

# Standardisation of techniques for bifurcation stenting optimisation: the journey continues

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Initial recognition of the inherent risk of side branch (SB) loss when treating coronary bifurcations led the pioneers of percutaneous coronary intervention (PCI) to propose kissing balloon angioplasty as a potential remedy, aiming at simultaneous treatment of both bifurcation branches<sup>1</sup>. As the evolution of PCI progressed, an increased awareness of the fractal nature of coronary bifurcations gave rise to the concept of bifurcation stenting optimisation, adapting the fixed-diameter metallic scaffold to different diameters of bifurcating coronary arteries. In 2008, the proximal optimisation technique (POT) was introduced to practising clinicians at the annual European Bifurcation Club (EBC) consensus meeting to optimise the expansion and apposition of the main vessel (MV) stent proximal to the SB, where the vessel is larger compared to the distal segment, beyond the SB<sup>2</sup>. Apart from circular expansion of the proximal MV stent, the expected benefits of POT were improvement in SB rewiring by minimising the risk of inadvertent abluminal wire position and facilitation of the distal cell access. Following encouraging data from the bench<sup>3</sup>, observational and registry-based clinical studies were designed to prove the concept *in vivo* (Table 1). Symmetrical expansion in the proximal MV stent following POT was confirmed by intracoronary imaging<sup>4</sup>, as well as the need for repeat POT in case of SB dilatation (SBD)<sup>5</sup>. Furthermore, attention was drawn to the crucial role of procedural accuracy in terms of POT balloon size and positioning<sup>6</sup>. Finally, a large contemporary registry recently showed that, while routine application of POT in everyday practice was still lower than expected (33.9%), its use was associated with improved clinical outcomes<sup>7</sup>.

Similar to POT, kissing balloon inflation (KBI) can correct underexpansion and malapposition in the proximal MV, the added value being regaining the central position of the carina, albeit at the cost of potentially causing elliptical deformation of the proximal MV stent by the overlapping balloons.

Against this background, the Proximal Optimisation Technique Versus Final Kissing Balloon Inflation in Coronary Bifurcation Lesions trial (PROPOT)<sup>8</sup> was the first randomised trial to compare POT + subsequent SBD versus KBI in 120 patients treated with provisional bifurcation PCI, in terms of OCT-assessed strut malapposition at the end of the procedure.

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The overall results showed similar malapposition rates for both KBI and POT + SBD in the proximal MV stent segment (7.7% vs 10.4%, respectively,  $p=0.33$ ), at the bifurcation core (1.1% vs 1.4%,  $p=0.67$ ), and in the distal segment adjacent to the carina (5.3% vs 6.2%,  $p=0.59$ ). The amount of SB obstruction, expressed by the rate of overhanging struts at the SB ostium, was also comparable (7.6% in the KBI group vs 9.9% in the POT+SBD group,  $p=0.16$ ). Importantly, the rate of clinical adverse events was low and similar in both groups. Hence, the authors concluded that POT+SBD may offer no advantage over conventional KBI without POT in simple crossover stenting. While this conclusion does reflect the presented data, there are at least three important issues to be considered when interpreting the overall trial results.

First, the ability of POT alone to correct proximal malapposition and underexpansion after crossover stenting, which is its primary

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**Table 1. Clinical studies evaluating the effects of the proximal optimisation technique for coronary bifurcation lesions.**

Study or first author	Study design	Year	Population		Procedural aspects of POT					Primary endpoint	Key findings
			Number of patients	% true bifurcation	MV stent diameter (mm)	POT balloon diameter (mm)	% KBI	% SBD	% SB stent		
Hakim et al <sup>4</sup>	Observational	2017	40	73.0	3.2±0.40	3.8±0.40	0	22.5	7.5	IVUS-derived	POT symmetrically expanded the MV stent in the proximal segment
rePOT <sup>5</sup>	Registry	2018	106	39.6	3.3±2.47	3.8±0.59	0	96.3	3.7	OCT-derived	Re-POT sequence (POT + SB dilatation + rePOT) reduced global strut malapposition and SB obstruction compared with MV stenting alone
3D-OCT <sup>6</sup>	Registry	2019	135	37.0	3.0±0.44	3.5±0.65	88.5	11.5	NA*	OCT-derived	If correctly performed, POT was associated with optimal proximal MV stent expansion and improved distal cell SB rewiring
e-Ultimaster <sup>7</sup>	Registry	2021	4,395	52.2	NR	NR	45.2	NR	28.0	TLF	POT was performed in 33.9% of all-corer bifurcation PCI and was associated with the reduced occurrence of TLF, ST and TV-MI
PROPOT <sup>8</sup>	RCT	2021	115	27.8	2.9±0.40	3.4±0.50	1.8	38.6	3.5	OCT-derived	POT + SBD was associated with comparable rates of malapposition as was KBI without POT

\*Patients requiring SB stenting were excluded from this analysis. IVUS: intravascular ultrasound; KBI: kissing balloon inflation; MV: main vessel; OCT: optical coherence tomography; PCI: percutaneous coronary intervention; POT: proximal optimisation technique; SB: side branch; SBD: side branch dilatation; ST: stent thrombosis; TLF: target lesion failure; TV-MI: target vessel myocardial infarction

function, was not directly tested. Instead, the PROPOT trial evaluated the impact of SBD on MV stent geometry following angiography-guided POT. However, routine SBD is not recommended after crossover stenting, especially for the non-left main bifurcations. Hence, the general recommendation to perform POT after crossover stenting seems to remain unchallenged by the results of the PROPOT trial and is furthermore supported by the existing clinical evidence base (Table 1).

Second, only a quarter of patients completed the rePOT sequence (POT-SBD-POT), which has previously been shown to correct the potential distortion of the MV stent if SBD alone, without repeat POT, is performed<sup>5</sup>. Hence, the lack of repeat POT may explain the observed greater maximum malapposition distance at the bifurcation core's distal edge in the POT+SBD group. Furthermore, if SBD after POT is needed, systematic use of a very short (4 mm) balloon, without repeat POT, was recently shown to reduce the risk of malapposition<sup>9</sup>, making it an attractive and simpler technique compared with either KBI or the rePOT sequence.

Third, clinical applicability of the PROPOT results may be limited by: a) the trial's specific definition of malapposition (<100  $\mu\text{m}$ ) that does not correspond to the current consensus (>400  $\mu\text{m}$ ), and b) the risk of performance bias, since the wire position was checked at the middle optical coherence tomography (OCT) run, and any abluminal wiring in the absence of POT could be routinely corrected before proceeding with KBI, potentially resulting in a lower rate of malapposition compared with everyday clinical practice, still mainly relying on angiographic guidance.

In summary, despite heterogeneity in the study design, the clinical data accumulated so far (Table 1) show the efficacy of POT to correct proximal underexpansion after crossover stenting and the potential to improve patient outcomes. Taking it a step further, procedural standardisation, including POT balloon sizing and positioning, is needed to ensure that the expected benefits of optimisation techniques seen on the bench are translated into the clinical

arena. What the PROPOT trial ultimately showed is that, if OCT is used as a standard to check the SB wire position following MV stenting and prior to any SBD, then KBI without POT appears to have similar effects on the MV stent geometry to POT+SBD.

## Conflict of interest statement

The authors have no conflicts of interest to declare.

## References

- Meier B. Kissing balloon coronary angioplasty. *Am J Cardiol.* 1984;54:918-20.
- Stankovic G, Darremont O, Ferenc M, Hildick-Smith D, Louvard Y, Albiero R, Pan M, Lassen JF, Lefèvre T; European Bifurcation Club. Percutaneous coronary intervention for bifurcation lesions: 2008 consensus document from the fourth meeting of the European Bifurcation Club. *EuroIntervention.* 2009;5:39-49.
- Foin N, Secco GG, Ghilencea L, Krams R, Di Mario C. Final proximal post-dilatation is necessary after kissing balloon in bifurcation stenting. *EuroIntervention.* 2011;7:597-604.
- Hakim D, Chatterjee A, Alli O, Turner J, Sattar A, Foin N, Leesar MA. Role of Proximal Optimization Technique Guided by Intravascular Ultrasound on Stent Expansion, Stent Symmetry Index, and Side-Branch Hemodynamics in Patients With Coronary Bifurcation Lesions. *Circ Cardiovasc Interv.* 2017;10:e005535.
- Dérinay F, Finet G, Souteyrand G, Maillard L, Aminian A, Lattuca B, Cayla G, Cellier G, Motreff P, Rioufol G. Benefit of a new provisional stenting strategy, the reproximal optimisation technique: the rePOT clinical study. *EuroIntervention.* 2018;14:e325-32.
- Murasato Y, Mori T, Okamura T, Nagoshi R, Fujimura T, Yamawaki M, Ono S, Serikawa T, Nakao F, Shite J; 3D-OCT Bifurcation Registry Investigators. Efficacy of the proximal optimization technique on crossover stenting in coronary bifurcation lesions in the 3D-OCT bifurcation registry. *Int J Cardiovasc Imaging.* 2019;35:981-90.
- Chevalier B, Mamas MA, Hovasse T, Rashid M, Gomez-Hospital JA, Pan M, Witkowski A, Crowley J, Aminian A, McDonald J, Beygui F, Fernandez Portales J, Roguin A, Stankovic G. Clinical Outcomes of Proximal Optimization Technique (POT) in Bifurcation Stenting. *EuroIntervention.* 2021 May 11. [Epub ahead of print].
- Watanabe Y, Murasato Y, Yamawaki M, Kinoshita Y, Okubo M, Yumoto K, Masuda N, Otake H, Aoki J, Nakazawa G, Numasawa Y, Ito T, Shite J, Okamura T, Takagi K, Kozuma K, Lefèvre T, Chevalier B, Louvard Y, Suzuki N, Kozuma K. Proximal optimisation technique versus final kissing balloon inflation in coronary bifurcation lesions: the randomised, multicentre PROPOT trial. *EuroIntervention.* 2021;17:747-56.
- Murasato Y, Nishihara M, Mori T, Meno K, Shibao K, Takenaka K, Iwasaki K. Feasibility and efficacy of an ultra-short side branch-dedicated balloon in coronary bifurcation stenting. *EuroIntervention.* 2021;17:e425-32.