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Tonometric Condition of Cellular Polypropylene Film Sensors in Measuring Arterial Pressure Waveform

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Abstract— **Tonometric continuous measurement of arterial pressure becomes feasible using a cellular polypropylene (Cellular PP) film sensor. A pulsatile arterial vascular phantom model was used to find the range of optimal tonometric conditions and the responsiveness to dynamic pressure changes. The optimal tonometric condition was assessed by the correlation coefficient between the hydraulic pressure and the Cellular PP output using two different types of tubes (the latex tube and the hydrogel tube) to simulate arteries. With a setting of the normal blood pressure range, the output of Cellular PP correlated strongly with the level of hydraulic pressure, 0.998 and 0.989 in the latex tube and the hydrogel tube, respectively. For maintaining the optimal tonometric condition, the depressed depths of the latex and the hydrogel tube were less than 1.2 and 0.6 mm, respectively. The phantom model also demonstrated that the Cellular PP sensor followed changes in a hydraulic pressure dynamically under the optimal tonometric conditions. The present results demonstrated the Cellular PP film sensor is applicable to the arterial tonometry in measuring the instantaneous blood pressure while the sensor is adjusted to maintain the minimal flatness of the underlying arterial wall.**

Clinical Relevance— **To understand the physiological characteristics of blood pressure and arterial system, the instantaneous measurement of blood pressure is necessary. The present study suggests that Cellular PP films are applicable to peripheral arteries tonometrically to obtain simultaneously the respective blood pressure waveforms.**

I. INTRODUCTION

Hypertension is the most common modifiable risk factor for cardiovascular diseases [1]. Epidemiological and clinical studies have shown a strong association between hypertension and adverse cardiovascular events [2-4]. Ameliorating high blood pressure is crucial to prevent clinical events related to cardiovascular diseases. The measurement of blood pressure (BP) is nowadays one of the popular maneuvers in healthcare.

The gold standard of BP measurement has been a sphygmomanometer with an inflatable cuff on the upper arm, listening to the Korotkoff sound with a stethoscope or applying an electrical oscillometric technique [5, 6]. The sphygmomanometer provides both systolic BP (SBP) and diastolic BP (DBP) intermittently, while the invasive method using a catheter is commonly used in operating rooms or ICU to monitor blood pressure continuously [7].

The non-invasive arterial tonometry method was invented in 1963 [8]. The instantaneous measurements of arterial blood pressure using this method have been developed to quantify arterial wall characteristics, including pulse wave velocity (PWV), central arterial pressure, and augmentation index [9-16]. However, many arterial tonometers available for clinical examinations are limited to a hand-held device [11-15] and a rather large wrist type device using an array of piezoresistive pressure transducers [15].

Recently, several applications using cellular polypropylene (Cellular PP) films have been reported with a high constant piezoelectric d_{33} coefficient over 100 pC/N [17] and a significant linear frequency response from 10 Hz to 5 kHz [18-20].

The aim of this study is to examine the feasibility of the Cellular PP film to applanation tonometry by (1) identifying the tonometric condition of the sensor on a fluid-filled phantom model and (2) exploring continuous measurements of arterial blood pressures.

II. MATERIALS AND METHODS

A. Cellular Polypropylene Film Sensor

Cellular polypropylene (Cellular PP) films are piezoelectric materials that are sensitive to dynamic forces to their surface with a high piezoelectric d_{33} coefficient. The d_{33} coefficient quantifies the amount of electricity change in the sensor when a vertical force is applied to the device. For the definition of the d_{33} coefficient, the output charge of sensor Q_{out} can be written as,

$$Q_{out} = d_{33}F \tag{1}$$

Where Q_{out} is generated charge and F is applied force to the device. When the capacitance C is given, the output voltage ΔV_{out} of the Cellular PP sensor can be calculated as

$$\Delta V_{out} = (1/C)\, Q_{out} = (1/C)\, d_{33}\, \Delta F. \tag{2}$$

The Cellular PP film used in this study[3] was 60 μm in thickness and sandwiched between two carbon electrodes with a thickness of 13 μm. The film, electrodes, and the IC circuit were shielded with copper foil. The skin contact surfaces are spray-coated with RTV silicon (FC-112), as shown in Fig. 1(a).

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[3] The cellular polypropylene (Cellular PP) film used in this study was provided by Yupo Corporation. The Cellular PP sensor, which functions as a piezo-electret pulse sensor, was assembled by Kobayasi Institute of Physical Research.

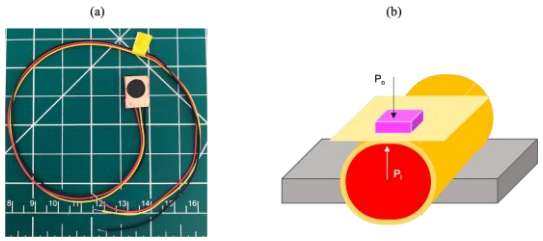

Figure 1. (a) The Cellular PP sensor used in this study. The sensor was covered with a copper film. The black area was attached to the skin. (b) The schematic diagram of tonometric condition.

This sensor had a thickness of approximately 1 mm, a diameter of 10 mm, and a weight of 1g. In preliminary experiments, the Cellular PP sensor used in this study showed d_{33} coefficient of 80 pC/N and capacitance of 70 pF, which yielded that the static sensitivity of the Cellular PP sensor was 1.143 V/N. In the preliminary study, the Cellular PP sensors could detect several peripheral arterial pulse waves such as radial artery, brachial artery and dorsalis pedis artery.

B. Principle of Arterial Tonometry

The applanation tonometry requires flattering of the measurement site of the artery [13]. The circumferential wall tension T of the artery is derived from the external pressure (P_o), the intravascular pressure (P_i), and the curvature radii of the external vascular wall (r_o) and the internal vascular wall(r_i), based on the law of Laplace [16],

$$T = P_i r_i - P_o r_o \tag{3}$$

$$P_i = r_o/r_i P_o + T/r_i . \tag{4}$$

When the artery is applanated, the r_i becomes infinity and $r_i \cong r_o$ by the external pressure P_o, and equation (4) can be calculated as

$$T/r_i = 0, \quad r_o/r_i \cong 1. \tag{5}$$

Based on equations (4) and (5), the following equation can be expressed as

$$P_i \cong P_o . \tag{6}$$

In other words, if the blood vessel is on the hard tissue such as bone and the appropriate pressing force flattens the upper part of the blood vessel, the pressure equals blood pressure. The representative state is called 'tonometric condition,' as shown Fig. 1(b).

C. Experiment using a Pulsatile Phantom Model

Bench tests were performed to find tonometric conditions of the Cellular PP sensor on the phantom model, as shown in Fig. 2(a). The model had two components; a blood pressure simulator and an arterial phantom. The blood pressure simulator consisted of tubes filled with water connected to a syringe and an IV bag at room temprature. The syringe was used to mimic the pumping action of the heart, by which pulse pressure (PP) was generated. The height-adjustable IV bag simulated the total peripheral resistance to represent the level of diastolic pulse pressure (DPP) in humans. Systolic pulse pressure (SPP) was calculated as DPP + PP. The arterial phantom consisted of a silicon sheet that simulates skin, a hard plate that mimics the bones of the wrist, and a tube simulating a large artery. Two types of the tube with the same diameter (approximate outer diameter = 7 mm and the wall thickness = 1 mm), but different stiffness were used: (a) commercial latex tube and (b) semi-realistic artery made of hydrogel (Lifelike Bio Tissue, London, Ontario, Canada). The Cellular PP sensor was pressed down perpendicularly to the silicone sheet over the tube, and the pressing force was measured by a force gauge (Maximum load value 50 N, minimum resolution 0.01 N). The intraluminal pressure was measured by a hydraulic pressure sensor as shown in Fig. 2(a). The output of the Cellular PP sensor and the hydraulic pressure (HP) were simultaneously recorded by MP-160 (BIOPAC System, Goleta, USA) at a sampling rate of 1000 Hz.

1) Tonometric condition (Protocol 1)

The experiment was performed to identify the tonometric condition of the Cellular PP sensor. (a) The latex tube and (b) the hydrogel tube were filled with water and pressurized at will by the height of the IV bag. The Cellular PP sensor was placed directly above the tube and pressed perpendicularly in every 0.2 mm increments, as shown in Fig. 2 (b). The degree of depression (Δd) and the pressing force at each depression were recorded. Stable pulses of 65 beats/min, the static pressure of 60 mmHg, and pulse pressure of 50 mmHg (SPP 110 mmHg/DPP 60 mmHg) were applied, and waveforms were recorded by MP-160. Pearson's correlation coefficient between the HP and the Cellular PP waveform was calculated. Besides, the sensor response (mV/mmHg) was calculated from the peak and bottom levels of HP and Cellular PP in each beat. Each tube was tested ten times.

2) Effects of pressure fluctuation (Protocol 2)

The purpose of this experiment was to examine whether the Cellular PP sensor can continuously detect changes in blood pressure under an optimal tonometric condition (*Protocol1*). The degree of depression of the Cellular PP was fixed at the value of the optimal tonometric condition.

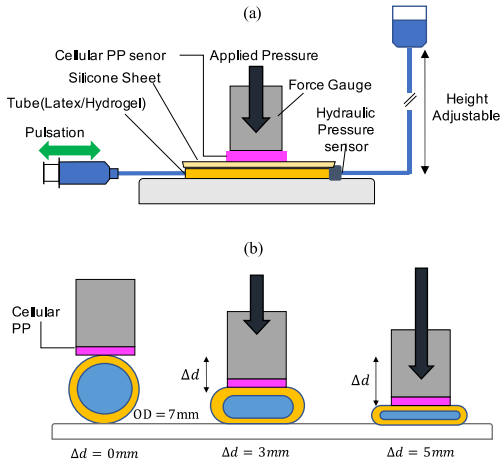

Figure 2. Arterial vascular phantom model. (a) A total system. The syringe generates pulse pressure (PP), and the height of the IV bag represents diastolic pulse pressure (DPP). (b) The schematic diagram of the depression of the tube. The tube was pressed down over the sensor perpendicularly. The depressed level of the tube was recorded every 0.2 mm. Δd = a depressed level of the tube.

HP in the tube was fluctuated with two modes: (a) DPP constant at 60 mmHg with PP variable from15 to 60 mmHg, (b) DPP variable from 40 to 100 mmHg with PP constant at 30 mmHg. Both modes were repeated five times, and the pulse rate was 65 beats/min. The duration of each perturbation was approximately 1 minute. The maximum and minimum values for each beat were defined as SPP and DPP, respectively. The first three beats of the respective stable waveforms of both the HP and the Cellular PP output were used for the calibration to convert Cellular PP output to calculate HP.

III. RESULTS

A. Range of Optimal Tonometric Condition

Fig. 3 shows the simultaneous recordings of hydraulic pressure (HP) in mmHg and output of Cellular PP in voltage when the depression of the tube (Δd) applied manually in both (a) the latex tube and (b) the hydrogel tube. When Δd was 0.4 mm, the waveform of the cellular PP corresponded well to the HP in both tubes, with the correlation coefficients higher than 0.99. As Δd increased, concordance of Cellular PP waveform to those of HP became inconsistent, which was obvious in the latex tube.

The relationship between the correlation coefficient and Δd was shown in Fig. 4(a). The highest values were 0.998 ± 0.001 (Δd = 0.6 mm, n = 10) and 0.989 ± 0.003 (Δd = 0.4 mm, n = 10) for the latex tube and the hydrogel tube, respectively. Fig. 4(b) shows the relationship between the pressing force to the Cellular PP sensor and Δd. A greater force was required to push down the latex tube than the hydrogel tube. Fig. 4(c) shows the sensor response of the Cellular PP. The positive correlation between the sensor response and the depression (Δd) in both tubes was noted. However, the response was saturated when it reached the steady-state value of about 7 and 12 mV/mmHg for the latex tube and the hydrogel tube, respectively.

B. Effects of Pressure Fluctuation

The representative waveforms of HP and the Cellular PP output during HP fluctuation under the tonometric condition were shown on the left side of Fig. 5. The right side of Fig. 5 shows the result of calibration from the peaks and bottoms of each beat of (a) the latex tube, (b) the hydrogel tube. The graphs indicate the Cellular PP sensor traced the fluctuation of HP concomitantly. The results of linear regression analysis between the measured values and the calculated value are shown in Fig. 6. The calculated value showed high linearity with the coefficients of determination (R^2) of 0.976 and 0.961 for SPP and DPP in the latex tube, while lower R^2 was shown as 0.691 and 0.623 for SPP and DPP in hydrogel tube, respectively.

IV. DISCUSSION

A. Tonometry using the Cellular PP sensor

In the present study, we have successfully demonstrated that the Cellular PP sensor traced intraluminal pressure in accordance with tonometry. We assumed the correlation coefficient of 0.980 or higher as the optimal tonometric condition, which was less than 1.2 mm of the depressed depth for the latex tube and 0.6 mm for the hydrogel tube, respectively.

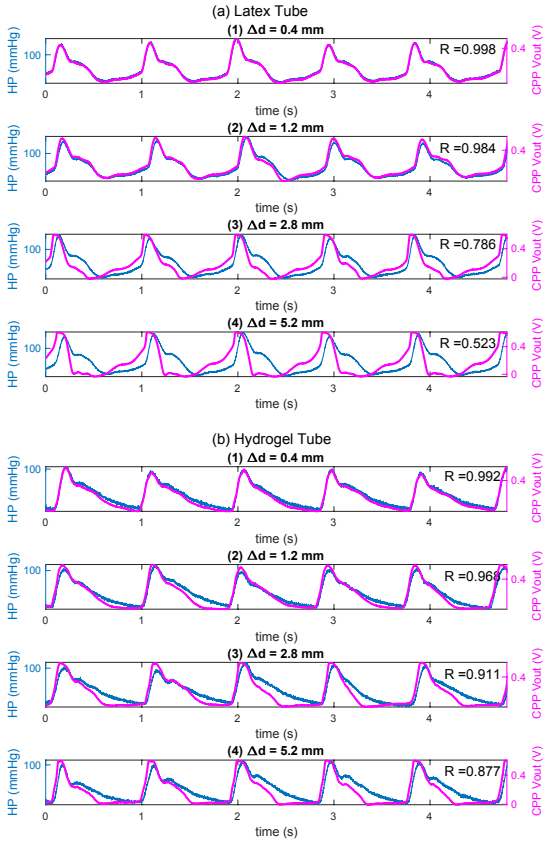

Figure 3. The representive waveform of HP and Cellular PP when (1) Δd = 0.4mm, (2) Δd = 1.2 mm, (3) Δd = 2.8 mm, and (4) Δd = 5.2mm of (a) latex tube and (b) hydrogel tube. Δd = depression of tube, HP = hydraulic pressure, CPP = Cellular PP, R= correlation coefficient.

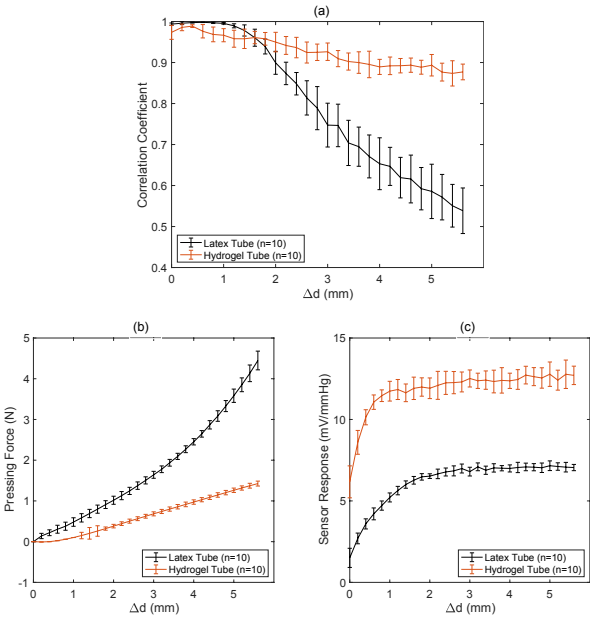

Figure 4. The relationship between depression of the tube (Δd) and (a) The correlation coefficient between HP (mmHg) and Cellular PP output (V), (b) The pressing force for keeping the depression, and (c) The sensor response (mV/mmHg) .

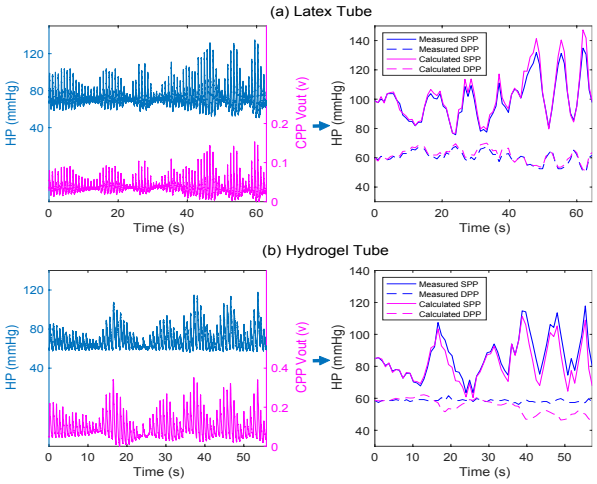

Figure 5. Representative recordings during two modes of pressure fluctuation (a) latex tube and (b) hydrogel tube, respectively. The figures on the left are raw waveforms of the measurement data of HP and Cellular PP V output, and the figure on the right shows the result of calibration from the peaks and bottoms of each beat. CPP = Cellular PP, HP = hydraulic pressure, DPP = diastolic pulse pressure, SPP = systolic pulse pressure.

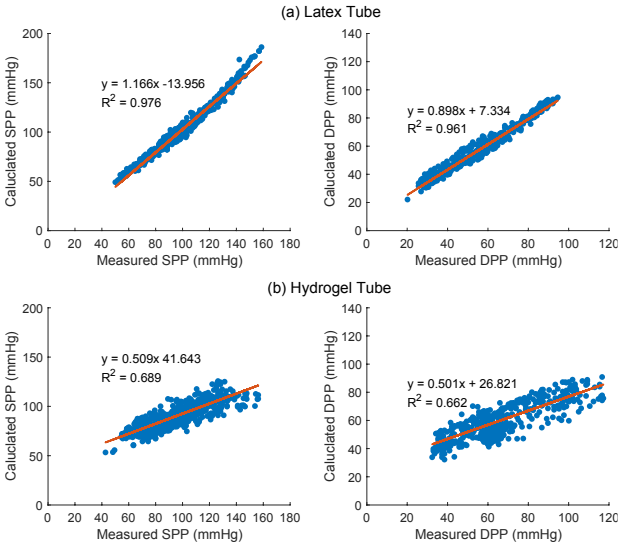

Figure 6. Relationship between measured hydraulic pressure and calibrated Cellular PP output of (a) latex tube, (b) hydrogel tube, respectively. Systolic pulse pressure (SPP) on the left side, Diastolic pulse pressure (DPP) on the right side. R^2 = Coefficient of determination.

The pressing forces to meet the optimal tonometric condition were less than 0.585 N for the latex tube and 0.024 N for the hydrogel tube, respectively. The present findings are in accord well with Laplace's law on which the roundness of the vessel is required to fulfill the equation (3). This finding also suggests that the appropriate pressing force for maintaining the optimal tonometric condition varies depending on the stiffness of the tube, or the stiffness of the blood vessel and the surrounding tissue in the case of human body.

The extent of sensor response correlated curvilinearly with the depression of the tube and reached a plateau, as shown in Fig. 4 (c). It was considered that the increase of depression might enlarge the contact area between the tube and the sensor. As a result, the Cellular PP output may increase despite the same intraluminal pressure, which means higher sensor responsiveness even at the same pressure. In addition, the difference in the sensor response between the latex tube and the hydrogel tube can also be explained by the difference in stiffness. The hydrogel tube is more elastic than the latex tubes, resulting in a larger contact area between the Cellular PP sensor and the tube. These results imply that the optimal tonometric condition and the sensor response of Cellular PP are influenced by the stiffness of target blood vessels in humans.

B. Continuous measurement during pressure fluctuations

The result of continuous measurement during dynamic pressure fluctuation demonstrated the usefulness of Cellular PP sensors to measure non-invasive continuous blood pressure monitoring in humans. As shown in Fig. 6, the latex tube showed very high linearity, indicating that the intraluminal pressure can be calibrated from the CPP output using this regression equation. However, the determination coefficients of the hydrogel tube were lower than those of the latex tube. This finding can be explained as follow; According to Segers et al.[21], the outer-diameter distension rate of the carotid artery during systole was 6.6%. On the other hand, the distension rates of outer diameters of the latex tube and the hydrogel tube used in this study were approximately 4% and 15%, respectively, which indicated that the elasticity of the latex tube was closer to the human's arteries than the hydrogel tube. In addition, there was no supporting structure around the tubes in this experiment. This environment may have caused non-physiological distension and resulted in a displacement of the tube during changes in hydraulic pressure.

V. Conclusion

We identified the tonometric condition of the Cellular PP sensor on the pulsatile phantom model and showed the potential usefulness of non-invasive continuous measurements of arterial blood pressures. The Cellular PP sensor is thin, lightweight, and easy to handle, suggesting the potential applications of the present system to a wearable device for continuous blood pressure monitoring.

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