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Clinical Data Supports Efficacy of New 3-D Stent

On May 21, Veryan Medical Ltd. presented data during the Trials and Innovations for Peripheral Interventions Session at EuroPCR 2013 in Paris, France, on its Biomimics 3D stent. A recent trial has demonstrated safety and promising clinical performance at 12 months in the treatment of patients with peripheral arterial disease (PAD) undergoing femoropopliteal artery intervention, the company reported. Data from the Mimics study appear to provide the first clinical substantiation for the hypothesis that a stent with 3-D geometric curvature will be patency-protective through stimulation of swirling flow and elevation of wall shear stress.

The Mimics study is a prospective, 2:1 randomized controlled trial, conducted at eight German investigational centers, comparing the safety and efficacy of the Biomimics 3D stent to a straight nitinol stent (primarily the Bard LifeStent) in 76 patients with PAD undergoing femoropopliteal artery intervention. Nitinol is a nickel titanium alloy that has shape memory qualities.
Professor Stephan Duda of Gefäßzentrum am Jüdischen Krankenhaus, Berlin, Germany, presented the data on behalf of the Mimics investigators. The data showed the 12-month Kaplan Meier (KM) estimate of freedom from clinically driven target lesion revascularization for subjects receiving the Biomimics 3D stent was 91.2 percent. The KM estimate of 12-month primary patency was 80.4 percent for Biomimics 3D subjects vs. 72.0 percent for the control group. No stent fractures have been reported by the independent core lab in either treatment group.

The Biomimics 3D stent features unique 3-D geometric curvature that closely mimics the natural helical

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geometry of the human vascular system—a spiral flow. This stent is designed to promote swirling blood flow through the stented segment, which preclinical data have reportedly shown to significantly reduce the formation of neointimal hyperplasia (swelling of vessels due to scar tissue), potentially conferring a vasoprotective effect through elevation of wall shear stress. Emerging data from the Mimics study are pointing to a correlation between 12-month primary patency and stent curvature.

Swirling flow induced by the Biomimics 3D stent and the resulting levels of wall shear stress are being investigated by ongoing analysis of ultrasound data from the Mimics study and computational fluid dynamic modeling. A substantial body of literature, built on the original work of Professor Colin Caro (founder of Veryan Medical) on blood flow mechanics and vascular disease, supports a threshold value for wall shear stress. Swirling flow induced cross-mixing and mass transport efficiencies at the vessel wall become vasoprotective above this threshold. Data from the Mimics study appear to provide the first clinical substantiation for the hypothesis that a stent with 3-D geometric curvature will be patency-protective through stimulation of swirling flow and elevation of wall shear stress.

The helical geometry of the Biomimics 3D stent, the company claims, also enhances mechanical performance and biomechanical compatibility, to reduce stent fracture, vessel and stent kinking, deformation and subsequent vessel trauma during leg flexion, compared to straight nitinol stents.

"These results indicate that the unique 3-D geometry of the Biomimics 3D stent is biomechanically compliant with the vessel which likely reduces the incidence of stent fracture and also chronic vascular injury of the unstented segment," said Professor Duda. "We now need additional longer-term data to confirm these effects."

Veryan received CE mark approval for the Biomimics 3D stent in November 2012.
Veryan Medical started as a spinoff from Imperial College in London, United Kingdom. The company makes vascular stent technology.