

Algorithm to Deliver Balloons and Microcatheters in an Otherwise Uncrossable Lesion

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Interventional cardiologists frequently encounter the inability to deliver balloons or microcatheters after crossing a stenosis with a coronary guidewire. This dilemma is more commonly encountered in patients with a previous coronary artery bypass grafting (CABG), a history of renal failure, or advanced age. The algorithm to solve this problem includes increasing the guide catheter support; using lower profile balloons or microcatheter; laser atherectomy; and, finally, primary recrossing with a dedicated atherectomy wire to perform orbital or rotational atherectomy procedures.

The 1.0 mm Sapphire® II PRO angioplasty balloon provides an excellent low crossing profile to cross the stubborn plaque when other devices have failed.

The following case examples illustrate the advantages of the Sapphire II PRO balloon and their ability to cross a heavily calcified plaque.

Case 1

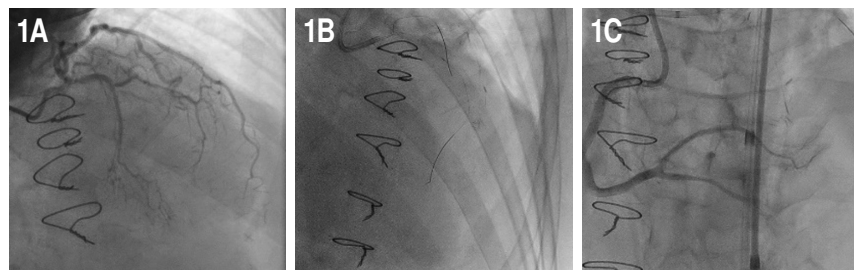
An 81-year-old male was referred after medical therapy failed to control his angina. He had a patent LIMA graft to the distal LAD. The proximal LAD was diffusely diseased and heavily calcified. The SVG to the RCA and the LCx were occluded (Fig. 1A). Fortunately, the native LCx did not have significant stenosis. A nuclear stress test demonstrated ischemia in the RCA territory. Collaterals fed the occluded RCA, but the distal RCA targets were poorly visualized and diffusely diseased. The RCA occlusion was long, calcified, and tortuous and had an ambiguous proximal occlusion cap.

We decided to proceed with a primary retrograde CTO PCI technique to treat the RCA CTO. Multiple attempts to cross the first septal and several epicardial collaterals failed. An angiography from the LIMA to the LAD showed one connecting collateral proximal to the LIMA insertion that fed the right PDA. We crossed the native LAD proximal stenosis with a polymer jacketed wire to the only remaining septal collateral. Unfortunately, the microcatheter and multiple 1.5 x 20 mm balloons failed to cross the proximal LAD lesion despite excellent guide catheter support. The remaining options included laser atherectomy or recrossing the lesion with an atherectomy wire.

While waiting to set up the laser, we attempted a 1.0 x 15 mm Sapphire II PRO balloon, which crossed and dilated the stenosis (Fig. 1B).

The Sapphire balloon's use made it possible to deliver the microcatheter to the septal collaterals distal to the diffusely calcified and highly stenotic proximal LAD lesion, thus avoiding the use of laser.

Once we advanced the microcatheter to the distal RCA branches retrogradely, we completed the procedure with rCART and final stenting with drug-eluting stents (Fig. 1C). The Sapphire II PRO balloon provided an easy, efficient, and cost-effective method to overcome the problem of wire-crossable but balloon-uncrossable plaque.



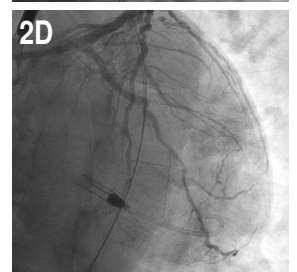
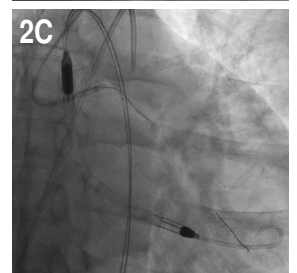
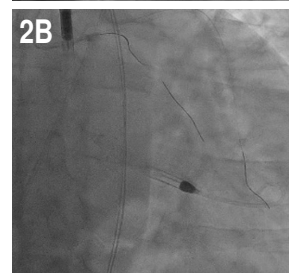
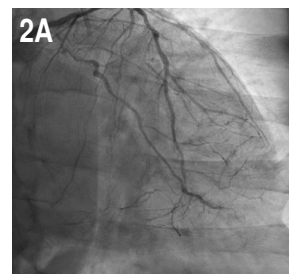
Case 2

A 64-year-old male was referred for multi-vessel PCI from our advanced heart failure service. The patient had known 3-vessel CAD with a 60% stenosis of the proximal LAD with an IFR of 0.64 consistent with physiologically significant disease; CTO of the RCA; and severe proximal LCx stenosis of >90% (Fig. 2A). Cardiac MRI revealed a left ventricular end diastolic diameter of 8.6 cm, EF of 10%, and late gadolinium enhancement of the subendocardium of the inferior wall measuring <25% consistent with viable myocardium*. The patient was considered high risk for surgery, and the heart team recommended high-risk PCI and future consideration of durable LVAD if needed.

Right heart catheterization was performed first, revealing a RA pressure of 4 mmHg, LVEDP of 8 mmHg, and a CI of 2.3 L/min/m². MCS was not placed prophylactically; however, 4 Fr access was obtain in the femoral artery and the PCI was performed using 7 Fr EBU 3.75 guide catheter from the right radial artery. Interventions were planned in a step-wise approach starting with the LCx.

The LCx was wired with a workhorse wire over a microcatheter. The wire crossed the lesion; however, multiple microcatheters would not pass the lesion. Multiple 2.5, 2.0, and 1.5 mm balloons did not cross the lesion as well. We then shifted our plan to anchor in the LAD; however, given the RCA was chronically occluded and the circumflex was subtended, MCS was placed; after ballooning, the LAD was treated with PCI using a 3.5 x 38 mm stent. We then shifted back to the LCx and performed an anchor technique with balloons in the LAD; however, we were unable to pass balloons into the LCx lesion. Finally, a 1.0 mm Sapphire II PRO balloon engaged into the proximal cap with balloon anchoring in the LAD and was inflated to 20 atm. This allowed for a microcatheter to be placed into the lesion and for subsequent free wiring the LCx using a ViperWire Advance® Coronary Guide Wire (Fig. 2B). The workhorse wire was then pulled out and orbital atherectomy using Diamondback 360® Coronary OAS was performed. A total of 3 short runs (24, 18, and 24 seconds) were performed (Fig. 2C). This allowed for angioplasty with good expansion. IVUS demonstrated fracture of the calcium. The LCx was stented using a 3.0 x 20 mm stent. Final coronary angiograms and imaging demonstrated fully expanded stents (Fig. 2D). Post PCI, the patient continues to do well with no hospitalization.

The above examples demonstrate the importance of modern-day complex PCI, emphasizing the importance of key tools in the CHIP toolbox, including imaging, mechanical circulatory balloons, microcatheters, atherectomy, and specialty balloons.



*Ejection fractions less than 25% have not been studied; use with low ejection fractions may require additional precautions due to compromised heart function.

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Indication: The Diamondback 360® Coronary Orbital Atherectomy System (OAS) is a percutaneous orbital atherectomy system indicated to facilitate stent delivery in patients with coronary artery disease (CAD) who are acceptable candidates for PTCA or stenting due to de novo, severely calcified coronary artery lesions. **Contraindications:** The OAS is contraindicated when the ViperWire Advance® Coronary guide wire cannot pass across the coronary lesion or the target lesion is within a bypass graft or stent. The OAS is contraindicated when the patient is not an appropriate candidate for bypass surgery, angioplasty, or atherectomy therapy, or has angiographic evidence of thrombus, or has only one open vessel, or has angiographic evidence of significant dissection at the treatment site and for women who are pregnant or children. **Warnings/Precautions:** Performing treatment in excessively tortuous vessels or bifurcations may result in vessel damage; The OAS was only evaluated in severely calcified lesions, a temporary pacing lead may be necessary when treating lesions in the right coronary and circumflex arteries; On-site surgical back-up should be included as a clinical consideration; Use in patients with an ejection fraction (EF) of less than 25% has not been evaluated. See the instructions for use before performing Diamondback 360 coronary orbital atherectomy procedures for detailed information regarding the procedure, indications, contraindications, warnings, precautions, and potential adverse events. **Caution:** Federal law (USA) restricts this device to sale by, or on the order of, a physician.

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