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·Clinical Research·

Repeatability of *in-vitro* optical quality measurements of intraocular lenses with a deflectometry technique effect of the toricity

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Abstract
● AIM: To evaluate the repeatability of an optical device for measuring the Zernike coefficients of toric intraocular lenses (IOLs) and assess whether its toricity has any impact in its repeatability.

● METHODS: An experienced technician used the NIMO TR1504 to measure the Zernike coefficients 30 times for an aperture of 4.50 mm for all lenses included. The IOLs included were divided into two group: toric and non-toric ones. The cylindrical powers of the toric lenses included in the present study were 1.00, 1.50, 2.25, 3.00 and 3.75 D. Finally, the repeatability of the NIMO TR1504 was described in terms of within subject standard deviation (Sw) and repeatability limit.

● RESULTS: The Sw was smaller than 0.011 μm for both lens groups and all Zernike coefficients, and the difference between both groups was smaller than 0.004 μm for all Zernike coefficients. Regarding the repeatability limit, this value was smaller than 0.025 μm for the toric lens group, and smaller than 0.031 μm for the non-toric lens one for all Zernike coefficients. Furthermore, the maximum difference between both lens groups was 0.010 μm.

● CONCLUSION: The repeatability of the NIMO TR1504 to measure the optical quality is high and independent of the lens toricity. These results reflect that this system is robust and could be used to measure the *in-vitro* optical quality of either toric or non-toric IOLs.

● **KEYWORDS:** *in-vitro* measurements; optical quality; intraocular lens; repeatability
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INTRODUCTION

Precise and repeatable measurements of the Zernike coefficients of both contact and intraocular lenses (IOLs) are required to assess how well the final product meets the design specifications. Nowadays, there are several *in-vitro* systems designed from different manufacturers, such as the NIMO (Lambda-X, Belgium) or the WaveMaster IOL (Trioptics, Germany), that can measure the optical quality of both contact and IOLs as previous studies have shown[1-4]. One of these studies used an optical bench design to measure the *in-vitro* optical performance of 9 IOLs, including monofocal and multifocal designs[1]. The results obtained in that study showed that there is a significant differences in the image quality at distance, intermediate and near distances among the different IOLs, but the intermediate vision was more prominent with trifocal lenses. On the other hand, another study evaluated the *in-vitro* optical quality of two trifocal IOLs, and a new lens designed to enlarge the depth of focus[2]. The results obtained in that study showed that the new design has two main areas, one for distance, and another one for intermediate and near vision; meanwhile the trifocal lenses have three. The *in-vitro* optical quality of two lenses designed to provide a continuous range of vision was also reported, and the results showed that both lenses might enlarge the depth of focus[3]. Finally, an *in-vitro* equipment have been also used to compare the optical quality of two phakic IOLs with different optical diameter diameters, and according to the results obtained, both designs have comparable optical quality[4]. From a clinical point of view, these measurements could help clinicians to know the optical behaviour of each lens objectively, and therefore, choose the proper lens that fits better with the patient's visual requirements.

When it comes to describe the optical quality, several metrics have been set to describe the wavefront, point spread function, and modulation transfer function (MTF)[5-8], and some of them have been used to describe the optical quality of contact lenses and IOLs[9-11]. From a clinical point of view, not only the optical quality is important, but also the impact of those aberrations in the visual system. In an attempt to predict the impact of the optical aberrations in the visual performance, several metrics have been defined. Among all of them, the visual Strehl ratio computed in frequency domain has been reported to be the best predictor since it accounts for 81% of the variance in high-contrast logMAR acuity[6].

The NIMO TR1504 is an optical device that measures the *in-vitro* optical aberrations of spherical and toric lenses. It is based on a deflectometry technique and combines the Schlieren principle with a phase-shifting method[12]. This device obtains information about the Zernike coefficients, power profiles, sphere, cylinder and axis of the lens with a single measurement. A previous study found a reproducibility standard deviation for monofocal contact lenses with the NIMO device of 0.05 D[13], and although its repeatability was not reported directly, the repeatability standard deviation was stated to be of the same order of magnitude as the reproducibility. When it comes to multifocal contact lenses, the repeatability of this device has been reported to be lower than 0.12 D[14]. Up to date, all previous studies have assessed the NIMO's repeatability to measure either monofocal or multifocal contact lenses. Nevertheless, there is no study assessing the repeatability of this equipment to measure the optical quality of spheric and astigmatic IOLs, and at the same time, the dependence of the NIMO's repeatability with the lens toricity has neither been studied.

The aim of this study was to evaluate the repeatability of the NIMO TR1504 for measuring the Zernike coefficients of IOLs and assess whether the lens toricity has any impact in its repeatability.

SUBJECTS AND METHODS

***In-vitro* System** Figure 1 displays the schematic diagram of the NIMO TR1504, which is designed to measure the optical quality and refractive power of IOLs. Generally speaking, this device measures light deviation, from which it is possible to calculate the optical characteristics of IOLs. Detailed descriptions of the method used to measure the lens power can be found elsewhere[12-13,15]. Furthermore, this device obtains with a single measurement the spherical and cylinder power with its axis, Zernike coefficients up to 7th order, and the power profile of the lens measured.

Intraocular Lenses The cylindrical powers of the toric lenses measured in this study were 1.00, 1.50, 2.25, 3.00 and 3.75 D. Additionally, these lenses have an optical zone diameter and overall length of 6.00 and 13.00 mm, respectively. Their optical design consists on a biconvex toric aspheric optic, and the front surface is designed with negative spherical aberration and at the same time, the supporting haptics provide proper positioning and fixation of the lens optics within the eye.

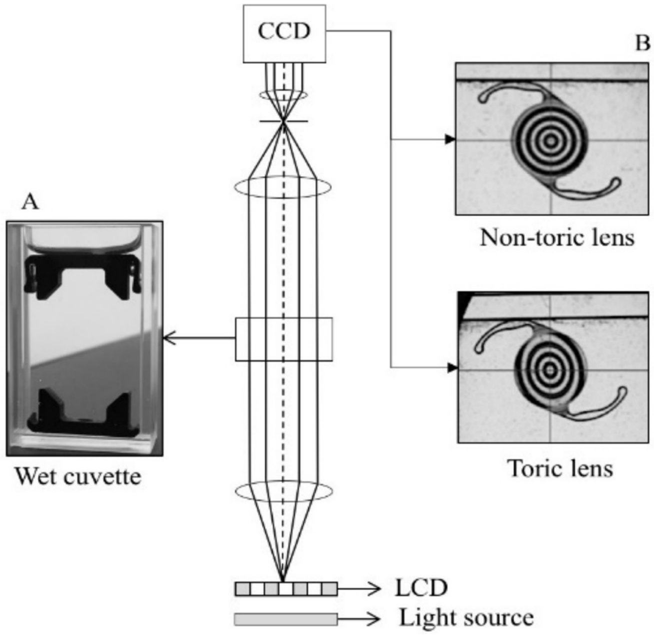

Figure 1 Schematic diagram of the optical device used to measure the intraocular lenses A: Wet-cuvette used to measure each lens; B: Image captured by the charge-coupled device (CCD) camera of the lens measured.

On the other hand, a group of non-toric lenses, which optical power was 16.00, 20.00, 23.00 and 25.00 D, was included as reference purposes. The optical design of the lenses included in this group consists on a biconvex optic with supporting haptics, and its posterior surface is designed with negative spherical aberration to compensate the positive spherical aberration of the average human cornea.

Experimental Procedure The optical quality of each IOL was measured as follows: 1) each lens was inserted into the NIMO's wet-cuvette (Figure 1A) using a pair of tweezers to avoid touching the optical zone of the IOL; 2) the ensemble lens-cuvette was transferred to the NIMO's plate of measurement, and then the optical axis of the lens was aligned with the NIMO's one (Figure 1B); 3) one measurement was taken of the Zernike coefficients up to 7th order; 4) the lens and wet cuvette were removed to obtain independent measurements, and at the same time the lens was removed and reinserted into the wet cuvette; 5) steps two to four were repeated 30 times for 4.50 mm aperture to achieve 30 measurements of each lens. It should be pointed out that the same IOL was used on the 30 measurements.

Several aspects were taken into account prior start taking the measurements, in order to ensure good quality in the measurements. On the one hand, the equipment was turned on 20min before taking the measurements in order to ensure

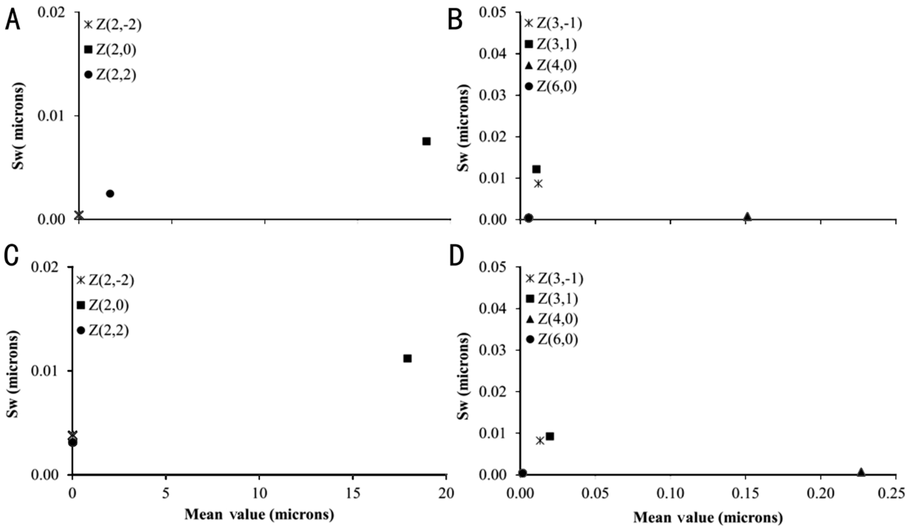

Figure 2 Plot displaying the average root mean square of each Zernike coefficient as a function of its corresponding Sw A and B display the results obtained for the toric lenses; C and D display the outcomes obtained for the non-toric lenses. In both cases, panels A and C represent the low order aberrations, and panels B and D do the high-order aberrations.

Table 1 Repeatability outcomes expressed in terms of Sw and repeatability limit for the toric, non-toric and the mix of both groups (labelled as all lenses)

Parameters	Sw (μm)			Repeatability limit (μm)		
	Toric lenses	Non-toric lenses	All lenses	Toric lenses	Non-toric lenses	All lenses
Z (2, -2)	0.003	0.004	0.003	0.001	0.010	0.007
Z (2, 0)	0.007	0.011	0.009	0.021	0.031	0.026
Z (2, 2)	0.002	0.003	0.003	0.007	0.008	0.008
Z (3, -1)	0.007	0.007	0.007	0.019	0.019	0.020
Z (3, 1)	0.008	0.008	0.008	0.023	0.024	0.024
Z (4, 0)	0.001	0.001	0.001	0.002	0.002	0.002
Z (6, 0)	0.0004	0.0003	0.0004	0.001	0.001	0.001

Sw: Within-subject standard deviation.

sufficient thermal stabilization. At the same time, the room humidity and temperature were kept constant during the whole session, all lenses were manipulated with extremely care, and all measurements were taken during the same session. Finally, and experienced technician was in charge of testing the IOLs.

Statistical Analysis The repeatability of the NIMO TR1504 to measure toric and non-toric IOLs was described in terms of within-subject standard deviation (Sw) and repeatability limit. The Sw was calculated with a one-way analysis of variance[16-18], where subject was used as a factor. Then, repeatability limit, which represent the value within two readings taken with the same method will be for 95% of measurements, was calculated as $1.96 \cdot \sqrt{2} \cdot Sw$ [18].

The repeatability analysis is calculated for each lens group (*i.e.* toric and non-toric groups), and then it is repeated for both groups mixed (labelled along the manuscript as 'all lenses') to clarify whether the repeatability depends on the lens design. In other words, three different groups were defined, one for each lens group and another one for the mix of both. Finally, the Sw and repeatability limit were calculated for the Zernike coefficients Z_2^{-2} (oblique astigmatism), Z_2^0 (defocus), Z_2^2 (vertical astigmatism), Z_3^{-1} (vertical coma), Z_3^1 (horizontal coma), Z_4^0 (primary spherical aberration), and Z_6^0 (secondary spherical aberration).

RESULTS

Figure 2 showed the plot between the average root mean square of each Zernike coefficient and its corresponding Sw. Although the toric and non-toric lens groups showed similar values for the same Zernike coefficient, the toric group resulted with larger values of vertical astigmatism (Z_2^2) than the non-toric one (Figure 2, panels A and C). On the contrary, the non-toric lenses showed larger values of primary spherical aberration (Z_4^0) than the toric ones (Figure 2, panels B and D).

Within Subject Standard Deviation Table 1 depicts the repeatability results expressed in terms of Sw and repeatability limit for the three groups. Regarding the Sw, all groups showed comparable values for the same Zernike coefficient, in which the highest difference was 0.004 μm. Furthermore, the Sw of the three IOLs groups was smaller than 0.011 μm for all Zernike coefficients.

Within the toric lens group, the coefficient Z_3^1 resulted with the highest Sw value, being equal to 0.008 μm; meanwhile the coefficient Z_6^0 showed the lowest outcome, which value was 0.0004 μm. On the other hand, within the non-toric lens group, the coefficient Z_2^0 resulted with the largest value (Sw=0.011 μm), and the coefficient Z_6^0 did with the smallest one (Sw=0.0003 μm). Finally, the same tendency was observed for the group including all lenses.

Repeatability Limit All in all, all lens groups showed similar repeatability limits for each Zernike coefficient, which maximum difference was 0.010 μm (Table 1). Besides, the repeatability limits obtained for each Zernike coefficient was smaller than 0.031 μm for all IOLs groups (Table 1).

Within the toric group, the repeatability limit was smaller than 0.010 μm for all Zernike coefficients, except for the defocus Z_2^0 and both coefficients of 3rd order, which values ranged between 0.019 and 0.023 μm. Similarly, the repeatability limit for the non-toric group was also smaller than 0.010 μm for almost all coefficients except the Z_2^0 and both coefficients of 3rd order, which values ranged from 0.019 to 0.031 μm. Finally, the same tendency was observed for the group including all lenses.

DISCUSSION

The aim of this study was to evaluate the repeatability of the NIMO TR1504 for measuring the Zernike coefficients of IOLs and assess whether the lens toricity has any impact in its repeatability. Besides, the results obtained in this study could elucidate the robustness of this device to measure the optical quality of IOLs.

Regarding to the root mean square of each Zernike coefficient, Figure 2 displays that the highest coefficients for the toric lenses are the defocus (Z_2^0), vertical astigmatism (Z_2^2) and primary spherical aberration (Z_4^0). On the contrary, for the non-toric lenses, the highest coefficients were only the defocus (Z_2^0) and the primary spherical aberration (Z_4^0). As was expected, the toric lens group resulted with higher values of Z_2^2 than the non-toric one because of the intrinsic design of that group.

From an optical point of view, the spherical aberration of an IOL is aimed to compensate the positive spherical aberration of the cornea, and hence improve the patient's visual performance[19]. Furthermore, different amounts of spherical aberrations can be generated modifying the asphericity of either the anterior or posterior lens surface[20]. Aspherical toric lenses have been reported to induce better image quality than spherical toric ones due to the compensation between the corneal positive spherical aberration and the negative lens one[21]. Thus, the retinal image quality of patients implanted with aspherical toric lenses could be expected to be better than those who are implanted with spherical toric ones.

The Sw was similar among all lenses groups (*i.e.* toric, non-toric and all lenses) within the same Zernike coefficient (Table 1), which maximum difference was 0.004 μm. Analogously,

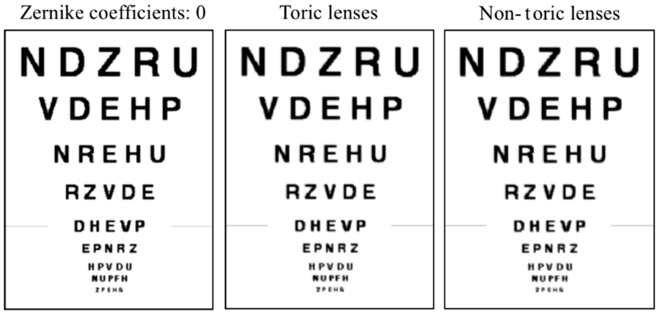

Figure 3 Convolution between the point spread function and a vision test when all Zernike coefficients were 0 μm (left panel), and when each coefficient is equal to its corresponding repeatability limit value for the toric (central panel) and non-toric (right panel) group for 4.50 mm aperture.

comparable values were also obtained in the repeatability limit among the three lens groups within the same Zernike coefficient. Thus, from these results it can be concluded that the repeatability of this device to measure the Zernike coefficients of IOLs is independent of the lens toricity.

Regarding the repeatability values, the Sw obtained within the toric lens group was smaller than 0.010 μm for each Zernike coefficient (Table 1), which values were similar to those obtained with the other two groups. Moving into the repeatability limits, the toric lens group showed values smaller than 0.023 μm for each Zernike coefficient, which outcomes were similar to the non-toric and all lenses groups. Concretely, the value within two readings taken with the NIMO TR1504 will be 0.031 μm for 95% of measurements. To show the effect of this variability graphically, Figure 3 displays the convolution between a point spread function and a vision test when all Zernike coefficients are 0 μm (left panel), and when each coefficient is equal to its corresponding repeatability limit value for the toric (central panel) and non-toric (right panel) group for a pupil diameter of 4.50 mm. As can be seen, the image quality between all panels is quite similar, reflecting that the repeatability of the NIMO TR1504 to measure the Zernike coefficients is good enough to have any impact in the optical quality of the IOL measured.

Two previous studies assessed the repeatability of this system when it comes to measure the spherical power[13] and power profiles[14] of monofocal and multifocal contact lenses, respectively. The former study assessed the reproducibility of the NIMO TR1504 to measure the lens power of spherical and toric contact lenses manufactured with soft and rigid materials. According to the results obtained, the reproducibility standard deviation for toric rigid lenses was found to be 0.014 D for the centered labelled sphere and 0.026 D for cylinder powers; meanwhile the centered labelled sphere and cylinder of the soft toric lenses was 0.059 and 0.093 D, respectively[13].

Regarding the repeatability of the NIMO TR1504 to measure the power profile of multifocal contact lenses, a previous study included 10 lenses of 4 major companies with the same nominal power for distance vision[14]. The results obtained showed that the repeatability limit was good for all multifocal lenses, and the variability of measurement errors of power profiles was homogeneous along the optical zone for all lenses, although the variability was slightly higher in the centre than peripherally for some lenses. At the same time, that study also reported that 1, 2, and 3 measurements would be needed for a measurement tolerance of 0.08, 0.06 and 0.05 D[14].

The main advantage of *in-vitro* measurements is the possibility to assess objectively the optical quality of both contact lenses and IOLs. These outcomes could be used in conjunction with the patient's visual requirements to select the proper lens that could achieve the best visual performance. The ISO 11979-2, which includes the standards to measure IOLs *in-vitro* has been updated recently[22], and recommends using an aberration-free and an aberrated cornea. Unfortunately, there is no consensus on the exact value of the spherical aberration that should be used. For example, Pieh *et al*[23] used a model eye with an aberration of 0.26 μm, and Maxwell *et al*[24] did a model eye with an aberration of 0.20 μm.

There are many systems available to measure the *in-vitro* optical quality of IOLs, such as those based on wavefront sensors, or those that measure the MTF. When it comes to multifocal IOLs, not only should the optical quality be measured at distance-vision focus, but also at their its best-vision foci, as previous studies have done[2-3,25-27]. All of them report the through focus MTF because it represents the variation in the MTF as a function of the vergence for a specific frequency. Additionally, the pupil dependence should also be evaluated to have an insight about the lens performance once it is implanted into the eye. In the end, all these results report objective evidences about the dependence of the lens optical quality with the aperture and vergence of the object. Thus, from all this information, clinicians would be able to choose the proper lens that fits better with the patient's visual requirements.

Differences between lenses of the same vendor, design, spherical power and toric due to the fabrication process have not been taken into account. Furthermore, the NIMO's repeatability to measure the optical quality of toric and non-toric contact lenses have neither been assessed. Thus, further studies should be aimed to assess the variability in the fabrication process, and also assess the repeatability of the NIMO TR1504 to measure the optical quality of toric and non-toric contact lenses. Finally, trueness of NIMO, which is defined as the closeness of agreement between the average value obtained from a large series of test results and the true value, was not studied because the real Zernike values were not known. Further studies could also assess the repeatability of this equipment varies when it measures tilted lenses.

In conclusion, not only is the repeatability of the NIMO TR1504 to measure the optical quality high, but also it does not depend on the IOL toricity. These results reflect that this is a robust system that could be used to measure the *in-vitro* optical quality of either toric or non-toric IOLs.

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