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Kissing Balloon or Sequential Dilation of the Side Branch and Main Vessel for Provisional Stenting of Bifurcations

Lessons From Micro-Computed Tomography and Computational Simulations

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Objectives This study sought to evaluate post-dilation strategies in bifurcation stenting.

Background In bifurcation stenting practice, it is still controversial how post-dilation should be performed and whether the kissing balloon (KB) technique is mandatory when only the main vessel (MV) receives a stent.

Methods A series of drug-eluting stents (DES) (n = 26) were deployed in a coronary bifurcation model following a provisional approach. After the deployment of the stent in the MV, post-dilation with the KB technique was compared with a 2-step, sequential post-dilation of the side branch (SB) and MV without kissing.

Results The percentage of the SB lumen area free of stent struts was similar after KB (79.1 ± 8.7%) and after the 2-step sequence (74.4 ± 11.6%, p = 0.25), a considerable improvement compared with MV stenting only without dilation of the stent at the SB ostium (30.8 ± 7.8%, p < 0.0001). The rate of strut malapposition in the ostium was 21.3 ± 9.2% after KB and 24.9 ± 10.4% after the 2-step sequence, respectively, a significant reduction compared with a simple SB dilation (55.3 ± 16.8%, p < 0.0001) or MV stenting only (47.0 ± 8.5%, p < 0.0005). KB created a significant elliptical overexpansion of the MV lumen, inducing higher stress concentration proximal to the SB. KB also led to a higher risk of incomplete stent apposition at the proximal stent edge (30.7 ± 26.4% vs. 2.8 ± 9.6% for 2-step, p = 0.0016).

Conclusions Sequential 2-step post-dilation of the SB and MV may offer a simpler and more efficient alternative to final KB technique for provisional stenting of bifurcations. (J Am Coll Cardiol Intv 2012;5:47–56) © 2012 by the American College of Cardiology Foundation

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Strut malapposition is still frequent after stenting of bifurcations: recent observations using optical coherence tomography (1) and intravascular ultrasound (2,3) show that apparently successful angiographic bifurcation procedures may in fact hide incomplete stent strut apposition.

Post-dilation with kissing balloon (KB) has demonstrated clear clinical benefits in trials with 2-stent strategies (4–7), but the need for side branch (SB) dilation and ostial strut opening remains controversial in provisional stenting when only the main vessel (MV) receives a stent (5,8).

The aim of this study was to provide insights into post-dilation strategies after provisional stenting comparing results of KB technique and a sequential 2-step inflation of the SB and MV without kissing.

Methods

Bench micro-computed tomography experiments. Optimization using final KB technique was compared with a simpler sequential 2-step post-dilation in a series of drug-eluting stents (DES) (total = 26) used as the MV stent in a coronary bifurcation model (proximal MV = 3.5 mm, distal MV = 2.75 mm, SB = 2.75 mm, MV/SB angle = 45°).

Abbreviations and Acronyms

3D = 3-dimensional
DES = drug-eluting stent(s)
KB = kissing balloon
MB = main branch
MV = main vessel
NC = noncompliant
SB = side branch(s)

The different stents tested were the everolimus-eluting Xience V (n = 4, Abbott Vascular, Santa Clara, California) and Promus Element (n = 6, Boston Scientific, Natick, Massachusetts), the paclitaxel-eluting Taxus Liberté (n = 10, Boston Scientific), the biolimus-eluting Biomatrix Flex (n = 4, Biosensors International, Morges, Switzerland), and the zotarolimus-eluting Resolute stents (n = 2, Medtronic, Santa Rosa, California).

In our study, we followed current recommendations on treatment of bifurcations (9) and size of stent according to the distal reference diameter to avoid shifting of the carina. The stents were deployed in the model MV following the manufacturer's compliance charts to reach a diameter of 3.0 mm. A guidewire was advanced in the SB with mid-distal cell crossing performed under direct visual observation.

SB dilation was performed at a pressure of 12 to 14 atm for 20 s using noncompliant (NC) balloons (Sprinter and Quantum Maverick 2.5 × 15 mm, Medtronic and Boston Scientific, respectively). Final KB was performed after SB dilation (10) using the same NC SB balloon and a second MV semicompliant 3.0-mm balloon (Maverick, Boston Scientific) simultaneously inflated at 10 atm for 20 s.

In the sequential approach, MV post-dilation with a 3.75-mm NC balloon (Quantum Maverick) was performed after SB dilation instead of KB to complete apposition of the stent in the proximal part of the MV. The distal radio-opaque marker was positioned in front of the SB, before the carina, to correct for potential stent distortion opposite the ostium caused by the SB dilation. For each stent deployed according to the KB approach, a stent of the same dimension and brand was deployed in parallel following a sequential 2-step SB-MV dilation. The exact same inflation pressure was used in each technique, and the models were scanned after deployment and post-dilation using micro-computed tomography (HMX ST micro-computed tomography scanner, X-Tek Systems, Tring, United Kingdom, courtesy the Natural History Museum, London) at a resolution up to 5 × 5 × 5 μm (Fig. 1).

Quantification and 3-dimensional reconstruction. The stents were scanned after each dilation step (n = 78), and the results were processed to extract quantitative measurements, including minimum lumen diameter and percentage of strut malapposition (strut–wall distance >150 μm) at different cross sections along the MV (Figs. 2 and 3).

Post-processing and 3-dimensional (3D) reconstruction of the model and the stent were performed with image processing software (Matlab, MathWorks, Natick, Massachusetts, and ImageJ, National Institutes of Health, Bethesda, Maryland). The 3D views, obtained by rotating and virtually slicing the models longitudinally, provided visualization of the stent strut apposition in the different regions of interest. The ostial area free of stent struts was measured from the 3D projection of the SB ostium (Fig. 2) and was defined as the ratio of the area of the largest opened stent cell to the referential SB lumen area. Ostial stenosis is defined as the area outside of the largest opened stent cell (referential SB lumen area − the largest opened stent cell lumen area) divided by the referential SB lumen area (10). All ostium measurements were repeated after blinding of the results of the first measurement; and an average of 2 measurements was used.

Computational flow simulation. Flow patterns and shear rate were analyzed using computational fluid dynamics to identify potential risk of flow disturbance and high shear rate induced by unapposed struts.

Micro-computed tomography scans in cases representative of MV bench stent deployment and post-dilation with KB and results after the 2-step sequential dilation were imported to a commercial 3D modeling software Mimics (Materialise, Leuven, Belgium) to reconstruct surface meshes with mixed tetrahedral/hexahedral elements and were imported to a commercial computational fluid dynamics suite (CFX 12.1, ANSYS, Canonsburg, Pennsylvania) for flow analysis. The inlet flow condition used was a flow waveform recorded in a human left anterior descending coronary artery by ultrasound Doppler (Combowire, Volcano, San Diego, California). The flow split between the main branch (MB) and SB was assumed to be 70% to MB and 30% to SB. Blood was assumed to be a Newtonian fluid.

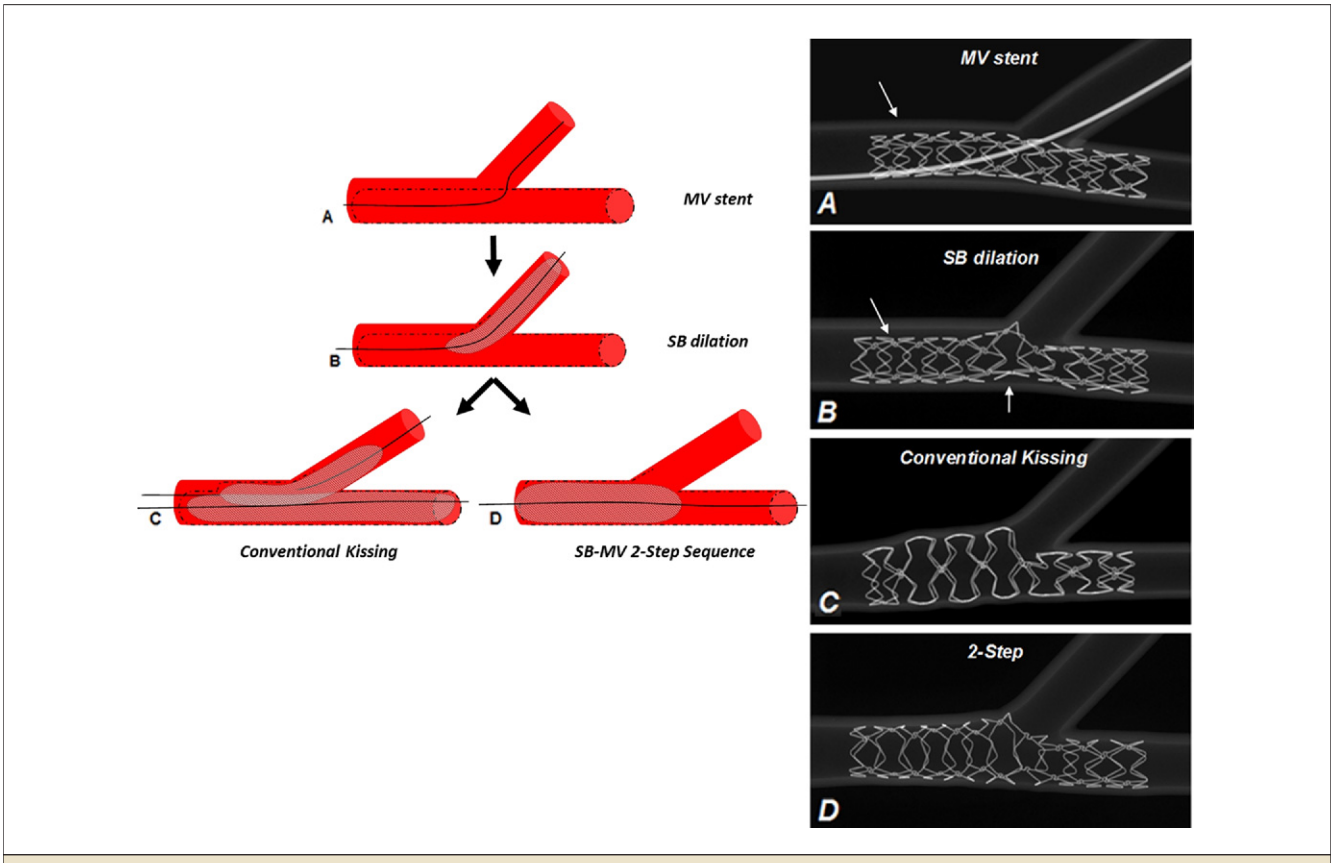

Figure 1. Flow Chart and Representative Planar Radiographic Images

The images were taken after each step **(A to D)** of provisional stenting and post-dilation with kissing balloon (KB) technique and 2-step sequential approach. **(A)** Deployment of the stent in the main vessel (MV) of the coronary bifurcation model and incomplete apposition proximal to the side branch (SB). **(B)** Dilation of the SB with a 2.5-mm noncompliant (NC) balloon. **(C)** KB inflation with a 3.0-mm balloon in the MB and a 2.5-mm balloon in the SB simultaneously inflated at 10 atm. **(D)** 2-Step sequential post-dilation using a 3.75-mm NC balloon inflated in the MV up to the MB ostium. See also Online Video 1.

Wall stress analysis by finite element modeling. Finite element–based computer simulations were used to investigate the stent strut deformations after each post-dilation technique (KB and 2-step sequence). The simulation strategy described previously was adopted (11), and a 3.0-mm Taxus Liberté stent was virtually implanted in a hyperelastic bifurcation model, representing the model used in the bench experiment. All virtual balloon models were validated against their respective compliance charts, and the simulations were performed combining the finite element solver Abaqus (Dassault Systèmes, Velizy, France) with the open-source pyformex preprocessor. After final balloon deflation, the deformations of the vessel wall were quantified in terms of strain to assess the potential risk of injury to the vessel wall.

Statistical analysis. Results are expressed as mean ± SD. Comparison among the different strategies was tested by analysis of variance and Tukey's multiple comparison tests. Paired *t* tests were used to compare results between pairs of samples. Results were considered statistically significant for p values <0.05.

Intraobserver variability on ostium area measurements was evaluated with Pearson correlation and a Bland-Altman analysis.

Results

MV stenting. Expansion of a stent in a bifurcation with a significantly large SB using a simple strategy without any post-dilation of the SB or proximal MV results in 2 major limitations:

1. Incomplete stent apposition in the MV, found proximal to the SB as a result of the mismatch between the stent diameter (3.0 mm), selected on the diameter of the distal MV, and the proximal MV reference diameter (3.5 mm) (Figs. 1A, 2A, and 3A). Percentage of strut malapposition in the proximal stent edge was on average 69.2 ± 25.4% after simple MV stenting.
2. Malapposition of all the struts of the stent implanted in the MV facing the SB ostium (Fig. 2A). The percent SB lumen not covered by struts, defined as the area of the largest open stent cell, was only 30.8 ± 7.8% (Fig. 2A).

Dilation of the SB ostium. SB dilation improved the SB luminal area (from 30.8 ± 7.8% after MV deployment only

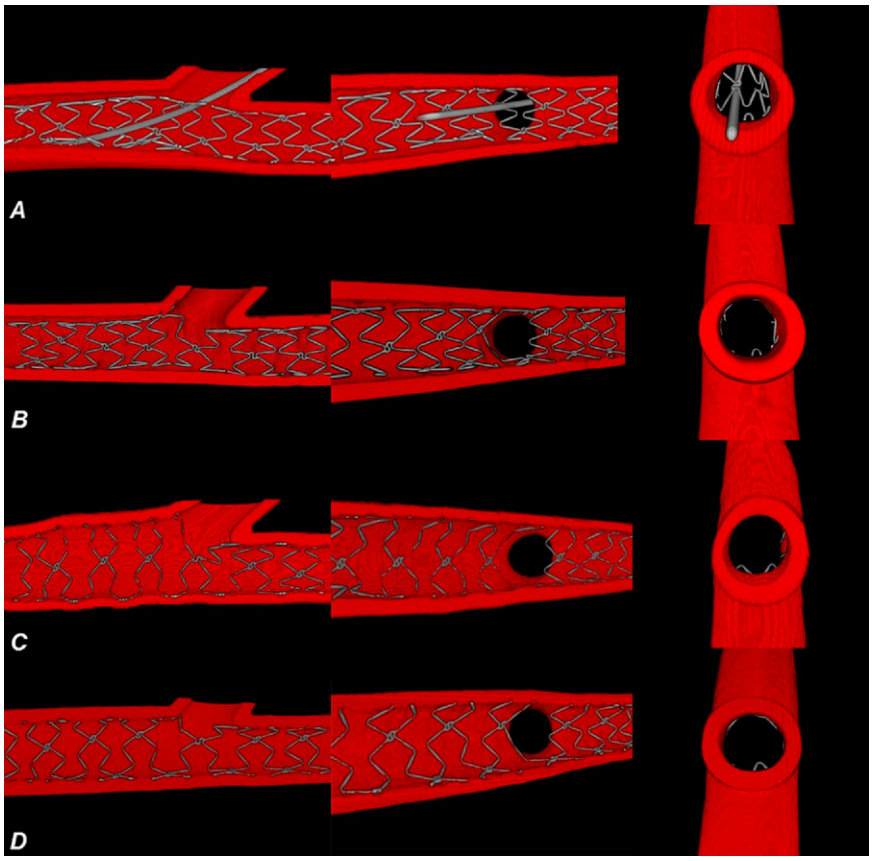

Figure 2. 3D Reconstruction of the Bifurcation Model After Deployment of a 3.0-mm Stent (Biomatrix Flex) and Successful Post-Dilation

(A) MV stenting only without SB ostium opening. **(B)** SB dilation with a 2.5-mm NC balloon. **(C)** Simultaneous 2.5-mm + 3.0-mm balloon KB dilation. **(D)** 2-Step sequence with redilation of the MV with a 3.75-mm NC balloon inflated proximal to the MB ostium. **(A to D) Left:** longitudinal cut-open view. **Middle:** ostium view from the MV. **Right:** ostium view from the SB. 3D = 3-dimensional; other abbreviations as in Figure 1.

to 74.6 ± 11.3% after dilation of the SB, $p < 0.0001$) (Fig. 2B). Despite the rate of strut malapposition being reduced toward the SB, SB dilation alone without further MV post-dilation is not recommended because of the distortion of the stent at the MB ostium and the high risk of stent malapposition opposite the SB (Figs. 1B and 3B). Average rate of malapposition within the bifurcation was increased from 47.0 ± 8.5% before SB dilation (simple MV stenting) to 55.3 ± 16.8% after only SB dilation, $p = 0.25$ (Fig. 4).

The 3D ostial measurements showed high intraoperator reproducibility with a correlation between 2 successive measurements of 0.98 (Pearson correlation) and a bias of only 0.73 with a SD of 3.67 (Bland-Altman test). Individual differences were observed between stent design and between different samples of the same platform. The percentage of ostial stenosis remaining after final post-dilation ranged from a minimum of 9% (Taxus Liberté) to a maximum of 46% (Promus Element). The study was, however, not statistically powered to discriminate differences among individual platform designs.

Kissing balloon. Post-dilation with KB increased significantly the SB lumen area compared with simple MV stenting without opening of the SB and post-dilation (79.1 ± 8.7% vs. 30.8 ± 7.8%, $p < 0.0001$).

KB restored the stent apposition opposite the SB ostium, but the technique induced a significant asymmetrical expansion of the lumen proximal to the SB (Figs. 1C, 2C, and 3C). The increase in the stent diameter with KB is also limited to the regions where the 2 balloons overlap, leaving a risk of incomplete stent apposition at the proximal stent edge. On average, 30.7 ± 26.4% of the struts at the proximal MV stent edge remained malapposed despite KB (Fig. 4).

2-step SB-MV sequence. Sequential 2-step optimization achieved an almost identical SB ostium opening to that of KB: Lumen percentage area free of struts at the SB ostium was on average 79.1 ± 8.7% after KB and 74.4 ± 11.6% after the 2-step sequence ($p = 0.25$).

Application of sequential 2-step post-dilation restored the stent apposition opposite the SB ostium and completed apposition of the stent in the proximal MV (Figs. 1D and 2D,

Online Video 1). Strut malapposition in the ostium after the 2-step sequence was similar to KB (respectively, 24.9 ± 10.4% and 21.3 ± 9.2% of struts malapposed, p = 0.36), a significant reduction compared with MV stenting only (47.0 ± 8.5%, p < 0.0005) and SB dilation only (55.3 ± 16.8%, p < 0.0001) (Figs. 2D and 3).

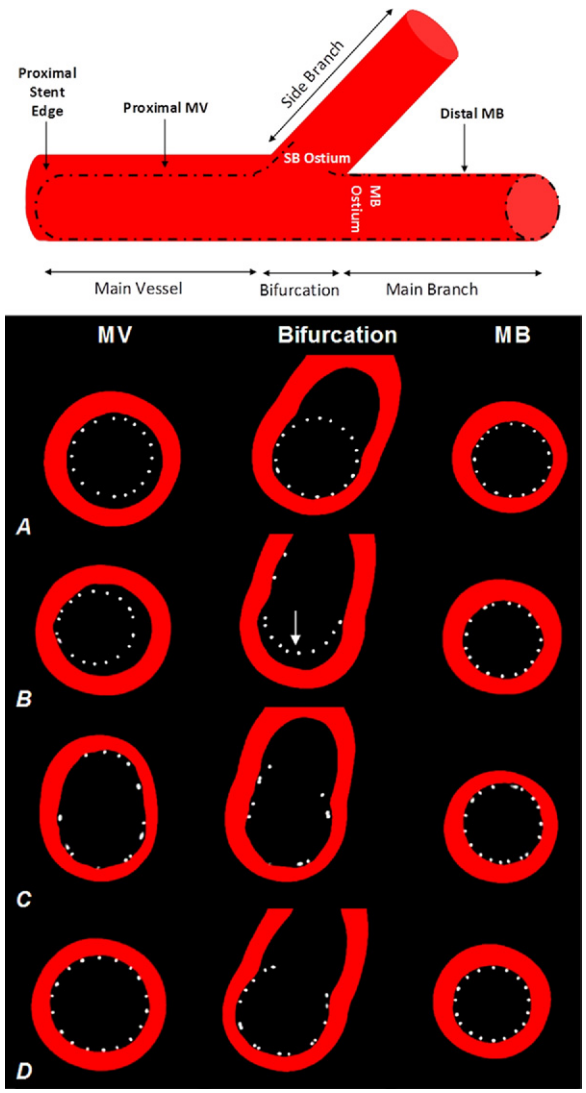

Figure 3. Stent Apposition in 3 Different MV Cross Sections

Cross sections are 5 mm proximal to the SB, in the bifurcation, and 5 mm distal to the SB. **(A)** MV stenting. **(B)** SB dilation. **(C)** KB. **(D)** 2-Step SB-MV sequence. Incomplete stent apposition proximal and at the SB ostium after MV stenting **(A).** SB dilation produces a risk of malapposition opposite the SB ostium **(arrow, B)**. With final KB, overlapping balloons produce an extensive distortion of the stent in the proximal MV **(C).** Only 2-step sequence with redilation of the MV using a larger NC balloon inflated up to the MB ostium achieves full circular expansion of the stent in the proximal MV **(D)**. Abbreviations as in Figure 1.

The risk of proximal stent malapposition was significantly reduced with the 2-step approach compared with KB (2.8 ± 9.6% after 2-step vs. 30.7 ± 26.4% after KB, p = 0.0023) (Fig. 4).

Lessons from computational fluid dynamics. Flow patterns for the MV-only stenting, conventional KB, and 2-step post-dilation were markedly different. Flow distribution toward the SB shows higher velocity near the carina and lower flow opposite the carina. This difference was more evident for the MV-only stenting case, where flow to the SB is impaired by the "jailing" struts: a large flow recirculation area with low wall shear stress formed in the proximal part of the SB on the wall opposite the carina. A large area of high shear rate was also created around the struts covering the SB ostium (Fig. 5).

Flow patterns observed after KB and 2-step cases are more stable and SB flow is less disturbed after apposition of the struts at the ostium. In the KB case, as a result of the dilated segment proximal to the branch, the peak velocity in the main vessel flow is shifted toward the SB while the flow approaches the bifurcation. High-velocity stream impacts the carina, and high shear rates are observed for malapposed struts found near the carina (Fig. 5, Online Videos 2 and 3).

Solid stress analysis. For every balloon used in the simulations, the predicted pressure/diameter relation of the virtual balloon model was in good agreement with the compliance chart provided by the manufacturer (difference <2%).

In addition, the simulated stent strut deformation of both virtual post-dilation strategies corresponded well with their experimental in vitro counterpart, confirming the experimental findings. Moreover, the simulations also allowed quantification of the mechanical stress/strain of each post-dilation strategy, and analysis indicates that because of the overlapping balloons, the KB approach results in much higher strains proximal to the SB as compared with the 2-step sequence (Fig. 6).

Discussion

In this study, we used bench and computer models to compare different post-dilation strategies after provisional stenting. The results confirm that:

1. Provisional MV stenting without simultaneous KB or further post-dilation generates incomplete stent apposition proximal to the SB and profound abnormal flow pattern across the jailed ostium.
2. SB dilation without simultaneous or subsequent MV dilation pulls the stent cell opposite the SB and leads to malapposition and stenosis at the MB ostium.
3. Despite recent stent platforms with larger cell design and final KB optimization, complete strut apposition remains a challenge even in simple bifurcation strategies.
4. Balloons overlapping during KB correct stent apposition opposite the SB but create an elliptical deforma-

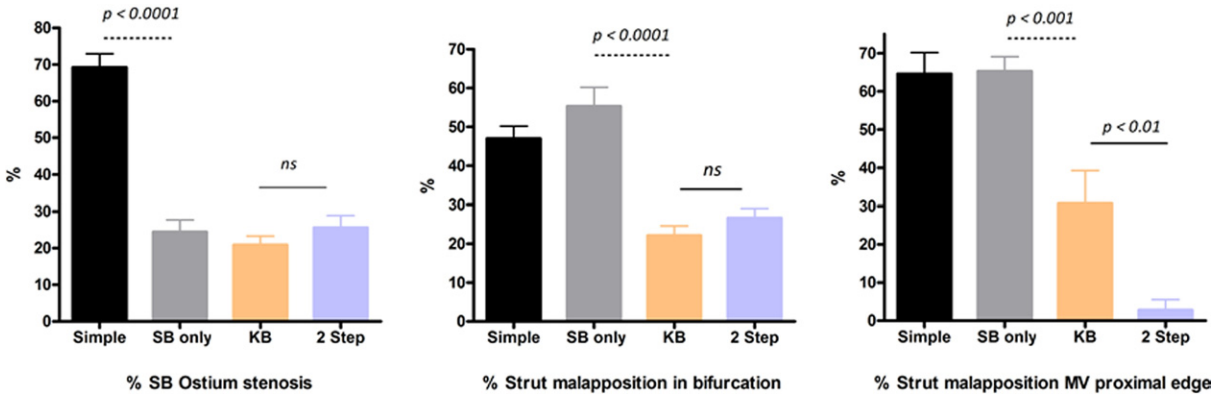

Figure 4. Ostial Stenosis and Strut Malapposition Measured in the Bifurcation and Proximal Stent Edge

Results from micro-computed tomography measurement analysis after deployment of the stents (n = 26) in the MV (simple), after SB opening, and with post-dilation using KB and with the 2-step sequential SB-MV approach. Abbreviations as in Figure 1.

tion of the stent segment proximal to the SB with high strains in the wall and increased risk of stent damage and injury to the vessel.

5. For provisional stenting of bifurcations, the sequential SB-MV dilation appears to offer a more effective method of final optimization than final KB.

Strut malapposition and thrombosis risk. Accumulating evidences show that malapposed drug-eluting stents (DES) have delayed and incomplete healing (12). Reports from pathological observations suggest that prolonged exposure to the disturbed flow pattern around unapposed and non-endothelialized struts in direct contact with the blood is one of the factors leading to increased stent thrombosis (12,13).

Some clinical studies in which incomplete stent apposition was assessed with intravascular imaging also suggest a correlation between malapposition and a higher risk of stent thrombosis (14–16), but these observations are not yet entirely compelling and have to be confirmed in other studies.

In vitro models have shown that shear can activate platelets (at a shear rate >1,000 s^{-1}) in a dose-dependent manner through von Willebrand factor binding to glycoprotein (GP) Ib and GP IIb/IIIa receptors (17). Protruding stent struts create back-facing steps that disturb the blood flow and result in flow separation and eddies with high shear gradient (18). Post-mortem examinations and in vitro experiments have shown that such flow patterns are associated with increased platelet adhesion (13,18).

This correlation is a particular concern in bifurcations, considering the high rate of strut malapposition and frequent incomplete stent apposition observed in vivo (1–3,13). Conventional stents are not designed to be implanted in bifurcations, and post-dilation is required to correct stent geometry and improve strut apposition. As shown here, even when following recommendations on treatment of bifurcations, complete dilation of the ostium remains challenging in large SB without a dedicated platform. In vivo, malapposition rates >50% have been reported at the ostium after bifurcation stenting, despite systematic final KB dilation (1). This might explain the high rate of stent thrombosis and major adverse cardiac events still observed with percutaneous coronary intervention in bifurcations (4–6,19).

A simple and reliable implantation strategy to limit malapposition in bifurcations is therefore desirable.

What to do with the SB ostium: perspective from recent trials. Dilation of the struts at the SB ostium and KB inflation are generally recommended in 2-stent strategies to improve outcome and prevent SB reocclusion (9,20,21).

Final post-dilation is becoming increasingly controversial for a single-stent strategy, with initial results of a recent clinical trial showing that despite improving angiographic restenosis at the SB ostium, SB dilation and final KB through the stent do not reduce hard clinical endpoints (8).

Malapposed struts at the SB ostium are not visible angiographically, with stent malappostion becoming apparent only when neointima and fibrin deposition cover the struts left jailing the ostium. Early follow-up results in patients treated with DES and under antiplatelet therapies (5,8) may underestimate the risk associated with leaving large SB jailed. A late catch-up phenomenon has been reported several years after DES implantation in humans (for review, see Finn et al. [22]), and it is not yet clear how unapposed DES struts heal.

Long-term follow-up studies are therefore needed to assess the fate of the jailed ostium and its clinical implications.

SB balloons straighten during inflation and tend to pull the MV stent struts toward the SB. The simple strategy of SB dilation alone is trading malapposition at the SB ostium for malapposition at the MB ostium and does not appear beneficial. Similar observations have been reported in bench

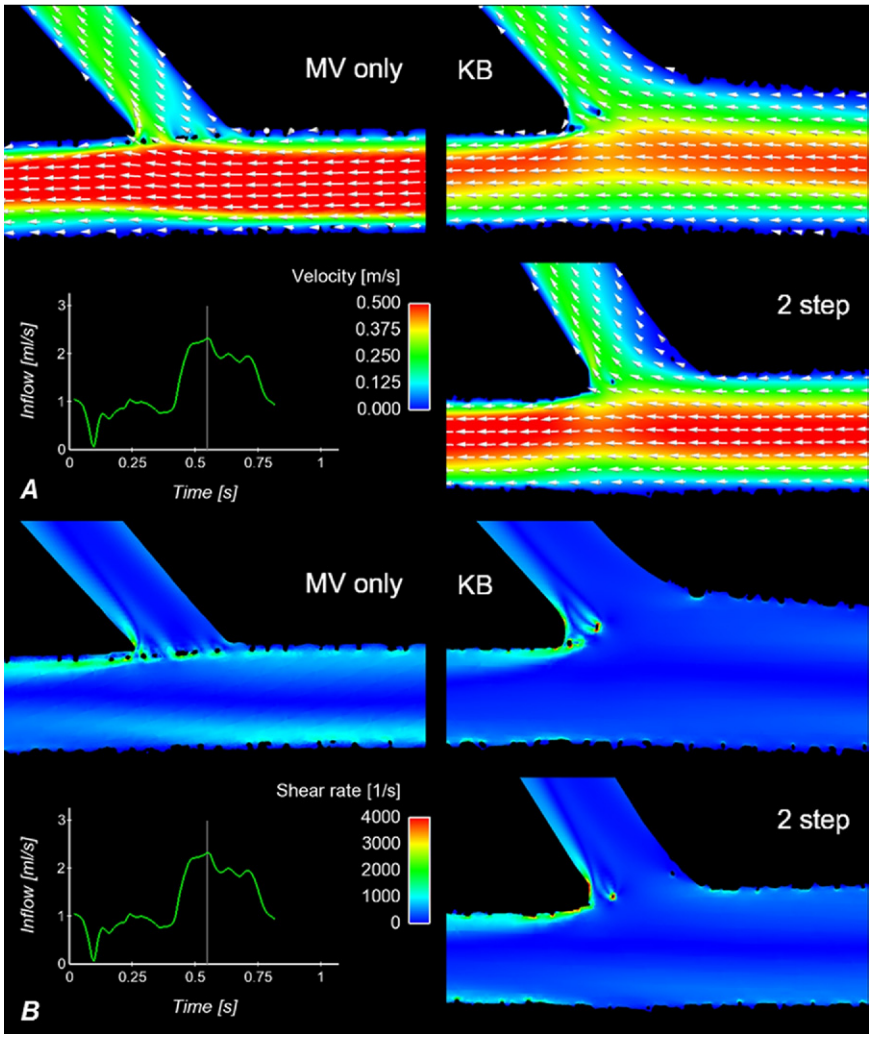

Figure 5. Computational Flow Simulation

Computational flow simulation of the velocity field **(A)** and shear rate **(B)** in cases representative of provisional technique with MV stenting only and post-dilation with KB or the sequential 2-step SB–MV dilation. Abbreviations as in Figure 1. See also Online Videos 2 and 3.

(21,23) and model experiments (24). This was confirmed in a recent trial on 1,318 patients receiving provisional stenting: a higher rate of major adverse cardiac events and target lesion revascularization was reported in patients treated with just post-dilation of the SB compared with MV stenting without SB dilation (25).

Proximal deformation with KB inflation. KB dilation is the technique usually recommended for optimization of stent results in bifurcations. Simultaneous inflation of a second balloon in the main vessel appears to correct in our data malapposition at the ostium of the distal MV.

Balloons overlapping during kissing technique lead to the oversizing of the stent proximal to the SB. In this study, the resulting maximal diameter of the stent in the long axis after KB was on average 4.29 ± 0.26 mm (ranging from 3.75 to 4.95 mm), a significant overexpansion compared with the proximal reference vessel diameter (3.5 mm).

Initial bench reports of KB post-dilation results in rigid models may have underestimated the stent oversizing in the proximal MV during kissing (20,21,23).

Advantage of sequential SB-MV dilation. The most important observation from this study is that a sequential 2-step post-dilation can be an alternative to KB technique because it provides equivalent strut apposition and avoids the detrimental distortion and higher wall stresses observed after application of KB technique.

For equally sized SB balloons, we showed here that the strut-free SB lumen area is only minimally smaller (4.7% difference) with 2-step SB-MV post-dilation compared with kissing, the difference remaining nonsignificant ($p = 0.25$).

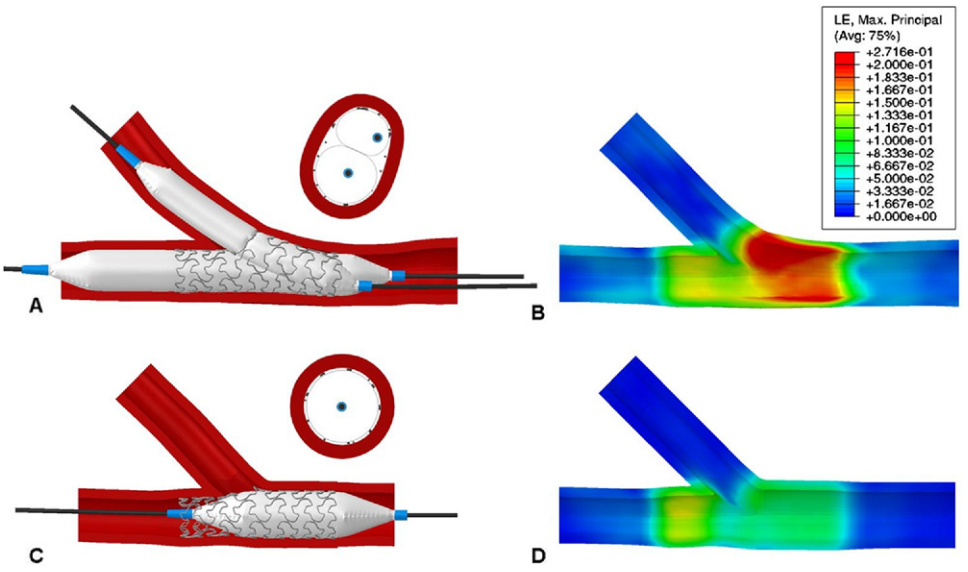

Figure 6. Finite Element Analysis in the Model Bifurcation

Simulation of post-dilation with KB **(A)** showing the resulting high strains proximal to the SB created by the 2 overlapping balloons simultaneously inflated **(B)**. Sequential SB-MV post-dilation **(C)** results in the circular expansion of the stent and significantly more homogeneous strain distribution proximal to the SB **(D)**. Abbreviations as in Figure 1.

A previous bench study (23) using first-generation bare-metal stents compared KB technique with a simple MV redilation and found that both techniques were equally successful for correcting stent stenosis in the MV induced by SB dilation.

The risk of proximal stent malapposition was, however, significantly reduced with the 2-step approach compared with KB and stenting MV only (2.8 ± 9.6% after 2-step vs. 30.7 ± 26.4% after KB, $p < 0.005$, and 69.2 ± 25.4% after MV only, $p < 0.001$).

The sequential approach has the benefits of considering the natural change in the MV diameter across the bifurcation and avoiding the proximal overstretching consecutive to KB.

We are hypothesizing here that in provisional stenting, the benefits of opening the strut at SB with KB may be outweighed by the stent overexpansion and potential injury in the MV caused by the overlapping balloons proximal to the SB during kissing.

Complete apposition of the stent struts proximal to the SB without detrimental overexpansion of the stent may limit risk of stent thrombosis. Despite previous evidence (23,26,27) suggesting that a SB-MV or SB-MV-SB sequence is suitable post-dilation after provisional stenting, clinical data evaluating this alternative for stent optimization are still needed.

Study limitations. Our study results must be carefully interpreted because bench and computational models only provide a representation of the stent behavior in vivo.

The impact of MV redilation on the final apposition and geometry of the stent is dependent on the position and diameter of the balloon used for MV redilation (Fig. 1). Position of the MV balloon for redilation may be harder to control in vivo: Positioning of the MV balloon too proximal may leave a risk of leaving some struts malapposed opposite the SB carina, whereas the opposite, positioning the balloon too distal, may cause a risk of the carina shifting if the balloon is sized according to the proximal reference diameter.

In vivo, redilation of the MV across the SB to the distal MB followed by a proximal post-dilation with a larger diameter balloon (sized according to the proximal reference diameter) may limit the chance of misaligning the balloon during MV redilation.

The model used did not include any lesions, and results obtained would certainly be affected by the presence of disease. In particular, with extensive disease proximal to the SB, malapposition after MV stenting is less likely to occur. Similarly, overstretching is expected to be less significant in a stiff, calcified vessel than in a compliant silicone model.

Benefits of KB technique have been extensively established for 2-stent strategies (7), and results presented here are only related to provisional treatment of bifurcations with only 1 stent. However, similar results are expected for post-dilation of provisional T-stenting strategy when the SB stent is not protruding into the MV lumen, and no additional layer of struts is covering the SB ostium.

The model represented a bifurcation with a large SB at a relatively acute takeoff angle. Results may be different in smaller diameter SB with wider SB angle. Low takeoff angle implies a larger SB ostium area (28), and KB is usually recommended in this type of geometry to avoid compromising the SB by carina shifting (29). In T-shape bifurcations with an angle >70°, the risk of carina shift is less significant, and by contrast, performing KB can produce an unfavorable straightening of the MV-SB angle. Sequential SB-MV post-dilation may be particularly appropriate for T-shape bifurcations.

In the experiment, as well as in the simulation, optimal cell crossing (mid-distal) was performed under visual control before dilation of the SB and final post-dilation. In vivo, control of cell recrossing and balloon position is significantly more challenging, and therefore, a higher rate of strut malapposition is expected in the ostium.

Conclusions

Stenting only the MV in a bifurcation without further post-dilation produces incomplete stent apposition proximal to the SB, leaving stent struts malapposed at the SB ostium that disturb flow and increase the risk of stent thrombosis. Post-dilation is necessary to ensure full apposition of the stent, and here, we provided insights into some of the negative consequences of KB and compared the technique to a sequential 2-step post-dilation without kissing.

Sequential post-dilation of the SB and MV may offer a simpler alternative to final KB inflation after provisional bifurcation stenting.

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REFERENCES

1. Tyczynski P, Ferrante G, Moreno-Ambroj C, et al. Simple versus complex approaches to treating coronary bifurcation lesion: direct assessment of stent strut apposition by optical coherence tomography. Rev Esp Cardiol 2010;63:904–14.
2. Costa RA, Mintz GS, Carlier SG, et al. Bifurcation coronary lesions treated with the "crush" technique: an intravascular ultrasound analysis. J Am Coll Cardiol 2005;46:599–605.
3. Hahn J-Y, Song YB, Lee S-Y, et al. Serial intravascular ultrasound analysis of the main and side branches in bifurcation lesions treated with the T-stenting technique. J Am Coll Cardiol 2009;54:110–7.
4. Colombo A, Bramucci E, Saccà S, et al. Randomized study of the crush technique versus provisional side-branch stenting in true coronary bifurcations: the CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) study. Circulation 2009;119:71–8.
5. Hildick-Smith D, de Belder AJ, Cooter N, et al. Randomized trial of simple versus complex drug-eluting stenting for bifurcation lesions: the British Bifurcation Coronary study: old, new, and evolving strategies. Circulation 2010;121:1235–43.
6. Steigen TK, Maeng M, Wiseth R, et al. Randomized study on simple versus complex stenting of coronary artery bifurcation lesions: the Nordic Bifurcation study. Circulation 2006;114:1955–61.
7. Ge L, Airoldi F, Iakovou I, et al. Clinical and angiographic outcome after implantation of drug-eluting stents in bifurcation lesions with the crush stent technique: importance of final kissing balloon post-dilation. J Am Coll Cardiol 2005;46:613–20.
8. Niemela M, Kervinen K, Erglis A, et al. Randomized comparison of final kissing balloon dilatation versus no final kissing balloon dilatation in patients with coronary bifurcation lesions treated with main vessel stenting: the Nordic-Baltic Bifurcation study III. Circulation 2011; 123:79–86.
9. Stankovic G, Darremont O, Ferenc M, et al. Percutaneous coronary intervention for bifurcation lesions: 2008 consensus document from the fourth meeting of the European Bifurcation Club. EuroIntervention 2009;5:39–49.
10. Ormiston JA, Webster MWI, Webber B, Stewart JT, Ruygrok PN, Hatrick RI. The "crush" technique for coronary artery bifurcation senting: insights from micro-computed tomographic imaging of bench deployments. J Am Coll Cardiol Intv 2008;1:351–7.
11. Mortier P, Holzapfel GA, De Beule M, et al. A novel simulation strategy for stent insertion and deployment in curved coronary bifurcations: comparison of three drug-eluting stents. Ann Biomed Eng 2010;38:88–99.
12. Joner M, Finn AV, Farb A, et al. Pathology of drug-eluting stents in humans: delayed healing and late thrombotic risk. J Am Coll Cardiol 2006;48:193–202.
13. Nakazawa G, Yazdani SK, Finn AV, Vorpahl M, Kolodgie FD, Virmani R. Pathological findings at bifurcation lesions: the impact of flow distribution on atherosclerosis and arterial healing after stent implantation. J Am Coll Cardiol 2010;55:1679–87.
14. Cook S, Wenaweser P, Togni M, et al. Incomplete stent apposition and very late stent thrombosis after drug-eluting stent implantation. Circulation 2007;115:2426–34.
15. Cook S, Ladich E, Nakazawa G, et al. Correlation of intravascular ultrasound findings with histopathological analysis of thrombus aspirates in patients with very late drug-eluting stent thrombosis. Circulation 2009;120:391–9.
16. Ozaki Y, Okumura M, Ismail TF, et al. The fate of incomplete stent apposition with drug-eluting stents: an optical coherence tomography-based natural history study. Eur Heart J 2010;31:1470–6.
17. Holme PA, Orvim U, Hamers MJAG, et al. Shear-induced platelet activation and platelet microparticle formation at blood flow conditions as in arteries with a severe stenosis. Arterioscler Thromb Vasc Biol 1997;17:646–53.
18. Duraiswamy N, Schoephoerster RT, Moreno MR, Moore JE. Stented artery flow patterns and their effects on the artery wall. Annu Rev Fluid Mech 2007;39:357–82.
19. Brar SS, Gray WA, Dangas G, et al. Bifurcation stenting with drug-eluting stents: a systematic review and meta-analysis of randomised trials. EuroIntervention 2009;5:475–84.
20. Ormiston JA. Drug-eluting stents for coronary bifurcations: bench testing of provisional side-branch strategies. Catheter Cardiovasc Interv 2005;67:49–55.
21. Lefèvre T, Louvard Y, Morice M-C, et al. Stenting of bifurcation lesions: classification, treatments, and results. Catheter Cardiovasc Interv 2000;49:274–83.
22. Finn AV, Nakazawa G, Kolodgie FD, Virmani R. Temporal course of neointimal formation after drug-eluting stent placement: is our understanding of restenosis changing? J Am Coll Cardiol Intv 2009;2:300–2.
23. Ormiston JA. Stent deformation following simulated side-branch dilatation: a comparison of five stent designs. Catheter Cardiovasc Interv 1999;47:258–67.
24. Mortier P, De Beule M, Van Loo D, Verhegghe B, Verdonck P. Finite element analysis of side branch access during bifurcation stenting. Med Eng Phys 2009;31:434–40.
25. Gwon HC, Song Y. TCT-13. Side branch ballooning after main vessel stenting may increase the long-term risk of target lesion revascularization rate in the coronary bifurcation lesion (abstr). J Am Coll Cardiol 2010;56 Suppl:B3.

26. Pan M, Medina A, de Lezo JS, et al. Coronary bifurcation lesions treated with simple approach (from the Cordoba and Las Palmas [CORPAL] Kiss trial). Am J Cardiol 2011;107:1460–5.
27. Gastaldi D, Morlacchi S, Nichetti R, et al. Modelling of the provisional side-branch stenting approach for the treatment of atherosclerotic coronary bifurcations: effects of stent positioning. Biomech Model Mechanobiol 2010;9:551–61.
28. Mortier P, Van Loo D, De Beule M, et al. Comparison of drug-eluting stent cell size using micro-CT: important data for bifurcation stent selection. EuroIntervention 2008;4:391–6.
29. Gil RJ, Vassilev D, Formuszewicz R, Rusicka-Piekarz T, Doganov A. The carina angle: new geometrical parameter associated with periprocedural side branch compromise and the long-term results in coronary bifurcation lesions with main vessel stenting only. J Interv Cardiol 2009;22:E1–10.

Key Words: bifurcation ■ kissing ■ malapposition ■ post-dilation ■ stent.

APPENDIX

For accompanying videos, please see the online version of this article.