Visual function after bilateral implantation of a new zonal refractive aspheric multifocal intraocular lens

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Running head: Visual performance with bilateral zonal refractive IOLs

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ABSTRACT

Purpose: To evaluate visual function after bilateral implantation of a zonal refractive aspheric multifocal intraocular lens (IOL).


Methods: A prospective study comprising 64 consecutive eyes of 32 cataract patients (mean age 63.6 ± 9.1 years, mean preoperative spherical equivalent 1.30 ± 2.56 D) to receive bilateral Lentis Mplus LS-312 (Oculentis GmbH, Berlin) multifocal IOLs. Distance, intermediate and near visual acuities, contrast sensitivity (CS), defocus curves and quality of vision questionnaire including presence of halos or dysphotopsia were evaluated at 6-month follow-up. A control group of 32 age-matched monofocal pseudophakic patients was used for comparison of CS function.

Results: Binocular distance corrected visual acuity (logMAR) was -0.04 ± 0.07 (SD) at 6 m, 0.11 ± 0.10 at 1 m, and 0.06 ± 0.07 at 40 cm. Defocus curve showed very little intermediate vision drop-off. Photopic CS for distance was similar to a monofocal IOL CS function while photopic CS for near and mesopic CS for distance with or without glare was reduced at high frequencies. The mean patient satisfaction was 8.09 ± 1.30 (scale 0 to 10) and 84% of patients were completely independent of spectacles. Moderate halos, glare and night vision problems were reported by 6%, 13% and 16% of patients, respectively.

Conclusion: The new-generation multifocal Lentis Mplus IOL provided adequate distant, intermediate and (to a lesser extent) near vision, giving high rates of spectacle freedom. Halos occurred exceptionally, while other photic phenomena should be expected in a small percentage of patients.
INTRODUCTION

Implantation of intraocular lenses (IOLs) in order to obtain refractive correction for all distances is the goal for lens-based refractive surgery. Several multifocal IOL designs have been introduced, including diffractive, zonal refractive, hybrid refractive-diffractive and pseudo-accommodating IOLs.\textsuperscript{1–10} Previous studies have reported better uncorrected near and intermediate vision with multifocal IOLs in comparison with monofocal IOLs, while maintaining comparable distance acuity.\textsuperscript{11-12} However, lack of satisfaction with the outcomes after multifocal IOL implantation is a relatively frequent complaint of patients who do not achieve visual goals, have limited quality of vision, or show new optical aberrations.\textsuperscript{5,13}

The Lentis Mplus IOL (Oculentis GmbH, Berlin) is a new one-piece refractive multifocal IOL with an aspheric posterior surface. The multifocality is achieved by implementing of a near vision sector of +3.0 diopters (D) in the lower IOL segment as in a bifocal ophthalmic lens, yielding +2.5 D at the spectacle plane. The Lentis Mplus is based on the concept of rotational asymmetry: the lens is divided into 2 different radial sectors, for distance and near vision, both on the optical axis of the lens. The light is refracted to the near focus only in a specific sector and the rest of the lens acts as a monofocal IOL. The potential advantages of this approach may include more light to the distance focus with improved contrast sensitivity (CS), less haloes and glare, and better image quality, avoiding the effect of light scatter due to diffraction.\textsuperscript{14} Comparison of this new-generation rotational asymmetric multifocal IOL versus a monofocal IOL has been carried out, but this report did not include subjective assessment on the presence of photic phenomena postoperatively.\textsuperscript{14} The aim of the
present study was to evaluate the clinical performance of the Lentis Mplus LS-312 multifocal IOL including photic phenomena assessment.
PATIENTS AND METHODS

Enrollment and baseline

This prospective consecutive nonrandomized interventional clinical study comprised patients having bilateral cataract surgery with implantation of a rotationally asymmetric multifocal IOL. Inclusion criteria were cataract causing a significant reduction in visual quality, potential visual acuity determined by dilated near-pinhole test $^{15}$ better or equal than 0.3 (logMAR) and corneal astigmatism equal or less than 1.00 D in both eyes. Exclusion criteria were ocular disease other than cataract including uveitis, amblyopia, glaucoma, retinal detachment, diabetic retinopathy, macular degeneration, corneal opacities, previous corneal refractive surgery and neuro-ophthalmic diseases. Written informed consent was obtained from all patients before surgery in accordance with the Declaration of Helsinki, and Institutional Review Board approval was obtained from the hospital Ethics Committee.

Preoperatively, all patients had a full ophthalmologic examination including refractive status, distance, intermediate and near monocular visual acuities, slit lamp evaluation, tonometry and fundoscopy. Uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) at 6 m, and uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate visual acuity (DCIVA) at 2 m, 1 m and 70 cm, were assessed using a calibrated Snellen chart. Uncorrected near visual acuity (UNVA), distance-corrected near visual acuity (DCNVA) and corrected near visual acuity (CNVA) using a +2.50 D addition over distance correction were tested at 50 cm, 40 cm, and 33 cm, with a ETDRS chart. Corneal refractive power was measured with a KR-7000 (Topcon) automated keratoreflectometer and axial length was measured using non-contact optical biometry (IOL Master, Carl Zeiss Meditec AG). Power of the
IOL was selected for a target of emmetropia applying the SRK/T formula for eyes with axial length > 22 mm, and the Hoffer-Q formula for eyes with axial length < 22 mm.\textsuperscript{16-18} The A constant used was 118.2. The data screening criteria proposed by Holladay et al\textsuperscript{19} was used to avoid refractive surprises.

**The Lentis Mplus IOL**

The Lentis Mplus (LS-312MF) is a biconvex single piece, multifocal acrylic lens made of hydrosmart material with an aspheric posterior surface design. The LS-312 MF model has an overall length of 12.0 mm, optics of 6.0 mm and C-loop haptics design with 0\(^\circ\) angulations. Although the Lentis Mplus is available in both plate and C-loop haptics designs, only the latter model was used in the present study. The Lentis Mplus is a non-rotational symmetric multifocal IOL with a refractive design, combining an aspheric asymmetric distance-vision zone with a sector-shaped near-vision zone with +3.0 D addition.

**Surgical Technique**

All eyes were operated by the same surgeon (GM) being the second-eye surgery performed within one week from the first. Phacoemulsification using a 2.75-mm clear-cornea incision placed on the steepest meridian, 5-mm capsulorrhexis and symmetric implantation of the IOL in the capsular bag was carried out in all the eyes. Intraocular lenses were implanted according to the manufacturer’s instructions using a disposable 2.2 mm injector (Viscoject 2.2 Cartridge-Set, Medicel AG), that is, with the horizontal reference marks in the optics of the IOL placed on the 0\(^\circ\)-180\(^{\circ}\) meridian (haptics at 90-270\(^{\circ}\)), thus with the near sector placed inferiorly. Postoperative topical therapy included diclofenac 0.1% (Dicloabak\textsuperscript{\textregistered}), tobramycin 0.3% and dexamethasone 0.1% (Tobradex\textsuperscript{\textregistered}) for 3 weeks.
Postoperative Assessments

Postoperative evaluations were performed 1 day, 1 week, 1, 3, and 6 months after the second-eye surgery and included refractive status, slitlamp evaluation, tonometry and fundoscopy. Monocular and binocular UDVA, CDVA, UIVA and DCIVA at 2 m, 1 m and 70 cm, and UNVA, DCNVA and CNVA at 50 cm, 40 cm, and 33 cm, were recorded.

To generate defocus curves, monocular visual acuity was measured with the Snellen chart at 6 m using a variety of lens powers in a phoropter. Patients were defocused to -5.0 D spherical from manifest refraction values and logMAR acuity was then recorded. Added negative spherical power was progressively reduced in 0.5 D steps and logMAR acuity was recorded after every step until reaching the original manifest refraction values. Patients were then defocused to +3.0 D spherical from manifest refraction, and logMAR acuity was again recorded. Positive spherical power was progressively reduced in 0.5 D steps and logMAR acuity recorded after every step until reaching manifest refraction values.

Contrast sensitivity was tested monocularly for both distance and near vision with best correction for distance under photopic (90 cd/m²) conditions, and for distance with and without glare under mesopic (5 cd/m²) conditions using a FACT test (Stereo Optical Co., Inc.). This test allows the presentation of sine-wave gratings at different spatial frequencies (1.5, 3, 6, 12, and 18 cycles per degree [cpd]), with increasing contrast values. Absolute values of log₁₀ CS were obtained for each combination of eye and spatial frequency, and means and standard deviations were calculated. The HD 9221 photometer (Delta OHM S.r.L.) was used to measure the room lighting conditions where CS was measured in order to ensure equal lighting levels for
all patients in all testing sessions. Under photopic conditions, luminance was 90 cd/m² and illumination was 450 lux. Mesopic conditions were 5 cd/m² and 4 lux. Patients remained 10 minutes inside the testing room under mesopic conditions for an appropriate adaptation before mesopic CS measurement was carried out. A control group was obtained measuring CS with appropriate correction for distance and near in 32 age-matched pseudophakic patients implanted with the AR-40e monofocal IOL (AMO, Abbott Park, IL, USA).

Posterior capsule opacification (PCO), IOL centration and tilt were assessed at 6 months. Posterior capsule opacification 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 Nd:YAG laser capsulotomy).

Quality of Vision Questionnaire

At the final follow-up visit after 6 months, all patients completed a 14-item questionnaire, which included the presence of visual disturbances or photic phenomena (4 items): glare (trouble seeing street signs due to bright light on oncoming headlights), halos (rings around lights), double vision and night vision difficulties; visual lifestyle activities (6 items): watching television, driving at night, using a computer, reading, using a cell phone and shaving/putting on make-up; spectacle independence for distance, intermediate and near vision (3 items) and overall satisfaction (1 item). The response rating scale for visual disturbance and lifestyle activities items was: 0 = no difficulty, 1 = minimal difficulty, 2 and 3 = moderate difficulty and 4 and 5 = severe difficulty; for spectacle use items 0 = never, 1= rarely or occasionally, 2 = often and 3 = always; and for overall satisfaction from 0 =
least to 10 = most satisfied. This questionnaire is a summarized version of that one
used by Kohnen et al\textsuperscript{22}, which is in turn based on the survey distributed in the FDA
clinical trials for the Alcon AcrySof IQ ReSTOR in the National Eye Institute Visual
Functioning Questionnaire-25\textsuperscript{23} and the Cataract TYPE questionnaire.\textsuperscript{24}

**Data Management and Statistical Analysis**

Visual acuity values were converted to logMAR notation for statistical purposes.
For intermediate visual acuities at 2 m, 1 m, and 70 cm, and for near visual acuities at
50 cm and 33 cm, scales were corrected accordingly as previously described.\textsuperscript{25}
Logarithmic scales were used for both statistical and graphical purposes with regards
to CS data. Manifest refractions were converted into power vectors coordinates as
proposed by Thibos and Horner.\textsuperscript{26} The revised abbreviations for reporting visual acuity
values proposed by Kohnen\textsuperscript{27} were used. Statistical analysis was carried out using
SigmaPlot v 11 (Systat Software Inc., 2008). The normality of all data samples was
evaluated with Kolmogorov-Smirnov test. The Student $t$-test for paired data was used
for all parameter comparisons between preoperative and postoperative examination
and the Student $t$-test for unpaired data was used for the comparison between the
multifocal and monofocal groups regarding CS. Results are presented as the mean ± SD
and statistical significance was set at $P < .05$.  


RESULTS

Data were collected from 64 eyes of 32 patients (18 men and 14 women). The mean age of the patients was 63.6 ± 9.1 years (range 48 to 71 years). The mean pupil size was 3.4 ± 0.8 mm under photopic conditions and 5.3 ± 0.7 mm under mesopic conditions. The mean preoperative spherical equivalent was 1.30 ± 2.56 D; 47 eyes (73%) were hyperopic, 12 (19%) were myopic, and 5 (8%) were emmetropic.

Adverse events and posterior capsule assessments

There were no intraoperative complications. There were no cases of iris trauma, IOL decentration or tilt. Two patients had minor adverse events: 1 patient had bilateral dry eye requiring punctual plug insertion and 1 patient reported bilateral dysphotopsia in the form of monocular diplopia. At 6 months, 59 of 64 eyes (92.2%) had no PCO, 4 eyes (6.3%) had grade 2 PCO, and 1 eye (1.5%) had grade 3 or severe PCO requiring capsulotomy.

Refraction

Refractive outcomes after cataract surgery with the Lentis Mplus IOL were very close to emmetropia with mean spherical equivalent (M) of -0.30 ± 0.33 D. There was no induced astigmatism as a consequence of cataract surgery, with no significant changes in $J_0$ or $J_45$ components of astigmatism after vector decomposition (Table 1). Fifty-eight eyes (90.6%) were within ± 0.50 D of spherical equivalent, while all the eyes were within ± 1.00 D. The 6 eyes (9.4%) with spherical equivalent higher than ± 0.50 D were all myopic, with a mean residual spherical equivalent of -0.75 ± 0.15 D

Distant, intermediate and near vision

Table 1 shows the comparison between monocular LogMAR visual acuity values before and 6 months after cataract surgery with the Lentis Mplus IOL. Table 2 shows
the monocular and binocular LogMAR visual acuity values achieved with the Lentis Mplus IOL at all tested distances. As expected after cataract surgery, there was a statistically significant improvement in monocular LogMAR UDVA from 0.49 ± 0.48 to 0.05 ± 0.10 ($P < .01$, paired Student t test) and monocular LogMAR CDVA from 0.39 ± 0.44 to -0.02 ± 0.05 ($P < .01$, paired Student t test). Binocular LogMAR UDVA and CDVA were 0.03 ± 0.11 and -0.04 ± 0.07, respectively. The improvements in monocular LogMAR UNVA to 0.11 ± 0.13, monocular LogMAR DCNVA to 0.07 ± 0.07, and monocular LogMAR CNVA to 0.00 ± 0.06 were also statistically significant after surgery (all $P < .01$, paired Student t test). Binocular UNVA and DCNVA at 40 cm were 0.09 ± 0.12 and 0.06 ± 0.07, respectively.

After cataract surgery there were also statistically significant improvements in monocular LogMAR UIVA and DCIVA for 1 m to 0.13 ± 0.12 and 0.14 ± 0.08 respectively (both $P < 0.01$, paired Student t test). Binocular LogMAR UIVA and DCIVA for 1 m were 0.13 ± 0.09 and 0.11 ± 0.10, respectively. Uncorrected visual acuity in decimal notation was at least 0.5 for near and distance in more than 98% of eyes and for all 3 intermediate distances in 76% of eyes. Binocular decimal CDVA was 1.10 ± 0.68 lines, decimal DCIVA was 0.92 ± 0.87 lines at 2 m, 0.78 ± 0.95 lines at 1 m, and 0.76 ± 0.72 lines at 70 cm. Binocular decimal UNVA at 40 cm was 0.82 ± 1.24 lines while binocular decimal DCNVA at 40 cm was 0.87 ± 0.72 lines.

Regarding the 6 eyes with residual spherical equivalent higher than -0.50 D, mean LogMAR UDVA was 0.08 ± 0.06 (0.83 ± 0.59 lines, decimal), mean LogMAR UIVA at 1 m was 0.04 ± 0.05 (0.91 ± 0.52 lines, decimal), and mean LogMAR UNVA at 40 cm was 0.13 ± 0.07 (0.74 ± 0.65 lines, decimal), meaning that the tolerance to myopic defocus after Lentis Mplus IOL was excellent.
Correlation between LogMAR CDVA and photopic pupil size was very low (0.15) and statistically not significant (p=0.23). The same occurred for LogMAR DCNVA and photopic pupil size (-0.09; p=0.52).

**Defocus curve**

The defocus curve in Figure 1 consisted of 2 peaks of maximum vision located at the far and near foci corresponding to 0.00 D and -2.50 D defocus, respectively, with reduced visual acuity for intermediate distances. The defocus curve showed a peak of optimum near vision (0.07 ± 0.07 logMAR) at the vergence of -2.5 D, the equivalent of 40 cm from the eye. The minimum intermediate vision occurred at a vergence of -1.0 D, or 1 m from the eye. Even though, the mean intermediate visual acuity at this point on the defocus curve remained good (0.14 ± 0.08 logMAR).

**Contrast sensitivity**

Photopic distance CS with the Lentis Mplus IOL was similar to the monofocal IOL control group (Figure 2, top), with no statistically significant differences at any of the tested frequencies (1.5 cpd, \( P = 0.23 \); 3 cpd, \( P = 0.49 \); 6 cpd, \( P = 0.71 \); 12 cpd, \( P = 0.20 \); 18 cpd, \( P = 0.10 \)). Photopic near CS (Figure 2, bottom) was similar at low frequencies (1.5 cpd, \( P = 0.20 \); 3 cpd, \( P = 0.71 \); 6 cpd, \( P = 0.34 \)) but was significantly lower in comparison with the monofocal CS function at 12 cpd (\( P < 0.01 \)) and 18 cpd (\( P < 0.01 \)).

Under mesopic conditions without glare (Figure 3, top), distant CS with the Lentis Mplus IOL was similar to the monofocal IOL at low frequencies (1.5 cpd, \( P = 0.12 \); 3 cpd, \( P = 0.12 \); 6 cpd, \( P = 0.09 \)), but was significantly lower at high spatial frequencies (12 cpd, \( P < 0.01 \); 18 cpd, \( P < 0.01 \)). The same happened for distant CS under mesopic conditions with glare (Figure 3, bottom) with no significant differences.
at 1.5 cpd \( (P = 0.14) \) and 3 cpd \( (P = 0.14) \) but with statistically significant lower values at higher frequencies \( (6 \text{ cpd, } P < 0.01; 12 \text{ cpd, } P < 0.01, 18 \text{ cpd, } P < 0.01) \).

**Visual Disturbances and Photic Phenomena**

The mean score for glare, halos, double vision and night vision disturbances indicated minimum to no difficulty at 6 months of follow-up (Table 3). Five patients (16%) reported moderate night vision problems, 4 patients (13%) reported moderate glare, 2 patients (6%) saw moderate halos, and 1 (3%) had monocular double vision in both eyes with caused moderate impairment. No patient reported severe difficulty for any of the 4 visual disturbance items evaluated.

**Visual Lifestyle Activities**

At 6 months, none of the patients reported severe difficulty with any of the 6 lifestyle activities evaluated. None reported moderate problems for watching television (distance vision) or using a computer (intermediate vision), while 3 out of 24 patients (13%) reported moderate difficulties for driving at night, 7 out of 32 (22%) moderate difficulties for reading or near work, 4 out of 32 (13%) for shaving/making-up, and 6 out of 30 (20%) for using a cell phone.

**Spectacle Independence and Overall Patient Satisfaction**

Out of the 32 patients, 84% were completely independent of spectacles for distance, intermediate, and near vision. The percentage of patients who never used glasses was 97% for distance vision, 97% for intermediate and 84% for near. The percentage of patients who needed glasses either often or always was 3% for distance vision, 3% for intermediate and 13% for near vision. The mean patient satisfaction score was 8.09 ± 1.30, with 78% of patients rating satisfaction as 8 or higher. Only 2 patients (6%) reported a satisfaction rating of less than 6.
DISCUSSION

There are two different categories for visual complaints after multifocal IOL implantation. The first one is decreased vision for distance, intermediate or near as a consequence of diminished CS. The second is photic phenomena including glare, halos and positive dysphotopsia or perception of lights, sparks, lines, or colours in some parts of the visual field. Contrast sensitivity can decrease up to 50% with some models of multifocal IOLs whereas it has been reported that photic phenomena are 3.5 times more likely with multifocal IOLs than with monofocal IOLs.

The Lentis Mplus is an acrylic non-rotational symmetric multifocal IOL designed to overcome the mentioned drawbacks of multifocal IOLs by providing high CS and minimizing halos and glare. The lens has a refractive design combining an aspheric asymmetric distance-vision zone with a sector-shaped near-vision with +3.0 D addition. According to the results reported here, cataract surgery using this new IOL is a very predictable procedure. The refractive outcomes using the Lentis Mplus IOL were very close to emmetropia in all cases, with a mean residual spherical equivalent near to -0.25 D and with only 6% of eyes showing a defocus higher than 0.75 D.

The Lentis Mplus IOL provided excellent results in terms of distance, intermediate and (to a lesser extent) near vision. Uncorrected visual acuity in decimal notation was at least 0.5 for near and distance in more than 98% of eyes with mean binocular logMAR UDVA of 0.03 (0.93 decimal), while the lens also performed well for near vision with mean binocular logMAR UNVA of 0.09 (0.82 decimal) at 40 cm, which was the best distance for near. After distance correction, mean binocular logMAR CDVA and DCNVA improved to -0.04 and 0.06, respectively (1.1 and 0.87 decimal, respectively). While far vision achieved with the Lentis Mplus IOL is comparable to
other multifocal IOLs, near vision is somewhat inferior.\textsuperscript{2,22-29} Diffractive and hybrid refractive-diffractive multifocal IOLs have shown superior near vision in several studies: de Vries et al\textsuperscript{6} and Kohnen et al\textsuperscript{22} reported binocular logMAR UNVA and DCNVA next to 0.00 (1.0 decimal) using the AcrySof ReSTOR SA60D3 or SN6AD1 (Alcon) IOLs respectively, and similar results with binocular decimal DCNVA around 1 were reported by Cillino et al\textsuperscript{2} using the multifocal diffractive pupil-independent Tecnis ZM900 (AMO) IOL and by Alfonso et al\textsuperscript{28} and Kaymak and Mester\textsuperscript{29} using the multifocal diffractive Acri.LISA 376D (Carl Zeiss Meditec) IOL. In summary, the Lentis Mplus IOL provided excellent near vision both UNVA (around 0.8 decimal) and DCNVA (around 0.9 decimal) for 40 cm, but near vision was inferior to that published for diffractive models. The most likely cause for this is the +3.0 D addition of the lens, which is inferior to the addition of all the aforementioned diffractive models except for the new +3D AcrySof ReSTOR.

On the other side, one of the strengths of the Lentis Mplus IOL is intermediate vision. Uncorrected decimal visual acuity was at least 0.5 for all 3 intermediate distances tested (70 cm, 1 m and 2 m) in 76% of eyes. Mean decimal DCIVA was higher than 0.7 for all intermediate distances: 0.74 at 70 cm, 0.72 at 1 m and 0.87 at 2 m. The performance of the Lentis Mplus in intermediate vision seems superior to the diffractive multifocal models, which usually provide excellent distant and near vision with a drop-off for intermediate vision causing intermediate blur in some patients.\textsuperscript{30-31}

Recently, there has been a trend towards reducing the power of the near addition in some models of diffractive IOLs (from + 4.0 D to +3.0 D) to improve intermediate vision or expand reading distance,\textsuperscript{22} and therefore the +3D AcrySof ReSTOR IOL models were developed with only 9 diffractive steps more widely spaced than the 12 steps of the
+4D IOL models. By reducing the addition for near, the near and the far points become closer and the gradual decline in vision between this two principal foci are minimized. Intermediate vision with diffractive models has been reported for several distances ranging from 50 cm to 70 cm.\textsuperscript{22,32-34} The +3D diffractive models showed mean logMAR intermediate vision for 50 cm of about 0.05 (0.9 decimal),\textsuperscript{22} much better than the mean logMAR intermediate vision for 50 cm provided by the +4D models of about 0.25 (0.56 decimal).\textsuperscript{33} However, even the +3D diffractive models showed a drop-off with more extended intermediate vision: for 60 cm and 70 cm mean logMAR visual acuity fell to about 0.12 and 0.20 respectively (0.75 and 0.63 decimal respectively).\textsuperscript{22} Intermediate vision for 1 m was approximately 0.6 decimal as can be deduced from the defocus curve of the +3D diffractive models.\textsuperscript{22} The Lentis Mplus provided mean decimal intermediate vision of 0.74 for 70 cm, 0.72 for 1 m and 0.87 for 2 m. Thus, the minimum intermediate vision was for 1 m but around 0.75 decimal, which was superior to the intermediate vision provided by the +3D diffractive models. In the authors’ opinion, it is important reporting visual results for these intermediate distances (70 cm and 1 m), since these are used in common activities such as using a computer.

Refractive multifocal IOL models such as the ReZoom (AMO) IOL have shown intermediate vision similar to that provided by the +3D diffractive models and thus inferior to the intermediate vision provided by the Lentis Mplus reported herein.\textsuperscript{35} The mean UIVA at the preferred intermediate distance (range 60 to 80 cm) in patients with +3.5D refractive IOLs was 0.23 logMAR (0.59 decimal).\textsuperscript{35} Near vision with the ReZoom is inferior in comparison with diffractive designs as shown in numerous studies\textsuperscript{9-10,35-36} and so this type of IOL has fallen into disuse within the multifocal IOL technology.
Defocus curve for the Lentis Mplus is consistent with everything mentioned above. The lens performance for distance is similar to a monofocal lens with visual acuity around 1 (decimal). The lens provides intermediate vision around 0.7 to 0.8 (decimal) between 50 cm and 2 m and shows best near vision at 40 cm with mean vision around 0.85 (decimal). Near vision drops for 33 cm to around 0.75 (decimal) and further yet for 25 cm (0.43 decimal). The Lentis Mplus IOL showed very little intermediate drop-off for intermediate distances with the lowest visual acuity threshold at 1 m (-1 D of defocus).

Regarding CS, photopic distant CS was similar to that of a monofocal IOL, meaning that the Lentis Mplus behaves very closely to a monofocal lens with regards to distance vision under high illumination conditions. Photopic near CS showed similar values to the monofocal control group except for higher frequencies. Mesopic distant CS values also showed differences at high frequencies, and medium and high frequencies in the case of mesopic vision with glare. Alió et al\textsuperscript{14} demonstrated similar photopic CS values comparing the Lentis Mplus IOL with a monofocal lens, and they also found a trend towards better CS outcomes (although not significant) for the monofocal IOL at high spatial frequencies under mesopic conditions. Zhao et al\textsuperscript{37} reported similar findings using the +3D AcrySof ReSTOR SA60D3 with reduced CS in comparison with a monofocal IOL. The reduction in mesopic visual performance at high spatial frequencies may result in reduced capability to resolve small objects in such conditions, for example road indications while driving at night.\textsuperscript{3,5}

The Lentis Mplus IOL showed a low incidence of significant photic phenomena: moderate halos were present only in 6% of patients, 13% reported moderate glare and 16% reported moderate night vision problems, with none of the patients mentioning
these photic phenomena as severe problems. Subjective scores for halos (0.38 ± 0.71), glare (0.69 ± 0.86) and night vision problems (0.84 ± 0.92) were very low. Using the same scale to subjectively evaluate visual disturbances caused by a diffractive multifocal IOL model, Kohnen et al\textsuperscript{22} reported a mean score of 1.3 ± 1.3 for halos, 1.7 ± 1.5 for glare and 1.1 ± 1.4 for night vision problems, higher in comparison with the results obtained in the present study. It therefore seems that one of the classic disadvantages of multifocal IOL technology, such as halos and glare, is minimized with the Lentis Mplus IOL. Alio et al\textsuperscript{14} showed statistically significantly larger amounts of primary coma and tilt with the Lentis Mplus in comparison with a monofocal IOL. In the present study aberrometry was not performed, and so, no correlation could be done between postoperative photic phenomena and residual coma or other higher order aberrations. We did not find a correlation between photic phenomena and residual astigmatism, lens tilt or capsulorhexis size.

We did not find a significative correlation between photopic pupil size and CDVA or DCNVA, meaning that the Lentis Mplus IOL showed pupillary independence with the pupil sizes measured in the current study.

Eighty-four percent of patients bilaterally implanted with the Lentis Mplus IOL achieved full spectacle independence and were satisfied with their distance, intermediate and near vision. Regarding far vision, the percentage of patients who never used glasses was 97% and only 1 patient (3%) indicated frequent or continued use of glasses for far vision. The outcome in this patient was -1 D in both eyes. It is noteworthy that the tolerance of Lentis Mplus IOL to myopic defocus was excellent. The six eyes with residual spherical equivalent higher than -0.50 D showed excellent UIVA at 1 m (around 0.9 decimal), and maintained adequate UDVA and UNVA at 40 cm
(around 0.8 and 0.7 decimal, respectively). It can be observed from the defocus curve, that low levels of residual myopia do not translate into deep decrease of visual performance with the Lentis Mplus IOL, which could represent another advantage of this new multifocal lens design.

In the present study secondary interventions to improve postoperative refractive results were not considered. A secondary excimer laser procedure might have provided a lower percentage of patients needing glasses for distance vision. Similar percentages of spectacle independence for distance vision have been reported for diffractive multifocal models. The percentage of patients free from glasses for intermediate vision activities was 97% and only 1 patient reported a frequent need for glasses for intermediate distance. This can be easily explained by the defocus curve of the Lentis Mplus IOL in which the typical drop-off at intermediate distances seen in other multifocal IOL models is minimized, which is one of the main advantages of the Lentis Mplus IOL in the authors’ opinion. The percentage of patients who never used glasses for near (84%) was high although lower to that reported for diffractive multifocal IOLs in previous studies. This fact maybe related to the near addition of +3D yielding a +2.5D addition at the spectacle plane that may be found as insufficient for some near activities.

Regarding the 6 lifestyle activities evaluated in the present study, none of the patients reported moderate or significant problems for activities related to distance vision (such as watching television) or intermediate vision (such as using a computer). However, between 13% and 22% of patients reported moderate difficulties for carrying out activities in which very accurate near vision was necessary such as reading/sewing, text messaging using a cell phone or shaving/ making-up. The mean patient
satisfaction score was 8.09 ± 1.30, with 78% of patients rating satisfaction as 8 or higher. Only 2 patients (6%) reported a satisfaction rating of less than 6. Using the same scale, a subjective score of 8.3 ± 1.6 was reported by Kohnen et al\textsuperscript{22} using a diffractive IOL model. Improvement in patient satisfaction and quality of life after bilateral implantation of multifocal IOLs in cataract patients or presbyopic clear-lens-extraction patients has also been reported in other recent studies\textsuperscript{38,39}.

In conclusion, the Lentis Mplus multifocal IOL provided excellent uncorrected distance, intermediate and (to a lesser extent) near vision. Defocus curve showed very little intermediate drop-off. Halos, glare and other photic phenomena as a consequence of multifocal IOL technology were minimized.
REFERENCES


FIGURE LEGENDS

**Figure 1:** Defocus curve for the Lentis Mplus IOL 6 months after implantation. Y-axis shows visual acuity (left, logMAR; and right, decimal Snellen) and X-axis vergence (top, cm, and bottom, diopters). Error bars represent ± deviation standard values for each vergence.

**Figure 2:** Photopic log CS function for far (top) and near (bottom) distances for the Lentis Mplus IOL and the monofocal IOL control group. * represents statistically significant differences between lenses. Error bars represent ± standard deviation values for each spatial frequency.

**Figure 3:** Mesopic log CS function for far (top) and near (bottom) distances for the Lentis Mplus IOL and monofocal IOL control group. * represents statistically significant differences between lenses. Error bars represent ± standard deviation values for each spatial frequency.