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Title: The effect of cataract surgery incision location and intraocular lens type on ocular aberrations

Short running head: Aberrations from incisions and IOLs Authors:

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Abstract

Purpose. Can Shack-Hartmann wavefront sensing (SHWS) detect differences in optical performance *in vivo* between Pharmacia PMMA and Alcon Acrysof intraocular lenses (IOLs) and between eyes with clear corneal and scleral tunnel incisions? Are optical differences manifested as differences in visual performance?

Setting. Department of Optometry, University of Bradford, Richmond Rd, Bradford, West Yorkshire, BD7 1DP, United Kingdom.

Methods. Seventy-four subjects (17 phakic normals, 20 with PMMA IOLs inserted through a scleral tunnel, 21 with Acrysof IOLs through a scleral tunnel and 16 with Acrysof IOLs through a corneal incision) underwent visual acuity (VA) and contrast sensitivity (CS) testing, ocular optical quality measurement using SHWS and corneal surface measurement with a videokeratoscope.

Results. There were significant differences between groups for total root mean square (RMS) wavefront aberration (WFA) over a 6mm pupil (F=3.91;df=3.70;p<0.05) mediated at 4th order RMS, specifically spherical aberration and tetrafoil aberrations. The PMMA-Scleral group had the least aberrations and the Acrysof-Corneal group the most. For a 3.5mm pupil, total WFA differences became non-significant (p>0.05). No group differences were found for corneal shape, VA or CS measurement.

Conclusions. The implantation of spherical PMMA lenses leads to a slight reduction in total WFA compared to phakic eyes. Acrysof IOLs induce more aberrations, especially spherical aberration. Corneal-based incisions for IOL implantation compound this increase. Studies looking at 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.

Synopsis. Shack-Hartmann wavefront sensing is a useful cataract surgery outcome measure as it can detect differences in optical performance due to IOLs or incisions with specificity not possible with vision measures.

Introduction

Methods of phacoemulsification cataract surgery may differ in terms of incision site or intraocular lens (IOL) used. Incisions may be corneal or scleral, and commonly used IOLs are rigid polymethyl methacrylate (PMMA) or foldable IOLs, including acrylic lenses. As corneal incisions are quicker to perform than scleral incisions, and do not need significant enlarging when a foldable IOL is used, this is an attractive proposition that gives excellent results.¹ Problems with foldable IOLs are rare. However, the increase in their use has led to an increase in complications requiring explanation.²⁻⁴ Optical complications leading to explanation include:⁵ incorrect refractive correction, damage to the IOL during insertion,⁶ troublesome photic phenomena (e.g. glare, haloes, and peripheral arcs or crescents of light), IOL opacification^{7,8} and IOL glistenings. Deciding to explant an IOL in patients who report optical problems is based on patient symptoms alone. No objective test has been shown to confirm the presence of IOL optical problems.

In this study, we compared the *in vivo* visual and optical performance of the Pharmacia 722C PMMA lens (inserted through a scleral incision) to the Alcon Acrysof lens (inserted through a scleral incision) and to a group of phakic normal subjects. Similarly, we investigated whether corneal-based surgery (with Acrysof IOL) leads to an alteration in optical and visual performance when compared to scleral-based surgery (with Acrysof IOL). This was done to see if differences exist in the optical performance of IOLs and incisions, as well as to see if differences in optical performance are reflected in visual performance in terms of visual acuity (VA) or contrast sensitivity (CS). *In vivo* optical

performance was measured using Shack-Hartmann wavefront sensing (SHWS).⁹ This is a widely-used technique for investigating whole-eye optical performance but has only recently been applied to the assessment of the optics of IOLs *in vivo* where elevated levels of trefoil aberration, tetrafoil aberration and spherical aberration have been found in pseudophakic eyes compared to phakic normal subjects,¹⁰ although the age matching of subjects, type of IOL and surgical procedure was not stated. Therefore, we aimed to determine whether SHWS is a viable technique for assessing ocular imaging quality differences resulting from IOL types and surgical techniques, as this may be helpful for patient care in cases of the above-mentioned IOL optical problems.

Materials and methods

Patients

Patients who had undergone cataract surgery at the Leeds General Infirmary or BUPA hospital Leeds by one of two surgeons (OGS, BAN) were identified from the theatre records and enrolled into the study. Inclusion criteria were cataract surgery performed by between January 2000 and June 2001 with insertion of a Pharmacia 722C (PMMA, refractive index of 1.49, equal-biconvex design, 6.50mm optic) IOL through a scleral tunnel or an Acrysof (flexible acrylic, refractive index of 1.55, unequal biconvex design with a longer radius of curvature anteriorly, 5.50mm (MA-30BA) or 6.0mm (MA-60BM) optic) IOL through a scleral-tunnel or a clear corneal incision.

The scleral-tunnel incision was made in the upper nasal or temporal quadrant (depending on which eye was being operated on), 1.5mm behind the limbus, using a "frown" incision of 5mm cord length. The tunnel was fashioned by splitting the sclera with a crescent blade before final penetration of the cornea with a 2.75mm keratome at the anterior extent of the tunnel. The incision was enlarged with either a 5.2mm keratome to permit the insertion of the PMMA lens or enlarged to 3.5mm with the 2.75mm keratome for the implantation of the folded Acrysof IOL. Clear corneal incision was made using a 2.75mm keratome similarly placed in the upper quadrant of the eye, in the posterior cornea in a 3-step incision. The wound was enlarged to 3.5mm using the same keratome, to permit the insertion of the IOL. Surgical procedure was identical other than location of incision and the type of IOL. Phacoemulsification was carried out through a continuous curvilinear capsulorrhexis of approximately 5mm in diameter; sutures were only used to close the wounds if they were leaking.

Exclusion criteria were capsular thickening; any post-operative complications including cystoid macular edema or unexplained decreased VA; any other ocular pathology; any neurological problem, any systemic disease, taking of any medication which may affect CS; any intra-operative complication or the IOL not centred or not in the capsular bag; inability to speak English sufficiently to be instructed to perform the tests; insufficient mental ability to perform the tests, and physical disability which would make testing arduous (e.g. wheelchair-bound). Subjects with astigmatism of 3.00 dioptres or greater were also excluded from the study as high natural astigmatism reduces the image quality obtainable from the SHWS image in our apparatus and is associated with higher levels of root-mean-

square (RMS) higher order wavefront aberration (WFA).¹¹ Exclusion was made in three phases – case-note review, telephone interview and ophthalmic examination at the time of testing (to ensure complete exclusion of potentially confounding conditions e.g. capsular thickening). Phakic normal subjects were also recruited, but from the Eye Clinic at Bradford University. The inclusion criteria were age over 60 years and no previous cataract surgery. The exclusion criteria were any ocular pathology plus those listed for the IOL groups, and were also applied in three phases.

A total of seventy-four subjects were enrolled in four groups: the "Phakic" group comprised 17 phakic normal subjects, the "PMMA-Scleral" group comprised 20 subjects with a PMMA IOL inserted through a scleral tunnel, the "Acrysof-Scleral" group comprised 21 subjects with an Acrysof IOL inserted through a scleral tunnel and the "Acrysof-Corneal" group comprised 16 subjects with an Acrysof IOL inserted through a corneal incision. Groups were matched for age, gender, pupil size and degree of spherical ametropia. The study complied with the principals of the Declaration of Helsinki, and was approved by the Leeds Regional Ethical Committee.

Visual and optical assessment

The subjects were refracted by one of us, HD who was unaware of which group the subject belonged to, using retinoscopy and subjective refraction including binocular balancing undilated under photopic lighting levels. Testing was then conducted undilated using optimal refractive correction. Best-corrected logMAR visual acuity was measured monocularly using standard ETDRS charts at 4 meters with a luminance of 100 cd/m^2 , 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, the Cambridge research systems VSG 2/3. A chromatically narrowband sinusoidal grating stimulus (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 c/deg) were used at two orientations (horizontal and vertical). The minimum possible Michelson contrast that could be presented by the system was close to 0.1%, which is well below the minimum contrast detectable by the human visual system. This ensured that the CS measurement was free from ceiling effects. The threshold was determined using a method of ascending limits with contrast increments of 2 dB. Following five minutes of luminance adaptation, the six stimuli were presented in a random order. For each stimulus the subject was shown the grating at a level above the contrast threshold prior to the threshold determination to ensure that the subject was responding to the correct stimulus waveform. The CRT monitor mean luminance was 34.8 cd/m^2 .

Photopic pupil size measured using a template, and dilated pupil size was measured from the SHWS image. Refraction, VA and CS testing, using the same techniques, were all repeated with a dilated pupil (1 drop of 0.5% Tropicamide).

Measurements of ocular aberrations were performed with a Shack-Hartmann aberroscope, by five photographic measurements, which is an established and effective method.¹³ The instrumentation and procedures used in our laboratory have been described in detail elsewhere.¹⁴ The only modifications applied in this work were the use of a wavelength of light of 632.8nm and the capture and averaging of WFA results from five SHWS images per eye. WFAs are described in terms of the orthonormal ernike 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 6.0mm or a 3.5mm pupil diameter. For pupils less than 6.0 mm radius, data is extrapolated from the maximum pupil diameter available up to 6.0 mm to facilitate valid comparison. Coordinate systems and ernike polynomial representation are as given in 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 *et a* (1995).¹⁶ The asphericity was expressed as a radially averaged p-value, from which corneal spherical aberration was calculated. Since SHWS measures whole eye wavefront aberrations, calculation of the corneal spherical aberration allows isolation of lenticular (phakic or IOL) spherical aberration. This allowed us to determine whether overall changes in the C_{12} spherical aberration were influenced by corneal changes following surgery, or if they were entirely due to the IOL.

Statistical analysis

One arm of the study compared corneal incision to the scleral incisions with the same IOL type (Acrysof-Corneal Acrysof-Scleral groups). The other arm of the study compared different IOL types through the same (scleral-based) incision (PMMA-Scleral Acrysof-Scleral groups). Age, spherical equivalent refraction, pupil size, vision measures, ocular aberrations and corneal aberrations for between the 4 groups were compared by one-way ANOVA with post-hoc Tukey Honest Significant Differences testing for unequal group sizes. This test was also chosen because it is not prone to alpha inflation, which is a risk when doing 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 (Holm step-down) Bonferroni adjustment within a composite endpoint paradigm was employed.¹⁷ In short, the ernike polynomial expansion can be treated as a composite measure, like a questionnaire, where total RMS is the total score and main outcome measure tested at a significance level of p<0.05. In the next level there are 4 orders of RMS wavefront error which are tested at p < 0.05/(4-(0 to 3 in sequence)) i.e. 0.0125 to 0.05. In the third level there are multiple ernike coefficients depending upon the order, which are tested at a significance level of 0.0125/(number of coefficients - (0 to number of coefficients -1)). Under this approach, testing only progresses to the next level when significance was demonstrated at the previous level.

The same adjustment is not appropriate for multiple visual performance measures as these are not composite but are highly correlated measures. Adjustment should be made for the number of measures, but this should take into account the correlation between measures.¹⁸

We employed a Holm step-down Bonferroni adjustment with a significance level of p<0.05, and therefore adjusted: 0.05 / (((number of measures – (0 to number of measures – 1)) x (1-correlation between measures)).

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

Results

The four groups were well matched (Table 1). They were similar for age (F=2.28;df=3,70;p>0.05), spherical equivalent refractive error with natural pupils (F=1.90;df=3,70;p>0.05) and photopic pupil size (F=0.78;df=3,49;p>0.05). The four groups were also similar for spherical equivalent refractive error measured under dilated pupil conditions (F=1.65;df=3,66;p>0.05) but were significantly different for the dilated pupil size (F=7.07;df=3,70;p<0.001). Post-hoc testing showed the only significant difference was between the Acrysof-Corneal group and the Phakic group (p<0.001).

The seven visual performance measures were highly correlated with an average correlation of 0.66 for 3.5 mm pupils, and 0.74 for 6.0mm pupils. To maintain a significance level of p<0.05, significance was adjusted per the method described above to p<0.021 for 3.5 mm pupils, and p<0.027 for 6.0mm pupils. The four groups were not significantly different for

any measure of visual performance (Table 2) for 3.5 mm pupil or 6.0mm pupils (Table 3). However, there were differences between the four groups in the level of aberrations (Table 4).

For a 3.5mm diameter pupil, representative of the average natural pupil diameter in our subjects, the total higher order RMS WFA was not significantly different between the groups (Phakic 0.121 ± 0.034 , PMMA-Scleral 0.088 ± 0.047 , Acrysof-Scleral 0.111 ± 0.052 , Acrysof-Corneal 0.107 ± 0.038 , p>0.05, Figure 1). Under the statistical model employed, 3.5mm pupil data testing ceased at this stage.

For a 6mm pupil diameter, representative of the average pupil diameter of the dilated pupil condition, the total RMS WFA (Table 4) was significantly different between the groups (F=3.91;df=3,70;p<0.05). The PMMA-Scleral group had significantly less WFA than the Acrysof-Corneal group (p<0.01) (Figure 1). The differences in total WFA were driven by significant differences in 4th order RMS error (F=6.37;df=3,70;p<0.001), whilst 3rd, 5th and 6th order RMS WFA did not show any significant differences between the groups. The 4th order RMS aberrations were greater for the Acrysof-Corneal group than the PMMA-Scleral group (p<0.001) (Figure 2). The differences in 4th order RMS WFAs were driven by significant differences in the C₁₂ (corrected 3rd order spherical aberration) (F=4.97;df=3,70;p=0.003) and C₁₄ (tetrafoil aberration) (F=5.72;df=3,70;p=0.001) coefficients. The differences were between the PMMA-Scleral and Acrysof-Corneal groups for C₁₂ (p=0.002) and between Phakic and Acrysof-Corneal for C₁₄ (p=0.001) with the Acrysof-Corneal group having more WFA for both coefficients. The corneal

asphericities were not significantly different between groups (F=0.294;df=3,65;p>0.05). The mean corneal p-value, at 0.75, was typical of that found in human subjects.¹⁶

Discussion

The Phakic group, and the three IOL groups were similar in terms of age, spherical equivalent refractive error and photopic pupil size. They were different in their dilated pupil size, with the IOL groups having smaller pupil sizes. The entrance pupil under dilated pupil conditions was measured using the SHWS image. Following IOL implantation this is effectively limited by the size of the capsulorrhexis, which is smaller than the size of the dilated pupil aperture. It is also worth noting in Table 1 the non-significant difference in spherical equivalent refractive error with the Phakic group having nearly 1 dioptre of hyperopia and the IOL groups approximating emmetropia. This simply reflects the natural prevalence of hyperopia amongst this age group, and targeted emmetropia in the IOL groups.

The overall amount of WFA is in line with previously reported values. Thibos and coworkers (2002) reported RMS levels of around 0.65 μ m for the 3rd-6th order WFA and 0.2 μ m for 4th order WFA when assessed over a 6mm diameter pupil in young subjects.¹⁹ Our values for 3rd-6th order RMS WFA for the Phakic group are similar, although the levels of 4th order RMS WFA (0.33 μ m) is somewhat larger. This order contains spherical aberration, 0.30 μ m in our group, which is larger than Porter and co-workers (2001) reported (0.15 μ m) for a 5.7mm diameter pupil in a group with a mean age of 41 years.²⁰ This may be in part explained by our slightly larger pupil size, but chiefly by age differences between the populations; an increase in ocular positive spherical aberration and a reduction in lenticular negative spherical aberration have been found with age.^{21,22} Miller and co-workers (2002) found the 3^{rd} - 6^{th} order RMS WFA to be approximately 0.8µm for a 6mm diameter pupil in a pseudophakic group.¹⁰ This is larger than our values (around 0.53µm), but overall, these WFA results are in broad agreement with the previously reported literature.

The significant differences in optical performance lead to the conclusion that PMMA lens insertion through scleral tunnel incisions give lower levels of aberration than normal phakic eyes, and significantly less than Acrysof lenses. Acrysof IOLs implanted through corneal incisions induce 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. The corneal shape analysis does not include tetrafoil, so it cannot confirm that this was induced at the cornea for the Acrysof-Corneal group, but this remains likely since similar tetrafoil did not occur in the Acrysof-Scleral group.

The statistical model used to control type 1 error, results in a decrease in power and a potential increase in type 2 error.¹⁷ For the 3.5mm pupil, stopping analysis because total higher order RMS was not significant, possibly conceals a significant finding in just one

order or one ernike mode because its effect was swamped by all the other information included in the RMS term. Indeed, for the 3.5 mm pupil simply tested at the p<0.05 level significant differences did exist in the 4th order RMS (F=2.91;df=3,70;p<0.05), which were driven by significant differences in the C₁₂ (corrected 3rd order spherical aberration) coefficient (F=3.69;df=3,70;p<0.05). The C₁₀ (tetrafoil aberration) coefficient was also significantly different between the groups (F=4.13;df=3,70;p<0.01) but this did not drive the difference in the 4th order RMS. The differences were between PMMA-Scleral (0.034 ± 0.018) and Acrysof-Scleral (0.053 ± 0.024), and PMMA-Scleral and Acrysof-Corneal (0.054 ± 0.019) (p<0.05) for C₁₂ with the Acrysof lens groups having more WFA. For C₁₀ the differences were between PMMA-Scleral (0.008 ± 0.012) and Phakic (0.009 ± 0.018), and PMMA-Scleral and Acrysof-Corneal (0.008 ± 0.011) (p<0.05). 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. While these differences cannot reported as significant in terms of our statistical model, they deserve mention since they are consistent with the significant 6mm pupil findings, and thereby gain some validity.

The difference in spherical aberration between IOLs is probably due to lens design. For typical values of corneal asphericity, an IOL shape factor of 1 is expected to minimize the ocular spherical aberration. This is a plano-convex lens design with the curved surface facing the cornea.²³ The Acrysof MA-30BA and MA-60BM lenses are unequal biconvex lens designs with a flatter front surface curvature, opposite to the ideal design, which 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 WFA in our data. IOL position is predicted to have a relatively small contribution to on-axis aberrations. It has a larger contribution to off-axis aberrations unless it is placed close to the iris.²⁴

The finding of significant differences in WFA without significant differences in visual performance raises the question of whether this study had the power to detect such a difference. If we test the key finding that the Acrysof-Corneal group has more aberrations than the PMMA-Scleral group: From previously published data 0.25 µm of C₁₂ spherical aberration will cause on average a 0.2 logMAR decrease in VA.³⁴ If we consider the 6.0 mm WFA data, C12 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 Type I error =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 VA from published data,³⁵ every 0.1µm 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 0.24µm and convert into an expected VA 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 =0.027, the required sample size per group to find differences between PMMA-Scleral and Acrysof-Corneal is 10 subjects per group. Again, the differences were not found because the measured difference in VA was much less (0.06 logMAR). So, for visual acuity, the study has sufficient power to find a difference. For contrast sensitivity there is a lack of quality published data demonstrating the predictive relationship between contrast sensitivity and RMS. However, there is no shortage of computer modeling which demonstrates that the impact of wave aberrations on vision are more profound at mid spatial frequencies e.g.¹³ than the high spatial frequency cut-off (VA) 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 WFA is an important finding. However, WFA is not the only possible cause of decreased CS. Forward light scatter provides one of several alternatives. Thickening of the posterior capsule after cataract extraction is a well-known cause of visually degrading forward light scatter.^{25,26} While all our subjects were screened for posterior capsular thickening, it is likely that a degree of "sub-clinical" thickening was present. Acrysof lenses, due to sharp optic edge design which inhibits capsular thickening,²⁷⁻²⁹ have lower prevalence of capsular thickening than PMMA IOLs with rounded optic edges used in this study.³⁰⁻³³ Thus it is possible that the PMMA-Scleral group had a higher incidence of mild capsular thickening than the other groups, enough to degrade CS as much as the extra WFA in the Acrysof groups. Anterior capsular opacity 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 capsulorrhexis and the dilated pupil margin. Lenticular scatter is not the only potential source of scatter in the eye that may interfere with retinal image quality and retinal scatter may also play a significant role. Similarly, contrast sensitivity can be affected by mechanisms other than aberrations and scatter including light reflection and absorption or retinal and neural function.

It seems that superior corneal incisions contribute to the increase in both spherical aberration and tetrafoil, but only when considering larger pupil diameters. Again this suggests that scleral-based incision may be preferred for minimizing aberrations under dim illumination. However, none of these differences in aberrations manifest as a visual performance difference. This suggests that the aberration differences demonstrated are of less significance to the subjects than other confounding factors. This is an important finding, as even if by chance our PMMA-Scleral group was contaminated by unequal amounts of subtle capsular thickening or resolved cystoid macular edema, the magnitude of visual impairment from aberrations is so small that such issues swamp it.

Recent reports have claimed the visual impact of spherical aberration differences from IOLs can be detected by photographic patch chart CS testing.³⁶ Our results contradict this. Similar visual performance in terms of CS with PMMA and acrylic IOLs has also been found previously.³⁷⁻³⁹ Afsar *et a* also failed to detect any difference in visual performance between phakic normal subjects and PMMA IOL subjects. However, their subjects were tested within two months of their surgery, whilst our subjects were examined between 12 and 18 months after their surgery, allowing a greater time for the development of capsular or retinal changes following the surgery. Despite careful exclusion of patients with any

other conditions likely to affect CS, the effect of aberrations on CS has been lost within the noise from other issues.

References

 Lyle WA, Jin GJ. 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 explantation or secondary intervention--2000 survey update. J Cataract Refract Surg 2001;27:1310-1317

5. Dick HB, Tehrani M, Brauweiler P, et al. [Complications with foldable intraocular lenses with subsequent explanation in 1998 and 1999. Results of a questionnaire evaluation]. Ophthalmologe 2002;99:438-443

 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

 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 Refractive Surg 2002;18:S579-S583

11. Cheng X. 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 2000;17:974-985

 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. J Refractive Surg 2002;18:S652-S660

 Douthwaite WA, Hough T, Edwards K, Notay H. The EyeSys videokeratoscopic assessment of apical radius and p- value in the normal human cornea. Ophthalmic Physiol Opt 1999;19:467-474

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 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 2001;18:1793-1803

21. Smith G, Cox MJ, Calver R, Garner LF. The spherical aberration of the crystalline lens of the human eye. Vis 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 1999;16:2069-2078

23. Smith G, Lu CW. The Spherical-Aberration of Intra-Ocular Lenses. OphthalmicPhysiol Opt 1988;8:287-294

24. Smith G, Lu CW. Peripheral Power Errors and Astigmatism of Eyes Corrected with Intraocular Lenses. Optom Vis Sci 1991;68:12-21

25. Cheng CY, Yen MY, Chen SJ, et al. Visual acuity and contrast sensitivity in
different types of posterior capsule opacification. J Cataract Refract Surg 2001;27:10551060

26. 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

27. 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

28. Nishi O, Nishi K, Wickstrom K. Preventing lens epithelial cell migration using intraocular lenses with sharp rectangular edges. J Cataract Refract Surg 2000;26:1543-1549

29. 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

30. 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

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

32. 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 54-45

33. Sundelin K, Friberg-Riad Y, Ostberg A, Sjostrand 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

34. 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

35. Smolek MK, Klyce SD. ernike polynomial fitting fails to represent all visually significant corneal aberrations. Invest Ophthalmol Vis Sci 2003;44:4676-4681

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

Incisions, IOLs and aberrations 27.

Legends for figures

Figure 1. A comparison of total $3^{rd}-6^{th}$ -order root mean square wavefront aberration for the four groups (mean and 95% confidence interval for the mean). • – results for a 6mm pupil diameter, \Box – results for a 3.5mm pupil diameter. For a 6mm diameter pupil the PMMA-Scleral group has the least wavefront error and the Acrysof-Corneal group has the most. These are statistical significantly different. For the 3.5mm diameter pupil the differences between the groups do not reach statistical significance.

Figure 2. A comparison of 4th order root mean square wavefront aberration for the four groups (mean and 95% confidence interval for the mean). • – results for a 6mm pupil diameter, \Box – results for a 3.5mm pupil diameter. The PMMA-Scleral IOL group has the least wavefront error and along with the Phakic group is statistically significantly less than the Acrysof-Corneal group for a 6mm pupil diameter. For a 3.5mm diameter pupil the 4 groups were statistically significantly different at the p<0.05 level (F=2.91;df=3,70;p<0.05), but not after adjustment for alpha inflation.

Legends for tables

Table 1. The four groups are well matched by age, spherical equivalent refractive error with natural pupils, photopic pupil size and spherical equivalent refractive error measured under dilated pupil conditions. The only difference was between the Phakic and Acrysof-corneal groups for the dilated pupil size, which was measured with the SHWS and so reflects capsulorrhexis contraction. The non-significantly higher spherical equivalent in the Phakic group reflects naturally existing hyperopia versus planned emmetropia after cataract surgery.

Table 2. The visual performance with natural pupils, represented by visual acuity (logMAR) and log (contrast sensitivity) (measured at 6, 12, 18 cycles per degree and in two orientations), for the four groups (mean \pm SD). A one-way ANOVA demonstrated no statistically significantly differences between the groups.

Table 3. The visual performance with dilated pupils, represented by visual acuity (logMAR) and log (contrast sensitivity) (measured at 6, 12, 18 cycles per degree and in two orientations), for the four groups (mean \pm SD). A one-way ANOVA demonstrated no statistically significantly differences between the groups.

Table 4. The optical performance in terms of wavefront error (μ m) over a 6mm diameter pupil for the four groups (mean ± SD). Analysis followed the sequence 1) root mean square (RMS) total higher order wavefront (excluding sphero-cylindrical, prismatic, and piston terms, 2) root mean square for each order and 3) each individual ernike coefficient for orders with significant differences. Only total RMS, 4^{th} order RMS, C_{12} and C_{14} were statistically significantly different between the groups.









Table 1.

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

* F=7.07; df=3,70; p<0.001, Acrysof-Corneal<Phakic (p<0.001).

Τ	ab	le	2.

Measure	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
CS 6 Horizontal	1.18 ± 0.16	0.97 ± 0.25	1.11 ± 0.21	1.07 ± 0.21
CS 12 Horizontal	0.68 ± 0.22	0.59 ± 0.27	0.65 ± 0.23	0.71 ± 0.32
CS 18 Horizontal	0.16 ± 0.12	0.16 ± 0.16	0.22 ± 0.21	0.21 ± 0.21
CS 6 Vertical	1.23 ± 0.18	1.00 ± 0.24	1.17 ± 0.24	1.14 ± 0.25
CS 12 Vertical	0.63 ± 0.20	0.47 ± 0.25	0.62 ± 0.26	0.57 ± 0.30
CS 18 Vertical	0.16 ± 0.16	0.08 ± 0.10	0.19 ± 0.17	0.16 ± 0.18

Table 3.

Measure	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
CS 6 Horizontal	1.17 ± 0.20	1.01 ± 0.21	1.08 ± 0.23	1.10 ± 0.21
CS 12 Horizontal	0.71 ± 0.27	0.58 ± 0.25	0.62 ± 0.26	0.62 ± 0.32
CS 18 Horizontal	0.18 ± 0.20	0.15 ± 0.15	0.17 ± 0.18	0.25 ± 0.23
CS 6 Vertical	1.17 ± 0.21	1.01 ± 0.24	1.14 ± 0.21	1.12 ± 0.23
CS 12 Vertical	0.67 ± 0.25	0.48 ± 0.23	0.63 ± 0.22	0.60 ± 0.31
CS 18 Vertical	0.17 ± 0.19	0.09 ± 0.11	0.16 ± 0.16	0.19 ± 0.17

Tab	le 4.
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Zernike Orders	Phakic	PMMA-Scleral	Acrysof-Scleral	Acrysof-Corneal
RMS total [*]	0.52 ± 0.15	0.42 ± 0.17	0.54 ± 0.25	0.66 ± 0.23
RMS 3 rd order	0.37 ± 0.12	0.28 ± 0.17	0.32 ± 0.17	0.38 ± 0.20
RMS 4 th order	0.33 ± 0.12	0.28 ± 0.09	0.38 ± 0.19	0.49 ± 0.16
RMS 5 th order	0.10 ± 0.04	0.09 ± 0.03	0.11 ± 0.06	0.13 ± 0.08
RMS 6 th order	0.08 ± 0.04	0.08 ± 0.04	0.10 ± 0.07	0.11 ± 0.05
4 th 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<0.05	Post-hoc PN	IMA-Scleral <acrys< td=""><td>of-Corneal, p<0.01</td><td></td></acrys<>	of-Corneal, p<0.01	
F=6.37; df=3,70; p<0.00	Post-hoc PN	IMA-Scleral <acrys< td=""><td>of-Corneal, p<0.001</td><td></td></acrys<>	of-Corneal, p<0.001	
F=4.97; df=3,70; p=0.003	B Post-hoc PN	IMA-Scleral <acrys< td=""><td>of-Corneal, p=0.002</td><td>2</td></acrys<>	of-Corneal, p=0.002	2
F=5.72; df=3,70; p=0.001 Post-hoc phakic <acrysof-corneal, p="0.001</td"><td></td></acrysof-corneal,>				