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ORIGINAL RESEARCH

Clinical Outcomes and Patient Satisfaction of an Enhanced Depth of Focus Intraocular Lens Targeted for Mini-Monovision

Nuno Campos[1,2]

[1]Hospital Garcia de Orta, Almada, Portugal; [2]Hospital CUF TEJO, Lisboa, Portugal

Correspondence: Nuno Campos, Ophthalmology Department, Hospital Garcia de Orta, Almada, Portugal, Email nunocampos.dr@gmail.com

Purpose: To assess the clinical outcomes, the rate of spectacle independence, and patient satisfaction of an enhanced depth of focus (EDOF) LuxSmart™ IOL targeted for mini-monovision in patients who had undergone bilateral cataract surgery.

Methods: Twenty patients underwent bilateral LuxSmart IOL implantation with the non-dominant eye targeted for −0.50 diopters. Best-corrected distance (CDVA) and uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA) at 66 cm, uncorrected near visual acuity (UNVA) at 40 cm, and defocus curve were assessed. Patient-reported visual function was inquired by Catquest-9SF, and the rate of spectacle independence in all daily-life activities was calculated. The presence of photic phenomena was evaluated. A *p*-value lower than 0.05 was considered statistically significant.

Results: The mean IOL power was +21.50 ± 4D (16.5–26D), and all were non-toric. Thirty-seven (92.5%) eyes were within ±0.5D of predicted target. The postoperative MRSE was 0.06 ± 0.42D and −0.45 ± 0.22D in dominant and non-dominant eyes. Every patient achieved distance binocular vision better than 0.1 logMAR. The non-dominant eyes showed lower CDVA ($p<0.001$). The UIVA was higher in non-dominant eyes ($p<0.001$). Binocular uncorrected near visual acuity was 0.12 ± 0.1, and uncorrected near visual acuity was higher in non-dominant eyes ($p<0.001$). LuxSmart IOL provided a sustained visual acuity of 0.3 logMAR or better between +1.00D and −2.50D. A total of 25% of patients reported frequent halos and glare. Despite achieving higher degrees of satisfaction, seven patients (35%) denied total spectacle independence in their daily-life activities, particularly for activities requiring continuous near vision.

Conclusion: This study shows that LuxSmart EDOF IOL in mini-monovision strategy performs well for distance and intermediate vision. Although visual acuity for near also achieved very good results, the considerable rate of spectacle dependence, in particular for near, and the rate of photic phenomena do not support this IOL to be safely implanted in patients desiring spectacle independence at time of cataract surgery.

Keywords: cataract, presbyopia, IOL, EDOF, LuxSmart, mini-monovision

Introduction

In recent years, cataract surgery has undergone several innovations, and its original purpose of restoring visual acuity rapidly changed to fit into the area of refractive surgery in which presbyopia became surgically managed.[1] The technological world we live in demands good intermediate and near vision (functional vision), and patients usually require spectacle independence for their daily-life activities.

The rate of implanted intraocular lens (IOL) to provide spectacle independence is continuously increasing and nowadays represents more than 10% of cataract surgeries worldwide (ESCRS 2022 Clinical Survey). There is a wide range of options to successfully meet these patients' needs, but some are not devoid of side effects which could be extremely incapacitating. Multifocal IOLs usually provide high rates of spectacle independence but could be associated with visually significant photic phenomena if patient selection is not appropriate.[2] Monovision with monofocal IOLs, meaning that the dominant eye is targeted for emmetropia and the non-dominant is targeted for a residual myopic error (−2.50D), has been used to overcome the photic phenomena of multifocal IOLs. Later, mini-monovision with

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monofocal IOLs (non-dominant eye targeted for −0.75D to −1.25D) was used and achieved similar results, reducing even more the rate of dysphotopsias, being harmless for stereopsis compared to traditional monovision.[3]

Extended depth of focus (EDOF) IOLs are a newer-generation IOLs which were conceived to improve the intermediate performance of monofocal IOLs while targeted to emmetropia. These types of IOL are a result of anatomical variations in their optics to widen the depth of focus. Our group previously showed that LuxSmart™ IOL performed better than a monofocal IOL for intermediate vision without impairing distance visual acuity and without increasing the rate of photic phenomena.[4] Although these IOLs were not designed to provide full spectacle independence, some groups tested EDOF IOLs in monovision and mini-monovision strategies to optimize uncorrected near vision, but none with LuxSmart™ IOL.[5,6]

This study aims to assess the clinical outcomes, the rate of spectacle independence, and patient satisfaction of LuxSmart™ IOL targeted for mini-monovision in patients who had undergone bilateral cataract surgery.

Methods

This was a prospective and non-randomized single-center study that included patients aged between 55 and 70 years who had undergone bilateral cataract surgery aiming at spectacle independence. The surgeries were performed in 2023 in the Ophthalmology Department of Hospital CUF Tejo (Lisboa, Portugal) and Hospital Garcia de Orta (Almada, Portugal). LuxSmart IOL (Bausch & Lomb GmbH, Berlin, Germany) was implanted. Inclusion criteria were clinical indication for cataract surgery, corneal regular astigmatism no more than 0.75 diopters (D), photopic pupil diameter greater than 2 mm, and axial length between 22.5 and 24.99 mm. Exclusion criteria included previous ophthalmological surgery, cornea, retina, or optic nerve diseases. The study was conducted by the principles of the Declaration of Helsinki; all patients were informed of the purpose of this study and gave consent. Approval was obtained by Ethical Committee of Hospital Garcia de Orta.

Preoperative evaluation included biomicroscopy, *Goldmann* applanation tonometry and fundoscopy after mydriasis. Biometry was performed using ACE™ (Bausch & Lomb GmbH, Berlin, Germany), and IOL power was calculated using the Barrett Universal II with the dominant eye targeted for emmetropia and the non-dominant eye for a slight myopia (−0.50D). Cataract surgeries were performed by a single surgeon via a 2.4 mm clear corneal incision. For astigmatism management, this incision was performed in the steepest meridian in eyes having a corneal astigmatism greater than 0.50D. A 5.5 mm capsulorhexis was performed, the cataract was removed using phacoemulsification technique, and the IOL was implanted in the capsular bag. Patients were medicated with a tapered dose of topical steroids and with topical non-steroid anti-inflammatory for one month and topical antibiotic for two weeks.

Patients were evaluated at postoperative day one, month one, and three months after the second eye surgery, and all observations were performed by the same physician. The eye dominance was tested by Mile's test. The primary outcomes measured were monocular and binocular distance (at 6 m), intermediate (at 66 cm), and near (at 40 cm) visual acuity (presented in logMAR). The residual spherical equivalent (and the difference between the two eyes), monocular and binocular corrected and uncorrected distance (CDVA and UDVA), intermediate (CIVA and UIVA), and near visual (CNVA and UNVA) acuities were tested. Binocular defocus curve was also assessed from −3.50D to +1.50D in 0.5D increments under photopic lighting conditions in two different conditions: with non-dominant eye corrected for emmetropia, and with dominant eye non-corrected.

Catquest-9SF questionnaire was given to the patients to evaluate patient-reported unaided visual function as related to day-to-day tasks. The presence of photic phenomena (halo, glare, and starburst) was also assessed by showing standard photographs to the patients. Emphasis on nocturnal driving was given.

The rate of full spectacle independence was calculated.

Statistical analysis was made by SPSS™ software version 23.0. Qualitative variables are presented as number and percentage. Data were confirmed to be normally distributed by Shapiro–Wilk test. Two-tailed Student's *T*-tests were applied to compare means by groups. The percentages of each answer on the Catquest-9SF questionnaire were calculated and compared between groups. Statistical significance was defined as <0.05.

Results

This study comprised a total of 40 eyes of 20 patients (50% males and 50% females). The mean age was 65 ± 8.7 years (range 61–78). The dominant eye was the right one in 16 patients (80%). The mean axial length was 22.7 ± 0.7 mm, K1 was 42.5 ± 1.4D, and K2 was 44.1 ± 1.5D. The mean preoperative spherical equivalent was +1.66 ± 4.25D (−3.25 – +4.50). The mean IOL power was +21.50 ± 4D (16.5–26D), and all were non-toric.

The clinical outcomes at 3 months after surgery and comparisons between dominant and non-dominant eyes are presented in Table 1. A total of 92.5% of eyes were within 0.5D of predicted target, and most that were not were non-dominant. The MRSE was 0.06 ± 0.42D and −0.45 ± 0.22D in dominant and non-dominant eyes, respectively, and the mean difference between both was 0.73 ± 0.53D. The mean postoperative cylinder was 0.48 ± 0.31D, with no statistically significant differences between eyes.

Every patient achieved both corrected (0.01 ± 0.12 logMAR) and uncorrected (0.09 ± 0.25 logMAR) distance binocular vision better than 0.1 logMAR. However, the non-dominant eyes showed lower CDVA (0.08 ± 0.04 vs 0.16 ± 0.15, $p<0.001$). The UDVA was 0.10 ± 0.25 and 0.32 ± 0.42 in dominant and non-dominant eyes, respectively.

Binocular uncorrected intermediate visual acuity was 0.18 ± 0.16 logMAR. The UIVA was higher in non-dominant eyes (0.10 ± 0.11 vs 0.03 ± 0.22, $p<0.001$), and CIVA did not differ (−0.05 ± 0.03 vs −0.06 ± 0.01, $p=0.66$).

Binocular uncorrected near visual acuity was 0.32 ± 0.1. Uncorrected near visual acuity was higher in non-dominant eyes (0.32 ± 0.28 vs 0.18 ± 0.12, $p<0.001$). Binocular CNVA was 0.11 ± 0.08 and did not differ according to dominance.

Regarding the defocus curve, LuxSmart provided a sustained visual acuity of 0.3 logMAR or better between +1.00D and −2.50D (Figure 1).

The prevalence of photic phenomena is presented in Table 2. Five patients (25%) reported frequent halos and glare but none incapacitating. Starburst was not reported.

The results of the Catquest-9SF questionnaire are presented in Table 3. The great majority of patients were satisfied regarding their uncorrected distance and intermediate vision, but some complained about uncorrected near vision. Despite achieving higher degrees of satisfaction, seven patients (35%) denied total spectacle independence in their daily-life activities. The patients reported more difficulties in activities which require continuous near vision, such as reading books and doing needlework.

Table 1 The Clinical Outcomes at 3 Months After Surgery

		Dominant	Non-Dominant	P-value
Binocular (logMAR)	CDVA	0.01 ± 0.12		–
	UDVA	0.09 ± 0.25		–
	CIVA	0.03 ± 0.09		
	UIVA	0.18 ± 0.16		–
	CNVA	0.11 ± 0.08		
	UNVA	0.32 ± 0.1		–
Monocular (logMAR)	CDVA	0.08 ± 0.04	0.16 ± 0.15	**<0.001**
	UDVA	0.10 ± 0.25	0.32 ± 0.42	**<0.001**
	CIVA	−0.05 ± 0.03	0.06 ± 0.01	0.66
	UIVA	0.10 ± 0.11	0.03 ± 0.22	**<0.001**
	CNVA	0.11 ± 0.06	0.10 ± 0.09	0.89
	UNVA	0.32 ± 0.28	0.18 ± 0.12	**<0.001**
Spherical equivalent, (D)		0.06 ± 0.42	−0.85 ± 0.32	**<0.001**

Note: Statistical significant values are highlighted in bold.
Abbreviation: logMAR, logarithm of minimum angle of resolution.

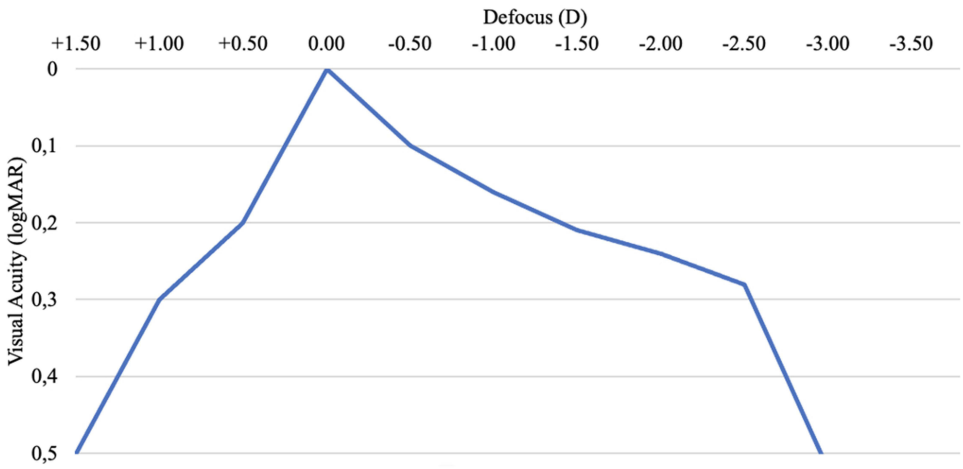

Figure 1 Monocular distance-corrected defocus curve 3 months after binocular implantation of IOL.
Abbreviation: logMAR, logarithm of minimum angle of resolution.

Discussion

This study shows that LuxSmart EDOF IOL performs well for distance and intermediate vision in mini-monovision strategy. However, near vision performance results in a considerable rate of spectacle dependence after cataract surgery.

The concerns regarding presbyopia correction at the time of cataract surgery led to the development of a wide range of options with similar refractive results.[7] However, little differences could transform a happy patient into a very dissatisfied one, and it is important to correctly arrange those options in order to offer the safest and most efficient results. Multifocal IOLs provide a high rate of spectacle independence, but the rates of photic phenomena and loss of contrast do not make them universally "fitable" and require a strict patient selection.[8,9] From this, our group previously evaluated the performance of an EDOF IOL, LuxSmart, targeting bilateral emmetropia, compared with a conventional monofocal IOL.[4] We found that LuxSmart provides very good uncorrected distance and intermediate vision, but, despite being better than monofocal IOLs, the rate of spectacle dependence was high (>50%) due to unsatisfactory near vision.[4]

Based on previous results, we decided to evaluate the performance of LuxSmart in a mini-monovision strategy for the first time, aiming for emmetropia for the dominant eye and slight myopia (−0.50D) for the non-dominant one.[5,6] The main goal of this paper was to compare the visual performance of LuxSmart in mini-monovision (MM group) with bilateral emmetropia (BE group) from our previous paper, so the comparisons between dominant and non-dominant eyes were not emphasized.[4] Every patient in MM achieved binocular UDVA, as did those in BE. Despite UDVA being lower in non-dominant eye as expected, the BCVA was also lower in these eyes, leading us to postulate that this IOL is not suitable in patients with residual refractive errors, but further studies are needed to corroborate this theory. Patients with prior refractive surgery are more prone to residual refractive errors due to IOL calculation issues and, in contrast, could benefit from this elongated depth of focus. Binocular UIVA was also similar between MM and BE groups. However, the

Table 2 The Incidence of Photic Phenomena

	Halos	Glare	Starburst
Never	11	11	17
Rarely	3	4	3
Sometimes	3	2	0
Often	2	2	0
Always	1	1	0

Table 3 Results of Catquest-9SF (Uncorrected Vision)

		n = 20
Reading newspaper print	Yes, very great difficulty	2
	Yes, great difficulty	3
	Yes, some difficulty	3
	No, no difficulty	12
	Cannot decide	0
Recognizing the faces of people	Yes, very great difficulty	0
	Yes, great difficulty	0
	Yes, some difficulty	0
	No, no difficulty	20
	Cannot decide	0
Reading the prices of goods while shopping	Yes, very great difficulty	0
	Yes, great difficulty	4
	Yes, some difficulty	6
	No, no difficulty	10
	Cannot decide	0
Seeing to walk on uneven ground	Yes, very great difficulty	0
	Yes, great difficulty	0
	Yes, some difficulty	0
	No, no difficulty	20
	Cannot decide	0
Reading television text	Yes, very great difficulty	0
	Yes, great difficulty	0
	Yes, some difficulty	2
	No, no difficulty	18
	Cannot decide	0
Seeing to use the computer	Yes, very great difficulty	0
	Yes, great difficulty	1
	Yes, some difficulty	5
	No, no difficulty	14
	Cannot decide	0

(*Continued*)

Table 3 (Continued).

		n = 20
Difficulties in performing everyday tasks	Yes, very great difficulty	0
	Yes, great difficulty	0
	Yes, some difficulty	4
	No, no difficulty	16
	Cannot decide	0
Satisfied or dissatisfied with your present vision	Very satisfied	16
	Rather satisfied	2
	Rather dissatisfied	2
	Very dissatisfied	0

UNVA was higher in the MM group, which translated into higher range of focus in defocus curve. These results seem to show us that mini-monovision strategy with this IOL could be the one of choice in case of patients that are not good candidates for trifocal IOLs.

The prevalence of photic phenomena was slightly higher in MM than BE group (45% vs 33%). However, none described those phenomena as incapacitating, and no IOL needed to be explanted. These results highlight the safety of EDOF IOLs over multifocal which could have higher rates of disabling photic phenomena and could require IOL exchange.[10] Moreover, we believe the rate of photic phenomena would be lower if patients were evaluated later because neuroadaptation could last 6 months.[11]

The rate of spectacle independence for every daily-life activity was 65% in MM, although better than those in BE group (50%). However, we were expecting a higher percentage of independence in MM group. We postulate that the lower age of this population (65 vs 69 years) could mean more demanding patients, which makes spectacle independence more difficult to achieve. Despite patients in MM group reporting less difficulties for near vision, the rate of patient satisfaction was similar to that of BE group.

Our results are in line with those of different EDOF IOLs, such as Isopure® (BVI) and AcrySof IQ Vivity (Alcon), in terms of visual acuity, spectacle independence, and patient satisfaction.[5,12] However, our paper seems to report higher rates of photic phenomena; this could be explained by methodological differences in evaluation of these phenomena which can induce positive responses. Despite this and keeping in mind that mini-monovision increases the risk of dysphotopsia, the rate of disabling phenomena was virtually negligible for these three IOLs.

Despite our small sample and short follow-up period, these results, compared with those of LuxSmart in emmetropia, show that mini-monovision strategy improves near vision performance of LuxSmart without compromising distance and intermediate visual acuity. However, the data may not support LuxSmart to be implanted in patients desiring total spectacle independence at time of cataract surgery in a mini-monovision strategy as the rate of spectacle independence was 65%. Possibly targeting the non-dominant eye for −0.75D could enhance near vision performance but could also be associated with more photic phenomena and loss of contrast and stereopsis. As such, in our opinion, this IOL should be recommended for patients who prioritize intermediate working vision and do not mind using reading glasses and for those who are not good candidates for multifocal IOLs.

Conclusion

These results shows that implanting LuxSmart in mini-monovision (non-dominant eye targeted for −0.50D) improves near vision performance with a neglectable increase in the risk of photic phenomena. However, this paper may not support LuxSmart implantation with this strategy in patients desiring total spectacle independence at time of cataract

surgery in a mini-monovision strategy. This IOL should be recommended for patients who prioritize intermediate working vision and do not mind using reading glasses for longer near vision demanding activities and for those who are not good candidates for multifocal IOLs.

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Disclosure

The author has no conflicts of interest to declare in this work.

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