A Prospective Randomized Controlled Study Using Optical Coherence Tomography to Evaluate the Strut Coverage of Sirolimus-, Paclitaxel-, Zotalorimus-Eluting Coronary Stents For Long Lesions Requiring Overlapping

ODESSA-OCT for DES Safety

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ODESSA

Prospective, Randomized, Controlled Study

Long lesions (> 20 mm in length) requiring stents in overlap

77 pts /189 stents Randomization 2:2:2:1

2.4 ± 0.6 stent/lesion

Taxus	Cypher	Endeavor	Libertè BMS
N=22	*N=22*	*N=22*	*N=11*

*Primary end-point: proportion of stent struts uncovered and/or malapposed at overlap in OCT at 6 month (BMS vs DES and among DES) **

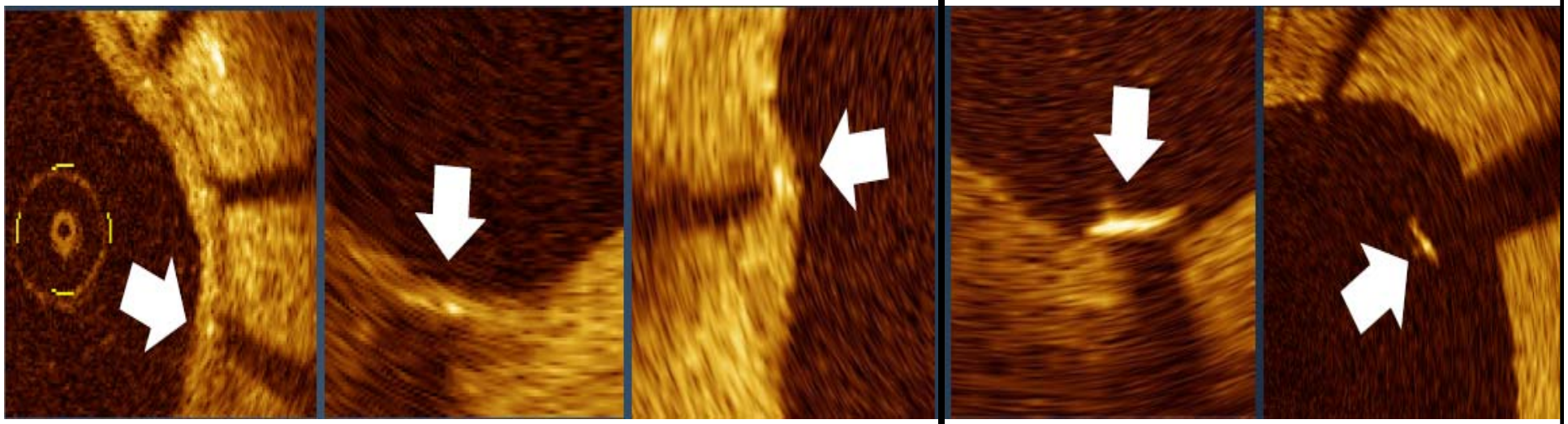
QCA, IVUS and OCT

*Independent Core Lab **BLIND** to the treatment assignment*

University Hospitals Cardialysis Cleveland, OH

* All patients in dual antiplatelet therapy

Primary End Points



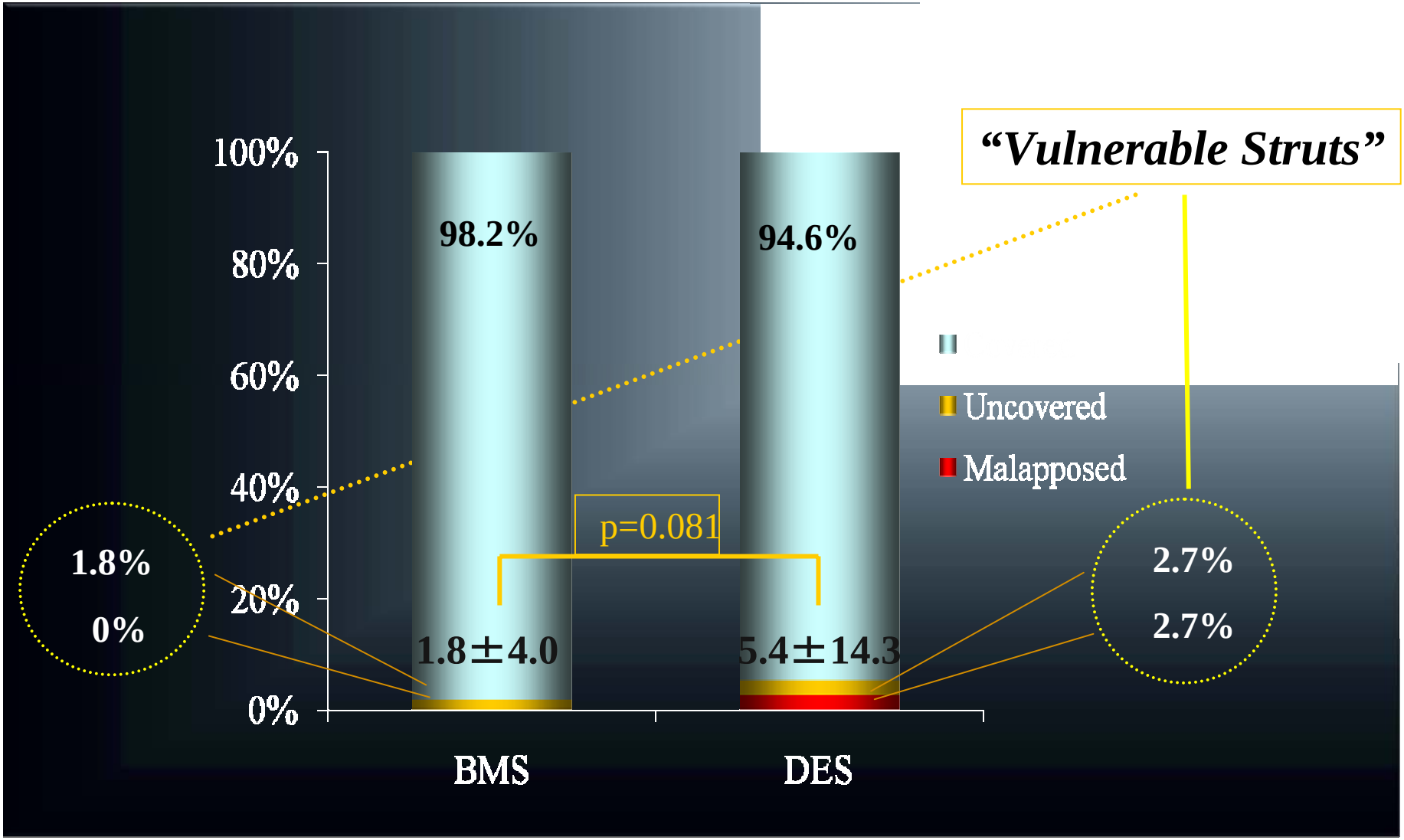
Embedded

Protruding
Covered

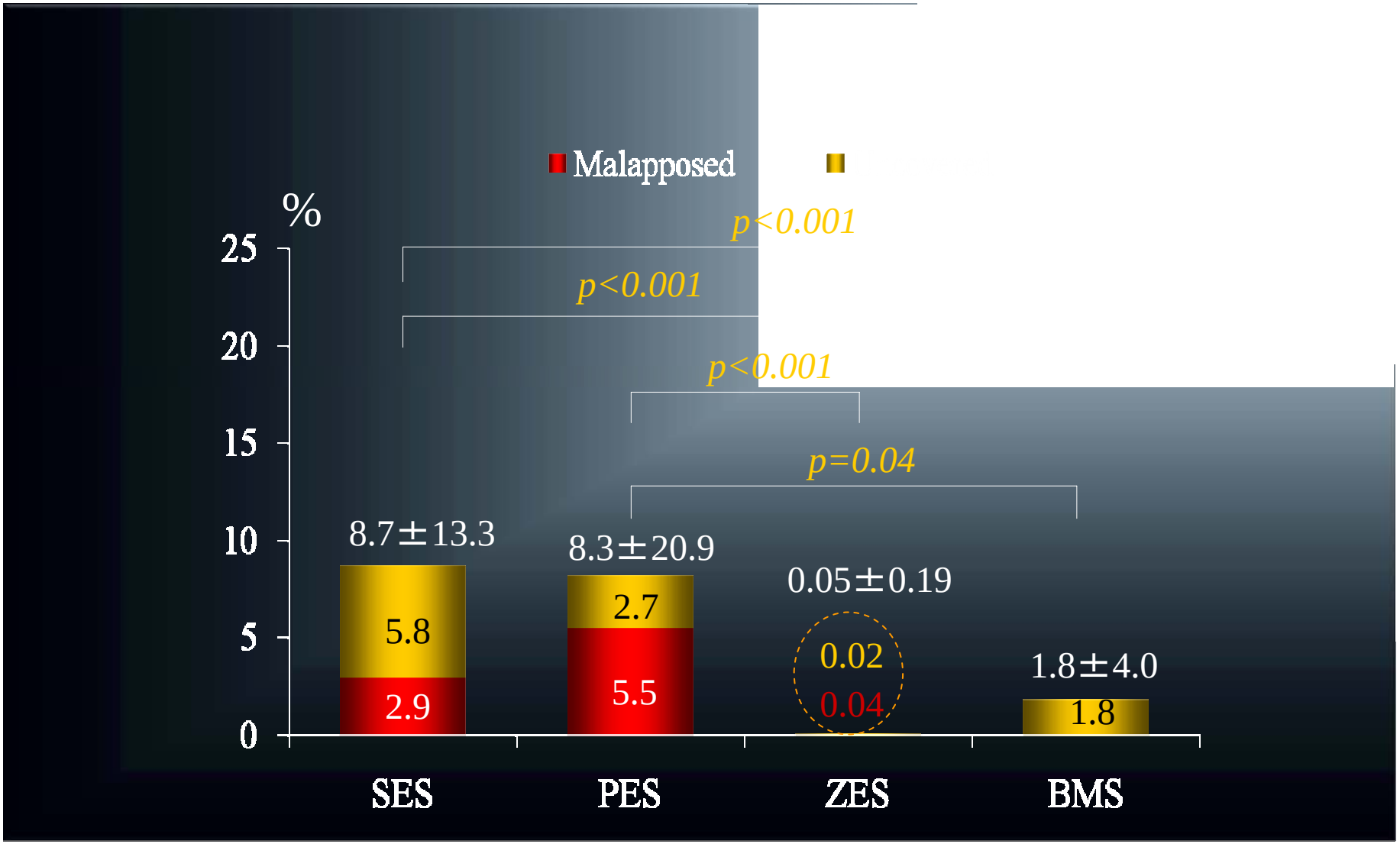
Protruding
Uncovered

Malapposed

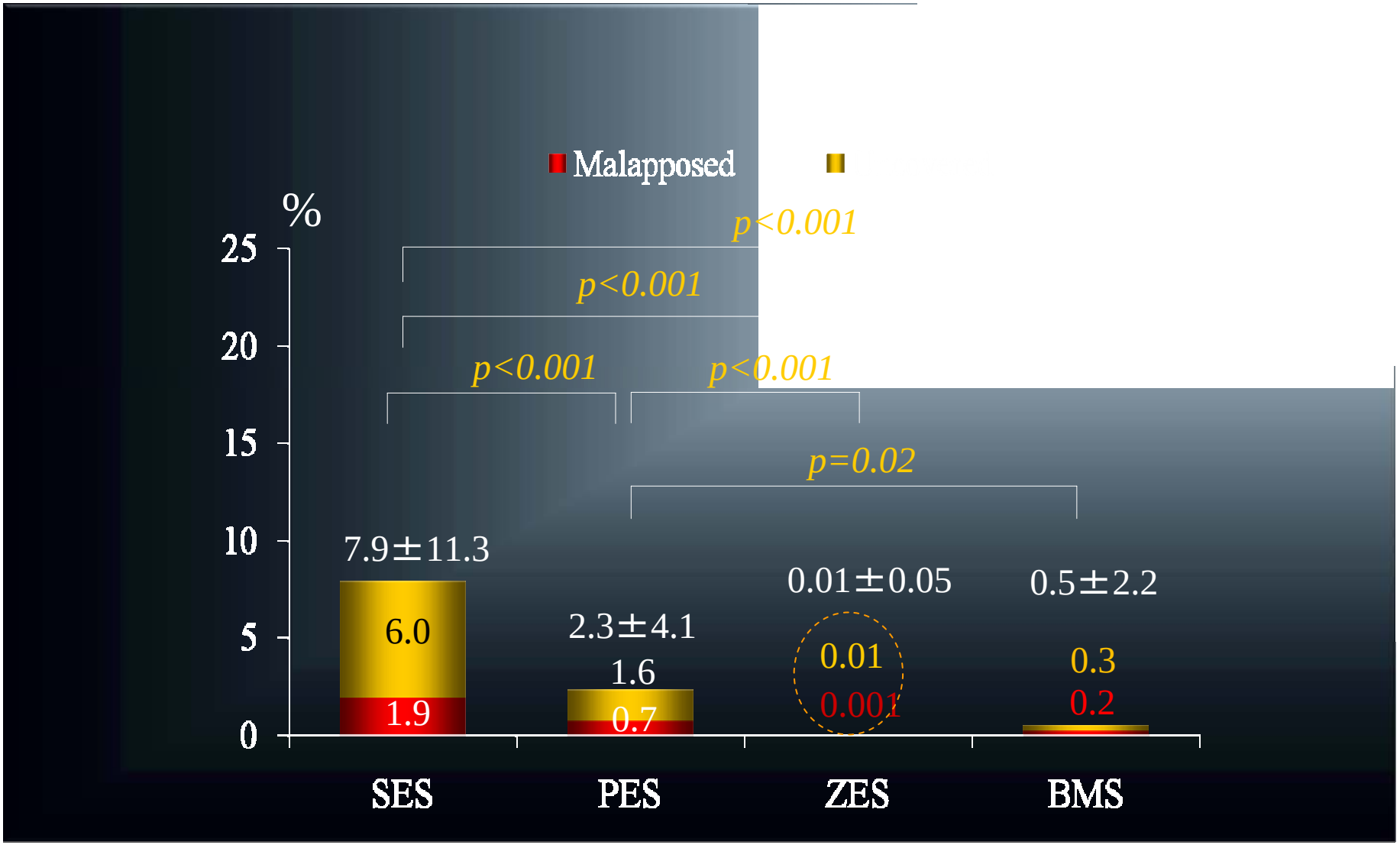
Primary Endpoint: Overlap Proportion of uncovered and/or malapposed struts in BMS vs DES



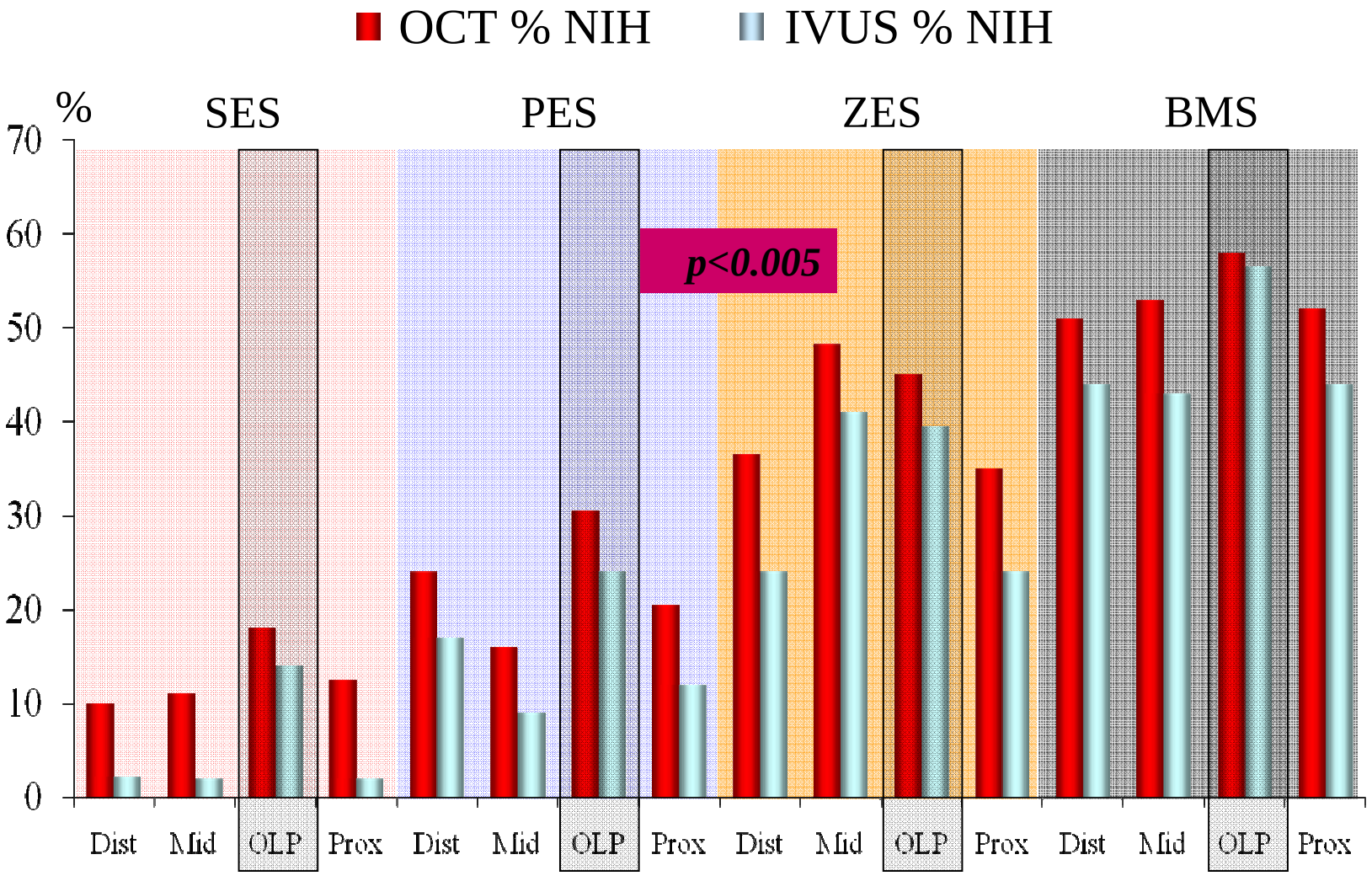
Secondary Endpoint: Overlap Proportion of uncovered and/or malapposed struts by stent type



Non-overlap Proportion of uncovered and/or malapposed struts by stent type



% Intimal Obstruction by Segments: OCT and IVUS



	SES	PES	ZES	BMS
Overlap length (mm)	3.6±1.8	3.1±1.9	3.8±2.2	3.9±4.0
% IH obstruction	19.3±14.1	31.5±14.3	45.2±16	57.8±25.2

Based on ANOVA test and Kruskal-Wallis test

Conclusions

The **ODESSA** trial demonstrated:

- Feasibility of using intravascular OCT in prospective clinical trials
- >90% strut coverage at 6-month follow-up
- Trend towards higher incidence of uncovered and malapposed struts at the OL site of DES than in BMS
- Different degrees of strut coverage and NIH among DES platforms:

SES : Highest rate of uncovered and malapposed struts ***(OL = non-OL)***
Lowest degree of NIH ***(OL> non-OL)***

ZES: Lowest rate (≈ 0%) of uncovered and malapposed struts (**OL = non-OL**)
Highest degree of NIH ***(OL> non-OL)***

PES: Higher incidence of uncovered and malapposed struts ***(OL> non-OL)***
Intermediate degree of NIH ***(OL> non-OL)***