

PRESSURE FIBER-OPTIC SENSORS IN INTRA-AORTIC BALLOON PUMPING THERAPY

The miniature (\varnothing 550 μm) fibre optic sensor developed by FISO is based on Fabry-Pérot white light interferometry principle. The sensor is constituted of a micromachined silicon diaphragm membrane, acting as the pressure sensing element, bonded on a cup-shaped glass base. This creates a Fabry-Pérot cavity, whose optical length changes with the pressure variation. The sensor is connected to a multimode optical fiber which acts as the light conveyor between the sensor and the signal conditioner. White light from a lamp is directed towards the Fabry-Pérot cavity which modulates the signal with a low coherence interference thus coding the sensor cavity length. The wavelength-modulated optical signal is then reflected back towards the signal conditioner which extracts the cavity length information using patented white-light cross-correlation technology.

Because of the electrically insulating nature of fiber and sensor materials, these sensors are not disturbed by incident radio frequency (RF), electromagnetic (EM) or microwave (MW) fields. This makes the FOS technology a perfect candidate for physiologic sensing solutions in the presence of equipments generating or using RF, EM, or MW fields now often seen in clinical environments.

Miniaturization of such sensors as well as the use of inert components in making optical sensors permits *in vivo* and *in situ* measurements in restricted areas such as small vessels or in delicate tissues such as the brain. With the increased development of minimally invasive surgery using instrumented catheters there is now a growing demand for miniaturized, reliable, and accurate sensors mainly for temperature and pressure measurement in medical fields such as cardiology, neurology and urology. Responsiveness combined with high sensitivity is another FOS asset exploited in applications requiring detection of fast and/or subtle physiological changes. Typical applications would be in intra-aortic balloon pumping (IABP) therapy which will be discussed in the present article.



Figure 1 : Fiber Optic Sensor FOP-MIV (\varnothing 550 μm) pictured here in a 24 gauge needle.

Intra-aortic balloon pumping therapy

The Intra-aortic balloon pumping (IABP) therapy developed more than 30 years ago now is one of the most popular forms of life-supporting mechanical assistance normally used when pharmacologic therapy fails or presents a high risk of mortality or morbidity due to high drug doses. This therapy is often used temporarily to help patients recover from critical heart diseases, cardiac surgery or to wait until a transplant is performed.

This therapy consists of inserting, generally through the femoral artery, a catheter terminated by an inflatable balloon which is then positioned into the descending aorta just below the subclavian artery. Once in place, the balloon is timed to inflate at the onset of the diastole (increasing diastolic blood pressure and myocardial oxygen supply) and to deflate just prior to ventricular ejection (decreasing blood pressure in the aorta, left ventricular afterload and myocardial oxygen demand). Such counter-pulsation therapy improves mean arterial pressure and cardiac output,

decreases left ventricular afterload and as a result the cardiac work. It also allows for improvement in blood pressure quality in the superior vessels thus also improving the oxygen delivery to the heart and brain.

Critical synchronization of balloon inflation and deflation with heart cycle phases is normally performed using the patient's electrocardiogram (ECG) or arterial pressure waveform. The use of ECG for accurate triggering is not possible in presence of heart pathology affecting heart electric signal as some types of arrhythmia or other cardiomyopathies. In such situations arterial pressure waveform monitoring is preferred. Pressure is currently remotely measured by the mean of fluidic pressure transduction through the catheter and an external pressure electrical transducer. However, fluidic transduction has a limited dynamic response due to fluid mass inertia and elasticity of the catheter conveying the fluid. In addition external effects may further disturb the pressure signal as patient movement, vibration encountered in transport vehicles like ambulance or helicopter or due to mishandling of fluid line that can introduce air bubbles.

Miniature fiber optic pressure sensor allows *in situ* pressure measurement avoiding all fluidic transduction problems and related measurement uncertainties. The fiber optic pressure sensor is positioned directly at the tip of the IABP catheter, exactly where the aortic pressure waveform has to be measured.

Figure 2 demonstrates the difference between remote pressure measurement with fluidic transmission (Graph B) and *in situ* pressure measurement performed with fiber optic sensor positioned directly where the pressure is to be measured, such as the tip of the IABP catheter (Graph A).

A Bio-Tek 601A pressure simulator was used to generate aortic pressure curve where the IABP catheter is normally positioned. Pressure wave forms were collected at the exit of the generator as it is the case when an optical pressure sensor is located at the tip of IABP catheter (Figure 2 graph A) and 3m apart with fluid transduction 8 French (\varnothing 2.75 mm) catheter at it is currently done with the fluidic-transduction combined with external electrical pressure measurement (Figure 2 graph B).

It could be seen on graphs A from 2 that the FOP-MIV pressure sensor S1 located near the pressure generator records the pressure with high fidelity and without dynamic artefact. The aortic waveform shows a characteristic shape where the systolic (S) and diastolic (D) events could clearly be separated by the dicrotic notch event (DN arrow) indicating the aortic valve closure and thus the transition between the systole and the diastole. The detection of this important minute pressure event is critical for IABP therapy since it indicates the exact moment when the intra-aortic balloon should be inflated. The need for a sensitive sensor capable of clearly identifying the dicrotic notch is actually essential. Balloon deflation is completed at the end of the diastole which is more easily detected by the rapid pressure increase observed at the beginning of the systole.

For the sensor S2 located at the extremity of the 8 French (\varnothing 2.75 mm) catheter the recorded pressure is in fact significantly different from the pressure generated by the Bio-Tek 601A pressure simulator. It can be seen on the waveform in B that pressure overshoots and undershoots are present indicating that fluidic pressure transduction is in fact a secondary dynamic system. Such pressure bouncing impacts the aortic waveform by artificially increasing the visibility of the dicrotic notch but also by slightly shifting its time position. Such an effect is not recommended for precise triggering purposes such as required in the IABP therapy.

On the right part of the graphs B in 2 (after 2 s) the fluid-filled catheter has been manually vibrated in order to simulate vibrations that could occur in real IABP therapy such as the one encountered during patient transportation. It could be seen on graphs that the vibrations of the catheter are creating erratic pressure fluctuations which make it virtually impossible to locate the dicrotic notch on the aortic pressure waveform. In opposition, during the disturbance, the sensor S1 located near the pressure generator did not see the erratic variations in pressure (pressure waveforms before and after 2 s are identical as seen in graph A).

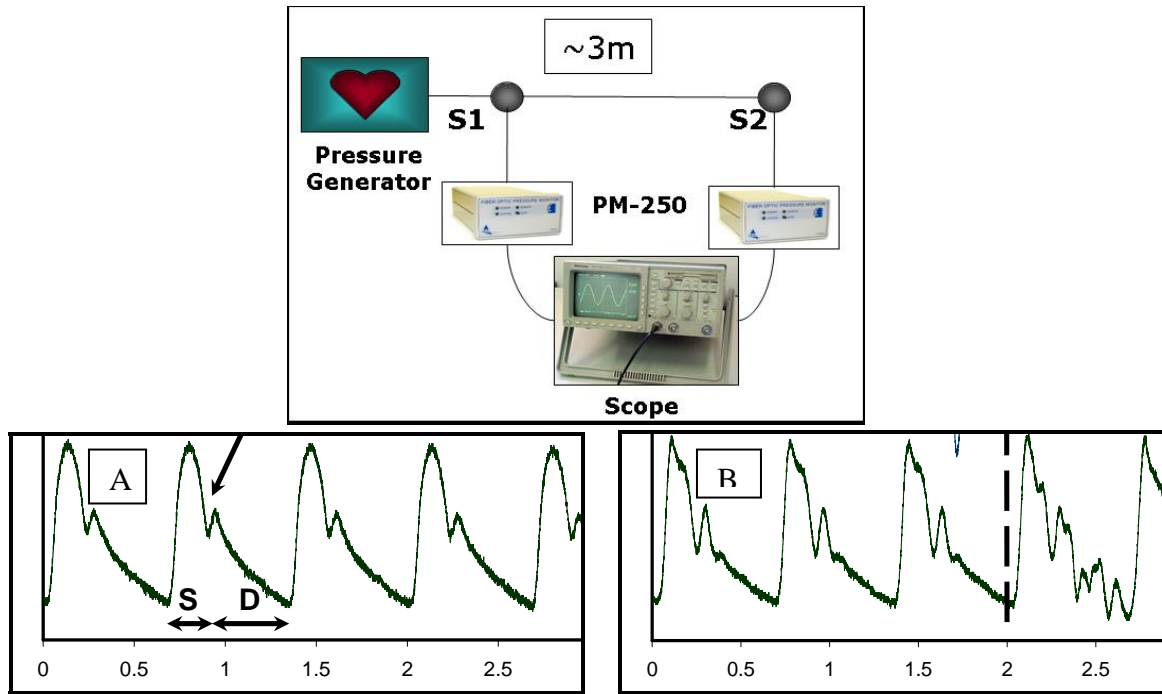


Figure 1: Top graph: Pressure generator (Bio-Tek 601A) simulates aortic pressure, S1 represents location of *in situ* measurement directly at the exit of the generator pump, S2 represents the pressure monitoring after the 3m fluidic-transduction catheter. A: Pressure waveforms (fluctuating with time expressed in seconds between 80 mmHg and 140 mmHg). Represents *in situ* measurement as measured by a Fiber Optic sensor at S1 position, which accurately duplicates the pressure curve generated by the Bio-Tek 601A generator. B: Represents remote fluidic transmission measurement at S2 position.

These examples simulating real life situations clearly demonstrate that *in situ* pressure monitoring is definitely more accurate and safer than external pressure monitoring via fluid-filled catheters. The use of FOS for IABP therapy should therefore provide a better control of triggering at the right time. Furthermore, it should be noted that the current intra-aortic catheter size of 7.5 to 8 French (\varnothing 2.5 mm to 2.75 mm) is probably the present physical limit for fluid pressure transduction. As a matter of fact, diameter reduction of the catheter is highly desirable in order to reduce the incidence of IABP vascular complications such as ischemia which represent the highest risk of the therapy. Integration of miniature pressure FOS into IABP catheters obviously offers such an opportunity without compromising the accuracy.

We have seen that FOS have many characteristics that make them suitable for various medical applications. The miniature size of such sensors is probably the most interesting feature for this field of application since it allows their integration into minimally invasive medical devices and permits direct *in situ* measurement of essential parameters such as temperature and pressure. This opportunity could dramatically change some well established procedures such as avoiding fluidic pressure transduction and associated illustrated drawbacks in favor of a point measurement exactly where it is needed. This concept will certainly revolutionize several diagnostics and therapies in the near future.

Thanks to their small size, FOS have also virtually no inertia and thus respond quickly to rapid physiological changes such as in the case of blood pressure. Being also accurate, they are perfectly suitable for the measurement of subtle changes that could be critical for some diagnostics or therapies. Finally the intrinsic immunity of FOS to RF, EM, or MW interference is a great advantage that not only increases the reliability of such devices in environments with potential interference sources, but also allows using such sensors in environments with high fields, where conventional electrical sensors usually fail. Specific diagnostics or therapies using such fields could therefore greatly benefit from the monitoring opportunities offered by FOS technologies.

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