

# OCT – TRIAL: YUKON<sup>DES</sup> VS. CYPHER

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## **Study Title:**

An optical coherence tomography study to determine 90-day coronary stent coverage and luminal protrusion in polymer coated versus polymer free rapamycin-eluting stents.

## **Source:**

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## **Abstract:**

**Purpose:** Delayed stent strut coverage and healing are frequent findings in autopsy series of patients who have died from thrombosis of drug eluting coronary stents (DES). Polymeric coatings have been implicated in these processes. In vivo stent coverage is therefore a reasonable surrogate for stent safety. Luminal stent strut protrusion has not been widely investigated. Optical coherence tomography (OCT) has a resolution of <20 microns making it suitable for these applications.

**Methods:** We conducted a randomized trial in patients receiving DES to compare stent strut coverage and luminal strut protrusion in polymer coated (PCRES, Cypher) and polymer-free (PFRES, Yukon Choice DES, 2% coating) rapamycin-eluting coronary stents. Follow up was with OCT at 90 days. Stent strut coverage (% of struts covered), mean neointimal thickness (NIT), and luminal stent strut protrusion (% of struts protruding into the vessel lumen) were quantified.

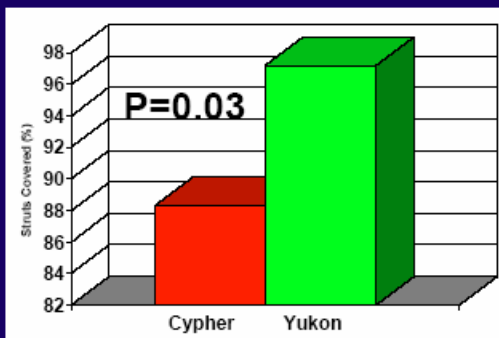
**Results:** Twenty-four patients (PFRES n=12, PCRES n=12) underwent stent deployment and had OCT follow-up at 90 days. No patient had angiographic restenosis. 5330 struts were analysed (PCRES 2465, PFRES 2865). Median stent strut coverage was 99.6% (PFRES) vs. 90.5% (PCRES) p=0.023. NIT was 219 µm (PFRES) vs. 77 µm (PCRES) p=0.016. Stent strut protrusion was 2.6% (PFRES) vs. 21.3% (PCRES) p=0.001. 3-Dimensional OCT reconstructions were generated.

**Conclusions:** This randomized OCT study indicated that at 90 days, the median NIT for the polymer coated RES was significantly less than for the non-polymer coated RES stent. However, this was at the cost of 10% of struts being uncovered compared with <0.5% with the PFRES and more than 20% of struts protruding into the vessel lumen compared with <3% with the PFRES. These findings may have important implications for thrombotic risk and future stent design.

# Results: Strut Coverage

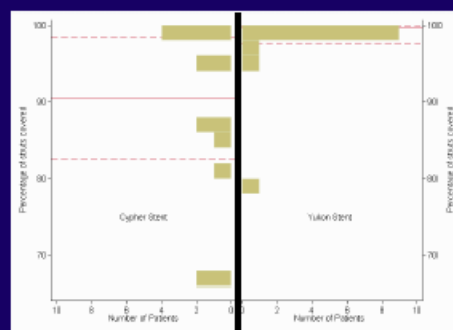
## Group Mean

Strut sections/Group Cypher n=2465 Yukon n=2865



## Patient

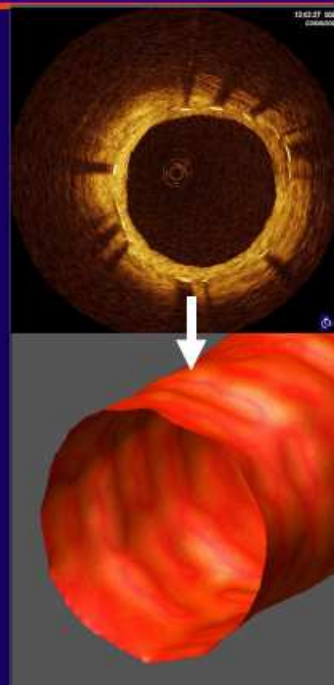
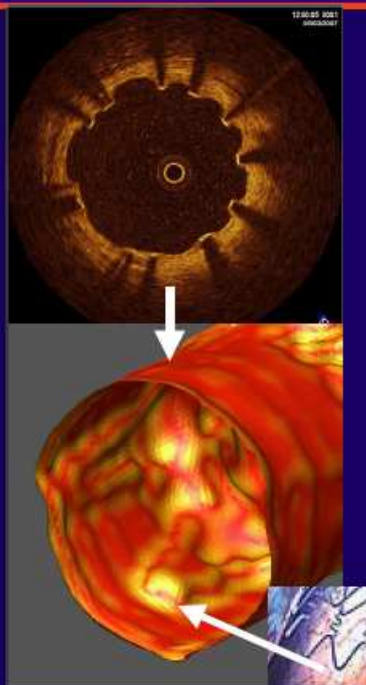
Strut sections/Patient: Cypher n=193 Yukon n=167



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# OCT and 3d reconstruction



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Comparison of Cypher (left) vs. polymer-free Yukon DES, 2%Rapamycin coating (right).