Journal of Current Science and Technology, January-April 2021 JCST Vol. 11 No.1, pp. 127-136

ISSN 2630-0656 (Online)

Cite this article: Naksaranyuyottana, P., Raktrakulwitthaya, T., Klongkidpanich, P., Phuwasinsawad, P., Ketru, C., Jeak-in, S., & Boonkrong, P. (2021, January). Inter-instrument agreement of anterior corneal curvature measurements: Topographer, auto kerato-refractometer and manual keratometer. *Journal of Current Science and Technology, 11*(1), 127-136. DOI: 10.14456/jcst.2021.14

Journal of Current Science and Technology

Journal homepage: https://jcst.rsu.ac.th

Inter-instrument agreement of anterior corneal curvature measurements: Topographer, auto kerato-refractometer and manual keratometer

Phongvarin Naksaranyuyottana[1,*], Thareerat Raktrakulwitthaya[1], Phatthanakan Klongkidpanich[1], Phanchita Phuwasinsawad[1], Chutiralai Ketru[1], Supasin Jeak-in[1], and Pichit Boonkrong[2]

[1]Faculty of Optometry, Rangsit University, Patumthani 12000, Thailand
[2]College of Digital Innovation and Information Technology, Rangsit University, Patumthani 12000, Thailand

*Corresponding author; E-mail: phongvarin.opto@gmail.com

Received 12 February 2020; Revised 5 August 2020; Accepted 17 November 2020
Published online 30 January 2021

Abstract

In this paper, inter-instrument agreement among topographer, auto kerato-refractometer and manual keratometer are the main concerns. The corneal steep, flat and average powers from the 61 right eyes of 61 healthy undergraduate students at Rangsit University were measured by three different instruments. In statistical analysis, measurement concordance and correlation between pairs of instruments were analyzed by Bland-Altman analysis. Intraclass correlation coefficient and paired *t*-test analysis were also performed. It was found that the three instruments showed indifferent mean corneal steep and flat and average powers at a significance level of 0.05. Therefore, topographer, auto kerato-refractometer and manual keratometer can be practically interchangeable.

Keywords: *auto kerato-refractometer; Bland-Altman analysis; corneal curvature measurements; inter-instrument agreement; manual keratometer; topographer.*

1. Introduction

The measurement of corneal power is required for several procedures in ophthalmology and optometry such as calculating intraocular lens (IOL), refractive surgery, orthokeratology, contact lens fitting, and screening or assessing corneal disorders (Arce, Martiz, Alzamora, Schor, & Campos, 2007; Chen & Lam, 2009; Dehnavi et al., 2015; Weisenthal, 2016; Gutmark & Guyton, 2010; Grosvenor, 2002). As a result, it is unquestionable that evaluating the measuring instruments for corneal power is clinically important. Currently, popular instruments measuring the radius, curvature and refractive power of the cornea are manual keratometer, automated keratometer, topographer, and optical coherence tomography (Huang et al., 2015a; Huang et al., 2015b; Cantor, Rapuano, & Cioffi, 2017-2018; Md Muziman Syah, Mutalib, Sharanjeet Kaur, & Khairidzan Khairidzan, 2020).

Comparative study of the corneal refractive power from four different instruments including Galilei dual scheimpflug analyzer (Ziemer, Port, Switzerland), Humphrey atlas corneal topographer (Carl Zeiss, Jena, Germany), IOL master (Carl Zeiss) and manual keratometer (Bausch & Lomb Inc, Rochester, New York, USA) found that all four types have high confidence values (Shirayama, Wang, Weikert, & Koch, 2009). Considering the corneal refractive power measured by Manual Keratometry (Javal schiotz type haagstreit AG, Koeniz, Switzerland), Automated-Keratometry (IOL master, Carl Zeiss Meditec, Jena, Germany), Topography (TMS4, Tomey, Erlangen, Germany), and Pentacam HR (Oculus, Wetzlar, Germany), results showed relatively high confidence values (Dehnavi et al., 2015). By investigating irregular corneal surface when comparing the refractive power of the cornea obtained from the Zeiss 10 SL/O Keratometer with TMS-1 video-keratoscope, it was found that the TMS-1 video-keratoscope and the Zeiss 10 SL/O keratometer cannot be used as a replacement for measuring the refractive power of the cornea after corneal surgery (Karabatsas, Cook, Powell, & Sparrow, 1998). The comparison between Galilei Dual-Scheimpflug analyzer and Topcon KR-8800 auto kerato-refractometer has an acceptability, but the K_{flat} values are different (Wang, Dong, & Wu, 2014).

2. Objectives

This study aims to assess the comparability of corneal powers obtained from the manual keratometer, auto kerato-refractometer and topographer for corneal power measurements. The overall presentation of this paper is organized as follows. The research methodology including data collection, measuring instrument and statistical data analysis are described in section 3 Materials and methods. Next, relevant and statistical data analysis are illustrated in section 4 Result. Finally, major concerns of inter-instrument agreement in clinical application corresponding to the results of this study are discussed in section 5 Discussion and the overall summary is accordingly given in section 6 Conclusion

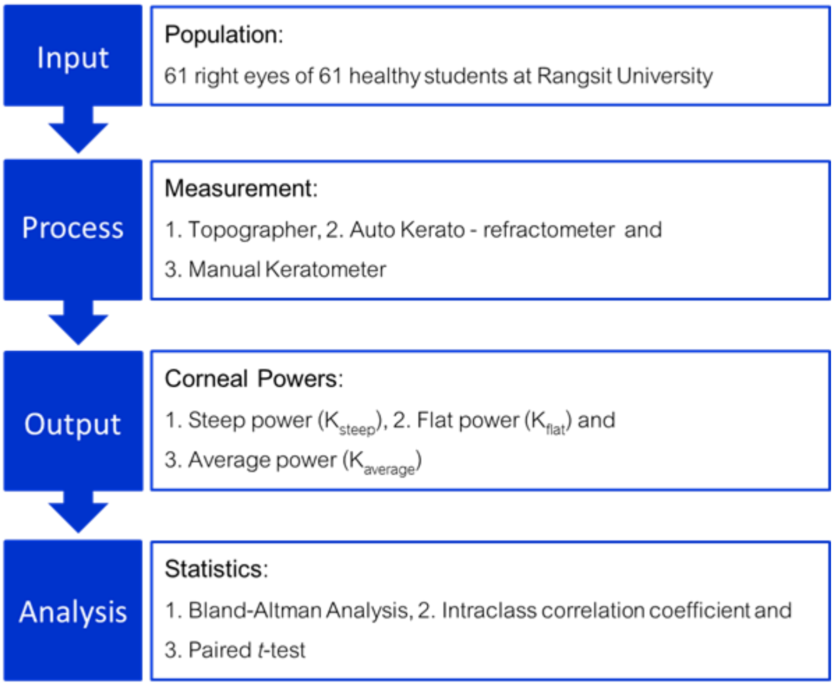


Figure 1 Research framework

3. Materials and methods

This comparative study of corneal power measurements has been carried out in correspondence with the research framework in Figure 1. Data collection began with registration, acknowledgment of research details and obtaining a signed approval to participate in this research. Assessment for anterior and posterior eye disease, refractive power were measured using the topographer, auto keratometer and manual keratometer, respectively. The measurement has been repeated for five times in the right eye of each subject. Statistical data analysis was finally executed and results were interpreted. Throughout this study, the guidelines from the tenets of the Declaration of Helsinki, The Belmont Report, CIOMS Guideline, and International Conference on Harmonization in

Good Clinical Practice (ICH-GCP) have been followed.

3.1 Data collection

Normal subjects were collected from 61 right eyes of 61 healthy undergraduate students who visited the optometry clinic at the Faculty of Optometry, Rangsit University. Exclusion criteria were: (1) contact lens wear (rigid contact lens within four weeks and soft contact lens within two weeks), (2) eye surgery history, and (3) eye or corneal related diseases. Five consecutive corneal power measurements in the right eyes were performed and the mean corneal steep power (K_{steep}), mean corneal flat power (K_{flat}) as well as mean corneal average power ($K_{average}$) were taken for each case. Each measuring instrument used in the study was correctly calibrated by technicians before examinations.

3.2 Measuring instruments

Considering inter-instrument agreement, three main measuring instruments of corneal power were used in this study including topographer (TP), auto kerato-refractometer (AK) and manual keratometer (MK). Specific information for each instrument used in the entire study is given in Table 1. In this study, the three mentioned instruments were used to measure the corneal powers, called keratometer calibration or K value (Wang et al., 2014; Yu et al., 2017). Clinically, there were three main K values as detailed in Table 2.

Table 1 Specification of measuring instruments

Instrument and version	Topographer, Oculus keratograph 5M (Oculus, Germany)	Auto kerato-refractometer KR-8800 (Topcon, Tokyo, Japan)	Manual keratometer Ophthalmometer OM-4 (Topcon, Tokyo, Japan)
Range of curvature	3.00 - 38.00 mm (min 0.01 mm)	5.00 - 10.00 mm (min 0.01 mm)	5.50 - 12.00 mm (min 0.01 mm)
Corneal refractive power	9.00 – 90.00 D (min 0.1D)	33.75 - 67.50 D (min 0.12 D/0.25 D)	28.00 - 60.00 D (min 0.125 D)
Axis of corneal astigmatism	0° - 180° (min 1°)	0° - 180° (min 1°/5°)	0° - 180° (min 1°)
Refractive index	1.3375	1.3375	1.3375

Table 2 Description of corneal powers

Notations	Technical terms	Description
K_{steep}	The mean corneal steep power	Keratometry reading of vertical corneal meridian
K_{flat}	The mean corneal flat power	Keratometry reading of horizontal corneal meridian
$K_{average}$	The mean corneal average power	The mean of K_{steep} and K_{flat}

3.3 Statistical data analysis

Statistical data were analyzed using SPSS 22.0 software. Mean corneal powers were given as a mean±standard deviation (SD). Bland-Altman concordance method with the 95% limits of agreement (95%LoA) and intraclass correlation coefficient (ICC) in groups (MK-AK, MK-TP, AK-TP) and paired *t*-test analysis were performed (Bland & Altman, 1986; Hidalgo et al., 2015; Koo & Li, 2016; Magar, 2013; Mehravaran, Asgari, Bigdeli, Shahnazi, & Hashemi, 2014; Wang et al., 2012). Bland-Altman is a graphical method used to analyze agreement between two different variables. The ICC indicates the degree to which measurements in the different instruments resemble each other. The paired *t*-test analysis is used to examine the mean difference between instruments.

4. Results

This study considered 61 right eyes of 61 participants (14 males and 47 females) with the mean age of 20.95±2.80 years old (range 18-31 years). Three different indicators for measuring corneal powers including the mean corneal steep power (K_{steep}), mean corneal flat power (K_{flat}) and mean corneal average power ($K_{average}$) from different instruments were the main concern. At the beginning of investigation, the distributions of K_{steep} , K_{flat} and $K_{average}$ from different instruments were plotted in Figure 2 and they had normal distributions at the significance level of 0.05. The agreement between pairs of instruments were assessed as follows.

4.1 Corneal steep power

Measuring the mean corneal steep power (K_{steep}), the values were: 44.09±1.39 D for topographer (range 40.80-46.72 D), 44.02±1.41 D for auto kerato-refractometer (range 40.74-46.49 D), and 44.00±1.43 D for manual keratometer (range 40.80-46.55 D).

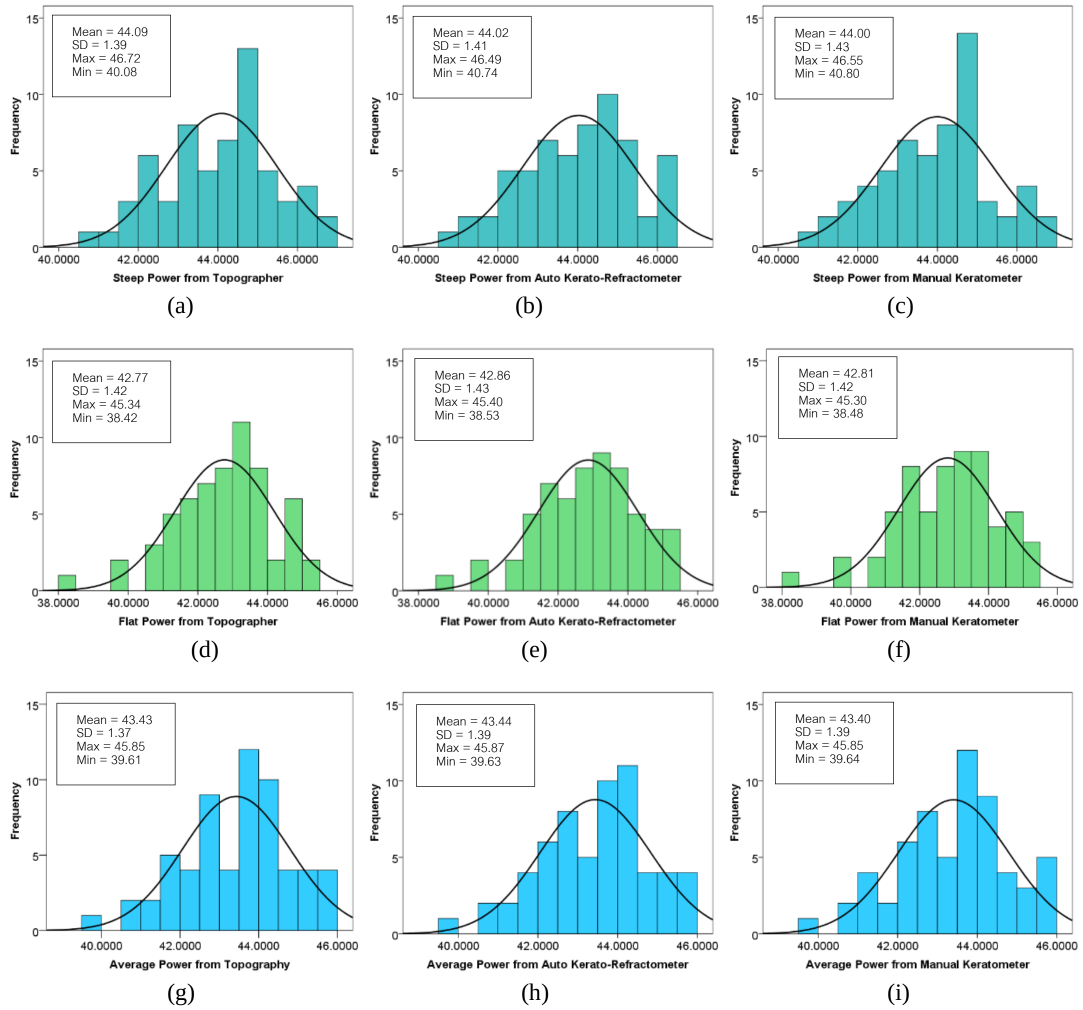


Figure 2 Distributions of corneal powers: (a)-(c) mean steep power, (d)-(f) mean flat power and (g)-(i) average power.

As shown in Table 3, manual keratometer value was 0.03±0.09 D, lower than auto kerato-refractometer (p = 0.036, ICC = 0.999) and manual keratometer value was 0.09±0.19 D which is lower than topographer (p = 0.000, ICC = 0.994). The agreement between pairs of instruments was calculated using ICC and 95%LoA values. The results shows that all three pairs were statistically significant as p-value < 0.05. That is, the three instruments show the evidence of strong concordance.

Table 3 Intraclass correlation coefficient (ICC) and 95% limits of agreement (95%LoA) between pairs of instruments for measuring corneal steep power (K_{steep}).

Pairs of instruments	ICC	Mean difference ± SD	95%LoA	*p*-value
TP-AK	0.995	0.07±0.19 D	-0.30 D to 0.44 D	0.007*
TP-MK	0.994	0.09±0.19 D	-0.28 D to 0.46 D	0.000*
AK-MK	0.999	0.03±0.09 D	-0.15 D to 0.21 D	0.036*

*Statistical significance when the *p*-value was < 0.05

Figure 3 shows the results obtained from the Bland-Altman analysis. The high concordance was found for all three pairs of instruments. The 95% limits of agreement (LoA = mean of the difference ± 1.96 × SD of the differences) indicate that the values on the error between the pairs of instrument have exceeded the limits of concordance.

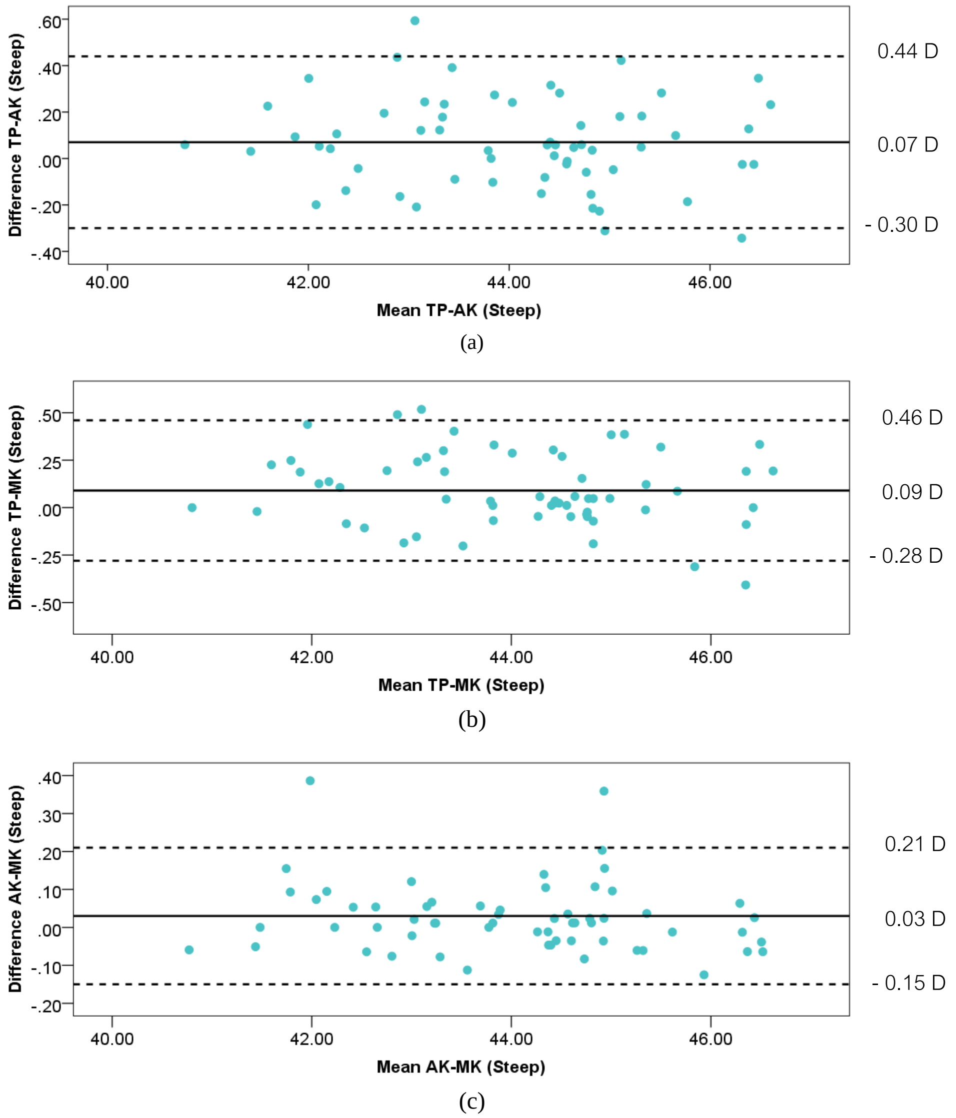


Figure 3 Bland-Altman plots comparing Manual keratometer (MK), Auto kerato-refractometer (AK), and Topographer (TP) for measuring corneal steep power (K_{steep}).

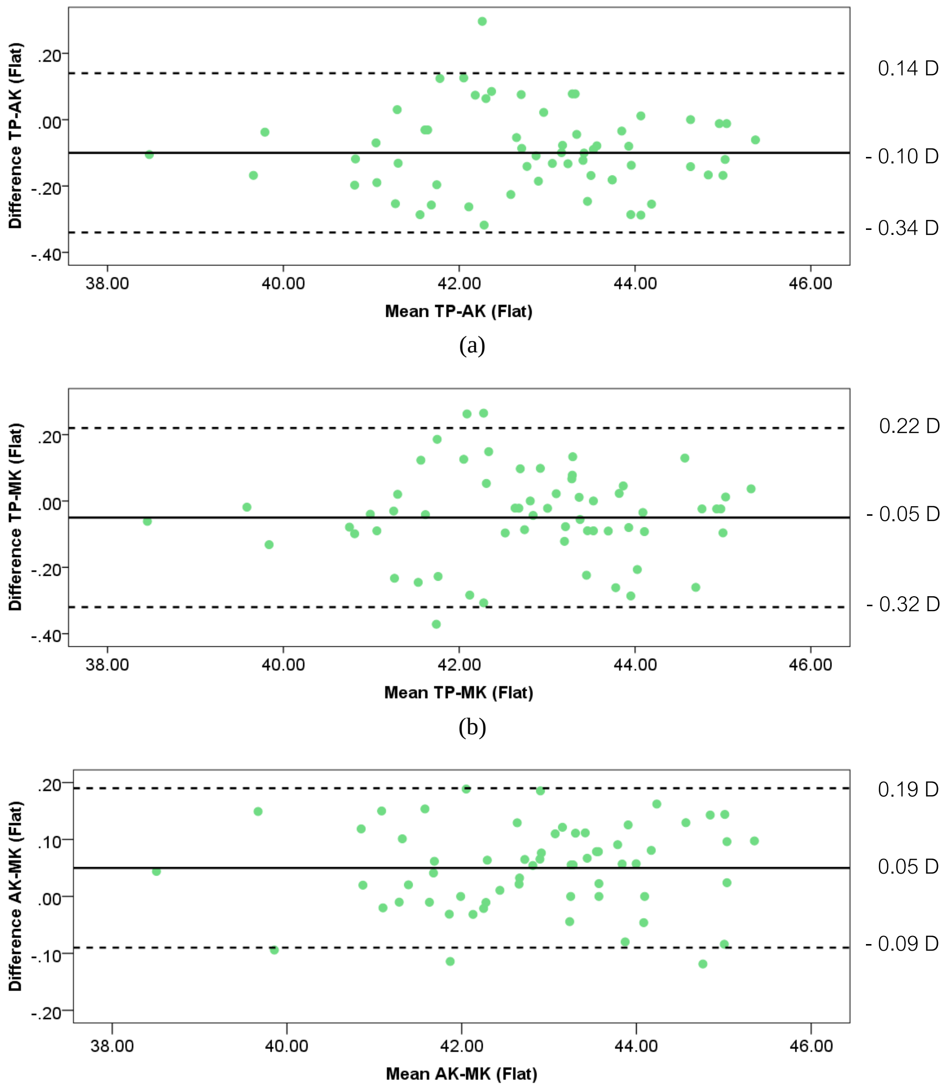
Table 4 Intraclass correlation coefficient (ICC) and 95% limits of agreement (95%LoA) between pairs of instrument for measuring corneal flat power (K_{flat}).

Pairs of instruments	ICC	Mean difference ± SD	95%LoA	*p*-value
TP-AK	0.997	-0.10±0.12 D	-0.34 D to 0.14 D	0.000*
TP-MK	0.997	-0.05±0.14 D	-0.32 D to 0.22 D	0.012*
AK-MK	0.999	0.05±0.07 D	-0.09 D to 0.19 D	0.000*

*Statistical significance when the *p*-value was < 0.05

4.2 Corneal flat power

Measuring the mean corneal flat power (K_{flat}) , the values were: 42.77±1.42 D for topographer (range 38.42-45.34 D), 42.86±1.43 D for auto kerato-refractometer (range 38.53 – 45.40 D) and 42.81±1.42 D for manual keratometer (range 38.48 – 45.30 D). Manual keratometer value was 0.05±0.07 D lower than auto kerato-refractometer (p = 0.000, ICC = 0.999), manual keratometer value was -0.05±0.14 D lower than topographer (p = 0.012, ICC = 0.997). The inter-instrument agreement between pairs of instruments was evaluated by ICC values as shown in Table 4. It is seen that the agreement between each pair was statistically significant (p-value < 0.05). As can be seen in Figure 4, the Bland-Altman plots present high concordance in all three pairs of instruments.



(c)

Figure 4 Bland-Altman plots comparing Manual keratometer (MK), Auto kerato-refractometer (AK), and Topographer (TP) for measuring corneal flat power (K_{flat}).

4.3 Corneal average power

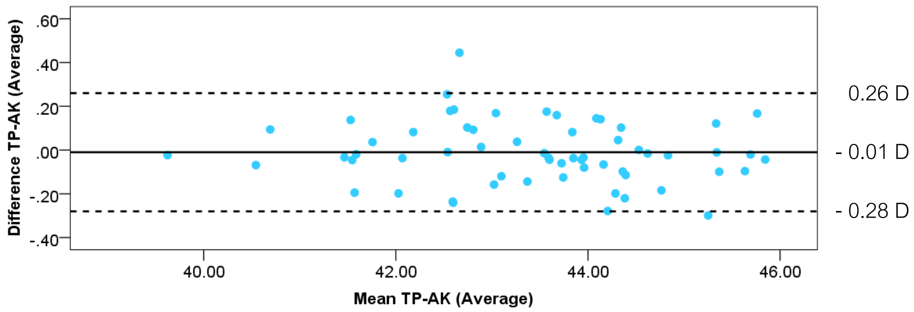
Measuring the mean corneal average power ($K_{average}$), the values were: 43.43±1.37 D for topographer (range 39.61-45.85 D), 43.44±1.39 D for auto kerato-refractometer (range 39.63-45.87 D) and 43.40±1.39 D for manual keratometer (range 39.64-45.85 D). Manual keratometer value was 0.04±0.06 D lower than auto kerato-refractometer (p = 0.000, ICC = 0.999), manual keratometer value was 0.02±0.14 D lower than topographer (p = 0.167, ICC = 0.997). The

ICC values between pairs of instruments are given in Table 5. The agreement between AK-MK pairs was statistically significant (p-value < 0.05). It can be interpreted that $K_{average}$ value between AK-MK pairs is different. Figure 5 shows the results obtained from the Bland-Altman analysis. The high concordance was found in all three pairs of instruments.

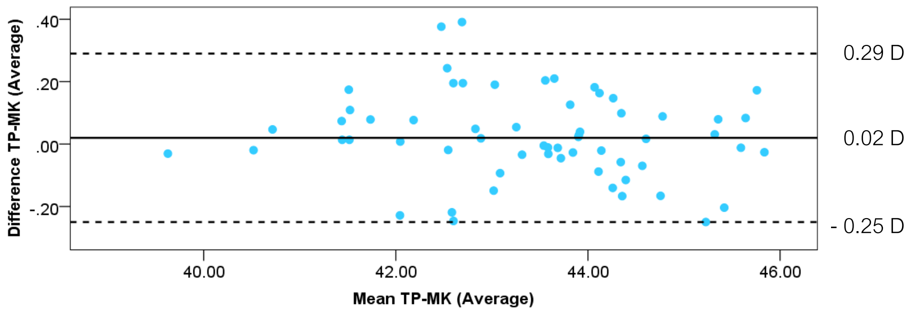
Table 5 Intraclass correlation coefficient (ICC) and 95% limits of agreement (95%LoA) between pairs of instruments for measuring corneal average power ($K_{average}$).

Pairs of instruments	ICC	Mean difference ± SD	95%LoA	*p*-value
TP-AK	0.997	-0.01±0.14 D	-0.28 D to 0.26 D	0.471
TP-MK	0.997	0.02±0.14 D	-0.25 D to 0.29 D	0.167
AK-MK	0.999	0.04±0.06 D	-0.08 D to 0.16 D	0.000*

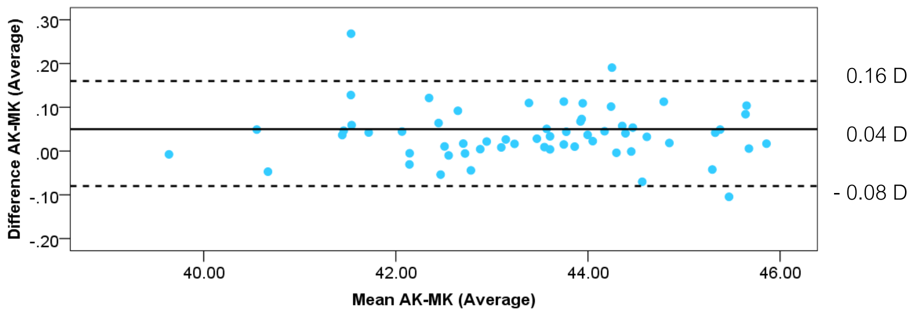
*Statistical significance when the p-value was < 0.05



(a)



(b)



(c)

Figure 5 Bland-Altman plots comparing Manual keratometer (MK), Auto kerato-refractometer (AK), and Topographer (TP) for measuring corneal average power ($K_{average}$).

5. Discussion

As the cornea is the major refractive element of the eye, the accurate measurements of corneal shape and refractive power are considerably indispensable to the design and ultimate success of vision corrective procedures, for instance, refractive and cataract surgeries (Dehnavi et al., 2015; Wang et al., 2014;

Shirayama et al., 2009; Karabatsas et al., 1998; Elbaz, Barkana, Gerber, Avni, & Zadok, 2007; Crawford, Patel, & McGhee, 2013; Huang et al., 2015a; Huang et al., 2015b; Razmju et al., 2011). Hence, the comparability of corneal powers obtained from the manual keratometer (ophthalmometer OM-4), auto kerato-refractometer (KR-8800), and topographer (oculus keratograph 5M) have been assessed as the main objective of this study. The results obtained from our research framework indicate that manual keratometer, auto kerato-refractometer, and topographer present the indifference of corneal power values even though each instrument was made by different technology. Thus, it is seen that the three instruments were in good agreement and interchangeability can be optionally allowed.

Particularly to this study, the measurement of these instruments were compared only in healthy eyes. It is still questionable whether these instruments provide the same results in abnormal eyes, for example, high corneal astigmatism, abnormal corneal surface, or post-refractive surgery corneas. Previous studies for comparison of keratometry and videokeratography after penetrating keratoplasty showed poor agreement between keratometer and videokeratoscope for irregular corneal surface measurements (Karabatsas et al., 1998). It was claimed that the two instruments cannot be used interchangeably in comparing the curvature of corneas after penetrating keratoplasty. Therefore, it is still interesting to further extend this study to cover the inter-instrument agreement in abnormal eyes.

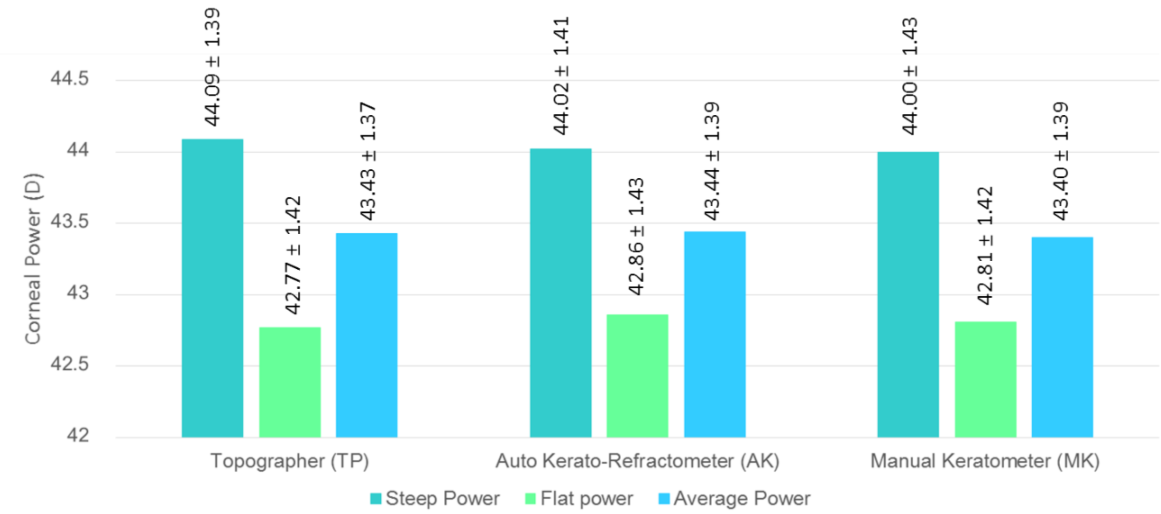


Figure 6 Comparison of corneal powers corresponding to topography, auto kerato-refractometer and manual keratometer.

6. Conclusion

The inter-instrument agreement of anterior corneal curvature measurements including auto kerato-refractometer, topographer and manual keratometer has been studied. Regarding the 61 subjects, intraclass correlation coefficient (ICC) and 95% limits of agreement (95%LoA) were evaluated and statistically examined by Bland-Altman plots, intraclass correlation coefficient and paired *t*-test analysis. Comparing the mean corneal powers including K_{flat}, K_{steep} and $K_{average}$ from the three different instruments as shown in Figure 6, it is found to be significantly indifferent. That is, the corneal power measurements from three different instruments have high concordance and good agreement for evaluating the corneal power in healthy eyes. However, the magnitude of the differences was 0.10 D or less. It is acceptable as the minimal clinical importance. One can conclude from these results that topographer, auto kerato-refractometer and manual keratometer are interchangeable in terms of corneal power measurements.

7. Acknowledgements

The authors would like to gratefully acknowledge the Optometry Clinic, Faculty of

Optometry, Rangsit University for the measuring instruments of corneal power and data collection in this study. Additionally, the authors would like to thank anonymous reviewers for the overall presentation of this manuscript.

8. References

Arce, C. G., Martiz, J., Alzamora, J. B., Schor, P., & Campos, M. S. Q. (2007). Sectorial and annular quantitative area pachymetry with the Orbscan II. *Journal of refract surgery*, *23*, 89-92.

Bland, J. M., & Altman, D. G. (1986). Statistical methods for assessing agreement between two methods of clinical measurement. *The Lancet*, *327*(8476), 307-310. DOI: 10.1016/S0140-6736(86)90837-8

Cantor, L. B., Rapuano, C. J., & Cioffi, G. A. (2017-2018). *Basic and clinical science course (BCSC), Section 8 external disease and cornea.* American Academy of Ophthalmology.

Chen, D., & Lam, A. K. (2009). Reliability and repeatability of the Pentacam on corneal curvatures. *Clinical & experimental optometry 92*(2): 110-118. DOI: 10.1111/j.1444-0938.2008.00336.x

Crawford, A. Z., Patel, D. V., & McGhee, C. N. (2013). Comparison and repeatability of keratometric and corneal power measurements obtained by Orbscan II, Pentacam, and Galilei corneal tomography systems. *American journal of ophthalmology*, *156*(1), 53-60. DOI: 10.1016/j.ajo.2013.01.029

Dehnavi, Z., Khabazkhoob, M., Mirzajani, A., Jabbarvand, M., Yekta, A., & Jafarzadehpur, E. (2015). Comparison of the corneal power measurements with the TMS4-Topographer, Pentacam HR, IOL Master, and Javal Keratometer. *Middle East African journal of ophthalmology*, *22*(2), 233-237. DOI: 10.4103/0974-9233.151884

Elbaz, U., Barkana, Y., Gerber, Y., Avni, I., & Zadok, D. (2007). Comparison of different techniques of anterior chamber depth and keratometric measurements. *American journal of ophthalmology*, *143*(1), 48-53. DOI: 10.1016/j.ajo.2006.08.031

Grosvenor, T. (2002). *Primary Care Optometry*. Oxford, UK: Butterworth-Heinemann.

Gutmark, R., & Guyton, D. L. (2010). Origins of the keratometer and its evolving role in ophthalmology. *Survey Ophthalmol*, *55*(5), 481-497. DOI: 10.1016/j.survophthal.2010.03.001.

Hidalgo, I., Rozema, J., Dhubhghaill, S., Zakaria, N., Koppen, C., & Tassignon, M. (2015). Repeatability and inter-device agreement for three different methods of keratometry: placido, scheimpflug, and color LED corneal topography. *Journal of refractive surgery (Thorofare, N.J.: 1995)*, *31*, 176-181. DOI: 10.3928/1081597X-20150224-01

Huang, J., Savini, G., Su, B., Zhu, R., Feng, Y., Lin, S., Chen, H., & Wang, Q. (2015a). Comparison of keratometry and white-to-white measurements obtained by Lenstar with those obtained by autokeratometry and corneal topography. *Contact lens and anterior eye*, *38*(5), 363-367. DOI: 10.1016/j.clae.2015.04.003

Huang, J., Savini, G., Chen, H., Bao, F., Li, Y., Chen, H., Lu, W., Yu, Y., & Wang, Q. (2015b). Precision and agreement of corneal power measurements obtained using a new corneal topographer OphthaTOP. *PLoS ONE 10(1): e109414.* DOI: 10.1371/journal.pone. 0109414

Horner, D. G., Salmon, T. O., & Soni, P. S. (2006). *Borish's Clinical Refraction*. Oxford, UK: Butterworth-Heinemann.

Karabatsas, C. H., Cook, S. D., Powell, K., & Sparrow, J. M. (1998). Comparison of keratometry and videokeratography after penetrating keratoplasty. *Journal of refractive surgery*, *14*(4), 420-426. DOI: 10.3928/1081-597X-19980701-08

Koo, T. K., & Li, M. Y. (2016). A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *Journal of chiropractic medicine*, *15*(2), 155-163. DOI: 10.1016/j.jcm.2016.02.012

Magar, J. (2013). Comparison of the corneal curvatures obtained from three different keratometers. *Nepalese Journal of*

Ophthalmology, *5*(1), 9-15. DOI: 10.3126/nepjoph.v5i1.7815

Md Muziman Syah, M. M., Mutalib, H. A. , Sharanjeet Kaur, M. S., & Khairidzan Khairidzan, M. K. (2020). A Comparative Study on the Inter-Session and InterExaminer Reliability of Corneal Power Measurement Using Various Keratometry Instruments. *IIUM Medical Journal Malaysia, 15(1). https://doi.org/10.31436/imjm.v15i1.409*

Mehravaran, S., Asgari, S., Bigdeli, S., Shahnazi, A., & Hashemi, H. (2014), Keratometry with five different techniques: a study of device repeatability and inter-device agreement. *International ophthalmology*, *34*, 869-875. DOI: 10.1007/s10792-013-9895-3

Razmju, H., Rezaei, L., Nasrollahi, K., Fesharaki, H., Attarzadeh, H., & Footami, F. J. (2011). IOLMaster versus manual keratometry after photorefractive keratectomy. *Journal of Ophthalmic and Vision Research*, *6*(3), 160-165.

Shirayama, M., Wang, L., Weikert, M. P., & Koch, D. D. (2009). Comparison of corneal powers obtained from 4 different devices. *American journal of ophthalmology*, *148*(4), 528-535.e1. DOI: 10.1016/j.ajo.2009.04.028

Wang, Q., Savini, G., Hoffer, K. J., Xu, Z., Feng, Y., Wen, D., Hua, Y., Yang, F., Pan, C., & Huang. J. (2012). A comprehensive assessment of the precision and agreement of anterior corneal power measurements obtained using 8 different devices. *PLoS ONE*, 7(9), e45607. DOI: 10.1371/journal.pone.0045607

Wang, X., Dong, J., & Wu, Q. (2014). Comparison of anterior corneal curvature measurements using a galilei dual scheimpflug analyzer and topcon auto kerato-refractometer. *Journal of Ophthalmology*, 2014: 140628. DOI: 10.1155/2014/140628

Weisenthal, R. W. (2015-2016). *Basic and clinical science course (BCSC), Section 8 external disease and cornea*. American Academy of Ophthalmology, 25-28.

Yu, J., Zhong, J., Mei, Z., Zhao, F., Tao, N., & Xiang, Y. (2017). Evaluation of biometry and corneal astigmatism in cataract surgery patients from Central China. *BMC Ophthalmology*, *17*(56), (2017). DOI: 10.1186/s12886-017-0450-2