Percutaneous Coronary Intervention

Comparative Analysis of Three Different Optimization Procedures for Coronary Bifurcation Provisional Stenting: Insights from Micro-Computed Tomography and Optical Coherence Tomography Imaging of Bench Deployments

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**Background:** Post-dilation with kissing balloon dilation remains controversial in the 1-stent approach, but many technical improvements are possible to refine the final results. This study aimed to evaluate the results of different side-branch (SB) ostial treatments after main vessel stenting, including ostial optimization technique (OOT), simultaneous kissing balloon dilation (KBD) and single balloon dilation (SBD).

**Methods:** Three different ostial side branch treatments (OOT, n = 5; KBD, n = 5; SBD, n = 5) were emulated in a synthetic bifurcated phantom using a second-generation sirolimus-eluting stent (Firebird2TM, Microport, Shanghai, China). Micro-computed tomography (micro-CT) and optical coherence tomography (OCT) were performed to assess morphologies.

**Results:** Compared to the non-OOT procedures (SBD and KBD), OOT was characterized by the sequential dilation of two snuggling balloons, creating a longer valgus struts length (OOT: 2.13 ± 0.39 mm, SBD: 1.23 ± 0.34 mm, KBD: 1.11 ± 0.39 mm, p < 0.01), broader angulation between the main-branch and valgus struts axes (OOT: 42.72 ± 0.91°, SBD: 31.78 ± 1.34°, p < 0.01), shorter neocarina length (OOT: 0.28 ± 0.31 mm, SBD: 0.64 ± 0.38 mm, KBD: 1.11 ± 0.37 mm, p < 0.01), larger SB ostial area (OOT: 6.76 ± 0.17 mm², SBD: 4.78 ± 0.86 mm², KBD: 5.87 ± 0.89 mm², p < 0.01), and lower index of stent cell distortion (OOT: 6.67 ± 3.33%, SBD: 10.67 ± 4.23%, KBD: 20.00 ± 5.29%, p < 0.01). In addition, the rate of severe strut malapposition was lower with the OOT procedure compared with the non-OOT procedures (OOT: 2.22 ± 0.48%, SBD: 10.31 ± 0.66%, KBD: 6.74 ± 1.24%, p < 0.01).

**Conclusions:** OOT, consisting of an initial proximal optimizing technique (POT) and sequential snuggling balloon dilation and then re-POT, significantly optimized the results of provisional bifurcation treatment. The physiological and clinical significance of our observations await further clarification.

**Key Words:** Bench testing • Micro-computed tomographic • Optical coherence tomography • Provisional stenting

INTRODUCTION

Coronary bifurcation lesions (CBLs) are one of most the complex lesion subsets, and they are still a challenging area in the field of percutaneous coronary interventions (PCIs). Compared to non-CBL interventions, PCIs for CBLs are associated with higher rates of target vessel revascularization, restenosis, thrombosis, and a lower
rate of procedural success.\textsuperscript{1-4} Therefore, optimization of the associated techniques remains an important subject for interventional cardiologists.

PCIs for CBLs can be categorized into one- or two-stent approaches, or a simple or complex strategy.\textsuperscript{5} Complex strategies, such as T-stenting, DK-culotte, and DK-crush, are designed to stent both the main-branch (MB) and side-branch (SB), while simple strategies are designed to stent the MB only. Alternatively, a provisional strategy can be used, in which SB stenting is only indicated when the SB is severely compromised. Due to the similar or more favorable clinical outcomes compared to a routine two-stent approach, simple strategies with one stent or provisional SB stenting has been generally accepted as the default approach in bifurcation interventions.\textsuperscript{5-7} In clinical practice, the European Bifurcation Club (EBC) also recommends the KISSS principle (Keep it Simple, Swift and Safe).\textsuperscript{8,9} The first priority in bifurcation treatment must be keeping MB patency. Nonetheless, it remains controversial whether simultaneous kissing balloon dilation (KBD) is necessary and the most effective use of KBD in simple strategy is unclear,\textsuperscript{10-15} irrespective of the necessity of final KBD for all two-stent approaches.\textsuperscript{1,16-18}

In bench testing, the aim of this study was to evaluate the results of different SB ostial treatments after MB stenting by comparing ostial optimization technique (OOT), simultaneous KBD and single balloon dilation (SBD).

**METHODS**

**Bench testing protocol**

After main vessel (MV) stenting, the three different SB ostial treatments (SBD, KBD, and OOT) were emulated in a synthetic bifurcated phantom, in which the proximal main vessel (PMV) was 3.5 mm, MB was 3.25 mm, and SB was 3.0 mm with a distal bifurcated angle of 45°. The phantom was made from polyvinyl alcohol which can simulate the elasticity and wall compliance of the coronary arteries. Each treatment was repeated six times with a total 18 tests. Drug-eluting stents (DESs) of 3.5 mm in diameter (Firebird\textsuperscript{TM}, Microport, Shanghai, China; total = 18) were used for the MV stenting. The Firebird2 stent is a second-generation sirolimus-eluting stent which has a cobalt-chromium alloy stent platform with a strut thickness of 0.0034 inch, and durable styrene-butylene-styrene polymer coating with better biocompatibility. A compliance balloon (Apex\textsuperscript{TM}, Boston Scientific) was used to pretreat the stent side-hole and non-compliance balloon (Quantum Maverick\textsuperscript{TM}, Boston Scientific) in the proximal optimizing technique (POT), OOT, SBD, and KBD.

**Stenting procedure**

1. The procedural steps of SBD were: 1) stenting the PMV-MB; 2) rewiring the SB through the most distal cell of the MB stent facing the SB ostium; 3) after SB rewiring, performing SBD with a 3.0 × 12 mm non-compliant (NC) balloon with an inflation pressure of 12 atm for 15 s; 4) after SBD, performing POT with a 4.0 × 8 mm NC balloon at 14 atm to end the procedure (Figure 1).

2. The procedural steps of KBD were: 1) stenting the PMV-MB; 2) rewiring the SB through the most distal cell of the MB stent facing the SB ostium; 3) after SB rewiring, performing simultaneous KBD by concurrently inflating the SB NC balloon (3.0 × 12 mm) and MB NC balloon (3.5 × 12 mm) both at 12 atm to dilate the SB ostium; 4) after KBD, performing POT with a...
The procedural steps of OOT were: 1) stenting the PMV-MB; 2) performing initial POT with a 4.0 × 8 mm NC balloon at 14 atm to facilitate rewiring the SB through the most distal cell of the MB stent facing the SB ostium; 3) after SB rewiring, performing sequential snuggling balloon dilation to optimize the ostial SB, which was achieved by first inflating the SB NC balloon (3.0 × 12 mm) at 6-8 atm and then an MB NC balloon (3.5 × 12 mm) at 8-10 atm to overturn the redundant struts covering the SB ostium onto the superior aspect of the ostial SB (so-called OOT); 4) repeating POT (re-POT) with a 4.0 × 8 mm NC balloon at 14 atm to end the procedure (Figure 3).

**Imaging modalities**

Each step was observed visually and recorded with a digital recorder (L-1ex/TT02RX, ELMO, Japan). Final results were acquired using micro-computed tomography (micro-CT) (SkyScan 1176, Kontich, Belgium) and optical coherence tomography (OCT) (C7-XRTM, St. Jude Medical). The X-ray parameters of micro-CT were set at 65 kV and 385 μA, and scanning with a high spatial resolution of 18 μm. Three-dimensional (3D) reconstruction was performed as previously described. After 3D reconstruction, the CT images were electronically rotated and dissected using CTvox software (Bruker microCT, Belgium) so that the stents could be analyzed in an arbitrary plane. In addition, 2D OCT was performed using a C7-XRTM OCT imaging system with a Dragonfly Duo imaging catheter (St. Jude Medical, St. Paul, MN, US). Automatic pullbacks were performed at 20 mm/s and recorded at 100 frames per second. All images were analyzed by an independent observer using proprietary software.

**Morphological analysis**

Bifurcated stents were divided into four distinct parts with the PMV, MB, SB, and polygon of confluence (POC) (Figure 4A), and the POC and its adjacent segments (3-mm proximal to POC, 3-mm distal to SB and MB ostium) were defined as the bifurcated connecting...
domain (BCD) (Figure 4B).

Micro-CT was used to examine the stented bifurcation from different perspectives, and the detailed parameters were measured as reported in previous studies. Quantitative parameters were calculated for all bifurcations, including the reference area ($A_{\text{REF}}$) and minimal area ($A_{\text{MIN}}$) in each segment, the area of branch ostium including the ostial area of MB or SB ($A_{\text{MBO}}/A_{\text{SBO}}$), the minimal diameter ($D_{\text{MIN}}$) and maximal diameter ($D_{\text{MAX}}$) at the most asymmetric site, and the special parameters associated with branch ostial treatment (OOT vs. non-OOT), including the length of the neocarina ($L_{\text{NC}}$), the length of the valgus struts ($L_{\text{VS}}$), and angulation ($A_{\text{VS}}$) between the MB and valgus struts axes (Figure 4A). Based on these measurements, the ellipticity index (EI) was calculated as $D_{\text{MIN}}/D_{\text{MAX}}$. Residual stenosis of the SB ostium was calculated as $\frac{A_1}{A_2} \times 100\%$, where $A_1$ is the total area of struts facing the ostium, and $A_2$ is the total SB ostium area.

In addition, stent distortion was analyzed in the BCD segment (Figure 4B). The ring-to-ring distance ($D_1$) was measured along the stent long-axis and divided by the nominated ring-to-ring distance ($D_0$) provided by the manufacturer, resulting in a cell distortion index ($D_1/D_0$). The total number of cells ($N$), and the cells with $D_1/D_0 > 1.5$ ($N_1$) were counted in the BCD. The index of stent cell distortion ($I_{\text{SCD}}, \%$) was calculated as $N_1/N_0 \times 100\%$.

OCT was performed at the end of each in vitro procedure to examine stent malapposition in the BCD, which was graded as in a previous study as follows: full apposition (no malapposition), incomplete apposition (malapposition $> 0$ um), marked malapposition (malapposition $> 200$ um), and floating struts (malapposition $> 500$ um). The rate of severe strut malapposition ($R_{\text{SMA}}$) was expressed as the percentage of strut footprint with malapposition $> 200$ um, as described previously.\(^{20,21}\)

**Statistical analysis**

All data analyses were performed using a commercially available statistical software package (SPSS 22.0; SSPI, Chicago, IL). Continuous variables are expressed as mean $\pm$ standard deviation (SD) and categorical data as counts (%). Comparisons between groups were performed using one-way ANOVA, followed by LSD t-test or Tamhane’s T2 test for post hoc comparisons between groups.

**RESULTS**

All 18 in vitro stented bifurcations were successfully performed according to the study protocol, and micro-CT and OCT analyses were completed in all phantoms. Figure 5 shows typical examples from the in vitro cases.

**Micro-CT image analysis**

Micro-CT analysis confirmed that OOT created a longer $L_{\text{VS}}$ compared with SBD and KBD (OOT: $2.13 \pm 0.30$ mm, SBD: $1.23 \pm 0.34$ mm, KBD: $1.11 \pm 0.39$ mm, $p < 0.01$). Post-procedural angulation ($A_{\text{VS}}$) between the MB and valgus struts axes showed that OOT created a broader $A_{\text{VS}}$ than SBD and KBD (OOT: $42.72 \pm 0.91^\circ$, SBD: $25.77 \pm 7.81^\circ$, KBD: $31.78 \pm 1.34^\circ$, $p < 0.01$). Compared with SBD and KBD, OOT significantly improved ostial MB
morphology with a shorter $L_{NC}$ (OOT: $0.28 \pm 0.31$ mm, SBD: $0.64 \pm 0.38$ mm, KBD: $1.11 \pm 0.37$ mm, $p < 0.01$), larger $A_{MBO}$ (OOT: $10.69 \pm 0.74$ mm$^2$, SBD: $9.68 \pm 0.62$ mm$^2$, KBD: $9.61 \pm 0.93$ mm$^2$, $p = 0.052$) and $A_{SBO}$ (OOT: $6.76 \pm 0.17$ mm$^2$, SBD: $4.78 \pm 0.86$ mm$^2$, KBD: $5.87 \pm 0.89$ mm$^2$, $p < 0.01$), lower $L_{SCI}$ (OOT: $6.67 \pm 3.33$, SBD: $10.67 \pm 4.23$, KBD: $20.00 \pm 5.29$, $p < 0.01$) and better stent circularity in the PMV segment (ellipticity index: OOT: $1.07 \pm 0.01$, SBD: $1.06 \pm 0.04$, KBD: $1.14 \pm 0.05$, $p < 0.01$). In addition, in the ostial SB, post-stenting residual stenosis was lower with the OOT procedure compared with the non-OOT procedures (OOT: $4.67 \pm 2.66$, SBD: $32.17 \pm 13.53$, KBD: $16.67 \pm 12.23$, $p < 0.05$) (Figure 3). Representative cross-sectional micro-CT images are shown in Figures 5 and 6. Detailed results of the analyses are shown in Table 1.

**OCT findings**

OCT detected much less malapposition with the OOT procedure than the non-OOT procedures (SBD and KBD), as indicated by a lower $R_{SMA}$ in the BCD (OOT: $2.22 \pm 0.48$, SBD: $10.31 \pm 0.66$, KBD: $6.74 \pm 1.24$, $p < 0.01$).

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**Figure 5.** In vitro observed (upper panels) and micro-CT images (lower panels) of representative cases of the SBD, KBD, and OOT. OOT (F) creates optimal SB ostium opening with adequate struts coverage and minimal malapposition in POC segment (black arrow), compared to SBD (D) and KBD (E). KBD, simultaneous kissing balloon dilation; OOT, ostial optimization technique; POC, polygon of confluence; SB, side branch; SBD, single balloon dilation.

**Figure 6.** Four different cross-sectional images are shown and compared for three different bifurcation techniques: SBD, KBD, OOT. Morphological characteristics of three different bifurcation techniques: SBD (1st row), KBD (2nd row), OOT (3rd row). The 1st column (A, E, I) shows full 3D images; the 2nd one (B, F, J) for coronal cutting images; the 3rd column (C, G, K) for cross-sectional images of POC segment and the 4th column (D, H, L) for SB ostium. The white and red dashed lines in coronal cutting images (the 2nd column) correspond to the cross-sectional images in the 3rd column and the 4th column, respectively. SBD and KBD cause significant ostial narrowing in SB (red circle) and severe struts malapposition (red arrow) in the POC segment, whereas OOT provides maximal SB ostium area, full struts coverage and less malapposition in the POC segment. KBD, simultaneous kissing balloon dilation; OOT, ostial optimization technique; POC, polygon of confluence; SB, side branch; SBD, single balloon dilation.
0.01). Notably, floating struts and marked malapposition were most frequently seen in the superior aspect of the SB ostium in the non-OOT groups (SBD and KBD), but rarely in the OOT group. Representative OCT images are shown in Figure 7.

**DISCUSSION**

Treatment of coronary bifurcation lesions remains a challenge in PCIs. Numerous stenting techniques have been developed for the intervention of CBLs, which can generally be categorized into simple and complex strategies. Several trials have revealed non-superiority, even inferiority, with complex strategies such as crush or culotte techniques compared with simpler strategies such as the provisional strategy.\(^1,6,17,22-25\) However, the incidence of side branch occlusion or narrowing after high-pressure main vessel stenting has been reported in 8% to 80% of coronary bifurcation PCIs.\(^26,27\) Higher rates of in-hospital ischemic complications have also been reported with side branch occlusion.\(^27-29\) In addition, if bailout SB stent implantation is necessary and the SB ostium is not optimally treated, there is inevitably a risk of strut protrusion into the main vessel or leaving a gap/non-coverage at the superior aspect of the SB ostium.\(^23,30-32\) Accordingly, how best to maintain SB ostium patency after MV stenting remains a technical challenge.

The current study is the first to evaluate the feasibility of OOT, and to compare the performance of OOT and non-OOT (SBD and KBD) in bifurcation stenting with DESs. The key findings of this study are summarized as

| Table 1. Comparison of the 3 different SB ostial treatments |
|---------------------------------|--|--|--|
|                                | SBD   | KBD   | OOT   |
| n                               | 6     | 6     | 6     |
| 1. Micro-CT analysis            |       |       |       |
| PMV segment                     |       |       |       |
| \(A_{REF} (\text{mm}^2)\)       | 11.07 ± 0.31 | 11.74 ± 0.71 | 11.16 ± 0.62 |
| \(A_{MIN} (\text{mm}^2)\)       | 10.77 ± 0.35 | 11.33 ± 0.70 | 10.75 ± 0.72 |
| \(E_{PMV}\)                     | 1.06 ± 0.04 | 1.14 ± 0.05* | 1.07 ± 0.01* |
| MB segment                      |       |       |       |
| \(A_{REF} (\text{mm}^2)\)       | 10.40 ± 0.54 | 10.19 ± 0.45 | 10.74 ± 0.66 |
| \(A_{MIN} (\text{mm}^2)\)       | 9.98 ± 0.92 | 9.58 ± 0.89 | 10.33 ± 1.04 |
| \(E_{MB}\)                      | 1.05 ± 0.02 | 1.04 ± 0.01 | 1.04 ± 0.02 |
| \(A_{MBO} (\text{mm}^2)\)       | 9.68 ± 0.62 | 9.61 ± 0.93 | 10.69 ± 0.74* |
| \(E_{MBO}\)                     | 1.12 ± 0.10 | 1.17 ± 0.16 | 1.06 ± 0.04 |
| SB ostium                       |       |       |       |
| \(A_{REF} (\text{mm}^2)\)       | 7.06 ± 0.22 | 7.05 ± 0.25 | 7.07 ± 0.16 |
| \(A_{SBG} (\text{mm}^2)\)       | 4.78 ± 0.86* | 5.87 ± 0.89* | 6.76 ± 0.17* |
| \(E_{SBG}\)                     | 1.37 ± 0.09 | 1.20 ± 0.20* | 1.22 ± 0.05 |
| Residual stenosis of SB ostium (%) | 32.17 ± 13.53 | 16.67 ± 12.23* | 4.67 ± 2.66* |
| Bifurcation segment             |       |       |       |
| \(A_{VS} (°)\)                  | 25.77 ± 7.81 | 31.78 ± 1.34* | 42.72 ± 0.91** |
| \(L_{NC} (\text{mm})\)          | 0.64 ± 0.38 | 1.11 ± 0.37* | 0.28 ± 0.31* |
| \(L_{VS} (\text{mm})\)          | 1.23 ± 0.34 | 1.11 ± 0.39 | 2.13 ± 0.30** |
| \(I_{SCD} (%)\)                 | 10.67 ± 4.23* | 20.00 ± 5.29* | 6.67 ± 3.34* |
| 2. OCT analysis                 |       |       |       |
| \(R_{SMA}, \text{Bifurcation segment} (%)\) | 10.31 ± 0.66* | 6.74 ± 1.24* | 2.22 ± 0.48** |

\(A_{MBO}\), area of MB ostium; \(A_{MIN}\), minimal area of scaffold lumen; \(A_{REF}\), reference area of stent lumen; \(A_{SBG}\), area of SB ostium; \(A_{VS}\), angle of valgus struts; \(E_I\), the ellipticity index; \(I_{SCD}\), index of stent cell distortion; KBD, simultaneous kissing balloon dilation; \(L_{NC}\), length of neocarina; \(L_{VS}\), length of valgus struts; MB, main-branch; MBO, main branch ostium; OOT, ostial optimization technique; PMV, parent main-vessel; POC, polygon of confluence; \(R_{SMA}\), rate of severe strut mal-apposition; SB, side-branch; SBD, single balloon dilation; SBO, side branch ostium.

Numbers are means ± standard deviation or proportions. * Compared to SBD, \(p < 0.05\). ** Compared to KBD, \(p < 0.05\).
follows: 1) initial POT after MV stenting was necessary, which could greatly facilitate the most distal cell rewiring and then decrease the length of the neocarina; 2) OOT effectively upturned the MB struts that jailed the SB ostium onto the superior aspect of the SB ostium with minimal stent cell distortion, resulting in lip-like strut ectropion; 3) the OOT procedure significantly reduced the marked malapposition and neocarina formation in the BCD segment compared to the non-OOT procedures; 4) final re-POT was necessary, which could optimize the elliptic index of PMV and decrease the rate of malapposition. However, re-POT dilation after the SBD procedure could return the valgus struts upturned by SBD back to the SB ostium and partly jail the SB ostium, although this was not observed in the OOT and KBD procedures (Appendix video); 5) KBD could not perfectly upturn the MB struts that jailed the SB ostium onto the superior aspect of the SB ostium and created an elliptical deformation in the distal PMV.

Ineffectiveness of SBD + re-POT

Several in vitro studies have demonstrated the detrimental effects of SBD without re-POT after main vessel stent implantation.33,34 Side branch dilation without re-POT can partially open the SB ostium but lead to malapposition opposite to the SB ostium and stenosis at the MB ostium. Previous studies have identified a possible correlation between strut malapposition and stent thrombosis.35-39 On the basis of in vitro bench testing, Finet et al. demonstrated that an ‘initial POT plus SBD with final POT’ after main vessel stenting could enable restoration of arterial circular geometry and improvements in strut apposition opposite the SB ostium.33 However, we found that re-POT dilation after the SBD procedure could return the valgus struts upturned by SBD dilation back to the SB ostium and partially jail the SB ostium, resulting in a high risk of strut malapposition or floating in the SB lumen (Figure 4A, B). In addition, after re-POT dilation, the LVS was much shorter than in OOT (1.23 ± 0.34 vs. 2.13 ± 0.30 mm), and this could result in a gap/non-coverage between the main vessel stent and the SB stent when the bailout SB stent was implanted. Although the T and small protrusion technique (TAP) can offer full coverage of the SB ostium, the protruded struts would result in suspension of a partial stent in the MV lumen.30,40 Unopposed struts or floating struts could disturb blood flow and provoke significant oscillations in arterial wall shear stress.41,42 From the standpoint of pathophysiology, both high endothelial shear stress (ESS) and low ESS promote stent thrombosis and in-stent restenosis, and low ESS promotes active inflammation and increases plaque thrombogenicity, whereas high ESS enhances platelet activation and adhesion.35,43,44

Negative effects of simultaneous KBD

Post-dilation with final KBD is currently considered to be mandatory for two-stenting strategies such as crush and culotte approaches, however the clinical benefits of
KBD after main vessel stenting remain controversial. Several highly contributive studies comparing a one stent approach with and without KBD consistently demonstrated no significant differences in the rates of major adverse cardiac events (MACEs) and the target lesion revascularization (TLR) between the two groups. The THUEBIS study, which compared mandatory KBD with provisional SBD after MV stenting in true bifurcation lesions, reported equivalent rates of MACEs and TLR (23.2% vs. 24.1%, p = 0.9; 17.9% vs. 14.8%, p = 0.7, respectively).\(^4\) The Nordic-Baltic III study, in which patients undergoing a one stent approach were randomly assigned to receive KBD versus non-KBD, observed no significant difference in the rate of TLR between the two groups (1.3% vs. 1.7%, p > 0.05).\(^4\) Similarly, the nonrandomized J-Cypher registry also generally reported equivalent cumulative incidence rates of TLR at 3 years between MV stenting with KBD versus non-KBD, observed no significant difference in the rate of TLR between the two groups (1.3% vs. 1.7%, p > 0.05).\(^4\) Similarly, the nonrandomized J-Cypher registry also generally reported equivalent cumulative incidence rates of TLR at 3 years between MV stenting with and without KBD (9.9% vs. 9.2%, p = 0.9).\(^4\)

However, the Coronary Bifurcation Stent (COBIS) Registry demonstrated that MV stenting with KBD had a higher risk of MACEs [hazard ratio (HR) 2.58; 95% confidence interval (CI) 1.52 to 4.37; p < 0.001] and TLR (HR 3.63; 95% CI 2.00 to 6.56; p < 0.001) compared with MV stenting without KBD during a mean follow-up of 22 months.\(^4\) Several potential mechanisms may be associated with the poor clinical outcomes of KBD after MV stenting: (1) juxtaposition of the MB and SB NC-balloons in the distal PMV leading to oversizing of the stent and then causing MV stent deformation; (2) SB vessel dissection and injury induced by the hugging balloon, resulting in SB ostial restenosis; and (3) abnormal fluid dynamics and delayed endothelialization induced by symmetrical over-dilatation, which could increase the risk of thrombosis and restenosis.\(^4,4^7,5^1\)

In the present study, the post-KBD procedure maximal diameter of the PMV segment was on average 4.10 ± 0.15 mm (ranging from 3.93 to 4.27 mm), a significant overexpansion and elliptic deformation compared with the reference vessel of PMV. After re-POT dilation, the ellipticity index decreased from 1.37 to 1.14. This finding is consistent with the study of Mortier et al., who reported an ellipticity index of 1.36 after kissing balloon dilation.\(^11\) Although re-POT partially corrected the post-procedure ellipticity index, limitations of KBD included significant attenuation of VS and AVS compared with OOT. Final OCT scans also revealed inadequate strut coverage and unopposed struts at the SB ostium. Accordingly, the main limitations of this technique (i.e., elliptic deformation, localized stent overexpansion, mal-apposed struts) might be associated with the poor clinical outcomes.

**Advantages of initial POT + sequential snuggling balloon dilation + re-POT (OOT)**

To address the aforementioned problems with SBD and KBD, we proposed a novel OOT to reduce the mal-apposition of bifurcation segments and optimize the SB ostium. Of note, the most distal cell rewiring was a key step after MV stenting in the OOT procedure compared with non-OOT procedures (SBD and KBD), which could be achieved by initial POT, with the aim of not only decreasing the length of the neocarina but also increasing the length of the valgus struts to optimize the SB ostium. Another key step in the OOT procedure was the sequential dilation of two snuggling balloons, which was performed in such a manner that the proximal radio-opaque marker of the SB balloon protruded slightly in the main vessel lumen and was dilated at low-pressure (6-8 atm) first; the main vessel balloon was then dilated at a pressure of 8-10 atm with little proximal overlap. This snuggling kissing balloon dilation minimized the overlap of the two NC balloons in the PMV segment, thus optimally decreasing deformation of the distal PMV. Meanwhile, the sequential dilation sequence of the two snuggling balloons could efficiently generate a resultant force toward the direction of the SB axis, thereby producing broader AVS (OOT: 42.72 ± 0.91 mm\(^2\) vs. KBD: 31.78 ± 1.34 mm\(^2\), p < 0.05), larger LVS (OOT: 2.13 ± 0.30 mm vs. KBD: 1.11 ± 0.39 mm, p < 0.05) and larger A\(_{\text{SB}}\) (OOT: 6.76 ± 0.17 mm\(^2\) vs. KBD: 5.87 ± 0.89 mm\(^2\), p < 0.05) compared with concurrent dilation of two juxtaposition balloons (KBD). After OOT, the valgus struts fully covered the superior aspect of the SB ostium, resulting in a ‘two-stent effect with one-stent implantation’ if a remedial SB stent was not necessary, or facilitating subsequent stent positioning and implantation if a remedial SB stent was necessary. Finally, re-POT dilation further optimized the morphology of distal PMV and decreased the rate of malapposition.

In the present analysis, OOT resulted in better bifurcation morphology and a lower rate of malapposition compared with SBD and KBD, which may be expected to
reduce in-stent restenosis and in-stent thrombosis. Although the current findings should be interpreted with caution due to the limited sample size and single stent platform, our data suggest that the OOT is feasible and effective for bifurcation treatment in vitro.

Study limitations

The limitations of the present study are as follows. First, the bifurcated bench model used can never entirely represent in vivo coronary anatomies such as bifurcation angle and plaque distribution, and may not exactly reflect real-life conditions. Second, for the OOT procedure, it is required that SB rewiring should be performed through the distal cell of the MV stent, which can be facilitated after performing initial POT and sometimes even requires the guidance of OCT-based 3D reconstruction in vivo coronary bifurcation treatment. While for the non-OOT procedures (SBD and KBD), no such procedures were implemented in this study. It should be noted that these differences may have influenced the morphological results but not the major findings in this study. Further studies are needed to clarify the extent of these influences. Finally, the limited sample size and no comparison with other stent platforms may have influenced the conclusions, and thus the results should not be applied to other strut design stents. Therefore, further studies are required to verify our observations.

CONCLUSIONS

OOT, consisting of an initial POT and sequential snuggling balloon dilation and then final POT, maintained the idealized circular geometry of the SB ostium and reduced global strut malapposition. It dramatically achieved the best optimization of the SB ostium in coronary bifurcations, resulting in a ‘two-stent effect with one-stent implantation’. Such benefits may translate into improved clinical outcomes, however further clinical validation is necessary.

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DECLARATION OF CONFLICT OF INTEREST

All the authors declare no conflict of interest.

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Bench Testing of Ostial Optimization Technique