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Bench Testing Analysis of Perforation Management in the Setting of Bifurcation Coronary Intervention

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ABSTRACT

Background: Management of coronary perforation in bifurcation lesions with covered stents remains challenging.
Aims: We aimed to describe a proper practice and toolbox for "jailed-branch" management after covered stent deployment.
Methods: Using a bench model, we tested various wires with a 120° angulated microcatheter for their ability to penetrate covered stents to access jailed side branches (SB). Next, four PCI techniques were assessed: Test #1 (main branch [MB] rupture simulation): MB covered stent, graft penetration, and kissing balloon inflation (KBI) ($n = 7$). Test #2: Test #1 completed with Culotte using a drug-eluting stent (DES) ($n = 3$). Test #3: Culotte with two covered stents simulating MB and SB rupture ($n = 3$). Test #4: Test #3 plus final DES in MB ($n = 3$).
Results: High tip-load wires (> 12 g) successfully penetrated covered stents within 14 s. All procedures were completed successfully. Test #1 showed lumen area reductions of −8% (MB) and −25% (SB), with graft overhang at the SB. Conversion to Culotte with DES (Test #2) improved SB lumen reduction to −8%. Test #3 showed reductions of −7% (MB) and −15% (SB), with graft overhang at MB, corrected in Test #4 by DES implantation, resulting in +9% lumen gain (MB) and improved SB lumen reduction (−11%).
Conclusion: In this bifurcation perforation in-bench model, high tip-load wires effectively penetrated covered stents toward excluded branches after crossover covered stent implantation. Conversion to Culotte, using either a DES or a second covered stent, was feasible. Overhanging graft material following SB fenestration could be addressed by overstenting with a DES.

1 | Introduction

Coronary artery perforation during percutaneous coronary intervention (PCI) represents a severe and potentially life-threatening complication [1]. Bail-out strategies consist of various methods for immediate and maintainable sealing of the luminal integrity. In certain cases of uncomplicated vessel ruptures purely a prolonged balloon inflation at the perforation site can result in safe sealing [2, 3]. Still, in several cases, when a more complex or more extensive rupture occurs, implantation of a covered stent becomes inevitable [3].

Covered stents are dedicated devices for the treatment of mid-vessel rupture. The devices, which are designed for intracoronary implantation, are typically regular balloon-expandable stents, carrying a specific skirting, designed for sealing the perforation site. The sealing materials are made of either synthetic or biological membranes, guaranteeing full coverage of the behind-lying structures [4].

While implantation of covered stents is per se a life-saving procedure, still, its successful implantation has certain "bystander" consequences to be kept in mind, once the acute life-threatening situation is managed. Most importantly, successful isolation of the lumen from the surrounding structures has acute relevance in case a coronary segment with relevant side-branches is involved. Considering that bifurcations are involved in approximately 20%–30% of all PCIs [5], the incidence of that situation is not negligible. In a life-saving situation, SB with small supplied myocardial territory can be considered to be expendable. On the other hand, large supplied territories, occlusion-induced arrhythmias, or hemodynamic instability might mandate efforts for its re-opening.

In the present bench study, we describe and assess various fenestration methods and bifurcation techniques for the management of jailed side branches (SB) after covered stent implantation.

2 | Methods

2.1 | Covered Stent

The present bench study focuses on side-branch management after PK Papyrus-covered stent (PCS) implantation (Biotronik, Bülach, Switzerland). The PK Papyrus is a cobalt chromium alloy stent with an amorphous silicon carbide coating and covered by a nonwoven, electrospun polyurethane membrane on its external surface.

2.2 | Optical Coherence Tomography (OCT)

OCT imaging was carried out systematically at the end of each procedure. Pullback runs were performed at 20 mm/s with a Dragonfly Duo OCT catheter (Abbott Vascular, Santa Clara, CA, USA) and analyzed using a dedicated workstation (C7-XR OCT intravascular imaging system; Abbott Vascular). Images were recorded at 100 frames per second. Note that the OCT pullback was only documentary and not meant to guide PCI.

Analyses were performed by two operators to reach a consensus on the minimal stent area or minimal lumen area (MLA) were measured for the proximal main branch (pMB), distal main branch (dMB), and SB. Percent lumen area reduction was determined by comparing the measured MLA to the known lumen area of the model. Accordingly, for the dMB and the SB, 7.07 mm^2 was set as reference area for the 3 mm diameters.

2.3 | Angioscopy

Angioscopic imaging was carried out systematically at the end of each procedure. Note that angioscopic images were only documentary and not meant to guide PCI. Images were analyzed independently by three reviewers and used for objective quantification of residual ostial stenoses at the level of dMB and SB ostia, as well as subjective visualization and description of cover-material overhang.

Relative lumen area reduction was described by comparing the ostial (CTO) sections to neighboring fully-expanded sections, as demarcated by the stent struts. Calculations were conducted using the ImageJ software. The average value across all attempts from the different reviewers was calculated and reported.

2.4 | Procedures

2.4.1 | *Wire Penetration*

A 3.5 mm PCS was implanted in a constant lumened vessel model with multiple side-holes, simulating SB ostia. Different guidewires were tested for their ability to penetrate the PCS through the side holes with the support of a 120° angulated microcatheter (Supercross 120°, Teleflex, Wayne, Pennsylvania, USA) (Video S1).

For each attempt, a previously untouched side hole was used. The duration of each attempt was recorded, and in case of no success within 5 min, further attempts were abandoned. The condition of the wire tip was visually assessed afterwards (intact or damaged). Tested wires were Infiltrac Plus (polymer, tapered tip, 14 g tipload; Abbott, Abbott Park, Chicago, Illinois, USA) Confianza Pro 12 (hydrophilic coating with uncoated distal tip; tapered tip; 12 g tipload; Asahi Intecc Medical, Seto, Aichi, Japan), Pilot 200 (hydrophilic coating over a full polymer jacket; nontapered; 3.9 g tipload; Abbott, Abbott Park, Chicago, Illinois, USA), and Fielder XT-A (polymer jacket with hydrophilic SLIP-COAT® coating; tapered tip; 1.0 g tipload; Asahi Intecc Medical, Seto, Aichi, Japan).

2.4.2 | *Bifurcation Techniques*

3D-printed soft silicone bifurcation models were used with a bifurcation angle of 70° and diameters of 4 mm, 3 mm, and 3 mm for the pMB, dMB, and SB, respectively. A representative illustration of the bench model tests is provided in Figure 1.

2.4.3 | *Simulation of Main Branch Perforation*

2.4.3.1 | *Test #1: Crossover Stenting With PCS*

In Test #1 primary main branch rupture was simulated ($n = 7$). PCS (3.5 mm) was implanted in the main branch, excluding the SB. POT was performed using a 4.5 mm noncompliant balloon. SB was penetrated with high tipload CTO wires (Confianza Pro 12 or Infiltrac Plus 14), supported by a 120° angulated microcatheter (Supercross 120°, Teleflex, Wayne, Pennsylvania, USA). Then, kissing dilation was performed with two 3.0 mm NC balloons (Figure 2).

Final OCT and angioscopy were performed toward both the dMB and the SB.

2.4.3.2 | *Test #2: Crossover Stenting With PCS, SB Optimized With DES*

In Test #2, the optimization of residual SB ostial stenoses caused by cover-material overhang was simulated ($n = 3$). As a continuation of Test #1, a Orsiro drug-eluting stent (DES) (3.5 mm) (Biotronik, Bülach, Switzerland) was implanted in the SB. POT was performed using a 4.5 mm NC balloon. MB was rewired, then kissing dilation was performed with two 3.0 mm NC balloons (Figure 2).

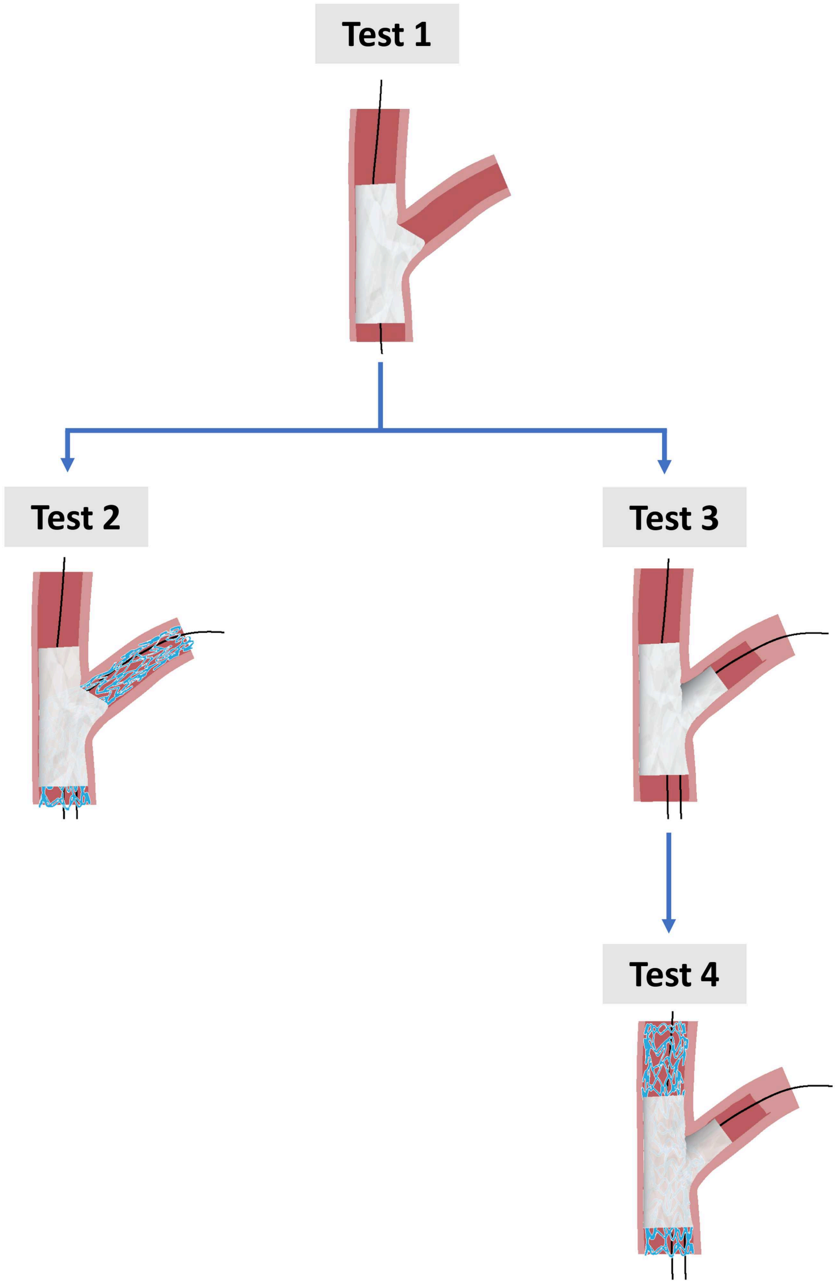


FIGURE 1 | Representative illustration of the bench test. Test 1 simulates a perforation in the main branch and demonstrates crossover implantation of a Papyrus-covered stent graft in the main branch, followed by fenestration of the side branch and subsequent kissing balloon inflation. Test 2 represents a continuation of Test 1, completed using the DK-Culotte technique with implantation of a drug-eluting stent (DES). Test 3 simulates a perforation involving both the main and side branches and builds upon the scenario in Test 1. It is completed using the DK-Culotte technique with implantation of a second Papyrus-covered stent graft, followed by fenestration of the graft and subsequent kissing balloon inflation. Test 4 extends Test 3 with additional implantation of a DES in the main branch, followed by kissing balloon inflation. [Color figure can be viewed at wileyonlinelibrary.com]

Final OCT and angioscopy were performed toward both the dMB and the SB.

2.4.3.3 | *Test #3: Double Stent PCS*

In Test #3, concomitant SB perforation was simulated ($n = 3$). As a continuation of Test #1, a PCS (3.5 mm) was implanted in the SB. POT was performed using a 4.5 mm NC balloon. MB was penetrated with high tipload CTO wires (Confianza Pro 12 or Infiltrac Plus 14), supported by a 120° angulated microcatheter. Then, kissing dilation was performed with two 3.0 mm NC balloons (Figure 2).

Final OCT and angioscopy were performed toward both the dMB and the SB.

2.4.3.4 | *Test #4: Double Stent PCS, MB Optimized With DES*

In Test #4, the optimization of residual dMB ostial stenoses caused by cover-material overhang was simulated ($n = 3$). As a continuation of Test #3, a DES (3.5 mm) was implanted in

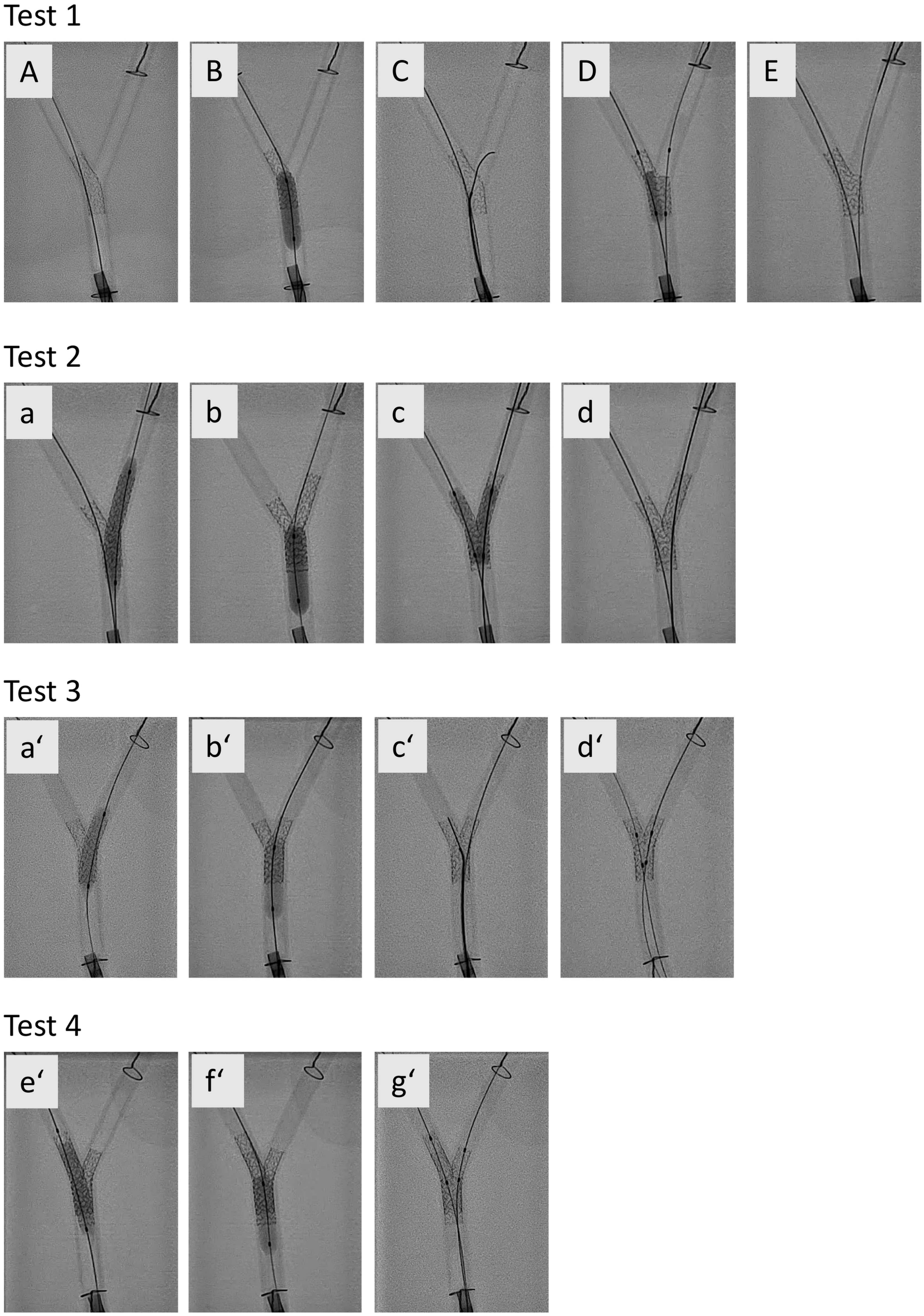


FIGURE 2 | Representative fluoroscopic images of the procedural steps during the bench test. In this silicon bifurcation model, Test 1 starts with implantation of a Papyrus stent graft in the main branch (A), followed by proximal optimization therapy (POT) (B), with subsequent penetration of the graft with a high tip load wire with the support of an angulated microcatheter (C). Afterwards, kissing balloon inflation is performed (D). (E) shows the Papyrus graft after fenestration and kissing balloon inflation. In the second row, Test 2 represents the continuation of Test 1, with completing the procedure in a DK-Culotte technique by implantation of a drug-eluting stent (DES) in the side branch (a), followed by POT (b), rewiring, and kissing balloon inflation (c). (d) shows the completed DK-Culotte procedure with the Papyrus graft in the main branch and a DES in the side branch. In the third row Test 3 represents the continuation of Test 1 with completing the procedure in a DK-Culotte technique by implantation of a second Papyrus into to side branch (a′), followed by POT (b′), subsequent penetration of the graft into the main branch with a high tip load wire with the support of an angulated microcatheter (c′) and kissing balloon inflation (d′). In the fourth row, Test 4 continues Test 3 with implantation of a DES in the main branch (e′), followed by POT (f′) and kissing balloon inflation (g′).

TABLE 1 | Performance of guide wires to penetrate the PK Papyrus graft.

Wire type	Duration of the attempt	Success	Tip damaged (at the end of the attempt)	Microcatheter crossing
Infiltrac Plus	60 s	Yes	No	Yes
	13 s	Yes	No	Yes
	11 s	Yes	No	Yes
Confianza Pro	14 s	Yes	No	Yes
Pilot 200	5 min	No	No	No
	1 min 39 s	Yes	No	Yes
	5 min	No	No	No
	4 min 05 s	Yes	No	No
Fielder XT-A	5 min	No	No	No
	5 min	No	No	No

TABLE 2 | OCT measurements of lumen areas of the pMB, dMB, and SB.

	Minimal area pMB (mm^2)	Minimal area dMB (mm^2)	Minimal area SB (mm^2)	% area reduction dMB	% area reduction SB
Test 1: Crossover Papyrus MB	11.13 ± 0.34	6.56 ± 0.23	5.33 ± 0.76	−8%	−25%
Test 2: DK-Culotte Papyrus MB + DES SB	11.51 ± 2.35	6.32 ± 0.58	6.50 ± 2.35	−11%	−8%
Test 3: DK-Culotte Papyrus MB + Papyrus SB	11.02 ± 1.54	6.58 ± 0.81	6.01 ± 0.17	−7%	−15%
Test 4: DK-Culotte Papyrus MB + Papyrus SB + DES MB	11.82 ± 0.61	7.71 ± 0.58	6.32 ± 0.22	+9%	−11%

Abbreviations: DES, drug-eluting stent; dMB, distal main branch; MB, main branch; pMB, proximal main branch; SB, side branch.

the MB. POT was performed using a 4.5 mm NC balloon. SB was rewired, supported by a 120° angulated microcatheter. Then, kissing dilation was performed with two 3.0 mm NC balloons (Figure 2).

Final OCT and angioscopy were performed toward both the dMB and the SB.

3 | Results

Wire penetration abilities are summarized in Table 1. Wires with hydrophilic coating and with a tip load higher than 12 g showed the most reliable penetration performance. Confianza Pro penetration was successful after 14 s and with Infiltrac Plus after 60, 13, and 11 s. Pilot 200 could penetrate after 1 min 39 s and 4 min 5 s. The microcatheter could be advanced only one time. Two further attempts with Pilot 200 were unsuccessful. Similarly, Fielder XT-A failed to penetrate the PK Papyrus graft.

All bifurcation tests were successfully performed. OCT runs were obtained in all bench models. MLAs of the pMBs, dMBs, and SB after the tests are summarized in Table 2. Both in Test #1 and Test #3, after the fenestration of the PCS and after kissing balloon inflation, cover-material overhang was observed at the level of the SB or dMB ostia, causing lumen reduction (5.33 ± 0.76 mm and 6.58 ± 0.81 mm MLA, respectively) (Figures 3 and 4). In Test #2 and Test #4, these residual stenoses could be corrected with the implantation of an additional DES toward the SB or MB as appropriate (6.50 ± 2.35 and 7.71 ± 0.58 mm MLA, respectively) (Figures 3 and 4).

The angioscopy analysis revealed similar results (Table 3). In Test #1 (Video S2) and Test #3, after the fenestration of the PCS and kissing balloon inflation, overhanging cover material in the SB or in the dMB ostium resulted in lumen area reduction (−38.2% and −41.6%, respectively). After the optimization of the residual SB or dMB stenoses with DES in Test #2 (Video S3) and Test #4, the percentages of lumen reductions improved (−27.8% and −17.2%, respectively) (Figure 5).

4 | Discussion

Implantation of a covered stent is typically a life-saving maneuver in case of a mid-vessel rupture. Still, in case of involvement of a relevant bifurcation, "jailed" covered-stenting might put a so far not impacted myocardial territory at risk. In the present paper, we aimed at bench-testing various

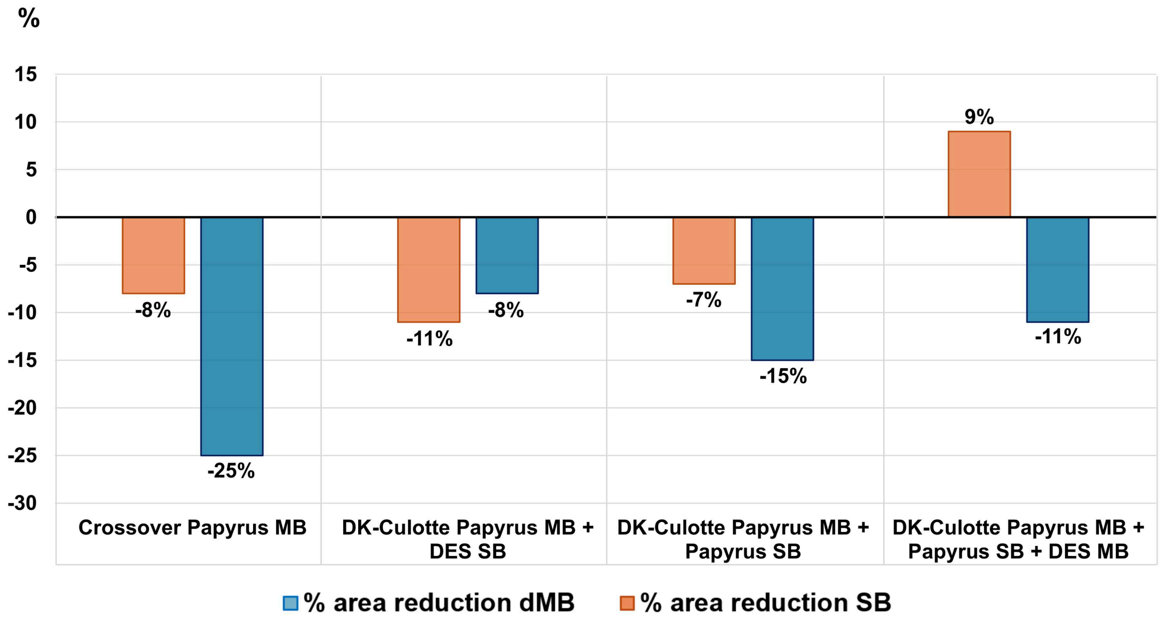


FIGURE 3 | Percent lumen area reductions in the distal main branch (dMB) and side branches (SB) (Tests 1–4) as assessed by optical coherence tomography (OCT). This figure presents the percent lumen area reductions in the dMB and SB across Tests 1–4, as assessed by OCT. All percentages are calculated relative to a theoretical reference area of 7.06 mm^2, corresponding to a vessel diameter of 3.0 mm, as defined by the model dimensions of both the dMB and the SB. [Color figure can be viewed at wileyonlinelibrary.com]

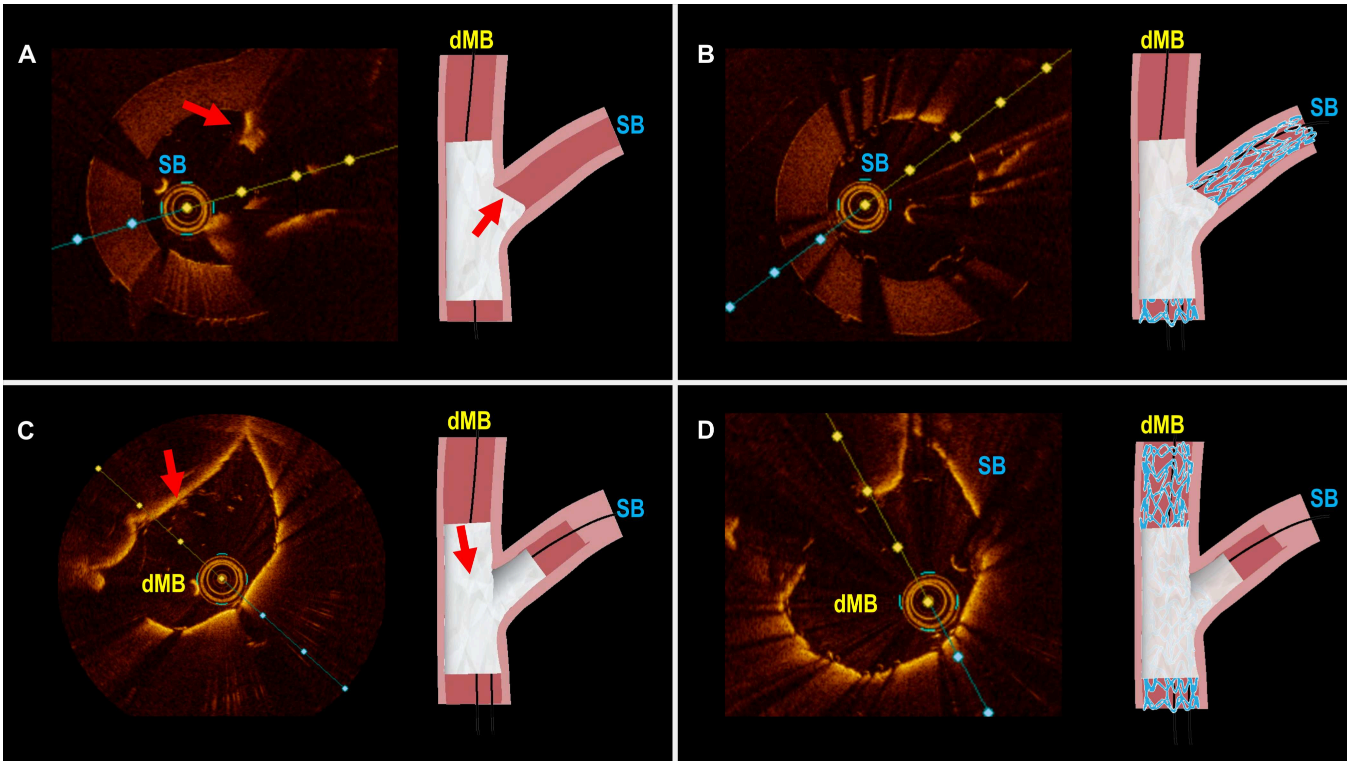


FIGURE 4 | Optical coherence tomography (OCT) images of overhanging graft material after fenestration of the graft. In Test 1, overhanging graft material (red arrow) is visible on OCT pullback from the side branch into the main branch following penetration of the covered stent into the side branch and subsequent kissing balloon inflation (A). After completing the procedure using a DK-Culotte technique with a DES, the graft material was successfully excluded in Test 2 (B). In Test 3, overhanging graft material (red arrow) is observed in the main branch after a DK-Culotte technique with two Papyrus-covered stents (C). Following DES implantation in the main branch, the graft material was excluded in Test 4 (D). [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 | Scope analysis of the dMB and SB.

	% area reduction dMB	% area reduction SB
Test 1: Crossover Papyrus MB	−20.3%	−38.2%
Test 2: DK-Culotte Papyrus MB + DES SB	−13.9%	−27.8%
Test 3: DK-Culotte Papyrus MB + Papyrus SB	−41.6%	−17.2%
Test 4: DK-Culotte Papyrus MB + Papyrus SB + DES MB	−17.2%	−13.5%

Abbreviations: DES, drug-eluting stent; dMB, distal main branch; MB, main branch; pMB, proximal main branch; SB, side branch.

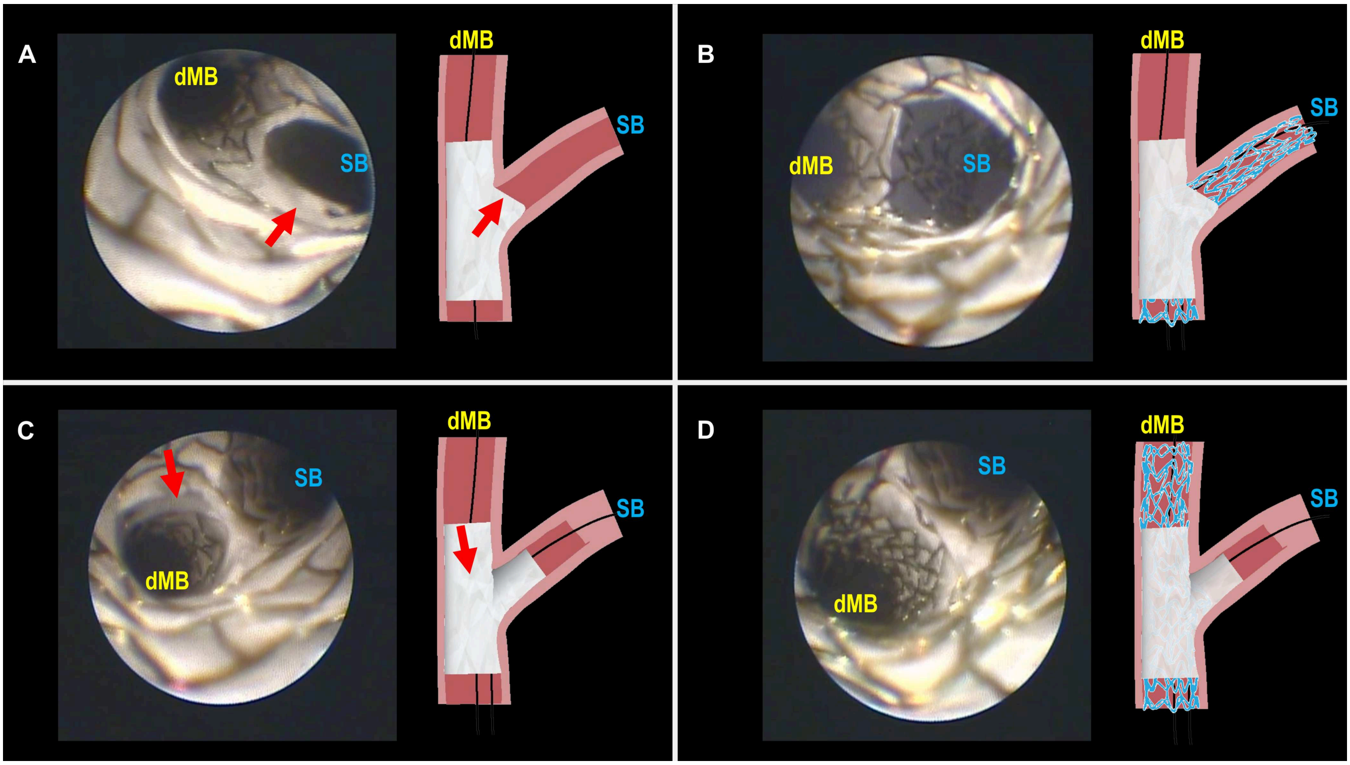
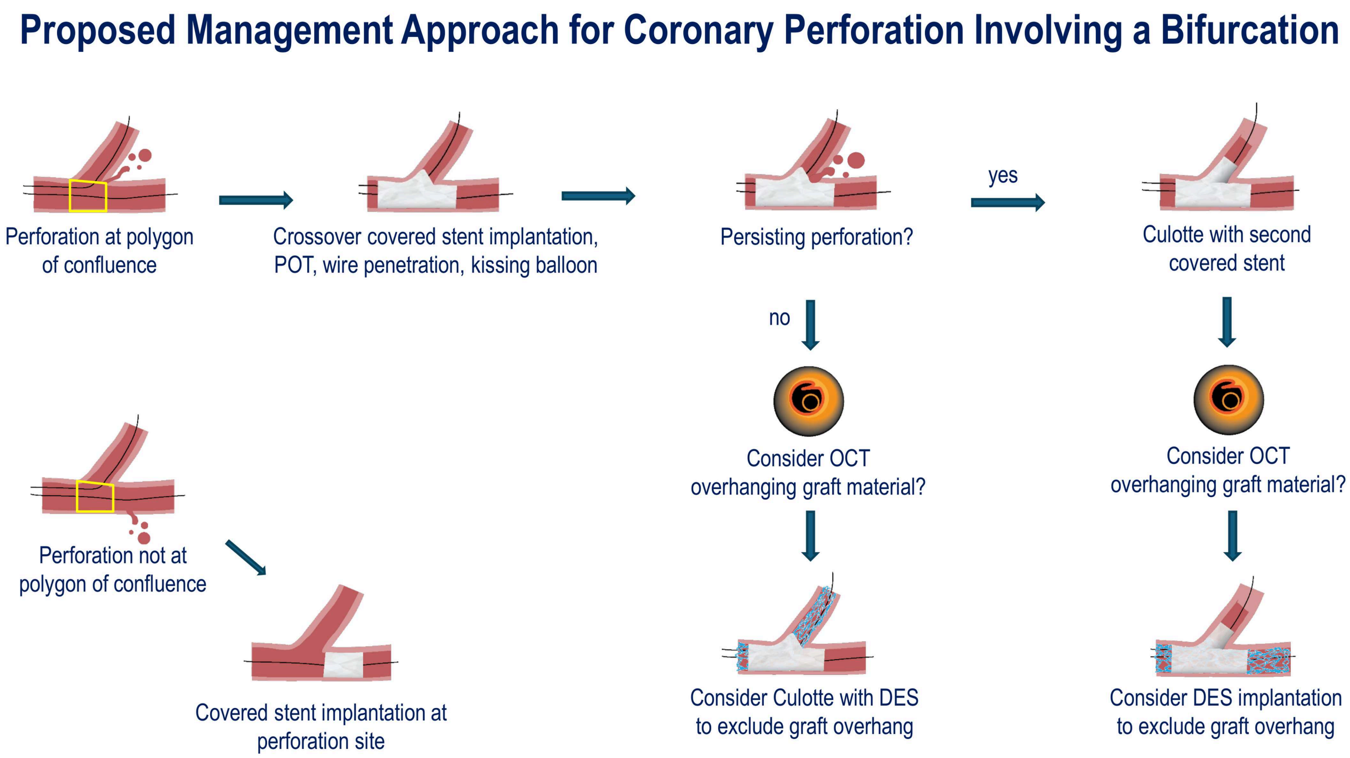


FIGURE 5 | Angioscopic images of overhanging graft material after fenestration of the graft. In Test 1, overhanging graft material (red arrow) is visible on angioscopy from the side branch into the main branch following penetration of the covered stent into the side branch and subsequent kissing balloon inflation (A). After completing the procedure using a DK-Culotte technique with a DES, the graft material was successfully excluded in Test 2 (B). In Test 3, overhanging graft material (red arrow) is observed in the main branch after a DK-Culotte technique with two Papyrus-covered stents (C). Following DES implantation in the main branch, the graft material was excluded in Test 4 (D). [Color figure can be viewed at wileyonlinelibrary.com]

bail-out methods and how access to the jailed territory can be reestablished with the least waste of time, which is essential in such an emergency situation. Accordingly, the following were demonstrated:

1. Addressing perforations at the level of a bifurcation stenosis is feasible with various bifurcation techniques using the PK-Papyrus covered stent platform.
2. High tip-load wires effectively penetrated the cover material of the stent into the SB, especially when directed and supported by an angulated microcatheter.
3. Crossover implantation of a covered stent followed by fenestration toward the jailed branch may lead to overhanging cover material at the SB ostium.
4. Implantation of a conventional DES toward the jailed branch in a DK-Culotte fashion can scaffold the overhanging cover material to achieve a favorable final result for both daughter branches.

Perforation at the level of a bifurcation is fortunately not a complication that happens frequently [1]. Still, when it occurs, there is no time for delay, and only immediate reaction can be life-saving. In the literature, several case reports have described the successful management of coronary perforations at bifurcation sites with covered stent graft implantation and subsequent fenestration [6–12]. Still, "standardized" stepwise approach and toolbox have not yet been described, although in an emergency situation, there is no time for experimenting. This gap was aimed to be filled by the present document.



CENTRAL_ILLUSTRATION 1 | This is a proposed practical management approach for coronary perforation involving a bifurcation. First, the exact site of perforation should be identified. If the perforation does not involve the polygon of confluence, seal the site with a covered stent without crossover the bifurcation. If the polygon of confluence is affected, crossover implantation of a covered stent into the main branch. After stent deployment, perform proximal optimization technique, followed by penetrating the covered stent into the side branch using a high tip-load wire supported by an angulated microcatheter. Perform kissing balloon inflation. Subsequent angiography should assess for persistent contrast extravasation. If no ongoing perforation is observed, perform OCT to assess for any overhanging graft material at the side branch ostium. If overhanging material is detected, completion of the procedure using a DK-Culotte technique with a DES may help to fully exclude the graft material. In cases where the perforation persists, complete the procedure with a second covered stent using a DK-Culotte strategy, including POT, a second penetration of the covered stent toward the main branch, and kissing balloon maneuver. OCT should again be performed to evaluate for overhanging graft material at the main branch ostium. If present, a second DES toward the main branch may be considered to exclude the material. [Color figure can be viewed at wileyonlinelibrary.com]

Once perforation is safely sealed, but the relevant SB gets jailed and closed out by the covered stent, the first and most essential step for restoring flow is the safe and properly targeted rewiring. In most case reports, high tip-load wires effectively penetrated the graft material [6–12]. The PK Papyrus graft material is electrospun rather than a planar membrane. Accordingly, we have tested an escalating sequence of various tip-load wire portfolios. Importantly, safer and softer wires, like Fielder-XT A and Pilot 200, have both failed to penetrate despite microcatheter support. Therefore, in an emergency situation, it is not recommended to make attempts with non-high-tip load wires, because the chance of success is minimal, but important time can be wasted. Very high-tip-load wires (≥ 12 g, i.e., Confianza Pro, Infiltrac) achieved effective penetration with the support of a microcatheter within 11–60 s. An angulated microcatheter can be beneficial due to better control over the penetration point. Alternatively, a dual-lumen microcatheter may be used, though its manipulation is more challenging, as after penetration of the graft material, the microcatheter has to be exchanged rather than directly advanced.

Although intracoronary imaging was performed in some of these cases in the literature, overhanging graft material was not described earlier. Present in-bench testing was modeled with combined multimodal imaging using OCT and angioscopy. That approach allowed a detailed understanding of the exact scenario, revealing the relevant cover-material overhang after fenestration. While its clinical relevance in terms of thrombogenity or restenosis is unknown, one might assume that, optimally, a restored luminal area should be achieved. Here, the efficacy of an additional DES implantation to scaffold the overhanging graft material from the lumen was demonstrated.

4.1 | Practical Management Approach for Coronary Perforation Involving a Bifurcation

We propose a practical step-by-step approach to managing coronary perforation in the setting of a bifurcation (Central Illustration 1). First, the exact site of perforation should be identified, if possible. This may require angiographic assessment in multiple projections.

If the perforation does not involve the polygon of confluence, sealing the site with a covered stent without crossover the bifurcation may be sufficient. However, if the polygon of confluence is affected, crossover implantation of a covered stent into the main branch is necessary. Consider wiring the SB to have a landmark.

After stent deployment, POT should be performed. This is followed by penetrating the covered stent into the SB using a high tip-load wire supported by an angulated microcatheter. Once access to the SB is achieved, the high tip-load wire may be exchanged for a workhorse wire. Consider tip injection to check for luminal positioning of the wire. A kissing balloon inflation should then be carried out.

Subsequent angiography should assess for persistent contrast extravasation. If no ongoing perforation is observed, we recommend performing OCT to assess for any overhanging graft material at the SB ostium. If overhanging material is detected, completion of the procedure using a DK-Culotte technique with a DES may help to fully exclude the graft material.

In cases where the perforation persists, we suggest completing the procedure with a second covered stent using a DK-Culotte strategy, including POT, a second penetration of the covered stent toward the main branch, and kissing balloon maneuver. OCT should again be performed to evaluate for overhanging graft material at the main branch ostium. If present, a second DES toward the main branch may be considered to exclude the material.

4.2 | Limitations

This study has certain limitations to be declared. Tests were conducted using an in-bench model, which always gives an idealized scenario compared to real-life conditions. Accordingly, direct translation to in vivo settings should be approached with caution. Additionally, only the PK-Papyrus product was tested in this study, and the findings may not be generalizable to other covered stents due to differences in design and graft materials. Procedures were not tested to determine whether the covered stents remained leakproof, particularly since this can only be evaluated in the presence of blood flow. However, the devices were not over-expanded at any location except within the fenestrated stent cells. Therefore, no findings suggest a potential risk of leakage.

Identifying the SB for re-entry remains a major challenge. In the bench setting, the puncture site is directly visible; however, in vivo, several risks must be considered: (1) inadvertent wire passage outside the vessel through the rupture site, (2) subintimal tracking with subsequent spiral dissection, and (3) distal coronary perforation caused by a stiff guidewire. Wiring and/or stenting the SB before covered stent implantation may provide a reliable anatomical landmark to facilitate accurate puncture alignment. This strategy could help mitigate these limitations and warrants further investigation in future studies.

5 | Conclusion

In this bifurcation perforation in-bench model, high tip-load wires effectively penetrated covered stents toward excluded branches after crossover covered stent implantation. Conversion to a DK-Culotte approach, using either a DES or a second covered stent, was feasible. Overhanging graft material following side-branch fenestration could be addressed by overstenting with a DES.

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Conflicts of Interest

Rayyan Hemetsberger has received speakers' honoraria from Boston Scientific, Biotronik, Abbott, Abiomed, Schockwave, Cordis, and BBraun outside the present work, and institutional research grants from Boston Scientific, Abbott, and Cordis. Daniel Lootz is an employee of Biotronik. Nader Mankerious has received speakers' honoraria from Biotronik outside the present work. Christian Hengstenberg has received proctoring/speaker fees from Boston Scientific and Edwards Lifesciences; and has received institutional research grants from Abbott, Boston Scientific, Edwards Lifesciences, and Medtronic. Tom W. Johnson received consultancy and speaker fees from Abbott Vascular, Boston Scientific, and Terumo, and research grants from Abbott Vascular outside the present work. Gabor G. Toth received consultancy fees from Abbott, Medtronic, Biotronik, Boston Scientific, and Terumo outside the present work. The other authors declare no conflicts of interest.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.

Video 1: Wire penetration test. Penetration of a Papyrus covered stent (Biotronik) with a high tip-load wire (Confianza 12, Asahi) penetrate supported by an angulated microcatheter (Supercross 120°, Teleflex). **Video 2:** Angioscopy Test #1. Angioscopy showing overhanging graft material at the side branch (SB) ostium after main branch stenting with a covered stent, followed by wire penetration towards the SB and kissing balloon inflation (Test #1). **Video 3:** Angioscopy Test #3. Angioscopy after completion of Test #1 with a double-kiss Culotte technique using a drug-eluting stent (DES) in the side branch. No overhanging graft material is now detected after exclusion with the DES.