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ORIGINAL RESEARCH

Visual and Refractive Outcomes After Implantation of an Isofocal Optic-Design Intraocular Lens with Double C-Loop Haptics in Japanese Eyes

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Purpose: To assess the refractive and visual outcomes after implantation of an isofocal optic-design intraocular lens (IOL) with double C-loop haptics following cataract surgery in Japanese eyes.

Methods: This was a single-centre prospective study considering 38 eyes of 19 patients who were implanted with the Isopure Serenity (Beaver-Visitec International, Inc. [BVI], Waltham, USA) IOL. This study analysed the refractive (sphere, cylinder and axis) and visual outcomes at 3 months post-surgery. Specifically, the visual performance was analysed by measuring monocular uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate visual acuity (DCIVA) at 80 and 66 cm, uncorrected near visual acuity (UNVA), and distance-corrected near visual acuity (DCNVA) at 40 cm. The photopic binocular defocus curve was also measured.

Results: About 100% of the eyes were within ±1.00D and 89.47% of the eyes within ±0.50D; the mean postoperative spherical equivalent was 0.12 ± 0.35D. The mean refractive cylinder was –0.11 ± 0.33D. 89.47% and 97.37% of patients presented a cumulative monocular UDVA and CDVA value of ≥20/20, respectively. About 57.89% and 42.11% of patients presented a monocular DCIVA value of ≥20/32 at 80 and 66 cm, respectively. About 55.26% of patients presented a monocular DCNVA value of ≥20/40. The mean monocular CDVA, DCIVA at 80 cm, DCIVA at 66 cm, and DCNVA were –0.08 ± 0.05, 0.23 ± 0.13, 0.28 ± 0.13 and 0.35 ± 0.14 logMAR, respectively. The through-focus curve showed good visual acuity at far and intermediate distances with a depth-of-focus value of about 1.75D.

Conclusion: Our current clinical study shows that the implantation of the new isofocal optic-design IOL with double C-loop haptics results in accurate refractive outcomes with excellent visual performance for distance vision and functional intermediate vision in Japanese eyes. The outcomes obtained evidence that this new IOL model is an effective option extending the range of vision when correcting aphakia.

Keywords: intraocular lens, isofocal, double C-loop, phacoemulsification, cataract

Introduction

A recent systematic review and meta-analysis considering 28 randomised controlled trials from the past 5 years comprising 2465 patients analysed the efficacy and safety of various presbyopia-correcting intraocular lenses (IOLs), including standard monofocal, bifocal, trifocal, extended depth-of-focus (EDOF) and enhanced monofocal IOLs after cataract surgery.[1] This study found that both trifocal and EDOF IOLs showed better uncorrected intermediate visual acuity (UIVA) than monofocal IOLs. They concluded that EDOF and enhanced monofocal IOLs have improved visual quality at intermediate distances and are a good choice if there are more activities in daily life at intermediate distances. The report published by the American Academy of Ophthalmology indicates that most multifocal and EDOF IOLs that were compared with a control monofocal IOL showed that patient-reported spectacle independence was superior to the monofocal IOL.[2]

Different EDOF IOLs have recently appeared on the market aiming to improve visual acuity at intermediate distances compared to monofocal IOLs. Several reviews and meta-analyses have been published showing their outcomes in comparison to trifocal models.[3,4] The Isopure 1.2.3. IOL (Beaver-Visitec International, Inc. [BVI], Waltham, USA) is an aspherical lens with an optical design based on an isofocal concept[5] aiming to give patients good distance visual acuity with improved UIVA

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whilst inducing minimal photic phenomena. Different in vitro studies[6–10] have analysed this IOL and using an adaptive optics simulator it has been found that the Isopure IOL shows a good balance between depth-of-focus and visual acuity at distance.[8] Different clinical studies have analysed this lens[11–22] and two studies with the largest sample of patients supported the optical bench assessments showing excellent distance-corrected visual acuity for far vision with improved unaided intermediate vision performance.[13,16] A new Isopure IOL model, named Isopure Serenity, has been launched on the market. This model is optically identical to the Isopure 1.2.3. IOL but with a different haptics platform. The Isopure Serenity shows a POD double C-loop posterior angulated haptic platform, which differs from the MICRO closed loop quadripode posterior angulated haptic of the Isopure 1.2.3 model. To our knowledge, there are no published studies reporting the clinical outcomes achieved either with this new IOL or with Japanese eyes. Therefore, the aim of the current study is to assess the visual and refractive outcomes in Japanese patients diagnosed with cataracts implanted with the Isopure Serenity IOL.

Methods

Study Design and Patients

In this clinical study, we prospectively examined 38 eyes from 19 patients at the Nihonbashi Cataract Clinic (Tokyo, Japan) between June 2024 and February 2025. The study was carried out in accordance with the tenets of the Declaration of Helsinki and was approved by the Nihonbashi Cataract Clinic Review Board. The inclusion criteria were cataracts, male or female adults aged 45 years or older on the day of treatment who were implanted with the Isopure Serenity IOL, maximum time between first and second eye treatment of 30 days, capacity to understand and sign the informed consent form and privacy authorisation and willing and able to conform to the study requirements. The exclusion criteria included age of patient <45 years at the day of surgery, time between first and second eye treatment >30 days, patients who underwent previous intraocular or corneal surgery other than IOL implantation, patients showing glaucoma, patients with diagnosed degenerative visual disorders (eg AMD), patients in whom surgical complications occurred (eg posterior capsule rupture) and patients in whom in-the-bag implantation was not possible.

Intraocular Lens

All eyes were implanted with the posterior chamber premium hydrophobic Isopure Serenity IOL (non-toric or toric model). This IOL is made of GFY hydrophobic acrylic material (refractive index = 1.53 and Abbe number = 42) with blue light and UV filter. The aspheric refractive optic design, based on an isofocal refractive concept, displays polynomial surface design parameters to extend the depth-of-focus compared to monofocal IOLs. The IOL shows the posterior angulated POD double C-loop haptic platform with RidgeTech. The optical zone of the lens is of 6.00 mm and the overall diameter is 11.4 mm. The spherical power ranges from +10.00D to +30.00D (in 0.50D steps) and from +31.00D to +35.00D (in 1.00D steps), and the cylindrical power at the IOL plane is of 1.00, 1.50, 2.25, 3.00, 3.75, 4.50, 5.25, and 6.00D.

Surgical Procedure and IOL Power Calculation

In this prospective study, the surgical procedure considered a phacoemulsification technique by means of the Centurion Phacoemulsification device (Alcon Labs, Fort Worth, TX, USA) through a 2.2 mm clear corneal incision with topical anaesthesia by an experienced surgeon (TA) using Phaco Prechop technique[23] following the standard procedure previously published.[24–26] In the case of toric lenses, the toric axis was marked by the Akahoshi Intra-operative Axis Marker with CCC Guide (ASICO AE-2933). IOL power was calculated using the Barrett Universal II formula and the target refraction was emmetropia in all eyes. The IOLMaster 700 swept-source OCT device (Carl Zeiss Meditec AG, Germany) was used to perform the optical biometry obtaining K1, K2, axis K1, axis K2, axial length, anterior chamber depth, lens thickness and white-to-white distance.

Visual and Refractive Measurements

At 3 months post-surgery the following visual metrics were recorded for distance, using the Sloan ETDRS tests (Precision Vision, Woodstock, IL, USA) on a LogMAR scale: monocular uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA); for intermediate (at 80 and 66 cm): UIVA and distance-corrected intermediate visual acuity (DCIVA); and for near (at 40 cm): uncorrected near visual acuity (UNVA) and distance-corrected near visual acuity (DCNVA). Visual acuity at difference vergences was obtained by means of the photopic binocular best-corrected distance defocus testing for spherical additions ranging from –4.00D to +1.00D in 0.5D steps. Refraction (sphere, cylinder and axis) was recorded and the spherical equivalent (SE) was calculated. In addition, the vector analysis for outcome reports was conducted using the double-angle plot tool[27] considering the preoperative corneal astigmatism obtained from the IOLMaster 700 optical biometer and the refraction obtained at the last post-operative visit. Any adverse event or complication during surgery and follow-up were also recorded.

Statistical Analysis

For visual acuities and refraction parameters, the mean, standard deviation (SD), minimum and maximum values were calculated using the Excel software (2019, version 16.43, Microsoft Corporation, Redmond, WA, USA). Standard graphs for reporting refractive and visual acuity outcomes for IOL-based refractive surgery were plotted.[28]

Results

Thirty-eight eyes of 19 patients implanted with the Isopure Serenity IOL were recruited in this study. Fourteen patients were female (73.68%). Patients' demographics and preoperative characteristics are shown in Table 1. The mean patient's age was 69.16 ± 10.28 years (ranging from 47 to 88 years). Neither surgical complications nor adverse events related to the IOL were reported in our sample during the study.

Table 1 Demographic Characteristics of Participants Shown as Means, Standard Deviations (SD) and Ranges

	Isopure Serenity IOL
Patients (n)	19
Eyes (n)	38
Age (y)	69.16 ± 10.28 (47 to 88)
Sphere (D)	0.18 ± 2.30 (−4.00 to 4.50)
Refractive cylinder (D)	−0.95 ± 0.81 (−2.50 to 0.00)
Spherical equivalent (D)	−0.29 ± 2.29 (−4.25 to 4.00)
Intraocular pressure (mmHg)	15.36 ± 2.22 (11 to 21)
K1 (D)	43.57 ± 1.36 (41.00 to 45.75)
K2 (D)	44.14 ± 1.52 (41.25 to 46.75)
Axial length (mm)	23.79 ± 1.63 (21.45 to 27.57)
Anterior chamber depth (mm)	3.01 ± 0.51 (2.01 to 3.95)
Lens thickness (mm)	4.57 ± 0.49 (3.25 to 5.42)
White-to-white (mm)	11.88 ± 0.51 (10.60 to 12.80)
Spherical IOL power (D)	20.53 ± 4.48 (11.50 to 29)

Abbreviations: CDVA, corrected distance visual acuity; K, keratometry; IOL, intraocular lens power.

In order to report the refractive and clinical outcomes of this sample, we have constructed the standard graphs for IOL-based surgery. Specifically, for accuracy, Figure 1 was created showing the distribution of SE (Figure 1A) and refractive cylinder (Figure 1B) after the surgery. Note that the highest percentage of eyes, 65.79%, was for the range between ±0.13D followed by 18.42% for the +0.14 to +0.50D range. About 100% of the eyes were within ±1.00D and 89.47% of the eyes within ±0.50D. At 3 months, the mean SE and refractive cylinder were 0.12 ± 0.35D (ranging from 1.00 to –0.75D) and –0.11 ± 0.33D (ranging from 0.00 to –1.50D), respectively. For the vector analysis assessment, Figure 2 was plotted, showing the preoperative corneal astigmatism before the surgery (Figure 2A) and the postoperative

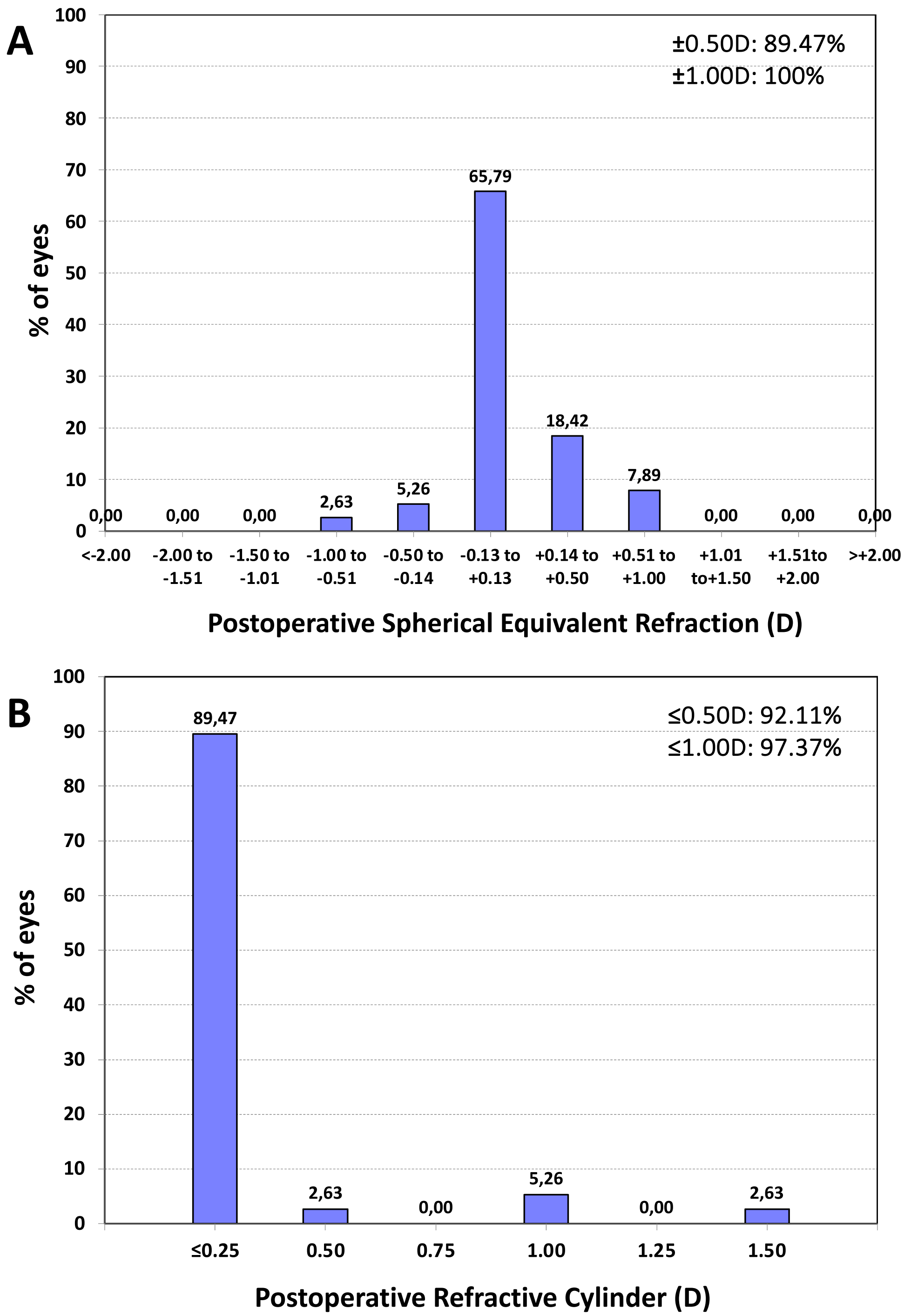

Figure 1 Distribution of postoperative spherical equivalent refraction (**A**) and refractive cylinder (**B**) at three months post-Isopure Serenity intraocular lens implantation.

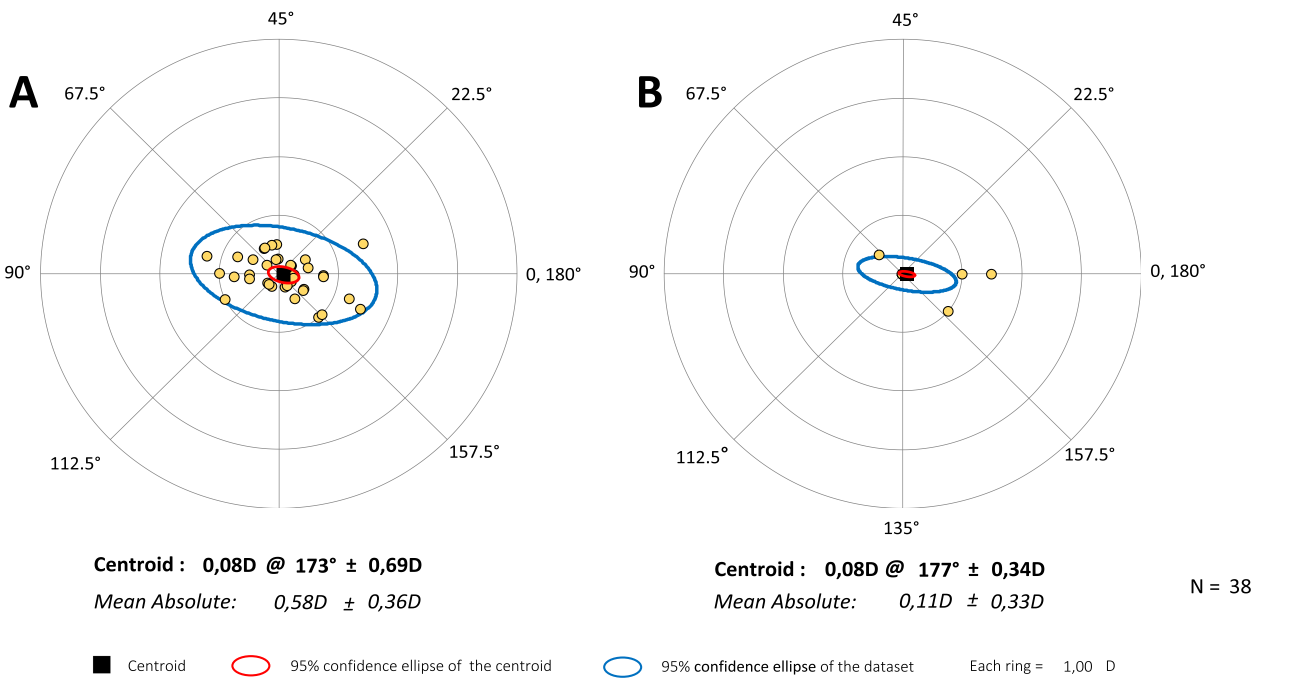

Figure 2 Double-angle plots for preoperative corneal astigmatism (**A**) and postoperative refractive astigmatism (**B**) at three months post-Isopure Serenity intraocular lens implantation. Centroids, mean absolute values with standard deviations, 95% confidence ellipse of the centroid and 95% confidence ellipse of the dataset are also shown.

refractive astigmatism at 3 months post-IOL implantation (Figure 2B). We may observe that the mean absolute of the corneal astigmatism before surgery was 0.58 ± 0.36D and that of the refractive astigmatism was 0.11 ± 0.33D after the intervention, showing its reduction.

For visual acuity outcomes, Figure 3 was plotted. This figure shows the cumulative proportion of eyes at 3 months post-surgery with a given UDVA and CDVA (Figure 3A), UIVA and DCIVA (Figure 3B) and UNVA and DCNVA (Figure 3C) values. At the last follow-up visit (3 months), 34 (89.47%) and 37 eyes (97.37%) had 20/20 or better UDVA and CDVA, respectively, with 36 (94.74%) and 37 eyes (97.37%) achieving 20/25 or better UDVA and CDVA, respectively (see Figure 3A). Specifically, the mean values for UDVA and CDVA were –0.05 ± 0.08 and –0.08 ± 0.05 logMAR, respectively. Table 2 shows the mean values for all the visual acuity measurements. For intermediate visual acuity (see Figure 3B), 22 (57.89%) and 16 eyes (42.11%) achieving 20/32 or better DCIVA at 80 and 66 cm, respectively, with 31 (81.58%) and 23 eyes (60.53%) achieving 20/40 or better DCIVA at 80 and 66 cm, respectively. The mean values for DCIVA were 0.23 ± 0.13 and 0.28 ± 0.13 logMAR at 80 cm and at 66 cm, respectively (Table 2). At near vision (see Figure 3C), 10 (26.32%) and 10 eyes (26.32%) had 20/32 or better UNVA and DCNVA, respectively, with 23 (60.53%) and 21 eyes (55.26%) achieving 20/40 or better UNVA and DCNVA, respectively. The mean DCNVA (40 cm) was 0.35 ± 0.14 logMAR (Table 2). In addition, in order to evaluate the change in visual acuity at different vergences (defocus values), Figure 4 was created. This figure shows the postoperative photopic binocular through-focus, best-corrected visual acuity from 1.0D to –4.0D at 3 months post-surgery. As expected, the best visual acuity is obtained at distance focus (0D of vergence) with a reduction in its value with increased lens power. Values of about 0.20 logMAR showed a depth-of-focus of about 1.75D.

Discussion

New EDOF IOLs are increasingly being used by cataract and refractive surgeons. This type of IOL aims to provide a continuous range of vision offering good visual acuity at far and intermediate distances. As we have indicated, the Isopure 1.2.3. IOL has been widely studied in different clinical reports[11–22] showing good outcomes in terms of accuracy and visual acuity. The current study constitutes the first report on clinical outcomes with a new model, the Isopure Serenity IOL. The objective is to assess the refractive and visual performance of this lens in Japanese eyes and to

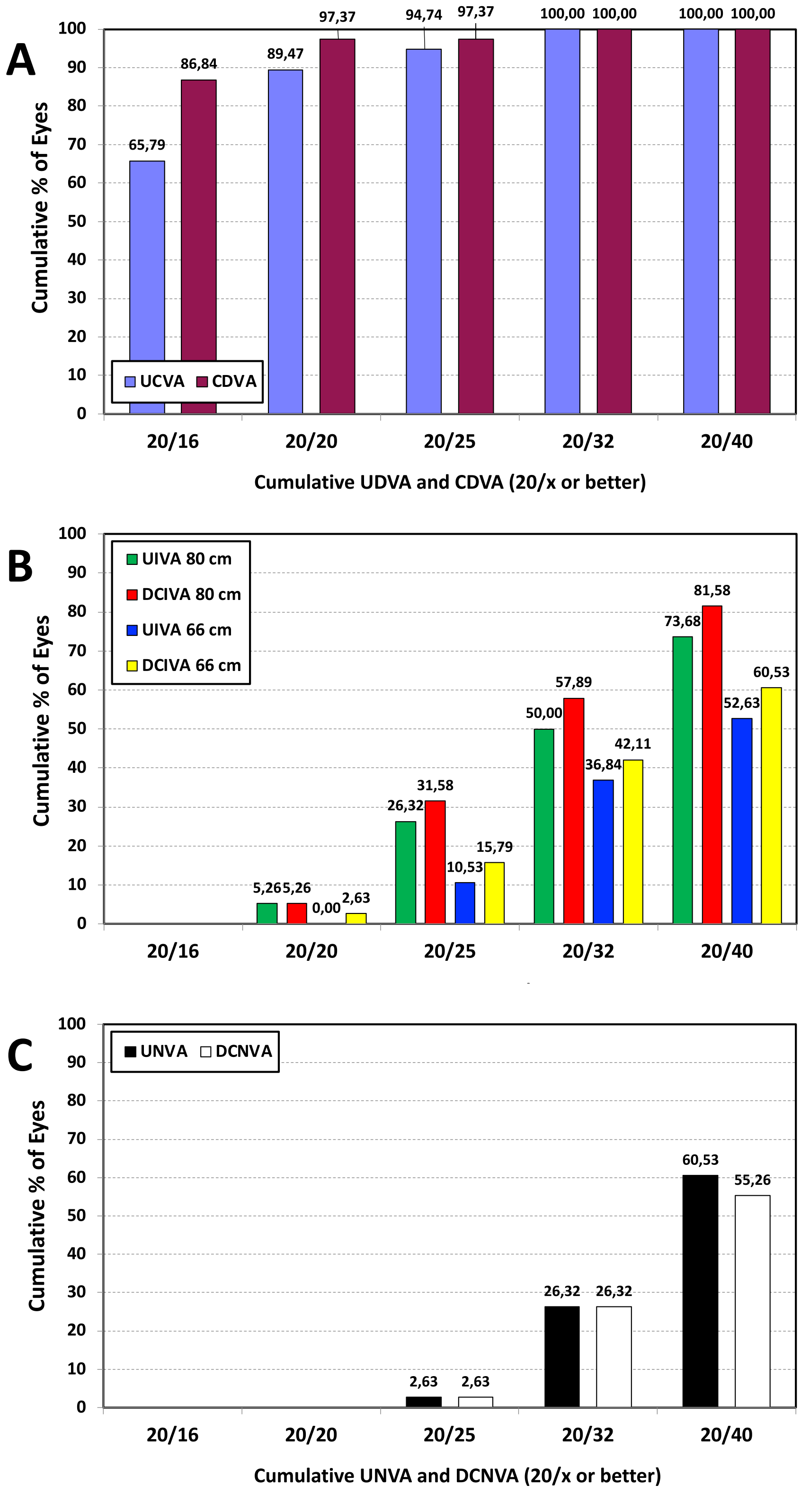

Figure 3 Cumulative proportion of eyes at three months post-Isopure Serenity intraocular lens implantation with a given postoperative uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA) (**A**), uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate visual acuity (DCIVA) at 80 and 66 cm (**B**), and uncorrected near visual acuity (UNVA) and distance-corrected visual acuity (DCNVA) at 40 cm (**C**).

Table 2 Monocular Visual Acuity Outcomes (logMAR) for Eyes Implanted with the Isopure Serenity Toric Intraocular Lens (IOL) Shown as Means, Standard Deviations (SD) and Ranges at 3 Months of Follow-Up

	Isopure Serenity IOL
UDVA	−0.05 ± 0.08 (0.15 to −0.10)
CDVA	−0.08 ± 0.05 (0.15 to −0.10)
UIVA (80 cm)	0.26 ± 0.14 (0.00 to 0.50)
DCIVA (80 cm)	0.23 ± 0.13 (0.00 to 0.50)
UIVA (66 cm)	0.32 ± 0.14 (0.10 to 0.60)
DCIVA (66 cm)	0.28 ± 0.13 (0.00 to 0.50)
UNVA (40 cm)	0.34 ± 0.14 (0.10 to 0.70)
DCNVA (40 cm)	0.35 ± 0.14 (0.10 to 0.70)

Abbreviations: UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; UIVA, uncorrected distance intermediate visual acuity; DCIVA, distance-corrected intermediate visual acuity; UNVA, uncorrected distance near visual acuity; DCNVA, distance-corrected near visual acuity.

compare it with previously published literature with the Isopure 1.2.3. IOL, specifically with two multicentre studies with the largest sample of patients of this IOL model: 183 eyes of 109 patients at 4 months carried out in Spain[13] and 130 eyes of 65 patients at 4–6 months carried out in the Philippines, the Czech Republic and Spain.[16]

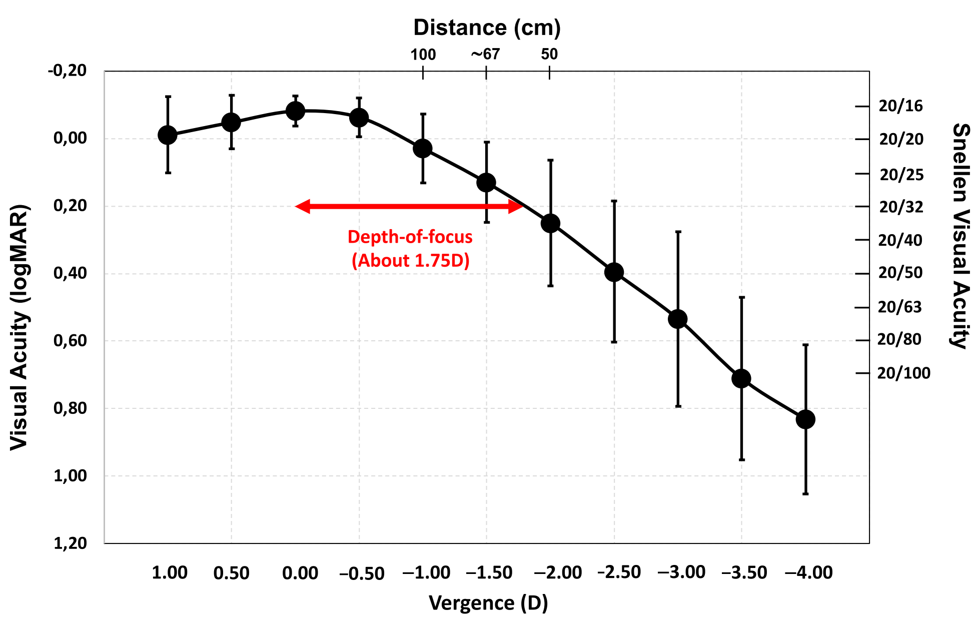

Figure 4 Mean photopic binocular logMAR visual acuity with best correction for distance as a function of the chart vergence from 1.0 D to −4.0 D at three months post-Isopure Serenity intraocular lens (IOL) implantation. Error bars represent standard deviation. The right y-axis shows Snellen feet acuity.

Analysing the refractive outcomes of the Isopure Serenity IOL obtained in the current study, 100% of the eyes were within ±1.00D and 89.47% of the eyes within ±0.50D (see Figure 1). The mean SE and refractive cylinder were 0.12 ± 0.35D and –0.11 ± 0.33D, respectively. These results are in agreement with those found by previous literature with the Isopure 1.2.3. IOL for Bernabeu-Arias et al[13] with 95.7% of eyes within ±1.00D and 73.2% of eyes within ±0.50D and a mean postoperative SE of –0.12 ± 0.42D and a refractive cylinder of –0.46 ± 0.43D, and Ang et al[16] with 99.23% of eyes within ±1.00D and 84.62% of eyes ±0.50D and a mean SE of −0.06 ± 0.36D and a refractive cylinder of −0.47 ± 0.37D. Then, we can consider both IOL models to be similar in terms of refractive accuracy. It should be considered that our cohort also includes Isopure Serenity toric IOLs. The Isopure Serenity shows a POD double C-loop posterior angulated haptic platform, which is the main difference with the Isopure 1.2.3. IOL model. This platform has been evaluated as showing excellent stability. This correlates with our good refractive outcomes in terms of spherical equivalent and astigmatism (see Figures 1 and 2). For example, a laboratory study assessing its mechanical stability using digital image correlation reported an axial displacement and tilt of 0.09 ± 0.06 mm and 0.76 ± 0.50 degrees against 0.09 mm and 1.74 degrees for a compression diameter of 9.50 mm.[29] Similar results were obtained for the other compression diameters. The results obtained are also comparable to in silico values (0.09 ± 0.06 mm versus 0.03 mm for a diameter of 9.50 mm), providing adequate mechanical stability for all the compression diameter range tested (11.00 to 9.50 mm).[30]

Now focusing on visual acuity, we also found good outcomes (see Figure 3), with 89.47% and 97.37% of eyes having monocular UDVA and CDVA ≥20/20, respectively. Bernabeu-Arias et al[13] found percentages of 50.82% and 76.57%, respectively, and Ang et al[16] found values of 56.2% and 84.6%, respectively. The mean values in our cohort for UDVA and CDVA were –0.05 ± 0.08 and –0.08 ± 0.05 logMAR, respectively, and for Bernabeu-Arias et al[13] 0.06 ± 0.12 and 0.01 ± 0.06 logMAR, respectively, and for Ang et al[16] 0.06 ± 0.11 and –0.01 ± 0.08 logMAR, respectively. In general, our values were slightly better to those reported in both previously published cohorts. The outcomes for intermediate vision showed 57.89% and 42.11% of eyes achieving ≥20/32 DCIVA at 80 and 66 cm, respectively, with 81.58% and 60.53% of eyes achieving ≥20/40 DCIVA at 80 and 66 cm, respectively. The cumulative outcomes for monocular conditions in the Bernabeu-Arias et al[13] study were 76.58% and 51.27% of eyes achieving ≥20/32 DCIVA at 80 and 66 cm, respectively, and in the Ang et al[16] 94.6% and 71.5% of eyes achieving ≥20/32 DCIVA at 80 and 66 cm, respectively. In this case, the cumulative values in our cohort were lower than these two studies. Note that possible differences in the measurement method, pupil size of the patients or the specific-population ocular characteristics of the population may play a role in these differences. The mean values for DCIVA were 0.23 ± 0.13 and 0.28 ± 0.13 logMAR at 80 cm and at 66 cm, respectively. These values for the Ang et al[16] study were better compared to ours, being 0.15 ± 0.11 and 0.19 ± 0.12 logMAR, respectively. In contrast, at near vision, 60.53% and 55.26% of eyes achieved a value ≥20/40 of UNVA and DCNVA, respectively, but with lower values in the Bernabeu-Arias et al[13] study: 33.88% and 21.52% of UNVA and DCNVA, respectively, and similar to that found in the Ang et al[16] study: 58.5% for DCNVA.

To ascertain how visual acuity changes with vergence (distance), Figure 4 shows the defocus curve under binocular conditions. This figure correlates with classical figures of defocus curve in this type of IOL showing a peak of best visual acuity located at 0D of defocus (far vision) and a smooth transition reduction with increasing negative lens power (closer distance to the eye). The good outcome is expected due to this lens maintaining good visual acuity at distance (>20/20 at 0D) while improving intermediate visual acuity (ranging from 20/32 to 20/20 between −1D and −2D vergence). Considering a 0.2 logMAR threshold, this lens offers a depth-of-focus of about 1.75D. Bernabeu-Arias et al[13] and Ang et al[16] also measured the binocular defocus curve showing both a peak at 0D with reduced values with closer distances. Bernabeu-Arias et al[13] consider the depth-of-focus in their cohort to be about 1.50D, and Ang et al[16] about 1.75D. The value obtained in our cohort is in agreement with these two studies. This amount of depth-of-focus provides our patients with good visual acuity at intermediate distances being useful for some daily life activities.

We want to indicate that our study has several limitations. The first is that we have included only one group, as this is a non-comparative design, and, therefore, the comparison was made with published literature by other authors. Our follow-up was 3 months and in spite of the fact that we consider this period long enough to study the performance of the lens, a longer follow-up is always desirable to confirm the early values. The analysis of centration and tilt of the IOL should be also analysed in future studies. And finally, it is interesting to consider other analyses that include quality of vision and patient satisfaction and photic phenomena questionnaires.

Conclusion

In conclusion, the present study shows that the new isofocal Isopure Serenity IOL with double C-loop haptics results in accurate refractive outcomes with excellent visual performance for distance vision and functional intermediate vision in Japanese eyes. This new IOL model performs similarly to the Isopure 1.2.3 IOL model, being an effective option to provide our patients with functional intermediate vision.

Disclosure

The author reports no conflicts of interest in this work.

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