Conclusions: The tested SES showed an antiproliferative efficacy similar to control SES and EES, and significantly less restenosis than BMS. All DES showed equivalent levels of low endothelialization and higher fibrin score than BMS, although the injury and inflammation scores were similar in all groups.

TCT-796
Safety and efficacy of different paclitaxel-eluting balloons in a preclinical model
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Background: The drug-eluting balloons (DEBs) have demonstrated a high anti-proliferative and antithrombotic efficacy in the treatment and prevention of restenosis. Nevertheless, not all the available devices are equally effective; so, the comparison of the results in all the available devices is equally relevant. Our objective is to assess the preclinical efficacy and safety of different DEBs.

Methods: In 17 domestic swine (25±3 kg), we implanted 51 Cobalt-Chromium metallic stents (Architect®, iVascular, Spain), one stent per major coronary artery. Stent postidilation was performed with different balloons to achieve high stent-artery ratios (1.21 ± 0.14). We used bare control balloons (n=10), Test1 (DEB Essential, iVascular; n=15), Test2 (Modified Essential -more hydrophilic matrix, iVascular; n=10), and commercial DEBs (In.Pact Falcon®, Medtronic, USA; n=10). Restenosis values (%diameter stenosis, late loss by angiography, and %area stenosis, neointimal area by histomorphometry) and vascular healing parameters (injury score, endothelialization rate, fibrin and inflammation scores) were analyzed at 28 days.

Results: All the DEBs showed similar stenosis values at follow-up, significantly lower than bare controls: angiographic, 9.1±2 vs 34.1±18 (p<0.0001); histomorphometric, 22.5±8 vs 51.1±18 (p<0.0001). The injury (0.6±0.5) and inflammation scores (0.8±0.3) were uniformly low in all the groups. As a marker of the pharmacologic effect, we observed lower values of endothelialization rate (87±10 vs 99.2±2%; p=0.0007) and higher fibrin scores (2.1±0.7 vs 0.4±0.5; p<0.0001) in all the DEB groups than in controls.

Conclusions: In this preclinical model, the analyzed DEBs showed a significant reduction in restenosis as compared with control balloons after stent implantation. No data of increased injury score or persistent inflammation was observed, but the delayed endothelialization and fibrin accumulation suggest a response to the drug deposition.

TCT-797
Vascular healing after AXERA™ Access and Closure: a 30 day histopathological assessment in the ovine model.

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Background: Conventional Seldinger access has been the standard of care for over 60 years. It is performed at a relatively steep 45° angle that results in relatively high axial tension in the artery wall; this in turn theoretically impedes closure of the access site. A novel technology, AXERA® (Arstasis, Redwood City), creates a shallow angle arteriotomy that significantly increases the tissue overlap within the cannulated track. By taking advantage of the patient’s own arterial pressure and the much lower axial tension, Axera provides a degree of self-sealing. This animal testing was designed to address whether or not the longer, shallower access track increases risk of dissection or pseudoaneurysm or potentially impedes healing.

Methods: AXERA and control (Seldinger access) arteriotomy were performed on contralateral femoral artery vessels in seven sheep. The vessels were examined histologically 30 days postoperatively after step sectioning through the entire arteriotomy. Histologic sections collected at each level of approximately 200 microns were stained by H&E and modified Movat pentachrome.

Results: Creation of the arteriotomy site was successful for both methods in all 14 arteries. There was no evidence of vascular aneurysms or ecstasia, medial dissection, or luminal thrombosis. Vascular healing in both groups was mainly characterized by transmural deposition of proteoglycan with infiltrating smooth muscle cells accompanied by varying degrees of neangiogenesis. Inflammation was generally minimal to mild with rare giant cells. Mild to moderate calcification, mostly involving the media, was noted in 6 arteries from 4 of 7 animals (3 Axera, 3 control) and is likely inherent to this pre-clinical model of injury. Advanced healing in both groups was indicated by the absence of fibrin and near complete endothelial coverage.

Conclusions: The data indicate that healing after AXERA access is similar to standard Seldinger access technique with no evidence of dissection or pseudoaneurysm. This study histologically reaffirms the safety profile of the Axera device evidenced by the clinical results of the SECURE II and RICTAL trials.

TCT-798
Anatomical Effect on Left Atrial After Transcatheter Left Atrial Appendage Devices: Watchman and Amplatzer Cardiac Plug in a Canine Model

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Background: Watchman (WM, Boston Scientific, Natick, MA) and Amplatzer Cardiac Plug (ACP, St. Jude Medical, St. Paul, MN) are the most commonly used LAA closure devices in patients with non-valvular atrial fibrillation. WM has a para-chute shape designed to sit within the ostium of the LAA. The ACP has a disc and lobe design, utilizing the disc to cover the LAA os. The impact of both devices on local anatomy as well as healing response following placement ex vivo and in vivo in a canine model at 28 days was evaluated.

Methods: WM (21mm) and ACP (16mm) devices were implanted in an adult canine heart ex vivo to evaluate device surface area and conformation to the LAA. Both devices (n=3/group) with 10% larger than the LAA os in size were deployed in six adult dogs under TEE and fluoroscopic guidance and histology analyzed at 28 days.

Results: WM conformed to the LAA os without intrusion of left upper pulmonary vein (LUPV) and mitral valve (MV), and was seated tightly in the LAA os. Space from either inferior or superior edges to the MV (in-mto-MV, measured 9.3±1.2 mm) and LUPV (sup-to-LUPV) allowed room for ablation. In comparison, the disc of the ACP clearly extended to both the LUPV and MV. In vivo, the in-mto-MV from the disc of ACP extended beyond the mitral leaflet, and its sup-to-LUPV impinged into the lateral ridge beneath the LUPV, potentially limiting access for other procedures (eg. pulmonary vein isolation). On histology, both devices were covered by mature collagen fibrosis with internate areas of early-organized fibrin and thrombus. The surface of WM inclusive of the threaded insert was completely endothelialized, but the inferior edge and end-screw hub of the ACP disc were uncovered. WM had a greater granulation tissue response and less fibrin deposition than ACP, while ACP had a greater inflammatory response.

Conclusions: These data demonstrate that conformation to the LAA and surrounding structures is different between WM and ACP LAA closure devices, and may have an effect on and the healing response following placement. Due to the design of the WM device, it does not obstruct or impact adjacent structures.

TCT-799
Direct Visualization of Pulmonary Vein Ablations within Reanimated Swine Hearts to Investigate Recent Advances in Cryo-balloon Technologies

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Background: The use of cryo-balloon ablation for pulmonary vein (PV) isolation has led to questions as to how best to optimize single procedure success. Specifically, what factors can be used to better determine ideal ablation durations as well as the best catheter orientations and catheter placements in the PV antra. Here we present unique data obtained by observing PV antral cryo-balloon ablation under direct vision.