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Research Article

Benefits of a Rotationally Asymmetric Enhanced Depth of Focus, Bifocal Segment Intraocular Lens in an Older Cataract Population Ranging from 74 to 82 Years

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Abstract

Purpose: Older patients are often ruled out from multifocal and enhanced depth of focus intraocular lens studies, as their possible visual acuity gain might be limited due to the increased risk of comorbidities, especially degenerative diseases. This is a prospective study to evaluate the postoperative outcomes and visual performance in an old population (74 to 82 years old) after bilateral implantation of a rotationally asymmetric enhanced depth of focus IOL.

Methods: Sixteen (16) eyes of 8 patients underwent bilateral cataract surgery with implantation of the Lentis Comfort LS-313/MF15 (Oculentis, Germany). Both eyes were targeted closest to emmetropia. Pre- and postoperative, monocular and binocular uncorrected and distance corrected visual acuity for far (UDVA, CDVA), postoperative refractive outcome, intermediate (UIVA, DCIVA at 90 cm, 80 cm and 60 cm) and near (UNVA, DCNVA 40cm) distances, and monocular and binocular defocus curves were evaluated. Additionally, we performed the HD Analyzer measurements, the Halo and Glare simulator and McAlinden questionnaire to assess optical quality and patient's satisfaction.

Results: The mean age was 78.37 ± 3.03 years old; the mean post-operative spherical equivalence was -0.039 +/- 0.68D. There was significant improvement in visual acuity with a binocular mean VA of 0.04 +/- 0.157 logMAR (UDVA), -0.008 +/- 0.128 logMAR (CDVA), 0.18 +/- 0.11 logMAR (DCIVA 90 cm), 0.17 +/- 0.17 logMAR (DCIVA 80 cm), 0.27 +/- 0.16 logMAR (DCIVA 60 cm), 0.31 +/- 0.18 logMAR (UNVA 40 cm) and 0.43 +/- 0.16 logMAR (DCNVA 40 cm). The binocular defocus curve showed a visual acuity of 0.2 logMAR or better in a range from -1,50 to +0,50D, and 62.5% had no halo or glare on the simulator. The McAlinden questionnaire revealed a high rate of satisfaction and spectacle independence in far and intermediate distances.

Conclusion: The Lentis Comfort LS-313/MF15 achieved very good uncorrected visual acuities for far and intermediate distances in our study with remarkably low dysphotopic phenomena. The old age of the patients and the spectacle use for near distance did not impact their satisfaction from the surgery.

Keywords: *Cataract; Old Population; Enhanced Depth of Focus; Intraocular Lens; Emmetropia; Halo and Glare*

Introduction

Nowadays, patient's need for spectacle independence in different distances became a crucial parameter to consider when selecting patients for cataract refractive surgery [1-6].

Recent developments in multifocal intraocular lenses have allowed surgeons to achieve good postoperative refractive results, especially for distance and near vision [7-12]. However, the need for intermediate vision is still claimed by patients according to their life styles.

We live in an era in which being able to monitor a computer or a tablet is essential in daily life. Other activities such as gardening, watching car's dashboard and enjoying hobbies such as playing chess also require the intermediate distance vision [13]. Multifocal IOLs were developed to offer full refractive correction at all distances [7-12]. Many studies report comparable distance visual acuity results between multifocal and monofocal IOLs and better near and intermediate vision with multifocal IOLs [14]. Different multifocal IOLs have been developed in the last years in order to offer patients the widest range of vision possible and to improve intermediate focus vision. However, the main dissatisfaction factor reported remains the occurrence of dysphotopsia, especially halo and glare [14-16].

Often older patient populations are excluded from multifocal and enhanced depth of focus intraocular lens studies as their possible visual acuity gain might be limited. The purpose of the present study was to evaluate refractive and functional outcomes of bilateral implantation of a novel enhanced depth of focus IOL Lentis Comfort LS-313/MF15 (Oculentis, Berlin, Germany), and to assess the photic phenomena in an older cataract population (range 74 to 82 years). Subjective patient questionnaire was also evaluated to assess satisfaction from the surgery, spectacle independence in different distances and dysphotopic phenomena to prove the thesis that also an older population is suitable for enhanced depth of focus IOL implantation.

Patients and Methods

This prospective, non-comparative ongoing clinical study enrolled 16 eyes of 8 patients. Inclusion criteria for this study were patients presenting bilateral cataract surgery and demanding spectacle independence in intermediate distances in an age range between 74 to 82 years. The exclusion criteria were any history of glaucoma, corneal disease or postoperative calculated astigmatism > 1.00D, iris anomalies, macular degeneration, retinopathy, retinal detachment, ocular inflammation, neuro-ophthalmic disease and previous corneal or intraocular surgery. Patients who had unrealistic expectations were also excluded. All subjects were adequately informed and signed an informed consent form. The study adhered to tenets of the Declaration of Helsinki and was approved by the local Ethics committee.

All patients had an ophthalmological examination before the surgery. It included objective and subjective refraction, uncorrected and distance corrected visual acuity using the ETDRS chart at 4m in logMAR, corneal topography, slit-lamp biomicroscopy, Goldmann tonometry, pupillometry, biometry using the IOLMaster 700 (Carl Zeiss Meditec, Germany), fundus examination under pupil dilation.

All patients were implanted bilaterally with the Lentis Comfort LS-313MF15 (Oculentis, Germany). They underwent conventional microincision cataract surgery by the same experienced surgeon. After topical anesthesia and mydriatic drops, the clear corneal incision was performed with 2.2 mm, the capsulorhexis was performed manually with an approximate diameter of 5 mm, the phacoemulsification was performed in a chop and stop technic, followed by a bimanual cortex peeling and capsule polishing, with implantation of the Lentis Comfort LS-313MF15 with continuous BSS irrigation.

The Lentis Comfort LS-313/MF15 is a single-piece, aspheric, rotational asymmetric, refractive enhanced depth of focus (EDOF) intraocular lens (IOL) with a depth of focus power of +1.5D on the IOL plane. It has a 6.0-mm biconvex optic and overall length of 11.0 mm. Based on the same platform as the other LS-313 models [12,17,18]; it is a foldable hydrophilic acrylate IOL with hy¬drophobic surface properties [2]. The 360° sharp optic edge design reduces the risk of posterior capsule opacification. Moreover, the haptic design provides high rotational stability. The reduced add power was developed to increase intermediate visual acuity and decrease optical phenomena.

Postoperatively, patients data was collected from their 3 to 6-months follow-up visit; the examination protocol was identical to the preoperative protocol, with additional examinations of manifest refraction (sphere, cylinder and axis) to evaluate deviation from targeted refraction using the spherical equivalent, uncorrected and distance corrected visual acuity for far (UDVA, CDVA), intermediate (UIVA, DCIVA at 90 cm, 80 cm and 60 cm) and near (UNVA, DCNVA 40cm) distances, and monocular and binocular defocus curve. Additionally, we performed MTF Cut Off, Objective scattering Index (OSI) and Strehl Ration measurements (HD Analyzer, Visiometrix, USA) and Halo and Glare simulator (Carl Zeiss Meditech, USA) to evaluate visual quality and optical phenomena that we interpreted using the strength formula (Developed by Dr. Hagen., *et al*, Düsseldorf). The function allows classifying halo and glare into 4 categories: none (0% - 25%), mild (25% - 50%), moderate (50% - 75%) and severe (75% - 100%). The subjective McAlinden questionnaire [19] was also handed to patients in order to evaluate the perception of photic phenomena, their severity, frequency and bother, the ability to perform daily activities without spectacles, spectacle independence in different distances and the satisfaction with the results of the surgery.

Results

All 8 patients were targeted for emmetropia, mean age was 78.37 ± 3.03 years old (ranging from 74 to 82 years old). The median IOL power was 21.71 ± 1.82D, the mean post-operative spherical equivalence was -0.039 ± 0.68D.

The uncorrected visual acuities were 0.16 ± 0.2 logMAR for distance (UDVA) monocularly and 0.04 ± 0.157 logMAR binocularly, and 0.4 ± 0.21 logMAR for near (UNVA 40 cm) monocularly and 0.31 ± 0.18 logMAR binocularly.

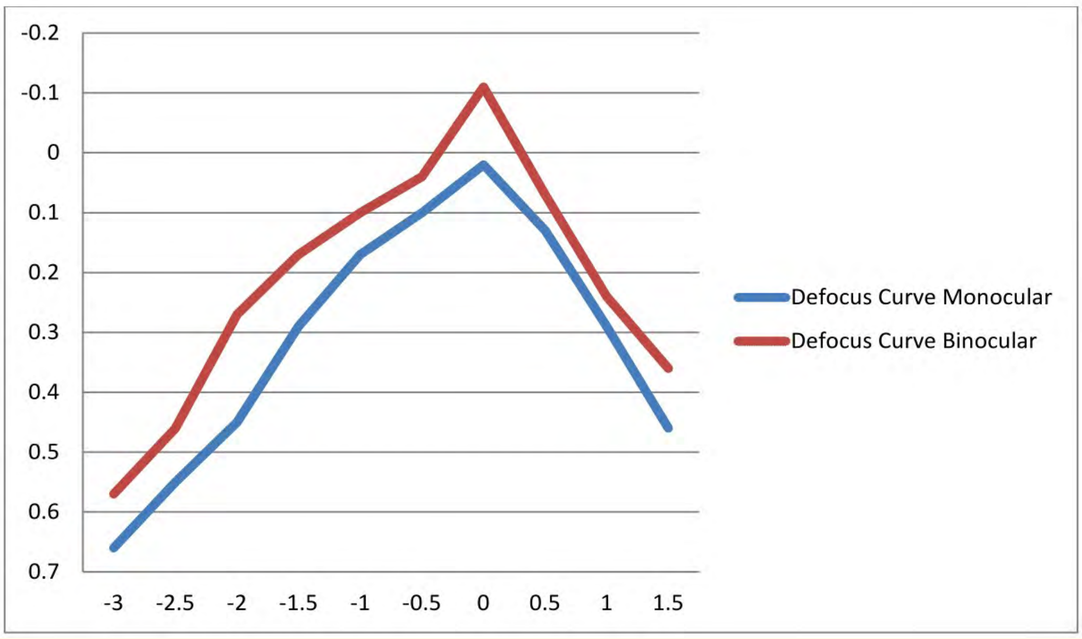
The distance corrected monocular visual acuities were 0.04 ± 0.13 logMAR (CDVA) 0.24 ± 0.13 logMAR (DCIVA 90 cm), 0.26 ± 0.16 logMAR (DCIVA 80 cm), 0.33 ± 0.15 logMAR (DCIVA 60 cm) and 0.5 ± 0.16 logMAR (DCNVA 40 cm). The distance corrected binocular visual acuities were -0.008 ± 0.128 logMAR (CDVA), 0.18 ± 0.11 logMAR (DCIVA 90 cm), 0.17 ± 0.17 logMAR (DCIVA 80 cm), 0.27 ± 0.16 logMAR (DCIVA 60 cm) and 0.43 ± 0.16 logMAR (DCNVA 40 cm) (Table 1).

	Monocular Mean ± SD (in LogMAR)		**Binocular Mean ± SD (in LogMAR)**	
UDVA	0.16	0.2	0.04	0.15
CDVA	0.04	0.13	-0.008	0.128
DCIVA 90cm	0.24	0.13	0.18	0.11
DCIVA 80cm	0.26	0.16	0.17	0.17
DCIVA 60cm	0.33	0.15	0.27	0.15
UNVA 40cm	0.4	0.21	0.3	0.18
DCNVA 40cm	0.5	0.16	0.43	0.16

Table 1: *Summary of the visual outcomes in the analyzed sample.*

UDVA: Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; DCIVA: Distance Corrected Intermediate Visual Acuity; UNVA: Uncorrected Near Visual Acuity; DCNVA: Distance Corrected Near Visual Acuity.

The defocus curves showed a visual acuity of 0.2 logMAR or better in a range from -1.00 to +0.50D monocularly and extended to -1,50 to +0,50D for binocular vision (Figure 1).



	-3	**-2.5**	**-2**	**-1.5**	**-1**	**-0.5**	**0**	**0.5**	**1**	**1.5**
Monocular	0.66	0.55	0.45	0.29	0.17	0.1	0.02	0.13	0.29	0.46
Binocular	0.57	0.46	0.27	0.17	0.1	0.04	-0.11	0.07	0.24	0.36

Figure 1: *Monocular and Binocular Defocus curve [logMar].*

We analyzed the occurrence of dysphotopia with the Halo and Glare simulator by using the strength formula (developed by P Hagen., *et al*, Breyer-Kaymak-Klabe Eye Surgery, Düsseldorf) that allows classifying halo and glare into 4 categories: none (0% - 25%), mild (25% - 50%), moderate (50% - 75%), severe (75% - 100%). The results we found showed 62.5% of patients with no halo or glare, 37.5% reported mild halo and glare; no patient reported neither moderate nor severe halo and glare (Figure 2).

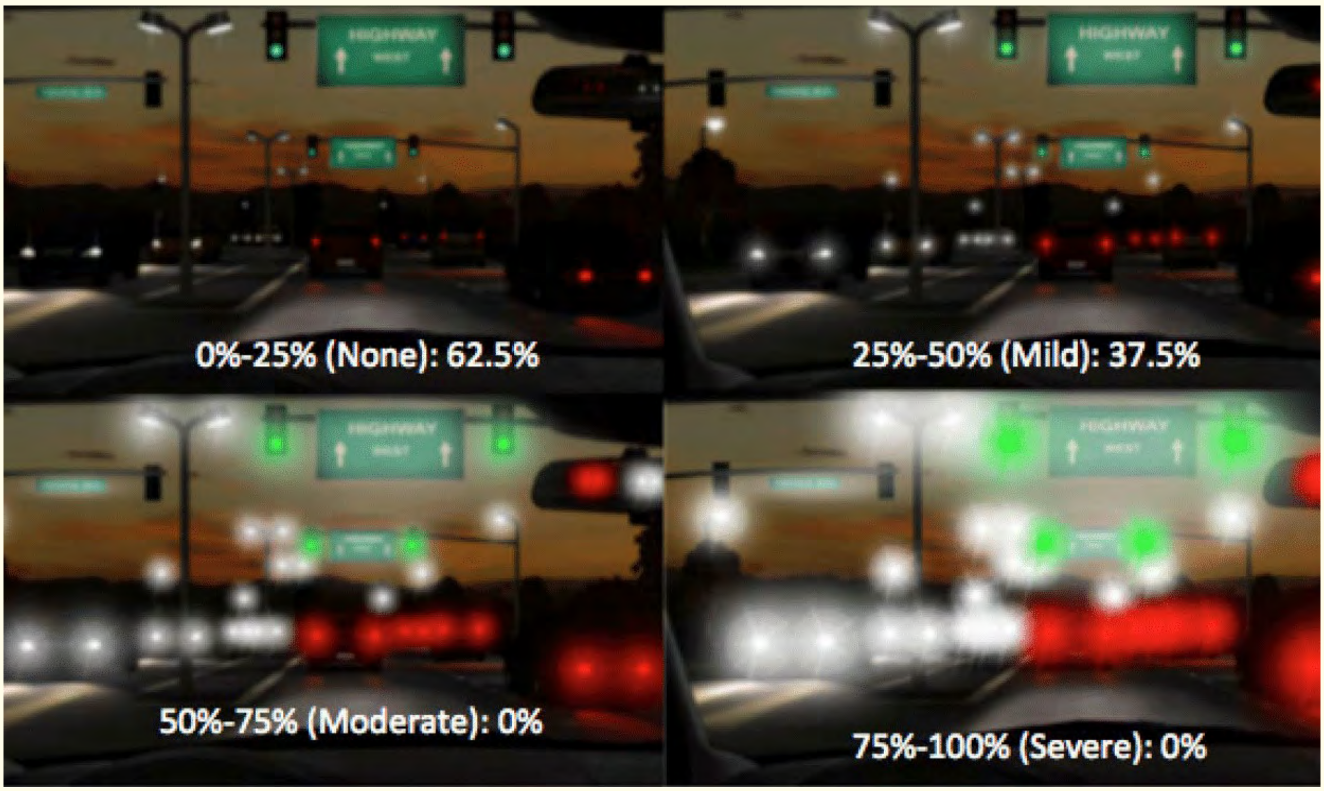


Figure 2: *Percentage of Halo and Glare strength categories.*

Regarding the HD Analyzer results, mean MTF cut-off value was 24.71 ± 10.82 c/deg, with a minimal value of 9.276 and a maximal value of 42.986, for a mean pupil size of 3.10 mm, and the mean Strehl Ratio was of 0.12 ± 0,03 (Min: 0.077 Max: 0.2), the OSI mean value was 2.60 ± 1.64 (Min: 0.6 Max: 4.6).

The McAlinden questionnaire contains 14 questions. For the Questionnaire results analysis, we used the most relevant 7 question to this study (Table 2) related to dysphotopsia, spectacle independence and satisfaction from the surgery. Regarding dysphotopic phenomena, 62.5% occasionally perceived glare that they described as mild severity, and a little bothersome. The halo perception was only reported by 37.5% that they described as mild to moderate. The perception of starbust was reported by 50% of the patients, they described it as mild and a little bothersome. There was only 12.5% patients who reported focusing difficulties that they described as not at all bothersome, and 60% said they would chose the same IOL again. Spectacle independence was achieved in 87.5% for distance and 75% for intermediate distances. 75% of the patients never used glasses for distance or intermediate distances, 25% used glasses half of the time and 75% all the time for near distance activities. Table 3 contains the score accorded to each question.

Question n°1	Question n°2	Question n°3	Question n°9
A: How often do you experience glare?	**A: How often do you experience haloes?**	**A: How often do you experience starbust?**	**A: How often do you experience focusing difficulties?**
Never	Never	Never	Never
Occasionally	Occasionally	Occasionally	Occasionally
Quite Often	Quite Often	Quite Often	Quite Often
Very Often	Very Often	Very Often	Very Often
B: How severe is the glare?	**B: How severe are the halos?**	**B: How severe are the starburst?**	**B: How severe are the focusing difficulties?**
Not at all	Not at all	Not at all	Not at all
Mild	Mild	Mild	Mild
Moderate	Moderate	Moderate	Moderate
Severe	Severe	Severe	Severe
C: How bothersome is the glare?	**C: How bothersome are the halos?**	**C: How bothersome are the starburst?**	**C: How bothersome the focusing difficulties?**
Not at all	Not at all	Not at all	Not at all
A little	A little	A little	A little
Quite	Quite	Quite	Quite
Very	Very	Very	Very

Question n°12	Question n°13	Question n°14
If you had to choose again, would you pick a multifocal intraocular lens again?	**Die the Surgery offer you spectacle independancy?**	**How often do you wear glasses?**
Yes	**A: Distance**	**A: Distance**
No	Yes	Never
Explenation if no	No	Seldom
	B: Intermediate	Half of the time
	Yes	Most of the time
	No	Always
	C: Near	**B: Intermediate**
	Yes	Never
	No	Seldom
		Half of the time
		Most of the time
		Always
		C: Near
		Never
		Seldom
		Half of the time
		Most of the time
		Always

Table 2: *McAlinden questionnaire (Questions 1,2,3,9,12,13,14).*

n/4	**n/4**	**n/4**	**n/4**	**n/4**	**n/4**	**n/4**	**n/4**	**n/4**	**n/4**	**n/4**	**n/4**	**n/2**	**n/2**	**n/2**	**n/2**	**n/5**	**n/5**	**n/5**
1A	1B	1C	2A	2B	2C	3A	3B	3C	9A	9B	9C	12	13A	13B	13C	14A	14B	14C
1.88	2	2	1.63	1.63	1.63	1.63	1.63	1.5	1	1	1	1.17	1.13	1.25	2	2	2	4.25

Table 3: *McAlinden Questionnaire results scores (Mean values in Bold).*

We adopted a novel approach to the analysis of the questionnaire results using a score from 1 to 4 (1 for high satisfaction and 4 for unsatisfied) for questions from 1 to 10, for question 11 and 14 (the score was from 1 to 5) and Questions 12 and 13 (score was from 1 to 2). The higher the numbers, the less the patients were satisfied. Then we calculated the mean score for each question. The mean values for all questions were between 1 and 2, except for the last question (Q.14) about spectacle need (Mean Score 4.25) in near distance activities.

Discussion

Multifocal IOLs were designed to improve vision at different distances by increasing the depth of vision in order to offer patients the most spectacle independence possible [20].

As intermediate focus became more important in daily life, one approach was the development of trifocal IOLs inducing a third focal point by a second diffractive structure reducing loss of light when compared to diffractive bifocal IOLs, thus offering a separate intermediate visual acuity [21]. Another approach was to reduce the add power of MIOLs to shift the focal point closer to an intermediate direction. The ability of multifocal IOLs to improve visual acuity in different distances has been proved by many studies [5,6].

The recent concept of extended depth of focus aims to enhance near and intermediate vision without compromising far distance vision and with the least possible visual disturbances, primarily the dysphotopic phenomena as they are often reported with diffractive multifocal IOLs, and are the first dissatisfaction factor, and sometimes the main reason for explantation [16].

In the present study, we evaluated the visual acuity outcomes, the optical quality as well as satisfaction in patients implanted with an IOL of a depth of focus power of +1.5D on the refractive IOL plane. The population of our study has the specificity of being an older typical cataract age (range from 74 to 82 years old). Our purpose was to evaluate the benefits of this innovative IOL in this specific population, in order to assess the impact on optical quality and vision restoration.

Regarding subjective refraction, the results showed good refractive predictability. The mean manifest sphere preoperatively was 1.89D ± 1.26 and the mean manifest cylinder was -1D ± 0.72, respectively the mean values postoperatively were 0.29D ± 0.78 and -0.67D ± 0.48 in patients targeted for emmetropia.

As expected, the outcomes showed a significant improvement in distance visual acuity, with a mean UDVA of 0.04 logMAR (Table 1), which is consistent with other studies evaluating MIOLs and finding similar good distance visual acuities when compared to monofocal IOLs [12,14,22-26]. The near add power of +1.5D in the Lentis Comfort LS-313/MF15 provided good intermediate visual acuity results in our patients with a mean binocular visual acuity (DCIVA) at three different distances (90, 80, 60 cm) of 0.27 logMAR or better, mean binocular uncorrected vision for near (UNVA) was better than the distance corrected near visual acuity (DCNVA), with a mean of 0.31 ± 0.18 logMAR. However, the near visual outcomes were poorer when compared with other IOLs with higher add power [1,4-6], as the purpose of this low add was to create better intermediate vision in patients that are willing to use glasses for near activities, especially reading small prints. Nevertheless, the Lentis Comfort LS-313/MF15 offered a true enhanced depth of focus with good visual acuities at different intermediate distances.

As for the defocus curve, it is a representative analysis of the visual behavior of the IOL in different levels of defocus that are equivalent to different viewing distances. In the shape of a continuous curve, the results we found indicate that the patients were able to maintain a good visual acuity in different distances, with a peak visual acuity for far, and a visual acuity of 0.3 logMAR or better over a range of 3 D (from -2D to +1D), which is equivalent to near intermediate (50 cm) to far distances. These results were consistent with the VA outcomes of this study.

The ocular optical quality was evaluated using the HD Analyzer. It is a double pass system that gives values to assess optical quality in patients before and after cataract surgery. The values used in cataract surgery assessment are the MTF cutoff, which represents the loss of contrast of a real scene after passing through the eye. The human eye maximum value is 60 c/deg, which corresponds to a visual acuity of 20/10 (-0.3 logMAR). The OSI (Objective scattering index) allows scattering light analysis and is considered normal when the value is between 0.5 and 1, and abnormal when it is higher than 1, while the Strehl ratio is the ratio of the maximum height of the light intensity of the point spread function (PSF) of the measured eye and the height of the PSF "diffraction limit" of an identical pupil diameter. The Strehl ratio allows evaluating the optical quality; the maximal value theoretically is 1. In general, for a pupil diameter of 6 mm of a healthy young human eye it does not exceed 0.15.

The mean ocular MTF (modulation transfer function) spatial frequency with complete loss of contrast was 24.71 c/deg (MTF cutoff) in out patients. The mean OSI was 2.6, and the mean Strehl ratio was 0.12. Taken into account the old age of the patients in our study, the interpretation of the results reveals a moderate contrast sensitivity and eye resolution, a good optical quality and considerable light scattering. This might explain partially the occurrence of photic phenomena.

We used the subjective Halo and Glare analyzer to have a better understanding of patients dysphotopic phenomena. The simulator shows a driving at night image in which the patients personally adjust the different parameters according to their perception in a similar situation.

The simulator uses a scale of intensity and size for both halo and glare from 0 to 100, according to 3 types of Halo and 2 types of Glare. The strength formula that we used allows classifying the photic disturbances into 4 categories. Despite the poor visual quality, and the multifocality of the IOL, only 37.5% of patients reported perception of Halo and Glare of mild size and intensity. Various studies reported higher numbers of Halo and Glare perception with other multifocal IOL models [14-16].

The analysis of answers given by patients to the questionnaire showed high satisfaction and spectacle independence in far and intermediate distances. However, considering the low add power and the loss of accommodation in our patients, the use of spectacles for near distance activities remains needed.

Still our sample size was rather small and won't prove any significance, but clearly shows that all patients had a benefit of the binocular enhanced depth of focus intraocular lens. Even our population didn't have a diagnosed macular degeneration, they had age related retinal changes such as drusen or RPE variations in the OCT which might be a reason for the overall slight underperformance of CDVA while still maintain comparable visual acuities to other studies with monofocal IOLS.

Conclusion

In summary, the low-add concept of the enhanced depth of focus Lentis Comfort LS-313MF15 restores the far and intermediate distances visual acuity thus providing a wide range of vision. The old age of the patients and poor visual quality does not seem to impact their satisfaction from the surgery. And although the photic phenomena remain present, they have been described as not bothersome, and do not affect their daily life. Conceivably, adapted solutions for this specific demographic range could be a good option, especially in a growing, yet demanding population.

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