

***Rapid Evaluation of Vessel HEaling after
AngiopLasty (REVEAL) Study: An Optical
Coherence Tomography Comparative Study Versus
Bare and Drug Eluting Stent at 7
and 30 Days***

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The REVEAL study

Rapid Evaluation of Vessel Healing After Angioplasty

Sponsor: CeloNova BioSciences Inc., Newnan GA, USA

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Ethical Committee: Azienda Ospedaliera V.E. Ferrarotto, S. Bambino

Clinicaltrials.gov identifier: NCT00799344

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Background

Stent thrombosis is likely to be due to **incomplete tissue coverage** of metallic stent struts

The contact between metallic stent struts and blood elements may lead to **platelet adhesion** and trigger vessel thrombosis

A **>0.3 uncovered to total stent struts ratio** is the best morphometric predictor of stent thrombosis

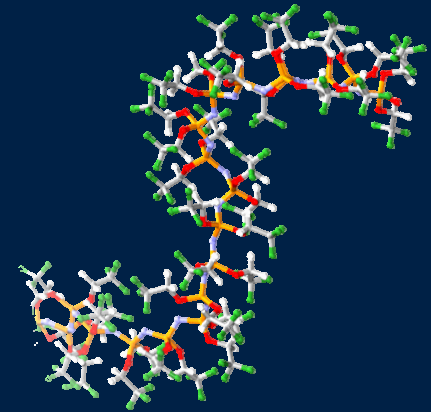
Background / 2

The **CATANIA[®] stent** is covered with a microfilm of Polyzene-F, a new polymer exhibiting anti-inflammatory action that promises to improve the process of vessel healing after stenting

Polyzene[®]-F Surface Modification

- **Anti-Inflammatory**
- **Bacterial Resistant**
- **Promotes Healthy Endothelial Cell Growth**

- Inorganic
- High Molecular Weight
- Ultra-Pure
 - Residual Chlorine < 0.003%
- Can Coat Multiple Substrates
- Applied on Stent at 40 Nanometers



Optical Coherence Tomographic Results at Six-Month Follow-Up Evaluation of the CATANIA Coronary Stent System

- 19,028 stent struts analyzed
- 95 (0.5%) non covered struts
- 29 (0.15%) malapposed struts

Optical Coherence Tomographic Results at Six-Month Follow-Up Evaluation of the CATANIA Coronary Stent System With NanoThin Polyzene-F Surface Modification (from the Assessment of The LAtest Non-Thrombogenic Angioplasty Stent [ATLANTA] Trial)

Alessio La Manna, MD^a, Davide Capodanno, MD^{a*}, Maria Cera, MD^b, Maria Elena Di Salvo, MD^a, Giorgio Sacchetta, MD^a, Thierry Corcos, MD^c, Francesco Prati, MD^b, and Corrado Tamburino, MD, PhD^a

images demonstrated neither occurrence of stent fractures nor thrombus. In conclusion, OCT assessment of the Polyzene-F–covered stent at follow-up showed a small percentage of neointima. Also, almost complete stent strut coverage was revealed by optical coherence tomography. These figures indicate that the CATANIA stent with Polyzene-F is a promising solution for decreasing late stent restenosis and preventing thrombosis. © 2009 Elsevier Inc. All rights reserved. (Am J Cardiol 2009;103:1551–1555)



Study endpoints

- Major Study Endpoint

Percentage of healed stent struts at 28-32 days, identified by the presence of an evenly apposed rim of tissue on stent struts and without apposition of thrombotic material between CATANIA stent and DES

- Secondary Study Endpoint

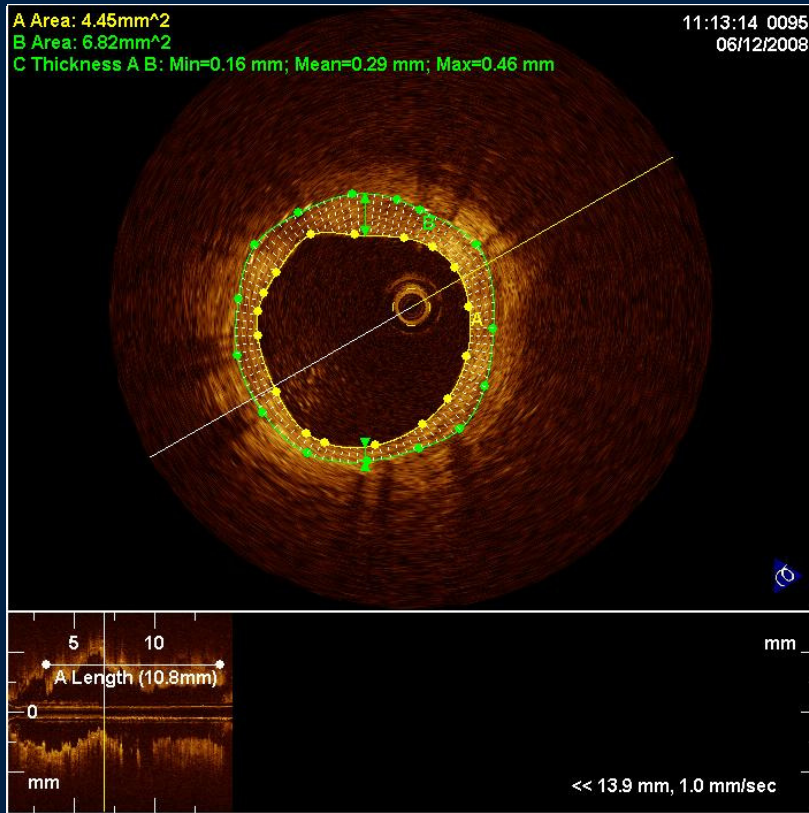
Percentage of healed stent struts in CATANIA stent versus DES at 7-10 days

Percentage of healed stent struts in CATANIA stent versus CoCr at 28-32 days

Percentage of healed stent struts in CATANIA stent versus CoCr at 7-10 days



Dedicated LightLab Imaging OCT workstation



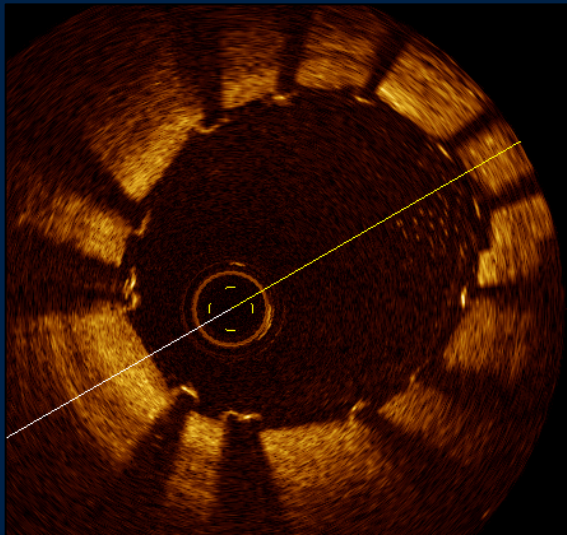
Qualitative and quantitative assessment of OCT images

All OCT frames have been digitally stored and **independently analyzed in a validated core laboratory** by a trained examiner (Rome Heart Research, Italy).

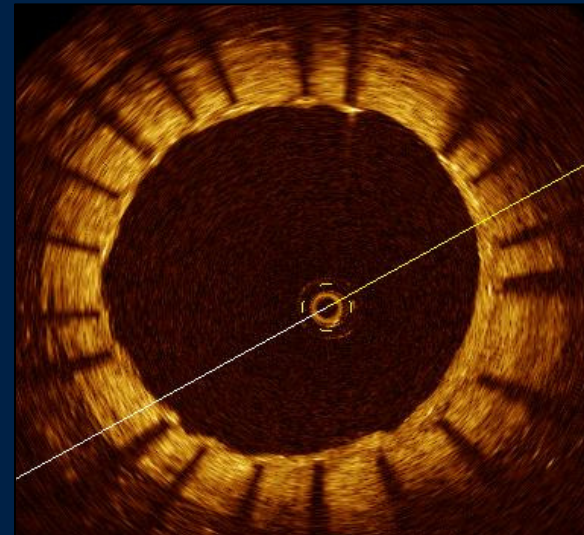
OCT ACQUISITION: Non occlusive.
Frame rate 15.6/sec. Speed 2 mm/sec

Frames with a sub-optimal visualization of stent struts (defined as the inability of OCT to address all stent struts in a specific cross-section) due to artifacts, have been discarded. Presence of sub-optimal stent visualization in more than 10% of stent struts was a reason for stent exclusion from analysis.

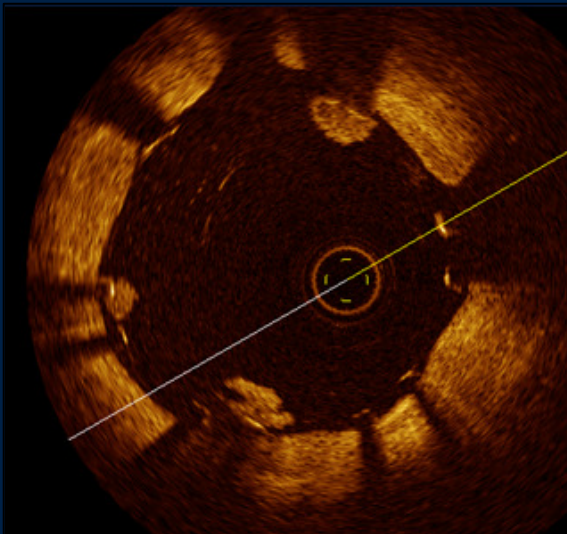
Uncovered struts



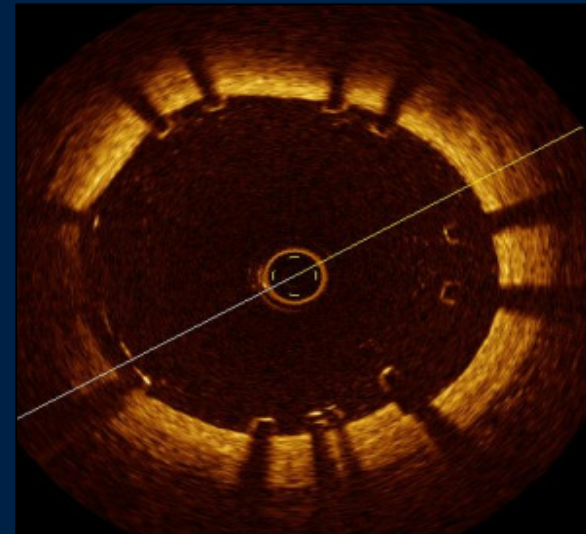
Covered struts



Covered struts with thrombus



Malapposed struts



Study design

Wave 1 OCT at 7-10 days

n = 10 patients with 2 significant short lesions (≤ 20 mm) located in the same or in remote vessels

n = 2 excluded
poor OCT images quality

n = 4
CAT vs DES

n = 4
CAT vs CoCr

Wave 2 OCT at 28-32 days

n = 24 patients with 2 significant short lesions (≤ 20 mm) located in the same or in remote vessels

N = 4 excluded
poor OCT images quality

n = 9
CAT vs DES

n = 11
CAT vs CoCr

**7-10 day follow up
15,624 analyzed stent struts**

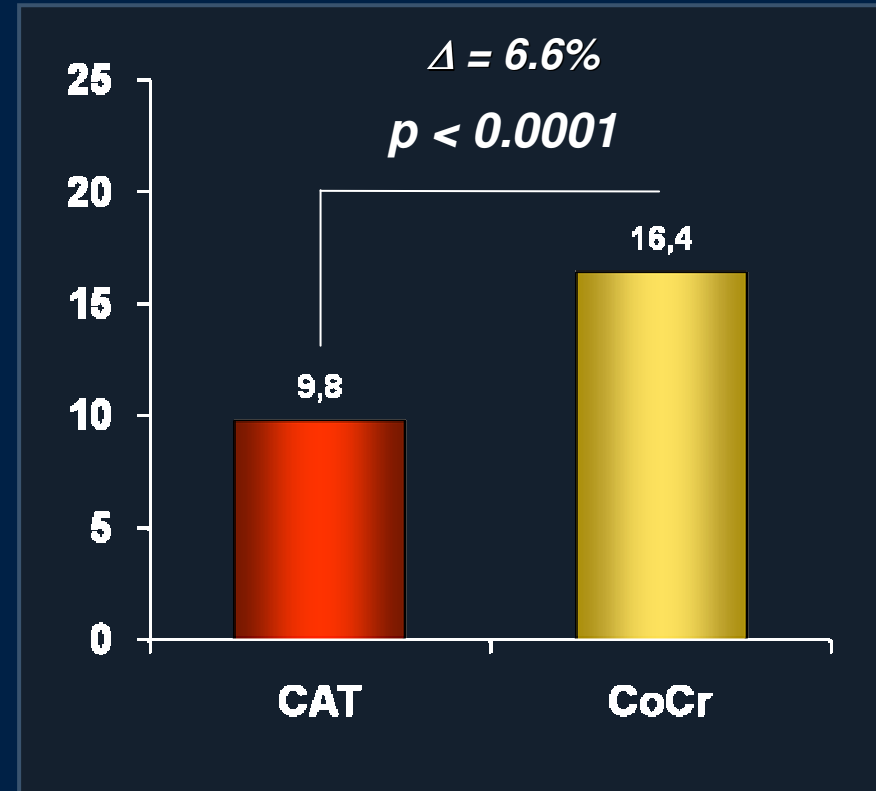
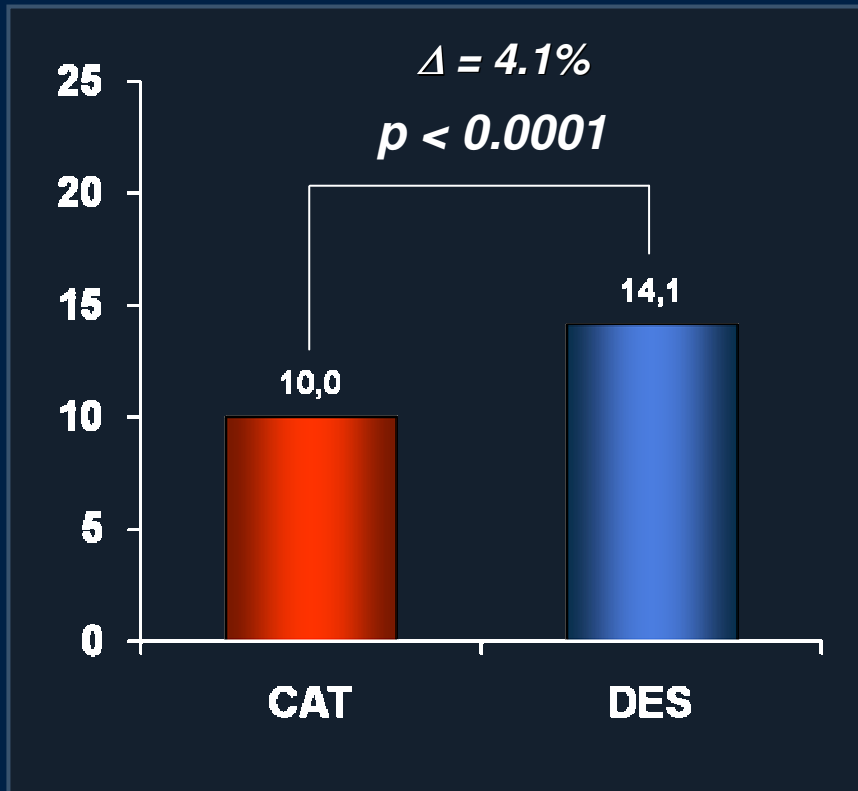


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7-day OCT follow up

Percentage of uncovered stent struts



**28-32 day follow up
45,408 analyzed stent struts**

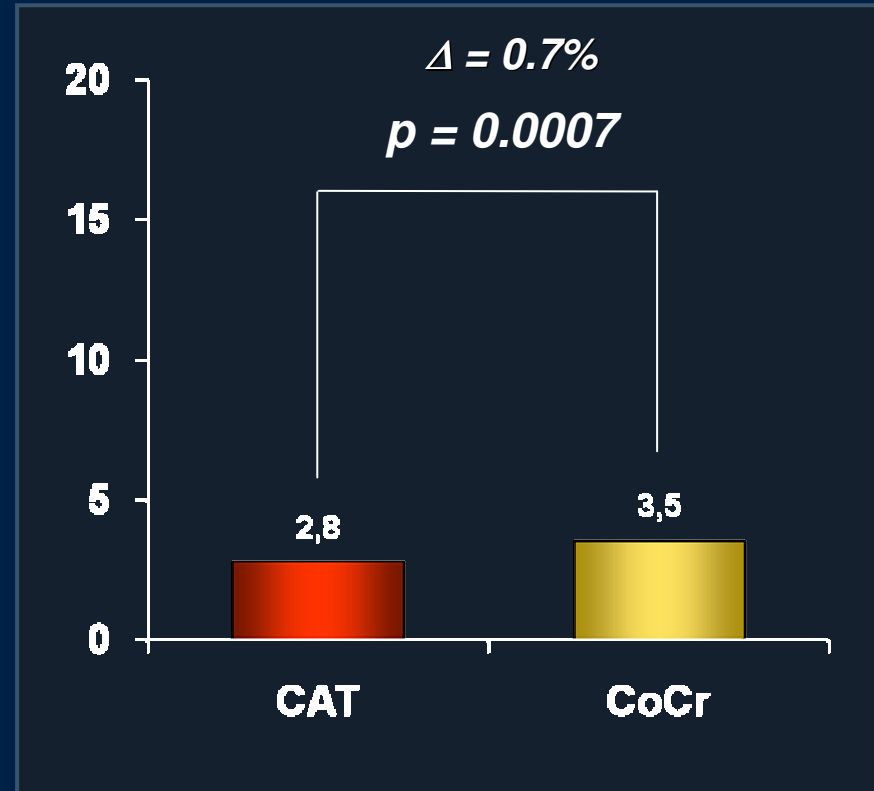
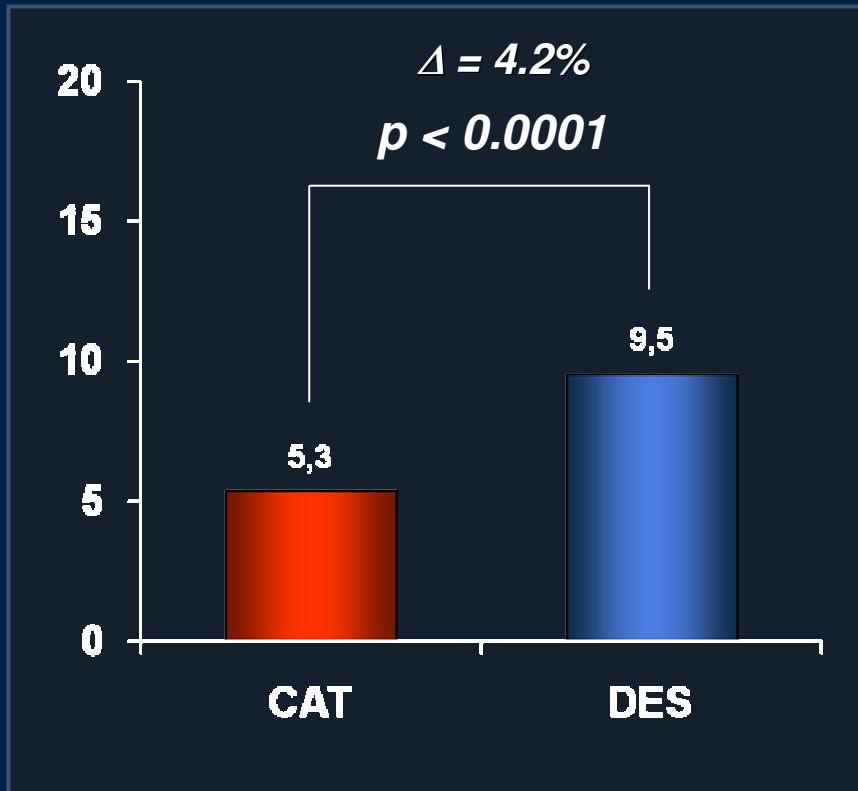


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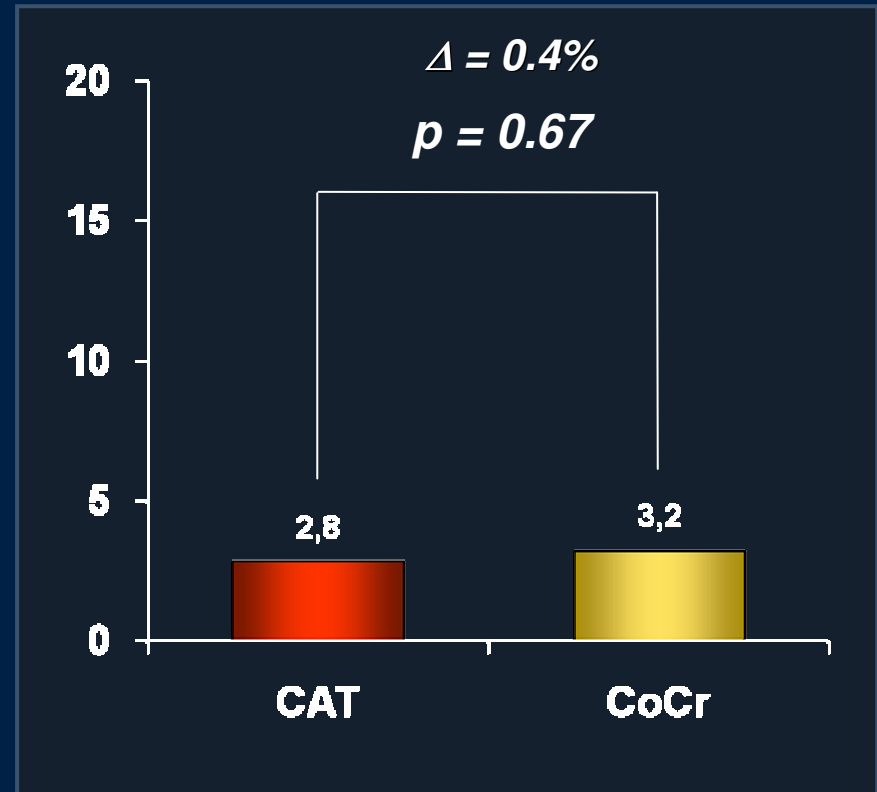
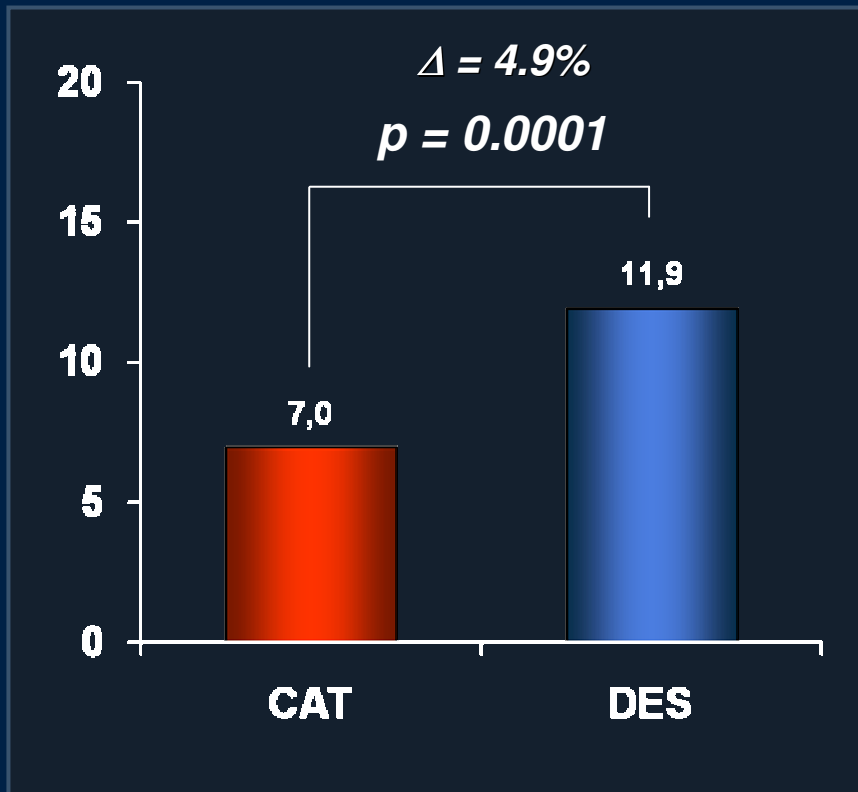
30-day OCT follow up

Percentage of uncovered stent struts

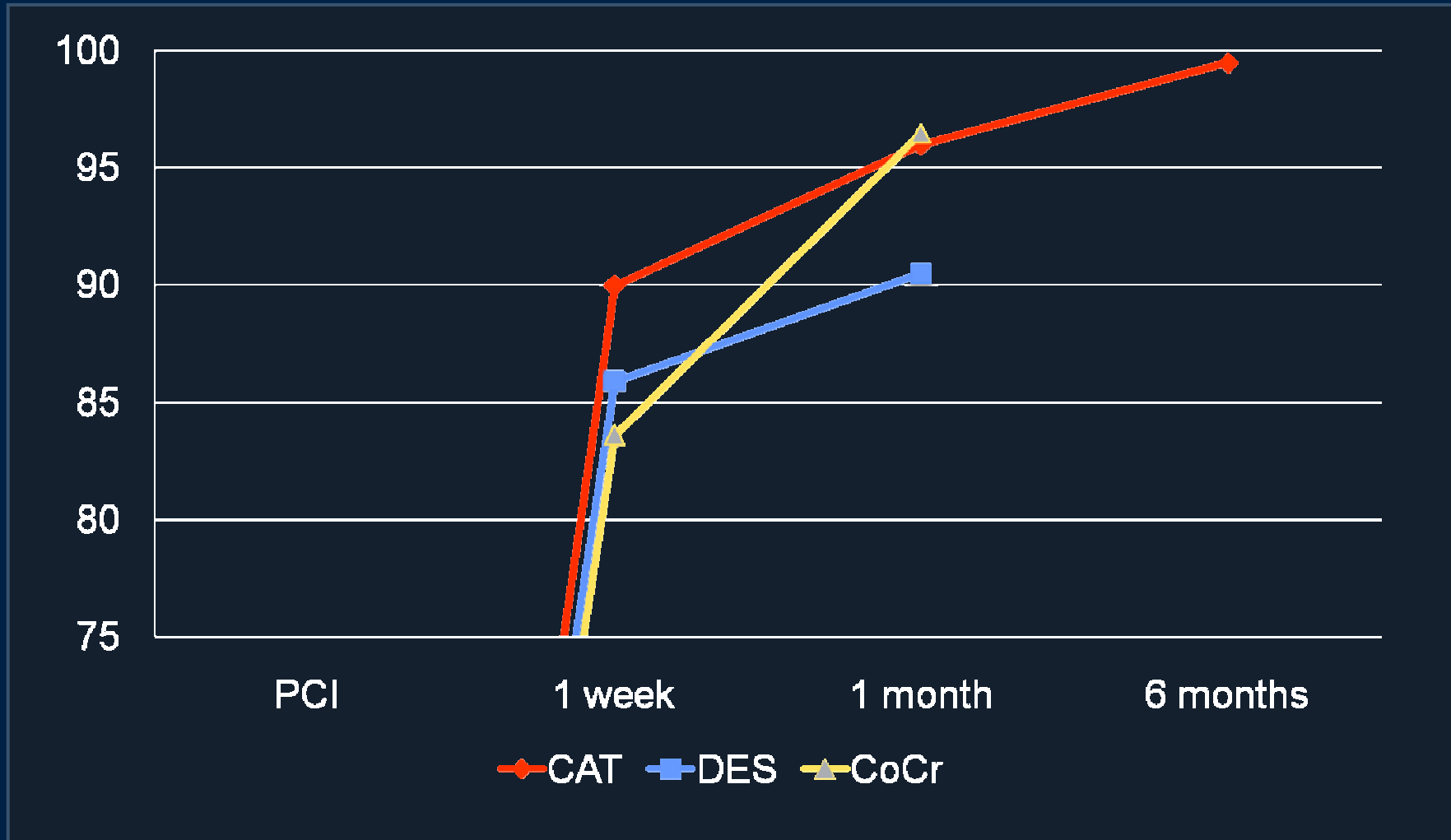


30-day OCT follow up

Percentage of cross sections with > 0.3 uncovered to total stent struts ratio



Timing of vessel healing



Conclusions

- 1) At 7 days CATANIA stent has a higher percentage of covered struts compared with DES and BMS
- 2) At 30 days in the CATANIA stent, the percentage of covered struts was considerable higher compared with DES and slightly higher compared with BMS

Take home messages

- 1) Healing of CATANIA stent is quick and almost complete at 1 week (~90%) and 1 month (~95%)
- 2) This may explain the very low rates of subacute stent thrombosis seen in the ATLANTA I (0%) and ATLANTA II (0.5%) studies