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CLINICAL TRIAL REPORT

Outcomes of Bilateral Implantation of a New Aspheric Hydrophobic Non-Diffractive Extended Depth of Focus IOL with a Mini-Monovision Approach

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Purpose: To evaluate binocular distance-target corrected (DC) near vision in patients having bilateral implantation of Clareon Vivity and Clareon Vivity Toric IOLs (Alcon Vision, LLC) targeted for mini-monovision, with the dominant eye set at emmetropia and the non-dominant eye at −0.50 D.

Patients and Methods: A prospective, unmasked single-armed observational study of 25 adult patients undergoing bilateral Clareon Vivity IOL with mini-monovision. Binocular uncorrected (U) and DC visual acuity (VA) at distance (6 m), intermediate (66 cm), and near (40 cm); mean refractive spherical equivalent (MRSE) for each eye and difference between contralateral eyes; binocular uncorrected reading performance using MNRead; and patient reported outcomes using the PRO Questionnaire (Research Insight, LLC) were collected at 3 months postoperatively. The primary outcome was proportion of subjects achieving DCNVA 20/32 or better.

Results: Mean MRSE was −0.17 and −0.49 D for dominant and non-dominant eyes at 3 months. 88% of subjects met the primary endpoint of DCNVA ≥ 20/32. MNRead testing showed a mean reading acuity of 0.12 logMAR, critical print size of 0.31 logMAR, and maximum reading speed of 144.78 wpm. 87.5% of subjects had little to no visual disturbances. 66.7% of patients reported occasional to no use of reading glasses. 95.8% patients were satisfied with their vision after surgery.

Conclusion: Bilateral implantation of Clareon Vivity lenses with a mini-monovision approach achieved good visual performance with low levels of visual disturbances and a high level of patient satisfaction. The majority of subjects were spectacle independent and reading performance was near normal for their age without correction.

Keywords: EDOF, vivity, mini-monovision, reading

Introduction

Non-diffractive extended depth of focus (EDOF) intraocular lenses (IOLs) represent a significant advancement in cataract surgery, improving range of vision compared to monofocal IOLs with generally less impact on quality of vision compared to diffractive multifocal IOLs.[1–3] Vivity (Alcon Vision, LLC) is an EDOF IOL that utilizes non-diffractive wave-shaping technology to provide a continuous elongated focus, rather than multiple discrete focal points. This design helps to minimize common issues associated with multifocal lenses, such as glare and halos.[1–3]

Originally approved by the FDA in 2020, Vivity was launched in a hydrophobic acrylic material called AcrySof. Since then, Alcon has introduced an improved hydrophobic acrylic material, Clareon, which offers lower levels of haze and subsurface nanoglistenings compared other IOLs.[4,5] In one study of AcrySof monofocal IOLs, 100% of IOLs had some degree of lenticular glistenings, including the earliest timepoint studied, 6–12 months postoperatively.[6] By contrast, studies of Clareon monofocal IOLs reported 0 to 4.7% of lenses with glistenings at 3 years of follow-up.[7,8] The lower

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prevalence of glistenings in Clareon lenses compared to AcrySof has been associated with better contrast sensitivity performance in multifocal lenses, and could affect the visual performance in Vivity IOLs.[9]

One of the limitations of EDOF IOLs compared to multifocal IOLs is that they often cannot achieve as much spectacle independence for near vision.[3] To improve near vision with EDOF IOLs, a common approach is mini-monovision, targeting one eye for distance and the other for a small amount of myopia. Multiple studies have examined the outcomes of a mini-monovision approach with Acrysoft Vivity IOLs, but not with Clareon Vivity IOLs.[10–16] Van Amelsfort et al reported good visual outcomes with higher rates of spectacle independence and fewer optical aberrations compared to FDA trial data.[10] Vasavada et al found mini-monovision outperformed bilateral emmetropia for binocular uncorrected near vision.[11]

This study aims to evaluate the visual and patient-reported outcomes following bilateral implantation of Clareon Vivity and Clareon Vivity Toric IOLs, with the dominant eye set at emmetropia and the non-dominant eye set at –0.50 D. The hypothesis is that mini-monovision with bilateral Clareon Vivity IOLs will provide functional binocular distance-target corrected (C) near vision of 20/32 or better for the majority of patients. We also measured binocular uncorrected reading performance using MNREAD, a continuous-text reading acuity test developed by the University of Minnesota and adapted for iPad use, which has not been previously evaluated in patients having Vivity IOLs with a mini-monovision approach.

Materials and Methods

This was a prospective, single-armed observational study approved by the Sutter Health Institutional Review Board (Reference Number: 2022.091EXP), compliant with HIPPAA regulation and adherent to the tenants of the Declaration of Helsinki. Written informed consent was obtained from participants prior to study commencement. The study was registered on clinicaltrials.gov (NCT05821101).

We enrolled 30 native or fluent English-speaking adult patients being treated at Palo Alto Medical Foundation with visually significant cataracts and otherwise healthy eyes receiving bilateral cataract surgery with Clareon Vivity and Clareon Vivity Toric IOLs, with refractive targets of plano in the dominant eye and −0.50 D in the non-dominant eye, to participate in the study. Eye dominance was determined by a Mile's test. A complete eye exam was performed and medical history reviewed to determine if patients had previous ocular or refractive surgery or ocular and systemic comorbidities that might alter or reduce visual acuity, contrast sensitivity, binocularity, or impaired reading performance, such as severe dry eye or ocular surface disease, irregular astigmatism, corneal dystrophy, pupil abnormalities, zonular laxity, glaucoma, macular degeneration, retinopathy, neuro-ophthalmic diseases, and strabismus/amblyopia. Only patients with potential best corrected distance visual acuity of 20/25 or better measured postoperatively in both eyes were included. Patients with intraoperative or postoperative complications were excluded from analysis.

Patients underwent bilateral sequential cataract surgery within 21 days. Small incision phacoemulsification was performed under topical anesthesia under monitored sedation by one of the two authors, who are experienced cataract surgeons. The implanted IOL power calculations were performed with an IOL Master 700 (Carl Zeiss Meditec AG, Jena, Germany) using the Barrett Universal-II and Barrett toric formulas. Toric lenses were considered for astigmatism ≥ 1 D, and limbal relaxing incisions were allowed for lower levels of astigmatism at the discretion of the surgeon. All cases were performed with ORA Intraoperative Aberrometry (Alcon Vision, LLC), a real-time measurement of the refractive power of the eye during cataract surgery, and adjustment of IOL power was allowed intraoperatively. The lens selected was the first minus lens closest to the intended refractive target. If a patient was significantly off target postoperatively, they were given the option to wear spectacles or undergo lens exchange after one-month postoperatively.

Study participants were followed through three months postoperatively. At one- and three-months following surgery, manifest refraction was performed and visual acuity was tested. Mean refractive spherical equivalent (MRSE) was calculated for each eye. Binocular uncorrected visual acuity for distance at 6 m (UDVA), intermediate at 66 cm (UIVA), and near at 40 cm (UNVA), and distance-target corrected (DC) binocular vision at the same focuses were measured. Distance visual acuity was measured using M&S Smart System (M&S Technologies, Niles, IL). Sloan ETDRS near and intermediate vision charts (Precision Vision, Woodstock, IL) were used. Average ambient illumination was 120 cd/m^2 measured with a 3251 Traceable Dual-Range Light Meter (Traceable Products, Webster, TX). At three-months

postoperatively, subjects underwent a binocular uncorrected reading performance test MNRead (University of Minnesota) on an iPad (9th Generation, Apple Inc) at 40 cm. The MNRead test adapted for iPad has been validated in native and fluent English-speaking patients.[17] This test measures reading speed as a function of print size and gives multiple measurements of reading performance: maximum reading speed is where the reading speed remains relatively constant in larger print sizes, critical print size is the print size after which reading speed decreases rapidly, reading acuity is the smallest print size that can be read.[18] Patient reported outcomes were assessed using the validated PRO Questionnaire (Research Insight, LLC) at 3 months.[3]

Descriptive statistics are presented and statistical analysis was performed with MedCalc Statistical Software (MedCalc Software, Ostend, Belgium). For MRSE, a paired *T*-test was used to results at the two timepoints. A one-sample *t*-test was also conducted compared to intended refractive target for each eye and the difference between eyes. For all *t*-tests, the data was found to follow a normal distribution by the Shapiro–Wilk test. $P < 0.05$ was considered statistically significant. Correlation between MNRead metrics and MRSE of each eye and difference between eyes was tested with Pearson's *r*. A post-hoc power calculation was performed for the primary endpoint, percentage of subjects with DCNVA 20/32 or better, compared to the population level in the FDA registration trial data (57.5%), and showed 95.6% power with alpha 0.05 to detect a difference.[19] A Fisher's exact test was used to compare proportions between groups.

Results

Thirty subjects were enrolled in the study, and 25 subjects were included in the analysis. Three patients withdrew from the study and two patients were excluded from analysis, one due to iritis with development of epiretinal membrane and one due to a change in IOL target for the second eye. One subject did not complete the PRO Questionnaire during the study period, but available data was included in analysis.

Baseline characteristics are shown in Table 1. The mean patient age was 69.0 ± 6.6 years. There were more females than males (19 vs 6, respectively) in the study. About half (48%) of the study subjects received a Clareon Vivity Toric in at least one eye and of these cases 50.0% (6/12) were bilateral. Two patients (8.0%) were treated with limbal relaxing incisions, one unilaterally and one bilaterally.

Mean MRSE was −0.17 ± 0.33 D (dominant eye) and −0.49 ± 0.34 D (non-dominant eye) with a −0.32 ± 0.30 D difference in eyes at 3 months postop. There were no significant differences between refractive results at 1 and 3 months postop (MRSE dominant eyes, 95% confidence interval −0.03 to 0.18, $p = 0.16$; MRSE non-dominant eyes, 95% confidence interval −0.14 to 0.14, $p = 1.0$). The difference between MRSE of dominant eyes and intended target was less than or equal 1.00 D in 100% (25/25) of subjects, 0.50 D in 88% (22/25) of subjects, and 0.25 D in 60% (15/25) of subjects (Figure 1). The difference between the MRSE of non-dominant eyes and intended target was less than or equal 1.00 D in 100% (25/25) of subjects, 0.50 D in 96% (24/25) of subjects, and 0.25 D in 68% (17/25) of subjects (Figure 1). At 3 months postop, MRSE of dominant eyes and difference in MRSE between eyes were significantly different from intended (dominant eyes, 95% confidence interval: −0.31 to −0.03, $p = 0.016$; difference in MRSE between eyes, 95% confidence interval: 0.06 to 0.031, $p = 0.006$), with more myopia in dominant eyes than intended, resulting in smaller differences in the amount of mini-monovision between eyes.

Table 1 Baseline Characteristics

	Mean ± SD or %
Age	69.0 ± 6.6 years
Sex *(F = 0, M = 1)*	24.0%
Axial Length *(Dominant Eye)*	24.36 ± 1.36 mm
Axial Length *(Non-dominant Eye)*	24.34 ± 1.31 mm
Average Cylinder *(Dominant Eye)*	0.87 ± 0.49 D
Average Cylinder *(Non-dominant Eye)*	0.91 ± 0.52 D
Toric in at least one eye	48.0%

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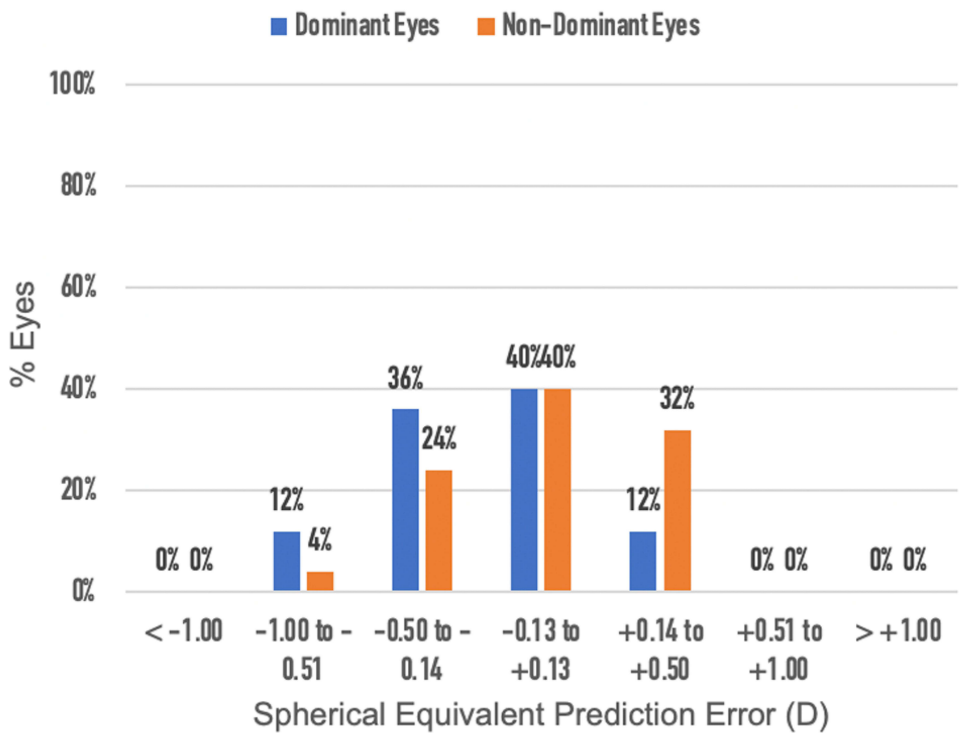

Figure 1 Spherical equivalent prediction error distribution. Percentage of eyes with specified ranges of deviation from intended target for dominant eyes (25 eyes with Plano target, blue bars) and non-dominant eyes (25 eyes with −0.50 D target, orange bars) at 3 months postoperatively are represented.

Mean corrected and uncorrected binocular visual acuity results at 3 months postoperatively are shown in Table 2. 88% of subjects met the primary end point of DCNVA ≥ 20/32 (Figure 2A). Additionally, 100% of subjects had DCIVA ≥ 20/32 and DCVA ≥ 20/25 (Figure 2B and C, respectively). UDVA was ≥ 20/25 in 88%, UIVA was ≥ 20/32 in 92%, and UNVA ≥ 20/32 in 48% of subjects (Figure 2).

Binocular reading performance was evaluated with the MNRead test administered on an iPad (Table 3). Reading acuity, the smallest resolvable print size without significant errors, was 0.12 ± 0.11 logMAR. There was a moderate correlation with reading acuity and MRSE of the dominant eye at 3 months postop (*r:* 0.46, $p = 0.02$) and a weak correlation between reading acuity and MRSE of the non-dominant eye at 3 months (*r*: 0.39) but this was not statistically significant ($p = 0.05$). Critical print size, the smallest print which patients could read at their maximum reading speed, was 0.31 ± 0.18 logMAR. Average maximum reading speed was 144.78 ± 58.76 words per minute. Reading accessibility index, calculated from the mean reading speed for the largest 10 print sizes, was 0.76 ± 0.31. There was no other significant correlation between achieved refractive outcomes and MNRead results.

Table 2 Binocular Visual Acuity at 3 Months Postoperatively

Binocular Visual Acuity	Range (LogMAR)	Mean (LogMAR)	Standard Deviation
DCDVA	0 – 0.10	0.01	0.03
UDVA	0 – 0.30	0.05	0.06
DCIVA	−0.10–0.20	0.06	0.08
UIVA	−0.10–0.30	0.10	0.10
DCNVA	−0.10–0.30	0.10	0.12
UNVA	−0.20–0.60	0.23	0.20

Abbreviations: DC, distance-target corrected; DVA, distance visual acuity (6 m); U, uncorrected; IVA, intermediate visual acuity (66 cm); NVA, near visual acuity (40 cm).

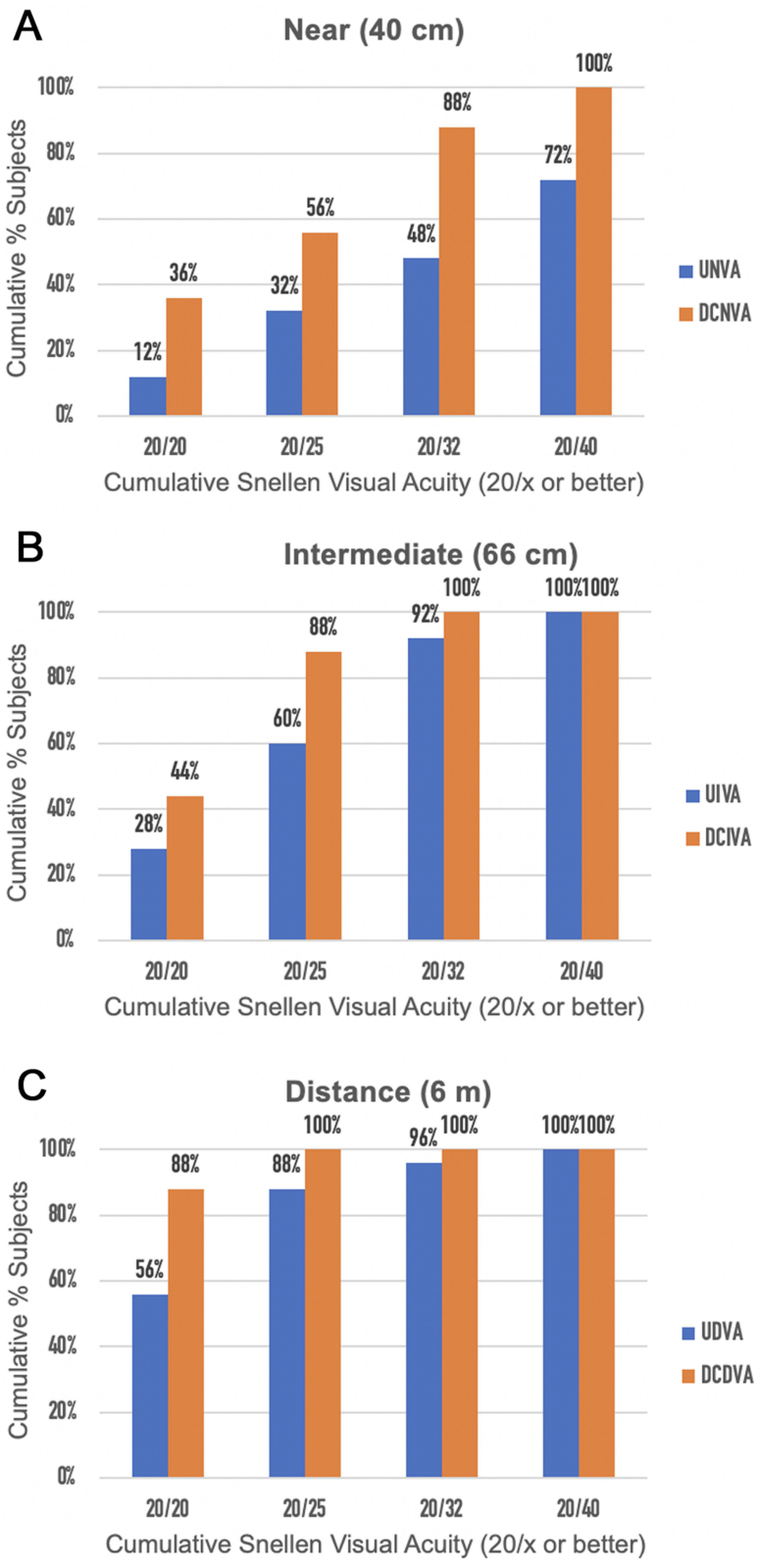

Figure 2 Visual acuity benchmarks at 3 months postoperatively. Cumulative percentage of subjects achieving distance (**A**), intermediate (**B**), and near (**C**) binocular uncorrected (blue bars) and distance-target corrected (orange bars) visual acuity targets are shown. There were a total of 25 subjects.

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Table 3 Uncorrected Binocular Reading Performance Using MNRead at 40 cm

	Mean ± SD	Reference Value[13] (32 Subjects in 60s–80s Wearing Habitual Reading Glasses)
Reading Acuity (logMAR)	0.12 ± 0.11	−0.05
Critical Print Size (logMAR)	0.31 ± 0.18	0.21–0.34
Maximum Reading Speed (wpm)	144.78 ± 58.76	175
Reading Accessibility Index	0.76 ± 0.31	0.88

Abbreviations: SD, standard deviation; wpm, words per minute.

On the PRO Questionnaire, 87.5% (21/24) patients reported little or no visual disturbances in dim light, 12.5% (3/24) reported a fair amount, and no patients reported severe symptoms (Figure 3A). Complete spectacle independence was achieved in 45.8% (11/24) of patients and reading glasses were used sometimes or not at all in 66.7% (16/24) subjects (Figure 3B). Of those that reported glasses use, 54.2% (13/24) was for reading, 12.5% (3/24) was for computer, 4.2% (1/24) for television and driving. Overall, 95.8% (23/24) of subjects were satisfied with their vision after surgery (Figure 3C), and 91.7% (22/24) would likely choose the same lens again.

Discussion

To our knowledge, this is the first reported study of the clinical outcomes of Clareon Vivity IOLs targeted for mini-monovision. Overall, bilateral implantation of Clareon Vivity lenses with a mini-monovision approach achieved good visual performance with low levels of visual disturbances and a high level of patient satisfaction.

The majority of the subjects (88%, 22/24) achieved our primary outcome of binocular DCNVA of 20/32 or better while maintaining good distance and intermediate vision. This finding is favorable compared to FDA registration data of Acrysof IQ Vivity without mini-monovision, which showed 57.5% of subjects achieving binocular DCNVA of 20/32 or better, supporting that mini-monovision is superior to bilateral emmetropia targeting for near vision outcomes (Fisher's exact test, $p = 0.005$).[19]

Fewer subjects achieved binocular UNVA of 20/32 or better (48%, 15/24) compared to DCNVA. While the majority of subjects were within 0.50 D of intended target in dominant eyes (88%, 22/25) and non-dominant eyes (96%, 24/25), fewer non-dominant eyes were equal to or more myopic than −0.5 D (48%, 12/25), which would affect UNVA negatively. Despite this difference between achieved refractive outcomes and intended refractive target, our result of

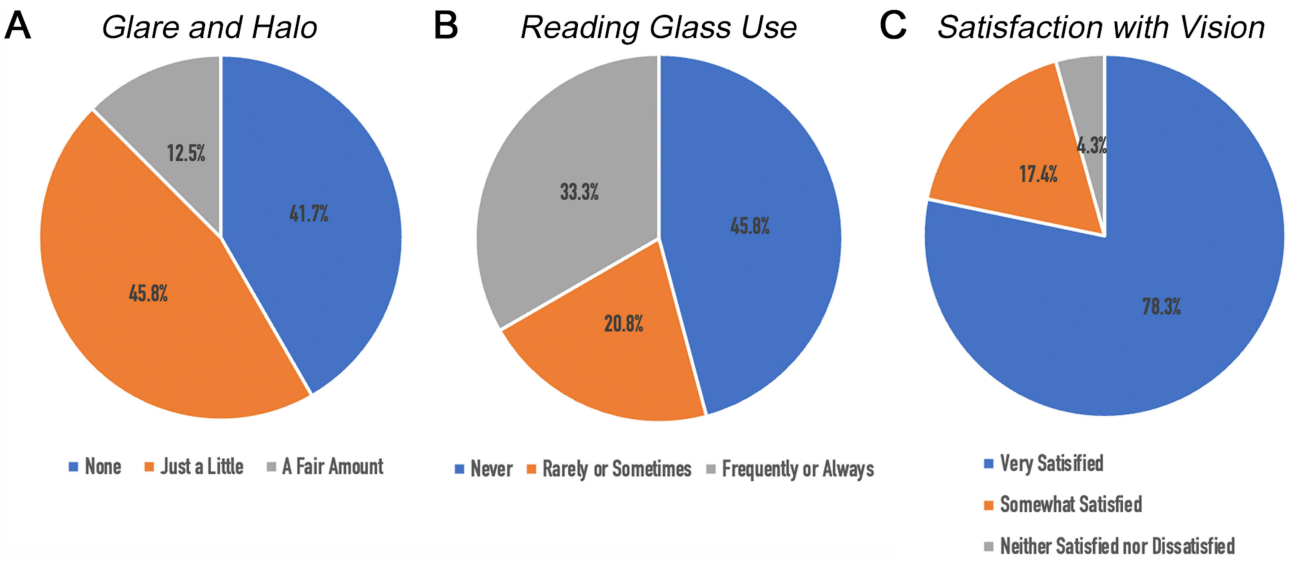

Figure 3 Patient reported outcomes with PRO Questionnaire. (**A**) shows percentage of subjects reporting no (blue), "just a little" (orange) and "a fair amount" (gray) glare and halo around lights under dim lights. (**B**) shows percentage of subjects using reading glasses never (blue), rarely or sometimes (orange), and frequently or all of the time (gray). (**C**) shows frequency of level of satisfaction with vision between "very satisfied" (blue), "somewhat satisfied" (orange), and "neither satisfied not dissatisfied" (gray).

mean binocular UNVA (0.23 logMAR) is similar to other studies of mini-monovision with Acrysoft IQ Vivity, which ranged from 0.19–0.26 logMAR.[10,11,13,16] Additional optimization may be needed in IOL power calculations and further studies may help to define the ideal the refractive target for non-dominant eyes when using a mini-monovision approach with Clareon Vivity IOLs.

Uncorrected near vision achieved with mini-monovision using Clareon Vivity IOLs was further evaluated using the MNRead test. The mean reading acuity of 0.12 logMAR, critical print size of 0.31 log MAR and the mean reading speed of 144.78 wpm indicate that subjects were reading comfortably at sizes consistent with everyday tasks. Of note, these values approached reading test performance similar to controls of similar age who were wearing their habitual reading glasses.[17] We are not aware of comparable studies evaluating MNRead performance in Vivity IOLs targeted for mini-monovision, but Fernandes et al reported a reading speed of 742.5 ± 37.4 characters per minute (giving an equivalent of 148.5 wpm using an average of 5 characters per word) with Acrysof IQ Vivity, which is similar to our result.[12] These reading-related outcomes align with the goal of the mini-monovision approach with Clareon Vivity IOLs to improve near vision performance, making it easier for patients to focus at a wide range of distances without correction.

In our study, a higher percentage of patients were spectacle independent compared to AcrySof IQ Vivity FDA registration data without mini-monovision.[19] Complete spectacle independence was achieved 45.8% (11/24) of patients with 66.7% (16/24) patients reported using reading glasses sometimes or not at all compared to 39.2% rarely or never using eyeglasses or contact lenses in FDA registration data. Our numbers were also higher than those reported by Solomon et al (58%) and Vasavada et al (63.5%) in studies of mini-monovision with Acrysof IQ Vivity, but it's not clear if there is a significant difference between Acrysof IQ Vivity and Clareon Vivity mini-monovision in regards to spectacle independence since all studies have relatively small numbers of subjects and would be expected to vary based on achieved refractive result compared to intended.[11,15]

Results from the PRO Questionnaire revealed low levels of visual disturbances and high patient satisfaction. The majority of subjects (88%, 22/25) reported little or no visual disturbances in dim light around lights. Importantly, no subjects reported severe visual disturbances. Using the PRO Questionnaire, Hovanesian et al compared patient reported outcomes for groups of patients receiving bilateral Acrysof IQ Vivity, PanOptix Trifocal, ReStor 2.5 Active Focus or ReStor 3.0 Multifocal lenses and found that 85% of patients had little to no visual disturbances in bilateral emmetropia targeted Vivity, which was significantly higher than other groups.[3] Our results are similar to Hovanesian et al supporting the idea that the mini-monovision approach does not increase unwanted visual phenomenon compared to bilateral emmetropia targeting.

One of the weaknesses of this study is that it is single armed, so there is no comparison group. Therefore, we have relied on the best available data from published studies to put our results in perspective, however these other studies may not have the same methods or study populations and were done using the Acrysof IQ Vivity rather than Clareon Vivity, which may affect the validity of comparison between groups and the ability to draw conclusions. Despite this, there are striking similarities in outcomes in the published studies of mini-monovision with Acrysof IQ Vivity and our study that lead us to believe that our results may be more generalizable and comparable to priors. Future randomized control or case–control studies are needed to compare the differences outcomes between monovision and mini-monovision approaches with Clareon Vivity IOLs, AcrySof versus Clareon Vivity, and Clareon Vivity versus other lens designs. Importantly, the long-term stability of visual outcomes, contrast sensitivity, and quality of vision with Clareon Vivity IOLs should be compared to AcrySof Vivity IOLs since the development of glistenings and haze may have an impact years after implantation.

Conclusion

The results from this study demonstrate that Clareon Vivity and Vivty Toric IOLs are highly effective in providing stable refractive outcomes with good visual performance across a broad range of vision. The mini-monovision approach with Clareon Vivity IOLs increased near performance compared to FDA registration data of Acrysof IQ Vivity IOLs set for distance, allowing for the majority of patients to eliminate or reduce their dependence on reading glasses.[19] Furthermore, we present the first study of reading performance with Clareon Vivity IOLs and found that study subjects without correction had near normal results compared to controls who were reading with correction. Clareon Vivity IOLs with

mini-monovision caused low levels of visual disturbances and high patient satisfaction rates. These results support the effectiveness of the mini-monovision approach using Clareon Vivity and Vivity Toric lenses in improving quality of life for patients and should be considered as an excellent option for patients seeking to improve their vision and dependence on glasses when bilateral cataract surgery is necessary.

Data Sharing Statement

The participants of this study did not give written consent for their individual data to be shared publicly, so the research supporting data is not available beyond the aggregated data presented in the paper.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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