Numerical Study of Cornea Applanation by Using a Portable Force-Displacement Sensor for Intraocular Pressure Measurements

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ABSTRACT

Intraocular pressure (IOP) is considered as a critical sign for glaucoma diagnosis. Tonometry, such as Goldmann applanation tonometry, Tono-Pen and noncontact tonometry, are widely used in clinical practices for IOP evaluations. However, limitations of the tonometry, such as high cost, operating complexity, and lack of feasibility are major concerns in a busy clinic. In this paper, we propose a facile method for IOP monitoring by utilizing a simple constructed force/displacement-hybrid sensor. The device is constructed by a capacitive force sensor mounted on handheld linear stage, which is able to record the force and travel distance simultaneously. A numerical study based on the finite element method (FEM) is used to evaluate the performance of the sensor for the IOP detections. In particular, a numerical corneal-sensor model is built by the FEM, in which the sensor is placed on the apex of the corneal structure. As the sensor presses against the cornea, the physical parameters, such as the contact pressure, the contact area between the sensor and the cornea, the travel displacement of the sensor are recorded. Importantly, to improve the modeling accuracy, we use a dynamic Young's modulus in the cornea model, considering the multi-layered structure of the human cornea whose Young's modulus varies as the IOP changes. Our sensor exhibits a highly linear relationship between the contact pressure and the travel displacement in the progress of cornea applanation, from which the IOP can be simply derived. A minimal pressure of 1mmHg can be sensitively detected by our sensor, which is highly desired in clinical trials.

KEYWORDS: *Intraocular pressure, cornea applanation, tonometry, force sensor, displacement detection*

1. Introduction

Intraocular pressure (IOP) has been regarded as a core vital sign in the diagnosis of glaucoma. The measurement of IOP (tonometry) in a reliable and continuous way is important, considering that IOP could be changed by the body postures, eye movements, and different times of a day [1]. The current tonometry includes flat Tonometer and Subsidence Tonometer, among which Goldmann applanation tonomety (GAT) is considered as the reference standard in clinics.

GAT is calculated based on the Imbert-Fick principle**:** IOP= W/ A, where W is the external force to flatten cornea and A is the flattened area of the cornea[1]. Additionally, noncontact tonometry (NCT) is also widely used in clinics which uses gas pulses to measure IOP and no direct contact with the cornea [1]. Tono-Pen tonometeris introduced as a hand-held, battery-powered device [2]. It is portable and easy to use. However, high-cost becomes the major limitation for the usages in a large area. A low-cost and portable solution is needed to monitor IOP continuously and reliably.

Numerical modeling is a powerful approach to represent real conditions without having simplifications in mathematical solution. Finite element simulation software meets the requirements of simulating various physics fields. The structural mechanics module analyzes the mechanical responses to a static or dynamic load. FEM effectively simulates the actual situation by setting the boundary conditions and material parameters of the solid model in physical field. Discretization increases the accuracy of results. As Arizagracia and Ahmed reported in corneal simulation, the stress at the corneal scleral junction has been investigated by establishing a model of the entire eye [3-5]. Sean group simulated the effect of IOP when there is a small change in the corneal diameter and thickness and this study provides importance reference for the study of corneal biomechanical behavior [6].

In this paper, we use the numerical modeling based on the FET analysis to set a representative model of the cornea applanation procedure once a force-displacement sensor (tonometer) presses against the corneal apex. The outputs of the tonometer are used to analysis and calculate the IOP accordingly. Specifically, a hybrid sensor consisting of a force-sensing unit and a moving distance-sensing unit is placed on the corneal apex. The parameters, such as contact forces, travelling distances, and the contact areas are recorded as the sensor presses down towards the cornea, from which the corresponding IOP can be derived. This simulation establishes a highly linear relationship between the flattened area and the travel displacement. When the cornea is flattened, a contact force between the sensor and the cornea is recorded by the sensor. In addition, the FET analysis provides a theoretical reference to the sensor design criteria. An optimized force sensor is designed to measure the IOP, from which a minimal pressure of 1mmHg can be detected.

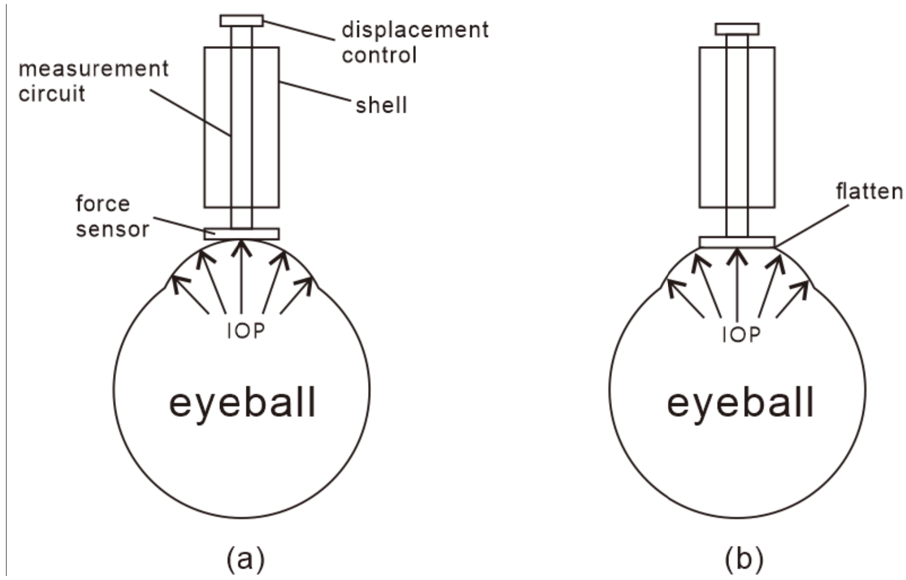


Figure 1 Schematic diagram of IOP measurement by using the proposed sensor (a) the sensor is placed on the apex of the cornea (b) the contact of the cornea and the sensor is flattened.

2. FEM modeling process

As aforementioned, our sensor composes of a force sensor, a displacement control section and a measuring circuit (top part in Fig. 1a). The sensor is placed vertically on the apex of the cornea and presses down to the cornea. As fig. 1b shows, the force sensor presses down until the contact of the cornea and the sensor is flattened. We have analysis the system by setting the corneal and sensor material parameters to mimic the actual situation.

2.1. Corneal structure and materials

The corneal parameters considered in the study are the thickness distribution, the corneal topography and the material properties. As shown in Fig. 2a, the thickness of the cornea varies from center to edge. The central thickness is 0.52 mm and thickness on the edge is 0.67 mm accordingly [7]. In addition, the radius of curvature of the anterior cornea is 7.8 mm, the radius of curvature of the posterior cornea is 6.8 mm and the diameter is 11 mm [8]. These parameters construct the corneal topography. A spherical corneal model can be constructed by 3-D axisymmetric rotation of the 2-D graphics (Fig. 2b). The material properties, such as Poisson's ratio, density, and Young's modulus, are important factors in the structural mechanics. The Poisson's ratio is 0.49 and the density is 1062 kg/m^3 [9]. Considering that the cornea consists of three distinct cell layers, including the endothelial, the epithelial and the stroma layers, which have different stiffness, we set a dynamic Young’s Modulus [10].

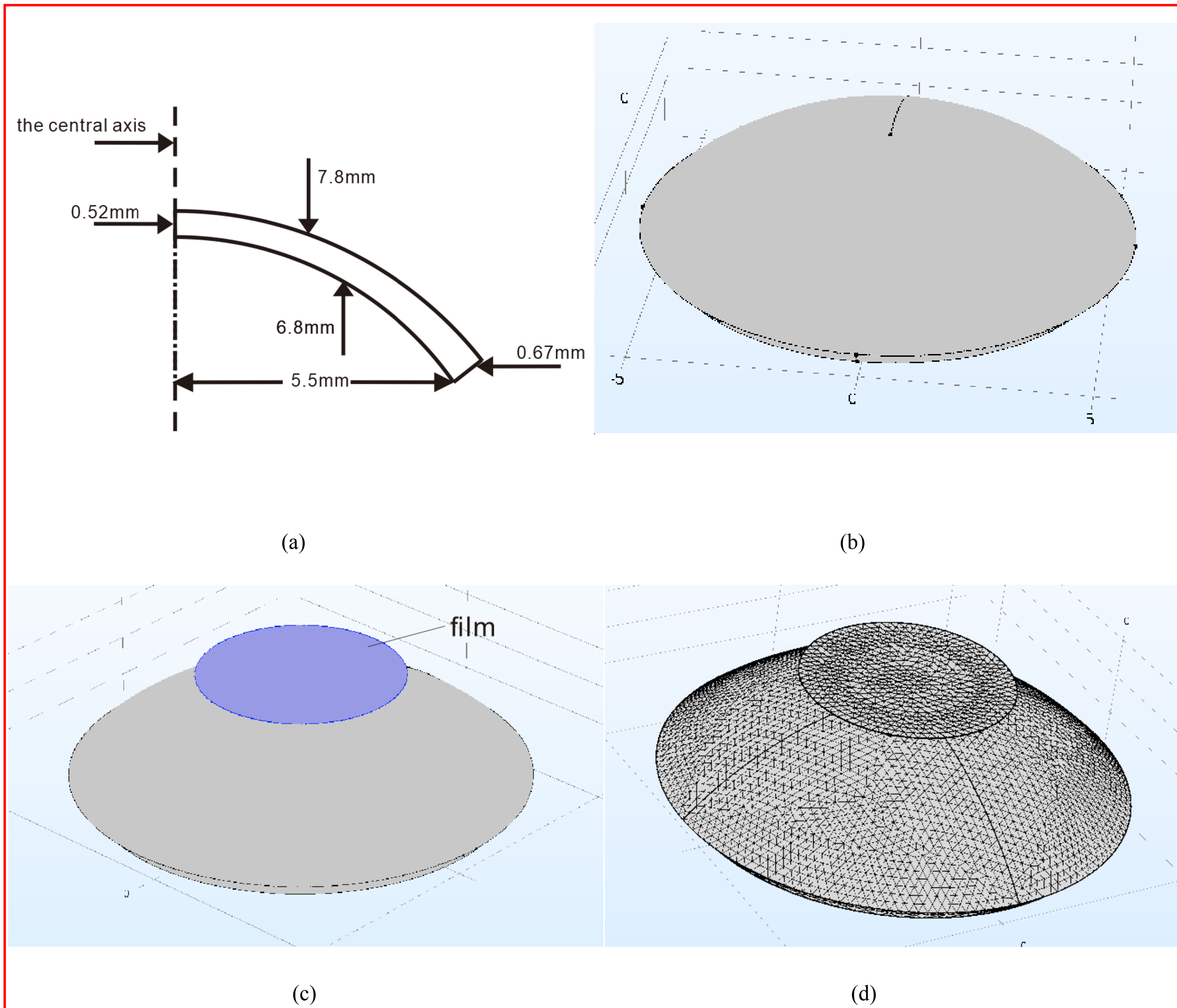


Figure 2 (a) Geometrical parameter illustrations of the cornea in the cross-sectional view; (b) the 3-D graphics of the cornea; (c) the sensor is simplified into a thin film and is paced on the apex of the cornea; (d) the mesh distribution of the model.

2.2. Sensor structure and materials

In this paper, the force sensing unit used to measure IOP in the sensor system is simplified as a thin film made of structural steel. Due to the large Young's modulus of structural steel, the deformation of the force sensor can be ignored compared to the deflection of the cornea. The thickness of the film is 0.01 mm (Fig. 2c). Moving distance from the distance control unit is represented by the travelling distance of the corneal apex. To optimize the sensor design, the diameter of the force sensor (thin film) is increased from 0.5 mm to 5 mm in 0.5 mm steps, which is used to analysis the IOP during the applanation procedure.

2.3. Boundary conditions of the model

A complete eyeball model that includes the cornea and sclera can better represent the actual state of the cornea. However, this leads to increased costs of calculation. In this paper, we set a fixed constraint on the corneal margin, considering the sclera is much stiffer than the cornea and restricts the movement of the cornea [11-12]. To simulate the different IOPs exert on the cornea, we set the boundary load ranging from 15 mmHg to 105 mmHg inside of the cornea. The cornea is flattened by the film with a prescribed displacement perpendicular to the apex of the cornea.

2.4. The mesh distribution of the model

Finite element analysis (FEA) is a discrete process, so setting the suitable mesh for the model is important. The greater density of the mesh in the FEA is, the more accurate the result is. However, the cost on the calculation time increases. In this simulation, we set the maximum mesh density at the sensor and the apex of the cornea to get the most accurate result. On the other hand, to simplify the whole model, we reduce the mesh density of the rest part with minimal influence on the result (Fig. 2d).

3. Results

3.1. Dynamic Young's modulus

As aforementioned, the Young's Modulus changes when the IOP inside of the cornea varies due to the multi-layer nature of the cornea [13]. Here, the Young’s modulus is studied according to the relationship between the apical rise and the IOP [14]. Fig. 3a illustrates the apical rise-IOP curves in dynamic and constant Young’s modulus cases. In the dynamic Young’ modulus scenario (black line), the apical rise increases 110% when the IOP changes from 15 mmHg to 37.5 mmHg, and increases slightly by 27% when the IOP varies from 37.5 mmHg to 105 mmHg. In contrast, in a constant Young's modulus case (red line), the apical rise increases with a constant slope of 0.0061 mm/mmHg, which is significantly different from the actual corneal biomechanical behavior. Fig. 3b shows the relationship between the IOP and the Young's Modulus. As can be seen, the Young's Modulus has nonlinear relationship initially that the Young’ modulus rises to 0.233 MPa when the IOP is 22.5 mmHg and then drops to 0.213 MPa at 30 mmHg, which is highly caused by the multi-layer structure of the cornea and different initial stiffness of three cell layers. The Young's Modulus has a highly linear relationship with IOP when the IOP exceeds 40 mmHg.

3.2. The relationship between the diameter and the travel displacement of the sensor

The relationship between the diameter and the displacement of the sensor during the corneal applanation procedure is analyzed in this study [15-16]. A cylindrical thin film is used with a diameter of 0.5mm to 5 mm to press against the cornea. A moving distance of the sensor is recorded when the cornea is flat. In order to analyze the travel displacement of the sensor to flatten the cornea under different IOPs, we applied a load ranging from 15 mmHg to 105 mmHg to the interior of the cornea. Fig. 3c shows a linear relationship between the diameter and the travel displacement of the sensor. Under the IOP of 15 mmHg, the travel distance of the sensor changes from 0.016 mm to 0.809 mm when the diameter of the sensor varies from 0.5 mm to 5 mm, accordingly. In addition, it is observed that when the diameter of the sensor is same, the travel displacement shows a slightly changes as the IOP varies. When the IOP changes from 15 mmHg to 105 mmHg, the sensor with a diameter of 5 mm generates the apical rises of 13.6 % (from 0.809 mm to 0.919 mm). Under a constant diameter, different IOPs inside of the cornea correspond to the same travel displacement.

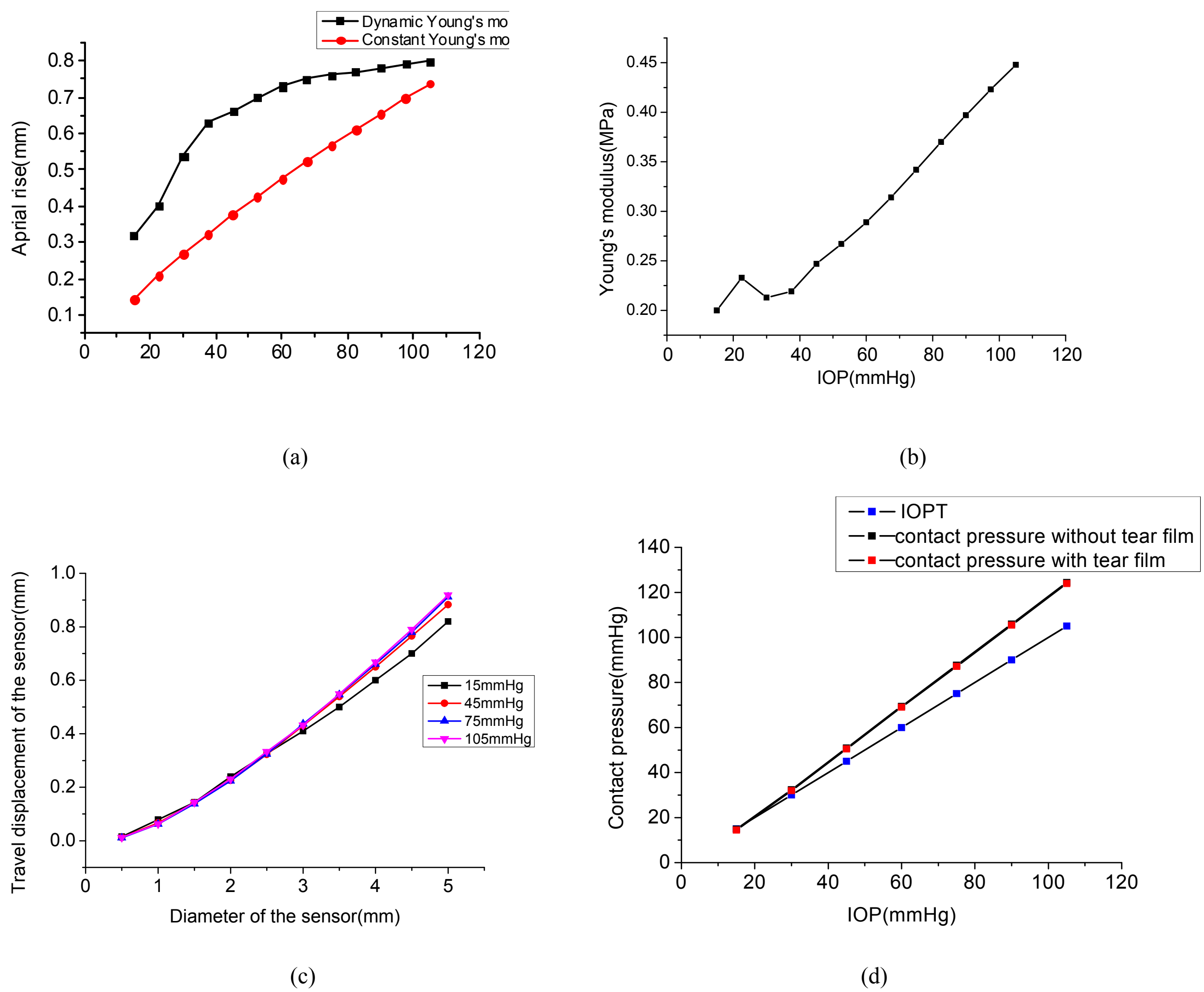


Figure 3 (a) the relationship between apical rises and pressure when the Young's Modulus is constant and dynamic; (b) Dynamic Young's Modulus with different IOPs; (c) the relationship between the diameter and the travel displacement of the sensor; (d) the relationship between the IOP and the contact force.

3.3. The effect of the surface tension of the tear film

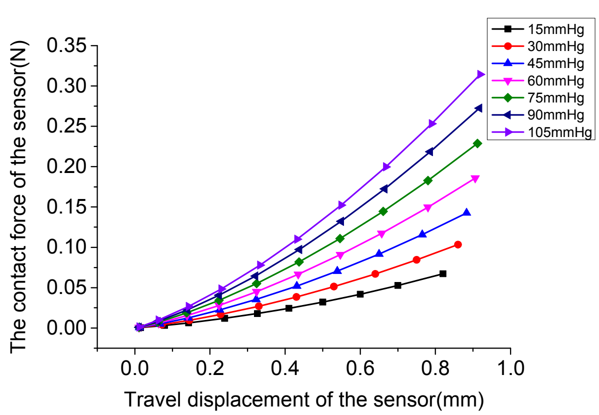
As the gold standard shows, the bending resistance of the cornea is equal to the surface tension of the tear film when the diameter of the tonometer is 3.06 mm, in which the force required to flatten the cornea is equal to IOP. The surface tension of the tear film can be calculated through the following equation:

$$0.0455*10^{-3}*(d*\pi)/((d/2)^2*\pi) \quad \text{Eq. (1)}$$

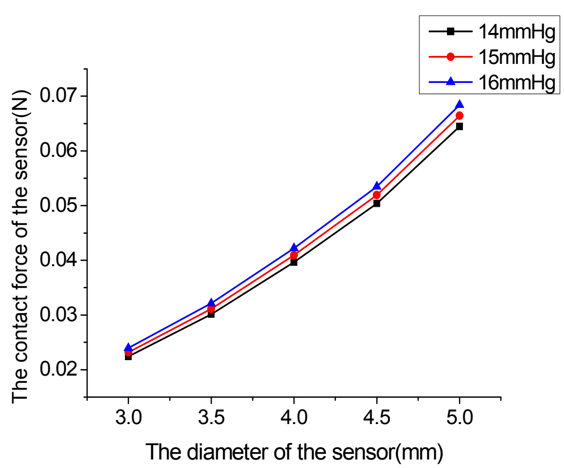
where d is the diameter of the sensor [7]. The effect of the surface tension from the tear film is introduced to the contact pressure between the sensor and the cornea. Fig. 3d compares the contact pressure with/without surface tension of the tear film and the true IOP (IOPT). The contact pressure shows a linear relationship with IOPT. As considering the effect of the surface tension of the tear film, the maximum deviation of the contact pressure from IOPT is 18% (when IOP=105 mmHg). In contrast, without the surface tension exerting on the cornea, the maximum deviation of contact pressure and IOPT is 18.5%. Therefore, the effect of tear film on the contact pressure between the cornea and the sensor is negligible.

3.4. The relationship between the diameter and the contact force of the sensor

Fig. 4a shows the contact force variations of the sensor when the travel displacement of the sensor is changed. A linear relationship between the travel displacement and the contact force of the sensor under different IOPs is observed. The slopes of the contact force-travel displacement curves increase from 0.083 to 0.345 as the IOP changes from 15 mmHg to 105 mmHg. In order to distinguish an IOP change as low as 1 mmHg, a relationship of the contact force and the diameter under a minimal IOP variation is plotted in Fig. 4b. As predicted, the diameter and the contact force of the sensor exhibits a linear relationship. As the diameter of the sensor increases from 3 mm to 5 mm, the force of the sensor shows a growth rate of 186.2% with a constant IOP of 15 mmHg. When the diameter of the sensor is 5 mm, the contact force has a detectable change of 2 mN with the IOP increases by 1 mmHg. Based on the study, the relationship of the diameter, the traveling distance and the contact force of sensor provides a theoretical prediction for the novel force/displacement-hybrid sensor.



(a)



(b)

Figure 4 (a) The relationship between the travel displacement of the sensor and the contact force exerted by the sensor to flatten the cornea; (b) the relationship between the diameter of the sensor and the contact force when IOP increases by 1mmHg

4. Discussion

In this paper, we propose a finite element method to guide the design of a sensor system. FEM is used to analyze the biomechanical behavior of the cornea under different IOPs, as well as to predict the force applied by sensor when the cornea is flattened.

By analyzing the applanation procedure, the relationship between the diameters, the travel displacement and the outputs of the sensor are obtained. By using this relationship, we design a very simple tonometer that mainly includes force sensors, the displacement control section and data processing circuit to measure the IOP. Such a tonometer is relatively small in size, low in cost and easy to operate, and is suitable for portability in order to continuously monitor the IOP for glaucoma patients.

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