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Perspective on Bifurcation PCI

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Coronary bifurcation lesion is a complex lesion with suboptimal angiographic and clinical results. There has been no satisfactory classification of the lesion that can guide selection of strategies and predict short- and long-term outcomes. The difference between left main (LM) bifurcation lesions and non-LM bifurcation is striking. So many stenting strategies have been proposed and tried in trials. They include the V, T, Y, one-stent, two-stent, crush, mini-crush, DK, and SKS techniques. However, because these techniques are time and labor intensive, dedicated bifurcated stents have been invented and trialed in humans. This review presents a historical perspective of interventions in bifurcated lesions, with the strengths and weaknesses of the major strategies and of the new dedicated stents.
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Introduction

Coronary bifurcation lesions are diagnosed if there is ≥50% diameter stenosis adjacent (<5 mm) to, and/or at, the ostium of both a main vessel (MV) and a side branch (SB).[1]

Classification

Bifurcation lesions can be further divided into true and false bifurcation in light of the lesion location. The significance of classification of bifurcation lesions lies in its effects on procedural safety and long-term outcomes. Most importantly, false bifurcation lesions might become true ones immediately after balloon inflation or stenting, mainly due to plaque shift. This underlies the complexity of interventions in bifurcation lesions, and reminds us of the need for precise classification before percutaneous intervention (PCI). From the procedural standpoint, vessel segments involved in bifurcation lesions are divided into three segments: prebifurcation MV, distal-to-bifurcation MV, and SB. According to lesion location in the MV or SB, several classifications of coronary bifurcation lesions were proposed; however, none provided detailed lesion characteristics. Among these, the classification by Medina et al.[2] is the most user-friendly. It consists of recording any narrowing in excess of 50% in each of the three segments in the following order (Fig. 1): proximal MV, distal MV, and SB, with 1 indicating the presence or 0 the absence of a significant stenosis. Furthermore, all published classifications lack important information guiding the selection of techniques and predicting clinical outcomes: (1) lesion length in the SB, (2) exact location of lesions at the level of carina, (3) presence of calcifications, (4) severity of angulation, (5) bifurcation angle between the MV and SB, and (6) presence of downstream lesions. Novel classification criteria based upon quantitative variables and intravascular ultrasound (IVUS) parameters are critical to facilitate the stenting procedure and to potentially improve clinical outcomes. The presence of lesions in SB and the lesion characteristics at the carina level determine the selection of a strategic approach.[3] This indicates that careful analysis of baseline lesion characteristics is crucial to improve clinical outcomes. As a result, classification by IVUS is the best in order to guide the stenting procedure.

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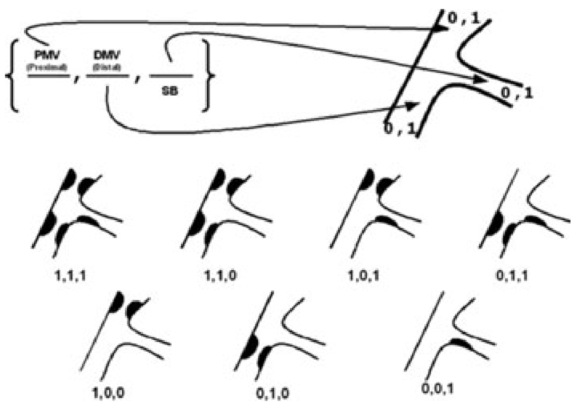

Figure 1. Medina classification of bifurcation lesions.

Classification of the Left Main Bifurcation. The classification of distal left main (LM) bifurcation lesions is more complex, because of its impact on mortality. The incidence of three-vessel disease in the setting of LM stenosis varies from 30% to 80%,[4–8] with an average rate of >50%. A relatively larger bifurcation angle is commonly seen if the distal LM bifurcation is involved, compared to non-LM bifurcation lesions. More importantly, the loss of an SB, either the left anterior descending (LAD) or the left circumflex (LCX) artery, could result in fatal complications.

Compared to bifurcation lesions located in other sites, high residual stenosis at the ostium of either the LAD or LCX artery results in higher incidences of target-lesion revascularization (TLR) or major adverse cardiac events (MACE). Cardiac death could occur in the presence of restenosis while in other non-LM bifurcation sites, more benign complications are presented. So far, no classification for distal LM bifurcation lesions has been published. Recently, we have proposed a novel classification that differentiates distal LM bifurcation lesions into Type I and II subgroups (Fig. 2) with Type I lesions being further classified into Types I a–g, and Type II lesions into Types II a–d. All Type I (including lesions from Type I(a) through Type I(g)) and Type II(b) lesions constitute the nonbifurcated unprotected left main (UPLM) lesions, whereas Type II(c) and Type II(d) lesions are assigned to distal bifurcated UPLM lesions. The presence of either downstream or upstream lesions would obviously increase the procedural complexity and risk for subsequent revascularization.

Percutaneous Strategies

The techniques used for the treatment of coronary bifurcation lesions must be accurately defined for at least two reasons. First, various techniques with an intention-to-treat analysis with respect to success rate, procedure duration, x-ray exposure, volume of contrast media used, and long-term follow-up must be compared. Second, the impact of elaborate techniques on outcomes can be decisive, for instance, the threefold decrease in TVR associated with the classical crush technique with versus without final kissing balloon inflation (FKBI).

Percutaneous Balloon Angioplasty. The percutaneous coronary angioplasty (POBA) approach for coronary bifurcation lesions is technically challenging,

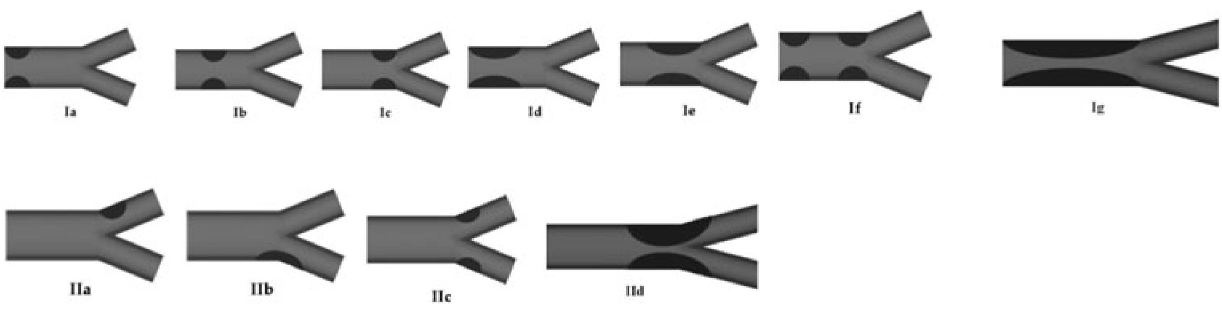

Figure 2. Classification for left main (LM) diseases. Type I, lesion in entire main stem without involvement of ostial left anterior descending (LAD) artery or circumflex; Type Ia, ostial LM stenosis (in first area); Type Ib, stenosis in LM shaft (in second area); Type Ic, distal nonbifurcated stenosis (in third area); Type Id, proximal stenosis in both first and second area (Type Ia + Type Ib); Type Ie, distal stenosis in both second and third areas (Type Ib + Type Ic); Type If, ostial and distal nonbifurcated stenosis (Type Ia + Type Ic); Type Ig, lesion in entire main stem without involvement of ostial LAD artery or circumflex. Type II, distal bifurcated stenosis involving both ostium of LAD artery and circumflex; Type IIa, ostial LAD stenosis; Type IIb, continuous stenosis from ostial LAD artery or circumflex to third area of LM; Type IIc, both ostial left anterior and circumflex stenosis without stenosis in third area of LM.

due to a higher rate of restenosis and TLR, and also to an unacceptable MACE rate.[9,10] In the POBA era, FKBI was recommended to maximally reduce the occurrence of restenosis in the MV,[11,12] without much improvement on ostial SB restenosis because of significant elastic recoil. Furthermore, POBA with larger diameter balloon and high-pressure inflation was so dangerous that emergent surgical bypass was needed in an unacceptably high number of patients, due to severe dissection or acute closure. As a result, coronary bifurcation lesions were considered to be contraindicated in POBA.[13]

Bare Metal Stenting. With the introduction of bare metal stents (BMS), bailout implantation of stents was effective in the prevention of elastic recoil and its emergent sequel of severe dissection with impaired blood flow.[14–16] Compared to POBA, BMS implantation dramatically reduced the restenosis rate in the entire cohort of patients undergoing PCI. However, the effect of BMS on bifurcation lesions remained unknown. In this period, several stenting techniques (such as T, V, culotte, and kissing) were introduced and tested in an ever-growing number of clinical studies.[17–21] In the early stage of the BMS era, interventionalists believed that patients would benefit more from two-stent over one-stent techniques for bifurcation lesions. However, none of these approaches have proven to be distinctly superior, and their applications have produced mixed short- and long-term results. The most important contribution in the BMS era was the realization that an FBKI is necessary to repair the distorted MV after recrossing the SB from the MV stent cells.[22] Several studies have applied the provisional T-stenting technique and reported promising results,[23–25] including rates of TLR between 10% and 15% at 7 months. This technique involves the placement of a stent within the MV, with or without "jailing" of a guidewire in the SB and crossing of the stent with a balloon toward the SB for performance of “kissing” balloon inflation. A stent is inserted in the SB only if the results obtained with the “kissing” balloon are unsatisfactory. The TULIP study,[26] a multicenter French trial, included 186 patients with either true or false bifurcation lesions treated by BMS. The SB was stented in 34% of the patients. At 7 months of follow-up, 3 patients (1.76%) had died, 1 suffered a non-Q-wave MI (0.59%), and 28 (15.88%) underwent TLR. Thus, with BMS, stenting both branches offers no advantage over stenting of the MV alone and may also be associated with greater restenosis.

Drug-Eluting Stenting. The introduction of drug-eluting stents (DES) has fundamentally changed the concept of percutaneous treatment for coronary bifurcation lesions, mainly because of the rate of in-stent restenosis (ISR).[27,28] In one study by Colombo et al., sirolimus-eluting stents were implanted in both the MV and SB.[29] Angiographic results showed restenosis rates as high as 27%, especially at the ostium of the SB. Further study elucidated that the gap between vessel wall and stent struts was the main reason contributing to the occurrence of ISR. Therefore, effective coverage of the SB would potentially result in a reduction of the incidence of ISR, particularly at the SB ostium.[30] Simultaneously, these studies implied that DES does not work well in the setting of bifurcation lesions, especially when a two-stent technique is used.[31–34] Based on the classical stenting techniques available in the BMS era, innovations in stenting techniques came about in the DES era.

One-Stent or Two-Stent Technique. Even after the availability of DES, interventionalists continued to face the same old question: to stent one or both branches? The issue on intention-to-treatment is that the one-stent technique entails stenting the MV only, with or without balloon inflation of the SB; in the two-stent technique, SB stenting is performed without waiting for the results after ballooning. From this way of analysis, the term “one-stent technique” does not answer the question of whether to stent the SB if the result of balloon angioplasty is suboptimal (including flow-limiting dissection and acute closure). In fact, no one-stent technique exists in real-world practice. Instead, provisional stenting is the default technique—some in the one-stent approach would be transferred to the two-stent arm.[35] From the technical point of view, it becomes apparent that the choice of two-stent technique is limited if the initial intention was to only place one stent because the SB stent had to be advanced into the SB through the stent struts of the MV. In this case, the choices of two-stent technique are limited to the inner crush, modified T stenting, and the culotte technique. Therefore, provisional stenting, especially the provisional optimization stenting (POT) technique, indicates the possibility of stenting the SB.

Even so, the controversy on one- versus two-stent technique still continued: which technique is better?[36] This conundrum was made even more apparent by a large prospective, multicenter, randomized NORDIC trial[30] in which a second stent for the SB was implanted only if there was impaired flow (TIMI 0∼1).

The results showed that both subgroups (one- and two-stent) had very low rates of MACE at 12-month follow-up. Further analysis demonstrated that a higher MACE rate was found in patients treated by classical crush stenting, compared to the culotte group. Thus, in the DES era, stenting the MV lesion, coupled with balloon angioplasty in the SB, still produced a high success rate and good clinical outcomes.

Procedures of Bifurcation Stenting

Some of the commonly used bifurcation stenting strategies are summarized in Table 1.

Classical Crush Stenting

In order to decrease the high rate of restenosis at the ostium of the SB by better covering the ostium of the SB with stent struts, Colombo et al. proposed the crush technique.[37] It involved simultaneous advancement of two stents into the MV and the SB, with 3–5 mm of the SB stent protruding into the MV (Fig. 3). In a study of 231 patients treated with classical crush, Hoye et al.[38] reported a survival free of TLR rate of 90.3%, a survival free of MACE rate of 83.5%, a possible stent thrombosis rate of 4.3%, and an SB restenosis rate of 25.3% at 9 months. In a prospective registry, Moussa et al.[39] revealed a 6-month TLR rate of 11.3% after classic crush stenting with sirolimus-eluting stents; however, FKBI was performed only in 87.5% of the patients.

The Importance of FKBI. Further analysis on the cause of restenosis at the SB ostium revealed that FKBI after classical crush was mandatory to improve long-term outcomes.[40–43] Most importantly, failure to perform FKBI after crush stenting was associated with higher incidence of stent thrombosis.[44] Ormiston et al.[42] demonstrated that an FKBI did not achieve full expansion of the SB stent if the bifurcation angle was >80 degrees.

In order to facilitate FKBI, Colombo et al. proposed a new technique: mini-crush stenting.[45] The mini-crush approach consisted of a minor retraction of the SB stent into the MV so that the proximal marker of the SB stent was situated in the MV at a distance of 1–2 mm proximal to the carina of the bifurcation. Another difference consisted of "crushing" the SB stent with a balloon instead of the MV stent as in the standard approach; this was accomplished by loading the balloon in the MV, covering the protruding SB stent segment, and crushing it against the MV wall. The procedure was then completed as in the standard crush with an FKBI. In a series of 45 consecutive patients treated by mini-crush stenting (and 94.2% of FKBI), there was one case of SB stent thrombosis (2.2%) at 72 days postprocedure. At follow-up of 7.5 ± 1.3 months, the restenosis rate in the MV was 12.2% while in the SB it was 2.0%. In reality, there was not much difference between the classical versus mini-crush technique. The only minor "difference" was the length of the SB stent protruding into the MV. From our IVUS study, the average length of the SB stent protruding into the MV was 3∼3.5 mm by the classical crush approach, compared to 1∼2 mm by the mini-crush approach. The shortened length of the SB stent in the MV raised concerns about full coverage of the SB ostium, especially in the setting of angulation and severe overlapping of both branches.

Factors Preventing FKBI. With a success rate of FKBI by classical crush at around 70∼80% or >90%

Table 1. Favorable Bifurcated Stent Techniques and Their Procedures

Crush stenting	Place two stents into the main vessel and side branch (SB) simultaneously with 3–5 mm SB stent into the main vessel (MV). SB stent is inflated. After withdrawing the balloon and guidewire from the SB, the MV stent is inflated to crush the SB stent. Then, FKBI is performed.
DK (double-kissing) crush stent	Deploy the SB stent first. Remove the balloon and guidewire. Then, an MV balloon crushes the SB stent. A first kissing balloon inflation is performed. A second stent is placed in the MV and inflated and further crushes the SB stent. Final kissing balloon inflation is performed.
Provisional T- stent	Stent the MV first. If SB result is not satisfactory then put a second stent in SB, FKBI.
TAP (T and protrusion)	Stent the MV first. Put a second stent in the SB with an uninflated balloon in the MV. The SB stent is deployed with protruding slightly inside the MV, then FKBI.
Culotte stenting	The more angulated branch is stented first. Then, a second balloon opens up the other branch followed by a second stent. FKBI is performed.
SKS (simultaneously kissing stents)	After predilatation, two stents are inserted into both branches. The proximal overlapping of stents is kept minimum. The stents are sequentially dilated and finished with FKBI.

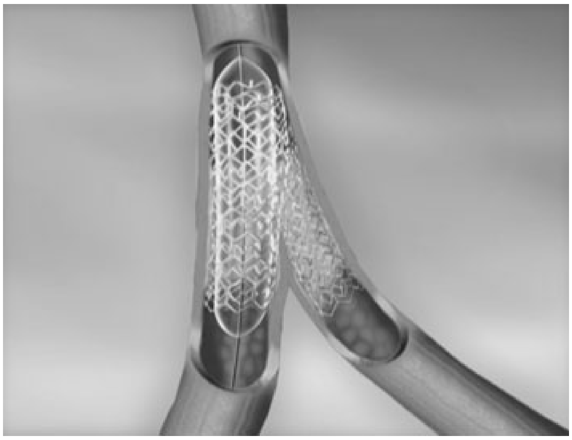

Figure 3. Classical crush stenting. Two stents were deployed in the main vessel and side branch (SB) vessels simultaneously. The SB stent is inflated first, with proximal portion protruded into the main artery. Main-artery stent is inflated after removal of stent balloon and wire from the SB. This main stent crushes the side stent from its ostium to the proximal portion. Final kissing balloon inflation is recommended.

in patients with distal LM bifurcation lesions,[46] which factors cause the failure of FKBI in the context of classical crush stenting? Distorted SB stent geometry and irregularity in overlapped stent strut layers at the carina of the bifurcation are two common geographic characteristics immediately after the classical crush technique.[47] In addition there are technical pitfalls, for example, the guidewire could be advanced outside the proximal segment of the SB stent, rather than in the true lumen of the SB; therefore, less expanded SB stents with irregular and small stent cells after classical crush do not allow for easy advancement of postdilation balloons.[48] Furthermore, multiple layers of metal mass, irregular overlapping of struts at the carina, and a distorted SB stent were the main factors preventing the optimal performance of FKBI and promoting a high rate of restenosis.[49] Murasato et al.[50] further confirmed that FKBI improved the apposition of the struts to the vessel wall. As a result, we proposed a modification of the classical crush technique and called it the double-kissing (DK) crush technique (Fig. 4).

Double-Kissing Crush. In short, two wires are positioned distal to lesions in both the MV and SB. A balloon is positioned in the MV and a stent in the SB with the proximal segment protruded in the MV. The stent in the SB is deployed first; then the SB wire and balloon are removed. The balloon in the MV is inflated and crushes the SB stent in its proximal segment. The SB is then rewired and a noncompliant balloon is advanced into the SB. A first kissing balloon inflation is performed to expand the opening of the stented ostium of the SB. Then the wire and balloon from the SB are removed. A stent is positioned in the MV and is deployed while further crushing the SB stent. A second kissing balloon inflation is repeated after the SB is rewired and reballooned until a perfect result is achieved.

Under IVUS investigation, which was used almost in every case of PCI for bifurcation, especially the LM lesion, the proximal segment of the SB stent was seen to be distorted after being crushed; the first kissing balloon angioplasty repaired the distorted proximal segment and fully expanded the ostium of the SB stent. Therefore, after stenting of the MV, recrossing into the SB stent and performance of FKBI became much easier, especially in the transradial approach where there was difficulty of advancing two stents inside a 6F guiding catheter.[51,52]

The feasibility and safety of this new DK crush technique was assessed in two pilot studies.[53,54] The results showed that FKBI by DK crush was successful in 100% of patients. Since then, a randomized, multicenter, prospective trial from 12 high-volume centers, the DKCRUSH-1 study with 313 patients, was designed to assess the differences in MACE between the DK and classical crush techniques.[49] FKBI was performed in 76% in the classical crush group and 100% in the DK crush group ($P < 0.001$). The incidence of stent thrombosis was 3.2% in the classical crush group (5.1% in lesions without FKBI and 1.7% in lesions with FKBI), and 1.3% in the DK crush group. The cumulative 8-month MACE rate was 24.4% in the classical crush (35.9% in patients without FKBI and 19.7% in patients with FKBI), significantly greater than that in the DK crush group (11.4%, $P = 0.02$).

Other Stenting Techniques

TAP Technique. In a large multicenter registry of provisional T-stenting and kissing SB balloon angioplasty, a 34% rate of SB stenting was reported.[26] However, under bench investigation, the T-stenting technique was seen to have a high rate of incomplete strut coverage at the SB ostium, especially when the angle between the MV and SB was acute. So the TAP (T and protrusion) technique was proposed.[55] It shares with the standard provisional T-stenting technique the first steps: stenting of MV, rewiring of the SB, and FKBI.

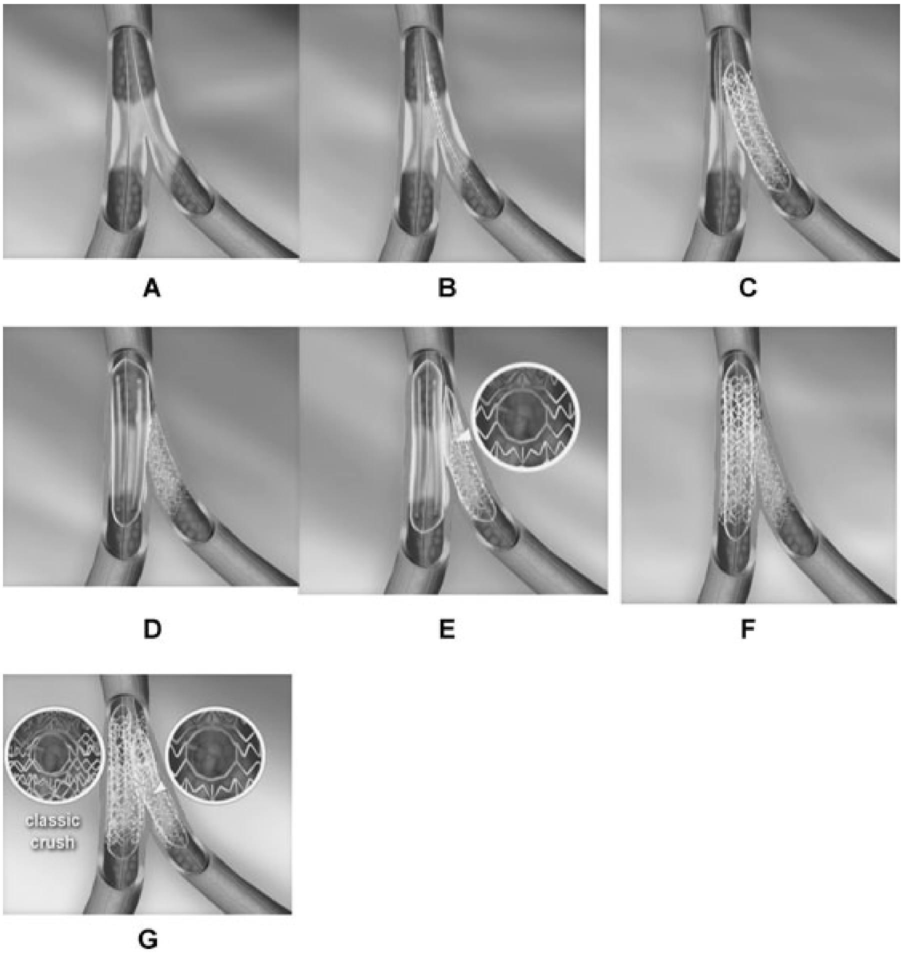

Figure 4. Double-kissing (DK) crush technique. Two wires are inserted into the main vessel (MV) and the side branch (SB) (A). One stent and balloon are advanced into the SB and MV, respectively (B). The SB stent is inflated first (C). The balloon in the MV is inflated after removal of stent balloon and wire from SB (D). First kissing balloon inflation is performed after successful rewiring of the SB (E). Stenting MV is undertaken (F), with final kissing inflation as the final step (G). The ostium of SB is relatively largely expanded, compared to classical crush (G).

If the results are not satisfactory, the procedure is continued by placing an uninflated balloon into the MV (which will be used for final kissing) and a stent in the SB. The position of the SB stent is adjusted to fully cover the proximal (or "upper") part of the SB ostium. Then, the SB stent is deployed while the MV balloon is kept uninflated. As shown in the bench test, in this position, the struts of the SB stent protrude inside the MV only at the distal part of the SB ostium. Finally, the SB balloon is slightly pulled back and final kissing balloon is performed by inflating simultaneously the SB and the MV balloon.[55]

Simultaneous Kissing Stenting Technique. The simultaneous kissing stenting (SKS) technique[56] is a preferred strategy when the bifurcation lesions involve both the MV and SB and have a large proximal MV segment, which can accommodate both stents.[57–58] Before the procedure, the degree of stenosis and morphological characteristics of MV and SB are carefully examined by angiography and IVUS. When the disease at the distal LM coronary artery extends to the ostial ramus intermedius branch, as well as the ostial LAD and LCX (trifurcation), this technique is contraindicated. In patients with tight stenosis, predilation is performed prior to stent positioning in order to facilitate stent delivery and good visualization of stent location. After predilation, two stents are inserted into both branches. Stent size is selected on the basis of angiographic and

IVUS findings of the proximal and distal references of both the MV and SB. To make a short new carina, the proximal overlapping segment is kept as short as possible. However, stents are positioned to cover the lesion completely while keeping the proximal marker of both stents overlapped at the same site. After repeated confirmation of stent positions, they are sequentially dilated at high pressure (more than 12 atm) to achieve adequate stent expansion distal to the bifurcation, with the stent in the MV dilated first in most patients. Simultaneous FKBI is performed before completing the procedure by dilating both stents with the balloon-to-artery ratio of ∼1.5 at the proximal segment. Inflation pressure of the two balloons is decided according to the size of both branches. If the stent(s) appears underdilated, additional balloon inflation is performed with more pressure. Following the introduction of DES, the SKS technique has been used more frequently because it is user-friendly. This technique does not require rewiring into the SB or reopening through the side struts of the MV stent and does not distort stent structure. In addition, overstretch of the proximal stent strut, which is often required for complete stent apposition in large bifurcations such as LM lesions, is not needed. A recent study showed the SKS with SES had a low TLR rate of 4%. However, this study had a very low angiographic follow-up rate. A more recent study from our group was designed to assess the outcomes of the SKS technique using SES with an angiographic follow-up rate of over 80% and a longer follow-up duration. Our findings of an overall restenosis rate of 16.7% and a TLR rate of 13.9% were comparable to those observed in the classic crush technique. Notably, a low restenosis rate of 10% at the SB was found to be similar to that of the crush technique with FKBI. A similar trend was also shown when comparing late luminal loss after the crush and the SKS technique (personal communication).

Culotte Technique. Both branches are wired and/or predilated alternately; subsequently, the wire from the straighter branch is removed and the more angulated branch is stented first. Then the wire and a balloon are advanced into the other branch. Once there is sufficient opening, a second stent is advanced and deployed with its proximal part in the MV. Finally, FKBI of both stents is performed.

The Nordic Bifurcation Stent Technique Study sought to compare the crush and the culotte technique in PCI of bifurcation lesions. Two hundred nine patients were randomized to crush stenting and 215 patients to the culotte technique. Complete angiographic follow-up at 8 months was available in 324 patients and showed no statistical difference between the two techniques, although investigators reported that the culotte technique was associated with better single-digit restenosis. ISR in both groups was localized mainly in the SB, a problem that was more common with the crush technique. However, the culotte technique should not be used when there is a striking difference in size between the MV and SB, a situation that brings a small stent into the MV. On the other hand, the culotte technique might appear to be more technically demanding because of the increased number of required steps. The investigators did not show which stent is optimal for the crush or culotte technique, but the difference between these two approaches is the risk of closure of the SB, as in the other provisional stenting techniques.[30]

Debulking Technique Prior to Stent

Tsuchikane et al. studied 99 patients with bifurcated lesions.[59] Directional coronary atherectomy was performed and followed by simple one-stent technique in 96 patients (97%). The TLR was only 2%. However, directional atherectomy is a difficult device to be trained. Also, the lesions must also be amenable to directional atherectomy. We don't anticipate this technique will be the mainstream in bifurcation stenting.

Dedicated Bifurcation Stents

The AST petal DSX dedicated bifurcation device[60] (Advanced Stent Technologies, Pleasanton, CA) is a 316L stainless steel slotted tube with a side aperture located at the middle of the stent. The purpose of the aperture is to allow access to the SB after stent deployment and to scaffold the SB ostium with outwardly deploying strut elements. The stent is 15 mm in length and 3.0 or 3.5 mm in diameter. The aperture can expand to accommodate an SB ostial diameter of 2.3–3.3 mm. The petal LP system is identical to the DSX except for a reduced profile. The study device is compatible with 7-Fr guide catheters. Lesion predilatation is mandatory. A guidewire is placed in the MV and another in the SB. The dual side-exchange delivery system has a main lumen that guides the catheter to the primary lesion over the MV guidewire. The secondary lumen (side sheath) facilitates proper alignment of the aperture to the SB ostium as it tracks over the SB guidewire. As the device is advanced in the coronary artery, it rotates and aligns into position at the bifurcation. In addition to a conventional cylindrical-shaped balloon, there is a secondary elliptical balloon adjacent to the main balloon and connected to the same inflation lumen so that a single inflation device is needed. The petal stent is crimped over both balloons such that the elliptical balloon is under the side aperture and petal elements. Upon inflation, the main balloon deploys the stent into the MV, while the elliptical balloon deploys the petal elements into the SB ostium. Following stent deployment, "kissing" balloon postdilatation is indicated to expand fully the MV stent and petal elements. The index lesion was successfully treated in 13 patients with the study stent being successfully implanted in 12. The in-hospital MACE rate was limited to two non-Q-wave MI. In-stent MV MLD increased from a mean of 0.63 mm to 2.61 mm at the index procedure, and for this initial BMS version of the stent, 4-month mean MLD measured 1.02 ± 0.42 mm with TVR on two patients

The SLK-View^{TM} stent (Advanced Stent Technologies) is a new coronary scaffolding device incorporating a side aperture that allows access to the SB of a bifurcation lesion after deployment of the stent in the MV.[61] The device is a 316L stainless steel flexible slotted tube stent with a side aperture located between the proximal and distal section. It is available in a single 17-mm length and in two sizes, 3.0 and 3.5 mm, in diameter. The side hole diameter is half a millimeter smaller than the nominal size of the MV. A proprietary balloon delivery system of dual over-the-wire design comprises a proximal dual lumen shaft that separates into two catheters at its distal segment, a balloon, and a side-sheath. There are a total of three radiopaque markers on the balloon, located at the distal edge, center, and proximal edge of the stent. An additional tungsten radiopaque marker band is located on the distal segment of the side sheath. The stent is premounted in the distal segment of the delivery system with the side sheath running under the proximal segment of the stent and exiting through the side hole.

Eighty-one patients underwent SLK-View^{TM} (Advanced Stent Technologies) stent implantation with subsequent kissing balloon postdilatation. Successful stent delivery was accomplished in 82/84 of the cases (97.6%). Technical success was obtained in 99% and 94% of the MV and SB, respectively. Stenting of the SB was performed in 21 lesions (25%). The SB was accessed effectively in 100% of bifurcations postprocedurally. Binary restenosis rate at 6-month follow-up was 28.3% and 37.7% for MV and SB, respectively. TLR rate at 6-month follow-up was 21% with a CABG rate of 6%.

The AXXESS stent[62] consists of the self-expanding nickel titanium platform with bioabsorbable polylactic acid as a carrier material that releases Biolimus A9, a sirolimus analogue. The stent is designed to be placed in the proximal part of the MV, at the level of the carina of the bifurcation. The stent is flared at the distal end to facilitate expansion at the carina. In addition, this stent has three radiopaque markers at the distal end and one at the proximal end to visualize stent ends, allowing operators to identify stent edges. Once the ostium is covered by an AXXESS stent, the branches can be covered with additional stents being placed through it. Predilation of the target lesion was mandatory. Atherectomy was not allowed. After AXXESS stent implantation, additional stents could be placed in the distal MV and/or distal SB to achieve an acceptable angiographic result. Postdilation, including FKI, was allowed but not mandatory. Data were obtained from 49 cases. Volumetric analysis using Simpson's method within the AXXESS stent, and cross-sectional analysis at the ostium of MV and/or SB, was performed. Impact of bifurcation angle on stent expansion at the carina was also evaluated. Within the AXXESS stent, neointimal volume obstruction percentage was 2.3%, with a minimum lumen area of 7.9 ± 2.6 mm^2. Lumen area was 5.2 ± 1.7 mm^2 at MV ostium, and 4.0 ± 1.5 mm^2 at SB ostium. In two cases, incomplete stent apposition was observed at the proximal edge of the AXXESS stent. In one case, a gap between the AXXESS stent and an additional stent was observed. Greater bifurcation angle inversely correlated with smaller stent area at SB ostium ($r = -0.54$, $P = 0.03$) but not at MV ostium ($r = -0.2$, $P = 0.29$).

The BIGUARD^{TM} stent[63] is a novel DES platform that is specifically designed for the treatment of ostial SB, and because it supplies enough space for exchange of devices in the MV (Fig. 5), it is expected to facilitate the use of different single- or double-stenting techniques for the treatment of coronary bifurcation lesions. The BIGUARD^{TM} stent system has a crossing profile of 0.038 inch and a maximum of 0.053 inch. The stent is tailored for drug elution (sirolimus-eluting) with 100 micrometers of stent struts, and it is advanced with a 6-Fr guiding catheter. Geographically,

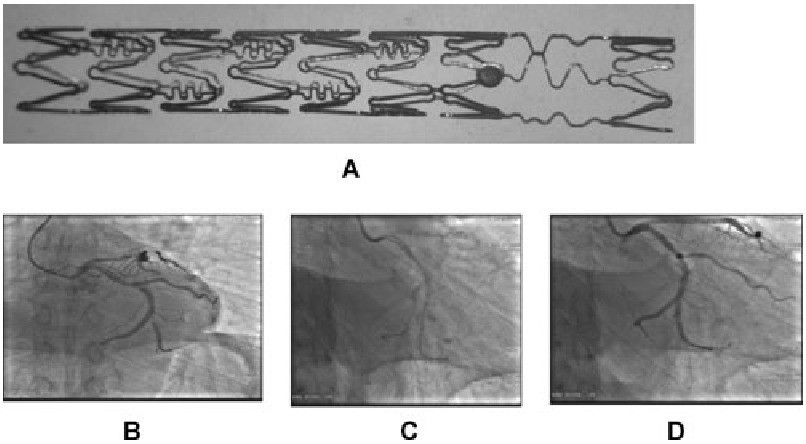

Figure 5. Biguard stent is divided into three segments: proximal portion (1 mm in length), middle (3 mm in length), and distal segment (A). The metal marker is located in the distal edge of the middle segment, which allows for the precise position. Typical in-stent restenosis is at the ostium of left circumflex (B). The Biguard stent is positioned (C), with the metal marker just at the bifurcation point. After inflation of the stent, no plaque shift and significant residual stenosis are seen (D).

three stent struts at the proximal segment (usually 3 mm in length) are separated at every 120 degrees, with the encircled space being large enough to allow the advancement of all kinds of devices (guidewire, balloon, stents). The final stent diameter depends on the balloon diameter used. For example, a 4.0-mm diameter balloon can open the 2.5-mm stent up to a 4.0-mm diameter. Interestingly, one need not advance another guidewire to the MV immediately after stenting the SB with the BIGUARD™ stent; moving the SB wire directly into the MV negates the need for guidewire recrossing. Notably, there are three markers on the BIGUARD™ stent: two at the proximal and distal points, respectively, and another at the intersection site providing SB positioning. In theory, the BIGUARD™ stent cannot completely cover the SB ostium in the setting of bifurcation angles < 70 degrees, and can fully cover the SB ostium when the bifurcation angle is >70 degrees. However, as is known, after kissing inflation the stent struts in the MV can protrude into the SB for 1∼1.5 mm, and therefore SB ostium coverage is not an issue.

Asian Bifurcation Club

Several years ago, the European Bifurcation Club (EBC) was started and significantly contributed to the development of treatment for bifurcation lesions, including classification, treatment strategies, and dedicated stents. In its annual club conference, many first-in-man studies were reported, and many educational activities have promoted and improved the performance of PCI in the bifurcation lesions for the interventional community worldwide.

In order to confront the challenges and complexity of performing PCI in bifurcation lesions by the Asian interventional community, Professor Run-Lin Gao and my team founded the Asia Bifurcation Club (ABC) in November 2007. It met for the first time at the 3rd China Interventional Therapeutics in Beijing. ABC is aimed as a meeting point for Asian interventionalists and as an education venue for improving the understanding and the success in treating bifurcation lesions. In the first meeting in Beijing, the team from Nanjing presented the results of its modified crush technique: the DK crush in the DKCRUSH-1 study. The results showed the superiority of DK crush over classical crush with respect to TLR, MACE, and stent thrombosis rates. Since that time, the DKCRUSH-2 study was launched to compare the DK crush versus provisional stenting in an entire cohort of patients with true bifurcation lesions. The DKCRUSH-3 is in its preparatory phase and aims at comparing DK crush versus Culotte for the treatment of distal LM bifurcation stenosis. An ABC team has designed a dedicated ostial SB stent, the BIGUIDE stent. A phase 1 preclinical study was started. Cooperation between the ABC and the EBC was further consolidated with the organization of the first Bifurcation Coronary Summit by both ABC and EBC in November 2008. The proceedings of this meeting are reported in this journal.

Bifurcation stenting technique is evolving. Several studies[30,64,65] have shown that one-stent technique with provisional stenting of SB is the preferred strategy. However, there is still a strong belief that many specific lesions and patients will benefit from bifurcation stenting with double stents. Only future well-designed multicenter randomized studies can answer these questions.

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