

Full 2-Year Mimics Data Confirm Long-term Patency Protection With BioMimics 3D Stent

New Orleans, 30th May 2014 – Full two-year data from the Mimics study, presented for the first time today at the 15th Annual New Cardiovascular Horizons (NCVH) Conference, have confirmed that BioMimics 3D™ provides a significant improvement in long-term patency compared to a straight nitinol control stent in patients undergoing femoropopliteal artery intervention. 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.

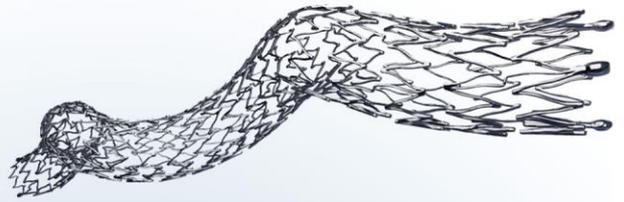
The Mimics study is a prospective, randomised, multicenter controlled trial conducted at eight German investigational centers and supported by an independent core lab. A total of 76 patients were enrolled and randomized 2:1 (50 BioMimics 3D v 26 Control) in patients undergoing femoropopliteal artery 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 C.R. Bard's LifeStent).

The BioMimics 3D stent incorporates Veryan's patented 3D helical technology, an advanced stent design that promotes natural swirling blood flow to elevate wall shear stress which has been shown to reduce neointimal hyperplasia and improve the biomechanical performance of the femoropopliteal artery during knee flexion, mitigating the risk of stent fracture and vessel kinking.

The full two-year data from Mimics were presented by Principal Investigator Professor Thomas Zeller, Universitäts-Herzzentrum, Freiburg-Bad Krozingen, Germany. There are two key findings; firstly, the Kaplan Meier (KM) survival analysis of freedom from loss of primary patency at two years was 72% for BioMimics 3D subjects vs. 55.0% for the control group: a significant difference ($P=0.0497$). Secondly, there was no increase in the clinically driven target lesion revascularisation (CDTLR) rate in the BioMimics arm between 12 and 24 months (9% at both time-points) compared to an increase of 16% (8% at 12 months and 24% at 24 months) in the control arm. The 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 improved blood flow and elevated wall shear, which may explain the longer term patency protective effect seen with BioMimics 3D. No stent fractures were detected by the independent core lab.

“The final 24-month data for the BioMimics 3D stent confirm that the flow effects produced by its helical design are contributing to an improved outcome compared to that achieved with the straight control stents. The results of the Mimics study show a significantly greater freedom from loss of primary patency with BioMimics in the 24-month Kaplan Meier survival analysis”, commented Professor Zeller. “Importantly, there was no change in the rate of clinically-driven target lesion revascularization in the 12 and 24 month follow-ups for BioMimics 3D and this longer-term benefit appears to correlate with a trend to lower peak systolic velocities. Overall, these data suggest that a biomimetic stent with 3D helical curvature may provide a new performance benchmark in femoropopliteal stenting”.

“We are very grateful to Professor Zeller and the Mimics Investigators for the support that has enabled Veryan to complete this benchmark evaluation of our biomimetic 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 plans to commercialise the stent later this year.

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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.

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

