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Comparing the corneal curvatures obtained from three different keratometers – IOL Master, Bausch & Lomb Manual keratometer and TOPCON KR – 8800 autokeratometer

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不同角膜仪测量的角膜曲率值的一致性分析

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摘要

目的:比较测得后三种不同角膜仪测量的角膜曲率,以评估其测量值之间的一致性。

方法:前瞻性研究。252 例患者(252 眼)使用 IOL Master(IM),Bausch & Lomb 手动角膜仪(Man)以及 TOPCON KR-8800 自动角膜仪(Top)进行角膜曲率测量。记录并对比平均角膜曲率值。使用 Bland Altman 统计方法进行仪器间的一致性分析。

结果:1)IOL Master 和 手动角膜仪:IOL Master 平均角膜曲率为 44.62±1.52 D,手动角膜仪为 44.60±1.52 D。t-test 显示差异具有统计学意义(P=0.001);Bland-Altman 图显示两种仪器间 95% 一致性区间(LOAs)为-0.22 ~ 0.22;2)IOL Master 和自动角膜仪:IOL Master 平均角膜曲率为 44.62±1.52 D,自动角膜仪为 44.46±1.53 D。t-test 显示差异具有统计学意义(P<0.0001)。Bland-Altman 图显示两种仪器间 95% LOAs 为 -0.24 ~ 0.55;3)自动角膜仪和手动角膜仪:自动角膜仪平均角膜曲率为 44.60±1.52 D,手动角膜仪为 44.46±1.53 D。t-test 显示差异具有统计学意义(P<0.0001)。Bland-Altman 图显示两种仪器间 95% LOAs 为-0.30 ~ 0.57。

结论:使用不同的仪器获得的角膜曲率数据是不可替换的,这对于白内障外科医生在外科手术计划和结果评估方面具有重要意义。

关键词:IOL Master;自动角膜仪;角膜仪;角膜曲率值

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Abstract

• AIM: To compare the corneal curvature and to investigate the agreement between three different keratometers.

• METHODS: In this prospective study, keratometry was performed using an IOL Master (IM), a Bausch & Lomb manual keratometer (Man) and TOPCON KR - 8800 autokeratometer (Top) on 252 eyes of patients recruited from camps for cataract surgery. The average keratometry values were recorded and compared. The agreements between the instruments were analyzed using the Bland-Altman statistical method. The main outcome measure was average keratometry values.

• RESULTS: 1) IOL Master and Manual keratometer: the mean corneal power was 44.62±1.52 D with the IOL Master and 44.60±1.52 D with the Manual keratometer. The paired t-test demonstrated a statistically significant difference in the mean corneal power between the IOL Master and Manual keratometer (P = 0.001). The 95% LOAs of the two devices were -0.22 to 0.22 as shown in the Bland - Altman plot; 2) IOL Master and autokeratometer: the mean corneal power was 44.62±1.52 D with the IOL Master and 44.46±1.53 D with the autokeratometer. The paired t - test demonstrated a statistically significant difference in the mean corneal power between the IOL Master and autokeratometer (P<0.0001). The 95% LOAs of the two devices were -0.24 to 0.55 as shown in the Bland - Altman plot; 3) Autokeratometer and Manual keratometer: the mean corneal power was 44.60±1.52 D with Manual keratometer and 44.46±1.53 D with the autokeratometer. The paired $t$test demonstrated a statistically significant difference in the mean corneal power between the autokeratometer and Manual keratometer (P<0.0001). The 95% LOAs of the two devices were -0.30 to 0.57 as shown in the Bland-Altman plot.

• CONCLUSION: Keratometry data obtained with different instruments may not be interchangeable, a fact that has important implications for cataract surgeons with respect to both surgical planning and outcomes auditing.

• KEYWORDS: IOL Master; autokeratometer;

keratometry; corneal curvature
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INTRODUCTION

Accurate measurement of corneal curvature is of vital importance in the diagnosis and treatment of various ocular diseases. A primitive form of the keratometer was invented approximately 250 years ago[1]. However at present a number of instruments are available for assessing corneal curvature, including Scheimpflug topography, optical coherence tomography, optical low-coherence reflectometry, partial coherence interferometry, and slit - scanning topography/pachymetry systems[2-9]. Since the working principles of different instruments vary, measurements are likely to differ from one to another.

The IOL Master (Zeiss Meditec) is a conventional automated keratometry device that projects six spots of light in a hexagonal array and analyses the reflection off the front corneal surface to finally determine the corneal curvature. It measures the curvature at 2.3 to 2.5 mm diameter (depending on the corneal curvature) from the corneal apex[10-11].

The Bausch & Lomb keratometer (Bausch & Lomb, Rochester) is a one-position manual keratometer which is capable of measuring two meridians simultaneously. The instrument uses the principle of fixed object and variable image. It employs an image doubling by means of axially movable horizontal and vertical prisms. A four-aperture Scheiner disc improves focusing accuracy and easier adjustment of distance[12].

The KR-8800 auto kerato-refractometer (Topcon, Tokyo, Japan) uses rotary prism technology to assess corneal refractive status[13].

In this study, we aimed to investigate if the commonly used three types of keratometers produce clinically interchangeable measurements. The instruments compared in the current study included a manual keratometer (Bausch & Lomb), Topcon KR-8800 autokeratorefractor (Topcon Inc, Japan) and IOL Master 500 (Zeiss Meditec).

SUBJECTS AND METHODS

This study was performed at a tertiary hospital in South India from December 2016 to December 2017. The research protocols were approved by the scientific and ethical committee and carried out in accordance with the tenets of the Declaration of Helsinki. Written informed consent was obtained from each subject after they were given a detailed explanation of the nature of the study.

This study included a total of 252 eyes with no ocular abnormalities other than cataracts from 252 patients selected from cataract camps.

Inclusion Criteria　1) All patients between age group of 18-65y and who have been advised for cataract surgery for one or both the eyes; 2) Either gender; 3) Willing to give informed consent.

Exclusion Criteria　1) Patients with history of prior intraocular and corneal surgery and trauma; 2) Corneal and other ocular diseases that could affect outcomes; 3) Subjects with contact lens wear; 4) Patients suffering from severe dry eyes; 5) Pregnant and lactating females.

In this study, keratometry values were obtained in diopters, directly from the instruments. Corneal powers of the two principal meridians were averaged for analysis.

The data capture procedure for both devices was as follows: the subject's chin was placed on the chin rest, the subject's forehead was pressed against the forehead strap, and the subject's eye was aligned to the visual axis by a central fixation light or target. A single trained operator performed all of the examinations using both instruments following the procedural guidelines for the IOL Master, autokeratometer and Bausch & Lomb instruments.

The statistical analyses were performed with commercial software (SPSS ver. 13.0; SPSS Inc.). The statistical significance of the inter-device differences in corneal curvature parameters was evaluated with the paired two-tailed -test. A $P < 0.05$ were considered statistically significant.

Inter-device agreement was evaluated using Bland-Altman analysis[14]. The inter-device differences were plotted against their means, and the 95% limits of agreement (LoA) were determined using this method. The confidence limit of less than 0.50 D was considered as good agreement. The significance level for all of the tests was set at 5%.

RESULTS

Totally 252 eyes of 252 patients were enrolled in the study. And 121 patients in this study were females and 131 patients were males. The mean age of the participants was 54.9 ± 14.4y.

Table 1 shows the mean of flat K, steep K, and average K values for each instrument.

Statistically significant differences in the mean of the average between IM and Man ($P = 0.009$), IM and Top ($P \leqslant 0.0001$) and Man and the Top ($P < 0.0001$) were observed (Table 2). The difference was highest between IOL Master and autokeratometer.

Figures 1-3 are Bland-Altman plots for the keratometry measurements with the three devices investigated in this study.

DISCUSSION

The accurate determination of corneal curvature is not only an important factor in the diagnosis and follow-up of corneal curvature disorders but also is important in the determination of the eligibility of patients for refractive surgery and the level of correction that can safely be performed during refractive

Table 1 Summary of anterior corneal curvature measurement

Devices	Mean K±SD (D)	Mean steep K(D)	Mean flat K (D)
IOL Master (IM)	44.62±1.52	45.07	44.62
Autokeratometer (Top)	44.46±1.52	44.90	44.46
Manual (Man)	44.60±1.51	45.05	44.15

Table 2 Mean of difference and *P* of differences between the keratometry values obtained from the three instruments

Difference between	Mean of difference	*P*
IM–Man	0.02±0.12	0.009
IM–Top	0.15±0.20	<0.0001
Man–Top	0.13±0.22	<0.0001

IM: IOL Master; TOP: autokeratometer; Man: Manual.

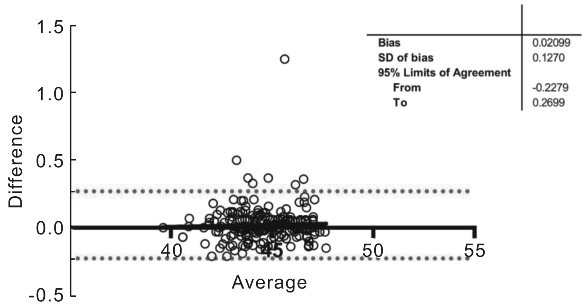

Figure 1 Bland–Altman mean difference plot for agreement between IM–Man i. e. IOL Master minus Manual for Mean K reading.

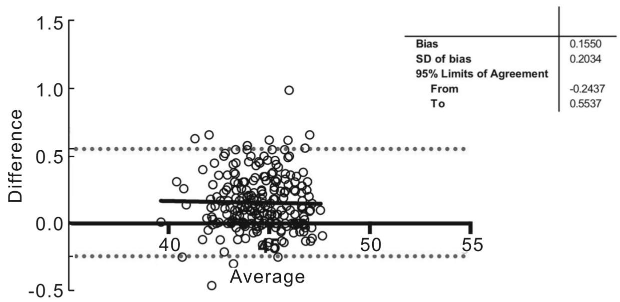

Figure 2 Bland–Altman mean difference plot for agreement between IM–TOP i. e. IOL Master minus autokeratometer for Mean K reading.

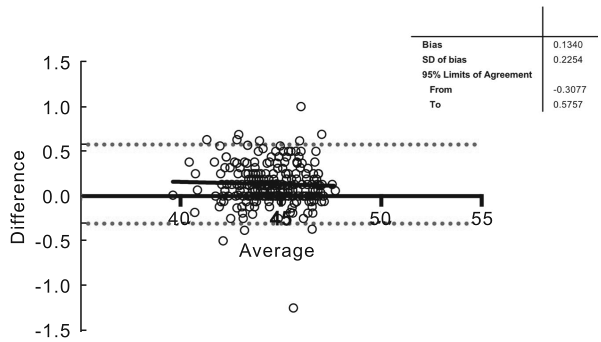

Figure 3 Bland–Altman mean difference plot for agreement between MAN – TOP i. e Manual minus autokeratometer of Mean K reading.

surgery. Several studies have reported the repeatability and accuracy of corneal powers measured by manual keratometry, automated keratometry, and computerized videokeratography[15-17].

While there are studies that compare modern day keratometer, there are very few which compare it to the manual Bausch & Lomb keratometer. Those published studies using the Bausch & lomb keratomer have used smaller study sample size ranging from 20 – 76 patients. Also the gender distribution was unequal with female preponderance[15,18].

Using the IOL master, the mean ±SD K steep was 45.06±1.6, K flat was 44.17±1.5, and Avg K was 44.62±1.52.

Using Manual keratometry the mean ±SD K steep was 45.04±1.6, K flat was 44.15±1.5 and Avg K was 44.6±1.52.

Finally, by autokeratore fractometer, we observed that the mean± SD K steep was 44.90±1.6, K flat was 44.02±1.51 and Avg K was 44.47±1.53.

In a study done by Wang *et al*[19] in 2014, the average K, steep K and flat K using automated Galilei was 43.36 ±1.63, 43.92±1.63 and 42.80±1.44; and that of autokeratometer was 43.40±1.63, 43.89±1.78 and 42.90±1.55. In our study, the IOL Master showed slightly steeper corneal curvatures compared to other two methods whereas the autokeratometer yielded the lowest average keratometry values.

It was seen that the mean of the differences of Avg K between autokeratometer and manual keratometer was significantly different. This was not in agreement with a study done by Ale Magar[20] where there was no statistical difference between the mean of differences obtained from the Manual and the automated keratometer. In a study by Sunderraj *et al*[21], comparison of automated and manual keratometry also showed no significant difference.

It was observed that the mean Avg K had significantly different values between IOL master and Manual keratometry. Also we observed that the mean Avg K had significantly different values between IOL master andAutokeratometer . The findings were similar with respect to the study done by Ale Magar. On the other hand according to some studies IOL Master and automater keratometer showed no significant difference with the manual keratometer[16,22].

The mean corneal powers from theautokeratometer, IOL Master, and manual keratometer were were statistically significant differences between all 3 groups. However, the highest mean difference was only 0.15D detected between IOL master and autokeratometer.

Using the Bland–Altman method of evaluating inter–device agreement, we compared keratometry data obtained from the three instruments. On analyzing the plots, both IOL Master and the Manual keratometer tended to over estimate K readings compared to theautokeratometer, the highest bias of 0.15 between the IOL Master and autokeratometer. This could be seen as clinically insignificant. The findings were similar to those observed in other studies where they observed that the IOL Master produced consistently steeper values[19-20].

On comparing the IOL Master and Manual keratometer using the Bland - Altman plot, the 95% confidence limits of agreement were from 0.26 to -0.22 D. The confidence limit being 0.48 D, thus showing agreement to be relatively good. This similar to what Hasan *et al*[23] noted where a significant difference between the IOL Master and Manual keratometer (Javal keratometer) was seen after PRK although there was no significant differences before PRK and the measurements for both devices had a strong correlation.

On comparing the IOL Master and automated keratometer using the Bland-Altman plot, the 95% confidence limits of agreement were from -0.24 to 0.55. The confidence limit being 0.79 D, thus showing poorer agreement.

Similarly, on comparing the Manual keratometer and automated keratometer using the Bland-Altman plot, the 95% confidence limits of agreement were from -0.30 to 0.57. The confidence limit being 0.87 D, thus showing poorer agreement.

These results were ascertained from healthy corneas. Factors including age, irregular corneas, refractive surgery, or dry eyes could limit the fixation and tear stability and alter the final readings. Possible reasons for the discrepancies between the measurements with the different devices include differences in the measuring principles, alignment errors and observer bias. Further studies are needed to investigate how these facts affect the results of the different devices.

In conclusion keratometry data obtained with different instruments is not interchangeable, a fact that has important implications for cataract surgeons with respect to both surgical planning and outcomes auditing. In addition the autokeratometer tends to underestimate K reading.

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