

# Stent coverage and malapposition assessed by OCT

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# Potential conflicts of interest

I have the following potential conflicts of interest to report:

**Consulting**

**Employment in industry**

**Stockholder of a healthcare company**

**Owner of a healthcare company**

**Other(s)**

I do not have any potential conflict of interest

# Traditional OCT image analysis

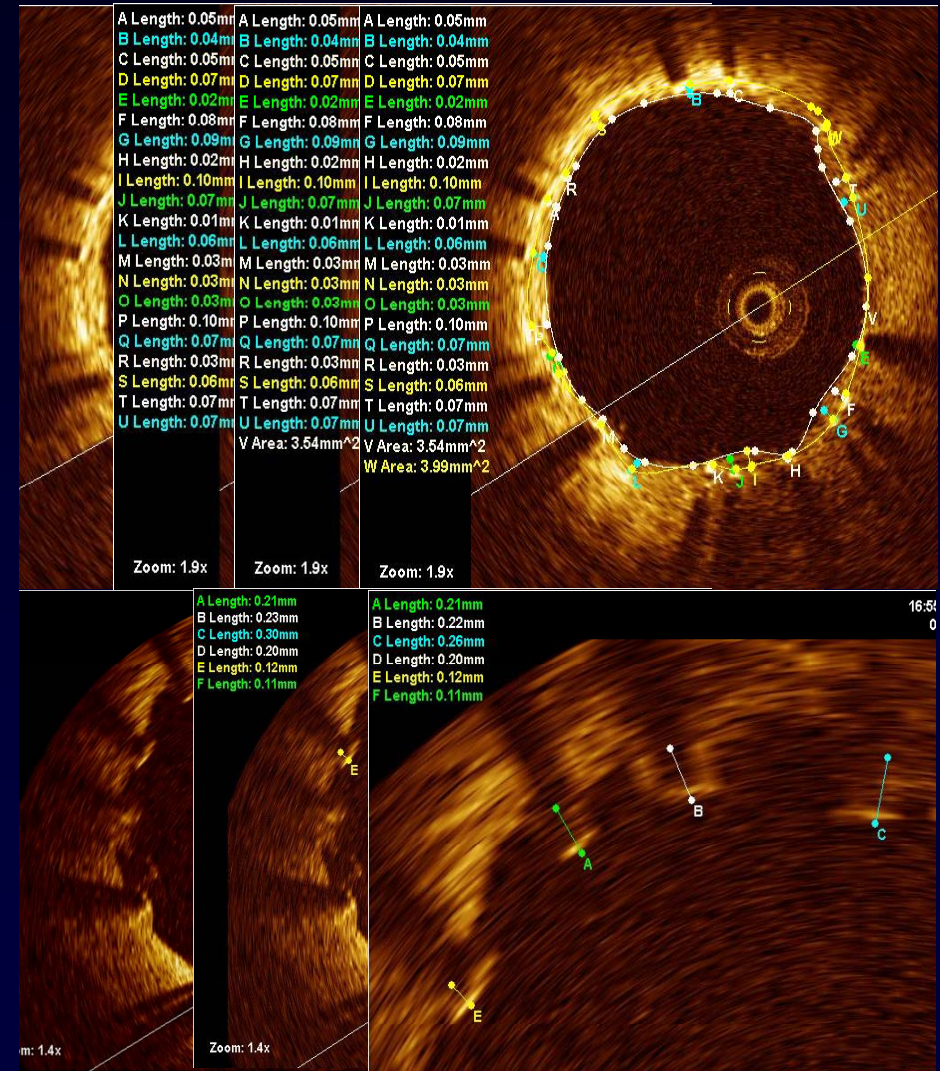
Analysis of cross-sectional OCT images at a 1-mm interval (every 15 frames).

## 1. Neointimal thickness

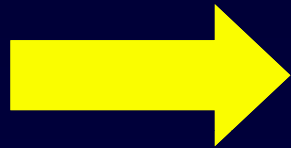
The distances between the endoluminal surface of neointimal and the strut reflection

## 2. Stent apposition

The distances between the endoluminal surface of the strut reflection and the vessel wall



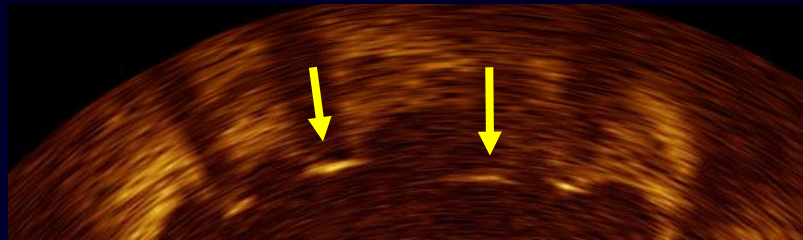
**What are the clinical implications of uncovered stent struts and stent malapposition by OCT ?**



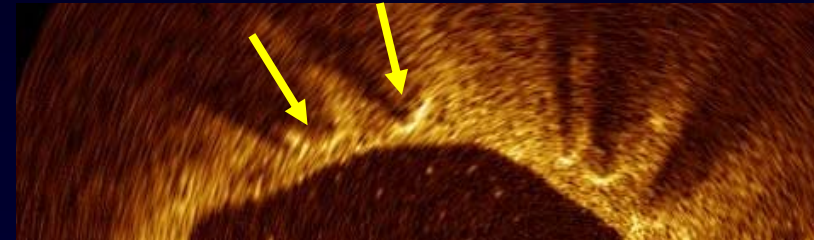
**So far, no definite clinical data, however.....**

# 9 months FU OCT - Cypher Stent

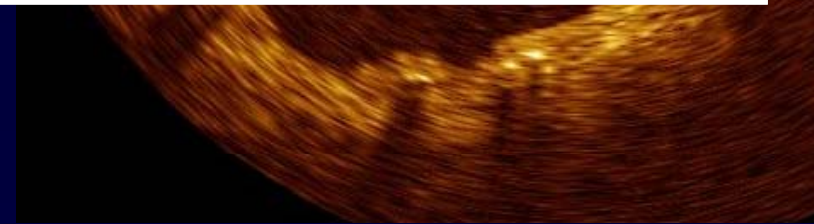
Malapposed and uncovered struts



Covered struts with neointima



Are you acceptable or OK when you look at the uncovered or malapposed struts at follow-up OCT ? Maybe everybody no .....



# Uncovered stent struts.



# Pathological Correlates of Late Drug-Eluting Stent Thrombosis

## Strut Coverage as a Marker of Endothelialization

The most powerful histological predictor of stent thrombosis was endothelial coverage.

The best morphometric predictor of LST was the ratio of uncovered to total stent struts.

The odds ratio for thrombus with a ratio of uncovered to total struts  $> 30\%$   $\Rightarrow 9.0$  (95% CI, 3.5 to 22)

*Finn AV, et al. Circulation 2007;115:2435-41*

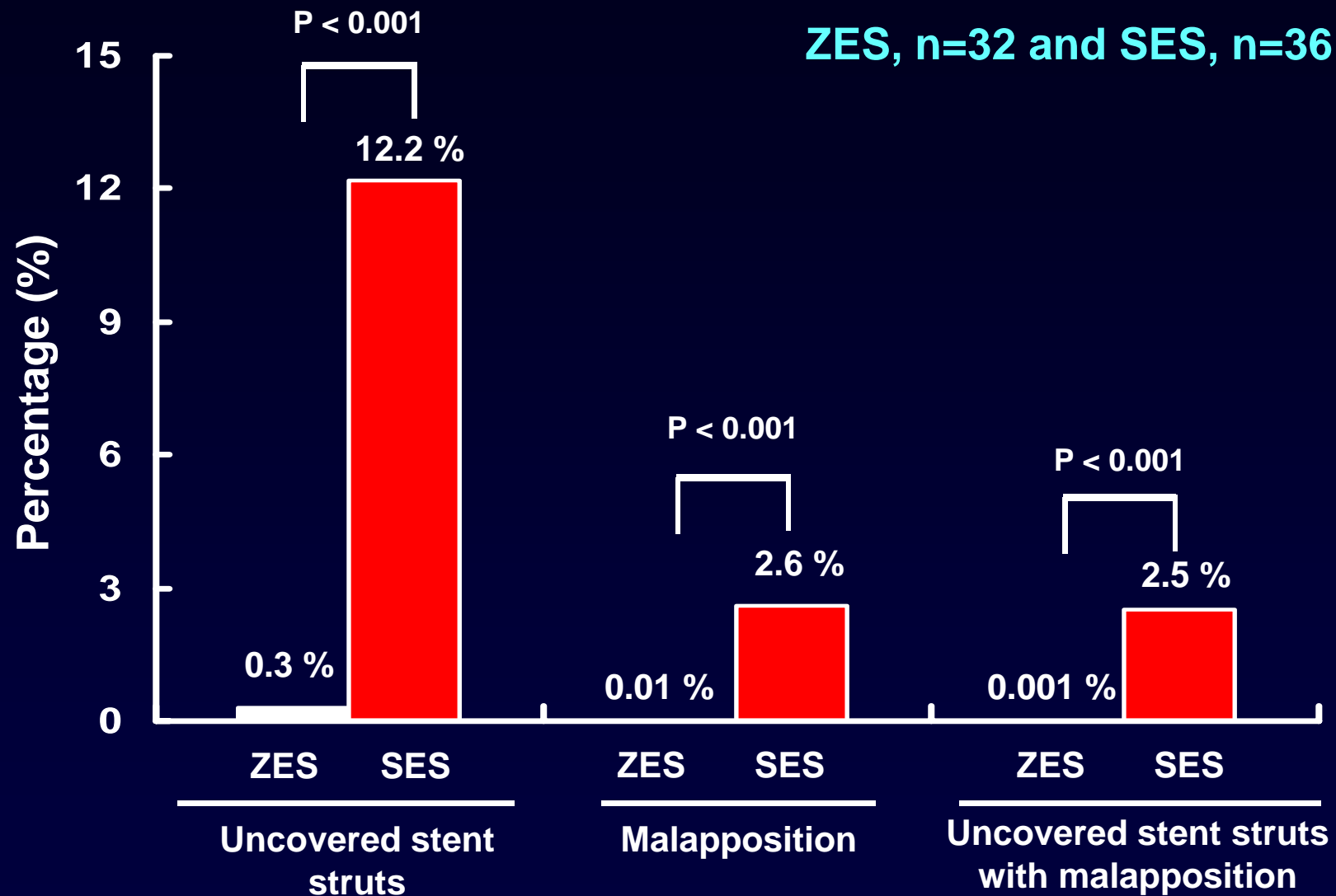
# OCT definition

Uncovered strut = Neointimal hyperplasia (NIH) thickness of 0  $\mu\text{m}$

The percentage of uncovered struts =  
(number of uncovered struts/total number of struts in all cross-sections of the lesion)  $\times$  100



# OCT Evaluation of ZES at 9 Month FU



Kim JS, et al. Heart 2009;95:1907-12

# Evaluation in 3 months Duration of neointima coverage after zotarolimus-eluting stent implantation by Optical Coherence Tomography (ENDEAVOR OCT)

Patients with Endeavor implantation in CAD

IVUS and OCT after stent implantation and at 3 months

Stable angina (n = 15)

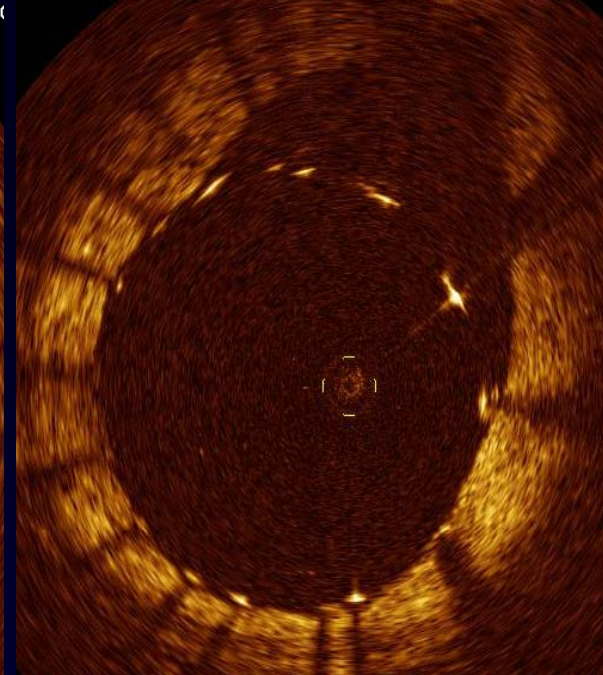
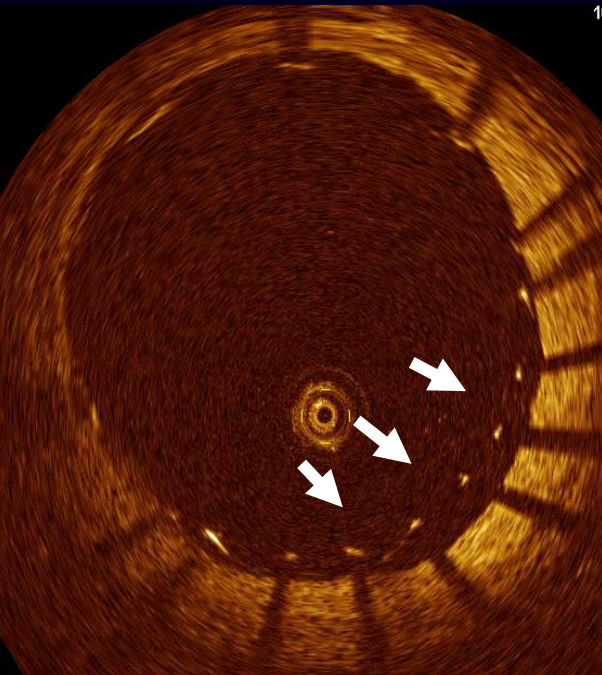
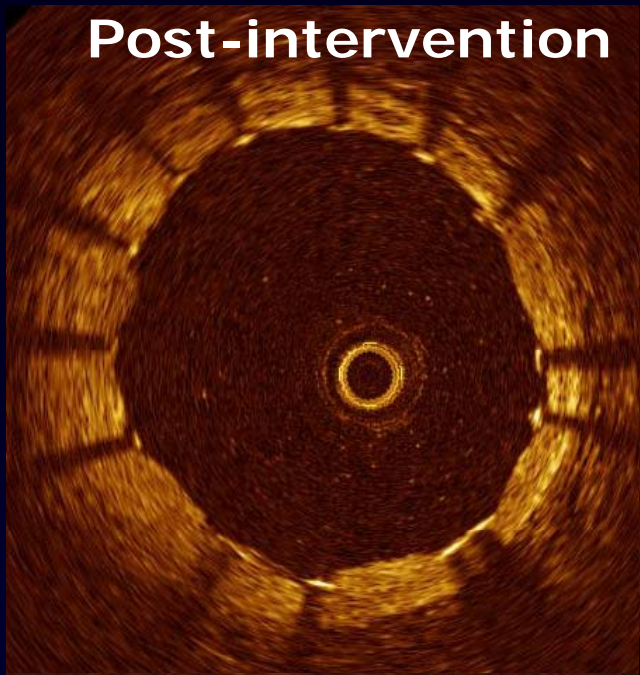
ACS (n = 15)

Primary end-point: Percent neointima coverage at 3 months

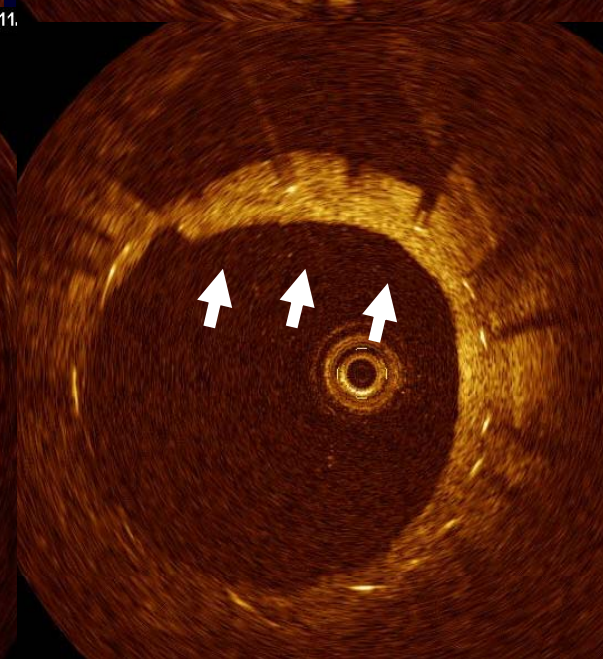
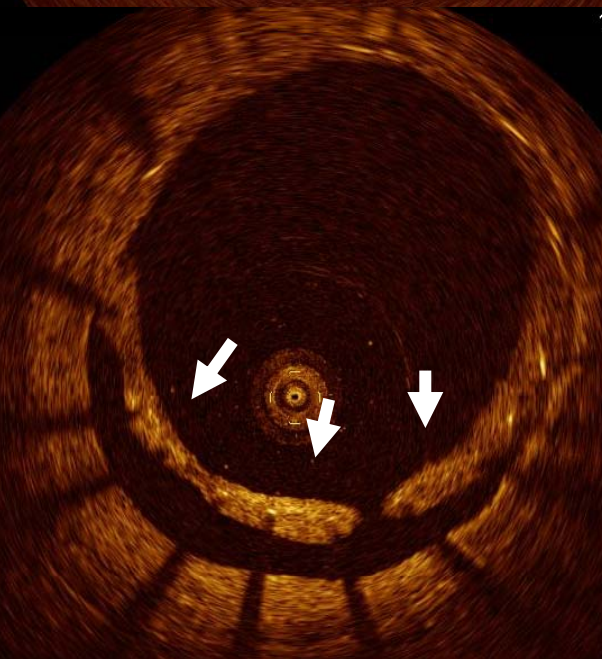
Secondary end-point: percent of malapposition and thrombus at follow-up OCT

*Kim JS, et al. J Am Coll Cardiol Intv 2009;12:1241-7*

Post-intervention



3-Month follow-up



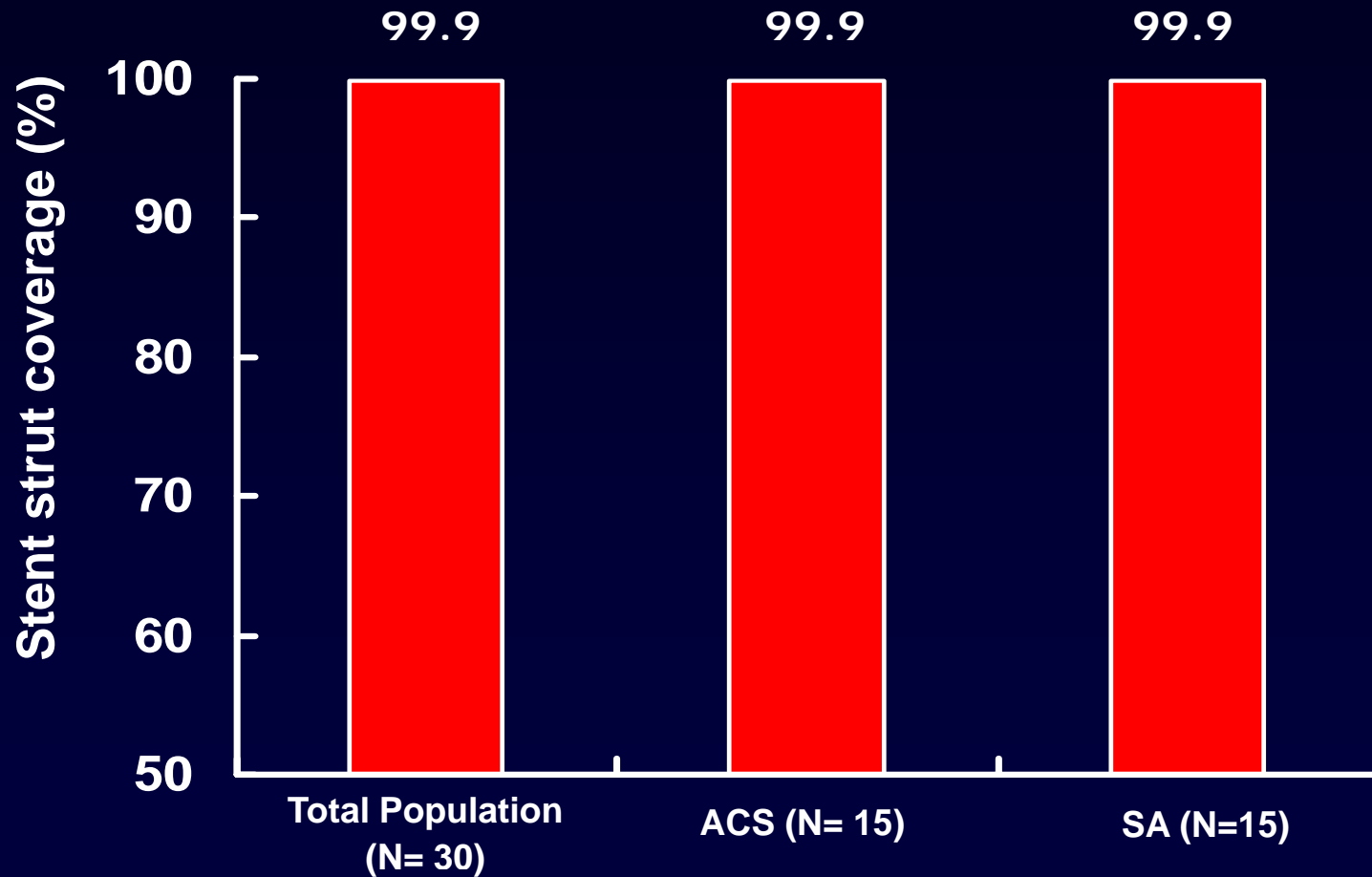


# OCT findings

Measured at every 0.5 mm

30 patients (16 stents in 15 ACS and 15 stents in 15 SA)

683 mm in stent length including 12074 struts



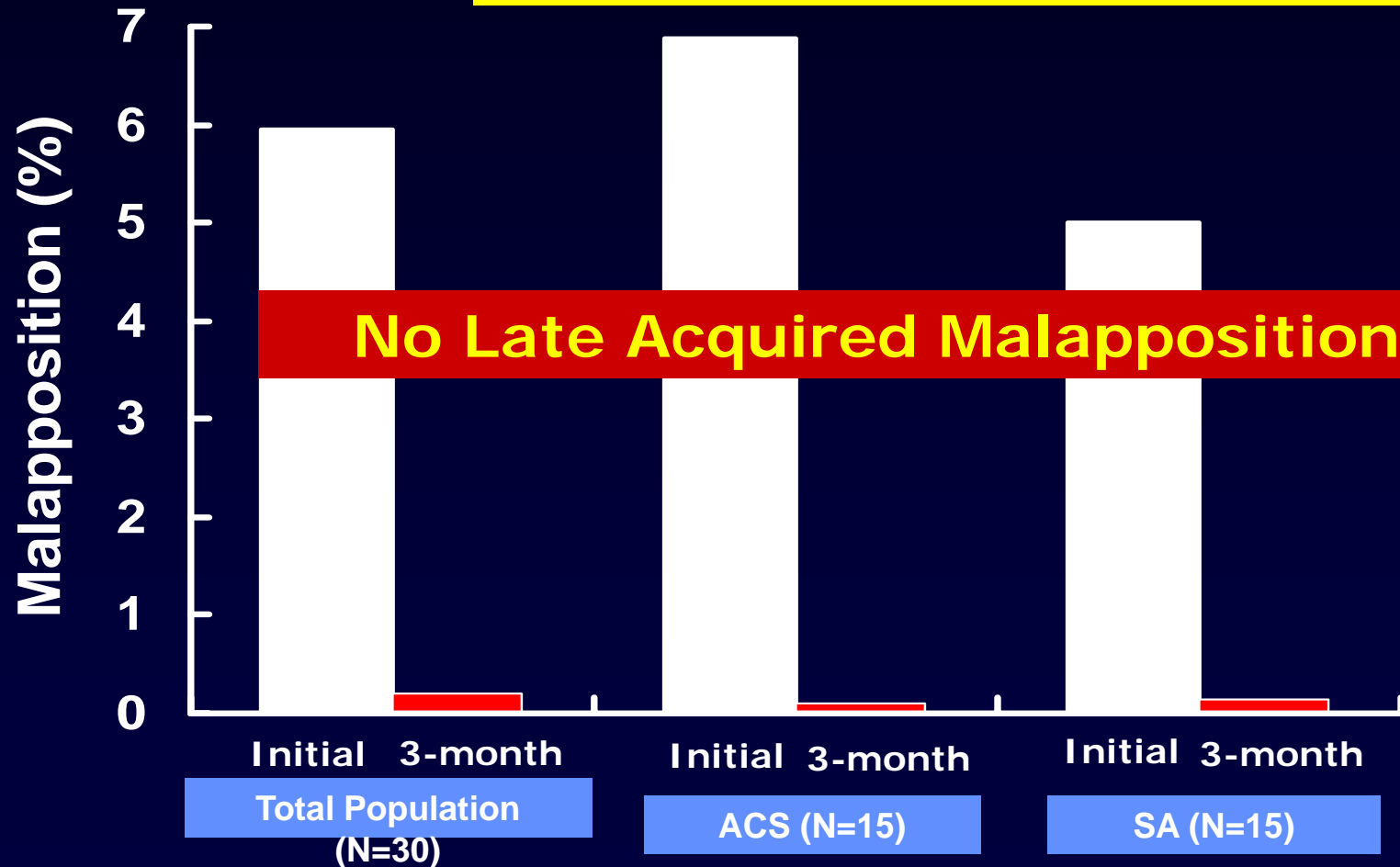
*Kim JS, et al. J Am Coll Cardiol Intv 2009;12:1241-7*

# OCT findings

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683 mm in stent length including 12074 struts

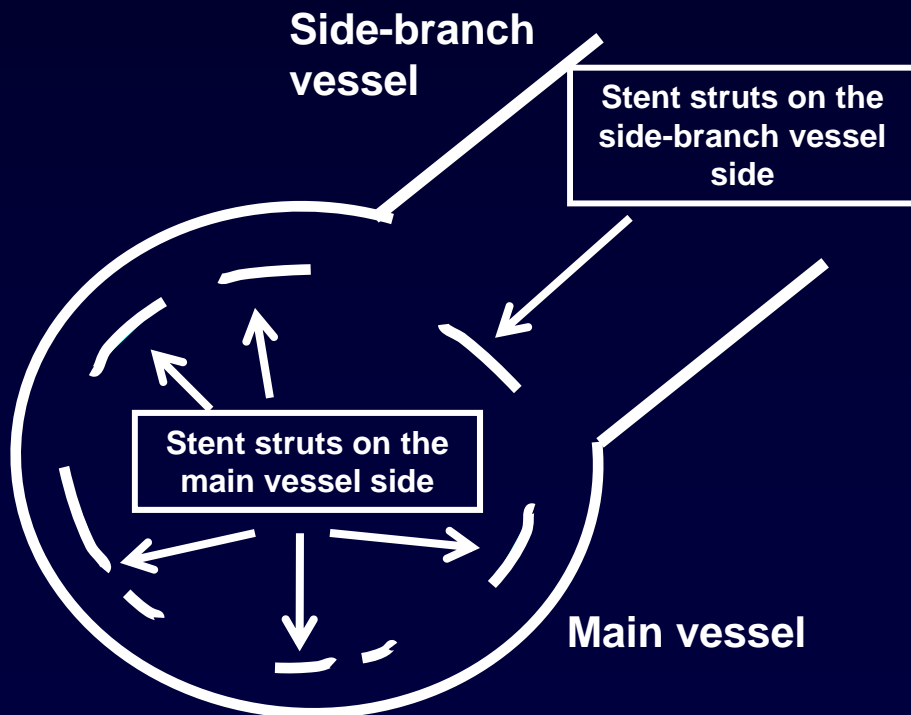
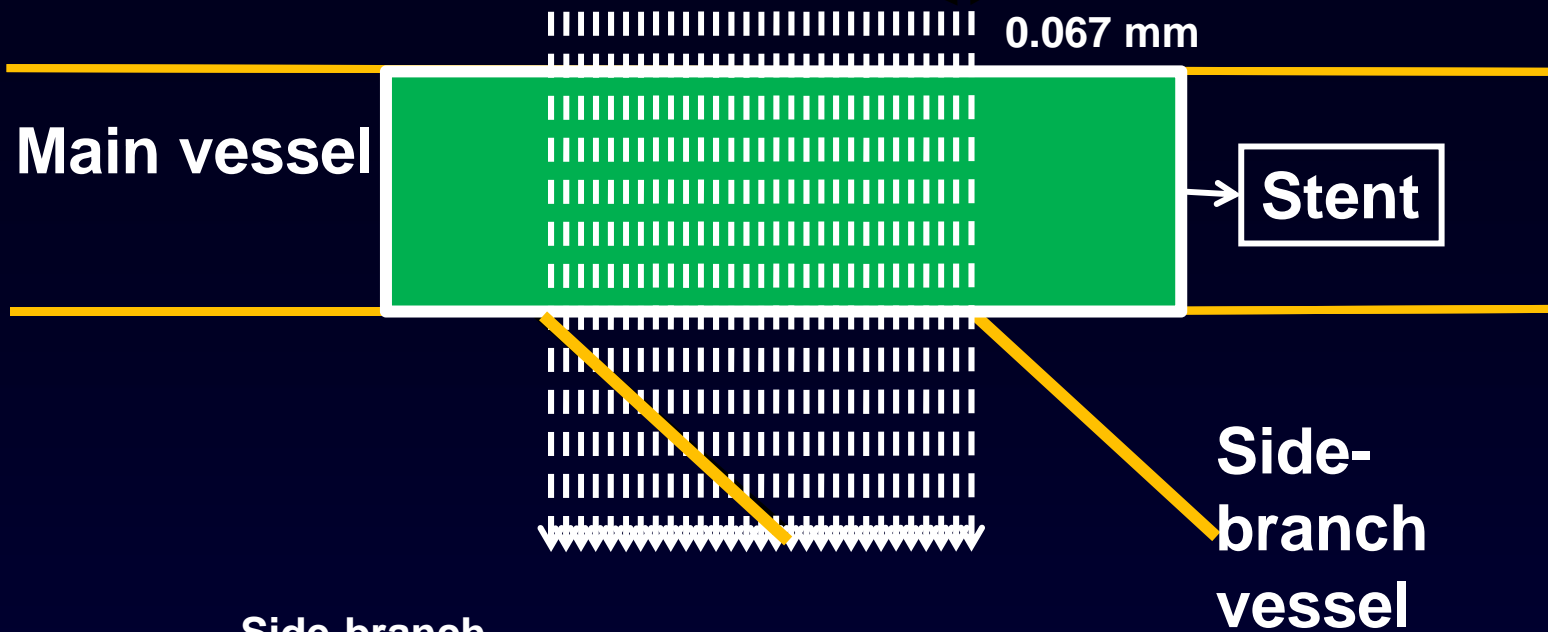
Visible thrombus: 1/31 stent (3.2 %)



Stent struts on Side Branch ?

**Neointimal Coverage on the DES  
Struts Crossing the Side-Branch  
Vessels: an OCT Study**

*Her AY, Hong MK et al, Am J Cardiol 2010;105:1565-69*

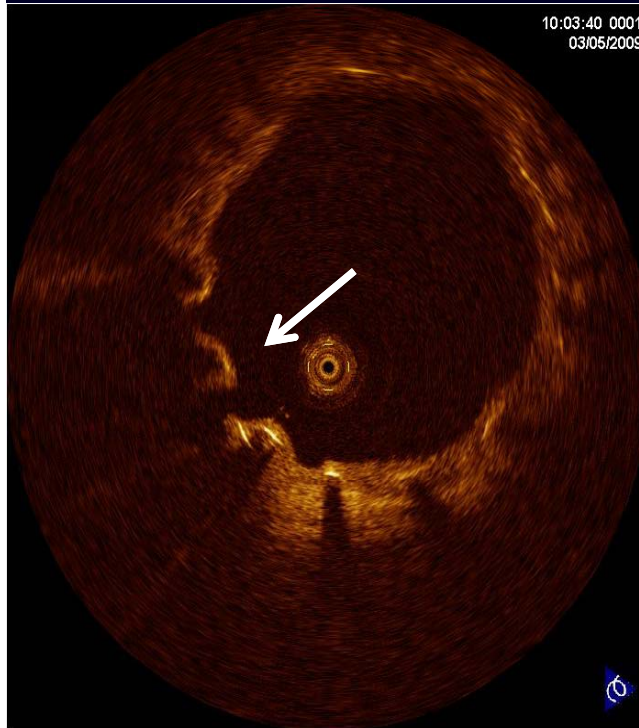




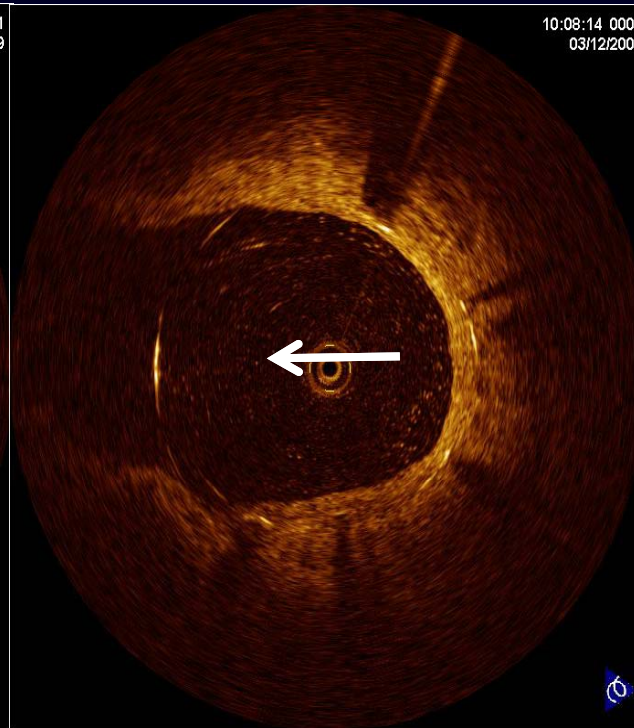
# OCT analysis among types of DESs

|                                      | SES<br>(n=22) | PES<br>(n=15) | ZES<br>(n=14) | P      |
|--------------------------------------|---------------|---------------|---------------|--------|
| <b>Side branch vessel side</b>       |               |               |               |        |
| Total No. of struts, n               | 356           | 165           | 143           |        |
| Percentage of covered struts, %      | 65 ± 37       | 20 ± 31       | 83 ± 29       | <0.001 |
| Neointimal hyperplasia thickness, mm | 0.04 ± 0.03   | 0.02 ± 0.02   | 0.08 ± 0.06   | 0.002  |
| Mean No. of struts                   | 16 ± 12       | 11 ± 7        | 13 ± 12       | 0.360  |
| No. of covered struts                | 10 ± 10       | 1 ± 2         | 11 ± 11       | 0.010  |

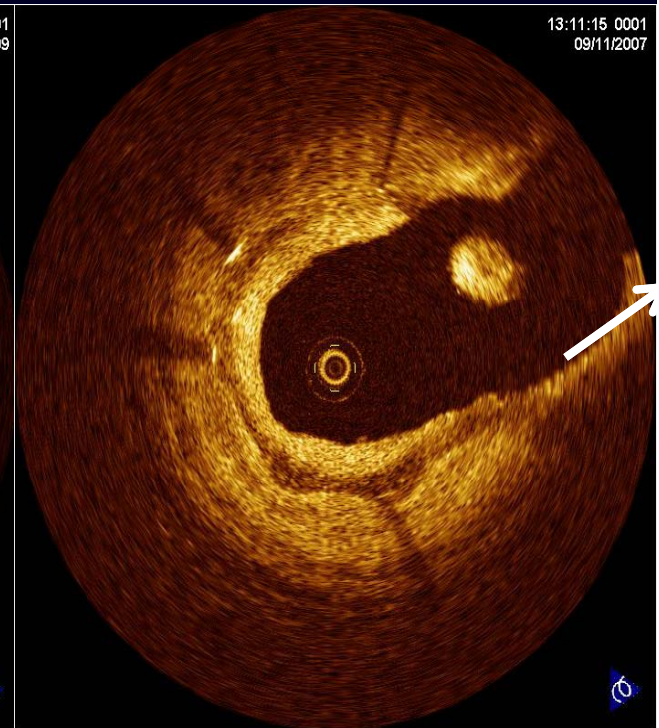
# Comparison of neointimal thickness on unapposed struts crossing the side-branch



Cypher (SES)

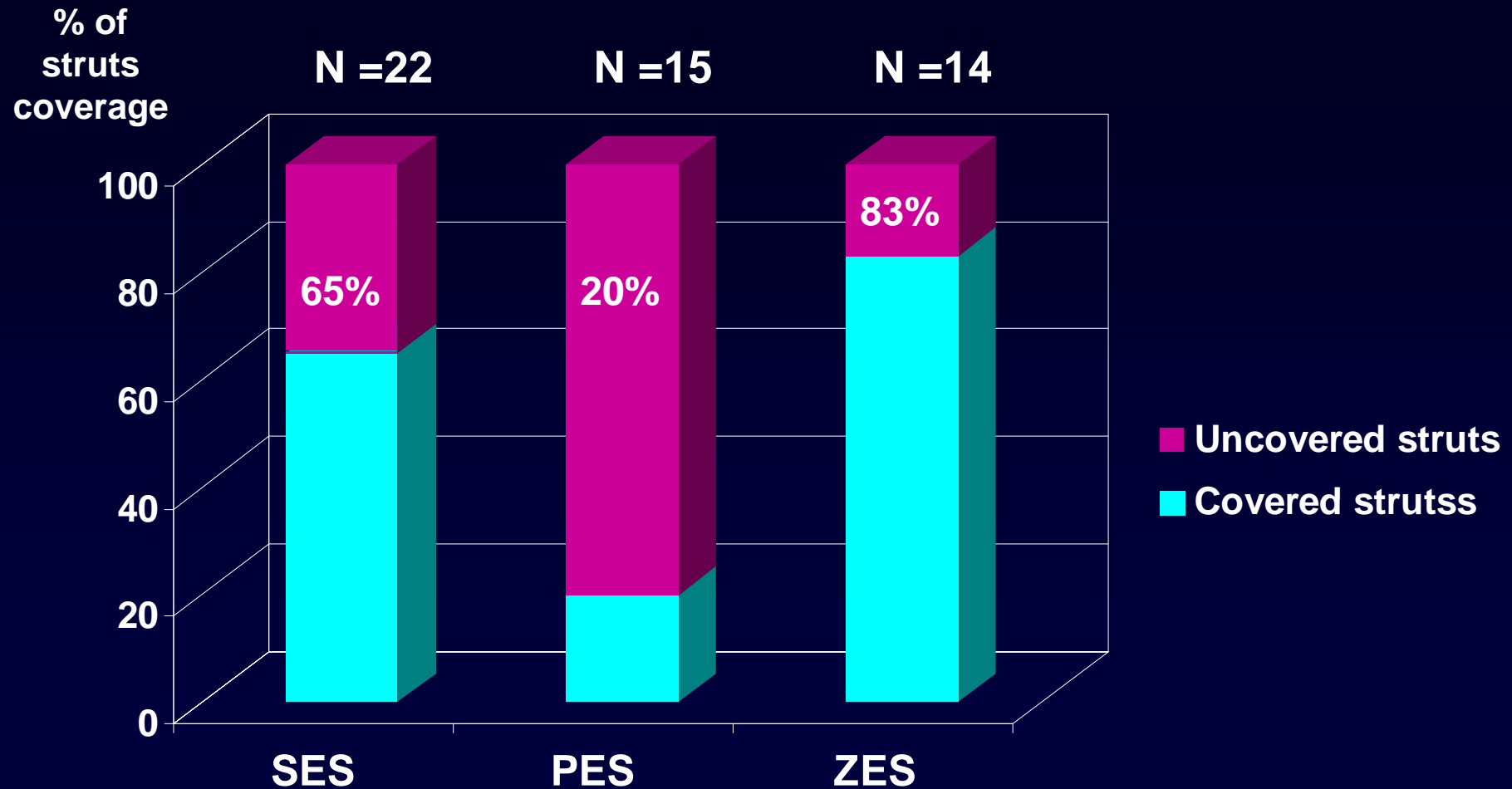


Taxus (PES)



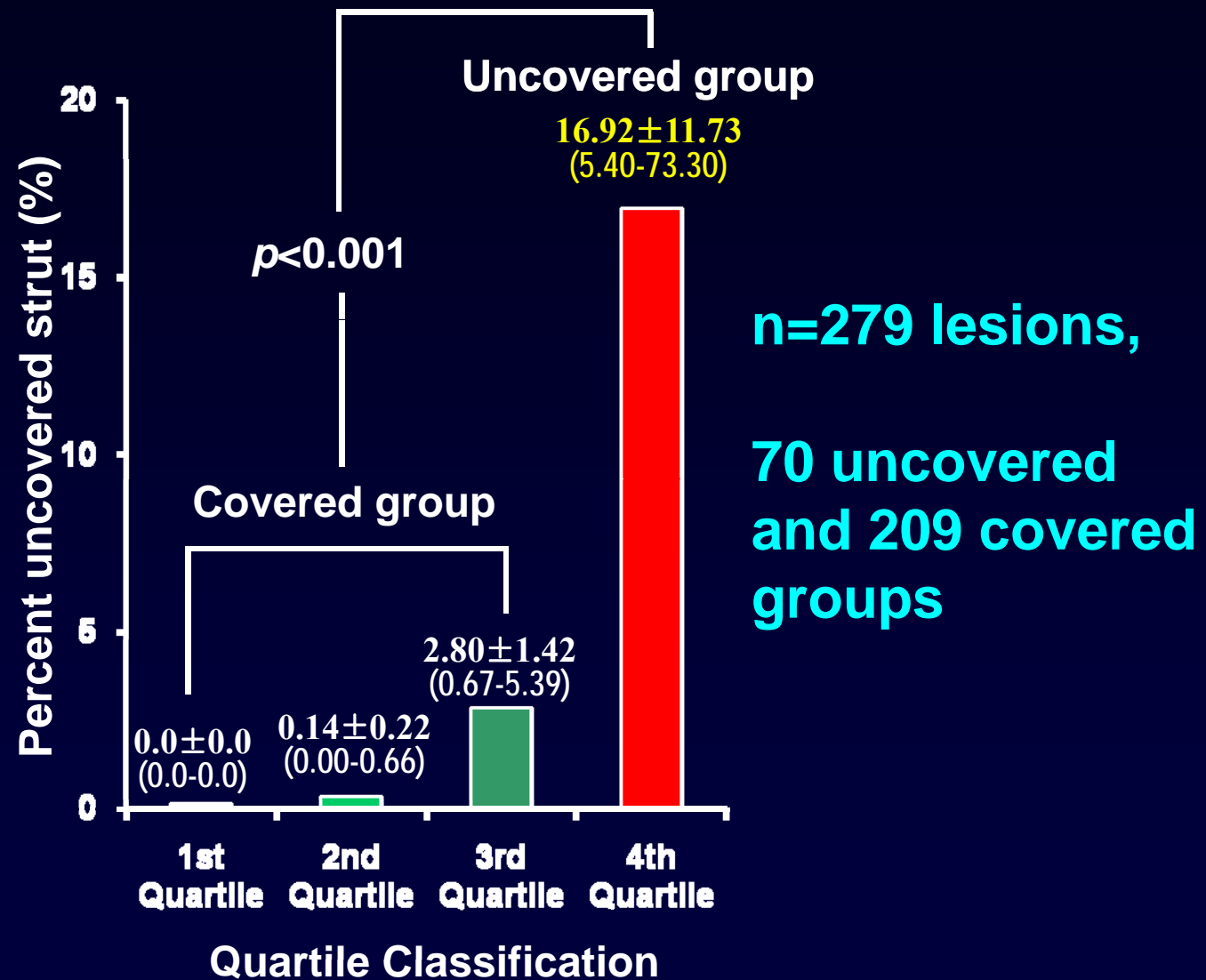
Endeavor (ZES)

# Composition of struts coverage crossing the side branch



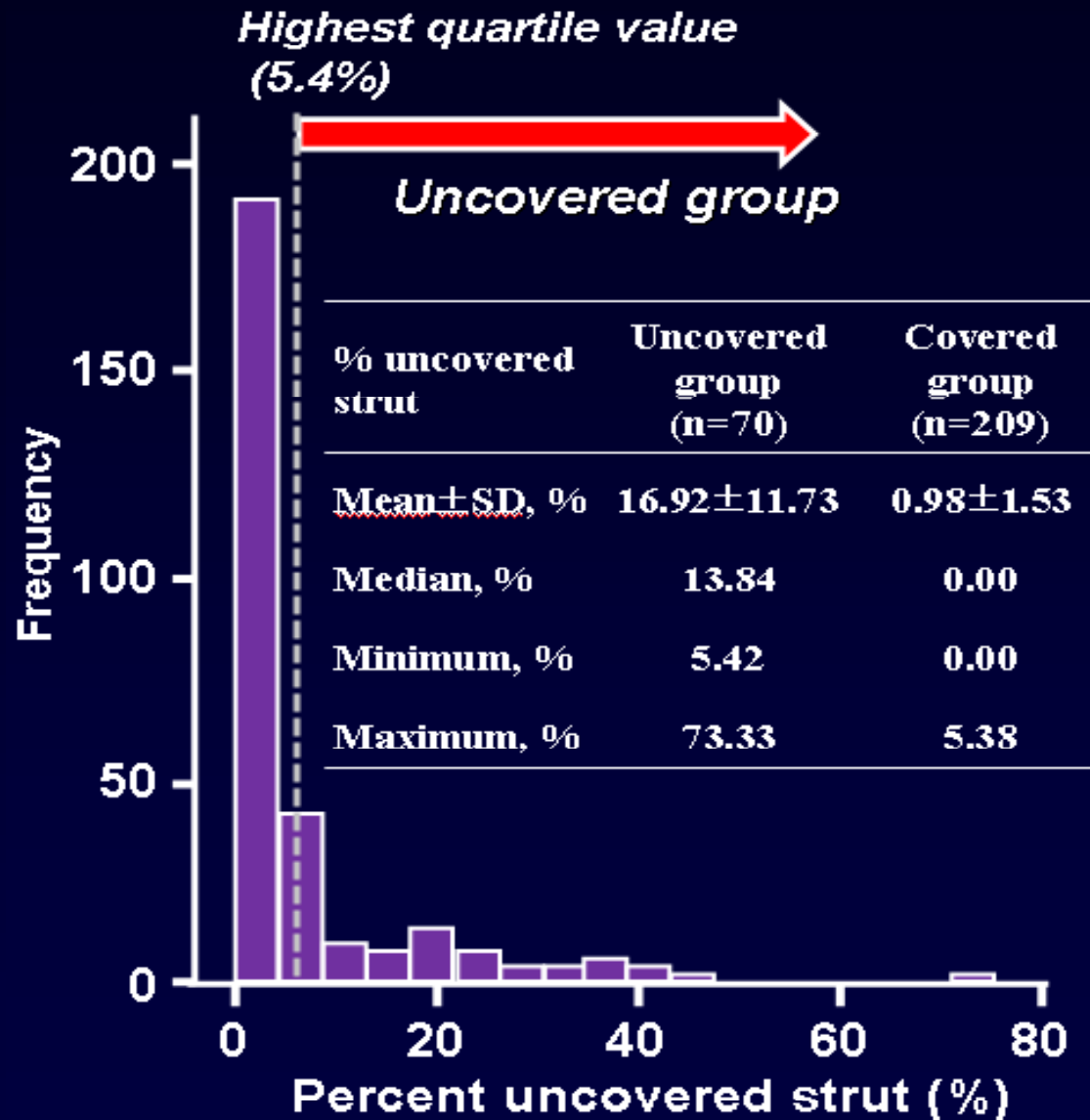
Her AY, Hong MK, et al. *Am J Cardiol* 2010;105:972-976

# Major determinants of uncovered struts



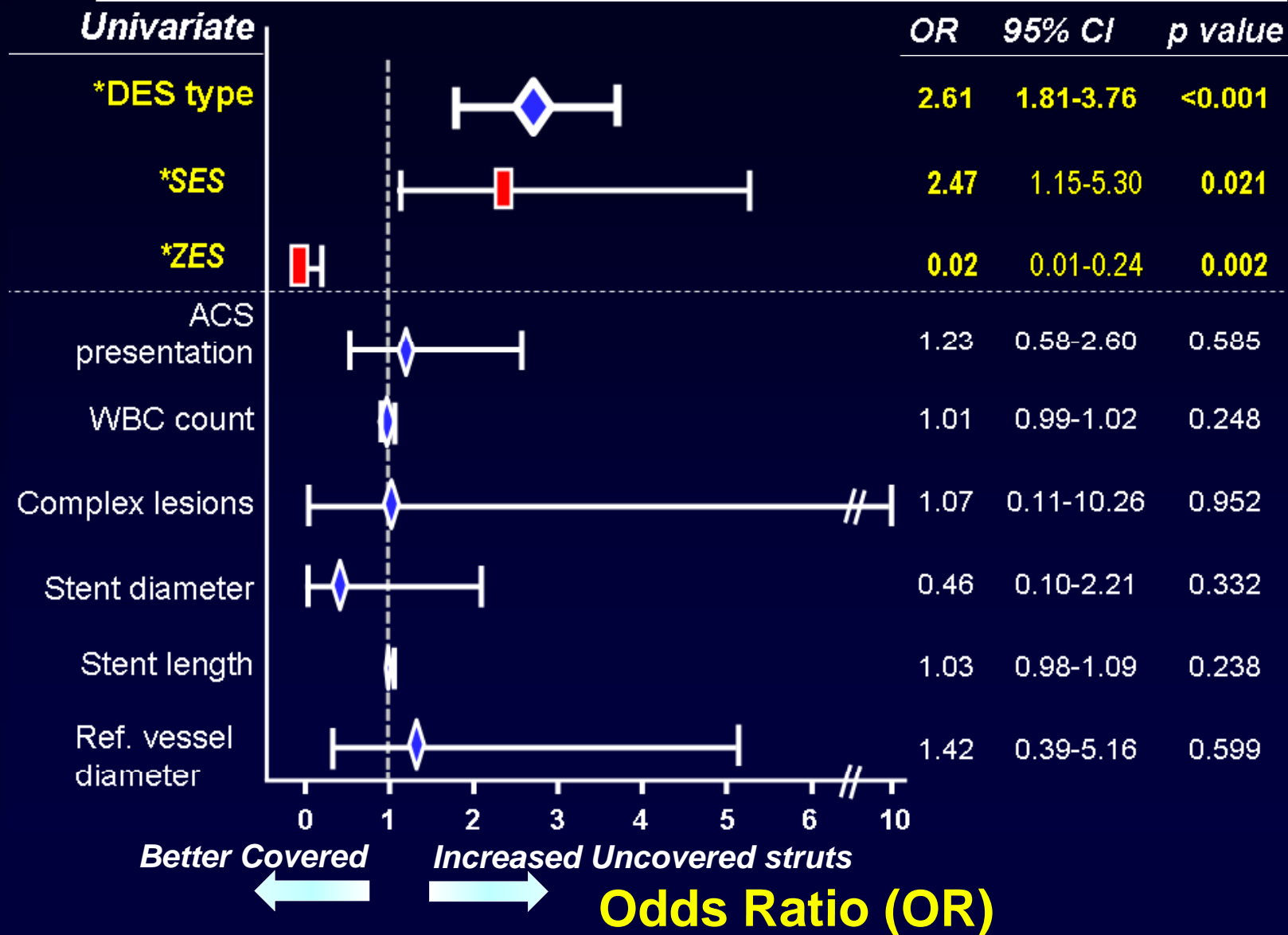
Kim BK, Hong MK, *Int J Cardiovasc Imaging* (in press)

# Major determinants of uncovered stent struts

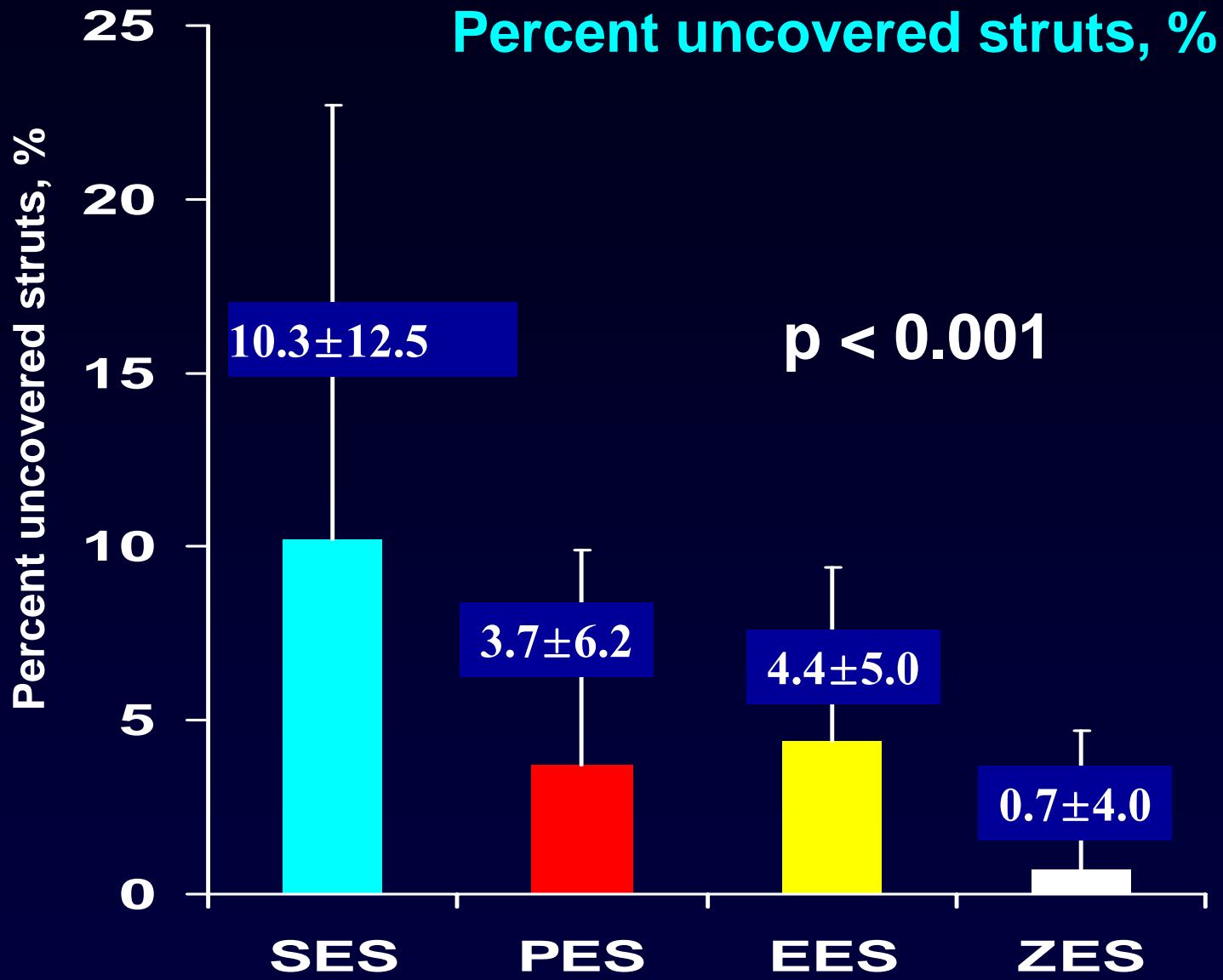


Kim BK, Hong MK, *Int J Cardiovasc Imaging* (in press)

## Major determinants of uncovered struts



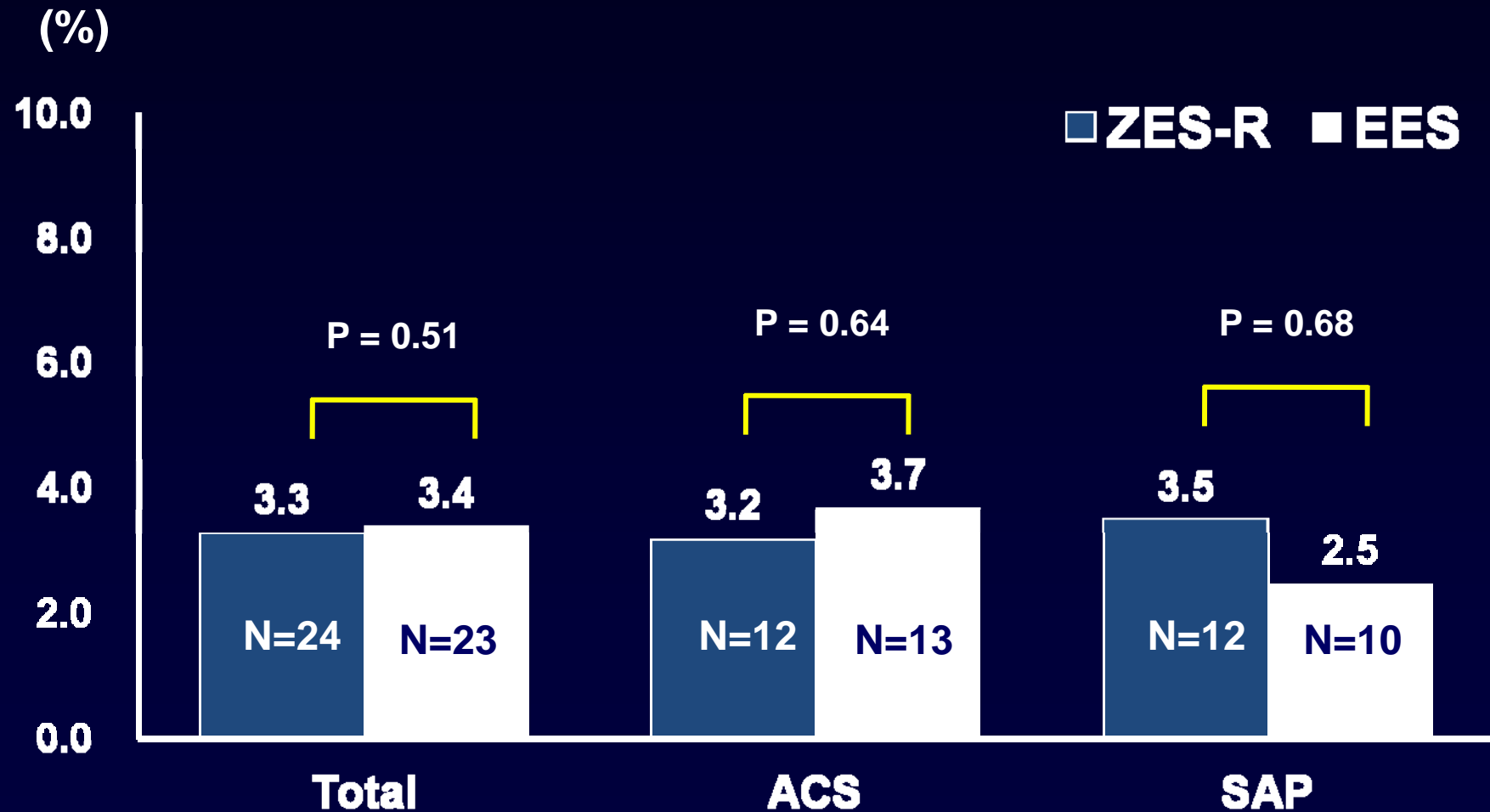
Kim BK, Hong MK, *Int J Cardiovasc Imaging* (in press)



Kim BK, Hong MK, *Int J Cardiovasc Imaging* (in press)



# The prevalence of uncovered struts in ZES-R and EES at 9-Month follow-up: Randomized study



Kim JS, et al. *Am Heart J* (in press)

# Stent malapposition

# Serial Changes of Tiny Stent Malapposition Not Detected by Intravascular Ultrasound (Follow-up Optical Coherence Tomography Study)

**Tiny post-SM: SM not detected by IVUS, but be visualized with OCT.**

## **Study population**

- 42 patients from the Yonsei OCT registry :
- Both post-stent & follow-up OCT examination after DES implantation

**Initial tiny post-SM was found in 26 (62%) of 42 patients**

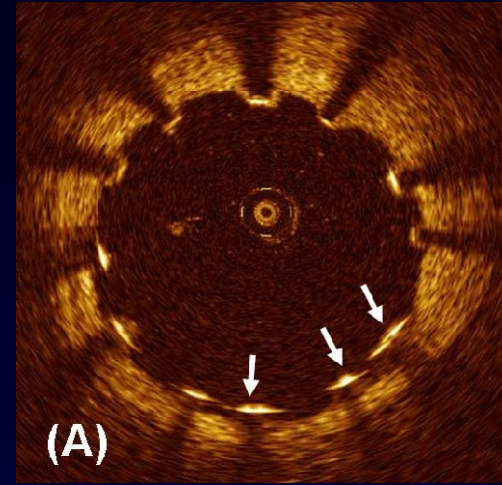
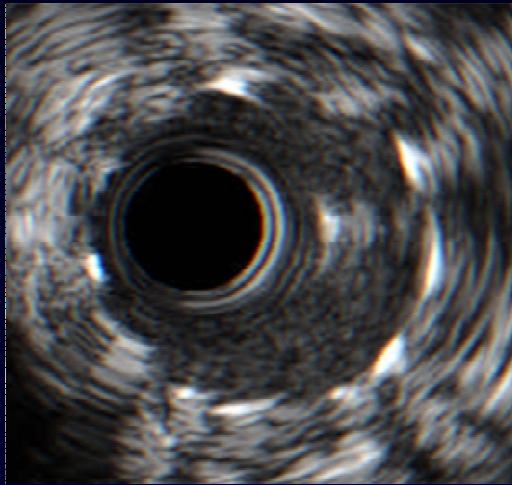
*Kim WH, Hong MK et al, Clin Res Cardiol 2010;99:639-644*

# OCT measurements (n=26)

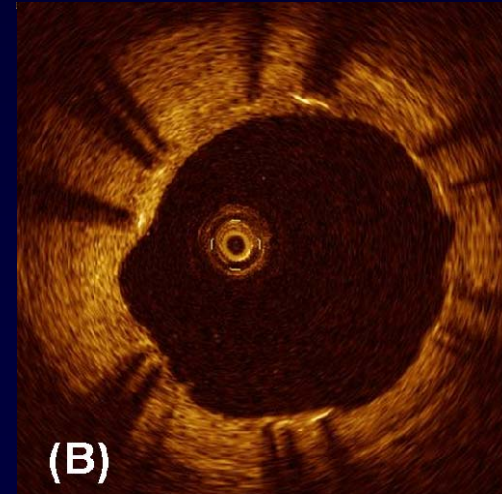
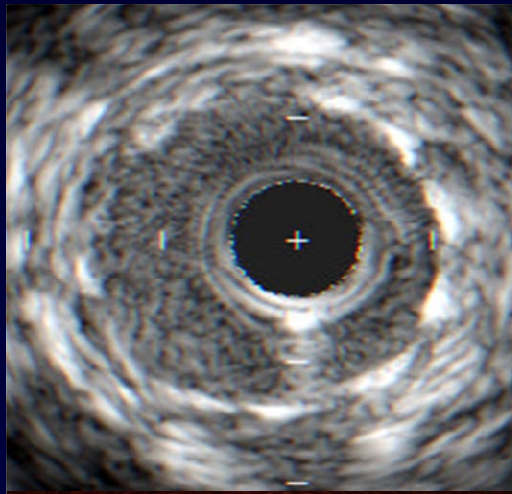
|                                                                          | Immediate post-stenting | Follow up   | P Value          |
|--------------------------------------------------------------------------|-------------------------|-------------|------------------|
| Number of analyzed stent struts                                          | 5615                    | 5474        |                  |
| Mean length of analyzed segment (mm)                                     | 22.8 ± 6.2              | 22.9 ± 5.1  | 0.22             |
| Length of malapposition segment (mm)                                     | 2.3 ± 2.3               | 0.1 ± 0.3   | <0.001           |
| Num. of malapposed struts (n)                                            | 27 ± 26                 | 2 ± 5       | <0.001           |
| <b>% of malapposed struts (%)</b>                                        | 12.2 ± 11.0             | 1.0 ± 2.2   | <b>&lt;0.001</b> |
| Mean stent area at the segment with malapposed struts (mm <sup>2</sup> ) | 7.37 ± 1.71             | 7.39 ± 1.65 | 0.08             |
| <b>Mean extra-malapposition area (mm<sup>2</sup>)</b>                    | 0.35 ± 0.16             | 0.04 ± 0.11 | <b>&lt;0.001</b> |
| Largest extra-malapposition area (mm <sup>2</sup> )                      | 0.54 ± 0.46             | 0.07 ± 0.18 | <0.001           |
| Mean NIH thickness at the segment with malapposed struts (mm)            |                         | 0.15 ± 0.1  |                  |

*Kim WH, Hong MK et al, Clin Res Cardiol 2010;99:639-644*

# Corresponding images of IVUS & OCT



**(A) Malapposed struts of an SES. 3 stent struts seem to float into the lumen with an extra-stent area (arrows). Small-sized post-SM is not be detected by IVUS, but be clearly visualized with OCT image follow-up OCT**



**(B) Follow-up OCT images shows that all strut surfaces is covered by neointima**

# Malapposed vs. Uncovered Struts.

| Variables                                                         | Non-malapposition<br>(n=232) | Malapposition<br>(n=74) | p value |
|-------------------------------------------------------------------|------------------------------|-------------------------|---------|
| No. of cross section, n                                           | 5448                         | 1731                    | -       |
| % malapposed struts, %                                            | 0                            | 3.2 ± 4.9               | -       |
| % uncovered struts from all cross sections, %                     | 3.7 ± 6.4                    | 11.6 ± 13.3             | <0.001  |
| % uncovered struts in the cross sections without malapposition, % | 3.7 ± 6.4                    | 10.1 ± 12.0             | <0.001  |
| Thrombi, n (%)                                                    | 20 (9%)                      | 18 (24%)                | <0.001  |
| Types of DES used                                                 |                              |                         | <0.001  |
| SES, n (%)                                                        | 59 (25%)                     | 37 (50%)                |         |
| PES, n (%)                                                        | 44 (19%)                     | 10 (14%)                |         |
| ZES-Sprint, n (%)                                                 | 54 (23%)                     | 4 (5%)                  |         |
| ZES-Resolute, n (%)                                               | 38 (16%)                     | 15 (20%)                |         |
| EES, n (%)                                                        | 37 (16%)                     | 8 (11%)                 |         |

*Kim BK, Hong MK, et al. J Interven Cardiol (in press)*

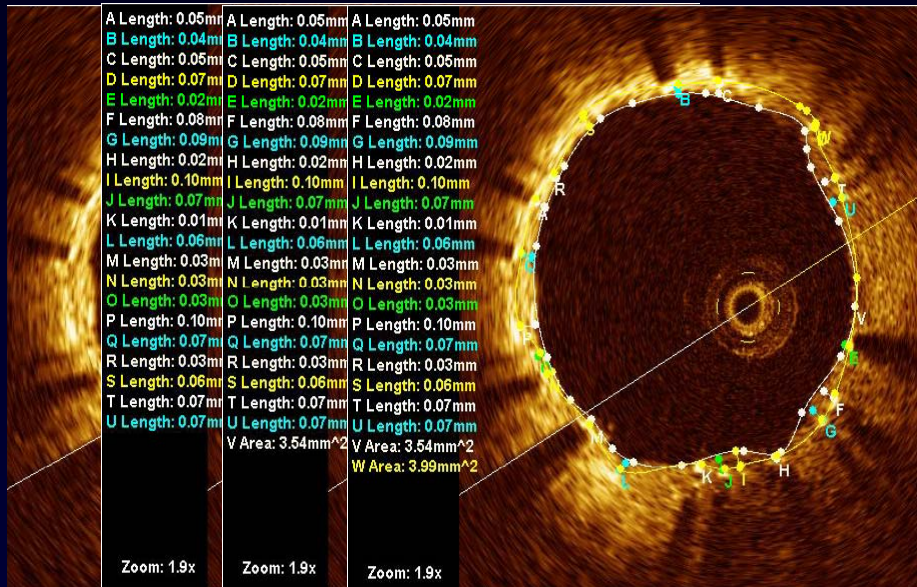
# Malapposed vs. Uncovered Struts.

| Variables                                                         | Non-malapposition (n=232) | Malapposition I % malapposed struts <1.3% (n=37) | Malapposition II % malapposed struts ≥1.3% (n=37) | p value |
|-------------------------------------------------------------------|---------------------------|--------------------------------------------------|---------------------------------------------------|---------|
| % malapposed struts, %                                            | 0%                        | 0.7 ± 0.3%                                       | 5.6 ± 6.1%                                        | <0.001  |
| % uncovered struts from all cross sections, %                     | 3.7 ± 6.4                 | 5.5 ± 5.6                                        | 17.6 ± 15.9                                       | <0.001  |
| % uncovered struts in the cross sections without malapposition, % | 3.7 ± 6.4                 | 5.2 ± 5.7                                        | 15.0 ± 14.4                                       | <0.001  |
| Thrombi, n (%)                                                    | 20 (9%)                   | 8 (22%)                                          | 10 (27%)                                          | <0.001  |
| Time to OCT (days)                                                | 312 ± 92                  | 303 ± 68                                         | 315 ± 81                                          | 0.785   |
| FU after OCT (days)                                               | 480 ± 315                 | 484 ± 282                                        | 475 ± 210                                         | 0.921   |
| Duration of DAT after OCT (days)                                  | 252 ± 214                 | 299 ± 227                                        | 313 ± 258                                         | 0.129   |
| MACE after OCT                                                    | 0                         | 0                                                | 1 STEMI                                           |         |

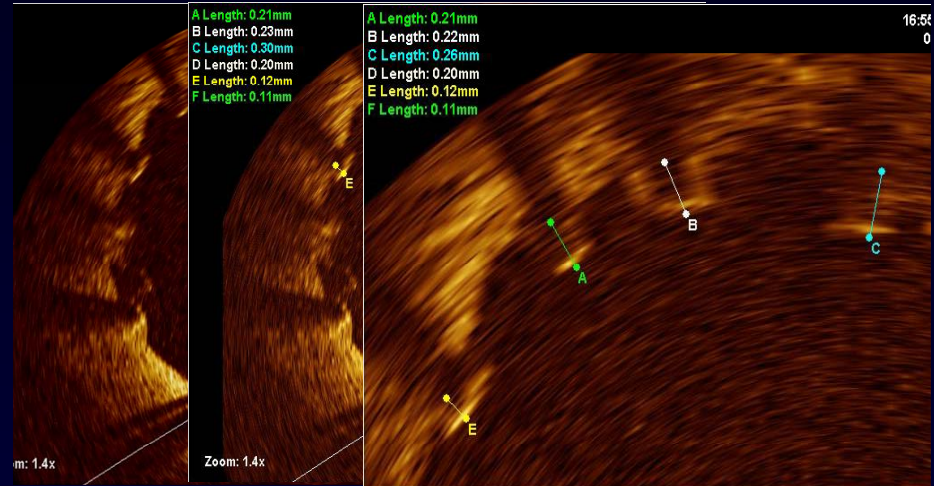
*Kim BK, Hong MK, et al. J Interven Cardiol (in press)*



# Is the traditional OCT analysis sufficient ?



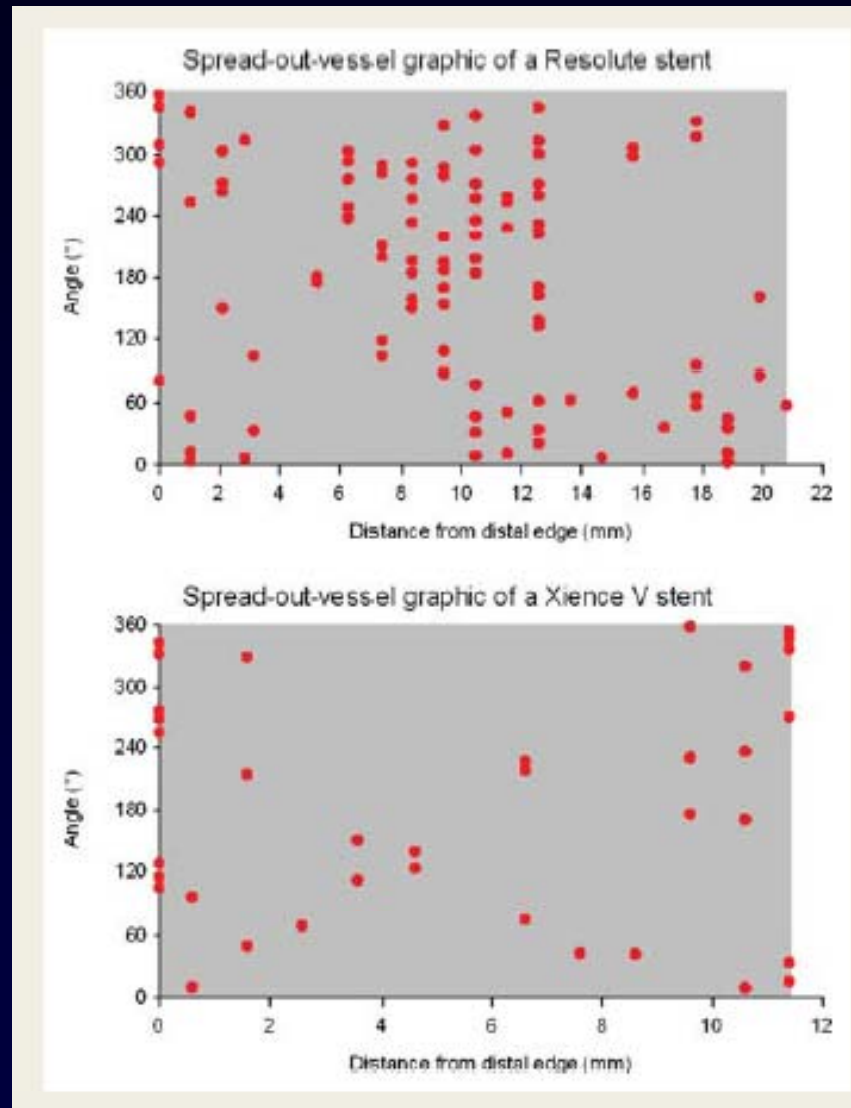
**Neointimal thickness**



**Stent apposition**

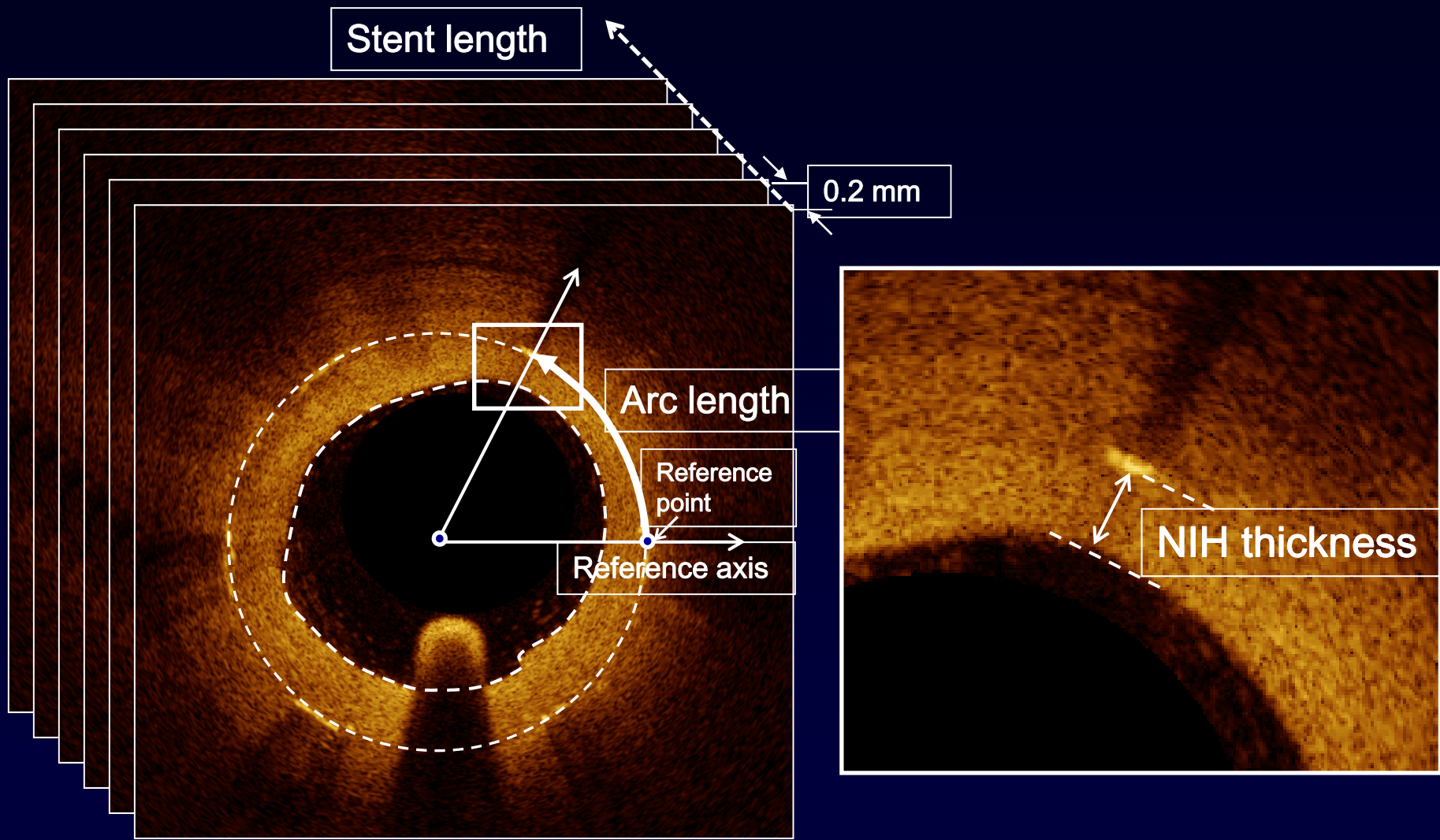
**What are the spatial distributions of uncovered or malapposed struts ?**

# Spread-out-vessel graphic



Gutiérrez-Chico JL et al, *Eur Heart J* 2011; 32: 2454-2463

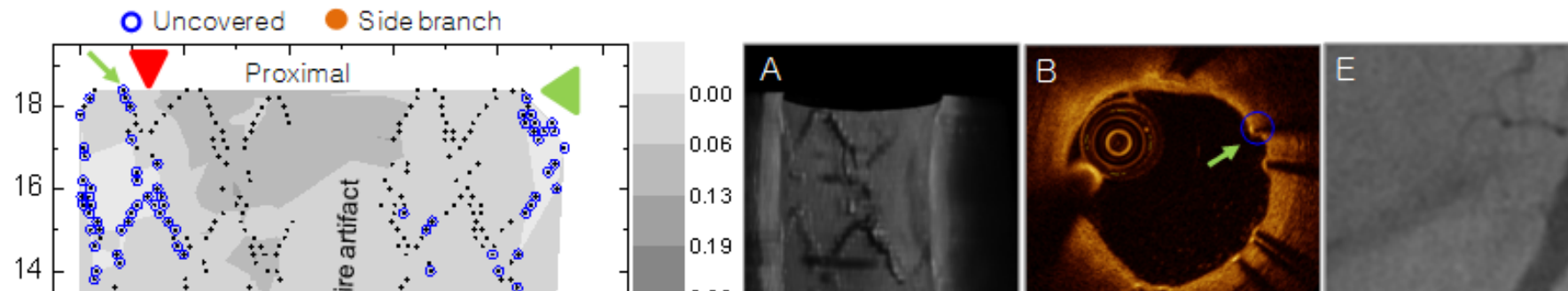
# Creation of contour map



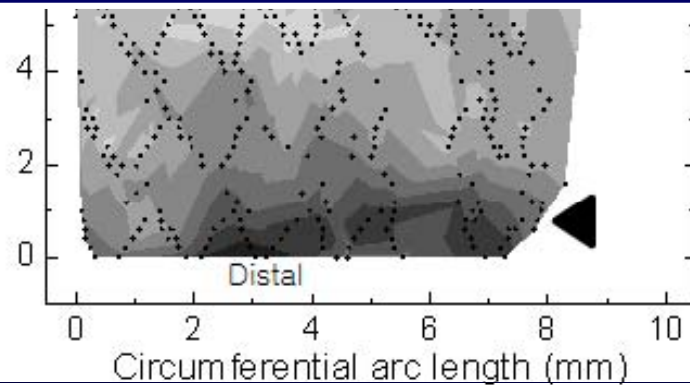
Data (x, y, z) = Data (arc length, stent length, NIH thickness)



# Creation of contour map

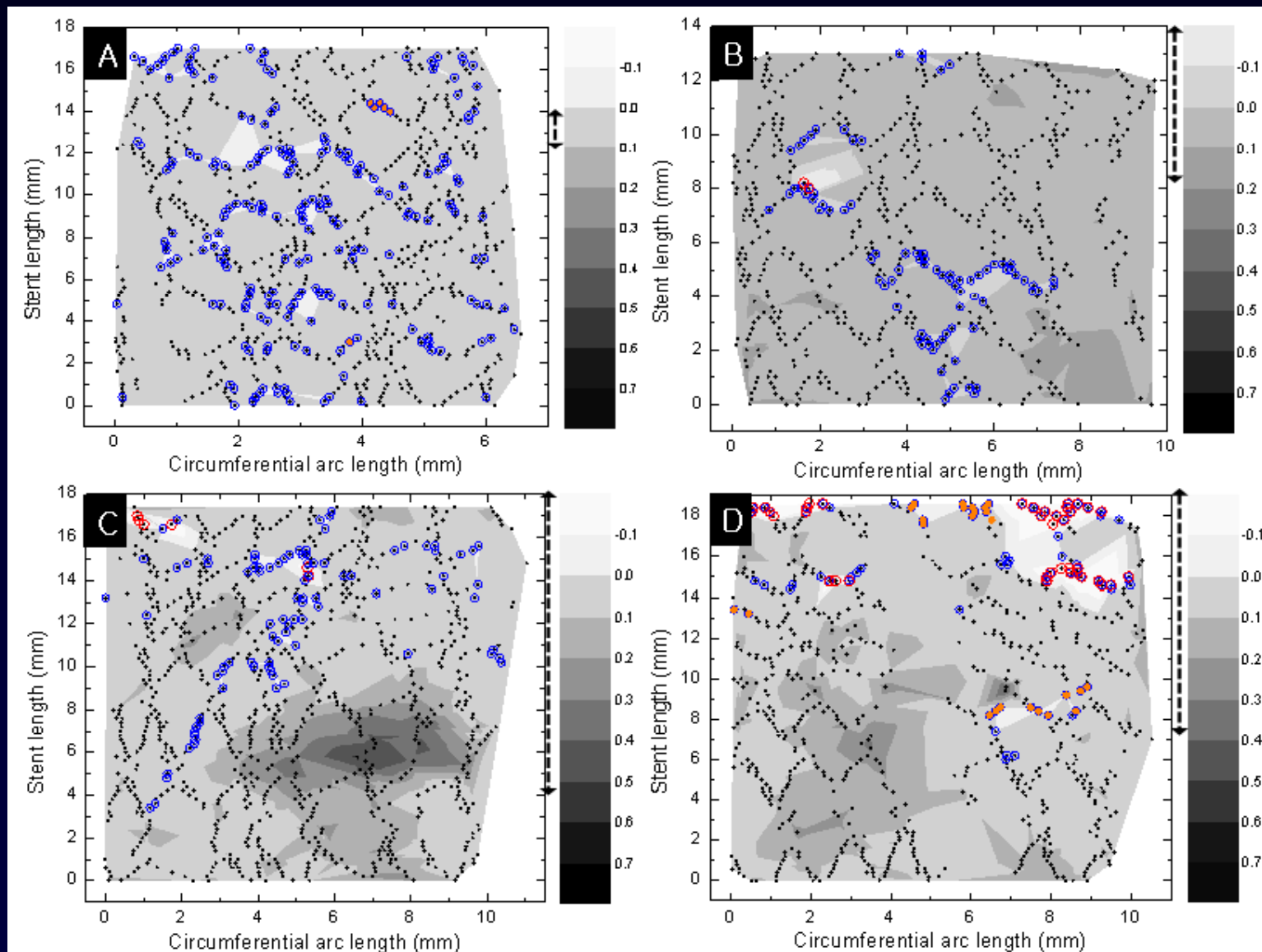


**This technology provides detailed information previously obtainable only by gross pathologic examination.**

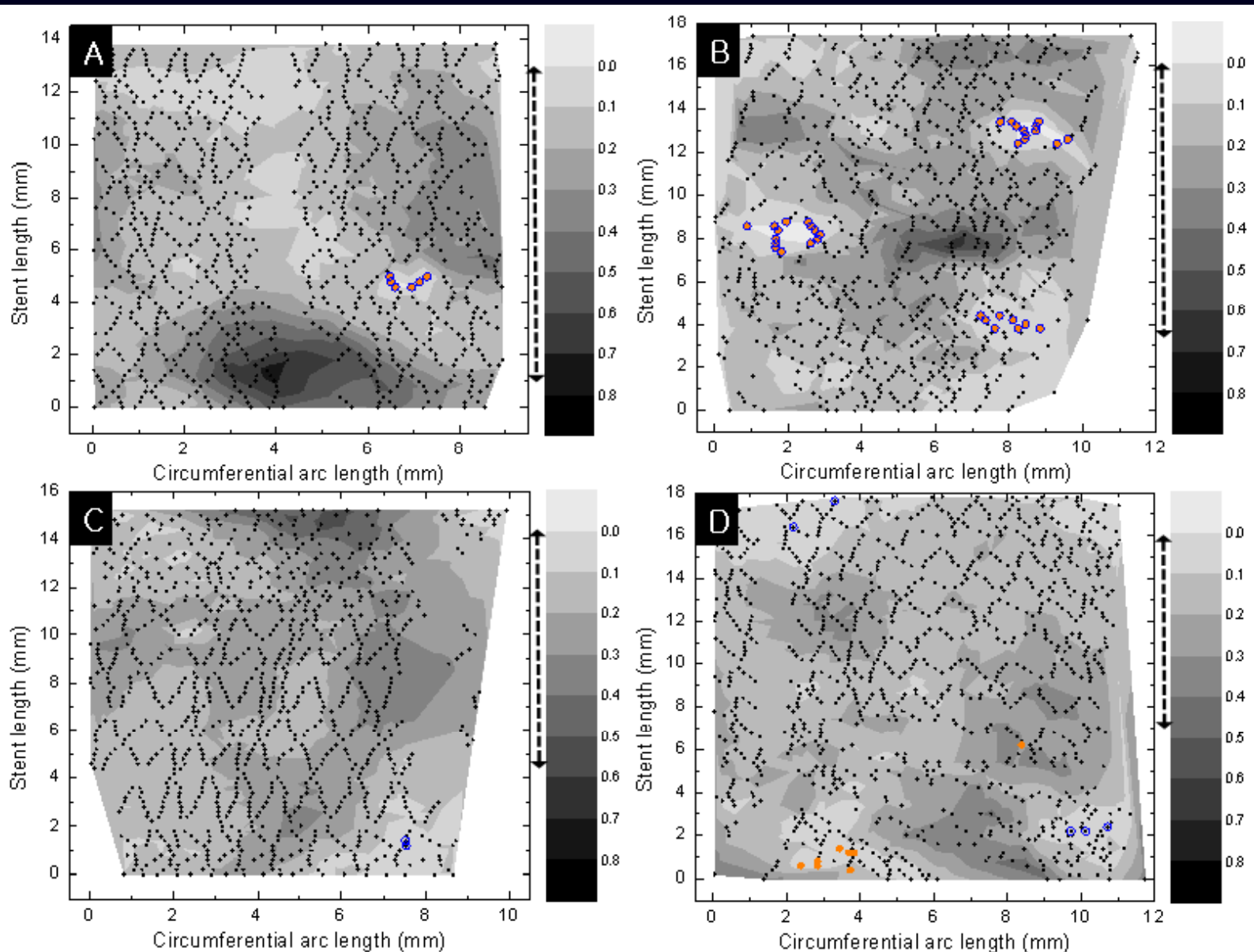


SES

# Contour map of SES at follow-up OCT



# Contour map of ZES at follow-up OCT



# Serial OCT



# Serial OCT

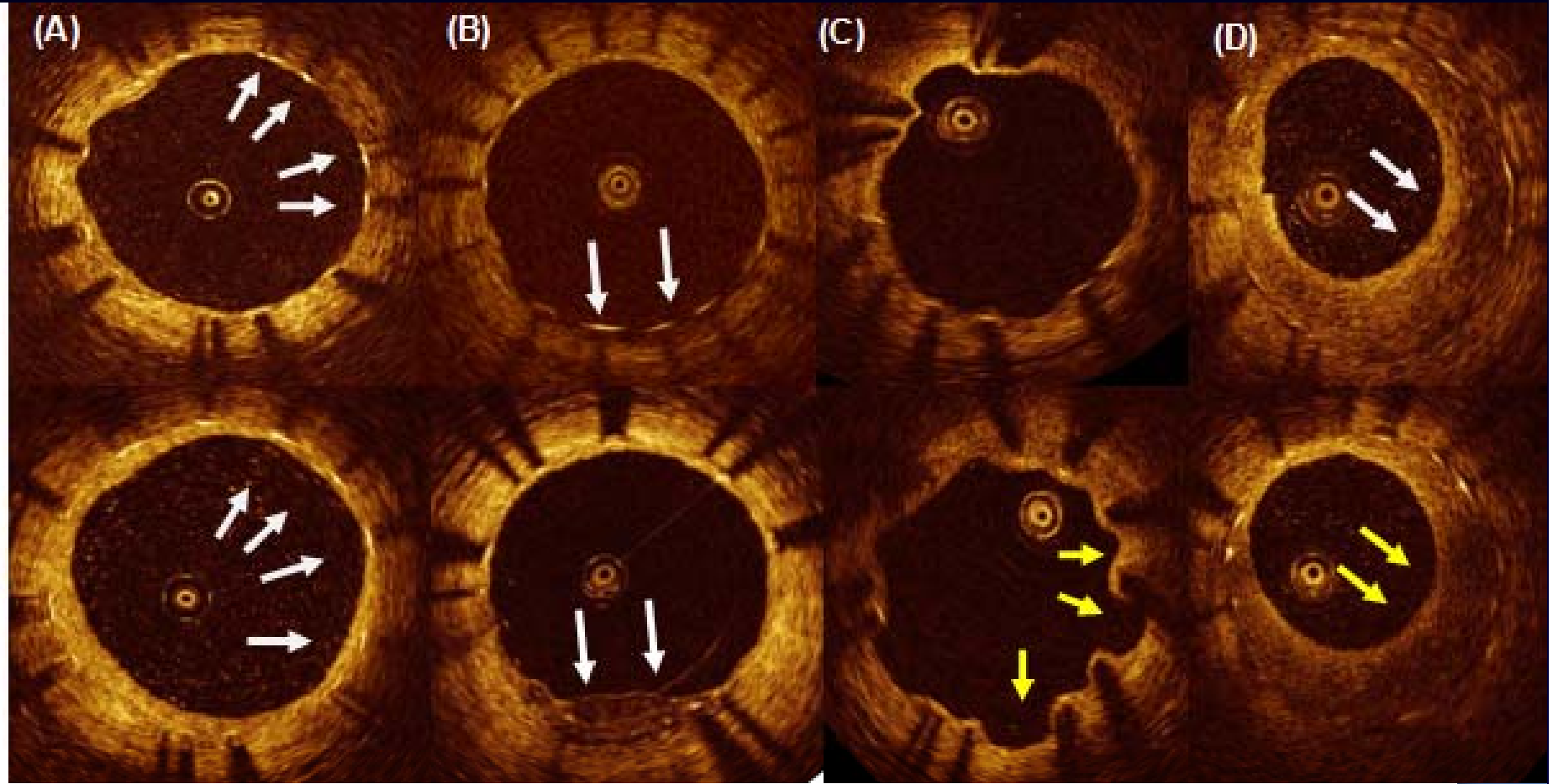
## Study population

From the OCT registry database of our institute, we identified 250 patients who underwent follow-up OCT examination at 9 months ( $\pm 3$  months) after DES implantation.

Among these patients, a second serial follow-up OCT examination at 2 years ( $\pm 3$  months) after stent implantation was performed in 72 patients with 76 stented lesions: 23 SESs, 20 PESs, 25 ZESs and 8 EESs.

9-month follow-up

2-year follow-up



## Quantitative OCT analysis

| <b>Cross-section (CS) level analysis</b>       | <b>9-month</b>     | <b>2-year</b>      | <b>p</b>         |
|------------------------------------------------|--------------------|--------------------|------------------|
| <b>Total cross sections</b>                    | <b>1947</b>        | <b>1947</b>        |                  |
| <b>Mean stent CSA (mm<sup>2</sup>)</b>         | <b>7.0 ± 1.6</b>   | <b>7.0 ± 1.6</b>   | <b>0.92</b>      |
| <b>Mean lumen CSA (mm<sup>2</sup>)</b>         | <b>5.7 ± 1.4</b>   | <b>5.4 ± 1.6</b>   | <b>0.01</b>      |
| <b>Mean NIH area (mm<sup>2</sup>)</b>          | <b>1.3 ± 0.9</b>   | <b>1.7 ± 1.1</b>   | <b>0.001</b>     |
| <b>Percent NIH CSA (%)</b>                     | <b>18.7 ± 11.3</b> | <b>23.4 ± 14.5</b> | <b>&lt;0.001</b> |
| <b>CSs with any uncovered strut</b>            | <b>418 (21.5%)</b> | <b>244 (12.5%)</b> | <b>&lt;0.001</b> |
| <b>CSs with uncovered strut ratio &gt; 0.3</b> | <b>153 (7.9%)</b>  | <b>91 (4.7%)</b>   | <b>&lt;0.001</b> |
| <b>CSs with any malapposed strut</b>           | <b>50 (2.6%)</b>   | <b>70 (3.6%)</b>   | <b>0.36</b>      |

## Quantitative OCT analysis

| <b>Strut level analysis</b>                          | <b>9-month</b>                 | <b>2-year</b>                   | <b>p</b>         |
|------------------------------------------------------|--------------------------------|---------------------------------|------------------|
| <b>Total strut number</b>                            | <b>19430</b>                   | <b>19475</b>                    |                  |
| <b>Mean NIH thickness (<math>\mu\text{m}</math>)</b> | <b>164 <math>\pm</math> 95</b> | <b>214 <math>\pm</math> 132</b> | <b>&lt;0.001</b> |
| <b>Percentage of uncovered struts</b>                | <b>787 (4.1%)</b>              | <b>468 (2.4%)</b>               | <b>&lt;0.001</b> |
| <b>Percentage of malapposed strut</b>                | <b>127 (0.7%)</b>              | <b>183 (0.9%)</b>               | <b>0.24</b>      |
| <b>Percentage of uncovered and malapposed struts</b> | <b>76 (0.4%)</b>               | <b>82 (0.4%)</b>                | <b>0.89</b>      |

# Serial OCT across side-branch

## 1<sup>st</sup> follow-up OCT at 9-month

|                                          | PES<br>(n=10)     | SES<br>(n=10)    | ZES<br>(n=10)   | P                 |
|------------------------------------------|-------------------|------------------|-----------------|-------------------|
| <b>Side branch vessel</b>                |                   |                  |                 |                   |
| Median no. of struts                     | 18(5~45)          | 17(4~39)         | 22(7~82)        | 0.524             |
| No. of uncovered struts                  | 15(5~42)          | 7(0~18)          | 4(0~23)         | 0.011             |
| <b>Percentage of uncovered struts, %</b> | <b>92(60~100)</b> | <b>39(0~100)</b> | <b>14(0~61)</b> | <b>&lt;0.0001</b> |
| Mean NIH thickness, mm                   | 0.02(0~0.15)      | 0.04(0~0.14)     | 0.05(0.01~0.22) | 0.168             |

# Serial OCT across side-branch

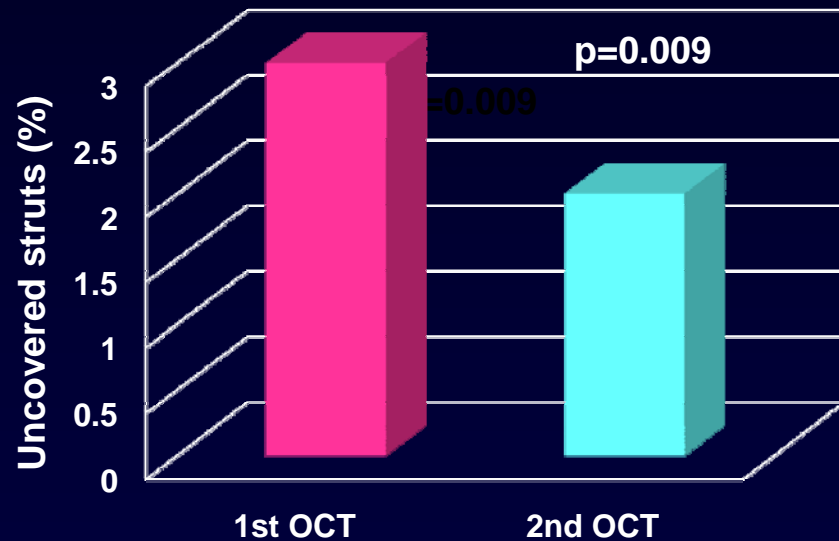
## 2<sup>nd</sup> follow-up OCT at 2-year

|                                          | <b>PES</b><br>(n=10) | <b>SES</b><br>(n=10) | <b>ZES</b><br>(n=10) | <b>P</b>     |
|------------------------------------------|----------------------|----------------------|----------------------|--------------|
| <b>Side branch vessel</b>                |                      |                      |                      |              |
| Median no. of struts                     | 13(5~36)             | 18(5~54)             | 19(2~93)             | 0.442        |
| No. of uncovered struts                  | 8(0~33)              | 6(0~20)              | 2(0~9)               | 0.052        |
| <b>Percentage of uncovered struts, %</b> | <b>82(0~100)</b>     | <b>26(0~59)</b>      | <b>5(0~44)</b>       | <b>0.001</b> |
| Mean NIH thickness, mm                   | 0.02(0~0.07)         | 0.05(0.02~0.14)      | 0.06(0.03~0.24)      | 0.021        |

# Change of uncovered struts grouped by serial OCT

N, 30

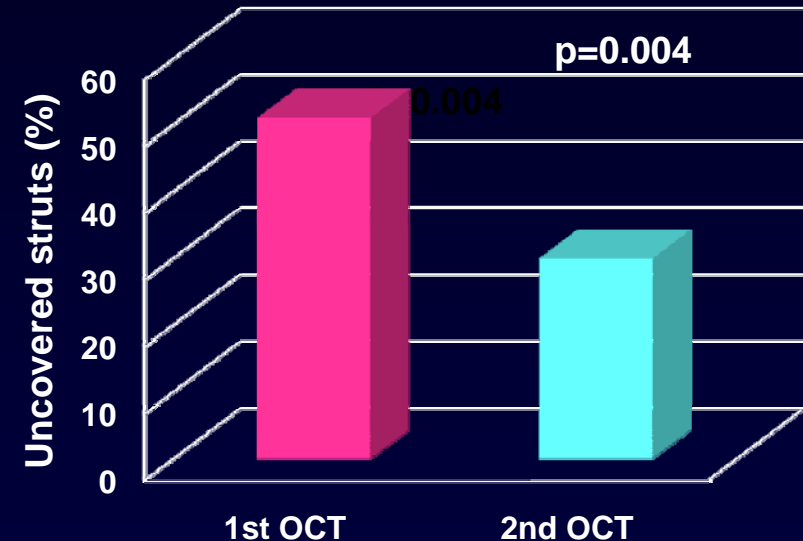
Main vessel



| Uncovered struts (%) | 1st OCT    | 2nd OCT    |
|----------------------|------------|------------|
|                      | 3 (0 ~ 26) | 2 (0 ~ 11) |

N, 30

Side branch



| Uncovered struts (%) | 1st OCT      | 2nd OCT      |
|----------------------|--------------|--------------|
|                      | 51 (0 ~ 100) | 30 (0 ~ 100) |

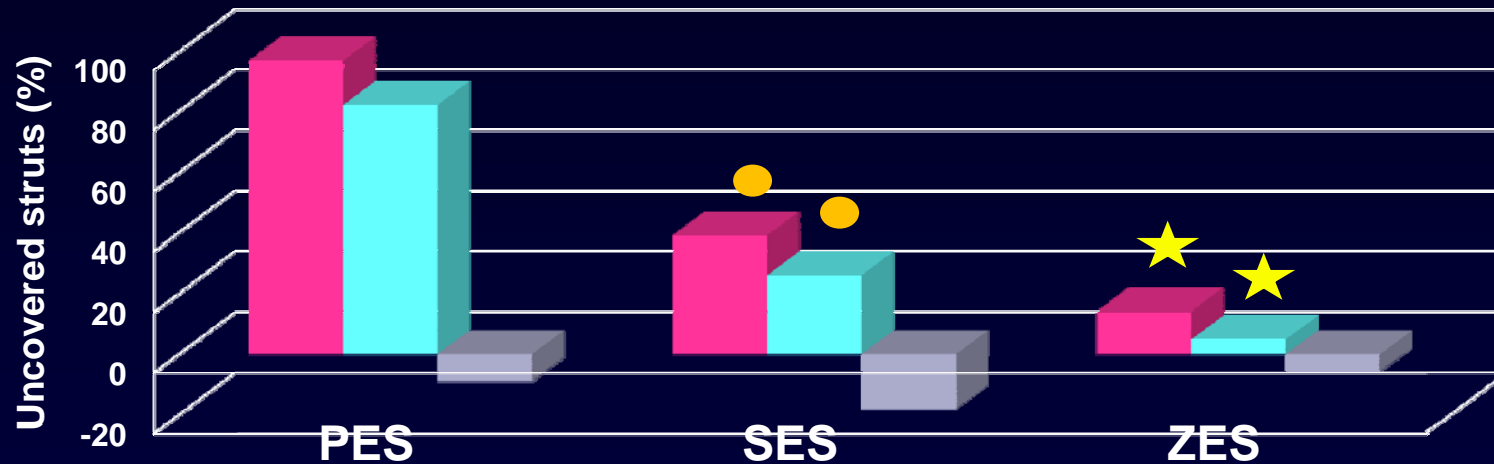


# Change of uncovered struts grouped by stent types

## Side branch

● P = 0.05

★ P = 0.028



|                | PES (N = 10)  | SES (N = 10)   | ZES (N = 10) |
|----------------|---------------|----------------|--------------|
| 1st OCT        | 92 (60 ~ 100) | 39 (0 ~ 100)   | 14 (0 ~ 61)  |
| 2nd OCT        | 82 (0 ~ 100)  | 26 (0 ~ 59)    | 5 (0 ~ 44)   |
| Net difference | -9 (-80 ~ 40) | -18 (-59 ~ 17) | -6 (-33 ~ 0) |

# Limitation

- **These studies were single center study with a relatively small population and might have a risk of selection bias.**
- **The detected neointima does not fully reflect an intact functioning endothelium.**
- **There were no data on clinical implications of neointimal coverage detected by OCT.**

# However.....

**After introduction of a frequency-domain OCT system (C7-XR) with faster pullback speeds (20 mm/s) in clinical practice, OCT examination could be a more useful and comfortable tools to evaluate the status of uncovered stent struts and stent malapposition.**

**I expect that clinical data to evaluate the impacts of uncovered or malapposed DES struts detected by OCT on long-term clinical outcomes will be available in near future.**