

## Contrast Sensitivity and Measuring Cataract Outcomes

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Functional vision means the ability of the visual system to receive, transmit, and report information. The optical system of the eye allows reception, whereas the neurosensory retina and the neural pathways to the visual cortex govern transmission. Cortical elements in turn report information.

Images form the elements of visual data. The formation of the image on the retina depends on the optical elements of the eye, including all of the ocular media: the tear film, cornea, aqueous humor, lens, and vitreous body. The principal elements in this system, the cornea and the lens, lie within the province of the anterior segment surgeon or ophthalmologist who performs cataract and refractive surgery.

The evaluation of functional vision in the clinic or laboratory may take a variety of approaches. Wavefront aberrometry, ray tracing, corneal topography, and double-pass devices enable one objectively to measure retinal image quality. Contrast-sensitivity testing, reading speed, and driving simulations represent subjective tests that measure the neural and the optical performance of the visual system. Both approaches add to the knowledge of functional vision.

As the understanding of the visual system has advanced, the evaluation of surgical techniques and devices has also evolved. Clinical studies have measured the outcomes of both corneal refractive

surgery and lenticular surgery with the full armamentarium of functional vision testing. The results of ongoing research help to guide further developments in these fields.

Patients' heightened expectations provide a challenge for the increasing sophistication of anterior segment surgeons. The methods used in clinical research today will likely become standards of clinical practice tomorrow. These methods highlight the limitations of currently entrenched techniques, such as measurement of Snellen acuity. Now the American National Standards Institute has adopted sine wave grating contrast sensitivity at five spatial frequencies and the Early Treatment of Diabetic Retinopathy Study logarithmic letter chart. Cataract and refractive surgeons should take notice of developments in visual science that will strongly affect their practices in the very near future.

Although the achievement of 20/20 uncorrected visual acuity remains a laudable target for any cataract or refractive surgeon, the goal of high-quality vision increasingly reflects the understanding of the visual system as a whole. In fact, Snellen acuity represents only a small portion of functional vision. A comparison of vision and hearing highlights the limitations of standard visual acuity tests: the auditory equivalent of a standard high-contrast Snellen eye chart is a hearing test with only one high level of loudness for all sound frequencies. Today, contrast-sensitivity testing is emerging as a more comprehensive measure of vision that will probably replace Snellen letter acuity testing, just as audiometric testing replaced the "click" and spoken-word tests used before World War II [1].

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Engineers understand that Fourier analysis allows the representation of any visual object as a composite of sine waves of various frequencies, amplitudes, and orientations. In fact, visual processing in the human nervous system works like Fourier analysis in reverse, with functionally independent neural channels filtering images to create what is seen [2]. Sine wave gratings are the building blocks of vision, just as pure tones are the building blocks of audition.

Ophthalmologists realize that patients may complain about haziness, glare, and poor night vision despite 20/20 Snellen acuity. This anomaly can be understood when one realizes that the Snellen acuity letter recognition test uses very high contrast. The jet black letters on the bright white background have a great deal of reserve contrast, so that even a patient with severely reduced contrast sensitivity can still read the chart. That patient perceives the letters as gray on white rather than black on white, but still is able to recognize them. The examiner has no way of knowing just how gray the letters look to any particular patient. Snellen acuity is a relatively insensitive test of visual function.

Contrast-sensitivity testing has the ability to detect differences in functional vision when Snellen visual acuity measurements cannot [3]. For example, a patient with loss of low-frequency contrast sensitivity may be able to read 20/20 but be unable to see a truck in the fog. Although blur caused by refractive error alone affects only the higher spatial frequencies, scatter of light caused by corneal or lenticular opacities causes loss at all frequencies. Glaucoma and other optic neuropathies generally produce loss in the middle and low frequencies. Contrast sensitivity testing offers critical information to help elucidate patients' diagnoses.

Numerous studies have demonstrated the relationship of contrast sensitivity and visual performance. From driving difficulty [4] and crash involvement [5], to falls [6] and postural stability in the elderly [7], to activities of daily living and visual impairment [8], to the performance of pilots in aircraft simulators [9], contrast sensitivity has consistently been found to provide a high degree of correlation with visual performance.

### Contrast sensitivity declines because of increasing aberrations

Unfortunately, contrast sensitivity declines with age even in the absence of ocular pathology,

such as cataract, glaucoma, or macular degeneration (Fig. 1). The pathogenesis of this decline in vision likely involves changes in the spherical aberration of the crystalline lens.

Spherical aberration is a property of spherical lenses. A spherical lens does not refract all parallel rays of incoming light to a single focal point. The lens bends peripheral rays more strongly so that these rays cross the optical axis in front of the paraxial rays. As the aperture of the lens increases the average focal point moves toward the lens, so that a larger pupil produces greater spherical aberration.

Spherical aberration of the cornea changes little with age. Total wavefront aberration of the eye increases more than threefold, however, between 20 and 70 years of age [10]. Wavefront aberration measurements combined with data from corneal topography demonstrate that the optical characteristics of the youthful crystalline lens compensate for aberrations in the cornea, reducing total aberration in younger people. Unfortunately, the aging lens loses its balance with the cornea, because both the magnitude and the sign of its spherical aberration change significantly [11]. A loss of balance between corneal and lenticular spherical aberration causes the degradation of optical quality in the aging eye.

The sine wave grating contrast sensitivity of a pseudophakic patient with a spherical intraocular lens (IOL) implanted is no better than that of

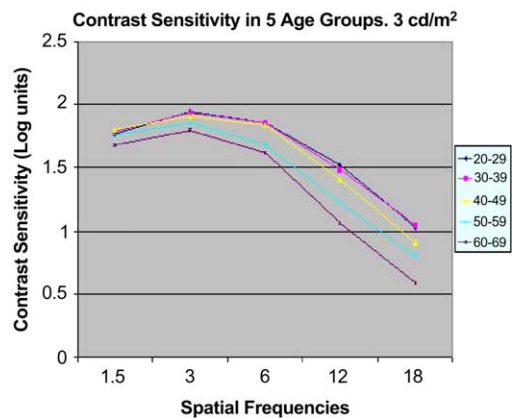


Fig. 1. Contrast sensitivity in five age groups 3 cd/m<sup>2</sup>. The decline in contrast sensitivity with age was demonstrated in a multicenter study of healthy normal subjects. (From Packer M. Contrast sensitivity in healthy subjects 20 to 69 years old. Presented at the Symposium on Cataract, IOL and Refractive Surgery, American Society of Cataract and Refractive Surgery. San Francisco, April 12, 2003; with permission.)

a phakic patient of a similar age who has no cataract [12]. When a 65-year-old patient with cataracts has the cataracts removed and is implanted with spherical IOLs the resulting visual outcome is no better than the visual quality of a 65-year-old without cataracts (Fig. 2). The fact that the visual quality of the IOL patients is no better than that of their same-age counterparts may seem surprising because an IOL is optically superior to the natural crystalline lens. This paradox is explained, however, when one realizes that the intraocular implant has positive spherical aberration like the aging lens. It is not the optical quality of the IOL in isolation that creates the image, but the optical quality of the IOL in conjunction with the optical quality of the cornea.

The spherical aberration of a manufactured spherical IOL is in no better balance with the cornea than the spherical aberration of the aging crystalline lens. Aberrations cause incoming light that is otherwise focused to a point to be blurred, which in turn causes a reduction in visual quality. This reduction in quality is more severe under low luminance conditions because ocular aberrations increase when the pupil size gets larger.

### Pseudophakic correction of spherical aberration

The youthful, emmetropic, minimally (or perhaps optimally) aberrated eye [13] has become the standard by which the results of cataract and refractive surgery are evaluated. The erosion of accommodation and the decline in functional vision that occurs with age [14] have both been linked to changes in the human lens [15,16]. Lens replacement surgery offers a natural avenue for the correction of presbyopia, and for the

reversal of increasing lenticular spherical aberration. Because the optical wavefront of the cornea remains essentially stable throughout life [17], refractive lens exchange seems to represent a permanent solution to the challenges of restoring accommodation and achieving youthful quality of vision. For these reasons the lens has started to come into its own as the primary locus for refractive surgery.

Recent advances in aspheric monofocal lens design also lend themselves to improvements in multifocal and accommodative IOLs. Because the positive spherical aberration of a spherical pseudophakic IOL tends to increase total optical aberrations, attention has turned to the development of aspheric IOLs [18]. These designs are intended to reduce or eliminate the spherical aberration of the eye, improve modulation transfer function as compared with a spherical pseudophakic implant, and enhance functional vision. A variety of aspheric IOL designs are currently marketed in the United States: the Tecnis Z900 IOL (Advanced Medical Optics, Santa Ana, California); the AcrySof IQ IOL (Alcon, Ft. Worth, Texas); and the SofPort AO IOL (Bausch and Lomb, San Dimas, California).

The Tecnis IOL was designed with a modified prolate anterior surface to compensate for the average corneal spherical aberration found in the adult eye. It shares basic design features with the CeeOn 911A IOL, including a 6-mm biconvex square edge optic and angulated “capsular C” polyvinylidene fluoride haptics. The Tecnis Z900 is a multipiece lens. It is available in both second-generation silicone and acrylic. The silicone IOL has a refractive index of 1.46, and the acrylic lens has a refractive index of 1.47. It introduces  $-0.27 \mu$

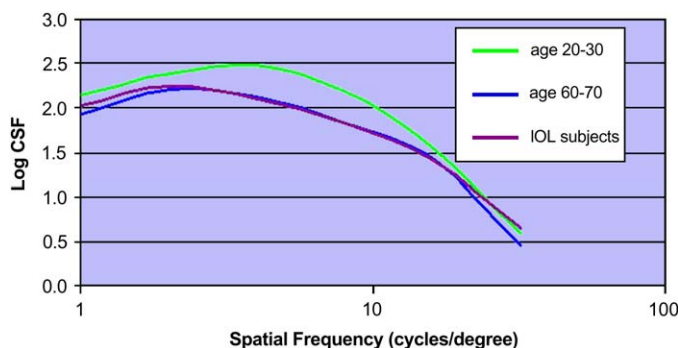


Fig. 2. Contrast-sensitivity function with 4-mm pupil. The contrast sensitivity of pseudophakic patients with spherical IOLs is no better than the contrast sensitivity of age-matched control subjects without cataract. (From Nio YK, Jansoni NM, Fidler V, et al. Spherical and irregular aberrations are important for the optimal performance of the human eye. *Ophthalmic Physiol Opt* 2002;22:103–12; with permission.)

of spherical aberration to the eye. The clinical investigation of the Tecnis IOL submitted to the US Food and Drug Administration (FDA) demonstrated elimination of mean spherical aberration and significant improvement in functional vision when compared with a standard spherical IOL [19]. The US Centers for Medicare and Medicaid Services announced New Technology IOL Status for the Tecnis IOL on January 26, 2006 [20]:

“Today’s announcement of coverage with additional payment for an innovative type of intraocular lens reflects Medicare’s attention to improved clinical benefits,” said CMS Administrator, Mark McClellan, MD, PhD. “For these lenses, there is clear evidence of improved functional vision and contrast acuity.”

The AcrySof IQ shares the UV and blue light-filtering chromophores found in the single-piece acrylic AcrySof Natural IOL. The special feature of this IOL is the posterior aspheric surface designed to compensate for spherical aberration by addressing the effects of overrefraction at the periphery. The AcrySof IQ is a single-piece lens made of hydrophobic acrylic, and it has a refractive index of 1.55. It adds  $-0.20 \mu$  of spherical aberration to the eye.

The SofPort Advanced Optics (LI61AO) IOL is an aspheric IOL that has been specifically designed with zero spherical aberration so that it does not contribute to any pre-existing higher-order aberrations. It is a foldable silicone IOL with polymethyl methacrylate haptics and square edges, and it was specifically designed for use with the Bausch and Lomb SofPort System, an integrated, single-use, single-handed planar delivery IOL insertion system. The SofPort lens is a multipiece lens made of second-generation silicone. It has a refractive index of 1.43, and it introduces no spherical aberration to the eye.

Peer-reviewed, prospective, randomized scientific publications have demonstrated reduction of spherical aberration and excellent contrast sensitivity and contrast acuity with the Tecnis modified prolate IOL when compared with a variety of spherical IOLs (as of this writing there are no peer-reviewed publications evaluating clinical results with either of the other two aspheric IOLs available in the United States) [21–28].

Mester [29] compared the quality of vision obtained with the Tecnis IOL and a spherical silicone IOL (SI 40, Advanced Medical Optics, Santa Ana, California). A total of 45 patients were enrolled and randomized to receive the

Tecnis IOL in one eye and the SI 40 in the fellow eye. The average photopic contrast-sensitivity values demonstrated a statistically significant advantage for the Tecnis IOL at all spatial frequencies (Fig. 3). The contrast-sensitivity curves show an even greater difference under mesopic conditions (Fig. 4), an expected result caused by the larger pupil size and consequent greater contribution from spherical aberration in dim light. A comparison of corneal and total ocular aberrations demonstrates the improved wavefront of the eye with the Tecnis Z9000 IOL (Fig. 5). This improvement in total aberrations demonstrates the critical compensatory relationship of cornea and lens in reducing spherical aberration.

Packer and coworkers [30] compared peak contrast sensitivity in healthy, normal eyes, stratified by age of patient, with eyes implanted with either the Tecnis IOL or an acrylic spherical IOL (AR40e, Advanced Medical Optics, Santa Ana, California). They reported that mesopic contrast sensitivity declined with age. Among 69 eyes of 36 patients, ranging in age from 21 to 61, they found mean peak mesopic contrast sensitivity at three cycles per degree of 72.4 units for the 20 to 30 year olds, whereas subjects aged 30 to 50 years demonstrated mean peak mesopic contrast sensitivity of 51.9 units. Ten eyes implanted with the Tecnis IOL in patients of average age 69.5 years achieved mean peak mesopic contrast sensitivity at three cycles per degree of 83.8, better than the 20 to 30 year old group. Meanwhile, 11 eyes implanted with the control IOL in patients of average age 69.4 years demonstrated mean peak mesopic contrast sensitivity at three cycles per

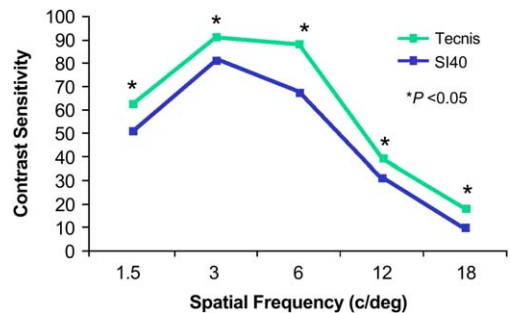


Fig. 3. Photopic contrast sensitivity of subjects implanted with the Tecnis Z9000 and SI40 IOLs. (From Mester U. Improved optical and visual quality with aspheric IOL. Presented at the American Society of Cataract and Refractive Surgery Symposium, Philadelphia, June 2, 2002; with permission.)

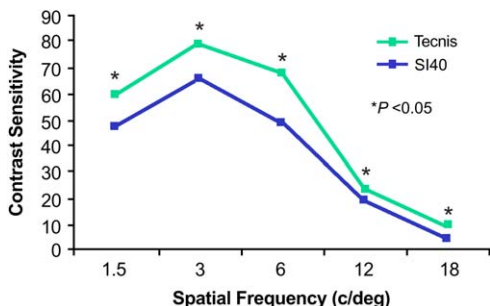


Fig. 4. Mesopic contrast sensitivity of subjects implanted with the Tecnis Z9000 and SI40 IOLs. (From Mester U. Improved optical and visual quality with aspheric IOL. Presented at the American Society of Cataract and Refractive Surgery Symposium. Philadelphia, June 2, 2002; with permission.)

degree of 47.1, worse than the 30 to 50 year old age group (Fig. 6).

The results of peer-reviewed publications on the Tecnis IOL are summarized in Table 1. The weight of evidence demonstrating superior functional vision and contrast sensitivity with the modified prolate IOL has continued to grow. That the pseudophakic elimination of spherical aberration reverses the age-related decline in contrast sensitivity confirms the hypothesis that decreased functional vision results primarily from aging changes in the human lens.

**The effect of tilt and decentration on wavefront-corrected intraocular lenses**

Optical laboratory studies have cast doubt on the efficacy of aspheric IOLs with negative

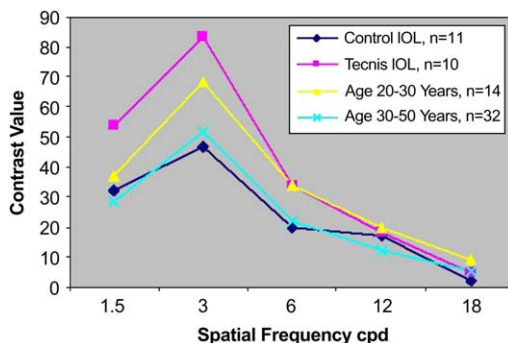


Fig. 6. Peak mesopic contrast sensitivity of subjects implanted with the Tecnis IOL is higher than that of healthy, normal subjects in their twenties. (From Packer M, Fine IH, Hoffman RS. Quality of vision with a modified anterior prolate aspheric intraocular lens. Presented at the European Society of Cataract and Refractive Surgery Symposium. Nice, France, September 11, 2002; with permission.)

spherical aberration, such as the Tecnis and AcrySof IQ, because of the range of tilt and decentration of pseudophakic lenses in general [31,32]. The eye model used to design the Tecnis IOL assumed a rotationally symmetric cornea reflecting the mean spherical aberration in a population of patients presenting for cataract surgery [18]. This model assumed monochromatic light and a symmetric cornea. Criticism of the model suggested, however, that it oversimplified the actual effects of the wavefront-corrected IOL by ignoring the contributions of polychromatic light and the implications of asymmetric corneal aberrations, such as coma [33].

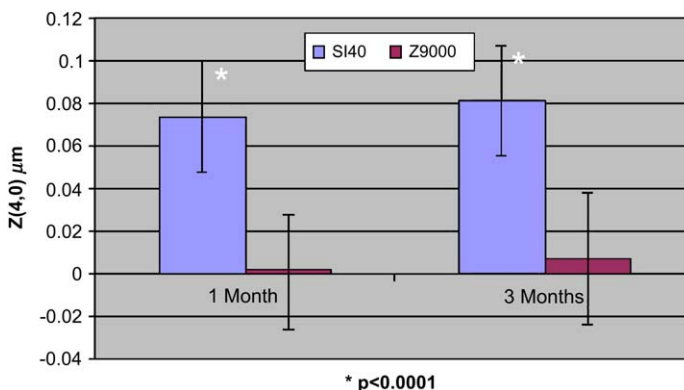


Fig. 5. Photopic and mesopic contrast sensitivity of subjects implanted with the Tecnis Z9000 and SI40 IOLs. (From Mester U. Improved optical and visual quality with aspheric IOL. Presented at the American Society of Cataract and Refractive Surgery Symposium. Philadelphia, June 2, 2002; with permission.)

Table 1  
Results of peer-reviewed publications on Tecnis IOL

Author	Journal	Date	Comparator IOLs: study design	Results
Mester	J Cataract Refract Surg	2003	SI40; intraindividual study; 37 patients	Spherical aberration in Tecnis eyes not significantly different from zero. Significantly better low-contrast visual acuity at all chart contrast levels after 3 months postoperatively. Significantly better contrast sensitivity under photopic conditions at all spatial frequencies at 3 months postoperatively. Significantly better contrast sensitivity under mesopic conditions at all frequencies at 3 months postoperatively.
Packer	J Cataract Refract Surg	2004	AR40e; interindividual study; 30 patients	After monocular comparison: at 3 months postoperatively, significantly better contrast sensitivity under photopic conditions at 6 cpd and under mesopic conditions at 1.5 and 3 cpd. After bilateral comparison: significantly better contrast sensitivity under photopic conditions at 3 and 6 cpd and under mesopic conditions at 1.5, 3, and 6 cpd.
Kershner	J Cataract Refract Surg	2003	Silicone plate-haptic and single-piece acrylic; 221 eyes of 156 patients	Compared with other lens, significantly greater improvement in postoperative contrast sensitivity over preoperative values under photopic conditions without glare at 1.5, 6, and 12 cpd. Enhanced retinal image contrast.
Bellucci	J Refract Surg	2004	911A; SA60AT; MA60BM; AR40e; interindividual study; 25 eyes of 25 patients	Lower total ocular spherical aberration at 4-mm and 6-mm optical zones compared with other IOLs in study. Lower myopic refractive shift with mydriasis.
Ricci	Arch Ophthalmol Scand	2004	911A; intraindividual study; 12 patients	Significantly better low-contrast photopic visual acuity for all contrast levels tested except 100%, with mydriasis

Kennis	Bull Soc Belge Ophthalmol	2004	AR40e; SN60AT; interindividual study; 98 eyes of 71 patients randomly received one of the three lenses	Compared with the AR40e, significantly better contrast sensitivity at 3 and 12 cpd under photopic conditions without glare; at 3, 12, and 18 cpd under photopic conditions with glare; at 1.5, 12, and 18 cpd under mesopic conditions without glare; and at 12 and 18 cpd under mesopic conditions with glare. Compared with the SN60AT, significantly better contrast sensitivity at 19 of 20 spatial frequencies tested (photopic and mesopic conditions with and without glare).
Bellucci	J Cataract Refract Surg	2005	SA60AT; interindividual study; 60 eyes of 60 patients randomly received one type of lens	Significantly better contrast sensitivity for spatial frequencies higher than 1.5 cpd under both photopic and mesopic conditions.
Casprini	Acta Ophthalmol Scand	2005	MA30BA; AR40; SA30AL; AR40e; interindividual study; 175 patients randomly received one type of lens	Statistically significant difference in mean spherical aberration coefficient (Z4.0) of the whole eye for a 5-mm pupil between the SA30AL, AR40e, and Tecnis groups, and the MA30BA group. Compared with the other IOLs, a lower percentage of patients experienced photic phenomena while driving at night at 2 months postoperatively.
Martinez-Palmer	Arch Soc Esp Oftalmol	2005	SA60AT; Inter-individual; bilateral implantation of same lens in 58 patients	Significantly better monocular and binocular visual acuity 3 months postoperatively. Better monocular and binocular mesopic contrast sensitivity at 3 months postoperatively.

*Abbreviation:* cpd, cycles per degree.



In fact, the eye model using monochromatic, symmetric optics does suggest tight tolerances for tilt and decentration of IOL correcting spherical aberration. For example, the model eye used in the Tecnis IOL design study demonstrates a tolerance of 0.4 mm decentration and 7-degree tilt for the modified prolate IOL with  $Z(4,0) = -0.27 \mu$  [18]. At this degree of decentration or tilt the 15 cycle per degree contrast ratio of the wavefront-corrected IOL with negative spherical aberration becomes equivalent to that of a standard spherical IOL.

The reason that decentration reduces the optical efficiency of an aspheric lens may be explained by the induction of higher-order aberration, such as coma [34]. As an example, consider an aspheric IOL decentered 0.5 mm along the 180-degree meridian for a 6-mm pupil. Given a coefficient of fourth-order spherical aberration in the IOL of  $-0.29 \mu\text{m}$ , then the coefficient of induced third-order horizontal coma is  $-0.30 \mu\text{m}$ .

A meta-analysis of the peer-reviewed literature on the subject of IOL tilt and decentration has been performed to determine the approximate percentage of pseudophakic eyes that may be expected to reside within the tolerances set by the reported Tecnis design eye model [35]. The selected studies required a complete, continuous curvilinear capsulorrhexis and in-the-bag IOL fixation. Postoperative measurement of IOL position was measured using Scheimpflug photography, which measures along the visual axis. When asymmetric aberrations and polychromatic light are taken into account, however, a newly developed model has suggested relatively relaxed tilt and decentration tolerances for wavefront-corrected

IOLs. This model was developed using corneal wavefront data from patients presenting for cataract surgery, including both symmetric and asymmetric aberrations, and was subsequently verified with these patients' clinical postoperative data [33]. In the verification study, three surgeons randomly assigned a wavefront-corrected IOL to one eye and a standard spherical IOL to the fellow eye of 79 patients. The Zernike terms predicted by the model for both the wavefront-corrected IOL and the control IOL closely approximated the clinical results. In particular, this model very closely predicted the  $Z(4,0)$  term for both the wavefront-corrected and the control IOL. This validated eye model was then used to evaluate the effects of decentration and tilt on the modulation transfer function of the wavefront-corrected IOL. Assuming polychromatic illumination and incorporating the effects of the clinically validated asymmetric aberrations, the degradation of modulation transfer function with decentration to the level of a control standard spherical IOL occurred at 0.8 mm instead of 0.4 mm as in the simplified, symmetric eye model. The degradation of modulation transfer function with tilt to this level occurs at 10 degrees instead of 7 degrees (Figs. 7 and 8).

By analyzing the peer-reviewed literature on decentration in terms of a tolerance of 0.8 mm, as demonstrated by the clinically verified eye model, a significant reduction in the percentage of cases outside of tolerance emerges. For example, the percentage of eyes with a three-piece silicone IOL with polymethyl methacrylate haptics decentered greater than 0.8 mm is expected to be 0.0001% (Table 2). The number of IOLs expected to tilt

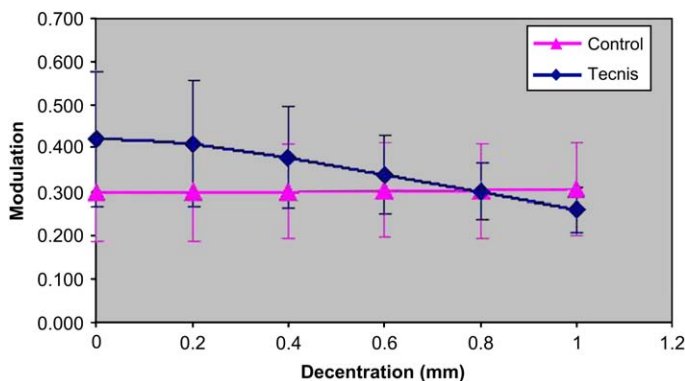


Fig. 7. Average radial modulation transfer function (MTF) versus decentration. Assuming polychromatic illumination and incorporating the effects of the clinically validated asymmetric aberrations, the degradation of MTF with decentration to the level of a standard spherical IOL occurs at 0.8 mm instead of 0.4 mm as in the simplified, symmetric eye model. (From Packer M. Tilt and decentration: toward a new definition of tolerance. *EyeWorld* 2005;10:65-6; with permission.)



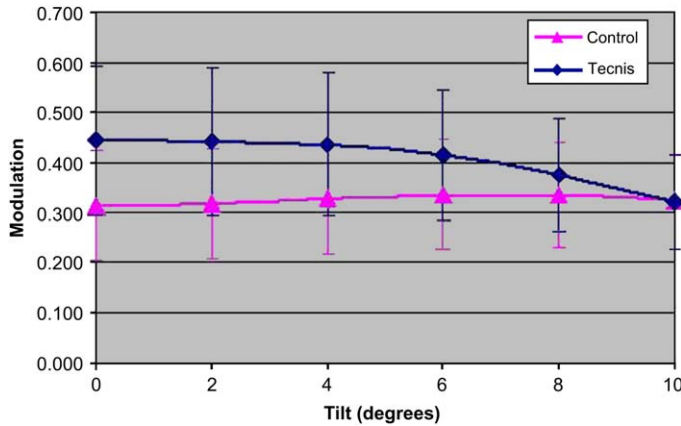


Fig. 8. Average radial modulation transfer function (MTF) versus tilt. Assuming polychromatic illumination and incorporating the effects of the clinically validated asymmetric aberrations, the degradation of MTF with tilt occurs at 10 degrees instead of 7 degrees as in the simplified, symmetric eye model. (From Packer M. Tilt and decentration: toward a new definition of tolerance. EyeWorld 2005;10:65–6; with permission.)

Table 2  
Percentage of eyes with a decentration >0.8 mm<sup>a</sup>

Overall	0.06
Optic-haptic materials	
Silicone-PMMA	0.0001
PMMA-PVDF	4.27
Silicone-prolene	0.33
PMMA 1 piece	0.07
Acrylic-PMMA	0.06
Hydrogel-PMMA	0.0002

Abbreviations: PMMA, polymethyl methacrylate; PVDF, polyvinylidene fluoride.

<sup>a</sup> In this analysis of the available peer-reviewed literature on decentration and tilt the means and standard deviations for each IOL design were used to calculate the percentage of IOLs expected to decenter more than 0.8 mm, the point at which the MTF of the modified prolate Tecnis IOL is equivalent to that of a standard spherical IOL. The analysis included the following reports:

Akkin C, Ozler SA, Mentis J. Tilt and decentration of bag-fixated intraocular lenses: a comparative study between capsulorhexis and envelope techniques. *Doc Ophthalmol* 1994;87:199–209.

Hayashi K, Harada M, Hayashi H, et al. Decentration and tilt of polymethyl methacrylate, silicone, and acrylic soft intraocular lenses. *Ophthalmology* 1997;104:793–8.

Kim JS, Shyn KH. Biometry of 3 types of intraocular lenses using Scheimpflug photography. *J Cataract Refract Surg* 2001;27:533–6.

Hayashi K, Hayashi H, Nakao F, et al. Comparison of decentration and tilt between one piece and three piece polymethyl methacrylate intraocular lenses. *Br J Ophthalmol* 1998;82:419–22.

Mutlu FM, Bilge AH, Altinsoy HI, et al. The role of capsulotomy and intraocular lens type on tilt and decentration of polymethylmethacrylate and foldable acrylic lenses. *Ophthalmologica* 1998;212:359–63.

Hayashi K, Hayashi H, Nakao F, et al. Intraocular lens tilt and decentration after implantation in eyes with glaucoma. *J Cataract Refract Surg* 1999;25:1515–20.

Wang MC, Woung LC, Hu CY, et al. Position of polymethyl methacrylate and silicone intraocular lenses after phacoemulsification. *J Cataract Refract Surg* 1998;24:1652–7.

Hayashi K, Hayashi H, Nakao F, et al. Anterior capsule contraction and intraocular lens decentration and tilt after hydrogel lens implantation. *Br J Ophthalmol* 2001;85:1294–7.

Taketani F, Matuura T, Yukawa E, et al. Influence of intraocular lens tilt and decentration on wavefront aberrations. *J Cataract Refract Surg* 2004;30:2158–62.

Dick HB, Schwenn O, Krummenauer F, et al. Refraction, anterior chamber depth, decentration and tilt after implantation of monofocal and multifocal silicone lenses. *Ophthalmologie* 2001;98:380–6.

10 degrees or more is vanishingly small and insignificant.

If common levels of tilt and decentration significantly affected the functioning of wavefront-corrected IOLs, it would be difficult to explain the evidence of elimination of spherical aberration and improved functional vision found in multiple investigations of the Tecnis IOL. The new clinically validated eye model described by Piers and coworkers [33] helps relieve this potential paradox. Areas for future research include verification of the decentration and tilt of the wavefront-corrected IOL itself.

### Customizing the correction of spherical aberration

Another important consideration for the general applicability of aspheric IOLs involves the range of spherical aberration in the human cornea. In the design study of the Tecnis IOL, it was determined that approximately 90% of the patient population would demonstrate a benefit from implantation of the IOL [18]. The distribution of corneal spherical aberration found in the study population clustered around the mean such that 10% of subjects would demonstrate greater absolute spherical aberration after implantation of the modified prolate IOL than they would have demonstrated after implantation of a spherical IOL. Additional data collection suggests that the proportion may in fact be closer to 4% of the population (Fig. 9). Regardless of the precise proportion of outliers, it is clear that

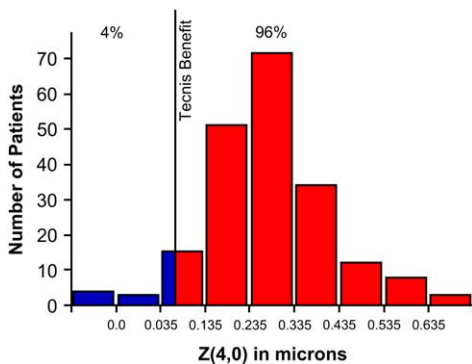


Fig. 9. Distribution of corneal spherical aberration values ( $N = 202$  patients). The Tecnis IOL was designed to correct the population mean corneal spherical aberration. A certain percentage of individuals to the left of the mean are not expected to show a demonstrable benefit from implantation of an IOL with negative spherical aberration.

further customization of the spherical aberration of IOLs could potentially create a wider benefit.

One approach to customization entails selection of patients based on their preoperative corneal spherical aberration. A limitation, however, of the selection process remains corneal aberrations induced by surgery with IOL implantation, particularly astigmatism and trefoil terms [36]. Nevertheless, selection has been shown capable of producing enhanced results, as demonstrated by sine wave grating contrast sensitivity with targeted postoperative total ocular spherical aberration [37]. In his study, Beiko [37] used the Easygraph corneal topographer (Oculus, Lynnwood, Washington) to select patients with corneal spherical aberration of  $+0.37 \mu$ , targeting a postoperative total ocular spherical aberration of  $+0.10 \mu$  (the Easygraph includes an optional software package that provides Zernike analysis). The selected patient group demonstrated significantly better contrast sensitivity than an unselected group of control patients under both mesopic and photopic conditions.

The development and popularization of wavefront-corrected and aspheric IOLs represents a significant trend in current cataract and refractive lens surgery. With preoperative corneal topography and wavefront analysis, surgeons can achieve enhanced results through patient selection. One method of proceeding with this approach might involve the following protocol:

1. Preoperative testing to include corneal topography and axial length determination, anterior chamber depth, phakic lens thickness, and corneal white-to-white diameter.
2. Application of a software package, such as VOL-CT (Sarver and Associates, Carbondale, Illinois) to transform the topography elevation data into preoperative corneal Zernike coefficients, with special attention to  $Z(4,0)$ , fourth-order spherical aberration.
3. Application of an IOL calculation formula, such as the Holladay 2 (available as part of the Holladay IOL Consultant and Surgical Outcomes Assessment Program, Jack T. Holladay, Houston, Texas) to determine correct IOL power for desired postoperative spherical equivalent.
4. Determination of desired postoperative total ocular spherical aberration and selection of IOL type.

For example, if the desired postoperative total ocular spherical aberration is zero and the

preoperative corneal spherical aberration measures about  $+0.27 \mu$ , the Tecnis with  $-0.27 \mu$  is selected. If the preoperative corneal spherical aberration is negative, a spherical IOL might represent the best choice because it adds to the total. This might be the case in a patient who had undergone previous hyperopic laser in situ keratomileusis or conductive keratoplasty.

One challenge of customization, however, is determining the desired postoperative state. Cataract and refractive surgeons have already faced this dilemma in terms of lower-order aberrations when they decide to target emmetropia, or achieve slight residual with-the-rule astigmatism. It seems that there exists a trade-off between spherical aberration and depth of focus: "Although best corrected optical quality is significantly better with aspheric IOLs, tolerance to defocus tended to be lower" [36]. The evidence of the clinical investigation of the Tecnis IOL, and in particular the results of the wavefront aberrometry and night driving simulation, offer a compelling argument for setting the postoperative spherical aberration to zero. The data show that the mean spherical aberration in the eyes implanted with the Tecnis IOL was, in the words approved by the FDA, "not different from zero," whereas the subjects performed functionally better in 20 of 24 driving conditions (and statistically better in 10 conditions) when using best-spectacle correction with the eye implanted with the Tecnis IOL, as compared with best-spectacle correction with the eye implanted with the AcrySof spherical IOL [19]. These findings represent the basis for the FDA labeling indication for improved functional vision, which may improve patient safety for other life situations under low-visibility conditions.

The ability to achieve superior functional vision with best spectacle correction reflects both the strength and weakness of wavefront-corrected IOLs. Given the state of the art of biometry and IOL power calculation, it is not possible to achieve precise emmetropia in all eyes. Many pseudophakic patients find that their uncorrected vision is adequate for most tasks of daily living and do not wear spectacles. The amount of defocus and astigmatism they accept may negate the pseudophakic correction of their spherical aberration. Nio and coworkers [12] noted in 2002, "Both spherical and irregular aberrations increase the depth of focus, but decrease the modulation transfer at high spatial frequencies at optimum focus. These aberrations, therefore, play an important role in the balance between acuity

and depth of focus." For some patients with adequate uncorrected distance acuity, the advantages of a bit more depth of focus may be worth a little loss of contrast. The ultimate expression of this trend is embodied in the multifocal IOL, which by its design reduces optical quality to enhance spectacle independence. The Tecnis multifocal IOL, currently under study in the United States through an FDA Investigational Device Exemption, represents a conscious compromise between optical efficiency and functional vision, and quality of life.

### **Practical implementation of contrast-sensitivity testing**

The implementation of contrast-sensitivity testing in practice requires investment in both technology and training. When shopping for new equipment it behooves the physician to compare testing systems with respect to validation, functionality, and ease of use. Critical parameters include control of luminance, consistency of viewing distance, and correction of refractive error. Standardization of testing methods in the office ensures comparability of results. Technicians should become proficient at practicing the established protocols for test administration with each specific system. In the United States, practitioners should note the systems accepted by the FDA in clinical investigations of cataract and refractive surgery. Frequently cited products include the CSV-1000 (VectorVision, Greenville, Ohio) and the Optec 6500 (Stereo Optical, Chicago, Illinois). A newly introduced product is the Holladay Automated Contrast Sensitivity Testing System (M & S Technologies, Skokie, Illinois).

As advances in technology allow cataract and refractive surgeons to address higher-order optical aberrations, the measurement of functional vision becomes increasingly critical as a gauge of progress. Contrast-sensitivity testing is assuming a prominent place in the evaluation of surgical modalities because it reflects functional vision, correlates with visual performance, and provides a key to understanding optical and visual processing of images.

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