Clinical Ophthalmology

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ORIGINAL RESEARCH

Visual Acuity, Defocus Curve, Reading Speed and Patient Satisfaction with a Combined Extended Depth of Focus Intraocular Lens and Multifocal Intraocular Lens Modality

This article was published in the following Dove Press journal:
Clinical Ophthalmology

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Purpose: To evaluate the vision, defocus curve, reading speed and patient satisfaction after implantation of an extended depth of focus (EDOF) IOL in one eye and a diffractive multifocal in the fellow eye.

Setting: One clinical practice in the USA.

Design: Prospective unmasked non-randomized clinical trial.

Methods: Subjects presenting for routine cataract surgery interested in reducing their dependence on spectacles were enrolled. Study endpoints included uncorrected and distance-corrected binocular distance (4 m), intermediate (66 cm) and near (40 cm) visual acuity at 3 months. Additional endpoints included the residual refraction, spectacle independence, overall satisfaction with vision, visual symptoms, reading speed and defocus curve.

Results: With a best distance correction, 77% (30/39) of subjects had 20/25 or better VA at distance, intermediate and near and nearly all subjects had 20/32 or better VA at all three distances. Defocus curve results showed mean continuous vision of 20/25 or better from plano to −2.50 D. Nearly 80% (31/39) of subjects had 20/25 visual acuity from 0.00 D to −2.50 D. The critical print size was between 0.3 and 0.4 logMAR (20/40 to 20/50 Snellen Equivalent). Spectacle independence was 100% at distance, 95% at intermediate and approximately 70% at near. The percentage of subjects who were "not at all" or "slightly" bothered by visual disturbances ranged from 64% (16/25) for Halos to 88% (22/25) for Starbursts.

Conclusions: EDOF/bifocal IOL blended implantation results in at least 20/25 mean visual acuity from distance to near with good spectacle independence and low reports of severe visual disturbances.

Keywords: extended depth of focus, EDOF, blended, presbyopia correction

Plain Language Summary

When patients present for cataract surgery, the cloudy lens in the eye is removed and an artificial intraocular lens (IOL) is implanted in the eye. The characteristics of the eye can be measured to calculate the best IOL to implant for good vision. Some lenses allow for good vision at more than one point of focus, providing vision at distance, intermediate and/or near, for instance. There are several different ways to provide this multifocal effect, with pros and cons associated with each. One way is to extend the depth of focus of the lens, much as can be done with cameras, but there is a limit to how far the focus can be extended so near vision may be compromised. Another way is to split the incoming light so that some goes to a near

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http://doi.org/10.2147/OPTH.S276120

focus and some to a far focus. This bifocal IOL approach provides for better near vision but increases the potential for visual disturbances such as glare and halos. The current study was conducted to evaluate patient satisfaction and visual performance when an extended depth of focus lens was implanted in one eye and a bifocal IOL implanted in the other.

Results demonstrated that more than 75% of subjects had 20/25 or better vision at far, intermediate and near working distances. Reports of severe visual disturbances were low. All subjects reported not needing spectacles for distant vision, 95% reported not needing spectacles for intermediate work (eg, computer) and 70% reported not needing them for near work (eg, reading).

Introduction

Patients presenting for presbyopia correcting lens implantation are generally interested in having clear and comfortable vision for distance, reading and intermediate work such as computer use. Available multifocal and extended depth of focus (EDOF) intraocular lenses (IOLs) meet these requirements with varying degrees of success. Matching patient expectations to the strengths and weaknesses of different presbyopia-correcting intraocular lenses is important in clinical practice.

Multifocal intraocular lenses (IOLs) are one option for patients; they provide 2 or 3 distinct foci to allow clear vision at varying distances. With these lenses, patients hope to reduce or eliminate their need for corrective lenses after cataract surgery, though this is not always achieved. A nationwide Japanese prospective study analyzed clinical outcomes after multifocal IOL implantation in 1384 eyes of 871 patients and found that 32% of patients were dependent on spectacle prescription.[1] In another study, residual refractive error and blurred near vision were found to be correlated to patient dissatisfaction.[2] Multifocal IOLs are associated with higher levels of visual disturbances, such as glare and halos, postoperatively. Negishi et al noted that patient dissatisfaction may be caused by complaints of glare and halos; 28.8% and 37.3% of patients noted bad or very bad glare and halos, respectively.[1] While complaints of glare and halos are common with all multifocal IOLs, the severity of these symptoms varies with IOL design.

Diffractive bifocal IOLs aim to provide good visual acuity (VA) at two foci, distance and near. This design often results in a drop in VA at intermediate. An example of a commonly used bifocal IOL is the TECNIS multifocal lens (Johnson and Johnson Surgical Vision, Santa Ana, CA) which is available in different add powers to accommodate various preferred working distances and preferences of patients (+4.0 D, +3.25 D, +2.75 D). The moderate add model has been shown to provide good spectacle independence (86%).[3] When this model was implanted in the non-dominant eye and the low-add model was implanted in the dominant eye, greater spectacle independence was reported (95% were spectacle independent at all distances).[4]

EDOF lenses provide an extended range of vision without producing a second or third distinct focal point; one such lens is the Symfony IOL (Johnson and Johnson Surgical Vision, Santa Ana, CA). When compared to a monofocal IOL, the EDOF IOL has been shown to provide similar visual quality outcomes without a statistically significant difference in contrast sensitivity while improving VA at all distances from far to near.[5] The EDOF IOL is available in both non-toric and toric versions. One potential disadvantage of the EDOF IOL is the visual performance at near, because there are limits on the ability to extend the depth of focus before visual quality is compromised. In a recent study, 100% of subjects reported spectacle independence at distance but only 71% were spectacle independent at near.[6]

Combining different types of presbyopia-correcting intraocular lenses (IOLs) at the time of cataract surgery is an approach that is often used by surgeons. The intent is to implant IOLs that are similar enough to allow for bilateral summation but are different enough to improve patients' range of vision. Different lens combinations have been explored in the literature, including refractive and diffractive as well as trifocal and bifocal IOL combinations.[7–9] Combining IOLs with different add powers were shown to potentially improve the uncorrected range of vision while maintaining the same visual quality when compared to placing the same add power in both eyes.[10] Best results appear to be achieved when the lowest add, or lens most resembling a monofocal IOL, is implanted in the dominant eye with the higher add lens in the non-dominant eye.[11,12] Previous studies have reported on the combination of the low-add (+2.75 D at the IOL plane) and moderate add (+3.25 D at the IOL plane) diffractive IOLs mentioned above. Results showed the combination provided a broader range of vision for patients.[4]

The Symfony non-toric (ZXR00) and toric IOL (ZXTx) are extended depth of focus (EDOF) IOLs design to improve the sharpness of vision at near, intermediate

and far distances reducing the need of glasses after cataract surgery in patients with or without astigmatism. The EDOF IOL, similarly to a monofocal IOL, has one focal point, it is elongated in the EDOF, having less of a halo and glare problem compared to multifocal IOLs. The Tecnis Multifocal +3.25 D Add is a diffractive bifocal and is indicated for primary implantation for the visual correction of aphakia in adult patients with a theoretical reading distance of 42 cm (16.5 inches). The +3.25 D Add at the IOL plane is equivalent to +2.37 D at the spectacle plane and could be comparable to +2.50 D readers.

Gil et al examined both an EDOF and bifocal (+3.25D at the IOL plane) IOL separately, and showed that the defocus curves for both IOLs complement each other; the EDOF IOL had excellent distance (about −0.1 logMAR) and intermediate VA (about 0.0 logMAR at 67 cm and 0.1 logMAR at 50 cm) while the bifocal IOL had good distance (about 0.0 logMAR) and near VA (about 0.1 logMAR at 40 cm).[13] Since EDOF lenses generally produce lower reported levels of visual disturbance, using such an IOL for distance/intermediate vision (instead of a low-add diffractive bifocal) and a +3.25D bifocal IOL for distance/near vision appears reasonable.

The objective of the current study was to evaluate the objective and subjective visual outcomes of a blended implantation strategy using an EDOF IOL in the dominant eye and a bifocal diffractive IOL in the non-dominant eye.

Methods

This was a prospective unmasked, non-randomized bilateral eye study designed to evaluate the clinical outcomes associated with using a Symfony EDOF lens in the dominant eye and a Tecnis Multifocal (+3.25 D add at the IOL plane) IOL in the non-dominant eye. The study was approved by an institutional review board (Salus IRB, Austin, TX, USA) and registered with clinicaltrials.gov (record NCT 03771274). The study was conducted in a manner consistent with the tenets of the Declaration of Helsinki. Data will not be shared.

Subjects 40 years of age or older interested in presbyopia correcting lenses who presented for routine cataract surgery in both eyes were recruited. Subjects with no pathology that might affect postoperative visual outcomes and a potential visual acuity of at least 20/32 (0.2 logMAR) were considered for enrollment. Exclusion criteria included uncontrolled diabetes, severe ocular pathology including severe dry eye, prior refractive or cataract surgery and any plans for an adjunct procedure (eg, concomitant glaucoma device implantation). No vulnerable subject populations were enrolled. All eligible subjects reviewed and signed an approved informed consent. The dominant eye received an EDOF lens and the non-dominant eye a +3.25 D add diffractive bifocal (~ +2.37 D at the corneal plane); all eyes were targeted for a plano (± 0.25 D) postoperative refraction. Toric and non-toric lenses were used, as required in the EDOF eye and astigmatism was treated in the fellow eye with corneal incisions.

Preoperative evaluation included uncorrected and best-corrected visual acuity (UCVA and BCVA, respectively), along with the clinic's standard cataract evaluation procedures, including surgical planning methods and formulas. Surgery was performed using the physician's standard procedures. Any subjects experiencing any intraoperative adverse event were documented and discontinued from the study; they were followed with the clinic's usual standard of care.

Postoperative evaluation was performed at 1 day, 1 month and 3 months. Clinical outcomes data included slit lamp examination, intraocular pressure, lens orientation (if toric IOL), manifest refraction and uncorrected visual acuity (VA). At the 1-month and 3-month visit, additional tests included the uncorrected and best distance-corrected VA at distance, intermediate (66 cm) and near (40 cm). Patient satisfaction, visual symptoms and spectacle independence questionnaires were also administered at both the 1-month and 3-month visits. The patient reported spectacle independence questionnaire (PRSIQ)[14] was used to determine subjects' need for spectacles or contact lenses and their satisfaction with vision at various distances. Visual symptoms were reported using a proprietary patient-reported visual symptom questionnaire. At the 3-month visit a binocular defocus curve was generated and a reading speed test using the Radner reading chart (Norbert Werner Ges.m.b.H., Vienna Austria) was administered. Adverse events were recorded at the operative and all postoperative visits. Reading acuity is reported in logRAD, the reading equivalent of logMAR.[15]

Measures of interest were the uncorrected and best distance-corrected distance (4 m), intermediate (66 cm) and near (40 cm) visual acuity at 3 months. Additional endpoints included the residual refraction (sphere, cylinder, spherical equivalent) at 3 months as well as the patient's overall satisfaction with vision, spectacle independence and visual symptoms. Changes in symptoms from 1 month to 3 months were also examined. Visual acuity was measured in logMAR and reported in converted Snellen values.

Data were collected on appropriate case report forms and collated in MS Excel, then imported into an Access database for data checking and preliminary analysis (both Microsoft Corp., Redmond, WA, USA). Subjects were assigned an ID number so that data analysis could be performed without patient identification. Statistical analyses were completed using the Statistica data analysis software system, version 12 (TIBCO Software Inc., Palo Alto, CA, USA). Parametric comparisons were made using analysis of variance (ANOVA) and non-parametric data were compared using the Chi-squared test. All statistical tests were two-sided with p = 0.05 considered significant.

Results

A total of 39 subjects (78 eyes) were enrolled in the study. The average age was 65.7 ± 6.2 years, with a range from 50 to 76 years. Just over half of subjects (56%, 22/39) were female. Preoperative biometry and postoperative refractive details are summarized in Table 1. As can be seen, there were no significant differences between the two groups, with excellent refractive results in both. At 3 months, 95% of all eyes (74/78) had a spherical equivalent refraction within 0.50 D of plano with 0.50 D or less of residual refractive cylinder.

Figure 1 shows a histogram of the uncorrected binocular distance, intermediate and near VA for all subjects. Almost two thirds of the subjects (64%, 25/39) had 20/25 or better VA at all three test distances. Figure 2 shows the results when all eyes were corrected for distance. Overall results were slightly better; 77% of subjects (30/39) had 20/25 or better VA at all three distances. Distance vision results improved slightly, though at the expense of intermediate and near vision.

Figure 3 shows the mean binocular defocus curve for all subjects, with the subjects' distance corrections in place. The EDOF/multifocal IOL combination provided mean continuous vision of 20/25 or better from +0.50 D to −2.50 D, corresponding to a range of vision from infinity to 40 cm. Individual results are not presented, but a review of the raw data showed that 79% of subjects (31/39) had 20/25 (0.1 logMAR) visual acuity at the tested vergences from 0.00 D to −2.50 D.

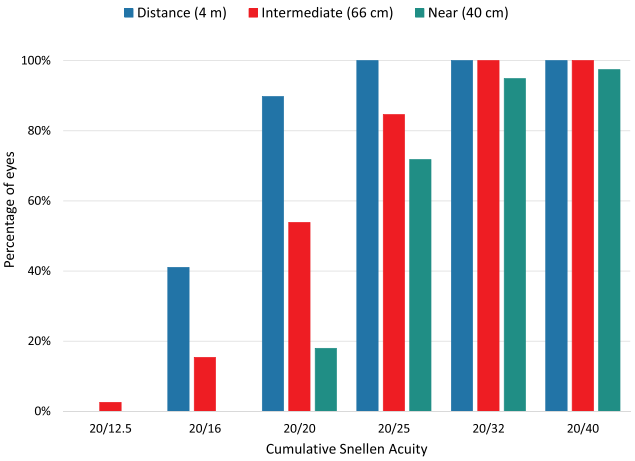

Figure 1 Binocular uncorrected visual acuity at distance, intermediate and near (n = 39).

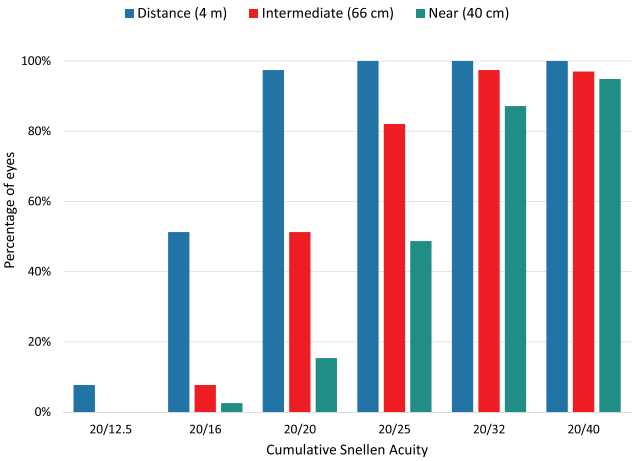

Figure 2 Binocular best distance-corrected visual acuity at distance, intermediate and near (n = 39).

Figure 4 shows the reading speed as a function of letter size. The critical print size is the size at which reading speed starts to substantially decrease – the "elbow" in the

Table 1 Biometry and Refractive Summary (n = 39 Subjects, 78 Eyes)

	All eyes	EDOF IOL	Bifocal IOL	p
Preoperative mean keratometry (D)	43.73 ± 1.69 (41.16 to 46.59)	43.71 ± 1.73 (41.16 to 46.44)	43.75 ± 1.68 (41.47 to 46.59)	0.9
Preoperative corneal astigmatism (D)	0.65 ± 0.42 (0.00 to 1.74)	0.67 ± 0.43 (0.11 to 1.74)	0.63 ± 0.41 (0.00 to 1.44)	0.62
Axial length (mm)	24.07 ± 1.26 (22.23 to 27.53)	24.06 ± 1.26 (22.23 to 27.35)	24.09 ± 1.28 (22.33 to 27.53)	0.92
IOL Sphere power (D)	18.7 ± 4.4 (7.5 to 26.0)	18.8 ± 4.5 (7.5 to 25.5)	18.7 ± 4.3 (7.5 to 26.0)	0.97
Postoperative MRSE (D)	−0.16 ± 0.23 (−1.00 to +0.375)	−0.17 ± 0.26 (−1.00 to +0.375)	−0.15 ± 0.19 (−0.50 to +0.375)	0.91
Postoperative refractive cylinder (D)	0.25 ± 0.25 (0.00 to 1.25)	0.25 ± 0.22 (0.00 to 0.75)	0.26 ± 0.27 (0.00 to 1.25)	0.58

Abbreviations: D, diopter; MRSE, mean refraction spherical equivalent; EDOF, extended depth of focus; IOL, intraocular lens.

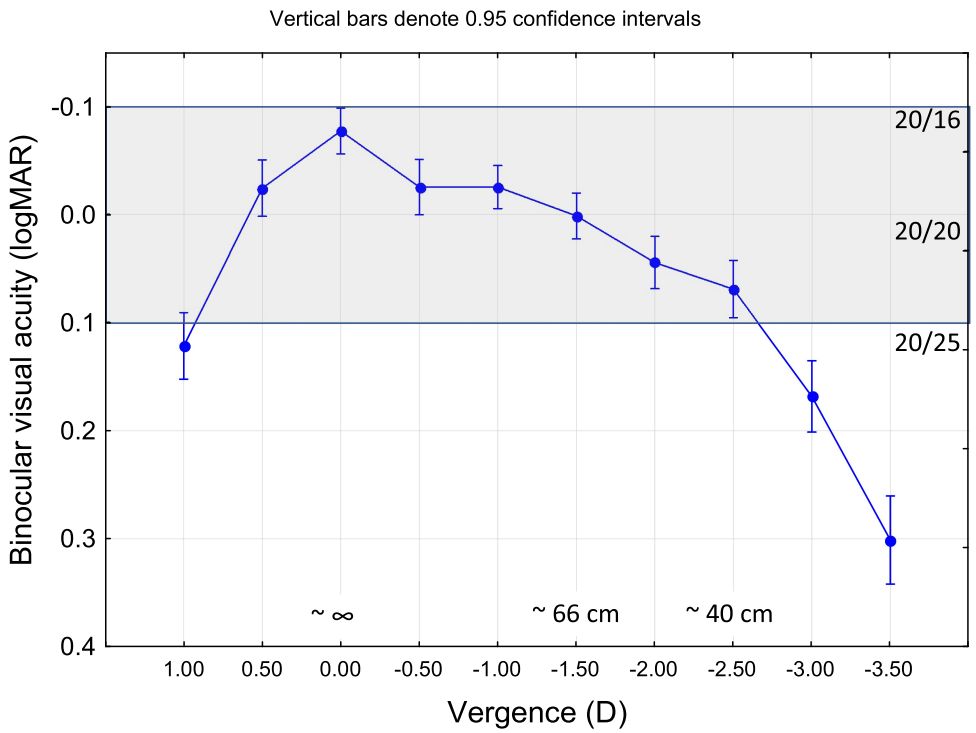

Figure 3 Mean binocular defocus curve.
Abbreviations: D, diopters; logMAR, log of the minimum angle of resolution.

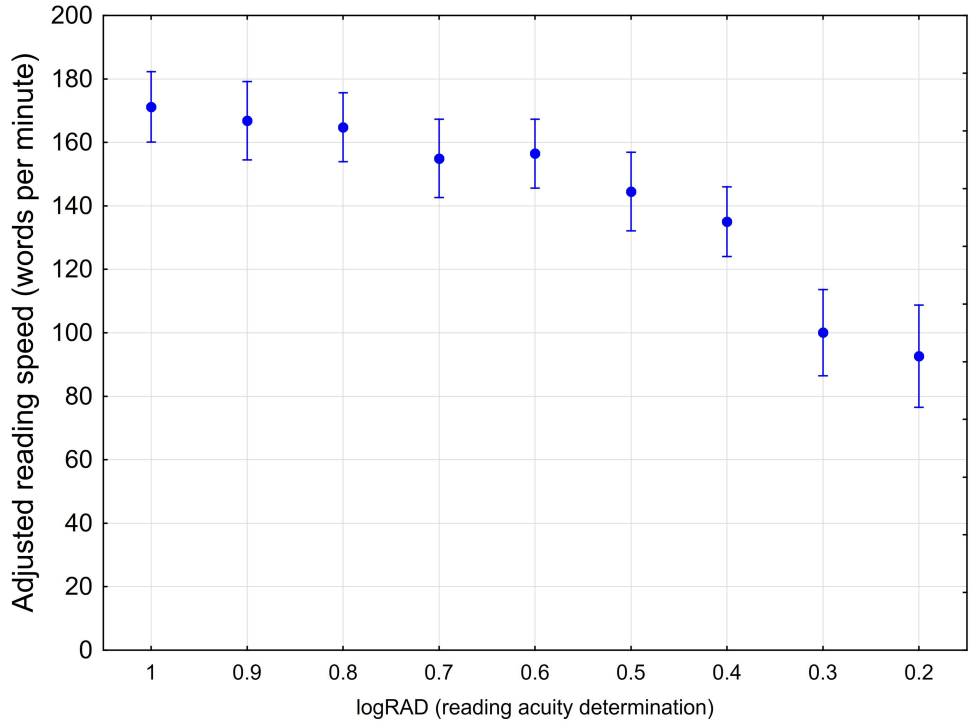

Figure 4 Reading speed based on reading acuity.
Abbreviations: logRAD, log of the reading acuity determination.

graph. For the subjects in this study, the critical print size appears to be between 0.3 and 0.4 logRAD (or between 20/40 and 20/50 Snellen).

No subjects reported needing glasses for distance work at 1 or 3 months, while only 2 of 39 (5%) reported needing them for intermediate work at either time point. Near vision was more problematic, with 28% of subjects (11/39) reporting a need to use glasses for near work at 1 month and 31% of subjects (12/39) reporting that need at 3 months. Figure 5 shows reported wearing of glasses for various viewing distances at the two time points. More than 90% of subjects were spectacle independent for distance and intermediate (computer) viewing, though only about 2 in 3 subjects reported not wearing spectacles for near work.

Figure 6 shows the distribution of subjects' ability to function without glasses at various distances at the 1- and 3-month follow-up visits. Overall, about 90% of subjects reported being able to function without glasses "all of the time" or "most of the time". Distance viewing had the highest reported independence from spectacles while near vision was most problematic. At near, 75% of subjects reported being able to function "all of the time" or "most of the time" without spectacles.

The distribution of reported satisfaction over time and at various viewing distances is shown in Figure 7. Overall, more than 94% of subjects reported being completely or mostly satisfied with their vision. Again, near work was more problematic for subjects in this study.

The frequencies of various visual disturbances reported at 1 and 3 months on the PRVSQ questionnaire are shown in Figure 8. Halos and sensitivity to light were the two phenomena reported most often. In general, the distribution of reported frequencies was similar at the two time periods, though the frequency with which halos and sensitivity to light were reported appears to increase slightly from 1 month to 3 months.

Figure 9 shows the level of severity that subjects assigned to the visual disturbances in Figure 6 at 3 months when they were experienced "all of the time" or "most of the time". Streaks and Occluded Vision are not shown because they were not reported at that frequency by any subjects at 3 months. The distributions are generally similar, though halos were reported to be relatively more severe than some other disturbances. The percentage of subjects who were "not at all" or "slightly" bothered by these visual disturbances ranged from 64% (16/25) for Halos to 88% (22/25) for Starbursts.

Discussion

The current study demonstrates the visual outcomes after implantation of an EDOF IOL in the dominant eye and

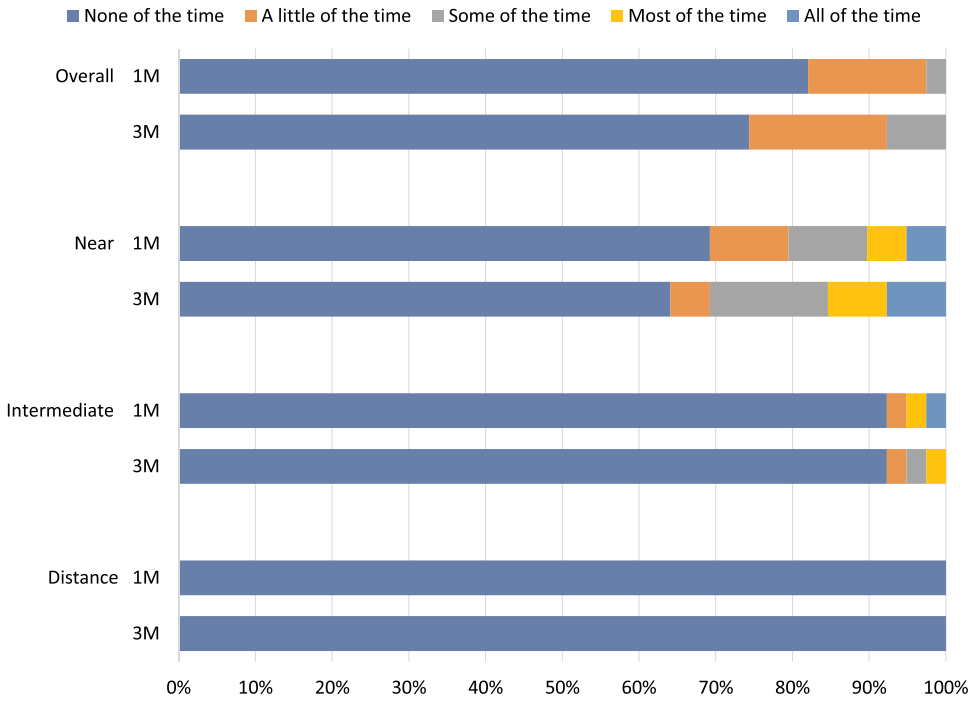

Figure 5 Reported percentage of spectacle wear by viewing distance and time.
Abbreviations: 1M, 1 month, 3M, 3 months.

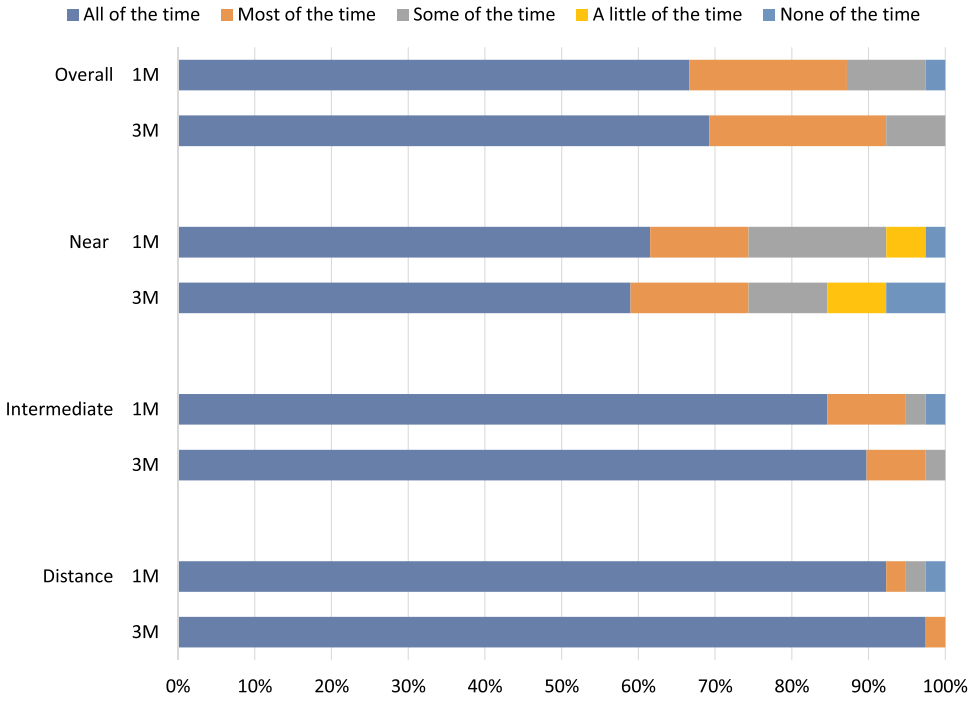

Figure 6 Reported ability to function without glasses by time point and viewing distances.
Abbreviations: 1M, 1 month; 3M, 3 months.

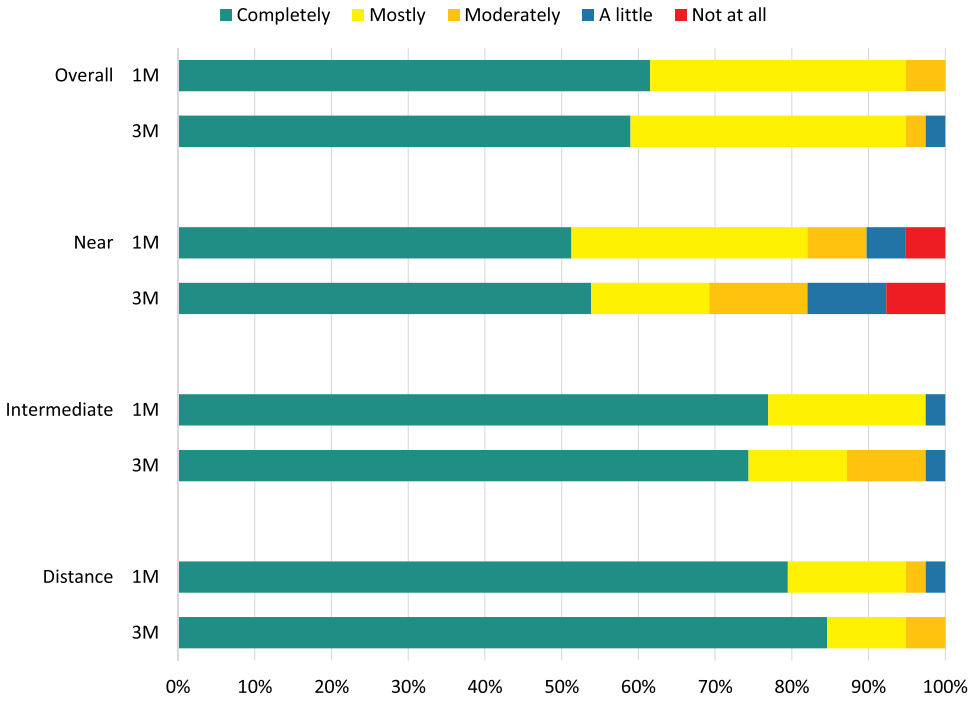

Figure 7 Satisfaction with vision over time and viewing distance.
Abbreviations: 1M, 1 month; 3M, 3 months.

a moderate add bifocal IOL in the non-dominant eye. Visual acuity results show that with best-distance correction, 77% (30/39) of subjects had 20/25 or better VA at distance, intermediate and near and nearly all subjects had 20/32 or better VA at all three distances. Results reported by Black were better than reported in current study despite implantation with the same IOLs where 93% (30/32) of subjects had 20/25 or better VA at all three distances.[16]

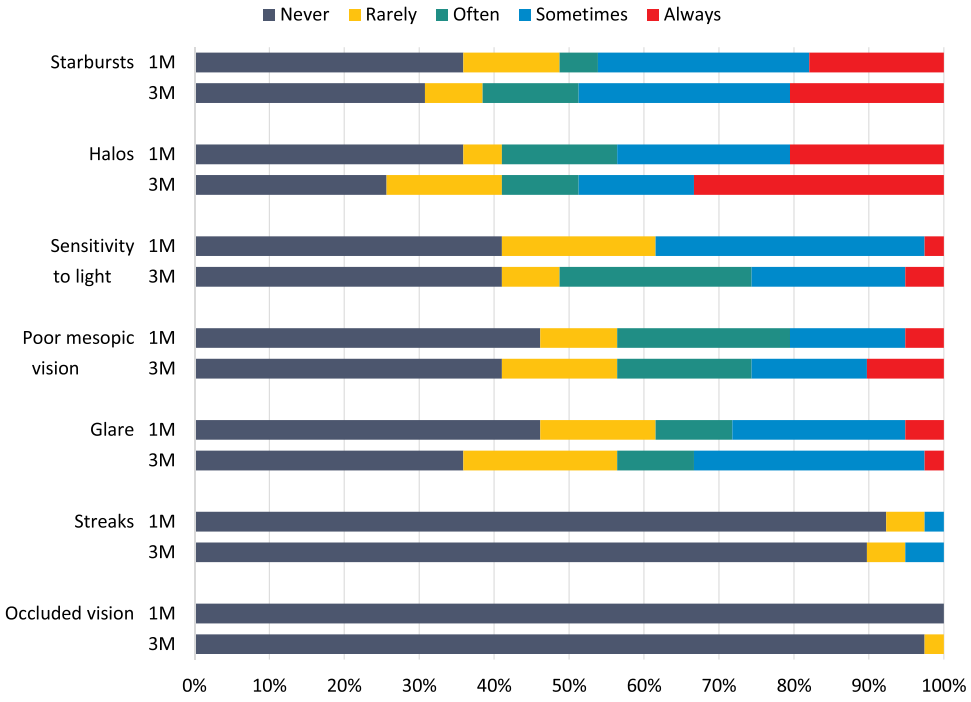

Figure 8 Reported frequency of visual disturbances at 1 and 3 months.
Abbreviations: 1M, 1 month; 3M, 3 months.

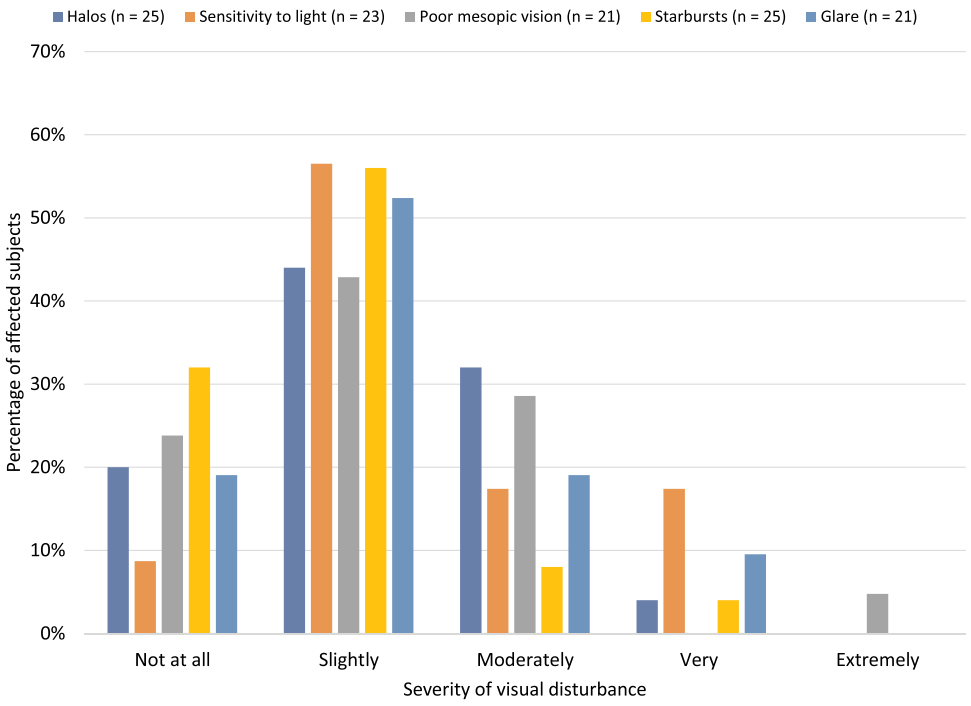

Figure 9 Severity of reported visual disturbances at 3 months, when reported.

The reason for the difference is unclear but could possibly be due to the amount of residual spherical equivalent refraction (SEQ); in the Black study, the non-dominant eye (implanted with EDOF IOL) had −0.13 D of residual SEQ while the dominant eye (implanted with bifocal IOL) had 0.05 of residual SEQ.[16] Compared to blended implantation of EDOF and a higher add bifocal (+4.0 D add), the results of the current study are similar at distance and near

with improved intermediate vision (intermediate distance was 60 cm vs 66 cm in the current study).[16] Compared to a trifocal IOL, the current study had better distance and intermediate VA but worse near VA.[17] VA results in the current study are similar or slightly better than the best results reported with various levels of monovision by Cochener.[18] Note that Cochener tested intermediate VA at 70 cm, compared to 66 cm in the current study. When compared to blended implantation of the current moderate add IOL in the non-dominant eye and a low add bifocal in the dominant eye, VA results were similar aside from intermediate VA which was better in the current study (0 vs 0.1 logMAR) though intermediate VA was measured at 60 cm instead of 66 cm.[4]

A blended or "mix and match" approach is an alternative to bilateral implantation of the same IOL type. The expectation is that the patient will gain some benefit from both, with little change in perceived visual disturbances. The combination here addresses the fact that the EDOF lens used in this study is known to be less likely to provide satisfactory near vision and the bifocal IOL used in this study is known to be less likely to provide satisfactory intermediate vision.[13,19]

Defocus curve results show a mean continuous vision of 20/25 or better from distance to 40 cm and 20/20 or better VA from 0.0 to −1.50 D where near 80% (31/39) of subjects had 20/25 visual acuity from 0.00 D to −2.50 D. When compared to blended bifocal defocus curves, the current IOL combination provided better VA at more distances; the blended bifocal modality had near 0.2 logMAR VA at 100 cm and approximately 20/25 VA at 66 cm.[10] When implanting a different EDOF in the dominant eye and a trifocal IOL in the non-dominant eye, the defocus curve was worse at near and intermediate by almost one-line of VA.[20]

The critical print size with the blended IOL implantation in the current study was between 0.3 and 0.4 logRAD (20/40 to 20/50 Snellen Equivalent). Sandoval et al[21] used a similar evaluation of the reading speed with micro-monovision EDOF IOL implanted bilaterally (SEQ was −0.19 D in dominant eye and −0.46 D in non-dominant eye) with greater critical print size of 0.6 logMAR. With bilateral implantation of higher add bifocal IOLs, a reading speed of 148 wpm at a smaller critical print size of Snellen 20/30 was noted.[22] In the current study, 0.2 logMAR (20/32 Snellen Equivalent) had a corresponding reading speed of above 80 wpm (Figure 4) which is above the suggested threshold for reading.[23]

Spectacle independence was 100% at distance, 95% at intermediate and approximately 70% at near; this compared favorably to the large study of 871 Japanese patients where 68% of patients reported they were almost or totally free of corrective eyewear after multifocal IOL implantation.[1] Similar results were also reported by Sandoval et al[21] where micro-monovision EDOF IOL was implanted bilaterally (SEQ was −0.19 D in dominant eye and −0.46 D in non-dominant eye) where nearly 92% were spectacle independent at distance and near while 72% were spectacle independent at near. Results in the current study were favorable when compared with bilateral implanted of the EDOF IOL with a target of micro-monovision and residual SEQ mean of −0.19 D where 63% (27/43) were spectacle independent at distance and 67% (29/43) were spectacle independent at near.[24] Greater spectacle independence has been reported when greater monovision was aimed and when a low add bifocal was placed in the dominant eye.[4,18] Cochener et al noted that the greatest spectacle independence reported was for monovision of greater than 1.0D where approximately 95% were spectacle independent at distance, intermediate and near; in contrast, without monovision, 76% were spectacle independent at all three distances.[18] When implanting the same moderate add bifocal lens model in the non-dominant eye but a low add lens model (+2.75 add) in the dominant eye, 100% were spectacle independent at distance and 95% were spectacle independent at intermediate and near.[4]

Halos and sensitivity to light were the two phenomena reported most often; halos were reported to be relatively more severe than some other disturbances. The percentage of subjects who were "not at all" or only "slightly" bothered by these visual disturbances ranged from 64% (16/25) for Halos to 88% (22/25) for Starbursts. This appears reasonably consistent with data in a large study of 871 Japanese patients who reported bad or very bad halos in 37% of subjects.[1] Cochener noted that the greatest percent of none or mild halos was reported for those without monovision (93%) and least for those with greater than 1.0D of monovision (79%).[18] In a study where subjects were implanted with the same IOLs as in the current study, the majority of subjects (97%) reported no halos.[17]

There are limitations to the current study. The evaluation conducted was related to binocular performance, so no monocular data for either lens modality (EDOF/multifocal) was collected.

In conclusion, when the dominant eye receives an EDOF IOL and the non-dominant eye receives a moderate add bifocal IOL, at least 20/25 visual acuity can be expected from distance to near with good spectacle independence and low reports of severe visual distortions.

Acknowledgments

Sarah Y. Makari, OD, a consultant to Science in Vision, received compensation for writing assistance in preparation of the manuscript. The results reported here were collected at 1 clinical practice (Solomon) in the USA. Subsets of the data were presented at the 2019 ASCRS meeting in San Diego, CA 5/3 – 5/7.

Author Contributions

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Helga P Sandoval, Richard Potvin, and Kerry D Solomon. The first draft of the manuscript was written by Richard Potvin and Helga Sandoval. All authors 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.

Funding

The study was supported by an investigator-initiated study grant from Johnson and Johnson Vision, Santa Ana, CA, USA.

Disclosure

Helga P Sandoval reports grants from Johnson and Johnson Vision, during the conduct of the study. Richard Potvin is a consultant to Alcon Laboratories, Inc and reports personal fees from Carl Zeiss Meditec, outside the submitted work. Kerry D Solomon is a consultant for Alcon Laboratories, Allergan, Aquesys, Bausch and Lomb, Clarvista Medical, Glaukos, Icon Bioscience, Imprimis, Integrity Digital Solutions, Johnson & Johnson Vision, Kala Pharmaceuticals, Lenstec, Mati Therapeutics, Octane Visionary VC Fund, Ocuhub, Omeros Corporation, Pogotec, PRN, Tearlab, and Versuant. He also reports grants from Johnson and Johnson Vision, during the conduct of the study; grants from Johnson and Johnson Vision, grants and personal fees from Alcon, outside the submitted work. The authors report no other conflicts of interest in this work.

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