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First Clinical Experience of "Flower Petal Stenting"

A Novel Technique for the Treatment of Coronary Bifurcation Lesions

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Objectives We sought to report the results of both bench-testing and our first clinical experience with this novel technique.

Background The optimal stenting technique for bifurcation lesions has yet to be defined.

Methods This technique works by flaring the proximal side of the stent in side branch out like a flower petal. We tested it in vitro and the resultant stent structure and stent polymer damage was observed in both main branch and side branch with an optical microscopy, multislice computer tomography, intravascular ultrasound, endoscopy, and by electron microscopy. We also applied this technique in 33 patients and assessed patient outcomes up to 9 months prospectively. Drug-eluting stents were used for the bench tests and for all patients.

Results Bench-testing showed complete coverage of the bifurcation with minimal stent-layer overlapping. There was little polymer damage by electron microscopy. Procedural success was achieved in all cases and restenosis occurred in 2 cases. In both restenosis cases, "petal" stenting technique was done reluctantly after another stent had already been deployed in the main branch before any stenting of the side branch. There were no incidences of restenosis when this technique was used electively.

Conclusions In terms of damage to the polymer and ostial strut coverage, this new "flower petal stenting" technique is effective for treatment of bifurcation lesion and it may well be superior to other available techniques. (J Am Coll Cardiol Intv 2010;3:58–65) © 2010 by the American College of Cardiology Foundation

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Coronary bifurcation lesions remain an unresolved problem for the interventional cardiologist. Compared with nonbifurcation lesions, percutaneous coronary intervention (PCI) of bifurcation lesions is associated with low procedural success rates, high restenosis rates, and high periprocedural complication rates (1–3). To overcome these problems, many different techniques of bifurcation stenting have been proposed, such as V-stenting, T-stenting, crush stenting,

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culottes stenting, and Y-stenting (4–8). In addition to these new techniques, drug-eluting stents (DES) were also introduced into the market during the same period. The use of DES improved outcomes for the main branch (MB), but demonstrated the continuing occurrence of restenosis at the ostium of the side branch (SB). Under expansion and incomplete coverage at the ostium of SB are probable causes of restenosis (9,10). To resolve these issues, we designed a new stenting technique, "flower petal stenting," and evaluated the mid-term outcomes after implantation of either sirolimus-eluting stents (Cypher, Cordis Corp., Warren, New Jersey) or paclitaxel-eluting stents (Taxus Express, Boston Scientific, Natick, Massachusetts) for bifurcation lesions using this novel technique.

Materials and Methods

Procedural description. We illustrated the different steps of "flower petal stenting" in Figure 1. The most important point of this technique is to cover the carina completely with stent struts. At first, a stent is deployed in the SB after insertion of wires into both the MB (MBw1) and the SB (SBw). The proximal marker of the SB stent is placed in the MB 1 to 2 mm proximal to the carina of the bifurcation with only 1 strut protruding into the MB (Figs. 1A and 1B). A third wire (MBw2) is then inserted through the strut of this stent, which is protruding into the MB (Figs. 1C and 1D) and the strut is dilated with a balloon catheter to allow the stent strut to contact the wall on the opposite side (Figs. 1E and 1F). Appropriate balloon size was determined by using the vessel diameter of the MB as a reference. The first kissing dilation is performed to attach the proximal stent strut to distal left main (Fig. 1G). After retracting the balloon with the MBw2 from the strut (Fig. 1H), a balloon catheter is delivered over the MBw1 to turn over the protruding part of the stent of the SB to distal in the MB while keeping the balloon in the MB inflated at low pressures (up to 1 to 3 atm) (Figs. 1I to 1L). After that, the second kissing dilation was performed. It was effective to use balloon proximal edge to cover the carina completely by a stent strut from the SB (Figs. 1M and 1N). Finally, a stent was implanted in the MB (Figs. 1O and 1P) and final kissing dilation was performed.

In vivo, MBw2 was often inserted using intravascular ultrasound (IVUS) through the protruding strut in the MB. Despite IVUS guidance, it was difficult to insert the wire through the protruding stent strut because either the protruding space was too small or the IVUS catheter interfered with wire manipulation of MBw2. Therefore, we developed a new method to pass both the guidewire and balloon catheter through the strut outside the body before advancing it into the coronary artery (Fig. 2).

Bench-top test. We deployed either sirolimus- or paclitaxel-eluting stents using the flower petal stenting technique into a silicone bifurcation model with 3.0-mm diameter stent into the MB and 2.5-mm stent into the SB. Kissing balloon dilation was then performed using 3.0/2.5-mm balloons for the MB and SB, respectively. The stent structure was observed using an optical microscope, multislice computed tomography, and IVUS. An electron microscope was used to visualize any polymer damage after deployment.

Clinical study. STUDY POPULATION AND ANGIOPLASTY PROCEDURE. From May 2005 to December 2008, 34 bifurcation lesions of 33 patients were treated using the flower petal stenting technique irrespective of the type of the lesion. The bifurcation lesion in this study was defined as a diameter stenosis >50% involving the MB with involvement of the origin or the ostium of the SB. Bifurcation lesions were classified according to the Medina classification (11). Patients with contraindications to antiplatelet therapy were excluded. Written informed consents for the PCI procedure were received from all patients.

Abbreviations and Acronyms

DES = drug-eluting stents
IVUS = intravascular ultrasound
MACE = major adverse cardiac events
MB = main branch
MI = myocardial infarction
PCI = percutaneous coronary intervention
SB = side branch
TLR = target lesion revascularization
w = wire

All patients were pre-treated with aspirin (100 mg) and either ticlopidine (200 mg daily) or clopidogrel (75 mg daily). During the procedure, patients received intravenous heparin administration to maintain activated clotting times between 250 and 300 s. All procedures were performed using DES. After the procedures, all patients continued on aspirin and ticlopidine or clopidogrel for as long as tolerated. Procedural success was defined as a final residual stenosis <30% in both branches without major adverse cardiac events (MACE) at any time during the hospital stay. We defined MACE as cardiac death, Q-wave or non–Q-wave myocardial infarction (MI) and target vessel revascularization, either percutaneous or surgical. All deaths were considered cardiac in origin unless otherwise documented. Non–Q-wave MI was defined as creatinine kinase ≥3 times the upper limit of normal with elevated MB fraction.

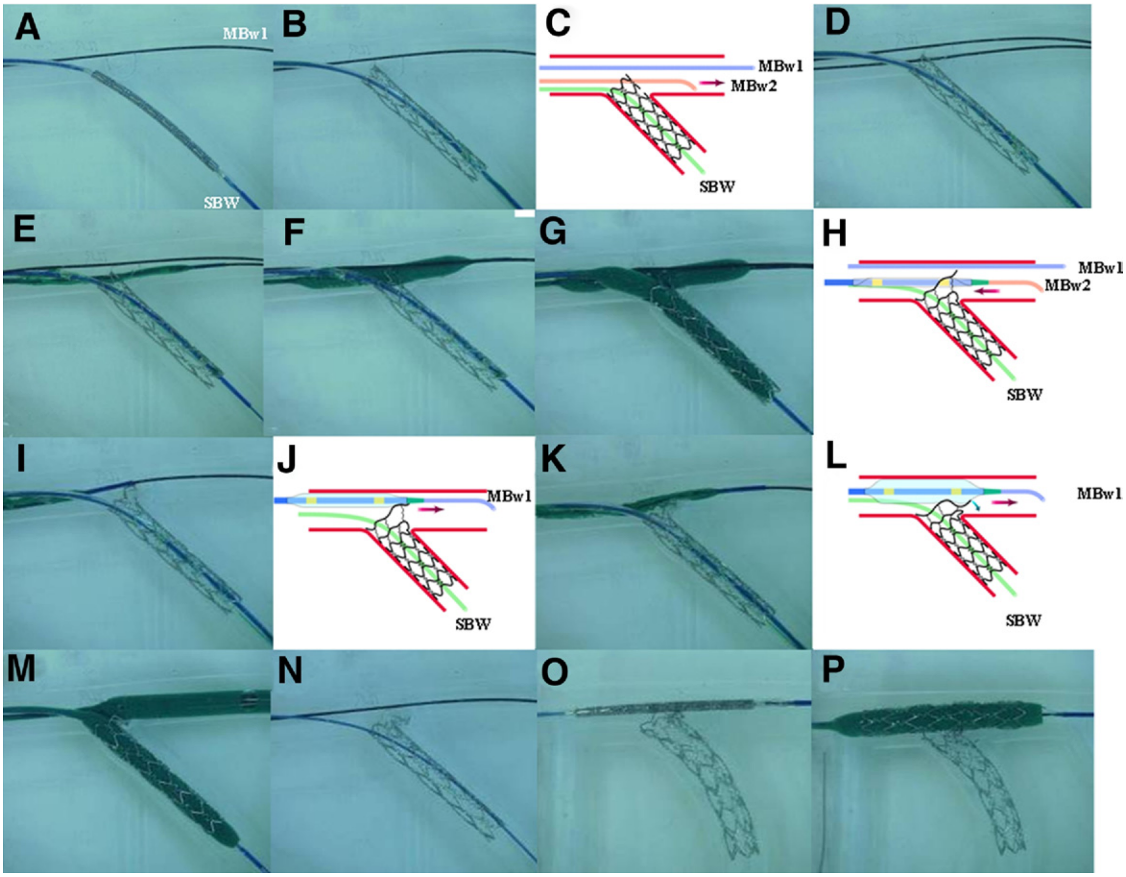

Figure 1. How To Create the Original Flower Petal Stenting

Each step is explained in the text. The other wire (MBw2) was inserted through the protruded strut under intravascular ultrasound guidance in clinical case **C**. MBw = main branch wire; SBW = side branch wire.

Q-wave MI was defined as new pathological Q waves in 2 or more leads in addition to elevated enzymes as previously discussed. Target vessel revascularization was defined as repeat revascularization within the treated vessel. Target lesion revascularization (TLR) was defined as a repeat revascularization with a stenosis ≥50% within the stent or

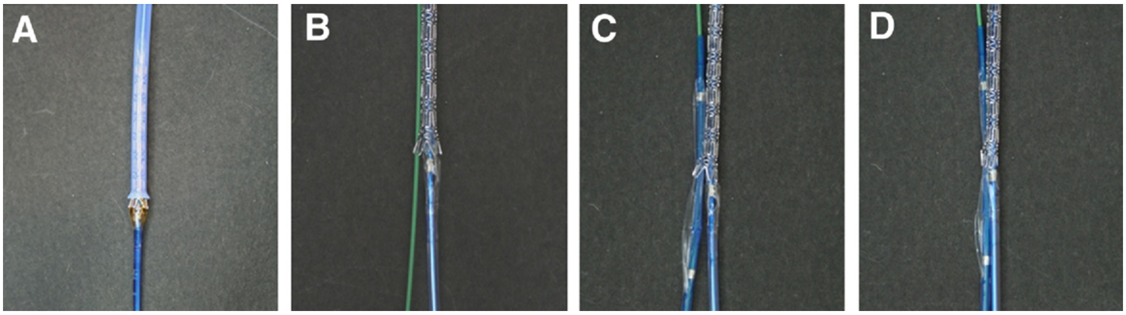

Figure 2. The First Few Steps of Modified Flower Petal Stenting

(A) The stent cover is removed to expose the proximal single strut of the stent and the stent delivery system balloon is inflated to 5 to 6 atm partially expanding the proximal single strut. **(B)** The stent cover is removed and before inserting the stent, the third wire is inserted into the main branch. **(C)** Another balloon catheter is passed through the proximal stent strut. **(D)** The expanded proximal strut is held stationary and the stent with balloon catheter is inserted until it can no longer be inserted more distally to the bifurcation. After these steps, the next procedure follows step D in Figure 1.

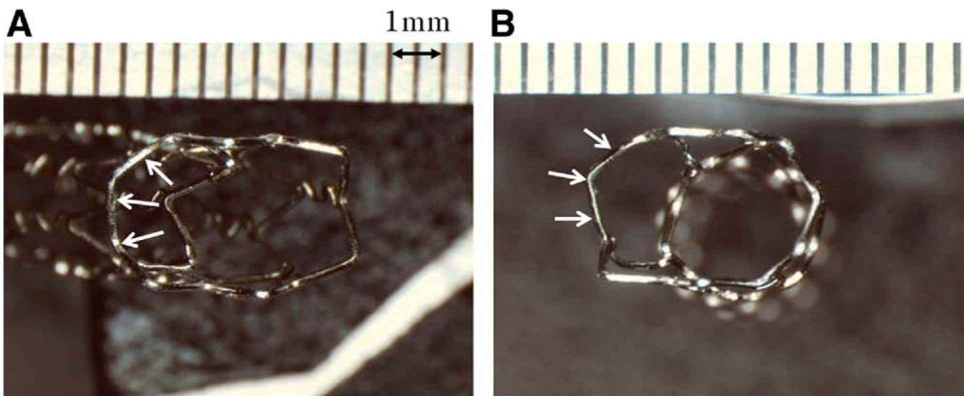

Figure 3. Verification With Optical Microscopy

The proximal strut of the stent in the side branch is opened widely and turned over well **(white arrows)**. There is no underexpansion at side branch ostium **(B)**.

5-mm proximal or distal segments adjacent to the stent. Target bifurcation revascularization was defined as a repeat revascularization with a stenosis ≥50% within 5 mm proximal or distal to the carina of bifurcation (12). Documented stent thrombosis was defined as angiographic demonstration of stent closure or intrastent thrombus. Suspected stent thrombosis was defined as unexplained sudden death or MI without angiographic or visual confirmation.

Up to 9 months, MACE were followed with office visits or telephone contact to all patients.

Angiographic analysis. Quantitative coronary angiography was performed at baseline, after procedure, and at 9-month follow-up using a computer-based algorithm developed by MEDIS 5.1 (Medical Imaging System, Leiden, the Netherlands). Quantitative angiographic measurements of target lesions were made at "in-stent" zone and "in-segment" zone, which includes both stented segment and margins 5 mm proximal and distal to the stent. Binary restenosis was defined as ≥50% diameter stenosis of the target lesion.

Statistic analysis. Continuous variables were presented as mean ± SD and were compared using paired *t* test. Categorical variables were presented as counts and percentages and compared using McNemar test. A p value <0.05 was considered significant. All data were processed using the Statistical Package Social Science, version 11 (SPSS Inc., Chicago, Illinois).

Results

Bench-top test. As shown in Figure 3, the proximal strut of the stent in the SB was turned over to distal in the MB and the proximal part of SB stent was opened widely. There was no protrusion of stent strut from SB into MB (Fig. 4). Less polymer damage was seen in the overlapping portion of stent (Fig. 5).

Clinical study. Thirty patients were treated using the flower petal stenting technique. Baseline clinical characteristics are shown in Table 1 (13). Three of the 33 patients (9.1%) were admitted due to unstable angina pectoris, and 14 (42.4%) suffered from diabetes mellitus. All patients were treated

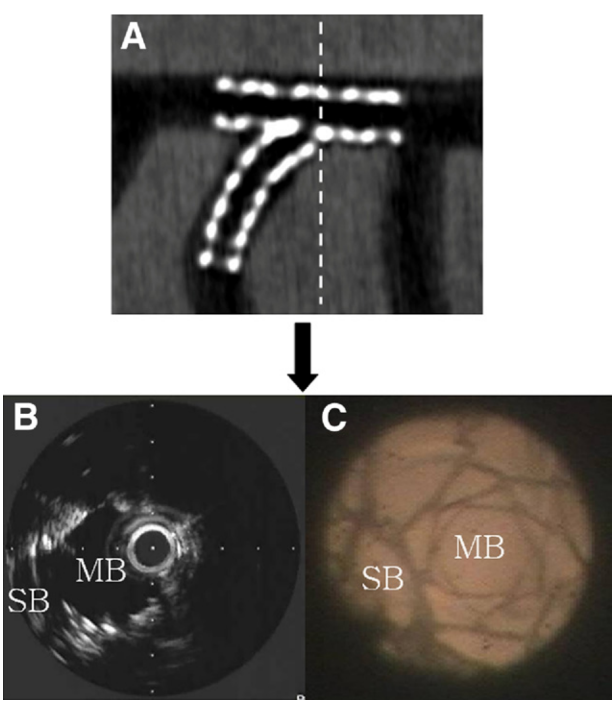

Figure 4. Verification With MSCT, IVUS, and Endoscopy

(A) A multislice computed tomography (MSCT) image. Carina was covered with stent in the side branch (SB). **Images in the lower panel** show intravascular ultrasound (IVUS) **(B)** and endoscopy **(C)** images at the **dotted line in A**, respectively. There was no protrusion of stent strut from SB into main branch (MB) and the SB ostium was opened widely.

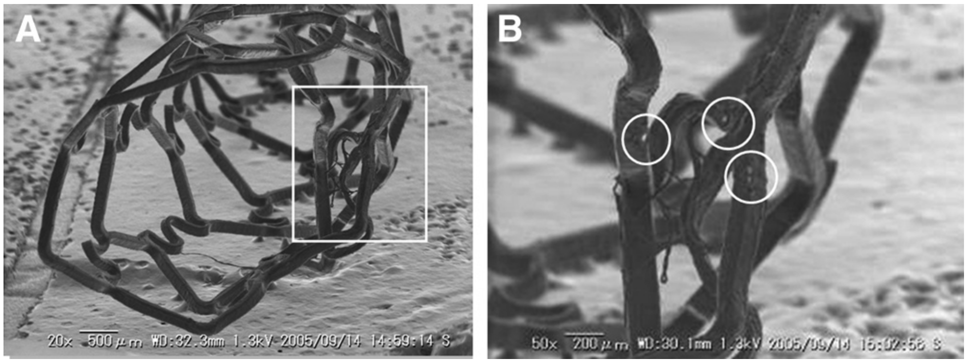

Figure 5. Verification With Electron Microscopy

(A) Overlapping portion of stent in the side branch. **(B)** A close-up image of the **white box in A**. Polymer damage was hardly seen in the overlapping portion of stent in the side branch **(white circles)**.

with a dual antiplatelet regimen (aspirin + clopidogrel sulfate or aspirin + ticlopidine).

Table 2 shows lesion characteristics. Type 1,1,1 bifurcation lesion accounted for approximately half of our cases (47.1%). In most cases, the bifurcation angle was <70° (85.3%).

Table 3 shows procedural data and initial results. Procedural success rate was 100%. In only 1 case, the flower petal stenting could not be performed and a stent strut fracture occurred at the proximal portion. Fortunately, we were able to obtain an optimal lumen of the side branch ostium using kissing balloon dilation. After the introduction of modified method as shown in Figure 2, we were able to perform the flower petal stenting successfully in all cases. Final kissing balloon dilation was performed in all cases. Four cases were completed with "reverse flower petal" stenting, by stenting in the SB after the MB was stented. There were no in-hospital MACE and 30-day MACE.

Quantitative coronary angiographic analysis results for both the MB and the SB were summarized in Table 4. Binary restenosis occurred in 2 lesions in the SB only.

Clinical follow-up at 9 months was available in 78.8% of patients with initial success for this technique (Table 5). Two patients showed MACE and both required TLR by PCI. All TLR occurred only in cases when reverse flower petal stenting was performed.

Discussion

We reported here the initial and mid-term results of this novel flower petal stenting technique for bifurcation lesion stenting. Although the issue of restenosis, which is the Achilles' heel of PCI, has improved with the introduction of DES, restenosis remains to be an issue in some specific lesion types. Bifurcation lesion is 1 such lesion in this DES era. Restenosis at the ostium of the SB due to incomplete

Table 1. Patient Characteristics (n = 33)

Age, yrs	69.7 ± 9.3
Male (%)	24 (72.7)
Hypertension (%)	24 (72.7)
Diabetes (%)	14 (42.4)
Hypercholesterolemia (%)	16 (48.5)
Smoking (%)	8 (24.2)
Family history of CAD (%)	9 (27.3)
Prior CABG (%)	0 (0)
Unstable angina (%)	3 (9.1)
CCS (%)	
1–2	31 (93.9)
3–4	2 (6.1)

CABG = coronary artery bypass graft; CAD = coronary artery disease; CCS = Canadian Cardiovascular Society angina classification class (13).

Table 2. Lesion Characteristics (n = 34)

Lesion location, cumulative	
Distal LMT/LAD-DB/LCX-OM	28/3/3
Bifurcation type (%)	
0,0,1	7 (20.6)
0,1,0	3 (8.8)
1,0,0	0
0,1,1	6 (17.6)
1,0,1	2 (5.9)
1,1,0	0
1,1,1	16 (47.1)
Calcification (%)	
Main branch	12 (35.3)
Side branch	2 (5.9)
Angulation >70° (%)	5 (14.7)

DB = diagonal branch; LAD = left anterior descending artery; LCX = left circumflex artery; LMT = left main trunk; OM = obtuse marginal.

Table 3. Procedural Characteristics and Initial Results (n = 34)

Stents (%)	
Only SES	25 (73.5)
Only PES	5 (14.7)
SES and PES	3 (8.8)
BMS and SES	1 (2.9)
Final kissing dilation (%)	34 (100)
Reverse flower petal stenting (%)	4 (11.8)
Angiographic success (%)	34 (100)
Periprocedure MI	0
In-hospital MACE	0
30-day MACE	0

BMS = bare-metal stent(s); MACE = major adverse cardiac event; MI = myocardial infarction; PES = paclitaxel-eluting stent(s); SES = sirolimus-eluting stent(s).

coverage and stent underexpansion (9,10) is still unresolved regardless of the variety of bifurcation stenting methods (4–8) introduced with DES. There are many reasons why adequate coverage and expansion at SB ostium cannot be achieved. The first reason is the anatomy at the bifurcation. In particular, the vessel size and bifurcation angle are important factors because the shape of the ostium of the SB depends on these 2 factors. The second reason is limitation of stent platform. If the bifurcation angle is shallow, the shape of SB ostium shifts from a circular shape into a more oval shape and the major axis is lengthened. Even when the SB <2.5 mm in diameter, the major axis becomes very large. For example, the major axis calculated using trigonometric function becomes 5 mm when the vessel diameter is 2.5 mm and angle is 30° (Fig. 6). We showed differences of SB ostial diameter varied by bifurcation angle in Figure 7. When we put a stent in the MB in this condition, a stent strut will definitely cover the ostium of the SB because there is no stent currently available that has a maximum cell diameter of 5 mm or more (14,15). We believe that this overlapping strut causes inadequate coverage and expansion at the ostium of the SB if conventional bifurcation stenting techniques such as V-stenting, T-stenting, crush stenting, culottes stenting, and Y-stenting are used (4–8). In these techniques, the stent is placed into the SB or an adjunctive balloon dilation through a stent strut of the MB is required. Each of these techniques has a limitation when dilating the ostium of the SB from both the overlapping stent strut of the MB and the crossover stent strut of the SB. However, it is difficult to get around stenting in the MB in the treatment of bifurcation lesions. To reduce the interference of strut and allow for adequate dilation of the SB ostium, this new stenting technique, which modifies the proximal edge of the stent into the SB, was developed.

In the flower petal stenting technique, a proximal strut of the SB stent is opened widely to resemble a flower petal and this "petal" does not cross over the ostium of the SB because

Table 4. Quantitative Coronary Angiographic Analysis

	Main Branch	Side Branch	p Value
Baseline (n = 34)			
Lesion length, mm	15.5 ± 6.8	11.3 ± 6.1	
RVD, mm	3.41 ± 0.72	3.04 ± 0.54	
MLD, mm	1.56 ± 0.47	1.33 ± 0.60	
Diameter stenosis, %	53.4 ± 11.8	51.4 ± 22.0	0.694
After procedure (n = 34)			
RVD, mm	3.64 ± 0.58	3.36 ± 0.53	
MLD, mm	3.09 ± 0.50	2.98 ± 0.48	
Diameter stenosis, %	14.7 ± 8.7	11.2 ± 6.5	0.067
Acute gain, mm	1.47 ± 0.59	1.61 ± 0.63	0.366
Follow-up (n = 26)			
RVD, mm	3.45 ± 0.58	3.17 ± 0.51	
MLD, mm	2.71 ± 0.57	2.21 ± 0.77	
Diameter stenosis, %	20.7 ± 12.6	27.4 ± 18.1	0.278
Late lumen loss, mm	0.36 ± 0.65	0.75 ± 0.66	0.139
Restenosis, %	0	2 (7.7)	0.500

MLD = minimal lumen diameter; RVD = reference vessel diameter.

Table 5. Clinical Follow-Up at 9 Months (n = 26)

Cumulative MACE (%)	2 (7.7)
Target lesion revascularization (%)	2 (7.7)*
Target bifurcation revascularization (%)	2 (7.7)*
Acute thrombosis	0
Late thrombosis	0
Myocardial infarction	0
Death	0

*All target lesion revascularization and target bifurcation revascularization occurred in reverse flower stenting cases.
MACE = major adverse cardiac event.

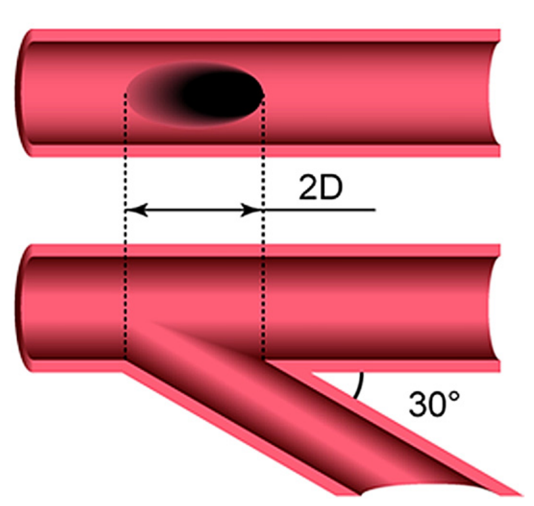

Figure 6. Relationship of Diameters of Major Axis at SB Ostium and SB

The theoretical relationship between the diameter of the major axis at side branch ostium and the diameter of side branch (SB). D = diameter of side branch.

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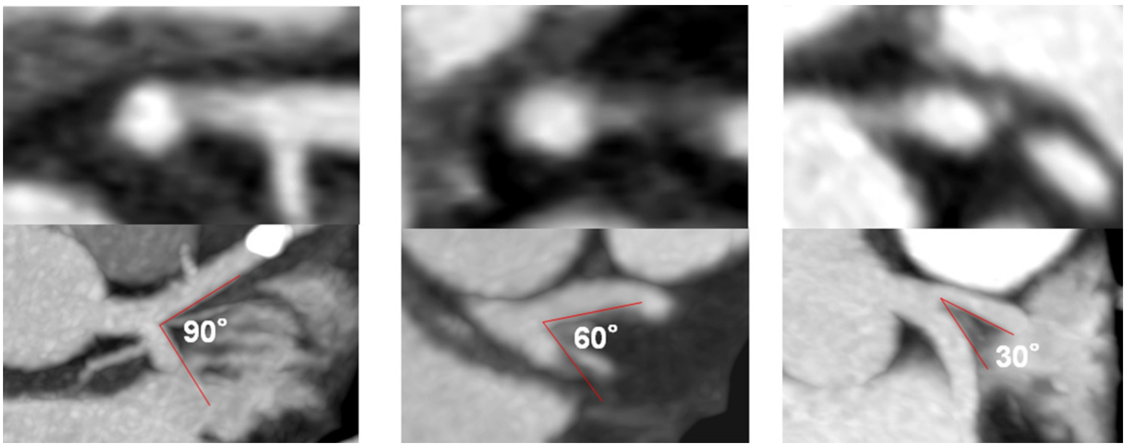

Figure 7. **Difference of Ostial Diameter of SB Varied by Take-Off Angle**

Upper panels show the shape of side branch (SB) ostium. The shape of SB ostium shifts from a circular shape into a more oval shape and the major axis is lengthened.

this portion of the stent is turned over into the distal portion of the MB before stenting in the MB. This technique is similar to the minicrush technique (12), T-stenting and small protrusion technique stenting (16), and Sleeve technique (17) because the proximal portion of the SB protrudes only slightly into the MB. However, it is not clear how the portion becomes protruded in those techniques. With these techniques, the protruded portion can turn over into the distal MB, cross over the ostium of the SB, or be crushed at the carina. Flower petal stenting technique is the only technique in which the direction of the protruded section of the stent can be controlled intentionally. Moreover the petal covers the carina of the bifurcation, which is one of the sites in which restenosis occurs often. Also as shown in Figure 3, there is very little polymer damage with this technique.

This technique can be used for all types of bifurcation lesions; however it involves a bit more procedural complexity. In some lesions where stents were already placed in the MB, this technique is not suitable because the stent struts in the MB adjacent to the SB ostium interfere in creating the flower petal effect. Actually, TLR was performed to 2 reverse flower stenting cases in this study.

In some cases, we could not insert the stent into the SB smoothly when we used the modified method because the wires were twisted within the anatomy. In this situation, we initially stopped advancing the stent-wire combination system and pulled back the SBw to the tip of the stent balloon and attempted to recross back into the SB without tangling the wires.

Understanding the limitations of this technique, flower petal stenting technique can be regarded as the most useful currently available technique in the treatment for bifurcation lesions.

Study limitations. We understand that there are limitations to this study. We identified the indication for this technique to be lesions with involvement of the SB ostium. Therefore, the number of patients in this study is too small for any statistical differences to be seen. Also, this study was performed in a single institution without a control group. A multicenter prospective randomized study would be necessary to clearly identify the efficacy of the flower petal stenting technique.

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Key Words: flower petal stenting ■ bifurcation lesions ■ drug-eluting stent.