

OCT Assessment of Fully Bioabsorbable Salicylate Based Drug Eluting Stent 540 Days Post Implantation

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Background: The BTI stent is a unique fully bioabsorbable sirolimus-eluting stent synthesized entirely from salicylic acid polymer derivatives. We sought to assess this stent (8.3µg sirolimus/mm) with optical coherence tomography (OCT) up to 18 month post implantation.

Methods: 93 bioabsorbable balloon-expandable stents were implanted in pig coronaries using QCA to optimize stent apposition. Animals underwent restudy at 1 month (1M), 3 month (3M), 6 month (6M), 9 month (9M), 12 month (12M), 15 month (15M), and 18 month (18M). Stent area, lumen area, strut thickness and strut area were measured by OCT.

Results: Though stent strut area could not be measured due to nearly disappearance of stent struts after 12M, stent struts maintained sufficient area up to 12M (1M: 6.50 mm² vs. 3M: 6.40 mm², P=0.76, 3M vs. 6M: 6.55mm², P=0.62, 6M vs. 9M: 6.76 mm², P=0.52, 9M vs. 12M: 5.96 mm², P=0.05). In contrast lumen area was significantly increased from 3M to 6M (3M: 2.58 mm² vs. 6M: 3.29 mm², P<0.05) and then maintained sufficient area over time (6M vs. 9M: 3.74 mm², P=0.13, 9M vs. 12M: 3.39 mm², P=0.30, 12M vs. 15M: 3.97 mm², P=0.08, 15M vs. 18M: 4.25 mm², P=0.44). Average strut thickness and area measured by OCT at 1M was similar to post implantation (implant: 0.25mm, 0.14mm², 1M: 0.26mm, 0.121mm²), then gradually decreased over time (3M: 0.23mm and 0.093mm²; 6M: 0.19mm and 0.070mm², 9M: 0.18mm and 0.066mm², 12M: 0.16mm and 0.055mm², 15M: 0.15mm and 0.053mm², 18M: 0.13mm and 0.021mm², respectively, P<0.05). 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: A novel fully bioabsorbable salicylate-based stent maintains lumen area and didn't show acute and/or chronic recoil during long term follow up. Furthermore, OCT demonstrated gradual degradation of this stent which was remarkably decreased from 1M to 18M.