



Comparative study of corneal tangent elastic modulus measurement using corneal indentation device



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ABSTRACT

The aim of this study is to examine the corneal tangent modulus measurement repeatability and performance of the corneal indentation device (CID). Twenty enucleated porcine eyes were measured and the eyes were pressurized using saline solution-filled manometer to 15 and 30 mmHg. Corneal tangent moduli measured using the CID were compared with those measured using high precision universal testing machine (UTM). The within-subject standard deviation (Sw), repeatability ($2.77 \times Sw$), coefficient of variation (CV) ($Sw/\text{overall mean}$), and intraclass correlation coefficient (ICC) were determined. The mean corneal tangent moduli measured using UTM and CID were 0.094 ± 0.030 and 0.094 ± 0.028 MPa at 15 mmHg, and 0.207 ± 0.056 and 0.207 ± 0.055 MPa at 30 mmHg, respectively, with a difference less than 0.13%. The 95% limit of agreement was between -0.009 and 0.009 MPa. The Sw, repeatability, CV and ICC of corneal tangent moduli measured by the CID were 0.006 MPa, 0.015 MPa, 4.3% and 0.993, respectively. The results showed that the corneal tangent moduli measured by the CID are repeatable and are in good agreement with the results measured by the high precision UTM.

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1. Introduction

Intraocular pressure (IOP) is generally measured using Goldmann Applanation Tonometry (GAT) [1]. Studies [2–6] showed that inter-individual variations in the central corneal thickness (CCT) and variations in the corneal radius of curvature may lead to measurement errors up to 3.5 mmHg. Studies [7–13] showed that inter-individual variation in the corneal elasticity may also lead to significant errors in IOP measurement.

Individual variations in corneal elasticity, which is currently ignored in tonometry, can come from race, sex, genetics and age [14–16]. The principal variation is associated with changes in stroma, which occupies over 90% of the corneal thickness. The stroma is not uniform. Stromal collagen fibrils undergo non-enzymatic cross-linking and the corneal stiffness may double with age [14–16]. Liu and Roberts [9] showed that corneal stiffness variation alone may lead to different IOP reading up to 17 mmHg.

Mechanically, the cornea is a pressurized shell structure. Standard elastic modulus measurement methods for measuring

linear elastic shell stiffness are available, but they are unsuited for characterization of the cornea because the cornea's mechanical behavior is nonlinear. Corneal mechanical behavior is characterized by the load-specific corneal tangent modulus (instead of an elastic modulus). Corneal indentation method developed for the measurement of the corneal tangent modulus was validated and tested on porcine corneas *ex vivo* and rabbit corneas *in vivo* [13]. In an earlier study [13], the corneal tangent modulus was measured using a desktop universal testing machine (UTM), but the UTM is not designed for routine clinical use. A portable corneal indentation device (CID) for clinical use has been developed. In this study, the corneal tangent modulus measurement repeatability and performance of the CID on porcine eyes are studied and compared with the results measured using the UTM.

2. Materials and methods

2.1. Corneal indentation device (CID)

The portable CID is designed for use on a slit-lamp (Fig. 1). The CID has a high precision load sensor (Bengbu Sensor System Engineering Company Ltd., Anhui, China) with a flat 2 mm cylindrical indenter mounted at the tip. The assembly is mounted onto a linear actuator (Haydon Kerk Motion Solutions, Inc., CT, USA) so that it can be moved forward on command to indent the cornea. Before

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Fig. 1. Prototype of the corneal indentation device.

measurement, the patient's eye is topically anesthetized with the head positioned and stabilized on the chinrest. Then, the indenter is aligned with the corneal apex, and on command from the operator, the actuator moves the indenter forward to indent the cornea. The indentation load–displacement curve is ascertained in less than 1 s and the corneal tangent modulus is determined from the curve.

2.2. Indenter and contact area

In comparison with the GAT, CID characterizes the structural corneal property while the GAT characterizes the intraocular pressure. The GAT uses only the load at a single indentation depth corresponding to an applanation contact area of 7.35 mm^2 . The CID measures corneal tangent modulus which is obtained from the slope of the indentation load–displacement curve. A variety of indenter sizes may be used for indentation. The effect of indenter contact area on the slope was examined. Indenters with diameters ranging from 1.7 to 5.1 mm were tested. Data showed that the slope of the load–displacement curves with larger indenter is steeper, but the slopes from indentation with different sizes become identical after they are normalized by the diameter of indenters. To minimize patient discomfort, a small 2-mm indenter that exerts a smaller load on the cornea is chosen in our tests.

2.3. Ex vivo experiments on porcine eyes

Twenty porcine eyes were obtained from a local abattoir. The porcine eyes were kept moist at 4°C in an insulated bucket filled with refrigerants; and the experiments were conducted within 12 h after sacrifice. The central corneal thickness and corneal radius of curvature of the porcine eyes were measured using a

camera-mounted Leica M205C stereomicroscope (Leica Microsystems, Wetzlar, Germany).

The eyes were mounted on a test jig and the anterior chamber was cannulated (Fig. 2). A needle connected to a saline-filled pressure-controlling manometer was inserted into the chamber to control the chamber pressure. The pressure in the test eyes was cycled 3 times between 5 and 50 mmHg by adjusting the bottle height of the manometer to condition the cornea, and set at 15 mmHg (normal eyes) and 30 mmHg (glaucomatous eyes) for testing. The intraocular pressure was measured using a pressure needle sensor inserted into the anterior chamber (OPP-M400, Opsens Inc., Canada) (Fig. 2), and the eyes were allowed to stabilize at the set IOP for over 10 min before experiments. After stabilization, the eyes were concentrically aligned with the indenter of the CID (Fig. 2). The indenter was then moved forward to touch the cornea until a small stable pre-load of less than 1 mN was registered. After the pre-load was stabilized, the indenter was actuated forward at 12 mm/s to indent the cornea to a set depth of 1 mm. After reaching the set depth, the motion was reversed at the same rate until the indenter was withdrawn from the corneal contact. With the high indentation rate, the indentation was completed in less than a quarter of a second, and the load–displacement curve ascertained was used for the calculation of the corneal tangent modulus.

For comparison, the eyes were also indented using high precision UTM. The UTM (Alliance RT/5; MTS Corporation, Eden Prairie, MN, USA; rated to support 5 kN) is designed for testing with sub-micron precision and is substantially more rigid than the CID. An indenter with 2 mm (diameter) tip was mounted onto a 10 N load cell (MTS 100-090-795, MTS Corporation, Eden Prairie, MN, USA) and the assembly was screw-mounted onto the crosshead of the UTM testing frame (Fig. 3). For all eyes tested, testing was first

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