Video Article

Scanning Light Scattering Profiler (SLPS) Based Methodology to Quantitatively Evaluate Forward and Backward Light Scattering from Intraocular Lenses

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Abstract

The scanning light scattering profiler (SLSP) methodology has been developed for the full-angle quantitative evaluation of forward and backward light scattering from intraocular lenses (IOLs) using goniophotometer principles. This protocol describes the SLSP platform and how it employs a 360° rotational photodetector sensor that is scanned around an IOL sample while recording the intensity and location of scattered light as it passes through the IOL medium. The SLSP platform can be used to predict, non-clinically, the propensity for current and novel IOL designs and materials to induce light scatter. Non-clinical evaluation of light scattering properties of IOLs can significantly reduce the number of patient complaints related to unwanted glare, glistening, optical defects, poor image quality, and other phenomena associated with the unintended light scattering. Future studies should be conducted to correlate SLSP data with clinical results to help identify which measured light scatter is most problematic for patients that have undergone cataract surgery subsequent to IOL implantation.

Video Link

The video component of this article can be found at https://www.jove.com/video/55421/

Introduction

The scanning light scattering profiler (SLSP) approach was first introduced to address the need to quantitatively evaluate light scattering characteristics of intraocular lenses (IOLs) in a non-clinical setting[1]. Developing a test methodology to evaluate the light scattering tendencies of IOL designs and materials is of significant interest in order to help identify potential unwanted light scattering problems. Light scatter is commonly reported by patients and observed as glare, glistening, optical imperfections, and other forms of dysphotopsia[2], sometimes leading to a patient requesting the IOL explantation. In addition to dysphotopsia, scattered light reduces the amount of ballistic light, resulting in lower overall image quality[3]. Developing a device that can non-clinically evaluate the IOL potential to scatter the incoming light (and later correlated with clinically reported outcomes) can be useful.

Evaluating optical properties of IOLs (the lens used to replace the human crystalline lens after cataract surgery) is of particular interest as it is the most commonly implanted medical device in the world (almost 20 million per year)[4] and the United States (over 3 million per year)[5]. As a result, even a small percentage of patients reporting dysphotopsia may have a large impact. In addition, rapidly improving technologies (*e.g.* new IOL designs, materials, and optical capabilities) have the potential to increase concerns related to light scattering. For example, multifocal IOLs have been designed to improve near and far visual acuity by designing lenses that utilize refraction and diffraction optical principles. Although highly successful, these lenses have also been found to increase the amount of reported halos and glare, largely associated with scattering of light[6].

A few non-clinical laboratory studies attempt to predict dysphotopsia from scattered light as it passes through IOLs[7]. For example, research has identified that IOL haptics (the arms of the IOL used to set it in place) and the edge of the IOLs are prone to induce a large amount of the observed glare scattered light[8]. One method, a ballistic-photon removing integrating-sphere method (BRIM), was introduced to quantitatively measure the amount of total non-ballistic light after passing through an IOL[9]. However, this highly sensitive technique is designed to measure the total intensity of scattered light and is unable to identify directionality of the scattered light. Computer simulation software can be used with model eyes to help predict intensity and directionality of light scatter from various IOL designs and materials. For example, the propensity for the IOL edge to induce the light scattering was simulated to identify designs that would limit the amount of scattered light[10]. Furthermore, computer simulations that incorporated the Mie scattering theory verified that increased light scatter can reduce the modulation transfer function (MTF) of the IOL (a direct correlation to image quality)[3]. Although helpful, real bench tests would be necessary to verify these predictive simulations.

To verify predictive simulations a bench test is necessary that is capable of detecting and quantitatively evaluating two distinct forms of scattered light, forward scattered and backward scattered light. Although not a source of dysphotopsia, backward scattered light (light scattering away from the eye) is a cause for reduced image quality, as less light passes through the IOL to ultimately reach the retina. Forward scattered light (light scattering towards the retina) is a concern for ophthalmologists as it may result in complaints of dysphotopsia (*e.g.* glare, halo, and glistening). One common example is patients reporting additional unwanted glare from passing oncoming cars during night driving; this issue is particularly common with multifocal IOLs[11]. However, current practice to identify potential forward scattered light is for ophthalmologists to shine light onto the patient's eye and qualitatively observe how much light is reflected back (backward scattered light) and assuming that the backward scattered light will be approximately the same as the forward scattered light (which is not always the case)[12].

Here, we describe a simple test methodology using goniophotometry principles to quantitatively measure the magnitude and direction of scattered light at it passes through an intraocular lens. The SLSP operates by rotating a photodiode sensor 360 degrees around an IOL that is exposed to a light source, see **Figure 1a**. We chose a green laser source (543 nm) to best represent the known photopic maximum and to agree with the international standard specifications[13]. Here, an IOL is adapted onto a rotational and translational holder where a photodiode sensor can circle around and observe light scattering off of the lens. As a result, the SLSP has the unique capability to quantitatively measurement the magnitude and directionality of scattered light. However, although not described here, for better predictive capabilities, experiments should be conducted within a controlled environment using an appropriate eye model. The distance between the IOL and the optical sensor (as well as the size of the sensor element) will determine the resolution capabilities of the device; however, there will be a tradeoff between resolution and signal strength that will need to be adjusted, as needed.

To accurately describe the principles of the SLSP platform we define three types of rotational angles, see **Figures 1b** and **1c**. Specifically, the rotation angle (˚R) represents the rotation of a photodiode sensor as it rotates around an IOL. Here, 0˚R would represent when the sensor is behind the lens (backward scattered light) and 180˚R represents when the sensor is in front of the lens (forward scattered light). Angles of 90˚ and 270˚ represent the transition points between forward and backward scattered light. The sensing angle (˚S) represents degrees that the sensor is pivoted (in the up and down direction) so that it can detect more than one plane of scattered light. Here, 0˚S means the sensor surface is parallel to the IOL (and light source). Finally, the angle of incidence (˚I) represents the angle that the light source is approaching the IOL from. Here, 0˚I corresponds to when the incident light is on the optical axis of the IOL and 90˚ would represent when the light source is perpendicular to the Meridional plane.

Protocol

1. SLSP Measurement Platform Preparation

NOTE: All alignment steps require precision and patience to ensure accurate quantitation when measuring light scatter. An overview of the SLSP setup in provided within **Figure 1**. Here, an illustration (**Figure 1a**) shows the basic concept of the SLSP setup. In addition, **Figures 1b** and **1c** help define the various angles referenced within the discussion. Specifically, the following three angles are defined within **Figures 1b** and **1c**: ˚R (sensor rotational angle), ˚S (sensor angle of measurement), and ˚I (IOL angle of incidence).

1. **SLSP Alignment (Figure 2).**
    1. Focus a narrow-linewidth laser source (here, a 543 nm central wavelength) into a single-mode delivery optical fiber using a 10× infinity corrected objective lens.
       NOTE: Test the light source to ensure that the lumen output is steady or measurements will be difficult to quantify. A focused beam is determined by observing light passing through the fiber, this will not achieve 100% efficiency, but should be enough so that light can ultimately be detected by the sensor.
    2. Collimate the light source by integrating the single-mode optical fiber with a 10X infinity corrected objective lens so that the fiber is positioned on the focal point of the objective lens. The output light should result in a uniform Gaussian beam profile.
    3. Position an iris aperture in front of light source to adjust the diameter of Gaussian beam.
       NOTE: Set the iris aperture diameter to be representative of a human eye (*e.g.* 1-6 mm diameter). As the light scatter type complaints are commonly associated with night driving, iris aperture diameters representative of a dilated iris may be preferable.
    4. Construct a goniophotometer by attaching a photodiode sensor to a motorized/programmable 360˚ rotational stage with linear translation (x, y, and z direction) capabilities using an extendable arm (metal post with post clamp).
       NOTE: Design a stage platform that enables translation as well as tilt adjustments. Design the sensor mount that enables 360˚ of sensor rotational angle (˚R) and can be adjusted to at least 45˚ of sensor angle rotation (˚S) to measure different planes of scatter. The distance of the extended arm is dependent on the sensitivity of the photodiode sensor and the desired angular precision.
    5. Adjust the sensor angle of detection (as needed) by angling the sensor face and adjusting the location of the arms.
2. **IOL Alignment**
    1. Construct an IOL holding platform so that the IOL is positioned above the goniophotometer (**Figure 2**).
        1. To accomplish this, build the IOL holding platform so that the IOL is suspended above the center of the goniophotometer (reversing the positions of the goniophotometer and IOL is also possible).
            1. To construct the platform use four, 18" long, ½" diameter cylindrical posts and post stands and attach them to a 18 x 18" breadboard. This breadboard is the base support for the platform.
    2. Attach a translational stage (x, y, and z direction) with tilting and rotational (I˚) capabilities underneath the breadboard so that the stage is facing down.
       NOTE: Translation stages with small step sizes (a few microns) enable higher precision during the alignment of the IOL and will improve goniophotometry accuracy. The specific dimensions of the platform can be customized to individual needs. As a result, the cylindrical posts and breadboard dimensions can be adjusted.
        1. Securely attach the IOL to the IOL holding platform by clamping one of the IOL haptics.

NOTE: In this proof of purpose experiment, IOLs are tested in air; however, IOLs in solution and temperatures that best represent *in vivo* conditions would be ideal.

3. Align the IOL directly in front of the light source (with the IOL plane of focus perpendicular to the light source) using linear and tilt adjustments from the IOL holding platform stage to ensure that the direction of light does not change while passing through the center of the IOL. This position will constitute an angle of incidence (I˚) of 0˚.
4. Identify the location of the focal spot of light from the IOL and position a small conical device at the focal spot to mitigate detection of defocused light (when necessary). Identify the focal spot of light by placing a piece of paper (such as a business card) behind the IOL and identifying where the light is most tightly focused. This can be a subjective measurement.
NOTE: This step is only necessary if wanting to measure purely non-ballistic light.
5. Position the motorized stage for the photodiode sensor directly underneath the IOL to ensure that the IOL is located in the center of the goniophotometer trajectory. Align the goniophotometer so that it is approximately 12 cm away from the IOL.
NOTE: The relationship of the IOL and the goniophotometer will determine the resolution of the tests, where the further away the goniophotometer is located the greater resolution can be achieved. However, increased distance (and smaller step sizes) will result in lower signal and longer experimentation times.
6. Adjust the angle of incidence (I˚) by rotating the IOL holding platform stage.
NOTE: Initial experiments should be conducted with an angle of incidence of 0˚ to 80˚. Beyond 80˚ will begin to near the grazing angle where all light will be reflected.

3. **Programming**
   1. Build a software program to coordinate the mechanical movement of the sensor with its corresponding light measurement using system design software (see **Supplemental file 1** and **Table of Materials**).
   NOTE: When building the software program take into consideration the speed of the sensor to ensure that the physical location of the sensor accurately reflects its recorded measurement. The program designed for this experiment is provided in **Supplemental file 1**.

2. SLSP Experimentation and Data Analysis

1. **Scanning (˚R)**
   1. Ensure that the IOL and the light source are properly aligned (see sections 1.1 and 1.2).
   2. Construct an enclosure around the photodiode sensor and the IOL using a container with non-reflective internal coating to minimize the detection of errant light. Ensure to provide an opening for the light source.
   NOTE: The specific design of the enclosure should be customized based on an external light in the room. As a result, multiple designs are usable. However, the purpose of the enclosure is to mitigate all external light from being detected by the sensor.
   3. Turn off all light sources within the room, except for the programming computer.
   4. Run the SLSP software program (step 1.3.1) so that the sensor rotates around the IOL to measure scattered light at each degree of rotation (˚R).
   5. To measure scattered light at more than one plane, run the SLSP software program multiple times while manually adjusting the sensor's extended arm and sensor angle of measurement (˚S).
   NOTE: The number of times the program is run is dependent on the desired outcome. The more angles of detection measured will result in more precision for identifying the directionality of scattered light.
   6. For studies on beam diameter, adjust the iris aperture to the desired diameter before running the SLSP program.
   NOTE: Here, the laser beam diameters of 1, 2, 3, 4, and 4.64 mm were used to best mimic typical iris diameters. 4.64 mm was the largest diameter used as this was the diameter of the collimated beam without passing through the iris aperture.
   7. For studies on angle of incidence, rotate the IOL mount to the desired angle of incidence before running the SLSP program. Here, angles of incidence (I˚) of 0˚, 20˚, 45˚, and 80˚ were studied.
   NOTE: A scientific data processing package is needed for the analysis of the collected data.
   8. For three dimensional imaging, stich together the data from each scan at differing ˚S with a data processing package. Stich the data by plotting a matrix book where the sensor angle of measurement (˚S) is plotted against the angle or rotation (˚R).
   NOTE: To better represent *in vitro* conditions, the SLSP platform can be reversed so that the goniophotometer is above the IOL and the IOL can then be placed inside of a temperature controlled saline solution bath. However, in these conditions, sensor dwell times will need to be considerably longer to take into consideration the motion of the saline solution as the sensor is moved from position to position and displaces the medium.

Representative Results

Goniophotometry measurements can produce 360˚R of signal when the sensor is not located on the plane of the light source. However, to collect measurements from scattered light on the plane of the light source (0˚I) the sensor will need to eclipse the light source, resulting in less than 360˚R of signal. In our experiments, it was determined that ~20˚R of signal was blocked as the sensor eclipsed the light source.

Experiments found that four main locations of light scatter are observed to the left and right of direct backward scattered light (~150˚-175˚R and ~185˚-225˚R) and to the left and right of direct forward scattered light (~10˚-25˚R and 325-350˚R). The influence of the laser beam diameter found that there is a direct correlation between the beam diameter and intensity of scattered light, as should be expected. As an example, **Figure 3** shows the difference in light scatter signal between an iris aperture of 1 mm and 4.64 mm (size of the collimated light source without an aperture). By integrating the area under the signal peaks, a quantitative difference in signal intensity can be calculated. Alternatively, the total intensity of the front or back scatter (or the combination of the two) can be calculated. This information may be helpful to ophthalmologists or manufacturers to evaluate the quality of the IOL.

Patients with implanted multifocal IOLs commonly report complaints about observing dysphotopsia associated with light scatter, particularly while driving at night. Patients report that the scattering of light is largely observed from passing cars (*i.e.* light with large angles of incidence [I˚]). As a result, light scatter from multifocal IOLs were testing using the SLSP method (see **Figure 4**). Experiments found that, compared to more typical monofocal IOLs, multifocal IOLs produced larger peak areas as well as more peaks. As an example, **Figure 4** shows the SLSP scan for a 45˚I angle of incidence with a multifocal IOL. **Figure 4** inset shows a photographic image of the projection of light passing through a multifocal IOL (green circle with concentric rings) along with the magnified SLSP signal between the rotational angles of 300-360˚. **Figure 4** shows that the visually observed nodes from the multifocal IOL can be detected and identified using the SLSP method and that the intense and broad signal could be the potential cause for the observed glare by night drivers.

The correlation between angle of incidence (I˚) and light scatter was studied for monofocal and multifocal IOLs (see **Figure 5**). Here, monofocal (left) and multifocal (right) IOLs were rotated at 0˚I (black line), 20˚I (tan line), 45˚I (teal line), and 80˚I (red line) for each SLSP scan. As seen in right panel, a broadening of the peaks is observed as the angle of incidence increases. In addition, as the angle of incidence approaches the grazing incidence angle (~80˚I) the intensity and of scattered light is dramatically increased. These results are expected as most light is reflected (*i.e.* grazed) off of the lens medium near this grazing angle. When comparing multifocal and monofocal IOLs light scatter from multifocal IOLs was observed to be more than twice as intense and with sharper peaks than monofocal IOLs. These observed differences may significantly impact the amount of glare reported by patients. In addition, as shown from 80˚I scan (red line of the right panel), the most intense peak is located at the boundary between front- and back-scattered light (90˚R). It is conceivable that this scattered light may propagate along the surface of the IOL and be detected at the retina and identified as glare.

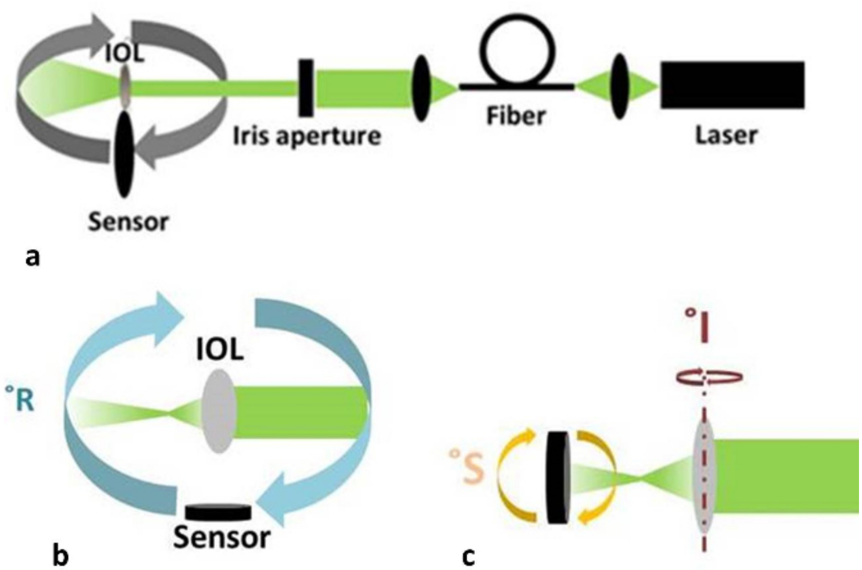

Figure 1: Schematic of SLSP Rotational Concepts. (**a**) SLSP principal setup to quantitatively profile the forward and backward light scattering after exposure to an intraocular lens. (**b**) Top view of SLSP setup where ˚R is the rotation angle of the sensor. 0˚R is the location where the sensor completely eclipses the light source. (**c**) Side view of the SLSP setup where ˚S is the sensing angle. 0˚S is the angle where the sensor is on the plane of light scatter that is perpendicular to the IOL. ˚I represents the angle of incidence with respect to the light source and IOL. Here, 0˚I is the angle where incident light is perpendicular to the surface of the IOL. This figure has been modified from Walker, B.N. *et al.*[1] Please click here to view a larger version of this figure.

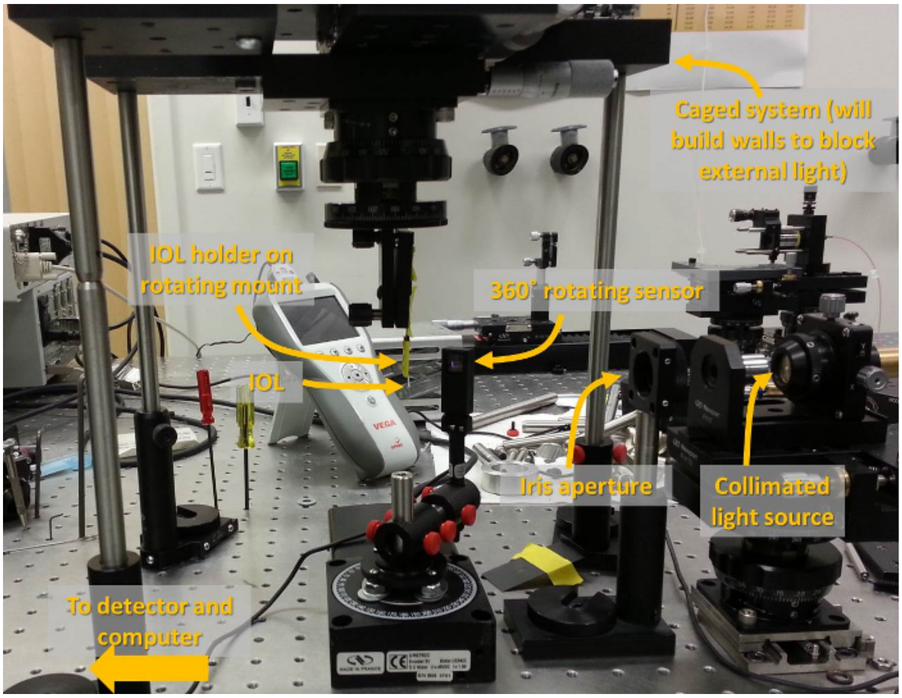

Figure 2: Image of SLSP Setup. Photographic image of SLSP setup showing the platform (without the light protective cover). Please click here to view a larger version of this figure.

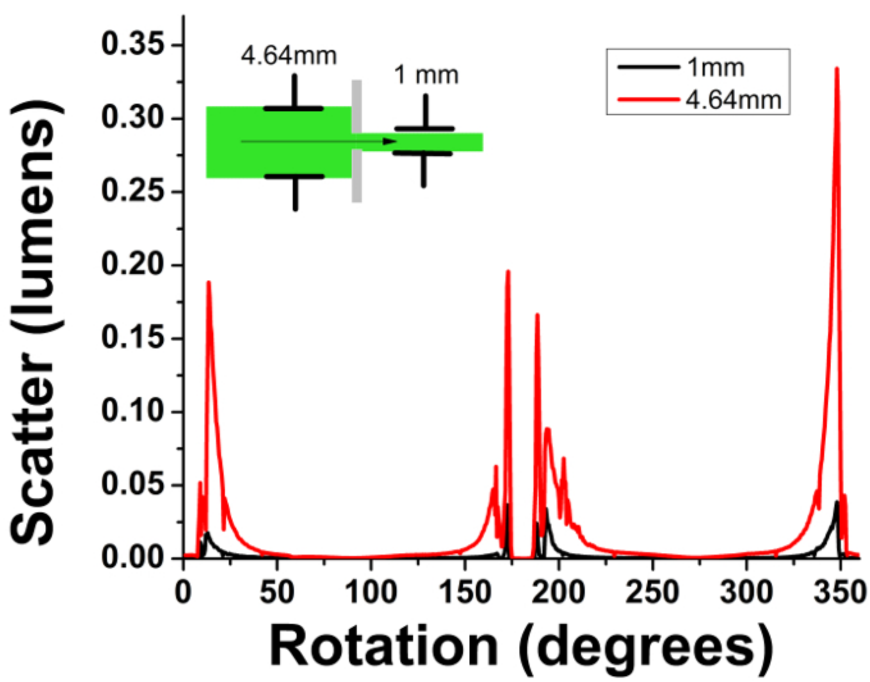

Figure 3: Correlation Between Light Scatter Intensity and Beam Diameter. Influence of beam profile diameter on the intensity of scattered light. Rotation angle profile of scattered light for 1 mm beam diameter and maximum beam diameter (~4.6 mm). This figure has been modified from Walker, B.N. *et al.*[1] Please click here to view a larger version of this figure.

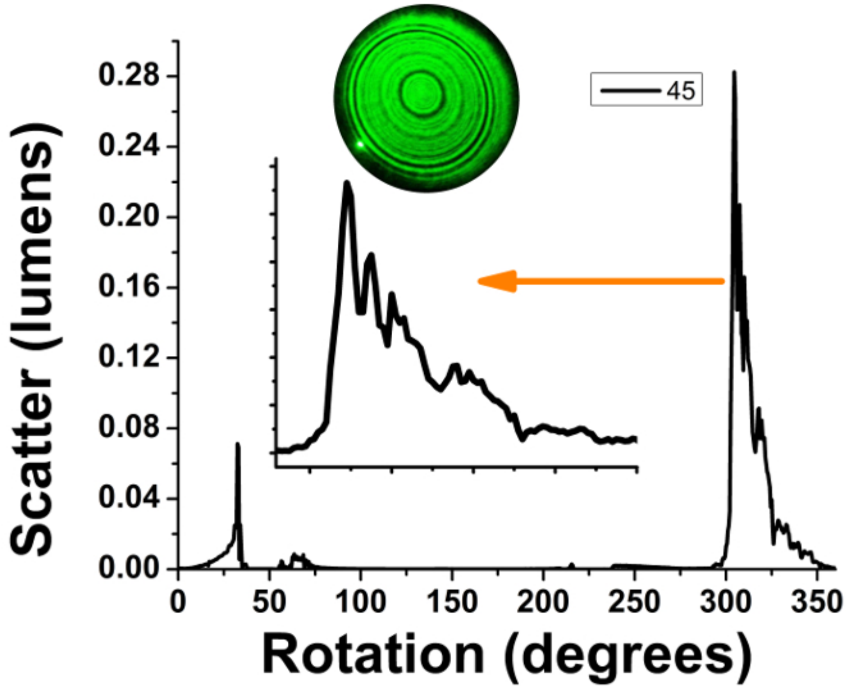

Figure 4: Observed Light Scatter of Multifocal IOL. SLSP Test of a Multifocal IOL Sample with an Angle of Incidence of 45˚. Inset shows a magnified profile of the most intense forward-scattered peaks corresponding to a camera image of the scattering of light (green circle) projected onto a plane surface. This figure has been modified from Walker, B.N. *et al.*[1] Please click here to view a larger version of this figure.

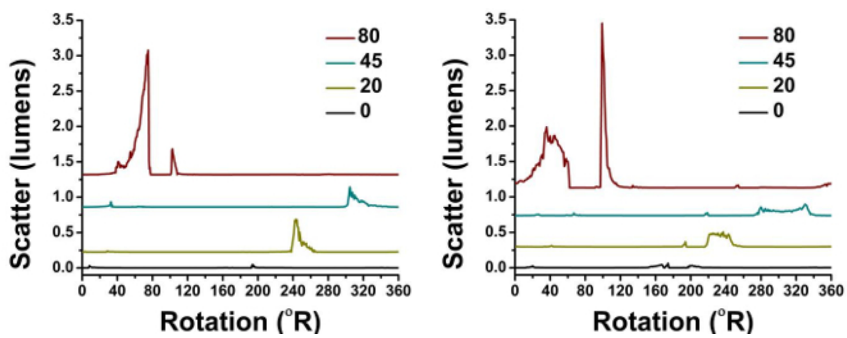

Figure 5: Correlation between light scatter intensity and angle of incidence (I˚). Influence of the angle of incidence on light scattering from IOLs comparing (left) monofocal and (right) multifocal IOLs. Note that the graphs only appear to be offset since changing the angle of incidence also shifts the location of the scattered of light. This figure has been modified from Walker, B.N. *et al.*[1] Please click here to view a larger version of this figure.

Supplemental file 1: Software Program to Coordinate the Mechanical Movement of the Sensor with its Corresponding Light Measurement. Please click here to download this file.

Discussion

The results from the SLSP platform experiments have found that using simple goniophotometry principles can lead to a powerful tool for evaluating the properties of light scatter associated with unique IOL designs and materials. Specifically, the SLSP platform has observed a direct correlation between the amount of detectable scattered light and the beam diameter of the light source. In addition, the multiple scattered peaks found in multifocal IOLs were easily observed with the SLSP. Furthermore, as the source of light approached the grazing angle, the SLSP observed a dramatic increase in scattered light as most light was reflected off the lens surface.

As discussed in the protocol, the alignment of the light source and the IOL is critical for accurate measurement of scattered light. In addition, it is essential that the location of the sensor is accurately correlated with the sensor measurement, via software programming. Alignment issues can be corrected by passing the light output through pinhole apertures that are on the same optical plane (X, Y, and Z). Pinhole apertures placed behind the IOL can also be used to ensure that the IOL is also aligned correctly. Troubleshooting the custom software program is accomplished by ensuring that each software step is accomplishing the desired outcome.

The SLSP platform has been demonstrated to quantitatively evaluate the magnitude and the direction of light scatter with a nearly 360˚R viewing capability. As a result, the SLSP platform could be a powerful tool to evaluate current and novel IOL designs and materials to better predict if they have the potential for excessive scattering of light, particularly when paired with powerful simulation programs. This non-clinical approach can decrease the amount of patient reported dysphotopsia and improve overall image quality of IOLs, leading to a reduction in unsatisfied patients and secondary surgeries to explant the lenses.

The current SLSP platform setup has limitations related to best representing *in vivo* conditions as the temperature and surrounding media do not imitate conditions of the eye. Modifications to the platform can be made to correct this limitation. Specifically, the platform can be inverted so that the sensor is above the IOL and the IOL can be placed in a temperature controlled saline solution bath and/or inside of a model eye. These results would better represent the conditions experienced by patients. In addition, 360˚ of imaging could be achieved by modifying the goniophotometer. These changes to the platform could be made to improve the evaluation of IOL light scatter; however, backscattered light (light reflecting away from the eye) is not a known concern for glare or glistenings as this light will not be detected by the retina. After these modifications are made, the SLSP can be applied for the direct evaluation of designs and materials of current and future IOLs. In addition, correlating SLSP results with validated patient reported outcomes and computer simulations could be a powerful tool to better predict outcomes and ultimately help move optical testing from clinical to non-clinical. Translation from clinical to non-clinical will lead to bringing innovative IOLs to the market sooner and reduce the need for potentially harmful (and expensive) clinical studies.

Disclosures

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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References

1. Walker, B.N., James, R.H., Calogero, D., Ilev, I.K. A novel full-angle scanning light scattering profiler to quantitatively evaluate forward and backward light scattering from intraocular lenses. *Rev. Sci. Instrum.* **86**(9): 5 (2015).
2. Vandenberg, T., On the relation between glare and straylight. *Doc. Ophthalmol.* **78**(3-4):,177-181. (1991).
3. De Hoog, E., Doraiswamy, A. Evaluation of the impact of light scatter from glistenings in pseudophakic eyes. *J. Cataract. Refract. Surg.* **40**(1), 95-103. (2014).
4. *Global Intraocular Lens Market 2013-18: Industry Nanotechnology Analysis, Size, Share, Strategies, Growth, Trends and Forecast Research Report.* http://www.prweb.com/releases/2013/6/prweb10886563.htm. (2013).
5. Congdon, N., et al. Prevalence of cataract and pseudophakia/aphakia among adults in the United States. *Arch. Ophthalmol.* **122**(4), 487-494. (2004).
6. Mester, U., et al. Impact of Personality Characteristics on Patient Satisfaction After Multifocal Intraocular Lens Implantation: Results From the "Happy Patient Study". *J. Refractive Surg.* **30**(10), 674-678. (2014).
7. Ferrer-Blasco, T., Montes-Mico, R., Cervino, A., Alfonso, J.F. Light Scatter and Disability Glare After Intraocular Lens Implantation. *Arch. Ophthalmol.* **127**(4), 576-577. (2009).
8. Landry, R.J., Ilev, I.K., Pfefer, T.J., Wolffe, M., Alpar, J.J. Characterizing reflections from intraocular lens implants. *Eye.* **21**(8), 1083-1086. (2007).
9. Kim, D.H., James, R.H., Landry, R. J, Calogero, D. Anderson, J., Ilev, I.K. Quantification of glistenings in intraocular lenses using a ballistic-photon removing integrating-sphere method. *Appl. Opt.* **50**(35), 6461-6467. (2011).
10. Portney, V. IOL with Square-Edged Optic and Reduced Dysphotopsia. *Optom. Vis. Sci.* **89**(2), 229-233. (2012).
11. Choi, J., Schwiegerling, J. Optical performance measurement and night driving simulation of ReSTOR, ReZoom, and Tecnis multifocal intraocular lenses in a model eye. *J. Refractive Surg.* **24**(3), 218-222 (2008).
12. Artigas, J.M., Felipe, A., Navea, A., Carmen Garcia-Domene, M., Pons, A., Mataix, J. Determination of scattering in intraocular lenses by spectrophotometric measurements. *J. Biomed. Opt.* **19**(12) (2014).
13. Ophthalmic implants - Intraocular lenses Part 2: Optical properties and test methods. *The International Organization for Standardization (ISO).* **ISO 11979**(2). (2014).