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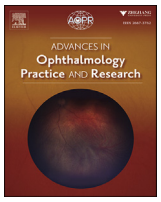

Full Length Article

Patient reported outcomes after implementation of an enhanced depth of focus intraocular lens with low postoperative myopia

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ABSTRACT

Background: Enhanced depth-of- focus intraocular lenses (EDOF IOL) have filled the gap between monofocal and multifocal intraocular implants with optical qualities of monofocal lenses and usually minor dysphotopsias typical for multifocal lenses. The purpose of this study was to evaluate visual outcomes after bilateral implantation of a new EDOF IOL in patients with requirements for perfect near and intermediate vision.
Methods: The study included 15 patients (29 eyes as one was amblyopic) with bilateral implantation of LUX-SMART EDOF IOL (Bausch & Lomb) with a targeted myopia (between –0.25 and –0.50D) in both eyes. Monocular corrected and uncorrected visual acuity for far, intermediate and near as well as refractive outcomes were evaluated at 1, 3, 6 and 12 months after the surgery. Additionally, binocular visual acuity, contrast sensitivity and defocus curve were measured at the final follow-up visit. At 12 months' visit patients completed a questionnaire evaluating patient satisfaction, spectacle independence and presence of dysphotopsias.
Results: Binocular uncorrected visual acuities at 12 month's visit were 0.13 ± 0.16, 0.06 ± 0.08, 0.07 ± 0.09 and 0.15 ± 0.09 logMAR for far distance, 80 cm, 66 cm and 40 cm respectively. Corrected binocular visual acuities at 12 months were 0.00 ± 0.00, 0.05 ± 0.07, 0.05 ± 0.06, 0.13 ± 0.16 respectively for distance, 80 cm, 66 cm and 40 cm. Automated refraction spherical equivalent at 12 months' visit stood at –0.70 ± 0.48D, which was 0.46D less than calculated biometric target, however spherical equivalent of subjective refraction at 12 months equaled –0.49 ± 0.46D, which was closer to preoperative biometric target. Defocus curve had gentle shape without peaks typical for monofocal IOLs. Binocular contrast sensitivity results were superior to average results for that age group and equaled 1.78 ± 0.16 logMAR without correction and 1.81 ± 0.13 logMAR with correction. Spectacle independence for near and intermediate distances was achieved in all patients and for far distance in 73.3% of patients. Burdensome dysphotopsias were not reported in any case.
Conclusions: EDOF IOLs targeted bilaterally at low myopia can provide excellent near and intermediate visual acuity and independence of any optical correction in majority of cases. This approach can be used in selected patients who are focused on stationary activities.

1. Background

Cataract surgery, since the onset of phacoemulsification technique, provides excellent results with just minor percentage of cases suffering from intraoperative or postoperative complications.[1,2] Introduction of multifocal intraocular lenses (MIOL), considered a premium product, has set up patients' expectations very high, especially regarding the spectacle independence and quality of vision. Despite providing relatively good uncorrected visual acuities at all distances, MIOLs also produce some optical phenomena, called dysphotopsias, that affect quality of vision and

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by the patients are perceived as disadvantages. These are typically "halos" or "glare" around the light points and decreased contrast sensitivity, especially at night. Burdensome optical patterns are the result of physical construction of MIOLs[3–6] and although they can be tolerated by most of the patients after a few months of neuroadaptation, actually they do not disappear.[7–9]

Enhanced depth of focus (EDOF) IOLs are a relatively new concept of premium intraocular lenses that could be placed between the mutifocal and monofocal IOLs. The difference between multifocal and EDOF IOL is that EDOF provide one elongated focus instead of two or three, which is the principle of design of MIOL.[9–12] The elongation of the focus provides possibilities for achieving a range of good uncorrected visual acuity in contrary to monofocal IOLs, in which there is only one principle uncorrected visual acuity target, usually set at far distance.[13] Typically, EDOF lenses are also calculated to correct vision for far distance, but with significant enhancement of visual performance at intermediate distances and usually some optical correction needed for near vision. The elongation of a single focus instead of creating a few focal points, as it is designed in MIOLs, prevents the overlap of the coexisting secondary out-of-focus images deriving from all the optical focuses.[14] Due to that design, EDOF IOLs produce less dysphotopsia (especially in case of refractive EDOF IOLs) and are generally well tolerated by the patients.[15,16] This, however, is for the sake of compromise with some optical correction for reading. The main goal of the study was to test the approach of targeting bilateral postoperative low myopia with a new type of EDOF IOL of purely refractive design in patients who are focused on stationary activities, such as reading and working with computer, and are willing to sacrifice some distant acuity for the sake of perfect near and intermediate vision. The outcome was evaluated by checking postoperative automated refraction spherical equivalent (ARSE), subjective refraction spherical equivalent (SRSE) equivalent to accepted optical correction at distance, postoperative visual acuity, contrast sensitivity, spectacle independence and frequency of dysphotopsias.

2. Materials and methods

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the local bioethical board (Komisja Bioetyczna at OIL in Gdańsk, approval no. KB-38/21, 2021). Informed consent was obtained from all the subjects involved in the study.

The retrospective study included a group of patients that had immediate sequential bilateral cataract surgery performed by one surgeon (MG) with the use of recently introduced LUXSMART EDOF intraocular lenses between January and March of 2021. The IOLs were provided by the manufacturer and offered to the patients without charge.

The study group consisted of consecutive patients who accepted the postoperative minor myopia concept with new EDOF IOL and consent to immediate sequential bilateral cataract surgery. Originally the group included 21 participants however finally 15 individuals completed the full study protocol and were included in the analysis. One eye was excluded from the analysis due to amblyopia detected after the surgery, thus the analyzed cohort included 29 eyes. All of the participants were interviewed according to their lifestyle and declared predominantly indoor activities such as reading and using computer and required good near and intermediate visual acuities. Most of the patients were not drivers or drove very seldom. They also accepted the possibility of small postoperative optical correction for distance for the sake of enhancement of near and intermediate vision. Only eyes without ocular disorders that could influence the visual outcome were included in the study. Exclusion criteria involved the following local conditions: macular degeneration, macular edema of any origin, vascular retinal disorders, disorders of vitreoretinal interface, glaucoma with visual field defects, corneal opacities, large astigmatism of >3D and amblyopia in medical history.

The following visual performance parameters were the subject of the analysis: corrected visual acuity (CVA) and uncorrected visual acuity (UVA) after the surgery for far distance (6 m), intermediate distances: 80 cm and 66 cm and near: 40 cm. Manifest refraction and optical correction after the surgery as well as percentage of patients independent of the use of spectacles were also evaluated. Testing was performed separately for the left and right eye at baseline and at 1, 3, 6 and 12 months postoperatively. Additionally, binocular visual acuities, defocus curve and contrast sensitivity were recorded at the final visit at the 12 month postoperatively. Defocus curve was measured with best accepted correction at 6 m. Spheric lenses from -4D to +2D in 1D increments were afterwards added to the best correction in both eyes and binocular visual acuity at 6 m recorded for each spherical value. Binocular contrast sensitivity was tested on standard Pelli-Robson chart at 1 m. Results were recorded separately for the best accepted correction and without correction. LogMAR values were used to report results of visual acuity and contrast sensitivity testing. All the measurements were performed by the optometrist, unaware of the type of the implanted IOL.

For the purpose of this study the following terminology was used: ARSE – automated refraction spherical equivalent, SRSE – subjective refraction spherical equivalent corresponding to spherical equivalent of accepted optical correction, CVA – corrected visual acuity, UVA-uncorrected visual acuity, UDVA – uncorrected distance visual acuity, CDVA – corrected distance visual acuity, UIVA – uncorrected intermediate visual acuity, CIVA – corrected intermediate visual acuity, UNVA – uncorrected near visual acuity, CNVA – corrected near visual acuity.

Manifest refraction was measured with the use of automated refractometer (Huvitz HRK-1, China 2020). Three measurements were performed and mean values were included in the analysis. The results were calculated to a spherical equivalent (ARSE). Subjective refraction at distance and defocus curve were manually determined by experienced optometrist. Results were also calculated to spherical equivalent (SRSE).

Additionally, all of the patients underwent a standard ophthalmological examination before the surgery and at each of the follow-up visit. That included assessment of anterior segment and fundus after dilation of the pupil and intraocular pressure measurement.

Biometry was performed using the IOL Master 700 Optical Biometry (Carl Zeiss 2019). IOL power was calculated from the Barrett Universal II Formula available online at. https://calc.apacrs.org. The calculation was performed for spherical IOL, as the used new EDOF IOL is available only in spherical powers (toric version of that IOL is not yet available). The patients targeted postoperative refraction was low myopia (between –0.25 and –0.50D) to enable spectacle independence for intermediate and near visual task.

Baseline characteristics of the study group is provided in Table 1.

2.1. Surgical technique

The surgical technique applied in all cases was lens phacoemulsification with the use of Stellaris machine (Bausch & Lomb) and clear corneal incision of 2.2mm. There were no intraoperative or postoperative complications noted in any case.

Table 1
Baseline characteristics of the study group (15 patients, 29 eyes).

Analyzed trait	M	SD	Min	Max
Age (years)	63.83	6.51	43.00	76.00
CDVA (logMAR)	0.64	0.39	0.10	1.40
ARSE (diopters)	–0.83	3.34	–9.00	5.75
SRSE (diopters)	–0.12	3.39	–7.00	8.00
Astigmatism (absolute value in cylinder diopters)	1.14	0.74	0.00	3.00
Biometric target (diopters)	–0.24	0.12	–0.51	0.10
IOL power (diopters)	22.41	3.47	16.50	31.00

CDVA – corrected distance visual acuity; SRSE – subjective refraction spherical equivalent; ARSE – automated refraction spherical equivalent; IOL – intraocular lens; M – mean value; Min – minimal value; Max – maximal value; SD – standard deviation.

2.2. EDOF IOL characteristics

LUXSMART EDOF IOL (Bausch & Lomb) is a pure EDOF IOL, which means that its design involves only the spherical aberration as a principle for enhancing the depth of focus.[12] The IOL is designed with 2 mm EDOF center, which employs combination of 4^{th} and 6^{th} orders of spherical aberration of opposite signs. Outside the EDOF center is placed relatively narrow patented transition zone to smoothly decrease the optic vergence. The transition is designed to control the trajectory of light rays to ensure no light is outside the range of vision. The remaining peripheral part is designed as aspheric monofocal (Fig. 1.).

The IOL is made of hydrophobic material and comes in preloaded form to be injected trough 2.2mm incision.

2.3. Patients' satisfaction questionnaire

All 21 patients completed an internally developed questionnaire at 12 months after surgery, however for the purpose of the consistency of the study, answers from 15 patients who completed the full study protocol were included in the analysis. The questionnaire included patient's satisfaction after the surgery, the ratio of active time with independence of glasses and perception of burdensome dysphotopsias or any inconveniences of that type after the surgery-halos, glare, light splitting, scotomas, loss of contrast, problems with night vision, especially night driving.

The questions asked and results of the survey are provided as Table 4 in the results section.

2.4. Statistical analysis

Numerical traits were described by using their mean, median, standard deviation, lower-to-upper quartile, and minimum-to-maximum values. The normality of distribution was assessed using the Shapiro–Wilk W test. A Friedman ANOVA was performed in order to test the significance of changes in the measurable variables throughout the 12-month period of observation. Multiple comparisons were performed with Bonferroni correction. The Pearson product-moment correlation r coefficient was computed when assessing relationships between selected numerical traits. A level of $P < 0.05$ was considered statistically significant. All the computational procedures were performed by using Statistica™, wersja 14 (TIBCO Software Inc., Palo Alto, CA, USA)

The minimal necessary sample size was calculated with parametric ANOVA test for repeated measurements, significance at $P < 0.05$, statistical power of a study at least 80%; this equaled >20 eyes.

3. Results

29 eyes of 15 patients were analyzed in the study, including 8 females and 7 males with the mean age of 63.83 ± 6.51 years. One eye was excluded from the study due to significant amblyopia detected after the surgery. All the patients consent to binocular cataract surgery, which was a preferred and recommended form of cataract treatment during COVID–19 pandemics in Poland. Patients were followed for twelve months after the surgery. The analysis included results of baseline examination and at follow-up visits at 1, 3, 6 and 12 months.

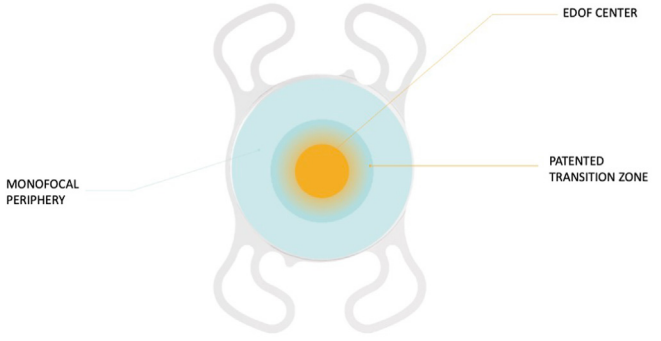

Fig. 1. Design of LUXSMART EDOF IOL. EDOF center consists of combination of spherical aberrations of opposite signs. Patented transition zone provides smooth transition of light. Monocular periphery has aspheric surface.

In each case at any point of the follow up, LUXSMART IOL remained well-centered in the lens bag. Significant posterior capsule opacifications were not observed during the follow-up period.

All the monocular postoperative results for AR, optical correction and corrected and uncorrected visual acuities for far, intermediate and near distances are provided in Table 2.

The outliers at BCVA examination were eyes that presented with pre- and postoperative astigmatism of more than 2.0 cyl. D.

Comparison of the CDVA before the surgery with both CDVA and UDVA at each of the four follow-up time-points proved statistically significant improvement ($P < 0.0001$) (Figs. 2 and 3). Variations of the corrected and uncorrected postoperative visual acuities at all distances are significant with $P < 0.001$. Pairwise comparisons show that significant visual acuity improvement is noted for all measurements between the first and third month post-surgery ($P < 0.05$) with stable results noted afterwards. Differences in visual acuities scores noted between month 3, 6 and 12 are less than 0.1 logMAR in every case.

Postoperative ARSE was stable without substantial difference between the values at month 1, 3, 6 and 12 ($P = 0.6113$ in ANOVA Friedmann test). Nevertheless, mean biometric target before surgery (–0.24D) was significantly different from final ARSE at six months (–0.70D) with $P = 0.0001$. The mean value of SRSE after the surgery was stable with the value of –0.49D at the final follow-up visit. It was also significantly different from the biometric target of –0.24D ($P = 0.0076$). Mean postoperative astigmatism was stable with the final value of –0.92 ± 0.57 cylinder D ($P = 0.5320$ in ANOVA test).

Results of binocular visual acuity and contrast sensitivity testing at the 12 month's visit are presented in Table 3.

Results of the measurements of defocus curve are presented at Fig. 4 The curve has a gentle shape without peaks and shows mean best corrected visual acuities better than 0.1 log MAR for defocus between 0 and 2 diopters (see Fig. 4).

3.1. Patients' satisfaction questionnaire

For the purpose of the study we decided to develop a simple questionnaire that comprised of a few questions that evaluated performance of the implanted IOL in everyday life: visual acuity at different distances, the ratio of active time with independence of glasses and perception of burdensome dysphotopsias. Results of questionnaire filled by all 15 patients 12 months after the surgery are presented in Table 4. None of the patients needed additional optical correction for near and intermediate distances and only 4 out of 15 patients (26.7%) occasionally used spectacles for distance. These situations included mainly watching television and sometimes outdoor activities, like shopping. The perception of burdensome dysphotopsias was not noted in any case.

4. Discussion

Majority of patients in our study achieved satisfactory postoperative uncorrected visual acuities with independence of spectacle correction for near and intermediate distances. As long as the numbers are considered, the uncorrected visual acuities at intermediate distances were close to perfect. Uncorrected near acuities were also sufficient to perform reading without optical correction.

Just 26.7% of patients required optical aid for distance, however according to our survey it was used for less than 50% of active time. In majority of cases postoperative UDVA was sufficient to perform routine everyday activities. Mean binocular UDVA was 0.13 ± 0.16

Table 2
Postoperative outcome at 1, 3 and 6 months. CVA and UVA values are provided in logMAR units and correction and refraction values in diopters.

Timepoint/ Parameter	1 month				3 months				6 months				12 months				*P*-value
	M	SD	Min.	Max	M	SD	Min.	Max	M	SD	Min.	Max	M	SD	Min.	Max	
ARSE	–0.73	0.57	–2.13	0.37	0.72	0.43	–1.75	0.38	-0.77	0.45	–1.75	0.25	–0.70	0.48	–1.75	0.25	0.6113
Astigmatism (D cyl. absolute value)	1.08	0.51	0.0	3.0	0.90	0.53	0.00	2.25	0.90	0.51	0.25	2.50	0.92	0.57	0.0	2.50	0.5320
UDVA	0.35	0.18	0.00	0.90	0.23	0.18	0.00	0.90	0.23	0.18	0.00	0.90	0.24	0.18	0.00	0.90	<0.00001
UIVA (80 cm)	0.18	0.16	–0.10	0.50	0.10	0.16	0.00	0.60	0.09	0.13	0.00	0.40	0.09	0.11	0.00	0.40	0.0002
UIVA (66 cm)	0.19	0.17	–0.10	0.50	0.10	0.16	0.00	0.50	0.10	0.14	0.00	0.40	0.10	0.11	0.00	0.30	0.0008
UNVA (40 cm)	0.20	0.17	–0.10	0.40	0.18	0,15	0.00	0.40	0.18	0.15	0.00	0.40	0.18	0.21	0.00	0.60	0.0006
SRSE	–0.54	0.40	–1.50	–0.25	–0.41	0.48	–1.75	0.38	–0.49	0.46	–1.75	0.13	–0.49	0.46	–1.75	0.13	0.4140
CDVA	0.10	0.18	0.00	0.90	0.04	0.15	0.00	0.90	0.04	0.14	0.00	0.90	0.03	0.06	0.00	0.20	<0.0001
CIVA (80 cm)	0.18	0.16	–0.10	0.50	0.10	0.16	0.00	0.40	0.09	0.13	0.00	0.40	0.08	0.11	0.00	0.40	0.0001
CIVA (66 cm)	0.20	0.17	–0.10	0.50	0.10	0.14	0.00	0.48	0.10	0.14	0.00	0.40	0.07	0.10	0.00	0.30	0.0001
CNVA (40 cm)	0.21	0.16	–0.10	0.40	0.18	0.15	0.00	0.40	0.18	0.15	0.00	0.40	0.18	0.20	0.00	0.70	0.0001

ARSE – autorefraction spherical equivalent; UDVA – uncorrected distance visual acuity; CDVA – corrected distance visual acuity; UIVA – uncorrected intermediate visual acuity; CIVA – corrected intermediate visual acuity; UNVA – uncorrected near visual acuity; CNVA – corrected near visual acuity; SRSE – subjective refraction spherical equivalent; SE – spherical equivalent; IOL – intraocular lens; M – mean value; Min – minimal value; Max – maximal value; SD – standard deviation; D cyl. – cylinder diopters.

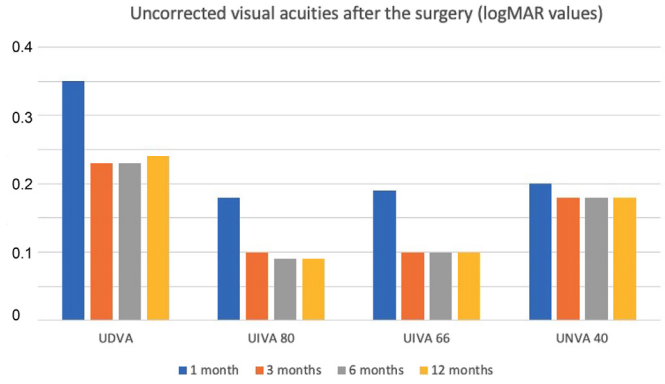

Fig. 2. Changes in uncorrected visual acuities after the surgery (logMAR values).
UDVA – uncorrected distance visual acuity; UIVA – uncorrected intermediate visual acuity; UNVA – uncorrected near visual acuity.

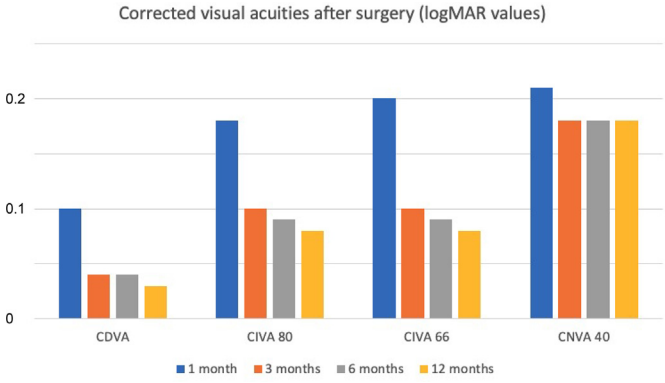

Fig. 3. Changes in corrected visual acuities after the surgery (logMAR values).
CDVA – corrected distance visual acuity; CIVA – corrected intermediate visual acuity; CNVA – corrected near visual acuity.

(corresponding to approximately 0.7 Snellen), which sustained a satisfactory result for the patient, who spent most of the time indoors. It has to be realized though, that active persons, performing more driving and outdoor activities, might not be fully satisfied with such result, thus precise patient selection is necessary for targeted myopia approach.

The analysis of optical outcome in our study has to take into account a few facts. Defocus curve of the analyzed EDOF IOL has a mild curvature

Table 3
Binocular visual acuity and contrast sensitivity (logMAR) recorded in the study participants after 12 months of observation (15 individuals). *P* values refer to differences between visual acuities at different distances.

Analyzed trait	M	SD	Min	Max	*P* - value
UDVA	0.13	0.16	0.00	0.50	0.1064
UIVA (80 cm)	0.06	0.08	0.00	0.20	
UIVA (66 cm)	0.07	0.09	0.00	0.20	
UNVA (40 cm)	0.15	0.09	0.00	0.50	
CDVA	0.00	0.00	0.00	0.00	0.0006
CIVA (80 cm)	0.05	0.07	0.00	0.20	
CIVA (66 cm)	0.05	0.06	0.00	0.20	
CNVA (40 cm)	0.13	0.16	0.00	0.40	
CS without correction	1.78	0.16	1.40	2.00	
CS with correction	1.81	0.13	1.55	2.00	

UDVA – uncorrected distance visual acuity; CDVA – corrected distance visual acuity; UIVA – uncorrected intermediate visual acuity; CIVA – corrected intermediate visual acuity; UNVA – uncorrected near visual acuity; CNVA – corrected near visual acuity; CS – contrast sensitivity; M – mean value; Min – minimal value; Max – maximal value; SD – standard deviation.

without peaks typical for monofocal IOLs, what explains noted visual enhancement for intermediate and near acuities. Moreover, results of contrast sensitivity testing revealed excellent acuities, higher than average results for that age group reported in the literature.[17] It has to be remembered though, that our biometric target was set at –0.25 to –0.50D to gain better vision for near and intermediate distances. This functional goal was achieved in 100% of eyes, however, it has to be considered, how this outcome was enhanced by the value of postoperative ARSE (–0.70D), which was significantly lower than the biometric target. On the other hand, the value of subjective refraction (SRSE) was lower than ARSE at all 4 follow-up points. According to available data, refraction readings obtained from eyes after implantation of EDOF IOLs with the use of automated autorefractors are usually lower than actual refraction. This is due to erroneous reading of the EDOF IOL by the machines: spherical aberration employed in EDOF IOLs causes myopic shift in that kind of measurements.[18,19] As final SRSE had a –0.49D value, we can assume, that our biometric target was exceeded by approximately a quarter of a diopter and that could have enhanced the IOL performance for near. We believe that this discrepancy is due to the use of A-constant that was provided by the manufacturer but not yet optimized. When the study was performed, the experience with this particular IOL was practically none, and later on, our and other studies provided data that led to change in A-constant for the LUXSMART lens.

Our approach with targeted bilateral minor myopia in both eyes is not a common strategy used with EDOF IOLs. Most of the recent studies on

Table 4
Results of patient's satisfaction survey at 12 months after cataract surgery.

Question	No	%
How do you grade your satisfaction of LUXSMART lenses at 6 months after surgery (1–5 scale)		
Very low – very dissatisfied	0	0
Low – rather dissatisfied	0	0
Moderate – moderately satisfied	0	0
High – satisfied but there are some faults	0	0
Very high – very satisfied	15	100
How often do you use any optical correction (for distance or near) after the surgery		
Never 0% of active time	11	73.3
Occasionally <50% of active time	4	26.7
Mostly > 50% of active time	0	0
Always 100% of active time	0	0
How often do you use optical correction for distance after the surgery		
Never 0% of active time	11	73.3
Occasionally <50% of active time	4	26.7%
Mostly > 50% of active time	0	0
Always 100% of active time	0	0
How often do you use optical correction for near after the surgery		
Never 0% of active time	15	100
Occasionally <50% of active time	0	0
Mostly > 50% of active time	0	0
Always 100% of active time	0	0
How often do you use optical correction at the computer		
Never use optical correction 0% of time	15	100
Occasionally use optical correction <50% of time	0	0
Mostly use optical correction > 50% of time	0	0
Always use optical correction 100% of time	0	0
How dysphotopic phenomena influence your activities		
Do not hinder my activities at all	15	100
Sometimes hinder my activities	0	0
Mostly hinder my activities	0	0
All the time hinder my normal activities	0	0

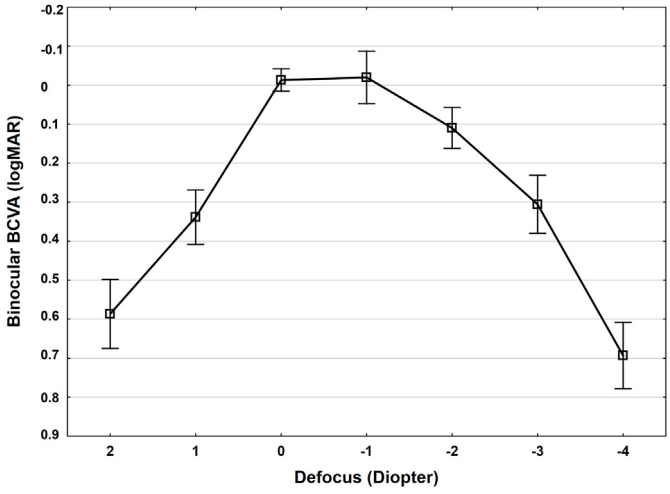

Fig. 4. Defocus curve for the study IOL based on the binocular measurements in 15 individuals.

EDOF IOL surgery adopt a principle of bilateral emmetropia[20–22] or postoperative monovision, with targeted emmetropia in dominant eye and minor myopia in non-dominant eye.[23–25] The first approach provides excellent distance and intermediate uncorrected acuities with some enhancement usually needed for near. The second form of management enables spectacle independence for the sake of inconveniences typical for monovision, such as decrease in distance vision or impairment of depth perception.[26,27] We believe that there is a specific group of patients who will benefit with the strategy that we employed. These are usually patients who perform a lot of reading, writing and work on the computer and who do not set independence of wearing glasses for distance as a primary goal of the surgery. For them, benefits of perfect near and intermediate vision with proper binocularity outweighs minor inconvenience of occasional need for wearing small optical correction for distance.

Another subject associated with the application of EDOF IOLs is the presence or rather absence of dysphotopsias. In our study none of the patients reported annoying optical sensations, such as halos or glare around sources of light, which are frequently reported with the use of multifocal IOLs. Impairment of the quality of vision, including poorer vison at nighttime, was not observed by any patient during the study. This finding has to be considered in the context of intraocular lens design, that is not uniform in all EDOF-type IOLs. The common feature of EDOF IOLs is the elongation of the optical focus, however this quality is achieved by an employment of different optical phenomena in the lens design. Hybrid diffractive/refractive optical construction used in some EDOF IOLs make them similar to MFIOLs: they provide substantial enhancement for intermediate and sometimes also near distances but are burdened with dysphotopsias attributed mainly to employment phenomenon of diffraction.[28,29] The other type of EDOF IOL, that we used, bases solely on refractive principle and as such is observed to generate less dysphotoptic phenomena.[30–32] This outcome was confirmed by the results of our study as well. Nevertheless, EDOF IOLs employing purely refractive construction are not yet commonly used as there are not many products of that type available on the market. So far, besides the IOL analyzed in this study, the examples of purely refractive design used in EDOF IOLs are Vivity (Alcon), Mini Well Ready (Si Fi), Eyhance ICB00 (Tecnis), Synthesis (Cutting Edge) or Evolve (Soleko).

Biometric calculations and patients' profiling applied in the studies on EDOF IOLs might seem complicated and induce to rise a question whether EDOF lenses have their position at the market if MFIOLs, correcting vision for all distances, are easily available. We believe that one of the most important advantages of pure refractive EDOF IOLs is the absence of major dysphotopsias perceived by the patient along with better performance compared to monofocal IOLs.[33,34] Diffractive or hybrid refractive-diffractive IOLs usually produce more dysphotopsias and more serious decrease in contrast sensitivity. Thus, their implantation is not recommended for demanding personalities and might result in dissatisfaction and legal claims. On the other hand, cataract surgery with refractive EDOF IOL can be proposed for such patients.

First experience with LUXSMART IOL included three months results of this IOL implantation in 38 eyes.[35] Similarly, to our study, myopic shift with originally provided A-constant was also reported. With classic biometric approach aiming at perfect UDVA, the author achieved excellent values for UDVA and UIVA 80 and UIVA 66 (respectively 0.06, 0.08 and 0.13 logMAR) without significant dysphotopsias. Mean postoperative UNVA in that study was 0.32 logMAR, so in that cohort spectacle aid for near will probably be needed.

Just recently two new comparative studies between Luxsmart IOL and monofocal IOLs have been published.[34,36] Luxsmart IOL provided superior to monofocal IOL performance for near and intermediate distance, without significant dysphotopic phenomena.

4.1. Limitations of the study

The retrospective character and relatively small sample are major limitations of the study. The possible bias of patient selection criteria that included only patients with specific lifestyle has also to be considered. As the study included patients who were less active and concentrated on activities that required good near vision, naturally the IOL's performance for near and intermediate distances was the main point of their interest with the distance performance of the lens relatively disregarded. Further comparative studies with control group operated with the use of traditional monofocal IOLs is necessary to fully evaluate advantages of that intraocular lens.

5. Conclusions

Pure refractive EDOF IOLs can provide independence of spectacle correction in terms of visual acuity in patients with stationary type of behavior. Setting biometric target to minor myopia provides good quality of uncorrected vision for near and intermediate distances with sufficient uncorrected distance visual acuity in majority of cases. Pure refractive EDOF IOLs do not elicit burdensome dysphotopsias that would compromise patients' comfort while performing everyday activities.

Study approval

The authors confirm that any aspect of the work covered in this manuscript that involved human patients or animals was conducted with the ethical approval of all relevant bodies and the study was performed in accordance with the Declaration of Helsinki, and the protocol was approved by the local bioethical board (Komisja Bioetyczna at OIL in Gdańsk, approval no. KB-38/21, 2021).

Author contributions

Conceptualization MG; methodology MG, AG; software: NP; validation: MG, NP, AG, AR, IKB; formal analysis MG; investigation MG, NP; resources MG, NP, AR, IKB; data curation NP, AR, IKB; writing– original draft preparation MG; writing – review and editing AG, MG; All authors have read and agreed to the published version of the manuscript.

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Declaration of competing interest

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References

1. Aaronson A, Viljanen A, Kanclerz P, Grzybowski A, Tuuminen R. Cataract complications study: an analysis of adverse effects among 14,520 eyes in relation to surgical experience. *Ann Transl Med*. 2020 Nov;8(22):1541. https://doi.org/10.21037/atm-20-845. PMID: 33313286 PMCID: PMC7729371.
2. Gawęcki M, Grzybowski A. Diplopia as the complication of cataract surgery. *J Ophthalmol*. 2016;2016, 2728712. https://doi.org/10.1155/2016/2728712. PMID: 26998351 PMCID: PMC4779543.
3. Camps VJ, Miret JJ, Caballero MT, Piñero DP, García C. Multifocal intraocular lenses: basic principles. In: Alió J, Pikkel J, eds. *Multifocal Intraocular Lenses. Essentials in Ophthalmology*. Cham: Springer; 2019. https://link.springer.com/chapter/10.1007/978-3-030-21282-7_3.
4. Auffarth GU, Rabsilber TM, Kohnen T, Holzer MP. Design und optische Prinzipien von Multifokallinsen [Design and optical principles of multifocal lenses]. *Ophthalmologe*. 2008 Jun;105(6):522–526. https://doi.org/10.1007/s00347-008-1744-9.
5. Ravikumar S, Bradley A, Thibos LN. Chromatic aberration and polychromatic image quality with diffractive multifocal intraocular lenses. *J Cataract Refract Surg*. 2014 Jul;40(7):1192–1204. https://doi.org/10.1016/j.jcrs.2013.11.035.
6. Malyugin B, Morozova T, Cherednik V. Fyodorov clinic innovation GRADIOL: Gradient refractive index optics multifocal intraocular lens. In: Alió J, Pikkel J, eds. *Multifocal Intraocular Lenses. Essentials in Ophthalmology*. Cham: Springer; 2014. https://doi.org/10.1007/978-3-319-09219-5_17.
7. Mester U, Vaterrodt T, Goes F, et al. Impact of personality characteristics on patient satisfaction after multifocal intraocular lens implantation: results from the "happy patient study. *J Refract Surg*. 2014 Oct;30(10):674. https://doi.org/10.3928/1081597X-20140903-05. PMID: 25291750.
8. Kamiya K, Hayashi K, Shimizu K, et al. Survey working group of the Japanese society of cataract and refractive surgery. Multifocal intraocular lens explantation: a case series of 50 eyes. *Am J Ophthalmol*. 2014 Aug;158(2):215–220. https://doi.org/10.1016/j.ajo.2014.04.010. PMID: 24792105.
9. Alio JL, Plaza-Puche AB, Férnandez-Buenaga R, et al. Multifocal intraocular lenses: an overview. *Surv Ophthalmol*. 2017;62:611–634. https://doi.org/10.1016/j.survophthal.2017.03.005. PMID: 28366683.
10. Zapata-Díaz JF, Rodríguez-Izquierdo MA, Ould-Amer N, et al. Total depth of focus of five premium multifocal intraocular lenses. *J Refract Surg*. 2020 Sep 1;36(9):578–584. https://doi.org/10.3928/1081597X-20200720-01. PMID: 32901824.
11. Philippaki E, Gobin L, Mandoda J, et al. Optical evaluation of new-design multifocal IOLs with extended depth of focus. *J Opt Soc Am Opt Image Sci Vis*. 2019 May 1;36(5):759–767. https://doi.org/10.1364/JOSAA.36.000759. PMID: 31045002.
12. Kanclerz P, Toto F, Grzybowski A, et al. Extended depth-of-field intraocular lenses: an update. *Asia Pac J Ophthalmol (Phila)*. 2020 May-Jun;9(3):194–202. https://doi.org/10.1097/APO.0000000000000296. PMID: 32511121 PMCID: PMC7299221.
13. Huh J, Eom Y, Yang SK, et al. A comparison of clinical outcomes and optical performance between monofocal and new monofocal with enhanced intermediate function intraocular lenses: a case-control study. *BMC Ophthalmol*. 2021 Oct 16;21(1):365. https://doi.org/10.1186/s12886-021-02124-w. PMID: 34656091 PMCID: PMC8520272.
14. Balgos MJTD, Alió JL. Updates in refractive surgery. In: Grzybowski A, ed. *Current Concepts in Ophthalmology*. Cham: Springer; 2020. https://doi.org/10.1007/978-3-030-25389-9_1.
15. Spadea L, Giannico MI, Formisano M, Alisi L. Visual performances of a new extended depth-of-focus intraocular lens with a refractive design: a prospective study after bilateral implantation. *Therapeut Clin Risk Manag*. 2021;17:727–738. https://doi.org/10.2147/TCRM.S320422. PMID: 34295162 PMCID: PMC8291859.
16. Savini G, Balducci N, Carbonara C, et al. Functional assessment of a new extended depth-of-focus intraocular lens. *Eye*. 2019 Mar;33(3):404–410. https://doi.org/10.1038/s41433-018-0221-1. PMID: 30266985 PMCID: PMC6460699.
17. Mäntyjärvi M, Laitinen T. Normal values for the Pelli-Robson contrast sensitivity test. *J Cataract Refract Surg*. 2001 Feb;27(2):261–266. https://doi.org/10.1016/s0886-3350(00)00562-9. PMID: 11226793.
18. Muñoz G, Albarrán-Diego C, Sakla HF. Validity of autorefraction after cataract surgery with multifocal ReZoom intraocular lens implantation. *J Cataract Refract Surg*. 2007 Sep;33(9):1573–1578. https://doi.org/10.1016/j.jcrs.2007.05.024. PMID: 17720072.
19. Ota Y, Minami K, Oki S, et al. Subjective and objective refractions in eyes with extended-depth-of-focus intraocular lenses using echelette optics: clinical and experimental study. *Acta Ophthalmol*. 2021;99:e837–e843. https://doi.org/10.1111/aos.14660. PMID: 33191658 PMCID: PMC8518701.
20. Sinha R, Sahay P, Saxena R, et al. Visual outcomes of binocular implantation of a new extended depth of focus intraocular lens. *Indian J Ophthalmol*. 2020;68(10):2111–2116. https://doi.org/10.4103/ijo.IJO_2139_19. PMID: 32971619 PMCID: PMC7727980.
21. Choi M, Im CY, Lee JK, et al. Visual outcomes after bilateral implantation of an extended depth of focus intraocular lens: a multicenter study. *Kor J Ophthalmol*. 2020 Dec;34(6):439–445. https://doi.org/10.3341/kjo.2020.0042. PMID: 33307603 PMCID: PMC7738229.
22. Titiyal JS, Kaur M, Bharti N, et al. Optimal near and distance stereoacuity after binocular implantation of extended range of vision intraocular lenses. *J Cataract Refract Surg*. 2019 Jun;45(6):798–802. https://doi.org/10.1016/j.jcrs.2018.12.024. PMID: 30876785.
23. Sandoval HP, Lane S, Slade S, et al. Extended depth-of-focus toric intraocular lens targeted for binocular emmetropia or slight myopia in the nondominant eye: visual and refractive clinical outcomes. *J Cataract Refract Surg*. 2019 Oct;45(10):1398–1403. https://doi.org/10.1016/j.jcrs.2019.05.019. PMID: 31444080.
24. Newsom TH, Potvin R. Evaluation of quality of vision and visual outcomes with bilateral implantation of a non-diffractive extended vision intraocular lens with a target of slight myopia in the non-dominant eye. *Clin Ophthalmol*. 2022 Jan 25;16:183–190. https://doi.org/10.2147/OPTH.S350850. PMID: 35115758 PMCID: PMC8800857.
25. Jackson MA, Edmiston AM, Bedi R. Optimum refractive target in patients with bilateral implantation of extended depth of focus intraocular lenses. *Clin Ophthalmol*. 2020 Feb 18;14:455–462. https://doi.org/10.2147/OPTH.S237457. PMID: 32109981 PMCID: PMC7035885.
26. Wolffsohn JS, Davies LN. Presbyopia: effectiveness of correction strategies. *Prog Retin Eye Res*. 2019 Jan;68:124–143. https://doi.org/10.1016/j.preteyeres.2018.09.004.
27. Kollbaum PS, Bradley A. Correction of presbyopia: old problems with old (and new) solutions. *Clin Exp Optom*. 2020 Jan;103(1):21–30. https://doi.org/10.1111/cxo.12987. PMID: 31734940.
28. Nowik KE, Nowik K, Kanclerz P, et al. Clinical performance of extended depth of focus (EDOF) intraocular lenses - a retrospective comparative study of Mini well Ready and symfony. *Clin Ophthalmol*. 2022 May 26;16:1613–1621. https://doi.org/10.2147/OPTH.S341698. PMID: 35651536 PMCID: PMC9150758.
29. Yeu E, Cuozzo S. Matching the patient to the intraocular lens: preoperative considerations to optimize surgical outcomes. *Ophthalmology*. 2021 Nov;128(11):e132–e141. https://doi.org/10.1016/j.ophtha.2020.08.025. PMID: 32882308.
30. Vounotrypidis E, Diener R, Wertheimer C, et al. Bifocal nondiffractive intraocular lens for enhanced depth of focus in correcting presbyopia: clinical evaluation. *J Cataract Refract Surg*. 2017 May;43(5):627–632. https://doi.org/10.1016/j.jcrs.2017.01.024. PMID: 28602323.

31. Dołowiec-Kwapisz A, Piotrowska H, Misiuk-Hojło M. Evaluation of visual and patient-reported outcomes, spectacle dependence after bilateral implantation with a non-diffractive extended depth of focus intraocular lens compared to other intraocular lenses. *J Clin Med*. 2022 Sep 5;11(17):5246. https://doi.org/10.3390/jcm11175246. PMID: 36079174 PMCID: PMC9456700.
32. Rementería-Capelo LA, Lorente P, Carrillo V, et al. Patient satisfaction and visual performance in patients with ocular pathology after bilateral implantation of a new extended depth of focus intraocular lens. *J Ophthalmol*. 2022 Apr 28;2022, 4659309. https://doi.org/10.1155/2022/4659309. PMID: 35529167 PMCID: PMC9071907.
33. Pedrotti E, Chierego C, Talli PM, et al. Extended depth of focus versus monofocal IOLs: objective and subjective visual outcomes. *J Refract Surg*. 2020 Apr 1;36(4):214–222. https://doi.org/10.3928/1081597X-20200212-01. PMID: 32267951.
34. Tahmaz V, Siebelmann S, Koch KR, et al. Evaluation of a novel non-diffractive extended depth of focus intraocular lens - first results from a prospective study. *Curr Eye Res*. 2022 Aug;47(8):1149–1155. https://doi.org/10.1080/02713683.2022.2074046. PMID: 35642558.
35. https://crstodayeurope.com/articles/feb-2021/luxsmart-edof-iol-a-novel-lens-design-for-presbyopia-correction.
36. Campos N, Loureiro T, Rodrigues-Barros S, et al. Preliminary clinical outcomes of a new enhanced depth of focus intraocular lens. *Clin Ophthalmol*. 2021;15:4801–4807. https://doi.org/10.2147/OPTH.S344379. PMID: 34992340 PMCID: PMC8714966.