examined at 1 (n=19 devices), 3 (n=21), 6 (n=21), 12 (n=21), 18 (n=19), 24 (n=19), 30 (n=20), 36 (n=32) and 42 mo. (n=21) by bright field microscopy or scanning electron microscopy (SEM) (110 BVS and 71 XV). In addition, pharmacokinetics and gel permeation chromatography (GPC) analysis were performed at various time points.

**Results:** Vascular responses to BVS and XV were largely comparable at all time points, with struts being obscured in neointima. SEM confirmed rapid endothelial coverage by 1 mo. in both BVS and XV implanted arteries. Inflammation was minimal to mild for both devices, though from 12 to 36 mo. mean scores were greater for BVS. Pharmacokinetics revealed a similar drug release profiles for BVS and XV. Drug elution, fibrin deposition was similar between BVS and XV at 1 mo. and rapidly decreased or was absent beyond 3 mo. Histomorphometry showed positive remodeling in BVS-implanted arteries that started beyond 12 mo. Similarly, histomorphometric changes of BVS dismantling were observed beyond 12 mo., and by 36 mo., resorption sites (pre-existing struts) of BVS were poorly discernible from the surrounding neointima. GPC analysis confirmed that degradation of BVS could be considered complete by 36 mo. Additional histochromic staining demonstrated infiltration of proteoglycans and collagen between acellular homograft hyaline material in resorption sites of BVS beginning beyond 12 mo. with resorption sites being near completely composed of connective tissue by 42 mo.

**Conclusions:** BVS demonstrates comparable safety to XV in porcine coronary arteries with positive remodeling, minimal inflammation, and near complete degradation at 36 mo.

**TCT-811**

**Stem Cell Viability Significantly Reduced After Passing Through a Standard Single Lumen Over-the-Wire 0.014” Balloon Angioplasty Catheter**

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**Background:** Intravascular infusion of stem cells has typically been administered through a standard single lumen, over-the-wire (OTW) 0.014” balloon catheter. These catheters are not optimized for stem cell delivery, can compromise stem cell viability and potential clinical efficacy.

**Methods:** A Mesenchymal Stem Cell (MSC) solution with cell concentration of 2.5x10^6/ml was infused through a standard single lumen over-the-wire (OTW) 0.014” balloon catheter during balloon inflation at 6, 8, 10 and 12 atmospheres (atms) at a flow rate of 1ml/min and during balloon inflation at 8 and 12 atm at flow rate of 4ml/min. MSC samples were tested using trypan blue for viability before and after passing through the standard balloon catheter wire lumen.

**Results:** Physical measurement of the inner lumen demonstrated collapsing of the wire lumen during balloon inflation. Infusing through the catheter at a flow rate of 1ml/min, cell viability decreased from (97.5% to 91.7%), (95.7% to 94.1%), (94.9% to 86.0%), (97.9% to 76.7%) at 6, 8, 10, and 12 atm respectively. When flow was increased to 4ml/min, the cell survival decreased from (92.3% to 62.0%) and from (91.3% to 60.8%) at 8 and 12 atm respectively.

**Conclusions:** A standard single lumen, over-the-wire (OTW) 0.014” angioplasty balloon catheter can decrease stem cell viability and potentially affect the clinical outcome of stem cell therapy.

**TCT-813**

**A Novel Method for Evaluation of Polymer Absorption from Sirolimus Eluting Stent and its Influence on Biological Effects**

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**Background:** Although many biodegradable polymer based technologies are widely used and tested in the clinical settings, still there is lack of data showing degradation kinetics of a polymer in vivo. The aim of this preclinical analysis was an evaluation of sirolimus kinetics and biodegradable polymer (BP, poly-lactic acid) absorption from the surface of drug eluting stent using a novel nuclear magnetic resonance (NMR) method.

**Methods:** In 18 domestic swine 18 BP only coated stents (BPS) and 36 biodegradable polymer sirolimus eluting stents (BP-SES) where implanted with 110% offset. The animals were sacrificed at 1, 3, 7, 14, 28 and 56 days follow-up (9 segments per time point). Vessel segments with BPS were harvested to evaluate polymer degradation with a novel NMR method, whereas BP-SES to test sirolimus tissue uptake and retention. In the NMR method a cryoplatform and cryoprobe were used to optimize observation of resonance signals in H-1 NMR spectrum. The lactide molecules as an internal standard were used to confirm quantity of polymers on stent surface. Sirolimus pharmacokinetic analysis was performed with the use of standard liquid chromatography (HPLC) method in order to check its correlation with BP absorption as the polymer degradation and drug release should run almost in parallel during the first four days after stent implantation.

**Results:** The NMR method showed a gradual absorption of the polymer over the six consecutive time points, from 5.48 µg of the polymer on the stent at 1 day follow-up, through 4.33 µg at 3 days, 3.16 µg at 7 days, 2.42 µg at 14 days, 1.92 µg at 28 days and 1.24 µg in the last day of the study. In addition this method showed a good correlation with widely used and standardized HPLC method for sirolimus elution.

**Conclusions:** The novel NMR method for BP absorption kinetics evaluation is a useful tool which may be widely adopted to test other biodegradable applications. Further, it may substantially improve their safety and efficacy by facilitating programmed polymer and drugs elution. The polymer degradation pattern will be essential in designing a study with the aim to shorten double antiplatelet therapy.