• Clinical Research •

Outcomes of a non-diffractive extended depth of focus intraocular lens in patients with well-controlled glaucoma and ocular hypertension

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Abstract

● **AIM:** To assess visual outcomes and satisfaction of a non-diffractive extended depth of focus (EDOF) intraocular lens (IOL) in individuals with ocular hypertension (OHT) and well-controlled mild glaucoma undergoing cataract surgery.

● **METHODS:** An investigator-initiated, single-center, prospective, interventional, noncomparative study conducted in Montreal, Canada. The study enrolled 31 patients (55 eyes) with OHT or mild glaucoma who received a non-diffractive EDOF IOL (Acrysof IQ Vivity). Participants underwent sequential cataract surgery with the Vivity IOL. Follow-up evaluations occurred at 1d, 1, and 3mo postoperatively, assessing uncorrected distance, intermediate, and near visual acuity. Questionnaires (QUVID: Questionnaire for visual disturbances and IOLSAT: Intraocular lens satisfaction) were administered pre and post-operatively to measure visual disturbances and spectacle independence in various lighting. Safety parameters included intraocular pressure (IOP), glaucoma medications, spherical equivalence, mean deviation and pattern standard deviation or square root of lost variance on Octopus visual field.

● **RESULTS:** At 1 and 3mo postoperatively, significant improvements were observed in uncorrected distance and intermediate visual acuity. Spectacle independence was enhanced for distance and intermediate vision, especially in bright light settings. Spectacle-free intermediate vision was improved even in dim lighting. Visual disturbances, particularly glare symptoms, were reduced, and there was a notable decrease in IOP and glaucoma medication burden at 3mo. There was more hazy vision postoperatively with no impact on visual acuity and visual satisfaction.

● **CONCLUSION:** The non-diffractive EDOF lens improves distance and intermediate spectacle-free visual function in patients with OHT and well-controlled glaucoma. The findings highlight significant improvements in visual acuity, reduced glare, enhanced spectacle independence, and improved visual performance in different lighting conditions.

● **KEYWORDS:** extended depth of focus; refractive; glaucoma; ocular hypertension; cataract; intraocular lens
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INTRODUCTION

Modern cataract surgery has experienced tremendous advancement in recent years with the variety of intraocular lenses (IOL) available. With increasing expectations of spectacle independence paralleling the technological advances in the design of IOL providing optical clarity at multiple distances, there has been increasing debate on the eligibility of patients with ocular comorbidities for premium lenses[1]. Patients with glaucoma preferentially experience reduced contrast sensitivity compared to reduced visual acuity (VA), which correlates with visual field loss[2]. Monofocal lenses are traditionally the lens of choice in glaucoma patients as multifocal lenses[3], with their diffractive design, trades increased spectacle-free near vision with reduced contrast sensitivity and more dysphotopsias compared to monofocal lenses[4-5]. Extended depth of focus (EDOF) lenses have a non-diffractive design, creating a single, elongated focal point to enhance the depth of focus and improve the intermediate and near vision compared to monofocal lenses, without the dysphotopsias often associated with multifocal lenses[6-7]. A recent comparative study by Pedrotti *et al*[5] has shown that

both diffractive and non-EDOF lenses have similar contrast sensitivity as monofocal lenses, and both have demonstrated significantly better contrast sensitivity preservation in comparison to multifocal lenses. Moreover, EDOF lenses have been shown to enhance spectacle-free intermediate and near vision at long-term compared to monofocal lenses[7-9]. In glaucoma patients, EDOF lenses could theoretically prove to be the more interesting option in the realm of presbyopia-correcting lenses, but prospective studies are lacking. In this study, we examine the visual satisfaction and refractive outcomes of EDOF lenses in ocular hypertension (OHT) and well-controlled glaucoma patients.

PARTICIPANTS AND METHODS

Ethical Approval This is an investigator-initiated, single-center, prospective, interventional, noncomparative, single-surgeon study based in Montreal, Quebec, CA. IRB approval was obtained from Advarra (Columbia, MD) and complies with Health Canada regulations (IRB number #00000971, protocol number Pro0049690). Verbal consent to participation in the study has been obtained in all patients. This study enrolled patients operated for cataract surgery from January 2020 to June 2023.

Participants This study aimed to enrol 20 OHT or mild glaucoma patients with bilateral or unilateral cataract surgery and EDOF IOL implantation (40 eyes). The definition of OHT and the staging of glaucoma was based on the Canadian Ophthalmology Society's practice guidelines[10]. OHT is defined as an intraocular pressure (IOP) of >21 mm Hg, glaucoma suspect is defined as OHT with a suspicious disc or cup to disc (C/D) asymmetry if >0.2; or suspicious 24-2 or similar visual field defect. Early to moderate glaucoma is defined as early glaucomatous features (C/D<0.85) and (or) mild visual field defects not within 10 degrees of fixation [*e.g.* mean deviation (MD) better than -12 dB on Humphrey Visual Field 24-2][10]. Well-controlled open angle glaucoma (OAG) was defined as an IOP of <18 mm Hg prior to cataract surgery. We included patients with IOL powers from 15 to 25 diopters of spherical power in both eyes using the Barrette Universal II/ Barrett Universal Toric formula[11].

Exclusion criteria included previous ocular trauma or zonular instability, previous refractive surgery, visually significant ocular comorbidity such as age-related macular degeneration, macular edema, corneal dystrophy, diabetic retinopathy, irregular corneal astigmatism, uncontrolled or advanced glaucoma, previous incisional glaucoma surgery or severe dry eye. Eligible patients underwent cataract surgery with the implantation of a non-diffractive EDOF non torique or toric IOL (AcrySof IQ Vivity or AcrySof IQ Vivity Toric, Alcon, Geneva, Switzerland). Patients who consent to the surgery and the study undergo routine glaucoma and pre-operative testing with a 24-2 visual field (Octopus, Haag-Streit, Köniz, Switzerland), optical coherence tomography (Cirrus OCT, Zeiss, Oberkochen, Germany), and corneal topography (OPD-Scan III, NIDEK, San Jose, USA). Cataract surgery was performed either in a unilateral, sequential fashion, or simultaneously as a bilateral procedure, based on surgeon and patient preferences. Patients were followed at 1d, 1 and 3mo after surgery to evaluate the visual outcomes and satisfaction. In all patients, the refractive target was closest to plano or the first minus, if the second choice was judged to be too positive.

EDOF Lens The Acrysof IQ Vivity IOL (Alcon, Geneva, Switzerland) was approved by the Food and Drug Administration (FDA) in February 2020[12]. It is a single-piece posterior chamber IOL consisting of a high refractive index hydrophobic acrylic material with blue light filtering chromophore. Using the wavefront-shaping technology on the anterior surface of IOL, it achieves a continuous focal range that allows for an improved range of vision with functional near VA to help reduce spectacle dependence[12]. The wavefront-shaping "stretches" light waves but does not refract or diffract light waves, which minimizes the visual disturbance profile[13].

Outcome Measures The primary outcome was uncorrected binocular VA in patients. Uncorrected distance (UDVA; 6 m), intermediate (UCIVA; 66 cm) and near (UCNVA; 40 cm) VA as measured by the Snellen chart was recorded at all follow-up visits. Binocular VA is recorded even in patients having only received unilateral cataract surgery. Visual satisfaction was measured by two validated, qualitative questionnaires. The Questionnaire for Visual Disturbances (QUVID) records the occurrence and severity of dysphotopsias[14]. The Intraocular Lens Satisfaction (IOLSAT) questionnaire measures spectacle independence at distance, intermediate and near, as well as bright or dim lighting, in order to record patient satisfaction and contrast sensitivity[15].

The secondary outcomes were safety parameters of glaucoma and included IOP, number of glaucoma medications, spherical equivalent (SE), MD and pattern standard deviation (PSD) or square root of lost variance (sLV) on visual field.

Statistical Analysis Statistical analysis was performed with IBM® SPSS Statistics version 29 (New York, USA). Paired *t*-tests were performed for continuous values. Bonferroni adjustment was performed to control for multiplicity of tests. Percentages were tabulated with Excel (Microsoft Office). Statistical significance was defined as a *P*-value <0.05.

RESULTS

Totally 31 patients (55 eyes) were included in the study at the end of recruitment. The demographic data is shown in Table 1. The mean age was 70.33±7.12y. Totally 17 patients were female (54.8%). Eleven patients had well-controlled primary

Table 1 Baseline demographic data *n* (%)

Characteristic	Total eyes (*n*=55)
Demographics	
Age, mean±SD	70.33±7.12
Left eye	27 (49.09)
Female	17 (54.84)
Visual acuity	
Preop. monocular CDVA, mean±SD, logMAR	0.24±0.55
Preop. binocular CDVA, mean±SD, logMAR	0.32±0.34
Preop. UDVA, mean±SD, logMAR	0.84±0.94
Preop. IOP, mean±SD, mm Hg	16.06±3.32
Preop. medication classes, mean±SD	1.13±1.45
Glaucoma type and severity disease type	
Primary open angle	11 (35.48)
Ocular hypertension	10 (32.26)
Normal tension glaucoma	5 (16.13)
Combined mechanism	5 (16.13)
Cup to disc ratio, mean±SD	0.69±0.11
Preop. mean deviation, mean±SD	-0.87±4.97
Preop. mean pattern standard deviation, mean±SD	4.44±2.88
Cataract and Refractive status	
Cataract grading based on LOCS II	
NS 0-1	15.00 (27.27)
NS 2	27.00 (49.09)
NS 3	13.00 (23.64)
Preop. refraction, mean±SD	-0.85±2.04
Preop. glaucoma Laser	
Previous SLT	12 (21.81)
Previous LPI	6 (10.91)

CDVA: Best corrected distance visual acuity; UDVA: Uncorrected distance visual acuity; NS: Nuclear sclerotic; SLT: Selective laser trabeculoplasty; LPI: Laser peripheral iridotomy.

OAG, ten were glaucoma suspect or OHT patients, five had normal-tension glaucoma (NTG) and five had a mixed mechanism glaucoma. The average pre-operative binocular UDVA was 0.84±0.94 logMAR which corresponded to 20/138 Snellen VA. The average binocular best corrected distance visual acuity (CDVA) was 0.32±0.34 logMAR (≈20/40 Snellen VA). Average pre-operative IOP was 16.06±3.32mm Hg, with an average of 1.13±1.45 classes of glaucoma medications. The pre-operative MD on visual field was -0.87±4.97 dB.

Primary Outcomes UDVA and UCIVA significantly improved from pre-operative values at 1mo and 3mo post-operatively (Figure 1). UDVA improved from 0.84 logMAR to 0.05 logMAR at 1mo (P<0.001) and 0.02 logMAR at 3mo (P<0.001). The 96% of eyes had a UDVA of 20/25 or better. UCIVA improved from 0.30 logMAR to 0.07 logMAR and 0.03 logMAR at 1mo and 3mo, respectively (P=0.002). Totally 84% of eyes had an UCIVA of 20/30 or better. Near vision remained preserved at 0.334 and 0.267 logMAR at 1mo and 3mo respectively (P=0.379). The 63% of eyes had a UCNVA of at least 20/40 at 3mo.

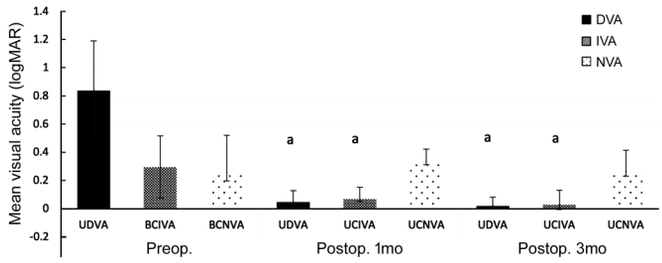

Figure 1 Distance, intermediate and near visual acuity at 1mo and 3mo post-operatively Both uncorrected distance and intermediate visual acuity significantly improved at 1 and 3mo. Near vision remained stable at 3mo postop. The different colors indicate the visual acuity at 3 different distances. DVA: distance visual acuity; IVA: intermediate visual acuity; NVA: near visual acuity; UDVA: Uncorrected distance visual acuity; BCIVA: Best corrected intermediate visual acuity; BCNVA: Best corrected near visual acuity; UCIVA: Uncorrected intermediate visual acuity; UCNVA: Uncorrected near visual acuity. [a]Statistical significance (P<0.05).

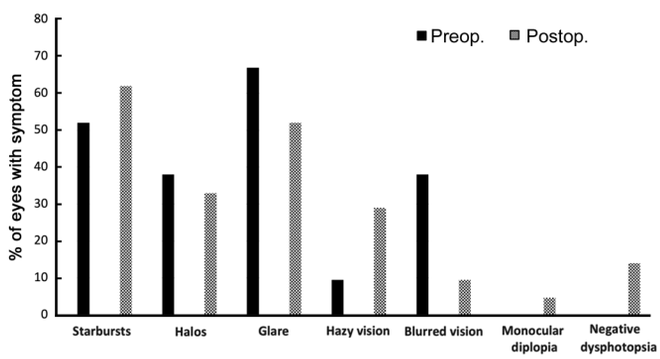

Figure 2 Percentage (%) of eyes with dysphotopsias preop. and postop. using the QUVID (questionnaire for visual disturbances) questionnaire Less eyes complained of halos, glare and blurred vision with the EDOF lens. More eyes complained of starbursts, hazy vision. One patient had monocular diplopia and a small percentage of patients reported negative dysphotopsia.

Visual disturbances were evaluated with the QUVID questionnaire. The most common pre-operative symptoms were starbursts, halos and blurred vision. After cataract surgery with the non-diffractive EDOF IOL, patients noticed a lower frequency of halos, glare and blurred vision (Figure 2).

Patients were also less bothered by glare and blurred vision with the non-diffractive EDOF IOL (near significance P=0.06 for glare and P=0.07 for blurred vision; Figure 3).

Post-operatively, slightly more patients noticed starbursts and negative dysphotopsia, although they were not significantly more bothered by them. One patient experienced monocular diplopia, but was not bothered by this symptom post-operatively. More patients noticed hazy vision after the surgery, with almost 29% (n=6) of eyes with this symptom compared to 9.5% (n=2) pre-operatively, and were more bothered by hazy vision (average score of severity preop.: 0.38; postop.: 2, near significance of P=0.056; Figure 3).

Figure 3 Severity of dysphotopsias preop. and postop. using the QUVID questionnaire Patients were less bothered by glare and blurred vision post-operatively. Patients were not more bothered by halos. Although slightly more patients reported starbursts, they were also slightly less bothered by them. Those with hazy vision were more disturbed by these symptoms. The y axis consists of the addition of scores over 3 questions regarding the same symptom. 0: never/not bothered, 1: rarely/slightly bothered, 2: sometimes/moderately bothered, 3: most of the time/quite bothered, 4: all the time/extremely bothered.

Spectacle independence was evaluated with the IOLSAT questionnaire. The need for glasses was significantly decreased with the non-diffractive EDOF lens at all distances in bright light setting, and at intermediate distance in dim light setting (Figure 4).

Overall, there was more spectacle independence at intermediate and far distances. Quality of vision without glasses at various distances in dim and bright lighting is non-significantly improved post-operatively, with significantly improved vision without glasses at all distances in bright light (average score 2.25 preop. *vs* 2.92 postop., P=0.05; Figure 5). Overall, patients were significantly more satisfied with their post-operative vision (average score 1.33 preop. *vs* 3 postop., P=0.004; Figure 5).

Secondary outcomes IOP was significantly decreased at month 3 postop. (16.23 mm Hg preop. *vs* 13.95 mm Hg 3mo postop., P=0.001; Figure 6). Patients were also weaned off glaucoma medications and had a significantly decreased medication burden at 3mo (1.19 class of medication preop. *vs* 0.81 class of medication at 3mo postop., P=0.11; Figure 6).

MD remained stable at 3mo postop. (-2.54 dB preop. *vs* -1.16 dB at 3mo, P=0.36). There were 19 out of the available 35 eyes with 3-month post-operative visual field testing that had an improvement in MD at 3mo (mean change in MD 4.03±4.43dB, 16 eyes who had worsened MD (mean change in MD -2.85±0.94 dB), and 4 eyes with no change in MD (<1 dB change). A subanalysis of visual disturbances in patients with a decreased MD at 3mo did not show a significantly higher incidence of dysphotopsias (P>0.05). In those with a lower MD at 3mo, there was no significant difference noted in the

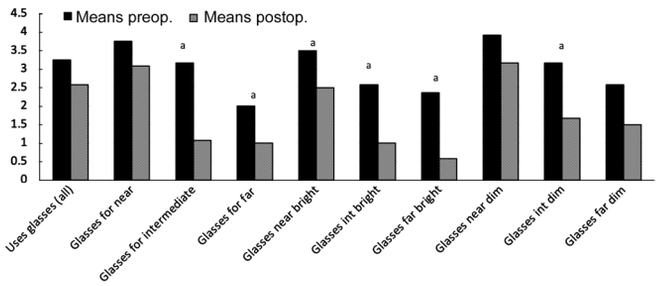

Figure 4 Need for glasses for near, intermediate and distance vision under bright or dim lighting using the IOLSAT questionnaire The need for glasses at all distances, regardless of the lighting, was improved post-operatively. The most significant improvements were for near, intermediate and distance vision under bright lighting, with improved intermediate vision under dim lighting as well. Score 0-4 for the frequency of need for glasses, 0: never, 1: rarely, 2: sometimes, 3: most of the time, 4: always. [a]Statistical significance (P<0.05).

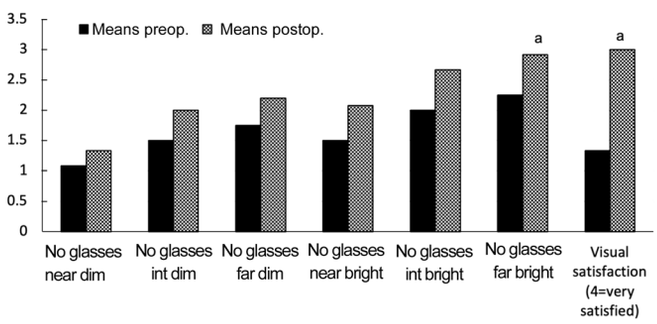

Figure 5 Mean IOLSAT (Intraocular lens satisfaction) questionnaire scores preop. and postop. with EDOF (extended depth of focus) lens Scores 1-4: 1: poor vision, 5: excellent vision. In general, there is a non-significant trend in improvement of quality of vision without glasses at 3mo at all distances in bright or dim light. There is a significant improvement in spectacle-free distance vision noted by patients. Overall, patients were much more satisfied with their vision post-operatively. [a]Statistical significance (P<0.05).

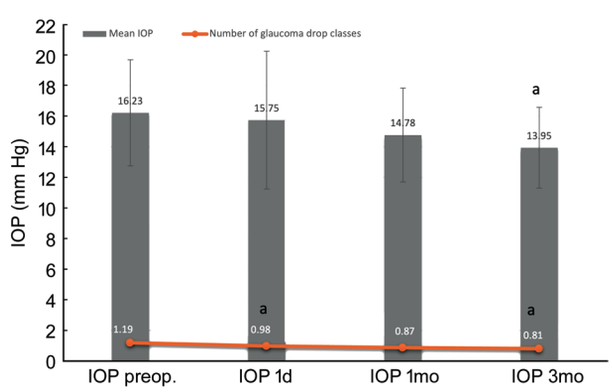

Figure 6 Intraocular pressure (IOP) and number of glaucoma drops at 1d, 1 and 3mo postop. IOP was significantly reduced at 3mo postop., and the number of glaucoma medications is significantly reduced at 3mo as well. [a]Statistical significance (P<0.05).

percentage of patients with spectacle independence at various distances under bright or dim lighting (P>0.05). Patients with a lower 3-month MD had a higher median number of glaucoma

drops pre-operatively and at 3mo than those who did not have a reduced MD (3 *vs* 1 class of drops, respectively). Three out of the 12 patients (25%) had developed posterior capsular opacification around the time of post-operative visual field testing. PSD was also stable at 3mo postop. (mean 4.46 3mo *vs* 4.45 preop., *P*=0.96). Visual field index was not available on the Octopus visual field. SE changed significantly closer to plano at 3mo postop. (-1.13 preop. *vs* -0.33 postop., *P*=0.04).

DISCUSSION

This is the first study looking at the visual outcomes and subjective dysphotopsias of patients with OHT or early glaucoma after cataract surgery with any EDOF lens in a Canadian cohort using validated questionnaires. The VA are consistent with previous studies that showed improved UCIVA in non-diffractive EDOF lenses without sacrificing distance VA in healthy eyes[7-9]. In a study examining patients with concurrent eye disease including 4 eyes with glaucoma who have received a diffractive EDOF lens, it was also reported that UDVA and UCIVA improved, with a nonsignificant trend for near vision improvement[16]. The slightly myopic SE that we aim for (-0.33), as well as a mini-monovision approach in adequate patients also aids in improving UCNVA[17]. We have a similar near VA that is reported in the FDA report of the EDOF lens in question[12].

It has been well-described that glaucomatous optic neuropathy negatively affects low-luminance and contrast sensitivity, glare symptoms and dark-adaptation time and extent[18]. Multifocal lenses were also found to perform less well in dim lighting in patients with glaucomatous optic neuropathy than monofocal lenses[19], and cause reduced contrast sensitivity in dim light[20]. Per the FDA safety and effectiveness data for the Vivity IOL, healthy patients with the Vivity IOL demonstrated one line reduced distance VA compared to the monofocal lens in both 10% and 25% contrast testing conditions[12]. However, there was a gain of at least one line in near VA and up to 3 lines in intermediate VA compared to the monofocal lens[12]. Although we did not compare EDOF to monofocal lenses, our cohort reported improved spectacle independence at all distances in bright light, even for near vision. Furthermore, patients did not complain of poorer distance vision in dim settings with a non-diffractive EDOF lens. Although our cohort includes several OHT patients with minimal or no signs of optic neuropathy, the subjectively improved intermediate vision in dim lighting suggests favourable outcomes for spectacle-independent vision even in settings of low illumination. Kerr *et al*[21] explored this initial finding in a prospective, comparative study of the Vivity and monofocal IOLs in patients with early glaucoma. They found significantly better spectacle independence and patient satisfaction with the non-diffractive EDOF lens compared to the monofocal lens, with improved intermediate and near vision in the non-diffractive EDOF lens. Contrary to the FDA report, Kerr *et al*'s[21] study did not report a significant difference in UCDVA in both the non-diffractive EDOF and monofocal IOLs (logMAR 0.12±0.15 *vs* 0.10±0.13 respectively, *P*=0.602). In our cohort, we have obtained an UDVA of 0.02 logMAR at 3mo, which is better than that reported in Kerr *et al*'s[21] monofocal group (although with no *P*-value analysis). Ferguson *et al*[9] also described a favourable preservation of contrast sensitivity of Vivity IOLs at a score of 1.78 on the Pelli-Robson chart, comparable to that reported in monofocal IOLs which ranges from 1.6 to 1.7, also in a cohort of patients with mild glaucoma. Our UDVA, UCIVA and UVNVA are also comparable or better than those reported by Ferguson *et al*[9]. One study showed minimal influence of diffractive EDOF lenses on the foveal threshold of Humphrey visual fields in healthy patients, and no difference when comparing the difference in the foveal threshold to that of monofocal lenses[22]. A more recent study by Bissen-Miyakima *et al*[23] also confirmed the non-inferiority of a diffractive EDOF IOL (ZXR00V, J&J) to monofocal IOLs in CDVA and photopic contrast sensitivity at 3, 6, 12 and 18 cycles per degree (cpd) even in patients with mild to moderate primary OAG. In sum, our findings are in line with these recent reports of favourable visual function with the Vivity lens in patients with mild visual field defects due to glaucoma, with comparable endpoint VA than those reported in the literature.

Additionally, in our cohort, patients with a reduced MD at 3mo did not show any significant difference in spectacle independence. Although the change in MD in these patients were small, it did not incur a deterioration in quality of vision in different lighting and distances at 3mo, and this was also true in eyes without glaucomatous damage (OHT). Interestingly, patients with a lower MD at 3mo had better mean pre-operative MD than those in whom MD did not progress, and hence could not support the hypothesis that the progression was due to a more advanced or uncontrolled disease in these patients. Overall, our findings support previous reports that these lenses as an interesting option for early glaucoma patients who want more spectacle independence without sacrificing contrast sensitivity, and prove to be reassuring for OHT patients as well.

Visual disturbances were also examined in our study using the QUVID questionnaire. Glaucoma patients experience more visually debilitating symptoms such as glare, and are increasingly disturbed by them as visual field deficits progress[24-25]. Objective and subjective VA is further reduced in patients with glaucoma in the presence of glare, with significant impact on their daily function and independence[26]. In our cohort, patients experienced less glare with the non-diffractive EDOF lens post-operatively and were less bothered

by it. Sánchez-Sánchez *et al*[27] found that healthy patients or pre-perimetric glaucoma patients implanted with a multifocal lens experience more halos but less glare than the established glaucoma and macular degeneration patients. In our patients with the non-diffractive EDOF lens, both symptoms seem to be controlled post-operatively, with less glare and a similar frequency of halos. As expected, blurred vision was improved after cataract surgery as well. Interestingly, patients reported more hazy vision after cataract surgery. Although this complaint did not have a negative impact on objective and subjective VA, a comparative study with monofocal or multifocal lenses could be warranted to examine this symptom in more detail. Postoperative negative dysphotopsias was comparable to rates previously published in literature (up to 42%) with around 15% of patients reporting them post-operatively at 3mo[28-29].

There was no comparative arm with either monofocal or multifocal lenses in glaucoma patients. Therefore, we are unable to compare the visual performance of patients with a non-diffractive EDOF to the other lenses in a prospective manner. Some eyes had OHT and thus no significant glaucomatous optic nerve damage that could have negatively affected visual outcomes with the EDOF lens. However, it was still interesting to look at specifically eyes with a reduction in MD and to note no significant deviations in visual outcomes and rate of dysphotopsias from the general cohort. Contrast sensitivity and point-wise perimetry were not assessed. MD was used as the control for any generalized decrease in visual field loss or decreased light stimulus sensitivity due to decreased contrast sensitivity, but may not uncover subtle changes in specific locations on the visual field. However, the lack of significant change in PSD and the relative low values are reassuring in confirming the stability of the visual field testing, and the mild visual field deficits expected in our cohort[30]. The follow-up of 3mo as the last endpoint may also limit the time for neuroadaptation to occur for the reported visual disturbances, as many dysphotopsias are expected to diminish and become insignificant in the first post-operative year[29]. Finally, there was loss of follow-up in several patients due to the COVID-19 pandemic which interrupted regular post-operative follow-up and administration of questionnaires, hence the decreasing number of responses retained at the 3-month follow-up. Longer follow-up duration is needed to assess if visual performance remains stable over time in patients with a chronic disease.

In conclusion, the present study highlights non-diffractive EDOF lenses as an option to improve spectacle independence for individuals with OHT or early glaucoma in the short term. Notably, patients experience significant improvements in spectacle-free distance and intermediate vision, as well as more spectacle independence at near, addressing critical visual needs for daily activities. We suggest aiming slightly myopic (-0.3 to -0.5 SE) with these lenses to aid in improving UCNVA vision. Improved VA in dim lighting with the non-diffractive EDOF lens in glaucoma patients also suggests a stable contrast sensitivity and underscores potential improvement in quality of life under various real-life conditions. Importantly, the acceptable dysphotopsia profile and notable reduction in glare emphasizes the potential of non-diffractive EDOF lenses in enhancing the overall visual experience for individuals with mild, well controlled glaucoma. These findings support the rationale for considering EDOF lenses as a valuable addition to the armamentarium for answering to increasing visual needs in patients with OHT or mild glaucoma. The positive patient satisfaction reported across various studies further supports the notion that EDOF lenses are well-tolerated and meet the visual expectations of individuals in this population.

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