

## **ew Cobalt-Chromium Ultra-Thin Strut Stent: Feasibility, Vascular Compatibility and Safety Evaluation in Porcine Coronary Arteries**

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**Background:** Stent-strut thickness is related to in-stent restenosis. Therefore, modern bare-metal stents (BMS) with lower strut thickness are in development. We sought to evaluate a new 'third-generation' BMS comprising an ultra-thin-strut, cobalt-chromium platform with fixed geometry and uniform cell sizes, in a clinically relevant animal model.

**Methods:** 36 BMS of two types were implanted in pig coronaries using quantitative coronary angiography (QCA) to optimize stent apposition: a commercially available cobalt alloy thin-strut stent (91 $\mu$ m) as control (n=18), and an ultra-thin-strut (65 $\mu$ m) cobalt-chromium stent (Protea CoCr; n=18). Animals underwent angiographic restudy and termination 1-wk and 1-mo post-implant for coronary artery histology. In addition, 12 overlapping Protea CoCr stents were analyzed at 1-mo.

**Results:** All stents deployed without difficulties. Thin neointima and mild inflammation was seen in both groups at 1-wk. For 1-mo, QCA % diameter stenosis was significantly less for Protea CoCr (2 $\pm$ 5% vs. 17 $\pm$ 16%, p=0.032). By histomorphometry, intima thickness (0.11 $\pm$ 0.05mm vs. 0.23 $\pm$ 0.11mm, p=0.003) and % area stenosis (19 $\pm$ 1% vs. 32 $\pm$ 11%, respectively, p=0.004) were also significantly lower for Protea CoCr. The strut injury score was low and similar between the two groups. QCA % stenosis; intima thickness; and % area stenosis of overlapping Protea CoCr were 3 $\pm$ 3%, 0.13 $\pm$ 0.02mm, and 22 $\pm$ 4%, respectively. Stable fibrocellular neointimal incorporation of all stents including overlapped Protea CoCr, with complete endothelialization and minimal inflammation, was seen at one month.

**Conclusions:** Protea CoCr showed favorable arterial response with significant reduction of neointima formation compared to a commercial cobalt alloy BMS, one month post implant in pig coronary arteries. This ultra-thin-strut stent platform therefore appears to be a suitable and attractive alternative to current BMS. Combining the lower levels of neointima formation, fixed geometry, and uniform cell size, the Protea CoCr may be a preferred platform for next-generation drug-eluting stents.