Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



CATH LAB SPOTLIGHT

Ochsner Medical Center – Kenner

Diverse team, diverse procedures, and cutting-edge technology

Zola M. N'Dandu, MD, Interventional Cardiology Head Section, and Deshinee Mcglothlin, RN, BSN, MHA, Regional Nursing Director of Cardiology/Cath Lab, Kenner, Louisiana

Tell us about your facility and cath lab.

Ochsner Kenner, Louisiana is a 110-bedded facility with two cath labs and a pre/post department. We are part of the John Ochsner Heart and Vascular Institute (JOHVI) service line. Our staff is a diverse group of individuals with international experience and share a common purpose: to save lives. Our team is compromised of cardiovascular technologists and registered nurses (RNs) who have worked together for five years now, but who possess more than 40 years of interventional experience combined.

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CLINICAL TRIAL UPDATE

Disrupt CAD III: Lithotripsy for Vessel Preparation in Calcified Coronary Arteries Prior to Stenting



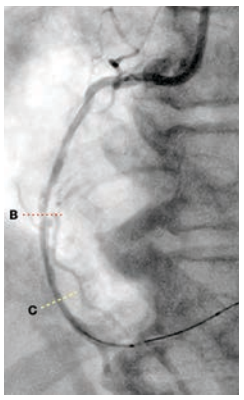
CLD talks with Dean Kereiakes, MD, FACC, FSCAI, Medical Director of The Christ Hospital Heart and Vascular Center and the Christ Hospital Research Institute, Cincinnati, Ohio; Professor of Clinical Medicine, The Ohio State University; Co-Principal Investigator of Disrupt CAD III.

Disrupt CAD III is a prospective, multicenter, single-arm, global investigational device exemption (IDE) study investigating the Shockwave Coronary Intravascular Lithotripsy (IVL) system (Shockwave Medical) in de novo, calcified, stenotic coronary arteries prior to stenting. IVL involves local delivery of sonic pressure waves to crack superficial and deep calcium within the vessel wall. The trial enrolled 384 patients at 47 sites in the United States, France, Germany, and the United Kingdom, including 100 patients in an optical coherence tomography (OCT) sub-study. All data were core-lab adjudicated. Results were presented at the Transcatheter Cardiovascular Therapeutics (TCT) meeting in September 2020 and published in the *Journal of the American College of Cardiology* (*JACC*).[1,2]

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PHYSIOLOGIC MANAGEMENT

OpSens OptoWire III: A Next-Generation Workhorse Pressure Guidewire



Eric A. Osborn, MD, PhD

Invasive pressure-sensing diagnostic wires have been used for decades to evaluate coronary stenosis functional severity in order to overcome the known limitations of visual angiography-based lesion severity assessment.[1]

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OpSens OptoWire III: A Next-Generation Workhorse Pressure Guidewire

Eric A. Osborn, MD, PhD

Of particular value, invasive physiology is able to provide clarity on the functional significance of intermediate lesions with 50-70% angiographic stenosis, a category where angiography visual estimates are approximately a coin toss as to whether or not the lesion is flow limiting.[2] In this way, invasive physiology tools resolve angiographic ambiguity by providing objective data to confidently guide operators on whether to proceed with percutaneous coronary intervention (PCI).[3]

Historically, fractional flow reserve (FFR) has been the essential invasive diagnostic physiology tool to interrogate lesion functional significance. Buoyed by a wealth of long-term data, FFR is associated with improved outcomes and resource utilization for both deferring PCI in non-significant lesions and intervening on those that are flow limiting.[4-6] FFR can reclassify lesions in multivessel disease,[7-9] such that only the flow-limiting stenoses are treated while the other non-obstructive lesions are safely left for guideline-directed medical therapy. More recently, the advent of a class of non-hyperemic pressure ratio (NHPR) metrics simplifies physiology measurements by enabling physiology interrogation at rest without the need for adenosine. NHPR offers reductions in procedural time, cost savings, and less potential patient discomfort, all while demonstrating similar outcomes compared to FFR independent of the NHPR metric utilized.[10-15]

Despite the clear benefits of invasive physiology, pressure wires remain significantly underutilized in routine clinical practice.[16] While several factors are likely responsible, one hindrance is the relatively subpar handling performance of pressure-sensing wires compared to traditional coronary workhorse wires. With increasingly complex coronary cases, pressure wires are being asked to do more than ever during PCI, with demands for favorable performance characteristics similar to standard workhorse wires, such as capability to navigate tortuous vessels and facilitate device delivery in challenging anatomy. Pressure wires must attempt to achieve all of these mechanical advantages while maintaining high-fidelity pressure signal reporting with minimal drift throughout the duration of the procedure. **Current limitations with pressure wire technology continue to motivate the need for new and improved, stable workhorse-like pressure wires for routine, everyday use.**

Built to tackle these challenges, the OptoWire III (OpSens) is a new fiber optic pressure-sensing wire engineered to be a coronary workhorse wire. Compared to other pressure wire designs that employ small, eccentric, stainless steel inner cores, the integral design of the OptoWire III boasts a large, concentric, nitinol inner core that is more akin to the design of typical workhorse wire construction. These physical attributes impart the OptoWire III with improved support, torque response, and control, as well as greater kink resistance over the prior generation, the OptoWire 2. Furthermore, the light-based fiber optic technology employed in the OptoWire III has greater accuracy and minimal pressure drift over traditional wires with mechanical piezoelectric sensors,[17,18] such that the **OptoWire III can be confidently used for repeated physiology measures before, during, and after the PCI.** Finally, OptoWire III can interrogate lesions by both traditional hyperemic FFR with cut-off of <0.80 for significance, or using a non-hyperemic resting diastolic pressure ratio (dPR) with a dichotomous cut-off value of <0.89 for significance. In addition, dPR can be used for pullback measurements readily visualized on the touchscreen OptoMonitor display to quickly interrogate serial lesions and locate functionally significant zones residing within diffuse disease. We tested the new OptoWire III in a cohort of real-world patients to evaluate its performance in our hands.

Case 1

An 82-year-old female presented to the outpatient cardiology clinic with exertional angina over the past month. She has a past medical history of hyperlipidemia and coronary artery disease status post remote bifurcation PCI of the left main coronary artery (LMCA) over 10 years earlier with bailout simultaneous kissing stents in the setting of an intraprocedural proximal LAD dissection. She has remained on dual antiplatelet therapy (aspirin 81 mg daily plus clopidogrel 75 mg daily) since the PCI, in addition to metoprolol succinate 50 mg daily. Until recently, she has been active without symptoms, but now reports chest discomfort associated with

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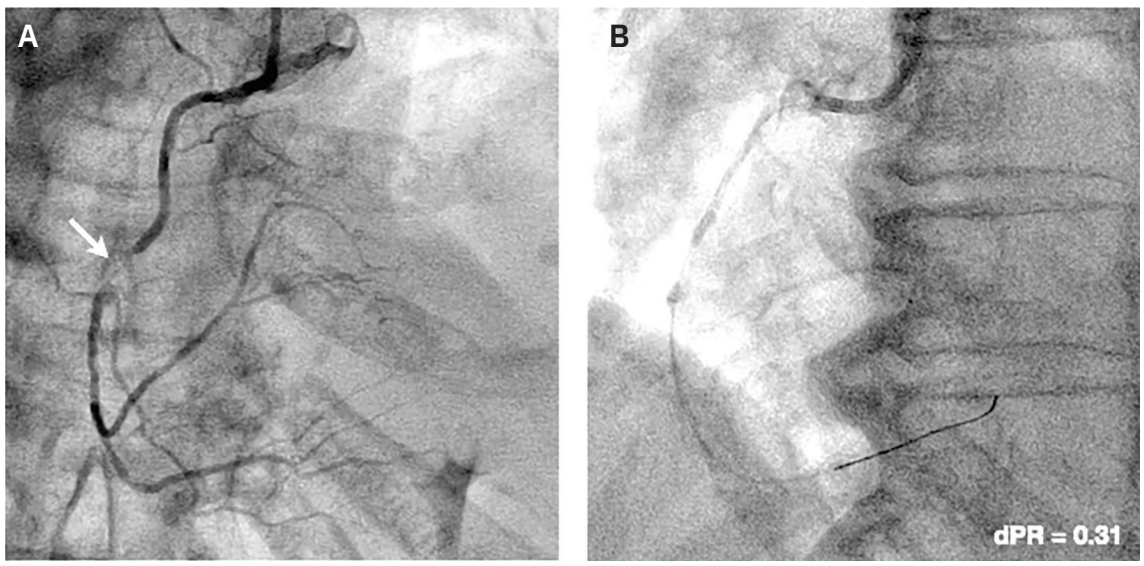


Figure 1. (A) Severe stenosis in the mid right coronary artery (RCA) (white arrow). (B) An OptoWire III was used to cross the lesion into the distal vessel where the resting diastolic pressure ratio (dPR) was markedly abnormal.

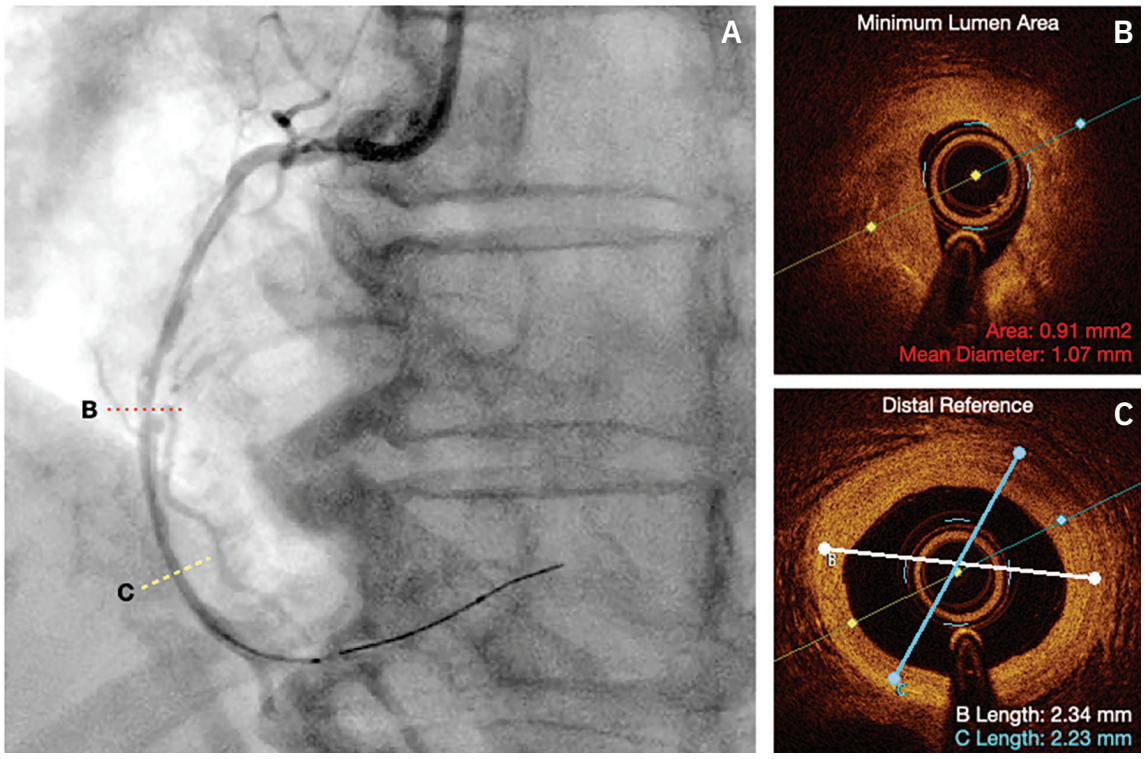


Figure 2. (A) Co-registered angiographic image obtained during intracoronary optical coherence tomography (OCT) of the RCA. Red dotted and yellow dashed lines identify locations of cross-sectional OCT images displayed in panels B and C, respectively. (B) OCT identified severely stenotic fibrolipidic plaque in the mid RCA. (C) OCT measurement of the distal reference vessel size was obtained according to the external elastic membrane.

dyspnea when walking briskly or climbing a flight of stairs. Given the worsening symptoms, she was referred directly for urgent coronary angiography without additional non-invasive testing.

Transradial access was obtained with a 6 French (Fr) Glidesheath Slender sheath (Terumo) placed in the right radial artery and an intravenous heparin bolus was administered. Diagnostic coronary angiography was performed with a 5 Fr Jacky diagnostic catheter (Terumo) demonstrating mild-to-moderate in-stent restenosis of the LMCA bifurcation stents and a new 99% stenosis of the mid right coronary artery (RCA) with distal TIMI-2 flow (Figure 1A, Video 1). Based on the angiographic findings, ad hoc PCI of the RCA subtotal occlusion was performed. Additional heparin boluses were given to achieve a therapeutic activated clotting time (ACT) >250 sec. A 6 Fr Judkins right (JR)-4 guide engaged the RCA with plans to use the OptoWire III as a workhorse wire to cross the lesion primarily, and enable pre- and post-PCI physiology measurements. After pressure equalization in the aorta, the lesion was crossed easily with the OptoWire III directed into the distal vessel (Figure 1B). The baseline resting diastolic pressure ratio (dPR) was 0.31, validating marked flow limitation in the angiographically severe stenosis. **The OptoWire III was then disconnected from the OptoMonitor interface and used as a workhorse wire for subsequent PCI.** The lesion was pre-dilated with a 2.0 mm × 12 mm Euphora balloon (Medtronic) at low pressure to facilitate contrast flushing for pre-PCI intracoronary optical coherence tomography (OCT) vessel assessment using a Dragonfly OpStar OCT catheter (Abbott Vascular). OCT revealed long, diffuse fibrolipidic disease with a reference vessel diameter of 2.25 mm measured according to the external elastic membrane (Figure 2, Video 2). Based on OCT vessel sizing, a 2.25 mm × 34 mm Onyx drug-eluting stent (Medtronic) was deployed and post dilated with a 2.25 mm × 15 mm NC Euphora balloon to high pressure. Final co-registered angiography and OCT revealed normal flow, and no significant dissection with good stent expansion and strut apposition (Figure 3, Videos 3-4). **The OptoWire III was then reconnected to the OptoMonitor and post-PCI physiology repeated with an increase in resting dPR to 0.97**, indicating no residual flow limitation. The OptoWire III was withdrawn to the tip of the guide catheter, **an absence of pressure drift** confirmed, and the wire and guiding catheter removed. The patient was symptom-free and in stable condition at the procedure end.

Figure 3. (A) Final angiography after RCA PCI, where the resting diastolic pressure ratio (dPR) measured with the OptoWire III demonstrated no residual flow limitation. Post PCI intracoronary OCT (B) cross-sectional and (C) longitudinal views demonstrated good stent expansion and strut apposition without significant edge dissection.

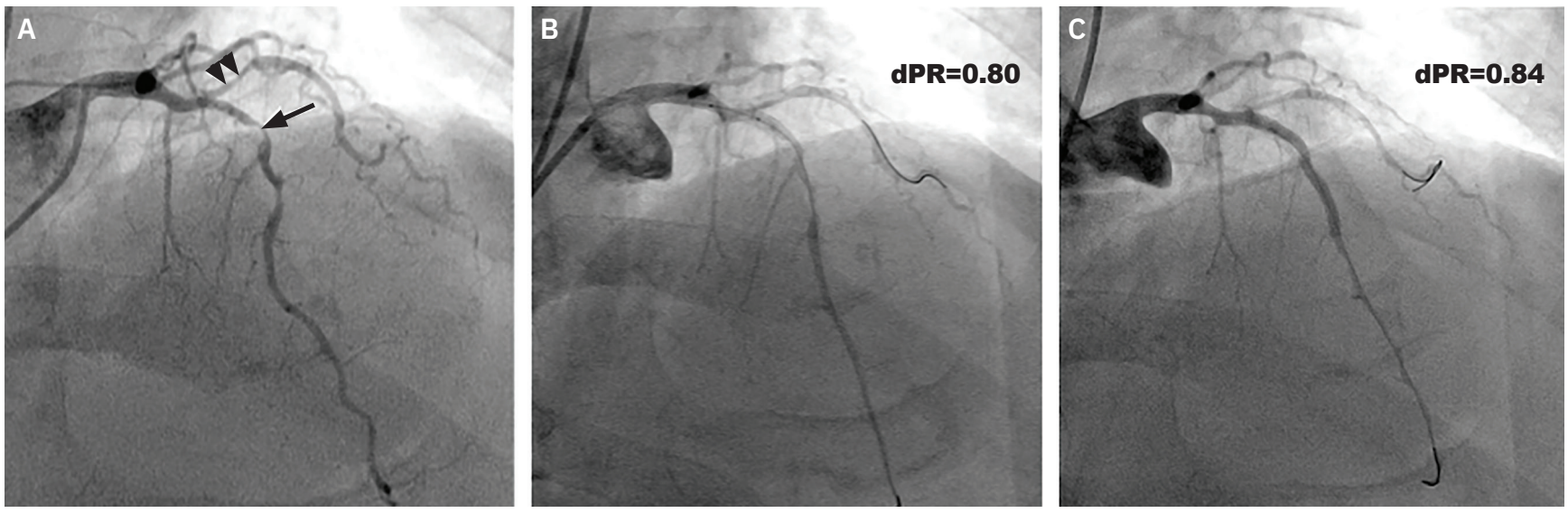


Figure 4. (A) Severe stenoses in the left anterior descending (LAD) (black arrow) and first diagonal branch (D1) (black arrowheads). (B) The OptoWire III was used to cross the D1 lesion and the resting diastolic pressure ratio (dPR) measured was positive. (C) After performing PCI of the LAD, the OptoWire III was used to re-cross into the jailed D1 side branch where the dPR remained functionally significant.

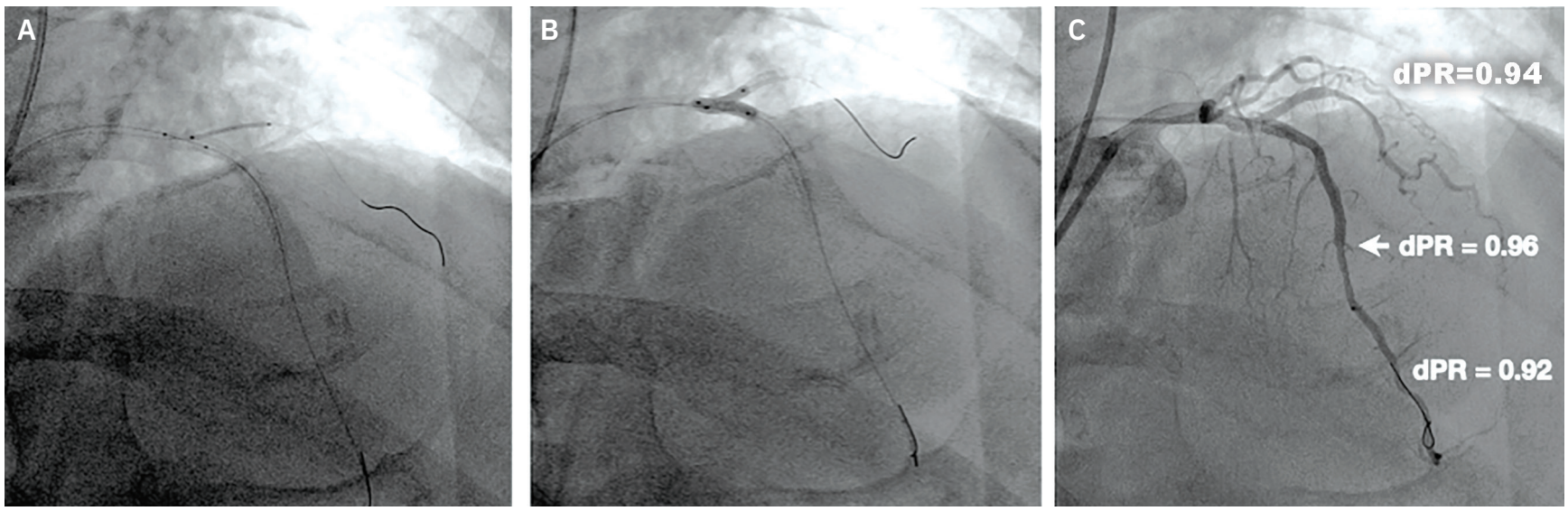


Figure 5. Bifurcation PCI of the LAD/D1 using the T and small protrusion (TAP) technique. (A) A 2.5 mm × 16 mm drug-eluting stent was advanced into D1 over the OptoWire III, with a 3.0 mm × 12 mm blocking balloon in the LAD. (B) Following D1 stent deployment, simultaneous kissing balloon inflations were performed. (C) Final angiographic result with annotation of post-PCI resting diastolic pressure ratio (dPR) measurements indicating no residual flow limitation in D1 and and no focal step-up to fix beyond the LAD stent on dPR pullback.

After a period of observation in the recovery unit, the patient was discharged home on the same day of the procedure, continued on uninterrupted daily aspirin and clopidogrel dual antiplatelet therapy. At outpatient two-week clinic follow-up, she had resumed light activity and reported complete resolution of her angina. Due to a prior intolerance of multiple statin medications, she was started on the proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor evolocumab (Amgen). A stress test was performed in anticipation of cardiac rehabilitation referral, which demonstrated no symptoms and no evidence of residual ischemia. Three months after PCI, she remained asymptomatic and had resumed her normal daily activities without limitations.

Case 2

A 57-year-old male with a past medical history of hypertension and end-stage renal disease on peritoneal dialysis developed new-onset chest discomfort on exertion. Prior to this, as part of evaluation for a potential kidney transplantation, he underwent a non-contrast chest computed tomography (CT) scan revealing severe coronary calcifications that prompted outpatient cardiology consultation. At this visit, he reported approximately two weeks of chest pain occurring with progressively less physical activity, and he was referred for coronary angiography.

Right radial artery access was obtained with placement of a 6 Fr Glidesheath Slender sheath followed by administration of an intravenous heparin bolus. Diagnostic coronary angiography was performed with 5 Fr Judkins left (JL)-3.5 and 5 Fr Amplatz right (AR)-2 Expo catheters (Boston Scientific), demonstrating diffuse, moderate proximal and mid left anterior descending (LAD) disease up to 90% after the first diagonal branch (D1), which had 70% stenosis (Figure 4A, Video 5); there was no significant obstructive coronary artery disease elsewhere. Ad hoc PCI of the LAD was planned, with provisional stenting of the D1 side branch based on serial assessment of flow limitation by pressure wire interrogation with the OptoWire III. Additional heparin boluses were administered to achieve a therapeutic ACT >250 sec. A 6 Fr Extra Backup (EBU)-3.5 Launcher guiding catheter (Medtronic) was used to engage the left main coronary artery (LMCA). After pressure waveform equalization, an OptoWire III crossed easily into D1 (Video 6) where the resting dPR was 0.80, indicating significant flow limitation. A Prowater wire (Asahi Intecc) was then passed to the distal LAD and the LAD disease predilated with a 2.5 mm × 15 mm Euphora balloon (Figure 4B). The LAD disease was then treated by deploying a 2.5 mm × 48 mm Synergy XD bioabsorbable polymer drug-eluting stent (Boston Scientific) across the D1 side branch, which retained normal flow. Optimization of the LAD stent proximal

As demonstrated in the preceding case vignettes, the OptoWire III can readily cross severe lesions, navigate tortuous side branches, and traverse jailed stents, while maintaining the ability to provide good rail support for equipment crossing.

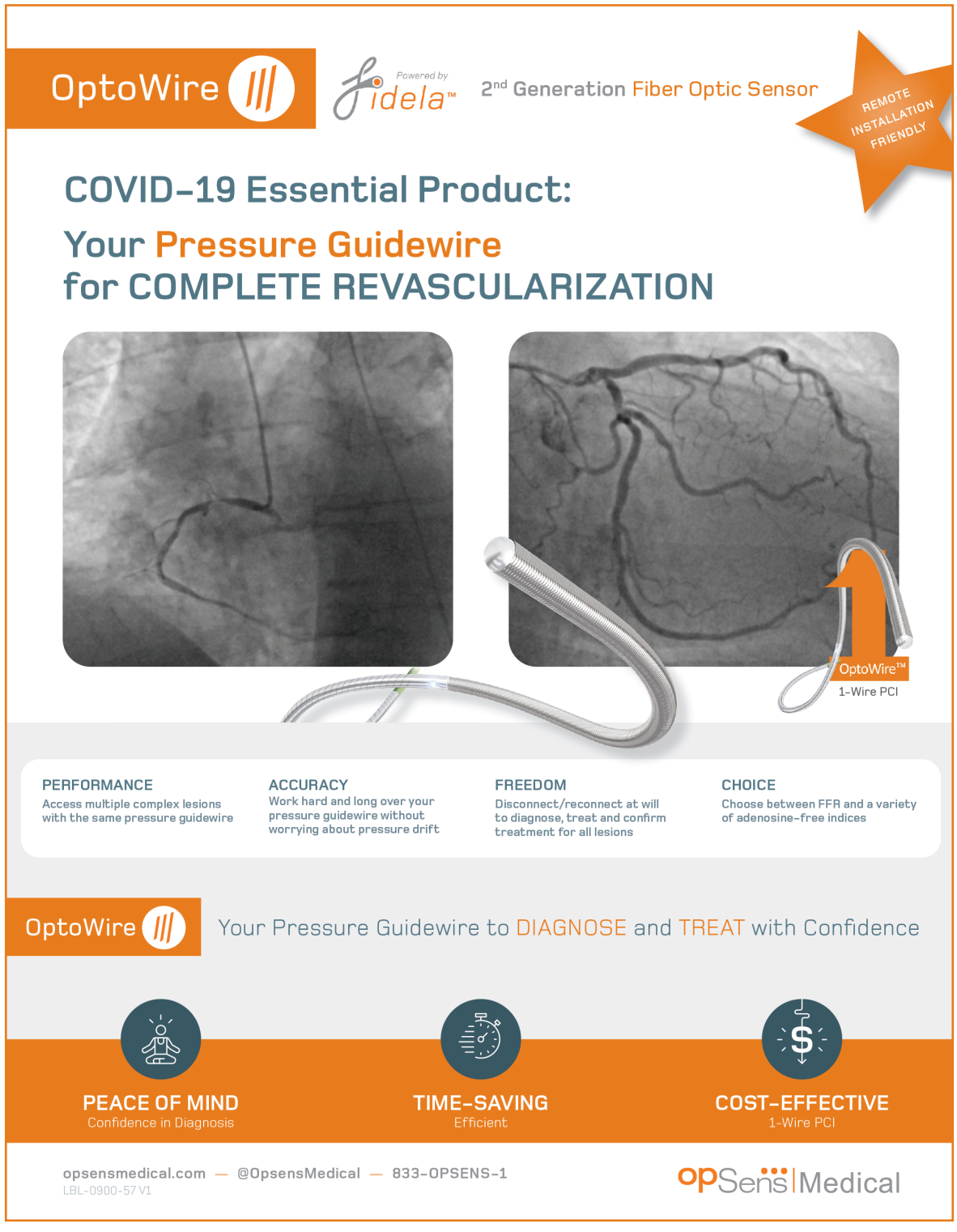
to D1 was performed with a 3.25 mm × 15 mm NC Euphora balloon at 18 atmospheres (atm). **The jailed OptoWire III was then removed from D1 and used to recross into the lumen of D1 through the struts of the newly deployed LAD stent.** Repeat non-hyperemic invasive physiology revealed continued significance of the D1 stenosis (dPR 0.84) despite successful treatment of the proximal LAD inflow disease (Figure 4C). Therefore, based on the invasive physiology information confirming significant disease in the D1 side branch, bifurcation PCI of the LAD/D1 was then performed using the T and small protrusion (TAP) technique. **Over the OptoWire III, the stent-jailed D1 was predilated** with a 2.5 mm × 15 mm Euphora balloon, and a 2.5 mm × 16 mm Synergy XD drug-eluting stent deployed with a 3.0 mm × 12 mm NC Emerge balloon (Boston Scientific) positioned in the LAD (Figure 5A, Video 7). Simultaneous kissing balloon inflations were performed with 3.0 mm x 12 mm and 2.5 mm x 12 mm NC Emerge balloons in the LAD and D1, respectively (Figure 5B). **Using the OptoWire III, post-PCI resting physiology of the final stent bifurcation result was then performed to confirm no residual flow limitation.** This was achieved first in D1 where the dPR was 0.94, and then by redirecting the OptoWire III from D1 into the distal LAD (Video 8) where the dPR was 0.92. **Pullback of the OptoWire III in the LAD showed no discrete physiology step-up** to fix in the distal vessel, with a gradual increase in dPR to 0.96 at the distal edge of the LAD stent. The OptoWire III was then withdrawn to the tip of the guide catheter demonstrating **no pressure drift** and the wire was subsequently removed. Final angiography demonstrated normal flow with no residual stenosis or dissection (Figure 5C, Video 9).

Following the procedure, the patient was monitored and discharged home the same day on a dual antiplatelet regimen of aspirin 81 mg daily and clopidogrel 75 mg daily. A follow-up stress echocardiogram test was performed 1 week after PCI due to atypical chest symptoms, for which the patient exercised 4.9 METS and stopped due to fatigue, with no electrocardiographic evidence of ischemia, and normal wall motion at rest and with exercise. He has remained angina-free since this time and is continuing to undergo further evaluation for kidney transplant candidacy.

Discussion

Invasive physiology wires are essential tools that both resolve uncertainty related to visual assessments of angiographic stenosis severity before PCI is performed, and also objectively evaluate the success of the final result after PCI is complete. While pressure wire technologies have come a long way since their initial development, prior generation pressure wires have underperformed in many respects compared to standard workhorse wires, particularly for more complex lesion subsets. With the advent of the OpSens OptoWire III pressure wire, the technological advancements incorporated into the new fiber optic OptoWire III are lighting the way for its use as a true coronary workhorse wire that can measure non-hyperemic dPR and hyperemic FFR, delivering reliable physiology measurements before, during, and after PCI.

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The OpSens OptoWire III is a next-generation fiber optic pressure guidewire with workhorse performance characteristics, hyperemic and non-hyperemic lesion assessment capabilities, pullback mode for serial lesion interrogation, minimal drift, and easy connectivity to check physiology in real time throughout the case.

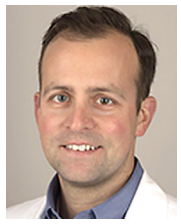
OptoWire III offers a simple, rapid connector interface to the table side touchscreen OptoMonitor that can be quickly disconnected to instill greater wire torque control for crossing challenging anatomy, and then seamlessly reconnected (with audible feedback notifying the operator of a proper connection) when additional invasive physiology evaluation is needed. Furthermore, the OptoWire III and OptoMonitor have a user-friendly live pressure wire pullback mode to interrogate serial lesions and diffuse disease, allowing the operator to minimize stent use while maximizing post-PCI blood flow by more precisely identifying and treating only the diseased regions that are functionally significant. Importantly, all of these maneuvers can be achieved with minimal-to-absent pressure drift over prolonged cases, providing a high level of confidence in the invasive physiology measurements obtained with the OptoWire III throughout the procedure.

Conclusion

The OpSens OptoWire III is a next-generation fiber optic pressure guidewire with workhorse performance characteristics, hyperemic and non-hyperemic lesion assessment capabilities, pullback mode for serial lesion interrogation, minimal drift, and easy connectivity to check physiology in real time throughout the case. By enabling use of a single wire with physiology capabilities to complete the entire case, the OptoWire III offers an efficient approach for interventional cardiologists to perform optimal physiology-guided PCI. ■

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Disclosure: Dr. Osborn reports he is a consultant for Abbott Vascular and Canon; member of the scientific advisory board of Dyad Medical and holds equity in the company; personal fees from Opsens for this article.

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