Stent Degradation Assessment by Serial Optical Coherence Tomography of Completely Bioabsorbable Salicylate-Based Sirolimus-Eluting Stent

Daisuke Matsumoto [1], Nicolas Chronos [1], Keith Robinson [1], Refat Jabara [1,2]

[1] *Cardiovascular Research Institute, Saint Joseph's Hospital, Atlanta, GA, USA,* [2] *Heart Institute, Hadassah-Hebrew University Medical Center, Jerusalem, Israel*

Background: Fully biodegradable stent is an attractive alternative strategy for current permanent metallic stents. We evaluated a novel, fully bioabsorbable sirolimus-eluting stent (8.3μg sirolimus/mm stent) synthesized entirely from salicylic-acid polymer in a clinically relevant animal model.

Methods: Bioabsorbable balloon-expandable stents (n=21) were implanted in pig coronaries using QCA to optimize stent apposition. In vitro studies demonstrated sirolimus elution over 30 days and complete stent degradation in 9-12 months. Animals underwent restudy and terminated at 1 month (1M), 3 month (3M), and 6 month (6M). Thickness and area of each strut (implantation: 1273 struts, 1M: 689 struts, 3M: 585 struts, and 6M: 292struts) were measured. Brightness of struts was semiquantitatively classified into 3 groups: 1) high 2) moderate 3) low signal intensity with or without clear strut border.

Results: Average strut thickness and area at 1M was similar to post implantation (implant: 0.27±0.025mm, 0.14±0.018mm2, 1M: 0.26±0.002mm, 0.12±0.002mm2, respectively, P=NS,). Strut Thickness and area gradually decreased over time (3M: 0.230±0.002mm and 0.093±0.002mm2, P<0.0001; 6M: 0.227±0.003mm and 0.085±0.002mm2, respectively, P<0.0001). OCT signal intensity was decreased with higher frequency of unclear border at 6M (P<0.01).

Conclusions: Degradation of a novel fully bioabsorbable salicylate-based stent was demonstrated by OCT. The size of this stent was remarkably decreased from 1M to 3M and 6M.