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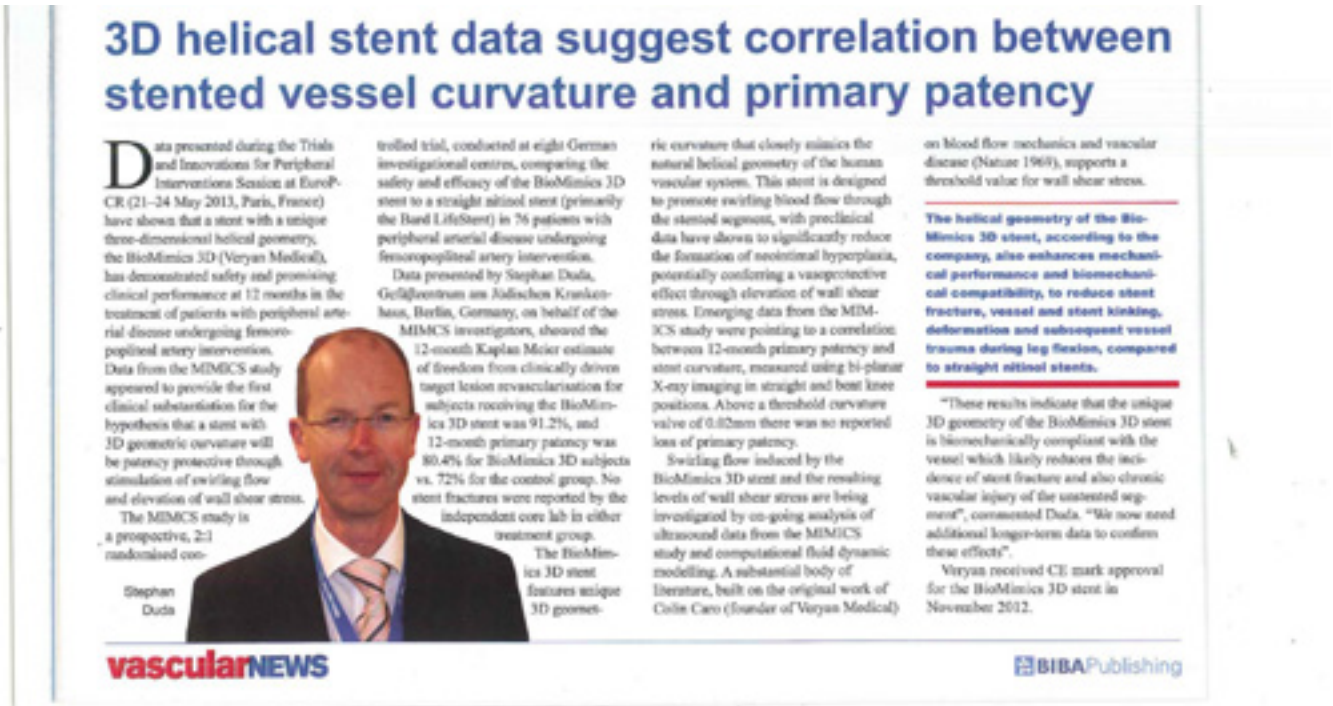
# 3D Helical Stent Twelve Month Data Suggest Correlation between Stented Vessel Curvature and Primary Patency

Data presented here today during the Trials and Innovations for Peripheral Interventions Session at EuroPCR 2013 show that a stent with unique three-dimensional helical geometry, BioMimics 3D™, developed by Veryan Medical Ltd., has demonstrated safety and promising clinical performance at twelve months in the treatment of patients with peripheral arterial disease (PAD) undergoing femoropopliteal artery intervention. Data from the MIMICS study appear to provide the first clinical substantiation for the hypothesis that a stent with 3D 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 randomised controlled trial, conducted at eight German investigational centres, 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.

Data presented by Professor Stephan Duda, Gefäßzentrum am Jüdischen Krankenhaus, Berlin, on behalf of the MIMICS investigators 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%. The KM estimate of 12-month primary patency was 80.4% for BioMimics 3D subjects vs. 72.0% for the control group. No stent fractures have been reported by the independent core lab in either treatment group.



## 3D helical stent data suggest correlation between stented vessel curvature and primary patency

Data presented during the Trials and Innovations for Peripheral Interventions Session at EuroPCR (21–24 May 2013, Paris, France) have shown that a stent with a unique three-dimensional helical geometry, the BioMimics 3D (Veryan Medical), has demonstrated safety and promising clinical performance at 12 months in the treatment of patients with peripheral arterial disease undergoing femoropopliteal artery intervention. Data from the MIMICS study appeared to provide the first clinical substantiation for the hypothesis that a stent with 3D geometric curvature will be patency protective through stimulation of swirling flow and elevation of wall shear stress.

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Stephan Duda

The BioMimics 3D stent features unique 3D geometric curvature that closely mimics the natural helical geometry of the human vascular system. This stent is designed to promote swirling blood flow through the stented segment, with preclinical data have shown to significantly reduce the formation of neointimal hyperplasia, potentially conferring a vasoprotective effect through elevation of wall shear stress. Emerging data from the MIMICS study were pointing to a correlation between 12-month primary patency and stent curvature, measured using bi-planar X-ray imaging in straight and bent knee positions. Above a threshold curvature value of 0.02mm there was no reported loss of primary patency.

Swirling flow induced by the BioMimics 3D stent and the resulting levels of wall shear stress are being investigated by on-going analysis of ultrasound data from the MIMICS study and computational fluid dynamic modelling. A substantial body of literature, built on the original work of Colin Caro (founder of Veryan Medical) on blood flow mechanics and vascular disease (Nature 1969), supports a threshold value for wall shear stress.

**The helical geometry of the BioMimics 3D stent, according to the company, 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 3D 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 untreated segment", commented 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.

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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 modelling. 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 (Nature 1969), 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 3D 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 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 3D 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", commented Professor Duda. "We now need additional longer-term data to confirm these effects".

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