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An implantable capacitive pressure sensor for biomedical applications

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Abstract

Cuff electrode is an indispensable component of a neural prosthesis system. It is often employed to apply electrical stimuli on motor nerve fibers that innervate muscles or alternatively to record neural signals from the peripheral nerves. It is reported that a pressure over 20 mmHg is harmful for the nerve trunk.

Therefore, measuring the interface pressure between the cuff and a nerve trunk provides a means to monitor the health of the nerve tissue. The goal of this study is to develop a micro capacitive pressure sensor which can be embedded into the cuff electrode for in situ monitoring of the interface pressure between implanted cuff and nerve tissue. By a compromise between the performance and size, the final design with a dimension of 7000 μm × 7000 μm, a range of measurement from 0 to 20 mmHg, and a sensitivity of 10–14 pF/(pF mmHg) is fabricated and tested in the study. The calibration results revealed two important design factors, namely, the geometric properties of dielectric layer and the thickness of insulating layer for developing the pressure sensor.

Keywords: Pressure sensor; Capacitance; Cuff electrode; Neural prosthesis

1. Introduction

In recent years, the application of cuff electrodes for detecting neural signals has been widely utilized in neural engineering. According to the literature, if a pressure applied to a nerve was larger than 20 mmHg, it would be harmful to the nerve [1]. This situation may occur when spiral cuff electrodes are implanted on the peripheral nerves. In previous work, we found that if radius of the cuff is much smaller than that of a nerve, it may induce an excessive pressure on the nerve tissue. Besides, an elliptic electrode was proposed by Tyler and Durand [2] to force the nerve trunk to become a flat shape for increasing the contact area between the nerve and the electrode. This electrode can measure signals better with higher signal-to-noise ratio as long as the nerve trunk healed automatically after a period of time. The index to judge the health condition of the nerve was the interface pressure between the flat electrode and the compressed nerve trunk. Both of the two electrodes, spiral and elliptic electrodes, need a sensor to measure the interface pressure between the nerve and the electrode. Moreover, this kind of pressure sensors may be applicable to detect the pressure on other tissues of human beings, such as blood vessels, bladder and skin.

There are mainly two types of micro pressure sensors, namely, the piezoresistive (PR) and capacitive pressure sensors. The former was first developed in 1980s and widely used in recent years. Piezoresistive pressure sensors can be easily fabricated since the sensing element, pizeoresistance, can be produced by doping boron ion on silicon. The PR pressure sensor has high linearity but it is very sensitive to temperature change and temperature compensation circuits have to be employed. On the other hand, the capacitive pressure sensors have better sensitivity and higher rejection to environmental temperature variations. For most biomedical applications, two important design factors have to be considered. One is the smaller pressure ranges of 500 mmHg and the other is that the pressure sensors should not be influenced by heat dissipation resulted from circuits or tissue while being implanted. So the capacitive pressure sensors better fit the design specifications of the biomedical applications.

In 1980, the micro capacitive pressure sensor was first fabricated by using the micro machining technology [3]. With a length of 3 mm and a height of 425 μm, the main structure of this sensor was a chamber and when a pressure deformed the thin upper layer of the chamber, the capacitance was changed. The

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measuring range was 0–300 mmHg and the sensor was designed mainly for biomedical applications. A thorough review on micro capacitive pressure sensors from 1980 to 1992 can be found in [4]. In 1995, Habibi et al. [5] used the glass as the substrate to make a capacitive pressure sensor by using the surface micromachining technologies. The micro pressure sensors were arranged as an array on the glass substrate and the measuring range of these sensors were 0–800 kPa. In 2004, Casey et al. [6] proposed a capacitive pressure sensor with a structure of five layers and the measuring range was 0–300 mmHg for IVRA (Intravenous regional anesthesia) application. In this sensor, ceramic materials were used as the isolated layers, gold was used as the sensing electrodes and the silicone elastomer was used as the dielectric layer.

In summary, the measurement of the pressure applied on the soft tissue is a direct method to monitor the health condition of tissue and capacitive pressure sensors are suitable in these applications. In this study, a micro capacitive pressure sensor was developed to measure the interface pressure between the cuff and the nerve trunk. The design factors to be considered were geometry, measurement range, sensitivity, material selection, environmental noise shielding and surface treatment to improve the adhesion between layers.

2. Methods

2.1. Design of capacitive pressure sensors

The sensing principle of the capacitive pressure sensors is based on the relationship between the capacitance change and the applied pressure. When a pressure is applied on the sensor, the gap between two sensing electrodes is reduced and the capacitance arises accordingly. The capacitance between two parallel electric conductive plates can be written as,

$$C = \varepsilon_r \varepsilon_0 \frac{A}{d} \tag{1}$$

where C is the capacitance, ε_0 is the dielectric constant of vacuum, ε_r is the relative dielectric constant of the material, A is the area of electrode plate, d is the gap between the two plates.

Based on the Hooke's Law, the change of thickness in the dielectric layer is proportional to the pressure and the original thickness (Eq. (2)). Therefore, the relationship between the applied pressure and the capacitance change can be expressed as Eqs. (2) and (3),

$$\Delta d = d_0 \frac{\Delta P}{E} \tag{2}$$

$$\Delta C = C_0 \frac{\Delta P}{E - \Delta P} \tag{3}$$

where Δd is the thickness change of dielectric layer, d_0 is the original thickness, ΔP is the external pressure, E is the Young's modulus of dielectric material, ΔC is the capacitive change when the pressure is applied, and C_0 is the original capacitance.

In this study, the structure of the capacitive pressure sensor consists of two parallel electrical sensing plates, one dielectric layer sandwiched between the two sensing plates, and two outer insulating layers (Fig. 1). Polyimide (PI, Durimide 7320) is chosen as the material of the insulating layers because of its biocompatibility and insulating capability. The polydimethylsiloxane (PDMS, Sylgard 184) is served as the material of the dielectric layer. The Young's modulus of PI and PDMS is 2.5 GPa and 750 kPa, respectively [7]. The dielectric constant of PDMS is 2.65. It is greater than the dielectric constant of air so that a larger initial capacitance and higher capacitance change can be obtained from Eq. (1). Left of Fig. 1 also shows the fabricated array of capacitive pressure sensors before the lifting.

It is assumed that the dielectric layer deforms in one dimension when an axial pressure is applied to the sensor. In fact, the Poisson's effect should be considered. According to the Poisson's effect, when the dielectric layer is compressed in one direction it expands in the other two directions orthogonal to the loading direction. In this sensor the dielectric material is spin-coated all over the substrate instead of coating on the area of the sensing electrode. Thus, the expansion in the other two directions of the dielectric material between the two sensing electrodes is bounded by the surrounding material. When a pressure is applied on the sensing electrode, the expansion in the other two directions will encounter obstruction from the portion of material that does not receive pressure. Therefore, it is not proper to assume

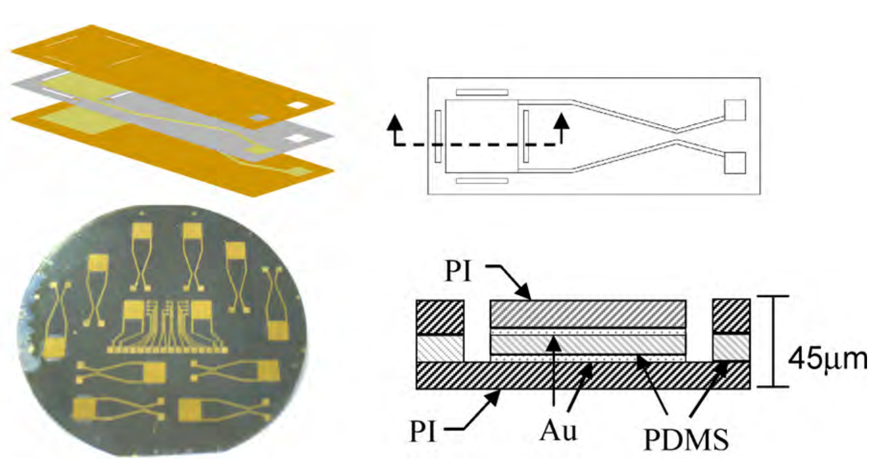

Fig. 1. Structure of the flexible capacitive pressure sensor.

the deformation of the dielectric layer is just a one-dimensional problem. Strictly speaking, it is a three dimensional problem. Considering the worst condition in which the dielectric material is constrained horizontally, i.e., no horizontal expansion permit, the deformation can be calculated by:

$$\Delta d = \frac{\Delta P}{E}(1 - 2\nu^2)d_0 \quad (4)$$

where ν is the Poisson's ratio of the PDMS and ΔP is the pressure. Since ν is greater than zero and less than 0.5 for most elastic material, the thickness change of the dielectric layer, Δd, is reduced due to the Poisson effect. Comparing with Eq. (2), Δd is about half of the original value if ν is closed to 0.5.

To overcome this problem, the structure of this sensor as shown in Fig. 1 is suggested. The sections of PDMS and PI that surround the sensing electrode are removed from the flat film to provide an expansion space of the compressed PDMS. The four rectangular slots are excavated from the upper PI layer to PDMS layer. The removed section is not connected and four anchors are formed to support the whole structure. By this design, the mechanical sensitivity of the sensor can be increased.

2.2. Fabrication of capacitive pressure sensor

The sensor is mainly fabricated by surface micromachining techniques. In a previous study, it was found that the adhesion between PDMS and gold or PI was poor, so the gold wires were easy to fall off during etching. In this study, plasma treatment of surfaces is used to improve the adhesive ability of the PDMS. After plasma treatment, gold successfully forms wires on the PDMS layer. The whole procedure of fabrication is depicted in Fig. 2. First, a layer of PI is spin-coated on the silicon wafer as the lower insulated layer. Gold is deposited by E-Beam and patterned as the first sensing electrodes. Second, the PDMS is spin-coated as the dielectric layer and then treated by the plasma. Third, gold is deposited again and patterned as the second sensing electrodes and the circuit. Fourth, a layer of PI is spin-coated as the upper insulated layer and etched to form holes to expose the bonding pads. Fifth, PDMS in the bonding pads and surrounding the electrodes is etched. Finally, the whole structure is peeled off from the silicon wafer.

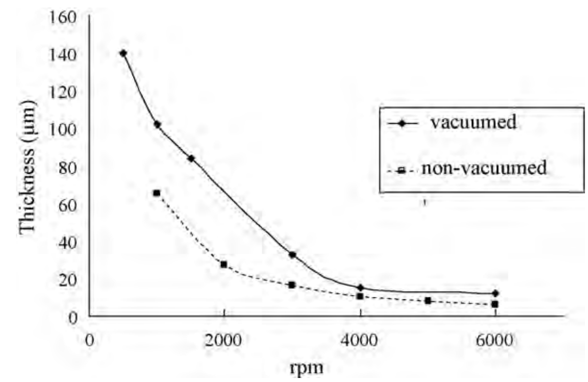

Fig. 3. Spin-coated PDMS film thickness vs. spin speeds under vacuumed and unvacuumed conditions.

PDMS is formed by mixing the lot-matched base and curing agent with a ratio of 10 parts base to one part curing agent. However, when the two parts are mixed, small air bubbles may appear. To reduce the number of air bubbles, the mixed liquid has to be vacuumed in a chamber. This process leads to different results in PDMS spin-coating. The thicknesses of spin-coated PDMS by using the vacuumed and non-vacuumed PDMS are compared in Fig. 3. Under the same rotating speed, the thickness of vacuumed PDMS is greater than that of non-vacuumed PDMS. This would yield two different initial capacitances of the sensors even with the same fabrication condition.

2.3. Normal saline test and calibration system

In previous study [8], it was found that the parasitic capacitance from the environment was severe for the measurement of

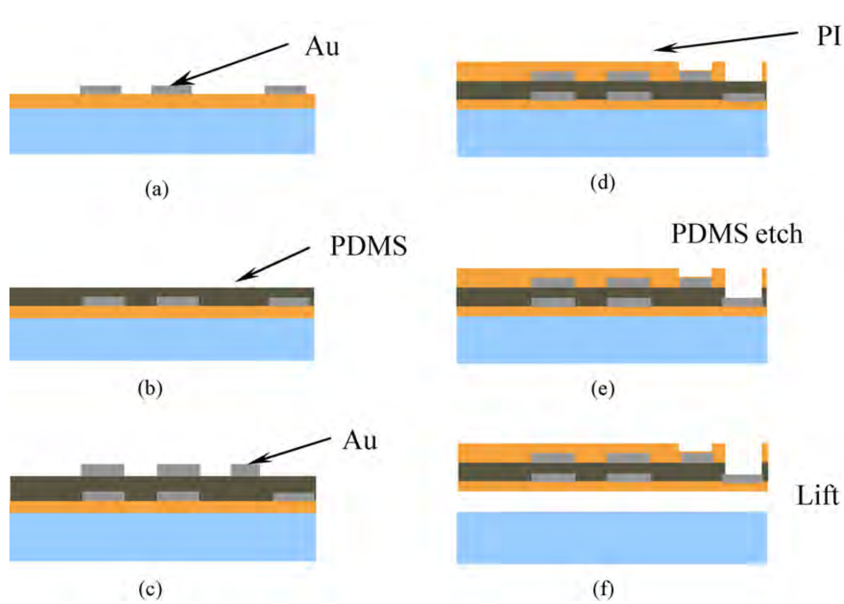

Fig. 2. Fabrication process.

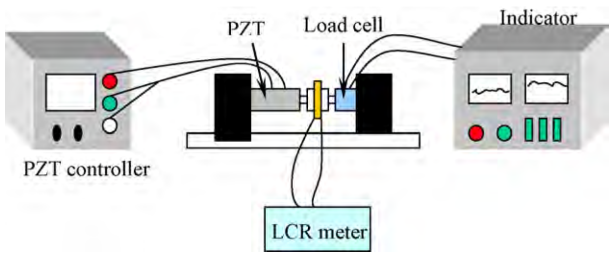

Fig. 4. Calibration system for the flexible capacitive pressure sensor.

capacitance when the capacitive pressure sensor was implanted in a rabbit even though PI was coated on the outer surface of the sensor as the insulating layer. It is hypothesized that increasing thickness of PI layer may alleviate the problem. Four sensors with different thicknesses of insulating layer (i.e., 10, 15, 20 and 25 μm) on outer surfaces are prepared to test the effect of PI thickness on noise shielding. The four sensors are then dipped into the normal saline and their initial capacitances are measured. The bonding pads of these sensors are exposed in the air because no matter how the wires are packaged, it affects the initial capacitance of the sensor when the wires are dipped in the normal saline.

To test the performance of the pressure sensor, a calibration system has been set up as shown in Fig. 4. The whole system consists of a load cell, a piezoelectric translators (PZT), and a platform. The LCR meter (accuracy 0.05%, 6 digits, resolution 0.01fF-9.99999F) is used to record the capacitance of the pressure sensor. The PZT applies a controlled displacement to the pressure sensor through an acrylic plate, and the resistant force can be measured by the load cell. By calculating the ratio of the force and area of acrylic plate, the pressure on the sensor can be obtained and compared with measured output capacitance signal from the pressure sensor.

2.4. *In vitro* test

For biomedical application, animal experiments will be conducted to test performance of the capacitive pressure sensor. In the *in vitro* test, a calibration system developed in our previous work was employed to measure the pressure between the outer surface of a silicone rubber tube and the inner surface of a cuff made by PI sheet [9]. The closed silicone rubber tube was filled with water and the flexible sensor was wrapped tightly on the silicone rubber tube and the capacitive pressure sensor was further encircled by a circular loop made of PI sheet to simulate the spiral cuff electrode (Fig. 5). The PI sheet has a thickness of 20 μm and width of 8 mm except 12 mm at center and the circular loop was formed by pulling one end of the sheet through a pre-cut small slit at the center. The other end of the circular loop is fixed on a platform and the movable end is fastened to a translation stage which can move forward to pull the PI sheet. A load cell fixed on the stage was utilized to measure the tension, T, on the PI sheet. The pressure, P_0, between the PI sheet and the silicon rubber can be formulated by [9]:

$$P_0 = \frac{T}{(1 + 2\pi\mu)r_0} \tag{5}$$

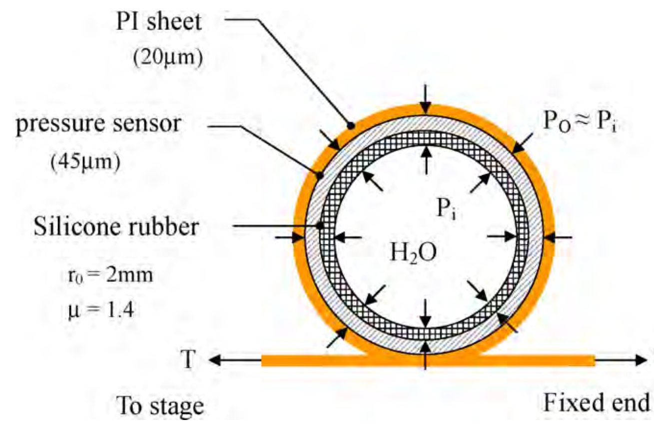

Fig. 5. *In vitro* circular compression test of the flexible pressure sensor.

where μ is the coefficient of static friction between the PI sheet and the flexible sensor, and r_0 is the outer radius of the silicon rubber. Pressure calculated from Eq. (5) is compared with the capacitance changed detected by the sensor.

3. Results

3.1. Normal saline test result

The parasitic capacitances of the sensors with different thicknesses are shown in Fig. 6. The parasitic capacitance is the disparity of the initial capacitances in the air and in the normal saline. The thicker the insulating layer of the sensor is, the lower the difference of initial capacitance of the sensor between air bound and in the saline. The relationship between the parasitic capacitance and the thickness of the insulating layer approximates an exponential curve and saturated when the thickness is greater than 20 μm. Although 25 μm thick insulating layer may be the best choice for reducing the parasitic capacitance, it also induces some problems. When the structure is bent, the thicker the insulating was, the larger the bending stress occurred under the same bending radius. The sensor was easier to fracture if thicker insulating layer is employed. A thickness of 20 μm was suggested to trade-off the flexibility and the shielding effect.

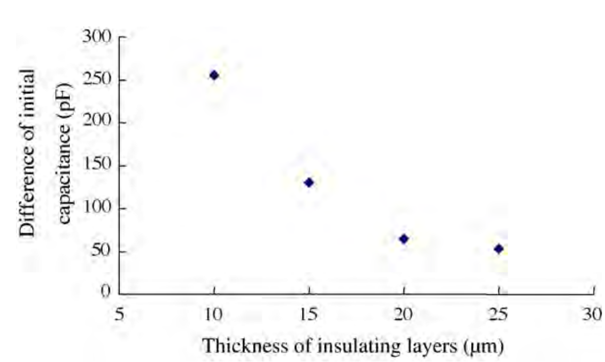

Fig. 6. Parasitic capacitances of pressure sensors with different thicknesses in normal saline.

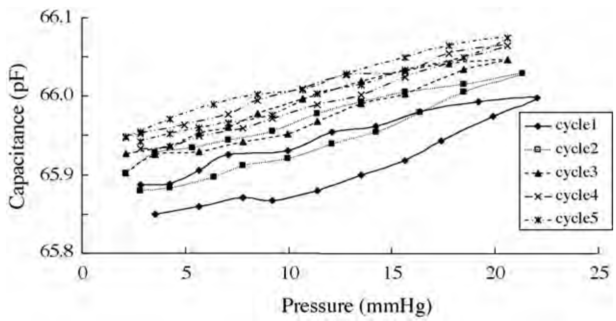

Fig. 7. The calibration curves of sample 1, included results of five loading/unloading cycles.

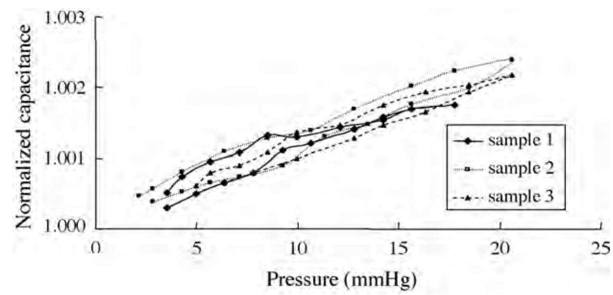

Fig. 9. Normalized capacitances of the fifth loading/unloading cycle in three sample sensors.

3.2. Calibration results

Three samples of capacitive sensors with a 20 μm thick insulating layer are tested in this study. The PDMS materials in sample #1 and #2 are processed with vacuumed treatment before spin-coated as the dielectric layer. The initial capacitances are 65.8 pF and 69.3 pF, respectively. Sample #3 used the PDMS without vacuumed treatment as the dielectric later and its initial capacitance was 106.0 pF. The difference of the initial capacitances between sample 1 and 3 may be resulted from the different thicknesses of PDMS while the difference between sample 1 and 2 may be resulted from the parasitic capacitance in the wires or packages. However, this difference does not affect the sensitivity of the sensor.

Sample 1 was calibrated in five repeated cycles of loading/unloading. The results are shown in Fig. 7. The applied pressure increases gradually from 5 mmHg to 20 mmHg and decreases to 5 mmHg and then, repeats four times in this way. It is found that there is a significant difference between the first cycle and the last cycle. The relationship between pressures and capacitances becomes more and more stable and the results in fourth and fifth cycles are even similar. These phenomena may be due to the viscoelasticity of the dielectric material, PDMS. The total change of capacitance in the test is about 0.12 pF. Sample 2 was calibrated in similar pressure range and the capacitance was recorded for 5 cycles (Fig. 8). When the sensors undergo the transient cycles, the results of the loading/unloading cycles are all similar as shown in Fig. 8 and fall on the similar range. For comparing these sensors with different initial capacitances, the measuring capacitance should be normalized by their initial capacitances, i.e., divided by their initial capacitance, respectively. The results revealed in Fig. 9 are the normalized capacitances of the last loading/unloading cycle. The loading/unloading curves in Fig. 9 are similar. So it is demonstrated that variation of the initial capacitance has no effect on sensitivity of the capacitive pressure sensor if all measures are normalized.

To display the mechanical response of the sensor, the relationship between the applied pressure and the measured capacitance can be transformed into the relationship between stress and strain. The transformation equation is given by,

$$\varepsilon = \frac{C_0 - C_m}{C_m} \tag{6}$$

where ε is the strain of dielectric material, C_0 is the initial capacitance of the sensor, and C_m is the measured capacitance. Fig. 10 reveals the relationship between stress and strain by transforming the results in Fig. 9. The maximal strain in the dielectric layer is about 0.3% while the maximum pressure is applied on the sensor. It is found that the sensor has a very large hysteresis ratio. The ratios of three samples are 21.3%, 22.8% and 18.1%, respectively. It is resulted from the viscoelastic property of PDMS.

3.3. In vitro test result

From the *in vitro* circular compression of the silicon rubber tube, a straight line between the pressure applied by the PI sheet and change of the capacitance of the flexible can be fitted (Fig. 11). The initial capacitance in this case is 94.87 pF and the pressure ranged from 3 mmHg to 37 mmHg. The total

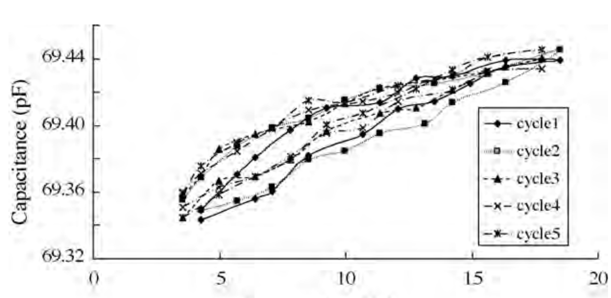

Fig. 8. The calibration curves of sample 2, included results of five loading/unloading cycles.

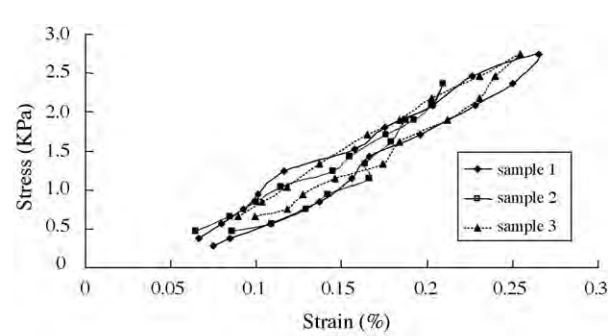

Fig. 10. Stress-strain relationship of pressure sensors.

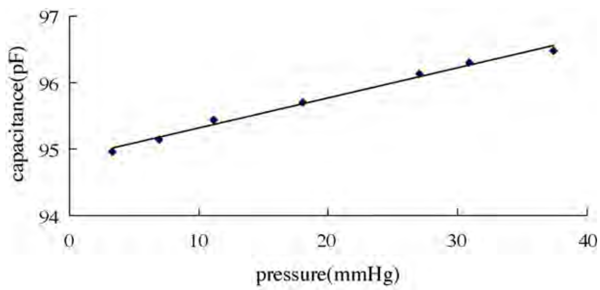

Fig. 11. Calibration results of the capacitive pressure sensor in circular compressing.

change of the capacitance is equal to 1.5368 pF and a sensitivity of 0.0452 pF/mmHg was achieved.

4. Discussions

4.1. Normal saline test

From the results shown in Fig. 6, we may find that thickness of the insulating layers to be an important factor for design of a capacitive pressure sensor. Apparently, increasing the thickness can reduce the influence from the environment. When a pressure sensor is placed in air (Fig. 12), due to the high resistance of air the current just passes through the dielectric layer, however, in the normal saline the leakage current may occur because the surrounding is more electrically conductive if resistance of the insulating layer is not sufficiently large. Fig. 12 shows the equivalent circuit of the capacitance pressure sensor and the environment. If the resistance of the insulating layer is small then the environment tends to be a conductor and leakage current can pass through the environment. The parasitic capacitance in the surrounding would be coupled to the sensor.

4.2. Sensor characteristics

Based on the results in Figs. 7–10, the sensor performances including allowable pressure range, sensitivities, and viscoelastic properties are obtained. It is concluded that the linear measured range of the pressure sensor is about 20 mmHg. The sensitivities of samples 1 and 2 with initial capacitance 65.8 pF or 69.3 pF are about 0.0073 pF/mmHg and the sensitivity of sample 3 was 0.0108 pF/mmHg. After normalization, the sensitivities of three samples are all about 1×10^{-4} mm / Hg. However, the averaged sensitivity of the samples is smaller than the theoretical

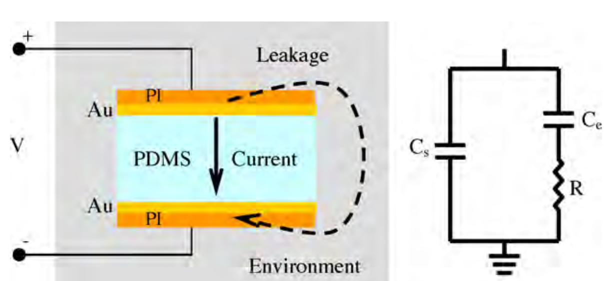

Fig. 12. Possible mechanism of the leakage current and its equivalent circuit.

value of 0.0192 pF/mmHg. There are two possible for the reduction of sensitivities. First, the Young's modulus of the dielectric layer in thin film is different to thick membrane. In this study, the Young's modulus in thin film calculated based on the results in Fig. 10 is around 1200 kPa which is larger than that of a thick membrane (750 kPa) and it may cause the decrease of the sensitivity. Second, although four rectangular slots are dug around the sensing electrodes, the Poisson's effect is not excluded completely. The Poisson's ratio of PDMS is close to 0.5 and from Eq. (4) one may find that the deformation is about half of the ideal one. Therefore, in this study, the sensitivities of the capacitive pressure sensors fall on the reasonable and acceptable range.

4.3. In vitro testing of the capacitive pressure sensor and acute animal experiment

From the *in vitro* circular compression test, one may observe that the linearity of capacitive pressure sensor is quite good within the pressure ranged from 3 mmHg to 37 mmHg and the corresponding change of capacitance is 1.5368 pF. It demonstrates that the flexible capacitive sensor developed in current work is feasible for detecting the interface pressure between the simulated nerve trunk (silicone rubber tube) and the cuff. The sensitivity of the sensor in the circular compression test is 0.0452 pF/mmHg which is about 4.5-fold of the value obtained from the parallel compression test depicted in Fig. 3. The increase of sensitivity may due to the geometric effect of the capacitive pressure sensor and effective compression on the dielectric material of the sensor. In deriving Eq. (5), we assumed that the pressure is uniformly distributed on the silicone rubber tube surface, the compressed tube remains cylindrical shape and there is no relative movement between the capacitive pressure sensor and the PI sheet. In the *in vitro* test, the pressure distribution may not be uniform and the deformed silicone rubber tube may become an elliptic tube. Therefore, lower interface pressure may be calculated however, the range of pressure should remain the same if the deformation of the tube is small.

For a pilot study, the pressure sensor was implanted on the sciatic nerve of a rabbit and a cuff electrode was wrapped around the pressure for acute testing. The results reveal that with a thicker insulation layer of 20 μm, the parasitic capacitance can be reduced from 200 pF to 10 pF when compared with previous work [8]. For long term implantation, further work on integrating capacitive circuit and telemetric system and packaging of the sensor system will be required. However, the *in vitro* circular compression and the acute animal experiments demonstrate that the prototype is quite feasible for detecting the interface pressure between the nerve trunk and the cuff electrode. Other possible applications of the flexible capacitive pressure sensor include the pressure of large blood vessels and the skin.

5. Conclusion

An implantable micro pressure sensor for measuring the interface pressure between nerve trunk and cuff electrode is designed and fabricated successfully. The adhesive capability of the PDMS is improved by a plasma treatment. The Poisson's ratio and hysteresis properties of the dielectric layer have significant effect on performance of sensor and thickness of the insulated layer affects severally the initial capacitance. It is proven that the excavation of a dielectric layer, PDMS, can reduce the Poisson's effect and increasing the thickness of insulated layers can lessen the influence of the parasitic capacitance in a conductive surroundings. Moreover, a thicker insulated layer of the sensor could reduce the noise due to parasitic capacitance generated inside the animal body effectively.

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Biographies

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