Understanding and Addressing the Dynamic Challenges of Treating the Distal SFA

Latest data from the next-generation mimetic BioMimics 3D stent.

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The superficial femoral artery (SFA) and popliteal artery have complex biomechanics and undergo severe conformational changes, which makes this vessel segment a hostile environment for stent placement.[1] This arterial segment is highly dynamic and exposed to forces such as compression, elongation, torsion, and bending (Figure 1). In the distal SFA and proximal popliteal artery, the axial shortening is even higher than in the distal popliteal artery.[2]

As demonstrated in cadaver studies, the native artery shortening results in a natural increase in the curvature of the vessel. This is particularly relevant in the distal SFA, as this region is prone to the most significant forces in the entire femoropopliteal segment.[1] Clinicians have long known about the challenges of treating occlusive disease in this area with a high incidence of native vessel disease, stent fracture, and reocclusion.

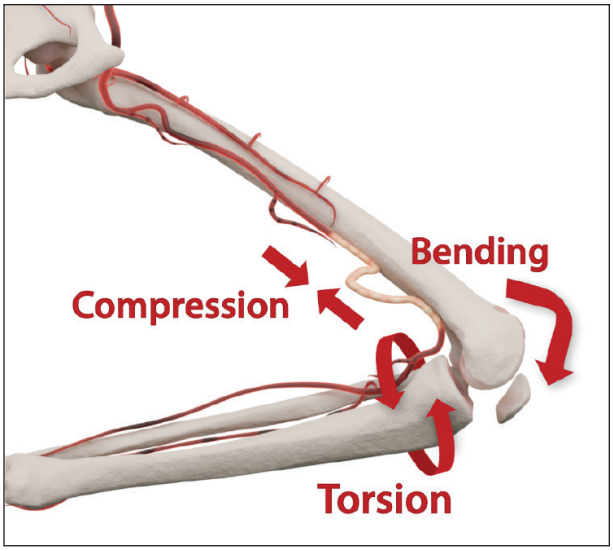

Figure 1. Forces on the femoropopliteal artery. The model demonstrates that the femoropopliteal artery is prone to forces such as compression, bending, and torsion and that the compression (shortening) is most significant in the distal SFA segment.

BIOMIMICS 3D

The BioMimics 3D helical centerline stent (Veryan Medical; Figure 2) has unique design characteristics that were specifically built to treat femoropopliteal lesions. It features improved biomechanical compatibility that allows the device to shorten, elongate, and twist with the artery as it moves. Subsequently, the risk of stent fractures, arterial damage, and kinking is reduced, ultimately reducing the risk of restenosis.[3] In preclinical studies, BioMimics 3D withstood the greatest axial compression before fracturing compared to conventional straight stents.[4]

Furthermore, the BioMimics 3D elevates wall shear stress, thus limiting neointimal hyperplasia and smooth muscle cell proliferation, reducing thrombus formation and inflammation, and ultimately reducing the risk for restenosis.[3-6]

Another beneficial factor in this highly dynamic environment is the gradually reduced radial force at

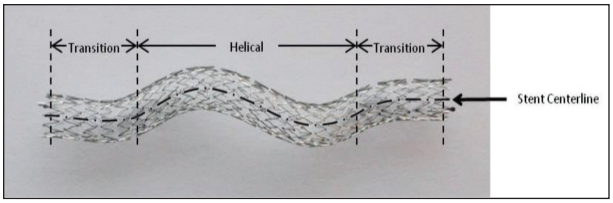

Figure 2. The BioMimics 3D stent with its helical centerline and transition zones. The transition zone consists of three crowns at each end, with gradually reduced radial force.

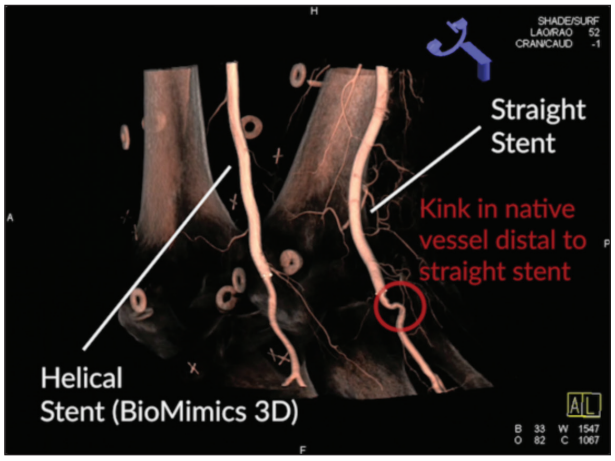

Figure 3. A femoropopliteal cadaver model showing the difference in arteries implanted with a straight stent versus a helical centerline stent.

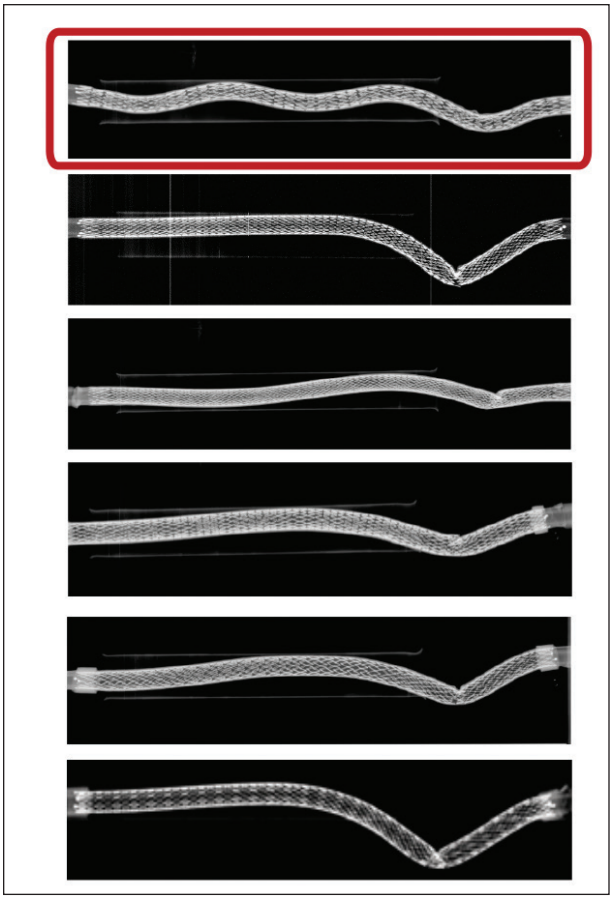

Figure 4. The BioMimics 3D (red rectangle) versus contemporary traditional stents in a mock vessel model. High-resolution x-rays of a selection of commercially available laser-cut nitinol stents undergoing axial compression in a bench test model, simulating the adductor canal–to–popliteal fossa junction.

the stent ends, which further reduces microtrauma, abnormal flow patterns, and step change at the junction between stent and native vessel.

In contrast, straight stents tend to straighten the blood vessel, reducing the vessel shortening (Figure 3). Therefore, adjacent, unstented arterial segments tend to deflect in an exaggerated manner during hip and knee bending because their ability to accommodate the arterial shortening is compromised. This exaggerated bending could lead to stent kinking, stent fractures, and accelerated intimal hyperplasia formation at the stent edges.[1,4]

Similarly, the mock vessel shown in Figure 4 mimics the anatomy when the stented segment exits the adductor canal into the popliteal fossa. This model demonstrates that the BioMimics stent has the ability to absorb axial compression, thereby reducing the bending load on the stent in the transition section from the constrained to unconstrained regions. At this juncture, stents are prone to extreme deformations, including axial and radial compression, bending, and torsion, which may result in stent fractures. The BioMimics 3D stent can absorb the axial compression along the length of the device and exhibits an undulating behavior similar to the native vessels. In contrast, straight stents are less able to accommodate the axial compressive force applied in the adductor canal region.

CLINICAL DATA

The MIMICS clinical investigation of the BioMimics 3D vascular stent system evolved from a first-in-human study to a randomized trial that demonstrated superior 2-year primary patency rate compared to a straight stent control in femoropopliteal lesions.[7] Similar excellent 2-year safety MIMICS 3D European registry and effectiveness results were reported in *Journal of Endovascular Therapy* from the MIMICS-2 investigational device exemption study.[8] Finally, evidence for the performance of the BioMimics 3D stent has been observed in large real-world registries within the MIMICS program.[9]

TABLE 1. BASELINE CHARACTERISTICS IN THE MIMICS 3D EUROPEAN REGISTRY (POST HOC ANALYSIS)			
	Distal SFA/Proximal PA	Proximal/Mid SFA	*P* Value
Age (y)	71.5 ± 9.6	68.5 ± 9.4	.010
Hypertension	147/177 (83.1%)	92/105 (87.6%)	.392
Hypercholesterolemia	108/177 (61.0%)	69/105 (65.7%)	.447
Previous MI, CABG, PCI, or coronary artery disease	61/177 (34.5%)	35/105 (33.3%)	.897
MI	24/177 (13.6%)	6/105 (5.7%)	.046
Diabetes mellitus	55/177 (31.1%)	47/105 (44.8%)	.029
Nonhealing wound target limb	24/177 (13.6%)	15/105 (14.3%)	.860
Lesion length (mm)	79.8 ± 46.8	102.2 ± 76.6	.054
Maximum RVD (mm)	5.3 ± 0.7	5.4 ± 0.8	.469
Occlusions	88/178 (49.4%)	40/105 (38.1%)	.083

Note: Data are displayed as mean ± SD or n (%). *P* value was calculated using Fisher's exact test for categorical variables and Student's *t* test for continuous variables.
Abbreviations: CABG, coronary artery bypass graft; MI, myocardial infarction; PA, popliteal artery; PCI, percutaneous coronary intervention; RVD, reference vessel diameter; SFA, superficial femoral artery.

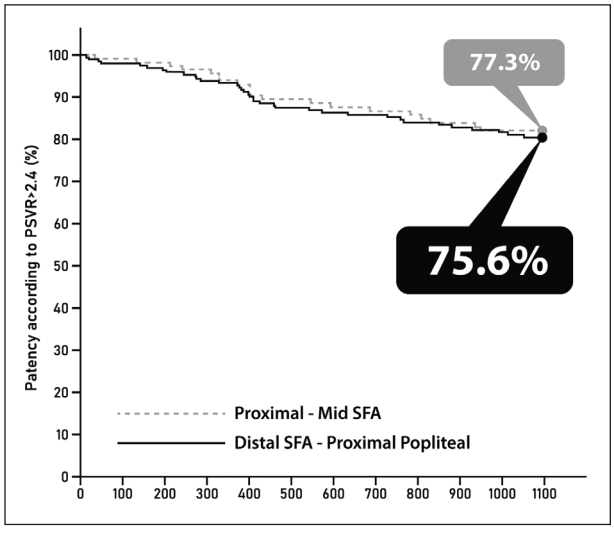

Figure 5. Primary patency through 3 years (1,095 days). PSVR, peak systolic velocity ratio.

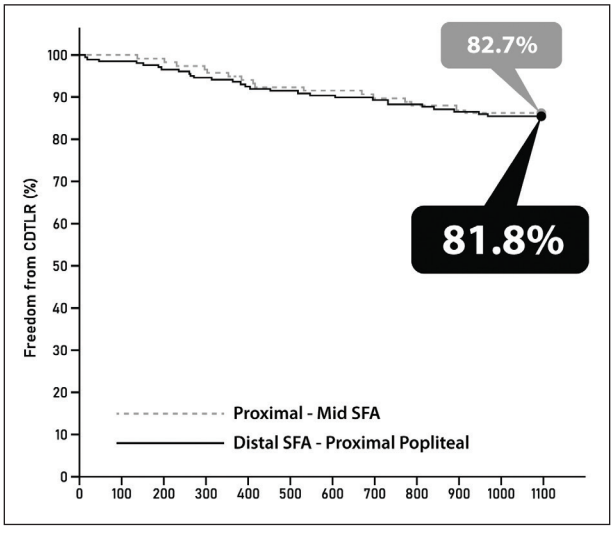

Figure 6. Clinically driven target lesion revascularization (CDTLR) through 3 years (1,095 days).

The MIMICS 3D European registry has enrolled 507 patients with 518 lesions and 3-year data, which were presented at the Leipzig Interventional Course in 2022.[10] A post hoc analysis was performed to compare outcomes between lesions located solely in the proximal to mid SFA (n = 105 lesions) compared with those located solely in the distal SFA/proximal popliteal (n = 178 lesions).

Baseline parameters were similar, except that the patients in the distal SFA/proximal popliteal group were older, had more previous myocardial infarctions (MIs), had less diabetes, and demonstrated a trend toward more occluded segments, with shorter lesion length (Table 1).

There was no difference in clinical outcomes through 3-year follow-up, with nearly identical outcomes in 3-year primary patency and 3-year freedom from clinically driven target lesion revascularization (75.6% for the distal SFA/proximal popliteal group vs 77.3% for proximal to mid SFA group, and 81.8% vs 82.7%, respectively) (Figures 5 and 6).

Certainly, outcomes might have been affected by baseline parameters. Patients with distal SFA/proximal popli-

teal lesions were older and had more MIs in their medical history, but patients with proximal to mid SFA lesions had more diabetes and longer lesions.

Importantly, despite the hostile environment, stent fractures occurred in < 1% of BioMimics 3D stents at 3 years in the distal SFA/proximal popliteal group. Furthermore, the results in this group compare well even to drug-eluting stents placed in the femoropopliteal bed. Selecting studies with similar lesion lengths, freedom from clinically driven target lesion revascularization was 92.7% at 12 months versus 85.8% to 94.7% in the Zilver PTX and the SuperNOVA trials[11-13]; 86.8% at 24 months versus 78% to 89.5% in the IMPERIAL, BATTLE, SuperNOVA, and Zilver PTX trials[11,13-15]; and 81.8% at 36 months versus 85.3% to 87.2% in the MAJESTIC and Zilver trials, which both had a shorter average lesion length (70.8 and 66.4 mm, respectively).[11,16]

CONCLUSION

The distal SFA/proximal popliteal segment is a hostile environment exhibiting mechanical forces where traditional nitinol stents do not generally perform well. The BioMimics 3D stent, with its helical centerline and transition zones, was specifically designed to react progressively to the dynamic changes of this vascular region during hip and knee bending. The subgroup analysis of the MIMICS 3D registry demonstrates the suitability of the BioMimics 3D stent for use in this segment, with no difference in 3-year primary patency or clinically driven target lesion revascularization compared to the straighter proximal to mid SFA segment and with data that are comparable to drug-eluting stents. We eagerly await the follow-up from the recently completed enrollment in the MIMICS 3D registry to further confirm these findings. ■

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