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Clinical Outcome of Lentis Comfort Intraocular Lens Implantation

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Purpose: To evaluate visual outcome and patient satisfaction following Lentis Comfort intraocular lens (IOL) implantation.

Method: This retrospective case series examined 68 eyes of 41 patients (mean age 72.0 ± 8.1 years) who underwent Lentis Comfort (LS-313 MF15, Oculentis GmbH, Berlin, Germany; Santen, Osaka, Japan) implantations. Patients were evaluated for visual acuity (VA) at several distances (0.3, 0.5 and 5 meters), refractive error, defocus curve and contrast sensitivity, in addition to answering a questionnaire on photic phenomena, visual discomfort and patient satisfaction.

Results: Uncorrected visual acuity was 0.05 ± 0.13 (logMAR) for distance, 0.23 ± 0.17 (logMAR) for intermediate, and 0.52 ± 0.20 (logMAR) for near. Defocus curve showed the binocular visual acuity attained was almost 20/20 within the range of +0.5 D to −1.5 D. Contrast sensitivity was within the normal range. The Lentis Comfort IOL tolerated astigmatism to some extent. Patient age could potentially be related to uncorrected visual acuity. Questionnaire results showed almost all patients were satisfied with Lentis Comfort IOL implantation.

Conclusion: Lentis Comfort IOLs provided better visual function at far and intermediate distances.

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Key words: low diopter addition, zonal refractive, rotational asymmetric, multifocal intraocular lens

Introduction

Recently, cataract surgery has been used to not only remove opacified crystalline lenses but also to correct refractive error. Furthermore, one of the major goals within the ophthalmological field is presbyopia correction. This is especially the case in the field of cataract and refractive surgery[1].

Development of multifocal intraocular lenses (IOLs) in the past few years, along with investigations of their specific properties, including optic designs, has helped to revolutionize refractive lens surgery. At the present time, there have been marked improvements in achieving uncorrected visual acuity at all distances due to the availability of new trifocal IOL designs[2–6].

With the introduction of new IOL technology, the new IOLs are now able to provide a better enhanced depth of focus as compared to previous multifocal or accommodating IOLs. As a result, this has led to improved visual acuity at all distances, better contrast sensitivity, along with a decrease in both halos and glare symptoms. In order to be able to provide an extended depth of focus, these new enhanced depth of focus IOLs are based on two principles, which include optical strategies designed to control the spherical chromatic aberration. In order to compensate for the positive corneal spherical aberration, a negative spherical aberration is added to the IOL, which helps to increase the depth of focus of the visual acuity, especially for the intermediate range[7–10].

Moreover, the retinal image quality can also be improved through the correction of the chromatic aberration. Although at the present time there are now different IOL designs that are commercially available with diffractive optics or with progressive multifocality, there have been side effects reported for these new designs, such as persistent glare and halos[11].

The current clinical study evaluated a new shape-

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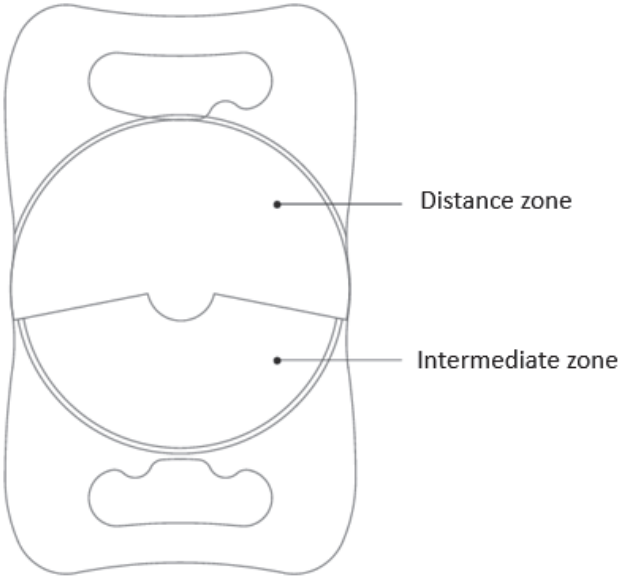

Fig. 1 Distance and intermediate sectors of the aspheric nonrotational symmetric and zonal refractive multifocal IOL

segmented refractive IOL, the Lentis Comfort IOL (LS-313 MF15, Oculentis GmbH, Berlin, Germany). Lentis Comfort IOLs are expected provide better intermediate vision due to the +1.5 diopters (D) addition. Moreover, the simple structure with only one transition line should also contribute to reduced photic phenomena, such as halo, glare[12,13] and waxy vision, which is one of the concerns with the implantation of diffractive multifocal IOLs.

Previous studies have shown that Lentis Mplus (Oculentis GmbH), which is similar to the Lentis Comfort IOL, provided excellent visual performance and high patient satisfaction as a whole[14–18]. Lentis Comfort IOLs have also been reported to provide excellent visual acuity along with a wide range of depth of focus[19–21]. Furthermore, usage of this IOL has been covered under the health insurance plan in Japan since March of 2019.

The primary aim of our current study was to evaluate the refractive outcome of this IOL, which included near, intermediate, and far distance visual acuity, as well as patient satisfaction after 1 month. Moreover, we additionally evaluated the defocus curve and the stability of the spherical equivalent (SE).

Patients and Methods

Patients

This retrospective study evaluated 68 eyes of 41 patients who underwent cataract surgery with IOL implantation from March to September 2019 at Nippon Medical School Musashi-Kosugi Hospital. Patients ranged in age from 40 to 87 years (72.0 ± 8.1 years, mean ± standard deviation), with 18 males and 23 females. Consecutive patient cases that met our inclusion criteria were selected for the study. In order to be included in the study, eyes could not have any history of previous ocular surgery. Furthermore, eyes that had any ocular diseases that could affect the surgical outcomes or any corneal astigmatism greater than 2.0 D were additionally excluded from the study. The Institutional Review Board at Nippon Medical School Musashi-Kosugi Hospital approved the study protocol (479-31-8). Written informed consent was obtained from each patient prior to the start of the study. The study adhered to the tenets of the Declaration of Helsinki.

Intraocular Lenses and Surgery

All patients underwent implantation of the same type of IOL, the Lentis Comfort IOL (LS-313 MF15, Oculentis GmbH, Berlin, Germany, **Fig. 1**). In this study, the specific IOL evaluated was a foldable plate-haptic hydrophilic acrylic IOL with hydrophobic surface properties. This rotationally asymmetric, refractive multifocal IOL contained an aspheric distance vision zone combined with a sector-shaped near vision zone. In this IOL, there was an add power of +1.5 D on the lens plane. Furthermore, it had a 6.0 mm biconvex optic and an overall length of 11.0 mm. All eyes were targeted emmetropia as

determined by the Haigis formula (a0; 0.647, a1; 0.400, a 2; 0.100). All surgeries followed standard techniques in which sutureless phacoemulsification was performed through a 2.4 mm sclerocorneal incision. After creation of an anterior capsulorhexis of approximately 5.5 mm in diameter, the IOL was implanted into the capsular bag using a specific injector recommended by the manufacturer (Accuject UniFit WJ-60M II, Santen Pharmaceutical Co., Ltd., Osaka, Japan).

Examinations

All patients underwent a preoperative examination that included autorefraction and tonometry (RC-5000, Tomey, Japan), corneal topography (TMS-5, Oculus, Inc.), uncorrected and corrected distance visual acuity (UDVA, CDVA), endothelial cell count (CEM-530, Nidek Co. Ltd., Japan), biometry (OA-1000, AL-4000, Tomey, Japan and IOL Master 500, Carl Zeiss Meditec, Jena, Germany), subjective and cycloplegic refractions, slit-lamp evaluation, and dilated funduscopy.

The ophthalmological examinations were performed before, and at 1 week and 1 month after surgery. Preoperative examination included measurements of UDVA and CDVA, manifest refraction, intraocular pressure, slit-lamp anterior segment examination, optical biometry, keratometry, and retina evaluation under pupil dilation. At each postoperative visit, UDVA, CDVA, uncorrected and corrected intermediate visual acuity (UIVA, CIVA) measured at 50 cm, and uncorrected and corrected near visual acuity (UNVA, CNVA) measured at 30 cm were evaluated. A defocus curve for 13 different levels of defocus ranging from +2.0 to −4.0 D in steps of 0.5 D was obtained at 1 month postoperatively. Contrast sensitivity was assessed at 1.1, 1.8, 2.9, 4.5, 7.1 and 10.2 cycles per degree (cpd) using a CGT-2000 device (Takagi Seiko, Nagano, Japan) under photopic and mesopic conditions at 1 month postoperatively. Before starting this study, at least one technician from each site was trained on how to conduct reproducible examinations. Using a questionnaire, patients were asked about the severity of the photic phenomena at 1 month postoperatively. The intensities of the glare, halo, star burst and waxy vision were graded as none, mild, moderate, or severe. Eyeglass dependence was graded as none, seldom, sometimes or always. (If necessary, the eyeglasses were prescribed 2 weeks after surgery.) The questionnaire also asked patients to rate their satisfaction levels with regard to their distance, intermediate and near vision along with their overall satisfaction, with the possible outcomes listed as, very high, high, medium, and low. In addition, any intraoperative and/or postoperative complications that occurred throughout the study period were also recorded.

Statistical Analysis

Data were analyzed using Microsoft Excel (Office 2019, Microsoft Corp., Redmond, WA, USA). Snellen visual acuity measurements were converted to logMAR equivalents in order to calculate the means and standard deviations.

Results

All 41 patients (68 eyes) completed 1-month follow-up examinations. Preoperatively, axial length was 23.46 ± 0.94 (range 20.83-25.49) mm, corneal astigmatism was 0.78 ± 0.40 (range 0.16-1.83) D and radius of curvature of the cornea was 7.59 ± 0.21 (range 7.02-8.29) mm.

Visual Acuity and Refraction

Figure 2 shows the distance, intermediate and near visual acuity at 1 week postoperatively, while **Figure 3** shows the visual acuity at 1 month postoperatively.

Postoperative UDVA was found to be very good at 1 week or 1 month, with values approximately 20/26 (0.11 ± 0.19 logMAR) and 20/22 (0.05 ± 0.13 logMAR), respectively. The UIVA improved from 1 week to 1 month postoperatively, with values ranging from 20/39 (0.29 ± 0.19 logMAR) to 20/34 (0.23 ± 0.17 logMAR). The UNVA was lower as compared to the UDVA and UIVA, with no improvement seen from 1 week to 1 month postoperatively, with values of 20/68 (0.53 ± 0.21 logMAR) and 20/66 (0.52 ± 0.20 logMAR), respectively. The CDVA, CIVA and CNVA were all found to be very good during the examination period. (CDVA was −0.02 ± 0.15 logMAR at 1 week, −0.04 ± 0.06 logMAR at 1 month. CIVA was 0.09 ± 0.13 logMAR at 1week, 0.02 ± 0.09 logMAR at 1 month. CNVA was 0.13 ± 0.14 logMAR at 1 week, 0.08 ± 0.11 logMAR at 1 month.)

Figure 4 shows the defocus curve measured at 1 month postoperatively. Visual acuity levels of 20/20, 20/25, and 20/40 were attained in the defocus range of 0 to −0.5 D, +0.5 to −1.5 D, and +1.0 to −2.5 D, respectively. These results indicate that postoperative uncorrected visual acuities of 20/25 and 20/40 were obtained at as close as 66 and 40 cm in distance, respectively.

The mean SE at 1 week postoperatively was −0.17 ± 0.55 D (range −1.125 to +2.25 D), while it was +0.0019 ± 0.42 D (range −1.125 to +1.375 D) at 1 month postoperatively. **Table 1** shows the stability of the SE was maintained up to 1 month postoperatively. Myopic shift was found in 13 patients (20%), with a mean of −0.29 ± 0.18 D. Hyperopic shift was found in 31 patients (47.7%), with

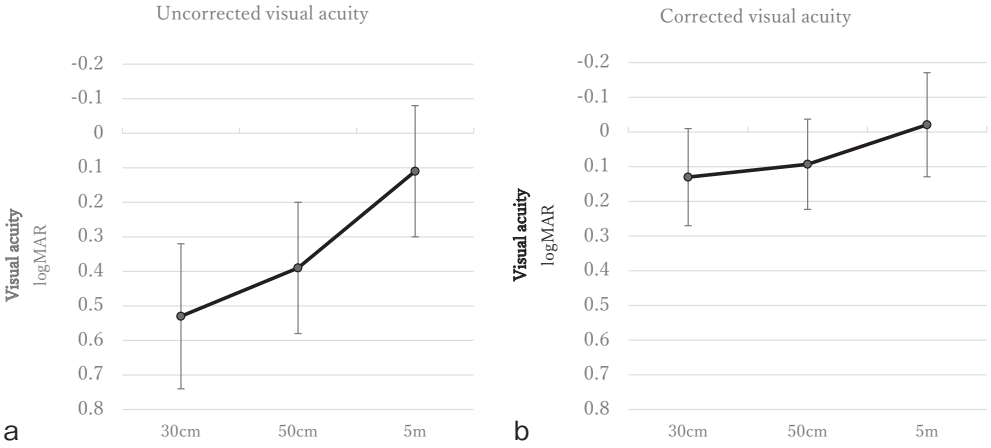

Fig. 2 Visual acuity at 1 week postoperatively (5 m: distance, 50 cm: intermediate, 30 cm: near)

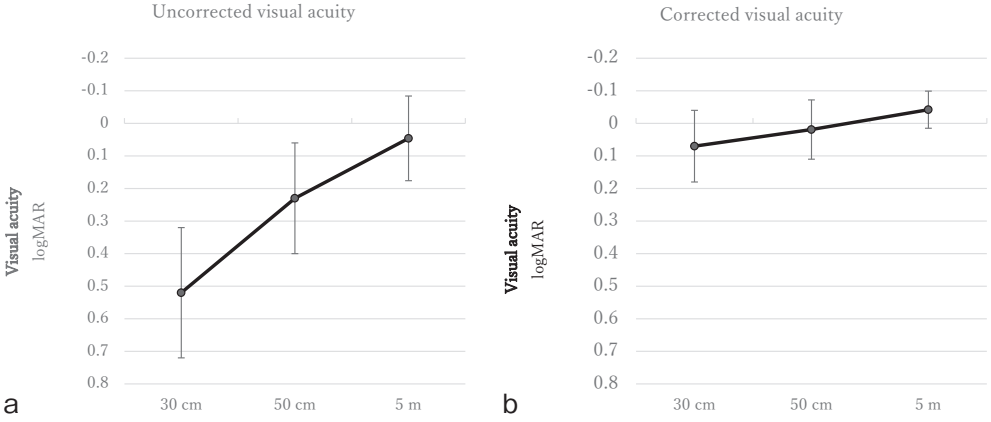

Fig. 3 Visual acuity 1 month postoperatively (5 m: distance, 50 cm: intermediate, 30 cm: near)

Fig. 4 Defocus curve at 1 month postoperatively

Table 1 Stability of spherical equivalent (SE) from 1 week up to 1 month postoperatively

	Number of patients	Diopters
Myopic shift	20.0% (n=13)	-0.29 D (±0.18)
Hyperopic shift	47.7% (n=31)	0.52 D (±0.40)
Unchanged	32.3% (n=21)	

a mean of +0.52 ± 0.4 D. There were 21 patients (32.3%) that remained unchanged. Out of all of the eyes examined, 64 (97.0%) were within ± 1.00 D of the SE at 1 month postoperatively.

There was no correlation between preoperative corneal astigmatism and UDVA (Pearson's correlation coefficient) (**Fig. 5**). As seen in **Figure 6**, after dividing all of the patients into two groups based on the degree of the preoperative corneal astigmatism, i.e., greater or less than 1 D, there were no significant differences observed between the two groups for the mean of the UDVA, UIVA and UNVA (Student's t- test).

Furthermore, as seen in **Figure 7**, we also investigated the correlation between the patient age and UDVA, UIVA or UNVA (Pearson's correlation coefficient). Results showed there was a significant correlation between the age and UDVA ($p<0.01$). However, there were no significant correlations observed between the age and the UIVA or UNVA.

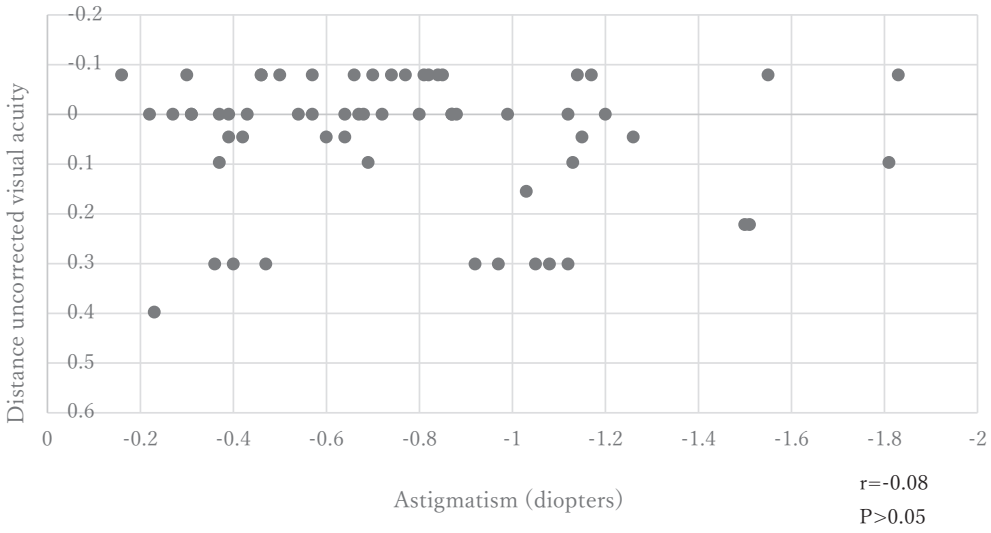

Fig. 5 Correlation between preoperative corneal astigmatism and UDVA

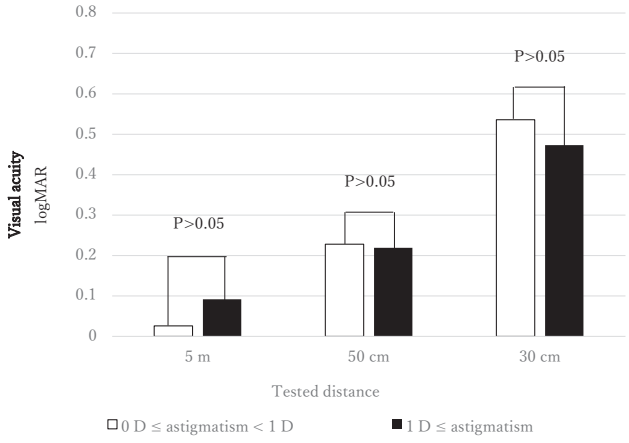

Fig. 6 Uncorrected visual acuity did not significantly differ at any distance between the two groups for low and high astigmatism

Contrast Sensitivity

Contrast sensitivity function was measured before and at 1 month postoperatively. These values were within the normal range (**Fig. 8**).

Photic Phenomena

Figure 9 shows the summary of the frequency and severity of the photic phenomena for glare, halo, star burst and waxy vision. Very few patients reported any severe subjective visual symptoms related to the procedure.

Eyeglass Dependence and Satisfaction

Figure 10 shows the eyeglass dependence. Although 50% of the patients reported being able to do everything without eyeglasses, 50% of other patients reported it was necessary to temporarily or commonly use eyeglasses. A total of 11% of the patients needed eyeglasses for distance activities, 39% for near activities, and 22% for intermediate and near activities, respectively. In this connection, we also investigated the correlation between the patient age and the eyeglass dependence. Questions on the eyeglass dependence were based on frequency scale from 0 to 3, with 0 representing "none", 1 representing "seldom", 2 representing "sometimes", and 3 representing "always". Consequently, no association was found between age and eyeglass dependence (Pearson's correlation coefficient) (**Fig. 11**).

When asked about the satisfaction level with regard to the visual function for distance, intermediate, near and overall, with the exception for near vision function, most of the patients answered very high or high (**Fig. 12**).

No other significant postoperative complications were reported in any of the patients.

Discussion

In this study, we followed up 68 eyes for 1 month and examined the time course of changes in visual function. UDVA and CDVA were approximately 20/22 (0.05 ± 0.13 logMAR) and 20/18 (0.04 ± 0.06 logMAR), respectively.

The intermediate visual acuity was also reported to be highly satisfactory, with both UIVA and CIVA approximately 20/34 (0.23 ± 0.17 logMAR) and 20/21 (0.02 ± 0.09 logMAR), respectively. In contrast, near visual acuity values were at much lower levels as compared with distance and intermediate visual acuities. UNVA and CNVA were approximately 20/66 (0.52 ± 0.20 logMAR) and 20/24 (0.08 ± 0.11 logMAR), respectively. Our results are consistent with the findings of a previous study[22]. In this previous study, Pedrotti et al. showed that the Lentis Comfort LS-313 MF15 IOL provided good distance and

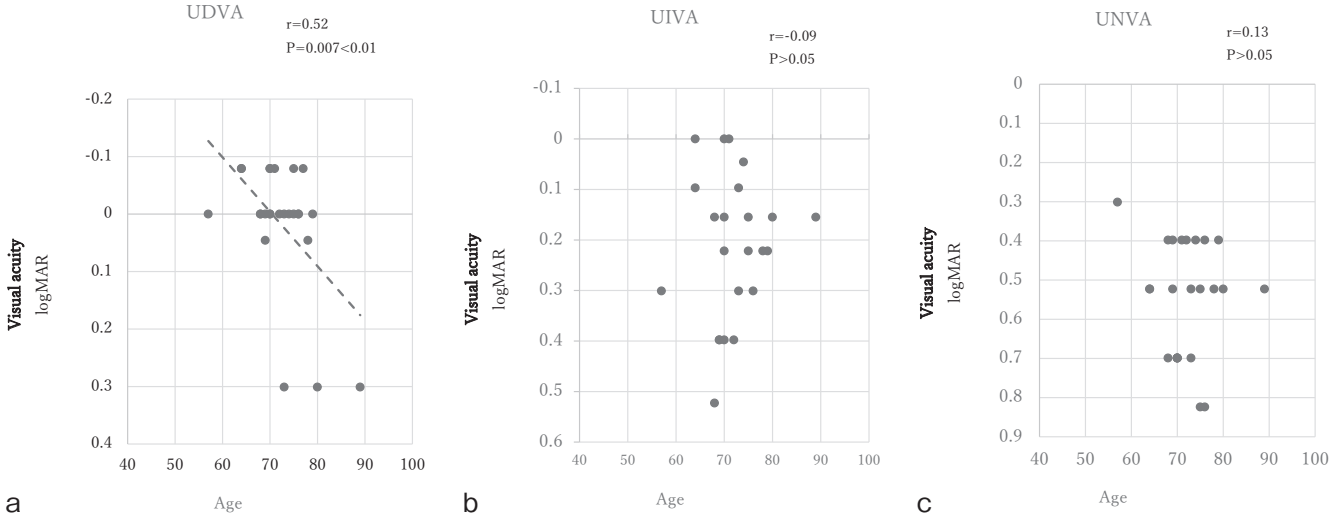

Fig. 7 Correlation between the patient age and UDVA, UIVA or UNVA

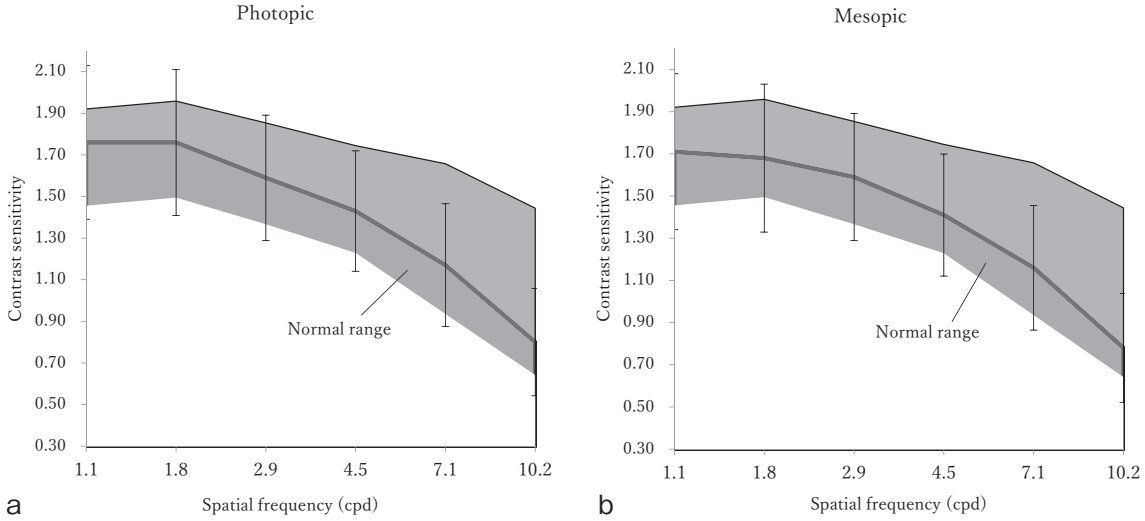

Fig. 8 Photopic and mesopic contrast sensitivity

intermediate vision (−0.01 logMAR for UDVA and 0.05 logMAR for UIVA at 70 cm), while near visual acuity remained relatively low (0.54 logMAR for UNVA at 30 cm)[22].

When patients have this level of uncorrected near visual acuity, while it is possible for subjects to read large print sizes, regular small print cannot be read, thereby requiring a need for reading aids.

We measured the defocus curve at 1 month postoperatively. As seen in **Figure 4**, the curve exhibited a gradual decrease from distance to near, unlike the 2-peak curve that was observed when using conventional distance/near bifocal IOLs[23].

The obtained curve demonstrated that an uncorrected visual acuity of 20/25 or better was attained at as close as 66 cm (−1.5 D), while 20/40 or better was attained at 40 cm (−2.5 D) for distance. Previous studies have also described finding similar single peak defocus curves associated with the Lentis Comfort LS-313 MF15 IOL[19,21,22,24].

This result can be attributed to the structure of the lens. The Lentis Comfort IOL contains a +1.5 D near addition, which allows patients to achieve excellent vision for far distances, and best results at intermediate distances. In contrast, this IOL is limited with regard to the near vision restoration. The defocus curve determined in our current study confirms this outcome.

In fact, 50% of all patients (11 cases) required reading glasses, with 20%-40% of these patients complaining about intermediate or near visual function. Thus, in Lentis Comfort IOL patients, similar to that with other monofocal IOLs, it is necessary to explain to the subjects that eyeglasses will still be required for near vision.

Contrast sensitivity function measured after surgery was within the normal range. In addition, previous stud-

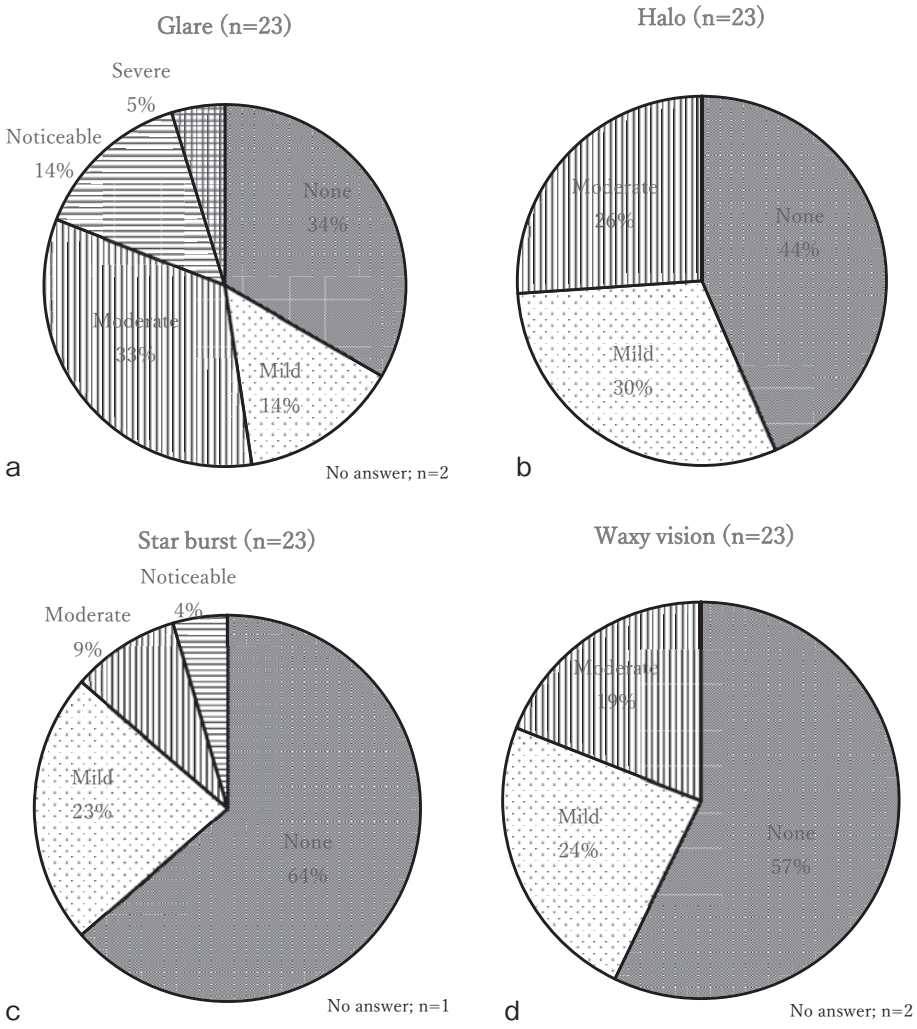

Fig. 9 Photic phenomena

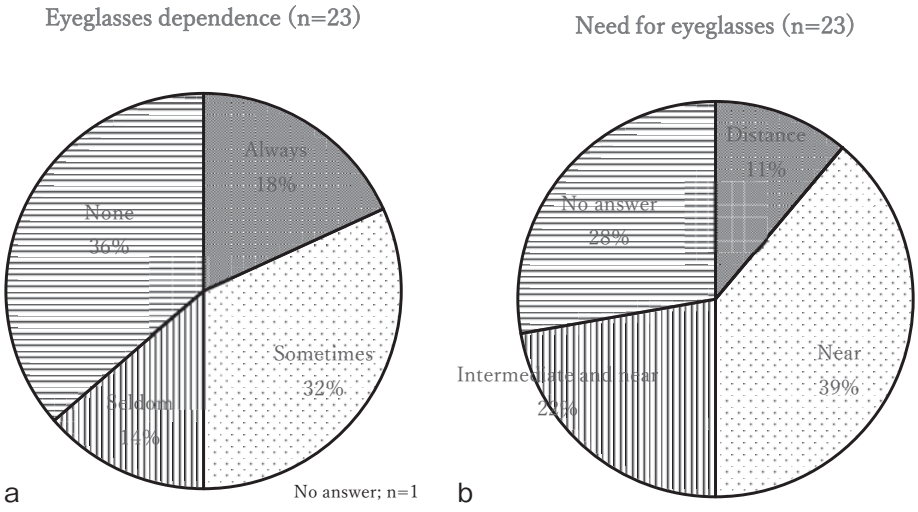

Fig. 10 Eyeglass dependence

ies have also reported that this IOL exhibited contrast sensitivity that was similar to that of monofocal IOLs[21,22].

It has been further demonstrated that while contrast sensitivity did not differ between extended-range-of-vision IOLs and monofocal IOLs, these two IOLs showed significantly better contrast sensitivity as compared to

Fig. 11 Correlation between eyeglass dependence and the patient age

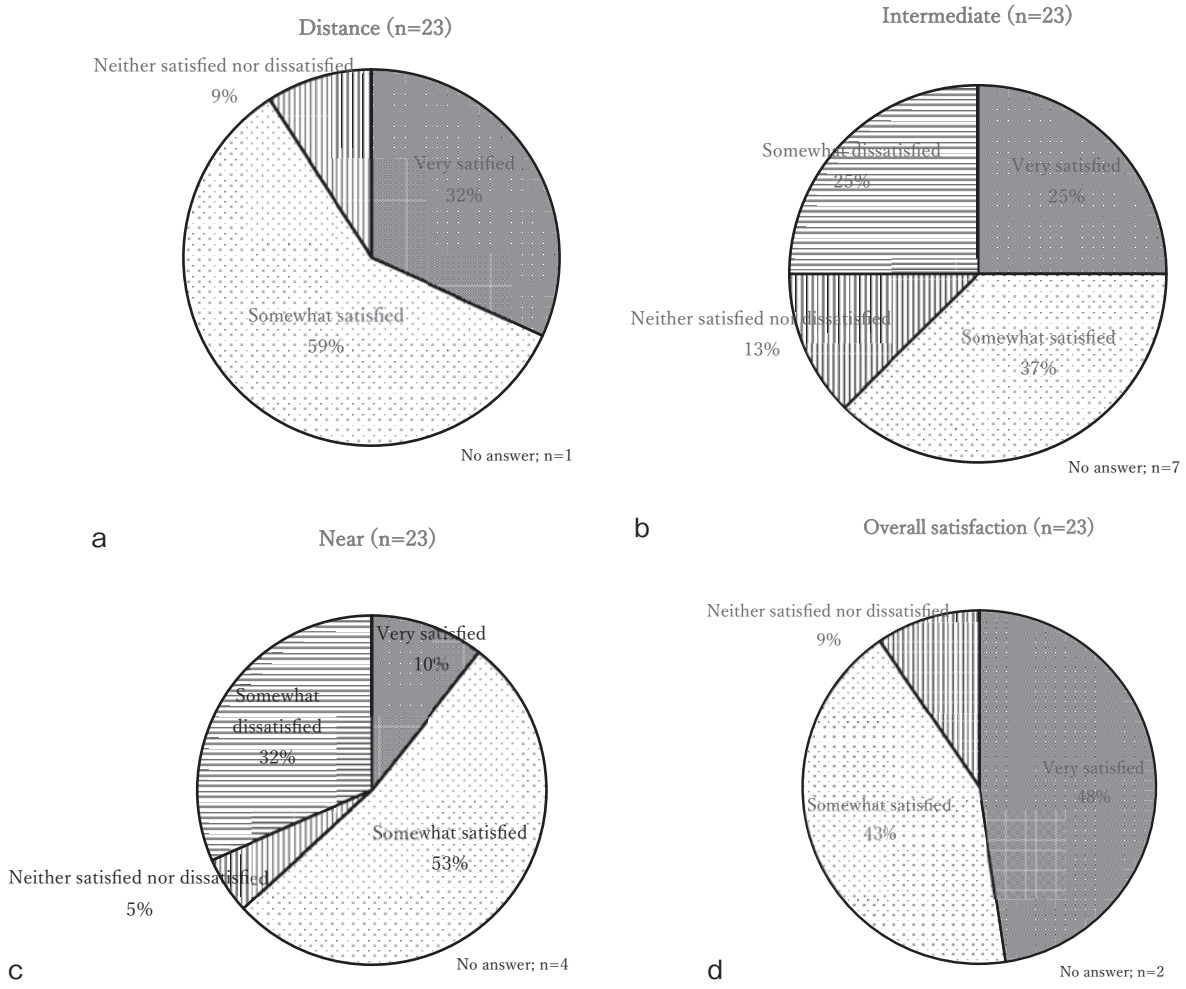

Fig. 12 Satisfaction level

multifocal IOLs with either a +2.0 D or +3.0 D addition[22].

Contrast sensitivity measures a person's ability to detect low contrast images. Thus, when using these images, contrast sensitivity can evaluate subtle changes in the vision that cannot be revealed by a routine visual acuity test. Therefore, this is a well-recognized subjective pa-

rameter that can be used to assess the quality of vision in patients implanted with premium IOLs.

Our current study also examined the frequency and severity of the photic phenomena, which included glare, halo, star burst, and waxy vision. With the exception for glare symptoms (complaints by 5% of patients), there were no severe subjective symptoms that caused visual disturbances. Thus, overall, the subjects in the current study generally reported a high satisfaction level.

In previous studies that examined the implantation of this segmented, rotationally asymmetric multifocal IOL with the +1.5 D addition, it was reported that a few of these patients had complained of disturbing photic phenomena after undergoing the procdure[19,21,23]. In contrast, it was reported that there was a significant decrease of difficulties associated with photic phenomena over time in patients who underwent implantation with conventional multifocal and trifocal IOLs[25,26].

Bissen et al. found that approximately 6% of patients with conventional diffraction-type multifocal IOLs were dissatisfied, with the primary reason due to waxy vision[27]. In addition, Higuchi et al. reported that approximately 8% of the complaints by the dissatisfied patients were related to waxy vision[28]. In our current study, there were almost no complaints associated with cases of waxy vision.

As shown by the defocus curve, the low-add design of this IOL allows for an elongated focal area without multiple foci. Thus, this minimizes the distinct out-of-focus images that generate halos. This may explain the low incidence of the photic phenomena disturbances associated with this IOL[20].

In general, it has been reported that visual function after multifocal IOL (MIOL) implantation was susceptible to corneal astigmatism[29].

In our current study, there were no correlations between the UDVA, UIVA and UNVA for the corneal astigmatism. The reason for this is due to the Lentis Comfort optic having a simple transition line between the distance zone and the intermediate zone, thereby there is less optical loss as compared to the conventional diffractive MIOL.

In this study, there was a moderate negative correlation between age and UDVA in patients. It is well known that visual function after conventional diffractive MIOL implantation decreases in conjunction with aging due to the declining retinal sensitivity[30]. The largest population by age in the current study was patients in their 70s, although there were few cases in their 40s, 50s, and 80s. The differences in the age population between the patients in their 70s and those in their 40s, 50s, and 80s might have influenced this statistical correlation.

Approximately half of the cases of this study changed to hyperopia at 1 month postoperatively as compared to 1 week postoperatively. The Lentis series IOLs are constructed of special HydroSmart material. HydroSmart is a copolymer material that combines 2-hydroxyethylmetacrylate (2-HEMA), which is a component contained in all hydrophilic raw materials, and 2-ethoxyethylmethacrylate, which is a built-in UV-light absorber. The characteristics of this material include having a high elasticity combined with high stability, in addition to preventing the binding of peptides and calcium salts to the material. Our hypothesis for the hyperopic shift is that the IOL moved backwards, in conjunction with postoperative anterior capsule contraction.

In summary, the Lentis Comfort IOL is an IOL that provides good distance and intermediate visual acuity, while exhibiting a lower impact on reading performance. Overall there was a high patient satisfaction, and a low incidence of the photic phenomena.

Conflict of Interest: none.

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