



Short communication

## Optimal balloon positioning for the proximal optimization technique? An experimental bench study

François Dérimay<sup>a,b,\*</sup>, Gilles Rioufol<sup>a</sup>, Takeshi Nishi<sup>b</sup>, Yuhei Kobayashi<sup>b</sup>, William F. Fearon<sup>b</sup>, Joëlle Veziers<sup>c</sup>, Patrice Guérin<sup>c</sup>, Gérard Finet<sup>a</sup>

<sup>a</sup> Department of Interventional Cardiology, Cardiovascular Hospital and INSERM Unit 1060 CARMEN, Lyon, France

<sup>b</sup> Stanford University Medical Center and Palo Alto VA Health Care Systems, Stanford, CA, USA

<sup>c</sup> CHU Nantes, PHUA OTONN, Nantes, F-44093, France

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### ABSTRACT

**Aims:** The proximal optimization technique (POT) in coronary bifurcation stenting improves apposition and side-branch obstruction. The POT balloon should be positioned with the distal radio-opaque marker at the carina cut plane. However, the real impact of positioning remains unknown.

**Methods and results:** Synergy™ stents (Boston Scientific, USA) were implanted on left-main fractal bench models. Initial POT was performed in 3 positions according to distal shoulder position (loss of balloon parallelism) relative to the carina cut plane (n = 5/group): i) “proximal”, 1 mm before carina; ii) “medium”, just at carina; iii) “distal”, 1 mm after carina. Results were quantified on 2D- and 3D-OCT.

Compared to implantation, initial POT improved malapposition in all positions (“proximal”: 61.5 ± 1.4% vs. 5.1 ± 2.7%; “medium”: 60.2 ± 2.4% vs. 1.3 ± 0.6%; “distal”: 60.5 ± 2.9% vs. 1.1 ± 1.8%, p < 0.05). However, residual malapposition was greater in “proximal” position (p < 0.05). “Proximal”, unlike “medium” or “distal” POT, also failed to improve side-branch obstruction. Conversely, “distal” POT significantly overstretched the main-branch ostium, with stent/artery ratio 1.22 ± 0.04 vs. 1.11 ± 0.07 for “medium” POT (p < 0.05).

**Conclusion:** Shoulder positioning is essential to optimize the mechanical benefit of POT without main-branch overstretch (too distal position). Experimentally, the best position is just at the carina cut plane (“medium”).

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## 1. Introduction

Initial and final POT (proximal optimization technique) are recommended by the European Bifurcation Club [1] to improve global malapposition and side-branch obstruction (SBO) while facilitating side-branch rewiring, as demonstrated experimentally and clinically [2–4]. It is classically recommended to position the balloon with the distal radio-opaque marker just at the carina cut plane [1], although the real impact is unknown.

## 2. Material and methods

### 2.1. Experimental protocol

Synergy™ (Boston Scientific, USA) 3.5 × 20 mm stents were implanted at 14 atm in left-main fractal coronary bifurcation bench models [2,3] (Segula Technologies, France). As recommended, stent diameter and inflation pressures were adjusted to obtain stent/

artery ratio (SAR) between 1.0 and 1.1 [1]. Initial POT used a 4.0 × 9 mm Maverick™ compliant balloon (Boston Scientific) at 16 atm, in three positions according to distal shoulder position (balloon parallelism loss) relative to the carina cut plane: i) “proximal”, 1 mm before carina; ii) “medium”, just at carina cut plane; and iii) “distal”, 1 mm after (Fig. 1).

### 2.2. OCT analysis

2D- and 3D-OCT analysis (Lunawave™ OFDI system, Terumo, Belgium), before and after POT, quantified mean diameter ( $D_{\text{mean}}$ ), ellipticity ratio and SAR. Three areas of interest were defined: 1) mother vessel (5 mm after stent entry), 2) carina cut plane, and 3) main branch. After millimetric cross-sectional stent analysis, global malapposition (threshold: 110 μm) was calculated as percentage malapposed/total struts. Final SBO and distal cell area were quantified by planimetry as:  $(A1 / A2) \times 100\%$  and  $(A3 / A2) \times 100\%$  ( $A1$  = total strut area in ostium;  $A2$  = total ostium area;  $A3$  = distal cell area). Analyses were blind to balloon position.

### 2.3. Optimal final POT position

To determine the best final-POT position, struts malapposed by attraction after side-branch inflation (SBI) were located by micro-CT according to stent design and the ostial cell used for rewiring (Fig. 2). Three stents (Synergy™, Xience™ Alpine (Abbott Vascular, USA) and Resolute™ Integrity (Medtronic, USA)) were implanted in fractal bench models, followed by initial POT and SBI, through the distal or proximal ostial cell. Significant distal or proximal cells were defined as >10% of the total ostium area. All stents (n = 6) were analyzed in 3D by micro-CT (SkyScan 1272; Bruker, Belgium) at 10 μm/pix. Strut

**Abbreviations:** POT, proximal optimization technique; SBO, side-branch obstruction; SBI, side-branch inflation; SAR, stent/artery ratio.

\* Corresponding author at: Fédération de Cardiologie Médicale, Hôpital Cardiologique Lyon-Monchat, 69394 Lyon Cedex 03, France.

E-mail address: [francois.derimay@chu-lyon.fr](mailto:francois.derimay@chu-lyon.fr) (F. Dérimay).

	Proximal POT		Medium POT		Distal POT	
	Before POT	After POT	Before POT	After POT	Before POT	After POT
<i>Mother vessel</i>						
<i>D<sub>mean</sub></i> (mm)	4.08±0.11	4.18±0.04	4.10±0.09	4.15±0.06	4.06±0.04	4.14±0.03*
Ellipticity ratio	1.03±0.02	1.02±0.01	1.05±0.02	1.04±0.02	1.04±0.02	1.04±0.01
Stent/artery ratio	0.82±0.01	1.03±0.02*	0.81±0.03	1.02±0.02*	0.83±0.02	1.02±0.01*
<i>Carina cut-plane</i>						
<i>D<sub>mean</sub></i> (mm)	3.22±0.07	3.32±0.09	3.28±0.09	3.57±0.23* <sup>p</sup>	3.26±0.12	3.96±0.09* <sup>pm</sup>
Ellipticity ratio	1.04±0.02	1.08±0.04	1.04±0.01	1.06±0.02	1.07±0.02 <sup>m</sup>	1.08±0.02
Stent/artery ratio	1.03±0.02	1.03±0.05	1.01±0.02	1.11±0.07*	1.03±0.03	1.22±0.04* <sup>pm</sup>
<i>Main branch</i>						
<i>D<sub>mean</sub></i> (mm)	3.35±0.05	3.38±0.09	3.44±0.08	3.41±0.09	3.41±0.16	3.41±0.09
Ellipticity ratio	1.04±0.02	1.04±0.2	1.03±0.01	1.03±0.02	1.04±0.02	1.04±0.02
Stent/artery ratio	1.02±0.02	1.03±0.03	1.04±0.03	1.02±0.02	1.05±0.03	1.05±0.01
Strut malapposition (%)	61.5±1.4	5.1±2.7* <sup>md</sup>	60.2±2.4	1.3±0.6*	60.5±2.9	1.1±1.8*
SBO (%)	26.9±11.1	30.2±5.7	29.2±4.7	21.0±8.3*	33.2±6.8	17.8±14.3
Ostium distal cell area (%)	34.1±23.6	32.0±21.8	17.6±8.2	49.7±33.7	40.4±16.9	66.0±31.0*

**Fig. 1.** Mechanical effects according to initial POT balloon position. Illustration of the feasibility of precise POT balloon positioning in left main bifurcation, with optimal view and image quality (30/s). Red line shows onset of loss of parallelism; yellow angle shows carina. Green area represents balloon segment with perfect parallelism. Values are mean ± SD. (n = 5/group). \*p < 0.05 vs. before POT, <sup>p</sup>p < 0.05 vs. “proximal” POT, <sup>m</sup>p < 0.05 vs. “medium” POT, <sup>d</sup>p < 0.05 vs. “distal” POT. D<sub>mean</sub>: mean diameter; POT: proximal optimization technique; SBO: side-branch obstruction.

malapposition was defined as absence of strut/bench contact, on double-blind interpretation, under micro-CT.

#### 2.4. Statistical analyses

Variables were expressed as mean ± standard deviation after confirmation of normal distribution by Shapiro-Wilk test. ANOVA with Bonferroni correction and paired *t*-test were performed on GraphPad Prism 5 software (GraphPad Software, USA). The significance threshold was *p* < 0.05.

### 3. Results

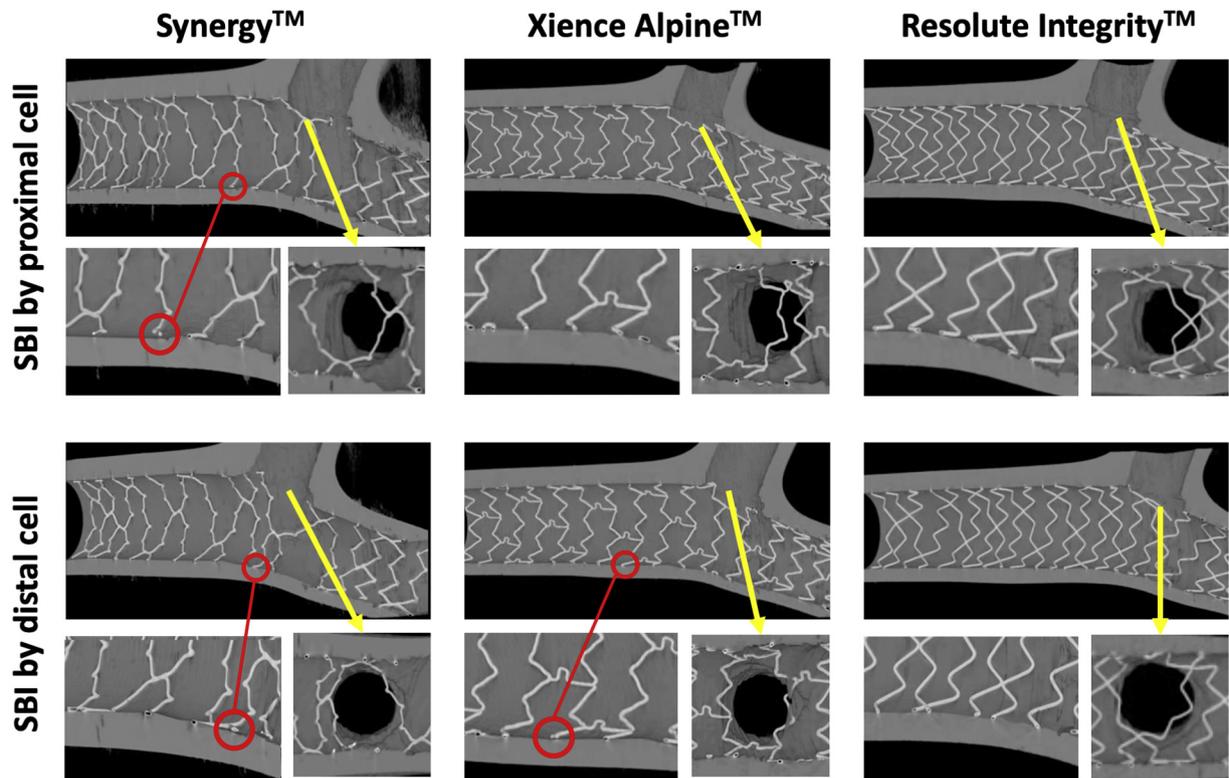
Fig. 1 shows initial POT effects according to balloon position. Compared with “proximal” POT, POT facing the side-branch ostium, like “medium” and “distal” POT, decreased SBO (19.2 ± 10.9% vs. 30.2 ± 5.7%, *p* < 0.05), and enlarged distal ostial cell area (57.9 ± 31.7% vs. 32.0 ± 21.8%, *p* = 0.12). I.e., optimal position was “medium”, just at the carina cut plane. Fig. 2 shows residual malapposition due to strut attraction after initial POT + SBI according to rewiring cell.

### 4. Discussion

This experimental study was the first to analyze POT balloon positioning. In all positions, initial POT improved stent apposition. However, overall mechanical effects on the side-branch ostium, without deleterious main-branch overstretch, were best with the distal shoulder just at the carina cut plane: i.e., “medium” position (Fig. 1). This same balloon position is advised for final POT, to optimize apposition (Fig. 2) [2–4].

#### 4.1. Too close or too far

“Proximal” POT failed to correct malapposition as effectively as “medium” or “distal” positioning (5.1 ± 2.7% vs. 1.3 ± 0.6% and 1.1 ± 1.8%, respectively; *p* < 0.05) and failed to optimize SBO and distal cell area [2] for rewiring [5] (Fig. 2). Conversely, “distal” POT overstretched the proximal main branch compared with “medium” POT (SAR: 1.22 ± 0.04 vs. 1.11 ± 0.07, *p* < 0.05). Thus, “medium” POT, with the distal shoulder at



**Fig. 2.** Micro-CT location of struts malapposed by attraction in side-branch inflation (SBI). Initial POT ( $4.0 \times 9 \text{ mm@18 atm}$ ) and SBI ( $3.0 \times 15 \text{ mm@12 atm}$ ) used Maverick™ compliant balloons (Boston Scientific, USA). The distal segment was always on the right. Red circles: malapposed struts.

the carina cut plane, achieved the best trade-off between side-branch ostium optimization and vessel integrity.

#### 4.2. Final POT position

In previous studies, SBI induced malapposition affecting all the polygon of confluence, up to the proximal main branch, by strut attraction [6]. However, these studies used non-fractal models without POT. In the present fractal bench, post-POT + SBI induced less residual malapposition, only limited at polygon of confluence entry (Fig. 2), totally corrected by final POT in “medium” position, like initial POT.

#### 4.3. Balloon parallelism and distal marker

Positioning the distal shoulder at the carina cut plane seems more essential than distal marker positioning [1]. The shoulder varies with respect to the marker, and perfect knowledge of specific POT balloon characteristics is required to optimize final mechanical results. In clinical practice, balloon position needs to approximate ideal positioning, by optimal angiographic view and good image quality (Fig. 1), and should not be too distal, due to risk of overstretch. The same precision is necessary for proximal positioning, to keep maximal diameter (balloon parallelism) strictly inside the stent to avoid a proximal edge effect. Thus POT should use a short balloon inflated once or twice to treat all the proximal stent, but not more.

#### 4.4. Limitations

The main study limitation was the use of non-pathological bifurcation bench models, not quantifying potential carina shifting. However, this did not significantly impact final malappositioning or SBO results.

## 5. Conclusion

POT balloon positioning is crucial in optimizing mechanical benefit in terms of apposition and side-branch obstruction. The POT balloon should be positioned so that the distal shoulder is just at the carina cut plane. This requires perfect knowledge of the specific balloon characteristics.

## Declaration of Competing Interest

All authors reported no disclosures.

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