# Visual Performance After Unilateral Implantation of an Extended Depth-of-Focus Intraocular Lens in Patients With Unilateral Cataract

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## ABSTRACT

**PURPOSE:** To investigate the visual performance after unilateral implantation of an extended depth-of-focus intraocular lens (IOL) in patients with unilateral cataracts.

**METHODS:** In this prospective study, uneventful phacoemulsification with LuxSmart IOL (Bausch & Lomb) implantation was performed in 25 eyes of 25 patients with unilateral cataracts. At postoperative 1, 4, 12, and 24 weeks, uncorrected and corrected visual acuity at far, intermediate, and near distances and the spherical equivalent in manifest refraction were measured. A Visual Function Index and modified Visual Function Index questionnaire were used to investigate glare, spectacle dependence, and satisfaction at 24 weeks in the eye that had surgery.

**RESULTS:** At 6 months postoperatively, uncorrected distance visual acuity was 20/20 (0.0 logMAR) in 96% of cases, distance

Gataract surgery currently is a procedure not only to replace an opaque crystalline lens but also to correct refractive errors and presbyopia thanks to the progress in intraocular lens (IOL) technology.<sup>1</sup> Despite trifocal IOLs having become the gold standard practice in recent years to correct presbyopia after cataract surgery,<sup>2</sup> their main limitation is the subsequently generated photic phenomena such as halo, glare, and starburst.<sup>3,4</sup> To overcome this problem, new extended depth-of-focus (EDOF) IOLs have been developed, aiming to provide better visual quality in corrected intermediate visual acuity was 20/32 (0.2 logMAR) in all cases (60 cm), and distance corrected near visual acuity was 20/32 (0.2 logMAR) in 60% of cases (40 cm). The patient satisfaction score was 100% based on the Visual Function Index questionnaire for far and intermediate distance, respectively. No patients complained of the permanent photic phenomenon. No patients reported bilateral imbalance. All of the patients became spectacle independent for most of their intermediate activities at 60 cm. A total of 96% of the patients reported 100% contrast sensitivity in the Pelli-Robson test.

**CONCLUSIONS:** The unilateral implantation of this EDOF IOL seems to be tolerated and effective in improving the visual function of patients with unilateral cataract with limited optical side effects such as halos or glare, providing spectacle-independent vision from far to intermediate object distances.

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the continuous addition range and avoid unpleasant photic phenomena.<sup>5</sup> On the other hand, near visual function deteriorates while keeping the distance and intermediate visual demands.<sup>5,6</sup> EDOF IOLs may use different optical designs to achieve their EDOF effect.

The LuxSmart EDOF IOL platform (Bausch & Lomb) is a one-piece hydrophobic acrylic lens with four-point fixation and a 360° square edge design offered in both ultraviolet and clear or violet light–filtering models (**Figure A**, available in the online version of this article). The biconvex, aspheric optic incorporates "Pure Refractive Optics"

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technology (called "PRO" technology) with an EDOF center, a patented transition zone, and a monofocal periphery. The central 2-mm part of the LuxSmart EDOF IOL contains a pure refractive optic that combines sixth-order and fourth-order spherical aberration (SA6 and SA4) of opposite signs to increase the subjective depth of focus<sup>7</sup> classified as group 5 in the category of new EDOF lens classification.<sup>8</sup> According to Benard et al,<sup>7</sup> the combination of SA6 and SA4 in various levels can increase the depth of focus (more than three times) for pupil sizes larger than 4.5 mm. The optic vergence smoothly decreases from the center to the periphery (transition zone) to control the trajectory of light rays to avoid light loss. This also helps to manage the amounts of SA6 and SA4 that are introduced in the EDOF center of the lens. The periphery of the LuxSmart IOL is just a monofocal aspheric surface to create a standard optical field in the periphery of the lens.

Few reports have investigated patient satisfaction with unilateral multifocal IOL implantation and, to the best of our knowledge, only one previous study has investigated it with unilateral EDOF IOLs. The cause of unilateral implantation of an EDOF IOL in the previous study was relative contraindications for implantation of this lens in the contralateral eye.<sup>9</sup> This study aimed to report visual and refractive outcomes, subjective patient satisfaction, and spectacle independence in patients with unilateral cataract undergoing LuxSmart EDOF IOL implantation.

#### PATIENTS AND METHODS

This prospective monocentric case series study was conducted from August 2021 to February 2022. Twenty-five eyes of 25 patients with presbyopia who visited the ophthalmology department of Quironsalud Hospital (Marbella, Spain) with confirmed unilateral cataract by slit-lamp exploration were willing to participate in the study. After informed consent, these patients preferred the suggested EDOF IOL over a monofocal IOL and were willing to be spectacle independent for intermediate activities (distances or vision). The study adhered to the tenets outlined in the Declaration of Helsinki and was approved by the local Ethics Committee of our center.

All patients presented with unilateral posterior subcapsular cataract. This was defined as either decreased corrected distance visual acuity (CDVA) worse than 20/32 (0.2 logMAR) or subjective visual complaints related to lens turbidity (eg, glare or decreased night vision). All included participants signed a consent form. Inclusion criteria were patients with unilateral visually significant cataract who underwent uneventful unilateral cataract surgery with the implantation of the LuxSmart EDOF IOL, were age 45 years or older, and had regular corneal astigmatism of 0.75 diopters (D) or less. Exclusion criteria were: pregnancy or breastfeeding, presence of other ocular diseases that may affect the stability of the lens capsule such as pseudoexfoliation syndrome, traumatic cataract, Marfan syndrome, uveitis, glaucoma, macular degeneration, presence of other ocular diseases that are expected to have a poor final visual acuity of worse than 20/30 after the cataract surgery such as amblyopia, pupil abnormality, a systemic or ocular medication that may affect the visual acuity, previous refractive surgery, previous intraocular or corneal surgery, patients with irregular astigmatism, and significant dry eye.

Preoperative examinations comprised subjective refraction and CDVA, intraocular pressure (Goldmann applanation tonometry), slit-lamp examination including diagnostic mydriasis, biometry (IOLMaster 700; Carl Zeiss Meditec AG), corneal tomography (Pentacam; Oculus Optikgeräte GmbH), and retinal spectraldomain optical coherence tomography (Cirrus 5000; Carl Zeiss Meditec AG). The IOLMaster 700 was used to calculate IOL power with the Barrett Universal II formula. Routine phacoemulsification through a temporal clear corneal incision was performed by a single surgeon (AN) in all cases.

Postoperative examinations used for the current study were performed at 1 day, 4 weeks, 3 months, and 6 months after surgery. All optometrical procedures were performed following the standard procedure of the European Vision Institute Clinical Research Network. They comprised subjective refraction with CDVA, uncorrected distance visual acuity (UDVA) at far (5 m), uncorrected intermediate visual acuity at 60 cm (UIVA), distance-corrected intermediate visual acuity (DCIVA), uncorrected near visual acuity (UCNVA) at 40 cm, and corrected distance near visual acuity (DCNVA), as well as slit-lamp examination, keratometry, and spectral-domain optical coherence tomography. For patient satisfaction, a quality of vision questionnaire was used. The Visual Function Index (VF-14) is a brief questionnaire designed to measure visual function in patients affected by cataract and after cataract surgery. It consists of 18 questions covering 14 aspects of visual function affected by cataracts. The VF-14 shows high internal consistency and is a reliable questionnaire (Figure B, available in the online version of this article). To evaluate the visual performance without spectacles, a modified VF-14 questionnaire was used including the same items of the VF-14 questionnaire and evaluating patient satisfaction without spectacles. Patient satisfaction with near, intermediate, and far tasks was measured on a scale from 0 (unsatisfactory) to 10 (very satisfactory) at postoperative 12 weeks without spectacles using the modified VF-14 questionnaire. Patients were

| Parameter   | Value           |
|---|-----------------|
| Age (years)   |                 |
| Mean ± SD   | 54.00 ± 10.00   |
| Range   | 44 to 64        |
| Sex (male:female)                                   | 15:5            |
| Preoperative visual acuity (logMAR),<br>mean ± SD   |                 |
| Distance (corrected)                                | $0.35 \pm 0.28$ |
| Distance (uncorrected)                              | $0.65 \pm 0.36$ |
| Intermediate  | $0.52 \pm 0.24$ |
| Near  | $0.52 \pm 0.24$ |
| Preoperative photopic pupil size (mm),<br>mean ± SD | 3.1 ± 0.5       |
| Preoperative spherical equivalent (D),<br>mean ± SD | -1.75 ± 3.24    |

asked about their spectacle dependence at near, far, and intermediate distances with 0%, 25%, 50%, 75%, and 100% of time.

Contrast sensitivity was tested with the Pelli-Robson test (a Pelli-Robson score of 2 indicates normal contrast sensitivity of 100%). Monocular defocus curves were tested, using best corrected distance correction and measuring visual acuity with 0.50 D defocus steps from +1.50 to -2.50 D. The depth of focus was defined as the range of lens powers with a mean visual acuity of -0.2 logMAR.

All data were recorded in electronic medical notes, and all data were collected by two independent ophthalmologists (AN, FO).

## STATISTICAL ANALYSIS

Statistical analysis was performed by the commercially available software Prism Version 9 (GraphPad). Correlation analysis of corneal parameters with visual acuity was performed with non-parametric Spearman correlation.

The Wilcoxon matched-pairs signed-rank test was used to compare two time points and repeated measures analysis of variance (rANOVA) was used to compare three or more time points. Data were presented as the mean  $\pm$  standard deviation (SD), and the differences were considered significant at a *P* value of less than.05.

## SURGICAL TECHNIQUE

All cataract surgeries were performed by a single surgeon (AN). After the conventional phacoemulsi-

fication through the temporal clear corneal incision, LuxSmart IOLs were implanted in the capsular bag. Postoperatively, topical moxifloxacin ophthalmic suspension (Vigamox; Alcon Laboratories, Inc) was administered four times a day for 4 weeks, topical tobramycin combination with dexamethasone 1 mg/mL and 3 mg/mL (Tobradex; Alcon Laboratories, Inc) eye drops were administered four times a day for 1 month, and topical bromfenac 0.9 mg/mL ophthalmic solution 0.09% (Yellox; Bausch & Lomb) was instilled twice a day for 2 months.

#### RESULTS

A total of 25 eyes from 25 patients were enrolled, and all patients completed a 24-week follow-up. The mean age was 54 years (range: 44 to 64 years). Demographic and preoperative data of patients are summarized in **Table 1**. None of the contralateral eyes presented with visually significant cataract, and the mean spherical equivalent of the opposite eyes was  $-0.25 \pm 2.00$  D.

Preoperative photopic pupil size (**Table 1**) was measured in all cases, and the photopic pupil size of less than 2.2 mm was considered a relative contraindication for the correct function of the IOL, considering the size of the central part of the IOL (Pro Technology) with higher order aberration induction (4th and 6th) of 2 mm and the peripheral monofocal part for distance vision.

#### **VISUAL OUTCOMES**

Six months after surgery, all eyes (100%) had UDVA of 20/25 or better, and 24 eyes (96%) had UDVA of 20/20 or better (**Figure 1A**). All 25 eyes (100%) gained two or more lines of CDVA after the surgery (**Figure 1B**). Mean CDVA was 20/16 (-0.1 logMAR) and mean DCIVA (at 60 cm) was 20/32 (0.2 logMAR). Mean DCNVA (at 40 cm) was 20/40 (0.38 logMAR). Defocus curve showed 0.2 logMAR or better range between -1.75 and +0.75 D. UDVA was improved at far (P < .0001, rANOVA), intermediate (P = .0002, rANOVA), and near (P = .0062, rANOVA) distances at 6 months after the surgery.

The mean preoperative spherical equivalent measured by manifest refraction was  $-1.75 \pm 3.24$  D, and the mean postoperative spherical equivalent was  $-0.25 \pm 0.50$  D at postoperative 24 weeks. Twenty-four eyes (96%) showed a spherical equivalent within  $\pm 0.50$  D at 24 weeks after the surgery (**Figures 1C-1D**). Only one case required a laser refractive enhancement of -0.75 D, which was done by photorefractive keratectomy. Double-angle plots are designed to compare preoperative corneal astigmatism with postoperative refractive astigmatism (**Figure 2**). Contrast sensitivity increased 100% at postoperative 12 weeks in 96% of patients (24 patients) with the Pelli-Robson test (a



**Figure 1.** (A) Uncorrected distance visual acuity (UDVA) 6 months after the surgery. (B) UDVA vs corrected distance visual acuity (CDVA) 6 months after the surgery. (C) Spherical equivalent (SE) refractive accuracy 6 months after the surgery. (D) Refractive cylinder 6 months after the surgery. D = diopters

Pelli-Robson score of 2 indicates normal contrast sensitivity of 100%) in all cases.

## PATIENT SATISFACTION

The VF-14 questionnaire was performed in all cases with 100% score satisfaction mainly for far and intermediate vision. No patient reported halos or starbursts in the standardized questionnaire. In the modified VF-14 questionnaire to determine dependence on spectacles in intermediate tasks (60 cm), none of our patients required spectacles. The mean spherical equivalent of the opposite eyes was  $-0.25 \pm 2.00$  D and the spectacle independence of the patients was not related to monovision due to myopia of the contralateral eye because we evaluated the eye that had surgery separately.

Patient satisfaction was measured using a subjective modified VF-14 questionnaire as  $9.00 \pm 1.00$  for far,  $8.00 \pm 1.00$  for intermediate, and  $6.00 \pm 2.00$  for near vision at postoperative 24 weeks without spectacles. Patient satisfaction scores were significantly higher at far (P = .0327, rANOVA) and intermediate (P = .0031) distance than at near vision. All patients did not need spectacles



Figure 2. Double-angle plots to compare preoperative cornea astigmatism with postoperative refractive astigmatism. D = diopters



**Figure 3.** Defocus curve 6 months after the surgery. CDVA = corrected distance visual acuity; D = diopters; EDOF - extended depth of focus

at far and intermediate distances at 24 weeks postoperatively. In near tasks (40 cm), 5 of the patients who had unilateral surgery required spectacles for less than 50% of the time, and 3 patients who had unilateral surgery required spectacles for more than 50% of the time.

#### **DEFOCUS CURVES**

The monocular defocus curves obtained 6 months after surgery at 20/32 Snellen (0.2 logMAR) had a depth of focus of 1.60 D. The EDOF IOL provides 0.77 D large pseudophakic pseudoaccommodation supporting intermediate vision (**Figure 2**). Intermediate visual acuity at -1.40 D (70 cm) and -1.51 D (66 cm) as derived from the defocus curve was 20/29 (0.16 logMAR) and 20/30 (0.18 logMAR) (**Figure 3**).

#### DISCUSSION

EDOF technology is used in a modern type of presbyopia-correcting lens with several optical designs to achieve partial spectacle independence over a wider range of object distances compared to monofocal lenses.<sup>2</sup> In this study, we evaluated a newly developed non-diffractive EDOF IOL in a clinical setting, reporting the first clinical study of this IOL, especially in unilateral implantation for patients with presbyopia and unilateral cataract.

In our study, 6 months after surgery, all eyes (100%) had UDVA of 20/25 or better, and 24 eyes (96%) had UDVA of 20/20 or better. We achieved better outcomes for UDVA compared to unilateral implantation of a diffractive design EDOF IOL in a previous study in which 70% of the cases obtained 20/20 or even better.<sup>8</sup>

At an intermediate range of object distances (tested at 60 cm), DCIVA of the LuxSmart IOL was superior to that of the monofocal lenses and achieved values of 20/25 Snellen (0.2 logMAR). DCNVA at 40 cm of 20/40 (0.38 logMAR) was also superior to the monofocal IOL performance, as confirmed in previous studies.<sup>11</sup> We also tried to evaluate our patient satisfaction using the VF-14 questionnaire and modified VF-14 questionnaire to differentiate patient satisfaction without spectacle correction. In our study, we found high percentages of spectacle independence in daily life, especially for intermediate activities, with this EDOF IOL in unilateral implantation, confirming previous results in bilateral implantation for this EDOF IOL.<sup>11</sup>

The LuxSmart EDOF IOL achieved high values for UDVA and CDVA, which were comparable to those of monofocal lenses. CDVA and UDVA values were also comparable to previously reported values for other EDOF lenses.<sup>5,6</sup> Thus, the LuxSmart EDOF IOL did not show lower performance compared to existing EDOF lenses regarding distance vision. These results are also comparable to a recently published report on 12 patients who received the LuxSmart EDOF IOL in both eyes.<sup>11</sup>

Our results are comparable to results reported for other EDOF lenses with non-diffractive optics in previous clinical studies.<sup>10,12</sup> Diffractive optics EDOF lenses seem to achieve slightly higher values of UIVA and DCIVA but are also more prone to higher rates of disturbing optical phenomena (glare, halos, and starburst).<sup>11</sup> Based on the results of a recent study reporting data on several diffractive EDOF and trifocal lenses and a novel non-diffractive EDOF IOL (Acrysof Vivity; Alcon Laboratories, Inc), this novel non-diffractive EDOF IOL achieved high values of UIVA and DCIVA comparable to diffractive EDOF IOLs.<sup>13</sup> Although this IOL did not cause severe photic phenomena, patients complained about halos and starbursts in up to 18% with mild symptoms and in approximately 9% with moderate symptoms.<sup>12</sup> In our study with the standard VF-14 questionnaire, none of the patients complained about halos or starbursts and the frequency of mild to moderate glare was comparable in EDOF and monofocal lenses compared to Campos et al's study<sup>11</sup> with the bilateral implantation of this EDOF IOL. In our study, we did not use a quality-of-life questionnaire. This is a limitation of our study and it should be used in further studies on this EDOF lens.

Corneal aberrations other than corneal astigmatism do not seem to have a strong influence on postoperative CDVA and DCIVA in our study. However, it would be interesting to correlate the amount of total (ocular) higher order aberrations related to the pupil size variance to overall patient satisfaction and the effect of neural response, especially for DCNVA, which in some cases were superior to the others.

Unilateral implantation of the LuxSmart EDOF IOL seems to be tolerated and effective in improving intermediate visual performance in patients with unilateral cataract, with limited optical side effects such as halos or glare, providing spectacle-independent vision from far to intermediate object distances. Further studies with larger numbers of participants should be performed to support our findings.

#### **AUTHOR CONTRIBUTIONS**

Study concept and design (AN, Jorge L. Alió del Barrio, NRK, Jorge L. Alió); data collection (AN, FD); analysis and interpretation of data (AN); writing the manuscript (AN); critical revision of the manuscript (Jorge L. Alió del Barrio, FD, NRK, Jorge L. Alió)

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**Figure A.** The LuxSmart intraocular lens (Bausch & Lomb) integrates pure refractive optic technology with an extended-depth-of-focus center, a patented transition zone, and a monofocal periphery.

# FIGURE B VISUAL FUNCTION INDEX (VF-14)

## Overview

The Visual Function Index (VF-14) is a brief questionnaire designed to measure functional impairment in patients due to cataract. It consists of 18 questions covering 14 aspects of visual function affected by cataracts. The VF-14 shows high internal consistency and is a reliable, valid instrument providing information not conveyed by visual acuity or general health status measures. The modified Visual Function Index (MVF-14) is a brief questionnaire designed to measure functional impairment in patients after cataract surgery without spectacles to evaluate the patient's satisfaction score in a subjective questionnaire with the simple scale of 0 (unsatisfactory) to 10 (very satisfactory).

# **General Functioning**

(1) Do you have any difficulty, even with spectacles, reading small print, such as labels on medicine bottles, a telephone book, food labels? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(2) Do you have any difficulty, even with spectacles, reading a newspaper or a book? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(3) Do you have any difficulty, even with spectacles, reading a large-print book or large-print newspaper or numbers on a telephone? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(4) Do you have any difficulty, even with spectacles, recognizing people when they are close to you? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(5) Do you have any difficulty, even with spectacles, seeing steps, stairs, or curbs? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(6) Do you have any difficulty, even with spectacles, reading traffic signs, street signs, or store signs? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(7) Do you have any difficulty, even with spectacles, doing fine handwork like sewing, knitting, crocheting, or carpentry? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(8) Do you have any difficulty, even with spectacles, writing checks or filling out forms? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(9) Do you have any difficulty, even with spectacles, playing games such as bingo, dominos, card games, or mahjong? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(10) Do you have any difficulty, even with spectacles, taking part in sports like bowling, handball, tennis, or golf? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(11) Do you have any difficulty, even with spectacles, cooking? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(12) Do you have any difficulty, even with spectacles, watching television? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

## Driving

(13) Do you currently drive a car? Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory). If Yes, go to question 14. If No, go to question 16.

(14) How much difficulty do you have driving during the day because of your vision? No difficulty (4 points), a little difficulty (3 points), a moderate amount of difficulty (2 points), a great deal of difficulty (1 point)

Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(15) How much difficulty do you have driving at night because of your vision? No difficulty (4 points), a little difficulty (3 points), a moderate amount of difficulty (2 points), a great deal of difficulty (1 point) Satisfaction for this activity without: 0 (unsatisfactory) to 10 (very satisfactory)

(16) Have you ever driven a car? If Yes, go to question 17. If No, stop. Satisfaction for this activity without spectacles: 0 (unsatisfactory) to 10 (very satisfactory).

(17) When did you stop driving? Less than 6 months ago 6 to 12 months ago, more than 12 months ago

(18) Why did you stop driving? Vision, other illness, other reason

## SCORING

An item is not included in scoring if the person does not do the activity for some reason other than their vision. Scores on all activities that the person performed or did not perform because of vision were then averaged, yielding a value from 0 to 4. This value was multiplied by 25, giving a final score from 0 to 100. A score of 100 indicates able to do all applicable activities and a score of 0 indicates unable to do all applicable activities and a score of 0 indicates unable to do all applicable activities because of vision.

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