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Fully Bioabsorbable Salicylate-Based Sirolimus-Eluting Stent: Evaluation of Stent Degradation by Optical Coherence Tomography

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Background: Fully biodegradable stents is an attractive alternative strategy for current permanent metallic stents.
Aim: We evaluated a novel, fully bioabsorbable sirolimus-eluting stent (8.3µg/mm stent) synthesized entirely from salicylic-acid polymer in a clinically relevant animal model.
Methods: Bioabsorbable balloon-expandable stents (n=33) were implanted in pig coronaries using QCA to optimize stent apposition. Animals underwent restudy and terminated at 1M, 3M, 6M, 9M, and 12M. Thickness and area of each strut (implantation: 1273 struts, 1M: 640 struts, 3M: 585 struts, 6M: 625 struts, 9M: 530 struts, and 12M: 319 struts) were measured by OCT and Intensity of each strut was measured as well.
Results: Average strut thickness and area at 1M were similar to post implantation (implant: 0.25mm and 0.14mm2; 1M: 0.26mm and 0.12mm2). Strut Thickness and area gradually decreased over time (3M: 0.23mm and 0.09mm2; 6M: 0.186mm and 0.07mm2, 9M: 0.179mm and 0.066mm2, 12M: 0.158mm and 0.055mm2, respectively, P<0.0001). On the other hand, OCT signal intensity gradually decreased from 1M to 3M (1M: 6.06W, 3M; 5.92W, P<0.001) and then increased gradually from 3M to 6 M (6M: 6.16W, P<0.001). However, there were no significant differences between 6M, 9M, and 12M in terms of signal intensity (P=0.51 and P=0.31, respectively).
Conclusions: Degradation of a novel fully bioabsorbable salicylate-based stent was demonstrated very well by OCT. The size of this stent was remarkably decreased from 1M to 3M, 6M, 9M, and 12M. However, remarkable changes of signal intensity were not observed from 6M to 9M and 12M.