

Optowire for measuring fractional flow reserve

Medtech innovation briefing
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Summary

- The **technology** described in this briefing is Optowire. It is used for measuring fractional flow reserve (FFR), to work out suitability for coronary artery stenting.
- The **innovative aspects** are that it has an optical sensor and could minimise or prevent drift.
- The intended **place in therapy** would be instead of existing pressure guide wires and other non-invasive devices used to measure FFR.
- The **main points from the evidence** summarised in this briefing are from 3 non-comparative cohort studies including a total of 173 people (with 183 lesions) who had a clinical indication for percutaneous coronary intervention. The studies suggest that Optowire could be associated with minimal pressure drift when measuring FFR.

- **Key uncertainties** around the evidence or technology include a lack of comparison with other invasive guide wires, uncertainty around the extent that FFR measurement improved because of reduced drift, and whether the evidence is generalisable to the NHS.
- The **cost** of Optowire is £475 per unit and the reusable monitor is £3,000 (exclusive of VAT). The **resource impact** would be greater than standard care. This could be offset if the device improves FFR-guided decision making compared with similar pressure wires or non-invasive devices, and prevents stenosis misclassification and associated resources from unnecessary stenting of an artery. There is no published evidence to support these claims.

The technology

Optowire (Opsens Medical, distributed in the UK by OscarTech UK Ltd) is a sterile, fibreoptic-based, disposable guide wire for measuring fractional flow reserve (FFR) during coronary angiography in coronary artery diseases.

The device comprises a proprietary optical pressure sensor near to the tip, which minimises temperature and moisture-related drift, and a stainless-steel outer tube with a nitinol core for enhanced handling. The device needs a monitor, Optomonitor, and hardware to function. The company claims that Optowire's fibreoptic connector can reconnect to and disconnect from the measurement system during the procedure without interference from fluids. To measure FFR, the pressure wire is put through a guiding catheter to the lesion in the coronary artery. It records the pressure before and after a stenosis (narrowing) of an artery. The company has told NICE that the device can also measure diastolic pressure ratio (dPR). The most recent version of the device is the Optowire Deux.

FFR is a physiological parameter that measures the severity and significance of stenosis of an artery during coronary angiography. FFR is based on the maximum blood flow within the artery and is measured as the ratio between maximum achievable blood flow in a blocked artery and the theoretical maximum flow in a normal coronary artery. FFR can inform decisions about the appropriateness of stenting to unblock arterial stenosis.

Pressure drift can happen during FFR measurement. Pressure drift is a source of error in intracoronary pressure measurements and can result in a misclassification of stenosis. Pressure drift may be caused by the sensor, catheters and wires.

Innovations

Optowire has an optical sensor and the company claims it has minimal or no pressure drift. Reducing drift improves FFR accuracy and stenosis is less likely to be misclassified.

Current care pathway

Coronary artery disease happens when arteries of the heart narrow because of deposits of atherosclerotic plaque. This narrowing can cause full or partial blockage of the coronary artery, leading to reduced blood flow and oxygen supply to the heart muscles. Coronary artery stenosis can lead to angina (chest pain), myocardial infarction (heart attack) and congestive heart failure.

Coronary artery disease is managed by lifestyle changes (for example, stopping smoking, regular exercise and diet) and medicines (such as antiplatelets, statins and beta-blockers). If lifestyle changes and medicines do not manage symptoms, interventional procedures and surgery can open or bypass blocked arteries.

Coronary angiography assesses if arteries are blocked and works out suitability for procedures such as percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). It involves injecting a contrast agent and using X-ray imaging to see the narrowing of the coronary artery. FFR is easily measured during routine coronary angiography by using a pressure wire. It is an add-on test for PCI.

[NICE's guideline on managing stable angina](#) recommends coronary angiography to guide treatment strategy in people whose angina symptoms are not controlled by drug therapy. [NICE's guideline on unstable angina or non-ST-segment-elevation myocardial infarction \(NSTEMI\)](#) recommends drug therapy once the condition has been diagnosed. Coronary angiography is recommended within 96 hours of first admission for patients who have an intermediate or higher risk of adverse cardiovascular events.

Coronary angiography is also recommended with follow on primary PCI if needed. This is for people with acute ST-elevation myocardial infarction (STEMI; see the [NICE guideline on myocardial infarction with ST-segment elevation](#)) if they present with symptoms within 12 hours of onset of symptoms and if PCI can be given within 120 minutes of when fibrinolysis could have been given. NICE medical technologies guidance on [HeartFlow FFRCT for estimating FFR from coronary CT angiography](#) recommends the non-invasive HeartFlow FFRCT for patients with stable, recent onset chest pain who are offered

coronary CT angiography. This is part of the [NICE Pathway on chest pain](#).

Population, setting and intended user

Optowire is for people with coronary artery disease, to measure FFR in interventional cardiology pressure wire procedures.

The device would be used by interventional cardiologists in a cardiac catheterisation laboratory setting, during PCI or diagnostic angiography.

Costs

Technology costs

A single Optowire device is £475 (excluding VAT) and the hardware costs £3,000 (excluding VAT). The cost per unit is lower depending on the length of the contract and the number of units purchased. Optowire can only be used with Optomonitor. Optomonitor has a 12-month manufacturer warranty and the service and all updates are included in the cost of the technology.

Costs of standard care

The cost of comparator guide wires ranges between £25 and £900. Based on the National Tariff, the best practice tariff for ST-segment elevation (actual or suspected myocardial infarction), ranges from £1,484 to £5,029 for the non-elective procedure. The best practice tariff for complex percutaneous or standard transluminal coronary angioplasty ranges from £2,617 to £7,889.

Resource consequences

According to the company, the device has been used in the diagnosis and treatment of over 60,000 patients in more than 30 countries.

The resource impact would be greater than standard of care because of the device cost. This could be offset if the technology prevents misclassification of stenosis and avoids unnecessary stenting of an artery more than similar guide wires or non-invasive devices

already in use.

There is minimal additional training required for insertion of Optowire for clinicians familiar with standard pressure wire guides. This training is included in the cost and provided at no charge.

Regulatory information

Opsens Optowire is CE marked as a class III medical device. It received its CE mark in 2014.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

No equality issues were identified.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Three studies are summarised in this briefing including a total of 183 lesions in 173 patients who had clinical indication for percutaneous coronary intervention (PCI). These studies have been assessed as most relevant from a wider evidence base.

[Table 1](#) summarises the clinical evidence as well as its strengths and limitations.

Overall assessment of the evidence

The evidence suggests that Optowire may be associated with less pressure drift when measuring fractional flow reserve (FFR). This may mean that FFR is measured more accurately.

The studies in this briefing are non-comparative, single-centre, cohort studies (2 full publications and 1 conference abstract) with a small number of patients. A common feature across these studies was that FFR measurements were used for clinical decision making about whether stenting a stenosis was necessary. Two of the studies showed the feasibility of measuring FFR in a side-branch lesion after main vessel stenting; a procedure which is often difficult to do. No comparison with other guide wires means it is unknown how much reduced drift improves accuracy in FFR measurements. It is also unclear how the studies got the pressure drift threshold and FFR cut-off points. A variation in FFR cut-off points is seen across the studies. Results should be interpreted with caution because the impact of this variation is uncertain. Other outcomes assessed include the usability, safety and accuracy of the device.

These studies were not done in the UK and it is likely that clinical practice at the study sites may vary. Therefore the generalisability of the evidence to the NHS may be limited.

There are several published abstracts and conference posters for optical sensor guide wires that were not included in the evidence summary because they give limited additional information.

Table 1 Summary of selected studies

<u>Hiroiyuki et al. (2017)</u>	
Study size, design and location	A cohort study to decide whether to treat a jailed (covered) side-branch lesion after main vessel stenting in 35 patients (37 lesions) with coronary bifurcation in a heart centre in Japan.
Intervention	Jailed pressure wire technique using Optowire.

Key outcomes	FFR was successfully measured in the SB in all cases. Pre- and post-procedure FFR values in the SB was 0.83 ± 0.12 and 0.84 ± 0.13 respectively in 84% of lesions. Based on an FFR cut-off of more than 0.75, these lesions had no further intervention. In 16% of lesions when FFR measured 0.75 or less, kissing balloon technique was used for further treatment of these lesions. None of the 37 lesions showed PD of more than 3 mmHg.
Strengths and limitations	The study addressed a clearly defined population and considered specific outcomes. This is a conference abstract with limited details about the study such as patient recruitment, baseline characteristics of patients, inclusion criteria and study design.
<u>Kawase et al. (2017)</u>	
Study size, design and location	A prospective study of 90 patients (95 consecutive lesions) who had clinical indications for elective PCI of native coronary artery in a heart centre in Japan.
Intervention	Coronary catheterisation based on FFR measurements using Optowire and coronary angiography for anatomic lesion measurement.
Key outcomes	Pre- and post-procedure FFR values were 0.63 ± 0.16 and 0.85 ± 0.07 respectively. PD assessment was performed at the discretion of the operator. PD was seen in 71% of cases. For the measurements with PD, the mean FFR change by PD correction was 0.01 (range -0.02 to 0.08). The decision changed from FFR of 0.80 or less, to above 0.80 in 7% of measurements and the other way around in 1%. The authors noted that PD correction contributed a significant positive bias (0.00960, 95% CI 0.00589 to 0.01331). The grey zone for FFR was defined as 0.75 to 0.80. When FFR values were between 0.78 and 0.82, classification changed in 53% of lesions. Absolute PD of less than 4 mmHg was seen in 66% of cases. Large PDs were seen in 4% of cases.
Strengths and limitations	Statistical analysis was used to assess the relationship between readout and PD-corrected FFR values. This potentially ruled out confounding factors. The authors noted that there was no established validation of FFR correction by PD and no consensus regarding an acceptable PD threshold.

Omori et al. (2019)	
Study size, design and location	A retrospective cohort study of 48 patients (51 consecutive lesions) who had the jailed pressure wire technique for PCI of CBL during main vessel stenting. Japan.
Intervention	Jailed pressure wire technique using Optowire.
Key outcomes	The primary endpoint was safety defined by rate of complication. No complication associated with the jailed pressure wire technique was reported. The study also reports successfully measuring FFR and retrieving pressure wires in all cases. It was not possible to assess drift retrospectively in 2 cases because of missing data records. FFR was measured without significant final drift in 95.9% of cases. FFR measurements helped interventionists change their decision to perform FKBD in 49% of the cases. There were 24 SB lesions deferred despite having over 50% angiographical stenosis based on the FFR value of 0.84. There was 1 SB lesion that had additional treatment without significant angiographical stenting.
Strengths and limitations	There was an institutional consensus and defined criteria about what cases to include and exclude. This potentially reduced selection bias. The source of funding was not mentioned. However, 1 of the authors is a consultant for the company and other authors noted no conflict of interest.
Abbreviations: CBL, coronary bifurcation lesions; CI, confidence interval; PCI, percutaneous coronary intervention; FFR, fractional flow reserve; FKBD, final kissing balloon dilatation; PD, pressure drift; SB, side branch.	

Recent and ongoing studies

- [The drift-reduction for improved FFR using fiberoptic technology \(DRIFT\) study \(OPSENS\)](#). ClinicalTrials.gov identifier: NCT03848650. Condition: left anterior descending coronary artery stenosis. Status: recruiting. Estimated completion date: January 2021. Location: US.

- [Assessing the accuracy of the Optowire Deux in a wire to wire comparison \(ACCURACY\)](#). ClinicalTrials.gov identifier: NCT01751906. Condition: coronary artery disease. Status: recruiting. Estimated primary completion date: January 2020. Location: Canada.

Specialist commentator comments

Comments on this technology were invited from clinical specialists working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Four specialists contributed to this briefing. Three had used Optowire.

Level of innovation

One specialist felt Optowire is a minor variation to pressure wires already used widely in the NHS. Another specialist referred to it as a fine tuning on existing pressure wires. Two specialists thought that the main innovation is that Optowire is fiberoptic. They noted that the technology has been superseded by pressure wires to measure non-hyperaemic indices (such as instantaneous wave-free ratio and diastolic pressure ratio) alone or as well as fractional flow reserve (FFR). One specialist noted that more established pressure wires (St Jude and Volcano) have greater functionality. Fiberoptic wires could have advantages including kink resistance, ease of delivery and less data drift. However, 2 specialists noted that in clinical practice, Optowire has no observable advantage over other pressure wires. Another specialist stated that the device reduced drift and increases test accuracy. Two specialists noted Boston Scientific's Comet as a comparator. Another specialist identified a fiberoptic pressure catheter: Acist-Navvus.

Potential patient impact

One specialist noted that the ease of use of the device could benefit the patient, particularly if reconnection to the measuring system is needed after a prolonged procedure. Another specialist felt patients will benefit from reduced procedure times, reduced contrast and radiation exposure. People with complex coronary arteries and people with cardiac symptoms who have been invited to have an angiogram are likely to benefit from the technology. All specialists agreed that the technology would not change the current clinical pathway.

Potential system impact

Three specialists thought the technology has little potential benefit to the healthcare system. One specialist noted that improved FFR accuracy and reduced procedure times would benefit the healthcare system. Three specialists agreed that there would be little or no resource impact if the technology was adopted. One specialist thought the higher price of the device compared with other pressure wires would have a sizable financial impact. In this specialist's opinion, the higher cost of the wire is not justifiable.

General comments

One specialist highlighted the need for comparative evidence that shows the claimed benefit and long-term impact of the device. Two specialists had stopped using the device because they found it had some drift. One of them felt it was less accurate than other wires. Two specialists stated that non-hyperaemic indices that do not need to widen the blood vessels are now supported by good data with clinical endpoints, and that these are now used routinely. Another specialist noted that drift can be corrected by an experienced clinician.

Specialist commentators

The following clinicians contributed to this briefing:

- Ian Purcell, consultant general and interventional cardiologist, Cardiothoracic Centre Freeman Hospital. No interests declared.
- Andrew Davie, consultant cardiologist, Queen Elizabeth University Hospital, Glasgow. No interests declared.
- Asif Qasim, consultant interventional cardiologist, Croydon University Hospital and King's College Hospital. Asif Qasim attended Opsens clinical meeting during the transcatheter cardiovascular therapeutics conference.
- Mohaned Egred, consultant interventional cardiologist and honorary senior lecturer, Freeman Hospital, Newcastle University. Has received honorarium unrelated to pressure wires from 2 companies (Abbott and Phillips) who promote pressure wires.

Development of this briefing

This briefing was developed by NICE. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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