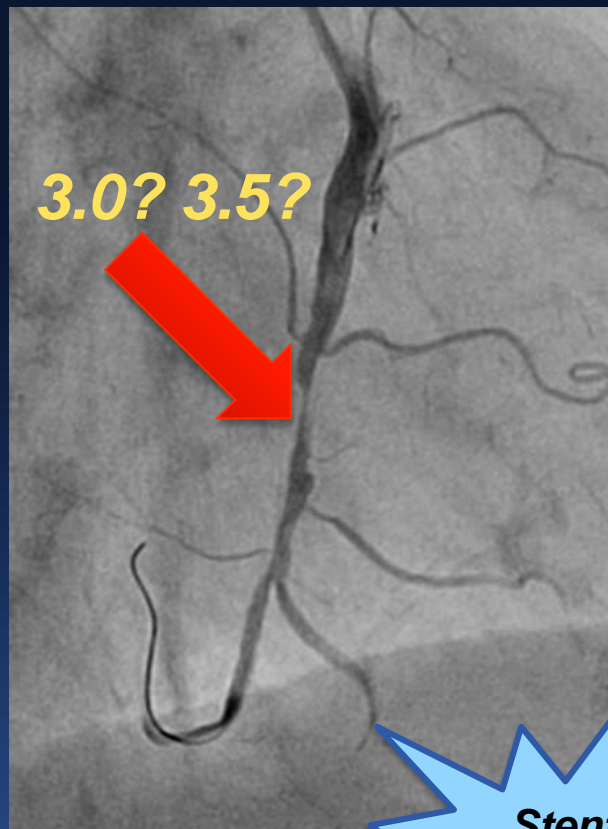
- Can be disconnected at level of side branch

AJJ Ijsselmuiden and S. Verheye.

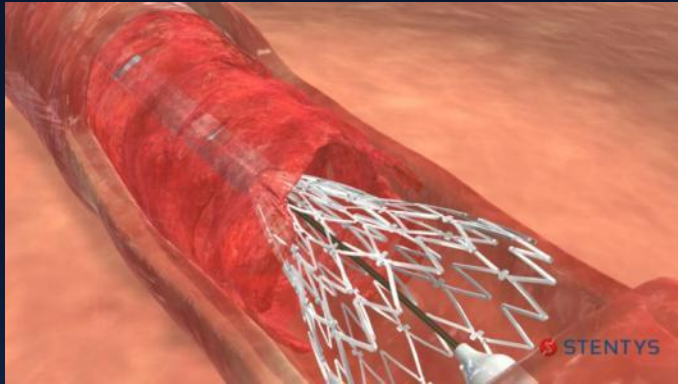
First report on the use of a novel self-expandable stent for treatment of STEMI.

Catheter Cardiovasc Interv. 74:6, pp 850–854, 15/11/2009

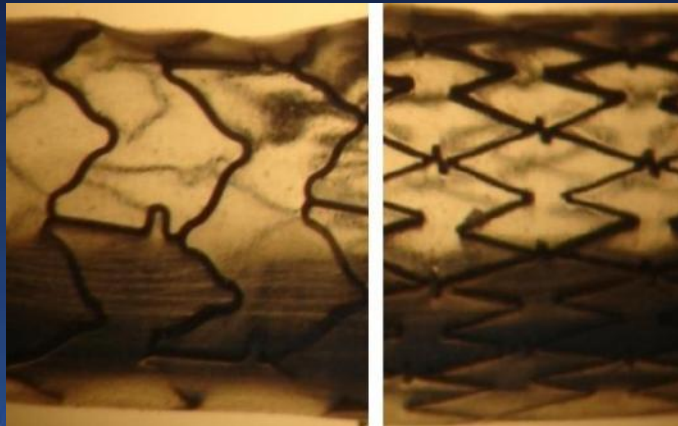
Background: stent sizing dilemma in STEMI



Potential Advantages



- No undersizing
- Better apposition without need for high pressure inflation



- Small cell area for better coverage of ruptured plaque

Comparison of Vision stent cell area (left, 3.86mm²) and STENTYS[®] stent cell area (right, 0.95mm²)

Clinical case

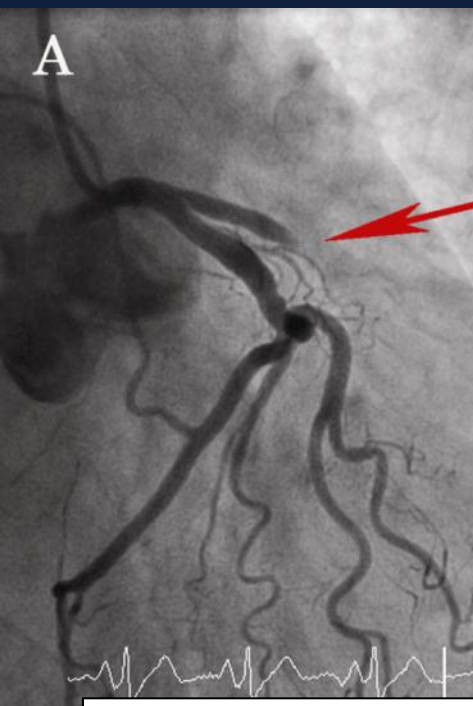
- **Female patient: 69 yr**
- **Clean past medical history**
- **Acute Anterior MI**
- **Proximal LAD occlusion (1-VD)**
- **Thrombus suction mandated**
- **Postdilatation guided by IVUS/Stent Boost**

AJJ Ijsselmuiden and S. Verheye.

TCT 2011 *First report on the use of a novel self-expandable stent for treatment of STEMI.*

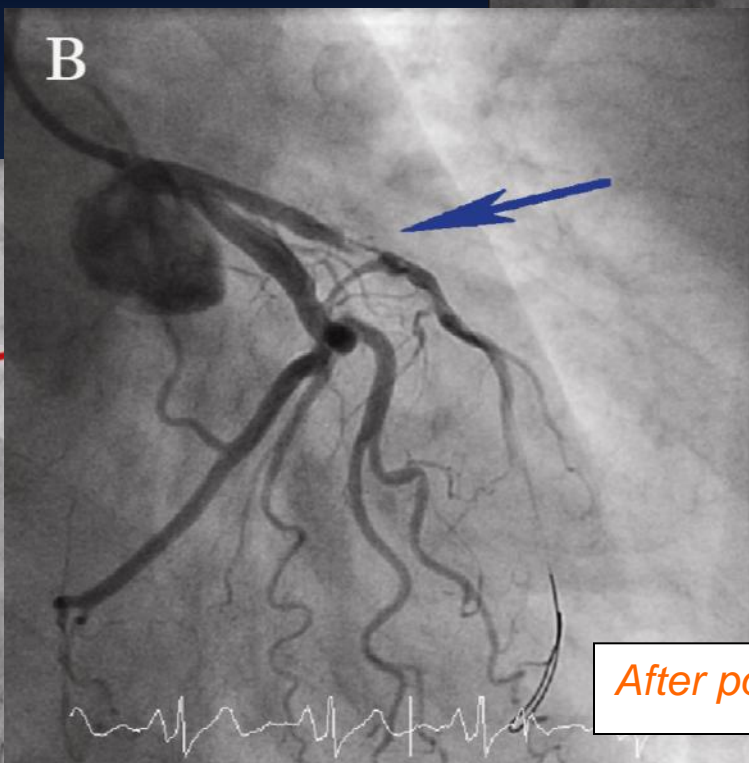
Catheter Cardiovasc Interv. 74:6, pp 850–854, 15/11/2009

Angiographic Images

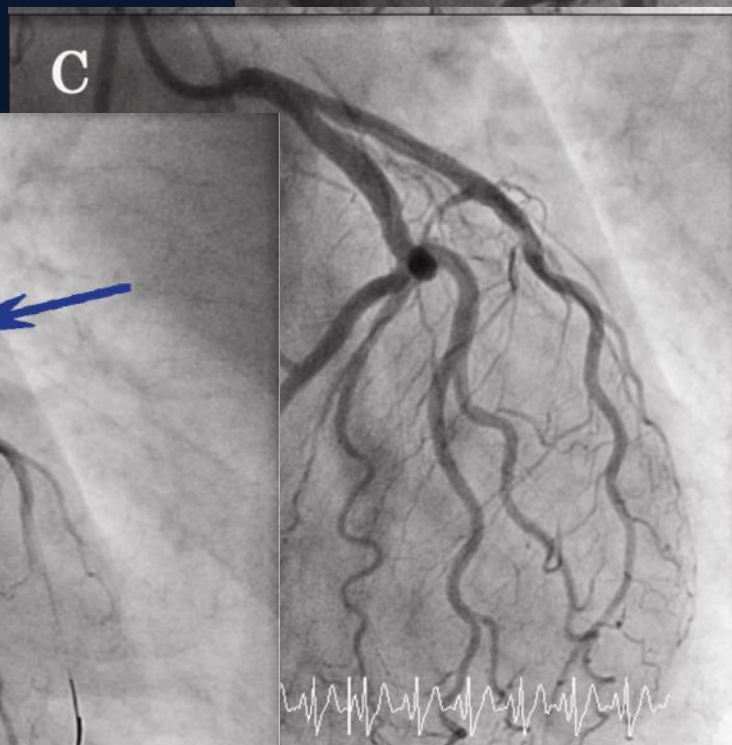


T

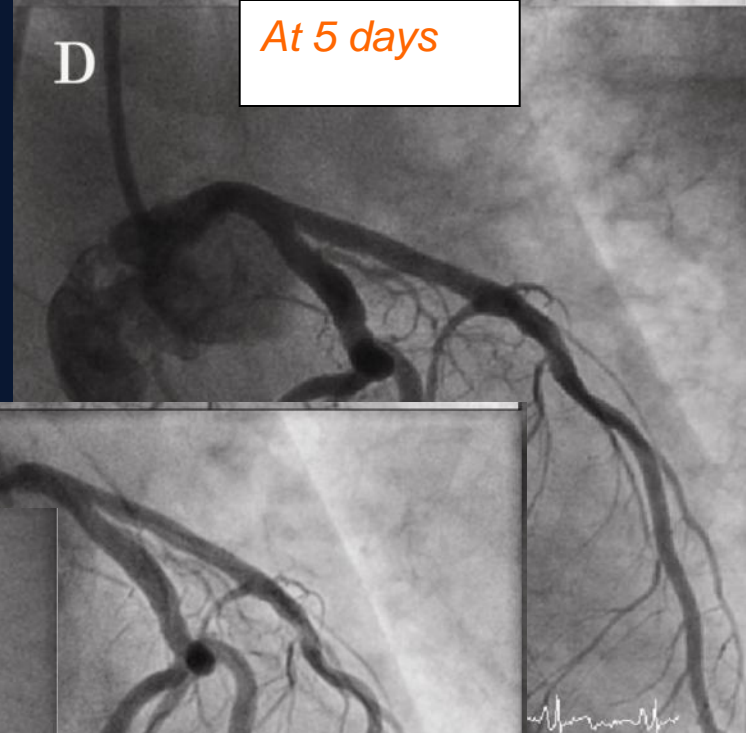
Occluded LAD



After wiring

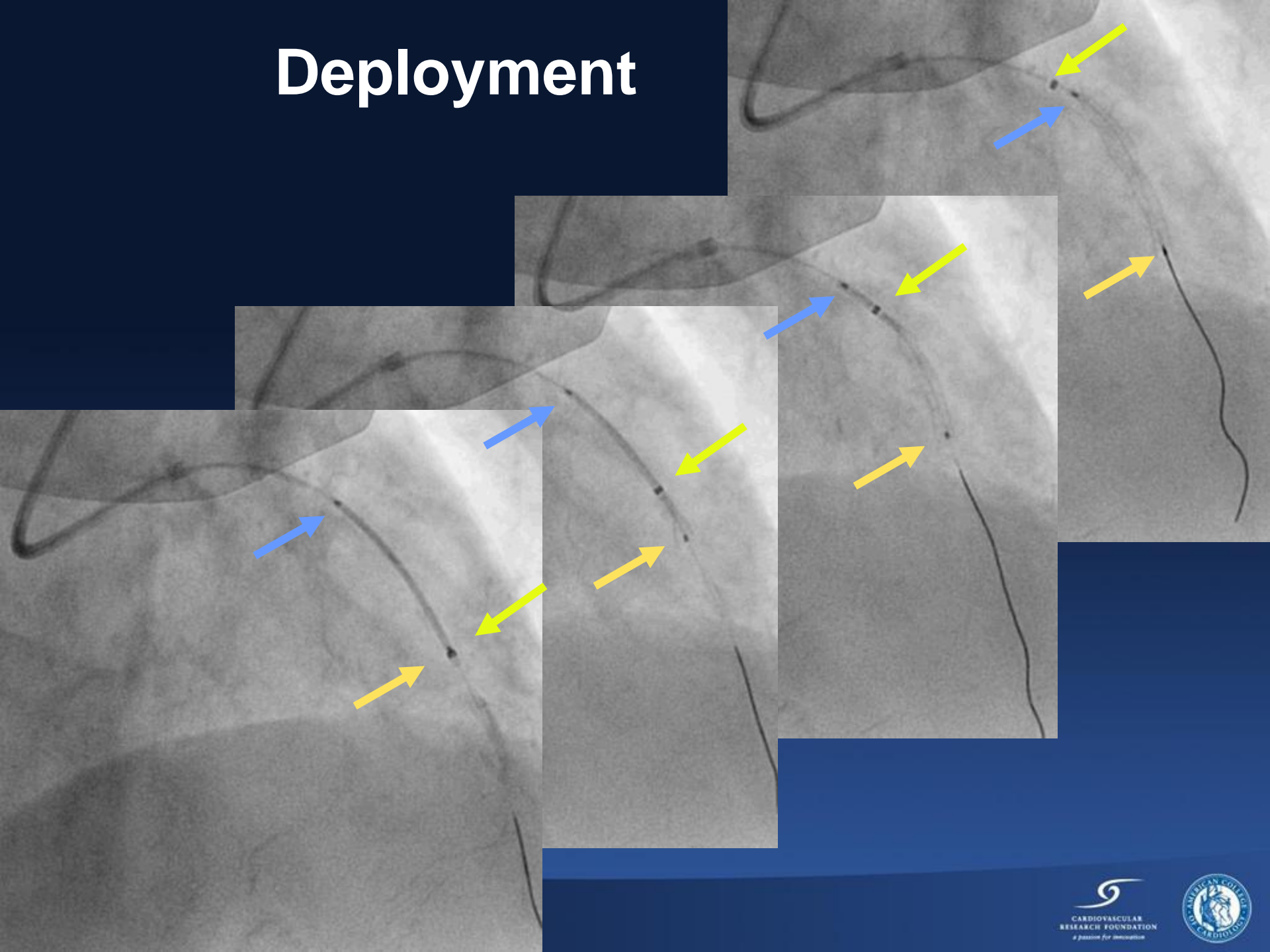


After postdilatation

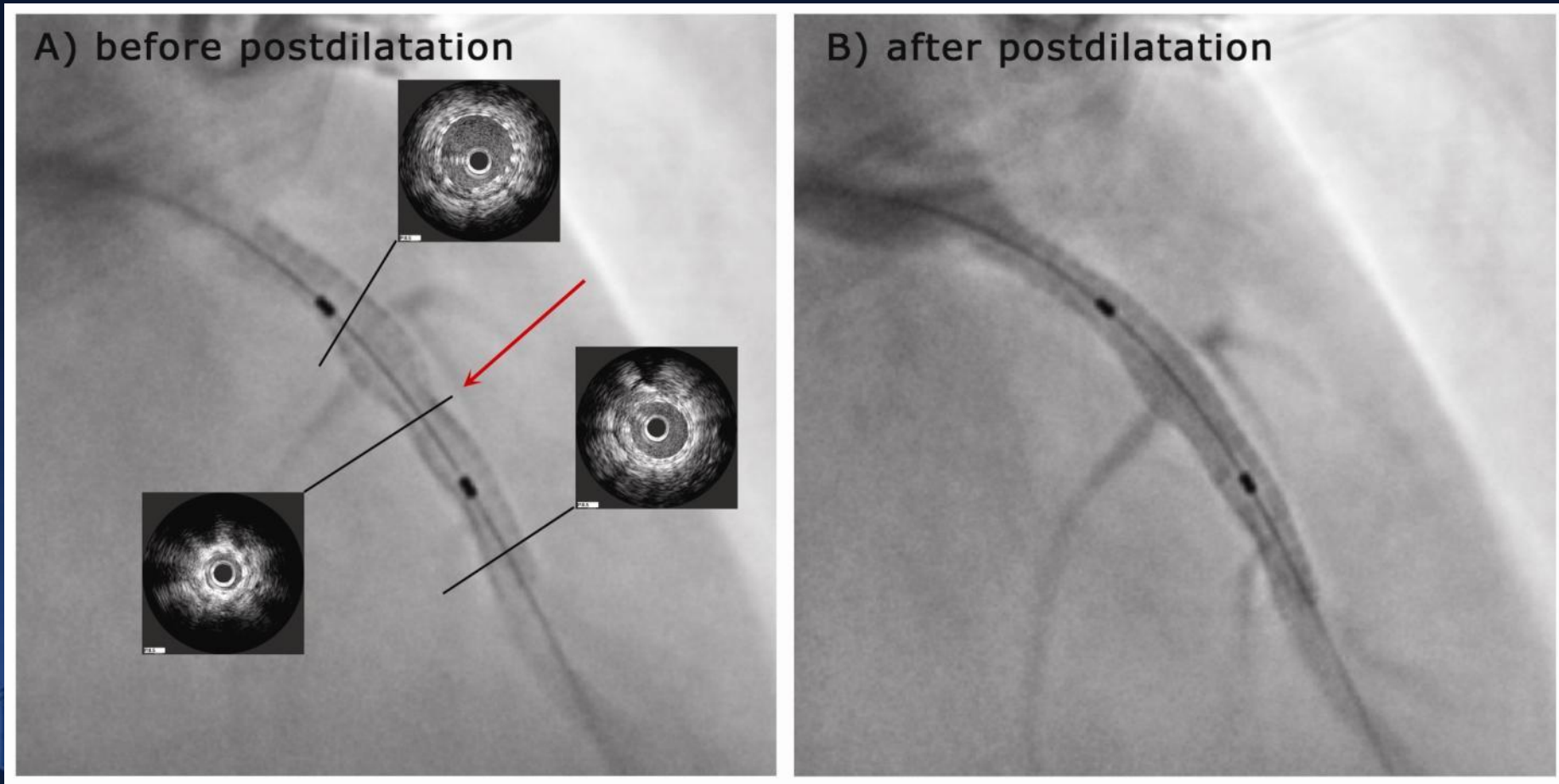


At 5 days

Deployment



Postdilatation guided by Stentboost/ IVUS

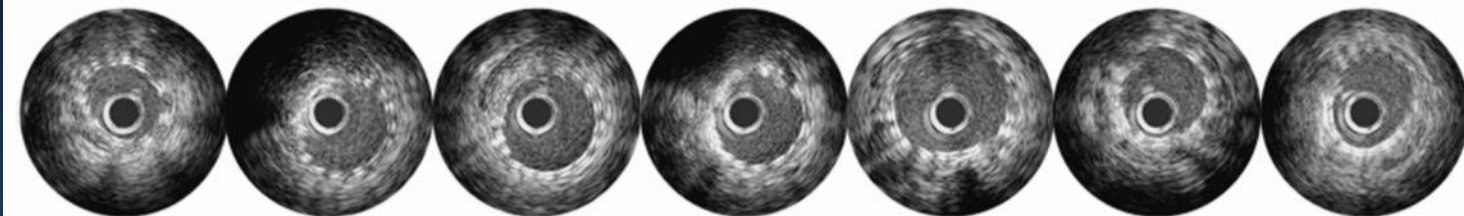


Max 355U/l, Patient discharged event-free at 6d

Intravascular Ultrasound

	Proximal	Distal	Lumen area	Vessel area
Day 0	3,7 mm	2,4 mm	10,3 mm ²	16,1 mm ²
Day 5	4,0 mm	2,9 mm	11,3 mm ²	17,5 mm ²

After post dilatation



APPOSITION I Study Design

Design

DESIGN

Prospective, non-randomized, single-arm, multi-center feasibility study

OBJECTIVE

To evaluate safety & efficacy of the STENTYS[®] Stent in AMI

ENDPOINTS

- Stent apposition & expansion at 3 days
- MACE at discharge & 6 month

Independent monitoring: MedPass

Core Lab: Cardialysis

Statistical analysis: INSERM U970 (Paris);

Prof. J.P. Tijssen (Amsterdam)

25 pts enrolled between March 2009 and Oct. 2009 in 5 European clinical sites

25 pts with STENTYS[®] stent (BMS)

IVUS at 0 and 3 days

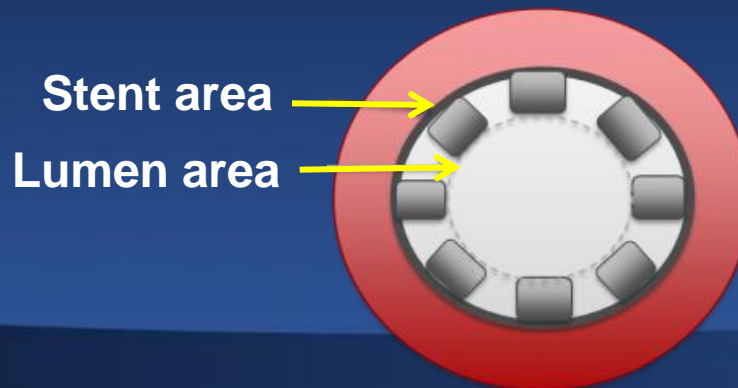
Clinical follow-up at 30 days

Angiographic and IVUS follow-up at 6 months

IVUS at baseline & 3 days (paired; N=16)

	Baseline	3 day	Δ	p
Mean Reference Area (mm²)				
Proximal	7.80 \pm 2.33	8.21 \pm 2.33	5%	NS
Distal	6.24 \pm 2.05	7.41 \pm 3.22	19%	p<0.02
Mean Lumen Area (mm²)	7.55 \pm 1.92	8.96 \pm 2.27	17%	p<0.001
Mean Stent Area (mm²)	7.60 \pm 1.90	9.13 \pm 2.41	18%	p<0.001
Minimum Lumen Area (mm²)	5.19 \pm 1.52	6.25 \pm 1.61	19%	p=0.001

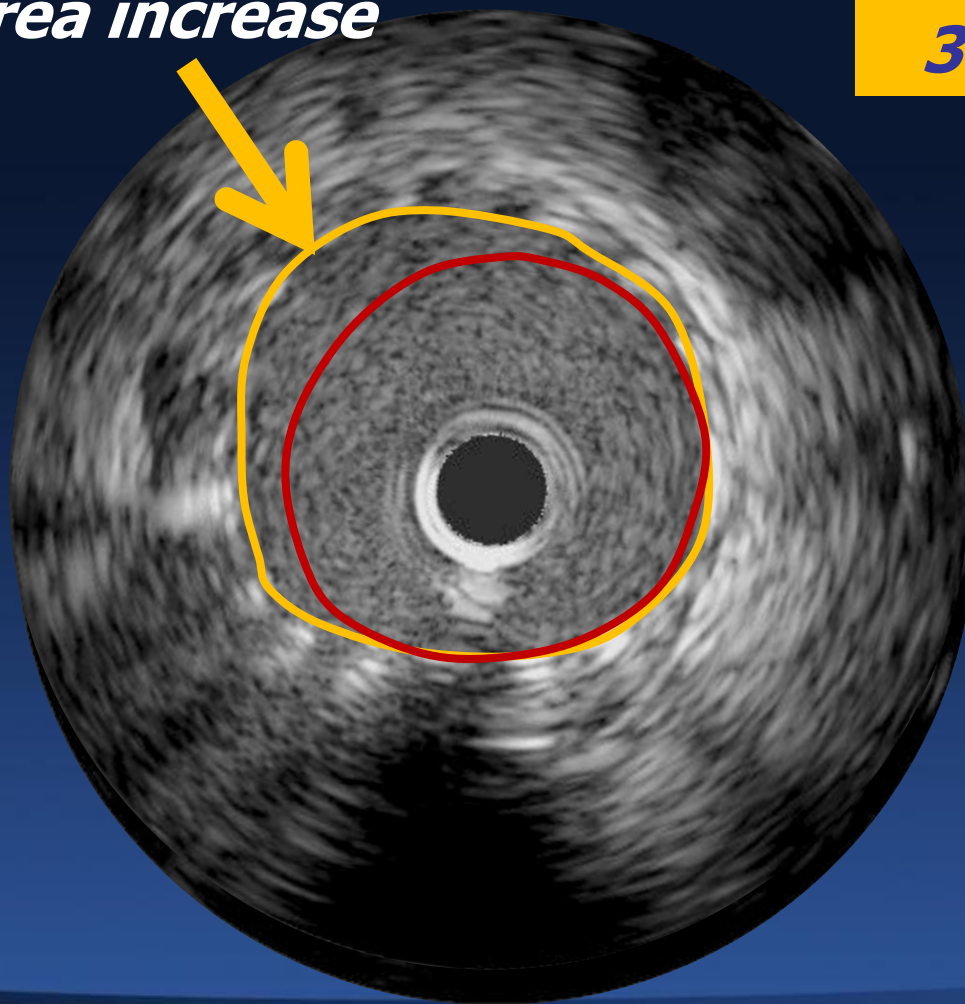
Minimum Lumen Area increase: 19%



17% mean lumen area increase

At implantation

3 day follow-up



APPOSITION I (n=25)

Clinical outcome up to 12 months

	30 days	12 months
Cardiac death	0	0
Re-MI	0	0
Clinically driven TLR	0	4
Stent thrombosis	0	0
Total MACE	0	4 (16%)

APPOSITION II Study Design

Design

DESIGN Prospective, randomized, two-arm multi-center study

OBJECTIVE

To compare the STENTYS® BMS with a balloon-expandable stent in AMI

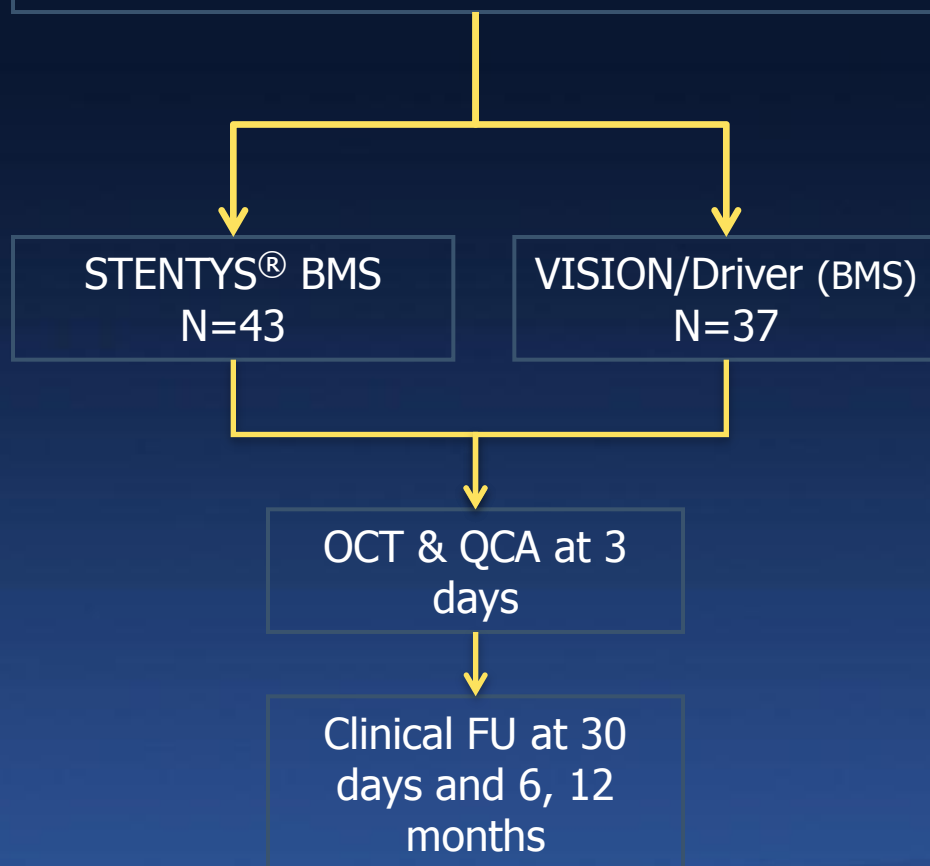
ENDPOINTS

- Stent strut apposition & expansion at 3 days
- MACE at 30 days and 6 months

Independent monitoring: Genae

Core Lab: Cardialysis

80 STEMI patients enrolled between Dec 2009 and June 2010 in 9 European clinical sites



Patient Characteristics

	STENTYS n=43	Control n=37	P Value
Age (mean)	61.7	59.3	NS
Male (%)	81.4	78.4	NS
Diabetes mellitus (%)	16.3	13.5	NS
Hypertension (%)	44.2	51.4	NS
Hypercholesterolemia (%)	44.2	51.4	NS
Smoking (current/previous)(%)	74.4	75.9	NS
Previous MI (%)	0.0	0.0	NA
Previous PCI (%)	0.0	0.0	NA
Target vessel LAD/LCX/RCA (%)	44 / 12 / 44	32 / 16 / 52	NS
Mean AMI time (hrs:min)	3:41	4:14	NS

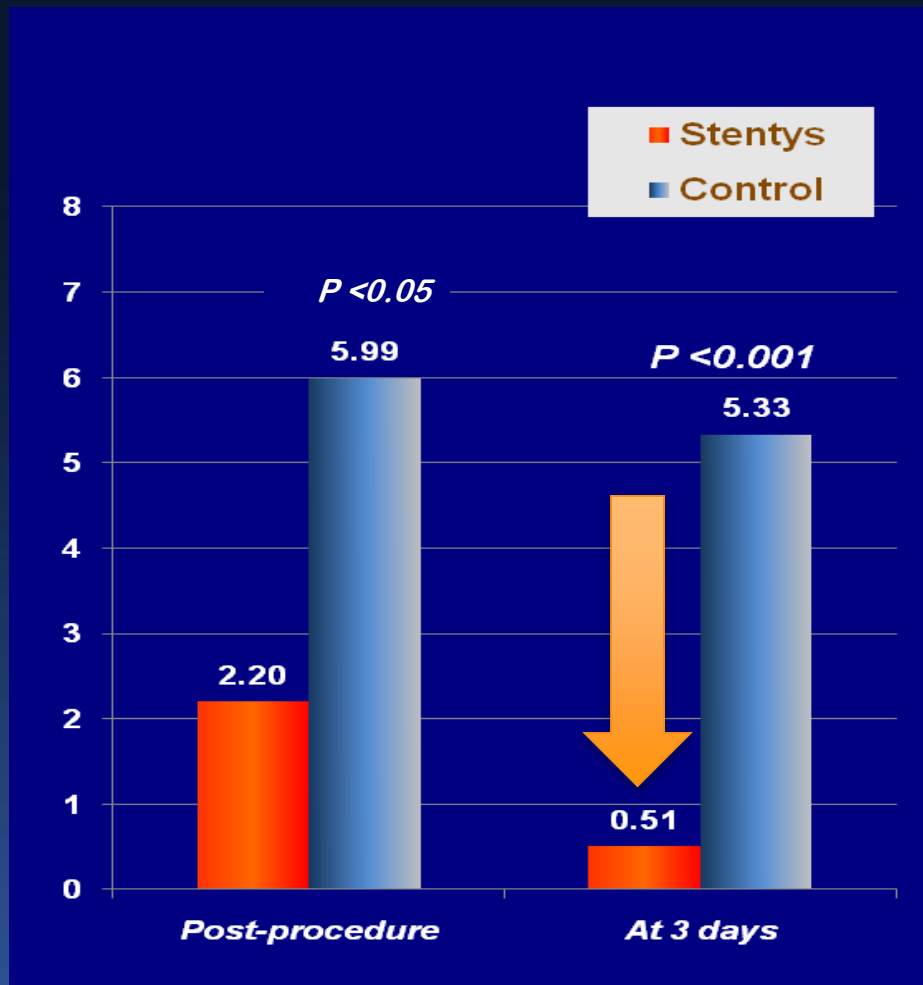
Optical Coherence Tomography

	STENTYS n=40	Control n=36	P Value
Post-PCI			
Mean Lumen area (mm ²)	7.88 ± 2.32	8.92 ± 2.22	NS
Mean Stent area (mm ²)	7.57 ± 2.29	8.95 ± 2.38	NS
Stent volume (mm ³)	191 ± 65	210 ± 83	NS
3 day follow-up			
Mean Lumen area (mm ²)	8.99 ± 2.39	8.81 ± 2.18	NS
Mean Stent area (mm ²)	9.02 ± 2.36	8.76 ± 2.26	NS
Stent volume (mm ³)	228 ± 72	206 ± 86	NS

14% increase

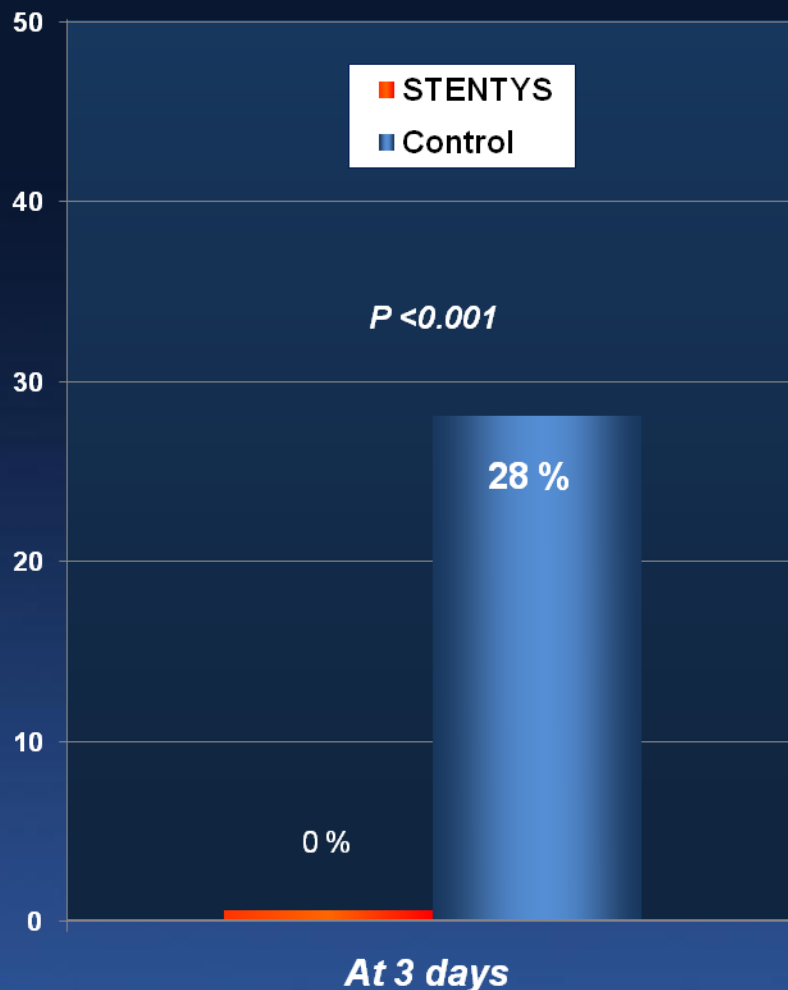
APPOSITION II

Stent strut malapposition at 3 days



APPOSITION II

Patients with malapposition* at 3 days

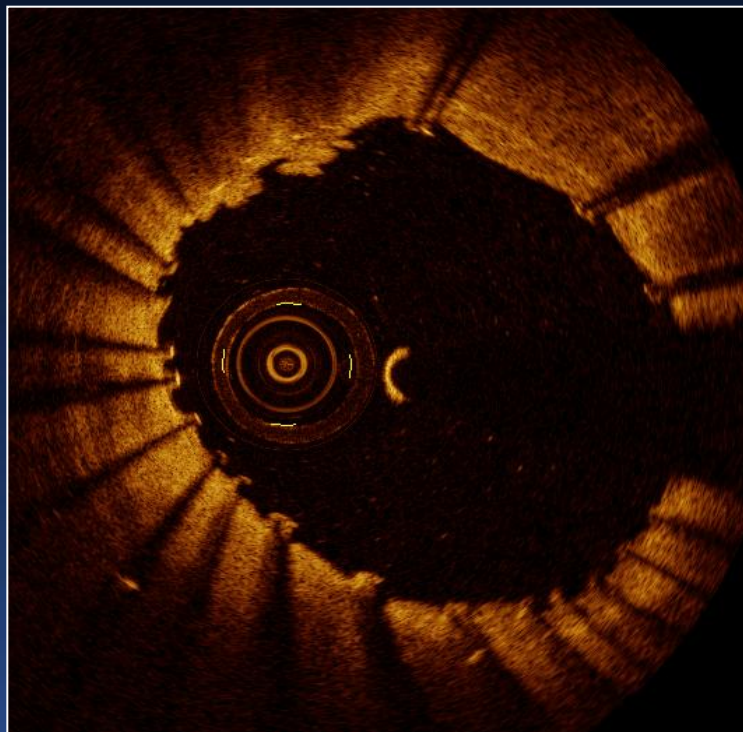


* $\geq 5\%$ malapposed struts

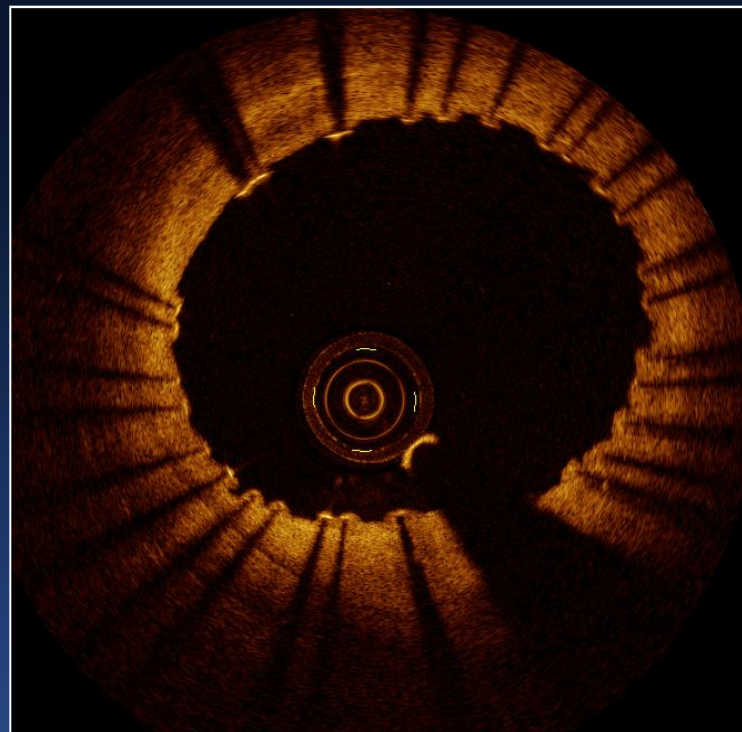
* Barlis P., Eur Heart J 2010
van Geuns R.J., & Verheye S., TCT 2010

STENTYS[®] BMS Stent

Day 0

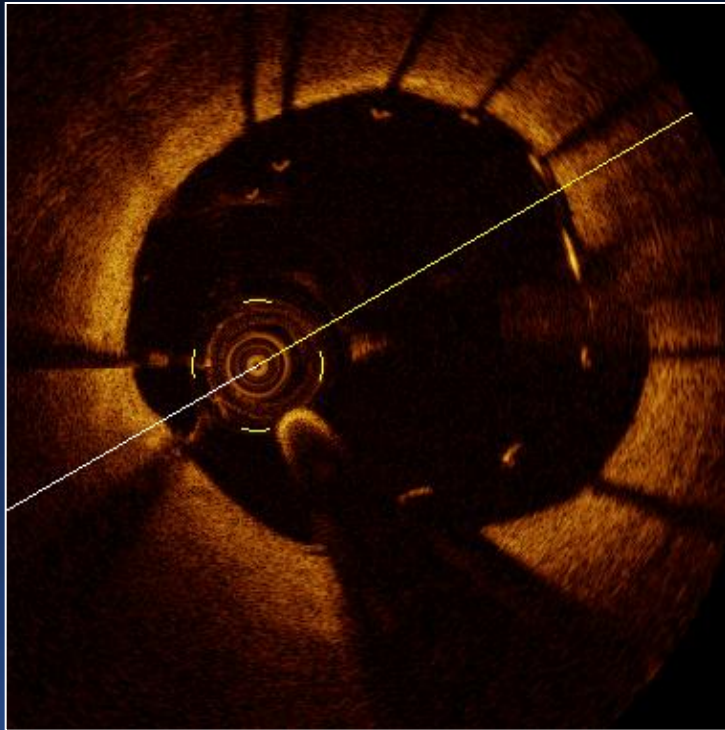


Day 3

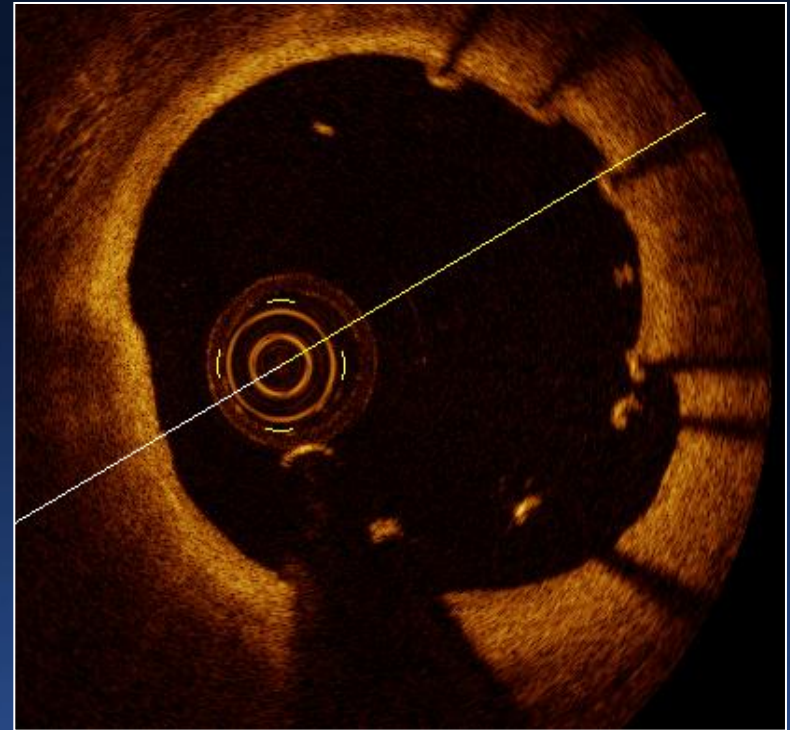


Balloon-expandable stent

Day 0



Day 3



APPOSITION II

Clinical outcome at 12 months

	STENTYS (n=43)
Cardiac Death	0
Re-Myocardial Infarction	0
Emergent Bypass Surgery	0
Clinically driven TLR	2
Stent thrombosis	0
Total MACE	2 (4.7%)

STENTYS BMS stent (N=68)

Combined clinical outcome at 12 months

Cardiac Death	0
Re-Myocardial Infarction	0
Emergent Bypass Surgery	0
Clinically-driven TLR	6
Stent thrombosis	0
Total MACE	6 (8.8%)

Conclusions

- APPOSITION I showed that vasodilation following PPCI can represent a 19% increase of vessel area
- APPOSITION II showed that 28% of balloon-expandable stents are malapposed and that the STENTYS stent eliminates malapposition (0% at 3 days)
- At 12 months, clinical results show a good efficacy of the STENTYS BMS
- APPOSITION III will evaluate the clinical benefits of improved stent apposition and sizing