Optik 127 (2016) 10108–10114

Contents lists available at ScienceDirect

Optik

journal homepage: www.elsevier.de/ijleo

Comparison of two different devices to assess intraocular lenses

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ARTICLE INFO

Article history:
Received 3 June 2016
Accepted 7 August 2016

Keywords:
Monofocal intraocular lens
Modulation transfer function
Dioptric power
International standard and reliability

ABSTRACT

In this paper, we have compared the performance of two commercial systems, Kaleo-I and IOLA Plus, in the characterization of monofocal intraocular lenses (IOLs) according to the International Standard requirements (ISO 11979-2). The dioptric power (DP) and the Modulation Transfer Function (MTF) at 100 lp/mm and 3.0 mm aperture have been measured with both instruments in twenty commercial monofocal HEMA IOLs and their agreement was assessed by Bland Altman analysis. Compared with the designed power, IOLA Plus gave lower values in 85% of measures; Kaleo I errors are dependent on the power of the lens: measurements were higher than the designed power in the low-medium power range and lower than the labelled power in the high-power range. Differences in the MTF measurements between instruments were statistically significant, with an agreement of ±0.12 within the 95% confidence interval. IOLA Plus was very much reliable than Kaleo I in DP measurements. On the other hand, the reliability in the MTF measurements was similar for both instruments.

1. Introduction

Nowadays, it is possible to achieve a near perfect refractive outcome in cataract surgery due to the improvements in several aspects including, surgical techniques, accuracy in preoperative measures, and intraocular lens technology. In fact, intraocular lens (IOL) manufacturing has become a large industry resulting in the production of improved materials and designs. In the last decade, new commercial devices have been proposed to assess the power and optical quality of IOLs. These devices are based on different principles and methods including: Imaging, Shack-Hartmann wavefront sensing [1], Moiré deflectometry [2], and multi-wave lateral shearing interferometry [3]. The quality criteria for monofocal IOLs manufacturing is specified by the International Standard Organization (ISO11979-2) [4]. A normative of this kind becomes necessary when one realizes that, for example, the accuracy of the dioptric power labeling is one of the determinative factors in the refractive outcome of cataract surgery [5,6]. In fact, in some cases a wrong labeling motivated the exchange of the IOL because of an unexpected postoperative refractive error [7]. However, surprisingly manufacturers are not required to report tolerance levels. In this respect, Zudans et al. [6] found that when implanted properly, IOLs available in 0.25 D increments with a labelled

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http://dx.doi.org/10.1016/j.ijleo.2016.08.005
0030-4026/

Table 1
Technical characteristics of the instruments employed in this study.

	IOLA Plus	Kaleo I
Range	−125 D to +170 D	−40 D to +40 D
Resolution:	0.01 D	0.05 D
Accuracy:	0.2%	<1%(MTF)
Repeatability (power):	0.02 D	<0.01 D
Reproducibility (power):	0.04 D	n.a.

tolerance of ±0.11 D have a positive impact on postoperative refractive outcomes. Therefore, in order to properly assess the manufacturing process of IOLs the industry needs to use instruments that allow repeatability and reliability measurements of dioptric power (DP) and Modulation Transfer Function (MTF) within the tolerances imposed by the normative. Validated instruments are essential to perform this task; however, to the best of our knowledge, to date there are no studies that compare the performance of different commercial instruments in IOLs characterization.

The purpose of this study was to test comparatively the performance of two commercial systems, Kaleo-I (Phasics S.A. Saint Aubin, France) and IOLA Plus (Rotlex, Omer, Israel) in measuring monofocal IOLs according to the international norm ISO11979-2. Intra-session repeatability and intra-rater reliability with these instruments has been also evaluated.

2. Methods

2.1. Instrumentation

Two commercial devices were used in this study: the IOLA Plus system [8], which working principle is Moiré deflectometry [2] and the Kaleo-I device [9], which is based on a four-wave interferometry [3] for wave–front sensing. Both instruments were calibrated by the manufacturers, and include: a model eye, consisting on an artificial cornea, and a wet cell where the IOL is immersed in a saline solution as described in the ISO 11979-2 Standard [4]. In each case, the curvature (power) map, the Point Spread Function (PSF) and the MTF are derived from the measured phase map by the corresponding software. Both instruments need the input of some parameters of the lens under investigation such as the IOL refractive index and its designed (labelled) power. The specifications of both instruments provided by the manufacturers are very limited, and are summarized in Table 1.

2.2. Samples and procedures

Twenty monofocal IOLs with labelled powers ranging from 8 D to 27 D in one diopter intervals, were analyzed in this study. These lenses: AIALA model F551250 (AJL Ophthalmic SA; Álava, Spain), were made of hydrophilic acrylic material [hydroxyethylmethacrylate (HEMA)]. A Cl-Na saline solution (Laboratorios ERN S.A, Barcelona, Spain) with a pH 5.5 was used as the surrounding medium for all experiments. Samples were masked and numbered in a random order which was used as a reference in the analysis. IOLs DP and MTF values at 100 lp/mm for a 3 mm pupil diameter were measured according to the manufacturer instructions at ambient temperature (23 °C ± 3 °C). Two different trained raters (Operator #1 and Operator #2) obtained repeated measures with each instrument in separated sessions. They carried out the measurements on the twenty IOLs in the same order.

Statistical analysis was performed using the SPSS 14.0 (SPSS Chicago, Illinois, USA) statistical package for Windows. The Shapiro–Wilk test was used to check the normality of data distribution. Significance of the differences between measurements was assessed using the paired *t*-test for normally distributed data, and the Wilcoxon signed rank test for non-parametric data. A p-value ($p < 0.05$) was considered statistically significant. The assessment of the repeatability (test–retest reliability) was tested with the measurements obtained by the same operator in two consecutive days. The reproducibility was assessed by comparing the values of DP and MTF measured on the same day in the same conditions by the two operators. The repeatability and reproducibility coefficients of were calculated as 1.96 SD of differences between sessions.

Bland-Altman graphs [10] were used to compare the agreement between instruments and for the assessment of the repeatability and reproducibility for normally distributed data. In these cases, limits of agreement (LoAs) were calculated as mean ± 1.96 SD and the 95% confidence intervals (CI) was computed as 2.093 SD according to the *t*-test table for 19 (n-1) degrees of freedom; otherwise, for non-normal distributed data, the median differences and 95th percentile were computed.

3. Results

3.1. Dioptric power measurements (for a 3 mm pupil diameter)

As a first test, we have computed the difference between the measured powers of the individual lenses with the corresponding designed power (provided by the manufacturer). Fig. 1a) shows the results. Note that almost all lenses were inside the tolerance limits imposed by the Standard (gray background in this figure). Exceptions were the 9.0 D lens when it was measured with IOLA Plus; and the lenses of 11 D; 23 D and 25 D measured with Kaleo I. We found that Kaleo I gives a small

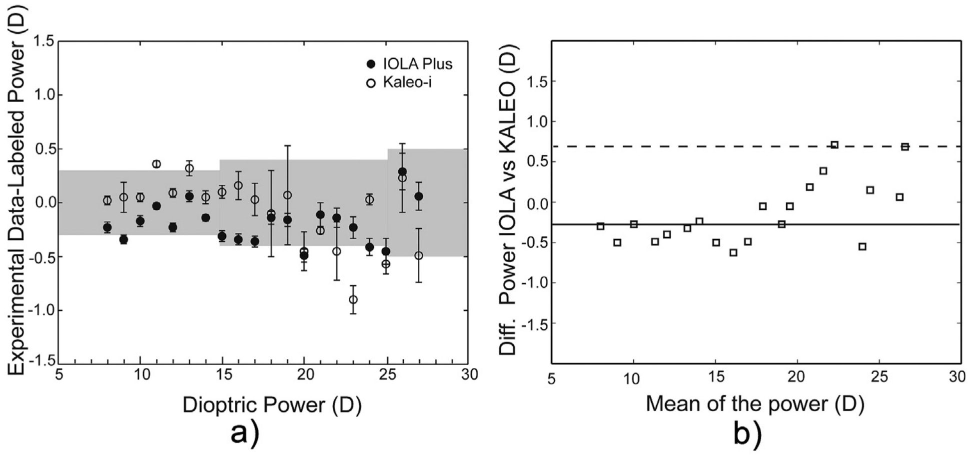

Fig. 1. (a) Differences between the measured and the labelled DP for each IOL. The gray area represents the tolerance limits admitted by the ISO11979-2 norm. Error bars represent the SD. (b) Agreement between instruments for DP measurements: The lines indicate: the median of the difference: IOLA Plus-Kaleo I (solid line: −0.22 D) and the 95% percentile agreement (dashed line: 0.57D).

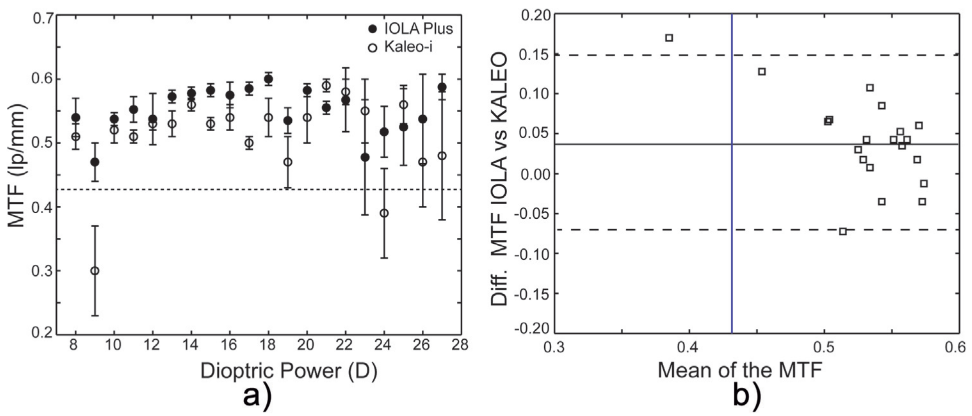

Fig. 2. a) MTFs at 100 lp/mm, for a 3 mm pupil diameter, measured for each IOLs. The dashed line represents the tolerance limit imposed by the ISO 11979-2 Norm. Error bars represent the SD. b) Bland Altman plot for the differences of MTF measurements. Mean of the difference: 0.04 SD: 0.06. The LoAs were (−0.07, 0.15) with 95% CI = ± 0.12.

overestimation of the lens DP for low power lenses (9 D < DP < 20 D), but the opposite occurs in general for DPs higher than 20 D. The vertical line in Fig. 1a) marks the limit of these two tendencies. Moreover, considering the full range of powers, a relative underestimation of DP was found with both instruments. In fact, the mean value of the difference between the measured power and the labelled power was (−0.08 ± 0.32) D for Kaleo I; and (−0.19 ± 0.19) D for IOLA Plus.

The agreement of both instruments for DP measurements is shown in Fig. 1b). A non-normal distribution was obtained for the DP difference. DPs had a median difference of −0.22 D, and the 95th percentile limit was 0.57 D. It should be noted that, due to the different performance of Kaleo I for low-medium DP lenses and high DP lenses, the mean difference of DP (IOLA Plus-Kaleo) was (−0.28 ± 0.14) D in the range (8–20) D, and (0.18 ± 0.25) D for lenses with power in the range 21 D–27 D (excluding the 23 D lens).

3.2. MTF (100 lp/mm for a 3 mm pupil diameter)

Fig. 2a) shows the values of the MTF measured with both instruments. It can be seen that for the whole sample, the values of the MTF obtained with IOLA Plus were higher than the tolerance limit imposed by the ISO norm (i.e. better than 0.43 for 100 lp/mm; dotted line). On the other hand, according to Kaleo-I, strictly only one lens (9 D) did not pass the MTF quality criterion. It can be observed that except from four lenses in the range (20–25) D, the MTF values obtained with IOLA-plus were higher than those obtained with Kaleo-I. The agreement of both instruments for MTF measurements is shown in Fig. 2b). The differences of the MTF measurements were statistically significant ($t(19) = 3.179$; $p = 0.005$). As can be seen, in general, differences between instruments on MTF readings increase with power, although the higher difference has been found for the 9 D lens.

Table 2
Repeatability coefficients for DP and MTF measurements obtained by both operators.

	IOLA Plus		KALEO I	
	Operator #1	Operator #2	Operator #1	Operator #2
DP (D)	0.17	0.15	0.44	0.62
MTF	0.14	0.07	0.08	0.14

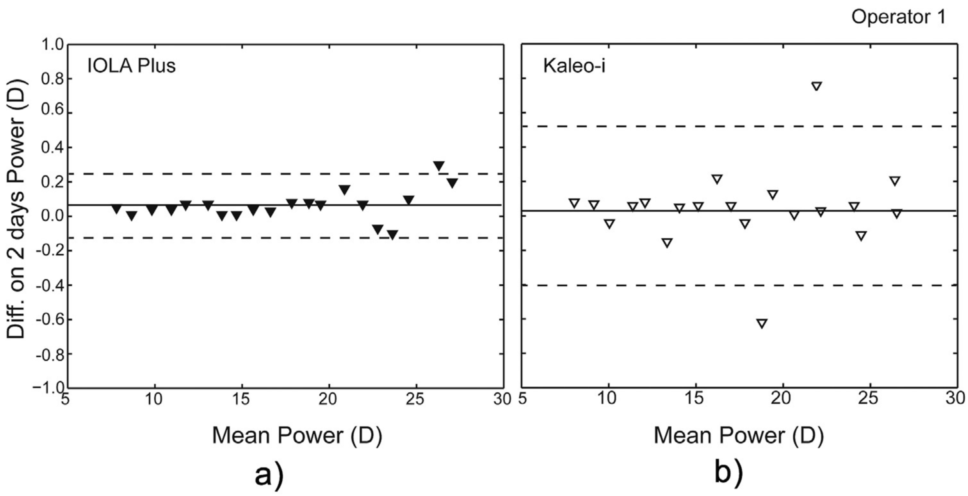

Fig. 3. Bland Altman plots of DP differences between measurements in two consecutive days. (Operator#1). a) IOLA Plus: Mean of the difference: 0.06 D, SD: 0.09; LoAs (dotted line): (0.23, −0.11) D with a 95% CI = ± 0.17D D. b) Kaleo I: Mean of the difference: 0.04 D; SD: 0.22 D; LoAs: (0.48, −0.40) D. with a 95% CI = ± 0.47 D.

Table 3
Reproducibility coefficients for DP and MTF measurements obtained by two operators in two days.

	IOLA Plus		KALEO I	
	Day #1	Day #2	Day #1	Day #2
DP (D)	0.09	0.13	0.64	0.54
MTF	0.09	0.10	0.11	0.14

3.3. Repeatability

Repeatability of both instruments was tested by two operators in two consecutive days. Table 2 shows the repeatability coefficients for DP and MTF measurements. We found that DP measurements for IOLA Plus were more repeatable than those performed with Kaleo I, although both operators obtained statistical significant differences between sessions ($p < 0.05$). Fig. 3 shows the intra-session Bland-Altmann plots for the DP values measured by Operator #1 with both instruments. Similar results (not shown) were obtained by Operator #2.

On the other hand, for the MTF measurements, the repeatability obtained by two operators with each instrument was opposite as reflected in Table 2. Operator #1 achieved better results with Kaleo I whereas Operator #2 obtained better results with IOLA Plus. In this case, each operator obtained no statistically significant differences between sessions [Operator #1: IOLA plus ($t(19) = 0.157$; $p = 0.877$) Kaleo-I ($t(19) = 1.230$; $p = 0.234$); Operator #2: IOLA plus ($t(19) = 0.064$; $p = 0.950$) Kaleo-I ($t(19) = 0.273$; $p = 0.787$)]. The Bland Altman plots for the repeatability of the MTF measurements obtained with both instruments by Operator #1 and Operator #2 are shown in Fig. 4.

3.4. Reproducibility

Table 3 shows the reproducibility coefficients for DP and MTF measurements obtained for two operators on the same day. As we found for the repeatability of DP, measurements for IOLA Plus were more reproducible than those performed with Kaleo I, the differences between operators with both instruments were statistically significant ($p < 0.05$). On the other hand, the MTF results were very similar for both instruments with no statistically significant differences between sessions [Day #1: IOLA plus ($t(19) = -0.276$; $p = 0.477$) Kaleo-I ($t(19) = 0.782$; $p = 0.44$); Day #2: IOLA plus ($t(19) = -0.939$; $p = 0.359$) Kaleo-I ($t(19) = 0.186$; $p = 0.855$)].

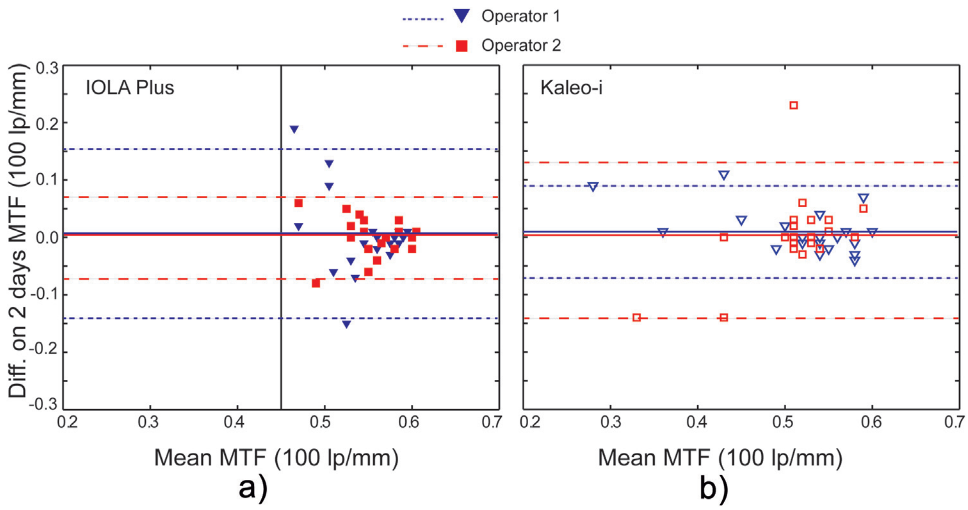

Fig. 4. Bland Altman plots of MTFs at 100 lp/mm, for a 3 mm pupil diameter. Differences between measurements in two consecutive days by Operator #1 and Operator #2. (a) Results for IOLA Plus Operator #1: LoAs: (0.14, −0.14) with a 95% CI = ±0.15. Operator #2: LoA (0.07, −0.07), with a 95% CI = ±0.07. (b) Kaleo Operator #1. LoAs (0.09, −0.07), with a 95% CI = ± 0.08. Operator #2. LoAs = (0.15, −0.14), with a 95% CI = ±0.15.

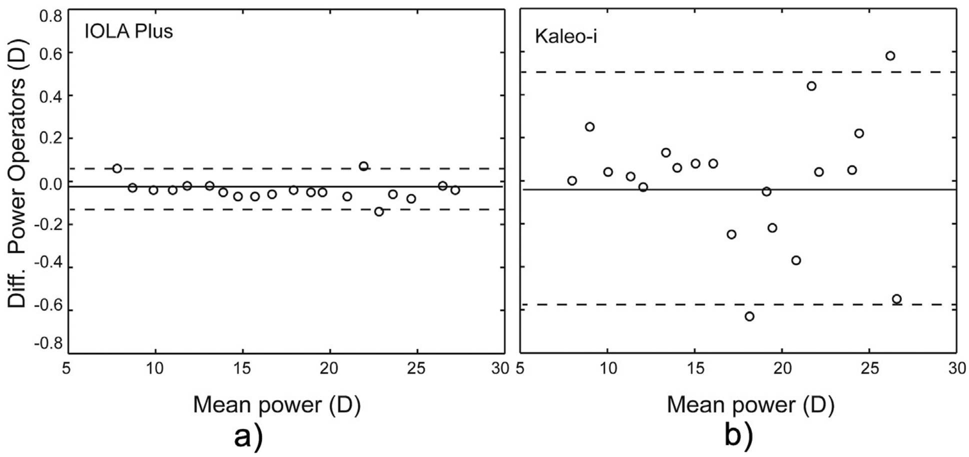

Fig. 5. Bland Altman plots for DP differences between measurements performed by two operators in the 1st. day. (a) IOLA Plus: Mean of the difference: −0.04 D; SD = 0.05 D. LoAs (dotted lines): (0.05,−0.13) D, with a 95% CI of ± 0.10 D. (b) KALEO I: Mean of the difference: −0.04 D, SD = 0.28 D; LoAs (dotted lines): (0.05,−0.58) D with a 95% CI of ±0.58 D.

Bland Altman plots of DP measurements performed by two operators performed in the same day (1st day) are shown Fig. 5. As can be seen the LoAs for Kaleo I, are twice wider than those of IOLA Plus. Similar results (not shown) were found for the 2nd day.

The reproducibility for MTF measurements in the 1st day for both instruments is represented Fig. 6. Although we found a slightly better performance with IOLA Plus, the performance of both instruments was comparable. Similar results (not shown) were found for the second day.

4. Discussion

In the assessment of twenty IOLs of different powers we found that the differences between the designed DP and the measurements obtained with IOLA Plus were inside the tolerance limits imposed by the ISO Standard for almost all (19/20) the IOLs assessed. On the other hand, several IOLs of the same set were outside these limits according to Kaleo I. With this apparatus measurements were higher than the labelled DP in the low-medium power range and lower than the labelled DP in the high-power range. Compared with the designed power, IOLA Plus gave lower values in 85% of measures with any particular distinction between high or low power lenses. Manufacturing errors may be the responsible, to some extent, of the differences between the designed and measured DP. Calibration errors are another potential reason of discrepancies.

In comparing the performance of both instruments for the optical characterization of IOLs, low agreement was found in DP measurements. In fact, the 95th percentile of agreement was 0.57 D which can be considered higher than the clinical

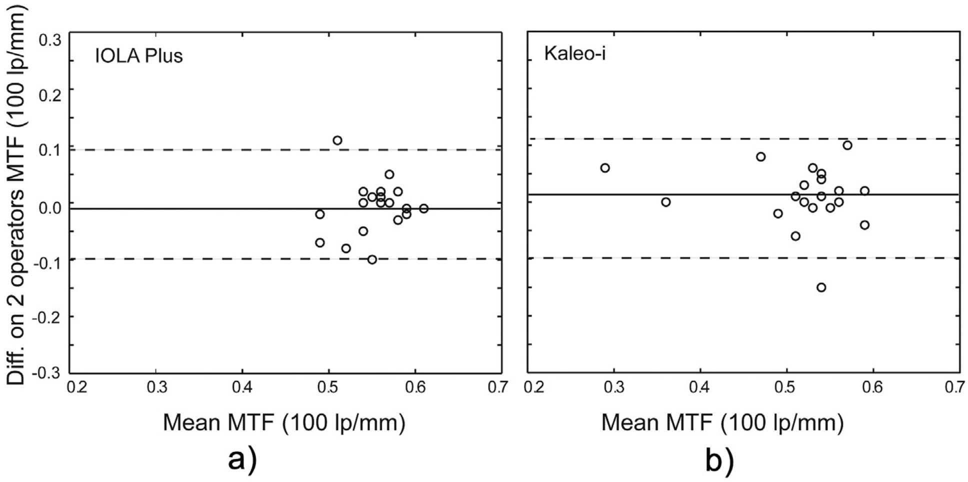

Fig. 6. Bland Altman plots of MTFs at 100 lp/mm, for a 3 mm pupil diameter. Differences between measurements performed by two operators on the same day. (a) IOLA Plus: Mean of the difference: −0.01; SD: 0.05. LoAs (dashed lines): (0.08,−0.10), with a 95% CI ± 0.10 (b) Kaleo I: Mean of the difference (solid line): 0.01; Sd: 0.05. LoAs (dashed lines): (0.12,−0.10), with a 95% CI ± 0.11.

tolerance [6]. We found that in the low range of DP, Kaleo I results were higher than Iola Plus and the opposite happened, in general, for high power lenses (see Fig. 1a) which confirms that Kaleo I errors are dependent on the lens DP.

Regarding to MTF measurements, strictly only one lens of the sample did not pass the quality criterium imposed by the ISO Standard as measured with Kaleo I (this lens, 9 D, also had the lowest MTF scores with IOLA Plus, probably due to manufacturing errors) while all the lenses passed the criteria with IOLA Plus. Although the differences in the MTF measurements between instruments were statistically significant, the agreement within the 95% CI was ±0.12.

Several factors may be responsible for the differences between instruments. Besides operating under different principles, how DP and MTF are calculated in each instrument is not known for users, and it is likely different.

With reference to reliability, our results show that IOLA Plus has a much better performance than Kaleo I in DP measurements; in fact, the SD of the differences between sessions were up to four times lower with this system (see Tables 2 and 3). On the other hand, the inter-tester agreement in the MTF measurements was similar for both instruments. Moreover, the comparison of Tables 2 and 3 show that IOLA Plus apparatus is slightly more reproducible than repeatable, being all the coefficients relatively low, which mean that this instrument is robust and relatively free from variability, what supports its use by different operators. This conclusion is not valid for Kaleo I DP measurements. It should be mentioned that repeatability and reproducibility provided by the manufacturers of both instruments highly differ from the reported values in this work.

The use of these instruments in scientific works is scarce. Actually, we did not found any one in which Kaleo I was employed. IOLA Plus system was recently used to compare the performance of a new methodology for intraocular lens characterization. In that work, Amaral et al. [11] measured the DP of seven monofocal IOLs obtaining that this system provided, in some cases, differences between design and measured values larger than 0.4 D. Furthermore, as we also found, almost all measured lenses provided a value of 100 lp/mm MTF greater than 0.43.

Recently Walker et al. [12] studied the impact of temperature on the optical properties of IOLs. A result of that study shows minimal overall influence of temperature on HEMA IOLs DP, being lower than 0.018 D per degree of temperature. Therefore, within the range of temperatures in which the measurements were taken in this work, the change in DP would only be significant if the lens was very close to the Standard tolerance level, because although thermal expansion of HEMA is negligible, the absorption of saline solution into the IOL material is also expected and will produce minimum but detectable changes in the volume and in turn the radii of curvature of the lens surfaces.

The main limitation of this study is that the sample of lenses comprises only twenty lenses of pure spherical powers, despite both instruments are capable of measuring toric and multifocal refractive IOLs. Nevertheless, the sample has been sufficient to evaluate the agreement between instruments and the repeatability and reproducibility of each machine for DP and MTF measurements.

In conclusion in the assessment of both instruments we found no agreement in measuring DP of simple monofocal IOLs. We found that Kaleo I is less reliable than IOLA Plus, and worse is that DP measurements are dependent on the power of the lens. On the other hand no statistically significant differences were obtained in the measurements of the MTF at 100 lp/mm with both instruments.

For the reasons mentioned in the introduction on the relevance and importance of the subject, we believe that improvements are necessary in the manufacturing and calibration process to obtain more reliable commercial instruments for the characterization of IOLs and we encourage researchers to perform other studies like this one, comparing the performance of other instruments and techniques.

Disclosure

The authors report no conflicts of interest and have no proprietary interest in any of the materials mentioned in this article.

Acknowledgments

This study was supported by the Ministerio de Economía y Competitividad and FEDER (Grant DPI2015-71256-R), and by the Generalitat Valenciana (Grant PROMETEOII-2014-072), Spain. The authors acknowledge AJL S.A. for providing the IOLA Plus instrument and the set of lenses employed in this work.

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