



DRAFT CONSENSUS STATEMENT FOR COMMENT

September 14 2015

This statement was developed as a result of breakout group recommendations from the March 24, 2014 Developing Novel Endpoints for Premium IOLs Workshop held in Silver Spring, Maryland. The primary goal of the workshop was to improve the regulatory science for evaluating premium IOLs, which in turn may enhance the efficiency with which safe and effective premium IOLs get to the market.

We are indebted to the Task Force on Developing Novel Endpoints for Premium IOLs formed after the Workshop for developing these statements based on the workshop discussions and recommendations, available peer-reviewed scientific literature, and other expert opinions. The Task Force includes the following : Jack Holladay, MD, Chair; Adrian Glasser, PhD, Scott MacRae, MD, Samuel Masket, MD, and Walter Stark, MD. The FDA liaisons to this Task Force include the following: Malvina Eydelman, MD, Don Calogero, MS, Gene Hilmantel, OD, MS, Tieuvi Nguyen, PhD, RAC, Eva Rorer, MD, and Michelle Tarver, MD, PhD.

We would like to solicit broad input from industry and other interested parties.

Please send your comments, your affiliation and contact information with the title of the referenced document to hoskinscenter@aaopt.org by the following deadline: **November 10, 2015**. Please note that comments received after close of the comment period will not be accepted.

**DRAFT AMERICAN ACADEMY OF OPHTHALMOLOGY TASK FORCE CONSENSUS STATEMENT ON
SPECULAR MICROSCOPY GUIDELINES FOR PHAKIC IOLS**

Endothelial Cell Data:

Specular Microscopy should be performed preoperatively and at the 6, 12, 24 and 36 month postoperative intervals. A minimum of 3 scans with good images should be performed at each visit. Care should be taken to minimize the artifact images caused by dry eye or a poorly focused image. The proportion of eyes with $\geq 25\%$ endothelial cell loss from preoperative cell density should be considered an endpoint for a clinical investigation of a new phakic IOL.

A $\geq 20\%$ endothelial cell loss or an endothelial cell count of $< 1,500$ cells/mm² should trigger recalling the subject, retesting specular microscopy to confirm the cell loss, and consideration of the appropriateness of implant removal.

The reading center should read the specular microscopy images and report the cell count in cells/mm² and the percentage increase or decrease in cell density compared to preoperatively to the sponsor of a clinical investigation within 180 days of when specular microscopy is performed. The sponsor should notify the investigator within 30 days of receiving a reading center report if the endothelial cell density decreases 20% or more from the preoperative value or falls below 1,500 cells/mm². The sponsor should also report annually to the investigator any eyes that have a 15% or higher cell density decrease from the preoperative value.

Specular microscopy imaging systems using validated manual counting methods are currently the standard of care for such studies. The American National Standards Institute (ANSI) Z80.13 Phakic Intraocular Lenses standard (clause D.4.2) provides detailed recommendations to minimize the variability of specular microscopy measurements.