ILUMIEN™ OPTIS™ PCI OPTIMIZATION AND OPTIS™ INTEGRATED SYSTEMS

Clinical Compendium

The ILUMIEN™ OPTIS™ PCI Optimization and OPTIS™ integrated systems combine proven fractional flow reserve (FFR) performance to identify culprit lesions for full functional revascularization and leading-edge intravascular optical coherence tomography (OCT) imaging technology to optimize stent implantation through superior visualization.

FFR is the gold standard for physiologic assessment of coronary artery stenosis and has received a class IA recommendation from the European Society of Cardiology and a Class IIA recommendation from the American College of Cardiology. OCT, with a resolution approximately 10 times higher than intravascular ultrasound, allows clinicians to observe various morphological features that could impact physician decision-making. The OPTIS integrated system’s Angio Co-Registered OCT creates a direct link between the angiographic and OCT images.

This compendium summarizes recent key clinical evidence supporting the use of FFR and OCT to optimize percutaneous coronary intervention (PCI).
AN FFR-GUIDED REVASCULARIZATION STRATEGY SIGNIFICANTLY REDUCES MAJOR ADVERSE CARDIAC EVENTS WHILE PROVIDING SUPERIOR ANGINA RELIEF

FFR has been validated in three randomized controlled trials to identify which coronary stenosis will benefit from PCI and which can be safely deferred and managed with medical therapy alone.5-7 FFR guidance has been shown to benefit patients with a wide variety of lesion types and is highly cost-effective.8 A large-scale meta-analysis of FFR-guided treatment of coronary artery disease by Johnson, et al. found that FFR-guided revascularization decreased major adverse cardiac events (MACE) by at least 20% and increased angina relief by at least 10% compared with an anatomy-based strategy.9 The paper, based on the experience at more than 30 institutions worldwide, expands and integrates previous knowledge about the prognostic benefits of FFR.

Prognostic Value of Fractional Flow Reserve: Linking Physiologic Severity to Clinical Outcomes


- The authors hypothesized that there is a continuous relationship between the FFR numeric value and prognosis.
- The hypothesis was tested via a meta-analysis of study-level and patient-level data.
  - A total of 9,173 (study-level) and 6,961 (patient-level) lesions with a median follow-up of 16 months and 14 months, respectively, were included in the study.
- This large-scale meta-analysis demonstrated the clear benefits of an FFR-assisted strategy compared to one based on coronary anatomy alone.
  - Revascularization performed roughly half as often
  - Lowered MACE by at least 20%
  - Provided superior angina relief of at least 10%
- There is an inverse relationship between immediate post-PCI measurements of FFR and subsequent clinical events.
- An FFR-guided revascularization strategy significantly reduces MACE and increases freedom from angina with less PCI or coronary artery bypass grafting (CABG) than an anatomy-based strategy.

Key takeaways:
- FFR value is a continuous and independent marker of subsequent MACE as modulated by medical therapy versus revascularization in a broad range of clinical scenarios incorporating the experience of thousands of patients from more than 12 countries and 15 years of publications.
- A strategy based on FFR leads to revascularization roughly half as often as one based only on coronary anatomy and lowers MACE by at least 20% while providing superior angina relief.
- FFR offers greater absolute benefits to patients for more severe values; the net benefit or risk of PCI for lesions close to the FFR threshold (0.75 to 0.80) is small.
  - Lesions with lower FFR values receive larger absolute benefits from revascularization.
  - When FFR values are high, revascularization can do harm.
- FFR demonstrates a continuous and independent marker for clinical outcomes. Low FFR values indicate an increased risk of events so that the absolute benefit from revascularization is greater. Near normal (high) FFR values indicate a lower risk of events, so that the risk from revascularization procedures equals or even exceeds any potential benefits. The curves cross in between these extremes and provide an outcomes-based FFR optimal threshold where the risks of revascularization are equal to the benefits.
Despite the documented advantages of FFR guidance during PCI, it requires induction of hyperemia to ensure that myocardial resistance is minimal and constant. As a result, clinicians have sought to develop hyperemia-free indices of hemodynamic significance, including the instantaneous wave-free ratio (iFR) and the resting distance coronary artery pressure/aortic pressure (Pd/Pa) ratio.

However, the comparative accuracy of these indices with FFR has been debated. The results of the following large-scale multicenter studies demonstrate that iFR is significantly less accurate than FFR in measuring hemodynamic significance and is not recommended for clinical decision-making alone. Hybrid strategies, including combining Pd/Pa with FFR, may be accurate in predicting ischemia without need for hyperemia in a subset of lesions.

**Does the Instantaneous Wave-Free Ratio Approximate the Fractional Flow Reserve?**


- The objective of this study was to examine the theoretical and clinical relationships between iFR and FFR to determine whether iFR approximates FFR.

- A combination of mathematical modeling and human clinical data was used to compare the two indices.

- Observations from 1,129 patients, including 120 with combined pressure-flow data, were aggregated. Separately, 1,000 Monte Carlo simulations were performed.
  - Monte Carlo modeling allows for exploration of a complex system involving many parameters whose values are uncertain or innately variable.

- Analysis of human clinical data found that iFR systematically overestimates FFR.
  - iFR was 0.09 higher on average than FFR, ± 0.17.
  - Diastolic resting resistance was 2.5 ± 1.0 times higher than mean hyperemic resistance in patients.

- There is a large trade-off between the diagnostic accuracy of iFR and the need for adenosine.

- Both iFR and rest Pd/Pa require similar frequency of adenosine to achieve desired accuracy.

**Key takeaways:**

- iFR should never be used interchangeably with FFR to manage an individual patient.

- There is no perfect iFR cutoff. Each possible threshold involves a compromise between diagnostic accuracy and the need for vasodilatation to measure FFR.

- Resting myocardial resistance does not equal mean hyperemic resistance.

- iFR offers no diagnostic advantage compared with distal pressure at rest averaged over the whole cardiac cycle (rest Pd/Pa).

- Given the relative ease of vasodilatation compared with the profound clinical consequences of an inappropriate decision regarding revascularization, iFR has limited clinical utility.

**Trade-off Between Accuracy and the Need for Adenosine**

A. False-positive (solid black line) and false-negative (dashed black line) rates vary as a function of the iFR cutoff. B. To improve accuracy, a greater proportion of patients must receive adenosine to measure FFR.
The objective of this study was to compare FFR with iFR in patients with coronary artery disease and to determine whether iFR is independent of hyperemia.

FFR and iFR were prospectively measured in 206 consecutive patients referred for PCI. A retrospective analysis was conducted using archived pressure recordings from 500 unselected patients.

Compared to the FFR cutoff value of ≤ 0.80, the diagnostic accuracy of an iFR value ≤ 0.80 was 60% (95% confidence interval [CI]: 53% to 67%) for all vessels studied.

Considering only patients with FFR between 0.60 and 0.90, the diagnostic accuracy of iFR dropped to 51% (95% CI: 43% to 59%).

- iFR values decreased significantly with hyperemia. Two different stenosis with identical iFRs can generate completely different hyperemic gradients and, therefore, different FFR values.

Receiver operating characteristics confirmed that the diagnostic performance of iFR was similar to that of resting Pd/Pa.

Key takeaways:
- iFR correlates weakly in the clinically important range for decision making of 0.60 to 0.90.
- iFR is not independent of hyperemia and changes markedly during adenosine-induced hyperemia.
- The wave-free period of diastole is not equivalent to mean resistance during maximal hyperemia over the complete cardiac cycle, negating the hypothesis underlying iFR.
- iFR has not been validated experimentally or relatively to any of the established noninvasive techniques for identifying reversible myocardial ischemia and cannot be recommended for clinical decision making in patients with coronary artery disease.
Multicenter Core Laboratory Comparison of the Instantaneous Wave-Free Ratio and Resting Pd/Pa with Fractional Flow Reserve: The Resolve Study

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- The objective of this retrospective study was to determine specific iFR and Pd/Pa thresholds with ≥ 90% accuracy in predicting ischemic versus nonischemic FFR based on an FFR cutoff point of 0.80.

- iFR, resting Pd/Pa and FFR values measured in 1,593 patients at 15 clinical sites were included in the analysis.

- The optimal iFR cutoff point for FFR ≤ 0.80 on receiver operating characteristic analysis was 0.90 (95% confidence interval: 0.79 to 0.83) and the overall accuracy was 80.4%.

- The optimal Pd/Pa cutoff point was 0.92 (95% confidence interval: 0.80 to 0.84) and the overall accuracy was 81.5%.

- There was no significant difference between both resting measures.

- For greater accuracy using iFR or Pd/Pa, fewer lesions would fall in the adenosine-free zone.

Key takeaways:

- Compared with FFR, the diagnostic accuracy of iFR or Pd/Pa is insufficient to use either parameter for procedural guidance. Approximately 20% of therapeutic decisions would be discordant from FFR.

- Although iFR and Pd/Pa are imperfect surrogates of FFR, they may still provide acceptable accuracy at greater or lesser degrees of functional stenosis severity – obvious coronary flow impairment or absence of any resting flow disturbance.

- There were no significant differences in the sensitivity, specificity, positive predictive value, negative predictive value or diagnostic accuracy between iFR and Pd/Pa.
Clinical Usefulness of Nonhyperemic Baseline Pd/Pa as a Hybrid Baseline Pd/Pa-Fractional Flow Reserve Strategy


- The objective of this study was to evaluate clinical outcomes using a hybrid strategy of baseline Pd/Pa and FFR compared with FFR alone to guide revascularization.

- A total of 570 lesions from 527 consecutive patients who had Pd/Pa and FFR measured were retrospectively evaluated.

- Patients were categorized into treatment, deferral, and undetermined groups based on their baseline Pd/Pa. Patients in the undetermined group were assigned to FFR-guided treatment or referral based on an FFR cutoff value of 0.80.

- Using a deferral based Pd/Pa value of 1.0 and a treatment baseline Pd/Pa value of < 0.86 and limiting use of adenosine to patients with a baseline Pd/Pa value between 0.87 and 0.99 would prevent the need for adenosine in 14.6% of lesions and 14.0% of patients.

  - Both the positive and negative predictive values for this strategy were 100%, thus, maintaining 100% agreement with an FFR-only strategy.

  - The adenosine-free population could be increased to 59.1% if agreement with FFR were reduced to 91%.

Key takeaways:

- It is challenging to evaluate the functional significance of a coronary stenosis with baseline Pd/Pa alone.

- A hybrid approach using baseline Pd/Pa and FFR to guide revascularization can reduce the need for adenosine, but only in a small fraction of patients.

- The cutoff value of nonhyperemic indices should be determined carefully because it can lead to under-treatment of functionally significant lesions or unnecessary PCI in physiologically insignificant lesions.
**FFR CAN PROVIDE INSIGHT INTO THE TREATMENT OF PATIENTS WITH ACUTE CORONARY SYNDROME**

Most studies of FFR have involved stable patients exclusive of acute coronary syndrome. The question of whether the hemodynamic significance of nonculprit lesions can be assessed reliably in the setting of acute myocardial infarction is currently under investigation. Recent papers have discussed the advantages of an FFR-guided strategy in the assessment of acute coronary syndrome, including nonculprit lesions in the settings of acute care and intermediate follow-up.

**Fractional Flow Reserve for the Assessment of Nonculprit Coronary Artery Stenoses in Patients With Acute Myocardial Infarction**


- This study investigated the reliability of FFR assessment of nonculprit coronary stenosis during PCI in acute myocardial infarction. A total of 101 patients undergoing PCI for an acute myocardial infarction (ST-segment elevation myocardial infarction [STEMI], n = 75; non-ST-segment elevation myocardial infarction [NSTEMI], n = 26) were prospectively recruited.
- FFR measurements were performed immediately after PCI of the culprit stenosis in 112 nonculprit stenosis in 101 patients. Patients underwent a second catheterization, and the measurements were repeated 35 ± 4 days later.
- The FFR value of the nonculprit stenosis did not change between the acute and follow-up visits (0.77 ± 0.13) in both cases. In only two patients, the FFR value was higher than 0.8 in the acute phase and 0.75 at follow-up.
- There was no significant difference in the FFR values acutely and at follow-up between STEMI and NSTEMI patients. Similarly, there was no significant change in the FFR measurements in “angiographically intermediate stenoses” (40% to 70%) between the acute and follow-up phases (0.79 ± 0.10 vs. 0.78 ± 0.10, p = NS).
- The reproducibility of the FFR values measured in the acute phase and at follow-up) was superior compared with the reproducibility of the angiographic percentage diameter of stenosis (r = 0.91, P < 0.0001 compared with r = 0.78, P < 0.0001).

**Key takeaways:**
- In this study, FFR measurements in nonculprit coronary artery stenosis did not change significantly when measured in the acute phase and follow-up visits.
- The severity of nonculprit stenoses can be reliably and safely assessed acutely with FFR.
- Acute assessment of nonculprit lesions might improve risk stratification and clinical decision-making about the need for additional revascularization.

**Multivessel PCI in STEMI: Ready to be the Recommended Strategy?**


- This review article discusses the available evidence regarding optimal management of nonculprit lesions in STEM patients undergoing primary PCI.
- In general three approaches have been defined for use in hemodynamically stable STEMI patients with multivessel disease.
  - Aggressive: PCI on the nonculprit lesion during the index procedure
  - Intermediate: Nonculprit PCI or CABG as a staged procedure during the index hospital stay or within 30 days
  - Conservative: Nonculprit PCI only in case of refractory symptoms or objective detection of ischemia
- STEMI patients with multivessel disease are very heterogeneous. However, available data and subsequent post hoc pooled analysis favor an intermediate approach with angiographic- or FFR-driven staged nonculprit revascularization.
- The recent PRAMI (Preventive Angioplasty in Acute Myocardial Infarction) study found that an aggressive preventive angioplasty strategy in nonculprit lesions was superior. It is important to note that PRAMI essentially compared the most aggressive strategy with a conservative strategy. The intermediate approach was not tested in the study.

**Key takeaways:**
- Because STEMI patients with multi-vessel disease are so varied, no study will be able to fully define a common strategy. Optimal decision making should ideally involve the heart team.
- Currently, an intermediate approach with angiographic – or FFR-driven assessment of nonculprit lesions in patients with STEMI is associated with the best clinical outcomes and is still used by the majority of physicians.
- Physiological evaluation of nonculprit lesions using FFR should be encouraged to define the right targets for revascularization.
Fractional Flow Reserve and the Index of Microvascular Resistance in Patients With Acute Coronary Syndromes


- This review article discusses what is currently known about the use of FFR and related coronary indices in patients with acute coronary syndromes including STEMI and NSTEMI.

- The use of FFR to assess culprit and/or nonculprit lesions in the setting of acute coronary syndrome is controversial due to the potential limitations in the ability to induce maximal hyperemia in patients with acute disturbances in the microvasculature.

- Current treatment guidelines have either found no indications for the use of FFR in acute coronary syndromes or recommend avoidance. However, the authors of the current review state that these are examples of the evidence being ahead of the guidelines.

- The review authors make nine recommendations regarding application of FFR in patients with STEMI or NSTEMI. These include:
  - Pressure wire studies in hemodynamically stable patients should not be avoided due to unnecessary concerns over adenosine safety given its short half-life and clinical safety.
  - FFR values in the nonculprit vessels of patients with STEMI may serve as a useful guide to treatment particularly if strongly indicative of ischemia with values < 0.75.
  - If an ischemic FFR value is confirmed in an acute setting, then intervention should be considered on an ad hoc or staged basis. If there is concern about a false negative FFR, then it would be appropriate to consider subsequent noninvasive testing or alternatively a repeat FFR assessment at a later date.
  - Measuring FFR in the nonculprit vessels of patients with NSTEMI is beneficial, just as it is in stable patients.
  - Measuring FFR in the culprit vessel of patients with NSTEMI appears reliable in the acute setting, but requires further study.

Key takeaways:
- Despite the theoretical concerns, the use of FFR is well validated in patients with NSTEMI in both the culprit and nonculprit vessels.
- There are indications in small clinical studies that FFR in nonculprit vessels of patients with STEMI may be a safe and sufficiently accurate modality of assessment.
- Further studies are required and the clinical trials outlined above will add greatly to what is currently known.

Fractional Flow Reserve Application in Everyday Practice: Adherence to Clinical Recommendations


- The objectives of this retrospective cohort study were to evaluate adherence to FFR guidelines in everyday clinical practice and to assess the effect of those decisions on long-term outcomes.

- A total of 189 patients (mean age: 62.5 ± 11.3 years; male: 80.4%) underwent FFR measurements for equivocal lesions during coronary angiography. The median follow-up was 27 months (range: 7-112 months). The clinical presentations were diverse: unstable angina (74.6%), stable angina (16.9%), acute MI (8.5%).

- A functionally significant stenosis was found in only 29.1% (n = 55) patients.

- Both angiography and quantitative coronary angiography measurements were poorly correlated with FFR measurements.

- A total of 18.5% (n = 35) were treated in discordance with FFR results.
  - Twenty-four patients underwent revascularization despite a functionally nonsignificant FFR; 11 patients with a functionally significant FFR were deferred.

- However, there was no significant difference in the cumulative MACE rate at two-year follow-up for patients treated in accordance with the FFR findings compared with those in discordance (3.4% vs. 11.7%, p = 0.23).

- Of the patients who were treated in discordance with the FFR results, 54.3% (n = 19) were slightly above or below the reference cutoff value. Only 2 patients who had an FFR value < 0.75 were treated conservatively; 14 patients with FFR > 0.85 underwent revascularization.

Key takeaways:
- In nearly 20% of cases, there was nonadherence to the FFR results.
- In 51.4% of the nonadherence cases, FFR was considered borderline.
- Despite the considerable contribution that FFR evaluations can make to decision making during coronary angiography, the operator’s subjective judgment may continue to play an important role in selected cases, mainly in the borderline ranges.
- These results should be validated in much larger cohort studies.
OCT-GUIDED REVASCULARIZATION STRATEGY MAY REDUCE NEED FOR STENTING IN SELECT PATIENTS WITH ACUTE CORONARY SYNDROME

The standard of care for early invasive treatment of acute coronary syndrome (ACS) has been to stent the culprit lesion. The goal is to prevent acute vessel closure after reperfusion. However, stenting in itself can result in both acute and late complications. Recently, this approach has been re-examined, and there have been efforts to identify alternative strategies to manage select ACS patients and reduce the use of immediate stenting. OCT has played a key role in two recent papers discussing the management of ACS without stents.\(^{18,19}\) OCT has been shown to enable in vivo analysis of arterial wall structure and atherosclerotic lesions and has demonstrated high sensitivity in thrombus detection.\(^{20}\) It has also been used to image ACS culprit lesions.\(^{21}\)

In the following studies, OCT was used to characterize the thrombus burden, the reference segment lumen area, and the presence of plaque rupture or erosion as part of a strategy to manage ACS without stenting.

Invasive Management Without Stents in Selected Acute Coronary Syndrome Patients With a Large Thrombus Burden: A Prospective Study of Optical Coherence Tomography Guided Treatment Decisions


- The objective of this study was to assess whether an OCT-guided strategy that avoided the use of stents was safe and feasible in the management of select patients with ACS and a large thrombus.
- Of 852 ACS patients who had undergone coronary angiography, 101 (11.8%) had a large thrombus burden and were included in the study group. These patients underwent thrombectomy to restore blood flow without stenting.
- A decision was made to stent 62% of the patients based on OCT assessment. However, overall 38% (n = 38) of the patients did not receive a stent in the culprit lesion and were treated medically.
- During a minimum follow-up time of 12 months in all patients, there were two MACE events (2%): one man who had been managed medically experienced a nonfatal MI that was treated with a drug-eluting stent; one man managed by angioplasty showed nonfatal ischemic ACS at eight months postprocedure.
- There were no cases of sudden death or myocardial infarction.

Key takeaways:

- Historically, stenting the culprit lesion has been the standard of care in ACS patients.
- However, stenting can be disadvantageous in certain circumstances.
- This study confirmed the feasibility and safety of a two-stage OCT-informed approach to clinical decision making on whether or not to treat the culprit lesion in an ACS patient with a stent or medical management alone.
- The two-stage approach enabled 38% of patients in this select ACS patient population to avoid stenting of the culprit lesion.

OCT-Based Diagnosis and Management of STEMI Associated With Intact Fibrous Cap

Prati F, Uemura S, Souteyrand G, et al. JACC Cardiovasc Imaging, 2013\(^{19}\)

- Because arterial lumen stenosis is not always significant in erosive pathology with an intact fibrous cap, an alternative approach not including stents was assessed.
- In this study, 31 patients at four centers with ST-segment myocardial infarction who were slated to undergo PCI with thrombus aspiration were identified. Of these patients, 12 (40%) patients were managed with thrombus removal and dual-antiplatelet therapy and 19 (60%) were managed with thrombus aspiration and stent implantation. Management decisions were left to physician preference.
- OCT was used to document the underlying plaque anatomy and erosion of the fibrous cap.
- At a median follow-up of 753 days, all patients were asymptomatic, regardless of stent implantation. Target lesion revascularization was performed in one patient in the stent implantation group.
- There were no instances of myocardial infarction, heart failure, or deaths in either group.

Key takeaways:

- Reliable identification of plaque morphology—erosion rather than rupture—in the pathogenesis of some cases of ACS may have practical implications for management.
- OCT could play an important role identifying features of plaque, enabling select patients to be treated with measures that reduce the burden of intravascular thrombus without stenting.
- Early and late complications associated with stenting could be reduced.
- Randomized controlled trials will be needed to clarify the role of therapies not involving stenting in cases of OCT-verified ACS with an intact fibrous cap.
Mechanisms of Atherothrombosis and Vascular Response to Primary Percutaneous Coronary Intervention in Women Versus Men With Acute Myocardial Infarction: Results of the OCTAVIA Study


- Autopsy studies have suggested sex-related differences in plaque morphology responsible for coronary thrombosis. Researchers have also postulated sex-related differences in the response to primary PCI.

- The objective of this prospective, multicenter study was to systematically assess the effect of sex-related differences on the pathophysiology of STEMI and vascular response to primary PCI in men and women. The comprehensive investigation was designed to account for age as a confounding factor.

- A total of 140 age-matched patients (70 men and 70 women) with STEMI undergoing primary PCI with an everolimus-eluting stent were enrolled between January 26, 2011, and January 19, 2012. Baseline characteristics were similar in both groups.

- Primary endpoints were the percentages of culprit lesion plaque rupture at baseline and stent strut coverage as determined by OCT. Secondary endpoints included histopathology and immunohistochemistry measurements, the response to drug-eluting stent implantation and clinical outcomes.

- Clinical examinations were scheduled for 30 days, nine months and one year. OCT was performed after vessel patency was restored (baseline), after stent implantation and at nine-month follow-up.

- At nine-month follow-up, OCT examination found that men and women had similar rates of plaque rupture (50.0% vs. 48.4%, risk ratio: 1.03, 95% CI: 0.73 to 1.47, p = 0.56. Nonruptured/eroded plaques comprised 25% of all cases in men and women, p = 0.86. There were no sex-related differences in the composition of aspirated thrombus and in immune and inflammatory biomarkers.

- Men and women had similar strut coverage at nine months (90.9% vs. 92.5%, 95% CI: 0.4% to 1.3%, p = 0.89. Additionally, there were no significant differences in in-stent neointimal obstruction (10.3% vs. 10.6%, p = 0.76) or clinical outcomes at 30-day or one-year follow-up.

Key Takeaways:
- There were no evident differences in culprit plaque morphology and local or systemic factors associated with acute coronary thrombosis in a cohort of age-matched men and women with STEMI.
- Implantation with an everolimus-eluting stent showed a similar high rate of stent strut coverage in both sexes.
- These findings suggest that disparities in age, risk factors, timing of presentation and management rather than different biological mechanisms and response to treatment might be more relevant in affecting clinical outcome.
- However, the study was not powered to detect differences in clinical outcomes so this result must be interpreted with caution.
Morphological Findings in Typical Variant Angina Presenting as Acute Coronary Syndrome Using Optical Coherence Tomography

- Coronary vasospasm plays an important role in the pathogenesis of variant angina as well as acute myocardial infarction, ventricular tachycardia, and sudden cardiac death.
- This study used OCT to evaluate the morphology of culprit vasospastic lesions in patients seeking treatment at an emergency clinic with chest pain due to vasospastic lesions.
- A total of 20 consecutive patients were enrolled in this prospective study between April 2009 and March 2011. Enrolled patients demonstrated sustained chest pain, transient ST elevation that resolved spontaneously or following nitroglycerine, no significant fixed lesions and positive provocation test for coronary vasospasm and agreed to undergo OCT examination.
- OCT examination found intraluminal microthrombi in 33% (n = 6) patients and intimal erosion in 10% (n = 2) patients.
- All of the lesions displayed fibrous atheromatous plaques with stenosis diameters between 30% and 50%, suggesting that intimal hyperplasia is a basic finding in coronary vessels with vasospasm.
- There was no case with fibrous cap disruption with or without red thrombi in this study.
- C-reactive protein levels were significantly higher in the patients with microthrombi (2.66 ± 3.33 mg/L) compared with those in patients without microthrombi (0.49 ± 0.30 mg/L), (p = 0.022). However, there were no significant differences in serum cardiac troponin-I and other parameters including creatinine kinase, residual stenosis, lesion length and coronary risk factors between the two groups.

Key takeaways:
- Microthrombi with or without intimal erosion were observed in a third of the patients presenting with vasospasm-induced ACS suggesting possible underlying intimal damage even when there are no abnormalities on coronary angiograms.
- OCT is a sensitive imaging technique for identifying intraluminal thrombi and superficial plaque characteristics.
- The finding suggests that in patients with typical variant angina, aspirin might be beneficial in preventing thrombus formation following intimal tear or erosion. Additionally, brief use of systemic anticoagulation may be indicated in some patients.
- Further large-scale studies are required for validations of these findings.

Unrestricted Utilization of Frequency Domain Optical Coherence Tomography in Coronary Interventions

- The objective of this study was to evaluate the safety, success and impact of FD-OCT on patient management in the catheterization laboratory.
- All patients undergoing a coronary interventional procedure at the study center from September to November 2010 were expected to have FD-OCT imaging with the exception of patients with target lesions located at the right coronary or left main ostium, or who had severe tortuosity or other safety concerns.
- There were 176 consecutive interventional procedures during the study period, and OCT was attempted in 150 patients with 297 FD-OCT acquisitions in 155 vessels.
- With the exception of the aorta-ostial lesions, the overall success rate for OCT acquisition was 85.7% (n = 180) of all target vessels when introducing OCT into the cath lab.
- PCI decisions based on angiography were changed in 81.8% (n = 27) of patients who underwent successful OCT prior to the planned PCI.
- Post-PCI OCT imaging was successful in 99.2% of cases when the target lesion was reached and led to further intervention in 54.8% (n = 68) of cases.
  - Post-PCI OCT revealed strut malapposition in 39.2% (n = 42) of the procedures and 89.4% (n = 47) underwent further balloon dilation.
  - 32.5% (n = 38) of cases had stent edge dissections and 21.1% (n = 8) of these dissections were stented.
  - There were no procedural-related cardiac adverse events.

Key takeaways:
- OCT is safe, can be incorporated into routine practice, and alters procedural strategy in a high proportion of patients undergoing PCI.
- OCT changed the strategy in 81.8% pre-PCI and 54.8% post-PCI target lesions.
- Stent malapposition was detected in 39.2% and edge dissection in 32.5% of the cases.
Impact of Coronary Artery Stent Edge Dissections on Long-Term Clinical Outcome in Patients With Acute Coronary Syndrome. An Optical Coherence Tomography Study


- The objective of the study was to assess the incidence, predictors and long-term prognosis of stent edge dissections identified by OCT after implantation of bare-metal stents and DES.

- A total of 74 patients (50 male and 14 female) undergoing PCI because of ACS had OCT imaging after successful stent implantation.

- A total of 82 stents (38 bare-metal stents and 44 DES) were implanted. Patients were followed in the clinic at one and six months postoperatively and then interviewed yearly by phone.

- Edge dissections were found in 29 of 74 patients (39.1%). Only nine of these dissections were detected by angiography.

- Patients with stent edge dissection had a significantly higher incidence of STEMI, p = 0.005; significantly smaller sized culprit vessels, p = 0.009; and significantly shorter stents, p = 0.013.

- During a mean follow-up of 25.6 ± 9.4 months, event-free survival was significantly decreased in patients with an edge dissection with a flap thickness > 0.31 mm compared with patients with a thinner flap or not dissection, p < 0.001.

Key takeaways:

- Edge dissections were frequently detected by OCT after stent implantation (39.1% of patients) in this first study reporting the impact of OCT-detected stent edge dissections on long-term clinical outcomes.

- STEMI presentation, small reference lumen diameter and implantation of short stents were independent predictors of STEMI presentation.

- Stent edge dissections > 0.31 mm were associated with an adverse prognosis.

- A large-sale study is warranted to confirm the findings in this small single-center study.
OCT AIDS IN OPTIMIZING THE RESULTS OF BIORESORBABLE VASCULAR SCAFFOLD IMPLANTATION

Bioresorbable vascular scaffolds (BVS) have emerged as a potential breakthrough in the treatment of coronary artery lesions. The mechanical properties of BVS differ substantially from those of metal stents and require special attention to lesion preparation and deployment technique for optimal results. OCT is a reliable technique to accurately assess the postimplantation characteristics of coronary stents. In regard to BVS, OCT has been demonstrated superior to intravascular ultrasound for the visualization of scaffold struts and allows for quantification of scaffold expansion and assessment of strut malapposition. The following articles discuss the use of OCT in guiding, assessing and optimizing BVS implantation.

Expansion and Malapposition Characteristics After Bioresorbable Vascular Scaffold Implantation


- The objective of this study was to investigate the postdeployment expansion and malapposition characteristics of BVS in a real-world patient population.
- OCT was performed both before and after scaffold implantation to assess plaque composition, scaffold expansion and strut apposition.
- Manufacturer’s compliance charts were used to predict expected minimal scaffold diameter and area. Predilation (1:1 vessel to balloon) was performed where possible. Post-dilation was only performed when the BVS had a > 15% residual stenosis on conventional angiography.
- OCT assessment determined that BVS achieved 82.5 ± 8.7% of the predicted minimal stent diameter and 79.8 ± 12.3% of the predicted cross-sectional area (SCA). Pre-dilation significantly improved SCA (82.8 ± 9.5%) compared with no predilation (78.6 ± 13.0%), p < 0.0001.
- A total of 7,600 stent struts were visualized of which 6.2% (n = 470) were malapposed.

Key takeaways:
- BVS exhibit similar expansion properties and rates of malapposition compared with historic studies of metallic stents.
- Expansion can be improved with 1:1 predilation.
- OCT assessment determined that 6.2% of BVS stents were malapposed. There was no clear improvement in scaffold expansion or strut apposition in scaffolds that underwent post-dilation.
- OCT can aid in vessel and BVS assessment, although physicians should avoid implantation when optimal lesion preparation cannot be achieved.
- The clinical implications of these findings require further research.

Clinical Utility of Optical Coherence Tomography (OCT) in the Optimisation of Absorb Bioresorbable Vascular Scaffold Deployment During Percutaneous Coronary Intervention


- The objective of this matched case controlled study was to compare the acute performance of BVS with that of second-generation DES in the treatment of complex lesions using OCT to assess stent deployment.
- OCT was used in most cases before stent deployment and repeated when stent expansion was considered angiographically optimal. In the event of suboptimal deployment as assessed by OCT, further interventions were performed. A final OCT scan was then performed.
- The results obtained in 50 lesions treated with 63 BVS in 35 patients were compared with those obtained in 50 lesions treated with 61 DES in 38 patients.
- After the final OCT scan, there were few significant differences in the deployment characteristics of BVS and DES. The minimal and mean lumen areas were similar as were the maximal stent diameters, percentage residual stenosis and eccentricity and symmetry index values. There was also no difference in the overall incomplete strut apposition.

Key takeaways:
- BVS represents a potential breakthrough technology for the treatment of coronary artery disease. However, the mechanical properties of BVS differ from conventional metal stents and differing implant procedures are required.
- In this study, OCT was used pre- and post-deployment to guide stent implantation. There were no significant differences in the deployment characteristics of BVS in DES in a group of patients with complex lesions.
- The results suggest that routine use of OCT can play an important role in ensuring optimal results with BVS.
ABSORB Biodegradable Stents Versus Second-generation Metal Stents: A Comparison Study of 100 Complex Lesions Treated Under OCT Guidance
JACC Cardiovasc Interv, 2014

- The objective of this retrospective study was to determine whether OCT assessment after successful BVS implantation influenced decision making regarding the need for further scaffold optimization.
- Case records of 19 lesions with 29 scaffolds were analyzed to determine whether further intervention was required based on OCT that was performed after what was determined to be an optimal result on angiography.
- Of the 29 BVS analyzed, eight (28%) required further intervention after OCT review, despite previously determined angiographic success. The reasons for further BVS optimization were underexpansion (n = 5, 62.5%) and malapposition (n = 3, 37.5%).
- There were no adverse events associated with OCT imaging.

Key takeaways:
- BVS are an important development in PCI technology and offer potential advantages over metal stents.
- Because of inherent biomechanical differences between BVS and metallic stents, it is imperative to ensure that the scaffold is optimally deployed to maximize successful outcomes.
- OCT identified the need for further BVS optimization in over 25% of patients – despite visually determined angiographic success in all patients.
- More specifically, this OCT study is novel in that it has determined the rates of OCT and defined underexpansion and malapposition associated with BVS.

OCT Assessment of the Long-Term Vascular Healing Response 5 Years After Everolimus-Eluting Bioresorbable Vascular Scaffold
J Am Coll Cardiol, 2014

- The objective of this study was to assess the in vivo vascular healing response five years after elective first-in-man implantation of the ABSORB BVS using OCT.
- Eight of the 14 living patients enrolled in the Thoraxcenter Rotterdam cohort of the ABSORB A study underwent invasive follow-up to include OCT analysis of luminal morphometry, assessment of the adluminal signal-rich layer separating the lumen from other plaque components, visual and quantitative tissue characterization and assessment of jailed side-branch ostia.
- No binary restenosis was observed in the five-year angiograms.
- Scaffold struts were not discernable in any of the eight patients as a result of complete bioresorption, and both the minimum and the mean lumen area increased significantly from two to five years.
- Minimum cap thickness over the necrotic core was 155 ± 90 μm (well beyond the 65 μm threshold that is generally accepted as at high risk for plaque rupture). However, there was plaque progression and discontinuity of this layer.
- All side branches were patent with TIMI flow grade 3. Side-branch ostia were preserved and tissue bridges overlaying the location of the side branch struts had thinned, creating a neo-carina.
- One patient showed a different response to BVS implantation with target-lesion progression and OCT findings consistent with macrophage infiltration, abluminal necrotic core accumulation, fibrous cap thinning and plaque rupture at follow-up. This patient underwent subsequent implantation of a metal drug-eluting stent in a nontarget lesion in the same artery. Signs of accelerated atherosclerosis became evident in the metal stent as well.

Key takeaways:
- Long-term OCT observations of a cohort of patients implanted with BVS suggests favorable vascular healing with late lumen enlargement, increased luminal symmetry, side branch patency, complete strut resorption, and formation of a potentially protective layer consistent with the proposed concept of plaque sealing.
- One of the 8 patients demonstrated a different reaction to BVS implantation that points out the need for further research on a possible responder/nonresponder reaction.
- There is a need to interpret the results of this small study cautiously and for confirmation of the results in larger studies.
Incidence and Imaging Outcomes of Acute Scaffold Disruption and Late Structural Discontinuity After Implantation of the Absorb Everolimus-Eluting Fully Bioresorbable Vascular Scaffold: Optical Coherence Tomography Assessment in the ABSORB Cohort B Trial (A Clinical Evaluation of the Bioabsorbable Everolimus Eluting Coronary Stent System in the Treatment of Patients With De Novo Native Coronary Artery Lesions)

Onuma Y, Serruys PW, Muramatsu T, et al.
J Am Coll Cardiol Intv, 2014

- The objective of the study was to describe the frequency and clinical impact of acute scaffold disruption and late strut discontinuity of bioresorbable polymeric vascular scaffolds (BVS) in the ABSORB cohort B study as assessed by OCT.

- The current analysis includes 51 patients with 143 OCT pullbacks who underwent OCT at baseline and follow-up.

- Acute scaffold disruption was observed in two patients (3.9%), which could have been related to scaffold overexpansion during implantation. Scaffold disruption was seen on IVUS in only one of the cases.
  - One patient experienced recurrent angina at rest and subsequently underwent target lesion revascularization with resolution of symptoms.
  - In the second case, post-PCI OCT revealed overhanging struts. Repeat OCT performed at 6 months demonstrated extremely malapposed struts close to the OCT catheter. The malapposition may have resulted from difficulties in crossing the scaffold during the imaging procedure, though the patient remained asymptomatic at two-year follow-up.

- Late acquired structural discontinuity was observed in 21 scaffolds (49%). On IVUS, late discontinuities were detected in only three cases. There were no major cardiac events associated with late discontinuities except for one patient who had a nonischemia driven target lesion revascularization.

Key takeaways:

- Both acute scaffold disruption and late discontinuity can be detected with OCT.

- Acute scaffold disruption can be categorized as an accidental occurrence resulting from overexpansion and has been anecdotally associated with angina symptoms.

- Late stent discontinuity can be viewed as a consequence of the normal bioresorption process without clinical implications.

- IVUS was less sensitive than OCT in the detection of both acute scaffold disruption and late stent discontinuity in this study.

- OCT might be recommended as an additional diagnostic technique for the assessment of BVS; however, follow-up later than 6 months requires careful use of the imaging device.
Rx Only

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

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