

Contemporary approaches to bifurcation stenting

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Abstract

Bifurcation lesions are common and associated with higher risks of major cardiac events and restenosis after percutaneous coronary intervention (PCI). Treatment requires understanding of lesion characteristics, stent design and therapeutic options. We review the evidence for provisional vs 2-stent techniques. We conclude that provisional stenting is suitable for most bifurcation lesions. We detail situations where a 2-stent technique should be considered and the steps for performing each of the 2-step techniques. We review the importance of lesion preparation, intracoronary imaging, proximal optimization (POT) and kissing balloon inflation

Keywords

Bifurcation, PCI, culotte, DK crush

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Introduction

Bifurcation lesions comprise up to 20% of lesions treated with percutaneous coronary intervention (PCI).¹ Blood flow dynamics at branch vessels results in differing shear stress, increasing the likelihood of atherosclerosis. Severe lesions commonly occur in these sites but the carina or flow-divider is usually spared from plaque formation because of relatively high blood flow. The anatomy also makes PCI more challenging² and rates of major adverse cardiac events (MACE) following PCI are much higher compared to non-bifurcation lesions.

Methods

Literature review was performed using PUBMED and the key words “coronary” and “bifurcation”, review of consensus documents and opinions of thought leaders in the field.

Definition of bifurcations and anatomic considerations

The most common classification system for bifurcation lesions is the Medina classification³ (Figure 1). This is a 3-digit binary code which defines a bifurcation by the presence of disease proximal and distal to the

bifurcation in the main vessel (MV) and presence/absence of disease in the side branch (SB). This system has proved popular due to its simplicity, however it does not provide insight on plaque morphology, extent of disease nor angulation, which are all key informatics when strategizing PCI therapeutic options. The Medina classification does not take in to consideration the size of the side branch, although modifications to address this have been suggested.⁴ Alternative classifications have been proposed that allow division of bifurcation lesions into simple and complex, using factors such as the relative angulation of the vessels, degree of calcification and lesion length (Figure 2). These criteria have been shown to predict outcomes following PCI and may help decision making between a provisional stent (PS, 1 stent) and 2-stent strategy.^{5,6}

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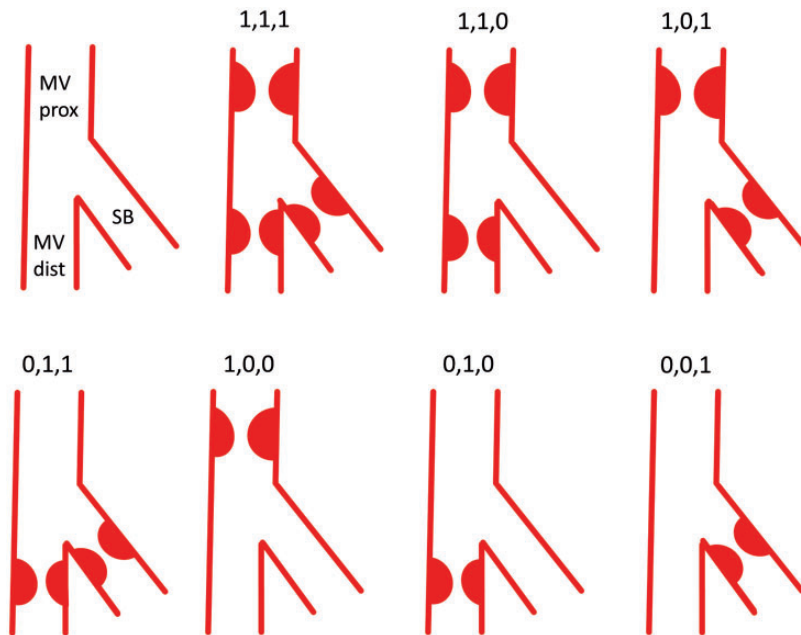


Figure 1. The Medina classification is based on anatomic lesions, giving each bifurcation a 3 digit binary code. If there is a lesion >50%, it is classified as “1” and if <50% it is a “0”. The first figure represents the proximal main vessel, the second, the distal main vessel and the third the side branch. Each classification is demonstrated in the figure. Reproduced from Ali et al.²

DEFINITION study: Complex bifurcation lesions

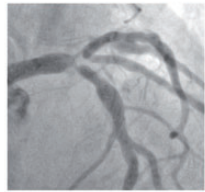
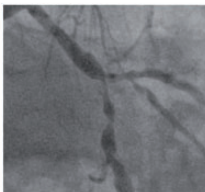
<p>LMS lesion with SB ≥70% and ≥10mm</p>  <p>or</p> <p>Non - LMS lesion with SB ≥90% and ≥10mm</p> 	+	<p>Any two of:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Moderate to severe calcification <input type="checkbox"/> Multiple lesions <input type="checkbox"/> Active thrombus <input type="checkbox"/> Bifurcation angle <45° <input type="checkbox"/> MB reference diameter <2.5mm <input type="checkbox"/> MB lesion >25mm length
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Figure 2. The DEFINITION study grouped bifurcation lesions into “complex” and “simple” lesions using criteria that predicted major adverse events post PCI. A complex lesion is defined as meeting the criteria in the first box and with at least two of the characteristics listed in the second box (adapted from Melikian et al.³).

Specific anatomic considerations in bifurcation lesions

A fundamental physical principle of bifurcation PCI is that a main vessel (MV) coronary artery diameter always diminishes after a major side branch (SB). The

size of MV and SB after a bifurcation is determined by the size of the proximal MV and may be approximated as follows⁷:

$$\text{Proximal MV diameter} = \frac{2}{3}(\text{distal MV diameter} + \text{SB diameter})$$

After adequate lesion preparation, the stent selected should therefore be sized to the distal MV reference diameter, either using angiographic images or adjunctive intra-coronary imaging (intravascular ultrasound, IVUS/optical coherence tomography, OCT). Oversizing of the stent diameter risks carina shift and closure of the SB. Following implantation, as the stent is a uniform diameter throughout its length, the segment proximal to the carina will be unapposed. The next step is therefore to use a larger diameter proximal balloon to expand the stent, the 'proximal optimization technique' (POT). This is essential in all bifurcation stenting strategies and is often applied multiple times during the PCI. Registry data supports better outcome in patients treated with POT (TLF 4% vs 6% for no POT, $p < 0.01$), ST (0.4% vs 1.3% with no POT, $p < 0.01$).⁸ The POT balloon must not extend beyond the carina to avoid over-expansion of the distal MV and closure of the SB through carina shift. Perfectly aligned POT balloon inflation affords stent strut opening into the SB whilst fully apposing the stent to the walls of the proximal vessel (Figure 3). Ensuring adequate stent length proximal to the carina is also essential to avoid geographical miss i.e. balloon injury outside of stent.

Stent expansion limits are fixed depending on stent design (open vs closed cells, number of cross linkages, crown number) and diameter, it is important to select a device that can be expanded to the MV diameter without deformation of the stent architecture. This is particularly pertinent when there is a large size differential between the proximal and distal vessel. The maximal expansion diameters of common stents may be found in the product IFU and selected publications.⁹

Choosing a strategy for bifurcation treatment

When deciding how to treat a bifurcation lesion, the first consideration is usually between an upfront PS or two stent strategy. The choice of approach for treatment of bifurcations depends on the lesion characteristics and complexity.⁵ The current European Bifurcation Club (EBC) guidelines¹⁰ suggest that PS may be the preferred option for most lesions, while an upfront 2-stent strategy may be considered for more complex lesions with a large side branch supplying a significant myocardial territory. However, the PS approach is in reality a philosophy that when followed, permits predictable results in both MV and SB. While in most situations a stent is implanted only in MV, additional SB stents can be deployed if necessary.

Lesion preparation and use of intra-coronary imaging

The lesion must be adequately prepared to ensure full stent expansion. There should be a low threshold for intracoronary imaging as this will guide lesion preparation and size of stent(s). Cutting and scoring balloons are helpful for fibrotic and mild/moderately calcified lesions, while severely calcified lesions may require rotablation. More recently, intravascular lithoplasty using the Shockwave balloon (Shockwave Medical, Santa Clara) has emerged as a promising treatment for circumferential calcification.¹¹

During bifurcation stenting, OCT allows identification of whether wire cross is through a proximal or distal strut¹² (Figure 4). Following stent implantation, IVUS and OCT may be used to ensure optimal stent expansion. OCT to guide bifurcation stenting will be assessed in the European Randomized Optical Coherence Tomography Optimized Bifurcation Event Reduction Trial (OCTOBER) trial.¹³

Provisional stent technique

The steps for PS are shown in Figure 5. Decision to wire the SB will depend on patient stability, the area of viable myocardium supplied by the SB (which may be estimated by visual assessment of the diameter and length of the SB), the likelihood of loss of flow following PS (based on degree and morphology of disease in the ostial/proximal SB) and how difficult it would be to wire the SB in the event of compromised flow. In practice, the SB is usually wired. Routine SB pre-dilatation is not recommended but may be considered if SB access is difficult or there is severe SB disease in the ostial/proximal vessel.¹⁰

Following PS, POT is performed, usually with the SB wire jailed behind the MV stent. Jailing the SB wire may help the SB to remain open and will provide a marker for position if flow is lost. For small SBs, once the MB is stented and POT is performed, if there is normal flow in the SB, there is no need to treat the SB as this may risk ostial SB dissection. If flow is lost, the SB is rewired after POT, either with a new wire or by bringing the MV wire back (avoiding unintentional abluminal wiring if the POT is sub-optimal) and gentle SB dilatation performed. Wire crossing through a distal MV stent strut is optimal to permit better scaffolding of the SB ostium during FKB and to avoid MV proximal stent deformation. This should be followed by repeat POT. For larger SBs, both SB and MV should be wired and following MV stenting and POT, wire re-cross into the SB and kissing balloon inflation (KBI) (see Figure 3) If KBI is performed, a final POT is necessary

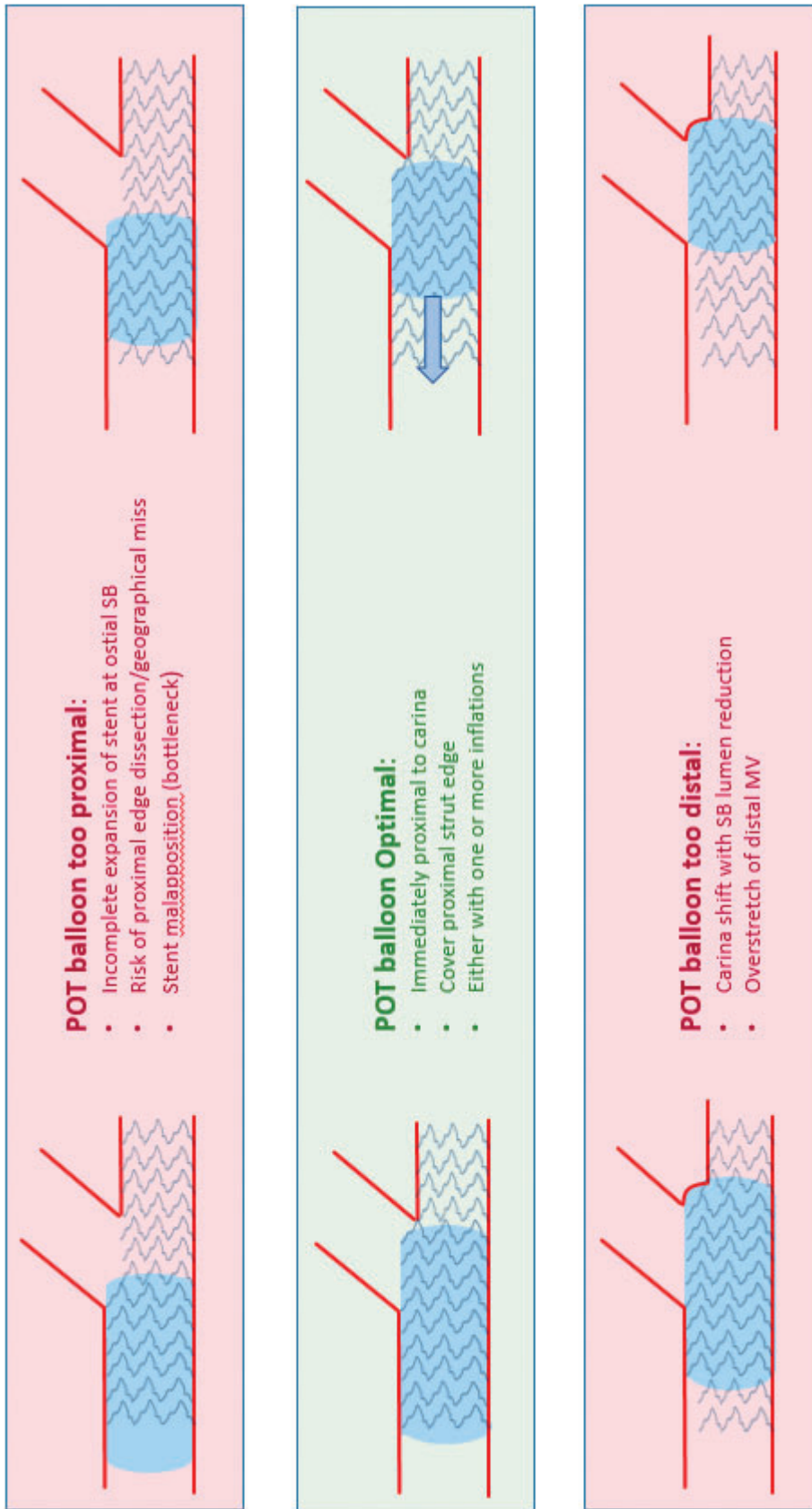


Figure 3. Importance of proximal optimization technique (POT). The POT balloon is sized 1:1 to the proximal MV. If the balloon is too proximal, there will be incomplete expansion of stent at the ostial SB and a risk of proximal edge dissection if the proximal balloon is outside of the stent. A too distal POT will deform the stent causing carina shift and reduction in the size of the ostial SB. The distal MV may be traumatized by the oversized balloon. There is also a risk of missing the proximal aspect of the stent which would then be under-expanded and unopposed to the vessel wall. Figure adapted from EBC.¹⁰

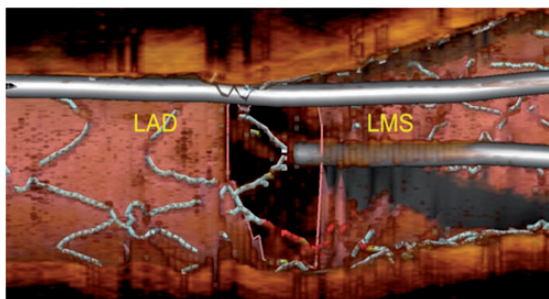


Figure 4. OCT may be used to guide recrossing during bifurcation PCI. Here, a fly through image shows a proximal cell recross into the circumflex in a distal left main bifurcation.

to restore circular geometry and reduce strut malapposition in the MV.¹⁴ The final POT should have a more proximal balloon position especially if the SB has been stented so as to avoid any neocarina that will have been created.

A second stent in the SB using either T, T and protrusion (TAP) or culotte as a bail-out 2 stent strategy may be needed in the following circumstances (1) compromised SB flow, (2) SB dissection that may compromise flow (3) severe stenosis. However, ensuring an optimal result in the MB should be prioritized over optimizing the SB.

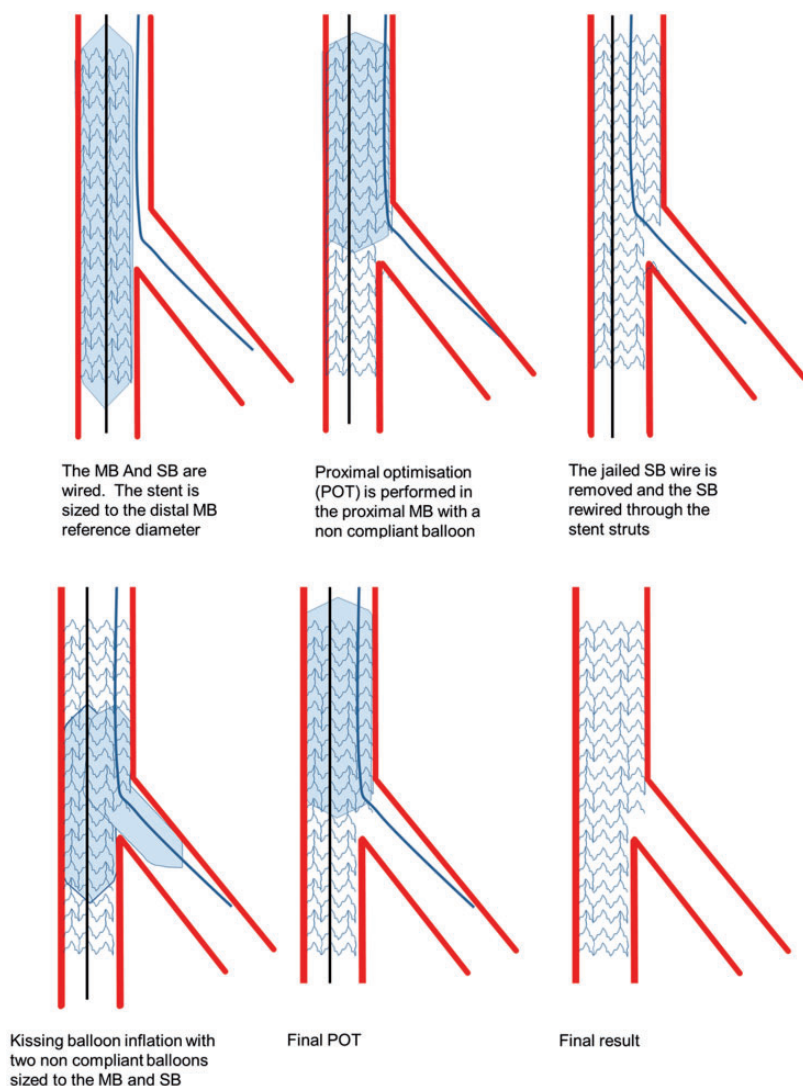


Figure 5. Provisional stent approach. A single stent is placed across the bifurcation. The proximal stent is optimised (POT) with a non compliant balloon sized to the proximal main vessel size. Rewiring of the side branch and kissing balloon inflation are commonly performed to optimize the ostium of the side branch but are not mandatory.

Table 1. Key trials in non-LMS bifurcation stenting.

Trial	n	Comparator arm 1	Comparator arm 2	Primary endpoint	Results
NORDIC Bifurcation Study I 2006 ¹⁸	413	PS	2 stent (classic crush, T-stenting, culotte)	MACE (death, MI, TVR, ST) at 6 months	Similar MACE between groups. Longer procedure time and higher rates of raised biomarkers post procedure in 2-stent group
DK crush I 2008 ¹⁵	311	Classic crush	DK crush	MACE (cardiac death, MI, TVR) at 8 months	DK crush associated with lower rates of MACE at 8 months compared to classic crush (11.4% vs 24.4%, p = 0.002). FKBI achieved in 100% of patients treated with DK crush compared to 76% in the classic crush group
BBK I 2008 ¹⁹	101	T stent	PS + KBI with bailout T stent if SB compromise	% stenosis of the SB at 9 month angiographic follow up.	No difference in SB stenosis between groups
CACTUS 2009 ²⁰	350	PS with bailout T stent	Classic crush	6 month angiographic restudy	Difference in re-stenosis between the two groups in either the MV or SB. Rates of major adverse events (cardiac death, MI, TLR) at 6 months similar between groups
BBC ONE 2010 ²¹	500	PS with optional FKB	2-stent (crush, T, culotte) with mandatory FKB	MACE (death, MI, TVF)	Higher rates of MACE in 2-stent compared to PS (8% vs 15%, p = 0.009), largely driven by periprocedural MI. 2-stent procedures had longer duration and fluoroscopy time
DK crush 2 2011 ²²	370	DK crush	PS	MACE (cardiac death, MI, TVR)	No difference in MACE between groups. DK crush associated with a significant reduction of TLR and TVR.
Nordic Baltic III 2011 ²³	477	PS + FKB	PS without FKB	MACE (death, MI, TVF)	No difference in MACE. Lower rates of SB stenosis in the FKB group (7.9% vs 15.4%, p = 0.039) on 8 month angiographic study
BBC I/Nordic Bifurcation 5 year follow up ²¹	890	PS	2 stent (classic crush, T-stenting, culotte)	all cause mortality at 5 years	Lower mortality with PS vs 2 stent (3.8% vs 7.0%, p = 0.04)
DK crush 6 2015 ⁴⁴	320	PS approach. Decision to stent SB guided by FFR	PS approach. Decision to stent SB made angiographically	1 year composite MACE (cardiac death, MI and clinically driven TLR)	No difference in MACE between groups. Numerically lower % of SB stent in FFR group (56% vs 63%, p = 0.07)
Nordic II 2009 ²⁵	424	Culotte	Classic Crush		

(continued)

Table 1. Continued.

Trial	n	Comparator arm 1	Comparator arm 2	Primary endpoint	Results
EBC TWO 2016 ²⁶	200	PS	Culotte	MACE (cardiac death, MI, TVR or ST) at 6 months	No difference in MACE between groups (crush 4.3%, culotte 3.7%, p = 0.87). Similar procedure and fluoroscopy times. Trend towards less in segment restenosis and in stent restenosis with culotte compared to crush
BBK II 2016 ¹⁸	300	Culotte	TAP	MACE (death, MI, TVR) at 12 months. Restenosis at 9 month angiographic follow up.	No difference in MACE (7.7% in T stent vs 10.3% in culotte, p = 0.53) Culotte group had lower % of angiographic restenosis (21 +/-20% vs 27 +/-25, p = 0.006). Trend to lower TLR rates (6% vs 12%, p = 0.069), TLF numerically lower (6.7% vs 12.0%, p = 0.11)
PERFECT 2015 - first randomization ¹⁴	306	FKB	no FKB	Angiographic assessment at 8 months. MACE at 12 months (death, MI, TVR)	Angiographic restenosis was higher in the MV in FKB group compared to no FKB (15.1% vs 3.7%, p = 0.004). No difference in the SB (2.8% vs 5.6%, p = 0.5). No difference in MACE (14.0% versus 11.6%, p = 0.57)
PERFECT 2015 - second randomization ¹⁴	419	PS	Mini crush	as above	No difference in angiographic restenosis between groups in the SB or MV. MACE similar between groups at 1 year (17.9 vs 18.5%, p = 0.84)
CELTIC (2018) ²⁷	170	Culotte with Xience (3 connector design)	Culotte with Synergy stent (2 connector design)	MACE:death, MI, CVA and TVR.	Synergy non-inferior to Xience (9 month MACE 19% for Xience and 16% for Synergy)
DEFINITION II (2020) ⁶	653	PS: complex bifurcation lesions (DEFINITIONS criteria)	2 stent (77% DK crush). Complex bifurcation lesions (DEFINITIONS criteria)	TLF at 1 year (cardiac death, target vessel MI, clinically driven TLR)	Favored 2 stent technique for complex bifurcation lesions; TLF occurred in 37 (11.4%) in the PS and 20 (6.1%) patients in the 2-stent group, respectively, HR 0.52, 95% CI 0.30–0.90; P = 0.019, largely driven by target vessel MI and clinically driven TLR in the PS group

PS – provisional stent, POT – proximal optimization technique, MI – myocardial infarction, TVR – target vessel revascularization, ST – stent thrombosis, DK – double kiss, MACE – major adverse cardiac events, FKB – final kissing balloon inflation, SB – side branch, TLR – target lesion revascularisation, MV – main vessel, LMS – left mainstem, FFR – fractional flow reserve, TIMI – thrombolysis in myocardial infarction, TLF – target lesion failure, TAP – T stent and protrude.

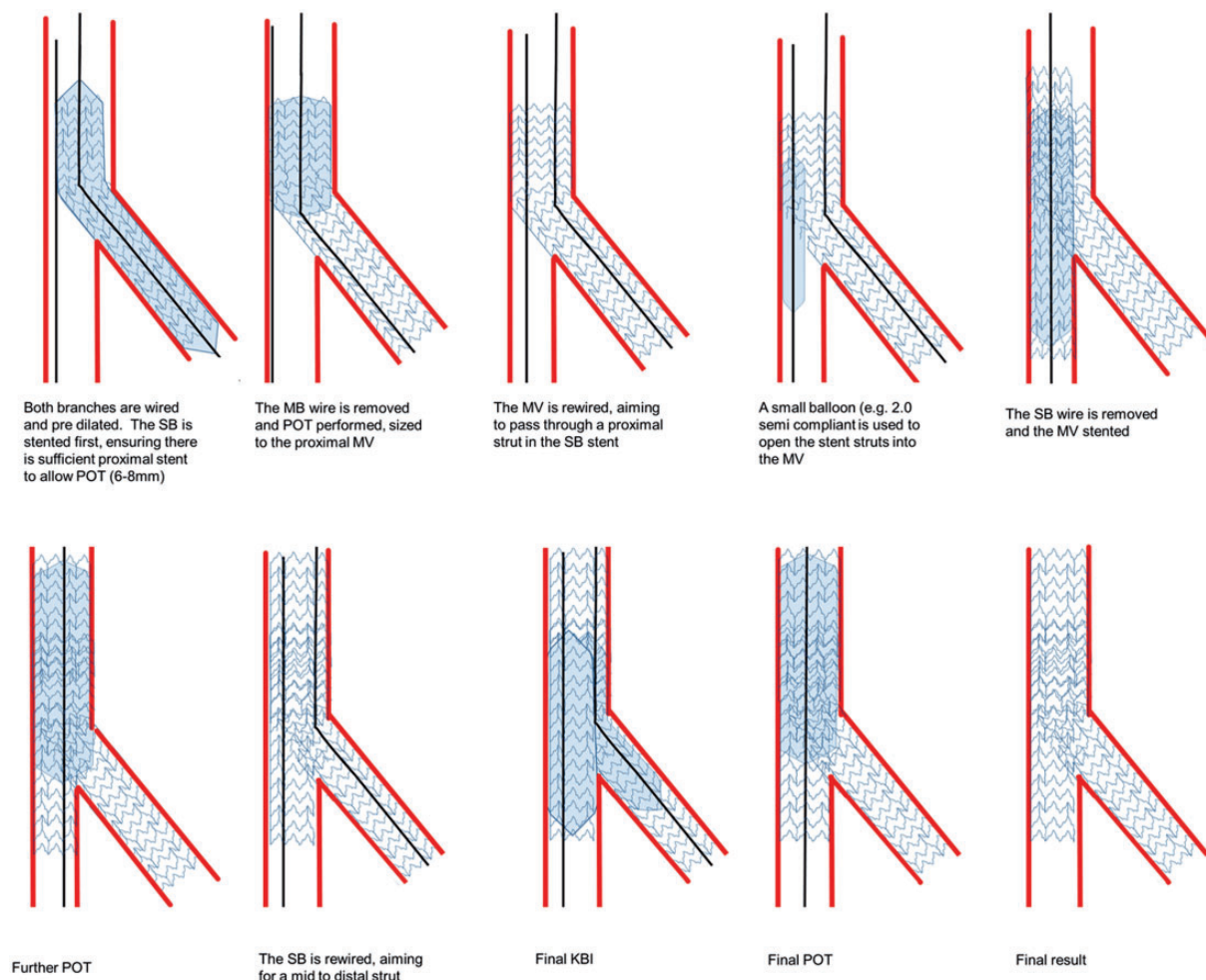


Figure 6. The culotte technique. This is most suited to lesions where the SB and the distal MW are of similar caliber. The SB is stented first, followed by a POT and rewiring of the MV, aiming for a proximal cross of the stent struts. The stent struts are opened with a low profile balloon and the MV stented. A further POT is performed before rewiring of the SB to minimize the risk of abluminal wiring. KBI inflation is performed, sized to the distal vessels.

Two-stent techniques

The sequence for the most common 2-stent techniques are in Figures 6 to 8 and the pros and cons of each technique summarized in Table 1. In the culotte and reverse culotte, the distal MV and SB each contain a “trouser leg” of stent, with 2 layers of stent in the proximal MV (Figure 6). In the traditional culotte, the SB stent is placed first, while the MV is stented first in the reverse culotte. Culotte was traditionally limited by large differences in MV and SB diameter but contemporary stent expansion flexibility permits up to 1.5 mm difference. T stenting and TAP (T-stent and protrusion) is best suited to lesions where the SB is close to 90° to the MV (Figure 7). Double kiss crush (DK crush) has multiple steps and wire re-crosses (Figure 8). It is a modification of the classic crush technique with the addition of a re-cross and KBI after

deployment of the SB stent, increasing the success of wire recross for the final KBI from 75% to close to 100%. A successful final KBI is associated with a reduction in major adverse events.¹⁵ DK crush is usually reserved for distal left main stem bifurcations where angulation is 90° or more. Trial data performed by high volume DK crush operators suggests superiority over other bifurcation techniques,^{16,17} however may not be generalizable to lower volume centres/operators. Whichever 2-stent technique is applied, it is mandated that FKB is performed with subsequent POT.

Trial data

The major trials of bifurcation stenting are summarized in Table 1, with details of left mainstem (LMS) trials in Table 2. The majority of trials were performed in the

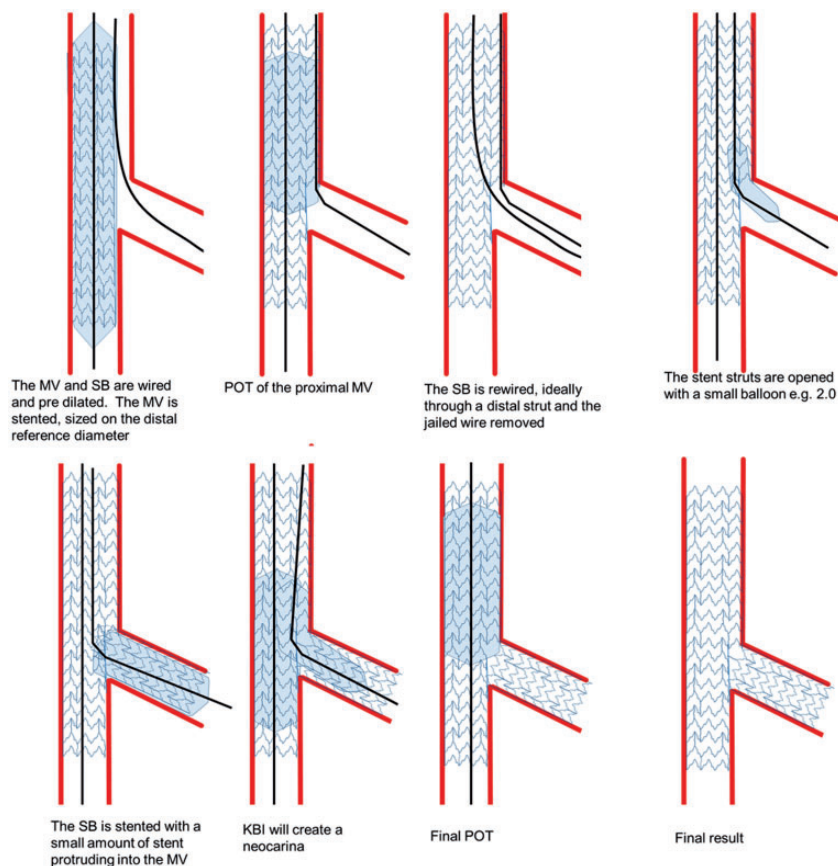


Figure 7. T stent/TAP, treating MV first. The first 4 steps of this procedure are the same as provisional stenting so this can be used as a bailout technique if there is a large dissection in the SB or compromise of SB flow, converting the provisional strategy to a T stent/TAP strategy.

first generation drug eluting stent (DES) era with thicker stent struts, durable polymer and paclitaxel in a high proportion. 2-stent techniques were also much less refined with absence of the POT concept, single kiss crush and low use of intra-coronary imaging. Perhaps not unsurprisingly the trial data largely supports the use of a PS strategy over an upfront 2-stent strategy. Importantly, many of these trials included small SB diameters. Pros and cons of each of the 2 stent techniques are detailed in Table 3.

Left main stem bifurcation lesions

The EXCEL²⁸ and NOBLE²⁹ trials suggested that PCI for unprotected LMS disease resulted in similar rates of cardiovascular mortality to bypass surgery but a higher risk of requirement for repeat revascularization and higher all cause mortality at 5 years.³¹ This 5-year outcome data for EXCEL generated a large amount of controversy and led to the European Association for Cardio-Thoracic Surgery (EACTS) withdrawing their support for the ESC IIa recommendation for LMS PCI

in low and intermediate syntax scores.³² In a post hoc analysis of EXCEL, patients with a Syntax II score that favored CABG but who were treated with PCI had higher mortality compared with those randomized to CABG (15.1% vs 4.1%, $P=0.02$).³³ The decision for PCI vs CABG in LMS disease should utilize a heart team approach, assessing anatomic complexity and relative risks/benefits of each approach.

If PCI is utilized for LMS revascularization, the results of DK crush III and V suggest that DK crush may be the preferred technique for true bifurcations and this has a class IIb recommendation in the most recent ESC guidelines.³⁴ However, the DK crush trials were performed by operators who performed >300 PCIs/year, including at least 20 LMS PCIs per year, raising the question of whether outcomes would be similar in lower volume operators. DK crush has not been similarly endorsed in the EBC¹⁰ or AHA/ACC guidelines. Subgroup analysis of distal LMS bifurcation lesions in EXCEL demonstrated a higher rate of composite end point (death, MI, stroke) at 3 years in patients treated with a planned 2-stent technique

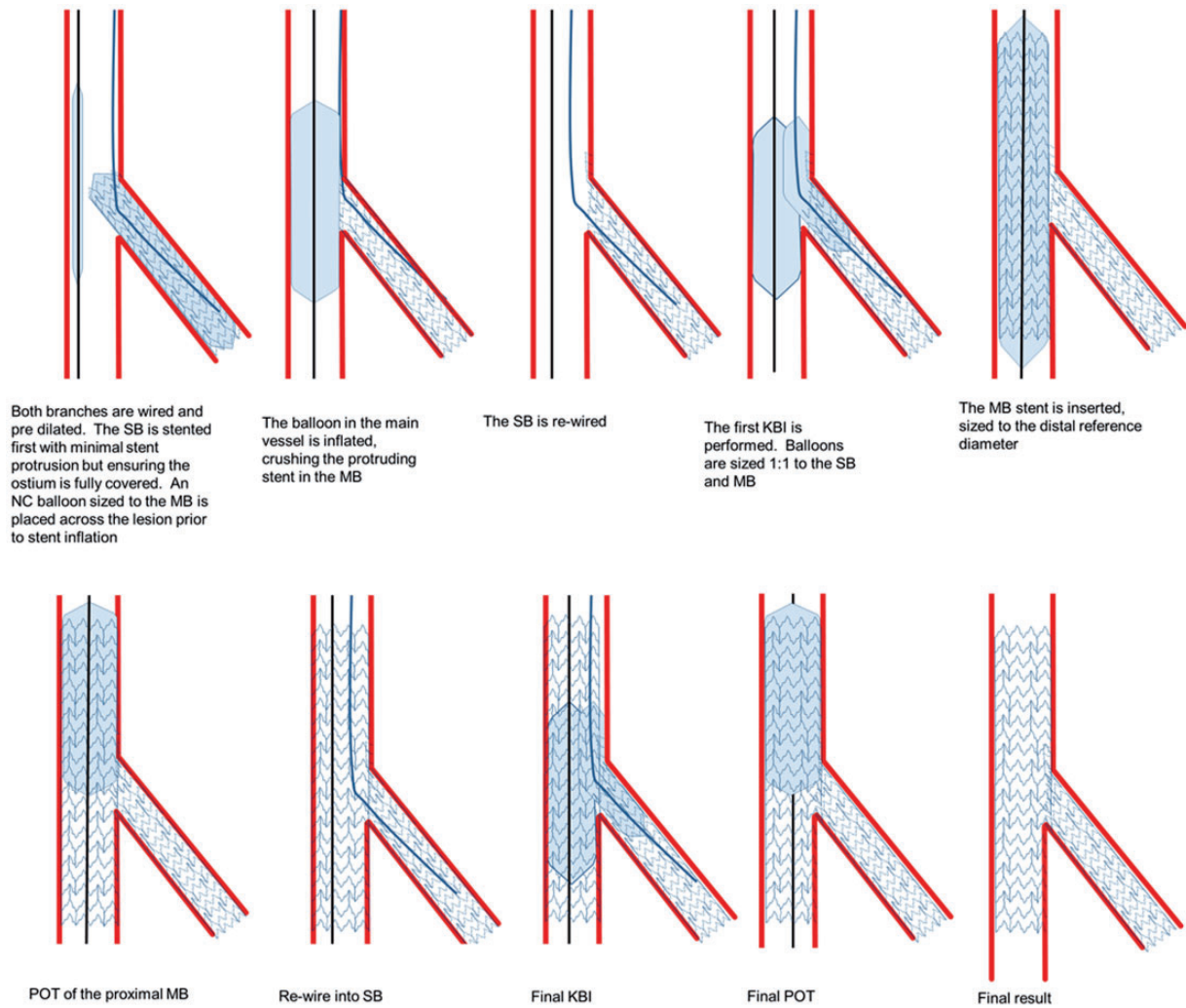


Figure 8. DK crush technique. This is the most complex of the bifurcation techniques. It has the advantage of maintaining wire access in the MV throughout. Two KBI (unlike classic or mini-crush) are performed which increases the success of re-cross after MV stenting.

compared to PS (20.7% vs 14.1%, $p = 0.01$), driven by differences in cardiovascular and MI.³⁵ The results of the EBC MAIN trial which randomizes patients to a 2-stent vs PS strategy for LMS bifurcation stenting are awaited and will help inform the PS vs 2 stent decision.

Dedicated bifurcation stent platforms

Whilst data supports a PS approach only whilst preserving flow in the SB, technically this can be difficult and it is often necessary to first secure the SB to prevent occlusion. Furthermore, when the SB is a large calibre vessel supplying extensive myocardial territory it may be necessary to provide a durable result in this vessel to improve angina independent of the MV. Anatomical variation of angulation and presence of fibro-calcific disease in these cases adds additional complexity and desire

to use the most simple and effective strategy is paramount.

The concept of using a dedicated bifurcation stent that could overcome some of the limitations of using standard stents to treat complex bifurcation lesions has been extensively explored. A number of devices have been developed that at first appeared promising but ultimately failed to prove superior to conventional techniques in clinical practice. Very few now exist in clinical use, which largely reflects a lack of evidence to support superiority of current bifurcation PCI techniques and that some were technically challenging to implant.

Devices can be divided into stents which cover the proximal aspect of the bifurcation lesion (e.g. Axxess), stents designed to cover the proximal and distal MV with SB access (e.g. Stentys coronary bifurcation stent) and side branch stents designed to be delivered in the proximal MV into the SB (e.g. Tryton).

Table 2. Key trials in LMS bifurcation stenting (abbreviations as per Table 1).

LMS trials						
Trial	n	Patient population	Comparator arm 1	Comparator arm 2	Primary endpoint	Results
DK crush 3 2013 ¹³	419	Unprotected distal LM bifurcation lesions (Medina 1,1,1 or 0,1,1)	DK crush	Culotte	MACE (cardiac death, MI and TVR)	Higher rates of MACE following culotte vs DK crush (16.3% vs 6.2%, $p < 0.05$), mainly driven by increased TVR (11% vs 4.3%, $p < 0.05$)
EXCEL (2016) ²⁸	1905	Unprotected LMS disease of low/intermediate complexity (Syntax score 32 or less)	PCI	CABG	composite of death from any cause, stroke, or MI at 3 years	Primary endpoint in 15.4% of PCI group vs 14.7% of CABG group ($P = 0.02$ for noninferiority, $p = 0.98$ for superiority). Secondary end-point of death, stroke, MI at 30 days occurred in 4.9% of PCI group vs 7.9% of CABG group ($P < 0.001$ for noninferiority, $P = 0.008$ for superiority).
NOBLE (2016) ²⁹	598	Unprotected LMS disease	PCI	CABG	MACCE at 5 years: composite of all-cause mortality, non-procedural MI, any repeat coronary revascularisation, stroke	MACCE at 5 years: 28% for PCI (121 events) vs 18% for CABG (80 events). HR 1.51 (95% CI 1.1-2.0). CABG was statistically superior to PCI ($p = 0.004$).
DK crush 5 2017 ³⁰	482	Unprotected distal LM bifurcation lesions (Medina 1,1,1 or 0,1,1)	PS	DK crush	Composite of TLF: cardiac death, target vessel MI, or clinically driven TLR at 1 year	Lower rates of TLF with DK crush vs PS (10.7% vs 5.0%, $p = 0.02$)

Table 3. Pros and cons of 2 stent techniques.

2 stent technique	Pros	Cons
PS	<ul style="list-style-type: none"> • Most simple technique • Can be converted to T stent/TAP/culotte as bail out • Data supports PS for most bifurcation lesions, except complex and LMS 	<ul style="list-style-type: none"> • Associated with higher rates of MACE in DEFINITIONS II (complex bifurcations) and DK crush V (udLMS)
DK crush	<ul style="list-style-type: none"> • Data for superiority over PS and culotte in LMS • Maintains wire access in MV 	<ul style="list-style-type: none"> • Complex with multiple steps • Results may not be replicated in low volume centres/operators • Greater fluoroscopy and contrast dye. • Can be difficult to perform through 6 F system (7 F often preferred)
T stent/ TAP Culotte	<ul style="list-style-type: none"> • Best in bifurcations where SB is at 90° • Best in bifurcation angles $< 70^\circ$ and where SB is of similar size to distal MV. 	<ul style="list-style-type: none"> • May result in geographic miss of ostial SB • 2 layers of stent in proximal MB • Multiple steps of re-wiring

The Axxess™ stent was a conical self-expanding nitinol stent that was coated with Biolimus with a bio-absorbable polymer. The device was designed to adopt a provisional approach with delivery in the MV across the carina permitting easy access to both SB and distal MV to allow additional DES overlap as required. When placed in an optimal position, the acute results and out to 5 years were excellent in over 125 implants in our centre and in some small published registries.³⁰ However, the learning curve for use, necessity to have very extensive lesion preparation and relatively high cost resulted in the withdrawal of Axxess from the market a few years ago.

The Stentys™ coronary bifurcation stent (Stentys, SAS, Paris, France) is a self-expanding, drug-eluting stent. The stent is composed of Z shaped cells in a mesh that can be folded into the ostium of the side branch using an angioplasty balloon. It is positioned in the MV across the SB and deployed by withdrawal of the covering sheath. The stent will then self expand and conform to the main vessel. The guidewire is then repositioned into the SB and a non-compliant balloon inflated in SB ostium causes some of the stent struts to disconnect, resulting in full expansion of the stent into the bifurcation. A workhorse drug eluting (or other) stent may be placed in the SB if desired.

The BiOSS (Bifurcation Optimization Stent System, Balton, Warsaw, Poland) is a stainless steel dedicated bifurcation stent, designed with a tapered shape to fit with the size differential of the main vessel between the proximal and distal segments, with a ratio of 1.3–1.15 of proximal: distal stent. It is inflated through a bottle shaped balloon, designed for an immediate “POT effect” on implantation. The POLBOS II trial (PMID 26600564) demonstrated non inferiority to provisional stenting with workhorse drug eluting stents.

The Tryton Bifurcation stent (TBS) is a slotted tube stent with three zones designed to be used in conjunction with a 2nd generation drug eluting stent when treating a bifurcation lesion using a culotte technique. The device was very simple to use adopting a modified Culotte strategy with treatment first to SB after lesion preparation. Due the tri-zone design, re-crossing from the SB to MV with the guide wire through the transition zone was easy and reproducible permitting completion of the culotte with DES to MV and effectively avoiding the double layer of proximal MV stent found in conventional DES culotte technique. Despite the cobalt-chromium device being free of drug, the TLR from many registries was relatively low and similar in my experience of over 75 cases (including 5 in a LM registry). However, it proved no better in terms of MACE against provisional approach in the major RCT of 700 patients and is now no longer available in the UK.³⁶

The Sideguard (Cappella Medical Devices Ltd, Galway, Ireland) was a self expanding stent designed to flare in a trumpet shape at the ostium of the side branch, with the aim to achieve full coverage of the side branch ostium. The device was relatively straightforward to use with application to the SB first after lesion preparation and then MV routine DES. However, the properties of this nitinol self-expanding device and lack of drug delivery resulted in case reports of MV migration and in my own experience of 10 cases within the UK Cappella registry we found TLR in 4 patients prompting early discontinuation.³⁷ The product is no longer available.

Current guidelines for bifurcation stenting

The European Bifurcation Club (EBC) has the following expert consensus recommendations¹⁰:

- The Medina classification should be used in description of bifurcation lesions
- A PS approach is recommended for most bifurcation lesions, however for complex lesions where the SB is large and supplies a significant coronary territory, a 2-stent approach may be used
- POT should be used routinely for all bifurcation lesions
- If a 2-stent approach is used, lesion preparation should be performed in MV and SB first and FKB and POT are mandatory
- There should be a low threshold for use of intracoronary imaging (IVUS or OCT).

Summary

Bifurcation lesions are common and associated with increased risks of re-stenosis. While a provisional stent approach may be suitable in many cases, an upfront 2-stent approach should be considered in patients with complex anatomy or a large myocardial area supplied by the side branch. In this case, choice of bifurcation technique should be determined by the specific anatomy and operator experience. It is therefore important that PCI operators remain competent in 2-stent techniques.

Declaration of conflicting interests

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