Agreement and Reproducibility of Tono-pen® XL Tip Covered with Ocufilm and Fingertip of Surgical Glove in Intra-ocular Pressure Measurement

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Objective: *To compare the effect of using the fingertip of a surgical glove over Ocufilm® (Reichert Technologies, NY, USA) on the agreement and reproducibility of measuring intra-ocular pressure (IOP) by the Tono-Pen® XL (Reichert Technologies, NY, USA).*

Study design: *Experimental, clinical study.*

Material and Method: *Patients were randomized into two groups to receive IOP measurements using Tono-Pen® XL with two different types of tip covers. In Group 1, the IOP of the right eyes were first measured using Ocufilm® as the tip cover, followed by using the fingertip of a surgical glove. As for the left eyes, the tip of the surgical glove was used first, followed by use of Ocufilm®. In Group 2, the IOP of the right eyes was first measured using the tip of the surgical glove, followed by use of Ocufilm®, while for the left eye the latter was used first, followed by the tip of the surgical glove. A single operator measured the IOP in each eye twice using each type of tip cover. Agreement between the Tono-Pen® XL measurements using the two different tip covers was analyzed using the Bland-Altman analysis. The difference between the repeated measures was assessed for reproducibility of the Tono-Pen® XL measurements with regard to each type of tip covers.*

Results: *100 patients (200 eyes) were recruited into the present study. The mean difference of IOP taken by the Tono-Pen® XL covered with Ocufilm® and the fingertip of a surgical glove was -0.21 mmHg (95%CI: -0.36 to -0.05). The limits of agreement (confidence interval 95%) as calculated by the Bland-Altman plots for Ocufilm-Fingertip of a surgical glove was -2.43 to +2.02 mmHg. The coefficient of repeatability of the Ocufilm® vs. the surgical glove was nearly the same (1.74 vs. 2.37, respectively).*

Conclusion: *A significant agreement exists between using Ocufilm® and the fingertip of a surgical glove to cover the tip of a Tono-Pen® XL for measuring IOP. The coefficient of repeatability was comparable between the two different types of tip covers. When measuring IOP, the tip of a Tono-Pen® XL could therefore be covered by either Ocufilm® or the fingertip of a surgical glove without compromising accuracy.*

Keywords: *Intra-ocular pressure, IOL, Tono-Pen® XL, Ocufilm®, Surgical glove, Agreement, Reproducibility*

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Accurate measurement of intra-ocular pressure (IOP) is important for screening, treating and following-up patients with glaucoma. The Goldmann applanation tonometer is the clinical gold standard for IOP measurement but it has some limitations in patients with an irregular corneal surface[1-3].

The Tono-Pen® XL is a portable electronic applanation device which works similarly to a Goldmann tonometer by using applanation. Briefly, the IOP reading is taken by applying light pressure to the cornea with its transducer tip. The pressure is then converted into an electrical signal. The internal microprocessor amplifies the electrical signal and translates it into IOP, which is automatically displayed on the screen in mmHg[1]. Portability is the main advantage as it can be used without a slit-lamp microscope. IOP can also be measured in patients with a corneal irregularity or edema[2]. An IOP measurement with a Tono-Pen® XL can be performed in either a sitting or lying position[4].

The probe tip is usually covered with a single-use disposable latex sheath (Ocufilm®) to reduce the potential for spreading infection[5,6]. The unit price, however, is about 30 baht, which is relatively costly for Thailand. To reduce the cost, the authors wanted to test the use of the cut-off end of a surgical glove

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fingertip (Gammex Micro Thin®-powder free by Ansell) for covering the probe tip instead of Ocufilm®. There have been no similar studies assessing the accuracy of IOP measured using a Tono-Pen® XL probe covered with the fingertip of a surgical glove.

The purpose of the present study was to evaluate the agreement and repeatability of the measurement of intra-ocular pressure using a Tono-Pen® XL covered at the end with Ocufilm® vs. the fingertip of a surgical glove.

Material and Method

This was a prospective study conducted in a group of patients at the outpatient eye clinic at Srinagarind Hospital, Faculty of Medicine, Khon Kaen University, Thailand. The present study was approved by the Human Research Ethics Committee of Khon Kaen University.

The inclusion criteria were patients (a) willing to participate (b) having normal corneae and (c) being 18 years or older. The exclusion criteria were patients with eye infections, corneal ulcer or scar, ruptured eyeball, allergy to latex[7] or tetracaine or uncooperative. All patients signed an informed consent form before entering the present study. Patients were randomized into two groups to receive IOP measurements using a Tono-Pen® XL with two different types of tip covers. In Group 1, the IOP of the right eyes were first measured using Ocufilm® as the tip cover, followed by using the fingertip of a surgical glove. As for the left eyes, the tip of the surgical glove was used first, followed by use of Ocufilm®. In Group 2, the IOP of the right eyes was first measured using the tip of the surgical glove, followed by the use of Ocufilm®, while for the left eye the latter was used first, followed by the tip of the surgical glove.

The techniques for measuring IOP were similar between the two types of tip covers. Tetracaine hydrochloride was applied to numb the eyes before doing the measurement. Ten to 15 seconds after instilling the tetracaine, the center of cornea was touched 8-10 times with the probe tip-covered with either Ocufilm® or the fingertip of a surgical glove-until a value for IOP was displayed. Only the readings with a reliability of 5% were accepted. Measurement of the IOP was performed twice with each type of tip covers, in each eye, by a single operator (Fig. 1).

Statistical analysis

The data were analyzed using the statistical software (Medcalc v. 11.5.1, Mariakerke, Belgium). Agreement of the IOP measurements using the Tono-Pen® XL with Ocufilm® and the fingertip of a surgical glove was assessed using the Bland-Altman technique[8,9]; in which the difference in IOP with Ocufilm® and the fingertip of surgical glove was plotted against the average IOP of both tip covers for each eye. The 95% confidence interval of agreement was also plotted.

Reproducibility of the IOP by the Tono-Pen® XL with Ocufilm® or the fingertip of a surgical glove was also analyzed using the Bland-Altman technique[8,9]. The coefficient of repeatability of each type of tip cover was calculated.

Differences with $p < 0.05$ were considered statistically significant.

Results

A total of 100 patients (200 eyes) (41 males and 59 females) were recruited into the study. The patients were between 18 and 69 years (average, 47) (95%CI: 45.89-51.10 years). The respective mean IOP obtained using Ocufilm® and the fingertip of a surgical glove was 15.03 mmHg (95%CI:14.46-15.6 mmHg) and

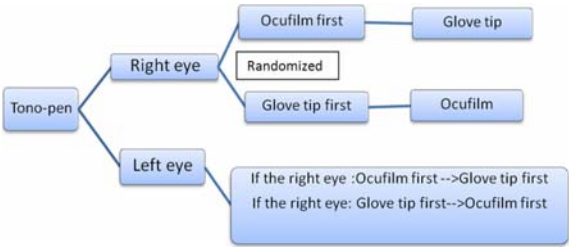

Fig. 1 Experimental sequence for measuring intraocular pressure by Tono-Pen® XL

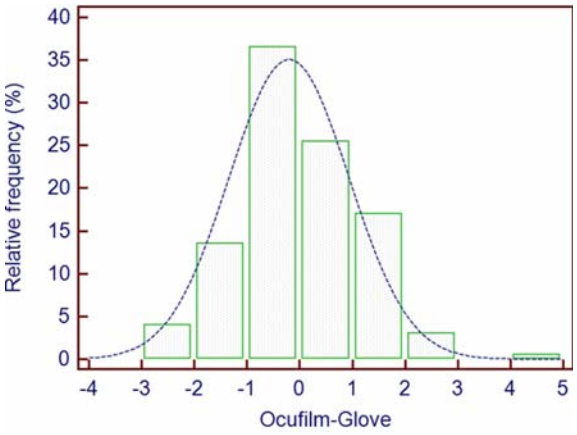

Fig. 2 Histogram of the difference in IOP measurements between Ocufilm® and the fingertip of a surgical glove for covering the Tono-Pen® XL

15.23 mmHg (95% CI: 14.67-15.8 mmHg). Two-thirds (65%) of IOP measurements using the fingertip of a surgical glove were greater than the Ocufilm®. The difference in the IOP with the two types of tip covers was ≤ 2 mmHg in 94% of the eyes (Fig. 2).

The Bland-Altmann plot analysis indicated that the mean difference in readings between the two types of tip covers was -0.21 mmHg (95% CI: -0.36 to -0.05 mmHg). The 95% limits of agreement were -2.43 to +2.02 mmHg and y = -0.3014 + 0.006372 x (Fig. 3), implying that the average IOP correlated positively with the differences in IOP with the two types of tip covers.

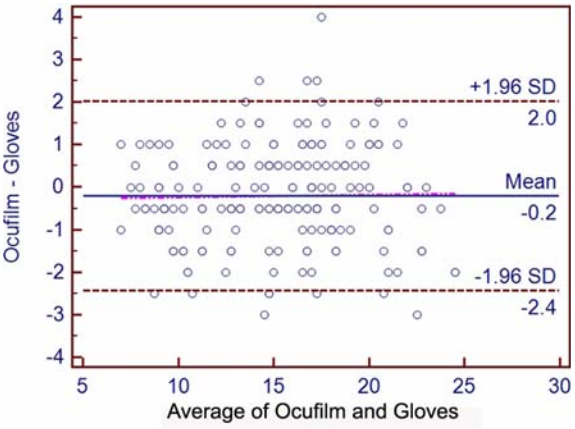

Fig. 3 Bland-Altman plot showing the difference between IOPs taken using Ocufilm® vs. glove tip and the average of both. The mean difference in readings between the two types of tip covers was -0.21 mmHg and the 95% limits of agreement were -2.43 to +2.02 mmHg and y = -0.3014 + 0.006372 x

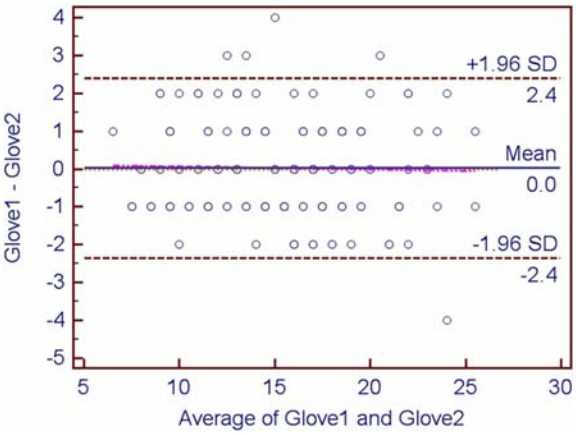

Fig. 4 Bland-Altman plots for repeatability of IOP using Tono-Pen® XL with the fingertip of a surgical glove for the tip cover. The coefficient of repeatability was 2.37

The coefficient of repeatability of the Ocufilm® and the fingertip of a surgical glove was 1.74 and 2.37, respectively, (Fig. 4); so, the reproducibility of Ocufilm® was a little higher than the fingertip of a surgical glove. There were no complications detected from using either the Ocufilm® or the fingertip of a surgical glove.

Discussion

The Tono-pen® XL has a precision sufficiently adequate for screening glaucoma[10]. The probe tip of the Tono-pen® XL is usually covered with Ocufilm®, ostensibly to protect the Tono-Pen® XL from dust and fluids and to prevent cross-contamination between eyes and patients[5,6]. Ocufilm® is a single-use tip cover designed for the Tono-pen® XL and costs about 30 baht per cover.

The authors wanted to test the results if the Ocufilm® was replaced with the less expensive, cut-out fingertip of a surgical glove. Based on the results of the present study, most (65%) of the IOPs taken using the fingertip of a surgical glove® were greater than the Ocufilm and 94% of the IOPs taken using the fingertip of a surgical glove differed by ≤ 2 mmHg of the Ocufilm®. According to the Bland-Altman analysis, the mean difference between the two types of tip covers was -0.21 mmHg and the 95% limits of agreement were -2.43 to +2.02 mmHg. This range in IOP measurement was not wide and the coefficient of repeatability using the Ocufilm was nearly the same as for the fingertip of a surgical glove (Fig. 4); thus, the two types of coverings tested may be used interchangeably albeit the IOPs taken using the fingertip of a surgical glove tended to overestimate compared to using Ocufilm®. In addition, the IOP using the fingertip of a surgical glove tended to underestimate when the IOP (done with Ocufilm®) was < 10 mmHg and overestimate it when the IOP was > 20 mmHg. The reason may be due to the different thickness of the two types of tip covers; *viz.*, the thickness of the fingertip of surgical glove (0.185 mm)[11] is greater than the Ocufilm® (0.0762 mm) [Pers. comm. with Reicher].

The limitation of the present study was that most of the patients had an IOP in normal range (10-20 mmHg). Several authors have demonstrated that the Tono-Pen® XL trends to overestimate low IOPs and underestimate high IOPs[1,6,12]. The present authors are therefore only able to conclude that in the normal range of IOP, the agreement between Ocufilm® and the fingertip of a surgical glove are comparable. The other limitation is that measurement of central corneal thickness (CCT) was not performed because CCT

influences the measurement of IOP when using the Tono-Pen® XL; that is, IOP tends to be overestimated compared to the Goldmann tonometer at CCTs > 520 mm and underestimate at CCTs < 510 mm[13].

Conclusion

In the authors' clinical study, significant agreement existed between the results of the measurement of IOP using the Tono-Pen® XL with either Ocufilm® or the fingertip of a surgical glove to cover the tip of the probe. The coefficient of repeatability between the two different types of tip covers was comparable. Ocufilm® may be replaced by the fingertip of a surgical glove to cover the tip of Tono-Pen® XL for glaucoma screening.

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Potential conflicts of interest

None.

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การศึกษาความสอดคล้องและ reproducibility ของการวัดความดันในลูกตาด้วย Tono-Pen® XL ที่หุ้มปลายด้วย Ocufilm® และปลายนิ้วถุงมือผ่าตัด

นิพนธ์ สายวัฒน์, ดวงดาว ดวงนำสว่าง

วัตถุประสงค์: เพื่อหาความสอดคล้องและ reproducibility ของการวัดความดันในลูกตาด้วย Tono-Pen® XL ที่หุ้มปลายด้วย Ocufilm® และปลายนิ้วถุงมือผ่าตัด

โครงการศึกษา: การศึกษาทางคลินิกแบบทดลอง

วัสดุและวิธีการ: ผู้ป่วยได้รับการสุ่มเป็นสองกลุ่มเพื่อได้รับการวัดความดันในลูกตาโดย Tono-Pen® XL ที่หุ้มปลายด้วยวัสดุที่แตกต่างกันสองชนิด ในกลุ่มที่ 1 ตาขวาได้รับการวัดความดันในลูกตาที่หุ้มด้วย Ocufilm® ก่อนต่อมาจึงวัดความดันในลูกตาที่หุ้มด้วยปลายถุงมือผ่าตัด ส่วนตาซ้ายวัดความดันในลูกตาที่หุ้มด้วยปลายถุงมือผ่าตัดก่อนแล้ววัดความดันในลูกตาที่หุ้มด้วย Ocufilm® ในกลุ่มที่ 2 ตาขวาได้รับการวัดความดันในลูกตาที่หุ้มด้วยปลายถุงมือผ่าตัดก่อนต่อมาจึงวัดความดันในลูกตาที่หุ้มด้วย Ocufilm® ส่วนตาซ้ายวัดความดัน ในลูกตาที่หุ้มด้วย Ocufilm® ก่อนแล้ววัดความดันในลูกตาที่หุ้มด้วยปลายถุงมือผ่าตัด การวัดความดันในลูกตาด้วย วัสดุหุ้มปลาย Tono-Pen® XL แต่ละชนิดทำการวัดสองครั้งในแต่ละตาโดยผู้ศึกษาเพียงคนเดียว การหาความสอดคล้อง (agreement) ของการวัดความดันในลูกตาด้วยวัสดุหุ้มปลาย Tono-Pen® XL ทั้งสองชนิดโดยใช้วิธีทางสถิติของ Bland-Altman ความแตกต่างของค่าความดันในลูกตาที่วัดซ้ำสองครั้งของวัสดุหุ้มปลายแต่ละชนิดนำมาคำนวณเพื่อหา reproducibility ของค่าความดันในลูกตาที่วัดด้วย Tono-Pen® XL ที่หุ้มปลายด้วยวัสดุแต่ละชนิด

ผลการศึกษา: ผู้ป่วย 100 คน (200 ตา) ได้เข้าร่วมการศึกษานี้ ค่าเฉลี่ยของความแตกต่างของการวัดความดันในลูกตา (mean difference) ที่วัดโดย Tono-Pen® XL ที่หุ้มปลายด้วย Ocufilm® และปลายถุงมือผ่าตัดเท่ากับ -0.21 มิลลิเมตรปรอท (95% CI: -0.36 to -0.05) limit of agreement ที่ช่วงความเชื่อมั่นร้อยละ 95 ของ Ocufilm® และปลายถุงมือผ่าตัดโดยคำนวณด้วยวิธี Bland-Altman plot เท่ากับ -2.43 ถึง +2.02 มิลลิเมตรปรอท ค่าสัมประสิทธิ์ของ repeatability ของ Ocufilm® และถุงมือผ่าตัดมีค่าใกล้เคียงกัน (1.74 และ 2.37 ตามลำดับ)

สรุป: พบความสอดคล้องระหว่างการใช้ Ocufilm® และปลายถุงมือผ่าตัดเพื่อหุ้มปลาย Tono-Pen® XL ในการวัดความดันในลูกตา ค่าสัมประสิทธิ์ของ repeatability มีค่าใกล้เคียงกันระหว่างวัสดุที่หุ้มปลาย Tono-Pen® XL ทั้งสองชนิด ดังนั้นปลายถุงมือผ่าตัดสามารถนำมาใช้แทน Ocufilm® ในการหุ้มปลาย Tono-Pen® XL เพื่อวัดความดันในลูกตา