

Functional Results and Photic Phenomena with new Extended-Depth-of-Focus Intraocular Lens

Bert C. Giers

David J. Apple International Laboratory for Ocular Pathology

Ramin Khoramnia

David J. Apple International Laboratory for Ocular Pathology

Dorottya Varadi

David J. Apple International Laboratory for Ocular Pathology

Hannah Wallek

David J. Apple International Laboratory for Ocular Pathology

Hyeck Soo Son

David J. Apple International Laboratory for Ocular Pathology <https://orcid.org/0000-0003-1065-4035>

Mary S. Attia

David J. Apple International Laboratory for Ocular Pathology

Gerd U. Auffarth (✉ auffarthg@aol.com)

Research article

Keywords: Cataract; Intraocular Lens; Multifocal; Visual Outcomes

Posted Date: October 11th, 2019

DOI: <https://doi.org/10.21203/rs.2.10020/v3>

License:   This work is licensed under a Creative Commons Attribution 4.0 International License.

[Read Full License](#)

Version of Record: A version of this preprint was published on August 28th, 2019. See the published version at <https://doi.org/10.1186/s12886-019-1201-3>.

Abstract

Background: Evaluation of clinical and functional results of a new extended depth of focus intraocular lens (EDOF-IOL). **Methods:** Fourteen cataract patients (twenty-eight bilateral implantations) were assessed for uncorrected (UDVA) and corrected (CDVA) distance visual acuities; uncorrected (UNVA), distance-corrected (DCNVA) and best corrected (CNVA) near visual acuities; and uncorrected (UIVA) and distance-corrected (DCIVA) intermediate visual acuities - as well as binocular defocus curves. Photopic and mesopic contrast sensitivity was recorded. Reading acuity was evaluated using an electronic reading desk at fixed distances and at the patient's preferred near and intermediate distances. Visual symptoms were assessed with a halo and glare simulator plus a patient questionnaire which also recorded quality of life. **Results:** Median postoperative monocular UDVA was 0.13logMAR (range -0.08 to 0.42logMAR), median CDVA was -0.01logMAR (range -0.20 to 0.22logMAR), median UIVA at 80 cm was -0.05logMAR (range -0.18 to 0.58logMAR) and median UNVA at 40 cm was 0.14logMAR (range -0.10 to 0.64logMAR). Binocular uncorrected reading acuity was 0.10logMAR at 40 cm and 0.11logMAR at 80 cm. Patients preferred a median intermediate reading distance of 62.8 cm over the predetermined 80 cm, which allowed them to read smaller letter size but did not improve reading acuity. Patients reported a high rate of spectacle independence and satisfaction in everyday life and little to no dysphotopsia. **Conclusion:** The Mini WELL Ready IOL provided good postoperative functional results at far and intermediate distances and improved the visual and reading acuity at reading distance. The lens caused little to no dysphotopsia.

Background

In recent years, multifocal intraocular lenses (MIOLs) were developed for patients who do not want to wear spectacles when using a desktop computer or mobile phone. The lenses either have a low to moderate addition for intermediate distances or are trifocal with an additional intermediate focus.^{1,2,3}

Trifocal IOLs deliver good functional vision at different focal planes to achieve spectacle independence⁴⁻⁸. A new development is extended-depth-of-focus IOLs (EDOF-IOLs), that aim to provide a continuous range of vision instead of multiple distinct foci. The first EDOF-IOL was the Tecnis Symphony (Abbott Medical Optics, Abbott Park, NY, USA), combining an apodized-diffractive surface with an echelette-design. Initial clinical results appear promising⁹⁻¹³.

A considerable disadvantage of diffractive designs is loss in contrast sensitivity due to reduced effective light energy reaching each focal plane. Perception of halos and glare, is another side-effect: arising from superposition of multiple images on the retina^{14,15}. Patient dissatisfaction can occur despite the functional visual results achieved.

An optical design not primarily based on diffraction ought to minimize these disadvantages. We examined the clinical outcomes with the Mini WELL Ready (SIFI, Catania, Italy), a new EDOF-IOL that relies on spherical aberrations of opposite signs to create an elongated focus. Standard visual acuity was

tested using charts for predefined distances and an electronic reading desk was used for visual acuity assessment at individually chosen distances^{16,17}. Furthermore, contrast sensitivity as well as subjective perception of glare and halos were assessed to further characterize the clinical performance.

Methods

Patients and Procedure

This prospective, non-randomized clinical study was approved by the local Ethics Committee and performed in accordance with the tenets of the Declaration of Helsinki. Patients were recruited between August 2016 and May 2017 for bilateral implantation of the Mini WELL Ready IOL. All patients gave informed consent form prior to inclusion to the study. Otherwise, they were not involved in the design of the study. Patients were aged 18 years or older, had a postoperative expected uncorrected visual acuity of 0.2logMAR (20/32) or better as well as a postoperative expected corneal astigmatism under 1.0D (diopters). Patients were excluded with previous ocular surgery or other ocular and monocular pathologies, except cataract, that could affect postoperative visual acuity.

The IOL

The SIFI Mini WELL Ready is a preloaded, single-piece hydrophilic acrylic IOL with a hydrophobic surface. The overall diameter is 10.75mm with four closed-loop haptics with 5-degree angulation. The biconvex optic of 6mm diameter has three annuli, an outer monofocal zone and two inner zones with spherical aberrations of opposite signs (Fig. 1). The innermost zone, or D1, is 1.8 mm wide and has a positive spherical aberration, creating the intermediate focus. The middle zone, or D2, is 3.0 mm wide and has a negative spherical aberration, contributing to near focus. The outermost zone, or D3, is a monofocal optic with a diameter of 6.0 mm that is responsible for creating the far focus. The lens features an equivalent addition of +3.0D corresponding to a spectacle plane addition of +2.4D. Power ranges from 0 to +30D (0.5D increments from +10.5 to 30.0D). The company's estimated A-constant is 118.6.

Figure 1: Schematic illustration of the Mini WELL Ready. A) D1 is shown in green, D2 in red, and D3 in blue. B) In D1, the central rays (Fc, green) come into focus behind the peripheral rays (Fp, green), while in D2, the central rays (Fc, red) come into focus in front of peripheral rays (Fp, red). LSA = Longitudinal spherical aberration; EDOF = Extended-depth-of-focus.

Surgical Procedure

The same experienced surgeon (G.U.A.) performed all surgeries using topical or general anesthesia. A 12 o'clock clear corneal incision preceded manual curvilinear (n=13) or a femtosecond laser-assisted capsulorhexis (n=1), followed by standard phacoemulsification. For femtosecond laser-assisted capsulorhexis, the size of the rhexis was 5.0 mm. For manual curvilinear capsulorhexis, the intended size of the rhexis was also 5.0 mm. The IOL was implanted in the capsule. Postoperative topical medication was a combination of antibiotic and a steroid for two weeks. IOL power for targeted emmetropia was

calculated with the Holladay formula; except where axial length was less than 22mm or over 25mm, (as measured on the IOLMaster (Carl Zeiss Meditec)), the Haigis formula was used.

Postoperative Examinations

Two to four months after surgery, patients were evaluated for visual acuity, reading performance, contrast sensitivity, photic phenomena and patient satisfaction. In addition to these monocular examinations, “real-life” binocular performance was evaluated.

Visual Acuity and Reading Acuity Examinations

Uncorrected and distance-corrected visual acuities were determined using Early Treatment Diabetic Retinopathy Study (ETDRS) charts (Precision Vision Inc, USA). The 4m charts were used for distance vision, the 80cm charts for intermediate vision, and the 40cm charts for near vision. For the binocular defocus curve, patients were tested distance-corrected using a 4m ETDRS chart and adding +5.0 to -3.0D in 0.5D increments. Standardized illumination of 500 lux was used, according to the DIN EN 12464-1 norm.

Electronic Reading Desk

Reading performance was evaluated with the Salzburg Reading Desk Version RDFD 1.0 (SRD Vision LLC, USA) at 40cm fixed distance for near and 80cm for intermediate visual acuity as well as at the patient's preferred near and intermediate distances^{18,19}. Patients read logarithmically-scaled Colenbrander sentences while reading distance is measured continuously using video-stereophotogrammetry. Overall reading acuity is calculated automatically in logMAR, with consideration of the reading distance in centimeters and the log-scaled print size of the smallest readable sentence with a minimum velocity of 80wpm.

Patient Questionnaire

Patients responded to questions on visual perception and satisfaction in performing daily activities, rating the occurrence of visual problems from 0 to 10, where 0 is complete absence of a problem and 10 is strong discomfort.

Contrast Sensitivity and Photic Phenomena

Contrast sensitivity was measured using a stereo optical functional acuity contrast test (F.A.C.T., CSV-1000, VectorVision, Greenville, OH) adjusted for distance under photopic (85 cd/m²) and mesopic (3 cd/m²) conditions.

To assess photic phenomena, we used a PC-based simulator software (Halo & Glare Simulator, Eyeland-Design Network GmbH, Vreden, Germany) where patients select from different kinds of preset halos and glare and then separately adjust for size and intensity on a slide bar with simultaneous visual

representation on the screen. What the patient perceives is classified into three types: diffuse halo, starburst or a single distinct halo ring. Patients are asked to adjust the slide bars so that the image on the screen gives a representation of how they perceive photic phenomena around light sources during nighttime driving. The slide bar positions for each item are translated into numeric values between 0 (minimum) and 100 (maximum) on a visual analogous scale.

Statistical Analysis

Using SPSS version 21 for Windows, (IBM, Armonk, NY), the results from binocular examinations were analyzed using Wilcoxon rank-sum test for paired non-parametric data. For monocular examinations, the linear mixed model of SPSS software was used. For all tests, the same level of significance was adopted ($p < 0.05$). The questionnaires and halometry results were analyzed descriptively.

Results

Visual Acuity and Refraction

Two patients were excluded from analysis: one had developed bilateral postoperative macular edema and another had died from heart-failure. Thus, only twenty-eight eyes of fourteen patients were analyzed, nine men (64.3%) and five women (35.7%). Median age was 66 years (range: 52 to 82 years).

The median spherical IOL power was 20D (range 14 to 24D). The median preoperative spherical equivalent was 0.00 D (range -2.50 to +2.38 D), target spherical equivalent was -0.23 D (range -0.56 to +0.25 D) and median achieved postoperative spherical equivalent was 0.00 D (range -1.63 to +2.13 D). Median postoperative residual cylinder was -0.50 D. There was no statistically significant difference between achieved and target refraction ($p = 0.24$). Fourteen eyes (50%) were within ± 0.50 D and twenty-four (85.7%) were within ± 1.00 D of the intended value.

Postoperative median UDVA (monocular) was 0.13logMAR (range -0.08 to 0.42logMAR), median UIVA at 80 cm was -0.05logMAR (range -0.18 to 0.58logMAR) and median UNVA at 40 cm was 0.14 log MAR (range -0.10 to 0.64logMAR). The median UDVA (binocular) was 0.05logMAR (range -0.08 to 0.22logMAR). The median CDVA improved significantly ($p < 0.001$) from 0.43logMAR preoperatively (range hand movements to 0.04logMAR) to -0.01logMAR postoperatively (range -0.20 to 0.22logMAR). Postoperative median DCIVA was 0.03logMAR (range -0.02 to 0.58logMAR) and median CNVA (median add. +1.50 D, range 0 to +2.75 D) was -0.08 log MAR (range -0.20 to 0.34 log MAR). 79% of tested eyes achieved both a UDVA and a UNVA of 0.20logMAR (20/32 Snellen or 0.63 Decimal) or better and 89% of eyes achieved a UIVA of 0.20logMAR or better (Table 1).

The binocular defocus curve shows a broad plateau with a visual acuity of 0.20logMAR or better between +1.50 and -2.50D (Fig. 2).

Figure 2: Binocular distance-corrected defocus curve (n = 14 patients)

Reading Performance

Table 2 summarizes the Salzburg Reading Desk results of binocular uncorrected and distance-corrected reading acuity at predetermined near (40cm) and intermediate (80cm) distances as well as at the subjectively preferred reading distance for both near and intermediate distances. The reading performance could only be tested in 11 subjects as three subjects could not speak any language that is supported by the Salzburg Reading Device fluently. There was no statistically significant difference between the predetermined near distance of 40cm (median 40.3cm) and the individually preferred reading distance (median 39.5cm) both for uncorrected ($p = 0.21$) and distance-corrected ($p = 0.92$) testing and no significant changes were observed for reading acuity, letter size and reading speed. Patients preferred an intermediate reading distance of approximately 60–65cm (median 62.8cm and 60cm for uncorrected and distance-corrected binocular testing respectively) over the predetermined, 80cm intermediate distance ($p = 0.003$), which allowed them to read smaller letter sizes ($p = 0.004$ and 0.045 for uncorrected and distance-corrected testing respectively). However, the reading acuity results did not significantly differ between the predetermined and the patient's preferred intermediate distance.

Photoc Phenomena

54% of patients reported not perceiving any type of halo and 30% reported no glare. 23% saw starburst type halos. The remaining 23% reported a classical concentric halo around light sources. Median scores for halo size and intensity were 0 (visual analogous scale) median scores for glare size and intensity were 10 and 36 (Fig. 3). These results correspond to the questionnaire responses, where respondents were less than mildly or not at all bothered by day glare, night glare and perception of halos (median scores 1.6, 2.4 and 1.3 respectively; Fig. 4).

Figure 3: Halometry. (A) Results of Halos and Glare Simulator (Median, Range; Visual Analogous Scale) as well as quantity and severity of photic phenomena. (B) Mean values for perceived Halos and Glare. (C) Minimum values and (D) maximum values for perceived Halos and Glare. No patient perceived photic phenomena of comparable severity, since the simulation shows the combination of maximum reported values for each individual category (Halo Size, Halo Intensity, Glare Size and Glare Intensity).

Figure 4: Questionnaire results for vision problems and perception of photic phenomena.

Patient Satisfaction

All fourteen patients completed the questionnaire. 78.6% stated they were able to perform their usual daily activities without additional spectacle correction. 71.4% would recommend the IOL to family and friends. Whereas the majority appeared to have little problems with unaided distance vision (watching TV: 100%, driving at day: 85.7%, shopping 92.9%) only 28.6% stated that they were able to read the newspaper and 35.7% were able to read books without glasses (Fig 5).

The most commonly cited complaint was difficulty in low lighting (median score 3.4 out of 10) followed by night glare (median score 2.4 out of 10). For all other given items, the median score was 1.6 or lower

(Fig 4).

Overall spectacle independence was high for all distances, but with large ranges for distance and near vision (Fig 5).

Figure 5: Quality of Life Questionnaire and Spectacle Independence.

Discussion

The Mini WELL Ready EDOF IOL showed good visual acuity outcomes that are consistent with that of IOLs such as the Tecnis Symphony.

Comparison of the two lenses is not easy because there are wide differences in the examinations performed in published reports on Symphony. Pedrotti et al. describe mean monocular UDVA, UIVA (60cm) and UNVA values of $0.08 \pm 0.12\text{logMAR}$, $0.24 \pm 0.11\text{logMAR}$ and $0.27 \pm 0.11\text{logMAR}$ (50 eyes of 25 patients, 3 month follow-up)¹². Kaymak et al. found a mean monocular UDVA, UIVA (70cm) and UNVA of $0.02 \pm 0.09\text{logMAR}$, $-0.05 \pm 0.08\text{logMAR}$ and $0.33 \pm 0.12\text{logMAR}$ (36 eyes of 18 patients, 3 month follow-up)¹¹. From other studies, only binocular visual acuity values are available: Ruiz-Mesa et al. report mean binocular UDVA, UIVA and UNVA values of $0.01 \pm 0.02\text{logMAR}$, $0.09 \pm 0.08\text{logMAR}$ and $0.17 \pm 0.06\text{logMAR}$ for this IOL (20 patients, 1 year follow-up)¹³. Similarly, Cochener et al. found a mean binocular UDVA, UIVA and UNVA of $0.03 \pm 0.09\text{logMAR}$, $0.13 \pm 0.16\text{logMAR}$ and $0.21 \pm 0.16\text{logMAR}$ (299 patients in the non-monovision group, 4-6 month follow-up)⁹.

Our results are generally comparable to those of the aforementioned studies. Median UDVA was 0.13logMAR , perhaps attributable to residual refractive error and a non-optimized A-constant since it was fully-correctable by spectacles (median CDVA -0.01logMAR). The Mini-Well performed even slightly better at intermediate and near distances with a median UIVA (80cm) and UNVA of -0.05 and 0.14logMAR respectively. Similar results were also observed in a multicenter study by Savini et al., who reported an enhanced depth of vision through 2.0 D of defocus, with the best performance at 1.0 and 1.5 D²⁰.

Our findings also appear to conform with laboratory observations. On the optical bench, Gatinel et al. showed the Symphony behaves rather like a bifocal IOL with a low add power¹⁰, whereas Domínguez-Vicent found the Mini WELL has a broad depth of focus in the intermediate to near vergence²¹. This is also revealed by the defocus curve of the Mini WELL that shows a broad plateau of functional vision overlapping more than 4 diopters of defocus.

For patients seeking spectacle independence in most of everyday activities, the alternative to an EDOF-IOL is a trifocal IOL. All the latest trifocal IOLs use diffractive optics to generate three distinct foci for far, intermediate and near vision. For the AcrySof Panoptix IOL (Alcon Laboratories, Ft. Worth, TX, USA) Lawless et al. report initial results for monocular UDVA, UIVA (60cm) and UNVA of $0.01 \pm 0.10\text{logMAR}$, $0.30 \pm 0.14\text{logMAR}$ and $0.18 \pm 0.10\text{logMAR}$ (66 eyes of 33 patients, 6 weeks follow-up)⁷ (Table 3). In a comparison of two trifocal IOL designs in 10084 eyes of 5042 patients, Bilbao-Calabuig et al reported

monocular UDVA, UIVA (80cm) and UNVA (40cm) outcomes of $0.04 \pm 0.08\text{logMAR}$, $0.00 \pm 0.17\text{logMAR}$ and $0.07 \pm 0.10\text{logMAR}$ for the AT Lisa tri 839MP (Carl Zeiss AG, Jena, Germany) and $0.06 \pm 0.08\text{logMAR}$, $-0.01 \pm 0.15\text{logMAR}$ and $0.08 \pm 0.10\text{logMAR}$ for the FineVision Micro F IOL (PhysIOL, Liege, Belgium) respectively (3 month follow-up)⁴. Other studies showed similar results for these two IOLs^{6, 22, 23}. However, it should not be overlooked, that initial studies with the same IOL models in smaller patient cohorts showed different results: Sheppard et al. reported a monocular UDVA of 0.19 ± 0.09 for the FineVision IOL (30 eyes of 15 patients, 2 month follow-up)²⁴ and Alió et al. found monocular UDVA, UIVA (80cm) and UNVA (40cm) values of $0.18 \pm 0.13\text{logMAR}$, $0.20 \pm 0.11\text{logMAR}$ and $0.26 \pm 0.15\text{logMAR}$ for the same IOL model (40 eyes of 20 patients, 6 month follow-up)⁵. Similarly, for the AT Lisa trifocal IOL Mojzic et al. recorded UDVA, UIVA (66cm) and UNVA (33cm) results of $-0.03 \pm 0.09\text{logMAR}$, $0.08 \pm 0.10\text{logMAR}$ and $0.20 \pm 0.12\text{logMAR}$ (60 eyes of 30 patients, 6 months follow-up)²⁵, Kretz et al. report a monocular UDVA, UIVA (80cm) and UNVA (40cm) of 0.10logMAR , 0.15logMAR and 0.10logMAR (76 eyes of 38 patients, 3 months follow-up)²⁶ and Mendicute et al. report a binocular UDVA, UIVA (80cm) and UNVA (40cm) of $0.03 \pm 0.09\text{logMAR}$, $0.10 \pm 0.15\text{logMAR}$ and $0.15 \pm 0.14\text{logMAR}$ (104 patients, 3 months follow-up)⁸.

Few studies have explicitly examined reading performance after MIOL implantation^{18, 19, 27-29}. The Salzburg Reading Desk measures reading acuity under close-to real-life conditions with simultaneous and continuous measurement of parameters, such as the patient's distance from the screen, reading speed, smallest readable letter size and reading acuity. Using this device Attia et al. recorded median binocular uncorrected and distance-corrected reading acuities of 0.18logMAR at intermediate distance (80cm) and of 0.05logMAR and 0.01logMAR at near distance (40cm) with AcrySof Restor, (Alcon, Laboratories, Ft. Worth, TX, USA) a diffractive bifocal IOL with +3.0 D near addition,¹⁸. For Lentis MPlus, (Oculentis GmbH, Berlin, Germany), a rotationally asymmetric bifocal IOL with a +3.0 D near addition, Linz et al. found median monocular uncorrected and distance-corrected reading acuities of 0.30logMAR and 0.18logMAR for intermediate distance (80cm) and of 0.18logMAR for near distance (40cm)¹⁹. With the diffractive trifocal FineVision IOL, Attia et al. reported median binocular uncorrected and distance-corrected reading acuities of 0.10logMAR and 0.11logMAR for intermediate distance (80cm) and of 0.11logMAR and 0.01logMAR for near distance (40cm)³⁰. We found Mini Well reading performance at intermediate distance is comparable to that of the FineVision IOL and better than that of bifocal IOLs. The same is true for uncorrected near reading acuity. With the trifocal IOL, on the other hand, patients achieved a better distance-corrected near reading acuity.

Photic phenomena are an intrinsic problem with all MIOLs since the diversion of light to different foci unavoidably causes superposition of multiple images on the retina^{10, 31, 32}. All diffractive IOLs are known to cause Halos to some extent, especially Starbursts¹⁴. The Mini WELL should cause less dysphotopsia since it does not rely on diffractive optics. However, assessment of photic phenomena is difficult and highly depends on the inquiry technique. Mendicute et al. correctly observed that the outcome of these questionnaires may vary according to whether one asks open or closed questions⁸. Indeed, if patients

were not at all specifically asked for photic phenomena, the amount reported would be much lower. It is therefore difficult to compare across different studies the significance of photic phenomena attributable to a given IOL. In inquiries that only used undirected questions ('Do you experience any difficulties with your vision') the incidence of dysphotopsia reported was low⁹. Explicitly asking for different types of photic phenomena yielded higher numbers⁸. Although several studies report high patient satisfaction and low incidence of halos and glare, dysphotopsia remains a major complaint among patients who are dissatisfied after MIOL implantation³³⁻³⁵.

We used a computer-based simulator to assess perception of Halos and Glare, one which our group has experience of in studying trifocal IOLs.³⁶ We found the patients with the Mini WELL were mildly or not at all disturbed by Halos and Starbursts in daily life. However, we still regard this simulator as exploratory and so far, we restrained our analysis to being solely descriptive.

The clinical results reported herein should be considered in the light of some limitations, such as the limited number of patients enrolled or the lack of a control group. Future studies should also evaluate the Mini WELL IOL's clinical performance with a longer follow-up period.

Conclusions

Previous clinical and laboratory studies, which directly compared EDOF-IOLs and Trifocal lenses, concluded EDOF-IOLs provide good far and intermediate visual results but fall short of trifocal IOLs for near visual acuity at common reading distances.^{10,13} Our results suggest the Mini WELL is different, showing good near visual acuity in addition to very good intermediate distance visual acuity. Laboratory observations support this finding²⁰. In general, the Mini WELL renders a level of visual rehabilitation similar to that of current trifocal IOLs. Overall perception of dysphotopsia is lower and less severe than in comparable IOLs. These results should be confirmed with increased patient numbers and longer follow-up periods.

Abbreviations

DOF=Extended Depth of Focus; IOL=Intraocular Lens; UDVA=Uncorrected Distance Visual Acuity; CDVA=Corrected Distance Visual Acuity; UNVA=Uncorrected Near Visual Acuity; DCNVA=Distance-Corrected Near Visual Acuity; CNVA=Corrected Near Visual Acuity; UIVA=Uncorrected Intermediate Visual Acuity; DCIVA=Distance-Corrected Intermediate Visual Acuity; MIOLs=Multifocal Intraocular Lenses; ETDRS= Early Treatment Diabetic Retinopathy Study.

Declarations

Ethics Approval and Consent to Participate

This clinical study was approved by the local Ethics Committee and performed in accordance with the tenets of the Declaration of Helsinki. All patients gave their written informed consent form prior to inclusion to the study.

Consent for Publication

Not applicable.

Availability of Data and Materials

All generated or analyzed during this study are included in this published article.

Competing Interests

There are no competing interests to disclose.

Funding

Klaus Tschira Foundation, Heidelberg, Germany, helped in the design and collection of the study. We acknowledge financial support by Deutsche Forschungsgemeinschaft within the funding programme Open Access Publishing by the Baden-Württemberg Ministry of Science, Research and the Arts and by Ruprecht-Karls-Universität Heidelberg.

Authors' Contributions

GUA and RK conceived and supervised the study. BCG, DV, HW, and MSA contributed to the collection and analysis of the data. BCG wrote the initial manuscript, revised by HSS and RK. All authors critically reviewed the paper for important intellectual content and approved the final version to be published.

Acknowledgements

Donald J. Munro contributed to the review of the pre-publication report.

References

- 1 Auffarth GU, Rabsilber TM, Kohnen T, Holzer MP. [Design and optical principles of multifocal lenses]. *Ophthalmologie* 2008; 105: 522-526
- 2 Madrid-Costa D, Ruiz-Alcocer J, Ferrer-Blasco T, Garcia-Lazaro S, Montes-Mico R. Optical quality differences between three multifocal intraocular lenses: bifocal low add, bifocal moderate add, and trifocal. *Journal of refractive surgery* 2013; 29: 749-754
- 3 Gatinel D, Pagnouille C, Houbrechts Y, Gobin L. Design and qualification of a diffractive trifocal optical profile for intraocular lenses. *Journal of cataract and refractive surgery* 2011; 37: 2060-2067

- 4 Bilbao-Calabuig R, Llovet-Rausell A, Ortega-Usobiaga J, Martinez-Del-Pozo M, Mayordomo-Cerda F, Segura-Albentosa C, Baviera J, Llovet-Osuna F. Visual Outcomes Following Bilateral Implantation of Two Diffractive Trifocal IOLs in 10,084 eyes. *American journal of ophthalmology* 2017
- 5 Alio JL, Montalban R, Pena-Garcia P, Soria FA, Vega-Estrada A. Visual outcomes of a trifocal aspheric diffractive intraocular lens with microincision cataract surgery. *Journal of refractive surgery* 2013; 29: 756-761
- 6 Cochener B, Vryghem J, Rozot P, Lesieur G, Chevalier JP, Henry JM, David T, Lesueur L, Gatinel D, Ganem C, Blanckaert J, Van Acker E, Heireman S, Ghekiere S. Clinical outcomes with a trifocal intraocular lens: a multicenter study. *Journal of refractive surgery* 2014; 30: 762-768
- 7 Lawless M, Hodge C, Reich J, Levitz L, Bhatt UK, McAlinden C, Roberts K, Roberts TV. Visual and refractive outcomes following implantation of a new trifocal intraocular lens. *Eye Vis (Lond)* 2017; 4: 10
- 8 Mendicute J, Kapp A, Levy P, Krommes G, Arias-Puente A, Tomalla M, Barraquer E, Rozot P, Bouchut P. Evaluation of visual outcomes and patient satisfaction after implantation of a diffractive trifocal intraocular lens. *Journal of cataract and refractive surgery* 2016; 42: 203-210
- 9 Cochener B, Concerto Study G. Clinical outcomes of a new extended range of vision intraocular lens: International Multicenter Concerto Study. *Journal of cataract and refractive surgery* 2016; 42: 1268-1275
- 10 Gatinel D, Loicq J. Clinically Relevant Optical Properties of Bifocal, Trifocal, and Extended Depth of Focus Intraocular Lenses. *Journal of refractive surgery* 2016; 32: 273-280
- 11 Kaymak H, Hohn F, Breyer DR, Hagen P, Klabe K, Gerl RH, Mueller M, Auffarth GU, Gerl M, Kretz FT. [Functional Results 3 Months after Implantation of an "Extended Range of Vision" Intraocular Lens]. *Klin Monbl Augenheilkd* 2016; 233: 923-927
- 12 Pedrotti E, Bruni E, Bonacci E, Badalamenti R, Mastropasqua R, Marchini G. Comparative Analysis of the Clinical Outcomes With a Monofocal and an Extended Range of Vision Intraocular Lens. *Journal of refractive surgery* 2016; 32: 436-442
- 13 Ruiz-Mesa R, Abengoza-Vela A, Aramburu A, Ruiz-Santos M. Comparison of visual outcomes after bilateral implantation of extended range of vision and trifocal intraocular lenses. *European journal of ophthalmology* 2017: 0
- 14 de Silva SR, Evans JR, Kirthi V, Ziaei M, Leyland M. Multifocal versus monofocal intraocular lenses after cataract extraction. *Cochrane Database Syst Rev* 2016; 12: CD003169
- 15 de Vries NE, Nuijts RM. Multifocal intraocular lenses in cataract surgery: literature review of benefits and side effects. *Journal of cataract and refractive surgery* 2013; 39: 268-278

- 16 Dexl AK, Schlogel H, Wolfbauer M, Grabner G. Device for improving quantification of reading acuity and reading speed. *Journal of refractive surgery* 2010; 26: 682-688
- 17 Hirschall N, Motaabbed JK, Dexl A, Grabner G, Findl O. Evaluation of an electronic reading desk to measure reading acuity in pseudophakic patients. *Journal of cataract and refractive surgery* 2014; 40: 1462-1468
- 18 Attia MS, Khoramnia R, Auffarth GU, Kirchner M, Holzer MP. Near and intermediate visual and reading performance of patients with a multifocal apodized diffractive intraocular lens using an electronic reading desk. *Journal of cataract and refractive surgery* 2016; 42: 582-590
- 19 Linz K, Attia MS, Khoramnia R, Tandogan T, Kretz FT, Auffarth GU. Clinical Evaluation of Reading Performance Using the Salzburg Reading Desk With a Refractive Rotational Asymmetric Multifocal Intraocular Lens. *Journal of refractive surgery* 2016; 32: 526-532
- 20 Savini G, Balducci N, Carbonara C, Rossi S, Altieri M, Frugis N, Zappulla E, Bellucci R, Alessio G. Functional assessment of a new extended depth-of-focus intraocular lens. *Eye (Lond)* 2019;33:404-410.
- 21 Dominguez-Vicent A, Esteve-Taboada JJ, Del Aguila-Carrasco AJ, Monsalvez-Romin D, Montes-Mico R. In vitro optical quality comparison of 2 trifocal intraocular lenses and 1 progressive multifocal intraocular lens. *Journal of cataract and refractive surgery* 2016; 42: 138-147
- 22 Kretz FT, Muller M, Gerl M, Gerl RH, Auffarth GU. Binocular function to increase visual outcome in patients implanted with a diffractive trifocal intraocular lens. *BMC ophthalmology* 2015; 15: 110
- 23 Jonker SM, Bauer NJ, Makhotkina NY, Berendschot TT, van den Biggelaar FJ, Nuijts RM. Comparison of a trifocal intraocular lens with a +3.0 D bifocal IOL: results of a prospective randomized clinical trial. *Journal of cataract and refractive surgery* 2015; 41: 1631-1640
- 24 Sheppard AL, Shah S, Bhatt U, Bhogal G, Wolffsohn JS. Visual outcomes and subjective experience after bilateral implantation of a new diffractive trifocal intraocular lens. *Journal of cataract and refractive surgery* 2013; 39: 343-349
- 25 Mojzis P, Pena-Garcia P, Liehneova I, Ziak P, Alio JL. Outcomes of a new diffractive trifocal intraocular lens. *Journal of cataract and refractive surgery* 2014; 40: 60-69
- 26 Kretz FT, Breyer D, Diakonis VF, Klabe K, Henke F, Auffarth GU, Kaymak H. Clinical Outcomes after Binocular Implantation of a New Trifocal Diffractive Intraocular Lens. *J Ophthalmol* 2015; 2015: 962891
- 27 Alio JL, Grabner G, Plaza-Puche AB, Rasp M, Pinero DP, Seyeddain O, Rodriguez-Prats JL, Ayala MJ, Moreu R, Hohensinn M, Riha W, Dexl A. Postoperative bilateral reading performance with 4 intraocular lens models: six-month results. *Journal of cataract and refractive surgery* 2011; 37: 842-852

- 28 Rasp M, Bacherneegg A, Seyeddain O, Ruckhofer J, Emesz M, Stoiber J, Grabner G, Dexl AK. Bilateral reading performance of 4 multifocal intraocular lens models and a monofocal intraocular lens under bright lighting conditions. *Journal of cataract and refractive surgery* 2012; 38: 1950-1961
- 29 Santhiago MR, Netto MV, Espindola RF, Mazurek MG, Gomes Bde A, Parede TR, Harooni H, Kara-Junior N. Comparison of reading performance after bilateral implantation of multifocal intraocular lenses with +3.00 or +4.00 diopter addition. *Journal of cataract and refractive surgery* 2010; 36: 1874-1879
- 30 Attia MS, Auffarth GU, Khoramnia R, Linz K, Kretz FT. Near and intermediate reading performance of a diffractive trifocal intraocular lens using a reading desk. *Journal of cataract and refractive surgery* 2015; 41: 2707-2714
- 31 Alba-Bueno F, Vega F, Millan MS. [Halos and multifocal intraocular lenses: origin and interpretation]. *Arch Soc Esp Oftalmol* 2014; 89: 397-404
- 32 Vega F, Alba-Bueno F, Millan MS, Varon C, Gil MA, Buil JA. Halo and Through-Focus Performance of Four Diffractive Multifocal Intraocular Lenses. *Invest Ophthalmol Vis Sci* 2015; 56: 3967-3975
- 33 de Vries NE, Webers CA, Touwslager WR, Bauer NJ, de Brabander J, Berendschot TT, Nuijts RM. Dissatisfaction after implantation of multifocal intraocular lenses. *Journal of cataract and refractive surgery* 2011; 37: 859-865
- 34 Kamiya K, Hayashi K, Shimizu K, Negishi K, Sato M, Bissen-Miyajima H, Survey Working Group of the Japanese Society of C, Refractive S. Multifocal intraocular lens explantation: a case series of 50 eyes. *American journal of ophthalmology* 2014; 158: 215-220 e211
- 35 Davies EC, Pineda R, 2nd. Intraocular lens exchange surgery at a tertiary referral center: Indications, complications, and visual outcomes. *Journal of cataract and refractive surgery* 2016; 42: 1262-1267
- 36 Kretz FT, Breyer D, Klabe K, Hagen P, Kaymak H, Koss MJ, Gerl M, Mueller M, Gerl RH, Auffarth GU. Clinical Outcomes After Implantation of a Trifocal Toric Intraocular Lens. *Journal of refractive surgery* 2015; 31: 504-510

Tables

	Mean	SD	Median	Min.	Max.
UDVA	0.13	0.13	0.13	-0.08	0.42
CDVA	0.00	0.11	-0.01	-0.20	0.22
UIVA	0.01	0.17	-0.05	-0.18	0.58
DCIVA	0.04	0.18	0.03	-0.02	0.58
UNVA	0.17	0.20	0.14	-0.10	0.64
DCNVA	0.20	0.21	0.18	-0.10	0.62
CNVA	-0.03	0.14	-0.08	-0.20	0.34
Near Add. (D)	+1.59	0.72	+1.50	0.00	+2.75

Table 1: Monocular (n = 28 eyes of 14 patients) visual acuity results in logMAR. UDVA = uncorrected distance visual acuity, CDVA = corrected distance visual acuity, UIVA = uncorrected intermediate visual acuity, DCIVA = distance-corrected intermediate visual acuity, UNVA = uncorrected near visual acuity, DCNVA = distance-corrected near visual acuity, CNVA = corrected visual acuity, Near Add. = near addition (in diopters of spherical power).

	Near Distance (40cm)	Preferred Near Distance	Intermediate Distance (80cm)	Preferred Intermediate Distance
Uncorrected				
Visual Acuity (logMAR)	0.10	0.13	0.11	0.11
Distance (cm)	40.30	39.50	79.20	62.80
Letter Size (log- scaled)	1.25	1.25	1.25	1.00
Reading Speed (wpm)	92.0	92.0	110.0	100.0
Distance-Corrected				
Visual Acuity (logMAR)	0.21	0.19	0.10	0.12
Distance (cm)	40.30	38.90	79.40	60.00
Letter Size (log- scaled)	1.50	1.50	1.25	1.00
Reading Speed (wpm)	97.0	102.0	103.0	97.0

Table 2: Median binocular (n = 11 patients) uncorrected and distance-corrected reading performance for near and intermediate distances with the Salzburg Reading Desk. wpm = words per minute.

First Author	IOL Studied	Patients included	Mean postoperative uncorrected binocular visual acuity (logMAR)		
			UDVA	UIVA (<i>distance</i>)	UNVA (<i>distance</i>)
Lawless et al. ⁷	<i>PanOptix</i>	33 patients	0.01 ± 0.10	0.30 ± 0.14 (60cm)	0.18 ± 0.10 (40cm)
Bilbao-Calabuig et al. ⁴	<i>AT Lisa tri 839MP</i>	2141 patients	0.04 ± 0.08	0.00 ± 0.17 (80cm)	0.07 ± 0.10 (40cm)
Bilbao-Calabuig et al. ⁴	<i>Micro F</i>	2901 patients	0.06 ± 0.08	-0.01 ± 0.15 (80cm)	0.08 ± 0.10 (40cm)
Sheppard et al. ²³	<i>FineVision</i>	15 patients	0.19 ± 0.09	-	-
Alio et al. ⁵	<i>FineVision</i>	20 patients	0.18 ± 0.13	0.20 ± 0.11 (80cm)	0.26 ± 0.15 (40cm)
Mojzis et al. ²⁴	<i>AT Lisa tri 839MP</i>	30 patients	-0.03 ± 0.09	0.08 ± 0.10 (66cm)	0.20 ± 0.12 (33cm)
Mendicute et al. ⁸	<i>AT Lisa tri 839MP</i>	104 patients	0.03 ± 0.09	0.10 ± 0.15 (80cm)	0.15 ± 0.14 (40cm)
Cochener et al. ⁶	<i>FineVision</i>	99 patients	0.01 ± 0.06	0.08 ± 0.10 (60cm)	0.00 ± 0.04 (30cm)
Kretz et al. ²¹	<i>AT Lisa tri 839MP</i>	50 patients	0.06 ± 0.10	0.09 ± 0.10 (66cm)	0.06 ± 0.05 (40cm)
Jonker SM et al. ²²	Micro F	15 patients	0.01 ± 0.11	0.32 ± 0.15 (70cm)	0.15 ± 0.13 (40cm)

Table 3: Mean postoperative uncorrected binocular visual acuity results (logMAR) of previous studies on different trifocal intraocular lens models.

Figures

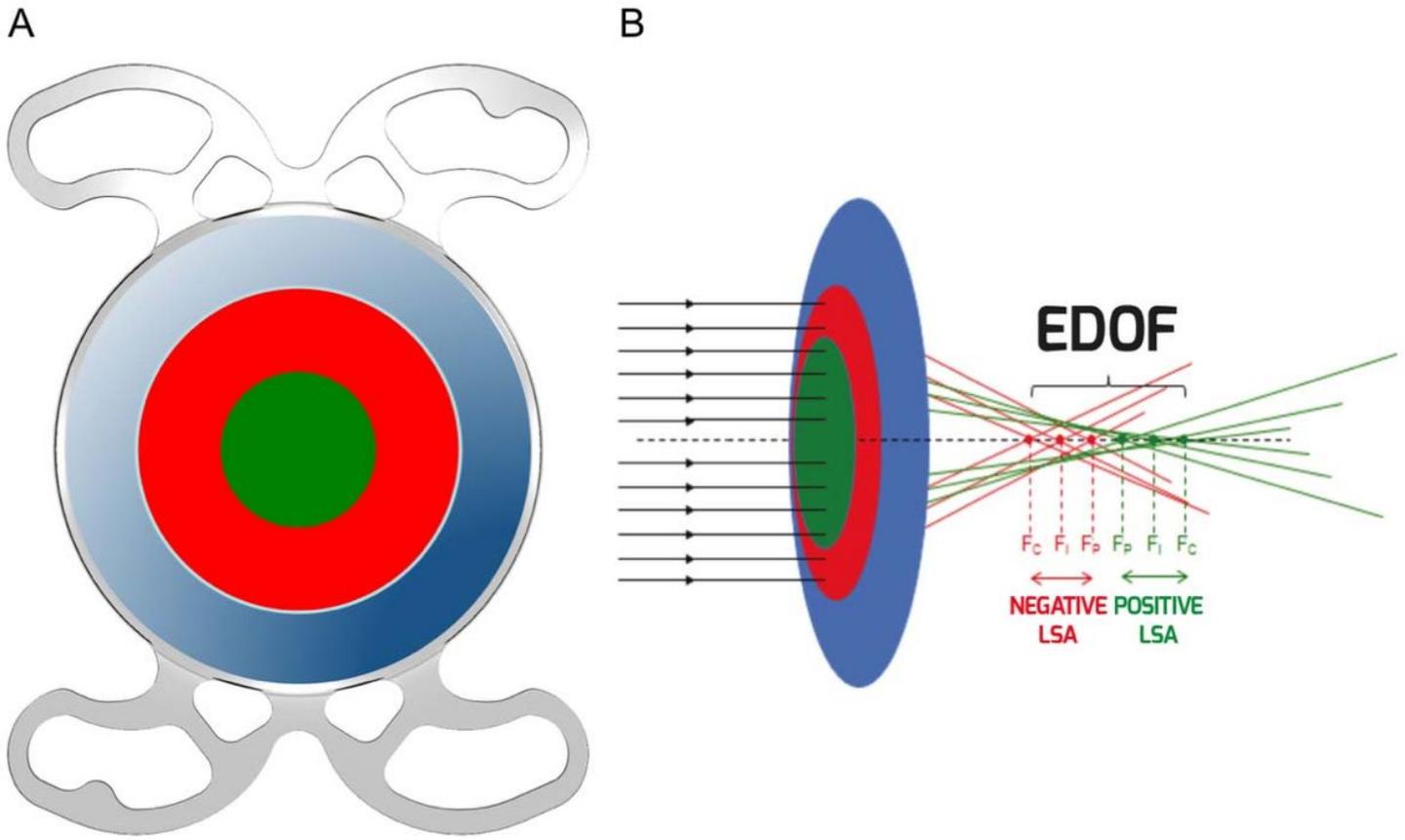


Figure 1

Schematic illustration of the Mini WELL Ready. A) D1 is shown in green, D2 in red, and D3 in blue. B) In D1, the central rays (Fc, green) come into focus behind the peripheral rays (Fp, green), while in D2, the central rays (Fc, red) come into focus in front of peripheral rays (Fp, red). LSA = Longitudinal spherical aberration; EDOF = Extended-depth-of-focus.

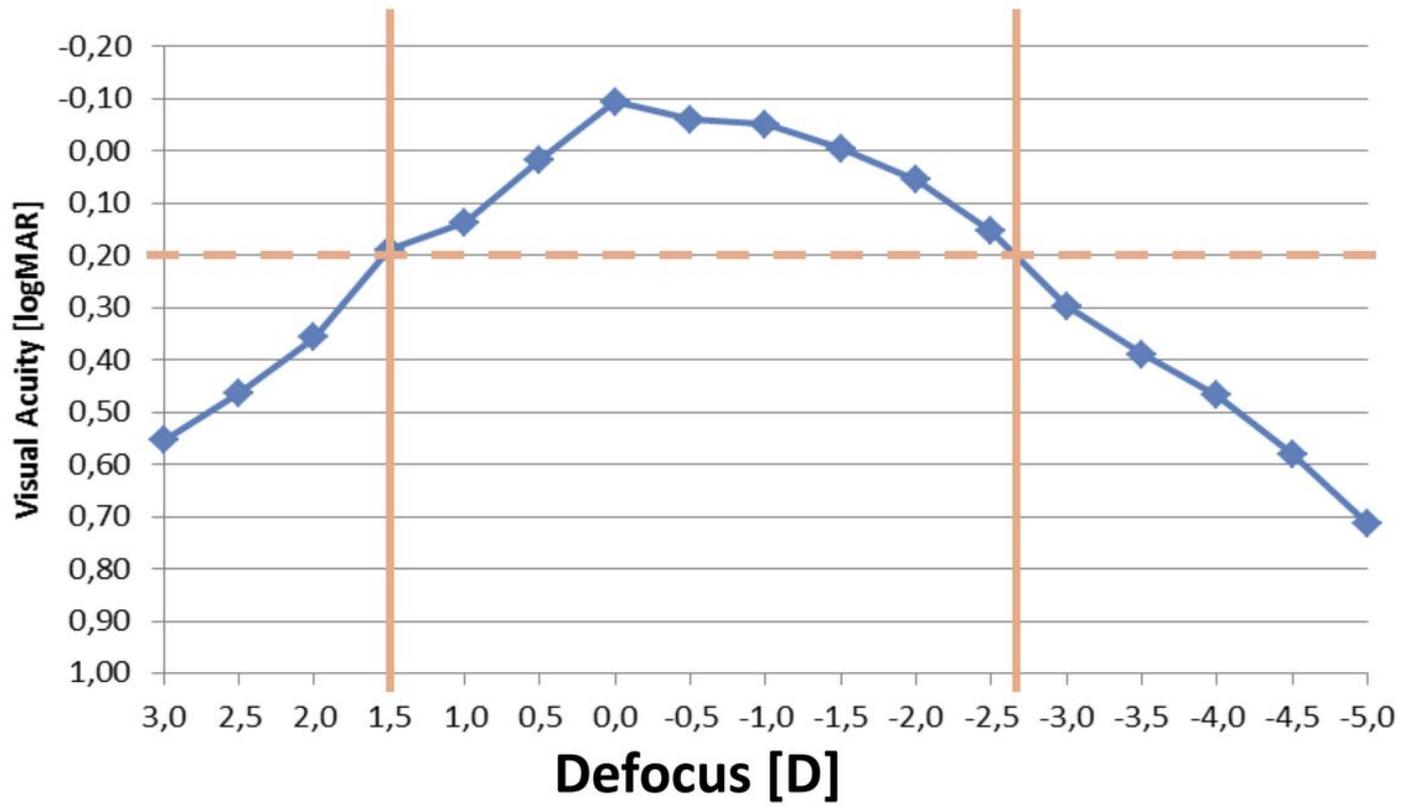


Figure 2

Binocular distance-corrected defocus curve (n = 14 patients)



Figure 3

Halometry. (A) Results of Halos and Glare Simulator (Median, Range; Visual Analogous Scale) as well as quantity and severity of photic phenomena. (B) Mean values for perceived Halos and Glare. (C) Minimum values and (D) maximum values for perceived Halos and Glare. No patient perceived photic phenomena of comparable severity, since the simulation shows the combination of maximum reported values for each individual category (Halo Size, Halo Intensity, Glare Size and Glare Intensity).

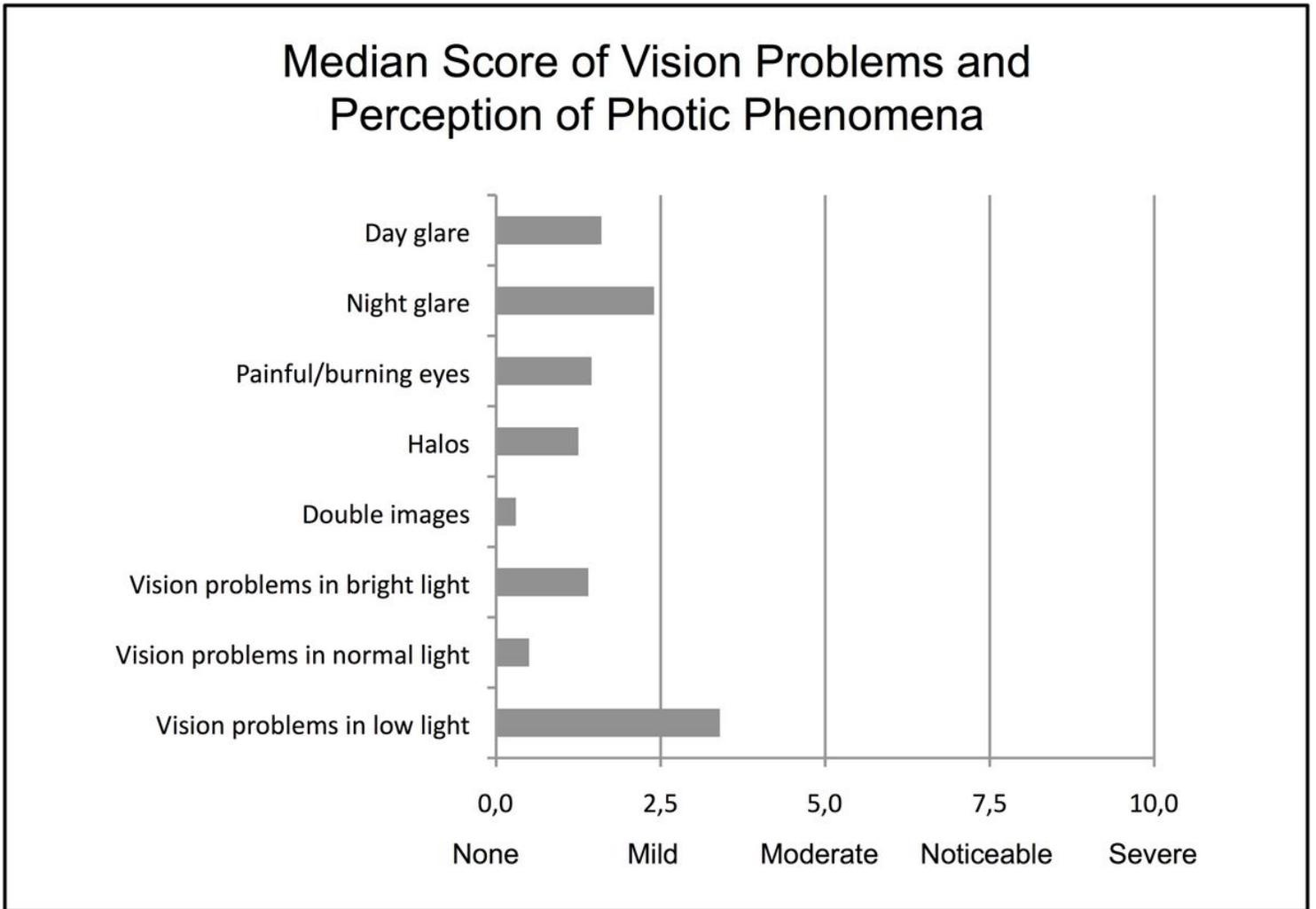


Figure 4

Questionnaire results for vision problems and perception of photic phenomena.

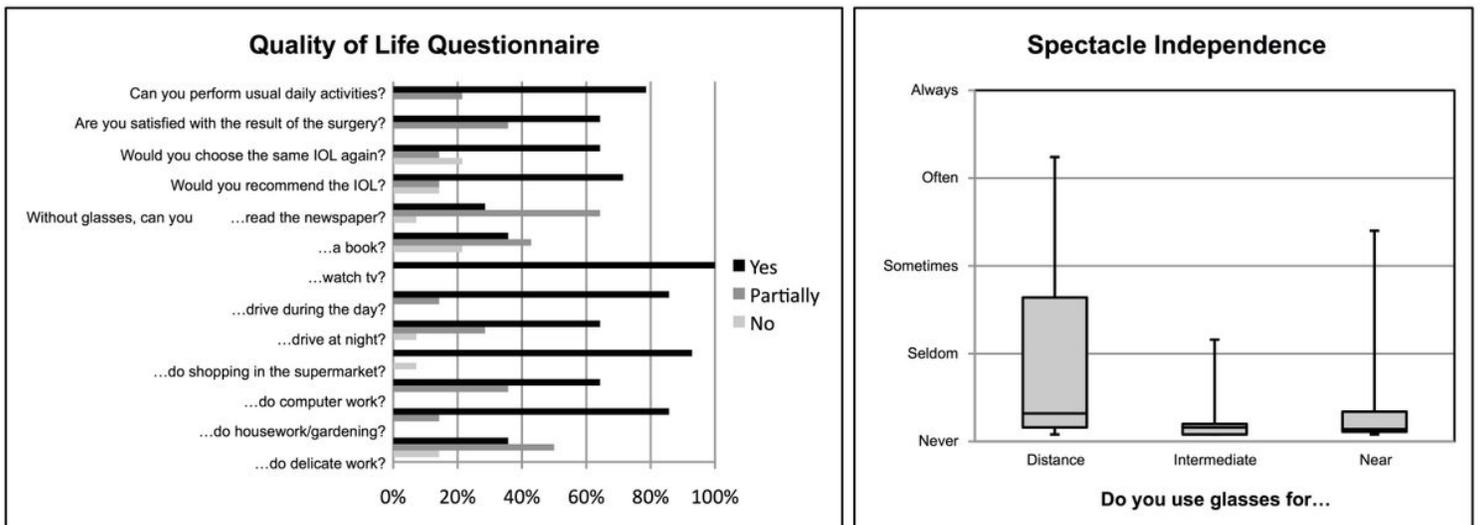


Figure 5

Quality of Life Questionnaire and Spectacle Independence.