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Research Article

Journal of Optometry and Ophthalmology Research

Inter-Device Agreement of Keratometric and Astigmatic Measurements Between Manual and Modern Keratometers pre-FLACS

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Received: March 30, 2026; **Accepted:** April 16, 2026; **Published:** April 27, 2026

ABSTRACT

Purpose: To compare the mean keratometry (K) readings and corneal astigmatism obtained from gold standard Manual keratometer with Automated keratometer, ORBSCAN II and IOLMaster 500 in patients undergoing Femto-second Laser Assisted Cataract Surgery (FLACS).

Methods: This prospective, non-randomized, comparative clinical study was done in 70 patients. A total of 120 eyes were included, each of which underwent keratometry with four different types of keratometers. Mean K values and corneal astigmatism were obtained from each machine and compared. Bland-Altman plots were used to determine the 95% limits of agreement (LoA) between different devices.

Results: The Average K value from manual keratometer was 43.695±1.884(SD). Mean K from Auto-K was 43.686±1.917, ORBSCAN II was 43.748±1.865 and IOLMaster 500 was 43.685±1.875. Thus, keratometric values from all three newer devices correlated significantly ($p \leq 0.01$) with the gold standard manual keratometer. In addition, the magnitude of corneal astigmatism measured by all three devices correlated significantly ($p \leq 0.01$) with the gold standard manual keratometer.

Conclusion: The newer keratometers including Automated Keratometer, ORBSCAN II and IOLMaster 500 were found to be comparable to the gold standard Manual Keratometer. The keratometric readings and corneal astigmatism from each of the newer keratometers showed high degree of correlation with that of manual keratometer.

Keywords: Keratometry, Inter-device correlation, Corneal Astigmatism, Keratometers, Manual keratometer

Introduction

In the modern era of cataract surgery, it is essential to accurately and reliably measure pre-operative corneal curvature for exact intraocular lens (IOL) power calculation and eliminate post-operative astigmatism and higher-order aberrations. Keratometer is an instrument which measures the curvature of anterior surface of cornea by assessing the magnitude and axis of corneal astigmatism [1,2]. Over the years, this instrument has evolved with several modifications and improvements in its design and working principle. Keeping in line with digitalization of various objective clinical measurements, a variety of auto-keratometers have been introduced which are rapidly gaining widespread popularity amongst clinicians and vision scientists [3].

Various keratometers that are commercially available for clinical use include Manual Keratometer (Bausch & Lomb, Javel-Schiotz Keratometer), automated (autokeratorefractors, IOLMaster) and devices for simulated keratometry (corneal topographers like ORBSCAN, Pentacam). These instruments differ from each owing to differences in their working principle [3]. Manual keratometer is the gold standard [4], to which newer automated keratometers and corneal topographers are compared [5-7].

Keratometry is paramount in estimation of corneal power and astigmatism in refractive surgeries, cataract surgeries and contact

Citation: Kritika Chopra Kumar, Swati Tyagi, Surbhi Aggarwal. Inter-Device Agreement of Keratometric and Astigmatic Measurements Between Manual and Modern Keratometers pre-FLACS. J Opto Opht Res. 2026. 2(2): 1-6. DOI: doi.org/10.61440/JOOR.2026.v2.09

lens fitting. Pre-existing astigmatism has been identified as an important factor which compromises the refractive outcome after cataract surgery and much importance is being given to its accurate measurement and correction [8]. Therefore, correction of pre-existing astigmatism has become an integral aspect of cataract surgery. During cataract surgery, corneal astigmatism can be corrected by toric IOL implantation, limbal relaxing incisions (LRIs) or their combination [9,10].

Keratometric estimation is even more relevant in latest techniques of cataract surgery such as Femtosecond laser-assisted cataract surgery (FLACS). This minimally invasive technique of cataract surgery is highly precise and safe, with more predictable outcomes [11]. Since nearly 40% of patients have significant pre-existing astigmatic error, a precise determination and understanding of measurement of corneal curvature prior to surgery becomes imperative, especially in patients undergoing laser assisted cataract surgery [12].

In this study, we sought to investigate whether the three newer types of keratometers, namely Automated Keratometer (TOPCON KR-1, Japan), ORBSCAN II (Bausch and Lomb Inc,, USA) and IOLMaster 500 (Carl Ziess Meditec, Germany) produce clinically interchangeable measurements of keratometric readings and the pre-operative corneal astigmatism, as measured by the gold standard Manual Keratometer (Bausch and Lomb Inc, Rochester, New York, USA) amongst patients undergoing the highly precise FLACS.

Patients and Methods

This study was a prospective, non-randomized, comparative clinical study done from May 2024 to April 2025 at a tertiary eye hospital in India, after obtaining requisite clearance from the ethical committee. The instruments used included Manual Keratometer (Bausch and Lomb Inc., Rochester, New York, USA), Automated Keratometer (TOPCON KR-1, Japan), ORBSCAN II (Bausch and Lomb, USA) and IOLMaster 500 (Carl Ziess Meditec, Germany).

This study included 120 eyes of 70 patients, aged 50 to 70 years and scheduled to undergo Femtosecond Laser Assisted Cataract Surgery (FLACS). Sample size calculation was performed using alpha error of 0.01 and power of 98%. Mean difference of 0.25 D was considered clinically relevant which resulted in minimum calculated sample size of 120. Patients with pre-operative corneal astigmatism of 0.5D or more were selected. Patients with glaucoma, corneal disorders, previous refractive surgery, dry eye disease, conjunctival disorder or ocular trauma were excluded from the study. This study was conducted in accordance with the tenets of declaration of Helsinki.

Ocular parameters including K1(D) and its axis, K2(D) and its axis, Mean or Average keratometric reading (D) and corneal astigmatism (D) were recorded separately from each instrument. A standard keratometric refractive index of 1.3375 was used [5,13]. A single examiner performed three sets of measurements with each of the four devices.

A calibrated manual keratometer was realigned before every measurement. The patient was positioned comfortably and appropriately in front of each keratometer and asked to focus at the fixating target. Testing was performed prior to installation of any topical eye medication. The patient was instructed to blink completely just before taking the reading. Lights were dimmed for easy visibility of the mires [14].

For each eye examined, three pairs of keratometric readings K1 (D) and K2 (D) along the principal meridian were taken. Each pair of keratometric readings was averaged to obtain Mean K or Average K value (D). The three values thus obtained were further averaged to obtain Net Average K (D) for each eye. The difference of corneal power provided a measure of corneal astigmatism (D) and the axis of steeper meridian was taken as the axis of astigmatism (in degrees). The net or average corneal astigmatism value was calculated using the aggregate analysis, as described by Holladay and associates [15].

Similarly, for each eye examined, the keratometric readings were obtained from the other three keratometers namely Automated Keratometer, ORBSCAN II and IOLMaster 500 for comparison and analysis. Each pair of keratometric readings, from each of the devices, was averaged to obtain Mean K or Average K value (D) [5,16,17]. The three values thus obtained were further averaged to obtain Net Average K (D) for each eye. The difference of the corneal power gave the measure of corneal astigmatism (D) and axis of the steeper meridian was taken as the axis (in degrees) of astigmatism. For each eye, the Net or Average Corneal Astigmatism value were calculated using the aggregate analysis of astigmatism as described by Holladay and associates [15]. The Net Average of the three readings of corneal curvature and astigmatism were used for comparison and statistical analysis. Notably, ORBSCAN II algorithm generated simulated keratometric readings (SimK) (D), Kmin and Kmax.

Data Management and Statistical Analysis

SPSS version 29.0 (SPSS Inc., Chicago, Illinois, USA) was the statistical software used for analysis of the data. Microsoft Excel and Word (Microsoft, Redmond, Washington, USA) was used to generate graphs and tables.

Descriptive and inferential statistical analysis was carried out in this study. Results of continuous measurements are presented as Mean $\pm$ SD (Min-Max) and results of categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. Standard deviation and Coefficient of Variation were used to assess variability among parameters obtained from each device. Intraclass Correlation Coefficient has been used to assess the agreement among devices [18]. One-way ANOVA (with Tukey's post hoc analysis) and Pearson Correlation Coefficient were used to assess agreement between devices. The pairwise correlation between devices was represented in the form of Bland- Altman plots.

Results

Demographically, the mean age of study subjects was 63.84 ± 5.5 years (SD; Range: 50- 70 years). Of these, 34 (48.57%) were females and 36 were (51.42%) males. Both eyes of 50 patients and one eye of 20 patients were included, out of which 10 were right and 10 were left eye.

To determine the repeatability of keratometric value within each device, coefficient of variation (COV), standard deviation (SD)

and Intraclass Correlation Coefficient (ICC) were calculated for the three repeated measurements of Average Keratometric readings [(K1+K2)/2]. The ICC among the repeated keratometric measurements was higher than 0.937 in all the devices and was strongly significant (P value: p ≤0.01) indicating high level of comparability. The COV of keratometric measurements was higher than 4.22% in all the devices. All SD values were higher than 1.844D. Each of the devices tend to provide higher COV and SD, indicating a high relative intra-device variability of the overall range of keratometric values.

Table 1: Repeatability of Net Average Keratometric Reading with four Different Keratometers

Parameter	Manual Keratometer	Auto - K	ORBSCAN II	IOLMaster 500
Coefficient of variation (COV) %	4.22	4.39	4.26	4.29
Standard Deviation (SD)	1.844	1.917	1.865	1.875
Intraclass Correlation Coefficient (ICC)	0.952**	0.947**	0.937**	0.939**

Table 2: Net Average Keratomteric values obtained from four devices

Device		Manual Keratometer	Auto - K	ORBSCAN II	IOLMaster 500
Net average K (D)		43.695	43.686	43.748	43.685
Standard Deviation (D)		±1.844	±1.917	±1.865	±1.875
Standard error		0.1683	0.1750	0.1703	0.1711
95% Confidence Interval for Net	Lower bound	43.361	43.340	43.411	43.346
	Upper bound	44.028	44.033	44.085	44.024
Minimum Value (D)		40.6	40.5	40.5	40.5
Maximum Value (D)		47.1	47.1	47.2	47

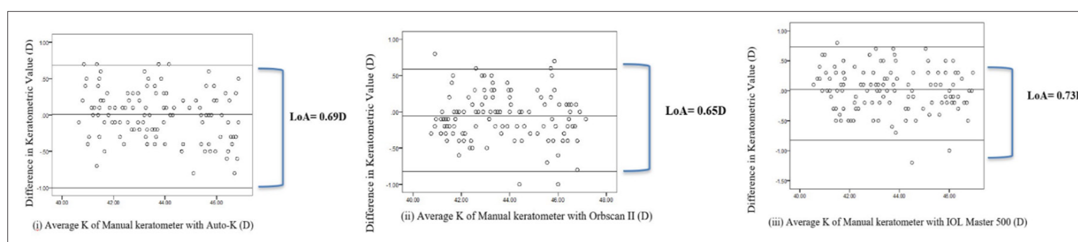
Table 2 shows the average keratometric value from manual keratometer was 43.695±1.884, Auto-K was 43.686±1.917, ORBSCAN II was 43.748±1.865 and IOLMaster 500 was 43.685±1.875. The highest mean difference was only 0.054 D, which was between the ORBSCAN II and manual keratometer.

Table 3: Mean Corneal Astigmatism obtained from four devices.

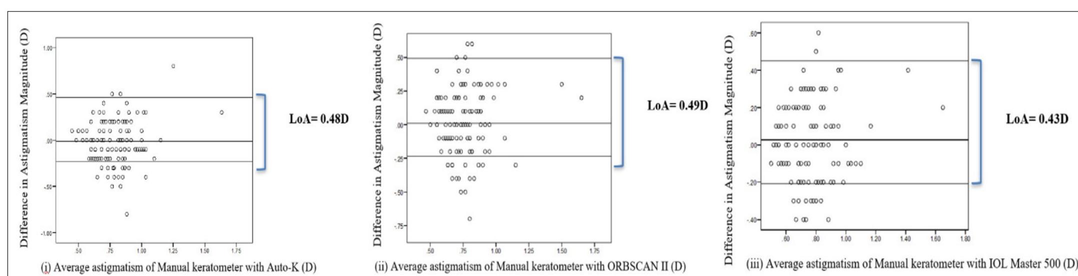
Device		Manual Keratometer	Auto - K	ORBSCAN II	IOLMaster 500
Mean Corneal astigmatism (D)		0.77	0.78	0.76	0.75
Mean Axis (degrees)		1170	880	970	960
Standard Deviation (D)		0.21	0.19	0.19	0.19
Standard error (D)		0.019	0.018	0.017	0.017
95 % Confidence Interval for Mean Corneal	Lower bound	0.730	0.748	0.722	0.712
	Upper bound	0.808	0.820	0.793	0.781
Minimum Value (D)		0.5	0.4	0.4	0.5
Maximum Value (D)		1.8	1.5	1.5	1.5

Table 3 shows the mean values for corneal astigmatism were 0.77D at 117 degrees, 0.78D at 88 degrees, 0.76D at 97 degrees and 0.75D at 96 degrees for Manual K, Auto- K, ORBSCAN II and IOLMaster 500 respectively. The differences in mean astigmatism values between devices were within 0.03D. The Auto K tended to give highest values for astigmatism (0.78D at 88 degrees).

The corneal astigmatism (magnitude) for all three devices correlated significantly (p ≤0.01) with the gold standard Manual



Graph 1: Bland-Altman plots showing differences in keratometric measurements between Manual Keratometer with 1(i) Auto-K; 1(ii) ORBSCAN II; 1(iii) IOLMaster 500 (range of 95% LoA)



Graph 2: Bland-Altman plots showing differences in corneal astigmatism (magnitude) between Manual Keratometer with 2(i) Auto-K; 2(ii) ORBSCAN II; 2(iii) IOLMaster 500 (range of 95% LoA)

K. Agreement between the corneal astigmatism of manual keratometer and other three devices is depicted in the form of Bland-Altman analysis, as shown in Figure 2.

Discussion

The repeatability of keratometric readings obtained from each of the four devices was evaluated by means of coefficient of variation (COV), standard deviation (SD) and Intraclass Correlation Coefficient (ICC). The Bland and Altman method was performed to assess agreement in measurements between devices.

In this study, COV% of Net keratometric values were 4.22, 4.39, 4.26, 4.29 for Manual Keratometer, Auto-K, ORBSCAN II and IOLMaster 500 respectively. Standard deviation (D) was found to be 1.844, 1.917, 1.865 and 1.875 for Manual K, Auto-K, ORBSCAN II and IOLMaster 500 respectively. Higher values of COV and SD indicate high relative intra-device variability of the overall range of keratometric values and hence were not clinically significant.

Intraclass Correlation Coefficients (ICC), indicating the consistency of multiple measurements of the same data set, were 0.952, 0.947, 0.939, and 0.937 for Manual K, Auto-K, ORBSCAN II and IOLMaster 500 respectively. All the values were found to be strongly significant (P value: $p \leq 0.01$) suggesting that all four devices give highly consistent ie. comparable values of keratometric power.

In a similar comparative study by Nakada et al the keratometric measurements by manual keratometer were compared with automated keratometer in 20 eyes. The observed correlation coefficient was as high as 0.94 between the keratometric values of the two instruments. Coefficient of variation was less than 0.10% [7].

Shirayama et al assessed the repeatability and comparability of keratometric values obtained from Galilei Dual Scheimpflug Analyzer (Ziemer, Port, Switzerland), Humphrey Atlas corneal topographer (Carl Zeiss, Jena, Germany), IOLMaster (Carl Zeiss) and manual keratometer (Bausch & Lomb Inc, Rochester, New York, USA) in 20 eyes. For each device, COV of repeated measurements was lower than 0.22%. SD of three repeated measurements ranged from 0.042 to 0.096 D and ICC was higher than 0.99 in all devices. Thus, it was concluded that corneal power measurements from these four devices were highly reproducible, comparable and correlated [19].

A comparative study done by Koch et al. to assess the accuracy and reproducibility of manual keratometer and EyeSys Corneal Analysis System Model I revealed that the accuracy of the latter approaches keratometer reproducibility in measuring the central 3-mm zone of cornea [20]. The standard deviations of intra-observer and overall reproducibility for dioptric measurements were 0.07D and 0.14D for keratometer and 0.13D and 0.19D for EyeSys in 20 eyes.

The reason for higher values of SD and COV in our study could be due to the higher sample size of 120 eyes, which led to higher degree of variation among the keratometric values measured.

Table 4: Previous studies evaluating repeatability and comparability among different devices

Device used and Study	Sample size	Number of measurements	Variables		
			ICC	COV (%)	Standard Deviation (D)
MANUAL KERATOMETER					
Koch et al [20]	20	3	N/A	N/A	0.07
Current study	120	3	0.952	4.22	1.84
AUTO-K					
Nakada S et al [7]	20	10	0.94	0.1	N/A
Current study	120	3	0.947	4.39	1.917
ORBSCAN II					
Kawamorita et al [21]	17	2	0.99	N/A	N/A
Current study	120	3	0.939	4.26	1.865
IOLMASTER					
Vogel et al [22]	10	20	N/A	0.17	0.073
Current Study	120	3	0.937	4.29	1.875

Comparison of Keratometric power of different keratometers with Manual Keratometer

In our study, the Average keratometric value from Manual keratometer was 43.695±1.884 (SD), Auto-K was 43.686±1.917, ORBSCAN II was 43.748±1.865 and IOLMaster 500 was 43.685±1.875.

Pearson coefficient was 0.981 for Auto-K and manual keratometer, 0.981 for ORBSCAN II and manual keratometer and 0.984 for IOLMaster 500 and manual keratometer. It indicates that the keratometric values of all three devices correlated significantly ($p \leq 0.01$) with the gold standard Manual keratometer. The range of 95% LoA was found to be less than 0.73D in the three pairs of devices.

Dehnavi et al. compared corneal curvature and power measured by Manual keratometry (Javal Schiotz type; Haag-Streit AG, Switzerland), automated keratometry (IOLMaster version 3.02, Carl Zeiss Meditec, Germany), topography (TMS4, Tomey, Germany) and Pentacam HR (Oculus, Wetzlar, Germany) [23]. They concluded that correlation of Pentacam, TMS4 topography, IOLMaster and manual keratometer in measuring keratometry was high and the IOLMaster had best agreement with manual keratometer.

A similar study done by Tennen et al. compared the accuracy of keratometry readings from a corneal topography system (Corneal Analysis System) to manual (Javal-Schiotz) keratometer [6]. No statistically significant difference in the reliability of keratometric readings between the two was found. Shirayama et al have shown that corneal power measurements from the Galilei, Atlas, IOLMaster and manual keratometer were highly reproducible, comparable, and correlated [19].

However, in a similar study conducted by Whang et al wherein keratometric values of manual keratometer (Topcon), an automated keratometer (Canon), ORBSCAN II (Bausch & Lomb), IOLMaster (Carl-Zeiss) and Pentacam (Oculus) were compared and analyzed [24]. They concluded that ORBSCAN

II showed statistically significant difference with other devices. Thus, keratometric values from standard devices are suitable for pre-operative IOL power calculation, whereas corneal topography is not accurate in pre-operative IOL power calculation.

In another study conducted by Magar, the average keratometry values obtained from different instruments, namely IOLMaster (Carl Zeiss), Manual keratometer (Bausch and Lomb) and Topcon Autokeratometer varied significantly [3]. IOLMaster consistently over-estimated the corneal power compared to manual and autokeratometer. All three instruments provided similar estimation of corneal astigmatism. Savini et al concluded that simulated keratometry values determined from videokeratography significantly correlated with measurements obtained from manual conventional keratometry [25].

Thus, the results of our study were found to be consistent with few of the previously conducted studies, while some studies have shown variable correlation between devices. Such differences in the results among studies can be explained by the fact that various devices are based on different principles. The inclusion criteria and sample sizes are variable, in addition to difference in experience of examiner in operating the devices.

Comparison of Corneal astigmatism of different keratometers with Manual Keratometer

In our study, the mean values for corneal astigmatism were 0.77 D at 117 degrees, 0.78 D at 88 degrees, 0.76 D at 97 degrees, and 0.75 D at 96 degrees for Manual Keratometer, Auto-K, ORBSCAN II and IOLMaster 500 respectively. The difference in mean astigmatism values between devices were within 0.03 D. The Auto K tended to give highest values for astigmatism (0.78 D at 88 degrees).

The magnitude of corneal astigmatism for all the three devices correlated significantly ($p \leq 0.01$) with the gold standard Manual keratometer. Pearson coefficients were higher than 0.381 between the devices. The range of 95% LoA was found to be less than 0.43D in the three pairs of devices. The axes of corneal astigmatism were found to be comparable but not clinically significant, between three pairs of devices. This could be attributed to the fact that different devices are based on different principles and measure different corneal zones. Additionally, the head posture of the subject may have varied while recording keratometric values and axis with different devices.

Magar showed that the mean differences in astigmatism were 0.02±0.11 for IOL Master and Manual K, 0.02±0.09 for IOLMaster and Auto-K and -0.01 ± 0.11 for Manual K and Auto-K[3]. The study concluded that all three instruments provided similar estimation of the corneal astigmatism.

Visser et al compared six different devices including IOLMaster (automated keratometry), Lenstar (automated keratometry), SMI Reference Unit 3 (automated keratometry), Javal (manual keratometry), KR-1W (corneal topography) and Pentacam (Scheimpflug imaging). They concluded that corneal astigmatism measurements using automated, manual, and simulated keratometry were comparable. The repeatability of astigmatism magnitudes was acceptable, but the repeatability of astigmatism meridians was moderate [26].

In conclusion, our results were comparable to most studies published on agreement of keratometric values and corneal astigmatism between devices.

Limitations of our study

Our study included eyes with regular and low (0.5D or more) corneal astigmatism and only healthy corneas were studied. However, comparison of these devices should be extrapolated to corneas with high corneal cylinder, ectatic corneas or post refractive surgery corneas, to extrapolate its role in contact lens fitting.

ORBSCAN II assesses simulated keratometry over the entire corneal surface, whereas other keratometers measure the central 3mm zone. Hence, ideally keratometry and astigmatism of the central 3mm zone should have been assessed by ORBSCAN II in the present study.

Conclusion

This study establishes a high level of concordance between contemporary keratometers, Automated Keratometer (TOPCON KR-1, Japan), ORBSCAN II (Bausch and Lomb, USA) and IOLMaster 500 (Carl Ziess Meditec, Germany) with the gold standard Manual Keratometer (Bausch and Lomb, USA). This confirms their reliability for clinical use. The close correlation in keratometric and astigmatic values, combined with strong intra-device repeatability, underscores the accuracy and consistency of these automated systems. Their ability to deliver precise, reproducible measurements supports their integration into preoperative assessment for modern cataract surgery, providing exacting refractive outcomes.

Beyond their technical equivalence, these instruments contribute to greater clinical efficiency by minimizing examiner dependence and enhancing workflow standardization. Their validated performance enables surgeons to make confident, data-driven decisions for astigmatism correction and IOL power selection, thereby improving postoperative predictability and patient satisfaction.

From a broader perspective, these findings advocate for adoption of advanced keratometry technologies across varied levels of eye care delivery. Incorporating such reliable diagnostic tools can promote uniform standards of care and support global initiatives aimed at reducing cataract-related visual impairment. Future research correlating these measurements with actual surgical and refractive outcomes will further refine their application in optimizing astigmatic management and advancing precision cataract surgery.

Footnotes

Acknowledgements section: not applicable

Author contributions: This study is the brain child of KCK. She played a pivotal role in formulating the study criteria, conducting the study and drafting the initial manuscript. ST contributed to conducting the study and processing and reviewing all the data collected. She critically evaluated and refined the manuscript to its present form. SA was the backbone of the study and conducted the clinical research and tabulated and rectified the data of all participants included. She also reviewed the manuscript. KCK and SA have approved the submitted version and have agreed

to be both personally accountable for their individual, as well as group contribution. All of us ensure that questions related to the accuracy or integrity of any part of the work has been appropriately investigated and resolved.

Statements & Declarations:

Ethical considerations: requisite approval from the institutional ethics review committee was taken prior to conducting this clinical study.

Consent to participate: A prior written approval consenting the willingness to participate was taken from all the patients included in this study.

Consent for publication: informed consent for clinical and ocular biometric data use was obtained from all participants prior to drafting this manuscript.

Declaration of conflicting interest: The authors declared no potential conflict of interest with respect to the research, authorship and publication of this article.

Funding statement: this study received no financial assistance.

Data availability statement: not applicable

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