SERIAL OPTICAL COHERENCE TOMOGRAPHY MORPHOMETRIC ASSESSMENT OF THE NOVEL STANZA™ BIORESORBABLE VASCULAR SCAFFOLD IMPLANTED IN SUPERFICIAL FEMORAL ARTERIES IN A PRE-CLINICAL SHEEP MODEL

Poster Contributions
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Background: Metallic stent implantation in superficial femoral artery (SFA) stenosis poses concerns in terms of impaired restoration of vascular biology and extrinsic compressions. Bioresorbable scaffolds (BS) may overcome these limitations while keeping the benefits of stenting. STANZA™ is a self-expanding BS composed of PLGA and elastomer that resorbs one year after implantation. Optical coherence tomography (OCT) delivers high-resolution imaging. We aim to present serial OCT assessments of this novel BS in a sheep model.

Methods: Single 7.0 x 40 mm BS were implanted in the SFA or the profunda artery of 15 non-diseased sheep followed by index OCT. Different animals were assigned for OCT at 3- (n=5), 6- (n=5), and 9-month (n=5) follow-up (Fig. 1). At baseline, scaffold expansion and structural changes were assessed. Strut coverage, changes in lumen and scaffold dimensions, and neointimal hyperplasia (NIH) were assessed at follow-up.

Results: At baseline, scaffold overexpansion was 105.13 ± 7.62% with good structural integrity. Complete coverage of scaffold struts and maintained deployed diameter (101.40±10.70%) were revealed at 3-months. NIH was mild and stable with reduction over time (6.69±2.23, 6.25±1.12, and 5.60±1.13mm², respectively at 3-, 6-, and 9-months, p<0.0001).

Conclusions: In a pre-clinical peripheral vascular model, serial OCT assessments of STANZA™ BS revealed thin and stable NIH coupled with complete scaffold coverage and maintenance of scaffold’s structural integrity.