

# Complex High Risk Percutaneous Coronary Intervention in a 54-Year-Old Patient After Surgical Turndown and a Unique Approach to the Heart Team

Aaron Ali Shaikh, MD<sup>1</sup>; Bernardo Cortese, MD, FESC, FSCAI<sup>2</sup>

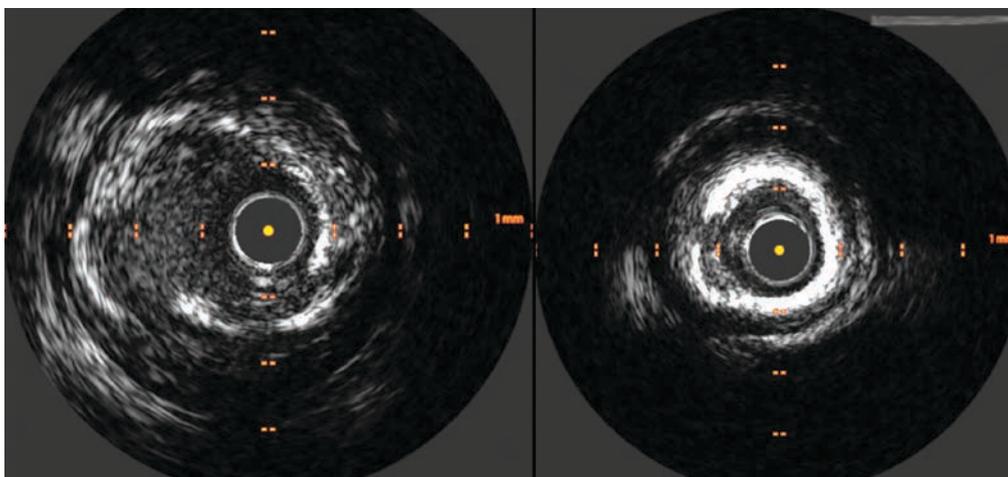
## Patient Presentation

A 54-year-old male with a past medical history of Hodgkin's lymphoma with previous chemo and radiation therapy 22 years ago and type II diabetes initially presented at an

outlying hospital with acute onset dyspnea. An initial electrocardiogram demonstrated atrial fibrillation with rapid ventricular response. He developed hemodynamic instability and was emergently cardioverted to normal sinus



**Figure 1.** Diagnostic coronary angiography demonstrating severe stenosis of the left main coronary artery (LMCA) and left anterior descending (LAD), as well as a chronic total occlusion (CTO) of the circumflex and non-obstructive right coronary artery (RCA) stenosis.



**Figure 2.** Initial intravascular ultrasound (IVUS) demonstrating fibrocalcific disease (left) and circumferential calcium (right).

rhythm. High-sensitivity troponin was elevated to 300 ng/L and trended upwards to >25,000 ng/L. He was admitted to intensive care unit, and redeveloped atrial fibrillation with rapid ventricular response and further hemodynamic instability that degraded to cardiac arrest with pulseless electrical activity. He received 3 minutes of cardiopulmonary resuscitation with spontaneous return of circulation and was initiated on mechanical ventilation, regaining consciousness shortly thereafter. A transthoracic echocardiogram demonstrated reduced left ventricular systolic function with apical hypokinesia.

At the outlying hospital, the patient underwent invasive coronary angiography that demonstrated severe multivessel coronary artery disease involving the entire left main coronary artery, severe diffuse disease in the left anterior descending artery (LAD), and a chronic total occlusion of the circumflex artery with right-to-left collateral flow from the distal right coronary artery that had mild-moderate stenosis in the mid segment. An intra-aortic balloon pump (IABP) was implanted via right common femoral access (Figure 1).

The patient was initially referred for transfer to the tertiary care center of the outlying hospital's healthcare system, but due to logistics, his transfer was significantly delayed. He was then promptly transferred to our tertiary care center, University Hospitals Harrington Heart & Vascular Institute at University Hospitals Cleveland Medical Center, for cardiac surgery consultation. He was extubated shortly after transfer.

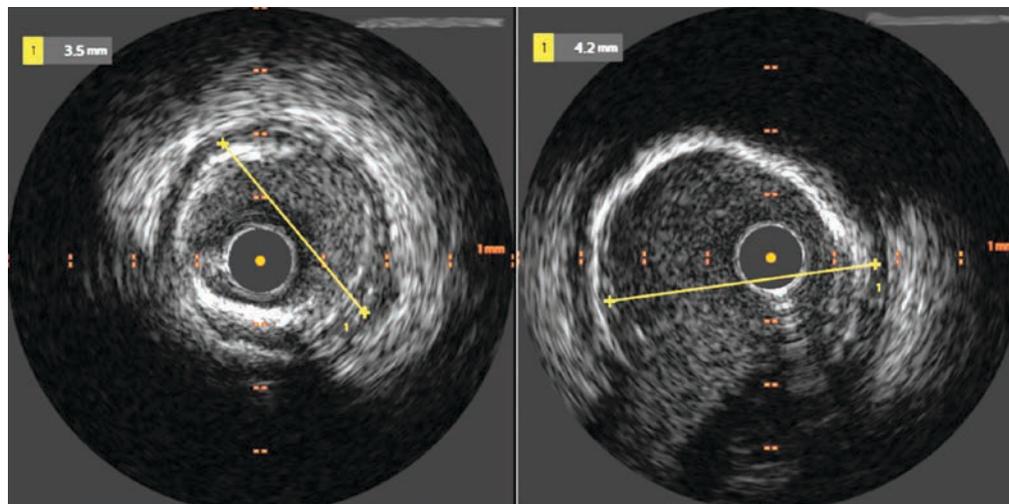
A multidisciplinary heart team discussion was performed immediately online on that Sunday morning. It included the cardiovascular intensive care unit (CICU) attending, the cardiac surgeon, and our team of interventional cardiology, and resulted in the decision of urgent percutaneous revascularization of the left main coronary artery and LAD under IABP assistance because cardiac surgery was refused due to previous radiotherapy. This plan was discussed with the patient who had excellent neurologic recovery and he gave his consent to undergo high-risk percutaneous coronary intervention (PCI).

## Case

A 6 French right radial access was obtained and the left main coronary artery (LMCA) was cannulated. The first diagonal branch was wired and the LAD was wired with a second wire. Pre-dilation from the mid LAD back into the LMCA was performed with 2.0 x 20 mm semicompliant balloon. Intravascular ultrasound (IVUS) was then performed with the Refinity short-tip rotational IVUS catheter (Philips) in the mid LAD into the LMCA, and demonstrated fibrocalcific plaque with segments of circumferential calcium (Figure 2). The distal reference diameter was measured as 3.4 mm in the LAD and proximal reference diameter as 4.2 mm in the LMCA (Figure 3).

Given the fibrocalcific disease visualized on IVUS, we performed plaque modification with a 3.5 x 15 mm Wolverine cutting balloon (Boston Scientific) with several inflations from the mid LAD to the ostium of the LMCA. IVUS re-assessment demonstrated calcium fracture, indicating the lesion was adequately prepared to accommodate a stent (Figure 4).

We then deployed a 4.0 mm x 24 mm Synergy Megatron stent (Boston Scientific)



**Figure 3.** Initial IVUS demonstrating distal reference diameter in the LAD (left) and proximal reference diameter in the LMCA (right).

covering the ostium of the LMCA to the proximal LAD. The mid LAD was treated with 2.75 mm x 15 mm Resolute Onyx stent (Medtronic) deployed just distal to the take-off of the first diagonal branch, with a good final result (Figure 5). Post-stent IVUS demonstrated a minimal stent area of 5.4 mm<sup>2</sup> within the mid-LAD stent and 13.7 mm<sup>2</sup> within the LMCA (Figure 6).

The IABP was removed the following day. The patient was discharged to home post-op day 2 on triple therapy with apixaban in the setting of new-onset atrial fibrillation during the initial presentation. He was seen in the outpatient clinic approximately two months after discharge and was asymptomatic with no clinical evidence of heart failure. Aspirin was discontinued.

<sup>††</sup>Third-party brands are trademarks of their respective owners.

<sup>1</sup>Based on bench test data on file at Medtronic. May not be indicative of clinical performance. N = 7 DES of each tested.

<sup>2</sup>Based on bench test data on file at Medtronic. May not be indicative of clinical performance. N = 5 DES of each tested: Onyx Frontier DES, Orsiro Mission DES, Resolute Onyx DES, XIENCE SkyPoint DES, SYNERGY™ DES.

### Onyx Frontier™ Zotarolimus-Eluting Coronary Stent System Brief Statement Indications

The Onyx Frontier™ zotarolimus-eluting coronary stent system is indicated for improving coronary luminal diameters in patients, including those with diabetes mellitus or high bleeding risk, with symptomatic ischemic heart disease due to *de novo* lesions of length ≤ 35 mm in native coronary arteries with reference vessel diameters of 2.0 mm to 5.0 mm. In addition, the Onyx Frontier™ zotarolimus-eluting coronary stent system is indicated for treating *de novo* chronic total occlusions and non-left main bifurcation lesions utilizing the provisional bifurcation stenting technique.

### Contraindications

The Onyx Frontier™ system is contraindicated for use in: • Patients with a known hypersensitivity or allergies to aspirin, heparin, bivalirudin, clopidogrel, prasugrel, ticagrelor, ticlopidine, drugs such as zotarolimus, tacrolimus, sirolimus, everolimus, or similar drugs or any other analogue or derivative • Patients with a known hypersensitivity to the cobalt-based alloy (cobalt, nickel, chromium, and molybdenum) or platinum-iridium alloy • Patients with a known hypersensitivity to the BioLinX™ polymer or its individual components. Coronary artery stenting is contraindicated for use in: • Patients in whom antiplatelet and/or anticoagulation therapy is contraindicated • Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system.

### Warnings

• Ensure that the inner package has not been opened or damaged as this would indicate the sterile barrier has been breached. • The use of this product carries the same risks associated with coronary artery stent implantation procedures, which include subacute and late vessel thrombosis, vascular complications, and bleeding events. • This product should not be used in patients who are not likely to comply with the recommended antiplatelet therapy.

### Precautions

• Only physicians who have received adequate training should perform implantation of the stent. • Subsequent stent restenosis or occlusion may require repeat catheter-based treatments (including balloon dilatation) of the arterial segment containing the stent. The long-term outcome following repeat catheter-based treatments of previously implanted stents is not well characterized. • The risks and benefits of the stent implantation should be assessed for patients with a history of severe reaction to contrast agents. • Do not expose or wipe the product with organic solvents such as alcohol. • The use of a drug-eluting stent (DES) outside of the labeled indications, including use in patients with more tortuous anatomy, may have an increased risk of adverse events, including stent thrombosis, stent embolization, myocardial infarction (MI), or death. • Care should be taken to control the position of the guide catheter tip during stent delivery, stent deployment, and balloon withdrawal. Before withdrawing the stent delivery system, confirm complete balloon deflation using fluoroscopy to avoid arterial damage caused by guiding catheter movement into the vessel. • Stent thrombosis is a low-frequency event that is frequently associated with MI or death. Data from the RESOLUTE clinical trials have been prospectively evaluated and adjudicated using the definition developed by the Academic Research Consortium (ARC). The safety and effectiveness of the stent have not yet been established in the following patient populations: • Patients with target lesions that were

treated with prior brachytherapy or the use of brachytherapy to treat in-stent restenosis of the stent • Women who are pregnant or lactating • Men intending to father children • Pediatric patients below the age of 18 years • Patients with coronary artery reference vessel diameters of < 2.0 mm or > 5.0 mm • Patients with evidence of an acute ST-elevation MI within 72 hours of intended stent implantation • Patients with vessel thrombus at the lesion site • Patients with lesions located in a saphenous vein graft, in the left main coronary artery, or ostial lesions • Patients with diffuse disease or poor flow distal to identified lesions • Patients with 3 vessel disease. The safety and effectiveness of the stent have not been established in the cerebral, carotid, or peripheral vasculature. Additionally, the safety and effectiveness of using atherectomy devices with the stent have not been established. The effect of potential drug interactions on the safety or effectiveness of the Onyx Frontier™ stent has not been investigated. Potential interactions of the stent with other drug-eluting or coated stents have not been evaluated and should be avoided whenever possible. Clinical studies of the Resolute stent did not suggest any significant differences in safety and effectiveness for male and female patients and did not include sufficient numbers of patients to assess for differences in safety and effectiveness due to ethnicity. Decisions about duration of DAPT are best made on an individual basis and should integrate clinical judgment, assessment of the benefit/risk ratio, and patient preference. Premature discontinuation or interruption of prescribed antiplatelet medication could result in a higher risk of stent thrombosis, MI, or death. Before PCI, if premature discontinuation of antiplatelet therapy is anticipated, physicians should carefully evaluate with the patient whether a DES and its associated recommended DAPT regimen is the appropriate PCI choice. Following PCI, if elective noncardiac surgery requiring suspension of antiplatelet therapy is considered, the risks and benefits of the procedure should be weighed against the possible risk associated with interruption of antiplatelet therapy. Patients who require premature DAPT discontinuation should be carefully monitored for cardiac events. At the discretion of the patient's treating physician(s), the antiplatelet therapy should be restarted as soon as possible.

### Instructions for Stenting of Bifurcation Lesions

The provisional technique of bifurcation stenting recommends a single stent placement in the Main Vessel (MV), finalized with proximal optimization technique (POT). POT includes performing post-dilatation to achieve full apposition of the stent proximal to the bifurcation and reduce the risk of side branch (SB) compromise. If inadequate results are found in the SB such as: threatened SB closure, TIMI flow < 3, dissection type B or worse, or residual stenosis > 30%, the provisional bifurcation stenting technique recommends placing a second stent in the SB as a bailout. As per cardiology societal recommendations, two-stent techniques following single stent provisional bifurcation stenting including T, TAP, and Culotte stenting may be utilized as needed. However, the RESOLUTE ONYX PAS Bifurcation Cohort did not evaluate the safety and effectiveness of two-stent bifurcation techniques, including planned (upfront) two-stent bifurcation techniques (such as DK-crush). Additionally, two-stent bifurcation techniques may introduce additional forces and/or failure modes to the stents, and the performance of the Resolute Onyx stent has not been evaluated under these conditions in nonclinical testing.

### Potential Adverse Events

Other risks associated with using this device are those associated with percutaneous coronary diagnostic (including angiography and IVUS) and

treatment procedures. These risks (in alphabetical order) may include but are not limited to: • Abrupt vessel closure • Access site pain, hematoma, or hemorrhage • Allergic reaction (to contrast, antiplatelet therapy, stent material, or drug and polymer coating) • Aneurysm, pseudoaneurysm, or arteriovenous fistula (AVF) • Arrhythmias, including ventricular fibrillation • Balloon rupture • Bleeding • Cardiac tamponade • Coronary artery occlusion, perforation, rupture, or dissection • Coronary artery spasm • Death • Embolism (air, tissue, device, or thrombus) • Emergency surgery: peripheral vascular or coronary bypass • Failure to deliver the stent • Hemorrhage requiring transfusion • Hypotension/hypertension • Incomplete stent apposition • Infection or fever • MI • Pericarditis • Peripheral ischemia/peripheral nerve injury • Renal failure • Restenosis of the stented artery • Shock/pulmonary edema • Stable or unstable angina • Stent deformation, collapse, or fracture • Stent migration or embolization • Stent misplacement • Stroke/transient ischemic attack • Thrombosis (acute, subacute, or late)

### Adverse Events Related to Zotarolimus

Patients' exposure to zotarolimus is directly related to the total amount of stent length implanted. The actual side effects/complications that may be associated with the use of zotarolimus are not fully known. The adverse events that have been associated with the intravenous injection of zotarolimus in humans include but are not limited to: • Anemia • Diarrhea • Dry skin • Headache • Hematuria • Infection • Injection site reaction • Pain (abdominal, arthralgia, injection site) • Rash

The potential adverse reactions in nursing infants from zotarolimus have not been determined. The pharmacokinetic and safety profiles of zotarolimus in infants are not known.

### Adverse Events Related to BioLinX™ polymer

Although the type of risks of the BioLinX™ polymer coating are expected to be no different than those of other stent coatings, the potential for these risks are currently unknown as the coating has limited previous use in humans. These risks may include but are not limited to the following: • Allergic reaction • Focal inflammation at the site of stent implantation • Restenosis of the stented artery

Please reference appropriate product Instructions for Use for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

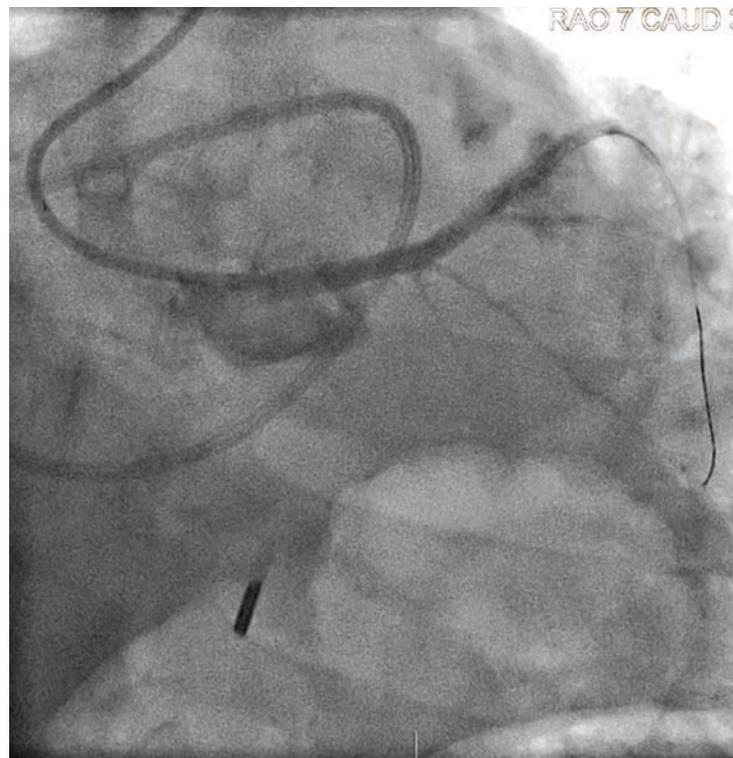
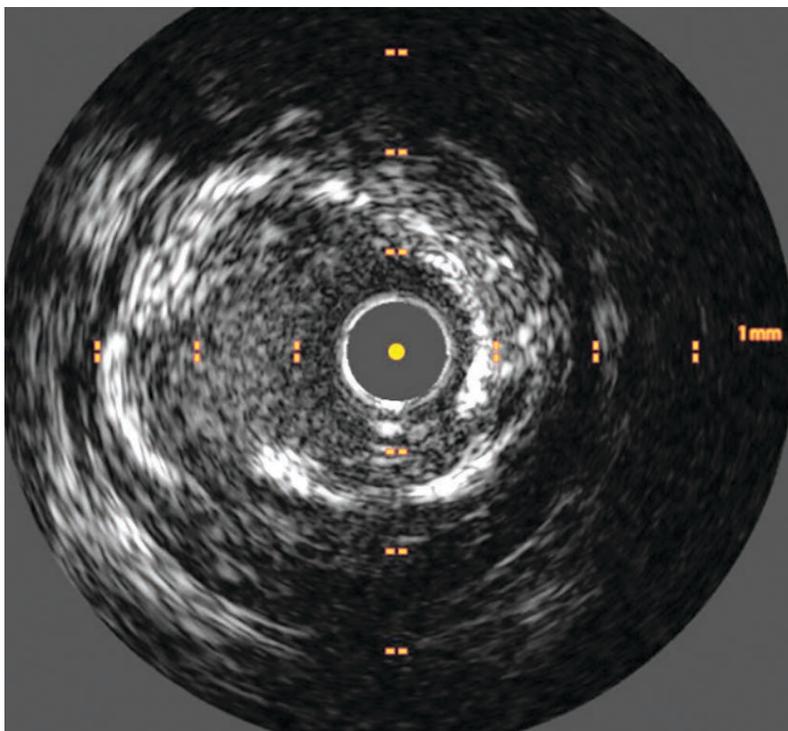
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**Figure 4.** IVUS after cutting balloon angioplasty, demonstrating calcium fracture.

**Figure 5.** Final angiography.

**Discussion**

This case highlights the effective utilization of the heart team approach at our institution. At University Hospitals Harrington Heart & Vascular Institute’s Coronary Center, we schedule weekly heart team discussions, during which patients with complex coronary anatomy and clinical presentation are discussed within a multidisciplinary group of interventional cardiologists, general cardiologists, and cardiac

surgeons. The goal of these discussion is to arrive at a plan — whether surgical, percutaneous, or medical — that is tailored to the individual patient. We longitudinally follow these patients and log their clinical outcomes. A heart team meeting can be at any time of the week due to the need for urgent consultation, because we realized that some patients arrive to our tertiary center with a need for acute intervention. We reserve time each day for the heart team to

*Learn more about this case and high-risk PCI at UH. Read the interview with Bernardo Cortese, MD, FESC, FSCAI:*

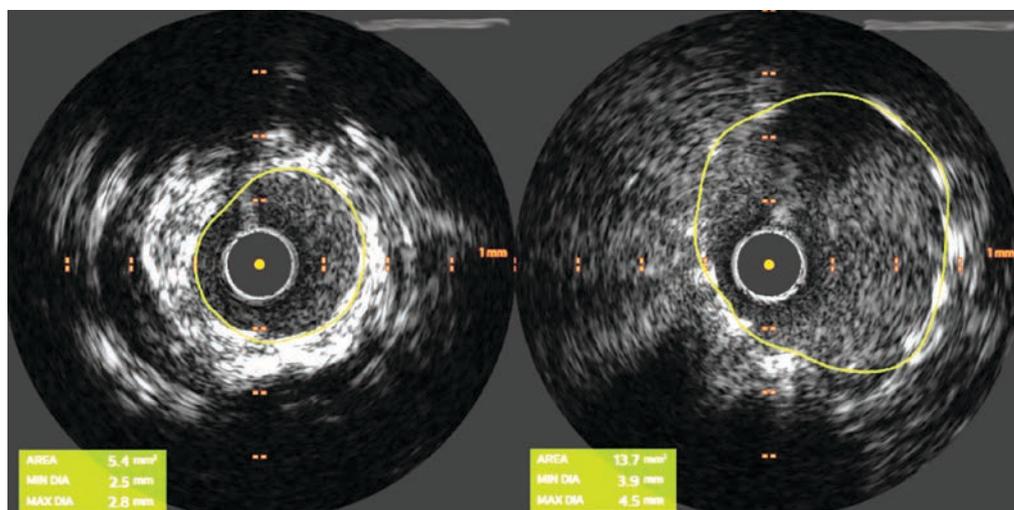


discuss these acute cases on an “as-needed” basis in order to provide efficient and effective care. We term this the Rapid Multidisciplinary Discussion (RMD). The case presented herein was refused by another healthcare system and arrived at our institution on a Sunday morning. It was presented to the RMD that same day and the patient immediately received an imaging-based, high-risk PCI. This efficient delivery of care was the result of nimbleness of our Coronary Center’s approach to the heart team via our unique RMD framework. ■

**Aaron Ali Shaikh, MD<sup>1</sup>; Bernardo Cortese, MD, FESC, FSCAI<sup>2</sup>**

<sup>1</sup>CHIP-CTO Fellow, University Hospitals; <sup>2</sup>Interventional Director of the Coronary Center, University Hospitals Harrington Heart & Vascular Institute, University Hospitals Cleveland Medical Center, Cleveland, Ohio

Dr. Cortese can be contacted at [bernardo.cortese@uhhospitals.org](mailto:bernardo.cortese@uhhospitals.org)



**Figure 6.** Minimal stent area (MSA) in the mid LAD (left) and LMCA (right).