Comparative Analysis of Sequential Proximal Optimizing Technique Versus Kissing Balloon Inflation Technique in Provisional Bifurcation Stenting

Fractal Coronary Bifurcation Bench Test

Gérard Finet, MD, PhD,* François Derimay, MD, MSc,† Pascal Motreff, MD, PhD,‡ Patrice Guerin, MD, PhD,§ Paul Pilet, B Eng,∥ Jacques Ohayon, PhD,∥ Olivier Darremont, MD,∥ Gilles Rioufol, MD, PhD,*

ABSTRACT

OBJECTIVES This study used a fractal bifurcation bench model to compare 6 optimization sequences for coronary bifurcation provisional stenting, including 1 novel sequence without kissing balloon inflation (KBI), comprising initial proximal optimizing technique (POT) + side-branch inflation (SBI) + final POT, called "re-POT."

BACKGROUND In provisional bifurcation stenting, KBI fails to improve the rate of major adverse cardiac events. Proximal geometric deformation increases the rate of in-stent restenosis and target lesion revascularization.

METHODS A bifurcation bench model was used to compare KBI alone, KBI after POT, KBI with asymmetric inflation pressure after POT, and 2 sequences without KBI: initial POT plus SBI, and initial POT plus SBI with final POT (called "re-POT"). For each protocol, 5 stents were tested using 2 different drug-eluting stent designs: that is, a total of 60 tests.

RESULTS Compared with the classic KBI-only sequence and those associating POT with modified KBI, the re-POT sequence gave significantly (p < 0.05) better geometric results: it reduced SB ostium stent-strut obstruction from 23.2 ± 6.0% to 5.6 ± 8.3%, provided perfect proximal stent apposition with almost perfect circularity (ellipticity index reduced from 1.23 ± 0.02 to 1.04 ± 0.01), reduced proximal area overstretch from 24.2 ± 7.6% to 8.0 ± 0.4%, and reduced global strut malapposition from 40 ± 6.2% to 2.6 ± 1.4%.

CONCLUSIONS In comparison with 5 other techniques, the re-POT sequence significantly optimized the final result of provisional coronary bifurcation stenting, maintaining circular geometry while significantly reducing SB ostium strut obstruction and global strut malapposition. These experimental findings confirm that provisional stenting may be optimized more effectively without KBI using re-POT. (J Am Coll Cardiol Intv 2015;8:1308-17)

© 2015 by the American College of Cardiology Foundation.
was also a significant difference in main vessel reintervention rates: 9.1% with KBI versus 3.4% without (2).

KBI juxtaposes 2 balloons of diameters adapted to the 2 daughter vessels: the main branch (MB) and side branch (SB). The expected proximal geometry often fails to match the linear fractal ratio between the 3 diameters of the bifurcation (5), inducing oblong proximal deformation and proximal arterial overstretch (2).

Several highly contributive studies have suggested technical improvements to alleviate this effect: reducing the nonuniformity of proximal stent expansion by proximal dilation of the mother vessel (MoV) with an optimally sized balloon after KBI (6), minimizing the overlap between the 2 balloons (7), applying asymmetric inflation pressures (8), and finally, foregoing KBI altogether in favor of a final proximal optimizing technique (POT) (9).

POT consists of inflating a balloon to the MoV reference diameter and positioning it forward of the carina. There are 2 advantages to this, which are recognized although not yet quantified: 1) there is a small opening between the side branch ostium struts; and 2) malapposition in the stented MoV segment is completely corrected while maintaining perfect arterial circularity (10).

The present experimental study used optical coherence tomography (OCT) on a fractal bifurcation bench model with 2 latest-generation drug-eluting stents to compare various KBI sequences with and without POT and 2 sequences without KBI associating initial POT plus side branch inflation (SBI) or POT plus SBI plus final POT; the latter is known as “re-POT.”

**METHODS**

**EXPERIMENTAL PROTOCOLS.** Six provisional stenting optimization protocols are shown in *Figure 1*, covering techniques used or suggested in a range of publications (1,2,4,9). For each protocol, 5 stents were assessed for each of the 2 drug-eluting models, for a total of 60 tests. Each protocol began with implantation of a stent with the main-branch reference diameter (10):

- **Protocol 1.** KBI with symmetric inflation pressure (12/12 atm) and noncompliant balloons (3.5 × 15 mm and 3.0 × 15 mm balloon in MoV and SB,

![FIGURE 1 Flow Chart of the 6 Provisional Stenting Optimization Protocols](image-url)

Two- and three-dimensional (2D-3D) optical coherence tomography (OCT) analysis at each step. BIP = balloon inflation pressure; KBI = kissing balloon inflation; MB = main branch; MV = main vessel; POT = proximal optimizing technique; SB = side branch.
respectively). This is the classic final kissing balloon technique implemented in clinical studies (11).

- **Protocol 2.** Same as protocol 1, but after POT.
- **Protocol 3.** Same as protocol 2, but with asymmetric KBI pressures. This was proposed by Mortier et al. (8), with 12 atm in SB then deflation to 4 atm and simultaneous main vessel inflation to 12 atm.
- **Protocol 4.** Same as protocol 3, but inversing the inflation asymmetry: 12 atm in SB, then KBI with 12 atm in SB, and 4 atm in main vessel.
- **Protocol 5.** POT sequence, then 12 atm SBI (without KBI).
- **Protocol 6.** POT sequence, then 12 atm SBI, and then final POT (without KBI). The final POT uses the same positioning and inflation pressure as the initial POT. The full sequence is called “re-POT.”

**DESCRIPTION OF POT.** POT should stretch the struts in the bifurcation up to the carina, to allow proximal stent expansion to the MoV diameter so as to correct the difference in diameter between MB and MoV (12). There are 3 factors to account for when selecting and deploying the balloon: 1) precise balloon positioning, guided by the distal radio-opaque marker, which is essential to ensuring the mechanical effects of inflation on the bifurcation region; 2) identifying the point where the sides of the inflated balloon cease to be parallel; and 3) determining the degree of balloon compliance, so as to adjust the final diameter. Figure 2 shows that the sides of the inflated balloon cease to be parallel precisely at the inner edge of the radio-opaque markers. Thus, balloon positioning for POT is such that the inner edge of the distal radio-opaque marker lies in the MB ostium cross section (i.e., just at the carina). A compliant balloon measuring 4.0 × 15 mm at 16 atm (Maverick, Boston Scientific, Natick, Massachusetts) was adapted for the bench models.

**FRAC TAL CORONARY BIFURCATION BENCH MODEL.** A vinyl polychloride bifurcation bench model (Figure 3A) with 1-mm thickness was specially designed with lumen diameters of 4.4, 3.4, and 3.1 mm for MoV, MB, and SB, respectively (Segula Technologies, Saint-Priest, France). These diameters respect the fractal geometry of coronary bifurcations (12). Bench model elasticity should approximate that of a fibrotic atherosclerotic arterial wall (i.e., 700 to 1,500 kPa) (13). All the bifurcation bench model measurements were precisely checked on OCT to determine the true geometry after manufacture. Elasticity was assessed on a uniaxial extension test (TA-XT2i texture analyzer, Stable Micro Systems, Surrey, United Kingdom) to determine the true Young’s modulus. All procedures were performed in a water bath held at 37° by thermostat. The bench models were fixed to a support to ensure angular positioning (Figure 3A) (5).

**STENT MODELS USED IN THE BIFURCATION BENCH MODEL.** Two latest-generation drug-eluting stents of different designs were used (Figure 3B): 1) the 3.5 × 20 mm Promus Premier (PP) (Boston Scientific, Maple Grove, Minnesota), a platinum-chromium stent platform with 81 µm strut thickness (þ abluminal 5-µm coating) and 6-sinusoid rings, and 2 offset peak-to-peak connectors between adjacent rings with 120° ring-to-ring offset, creating a helical aspect; and 2) the 3.5 × 24 mm Ultimaster (UL) (Terumo Europe, Leuven, Belgium), a cobalt-chromium stent platform with 80 µm strut thickness (þ abluminal 15-µm coating) and 6-sinusoid rings, and 2 in-phase peak-to-peak connectors between adjacent rings with 90° ring-to-ring offset.

**2- AND 3-DIMENSIONAL OCT IMAGE ACQUISITION AND ANALYSIS.** Two-dimensional OCT was performed using the ILUMEN OCT imaging system (St. Jude Medical, Minneapolis, Minnesota) with a C7 Dragonfly intravascular imaging catheter. Automatic pullbacks were performed at 10 mm/s. Offline quantitative analysis of the 2-dimensional OCT images used proprietary software. Three reference sites
(MoV, MB, and SB) were defined per bifurcation bench model, as were 3 stent sites: 1) most proximal site in MoV; 2) midsegment site between the bifurcation and the proximal end of the stent; and 3) distal stent site in MB. For each site, the parameters measured were: area, mean diameter, maximum diameter \(D_{\text{max}}\), and minimum diameter \(D_{\text{min}}\) (Figure 3C). An ellipticity index was calculated as \(D_{\text{max}}/D_{\text{min}}\). The OCT strut malapposition threshold was defined for either stent model as strut thickness + coating thickness + 15-µm axial OCT resolution (i.e., 100 µm for PP and 110 µm for UL). Four regions of strut malapposition analysis were defined (Figure 3C): 1) a global region covering the entire length of the stent; 2) a proximal region, in the MoV; 3) a semicircular \((180^\circ)\) region comprising carina

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure_3.png}
\caption{Methodological Aspects of the Experimental Protocol}
\end{figure}
TABLE 1 Quantitative Analysis of the Mechanical Effects of POT

<table>
<thead>
<tr>
<th>Pooled Results (Promus Premier and Ultimaster Stents)</th>
<th>Before POT (n = 40)</th>
<th>After POT (n = 40)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean MoVref D, mm</td>
<td>4.08 ± 0.03*</td>
<td>4.23 ± 0.08</td>
</tr>
<tr>
<td>Proximal mean stent D, mm</td>
<td>3.32 ± 0.08</td>
<td>4.23 ± 0.08</td>
</tr>
<tr>
<td>Expected stepwise difference in diameter between MoVref and stent, mm</td>
<td>0.83 ± 0.03</td>
<td>NA</td>
</tr>
<tr>
<td>Measured diameter difference between MoVref and stent, mm</td>
<td>0.76 ± 0.06</td>
<td>0</td>
</tr>
<tr>
<td>Ellipticity ratio of reference MoV</td>
<td>1.03 ± 0.02</td>
<td>1.03 ± 0.01</td>
</tr>
<tr>
<td>Ellipticity ratio of stent in MoV</td>
<td>1.04 ± 0.02</td>
<td>1.03 ± 0.02</td>
</tr>
<tr>
<td>Stent strut obstruction in SBO, %</td>
<td>34.0 ± 7.4</td>
<td>26.0 ± 4.2</td>
</tr>
</tbody>
</table>

Distal cell area ratio in SBO, %

|                                | 22.1 ± 15.9         | 28.7 ± 19.6       |

Values are mean ± SD. *p < 0.05 versus after POT.

D = diameter; MB = main branch; MoV = mother vessel; NA = not applicable; POT = proximal optimizing technique; ref = reference; SBO = side branch ostium.

and SB; and 4) a complementary semicircular region facing the carina and SBO. In the global region, strut malapposition was expressed as the percentage of analyzed struts found to be malapposed; OCT slices were acquired every millimeter. In the other 3 regions, results were expressed as the maximum distance of the most malapposed strut in the region in question and as the number of observed malappositions per protocol.

Three-dimensional (3D) OCT was performed using the LUNAWAVE optical frequency domain imaging (OFDI) system (Terumo Europe, Leuven, Belgium) with a FastView optical frequency domain imaging catheter. A 3D representation of each acquisition was displayed in a carpet view using proprietary software and was oriented so as to be perpendicular to the SB. Stent-strut obstruction in the SBO was calculated as: (A1/A2) × 100%, where A1 is the total area of the struts projecting into the SBO, and A2 is the total SBO area. The area of the most distal strut cell in the SBO was measured to provide the ratio (%) of distal strut cell area to SBO area.

TABLE 2 Comparison of the 6 Provisional Stenting Optimization Protocols: Promus Premier Stent

<table>
<thead>
<tr>
<th>With KBI</th>
<th>Without KBI</th>
<th>With KBI</th>
<th>Without KBI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metric</th>
<th>No POT</th>
<th>With POT</th>
<th></th>
<th></th>
<th>With POT</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Area overstretch, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ellipticity ratio</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midstent segment in MB</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Area overstretch, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ellipticity ratio</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Distal stent segment in SBO, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ellipticity ratio (MB)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stent strut obstruction in SBO, %</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Global stent MAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total number of analyzed struts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% of malapposed struts</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proximal stent segment MAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of cases with malapposed strut</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max distance of malapposed struts, μm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carina MAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of cases with malapposed strut</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max distance of malapposed struts, μm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wall facing SBO MAP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of cases with malapposed strut</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max distance of malapposed struts, μm</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Values are mean ± SD. *p < 0.05 versus re-POT.

Asym = asymmetric; KBI = kissing balloon inflation; MAP = malapposition; MB = main branch; Mid = mid segment; MoV = mother vessel; MV = main vessel (mother vessel + main branch axis); POT = proximal optimizing technique; SBI = side branch inflation; Sym = symmetric; re-POT = + POT final; SBO = side branch ostium.
**STATISTICAL ANALYSIS.** The quantitative variables indicate changes in the bifurcation bench model geometry during the various stenting optimization phases for each protocol, and are presented as mean ± SD. The Wilcoxon nonparametric matched pairs test was used to compare the quantitative effects of POT (n = 40 per group). In the comparison between the 6 bifurcation stenting optimization protocols, the re-POT sequence was compared with the other 5 protocols by the Mann-Whitney nonparametric unmatched test for continuous quantitative variables and by chi-square test for discontinuous quantitative variables (n = 5 per group). Analysis used SPSS version 16.0 software (SSPS Inc., Chicago, Illinois). A p value <0.05 was considered statistically significant.

**RESULTS**

**FRACTAL BIFURCATION BENCH MODEL GEOMETRY AND ELASTICITY CHECKS AFTER MANUFACTURE.** After polymerization and stripping, the bench models were subject to retraction that was not perfectly isotropic. The lumen diameters of the 50 bifurcation bench models were slightly less than those specified at the design stage: the mean measured MoV, MB, and SB diameters were 4.08 ± 0.03 mm, 3.20 ± 0.07 mm, and 2.94 ± 0.06 mm, respectively. The mean difference in diameter between MoV and MB was 0.83 ± 0.03 mm. The mean MoV ellipticity ratio was 1.03 ± 0.02. The mean fractal ratio was 0.66 ± 0.01. The mean Young’s modulus on uniaxial extension test was 1,450 kPa.

**ANALYSIS OF MECHANICAL EFFECTS OF POT.** Whichever the stent design, POT: 1) completely corrected the expected proximal malapposition in the MoV, conserving circularity; and 2) significantly optimized the enlargement of struts initially projecting into the SBO, reducing SBO strut obstruction (Table 1).

**COMPARATIVE ANALYSIS OF PROVISIONAL STENTING OPTIMIZATION PROTOCOLS.** Tables 2 and 3 compare the 6 protocols for the 2 drug-eluting stent platforms (PP and UL). Figure 4 shows the statistical

| TABLE 3 Comparison of the 6 Provisional Stenting Optimization Protocols: Ultimaster Stent |
|---------------------------------------------|---------------|---------------|---------------|---------------|---------------|---------------|
|                                  | No POT | With POT | Without KBI | With POT first |
|---------------------------------------------|---------------|---------------|---------------|---------------|---------------|
|                                | Sym KBI | Sym KBI | Asym KBI | Asym KBI | + SBI Alone | + POT (re-POT) |
|                                | (12/12 atm) | (12/12 atm) | (4 atm SB 12 atm MV) | (12 atm SB 4 atm MV) |           |               |
| n                             | 5      | 5       | 5         | 5          | 5           | 5             |
| Proximal stent segment in MoV |        |         |           |            |             |               |
| Area overstretch, %            | −0.3 ± 3.4* | 10.4 ± 3.2 | 13.6 ± 1.6 | 13.2 ± 2.4 | 7.6 ± 0.7  | 10.9 ± 2.8     |
| Ellipticity ratio               | 1.05 ± 0.03  | 1.01 ± 0.01 | 1.02 ± 0.01 | 1.02 ± 0.01 | 1.03 ± 0.01 | 1.03 ± 0.02    |
| Midstent segment in MoV |        |         |           |            |             |               |
| Area overstretch, %            | 17.1 ± 1.6*  | 18.4 ± 4.0* | 16.5 ± 1.2* | 15.5 ± 0.9* | 11.1 ± 1.7  | 11.6 ± 2.8     |
| Ellipticity ratio               | 1.36 ± 0.02* | 1.24 ± 0.03* | 1.13 ± 0.02* | 1.14 ± 0.02* | 1.03 ± 0.02 | 1.03 ± 0.01    |
| Distal stent segment in MB |        |         |           |            |             |               |
| Area overstretch (MB), %       | 0.7 ± 1.3   | 8.2 ± 6.7  | 6.7 ± 6.2  | 3.5 ± 2.8  | 3.8 ± 1.8  | 4.9 ± 3.3      |
| Ellipticity ratio (MB)         | 1.03 ± 0.01 | 1.02 ± 0.01 | 1.03 ± 0.01 | 1.02 ± 0.00 | 1.04 ± 0.01 | 1.04 ± 0.02    |
| Stent strut obstruction in SBO, % | 19.3 ± 16.2 | 12.4 ± 7.1 | 15.6 ± 4.4 | 12.0 ± 8.4 | 13.4 ± 6.7 | 17.7 ± 4.4     |
| Global stent MAP |        |         |           |            |             |               |
| Total number of analyzed struts | 1,179    | 1,069   | 1,099     | 1,082      | 1,112       | 1,096          |
| % of malapposed struts          | 42.8 ± 5.8* | 0.7 ± 0.5 | 0.3 ± 0.2  | 0.92 ± 1.2 | 1.6 ± 1.2*  | 0.1 ± 0.2      |
| Proximal stent segment MAP |        |         |           |            |             |               |
| Number of cases with malapposed strut | 5*    | 0       | 0         | 0          | 0           | 1              |
| Max distance of malapposed strut, μm | 830    | 0       | 0         | 0          | 0           | 170            |
| Carina MAP |        |         |           |            |             |               |
| Number of cases with malapposed strut | 5*    | 0       | 3*       | 3*        | 4*          | 0              |
| Max distance of malapposed strut, μm | 800    | 230     | 390       | 590        | 0           | 0              |
| Wall facing SBO MAP |        |         |           |            |             |               |
| Number of cases with malapposed strut | 1      | 1       | 0         | 0          | 0           | 0              |
| Max distance of malapposed strut, μm | 230    | 190     | 0         | 210        | 0           | 0              |

Values are mean ± SD. *p < 0.05 versus re-POT. Abbreviations as in Table 2.
variations in the main 3 mechanical criteria. Figure 5 presents the main effects of the various provisional stenting optimization techniques.

**DISCUSSION**

The present experimental fractal bifurcation bench model study compared 6 procedural sequences with and without KBI, with a view to optimizing the final result of provisional stenting with 2 different stent platforms: PP and UL stents. One of the 6 sequences was a novel non-KBI sequence comprising initial POT + SBI + final POT, called “re-POT.” Re-POT achieved better geometric results than the classic isolated KBI sequence or the other sequences associating POT and modified KBI, with SBO stent-strut obstruction reduced from 23.2 ± 6.0% to 5.6 ± 8.3% (p < 0.05) (PP) and from 19.3 ± 16.2% to 17.7 ± 4.4% (p = ns) (UL); almost perfect MoV circularity, with ellipticity index reduced from 1.23 ± 0.02 to 1.04 ± 0.01 (p < 0.05) (PP) and from 1.36 ± 0.02 to 1.03 ± 0.01 (p < 0.05) (UL); and global stent-strut malapposition reduced from 40.0 ± 6.2% to 2.6 ± 1.4% (p < 0.05) (PP) and from 42.8 ± 5.8% to 0.1 ± 0.2% (p < 0.05) (UL). Stent design affected the scale and variability of the quantitative results but did not affect the principle of optimization.

**DETRIMENTAL EFFECTS OF KBI.** The detrimental effects of KBI are induced by oblong proximal deformation caused by the juxtaposition of the 2 balloons. The present results agree with those of Mortier et al. (8), who reported an ellipticity index of 1.36 with KBI. The detrimental effects on fluid dynamics and parietal stress distribution have been clearly demonstrated (7,9).

Several highly contributive studies have described improvements in KBI techniques to reduce this proximal deformation. Completing KBI with a final POT can partially restore proximal stent circularity (ellipticity index 1.11 ± 0.04 vs. 1.39 ± 0.06) and reduce malapposition (0.6% vs. 33%; p = 0.02), but does not abolish arterial overstretch in the proximal segment (8.5 ± 0.6 mm² vs. 6.8 ± 0.4 mm²; p < 0.0001) (6). Another interesting comparison is between classic KBI and a more sequential approach without KBI (SB first and final POT) on a bench model (9): malapposition in the proximal segment was significantly reduced (2.8 ± 9.6% vs. 30.7 ± 26.4% after KBI; p = 0.002). Mortier et al. (8) sought to reduce proximal deformation in KBI using asymmetric inflation pressure, and achieved a significant reduction in ellipticity index, from 1.36 to 1.17 (p = 0.001), with an unchanged rate of malapposition (6.4% vs. 6.3%; p = 0.02) and reduced ostial area stenosis (15 ± 9% vs. 20 ± 11%; p < 0.001).

Finally, the balloon in the SB overlaps the bifurcation point, so that balloon juxtaposition in the MoV is about one-half of the balloon length. If the stented length in the MoV is greater than the balloon overlap, the proximal malapposition predicted by fractal bifurcation geometry will not be corrected, and circular proximal malapposition (“bottle-neck”) may be induced (6). The present study found exactly this defect.

**CONFIRMATION OF THE DOUBLE ADVANTAGE OF POT.** Olivier Darremont’s POT, described in 2010 in the consensus of the 5th European Bifurcation Club meeting (14), consists of balloon inflation adapted to the MoV diameter with the balloon situated so that the proximal radio-opaque marker is just forward of the carina (10). The present study
previously quantified the 2 recognized associated benefits (6,15): 1) moderate SBO strut-cell opening, facilitating distal cell rewiring; and 2) complete circular correction of expected proximal strut malapposition (5).

**BENEFITS OF THE POT-SBI-POT SEQUENCE (CALLED “RE-POT”).** The re-POT sequence described and assessed here: 1) has all the advantages of initial POT; 2) provides very complete SBO strut-cell opening by SBI, with stent design playing a significant role; and 3) corrects, with the final POT, strut malapposition, mainly situated in the carina and the wall facing the SBO. The re-POT sequence gives better results than isolated KBI and also than modified KBI sequences. Mortier et al. (8), as mentioned in the previous text, described a modified final KBI approach using asymmetric inflation pressure, achieving significantly reduced proximal deformation with an unchanged malapposition rate and reduced ostial area stenosis, as confirmed by the present study. In comparison, the re-POT sequence achieved better reductions in ellipticity index (1.06 ± 0.03 vs. 1.04 ± 0.01; p < 0.05), malapposition rate (8.8 ± 2.8% vs. 2.6 ± 1.2%; p = 0.02), and ostial area stenosis (7.3 ± 4.7% vs. 5.6 ± 4.9%; p < 0.001). The final POT turned out to be necessary, compared with the simple POT-SBI sequence, to correct strut malapposition induced in the bifurcation itself by SBI (2.6 ± 1.2% vs. 7.9 ± 3.9%; p < 0.05), although the reduction in SBO strut obstruction was slight (5.6 ± 2.7% vs. 2.8 ± 2.8%; p = NS). The 2 different 2-connector stent designs produced different re-POT results: PP was associated with less SBO strut obstruction (5.6 ± 2.7%) than UL (17.7 ± 3.4%), but with a slightly higher overall malapposition rate (2.6 ± 1.2% vs. 0.1 ± 0.2%).

The re-POT sequence induces a moderate shift of the carina (flow divider) toward the MB on SB balloon inflation and the converse during final POT. Finally, however, SB ostial area stenosis is
only slightly affected (5.6 ± 8.3% vs. 3.3 ± 3.6% [PP stent]; 17.7 ± 4.4% vs. 13.4 ± 6.7% [UL stent]), and MB and MoV ellipticity ratios remain identical. The final POT is indispensable to correct residual strut malapposition induced on the MB side of the flow divider and on the side of the bifurcation facing the SB ostium.

**RE-POT IN CLINICAL PRACTICE.** Re-POT sequences on bench models provide the best optimization of provisional stenting in coronary bifurcations. Randomized clinical studies will be needed. Meanwhile, acute clinical assessment on endovascular imaging should confirm the geometric and morphologic parameters found in the present bench study.

The re-POT sequence can be used for any of the types of bifurcation lesion described by Medina et al. (16): (0/1), (0/1), (0/1). Carina shifting induced by stent expansion in the main vessel (MoV-MB) will be absent for bifurcation angles close to 90° and maximal for angles close to 30°. Balloon positioning should be identical for final POT, to correct strut malapposition against the carina and the side facing the SB, but inflation pressures for final POT should be lower so as to limit balloon diameter and thus final expansion (usefulness of a compliant balloon). Any coronary bifurcation angioplasty may suffer from carina shifting: 1) for bifurcations graded (0/1), (0/1), 0, the angular impact will be lesser or absent; and 2) conversely, bifurcations graded (0/1), (0/1), 1 incur a risk of SB ostium closure, and initial SB pre-dilation followed by POT is needed to achieve lesion plasticity ahead of the actual re-POT sequence itself.

The re-POT sequence without KBI becomes 5F-compatible.

**STUDY LIMITATIONS.** The fractal bifurcation bench models conformed to optimal coronary bifurcation geometry (12). Like any model, however, they showed intrinsic limitations. They were made in polyvinyl chloride polymer or silicone. The geometry and theoretic dimensions at the design stage are generally altered by the polymerization process, which creates residual stress that is released on mold stripping, reducing the original dimensions. We therefore carefully measured all of the bench models after manufacture to optimize the choice of dimensions and balloon inflation pressures. We also tested real elasticity by measuring the exact Young’s modulus. The bench model did not account for stenosis; stenosis location and form vary greatly (16,17). We chose to use cylindrical, axially symmetric models with constant 1-mm thickness but with rigidity (Young’s modulus) approximating that of hypocellular or acellular fibrosis (13). However, models mimicking certain types of bifurcation stenosis can be created with computer-aided design and manufactured by stereolithography. An experimental study with complete digital simulation of the complex process of angioplasty (interaction among balloon inflation, stent expansion, and the visco-elastic behavior of a pathological coronary artery wall) on the basis of models including coronary stenosis should complement the present type of bench study (18). Yet, precise comparative validation remains lacking.

**CONCLUSIONS**

A sequence without KBI, associating initial POT, SBI, and final POT (“re-POT”), achieved the best optimization of provisional stenting in coronary bifurcations. A fractal bifurcation bench model compared 6 sequences, with and without KBI: the re-POT sequence optimized the proximal stent segment, with circular geometry, a strut-free SBO, and minimal strut malapposition. These experimental data confirm that provisional stenting optimization can be achieved more effectively without KBI using re-POT. These findings justify further clinical studies.

**REPRINT REQUESTS AND CORRESPONDENCE:** Prof. Gérard Finet, Département de Cardiologie, Hôpital Cardiologique L. Pradel, B.P Lyon-Monchat, 69394 Lyon Cedex 03, France. E-mail: gerard.finet@univ-lyon1.fr.

**PERSPECTIVES**

**WHAT IS KNOWN?** In provisional bifurcation stenting, final KBI fails to improve the rate of major adverse cardiac events. Proximal geometric deformation induced by juxtaposing the 2 balloons increases the rate of in-stent restenosis and target lesion revascularization.

**WHAT IS NEW?** In comparison with 5 other techniques in a fractal bifurcation bench model, a novel sequence without KBI, called re-POT, significantly optimized the final result, maintaining circular geometry while significantly reducing SB ostium strut obstruction and global strut malapposition.

**WHAT IS NEXT?** The present results encourage moving on to comparative clinical trials.


KEY WORDS: bifurcation bench model, coronary bifurcation, kissing balloon inflation, stent design.