

# Clinical Outcomes of a Multicenter Study Following Implantation of an Isofocal Optic IOL with Double C-Loop Haptics

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**Purpose:** To report clinical outcomes in patients implanted with an isofocal optic-design intraocular lens (IOL) with double C-loop haptics following cataract surgery.

**Methods:** This was a multicentre-prospective-study involving 108 eyes (54 subjects) implanted with the Isopure Serenity (BVI, Inc). IOL. At least 3 months after the surgery, the following parameters were analysed: refraction, monocular uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA) and distance corrected-intermediate visual acuity (DCIVA) both at 80 and 66 cm, uncorrected near visual acuity (UNVA), and distance corrected near visual acuity (DCNVA) at 40 cm. In addition, the binocular defocus curve was measured.

**Results:** 79.63% and 98.15% of eyes were within  $\pm 0.50D$  and  $\pm 1.00D$  of the target spherical equivalent, respectively. 68.41% and 98.15% of eyes had a UDVA and CDVA of 20/20 or better, respectively, with 88.89% and 99.07% achieving 20/25 or better, respectively (the mean values for UDVA and CDVA were  $0.02 \pm 0.11$  and  $-0.04 \pm 0.05$  logMAR, respectively). 77.14% and 39.39% of eyes achieved a DCIVA of 20/32 or better at 80 cm and 66 cm, respectively, and 90% and 72.73% achieved a DCIVA of 20/40 or better at 80 and 66 cm, respectively (the mean values for DCIVA were  $0.19 \pm 0.10$  and  $0.28 \pm 0.11$  logMAR, 80 cm and at 66 cm, respectively). 25% and 15.15% of eyes had a UNVA and DCNVA of 20/32 or better, respectively, with 39.81% and 31.82% achieving a UNVA and DCNVA of 20/40 or better, respectively (mean values for UNVA and DCNVA were  $0.37 \pm 0.15$  logMAR and  $0.40 \pm 0.13$  logMAR, respectively). The defocus curve showed a peak of visual acuity at far distance with a depth-of-focus value of about 1.75D.

**Conclusion:** Patients implanted with the new Isopure Serenity IOL with double C-loop haptics showed good visual performance at far distance with functional intermediate vision and accurate refractive outcomes.

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

## Introduction

The advances in cataract surgery in terms of techniques, instruments and intraocular lenses (IOL) has led to a great improvement in quality of life and vision for patients. In addition, presbyopia correcting or high performance IOLs have minimised spectacle dependence for some daily activities, especially those involving intermediate and near vision. Trifocal IOLs create three focal points to provide good outcomes at far, intermediate and near distances, while extended-depth-of-focus (EDOF) IOLs create a continuous area of focus, optimising intermediate vision. A systematic review and meta-analysis based on 22 publications enrolling 2200 eyes compared the outcomes of trifocal IOLs and EDOF IOLs in patients undergoing IOL implantation after cataract surgery and refractive lens exchange.<sup>1</sup> This study concluded that trifocal lenses improved near visual acuity compared to EDOF IOLs but no difference was reported in terms of far and intermediate visual acuity. Specifically, when the defocus curve was analysed, the trifocal lenses showed favourable outcomes for near vision, whereas the EDOF lenses had better results for intermediate vision. EDOF IOLs are a new

approach in the armamentarium available to cataract and refractive surgeons. Also, new IOLs, namely advanced monofocal or monofocal plus or enhanced monofocal lenses, have been launched onto the market that provide a relatively good depth of focus although this is not comparable to that produced by EDOF IOLs.

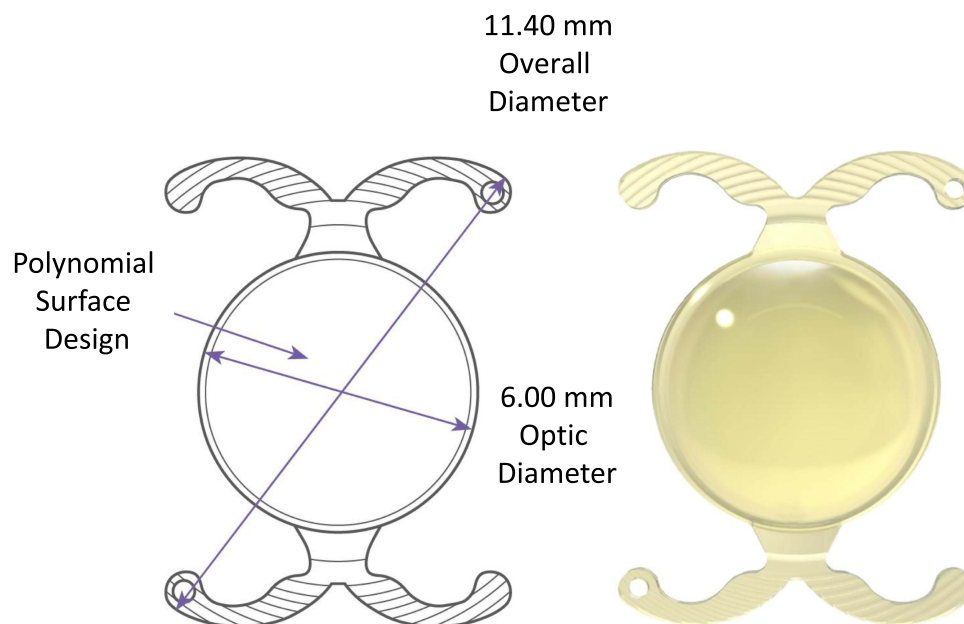
The Isopure Serenity IOL (BVI, Inc., Waltham, USA) is a lens recently launched onto the market with an optical aspheric design based on an isofocal concept.<sup>2</sup> This IOL is identical to the Isopure 1.2.3 IOL except for the haptic-design, which has a double C-loop posterior angulated haptic platform. This POD platform is used in other IOL models from the same company. Over the last 5 years, a number of clinical studies have analysed the Isopure 1.2.3 IOL, reporting good outcomes in terms of refraction, visual acuity, optical quality, photic phenomena and patient-reported questionnaires.<sup>3–15</sup> These studies analysed samples containing from 22 up to 183 eyes with follow-up periods from 1 to 12 months. Taking into account these studies, we consider that this lens is an effective choice for our patients and provides them with good vision at far distance and functional intermediate vision due to the extended-range of vision created. The purpose of this multicentre study is to analyse the refractive accuracy and vision at different distances in subjects implanted with the new Isopure Serenity IOL.

## Methods

This is a multicentre-prospective open-label clinical study. The study was carried out in accordance with the tenets of the Declaration of Helsinki and was approved by each of the local Review Boards (IRB) of the different centers participating in the study: Centre For Sight, Nihonbashi Cataract-Clinic, Institut Ophtalmologique de l'Ouest Jules Verne, Centre Ophtalmologique Kléber, Clinique Beau Soleil, Hospital CHU Ambroise Paré, IRCCS Humanitas Research Hospital and Università degli studi di Milano. Patients signed informed consent to participate in the study. The inclusion criteria considered patients aged 45 years or older on the treatment day that were bilaterally implanted with Isopure Serenity IOLs, with a maximum time of 30 days between the first and second eye treatment. The exclusion criteria considered patients who had undergone previous intraocular surgery, diagnosed with degenerative visual disorders such as age-related macular degeneration or cystoid macular oedema, patients for whom in-the-bag implantation was not possible, and patients who experienced surgical complications (eg, posterior capsule rupture).

## Isopure Serenity Intraocular Lens

All the eyes in this study were implanted with the posterior chamber hydrophobic Isopure Serenity IOL (non-toric or toric model PODS49P/PODST49P, Figure 1). This IOL model is made of GFY material (hydrophobic acrylic with



**Figure 1** Posterior chamber hydrophobic Isopure Serenity intraocular lens. Left: lens design with sizes; right: photography.

refractive index of 1.53 and an Abbe number of 42, with blue light and UV filters). The IOL, with optical and overall diameters of 6.00 mm and 11.4 mm, respectively, has a posterior angulated POD double C-loop haptic platform with RidgeTech. The RidgeTech wavy structures are prone to limit the problematic of the mutual attachment of the two trailing haptics during lens implantation with standard injection systems. The IOL is manufactured in spherical powers ranging from +10 D to +30 D (0.50 D steps) and from +31 D to +35 D (1.00 D steps); the cylindrical power (IOL plane) is manufactured for the following powers: 1.00/1.50/2.25/3.00/3.75/4.50/5.25/6.00 D. The Medice Accuject 2.1/2.2 injection system is employed to implant the IOL model. Swept-source optical biometry with the IOL Master 700 (Carl Zeiss Meditec, Jena, Germany) and Anterior (Heidelberg Engineering GmbH, Heidelberg, Germany) devices was employed with the Barrett-Universal II, Barrett TK and Holladay 2 formulas.

## Refraction Accuracy and Visual Performance at Different Distances

All the data was recorded at least 3 months post-surgery. Refraction was recorded in all the eyes. Vector analysis was carried out using the double-angle plot tool.<sup>16</sup> For visual performance, the monocular-uncorrected-distance-visual acuity (UDVA), corrected-distance-visual acuity (CDVA), uncorrected-intermediate-visual acuity (UIVA), distance-corrected-intermediate-visual acuity (DCIVA) both at 80 cm and 66 cm, uncorrected-near-visual acuity (UNVA), and distance-corrected-near-visual acuity (DCNVA) at 40 cm were measured. In addition, binocular photopic defocus curves were measured from +1.00 D to −4.00 D (25 cm) in 0.5 D steps. Any possible adverse event was registered.

The information recorded from all the subjects was registered into an Excel spreadsheet (Microsoft Corporation, Redmond, USA) to provide mean, standard deviation and ranges for all the variables studied. In addition, several graphs to report standard outcomes after IOL surgery were created.<sup>17</sup>

## Results

In this multicentre clinical study, 108 eyes (54 subjects) were implanted with the Isopure Serenity IOL. Table 1 shows the patient demographics and preoperative main characteristics. Specifically, the average age of the subjects was 72.13±8.60 years (from 47 to 88 years); and 39 patients were female. The average IOL power was +21.40±3.85 D, ranging from +10.00 to +29.00 D. No related adverse IOL events were reported.

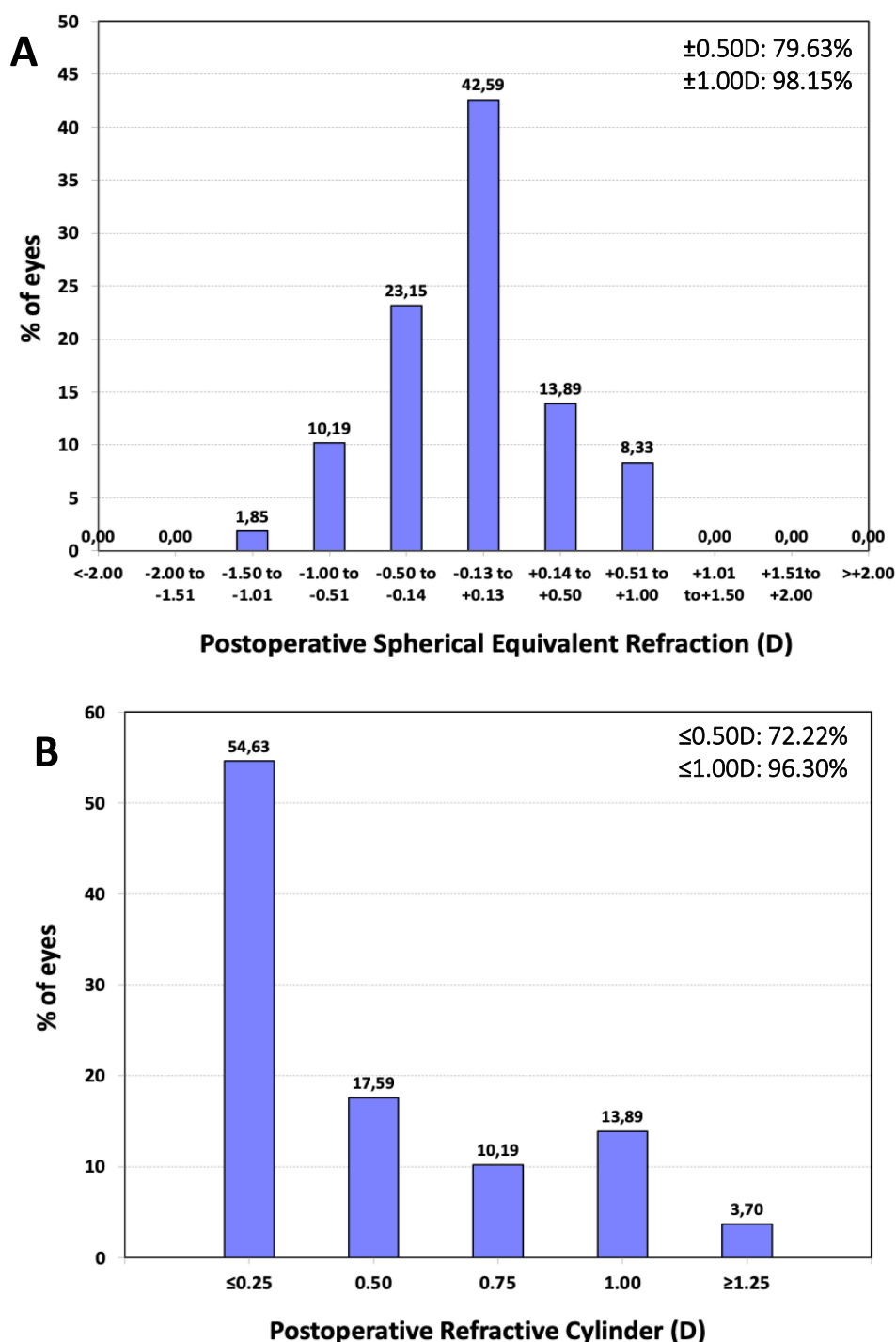
**Table 1** Demographic Characteristics of Participants Shown as Means, Standard Deviations (SD) and Ranges

|                                    | Isopure Serenity IOL        |
|------------------------------------|-----------------------------|
| <b>Patients (n)</b>                | 54                          |
| <b>Eyes (n)</b>                    | 108                         |
| <b>Age (y)</b>                     | 72.13±8.60 (47 to 88)       |
| <b>Sphere (D)</b>                  | 0.50±2.27 (−6.00 to 5.25)   |
| <b>Refractive cylinder (D)</b>     | −0.82±0.69 (−2.50 to 0.00)  |
| <b>Spherical equivalent (D)</b>    | 0.08±2.29 (−7.14 to 4.38)   |
| <b>Intraocular pressure (mmHg)</b> | 15.21±2.26 (10.00 to 21.00) |
| <b>K1 (D)</b>                      | 43.56±1.44 (40.34 to 46.54) |
| <b>K2 (D)</b>                      | 44.19±1.48 (41.13 to 47.49) |
| <b>Corneal Astigmatism (D)</b>     | 0.63±0.34 (0.09 to 1.65)    |
| <b>Axial length (mm)</b>           | 23.48±1.55 (14.64 to 27.57) |
| <b>Anterior chamber depth (mm)</b> | 3.00±0.44 (2.01 to 3.95)    |
| <b>Lens thickness (mm)</b>         | 4.66±0.49 (3.25 to 6.02)    |
| <b>White-to-white (mm)</b>         | 11.85±0.44 (10.60 to 12.80) |
| <b>Spherical IOL power (D)</b>     | 21.40±3.85 (10.00 to 29.00) |

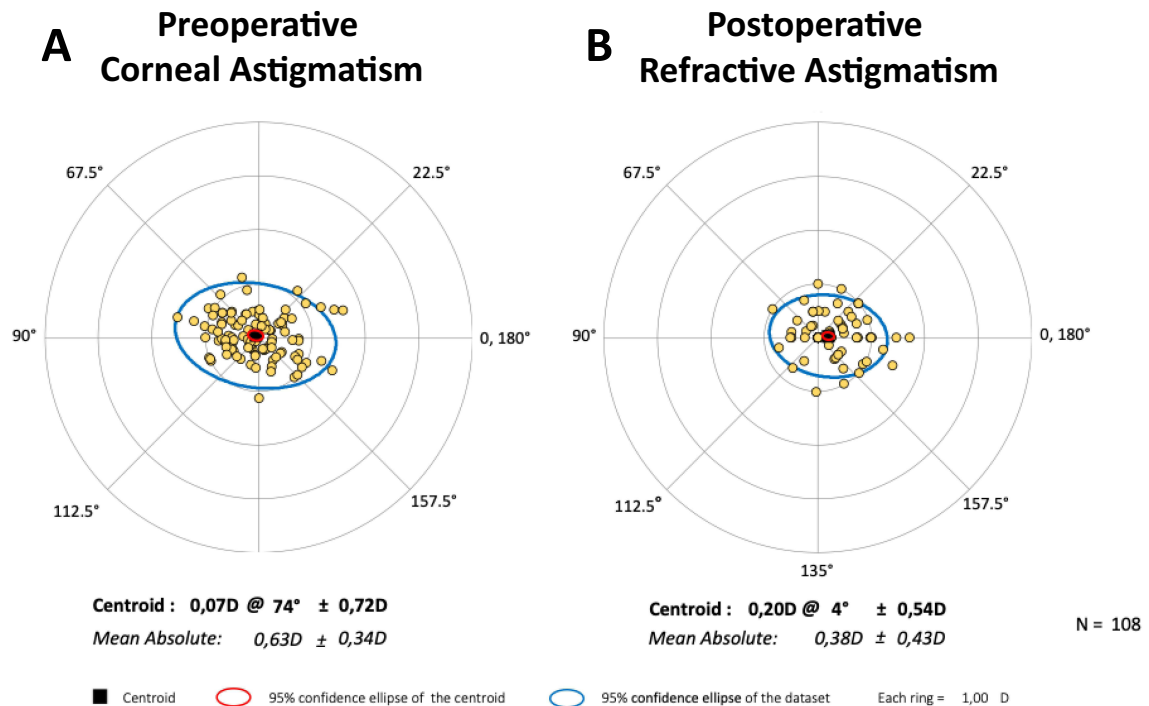
**Abbreviations:** CDVA, corrected distance visual acuity; K, keratometry; IOL, intraocular lens power.

# Refractive Outcomes

Figure 2 plots the refractive accuracy of the surgery for the postoperative spherical equivalent refraction (A) and the refractive cylinder (B). In our cohort, 79.63% of eyes were within  $\pm 0.50$  D and 98.15% of eyes were within  $\pm 1.00$  D of the target spherical equivalent. In relation to refractive astigmatism, 72.22% and 96.30% of eyes showed a refractive cylinder of  $\leq 0.50$  D and  $\leq 1.00$  D, respectively. The average refractive spherical equivalent and cylinder values were –



**Figure 2** Distribution of postoperative spherical equivalent refraction (A) and refractive cylinder (B) post-Isopure Serenity intraocular lens implantation.



**Figure 3** Double-angle plots for preoperative corneal astigmatism (A) and postoperative refractive astigmatism (B) 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.

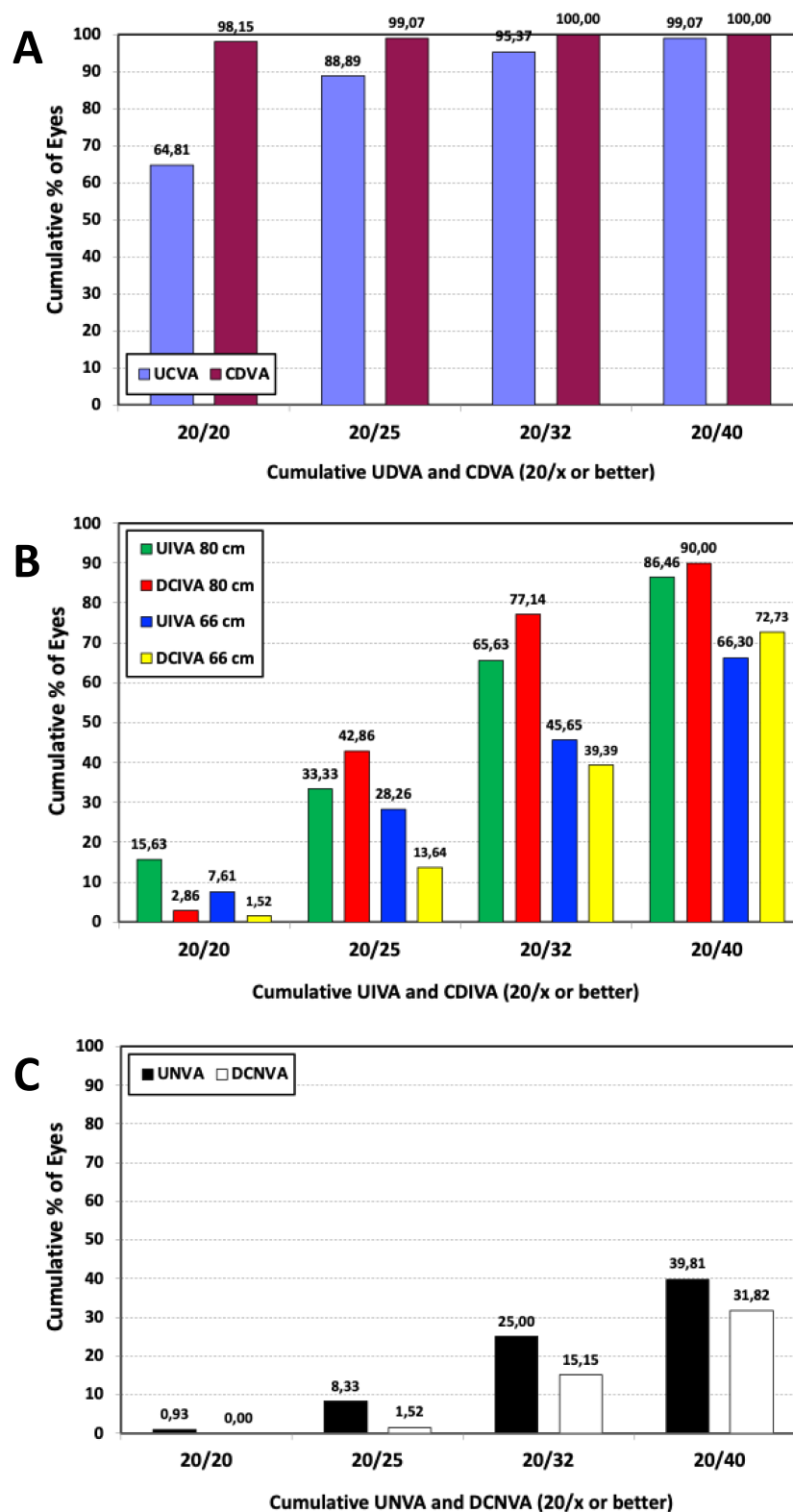
0.06±0.44 D and −0.37±0.44 D, respectively. Vector analysis was performed; Figure 3 shows the outcomes for preoperative corneal astigmatism prior to the surgery (Figure 3A) and the postoperative refractive astigmatism post-IOL implantation (Figure 3B). Note that the mean absolute of the corneal astigmatism before IOL implantation was 0.63 ±0.35 D and that of the refractive cylinder was 0.38±0.43 D after the intervention, showing its postoperative reduction.

## Far, Intermediate and Near Visual Acuity Outcomes

For visual acuity outcomes, Figure 4 was plotted. This figure plots the cumulative percentage of eyes post-surgery with given UDVA and CDVA (Figure 4A), UIVA and DCIVA (Figure 4B), and UNVA and DCNVA (Figure 4C) values. We can see that 68.41% and 98.15% of eyes showed a UDVA and CDVA of 20/20 or better, respectively, with 88.89% and 99.07% of eyes achieving a UDVA and CDVA of 20/25 or better, respectively (see Figure 4A). Specifically, the average values for UDVA and CDVA were 0.02±0.11 logMAR and −0.04±0.05 logMAR, respectively. Mean visual acuities are illustrated in Table 2 (note that some values were not recorded for the whole sample). For intermediate vision, Figure 4B shows that 77.14% and 39.39% of eyes achieved a DCIVA of 20/32 or better at 80 cm and 66 cm, respectively, and 90% and 72.73% eyes achieved a DCIVA of 20/40 or better at 80 and 66 cm, respectively. The average values for DCIVA were 0.19±0.10 and 0.28±0.11 logMAR, at 80 cm and at 66 cm, respectively (see Table 2, which also shows the mean values for UIVA). At near distance (40 cm), Figure 4C shows that 25% and 15.15% of eyes had a UNVA and DCNVA of 20/32 or better, respectively, with 39.81% and 31.82% achieving a UNVA and DCNVA of 20/40 or better, respectively. The average values for UNVA and DCNVA were 0.37±0.15 logMAR and 0.40 ±0.13 logMAR, respectively (see Table 2).

## Defocus Curve

Figure 5 plots the photopic binocular through-focus, best-corrected visual acuity from +1.0 D to −4.0 D in the whole cohort. Note that there is a peak of best visual acuity (−0.05±0.06 logMAR) at far distance focus of the IOL, ie, 0 D of vergence, with its value reducing with increased lens power, showing a broad range of functional vision from far distance



**Figure 4** Cumulative proportion of eyes post-Ispure 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).

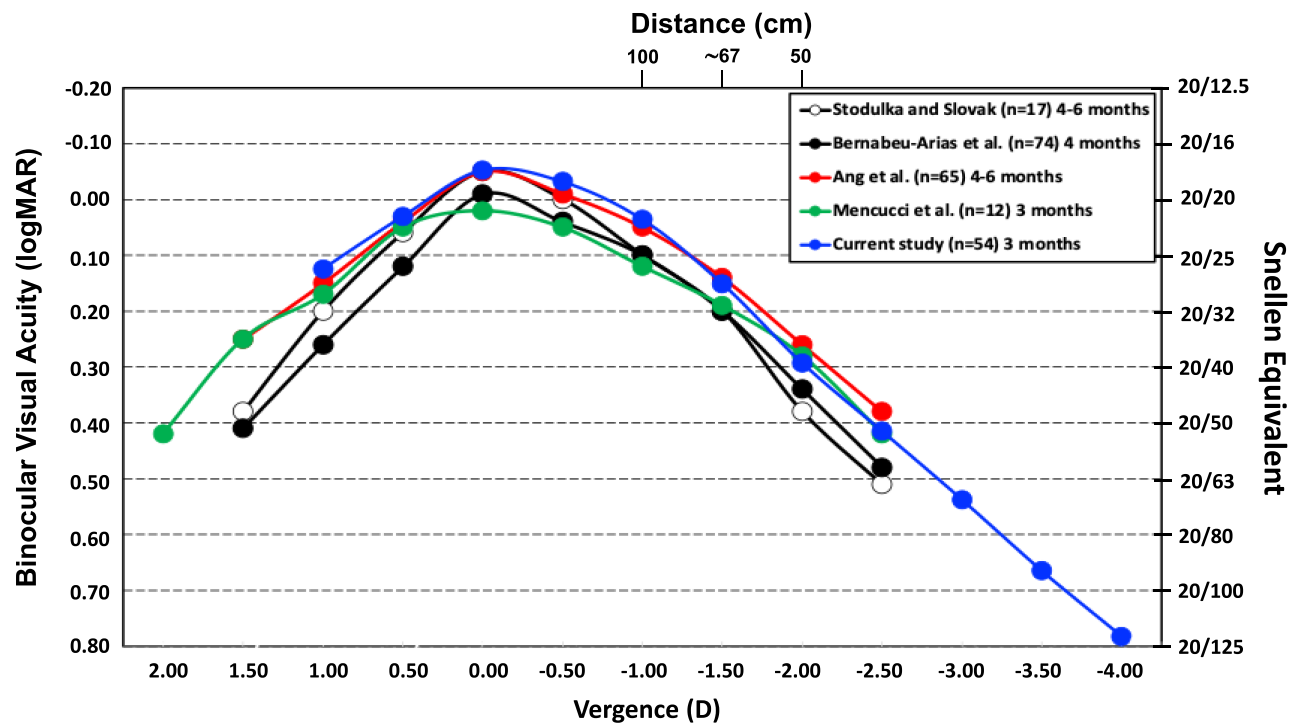
**Table 2** Monocular Visual Acuity Outcomes (logMAR) for Eyes Implanted with the Isopure Serenity Toric Intraocular Lens (IOL) Shown as Means, Standard Deviations (SD) and Ranges at 3 months of Follow-Up

|                      | Isopure Serenity IOL                  |
|----------------------|---------------------------------------|
| <b>UDVA</b>          | 0.02±0.11 (−0.11 to 0.50)             |
| <b>CDVA</b>          | −0.04±0.05 (−0.10 to 0.15)            |
| <b>UIVA (80 cm)</b>  | 0.20±0.15* (−0.10 to 0.50)            |
| <b>DCIVA (80 cm)</b> | 0.19±0.10 <sup>§</sup> (0.00 to 0.50) |
| <b>UIVA (66 cm)</b>  | 0.26±0.15 <sup>†</sup> (0.00 to 0.60) |
| <b>DCIVA (66 cm)</b> | 0.28±0.11 <sup>‡</sup> (0.00 to 0.50) |
| <b>UNVA (40 cm)</b>  | 0.37±0.15 (0.00 to 0.70)              |
| <b>DCNVA (40 cm)</b> | 0.40±0.13 <sup>‡</sup> (0.10 to 0.70) |

Note: \*n=96; <sup>§</sup>n=70; <sup>†</sup>n=92; <sup>‡</sup>n=66.

**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.

down to vergences of around 1.75 D (with reference to 0.20 logMAR). This figure also shows binocular values from different studies<sup>3,5,8,9</sup> with the Isopure 1.2.3 IOL illustrated for comparative purposes. It should be considered that these values were estimated from the different graphs published in their respective studies.



**Figure 5** 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 post-Isopure Serenity intraocular lens (IOL) implantation. The error bars represent the standard deviation. The right y-axis shows Snellen acuity in feet. Distance (cm) is shown in the upper x-axis for intermediate distances. Binocular values from different studies with the Isopure 1.2.3 IOL are depicted for comparative purposes. Note that these values were estimated from the graphs published in the different studies. All the curves were smoothed for graphical representation.



# Discussion

Some clinical publications have reported the visual and refractive outcomes of eyes implanted with the Isopure 1.2.3 IOL,<sup>3–15</sup> reporting good visual performance for this lens at different distances and excellent refractive accuracy when implanted. The objective of this multicentre-study was to analyse the visual and refractive outcomes in a cohort of eyes implanted with the new model, the Isopure Serenity IOL, which uses 4 C loop haptics as opposed to 4 closed loop haptics with the prior model.

## Refractive Accuracy

A key indicator of IOL performance is the predictability of the postoperative refractive outcome. Figure 2 plots the accuracy for the spherical equivalent and cylinder at the last postoperative visit for our sample. The percentage of eyes within  $\pm 1.00$  D of the spherical equivalent and  $\leq 1.00$  D of the refractive cylinder were high: 98.15% and 96.30%, respectively. Spherical equivalent outcomes were excellent ( $-0.06 \pm 0.44$  D) as was mean refractive astigmatism ( $-0.37 \pm 0.44$  D). The reduction of refractive astigmatism is evident with the scatter plot (Figure 3) revealing a centroid mean of  $0.20 \pm 0.54$  D. By contrast, EUREQUO outcomes, which analysed more than 280,000 cataract and refractive procedures, reported 72.7% of eyes as being within  $\pm 0.50$  D and 93% of eyes within  $\pm 1.00$  D.<sup>18</sup> In order to compare our outcomes with previous publications using the Isopure 1.2.3 IOL, we created Table 3. This table indicates some studies that published refractive and visual outcomes based on a minimum of number of eyes and follow-up times (40 eyes and 3 months of follow-up). Bova and Vita<sup>4</sup> recruited the smallest sample of eyes ( $n=42$ ) and Bernabeu-Arias et al<sup>5</sup> the largest ( $n=183$ ). Bova and Vita<sup>4</sup> published outcomes with the longest follow-up period (1 year). Our results largely agree with those found by other colleagues for the Isopure 1.2.3. IOL. For example, we obtained, together with Ang et al<sup>8</sup> the lowest mean spherical equivalent value ( $-0.06$  D), with the refractive astigmatism being similar to that recorded in other studies,

**Table 3** Refractive and Monocular Visual Outcomes of Several Clinical Studies Carried Out on Patients Implanted with the Isopure 1.2.3. Intraocular Lens and the Current Study with the Isopure Serenity Intraocular Lens. This Table Considers Studies with a Minimum of 40 Eyes and 3 Months of Follow-Up

| Parameter                         | Bova and Vita <sup>4</sup> (2022) | Bernabeu-Arias et al <sup>5</sup> (2023) | Ang et al <sup>8</sup> (2023) | Pérez-Sanz et al <sup>10</sup> (2023) | Current Study (2025) |
|-----------------------------------|-----------------------------------|------------------------------------------|-------------------------------|---------------------------------------|----------------------|
| Eyes (n)                          | 42                                | 183                                      | 130                           | 44                                    | 108                  |
| Follow-up (months)                | 12                                | 4                                        | 4-6                           | 3                                     | 3                    |
| Mean SE (D)                       | NR                                | $-0.12 \pm 0.42$                         | $-0.06 \pm 0.36$              | $-0.08 \pm 0.34$                      | $-0.06 \pm 0.44$     |
| SE $\pm 0.50$ D (%)               | NR                                | 73.2                                     | 84.62                         | NR                                    | 79.63                |
| SE $\pm 1.00$ D (%)               | NR                                | 95.7                                     | 99.23                         | NR                                    | 98.15                |
| Mean Cylinder (D)                 | NR                                | $-0.46 \pm 0.43$                         | $-0.47 \pm 0.37$              | $-0.23 \pm 0.27$                      | $-0.37 \pm 0.44$     |
| Cylinder $\leq 0.50$ D (%)        | NR                                | NR                                       | 74.6                          | NR                                    | 72.22                |
| Cylinder $\leq 1.00$ D (%)        | NR                                | NR                                       | 96.2                          | NR                                    | 96.30                |
| Mean CDVA*                        | $0.03 \pm 0.05$                   | $0.01 \pm 0.06$                          | $-0.01 \pm 0.08$              | $0.00 \pm 0.06$                       | $-0.04 \pm 0.05$     |
| Mean DCIVA* (80 cm)               | NR                                | NR                                       | $0.15 \pm 0.11$               | NR                                    | $0.19 \pm 0.10$      |
| Mean DCIVA* (66 cm)               | $0.23 \pm 0.07$                   | NR                                       | $0.19 \pm 0.12$               | NR                                    | $0.28 \pm 0.11$      |
| Mean DCNVA* (40 cm)               | NR                                | NR                                       | NR                            | NR                                    | $0.40 \pm 0.13$      |
| CDVA (Cum%) $\geq 20/20$          | NR                                | 76.57                                    | 84.6                          | NR                                    | 98.15                |
| DCIVA (Cum%) (80 cm) $\geq 20/32$ | NR                                | 76.58                                    | 94.6                          | NR                                    | 77.14                |
| DCIVA (Cum%) (66 cm) $\geq 20/32$ | NR                                | 51.27                                    | 71.5                          | NR                                    | 39.39                |
| DNVA (Cum%) (40 cm) $\geq 20/40$  | NR                                | 21.52                                    | NR                            | NR                                    | 31.82                |

**Note:** \*logMAR; Cum%: cumulative percentage of eyes with a visual acuity  $\geq X$ .  
**Abbreviations:** SE, spherical equivalent; CDVA, corrected distance visual acuity; DCIVA, distance corrected intermediate visual acuity; DCNVA, distance corrected near visual acuity; NR, not reported.



between a quarter to close to half of a dioptre. The number of eyes with a spherical equivalent within  $\pm 0.50$  D and  $\pm 1.00$  D were similar to those found by our colleagues (from 73.2%<sup>5</sup> to 84.62%,<sup>8</sup> and 95.7%<sup>5</sup> and 99.23%,<sup>8</sup> respectively). This was also similar for the refractive astigmatism  $\leq 0.50$  D and  $\leq 1.00$  D: Ang et al<sup>8</sup> found 74.6% and 96.2%, respectively. Perez-Sanz et al<sup>19</sup> analysed the tolerance of residual astigmatism of the Isopure 1.2.3 IOL with comparison to the monofocal Micropure IOL (BVI Inc). They found that the performance of the two models was quite similar for 2- and 3-mm pupils, while the Isopure exhibits a significant reduction in optical quality for a 4.5-mm pupil in comparison with the monofocal lens. However, no statistically significant differences were reported between the lenses when visual performance was examined for any power of induced astigmatism. They concluded that the tolerance to residual astigmatism for the Isopure model was similar to that of the monofocal Micropure lens with a pupil of up to 3.5-mm. They reported that tolerance was worse for the Isopure when the residual astigmatism was induced at 90° versus 180°. Based on our results, we consider that the performance of the Serenity Isopure is similar to the Isopure 123.

## Visual Acuity

Focusing now on visual acuity, our results showed that this IOL model provides good far distance visual acuity with functional intermediate vision. Table 2 shows the mean values for the different distances and Figure 3 plots the different cumulative percentages. The CDVA values in our trial exceed that of the real-world data reported by EUREQUO<sup>20</sup> based on more than 368,000 cataract operations. Specifically, EUREQUO<sup>20</sup> reported that a CDVA of  $\geq 20/40$  and  $\geq 20/20$  was obtained in 94.3% and 61.3% of the cases, respectively, versus 100% and 98.15%, respectively, with this study. The average values for UDVA and CDVA in our study were  $0.02 \pm 0.11$  logMAR and  $-0.04 \pm 0.05$  logMAR, respectively. Compared with previous publications on the Isopure 1.2.3, IOL we can see from Table 3 that the mean values are comparable and about 20/20 (although in our case and for Ang et al<sup>8</sup> they were better than 20/20:  $-0.04 \pm 0.05$  logMAR and  $-0.01 \pm 0.08$  logMAR, respectively). At intermediate vision, our mean DCIVA was slightly worse than that reported by Ang et al<sup>8</sup> at 80 cm, and also at 66 cm when compared with these authors and Bova and Vita.<sup>4</sup> This may be partially explained by differences between the sample size and follow-up period. For near vision, unfortunately, there were no mean DCNVA values reported that could be compared with our sample. The cumulative percentages of visual acuity at different distances were reported by Bernabeu-Arias et al<sup>5</sup> and Ang et al<sup>8</sup> both studies with a similar follow-up period (4–6 months). For CDVA, our percentage of eyes  $\geq 20/20$  was better than that reported by those authors (98.15% versus 76.57%<sup>5</sup> and 84.6%<sup>8</sup>). At 80 cm our value was comparable to that reported by Bernabeu-Arias et al<sup>5</sup> and both were worse (about 77%) than that reported by Ang et al<sup>8</sup> (about 95%) for cumulative values  $\geq 20/32$ . At 66 cm, our percentage was lower than in those two studies, with Ang et al<sup>8</sup> showing the best outcomes (about 72%). For near vision, our value was better than that published by Bernabeu-Arias et al<sup>5</sup> (about 32% versus 22%, for a DCNVA of  $\geq 20/40$ ). These results correlate with the expected outcomes for good vision at far distance with functional intermediate vision due to the extended range of vision created with the isofocal concept based on a polynomial complex surface design.

## Defocus Curve

An important parameter in IOLs aiming to give vision at different distances is the defocus curve, which illustrates visual acuity as a function of distance/vergence and compares outcomes in this study with previous reports on the Isopure 123. The Isopure Serenity IOL demonstrated good visual performance across a range of distances. For example, the average binocular defocus curve revealed a visual acuity peak located at 0 D ( $-0.05 \pm 0.06$  logMAR), while maintaining good vision through intermediate defocus levels and reaching the 0.2 logMAR threshold at about  $-1.75$  D of vergence (see Figure 5). The graph of our outcomes exhibits reducing values in a continuous way, proving that there was gap in vision at intermediate distances (from 100 to 67 cm). This level of performance is of practical benefit to its patients, who should be able to comfortably carry out tasks such as viewing a car dashboard or computer monitor without the need for refractive correction. Figure 5 also includes the outcomes obtained in previous studies<sup>3,5,8,9</sup> of the Isopure 1.2.3 IOL. These studies consider samples from 17<sup>3</sup> to 74<sup>5</sup> patients and follow-up periods from 3<sup>9</sup> to 4–6<sup>3,8</sup> months. The outcomes of the Isopure Serenity IOL model obtained in our study broadly agree with them, and we consider that the two IOL models perform similarly. The best visual acuity reported by all the studies, as expected, is at 0 D of vergence (far vision), this being about 0 logMAR for Bernabeu-Arias et al<sup>5</sup> and Mencucci et al<sup>9</sup> and better, about  $-0.05$  logMAR, for

Ang et al<sup>8</sup> and this study. All the studies show a smooth reduction in visual acuity as a function of vergence (closer distances), with no gaps from far to near vision. The depth of focus considering a 0.2 logMAR limit for all studies in the figure was about 1.50 D for Bernabeu-Arias et al<sup>5</sup> and Mencucci et al<sup>9</sup> and about 1.75 D for Ang et al<sup>8</sup> and in our study. The difference, about 0.25 D, is minimal and, therefore, we consider that both IOL models offer the same depth-of-focus when implanted.

While the follow-up period of 3 months is a limitation, it is sufficient to consider lens performance, which is similar to its predecessor. Contrast sensitivity testing and aberrometry along with patient reported outcome measures are useful outcomes measures, which should be included in future studies.

## Conclusions

In summary, we conclude that the clinical outcomes of this multicentre study indicate that Isopure Serenity IOL implantation allows accurate refractive outcomes and good far distance and functional intermediate vision. Future clinical studies with larger samples and, when possible, longer follow-ups would be desirable to ratify the present outcomes.

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## Disclosure

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