Completely Bioabsorbable Salicylate-Based Sirolimus-Eluting Stent: In-Vivo Intravascular Imaging in Pig Coronary Artery Implants

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Background: Recent advances in bioabsorbable stent technology have contributed to awakened interest in their role as alternatives to current metallic drug-eluting stents. We sought to evaluate a novel, fully bioabsorbable sirolimus-eluting stent (SES) synthesized entirely from salicylic-acid polymer, in a clinically relevant animal model.

Methods: Bioabsorbable balloon-expandable stents (n=32) were implanted in pig coronaries using quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS) to optimize stent apposition. Dose density of sirolimus was 8.3 μg/mm stent length with *in-vitro* studies demonstrating elution over 30 days and complete stent degradation in 9-12 months. Animals underwent QCA and IVUS restudy and were terminated at 7, 14, 30, 90, and 180 days for histologic assessment. Optical coherence tomography (OCT) was also performed for the 90- and 180-days samples.

Results: All stents were deployed successfully without notable mechanical difficulties. No edge dissection or vasospasm was observed during implant. No stent migration was observed at any time. Angiographic diameter stenosis (DS) was 20±16%, 24±4%, and 23±17%, at 1, 3, and 6 months, respectively. In parallel, IVUS showed good apposition of the stent to the vessel wall with DS of 21±9%, 25±7%, and 18±3%; and area stenosis (AS) of 35±13%, 33±7%, and 32±4% at 1, 3, and 6 months, respectively. OCT demonstrated good apposition of the stent with DS of 28±7% and 20±6%, and AS of 37±10% and 33±13% at 3 and 6 months, respectively. OCT showed reduction of stent thickness by 23% from 3 to 6 months. Histologic analysis confirmed these in-vivo findings and revealed a favorable healing process of absorbable stent incorporation into the arterial wall, without excessive thrombotic or inflammatory reactions.

Conclusions: This study shows favorable vascular compatibility and efficacy for a novel fully bioabsorbable salicylate-based SES. This device has good mechanical performance during deployment and stays well-apposed to the vessel wall at long term follow-up. These initial results are highly encouraging and support progress into more extensive preclinical studies as well as early clinical testing.