A Prospective, Randomized, Double-masked Comparison of a Zonal–Progressive Multifocal Intraocular Lens and a Monofocal Intraocular Lens

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Introduction: Multifocal intraocular lenses (IOLs) have been designed to provide improved near visual acuity without spectacles compared with monofocal IOLs. Early studies have reported variable amounts of decreased visual acuity and contrast sensitivity with multifocal IOLs, and some patients have experienced halos and glare.

Methods: The authors performed a prospective, double-masked, multicenter evaluation of 62 patients randomized between a new zonal–progressive optic multifocal IOL and a monofocal IOL.

Results: Mean postoperative spherical equivalent, astigmatism, and uncorrected and best-corrected distance visual acuity were similar between the two groups. Patients with a multifocal IOL achieved significantly better uncorrected near visual acuity than patients with monofocal IOLs (J3+ versus J7; $P < 0.0001$). With distance correction only, mean near visual acuity was J2 versus J5– ($P = 0.0001$). Best-corrected near visual acuity was J1 for both groups, with 1.36 diopters (D) for the multifocal group versus 2.37 D for the monofocal group ($P < 0.0001$). Regan contrast sensitivity was lower for the multifocal patients at all contrast levels, and achieved statistical significance at very low contrast (11% contrast; $P = 0.0024$). Fifty-two percent of patients with a multifocal IOL reported that they did not need spectacles at all or used them only for their fellow eye, compared with 25% of the patients with monofocal IOLs.

Conclusion: Both monofocal and multifocal implant patients were very satisfied with the results of their cataract extraction and IOL implant surgery. A small loss of contrast sensitivity with the multifocal IOL was demonstrated, consistent with theoretical predictions. The functional significance of the loss of contrast sensitivity appears to be small and counterbalanced by the advantage of improved uncorrected near visual acuity.

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Maximal visual rehabilitation of a pseudophakic patient should mimic the optical performance of the normal human crystalline lens. Current intraocular lens (IOL) implant technology does not allow an implanted lens prosthesis to vary its focus with a mechanism similar to the pre-presbyopic crystalline lens. Efforts to achieve pseudoaccommodation in pseudophakic patients have concentrated on optimizing visual function in the final refractive error (compound myopic astigmatism),[1,2] unilateral myopia ("monovision"),[3] and the implantation of bifocal or multifocal IOLs.[4–7]

Bifocal and multifocal IOL evaluations have included optical bench studies[8–10] and objective and subjective clinical measurements.[4–7,11] Improvement in uncorrected near visual acuity is achieved with these lenses, but variable amounts of loss of clarity, contrast sensitivity, and complaints of halos and glare have been reported.[6,7,12,13] Evaluation of the clinical function and patient satisfaction rates in these studies has been hampered by the lack of adequate control groups, particularly in view of the varying but ill-defined candidate selection criteria by investigating surgeons and the differing expectations of patients receiving these investigational IOLs.

The Allergan Medical Optics Array (Allergan, Irvine, CA) intraocular lens uses concentric zones of progressive aspheric surfaces to provide repeatable power distributions. The design is termed *zonal progressive.* A goal of this design is to achieve functionally useful pseudoaccommodation while minimizing clinically significant degradation of visual function compared with conventional monofocal IOLs.

We designed a prospective, randomized, multicenter, double-masked trial in an effort to accurately assess the subjective and objective performance of the Array multifocal intraocular lens. Both the patient and the ophthalmic technical staff performing postoperative measurements were masked regarding the type of IOL implant. This study was designed to allow appropriate risk and benefit comparisons of multifocal and monofocal IOL rehabilitation. We also examined the correlation between objective data and subjective patient evaluations to determine the clinical significance of differences, if any, in visual acuity at distance and near, pseudoaccommodative characteristics of the lens in providing continuous imaging from far to near, contrast sensitivity, glare, and subjective optical aberrations.

Materials and Methods

Patients scheduled to undergo routine phacoemulsification with implantation of a posterior chamber IOL were randomized into one of two groups. Group I patients were implanted with the AMO Array MPC-25NB multifocal IOL. Patients in group II were implanted with the AMO PC-25NB monofocal IOL. As shown in Figure 1, these two IOLs are structurally identical, differing only in the optic. The Array optic is designed with 5 annular refractive zones incorporated into a 4.7-mm diameter of the anterior surface. Each zone contains a family of continuous curves with a 3.5 D range. The far (distance) power is predominantly located centrally in a 2.1-mm diameter zone. The near power is predominantly maximal within zone diameters of 2.1 to 3.4 mm and 3.9 to 4.5 mm (Fig 1B). The lenses supplied in this study were available only in 1.0-D increments. The lenses were centrally encoded and labeled such that the patient record did not indicate which IOL was implanted. Both the patient and the ophthalmic technical staff performing objective measures were masked regarding the identity of the implant.

Patients with no known noncataract ocular pathologies and with functionally disabling cataracts were enrolled based on criteria of potential acuity of 20/25 or better, preoperative cylinder of 1.5 D or less, axial myopia less than 26 mm, phakic fellow eye, and informed consent to participate in a randomized study. Before giving consent, patients were told that they would not know which lens they had received until 1 year after surgery. To provide balance in groups at each of the 10 sites, a randomized block design was used. Patient demographics, shown in Table 1, indicate comparable parameters except for gender difference (significant at $P = 0.033$).

Of 80 eligible patients, 32 group I patients and 30 group II patients were available for 3- to 6-month follow-up examinations as of data base closure. Two patients had died, 1 had moved and could not be located, and the remainder missed their 3-month follow-up appointments (6 group I patients, 9 group II patients).

A variety of measurement parameters was used to compare performance of these lenses at the 3-month postoperative evaluation. First, defocus testing predicted how patients would see, with distance correction in place, from far through intermediate to near ranges of distance. This test first determined the patient's best-corrected distance vision, then subsequently defocused the patient in 0.25- to 1.0-D increments (up to 6.0 D in both directions). Distance visual acuity was recorded at each defocus point.

Uncorrected distance and near visual acuities were assessed to compare how well patients would see without correction. Keratometric and refractive cylinder values were compared to determine the sensitivity to astigmatism. In addition, spherical equivalent readings were compared to determine the effectiveness of current IOL power calculations.

Testing of near acuity also included vision at the patient's preferred distance with best distance correction in place and acuity at 35 cm with any additional correction needed. We also measured this additional power required to achieve best near visual acuity at 35 cm.

Corrected distance acuities were measured to determine the best distance vision possible. Corrected vision also was tested at varied contrast levels to simulate viewing objects at different levels of contrast, and at varied glare levels to simulate actual conditions where diminished or suboptimal lighting exists, as in driving at night or in bright sunlight.

A self-administered patient questionnaire was given to all patients to determine their satisfaction with their vision and to evaluate their impressions of vision in different environmental situations. Patients also were asked to describe if and why they used spectacles for any task.

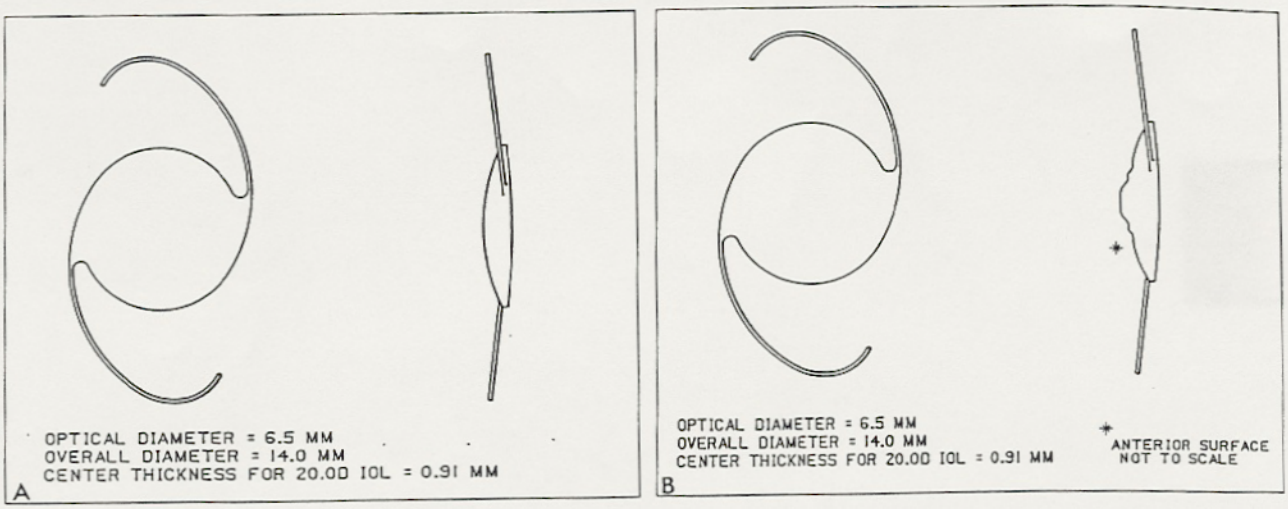

Figure 1. Schematic representations of the IOLs used in the study. A, all polymethylmethacrylate monofocal posterior chamber IOL. B, identically configured lens except for zonal-progressive multifocal optic (note that the optic contour is greatly exaggerated in drawing for clarity).

Regan contrast acuity charts[14] were used for all distance acuity measurements. The 96% contrast chart was used for defocus testing, uncorrected and corrected distance acuities, and glare testing. The 50%, 25%, and 11% charts were used for contrast comparisons. The Brightness Acuity Tester[15] was used as the light source for glare testing. To standardize testing, the Regan line values obtained were normalized to a standard 10 foot test distance. The mean of these values was then determined and also converted to a Snellen line equivalent. For most measurements, patients read at least one letter on the chart. However, for the outer limits of defocus testing (< -3 D and $\geq +3$ D for group I; < -2 D and $\geq +3$ D for group II), some patients were unable to read the charts. For these patients, the Regan score used was 0 (if measured at 10 feet) or -1 (if measured at 8 feet). Regan-type contrast charts are not available for near vision testing.

Rosenbaum near acuity cards were used for all near acuity measurements. Near acuity cards were illuminated by a 40-watt bulb with overhead lights off. The standard test distance for these cards is 35 cm. Jaeger values were adjusted for the test distance used. Geometric mean visual acuity scores were determined according to the method described by Holladay and Prager.[16]

Comparisons between lens groups for distance visual acuities, spherical equivalents, cylinder, and age were performed using two-sided two-sample t tests. For questionnaire data and near visual acuities, comparisons were made using the Mann–Whitney U test. With 30 patients per group, a statistical power of 0.80, and a significance level of 0.05, this study had sufficient power to detect a difference between distance visual acuity scores of 1.25 lines or more.

Results

Figure 2 summarizes defocus test results in terms of mean Regan scores at each point of defocus from the distance point. Using a visual acuity threshold value of Regan line 3.75 (Snellen equivalent of 20/50) the depth of focus around the distance image was comparable for the two groups. However, the range of focus for the multifocal group extended into the near distance region to provide a total range of 4.75 D where the vision attained was 20/50− or better. This range was substantially larger than in the monofocal group, for which the range where visual acuity was 20/50− or better was 2.75 D.

Table 2 gives mean values for uncorrected visual acuity. These were comparable for the groups, averaging 6.33 Regan lines (±1.73) for multifocal patients versus 6.37 lines (±1.93) for monofocal patients. Stratification of these data (Table 3) shows that 78% of multifocal patients achieved unaided acuities of 20/40 or better, compared with 90% of monofocal patients. Some patients whose vision was worse than 20/40 had cylinder greater than 1 D (n = 4 in group I, n = 2 in group II) and/or posterior capsular haze (n = 3 in group I).

Also shown in Table 2 are mean values for near uncorrected acuity. In conjunction with the trend portrayed in Figure 2, mean uncorrected near acuities were measured as J3+ for group I and J7 for group II. This difference was significant ($P < 0.0001$).

Table 1. Patient Demographics

	Group I (Multifocal)	Group II (Monofocal)
Number of patients	32	30
Mean follow-up (days)	121	129
Mean age (yrs)	71.7	71.4
Sex	22 F/18 M	31 F/9 M
Mean potential acuity	20/23	20/23
Mean preoperative keratometric cylinder (standard deviation)	0.55 D (0.32 D)	0.58 D (0.38 D)

D = diopters.

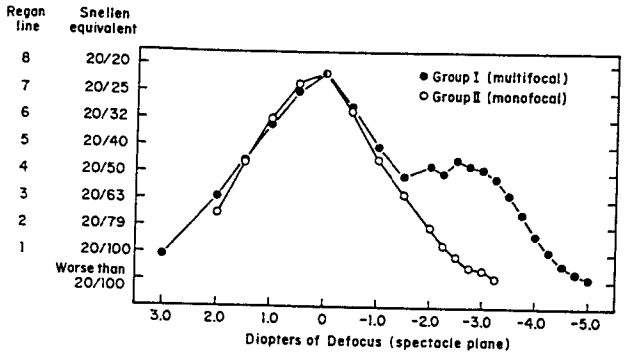

Figure 2. Graph of distance visual acuity with defocus of the patient from emmetropia. The two lenses show identical depth-of-field around emmetropia. The multifocal optic retains useful resolution into the near range through 3 diopters.

Table 3, which stratifies distance visual acuity, shows that 88% of patients in the multifocal group I achieved a corrected visual acuity of 20/25 or better compared with 90% of monofocal patients. All patients achieved corrected visual acuity of 20/40 or better. Examination of mean scores for best distance acuities (Table 4) indicates the groups were not significantly different. Note, however, that 14 monofocal IOL patients achieved best-corrected distance acuities better than the Snellen equivalent of 20/20, compared with 8 multifocal IOL patients.

Testing of near visual acuity is summarized in Table 5. Compared with their uncorrected acuities (Table 2), near vision improved for both groups with the distance correction in place. The multifocal patients achieved a mean value of J2 (from J3+ uncorrected) and the monofocal patients improved from J7 to J5− (group I versus group II; $P = 0.0001$). In both groups, the best-corrected near vision achieved was J1. However, the additional correction required to achieve this level of vision was 1.36 D (±1.17) for the multifocal group versus 2.37 D (±0.52) for the monofocal group. This difference was significant ($P < 0.0001$).

Table 3. Distance Visual Acuity

Regan Score	Mean Snellen Equivalent	Group I (Multifocal) scVA (n)	Group I (Multifocal) ccVA (n)	Group II (Monofocal) scVA (n)	Group II (Monofocal) ccVA (n)
9.50–11.00	20/12.5	2	4	1	3
8.50–9.49	20/16	2	4	4	11
7.50–8.49	20/20	2	12	3	7
6.50–7.49	20/25	12	8	8	6
5.50–6.49	20/32	4	3	6	2
4.50–5.49	20/40	3	1	5	1
3.50–4.49	20/50	7	0	1	0
2.50–3.49	20/63	0	0	1	0
<2.50	>20/71	0	0	1	0

Table 6 stratifies best near acuity achieved with additional correction in place. As shown, 40% of multifocal patients achieved J1+ (versus 14% for monofocal), and 93% were J2 or better (versus 97% of monofocal). The one patient who had J5 reading acuity also had macular edema. However, at the patient's next visit, the vision was reported to have improved to J2.

Table 7 provides mean values for postoperative keratometric cylinder, refractive cylinder, and spherical equivalent. These results were not significantly different between lens groups.

Table 4 summarizes the impact of decreased contrast and increased glare conditions on best-corrected vision. At the higher contrast levels of 96%, 50%, and 25%, there was an approximately one-half line difference in visual acuity between the monofocal and multifocal groups. This difference did not achieve statistical significance, not unexpected given the power of this relatively small study. As shown, the only statistically significant difference found between the two groups was at the 11% contrast level

Table 2. Uncorrected Distance and Near Acuities

	Group I (Multifocal)	Group II (Monofocal)
Mean Distance VA		
Regan line	6.33	6.37
Standard deviation	1.73	1.93
Snellen equivalent	20/30	20/29
Mean Near VA		
Jaeger line*	J3+	J7
Mean test distance (SD)	36.4 cm (±6.2 cm)	36.1 cm (±7.5 cm)
Snellen equivalent (SD)	20/36 (±2.1 lines)	20/74 (±2.6 lines)

VA = visual acuity; SD = standard deviation.
* Values adjusted for test distance.

Table 4. Corrected Distance Visual Acuity with Varied Contrast and Glare

Condition	Group I (Multifocal) Mean Regan Line (SD)	Group I (Multifocal) Snellen Equivalent	Group II (Monofocal) Mean Regan Line (SD)	Group II (Monofocal) Snellen Equivalent
96% Contrast	7.67 (1.25)	20/22	8.19 (1.49)	20/19
50% Contrast	6.53 (1.79)	20/28	7.22 (1.82)	20/24
25% Contrast	5.59 (1.90)	20/35	6.20 (1.53)	20/30
11% Contrast*	2.59 (2.01)	20/70	4.37 (2.05)	20/46
Glare low	7.05 (1.59)	20/25	7.43 (1.99)	20/23
Glare medium	6.81 (1.63)	20/26	7.24 (1.76)	20/24
Glare high	5.67 (2.23)	20/34	6.42 (2.43)	20/29

SD = standard deviation.
* Difference significant with $P = 0.0024$.

Table 5. Corrected Vision with Near Acuity Cards

	Group I (Multifocal)		Group II (Monofocal)		
	Jaeger Line	*Snellen Equivalent*	*Jaeger Line*	*Snellen Equivalent*	
Mean VA with distance correction at best distance (SD)	J2	20/31 (±1.7 lines)	J5-	20/58 (±2.5 lines)	$P = 0.0001$
Mean distance (SD)		36.7 cm (±4.9)		38.5 cm (±7.0)	
Mean best ccVA with additional correction (SD)	J1	20/25 (±1.0 lines)	J1	20/26 (±0.7 lines)	
Mean additional power required (SD)		1.36 D (±1.17)		2.37 D (±0.52)	$P < 0.0001$

VA = visual acuity; SD = standard deviation; D = diopters.

($P = 0.0024$). Mean Regan scores at this level of contrast were 2.59 lines ±2.01 (Snellen equivalent = 20/70) for the multifocal group and 4.37 lines ±2.05 (Snellen equivalent = 20/46) for the monofocal group. Figure 3 portrays the threshold contrast at visual acuity levels for both lens groups.

Table 8 reports the frequency and reason for postoperative spectacle use. Fifty-two percent of group I patients reported they did not need spectacles or needed them only for their fellow eye, compared with 25% of group II patients. Other responses included spectacle usage out of habit (10% in group I versus 7% in group II), spectacle usage for operative or both eyes (32% in group I versus 50% in group II), and other or unknown.

Additional data from the patient questionnaire are provided in Table 9. Patients in both groups responded with similar satisfaction ratings. In addition, when rating their vision in different environmental conditions such as glare and poor lighting, patients in both groups responded similarly. No clinically important differences were detected. Two patients in group I reported "unhappiness." One had uncorrected and best-corrected near visual acuity of J5. This was clinically attributed to macular degeneration. The other patient complained of glare. This was attributed to posterior capsular haze. A neodymium:YAG capsulotomy had not been performed within the study reporting interval. At the time of completing the questionnaire, the visual acuity in the patients' fellow eye was generally quite good (Table 10).

Mean pupillary size was comparable between the two groups. The mean ± standard deviation for each group was 3.38 ± 0.73 mm for group I and 3.33 ± 0.79 mm for group II. For the small number of patients with pupils less than 3 mm or greater than 4 mm, no trend toward different acuity, contrast, or glare values was seen. In the few patients with greater than 1 D of astigmatism (group I, n = 4; group II, n = 10) no trend toward different optical performance was discernible.

Table 6. Best-corrected Near Vision with Additional Power

	Group I (Multifocal) (n = 30)	Group II (Monofocal) (n = 29)
ccVA J1+	12	4
J1	9	17
J2	7	7
J3	1	1
J5	1	0

Discussion

In an evaluation of bifocal and multifocal IOLs, the fundamental concerns that need to be examined are: (1) the frequency of spectacle use for distance and near vision; (2) the quality of the retinal image; (3) measurable psychophysical performance degradation due to the modified optic; (4) the clinical significance of these measured differences; and (5) identification of patient characteristics predicting acceptance or displeasure with the bifocal/multifocal optics.

Table 7. Postoperative Keratometric Cylinder, Refractive Cylinder, and Spherical Equivalent

	Group I (Multifocal)		Group II (Monofocal)	
	Mean	*SD*	*Mean*	*SD*
Keratometric cylinder (D)	0.69	0.64	1.02	0.69
Refractive cylinder (D)	0.80	0.64	0.79	0.66
Spherical equivalent (D)	0.21	0.61	0.13	0.92

SD = standard deviation; D = diopters.

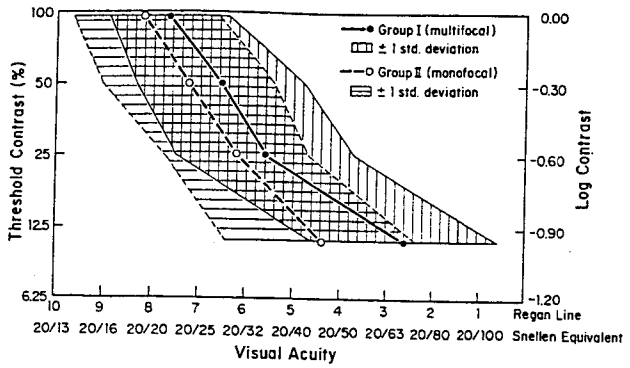

Figure 3. Threshold contrast (Regan charts) at visual acuity levels for the monofocal and multifocal IOLs. The shaded areas represent 1 standard deviation. The 2 curves become statistically significantly different at 11% contrast.

In this study, using prospective, randomized, and masked controls, 52% of patients reported that they did not require spectacles for the zonal–progressive multifocal IOL eye, compared with 25% of monofocal patients. The defocus curves shown in Figure 2 clearly demonstrate the additional lens power for near focus with the multifocal optic, while maintaining identical depth of focus at distance compared with the monofocal optic. This curve is quite comparable to the depth of focus of the normal phakic eye determined by Holladay et al.[17] In a study of the diffractive optic bifocal IOL, Gimbel et al[7] reported that 63% of their bifocal patients did not require spectacle correction, compared with only 4% for a group of retrospectively analyzed monofocal patients. In contrast, Percival[6] found that 54% of his diffractive optic bifocal patients reported the ability to read without glasses compared with 13% of monofocal IOL control patients analyzed retrospectively. The patients' residual spherical and myopic error and expectations will influence this outcome.

The far image quality was excellent for both multifocal and monofocal patients. The geometric mean visual acuity was 20/22 for multifocal patients and 20/19 for monofocal patients. All multifocal patients corrected to 20/40 or better, and 88% had best-corrected distance visual acuity of 20/25 or better. Percival,[6] Gimbel et al,[7] and Duffey[4] all reported comparably high levels of best-corrected distance acuity in their studies. However, more monofocal than multifocal patients achieved best-corrected distance acuity levels of 20/16 or better Snellen equivalent (14 patients versus 8 patients). In this small study, we cannot conclude whether this disparity is a true difference. At this level of extremely high resolution, such a difference is expected due to the inherent reduced contrast sensitivity of the multifocal optic.

The principal anticipated drawback for multifocal IOLs is loss of contrast sensitivity.[7–11] In our small study, at high and moderate levels of contrast as well as all glare levels, the data were similar and not statistically significantly different between groups. Individual patient variability, as indicated by the standard deviation, exceeded the mean differences between the groups. Nevertheless, mean values slightly but consistently favored the monofocal IOLs. At the more demanding 11% contrast level, the difference was greater and achieved statistical significance (20/70 for multifocals versus 20/46 for monofocals). Gimbel et al[7] also reported that the 11% Regan contrast acuity was lower for bifocal patients (20/48) than monofocal patients (20/36).

In clinical terms, Figure 3 shows that multifocal IOL patients require about 0.20 log units or about 30% more contrast to achieve the same acuity level as a monofocal IOL patient. At the same contrast level, the multifocal IOL patients lose an average of one-half lines of Snellen equivalent visual acuity. These differences are consistent with the laboratory measurements of Holladay et al.[10]

The patient satisfaction survey in this study did not demonstrate any perceived drawbacks attributable to contrast sensitivity. Scores for quality of vision at distance and near in different lighting conditions were comparable between multifocal and monofocal patients. Reported difficulty with glare, night vision, and light sensitivity were all comparable in our masked prospective trial, and overall patient satisfaction scores were similar. The defocus testing yielded a lower mean acuity at the simulated "near" distance compared with the Rosenbaum charts. This may be due, at least in part, to differences in vertex distance with the phoropter and the unfamiliarity and fatigue of the defocus methodology.

In making subjective judgments, a patient is inevitably assessing the outcome relative to an individual's theoretical "ideal," recollection of vision before the onset of cataract and presbyopia, and the fellow eye. In our study, the fellow eye was, in most cases, phakic, presbyopic, and only mildly cataractous.

In the study by Gimbel et al[7] of the diffractive optic lens, 14% of bifocal patients rated vision as fair to poor compared with 10% of monofocal patients. Halos, rings, flare, glare, and near and distant blurred vision were each reported significantly more often by their bifocal patients than by their monofocal patients. Percival[6] found that 75% of his diffractive optic bifocal patients were satisfied

Table 8. Postoperative Spectacle Usage Survey

What Visual Aid Do You Use to Improve Vision?	Group I (Multifocal) (n = 31)	Group II (Monofocal) (n = 28)
	Number	*Number*
None	9	3
Spectacles used for fellow eye	7	4
Spectacles used out of habit	3	2
Spectacles used for operative eye	2	1
Spectacles used for both eyes	8	13
Spectacles used—reason not provided	2	5

Table 9. Patient Survey Results

	Group I (Multifocal)	Group II (Monofocal)
	Mean (SD)	*Mean (SD)*
Rate Degree of Difficulty With:		
Glare/flare	2.21 (1.50)	2.04 (1.26)
Night vision	1.62 (1.15)	1.17 (1.15)
Light sensitivity	2.13 (1.61)	2.07 (1.33)
Ability to focus on distant objects	1.50 (1.08)	1.50 (1.23)
Ability to focus on near objects	1.93 (1.17)	2.14 (1.58)
Color perception	1.30 (1.12)	1.36 (1.16)
Depth perception	1.30 (0.75)	1.54 (1.32)
Rate Limitation of Vision With:		
Reading	1.90 (1.30)	1.70 (1.17)
Writing	1.37 (0.85)	1.33 (0.68)
Watching television	1.33 (0.92)	1.22 (0.51)
Driving	1.32 (0.86)	1.39 (0.89)
Playing cards/board games	1.23 (0.65)	1.21 (0.51)
Mobility	1.23 (0.63)	1.26 (0.53)
Food preparation	1.07 (0.26)	1.15 (0.36)
Shopping	1.14 (0.35)	1.33 (0.83)
Housekeeping	1.07 (0.26)	1.11 (0.32)
Recreational activities	1.25 (0.80)	1.26 (0.71)
Rate Quality of Near Vision:		
Indoors	1.50 (0.95)	1.54 (1.14)
Daytime outdoors	1.41 (0.88)	1.80 (1.38)
Night-time outdoors	1.56 (1.05)	1.67 (1.17)
Rate Quality of Far Vision:		
Indoors	1.41 (1.04)	1.33 (0.92)
Daytime outdoors	1.50 (1.22)	1.30 (0.91)
Night-time outdoors	1.59 (1.32)	1.32 (0.95)
How satisfied with Results of Surgery:	1.77 (1.36)	1.35 (0.80)

Patient response rated on a scale of 1 to 7, where a score of 1 indicated "no problem," "no limitation," or "very satisfied" and 7 indicated "major problem," "big limitation," or "not satisfied."

with the results of their surgery, compared with 87% of monofocal patients. Problems with near vision were higher for bifocal patients; for example, 21% of bifocal patients noted poor vision in dim light, compared with 4% of monofocal patients. Seventeen percent of his bifocal patients could not read J2 regardless of the reading spectacle power. In Ellingson's[12] series of diffractive optic IOLs, 12 of 14 bifocal patients reported "ghost images" at near. Three of his patients underwent explantation of the bifocal lens and implantation of a monofocal lens. After IOL exchange, measured visual acuity improved as did patient satisfaction and relief from monocular diplopia with the bifocal implant. In all of the earlier reports, a diffractive optic IOL was used, and the bifocal patients' expectations were potentially altered compared with the monofocal patients used as retrospective control groups.

The mean values for astigmatism and for spherical equivalent required were not different between the two groups. This demonstrates that the effectiveness of current IOL power calculation formulas is equivalent between these two groups. Previous multifocal and bifocal IOL designs have been associated with a concern that new, more precise formulas may be required, due to the narrower depth of focus around the distance region. The zonal–progressive optic in this study was designed to provide depth of focus around the distance image at least as large as that of a monofocal IOL.

This prospective, randomized, double-masked, multicenter study provided a methodology for meaningful comparisons between two IOL designs. A separate control group of patients implanted with a monofocal IOL, rather than a fellow eye control group, was chosen for several

Table 10. Visual Acuity of the Fellow Eye at the Time of Completing the Patient Questionnaire

	Group I (Multifocal) (n = 32)		Group II (Monofocal) (n = 30)	
	Regan Lines	*Snellen Equivalent*	*Regan Lines*	*Snellen Equivalent*
Mean score	6.52	20/28	6.91	20/26
Standard deviation	1.78	—	1.48	—
Range	2.43–10.89	20/72–20/10	4.75–9.41	20/42–20/15
Percent 20/16 or better		13%		17%
Percent 20/25 or better		50%		57%
Percent 20/40 or better		91%		100%

reasons. First, we wished to eliminate historical biases and to ensure that the eyes would be similar for known and unknown variables such as expectations, awareness, and test sensitivity during the postoperative period. Because differences in IOL performance were possible, this study was designed to avoid the potential for patient dissatisfaction arising from a preference for one IOL over another IOL. Finally, the study design was chosen to avoid any potential conflict in refraction with a monofocal implant in one eye and a multifocal implant in the other eye. Future decisions to implant a monofocal or multifocal design in the second eye could then be made based on the results of clinical data. The study demonstrates that the zonal–progressive aspheric multifocal IOL can provide a useful level of near visual acuity without spectacles and without demonstrable difference in subjective patient satisfaction compared with monofocal IOLs. The theoretical loss of contrast sensitivity inherent in the multifocal IOL concept was confirmed by contrast sensitivity testing. The measured difference in contrast sensitivity was not perceived as functionally significant by these monocularly implanted patients. Further experience with these implants in a larger number of patients is necessary to validate and expand on these findings, as well as to identify which preoperative patient characteristics correlate with postoperative satisfaction. The postoperative survey of these patients who had comparable preoperative expectations and who were masked regarding the identity of their implants demonstrated a high level of satisfaction with the outcome of their cataract and IOL surgery for patients with either monofocal or multifocal implanted lenses.

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Discussion
by
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Steinert et al have provided us with some very important clinical information regarding the performance of a multifocal intraocular lens. The design of this lens makes it virtually independent of pupil size. This study has documented the contrast sensitivity loss from multifocal lenses compared to similar monofocal lenses. In the Table below, I have summarized the findings and added the other studies by Gimbel et al,[1] Percival,[2] and Lindstrom (unpublished data; presented at 1991 AAO annual meeting). From this Table, it is apparent that the loss in the image contrast with the multifocal lenses results in slightly

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Table 1. Acuity Lines Decrease for Multifocal Intraocular Lenses at Different Contrasts Compared with Monofocal Intraocular Lenses

Investigator	96% Contrast	50% Contrast	25% Contrast	11% Contrast
Gimbel (20)	0.6	0.5	0.7	1.2
Percival (25)	0.7	0.7	1.1	2.1
Steinert (30)	0.5	0.7	0.6	1.8
Lindstrom (162)	0.8	1.1	1.2	1.4
Mean	0.7	0.8	0.9	1.6
Holladay (optical)	1.1	1.2	1.2	2.3

Clinical = 31% decrease contrast; optical = 42% decrease contrast.

less than a 1-line drop (0.7 line) in the best-corrected acuity using a high-contrast chart (96%). This acuity decrease becomes larger with lower contrast, resulting in a 1.6-line loss with the 11% contrast chart. These results are expected because of the 30% to 50% decrease in the contrast of the retinal image with multifocal lenses.[3–5]

These clinical values are slightly less than the values predicted in the optical laboratory.[5] The slight difference in the results are due to the monofocal lenses performing approximately 0.5 lines better with optical bench testing than in clinical studies. This finding indicates that, in the monofocal patient, something other than the IOL was limiting the patient's vision, such as the retina or cornea. The consistency of the values in the Table allows surgeons to quantitatively better inform patients about expectations.

The results of Steinert et al's patient survey must be interpreted with caution. They state that there were no significant differences in the quality of vision between the multifocal patients and the monofocal patients. Since all of these patients were phakic in the unoperated eye and averaged 72 years of age, it is probable that the unoperated eye also had a cataract, but to a lesser degree. The patients in both groups would be comparing their postoperative vision to the preoperative vision and/or to the vision in the unoperated, cataractous eye. Therefore, it is not surprising that responses from these two groups would be similar since all subjects should have had a substantial improvement in the quality of vision in the operated eye. The best experimental design would have been patients with a monofocal lens in one eye and a multifocal lens in the other. Questioning these patients would truly elicit any subjective differences.

Finally, it is clear from all of these studies that proper patient selection is the most important criteria for a successful result and a happy patient. Most of these patients are highly motivated not to wear glasses and are willing to accept a small compromise in contrast and the presence of rings, halos, or glare. To achieve the goal of no glasses, the surgeon must come very close to emmetropia with his IOL power calculation and have less than 1 diopter of postoperative astigmatism. When these results are achieved surgically and the patients are selected properly, success will equal monofocal lenses.[1]

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