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Symptoms and Satisfaction Levels Associated with Intraocular Lens Implants in the Monofocal and Premium IOL Patient-Reported Outcome Measure Study

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Purpose: To develop a questionnaire with standardized questions and images about visual symptoms and satisfaction administered before and after cataract surgery with monofocal and various (premium) intraocular lenses (IOLs).

Design: A prospective, observational study of cataract surgery patients completing a self-administered questionnaire preoperatively and postoperatively at 4 to 6 months.

Participants: Five hundred fifty-four patients with plans to undergo implantation of the same IOL in both eyes on separate occasions in 20 ophthalmology practices.

Methods: An 86-item questionnaire with standardized images assessed the following 14 symptoms: glare, blurry vision, starbursts, hazy vision, snowballs, halos, floaters, double images, rings and spider webs, light flashes with eyes closed, distortion, light flashes with eyes open, shimmering images, and dark crescent-shaped shadows.

Main Outcome Measures: Symptom severity and level of symptom bother, satisfaction with vision, quality of vision, and ability to see without corrective lenses or eyeglasses.

Results: Except for dark crescent-shaped shadows, the report of visual symptoms significantly decreased postoperatively. Best uncorrected binocular visual acuity improved from 0.47 (20/59 Snellen visual acuity values) ± 0.35 logarithm of the minimum angle of resolution (logMAR) preoperatively to 0.12 (20/26 Snellen visual acuity values) ± 0.12 logMAR postoperatively. Patients' ratings of intermediate vision as good to excellent improved significantly from 12% preoperatively to 71% postoperatively, and patients' ratings of distance vision improved from 8% preoperatively to 85% postoperatively. After surgery, 84% reported that they were somewhat, very, or completely satisfied with their vision. Most patients (88%) reported that they could see pretty well, very well, or perfectly well without corrective lenses after surgery.

Conclusions: The Assessment of IntraOcular Lens Implant Symptoms questionnaire can be used across a wide variety of IOLs to evaluate visual symptoms and satisfaction with a growing segment of the market, premium IOLs, that target intermediate and near vision, in addition to distance vision. Compared to patients receiving monofocal IOLs, patients receiving premium IOLs appear to be more challenging to satisfy because of their requirements for distance, intermediate, and near vision, and their desire to be free of eyeglasses postoperatively. This instrument provides a structured, uniform tool for regulators, researchers, and ophthalmologists in everyday practice to gain insights into patients' experiences.

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Cataract surgery is the most performed surgical procedure in the Medicare population.[1] The benefits of cataract surgery are well documented,[2] with recent studies demonstrating an association between cataract surgery and a decreased risk of dementia,[3] as well as delays in cataract surgery being associated with a greater incidence of falls in Medicare patients.[4] A randomized controlled study found that cataract surgery in the first eye reduced the rates of falls and fractures by 34%.[5] A study of 277 patients with cataract found that those who had cataract surgery had half the rate of accidents compared to those who did not receive surgery.[6] Vision loss was recognized as the worst

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possible health condition by 47% of respondents, and eye health was viewed as critical to current health in a poll representative of United States racial and ethnic groups.[7] The primary concerns of respondents about vision loss revolved around independence and productivity.

Because of the increasing diversity of intraocular lenses (IOLs), with the availability of novel or premium IOLs, there is an abundance of choice and greater opportunity for spectacle independence for patients beyond the monofocal IOL selections, and an expanded array of device innovation abounds in the future. Premium IOLs are defined as IOLs that correct more than the spherical equivalent error at distance and include multifocal, toric, phakic, and accommodating lenses.[8] This expansion is congruous, because the baby boomer generation desires greater spectacle independence and seamless usage of smartphones, computers, and other devices that are enabled by enhanced near and intermediate distance visual acuity.

This augmentation of therapeutic options creates a greater complexity and intensity of preoperative decision-making by patients and cataract surgeons to select the appropriate IOL for the patient's individual needs as well as postoperative evaluation to monitor the patient's vision and symptoms. Although patients undergo clinical testing and evaluation prior to surgery, several visual phenomena such as halos, blurry vision, starbursts, hazy vision, snowballs, floaters, and rings cannot easily be evaluated objectively. Different visual phenomena are associated with various IOL types because of differences in optic and optic edge design as well as in optic and haptic materials. For example, diffractive IOLs are associated with more reduced contrast sensitivity and greater glare and halos because light is distributed across various focal points.[9] A review of dysphotopsia found 7 articles that indicated the cause of positive dysphotopsia was related to the square edge of the IOL and multiple internal reflections including reflection of light to the retinal surface.[10]

Some visual symptoms are preexisting, and not related to the IOL implant, so it is important to ask questions both before and after cataract surgery. Patients can also adapt or become more tolerant to changes in the quality of their vision over time, but this is dependent upon the individual. A more informed patient population would be expected to have higher expectations for visual outcome, not only improved distance vision but also near and intermediate vision for computer use and smartphone viewing. All these factors support the use of a psychometrically sound questionnaire to identify and incorporate the patient's perspective into regulatory decision making.

The United States Food and Drug Administration (FDA) defines a patient-reported outcome (PRO) as the following: "A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else."[11] The FDA uses PROs as valid scientific evidence as part of their assessment of benefits and risks in their regulatory decision-making and in medical device labeling to communicate the impact of the device on patients.[12]

The genesis of the Assessment of IntraOcular Lens Implant Symptoms (AIOLIS) questionnaire was a consensus recommendation from the joint FDA and American Academy of Ophthalmology Developing Novel End Points for Premium Intraocular Lenses workshop held on March 24, 2014.[8] The workshop participants outlined limitations to the current PRO measures (PROMs), including lack of relevance to specific types of premium IOLs and types of patients who are performing challenging tasks requiring good distance, intermediate, or near vision. There also may be a paucity of clear visual demonstration of common symptoms both for clinicians and patients with regard to common symptoms classified by physicians as glare, halos, starbursts, and so forth. The workshop recommendation was as follows: to develop patient-focused definitions and images for symptom areas including dysphotopsias, including evaluation of visual function tailored for patients with higher visual functioning and updated for newer tasks (e.g., smart phone use and IOL design goals [e.g., intermediate vision]). Specifically, the workshop breakout groups defined 4 concepts in the following order to address in the PROM development: reduced spectacle dependence, visual symptoms, visual function across a range of viewing distances, and patient satisfaction. The American Academy of Ophthalmology commissioned a multistakeholder Advisory Committee on a PROM for Premium IOLs, including the FDA, to develop a questionnaire that could assess visual symptoms, function, and satisfaction in the population receiving premium IOLs in a manner that would allow it to support the collection of valid scientific evidence in the process of medical device evaluation. The Advisory Committee had 4 distinct collaborative arms: (1) *ophthalmologists from the Academy*, (2) survey design experts from the *RAND Corporation and UCLA*, (3) select *IOL manufacturers of* the Medical Device Manufacturers Association, and (4) *FDA* representatives serving in an advisory capacity. This *unprecedented four-armed committee* collaboration was remarkable and led to a firm consensus as to what could be valuable information from the patient perspective as it might relate to clinicians, IOL manufacturers and the FDA.

The American Academy of Ophthalmology Task Force also defined safety and performance end points and indications for device exchange, removal, or reposition for premium IOLs.[13] Among these indications for device exchange or removal were patient-reported undesirable optical phenomena, including severe dysphotopsia (positive or negative or both), monocular diplopia, intolerable glare, halos, or other visual symptoms that are not attributable to any other problems associated with the IOL implantation. We conducted a study with the aim to understand the frequency of various visual symptoms and patient satisfaction in patients undergoing cataract surgery with placement of various IOLs.

Methods

The field test methods and the psychometric results of the AIOLIS instrument are described elsewhere in this issue of the journal (see

pg. 715).[14] Institutional review board approval was obtained, and the research adhered to the tenets of the Declaration of Helsinki. Volunteer surgeons from 18 domestic and 2 international practice sites participated, and a total of 554 patients completed the field test of the preoperative and postoperative questionnaires. The patient population was eligible if they met the following criteria: binocular implantation of the same IOL, dominant eye targeted for emmetropia, nondominant eye targeted for emmetropia or up to −0.75 diopter (D) of myopia, and potential visual acuity estimated to be 20/30 or better after surgery. The resultant postsurgical sample consisted of patients from 31 to 71 years of age and older; with 64% female, 84% White, 9% Hispanic, and 6% Black; with 29% being a high school graduate and 63% having more than a high school degree; and with a mean best uncorrected binocular visual acuity of 0.47 logarithm of the minimum angle of resolution (logMAR). One aspect of the preoperative patient selection was a criterion that eligible patients needed to have a potential visual acuity of 20/30 or better (by potential acuity meter testing or other potential acuity testing) after cataract removal and premium IOL implantation. Another unique aspect of the field testing was the variety of IOLs implanted in patients, reflecting the broad spectrum of available options: (1) accommodative, (2) extended depth of focus, (3) monofocal, (4) multifocal, (5) toric accommodative, (6) toric extended depth of focus, (7) toric monofocal, (8) toric multifocal, and (9) trifocal.

An important feature of this PROM is the provision of images as a reference for relating visual symptoms and effects of IOL implantation. The use of terms such as *glare* and *halos* are not well understood vocabulary for patients, so the addition of illustrations of each symptom was critical to standardize patient understanding of these concepts and enhance interpretability of reporting (Appendix A: AIOLIS Questionnaire, available at www.aaojournal.org). The details of the questionnaire are described elsewhere in the journal. The primary intent of the study was to identify questions that could systematically assess patient symptoms and satisfaction after premium IOL implantation.

Patients were asked presurgery and postsurgery (4−6 months typically) the frequency, presence with or without wearing corrective lenses, and level of symptom bother and severity of 14 symptoms: glare, blurry vision, starbursts, hazy vision, snowballs, halos, floaters, double images, rings and spider webs, flash with eyes closed, distortions, flash with eyes open, shimmering images, and dark crescent-shaped shadows. The general vision scale consisted of questions about satisfaction with patients' vision, the rating of their vision, and spectacle independence before and after surgery.[14] Response options for satisfaction with vision were the following: completely satisfied, very satisfied, somewhat satisfied, somewhat dissatisfied, very dissatisfied, and completely dissatisfied. Response options for the rating of vision were the following: poor, fair, good, very good, and excellent. Response options for how well patients can see without correction were the following: perfectly well, very well, pretty well, and not very well.

Results

Clinically relevant results of the field tests in terms of patients' symptoms and assessment of vision are emphasized here, and the complete results of the field test are described elsewhere.[14] The study was intended to include only patients with bilateral implantation of the same IOL, but 6% of the group received only 1 IOL rather than IOLs in both eyes.

The rates of intraoperative complications and postoperative complications were 1% and 6%, respectively (Table 1). The prevalence of visual symptoms decreased postoperatively except for dark crescent-shaped shadows ($P < 0.0001$). Best uncorrected binocular visual acuity improved from 0.47 (20/59 Snellen visual acuity values) ± 0.35 logMAR preoperatively to 0.12 (20/26 Snellen visual acuity values) ± 0.12 logMAR postoperatively, or a 4-line improvement.

The percentage of patients who rated their intermediate vision as good, very good, or excellent increased significantly from 12% preoperatively to 71% postoperatively. The percentage of patients who rated their near vision as good, very good, or excellent increased significantly from 15% preoperatively to 38% postoperatively. The percentage of patients who rated their distance vision as good, very good, or excellent increased significantly from 15% preoperatively to 85% postoperatively. After surgical correction, 84% reported that they were somewhat, very, or completely satisfied with their vision (Table 2). Most patients (88%) reported that they could see pretty well, very well, or perfectly well without corrective lenses and used correction only for reading after surgery.

The results of the field test underscored the common issues and disadvantages cited by patients with premium IOLs. The most common symptoms reported by this patient population postoperatively were glare (36%), floaters (35%), starbursts or streaks (28%), blurry vision (22%), halos (22%), hazy vision (18%), snowballs (17%), and rings and spider webs (11%; Table 3). Before surgery, the proportion of patients self-reporting severe symptoms was greatest for halos (27%), glare (26%), snowballs (24%), hazy vision (23%), and blurry vision (23%). The proportion of patients self-reporting extreme and quite a bit levels of symptom bother correlated well with the severe level of symptoms, with most of the same symptoms as the most bothersome: blurry vision (54%), snowballs (52%), glare (49%), halos (46%), rings and spider webs (43%), and hazy vision (43%).

The proportion of patients who had these symptoms preoperatively but not postoperatively were all greater than the patients who did not have these symptoms preoperatively but did have these postoperatively (Table 3). All but 2 of these symptoms had a statistically significant decrease after IOL implantation, indicating a reduction, albeit not complete absence, of symptoms. Both the severity of symptoms and the level of symptom bother after surgery declined for most symptoms. These symptoms were significantly associated with dissatisfaction with vision after surgery: blurry vision, distortion, double images, shimmering images, hazy vision, flash with eyes open, rings and spider webs, halos, and dark crescent-shaped shadows (Table 4; with $P < 0.001$ for all correlations).

Comparing patients with monofocal IOLs with patients with multifocal IOLs, there was a larger postoperative reduction of halos for the patients with monofocal IOLs, 36% versus 20%, respectively (Table 5). Satisfaction with general vision was higher postoperatively with patients with multifocal IOLs, 73% versus 67%, respectively. Small amounts of myopia (defined as spherical equivalent ≤ -0.50 D in either eye), hyperopia (spherical equivalent ≥ 0.50 D in either eye), and astigmatism (magnitude of cylinder error of ≥ 0.50 D at any axis) were not significantly associated with visual symptoms. Hyperopia was associated with less satisfaction with vision ($r = -0.23$; $P = 0.0079$) and worse general perceptions of vision ($r = -0.20$; $P = 0.0242$), but was not correlated with spectacle dependence. Astigmatism was significantly negatively associated with self-reported general vision and spectacle dependence, but was not significantly correlated with satisfaction with vision. Myopia was not significantly associated with satisfaction with vision, general perceptions of vision, or spectacle dependence. However, uncorrected visual acuity worse than 20/40 was associated with

Table 1. Investigator-Reported Adverse Events, Intraoperative Complications, and Visual Acuity Outcomes

Variable	Patient Data
Postoperative complications*	6%
Surgical complications†	1%
BCDVA worse than 20/40 (at 3 mos or later)	
Percentage of patients	4%
BCDVA 20/20 or better	
Percentage of patients	67%
UCDVA (% of patients)	
20/200 or better	99.7%
20/40 or better	99.7%
Spherical equivalent (D)	Left, 0.04 ± 0.82
Mean ± SD	Right, −0.02 ± 0.83

BCDVA = best-corrected distance visual acuity; D = diopter; SD = standard deviation; UCDVA = uncorrected distance visual acuity.
*List of postoperative complications.[15]
†List of surgical complications.[15]

decreased satisfaction with vision (Table 6). Most patients who reported dark crescent-shaped shadows also reported floaters (72% preoperatively and 68% postoperatively), which was considerably higher than noted for the entire cohort (49% preoperatively, 35% postoperatively).

Discussion

The goals of IOL implantation surgery were generally accomplished in terms of vision improvement, satisfaction with vision, and spectacle independence. One important and consistent result of the field testing is that residual refractive error is dominant, that is, the correction of refractive error appears to reduce or minimize the impact of optical side effects. The findings showed that there was an increase of postsurgery visual symptoms when patients were not wearing glasses or contact lenses. This might be because when uncorrected, patients notice the visual symptoms much more and ametropia increases awareness of undesired optical side effects of surgery. Patients' residual refractive error appears to play a primary role in their satisfaction with their vision and their reporting of symptoms postsurgery. It is also possible that their experience of spectacle independence outweighs their perception or level of symptom bother from optical effects. Hence, it is critical for ophthalmologists to assess their patients' desires and motivations to achieve eyeglass independence prior to cataract surgery. Clinicians evaluating the feasibility of these goals and setting realistic expectations during the informed consent process and preoperative discussions with patients may lead to better patient satisfaction. Interestingly, in this study, astigmatism was not found to be associated with lesser satisfaction with vision, as was reported in one much larger study of pseudophakic patients at the 0.75- to 1.00-D level.[16] The correlation of residual astigmatism with satisfaction with vision could be explored in future studies.

Table 2. Distribution of Patient-Reported Satisfaction with Vision

Satisfaction with Vision	Preoperative	Postoperative
Completely satisfied	1%	21%
Very satisfied	1%	41%
Somewhat satisfied	14%	22%
Somewhat dissatisfied	37%	5%
Very dissatisfied	35%	8%
Completely dissatisfied	12%	3%

There were some unexpected findings based on patient responses. Floaters are a known complication after cataract surgery because of disruptions to the vitreous inducing posterior vitreous detachment.[17] Interestingly, more patients reported a decrease rather than an increase in floaters after cataract surgery. This might be because during the 45-day period after cataract surgery, patients did not experience, remember, or conceptualized floaters as another symptom, illustrating the importance of eliciting what patients see and experience, instead of using terms that clinicians commonly use to describe symptoms. Also, the presence of a cataract may enhance the perception of floaters. One possibility is that patients are interpreting their lens opacities preoperatively as floaters that are resolved with cataract removal.

Another puzzling difference was found in the reporting of dark crescent-shaped shadows presurgery, because it is a known effect of any IOL type implantation.[18] Interestingly, 4% of patients reported this symptom prior to surgery, and the dark shadows group also noted a higher rate of floaters preoperatively and postoperatively, suggesting that this symptom may be somehow associated with floaters. Further studies may help clarify this finding. Again, based on patient perspective, dark crescent-shaped shadow was retained as a symptom in the final questionnaire.

The terms *glare*, *snowballs*, *starbursts* or *strings*, and *rings* and *spider webs* all describe aspects of glare and even floaters, but patients perceived these differently in terms of frequency, level of symptom bother, and severity. Any differences between the ratings of severity and level of symptom bother are likely explained by the overlap of these terms, even though there were representative images to illustrate each type of symptom. It was important, then, to retain these as separate symptoms, each with its associated image, in keeping with viewing unique optical effects through the patient's lens or perspective.

Refractive correction in the form of eyeglasses can introduce optical effects as well because of their reduced field of view, blurriness of the field of view around the frame of the eyeglasses, distortion of the field of view around the frame, and so forth. However, instead of decreases in symptoms after surgery, there were increases of symptoms reported by patients when not wearing glasses or contact lenses, including glare, starbursts, snowballs, halos, rings and spider webs, and distortions, which may be related to uncorrected refractive error.

There are still factors associated with dissatisfaction and symptoms that cannot be explained by visual acuity alone. The role of neural adaption could vary by patient and by type of IOL, accounting for unexplained optical phenomenon causing dissatisfaction, and the 4- to 6-month

Table 3. Visual Symptoms Reported on the Questionnaire by Patients (Participants)

Variable	Symptom Prevalence		Symptom Development*	Symptom Resolution†	Quite a Bit or Extremely Bothersome Symptoms	
	Before Surgery	*After Surgery*	**After Surgery**	**After Surgery**	*Before Surgery*	*After Surgery*
Glare	84%	36%	19%	38%	49%	15%
Blurry vision	68%	22%	13%	26%	54%	15%
Starbursts or streaks	66%	28%	20%	31%	42%	17%
Hazy vision	63%	18%	9%	22%	43%	11%
Snowballs	55%	17%	9%	24%	52%	14%
Halos	52%	22%	16%	28%	46%	14%
Floaters	49%	35%	18%	53%	17%	10%
Double images	29%	9%	4%	20%	36%	8%
Rings and spider webs	29%	11%	10%	14%	43%	15%
Flashes with eyes closed	18%	8%	6%	18%	25%	4%
Distortion	17%	6%	4%	14%	30%	22%
Flashes with eyes open	17%	9%	7%	18%	37%	10%
Shimmering images	8%	3%	2%	12%	20%	12%
Dark crescent-shaped shadow	4%	4%	4%	14%	29%	32%

Adapted from Hays et al.[14]
*Patients did not have the symptom before, but had after cataract surgery.
†Patients had the symptom before, but did not have after cataract surgery

postoperative period for reassessment might not be long enough for neural adaption.[19,15] Patients receiving premium IOLs probably have higher criteria for meeting satisfaction, because they have requirements not only for distance vision, but also for intermediate vision and near vision, and for eyeglass independence, in addition to an out-of-pocket expense for the device.

The limitations of this study have been described.[14] In addition, the clinical data accompanying the patient responses were not audited onsite or independently verified. Because of the ongoing COVID-19 pandemic, 6% of patients did not receive the second IOL as originally planned, but the inclusion of their data did not change the overall results significantly.

Other PROMs have been developed and utilized for cataract surgery, namely the Visual Function-14 Index, developed by the Cataract Patient Outcomes Research Team,[20] and the Catquest self-assessment questionnaire.[21] However, these instruments were created in the late 1990s, when the focus was primarily on distance vision

Table 4. Spearman Correlations* of Satisfaction Scores at Distance with Visual Symptoms

Symptom	Satisfaction with Vision at Distance		Satisfaction with Vision at Intermediate Distance		Satisfaction with Vision at Near Distance		Satisfaction with Vision (Overall)	
	Before Surgery	*After Surgery*	*Before Surgery*	*After Surgery*	*Before Surgery*	*After Surgery*	*Before Surgery*	*After Surgery*
Glare	−0.32	−0.30	−0.27	−0.23	−0.09	−0.09	−0.40	−0.22
Blurry vision	−0.31	−0.31	−0.28	−0.26	−0.13	−0.12	−0.51	−0.33
Starbursts or streaks	−0.19	−0.24	−0.19	−0.19	−0.06	−0.04	−0.28	−0.15
Hazy vision	−0.24	−0.30	−0.24	−0.24	−0.16	−0.15	−0.38	−0.27
Snowballs	−0.20	−0.20	−0.25	−0.19	−0.12	−0.04	−0.27	−0.16
Halos	−0.18	−0.22	−0.15	−0.13	−0.02	0.00	−0.28	−0.18
Floaters	−0.11	−0.11	−0.15	−11	−0.05	−0.10	−0.14	−0.15
Double images	−0.15	−0.17	−0.16	−0.11	−0.10	−0.10	−0.22	−0.20
Rings and spider webs	−0.11	−0.09	−0.10	−0.02	−0.07	0.05	−0.17	−0.14
Flashes with eyes closed	−0.12	−0.12	−0.15	−0.09	−0.11	−0.10	−0.16	−0.11
Distortion	−0.10	−0.23	−0.12	−0.21	−0.09	−0.16	−0.14	−0.22
Flashes with eyes open	−0.08	−0.16	−0.16	−0.09	−0.13	−0.05	−0.14	−0.16
Shimmering images	−0.05	−0.12	−0.05	−0.11	−0.01	−0.07	−0.07	−0.08
Dark crescent-shaped shadow	−0.03	−0.06	−0.10	−0.11	−0.07	−0.10	−0.04	−0.05

*Spearman rank correlation coefficient; $P < 0.001$ for all correlations.

Table 5. Differences between Patients with Multifocal Intraocular Lenses and Monofocal Intraocular Lenses

Symptoms	Multifocal			Monofocal		
	Had before Surgery	*Had after Surgery*	*Change*	*Had before Surgery*	*Had after Surgery*	*Change*
Halos	52%	33%	−20%	52%	16%	−36%
Starbursts	64%	42%	−23%	67%	24%	−44%
Glare	82%	47%	−36%	85%	33%	−52%
Rings	21%	24%	−3%	32%	7%	−26%
Satisfaction with general vision	19%	73%	+53%	20%	67%	+47%

activities, rather than intermediate and near vision activities that predominate in current society with widespread use of cell phones, computers, and tablets. Questionnaires such as the CAT-PROM5 and Catquest-9SF focus on visual disability, and the Catquest-9SF has 2 global assessment items, including one on satisfaction, but these do not elicit responses on specific symptoms.[22,23] A recent instrument, Questionnaire for Visual Disturbances, was developed to evaluate 7 symptoms, including dark area, double vision, blurred vision, hazy vision, glare, halo, and starburst.[24] However, it is limited by the lack of questions on satisfaction, spectacle dependence, and vision across different working distances. These were identified as important assessments at the cosponsored FDA/American Academy of Ophthalmology workshop, as well as recent recommendations by Evans et al.[25]

The field test results confirmed the widely known benefits and limitations of monofocal IOLs versus premium IOLs.[14] Patients with monofocal IOL implantation had greater reduction in symptoms than those with multifocal IOLs for symptoms known to be associated with premium IOL implantation, but patients with monofocal IOLs reported less improvement in the general vision scale than patients with premium IOLs. This study was not designed to evaluate differences among the premium IOL types, but the analysis of results did not find any statistically significant associations between IOL type and symptoms or visual acuity improvement.

The AIOLIS questionnaire is important because it illuminates which symptoms are bothersome and the extent of their effect on patients' visual function and activities of daily living. Ophthalmologists can base their selection of an IOL on their experience, also taking into consideration that patients with significant corneal higher-order aberrations are more likely to experience symptoms such as glare and halos.[26] Patient selection and counseling is particularly relevant,[2] because there might be a reduction of the quality of distance vision if other ocular comorbidities are present, for example, amblyopia, optic disc abnormalities, macular disease, or corneal conditions,[27] and other factors associated with reduced quality of vision.

The results of the AIOLIS instrument field test confirmed the experience to date of cataract surgeons with premium IOL implantation and the package insert descriptions of potential visual disturbances, including glare, rings around lights, starbursts, blurred vision, reduced contrast sensitivity or hazy vision, and other visual disturbances. A 2019 systematic review and meta-analysis identified improved corrected and uncorrected near and intermediate vision and better spectacle independence for patients with multifocal IOLs, but more of these patients reported symptoms of glare, reduced contrast sensitivity, and halos than patients with monofocal IOLs.[28] However, the questionnaires and methods for asking patient questions varied from study to study, limiting interpretation.

Although the focus of the questionnaire was on patients with premium IOLs, the comparison of patient groups with monofocal IOLs highlighted the expected differences in these two types of IOLs and the tradeoffs to consider when ophthalmologists and their patients discuss the spectrum of options for particular needs and settings, including visual goals, profession, leisure activities, and lifestyle.[29] Patients with monofocal IOLs, as expected, had fewer halos, starbursts, glare, and rings than patients with multifocal IOLs, but they also had less improvement in their rating of their general vision than patients with multifocal IOLs, which included rating their eyesight for seeing at an intermediate and near distance as well as at distance and

Table 6. Mean Patient Satisfaction Scores Stratified by Reports of Adverse Events or Intraoperative Complications, Postoperative Visual Acuity, and Postoperative Use of Corrective Lenses

Variable	Satisfaction with Vision after Surgery Score (1-6)
AEs or ICs	
≥ 1	3.8
0	4.6
P value*	$t = 2.87$, $P = 0.0042$
UCDVA	
20/40 or better (monocular, either eye)	4.6
Worse than 20/40 (monocular, in both eyes)	3.6
P value*	$t = 3.67$, $P = 0.0003$
Corrective lenses	
Use	4.5
Do not use	4.6
P value*	$t = -0.75$, $P = 0.4538$

AE = adverse event; IC = intraoperative complication; UCDVA = uncorrected distance visual acuity.
Satisfaction scored from 1 to 6: 1 = completely dissatisfied, 2 = very dissatisfied, 3 = somewhat dissatisfied, 4 = somewhat satisfied, 5 = very satisfied, and 6 = completely satisfied.
*Mann–Whitney *U* test.

their overall satisfaction with vision. Perhaps the improvement in the rating of their general vision scale with premium lenses is related to neural adaptation[19,15] and their acceptance of some optical symptoms, which they accept as a tradeoff for greater spectacle independence with activities like walking, driving, and near vision tasks like reading and texting.

Now, clinical trialists, the medical device industry, physicians, and most importantly the public can have an evidence-supported tool, the AIOLIS instrument, to assess visual symptoms and satisfaction in patients undergoing cataract surgery. This instrument was developed with patient, industry, and clinician input, following the FDA Guidance to Industry on PROMs,[12] and addressed the concepts described during the cosponsored FDA/American Academy of Ophthalmology workshop.[8] The FDA states in its guidance document that information from well-defined and reliable PRO instruments can provide valuable evidence for benefit-risk assessments and can be used in medical device labeling to communicate the effect of a treatment on patient symptoms, functioning, or health-related quality of life when the use is consistent with the PRO instrument's documented and supported measurement properties.[12] The FDA Medical Device Development Tool Program[30] is an approach for qualifying instruments for use in regulatory decision-making. By submitting instruments like the AIOLIS for qualification under the Medical Device Development Tool Program, we can provide a tool for the medical device industry, clinicians, and other researchers to incorporate PROs into their studies and include them in the labeling for IOLs.[31] This information on PROs can help inform both the surgeon's and patient's decision to have a particular IOL implanted.

By eliciting and understanding patients' perceptions and needs and what is most important to them in everyday life in a detailed preoperative history and examination, ophthalmologists can include the patient's voice in a collaborative decision-making process towards their medical care. The patient's residual refractive error and spectacle independence may overshadow symptoms and other aspects of quality of vision and may be an important factor in satisfaction with surgery, and a small amount of residual myopia does not appear to negatively impact satisfaction or perception of general vision in this cohort.

Moreover, this study may help guide clinicians in their understanding and the language and visual images they can utilize to advise their patients. Clinicians, manufacturers, and regulators are being asked to evaluate an increasing variety of IOL strategies including toric, diffractive, extended depth of focus, and accommodative lenses without a validated, standardized system for comparison. The current study was designed with extensive input from the manufacturers, regulators, and clinicians to standardize PRO measures and create a level playing field for all groups for comparisons and interpretations. Patient symptomatology before and after cataract surgery and their verbal description of their experience can often be challenging to communicate. The use of images and word descriptions obtained in the early focus groups and the later survey patients that simulated the various forms of glare, halos, blur, and other dysphotopsias may help both the clinician and patient to have a shared understanding of various symptoms. Using assessments of visual symptoms and functioning such as the AIOLIS instrument in clinical care can aid ophthalmologists in learning from their patients about their experiences with different IOLs, facilitating more informed discussions with patients about goals and objectives for vision and lifestyle.

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Footnotes and Disclosures

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HUMAN SUBJECTS: Human subjects were included in this study. This study was approved by the UCLA Human Subjects Committee (IRB#17-000146) and the RAND Human Subjects Committee (IRB#2018-1047-AM01) and waived the requirement for informed consent because of the retrospective nature of the study. All research adhered to the tenets of the Declaration of Helsinki.

No animal subjects were included in this study.

Author Contributions:

Conception and design: Lum, Masket, Hays, Tarver, Holladay, Yoon, Nguyen, Stark, Kumar, Lau, Schallhorn, Eydelman

Analysis and interpretation: Lum, Masket, Hays, Tarver

Data collection: Hays

Obtained funding: Masket, Hays

Overall responsibility: Lum, Masket, Hays, Tarver, Holladay, Yoon, Nguyen, Stark, Kumar, Lau, Schallhorn, Eydelman

Abbreviations and Acronyms:
AIOLIS = Assessment of IntraOcular Lens Implant Symptoms; **D** = diopter; **FDA** = Food and Drug Administration; **IOL** = intraocular lens; **logMAR** = logarithm of the minimum angle of resolution; **PRO** = patient-reported outcome; **PROM** = patient-reported outcome measure.

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Cataract surgery, IOLs, Patient-reported outcomes, Symptoms.

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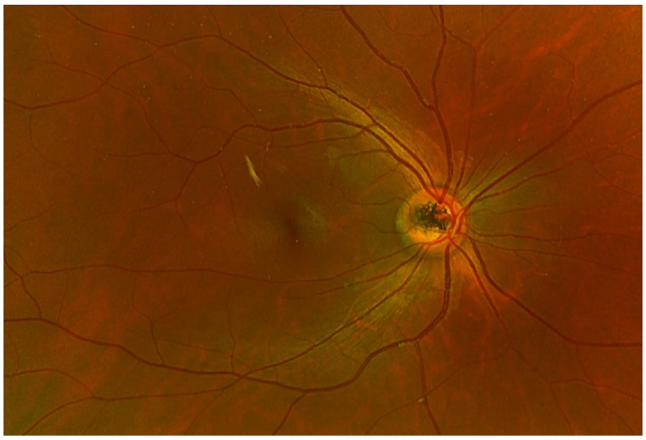
Pictures & Perspectives



Pigmented Lamina Cribrosa

An 11-year-old Asian-American boy presented for evaluation of optic nerve pigmentation. Vision was 20/20 in each eye without correction. Color fundus photography of the right eye revealed a cup-to-disc ratio of 0.6, and a pigmented cribriform structure in the optic cup. We believe this represents melanocytic pigmentation of the scleral fibers of the lamina cribrosa. It could also be a very early optic nerve melanocytoma. However, melanocytoma has been described as a pigmented lesion that obscures part or all of the optic disc. There is pigmentation of the scleral fibers, without forming a discrete mass (Magnified version of Figure 1 is available online at www.aaojournal.org).

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