

## Veryan's BioMimics 3D Nitinol stent with helical curvature shows improved patency at 2-year follow-up in Mimics randomized controlled study

**Las Vegas, 4<sup>th</sup> November 2014** – Two-year data from the Mimics study, presented at today's Late-Breaking Clinical Trials session at the VIVA Symposium, have confirmed that BioMimics 3D™ provides a significant improvement in long-term primary patency compared to a straight nitinol control stent in patients undergoing femoropopliteal artery intervention. A new 12-month Landmark analysis presented today reinforces the longer term benefit of Veryan's helical stent technology and showed a statistically significant improvement in the Kaplan Meier estimate of survival from clinical-driven TLR through 24 months, compared to the control stent ( $P < 0.05$ ).

BioMimics 3D, a nitinol stent with unique three-dimensional helical geometry, has been developed by Veryan, based on pioneering research by Prof Colin Caro at Imperial College London into the link between blood flow mechanics and vascular disease. The BioMimics 3D nitinol stent has unique helical centerline geometry to mimic natural vascular curvature that promotes secondary (swirling) flow and elevated hemodynamic shear stress, which has a protective effect on the endothelium. The helical geometry of the BioMimics 3D femoropopliteal stent is also designed to enable coil-spring shortening of the stented segment during knee flexion and mitigate the risk of stented segment compression causing localized strains in a straight stent that may lead to stent fracture and chronic vascular injury.

The Mimics study is a prospective, randomized, multicenter controlled trial conducted at eight German investigational centers and supported by an independent core lab. A total of 76 patients were enrolled and randomized 2:1 (50 BioMimics 3D v 26 Control) in subjects undergoing femoropopliteal artery intervention. Mimics' investigators compared the safety, efficacy and vascular hemodynamics of the BioMimics 3D stent to straight nitinol stents (24/26 control subjects were treated with LifeStent (CR Bard)).

Mimics data were presented during the VIVA session by Principal Investigator Professor Thomas Zeller, Universitäts-Herzzentrum, Freiburg-Bad Krozingen, Germany. The Kaplan Meier (KM) survival estimate of freedom from loss of primary patency\* at two years was 72% for BioMimics 3D subjects vs. 55.0%

for the control arm. The difference in survival estimate between the two groups by log rank test was significant ( $P < 0.05$ ). Importantly, there was no increase in the KM estimate of clinically driven target lesion revascularization (CDTLR) rate in the BioMimics arm between 12 and 24 months (9% at both time-points) compared to a 3-fold increase (8% at 12 months and 24% at 24 months) in the straight stent control arm.

An improvement of one or more Rutherford categories was observed in 87% of BioMimics 3D patients at 24-months compared to baseline. A core lab review of straight and flexed knee X-rays did not detect any stent fractures in any BioMimics 3D Stent. Bi-planar X-ray imaging data indicate the ability of the femoropopliteal artery to adopt the three-dimensional curvature of the BioMimics 3D stent and computational fluid dynamic modelling provided evidence of secondary (swirling) flow within the stented segment and predicted zones of elevated wall shear stress.

Mimics Study data indicate a correlation between primary patency and stent curvature. BioMimics 3D stented segments showed significantly greater curvature ( $P = 0.02$ ) compared with the control, providing swirling blood flow and elevated wall shear, which may explain the longer term patency protective effect seen with BioMimics 3D. Across all patients, stent curvature was greater for BioMimics 3D stents compared to the straight control stents and no loss of patency was observed in patients with mean straight leg stent curvature above  $0.02 \text{ mm}^{-1}$ .

“These data suggest the existence of a patency protective effect provided by the biomimetic characteristics of the BioMimics 3D Nitinol stent resulting in hemodynamic and biomechanical performance advantages over straight Nitinol stents”, commented Professor Zeller.

“We are very grateful to Professor Zeller and the Mimics’ Investigators for enabling Veryan to complete this benchmark evaluation of the unique BioMimics 3D helical stent technology. We believe this advanced stent design offers outstanding benefits in femoropopliteal use and has potential for innovation in many other areas of endovascular intervention. Presentation of the full two-year Mimics’ results represents a major step forward in this endeavour”, added Veryan Chief Executive Chas Taylor.

Veryan has received CE Mark approval for the BioMimics 3D stent and is planning commercialization through an international distributor starting in the first quarter of 2015.

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**About Veryan Medical Ltd.**

Veryan is developing innovative solutions to improve the performance of vascular stents using the principles of biomimicry. Veryan's BioMimics 3D® stent technology involves adapting traditional straight stent designs to a patented three-dimensional helical shape, which more closely mimics the natural geometry of the human vascular system. BioMimics 3D technology is designed to enhance clinical performance by improving flow conditions in, and biomechanical performance of, stented vessels. The advanced, biomimetic design of the BioMimics 3D stent is intended to provide more flexibility, kink and fracture resistance than other laser-cut nitinol tube stents, making its unique design of particular importance in the hostile environment of the femoropopliteal artery. Veryan's Research & Development facility is located in Galway, Ireland.

BioMimics 3D is a registered trademark of Veryan Medical Ltd.

\*Primary patency is defined as peak systolic velocity ratio >2.0, or where angiography reveals >50% diameter stenosis; or CDTLR through 24 months.

CAUTION: The BioMimics 3D stent is not available for sale or investigational use in the United States.

For further information, please visit: [www.veryanmed.com](http://www.veryanmed.com)