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Special Report: American Academy of Ophthalmology Task Force Recommendations for Test Methods to Assess Accommodation Produced by Intraocular Lenses

In clinical studies for accommodative intraocular lenses (A-IOLs) intended to restore active and dynamic accommodation to the eye, appropriate clinical tests are essential for proving the existence of accommodation. Because accommodation is defined as a change in optical power of the eye, clinical accommodation studies for A-IOLs must necessarily include objective measurement of accommodation.[1–7] The A-IOLs differ in their mode of action from multifocal or extended depth of focus intraocular lenses (IOLs) in that they afford functional distance and near vision through a true change in optical power of the eye. Patient benefits from multifocal or extended depth of focus IOLs can be assessed clinically with subjective tests, such as distance-corrected near visual acuity and defocus curve tests. However, these tests are not suitable as the ultimate clinical end point for A-IOL clinical studies because they cannot unequivocally prove that a near-vision benefit is from a true change in optical power of the eye. Therefore, clinical trials for A-IOLs will need to include objective accommodation measurements. Clinical accommodation studies require the use of an objective instrument from which objective measurements of accommodation can be obtained. Accommodation with an A-IOL could be achieved with a movement of the IOL, a change in optical power of the IOL (e.g., through a change in surface curvature or thickness or increased separation of the optics of a dual optic IOL), all of which would result in a change in optical power of the eye. Physical changes, movements, or a change in power of the eye can be measured with objective instruments that measure a change in refraction of the eye, such as an autorefractor, a photorefractor, an aberrometer, or an instrument that measures a physical movement or change in shape of an IOL in the eye. Physical accommodative changes in the eye are referred to as "biometric changes" and can include a change in anterior chamber depth, IOL thickness, surface curvatures, or IOL position. Instruments that can measure biometric parameters include optical coherence tomography (OCT), ultrasound biomicroscopy, Scheimpflug, partial coherence interferometry, and A-scan ultrasound, for example. Accommodative biometric changes may be small, but if an optical change in power occurs through a biometric change, then the biometric change is measurable. The optical system of a pseudophakic eye can readily be modeled with simple Gaussian optics or ray-tracing. The equations for schematic eye calculations are readily available,[8] and optical calculations or ray-tracing can be performed in optics software, spreadsheets, and programming languages. If the basic optical and biometric parameters of an eye are known, including axial distance, surface radii of curvatures, and refractive indices of the various optical media, then it is possible to calculate the overall optical power of an eye. Likewise, the change in optical power of an eye can be calculated from a measured biometric change.[9] Therefore, if an A-IOL produces accommodation, this can be measured directly as a refractive change or a biometric change can be measured and the corresponding power change can be calculated. This document

details the steps that are necessary to demonstrate the presence of accommodation in future clinical accommodation studies.

Consensus Statement

Measurement Methodology, Calibration, and Pilot Studies

1. Purpose

The purpose of this section is to provide the steps needed to provide validation for the objective measurement methods and protocol to be used. This document is not intended to replace other relevant standards documents, but to provide supplemental information. Objective measurements are required to show a true accommodative change in the power of the eye.

2. Introduction

It is recommended that clinical accommodation studies for A-IOLs include a substudy in which objective methods are used to measure the accommodative changes, either through optical or biometric methods.[3,4,7] Given the possible new and unique A-IOLs that may be investigated, it is not possible to dictate what instrumentation can or should be used for objective measurements in these clinical studies or what the specific methods or protocols should be. If commercially available instruments that have been validated in peer-reviewed, published clinical studies are to be used, given the unique nature of the A-IOLs, it may still be necessary to validate the measurement methods on the specific A-IOL being investigated. Objective measurements can include static or dynamic measurements.

3. Calibration

Instruments to be used should include a calibration procedure. For those commercially available instruments with standard calibration procedures, the calibrations recommended by the instrument manufacturer should be performed. For those instruments without standardized calibration procedures, appropriate calibration procedures should be developed consistent with how the study eyes will be tested. Calibration curves should be generated for at least 5 standard samples that encompass the range of parameters expected to be measured in the clinical study. All quantitative metrics to be recorded in the clinical study should have such calibration curves. For example, if sphere and cylinder are to be measured with an optical instrument, then calibration curves for sphere and cylinder should be provided. These can be generated by, for example, placing trial lenses in front of model eyes or in front of real eyes at least 30 minutes after a cycloplegic agent has been administered, in which accommodation is demonstrated to be paralyzed and in front of which an artificial pupil has been placed to achieve a pupil diameter comparable to the uncycloplegeed eye. If an artificial pupil is used, then appropriate alignment procedures should be performed to ensure accurate and stable alignment of the artificial pupil with the natural pupil during the testing. As an alternative to the use of an artificial pupil, if the instrument permits, an analysis can be performed for a sub-aperture of the dilated pupil comparable to an undilated pupil.

If the measurement instruments generate images, such as OCT or ultrasound biomicroscopy, and various ocular parameters will be measured from the images, then calibrations should be provided for all of the measured parameters, encompassing the range of values expected to be measured in the clinical study. Although some instruments may provide internal calibrations, these calibrations in all instances will need to be verified with external calibrations to demonstrate the accuracy of the internal calibrations or to correct the calibrations if necessary. For example, if lens surface curvatures are to be measured, then calibration surfaces or spheres should be imaged under the same conditions as they would be in the clinical study and measured from the images and the calibration curves shown. If axial distances are measured, then appropriate calibration objects of different dimensions should be imaged, such as a stack of thin Plexiglas plates or microscope slides offset on the ends to create a staircase-like object of appropriate and known dimensions.

Imaging methods can suffer from image distortion, so image distortions of magnitudes sufficient to influence the overall results will need to be corrected. The procedure whereby these distortion corrections are achieved should be explained. Optical instruments can suffer from optical distortions, so those optical distortions will need to be corrected. The procedure whereby the optical distortions are corrected should be explained, and the calibration curves shown to demonstrate the accuracy of the calibrations. Optical instruments that image an ocular or optical surface through preceding optical surfaces also introduce optical distortions due to refraction from the preceding optical interfaces. Those optical distortions will need to be corrected if they are of a magnitude great enough to influence the overall results. The procedure whereby these optical distortions are corrected should be explained, and the calibration curves shown to verify and demonstrate the accuracy of the calibrations.

4. Validation Pilot Study

Before initiating the clinical study, it is recommended that a pilot study be conducted on at least 5 eyes. Objective instruments used in a clinical study should be validated in the pilot study using the same methods and protocol used in the clinical study.

If the parameter to be measured can be measured in a phakic eye, then it is appropriate that phakic eyes be used in the pilot study. If the parameter to be measured can be measured in a standard monofocal IOL pseudophakic eye, then it is appropriate to use such eyes for the pilot study. For example, if the objective instrument to be used is a dynamic autorefractor, then the dynamic autorefractor could be used in a group of monofocal pseudophakic eyes to demonstrate that it measures refraction accurately in these eyes compared with an established instrument. To demonstrate that the dynamic instrument measures refractive changes accurately compared with an established instrument, trial lenses could be placed in front of the test eye to induce refractive changes to simulate accommodation. If the instrument to be used is an OCT instrument that would be used to, for example, measure changes in lens surface curvatures, then it can be used on monofocal IOL subjects with monofocal IOLs of known curvatures to demonstrate that the IOL surface curvatures that are measured are accurate. If the parameter to be measured is something unique or exclusive to the A-IOL being tested, and a validation cannot be performed in control subjects, then the pilot study would need to be conducted on the eyes of study patients. For the pilot study, the entire protocol should be run on these study subjects, including the data collection, data analysis, and presentation of the data.

5. Measurement Protocol

Subjects need to be distance corrected for accommodation testing. Any accommodation testing protocol should at least include measurements at distance (6 m; 0 diopters [D]), intermediate (66 cm; 1.5 D), and near (40 cm; 2.5 D). If an examination is not available for

6-m testing distance, a 4-m testing distance could be used with a 0.25 D near add, but for reasons explained next, this would depend on whether testing is being performed monocularly or binocularly. Monocular or binocular testing can be used at the discretion of the sponsor, but should be consistent with the overall study design and depending on whether patients receive monocular or binocular implants. If binocular testing is performed, vergence becomes a factor, so additional considerations may be required to account for this. Furthermore, proximity of a stimulus alone is a stimulus for accommodation. The best way to ensure that the starting point of an accommodative stimulus–response function is a truly unaccommodated state is to use a 6-m testing distance. Furthermore, given that the accommodative response lags behind the stimulus amplitude, a 2.5 D stimulus may not be sufficient to produce the maximum response. Rigorous accommodation testing protocols ideally would include more stimulus amplitudes (e.g., 0.0, 1.0, 1.5, 2.0, 2.5, 3.0 D) to allow for a stimulus–response function to be plotted. If the stimulus amplitudes chosen are sufficient to achieve the maximum accommodative response amplitude, then the plotted stimulus–response function would show a plateau or an asymptote. This would provide sufficient data to identify the maximum objectively measured accommodative response amplitude. The sponsor is encouraged to use optimal conditions to achieve the maximum accommodative response. Static or dynamic measurements can be used. If static measures are used, then at least 3, independent, repeated measures should be performed at each stimulus amplitude for reasons identified in the next section. If dynamic measures are used, then the sponsor should include detailed definitions of the parameters to be measured, the procedures whereby these parameters are obtained, and the analyses methods used.

6. Measurement Precision

It is necessary to know and demonstrate the standard deviation of the chosen measurement method. Therefore, the protocol should include at least 3 repeated measures for each stimulus amplitude. This allows for calculation of a mean and standard deviation. Because of the instability of accommodation, particularly at higher stimulus amplitudes, it is possible that the standard deviations may increase with increasing stimulus amplitude. Therefore, to determine the precision of the chosen measurement method, standard deviations from repeated measures to all the stimulus amplitudes tested should be calculated. The overall population mean standard deviation of the chosen measurement method should be determined from the pilot study. This could be obtained from an analysis of variance or a regression model, for example.

Conversion of Accommodative Biometric Measurements to Accommodative Optical Changes

1. Purpose

The purpose of this section is to provide additional information for validation studies using objectively measured accommodative biometric changes to demonstrate accommodation for A-IOLs.

2. Introduction

Clinical accommodation studies for A-IOLs should, if possible, use objective optical measurements of accommodation as the primary effectiveness end point to unequivocally demonstrate an accommodative optical change in the power of the eye. In some circumstances, there may be practical limitations on the ability to measure accommodative optical changes. In such cases, biometry measurements may be more suitable or desirable to demonstrate the presence of accommodation. However, if such biometric measurements are to be undertaken in clinical studies, the measured biometric changes will need to be converted into dioptric accommodative changes in the power of the eye.[9–11] This section is aimed at providing recommendations for how this can be accomplished. Table 1 identifies various classes of instruments suitable for objective biometry measurements.

Instruments included in Table 1 are all objective measurement methods that provide quantitative data in the form of images or transit times that can be converted to represent physical measurements, such as axial distances, thicknesses, or surface curvatures of the component elements of the eye.

3. Validation Pilot Study

If a biometric measurement is to be used in a clinical study, it needs to be a validated measurement method. Validation can come from using the methods described in the peer-reviewed, published literature or can entail a preliminary validation study.

4. Schematic Eyes

Schematic eyes can be used to convert measured accommodative biometry changes into a dioptric change in the power of the eye.[8] The general scheme for schematic eye calculations is as follows:

1. Measure axial distances
   - corneal thickness, anterior chamber depth, lens thickness, vitreous chamber depth
2. Measure optical surface curvatures
   - anterior cornea, posterior cornea, anterior lens, posterior lens
3. Obtain refractive index values
   - cornea, aqueous, lens, vitreous
4. Calculate surface powers
   - anterior cornea, posterior cornea, anterior lens, posterior lens
5. Calculate equivalent powers
   - cornea, lens, eye
6. Perform optical calculations
   - principle points, focal points, refractive error
7. Induce accommodation
8. Measure axial distances
9. Measure surface curvatures
10. Calculate accommodative change in optical power

Schematic eyes should be calculated from measured biometry parameters (Fig 1). For a normal phakic eye, the parameters shown

Table 1. Objective Biometry Instruments

Ultrasound Biomicroscopy	Corneal Topographers
A-scan ultrasound	Keratometers
Scheimpflug photography	Corneal pachymeters
Partial coherence interferometry	
OCT	
Phakometry	
Magnetic resonance imaging	

OCT = optical coherence tomography.

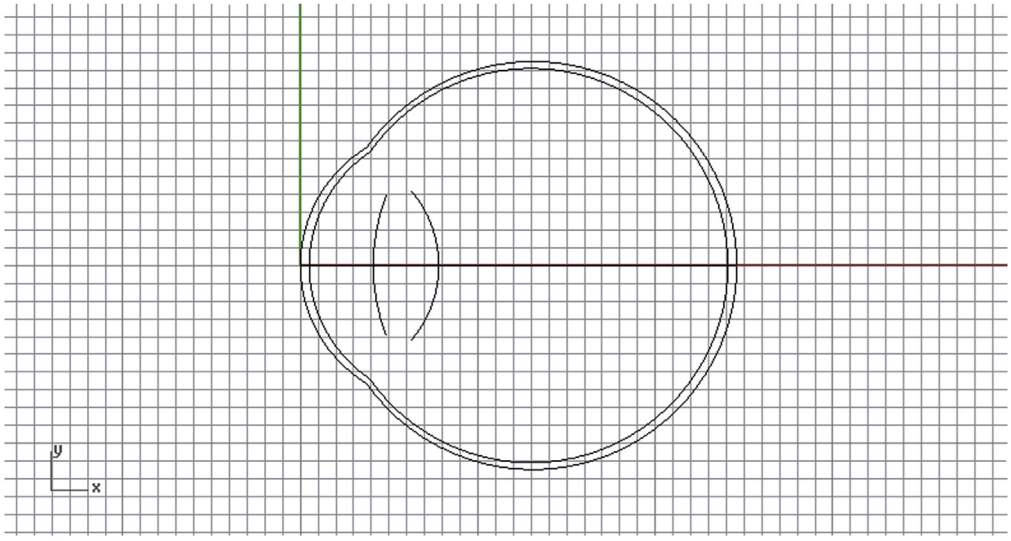

Figure 1. Diagram of phakic Le Grand full theoretical schematic eye.

in Table 2 are required to construct a simple paraxial schematic eye.

Any variation from the normal phakic eye also would need to be incorporated into the schematic eye calculations. For example, if a dual optic A-IOL were to be considered, then the additional surface curvatures, axial distances, and refractive indices of the 2 optical elements of the dual optic A-IOL also would need to be included in the schematic eye and schematic eye calculations.

The refraction of the schematic eye can be calculated when the eye is in an unaccommodated state and then again when the eye is in various progressively increasing accommodative states, and the change in the refraction will represent the dioptric accommodative refractive change.

More complex, nonparaxial schematic eyes can be used to calculate how biometric changes relate to accommodative optical changes. In addition to the parameters identified earlier, aspheric surface profiles, gradient refractive index elements, and variations in pupil diameter can be considered in nonparaxial schematic eyes. Although the optical calculations for such schematic eyes are more involved, the process of calculating such schematic eyes can be considerably simplified by using ray-tracing software into which the various parameters of the eye can be entered, and software calculates the refractive power of the eye. If such nonparaxial optical systems are considered, then consideration needs to be given for additional details, such as how optical aberrations are to be considered, how a dioptric change in power of the nonparaxial eye can be calculated, and what pupil diameter to consider or how changes in pupil diameter will be considered.

Table 2. Parameters Required for a Schematic Eye

Refractive Indices	Surface Curvatures	Axial Distances
Cornea	Anterior corneal surface	Corneal thickness
Aqueous humor	Posterior corneal surface	Anterior chamber depth
Lens	Anterior lens surface	Lens thickness
Vitreous humor	Posterior lens surface	Vitreous chamber depth
		Axial length (sum of corneal thickness, lens thickness, and vitreous chamber depth)

The efficiency of any optical system to undergo a change in optical power varies, with variations in any 1 or a combination of some of or all of the optical elements. Therefore, it may not be suitable or appropriate to use a single schematic eye, but rather it may be necessary to use a population of schematic eyes. This population of schematic eyes should come from a population of actual eyes. One way of obtaining such a population is to derive the schematic eyes from measured real eyes. This is the most effective way to represent the natural diversity in human eyes, provided that the real eyes are representative of the foreseen patient population. A population of subjects should be selected who match the inclusion and exclusion criteria to be used in the clinical study. On each of those eyes in the selected population, all the schematic eye biometry parameters should be measured using the methods and instrumentation selected for the clinical study. The schematic eye parameters would be measured in the unaccommodated eye and then again as the eyes accommodate to at least 3 increasing accommodative stimulus demands. In addition, the static biometry parameters, such as corneal surface curvatures and thickness and axial length that would not be expected to change with accommodation, should be measured. These latter parameters that are not expected to change with accommodation can be measured only in the unaccommodated state, and then the same parameters could be used for calculation of the refractive changes during accommodation.

All the measured (static and changing) parameters would be assembled to produce a schematic eye for each subject and for each accommodative stimulus demand. The schematic eye calculations (Table 3) could be performed by using formulas entered into an Excel Worksheet (Microsoft Corp., Redmond, WA), programmable code such as MATLAB (MathWorks, Natick, MA), or ray-tracing software such as Zemax (Kirkland, WA). The calculations would be used to demonstrate how much

Table 3. Le Grand Full Theoretical Eye[8]

Radii of curvature		
Anterior corneal curvature		7.8000
Posterior corneal curvature		6.5000
Anterior lens curvature		10.2000
Posterior lens curvature		−6.0000
Axial distances		
Corneal thickness		0.5500
Anterior chamber depth		3.0500
Lens thickness		4.0000
Vitreous chamber depth		16.596550
Axial length		24.1966
Mean refractive indicies		
Air	n1	1.0000
Cornea		1.3771
Aqueous humor	n2	1.3374
Equivalent lens	n3	1.4200
Vitreous humor	n4	1.3360
Surface powers		
Anterior cornea		48.3462
Posterior cornea	F1	−6.1077
Anterior lens	F2	8.0980
Posterior lens	F3	14.0000
Equivalent powers		
Cornea		42.3564
Lens	FL	21.7787
Eye	F0	59.9404
Principle points of the cornea		
	A1P1	−0.0576
	A2P′1	−0.6097
	A1P′1	−0.0597
Principal points of the lens		
	A3P2	2.4218
	A4P′2	−1.3994
	A1P2	6.0218
Equivalent focal lengths of eye		
First focal length	f0	−16.6832
Second focal length	f1	22.2888
Distances from corneal vertex		
First principle point	A1P	1.6360
	P′2P′	−4.2508
Second principle point	A1P′	1.9499
First nodal point	A1N	7.2415
Second nodal Point	A1N′	7.5555
First principle focus	A1F	−15.0473
Second principle focus	A1F′	24.2387
Posterior nodal distance		16.9550
Other distances		
Second pp to retina	P′M′	22.2467
	K′	60.0539
	K	0.1135 D
	k	8.8095 m
Object distance	R	8.8111 m
		8811.1363 cm
Object vergence		0.1135 D
Refractive error at corneal vertex		0.1135 D

accommodative optical change in power each schematic eye undergoes with the measured biometric changes. Then for each schematic eye, a stimulus−response function would be calculated that would show on the y-axis the calculated accommodative refractive change from the schematic eyes for the increasing stimulus demands shown on the x-axis. Also, it is recommended that an analysis be performed to show how the dioptric response depends on corneal curvature, anterior chamber depth, IOL power, vitreous chamber depth, and axial length. It is recommended that this kind of analysis be included with all dioptric conversions.

5. Correlation Between Objective Measured and Subjectively Measured Accommodation

Objective optical measurement methods always should be used if it is possible to do the objective optical measurements. The choice to use objective biometric measures to demonstrate accommodation assumes that objective optical refractive measurements cannot be made. However, if accommodative biometric changes do occur, the expectation is that these are correlated with the accommodative optical changes in the eye. Therefore, a study should be performed in which the objectively measured biometric change can be shown to be reasonably correlated with subjectively measured accommodation. First the subjectively measured accommodative amplitude should be measured by any method chosen at the discretion of the sponsor, and the stimulus amplitude to achieve this response should be recorded. Then the objective biometric changes should be measured in response to this same stimulus amplitude. Both the subjective and the objective measures should be repeated 3 times, and the means and standard deviations calculated. This procedure should be repeated on 1 eye of each subject, and the data plotted and fitted with a linear regression line to demonstrate that a correlation exists. Known covariates such as pupil size could be incorporated into the regression analysis, if desired. A similar separate analysis should be performed on the control group.

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Special Report: American Academy of Ophthalmology Task Force Consensus Statement for Extended Depth of Focus Intraocular Lenses

With the advent of wavefront technology, our clinical understanding of human optics and visual performance allows intraocular lens (IOL) manufacturers to manipulate lens design to optimize our visual world. These specially designed extended depth of focus (EDF) lenses use optics that increase depth of focus, potentially allowing better intermediate vision while minimally affecting distance vision. The tradeoff with use of EDF lenses is a reduction in distance image quality if the aberration magnitude is too large.

The American Academy of Ophthalmology Task Force Consensus Statement on EDF IOLs provides criteria to evaluate the implant performance under photopic, mesopic, and glare conditions. The criteria define minimum performance levels to categorize the device as an EDF IOL based on testing at distance, intermediate, and defocus curve testing. The consensus statement also provides recommendations on defocus curve testing methodology, lighting conditions, and the use of digitized charts with randomized presentation of test letters. Implementation of these recommendations will improve the sensitivity of testing and provide more objective data for the U.S. Food and Drug Administration and clinicians.

Intermediate vision and varied lighting conditions have become more critical with the advent of smartphones, tablets, and desk computers. Concise objective testing of patients implanted with EDF IOLs using intermediate tasks will enable us to understand how these lenses perform under these circumstances.

The human visual system is an elegant optical system that provides less-than-perfect images within our neural system. Our neural system then modifies and interprets the images based on past experiences to optimize our performance in daily activities. Understanding the relationship between optics and visual performance of EDF IOLs allows clinicians to guide our patients wisely on the advantages and limitations of such lenses. The information that follows will provide a consensus statement for EDF clinical studies to evaluate the clinical performance of patients receiving these IOLs.

Consensus Statement

The criteria for EDF IOLs are as follows:

The EDF IOL group should consist of a minimum of 100 patients. The control group cohort should be similar for comparisons. The EDF IOLs need to demonstrate comparable monocular mean best-corrected distance visual acuity (BCDVA).

The monocular depth of focus for the EDF-implanted eyes needs to be at least 0.5 diopters (D) greater than the depth of focus for the monofocal IOL controls at logMAR 0.2 (20/32) (see Defocus Curve Testing Methodology, below).

The mean (logMAR) monocular distance-corrected intermediate visual acuity (DCIVA) should be tested under photopic conditions at 66 cm at 6 months and should demonstrate statistical superiority over the control (1-sided test using significance of 0.025).