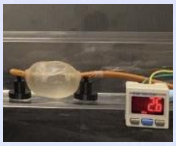

Stretchable Capacitive Pressure Sensing Sleeve Deployable onto Catheter Balloons towards Continuous Intra-Abdominal Pressure Monitoring

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Introduction

Intra-abdominal pressure (IAP) is closely correlated with intra-abdominal hypertension (IAH) and abdominal compartment syndrome (ACS) diagnoses, indicating the need for continuous monitoring. Early intervention for IAH and ACS has been proven to reduce the rate of morbidity. However, the current IAP monitoring method is a tedious process with a long calibration time for a single time point measurement. Thus, there is a need for an efficient and continuous way of measuring IAP. Herein, a stretchable capacitive pressure sensor with controlled microstructures embedded into a cylindrical elastomeric mold, fabricated as a pressure sensing sleeve, is presented. The sensing sleeve can be readily deployed onto intrabody catheter balloons for pressure measurement at the site. The thin and highly conformable nature of the pressure sensing sleeve captures the pressure change without hindering the functionality of the foley catheter balloon.

Intra-abdominal pressure (IAP) is the pressure within the abdominal cavity enclosed by the abdominal wall and the viscera. Normal IAP is defined to be below 12 mmHg. Sustained elevation of IAP > 12 mmHg (1.6 kPa) is termed as intra-abdominal hypertension (IAH), and elevation >20 mmHg (2.7 kPa) is defined as abdominal compartment syndrome (ACS). These IAP elevations can lead to conditions altering organ perfusion and organ dysfunctions [1,2], or even organ failure in extreme cases [3].

Steps	Current Practice For Measuring IAP through Intravesical Pressure (IVP)
1	A ramp with three stopcocks is connected to the drainage tubing of the Foley catheter.
2	An IV infusion bag, 60 mL syringe, and a pressure transducer are connected to the ramp.
3	The bladder and the system are flushed with normal saline.
4	The pressure transducer is fixed at the top of the patient's symphysis pubis bone or thigh.
5	Zero-point calibration of the pressure transducer is done upon stabilization.
6	Urine drainage tubing is clamped.
7	Bladder filled with <25 mL saline solution.
8	The IVP value is recorded as shown on the monitor.

Method

The stretchable pressure sensor comprises two electrode layers and a dielectric layer (Figure 1). The dielectric layer was obtained by a composite mixture of Ecoflex (Smooth-onOn, Inc., Macungie, PA, USA Inc, USA) and cyanoethyl pullulan (CEP) (Shin-Etsu Chemical Co., Ltd., Japan) suspension in a 4:1 ratio. The CEP suspension consists of 4.5 g of CEP in 16 g of propylene carbonate (PC) (Sigma-Aldrich, Inc., St. Louis, MO, USA). The Ecoflex–CEP composite was spin-coated onto an abrasive paper by filling it into the abrasive paper's voids. Upon curing, the abrasive paper was peeled off, leaving the irregularly-patterned microstructures transferred onto the Ecoflex–CEP dielectric layer (Figure 1b). Electrodes were fabricated through a layer-by-layer scalable assembly process (Figure 1c).

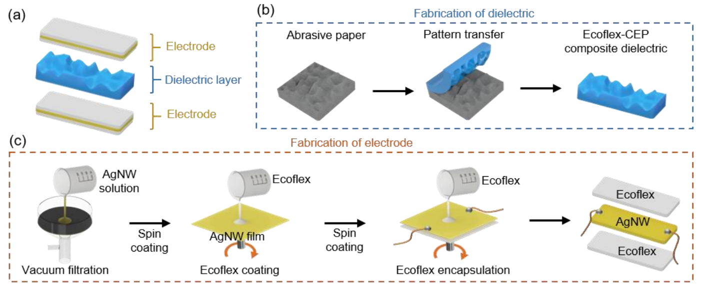
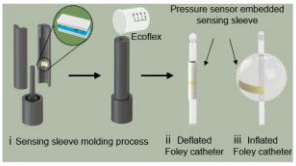


Figure 1 - Schematic representation IAP pressure sensor: (a) components and sandwich layer structure of the pressure sensor, and the fabrication process of the (b) dielectric and (c) electrode.



The measurement of IAP through the Bard 1236-14 Foley catheter balloon requires the assembled pressure sensor to be incorporated into a sensing sleeve, the methods are shown in Figure 2.

Figure 2 - Pressure sensing sleeve on a Foley catheter: Schematic representation of the fabrication of the pressure sensing sleeve.

Results

Owing to the microstructural changes in the dielectric, the sensor exhibits two distinct linear ranges—low-pressure (P < 1 kPa) and higher-pressure (1 kPa < P < 5 kPa). Their linear relationship in the low-pressure range can be attributed to (1), with an R2 correlation of 0.98. Similarly, the linear relationship in the higher-pressure ranges conforms to (2), with an R2 correlation of 0.99.

$$\Delta C/ C_0 = 0.1782P + 0.0127 \quad (1)$$

$$\Delta C/C_0 = 0.0253P + 0.1582 \quad (2)$$

Despite the non-linear characteristics in the IAP working range, the results show that the applied pressure was still directly correlated with the capacitance change, closely following a second-order polynomial of Equation (3) with an R2 correlation of 0.97.

$$\Delta C/C_0 = -0.0354P^2 + 0.1695P + 0.0255 \quad (3)$$

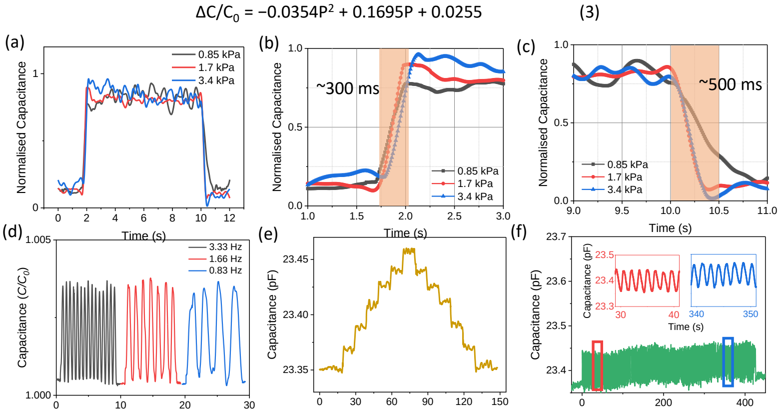


Figure 3 - In-vitro sensor characterizations. (a) Response time characterization under clinically relevant pressure settings. (b) Rise-time of the pressure sensor. (c) Fall-time of the pressure sensor. (d) The sensor response to pressure change is applied in various frequencies. (e) Drift response of the sensor with incremental and decremental small pressure. (f) Cyclic loading performance evaluation of the sensor showing a negligible drift up to 400 cycles. Insets show the obtained pressure cycles in the initial and final stages.

Discussion

In this work, we presented a stretchable pressure sensing sleeve, readily deployable on Foley catheter balloons for continuous IAP monitoring. We focused on optimizing the capacitive sensor to a clinically relevant pressure range (0 kPa–4 kPa) and on integrating the sensor into a sleeve. The workability of the sensing sleeve was demonstrated with a bench-top pressure varying model. Our sensing sleeve will potentially reduce the man-power and time required to monitor patients' IAP continuously. For post-operative patients with a prophylactic open abdomen strategy, our device could be an alternative to reduce the need for follow-up surgery.

In addition, we seek to explore other application areas such as resuscitative endovascular balloon occlusion of the aorta (REBOA) and monitoring of intra-renal pelvic pressure during endoscopic surgery.

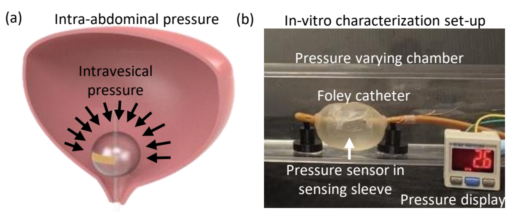


Figure 3 - In-vitro sensor characterizations. (a) Pressure sensing concept. Correlation between IAP and IVP intravesical pressure (IVP). (b) Photograph of the pressure varying chamber set-up.

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