



New Categories of IOLs for Improved Near and Intermediate Performance

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FDA/AAO workshop:
Developing Novel Endpoints for Premium
Intraocular Lenses
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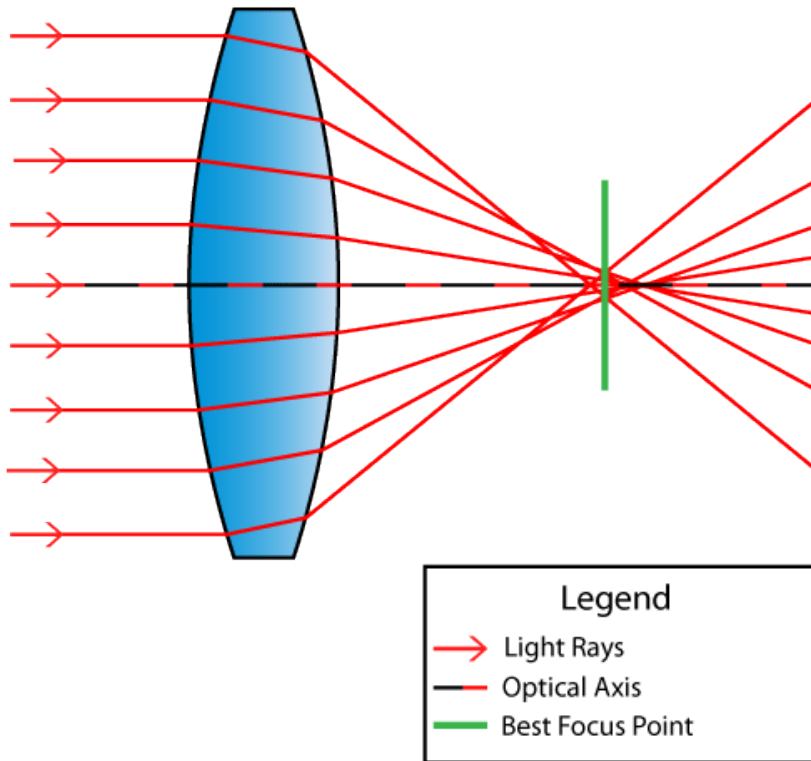


Disclosures

No Financial Relationships to Disclose

Evolution Of IOL Designs

Lens with Spherical Aberration



- IOL optics originally had simple spherical monofocal surfaces

Evolution Of IOL Designs

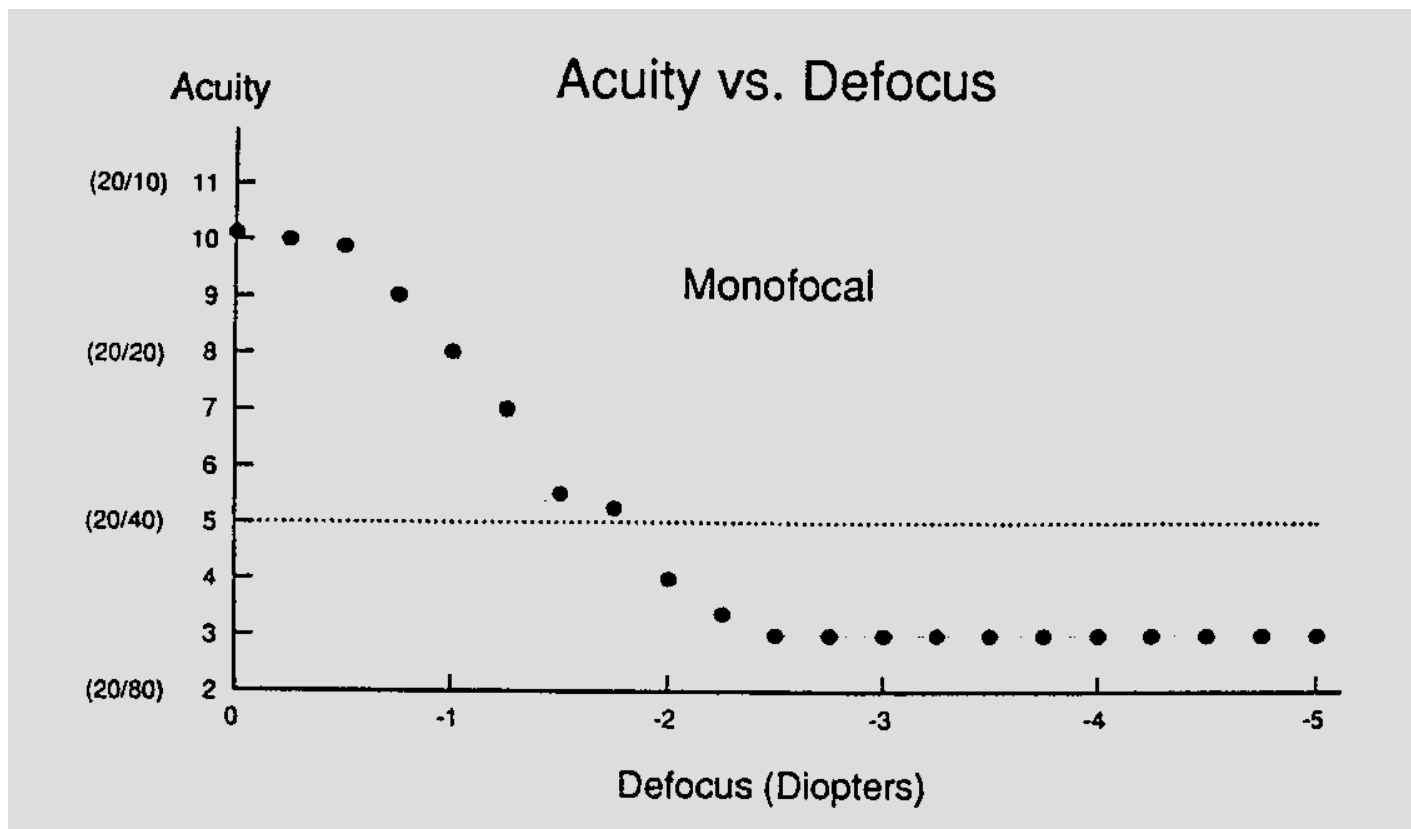
Current IOL designs offer a range of optical corrections beyond distance spherical correction:

- Accommodating designs correct defocus at near and intermediate distances by changing the optical power of the eye
- Toric designs correct astigmatism
- Aspheric designs correct corneal spherical aberration
- Multifocal designs correct defocus at distance, near and often intermediate distances by focusing to more than one image plane

Evolution Of IOL Designs

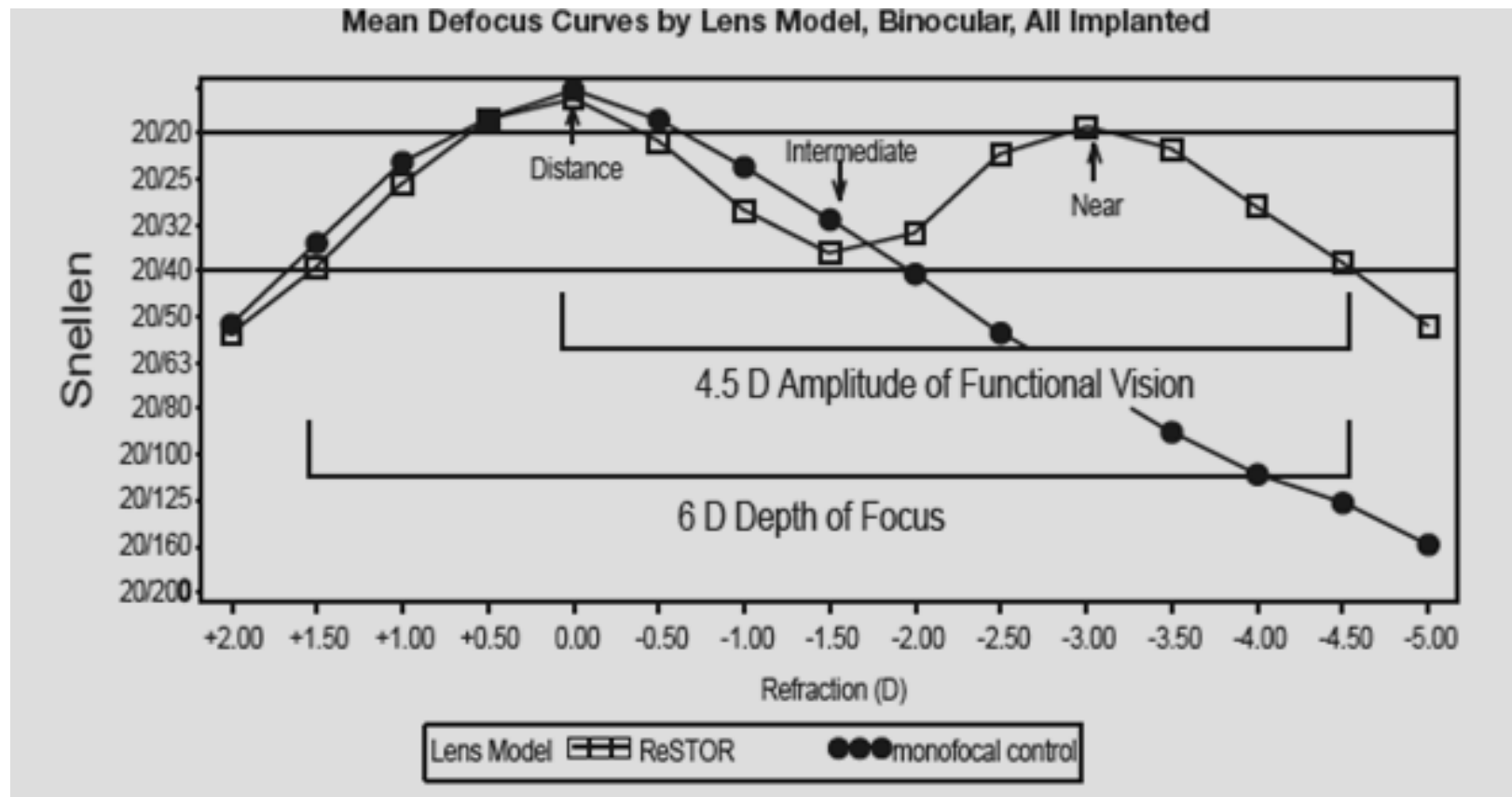
- All of these optical designs (except multifocal) optimize the quality of a single primary focus on the retina, with out-of-focus rays providing depth of focus (DOF)
- Multifocal optical designs have multiple foci, with DOF around each focus.
- Clinically, pseudophakic DOF is largely related to IOL aberrations, corneal aberrations, and pupil size

Preclinical Monofocal IOL DOF



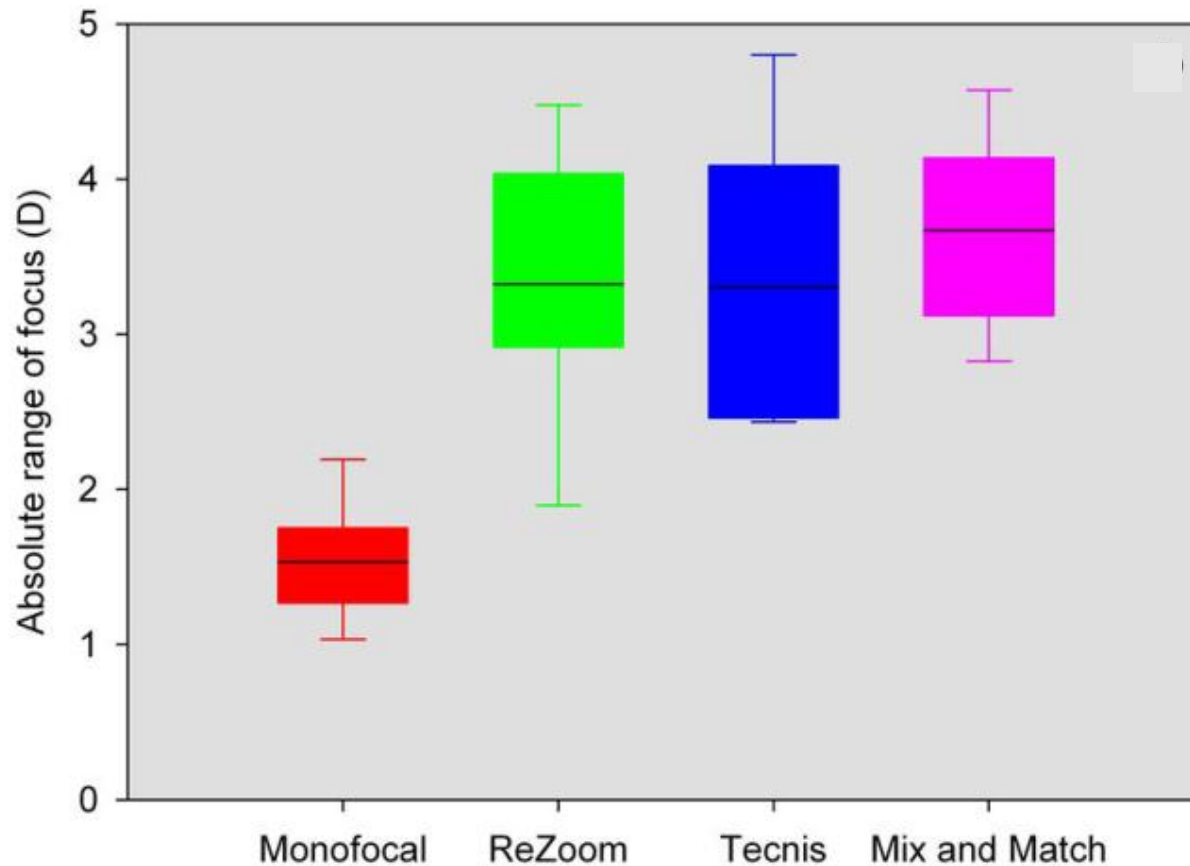
- Holladay et al reports 1.5 D DOF at 20/40 for a monofocal optic tested in isolation in a wet cell with a 3 mm aperture

Clinical Defocus Curves



Alcon Restor Labeling

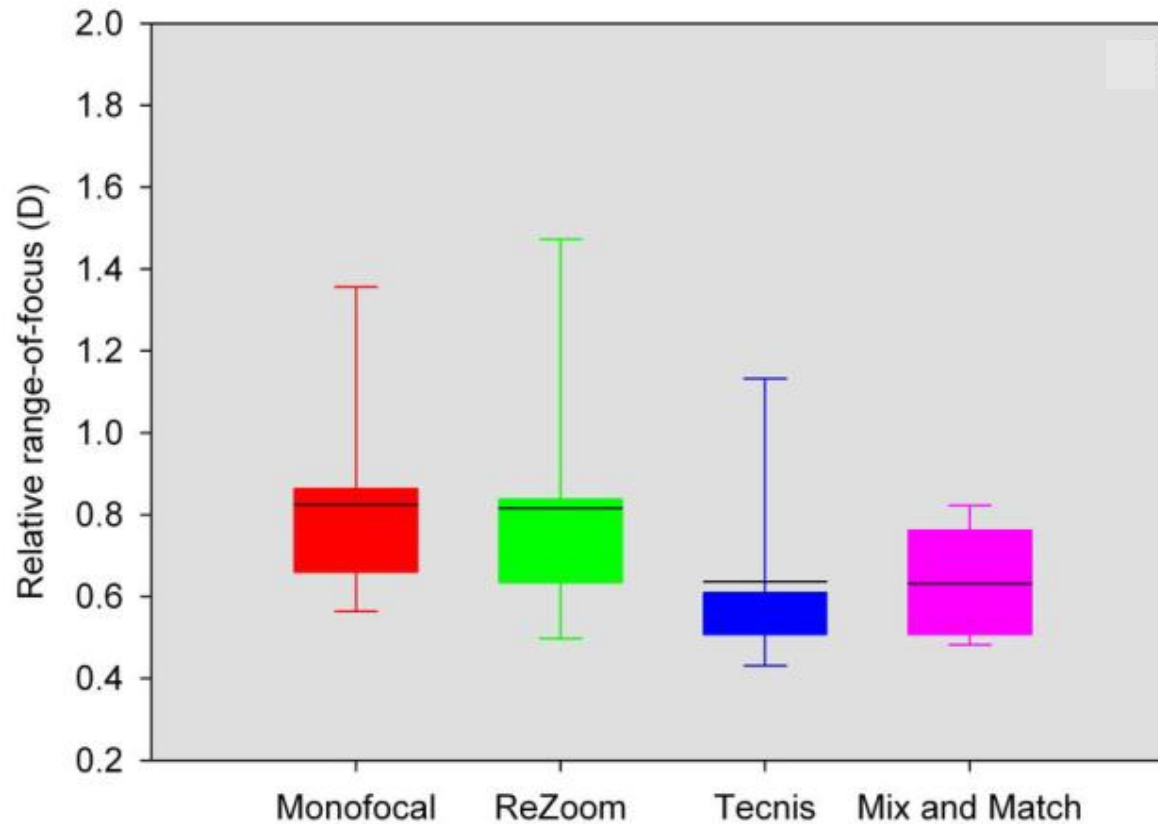
Clinical absolute range of defocus



- N=60 bilateral implants, tested binocularly
- (0.3 LogMAR)

Buckhurst, P. et al. MIOL Differentiation using Defocus Curves. IOVS 2012:11-9234.

Clinical relative range of defocus



- N=60 bilateral implants, tested binocularly
- At Best Acuity plus 0.04 LogMAR

Extended Depth of Focus (EDOF) IOL Optics

New type of IOL category is emerging – IOLs with optics with an extended depth of focus

- Design concept – to increase positive depth of focus to enhance intermediate and near visual performance while having minimal impact on distance performance.
- Implementation – increase in aberrations through refractive/ diffractive changes to the optic surface

Extended Depth of Focus (EDOF) IOL Optics

Advantages compared to multifocal optics –

- Less glare/ halos
- Less loss of contrast at distance focus

Disadvantages compared to multifocal optics –

- Visual performance improvement at near may be modest

Extended Depth of Focus (EDOF) IOL Optics

Optical Combinations

- EDOF optics added to toric optics to provide added DOF
- EDOF optics added to accommodating IOLs to provide a synergistic effect for near performance

EDOF IOLs

- No currently approved IOLs in US with EDOF claims
- Literature indicates several in development
- No current standards or draft standards
- No guidance
- Today – the first public discussion of preclinical and clinical testing to support marketing approval

Potential Preclinical Assessments: EDOF IOLs

- MTF performance at 100 c/mm compared to ISO monofocal requirements
- MTF Through-Frequency Response testing centered, decentered, and tilted (3 mm aperture only)
- MTF Through-Focus Response testing (centered, 3 mm aperture) at 50 c/mm and 100 c/mm – before and after simulated injection
- Simulated testing in a model eye for glare/ halos and defocus performance compared to parent or analog non-EDOF optic

Potential Clinical Assessments: EDOF IOLs

- Distance visual performance (BCVA, CS), and intermediate and near visual performance (intermediate/ near VA with BCDVA) compared to monofocal control as related to pupil size
- Functional performance testing in cases of significant degradation of distance performance
- PRO data on visual disturbances from glare/ halos compared to monofocal control
- Defocus testing to characterize the EDOF IOL through-focus performance compared to monofocal control as related to pupil size

EDOF IOL – Clinical Assessment Issues

- When using subjective methods to assess the diopter range of focus and VA, it is critical to use procedures that have high repeatability and minimize bias in testing in addition to using randomization and masking.
- Issue with performing repeatable manifest refractions in subjects with extended depth of focus needs to be addressed.

EDOF IOL – Standards Activities

ISO TC 172/ SC 7/ WG 7 (Ophthalmic Implants) –

This working group has begun discussions on updating technical report (TR) 22979 to standardize recommendations for IOL modifications.

It has been proposed to add EDOF optical changes as a modification of a clinically studied IOL that has met all the requirements of the ISO 11979 series of standards. This TR will provide insight into testing for new EDOF models.



Thank you.