Comparison of Corneal Keratometry Measured by Three Different Methods

Farklı Üç Yöntemle Ölçülen Korneal Keratometrik Verilerin Karşılaştırılması

Konuralp YAKAR[1], Göksu ALAÇAMLI[2]

[1]Atılım University, Medicine Faculty, Department of Ophthalmology, Ankara
[2]Muğla Sıtkı Koçman University, Medicine Faculty, Department of Ophthalmology, Muğla

Öz

Kısmi koherens interferometri reflektometri optik biyometri (Nidek AL Scan, 2.4-3.3 mm zonlar, Nidek Teknoloji, Gamagori, Japonya), korneal aberrometre/topograf (Nidek OPD Scan II, Nidek Teknoloji, Gamagori, Japonya) ve standart otorefraktokeratometre (Topcon KR 8900, Topcon, Tokyo, Japonya) cihazları kullanılarak elde edilen korneal keratometri ölçümleri (en düz-en dik keratometri, ortalama keratometri ve korneal astigmatizma) arasındaki değiştirilebilirliği ve uyumu test etmek için yapılan bu prospektif karşılaştırmalı çalışmaya yaş ortalaması 24.37±3.91 yıl olan 360 sağlıklı gönüllünün 360 sağ gözü dahil edildi. İkili karşılaştırmaları değerlendirmek için eşleştirilmiş t-testi kullanıldı. Üç cihaz arasındaki uyumu değerlendirmek için %95 uyum sınırları ile Bland-Altman testi kullanıldı. Nidek AL Scan'in 2.4 ve 3.3 mm bölgelerinde elde edilen tüm keratometrik değerleri arasında istatistiksel olarak anlamlı bir fark yoktu (p>0.05). Nidek AL Scan (2.4 -3.3 mm bölgesi) ve Nidek OPD Scan II in ikili karşılaştırmaları arasında AstK değerleri açısından istatistiksel olarak anlamlı bir fark saptanmadı (p>0.05). Nidek OPD Scan II ve Topcon KR 8900 ile ölçülen K1, K2 ve ortalama K değerleri Nidek AL Scan (2.4 -3.3 mm bölge) ile ikili karşılaştırıldığında, istatistiksel olarak anlamlı bir fark olduğu görüldü (p<0.05). AstK değerleri de Topcon KR 8900 ile Nidek AL Scan (2.4 -3.3 mm zonlar) ve Nidek OPD Scan II arasında istatistiksel olarak farklıydı (p<0.05). Sadece Nidek AL Scan, kendi içinde 2.4 ve 3.3 mm korneal zonlarda elde edilen tüm keratometrik parametreler için karşılaştırılabilir ölçümler sağlamıştır. Her bir cihazlar arası uyum için elde edilen %95 uyum sınırlarının geniş olması (>1.0 D) bu üç cihazın birbirinin yerine kullanılamayacağını düşündürmektedir.

Anahtar Kelimeler: AL Scan, Biyometri, Keratometri, OPD Scan, Topcon Otorefraktometre

Abstract

To compare and evaluate the interchangeability and agreement between corneal keratometry measurements (flattest-steepest keratometry, mean keratometry and corneal astigmatism) using partial coherence interferometry reflectometry optical biometry (Nidek AL Scan, 2.4–3.3 mm zones, Nidek Technologies, Gamagori, Japan), corneal aberrometer/topographer (Nidek OPD Scan II, Nidek Technologies, Gamagori, Japan) and standard autorefractokeratometer (Topcon KR 8900, Topcon Inc., Tokyo, Japan) a total of 360 right eyes of 360 healthy volunteers with a mean age of 24.37±3.91 years were enrolled in this prospective comparative study. Paired t-tests were used to evaluate pairwise comparisons. The Bland–Altman test with 95% limits of agreement was used to evaluate the agreement between the three devices. There were no statistically significant differences between all keratometric values of the Nidek AL Scan obtained in the 2.4 and 3.3 mm zones (p>0.05). There were no statistically significant differences in AstK values between the Nidek AL Scan (2.4 -3.3 mm zone) and the Nidek OPD Scan II pairwise comparisons (p>0.05). When the K1, K2, and Kmean values measured with the Nidek OPD Scan II and Topcon KR 8900 were compared with the Nidek AL Scan (2.4 -3.3 mm zone), a statistically significant difference was found (p<0.05). AstK values were also statistically different between Topcon KR 8900 versus Nidek AL Scan (2.4 -3.3 mm zone) and Nidek OPD Scan II (p<0.05). Only the Nidek AL Scan provided comparable measurements for all keratometric parameters analyzed in the 2.4 and 3.3 mm zones. The LoA obtained for each inter-device agreement should be analyzed carefully to consider the interchangeability of these three devices.

Keywords: AL Scan, Biometry, Keratometry, OPD Scan, Topcon Autorefractokeratometre

Introduction

The cornea accounts for approximately two-thirds of the total refractive capacity of the optical system in the eye (1). Measuring the refractive capacity and curvature of the cornea is known as keratometry (2). The most accurate and precise measurement of keratometry is vital for calculating the power of the intraocular lens to be used in modern cataract surgery, refractive surgery, contact lens applications, diagnosis, and follow-up of ectatic diseases, such as keratoconus (3-6). Abnormal values of corneal keratometry can result in serious ametropia and amblyopia at a tender age. Moreover, it is crucial to consider the difference between keratometry values in the principal meridians when determining corneal astigmatism. Hence, accurately measuring keratometry is essential to comprehend the state of refractive errors (7,8).

The gold standard method for keratometry measurement is manual keratometry; Helmholtz and Javal keratometry (9). Since this method is practitioner dependent and time consuming, it has been replaced by computerized automated systems (10). Currently, corneal topography/tomography devices, optical biometry devices, optical coherent tomography devices and standard autorefractokeratometers are the most preferred devices for keratometric measurements worldwide. The different optical and technical principles of each

	ORCID No
Konuralp YAKAR	0000-0002-3839-5699
Göksu ALAÇAMLI	0000-0001-5013-9981

Adres / Correspondence : Konuralp YAKAR
Atılım University, Medicine Faculty, Department of Ophthalmology, Ankara
e-posta / e-mail : alpyakar@yahoo.com

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of these devices have led to frequent testing of their reliability and interchangeability (11-15).

The aim of this study is to compare the corneal keratometric data obtained from Nidek AL Scan optical biometry (Nidek Technologies, Gamagori, Japan), Nidek OPD Scan II aberrometer/topographer (Nidek Technologies, Gamagori, Japan) and Topcon KR 8900 autorefractokeratometer (Topcon Inc., Tokyo, Japan) devices which are frequently used in daily clinical practice and to determine whether the keratometric data of these devices can be used interchangeably.

Material and Method

This prospective comparative study included keratometric data from the right eyes of 360 participants (180 females, 180 males) aged 20-30 years who were recruited for a routine ophthalmologic examination at our clinic between January 2024 and May 2024. The study was granted approval by the Samsun Ondokuz Mayıs University ethics committee (Date: 14/12/2023, Decision no: 2023/401) and was executed in compliance with the principles outlined in the Declaration of Helsinki. All participants underwent a comprehensive ophthalmologic examination, including refraction and biomicroscopy, fundoscopy, and intraocular pressure measurements. Patients who had undergone any previous ocular surgery (cataract, refractive, pterygium, glaucoma, vitrectomy, etc.), had any corneal pathology, active ocular surface infection, nystagmus or albinism, or were unable to cooperate with any of the devices were excluded. Patients who had worn contact lenses within 24 h prior to the examination were also excluded. All participants provided informed consent to participate in this study.

Prior to the ophthalmologic examination, the same technician utilized Nidek AL Scan optical biometry (Nidek Technologies, Gamagori, Japan), Nidek OPD Scan II aberrometer/topographer (Nidek Technologies, Gamagori, Japan), and a Topcon KR 8900 standard autorefractokeratometer (Topcon Inc., Tokyo, Japan) to measure keratometric data. The results obtained from each device (including the flattest-K1 and steepest-K2 keratometry, mean keratometry, and corneal astigmatism) were subsequently compared. The Nidek AL Scan device was utilized to obtain data in two distinct corneal zones, measuring 2.4 mm and 3.3 mm. The data obtained from the two zones of the Nidek AL Scan device were compared with each other and with the data from other devices separately. The study aimed to determine whether the corneal keratometric data from the devices were interchangeable and whether they were compatible with one another.

The following formulas were used to calculate mean corneal keratometric value (Kmean) and corneal astigmatism (AstK).

Mean corneal keratometric value (Kmean) = (K1+K2)/2

Corneal astigmatism (AstK) = K2-K1

Devices

Nidek AL Scan

Nidek AL Scan (Nidek Technologies, Gamagori, Japan) is an optical biometer that measures the axial length without contact with the eye using partial coherence interferometry (830 nm). It projects a double ring with diameters of 2.4 and 3.3 mm on the cornea and calculates corneal keratometry using images obtained from 360 points in each ring. The device also measures anterior chamber depth, central corneal thickness, pupil diameter and corneal white-to-white distance, and provides data on the anterior segment and axial length of the eye in six different parameters within 10 seconds. Using these data it calculates the power of the intraocular lens to be used in cataract surgery.

The Nidek OPD- Scan II

The Nidek OPD-Scan II (Nidek Technologies, Gamagori, Japan) combines a wavefront aberrometer, Placido disc topographer, autorefractometer, and pupillometer into a single unit manufactured by Nidek Technologies in Gamagori, Japan. This device is capable of measuring wavefront errors through dynamic skiascopy, which involves sending 1.440 individual beams of light through the pupil and on to the retina. The time it takes for the beams to return to the instrument's sensors, with a resolution of 0.4 seconds or less, is analysed to determine the wavefront errors of the visual system, including lower-order aberrations such as sphere and astigmatism, which are measured in a 2.6-mm zone in the pupil, similar to a traditional autorefractor. Additionally, the OPD-Scan II measures the low-order wavefront error across a 4-6 mm zone in the pupil and calculates the spherical, cylindrical, and axes values using Zernike vector analysis. The root-mean-square wavefront error is then calculated.

Topcon KR 8900 Autorefractokeratometer

The Topcon KR 8900 autorefractometer (Topcon Inc., Tokyo, Japan) is a versatile device that assesses the refractive status of the eye through rotary prism evaluations. It measures objective spherical refractive power (ranging from -25 D to +22 D), cylindrical refractive power (between -10 D and +10 D), astigmatic axis (varying from 0° to 180°), corneal curvature, principal meridian direction, and corneal refractive power. To ensure accurate results, the device requires a minimum pupil size of 2 mm and employs a three-dimensional auto-alignment mechanism. The KR 8900 also incorporates the Scheiner double-pinhole principle for data collection, which involves projecting two light

sources onto the plane of the pupil to simulate the Scheiner pinhole apertures.

Statistical analysis

The obtained data were analysed using SPSS (version 21.0, SPSS, Inc., Chicago, IL, USA). First, the data distribution was evaluated using the Kolmogorov–Smirnov test. Normally distributed data are expressed as the mean±standard deviation, and non-normally distributed data are expressed as the median and maximum–minimum values. Categorical data are expressed as numbers and percentages. A paired t-test was employed to evaluate the measurements taken from the devices. The methodology put forth by Bland and Altman was utilized to determine the level of agreement between the devices. The Bland–Altman test with 95% limits of agreement (LoA; calculated as: the mean difference of two methods ±1.96 S.D.) was used to evaluate the differences between the individual measurements for each subject and illustrated using the Bland-Altman plot.

Results

The mean age of the 360 patients (180 males, 180 females) included in the study was 24.37±3.91 years. The flattest keratometry values (K1), steepest keratometry values (K2), mean keratometric value (K mean), corneal astigmatism values (AstK) obtained with Nidek AL-Scan biometry (2.4 and 3.3 mm zones), Nidek OPD Scan II aberrometer/topography and Topcon KR 8900 device are summarized in Table 1.

Table 1. Keratometric values measured with three different devices.

Parameter	Nidek AL Scan-2.4mm	Nidek AL Scan-3.3mm	Nidek OPD Scan II	Topcon KR 8900
K1 (D)	42.22±1.57	42.27±1.59	42.74±1.55	42.66±1.59
K2 (D)	43.76±1.46	43.79±1.51	44.22±1.45	43.97±1.47
Kmean	42.99±1.44	43.03±1.46	43.48±1.42	43.31±1.46
AstK	1.53±1.00	1.52±1.00	1.48±0.99	1.30±0.90

When comparing the K1, K2, Kmean, and AstK values obtained with the Nidek AL Scan biometry in the 2.4 and 3.3 mm zones, no statistically significant differences were observed among the two different zone measurements ($p>0.05$). There were no statistically significant differences in AstK values between the Nidek AL Scan (2.4 -3.3 mm zone) and the Nidek OPD Scan II pairwise comparison ($p>0.05$). However, significant differences were identified among the K1, K2 and Kmean measurements obtained with the Nidek AL Scan biometry (2.4-3.3 mm zones) compared with the Nidek OPD Scan II and Topcon KR 8900 devices ($p<0.05$). Significant differences were also observed between Nidek OPD Scan II and Topcon KR 8900 in whole keratometric values. All p-values are summarized in Table 2.

Table 2. Pairwise comparisons of K1, K2, Kmean and AstK among three devices.

Pair of devices	K1	K2	Kmean	AstK
AL Scan-2.4 / AL Scan-3.3	**0.074***	**0.449***	**0.074***	**0.744***
AL Scan-2.4 / OPD Scan II	0.000*	0.000*	0.000*	**0.092***
AL Scan-2.4 /Topcon KR 8900	0.000*	0.000*	0.000*	0.000*
AL Scan-3.3 / OPD Scan II	0.000*	0.000*	0.000*	**0.337***
AL Scan-3.3 /Topcon KR 8900	0.000*	0.000*	0.000*	0.000*
OPD Scan II /Topcon KR 8900	0.002*	0.000*	0.000*	0.000*

*Paired t-test, $p<0.05$.

Bland-Altman analysis identified the lowest mean differences (95% CI of limits of agreement) -0.04±0.32 in K1, -0.03±0.49 in K2, -0.04±0.26 in Kmean, 0.02±0.64 in AstK for Nidek AL Scan between 2.4 and 3.3 mm zones values. The mean difference was highest in K1 -0.51±0.24, K2 -0.46±0.39, Kmean -0.49±0.24 between Nidek AL Scan (2.4 mm zone) and Nidek OPD Scan II respectively. The mean difference was highest in AstK 0.24±0.43 between Nidek AL Scan (2.4 mm zone) and Topcon KR 8900. Bland-Altman plots showing differences between Nidek AL Scan (2.4 and 3.3 mm zones), Nidek OPD Scan II and Topcon KR 8900 at K1, K2, Kmean, AstK values were presented in Fig.1 and Fig.2.

Although the mean difference was below 0.50 D in pairwise comparisons between all three devices, the 95% LoA agreement range was wider than 1.0 D, suggesting that these three devices are not interchangeable in a clinical setting.

Discussion

This study investigated corneal keratometry data obtained using three different methods in a sample of 360 healthy volunteers who underwent routine ophthalmic examination at our clinic. The Nidek AL Scan keratometric data did not show significant differences, and exhibited good agreement in two different corneal zones. A statistical difference was found in all keratometric data obtained from the Topcon KR 8900 between the Nidek AL Scan device (in two different corneal zones) and Nidek OPD Scan II. There was no statistically significant

distinction observed between the Nidek OPD scan II and Nidek AL Scan (2.4-3.3 mm zones) solely with regards to the AstK value. Rather than assessing repeatability, this study assessed the mean differences and used pairwise comparisons to better understand whether the three devices were comparable and interchangeable.

Schultz et al. compared keratometry and astigmatism measurements provided by the Verion Reference Unit (an image-guided system) with the Tonoref II automated tonometer–refractometer, AL-Scan optical biometer, IOL Master 500 biometer, Pentacam rotating Scheimpflug camera and OPD Scan III wavefront aberrometer (16). The similar result between the keratometric data of the Nidek AL Scan in the 2.4 and 3.3 mm zones is consistent with the findings of the current study. On the other hand, the absence of a difference between the Nidek OPD Scan III, Tonoref II, and AL Scan biometry is in contrast. This disparity may be attributed to the fact that we employed OPD Scan II and Topcon KR 8900 autorefractometer in the current study and their study population comprised older patients.

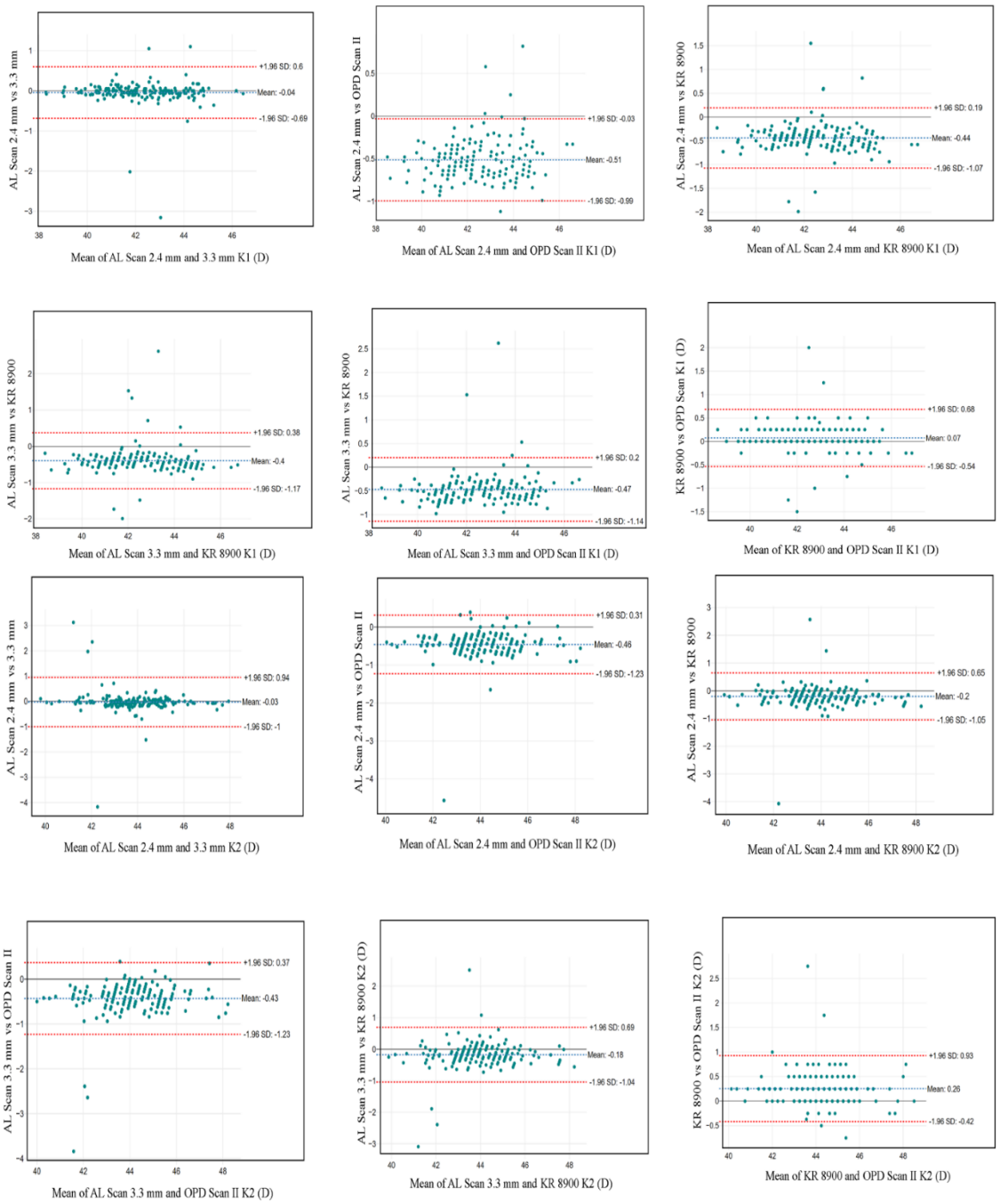

Figure 1. Bland-Altman plots showing agreement between Nidek AL Scan (2.4 and 3.3 mm), Nidek OPD Scan II, Topcon KR 8900 at K1 and K2 keratometric measurements. The middle line presents the mean difference, the bottom and the top dashed lines show the lower and upper 95% limits of agreement.

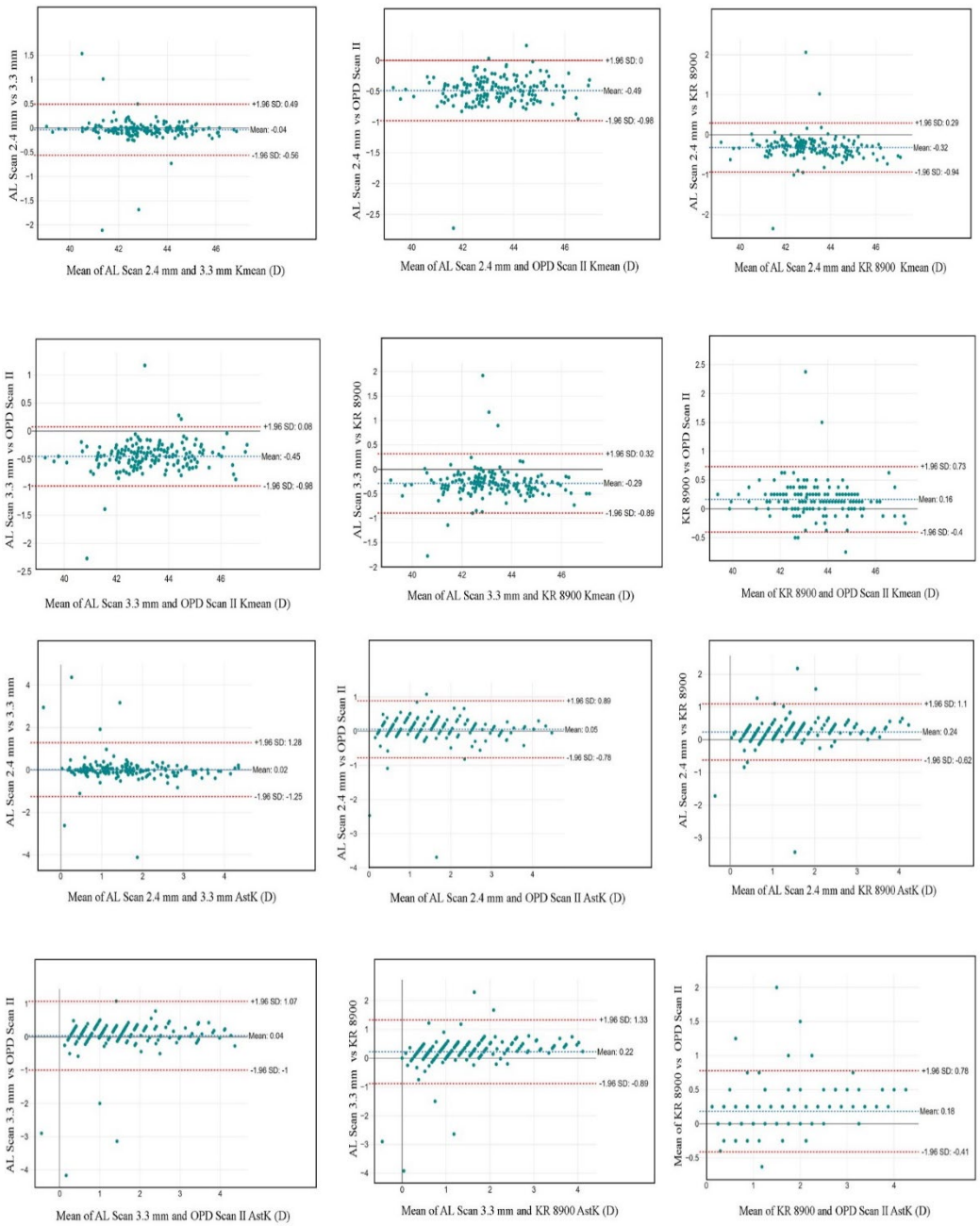

Figure 2. Bland-Altman plots showing agreement between Nidek AL Scan (2.4 and 3.3 mm) Nidek OPD Scan II, Topcon KR 8900 at Kmean and AstK keratometric measurements. The middle line presents the mean difference, the bottom and the top dashed lines show the lower and upper 95% limits of agreement.

Shirayama et al. investigated the reproducibility and comparability of anterior corneal power measurements obtained using the Humphrey Atlas corneal topographer, Galilei Dual Scheimpflug Analyzer, IOL Master, and a manual keratometer (17). The study found that the intraclass correlation coefficients (ICCs) for all the devices tested were higher than 0.99, indicating a high degree of agreement. The 95% limits of agreement (LoAs) for the mean keratometry values were less than 0.5 D for each pair of devices. Based on these findings, the authors concluded that the corneal power measurements from the four devices were highly reproducible and comparable. While the study did not make any specific recommendations regarding the interchangeability of the devices, the reported 95% LoAs suggest that the measurements could be considered interchangeable, given the clinical relevance implied by a 0.50 D difference.

In a study conducted by Çağlar et al., the authors evaluated Nidek AL Scan biometry, Sirius topography (CSO, Florence, Italy) and ultrasound biometry (Aviso A/B, Quantel Medical, MT, USA) in a population with a mean age of 39.24±14.37 years (18). The researchers reported no statistically significant difference in average keratometry

between the 2.4 and 3.3 mm zones of the AL Scan and SimK of the Sirius topography device, and they found a very high correlation coefficient between the devices (0.977). The highest mean difference between the parameters was 0.059 D and the widest LoA was-0.715 to 0.730 D. The authors claimed that AL Scan biometry and Sirius Scheimpflug/Placido photography-based topography could be used interchangeably in terms of keratometry. The finding of no difference in average keratometry measurement between the two zones of AL Scan biometry is consistent with current research. However, their study's finding of compatibility with Sirius topography differs from our results, which may be attributed to the use of the Nidek OPD Scan II as the topography device. Duman et al compared Nidek AL Scan with Sirius topography system in a population with a mean age of 71.79±7.91 years with cataract (19). Opposite to the Çağlar et al.'s study they only found good agreement in keratometric values with Sirius and AL Scan in 2.4 mm zones. Keratometric measurements of AL Scan in 3.3 mm zones were statistically different from Sirius device. The researchers suggested that 2.4 mm corneal zone measurements of AL Scan could be more appropriate for determining the lens power in clinical settings. The reason for this disparity, as they perceived it, was attributed to the dissimilar age range of patients with cataracts encompassed.

Hashemi et al. conducted a study comparing the Nidek ARK-510A autorefractokeratometer to rotating Scheimpflug imaging with Pentacam and Lenstar LS 900 biometry in a population of children aged 6-12 years old (20). The results of the study indicated that these three devices are not interchangeable in the evaluation of corneal astigmatism in children. The authors determined that the difference between the devices may be due to the fact that targets used by the devices stimulate the accommodation at different levels and affect the corneal curvature and that the amplitude of accommodation is higher in the paediatric age group.The young age of the participants in our current investigation might have also contributed to the occurence of notable variations between the devices.

Six different keratometers—Javal-Schiotz, IOL Master, Pentacam, OPD Scan III, Medmont and TMS-5—were evaluated in a population with a mean age of 36±11.4 years, as reported by Hamer et al (21). According to the study, OPD Scan measurements were found to be significantly different from those obtained using the other devices with lower results being observed. Additionally, Javal-Schiotz was found to produce significantly higher results compared to the other devices. The study also revealed a weaker correlation between OPD Scan and IOL Master measurements. The researchers observed that Placido disc systems generated a broader distribution of data with a higher incidence of outliers in comparison to both Scheimpflug and automated keratometric methods. The possibility of an unstable tear film was cited as a contributing factor, and it was suggested that the use of ocular lubricant before measurement with Placido disk systems may be beneficial.

Mehravaran et al. compared min-K, max-K and mean-K values obtained by using Topcon 8800 autorefractokeratometer, IOL Master, EyeSys 3000 Corneal Analysis System (EyeSys Vision), and Pentacam HR with a manual Javal keratometer in 42 eyes of 21 patients aged 31.74±6.82 years old (22). For both values, Topcon 8800 and IOL Master generated higher readings than Javal, while EyeSys 3000 and Pentacam showed lower results. Compared to Javal, the smallest difference in measuring min-K was observed with the IOL Master, with a mean inter-device difference of -0.09±0.24 D. However, in terms of inter-device agreement, the IOL Master and Topcon yielded comparable results. When comparing to Javal, the smallest difference for max-K readings was seen between Javal and Pentacam, but the 95% LoA suggested better agreement for Topcon. For mean-K readings, the smallest difference was observed between Javal and Topcon, while the IOL Master showed slightly better agreement. Researchers have reported that Topcon and IOL Master were safe to be interchanged with Javal keratometry in a clinical setting.

The discrepancies among keratometers are attributable to the fact that manufacturers do not employ a uniform index of refraction or measurement area or method. Placido-based systems gauge the cornea paracentrally rather than centrally, thereby creating a blind spot that may neglect from 1.3 to 2.1 mm of the central zone. As the measurement area approaches the center, the corneal curvature increases in steepness. Although some differences among keratometers may be negligible, others may hold clinical significance, particularly when determining the intraocular lens power for cataract surgery. In fact, a 0.25 D error in measuring the corneal refractive power can result in an approximate correction error of 0.28±0.04 to 0.31±0.05 D (23). Norrby et al. also demonstrated that inaccurate corneal power constitutes a significant source of error in intraocular lens (IOL) power calculations. A 1 D error in the corneal power measurement results in an approximately 1 D error in the calculation of the IOL power (24). The authors asserted that inaccurate keratometry measurement constitutes one of the primary sources of postoperative refractive surprise following intraocular lens implantation.

Conclusion

In conclusion, various studies have documented differences and similarities in keratometric measurements among different age groups using

different devices. Despite the mean difference of 0.5 D or less between the three devices in our study, the 95% LoA range between three devices was over 1.00 D, highlighting that Nidek AL Scan, Nidek OPD Scan II and Topcon KR8900 devices cannot be used interchangeably in terms of corneal keratometric measurements.It is important to note that these devices may yield different results when utilized interchangeably in clinical practice. Further studies are needed to evaluate these three devices' keratometric data on different age populations with without corneal diseases such as kerakonus.

Study Limitations

Limitations of the study include the absence of a manual keratometer and the fact that only healthy corneas were included. An additional limitation is the lack of postoperative outcomes from refractive surgery procedures conducted based on keratometric data obtained from these three distinct keratometric devices.

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Conflict of interest statement

The authors declare that they have NO affiliations with or involvement in any organization or entity with any financial interest in the subject matter or materials discussed in this manuscript.

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