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## OCT and histopathological pre-clinical evaluation of an enhanced polytetrafluoroetylene-covered stent in a peripheral swine animal model: addressing the anatomical challenges of the lower limb stenting procedure

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THEME: Peripheral Interventions

TOPIC(S): Below the knee, Iliac / Femoral / Popliteal, Other peripheral interventions

## AIMS

We aim to evaluate the performance and vascular response of a novel, high flexibility, high biocompatibility peripheral covered stent in a porcine restenosis model.

## METHODS AND RESULTS

Six domestic swine were included in this study (45±1 kg). Based on angiographic QVA, the superficial femoral arteries were randomized for either the implantation of a Solaris (Scitech, Sao Paulo, Brazil) or Fluency (Bard, Tempe, AZ) 40 mm long stent grafts with 110% overstretch. Subsequently, animals were followed for 30 days. At terminal imaging, all stents were evaluated with optical coherence tomography (OCT), explanted and subjected to stent integrity analysis and histopathological evaluation. A total of 11 stents were evaluated (Solaris n=6, Fluency n=5). Solaris stent demonstrated improved deliverability when compared to the reference stent graft. At 30 days, OCT revealed a similar stent area for both groups (Solaris 25.8±4.7 vs Fluency 24.7±5mm2; p=0,7). There was a trend toward higher lumen area in the Solaris stent (18±4.2mm vs Fluency 13.9±3.4mm2;p=0.11) as a consequence the neointimal hyperplasia was lower as expressed as lower percentage stenosis in the study group (Solaris 31.9±7 vs Fluency 44.8±6%; p). The integrity analysis of the stents via radiographs revealed no fractures in any stent from either group. The results of the histopathological evaluation will be presented in the meeting.

## CONCLUSIONS

The Solaris PTFE-covered peripheral stent demonstrated a resistance to fracture with increased flexibility and navigability and better conformability to artery curvature. The release system allowed for an accurate geographical delivery and the components of the device produced a lower OCT morphometrically-assessed neointimal response when compared to the control group.

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