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Original Article

# Assessment of Coronary Bifurcation Stenting using Optical Coherence Tomography

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## ABSTRACT

**Introduction:** Percutaneous coronary intervention (PCI) in coronary bifurcation lesions (CBL) is challenging and has poorer outcomes compared to non-bifurcation lesions. Conventional angiography alone is insufficient to assess procedural results because of poor resolution and complex anatomy involving bifurcations. We evaluate the use of optical coherence tomography (OCT) during bifurcation PCI to evaluate procedural results. **Methods:** This single-center, prospective, observational study included 13 patients with 14 CBLs undergoing PCI (one-stent or two-stent strategy) who were evaluated with OCT. After stent placement, OCT was used to assess acute stent malapposition, underexpansion, stent edge dissection, tissue protrusion, and microthrombi. To study malapposition in detail, bifurcation region was divided into four segments (proximal, distal and bifurcation segments of main vessel and side-branch segment). **Results:** The overall incidence of stent malapposition was 64%. It was more common with two-stent strategy compared to one-stent strategy (83% vs 50%). The incidence of malapposition was highest in side-branch and least in distal segment of main vessel. Stent underexpansion was seen in 21% of cases. Stent edge dissection, microthrombi, tissue prolapse were noted in 21% of cases. OCT findings led to additional interventional steps in 38% of cases. **Conclusions:** OCT can be used to comprehensively assess procedural results after bifurcation stenting. The incidence of acute stent malapposition is high after stenting at bifurcation sites and is more common when the two-stent techniques are used compared to the one-stent technique. Whether long-term clinical outcomes are affected by findings uncovered on OCT needs to be studied in prospective trials.

**Key words:** Optical coherence tomography; Coronary bifurcation; Stent malapposition; Stent underexpansion; Percutaneous coronary intervention; Percutaneous transluminal coronary angioplasty.

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## INTRODUCTION

Coronary bifurcation lesions constitute about 15 - 20% of total percutaneous coronary interventions (PCI).[1] Bifurcation PCI is technically challenging despite improvement in techniques and devices. Side-branch occlusion occurs in about 10% of bifurcation PCI cases.[2] The long-term clinical outcome is also poor in these cases compared to non-bifurcation PCI.[3,4] Conventional coronary angiography has several limitations in assessing this complex bifurcation site, both before and after PCI.[1] Intravascular imaging has helped in better assessment of bifurcations lesions and improved procedural outcomes.[5,6] Recently, with frequent use of high-resolution optical coherence tomography (OCT), these lesions can be better-assessed pre- and post-PCI.[1,7] We evaluate the use of OCT for PCI optimization in bifurcation lesions, using provisional one-stent and elective two-stent strategies.

## METHODS

This is a single centre, prospective observational study of 13 consecutive patients undergoing bifurcation PCI, who were assessed with OCT. Patients of more than 18 years of age, undergoing PCI of de-novo coronary bifurcation lesions, with main vessel diameter ranging from 2.5- 4 mm, side-branch diameter of ≥ 2 mm, treated with one or two-stent strategy were included in the study. Those patients with hemodynamic instability or shock, baseline creatinine ≥ 2 mg/dL, bleeding diathesis, coagulopathy, recent stroke, hypersensitivity or contraindications to contrast agent, and pregnancy were excluded from the study. Coronary lesions with heavy calcification, large thrombus, total occlusion, excessive tortuosity or another stent within 10 mm of target lesion were also excluded.

Institute's ethics committee clearance was obtained before enrollment of the eligible patients. Baseline data such as demographic profile, clinical presentation, risk factors for coronary artery disease, electrocardiogram (ECG), 2-dimensional echocardiography, routine serum biochemistry tests, and creatine kinase MB (CKMB) were recorded in all the patients. OCT imaging of bifurcation lesion was performed at baseline and following PCI. The rapid exchange C7 DragonFly™ OCT catheter was connected to a frequency-domain OCT system (C7-XR FD-OCT™ Imaging System, LightLab Imaging Inc., Westford, Massachusetts) and advanced over a 0.014″ coronary guidewire. Images were acquired at an automated pullback speed of 20 mm/s and a frame rate of 100 Hz during contrast flushing and were digitally stored to be analyzed offline.[8] Before PCI, OCT pullbacks of both the main vessel and the side-branch were acquired in all patients. Reference vessel diameters (proximal and distal main vessel and side-branch), minimal luminal diameter, percentage diameter stenosis, and lesion length were calculated. PCI was done using either the provisional one-stent strategy or elective two-stent strategy based on the operator's discretion. Standard angioplasty techniques including post-dilatation, final kissing balloon inflation and proximal optimization technique (POT) were used in each case to achieve optimal angiographic results. After stent placement, OCT catheter pullback was performed in all the 14 main vessels and the 6 side-branches which were stented. Post-PCI OCT imaging of the side-branch was not performed in those with the single-stent strategy. All patients received FDA-approved Xience Everolimus-eluting stent (Abbott Vascular, Santa Clara, California).

Stent malapposition was defined as a stent-wall (the gap between the stent strut and the arterial wall inner surface) distance of > 200 µm.[9,10] The bifurcation lesion was divided into four segments (Figure 1) for detailed strut analysis of malapposition. In each segment, the total number of struts and number of malapposed struts were counted.[11] A cross-sectional level analysis was done to identify stent underexpansion in various segments of the bifurcation site. Stent was said to be underexpanded when the stent expansion index was less than 0.8. Stent expansion index was defined as the ratio of observed in-stent lumen diameter to the manufacturer predicted stent diameter according to the maximum inflation pressures used, including post-dilation.[9,12] Other OCT findings like microthrombi, tissue prolapse/protrusion, and dissections involving stent edges and the side-branch ostium were also recorded. Thrombus was defined as intraluminal mass ≥200 µm, with no direct continuation with the surface of the vessel wall with dorsal shadowing.[13-16] Tissue protrusion was defined as tissue extrusion through the stent struts.[13] Edge dissection was defined as the presence of a linear rim of tissue, with a width of ≥200 µm and a clear separation from the vessel wall or plaque that was adjacent (< 5 mm) to a stent edge.[9,15] Electrocardiogram, echocardiography, CK-MB levels and renal function tests were repeated in all patients following PCI. All patients had a clinical follow-up for 6-months following discharge.

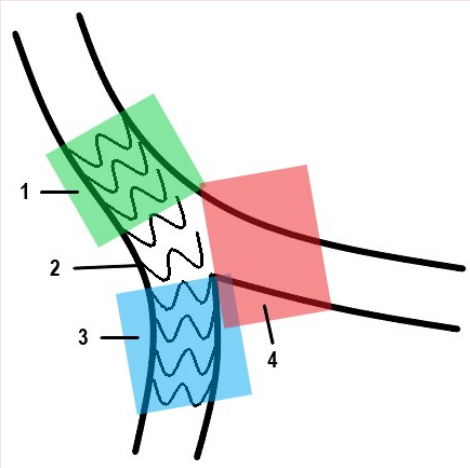


**Figure 1:** Segments at a bifurcation for OCT analysis. (1) Proximal, (2) bifurcation, and (3) distal segments of the main vessel; (4) Side-branch segment.

## RESULTS

Thirteen patients of mean age 61 ± 9 years, 10 men and 3 women, having 14 bifurcation lesions were enrolled in the study. Out of 14 bifurcations, ten (72%) were true bifurcation lesions where both the main vessel and the side-branch had > 50% stenosis [Medina (1,1,1) or (1,0,1) or (0,1,1)]. General and procedural characteristics are summarized in Table 1. The provisional one-stent strategy was adopted in 8 cases (57.1%) and elective two-stent stenting in 6 cases (42.9%). The techniques used for bifurcation stenting was mini-crush in 3 lesions (50%); and Culotte, TAP (T- And Protrusion) and V-stenting in 1 lesion, each. A total of 22 stents were deployed: 16 in the main vessels and 6 in the side-branches.

All the 14 main vessels and side-branches were individually assessed by OCT, prior to stenting. Six-patients had pre-dilatation of the lesion (6 main vessels, 2 side-branches) prior to baseline OCT imaging (Table 2). After stenting, repeat OCT was done to assess the luminal area and malapposition at 4 bifurcation segments defined earlier (Figure 1; Tables 2, 3 & 4). Stent malapposition was observed in 64.3% of cases (Figure 2; Table 3). It was most frequent in the side-branch segment. The proximal segment of the main vessel is the next common site for malapposition. Stent underexpansion was seen in 21.4% of the cases. Minor edge dissection and small thrombi were seen in 2 and 3 patients, respectively. Based on OCT findings, 5 (38%) patients had additional intervention in form of post-dilatation for optimal PCI results. Additional kissing balloon inflation was done in 2 (14.3%) patients with both main vessel and side-branch stents. No additional stents were deployed based on OCT findings. There was no post-procedural MI (as per CK-MB levels) in any of the patients.

Mean contrast usage per patient was 197±71 ml (one-stent vs. two stent strategies: 268±14 ml vs. 136±28 ml) out of which 53±18 ml was used for OCT runs (one-stent vs. two stent strategies: 69±8 ml vs. 39±7 ml). However, none of the patients developed contrast-induced nephropathy in our study (mean creatinine pre-procedure vs. post-procedure: 0.96 vs. 1.07). This is probably due to the lower baseline risk of developing contrast-induced nephropathy among the patients included in the study.

There were no major adverse cardiac events (MACE) such as cardiac death, non-fatal MI, target vessel revascularization or stent thrombosis in any of the patients during the 6-month clinical follow-up period.

**Table 1:** General and procedural characteristics of the study population.

| No. of patients (n) | 13 |
|---|---|
| Age (years) | 61 ± 9 |
| Male gender | 10 (77%) |
| **Risk Factors** | |
| Hypertension | 8 (62%) |
| Diabetes mellitus | 4 (31%) |
| Hypercholesterolemia | 6 (46%) |
| Family history of cardiovascular disease | 1 (8%) |
| Active smoking | 2 (15%) |
| Previous percutaneous coronary intervention | 2 (15%) |
| **Clinical Presentation** | |
| MI | 4 (31%) |
| Unstable angina | 3 (23%) |
| Stable angina | 6 (46%) |
| **Target vessel** | |
| Left anterior descending coronary artery | 2 (17%) |
| Left circumflex coronary artery | 8 (66%) |
| Right coronary artery | 2 (17%) |
| Ejection fraction | 53 ± 9.1 |
| **Bifurcation lesions analysed (n)** | 14 |
| **Bifurcation site** | |
| LAD/Diagonal | 11 (78.6%) |
| LCX/OM | 2 (14.3%) |
| RCA/PD | 1 (7.1%) |
| True bifurcation | 10 (72%) |
| **Bifurcation stenting strategy** | |
| Provisional one-stent | 8 (57%) |
| Elective two-stent | 6 (43%) |
| **PCI details** | |
| Stent length (mm) | 27 ± 8.1 |
| Stent diameter (mm) | 2.9 ± 0.5 |
| **Pre-dilatation before OCT** | |
| Main vessel | 6 (42%) |
| Side branch | 2 (20%) |
| Procedural success | 100% |

Data presented as mean ± standard deviation or n (%).
LAD: Left anterior descending artery; LCX: Left circumflex artery; MI: Myocardial infarction; OCT: Optical coherence tomography; OM: Obtuse major; PD: Posterior descending.

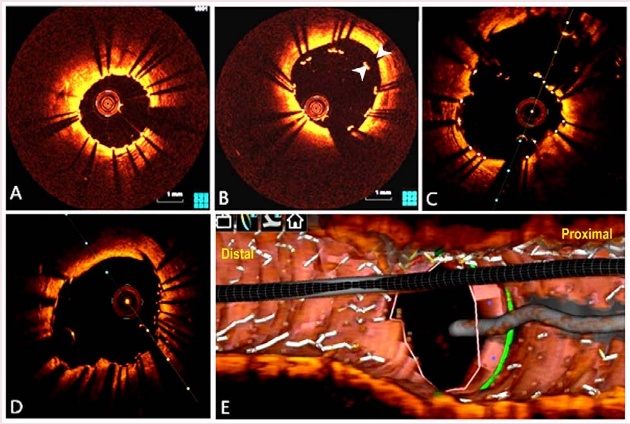


**Figure 2:** OCT images. *Provisional stenting strategy* (One stent in the main vessel): Well apposed stent in the distal segment of the main vessel (A); Malapposed stent (arrow heads showing the gap between stent strut and the inner surface of vessel wall) in the proximal segment of the main vessel (B). *Elective two-stent strategy:* Stent struts seen in the bifurcation segment following T-stenting (C); Stent strut layers in the proximal segment of the main vessel following Culotte stenting (D); Three-dimensional reconstruction of bifurcation segment showing coronary guidewires in both the main vessel and the side-branch following Culotte stenting (E).

**Table 2:** OCT data before and after stent implantation.

| OCT parameter | Main vessel | | | Side branch | | |
|---|---|---|---|---|---|---|
| | Pre-PCI (n = 14) | Post- PCI (n = 14) | P value | Pre-PCI (n=14) | Post-PCI (n=6) | P value |
| Reference vessel diameter (mm) | 3.1 ± 0.3 | 3.2 ± 0.3 | 0.592 | 2.4 ± 0.2 | 2.3 ± 0.2 | 0.16 |
| Minimal luminal diameter (mm) | 1.4 ± 0.2 | 2.9 ± 0.3 | 0.001 | 1.5 ± 0.6 | 2.2 ± 0.2 | 0.01 |
| Diameter stenosis (%) | 55.2 ± 7.9 | 7.2 ± 6.7 | 0.001 | 40.3 ± 21.0 | 6.1 ± 3.5 | 0.01 |

OCT: Optical coherence tomography; PCI: Percutaneous coronary intervention.

**Table 3:** Stent malapposition observed with OCT.

| Vessel segment | N | Malapposition |
|---|---|---|
| Main Vessel | 14 | 9 (64.3%) |
| Distal Segment | 14 | 4 (28.6%) |
| Proximal Segment | 14 | 7 (50.0%) |
| Bifurcation Segment | 14 | 6 (42.9%) |
| Side-Branch | 6 | 4 (66.7%) |
| Overall* | 14 | 9 (64.3%) |
| **Bifurcation PCI Technique** | | |
| Provisional one-stent | 8 | 4 (50.0%) |
| Elective two-stent | 6 | 5 (83.3%) |

One-stent vs two-stent technique: P = 0.238
*Some cases showed malapposition in more than one segment
OCT: Optical coherence tomography; PCI: Percutaneous coronary intervention.

**Table 4:** Cross-section level and strut level analysis of OCT data.

| | Overall | Distal segment | Bifurcation segment | Proximal segment | Side-branch segment |
|---|---|---|---|---|---|
| **Cross-section level analysis** | | | | | |
| Analysed cross-sections (n) | 664 | 243 | 78 | 246 | 97 |
| Mean lumen area ($mm^2$) | 6.56 ± 1.08 | 6.01 ± 1.01 | 7.24 ± 1.39 | 7.88 ± 1.58 | 5.13 ± 0.90 |
| Mean stent area ($mm^2$) | 6.35 ± 1.11 | 5.62 ± 0.97 | 6.81 ± 1.32 | 7.34 ± 1.50 | 4.51 ± 0.69 |
| Stent underexpansion, n (%) | 3 (21.4%) | 0 | 1 (7.1%) | 3 (21.4%) | 0 |
| **Strut level analysis** | | | | | |
| Analysed struts (n) | 6802 | 2504 | 704 | 2693 | 901 |
| Malapposed struts, n (%) | 81 (1.2%) | 5 (0.2%) | 21 (3%) | 41 (1.5%) | 14 (1.6%) |
| Malapposed distance (mm) | 0.27 ± .02 | 0.25 ± 0.03 | 0.27 ± 0.02 | 0.29 ± 0.05 | 0.26 ± 0.01 |

# DISCUSSION

## Stent Malapposition

Stent malapposition is a frequent OCT finding in bifurcation lesions. Its incidence varies from 40 - 80% with provisional one-stent technique and is higher with two-stent technique.[11,17-20] We observed it in 64% of cases. Four out of 8 (50%) patients with provisional one-stent technique and 5 out of 6 (83.3%) patients with two-stent technique had malapposition in the present study. To the best of our knowledge, the incidence of acute stent malapposition following two-stent strategy in bifurcation PCI using dedicated side-branch OCT pullback has not been reported before.

Overall, malapposition was most frequently noted in the side-branch (66.7%) followed by the proximal segment of the main vessel (50%). The distal segment showed the least incidence of malapposition (28.6%). In the provisional stenting strategy, the proximal segment showed the highest incidence of stent malapposition (50%) because only a main vessel stent was deployed. Similar findings were reported in a study by Burzotta et al using provisional stenting strategy.[17] Interestingly, two other studies had reported that the side-branch ostium showed the highest malapposition with provisional strategy.[19,21] However, in both these studies, the bifurcation segment of the main vessel (as defined in the present study) was further divided into two halves for analysis: one facing the side-branch ostium and the other opposite the side-branch ostium. Technically, stent struts at the side-branch ostium are "jailed struts" overhanging the side-branch ostium and are excluded from malapposition analysis in the more recent studies.[11] If these struts were excluded from the analysis, the proximal segment shows the highest incidence of malapposition.

Simply reporting the presence or absence of malapposition does not give any information on the extent of the problem. In this regard, more recent studies report percentage malapposed struts ("Malapposition burden") in each segment after a strut level analysis.[11] We observed that the bifurcation segment showed the highest percentage of malapposed struts (3%) followed by the proximal segment (1.6%) whereas the distal segment showed the least (0.2%). In the side-branch, 1.5% struts were malapposed. A study of 12 patients using provisional strategy, Sgueglia et al reported that the proximal and bifurcation segments (4.5% combined) show the highest percentage of malapposed struts.[11] The J-REVERSE OCT sub-study also showed similar findings.[20] Malapposition is frequent after bifurcation stenting because of the complex anatomy at these sites involving three different vessel sizes in a small area. Because of the vessel tapering across the bifurcation site, the selection of stent size in the main vessel is usually a compromise between the two sizes of proximal and distal vessel. When a stent is deployed in the main vessel, it conforms to the lumen of the distal segment more tightly than it does in the proximal segment. This explains the higher malapposition rates in the proximal and bifurcation segments when compared to the distal segment. It also explains the higher rate of tissue prolapse (because of a higher stent-to-artery ratio) in the distal segment observed in a previous study.[17] The two-stent strategy presents additional problems because of stent-stent interaction, extra stent-strut layers in the main vessel and bifurcation angle affecting stent conformation in both the main vessel and the side-branch. However, in our study, there was no statistically significant difference in malapposition burden between the one-stent and two-stent groups probably because of small patient number.

Stent malapposition is more readily detected by OCT compared to IVUS.[22] Registry-based studies and smaller single center OCT studies of stents presenting with thrombosis have consistently identified stent strut malapposition as a major underlying cause of stent thrombosis.[23-28] However, in prospective studies, acute malapposition was not found to be an independent predictor of stent thrombosis.[29,30] Most of these studies are based on non-bifurcation lesions. The risk of extensive stent malapposition is higher in bifurcation PCI as found in this study and therefore likely to be more clinically relevant. This hypothesis needs to be confirmed by prospective studies.

Sub-group analysis based on risk factors, clinical presentation or bifurcation stenting strategy was not possible in this study because of low patient number. Factors likely to influence malapposition rates are vessel and stent characteristics, techniques and strategy of bifurcation stenting used and possibly, presentation with acute coronary syndrome due to time constraints, priority to flow establishment and less frequent use of post-dilation or kissing balloon dilations. An adequately powered study is needed to assess the influence of these factors on malapposition rates and outcomes.

### Other features on OCT

Stent underexpansion was seen in 3 cases (21.4%). Burzotta et al reported stent underexpansion in 47% of the lesions (39% minor and 9% major) using provisional strategy alone.[17]

OCT also disclosed additional intracoronary findings undetected by angiography like edge dissections (14.3%), small thrombus (21.4%), tissue prolapse, in-stent dissection, and side-branch ostium dissection. The occurrence of stent malapposition and other adverse features did not appear to be related in the present study (p=0.203). In previous studies, edge dissections have been reported in up to 45% of cases and small thrombi in 40-50% cases.[17,18] Findings on OCT led to additional intervention in more than a third of our cases; all in the form of post-dilation with a non-compliant balloon and/or kissing balloon dilation. In one previous study, OCT led to additional interventions in as many as 30% of the cases including 16.4% additional stent deployments and 9.1% kissing-balloon inflations.[17] Larger, adequately powered studies with longer follow-up are needed to fully assess the impact of OCT in bifurcation intervention. We found that OCT use is safe as it did not have any adverse outcome during PCI. Clinical outcomes such as cardiac death, non-fatal MI, target lesion revascularization (TLR) and stent thrombosis did not occur during the 6-month clinical follow-up in our study.

### Limitations of study

The present study is likely to over-estimate the incidence of stent malapposition and underexpansion, because of the limited number of cases. Clinical outcomes cannot be predicted, and sub-group analysis cannot be done with a limited number of cases. Further studies with larger number of patients are required to confirm the role of OCT in the optimization of bifurcation PCI and its clinical significance.

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## CONFLICTS OF INTERESTS

None of the authors has any competing interests or conflicts of interests to declare.

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## ABBREVIATIONS

CBL: Coronary bifurcation lesions, IVUS: Intravascular ultrasound, OCT: Optical coherence tomography, PCI: Percutaneous coronary intervention.

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