
Cataract extraction with multifocal intraocular lens implantation: Clinical, functional, and quality-of-life outcomes

Multicenter clinical trial in Germany and Austria

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ABSTRACT

Purpose: To compare bilateral implantation of a multifocal intraocular lens (IOL) versus a monofocal lens with respect to visual function, patient satisfaction, and quality of life.

Setting: Seven clinical sites in Germany and 1 site in Austria.

Methods: A prospective randomized masked clinical trial included 124 randomly assigned bilateral pseudophakic individuals, 64 of whom had bilateral implantation of an Array® foldable multifocal IOL (model SA-40N, Allergan) and 60 of whom had bilateral implantation of an AMO®PhacoFlex II® silicone monofocal IOL (model SI-40NB). Clinical data included binocular uncorrected and corrected distance and near visual acuities, complications, adverse events, and reports of halos and glare. Quality-of-life data were collected on 3 occasions using the modified Cataract TyPE Specification instrument. The functional status of the 2 groups was compared from baseline to final postoperative interview.

Results: Three months after surgery, a higher proportion in the Array group achieved a Jaeger value of J3 (20/40 Snellen) or better uncorrected binocular near visual acuity and 0.5 (20/40) or better distance-corrected binocular near visual acuity than in the monofocal groups (97% versus 68% and 95% versus 59%, respectively; $P < .001$). A higher proportion in the multifocal group achieved both 0.5 (20/40) and J3 or better uncorrected binocular distance and near visual acuities (97% versus 66%; $P < .001$). Those in the Array group were more likely than those in the monofocal group to never wear glasses overall (41% versus 12%; $P < .001$). Multifocal patients rated their vision without glasses better overall, at near and at intermediate distances ($P < .05$), and demonstrated better visual function for near tasks and social activities.

Conclusions: Those who had bilateral implantation of the Array multifocal IOL obtained better uncorrected and distance-corrected near visual acuities and reported better overall vision, less limitation in visual function, and less spectacle dependency than patients with bilateral monofocal IOLs. *J Cataract Refract Surg* 2000; 26:1356–1366
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The Array[®], a zonal-progressive silicone multifocal intraocular lens (IOL), is the first multifocal IOL to be approved by the U.S. Food and Drug Administration. Essential to the ultimate acceptance of this or any new technology are the outcomes produced by that technology in terms of functional performance, patient satisfaction, and quality of life. We have reported the results of a retrospective study¹ that suggest that patients with a zonal-progressive multifocal IOL had better visual function and satisfaction than patients who received monofocal lenses of comparable design. However, as acknowledged in that report, retrospective studies are subject to well-known issues of bias and confounding.

We present the results of a multicenter randomized prospective clinical trial designed to test the following hypothesis: Patients who have cataract extraction with bilateral implantation of the Array multifocal IOL are likely to have better near visual acuity, improved visual function, and greater visual satisfaction than patients with standard-technology IOLs.

Patients and Methods

A prospective randomized masked clinical trial was conducted to compare eyes bilaterally implanted

with the zonal-progressive Array multifocal IOL (model SA-40N, Allergan) versus eyes bilaterally implanted with the AMO[®]PhacoFlex II[®] silicone monofocal IOL (model SI-40NB). The study was conducted between February 8, 1996, and March 10, 1997. Patients were enrolled from 7 investigational sites in Germany and 1 site in Austria. Inclusion criteria included all patients between the ages of 50 and 85 years and with bilateral cataracts, less than 1.50 diopters (D) of keratometric cylinder, 0.7 (20/30) or better potential visual acuity, and no indication of existing ocular pathology.

Enrollment and Consent

The study protocol was approved by the institutional review board or ethics committee of each participating institution. Enrollment and consent were conducted in accord with the Declaration of Helsinki. Prospective participants were offered the opportunity to be part of a clinical trial in which they would be randomly allocated to have cataract surgery with implantation of a standard monofocal IOL or a then-experimental multifocal IOL. The potential benefits of the multifocal lens included reduced spectacle dependence and improved uncorrected near visual acuity. The potential drawbacks of the multifocal lens included increased glare and halo. Prospects were told that the study anticipated, but did not require, bilateral surgery and that the same lens type would be implanted in both eyes. To protect patient safety, those randomly allocated to the multifocal lens group were asked after the first-eye surgery whether they wished to have the same lens type in the second eye, without being told what type that was.

The patients, ophthalmic technicians who collected clinical data, and interviewers who collected quality-of-life data were masked as to the type of IOL each patient received. Patients were followed from the initial preoperative examination until 3 months after surgery in the second eye.

A randomization schedule was prepared for each site using SAS software, with IOL groups assigned in blocks of 2. The number of patients in the monofocal and multifocal groups was not equal as a result of patients withdrawing from the study after having 1 IOL implantation, sites stopping ahead of schedule, and chance outcomes.

Accepted for publication January 14, 2000

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Presented in part at the Symposium on Cataract, IOL and Refractive Surgery, San Diego, California, USA, April 1998, and the XVIIth Congress of the European Society of Cataract & Refractive Surgeons, Nice, France, September 1998.

Funding by Allergan Surgical, Inc.

None of the authors has a financial or proprietary interest in any product or device mentioned.

Warner Fox Associates, Ltd., conducted patient interviews for the clinical study.

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Intervention and Assessment

All investigators performed cataract surgery using phacoemulsification through a clear corneal, scleral tunnel, or limbal incision. Incision size ranged from 3.0 to 4.0 mm with single or no-stitch closure with the following exceptions: 3 first eyes each had 2 sutures, 1 monofocal second eye had 2 sutures, and 1 monofocal first eye had a 6.0 mm incision.

The 2 posterior chamber IOLs used in this study were identical in design with the exception of multifocal properties. The Array is a silicone zonal-progressive multifocal IOL and the PhacoFlex II is a silicone monofocal IOL. Both lenses have extruded poly(methyl methacrylate) monofilament haptics, a 6.0 mm optic, a constant center thickness, and an optic constructed of SLM-2 silicone, which is a high-refractive-index (1.46), second-generation silicone elastomer that enables folding and implantation through a small incision (approximately 3.2 mm). The optic of the Array lens (Figure 1) is designed with 5 zones of power with up to +3.50 D of add power at the IOL plane for near vision and to provide distance visual acuity comparable to that of the PhacoFlex monofocal lens. The Array is also designed to provide functional visual acuity for performing common visual tasks at intermediate distances of 50 to 150 cm (20 to 59 inches).

The primary endpoints of the study were frequency of spectacle wear, quality of life, and vision-related functional status as measured by the modified Cataract TyPE Specification (quality-of-life questionnaire). Secondary endpoints included distance acuity at 3 meters, both uncorrected and best corrected; near acuity at 35 to 46 cm, both uncorrected and best distance corrected; best distance corrected with additional add power; complications and adverse events (throughout duration of study); postoperative refractive error; use of medical services and supplies; and election of a second multifocal IOL implantation.

Data Collection

Distance visual acuity was measured with the Regan 96% contrast chart.² The Regan value was normalized to 3 meters and converted to the Snellen equivalent. Near visual acuity was measured using the Rosenbaum near acuity card held at a distance of 35 to 46 cm. Values were adjusted for the test distance used and reported in Jaeger (J) values.

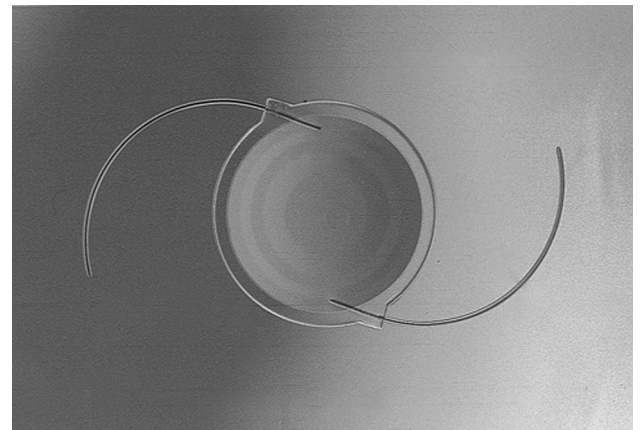
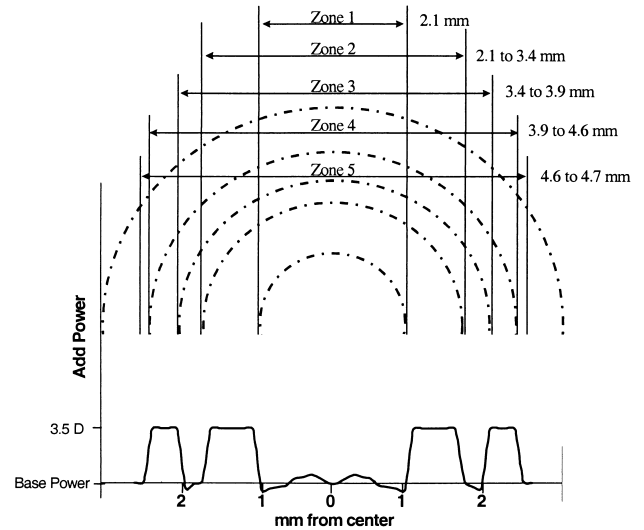


Figure 1. (Javitt) *Top:* Schematic of the zonal-progressive multifocal design of the Array IOL. *Bottom:* Photograph of the Array shows aspheric rings on the IOL's anterior surface.

The quality-of-life instrument was a modified Cataract TyPE Specification designed to measure the quality-of-life primary endpoints relative to multifocality. The questionnaire was previously validated in a retrospective clinical study by Javitt et al.¹ and in a multicenter observational study involving 900 U.S. patients.³ The survey instrument was translated into German and then reverse translated to ensure accurate translation. Clinical data were collected preoperatively and 1 week and 3 months postoperatively for each eye.

Telephone interviews were conducted at 3 points: before the first-eye cataract surgery, before the second-eye cataract surgery, and approximately 3 to 6 months after the second-eye surgery. All interviewers administering the quality-of-life instrument were masked to what IOL the patient had.

Statistical Analyses

For visual acuity data, the proportion of patients achieving a specific Snellen equivalent value of 0.5 (20/40) was compared between the multifocal and monofocal groups using the Fisher exact test. For distance acuity, the mean Regan line score and standard deviation were determined for each lens group, and comparisons of mean scores between groups were evaluated using the 2-sample *t* test. For near acuity, data were converted to logMAR values, and comparisons between lens groups were performed using the Wilcoxon rank sum test.

Mean spherical equivalent and refractive cylinder of the 2 IOL groups were also compared for first eyes and again for second eyes using the Wilcoxon rank sum test. Comparisons between lens groups for the proportion of patients who did not experience halos in either eye were performed using the Fisher exact test.

Questionnaire data were analyzed in several ways to compare the visual status, self-reported rating and satisfaction with vision, trouble with vision, and limitation in specific vision-related activities between IOL groups. Mean scores for each question and subset of questions were also compared. Summary scales were calculated to create subscales reflective of distance-vision-related, near-vision-related, and social activities. Skewness and kurtosis were assessed for each item to test normality. Most subscale responses were not normally distributed. Therefore, the Wilcoxon rank sum test was used to assess the significance of observed differences between lens groups. Categorical data were compared using the chi-square test or the Fisher exact test when assumptions for the chi-square test were not met. The correlations between halos and trouble with vision and between halos and satisfaction with vision were evaluated using the Spearman correlation coefficient.

For all statistical comparisons, 2-sided testing was performed, with alpha set at 0.05. This study had a power of 0.80 to detect a difference between groups in self-reported rating-of-vision questions of 10% on the 10-point scale.

Results

Of 133 enrolled patients, 124 had bilateral implantation: 64 of a multifocal IOL and 60 of a monofocal IOL. Nine patients (4 multifocal and 5 monofocal) were

excluded from the study after IOL implantation in the first eye. Reasons for exclusion were the wrong lens model implanted in the second eye (1 multifocal), unwillingness or inability to have second-eye surgery (3 multifocal, 1 monofocal), dissatisfaction with results in first eye (1 monofocal), declined to continue because of vision loss in first eye resulting from macular edema (1 monofocal), did not meet age criteria (1 monofocal), and lost to follow-up despite diligent attempts (1 monofocal).

Of the 124 remaining patients having bilateral IOL implantation, 118 (64 multifocal, 54 monofocal) completed the final postoperative quality-of-life questionnaire (Table 1). In addition, 114 patients (61 multifocal, 53 monofocal) completed the final postoperative clinical examination (postop 2) for the second eye.

Several preoperative protocol deviations were noted that did not result in patients withdrawing from the study. Six patients with higher than 1.50 D of corneal astigmatism in 1 eye were included: 2 in the multifocal group (1.62 and 1.75 D) and 4 in the monofocal group (1.55, 1.88, 2.25, and 3.75 D). Some patients with pre-existing preoperative pathologies in 1 or both eyes were also included. In the multifocal group, 1 patient had corneal guttata in both eyes and another had a pre-exist-

Table 1. Patient characteristics.

Characteristic	Group, Number (%)		P Value*
	Monofocal (n = 54)	Multifocal (n = 64)	
Age (years)			
50–64	10 (18.52)	12 (18.75)	.688
65–74	25 (46.30)	34 (53.13)	
75+	19 (35.19)	18 (28.13)	
Sex			
Female	26 (48.15)	21 (32.81)	.131
Male	28 (51.85)	43 (67.19)	
Occupation			
Yes	0	4 (6.25)	.124
No	54 (100)	60 (93.75)	
Household status			
Living alone	16 (30.77)	25 (39.06)	.436
Living with another adult	36 (69.23)	39 (60.94)	
Not given	2 (0.37)	0	

*Exact test

ing small corneal scar in 1 eye. In the monofocal group, 5 eyes (4 patients) had pre-existing corneal scars and 3 eyes (2 patients) had controlled glaucoma. All patients with preoperative protocol deviations attained 0.5 (20/40) or better corrected distance visual acuity 3 months after IOL implantation in the second eye.

The final postoperative examination occurred at 60 to 165 days (3 month visit for the second eye). Data from 3 patients (1 monofocal, 2 multifocal) were excluded from analysis because the final clinical examination did not take place within this interval.

Clinical

Surgical technique. Eight surgical complications were encountered during the study. Three episodes of posterior capsule rupture were reported, all in the monofocal group; 2 required anterior vitrectomy, 1 of which resulted in both haptics being placed in the sulcus. Two intraoperative posterior capsulotomies were performed for dense posterior capsule fibrosis at the time of surgery (both in the multifocal group); 1 eye also required an anterior vitrectomy. There was 1 report of zonular rup-

ture, and corresponding vitrectomy was noted that resulted in implantation of a capsular fixation ring (multifocal group). All eyes with surgical complications obtained 1.0 (20/20) or better corrected distance visual acuity at the last postoperative visit.

Uncorrected binocular distance visual acuity. Mean binocular distance visual acuities in the multifocal and monofocal groups at the final postoperative examination are shown in Table 2. There was no significant between-group difference in mean uncorrected binocular distance visual acuity. Mean uncorrected binocular distance visual acuity was 1.0 (20/21) in the multifocal group and 0.9 (20/22) in the monofocal group.

All 61 patients receiving bilateral implantation of the multifocal IOL achieved 0.5 (20/40) or better uncorrected binocular distance visual acuity at the final postoperative visit, with 62.3% (38/61) achieving 1.0 (20/20) or better at the final postoperative visit. In the monofocal group, 98.1% (52/53) achieved 0.5 (20/40) or better uncorrected binocular distance visual acuity, with 54.7% (29/53) achieving 1.0 (20/20) or better.

Table 2. Mean binocular visual acuity scores* at final postoperative exam.†

Visual Acuity/Group	Number	Snellen Equivalent	Binocular Visual Acuity			P Value
			Mean ± SD	Minimum	Maximum	
Uncorrected distance						
Multifocal	61	20/21	7.85 ± 1.23	5.25	10.50	.446
Monofocal	53	20/22	7.63 ± 1.69	2.50	10.50	
Best corrected distance						
Multifocal	61	20/18	8.52 ± 0.97	5.38	10.50	.308
Monofocal	53	20/17	8.71 ± 1.02	6.13	10.50	
Uncorrected near						
Multifocal	61	20/25	0.10 ± 0.16	-0.08	1.00	<.001‡
Monofocal	53	20/41	0.31 ± 0.24	-0.06	0.98	
Distance-corrected near						
Multifocal	60	20/26	0.12 ± 0.13	-0.06	0.54	<.001‡
Monofocal	53	20/46	0.36 ± 0.19	0.04	1.00	
Best corrected near (add power)						
Multifocal	61	20/20	-0.01 ± 0.05	-0.06	0.12	.485
Monofocal	53	20/20	-0.01 ± 0.05	-0.06	0.15	

*All visual acuity scores were adjusted for the test distance. Mean scores for distance vision are reported in Regan lines, and mean scores for near vision are reported in logMAR values. A standard deviation of 1.0 for Regan data corresponds to approximately 1 Snellen line, whereas a standard deviation of 0.1 for logMAR data corresponds to approximately 1 Snellen line.

†60 to 165 days postoperatively

‡Statistically significant

Best corrected binocular distance visual acuity. There was no significant between-group difference in mean best corrected distance visual acuity (Table 2). The multifocal group achieved a mean binocular corrected distance visual acuity of 1.1 (20/18) and the monofocal group, of 1.2 (20/17).

There was no significant difference between groups as all 61 multifocal patients and all 53 monofocal patients achieved a best corrected distance visual acuity of 0.5 (20/40) or better. In addition, 88.5% (54/61) in the multifocal group and 86.8% (46/53) in the monofocal group achieved 1.0 (20/20) or better best corrected distance visual acuity.

Uncorrected binocular near visual acuity. A statistically significant difference ($P < .001$) was found between the multifocal and monofocal groups in mean uncorrected binocular near visual acuity: 0.8 (20/25) in the multifocal group and 0.5 (20/41) in the monofocal group (Table 2).

A significant difference ($P < .001$) between groups was found in uncorrected binocular near visual acuity of J3 (20/40 Snellen) or better: 96.7% (59/61) in the multifocal group and 67.9% (36/53) in the monofocal group achieved J3 or better. In addition, 80.3% (49/61) in the multifocal group and 28.3% (15/53) in the monofocal group achieved J1 or better uncorrected near visual acuity.

Binocular near visual acuity with best distance correction. For binocular near visual acuity with best distance correction, a statistically significant difference ($P < .001$) was found between the multifocal and monofocal groups, with means of 0.8 (20/26) and 0.4 (20/46), respectively (Table 2).

Postoperative binocular near visual acuity with best distance correction of J3 or better was 95.0% (57/60) in the multifocal group and 58.5% (31/53) in the monofocal group. Also, 70.0% (42/60) and 11.3% (6/53), respectively, achieved J1 or better. Both differences were significant ($P < .001$).

Binocular near visual acuity with best distance correction and add power. There was no statistically significant difference between the multifocal and monofocal groups in mean binocular near visual acuity with best distance correction and additional add power. Both groups achieved a mean visual acuity value of J1⁺ (20/20) (Table 2).

Binocular near visual acuity with best distance

correction and additional add power of J3 (20/40) or better was achieved by all patients in both groups. All patients (61/61) in the multifocal group and 98.1% (52/53) in the monofocal group achieved J1 or better.

Combined visual acuities. The proportion of patients who achieved 0.5 (20/40) or better uncorrected binocular distance visual acuity and J3 or better uncorrected binocular near visual acuity at the final postoperative examination was significantly different between groups ($P < .001$). Combined distance and near visual acuities of 0.5 (20/40) or better and J3 or better were achieved by 96.7% (59/61) in the multifocal group and 66.0% (35/53) in the monofocal group. The proportion of patients who achieved 1.0 (20/20) or better uncorrected binocular distance and J1 or better uncorrected binocular near visual acuity was also significantly different ($P < .001$), with 55.7% (34/61) in the multifocal group and 13.2% (7/53) in the monofocal group achieving these criteria.

Mean refractive results. No statistically significant difference was found between groups in the mean spherical equivalent after either first or second IOL implantation, with mean results ranging from -0.27 to -0.51 D. No statistically significant difference in mean scores was found for refractive cylinder for first-eye implantation, with a mean score of 0.40 D in the multifocal group and 0.47 D in the monofocal group. A significant difference ($P = .011$) was found between groups in second-eye implantation, with monofocal patients having a higher mean refractive cylinder (0.60 D) than multifocal patients (0.35 D).

Sight-threatening and other complications. The incidence of cumulative sight-threatening complications in both groups was low and similar. The incidence of cumulative "other" medical complications was low and similar, with less than 7.0% in both groups reporting moderate to severe posterior capsule haze.

Lens complications and subsequent capsulotomy. No difference between the 2 groups was noted in lens complications. Of the 64 multifocal patient, 61 (95.3%) did not require a neodymium:YAG (Nd:YAG) capsulotomy. Of the 54 monofocal patients, 53 (98.1%) did not require an Nd:YAG procedure. Four patients, 1 in the monofocal group and 3 in the multifocal group, had an Nd:YAG capsulotomy, with 1 in the multifocal having a capsulotomy in both eyes. The difference in Nd:YAG

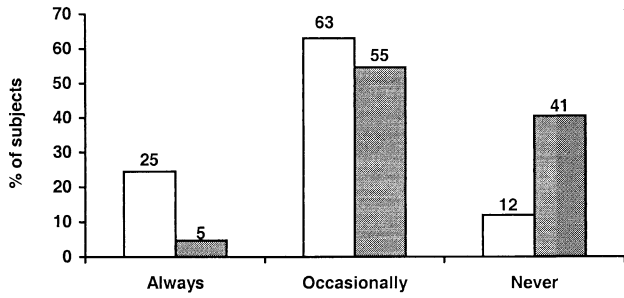


Figure 2. (Javitt) Proportion of patients who always, occasionally, or never wore glasses (left bars = monofocal; right bars = multifocal).

rates between the groups was not significant ($P = .624$).

Optical/visual symptoms. Night flare/halos were reported most often by multifocal patients. In the monofocal group, 98.0% (49/50) and in the multifocal group 59.6% did not report halos in either eye. However, multifocal patients were significantly more likely ($P < .001$) to report halos in 1 or both eyes than monofocal patients.

Adverse events. The 1 adverse event was a lens exchange in the second eye implanted with a multifocal lens. The lens exchange was done because of dislocation and decentration of the lens (1.5 mm) and was not considered by the investigator to be lens related.

Quality-of-Life

Overall visual status. Patients were asked how often they wore glasses. Possible responses were always, occasionally, and never. Those in the multifocal group wore glasses less often than those in the monofocal group, with 41% and 12%, respectively, never wearing glasses.

The difference was statistically significant ($P < .001$) (Figure 2). Patients were also asked how often they wore glasses for distance and near vision. Possible responses were none of the time, some of the time, half of the time, most of the time, and all the time. Multifocal patients wore glasses less often than monofocal patients for distance vision ($P = .005$) and for near vision ($P = .001$) (Figure 3).

Self-reported rating of vision. Based on a scale of 0 to 10 (0 = worst possible vision; 10 = best possible vision), patients with multifocal IOLs rated their distance, intermediate, near, and overall vision without glasses as better than the monofocal patients. The difference in overall vision was significant ($P = .017$). A significant difference in favor of the multifocal lens was noted in intermediate vision ($P = .005$) and near vision ($P = .005$) (Figure 4). Significant differences favoring the multifocal group remained after adjusting for astigmatic results (those with or without 0.50 D or more of postoperative refractive cylinder).

When asked to rate their vision with glasses on the same scale, patients with multifocal IOLs rated their distance, near, and overall vision with glasses better than those with monofocal IOLs. The difference between the 2 groups in overall vision was significant ($P = .031$). There was no difference in results when the study group was stratified by whether they had had a subsequent Nd:YAG capsulotomy.

Rating of glare and halo. Patients were asked to rate glare disability on a scale of 0 to 4 (0 = no limitation due to glare; 4 = extreme limitation due to glare) for the following activities: general daily activities; reading text on shiny paper; driving toward the sun; driving toward

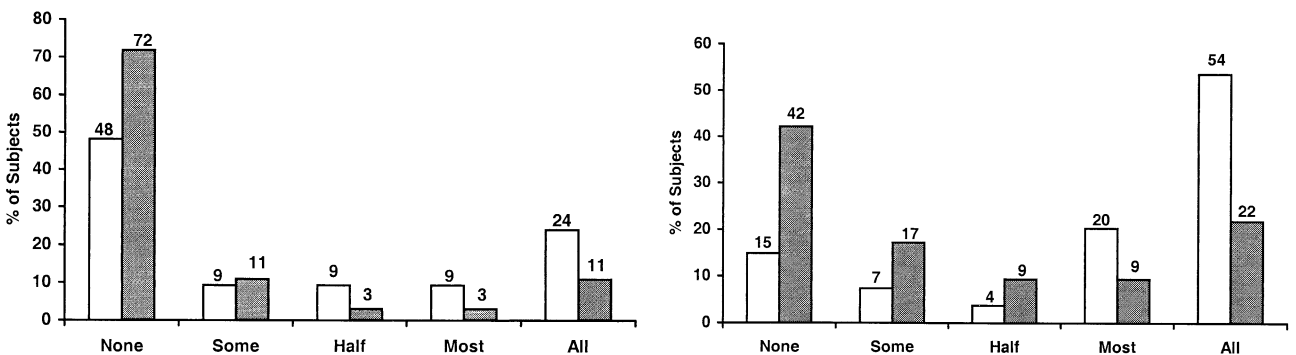


Figure 3. (Javitt) *Left:* Percentage of patients reporting use of spectacles never, some of the time, half of the time, most of the time, or all of the time for distance vision (left bars = monofocal; right bars = multifocal). *Right:* Percentage of patients reporting use of spectacles never, some of the time, half of the time, most of the time, or all of the time for near vision (left bars = monofocal; right bars = multifocal).

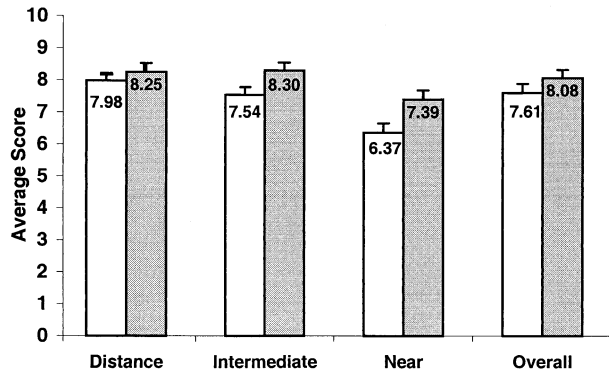


Figure 4. (Javitt) Self-reported rating of overall vision (0 = worst possible vision; 10 = best possible vision) (left bars = monofocal; right bars = multifocal). Error bars represent standard error of mean.

oncoming headlights; walking outside on sunny days; reading signs in supermarkets. No statistically significant differences were found between the 2 groups in most activities. Patients with multifocal IOLs reported less limitation from glare when reading text on shiny paper and reading signs in supermarkets than patients with monofocal IOLs ($P = .03$).

The degree of “bother” caused by double or distorted vision was assessed on a scale of 0 to 4 (0 = not at all bothered; 4 = extremely bothered). No statistically significant difference was found between groups for double or distorted vision with or without glasses. The same scale of 0 to 4 was used to assess the degree of bother caused by seeing glare, halos, or rings around lights. Patients with multifocal IOLs were more likely to report seeing glare, halos, or rings around lights than monofocal patients. The difference between the 2 groups was significant ($P < .001$) with or without glasses (Figure 5).

Trouble with vision. The degree of trouble with vision with and without glasses was assessed using a scale of 0 to 4 (0 = none of the time; 4 = all of the time) (Figure 6). Patients with multifocal IOLs reported significantly less trouble without glasses during the day ($P = .005$) and at night ($P = .05$). The difference was not significant when glasses were used.

Limitation in vision-related activities. Limitation in vision-related activities was assessed on a scale of 0 to 4 (0 = not at all limited; 4 = extremely limited). No significant differences were found between the groups in distance-vision-related activities with or without glasses (Figure 7). Distance-vision-related activities were usual

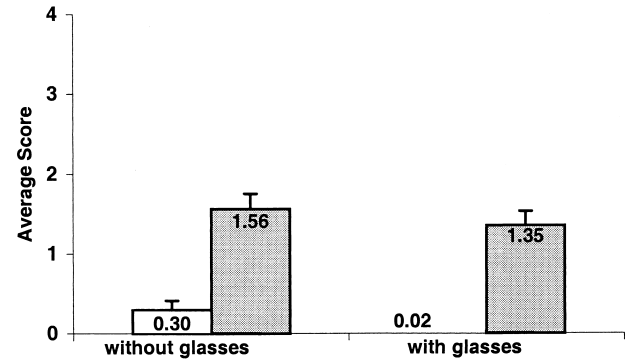


Figure 5. (Javitt) Degree of bother from glare, halos, or rings around light (0 = not bothered at all; 10 = extremely bothered) (left bars = monofocal; right bars = multifocal). Error bars represent standard error of mean.

daily activities; recognizing people or objects across the street; daytime driving; nighttime driving; reading street or freeway signs; seeing traffic lights; watching television; walking up or down stairs.

Using the same scale of 0 to 4, patients with multifocal IOLs reported less limitation in 3 of 5 near-vision-related activities without glasses than monofocal IOL patients. The differences between the groups were significant for reading a magazine, newspaper, or telephone book ($P < .001$), crafts or hobbies ($P = .002$), and reading labels or prices ($P < .001$), but not for depth perception (pouring coffee, hitting a golf ball, parking a car) or shaving or putting on makeup. Overall, those in the multifocal group were less limited ($P = .001$) in near-vision-related activities.

Based on the same 0 to 4 scale, patients were asked to rate their ability to perform the following social activities: going out to dinner in a restaurant; going to movies or the theater; visiting with friends or relatives; going to a party or dance; going to a sporting activity. At least 70% of patients did not participate in the following social activities for reasons other than poor vision: going to the movies or theater, to a party or dance, or to a sporting activity. Overall, a significant difference was found between groups without glasses in going out to dinner and social activities, with multifocal patients reporting fewer limitations than monofocal IOL patients ($P = .020$ and $P = .031$, respectively).

In summary, patients with multifocal IOLs reported significantly less limitation in function without glasses in near-vision-related activities ($P < .001$), social activities ($P = .031$), and overall activities ($P =$

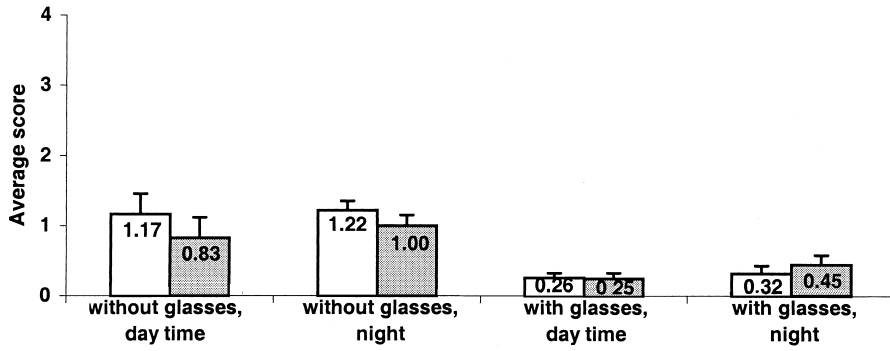


Figure 6. (Javitt) Patients reporting degree of trouble with vision (0 = none of the time; 4 = all of the time) (left bars = monofocal; right bars = multifocal). Error bars represent standard error of mean.

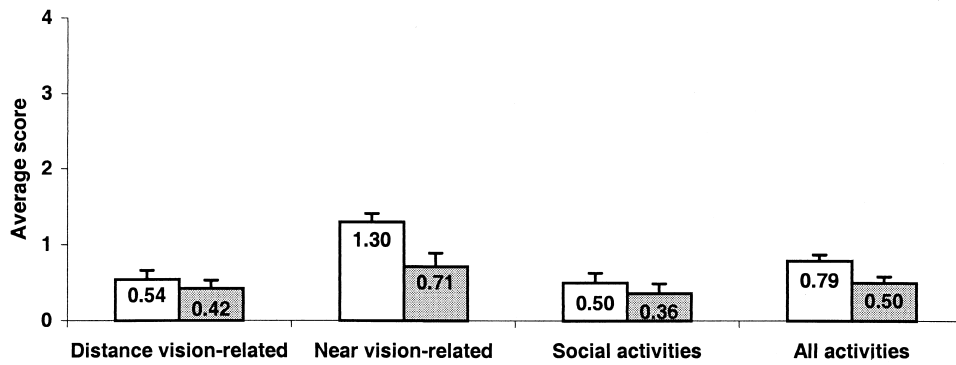


Figure 7. (Javitt) Summary of limitations in vision-related activities without wearing glasses at last follow-up (0 = not at all limited; 4 = extremely limited) (left bars = monofocal; right bars = multifocal). Error bars represent standard error of mean.

.001) than patients with monofocal IOLs (Figure 7). No significant differences were found between groups when patients assessed vision-related activities with glasses.

Recent health and happiness. Self-reported overall health in the recent past and self-reported happiness in the recent past were assessed on a scale of 0 to 10 (0 = worst possible health/happiness; 10 = best possible health/happiness). Both multifocal and monofocal patients had mean scores above 6 for both questions. No significant differences were found between groups on either question.

Discussion

For emerging health technologies to be adopted, they must be not only clinically efficacious, but they must also result in measurable outcome benefits from the patient's perspective. In this report, we presented results of a European-based randomized prospective multicenter double-masked clinical trial used to evaluate a multifocal IOL. Our endpoints measured clinical efficacy (visual acuity) as well as patient satisfaction and visual function.

Because monofocal IOLs have historically achieved outstanding results and have been the standard lens for cataract extraction and IOL implantation, we were uncertain whether any quality-of-life difference would be detected between the patients with bilateral multifocal IOLs and those with bilateral monofocal IOLs. Previous studies of cataract outcomes failed to detect any patient-perceived benefit associated with new technologies such as small incision surgery, foldable lenses, or other advances.^{4,5} The significant differences that were detected between bilateral multifocal and bilateral monofocal patients confirm that the Array zonal-progressive multifocal IOL offers better visual function than monofocal silicone IOLs.

This double-masked study of 124 German-speaking patients who had cataract extraction and bilateral implantation of the zonal-progressive multifocal IOL found significant differences in spectacle wear, rating of vision, satisfaction with vision, and vision-related function between these patients and those who had bilateral implantation of an IOL that was similar but monofocal.

The data show that spectacle use at both distance and near was substantially lower in the multifocal IOL

group. As in our retrospective study,¹ multifocal patients rated their vision without glasses better overall and at the near and intermediate ranges than monofocal patients.

Patients with multifocal IOLs reported less limitation in the ability to perform near-vision activities, social activities, and activities overall than monofocal patients without glasses. Those in the multifocal group also reported less trouble without glasses in the daytime or at night. In addition, multifocal patients reported less limitation from glare in specific near-vision activities. Although multifocal patients were more likely to report seeing halos and rings around lights, the multifocal group had better visual function and rated vision more highly than the monofocal group.

Although we expected to find improved visual function associated with near-vision tasks in the multifocal IOL group, we were surprised that this difference extended to functions commonly associated with distance vision, as well as to social activities. Examination of the individual items in the functional status instrument found consistently better self-reported function in each domain without spectacles in the multifocal IOL group than in the monofocal IOL group. In both groups, reported limitation was on the low end of the scale, with means generally less than 1.0 (1.0 = slightly limited) for any item. This finding is consistent with published studies of cataract surgery outcomes.^{4–8}

The same trend toward less limitation in vision-related functional status was evident in connection with spectacle-corrected vision but was not, in general, significant. The important finding, from our perspective, is that the significant advantage in unaided vision associated with multifocal IOLs was not associated with a perceived decrease in visual function compared with monofocal lenses when spectacles were worn.

There was a higher degree of bother reported by multifocal patients in response to a specific question about glare, halos, or rings around lights. The mean score of 1.56 without spectacles and 1.35 with spectacles fell between slightly bothered and somewhat bothered on the response scale and was nearly identical to findings of our retrospective study.¹ However, all multifocal patients, including those reporting glare and halos, chose to have the same lens implanted in the second eye. Also, despite the higher degree of disturbance from glare and

halos, overall quality of life and satisfaction were higher in the multifocal group.

The positive quality-of-life outcomes reported by Array patients are supported by the clinical efficacy results of our study. These data show that 3 months after surgery, patients with the Array lens had significantly better uncorrected and distance-corrected near visual acuity than those with a monofocal IOL. Mean uncorrected and corrected distance visual acuities were similar between groups, but a higher proportion of multifocal patients achieved both 20/40 and J3 or better uncorrected, binocular, distance, and near visual acuity. These clinical efficacy results are consistent with those of the Array safety and efficacy study by Steinert et al.⁹ This prospective study included a nonrandomized fellow-eye control group (1 eye with monofocal IOL and fellow eye with multifocal IOL). Multifocal eyes in this group achieved a mean 2-line increase over monofocal eyes in uncorrected and distance-corrected near visual acuity 1 year postoperatively. Steinert et al. also showed that mean uncorrected distance visual acuity was similar between multifocal and monofocal eyes. Our current study results and those of the safety and efficacy study show that the Array multifocal IOL can improve near vision while providing a high level of distance vision.

Study Limitations

Because our study was conducted as a randomized prospective multicenter double-masked clinical trial, it was not subject to many of the issues of bias and confounding we noted in our earlier retrospective study. The chief limitation is that, as with most clinical trials, patients who enroll may differ from the general population in health status, personality, and attitudes toward medical care. The multifocal and monofocal patients were comparable in terms of demographics, lack of ocular co-morbidity, postoperative best corrected acuity, surgical approach, and IOL characteristics, but not in terms of multifocality.

Summary

For new medical technology to be widely adopted, it must be safe and efficacious. It must also provide superior outcomes in terms of patient function, satisfaction, and quality of life. The results of this clinical trial suggest that the Array multifocal IOL meets all these criteria. Typically, studies of patient outcome have been obser-

vational rather than experimental in design. This report serves to support the thesis that patient outcomes can be measured within a rigorous experimental design in the same manner as safety and efficacy.

References

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