The Role of the BioMimics 3D® Stent in FemPop Intervention: A Look Ahead at Use in the United States

Thomas Zeller, MD, talks with Sahil A. Parikh, MD, Miguel Montero-Baker, MD; and Robert E. Beasley, MD, about how the recent availability of the BioMimics 3D system in the United States will impact their clinical practice.

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The BioMimics 3D® Vascular Stent System (Veryan Medical) is available in the United States as of September 2020, and has been available in Europe since 2015. BioMimics 3D features a nitinol stent with a unique three-dimensional (3D) helical centerline intended to promote swirling flow to elevate wall shear stress, which has been shown to be patency protective.[1]

I implanted the first-in-human BioMimics 3D® Vascular Stent System and have been an investigator in each of the company-sponsored clinical trials in the MIMICS clinical program. I use BioMimics 3D routinely in my clinical practice for both standard and more challenging lesions. As Principal Investigator (PI) of MIMICS-2, I recently presented the 3-year results that showed comparable outcomes to drug-coated balloons, drug-eluting stents, and the Supera peripheral stent (Abbott), despite more challenging lesions and with the clinical benefit maintained out to 3 years. These results are reproducible, reliable, high-quality data from the United States, Japan, and Europe.[2] BioMimics 3D has had significant impact on my clinical practice in Germany.

– Prof. Thomas Zeller

Figure 1. BioMimics 3D Stent System.

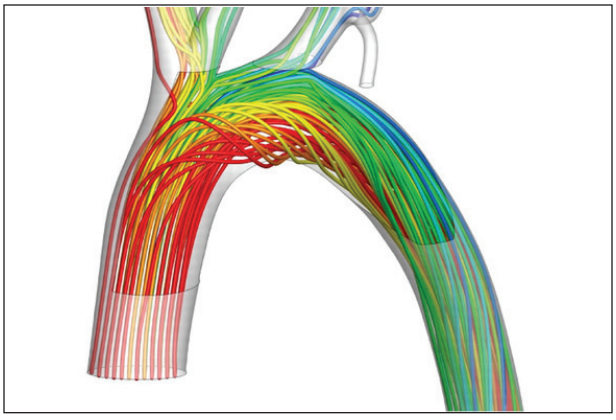

Figure 2. Computation fluid dynamics representation of swirling blood flow in the aorta.

Prof. Zeller: Dr. Parikh, what are your views on having this stent available to use in your clinical practice?

Dr. Parikh: I was happy to be asked to be Co-National PI for the MIMICS-3D USA study, which will start enrollment in late 2020; I am looking forward to using this innovative device in my clinical practice. I have watched the clinical data coming from Europe with interest and the design concept of the device is fascinating. The BioMimics 3D system has a helical centerline that induces swirling flow (Figure 1). It is now well understood that the normal pattern of laminar blood flow in the aorta and proximal branches has a swirling component that increases wall shear stress resulting in a reduced propensity to develop atherosclerosis and restenosis (Figure 2).[1,3] The BioMimics 3D stent is designed specifically to impart a helical shape onto the vessel with the intention of increasing wall shear stress, thereby limiting intimal hyperplasia. Another significant benefit of the stent's helical shape, which is more mechanically biocompatible than a straight stent, is its ability to shorten with the superficial femoral artery (SFA) as the knee or hip is flexed (Figure 3).[4] This has been consistently demonstrated and there were no fractures in the MIMICS-2 investigational device exemption (IDE) study. I am sure many physicians in the United States will be intrigued to use this device and to see for themselves how inducing swirling flow in the treatment of femoropopliteal arterial disease can potentially improve their clinical outcomes.

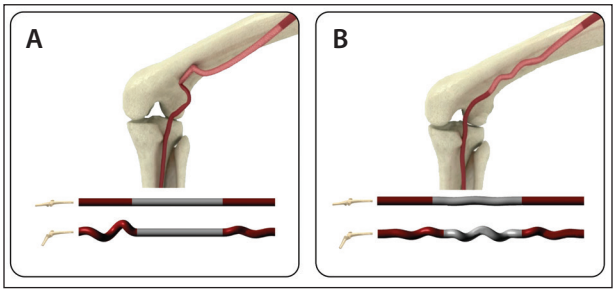

Figure 3. Impact of straight (A) and BioMimics 3D (B) stents on the femoropopliteal artery. The straight stent resists compression, risking damage to stent and vessel. The BioMimics 3D unique stent design accommodates shortening and stress is distributed across the entire stent, reducing the risk of stent fracture and associated vascular injury.[4]

Prof. Zeller: What are your thoughts, Dr. Montero-Baker?

Dr. Montero-Baker: I am also eager to be Co-National PI for the MIMICS-3D USA registry, which will give many physicians early access to BioMimics 3D and I am interested to see how the device performs. The three Co-National PIs represent the three relevant interventional disciplines: cardiology, radiology, and vascular surgery; something we all felt would add value to the study. MIMICS-3D USA will evaluate safety, effectiveness, and device performance within a real-world clinical population of patients undergoing femoropopliteal intervention, enrolling 500 patients at 40 sites across the United States over the next 2 years. The primary safety endpoint is clinical events committee–adjudicated major adverse events (MAEs), which comprises death, any unplanned major amputation performed on the index limb, or clinically driven target lesion revascularization (CD-TLR) through 30 days. The primary effectiveness endpoint is freedom from CD-TLR through 12 months. As a direct result of physician feedback, stent patency will be a secondary endpoint and will be core-lab–adjudicated adding to the already robust data available on the stent. Follow-up will be out to 3 years.

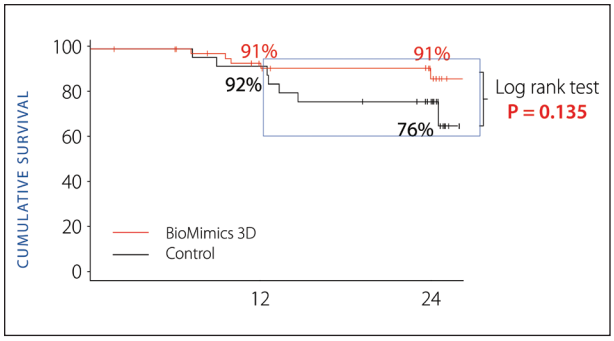

Figure 4. Kaplan-Meier estimate of MIMICS RCT 2-year freedom from CD-TLR (as determined through event adjudication).

Dr. Montero-Baker: Prof. Zeller, what has been your experience with the device?

Prof. Zeller: The BioMimics 3D stent was initially clinically tested in the first randomized controlled trial (RCT) to directly compare two nitinol stents in the femoropopliteal segment.[5] The MIMICS-RCT was a multicenter, core lab–controlled, prospective, randomized trial in which the BioMimics 3D stent was compared with a conventional straight stent control (LifeStent, BD Interventional) in 76 patients with symptomatic occlusive disease of the SFA and proximal popliteal artery. That study showed with conventional radiographs, angiograms, duplex ultrasound data, and computational fluid dynamics that the BioMimics 3D stent imparts nonplanar (helical) curvature to the diseased artery. The superior biomechanical compatibility and induction of swirling flow and elevated wall shear stress resulted in significantly better primary patency through 2 years. The difference in CD-TLR was also clear; there was no CD-TLR in the BioMimics 3D arm between 12 and 24 months, whereas there was a threefold increase in reintervention in patients treated with the straight stent over the same time period (Figure 4). This difference was significantly different. Since then, in addition to being the Principal Investigator for the MIMICS-2 IDE study, I was also an investigator in the pan-European MIMICS-3D study, the data from which will be pooled with the data from the MIMICS-3D USA registry to give a combined total clinical database of > 1,750 patients treated with the BioMimics 3D Vascular Stent System.

Prof. Zeller: Dr. Beasley, what are your thoughts on having BioMimics 3D available in the United States?

Dr. Beasley: I am interested in how BioMimics 3D will impact the office-based lab (OBL) practice. This stent system has compelling clinical results and it is competitively priced compared with drug-eluting devices, and that is key to our practice. In addition, it has an easy-to-use delivery system that results in very accurate stent placement with minimal training. This again will increase our efficiency, saving time and costs with the expectation of achieving similar clinical results to those with drug-eluting devices. Femoropopliteal stenting within OBLs is growing considerably, and being able to use a device that does not add to our costs or require significant training but still delivers compelling clinical results is very interesting to me and my partners and will be of great interest to physician colleagues across the United States.

I am eager to work with Sahil and Miguel as Co-National PI for the MIMICS-3D USA registry and look forward to hearing the feedback from fellow investigators as enrollment grows—particularly when we hold our first investigator meeting later this year.

Dr. Beasley: Prof. Zeller, I understand you have now implanted hundreds of BioMimics 3D stents; in which indications do you use them?

Prof. Zeller: BioMimics 3D is now my go-to bare-metal stent for routine procedures and the clinical data consistently show that the presence of severe calcification, longer lesion length, or total occlusions do not impact freedom from CD-TLR, so it really can be used in challenging, complex lesions with no statistically significant difference in outcomes.[1] The MIMICS clinical program is gathering clinical evidence from a real-world patient population in multiple countries from single de novo to complex, long, and severely calcified lesions and the outcomes are consistent and reproducible in any lesion complexity.

The device is now commercially available in the United States, so even those physicians who are not involved in the registry can now use BioMimics 3D in their clinical practice. Having been involved with Veryan from the start of their clinical program, I will watch with interest to see how BioMimics 3D impacts your clinical practices and those of your United States colleagues. ■

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