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ORIGINAL STUDIES

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Effect of proximal balloon edge dilation technique for opening a side branch ostium in repetitive-proximal optimizing technique sequence

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Abstract

Objective: The purpose of this experimental bench test was to compare stent deformation, obstruction of stent struts at a jailed side branch (SB) ostium, and stent strut malapposition between SB inflation using proximal balloon edge dilation (PBED) technique and SB inflation using conventional balloon dilation in repetitive-proximal optimizing technique (re-POT) sequence.

Background: The second proximal optimizing technique (POT) procedure in the re-POT sequence might increase obstruction of stent struts at a jailed SB ostium, because deformation of stent cells at the main branch (MB) occurred during SB inflation for opening the SB ostium.

Methods: A fractal coronary bifurcation bench model made of flexible urethane was used, and crossover single-stent implantation (Xience Sierra, Abbott Vascular, Santa Clara, CA, n = 12) was performed from the MB with the re-POT sequence. During the re-POT sequence, the jailing rate at the SB ostium assessed by videoscopy was compared between SB inflation using PBED technique (PBED group, n = 6) and SB inflation using conventional balloon dilation (conventional group, n = 6).

Results: The jailing rate after the second POT procedure tended to be lower in the PBED group than in the conventional group (26 ± 12% vs. 34 ± 8%, p = .211), and the change in the jailing rate during the second POT procedure was significantly smaller in the PBED group than in the conventional group (4.8 ± 5.3% vs. 11.6 ± 3.5%, p = .026).

Conclusions: In the re-POT sequence, the PBED technique with a short balloon for SB inflation might minimize worsening of the jailing rate at the SB ostium during the second POT procedure.

KEYWORDS

optical coherence tomography, percutaneous coronary intervention, stenting technique

1 | INTRODUCTION

Optimal coronary bifurcation treatment requires controlled deformation of the three-dimensional stent cells and, as far as possible, to free the stent struts at the jailed side branch (SB) ostium. Recent, very informative experimental studies demonstrated that a repetitive-proximal optimizing technique (re-POT) sequence, comprising an initial proximal optimizing technique (POT), SB inflation, and a second POT, significantly improved the final result of crossover single-stent implantation in bifurcation lesions.[1,2] However, the second POT procedure in the re-POT sequence increased obstruction of stent struts at a jailed SB ostium, because deformation of stent cells at the main branch (MB) occurred during SB inflation for opening the SB ostium.[3] The second POT procedure might reform the stent back to its original shape and pull the well-deployed stent struts at the SB vessel wall toward the MB, and thus increasing obstruction of stent struts at a jailed SB ostium. Therefore, we hypothesized that SB inflation using proximal balloon edge dilation (PBED) technique with a short balloon might minimize not only the deformation of stent cells at the MB, but also vessel injury at the SB and thus obtain the optimal final result of crossover single-stent implantation in bifurcation lesions using the re-POT sequence. To test this hypothesis, we performed an ex vivo experimental bench test to compare stent deformation, obstruction of stent struts at a jailed SB ostium, and stent strut malapposition between SB inflation using PBED technique with a short balloon and SB inflation using conventional balloon dilation.

2 | METHODS

2.1 | Experimental protocols

A fractal coronary bifurcation bench model made of flexible urethane with 1-mm thickness was specially designed (Figure 1, Cross Medical Service Co., Ltd., Tokyo, Japan). An experimental bench test was performed with a series of coronary stents used as the MB stent in the coronary bifurcation model (Xience Sierra, Abbott Vascular, Santa Clara, CA, *n* = 12). The stents were deployed in the re-POT sequence (initial POT, SB inflation, and final POT), described in detail by Finet et al.[2] The major steps of the re-POT sequence are described as follows: (a) The 3.5-mm stents at the MB were implanted following the manufacturer's compliance charts to reach a diameter of 3.70 mm for 10 s. (b) An initial POT was performed using a 4.0-mm noncompliant balloon at the rated burst pressure (manufacturer's compliance charts to achieve a diameter of 4.13 mm) for 10 s. The POT balloon was positioned precisely, with the medial edge of the distal radiopaque marker lying in the cross-sectional plane of the carina. (c) Another guidewire was then advanced into the SB with distal cell crossing under direct visual observation using a videoscope (IPLEX TX, Olympus, Tokyo, Japan), because it has been reported that the distal cell rewiring at the SB ostium could minimize stent deformity and obstruction of stent struts at jailed SB ostia after SB balloon dilation.[4,5] The SB ostium strut cells were opened using a 3.0-mm noncompliant balloon at the nominal pressure (manufacturer's compliance charts to achieve a diameter of 2.97 mm) for 10 s. (d) A final POT (second POT) was performed with the same criteria as for the initial POT. During the re-POT sequence, stent deformation assessed by optical coherence tomography (OCT) and the jailing rate at the SB ostium assessed by videoscopy were compared between SB inflation using PBED technique with a short balloon (3 × 8 mm) (PBED group, *n* = 6) and SB inflation using conventional balloon (3 × 15 mm) dilation (conventional group, *n* = 6) (Figure 2).

2.2 | OCT and videoscope analysis

OCT images were obtained using an FD-OCT system (Dragonfly OPTIS and OPTIS stent optimization software; Abbott Vascular, St. Paul, MN). The FD-OCT catheter was placed distal (>10 mm) to the stented lesion and pulled back to the stent proximal edge using a motorized catheter pullback system (18 mm/s). OCT recording was performed before and after the second POT procedure. The ellipticity ratios at the proximal and distal MBs were calculated as the maximal diameter/minimal diameter, with 1.0 corresponding to perfect circularity. OCT analysis was performed millimeter by millimeter. Malapposed struts on OCT imaging were defined as the distance between the center reflection of the strut and the vessel wall of greater than the actual stent thickness + 20 μm OCT axial resolution.[6] Overall malapposed struts at the opposite site of the SB ostium including 3-mm proximal and distal to the bifurcation were quantified on each slice as percentage malapposed struts of the total number of struts analyzed.

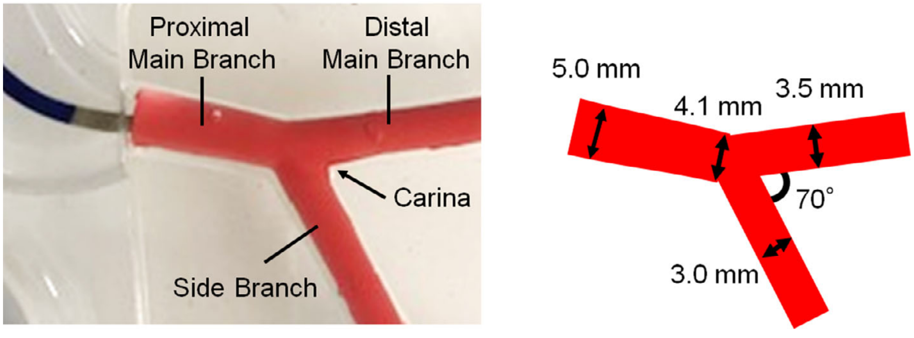

FIGURE 1 Coronary bifurcation bench model. A flexible urethane coronary bifurcation bench model with 1-mm thickness was specially designed with lumen diameters of 3.5 and 3.0 mm for the main branch and side branch, respectively

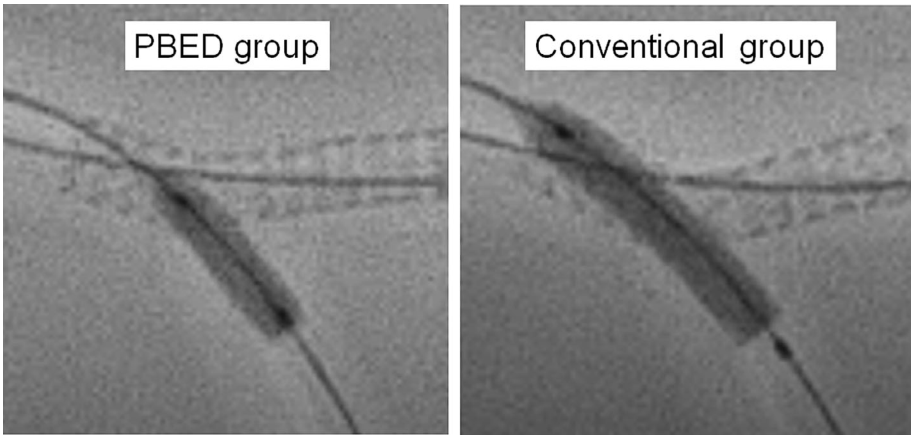

FIGURE 2 Comparison between side branch (SB) inflation using the proximal balloon edge dilation (PBED) technique with a short balloon and SB inflation using conventional balloon dilation. The stent deformation, obstruction of stent struts at a jailed SB ostium, and stent strut malapposition were compared between SB inflation using the PBED technique with a short balloon (3 × 8 mm) and SB inflation using conventional balloon (3 × 15 mm) dilation

TABLE 1 Comparison of stent parameters before and after repetitive-proximal optimizing technique procedure between proximal balloon edge dilatation group and conventional group

	Overall (*n* = 12)	PBED group (*n* = 6)	Conventional group (*n* = 6)	*p* value
Ellipticity ratio at proximal segment				
Before second POT	1.02 ± 0.02	1.01 ± 0.01	1.03 ± 0.03	.314
After second POT	1.02 ± 0.01	1.02 ± 0.01	1.01 ± 0.01	.239
Ellipticity ratio at distal segment				
Before second POT	1.03 ± 0.03	1.02 ± 0.02	1.04 ± 0.04	.323
After second POT	1.02 ± 0.01	1.02 ± 0.01	1.02 ± 0.01	.562
Rate of malapposed struts at opposite site of the side branch ostium (%)				
Before second POT	10.1 ± 16.0	2.5 ± 3.5	17.6 ± 20.3	.100
After second POT	2.6 ± 3.4	3.0 ± 4.3	2.1 ± 2.6	.687
Change in rate of malapposed struts (%)	−7.6 ± 16.8	0.5 ± 2.1	−15.6 ± 21.5	.099
Jailing ratio (%)				
Before second POT	22 ± 8	21 ± 8	23 ± 8	.772
After second POT	30 ± 11	26 ± 12	34 ± 8	.211
Change in jailing ratio (%)	8.2 ± 5.6	4.8 ± 5.3	11.6 ± 3.5	.026

Note: Values are mean ± *SD*.
Abbreviations: PBED, proximal balloon edge dilatation; POT, proximal optimizing technique.

The videoscope was inserted into the SB to obtain images of the SB ostium. The SB jailing ratio was calculated as (A1/A2)×100%, where A1 is the total jailed area by stent struts, and A2 is the area of the ostium; A1 and A2 were measured manually on digital planimetry using the image J software (version 1.50i, National Institutes of Health). Before and after the second POT procedures, stent parameters, such as the ellipticity ratio, the rate of malapposed struts, and the SB jailing ratio were assessed and compared between the PBED group and the conventional group by OCT and videoscopy.

3 | STATISTICAL ANALYSIS

All analyses were performed with SPSS 15.0 (SPSS Inc., Chicago, IL). Continuous variables are presented as mean ± *SD*. The unmatched Mann–Whitney nonparametric test for continuous quantitative variables was used to compare the PBED group and the conventional group. The changes of stent parameters before and after the second POT procedure were assessed by the Wilcoxon signed-rank test. A *p* value <.05 was considered significant.

4 | RESULTS

4.1 | Changes of stent parameters during the second POT procedure

The ellipticity ratio was not significantly changed during the second POT procedure (at the proximal segment: from 1.02 ± 0.02 to 1.02 ± 0.01, *p* = .930; at the distal segment: from 1.03 ± 0.03 to 1.02

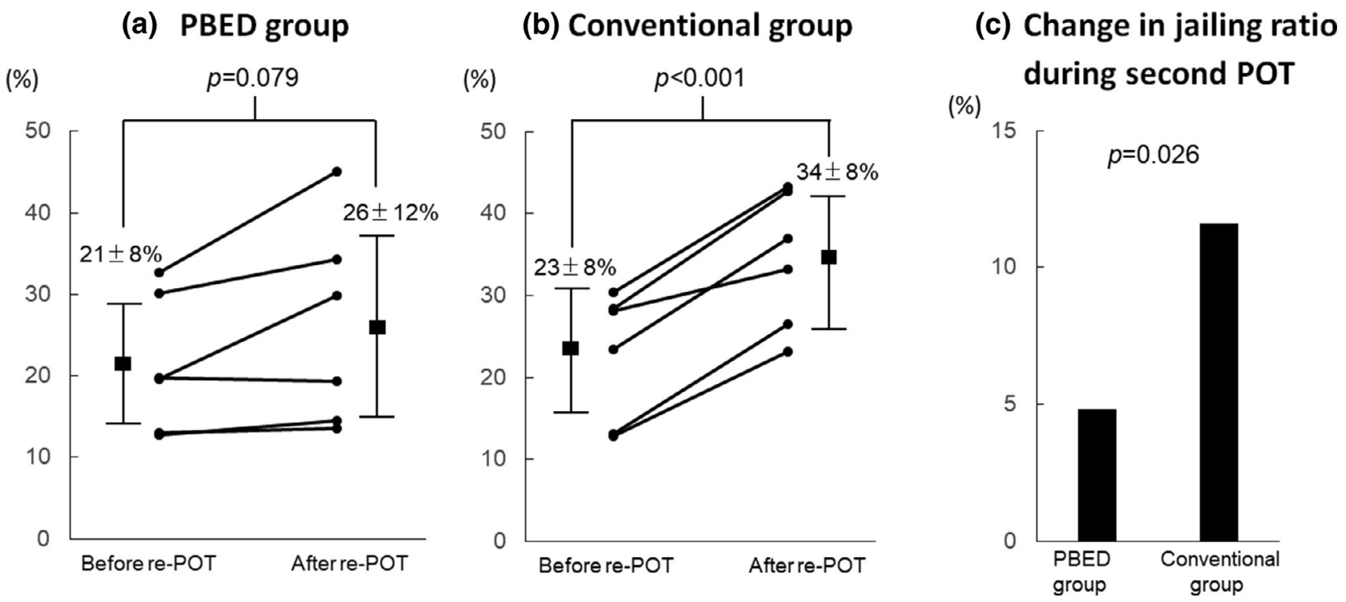

FIGURE 3 The change of the side branch jailing ratio during the second proximal optimizing technique (POT) procedure in the proximal balloon edge dilation (PBED) group and in the conventional group. (a) The jailing ratio in the PBED group was numerically increased after the second POT procedure, but it was not significant (from 21 ± 8% to 26 ± 12%, p = .079). (b) On the other hand, the jailing ratio in the conventional group was significantly increased after the second POT procedure (from 23 ± 8% to 34 ± 8%, p < .001). (c) The change in the jailing ratio during the second POT procedure was significantly smaller in the PBED group than in the conventional group (4.8 ± 5.3% vs. 11.6 ± 3.5%, p = .026)

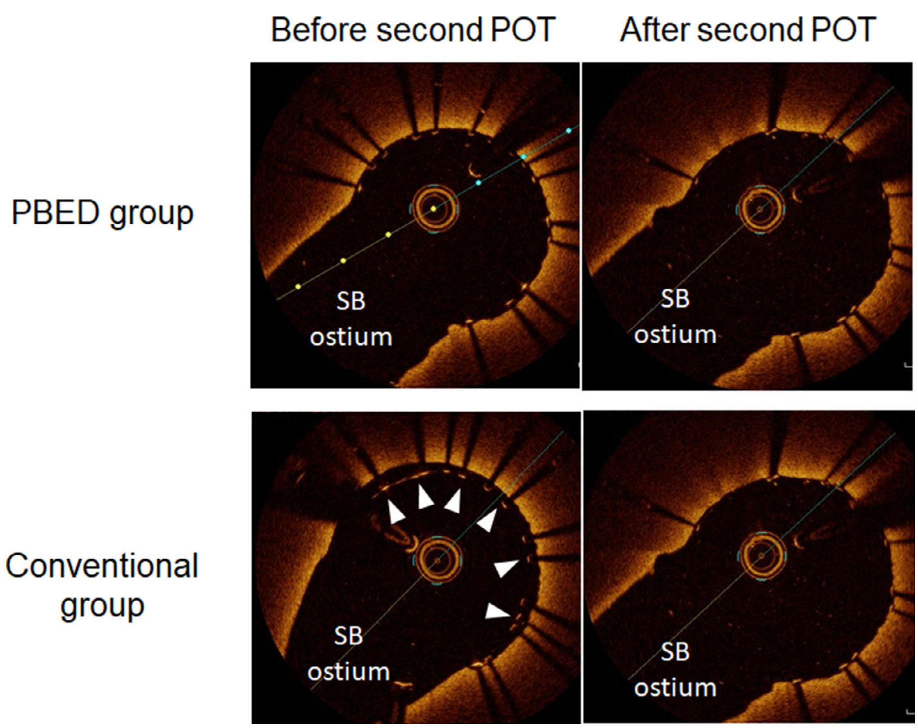

FIGURE 4 Representative optical coherence tomography images before and after the second proximal optimizing technique (POT) procedure in the proximal balloon edge dilation (PBED) group and the conventional group. Malapposed struts at the opposite site of the side branch (SB) ostium before and after the second POT procedure are not observed in the PBED group. However, malapposed struts at the opposite site of the SB ostium before the second POT procedure are observed in the conventional group (arrowhead). These malapposed struts are fixed by the second POT procedure, and these stent struts are well-apposed to the vessel wall after the second POT procedure

± 0.02, p = .333). The rate of malapposed struts was numerically decreased after the second POT procedure, but it was not significant (10.1 ± 16.0% vs. 2.6 ± 3.4%, p = .147). The jailing ratio was significantly increased after the second POT procedure (22.0 ± 7.8% vs. 30.2 ± 11.0%, p < .001).

4.2 | Comparison of stent parameters between the PBED group and the conventional group

Table 1 shows the comparison of the ellipticity ratio before and after the second POT procedure between the PBED group and the

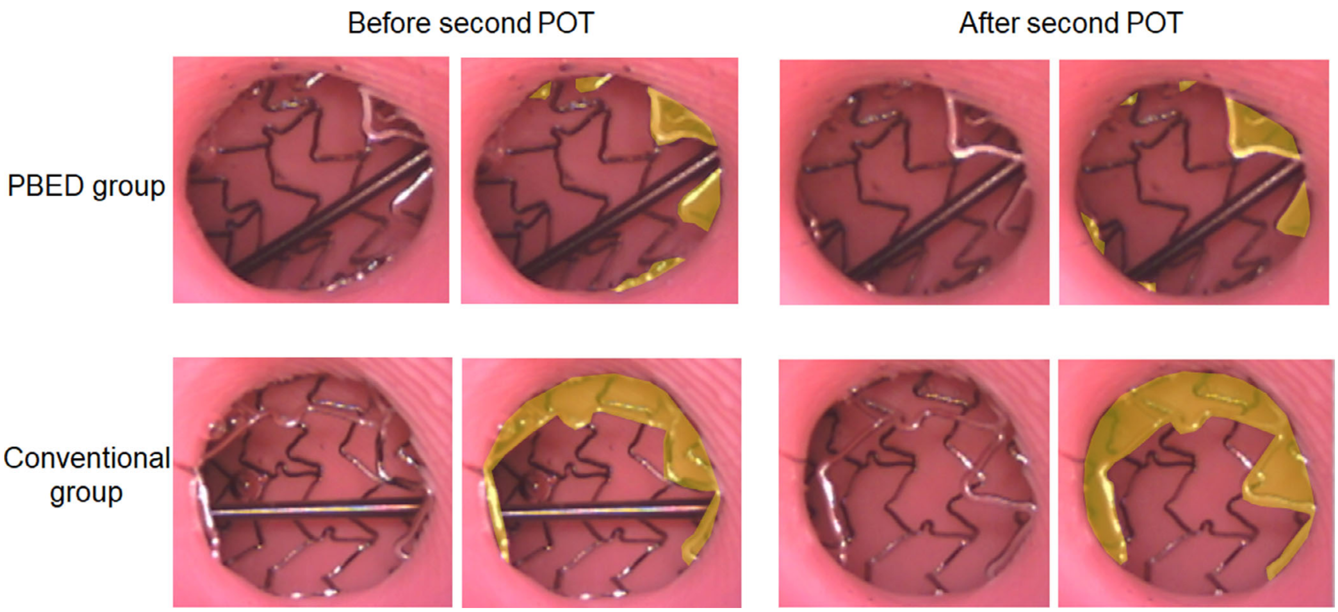

FIGURE 5 Representative videoscope images of the side branch ostium before and after the second proximal optimizing technique (POT) procedure in the proximal balloon edge dilation (PBED) group and the conventional group. The jailing ratio is not increased during the second POT procedure in the PBED group (from 13 to 14%) (upper). On the other hand, the jailing ratio is increased during the second POT procedure in the conventional group (from 28 to 43%) (lower). The SB jailing area is highlighted by yellow color

conventional group. Before the second POT procedure, the ellipticity ratios at both proximal and distal segments were not significantly different between the two groups. After the second POT procedure, the ellipticity ratios at both proximal and distal segments were similar between the two groups as well.

As for stent apposition, the rate of malapposed struts at the opposite site of the SB ostium tended to be lower in the PBED group than in the conventional group before the second POT procedure (2.5 ± 3.5% vs. 17.6 ± 20.3%, p = .100) (Table 1). On the other hand, the rate of malapposed struts after the second POT procedure was similar between the two groups (PBED group: 3.0 ± 4.3% vs. conventional group: 2.1 ± 2.6%, p = .687). Therefore, the change in rate of malapposed struts during the second POT procedure was numerically less in the PBED group than in the conventional group (0.5 ± 2.1% vs. −15.6 ± 21.5%, p = .099).

In terms of obstruction of stent struts at a jailed SB ostium, the jailing ratio before the second POT procedure was similar between the two groups (PBED group: 21 ± 8% vs. conventional group: 23 ± 8%, p = .772). However, the jailing ratio after the second POT procedure tended to be lower in the PBED group than in the conventional group (26 ± 12% vs. 34 ± 8%, p = .211). Figure 3 shows the change of the SB jailing ratio during the second POT procedure in the PBED group (Figure 3a) and in the conventional group (Figure 3b). The jailing ratio in the conventional group was significantly increased after the second POT procedure (from 23 ± 8% to 34 ± 8%, p < .001). The change in the jailing ratio during the second POT procedure was significantly smaller in the PBED group than in the conventional group (4.8 ± 5.3% vs. 11.6 ± 3.5%, p = .026, Figure 3c). Figures 4 and 5 show representative OCT images and SB ostial videoscope images before and after the second POT procedure in the different groups.

5 | DISCUSSION

The present experimental bifurcation bench model study showed a good effect on obstruction of stent struts at a jailed SB ostium using PBED technique in the re-POT sequence compared with SB dilation using a conventional balloon. The re-POT sequence was introduced as an optimal bifurcation percutaneous coronary intervention (PCI) procedure in a recent very informative experimental study performed by Finet et al.[2] However, we reported that the SB jailing ratio was increased during the second POT procedure.[3] This negative finding was confirmed in the present study as well. The possible mechanism of an increased SB jailing ratio during the second POT procedure is that stent struts at the MB are deformed toward the SB after SB dilation, especially in the conventional group. The second POT procedure reforms the stent back to its original shape, thus increasing the SB jailing ratio due to the deployed stent struts at the SB vessel wall being pulled toward the MB. The numerically higher rate of malapposed struts at the opposite site of the SB ostium before the second POT procedure in the conventional group might support this conjecture.

Anatomical parameters such as the bifurcation angle are important for the obstruction of stent struts at a jailed SB ostium in the re-POT sequence. In the present study, coronary bifurcation bench model with bifurcation angle of 70° assuming left main bifurcation was used with reference to a consensus document for bench testing and coronary artery bifurcations from the European Bifurcation Club.[7] A wide bifurcation angle would be associated with higher rate of malapposed struts at the opposite site of the SB ostium after SB inflation and thus, result in increasing the SB jailing after second POT procedure. This negative phenomenon could be observed more in the conventional group. The re-POT sequence with PBED technique could suppress this deterioration of SB jailing in lesions with wide bifurcation angle. In addition, the Glider balloon (TriReme Medical, Pleasanton, CA) is useful for SB dilation. It is a dedicated balloon designed for crossing through struts of deployed stents toward a SB and available in balloon lengths from 4 to 20 mm. Using shorter Glider balloon with PBED technique in the re-POT sequence, not only easily recrossing stent struts at the SB ostium but also less SB jailing ratio after the second POT could be obtained.

Stent struts at a jailed SB ostium have been recognized to pose certain risks for late or very late stent thrombosis.[8-11] Furthermore, obstruction of stent struts at a jailed SB ostium could impact on the narrowing of the SB ostial area at follow-up. Previous clinical studies reported that stent cell number and the presence of a stent link on the SB ostium were related to SB narrowing in the chronic phase.[12,13] These data suggest that obstruction of stent struts at a jailed SB ostium are important for SB flow disturbance due to delayed neointimal coverage at follow-up. The re-POT sequence showing less stent deformity and malapposed struts compared with kissing balloon inflation might provide better optimization of single stenting in coronary bifurcations.[2] The re-POT sequence with PBED technique could suppress deterioration of SB jailing during the second POT procedure, adding to the effectiveness of the re-POT sequence for bifurcation PCI treatment. Furthermore, in the present study, SB dilation with PBED technique after initial POT could show acceptable results of the rate of malapposed struts (2.5 ± 3.5%) and the jailing ratio (21 ± 8%) without the second POT procedure. These data suggested that SB dilation with PBED technique could eliminate the second POT procedure in the re-POT sequence and thus, reduce the procedure time and avoid stent deformation due to the insertion of the second POT balloon. The present findings may help improve bifurcation PCI to achieve better clinical outcomes. However, the clinical benefit of PBED technique in the re-POT sequence is still unclear. The clinical impact of the PBED technique in the re-POT sequence should be evaluated in a future clinical study.

6 | LIMITATIONS OF THE STUDY

There are several limitations in this study. First, the present experimental study used a flexible urethane coronary bifurcation bench model without stenosis. Lumen narrowing with coronary plaque might affect the results of stent deformation and the SB jailing ratio in the re-POT sequence. Second, the results of the present study cannot be applied to non-left main trunk bifurcation lesions because of a small difference in the vessel size between the MB and SBs. Third, the present experimental study used one type of coronary stent, which had three links between stent rings. Further bench tests are needed to compare the effectiveness of SB inflation using PBED technique among different type of coronary stents, including two-link cell design coronary stents. Fourth, in the present study, influence of link location at SB ostium could not be compared between the PBED group and the conventional group due to the small sample size. Therefore, to avoid the influence of link location, we intentionally set the presence (link connecting type: n = 3 in the PBED group and n = 3 in the conventional group) or absence (link free type: n = 3 in the PBED group and n = 3 in the conventional group) of stent link at distal semicircle of SB ostium under videoscope observation. Link location at SB ostium is thought to be an important factor for the stent deformation in bifurcation PCI. Future large-scale investigations are necessary to elucidate the impact of link location on stent behavior in the PBED group.

7 | CONCLUSIONS

In the re-POT sequence, PBED technique with a short balloon for SB inflation might minimize the worsening of the jailing rate at the SB ostium during the second POT procedure and thus decrease SB narrowing due to neointimal coverage in the chronic phase.

CONFLICT OF INTEREST

Dr. Kume has received personal fees from Abbott Japan Co., Ltd. Dr. Uemura has received academic funding and personal fees from Daiichi Sankyo Company, Astellas Amgen Biopharma, Abbott Japan Co., Ltd., and Terumo Corporation. The other authors report no financial relationships to disclose. All other authors have reported that they have no relationships relevant to the contents of this article to disclose.

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