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ORIGINAL RESEARCH

Extended Depth-of-Focus Intraocular Lens Implantation in Patients with Age-Related Macular Degeneration: A Pilot Study

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Purpose: To assess visual outcomes of the implantation of a non-diffractive extended depth of focus (EDOF) intraocular lens (IOL) in patients with age-related macular degeneration (AMD).

Setting: Ophthalmology practice, Sydney, Australia.

Design: Retrospective chart review.

Methods: Patients with AMD undergoing cataract surgery and receiving non-diffractive EDOF AcrySof IQ Vivity IOL implantation over a 2-year period were identified. Corrected distance visual acuity (CDVA), distance-corrected near visual acuity (DCNVA; 50 cm), contrast sensitivity, central foveal thickness, VF-14 questionnaire results, and quality of life where available were analyzed.

Results: A total of 28 sequential patients (51 eyes) were included in this pilot study (46% male, mean age 77.4 years). Of 27 eyes that had late AMD, 17 (63%) had wet AMD. Mean patient preoperative CDVA was logMAR 0.32±0.29. Postoperative monocular CDVA and DCNVA were logMAR 0.20±0.25 and N9±5 (range N5–N36), respectively. Eyes achieving postoperative CDVA of Snellen 6/5–6/12 (n=42, 82%), 6/15–6/24 (n=7, 14%), and greater than 6/24 (n=2, 4%) achieved a mean DCNVA of N8 (range N5–N10), N13 (range N10–N18), and N27 (range N18–N36), respectively. Eyes achieving CDVA of Snellen 6/5–6/12 showed contrast sensitivity within the normal range. On postoperative VF-14 questionnaire, patients with CDVA of Snellen 6/5–6/12 reported minimal visual impairment, while patients with CDVA greater than 6/15 reported mild impairment. A majority of patients (96%, n=27) were satisfied with the improvement in quality of life postoperatively. No intraoperative complications were reported.

Conclusion: The EDOF AcrySof IQ Vivity IOL provides improved near vision proportional to distance vision in patients with early AMD.

Keywords: age-related macular degeneration, cataract, intraocular lens, extended depth of focus, non-diffractive

Introduction

Age-related macular degeneration (AMD) and cataract contribute significantly to the burden of global vision impairment.[1] With newer advances in imaging modalities, the coexistence of both pathologies in patients has been increasingly identified, with one study reporting 50% of standard cataract patients having AMD.[2] Although cataract extraction and intraocular lens (IOL) implantation can reduce visual impairment, there is significant reluctance in offering presbyopia-correcting IOLs to patients with AMD. Furthermore, consideration must be given to the possibility of patients developing AMD years after implanting presbyopia-correcting IOLs.

In patients with normal retinae, multifocal IOLs, such as diffractive trifocal IOLs, have been found to be effective for near, intermediate, and distance vision, but are associated in a subset of patients with dysphotopsia.[3] Several trials have documented a reduction in contrast sensitivity and increase in optical aberration.[4,5] In patients with compromised retinal function, such as those with AMD, multifocal IOLs may further reduce contrast sensitivity to an unacceptable level, and are felt by some to be relatively contraindicated. Others have reported a benefit of multifocal IOL implantation in a subset of patients with AMD and have proposed its use as a low-vision aid.[6–8] Nevertheless, careful consideration must be taken when considering multifocal IOLs in AMD patients.

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Extended depth of focus (EDOF) IOLs have been proposed to cause less reduction in contrast sensitivity than diffractive IOLs while maintaining a larger range of spectacle-free vision than monofocal IOLs. The AcrySof IQ Vivity IOL (Alcon) is a non-diffractive presbyopia-mitigating EDOF IOL that has been reported to produce comparable distance vision and better intermediate and near vision compared to monofocal IOLs.[9] Some spectacle dependence has been reported for near vision; however, the degree of independence is greater than that of monofocal IOLs.[9–11] The AcrySof IQ Vivity IOL, being non diffractive, appears to have a similar dysphotopsia profile to monofocal IOLs and lower rates of dysphotopsia and higher patient satisfaction than diffractive multifocal IOLs.[9,11] Additionally, no clinically significant difference in contrast sensitivity has been observed between it and monofocal IOLs.[9] By providing a range of spectacle-free vision while preserving contrast sensitivity, the non-diffractive EDOF IOL may be a promising option for patients with AMD.

No evidence currently exists on outcomes of the AcrySof IQ Vivity EDOF IOL in the AMD population. We aimed to assess postoperative functional monocular visual outcomes, including corrected distance visual acuity (CDVA) and distance-corrected near visual acuity (DCNVA) at 50 cm and contrast sensitivity post implantation of the AcrySof IQ Vivity EDOF IOL in eyes with AMD. Secondary outcomes included postoperative quality of life in patients and assessment for a relationship between central foveal retinal thickness and CDVA in eyes with AMD.

Methods

A retrospective review was performed of patients who had clinically diagnosed AMD (early, intermediate, or late) with age-related cataract and had undergone lens extraction and AcrySof IQ Vivity IOL implantation from June 2020 to December 2022 at an ophthalmology center in Sydney, Australia as part of their routine care. AMD patients receiving AcrySof IQ Vivity IOLs during cataract surgery were included. Ethics approval for this study was granted by an external human research ethics committee (Bellberry Limited). This study met the requirements of the National Statement on Ethical Conduct in Human Research (2007) and complied with the principles of the Declaration of Helsinki. A waiver of consent was granted by the institutional review board for this retrospective review, and all data were deidentified and kept confidential.

Medical records of patients were reviewed to obtain relevant data for visual outcomes and demographics. DCNVA was routinely recorded at 50 cm using Times New Roman near-vision charts on postoperative follow-up visits. Postoperative distance-corrected contrast sensitivity (CS) was measured in clinics on Frey CP-400 charts (Frey Medical, Piaseczno) in photopic conditions. Values were measured at spatial frequencies of 1.5, 3, 6, 12, and 18 cycles per degree. Using SD-OCT imaging results and medical records, eyes were clinically classified according to the Beckman clinical classification for AMD.[12] Images from SD-OCT were taken from either a Heidelberg Spectralis HRA+OCT (Heidelberg Engineering Inc, Franklin, MA) or Cirrus HD-OCT 500 (Carl Zeiss Meditec, Dublin, CA). Eyes were additionally classified byy visual impairment according to postoperative CDVA into groups including CDVA Snellen 6/5–6/12 (early), 6/15–6/24 (intermediate) and greater than 6/24 (late). These groups were then used to compare postoperative DCNVA outcomes.

Central foveal thickness was manually measured and averaged using the horizontal slice representative of the fovea on SD-OCT. From the center most foveal point, five points 100 μm apart nasally and temporally were identified and used to measure retinal and outer nuclear layer thicknesses on ImageJ (United States National Institutes of Health). These points were averaged to obtain the mean thickness within 1 mm diameter from the centermost point of the fovea to represent central foveal thickness. Microsoft Excel (Microsoft, Redmond, WA) and GraphPad Prism 8 (GraphPad Software, San Diego, CA) were used for statistical analysis and production of figures. Simple linear regression was used to assess the relationship between ONL or central retinal thickness with Snellen CDVA.

Results

Study Population

The study population of 28 patients (51 eyes) had a mean age of 77.4±8.2 years and was 46% male (n=13). Among these eyes, 7 (14%) had early-, 17 (33%) had intermediate-, and 27 (53%) had late-stage AMD based on Beckman clinical classification (Table 1). Of eyes with late AMD, 17 (63%) had wet AMD. Mean patient preoperative monocular CDVA for the study population was logMAR 0.32±0.29 (Table 2). No intraoperative complications were reported in this study population during IOL implantation. One eye developed a posterior vitreous detachment postoperatively.

Table 1 Cohort

Demographics	
Patients, n	28
Eyes, n	51
Age (years), mean ± SD	77.4±8.2
Sex	
Male, n (%)	13 (46)
Comorbidities	
Hypertension, n (%)	13 (46)
Diabetes, n (%)	5 (18)
Clinical classification of AMD for each eye	
Early, n (%)	7 (14)
Intermediate, n (%)	17 (33)
Late, n (%)	27 (53)

Abbreviation: AMD, age-related macular degeneration.

Table 2 Visual acuity postoperative outcomes

Mean visual acuity of all eyes ± SD, range			
Preoperative CDVA		LogMAR 0.32±0.29 (Snellen 6/5–6/150)	
Postoperative CDVA		LogMAR 0.20±0.25 (Snellen 6/5–6/150)	
Postoperative DCNVA		N9±5 (N5–N36)	
Eyes by preoperative Snellen CDVA, n (%)			
6/5–6/12		35 (69)	
6/15–6/24		9 (18)	
>6/24		7 (14)	
Eyes by postoperative Snellen CDVA, n (%)			
6/5–6/12		42 (82)	
6/15–6/24		7 (14)	
>6/24		2 (4)	
Postoperative outcomes categorized by Snellen CDVA			
CDVA range	**6/5–6/12**	**6/15–6/24**	**>6/24**
Postoperative CDVA (mean ± SD)	LogMAR 0.11±0.12	LogMAR 0.46±0.09	LogMAR 1.10±0.42
Postoperative DCNVA (mean ± SD, range)	N8±2 (N5–N10)	N13±3 (N10–N18)	N27±13 (N18–N36)
Postoperative outcomes categorized by clinical AMD classification			
CDVA Range	**Early**	**Intermediate**	**Late**
Postoperative CDVA (mean ± SD)	LogMAR 0.00±0.09	LogMAR 0.14±0.12	LogMAR 0.29±0.30
Postoperative DCNVA (mean ± SD, range)	N7±2 (N6-10)	N8±2 (N5–N10)	N11±6 (N5-36)

Abbreviations: AMD, age-related macular degeneration; CDVA, corrected distance visual acuity; DCNVA, distance-corrected near visual acuity.

Visual Acuity

Postoperative monocular CDVA and DCNVA in the study population was logMAR 0.20±0.25 and N9 (range N5–N36), respectively (Table 2). A majority of eyes achieved a CDVA of Snellen 6/7–6/12 and DCNVA of Times New Roman N8–N10 (Figure 1). Eyes achieving postoperative CDVA of Snellen 6/5–6/12 (n=42, 82%), 6/15–6/24 (n=7, 14%), and

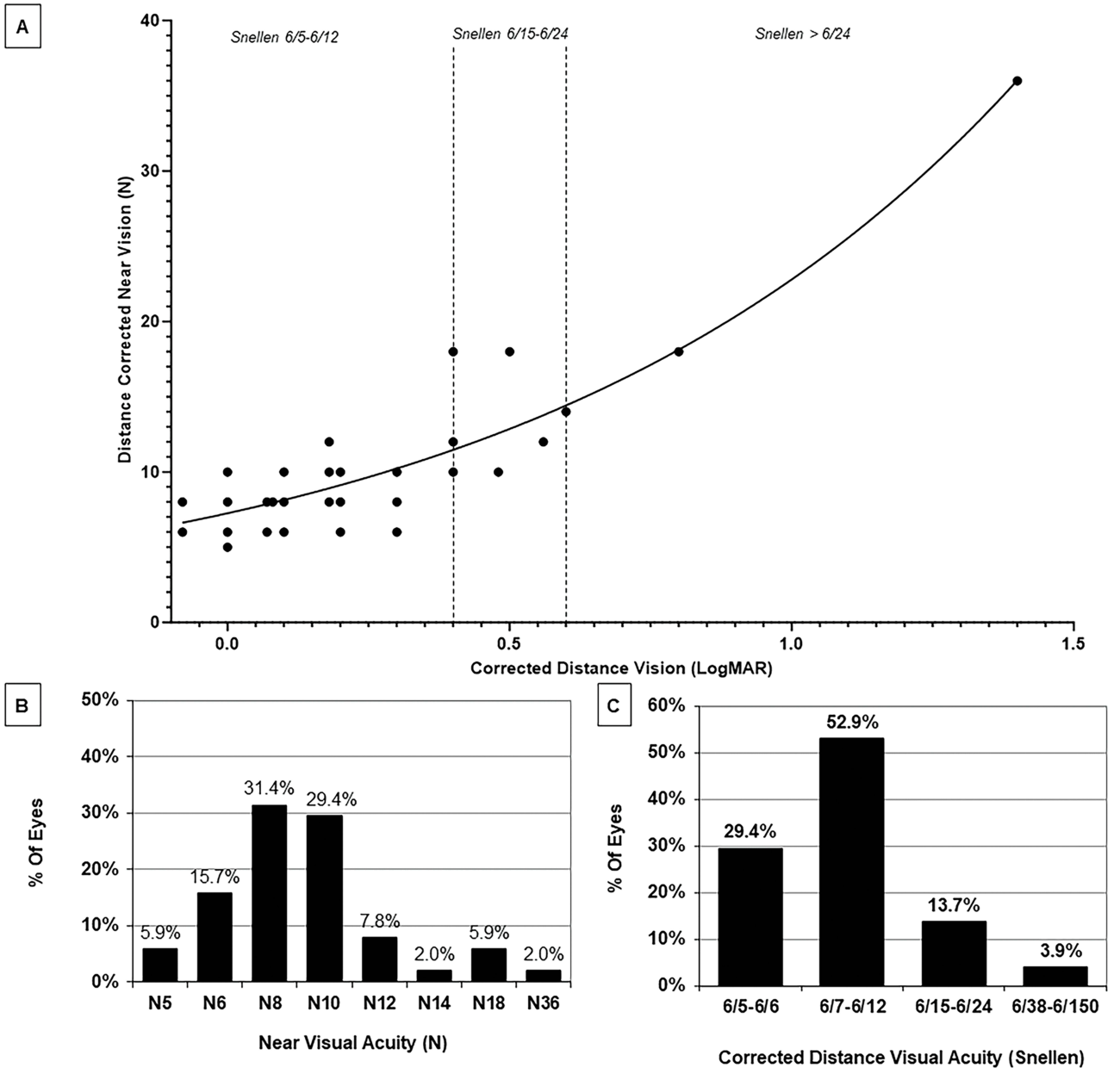

Figure 1 Visual performance following AcrySof IQ Vivity IOL implantation. (**A**) Monocular corrected distance visual acuity (CDVA) vs distance-corrected near visual acuity (DCNVA) with best-fit line (R^2=0.83) (n=51). Dashed lines represent Snellen 6/15 and 6/24. (**B**) Distribution of postoperative DCNVA. (**C**) Distribution of postoperative CDVA.

greater than 6/24 (n=2, 4%) achieved a mean DCNVA of N8 (N5–N10), N13 (N10–N18) and N27 (N18–N36), respectively. Better DCNVA was observed in eyes with better CDVA (Figure 1). A significant improvement in CDVA was observed in eyes achieving Snellen 6/5–6/12 compared to preoperative CDVA (preoperative logMAR 0.28±0.24 and postoperative logMAR 0.11±0.12, *t*-test $p<0.0001$). Change in CDVA in eyes achieving a Snellen CDVA of 6/15–6/24 and greater than Snellen 6/24 was insignificant (*t*-test $p=0.32$ and $p=0.99$ respectively). When comparing postoperative outcomes of eyes between clinically classified AMD groups, eyes with early AMD had the best mean postoperative CDVA and DCNVA (Table 2). Mean and range of DCNVA were higher in the clinically late AMD group than the early and intermediate groups. Eyes with wet AMD and dry AMD had a mean CDVA of logMAR 0.17±0.17 and logMAR 0.50 ±0.37 and DCNVA of N9 (N5–N18) and N15 (N10-N36), respectively.

Contrast Sensitivity

Postoperative monocular distance-corrected contrast sensitivity was reported in 33 eyes. Eyes with postoperative CDVA of Snellen 6/5–6/12 had contrast sensitivity at the lower end of the normal range (Figure 2). Eyes with CDVA of 6/15–6/24 and greater than 6/24 had reduced contrast sensitivity below normal. Reduction was more observed at higher spatial frequencies.

Quality of Life

On routine postoperative administration of the VF-14 questionnaire (n=25), which assesses level of visual impairment, a significant difference was found between groups with CDVA Snellen 6/5–6/12, 6/15–6/24, and greater than 6/24 (one-way ANOVA p=0.003). Patients with postoperative CDVA of Snellen 6/5–6/12 fell within the minimal functional visual impairment category (VF-14 questionnaire 0.96±0.04), while patients with Snellen 6/15–6/24 and greater than 6/24 reported mild impairment (0.92±0.09 and 0.75±0, respectively).

On further chart assessment, 100% of patients (n=28) reported improvement in daily activities postoperatively. A majority of patients (75%, n=21) did not report symptoms of dysphotopsia on routine clinical follow-up visits. No patients reported dysphotopsia to be a limiting factor in daily activities, and 96% (n=27) were satisfied post-IOL implantation with quality of life and the degree of spectacle independence they achieved, with primary spectacles use being for fine near-vision tasks. One patient achieving a CDVA of Snellen >6/24 reported limited satisfaction due to persistent spectacle dependence for distance and near vision and minimal improvement in activities of daily living.

Retinal Thickness

Linear regression showed no relationship between central retinal thickness and CDVA (r^2=0.00007, p=0.96).

Discussion

Non-diffractive EDOF IOLs function by creating an elongated focal point, allowing for an enhanced depth of field, which is in contrast to monofocal and multifocal IOLs, which focus light on one or more discrete points.[13] The AcrySof IQ Vivity IOL uses wavefront-shaping technology to shape and stretch the wavefront using two smooth-surface transition elements to deliver an extended focal range.[9] By creating a continuous range of vision and eliminating the overlap caused

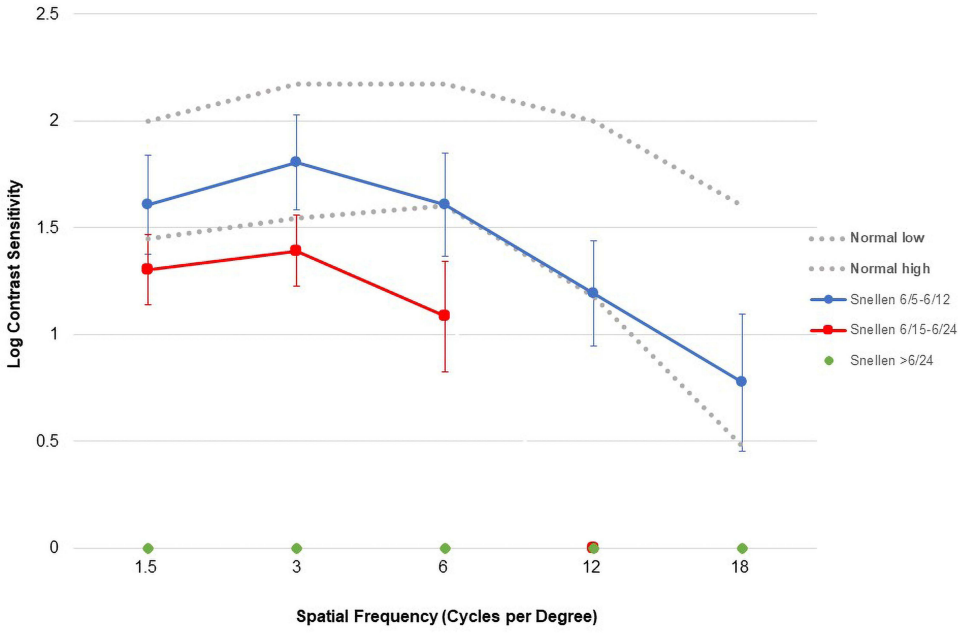

Figure 2 Monocular distance -corrected log contrast sensitivity vs spatial frequency with standard deviation error bars. (n=33).

by near and far focal points, the EDOF lens is thought to provide optimal near, intermediate, and distance vision while reducing dysphotopsia.[13] The AcrySof IQ Vivity EDOF IOL has been shown to produce comparable retinal optical image quality to monofocal IOLs and to be less influenced by residual refractive error than trifocal IOLs.[14]

Multifocal focal IOLs implanted in patients with concurrent retinal disease, including AMD, have been reported to achieve greater subjective satisfaction, with a significantly higher number of eyes achieving an CDVA of 6/12 or better and DCNVA of N8 or better compared to monofocal IOLs.[15] However, dysphotopsia secondary to diffractive multifocal IOLs is a general concern in the ophthalmic population. A pilot study by Gayton et al[7] showed overall improvement in near and distance vision in patients with AMD post–AcrySof Restor SN60D3 multifocal IOL implantation. While patient questionnaires showed improvement in overall vision, they showed insignificant improvement in performance of near-vision tasks, driving, and limitation in social functioning. Kamath et al[16] reported outcomes of multifocal IOLs and monofocal IOLs in eyes with concurrent retinal diseases, including AMD, and showed comparable distance vision and superior distance-corrected near vision post–multifocal IOL implantation. However, symptoms of dysphotopsia were reported in the multifocal group. In our study, 82% of eyes achieved a Snellen CDVA of 6/5–6/12 and a near VA of N5–N10 with the AcrySof IQ Vivity EDOF IOL. These eyes not unexpectedly achieved better DCNVA proportional to their CDVA. Functional near visual acuity is equivalent to no less than N8–N10 in a normal population, with newspapers, directories and magazines being between N8 and N9.[17] In our study, all eyes with clinically classified early and intermediate AMD were able to achieve functional near visual acuity. A minimum of Snellen distance VA of 6/12 must be achieved to maintain a driver's license. Eyes with clinically early and intermediate AMD in our study achieved a mean CDVA that met this requirement. Eyes with clinically late AMD showed a larger spread of CDVA and DCNVA. This may be due to larger variability in visual impairment with progression of disease and/or secondary to anti-VEGF therapy in eyes with wet AMD. Visual outcomes of anti-VEGF therapy on eyes with AMD are known to be variable and influenced by factors including pretreatment visual acuity, age, and extent of choroidal neovascularization.[18] When comparing eyes with wet and dry late AMD in our study, eyes with wet AMD had better postoperative CDVA and DCNVA.

In eyes with intermediate levels of visual impairment, the AcrySof IQ Vivity IOL was able to achieve satisfactory near vision of up to N12–N14 in patients with CDVA Snellen 6/15–6/24. In this subgroup, the near-vision addition of 1.5 D can be further augmented with the use of spectacle addition to improve near-vision ability. Low-vision aids and rehabilitation programs can utilize the +1.5 D to improve vision, reading speed, and quality of life in patients with AMD.[19,20] In patients with later stages of AMD with significant visual impairment achieving CDVA worse than 6/24, the near-vision benefit from the EDOF IOL not unexpectedly declines.

AMD is characterized by central loss of vision, and to implant monofocal IOLs that project light at the one place where there are no photoceptors appears illogical. However, the implantation of presbyopia-correcting IOLs should not adversely jeopardize the diminishing vision by reducing contrast and quality of life. Contrast sensitivity in patients with AMD has been shown to be reduced, with a peak shift toward lower spatial frequencies and increased reduction at higher spatial frequencies.[21,22] In our study, patients achieving satisfactory vision of Snellen 6/5–6/12 achieved contrast sensitivity within the low-normal range. Lower contrast sensitivity was found in patients with later stages of AMD who had worse CDVA. With progressive macular destruction in AMD, patients have to rely on eccentric viewing. With increasing eccentricity, both contrast sensitivity and visual acuity decrease. This is similar to the results in this study, and suggests that our contrast sensitivity results showed a reduction pattern primarily due to AMD rather than IOL implantation. Diffractive EDOF IOLs have been reported to have reduced contrast sensitivity, particularly at higher spatial frequencies and mesopic conditions, as compared to monofocal IOLs.[23] Non-diffractive EDOF IOLs such as AcrySof IQ Vivity IOL have shown no clinically significant reduction in contrast sensitivity in the normal population.[9] To our knowledge, no literature exists reporting contrast sensitivity after AcrySof IQ Vivity IOL implantation in patients with AMD. The comparability of our contrast-sensitivity results to other IOLs in this patient population is limited. The present study only examined photopic contrast sensitivity, which showed a reduction likely from the AMD rather than the IOL, as evidenced by the normal results in early AMD.

All patients in our study reported improvement in daily activities post-IOL implantation. Patients with Snellen 6/5–6/12 reported satisfactory near vision for general task performance, such as reading traffic signs, playing games, cooking, and recognizing faces, with patients requiring spectacles for fine-reading tasks on routine VF-14 questionnaires. This is

similar to previous data by Hovanesian et al[11], who reported most spectacle use to be for near-vision activities with this IOL. Patients with Snellen 6/12–6/24 were satisfied with postoperative vision and reported mild visual impairment. Patients achieving worse than 6/24 vision reported the least satisfaction with postoperative vision. Low satisfaction reported in this group is likely due to limited improvement in both distance and near vision. The lack of literature reporting monofocal VF-14 quality-of-life outcomes in patients with AMD makes comparison of our data limited.

Limitations of our study include the lack of a control group and randomization. Furthermore, contrast-sensitivity data were not available for mesopic conditions. The spread of our study population represents a wide-ranging cohort of patients who range from early AMD to wet neovascular AMD requiring regular anti-VEGF injections. The data, however, represent real-world outcomes and experiences. There is a predominance of early-AMD patients, and it is ethically appropriate that they be given a presbyopia-mitigating IOL so that they may take advantage of it. Questionnaires represent experiences from an individual perspective, and so the picture is mixed when the vision is presented for the eye. This can be addressed in a single-eye study but perhaps may not be appropriate in a cohort that who need all the functional retinae they have to function. The present study is an exploratory chart review of EDOF IOL implantation in patients with AMD that may help to provide generic guidelines on who may and may not benefit from the implantation of this lens, as well as whether any harm is done. Further studies to assess uncorrected visual acuity (near, intermediate, and distance) as well as spectacle independence in the AMD population may be of benefit to guide clinical decision-making.

In summary, the non-diffractive AcrySof IQ Vivity EDOF IOL provides a range of spectacle-free vision in the AMD population. It adds satisfactory near and intermediate range of vision to patients with early AMD that would not otherwise be achieved with monofocal IOL implantation. Eyes with early AMD are able to maintain a contrast sensitivity within the normal range, suggesting that implantation of this IOL is worthwhile in eyes with early AMD. In intermediate stages of visual impairment, benefits of this IOL may be augmented with near-addition and low-vision aids. Visual benefits of multifocality reduce significantly in eyes with loss of CDVA greater than 6/24. No reduction in daily living was reported in any group postoperatively. If retinal disease were to progress in eyes with early AMD that have undergone non-diffractive EDOF IOL implantation, there will be a loss of effectiveness, but no harm. The AcrySof IQ Vivity IOL should be considered in clinical practice for patients with AMD to allow them to achieve the benefits of multifocality that patients without AMD are achieving while preserving contrast sensitivity.

Conclusion

The is the first study to report outcomes of the non-diffractive EDOF IOL in patients with AMD. The non-diffractive EDOF IOL is safe and provides a satisfactory range of vision in patients with early AMD while maintaining a degree of contrast sensitivity.

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Disclosure

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