Instruction Manual: Scanning Light Scattering Profiler (SLSP) Method for Quantitative Evaluation of Light Scattering in Intraocular Lens Implants

Tool Reference

RST Reference Number: RST26OM08.01

Date of Publication: 08/27/2026

Recommended Citation: U.S. Food and Drug Administration. (2026). *Scanning Light Scattering Profiler (SLSP) Method for Quantitative Evaluation of Light Scattering in Intraocular Lens Implants* (RST26OM08.01). https://cdrh-rst.fda.gov/scanning-light-scattering-profiler-slsp-method-quantitative-evaluation-light-scattering-intraocular

For more information

Catalog of Regulatory Science Tools to Help Assess New Medical Devices

Disclaimer

About the Catalog of Regulatory Science Tools

The enclosed tool is part of the [Catalog of Regulatory Science Tools], which provides a peer-reviewed resource for stakeholders to use where standards and qualified Medical Device Development Tools (MDDTs) do not yet exist. These tools do not replace FDA-recognized standards or MDDTs. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed. These tools use the most innovative science to support medical device development and patient access to safe and effective medical devices. If you are considering using a tool from this catalog in your marketing submissions, note that these tools have not been qualified as Medical Device Development Tools and the FDA has not evaluated the suitability of these tools within any specific context of use. You may request feedback or meetings for medical device submissions as part of the Q-Submission Program.

For more information about the Catalog of Regulatory Science Tools, email RST_CDRH@fda.hhs.gov.

Instruction Manual

This instruction manual describes the implementation of the scanning light scattering profiler (SLSP) method, which provides quantitative evaluation and nonclinical prediction of light scattering characteristics of both current and new-technology intraocular lens (NTIOL) implants [1-4]. Due to the lack of standard test methods, protocols, and guidance documents for evaluating the critical light scattering characteristics of IOL implants, the development of new test methodologies and tools to evaluate the light scattering properties of IOL designs and materials can be used to help identify potential light scattering concerns. Light scatter is commonly reported by patients and observed as unintended vacuoles, glare, optical imperfections, poor image quality, and other forms of dysphotopsia [5-6], which can sometimes result in IOL explantation and replacement. In addition to dysphotopsia, scattered light also reduces the amount of ballistic light, resulting in lower image quality. Therefore, a test tool that can quantitatively evaluate and nonclinically predicting potential IOL light scattering will improve public health outcomes.

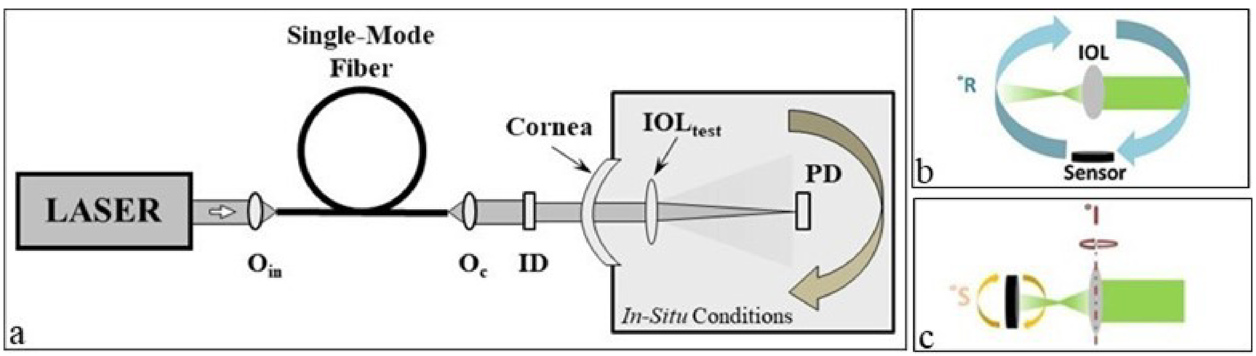

Figure 1: The SLSP tool principle of operation: (a) Design includes three angular scans of a rotational angle ***R*** (b), a sensing angle *S* (c), and an angle of incidence ***I*** (c) [1-4].

The SLSP setup, developed to quantitatively profile the forward and backward light scatter after interacting with an IOL, is illustrated in Fig. 1a [1-4]. The SLSP platform uses a full 360°-angle scanning design, in which the test IOL sample is illuminated by a collimated Gaussian laser beam provided by a single-mode fiber-optic delivery system. The SLSP's multifunctional capabilities include three angular scans: a rotational angle ***R*** (Fig. 1b), a sensing angle ***S***, and an angle of incidence ***I*** (Fig. 1c). The IOL light scattering characteristics are evaluated under *in-situ* simulation conditions, including a model cornea and the test IOL submerged in a saline solution bath.

The RST test procedure includes the following key steps:

- Set up the SLSP test apparatus shown in Fig. 1 [1-4]. The referenced papers include properties and specifications of the key SLSP components required for assembly. IOL targets can be tested in both dry and *in-situ* simulation conditions.
- Follow the step-by-step procedures described in [2] to perform precise alignment of the SLSP setup including the test IOL sample alignment.

- Perform experimental measurements of SLSP dependences between forward and backward light scattering radiant powers and rotational angles, depending on critical tool parameters such as the three-dimensional angular scan (rotational angle **R**, sensing angle ***S***, and angle of incidence ***I***, Fig. 1 b,c) and test beam diameter, using monofocal, multimode, extended depth-of-focus, and graded IOL samples (Fig. 2a) [1, 2].
- Evaluate the SPSL light scattering profiles of the test IOLs by estimating the scatter point spread function (PSF) using the measured irradiance, input radiant power, and the solid angle defined for each IOL sample (Fig. 2b) [4].
- Conduct ray-tracing analytical modeling for simulating test IOL and SLSP *in-situ* conditions and compare the light scattering profiles obtained through the SLSP experimental and analytical methods, enabling nonclinical prediction of IOL light scattering characteristics [3,4].
- Compare the IOL light scattering characteristics measured though SLSP with those evaluated using an alternative high-magnification digital microscopy approach to classify the IOL light scattering properties [2-4].
- Conduct comprehensive correlation analysis of multiparameter IOL light scattering characteristics obtained from both experimental and analytical test methods to provide highly accurate quantitative evaluation and nonclinical prediction of the IOL light scattering.

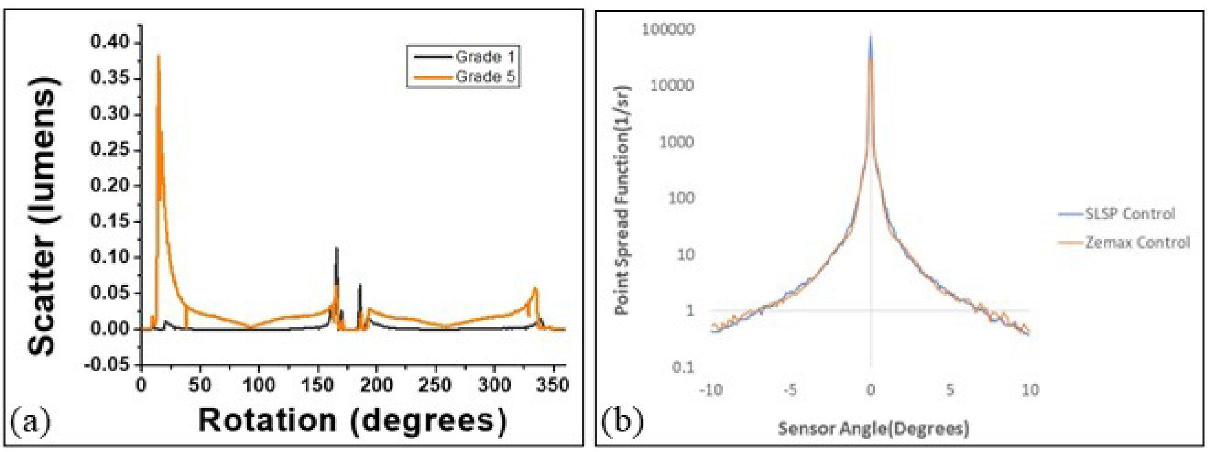

Figure 2: SLSP measured rotation angle profile of light scatter for various graded IOLs (a) [1, 2]; and SLSP measured and simulated PSF of a test IOL sample (b) [4].

References:

[1] B. Walker, R. James, D. Calogero, and I. Ilev, "A novel full-angle scanning light scattering profiler (SLSP) to quantitatively evaluate forward and backward light scattering from intraocular lenses", **Review of Scientific Instruments**, v. 86, pp. 095004, 2015.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10961904/

[2] B. Walker, R. James, D. Calogero, and I. Ilev, "Scanning light scattering profiler (SLPS) based methodology to quantitatively evaluate forward and backward light scattering from intraocular lenses", **Journal of Visualized Experiments**, v. 124, pp. e55421, 2017.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5608261/

[3] V. Spiezio, B. Walker, D. Calogero, and I. Ilev, "Quantitative evaluation of light scattering glistenings in intraocular lenses employing a high-magnification digital microscopy method", **Journal of Ophthalmology**, v. 2019, pp. 7929014, 2019.

https://www.hindawi.com/journals/joph/2019/7929014/

[4] V. Spiezio, B. Walker, D. Calogero, and I. Ilev, "Experimental and analytical quantification of light scattering from vacuoles in intraocular lenses", **Journal of Cataract and Refractive Surgery**, v. 46, pp. 762-773, 2020.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10824253/pdf/nihms-1958417.pdf

[5] D Kim, R James, R Landry, D Calogero, J Anderson, and I. Ilev, "Quantification of glistenings in intraocular lenses using a ballistic-photon removing integrating-sphere method", **Applied Optics**, v. 50, pp. 6461-7, 2011.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10961905/

[6] R. Landry, I. Ilev, J. Pfefer, M. Wolffe, and J. Alpar, "Characterizing reflections from intraocular lens implants", **EYE**, v. 21, pp. 1083-1086, 2007 (Nature Journal).

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11384229/