ARTICLE

Pupil influence on the quality of vision in rotationally asymmetric multifocal IOLs with surface-embedded near segment

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Purpose: To evaluate the influences of preoperative pupil parameters on the visual outcomes of the SBL-3, a rotationally asymmetric multifocal intraocular lens (IOL) with a surface-embedded near segment.

Setting: Cathedral Eye Clinic, Belfast, Northern Ireland, United Kingdom.

Design: Retrospective comparative case series.

Methods: Postoperatively, patients divided into 4 groups according to their pupil size as follows: Group A: 2.50 to 2.99 mm, Group B: 3.00 to 3.50 mm, Group C: 3.51 to 4.00 mm, and Group D: 4.01 to 4.50 mm. The uncorrected distance (UDVA), intermediate (UIVA), and near (UNVA) visual acuities, IOL centration and tilt, and quality of vision (QoV) questionnaires were compared between the 4 groups for 18 months postoperatively.

Results: The study comprised 90 patients (180 eyes). The mean preoperative pupil (photopic and mesopic) diameter was 4.3 mm $\pm$ 0.3 (SD) and 5.6 $\pm$ 1.4 mm, respectively, which decreased to 3.8 $\pm$ 0.7 mm and 4.9 $\pm$ 1.2 mm, respectively, at 18 months. Eighteen months postoperatively, both photopic and mesopic pupil groups had a statistically significant reduction in size from preoperative levels. No significant differences in UDVA, UIVA, and UNVA were found between the groups ($P > .001$). Significant differences in the QoV questionnaire day scores and night scores were found between the 4 groups ($P < .001$).

Conclusions: The rotationally asymmetric multifocal IOL provided excellent optical performance during 18-months follow-up. The preoperative photopic pupil is an important parameter for consideration of this type of IOL because smaller pupils have a significant negative subjective impact on QoV.

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The aim of multifocal intraocular lens (IOL) use is to restore distance, intermediate, and near visual function after cataract extraction or refractive lens exchange.[1,2] Various methods have been implemented to achieve some degree of pseudoaccommodation, such as aiming for myopic astigmatism,[3] targeting 1 eye for myopia (monovision),[4] or multifocal IOL implantation.[5]

The new generation of refractive rotationally asymmetric multifocal IOLs aims to alleviate the occurrence of optical side effects.[2,6] Asymmetric multifocal IOLs, such as the SBL-3 (Lenstec, Inc.), in general provide both far and near vision by splitting light to 2 or more focal points.[6] The SBL-3 is an asymmetric multifocal IOL with a +3.0 diopter (D) near portion and a seamless transition zone between the distance section and the near section (Figure 1). It is crucial that ophthalmologists help elderly patients retain the ability to see a range of distances, enabling multiple daily-life scenarios including driving.[7] Anecdotal evidence from patients and a case report by Pazo et al.[8] of bilateral implantation of asymmetric multifocal IOLs suggests that because of the asymmetric design of the IOL, patients can have a reduced quality of vision (QoV) while driving and in bright supermarket lighting conditions.[9] The center of the pupil has a tendency to move slightly nasally when constricting.[10] Therefore, a small photopic pupil can alter the amount of incident light directed to either the distance or near section. The visual performance and subjective experience of multifocal IOLs is dependent on pupil size.[11–13] A case report by Pazo et al.[8] and Montés-Micó et al.[13] highlights that a variation in pupil size affects the relative

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Figure 1. The asymmetric multifocal IOL.

exposure of sections of IOLs. Kawamorita and Uozato's[12] of zonal progressive multifocal IOLs found that a pupil diameter of 3.4 mm or larger was desirable to enhance near vision.

However to our knowledge, there is no report of the influence of pupil diameter on visual acuity and subjective QoV in patients with the SBL-3 IOL. The objective of our study was to determine whether pupil size is correlated with QoV in eyes with this asymmetric multifocal IOL.

PATIENTS AND METHODS

This retrospective study included cataract patients that had bilateral phacoemulsification followed by implantation of the SBL-3 asymmetric multifocal IOL. The near section of the IOL was placed in an inferonasal position within a dilated pupil. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee. All patients received thorough informed consent detailing individual benefits, risks, and alternatives to surgery. In addition, all patients signed a consent form indicating their permission to publish their anonymized results.

Exclusion criteria were previous ocular surgery; ocular disease such as corneal opacity; corneal irregularity; dry eye; any degree of amblyopia, glaucoma, or retinal disease; and complications during surgery.

Photopic pupil diameters were assessed using the OPD-Scan II scanning system (Nidek Co., Ltd.). To determine the effect of pupil size on the QoV during the day, patients were divided into 4 groups based on the photopic pupil diameter as follows: 2.50 to 2.99 mm (Group A), 3.00 to 3.50 mm (Group B), 3.51 to 4.00 mm (Group C), and 4.01 to 4.50 mm (Group D).

Preoperative and Postoperative Examinations

Preoperatively, all patients had a full ophthalmic examination including uncorrected measurement of logarithm of the minimum angle of resolution (logMAR) uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) at 4 m using the Early Treatment of Diabetic Retinopathy Study Chart 1. The uncorrected near visual acuity (UNVA) and corrected near visual acuity (CNVA) were measured at 40 cm with Radner reading charts under standard mesopic lighting conditions. Radner charts allow direct conversion; that is, 0.2 logMAR distance acuity is comparable to 0.2 logarithm of the reading acuity determination reading acuity with high correlation at 40 cm to a logMAR equivalent for size of letters. The uncorrected intermediate visual acuity (UIVA) and corrected intermediate visual acuity were measured at 70 cm. Further examinations included keratometry, topography, and autorefraction (OPD-Scan aberrometer, Nidek Co., Ltd.), subjective refraction, slitlamp examination, Goldmann tonometry, dilated fundoscopy and partial coherence interferometry (IOLMaster, version 4.3, Carl Zeiss Meditec AG), and pupil diameter and κ/P-Dist (P-Dist being the distance between the pupil center and the coaxially sighted corneal light reflex) with the pupil-scanning component of the aberrometer.

Partial coherence interferometry was used to measure the corneal curvature, anterior chamber depth, and axial length (AL) and perform the subsequent IOL calculation using the Hoffer Q formula[14] for eyes with an AL less than 22.0 mm, the SKR/T formula[15] for eyes with an AL from 22.0 to 25.0 mm, and the Haigis formula[16] for eyes with an AL over 25.0 mm (A-constant 118.2 for SRK/T; a0 constant 0.83, a1, a2 for Haigis). Emmetropia was the target in all cases.

Postoperatively, patients were evaluated at 1 day, 1 month, 3 months, 6 months, 12 months, and 18 months. In addition to the above-mentioned examinations, the UIVA, UNVA, distance-corrected intermediate visual acuity, and distance-corrected near visual acuity were assessed looking for evidence of differences in their mean or in their level of variation through assessment of outlier differences. Posterior capsule opacification (PCO) was graded by an ophthalmologist as follows: 1 = none, 2 = mild (early development of PCO), 3 = moderate (increased PCO with early visual acuity changes not requiring secondary capsulotomy), or 4 = severe (PCO affecting vision and requiring neodymium:YAG laser capsulotomy).

Surgical Technique

The same experienced surgeon (J.E.M.) performed all surgeries. The steep axis was marked in all patients preoperatively at the slitlamp. Sub-Tenon or topical anesthesia was administered in all cases. Standard sutureless on-steep axis corneal phacoemulsification (2.75 mm incision) was performed through a 5.0 mm anterior capsulorhexis. After irrigation/aspiration of the cortex, the multifocal IOL above was implanted using the recommended injector cartridge. All residual ophthalmic viscosurgical device was removed before an intracameral antibiotic injection (cefuroxime). When on-axis surgery was not possible, a 2.75 mm superotemporal corneal position was used to minimize induced astigmatism. A capsular tension ring (CTR) was used in all eyes to benefit tilt and decentration. Postoperative topical therapy included 1 drop of ofloxacin 0.3% (Exocin) 4 times daily for 2 weeks, 1 drop of ketorolac trometamol 0.5% (Acular) 2 times daily for 1 month, and 1 drop of dexamethasone 0.1% (Maxidex) 4 times daily for 3 weeks.

Pupil Assessment

All pupil assessments using the pupil-scanning system and were performed in the same test room, which had a constant ambient illumination of 0.63 lux. To standardize the postoperative pupil assessments, the ambient lighting was continuously monitored using a handheld illuminometer light meter (Sekonic Corp.). Concurrently, before the pupil size was measured, the patient's orbital region illumination was recorded and maintained at 0.63 lux to ensure a minimum discrepancy between patient groups. The minimum luminance the photometer could record was 0.63 lux.

Intraocular Lens Tilt and Centration Assessment

Eyes were examined 6 months, 12 months, and 18 months after IOL implantation to confirm IOL clarity and IOL tilt. A rotating Scheimpflug camera (Pentacam, Oculus Optikgeräte GmbH) was used to evaluate and measure IOL tilt. A validated methodology for IOL tilt assessment previously developed by Taketani et al.[17] was applied.

Questionnaire

In this study, a validated quality of vision (QoV) questionnaire[18] was used postoperatively. The questionnaire was administered after 6 months, 12 months, and 18 months to assess for possible neural adaption. The patients were asked to rate their overall QoV separately for day and for night from very poor (0) to excellent (10).

Statistical Analysis

Data analysis was performed using SPSS for Windows software (version 22, IBM Corp.). The relationship between pupil size and QoV was modeled using a linear regression model, and the differences in QoV between pupil size groups were evaluated by analysis of variance. Normality was checked by the Shapiro-Wilk test and Q-Q plot test. To assess the contribution of pupil size to the QoV, a linear regression analysis was performed. Differences were considered statistically significant when the P values were less than 0.05 and 0.001.

RESULTS

The study comprised 90 patients (180 eyes). Table 1 shows the preoperative characteristics of patients. No patient had intraoperative or postoperative complications up to the 18-month follow-up.

Quality of Vision and Pupil Size

Statistically significant differences in postoperative QoV questionnaire score for 6 months, 12 months, and 18 months were found between the groups ($P < .001$). A regression analysis was performed between the pupil diameter (photopic and mesopic) and the QoV (day and night) score to determine whether pupil size was a predictor for the QoV. At the 6-month postoperative assessment, the QoV score correlated with the postoperative photopic pupil area ($r^2 = 0.517, P < .001$) (Figure 2). The relationship between postoperative photopic pupil diameter with QoV score decreased slightly at the 1-year postoperative assessment but was still significant ($r^2 = 0.480, P < .001$). The relationship for QoV score at 18 months was also significant ($r^2 = 0.472, P < .001$) (Figure 2). The regression analysis between the postoperative mesopic pupil size and QoV night scores showed $r^2 = .397$ and $P < .001$ (6 months), $r^2 = 379$ and $P < .001$ (12 months), and $r^2 = .360$ and $P > .001$ (18 months) (Figure 3).

Table 2 shows the mean preoperative and postoperative photopic size and mesopic pupil size. Eighteen months postoperatively, the photopic and mesopic pupil diameter decreased by 0.5 mm and 0.7 mm, respectively (Table 2). There were statistically significant differences between the mean preoperative pupil size (photopic and mesopic) and the 18-month postoperative pupil size (photopic and mesopic) ($P < .001$). The comparison between the mean QoV scores between groups showed a statistical difference 6 months, 12 months, and 18 months postoperatively (Table 3). Groups B, C, and D with pupil sizes greater than 2.99 mm reported better mean QoV scores for day and night than Group A reported.

Visual Acuity and Refraction

Table 3 shows a between-group comparison of postoperative data. There were no statistically significant differences in the mean ocular parameters, visual, or refractive outcomes 6 months, 12 months, and 18 months postoperatively. Postoperatively, the mean UNVA was better in patients with larger pupils (Groups B, C, and D) than in patients with smaller pupils (Group A).

Safety

By 18 months postoperatively, no eye had lost lines of CDVA or CNVA compared with preoperatively. Thus, the safety profile was excellent.

Efficacy

The mean preoperative UDVA, UIVA, and UNVA was 0.67 ± 0.09 logMAR, 0.25 ± 0.01 logMAR, and 0.75 ± 0.25 logMAR, respectively. At the 18-month postoperative assessment, all 4 groups had a significant improvement in UDVA, UIVA, and UNVA (Table 3).

Tilt and Centration

All IOLs retained clarity throughout the 18-month follow-up as seen after pupil dilation on direct slitlamp examination. The mean absolute IOL tilt between the groups was less than 2.0 ± 0.5 degrees, exceeding the standard for stability (≥90% of eyes with ≤5 degrees). No IOL required repositioning during the study. There were also no statistical

Table 1. Patient demographics.

Demographic	Group A (2.50–2.99 mm)	Group B (3.00–3.50 mm)	Group C (3.51–4.00 mm)	Group D (4.01–4.50 mm)	P Value
Mean age (y)	59.80 ± 8.30	60.12 ± 7.42	59.63 ± 7.90	61.37 ± 7.65	.004
Male/female sex (n)	8/14	10/12	11/10	10/15	—
Mean follow-up (mo)	19.33 ± 5.24	19.25 ± 5.62	19.80 ± 5.83	20.12 ± 6.21	.281
Mean astigmatism (D)	0.79 ± 0.10	0.76 ± 0.24	0.77 ± 0.45	0.82 ± 0.10	.342
Mean CDVA (logMAR)	0.2 ± 0.12	0.18 ± 0.17	0.2 ± 0.15	0.19 ± 0.13	.097
Mean QoV score (0–10)	6.5 ± 1.2	6.7 ± 1.1	6.5 ± 1.5	6.7 ± 1.4	.265

Means ± SD
CDVA = corrected distance visual acuity; logMAR = logarithm of the minimum angle of resolution; n = number of patients; QoV = quality of vision

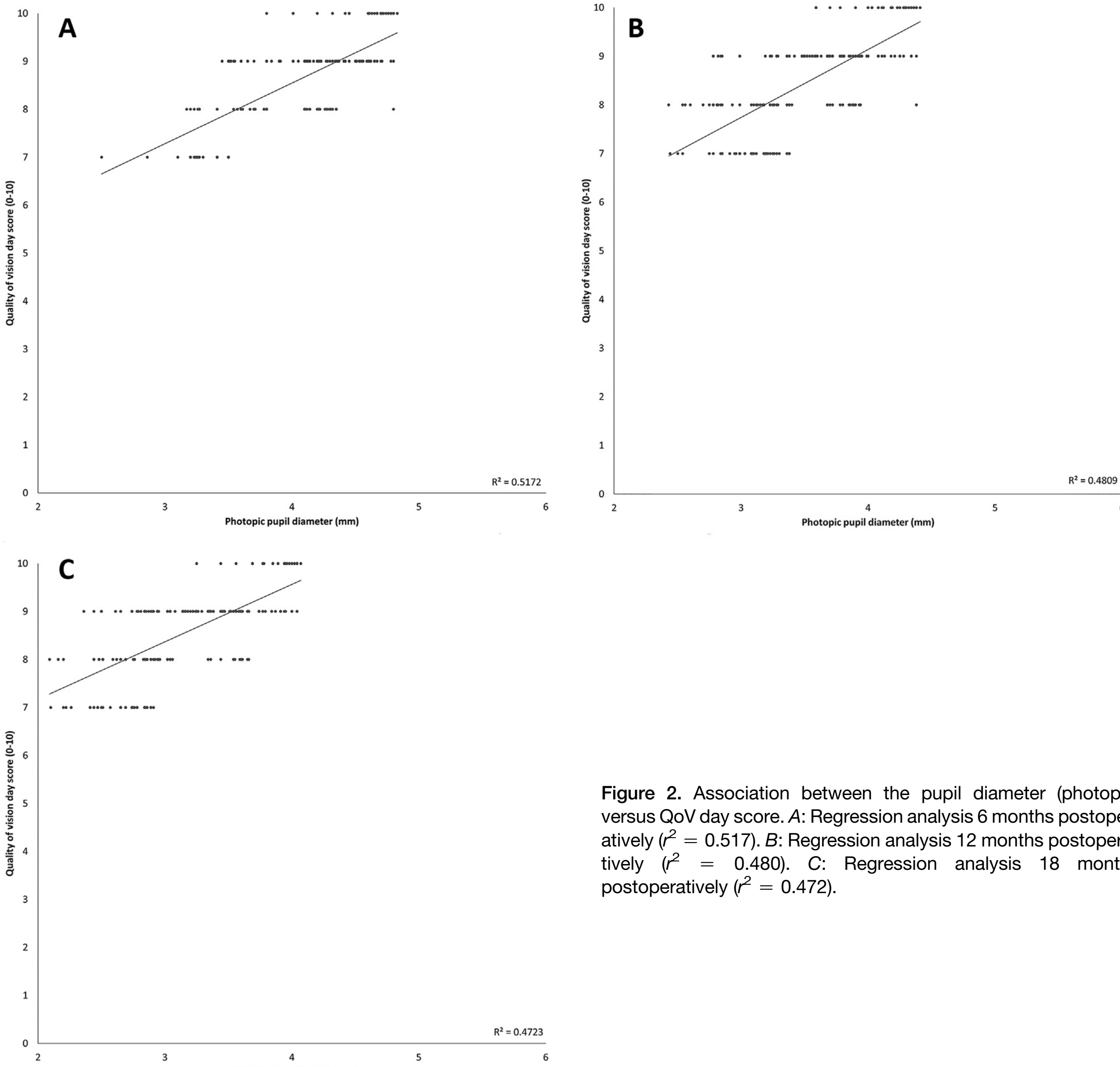


Figure 2. Association between the pupil diameter (photopic) versus QoV day score. *A*: Regression analysis 6 months postoperatively ($r^2 = 0.517$). *B*: Regression analysis 12 months postoperatively ($r^2 = 0.480$). *C*: Regression analysis 18 months postoperatively ($r^2 = 0.472$).

differences in the IOL tilt between the groups (Table 3). Eyes with grossly decentered IOLs on dilated slitlamp examination and photographic analysis were excluded.

Adverse Events and Posterior Capsule Assessment

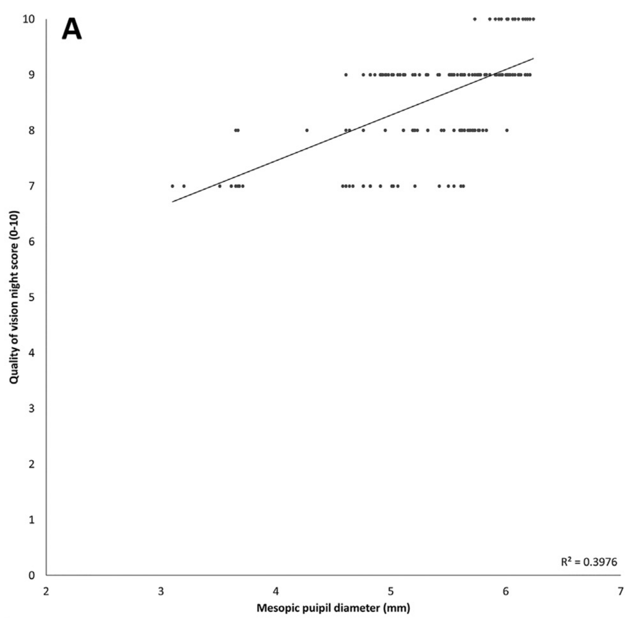
No serious complications (posterior capsule rupture, endophthalmitis, macular edema, or persistent raised intraocular pressure) occurred during the study. All 180 eyes (90 patients) were retrospectively assessed and categorized into the respective pupil size groups. At 6 months, 12 months, and 18 months, the same experienced ophthalmologist examined all 180 eyes and confirmed that the eyes had no or mild PCO. Cases with PCO were excluded from this retrospective analysis.

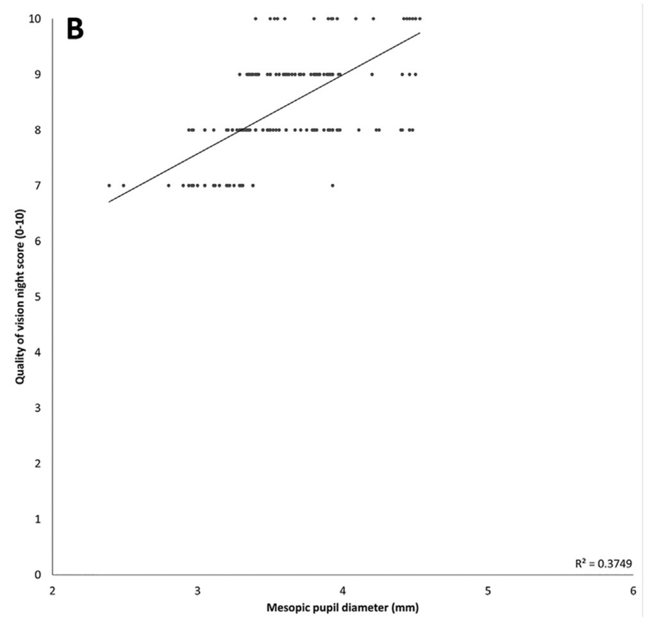
Visual Disturbances and Photopic Phenomena

Table 4 shows the individual symptom responses found in each group. Scores for glare and halos were significantly different between the groups 6 months postoperatively, with Group A reporting the highest mean score for glare and halos than other groups. During the 1-year assessment, glare was the only significantly difference between the groups; Group A once again had the highest score. At the 18-months assessment, no visual disturbance was significantly different between the groups and the mean scores in all groups were lower than the mean 6-month postoperative score.

Patient Satisfaction

Table 5 shows the key questions related to the visual performance from a computer-based questionnaire 18 months postoperatively. The number of patients participating was 90. The results show high patient satisfaction, with no patient being dissatisfied or very dissatisfied. Most reported they were very satisfied with the outcome





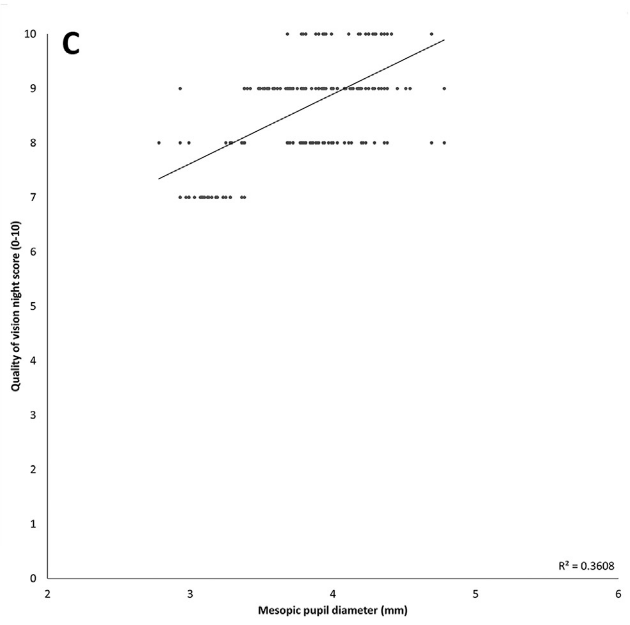


Figure 3. Association between the pupil diameter (mesopic) versus QoV night score. *A*: Regression analysis 6 months postoperatively ($r^2 = 0.397$). *B*: Regression analysis 12 months postoperatively ($r^2 = 0.374$). *C*: Regression analysis 18 months postoperatively ($r^2 = 0.360$).

of the procedure, (96%) stated that they would choose the procedure again, and said that they would recommend the procedure.

DISCUSSION

The use of rotationally asymmetric multifocal IOLs to achieve pseudoaccommodation is a popular surgical

Table 2. Photopic and mesopic pupil size.

	Mean (mm) ± SD			
		Postoperative		
Condition	Preoperative	6 Months	12 Months	18 Months
Photopic	4.3 ± 0.3*,†	4.2 ± 1.21†	4.1 ± 1.05‡	3.8 ± 0.7*‡§
Mesopic	5.6 ± 1.4*,†	5.4 ± 1.63†	4.9 ± 1.73‡§	4.9 ± 1.2‡§

*Statistically significant change compared with 12 months postoperatively
†Statistically significant change compared with 18 months postoperatively
‡Statistically significant change compared with preoperatively
§Statistically significant change compared with 6 months postoperatively

Table 3. Between-group comparison of postoperative parameters over time.

Postop Time/Parameter	Mean ± SD				
	Group A (2.50–2.99 mm)	Group B (3.00–3.50 mm)	Group C (3.51–4.00 mm)	Group D (4.01–4.50 mm)	*P* Value*
At 6 months					
Sphere (D)	0.16 ± 0.36	0.09 ± 0.47	0.18 ± 0.21	0.1 ± 0.44	.081
Cylinder (D)	0.37 ± 0.40	0.4 ± 0.34	0.29 ± 0.35	0.39 ± 0.33	.174
Monocular acuity					
LogMAR UDVA	−0.04 ± 0.21	−0.03 ± 0.10	−0.03 ± 0.07	−0.03 ± 0.09	.132
LogMAR UIVA	0.26 ± 0.2	0.25 ± 0.09	0.25 ± 0.3	0.24 ± 0.15	.077
LogMAR UNVA	0.09 ± 0.15	0.09 ± 0.11	0.08 ± 0.11	0.09 ± 0.10	.952
Angle κ (°)	4.7 ± 0.8	4.3 ± 0.4	4.2 ± 0.9	4.2 ± 0.6	.074
QoV (0−10)					
Day	7.7 ± 0.4†‡§	8.5 ± 0.3¶	8.7 ± 0.7¶	8.6 ± 0.5¶	<.001*
Night	7.0 ± 1.6†‡§	7.5 ± 1.7¶	7.6 ± 1.5¶	7.6 ± 0.8¶	<.001*
Tilt (°)	1.5 ± 0.50	1.5 ± 0.50	1.5 ± 0.50	1.7 ± 0.70	.59
Centration (mm)	0.20 ± 0.05	0.25 ± 0.05	0.25 ± 0.05	0.15 ± 0.05	.24
At 12 months					
Sphere (D)	0.15 ± 0.35	0.09 ± 0.49	0.19 ± 0.33	0.11 ± 0.32	.084
Cylinder (D)	0.35 ± 0.44	0.39 ± 0.37	0.3 ± 0.38	0.39 ± 0.30	.061
Monocular acuity					
LogMAR UDVA	−0.04 ± 0.03	−0.03 ± 0.04	−0.03 ± 0.15	−0.03 ± 0.03	.752
LogMAR UIVA	0.27 ± 0.10	0.24 ± 0.15	0.25 ± 0.10	0.24 ± 0.14	.461
LogMAR UNVA	0.09 ± 0.12	0.08 ± 0.15	0.08 ± 0.25	0.08 ± 0.12	.952
Angle κ (°)	4.3 ± 0.8	4.3 ± 0.9	4.1 ± 0.2	4.2 ± 0.5	.145
QoV (0−10)					
Day	7.5 ± 0.7†‡§	8.6 ± 0.5¶	8.7 ± 0.5¶	8.7 ± 0.4¶	<.001*
Night	7.2 ± 0.3†‡§	7.7 ± 1.2¶	7.7 ± 0.5¶	7.9 ± 1.1¶	<.001*
Tilt (°)	1.5 ± 0.50	1.5 ± 0.70	1.5 ± 0.60	1.° ± 0.60	.675
Centration (mm)	0.20 ± 0.05	0.25 ± 0.05	0.35 ± 0.05	0.25 ± 0.05	.091
At 18 months					
Sphere (D)	0.16 ± 0.38	0.1 ± 0.48	0.18 ± 0.35	0.1 ± 0.32	.065
Cylinder (D)	0.34 ± 0.43	0.37 ± 0.40	0.29 ± 0.31	0.38 ± 0.40	.057
Monocular acuity					
LogMAR UDVA	−0.04 ± 0.12	−0.04 ± 0.10	−0.03 ± 0.09	−0.03 ± 0.13	.065
LogMAR UIVA	0.27 ± 0.13	0.25 ± 0.10	0.26 ± 0.12	0.25 ± 0.15	.072
LogMAR UNVA	0.10 ± 0.12	0.09 ± 0.12	0.08 ± 0.15	0.08 ± 0.10	.729
Angle κ (°)	4.3 ± 0.9	4.4 ± 0.1	4.2 ± 0.3	4.3 ± 0.7	.29
QoV (0−10)					
Day	7.8 ± 0.5†‡§	8.7 ± 0.4¶	8.8 ± 0.7¶	8.7 ± 0.6¶	<.001*
Night	7.2 ± 0.10†‡§	7.7 ± 0.9¶	7.8 ± 1.2¶	7.9 ± 0.9¶	<.001*
Tilt (°)	1.0 ± 0.50	1.5 ± 0.60	1.5 ± 0.50	1.5 ± 0.60	.621
Centration (mm)	0.20 ± 0.05	0.25 ± 0.05	0.25 ± 0.05	0.24 ± 0.07	.248

logMAR = logarithm of the minimum angle of resolution; QoV = quality of vision; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity
*Statistically significant across groups
†Statistically significant change compared with Group B
‡Statistically significant change compared with Group C
§Statistically significant change compared with Group D
¶Statistically significant change compared with Group A

option to improve postoperative visual performance and spectacle independence. Although several studies have reported clinical outcomes after implantation of rotationally asymmetric multifocal IOLs,[1,6,8] there is a paucity of literature comparing the subjective optical performance of these IOLs in daily routines, such as driving and shopping in brightly lit rooms.

In addition to postoperative unaided visual acuity, the aim of multifocal IOL implantation has been to improve quality of life through better contrast sensitivity and night vision.[2] The SBL-3 a relatively new asymmetric multifocal IOL, and a case series of bilateral implantation in 53 eyes by Venter et al.[6] reported a good range of visual acuity and that intermediate vision was retained with minimal dysphotopsias.

Intraocular lens tilt and decentration play an essential role in the postoperative QoV with multifocal IOLs, and they have been found to significantly decrease retinal image quality when greater than 5 degrees.[2] In our study, tilt in all

Table 4. Between-group comparison of subjective responses postoperatively.

Postop Time/QoV Visual Symptoms Question	Mean Score* ± SD				P Value
	Group A (2.50–2.99 mm)	Group B (3.00–3.50 mm)	Group C (3.51–4.00 mm)	Group D (4.01–4.50 mm)	
At 6 months					
How much does glare bother you?	0.64 ± 0.73[†,‡,§]	0.36 ± 0.49[¶]	0.38 ± 0.50[¶]	0.28 ± 0.46[¶]	.039[‖]
How much do the halos bother you?	0.55 ± 0.67[†,‡,§]	0.32 ± 0.60[¶]	0.38 ± 0.50[†]	0.36 ± 0.49[¶]	.023[‖]
How much do the starbursts bother you?	0.50 ± 0.60	0.45 ± 0.60	0.33 ± 0.48	0.32 ± 0.48[¶]	.835
How much does hazy vision bother you?	0.27 ± 0.55	0.25 ± 0.51	0.33 ± 0.58	0.28 ± 0.54	.286
How much does blurred vision bother you?	0.32 ± 0.57	0.32 ± 0.57	0.29 ± 0.56	0.24 ± 0.52	.557
How much does distortion bother you?	0.15 ± 0.22	0.05 ± 0.21	0.14 ± 0.36	0.12 ± 0.33	.253
How much do double images bother you?	0.18 ± 0.39	0.18 ± 0.39	0.10 ± 0.30	0.08 ± 0.28[¶]	.211
At 12 months					
How much does glare bother you?	0.47 ± 0.50[†,‡,§]	0.22 ± 0.48[¶]	0.23 ± 0.48[¶]	0.20 ± 0.41[¶]	.042[‖]
How much do the halos bother you?	0.36 ± 0.58	0.30 ± 0.50	0.29 ± 0.46	0.20 ± 0.41	.521
How much do the starbursts bother you?	0.45 ± 0.57	0.32 ± 0.48	0.33 ± 0.48	0.28 ± 0.46	.311
How much does hazy vision bother you?	0.23 ± 0.53	0.23 ± 0.53	0.29 ± 0.56	0.24 ± 0.52	.152
How much does blurred vision bother you?	0.27 ± 0.50	0.25 ± 0.55	0.22 ± 0.54	0.24 ± 0.52	.647
How much does distortion bother you?	0.18 ± 0.08	0.00 ± 0.20	0.05 ± 0.22	0.00 ± 0.00	.402
How much do double images bother you?	0.09 ± 0.29	0.14 ± 0.35	0.10 ± 0.30	0.28 ± 0.08	.233
At 18 months					
How much does glare bother you?	0.27 ± 0.46	0.23 ± 0.43	0.24 ± 0.44	0.16 ± 0.37	.138
How much do the halos bother you?	0.27 ± 0.55	0.24 ± 0.39	0.19 ± 0.40	0.16 ± 0.37	.291
How much do the starbursts bother you?	0.35 ± 0.47[§]	0.32 ± 0.48	0.14 ± 0.36	0.16 ± 0.37[¶]	.623
How much does hazy vision bother you?	0.26 ± 0.55[§]	0.22 ± 0.43	0.24 ± 0.44	0.12 ± 0.33[¶]	.541
How much does blurred vision bother you?	0.23 ± 0.53	0.18 ± 0.39	0.19 ± 0.40	0.24 ± 0.52	.642
How much does distortion bother you?	0.00 ± 0.00	0.00 ± 0.00	0.05 ± 0.25	0.04 ± 0.20	.376
How much do double images bother you?	0.00 ± 0.00	0.00 ± 0.00	0.10 ± 0.30	0.08 ± 0.28	.753

QoV = quality of vision
*Grading scale: 0 = not at all; 1 = a little; 2 = quite; 3 = very
†Statistically significant change compared with group B
‡Statistically significant change compared with group C
§Statistically significant change compared with group D
¶Statistically significant change compared with group A
‖Statistically significant across groups

groups was within ±2 degrees and the difference among the groups was not significant ($P > .05$). This relatively low level of tilt and decentration can also be attributed to the better haptic design of the IOL and the use of CTRs in all study eyes. Therefore, we can safely state that the QoV in all groups was not affected by postoperative IOL tilt or decentration.

Assessment of pupil (photopic and mesopic) diameter and pupil shift[19] has become an integral part of preoperative patient suitability evaluation criteria for

Table 5. Survey of patient satisfaction with the procedure (90 patients).

Question/Response	Number of Patients				Number (%)
	Group A	Group B	Group C	Group D	All Patients
How is your vision after the procedure?					
Very satisfied	15	20	21	25	81 (90)
Satisfied	7	2	0	0	9 (10)
Dissatisfied	0	0	0	0	0
Very dissatisfied	0	0	0	0	0
Would you choose this procedure again?					
Yes	21	20	21	24	86 (96)
Maybe	1	2	0	1	4 (4)
No	0	0	0	0	0
Would recommend the procedure					
Yes	21	22	21	24	88 (98)
Maybe	1	0	0	1	2 (2)
No	0	0	0	0	0

refractive surgery.[20,21] The varying designs of multifocal IOLs along with pupil size have a considerable effect on the objective and subjective vision of the patient.[22,23] Aging, in general, has been documented to have an impact on pupil size.[22,24] Our study showed a decrease in the mean photopic and mesopic pupil size as time progressed. Although our pupil size data were limited to eyes of white patients, there is no conclusive evidence regarding differences between races. However, Koch et al.[21] did find that eyes with brown irides had a larger pupil than eyes with another iris color. The mean preoperative photopic and mesopic pupil diameter in our study decreased at 18 months by 0.5 mm and 0.7 mm, respectively. Studies[20,25] suggest that the decrease in pupil size after cataract surgery could be the result of the release of miotic neuropeptides. However, in our study, we did not observe a significant early postoperative reduction in pupil size. The change in pupil size over time is crucial in understanding postoperative visual outcomes[8,26,27] over the long term because significant changes in pupil size after IOL implantation have a tendency to affect subjective and objective QoV.

In our study, a curious but consistent finding was that of the 4 groups, Group A (pupil 2.5 to 2.99 mm) had reduced subjective QoV scores but overall had similar unaided distance visual acuity after surgery as measured under clinic lighting conditions. Conventional wisdom would suggest that patients with good visual acuity after surgery would also have better subjective visual outcomes and, hence, report a higher level of visual satisfaction and high QoV scores. However in our study, Group A had a lower mean QoV than the other groups. Even though all the groups had equivocal and excellent distance, intermediate, and near vision, their subjective scores were significantly different. Our findings are congruent with those in earlier reports that variations in normal pupil size have little to no effect on the visual acuity in patients with asymmetric multifocal IOLs.[6] The overall objectively measured UDVA, UIVA, and UNVA in this study showed significant improvements between preoperative measurements and postoperative measurements, and this improvement was found in all groups. The reason for either group performing similarly well during visual acuity tests might possibly be that under controlled "office room" lighting conditions,[28] the design of the IOL allows the principal refractive foci to lie on the central axis and not on diffractive concentric constructive interference for a clear image at a given focal length.[29] However, the subjective QoV might have been affected by pupil miosis, which prevents sufficient incident light to expose the central axis of the IOL, thus providing only partial exposure of the distance or near section of these asymmetric multifocal IOLs. Therefore, the energy light distribution to distance focus and near focus seems to have an impact on the patient's QoV. We also found that the correlation (r^2 value) between pupil size and QoV scores decreased over time; this may be have been the result of neuroadaptation after IOL implantation. A comparison of the r^2 (correlation) value of photopic pupils and mesopic pupils found that the mesopic pupil size had a weaker relationship with the QoV than the photopic pupil size. This might be the result of increased dysphotopsias at night induced by the effect of larger pupils.

Pazo et al.[8] found that increasing the distance section of an asymmetric multifocal IOL within a photopic pupil resulted in improved subjective and objective visual outcomes. This highlights the importance of centration of these asymmetric multifocal IOLs and the pupil area[11–13,30] in attaining good QoV. Preoperative prediction of the centration of any multifocal IOL with respect to the physiologic pupil center can be difficult to determine exactly, principally because it is generally dictated by the position of capsular bag periphery[11] and during surgery the only reference a surgeon has to centration is the pharmacologically dilated pupil in which the center can be quite different from that of the photopic pupil center.[8]

A recent literature search showed no published data on the impact of a near or distance segment of a rotationally asymmetric multifocal IOL being exposed within a photopic/small pupil. Studies of the near segment of the Lentis Mplus asymmetric IOL (Oculentis GmbH) by de Wit et al.[1] and Song et al.[31] focused on the placement of the IOL and its resulting visual acuity only. The specific assessment of percentage or area of near and distance segment in a rotationally asymmetric multifocal IOL, especially within a small or photopic pupil, has yet to be explored. Anecdotal evidence of patients experiencing mild to moderate blurred, glare, and hazy vision while driving at night and in brightly lit rooms coincides with the fact that pupil constriction can occur while driving at night in the presence of incoming headlights or while shopping in brightly lit supermarkets. Although this study has not completely addressed the relationship between pupil size and the surface area of near and distance segments exposed to incident light, our initial findings suggest smaller photopic pupils (Group A, 2.50 to 2.99 mm) have a tendency to affect the postoperative QoV with asymmetric multifocal IOLs during miosis with no alterations in visual acuity. Our study will be extended to further assess the relationship between the pupil and the area of asymmetric multifocal IOL segment exposed by the incident light entering through the mesopic pupil and photopic pupil.

All groups reported a low incidence of visual symptoms. However, Group A was the most affected by each questioned symptom except for "double image" at the 6-month postoperative assessment. However, these symptoms in all groups subsided by the 1-year and 18-month postoperative assessments, suggesting a neuroadaptive effect. However, Group A had a greater mean score than the other groups and especially than Group D, suggesting that pupil size has an impact on visual symptoms in asymmetric multifocal IOL implantation.

It is well documented that decentration of multifocal IOL can lead to decreased visual acuity and decreased QoV for the patient.[8] The findings of IOL centration and tilt in our study show all eyes had well-centered IOLs, with less than 0.5 mm of mean decentration and a mean tilt of less that 3 degrees. Also, a CTR was used in all eyes, and no significant capsule contraction was found between 1 month and 18 months, there was no evidence of IOL rotation or movement, indicating that a small photopic pupil size is the most probable reason for the reduced postoperative QoV scores. Kawamorita and Uozato[12] reported that with an Array multifocal refractive IOL (Abbott Medical Optics, Inc.), eyes with a pupil smaller than 4.5 mm were not able to achieve useful near visual acuity. However, with asymmetric multifocal IOLs, visual acuity found in eyes with a small photopic pupil (Group A) was at par with in eyes with a large photopic pupil (Groups B, C, and D); even so, the subjective QoV was lower in Group A. One benefit of this study is the follow-up of 18 months, which allows time to show a possible neuroadaptive effect with a general improvement in QoV overall in the groups with time; however, despite this, the deleterious impact of smaller pupil was still evident even at 18 months. Future studies of the visual performance of multifocal IOL patients will include contrast sensitivity and optical aberrations to verify and validate the neuroadaptation phenomenon.

In summary, the postoperative pupil diameter in eyes with a rotationally asymmetric multifocal IOL had significant subjective effects on the QoV under miosis. Pupil size was significantly decreased from the preoperative level 18 months after surgery. It is key to ensure that both the near and distance sections of asymmetric multifocal IOL are proportionally exposed under photopic pupil conditions. Because asymmetric multifocal IOLs such as the SBL-3 are not circular, nor is the capsular bag, the most effective method of ensuring proportionate exposure of the near and distance sections is to try to ensure that the postoperative photopic pupil is larger of than 2.99 mm.

WHAT WAS KNOWN

- Preoperative pupil size is 1 parameter to consider when an asymmetric multifocal IOL model is contemplated for surgery.
- The pupil tends to decreases in size after cataract surgery.

WHAT THIS STUDY ADDS

- The rotationally asymmetric multifocal IOL studied was subjectively affected by a decreasing photopic pupil size.
- The asymmetric design makes this multifocal IOL more suitable for patients with a postoperative photopic pupil diameter greater than 2.99 mm.

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