

A Third Generation Ultra-Thin Strut Cobalt Chromium Stent: Histopathological Evaluation in Porcine Coronary Arteries

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Objectives: The present study was designed to evaluate a novel 'third-generation' bare-metal stent (BMS) comprised of an ultra-thin-strut, cobalt-chromium platform with fixed geometry, uniform cell size, and superior surface finish in a porcine coronary artery model.

Methods: A total of 47 BMS of two types were implanted in pig coronary arteries using QCA to optimize stent apposition: a commercially available cobalt alloy thin-strut stent (91µm) as control (Driver; n=17), and an ultra-thin-strut (65µm) cobalt-chromium stent (Protea; n=18).

Animals underwent angiographic restudy and termination 1-week and 1-month post-implant for coronary artery histology. In addition, 12 overlapping Protea stents were analyzed at 1-month.

Results: At 1-week, comparable thin neointima and mild inflammation were observed in both groups. At 1-month, Protea demonstrated significantly lower angiographic % stenosis (2±1% vs. 17±5%, p=0.006), intimal thickness (0.11±0.01mm vs. 0.23±0.03mm, p=0.003), and histologic % area stenosis (19±2% vs. 32±3%, p=0.003). Mean stent strut injury scores were low and similar between groups. Angiographic % stenosis, intimal thickness, and histologic % area stenosis of overlapping Protea stents were 3±1%, 0.13±0.01mm, and 22±2%, respectively, and similar to the single Protea group. Stable fibrocellular neointimal incorporation, with complete endothelialization and minimal inflammation, were observed at 1-month in all stents, including overlapped Protea segments.

Conclusions: When compared to a commercially-available cobalt alloy BMS, the new third-generation Protea stent demonstrated favorable coronary arterial response with significant reduction of neointimal formation in the porcine model. Our results support the notion that apparently small improvements in basic but fundamental aspects of the BMS technology can result in actual biological benefits and ultimately pave the way to better DES platform.