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Research Article

Clinical Outcome After Bilateral Implantation of a Bifocal Rotationally Asymmetric Near Segment Refractive Intraocular Lens with a Near Addition of +1.5 Diopters

Rüfer F and Holland D*

Cataract and Refractive Surgeon, nordBLICK Augenklinik Bellevue, Kiel, Germany

***Corresponding Author:** Holland D, Cataract and Refractive Surgeon, nordBLICK Augenklinik Bellevue, Kiel, Germany.

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Abstract

Background: Various approaches to improve visual quality with multifocal intraocular lenses (MIOL) have led to the development of new and modified optical principles. The goal of this study is the evaluation of clinical outcomes after cataract surgery with implantation of a refractive intraocular lens (IOL) with rotationally asymmetric section-shaped near addition of +1.5 D.

Methods: Sixty-six eyes of 33 patients with an age range from 43 to 82 years were enrolled in the study under ethics committee approval. All patients underwent bilateral cataract surgery with implantation of the bifocal low-add IOL Lentis Comfort LS-313-MF15 (Oculentis, Berlin, Germany) by one surgeon. Visual acuity (VA), refraction, contrast sensitivity (CS) under photopic and mesopic conditions as well as the subjective incidence of photic phenomena under photopic and scotopic conditions were evaluated at 3 months after surgery.

Results: Postoperative uncorrected distance, intermediate and near VA of 20/25 or better was achieved by 86.4%, 68.2% and 25.8% of eyes, respectively. Binocularly, these percentages increased to 93.9%, 78.8% and 27.3%, respectively. Mean postoperative spherical equivalent was -0.29 ± 0.52 D. Photopic and mesopic CS outcomes were within normality ranges. Fifteen patients (45.5%) required glasses for near distance activities. Under low light conditions, mean scores (scale: 0-none to 100-severe) for glare impairment, halos, starburst, blurred distance vision, blurred intermediate vision, and double image were 23.4 ± 27.8, 20.8 ± 28.3, 18.6 ± 25.5, 11.6 ± 19.7, 21.6 ± 29.9, and 8.8 ± 19.4, respectively (0 not at all to 100 severe).

Conclusion: The evaluated low addition IOL provided a complete distance and intermediate visual rehabilitation after cataract surgery, with excellent visual quality and minimal induction of photic phenomena. Functional near vision with spectacle independence was found in more than half of the patients.

Keywords: *Near Segment IOL; Defocus Curve; Contrast Sensitivity; Intermediate Vision; Patient Satisfaction*

Background

In the past, bifocal intraocular lenses (IOLs) were developed to provide good uncorrected distance vision as well as functional reading acuity after cataract surgery [1,2]. These initial IOL designs were developed with a high near addition of +4.0 D, resulting in a suboptimal intermediate vision [3]. New multifocal IOL designs were developed afterwards and aimed at improving intermediate vision. These lens optics divide the incoming light in three different foci for far, intermediate and near distances (trifocal IOLs) [4]. However, although this type of IOLs provides a complete visual rehabilitation, photic phenomena still remain a concerning issue in some patients [5]. For this reason, new IOL designs have been developed to provide a balance between visual rehabilitation at intermediate and near distances and the level of induced photic phenomena [5]. Low addition diffractive multifocal IOLs [6-9] and extended range of vision IOLs [10] are examples of these new concepts of IOLs, attempting to minimize photic phenomena while maintaining acceptable ranges of near and

intermediate vision. Another approach is a refractive lens optic with an integrated sector for near vision. The aim of the current study was to evaluate the clinical outcomes in terms of visual acuity, contrast sensitivity (CS), defocus curve and incidence of photic phenomena after cataract surgery with implantation of a bifocal refractive IOL with a rotationally asymmetric section-shaped near addition of +1.5 D. The IOL design is not combined with a special learning curve because the implantation is not different to any other hydrophilic acrylic plate haptic IOL. In the rare case of the necessity of an IOL exchange within the first year there is no special risk, later explanation can be challenging because of the plate haptic design.

Methods

Patients

Sixty-six eyes of 33 consecutive patients with an age range from 43 to 82 years were enrolled in the study. The patients underwent bilateral cataract surgery with implantation of the bifocal low-add IOL Lentis Comfort LS-313-MF15 (Oculentis, Berlin, Germany). This aspheric IOL which is made of an acrylic copolymer with hydrophobic surface, has a segment with a +1.5-D near add to provide optimum intermediate vision and visual improvement at near. Inclusion criteria for the study were bilateral cataract, an age between 40 and 80 years, an expected postoperative astigmatism of less than 0.75 D and discontinuation of contact lens wearing during a period of 2 weeks before performing biometry and corneal topography. Exclusion criteria included history of amblyopia or strabismus, irregular astigmatism, active ocular pathologies except cataract with the potential of reducing the corrected distance visual acuity (CDVA) to less than 0.3 logMAR, and patients with diabetes mellitus, even without presence of diabetic retinopathy. Photopic pupil size below three mm and mesopic above six mm was also excluded. The study was approved by the local ethics committee and adhered to the tenets of the Declaration of Helsinki. All patients were informed about the scope of the study and gave their written consent.

Examination and surgical protocol

Preoperatively, all patients underwent a complete ophthalmologic examination including measurement of monocular and binocular uncorrected distance visual acuity (UDVA) and CDVA, measurement of monocular and binocular uncorrected (UIVA) and distance-corrected intermediate visual acuity (DCIVA) at 80 cm, measurement of monocular and binocular uncorrected (UNVA) and distance-corrected near visual acuity (DCNVA) at 40 cm, manifest refraction, Goldmann applanation tonometry, slit lamp examination, funduscopy under mydriasis, optical biometry (IOL-Master, Carl Zeiss Meditec AG, Jena, Germany) and corneal topographic analysis with a Scheimpflug imaging-based system (Sirius®, CSO, Florence, Italy) to exclude irregular astigmatism. The IOL power was calculated using the IOL-Master with the Haigis formula (A-constant 118.0, a0: 0.95, a1: 0.4, a2: 0.1). Target refraction was emmetropia for distance.

All surgeries were performed by the same surgeon (DH) under local anesthesia. After phacoemulsification, the IOL was implanted into the capsular bag via a 2.4-mm clear corneal incision. Follow-up examinations were performed at 1 day, 1 week, 1 month and 3 months after surgery. The postoperative examination protocol included the same tests as the preoperative visit, but with the additional assessment of the defocus curve from +1.5 to -3.0 D. Likewise, mesopic (3 cd/m^2) and photopic (85 cd/m^2) CS was measured at the last postoperative visit with the Functional Acuity Contrast Test (FACT) (Stereo Optical Co. Inc., Chicago, IL, USA) incorporated in a Ginsburg box for the spatial frequencies of 1.5, 3, 6, 12 and 18 cycles/degree with and without a glare source. Furthermore, at the last postoperative visit, the incidence of photic phenomena (halos, starburst) under daylight, ambient light and low light conditions was self-reported semi-quantitatively by patients using a questionnaire (scale from 0 = not at all; 100 = definitely true).

Data analysis

Data analysis was performed with the SPSS statistics software package version 15.0.1 for Windows (IBM, Armonk, NY, USA). The Kolmogorov-Smirnov test was used to check the normality of the data distribution. When parametric analysis was possible, the Student t test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations as well as between consecutive postoperative visits, whereas the Wilcoxon Rank Sum test was applied for such purpose when the data samples compared did not follow a Normal distribution. In all cases, the same level of significance ($p < 0.05$) was considered.

Results

The sample included 12 males (36.4%) and 21 females (63.6%) with a mean age of 69 ± 8 years (mean ± standard deviation [SD], range 43 - 82 years). Mean preoperative pupil size was 3.41 ± 0.71 mm and 4.37 ± 0.94 mm under photopic and scotopic conditions, respectively. Mean preoperative IOP was 15 ± 3 mm Hg. Table 1 summarizes the preoperative and postoperative visual outcomes.

Mean (SD) Median (Range)	Preoperative	Week 1	Month 1	Month 3	p-value (preop vs month 3)
Monocular LogMAR UDVA	0.48 (0.31) 0.40 (0.05 to 1.30)	0.06 (0.14) 0.00 (-0.15 to 0.40)	0.04 (0.11) 0.00 (-0.15 to 0.30)	0.03 (0.11) 0.00 (-0.15 to 0.40)	< 0.001
Monocular LogMAR CDVA	0.21 (0.18) 0.18 (-0.10 to 0.70)	-0.01 (0.10) 0.00 (-0.15 to 0.30)	-0.03 (0.11) 0.00 (-0.20 to 0.40)	-0.04 (0.08) 0.00 (-0.15 to 0.15)	< 0.001
Binocular LogMAR UDVA	0.30 (0.22) 0.30 (0.00 to 0.70)	---	-0.02 (0.09) 0.00 (-0.15 to 0.30)	-0.03 (0.09) 0.00 (-0.15 to 0.20)	< 0.001
Binocular LogMAR CDVA	0.09 (0.11) 0.05 (-0.10 to 0.40)	---	-0.07 (0.08) -0.10 (-0.15 to 0.15)	-0.08 (0.07) -0.10 (-0.20 to 0.05)	< 0.001
Manifest sphere (D)	1.04 (1.63) 1.25 (-3.75 to 3.25)	-0.23 (0.65) -0.25 (-1.25 to 2.25)	-0.22 (0.49) -0.25 (-1.25 to 0.75)	-0.04 (0.54) 0.00 (-1.25 to 1.25)	< 0.001
Manifest cylinder (D)	-0.56 (0.55) -0.50 (-2.00 to 0.75)	-0.60 (0.58) -0.50 (-2.25 to 0.00)	-0.58 (0.49) -0.50 (-2.50 to 0.00)	-0.50 (0.54) -0.50 (-2.75 to 0.00)	0.735
Monocular LogMAR UNVA	0.67 (0.29) 0.70 (0.20 to 1.30)	---	0.31 (0.23) 0.30 (0.00 to 1.00)	0.31 (0.20) 0.30 (0.00 to 1.20)	< 0.001
Monocular LogMAR DCNVA	0.62 (0.26) 0.60 (0.10 to 1.30)	---	0.46 (0.22) 0.50 (0.10 to 1.00)	0.36 (0.21) 0.40 (0.10 to 0.90)	< 0.001
Binocular LogMAR UNVA	0.58 (0.27) 0.50 (0.20 to 1.10)	---	0.24 (0.21) 0.20 (0.00 to 0.80)	0.29 (0.16) 0.30 (0.00 to 0.60)	< 0.001
Binocular LogMAR DCNVA	0.53 (0.15) 0.50 (0.20 to 1.00)	---	0.35 (0.20) 0.30 (0.00 to 0.70)	0.35 (0.19) 0.40 (0.10 to 0.90)	< 0.001
Monocular LogMAR UIVA	0.63 (0.25) 0.60 (0.20 to 1.20)	---	0.20 (0.26) 0.10 (-0.10 to 1.30)	0.17 (0.21) 0.10 (-0.10 to 0.90)	< 0.001
Monocular LogMAR DCIVA	0.42 (0.21) 0.40 (0.10 to 0.90)	---	0.21 (0.18) 0.20 (-0.10 to 0.70)	0.17 (0.19) 0.10 (-0.10 to 0.80)	< 0.001
Binocular LogMAR UIVA	0.49 (0.25) 0.40 (0.10 to 0.90)	---	0.09 (0.15) 0.00 (-0.10 to 0.50)	0.12 (0.19) 0.10 (-0.10 to 0.80)	< 0.001
Binocular LogMAR DCIVA	0.33 (0.15) 0.30 (0.10 to 0.70)	---	0.14 (0.12) 0.10 (0.00 to 0.50)	0.12 (0.19) 0.10 (-0.10 to 0.80)	< 0.001

Table 1: *Preoperative and postoperative visual and refractive data.*

**Abbreviations: D: Diopter; UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; UNVA: Uncorrected Near Visual Acuity; DCNVA: Distance-Corrected Near Visual Acuity; UIVA: Uncorrected Intermediate Visual Acuity; DCIVA: Distance-Corrected Intermediate Visual Acuity.*

A significant improvement was observed in UDVA, CDVA, UNVA, DCNVA, UIVA and DCIVA ($p < 0.001$) postoperatively. A 3-month postoperative monocular UDVA, UIVA and UNVA of 20/25 or better was achieved by 86.4%, 68.2% and 25.8% of eyes, respectively (Figure 1). Binocularly, these percentages increased to 93.9%, 78.8% and 27.3%, respectively (Figure 2). A significant reduction of sphere was observed after surgery ($p < 0.001$), with no significant change in manifest cylinder ($p = 0.735$). Mean 3-month postoperative spherical equivalent was -0.29 ± 0.52 D. After 3 months the postoperative spherical equivalent was within ± 0.50 D and ± 1.00 D in 73.2% (41/56) and 92.9% (52/56) of the eyes, respectively. Figure 3 displays the mean defocus curve obtained at 3 months postoperatively. As shown, the curve decreases progressively with the level of defocus.

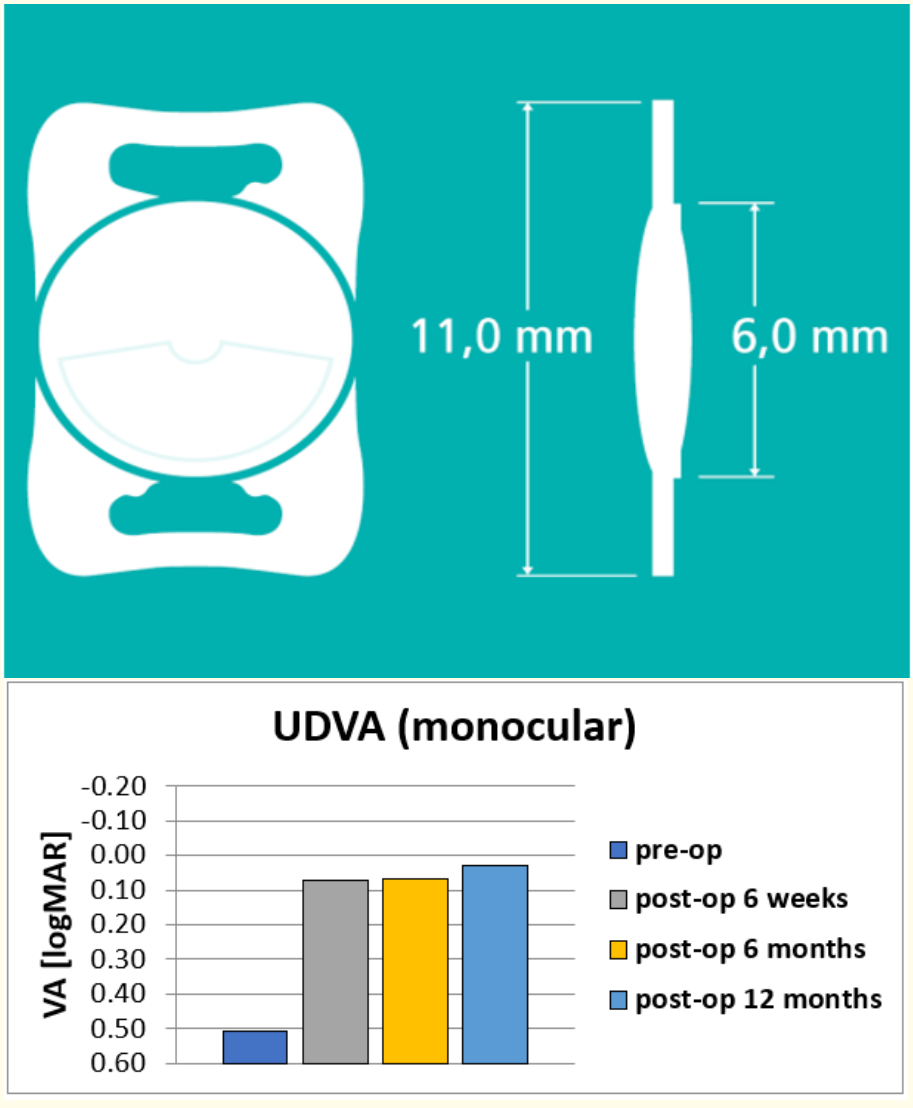

Figure 1: *Distribution of 3-month postoperative monocular uncorrected distance (UDVA), intermediate (UIVA) and near visual acuity (UNVA).*

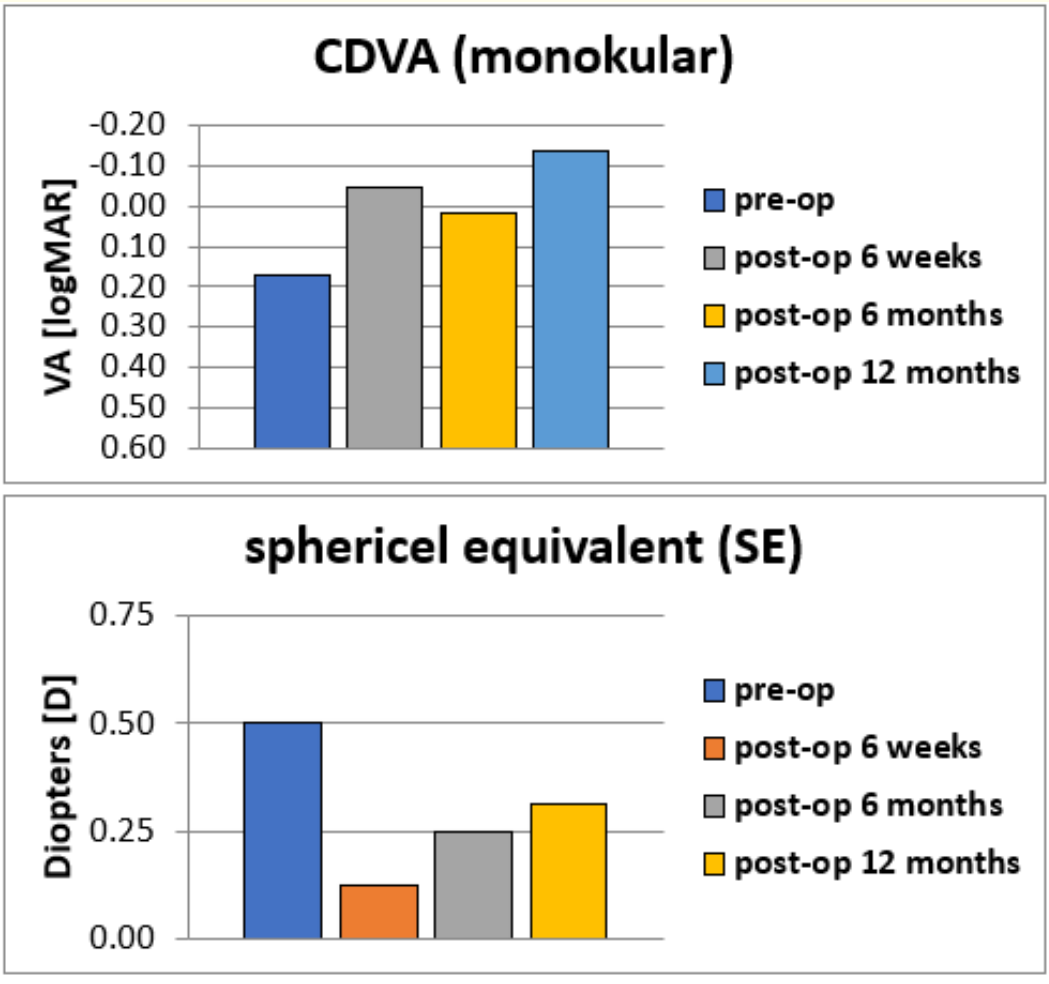

Figure 2: *Distribution of 3-month postoperative binocular uncorrected distance (UDVA), intermediate (UIVA) and near visual acuity (UNVA).*

Figure 4 displays the 3-month postoperative CS outcomes under photopic and mesopic conditions with and without glare. Photopic CS was significantly worse when measured with a glare source at spatial frequencies of 1.5 ($p = 0.02$), 6 ($p < 0.01$), and 12 cycles/degree ($p = 0.03$). The same was found for mesopic CS at all spatial frequencies (all $p < 0.001$).

According to the results of the subjective questionnaire, 15 patients (45.5%) required glasses only for near distance activities. Mean score for optical quality problems with the IOL was 19.2 ± 22.4. Under daylight conditions, mean scores for glare impairment, halos, starburst, blurred distance vision, blurred intermediate vision, and double image were 18.1 ± 21.1, 4.0 ± 7.0, 6.0 ± 13.1, 11.8 ± 17.0, 13.4 ± 22.6 and 5.8 ± 16.4, respectively. These mean scores changed to 8.8 ± 12.9, 4.0 ± 7.3, 5.6 ± 8.4, 8.2 ± 12.1, 13.2 ± 21.5, and 5.0 ± 10.0 under medium illumination, respectively. Under low light conditions, mean scores for glare impairment, halos, starburst, blurred distance vision, blurred intermediate vision, and double image were 23.4 ± 27.8, 20.8 ± 28.3, 18.6 ± 25.5, 11.6 ± 19.7, 21.6 ± 29.9, and 8.8 ± 19.4, respectively.

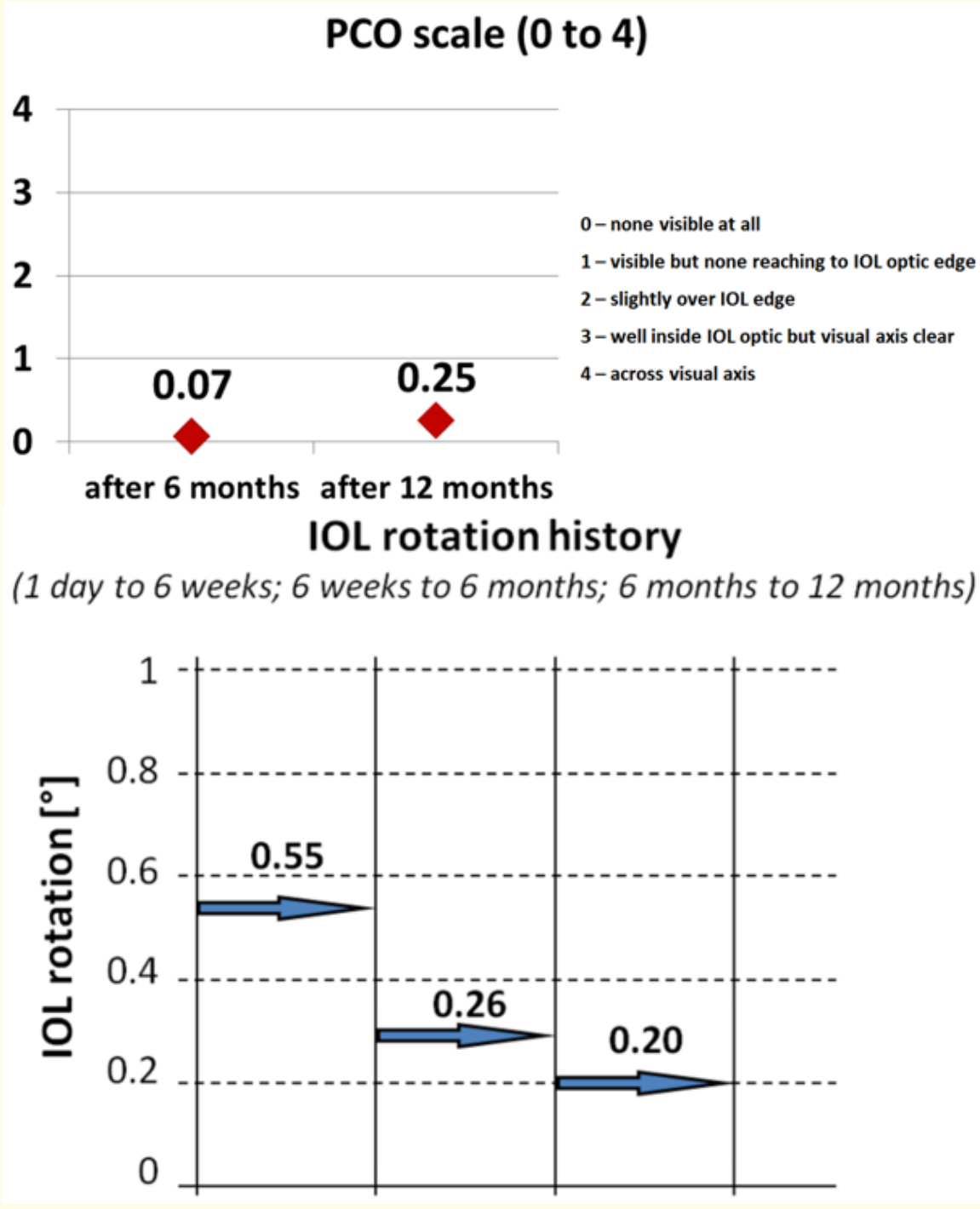

Figure 3: *Mean 3-month postoperative defocus curve.*

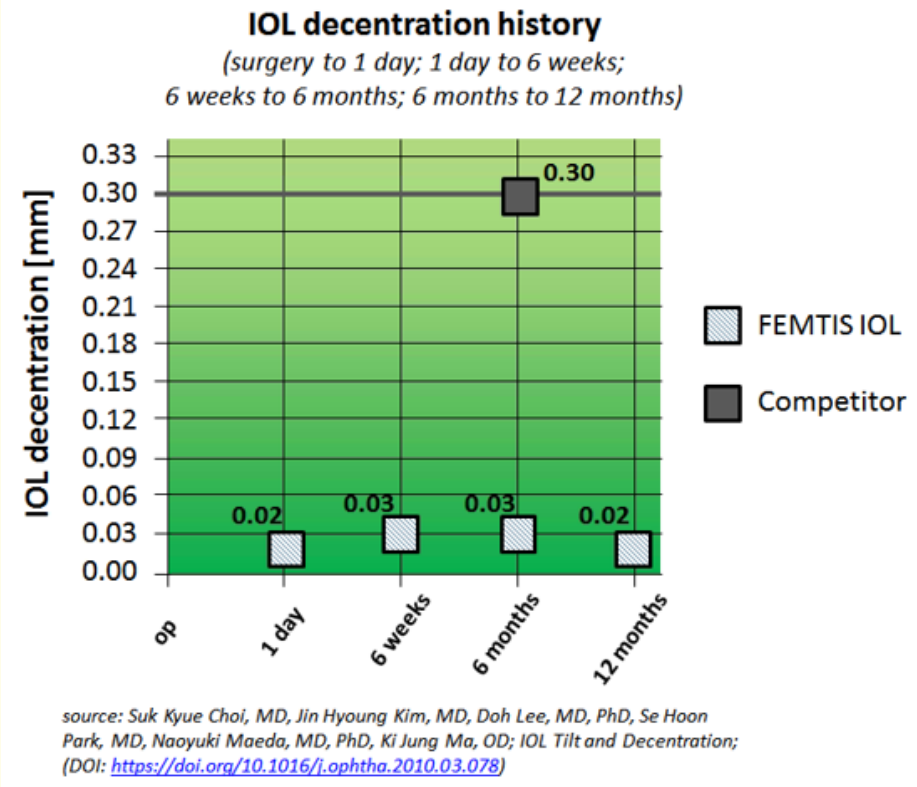

Figure 4: *Mean 3-month postoperative contrast sensitivity function under photopic (left) and mesopic (right) conditions with (grey line) and without glare (black line).*

Discussion

The use of different models of multifocal IOL spread more and more around the world with the aim to reduce spectacle independence in cataract and refractive lens exchange. The use of low addition IOLs has been suggested as a new option for visual rehabilitation after cataract surgery with less photic phenomena compared to conventional multifocal IOLs [6-9]. Studies have shown that the diameter of the halo perceived with a multifocal IOL is directly related to the magnitude of the addition of the IOL [11]. Vega and colleagues [5] compared in an optical bench experiment the level of halos associated to three different multifocal IOLs with different magnitude of addition (ReSTOR +2.5 D SV25T0, Tecnis +2.75 D ZKB00, and AT LISA +3.75 D 809M). The research group found that the distance focus of the low addition apodized diffractive-refractive IOL created the smallest halo. The aim of the current study was to evaluate visual acuity and quality of vision outcomes as well as the incidence of photic phenomena with a low addition rotationally asymmetric refractive multifocal IOL in order to confirm its applicability in clinical practice.

A good distance visual outcome was obtained with the evaluated IOL, with 86.4% and 93.9% of eyes achieving a monocular and binocular UDVA of 20/25 or better, respectively. This visual outcome was consistent with the mean 3-month postoperative spherical equivalent being close to zero (-0.29 ± 0.52 D). Alió and coauthors [9] compared the outcomes of the high and low addition models of the same refractive multifocal IOL as in the current series and did not find significant differences in distance visual outcome. These authors reported slightly worse UDVA results compared to our study, but this might be related with the trend to a more myopic residual refraction obtained in their study. Several factors may have accounted for this finding, such as differences in the patient characteristics, clinical procedures and even in the applied IOL constant. Some adjustments have been developed to optimize and improve the precision of the refractive correction with the high addition model of the same IOL platform [12]. Nuijts., *et al*. [13] found in another comparative study that the bilateral implantation of a +2.5-D apodized diffractive-refractive IOL resulted in a similar distance visual performance compared to contralateral implantation of the +2.5 D (dominant eye) and +3.0 D (non-dominant eye) models of the apodized diffractive-refractive IOL. Kim., *et al*. [14] did not find significant differences with regard to distance vision with three different magnitudes of addition, +2.75, +3.25 and +4.00 D of the same diffractive multifocal IOL platform. In optical bench experiments, a better in-vitro optical quality of the distance focus has been found with a +2.5-D apodized diffractive-refractive IOL compared to trifocal diffractive and +3.0-D apodized diffractive-refractive IOLs [14]. In this findings we see an explanation why the subjective visual distance function is very good in the examined low add MIOL.

Clinically, our study shows that the evaluated low addition IOL provides an excellent distance visual outcome compared to that achieved with high addition IOL models [8,9,13,14].

A monocular and binocular UIVA of 20/25 or better was achieved by 68.2% and 78.8% of eyes, respectively. This outcome was similar to that reported in another series evaluating the same +1.5 D IOL [9]. The lower magnitude of the addition leads to an optimization of the intermediate visual acuity, as has been demonstrated with the same [9] and other types of low addition multifocal IOLs [7,15,16]. High near additions of diffractive IOLs have been demonstrated to provide to a poorer intermediate visual function [3,15]. As expected, near visual acuity is limited with the evaluated IOL, with 25.8% and 27.3% of eyes achieving a postoperative monocular and binocular UNVA of 20/25 or better, respectively. Several studies have confirmed a limited near visual function of low addition IOLs compared to IOLs with a high near add [8,9,15,16]. The intermediate and near visual acuity outcome in the present study is consistent with the shape of the defocus curve, which shows a progressive decrease of visual acuity with increasing level of defocus, but maintaining visual acuity values of 0.20 logMAR or better up to a defocus of -1.5 D. This result confirms the defocus curve outcome reported in a previous series evaluating the same +1.5-D addition multifocal IOL [9].

The Lentis Comfort LS-313-MF15 provided excellent contrast sensitivity outcomes, suggesting that reducing the magnitude of the addition has a positive impact on visual quality. Alió and coauthors [9] found in a comparative study of the +1.5 and +3.0-D addition models of the same rotationally asymmetric refractive multifocal IOL that there was a trend toward better contrast sensitivity under

scotopic conditions with the +1.5 D IOL. This good visual quality is one of the factors contributing to the high level of patient satisfaction with their visual performance. Furthermore, in spite of the relatively limited near visual function with the evaluated IOL, only 45.5% of patients required glasses for near distance activities. This suggests that the visual rehabilitation provided by this low addition IOL is sufficient to generate a functional range of vision. Comparable results are found by Kim., *et al.* [15] in a comparative study of a diffractive IOL with a +2.75-D add which lead to a higher level of satisfaction and spectacle independence as well as fewer visual symptoms compared to those implanted with the same type of IOL, but with an addition of +4.00 D. This results may suggest that MIOL with lower Add may provide higher level of patient satisfaction. In our study, the level of photic phenomena reported by patients was low and only slightly worse under low light conditions. Alió and colleagues [9] compared the +1.5 and +3 D addition Mplus IOLs and found a trend toward more frequent perception of halos in eyes implanted with the high addition IOL. The high patient satisfaction with the evaluated low addition IOL in our series seems to be related to the minimal induction of photic phenomena as well as to the functional range of vision and good levels of visual quality. Regarding the possibility of a more myopic target refraction in the non dominant eye a better near VA is possible with this lens without increasing photopic symptoms as shown by Breyer., *et al*. with the Düsseldorf formula [17,18].

Conclusion

In conclusion, the Lentis Comfort LS-313-MF15 provides a complete distance and intermediate visual rehabilitation after cataract surgery, with excellent visual quality, high patient satisfaction and minimal induction of photic phenomena. Near visual acuity of the majority of patients is within a functional range which leads to acceptable levels of spectacle independence.

Ethics Approval and Consent to Participate

This study was approved by the ethics committee responsible for the Nordblick Bellevue Clinic (Ärztekammer Schleswig-Holstein). All patients were informed on the scope of the study and signed a consent form.

Consent for Publication

Not applicable.

Availability of Data and Material

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Competing Interests

The authors have no financial interest in any product mentioned in this manuscript.

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