Testing the dioptric power accuracy of exact-power-labeled intraocular lenses

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PURPOSE: To test the accuracy of exact-power-labeled intraocular lenses (IOLs) in a limited independent study.

SETTING: U.S. Food and Drug Administration Optical Testing Lab.

METHODS: Hydrophilic acrylic IOLs were measured using a new confocal laser method for dioptric power measurement per International Organization for Standards standard 11979-2 and American National Standards Institute standard Z80.7. Some of the IOLs were measured at 22°C and 35°C.

RESULTS: For the 18 IOLs tested, the mean difference between the manufacturer's exact labeled power (D_{EL}) and the power measured in the study (D_M) was 0.18 diopter (D) ± 0.12 (SD) and between D_M and the usual normal rounded-off (0.50 D steps) dioptric power (D_{UL}) labeling, 0.23 ± 0.09 D (difference 0.05 D). For 15.00 to 20.0 D IOLs, the mean difference between D_M and D_{EL} was 0.08 ± 0.05 D and between D_M and D_{UL}, 0.17 ± 0.06 D (difference 0.09 D). For IOLs of 20.00 D or greater, the mean difference between D_M and D_{EL} was 0.24 ± 0.11 D and between D_M and D_{UL}, 0.27 D ± 0.08 D (difference 0.03 D). When the IOL hydration temperature increased from 22°C to 35°C (4 IOLs tested), the IOL power increase on average was approximately 0.13 D.

CONCLUSIONS: The small improvement in power-prediction accuracy for exact-power-labeled IOLs decreased in IOLs of 20.00 D or greater. For IOLs of 15.00 to 20.00 D, the increased accuracy (±0.09 D) was statistically significant and could increase predictability of postoperative refractions. Acrylic dioptric power was directly proportional to temperature.

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The first intraocular lenses (IOLs) used by Ridley in the 1950s were not specifically standardized to an international standard but were supplied in 0.50 diopter (D) steps. The international standard[1] (International Organization for Standardization [ISO]) for IOL dioptric power tolerance was first published in 1999, and the United States standard for IOL dioptric power tolerance was published in the 1970s (American National Standards Institute [ANSI]); the standards have undergone numerous revisions.[2] Few surgeons are aware of the tolerances these standards allow for the labeled dioptric power versus the measured dioptric power.

Current ISO[1] and ANSI[2] standards allow a tolerance of ±0.30 D for IOLs of 0.00 D to 15.00 D or less. The tolerance increases to ±0.40 D for IOLs with a power from greater than 15.00 D to 25.00 D or less, meaning an IOL of 19.61 D and another of 20.39 D could be labeled with a dioptric power of 20.00 D. For IOLs from 25.00 D to 30.00 D or less, the tolerance increases again to ±0.50 D; thus, IOLs of 26.51 D and 27.49 D could be labeled with a dioptric power of 27.00 D. The tolerance is ±1.00 D for IOLs greater than 30.00 D; thus, a 30.01 D IOL and a 31.99 D IOL can be labeled with a dioptric power of 31.00 D. These tolerances include the measurement tolerance, which increases with increasing dioptric power.

Over the years, many surgeons have suggested that manufacturers provide IOLs in 0.25 D steps. This has not occurred, mainly because of the costs of increased inventory. In August 2005, Technomed, Inc., announced that for the first time it would begin supplying IOLs labeled with the exact measured dioptric power (J. Schultz, "Exact Refraction Labeling Fills Niche in IOL Industry," Ocular Surgery News, August 15, 2005, pages 19–20. Available at: http://www.osnsupersite.com/view.aspx?rid=6015). The label for a 19.50 D IOL, for example, would also include the 19.63 D that the manufacturer measured. Many lauded this development as an important improvement in the accuracy of IOL dioptric power calculation and questioned why anyone would oppose improved labeling of IOLs. Others believe this factor will not improve IOL dioptric power prediction accuracy because

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other error factors are more important. For example, Norrby[3] suggests that the inaccuracy of the postoperative refraction is much more important than the tolerance of the IOL dioptric power labeling. He stresses that exact power labeling would not improve accuracy because (1) inevitable measurement errors in the manufacturer's exact measurements might negate any advantages and (2) the accuracy of measuring postoperative refractive errors is greater than that resulting from present IOL dioptric power labeling. According to Norrby, if these measurement errors were greater than 0.50 D steps, exact dioptric power labeling would be useless. Evoked by these recent discussions, we thought it might be useful to test exact power labeling of IOLs, which led to the present study.

The conventional methods currently used to measure IOL focal length (or dioptric power) include image magnification, nodal slide, Talbot interferometry, the Bessel method, Moiré deflectometry, and autocollimation.[1,4] The effectiveness of most of these methods is often limited by inaccuracy, spatial sample alignments, subjective image observation/evaluation, and the dynamic range over which measurements can be performed (for positive and negative dioptric powers). Recently, a new confocal laser method for accurate and objective measuring of the dioptric power of both positive and negative IOLs has been developed and used at the U.S. Food and Drug Administration (FDA). [5,6] The confocal laser method is based on an intensity-sensing fiberoptic confocal laser design using a single-mode fiber component that serves simultaneously as a point light source (3 to 5 μm fiber diameter) for formation of a collimated Gaussian laser beam and as a confocal point receiver that is highly sensitive to spatial displacement of the focused back-reflected laser emission. The confocal laser method is highly accurate (in the micron and submicron range) in spatially locating the IOL focal point and in measuring the focal length in a broad range of positive and negative dioptric powers, including high-magnification IOLs with a dioptric power greater than ±20.00 D. The method is also simple, objective, quick, and relatively inexpensive. It provides an independent source of IOL dioptric power measurement data and information for evaluating the effectiveness and safety of new IOL products.

We used the confocal laser method to independently test the dioptric power accuracy of exact-power-labeled IOLs under in situ conditions.

MATERIALS AND METHODS

The FDA 3-piece hydrophilic acrylic IOLs with exact power labeling (EasyCare 600, Technomed, Inc.) for independent testing. The IOLs were provided to the FDA with knowledge of the rounded-off dioptric power label (eg, 19.50 D) but without knowledge of the manufacturer's exact measured dioptric power labeling. The FDA tested all IOLs according to the procedures outlined in ISO 11979-2[1] and ANSI Z80.7.[2] Each IOL was hydrated at room temperature (22°C) for 24 hours and then mounted in a wet cell controlled to a temperature of 35°C (simulating body temperature). The IOLs were tested 1 at a time to prevent a mixup. Even though the rounded-off dioptric powers were on the vial, they could not bias the scientist making the measurement because he was not aware of the values and only measured the back focal length. The measured back focal length at the paraxial focus with the calculated principle plane correction (calculated from manufacturer-provided data) was used to calculate the IOL dioptric power.

As a secondary study, the FDA tested a sample of the IOLs after room temperature hydration at 22°C and then after hydration to body temperature at 35°C to determine the effect of temperature change on the measured dioptric power.

A confocal laser method for IOL dioptric power measurement[5,6] was used to test the dioptric power accuracy of the exact-power-labeled IOLs. Figure 1 shows a basic optical design of the confocal laser method. Basic confocal laser systems include IOL testing setups for measurement of positive and negative IOLs.

Using the confocal laser method, the FDA recently tested various IOL samples with positive (+5.00 to +30.00 D) and negative (−5.00 to −20.00 D) dioptric powers and found high levels of dioptric power testing repeatability estimated by a standard deviation that was typically less than ±0.02 D for positive IOLs and less than ±0.01 D for negative IOLs. The relative errors were typically less than 0.05% for positive IOLs and negative IOLs. These findings show that the confocal laser method has advanced potential for precise IOL dioptric power measurement because the values are significantly smaller than those of the ISO/ANSI dioptric power labeling tolerance limits[1,2] and the dioptric power

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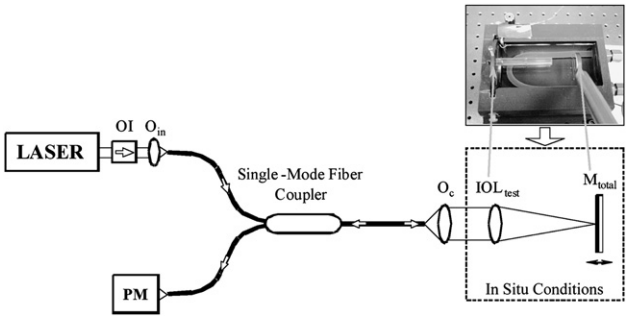

Figure 1. A basic optical design of the confocal laser method for exact dioptric power measurement of IOLs. The upper photograph shows a wet cell used for simulation of in situ conditions (In Situ Conditions = intraocular lens sample container for simulating in situ conditions in a balanced salt solution at temperature of 35°C ± 2°C; IOL_{test} = intraocular lens sample for focal-length testing; LASER = intensity stabilized continuous-wave laser; M_{total} = total reflectance mirror; O_c = infinity-corrected collimating microscope objective; OI = optical isolator; O_{in} = input microscope objective; PM = precise digital optical power meter; Single-Mode Fiber Coupler = 2×1, 50/50 single-mode fiber coupler).

measurement repeatability (typically on the order of 0.15 D) provided by the standard test methods.[1,2] This will be a benefit when newly developed IOL products are tested, such as when testing exact-power-labeled IOLs under in situ conditions, as in this study.

Confocal laser testing systems have no limitation to the wavelength range of the laser source that can be used. The only wavelength requirements are related to the optical fiber coupler component, which should be single mode and within the laser wavelength range, and to the detecting system. Laser sources with various wavelengths in the green–red visible range have been used. However, for reproducibility and to conform to ISO standard requirements, the light source should be in the green spectral range of 546 ± 10 nm. If a light source with different wavelength is used, the dioptric power data measured should be corrected to the green light using ray tracing–based analytical calculations or single reference measurements using a green light source. For testing the dioptric power accuracy of the exact-power-labeled IOLs in this study, an intensity-stabilized low-noise laser source with a wavelength of 658 nm was used. Dioptric power measurement data were corrected using a reference measurement with a green light source.

The accuracy of the confocal laser method of IOL dioptric power measurement depends on several basic factors including the accuracy of focal point location and measurement of back focal length, laser power/detection system signal fluctuations, accuracy of back reflectance mirror scanning, and certain IOL optical properties (eg, aberrations). For testing the dioptric power of all exact-power-labeled IOLs in this study, the confocal laser setup included an intensity stabilized laser (<0.1% power stability), a sensitive photodetecting system, and a 1 μm linear mirror displacement. The signal levels registered at the maximum of the confocal response curve were higher than the signal fluctuations, which did not exceed 1%. Thus, when aberration effects were minimal, focal length measurements were accurate to approximately 1 μm. The corresponding accuracy for determining dioptric power was approximately 0.001 D for the exact-power-labeled IOLs tested. The influence of possible aberration effects on the confocal laser method measurement accuracy is negligible because the confocal laser method approach is based on the use of a monochromatic laser emission with Gaussian beam intensity distribution and relatively small beam diameter, which provides near to theoretical paraxial conditions for collimating and focusing the testing laser beam. Because of these paraxial conditions, the confocal laser method procedure is based on spatially locating the paraxial focal point and in general, this procedure neglects the influence of aberration effects on the measurement accuracy. However, in the case of significant spherical aberration effects, the confocal laser method is compatible with the procedure used in ISO 11979-2 standard[1] for making corrections between the paraxial and the best focal points.

Table 1. Measured dioptric powers of the IOLs.

IOL S/N	Diopters			Difference	
	D_{EL}	D_{UL}	D_M*	$D_M - D_{EL}$†	Between $D_M - D_{UL}$†
01	16.00	16.00	15.912	−0.09	−0.09
02	16.34	16.50	16.307	−0.03	−0.19
03	16.34	16.50	16.318	−0.02	−0.18
04	17.35	17.50	17.294	−0.06	−0.21
05	17.34	17.50	17.239	−0.10	−0.26
06	17.97	18.00	17.82	−0.15	−0.18
07	18.04	18.00	17.895	−0.15	−0.11
08	20.36	20.50	20.151	−0.21	−0.35
09	20.42	20.50	20.177	−0.24	−0.32
10	21.37	21.50	21.148	−0.22	−0.35
11	21.48	21.50	21.158	−0.32	−0.34
12	21.94	22.00	21.613	−0.33	−0.39
14	22.25	22.00	21.789	−0.46	−0.21
16	23.88	24.00	23.717	−0.16	−0.28
17	24.03	24.00	23.769	−0.26	−0.23
18	24.12	24.00	23.878	−0.24	−0.12
19	27.01	27.00	26.787	−0.22	−0.21
20	27.30	27.50	27.299	0.00	−0.20

D_{EL} = manufacturer's exact labeled power; D_M = power measured in the study; D_{UL} = usual normal rounded-off; IOL = intraocular lens; S/N = serial number
*Corrected for the principal plane
†Rounded power differences

RESULTS

Twenty exact-power-labeled IOLs were tested, 4 of which were used in the temperature-change study. Two of the 20 IOLs (#13 and #15) were switched in their vials before arrival at the FDA, as evidenced by each IOL having the measured dioptric power labeled on the other vial. These 2 IOLs were not included in the study.

Table 1 shows the results for each of the 18 IOLs. Table 2 shows a comparison between IOLs from 15.00 to 20.00 D and IOLs greater than 2.00 D) as

Table 2. Effect on increased accuracy of labeling the exact measured dioptric power of the IOL versus using the standard 0.50 D rounded usual labeling.

	Difference (D)					
	All IOLs		15.00 to 20.00 D IOLs		>20.00 D IOLs	
Parameter	D_M-D_{EL}	D_M-D_{UL}	D_M-D_{EL}	D_M-D_{UL}	D_M-D_{EL}	D_M-D_{UL}
Mean absolute difference	0.18	0.23	0.08	0.17	0.24	0.27
Standard deviation	0.12	0.09	0.05	0.06	0.11	0.08
Increased accuracy	0.05		0.09		0.03	
P value*	.068		.038		.448	

D_{EL} = manufacturer's exact labeled power; D_M = power measured in the study; D_{UL} = usual normal rounded-off; IOL = intraocular lens
*Paired *t* test

well as the values for all IOLs. Results show that the IOLs with exact dioptric power labeling were, on average, 0.05 D closer to the actual dioptric power (P = .068). The 15.00 to 20.00 D IOLs with exact dioptric power labeling were, on average, 0.09 D closer to the actual dioptric power than the standard 0.50 D rounded usual labeling (P = .038). The IOLs with 20.00 with exact dioptric power labeling were, on average, 0.03 D closer to the actual dioptric power, essentially no different than the results of standard 0.50 D rounded usual labeling (P = .448). The increased accuracy associated with the exact power labeling was statistically significant only in the 15.00 to 20.00 D group.

Table 3 shows the results in the temperature-change study. The differences between the 2 sets of temperature values ranged from −0.236 to +0.145 D, with a mean increase of 0.13 D with increase in temperature. This may be another source of a slight error after the IOL rehydrates in the eye.

DISCUSSION

It is a laudable goal to attempt to increase the specificity of labeling the dioptric power of IOLs in the hope of increasing the accuracy of IOL dioptric power prediction for patients. Overall, it appears as though the 0.05 D increase in accuracy with exact labeling is not significant. However, when IOLs were divided into 2 groups by dioptric power ranges IOLs in the 15.00 to 20.00 D range performed better (0.09 D) than the IOLs greater than 2.00 D (0.03 D). This observation may result from the greater measurement uncertainty associated with increased dioptric powers. The 0.09 D improvement in accuracy may not seem clinically significant; however, it is 3 times greater than that for the 20.00 D or higher IOLs. Today, when we are trying to eliminate as many errors as we can, a tenth of a diopter may be an improvement worth making. We hope that manufacturers would evaluate ways to improve this accuracy.

A mean increase in dioptric power of 0.13 D was observed when going from room-temperature testing (22°C) to eye-temperature testing (35°C). This change in dioptric power is related to the differences in hydration and refractive index of the optic material between the 2 temperatures. It is not known whether the manufacturer of the IOLs used in our study test the dioptric power at eye temperature; however, the 0.13 D difference in dioptric power shows the importance such testing when determining the dioptric power of IOLs of certain materials.

Table 3. Results of dioptric power measurement depending on temperature of hydration.

		IOL Room Temperature: Hydration at 22°C		IOL Body Temperature: Hydration at 35°C		
IOL S/N	D_{EL}	D_M	Diff D_M-D_{EL}	D_M*	D_M-D_{EL}	Diff (D_M-D_{EL} at 35°C)−(D_M-D_{EL} at 22°C)
01	16.00	15.873	−0.127	16.045	0.045	0.172
09	20.42	20.184	−0.236	20.408	−0.012	0.224
17	24.03	23.880	−0.150	23.868	−0.162	−0.012
20	27.30	27.299	−0.001	27.445	0.145	0.146

D_{EL} = manufacturer's exact labeled power; Diff = difference; D_M = power measured in the study; D_{UL} = usual normal rounded-off; IOL = intraocular lens; S/N = serial number
*Corrected for the principal plane

In conclusion, using a new confocal laser method for precise and objective, we independently tested the dioptric power accuracy of exact-power-labeled IOLs. The dioptric power for the tested 18 hydrophilic acrylic 3-piece IOLs increased, on average, by approximately 0.13 D when the temperature was changed from 22°C to 35°C. There was a relatively small improvement in IOL power prediction accuracy (0.05 D). The improvement decreased as the IOL power increased. The IOLs of 15.00 to 20.00 D had a 0.09 D improvement in IOL power prediction accuracy, and IOLs greater than 20.00 D had a 0.03 D improvement. The increased dioptric power accuracy (3 times greater) with the IOLs less than 20.00 D may be related to the lower labeled tolerance associated with the lower power group of IOLs than that with the higher power group of IOLs.

REFERENCES

1. International Organization for Standardization. Ophthalmic implants – Intraocular lenses – Part 2: Optical Properties and Test Methods. Geneva, Switzerland, ISO, 1999 (ISO 11979-2)
2. American National Standards Institute, Inc. American National Standard for Ophthalmics – Intraocular Lenses. ANSI Z80.7, 2002
3. Norrby S. Sources of error in intraocular lens power calculation. J Cataract Refract Surg 2008; 34:368–376
4. Smith WJ. Modern Optical Engineering: The Design of Optical Systems 2nd ed. New York, NY, McGraw-Hill, 1990; 494–514
5. Ilev IK. A simple confocal fibre-optic laser method for intraocular lens power measurements. Eye 2007; 21:819–823
6. Ilev IK, inventor; Venable LLP, agent. Confocal fiber-optic laser device and method for intraocular lens power measurements. International Patent 60/668 239, March 3, 2005. Available at: http://www.faqs.org/patents/app/20080278712. Accessed July 21, 2009