
Effect of cataract surgery incision location and intraocular lens type on ocular aberrations

Konrad Pesudovs, PhD, Holger Dietze, MSc, Owen G. Stewart, FRCOphth, Bruce A. Noble, FRCOphth, Michael J. Cox, PhD

Purpose: To determine whether Hartmann-Shack wavefront sensing detects differences in optical performance in vivo between poly(methyl methacrylate) (PMMA) and foldable acrylic intraocular lenses (IOLs) and between clear corneal and scleral tunnel incisions and whether optical differences are manifested as differences in visual performance.

Setting: Department of Optometry, University of Bradford, West Yorkshire, United Kingdom.

Methods: This study comprised 74 subjects; 17 were phakic with no ocular pathology, 20 had implantation of a Pharmacia 722C PMMA IOL through a scleral tunnel, 21 had implantation of an Alcon AcrySof IOL through a scleral tunnel, and 16 had implantation of an AcrySof IOL through a corneal incision. Visual acuity and contrast sensitivity testing, ocular optical quality measurement using Hartmann-Shack wavefront sensing, and corneal surface measurement with a videokeratoscope were performed in all cases.

Results: There were significant differences between groups in the total root-mean-square (RMS) wavefront aberration over a 6.0 mm pupil ($F = 3.91$; degrees of freedom = 3,70; $P < .05$) mediated at the 4th-order RMS, specifically spherical and tetrafoil aberrations. The PMMA-scleral group had the least aberrations and the AcrySof-corneal group the most. For a 3.5 mm diameter pupil, the total higher-order RMS wavefront aberration was not significantly different between the groups ($P > .05$). There were no differences between groups in corneal shape, visual acuity, or contrast sensitivity.

Conclusions: Implantation of the spherical PMMA IOL led to a slight reduction in total wavefront aberration compared to phakic eyes. AcrySof IOLs induced more aberrations, especially spherical aberration. Corneal-based incisions for IOL implantation compounded this increase. Studies of the optical performance of IOLs in vivo should use wavefront sensing as the main outcome measure rather than visual measures, which are readily confounded by multiple factors.

J Cataract Refract Surg 2005; 31:725-734 © 2005 ASCRS and ESCRS

Phacoemulsification cataract surgery is performed by many techniques that use different incision sites and types of intraocular lenses (IOLs). Incisions are corneal or scleral, and the most commonly used IOLs are rigid poly(methyl methacrylate) (PMMA) or foldable, including acrylic lenses. Corneal incisions have several benefits over scleral incisions. They take less time to create, and they do not need to be significantly enlarged when a foldable IOL is implanted. These characteristics make corneal incisions an attractive option that yields excellent results.¹ Although foldable

IOLs cause few problems, the increase in their use has led to a higher rate of complications requiring their explantation.²⁻⁴ Optical complications that can lead to explantation⁵ include incorrect refractive correction, damage to the IOL during insertion,⁶ photic phenomena (eg, glare, halos, and peripheral arcs or crescents of light), IOL opacification,^{7,8} and IOL glistenings. In patients with optical problems, the decision to explant the IOL is based on patient symptoms alone. No objective test has been shown to confirm the presence of optical problems with IOLs.

In this study, we compared the *in vivo* visual and optical performance of Pharmacia 722C PMMA IOLs and Alcon AcrySof IOLs, both inserted through a scleral incision. The results were compared with those in a group of subjects with normal phakic eyes. We also evaluated whether corneal-based surgery with AcrySof IOLs alters optical and visual performance compared with scleral-based surgery with the AcrySof IOL. The goal was to determine whether there are differences in the optical performance of IOLs and incisions and if so, whether these differences affect visual performance in terms of visual acuity and contrast sensitivity.

We also sought to determine whether Hartmann-Shack wavefront sensing⁹ is a viable technique for assessing differences in ocular imaging quality between IOL types and surgical techniques with the goal of helping patients with optical problems. The Hartmann-Shack is a widely used technique for evaluating the optical performance of the entire eye; however, it has only recently been used to assess the optics of IOLs *in vivo*. Using this method, Miller and coauthors¹⁰ found higher levels of trefoil aberrations, tetrafoil aberrations, and spherical aberrations in pseudophakic eyes than in normal phakic eyes, although the authors did not state whether the subjects were age matched or the type of IOL and surgical procedure used.

Patients and Methods

Cohort

Patients who had cataract surgery at the Leeds General Infirmary or BUPA Hospital Leeds by 1 of 2 surgeons (O.G.S., B.A.N.) were identified from the surgical records and enrolled in this study. The study complied with the

Accepted for publication August 5, 2004.

From the Department of Optometry, University of Bradford (Pesudovs, Dietze, Cox), and the Department of Ophthalmology, Leeds General Infirmary (Stewart, Noble), West Yorkshire, United Kingdom.

Supported by the Sir Neil Hamilton Fairley Fellowship 0061, National Health and Medical Research Council, Canberra, Australia (Dr. Pesudovs), and in part by Small Equipment Grant number 002, the National Eye Research Centre, Leeds, Yorkshire, United Kingdom.

No author has a financial or proprietary interest in any material or method mentioned.

Reprint requests to Michael J. Cox, PhD, Department of Optometry, University of Bradford, Richmond Road, Bradford, West Yorkshire, BD7 1DP, United Kingdom.

principles of the Declaration of Helsinki and was approved by the Leeds Regional Ethical Committee.

Inclusion criteria were cataract surgery performed between January 2000 and June 2001 and implantation of a 722C PMMA IOL through a scleral tunnel (PMMA-scleral group, $n = 20$) or an acrylic MA30BA or MA60BM AcrySof IOL through a scleral tunnel (AcrySof-scleral group, $n = 21$) or a clear corneal incision (AcrySof-corneal group, $n = 16$). The 722C IOL has a refractive index of 1.49, an equal-biconvex design, and a 6.5 mm optic. The MA30BA (5.5 mm optic) and MA60BM (6.0 mm optic) IOLs have a refractive index of 1.55 and an unequal biconvex design with a longer radius of curvature anteriorly.

Exclusion criteria were capsule thickening, intraoperative or postoperative complications including cystoid macular edema or unexplained decreased visual acuity, other ocular pathology, neurological problems, systemic disease, use of medication that could affect contrast sensitivity, IOL decentration, IOL out of the capsular bag, inability to speak English well enough to follow test instructions, and a mental or physical disability (eg, wheelchair-bound) that would impede testing. Patients with astigmatism of 3.00 diopters (D) or greater were also excluded as high natural astigmatism reduces the image quality obtainable from Hartmann-Shack wavefront sensing and is associated with higher levels of root-mean-square (RMS) higher-order wavefront aberration.¹¹ Exclusion was done in 3 phases: case-note review, telephone interview, and ophthalmic examination at the time of testing to ensure the absence of a potentially confounding condition (eg, capsule thickening).

In addition, subjects with normal phakic eyes were recruited from the Eye Clinic at Bradford University. The inclusion criteria were age over 60 years and no previous cataract surgery. In this group, ocular pathology and the criteria used in the 3 IOL groups were used to exclude subjects from the study. The criteria were applied in 3 phases as described.

All 4 groups (ie, 3 IOL-incision groups and phakic group) were matched for age, sex, pupil size, and degree of spherical ametropia.

Surgical Technique in IOL Groups

Scleral tunnel frown incisions with a 5.0 mm cord length were made in the upper nasal or temporal quadrant (depending on which eye was being operated on) 1.5 mm behind the limbus. The tunnel was fashioned by splitting the sclera with a crescent blade before final penetration of the cornea with a 2.75 mm keratome at the anterior extent of the tunnel. The incision was enlarged with a 5.2 mm keratome for PMMA IOL implantation or to 3.5 mm with a 2.75 mm keratome for AcrySof IOL implantation.

Three-step clear corneal incisions were made using a 2.75 mm keratome in the upper quadrant in the posterior

cornea. The same keratome was used to enlarge the wound to 3.5 mm for IOL implantation.

Except for the location of the incision and type of IOL, the surgical procedure was identical in all patients. Phacoemulsification was performed through a continuous curvilinear capsulorhexis approximately 5.0 mm in diameter. The incision was closed with sutures only in eyes in which the wound was leaking.

Visual and Optical Assessment

Refraction was performed by 1 examiner (H.D.), who was unaware of group allocation, using retinoscopy and subjective refraction including binocular balancing under photopic lighting levels with the eye undilated. Testing visual acuity and contrast sensitivity was then done with the eye undilated. The best corrected logMAR visual acuity was measured monocularly using standard Early Treatment Diabetic Retinopathy Study charts at 4 m with a luminance of 100 cd/m², a forced-choice protocol, and letter-by-letter scoring.¹²

Contrast sensitivity was measured monocularly under the same conditions using sinusoidal gratings generated by an RGB framestore, which was part of a purpose-built display controller (Cambridge Research Systems VSG 2/3). A chromatically narrowband sinusoidal grating stimulus (ie, only the green gun on the CRT monitor was driven by the display controller) was presented with random phase within a Gaussian spatial envelope. The spatial envelope had a standard deviation of 2 grating cycles and was truncated at a radius of 4 grating cycles to limit the spread of contrast energy into a narrow band of spatial frequencies. Three spatial frequencies (6, 12, and 18 cycles per degree) were used at 2 orientations (horizontal and vertical). The minimum Michelson contrast the system could present was approximately 0.1%, well below the minimum detectable by the human visual system. This ensured that the contrast sensitivity measurement was free of ceiling effects. The threshold was determined using a method of ascending limits with contrast increments of 2 dB. After 5 minutes of luminance adaptation, the 6 stimuli were presented in random order. For each stimulus, the subject was shown the grating at a level above the contrast threshold before the threshold determination to ensure that he or she was responding to the correct stimulus waveform. The mean luminance of the CRT monitor was 34.8 cd/m².

Photopic pupil size was measured using a template, and the dilated pupil size was measured from the Hartmann-Shack wavefront sensing image. Refraction, visual acuity, and contrast sensitivity testing were repeated using the same techniques with the pupil dilated with 1 drop of tropicamide 0.5%.

A Hartmann-Shack aberroscope was used to obtain 5 photographic ocular aberrations measurements.¹³ The instrumentation and procedures have been described in detail.¹⁴

The only modifications were the use of a 632.8 nm light wavelength and the capture and averaging of wavefront aberration results from 5 Hartmann-Shack wavefront sensing images per eye. Wavefront aberrations were described in terms of the orthonormal Zernike polynomials up to the 6th order and RMS values for each higher order (3rd to 6th) and total higher order (3rd to 6th) over a 6.0 or 3.5 mm pupil diameter. For pupils with a radius less than 6.0 mm, data were extrapolated from the maximum pupil diameter available up to 6.0 mm to facilitate valid comparison. Coordinate systems and Zernike polynomial representation were recorded according to the proposed international standard for reporting ocular wavefront aberrations using a single indexing scheme.¹⁵

Corneal topography was measured using an EyeSys videokeratoscope system. The topography data were fit to the equation for an elliptical section to calculate the apical radius and asphericity as described by Douthwaite and coauthors.¹⁶ Asphericity was expressed as a radially averaged *P* value, from which corneal spherical aberration was calculated. The Hartmann-Shack technique measures wavefront aberrations of the whole eye; thus, the lenticular (phakic or IOL) spherical aberration was isolated by calculating the corneal spherical aberration. This allowed determination of whether overall changes in *C*₁₂, the corrected 3rd-order spherical aberration, were influenced by corneal changes after surgery or whether they were entirely due to the IOL.

Statistical Analysis

One arm of the study compared the corneal incision and scleral incision with the same IOL type (AcrySof–corneal and AcrySof–scleral groups). The other arm compared IOLs with the same incision type (scleral based) (PMMA–scleral and AcrySof–scleral groups). Age, spherical equivalent refraction, pupil size, vision measures, ocular aberrations, and corneal aberrations were compared between the 4 groups using a 1-way analysis of variance with post hoc Tukey honest significant differences testing for unequal group sizes. This test was chosen because it is not prone to alpha inflation, which is a risk with statistical tests across multiple groups. Alpha inflation was also an issue as multiple aberration measures were to be compared. To control for this, a modified Bonferroni (Holm step-down) adjustment within a composite endpoint paradigm was used.¹⁷ In short, the Zernike polynomial expansion can be treated as a composite measure, like a questionnaire, where the total RMS is the total score and the main outcome measure is tested at a significance level of $P < .05$. In the next level, 4 orders of RMS wavefront error are tested at $P < .05/[4 - (0 \text{ to } 3 \text{ in sequence})]$; ie, 0.0125 to 0.05. In the third level, multiple Zernike coefficients, depending on the order, are tested at a significance level of $0.0125/[\text{number of coefficients} - (0 \text{ to } \text{number of coefficients} - 1)]$. With this approach, testing only progresses to

the next level when significance is demonstrated at the previous level.

The same adjustment is not appropriate for multiple visual performance measures as these are highly correlated measures rather than composite measures. Adjustment should be made for the number of measures; however, this should take into account the correlation between measures.¹⁸ A Holm step-down Bonferroni adjustment with a significance level of $P < .05$ was used and adjusted as follows: $0.05 / \{[\text{number of measures} - (0 \text{ to number of measures} - 1) \times (1 - \text{correlation between measures})]\}$.

Sample size was not predetermined as the magnitude of the likely differences between the groups was unknown. The initial target sample size was 20 subjects per group, with further recruitment depending on identification of non-significant trends. Statistical analyses were performed using Statistica for Macintosh (StatSoft Inc.).

Results

Table 1 shows the characteristics in the 4 groups, which were well matched for age ($F = 2.28$; degrees of freedom [df] = 3,70; $P > .05$), spherical equivalent refractive error with undilated pupils ($F = 1.90$; df = 3,70; $P > .05$), and photopic pupil size ($F = 0.78$; df = 3,49; $P > .05$). The spherical equivalent refractive error measured with a dilated pupil was also similar between groups ($F = 1.65$; df = 3,66; $P > .05$); however, the mean dilated pupil size was significantly different ($F = 7.07$; df = 3,70; $P < .001$). Post hoc testing showed the only significant difference was between the AcrySof–corneal group and the phakic group ($P < .001$).

The 7 visual performance measures were highly correlated. The mean correlation was 0.66 for 3.5 mm pupils and 0.74 for 6.0 mm pupils. To maintain a significance level of $P < .05$, significance was adjusted according to the statistical model to $P < .021$ for

3.5 mm pupils and $P < .027$ for 6.0 mm pupils. There was no statistically significant difference between the 4 groups in any measure of visual performance (Table 2) for 3.5 mm pupils or 6.0 mm pupils (Table 3). However, there were differences between the four 4 groups in the level of aberrations (Table 4).

For a 3.5 mm diameter pupil, representative of the average natural pupil diameter in the study's cohort, the total higher-order RMS wavefront aberration was not significantly different between the groups ($P > .05$). The mean was 0.121 ± 0.034 (SD) in the phakic group, 0.088 ± 0.047 in the PMMA–scleral group, 0.111 ± 0.052 in the AcrySof–scleral group, and 0.107 ± 0.038 in the AcrySof–corneal group (Figure 1). Under the statistical model, 3.5 mm pupil data testing ceased at this stage.

For a 6.0 mm pupil diameter, representative of the average diameter of the dilated pupils, the total RMS wavefront aberration was significantly different between the groups (Table 4). The PMMA–scleral group had significantly less wavefront aberration than the AcrySof–corneal group ($P < .01$) (Figure 1). The differences in total wavefront aberration were driven by significant differences in 4th-order RMS error; the 3rd-, 5th-, and 6th-order RMS wavefront aberrations were not significantly different between the groups. Fourth-order RMS aberrations were greater in the AcrySof–corneal group than in the PMMA–scleral group ($P < .001$) (Figure 2). The differences in 4th-order RMS wavefront aberrations were driven by significant differences in the C_{12} (corrected 3rd-order spherical aberration) and C_{14} (tetrafoil aberration) coefficients. The differences were significant between the PMMA–scleral and AcrySof–corneal groups for C_{12} ($P = .002$) and between the phakic and AcrySof–corneal groups for C_{14} ($P = .001$),

Table 1. Characteristics of study population.

Measure	Mean \pm SD			
	Phakic	PMMA–Scleral	AcrySof–Scleral	AcrySof–Corneal
Age (y)	68.9 \pm 4	76.5 \pm 7.5	72.7 \pm 10.2	71.9 \pm 11.9
Spherical equivalent refractive error (undilated pupils) (D)	0.93 \pm 1.97	0.11 \pm 1.21	0.02 \pm 0.87	0.09 \pm 0.89
Photopic pupil size (mm)	3.50 \pm 0.74	3.45 \pm 0.60	3.13 \pm 0.37	3.50 \pm 0.73
Spherical equivalent refractive error (dilated pupils) (D)	0.90 \pm 2.03	0.05 \pm 1.18	0.05 \pm 0.98	0.10 \pm 0.93
Dilated pupil size (mm)*	6.40 \pm 0.96	5.84 \pm 0.50	5.84 \pm 0.60	5.34 \pm 0.52

* $F = 7.07$; df = 3,70; $P < .001$, AcrySof–corneal < phakic ($P < .001$)

Table 2. Visual performance with undilated pupils.

Measure	Mean ± SD			
	Phakic	PMMA–Scleral	AcrySof–Scleral	AcrySof–Corneal
Visual acuity*	-0.04 ± 0.08	-0.04 ± 0.08	0.00 ± 0.09	0.00 ± 0.09
Contrast sensitivity				
6 cpd horizontal	1.18 ± 0.16	0.97 ± 0.25	1.11 ± 0.21	1.07 ± 0.21
12 cpd horizontal	0.68 ± 0.22	0.59 ± 0.27	0.65 ± 0.23	0.71 ± 0.32
18 cpd horizontal	0.16 ± 0.12	0.16 ± 0.16	0.22 ± 0.21	0.21 ± 0.21
6 cpd vertical	1.23 ± 0.18	1.00 ± 0.24	1.17 ± 0.24	1.14 ± 0.25
12 cpd vertical	0.63 ± 0.20	0.47 ± 0.25	0.62 ± 0.26	0.57 ± 0.30
18 cpd vertical	0.16 ± 0.16	0.08 ± 0.10	0.19 ± 0.17	0.16 ± 0.18

cpd = cycles per degree; horizontal = horizontal orientation; vertical = vertical orientation

*LogMAR

with the AcrySof–corneal group having more wavefront aberration for both coefficients. The corneal asphericities were not significantly different between groups ($F = 0.294$; $df = 3,65$; $P > .05$). The mean corneal P value, 0.75, was typical of that found in humans.

Discussion

The phakic group and the 3 IOL groups were similar in age, spherical equivalent refractive error, and photopic pupil size. The phakic group had nearly 1.00 D of hyperopia, and the IOL groups had a refraction approximating emmetropia. This reflects the natural prevalence of hyperopia in this age group and that the target was emmetropia in the IOL groups. There were differences between groups in dilated pupil

size, with the IOL groups having smaller pupils. The entrance pupil under dilation was measured using the Hartmann-Shack wavefront sensing image. After IOL implantation, this is effectively limited by the size of the capsulorhexis, which is smaller than the dilated pupil aperture.

The overall amount of wavefront aberration is in line with previously reported values. Thibos and co-authors¹⁹ report RMS levels of approximately 0.65 μm for the 3rd- to 6th-order wavefront aberration and 0.20 μm for 4th-order wavefront aberration when assessed over a 6.0 mm diameter pupil in young subjects. Our values for 3rd- to 6th-order RMS wavefront aberration in the phakic group are similar, although the 4th-order RMS wavefront aberration (0.33 μm) is somewhat larger. This order contains spherical aberration, 0.30 μm

Table 3. Visual performance with dilated pupils.

Measure	Mean ± SD			
	Phakic	PMMA–Scleral	AcrySof–Scleral	AcrySof–Corneal
Visual acuity*	-0.06 ± 0.07	-0.04 ± 0.08	0.01 ± 0.10	0.02 ± 0.11
Contrast sensitivity				
6 cpd, horizontal	1.17 ± 0.20	1.01 ± 0.21	1.08 ± 0.23	1.10 ± 0.21
12 cpd, horizontal	0.71 ± 0.27	0.58 ± 0.25	0.62 ± 0.26	0.62 ± 0.32
18 cpd, horizontal	0.18 ± 0.20	0.15 ± 0.15	0.17 ± 0.18	0.25 ± 0.23
6 cpd, vertical	1.17 ± 0.21	1.01 ± 0.24	1.14 ± 0.21	1.12 ± 0.23
12 cpd, vertical	0.67 ± 0.25	0.48 ± 0.23	0.63 ± 0.22	0.60 ± 0.31
18 cpd, vertical	0.17 ± 0.19	0.09 ± 0.11	0.16 ± 0.16	0.19 ± 0.17

cpd = cycles per degree; horizontal = horizontal orientation; vertical = vertical orientation

*LogMAR

Table 4. Optical performance in terms of wavefront error over a 6.0 mm diameter pupil. Analysis followed this sequence: (1) RMS total higher-order wavefront (excluding spherocylindrical, prismatic, and piston terms); (2) RMS for each order; (3) each Zernike coefficient for orders with significant differences.

Zernike Orders	Mean ± SD (μm)			
	Phakic	PMMA-Scleral	AcrySof-Scleral	AcrySof-Corneal
Root mean square				
Total*	0.52 ± 0.15	0.42 ± 0.17	0.54 ± 0.25	0.66 ± 0.23
3rd order	0.37 ± 0.12	0.28 ± 0.17	0.32 ± 0.17	0.38 ± 0.20
4th order [†]	0.33 ± 0.12	0.28 ± 0.09	0.38 ± 0.19	0.49 ± 0.16
5th order	0.10 ± 0.04	0.09 ± 0.03	0.11 ± 0.06	0.13 ± 0.08
6th order	0.08 ± 0.04	0.08 ± 0.04	0.10 ± 0.07	0.11 ± 0.05
4th-order coefficients				
C ₁₀	-0.01 ± 0.19	-0.03 ± 0.07	-0.02 ± 0.09	0.03 ± 0.08
C ₁₁	-0.05 ± 0.09	-0.06 ± 0.06	0.00 ± 0.06	-0.01 ± 0.07
C ₁₂ [‡]	0.30 ± 0.14	0.24 ± 0.09	0.32 ± 0.17	0.42 ± 0.15
C ₁₃	-0.05 ± 0.13	-0.01 ± 0.08	0.02 ± 0.08	-0.01 ± 0.04
C ₁₄ [§]	-0.03 ± 0.15	0.04 ± 0.07	0.04 ± 0.09	0.12 ± 0.10

*F = 3.91; df = 3,70; P < .05; post hoc, PMMA-scleral < AcrySof-corneal, P < .01

[†]F = 6.37; df = 3,70; P < .001; post hoc, PMMA-scleral < AcrySof-corneal, P < .001

[‡]F = 4.97; df = 3,70; P < .003; post hoc, PMMA-scleral < AcrySof-corneal, P < .002

[§]F = 5.72; df = 3,70; P < .001; post hoc, phakic < AcrySof-corneal, P < .001

in our group, which is larger than Porter and coauthors²⁰ reported (0.15 μm) for a 5.7 mm diameter pupil in a group with a mean age of 41 years. This may be

explained in part by the slightly larger pupil size in our study but chiefly by the age differences between the populations; an increase in ocular positive spherical

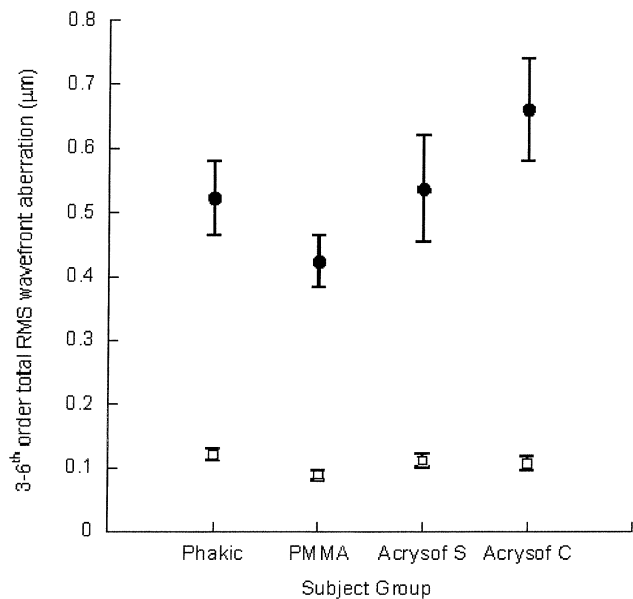


Figure 1. A comparison of total 3rd- to 6th-order RMS wavefront aberration in the 4 groups (mean and 95% confidence interval for the mean) (● = results for a 6.0 mm pupil, □ = results for a 3.5 mm pupil).

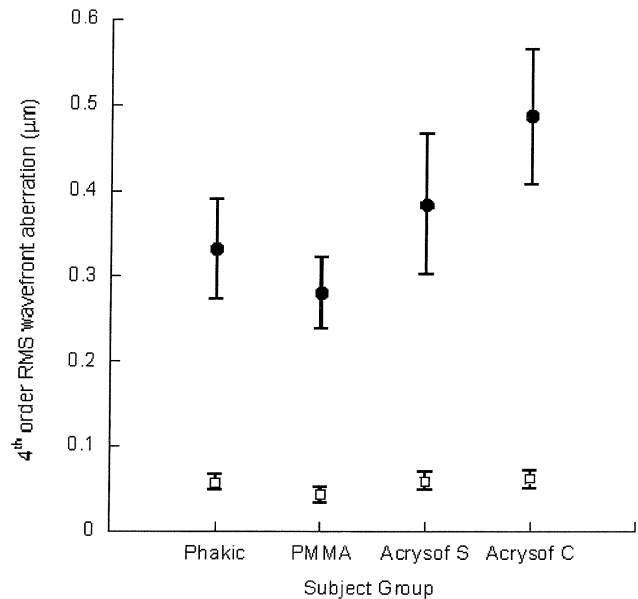


Figure 2. A comparison of 4th order RMS wavefront aberration in the 4 groups (mean and 95% confidence interval for the mean) (● = results for a 6.0 mm pupil, □ = results for a 3.5 mm pupil).

aberration and a reduction in lenticular negative spherical aberration have been found with age.^{21,22} Miller and coauthors¹⁰ found the 3rd- to 6th-order RMS wavefront aberration to be approximately 0.8 μm for a 6.0 mm diameter pupil in a pseudophakic group. This is larger than our value (approximately 0.53 μm); but overall, our wavefront aberration results are in broad agreement with the results in the literature.

The significant differences in optical performance led to the conclusion that PMMA lens implantation through scleral tunnel incisions causes lower levels of aberration than in normal phakic eyes and significantly less than in eyes with AcrySof lenses. AcrySof IOLs implanted through corneal incisions induced slightly more aberration than those inserted through scleral incisions. The differences in aberration under dilated pupil conditions seem to be mediated by 4th-order aberrations, in particular corrected spherical aberration and tetrafoil aberration. The differences found in the spherical aberration between the groups cannot be ascribed to corneal shape as this was examined and no such differences existed. Because corneal shape analysis does not include tetrafoil, we cannot confirm tetrafoil aberrations were induced at the cornea for the AcrySof–corneal group. However, this is likely since similar tetrafoil aberrations did not occur in the AcrySof–scleral group.

The statistical model used to control type I error results in a decrease in power and a potential increase in type II error.¹⁷ For 3.5 mm pupils, stopping the analysis because total higher-order RMS was not significant may have concealed a significant finding in just 1 order or 1 Zernike mode because its effect was overshadowed by all the other information included in the RMS term. Indeed, significant differences existed in the 4th-order RMS ($F = 2.91$; $df = 3,70$; $P < .05$) when the 3.5 mm pupil was tested at the $P < .05$ level. This was driven by significant differences in the C_{12} coefficient (corrected 3rd-order spherical aberration) ($F = 3.69$; $df = 3,70$; $P < .05$). The C_{10} coefficient (tetrafoil aberration) was also significantly different between the groups ($F = 4.13$; $df = 3,70$; $P < .01$) but this did not drive the difference in the 4th-order RMS. The differences in C_{12} were significant between the PMMA–scleral (0.034 ± 0.018) and AcrySof–scleral (0.053 ± 0.024) groups and the PMMA–scleral and AcrySof–corneal groups (0.054 ± 0.019) ($P < .05$), with the AcrySof

groups having more wavefront aberration. For C_{10} , the differences were significant between the PMMA–scleral (-0.006 ± 0.012) and phakic (0.009 ± 0.018) groups and the PMMA–scleral and AcrySof–corneal groups (0.008 ± 0.011) ($P < .05$). In this case, the magnitude of the coefficients was similar but the sign was reversed, hence its lack of contribution to 4th-order RMS differences. Although these differences cannot be reported as significant in our statistical model, they deserve mention because they are consistent with the significant 6.0 mm pupil findings and thereby gain some validity.

The difference in spherical aberration between IOLs is probably a result of the lens design. For typical values of corneal asphericity, an IOL shape factor of 1 is expected to minimize ocular spherical aberration. This is a plano-convex lens design, with the curved surface facing the cornea.²³ AcrySof MA30BA and MA60BM IOLs have an unequal biconvex lens designs with a flatter front surface curvature, which is opposite the ideal design; this was probably the source of the increased spherical aberration. We would also expect IOLs with higher refractive indices to induce smaller amounts of spherical aberration as their surface curvatures will be smaller for a given power, leading to more normal angles of incidence and refraction and a closer approximation to Gaussian (aberration-free) optics. The AcrySof IOL has a higher refractive index (1.55) than PMMA (1.49) and yet was associated with higher wavefront aberration in our study. Intraocular lens position is predicted to have a relatively small contribution to on-axis aberrations; it plays a larger role in off-axis aberrations unless it is placed close to the iris.²⁴

The finding of significant differences in wavefront aberration without significant differences in visual performance raises the question of whether this study had the power to detect such a difference. Let's test the key finding; that is, the AcrySof–corneal group had more aberrations than the PMMA–scleral group. From previously published data,²⁵ a 0.25 μm C_{12} spherical aberration will cause an average 0.2 logMAR decrease in visual acuity. If we consider the 6.0 mm wavefront aberration data, C_{12} values are PMMA–scleral 0.24 and AcrySof–corneal 0.42. This difference of 0.18 can be converted to a predicted logMAR difference of 0.144. Given the logMAR standard deviations for each group (0.08, 0.11), a power of 80%, and a type I error of 0.027, the required sample size per group to find

differences between PMMA–scleral and AcrySof–corneal is 10 subjects per group. However, differences were not found because the measured differences in vision were much less (0.06 logMAR). Alternatively, if we look at total RMS wavefront error regressed against visual acuity from published data,²⁶ every 0.1 μm accounts for 0.06 logMAR. For the raw data of total RMS measured (PMMA–scleral 0.42, AcrySof–corneal 0.66), we derive the difference 0.24 μm and convert it into an expected visual acuity difference of 0.144 logMAR. Given the logMAR standard deviations for each group (0.08, 0.11), a power of 80%, and type I error of 0.027, the required sample size per group to find differences between PMMA–scleral and AcrySof–corneal is 10 subjects per group. Again, differences were not found because the measured difference in visual acuity was much less (0.06 logMAR). Thus, the study has sufficient power to find a difference in visual acuity.

For contrast sensitivity, there is a lack of quality published data showing the predictive relationship between contrast sensitivity and RMS. However, many computer models that demonstrate that the impact of wave aberrations on vision are more profound at mid spatial frequencies (eg, Moreno-Barriuso and Navarro¹³) than the high spatial frequency cut-off (visual acuity) and therefore even more power should exist to detect a difference between groups on contrast sensitivity testing.

That visual performance did not differ despite differences in wavefront aberration is an important finding. However, wavefront aberration is not the only possible cause of decreased contrast sensitivity. Forward light scatter is one of several alternatives. Thickening of the posterior capsule after cataract extraction is a well-known cause of visual degradation from forward light scatter.^{27,28} Although all our subjects were screened for posterior capsule thickening, it is likely that a degree of subclinical thickening was present. AcrySof IOLs have a sharp optic edge design that inhibits capsule thickening^{29–31}; thus, eyes with AcrySof IOLs have a lower incidence of thickening than eyes with the round-edged PMMA IOLs used in our study.^{32–35} Thus, it is possible that the PMMA–scleral group had a higher incidence of mild capsule thickening than the other groups, enough to degrade contrast sensitivity as much as the extra wavefront aberration in the AcrySof

groups. Anterior capsule opacification may also play a role, but only when the pupil is dilated and light scatters off the annular zone of anterior capsular opacity between the capsulorhexis and the dilated pupil margin. Lenticular scatter is not the only potential source of scatter in the eye that can interfere with retinal image quality; retinal scatter may also play a significant role. Similarly, contrast sensitivity can be affected by mechanisms other than aberrations and scatter such as light reflection, light absorption, retinal function, and neural function.

It seems that superior corneal incisions contribute to the increase in spherical and tetrafoil aberration, but only with larger pupil diameters. Again, this suggests that scleral-based incisions may be preferred for minimizing aberrations under dim illumination. However, none of the differences in aberrations manifests as a visual performance difference. This suggests that the aberration differences are of less significance to the subjects than other confounding factors.

Recent reports suggest the visual impact of spherical aberration differences from IOLs can be detected by contrast sensitivity testing using a photographic patch chart.³⁶ Our results contradict this. Other studies^{37–39} had contrast sensitivity results with PMMA and acrylic IOLs that are similar to our results. Afsar and co-authors³⁸ also found no difference in visual performance between subjects with normal phakic eyes and those with PMMA IOLs. However, they tested visual performance within 2 months after surgery. We performed the testing between 12 and 18 months after surgery, allowing capsule or retinal changes to develop. Despite careful exclusion of patients with other conditions likely to affect contrast sensitivity, the effect of aberrations on contrast sensitivity has been lost within the noise from other factors.

References

1. Lyle WA, Jin GJC. Prospective evaluation of early visual and refractive effects with small clear corneal incision for cataract surgery. *J Cataract Refract Surg* 1996; 22:1456–1460
2. Mamalis N. Complications of foldable intraocular lenses requiring explantation or secondary intervention—2001 survey update. *J Cataract Refract Surg* 2002; 28:2193–2201

3. Mamalis N. Complications of foldable intraocular lenses requiring explanation or secondary intervention—1998 survey. *J Cataract Refract Surg* 2000; 26:766–772
4. Mamalis N, Spencer TS. Complications of foldable intraocular lenses requiring explanation or secondary intervention—2000 survey update. *J Cataract Refract Surg* 2001; 27:1310–1317
5. Dick HB, Tehrani M, Brauweiler P, et al. Komplikationen faltbarer Intraokularlinsen mit der Folge der Explantation von 1998 und 1999; Ergebnisse einer Fragebogenauswertung. *Ophthalmologie* 2002; 99:438–443
6. Schmidbauer JM, Peng Q, Apple DJ, et al. Rates and causes of intraoperative removal of foldable and rigid intraocular lenses: clinicopathological analysis of 100 cases. *J Cataract Refract Surg* 2002; 28:1223–1228
7. Frohn A, Dick HB, Augustin AJ, Grus FH. Late opacification of the foldable hydrophilic acrylic lens SC60B-OUV. *Ophthalmology* 2001; 108:1999–2004
8. Trivedi RH, Werner L, Apple DJ, et al. Post cataract-intraocular lens (IOL) surgery opacification. *Eye* 2002; 16:217–241
9. Liang J, Grimm B, Goelz S, Bille JF. Objective measurement of wave aberrations of the human eye with the use of a Hartmann-Shack wave-front sensor. *J Opt Soc Am A* 1994; 11:1949–1957
10. Miller JM, Anwaruddin R, Straub J, Schwiegerling J. Higher order aberrations in normal, dilated, intraocular lens, and laser in situ keratomileusis corneas. *J Refract Surg* 2002; 18:S579–S583
11. Cheng X, Bradley A, Hong X, Thibos LN. Relationship between refractive error and monochromatic aberrations of the eye. *Optom Vis Sci* 2003; 80:43–49
12. Bailey IL, Bullimore MA, Raasch TW, Taylor HR. Clinical grading and the effects of scaling. *Invest Ophthalmol Vis Sci* 1991; 32:422–432
13. Moreno-Barriuso E, Navarro R. Laser ray tracing versus Hartmann-Shack sensor for measuring optical aberrations in the human eye. *J Opt Soc Am A Opt Image Sci Vis* 2000; 17:974–985
14. Hazel CA, Cox MJ, Strang NC. Wavefront aberration and its relationship to the accommodative stimulus-response function in myopic subjects. *Optom Vis Sci* 2003; 80:151–158
15. Thibos LN, Applegate RA, Schwiegerling JT, Webb R. Standards for reporting the optical aberrations of eyes; VSIA Standards Taskforce Members. *J Refract Surg* 2002; 18:S652–S660
16. Douthwaite WA, Hough T, Edwards K, Notay H. The EyeSys videokeratographic assessment of apical radius and p-value in the normal human cornea. *Ophthalmic Physiol Opt* 1999; 19:467–474
17. Sankoh AJ, D'Agostino RB Sr, Huque MF. Efficacy endpoint selection and multiplicity adjustment methods in clinical trials with inherent multiple endpoint issues. *Stat Med* 2003; 22:3133–3150
18. Sankoh AJ, Huque MF, Dubey SD. Some comments on frequently used multiple endpoint adjustment methods in clinical trials. *Stat Med* 1997; 16:2529–2542
19. Thibos LN, Hong X, Bradley A, Cheng X. Statistical variation of aberration structure and image quality in a normal population of healthy eyes. *J Opt Soc Am A Opt Image Sci Vis* 2002; 19:2329–2348
20. Porter J, Guirao A, Cox IG, Williams DR. Monochromatic aberrations of the human eye in a large population. *J Opt Soc Am A Opt Image Sci Vis* 2001; 18:1793–1803
21. Smith G, Cox MJ, Calver R, Garner LF. The spherical aberration of the crystalline lens of the human eye. *Vision Res* 2001; 41:235–243
22. Calver RI, Cox MJ, Elliott DB. Effect of aging on the monochromatic aberrations of the human eye. *J Opt Soc Am A Opt Image Sci Vis* 1999; 16:2069–2078
23. Smith G, Lu C-W. The spherical-aberration of intraocular lenses. *Ophthalmic Physiol Opt* 1988; 8:287–294
24. Smith G, Lu C-W. Peripheral power errors and astigmatism of eyes corrected with intraocular lenses. *Optom Vis Sci* 1991; 68:12–21
25. Applegate RA, Marsack JD, Ramos R, Sarver EJ. Interaction between aberrations to improve or reduce visual performance. *J Cataract Refract Surg* 2003; 29:1487–1495
26. Smolek MK, Klyce SD. Zernike polynomial fitting fails to represent all visually significant corneal aberrations. *Invest Ophthalmol Vis Sci* 2003; 44:4676–4681
27. Cheng C-Y, Yen M-Y, Chen S-J, et al. Visual acuity and contrast sensitivity in different types of posterior capsule opacification. *J Cataract Refract Surg* 2001; 27:1055–1060
28. Goble RR, O'Brart DPS, Lohmann CP, et al. The role of light scatter in the degradation of visual performance before and after Nd:YAG capsulotomy. *Eye* 1994; 8:530–534
29. Nishi O, Nishi K. Preventing posterior capsule opacification by creating a discontinuous sharp bend in the capsule. *J Cataract Refract Surg* 1999; 25:521–526
30. Nishi O, Nishi K, Wickström K. Preventing lens epithelial cell migration using intraocular lenses with sharp rectangular edges. *J Cataract Refract Surg* 2000; 26:1543–1549
31. Peng Q, Visessook N, Apple DJ, et al. Surgical prevention of posterior capsule opacification. Part 3: intraocular lens optic barrier effect as a second line of defense. *J Cataract Refract Surg* 2000; 26:198–213
32. Hayashi H, Hayashi K, Nakao F, Hayashi F. Quantitative comparison of posterior capsule opacification after polymethylmethacrylate, silicone, and soft acrylic intraocular lens implantation. *Arch Ophthalmol* 1998; 116:1579–1582

33. Halpern MT, Covert D, Battista C, et al. Relationship of AcrySof acrylic and PhacoFlex silicone intraocular lenses to visual acuity and posterior capsule opacification. *J Cataract Refract Surg* 2002; 28:662–669
34. Hollick EJ, Spalton DJ, Ursell PG, et al. The effect of polymethylmethacrylate, silicone, and polyacrylic intraocular lenses on posterior capsular opacification 3 years after cataract surgery. *Ophthalmology* 1999; 106:49–54; discussion by RC Drews, 54–45
35. Sundelin K, Friberg-Riad Y, Östberg A, Sjöstrand J. Posterior capsule opacification with AcrySof and poly(methyl methacrylate) intraocular lenses; comparative study with a 3-year follow-up. *J Cataract Refract Surg* 2001; 27:1586–1590
36. Packer M, Fine IH, Hoffman RS, Piers PA. Prospective randomized trial of an anterior surface modified prolate intraocular lens. *J Refract Surg* 2002; 18:692–696
37. Kohnen S, Ferrer A, Brauweiler P. Visual function in pseudophakic eyes with poly(methyl methacrylate), silicone, and acrylic intraocular lenses. *J Cataract Refract Surg* 1996; 22:1303–1307
38. Afsar AJ, Patel S, Woods RL, Wykes W. A comparison of visual performance between a rigid PMMA and a foldable acrylic intraocular lens. *Eye* 1999; 13:329–335
39. Gozum N, Safgonul Unal E, Altan-Yaycioglu R, et al. Visual performance of acrylic and PMMA intraocular lenses. *Eye* 2003; 17:238–242