Methods: e-MISAGO enrolled more than 3000 patients treated with the Misago stent in 94 European centers. All clinical data collected through an EDC platform are fully monitored and all reported serious adverse events are independently adjudicated. Primary safety (at 30 days) and efficacy endpoint (at 1 year) match the VIVA criteria.

Results: Patients (68% male) were 67 ± 10 years old, 63% were smokers, 36% had diabetes mellitus (36% IDDM), 46% had hypercholesterolemia and 76% arterial hyper-tension. Patients had history of previous coronary artery disease in 32% of the cases and 14% previous myocardial infarction. Claudication and symptomatic ischemia concerned 99% and 96% of the patient population. Mean lesion length was 64.5 ± 59.0 mm, with reference vessel diameter 6.5 ± 1.3 mm. Mean lesion stenosis was 88.6 ± 12.4% and 43.3% of the lesions were totally occluded. On average 1.2 ± 0.5 vessels per patient were treated with 1.2 ± 0.45 stents per lesion. At baseline mean ABI was 0.59 ± 0.22 and mean Rutherford score was 2.51 ± 1.31. At 12 months ABI improved in 81% patients and the mean increased to 0.85 ± 0.24; Rutherford score improved in 76% patients with mean value of 0.72 ± 1.16. The overall composite adverse events rate of death, amputation, and revascularization was 9.7%.

Conclusions: The interim results from the e-MISAGO registry indicate promising device performance of the Misago RX nitinol stent at 1 year.

TCT-170
Vascular Injury Influences Drug Transfer and Vessel Healing Following Paclitaxel Coated Balloon Delivery in the Peripheral Arteries of Swine
Maxwell Afari1, Taylor Palmieri1, Armando Tellez2, Piotr Buszman1, TCT-170
revascularization was 9.7%.

Methods: A total of 19 PCB (Covatance, Medrad, Inc, Indiana, PA) were inflated in the iliofemoral territory of 8 domestic swine targeting a 1.2/1.1 balloon to artery ratio (BAR). All arteries were harvested at either 14 (n = 9) or 30 (n = 10) days for the evaluation of tissue paclitaxel levels and histology. Based on the histological injury scores, all vessel segments were classified into IEL-raptured (IEL-R) or IEL-nuanced (IEL-N).

Results: A total of 19 iliofemoral arteries were included in the analysis. The IEL-R group had a higher BAR (1.44 ± 0.08) compared to the IEL-NR (1.34 ± 0.11, p = 0.1). At 14 days, the median concentration of paclitaxel in the IEL-R group (1.25 μg/g) was higher than in the IEL-N group (465 μg/g, p = 0.13). However, the % area of stenosis was comparable among both groups at 14 and 30 days (see table). At 30 days, Paclitaxel tissue levels were comparable among both groups, Tissue paclitaxel scoring scores were consistently higher in the IEL-R group compared to the IEL-N group at both 14 and 30 days (see table).

Conclusions: The degree of mechanical injury induced by balloon dilatation seems to influence short-term drug transfer and long-term vessel healing following PCB use. The implications of these findings on clinical outcomes deserve further evaluation in the human setting.

<table>
<thead>
<tr>
<th>Follow Up</th>
<th>IEL</th>
<th>Balloon to Artery Ratio</th>
<th>Fibrin Score</th>
<th>Mean Inflammation Score</th>
<th>Area Stenosis (%)</th>
<th>Median Concentration (μg/g)</th>
</tr>
</thead>
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<tr>
<td>15 Days</td>
<td>Yes</td>
<td>1.44 ± 0.08</td>
<td>0.00 ± 0.00</td>
<td>1.26 ± 0.5</td>
<td>5.34 ± 1.39</td>
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<td>No</td>
<td>1.34 ± 0.11</td>
<td>1.74 ± 0.15</td>
<td>0.74 ± 0.45</td>
<td>5.78 ± 2.25</td>
<td>465.00</td>
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<tr>
<td>p value</td>
<td></td>
<td>0.10 ± 0.001</td>
<td>0.13 ± 0.13</td>
<td>0.75 ± 0.13</td>
<td>0.13 ± 0.13</td>
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<tr>
<td>30 Days</td>
<td>Yes</td>
<td>1.61 ± 0.26</td>
<td>1.78 ± 0.83</td>
<td>1.00 ± 0.05</td>
<td>11.43 ± 4.46</td>
<td>79.60</td>
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<tr>
<td></td>
<td>No</td>
<td>1.39 ± 0.25</td>
<td>1.07 ± 0.12</td>
<td>0.67 ± 0.49</td>
<td>18.71 ± 10.45</td>
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<tr>
<td>p value</td>
<td></td>
<td>0.06 ± 0.11</td>
<td>0.13 ± 0.13</td>
<td>0.10 ± 0.06</td>
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</tbody>
</table>

TCT-172
Drug-Coated Balloon for Peripheral Arteries: Results from preclinical experiments using the Freeway DCB
Rembert Pogge von Strandmann1, Mariann Gyöngyösi2, Stefanie Stahnke1
1Eurcor GmbH, Bonn, Germany, 2Medical University of Vienna, Vienna, Austria

Background: Due to the mechanism of drug transfer, Paclitaxel coated balloons (PCB) are thought to result in non-uniform inhibition of neointima. We sought to investigate the pattern of neointima distribution along the stented and reference(edges) segments following PCB dilatation as compared to POBA controls in a peripheral swine model.

Methods: 16 iliofemoral arteries were injured with balloon overstretch followed by a BMS deployment. At 14 days, the in-stent restenosis was treated with either a PCB (Covatance, Medrad Inc, PA) or an identical uncoated balloon (POBA). At 28 days following balloon inflation, all segments were analyzed by QVA and OCT. The OCT percent area stenosis (%AS) was analyzed every 2mm along the treated segment. Percent diameter stenosis (%DS) was analyzed within 5mm proximal and distal to the stent marker by QVA.

Results: In vivo OCT analysis showed a homogeneous inhibition of neointimal formation following paclitaxel delivery. In addition the use of PCB reduces neointimal proliferation at the borders of the stent.

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Results: At follow up, POBA demonstrated a progression in neointimal proliferation at distal (26.9% increase, p<0.001) and proximal (8.0% increase, p<0.05) vessel reference segments. Conversely, PCB exhibited neointimal regression in the distal (7.7%, p<0.05) and proximal (1.4%, p<0.05) reference segments.

Conclusions: In vivo OCT analysis showed a homogeneous inhibition of neointimal formation following paclitaxel delivery. In addition the use of PCB reduces neointimal proliferation at the borders of the stent.

TCT-171
Paclitaxel Balloon Delivery Results In Homogeneous In-Stent Neointimal Distribution and Reduction of Stent Edge Stenosis Progression in the Peripheral Swine Model
Maxwell Afari1, Armando Tellez2, Seung-Jin Oh2, Piotr Buszman1, Yanping Cheng3, Jong Shuan Yeh1, Gerard Conditt1, Greg Kaluza1, Juan Granada4
1Cardiovascular Research Foundation, Orangeburg, NY, 2American Heart of Poland, Katowice, Silesia, 3Jack H Skirball Center for Cardiovascular Research, Cardiovascular Research Foundation, Orangeburg, NY, 4CRF, Orangeburg, USA

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