



Visual quality and performance comparison between 2 refractive rotationally asymmetric multifocal intraocular lenses

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Purpose: To compare the 12-month postoperative quality of vision and visual performance of 2 different refractive rotationally asymmetric multifocal intraocular lenses (IOLs).

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

Design: Retrospective case series.

Methods: Refractive lens exchange (RLE) patients were divided into 2 groups. Group A comprised eyes receiving a Lentis Mplus LS-312 MF30 IOL and Group B, eyes receiving a Lenstec SBL-3 IOL. Refraction, uncorrected (UDVA) and corrected distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, distance-corrected intermediate and near (DCNVA) visual acuities, and quality of vision were evaluated preoperatively and up to 12 months postoperatively.

Results: Each group comprised 90 eyes. Both groups had a high level of quality of vision 12 months postoperatively with no significant difference between the 2 groups ($P = .919$). There was no significant between-group difference in mean monocular and binocular UDVA, monocular UIVA, or monocular UNVA. Group B had statistically significantly better mean monocular DCNVA ($P = .049$), binocular UNVA ($P = .011$), and binocular DCNVA ($P = .035$). Group B had a higher percentage of complete spectacle independence.

Conclusions: Both refractive rotationally asymmetric multifocal IOLs provided an excellent level of quality of vision 12 months postoperatively. Both IOL models restored distance, intermediate, and near visual function; however the IOLs in Group B provided better near visual performance.

J Cataract Refract Surg 2017; 43:1020–1026 © 2017 ASCRS and ESCRS

Asymmetric multifocal intraocular lenses (IOLs) provide excellent levels of unaided visual acuity at a range of distances as well as high postoperative patient satisfaction^{1–5} and are now widely used in cataract extraction surgery and refractive lens exchange (RLE). At present, there are 2 commercially available asymmetric multifocal IOLs: the Lentis Mplus (Oculentis GmbH) and the SBL-3 (Lenstec, Inc.). The Lentis Mplus was the first commercially available asymmetric multifocal IOL, and several studies^{1,5,6} outline the visual performance and patient satisfaction after implantation with this IOL. The SBL-3 IOL has since been introduced and is currently undergoing a trial in the United States. An initial study by Venter et al.⁷ outlined the performance of the SBL-3 IOL up to 3 months postoperatively.

It has been reported that there is a period of neuroadaptation with multifocal IOLs during which visual symptoms appear to subside and overall patient satisfaction increases.⁸ This is in agreement with a study by McNeely et al.⁹ that assessed the SBL-3 IOL 3 and 12 months postoperatively to determine overall patient satisfaction. The study found that the overall quality of vision improved from 3 to 12 months postoperatively despite no statistically significant change in objective visual or refractive outcomes.

The aim of this study was to compare the quality of vision and visual performance of both rotationally asymmetric multifocal IOLs 12 months postoperatively. The duration of the postoperative follow-up would allow for neuroadaptation to occur to determine whether there is any difference between the 2 IOLs.

Submitted: December 15, 2016 | Final revision submitted: April 27, 2017 | Accepted: May 11, 2017

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PATIENTS AND METHODS

This retrospective study recruited consecutive patients who had RLE followed by bilateral implantation Lentis Mplus LS-312 MF30 IOLs (Group A) or SBL-3 IOLs (Group B). Patients were adequately informed of the risks and the possible need for further corneal laser refractive surgery, and each gave their informed consent. The study adhered to the tenets of the Declaration of Helsinki. The exclusion criterion was any active ocular disease.

Patient Assessment

Preoperatively, all patients had a full ophthalmologic assessment. Visual acuities were evaluated with logarithm of the minimum angle of resolution (logMAR) charts (6 m) and with Radner reading charts in M notation. Evaluated were the uncorrected (UDVA) and corrected distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, and distance-corrected intermediate (DCIVA) and near (DCNVA) visual acuities. The intermediate visual acuities were measured at 70 cm and the near visual acuities at 40 cm (Radner reading charts). Keratometry, topography, slitlamp examination, Goldmann tonometry, dilated funduscopy, and retinal optical coherence tomography (Cirrus 4000, Carl Zeiss Meditec AG) were also completed. The IOLMaster (Carl Zeiss Meditec AG) was used to measure corneal curvature, anterior chamber depth, and axial length (AL) for subsequent IOL calculation. The Hoffer Q¹⁰ formula and the SRK/T¹¹ formula were used depending on the AL.

Patients were examined 3 months and 12 months postoperatively. A full ophthalmologic examination was performed preoperatively. The position of the near segment was also assessed at the postoperative visits to ensure that the near segment remained in the inferonasal position.

Patient satisfaction was assessed through a previously validated Quality of Vision (QoV) questionnaire¹² 12 months postoperatively. The questionnaire assessed the effect of certain visual phenomena and dysphotopsias, with patients responding not at all (0), a little (1), quite (2), or very (3). In addition, patients were asked about the frequency of reading glasses use, with the patient responding never (0), occasionally (1), quite often (2), or always (3). To gain an understanding of how the patient actually perceives their quality of vision and therefore how satisfied they are postoperatively, the patient was then asked to rate his or her quality of vision out of 10 (0 the worst, 10 the best). Also, to assess functional intermediate vision the patients were also asked to report the quality of their intermediate vision.

Intraocular Lenses

The first Lentis Mplus LS-312 MF30 has a refractive design and is rotationally asymmetric, with an aspheric distance-vision zone and a 3.00 diopter (D) posterior sector-shaped near-vision segment (Figure 1). Superposition of interference or diffraction is avoided because light is reflected away from the optical axis when it hits the transition zone of the near segment. It is a foldable biconvex 1-piece multifocal acrylic IOL with a 6.0 mm optic and a 12.0 mm overall length.

The SBL-3 is a bi-aspheric asymmetric refractive multifocal IOL (Figure 1). It has a distance section combined with a 3.00 D near-vision segment in the anterior optic separated by a small wedge-shaped transition zone. It is an acrylic multifocal IOL with a neutral aberration profile and has a 5.75 mm optic and an 11.00 mm overall length.

Surgical Technique

The same experienced surgeon (J.E.M) performed standard on-axis clear corneal phacoemulsification surgery in all cases. The surgery was performed using sub-Tenon or topical anesthesia. A 2.75 mm incision was placed on the steepest meridian to avoid the introduction of oblique astigmatism and to reduce postoperative corneal astigmatism. After a 5.0 mm anterior capsulorhexis

was created, the IOL was implanted in the capsular bag with the vertical axis (reading segment) positioned inferiorly with slight nasal deviation. The refractive aim was emmetropia.

Statistical Analysis

Statistical analysis was performed with SPSS for Windows software (version 22.0, IBM Corp.) and Excel software (Microsoft Corp.). The normality of the data was assessed using the Kolmogorov-Smirnov test. Then, the independent *t* test was used for parametric analysis and the Mann-Whitney *U* test for nonparametric data. Following the methods outlined by Goodall et al.,¹³ a sample size of 36 patients was required for an 80% statistical power. The standard deviation (SD) of the quality of vision was determined to be 0.90, which was motivated by insights gained through results from previous use of the same QoV questionnaire.¹⁴ A 0.60 difference in quality of vision was considered to be clinically significant as determined by clinical experience. For all statistical analysis, the level of significance was a *P* value less than 0.05.

RESULTS

Demographics

This retrospective audit study comprised 180 eyes of 90 consecutive patients. Group A and Group B each consisted of 45 consecutive patients. Table 1 shows the preoperative parameters.

Overall Satisfaction and Spectacle Independence

The mean quality of vision score was 8.84 ± 0.90 (SD) in Group A and 8.87 ± 1.16 in Group B. There was no significant difference between the 2 groups (*P* = .919, independent *t* test). Figure 2 shows the percentage of responses regarding spectacle independence.

Both groups had high levels of functional intermediate visual acuity, with 36 (80.0%) of 45 patients reporting clear intermediate vision and 43 patients (95.6%) reporting clear intermediate vision or a slight problem with intermediate vision in Group A. In Group B, 38 (84.4%) of 45 patients reported clear intermediate vision and 42 patients (93.3%) reported clear or a slight problem with intermediate vision.

Visual Disturbances and Photopic Phenomena

Table 2 shows the visual disturbances and photopic phenomena reported by patients in both groups 12 months postoperatively. There was no significant difference in any parameter between the 2 groups.

Visual Acuity and Refraction

Table 3 shows the visual outcomes of the 2 groups 12 months postoperatively. Group B displayed significantly better monocular DCNVA, binocular UNVA, and binocular DCNVA than Group A. Figure 3 shows the cumulative monocular UDVA, UIVA, and UNVA by group, and Figure 4 shows the cumulative binocular visual outcomes 12 months postoperatively. The safety plots in Figure 5 and Figure 6 show the accuracy of the attempted spherical equivalent (SE).

There was no significant difference in the 12-month postoperative refractive sphere between the 2 groups; however, there was a statistically significant difference in the postoperative refractive cylinder. The mean postoperative refractive cylinder was -0.13 ± 0.24 D in Group A and



Figure 1. Top: The IOL used in Group A. Bottom: The IOL used in Group B.

-0.38 ± 0.40 D in Group B ($P \leq .001$, independent *t* test). The mean postoperative SE was 0.02 ± 0.38 D and 0.00 ± 0.45 D, respectively, with no statistically significant difference between the groups.

Complications

Posterior capsule opacification developed in 12 (13.3%) of 90 eyes in both Group A and Group B. It presented before

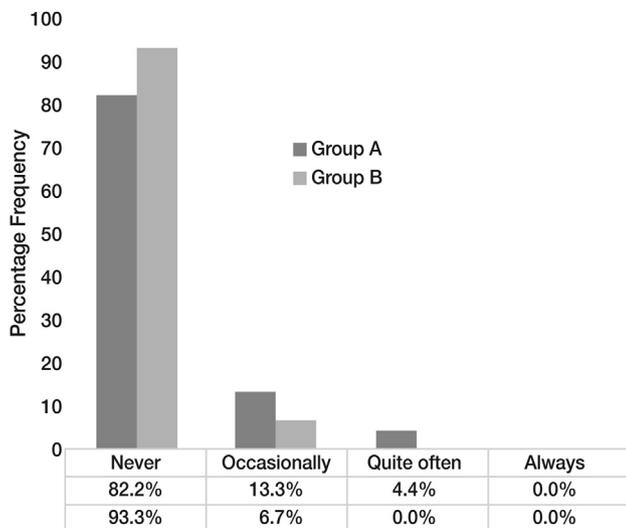


Figure 2. Percentage frequency of patients' responses to how often they wore reading glasses (45 patients in each group).

Parameter	Group A	Group B	P Value
Eyes (n)	90	90	—
Sex, n (%)			—
Male	22 (49)	11 (24)	
Female	23 (51)	34 (76)	
Age (y)			
Mean ± SD	63.03 ± 6.78	59.82 ± 6.86	.034
Median	62	59	
Range	46, 74	47, 73	
Sphere (D)			
Mean ± SD	0.47 ± 4.36	1.33 ± 2.51	.118
Median	1.75	1.50	
Range	-16.50, 6.00	-5.50, 8.75	
Cylinder (D)			
Mean ± SD	-0.68 ± 0.55	-0.59 ± 0.53	.252
Median	-0.50	-0.50	
Range	-2.25, 0.00	-2.25, 0.00	
LogMAR CDVA			
Mean ± SD	-0.04 ± 0.09	-0.05 ± 0.11	.351
Median	-0.02	-0.10	
Range	-0.20, 0.30	-0.20, 0.32	

CDVA = corrected distance visual acuity

the 12-month postoperative assessment, and a neodymium:YAG capsulotomy was performed before this final assessment. No other adverse events occurred, and no IOL rotation was noted.

DISCUSSION

To our knowledge, this is the first study to compare the objective and subjective outcomes of the 2 commercially available rotationally asymmetric multifocal IOLs. Various studies have outlined the outcomes achieved with the Lentis Mplus IOL^{1,4,15} and the SBL-3 IOL⁷; however, no direct comparison has been performed. Therefore, the purpose of this study was to determine whether there was any significant difference in subjective and objective outcomes between the 2 multifocal IOL models. Neuroadaptation occurs after multifocal IOL implantation⁸; therefore, this study sought to compare the 2 IOLs 12 months after implantation to allow for neuroadaptation.

Symptom*	Mean ± SD		P Value
	Group A (45 Patients)	Group B (45 Patients)	
Glare	0.52 ± 0.54	0.54 ± 0.81	.745
Halos	0.32 ± 0.74	0.20 ± 0.40	.138
Starburst	0.48 ± 0.81	0.42 ± 0.73	.85
Hazy vision	0.34 ± 0.72	0.42 ± 0.78	.536
Blurred vision	0.56 ± 0.81	0.36 ± 0.75	.945
Distortion	0.08 ± 0.34	0.06 ± 0.31	.326
Double vision	0.06 ± 0.24	0.16 ± 0.55	.13
Vision fluctuation	0.46 ± 0.79	0.32 ± 0.68	.439
Depth perception difficulty	0.10 ± 0.36	0.02 ± 0.14	.077

*Grading scale: 0 = Not at all; 1 = A little; 2 = Quite; 3 = Very

Table 3. Between-group comparison of 12-month postoperative monocular and binocular visual outcomes.

Parameter	Monocular			Binocular		
	Group A (90 eyes)	Group B (90 eyes)	P Value	Group A (45 Patients)	Group B (45 Patients)	P Value
LogMAR UDVA						
Mean ± SD	-0.03 ± 0.09	-0.01 ± 0.10	.217	-0.07 ± 0.07	-0.06 ± 0.09	.629
Range	-0.20, 0.24	-0.20, 0.20		-0.20, 0.10	-0.20, 0.20	
LogMAR CDVA						
Mean ± SD	-0.07 ± 0.07	-0.08 ± 0.09	.400	-0.09 ± 0.06	-0.11 ± 0.07	.087
Range	-0.20, 0.10	-0.20, 0.20		0, 0.20	-0.20, 0.04	
LogMAR UIVA						
Mean ± SD	0.39 ± 0.10	0.40 ± 0.11	.55	0.36 ± 0.09	0.36 ± 0.09	.723
Range	0.20, 0.60	0.20, 0.60		0.20, 0.50	0.20, 0.60	
LogMAR UNVA						
Mean ± SD	0.15 ± 0.10	0.14 ± 0.12	.411	0.10 ± 0.07	0.05 ± 0.10	.011
Range	0.00, 0.50	-0.10, 0.40		-0.10, 0.20	-0.20, 0.30	
LogMAR DCIVA						
Mean ± SD	0.39 ± 0.10	0.36 ± 0.16	.179	0.34 ± 0.11	0.35 ± 0.11	.633
Range	0.20, 0.60	0.00, 0.70		0.00, 0.50	0.00, 0.50	
LogMAR DCNVA						
Mean ± SD	0.16 ± 0.11	0.12 ± 0.12	.049	0.10 ± 0.07	0.06 ± 0.09	.035
Range	0.00, 0.50	-0.10, 0.50		0.00, 0.20	-0.10, 0.30	

CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

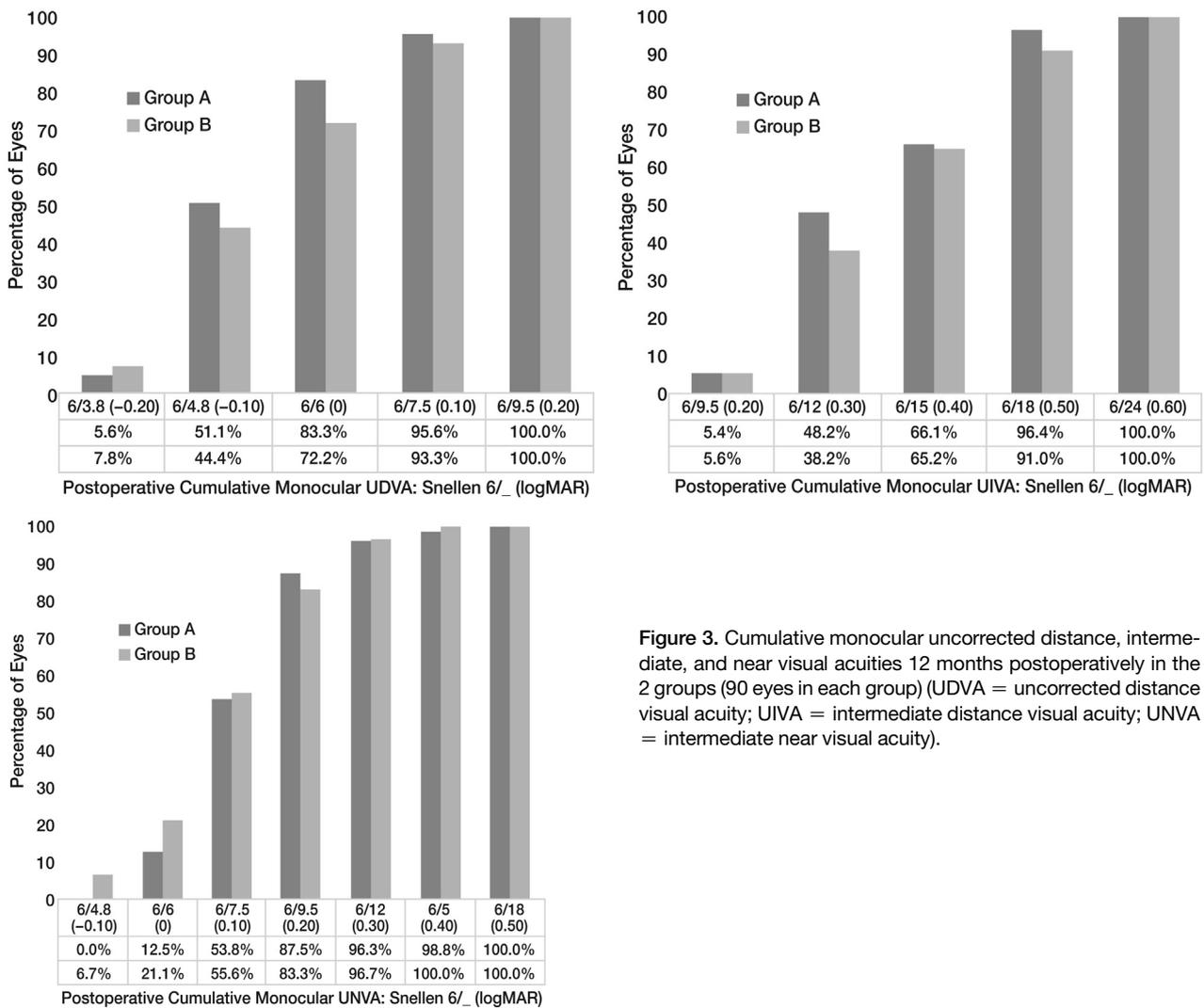


Figure 3. Cumulative monocular uncorrected distance, intermediate, and near visual acuities 12 months postoperatively in the 2 groups (90 eyes in each group) (UDVA = uncorrected distance visual acuity; UIVA = intermediate distance visual acuity; UNVA = intermediate near visual acuity).

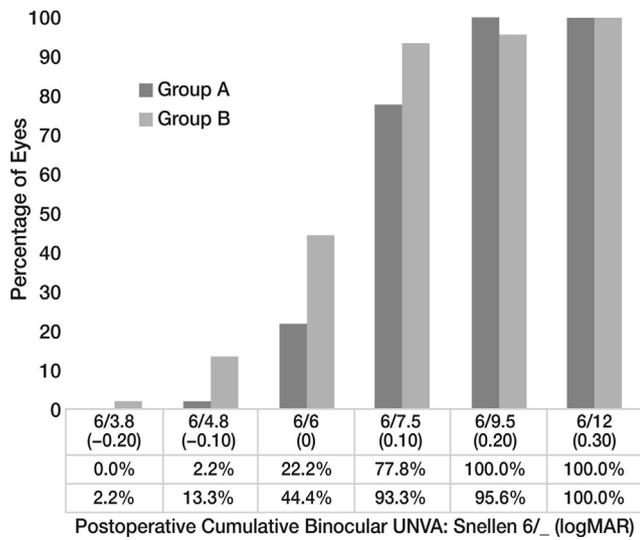
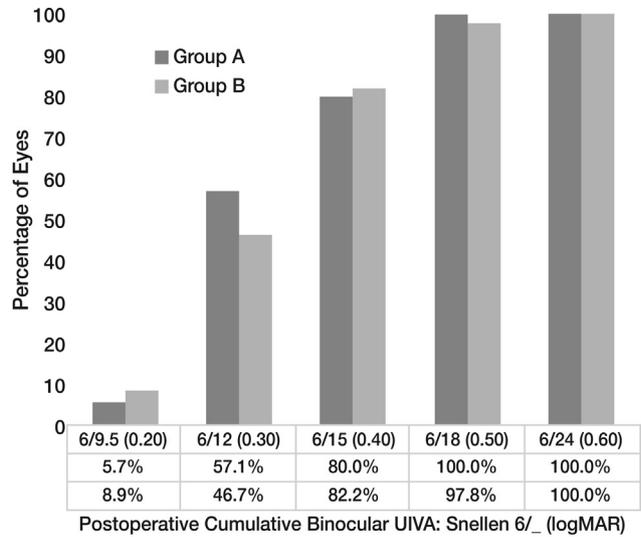
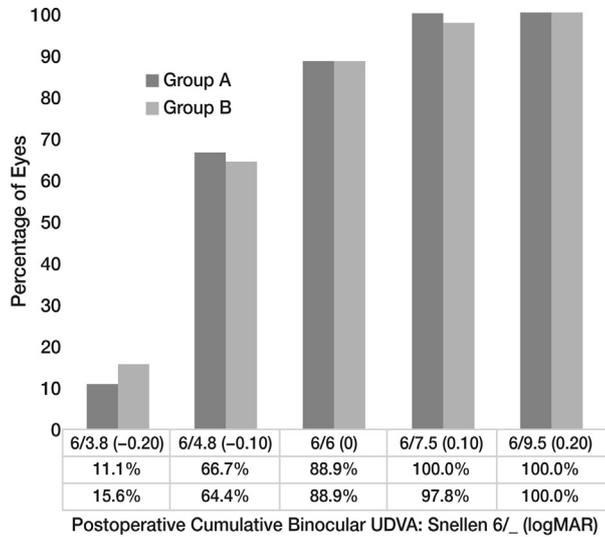


Figure 4. Cumulative binocular uncorrected distance, intermediate, and near visual acuities 12 months postoperatively in the 2 groups (90 eyes in each group) (UDVA = uncorrected distance visual acuity; UIVA = intermediate distance visual acuity; UNVA = intermediate near visual acuity).

A study by McNeely et al.¹⁴ found that bilateral implantation of asymmetric multifocal IOLs with a combination of superotemporal placement of the near segment in the dominant eye and inferonasal placement of the near segment in the fellow eye yielded enhanced quality of vision compared with bilateral inferonasal placement. Another study¹⁶ found that the placement of the near segment had no significant effect on visual performance; however, the numbers in this study were too small. Because of the impact of near-segment position with asymmetric multifocal IOLs, the near-segment position was assessed and confirmed to be inferonasally to ensure it did not affect the outcomes in this study.

In the present study, both IOL models achieved high levels of quality of vision 12 months postoperatively. There was no significant difference in the overall scores between the 2 groups. Group A (Lentis Mplus LS-312 MF30 IOLs) achieved a mean score of 8.84 ± 0.90 and Group B (SBL-3 IOLs), a score of 8.87 ± 1.16 . This is similar to results in a study by Muñoz et al.,¹⁷ which found that the Lentis Mplus IOL had an overall satisfaction score of 8.80 ± 0.88 (0 [least satisfied] to 10 [most satisfied])

6 months postoperatively. In an initial study of the SBL-3 IOL,⁷ 75.5 % of patients were very satisfied and 18.9 % were satisfied with the procedure 3 months after bilateral implantation. In addition, in the present study there was no statistically significant difference in individual symptom responses between the 2 groups 12 months postoperatively. The patients were also asked how often they required reading glasses. Group B had a higher percentage of patients who reported never needing reading glasses, (42 patients [93.3 %] versus 37 patients [82.2 %] in Group A).

The mean UDVA in Group A was -0.03 ± 0.09 logMAR, which is similar to that found in previous studies^{6,17} of bilateral Lentis Mplus IOLs up to 6 months postoperatively. In an initial study of bilateral SBL-3 IOL implantation,⁷ the 3-month postoperative monocular UDVA was -0.03 ± 0.09 logMAR, which is similar to that in the current study. There was no significant difference in binocular UDVA between the 2 groups, and 40 patients (88.9%) in each group achieved a binocular UDVA of 6/6 (0.0 logMAR) or better, which is better than that found in an extensive study by Venter et al.⁶

There was no significant difference in monocular or binocular UIVA and DCIVA between the 2 groups in our

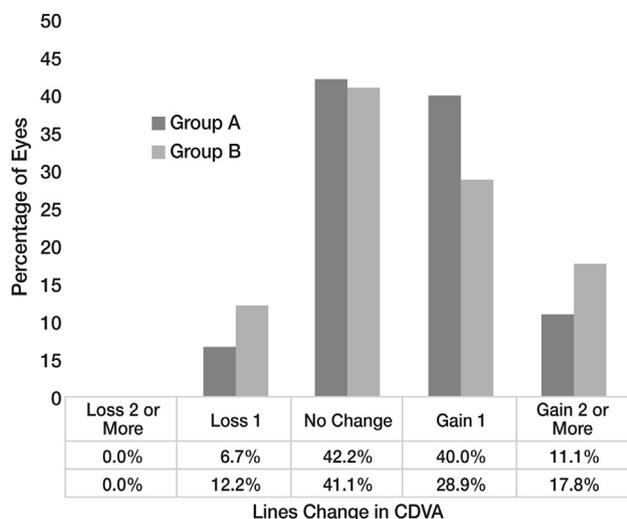


Figure 5. Safety comparison of 12-month postoperative monocular CDVA 12 months postoperatively in the 2 groups (90 eyes in each group) (CDVA = corrected distance visual acuity).

study. The UIVA and DCIVA in our study was worse than results in previous studies.^{17,18} However, McAlinden and Moore¹⁹ reported a mean intermediate vision of M0.89 (approximately 0.35 logMAR) after implantation of a +1.50 D addition (add) in the dominant eye and a +3.00 D add in the fellow eye, which is similar to results in the current study, and the +1.50 D in the dominant eye was used to optimize intermediate visual acuity. To understand the level of functional intermediate visual acuity, patients were asked to report if their intermediate vision was clear or whether they find it problematic. Both groups had high levels of functional intermediate visual acuity, with 43 patients (95.6%) in Group A and 42 patients (93.3%) in Group B reporting clear intermediate vision or a slight problem with intermediate vision.

In addition, both groups achieved monocular UNVA similar to that found in an extensive study by Venter et al.,⁶ with no statistically significant difference between the groups. However, the binocular UNVA was statistically significantly better in Group B and was slightly better than that found in the earlier study of the SBL-3 IOL.⁷ Group B also had statistically significantly better monocular DCNVA than Group A. The DCNVA in Group B in our study was similar to that in the earlier study of the SBL-3 IOL,⁷ in which the binocular DCNVA was 0.08 ± 0.09 logMAR. Group A had a mean DCNVA of 0.16 ± 0.11 logMAR, which is similar to that found by Rosa et al.²⁰ 3 months postoperatively. However, a study of the 6-month outcomes after bilateral implantation of Mplus IOLs found a DCNVA of 0.07 ± 0.07 logMAR. Likewise, the binocular DCNVA in our study was better in Group B and was better than that in the initial study of the SBL-3 IOL.⁷ This would appear to suggest that the SBL-3 IOL provides better near visual performance than the Mplus IOL, as shown by better near performance when lower-order aberrations are corrected when assessing DCNVA and by the better binocular UNVA. The reason for this apparently better near vision

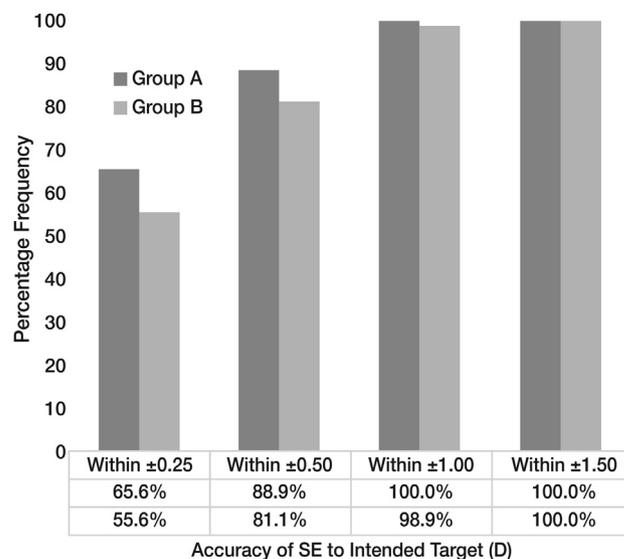


Figure 6. Accuracy to the intended SE refraction at the 12-month postoperative assessment in the 2 groups (90 eyes in each group) (SE = spherical equivalent).

with the SBL-3 IOL is unknown; however, it has a larger surface area of near add without loss of the central aspect, the add reaches almost completely to the edge, and it has an equiconic biaspheric platform. These characteristics might contribute to its enhanced efficacy. Thus, when considering multifocal IOL implantation for an individual who has high near-vision demands, bilateral implantation of IOL might be more suitable. This is supported by a higher percentage of patients reporting that they never required reading glasses when questioned specifically about spectacle independence.

Both IOL models had an excellent level of safety 12 months postoperatively and accuracy in terms of the intended SE. The intended spherical results were better than those in a large population study.²¹ There was no significant difference in mean SE at 12 months between the 2 groups (0.02 ± 0.38 D in Group A; 0 ± 0.45 D in Group B), which is a very good outcome and similar to results in a previous study of the Mplus IOL up to 6 months postoperatively.⁶ There was a significant difference in refractive cylinder; however, it was not clinically relevant. The difference in postoperative refractive cylinder was deemed not to be clinically significantly different because there was only a difference of 0.25 D between the 2 groups and McNeely et al.²² found that an increasing magnitude of postoperative refractive cylinder does not have a significant effect on the quality of vision, UIVA, and UNVA after implantation of an asymmetric multifocal IOL.

In conclusion, to our knowledge, this is the first study to evaluate the Mplus IOL or SBL-3 IOL up to 12 months postoperatively and the first to directly compare the 2 IOL models. Both IOLs provided excellent postoperative outcomes up to 12 months postoperatively. There was no significant difference in overall patient satisfaction or visual phenomena or dysphotopsias between the 2 IOL models. Unaided visual acuity was excellent with both IOL models, although the SBL-3 IOL appeared to provide better near-vision performance and this IOL might prove to be a

more suitable choice for patients with high near-vision demands.

WHAT WAS KNOWN

- The 2 available asymmetric multifocal IOLs both provide excellent levels of unaided visual acuity and patient satisfaction.

WHAT THIS PAPER ADDS

- Both asymmetric multifocal IOLs provided an excellent level of unaided visual acuity and quality of vision, with no significant difference between the 2 IOLs. However, the newer IOL model appeared to provide better near visual performance.

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Disclosure: None of the authors has a financial or proprietary interest in any material or method mentioned.



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