Miniature Fiber Optic Pressure Sensor for Medical Applications: an Opportunity for Intra-Aortic Balloon Pumping (IABP) therapy

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ABSTRACT

In this paper we present how a miniature fiber optic pressure sensor based on micro-optical mechanical systems (MOMS) could solve most of the problems associated with fluidic pressure transduction presently used for triggering purposes in IABP therapy. The small size of the MOMS (∅ 550 µm) allows a positioning of the sensor directly at the tip of the intra-aortic catheter, exactly where the pressure should be monitored. With outstanding performances in terms of resolution and frequency fidelity, this absolute pressure sensor can precisely detect small pressure variations such as the dicrotic notch in the intra-aortic pressure waveform, which is used as a trigger point in IABP therapy. Such technology could probably help in the development of a less invasive therapy with reduced catheter size associated with reduction of vascular complications such as ischemia.
The presented optical fiber sensor has intrinsic immunity to electromagnetic fields and noise perturbations. Furthermore, the patented white-light cross-correlation technology of the signal conditioner makes it immune to optical fiber binding and highly tolerant to optical losses. Such solution is extremely well adapted for *in situ* pressure monitoring in many medical applications.

Keywords: Fabry-Perot interferometer, white light interferometry, Micro-Optical Mechanical System (MOMS), pressure transduction, *in situ* monitoring, cardiac blood pressure, mechanical heart support, assist device, waveform, dicrotic notch

1. Introduction

Over the past twenty years, rapid development in fiber-optic communications has lead to the creation of high-sensitivity control and measurement systems based on fiber light guides. Along with the emergence of fiber optic, the advance of micro-optical mechanical systems (MOMS) have generated tremendous interests in these optical systems as sensing devices. These optical systems possess a number of advantages in comparison with electronic systems. Because of the electrically insulating nature of the fiber and sensor material, these fiber-optic probes are not perturbed by incident radio frequency (RF), electromagnetic (EM) or microwave fields. They may be used in the presence of harsh environmental conditions such as noise, strong EM fields (*e.g.* characteristic of magnetic resonance imaging applications), high voltages (as generated by power transformers), nuclear radiations, or in explosives or chemically corrosive environments.

Also, MOMS-based sensors are orders of magnitude smaller than their conventional electrical counterparts. This miniaturization allows these devices to be used as monitoring systems for hard-to-reach objects. Finally, the use of such systems, for example in medicine, has made it possible for clinicians to perform research studies in real time. As new applications are now emerging for that technology especially in the medical area, we present here why a miniature fiber optic pressure sensor could be a great opportunity for intra-aortic balloon pumping therapy.

2. Experimental set-up

The experimental set-up is presented in Figure 1. To test the sensor performance, a Bio-Tek Instruments' blood pressure systems calibrator Model 601A was used as a calibrated waveform generator. This system simulates in a sealed liquid environment (water) different waveforms including typical aortic pressure waves. The pressure was measured with our commercial FOP-MIV miniature pressure sensor connected to our commercial PM-250 signal conditioner operating at

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250 Hz. Real time signal was visualized on a Tektronix TDS 3014 digital oscilloscope connected to the PM-250 with a coaxial cable. Data was transferred to a computer with RS232-DB9 communication link for further analysis. As will be shown in this paper, the FOP-MIV sensor's performances are suitable for physiological applications.

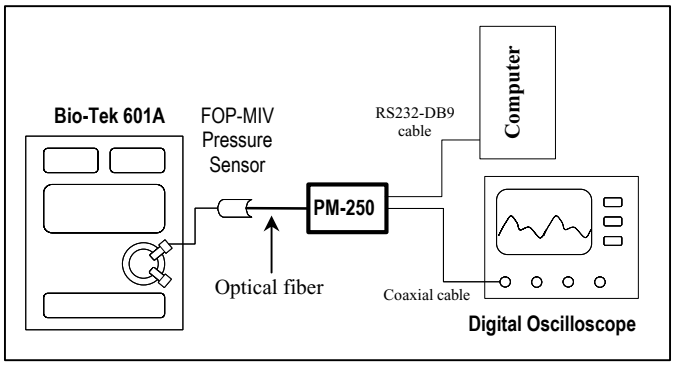

Figure 1 : Experimental set-up for pressure recording

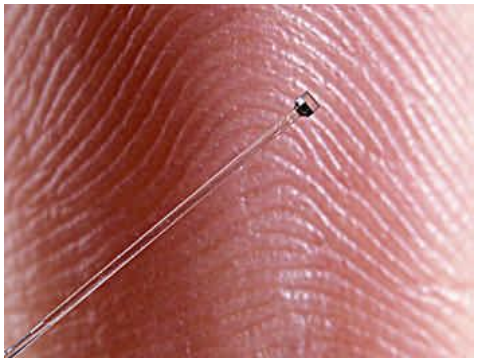

Figure 2 : Miniature FOP-MIV pressure sensor

3. Sensing technology

The heart of FISO's FOP-MIV pressure sensor is a miniaturized Fabry-Perot cavity constituted by a micromachined silicon diaphragm membrane, acting as the pressure sensing element, bonded on a cup-shaped glass base. Using vacuum inside the cavity, rather than an inert gas, prevents changes of internal pressure caused by gas thermal expansion that would distort the pressure measurements. Since high vacuum is maintained inside the cavity, the FOP-MIV is measuring absolute external pressure.

The FOP-MIV pressure sensor is produced in large quantities using manufacturing technologies derived from the semiconductor industry (photolithography processes and automated robot assembly). It 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-Perot 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[1] white-light cross-correlation technology. When pressure is increased on the sensor, the thin membrane is deflected and the Fabry-Perot cavity length is reduced. The monitored pressure variation ΔP can be derived using the formula $\Delta P = \Delta L / S$, where ΔL is the variation of cavity length and S (< 0) is the gauge factor derived from factory calibration.

4. IABP technology

Among the available therapeutic options for cardiac patients, Intra-Aortic Balloon Pumping[2,3] (IABP) continues since more than 30 years[4] to be one of the most popular forms of life-supporting mechanical assistance usually used when pharmacologic therapy fails or presents high risk of mortality or morbidity due to high drug doses. This therapy is usually used temporarily to help patients recover from critical heart diseases or to wait until a transplant is performed.

In modern IABP techniques, an intra-aortic catheter terminated by an inflatable balloon is inserted percutaneously into the femoral artery and is advanced into the descending thoracic aorta with the tip of the catheter positioned just bellow the bifurcation of the subclavian artery. Once in place, balloon pumping is synchronized to the cardiac cycle in order to help severely weakened heart to pump blood efficiently. The intra-aortic balloon is timed to inflate at the onset of diastole (resulting in an increase in diastolic blood pressure and myocardial oxygen supply) and to deflate just prior to ventricular ejection (decreasing the pressure in the aorta, left ventricular afterload and myocardial oxygen demand). This counter-pulsation therapy improves mean arterial pressure and cardiac output, decreases left ventricular preload and afterload and as a result the cardiac work. It also permits to improve the blood pressure quality in the superior vessels thus also improving the oxygen delivery to the brain.

Synchronization with the mechanical cardiac cycle is usually performed using the patient's electrocardiogram (ECG) or arterial waveform. Tachyarrhythmia, cardiac pacemaker function or poor ECG signal may cause difficulties in obtaining synchronization when the ECG mode is used. In such cases, the arterial waveform may be used for triggering, requiring a dynamic blood pressure monitoring. Such pressure is usually measured at the pump unit or at an external patient monitor using a fluidic transduction through the whole catheter and interconnecting hydraulic tubing. In order to have accurate readings, the pressure has to be zeroed to atmospheric pressure and referenced to subtract the hydrostatic pressure contribution of the fluid due to different levels between the catheter end tip and the external measuring unit. One great disadvantage of such measurement is related to the dynamic response of the fluidic transduction: any factor which affects impulse transmission (such as compressible tiny bubbles inside the line or any movement of the tubing) will therefore distort the waveform traveling through the fluid-filled system. It should be noted as well that the tubing may distend as the pulsating waveform travels through it, dissipating energy and thus, long lengths of tubing may not accurately reproduce the blood pressure signal, especially if the tubing diameter is reduced. As a matter of fact the current intra-aortic catheter size of 7.5 to 8 French (∅ 2.5 to 2.75 mm) is probably the present physical limit for such fluid pressure transduction[5]. It should be mentioned that reduction of the size of the catheter is highly desirable in order to reduce the incidence of IABP vascular complications such as ischemia[6,7] another approach for pulsating waveform analysis is thus necessary.

5. Miniature pressure sensor performances

The miniaturized fiber optic pressure sensor that we developed solves most of the problems caused by fluidic pressure transduction as presently used in IABP therapy. First the sizes of the sensor (∅ 550 µm) and of the multimode optical fiber (∅ 155 µm) make possible an insertion of the sensor directly at the tip of the catheter exactly where the aortic pressure has to be monitored thus reducing considerably transduction errors. Intra-aortic catheter with diameter smaller than the current sizes could be accessible with such miniature sensor.
Since the pressure signal is directly coded into optic interferences and is transferred to the signal conditioner by an optical fiber, the readings are intrinsically immune to any electromagnetic interference that could occur in a hospital environment or during a surgery (such as electric knife, electroshocks) or during magnetic resonance imaging (MRI) of an instrumented patient. Thanks to the white light cross-correlation technology used in the PM-250 signal conditioner, the pressure readings are not affected by the binding or displacement of the optical fiber: the system measures an interference position directly related to the Fabry-Perot cavity length of the pressure sensor and not a light intensity level which would have been affected by optical fiber binding (due to increased leaky modes inside the multimode fiber). This feature is a great advantage over fluid transduction for IABP applications. Furthermore, with such optical absolute pressure sensor there is no need for hydrostatic fluid correction.

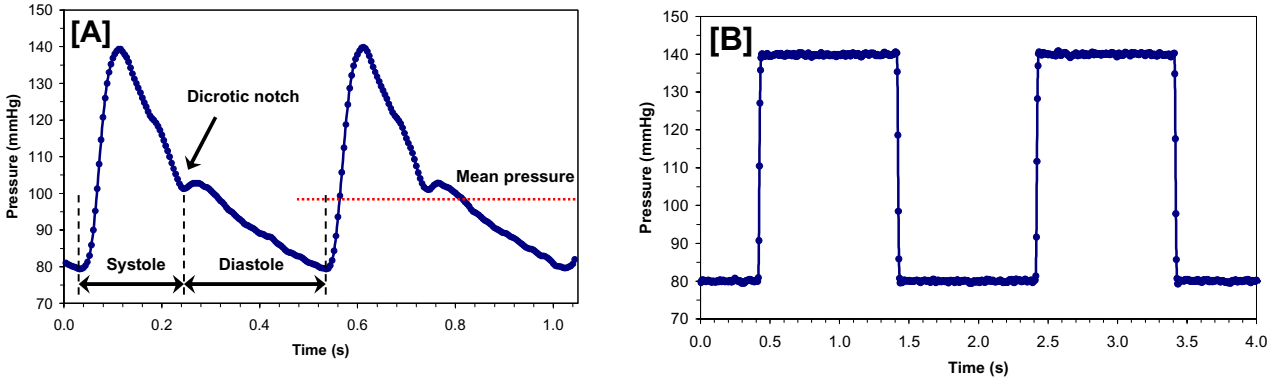

Figure 3 : Pressure fluctuations simulated by Bio-Tek 601A pressure waveform generator as recorded using a FOP-MIV pressure sensor with a PM-250 conditioner. [A] Aorta tachycardia 120 bpm (80/140 mmHg) [B] Square pressure 30 bpm (80/140 mmHg)

The Figure 3 shows the pressure sensor performances in the dynamic mode using the experimental set-up described above (see Figure 1). In each graph the experimental data points are indicated with circles. Since the acquisition rate is

250 Hz, the PM-250 signal conditioner collects a data point every 4 ms. In fact the dynamic response of the miniature sensor is certainly limited here by the signal conditioner. Faster acquisition systems are commercially available (such as FISO's BUS System operating at 1 kHz) and may be needed for small animal blood pressure monitoring (with heart beating faster), but for human medical applications a rate of 250 Hz is sufficient as seen in Figure 3 [A] simulating an aorta tachycardia at 120 bpm (2 beats / second). The non linear decay of pressure during diastole corresponds to the "Windkessel" model of the aorta and the systemic circulation[8]. The resolution of our FOP-MIV pressure sensor (0.5 mmHg) is sufficient to clearly detect the dicrotic notch (see arrow in Figure 3 [A]) indicating the aortic valve closure and the transition between the systole and the diastole. The detection of this important pressure event is critical for IABP therapy since it indicates the exact moment when the intra-aortic balloon should be inflated. 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.
The Figure 3 [B] shows that the FOP-MIV sensor is responding to square pressure waveform with high fidelity and without damping effects such as commonly observed in fluidic pressure transduction of commercial IABP systems[9]. The fact that the optical sensor is recording the "true" blood pressure frequency response is therefore a great advantage which makes the signal analysis much simpler (no need for damping coefficient calculation and for dynamic compensation) and reduces dramatically the number of false readings. The net result of our technology is a fast and reliable pressure reading that could safely be used for IABP triggering.

CONCLUSION

We showed that our miniature fiber optic pressure sensor (FOP-MIV) associated with our robust and fast signal processing unit (PM-250) may solve many of the fluidic pressure transduction problems encountered in IABP present technology. Sub millimeter dimensions of the sensor and outstanding resolution and frequency response performances also offer the possibility of integration inside a smaller diameter catheter which will make IABP therapy less invasive.

Those advantages correlated with an optical detection method intrinsically immune to electromagnetic perturbations suggest that the FOP-MIV sensor may also be a good candidate for other medical applications such as urodynamics or intrauterine or intracranial pressure monitoring. Since our Fabry-Perot technology offers interchangeability with our commercial miniature sensors, other physical parameters such as temperature, strain/force could be interesting physiological parameters to measure for medical applications (see www.fiso.com).

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