REVIEW/UPDATE

Measures of visual disturbance in patients receiving extended depth-of-focus or trifocal intraocular lenses

Thomas Kohnen, MD, PhD, FEBO, Rajaraman Suryakumar, BS(Optom), PhD, FAAO

The degree of visual disturbance associated with a particular model of intraocular lens (IOL) depends on several factors, including IOL optic, material, and mechanics. Characterization of visual disturbance profiles is paramount for informing clinical IOL selection. Although many studies evaluating presbyopia-correcting IOLs include subjective assessment of visual symptoms, the types of patient-reported outcome measures (PROMs) used to capture these outcomes are inconsistent across studies, complicating data contextualization. Furthermore, some tools produce more meaningful results than others. This review presents a discussion on the scientific literature published on the subjective and semiobjective (halo and glare simulator, light-distortion analyzer, vision monitor, and halometers) methods used to assess visual disturbances in patients implanted with trifocal or extended depth-of-focus IOLs, highlighting their advantages and limitations. It underscores the importance of between-study comparisons and the need for standardized PROMs in clinical IOL research to provide more accurate information for IOL selection.

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Despite achieving objectively good visual acuity, some patients might continue to express dissatisfaction with their vision after implantation of a presbyopia-correcting intraocular lens (IOL).[1,2] This is because, in addition to quantity of vision (residual refractive error), multiple other visual symptoms and psychological factors contribute to an individual's perceived quality of vision (QoV), which in turn impacts their subjective quality of life (QoL).[3] It is, therefore, important to include reliable, validated patient-reported outcome measures (PROMs) and individual patient outcomes in clinical trials to capture subjective patient experience and provide a more holistic assessment of IOL performance.[4]

Visual disturbances have been highlighted as a key cause of dissatisfaction in patients implanted with an IOL, a problem that is common to both monofocal and presbyopia-correcting IOL recipients.[2,5,6] The most frequent concerns relate to blurred vision and the presence of photic phenomena, such as glare, halo, and starburst.[6–8] These latter disturbances, termed positive dysphotopsias, arise from unwanted light being directed onto the retina by elements of the IOL's optical structure.[8–11] Negative dysphotopsias are defined as the perception of an arc-shaped shadow obscuring the temporal field of vision; their etiology is believed to be multifactorial, with small pupil size, a higher angle κ, an angle α of 5.2 degrees, a shallow orbit and prominent globe, and the larger potential optic area in acrylic IOLs identified as potential risk factors.[12–14] As such, the type, frequency, and severity of visual disturbances might be expected to differ according to the optic, material, and mechanics of the implanted IOL.

Although monofocal IOLs direct all of the light energy to a single, typically distant focal point, avoiding light splitting and resulting in minimal visual disturbances, multifocal IOLs split the light between multiple focal points to provide distance, near, and/or intermediate vision.[5,15] This inherent light splitting might result in increased scattered light and the generation of multiple defocused images on the retina, which might translate into more frequent or pronounced dysphotopsia compared with a monofocal IOL.[5,11,15–19] For example, nighttime halos have been suggested to be due to defocused light that is directed to the second image of a multifocal IOL.[20] Extended depth-of-focus (EDoF) IOLs have been developed to bridge the gap between monofocal and multifocal lenses, providing a continuous range of functional vision from distance to near.[21] Diffractive EDoF technology also relies on light splitting and has been associated with a significantly greater degree of visual disturbance compared

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From the Department of Ophthalmology (Kohnen), Goethe University Frankfurt, Frankfurt, Germany; and Alcon Vision LLC (Suryakumar), Fort Worth, Texas, USA.

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Corresponding author: Thomas Kohnen, MD, PhD, FEBO, Department of Ophthalmology, Goethe-University Frankfurt am Main, Theodor-Stern-Kai 7, 60590 Frankfurt am Main, Germany. Email: kohnen@em.uni-frankfurt.de.

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with monofocal technology.[11] Several EDoF designs that do not rely on light splitting are available, including non-diffractive, small-aperture, and bioanalogic optics; however, to our knowledge, there are currently no published randomized controlled trials demonstrating reduced visual disturbances with these designs compared with diffractive EDoF IOLs.[21–23]

Given the wide range of IOLs now available, reliable visual disturbance profiling is essential for informing clinical choice; however, there is no consensus on the best way to measure these symptoms. This review presents a discussion on the scientific literature published on the subjective and semiobjective methods used to assess visual disturbances in patients implanted with trifocal or EDoF IOLs, highlighting their advantages and limitations. The aim is to help researchers and eyecare professionals interpret published data and select appropriate QoV outcome measures for future studies. In light of the large volume of published data on this subject, the review focuses on studies reporting visual disturbance outcomes in recipients of EDoF and trifocal IOLs, given that these are the newer presbyopia-correcting technologies.[24] The methodology for the literature search is provided in Appendix 1 (see Supplemental Digital Content 1, available at http://links.lww.com/JRS/A156), with details of the designs and findings of the retrieved studies summarized in Tables 1 and 2 (see Supplemental Digital Content 2, available at: http://links.lww.com/JRS/A157).

SUBJECTIVE MEASURES

A PROM is a tool, or instrument, used to measure patient-reported outcomes, such as visual symptoms, QoL, or convenience, and to assess the impact of treatment from an individual patient's perspective.[4] A PROM consists of a set of questions, or items, which capture information on health. Although measuring symptoms is unidimensional, the impact of the treatment on QoL is challenging because it is multidimensional, with each trait, or domain of interest, requiring consideration and measurement. Therefore, these domains should be identified upfront, so that the best PROM can be selected from the pool of available instruments and tested to establish validity for use in a new setting or a new PROM developed where necessary.[4]

In addition to standard clinical measurements, the need for subjective PROMs as part of a comprehensive assessment of treatment utility has been highlighted by the U.S. Food and Drug Administration (FDA), which now recommends the use of patient experience data to inform clinical trial design, endpoint selection, and regulatory review.[25–27,A,B] Such data might also contribute to product labeling, clinical guideline recommendations, policy planning, service provision, and appraisal of healthcare providers, with patient perspectives considered particularly valuable where objective measurements suggest similar effectiveness between devices or procedures.[4,28,A] Subjective feedback might also be helpful for revealing unexpected patient preferences or for refining candidate selection.[4,25] Thus, the demand for validated PROMs in modern ophthalmic research and clinical practice is on the rise.[4] This is particularly the case for disease areas in which objective factors have been identified as poor indicators of patient experience, such as intraocular pressure as a marker of neuropathy in patients with glaucoma and visual acuity as a marker of visual quality in patients who have undergone cataract surgery.[29,30]

Several types of subjective PROMs exist, and for the purposes of this review, we have categorized them as traditional and Rasch calibrated. Subjective PROMs that capture the frequency, severity, and/or disruptiveness of visual disturbances have been adopted in studies evaluating EDoF and trifocal technology (Table 1); however, there is a lack of standardization regarding the type of tool used with studies featuring a mixture of validated and nonvalidated scores and questionnaires that use directed (specific, sometimes with reference images) and/or nondirected (open) questions. The reporting of symptoms can also be highly variable, with some tools adopting a simple yes/no occurrence and others using a rating system or severity scale; numerous variations exist within the latter regarding which symptoms are asked about, the severity scale range, and/or the wording of responses.[22,23,31,32] This lack of consistency limits outcome comparisons between studies, precludes unambiguous characterization of the key QoL benefits offered by the technologies, and hinders the establishment of relative visual disturbance profiles for the different EDoF and trifocal IOLs. Furthermore, only PROMs developed in line with FDA guidance might be used to substantiate medical product labeling; such validated tools must demonstrate appropriateness for the population and medical condition tested, an evolved and evidence-based conceptual framework, content validity, and the ability to detect change, among other measurement properties.[C]

TRADITIONAL PROMs

Traditional PROMs typically entail paper–pencil questionnaires comprising several domains, with a number of items per domain.[27,28] Responses are often captured on a Likert-type scale, with the final output being an overall rating based on the summative scoring method.[3,7] The results of verbal interviews and subject-initiated complaints might also be captured.[7] A systematic review identified 48 PROMs demonstrating interval measurement properties relevant to 9 applications including glaucoma, dry eye, refractive errors, and cataract.[33] These instruments were evaluated against the psychometric property quality criteria (content development, performance of the response scale, dimensionality, measurement precision, validity, reliability, targeting, differential item function, and responsiveness) and rated for quality based on the number of criteria met, to inform researchers and clinicians on the choice of the highest-quality instrument suitable for their purpose.[33]

Unfortunately, many traditional PROMs have important shortcomings. They can involve a lengthy process that is burdensome to both the administrator and the respondent, with repetitive or complex content.[28,34] They might also be overly generic, unvalidated, partially validated, or unrefined;

Table 1. Overview of subjective measures used to assess visual disturbances.

Type	Description	Critical Evaluation	Examples from EDoF and Trifocal Studies
Traditional PROMS	Paper–pencil questionnaires or verbal interviews comprising several domains, with a number of items per domain[27,28]	Tend to have important shortcomings, including:[3,4,27,28,34–38] Repetitive, generic, or complex content A high response burden Confusing or misleading language Lack of weighting Limited sensitivity Limited relevance to different populations Multidimensional items that are inappropriate for measuring individual traits Poor facility for person separation	NEI-VFQ-25[39–41] NEI-VFQ-39[42] NEI-RQL-42[43,44] Bespoke questionnaires[8,22,23,31,39,45,47,49,50,63,65,69,76–92,D]
Rasch-based PROMs	Questionnaires developed to address the limitations of traditional PROMs[51]	Include many features that improve on traditional PROMs, including:[51] Item weighting Unidimensional questions Response scaling	QoV questionnaire[3] Catquest-9SF[4] Cat-PROM5[4,9]
Item banking	Computer-based questionnaires in which the difficulty of each item is calibrated and items are selectively presented to the respondents based on their responses to previous questions and level of impairment[28,35,36]	Advantages include the following[28,35,36] Allow tailoring of questions to an individual's ability and daily visual needs Reducing test burden Increasing flexibility Increasing efficiency Increasing accuracy Drawbacks include following: Need for computerized infrastructure; Considerable time for development, background research, planning, and data analysis Comparison of the same questionnaire between studies might not be feasible	Not yet used to assess visual disturbances

EDoF = extended depth-of-focus; IOL = intraocular lens; NEI-VFQ-25 = National Eye Institute Visual Functioning Questionnaire 25; NEI-VFQ-39 = National Eye Institute Visual Functioning Questionnaire 39; NEI-RQL-42 = National Eye Institute Refractive Error Quality of Life Instrument 42; PROMs = patient-reported outcome measures; QoV = quality of vision

contain confusing or misleading language; fail to adequately measure all applicable domains; lack weighting or sensitivity; be limited in their relevance to different populations; and ultimately provide a poor reflection of an individual respondent's experience.[3,4,27,28,35–37] For example, a questionnaire measuring postoperative visual function might have multiple items related to night driving that would be inapplicable to respondents who do not drive, without the flexibility to detect and account for this element. Furthermore, questionnaire subscales might contain misused response categories, consist of multidimensional items that are inappropriate for measuring individual traits, and be inadequate for allowing clear person separation.[38] As a result, some traditional PROMs fail to measure the true impact of an intervention; to properly evaluate visual disturbances in IOL recipients, there is a clear need for validated PROMs developed in line with FDA guidance.

The National Eye Institute (NEI)-Visual Functioning Questionnaire (VFQ)-25, NEI-VFQ-39, and NEI-Refractive Error Quality of Life Instrument (RQL)-42 are examples of large-scale, traditional PROMs that have been used to assess QoV in patients implanted with EDoF and trifocal IOLs.[39–44] Comparative studies using these complex tools have reported a trend toward more frequent dysphotopsia symptoms with diffractive technology compared with monofocal IOLs, although have not demonstrated statistically significant differences.[43,44] It is possible that any significant effects might have been masked by the aforementioned limitations of these multidimensional, traditional PROMs.

Smaller-scale, bespoke questionnaires and interviews have also been used in a large number of EDoF and trifocal IOL studies. Of particular note is an FDA registrational study for the TECNIS Symfony diffractive EDoF IOL, which assessed the impact of visual disturbances using a simple questionnaire that required patients to rate their symptom bother on a scale from none to severe.[D] In line with the larger traditional questionnaires, this tool also identified a higher degree of bother from photic phenomena in recipients of the TECNIS Symfony IOL

compared with a monofocal IOL, with the proportion of patients reporting very or severely bothersome starburst and halo more than 3-fold higher in the former group.[D] This supports the idea that, despite their limitations, traditional PROMs might be useful for capturing trends. This concept is further supported by a number of trifocal IOL studies that reported evidence of neuroadaptation over time using traditional PROMs, regardless of the different bespoke questionnaires used and the slightly different paradigms measured.[45–48]

A head-to-head comparison between the Mini Well EDoF IOL, which is based on alternating positive and negative spherical aberration, and an aspheric monofocal IOL found no significant difference in dysphotopsia symptoms between groups using a bespoke questionnaire on nighttime visual disturbances.[23] However, the unvalidated nature of the PROM used to measure symptoms complicates the interpretation and contextualization of the data. In addition, the use of different PROMs in studies evaluating different types of EDoF IOL technology makes between-study comparisons even more problematic.

A further demonstration of the potential issues with nonstandardized, bespoke questionnaires is provided by 2 studies comparing patients implanted with AT LISA Tri and FineVision trifocal IOLs.[49,50] Although recipients in 1 study reported a relatively low level of trouble with halo, glare, and starburst at 3 months, with no difference between AT LISA Tri and FineVision groups, a significantly higher degree of bother from halos in AT LISA Tri recipients at 1 month was reported in another study.[49,50] Besides follow-up length, a key difference between these studies was the lexicon used to assess the visual disturbances, with the different terminology used in each of the Likert scale–based assessment tools measuring a slightly different paradigm.[49,50]

RASCH-BASED AND OTHER VALIDATED PROMs

Rasch-based and other validated PROMs have been developed to address the limitations of past iterations. Rasch analysis is a psychometric technique that permits item weighting, unidimensional questions, and response scaling, allowing for more meaningful comparisons.[51] Perhaps the most important drawback of traditional PROMs addressed by the Rasch approach is the unknown spacing between scores; in a questionnaire featuring a Likert-type scale, the magnitude of the jump from none to mild might not be the same as that from moderate to severe, impeding interpretation. Relative jump sizes are also likely to differ between the different items in a questionnaire. Rasch analysis accounts for these differences, allowing the translation of raw, ordinal scores into linear intervals and, thereby, creating a continuous scale of underlying latent traits along which questionnaire items can be positioned.[3,30] Such appropriate scaling is essential for parametric statistical analysis and for allowing easy management of omitted items and more accurate capture of symptom changes.[3,27]

One example of a Rasch-calibrated PROM is the QoV questionnaire developed by McAlinden et al., an extensively refined, 10-symptom tool, featuring 3 separate scales that measure the frequency, severity, and bother of each visual symptom.[3] The QoV questionnaire was also developed and refined through extensive literature appraisal, focus groups, and patient interviews to ensure content validity.[3] The accuracy and reliability of patient responses are aided by the provision of illustrative images alongside questions 1 to 7, with wording optimized for ease of comprehension. Testing of the QoV questionnaire in its target population, which includes patients undergoing intraocular refractive surgery with various types of IOLs, revealed good precision, reliability, and internal consistency for all 3 symptom scales and showed stable item difficulty and good person-discriminative ability.[3] As such, this might be considered a valuable tool for assessing visual disturbances from a patient perspective.

Other Rasch-calibrated questionnaires for assessing vision in cataract surgery patients include the 9-item Catquest-9SF and the 5-item Cat-PROM5.[4,9] Both short tools have been highlighted as robust and suitable for use in high-volume centers. Patients reportedly prefer Cat-PROM5 over Catquest-9SF because of its brevity and greater freedom of response.[4,9] However, these 2 questionnaires contain broad questions intended to capture overall visual function, rather than specifically assessing visual disturbances.[9]

Multiple clinical studies have used the QoV questionnaire to evaluate visual disturbances in patients receiving EDoF and trifocal IOLs.[11,32,42,52–56] In one of these studies, the tool detected a significantly higher degree of visual symptom bother in recipients of the TECNIS Symfony diffractive EDoF IOL compared with 2 models of trifocal IOL (FineVision and PanOptix IOLs) 1 month to 3 months after implantation (47.2/100 vs 32.8/100 and 37.9/100, respectively).[32] This was despite a lack of significant difference between the 2 groups for subjective symptom frequency and severity and the results of an objective measure of visual disturbance (Light-distortion Analyzer, CEORLab, University of Minho). These findings emphasize the importance of separate, trait-specific scales when designing questionnaires for use in clinical studies. In addition, the discordance between subjective and objective measures highlights the fact that subjective PROMs involve the element of personal perception.

Two additional studies using the QoV questionnaire to compare visual disturbance profiles between the TECNIS Symfony diffractive EDoF and trifocal IOLs also reported overall visual symptoms scores to be similar between groups, with patients reporting higher scores than monofocal IOL recipients.[11,54] Unfortunately, these studies did not report item-specific results.

By contrast to the studies in diffractive EDoF IOL recipients, an additional study using the QoV questionnaire to compare the experience of those receiving the nondiffractive, aspheric Mini Well EDoF IOL with those receiving a multifocal IOL with an apodized diffractive structure (ReSTOR, Alcon Laboratories, Inc.) found lower rates of halo and starburst in the EDoF IOL group.[11,32,52,54] However, this was only a retrospective, comparative case study in a small patient population (20 patients in the EDoF IOL group vs 37 in the multifocal IOL group), and results should be interpreted with caution. A randomized controlled study comparing outcomes in recipients of a nondiffractive presbyopia-correcting IOL based on Wavefront-Shaping technology (AcrySof IQ Vivity) with

those receiving an aspheric monofocal IOL also used the QoV questionnaire; the study found that 73% or more of Vivity recipients were not at all bothered by starbursts, halos, and glare, compared with 58% or more of aspheric monofocal recipients.[57,E] These data suggest that the nondiffractive Vivity IOL has a visual disturbance profile that is similar to or better than that of a monofocal IOL.

Given the use of the same validated, robust tool in all above-mentioned studies, the relative implications of the data can be better contextualized; it is possible to surmise that the diffractive and nondiffractive designs of the featured EDoF IOLs might have contributed to the different visual disturbance outcomes observed. This highlights the advantage of using standardized measures across studies, although randomized controlled trials are needed to corroborate findings.

ITEM BANKING

More recently developed PROMs use item banking and computer-adaptive testing to tailor questions to an individual's ability and daily visual needs, thus increasing the tool's flexibility, efficiency, accuracy, and targeting.[28,35] Unlike traditional questionnaires in which all items are of equal difficulty and the respondent must answer all questions whether relevant or not, in PROMs using item banking with computer-adaptive testing, the difficulty of each item is calibrated, and items are selectively presented to the respondents based on their responses to previous questions and level of impairment.[28,35,36] As such, these PROMs require responses to fewer and more relevant items, reducing test burden.[36] However, some drawbacks of these PROMs include that they require computerized infrastructure and considerable development, background research, planning, and data analysis, and knowledge of Rasch analysis to develop but not to use.[58] In addition, item banking means that each individual effectively receives a different questionnaire, and although the difficulty of each question is calibrated, the comparison of the same questionnaire between studies might not be feasible. To the author's knowledge, item banking has not yet been used in the assessment of visual disturbances.

SEMIOBJECTIVE MEASURES

More recently, semiobjective measures have been developed to quantify photic phenomena. These include the Halo & Glare Simulator (Eyeland Design Network GmbH), Halo v1.0 software (Laboratory of Vision Sciences and Applications, University of Granada), the Light-distortion Analyzer, the Vision Monitor (MonCV3; METROVISION), and the Aston Halometer (Wolffsohn Research Ltd.) (Figure 1, A to E).[7,16,59–61,F,G] In addition, there have been reports of in-house, custom-made experimental devices to quantify photic phenomena.[62] These semiobjective tools are largely restricted to measuring halo and glare and might not capture the perceived impact of visual disturbances on QoL. As such, their use so far has been largely supplementary to subjective PROMs.[50,52,53,63] An overview of semiobjective measures can be found in Table 2.

HALO AND GLARE SIMULATOR

The Halo and Glare Simulator is software that emulates a night-driving scene (Figure 1, A).[64] Patients are required to adjust the glare and halo type, size, and intensity using sliding buttons until the image matches the experience they are having with their vision.[F] This generates data akin to a visual analog scale, which clinicians can use to quantify photic phenomena and to directly compare the performance of IOLs after implantation.[F] Quantifying both size and intensity of photic phenomena (albeit in a subjective manner because it relies on patient experience and memory) provides more information than simply asking whether a particular symptom is present or not through a questionnaire.

The Halo and Glare Simulator is already in use in clinical investigations ranging from case series to multicenter, international prospective studies.[47,53,65] In studies using both the simulator and a questionnaire to assess photic phenomena, data from the simulator correspond well with questionnaire data.[47] A drawback of this tool might be its reliance on patient memory to accurately re-create their night-time vision, which might also introduce subjectivity bias. In addition, only halo, starburst, and glare can be emulated by the software, that is, not all photic phenomena. Finally, the tool has not yet been validated in a controlled study, so contextualization of results is problematic.[53]

To date, 6 studies have used the Halo & Glare Simulator to assess visual disturbances in EDoF and trifocal IOL recipients.[23,47,53,65–67] Two of these investigate implantation of an EDoF IOL based on positive and negative spherical aberration, finding it to result in a rate of halo similar to that of a monofocal IOL and rate of halo less than that of a diffractive multifocal IOL.[23,53]

Three prospective studies report outcomes using the Halo and Glare Simulator in patients with (predominantly) bilateral implantation of the AT LISA Tri toric diffractive trifocal IOL.[47,65,67] Despite their similar designs and patient populations, one study reported small (type 1) halos in 77% of patients at 1 month, remaining stable at 6 months; a second study reported this proportion to be 55.6% at 3 months; and a third study 31.3% at 3 months.[47,65,67] Halo sizes also differed substantially, ranging from 35 of 100 in one study to 51 of 100 in another.[47,65] This surprising discordance might be due to the need for an individual's subjective interpretation of their visual experience when adjusting the tool, rendering the technology not truly objective. The small sample size included in 2 of the studies might also have contributed.[65,67] It is also not yet clear how the level of halo or glare corresponds to functional impairment, meaning that it is difficult to ascertain the clinical significance of the findings. Moreover, visual disturbance is a multidimensional phenomenon that can have perceptual consequences, for example, a halo might be present but not be bothersome for some patients or small degrees of starbursts might bother a more sensitive patient. However, in these studies, visual disturbances are measured with a unidimensional tool that does not take into account these variations in perception.

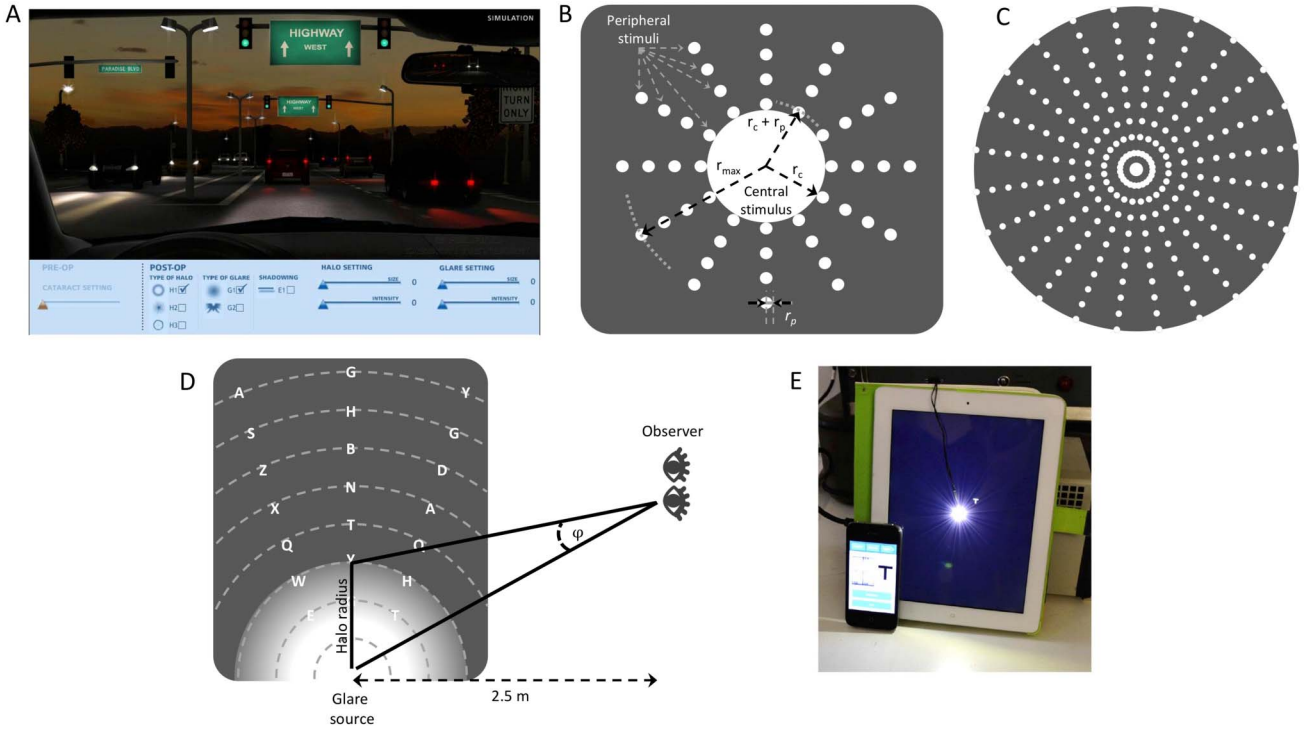

Figure 1. Semiobjective measures of visual disturbances. *A*: Halo and Glare Simulator (image reproduced with permission from El Naggar et al.): patients adjust the glare and halo type, size, and intensity using sliding buttons until the image matches their experience, generating data akin to a visual analog scale. *B*: Halo v1.0 software (Laboratory of Vision Sciences and Applications, University of Granada): peripheral stimuli are randomly presented around the central glare source; the patient presses a button on perceiving a peripheral stimulus and the VDI is calculated by taking into account the nondetected compared with the presented peripheral stimuli.[60] *C*: Light-distortion Analyzer (CEORLab, University of Minho): an LED in the center of an electronic black board acts as the glare source and the 240 smaller surrounding LEDs (used as markers to discriminate the edge of the patient's visual field) are presented in random sequences; the patient presses a button on perceiving a peripheral stimulus and the LDI is calculated as the proportion of the area missed relative to the total area tested; this is a physical device rather than software.[71] *D*: Vision Monitor MonCv3 (METROVISION): patients read the optotypes sequentially starting from the darker side of the screen and moving toward the glare source; the halo radius is identified at the level where the letters are no longer discernable, and the corresponding visual angle is calculated in minutes of arc (arcmin). *E*: Aston Halometer (image reproduced with permission from Buckhurst et al.[61]): 0.3 logMAR-equivalent letters are moved eccentrically away from a central LED glare source on an iPad tablet until they are recognized by the patient; the area of obscuration caused by the patient's halo is then calculated in degrees (LDI = light distortion index; r_c = main stimulus radius; r_{max} = maximum radius; r_p = peripheral stimulus radius; VDI = visual disturbance index).[61]

HALO v1.0 SOFTWARE

Halo v1.0 software is a freeware program that quantifies visual discrimination under low-light conditions (Figure 1, B).[59,60] It consists of a high-luminance central stimulus, which serves as the glare source, over a dark background.[59] Peripheral stimuli appear progressively at different, customizable positions and distances from the central stimulus, with patients asked to indicate when they perceive a peripheral stimulus.[59] The main output of the test is a visual disturbance index (VDI), calculated as the ratio of undetected peripheral stimuli to the total number of stimuli presented, taking into account their distance from the central stimulus.[59] VDIs range from zero to 1, with values nearer to 1 indicating a greater influence of halos or nighttime visual disturbances.[52,59,68]

In early tests of the Halo v1.0 software, the visual performances of 2 groups of patients with differing ocular pathologies (keratitis, n = 15; age-related macular degeneration, n = 14) were evaluated using the software's VDI.[59] In both patient groups, VDI was able to differentiate between diseased eyes and contralateral healthy eyes (average $P = .012$), demonstrating the utility of Halo v1.0. In the same study, an objective Strehl ratio ranging from zero (worst retinal image quality) to 1 (best retinal image quality) was also generated using a double-pass visual-quality device (the Optical Quality Analysis System, Visiometrics SL).[59] VDI was found to increase (worsen) as the Strehl ratio decreased, showing good agreement between the 2 measures. Similarly, a study of healthy eyes found that VDI increased significantly ($P < .001$) after alcohol consumption, representing increased impairment in the degree of visual discrimination; this was in agreement with the objective modulation transfer function cutoff values recorded using a double-pass device, which are commonly used to measure loss-of-contrast in an optical system.[60] Despite these encouraging results, the Halo v1.0 software is limited in that its settings are determined by the user, with no standardization between studies and no clinically meaningful cutoff value determined. Another limitation might be the variability among the type and make of screens being used in different testing centers; different screens will

Table 2. Overview of semiobjective measures used to assess visual disturbances.

Technology	Description	Critical Evaluation	Figure
Halo and Glare Simulator[a,f]	Software emulates night-driving; patients adjust glare and halo type and size, generating data akin to a visual analog scale[F]	Data seem to correspond well with subjective PROMs data[47] Tool requires further validation[53] Tool seems to rely on patient memory of their experience Mixed results seen in several studies using the same IOL and similar patient populations[47,65,67]	Fig. 1, A
Halo v1.0 software[b,59,60]	Freeware program quantifies visual discrimination under low-light conditions[59,60]	Data seem to correspond well with subjective PROMs data[50,52,63] Differences in software settings might hamper comparisons across the literature[52]	Fig. 1, B
Light-distortion Analyzer[c,16]	Experimental prototype designed to assess size, shape, and regularity of halos under high-glare conditions[16]	Data in EDoF and trifocal IOL recipients are extremely limited Requires further validation and standardization prior to clinical application	Fig. 1, C
Vision Monitor[d,H]	Multifunctional system capable of performing several computerized tests to evaluate patient visual function, including a disability glare test[H]	Has demonstrated good repeatability in clinical studies[73] Data are needed in studies of EDoF and trifocal IOLs	Fig. 1, D
Aston Halometer[e,7,61]	Comprises a bright LED positioned in the center of an iPad 4 with optotypes oriented in 8 directions separated by 45 resulting in a quantitative measure in degrees of the extent that glare obscures a target in multiple directions of gaze[7,61]	Sensitive method for quantifying discomfort glare[61] Good intraobserver variability[7] Data are needed in studies of EDoF and trifocal IOLs	Fig. 1, E

EDoF = extended depth of focus; IOL = intraocular lens; PROM = patient-reported outcome measure
[a]Eyeland Design Network GmbH
[b]Laboratory of Vision Sciences and Applications, University of Granada
[c]CEORLab, University of Minho
[d]MonCV3; METROVISION
[e]Aston Eye Tech Ltd.

offer different levels of luminosity, which could potentially also impact the brightness of the central stimulus.

Again, only a limited number of EDoF and trifocal IOL studies have so far reported outcomes using Halo v1.0 software.[50,52,63,68–70] Many of these studies feature the FineVision trifocal IOL, with a wide range of mean VDI values reported (from 0.07 to 0.29, depending on the study).[50,63,69,70] Two further studies featuring the TECNIS Symfony diffractive EDoF IOL reported mean VDI values of 0.15 and 0.45, which were similar to the values reported for the trifocal IOLs in each study.[68,69] The relatively large differences between studies investigating the same type and make of IOL might partly reflect differences in Halo v1.0 software settings, hampering comparisons across the literature.[52] Nevertheless, all studies reporting subjective data alongside Halo v1.0 data have shown good agreement between the 2 measures.[50,52,63]

LIGHT-DISTORTION ANALYZER

The Light-distortion Analyzer is an experimental prototype designed to assess the size, shape, and regularity of halos under high glare conditions (Figure 1, C).[71] Unlike the Halo v1.0 software, it is a physical device, ensuring comparable experimental conditions across users.[71] The display, which is connected to a computer, consists of a central white LED surrounded by 240 small, white LEDs (peripheral stimuli) distributed in 24 semimeridians, with an angular separation of 15 degrees and covering an area of 10 degrees at a 2 m examination distance.[16] The patient, who sits 2 m from the display device, is instructed to press a remote response device as soon as the small LED is visualized as distinct from the central white LED. With each response, the system proceeds to the next semimeridian randomly, and the process repeats until all meridians are tested. The higher the values of the best-fit circle radius (defined as the circle that best fits the distortion area resulting from the linear binding of all points in each meridian of the device) and light distortion index (LDI; calculated as the ratio of the area of points missed by the patient and the total area explored and expressed as a percentage), the lower the ability of the patient to discriminate small light stimuli surrounding the central source of light. The characteristics, examination routines, and main outcome measures have been validated in several clinical studies.[16,32,71,72]

Only 2 studies have so far used the Light-distortion Analyzer to assess visual disturbances in patients receiving EDoF or trifocal IOLs.[16,32] The first of these

reported a higher mean LDI and best-fit circle radius in the AT LISA trifocal IOL group compared with that of the monofocal IOL group, suggesting that trifocal recipients might have a lower ability to discriminate between small-light stimuli surrounding a central source of light.[16] This was attributed to IOL design, with the diffractive optical system typical of current multifocal IOLs causing a higher degree of light distortion.[16] The findings of a prospective, nonrandomized, examiner-masked case series supported this notion, showing higher LDI in recipients of the TECNIS Symfony diffractive EDoF IOL compared with 2 trifocal IOLs (FineVision and PanOptix).[32] The authors postulated that this was due to increased light scatter caused by an increase in negative spherical aberration in combination with the diffractive echelette design that underpins the mechanism of action of this particular EDoF IOL.[32]

VISION MONITOR (MonCv3)

The Vision Monitor is a multifunctional system capable of performing several computerized tests to evaluate a patient's visual function (Figure 1, D).[73,H] Among its repertoire is a disability glare test, during which a glare source (single luminance, 200 000 cd/m^2) is displayed on the side of a screen, with 3 radial lines of 10 low-luminescence optotypes projecting outward across the screen.[73] The letters from the 3 lines are read moving from the screen periphery toward the glare source, with halo radius calculated by averaging the distance at which subjects are no longer able to identify the letters.[73] The repeatability of the Vision Monitor's glare test was demonstrated in a study measuring halo size in healthy subjects (n = 37) by calculating the Bland-Altman coefficient of repeatability (±44 arcmin).[73] This test has also shown good capacity for differentiating the extent of dysphotopsia between monofocal and bifocal IOL recipients.[74]

To the authors' knowledge, only one study has used the Vision Monitor to investigate glare outcomes in trifocal IOL recipients, reporting no change in the proportion of optotypes patients were able to read under glare conditions between postoperative month 1 and 12;[75] the size of the letters was not included in the methodology of this study, which limits the interpretation of these results. In addition, studies are yet to report the use of this technology for EDoF IOL assessment; this makes the tool difficult to evaluate.

ASTON HALOMETER

The Aston Halometer comprises a bright LED positioned in the center of an iPad (Apple) with optotypes in a default setting of 8 orientations that are separated by 45 degrees (Figure 1, E).[7,61] Bangerter foils are used to simulate different levels of light spread on the retina.[61] As the test progresses, letters are moved away from the glare source in 0.05-degree increments in one of the orientations. The first increment where the patient correctly identifies the letter twice is recorded, and the process is repeated in the next orientation.[7,61] The test is complete when all orientations are assessed, resulting in a quantitative measure in degrees of the extent that glare obscures a target in multiple directions of gaze.[61]

A validation study compared the performance of the Aston Halometer with the previously validated C-Quant straylight meter (OCULUS Optikgeräte GmbH) in 20 patients with no ocular pathology or previous surgery, showing that the halometer provides a sensitive and repeatable method to quantify a patient-recognized form of disability glare in multiple orientations, thereby adding objectivity to subjectively reported discomfort glare.[61] In a study comparing halo size between 2 bifocal IOL designs (refractive Lentis Mplus MF30 and diffractive TECNIS ZM900 IOLs) and a monofocal IOL in postcataract surgery patients (n = 45), the Aston Halometer was able to detect differences in the glare area between each type of IOL that the C-Quant meter did not capture.[7] This suggests that factors other than straylight might contribute to glare perception. Furthermore, the intraobserver variability, as measured by the intraclass correlation coefficient of the Aston Halometer measurements, averaged 0.89.[7] Currently, no studies have reported use of this tool to evaluate the performance of EDoF or trifocal IOLs.

CUSTOM-MADE HALOMETER

One study reported use of a custom-made semiobjective tool to measure dysphotopsia in patients implanted with trifocal IOLs.[62] Similar to the Aston Halometer, this technology comprises a bright LED positioned in the center of a flat-screen monitor on a black background, with letters (equivalent to 0.3 logarithm of the minimum angle of resolution) that move along 45-degree meridians. In this case, however, the letter travels from the edge of the screen toward the glare source, changing randomly as it does so. The eccentricity of the closest location to the LED at which the patient can correctly identify the letter is recorded. In the study, the size and shape of photopic scotoma in trifocal IOL recipients were determined under mesopic (5 cd/m^2) conditions by repeating this method for each of the 8 meridians. Data suggested that the mean photopic scotomas with trifocal IOLs were generally uniform in shape, extending binocularly between 0.69 degrees and 1.03 degrees for all 8 meridians.[62] Although interesting, these custom-made semiobjective measurements have not yet been validated.

LIMITATIONS

While the aim of this review is to provide a thorough overview of PROMs methodology used for the assessment of patient experience with IOLs, the large volume of publications on this subject made it necessary to focus on key IOL models and types when conducting our literature searches. As a result, the review is not exhaustive and might not have captured studies investigating IOL types outside of the new-generation EDoF and trifocal technologies, such as bifocal IOLs, or models other than those listed in Tables 1 and 2 (see Supplemental Digital Content 2, available at http://links.lww.com/JRS/A157), which were selected due to their frequent occurrence in the literature.

CONCLUSIONS

Visual disturbances, which might cause dissatisfaction in patients implanted with an IOL, are known to differ according to the underlying IOL technology. Multifocal IOLs have been reported in previous reviews/studies to be associated with greater levels of positive visual disturbances (halo, glare, and starburst) due presumably to their inherent light-splitting technology.[5,11,15–18] Although EDoF IOLs have been designed to provide an extended visual range without inducing significant visual disturbances, current data suggest that diffractive-based EDoF optics have not achieved this goal. An EDoF IOL providing a monofocal-like disturbance profile along with extended visual range would be likely to increase the uptake of these advanced technologies in the clinic. The ever-increasing choice of IOL types and designs means that reliable characterization of the unique visual disturbance profile associated with each IOL is essential for informing clinical decision-making. However, there is currently no consensus on the most appropriate way to measure these symptoms. Reliable, validated measures of visual disturbance frequency, severity, and impact are needed to allow for standardized, consistent, clinically meaningful comparisons and to identify the presbyopia-correcting IOL designs that provide best-in-class subjective vision quality.

Validated PROMs and those based on Rasch calibration have improved on many of the shortcomings of traditional, unvalidated questionnaires, with item banking aiming to address further shortfalls.[3,27,36] Considering that the latter tools are yet to be fully developed for use in IOL recipients, current fit-for-purpose PROMs, such as the Rasch-based QoV questionnaire, should be considered for assessing dysphotopsia symptoms in EDoF and multifocal IOL studies. However, even though an increasing number of studies now use Rasch-based PROMs, they do not report Rasch scores, likely because it is not yet clear what constitutes a clinically significant value; therefore, further studies are needed to determine a clinically relevant cutoff value, which would allow more meaningful comparisons. Because of the recognized importance of capturing patient perception, semiobjective measures have been developed and are increasingly being used.[27] These tools either measure the size or the veiling effects of the photic phenomena; however, how they relate to visual outcomes and how they change after an intervention is still unknown, warranting further investigation. At present, these tools are largely used as supplementary methods to measure visual disturbance. In future, standardization of the PROMs used in clinical research on IOLs will be necessary to facilitate cross-study comparisons, rendering the data more valuable and informative for IOL selection.

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First author:
Thomas Kohnen, MD, PhD, FEBO

Department of Ophthalmology, Goethe University Frankfurt, Frankfurt, Germany