31

PRESBYOPIA CORRECTION

EVALUATING SUCCESS USING BEHAVIORAL METHODS

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Currently, many prescriptive and surgical approaches are available that can potentially satisfy the needs of the presbyope (see previous chapters). Most of the available modalities (eg, monovision, multifocal contact lenses and IOLs, presbyopic LASIK, and corneal inlays) ameliorate the effects of reduced amplitude of accommodation in the aging eye by extending the ocular depth of focus (DOF). Other alternatives, such as the use of A-IOLs, femtosecond laser lentotomy, lens refilling, and scleral microexcisions, are focused on accommodation restoration.

To assess the relative efficacy of each procedure and to establish the best treatment pattern among them, it is important to carry out comparative evaluations using standardized tests of visual performance. In the past, most of the tests and methods used for assessing presbyopia correction were subjective. It was common simply to measure visual acuity for far, near, and intermediate distances, and/or the subjective amplitude of accommodation in the patient before and after the presbyopic correction was introduced.

More recently, various objective computational and pharmaceutical measures, coupled with imaging, have been devised to allow the extent of the restoration of effective distance and near vision to the presbyopic eye to be more fully assessed. These measurements are capable of providing better insight into the visual performance achieved after a presbyopic correction has been introduced. In particular, they allow real changes in accommodation to be distinguished from changes in other optical (eg, reduced pupil diameter, astigmatism, and higher-order aberrations) and neural (eg, blur sensitivity and binocular summation) factors, which may also improve visual function at near.

Despite their clear advantages over subjective methods in terms of repeatability and avoidance of subjective bias, objective and computational techniques are not completely representative of clinical outcomes. The ultimate goal for all approaches to presbyopia correction is to help individuals to successfully perform their daily living tasks and activities, as it is the patient who finally judges whether his or her "real-world" visual experience is improved. Thus, behavioral methods, as well as patient-based subjective ratings, form a complementary and indispensable way to assess visual performance along with objective measurements (see Chapter 30).

This chapter presents a range of subjective and behavioral methods for the evaluation of the effectiveness of various approaches to presbyopia correction.

Pallikaris IG, Plainis S, Charman WN.
Presbyopia: Origins, Effects, and Treatment (pp. 257-266).

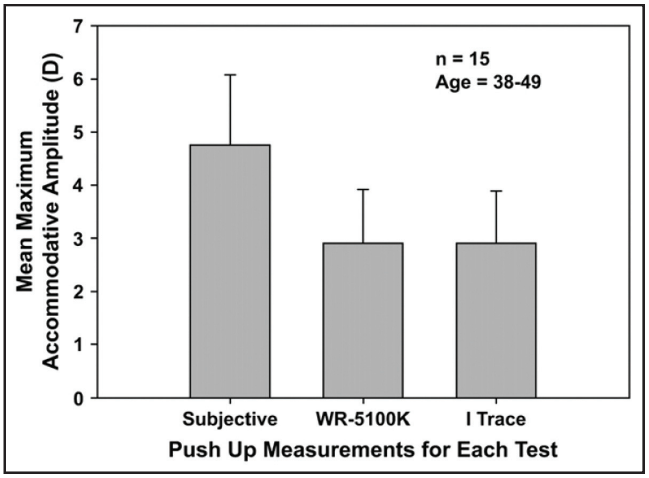

Figure 31-1. Average maximum accommodative amplitudes measured subjectively with the push-up test in free space and objectively for push-up near distances with the WR-5100K autorefractor (Grand Seiko Co, Hiroshima, Japan) and iTrace aberrometer (Tracey Technologies, Houston, TX). Error bars represent 1 standard error of the mean. Data are for 15 prepresbyopic patients, aged 38 to 49 years. (Reprinted from *J Cataract Refract Surg*, vol 34(5), Win-Hall DM, Glasser A, Objective accommodation measurements in prepresbyopic eyes using an autorefractor and an aberrometer, pp 774-784, Copyright 2008, with permission from Elsevier.)

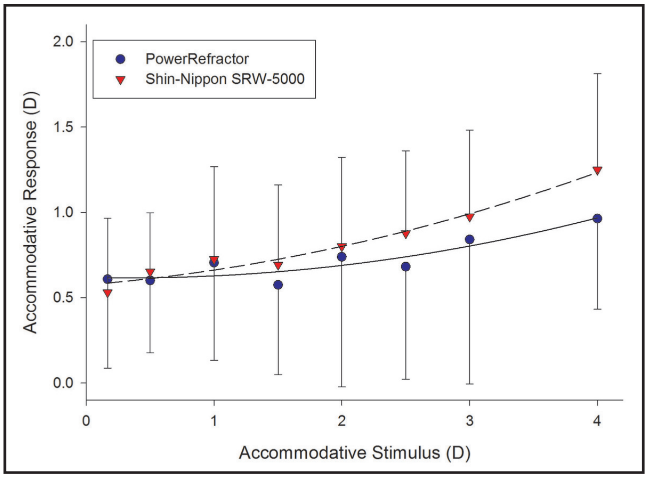

Figure 31-2. Objective accommodation response/stimulus curves in 20 eyes of 12 patients implanted with the 1CU accommodating intraocular lens measured with 2 autorefractors. The average objective accommodation achieved of 0.72 ±0.38 D is much lower than that subjectively measured with the push-up test (2.20 ±0.40 D).

Amplitude of Accommodation: Subjective Versus Objective Measures

Subjective amplitude of accommodation is a measurement of the focusing range of the eye, that is, the dioptric difference between the far point (optical infinity for emmetropes or fully corrected ametropes) and the nearest point where an object (usually an optotype) is focused clearly (see Chapter 2). In young eyes, it is usually interpreted as an index of maximum accommodation effort, although it is well-known that subjective amplitudes of accommodation are higher than objectively measured optical changes due to the inclusion of DOF effects[1,2] (Figure 31-1; see Chapter 3 for a review on ocular DOF).

Amplitude of accommodation declines progressively with age, and it is generally accepted that presbyopia begins when the subjective amplitude of accommodation falls below 3.00 D.[3] However, presbyopia is better defined as "where the normal age-related reduction in amplitude of accommodation reaches a point when the clarity of vision at near cannot be sustained for long enough to satisfy an individual's requirements."[4] When assessed monocularly in healthy eyes, the subjective amplitude decreases to a minimum value of approximately 1.00 to 2.00 D at approximately age 55 years.[5] However, longitudinal studies of objective amplitudes suggest that, for any individual, these fall almost linearly with age to reach 0 at approximately age 50 to 55 years,[6] although a notable intersubject variability has been observed. In older individuals (age >55 years), higher subjective accommodative amplitudes have been found in pseudophakes,[7] possibly due to increased levels of ocular aberrations (eg, astigmatism) following IOL implantation and age-related pupillary miosis.

Subjective amplitude of accommodation is inadequate for the assessment of whether any true accommodation is present in the presbyopic eye after treatment, such as when using A-IOLs to partially reverse presbyopia. This is because subjective recordings of accommodation amplitude fail to differentiate between passive DOF and an active accommodative power change in the eye. Thus, an objective measurement of accommodation, capable of determining the true dioptric change in refraction, has to be implemented in such cases. As an example, Figure 31-2 shows the accommodation response/stimulus curve for patients whose mean monocular subjective amplitude after A-IOL implantation was 2.20 D, whereas the objective change in accommodation provided by the A-IOL was only ~0.70 D.[8]

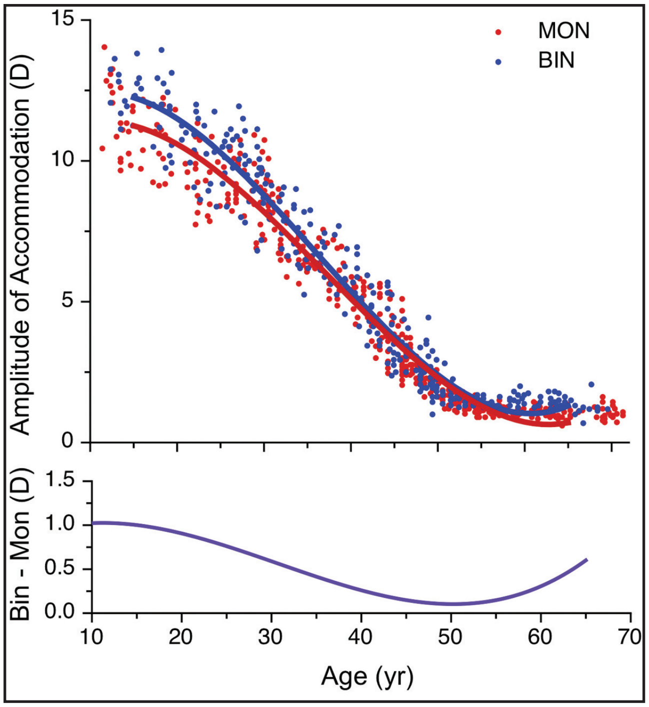

Figure 31-3. Comparison of binocular (blue dots) and monocular (red dots) amplitudes of accommodation (upper) and their difference (lower) as a function of age. (Based on data compiled and replotted from Duane A. Studies in monocular and binocular accommodation, with their clinical application. *Trans Am Ophthalmol Soc.* 1922;20:132-157.)

Real-world activities are usually performed with binocular viewing, which provides normal proximity cues and allows more natural convergence. Figure 31-3 compares binocular versus monocular subjective amplitude of accommodation recordings (Duane's data[5]). This shows that although the individual differences between the amplitudes under the 2 observing conditions may range up to 1.50 D or more, the average difference deduced from the entire mass of observations is comparatively moderate, being approximately 0.60 to 0.70 D for ages up to 18 years, 0.50 D for ages between 19 and 30 years, and 0.40 D for ages between 31 and 50 years. The higher difference in young eyes is possibly due to extra convergence-driven accommodation (quite high because targets are close). This is not so evident in older eyes because the target is only clear to approximately 0.5 m, and there is little convergence demand. Increased demand in convergence may also result in further pupil contraction and a corresponding increased DOF.[9] However, it is of interest to note that binocular-minus-monocular difference increases for ages older than 55 years. This may be attributed to a reduction in both visual acuity and contrast sensitivity above the age of 50,[10] which results in an increase in binocular summation and hence permits a larger error of focus to be tolerated.

Through-Focus Performance: Defocus Curves

Visual Acuity

Measuring visual acuity (VA) through a range of powered lenses creates a performance profile over a range of focal demands. This is equivalent to determining VA over a range of distances, without the issues of resizing the letters and maintaining a constant illumination. The profile generated is known as a defocus curve (Figure 31-4). This replaces the need for measurements of near and intermediate VA at arbitrarily chosen distances, which may suit the optics of 1 lens but not those of a competing device. Measurements of VA at distance, intermediate, and near nominally represent 3 points on the defocus curve. However, the frequent use of different types of chart and illumination conditions for the distance and near measurements, often combined with poorly defined testing distances, may make it difficult to compare the results with those of a properly controlled, full defocus curve.

Although defocus curves are a great improvement on measuring visual acuity for a range of distances, care is needed regarding the techniques used and their interpretation.

Measurements of defocus curves should be performed with the best-corrected distance correction in place, ensuring that manifest refraction does not influence the results. Figure 31-4 presents characteristic defocus curves in normal young, cyclopleged patients under binocular and monocular vision with 2 artificial pupil sizes. Gupta et al[11] advocated that, to increase accuracy and to minimize memorization effects, both the lenses used and the letters read should be randomized between VA measurements when quantifying defocus curves. This can be achieved easily by using a computerized logMAR test chart, where letters can be randomized and the back-illuminated monitor standardizes luminance. The magnification effects of lenses in the spectacle plane should be compensated for mathematically.[12] If measured monocularly, the disrupted natural association with convergence and pupil size can affect the measure of VA.[13]

The methods used to analyze defocus curves vary greatly in different studies. The direct comparison

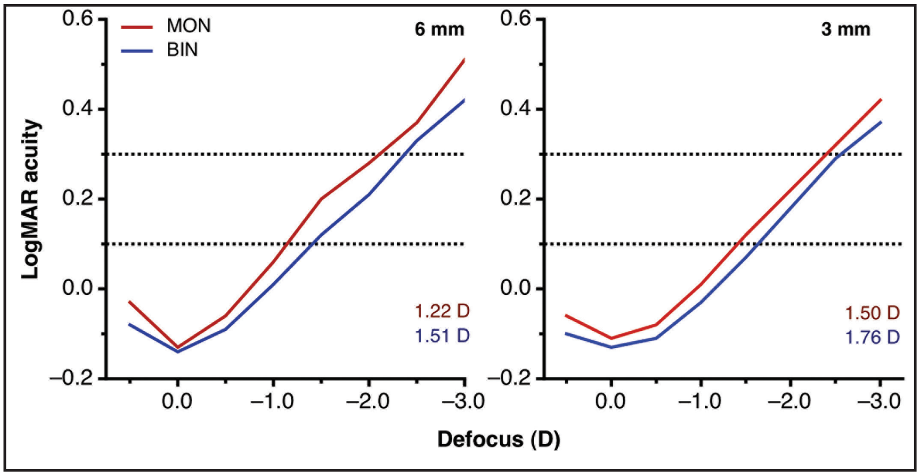

Figure 31-4. Defocus curves showing logMAR acuity over a range of focus distances induced by negative powered lenses for 2 pupil sizes and under monocular (dominant eye) and binocular vision. The horizontal dotted lines correspond to 2 possible criteria of logMAR acuity (0.1 and 0.3, equivalent to 6/7.5 and 6/12, respectively) used for calculating depth of focus (DOF); DOF values are given for the logMAR 0.1 criterion. Data are average values from 13 young (27 ±5 years) cyclopleged patients with the best-corrected distance correction in place. DOF increases with binocular view and reduced pupil diameter.

analysis method statistically compares the VA at each level of defocus. However, because the more times individual statistical tests are repeated, the more likely they are to incorrectly suggest that some results are significantly different, this artifact of multiple testing needs to be corrected. Depth of focus metrics, derived from the full defocus curve, provide a single-figure summary of the effectiveness of the presbyopic correction in providing acceptable near, intermediate, and distance vision. Using the defocus curve, the DOF is the dioptric range over which the patients can sustain a specific absolute or relative level of VA. For example, Figure 31-4 shows the DOFs derived on the basis that the acuity should always be ≤0.1 logMAR. No consensus exists for the level of acuity considered to be the limit for DOF, and often the criteria are not stated, thus preventing comparison between studies. The limit of 0.3 logMAR (6/12 equivalent) is the most common criterion used with multifocal IOL studies and matches the level of VA defined as the driving standard in Europe.[14] With an absolute criterion, the chosen VA and the limits of the DOF are independent of best VA. In contrast, a relative criterion determines its VA cutoff relative to the best-attained level of VA. Relative criteria have not been used in multifocal IOL studies, but have been used in the assessment of accommodating IOLs.[15] A criterion of 0.04 logMAR drop in VA from the best-corrected distance VA (to account for the variability in logMAR chart measurement, which is relatively unaffected by age) has been shown to give the most reliable results for eye focus.[12]

The 2 or more focal points created by simultaneous bifocals and multifocals result in a distinctive defocus curve profile with 2 or more peaks of optimum acuity (ie, troughs in logMAR), one at distance and the others corresponding to the near additions of the lenses (Figure 31-5).[16] Hence, defocus curves demonstrate the strength of the near additions (the separation in diopters between the distance and intermediate/near peaks) as well as the quality of vision at distance, near, and intermediate distances. Although an absolute criterion with a drop in VA of 0.04 logMAR has been shown to be most appropriate for prepresbyopes and accommodative restoration procedures, the defocus curve of a simultaneous-vision bifocal or multifocal can pass through the DOF criterion several times. Hence, a new area metric has been developed and validated[16] with the area between a 0.3 logMAR absolute cutoff and the defocus curve calculated

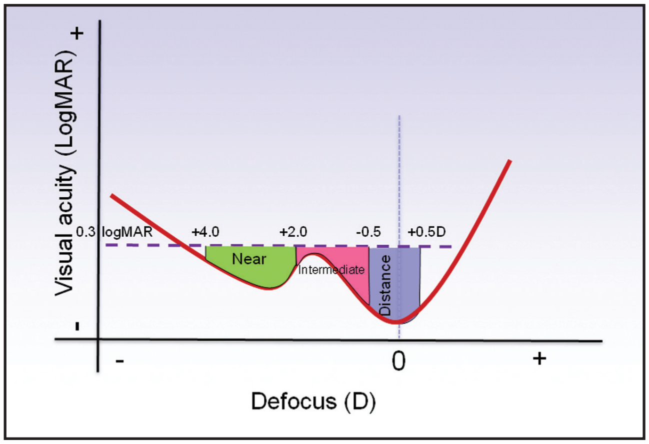

Figure 31-5. Defocus curve showing the visual acuity over a range of focus distances induced by a simultaneous vision bifocal lens. The area metric developed and validated by Wolffsohn et al[16] is shown with the area between a 0.3 logMAR absolute cutoff and the defocus curve calculated for the upper and lower limit of distance (-0.50 and +0.50 D), intermediate (-2.00 and -0.50 D), and near (-4.00 and -2.00 D).

for the upper and lower limit of distance (-0.50 and +0.50 D), intermediate (-2.00 and -0.50 D), and near (-4.00 and -2.00 D). This introduces a standardization that will allow the comparison of different strategies for increasing the subjective range of clear vision.

Although through-focus VA and the corresponding DOF are usually measured under photopic conditions with high-contrast letter charts, defocus curves can be repeated with letters of lower contrast or at lower ambient lighting levels. This allows exploration of the quality of vision achieved with simultaneous multifocal designs in which the proportions of light split to different focal planes depend on the pupil size.

CONTRAST SENSITIVITY

Despite the widespread advocacy for the measurement of contrast sensitivity (CS), to better simulate visual performance in our mixed-contrast visual environment, there is little standardization in the methods used. Most clinical studies that incorporate a measurement of CS use the Pelli-Robson chart, which presents capital-letter triplets of the same size but varying contrast, or the CSV1000 backlit chart, which presents a sine wave grating at 1 of 4 orientations at 4 spatial frequencies and 8 contrast levels. The repeatability of both of these tests is reasonable,[17,18] and they outperform liquid-crystal display (LCD) computerized charts, although the latter have attractive features such as the randomization of letters and the possibility of selecting from a full range of contrast and acuity variables.

The range of chart vergence over which contrast sensitivity does not fall below a particular level can be used to calculate the DOF. If grating charts are used, contrast sensitivity can be measured for a range of spatial frequencies, and it is expected that DOF will be affected by the spatial frequency of the target[19] (see Figure 3-3, Chapter 3).

Visual Reaction Times

Experiments with human observers have shown that the speed of visual processing, as measured using simple visual Reaction Times (RTs)*, becomes slower in a predictable way as stimuli become less visible, ie, as stimulus contrast decreases.[20] Because the sensory component of simple visual RTs is limited by the properties of neurons in the retinocortical pathways, it is expected to reflect (1) the spatiotemporal properties of these neurons[21,22] and (2) the quality (eg, contrast and resolution) of the retinal image, which in turn relates to the effectiveness of the presbyopic correction.

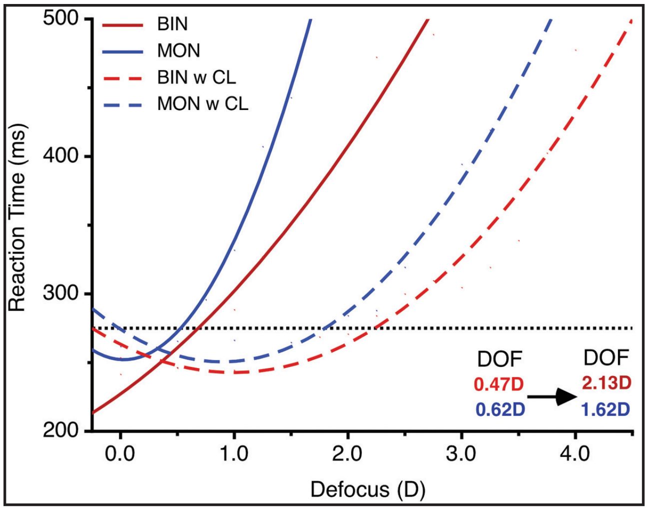

Figure 31-6. Plot of reaction times as a function of defocus under monocular (blue) and binocular (red) viewing conditions in "unaided vision" (solid lines) and in the presence of a low-add multifocal contact lens for the correction of presbyopia. The stimulus used was a 4 cpd vertical grating of 10% contrast. The values on the right correspond to calculations of the depth of focus in the 2 conditions, using a criterion reaction time of 275 ms.

Visual RTs have a direct relevance to perceptual-motor tasks, such as driving. For example, they have been used to estimate the time to collision with an approaching object under specific conditions and can be easily translated into stopping distances.[20]

Similar to visual acuity and contrast sensitivity, RTs can be used to assess through-focus performance, offering the advantage of suprathreshold (ie, real-world, task, evaluation). Figure 31-6 depicts the effect of defocus blur on RTs under monocular (dominant eye) and binocular viewing conditions in "unaided vision" and in the presence of simultaneous vision correction achieved by using a multifocal, aspheric contact lens. It is evident that, when wearing the lens, DOF calculated by using a RT criterion of 275 ms is increased compared with "unaided vision," with the effect being more pronounced under binocular vision.

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*Simple visual reaction time is the elapsed time between the presentation of a visual stimulus, such as a grating, and the subsequent behavioral response, under the condition that the subject is instructed to respond (eg, to press a button) as rapidly as possible. In a typical experiment, each trial represents a block of 32 measurements.

SUBJECTIVE (OR PERCEPTUAL) BLUR LIMITS (SENSITIVITY)

A practical criterion for DOF that is relevant to clinical and everyday situations is the perception of blur. In conventional laboratory-based subjective measures of blur resolution, the participant is asked to indicate the defocus limits at which a target's clarity, contrast, and/or form has changed relative to the in-focus situation. Resolution of blur is affected by a range of optical factors (eg, pupil size and optical imperfections) and stimulus characteristics (eg, size and contrast), with defocus limits being smallest with targets having the smallest details.[23,24] Moreover, blur tolerance has also been found to vary with personality characteristics,[25] refractive error (ie, higher blur sensitivity for emmetropes[26]), and age.[24,27] Older patients demonstrate higher levels of experience-based blur compensation resulting in a lower sensitivity to blur.[27]

However, when the task is more complex, that is, if the participant has to judge whether the resultant blur might become "bothersome" by invoking a sensation of annoyance or "objectionable" by affecting his or her functional performance, then a significant higher-level cognitive aspect is added to the primary neurosensory task.[24] Thus, the perceptual criterion that is introduced to judge the blur in a defocused image will influence the defocus limits, and hence the effective DOF for each individual.

Several studies have investigated the effect of the perceptual criterion of blur on vision function. Plakitsi and Charman[28] selected the criterion of "adequate vision" to specify the effective DOF. Using this criterion, the total DOF for 20/40 (0.3 logMAR) letters was unusually large in the young adults tested, ranging from ~1.60 to ~2.20 D. Atchison et al[23] used 3 functional dioptric-based blur criteria with reference to the position of maximal target clarity. These included (1) "just noticeable blur," the point at which one first notices slight blur of previously in-focus letters, representing approximately 60% of the DOF[29]; (2) "just troublesome blur," the point at which one is first troubled by the blur of the still-readable letters; and (3) "just objectionable blur," the point at which the level of image degradation is unacceptable, even if the letters are still readable. Although the blur criteria were affected by pupil size and target detail, the "just objectionable" blur was found to result approximately 2.7 times the limits of the "just noticeable" blur criterion (see Figure 31-1 in Chapter 3). In another study[24] in which similar blur criteria were employed, the threshold of "bothersome" blur was found to be on average 1.02 D for isolated 20/50 (0.4 logMAR) letters and 1.34 D for 20/50 text.

EFFECT OF TRAINING/LEARNING AND ADAPTATION

One feature of any type of presbyopic correction is that visual performance may improve with time. In the visual system, prolonged viewing of a close-to-threshold target, such as a defocused image, results in improved sensitivity. This dynamic and experience-dependent adjustment in functional performance is often labeled as adaptation or perceptual learning, 2 known forms of neuronal plasticity that are difficult to separate.[30]

Adaptation to blur describes any change in visual performance (or patient's tolerance) after exposure to defocus, which is unaccompanied by a change in refractive error.[31,32] Variation in blur detection has usually been measured indirectly, by tracking the changes in visual acuity following exposure to myopic defocus. Figure 31-7, for example, shows the improvement in logMAR acuity (using Landolt C or letter optotypes) following 1 hour of adaptation to a +2.00 D defocus.

Jung and Kline[27] postulated that older patients' ability to identify blurred text involves not only age-related optical changes, but also experience-mediated neural compensation. However, the neuroadaptive responses in presbyopes have not been adequately studied to gain insight into the mechanisms involved. There is evidence, however, that the neural responses that underlie adaptation to transient blur are intact in the aging visual system.[33] Moreover, it has been observed that older patients chose significantly more blurred images as being perceptually focused, as compared with young adults. This is consistent with habitual adaptation to their uncorrected level of blur (see Chapter 10). Individual patient factors, such as stereopsis, monovision abilities, personality characteristics, and past or induced astigmatism, may also influence long-term perceptual adjustments.

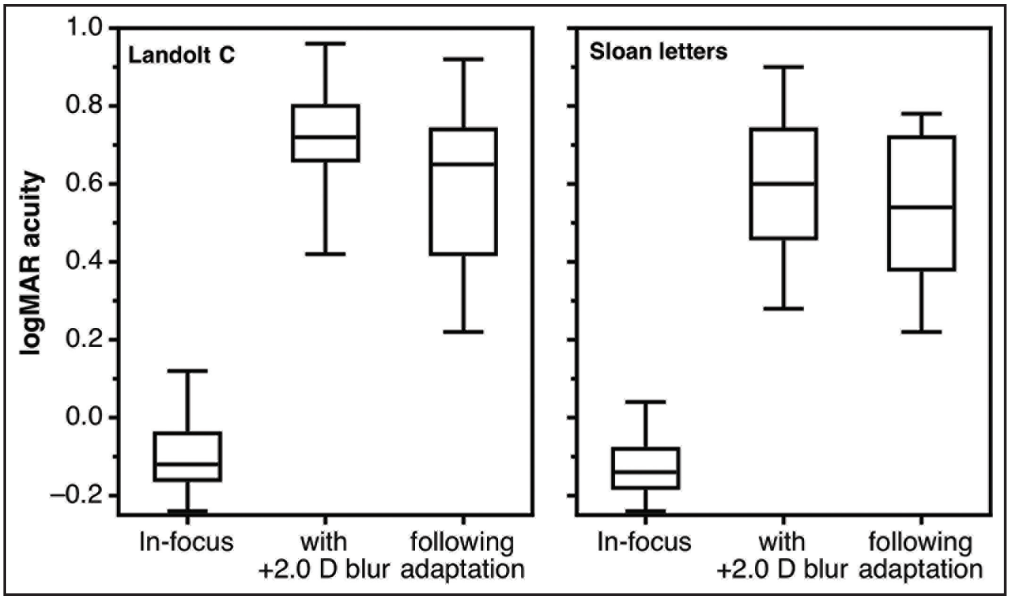

Figure 31-7. Box plots of logMAR acuity using Landolt C (left) and Sloan letters (right) logMAR charts at best focus following +2.00 D (myopic) defocus and after 1 hour of adaptation.[32]

DYSPHOTOPSIA AND GLARE EFFECTS

Any refractive boundaries that intercept with the light entering the pupil can cause the scattering of light, reported by patients as glare or halos. Such effects are minimal with changes in asphericity or optical power during accommodation, but they may become marked with simultaneous bifocal and multifocal designs of correction.[34,35] This is particularly the case under mesopic or scotopic lighting conditions when the pupil is large. However, neuroadaptation appears to decrease symptoms of dysphotopsia with time.[36]

Dysphotopsia has been examined in a number of ways in research studies, using patient drawings,[37] questionnaires,[38] visual acuity or contrast sensitivity measurement difference when a glare source is added, psychophysical flickering luminance matching such as the C-Quant,[34,38] and the visual field extent of halo obscuration of letters (Halometer).[39]

PHARMACOLOGICALLY INDUCED ACCOMMODATION

To establish the level of success with any design of A-IOLs, it is important to objectively identify the refractive and/or biometric changes that occur with accommodative effort (Figure 31-8; see Chapter 19). Most studies have relied on pharmacological stimulation of the ciliary muscle to induce accommodation, which is known to maintain its activity well beyond the onset of presbyopia (see Chapter 11). This technique is critical with ultrasound imaging where the probe obscures the visual axis, but it has also been used with noninvasive techniques, such as optical coherence tomography, where the eye being measured can be presented with a visual stimulus at different levels of accommodative demand. In humans, accommodation is most commonly stimulated by topical application of pilocarpine, a direct-acting parasympathomimetic agent that stimulates the muscarinic receptors present at the junction of post-ganglionic parasympathetic nerves and their effector organs. When instilled into the conjunctival sac, pilocarpine acts as a muscarinic agonist and causes contraction of the smooth muscle of the iris sphincter and the ciliary muscle, resulting in pupillary miosis and lens accommodation, respectively.

The advantage of pharmacological over stimulus-driven accommodation is that patient compliance in fixating on an accommodative stimulus is not required. On the other hand, there are certain drawbacks when pilocarpine is used as a stimulant. First, pilocarpine may result in an overestimation of accommodation (usually referred to as a "superstimulus" accommodative response[40]) compared with stimulus-driven accommodation, especially in presbyopic phakic patients.[41] Second, a considerable variability in the estimated amplitude of accommodation is observed between patients (Figure 31-9A)[41,42,43] which is mainly dependent on absorption of the drug and iris color, or

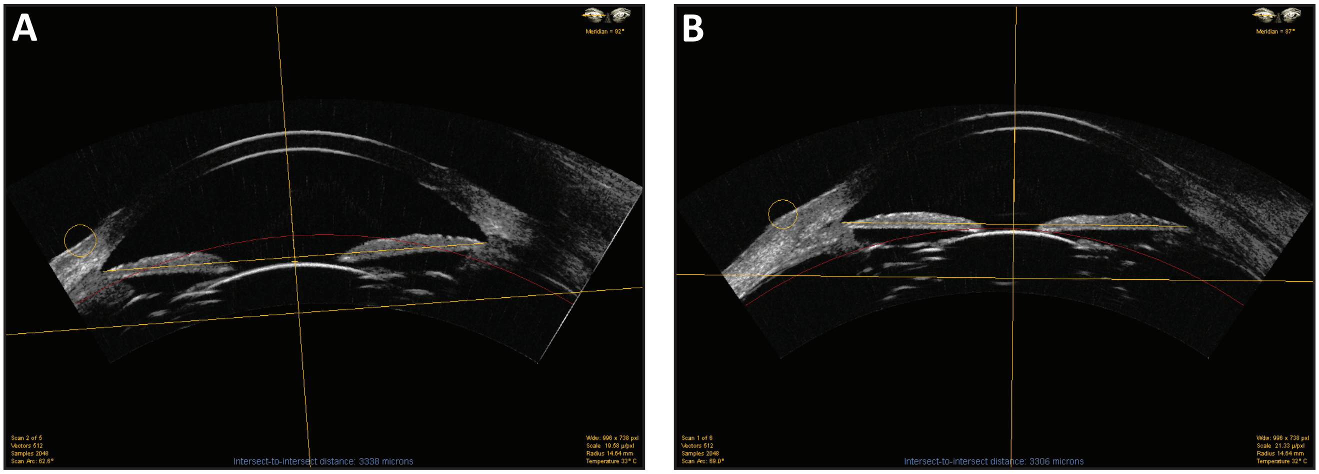

Figure 31-8. Images of horizontal B-scan with a very high-frequency digital ultrasound arc scanner (Artemis 2, ArcScan, Inc, Morrison, CO) through an eye of a patient with an accommodating intraocular lens (IOL). Images were taken 1 month following surgery, (A) before and (B) after application of 1 drop of pilocarpine 4%. Note the forward movement of the implanted IOL, accompanied by pupil miosis.

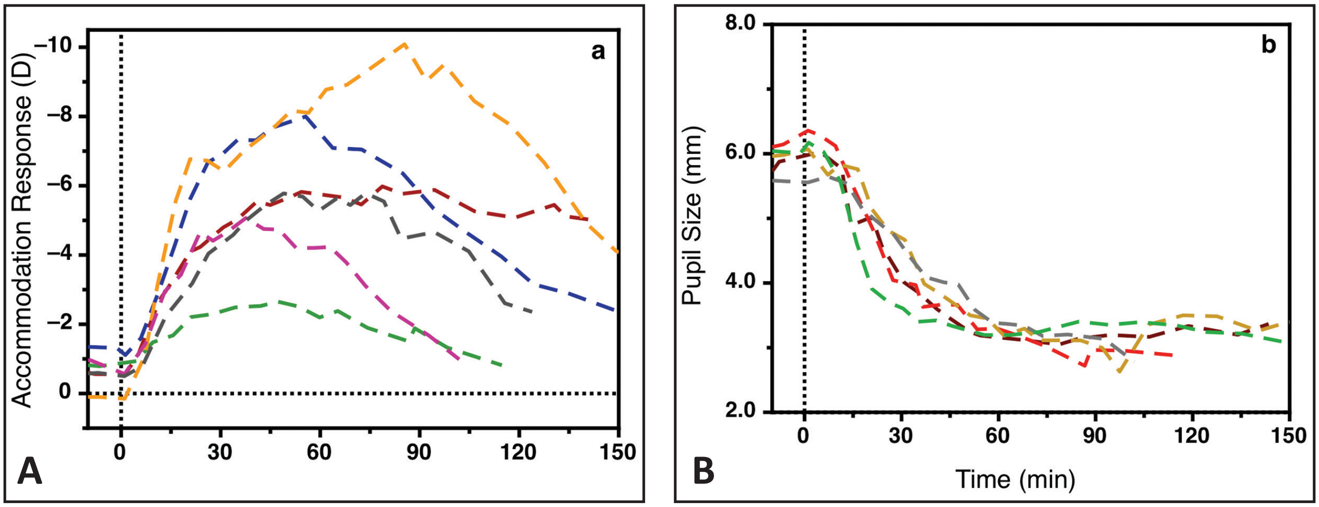

Figure 31-9. Pharmacologically driven accommodation in young adults aged 23 to 33 years (A, left), and pupil (B, right) response as a function of time following instillation (at time 0) of pilocarpine hydrochloride 4%. Accommodation was measured using a wavefront analyzer (COAS) in conjunction with a purpose-built Badal optometer. Analysis was performed for natural pupils. Note the high interpatient variability in the accommodation response, in contrast to the effect of pilocarpine on pupil diameter, which did not vary between patients. (Based on data compiled and replotted from Plainis S, Plevridi E, Pallikaris IG. Comparison of the ocular wavefront aberration between pharmacologically-induced and stimulus-driven accommodation. *Ophthalmic Physiol Opt.* 2009;29(3):272-280.)

differences in the thickness and the shape of the crystalline lens, and in the anterior chamber depth. Third, the resultant ciliary muscle contraction is accompanied by pupillary miosis, which hinders attempts to objectively evaluate any changes in refraction or higher-order ocular aberration (Figure 31-9B). Finally, the time course of the topically induced accommodative response is slow and highly variable between patients of similar age (see Figure 31-9A). Therefore, the accommodative response achieved will strongly depend on the time after topical application at which the response is measured. In conclusion, stimulation of accommodation by topical application of pilocarpine may be inappropriate for evaluating the efficacy of A-IOLs.

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