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Flexible Thin-Film PVDF-TrFE Based Pressure Sensor for Smart Catheter Applications

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Abstract—We demonstrate the design of thin flexible pressure sensors based on piezoelectric PVDF-TrFE (polyvinyledenedifluoride-tetrafluoroethylene) co-polymer film, which can be integrated onto a catheter, where the compact inner lumen space limit the dimensions of the pressure sensors. Previously, we demonstrated that the thin-film sensors of one micrometer thickness were shown to have better performance compared to the thicker film with no additional electrical poling or mechanical stretching due to higher crystallinity. The pressure sensors can be mass producible using standard lithography process, with excellent control of film uniformity and thickness down to one micrometer. The fabricated pressure sensors were easily mountable on external surface of commercial catheters. Elaborate experiments were performed to demonstrate the applicability of PVDF sensors towards catheter based biomedical application. The resonant frequency of the PVDF sensor was found to be 6.34 MHz. The PVDF sensors can operate over a broad pressure range of 0–300 mmHg. The average sensitivity of the PVDF sensor was found to be four times higher (99 μV/mmHg) than commercial pressure sensor while the PVDF sensor (0.26 s) had fivefold shorter response time than commercial pressure sensor (1.30 s), making the PVDF sensors highly suitable for real-time pressure measurements using catheters.

Keywords—Piezoelectricity, Pressure sensor, Thin film, PVDF-TrFE, Crystallinity, Microfabrication, Catheter.

INTRODUCTION

Endovascular techniques are emerging as an important adjunct for the treatment of large blood vessels in traumatic injury.[9,18,24,25] Accessing a bleeding vessel from within the vascular system can avoid the need for large, morbid incisions to access these deep-lying structures. Injuries of the largest blood vessel in the body, the aorta, are now routinely managed by these techniques.[2,12,15,29] In order to treat other major vessels with more complex anatomy, it is desirable to be able to monitor perfusion pressures at multiple sites along an interventional catheter. Sensors capable of such pressure monitoring will allow the determination of hemorrhage control in the artery of interest, the adequacy of residual flow in other vascular beds, and direction of flow between sensors. However, lumen space within the catheter must be preserved for other interventional apparatus, putting constraints on the size and bulkiness of the extant implantable pressure sensors.

Implantable pressure sensors have been a topic of interest since the 1950s.[5,19,29] Currently, the commonly employed pressure sensors use optical,[7,13,14,23] piezoresistive[6,8,21,30] or capacitive[1,4,20,22] technology. Such sensors are bulky, however, which makes them unsuitable for use in catheters, which must have internal space for interventional apparatus. Further, the stiffness imparted to the catheter by such sensors is highly undesirable. A compact, flexible pressure sensor would allow development of an interventional catheter that includes multiple points of pressure measurement, including inflation pressure as well as upstream and downstream blood pressure. Figure 1 shows the schematic of such a catheter mounted with two sensors on either side a balloon catheter.

In this study, we report the development of flexible, compact structures for biosensing application using piezoelectric materials, which could be easily integrated on curved surfaces of catheters. Conventionally used piezoelectric materials for pressure sensing applications,[3,36] like PZT, BaTiO3, show high piezoelectricity[34]

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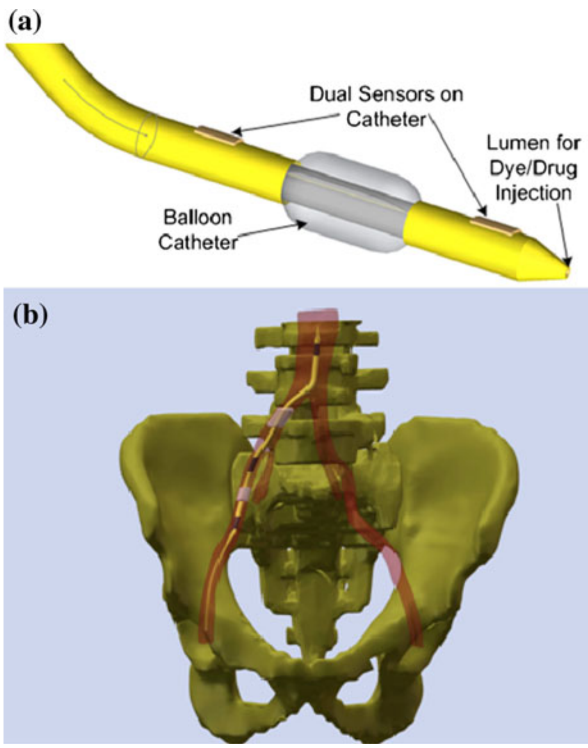

FIGURE 1. Concept of smart catheter with integrated pressure sensors. (a) Schematic showing the desired placement of PVDF based thin film pressure sensors on catheter; and (b) schematic showing placement of a two-balloon catheter in illiac artery with multiple pressure sensors on either side of the balloon.

(Table S1) but are either brittle or not biocompatible. The fabricated sensors were tested under *in vitro* and *ex vivo* physiological conditions. Development of such versatile sensors can profoundly revolutionize the catheter development, especially for trauma care surgery.

MATERIALS AND METHODS

PVDF-TrFE Co-polymer

Figure S1 (electronic supplementary information) shows atomic structure of α-phase PVDF and β-phase PVDF respectively. Untreated PVDF itself cannot have β phase without delicate mechanical stretching or electrical poling processes. Additionally, due to its incompatibility with the standard lithography process, many alternative fabrication methods such as screen printing and shadow mask process[11] have been developed. Previously, we reported a practical option to overcome these limitations, and offer cost-effective batch process with high film uniformity and high resolution of polymer on silicon patterning towards enhanced sensor performance using standard clean room techniques.[27,28]

Here we developed flexible sensors which could be easily integrated on curved surfaces of catheters. The fabricated sensors were tested under *in vitro* and *ex vivo* physiological conditions. Development of such versatile sensors can profoundly revolutionize the catheter development, especially for trauma care surgery.

PVDF-TrFE powder (70:30 molar ratio) was obtained from Solvay Inc. MEK (2-butanone), Acetone and IPA (isopropyl alcohol) were obtained from Sigma Aldrich. All the above mentioned chemicals were used as obtained. PVDF solution was prepared by dissolving the PVDF-TrFE powder in MEK, resulting in 8% concentration of the solutions.

Thin-Film Sensor Design and Fabrication

In the present study, we fabricated single and dual membrane geometries in the following bottom electrode sizes: 2×10 and 5×5 mm^2 to optimize the signal output while maintaining compact form factor for catheter integration. Previously, we have shown that higher surface area of the piezoelectric devices correspond to higher signal output.[28] However, the 2×10 mm^2 devices were fabricated to facilitate ease of integration with catheters (described below).

Figure S2 summarizes the fabrication process for flexible sandwich sensors. Starting with a kapton (polyimide, McMaster Carr) film fixed on a test silicon wafer (4″ diameter), photoresist was spin-coated to pattern the bottom Al electrode (2000 Å thick) using lift-off process. The prepared PVDF solution was spin coated on the Al-patterned wafer at 2000 rpm for 30 s to get 1 μm thick film, as reported before.[28] The spin-coated wafer was annealed at 110 °C for 1 h in a vacuum oven to increase adhesion between the film and the substrate.[28]

Another patterned photoresist was used as a Reactive Ion Etch (RIE) mask to pattern the PVDF-TrFE thin film. Then dry etch was performed under 100 sccm oxygen gas environment with 200W RF power and 5 mT pressure. The PVDF-TrFE thin film etch rate was 150 nm/min. The photoresist mask was etched simultaneously with an etch rate of 100 nm/min and dry etch was continued until the photoresist mask was etched fully. Top Cu electrode (2000 Å thick) was patterned by wet etch and the photoresist mask was removed by dry etch.

Thin-Film Sensor Charge Amplifier Circuit

In the present study, we used two different charge amplifiers. One was a commercial charge amplifier (Measurement Specialties Inc.) providing output gain of 40 dB. For recording simultaneous input from dual sensors, a dual-channel charge amplifier was also assembled, capable of up to 60 dB gain. The electrical circuit for the custom-built charge amplifier is shown in Figure S3a using operational amplifiers OPA227 and AD620, specifically were used to convert the high impedance signal to low-impedance signal and for output voltage amplification, respectively. The feedback capacitance, which determines the sensitivity of the charge amplifier, was selectable from 3 pF to 100 μF. The resulting custom-built charge amplifier contained two of the above described circuits (Figure S3) to enable simultaneous reading of two PVDF sensors. Figure S3b shows the completely assembled charge amplifier used in the present study.

Flow Chamber for Sensor Characterization

A 5 × 5 × 6 cm^3 chamber was fabricated, sufficient to accommodate our fabricated PVDF sensor alongside a commercial pressure sensor, for custom based pressure testing of PVDF devices (Fig. 2a). The PVDF device was placed at the center of the chamber. The backside of the device was fixed to the device holding plate using the adhesive kapton film. A commercial pressure sensor (Freescale Semiconductor, MPX2300DT1) was placed on the second plate. The commercial pressure sensor was supplied an input of 5V$_s$, making the sensitivity up to 25.3 μV/mmHg. Both, the device and the sensor were so placed that the sensing element was perpendicular to the direction of the air flow. The inlet was kept at a certain air flow rate, while the exit of air from chamber was controlled using a programmable solenoid valve (Dwyer Instruments). The switching frequency of solenoid valve was controlled using LabVIEW program. The air pressure inside the chamber was controlled by manipulating the time for which the valve remains closed. The two electrodes of the PVDF devices were connected to the terminals of the charge amplifier (Fig. 2b), as described above. Outputs from the charge amplifier were connected to a USB-type (6009) Data Acquisition Kit (National Instruments). The output was further filtered using a digital low-pass filter (set to 8 Hz) with Infinite impulse response filter set to inverse Chebyshev filter of order three. A low threshold values of 8 Hz was selected for the low pass filter because most of the physiological processes occur at 1–3 Hz range, corresponding to 60–180 heart beats per minute. The chamber plates were sealed using custom-shaped o-ring made from flexible silicone elastomer. The electrode pads of the PVDF devices were connected to external wires using silver print (GC electronics).

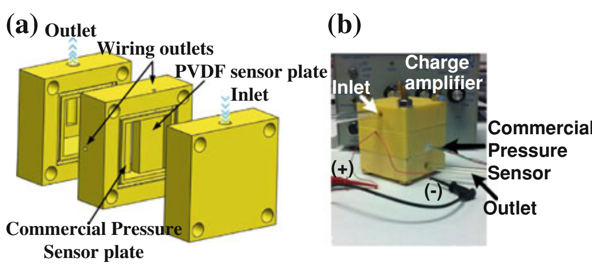

FIGURE 2. Flow chamber assembly for sensor measurements. (a) Schematic showing chamber with air flow through the system; and (b) actual photograph of chamber in the testing setup.

Vascular Testing Model

To simulate physiological blood flow, a 3D model of the aorta and lower arteries was fabricated using a laser sintering machine (Sinterstation HiQ, 3D Systems, Rock Hill, SC). The model was created by extracting the vascular structures from contrast-enhanced computed tomography (CT) scan data from an average sized male patient. The walls were made slightly thicker than normal in order to stabilize the structure. Barbed tubing connectors were fixed to the terminal ends of this 3D model with one of the segment connected to a 0.5″ tubing to act as the catheter insertion port (Fig. 3).

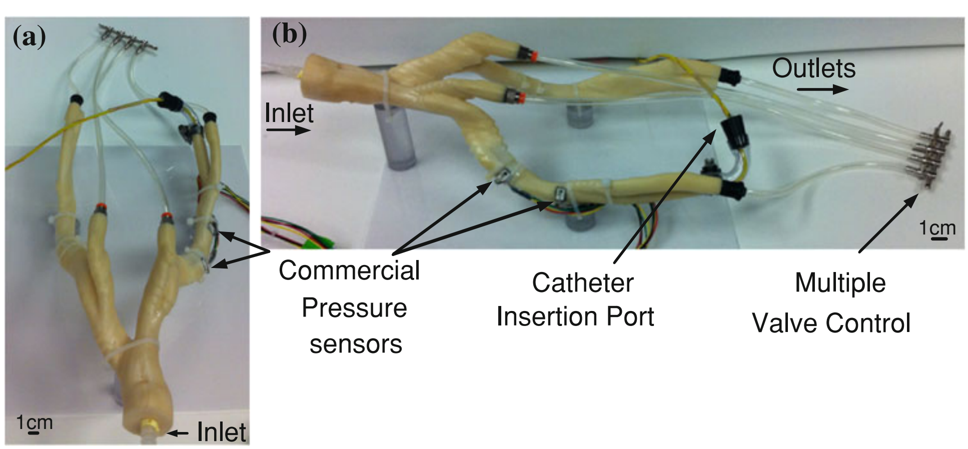

FIGURE 3. Vascular testing model with integrated sensor.

Through-wall holes were drilled in the same segment holding the catheter for placement of the same commercial sensors (mentioned above). The commercial sensors were sealed in place using epoxy in a way such that the transducer element was open to the fluid flowing inside the arterial segments.

For catheter assembly, commercial aortic occlusion catheter was used for testing (10Fr gauge, Coda Aortic Catheter, Cook Medical, Bloomington, IN). Pair of 40 gauge insulated magnetic wires was used to make connections to the device electrode pad. The electrical wires were wrapped around the catheter surface or passed through the internal lumen space of the catheter (Fig. 4b). The electrical connection was made using silver print. The whole joint was insulated using UV curable epoxy.

RESULTS

Figure S4 shows higher crystallinity obtained from 1 μm thick PVDF films. Figure S4b shows the DSC curve for PVDF melt showing the loss in polarization (Tc ~ 115 °C) of PVDF films upon recrystallization. Therefore, all the PVDF films were annealed at temperature of 110 °C after spin coating.

Since higher crystallinity was obtained from 1 μm thick films previously, this thickness was only used in the present study to fabricate thin film sensors.[27,28]

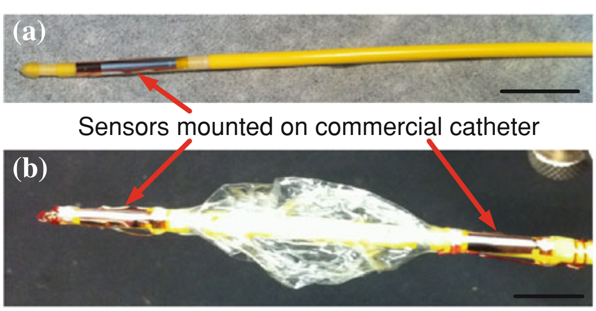

FIGURE 4. (a) Photographs showing PVDF pressure sensors mounted on catheter; and (b) on either side of balloon. Scale bars: 1 cm.

Patterning of devices directly on kapton film (Fig. 5) enabled development of flexible pressure sensors, which could be later transferred to desirable curved surfaces.

Figure 5 shows the 5 × 5 mm^2 type of devices that were fabricated and used in the present study. Individual devices were peeled off from the test wafer using a scalpel and placed against the hard wall surface of the air testing chamber as indicated in Fig. 2. The electrical wires from the PVDF sensor device were connected to an external charge amplifier (Fig. 2b).

When tested inside the air chamber, PVDF sensors were initially tested for response to the variation in the air pressure. The solenoid valve was set to operate at a frequency of 1 Hz and the flow rate into the air chamber was increased.

The devices showed good peak-to-peak correlation compared to the commercial pressure sensor (Fig. 6). An increase in the input flow rate increased the chamber pressure and similar result was observable using the PVDF pressure sensor in the air chamber. By keeping the air in-flow rate constant and varying the solenoid valve operating frequency, the air pulsating frequency in the chamber could be varied. Again, the PVDF pressure sensors show a good correlation with the commercial pressure sensors. Electrical impulse inputs to these devices yielded a resonant frequency of 6.34 MHz for the films and a damping ratio of 0.442, indicating under damped nature of the PVDF pressure sensor film (data not shown).

When two electrode devices were connected, the top two electrodes were connected to independent channels and the bottom electrode acted as the common ground electrode. Output from such a device is shown in Fig. 7. The plot shows the output obtained from the devices after charge amplification, in mV and the corresponding ambient pressure in mmHg. The PVDF sensors performed at a sensitivity of 99 μV/mmHg.

For water based testing in the vascular testing model, the assembled catheters were inserted through the port up to a distance such that the PVDF sensors were in proximity of the commercial sensors in the same segment. The inserted catheter was locked in

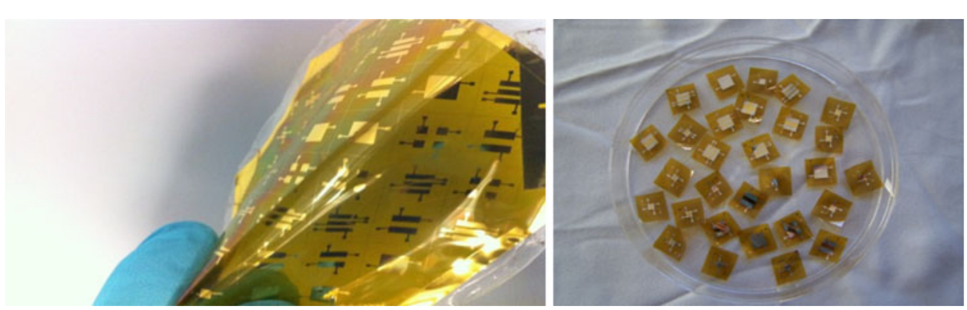

FIGURE 5. Images of flexible pressure sensors on kapton film.

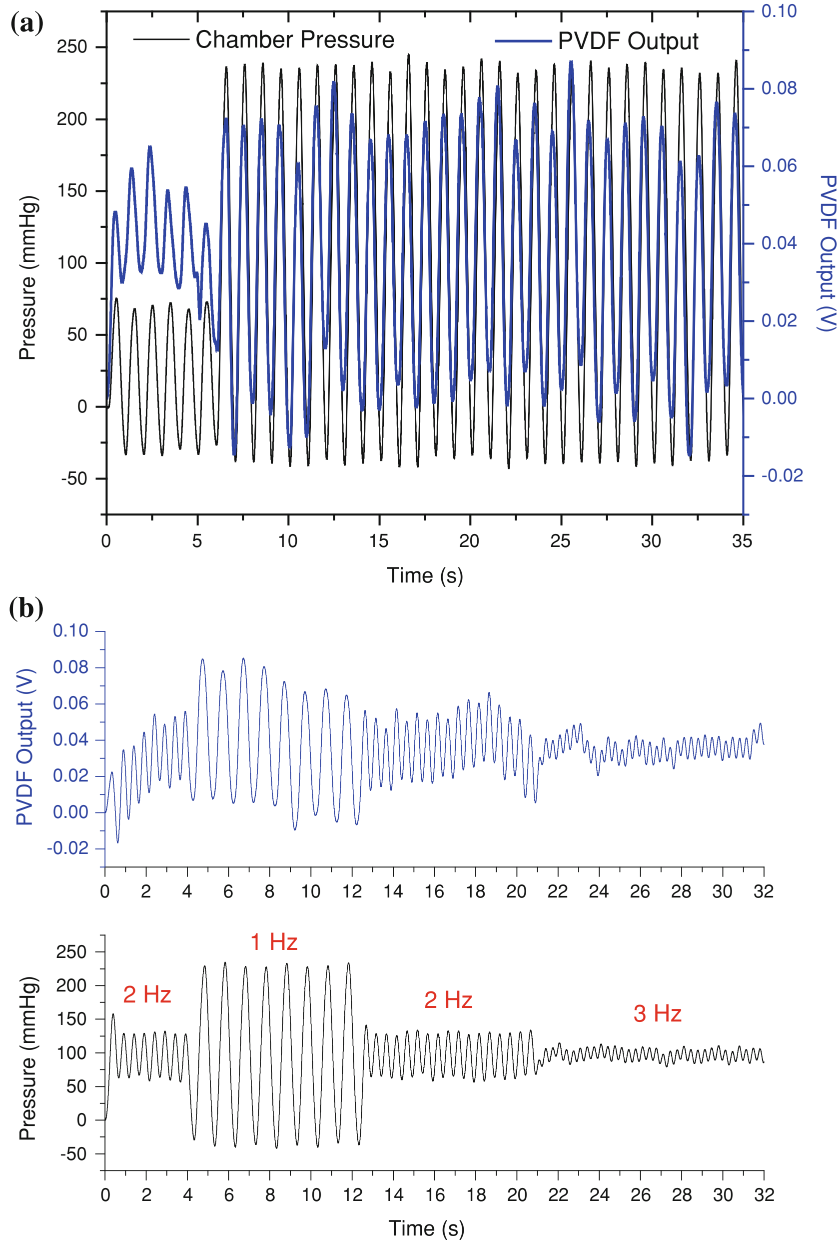

FIGURE 6. Comparison of real-time pressure measurements using PVDF thin-film sensor (blue curve) and Freescale pressure sensor (black curve) as a function of the (a) ambient pressure change in chamber; and (b) chamber pressure frequency.

place using butyl rubber cork which with custom drilled bore size and made water-tight using hot-glue.

Water was injected into the completely assembled vascular testing model with the help of a roller pump. The catheter port segment was first kept unsealed to allow escape of air. The water pressure and flow rate in the various segments was controlled using a multi-flow valve (Fig. 3a). The fluidic pressure inside the vascular testing model was controlled manually by manipulating the fluid flow rate and the time for which the valve was closed.

PVDF sensors were secured on commercial catheters and placed inside a custom-built 3D vascular model (Fig. 3b) for simulating physiological pressure variations (0–300 mmHg). The water fluid pressure inside the vascular model was controlled manually and simultaneous signals were recorded from both the PVDF devices and the commercial pressure sensors. The signal output from the sensors is shown in Figure S5 and Fig. 8. From the plot, we see a good correspondence from PVDF devices under wet conditions as well. Further, the signal to noise ratio is higher from PVDF devices compared to the commercial sensor. Similar results were obtained from dual sensors mounted on a catheter and tested in the 3D vascular model.

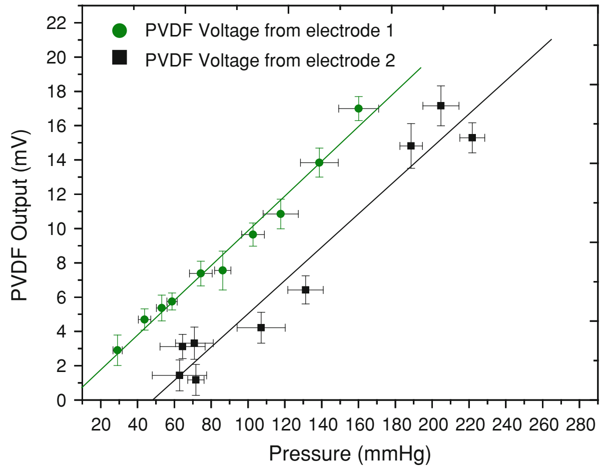

FIGURE 7. The flexible-PVDF sensor response versus the chamber pressure for two independent top electrodes. Slope of the graphs indicate reliable performance from the two electrodes with different zero errors and a high sensitivity of 99 μV/mmHg.

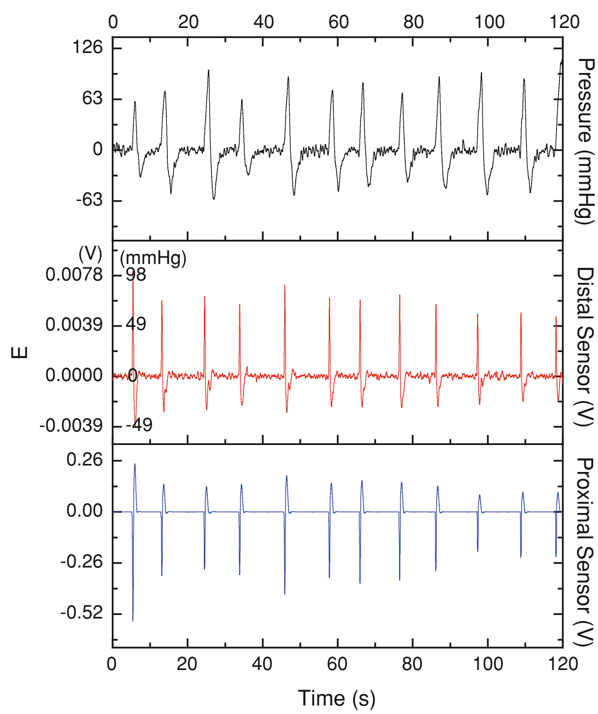

FIGURE 8. Comparison of the proximal (closer to catheter tip) and distal (away from catheter tip) PVDF sensors against the fluid-pressure inside the vascular model. It shows shorter response times of PVDF sensors (0.26 s) compared to the commercial pressure sensor (1.30 s).

DISCUSSIONS

Previously, we demonstrated that curing of PVDF films increase the beta crystalline phase considerably[28] using techniques like Raman and Fourier transform infrared spectroscopy. We also showed that the 1 μm thick PVDF film based devices demonstrate higher sensitivity compared to the 6 μm thick films.[28] These results were further supported by techniques like differential scanning calorimetry (DSC) in the present study. Thinner films show inherently higher crystallinity due to higher stretching during the spin-coating process, without the need for additional electrical poling.

Even with the higher crystallinity of the films obtained here, the signal output from smaller devices is not directly readable by oscilloscopes. However, charge amplification is possible since the sensing element presents a sufficiently large internal capacitance. The charge amplifier is capable of converting the high impedance signal generated by PVDF sensors to low-impedance signal, which can be easily amplified and transmitted to the downstream circuitry.

The testing of the fabricated PVDF sensors show good performance compared to the ambient pressures in the chamber. From Fig. 6a we observe that the travelling average has a noisy nature, which is due to the absence of baseline subtraction. The maximum frequency shown in Fig. 6b is 3 Hz, which also happens to be the range for normal physiological frequencies. Therefore, the PVDF pressure sensor is capable of resolving physiological pressure variations even in miniature flexible version. Thus the output from the PVDF pressure sensor is uniform through the operational frequencies. In other words, there is minimal drift observed for the PVDF sensors.

The dual top electrode based PVDF sensors show a good linear response even with very low functional surface area. Larger devices have show more reliable reproduction of pressure measurements.[28] Since the ambient chamber pressure was measured using a commercial pressure sensor, the data obtained from the commercial pressure sensor was in voltage as well. Using the custom-calibrated equation, this data was used to determine the ambient chamber pressures. Since the commercial pressure sensors perform in a similar manner compared to our PVDF sensors (Fig. 7), we could also calculate the error in measurement using the commercial sensors from the acquired data. This error from the commercial pressure sensor is plotted on the chart as the x-axis error. A quick comparison of the error bars of PVDF sensors versus the commercial pressure sensor indicates that the performance of the PVDF sensors is as reliable as the commercial pressure sensors used in the present study. Further, the sensitivity of the PVDF pressure sensor was found to be 99 μV/mmHg, nearly four times higher than the commercial pressure sensor used in the present study (25.3 μV/mmHg).

Figure 8 shows precise correlation of the signal output with the ambient pressure from the two PVDF sensors mounted on either side of a balloon. Further, there is negligible delay in the signal received when the balloon is deflated. The average response time of the PVDF sensors (0.26 s) was found to be five times higher than the commercial pressure sensor (1.30 s) when evaluated for the 0–100% pressure change. When the balloon is inflated, pressure is recorded from the proximal PVDF sensor only, as expected (data not shown). Again, the commercial pressure sensors in the present case show a lot of noise compared to the high quality signal from PVDF sensors.

For the future prototype ready for catheter based *in vivo* measurements multi-lumen catheters will be used for multiple sensor integration onto a single catheter. In such an assembly, the electrical wirings will be internally present and will not be exposed or affected by blood flow or bodily fluids. For the potential long term biocompatible experiments, the devices can be readily laminated using thin coating of parylene C, which has been shown to be biocompatible,[17,26,32] impermeable[10] and highly stable.[16] Since the young's modulus of parylene C (4.5 GPa,[35]) is similar to that of PVDF (Table S1), a thin layer of parylene C will have minimal-to-no affect the device performance. Further, it has been previously shown that lamination of PVDF films increases the voltage output from the devices.[33]

SUMMARY

In the present study, we demonstrated sensitive pressure sensors that can be directly mounted on catheter and will allow monitoring the blood pressure inside the organ for effective venous balloon inflation pressures. In addition, the dual-sensor system will be able to determine the blood flow direction downstream of balloon, which will enable the surgeons to monitor back-flow effectively. Development for such highly sensitive sensors can eliminate all the guess work during a trauma surgery and provide the surgeons with efficient tools to monitor the catheter placement. Further, this technique has great potential to allow access to regions now inaccessible, or to enhance the surgeon's abilities in applications where current minimally invasive techniques do not permit the full range of human dexterity and perception. In addition, they can even extend the surgeon's capability over great distances, *via* telesurgery.[31]

We demonstrated high sensitivity, shorter response time, and reduced form factor of *in situ* blood pressure and flow monitoring sensors on a catheter for the surgeons to monitor the pressure of the blood vessel. On the broader scale, the piezoelectric thin film technology generated from this research can be extended for both implantable sensing and energy harvesting applications, such as implantable self-powered blood pressure sensors and wireless data transmitters for monitoring real-time patient physiological conditions.

ELECTRONIC SUPPLEMENTARY MATERIAL

The online version of this article (doi:10.1007/s10439-012-0708-z) contains supplementary material, which is available to authorized users.

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