Drug-Eluting Stents in Bifurcations
Bench Study of Strut Deformation and Coating Lesions

Patrice Guéрин, MD, PhD; Paul Pilet, B Engl; Gérard Finet, MD, PhD; Yann Gouëffic, MD, PhD; Jean Michel N’Guyen, MD; Dominique Crochet, MD; Isabelle Tijou, B Tech; Pierre Pacaud, PhD; Gervaise Loirand, PhD

Background—The use of a drug-eluting stent (DES) has strongly limited the incidence of in-stent restenosis in bifurcation lesions; nevertheless, restenosis still remains a problem at the origin of the bifurcation side branch. The aim of this study is to analyze the consequences of the kissing postdilatation technique on 5 DESs, using microfocus x-ray computerized tomography and scanning electron microscopy.

Methods and Results—Five different DESs (Cypher, Cypher Select, Endeavor, Taxus Express, and Taxus Liberté) were deployed using kissing postdilatation protocols in a bench-top model. For all types of DES, microfocus x-ray computerized tomography analysis showed that (1) kissing postdilatation of the stent by 2 coaxial balloons caused elliptic deformation in the proximal segment and (2) kissing postdilatation technique reduced the ratio of potential metal to artery (manufacturer’s data/calculated ratio [%]: Cypher, 12.7/8.8; Cypher Select, 13.5/10.2; Endeavor, 19.0/13.3; Taxus Express, 20.5/4.7; Taxus Liberté, 17.9/12.5) and the potential drug application to area in the proximal segment, including the ostial struts (struts adjacent to and lying around the side branch ostium) (manufacturer’s data/calculated drug application [µg/mm²]: Cypher, 1.4/1.0; Cypher Select, 1.4/1.1; Endeavor, 1.6/1.1; Taxus Express, 1.0/0.7; Taxus Liberté, 1.0/0.7). Scanning electron microscopy analysis showed a significantly greater coating damage to the ostial struts in all stents evaluated (P<0.05).

Conclusions—Commercially available DESs subjected to simultaneous kissing balloon postdilatation in an unconstrained model may contribute to side branch ostial restenosis by proximal segment elliptic deformation and damage to the polymer coating. (Circ Cardiovasc Interv. 2010;3:00-00.)

Key Words: bifurcations ■ stents ■ angioplasty ■ coronary disease ■ restenosis

Bifurcation lesions frequently occur in ≈15% of percutaneous coronary interventions.1,2 Angioplasty with bare-metal coronary stenting became the routine treatment for these lesions, but bifurcation stenting was still associated with a high rate of restenosis, especially when multiple stents were used.2,3 The use of a drug-eluting stent (DES) has been reported to reduce restenosis in bifurcation lesions; however, side branch (SB) ostial restenosis still remains a problem in 10% to 20% of cases.4–7 Implanting a second stent in the SB does not limit restenosis,6 and systematic SB stenting seems to be associated with a higher risk of restenosis than with the provisional T-stenting technique.6,8 The high rate of SB ostium restenosis could be due to limited strut coverage in this area, with consequently inadequate drug distribution to the stented artery.9 The aim of this study was to analyze the consequences of the kissing postdilatation technique (postdilatation by using simultaneous kissing balloon inflation) on 5 DESs commercially available in France, using microfocus x-ray computerized tomography (MFCT) and scanning electron microscopy (SEM).

Clinical Perspective on p ●●●

Methods

Stent Deployment

The following 5 different 3-mm-diameter DESs were analyzed: Cypher and Cypher Select, Taxus Express and Taxus Liberté, and Endeavor. Ten stents of each type were deployed in 37°C physiological serum in a controlled temperature bath under direct visualization. Stents were secured by fixation on the first and the last struts (needles) during postdilatation, and no phantom was
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onds (using two 3-mm balloons, both inflated at 10 atm for 10 seconds). The kissing balloon postdilatation was performed using two 3-mm balloons, both inflated at 10 atm for 10 seconds.

First, each stent was deployed at its nominal diameter (10 atm during 10 seconds). Next, the first balloon was deflated, and the second was inserted and passed through a cell in the middle of the stent. The kissing balloon postdilatation technique was performed by using two semicompliant 3-mm balloons. Both were inflated at 10 atm for 10 seconds. Finally, both balloons were retrieved simultaneously. Before analysis, the stents were preserved in a physiological saline solution. Two stent segments were defined as the proximal segment (PS), which was dilated with 2 balloons and included the ostial struts (struts adjacent to and lying around the SB ostium), and the distal segment (DS), which was deployed with 1 balloon at the nominal stent diameter. Each stent was defined as having 1 mural (outer) and 1 luminal (inner) surface; the struts of each segment were defined in terms of a mural (outer) surface and of a luminal surface, which included 1 inner face and 2 lateral faces (facing the adjacent strut along the long axis of the stent). One DES of each type was used for MFCT analysis. For each type of DES, we have investigated the size of the PS compared with the DS if two 3-mm balloons were used for kissing postdilatation technique.

MFCT
Five new stents of each type were inserted in the MFCT apparatus and fully analyzed. Transactional representation enabled the 2 segments (PS and DS) of each stent to be assessed. Next, the ratio between the struts and the hypothetical arterial wall in each segment was calculated and compared with the theoretical values for nominal diameter of each DES (manufacturer data). Finally, a 3D reconstruction of the device was made, allowing high-precision analysis of the device and of strut deformation. Following Finet et al.,10 the linear ratio was applied, which was defined as a fractal mathematical relation between the diameters of each vessel concerned in the bifurcation as follows: mean mother vessel diameter=0.67 (daughter vessel-1 diameter+daughter vessel-2 diameter). It was hypothesized that the 2 daughter vessel diameters were similar in our particular conditions. Measurements were performed on the cross-sections through MFCT analysis. To assess the deformation of each type of DES in the PS deployed with two 3-mm balloons, the mean eccentricity on transections was calculated. The shape of an elliptic deformation can be expressed by the eccentricity, which is a positive number <1 and ≥0 (an eccentricity of 0 means that the ellipse is in fact a circle).

Statistical Analysis
Mixed models were used to take into account the clustered structure of the data. The interaction between type of stent and type of segment of the stent was tested, and if significant, Friedman test was used to compare differences between segments within each stent type. If the overall Friedman test was statistically significant, the Wilcoxon signed-rank test was then applied. S-Plus version 6.2 statistical software was used for all analyses. A P<0.05 was considered statistically significant. No correction has been used because the Wilcoxon tests were all conditioned by 2 significant tests.
Concordance was assessed with the Wilcoxon signed-rank test (interobserver variability calculated with all DES, intraobserver variability calculated with 3 DES of each type). If the 2 observers disagreed, their mean value was used for analysis.

Results
Stent Deployment Using Kissing Postdilatation Decreases the Potential Drug Application/Area Ratio
For each type of DES, kissing postdilatation caused overexpansion of the PS (compared with nominal diameter), especially on the ostial struts (Figure 2A and 2B). For each type of DES, the calculated value of the constant (A) linking the various mean diameters in the bifurcation (PS diameter=A[SB1 diameter+SB2 diameter]) was ≈0.67, indicating that in our experimental condition, kissing postdilatation of the various DESs respected the potential size of each vessel in the bifurcation (Table). The range of the mean eccentricity for each type of DES was between 0.73 and 0.78, confirming that the elliptic deformations in the PS segment after the kissing postdilatation technique with 2 coaxial 3-mm balloons were similar (Table). Compared with the DS, the PS of all DESs was overstretched, with a range of the mean enlargement between 24% and

Figure 1. Stents were deployed (10 atm during 10 seconds) at nominal diameter in 37°C physiological serum in a controlled temperature bath under direct visualization. Next, the stents were secured by fixation on the first and the last struts (needles) for kissing postdilatation (magnification) technique. A second balloon was inserted and passed through a cell in the middle of the stent. The kissing balloon postdilatation was performed using two 3-mm balloons, both inflated at 10 atm for 10 seconds. Finally, both balloons were retrieved simultaneously. Before analysis, the stents were conserved in a physiological saline solution. Two stent segments were defined as the proximal segment (PS), which was dilated with 2 balloons and included the ostial struts (struts adjacent to and lying around the SB ostium), and the distal segment (DS), which was deployed with 1 balloon at the nominal stent diameter. Each stent was defined as having 1 mural (outer) and 1 luminal (inner) surface; the struts of each segment were defined in terms of a mural (outer) surface and of a luminal surface, which included 1 inner face and 2 lateral faces (facing the adjacent strut along the long axis of the stent). One DES of each type was used for MFCT analysis. For each type of DES, we have investigated the size of the PS compared with the DS if two 3-mm balloons were used for kissing postdilatation technique.

SEM
Stents were carefully removed from the bath and then rinsed in distilled water to eliminate physiological serum, which could be responsible for salt crystal deposits during SEM. SEM analysis with low vacuum and without sputter coating was immediately performed. The back-scattered electron microscopy was used to highlight the bare parts of stents surfaces. Rotation of the support (5-axis motorized specimen stage) allowed us to observe a large area of the DES, except for a small area behind the ostial face that could not be imaged because of stent fixation on the support using a conductive carbon tape. The coating lesion (defined as the percentage of visible polymer surface fully destroyed [coating lesion and strut denudation confirmed during back-scattered electron microscopy analysis] or partially damaged [coating lesion without full strut denudation]) was graded by 2 independent observers as follows: 0 indicates no significant lesion of the polymer coating (0%); 1, low degree of damage (25%); 2, moderate damage (50%); 3, high degree of damage (75%); and 4, complete destruction (100%). This analysis was performed for 10 stents of each type and for 3 segments per stent (PS, PS on the ostial struts, and DS). The mean±SD value was calculated for each segment in each group of stents.
Therefore, we calculated the ratio between new potential metal and artery and of the new potential drug application and area and compared them with the normal values (ie, manufacturer’s declared nominal diameter). Stent deployment followed by kissing balloon postdilatation decreases the metal-to-artery ratio for all stents and, consequently, the potential drug application in the PS (Table).

### Table. Geometric Analysis of DES Deformation After Kissing Postdilatation

<table>
<thead>
<tr>
<th></th>
<th>Eccentricity, PS</th>
<th>Enlargement, % PS vs DS</th>
<th>PS Metal/Artery Ratio (Normal*/Kissing), %</th>
<th>Drug Delivery/Surface Ratio (Normal*/Kissing), μg/mm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cypher</td>
<td>0.72±0.01</td>
<td>0.78±0.01</td>
<td>31±2</td>
<td>12.7/8.8</td>
</tr>
<tr>
<td>Cypher Select</td>
<td>0.66±0.03</td>
<td>0.73±0.01</td>
<td>24±3</td>
<td>13.5/10.2</td>
</tr>
<tr>
<td>Endeavour</td>
<td>0.72±0.01</td>
<td>0.75±0.03</td>
<td>30±3</td>
<td>19.0/13.3</td>
</tr>
<tr>
<td>Taxus Express</td>
<td>0.69±0.02</td>
<td>0.75±0.00</td>
<td>28±3</td>
<td>20.5/14.7</td>
</tr>
<tr>
<td>Taxus Liberté</td>
<td>0.72±0.04</td>
<td>0.75±0.02</td>
<td>30±4</td>
<td>17.9/12.5</td>
</tr>
</tbody>
</table>

Data are presented as mean±SD. The calculated value of the constant (A) and geometric parameters for each type of DES are shown.

*Normal value of DES declared by the manufacturer at nominal diameter.*
Stent Deployment Using Kissing Postdilatation Technique Induces Coating Lesions

SEM analysis showed that kissing postdilatation of the Cypher stent induced coating lesions, especially along the overstretched segment (PS) on each knee of the struts (cracking effect) (Figure 2C, Cypher, white arrow and white circle). The polymer coating lesions exposed the metal of the stent just below. The most severe coating lesion was observed on the ostial struts (black circle), with variable, but increased destruction of the polymer coating (double white arrow). The DS inflated to its nominal diameter, on the other hand, usually was free of coating lesions.

The Cypher Select showed a higher degree of polymer damage all along the luminal surface of the stent in contact with the balloon during delivery (Figure 2C, Cypher Select, white arrow). Few lesions were observed on the visible mural and lateral strut faces, especially in the PS and on the ostial struts (double white arrow). In the DS, open at its nominal diameter, the polymer coating was conserved.

The Endeavor stent showed subtotal destruction of its coating on the luminal surface of the stent, whatever the segment observed (Figure 2C, Endeavour, white arrow and white circle). On the visible mural surface and lateral face of the struts, a little damage was observed (double white arrow) and was concentrated on the overstretched PS with a maximum on the ostial struts (black circle). The DS presented less damage than with the other stents.

The findings for the Taxus Express stent were similar to those observed with the Cypher stent (Figure 2C, Taxus Express, white arrow), except for a specific abnormality of the polymer bridging 2 adjacent lateral struts in what is known as a webbing effect (white circle). Webbing occurred without coating lesions in the DS or associated with torn coating in the PS (black circle). More severe coating lesions usually were observed on the ostial struts (double white arrow).

The Taxus Liberté presented similar coating lesions to the Taxus Express except for more frequent webbing effects (Figure 2C, Taxus Liberté, white arrows). A greater degree of tearing was observed in the PS of the stent overexpanded by the 2 balloons (double white arrow). As noted for the other stents, coating lesions seemed to predominate on the ostial struts, without significant lesion in the DS.

The polymer coating lesions graded on 10 stents of each type were significantly more severe in PSs overexpanded by the two 3-mm balloons, especially on the ostial struts, than in the DS, inflated to its nominal diameter with 1 balloon, whatever the type of stent (Figure 3). No significant inter- and intraobserver variability was observed ($P<0.05$, **$P<0.01$, ***$P<0.001$).

Discussion

There were 3 important findings of this analysis of DESs in bifurcations after kissing postdilatation technique. First, over-inflation by 2 coaxial balloons caused elliptic deformation in the PS compared to the DS. Second, DES overinflation reduced the ratio of potential metal to artery and thus may reduced the ratio of potential drug application to area in these overexpanded segments, which could impair the antiproliferative effect of the DES. Third, the coating damage on the ostial struts may reduce drug delivery and increase the restenosis risk. Taken together, these observations suggest that current DESs, when deployed under these conditions, are probably poorly adapted for the treatment of bifurcation lesions.

In a previous study, we demonstrated that one of the consequences of balloon angioplasty was the complete de-
struction of the endothelial lining.\textsuperscript{11} In the case of DES implantation after predilatation, it was shown that if the DES did not cover the entire predilated segment, the edge area free of endothelial cells would be at risk of an edge effect caused by a increased neointimal thickness.\textsuperscript{12} Lemos et al\textsuperscript{13} confirmed that edge restenosis was associated with balloon trauma outside the stented segment. The SB origin may be considered as a kind of edge area, thus partially accounting for restenosis; but this explanation is not sufficient in itself because the risk of restenosis is significantly higher than the risk of edge effect in this area (14\% and 5.7\%, respectively).\textsuperscript{6,14}

In clinical practice, restenosis frequent occurs at the SB origin, a location that can easily be left without strut coverage in the case of provisional T-stenting, whether the SB is stented or not.\textsuperscript{6,9} Incomplete SB coverage has been implicated as a possible cause of the high restenosis rate found at the SB origin.\textsuperscript{6,8} It could be the consequence of different factors, such as recoil and struts malapposition at the SB origin (leading to a potential lack in drug application).\textsuperscript{15–17} To limit this risk, different techniques are under assessment, such as the crush technique or dedicated bifurcation stents.\textsuperscript{18–20} The common aim of these procedures is to improve arterial wall coverage in this traumatized area, providing mechanical support and optimizing drug delivery to limit the risk of restenosis.\textsuperscript{19–22} Nevertheless, with the crush technique, despite an apparent full coverage of the ostium of the SB, restenosis risk at the origin of the SB still occurred.\textsuperscript{18,23} One possible explanation involves polymer breakage due to overlapping strut layers and uneven strut distribution at the SB ostium.\textsuperscript{24} Interestingly, however, recent bench test and clinical studies showed these different techniques to be consistently associated with a risk of malapposition, which in turn had been shown previously to be associated with restenosis or late stent thrombosis.\textsuperscript{25–27} Dedicated DESs may limit the risk of polymer breakage, improving arterial wall coverage; indeed, the risk of ostial restenosis does seem to be reduced, but these studies need to be confirmed.\textsuperscript{20–22,28} At least, the results of the recent Nordic Bifurcation Study III point the interest to discuss the systematics of DES kissing postdilatation in bifurcation lesions (M Niemela, Transcatheter Cardiovascular Therapeutics, unpublished data, 2009).

Our observation in this test preparation showed that simultaneous kissing balloon inflations caused elliptic deformation in PS. Ormiston et al\textsuperscript{29} did not observe this effect when stents were deployed within a silicon phantom using a similar technique. This difference likely reflects the difference in test conditions (ie, forces exerted on the stent during deployment by the test apparatus). Moreover, the importance of this elliptic deformation probably is accentuated in our study as the consequence of using a relatively large balloon for the SB in an unconstrained test apparatus. The clinical importance of this finding is unclear.

In our study, different 3-mm DESs were deployed without any phantom and without any angulation imposed during simultaneous inflation of two 3-mm balloons. The aim of our study was to observe the consequences of kissing postdilatation in these conditions far away from human use, with no external forces exerted on the stent and no struts sliding against the arterial wall during stent deployment. Even if the stent-vessel wall interactions may limit polymer damage by constraining the stent expansion, we assumes that coating polymer is more preserved in the conditions of our bench test than in the real life, especially in case of severe and calcified coronary narrowing, which may be deleterious for the polymer on the mural surface of the stent. Additional studies focused on vessel wall-stent interactions are needed to better understand these findings. The finding of coating lesions in our conditions just demonstrates that kissing postdilatation in physiological serum, using two 3-mm balloons (as in the case of large SB diameter), without any potential deleterious contact between mural surface of DES and arterial wall, leads to coating lesions, especially on the ostial strut. No comparison of balloon diameter and simultaneous or sequential inflations have been performed because we assume that in the conditions of our study, comparison could not be extrapolated in human use. Experiments using different protocols (eg, sequential inflations) and with different size balloons have not been performed. It is unclear under what threshold conditions the polymer lesions we observed occur. It is reasonable to speculate that polymer lesions occur as a function of overstretch (determined primarily by SB balloon diameter) and the test conditions the under which deployment is performed. Further studies will be required to elucidate these relationships.

To our knowledge, this study is the first to report coating lesions after a kissing postdilatation. Our observations in the DS of stents deployed at nominal pressure are in agreement with a previous SEM analysis of DESs after single deployment by Otsuka et al. In their study, DESs were deployed in the same conditions as in ours but without postdilatation. Polymer bridging across strut loops (webbing effect) and linear cracking of the bridges were common with the Taxus stent, as were inner-surface polymer defects with bare-metal exposure. The Cypher stent showed an undulating outer surface with irregularities.\textsuperscript{30} Additionally, polymer defects appeared with bare-metal exposure and peeling of the topcoat polymer layer in the loop region. Nevertheless, the low incidence of coating lesions in Otsuka et al and in ours may partly explain the unimpaired antirestenosis effect of both stents when implanted in a coronary segment without bifurcation.\textsuperscript{31,32} In the case of bifurcation lesions, the higher incidence of coating lesions on the ostial struts could be a risk factor for restenosis in this area.

**Study Limitations**

These results, obtained under the usual conditions of bench test analysis and the particular conditions of a kissing postdilatation with two 3-mm balloons, cannot be directly extrapolated to the clinical context and will have to be confirmed in an in vivo analysis. There are other potential contributors to ostial restenosis, such as flow disturbances, that were not investigated in this study.

In conclusion, this bench test analysis suggests that the unresolved problem of restenosis at the origin of the SB in the case of kissing postdilatation of a DES in a bifurcation lesion may be the consequence of at least 2 phenomena due to the
DES itself. First, DES overstretch with elliptic deformation in the PS reduces the ratio between struts and arterial wall and may impair local drug application. Second, polymer coating lesions, probably due to stent overstretch, especially on the ostial struts, may limit the effectiveness of these DESs. Our analysis suggests that current practice of using simultaneous postdeployment balloon inflations may lead to coating lesions in the DES. The clinical implications of these findings are unclear but may contribute to the high rates of SB restenosis observed when using a single-stent strategy.

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Disclosures

None.

References


**CLINICAL PERSPECTIVE**

The side-branch ostium is the most common site for restenosis after drug-eluting stent (DES) deployment in coronary bifurcation lesions. The aim of our study was to analyze the consequences of the kissing postdilatation technique on 5 DESs, using microfocus x-ray computed tomography and scanning electron microscopy. This bench test analysis suggests that when commercially available DESs are subjected to simultaneous kissing balloon postdilatation in an unconstrained model, elliptical deformation of the proximal segment, reduction of stent-to-artery ratio, and polymer coating damage at the side branch ostium are observed. These DES changes may impair local drug delivery, thus limiting the effectiveness of these DESs and contributing to ostial side branch restenosis. The results of our study could clarify restenosis mechanisms at the origin of the side branch in the case of kissing deployment of DESs and could lead to improving DESs or their use in clinical practice.
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Pose de stents à libération de principe actif au niveau des bifurcations
Simulation en laboratoire de la déformation des entretoises et de la dégradation de l’enrobage

Patrice Guérin, MD, PhD ; Paul Pilet, B Engl ; Gérard Finet, MD, PhD ; Yann Gouëffic, MD, PhD ; Jean-Michel N’Guyen, MD ; Dominique Crochet, MD ; Isabelle Tijou, B Tech ; Pierre Pacaud, PhD ; Gervaise Loirand, PhD

Contexte—Bien que l’emploi des stents à libération de principe actif (SLPA) ait fortement réduit l’incidence des resténoses intra-stent au sein des lésions de bifurcation, le risque de resténose continue à poser un problème au niveau de l’émergence des rameaux latéraux. Notre étude avait pour objet d’analyser les effets exercés par une post-dilatation « en embrassade » sur cinq SLPA différents, en nous appuyant sur la tomodensitométrie rayons X à micro foyer et la microscopie électronique à balayage.

Méthodes et résultats—Cinq types différents de SLPA (Cypher, Cypher Select, Endeavor, Taxus Express, et Taxus Liberté) ont été déployés en utilisant la technique de post-dilatation en embrassade dans des conditions de laboratoire. Pour chacun des SLPA étudiés, la tomodensitométrie rayons X à micro foyer a montré que (1) la post-dilatation en embrassade au moyen de deux ballonnets coaxiaux avait provoqué une déformation elliptique du segment proximal du stent et que (2) l’emploi de cette technique avait contribué à diminuer le rapport métal/artère potentiel (valeur communiquée par le fabricant/valeur calculée [%] : Cypher, 12,7/8,8 ; Cypher Select, 13,5/10,2 ; Endeavor, 19,0/13,3 ; Taxus Express, 20,5/4,7 ; Taxus Liberté, 17,9/12,5) ainsi que la libération potentielle du principe actif au sein de la portion proximale du stent et, notamment, au niveau des entretoises ostiales (c’est-à-dire celles siégeant en regard de l’orifice du rameau latéral) (valeur communiquée par le fabricant/valeur calculée [µg/mm²] : Cypher, 1,4/1,0 ; Cypher Select, 1,4/1,1 ; Endeavor, 1,6/1,1 ; Taxus Express, 1,0/0,7 ; Taxus Liberté, 1,0/0,7). L’analyse en microscopie électronique à balayage a, par ailleurs, montré que l’utilisation de cette technique de post-dilatation avait significativement majoré la dégradation de l’enrobage au niveau des entretoises ostiales de tous les stents évalués (p <0,05).


Mots clés : bifurcations ■ stents ■ angioplastie ■ maladie coronaire ■ resténose