Visual function and patient satisfaction: Comparison between bilateral diffractive multifocal intraocular lenses and monovision pseudophakia

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PURPOSE: To compare visual function and patient satisfaction in patients with bilateral diffractive multifocal intraocular lenses (IOLs) and patients with monofocal IOL monovision.

SETTING: Department of Ophthalmology, Henry Ford Health System, Detroit, Michigan, USA.

DESIGN: Cohort study.

METHODS: This study comprised consecutive bilateral cataract patients having implantation of AcrySof ReSTOR SN60D3 multifocal IOLs or AcrySof SN60WF IOLs as monovision between July 2007 and June 2009. Parameters analyzed 3 months postoperatively included binocular uncorrected distance, intermediate, and near visual acuities; stereo vision; spectacle independence; subjective visual symptoms; and patient satisfaction. Patients were administered the Visual Function Questionnaire-25 preoperatively and postoperatively.

RESULTS: The multifocal IOL group comprised 21 patients and the monovision group, 22 patients. Although bilateral uncorrected distance vision and near vision were slightly better in the multifocal IOL group than in the monovision group, there was no statistically significant difference between the 2 groups. The monovision group had better intermediate vision than the multifocal IOL group and had less difficulty using computers without glasses; the differences between the 2 groups were statistically significant. Patients with monovision had a slightly higher overall satisfaction score, significantly fewer complaints, and less out-of-pocket cost.

CONCLUSIONS: Pseudophakic monovision achieved distance vision and near vision that were comparable to those with bilateral multifocal IOLs without the inherent risk for disturbing visual symptoms associated with multifocal IOLs. Monovision patients also had significantly better intermediate vision and less difficulty using computers without glasses.

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Cataract surgery is no longer simply a rehabilitation procedure for many cataract patients. Increasingly, patients prefer, or even demand, no glasses or contact lenses after surgery to meet their lifestyle. Since the introduction of the early Array multifocal intraocular lens (IOL) in the late 1990s,[A] technology has advanced significantly. Although replacement of accommodation is something all patients would appreciate, at this time, in the absence of a scientifically and clinically proven true accommodating IOL to provide a full range of high quality vision, compromise solutions are available. Bifocal IOLs share light from near and distance vision and use depth of focus to facilitate intermediate vision. In March 2005, the U.S. Food and Drug Administration approved the AcrySof ReSTOR multifocal IOL (Alcon Laboratories, Inc.) for cataract patients with and without presbyopia. This IOL uses an apodized diffractive technology that attempts to give patients a full range of vision (near, distance, and intermediate) and to increase their independence from glasses after surgery. Excellent clinical outcomes have been reported[1-3]; however, patient dissatisfaction

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and secondary procedures, including IOL exchange, can also be significant.[4–6] With the same purpose, monovision has long been used to provide near, intermediate, and distance vision and is one of the most common methods cataract patients use to address presbyopia.[7-10,B–E] Overall satisfaction with pseudophakic monovision has been approximately 80%[9] or better.[7,10] Most studies comparing visual function and satisfaction were performed separately; however, it is desirable to have comparative studies with control groups using comparable protocols for multifocal IOLs and monovision.[11] This comparative study was designed for that purpose and was performed in a single ophthalmologist's practice. To our knowledge, this was the first prospective comparative study in the literature at the time of submission.

PATIENTS AND METHODS

Patient Population

This study includes all consecutive bilateral cataract surgery patients seeking good uncorrected near and distance vision at the Department of Ophthalmology, Henry Ford Health System (Taylor and Southgate, Michigan, branches), from July 2007 to June 2009. The Henry Ford Health System Institutional Review Board approved the study design and protocol, and all patients signed an informed consent before the surgery.

Inclusion and Exclusion

All patients with good potential for visual improvement and who desired bilateral cataract surgery and independence from glasses were offered inclusion in this study. Patients who did not mind wearing glasses after surgery were excluded because they were not offered multifocal IOL implantation or monovision. Other exclusion criteria were significant ocular disease (eg, diabetic retinopathy, macular degeneration, glaucoma with field defects, and irregular corneal astigmatism), implantation of a Crystalens IOL (Bausch & Lomb) or toric IOL, severe connective tissue disease for those patients who would need limbal relaxing incision, and corneal epithelial basement membrane dystrophy. Patients with a mesopic pupil of 5.0 mm or larger were excluded from both groups.

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Patient Assignment

Depending on his or her lifestyle and financial status, each patient chose bilateral implantation of AcrySof ReSTOR SN60D3 multifocal IOLs (multifocal IOL group) or full monovision with AcrySof SN60WF IOLs (monovision group). There was an out-of-pocket cost to patients who chose the multifocal IOL but no extra cost to monovision patients unless the patient required astigmatism correction with LRIs. The mean out-of-pocket cost was $1895/eye for the multifocal IOL and $367/eye for monovision patients requiring LRIs. The detailed advantages and disadvantages of multifocal IOLs and monovision were fully discussed with all patients. It was impossible to randomize between the 2 groups because of the cost difference. Because this was a convenience sample, a priori power and sample size were not examined.

Preoperative Evaluation

All patients were given a modified Dell preoperative questionnaire (with written permission from Steven Dell, MD) to list their lifestyle and whether they would prefer no glasses after surgery. Most patients received the survey material by mail after they made the appointment. All patients had a complete ocular history and examination and had at least 2 eye-dominance tests. The dominant eye was corrected for distance and the nondominant eye for near. Corneal topography (TMS-4 version 3.5E, Tomey) was performed. Manual Marco keratometry, IOLMaster (Carl Zeiss Meditec AG), or rarely, immersion A-scan biometry, was also performed.

A monovision threshold test[F] was given to all monovision patients before surgery to determine what degree of IOL power difference between the 2 eyes the patient could tolerate. Most patients were given an approximate 2.00 diopter (D) difference between the dominant eye and the nondominant eye.

Visual Function Questionnaire-25

Patients were administered the Visual Function Questionnaire-25 (VFQ-25)[12] preoperatively after being scheduled for the first-eye surgery and 3 months after the second-eye surgery. The original VFQ-25 was modified to add a few specific questions, such as complaint level for halo/glare, overall satisfaction level with the chosen IOL/surgery, and whether the patient would consider recommending the same IOL and procedure to his or her family members and friends.

Surgical Technique

The same surgeon (F.Z.) performed all surgeries using topical anesthesia. A temporal 2.7 mm clear cornea incision was created at 205 degrees in right eyes and 25 degrees in left eyes created. This was followed by phacoemulsification using the Infiniti OZil system (Alcon Laboratories, Inc.), after which the IOL was implanted in the capsular bag.

Limbal relaxing incisions were performed in eyes with regular with-the-rule corneal astigmatism of 0.50 D or more, or regular against-the-rule corneal astigmatism of 0.75 D or more on corneal topography. The LRI was performed at the beginning of the procedure, with the location based on the cylinder location on the corneal topography and the LRI Calculator (Abbott Medical Optics, Inc.). The

Table 1. Postoperative UDVA in both eyes and spectacle independence for driving.

Parameter/Group	Patients, n (%)	*P* Value
Snellen UDVA 20/20		.432
Multifocal (n = 21)	13 (62)	
Monovision (n = 22)	11 (50)	
Distance Snellen UDVA 20/25 or better		.674
Multifocal (n = 21)	19 (90)	
Monovision (n = 22)	19 (86)	
Never need glasses for driving		.150
Multifocal (n = 21)	17 (81)	
Monovision (n = 21)	15 (71)	

UDVA = uncorrected distance visual acuity

length and depth of the LRI were based on the Nichamin nomogram.[13]

Routine antibiotic drops, including prednisolone acetate 1% (Omnipred) and nepafenac 0.1% (Nevanac), were used for 1 week and antiinflammatory drops for 4 weeks postoperatively.

Postoperative Follow-up

The patients were examined 1 day and 2 weeks after the first surgery (which was typically in the nondominant eye) and 1 day, 2 weeks, and 3 months after the second surgery. At the 3-month visit, binocular uncorrected intermediate visual acuity (binocular UIVA) and stereo vision without correction were also measured. The postoperative VFQ-25 form and a pre-stamped envelope were given to all patients at the 3-month visit. Three or 4 weeks after the second-eye surgery, patients requiring glasses were seen by an optometrist. Because of the postoperative differences between groups, the examinations were not masked.

Statistical Analysis

The same team member (M.C.) collected all data independently and another member (G.J.) performed an independent statistical analysis of the data. The 2 study groups were compared using the standard chi-square test for dichotomous data and the Cochran-Armitage trend test for ordinal data. A *P* value less than 0.05 was considered statistically significant.

RESULTS

The study enrolled 43 patients, 21 (14 women) in the multifocal IOL group and 22 (15 women) in the monovision group. The mean age was 69 years (range 50 to 92 years) and 67 years (range 49 to 83 years), respectively. One patient in the multifocal IOL group was excluded because of a late-onset wound infection (6 months after surgery) in the first operated eye; the infection developed 2 weeks after second-eye surgery. One patient in the monovision group was excluded for not returning the VFQ-25.

Table 2A. Postoperative driving-related problems.

Problem/Group	Mean ± SD	Median	*P* Value
Halos			<.001
Multifocal	2.95 ± 1.47	4.00	
Monovision	4.77 ± 0.53	5.00	
Glare			.024
Multifocal	3.24 ± 1.45	4.00	
Monovision	4.09 ± 0.87	4.00	
Difficulty with daytime driving			.679
Multifocal	1.19 ± 0.40	1.00	
Monovision	1.14 ± 0.36	1.00	
Difficulty with night driving			.129
Multifocal	2.20 ± 1.11	2.00	
Monovision	1.76 ± 0.70	2.00	
Difficulty in difficult driving*			.093
Multifocal	1.90 ± 0.85	2.00	
Monovision	1.48 ± 0.75	1.00	

*Difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic

No major intraoperative complications occurred. No further procedures, such as refractive adjustment or IOL exchange, were performed in either group.

In the multifocal IOL group, both eyes were targeted for plano; the mean spherical equivalent (SE) difference between the 2 eyes was 0.30 D ± 0.35 (SD) (median 0.25 D). In the monovision group, the mean difference between the 2 eyes was 1.92 ± 0.57 D (median 1.88 D); 7 patients (31.8%) had anisometropia of 1.50 D or less, and 15 patients (68.2%) had 1.75 D or more anisometropia.

All patients in both groups achieved a binocular corrected distance visual acuity (CDVA) of 20/25 or better; 2 patients in each group had a CDVA of 20/25, and the other patients had a CDVA of 20/20 or better. Table 1 shows the postoperative bilateral uncorrected distance visual acuity (UDVA) and spectacle independence for driving at the 3-month postoperative follow-up; there was no statistically significant difference between the 2 groups in either parameter.

Table 2A shows the patient-reported postoperative driving-related problems and Table 2B, the postoperative driving difficulty. Although there was no statistically significant difference between the 2 groups, the monovision group had more favorable scores for driving difficulty at night ($P=.129$) and driving in difficult conditions ($P=.093$). Significantly more patients in the multifocal IOL group than in the monovision group reported having halo and glare symptoms (Tables 2A and 2C).

Table 2B. Postoperative driving difficulty.

Parameter/Group	Patients (n)					*P* Value
	No Difficulty	A Little Difficulty	Moderate Difficulty	Extreme Difficulty	Stopped Driving Due to Difficulty	
Daytime						.679
Multifocal	17	4	0	0	0	
Monovision	18	3	0	0	0	
Nighttime						.129
Multifocal	6	7	5	1	1	
Monovision	8	10	3	0	0	
Difficult conditions*						.094
Multifocal	7	9	3	1	0	
Monovision	14	4	3	0	0	

*Difficult conditions, such as in bad weather, during rush hour, on the freeway, or in city traffic

Table 3 shows the postoperative binocular uncorrected near visual acuity (UNVA) and spectacle independence for reading at the 3-month postoperative follow-up. The binocular UNVA was 20/20 in 19 (90%) of 21 eyes in the multifocal IOL group and 13 (59%) of 22 eyes in the monovision group. Although the between-group difference was statistically significant ($P=.018$), there was no significant difference in the percentage of eyes with a UNVA of 20/25 or better ($P=.157$). There was no statistically significant between-group difference in the percentage of patients never requiring glasses for newspaper reading ($P=.331$).

Table 4 shows the intermediate UIVA in both eyes and spectacle independence for computers. Significantly more patients in the monovision group than in the multifocal IOL group achieved a UIVA of 20/40 or better and reported no difficulty or little difficulty using computer without glasses; both differences were statistically significant ($P<.001$ and $P=.048$, respectively). The difference between the 2 groups in the percentage of patients who reported never needing glasses for computer work was not statistically significant ($P=.675$).

Table 5 shows the stereo vision results at 3 months. Seventeen (81%) of 21 patients in the multifocal IOL group and 15 (68%) of 22 patients in the monovision group had 100 seconds of arc (arcsec) or better of stereo vision. Table 6 shows the Cochran-Armitage trend test results for postoperative stereo vision analysis. The difference in the mean values was not statistically significant between the 2 groups, with the monovision group having a higher mean ($P=.076$). Table 7 shows the functional stereo vision results (ie, (postoperative difficulty with going down steps, stairs, or curbs in dim light or at night without glasses). The levels in the 2 groups were similar.

There were no statistically significant differences in satisfaction with cost, willingness to recommend the procedure/IOL to family members, and overall satisfaction with the surgery/IOL styles between the 2 groups. However, the scores in the monovision group were more favorable in all 3 components (Table 8).

DISCUSSION

Our study found that neither bilateral implantation of AcrySof ReSTOR SN60D3 multifocal IOLs nor

Table 2C. Postoperative halo and glare.

Parameter/Group	Patients (n)					*P* Value
	All the Time	Most of the Time	Some of the Time	A Little of the Time	None of the Time	
Halo						<.001
Multifocal	6	2	2	9	2	
Monovision	0	0	1	3	18	
Glare						.024
Multifocal	5	1	2	10	3	
Monovision	0	1	4	9	8	

Table 3. Postoperative UNVA in both eyes and spectacle independence for reading.

Parameter/Group	Patients, n (%)	*P* Value
Snellen UNVA 20/25 or better		.157
Multifocal (n = 21)	21 (100)	
Monovision (n = 22)	20 (91)	
Never need glasses for reading		.331
Multifocal (n = 21)	14 (67)	
Monovision (n = 22)	17 (77)	

UNVA = uncorrected near visual acuity

Table 4. Intermediate UIVA in both eyes and spectacle independence for computers.

Parameter/Group	Patients, n (%)	*P* Value
Snellen UIVA 20/40 or better		<.001
Multifocal (n = 21)	2 (9)	
Monovision (n = 22)	16 (73)	
Never need glasses for computer		.675
Multifocal (n = 20)	13 (65)	
Monovision (n = 21)	16 (76)	
No difficulty or a little difficulty using computer without glasses		.048
Multifocal (n = 19)	14 (74)	
Monovision (n = 21)	20 (95)	

UNVA = uncorrected intermediate vision acuity

bilateral implantation of AcrySof SN60WF IOLs for monovision is a perfect solution for presbyopia. However, both are good compromises for patients who desire a good range of vision and a high level of spectacle independence.

At the 3-month follow-up visit, all patients had a binocular UDVA of 20/30 or better. Sixty-two percent (13/21) in the multifocal IOL group and 50% (11/22) in the monovision group achieved a UDVA of 20/20 (P=.432). In a study by Chiam et al.[1] of 50 patients with bilateral AcrySof ReSTOR SA60D3 IOLs, 46% achieved a UDVA of 20/20 and 84% of 20/25 UDVA 6 months postoperatively. In the present study, 90% (19/21) in the multifocal IOL group and 86% (19/22) in monovision group achieved a UDVA of 20/25 or better. Finkelman et al.[7] report a UDVA of 20/30 or better in 24 (96%) of 25 pseudophakic monovision patients. Regarding spectacle independence, in our study 81% (17/21) in the multifocal IOL group and 71% (15/21) in monovision group reported that they never needed to wear glasses to drive. In our study, the multifocal IOL group did better than the monovision group in all 3 distance-vision components, which was probably because the target in both eyes in the multifocal IOL group was plano while only 1 eye in the monovision group was targeted for plano. However, there was no statistically significant difference in the 3 components between the 2 groups.

Historically, a challenge for pseudophakic monovision patients has been night driving,[B] and 14% (3/21) of monovision patients in our study reported having moderate difficulty driving at night. Having backup distance glasses for night driving typically solves this problem. Most patients in the multifocal IOL group reported halo symptoms, while the opposite was true for monovision patients. Patients in the multifocal IOL group also had more glare complaints. One patient in the multifocal IOL group reported night driving as being extreme difficulty, and another patient in that group stopped driving at night because of halo and glare. Halo and glare, not visual acuity or spectacle independence per se, were often the main complaints of patients in the multifocal IOL group. Halo and glare were not major concerns for our monovision patients. Halo and glare symptoms with multifocal IOLs have been well described.[1,3,4,14,15]

In this study, all 21 patients in the multifocal IOL group and 91% of 22 monovision patients achieved a bilateral UNVA of 20/25 (P=.157). A major review by Leyland and Pringle[16] noted that multifocal IOLs typically provide good vision for both distance and near. In the study by Chiam et al.,[1] 50 patients with bilateral AcrySof SN60D3 ReSTOR IOLs and 50 patients with bilateral ReZoom NXG1 zonal-progressive IOLs (Abbott Medical Optics) had a mean bilateral UNVA of 20/26 (median 20/25; range 20/20 to 20/50).

Table 5. Three-month postoperative stereo vision without glasses.

	Seconds of Arc							
Group	40	50	60	80	100	140	200	400
Multifocal (n)	9	2	0	1	5	2	2	0
Monovision (n)	3	2	3	2	5	1	4	2

n = number of patients

Table 6. Cochran-Armitage trend test for postoperative stereo vision analysis (P=.076).

Study Group	Pt (n)	Mean ± SD	Median
Multifocal	21	81.90 ± 52.02	50.00
Monovision	22	127.27 ± 103.89	100.00

Pt = patients

Table 7. Postoperative difficulty with going down steps, stairs, or curbs in dim light or at night without glasses ($P=.716$).

Group	No Difficulty	A Little Difficulty	Moderate Difficulty	Extreme Difficulty	Mean ± SD	Median
Multifocal	12	7	2	0	1.52 ± 0.68	1.0
Monovision	13	8	1	0	1.45 ± 0.60	1.0

A recent study by Cionni et al.[2] also found that ReSTOR SN60D3 IOLs provided excellent UNVA.

In our study, 77% (17/22) of monovision patients and 67% (14/21) of multifocal IOL patients reported never needing glasses for newspaper reading ($P=.331$). In a study of 38 monovision patients and 22 multifocal IOL patients, Ito and Shimizu[8] found better reading acuity and reading ability in the monovision group; however, the multifocal IOL in their study was the Array, which has a refractive multifocal design. Ito and Shimizu discuss how diffractive IOLs provided better visual performance with less glare and halo and reduced the need for spectacles postoperatively. In our study, multifocal IOL patients had better near vision but not better spectacle independence for newspaper reading. A possible reason is that reading a newspaper may require an acuity of only 20/40 and visual acuity is not the only factor in reading.

Table 8. Overall satisfaction and willingness to recommend to family members.

Parameter	Patients (n)	
	Multifocal Group (n = 21)	Monovision Group (n = 22)
Overall satisfaction with cost		
Very happy	12	18
OK, not too bad	8	4
Not worth the money	1	0
P value	.061	
Recommend to family members		
Absolutely	14	18
Maybe	1	3
Not sure	5	1
Never	1	0
P value	.077	
Overall satisfaction		
Excellent	9	13
Very good	8	4
Good	3	4
Fair	1	1
Poor	0	0
P value	.639	

At the 3-month postoperative visit, the bilateral UIVA was 20/40 or better in 9.5% (2/21) in the multifocal IOL group and 72.7% (16/22) in the monovision group ($P<.001$). Although the 2 groups had comparable spectacle independence for computer work without glasses (65% in multifocal IOL group and 76% in monovision group; $P=.675$), more patients in the monovision group (20/21; 95%) than in the multifocal IOL group (14/19; 74%) reported having less difficulty using a computer without glasses ($P=.048$). This probably was related to the difference in intermediate vision between the 2 groups. Chiam et al.[1] also found that patients with ReSTOR SN60D3 IOLs had a higher rate of needing spectacle for computer work than patients with ReZoom NXG1 IOLs. One limitation of our study was that the AcrySof ReSTOR model was the SN60D3, which is an early-generation multifocal IOL with a spherical apodized diffractive design. At the time of the study design, the SN60D3 model was the newest available. The newer generation AcrySof ReSTOR SN6AD1 model may provide better intermediate vision; in recent studies,[17,18] patients with the newer SN6AD1 model with a +3.00 D addition (add) had better intermediate vision than patients with the older model with a +4.00 D add.

Stereopsis is a major concern with monovision. Overall, stereo vision was better in the multifocal IOL group in our study. Although fine stereo vision at near without glasses was better in the multifocal IOL group than in the monovision group, the difference between the 2 groups was not statistically significant ($P=.076$). For the gross stereo function of going down steps, stairs, or curbs in dim light or at night without glasses, the 2 groups were very similar, with a slightly more favorable mean score in the monovision group than in the multifocal IOL group ($P=.716$). In a study of 100 patients with bilateral pseudophakia, Hayashi et al.[19] report a mean stereoacuity of 57.1 ± 36.9 arcsec. Hayashi et al.'s study also found that SE anisometropia was the main factor affecting stereopsis, although visual acuity, pupil size, and age could also play a role. In a study of 26 pseudophakic monovision patients by Finkelman et al.,[7] the mean postoperative anisometropic SE was 1.38 ± 0.42 D and the mean stereopsis, 175.6 arcsec (median 70 arcsec). As in the present study, Finkelman et al.[7] found no significant problems with stereo vision in

their patients with pseudophakic monovision. In a study by Ito et al.,[9] the mean anisometropia was 2.27 D in patients with pseudophakic monovision; 87% of patients reached 100 arcsec of stereo vision without correction. An advantage of monovision is that it is reversible and that full binocular vision and stereo vision are easily restored with a simple pair of backup glasses. The need for further refractive procedures or IOL exchange in monovision is rare.

A conventional IOL is still often the best choice for presbyopic correction.[C] Preoperative patient selection, an anisometropia tolerance test, accurate biometry, corneal astigmatism correction, and flawless surgical skills are prerequisites to successful monovision. The results in our study suggest that pseudophakic monovision is one option to manage postoperative presbyopia; however, ours was not a randomized study and patient selection was biased. Monovision may not be an option for every patient and certainly should not be used without adequate patient counseling, an informed patient decision, and preoperative anisometropia tolerance screening.

Astigmatism correction is important for monovision, modified mini monovision or full range; otherwise, it is hard to achieve a high rate of spectacle independence.[D,E] This is especially true for the dominant eye for distance vision.

Overall satisfaction, satisfaction with cost, and the willingness to recommend the same IOL and procedure were high in both groups in our study, with slightly more favorable scores in the monovision group but no statistically significant difference between the 2 groups. In our study, 95.24% of ReSTOR patients (20/21) and 95.45% of monovision patients (21/22) reported their overall satisfaction as good, very good, or excellent ($P=.639$). Greenbaum[20] also found a cost advantage to pseudophakic monovision over multifocal IOLs.

Limitations of our study include the small number of patients, which limited the power of many comparisons; the inability to randomize between the 2 groups; and that the newest generation AcrySof ReSTOR IOL was not available at the early part of this study. The newer model may have provided better intermediate vision because it moves the reading distance farther from the eye[17,18]; in addition, the aspheric surface may yield better visual quality than the older spherical IOL.[21]

In summary, the AcrySof ReSTOR IOL has become popular in recent years in the management of presbyopia in cataract patients. The IOL provided good distance and near vision, although intermediate and computer vision was not very satisfactory. Although glare and halos can be very disturbing to some patients, bilateral implantation of the IOL remains a good option for patients who do not drive much at night but desire good vision and spectacle independence. Monovision can provide comparable good distance and near vision and more favorable intermediate and computer vision with less symptomatic glare and halos than multifocal IOLs. Overall, monovision patients in our study had a more favorable satisfaction level than multifocal IOL patients.

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