Innovative confocal laser method for exact dioptric power measurement of intraocular lens implants

Invited Paper

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Received September 18, 2008

We present a novel confocal laser method (CLM) for precise testing of the dioptric power of both positive and negative intraocular lens (IOL) implants. The CLM principle is based on a simple fiber-optic confocal laser design including a single-mode fiber coupler that serves simultaneously as a point light source used for formation of a collimated Gaussian laser beam, and as a highly sensitive confocal point receiver. The CLM approach provides an accurate, repeatable, objective, and fast method for IOL dioptric power measurement over the range from 0 D to greater than ±30 D under both dry and *in-situ* simulated conditions.

OCIS codes: 170.1790, 170.4460, 170.3890, 060.2370.
doi: *10.3788/COL20080612.0876.*

Refractive cataract surgery using intraocular lens (IOL) implantation has become one of the most commonly performed operations in medicine since the invention of the IOL in 1949[1] with more than 500 million IOLs implanted worldwide. The surgery involves removing the clouded crystalline lens (cataract) through a small incision in the eye and implanting an IOL prosthesis that provides clear corrected vision. A significant number of visually impaired patients will result if even a small percentage of these implantations result in complications that require a second surgery to explant and replace the IOLs. Most of these complications are directly related to some fundamental IOL optical properties such as incorrect dioptric power, reflected glare, light scattering, imaging quality, material refractive-index, thickness, and geometrical shape. The focal length (or dioptric power) is a key parameter whose precise preclinical measurement is of critical importance for characterizing and evaluating the effectiveness and safety of IOLs. Conventional methods currently used for IOL dioptric power testing are based on some indirect measurement approaches such as image magnification, nodal slide, Talbot interferometry, Bessel's method, Moiré deflectometry, and autocollimation[2−7]. The effectiveness of most of these methods is often limited in terms of accuracy, spatial sample alignments, subjective image observation/evaluation, and the dynamic range over which measurements can be performed (for both positive and negative dioptric powers). Moreover, recently developed new IOL materials and designs such as toric, multifocal, and aspheric IOLs, have introduced new problems which include difficulty in testing precise IOL dioptric power. To resolve some of the disadvantages of the currently used testing methods, we demonstrate an alternative fiber-optic-based confocal laser method (CLM) for precise IOL dioptric power measurement. Using the CLM approach, we present results on preclinical testing of various IOL samples including positive, negative, and high-power IOLs under both dry and *in-situ* simulated conditions.

The CLM principal design is illustrated in Fig. 1. It includes a simple apertureless fiber-optic laser confocal arrangement[8,9]. The key CLM element is a 2×1 50/50 single-mode fiber coupler that converts the output emission of an intensity-stabilized continuous-wave laser (a 658-nm wavelength diode laser) into a precisely collimated Gaussian laser beam which is focused on a backreflectance mirror surface (M_{total}) by the focusing IOL element to be tested (IOL_{test}). Because of its high sensitivity to spatial displacements of the focused backreflectance laser beam, the fiber-optic CLM design provides a precise spatial location of the focal point when the total backreflectance mirror is axially scanning and therefore, a high accuracy in measuring the focal length of the tested IOL elements can be achieved. The single-mode fiber coupler includes small core diameter ($3 - 5$ μm) fibers and it simultaneously performs several significant functions. First, the fiber coupler ensures

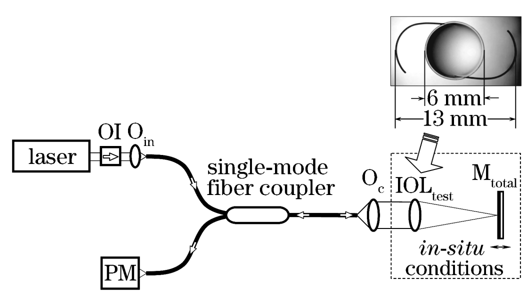

Fig. 1. Principal optical design of the fiber-optic CLM for exact dioptric power measurement of IOLs. laser: intensity stabilized continuous-wave laser; OI: optical isolator; O_{in}: input microscope objective; PM: precise digital optical power meter; single-mode fiber coupler: 2×1 50/50 single-mode fiber coupler; O_c: infinity corrected collimating microscope objective; IOL_{test}: IOL sample for focal-length testing; M_{total}: a total reflectance mirror. The upper photograph shows a typical IOL design.

effective launching and delivery of the input laser emission. Second, the output small-core diameter single-mode fiber tip serves as a point light source that delivers a Gaussian laser beam distribution. In combination with the advantages ensured by the use of a point-light-source fiber tip and an infinity corrected objective (O_c), the Gaussian beam distribution provides a means for precisely collimating the input laser emission directed to the test focusing lens. Third, the same output single-mode fiber tip used as a point light source serves as a point receiver that is highly sensitive to spatial displacements of the focused backreflectance laser emission. Fourth, the fiber coupler ensures delivery of the spatially separated backreflected laser emission to a detector system. Thus, the combination of these specific CLM features provides high accuracy (≤ 1 μm) in spatially locating the IOL focal point and therefore, in measuring the IOL dioptric power.

Using the CLM principle (Fig. 1), the IOL dioptric power is determined by precise spatial location of the back focal point and measurement of the IOL back focal length (BFL), which is the distance from the vertex of the last IOL optical surface to the rear focal point located. The CLM design can be applied to both positive and negative dioptric power IOLs. For positive dioptric power measurements, the IOL effective focal length (F_{eff}) is determined by the directly measured BFL (F_{BFL}) of the IOL sample. F_{BFL} is measured in two steps: 1) spatially locating the back focal point of the IOL sample by axial scanning of the backreflectance mirror and maximizing the detected backscattered laser power; and 2) measuring the distance between the located back focal point and the IOL's back vertex using precise translational micrometric stages. To obtain the IOL effective focal length F_{eff}, the CLM procedure includes a correction for the distance from the back vertex to the back principal plane of the IOL, which is made by using the measured back focal length F_{BFL} and the following equation[2]:

$$F_{\text{eff}} = F_{\text{BFL}}/[1 - t(n_{\text{IOL}} - n_{\text{med}})/n_{\text{IOL}}R_1], \tag{1}$$

where t is the IOL thickness; R_1 is the front surface radius of curvature; n_{IOL} and n_{med} are the refractive indexes of the IOL and the surrounding medium (in air $n_{\text{med}} = 1$), respectively.

For negative dioptric power measurements, the principal CLM design (Fig. 1) is modified as shown in Fig. 2. It includes an additional conventional positive lens with known focal length L_p (Fig. 2). The IOL_{test} focal length is determined using the experimentally measured BFL of the negative-positive lens configuration[8,9].

We have measured IOL dioptric powers under two environmental conditions: 1) in air with dry IOL samples; and 2) in *in-situ* simulation conditions using either a thin

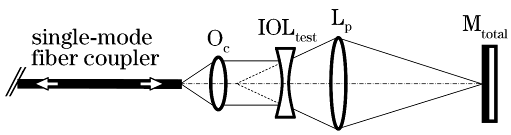

Fig. 2. An additional set-up to the principal CLM optical design shown in Fig. 1 for negative IOL dioptric power testing. L_p: a conventional positive lens with known focal length.

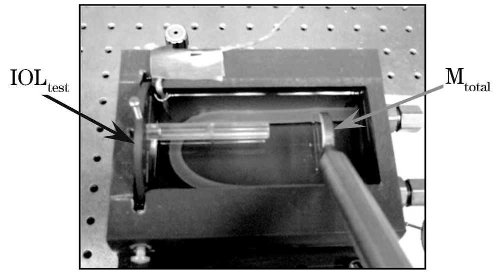

Fig. 3. *In-situ* simulation design including a bulk wet cell with balanced saline solution for all optical elements.

glass/quartz cuvette ($1-2$ mm optical path in balanced saline solution) or a bulk wet cell (shown in Fig. 3). When the bulk wet cell is used, the IOL sample is placed in balanced saline solution of various concentrations and maintained at a constant temperature of 35 °C ± 0.5 °C (simulating implantation in the human eye), in accordance with the International Standard published by ISO[10]. To determine the IOL dioptric power in air $D_{\text{IOL-air}}$) or *in-situ* simulation conditions ($D_{\text{IOL-In}}$), we can use the equations:

$$D_{\text{IOL-air}} = 1/F_{\text{eff-air}}, \tag{2a}$$

$$D_{\text{IOL-In}} = n_{\text{med}}/F_{\text{eff-In}}, \tag{2b}$$

where n_{med} is the refractive index the surrounding balanced-saline-solution medium; $F_{\text{eff-air}}$, $F_{\text{eff-In}}$, are the effective focal lengths of the IOL sample in air and *in-situ* simulation conditions, respectively, which for positive dioptric power IOL measurements can be determined using Eq. (1).

The new CLM designs described (Figs. $1-3$) have been used for testing various IOL samples with both positive and negative dioptric powers. For positive power measurements, we have tested IOLs having dioptric powers over the range from 0 D to $\geq +30$ D. Table 1 displays some typical CLM measurements of positive dioptric power IOLs. The CLM design provides a high repeatability in the range of 0.004 D to 0.06 D and a relative error in the range of 0.015% to 0.3%, estimated by a standard deviation analysis using the experimental data obtained from IOL test samples with positive dioptric powers spanning the range +5 D to +30 D.

For negative dioptric power measurements, we have tested IOLs with powers in the range of 0 D to ≥ -20 D. Some typical CLM results obtained from negative dioptric power measurements are shown in Table 2. In this case, the CLM measurement repeatability is in the range of 0.003 D to 0.013 D and a relative error in the range of 0.02% to 0.16%, which has been estimated using the experimental data obtained from IOL test samples with negative powers in the range -5 D to -20 D.

An advanced feature of the proposed CLM concept is that it has no limitations with regards to the testing dioptric power of various focusing elements and systems. Using simple, precise, and objective alignment procedures, the CLM design is applicable in a broad range of both positive and negative dioptric powers including high-magnification IOLs with dioptric powers, in magnitude, greater than ±20 D as well as conventional focusing

Table 1. Typical CLM Measurements of Positive Dioptric Power IOLs

Test IOL S/N	Labeled Power [D]	Measured Power [D]	Average Power [D]	Repeatability (Standard Deviation [D])	Repeatability (Relative Error [%])
1	+18.50	+18.403 +18.442 +18.411	+18.418	0.020	0.108
2	+20.00	+20.032 +20.072 +20.061	+20.065	0.021	0.105
3	+25.50	+25.491 +25.502 +25.499	+25.497	0.006	0.023

Table 2. Typical CLM Measurements of Negative Dioptric Power IOLs

Test IOL S/N	Labeled Power [D]	Measured Power [D]	Average Power [D]	Repeatability (Standard Deviation [D])	Repeatability (Relative Error [%])
1	−8.00	−7.762 −7.756 −7.751	−7.756	0.005	0.06
2	−12.00	−12.034 −12.039 −12.040	−12.038	0.003	0.02
3	−14.50	−14.701 −14.719 −145.716	−14.712	0.0096	0.06

elements and systems. Furthermore, additional advantages include the CLM potential for significantly improved accuracy ($\leq$ 1 μm in locating the IOL focal point versus more than several tens of microns for the standard test methods[10]) and repeatability (typically $<$ 0.03 D versus 0.15 D using the standard test methods) in IOL dioptric power testing. In addition, because the CLM concept involves the use of a monochromatic laser emission with Gaussian beam intensity distribution and relatively small beam diameter, it provides near-to-the-theoretical paraxial conditions for collimating and focusing the testing laser beam while various aberration effects have a negligible influence on the CLM measurement accuracy. Thus, the CLM 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 CLM procedure is compatible with the procedure used in the International Standard published by ISO[10] for making corrections between the paraxial and the best focal points. These are essential advantages when newly developed IOL products are tested such as exact-diopter-labeled IOLs under *in-situ* conditions.

In conclusion, the CLM operating principle and designs provide a simple, accurate, completely objective, quick, and inexpensive method for measuring the dioptric power of both positive and negative IOLs. In addition, the CLM concept can be used for measuring the focal length of various focusing optics including positive and negative lenses, objectives, contact lenses, eyeglasses, and mirrors.

The mention of commercial products, their sources, or their use in connection with material reported herein is not to be construed as either an actual or implied endorsement of such products by the Department of Health and Human Services.

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