

Study examines use of stent with bioabsorbable polymer

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Three-year data demonstrated that satisfactory clinical and safety outcomes of sirolimus eluting stents with a biodegradable polymer were sustained in a real world setting. The results were presented at the 22nd annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation.

"The three-year data from the CREATE study is further evidence that biodegradable polymers represent the future of stent design," said Yaling Han, MD, the lead investigator and Director in the Department of Cardiology, Shenyang Northern Hospital (Shenyang, China.) "This study demonstrates sustained clinical safety and efficacy of [biodegradable-polymer](#) based sirolimus eluting stents when used with 6 months of dual antiplatelet therapy in a 'real-world' setting."

The CREATE study was a post-marketing surveillance multi-center registry that demonstrated satisfactory angiographic (at 9 months) and clinical (at 12 and 18 months) outcomes of biodegradable polymer-based sirolimus eluting stents for real world patients. The aim of the study was to evaluate the 3-year clinical safety and efficacy outcomes in patients enrolled in the CREATE trial.

A total of 2077 patients, exclusively treated with EXCEL stents at 59 centers from 4 countries, were enrolled in the CREATE study. The recommended antiplatelet regimen was clopidogrel and aspirin for 6 months followed by chronic [aspirin therapy](#).

The cumulative rates of major adverse cardiac events (MACE) were 2.7% at 1 year and 4.5% at 3 years. The rate of stent thrombosis with Academic Research Consortium definitions was 0.83% at 1 year and 1.53% at 3 years. At 6 months to 3 years, prolonged [clopidogrel](#) therapy (> 6 months) was not beneficial in reducing cumulative hazards of MACE (5.2% vs. 4.6%, log rank $p=0.629$) or stent [thrombosis](#) (1.5% vs. 0.6%, log rank $p=0.052$).

3-year outcome data will be presented during the Poster Abstracts Sessions in the Lower Level of the Washington Convention Center.

Provided by Cardiovascular Research Foundation

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