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

[1] National The Eye Diseases Prevalence Research Group. Prevalence of cataract and pseudophakia/aphakia among adults in the United States. Arch Ophthalmol 2004; 122:487–494

[2] ASD Reports 2012. wwww.asdreports.com/news.asp?pr_id=275

[3] http://health.usnews.com/health-news/news/articles/2013/10/11/more-americans-getting-cataract-surgery

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

[1]Stark, et. al. The FDA Report on Intraocular Lenses. Ophthalmology, April 1983, Volume 90, Issue 4, pages 311-317

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 IOLs[1]
- 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

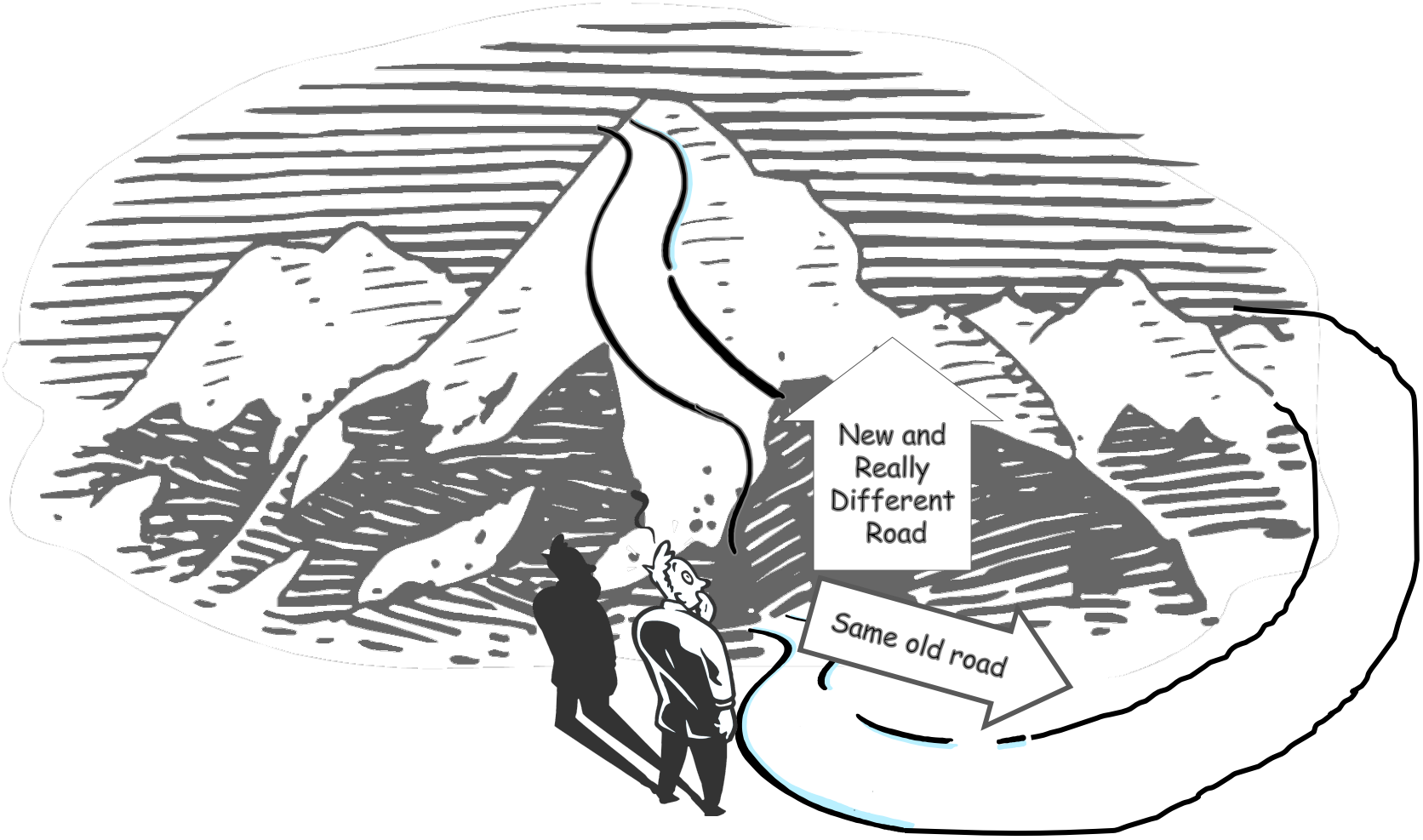
Premium IOLs: FDA

- 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

Developing Novel Endpoints for Premium Intraocular Lenses



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!