Study shows low rate of late lumen loss with bioresorbable DESolve device

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The DESolve bioresorbable coronary scaffold system achieves good efficacy and safety with low rates of late lumen loss and major coronary adverse events at six months, show first results from the pivotal DESolve Nx trial reported at EuroPCR 2013 today.

DESolve (Elixir Medical Corporation) is the first bioresorbable PLLA-based polymer scaffold that releases novolimus, a major metabolite of sirolimus. "The degradation time is about one year," explained the lead study author Alexandre Abizaid, Director of Interventional Cardiology at Institute Dante Pazzanese de Cardiologia, São Paulo, Brazil. He added, "One of the most attractive features, which we don't see with most bioresorbable scaffolds, is that this device shows significant increase in vessel scaffold and luminal area at six months."

The DESolve Nx trial treated target lesions in 126 patients with single de novo coronary artery lesions with the DESolve device. Results showed the primary endpoint of in-stent late lumen loss was 0.21mm (+0.34) at six months. Major adverse cardiac events occurred in 3.25% of patients, including one cardiac death. Acute recoil occurred in 6.6% of patients at six months.

Stents and vessels were assessed by IVUS in a subset of 40 patients. "There was a clearly significant increase in vessel area," Abizaid reported. Mean vessel area increased by 16.8% at six months (p