

Regulatory Considerations for Adaptive Optics Technology

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Adaptive Optics Definitions



- “Geometry of the blooming scenario (location of absorption region, slue rate, etc.) and the parameters of the adaptive system (bandwidth, correction algorithm, etc.) can strongly affect the observed correction factor.” Pearson JE., 1978, Opt Lett.
- “A comparison is presented of several optimization techniques using a multidither zonal coherent optical adaptive technique system within a laser resonator for *the correction of astigmatism.*” Spinhirne JM, Anafi D, Freeman RH, Garcia HR., 1981, Appl Opt.
- “Adaptive optics, a technique used to overcome blur in ground-based telescopes, can also overcome blur in the eye, allowing the *sharpest images ever taken of the living retina.*” Roorda & Williams, 1999, Nature

Opt Lett. 1978 Jan 1;2(1):7-9.; Thermal blooming compensation with adaptive optics., Pearson JE.

Appl Opt. 1981 Mar 15;20(6):976-84., Intracavity adaptive optics. 1: Astigmatism correction performance., Spinhirne JM, Anafi D, Freeman RH, Garcia HR.

Nature. 1999 Feb 11;397(6719):520-2., The arrangement of the three cone classes in the living human eye., Roorda A, Williams DR. 2

Adaptive Optics Definitions



- **ClinicalTrials.gov search for “adaptive optics”:**
 - 46 active studies at NIH and labs around the world
- **ISO and ANSI databases:**
 - No references to adaptive optics
 - No definition

Commercially Available AO Devices



- Currently, FDA has not cleared or approved any medical devices equipped with AO
- No guidance or recognized standard with the definition of AO

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Safety and Effectiveness Considerations



- Safety and Effectiveness questions will determine the appropriate regulatory pathway for AO devices
 - Likely regulatory pathway to the US Marketplace will be either 510(K) or *De Novo*

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Potential Considerations: Light Safety



- An AO-equipped imaging device's light source will have a higher transverse resolution than without AO.
- ANSI Z80.36-2016 : ***Ophthalmics - Light Hazard Protection For Ophthalmic Instruments*** (FDA Recognized)
 - applicable to all ***ophthalmic instruments that direct optical radiation into or at the eye***



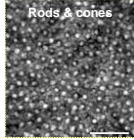
<https://courses.lumenlearning.com/physics/chapter/25-6-image-formation-by-lenses/>

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Potential Considerations: Field of View



- What is the clinical effectiveness of a 1° field of view?
 - How will the images be useful clinically?
 - Are there clinical comparators to which equivalence can be compared?



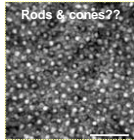
Liu, Tam, Saeedi, and Hammer, Biomed. Opt. Exp., 9, 4246-4262 (2018)

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Potential Considerations: Visualization



- How can the ability to visualize cells be confirmed?
 - Physical phantoms might assist with confirmation of image content with a known physical entity



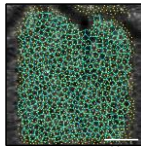
Liu, Tam, Saeedi, and Hammer, Biomed. Opt. Exp., 9, 4246-4262 (2018)

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Potential Considerations: Quantification



- How can the ability to quantify cell density be confirmed?
 - Physical phantoms might be considered
 - Creation of synthetic image volumes may allow verification of processing algorithms under various conditions of image noise, data dropout, etc.



- Measures
- Density
 - Size
 - Geometric arrangement
 - PR/RPE ratio

PR density = 12,208 cells/mm²
RPE density = 4,262 cells/mm²
PR/RPE ratio = 2.84

Green: overlying PR locations
Cyan: RPE mosaic Voronoi map

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Summary



- Safety concerns with the introduction of AO technology
 - Light safety may be addressed with compliance to FDA-recognized standards
 - Sponsors may also offer alternatives to compliance to standards
- Effectiveness, including new functionality, should be supported by performance data
 - Challenging as new AO functionality has no easily identified gold standard comparator
- **Regulatory Pathway** depend on questions of:
 - Technical Characteristics
 - Indications for Use

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Today's Workshop



Improve Regulatory Science

- Foster Medical Device Innovation

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Thank you



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