## 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 to-mography, 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,

#### See page 66

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.

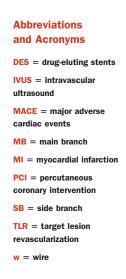
### **Materials and Methods**

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 paclitaxeleluting 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 POPULA-TION AND ANGIOPLASTY PRO-CEDURE. 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.

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-Qwave 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  $\geq 3$  times the upper limit of normal with elevated MB fraction.

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