Improvements in vision-related quality of life with AcrySof IQ SN60WF aspherical intraocular lenses

I-Chan Lin, MD, I-Jong Wang, MD, PhD, Mei-Shu Lei, MD, PhD, Luke L.-K. Lin, MD, PhD, Fung-Rong Hu, MD

PURPOSE: To compare vision-related quality of life and higher-order aberrations (HOAs) with an aspherical intraocular lens (IOL) (AcrySof IQ SN60WF) and a conventional spherical IOL (AcrySof SA60AT) (both Alcon) after phacoemulsification.

SETTING: Department of Ophthalmology, National Taiwan University Hospital, Taipei, Taiwan, Republic of China.

METHODS: Sixty-five patients were prospectively randomized to receive an Alcon AcrySof IQ SN60WF IOL (30 eyes) or an AcrySof SA60AT IOL (35 eyes). All patients had a complete ophthalmologic examination including uncorrected visual acuity, best spectacle-corrected visual acuity (BSCVA), and wavefront analysis preoperatively and 3 months postoperatively. Patients also completed the National Eye Institute Visual Functioning Questionnaire (NEI VFQ-25) to evaluate vision-related quality of life.

RESULTS: The mean postoperative BSCVA (logMAR) was 0.09 ± 0.07 (SD) in the aspherical IOL group and 0.12 ± 0.08 in the spherical IOL group; the difference was not statistically significant. Spherical aberrations were statistically significantly lower in the aspherical IOL group (mean 0.12 ± 0.23 μm) than in the spherical IOL group (mean 0.33 ± 0.20 μm) ($P = .001$). Both IOL types improved most aspects of patients' vision-related quality of life. The aspherical IOL group had clinically significant improvement on more NEI VFQ-25 subscales, although the difference between groups in vision-related quality of life was not statistically significant.

CONCLUSION: Eyes with the aspherical AcrySof IQ SN60WF IOL had reduced HOAs and spherical aberrations compared with eyes with the spherical AcrySof SA60AT IOL; however, there were no statistically significant differences in visual acuity or vision-related quality of life between groups.

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Cataract extraction techniques have evolved from intracapsular lens extraction to small-incision phacoemulsification, and better intraocular lens (IOL) materials and designs have improved the quality of vision after surgery. Despite the success of modern cataract surgery with IOL implantation and an adequate refractive outcome, patients are often bothered by visual side effects, most often glare and halos, and other health-related quality-of-life problems caused by the discrepancy between the optical designs of the IOLs and the optical properties of the individual eye. Wavefront analysis has shown that patients with conventional spherical IOLs have a large amount of spherical aberration postoperatively.[1] Based on these observations, an aspherical IOL was designed to optimize image quality by limiting ray diffraction. In a series of clinical trials comparing the aspherical IOL with a variety of conventional spherical IOLs, the aspherical IOL was found to reduce spherical aberrations and thus improve contrast sensitivity.[2–5] Although various tests have been used to measure subjective visual function and health-related quality-of-life after aspherical IOL implantation, the degree of improvement remains unclear.

The 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) measures the self-reported, vision-targeted health status of people with chronic eye disease.[6,7] The survey measures the effect of visual disability and visual symptoms on general health, such as emotional well-being and social functioning, and on daily visual function. It also measures the extent to which the eye disease affects a patient's

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ability to live without pain, work productively, and interact with loved ones.[7] The NEI VFQ-25 has been used with people who are free of eye disease as well as with those with eye disease such as age-related macular degeneration, cataract, glaucoma, and Graves ophthalmopathy.[6,8,9] It also has been used to evaluate the subjective visual function changes after various intraocular procedures such as cataract surgery and macular hole surgery.[10,11] Therefore, the NEI VFQ-25 is useful in measuring health-related quality of life in patients with various eye diseases and treatments.

The purpose of this study was to compare the vision-related quality of life using the NEI VFQ-25 questionnaire, higher-order aberrations (HOAs), and visual acuity in eyes with an aspherical IOL (AcrySof IQ SN60WF) and eyes with a spherical IOL (AcrySof SA60AT) (both Alcon Laboratories).

PATIENTS AND METHODS

This prospective randomized parallel-group design study comprised patients having unilateral cataract extraction and implantation of an AcrySof IQ SN60WF IOL (aspherical group) or AcrySof SA60AT IOL (spherical group) from September 2006 to March 2007. Table 1 shows the characteristics of the 2 IOLs. The study was performed at National Taiwan University Hospital. The protocol was approved by the Ethical Committee and was in compliance with the Declaration of Helsinki. All patients provided informed consent.

Inclusion criteria were the presence of cataract in both eyes, age between 50 years and 80 years, and pupil diameter measured by a handheld pupil gauge of 3.5 mm or more under mesopic light conditions. Patients with corneal astigmatism less than 2.0 diopters (D) and potential acuity meter readings better than 0.2 logMAR units were eligible for inclusion. Exclusion criteria were complicated cataract, corneal opacities or irregularity, dry eye, amblyopia, anisometropia, surgical complications, IOL tilt or decentration, coexisting ocular pathology, glaucoma, nondilating pupil, history of intraocular surgery, laser therapy, retinopathy, optic nerve or macular disease, refusal or unable to maintain follow-up, and posterior capsule opacification (PCO). Eyes with intraoperative complications (eg, posterior capsule tear, vitreous loss, zonular dialysis, uveal manipulation) were also excluded.

Table 1. Characteristics of the 2 IOLs used in the study.

Characteristic	AcrySof IQ SN60WF	AcrySof SA60AT
Optic		
Design	Square edge	Square edge
Diameter	6.0	6.0
Material	Hydrophobic acrylic	Hydrophobic acrylic
Refractive index	1.55	1.55
Loop		
Design	One piece	One piece
Material	Hydrophobic acrylic	Hydrophobic acrylic
Blue-light filtering	Yes	No
Aspherical design	Yes	No

Patient Evaluation

Patients had a complete ophthalmological examination preoperatively and 1, 7, 21, and 90 days after surgery. The examination included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA) (Early Treatment Diabetic Retinopathy Study chart), biomicroscopy, autorefraction (KR 7100P, Topcon), intraocular pressure by applanation tonometry, and fundus evaluation. Biometry was performed by applanation A-scan ultrasonography (Sonomed Ultrasound A-1500), and IOL power was calculated using the SRK/T formula. Wavefront analysis was performed 3 months after surgery with a Hartmann-Shack sensor (Zywave, Bausch & Lomb Surgical). The wavefront maps were analyzed with 6.0 mm pupils and up to the 6th order of Zernike coefficients.

Surgical Technique

Clear corneal phacoemulsification and IOL implantation were performed by the same surgeon (I-J.W.) using an identical technique to minimize differences in surgically induced aberrations between groups. Surgery comprised topical anesthesia, a 3-step clear corneal incision (2.75 mm) at 180 degrees (temporal in both eyes), a 5.0 mm continuous curvilinear capsulorhexis, phacoemulsification using the stop-chop technique, IOL implantation with an injector, IOL centration, and a sutureless incision. The IOL power ranged from 18.0 to 26.0 D.

Questionnaire

Subjective quality of vision was evaluated with the NEI VFQ-25. Patients completed the self-administered questionnaire twice. The first time was preoperatively, when patients had bilateral cataract (baseline), and the second time was 90 days after surgery (second assessment). In general, questionnaires were completed without assistance; however, if the patient requested, explanations of the questions were given.

The NEI VFQ-25 contains 25 questions. Each question is assigned to 1 of 12 subscales. The subscales include general health, general vision, ocular pain, difficulty with distance, difficulty with near tasks, dependency on others, role limitation, mental health, social function, driving, peripheral vision, and color vision difficulty. For each question, the

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From the Department of Ophthalmology (I-C. Lin, Wang, L. Lin, Hu), National Taiwan University Hospital, and Graduate Institute of Preventive Medicine (Lei), College of Public Health, National Taiwan University, Taipei, Taiwan, Republic of China.

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Corresponding author: Dr. I-Jong Wang, Department of Ophthalmology, National Taiwan University Hospital, 7 Chung-Shan South Road, Taipei, Taiwan, Republic of China. E-mail: ijong@ms8.hinet.net.

answer is converted into a 100-point scale, with 100 being the best score and 0 the worst score. One or more questions are specific to each subscale; therefore, the subscale score is the average of 1 or more questions specific to the subscale.[7]

Statistical Analysis

All data are reported as mean ± SD. Visual acuity is reported as logMAR values. Statistical analysis was by the Student *t* test for analysis of variance and the *Z* test for analysis of proportions.

For each NEI VFQ-25 subscale, 2-tailed 2-sample *t* tests were used to compare the treatment effect between the 2 IOL groups based on the change in scores from baseline to the second assessment. Two-tailed paired *t* tests were used to test for a significant within-group difference in mean change from baseline to the second assessment. The Bonferroni method was used to adjust for multiplicity. To better represent the magnitude of change on each scale, the mean change was converted to a standardized effect size by dividing the mean change on each subscale by the observed baseline standard deviation of scores on each scale for the pooled study sample.[12]

Table 2. Patient demographics.

Characteristic	IOL Group		*P* Value
	Aspherical	Spherical	
Patients/eyes (n)	30/30	35/35	
Male/female (%)	30.00/70.00	34.28/65.72	.712
Mean age (y) ± SD	67.77 ± 8.78	71.06 ± 7.36	.10
Mean AL (mm) ± SD	23.60 ± 1.47	23.95 ± 2.11	.44
Mean IOL power (D) ± SD	20.12 ± 2.56	19.69 ± 5.08	.66
Mean preoperative BSCVA (logMAR) ± SD			
Preop	0.76 ± 0.39	0.76 ± 0.33	.97
Final	0.09 ± 0.07	0.12 ± 0.08	.11
Mean final UCVA (logMAR) ± SD	0.26 ± 0.09	0.26 ± 0.13	.92

AL = axial length; BSCVA = best spectcale-corrected visual acuity; IOL = intraocular lens; UCVA = uncorrected visual acuity

RESULTS

Of the 74 eyes included in the study, 9 (12.16%) were excluded for intraoperative capsule rupture (1), cystoid macular edema (1), retinal detachment (1), or loss to follow-up (6). Of the 65 eyes that remained in the study, 30 had implantation of the aspherical IOL and 35, of the spherical IOL. All eyes had a mean postoperative BSCVA of 20/32 or better. There were no significant differences between the 2 IOL groups in age, sex, axial length, IOL power, mean preoperative BSCVA, mean postoperative BSCVA, or mean postoperative and UCVA. Table 2 shows the patients' demographics.

Before surgery, wavefront aberrations could be detected in only 8 of 65 eyes due to interference of cataract on the measurement. Therefore, preoperative wavefront analysis was not included in the study. The postoperative root-mean-square (RMS) values for total HOAs calculated with a 6.0 mm pupil were lower in the aspherical IOL group (mean 0.51 ± 0.45 μm) than in the spherical IOL group (mean 0.77 ± 0.36 μm) ($P = .02$). Further analysis using Zernike polynomial decomposition showed spherical aberration Z(4,0) was significantly lower in the aspherical IOL group (mean 0.12 ± 0.23 μm) than in the spherical IOL group (mean 0.33 ± 0.20 μm) ($P = .001$) (Figure 1).

Table 3 shows the baseline NEI VFQ-25 scores. The aspherical IOL group had a slightly higher mean score on the peripheral vision subscale. If adjustments for the effects of multiple testing had been made, these differences would not have been statistically significant.

Table 4 shows the changes in mean NEI VFQ-25 scores from baseline to the second assessment. In both IOL groups, improvements were observed from baseline to the second assessment on all vision-specific subscales and in the composite score. Numerically, the largest improvement in both groups was in the driving subscale. The domain exceeded a 20-point improvement from baseline. Figure 2 shows the degree of the mean changes in all subscales converted to standardized effect sizes.

Table 4 also shows a comparison of the NEI VFQ-25 scores between the 2 groups. The aspherical group had a slightly higher mean score on the distance activity subscale, but the difference was not statistically significant. Although there were similar improvements in both groups on the driving subscales, the following 3 items were compared separately to ascertain whether there was a difference between the 2 groups in the change in driving condition: (1) in the daytime; (2) at night; (3) in difficult conditions (eg, bad weather, heavy traffic). Table 5 shows the comparisons. Both groups had a statistically significant improvement,

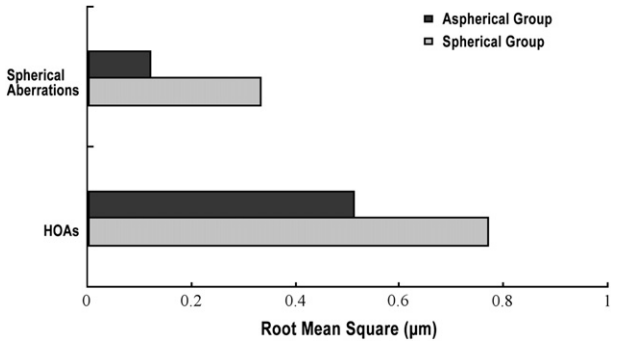

Figure 1. Comparison of RMS of spherical aberrations and total HOAs between the 2 groups.

Table 3. Mean NEI VFQ-25 questionnaire scores at baseline by group.

Subscale	Mean Score ± SD: Aspherical IOL (n = 30)	Mean Score ± SD: Spherical IOL (n = 35)	*P* Value
General health	50.83 ± 26.65	39.83 ± 21.97	.07
General vision	49.16 ± 20.21	41.96 ± 18.07	.15
Ocular pain	63.75 ± 15.86	58.48 ± 11.31	.15
Near activities	62.76 ± 15.89	56.69 ± 19.65	.19
Distance activities	71.94 ± 14.92	64.81 ± 15.44	.08
Social function	85.41 ± 17.39	82.14 ± 19.66	.50
Mental health	55.00 ± 20.26	54.01± 19.99	.85
Role difficulties	52.50 ± 23.07	48.21 ± 23.98	.49
Dependency	64.44 ± 21.65	54.46 ± 24.05	.10
Driving	42.18 ± 33.81	52.38 ± 30.73	.39
Color vision	82.50 ± 22.88	82.14 ± 25.32	.95
Peripheral vision	78.33 ± 19.40	66.96 ± 21.57	.04*
Composite	63.52 ± 13.10	59.70 ± 14.11	.29

IOL = intraocular lens
*Not statistically significant after Bonferroni adjustment for multiple testing

and the difference between the groups was not statistically significant. Because it was thought that the item asking about "difficulty going down steps, stairs, or curbs in dim light or at night" would be associated with the patient's spherical aberrations, this item was analyzed separately. The aspherical IOL group had a slightly higher mean score. If adjustments for the effects of multiple testing had been made, the differences would not have been statistically significant.

Three months after surgery, there were no cases of posterior capsule folds or PCO.

DISCUSSION

Our prospective randomized controlled study examined and compared subjective visual function in eyes with an aspherical IOL (AcrySof IQ SN60WF) and eyes with a spherical IOL (AcrySof SA60AT). The 2 IOLs have identical dimensions and materials except the AcrySof IQ SN60WF IOL has an aspherical surface and blue-light-filtering function. We found that the RMS values of spherical aberrations and total HOAs were lower in eyes with the aspherical IOL than in eyes with the spherical IOL. Although the differences in visual acuity and NEI VFQ-25 questionnaire results were not significant between the 2 groups, the aspherical IOL group had improvement in more NEI VFQ-25 subscales. This indicates that the objective optical performance of the aspherical IOL is associated with some subjective improvement in patients' daily living, although there was no statistically significant difference between the 2 IOL groups.

Both IOL groups had significant improvement in all vision-related subscales. Our results confirm those in previous studies of the benefits of cataract surgery,[10,13] which found large improvement in vision-related functions. In our study, the degree of improvement was expressed by a standardized effect size. According to commonly used guidelines, an effect size of 0.8 or greater is considered important; 0.5, moderate; and 0.2, small.[12] The aspherical IOL group had significant improvement in 6 subscales (general vision, ocular pain, near activities, distance activities, mental health, peripheral vision). The spherical IOL group had significant improvement in only 2 subscales (ocular pain, distance activities). The improvements in distance activity were significant in both groups,

Table 4. Mean change in NEI VFQ-25 scores from baseline to second assessment.

Subscale	Aspherical IOL (n = 30) Mean Change ± SD	*P* Value	Spherical IOL (n = 35) Mean Change ± SD	*P* Value	*P* Value for Treatment Comparison
General health	0.83 ± 4.56	.032*	2.58 ± 7.74	.08	.29
General vision	17.5 ± 11.65	<.0001	12.09 ± 12.70	<.0001	.08
Ocular pain	13.33 ± 9.81	<.0001	10.83 ± 10.21	<.0001	.33
Near activities	15.55 ± 11.10	<.0001	14.44 ± 10.92	<.0001	.69
Distance activities	20.00 ± 8.64	<.0001	16.11 ± 9.77	<.0001	.10
Social function	8.75 ± 8.77	<.0001	10.00 ± 10.06	<.0001	.61
Mental health	18.95 ± 8.44	<.0001	15.41 ± 9.81	<.0001	.13
Role difficulties	10.83 ± 9.07	<.0001	15.00 ± 11.55	<.0001	.13
Dependency	12.5 ± 8.95	<.0001	15.00 ± 10.12	<.0001	.31
Driving	23.61 ± 7.27	<.0001	20.41 ± 4.82	<.0001	.18
Color vision	14.16 ± 12.6	<.0001	12.50 ± 12.71	<.0001	.61
Peripheral vision	17.5 ± 11.65	<.0001	15.83 ± 12.25	<.0001	.59
Composite	13.95 ± 4.69	<.0001	13.02 ± 5.79	<.0001	.49

IOL = intraocular lens
*Not statistically significant after Bonferroni adjustment for multiple testing

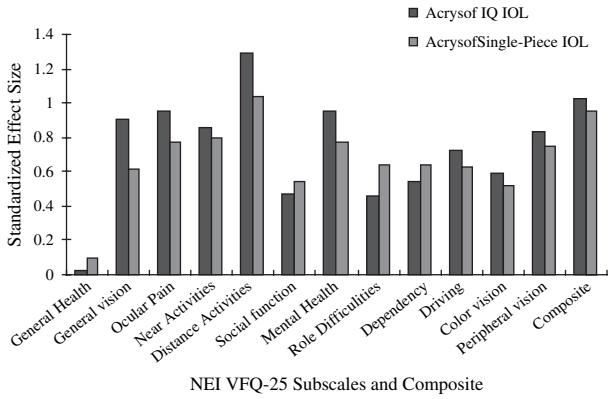

Figure 2. Changes in NEI VFQ-25 scores expressed as scales with standardized effect size.

although they were greater in the aspherical IOL group. Our results are similar to those in a study by Denoyer et al.,[14] who used the Activities of Daily Vision Scale to compare aspherical Tecnis Z9000 IOLs and spherical CeeOn Edge 911 IOLs. They found better subjective quality of distance vision with the Tecnis Z9000 IOL.

The Moorfields IOL Study Group[15] used the Visual Function-14 (VF-14) test to compare vision-related quality of life after binocular implantation of a Tecnis Z9000 IOL and an AcrySof MA60AC IOL and found that subjective visual function was similar between the 2 groups. We used the NEI VFQ-25 questionnaire to compare the 2 IOLs in our study because it has more dimensions than VF-14 and it includes items associated with the effect of spherical aberrations on the quality of life (eg, "driving at night and in difficult conditions" and "difficulty going down steps, stairs, or curbs in dim light or at night"). There was greater improvement in the item "difficulty going down steps, stairs, or curbs in dim light or at night" in the aspherical IOL group; however, the differences in driving scores between the 2 IOL groups were not significant. We attribute these findings to the fact that most of our patients lived in cities and many did not drive. More specific questions associated with the severity and frequency of glare symptoms were not evaluated in the NEI VFQ-25 questionnaire. More significant differences in subjective visual function between eyes with aspherical IOLs and eyes with spherical IOLs might emerge with questionnaires that are more specific regarding glare-related symptoms.

Table 5. Mean change in scores (0 to 100 scale) on selected NEI VFQ-25 items from baseline to second assessment.

Item	Mean ± SD: Aspherical IOL (n=30)	Mean ± SD: Spherical IOL IOL (n=35)	*P* Value Between IOLs
Going down steps, stairs, or curbs in dim light or at night	25.00 ± 14.68	17.74 ± 13.21	.04*
Driving in daytime	18.42 ± 14.04	13.46 ± 12.97	.32
Driving at night	31.25 ± 14.43	26.92 ± 12.33	.39
Driving in difficult conditions	26.66 ± 11.44	28.84 ± 13.86	.65

IOL = intraocular lens
*Not statistically significant after Bonferroni adjustment for multiple testing

Our study also found no differences between the 2 IOL groups in color vision using the NEI VFQ-25 questionnaire. These findings are consistent with those in a study by Espindle et al.[13] in which the NEI VFQ-39 was used to compare the AcrySof Natural IOL and the AcrySof single-piece IOL. Both have a blue-light-filtering chromophore that gives them a visible yellow tint. Our results confirm that color vision does not change after implantation of blue-light-filtering IOLs.

Wavefront analysis in previous studies has consistently shown reductions in spherical aberrations after implantation of the AcrySof IQ SN60WF IOL versus standard spherical IOLs[3,5]; however, contrast sensitivity testing results have been inconsistent in these studies.[3,5,16] Similar to findings in previous studies, we also observed a reduction in spherical aberrations and HOAs in eyes with an AcrySof IQ SN60WF IOL. We observed no significant differences in visual acuity or driving scores, the cause of which might be related to change in contrast sensitivity and mesopic or scotopic visual acuity. In contrast, Mester et al.[17] found better mesopic visual acuity after implantation of aspherical IOLs than after implantation of standard spherical IOLs.

Our results indicate aspherical IOLs might have visual benefits by reducing spherical aberrations. Nevertheless, some limitations of our study could affect the assessment of spherical aberration–related visual symptoms. For example, the centration of the IOL also plays a role in these symptoms. Altmann et al.[18] report that decentration, even as little as 0.3 mm, might be sufficient to negate the theoretical optical advantages of the Tecnis Z9000 aspherical IOL. In our study, we could not detect subtle IOL decentration and we did not measure IOL tilt, factors that might have affected our results.

In summary, the aspherical design of the AcrySof IQ SN60WF IOL reduced spherical aberrations and HOAs. However, there were no significant differences in visual acuity measurement or vision-related quality of life between the spherical IOL and aspherical IOL groups. Questionnaires that are specific to glare-related

symptoms are needed to detect the full benefits of subjective vision in eyes with aspherical IOLs.

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First author:
I-Chan Lin, MD

Department of Ophthalmology, National Taiwan University Hospital, Taipei, Taiwan, Republic of China