Inter-device measurement variability of vital data parameters for keratorefractive and cataract refractive surgery

Piotr Kanclerz iD **, Katarzyna Przewłócka and Xiaogang Wang**

Abstract

Introduction: The measurements of corneal white-to-white (WTW) diameter and pupil size are critical for decision making in refractive surgery. Currently, automatic measurement of keratometry, corneal WTW, and pupil size are implemented in several ocular devices. The purpose of this study was to examine the agreement between two commonly used devices, an autorefractor and an optical biometer, for these parameters.

Methods: Measurements were performed with both a Lenstar LS-900 and Nidek ARK-1 by an experienced examiner in random order. The devices were placed in close proximity within the same dimly lit room.

Results: The measurements of 65 right eyes were analyzed. The results of the flat, steep, and mean keratometric reading were not significantly different ($p = 0.96$, $p = 0.90$, $p = 0.93$, respectively). Corneal WTW distances showed only moderate agreement between devices and were found to be significantly different ($r = 0.8071$; $p < 0.01$). Pupil diameters showed poor agreement between devices and were significantly different ($r = 0.4890$; $p < 0.01$). Agreement between implantable contact lens sizing, based on the measurements obtained by the two devices, was achieved for 19 of the 51 eyes (37.3%).

Conclusion: We found a significant difference in WTW and pupil size measurements between ARK-1 and Lenstar. Results for both of the devices cannot be considered interchangeable for these data parameters.

Keywords: automated measurements, corneal size, corneal white-to-white, intraocular lens calculation, pupil size

Introduction

The accurate measurements of corneal power and astigmatism are essential for the performance of refractive surgery. Keratometry is required by all formulas used to calculate intraocular lens (IOL) power, while the degree of astigmatism is used to plan toric IOL implantation and limbal relaxing incisions.[1–4] The accurate estimation of pupil dimensions is necessary for clinical decisions in refractive surgery, including candidates for corneal refractive surgery and before multifocal intraocular lens implantation.

The measurement of the corneal white-to-white (WTW) diameter is used during the diagnosis of several malformations, such as microcornea, and to detect and monitor congenital or infantile glaucoma. WTW measurements are also required for some IOL calculation formulas (e.g. Hill-RBF), and IOL size adjustments, such as those performed for sulcus implantation or implantable contact lenses (ICLs). Moreover, sizing is critical for the proper adjustment of manual microkeratome settings in laser *in situ* keratomileusis, as incorrect sizing could potentially result in flap-related complications.

Correspondence to:
Piotr Kanclerz
Hygeia Clinic, ul. Jaśkowa
Dolina 57, 80-286 Gdańsk,
Poland.
p.kanclerz@gumed.edu.pl

Katarzyna Przewłócka
Hygeia Clinic, Gdańsk,
Poland

Xiaogang Wang
Shanxi Eye Hospital,
Shanxi, China

The purpose of this study was to examine the agreement between two commonly used methods for the measurement of keratometry variables, corneal size, and pupil size: an autorefractor and an optical biometer.

Methods

This prospective study included healthy volunteers at the Hygeia Clinic, Gdańsk, Poland, between July 2018 and August 2018. Patients with ocular diseases, including cataracts, with visual acuity worse than 20/25 or previous ocular surgery/trauma were excluded. All subjects underwent a complex ophthalmic examination, including subjective refraction, air-puff tonometry, slit-lamp examination, and ophthalmoscopy. Measurements were performed with both a Lenstar LS-900 (Haag-Streit Diagnostics, Köniz, Switzerland) and a Nidek ARK-1 (Nidek Co., Ltd., Aichi, Japan) by an experienced examiner (K.P.). The Lenstar analyzes the keratometry variables at diameters of 1.6 mm and 3.2 mm, whereas the ARK-1 of 2.4 mm and 3.3 mm. Both devices capture a static image for the automatic assessment of pupil size and corneal WTW values. The devices were standing in close proximity to each other in the same dimly lit room, and the measurements were performed after a period of 2 min of patient adaptation. The examinations were performed sequentially in random order. For every patient, up to three attempts to achieve reliable measurements were made. The keratometric readings, as well as corneal WTW and pupil size measurements, were compared between the two devices. The ICL sizing was calculated using the dedicated online calculator v. 4.08.[5] The study adhered to the tenets of the Declaration of Helsinki for the use of human participants in biomedical research and was approved by the local bioethics committee (*Komisja Bioetyczna przy Okręgowej Izbie Lekarskiego w Gdańsku*, KB-11/18). All participants signed informed consent after the purpose of the study was described to them.

Statistical analysis was performed using Statistica software (version 12.5, StatSoft, Poland). Because the data were normally distributed (Kolmogorov-Smirnov test), the results are presented as the mean ± standard deviation (SD), and a paired, two-tailed t test was used to compare the results. Bland-Altman graphs were used to show measurement differences between the mean values and to assess the agreement between the measurements of the compared devices. The 95% limits of agreements (LoA) were defined as the mean ± 1.96 SDs of the differences between the compared devices. A value of $p < 0.05$ was considered significant. Correlation coefficient was calculated using the R environment, "irr" package version 0.84.1; values between 0 and 0.3 were considered as weak positive, between 0.3 and 0.7 as moderate positive, while between 0.7 and 1.0 as strong positive linear relationships.[6] Sample size calculation was performed using the PS program (version 3.1.6) for power and sample size calculations.[7] A sample size of 15 eyes per group was estimated to detect a difference in WTW of 0.1 mm, based on a standard deviation of difference between the devices of 0.01 mm, a power of 95% at a significant level of 5%.

Results

This study analyzed the results for 65 right eyes from 65 patients (45 women). The mean age was 41.8 ± 13.8 years. The mean spherical equivalent refraction was −0.11 ± 2.02 diopters (D, range −5.38 D to + 4.63 D). Keratometric measurements were obtained, in all cases, by both the ARK-1 and the Lenstar. Pupil size measurements were obtained in 63 eyes with the ARK-1, and in 62 eyes with the Lenstar. It was not possible to obtain corneal WTW size in 1 eye with Lenstar, and in 14 eyes with the ARK-1; thus, device-pair comparison of WTW size and ICL sizing calculations were performed in 51 cases.

The results of the flat, steep, and mean keratometric readings (Table 1) showed high agreement between devices and these measurements were not significantly different ($p = 0.96$, $p = 0.90$ and $p = 0.93$, respectively). The corneal WTW distance manifested was significantly different between the devices and showed moderate agreement (Figure 1; $p < 0.01$). The pupil diameters showed poor agreement between devices (Figure 2). The supplementary Table 1 presents the ICL sizes calculated based on the corneal WTW measurements obtained from both devices. ICL size agreements were achieved in 19 of 51 eyes (37.3%). The corneal WTW measurements showed larger values with the Lenstar device in 58.8% of cases (30/51), while with ARK-1 in 41.2% of cases (21/51). The pupil size measurement showed larger values in 84.1% of ARK-1 (53/63), and in 15.9% of Lenstar measurements (10/63).

Table 1. Mean anterior eye distances (expressed as mean ± standard deviation) obtained with Nidek ARK-1 and Lenstar LS-900 systems.

	Device	Result	Mean difference ± SD	95% limits of agreement	Correlation coefficient *r* (*p*)
Flat keratometry (D)	ARK–1	43.36 ± 1.80	−0.02 ± 0.24	−0.49 to 0.46	0.9911 (0.96)
	LS–900	43.38 ± 1.78			
Steep keratometry (D)	ARK–1	44.40 ± 1.92	−0.04 ± 0.29	−0.61 to 0.53	0.9889 (0.90)
	LS–900	44.44 ± 1.88			
Mean keratometry (D)	ARK–1	43.88 ± 1.82	−0.03 ± 0.21	−0.44 to 0.39	0.9933 (0.93)
	LS–900	43.91 ± 1.78			
Corneal white-to-white (mm)	ARK–1	12.01 ± 0.44	−0.23 ± 0.28	−0.78 to 0.32	0.8071 (<0.01)
	LS–900	12.19 ± 0.42			
Pupil diameter (mm)	ARK–1	5.15 ± 0.95	0.90 ± 0.87	−0.80 to 2.60	0.4890 (<0.01)
	LS-900	4.38 ± 0.79			
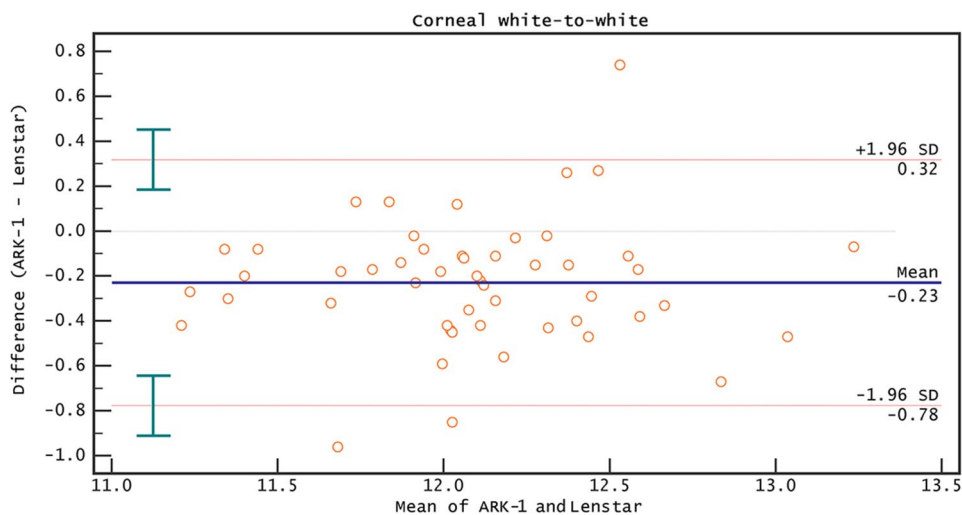
Figure 1. Agreement in measurements of corneal white-to-white between ARK-1 and Lenstar LS-900 presented in Bland-Altman plot.

Discussion

Automatic WTW measurements are known to be more precise than manual methods due to the inter-examiner variability.[8] Currently, WTW estimation is the most important parameter in ICL sizing calculation. This study revealed that the horizontal WTW diameter might vary significantly even between automated devices, which translated into significantly different ICL sizing in 37.3% of cases. The previous studies that have assessed results of automated methods for obtaining WTW measurements are presented in Table 2. Several investigations found a significant difference for the automatic methods,[9–12] with wide 95% limits of agreement greater than 1.0 mm in some studies.[8,9,12] This high variability in WTW among instruments can have serious surgical and clinical consequences. If the ICL is too large, it
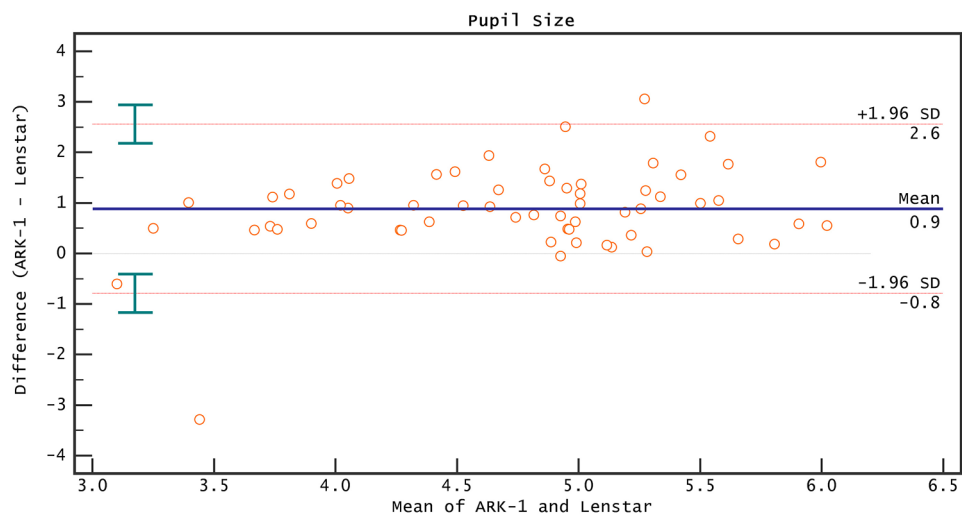
Figure 2. Agreement in measurements of pupil size between ARK-1 and Lenstar LS-900 presented in Bland-Altman plot.

Table 2. Differences in automated methods for corneal WTW assessment, presented as mean $\pm$ SD, 95% LOA.

Study	Devices	Mean difference in WTW $\pm$ SD (mm)	95% LOA (mm)
Fernández et al.[15]	Keratograph 5M vs. Orbscan IIz	0.01 ± 0.19	−0.18; 0.20
Chan et al.[9]	IOLMaster700 vs. AL-Scan	0.28 ± 0.3^a	−0.31; 0.88
Ferrer-Blasco et al.[10]	IOLMaser700 vs. Atlas 9000	-0.14 ± 0.17^a	−0.47; 0.18
	IOLMaster 700 vs. Sirius	0.28 ± 0.19^a	−0.10; 0.65
Muzyka-Woźniak et al.[11]	IOLMaster 500 vs. Pentacam AXL	0.4 ± 0.2^a	0.3; 0.5
Salouti et al.[12]	Galilei vs. Orbscan	0.38 ± 0.56^a	−0.75; 1.48
	Galilei vs. EyeSys	0.05 ± 0.75^a	−1.52; 1.42
Buckhurst et al.[16]	IOLMaster 500 vs. Lenstar	0.06 ± 0.17	−0.25; 0.39
Baumeister et al.[8]	IOLMaster vs. Orbscan	0.24 ± 0.42	−0.61; 1.08

LOA, limits of agreement; WTW, white to white.
[a]Difference statistically significant.

will bow anteriorly, causing anterior chamber shallowing and introduce a risk of pupillary block and angle-closure glaucoma.[13] An ICL that is too small might have an insufficient vault, potentially resulting in contact between the ICL and the crystalline lens, causing subsequent cataract formation.[14]

To our knowledge, there are not many studies analyzing pupil size; previously, the subjective assessment of pupil diameter was reported to be fairly inaccurate.[17] Litvan et al.[18] suggested application of a graded scale rather than an attempt for precise estimation of the pupil diameter to improve inter-examination reliability. Smith et al.[19] reported no significant disagreements between manual and automated pupillometer observations; however, their study used a small group size and manifested wide 95% limits of agreement (−1.29 to + 1.60 mm). Piñero et al.[20]

reported that in most measurements obtained with the VX120 system (Visionix-Luneau Technologies, Chartres, France), the differences between repeated measures did not exceed 0.5 mm (82% of scotopic and 100% of photopic below such value). Although minor variabilities in pupil size assessment may not be clinically significant, interdevice differences should be taken into consideration.[21] With that, measurement consistency remains necessary.[22] Presumably, the difference in pupil size could be related to illumination of the eye by the device during pupil size assessment. Despite an official inquiry to the producers of the devices, we did not obtain information about the applied technique and illuminance levels used by the devices during pupil size measurements. Another limitation of this study is that we did not dilate the pupil; thus, the pupil size during all measurements cannot be considered to be constant. Moreover, calculation of ICL sizing was conducted on a cohort of healthy individuals instead of on patients with high refractive errors; thus, the degree of ICL sizing disagreement could be different in a population of patients undergoing ICL implantations.

The results of our study could provide several implications for both clinicians and manufacturers of medical devices. Presumably, the difference in WTW measurements could be related to difficulties in detecting the gray transition between the cornea and sclera using automated methods.[15] It would be useful to have an option to display the image of the eye with the borders of automatically detected structures shown; none of these devices allowed such an evaluation. Such an image would allow one to critically analyze if the software detects borders properly and to adjust the borders manually. In the pro version, Lenstar has a manual setting that may help the observer to obtain a better measurement of the WTW; however, it was not available in our device. The illuminance levels for pupil analysis should be provided in the specification of the device and standardized. Finally, although minor variabilities may not be clinically significant,[21] clinicians should be aware of these differences and potential imprecision of the measurements when planning the treatment.

In conclusion, we found a significant difference in WTW and pupil size measurements between ARK-1 and Lenstar. Results for both of the devices cannot be considered interchangeable for these specific data parameters.

ORCID iD
Piotr Kanclerz iD https://orcid.org/0000-0002-8036-7691

Supplemental material
Supplemental material for this article is available online.

References
1. Wang Q, Savini G, Hoffer KJ, *et al.* A comprehensive assessment of the precision and agreement of anterior corneal power measurements obtained using 8 different devices. *PLoS ONE* 2012; 7: e45607.

2. Kanclerz P, Hoffer KJ, Rozema JJ, et al. Repeatability and reproducibility of optical biometry implemented in a new optical coherence tomographer and comparison with a optical low-coherence reflectometer. *J Cataract Refract Surg* 2019; 45: 1619–1624.

3. Kanclerz P, Hoffer KJ, Przewłócka K, et al. Comparison of an upgraded optical biometer with 2 validated optical biometers. *J Cataract Refract Surg* 2021; 47: 859–864.

4. Kanclerz P, Khoramnia R, Wang X. Current Developments in Corneal Topography and Tomography. *Diagnostics* 2021; 11: 1466.

5. OCOS STAAR AG: STAAR surgical online calculation & ordering system, https://ocos.staarag.ch (accessed 30 August 2019).

6. Ratner B. The correlation coefficient: its values range between 1/−1, or do they? *J Target Meas Anal Mark* 2009; 17: 139–142.

7. PowerSampleSize < main < Vanderbilt biostatistics wiki, https://biostat.app.vumc.org/wiki/Main/PowerSampleSize (accessed 17 June 2021).

8. Baumeister M, Terzi E, Ekici Y, *et al*. Comparison of manual and automated methods to determine horizontal corneal diameter. *J Cataract Refract Surg* 2004; 30: 374–380.

9. Chan TCY, Wan KH, Tang FY, *et al*. Repeatability and agreement of a swept-source optical coherence tomography-based biometer IOLMaster 700 versus a Scheimpflug imaging-based biometer AL-scan in cataract patients. *Eye Contact Lens* 2020; 46: 35–45. DOI: 10.1097/ICL.0000000000000603.

10. Ferrer-Blasco T, Esteve-Taboada JJ, Martínez-Albert N, *et al*. Agreement of white-to-white measurements with the IOLMaster 700, Atlas 9000, and Sirius systems. *Expert Rev Med Devices* 2018; 15: 453–459.

11. Muzyka-Woźniak M and Oleszko A. Comparison of anterior segment parameters and axial length measurements performed on a Scheimpflug device with biometry function and a reference optical biometer. *Int Ophthalmol* 2019; 39: 1115–1122.

12. Salouti R, Nowroozzadeh MH, Zamani M, *et al*. Comparison of horizontal corneal diameter measurements using Galilei, EyeSys and Orbscan II systems. *Clin Exp Optom* 2009; 92: 429–433.

13. Khalifa YM, Goldsmith J and Moshirfar M. Bilateral explantation of Visian Implantable Collamer Lenses secondary to bilateral acute angle closure resulting from a non-pupillary block mechanism. *J Refract Surg* 2010; 26: 991–994.

14. Gonvers M, Bornet C and Othenin-Girard P. Implantable contact lens for moderate to high myopia. *J Cataract Refract Surg* 2003; 29: 918–924.

15. Fernández J, Rodríguez-Vallejo M, Martínez J, *et al*. Confounding sizing in posterior chamber phakic lens selection due to white-to-white measurement bias. *Indian J Ophthalmol* 2019; 67: 344–349.

16. Buckhurst PJ, Wolffsohn JS, Shah S, *et al*. A new optical low coherence reflectometry device for ocular biometry in cataract patients. *Br J Ophthalmol* 2009; 93: 949–953.

17. Kerr RG, Bacon AM, Baker LL, *et al*. Underestimation of pupil size by critical care and neurosurgical nurses. *Am J Crit Care* 2016; 25: 213–219.

18. Litvan I, Saposnik G, Mauriño J, *et al*. Pupillary diameter assessment: need for a graded scale. *Neurology* 2000; 54: 530–531.

19. Smith J, Flower O, Tracey A, *et al*. A comparison of manual pupil examination versus an automated pupillometer in a specialised neurosciences intensive care unit. *Aust Crit Care* 2020; 33: 162–166. DOI: 10.1016/j.aucc.2019.04.005.

20. Piñero DP, de Fez D, Cabezos I, *et al*. Intrasession repeatability of pupil size measurements under different light levels provided by a multidiagnostic device in healthy eyes. *BMC Ophthalmol* 2020; 20: 354.

21. Kanclerz P and Przewłócka K. Accuracy of pupil size assessment methods. *Aust Crit Care* 2020; 33: 3.

22. Clark A, Clarke TNS, Gregson B, *et al*. Variability in pupil size estimation. *Emerg Med J* 2006; 23: 440–441.