# ARTICLE

# Visual outcomes and patient satisfaction 3 and 12 months after implantation of a refractive rotationally asymmetric multifocal intraocular lens

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**Purpose:** To assess the 3-month and 12-month postoperative visual performance and subjective patient satisfaction after refractive lens exchange (RLE) with implantation of a rotationally asymmetric multifocal intraocular lens (IOL).

Setting: Cathedral Eye Clinic, Belfast, United Kingdom.

Design: Prospective case series.

**Methods:** The refraction, uncorrected (UDVA) and corrected distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, distance-corrected intermediate and near visual acuities, and a quality of vision (QoV) questionnaire were evaluated 3 months and 12 months after implantation of an SBL-3 IOL.

**Results:** The study enrolled 100 eyes of 50 patients. The mean monocular UDVA was -0.02 logarithm of minimum angle of

resolution (logMAR)  $\pm$  0.12 (SD) 3 months postoperatively and  $-0.01~\pm~0.10$  logMAR at 12 months (P=.393). The mean monocular UIVA was 0.39  $\pm$  0.11 logMAR and 0.41  $\pm$  0.12 logMAR, respectively (P=.06). The mean monocular UNVA was 0.12  $\pm$  0.13 logMAR and 0.14  $\pm$  0.12 logMAR, respectively (P=.077). The mean QoV score was 8.26  $\pm$  1.16 at 3 months with a significant improvement at 12 months, at which time the mean QoV score was 8.84  $\pm$  1.08 ( $P\leq.001$ ).

**Conclusions:** This asymmetric multifocal IOL provided excellent unaided vision with no significant difference in near, intermediate, and distance vision 3 months and 12 months postoperatively. However, there was a significant improvement in subjective outcomes at the second postoperative assessment, during which patients reported a significantly better QoV score and less blurred vision.

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Refractive rotationally asymmetric multifocal intraocular lenses (IOLs) are now widely accepted as an effective method to treat presbyopia after cataract extraction surgery or refractive lens exchange (RLE). Rotationally asymmetric multifocal IOLs have 2 distinct zones; that is, a distance zone and a near zone. This differs from the traditional rotationally symmetrical multifocal IOLs, which consist of concentric rings to provide multifocality.

The Lentis Mplus (Oculentis GmbH) was the first rotationally asymmetric multifocal IOL, and various studies<sup>1–5</sup> have outlined the excellent vision achieved at various distances and a high level of subjective patient satisfaction with reduced dysphotopsias and improved contrast sensitivity compared with some diffractive multifocal IOLs. Another rotationally asymmetric multifocal IOL, the SBL-3 (Lenstec, Inc.), has been developed. In the United States, this IOL is being evaluated at present under IDE G140134 and Clinical Trials NCT02487160<sup>A</sup> in a prospective multicenter masked randomized 2-arm parallel group study. Subjects are enrolled after meeting strict inclusion and exclusion criteria and are followed for up to 1 year. An initial study by Venter et al.<sup>6</sup> outlined the 3-month postoperative predictability, visual outcomes, and patient satisfaction of this new rotationally asymmetric IOL. However, to our knowledge this is the only study of this multifocal IOL published at present; therefore, there are no studies of the performance of this IOL over a longer postoperative period.

This study sought to determine the visual performance and patient satisfaction after bilateral implantation of the new rotationally asymmetric multifocal IOL up to 1 year



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postoperatively. The goal was to determine whether or how the visual performance of the IOL and the subjective quality of vision (QoV) perceived by patients alter over time.

# PATIENTS AND METHODS

This prospective consecutive case series recruited patients receiving SBL-3 bilateral rotationally asymmetric multifocal IOLs after RLE. The research was approved by the local research ethics committee, and the study adhered to the tenets of the Declaration of Helsinki. All patients gave informed consent to be included in the study, and the possible risks of the operation and the possible need for further laser refractive surgery were explained. Patients who developed posterior capsule opacification or who had active ocular disease were excluded from the study.

#### Patient Assessment

All patients had a full preoperative ophthalmologic assessment. The examination included a medical history, keratometry, topography, and autorefraction (OPD-Scan II ARK-10000, Nidek Co., Ltd.), subjective refraction (RT-5100 Auto Phoropter Head, Nidek Co., Ltd.), slitlamp evaluation, Goldmann tonometry, dilated fundoscopy, and retinal optical coherence tomography (Cirrus 4000, Carl Zeiss Meditec AG). Biometry performed with the IOLMaster (Carl Zeiss Meditec AG) measured corneal curvature, anterior chamber depth, and axial length (AL) for subsequent IOL calculation. The Hoffer Q formula<sup>7</sup> was used for eyes with an AL of less than 22.0 mm, and the SRK/T formula<sup>8</sup> was used for ALs of 22.0 mm or more. Uncorrected (UDVA) and corrected (CDVA) distance visual acuities, uncorrected intermediate (UIVA) and near (UNVA) visual acuities, and distance-corrected intermediate and near visual acuities were measured using logarithm of minimum angle of resolution (logMAR) charts for distance (6 m) and with Radner reading charts for intermediate and near vision (70 cm and 40 cm).

The postoperative assessments were performed at 3 months and 12 months. They included the same assessments as the preoperative examination with the main postoperative measurements including UDVA, UNVA, and UIVA. The rotational position of the IOL was assessed at each postoperative visit to confirm inferonasal placement of the near segment.

To assess postoperative subjective patient satisfaction, a previously developed QoV questionnaire<sup>9</sup> was completed. The QoV questionnaire determined how bothered the patients were by various visual disturbances and photopic phenomenon. The patients responded to each question with not at all (0), a little (1), quite (2), or very (3). The QoV questionnaire has a 0 to 10 overall QoV score, with 0 being the worst and 10 the best. This provides a linear subjective score of how each individual rates his or her overall vision. In addition to the QoV questionnaire, patients were asked how often they required reading spectacles. Patients responded with never (0), occasionally (1), quite often (2), or always (3). Patients were also asked to report the quality of their intermediate vision by responding with clear, slight problem, moderate problem, severe problem, or intolerable problem.

#### Intraocular Lens

Venter et al.<sup>6</sup> outlined the design and characteristics of the new asymmetric multifocal IOL. It is a bi-aspheric asymmetric refractive multifocal IOL with 2 distinct zones. One zone is for distance vision, and the other is a +3.00 diopter (D) near segment with a wedge-shaped transition zone. The near segment occupies 42% of the IOL. The IOL has an overall length of 11.00 mm with a 5.75 mm optic. It is of a hydrophilic acrylic material and has a neutral aberration profile.

#### Surgical Technique

Standard on-axis clear corneal phacoemulsification surgery was performed by the same experienced surgeon (J.E.M.) in all cases.

To avoid the introduction of oblique astigmatism and reduce the likelihood of an increase in postoperative corneal astigmatism, a 2.75 mm incision was made at the steepest meridian. In all cases, the surgery was performed under sub-Tenon or topical anesthesia. A 5.00 mm anterior capsulorhexis was created and the multifocal IOL implanted in the capsular bag. The vertical axis (reading segment) of the IOL was positioned inferiorly with slight nasal deviation. The refractive aim was emmetropia.

#### **Statistical Analysis**

Statistical analysis was performed using SPSS for Windows software (version 22, Statistical Package for the Social Sciences, Inc.) and Excel software (Microsoft Corp.). Initially, the Kolmogorov-Smirnov test was used to assess normality of the data. When comparing the data between the 2 postoperative assessments, the Student t test for paired data was used for parametric analysis. For assessing nonparametric data, the Wilcoxon rank-sum test was used. The level of significance was a P value less than 0.05.

# RESULTS

One hundred eyes of 50 patients were included in the study. Table 1 shows the patients' demographics and the preoperative examination results.

#### Visual Acuity and Refraction

Table 2 shows a comparison of the objective visual and refractive results between the 3-month and 12-month postoperative assessments. Figure 1, *A*, *B*, and *C*, shows the cumulative monocular UDVA, UIVA, and UNVA, respectively, at each postoperative assessment. Figure 2 shows the changes in CDVA Snellen lines postoperatively.

Figure 3 shows the accuracy of the attempted spherical equivalent (SE) correction at 3 months and 12 months. Eighty-six eyes (86%) at 3 months and 82 eyes (82%) at 12 months were within  $\pm 0.50$  D of emmetropia. Ninety-nine eyes (99%) and 98 eyes (98%) were within  $\pm 1.00$  D of emmetropia at the 2 respective follow-up assessments.

Figure 4 shows the stability of the SE up to 12 months postoperatively. Ninety-eight eyes (98%) had a change in

Table 1. Preoperative patient demographics.				
Parameter	Value			
Eyes (n)	100			
Sex, n (%) Male Female	13 (26) 37 (74)			
Age (y) Mean ± SD Median Range	60.12 ± 7.75 59 43, 83			
Sphere (D) Mean ± SD Median Range	1.21 ± 2.90 1.50 –10.75, 8.75			
Cylinder (D) Mean ± SD Median Range	-0.59 ± 0.55 -0.50 -2.25, 0			
CDVA (logMAR) Mean ± SD Median Range	-0.05 ± 0.12 -0.10 -0.20, 0.32			

CDVA = corrected distance visual acuity;  ${\rm log}{\sf MAR}$  =  ${\rm logarithm}$  of minimum angle of resolution

Parameter	Postop 1	Postop 2	P Value			
UDVA (logMAR) Mean ± SD Median Range	-0.02 ± 0.12 -0.06 -0.20, 0.42	-0.01 ± 0.10 0.00 -0.20, 0.20	.393			
Sphere (D) Mean ± SD Median Range	0.12 ± 0.43 0.00 -0.75, 1.25	0.22 ± 0.50 0.00 -0.75, 1.50	.007			
Cylinder (D) Mean ± SD Median Range	-0.28 ± 0.40 0.00 -1.50, 0.00	-0.38 ± 0.40 -0.25 -1.50, 0.00	.001			
SE (D) Mean ± SD Median Range	-0.02 ± 0.41 0.00 -1.00, 1.25	0.03 ± 0.46 0.00 -1.00, 1.25	.132			
CDVA (logMAR) Mean ± SD Median Range	-0.09 ± 0.07 -0.10 -0.20, 0.10	-0.09 ± 0.08 -0.10 -0.20, 0.18	.186			
UIVA (logMAR) Mean <u>±</u> SD Median Range	0.39 ± 0.11 0.40 0.20, 0.60	0.41 ± 0.12 0.40 0.20, 0.60	.06			
UNVA (logMAR) Mean ± SD Median Range	0.12 ± 0.13 0.10 -0.20, 0.50	0.14 ± 0.12 0.10 -0.10, 0.40	.077			
DCIVA (logMAR) Mean ± SD Median Range	0.38 ± 0.11 0.30 0.20, 0.70	0.39 ± 0.10 0.40 0.20, 0.70	.17			
DCNVA (logMAR) Mean ± SD Median Range	0.11 ± 0.13 0.10 -0.10, 0.70	0.11 ± 0.12 0.10 -0.10, 0.40	.921			

Table 2. Comparison of 3-month and 12-month objective postoperative data after bilateral asymmetric multifocal IOL implantation.

CDVA = corrected distance visual acuity; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; logMAR = logarithm of minimum angle of resolution; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity

SE refraction of 1.00 D or less between 3 months and 12 months.

#### **Overall Satisfaction and Spectacle Independence**

Figure 5 shows the overall QoV scores for the 2 postoperative assessments. There was a statistically significant improvement in the postoperative QoV from 3 months to 12 months ( $P \le .001$ , paired *t* test).

There was no significant difference in spectacle independence and the percentage of responses between the 2 assessments (Figure 6).

In addition, 39 (78%) of 50 patients reported their intermediate vision was clear and 45 patients (90%) reported their intermediate vision was either clear or a slight problem to them at the 3-month assessment. At the second postoperative assessment 43 (86%) of 50 patients reported clear intermediate vision and 48 (96%) patients reported their intermediate vision was clear or only a slight problem.

# Visual Disturbances and Photopic Phenomena

Table 3 shows the subjective responses from both postoperative assessments. Patients were statistically significantly less affected by blurred vision 12 months postoperatively than they were 3 months postoperatively.

#### DISCUSSION

Multifocal IOLs using diffractive or refractive optics through a range of concentric rings have been used since the early 1990s. However, approximately 7 years ago, a new design of refractive multifocal IOL that consisted of 2 distinct zones was introduced. One zone was for distance vision and the other for near vision, creating a rotationally asymmetric multifocal IOL. Several studies<sup>10–12</sup> report the outcomes with the first commercially available asymmetric multifocal IOL. A second asymmetric multifocal IOL has since been introduced, and an initial study<sup>6</sup> showed this IOL provided excellent results up to 3 months postoperatively.

This present study sought to determine the objective and subjective outcomes after bilateral implantation of the new asymmetric multifocal IOL up to a longer postoperative timepoint than in previous studies. This study sought to compare objective and subjective parameters 3 months and 12 months postoperatively to determine how they alter, if at all, over this period.

In this study, visual and refractive outcomes at both postoperative assessments showed excellent unaided visual acuity. The mean UDVA was  $-0.02 \log MAR \pm 0.12$  (SD) and  $-0.01 \pm 0.10 \log$ MAR at the 2 respective postoperative assessments. These findings were similar to the results of Venter et al.<sup>6</sup> 3 months after bilateral implantation of the new asymmetric multifocal IOL. Our study also had better postoperative UDVA results than studies that evaluated the postoperative outcomes after bilateral implantation of the first asymmetric multifocal IOL.<sup>3,13</sup> In addition, in this study there was no statistically significant difference in the UDVA between the 2 assessments; 77 eyes (77%) and 71 eyes (71%), respectively, achieved a monocular UDVA of 6/6 (0.0 logMAR) or better. These UDVA findings are better than those in a study of bilateral implantation of the first asymmetric multifocal IOL up to 6 months postoperatively.<sup>14</sup> The UIVA results found in this study was worse than those found by Venter et al.<sup>6</sup> 3 months after implantation of the new asymmetric IOL. Likewise, the UIVA results in this study were worse than the results observed with the first asymmetric multifocal IOL 6 months postoperatively.<sup>13</sup> However, when asked about the quality of their intermediate vision, 45 patients (90%) in our study reported clear or a slight problem 12 months postoperatively. This shows that the asymmetric multifocal IOL in this study provided good functional intermediate vision. There was no significant difference between the 2 assessments in UIVA.

Comparing the mean monocular UNVA with the initial asymmetric multifocal IOL study<sup>6</sup> again showed outcomes comparable to both postoperative assessments in our study. The observed mean monocular UNVA was also better than that in other studies of bilateral implantation of





Figure 1. Cumulative monocular uncorrected (A) distance, (B) intermediate, and (C) near visual acuity 3 months and 12 months postoperatively ( $\log MAR = \log arithm of minimum angle of resolution;$ UDVA = uncorrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; UNVA = uncorrected near visual acuity).

the first asymmetric multifocal IOL.<sup>5,15</sup> For the monocular UNVA in our study, 95 eyes (95%) and 90 eyes (90%) achieved 6/12 (0.30 logMAR) at the 2 respective postoperative assessments, which was better than that observed by Venter et al.<sup>6</sup>

The excellent functional intermediate vision and unaided near visual acuity were most likely the result of the smooth transition between the 2 zones of the IOL, with additional



**Figure 2.** Changes in CDVA Snellen lines postoperatively (CDVA = corrected distance visual acuity).

depth of focus produced through residual corneal spherical aberration.<sup>6</sup> This study did not analyze the effect of higherorder aberrations on depth of focus, and future studies to assess this would be beneficial. In addition, further comparative studies with other multifocal IOLs, such as the first asymmetric multifocal IOL and rotationally symmetrical multifocal IOLs, would allow for further discussion regarding the intermediate and near vision achieved with this IOL.

In this current study, the level of safety was excellent. At the second postoperative assessment, 1 eye lost 2 lines of CDVA; however, this eye still achieved a CDVA of 0.0 logMAR. In addition, 15 eyes (15%) at 3 months and 22 eyes (22%) at 12 months lost 1 line of CDVA. The initial study of this  $IOL^6$  found a loss of 1 line, similar to the 3-month result in the current study. An increase in the percentage of eyes that lost 1 line was observed at 12 months; however, 19 of the 22 eyes achieved a CDVA of 0.0 logMAR or better.

This study found the predictability of the asymmetric multifocal IOL to be excellent. For the accuracy of the SE to the intended target, 86 eyes (86%) were within  $\pm 0.50$  D and 99 eyes (99%) were within  $\pm 1.00$  D of emmetropia 3 months postoperatively, which is similar to the 84.9% of eyes within  $\pm 0.50$  D and 99.1% of eyes within  $\pm 1.00$  D



Figure 3. The accuracy of the intended SE refraction at the 3-month and 12-month postoperative assessments (SE = spherical equivalent).



Figure 4. Stability up to 12 months postoperatively plotted as the mean  $\pm$  SD of the SE refraction.

of emmetropia found by Venter et al.<sup>6</sup> At the 12-month assessment in our study, 82 eyes (82%) were within  $\pm 0.50$  D and 98 eyes (98%) were within  $\pm 1.00$  D of emmetropia. In addition, no significant difference was found in the SE refraction between the 3-month and 12-month assessments, highlighting excellent stability after implantation of the asymmetric multifocal IOL. However, there was a statistically significant difference in both the refractive sphere and cylinder between the 2 postoperative assessments (0.10 D), which was not clinically significant.

It is well recognized that assessment of subjective perception of vision is important in fully understanding how individuals perceive their vision. Therefore, this study sought to determine subjective patient satisfaction through a QoV questionnaire.<sup>9</sup> We added a new feature to our QoV questionnaire. We asked each patient to rate his or her overall QoV out of 10, with 0 being the worst and 10 the best. We found an excellent mean QoV score at the 3-month assessment, which was similar to that found 3 months postoperatively with the first asymmetric multifocal IOL positioned inferonasally in each eye.<sup>16</sup> However, there was a significant improvement in overall QoV at 12 months in our study ( $P \le .001$ , paired *t* test). In



Figure 6. The percentage frequency of the 3-month and 12-month postoperative responses to how often the patients wore reading spectacles.



Figure 5. The mean overall QoV scores (0 = worst; 10 = best) for the 2 postoperative assessments (QoV = quality of vision).

addition, the incidence of patients affected by symptoms was low at both assessments. Blurred vision is 1 of the most common causes of dissatisfaction after multifocal IOL implantation.<sup>17-19</sup> Our patients said they were significantly less affected by blurred vision at the 12-month assessment than they were at the 3-month assessment (P = .049, Wilcoxon rank-sum test). The asymmetric multifocal IOL provided excellent visual and refractive outcomes, and there was no significant difference between the 2 postoperative assessments; however, there was a statistically significant improvement in overall QoV at the 12-month assessment. It seems as though neuroadaptation might potentially be involved in the reported subjective patient findings of significantly less blurred vision and a higher level of overall QoV (8.84  $\pm$  1.08) 12 months postoperatively that occurred between the 2 timepoints in this study.

In many cases, spectacle independence is the motive for having multifocal IOL implantation, and our study found that the asymmetric multifocal IOL resulted in an excellent level of freedom from reading spectacles. At both postoperative assessments, the majority of patients reported never requiring reading spectacles, with a greater percentage of patients in this category 12 months postoperatively. No patients reported requiring reading spectacles quite often or always at the second postoperative assessment. A previous

Table 3. Comparison of 3-month and 12-month subjective postoperative data after bilateral asymmetric multifocal IOL implantation.*						
Parameter	Postop 1	Postop 2	P Value <sup>†</sup>			
Glare	0.52 ± 0.54	0.54 ± 0.81	.948			
Halos	0.32 ± 0.74	0.20 ± 0.40	.268			
Starburst	0.48 ± 0.81	0.42 ± 0.73	.659			
Hazy	0.34 ± 0.72	0.42 ± 0.78	.49			
Blurred vision	$0.56 \pm 0.81$	0.36 ± 0.75	.049			
Distortion	0.08 ± 0.34	0.06 ± 0.31	.783			
Double vision	$0.06 \pm 0.24$	0.16 ± 0.55	.197			
Vision fluctuation	0.46 ± 0.79	0.32 ± 0.68	.315			
Depth-perception difficulty	0.10 ± 0.36	$0.02 \pm 0.14$	.102			

\*Grading scale: 0 = not at all; 1 = a little; 2 = quite; 3 = very <sup>†</sup>Wilcoxon rank-sum test study that assessed an asymmetric multifocal IOL at 6 months<sup>13</sup> found that 84.4% of patients never used spectacles for reading, which is similar to the result in our study at 3 months. However, we had a higher rate of spectacle independence 12 months postoperatively, which was similar to the 12-month postoperative rate found in a study that assessed mix-and-match multifocal IOL implantation.<sup>20</sup>

In conclusion, our study of the newest asymmetric multifocal IOL up to 12 months after bilateral implantation found that this refractive rotationally asymmetric IOL provided excellent vision at a range of distances with excellent predictability and stability. Although there were no statistically significant differences in the objective visual findings, there was a statistically significant difference in subjective QoV scores between the 2 postoperative assessments. At both postoperative assessments, patients reported an excellent overall QoV score; however, it seems as though neuroadaptation might have occurred between 3 months and 12 months postoperatively, resulting in significantly less blurred vision and a significantly better overall QoV score. This study provides the clinician with information on how this asymmetric multifocal IOL performs up to 12 months postoperatively and how the perception of QoV alters over this period.

#### WHAT WAS KNOWN

 The IOL assessed here provides good vision at a range of distances with high patient satisfaction up to 3 months postoperatively.

#### WHAT THIS STUDY ADDS

- The asymmetric multifocal IOL provided excellent and similar objective visual and refractive outcomes 3 months and 12 months postoperatively.
- The asymmetric multifocal IOL provided excellent subjective outcomes 3 months and 12 months postoperatively; however, neuroadaptation occurred between the 2 timepoints, resulting in a significantly better overall QoV at 12 months.

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