Treatment of long coronary lesions with single stent: BioMime Morph sirolimus-eluting tapered coronary stent system

The success of interventional cardiology practice lies in its ability to reduce the severity of disease and to extend and improve the quality of life in patients with coronary artery disease.[1] Treatment of complex lesions in coronary arteries with tapered shape remains challenging due to high-risk and vessel-stent diameter mismatch. Although interventional cardiologists try to avoid the problems of mechanical mismatch between the stent and coronary artery, it becomes a particular concern in cases where arterial diameter changes to a significant degree over the length of a coronary lesion. Such diameter changes are commonly encountered due to natural tapering of coronary artery or due to a need to deploy a stent from parent vessel into its narrower branch.[2]

Angiographic data suggested that left anterior descending (LAD) and right coronary arteries (RCA) taper approximately 14% and 9%, respectively, along their lengths.[3] A study analyzed tapered coronary anatomy, 1 cm proximal as well as distal to the stenosis, in 100 consecutive coronary arteries. They observed that 23% of the arteries had ≥1 mm taper and 19% arteries had a 0.5–0.99 mm taper. Such a tapered coronary anatomy poses a significant challenge during percutaneous coronary intervention, especially in long coronary lesions.[4]

Currently available balloon-expandable stents exhibit limitations such as stent malapposition, conformability, no self-adjustment to tapered lesions, stent overexpansion, stent underexpansion, edge dissection, and immediate vascular injury while treating long lesions in tapered coronary arteries.[5] A novel dedicated long-tapered drug-eluting stent (DES) may overcome these challenges of deploying stents in coronary arteries with the tapered shape.[6] The long-tapered DES is particularly designed to resolve length and tapering issues of long and diffusely diseased segments. The tapered stent provides better safety approach over overlapping stents and also saves the time of intervention cardiologist as well as the cost of patients.[7,8]

BioMime Morph™, Meril Life Sciences, India, is the world's first commercialized tapered DES system intended to deal with the aforementioned unmet clinical needs for long and tapered lesions without any change in core stent design. The purpose of this system is to deploy the stent into the coronary arteries such as LAD and RCA with *de novo* lesions of ≤56 mm lengths. It is possible to treat multiple blockages of the tapered coronary artery as well as the long length lesions with the implantation of the single BioMime Morph long sirolimus-eluting stent (40–60 mm). This stent is used to position in the proximal, mid, and distal segments of the diseased coronary artery with adaptability to artery anatomy, i.e., vessel conformability, homogenous radial force, mechanical stress, and stent-arterial wall ratio along the stented segment. Furthermore, this stent has features such as flexibility, vessel wall coverage, and deployment accuracy to ensure lesion coverage. This long and tapered stent system allows the interventional cardiologist to safely expand the stenosed segment to the diameter of the artery. It is mounted on a long and tapered percutaneous transluminal coronary angioplasty balloon catheter, especially designed to suit the tapered artery.

Safety and efficacy of the BioMime Morph have been documented in real-life patients. Recently, Valero *et al*. shared their experience of treating coronary lesions (a long and diffuse disease with >48 mm of length or multiple tandem lesions with >48 mm of total length) with 60 mm-long BioMime Morph. Deployment of the stent was achieved in 92% cases despite unfavorable anatomical conditions. It should be noted that no major adverse cardiac event was observed in a median follow-up of 275 days.[6] Similarly, the use of long sirolimus-coated stents demonstrated safety and efficacy in long lesion of the coronary arteries with lower risk of repeated revascularization of the target lesion and other adverse cardiovascular events.[8] Moreover, the technical feasibility of BioMime Morph stent has been documented for the treatment of long diffused lesions in patients with chronic total occlusion.[7]

However, the efficacy of the BioMime Morph stent has not been yet documented in clinical conditions such as unresolved vessel thrombus at the lesion site, coronary artery reference vessel diameters <2.25 mm or >3.50 mm, lesion length >56 mm, lesions located in saphenous vein grafts,

lesions located in unprotected left main coronary artery, ostial lesions, lesions located at a bifurcation, previously stented lesions, excessive tortuosity proximal to the lesion, recent acute myocardial infarction, or evidence of thrombus in the target vessel and in-stent restenosis.

CONCLUSION

The novel BioMime Morph long-tapered sirolimus-eluting stent is designed to treat *de novo* long lesions in native coronary arteries with tapered anatomy.

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Access this article online	
Website: www.heartindia.net	**Quick Response Code**
DOI: 10.4103/heartindia.heartindia_24_18	

How to cite this article: Patted SV. Treatment of long coronary lesions with single stent: BioMime Morph sirolimus-eluting tapered coronary stent system. Heart India 2018;6:113-4.