Developing Novel Endpoints for Premium Intraocular Lenses Workshop

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Disclosure

• No Financial Relationships to Disclose
Cataract Surgery in U.S.

• Cataracts affect more than 22 million Americans and is expected to rise to 30 million by 2020\(^1\)

• Cataract surgery\(^{1,2}\)
  – >3 million performed per year in US and rising\(^3\) due to aging of population
  – It is the third most common procedure performed during outpatient surgery visits

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Monofocal Intraocular Lenses (IOLs)

- 1949 - First IOL implantation by Sir Harold Ridley
- 1970’s – Investigational Device Exemption studies started in US
- 1981 - First IOL approved in US
- 1983 - IOL grid published\(^1\)
  - Safety and effectiveness criteria
  - Resulted in quicker approvals

Monofocal IOLs: 2014

• 59 original PMAs approved
  – Most PMAs have supplements with IOL modifications
    → hundreds of different lenses on the U.S. market
Premium IOLs

• Correct more than the spherical error at distance
• First approval in US (multifocal) - 1997
• Currently approved in US:
  • 3 Multifocals
    – Alcon Acrysof ReStor; Tecnis Multifocal; AMO Array Multifocal
  • 1 Accommodating
    – B+L Crystalens
  • 4 Toric
    – STAAR Toric IOL; Alcon Acrysof Toric; B+L Trulign Toric; AMO Tecnis Toric
  • 2 Phakic
    – STAAR Visian ICL; Ophtec Aristan Myopia Lens
Premium IOLs in US

• “Increasing life expectancy, the need for people to work longer and the evolution of technology from laptops to tablets to cell phones all bode well for premium IOL conversions.”¹

• About 14% patients implanted with premium IOLs¹

• Industry motivation:
  – Large patient out of pocket cost leading to more revenue for the device
    » Monofocal IOLs- Insurance reimbursement
    » Premium IOLs - Out of pocket expense ($1500 - $5000 per eye, average $3300)²
  – New Technology IOL (NTIOL) designation
    » Designation by CMS leading to $50 increased reimbursement per lens for 5 years after the decision

¹ http://www.ophthalmologymanagement.com/articleviewer.aspx?articleID=108644
² http://eyesurgeryeducation.org/surgery-options-presbyopia-lr-costs.php
Premium IOLs: FDA

• Increasing number of submissions for premium IOLs
  – Significant technological advances in lens design

• Limited availability of FDA guidance or recognized standards
  – CDRH evaluates many submissions on a case-by-case basis
  – FDA and sponsors spend significant resources on repeat submissions
  – Delayed or limited benefit to other devices with similar characteristics
Premium IOLs: Current Roadblocks

• Lack of consensus:
  – Some pre-clinical issues
  – Best clinical trial design for some Premium IOLs
  – Appropriate safety and effectiveness endpoints

• Need for new categories for IOLs based on new optical properties and/or benefits to the patients
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FDA’s Goals for Today’s Workshop

- Extended Depth of Focus (EDOF) IOLs
  - Introduce a new category of IOLs for improved near and intermediate performance
  - Discuss some requirements for preclinical and clinical testing
  - Create a foundation for development of “Leap-Frog”

Guidance for EDOF IOLs:

- Mechanism via which we can share our initial thoughts regarding the content of premarket submissions for emerging technologies
- Speed development and approval of future submissions
FDA’s Goals for Today’s Workshop (Continued)

- Discuss current limitation of endpoints for all premium IOLs
- Assess pros and cons of various methodologies for each endpoint
- Obtain recommendations on the best way to develop the needed endpoints
  - Consensus statements
  - Preclinical or clinical studies
- Facilitate collaboration of all interested parties to work together to increase the efficiency of tool development through joint efforts
  - Could potentially be used in multiple device development programs (beyond Premium IOLs)
- Deliver transformational change by combining the best internal and external talent to shorten the time from conception to market
You are the Change Agents!