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VERY LONG-TERM (1 AND 2-YEAR) COMPARISON OF BIORESORBABLE VS. PERMANENT POLYMER LIMUS-ELUTING STENTS IN A PORCINE CORONARY ARTERY MODEL

i2 Poster Contributions
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Background: A Biolimus A9 self-expandable nitinol stent (BA9SES) stent was engineered with a permanent primer layer consisting of parylene and a bioabsorbable abluminal layer of polylactic acid (PLA) and Biolimus A9 (~22 µg/mm of stent length), in contrast to the permanent polymer-based, sirolimus-eluting Cypher.

Methods: BA9SES and Cypher stents were implanted in coronary arteries of Yucatan miniswine. Quantitative angiography and histopathology were examined at Day 7 (9+9), 30 (9+9), 90 (13+12) 180 (9+10), 1 year (9+8) and 2 Years (9+9).

Results: In a trend started at 90 days and sustained up to 2 years in this model, BA9SES appeared having consistently less neointimal formation in angiography than Cypher (1-year % Diameter Stenosis 6±8% in BA9SES, vs. 22±15% in Cypher; late loss -0.03±0.23 vs. 0.64±0.46mm). Similarly, the 365-day neointimal thickness by histology was higher in Cypher than in BA9SES (0.29±0.18 vs. 0.14±0.10mm). Higher prevalence of persistent inflammation, granulomas and chronic injury in Cypher over BA9SES contributed to difference in the amount of neointimal growth. This was despite equivalent and favorable long term outcomes in endothelialization and fibrin resorption. At 2 years, these angiographic and histologic differences were no longer significant but still discernible. Of note, at 1 and 2 years, BA9SES featured much higher percentage of struts with calcification, not evident at earlier time points and presumably a late resolution of PLA resorption.

Conclusions: The animal results suggest a sustained (2-year) advantage in healing pattern and biocompatibility for a technology combining a contemporary self-expandable stent design with drug elution off a bioabsorbable coating, when compared to first-generation, permanent polymer-based drug-eluting stent.