

# APPOSITION II study results

**Stefan Verheye, MD, PhD**

*Antwerp Cardiovascular Center  
ZNA Middelheim, Antwerp, Belgium*

On behalf of the  
**APPOSITION II Investigators**

# APPOSITION II

## Study Objective

Compare safety and efficacy of the STENTYS® self-expanding stent with balloon-expandable stents in the treatment of STEMI patients

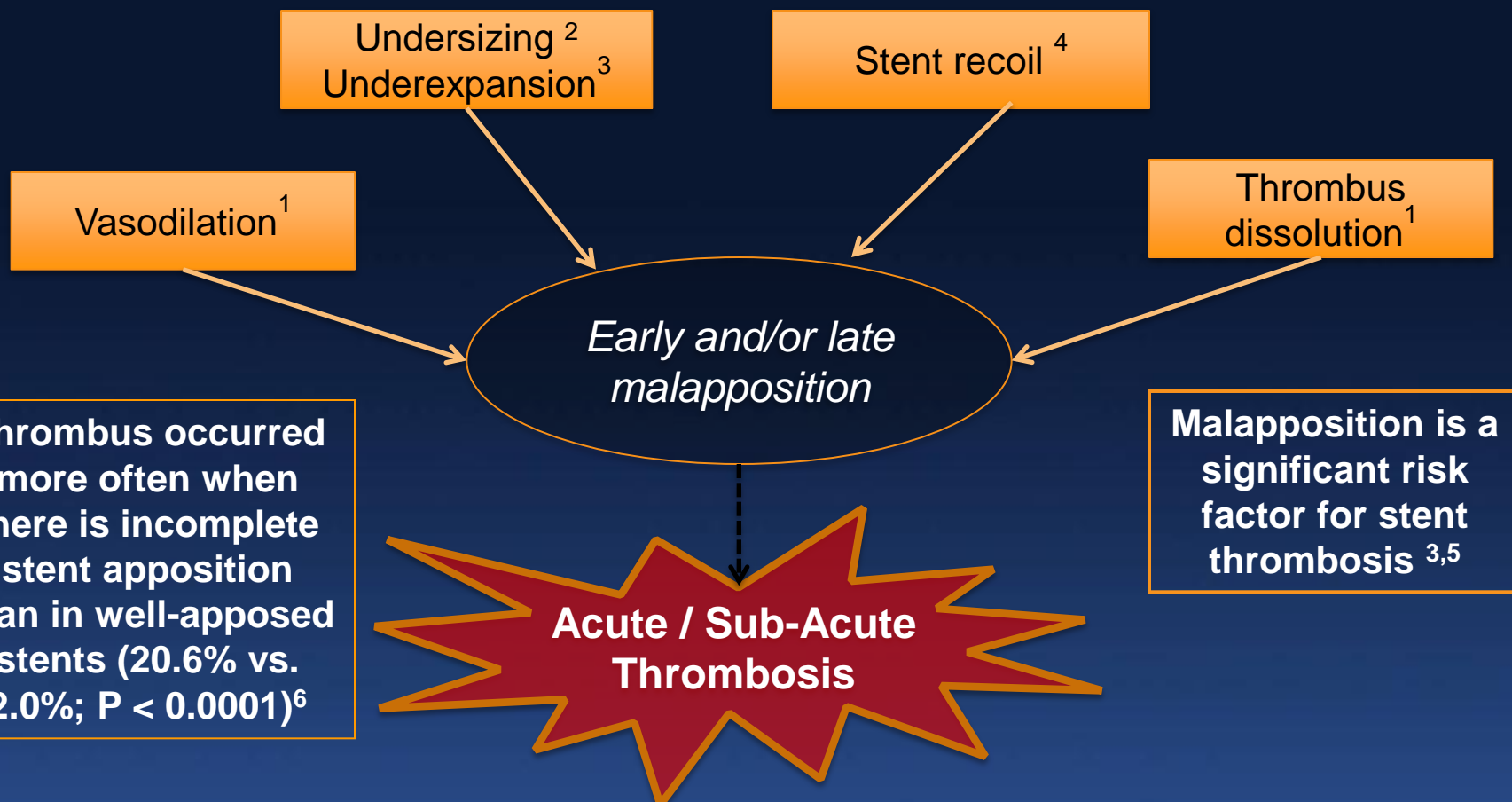
## Study Hypothesis

Self-expanding stents provide better stent apposition than balloon-expandable stents

## Primary Endpoint

Stent strut malapposition at 3 days measured by OCT

# Current issues in PCI for ACS



1. C. Spaulding, "Clinical Application of a Novel Self-expanding Coronary Stent in AMI" *European Cardiology* 2009;5(2):71-73
2. Van Werkum J.W. "Predictors of Coronary Stent Thrombosis" *JACC* 2009 53:16:399-409
3. Stéphane Cook and Stephan Windecker, *Circulation* 2009;119:657-659
4. Stéphane Cook, *Circulation* 2007;115:2426-2434
5. Renu Virmani, MD, of CVPPath Institute (Gaithersburg, MD) in a telephone interview with TCTMD
6. Ozaki Y, Okumura M, Ismail TF, et al. The fate of incomplete stent apposition with drug-eluting stents: An optical coherence tomography-based natural history study. *Eur Heart J.* 2010; (31), 1470-1476

# Challenges in treating STEMI patients

## Results from HORIZONS Trial<sup>4</sup> – BMS arm

MACE <sup>1</sup>	11.2%
Mortality risk <sup>2</sup>	5.2%
Stent thrombosis <sup>3</sup>	
30 days	2.7%
2 years	4.1%
Malapposition IVUS sub study	35.2%

1. Death, stroke, reinfarction or stent thrombosis for bare arm at 2yrs in Horizons, TCT 2009

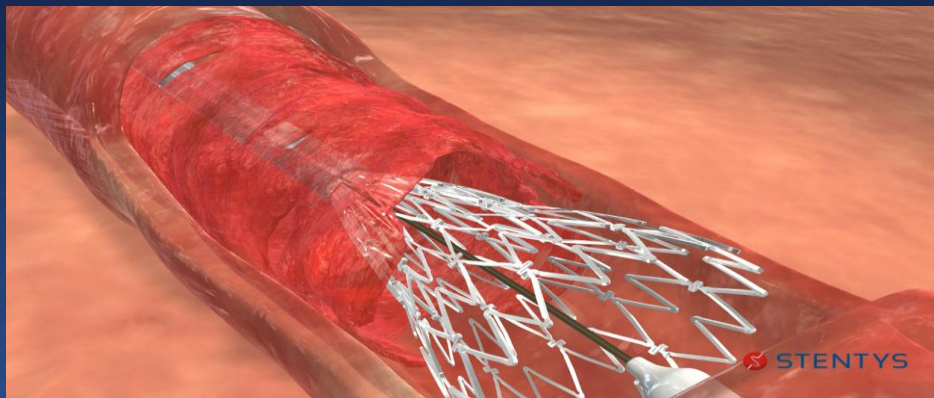
2. All-cause mortality for bare arm at 2 years in Horizons, TCT 2009

3. BMS Stent Thrombosis. Horizons Trial TCT 2008.

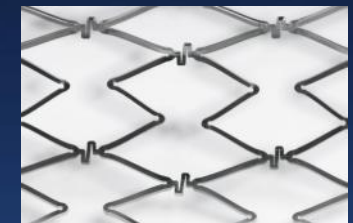
4. Stone GW et al. Paclitaxel-eluting bare metal stents in AMI; NEJM 2009;360:1946-1959

# STENTYS Technology

- Nitinol, self-apposing stent (BMS and DES)
- 6F single-wire, rapid exchange
- Disconnectable struts over full length\* for easy access to side branches



Deployment of STENTYS stent



↑ ↑ ↑  
Disconnectors  
along the stent

\* Except the first and last 2 rows of the stent

# APPOSITION II

## DESIGN

Prospective, randomized, two-arm multicenter study

## OBJECTIVE

To compare the STENTYS<sup>®</sup> Stent with a balloon-expandable stent in AMI

## HYPOTHESIS

Superior apposition with self-expanding stent compared to balloon-expandable stent

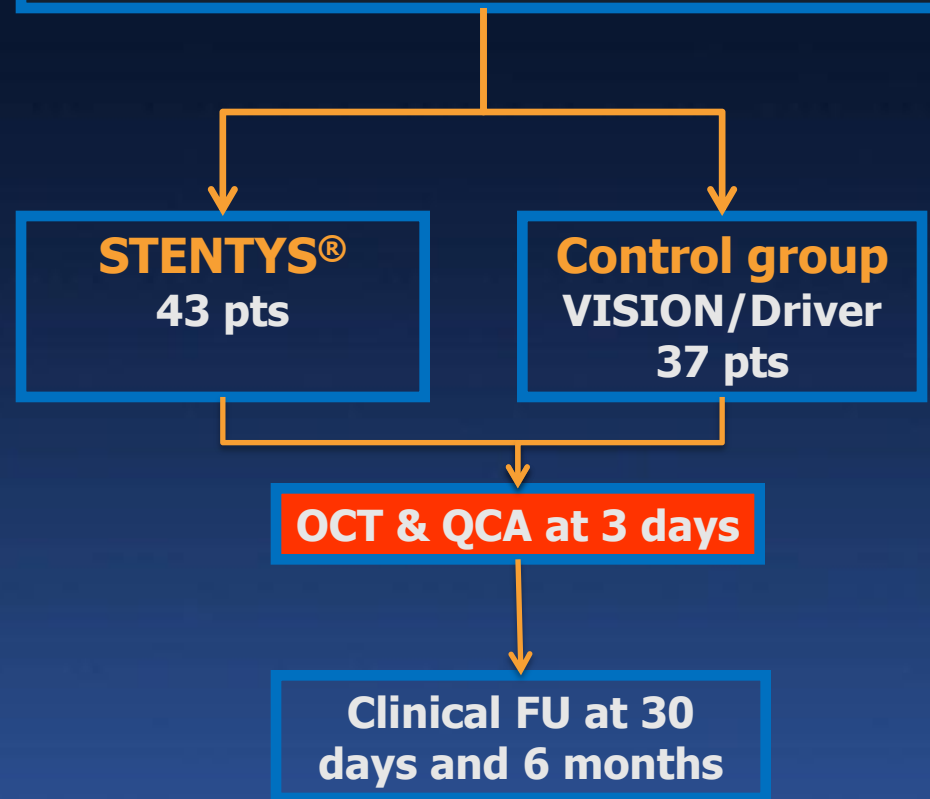
## PRIMARY ENDPOINT

Stent strut apposition at 3 days by OCT

## STUDY ORGANIZATION

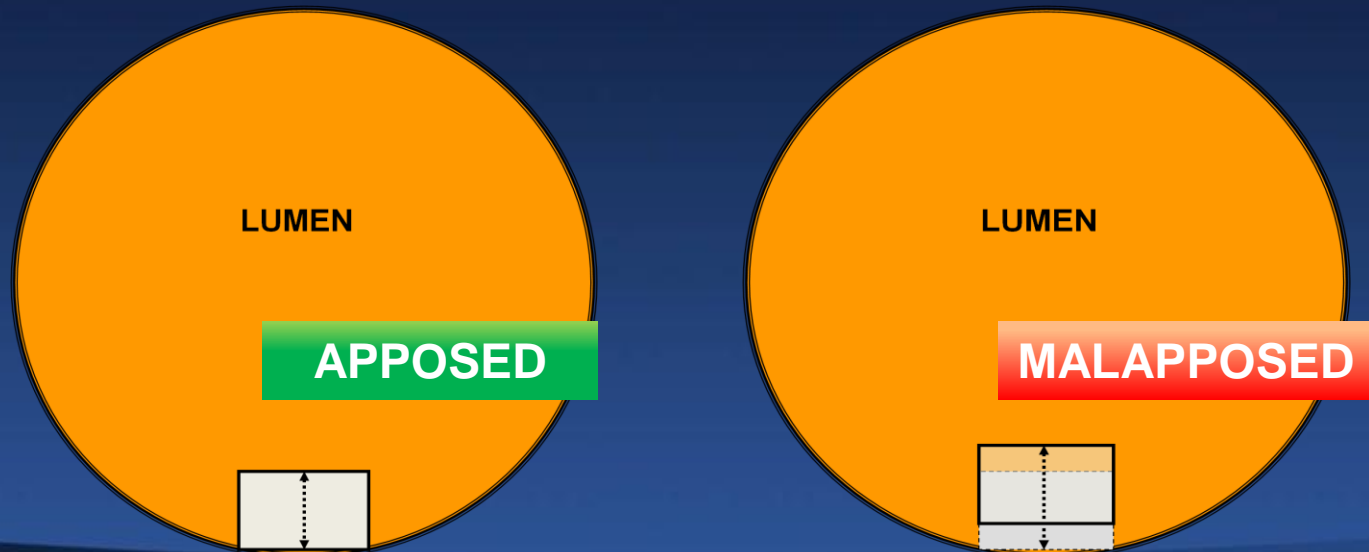
CEC, DSMB, Core Lab, Independent monitoring

**80 STEMI patients  
randomized**  
between December 2009 and June 2010  
in 9 European clinical sites



# OCT methodology

- C7 XR LightLab Imaging
- Analysis by an independent Core lab (Cardialysis)
- Analyzed region: stented segment plus 5 mm proximal and distal
- Lumen and stent area were measured at 1 mm intervals
- Malapposition defined as the distance between the leading edge of the strut and the leading edge of the contour bigger than the strut thickness



# Study sites (n=9)

Investigator	Centre	Patients
C. Tamburino	Catania, Italy	19
J. Fajadet	Toulouse, France	11
M. Vrolix	Genk, Belgium	9
B. Witzenbichler	Berlin, Germany	9
E. Eeckhout	Lausanne, Switzerland	8
R-J. van Geuns	Rotterdam, The Netherlands	7
C. Spaulding	Paris, France	7
S. Verheye	Antwerp, Belgium	6
K. Reczuch	Wroclaw, Poland	4
	<b>TOTAL</b>	<b>80</b>

# Patient Characteristics

	<b>STENTYS N=43</b>	<b>Control N=37</b>	<b>P Value</b>
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

# Procedural data

	<b>STENTYS N=43</b>	<b>Control N=37</b>	<b>P Value</b>
<b>Stents used</b>	<b>1.1</b>	<b>1.2</b>	<b>NS</b>
<b>Device success (%)</b>	<b>97.6%<sup>1</sup></b>	<b>100%</b>	<b>NS</b>
<b>Procedure success (%)</b>	<b>97.6%</b>	<b>100%</b>	<b>NS</b>
<b>Thrombectomy device used (%)</b>	<b>72.1</b>	<b>83.8</b>	<b>NS</b>

<sup>1</sup>One patient >30% residual stenosis after stent placement; residual stenosis was <30% at 3 day follow-up

# Pre- and Post-dilatation

	<b>STENTYS N=43</b>	<b>Control N=37</b>	<b>P Value</b>
<b>Pre- dilatation</b>	<b>60%</b>	<b>40%</b>	<b>0.075</b>
Mean pressure (atm)	12.7	13.2	NS
<b>Deployment</b>	<b>0%</b>	<b>100%</b>	<b>&lt; 0.001</b>
Mean pressure (atm)	0	14.7	< 0.001
<b>Post- dilatation</b>	<b>63%</b>	<b>24%</b>	<b>&lt; 0.001</b>
Mean pressure (atm)	14.7	16.4	NS
<b>Diameter largest balloon (mm)</b>	<b>2.78</b>	<b>3.32</b>	<b>0.014</b>
<b>At least one balloon inflation</b>	<b>93%</b>	<b>100%</b>	<b>NS</b>

# Quantitative Coronary Angiography

	Stentys N=42	Control N=40	P Value
<b>Pre-PCI</b>			
Lesion length (mm)	13.10 ± 10.12	13.97 ± 4.99	NS
RVD (mm)	2.82 ± 0.51	2.92 ± 0.42	NS
MLD (mm)	0.42 ± 0.55	0.47 ± 0.57	NS
Total Occlusion (%)	58	55	NS
<b>Post-PCI</b>			
MLD (mm)	2.44 ± 0.44	2.70 ± 0.41	NS
TIMI 2/3	100%	100%	NA
<b>3 days follow-up</b>			
In-stent lumen loss	-0.11 ± 0.29	0.04 ± 0.21	0.01

# Optical Coherence Tomography

## Post-PCI

Mean Lumen area (mm<sup>2</sup>)

Mean Stent area (mm<sup>2</sup>)

Stent volume (mm<sup>3</sup>)

## 3 days follow-up

Mean Lumen area (mm<sup>2</sup>)

Mean Stent area (mm<sup>2</sup>)

Stent volume (mm<sup>3</sup>)

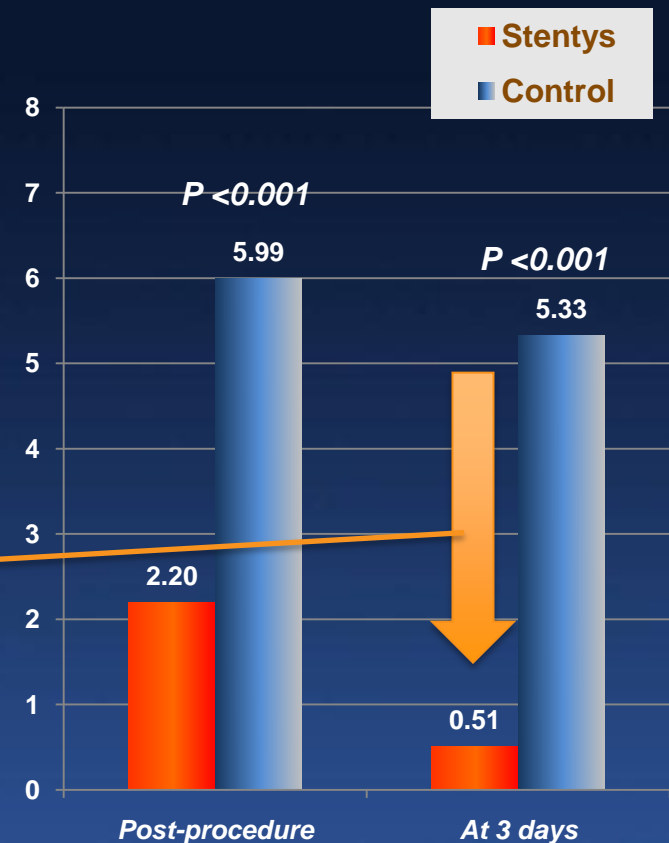
	Stentys N=40	Control N=36	P Value
Mean Lumen area (mm <sup>2</sup> )	7.88 ± 2.32	8.92 ± 2.22	NS
Mean Stent area (mm <sup>2</sup> )	7.57 ± 2.29	8.95 ± 2.38	NS
Stent volume (mm <sup>3</sup> )	191 ± 65	210 ± 83	NS
Mean Lumen area (mm <sup>2</sup> )	8.99 ± 2.39	8.81 ± 2.18	NS
Mean Stent area (mm <sup>2</sup> )	9.02 ± 2.36	8.76 ± 2.26	NS
Stent volume (mm <sup>3</sup> )	228 ± 72	206 ± 86	NS

# Primary study endpoint

## Stent strut malapposition at 3 days

	<b>STENTYS</b> n = 40	<b>Control</b> n = 36	<b>P</b> <b>Value</b>
<b>Post PCI</b>	<b>2.20%</b>	<b>5.99%</b>	<b>&lt;0.05</b>
<b>3 days</b>	<b>0.51%</b>	<b>5.33%</b>	<b>&lt;0.001</b>

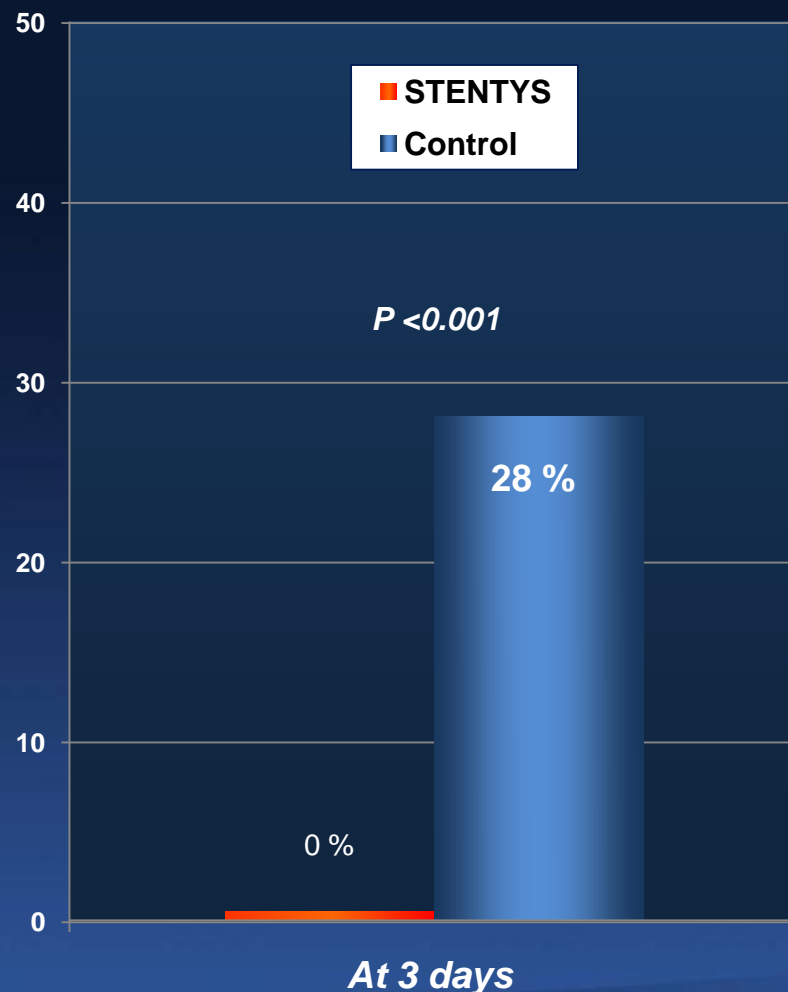
10-fold reduction in malapposition with STENTYS self-expanding stent



# Patients with malapposed stents

STENTYS n = 40	Control n = 36	P Value
0 %	28 %	<0.001

**Definition malapposed stent<sup>1</sup>:  
≥ 5% malapposed struts**



# Malapposition in a STEMI patient

Balloon-expandable stent



STENTYS<sup>®</sup> stent



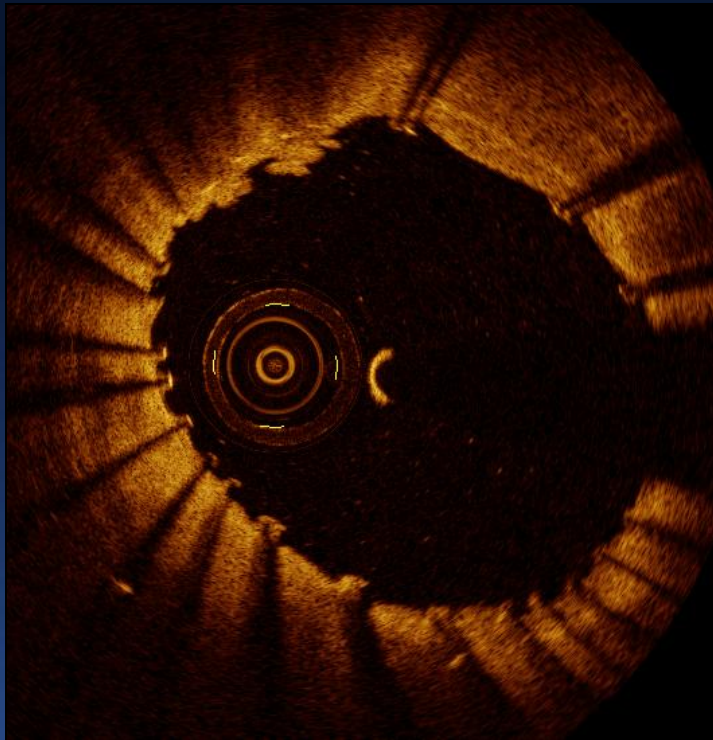
# Events at 30 days

	<b>STENTYS N=43</b>	<b>Control N=37</b>
<b>MACE<sup>1</sup> (%)</b>	<b>0</b>	<b>0</b>
<b>Cardiac death (%)</b>	<b>0</b>	<b>0</b>
<b>Re-MI (%)</b>	<b>0</b>	<b>0</b>
<b>CABG (%)</b>	<b>0</b>	<b>0</b>
<b>TLR (%)</b>	<b>0</b>	<b>0</b>
<b>Stent thrombosis (%)</b>	<b>0</b>	<b>0</b>

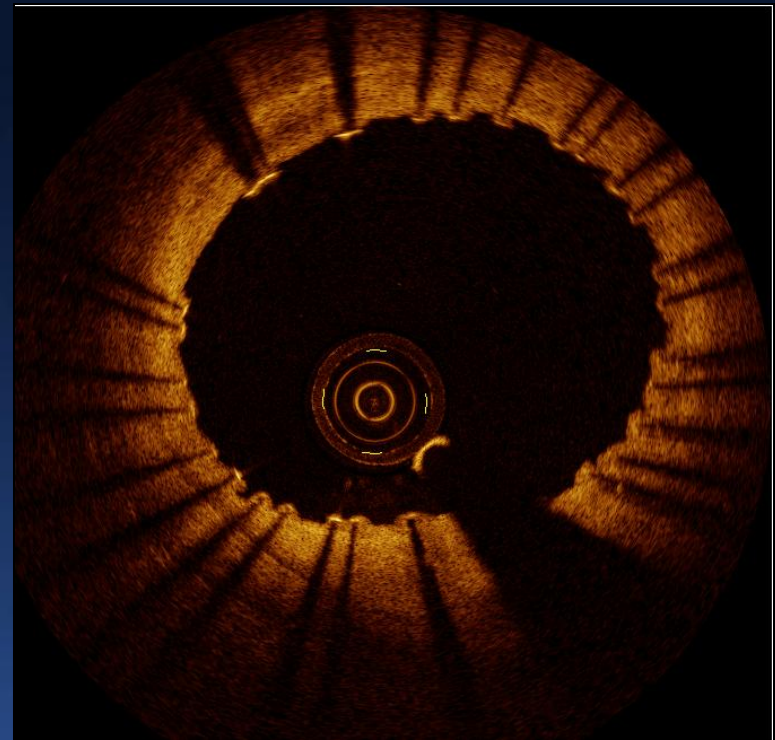
<sup>1</sup>MACE: cardiac death, re-MI, emergent bypass surgery (CABG), or clinically driven TLR

# STENTYS<sup>®</sup> Coronary Stent

Day 0

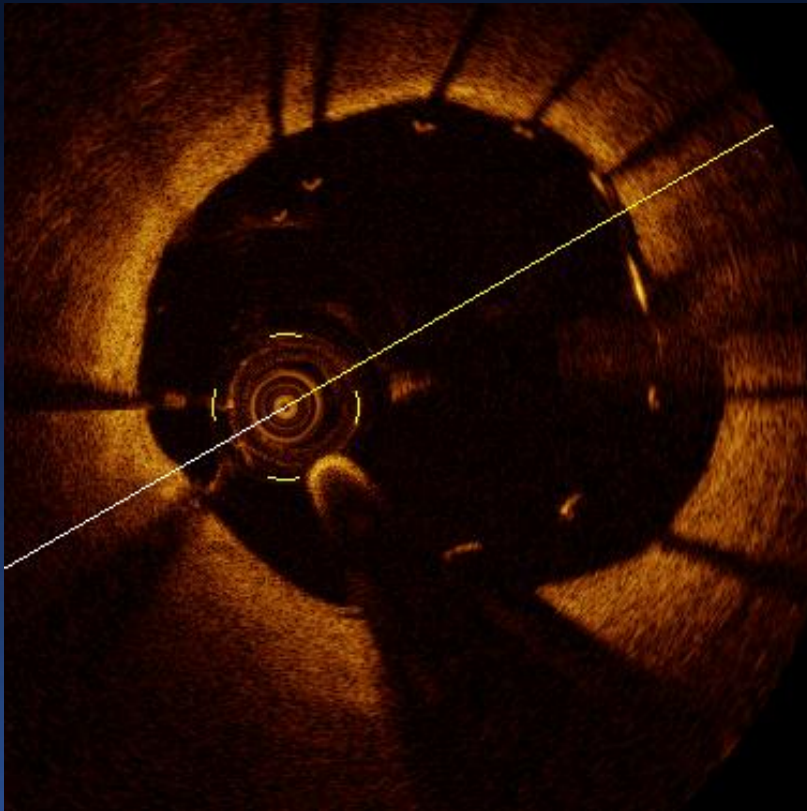


Day 3

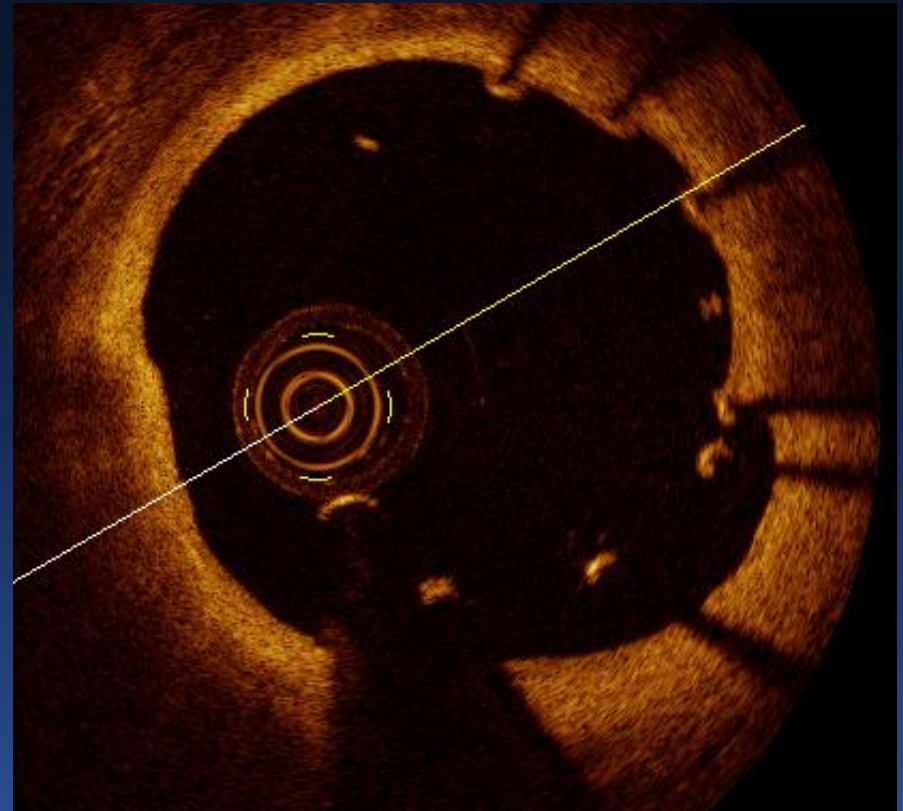


# Balloon-expandable stent (1)

Day 0

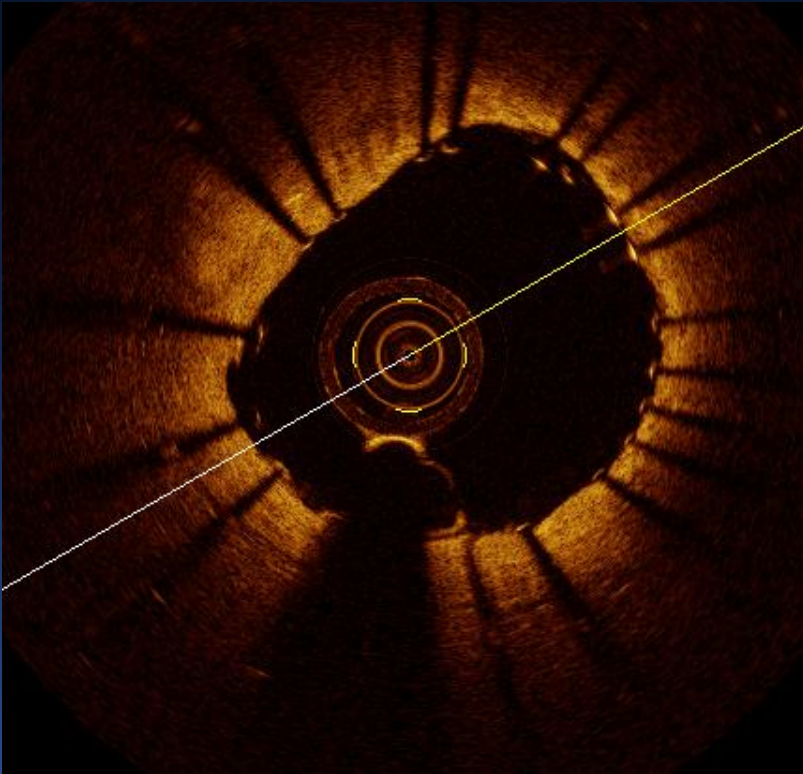


Day 3

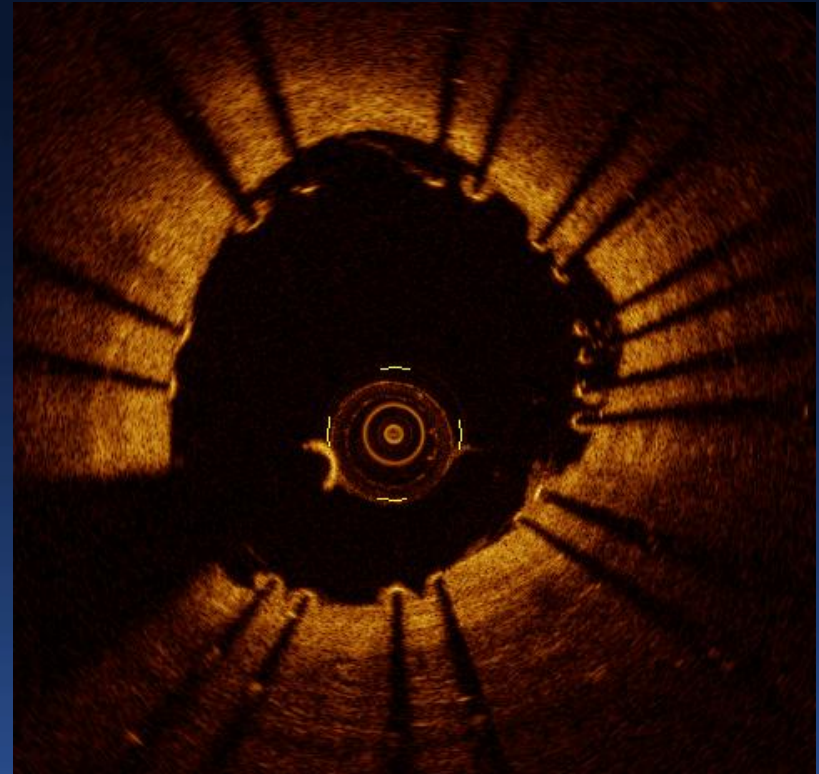


# Balloon-expandable stent (2)

Day 0

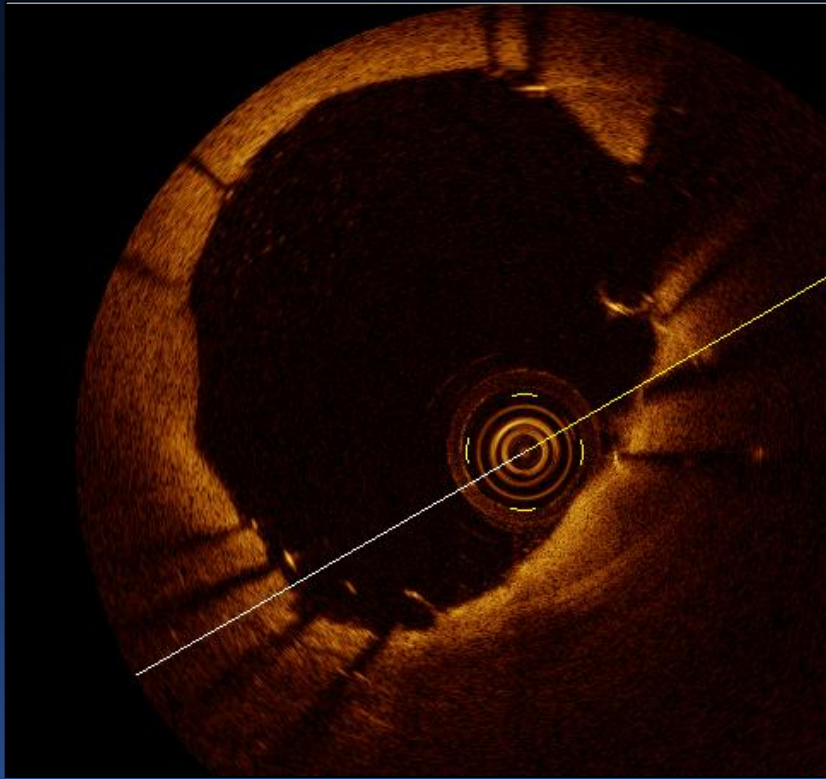


Day 3

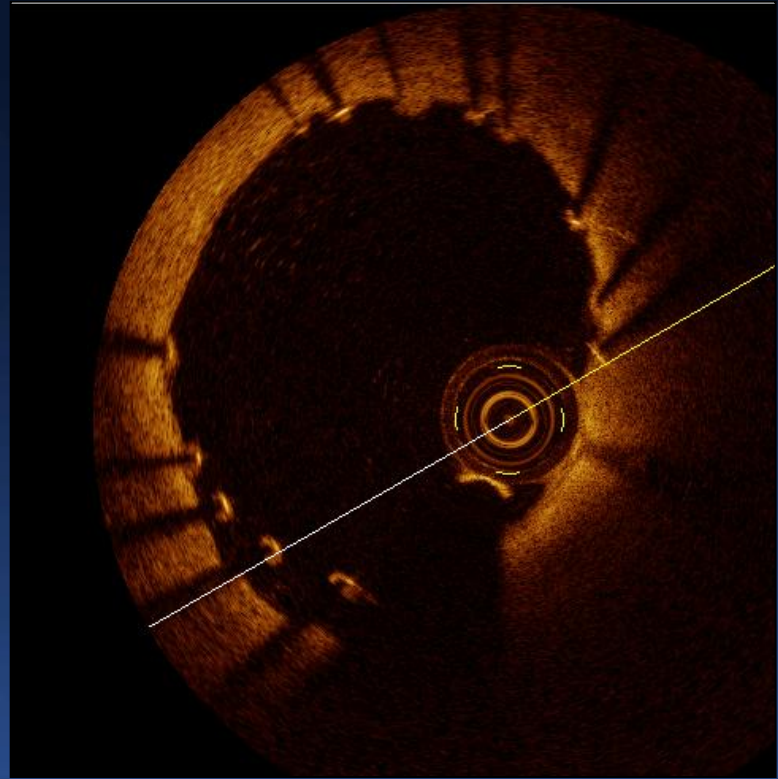


# Balloon-expandable stent (3)

Day 0



Day 3



# Conclusions

The **APPOSITION II** study shows that 0.51% of struts were malapposed in the STENTYS group vs. 5.33% in the balloon-expandable group at 3 days by OCT representing a 10-fold reduction

No STENTYS patients had malapposed stents; 28% of the balloon-expandable stents were malapposed

Further studies need to assess the clinical impact of improved early stent apposition