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ORIGINAL STUDIES

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A novel fiber-optic based 0.014″ pressure wire: Designs of the OptoWire™, development phases, and the O_2 first-in-man results

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Abstract

Objectives: To review the technical limitations of available pressure-wires, present the design evolution of a nitinol fiber-optic pressure wire and to summarize the First-in-Man (FIM) O_2 pilot study results.

Background: Despite increasing use of physiology assessment of coronary lesions, several technical limitations persist. We present technical details, design evolution and early clinical results with a novel 0.014" nitinol fiber-optic based pressure-wire.

Methods and Results: The 0.014' OptoWire™ (Opsens Medical, Quebec, Canada) was designed to combine improved handling properties compared to standard pressure-wires and to offer extremely reliable pressure recording and transmission due to fiber-optic properties compared to piezo-electric sensors and electrical wires. In vitro assessment showed that OptoWire™ steerability, pushability and torquability properties were closer to regular PCI wires than standard electrical pressure wires. In the First-in-Man O_2 study, 60 patients were recruited at 2 centers in Canada. A total of 103 lesions were assessed with the OptoWire™ and OptoMonitor™, 75 lesions at baseline and 28 lesions post-PCI (without disconnection). In all crossed lesions (n = 100, 97%), mean Pd/Pa and FFR could be adequately measured. In 11 cases assessed successively with OptoWire™ and Aegis™ (Abbott Vascular, USA) bland-Altman analysis showed a mean difference of 0.002 ± 0.052 mmHg (p = .91) for Pd/Pa and 0.01 ± 0.06 for FFR calculation (p = .45). There was no device-related complication. Upon these initial results, several design changes aimed to improve overall performance including torquability, stiffness, resistance to kink and pressure drift were completed.

Conclusion: The novel 0.014" fiber-optic OptoWire™ provides superior wire handling with reduced risk of pressure drift allowing reliable pre- and post-PCI physiology assessment.

KEYWORDS

angiography, catheterization, coronary, coronary artery disease, coronary blood flow/physiology, diagnostic, fractional flow reserve

1 | INTRODUCTION

Measurement of the distal (Pd) and proximal (Pa) pressures to coronary lesions both during basal conditions (as whole cycle or diastolic-derived indexes) or after maximal vasodilatation (fractional flow reserve [FFR]) are now established as better and more reliable methods to assess the functional significance of lesions.[1,2]

Although studies in the nineties had initially identified an FFR < 0.75 as the threshold value to decide upon on revascularization or not,[3,4] more recent guidelines have adopted the 0.80 cut-off as the clinical value to be used in clinical practice.[1,5] It must be stressed that this was not based on additional evidence but rather as a consensus value shared by experts in the field.[6-8]

Whereas it comes to no surprise that a single value could never differentiate the "abnormal" to "normal" values in human pathophysiology, it is often forgotten that many technical factors involved with the Pa and Pd measurements play a critical role. Furthermore, it should also be reminded that pressure estimates are only surrogates for flow estimates, and that there are several assumptions to be respected in order to ensure that Pd and Pa measurements are reliable to make clinical assessments and to make important clinical decisions as to whether or not to proceed with revascularization (treat or defer). Hence the technical limitations related to resting pressures and FFR measurements play an important role.

It is our objective in this manuscript:

1. To review the different available technologies for pressure-wires and their limitations;
2. To summarize the First-in-Man O_2 pilot study results;
3. To present the OptoWire™ design features for the optimization of pressure measurements and wire handling.

We will first focus on the technological limitations and design aspects, which might impact pressure signal reliability with the 0.014" piezo-resistive and optical-based pressure wires (i.e., Pd assessment), and will briefly discuss how signals might be affected with proximal pressure (i.e., Pa assessment); followed by the main results from the O_2 study using the first generation of the OptoWire™ to asses coronary lesions before and after percutaneous coronary intervention (PCI) and present the design changes of the OptoWire™ aimed at enhancing the wires' overall performance.

2 | PRESSURE-DERIVED FLOW MEASUREMENT: PRINCIPLES AND LIMITATIONS

FFR is an assessment of stenosis severity as it reflects the fraction of preserved flow after a stenosis in terms of the pressure drop along the system. This ratio assumes negligible microvascular resistance to flow (maximal hyperemia) and vessel geometry independence and can be derived from simultaneous proximal (Pa) and distal (Pd) pressure readings as Pd/Pa.

Available methods used to measure these pressure gradients face technical limitations inherent to the design, specifically the stability of the signal (i.e., drift); and the handling of the systems, the latter directly influencing the adoption of FFR for the postprocedural assessment of cardiac physiology as well as its use in complex multivessel lesions. The need to induce maximal hyperemic flow also might present a limitation, however it is being addressed by the introduction of "resting" pressure indices.[9,10]

3 | DESIGN ASPECTS OR PRESSURE WIRES

Pressure wires consist of four main parts: A distal tip (a) that enables the wire to reach the coronary vessels, connected to the sensor housing (b), followed by the intermediate section (c), and the shaft (d). The sensor housing is the area where the sensor is located and comprises a rectangular or oval opening (pressure window) to allow blood to get in contact with the diaphragm of the pressure sensor, just distal to the sensor position.

3.1 | Overall technology-related challenges

The challenge with current 0.014″ pressure-wires relies with the need to accommodate for the sensor and wiring integration through the body of the guide wire and through a connector handle back to the console; significantly modifying the way the guide wire is constructed, which in turn influences the feel and performance of the guide wire. The operator may also face issues while attempting to reconnect the currently available pressure-wires after PCI or for multiple coronary lesion assessment. Furthermore, in some cases, there might be signal drifts during pressure recording which make pressure assessment unreliable.

Optical fiber-based pressure wires remove the need of electrical wiring integration, using instead a single fiber, which allows for a seamless concentric construction like regular guidewires. This change in sensing technology indirectly improves the feel, handling, and performance. Other improvements brought with the change in technology include the ability of disconnecting and reconnecting the pressure wires throughout a PCI with minimal distal signal drifts, facilitating multiple lesion assessment both before and after intervention without requiring multiple equalization maneuvers.

3.2 | The sensor housing and pressure sensor: Pressure stability and drift

Piezo resistor-based sensors, measure diaphragm stress changes induced by arterial pressure and transform them into electrical signals which are then transmitted using three electrical wires to the proximal end of the pressure-wire; environmental factors such as moisture and temperature-induced stress may interfere with the signal and affect measurements, as they are intensity-modulated, thus electrical

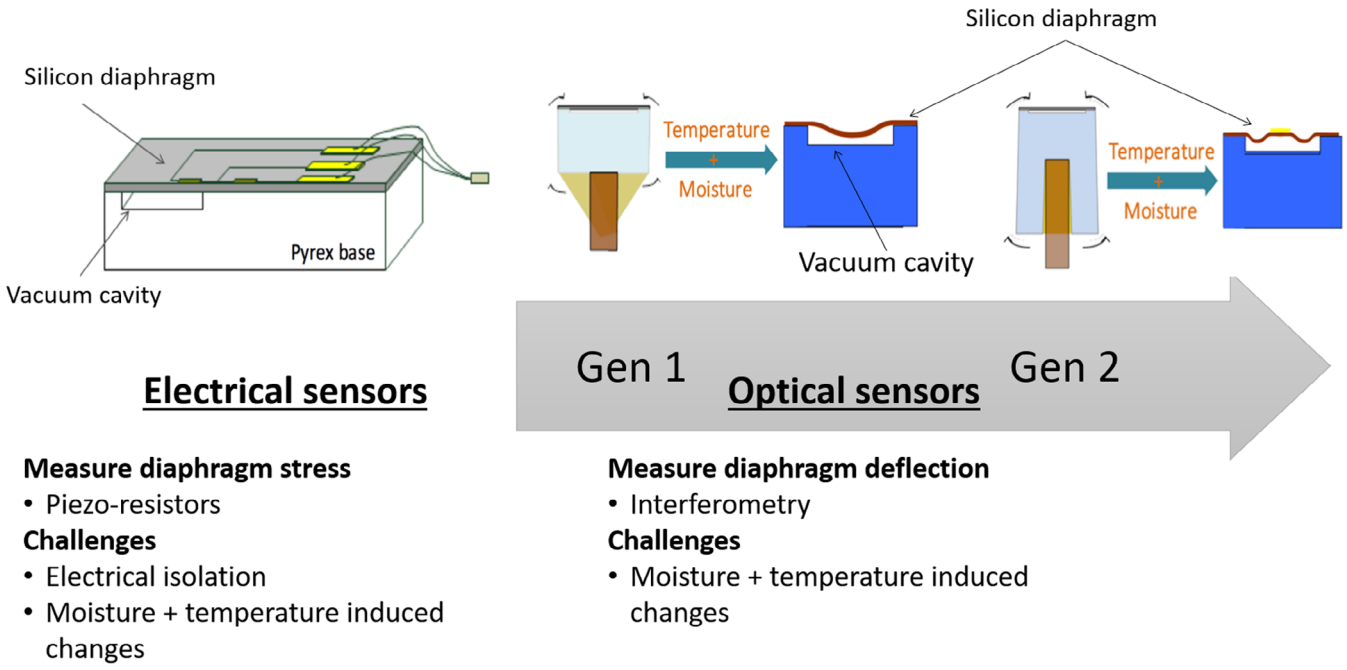

FIGURE 1 Comparison of pressure sensing technologies: Electrical sensors (left). Optical sensor technologies. Opsens corrugated membrane and assembly for decreased impact of temperature and moisture on pressure readings (right) and Fiso optical sensor (center) [Color figure can be viewed at wileyonlinelibrary.com]

insulation remains a major challenge to avoid artifacts on pressure recordings and transmission.

Fiber-optic systems are based on a Fabry–Perot interferometer and do not use electrical wiring. The arterial pressure will induce a deformation on the membrane of the pressure transducer; this deformation will affect the reflected spectrum of an incoming white light beam circulated by a multimode optical fiber at the center of the pressure-wire (Figures 1 and 2). The resulting pressure encoded light signal is then transmitted through the fiber optic to a fiber interface cable (FOIC) at the proximal end of the pressure-wire. Since measurements are based on light interferometry and frequency-modulated, the system is binary, that is, the signal is either perfect or, in the event of wire rupture, absent. Hence, measurements will be more stable as they are not affected by bending of the wire or blood contamination as their intensity modulated counterparts.

Currently there are two types of pressure transducers using Fabry–Perot interferometers and optical wires. The first optical sensor design was developed by the Fiso Technologies (Quebec City, QC, Canada) over 20 years ago and is used by the Navvus™ microcatheter (Acist Medical Systems, MN) and the Comet™ (Boston Scientific, MN) wire. In this first generation, a "flat" diaphragm is supported by a Pyrex base to which an optical fiber is glued on. A second generation of optical sensor used by the OptoWire™ pressure wires, developed by Opsens Medical (Quebec City, QC, Canada); includes a corrugated diaphragm supported by a hollow pyrex base into which an optical fiber is inserted and secured. The corrugated configuration drastically reduces the impact of temperature and moisture on the diaphragm deformation, while the hollow receptacle minimizes the adhesive required to secure the optical fiber, further reducing moisture-induced drift (Figure 1).

3.3 | Midsection and shaft: Handling and feel

Another design compromise observed with electrical-based pressure wires is the eccentric positioning of the three 40 μm-thick electrical wires, within the core of the pressure-wire, whereas with optical-based systems, a single 100 μm optical fiber runs along the neutral axis of the hollow tube, showing mechanical properties such as torquability, pushability, or whipping[1] similar to standard PCI wires like the Balance Middleweight Wire (BMW) (Abbott vascular) (Figure 3). Figure 6 shows in vitro results for torquability and stiffness of different pressure wires compared to the BMW guidewire.

4 | SIGNAL STABILITY: SOURCES OF PRESSURE ERRORS WITH Pd AND Pa READINGS

Estimating coronary physiology at rest or after maximal vasodilatation, requires stable and reliable proximal (aortic) and distal (coronary) pressure measurements. These distal and proximal pressures ultimately may vary by several mmHg and any error or drift may dramatically affect the ratio and influence clinical decisions. Factors inherent to the procedure (external) or related to the pressure wire may affect the pressure readings. Procedural related factors include the height of the aortic pressure transducer, the use of semiautomated contrast injectors; errors with equalization or zeroing; changes in temperature, moisture, air entrapment induced pressure drift; and connection induced pressure shift, among others.

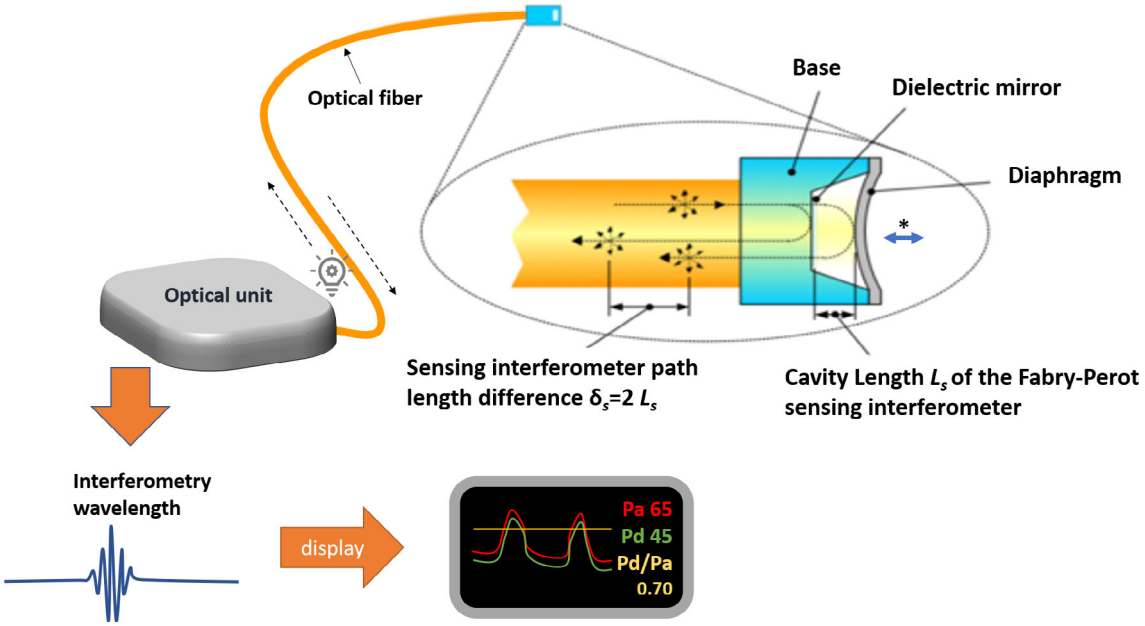

FIGURE 2 Pressure transducer based on the Fabry–Perot interferometer. A light signal is sent through the optical fiber to the transducer. The diaphragm's deflection changes in response to pressure, and in turn, affects the path length of the transmitted light. The optical unit receives the light signal back from the transducer and identifies the interferometry wavelength, associated to a change in pressure, which is in turn used in calculations and sent to the monitor for visualization [Color figure can be viewed at wileyonlinelibrary.com]

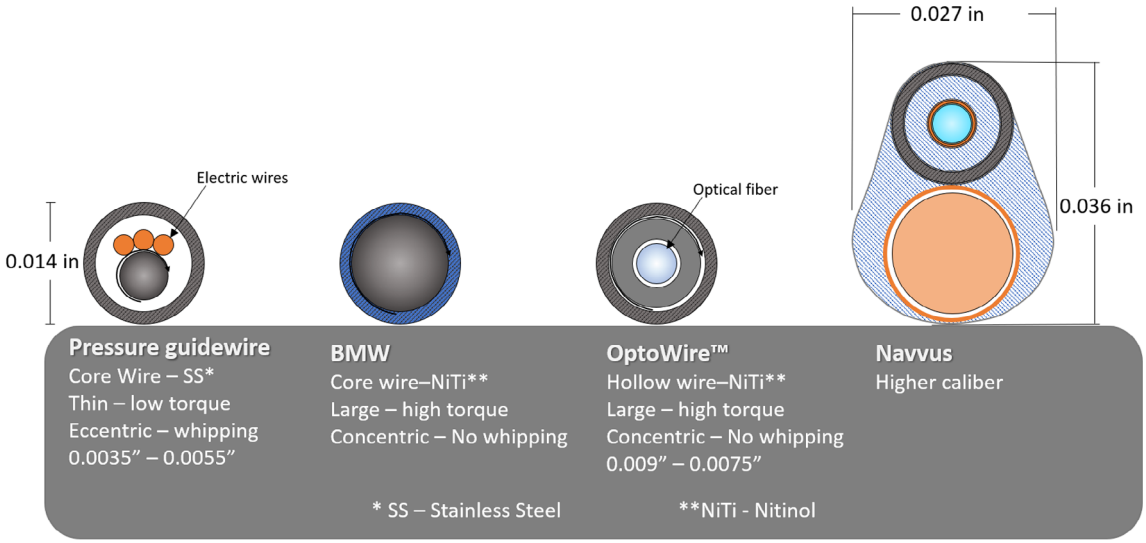

FIGURE 3 Wire structure profile comparison. Left to right: Pressure guidewire, BMW™ guidewire, OptoWire™, and Navvus® FFR catheter [Color figure can be viewed at wileyonlinelibrary.com]

4.1 | Errors in Pa readings: Transducer height and semiautomated contrast injectors

At the time of initial introduction of pressure wires into the Cath-Lab process flow, as well as the initial description of methods to be used during the O_2 study, aortic pressure was measured by a pressure-transducer connected to a fluid-filled line. It was recommended to place the transducer at mid-thorax height, at the level of the right atrium and zero it at atmospheric pressure. Once zeroing is completed and the valve is closed, pressure line change in height is generally not expected to induce any pressure change. However, this is true only if, the pressure line is not filled, partly or otherwise, with contrast agent. The higher density of contrast agent relative to saline may induce significant pressure shift (±2 mmHg per inch or more) when aortic pressure tubing is moved. With the introduction of semiautomated contrast injectors, the aortic pressure transducer is now placed at the end of the pressure line (at the Y-connector) which ideally means that the connector will always remain at the mid-thorax level; however,

this is not always maintained during catheter manipulation and drug administration. Furthermore, the line connected between the semiautomated injector and the Y-connector is typically zeroed at the early stage of the procedure when it is filled with saline, and thereafter may be filled with contrast agent, two fluids with different density, which may adversely impact the pressure reading if the tubing is moved. These errors can be minimized by ensuring the transducer remains always at mid-thorax level and by flushing the line with saline solution to stabilize the fluid column pressure before connecting the pressure wire, however the latter involves injecting a larger than needed amount of contrast agent into the patients' blood stream with its associated risks. The operator should evaluate whether the potential error in pressure reading outweighs these risks. Another method consists in zeroing the Pa with all fluid lines filled as during the procedure, and to always place them in the same position during zeroing, equalization, and pressure measurement.

4.2 | Errors in Pd readings: Temperature changes and air bubble entrapment

Air bubbles have been observed to be captured within the distal pressure chamber after inserting the wire and may influence distal pressure readings by affecting the deflection of the sensor membrane or causing a sudden negative pressure drift upon their release (online material). Manufacturers recommend flushing the line with saline prior to connecting the wire to help release any bubbles remaining and to stabilize the distal pressure transducer.

Another source of errors is the change in temperature; Exposing the pressure wire to the blood induces significant temperature changes (from 20°C room temperature to 37°C body temperature). It has been observed that this might create gas expansion in the hollow portion of the pressure wire, ultimately releasing microbubbles that migrate to the pressure chamber level and affect pressure measurement (Video S1). To minimize the potential effects of this phenomenon, it is recommended to first advance the pressure wire a few centimeters into the coronary tree to stabilize pressure measurements and then slowly retrieve it at the level of the guiding catheter and wait approximately 1 min to perform the equalization phase.

4.3 | Other sources of errors and pressure artifacts

The optimization of pressure measurements requires ideally, closed systems. Any leaks throughout the system can induce up to a 10-mmHg change in pressure readings, which is why needle introducers should be removed once the pressure wire reaches the distal part of the guiding catheter and valves should be tightened prior to performing the equalization process to ensure that there is no pressure gradient between Pa and Pd (Pd/Pa = 1.0) before crossing the target lesion.

The guide catheter may create a stenotic artifact dampening the aortic pressure at the coronary ostium due to the obstruction of flow into the coronary vessel that may be significant depending on the coronary ostium diameter and the catheter size. The hemodynamic disturbances induced by intracoronary flushing may also temporarily affect the Pa readings.

Abnormally long procedures may also induce drift, more so in piezoelectric sensors than optical sensors, due to the interference of blood and saline solution at connection points; as will direct contact between the transducer and the vessel wall and the positioning of the transducer distally to the lesion due to local dynamic pressure gradients at the poststenotic region.

5 | THE O_2 FIRST IN MAN STUDY

After completion of animal experiments, a protocol for first-in-man (FIM) clinical use was submitted to Canadian Health Authorities in October 2014 (NCT 02144090). With the O_2 protocol, the study intended to assess the usability, functionality and safety of the Opsens system (OptoWire™ [OW] and OptoMonitor™) in patients with ischemic coronary artery disease who were referred for diagnostic angiography and possible PCI.

5.1 | Methods

Any stable or unstable patient referred for investigation of chest pain or equivalent thought to be of ischemic origin was eligible. The main objectives were to assess whether the OW could cross all types of coronary lesions and reliable physiology measurements could be obtained. Furthermore, if PCI was indicated, the operator could choose to disconnect the OW and use it as a regular wire. After PCI completion, operator could re-connect the OW and evaluate Pd/Pa and FFR values. A final pressure measurement was performed with the pressure transducer positioned at the guiding catheter level to re-evaluate any difference between pressures measured by the OW and the Cath lab system.

Prior to insertion of OW into the coronary system, all patients were fully anticoagulated according to institution's practice. To perform FFR assessment, it was recommended to position the OW as distal as possible and with the pressure transducer at least 3 cm from the target lesion as currently recommended. In order to obtain maximal coronary vasodilation, continuous adenosine infusion (140 μg/kg/min) or large intracoronary boluses of adenosine (suggested dose of 300 μg for left system and 150 μg for right coronary artery as per our routine) were administered. If PCI was indicated, the choice of balloons, stent and inflation protocols were left to operator's choices. Results are presented as mean ± *SD*s for continuous variables and as % if categorical variables.

5.2 | Results

From May 2014 to April 2015, 60 patients were recruited at two centers in Canada. The mean age was 65 ± 10 years and 67% were males.

Indications were stable angina in 52% (31) of the cases, unstable angina in 28% (17), non-ST elevation myocardial infarction (STEMI) in 18% (11), and STEMI (nonculprit vessel) in one case. Transradial approach was used in 93% (56) of the cases, two cases were completed by ulnar approach and two cases by femoral approach. Lesions assessed by FFR were located in left main artery in 6.7%, left anterior descending artery in 58%, circumflex artery in 40%, and right coronary artery in 50% of cases. Operators used guiding catheters and diagnostic catheters in 89 and 11% of the cases, respectively. The majority of cases (67%) were performed using 5Fr catheters.

A total of 103 lesions were assessed with the Opsens system, 75 lesions were assessed at baseline and 28 lesions after PCI (24 lesions were assessed with OptoWire™ pre- and post-PCI). PCI were performed in 40 patients and OptoWire™ was used as PCI wire in 30 cases (63%). In all lesions successfully crossed with OW (n = 100, 97%), mean Pd/Pa and FFR could be adequately measured. In 11 cases, pressure measurements using standard pressure-wires (St Jude Medical) and consoles were performed prior PCI and compared with measurements with Opsens system (OptoWire™/OptoMonitor™). Measurements obtained successively with both systems presented with a mean difference of 0.002 ± 0.052 mmHg for Pd/Pa (p = .91) and 0.01 ± 0.06 for FFR calculation (p = .45). There were no device-related complications during study conduct. One technical failure occurred during the initial phase with prototype version of OW. Prior to insertion, one operator broke the proximal part of the OW. The manufacturer decided to modify and reinforce the shaft (Stiffness results – Figure 6b). Since that event, there have been few cases of ruptured wires reported with clinical use with OptoWire™ One and Deux, all prior to insertion, with no patient injury recorded. There have been no reports so far with OptoWire™ III.

The mean baseline measurements were 0.91 ± 0.11 and 0.82 ± 0.13 for Pd/Pa ratio and hyperemic FFR, respectively. Upon removal at the ostium of guiding catheter for diagnostic cases, the mean Pd/Pa value was 0.99 ± 0.02 and after disconnection and reconnection, the mean Pd/Pa value was 0.98 ± 0.03. Thirty-four post-PCI pressure measurements were performed and the mean Pd/Pa ratio was 0.91 ± 0.06 and the FFR value was 0.84 ± 0.08. Upon removal at the ostium of guiding catheter after PCI completion, mean Pd/Pa value was 0.98 ± 0.02.

6 | THE OptoWire™

6.1 | Design evolution and impact on performance

Over time, the OptoWire™ has undergone several design modifications aimed to improve the performance of the pressure wire, specifically to minimize the pressure drift, and to improve the wire's feel and handling to enable its use as a regular PCI wire and thus facilitate post-procedural as well as complex multivessel physiological evaluations. Figure 4 shows the different generations of OptoWire™ highlighting the main modifications in each iteration here described in detail.

OptoWire™ 0 (OW0), used during the initial phase of the O_2 study (see above), presented a sensor housing with two small pressure windows spaced 180° and an intermediate section with a hydrophobic coating. It was observed that air bubble entrapment within the pressure windows could induce significant pressure drift; version 1 was developed to reduce this risk. The OptoWire™ One (OW1) presented essentially a sensor housing redesign to include one larger pressure window instead of two for the reduction of air bubble entrapment; as well as the addition of a core wire to provide better resistance to shaft kinking. This was the first commercially available version, initially launched in Japan in 2014.

The OptoWire™ Deux (OW2), presented a change from the original hydrophobic coating to a hydrophilic version to improve the wire's performance in handling and ability to access especially in highly calcified vessels. The OptoWire™ Deux, was introduced to the market in November 2015. The design has been further modified, resulting in the current version in the OptoWire™ III (OW3), which includes a shorter tip and sensor for improved steerability; an improved sensor housing design, with a smaller and smoother pressure window for further reduction of air bubble entrapment and minimized pressure drift

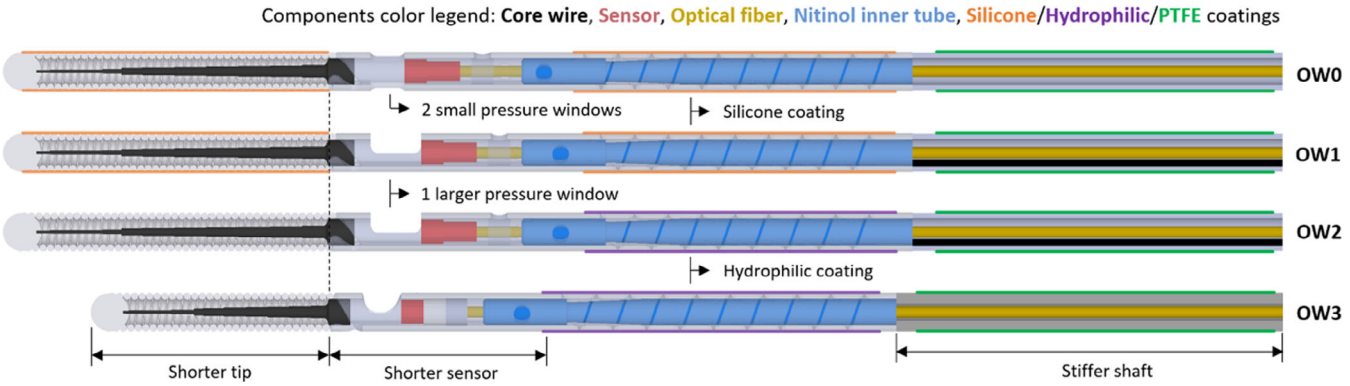

FIGURE 4 OptoWire ™ design evolution, top to bottom: OW0, OW1, and OW2 (Deux), OW3 (III). Courtesy of Opsens Medical [Color figure can be viewed at wileyonlinelibrary.com]

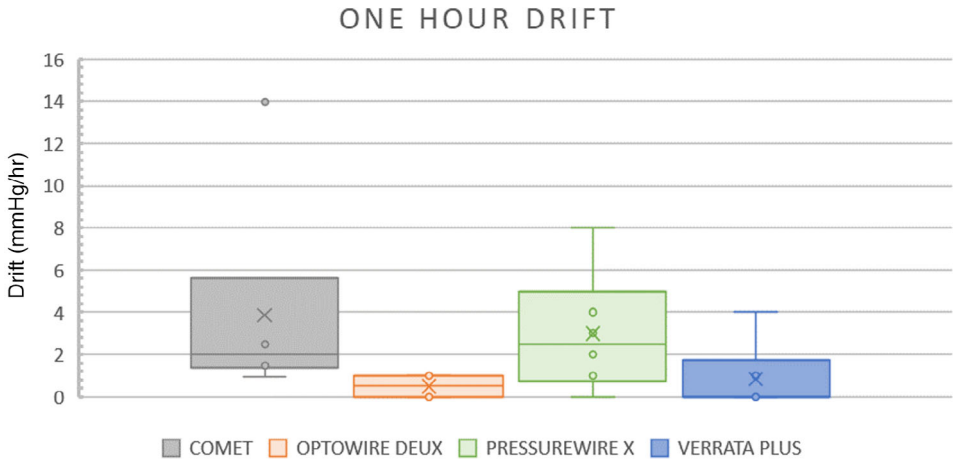

FIGURE 5 One-hour drift test comparing the Comet™ (Boston Scientific); OptoWire™ Deux (Opsens Medical); Pressurewire X (St. Jude Medical), and Verrata Plus (Philips Volcano). Mean drift/hr. is noted by the X. Note the variability in drift observed with the different pressure-wire systems [Color figure can be viewed at wileyonlinelibrary.com]

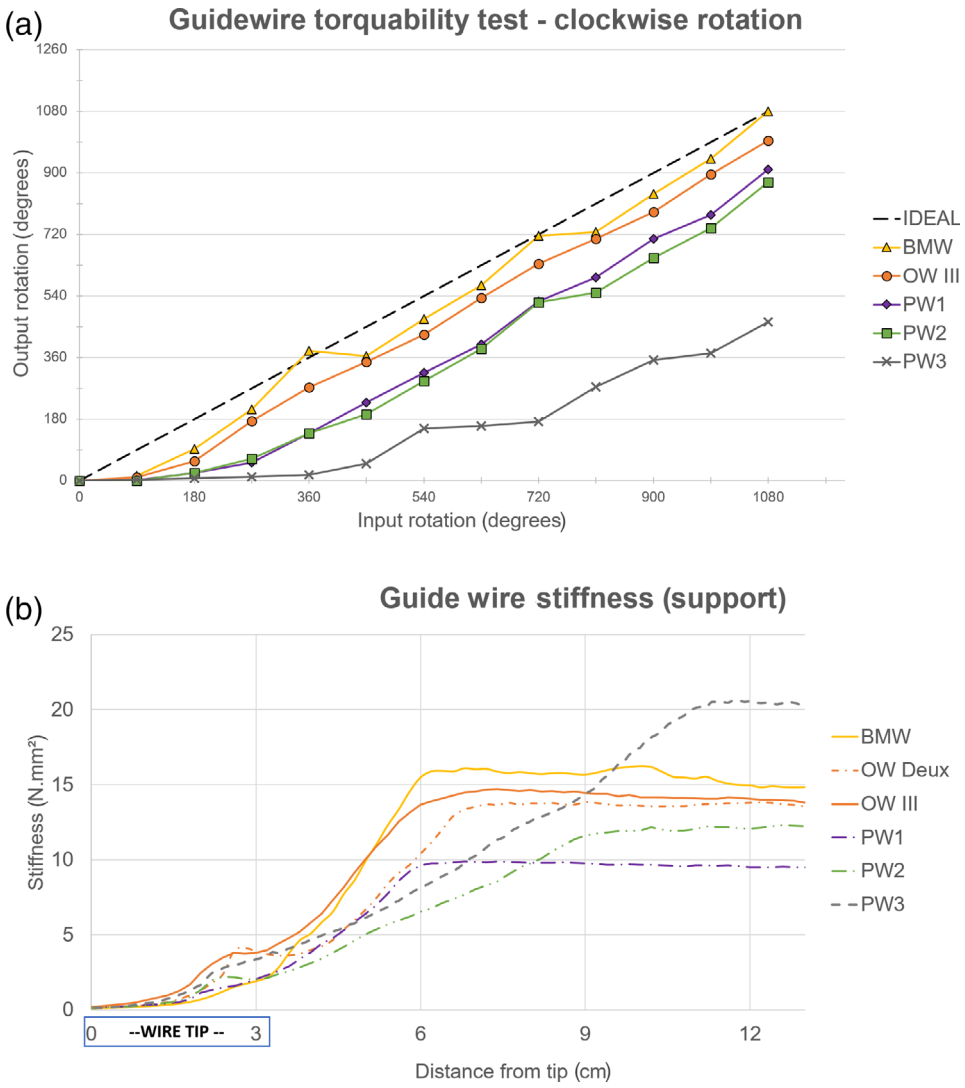

FIGURE 6 In vitro performance evaluation: Torquability (a), and stiffness (b) of the OptoWire™ iterations, compared to the BMW guidewire (Abbott, IL), and other commercially available pressure wires [Color figure can be viewed at wileyonlinelibrary.com]

(Figure 5); an increased wall thickness for improved shaft strength and resistance to kink; and a redesign of the intermediate section for better control of tolerances of the nitinol core with the spiral external layer to further improve torquability.

6.2 | Methods

Overall performance and handling were assessed in terms of pressure drift, and wire torquability and stiffness respectively; and compared to

other commercially available pressure wires; wires used include the Comet™ (Boston Scientific); the OptoWire™ (Opsens medical); the Pressurewire X (St. Jude Medical) and the Verrata Plus (Philips Volcano). All wires were preconditioned in a physiological solution at 37 C for a minimum of 5 min before testing.

Drift: One-hour drift was obtained for each wire and reported as mean drift/hr. All transducers were positioned at a 25 cm height from the surface of a saline solution column at 37 C and equalized. Atmospheric and wire read pressure measurements were recorded immediately postequalization and at 30- and 60-min. Time points.

Drift was calculated as:

$$\Delta P = (P_{60} - P_0) - \Delta P_{\text{atm}}$$

Torquability: Torque response was assessed as the correlation between the wires' proximal end rotation and the corresponding distal end rotation in a simulated anatomic tortuous path.

Stiffness: Stiffness throughout the wire was assessed by a 3-point bending test as per ASTM D790 and was defined as a function of the material's modulus of elasticity (E) and its moment of inertia (I) by:

$$EI = \frac{FL^3}{48 \cdot \delta}$$

where F is the load applied measured, L the length of the 3-point system and δ the deflection of the guidewire.

6.3 | Results

Figure 5 shows drift per hour in the tested wires with mean, maximum, minimum and *SD* values. The more stable wires were the OptoWire™ and the Verrata Plus, with mean drift of 0.50 ± 0.55 mmHg/hr and 0.83 ± 0.60 mmHg/hr, respectively, followed by the Pressurewire X (3.0 ± 2.83 mmHg/hr) and the Comet™ (3.87 ± 4.98 mmHg/hr).

In vitro results showed that torquability of OptoWire III (latest generation) was closer to that of BMW wire used a reference (1:1.14 vs. 1:1.06) compared to electrical-based pressure wires (1:1.44, 1:1.36, and 1:3). Torquability results are shown in Figure 6a. Note that the ideal torque ratio is 1:1 where one full proximal turn will be reflected as one full turn distally, allowing the operator to know how the wire will always behave.

Stiffness results (Figure 6b), show the transition in stiffness throughout the wire, with a low stiffness zone in the first 3 cm, corresponding to the flexible wire tip. The curve for the different pressure wires studied, presents with an initial plateau around the length where the sensor housing is located, followed by a smooth increase in stiffness at the midsection. This increase in stiffness, provides the wire with the required support to allow the operator to cross lesions and navigate through tortuous vessels. A stiffer midsection together with an adequate torque ratio provide ideal wire characteristics, which on a pressure wire translate into the use of a single wire throughout the procedure.

7 | DISCUSSION

Pressure measurement of coronary lesions before and after intervention has been part of interventional cardiology since the early days of percutaneous transluminal coronary balloon angioplasty pioneered by A Gruentzig in 1977. Yet, at that time measurements across lesions were performed with balloon material, which were bulky, caused significant obstruction to flow and hence, provided unreliable measurements.

Until 2014, 0.014″ pressure wires from two manufacturers (Abbott vascular and Philips-Volcano) were based on piezo-electric pressure transducers and electrical wires. Despite significant improvements over the last two decades, severe limitations inherent to the electrical technology still result in suboptimal handling for crossing all types of coronary lesions and remain associated to significant pressure drifts in several cases. Today, fiber-optic systems have been associated with a decrease in risk of pressure drifts and much better wire behavior and present the optimal tool for physiological assessment after intervention.[6,11,12]

It should be reminded that even though optical-based pressure wires are more reliable and provide operators with stable pressure measurements without drifts even after disconnection and reconnection, the stability issues of Pa measurements are yet to be resolved. The two pivotal phases, which remain critical are the zeroing of Pa with the valve at a fixed height and the equalization processes with Pd/Pa. In that regard, the popularity of automated contrast injectors poses new challenges in catheterization laboratories. Further studies are required to evaluate the reliability of these systems compared to standard pressure-transducers fixed at a predetermined height in assessing physiological pressures on which clinical decisions are based.

The availability of new tools has been made possible by the iterative improvement on existing technologies. Optical pressure transducers present as a reliable alternative to conventional pressure wires by significantly improving distal pressure stability and reliability. Modifications to the overall wire construction for handling and support improvement could potentially facilitate the use of this pressure wire as a conventional guide wire and allow the operator to navigate tortuous anatomies, assess multivessel lesions, and perform postprocedural physiology assessments without adding extra time or resources to the procedure.

In conclusion, introduction of fiber-optic based pressure wires in clinical practice provides clinicians improved tools to assess physiology pre- and post-PCI in a growing number of coronary lesions types. Yet continuous efforts remain required from the industry to provide ultimately pressure-wires, which could behave similarly to current PCI workhorse wires as well as providing stable and reliable pressures.

CONFLICTS OF INTEREST

Paola Ulacia is a PhD student which received a grant from Opsens. Sébastien Lalancette and Claude Belleville are present or past Opsens employees. Olivier F. Bertrand and Hitoshi Matsuo are consultants to Opsens. The O_2 FIM study was designed by investigators in

partnership with Opsens, which submitted the protocol to Health Canada. Opsens provided a grant to the International Chair on Interventional Cardiology and Transradial Approach to perform the study but had no role in study conduct or data analysis.

DATA AVAILABILITY STATEMENT

We do agree to provide any data related to our work.

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ENDNOTE

[1] Whipping refers to the sudden distal rotation of the wire resulting from the accumulated or nontransmitted torque along the wire generated from proximal rotation.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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