Effect of position of near addition in an asymmetric refractive multifocal intraocular lens on quality of vision

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PURPOSE: To evaluate the impact of the position of an asymmetric multifocal near segment on visual quality.

SETTING: Cathedral Eye Clinic, Belfast, United Kingdom.

DESIGN: Retrospective comparative case series.

METHODS: Data from consecutive patients who had bilateral implantation of the Lentis Mplus LS-312 multifocal intraocular lens were divided into 2 groups. One group received inferonasal near-segment placement and the other, superotemporal near-segment placement. A +3.00 diopter (D) reading addition (add) was used in all eyes. The main outcome measures included uncorrected distance visual acuity (UDVA), uncorrected near visual acuity (UNVA), contrast sensitivity, and quality of vision. Follow-up was 3 months.

RESULTS: Patients ranged in age from 43 to 76 years. The inferonasal group comprised 80 eyes (40 patients) and the superotemporal group, 76 eyes (38 patients). The mean 3-month spherical equivalent was −0.11 D ± 0.49 (SD) in the inferonasal group and −0.18 ± 0.46 D in the superotemporal group. The mean postoperative UDVA was 0.14 ± 0.10 logMAR and 0.18 ± 0.15 logMAR, respectively. The mean monocular UNVA was 0.21 ± 0.14 logRAD and 0.24 ± 0.13 logRAD, respectively. No significant differences were observed in the higher-order aberrations, total Strehl ratio (point-spread function), or modulation transfer function between the groups. Dysphotopic symptoms measured with a validated quality-of-vision questionnaire were not significantly different between groups.

CONCLUSION: Positioning of the near add did not significantly affect objective or subjective visual function parameters.

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Multifocal intraocular lenses (IOLs) have been used extensively over the past 20 years to enhance near as well as distance vision in the pseudophakic patient. A thorough metaanalysis of numerous studies involving different multifocal IOL technologies in use[1] shows convincing evidence of their ability to restore both near and distance vision. This achievement is not without a small, but significant risk for debilitating visual side effects, such as glare, halo, and reduced contrast sensitivity, that might be severe enough to warrant a technically challenging IOL explantation and exchange.[2–4]

Different design strategies (rotationally symmetric refractive, diffractive, and mixed) have led to varying rates of dysphotopsias and eventual IOL explantation.[5,6] The new Lentis Mplus LS-312 multifocal IOL (Oculentis GmbH) corrects presbyopia through use of a refractive design; however, it incorporates a new approach in multifocal IOL technology by virtue of its sector-shaped near vision section.[7,8] This IOL has been shown to provide high-quality vision with high patient tolerance of abnormal visual phenomena[9] and less loss of contrast sensitivity.[7,10] The asymmetric nature of this IOL enables the near segment to be

placed in various rotational positions. At present, the manufacturer recommends placing the near segment inferiorly and slightly nasally displaced; however, it also states that the near segment can be placed in various positions without untoward effects. At our clinic, initial routine treatment followed recommended placement of the near segment inferiorly. Anecdotal cases of superiorly placed or rotated near segments had potentially indicated lower rates of dysphotopsias without untoward side effects, prompting us to subsequently actively place near segments superiorly.

This retrospective study sought to assess and compare the visual performance of the IOL near segment when placed superiorly compared with inferiorly. Attention was given to determining whether variations in statistical outliers as well as the actual mean in each group existed to ascertain whether either group had an increased frequency of cases with poor distance or reading vision.

PATIENTS AND METHODS

This retrospective nonrandomized study enrolled consecutive patients who had bilateral phacoemulsification followed by Lentis Mplus IOL implantation between May 2011 and May 2012. Patients were divided into 2 groups based on the type of surgery. The initial group had inferior near-segment placement (inferonasal group). Later surgeries were performed using superior near-segment placement (superotemporal group). All presbyopic 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 results anonymously. The study adhered to the tenets of the Declaration of Helsinki and was approved by the local ethics committee. Exclusion criteria were a history of glaucoma or retinal detachment surgery, any grade of cataract, amblyopia, corneal or macular disease, and corneal astigmatism greater than 1.5 diopters (D) assessed by keratometry.

Patient Assessment

Preoperatively, all patients had a full ophthalmic examination that included keratometry, topography and autorefraction (OPD-Scan aberrometer, Nidek Co., Ltd.), subjective refraction, uncorrected (UDVA) and corrected (CDVA) distance visual acuities, uncorrected near visual acuity (UNVA), contrast sensitivity (Pelli-Robson contrast sensitivity chart), slitlamp examination, Goldmann tonometry, dilated fundoscopy, and biometry using partial coherence interferometry (PCI) (IOLMaster, Carl Zeiss Meditec AG).

Vision examinations included UDVA and CDVA (logMAR, original Early Treatment Diabetic Retinopathy Study chart 1 at 4 m) and UNVA at 40 cm with Radner reading charts under a standard mesopic lighting condition. The Radner charts allow direct conversion (0.2 logMAR distance acuity is comparable to 0.2 logRAD reading acuity) with high correlation at 40 cm to a logMAR equivalent for the size of letters. Contrast sensitivity was measured with the Pelli-Robson contrast sensitivity chart at 1 m and 85 candelas/m^2. The PCI device was used to measure corneal curvature, anterior chamber depth, axial length (AL), and subsequent IOL calculation using the Hoffer Q formula[11] for eyes with an AL less than 22.0 mm, the SKR/T formula[12] for eyes with an AL of 22.0 to 25.0 mm, and the Haigis formula[13] for eyes with an AL of more than 25.0 mm (A-constant 118.5 for SRK/T[12] and a0 constant of 0.83, a1, a2 for Haigis[13]). Emmetropia was the target in all cases.

Quality-of-vision scores were obtained using a validated quality-of-vision questionnaire[14] using a Rasch-tested linear-scaled 30-item instrument on 3 scales, providing a score in terms of symptom frequency, severity, and bothersome nature. Standardized mesopic lighting conditions were used.

Intraocular Lens

The Lentis Mplus is a single-piece refractive multifocal hydrophilic acrylic (hydrophobic surface) IOL embedded with a rotationally asymmetric near addition (add) that can vary in strength from +1.5 to +3.0 D. The distance and near principal foci lie on the optical axis with light from the meridional transition zone reflected away.

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 used in all cases. Standard sutureless on-steep axis corneal phacoemulsification (2.8 mm incision) was performed in all cases. A standard 5.5 mm anterior capsulorhexis was created and after irrigation/aspiration of cortex, the IOL was implanted with an injector (Viscojet 2.2 Cartridge-Set LP604240M, Oculentis GmbH). When on-axis surgery was not possible, a 2.8 mm superotemporal corneal position was used to minimize surgically induced astigmatism.

Postoperative Protocol

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) 3 times daily for 1 month, and 1 drop of dexamethasone 0.1% (Maxidex) 4 times daily for 3 weeks.

Postoperatively, patients were evaluated at 1 day and 1 and 3 months. In addition to the preoperative examinations, high-quality postoperative cylinder and higher-order aberrations (HOAs) data were obtained with the aberrometer,

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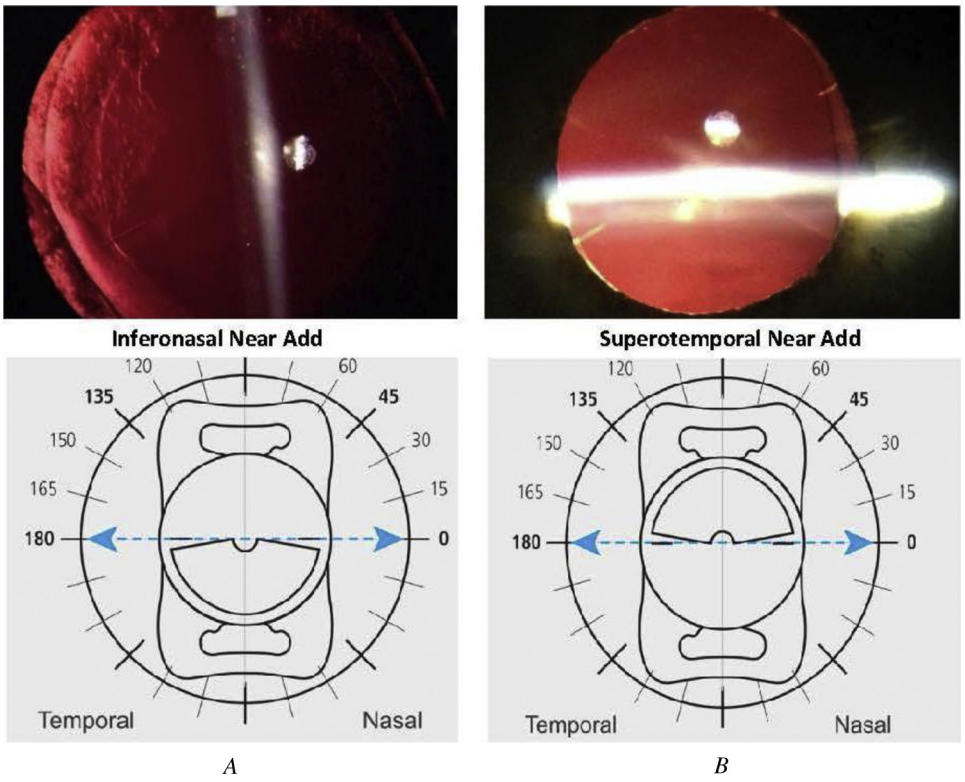

Figure 1. Schematic images show the IOL placed vertically with the near add inferior (*A*) and the near add superior (*B*). The overlying clinical retroillumination images show anticlockwise rotation of the IOL from the vertical position to produce an inferonasal near add position (*A*) and superotemporal near add position (*B*). It can be difficult in vivo to appreciate where the near position is situated, thus the requirement to carefully document this during surgery (add = addition).

which uses dynamic skiascopy-based ocular aberrometry using 1440 points and Placido-disk corneal topography to obtain wavefront data.

The main outcome measures were mean postoperative UDVA, UNVA, contrast sensitivity, defocus curve profile, and quality of vision. In addition the amount of residual cylinder, HOAs, point-spread function (PSF), and modulation transfer function (MTF) curves were assessed. All measurements were taken with a 4.0 mm pupil to conform more closely to physiologic pupil sizes. When necessary, phenylephrine 2.5% used for dilation to obtain a 4.0 mm pupil. All aberration coefficients and root-mean-square (RMS) values were measured up to the 7th Zernike order. The following parameters were analyzed and recorded: total RMS; HOA RMS; coma values for 3rd-order aberrations, total coma terms vertical and horizontal, respectively, $Z(3,-1)$ and $Z(3,+1)$; and spherical aberration $Z(4,0)$ values. The MTF and PSF were calculated based on the effect of HOAs. All measurements were performed simulating distance-vision conditions. Outcomes were repeated at least 3 times to obtain a well-focused aligned image of the eye and were measured 3 months postoperatively. Defocus curves were measured using the technique described by Alió et al.[15] using Radner reading charts to simulate distance visual acuity at 33 cm monocularly. At first, positive lenses ranging from +4.50 to +0.50 D were added followed by negative lenses from −0.50 to −1.50 D; the best visual acuity obtained by the patient was recorded for each lens power.

Analysis of the Intraocular Lens Position Effect on Vision

Intraocular lens centration and tilt were assessed by postoperative dilated slitlamp examination. Superotemporal positioning was defined as the near segment overlapping 90 to 180 degrees and inferonasal as the near segment overlapping 270 to 0 degrees (Figure 1). Any near segments found to have no overlap of both horizontal and vertical designated axes were excluded. Grossly tilted or displaced IOLs on slitlamp examination were also excluded. Posterior capsule opacification (PCO) was graded as follows: 1 = none; 2 = mild (early development of PCO); 3 = moderate (increased PCO with early visual acuity changes not requiring secondary capsulotomy); 4 = severe (PCO affecting vision and requiring neodymium:YAG laser capsulotomy). The UDVA, CDVA, and near vision were assessed with the goal of determining whether there was evidence of differences in their mean or in their level of variation through assessment of outlier differences. In addition, all patients with a mesopic pupil smaller than 3.5 mm and patients with angle κ measurements (aberrometer) greater than 0.3 mm[16] were excluded to minimize potential confounding factors based on pupil size and position, respectively.

Statistical Analysis

Descriptive statistics of age, sex, manifest refraction (sphere, cylinder, axis), contrast sensitivity, and Zernike coefficients of HOAs and lower-order aberrations in each group as well as the PSF and MTF were created using SPSS software (version 11.5, SPSS, Inc.) and Excel software (Microsoft Corp.).

The Shapiro-Wilk test was used to assess normality. Independent *t* tests were used to compare the means of the 2 groups when assessing continuous normal data. Ordinal median data were compared between the 2 groups using the nonparametric Mann-Whitney *U* test. A *P* value less than 0.05 was considered statistically significant. The Student *t* test was used to determine whether the proportion of good near vision or poor near vision was more prevalent in either group.

RESULTS

After 1 patient (2 eyes) was excluded for a high angle κ, the inferonasal group comprised 80 eyes of 40 patients and the superotemporal group, 76 eyes of 38 patients. Table 1 shows the between-group comparison of preoperative data. There were no statistically significant differences in any preoperative parameter between the groups.

There were no intraoperative complications. Two cases, 1 in each group, required phenylephrine 2.5% for dilation to obtain a 4.0 mm pupil.

Visual Acuity and Refraction

Table 2 shows the mean 3-month postoperative visual and refractive outcomes. There was a statistically significant improvement in UDVA in the inferonasal group ($P=.02$, Student paired t test) and in the superotemporal group ($P=.03$, Student paired t test). There was also a statistically significant improvement in UNVA in both groups ($P=.02$ and $P=.03$, respectively; Student paired t test).

There was no statistically significantly difference in the mean spherical equivalent ($P=.22$) or mean postoperative cylinder refraction between the 2 groups ($P=.37$).

Safety

Three months after surgery, no eye lost CDVA or corrected near visual acuity compared with preoperative values.

Efficacy

Figure 2 shows the percentage of patients achieving certain levels of UDVA by group. Seventy-five patients (94%) in the inferonasal group and 71 patients (93%) in the superotemporal group achieved a UDVA of 0.3 logMAR or better. Sixty-two patients (77%) in the inferonasal group and 57 patients (75%) in the superotemporal group achieved 0.1 logMAR or better. No statistically significant difference was found between the 2 groups ($P=.22$, Mann-Whitney U test).

Figure 3 shows the percentage of patients achieving certain levels of UNVA by group. Similarly, 70 patients (87%) in both groups achieved a UNVA of 0.3 or better, with no statistically significant difference between groups ($P=.17$, Mann-Whitney U test). There was no statistically significant between-group difference in any acuity range. Student t tests showed that neither group had better or worse vision in terms of the mean and the outlying spread.

Table 1. Between-group comparison of preoperative data.

Parameter	Inferonasal Group	Superotemporal Group	*P* Value
Age (y)			
Mean ± SD	60.25 ± 7.02	59.42 ± 7.68	.30
Median	60.5	58	
Range	43,76	45,73	
LogMAR UDVA			
Mean ± SD	0.57 ± 0.25	0.65 ± 0.37	.42
Median	0.53	0.64	
Range	0.15, 1.25	0.04, 1.30	
Sphere (D)			
Mean ± SD	+1.14 ± 1.23	+1.56 ± 2.00	.39
Median	+0.75	+1.00	
Range	−2.5, +3.25	−3.25, +3.50	
Cylinder (D)			
Mean ± SD	−1.21 ± 0.85	−1.05 ± 0.70	.43
Median	−0.75	−0.75	
Range	−2.50, 0.00	−3.00, 0.00	
LogMAR CDVA			
Mean ± SD	0.31 ± 0.25	0.23 ± 0.19	.21
Median	0.17	0.12	
Range	0.02, 0.71	0.00, 0.64	
LogMAR UNVA			
Mean ± SD	0.81 ± 0.25	0.59 ± 0.16	.18
Median	0.83	0.62	
Range	0.35, 1.20	0.20, 1.20	
LogMAR CNVA			
Mean ± SD	0.32 ± 0.23	0.29 ± 0.17	.45
Median	0.29	0.25	
Range	0.10, 0.84	0.00, 0.61	
Km (D)			
Mean ± SD	44.84 ± 1.58	44.62 ± 1.23	.62
Median	44.61	44.53	
Range	42.23, 46.62	41.09, 47.83	
Axial length (mm)			
Mean ± SD	22.73 ± 0.74	22.59 ± 0.63	.24
Median	22.63	22.38	
Range	20.92, 23.98	21.21, 23.61	
IOL power (D)			
Mean ± SD	20.94 ± 1.34	21.54 ± 1.59	.13
Median	20.50	22.50	
Range	19.00, 23.50	19.50, 25.50	

CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; IOL = intraocular lens; Km = mean keratometry; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity

The median CDVA was 0.04 in the inferonasal group and 0.03 in the superotemporal group, with no clinically relevant or statistically significant difference between groups ($P=.47$, Mann-Whitney U test). The interquartile range was 0.12 in the inferonasal group and 0.14 in the superotemporal group, with a similar spread between the 2 groups.

The mean preoperative contrast sensitivity was similar between the inferonasal group (1.4 ± 0.13

Table 2. Between-group comparison of 3-month postoperative visual and refractive outcomes.

Parameter	Inferonasal Group	Superotemporal Group	*P* Value
LogMAR UDVA			
Mean ± SD	0.14 ± 0.10	0.18 ± 0.15	.40
Median	0.13	0.16	
Range	−0.20, 0.50	−0.20, 0.54	
Sphere (D)			
Mean ± SD	−0.14 ± 0.46	−0.10 ± 0.60	.83
Median	0.00	0.00	
Range	−1.25, +0.50	−1.25, +0.75	
Cylinder (D)			
Mean ± SD	−0.85 ± 0.91	−0.87 ± 0.82	.37
Median	−0.50	−0.75	
Range	−2.25, 0.00	−2.75, 0.00	
SE (D)			
Mean ± SD	−0.11 ± 0.49	−0.18 ± 0.46	.22
Median	0	−0.1	
Range	−1.375, 0.75	−1.75, 0.50	
LogMAR CDVA			
Mean ± SD	0.04 ± 0.09	0.04 ± 0.07	.47
Median	0.03	0.04	
Range	−0.20, 0.20	−0.20, 0.18	
LogRAD UNVA			
Mean ± SD	0.21 ± 0.14	0.24 ± 0.13	.32
Median	0.22	0.23	
Range	0.00, 0.63	0.00, 0.52	
LogRAD CNVA			
Mean ± SD	0.17 ± 0.13	0.21 ± 0.15	.41
Median	0.15	0.19	
Range	0.00, 0.57	0.00, 0.55	

CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; SE = spherical equivalent; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity

log units) and superotemporal group (1.4 ± 0.11 log units) and was within age-acceptable limits. Postoperatively, there was no recorded loss of contrast sensitivity in either group at 3 months, and contrast sensitivity scores were repeatable to within ±0.15 log units. At 3 months, no eye showed evidence of posterior capsule thickening.

Higher-Order Aberrations

Table 3 shows the total HOAs and Strehl ratio for a 4.0 mm pupil diameter. Table 4 shows the internal aberrometer scan data and Strehl ratio at 3 months for a 4.0 mm pupil diameter. The total RMS HOA increased in both groups from a mean preoperative level of 0.2 µm up to 0.48 µm postoperatively in both groups ($P>.001$). The total RMS and HOA RMS were very similar between the groups. There were

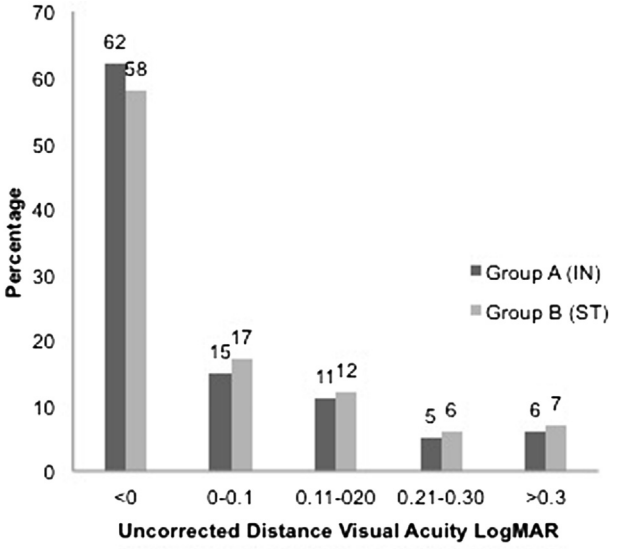

Figure 2. The UDVA for stepwise logMAR visual acuity levels less than 0.0 to more than 0.3 (IN = inferonasal; ST = superotemporal).

no statistically significant between-group differences in total spherical aberration postoperatively (Table 3).

Significant between-group differences were noted in total vertical coma aberration and trefoil (Table 3). The differences varied in magnitude, and the inferonasal group showed negative values. There was no statistically significant difference in total horizontal coma between groups ($P>.05$, Student *t* and Mann-Whitney *U* tests).

Internal spherical aberration and trefoil appeared more polarized between groups, with negative values in the inferonasal group and positive values in the superotemporal group, although the difference did not reach statistical significance ($P>.05$, Mann-Whitney *U* test). Vertical coma was significantly statistically different between groups ($P=.0001$, Mann-Whitney *U* test).

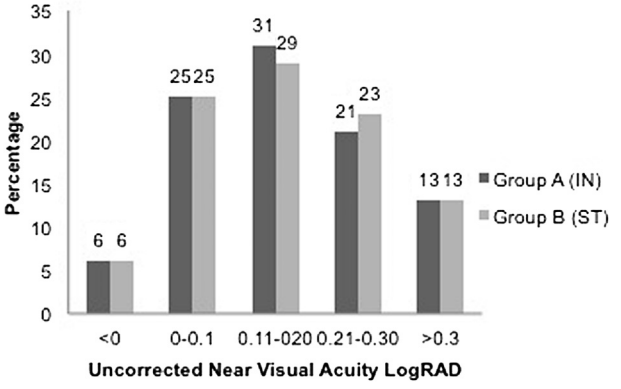

Figure 3. The UNVA for stepwise logRAD visual acuity levels less than 0.0 to more than 0.3 (IN = inferonasal; ST = superotemporal).

Table 3. Total aberrometer HOAs and Strehl ratio for a 4.0 mm pupil diameter.

Parameter	Inferonasal Group	Superotemporal Group	*P* Value
Total RMS (μm)			
Mean± SD	0.997 ± 0.053	1.045 ± 0.037	.49
Range	0.944, 1.050	1.008, 1.082	
HOA RMS (μm)			
Mean± SD	0.467 ± 0.030	0.477 ± 0.018	.79
Range	0.447, 0.497	0.459, 0.495	
SA (μm)			
Mean ± SD	−0.009 ± 0.005	0.003 ± 0.006	.44
Range	0.004, 0.014	0.003, 0.009	
Trefoil (μm)			
Mean ± SD	−0.210 ± 0.029	0.090 ± 0.044	.02
Range	0.181, 0.239	0.046, 0.134	
Vertical coma (μm)			
Mean ± SD	−0.079 ± 0.010	0.129 ± 0.014	.00
Range	0.069, 0.089	0.115, 0.143	
Horizontal coma (μm)			
Mean ± SD	−0.021 ± 0.008	−0.023 ± 0.008	.86
Range	0.013, 0.029	0.015, 0.031	
Strehl ratio			
Mean ± SD	0.024 ± 0.002	0.025 ± 0.003	.77
Range	0.022, 0.026	0.022, 0.028	

HOA = higher-order aberration; RMS = root mean square; SA = spherical aberration

Modulation Transfer Function and Strehl Ratio

Similarly, the difference in the MTF was not statistically significant between groups ($P > .05$). The MTF value at 5 cycles per degree (cpd) was 0.4 in both groups; at 10 cpd, 0.2; at 15 cpd, 0.13; at 20 cpd, 0.09; at 25 cpd, 0.07; and at 30 cpd, 0.06 (Figure 4).

Table 4. Internal aberrometer scan data and Strehl ratio of eyes at 3 months for a 4.0 mm pupil diameter.

Parameter	Inferonasal Group	Superotemporal Group	*P* Value
Total RMS (μm)			
Mean ± SD	0.944 ± 0.055	1.043 ± 0.046	.19
Range	0.889, 0.999	0.997, 1.089	
HOA RMS (μm)			
Mean ± SD	0.462 ± 0.027	0.505 ± 0.017	.21
Range	0.435, 0.489	0.488, 0.523	
SA (μm)			
Mean ± SD	−0.062 ± 0.007	0.054 ± 0.007	.43
Range	0.055, 0.069	0.047, 0.061	
Trefoil (μm)			
Mean ± SD	−0.184 ± 0.027	0.123 ± 0.044	.22
Range	0.157, 0.211	0.079, 0.167	
Vertical coma (μm)			
Mean ± SD	−0.049 ± 0.010	0.111 ± 0.013	.00
Range	0.039, 0.059	0.098, 0.124	
Horizontal coma (μm)			
Mean ± SD	−0.035 ± 0.011	−0.013 ± 0.012	.18
Range	0.024, 0.046	0.001, 0.025	
Strehl ratio			
Mean ± SD	0.031 ± 0.002	0.025 ± 0.002	.04
Range	0.029, 0.033	0.023, 0.027	

HOA = higher-order aberration; RMS = root mean square; SA = spherical aberration

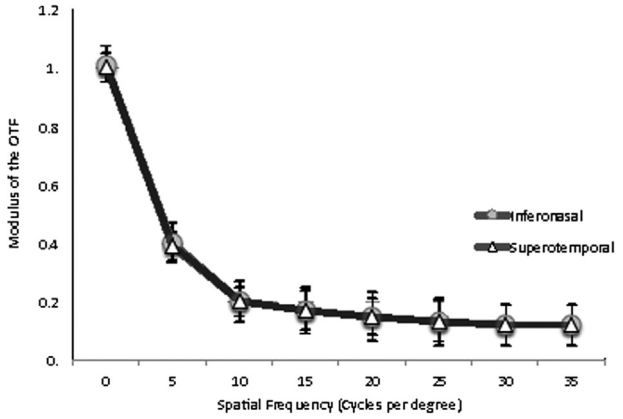

Figure 4. Inferonasal versus superotemporal near-add position spatial frequency MTF curve at 3 months (OTF = optical transfer function).

There was no statistically significant between-group difference in the total aberration Strehl ratio between the 2 groups (Table 3). However, this became statistically significant for internal aberration data values, with a higher Strehl ratio in the inferonasal group ($P = .04$, Mann-Whitney *U* test).

Defocus Curve

Figure 5 shows the mean defocus curve in both groups. The defocus curves showed largely similar results with no significant differences at any individual defocus level between the inferonasal group or the superotemporal group ($P > .05$, Mann-Whitney *U* test).

Patient Self-Reported Outcomes

Results of the quality-of-vision questionnaire completed by patients 1 month and 3 months postoperatively showed trend toward a reduction in the frequency and severity of dysphotopic symptoms of glare, halos, and starbursts in both groups, with starbursts the slightly more prevalent of the 3. The difference in the amount of adverse symptoms perceived was not statistically significant between the 2 groups ($P > .05$) (Table 5).

DISCUSSION

The largest published case series of bilateral implantation of the Lentis Mplus LS-312 multifocal IOL by Venter et al.[9] found excellent distance and near visual acuity in patients after placement of the near segment inferiorly as per the manufacturer's instructions. Incidental rotation of the IOL away from its intended axis has been found to be well tolerated,[9,17] spurring interest in the possibility of deliberate rotation of the near add segment into other positions to gain certain clinical refractive advantages. One suggestion is to rotate the near add superotemporally to maximize the theoretical beneficial effect of displacing unwanted near segment coma-induced glare without introducing further unwanted photic symptoms. Another is to place the near add nasally to potentially reduce the patient's appreciation of dysphotopic symptoms due to reduced retinal sensitivity; it has been shown that retinal sensitivity varies significantly topographically, with reduced sensitivity noted nasally compared with temporally.[17]

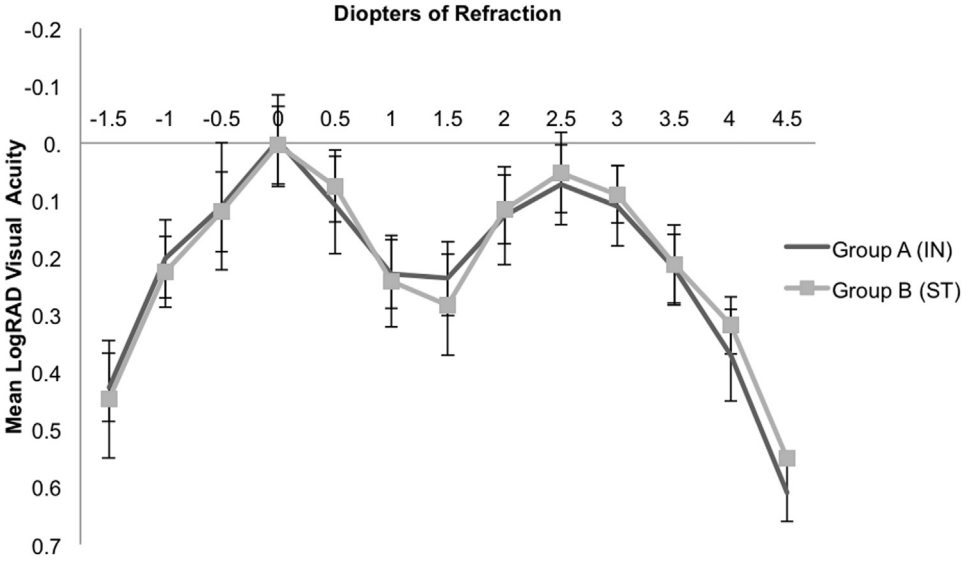

Figure 5. Mean binocular defocus curves with standard deviation (*error bars*) at the 3-month visit (IN = inferonasal; ST = superotemporal).

Table 5. Subjective quality of vision questionnaire given 3 months postoperatively.*

Visual Symptom	Mean Score ± SD		*P* Value†
	Inferonasal Group	Superotemporal Group	
Glare	0.65 ± 0.82	0.64 ± 0.77	.43
Halos	0.51 ± 0.67	0.65 ± 0.72	.32
Starburst	0.71 ± 0.83	0.70 ± 0.84	.21
Hazy	0.42 ± 0.63	0.40 ± 0.66	.42
Blurred vision	0.36 ± 0.59	0.40 ± 0.80	.30
Distortion	0.14 ± 0.40	0.10 ± 0.37	.35
Double images	0.20 ± 0.40	0.08 ± 0.35	.44
Vision fluctuation	0.45 ± 0.61	0.35 ± 0.76	.25
Reading glasses for near tasks	0.61 ± 0.66	0.48 ± 0.67	.32
Depth perception difficulty	0.14 ± 0.40	0.18 ± 0.44	.51
Overall QoV night‡	7.13 ± 3.74	7.72 ± 2.81	.42
Overall QoV day‡	8.19 ± 1.89	8.28 ± 1.70	.22

QoV = quality of vision
*Grading scale: 0 = never; 1 = occasionally; 2 = quite often; 3 = always
†Mann-Whitney *U* Test
‡Grading scale: 0 (worst possible) to 10 (best possible)

Both diffractive and concentric refractive multifocal IOLs have been found to significantly increase spectacle-free near vision.[1] However, visually significant photic symptoms (eg, glare and halo) have required an eventual IOL exchange in up to 11% of patients.[2]

The severity of photic symptoms from multifocal IOLs appears independent of pupil size under photopic, mesopic, and scotopic conditions.[18] With the asymmetric refractive design of the Lentis Mplus LS-312 IOL, pupil size independence appears to be higher than with previous diffractive multifocal IOLs,[19] with fewer patient reports of photic phenomena overall. We found no functional significant difference between the 2 groups in the patients' subjective quality of vision reporting in each of the 10 question categories. We also found no significant difference between overall quality of vision at night or during the day between the groups.

Decentration of multifocal IOLs has been reported as a main indication for IOL exchange.[20] In optical bench tests, this may be explained by the increasing eccentricity of the optic center in relation to the pupil center, causing significant increases in HOAs.[21]

As with other multifocal IOLs, decentration from an eccentric capsulorhexis or asymmetric capsule fibrosis with Lentis Mplus LS-312 IOLs might lead to significant glare and halo symptoms with an eventual

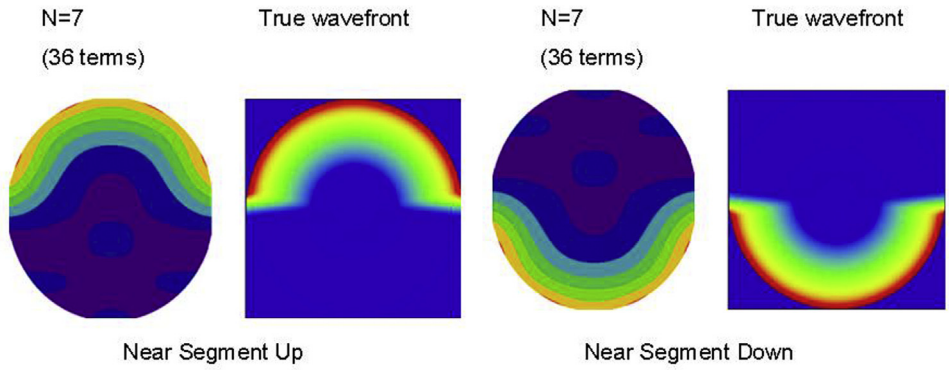

Figure 6. The first image depicts the apparent coma as indicated by ray tracing, where the near segment is positioned downward. The second image indicates a similar phenomenon induced by the near segment positioned superiorly (iTrace = in-house ray tracing on optical bench at Oculolentis).

It is not possible to fit the Asymmetric Mplus optic with Zernike polynomials

- iTrace is not able to reconstruct the Mplus optic correctly
- iTrace cannot distinguish a monofocal IOL from a diffractive IOL

need for IOL explanation in a minority of cases.[9] In this study, we found it challenging through an undilated pupil to be certain that centration of the IOL was exact; therefore, all pupils were dilated for a thorough slitlamp examination to confirm that no gross IOL decentration existed. The potential use of internal HOA values (coma, spherical, and tilt) to assist in determining the presence of decentration or tilt of the IOL was not possible because of the unique aberrometry results obtained with this IOL (Figure 6). Our study examined the effect of rotating the near segment about the optical axis rather than decentration of the IOL.

We found that a bilateral near-segment superotemporal IOL position provided equivocal excellent distance and near vision results with high levels of patient satisfaction compared with bilateral inferonasal implantation, supporting earlier anecdotal reports of well-tolerated IOL rotation away from the manufacturer's inferior nasal near-segment recommended position.[15,17] This might be a protective feature of this type of IOL design, in which both the principal refractive foci lie on the central axis and do not rely on diffractive concentric constructive interference for a clear image at a given focal length.[22] This might be adversely affected by decentration with pupil edge distortion and concomitant glare and halo generation. Theoretically, caution must be exercised in patients with smaller pupils (<3.5 mm) and a large angle κ or large amplitude pupil shift where the superotemporal near segment might become occluded. Thus, in our study, we developed exclusion criteria for patients with a large angle κ and small pupils, leading to the exclusion of 1 patient (angle κ 0.37 mm). Although excluded, on examination this patient did not report or show obvious deficiencies in near or far corrected or uncorrected vision, falling well within the observed confidence intervals in the current study population.

Although there were no cases of IOL decentration or tilt on slitlamp examination, there was a significant increase in total measured coma and trefoil aberrations, which is in keeping with measured aberrometry findings in studies with rotationally asymmetric IOLs.[23] Limitations of Hartmann-Shack wavefront aberrometry measurements in eyes with diffractive[24] and refractive[25] multifocal IOLs are well known. One study using double-pass time-based dynamic skiascopy of diffractive multifocal IOLs showed good correlation between subjective visual performance and aberrometry results.[26] Dynamic skiascopy was shown in 1 study to provide less repeatable coma and trefoil HOAs results with 4.0 mm and 5.0 mm pupil diameters than results with Hartmann-Shack and ray-tracing wavefront aberrometry,[27] although increased coma and trefoil aberration measurements with good repeatability using Hartmann-Shack aberrometry have been shown in Lentis Mplus LS-312 IOLs.[15]

The principle of using a full 360-degree wavefront result with rotationally asymmetric IOLs measured with current aberrometers has been called into question[A] (Figure 6). The first 36 Zernike terms are not sufficient to accurately reconstruct the Lentis Mplus LS-312 wavefront aberration, and most aberrometers use a maximum of 6th-order Zernike terms, or only about 28 coefficients to fit the wavefront. Many more terms are needed to fit the Lentis Mplus LS-312 wavefront accurately. The Lentis Mplus LS-312 far and near component optics do not show coma aberration when independently ray traced; only mathematically combining the sum of the 2 optics measurements will produce a coma term, which is shown in the graph in Figure 6. This is an important distinction should these wavefront measurements be incorporated into treatment planning for non-topographically guided refractive laser enhancement treatments in these patients.

The rotational asymmetry of the Lentis Mplus LS-312 IOL might be expected to increase primary coma and affect the position of the induced coma. Moreover, the specific geometry in such an optic platform might induce different levels of primary coma, depending on the magnitude of the asymmetry and thus be affected by the level of the near add.[8] Most important, because of the design of this IOL, it is impossible with regular aberrometers to determine whether measured coma is truly coma or simply an artifact (Figure 6).

The exact functional effects of this coma are not fully known; however, there are reports that moderate vertical coma after spherical IOL implantation has a positive effect on near visual acuity, enhancing depth of focus as well as the range of accommodation.[9,15] It has also been suggested, however, that for vertical coma to have a beneficial effect, it should be in the region of 0.20 μm so it exerts an isolated effect on depth of focus and also be lower than 0.35 μm to reduce side effects such as diplopia and glare.[9] The mean magnitude in the superotemporal group was higher than in the inferonasal group (0.129 ± 0.014 μm versus −0.079 ± 0.010 μm). Although this difference was statistically significant ($P = .0033$), measurements in both groups were less than 0.35 μm and therefore would not be expected to have a negative impact on visual performance with a 4.0 mm pupil. This particular magnitude of 0.35 μm of coma-inducing side effects might also pertain to symmetrical multifocal IOLs only.

Horizontal coma was also significantly increased postoperatively, but with no difference between groups. However, the magnitude of the horizontal

coma was reduced to a large degree compared with the magnitude of vertical coma and as such is unlikely to have significant negative effects on vision. Another asymmetric aberration, trefoil, was also statistically higher postoperatively in both groups and statistically higher in the inferonasal group than in the superotemporal group (-0.210 ± 0.029 μm versus 0.090 ± 0.044 μm) ($P < .02$).

The results in this study therefore show that the measured position and level of 2 of the asymmetric HOAs (vertical coma and trefoil) are altered by the position of the IOL near add. However, although reproducible, the clinical significance of this monochromatic aberrometry measurement is not fully understood, especially in a setting in which neural adaptation is a significant contributing factor to overall patient satisfaction and in which most of the coma noted is actual artifact.

A limitation of our study is the lack of intermediate vision testing. The intermediate vision results of Lentis Mplus LS-312 IOLs in similar study population have been extensively published[17,23,28] and show variability. The Lentis Mplus LS-312 distance and near visual acuity results across studies[7,8,15,17,19] are more consistent and have also been established in the single largest study cohort involving 9366 eyes with Mplus IOLs.[9] The Lentis Mplus LS-312 defocus curves in smaller and larger studies consistently support a clear bifocal profile at 0.0 D and −2.5 D, which correspond only to far and near visual acuity ranges, respectively. It is possible that differences exist in intermediate vision between inferonasal near add positioning and superotemporal near add positioning, although any difference arising from rotating this IOL around the central axis would be expected to be of a higher magnitude in the 2 polar principal focal refractive powers of far and near, which are farther from the central axis than the intermediate vision transition zone. Given the above rationale, we chose to focus on far and near visual acuity results to unambiguously answer the question of our study. The retrospective nature of our study makes it vulnerable to bias. A randomized controlled trial might have helped eliminate this bias and confirm the findings. The consecutive nature of the 2 groups in our study might have added a confounding learning effect to the results in terms of improvements in surgical technique or in biometric calculations.

The Lentis Mplus LS-312 IOL retains normal contrast vision while providing dual focal lengths and thus an increased visual range. The results in this study indicate that in the majority of cases, the positioning of the near add has no statistically significant positive or negative effect on visual quality in the majority of patients.

WHAT WAS KNOWN

- The manufacturer's current recommendation for placement of the near add of a new asymmetric IOL is to place it in the inferonasal position in each eye. Various surgeons advocate placing the near add superiorly to reduce dysphotopic symptoms.

WHAT THIS PAPER ADDS

- Placement of the near add in the superior or inferior position produced no consistent statistically significant difference in subjective or objective visual parameters, including dysphotopic symptoms. Although changing the placement of the near add induced differences in coma and trefoil HOAs, these changes are not clinically relevant and rather represent current limitations in aberrometry measurement of HOAs with this IOL design.

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