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Capacitive contact lens sensor for continuous non-invasive intraocular pressure monitoring

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ABSTRACT

Intraocular pressure (IOP) is a primary indicative factor in the diagnosis and treatment monitoring of glaucoma. Measurement of IOP during conventional single office consultation is insufficient for determination of the pressure peak, and IOP profile is needed for peak determination. A capacitive wearable contact lens sensor for monitoring of the IOP is developed in this study. A curvature-sensitive inductor–capacitor sensor is fabricated and embedded inside a silicone rubber contact lens, such that the curvature of the lens is correlated with the resonance frequency of the sensor. The curvature of the lens is mechanically related to the IOP in the underlying eye such that the IOP can be determined from the resonance frequency of the sensor. To fit human eyes, the sensor was designed to have an outer diameter of 14 mm, radius of curvature of 8.5 mm, and operates in human IOP range between 5 and 40 mmHg. The frequency responses and the ability of the sensor to track IOP cycles were tested. Tests on model silicone eyes and enucleated porcine eyes showed that the sensors have a linearity $R > 0.997$ and a sensitivity >200 ppm/mmHg for IOP monitoring. Together with wireless reading circuitry taped around the eye socket, the new contact lens sensor can be used for continuous IOP monitoring in clinics and at home for determination of the peak IOP for use in glaucoma diagnosis and monitoring.

1. Introduction

Intraocular pressure (IOP) is the main risk factor in the pathogenesis of glaucoma, and is the primary indicative factor in the diagnosis and management of glaucoma [1–3]. Since glaucomatous vision loss is irreversible and up to 50% vision maybe lost before detection by the patient, accurate IOP screening is an important key to halt vision loss. IOP peak often occurs at night rather than during office hours. Studies showed that IOP peaks and fluctuations from IOP profiles taken over 24-h are accurate indicative factors for visual field loss in glaucoma patients [4,5]. However, because of convenience, IOP is often measured during the daytime during single office visit. Since single daytime IOP measurement is often lower than the peak IOP, glaucoma patients suffering from vision loss exhibiting below threshold IOP will be given a pass while their vision damage continues. Studies showed that if mean 24-h IOP was used instead of mean office IOP, diagnosis accuracy would increase by >50% [6].

IOP can be measured directly using ocular implants [7–10] or determined non-invasively using contact lens sensors [11–15]. The non-invasive sensors generally measure the corneal curvature and determine the IOP from the curvature. In one approach, the curvature is detected using strain gauge sensing element. The contact lens held down by surface tension will deform conformally with the cornea when the IOP in the eye changes. The soft contact lens will theoretically deform the sensing element embedded inside the lens, which produces a resistance change. Metallic strain sensing elements are typically designed for use on high strength structures that operates with high load. Eyes are soft structures and forces acting on the contact lens are generally in the range of surface tension, which are typically small and can generate only small resistance changes in the embedded metallic strain sensing elements. The small changes are typically conditioned and amplified by on-board silicon chip embedded inside the soft contact lens. The addition of a hard silicon die, *i.e.*, a hard grain of sand, in such close proximity of the cornea increases the risk that the cornea will be scratched during wear.

In this work, a low force capacitive contact lens sensor to monitor the IOP continuously is developed. Instead of relying on strain sensing elements to convert the force into characteristic signal, the new design utilizes capacitive sensing, which is more suited for low force applications. To facilitate wireless signal transmission, the curvature-sensing capacitor (C) is coupled with an inductive coil (L) with fixed inductance to form a LC resonant circuit. Changes in the curvature of the soft cornea and contact lens would change

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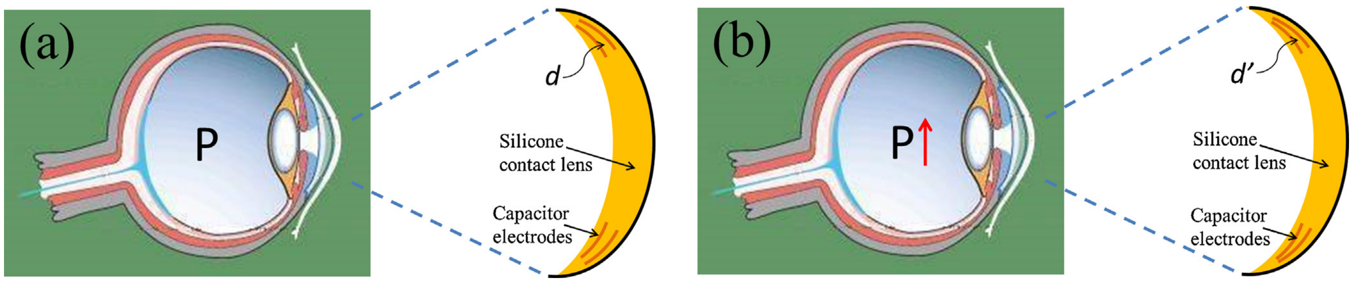

Fig. 1. Sensing mechanism of the capacitive contact lens sensor to measure the IOP fluctuations. The change of the corneal curvature can be tracked by the change of the capacitance. (a) Contact lens sensor configuration on eye with normal IOP. (b) Contact lens sensor configuration on eye with high IOP (the distance of the capacitor electrodes decreases when the IOP increases).

the capacitance and the resonance frequency of the LC circuit. The resonance frequency can be measured wirelessly by a reader in a glass frame worn by the user [16].

In this study, the detail design and fabrication of the contact lens sensor are reported. The sensing resolution and IOP performance of the prototypes were tested on silicone rubber model eyes and porcine eyes *ex vivo*. Tests showed that the new sensor can accurately track the IOP changes in the human range from 5 to 40 mmHg with mmHg IOP reading resolution.

2. Design and fabrication

2.1. Sensing and electrical design overview

Piezo-resistive strain gauge and capacitive pressure sensors have widely been used for pressure sensing in biomedical applications [17]. However, capacitive pressure sensors are more suitable for low force application due to their high sensitivity to pressure changes and low consumed power [7,18]. When a capacitor is coupled with an inductive coil, it forms an inductor–capacitor (LC) resonance circuit, the resonance frequency is,

$$f = \frac{1}{2\pi\sqrt{L_2C_2}}, \qquad (1)$$

where L_2 and C_2 are the inductance and capacitance of the resonance circuit, respectively. When the capacitor's parallel electrodes are embedded into a contact lens, changes in the corneal curvature can lead to changes in the capacitive gap spacing and change the capacitance, which results into change of the resonance frequency (Fig. 1).

The corresponding reading circuitry and electrical circuit of the contact lens sensor are shown in Fig. 2. An inductive coupling link with the sensor can be built and placed in the proximity of the contact lens sensor to read the resonance frequency [19].

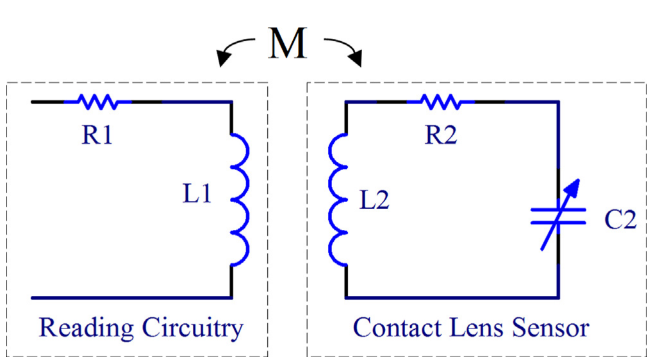

Fig. 2. Reading circuitry schematic of the contact lens sensor.

The equivalent input impedance Z_1 at the terminals of the readout coil is,

$$Z_1 = R_1 + j2\pi f L_1\left(1 + \frac{k^2(f/f_2)^2}{1 + jf/(f_2Q_2) - (f/f_2)^2}\right), \qquad (2)$$

where f is the excitation frequency, k is the coupling coefficient of the inductive link, Q_2 is the quality factor and f_2 is resonance frequency of the sensor, respectively. Z_1 can be further split up into a real part as:

$$Re(Z_1) = R_1 + 2\pi f L_1 k^2 Q_2 \frac{f/f_2}{1 + Q_2{}^2(f/f_2 - f_2/f)^2}. \qquad (3)$$

If $Q_2 \gg 1$, Re(Z_1) arrives at maximum value when $f = f_2$. Eq. (3) shows that the measured resonance frequency of the sensor is independent of the reading distance and reading angel between the coupling coil and the sensor when $Q_2 \gg 1$. Consequently, the resonance frequency of the sensor can be measured wirelessly based on the real part of the input impedance of the reading coil Re(Z_1).

2.2. Sensor physical design

The sensing element of the contact lens sensor is a variable gap sensing capacitor that can sense changes in curvature. An electrode with a soft gap is fabricated in a soft silicone rubber sensing layer on the corneal side of the lens, while a reference electrode and an inductive coil are fabricated in a hard silicon rubber layer on the air side of the lens (Fig. 3). The sensing capacitor is electrical coupled with the inductive coil with fixed geometry.

The sensor is designed to be worn on humans. For a typical person, the curvature change for typical IOP variation between 5 and 40 mmHg is 0.12 mm for a typical cornea (radius of curvature 8 mm). To maximize linearity, the difference in radius between the sensing layer and the reference layer should be maximized, but an overly large difference would reduce the IOP sensitivity. A linear, but reasonably comfortable range of 0.5 mm curvature change was implemented in for the capacitor. In addition to the capacitor, a circular spiral multi-turn inductive coil designed to have a high Q factor to maximize the reading resolution of the LC resonance circuit [20]. The design parameters of the contact lens sensor are detailed in Table 1. For wear comfort, 8 mm was used for the radius of the curvature of the sensing layer and 14 mm was used as diameter of the contact lens sensor.

Table 1
Contact lens sensor design parameters.

Contact lens diameter (mm)	14.0
Radius of curvature of the reference layer (mm)	7.5
Radius of curvature of sensing layer (mm)	8.0
Thickness of each contact lens layer (μm)	100
Dynamic range (mmHg)	35