

Visual Performance of a Polynomial Extended Depth of Focus Intraocular Lens

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Abstract

Purpose: To clinically evaluate a new extended depth of focus intraocular lens (ISOPURE, PhysIOL) with optic design modification based on a unique polynomial concept to improve intermediate vision while keeping the quality of distance vision equal to a monofocal lens. **Methods:** 18 patients (11 female, 7 male, mean age of 69.4 years) with bilateral cataract and regular corneal astigmatism ≤ 1.0 D underwent bilateral cataract surgery with ISOPURE implantation. Patients were followed for up to 6 months. Measured parameters were uncorrected (UDVA) and corrected distance visual acuity (CDVA), uncorrected (UIVA) and distance-corrected intermediate visual acuity at 80 cm and 66 cm (DCI80VA, DCI66VA) subjective refraction, defocus curve, tolerance of cylinder induction, and contrast sensitivity. The data from all implanted eyes (all-eyes) and a subset only including the first eye implanted for each patient were analysed. **Results:** The mean manifest refraction spherical equivalent (MRSE) decreased from 1.05 D pre-operatively to -0.15 D at the 4 - 6 month assessment, with 80.6% of eyes within ± 0.50 D of emmetropia. At the final follow-up, mean (SD) monocular CDVA was -0.06 (0.04) logMAR, DCI80VA was 0.18 (0.08) logMAR and DCI66VA was 0.27 (0.13) logMAR. Despite a cylinder induction of -0.50 D, uncorrected distance visual acuity of 0.02 logMAR was still achieved. **Conclusion:** The ISOPURE intraocular lens provides excellent distance corrected visual acuity for far and intermediate distances along with high contrast sensitivity and good tolerance of residual refractive cylinder.

Keywords

Intraocular Lens, Extended Depth of Focus, EDOF, IOL

1. Introduction

Since 2014, extended depth of focus (EDOF) intraocular lenses (IOLs) have in-

creased in popularity. They have produced satisfactory clinical outcomes, by providing improved visual acuity at intermediate distances, which is important for an active lifestyle. EDOF lenses provide the effect of a continuous extended focus, minimizing unwanted photic phenomena and loss of contrast sensitivity when compared to bifocal and trifocal IOLs [1] [2].

The earliest EDOF IOL commonly implanted was the Tecnis Symphony® (J & J Vision, Inc., Santa Ana, CA, USA) [3] [4]. More recently, a new generation of monofocal IOLs with enhanced intermediate vision and increased depth of field has been introduced [5] [6] [7] [8].

The ISOPURE 1.2.3 (PhysIOL S. A., Liège, Belgium) is a new EDOF lens (Figure 1). It is a fully refractive, aspheric, preloaded lens with four closed-loop haptics made of a hydrophobic glistening free material. The dimensions of this IOL depend on the refractive power. From 10 diopters (D) to 24.5 D, the overall and optic diameters are 11.0 mm and 6.0 mm, respectively. Between 25 D and 30 D, the lens is slightly smaller (overall: 10.75 mm/optic: 5.75 mm).

The optic design is based on unique polynomial technology designed to improve intermediate vision without inducing photic phenomena [9].

On the optical bench, the ISOPURE lens achieves approximately 1 D of EDOF. This should represent an increase of around 50% depth of focus when compared to a standard aspheric monofocal IOL (MicroPure; PhysIOL) [9].

The 1-week and 1-month post-operative outcomes with the ISOPURE IOL have already been reported by our group and results indicated high-quality distance and improved intermediate visual acuities [10]. Here, we present the first clinical results of the ISOPURE IOL with an extended follow-up of 4 to 6 months.



Figure 1. The new ISOPURE 1.2.3 EDOF lens.

2. Patients and Methods

Study design

18 patients were scheduled for bilateral cataract surgery and followed up at 1 to 2 weeks (1 - 2 W), 1 to 2 months (1 - 2 M), and 4 to 6 months (4 - 6 M). All patients gave their informed consent to receive bilateral implantation of the ISOPURE IOL and the use of their post-operative data for publication purposes.

Polynomial technology

The ISOPURE lens is an EDOF IOL based on the patented polynomial technology. Its aspheric optic is based on a 100% refractive mechanism and features complex polynomial surface design parameters to extend the depth of field compared to monofocal IOLs. With respect to the aspheric optic design of the monofocal parent device MicroPure (PhysIOL S.A.), the ISOPURE lens differs by the amount of spherical aberration (SA). The SA of both IOLs is negative (< 0) and decreases rapidly with the size of the aperture. However, the amplitude of the SA is comparatively more negative for the ISOPURE lens. In the case of the ISOPURE IOL, the residual SA of the pseudophakic eye is basically given by the SA of the IOL since the lens overcompensates the corneal SA. Thus, the residual SA is only slightly influenced by the type of cornea. Measurements on the optical bench show that compared to the monofocal parent device MicroPure, the depth of field is increased from 48% to 86% for corneal spherical aberrations ranging from 0 to 0.28 microns at 6 mm diameter according to information from manufacturer.

Inclusion and exclusion criteria

The study included patients 45 years or older with bilateral cataract, no significant ocular comorbidities and regular corneal astigmatism ≤ 1.0 D (measured by automatic keratometry) in each eye. Exclusion criteria were negative corneal spherical aberration (measured with the Pentacam at a 4 mm pupil size); irregular astigmatism; degenerative ocular diseases (e.g. macular degeneration or other retinal or optic nerve disease) determined by optical coherence tomography (OCT) scanning; eyes that might require retinal laser treatment during the study or are at a greater risk of developing cystoid macular edema; previous intraocular or corneal surgery; traumatic cataract; history or presence of macular edema; instability of keratometry or biometry measurements; ocular hypertension; presence of glaucoma or clinically significant dry eye.

Intervention

Experienced surgeons performed standard phacoemulsification under topical and intracameral anaesthesia through a 2.2 mm incision at the steep corneal meridian with in the bag IOL implantation. The preloaded IOL was delivered by a single-use injector (1.2.3, PhysIOL) and centred in the capsular bag (**Figure 2**). Mean duration between first and second eye surgery was 6.0 ± 2.7 days.

Post-operative care

The following topical medication was used: tobramycin/dexamethasone drops five times a day for the first 3 post-operative days and then three times a day until

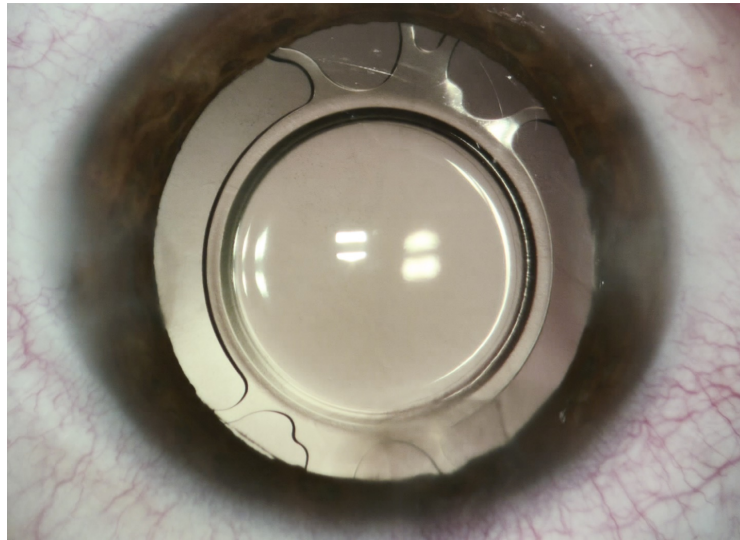


Figure 2. Implanted hydrophobic polynomial extended depth of focus intraocular lens.

the bottle was finished; bromfenac sodium salt sesquihydrate drops twice a day until the bottle was finished.

Outcome measures

Monocular visual acuities were assessed at all visits while binocular visual acuities were assessed only at the 4 - 6 M visit. Uncorrected Distance Visual Acuity (UDVA), Corrected Distance Visual Acuity (CDVA) and manifest refraction spherical equivalent (MRSE) were assessed using a modified Snellen optotype with five letters per line. All values are expressed in the logarithm of the minimum angle of resolution (logMAR) with an accuracy of 0.02 logMAR per letter read. Uncorrected and Distance Corrected Intermediate Visual Acuity (UIVA, DCIVA) were examined at 80 cm (UI80VA, DCI80VA) using the ETDRS Chart 2106C-80 (Precision Vision Inc., USA) and at 66 cm (UI66VA, DCI66VA) using the ETDRS Chart 2106-66 (Precision Vision Inc., USA).

Defocus curves were completed using a standard approach where the subject's eye is corrected to their best distance refraction followed by defocusing the eye by 0.5 D increments between -5.0 D to $+1.5$ D. Additionally, $+0.25$ D and -0.25 D lenses were used. The tolerance of induced astigmatism defocus was determined over the manifest distance refraction with minus cylinders from -0.25 D to -1.5 D (in 0.25 D steps) and with plus cylinders from 0.25 D to 1.5 D (in 0.25 D steps) at two-axis orientations, 90° and 180° . The modified Snellen optotype with five letters per line was used to measure the visual acuity at each intolerance of induced astigmatism defocus and for defocus curve assessment. All visual acuities were expressed in logMAR.

Monocular and binocular contrast sensitivity tests were performed using CSV1000 (Vector Vision, USA) in photopic and mesopic conditions at the 1 - 2 M and 4 - 6 M follow up. Mesopic conditions were induced by adding mesopic filters (Vector Vision, USA) into the trial frame. Slit-lamp examination was performed, and all adverse events were documented at each visit.

Statistical analyses

This was the first clinical series exploring refractive and visual acuity outcomes following bilateral implantation of the ISOPURE EDOF IOL. Therefore, no formal sample size calculation was performed as the first implantation of the ISOPURE IOL in Europe was in July 2019. Results from the all-eyes dataset (both eyes for each subject included) and the first treated eye (for each subject) subsets are presented. The all-eyes set contains the monocular data from both eyes of each patient. Two interrelated data points are excluded, monocular data of the first treated eye subset includes only one eye per patient. The initial eye implanted for each patient was selected for this subset. The Kolmogorov-Smirnov test was used to test for the normal distribution of data. Except for the following observations, data was normally distributed ($p > 0.05$): Contrast sensitivity mesopic binocular at 6 cpd; Defocus binocular at 0 D; Defocus monocular at 0 D; Defocus monocular at -0.25 D. Data is presented as mean and standard deviation unless it is indicated otherwise.

3. Results

Demographic data and preoperative clinical parameters

The analyses include outcomes of 36 eyes from 18 patients (11 female). The mean age and Standard Deviation (SD) of patients who completed the 4 - 6 M follow-up were 69.4 (± 6.9) years. Anterior chamber depth, axial length, white-to-white, keratometry, corneal astigmatism, and intraocular lens power were in the standard ranges for the first implanted eye subset and the all-eyes data set (**Table 1**).

Manifest refraction

MRSE for the all-eyes set and the first implanted eye set pre-operatively show similarity. Preoperative MRSE decreased from 0.82 D (2.88) to -0.16 D (0.46) postoperatively in the first implanted eyes at 4 - 6 months. Results indicated 80.6% of eyes had MRSE within ± 0.50 D of emmetropia and there were no eyes with refraction deviating more than $+1.00$ D or -1.50 D from emmetropia (**Figure 3(a)**). The refractive cylinder magnitude was not significantly different from preoperative -0.31 D (-0.35) to postoperative -0.35 D (0.46) at 4 - 6 M follow up (**Table 2**).

Postoperative refractive astigmatism was stable for both data sets over the follow-up period (**Table 2**). Refractive cylinder was smaller or equal to 0.25 D in 55% of eyes. The postoperative refractive cylinder was not bigger than 1.50 D for any of the patients (**Figure 3(b)**).

Monocular and binocular visual acuity

The visual acuity (VA) was stable during the follow-up period (**Table 3**). Monocular visual acuity for the first implanted eye data set improved from pre-operative CDVA of 0.26 (0.13) logMAR to -0.06 (0.04) logMAR at 4 - 6 M. Mean DCI80VA was 0.18 (0.08) logMAR and DCI66VA 0.27 (0.13) logMAR at 4 - 6 M. All-eyes achieved monocular VA of at least 0.3 logMAR at far distance

Table 1. Demographics and preoperative clinical information.

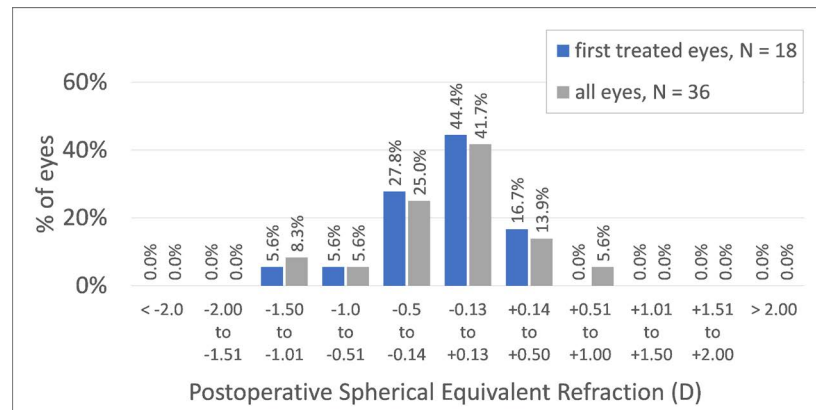
		Mean	%	SD	Median	Min	Max
age		69.4	-	6.9	70.5	56.0	78.0
gender	Female	11/18	61.10%	-	-	-	-
	Male	7/18	38.90%	-	-	-	-
ACD	all eyes	3.04	-	0.25	3.01	2.52	3.43
	first implanted eyes	3.02	-	0.25	3.00	2.53	3.40
AL	all eyes	23.24	-	0.77	23.36	21.78	24.95
	first implanted eyes	23.25	-	0.79	23.42	21.78	24.94
WtW	all eyes	11.79	-	0.31	11.89	11.10	12.30
	first implanted eyes	11.79	-	0.35	11.89	11.10	12.30
K1	all eyes	43.35	-	1.26	43.25	40.72	45.79
	first implanted eyes	43.42	-	1.23	43.25	41.35	45.79
K2	all eyes	44.00	-	1.29	43.76	41.44	47.04
	first implanted eyes	43.99	-	1.23	43.80	41.94	46.57
CA	all eyes	0.65	-	0.29	0.70	0.16	1.26
	first implanted eyes	0.58	-	0.28	0.59	0.17	1.19
IOL power	all eyes	22.81	-	2.23	22.75	16.50	26.50
	first implanted eyes	22.75	-	2.20	22.50	17.00	26.50

SD = standard deviation; ACD = anterior chamber depth; AL = axial length; WtW = white-to-white; K = keratometry; CA = corneal astigmatism; IOL = intraocular lens.

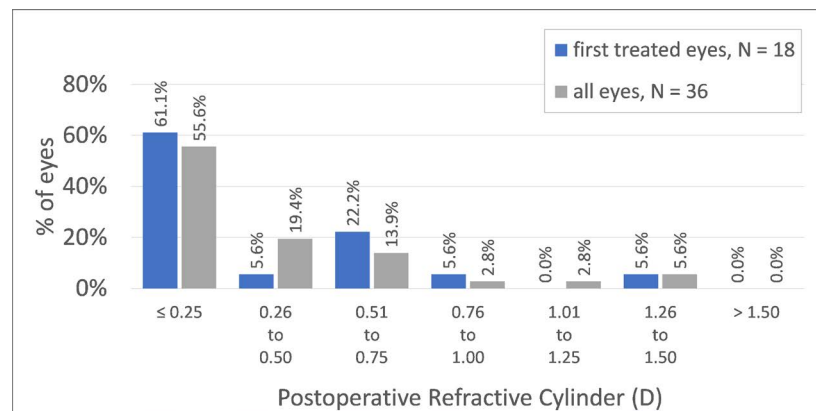
Table 2. Manifest refraction data pre- and postoperatively.

		Mean	SD	Median	Min	Max
Cylinder all eyes	preop	-0.42	0.46	-0.50	-2.00	0.00
	1 - 2 W	-0.41	0.43	-0.38	-1.50	0.00
	1 - 2 M	-0.42	0.46	-0.38	-1.50	0.00
	4 - 6 M	-0.36	0.45	-0.13	-1.50	0.00
Cylinder first implanted eye	preop	-0.31	0.35	-0.13	-1.00	0.00
	1 - 2 W	-0.46	0.43	-0.50	-1.50	0.00
	1 - 2 M	-0.43	0.48	-0.38	-1.50	0.00
	4 - 6 M	-0.35	0.46	0.00	-1.50	0.00
MRSE all eyes	preop	1.05	2.73	1.63	-7.38	5.13
	1 - 2 W	-0.27	0.40	-0.25	-1.25	0.25
	1 - 2 M	-0.26	0.42	-0.13	-1.38	0.25
	4 - 6 M	-0.15	0.51	0.00	-1.38	1.00
MRSE first implanted eye	preop	0.82	2.88	1.63	-7.38	5.00
	1 - 2 W	-0.28	0.37	-0.25	-1.25	0.25
	1 - 2 M	-0.22	0.36	-0.06	-1.00	0.25
	4 - 6 M	-0.16	0.46	0.00	-1.38	0.50

SD = standard deviation; preop = preoperatively; W = weeks; M = months; MRSE = manifest refraction spherical equivalent.



(a)



(b)

Figure 3. Accuracy of refractive spherical equivalent at 4 - 6 months (% of eyes, (a) top), Refractive cylinder at 4 - 6 months (% of eyes, (b) bottom).

and 80 cm, with and without correction, and more than 83% of eyes reached the same acuity at 66 cm (**Figure 4(a)**).

Binocular VA in comparison to monocular VA improved only slightly, the binocular CDVA was -0.09 (0.06) logMAR, DCI80VA was 0.14 (0.08) logMAR and DCI66VA was 0.20 (0.11) logMAR (**Table 3**) at 4 - 6 M. The vast majority of the patients had binocular visual acuity of at least 0.3 logMAR at all evaluated distances, both with and without distance correction (**Figure 4(b)**). Bilateral UDVA and CDVA were the same or only up to one line worse for 88.2% participants at the 4 - 6 M assessment (**Figure 5**).

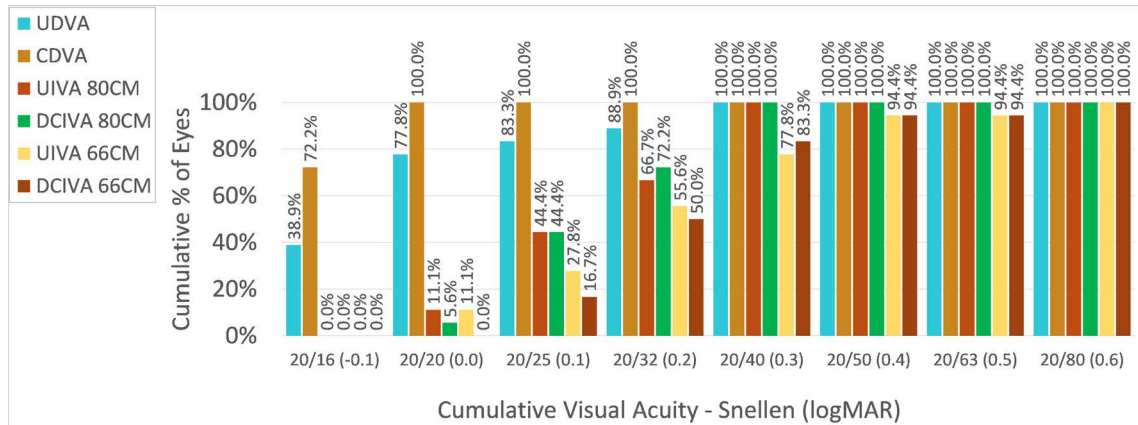
Defocus curve

The mean monocular defocus curve ranged from -1.0 D to $+0.6$ D for the visual acuity level of 0.2 logMAR as per the American National Standard (ANSI Z80.35-2018) (**Figure 6**). The binocular defocus curve at 4 - 6 M demonstrated greater depth of focus with a range from -1.5 D to $+1.0$ D. This gives a potential depth of focus of up to 66 cm ($1/1.5 = 0.66$).

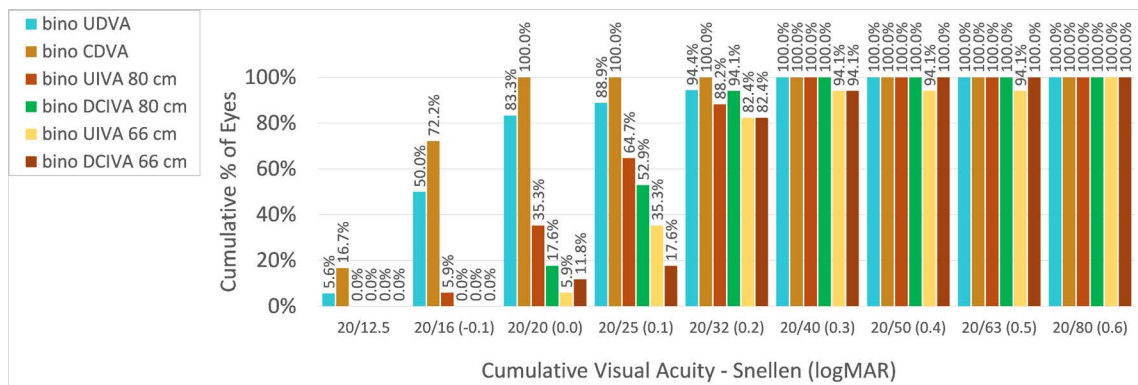
Monocular visual acuity at 4-6M after induction of negative or positive cylinder

Figure 7(a) shows the monocular visual acuity after the induction of different

values of negative cylinder (mean values) at 4 - 6 M (n = 12 eyes). Both axis and power had an effect on visual acuity: with an induced cylinder of -0.50 D, the IOL still achieved a good visual acuity of 0.02 logMAR. Cylinder at an axis of 180° showed a slightly better visual acuity compared to at a 90° axis. Results were



(a)



(b)

Figure 4. Cumulative monocular ((a) top) and binocular ((b) bottom) visual acuity (% of eyes) at distance, intermediate, and near at 4 - 6 months; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; DCIVA = distance-corrected intermediate visual acuity.

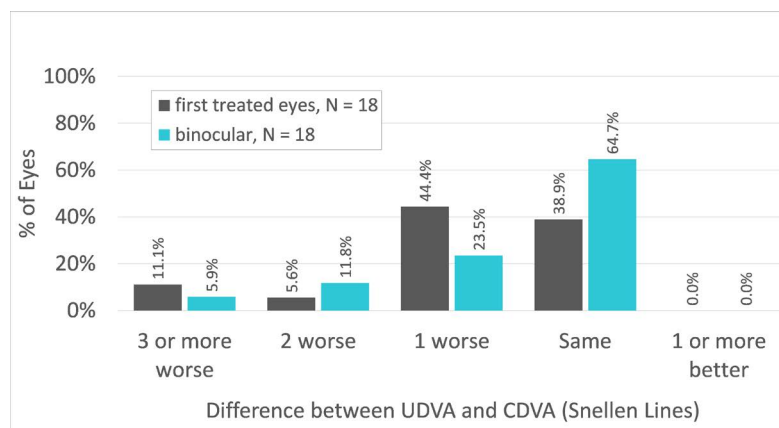


Figure 5. Difference between UDVA and CDVA (Snellen Lines) at 4 - 6 months; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity.

Table 3. Monocular and binocular photopic UDVA, CDVA, UIVA, and DCIVA pre- and postoperatively.

		Mean	SD	Median	Min	Max	
UDVA	binocular 4 - 6 M	-0.02	0.13	-0.05	-0.16	0.34	
	preop	0.73	0.33	0.75	0.28	1.50	
	first implanted eye	1 - 2 W	0.06	0.12	0.02	-0.08	0.44
		1 - 2 M	0.07	0.11	0.02	-0.08	0.34
		4 - 6 M	0.03	0.13	0.00	-0.10	0.34
CDVA	binocular 4 - 6 M	-0.09	0.06	-0.09	-0.20	0.00	
	preop	0.26	0.13	0.25	0.04	0.54	
	first implanted eye	1 - 2 W	-0.04	0.07	-0.01	-0.18	0.12
		1 - 2 M	-0.03	0.05	0.00	-0.10	0.10
		4 - 6 M	-0.06	0.04	-0.06	-0.14	0.00
UIVA (80 cm)	binocular 4 - 6 M	0.12	0.11	0.10	-0.06	0.32	
	1 - 2 W	0.13	0.14	0.14	-0.14	0.34	
	first implanted eye	1 - 2 M	0.19	0.16	0.14	0.00	0.68
		4 - 6 M	0.19	0.09	0.20	0.04	0.32
		DCIVA (80 cm)	binocular 4 - 6 M	0.14	0.08	0.14	-0.02
1 - 2 W	0.16		0.11	0.15	0.00	0.40	
first implanted eye	1 - 2 M		0.23	0.16	0.16	0.04	0.60
	4 - 6 M		0.18	0.08	0.18	0.04	0.30
	UIVA (66 cm)		binocular 4 - 6 M	0.20	0.14	0.16	0.00
1 - 2 W		0.17	0.14	0.17	-0.06	0.42	
first implanted eye		1 - 2 M	0.21	0.20	0.12	-0.04	0.68
		4 - 6 M	0.26	0.15	0.24	0.02	0.64
		DCIVA (66 cm)	binocular 4 - 6 M	0.20	0.11	0.20	0.00
1 - 2 W	0.21		0.13	0.23	-0.08	0.42	
first implanted eye	1 - 2 M		0.30	0.19	0.24	0.06	0.72
	4 - 6 M		0.27	0.13	0.25	0.10	0.64

UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UIVA = uncorrected intermediate visual acuity; DCIVA = distance-corrected intermediate visual acuity.

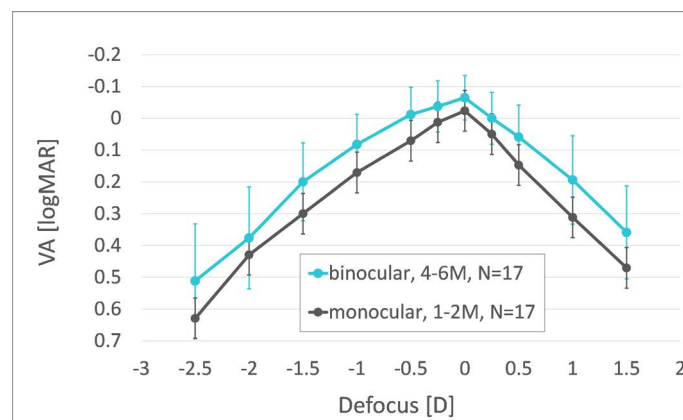
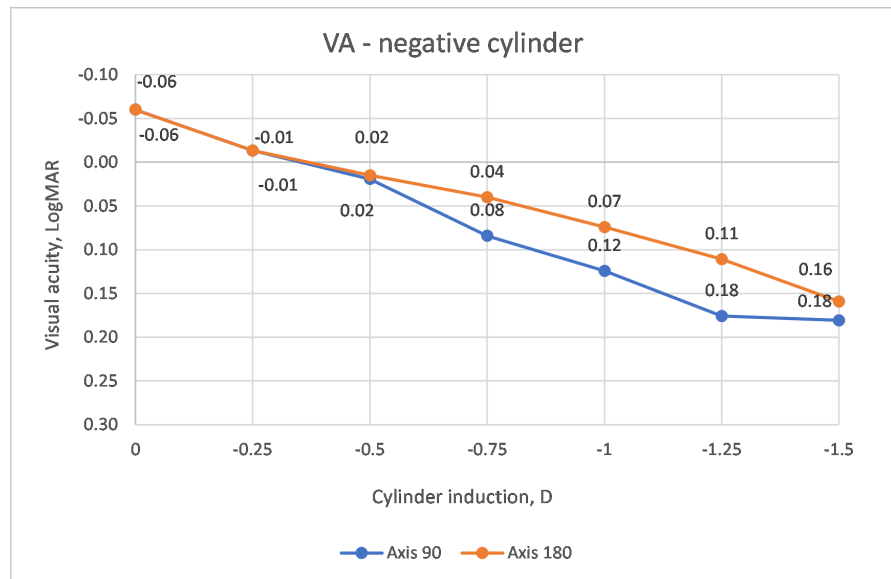
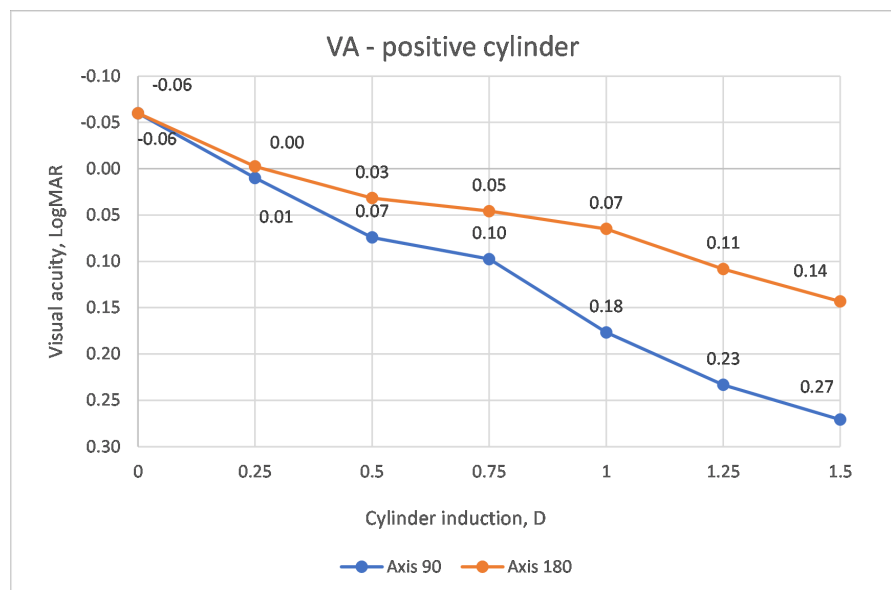


Figure 6. Monocular (1 - 2 months) and binocular (4 - 6 months) defocus curve (mean ± SD); VA = visual acuity.



(a)



(b)

Figure 7. Mean Monocular visual acuity after the induction of different values of negative cylinder ((a) top) and of positive cylinder ((b) bottom) at 4 - 6 months; VA = visual acuity.

similar when analysing the monocular visual acuity after the induction of different values of positive cylinder. However, an axis of 180° showed much better visual acuity compared to the 90° axis, especially at cylinder inductions higher than +1.00 D (Figure 7(b)).

Contrast sensitivity

Mean monocular photopic contrast sensitivity at 1 - 2 M was within the normal range for the age group 50 - 75 years [11]. Mean monocular mesopic contrast sensitivity was worse at all spatial frequencies compared to photopic conditions. It was however around the normal average range [12] for a younger age

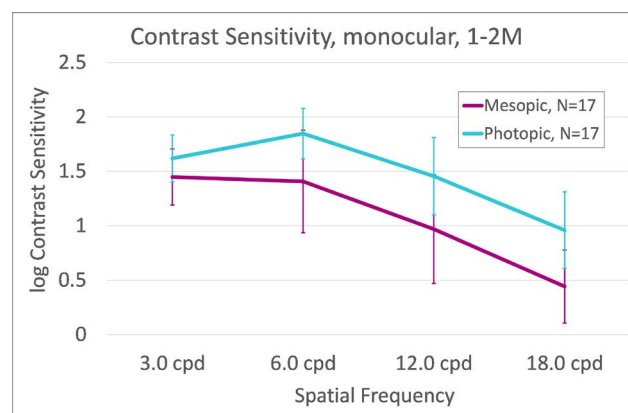
group of 20 - 50 years as there was no mesopic data available for the older age group (**Figure 8(a)**). Similar results were found for binocular contrast sensitivity at 4 - 6 M (**Figure 8(b)**).

Additional procedures

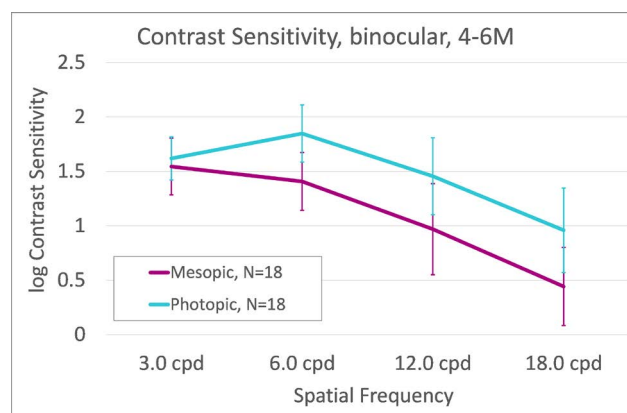
Six eyes (16.7%) from three patients required neodymium-doped yttrium aluminum garnet (Nd:YAG) laser posterior capsulotomy due to posterior capsular opacification (PCO). Four eyes were treated 3 - 4 months after the initial surgery, and 2 eyes were treated after the study. Two eyes (5.6%) from one patient showed slight edema in the photoreceptor layer 1 week after surgery with regression after 2 months. This was probably due to non-compliance of treatment post-operatively. No further intervention was required.

4. Discussion

This study presents the first clinical results of the ISOPURE IOL in patients undergoing bilateral cataract surgery with a 4 - 6 month follow-up. This innovative polynomial technology aims to enhance the intermediate vision while providing uncompromised distance vision.



(a)



(b)

Figure 8. Monocular photopic and mesopic contrast sensitivity (mean \pm SD) at 1 - 2 months ((a) top); Binocular photopic and mesopic contrast sensitivity (mean \pm SD) at 4 - 6 months ((b) bottom); VA = visual acuity); cpd = cycles per degree.

Given the ISOPURE lens has only recently been developed, there have been no comparative studies published. However, some literature exists on other new-generation IOLs, and indirect comparisons can be made. Unlike the traditional EDOF and multifocal IOLs based on a diffractive design, the profiles of these new generation refractive EDOF IOLs are characterized by smooth and progressive changes of the superficial geometry, thus reducing the risk of unwanted photic phenomena [13]. However, since these refractive EDOF IOLs have only been on the market for a relatively short time, the existing literature is still limited and it is not yet possible to make definite statements about the incidence of photic phenomena.

When assessing post-operative refractive spherical equivalent at 4 - 6 months, we found that the majority of eyes (80.6%) had a MRSE within ± 0.50 D and no eyes had more than +1.00 D or -1.50 D. These results are consistent with those reported by Mencucci *et al.* showing that 62.5% of eyes had a MRSE within ± 0.50 D with the Tecnis Eyhance ICB00 lens (Johnson & Johnson Vision Care, Inc.) [14], and similarly the results reported in a recent multicenter randomized trial for the EDOF lens AT LARA 829 MP (Carl Zeiss Meditec) and Tecnis Symphony (Johnson & Johnson Vision Care, Inc.) [15].

ISOPURE monocular and binocular CDVA were on average better by one line in comparison to results for AT LARA 829 MP and Tecnis Symphony. DCI66VA of these two IOLs was superior by 1 to 1.5 lines compared to the ISOPURE, resulting in 0.12 ± 0.18 logMAR and 0.18 ± 0.17 logMAR [15], respectively. In another study, Tecnis Eyhance ICB00 was comparable to ISOPURE at the intermediate distance where DCIVA was 0.27 ± 0.11 logMAR [14]. Here the ISOPURE CDVA also shows slight superiority against the Eyhance ICB00 [14]. Essentially, this study found that the ISOPURE CDVA was superior to the other EDOF IOLs, but at an intermediate distance of 66 cm, the AT LARA 829 MP and the Tecnis Symphony were superior to the Eyhance ICB00 and the ISOPURE, which achieved similar results. Monocular and binocular defocus curves of the ISOPURE IOL exhibited a very similar pattern to the AT LARA 829 MP and Tecnis Symphony [14] [15].

When compared to a study that evaluated bifocal, trifocal and EDOF lenses, our results were very similar to the Tecnis Symphony with higher levels of subjective and objective depth of field reported [16]. Due to the optical characteristics of EDOF IOLs it is expected that photopic phenomena will be minimal. However, the Tecnis Symphony IOL is still associated with some level of photic phenomena [15] [17] [18] [19] [20] [21]. Since the ISOPURE lens is a fully refractive, aspherical lens based on polynomial technology and the Tecnis Symphony is a diffractive lens, we speculate that ISOPURE should induce less photic phenomena.

The visual acuity obtained with the ISOPURE after the induction of different values of positive and negative cylinder was dependent on the axis, with superior vision at axis 180° compared to at 90° . Previously, Carones examined the impact

on visual acuity with three multifocal intraocular lenses (MIOLs) and the Tecnis Symphony (EDOF) after the induction of different values of positive and negative cylinder [22]. In this study the ISOPURE performed better at an axis of 180° with similar results at an axis of 90° in comparison to the MIOLs. The outcomes for the ISOPURE were very similar in comparison to the Tecnis Symphony. Residual cylinders from +1.0 D to -1.25 D should therefore have no significant impact on visual acuity (better than 0.2 logMAR) and patient satisfaction [22]. As some studies have shown, especially with MIOLs, residual refractive errors have a significant negative impact on visual acuity outcomes [23] [24]. The ISOPURE lens may present an advantage as it has shown some range of tolerance.

Monocular photopic contrast sensitivity at 1 - 2 months post-surgery was better by 0.5 logCS than monocular mesopic contrast sensitivity at spatial frequencies 6 - 12 cpd, with similar results found for binocular contrast sensitivity at 4 - 6 months. Contrast sensitivity at 3 cpd was almost identical between the testing conditions. In a previous study, a similar contrast sensitivity level under photopic and mesopic conditions was obtained between the EDOF Tecnis Symphony IOL and two trifocal IOLs (Panoptix, Alcon Laboratories Inc. and AT LISA tri 839 MP, Carl Zeiss Meditec AG) [17]. The ISOPURE results are consistent with these findings.

The limitations of this study are surely a small sample size and a lack of subjective assessment evaluating photic phenomena, quality of vision, and patient satisfaction. Since this was the first clinical experience there was no direct comparison to other monofocal or EDOF IOLs but future studies should focus on this as well as aligning the study design with the American National Standard for Extended Depth of Focus Intraocular Lenses (ANSI Z80.35-2018). Furthermore, in addition to visual acuity in the distance and intermediate range, data on near visual performance should be collected and assessed.

5. Conclusion

In conclusion, the ISOPURE EDOF IOL provides uncompromised distance vision and improves intermediate vision when compared with monofocal IOLs. As ISOPURE has no diffractive rings on the optic surface, it is expected to induce less photic phenomena. Future studies comparing its visual performance with other monofocal and EDOF IOLs, including a higher number of patients and longer follow-up time, as well as inclusion of patients with ocular comorbidities, would be valuable.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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