Very long stent technology: clinical and practical value

"Given the clinical need and the procedural advantages, it is likely that very long stent lengths ≥40–50 mm will become more widely available from a range of manufacturers over the next 5 years."

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Commentary
Future Cardiology

Contemporary interventional strategies often require treatment of diffuse, long lengths of coronary disease. However, use of multiple stents, with one or more overlap zones, has been associated with several potential risks, including side branch compromise, inadvertent gaps between adjacent stents, perforation, stent fracture and, for drug-eluting stents, the delivery of a double dose of drug and exposure to a double area of polymer. We describe the first use in Europe, to our knowledge, of a very long (40 mm) Biomime™ drug-eluting stent (Meril Life Sciences, Pvt Vapi, Gujarat, India) and evaluate the advantages and limitations of such a strategy.

Diffuse, long-length coronary disease is commonly encountered in real-world coronary intervention. The all-comers LEADERS trial reported that almost a third of the 1707 patients recruited had long-length coronary disease (>20 mm, often much longer) [1]. The maximum single stent length available for current stent platforms is typically in the range of 28–38 mm and thus overlapping stents are often required to cover longer segments of coronary disease. However, overlapping stents may be associated with several theoretical disadvantages. Overlapping stents at the level of a side branch may increase the risk of side branch occlusion and periprocedural myocardial infarction due to the physical double layer of stent struts, or by increased plaque shift. This may be particularly likely with earlier generation thicker polymer stents [2–6]. The double stent layer may make side branch rewiring more difficult, should this be required after main vessel stent deployment. Inadvertently leaving a short gap between stents, despite the intention to overlap, occurs more frequently than appreciated and was reported in an eighth of patients in a recent coronary computed tomography follow-up study [7]. Such gaps can increase the risk of acute/subacute stent thrombosis and late restenosis at the gap zone. Excessive dilatation of the inflow of the distal stent during proximal stent deployment or during postdilatation, particularly if there is a diameter difference ≥1 mm between stents, can increase the risk of coronary perforation. Stent strut fatigue fractures at overlap zones have been described, particularly in the presence of geometric curvature, such as the mid right coronary artery [8]. In drug-eluting stent technology, an overlap zone potentially delivers double the drug dosage to the vessel wall and presents double the exposure to stent polymer coating. For this reason, assessment of stent overlap zones is standard practice during pre-clinical stent safety evaluation. Finally, provided that deliverability is acceptable, use of one long stent, rather than two short stents, may save procedural time and cost.

Long-length coronary disease

Figure 1 shows a long length of left anterior descending (LAD) stenosis in a 63-year-old man with a recent non-ST elevation myocardial infarction. He had a history of hypertension and hyperlipidemia, and a preserved left ventricular ejection of 50–55%. Avoiding stent overlap was desirable given the presence of two diagonal side branches and at least four septal side branches along the length of the diseased LAD segment. Guidewires were passed to the distal LAD and second diagonal branches. Following predilatation with a 2.5 × 8 mm balloon, a CE-marked 3.5 × 40 mm Biomime stent tracked easily and was deployed covering the entire diseased LAD segment (Figure 2). To our knowledge, this is the longest length of single (one segment) stent deployed in Europe. Postdilatation of the Biomime stent was performed with 3.5 × 15 mm noncompliant balloon, and a 2.5 × 11 mm stent was also deployed in the proximal (but not ostial) second diagonal branch.

Biomime stent

The Biomime stent (Figure 3) comprises a thin-strut (65 µm) cobalt chromium stent platform

Keywords
■ biodegradable polymer ■ Biomime™ ■ coronary artery disease ■ drug-eluting stent ■ long stent ■ side branch occlusion ■ sirolimus ■ stent overlap

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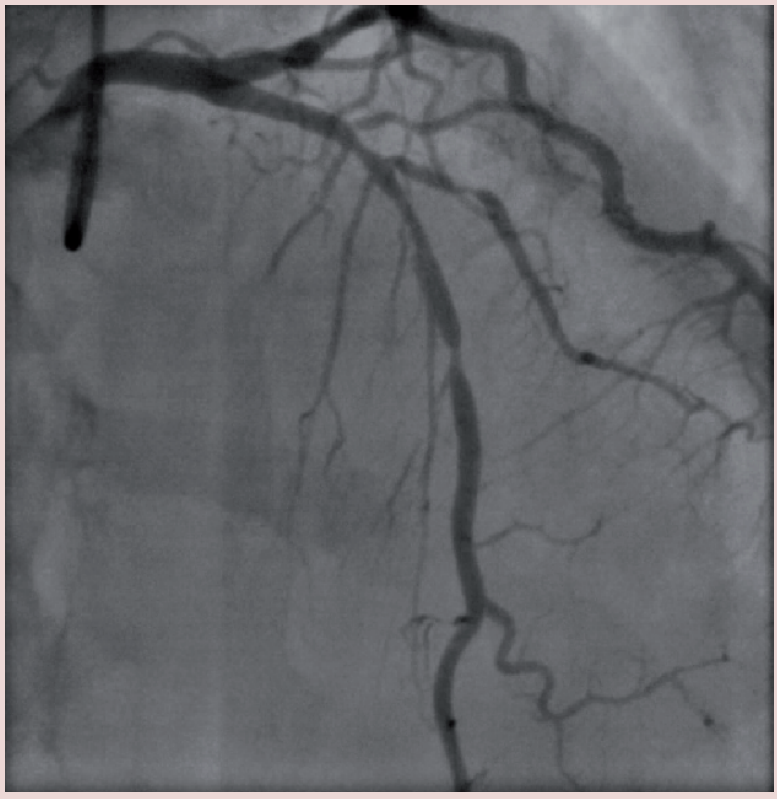

Figure 1. Left anterior descending artery showing a long length of disease from proximal- to mid-vessel, and the presence of two diagonal and four septal side branches arising from within the diseased segment.

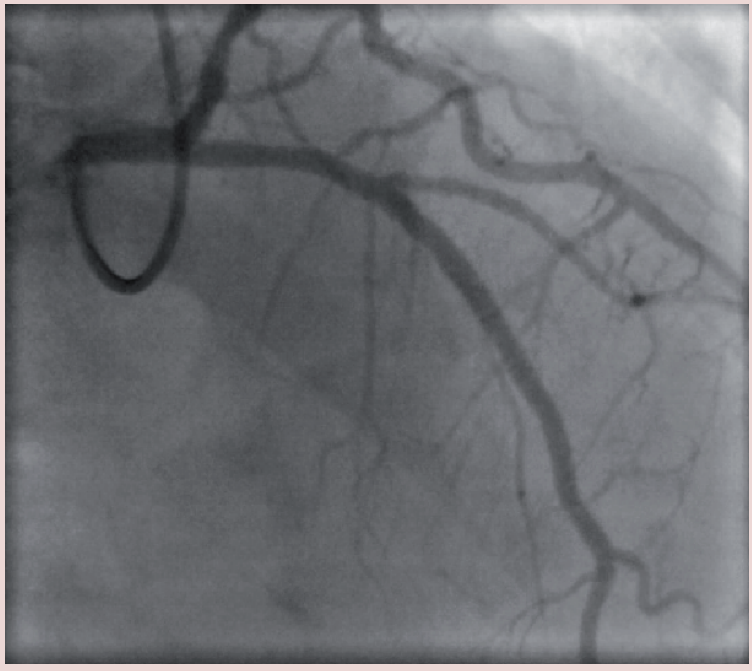

Figure 2. Left anterior descending artery following deployment of a single very long length (40 mm) stent showing a good main vessel result and preservation of all major side branches.

with a hybrid design (closed cell at ends, open cell in middle), mounted on a flexible delivery system with a low balloon overhang to reduce edge injury. A thin (2 µm) biodegradable copolymer layer of poly-L-lactide and poly-L-co-glycolide elutes sirolimus over 30 days. As seen in our case, the thin-strut, thin-polymer layer and open-cell design of the mid-part of the stent may have contributed to side branch preservation in addition to the potential advantages of avoiding stent overlap, as described above (reduced side branch occlusion, no gap, less risk of perforation or strut fatigue, and avoidance of double drug/polymer).

Limitations of very long stents

A very long stent may have certain disadvantages. As the LAD is typically a tapering artery, sizing the stent to the distal reference may lead to undersizing at the proximal reference. This can usually be overcome by the use of a larger postdilatation balloon in the proximal stent segment. Development of a tapered stent/delivery system is also being considered for ultra-long lengths. 'Dog-boning' of the delivery balloon during stent deployment may be a greater problem with longer stent length. The hybrid design of the Biomime stent helps to address this due to preferential expansion of the open-cell midsection before expansion of the closed-cell inflow/outflow (morphology-mediated expansion). Stent trackability and deliverability may be compromised as stent length increases, particularly in more tortuous vessels. Our experience so far has been good, but the use of ultra-long stents may, on occasion, require more active guide support or use of a mother and child guide–extension device with or without anchor technique. Foreshortening can be of greater concern with longer stent lengths, thus it is reassuring that, despite the use of a cobalt chromium alloy, observed foreshortening of the Biomime stent is only 0.29%.

Conclusion

Diffuse long-length disease is common in clinical practice. Creation of an overlap zone between two stents is associated with several potential risks including side branch compromise, inadvertent gaps between adjacent stents and, for drug-eluting stents, the delivery of a double dose of drug and exposure to a double area of polymer. The emerging availability of very long stents may help to overcome some of these clinical and device-related concerns.

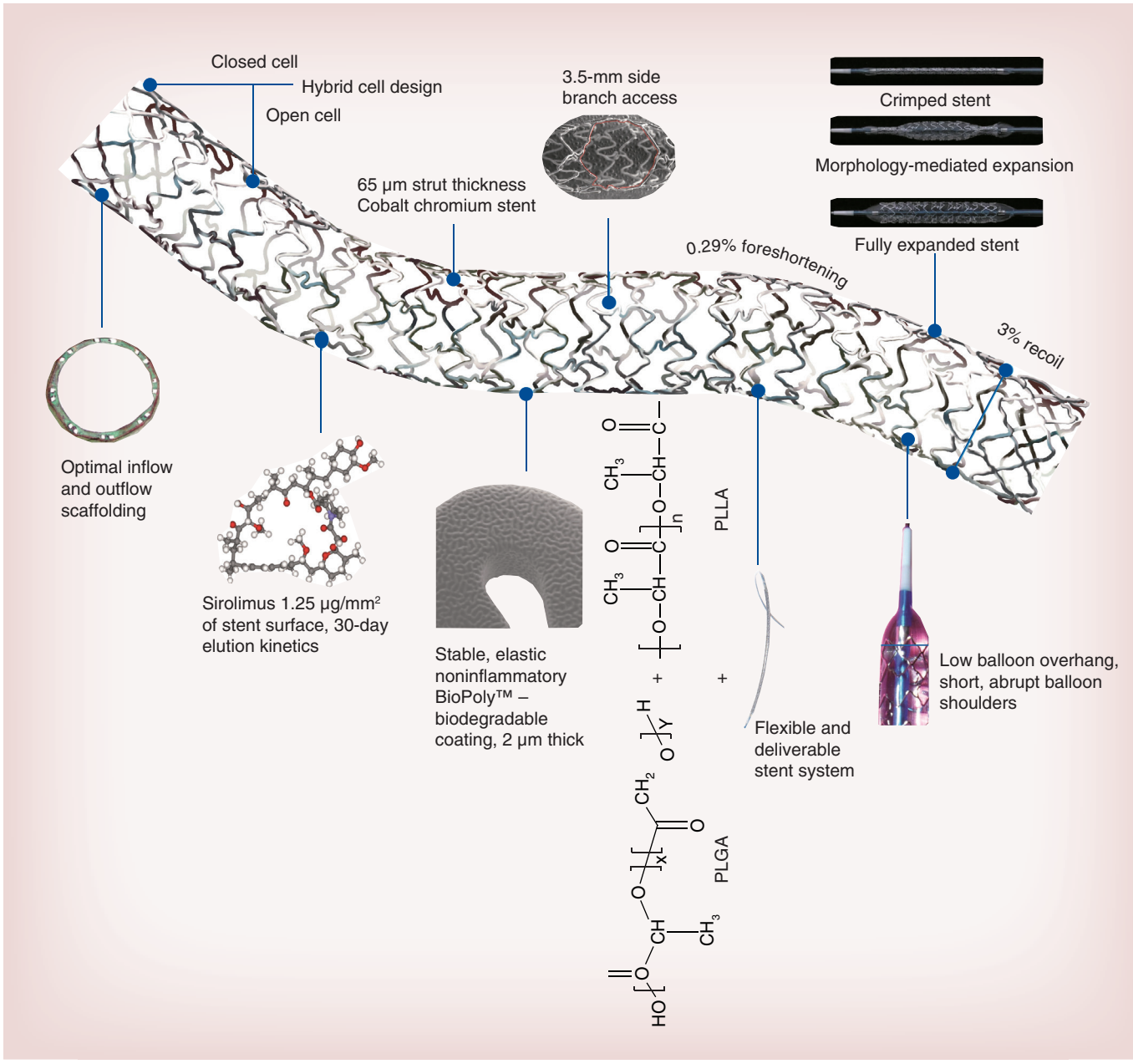

Figure 3. Biomime™ stent illustrating its hybrid design (closed cell at ends and open cell in middle) reducing risk of delivery balloon 'dog-boning' and biodegradable copolymer layer of poly-L-lactide and poly-L-co-glycolide, which elutes sirolimus over 30 days.
PLLA: Poly-L-lactide; PLGA: Poly-L-co-glycolide.

Future perspective

Given the clinical need and the procedural advantages, it is likely that very long stent lengths ≥40–50 mm will become more widely available from a range of manufacturers over the next 5 years. Ensuring adequate stent apposition will require a high-quality delivery balloon and the use of postdilatation in most cases. Production of a very long stent that tapers by 0.5–1 mm from proximal to distal presents an engineering challenge, but one which is likely to be overcome.

Financial & competing interests disclosure

IB Menown is principal investigator for the UK-Miles registry evaluating the use of the Biomime stent in an all-comers population. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Executive summary

- In real-world contemporary interventional practice, up to a third of patients may require treatment of long coronary lesions.
- The maximum single stent length available for current stent platforms is typically in the range of 28–38 mm, thus overlapping stents are often required to cover longer segments of disease.
- The overlap zone between two stents has been associated with several potential risks, including side branch compromise, inadvertent gaps between adjacent stents, perforation, stent fracture and, for drug-eluting stents, the delivery of a double dose of drug and exposure to a double area of polymer.
- The successful first use in Europe of a very long (40 mm) single-unit Biomime™ drug-eluting stent is described.
- The Biomime stent is comprised of a thin-strut cobalt chromium stent platform with hybrid design (closed cell at ends and open cell in middle) and a thin (2 μm) biodegradable copolymer layer of poly-L-lactide and poly-L-co-glycolide, which elutes sirolimus over 30 days.
- Limitations of very long stents may include size mismatch between distal and proximal reference in a tapering vessel, 'dog-boning' of the delivery balloon during stent deployment, reduced deliverability and increased foreshortening.
- The novel design of the Biomime stent may help to address some of these limitations.

References

Papers of special note have been highlighted as:
- ▪ of interest
- ▪▪ of considerable interest

1. Windecker S, Serruys PW, Wandel S *et al.* Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomised non-inferiority trial. *Lancet* 372(9644), 1163–1173 (2008).
2. Applegate R, Hermiller J, Williams J *et al.* Evaluation of the effects of everolimus-eluting and paclitaxel-eluting stents on target lesions with jailed side branches: 2-year results from the SPIRIT III randomized trial. *Catheter Cardiovasc. Interv.* 76, 644–651 (2010).
3. Popma JJ, Mauri L, O'Shaughnessy C *et al.* Frequency and clinical consequences associated with side branch occlusion during stent implantation using zotarolimus-eluting and paclitaxel-eluting coronary stents. *Circ. Cardiovasc. Interv.* 2, 133–139 (2009).
4. Dawkins KD, Grube E, Guagliumi G *et al.* Clinical efficacy of polymer-based paclitaxel-eluting stents in the treatment of complex, long coronary artery lesions from a multicenter, randomized trial. *Circulation* 112, 3306–3313 (2005).

▪▪ **Important study from which the advantage of lower polymer thickness was identified.**

5. Yamawaki M, Muramatsu T, Araki M *et al.* Natural history of side branches jailed by drug-eluting stents. *J. Interv. Cardiol.* 25, 37–46 (2012).
6. Lansky AJ, Yaqub M, Hermiller JB *et al.* Side branch occlusion with everolimus-eluting and paclitaxel-eluting stents: three-year results from the SPIRIT III randomised trial. *EuroIntervention* 6(Suppl. J), J44–J52 (2010).
7. Zhang X, Yang L, Ju H *et al.* Prevalence and prognosis of coronary stent gap detected by multi-detector CT: a follow-up study. *Eur. Radiol.* 22(9), 1896–1903 (2012).

▪ **Very useful description of the frequency and predictors for stent gap in complex intervention.**

8. Kapnisis KK, Halwani DO, Brott BC, Anderson PG, Lemons JE, Anayiotos AS. Stent overlapping and geometric curvature influence the structural integrity and surface characteristics of coronary nitinol stents. *J. Mech. Behav. Biomed. Mater.* 20, 227–236 (2013).