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Assessing the effect of laser beam width on quantitative evaluation of optical properties of intraocular lens implants

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Abstract. The design and manufacture of intraocular lenses (IOLs) depend upon the identification and quantitative preclinical evaluation of key optical properties and environmental parameters. The confocal laser method (CLM) is a new technique for measuring IOL optical properties, such as dioptric power, optical quality, refractive index, and geometrical parameters. In comparison to competing systems, the CLM utilizes a fiber-optic confocal laser design that significantly improves the resolution, accuracy, and repeatability of optical measurements. Here, we investigate the impact of changing the beam diameter on the CLM platform for the evaluation of IOL dioptric powers. Due to the Gaussian intensity profile of the CLM laser beam, the changes in focal length and dioptric power associated with changes in beam diameter are well within the tolerances specified in the ISO IOL standard. These results demonstrate some of the advanced potentials of the CLM toward more effectively and quantitatively evaluating IOL optical properties. © 2014 Society of Photo-Optical Instrumentation Engineers (SPIE) [DOI: 10.1117/1.JBO.19.5.055004]

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1 Introduction

Intraocular lens (IOL) implantation is the most commonly performed surgical procedure, averaging approximately 3 million/year in the United States¹ and 19.7 million/year worldwide.² The IOL industry is growing rapidly, with new IOL designs and materials emerging each year and a market value projected to reach \$3.8 billion by 2019.² Some new designs have led to additional complications resulting in explantation to realign or exchange the lens.^{3,4} As a result, the implementation of novel methods to evaluate current and future IOL optical properties is needed to reduce IOL complications.

The international organization for standardization (ISO) specifies environmental parameters and tolerances to accurately characterize optical properties of IOL designs (e.g., temperature, solution conditions, and optical parameters of the testing system).⁵ In addition to environmental parameters, the ability to identify and evaluate critical optical properties (e.g., dioptric powers and image quality) is important, as they may impact IOL performance and can themselves be influenced by environmental parameters.

The IOL dioptric power⁶ is a critical optical characteristic for evaluating IOL efficacy, and its accurate assessment is a major factor in implanting the appropriate lens for improving vision to precataract states. One of the conventional methods currently used for determining the IOL dioptric power is based on measuring the back focal length (F_{BFL}) with an optical microscope with standard deviations as low as 0.01 mm.⁷ In this evaluation, the microscope is focused onto the back surface of the IOL and

subsequently the image of the IOL target. The distance between these two focused locations provides the F_{BFL} . The effective focal length (F_{eff}) is then calculated by Eq. (1) below:

$$F_{\text{eff}} = F_{\text{BFL}} / [1 - t(n_{\text{IOL}} - n_{\text{med}}) / (n_{\text{IOL}}R)], \quad (1)$$

where t is the thickness of the IOL, R is the IOL front surface radius of curvature, and n_{IOL} and n_{med} are the refractive indices of the IOL and surrounding medium, respectively. Finally, the effective focal length is directly converted into dioptric power (D_{IOL}) by $D_{\text{IOL}} = n_{\text{med}} / F_{\text{eff}}$.⁵

ISO standards recommend using a 3-mm aperture for all F_{BFL} measurements to standardize measurements and minimize deviations due to defocusing from the nonparaxial beams of the optical microscope. Longitudinal spherical aberrations (LSA) inhibit the ability to distinguish an object from its background, resulting in a significant defocusing factor.⁸ By using a standard aperture diameter, a known defocusing (D_{ef}) correction of $D_{\text{ef}} = \text{LSA}/2$ can be incorporated into all D_{IOL} measurements where LSA is the first primary aberration.⁹ However, measuring the LSA numerical value is not trivial and requires a ray-tracing analysis to determine the distance between the back paraxial focal point and the intersection of the meridional ray; this process has been described as “both a science and an art.”⁹ As a result, estimating LSA ultimately leads to some dioptric power uncertainties even with the use of a standardized aperture diameter.

In certain measurements, a 3-mm aperture diameter may not be suitable for measuring IOL dioptric powers. For example, a measurement of the primary dioptric power of a multifocal

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IOL requires the light source to be smaller than the IOL's first concentric ring, which can be as small as 1 mm. Additionally, with nonparaxial light sources, these changes in aperture diameters may result in different LSA values, due to changes in longitudinal spherical aberrations, and lead to further IOL dioptric power calculation uncertainties.

Recently, an advanced confocal laser method (CLM) was developed to improve the accuracy, repeatability, and precision of testing IOL dioptric powers.^{10–13} The CLM operating principle is based on a simple fiber-optic confocal laser design that integrates properties of high-resolution confocal microscopy and fiber-optic sensing.¹⁰ A key component of the CLM design is a single-mode fiber module that serves simultaneously as a point light source (3–5- μm fiber core diameter) for the formation of a collimated laser beam with a Gaussian intensity profile and as a highly sensitive confocal point receiver to measure spatial displacement of the focused back-reflected laser emission. As a result, LSA defocusing is minimized and diminishes the importance of a standardized beam diameter, which can be helpful when evaluating different IOL designs.

We have added an adjustable iris aperture to the CLM platform, which allows the beam diameter to be precisely manipulated to determine its influence on the IOL dioptric power measurements. Here, we present the quantitative results of these experiments for measurements of monofocal IOL dioptric powers and demonstrate that aperture diameters do not significantly impact CLM measurements. As a result, the CLM technique can be used to accurately evaluate the dioptric powers of more complex designs that require different aperture diameters, such as multifocal IOLs, as well as improve the overall accuracy and repeatability of dioptric power measurements by potentially eliminating the need for LSA corrections.

2 Experimental Method

The CLM-based optical setup¹⁴ used for this study is illustrated in Fig. 1. The laser beam profile assessment was conducted with monofocal IOLs of different dioptric powers and materials. Dioptric powers were measured with IOLs in air and at room temperature (approximately 20.0°C) using a 543-nm (± 1 -nm) low-noise laser (Opto Engine LLC, Midvale, Utah). The laser spatial intensity distribution and beam profile were determined using a laser beam profiler (Ophir-Spiricon Inc., North Andover, MA).

A thorough description of the CLM technique for its precise measurement of IOL dioptric powers has been described previously.^{10–12} Briefly, a 1×2 single-mode optical fiber coupler (Newport Corp., Irvine, California) was integrated with a

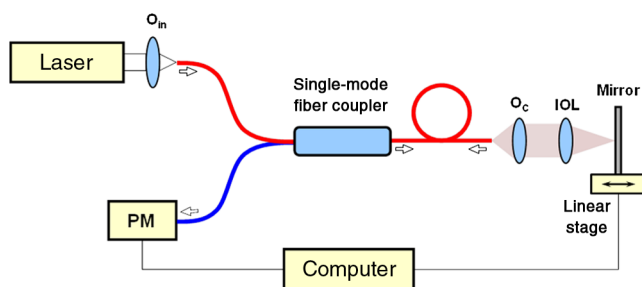


Fig. 1 The configuration of the experimental setup using the CLM method where O_{in} is the optical input, OC depicts the collimation of the beam using the 10 $\times$ objective lens, and PM portrays the Ophir power sensor and meter used to measure the focal point profile.

10 $\times$ infinity corrected objective lens (Edmund Optics Inc., Barrington, New Jersey) to establish a collimated Gaussian beam. Figure 2 shows typical three- and two-dimensional Gaussian laser beam profiles formed by the single-mode fiber coupler. An IOL was then placed in front of the collimated laser beam where the back reflectance of the focused light (F_{BFL}) was detected and measured back through the fiber coupler using a low-power thermal sensor connected to a computerized power meter (Ophir, North Andover, Massachusetts), as shown in Fig. 1. Alignment of the setup, as well as IOL positioning, is critical for accurate measurements utilizing confocal microscopy. Beam collimation is confirmed quantitatively without the presence of an IOL by measuring a constant back reflected power from a linearly translating total reflectance mirror.

By measuring the distance between observed focal and half-focal points, IOL dioptric powers can be accurately measured. To improve precision and repeatability, the back-reflectance mirror was attached to an automated linear stage (Thorlabs Inc., Newton, New Jersey) with step sizes as short as 1 μm . The laser beam diameter was changed using a ring-activated iris diaphragm (Thorlabs Inc., Newton, New Jersey) integrated within the platform. The resulting focal peak locations, laser intensity distributions, and beam widths were determined and compared using a scientific data processing package (OriginLab Corp., Northampton, Massachusetts).

The use of a monochromatic laser emission with a Gaussian beam profile and relatively small beam diameter provides near to the theoretical paraxial conditions for collimating and focusing the testing laser beam. As a result, various aberration effects have negligible influences on measurement accuracies. Dioptric power measurements, as well as focal point profiles, were studied for fully open (3.43-mm), 3-mm (ISO Standard requirement), 2-mm, and 1-mm diameter apertures. The actual shape of the focal point profiles (or confocal response curve) was not perfectly symmetrical, which made the peak location difficult to determine, particularly as the full width at half maximum changed with different aperture settings. With confocal microscopy techniques, various peak identification algorithms are often used to improve confocal axial resolution, such as a real peak detection approach.^{14,15} Here, the raw data of the focal point profiles were analyzed by fitting a Gaussian peak to the top 20% of each curve, improving the accuracy compared to basic peak fitting techniques.

Acrylic monofocal IOL test samples were used for the experiments from three common IOL dioptric power ranges: low (10.0 D), medium (20.0 D, 20.75 D), and high (34.0 D), and labeled as IOL #1, #2, #3, and #4, as shown in Table 1.

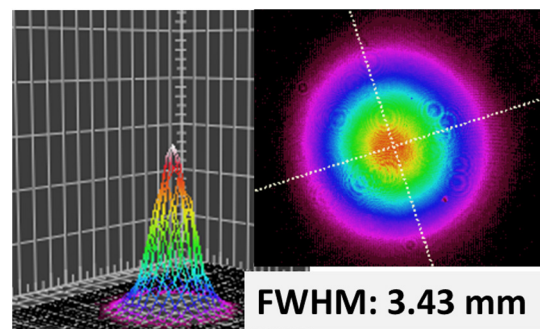


Fig. 2 Laser beam profile using the Beamstar FX50 laser beam profiler from single-mode fiber. Inset shows cross section of laser signal.

Table 1 Measured dioptric power changes when changing diameter of exposed laser beam. Averages, percent errors, and standard deviations are shown in the last three columns.

IOL #	Labeled dioptric power (D)	Dioptric power at varied laser beam widths (D)				Average	% Error	Standard deviation
		1 mm	2 mm	3 mm	3.43 mm			
1	10.0	10.294	10.312	10.305	10.297	10.302	2.93	0.009
2	20.0	19.999	20.003	19.999	19.998	20.000	0.00	0.002
3	20.75	20.764	20.758	20.743	20.762	20.757	0.03	0.011
4	34.0	34.199	34.186	34.207	34.201	34.198	0.58	0.011

The IOL materials used were hydroxyethylmethacrylate and polymethylmethacrylate. All IOL types were measured in identical environmental conditions to ensure accuracy.

3 Results and Discussion

The changes in IOL dioptric power due to the variable aperture are shown in Table 1, where IOLs of varying dioptric powers are labeled #1, #2, #3, and #4. Figure 3 shows the focal point peak profile for IOL #2, where a change in profile shape or peak with respect to aperture diameter turned out to be insignificant. These results suggest that the focused light from the IOL produces a paraxial ray of light with negligible aberration effects. Since the focal point peak profile shapes and locations remain constant, the measured dioptric powers also remain accurate and repeatable, as shown in Table 1. The 8th column in Table 1 shows the percent errors compared to the labeled powers. IOLs #2, #3, and #4 were found to be within the acceptable ISO tolerance range, while IOL #1 was on the fringe. The reason for this discrepancy is not fully understood and is currently being studied further.

The final column of Table 1 shows minimal standard deviations for all the laser beam diameter measurements with negligible variances in the dioptric power readings. The actual dioptric power differences within trials range from 0.005 D to 0.021 D, which is within the range of CLM accuracy and are significantly lower than the tolerances specified in the ISO Standard.⁵ These findings strongly suggest that LSA effects

are negligible when determining IOL dioptric powers with the CLM technique.

Although the dioptric power measurements remained relatively consistent for all aperture diameters, at 1-mm an increase in measurement deviations and inaccuracies was observed. Observed deviations were likely due to alignment issues that become exaggerated as the beam diameter decreases as opposed to known discrepancies due to LSAs. These observations occurred for the thicker, higher IOL dioptric power lenses, suggesting that the decrease in signal intensity may be the more significant factor. However, it should be noted that although dioptric power measurement differences are observed, these differences are still insignificant according to ISO standard specifications.⁵

The inset of Fig. 3 shows the calculated Gaussian fit for the focal point profile for the 3-mm aperture with a 0.999 R^2 fit. Similar observations were observed for all IOLs measured as well as for different aperture diameters. The ability to use a Gaussian fit to describe the focal and half-focal points significantly improves the accuracy of IOL dioptric power measurements. These results suggest that the focal spots with the CLM platform, particularly at the top of the profile curve, can be treated as paraxial. As a result, LSA affects could be considered negligible and the corresponding corrections may no longer be necessary.

Although not discussed here, the CLM technique can be used to evaluate the dioptric powers of other IOL types (e.g., multifocal and toric IOLs). Furthermore, the flexibility of changing the aperture diameter may improve the accuracy and feasibility of results from newly introduced IOL types.

4 Conclusions

The discussed results suggest that the CLM technique is a highly accurate quantitative approach for determining IOL dioptric powers. Furthermore, fitting the focal point profiles to Gaussian curves results in improved accuracies ($\leq 1 \mu\text{m}$) and repeatability (≤ 0.021 D). Moreover, due to the paraxial Gaussian shape of the focal point profile, changes in diameter of the laser beam profile as well as longitudinal aberrations may be negligible and no longer require LSA corrections.

This particular study is focused on monofocal IOLs for comparison purposes. However, the CLM platform is capable of testing dioptric powers from other IOL designs (e.g., multifocal and toric) and the discussed results may lead to improved optical property evaluations for all IOL designs. Nevertheless, the optical properties of each new IOL design should be independently evaluated to determine its safety and efficacy. Other potential

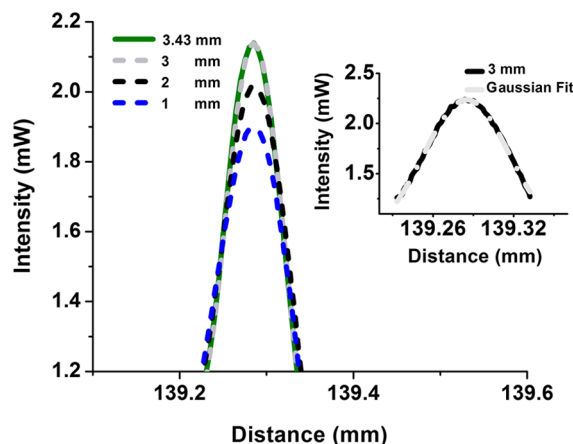


Fig. 3 Effects of laser beam diameter changes on the shape and positioning of the IOL focal point profile for IOL #2. Inset shows Gaussian fit for the 3-mm beam profile with a 0.999 R^2 value. Results show that minimal change is observed with change in diameter of the laser beam, indicating a paraxial configuration with CLM.

parameters that may influence IOL dioptric power measurements (e.g., surrounding medium and optical properties of the incident light) require equal scrutiny to determine their specific impacts when evaluating intraocular lenses.

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Bennett N. Walker received his PhD in chemistry at George Washington University, where he focused on the development, understanding, and application of nanophotonic ion sources. He specialized in laser-nanostructure interactions, which resulted in two patents. He joined the FDA as a research fellow, where he focuses on understanding photonic properties of intraocular lenses and the development of test methods for precise and objective preclinical laboratory testing of IOL optical characteristics.

Robert H. James has more than 40 years of experience in the US Food and Drug Administration, where he has developed laboratory evaluation procedures for optical radiation safety of light emitting products, medical lasers, and intraocular lenses. He has published in peer-reviewed journals, presented at conferences, and has been active in ANSI and ISO standards committees. In recent years he transitioned away from supervisory duties to a part-time research position concentrating on optical medical devices.

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Don Calogero has a master's degree in biomedical engineering from the State University of NY at Stony Brook and has 34 years of experience evaluating intraocular devices such as intraocular lenses prior to their clinical investigation and FDA approval. He has published in peer-reviewed journals, presented at major national and international ophthalmic meetings, and has led the development of ANSI and ISO intraocular implant standards.

Iiko K. Ilev is the leader of the Optical Therapeutics and Medical Nanophotonics Laboratory, and he is appointed to the Senior Biomedical Research Service (SBRS) at U.S. FDA. He has a PhD in quantum and laser physics. He has over 25 years of experience in the United States, Europe and Japan, with more than 350 publications in the field of laser technologies, biophotonics, nanobiophotonics, high-resolution imaging and sensing, biomedical and fiber optics, and laser safety.