

A comparison of visual performance between a rigid PMMA and a foldable acrylic intraocular lens

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Abstract

Purpose To examine post-operative visual outcomes when using micro-incision surgery and a three-piece, foldable acrylic intraocular lens (IOL) and when using small-incision surgery and a one-piece, rigid polymethyl-methacrylate (PMMA) IOL.

Methods Phacoemulsification and IOL implantation was conducted by one surgeon on 86 subjects (aged 50–89 years) with cataracts. Of these subjects, 67 completed the study. Subjects were implanted either with a foldable IOL ($n = 38$) or a rigid IOL ($n = 29$). Best corrected Snellen visual acuity and contrast sensitivity (2–28 cycles/degree) were measured approximately 2 months post-operatively. Comparisons were made between the pseudophakic groups and an additional group of 28 age-matched, normal subjects (aged 58–81 years). Non-parametric (Kruskal–Wallis and Mann–Whitney U) as well as parametric (ANOVA and Pearson) statistics tests were used in the analysis of results.

Results All pseudophakes had corrected visual acuity of 6/9 or better. There were no significant differences in visual acuity (Kruskal–Wallis, $p = 0.61$) or contrast sensitivity (ANOVA, $p = 0.33$) between the three groups. The mean residual refractive error of the foldable IOL group was hypermetropic in comparison with the rigid IOL group but not significant at the 99% level of probability (Mann–Whitney U , $p = 0.02$). There was no significant difference in astigmatism between the groups.

Conclusions Implanting a foldable acrylic IOL gave no post-operative benefit in visual acuity and contrast sensitivity to pseudophakes over a less expensive rigid PMMA IOL, within this post-operative period. This study did not provide a comparison between the two lenses regarding post-operative complications, in particular the important long-term complication of posterior capsular opacification (PCO). Until and if any particular advantage of a given IOL in reduced

incidence of PCO is confirmed, it appears more economical to implant the conventional rigid PMMA IOL using small-incision surgery.

Key words Intraocular lens (foldable, rigid), Pseudophakia, Vision performance

Since the first intraocular lens (IOL) implantation surgery in 1949 by Harold Ridley there have been many improvements in the procedure and the device. Phacoemulsification has allowed dramatic reductions in the size of the incision. The earlier large, typically 10–12 mm, incision required to allow intact removal of the crystalline lens required multiple sutures and frequently caused high levels of induced astigmatism. Following the introduction of phacoemulsification, IOL size became the limiting factor.¹ This 'small-incision' surgery, with typical incisions of 5.0–5.5 mm, commonly required a single suture. A foldable IOL allows 'micro-incision' surgery, which is limited by the 3 mm diameter of the phacoemulsification probe, the incision being small enough to be self-sealing.²

Induced astigmatism is reduced by decreasing the size of the incision^{3–5} and by making scleral incisions rather than corneal incisions.^{6–10} These previous investigations indicate that there is little induced astigmatism with small or micro-incisions. It also appears that when the incision is small, suturing makes no significant contribution to the magnitude of induced astigmatism.¹⁰ Hence it would be reasonable to assume that surgery using scleral, self-sealing micro-incisions would minimise induced astigmatism.

As improvement in vision is the major goal of most IOL surgery, visual acuity and contrast sensitivity (CS) are appropriate outcome measures. CS is often considered the best available measure of visual function in daily life.¹¹ Various studies have compared vision between IOL designs and materials. For example Skorpik *et al.*¹² reported no difference in CS between PMMA and silicone IOLs, while

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This study was reported, in part, at the annual meeting of the American Academy of Optometry, Orlando, Florida, USA, 9 December 1996; at the annual meeting of the Association for Research in Vision and Ophthalmology, Fort Lauderdale, Florida, USA, 13 May 1997; and at the annual meeting of the British Congress of Optometry and Visual Science, City University, London, UK, 11 September 1997

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Lowe and Easty¹³ reported similar visual acuity but better letter CS with polymethyl-methacrylate (PMMA) than HEMA IOLs. Comparing rigid with foldable IOLs Kohnen *et al.*¹⁴ found no difference in Snellen visual acuity between the three IOL types, but low-contrast visual acuity with rigid PMMA lenses was better than with foldable silicone IOLs. Re-analysis of their data indicates that there was no difference in low-contrast visual acuity between rigid PMMA and foldable acrylic IOLs. Conversely, Mäntyjärvi and Tuppurainen¹⁵ reported that silicone IOLs gave better overall CS at 3 cycles/degree, but not at other spatial frequencies, than PMMA IOLs. Whilst these results are slightly contradictory it is apparent that PMMA IOLs gave visual acuity and CS at least equal to several other materials, including silicone. Hence it is not clear that foldable IOLs offer visual benefits above those shown by rigid IOLs.

Good optical properties, dimensional and material stability, and few post-operative complications are desirable properties of any IOL. Since the availability of the first approved foldable silicone IOLs in 1991,² difficulties associated with uncontrollable unfolding characteristics¹⁶ and discolouration¹⁷ have been reported along with an incidence of posterior capsular opacification (PCO) higher than reported for PMMA IOLs.¹⁸ Consequently there is interest in alternatives such as foldable acrylic IOLs.

Since such foldable IOLs are usually more expensive than rigid IOLs, advantages, such as improved vision, accruing from foldable IOL use must be demonstrated to justify their use. Hence, we compared the vision and residual refractive error with a foldable acrylic IOL implanted using micro-incision surgery and a rigid PMMA IOL implanted using small-incision surgery. Also, these groups of pseudophakic subjects were compared with phakic age-matched normal subjects.

Materials and methods

Eighty-six subjects (aged 50–89 years) with cataracts were recruited prior to IOL implantation from the Southern General Hospital, Ophthalmology Department, Glasgow as part of a 2 year prospective, randomised study. All subjects provided informed consent prior to inclusion in the study, and full ethical approval for the study was granted by the Southern General Hospital Ethics Committee. Subjects were carefully selected to exclude any ocular disease other than the presence of cataract by the operating surgeon (W.W.). A three-piece, foldable, acrylic IOL was implanted in 43 subjects and a one-piece, rigid, PMMA IOL was implanted in 43 subjects.

During post-operative examination, 2 subjects, both with the foldable IOL, were found to have best corrected Snellen visual acuity worse than 6/9 (20/30). For both subjects there was evidence of macular drusen that had not been noted during the pre-surgical assessment. It was concluded that these subjects should not have been recruited into the study and hence were not included in the analysis. A further 17 subjects (3 from the foldable

IOL group and 14 from the rigid IOL group) were unable to complete the study for reasons unrelated to their cataract surgery. Therefore, data were analysed for 38 pseudophakes with the foldable IOL and 29 with the rigid IOL. A further 28 age-matched subjects (aged 58–81 years) with no evidence of ocular disease and best corrected Snellen visual acuity better than or equal to 6/9 were recruited from Glasgow Caledonian University Eye Clinic as a control group.

The 6/9 Snellen visual acuity limit was chosen for the age-matched group since it was the next line on the available Snellen acuity chart greater than the 95% confidence limits of the expected normal visual acuity for this age group as described by Elliott *et al.*¹⁹

A pre-programmed Storz biometer incorporating the SRK formula was used to calculate IOL power, P (D), required for the desired post-operative refraction:²⁰

$$P = A - 2.50L - 0.90K \quad (1)$$

where A was the A-constant for a particular IOL and/or manufacturer, L (mm) was the measured axial length, and K (D) the average Bausch and Lomb keratometer nominal dioptric power. Further modifications to equation (1) were made for $L < 22$ mm or $L > 24.5$ mm and where ametropia was planned, in accordance with the SRKII formula.²⁰ The IOL implanted for each subject was as close as possible to the desired optical power, within the limits of availability (± 0.50 D). The desired post-operative equivalent spherical ametropia ranged from -1.3 to $+5.4$ D. Two types of IOLs were implanted, both manufactured by the same manufacturer: a foldable acrylic IOL or a rigid PMMA IOL.

The foldable IOL was the Alcon Acrysof model MA60BM, which consisted of a 6.0 mm, bi-convex, acrylic optic and modified-C monofilament PMMA haptic. Model MA60BM had an overall IOL length of 13 mm, a suggested A-constant of 118.8 and was available in powers from $+10$ to $+30$ D in 0.50 D steps. The rigid IOL was the Alcon model LX10BD, which consisted of a one-piece bi-convex PMMA design. Model LX10BD had an overall length of 12 mm, with a 5.25 mm optic, a suggested A-constant of 118.7 and was available in powers from $+10$ to $+30$ D in 0.50 D steps.

All subjects with cataract received monocular phacoemulsification cataract extraction and IOL implantation by one surgeon (W.W.) conducted at the Southern General Hospital, Glasgow. The scleral incision was either 5.5 or 4.0 mm in length depending on whether the IOL to be implanted was rigid or foldable, respectively. The IOL was implanted in the capsular bag of each subject and the incision was either sealed with one 10° nylon cross-over suture or left to self-seal. Once the pseudophakic patient had been discharged from the Southern General Hospital Ophthalmology Department, typically following the 1 month routine post-operative examination by the consulting surgeon (W.W.), vision measurements of the best corrected Snellen visual acuity

and CS were conducted using the post-operative refractive error measured to threshold. This was usually at between 1 and 2 months post-operatively.

This post-operative period was chosen since most patients were discharged from the Southern General Hospital after their 1 month post-operative visit if ocular status was stable. Each patient was advised during this visit to attend for an eye examination with their favoured optometrist for a change in spectacle lenses as required. Although the interval between cataract surgery and the appearance of PCO varies considerably, McDonnell *et al.*²¹ have reported that PCO usually does not occur until at least 3 months post-operatively, with about 50% of IOL implant patients developing PCO within 5 years. Since we were interested in the visual outcomes of the surgery unhindered by PCO, the chosen post-operative period should have been a relatively stable period in which eyes had recovered sufficiently from the effects of the surgery and were unlikely to have developed PCO.

Refractive error in the typical sphere, cylinder and axis format is not suitable for relatively simple statistical analyses. Hence we used the Fourier analysis technique described by Thibos *et al.*²² to examine the post-operative refractive error. The three parameters of the spherocylindrical lens can be expressed by a spherical lens of power M , and two Jackson cross-cylinders, one at an axis of 0° with power J_0 , and the other at an axis of 45° with power J_{45} . The 'power vector'²² which joins the point (M_i, J_{0i}, J_{45i}) in this three-dimensional dioptric space to the origin is a complete description of the spherocylindrical lens. In this dioptric space, conventional statistical methods can be used to evaluate differences between groups. Although the conventional polar plot of cylinder power and axis is no more informative, to aid the reader unfamiliar with the vector form (J_0 and J_{45}), we also present the cylindrical correction information in the polar format. As M is the equivalent sphere (sphere + cylinder/2), comparison with the calculated IOL power, P , and desired refractive error was simple. Residual refractive error was defined as the spherical equivalent difference between the post-operative and desired refractive errors.

Astigmatic error is affected by corneal shape, hence corneal shape changes due to the surgery can induce astigmatism.³⁻¹⁰ Since cataract can induce astigmatism, it was not possible to ascertain the presence of surgically induced astigmatism from a difference between pre-operative and post-operative refractive error. However, if there was induced corneal distortion, a difference between post-operative astigmatism of the pseudophakes and the astigmatism of the control group would be expected. All incisions were centred at 110° , irrespective of whether they were right or left eyes (i.e. incision approximately from 130° to 90° or 125° to 95° for small-incision or micro-incision respectively). Therefore, if the surgical procedure had a steepening or flattening effect, the mean power vector of the IOL groups would be expected to have a different orientation and magnitude from that of the control group.

For vision measurement all subjects wore the appropriate optical correction (as determined from the post-operative refractive error) adjusted for the viewing distance. Visual acuity was measured, to threshold, at 6 m using an internally lit ($756.0 \pm 80.8 \text{ cd/m}^2$) Snellen chart. Although visual acuity measured using a Bailey-Lovie chart would have been more precise,²³ the pre-assessment of the subjects with cataract and part of the post-operative assessment were conducted in a hospital environment where a Snellen chart was the standard.

CS was measured using a computer-based system with a Cambridge VSG2/3 board and an EIZO monitor (Flexscan T560i-T) which displayed sine-wave gratings of 2, 4, 8, 16 and 28 cycles/degree with a mean luminance of $53 \pm 4 \text{ cd/m}^2$. The stimulus was circular, subtending 1° at the eye, and was viewed at 2 m in all cases. Following a practice session, subjects responded to a spatial, two alternate forced choice presentation by indicating on which side of the monitor, left or right, the stimulus was presented. Stimuli were randomly interleaved, with contrast determined by a staircase algorithm. Threshold contrast was defined as the mean of the log contrast at each reversal within the 30 presentations per spatial frequency.

As Snellen visual acuity has unequal intervals and the level of difficulty varies with each line of the chart, non-parametric statistics appropriate for ordinal data were used (Mann-Whitney U -test, Kruskal-Wallis one-way analysis of variance). CS data were approximately normally distributed and hence parametric statistics were appropriate (repeated measures analysis of variance: ANOVA). Where refractive correction data were not normally distributed, non-parametric statistics were applied. Though mean age was not significantly different between the three groups (Kruskal-Wallis, $p = 0.09$), since vision varies with age, age was included

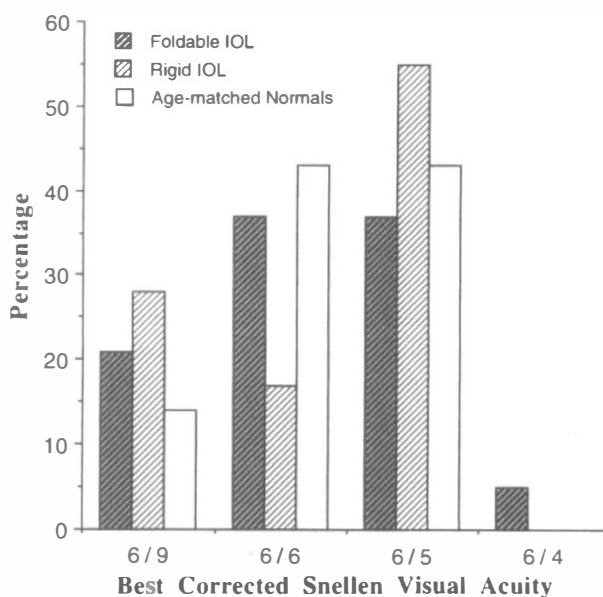


Fig. 1. There was no significant difference in Snellen visual acuity between the three groups (Kruskal-Wallis, $p = 0.61$).

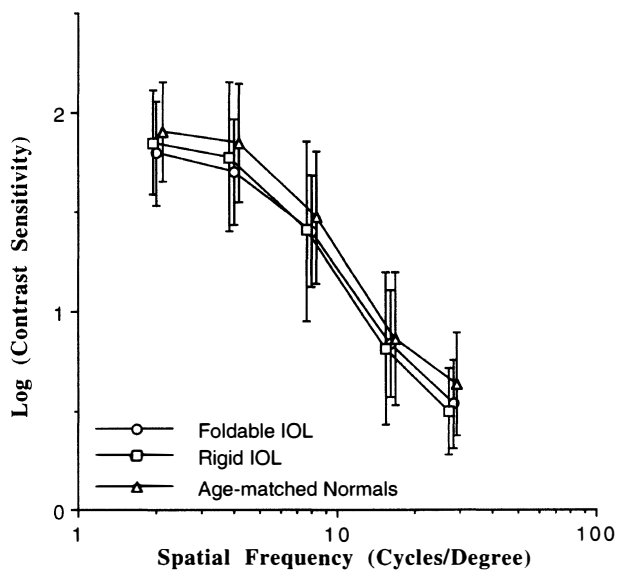


Fig. 2. There was no significant difference in contrast sensitivity between the three groups (ANOVA, $p = 0.33$). The spatial frequencies of points have been staggered to show the error bars (standard deviation) more clearly.

where possible as a co-variate in analyses. A probability level of $\alpha < 0.01$ was accepted as significant for all analyses.

Results

During surgery all subjects with rigid IOLs were sutured as described. In addition, 15 subjects with foldable IOLs were sutured during surgery as deemed necessary by the operating surgeon (W.W.) for ocular health and safety. These 15 subjects had slightly worse best corrected Snellen visual acuity than the remaining 23 subjects with foldable IOLs who had no suture. This finding was not significant at the 99% level of probability (Mann–Whitney U , $p = 0.02$). Further, the CS of this foldable IOL with-suture group appeared lower than that of the foldable IOL no-suture group (Fig. 2), although there was a lack of statistical significance (ANOVA, $p = 0.09$) to support this claim. Consequently we pooled all subjects with foldable IOLs as one group of subsequent analyses.

All pseudophakes had a Snellen visual acuity of 6/9 or better (Fig. 1). There was no significant difference in Snellen visual acuity (Kruskal–Wallis test, $p = 0.61$) and no significant difference in contrast sensitivity (ANOVA, $p = 0.33$) between the foldable IOL, rigid IOL and control groups.

Most pseudophakes implanted with the foldable IOL had a post-operative refractive error more hypermetropic than the desired refractive error (Table 1). The average

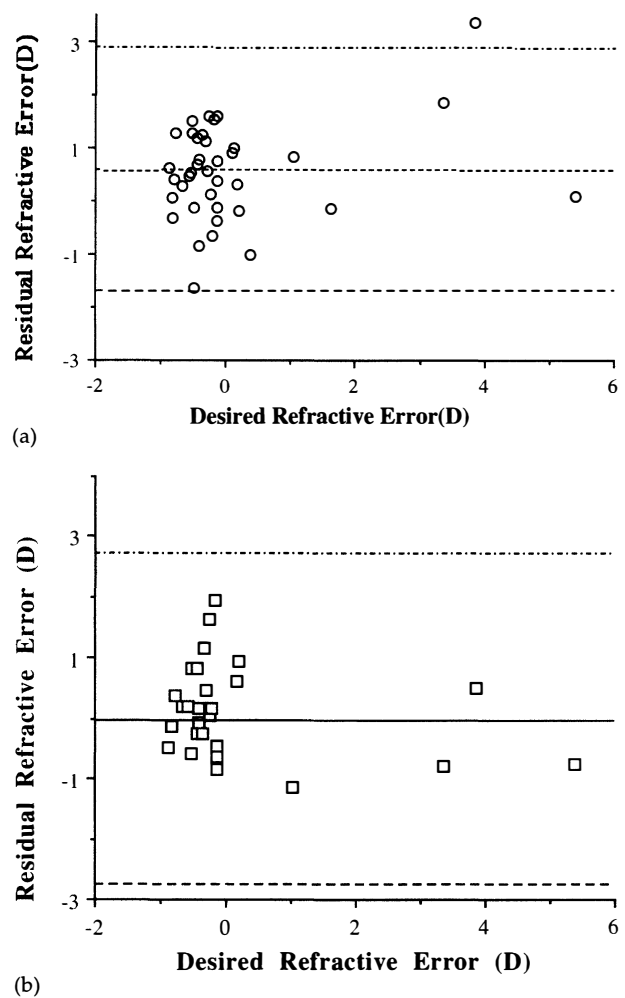


Fig. 3. Mean residual refractive error of the acrylic foldable IOL group was more hypermetropic than that of the rigid IOL group (Mann–Whitney U , $p = 0.02$) but not significant at the 99% level of probability. The ability to achieve the desired post-operative refractive error, as described by the limits of agreement (99% confidence limits) of the residual refractive error, was slightly, but not significantly, better for (a) the acrylic foldable IOL group than (b) the rigid PMMA IOL group. Residual refractive error did not vary with the power of the desired post-operative refractive error for either group.

residual refractive error of pseudophakes implanted with foldable IOLs ($+0.56 \pm 0.93$ D) was greater than that of those implanted with rigid IOLs (-0.03 ± 1.06 D), although this was not significant at the 99% level of probability (Mann–Whitney U , $p = 0.02$). Given the more hypermetropic residual refractive errors of the foldable IOL groups it is not surprising that fewer subjects in the foldable IOL groups (62%) had a residual refractive error within the range ± 1.00 D than for the rigid IOL group (82%). Overall 72% of pseudophakes had a residual refractive error within the range ± 1.00 D. There was no

Table 1. Means, standard deviation and range of values for the two groups of pseudophakes and the group of age-matched normals

	Foldable IOL		Rigid IOL		Age-matched normals	
	Mean \pm SD	Range	Mean \pm SD	Range	Mean \pm SD	Range
Age (years)	74 \pm 9	50 to 89	70 \pm 9	53 to 87	69 \pm 6	58 to 81
Desired refractive error (D)	0.1 \pm 1.3	-0.9 to 5.4	-0.4 \pm 0.6	-1.3 to 1.7	N/A	N/A
Post-operative refractive error (D)	0.6 \pm 1.8	-2.1 to 7.3	-0.4 \pm 1.2	-4.1 to 1.9	N/A	N/A
Residual refractive error (D)	0.6 \pm 0.9	-1.6 to 3.4	-0.03 \pm 1.1	-4.0 to 1.9	N/A	N/A

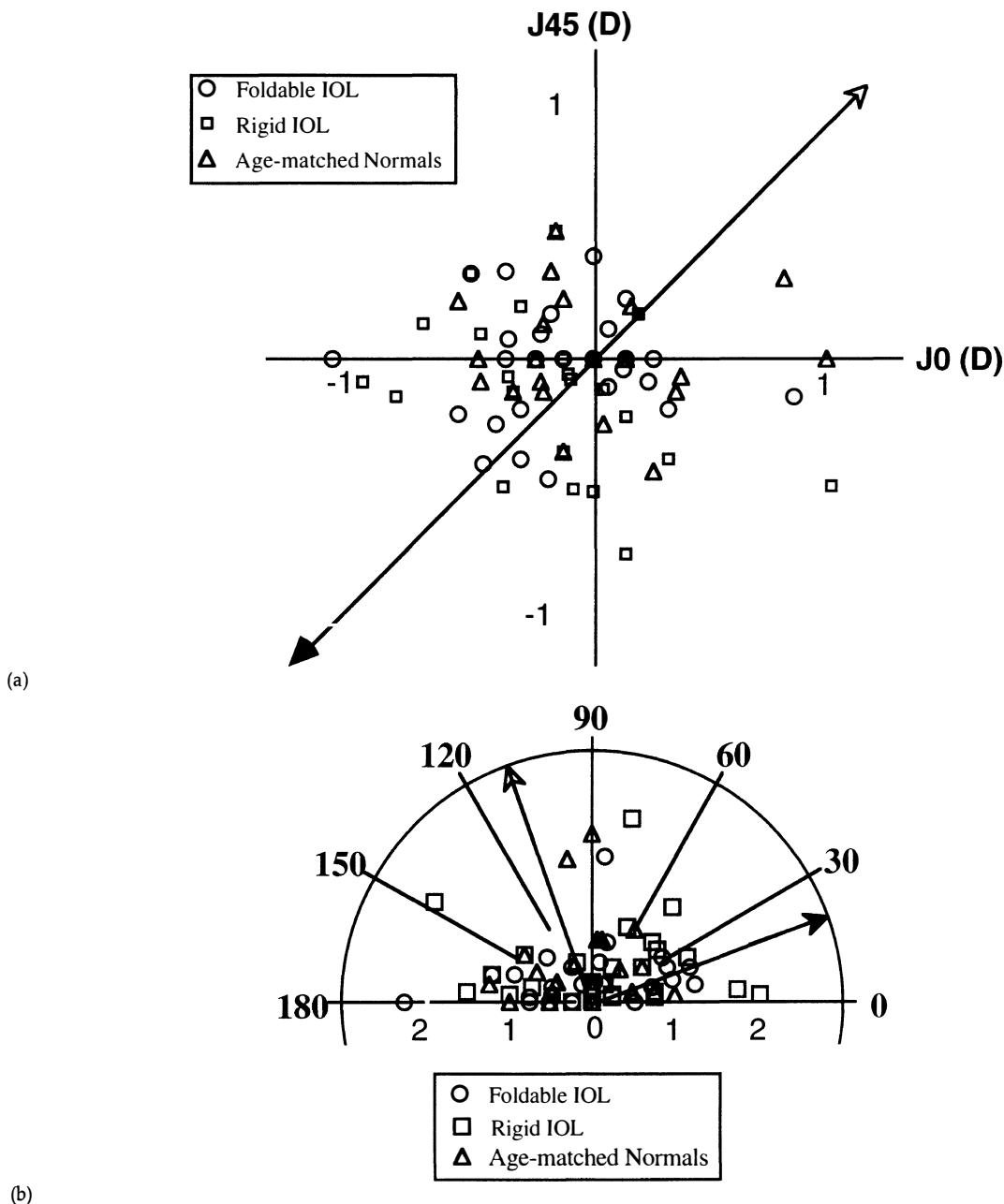


Fig. 4. (a) Fourier cylindrical components²² of the refractive corrections of the three groups. The surgical incision was centred at 110°. For induced astigmatism, the expected mean power vector would lie in the direction of the two arrows (unfilled arrow, 'steepening' effect; filled arrow, 'flattening' effect), if corrected using a negative cylinder. The magnitude of the mean power vector for the age-matched group was found to be not significantly different from zero (t-test, $p > 0.5$). The magnitudes of the mean power vectors for the two pseudophakic groups were found to be not significantly different from that of the age-matched mean power vector (t-test, $p > 0.5$). (b) Polar plot of the positive cylinders and axes. The arrows indicate the direction of the mean power vector transformed to the positive cylinder form if there had been any induced astigmatism (unfilled arrow, 'steepening' effect; filled arrow, 'flattening' effect).

significant correlation between the desired and residual refractive errors for any group of pseudophakes (Fig. 3). The 99% limits of agreement, as described by Bland and Altman²⁴ and shown in Fig. 3, were ± 2.30 (range 2.90 to -1.70 D) for the foldable IOL group, and ± 2.74 D (range 2.71 to -2.77 D) for the rigid IOL group. There was no significant difference in the limits of agreement between the two groups ($F = 1.4$, $p > 0.10$).

Residual refractive error is a function of the A-constant of the SRK equation (equation 1). As the average residual refractive error of the foldable IOL groups was significantly greater than zero, the

A-constant for the foldable IOL was not correct.

Modification of the A-constant for the individual surgeon (a 'personal' A-constant) has been recommended by Retzlaff *et al.*²⁰ We had used A-constants recommended by the manufacturer. The A-constant appears to have been correct for the rigid IOL, which is reflected in the greater proportion of subjects with the rigid IOL having a post-operative refractive error within ± 1.00 D.

The relationship between the post-operative J_0 and J_{45} astigmatic components²² of the power vector is illustrated in Fig. 4a. Fig. 4b shows the same data plotted in the conventional polar (positive cylinder) form. There

was no difference in astigmatism (J_0 and J_{45}) between the foldable IOL and control groups. The rigid IOL group had a slightly more negative J_0 component than the other groups (ANOVA, $p = 0.01$). The mean vector length (0.03 D) for the age-matched group was found to be not significantly different from zero (t -test, $p > 0.5$). As the mean power vectors of the rigid and foldable IOL groups (0.17 D and 0.13 D respectively) were not significantly different from zero or from the control group (t -test, $p > 0.5$), there was no significant surgically induced astigmatism.

Discussion

All subjects had a best corrected Snellen visual acuity of 6/9 or better, a result similar to previous reports.^{9,14,25} Apart from the report by Kohnen *et al.*¹⁴ we are not aware of any other study comparing acrylic foldable and rigid PMMA IOLs. Low-contrast visual acuity is typically 0.2–0.3 LogMAR units (2 to 3 lines on a Bailey-Lovie chart) lower than high-contrast visual acuity, and therefore measures vision at slightly lower spatial frequencies. Kohnen *et al.*¹⁴ found no difference in low-contrast visual acuity between the IOL types – a result confirmed and extended by our CS measurements at spatial frequencies of 2–28 cycles/degree.

Residual spherical refractive error is an indication of the accuracy of prediction of the appropriate IOL power. The SRK formula (equation 1) and its modifications (SRKII)²⁰ were used to predict the IOL power required for each eye. These formulae were reasonable predictors of the IOL power required for the desired refractive error (99% confidence limits between ± 2.30 D and ± 2.74 D). While these limits of agreement, a measure of the predictability of the refractive outcome, were smaller (i.e. better) with the foldable IOL than the rigid IOL (Fig. 3), this difference was not statistically significant. Similarly, as no significant induced astigmatism was found, it appears that both small-incision and micro-incision surgery caused minimal post-operative astigmatism.

Optimal IOL surgery would not reduce the optical quality of the eye. Post-operative vision is an indirect measure of the optical quality of the eye. As there was no difference in visual acuity or contrast sensitivity between the foldable IOL, rigid IOL and control groups, and no apparent corneal distortion, we conclude that both small-incision and micro-incision implantation surgery can achieve this goal. Therefore, there was no apparent visual benefit of implanting an acrylic foldable IOL using micro-incision surgery over implanting a rigid PMMA IOL using small-incision surgery.

If there is no benefit to micro-incision surgery and foldable IOLs, implantation of the more expensive foldable IOL may be an unnecessary expense. However, visual and refractive outcomes may not be the only important measures of cost-effectiveness. Although long-term post-operative complications were not considered for this report, possible long-term benefits of acrylic IOLs have been suggested by recent reports.^{26,27} If acrylic foldable IOLs cause fewer post-operative complications

(e.g. PCO) and require less post-surgical care they may be cost-effective. Until these reports are confirmed by further, independent studies, it would appear more economical to implant the conventional rigid PMMA IOL using small-incision surgery, as we have found no additional visual benefits from implanting an acrylic foldable IOL using micro-incision surgery.

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