Comparison of visual function with aspheric yellow, aspheric clear and spherical clear intraocular lenses

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PURPOSE: To compare visual outcomes, contrast sensitivity, color vision and patient satisfaction after implantation of yellow-tinted aspheric intraocular lenses (IOLs) or clear (untinted) IOLs with either aspheric or spherical designs.

SETTING: Eye Surgery Center, Erlangen, Germany.

METHODS: Patients with senile monocular cataract were randomly assigned to receive either a blue light-filtering aspheric IOL (Aspira-aAY group), its clear aspheric counterpart (Aspira-aA group) or the clear spherical model (AS group). The primary outcome measures were visual acuity for distance, intermediate (1 m), near (40 cm), contrast sensitivity under photopic (85 cd^2) and mesopic (3 cd^2) conditions, with and without glare (Optec 6500 Vision Tester), color vision (Farnsworth-Munsell 100-hue test, photopic conditions) and patient satisfaction.

RESULTS: One-year postoperatively, there were 28 eyes in the Aspira-aAY group; 19 eyes in the Aspira-aA group and 24 eyes in the AS group. There were no significant differences between the 3 groups in terms of uncorrected and distance corrected visual acuity for far, intermediate and near and for color vision. Contrast sensitivity under all lighting conditions tested and patient satisfaction were similar between the Aspira-aAY and Aspira-aA groups. The AS group achieved slightly worse contrast sensitivity scores and patient satisfaction levels than the other groups. Slitlamp examinations revealed no glistening, IOL decentration or tilt in any of the cases.

CONCLUSIONS: One year postoperatively, the yellow-tinted and clear aspheric IOLs gave similar outcomes for visual acuity, contrast sensitivity, color perception and patient satisfaction. The spherical IOL provided slightly worse contrast sensitivity and patient satisfaction.

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In the last decade, many manufacturers have developed aspheric intraocular lenses (IOL) that incorporate a blue-light filter with the aims of optimizing the postoperative visual performance and safety of the pseudophakic eye. Whereas numerous clinical studies have confirmed the advantages of aspheric IOLs over conventional spherical IOLs in terms of improved optical image quality and contrast vision, particularly under mesopic conditions[1-10], there have been more controversies regarding the benefits of blue-light filtering IOLs. On one hand, the hypothesis that blocking harmful blue light from reaching the retina will protect eyes from age-related diseases such as macular degeneration has been supported by several in vitro studies[11-14]. On the other hand, there have been some concerns that blue-light filtering IOLs might compromise mesopic and scotopic vision, color perception and circadian rhythms[15]. However, there is now an increasing amount of literature showing that IOLs with and without the blue light-feature performed similarly in terms of contrast sensitivity under photopic and mesopic conditions[16-21]. Furthermore, blue-filtering IOLs have

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also demonstrated enhancement of some aspects of visual performance by reducing glare disability and improving the heterochromatic contrast threshold and the recovery of photostress[22]. The results of color vision testing in the literature have been more controversial, with several studies reporting no significant difference in color vision between yellow and clear IOLs[16,21,23,24] and others showing some impairment of the blue perception with yellow IOLs[18, 20,25,26]. In fact, the reasons of this apparent discrepancy may lie in the testing conditions and the sensitivity of the methods used to perform the investigations which were different among studies.

It is also worth mentioning that most clinical investigations on blue-light-filtering IOLs have been performed with the AcrySof® Natural (Alcon Laboratories, Inc; fort Worth, TX, USA) and the AF-1 (UY) (Hoya, Tokyo, Japan) lenses. However, blue-light filtering IOLs of various materials and from different manufacturers exhibit different light transmittance characteristics[27] and, therefore, their performance on functional vision might differ as well. In this prospective study, we evaluated the performance of the blue-light filtering aspheric Aspira-aAY IOL, (HumanOptics/Dr Schmidt Intraocularlinsen, Erlangen, Germany) and compared the outcomes with those of the Aspira-aA IOL (the clear aspheric counterpart) and the AS IOL (the clear spherical model).

PATIENTS AND METHODS

This prospective randomized clinical study was conducted at the Eye Surgery Center (Erlangen, Germany) in accordance with the Declaration of Helsinki. The clinical investigation plan was reviewed and approved by the local ethics committee (Friedrich-Alexander University Nuremberg-Erlangen). All patients provided written informed consent before enrolment in the study.

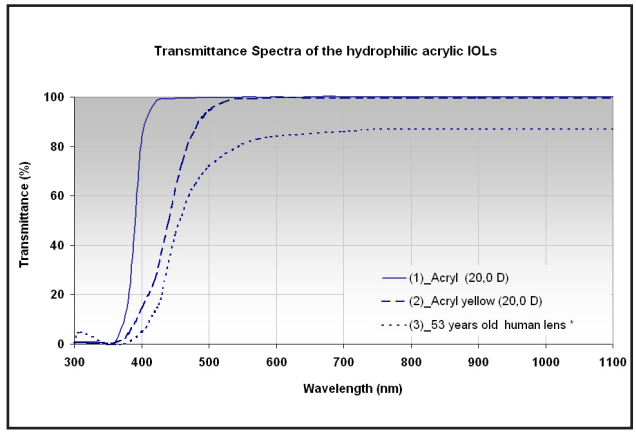

Figure 1. Transmission curve of the yellow-tinted Aspira-aAY IOL (Acryl yellow) and the clear Aspira-aA (Acryl), package inserts from HumanOptics AG. *Transmission of Ocular Media[28]

Ninety patients with senile unilateral cataract were screened and enrolled in the study. Exclusion criteria included previous or coexisting ocular pathology including diabetic retinopathy and amblyopia, astigmatism > 1.5 D, IOL power calculation less than +18.0 D or greater than +26.0 D, and refusal or inability to attend follow-up appointments.

Patients were randomly assigned to implantation of the yellow aspheric Aspira-aAY IOL (n = 30 eyes), the clear aspheric Aspira-aA IOL (n = 30 eyes) or the clear spherical AS IOL (n = 30 eyes). The Aspira-aAY IOL contains a yellow coloring agent (azopyrazolon methacrylate) which filters light in the 400-475 nm blue light wavelength range (Figure 1). The detailed characteristics of the 3 IOLs are shown in Table 1. The biometric measurements were performed with the IOLMaster (Carl Zeiss Meditec, Jena, Germany) and the IOL power was calculated with the Haigis formula (A constant = 118.4; Haigis formula: a0 = 0.885, a1 = 0.312, a2 = 0.125).

Table 1. Characteristics of the 3 IOLs involved in this study

	Aspira-aA Aspira-aAY	AS
Design	1 piece Aspheric (aberration-free) Posterior 360° square-edge barrier	1 piece Spherical -
Optic material	Hydrophilic MicroCryl®	Hydrophilic MicroCryl®
UV filter	Yes	Yes
Blue light filter	No (Aspira-aA) Yes (Aspira-aAY)	No
Optic shape	Concave-convex (0.0 to 9.0 D) Biconvex (10.0 to 50.0 D)	Concave-convex (0.0 to 9.0 D) Biconvex (10.0 to 35.0 D)
Optic diameter (mm)	6	5.75
Total diameter (mm)	12.5	12
Haptic shape	C-loop	C-loop
A constant	118.4	118.4

Surgical technique

All surgeries were performed by the same surgeon (M.K.) under topical anesthesia using standard surgical procedures and medications. Surgery consisted of 2.5 mm self-sealing clear corneal incision in the steepest corneal axis. A 5.00 to 5.25 mm continuous curvilinear capsulorhexis, slightly smaller than the IOL optic diameter to ensure an optic overlap, was made followed by phacoemulsification and IOL implantation in the capsular bag. All IOLs were inserted through an incision size of approximately 2.5 mm using the ViscoJect 2.2 injector (Medicel AG, Wolfhalden, Switzerland) and posterior capsule polishing was performed.

Postoperative assessments

Postoperative visits were scheduled 1 month, 3 months and 1 year after surgery and included refractive status, slit-lamp evaluation and the measurement of monocular uncorrected and distance corrected visual acuity for far, intermediate and near. The distance visual acuity was evaluated using a Snellen projector system (Möller-Wedel M1000) at 5 m. Intermediate (1 m) and near visual acuities (40 cm) were evaluated using their respective ETDRS charts (Precision Vision, La Salle, USA). Other clinical endpoints were assessed 1-year after surgery and included monocular contrast sensitivity, monocular color vision and patient satisfaction.

Contrast sensitivity was measured with distance correction under photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions, without and with glare using the FACT™ Optec 6500 Vision Tester (Stereo Optical Co, Inc, USA). Color vision was evaluated with distance correction under day-light conditions using the Farnsworth-Munsell (FM) 100-hue test. The test consists of four trays containing many small disks of varying hues. Each tray has a colored reference disk at one end. The person being tested must arrange the other disks within the tray to create a continuum of gradually changing hue. Because of the blue-light filter in one of the three study IOLs, box 3 with the blue/green hues and, to a lesser degree, box 4 with the purple/pink hues were of particular interest. All disks were taken out of the two boxes and placed on a table with a halogen light source. Patients were asked to place the disks in the box in the correct order. When boxes were completed, the results were recorded by the examiner. The error score for each disk was calculated using Hidayat's method[29]. Finally, patients were asked about their overall satisfaction with their vision.

Statistical analysis

Statistical analysis was performed using Analyse-it® software (Analyse-it Software, Ltd, Leeds, UK). Decimal visual acuity and contrast sensitivity scores were converted to the logMAR scale and logarithm units for statistical purposes, respectively. Comparison between the three IOL models for age, IOL power, axial length, visual acuity and contrast sensitivity were performed with a 1-way analysis of variance test (ANOVA) and, whenever a main effect reached statistical significance, post-hoc pairwise comparisons were used. Comparisons between groups for colour vision scores were conducted with the Kruskal-Wallis test for independent samples and the Mann-Whitney U test for pairwise analysis. A p value of 0.05 or less was considered significant.

RESULTS

Because of dropout from patient illness, death or unavailability, 71 of 90 patients were available for the one-year follow-up visit (Aspira-aAY group, n = 28; Aspira-aA group, n = 19; AS group, n = 24). There were no significant differences between the 3 IOL groups in

Table 2. Patient demographics

	Aspira-aAY Yellow/Aspheric	Aspira-aA Clear/Aspheric	AS Clear/Spherical	*P* value*
Number of eyes	28	19	24	
Sex (M/F)	11/17	6/13	11/13	
Mean age (years)	75.4 ± 8.0	78.1 ± 6.0	77.6 ± 6.0	
(range)	(53 – 90)	(64 – 86)	(67 – 87)	0.353
Mean IOL power (D)	22.5 ± 2.0	21.9 ± 1.8	21.5 ± 1.7	
(range)	(19.5 – 26.0)	(19.0 – 25.5)	(18.5 – 24.0)	0.199
Mean axial length (mm)	22.91 ± 0.60	23.13 ± 0.86	23.24 ± 0.52	0.219
(range)	(21.37 – 24.65)	(21.92 – 24.87)	(22.27 – 24.33)	

*Analysis of variance (ANOVA)

terms of age, IOL power, axial length and postoperative pupil size, spherical equivalent, uncorrected and distance corrected visual acuity for far, intermediate and near (Tables 2 and 3). Best distance corrected visual acuity of 20/20 or better was achieved by 78.6% of eyes in the Aspira-aAY group, 63.2% in the Aspira-aA group and 75.0% in the AS group.

Three patients (12.5%) from the AS group required neodymium:YAG laser capsulotomy for PCO 6-month post-surgery. In the other groups, one patient in the Aspira-aA group (5.3%) and one in the Aspira-aAY group (3.6%) required PCO treatment 11-month post-surgery. The data of these patients are included in the results.

Contrast sensitivity

Overall mean monocular contrast sensitivity scores (i.e., mean of all tested spatial frequencies per illumination level) in each IOL group is shown in Table 4. The AS IOL group exhibited a lower mean contrast sensitivity than the other groups under all illuminations tested, although this did not reach significance. When data were evaluated separately for each frequency, there was no significant difference between the 3 IOL groups under photopic conditions with and without glare. Under mesopic conditions, the ANOVA test yielded a significant P value at the frequency of 18 cpd without glare (P = 0.004). Post-hoc pairwise comparisons showed significant higher contrast sensitivity scores in the aspheric Aspira-aAY IOL group *versus* the spherical AS IOL group (P = 0.006). No other significant differences were observed between groups.

Color vision

Table 3 shows the total error scores obtained with the yellow-tinted and clear IOLs at the 1-year follow-up. Measurements were carried out under photopic conditions. There was no statistically significant difference between the 3 groups.

Patient satisfaction

In the Aspira-aA / Aspira-aAY groups, all patients reported to be "very satisfied" (n = 17, 89.4% / n = 23, 82.1%) or "satisfied" (n = 2, 10.5% / n = 5, 17.8%) with their vision. In the AS group, 23 patients reported to be "very satisfied" (n = 16, 66.6%) or "satisfied" (n = 7, 29.2%) with their vision. One patient (4.2%) was "moderately satisfied", due to disturbing halos in her eye.

Table 3. Monocular visual outcomes 1-year postoperatively

	Aspira-aAY Yellow/Aspheric	Aspira-aA Clear/Aspheric	AS Clear/Spherical	*P* value*
Mean pupil size (mm) (range)	3.32 ± 0.29 (2.75 – 3.83)	3.56 ± 0.42 (2.83 – 4.33)	3.41 ± 0.38 (2.50 – 4.17)	0.094
Mean SE (D)	– 0.17 ± 0.37	– 0.11 ± 0.40	– 0.15 ± 0.37	0.880
Mean VA (LogMAR; Snellen)				
UDVA (5 m)	0.10 ± 0.14 20/25.2	0.14 ± 0.21 20/27.6	0.10 ± 0.17 20/25.2	0.683
CDVA (5 m)	0.00 ± 0.07 20/20.0	0.02 ± 0.07 20/20.9	0.01 ± 0.05 20/20.5	0.650
UIVA (1 m)	0.20 ± 0.11 20/31.7	0.22 ± 0.11 20/33.2	0.19 ± 0.11 20/31.0	0.702
CIVA (1 m)	0.24 ± 0.13 20/34.8	0.25 ± 0.13 20/35.6	0.24 ± 0.14 20/34.8	0.962
UNVA (40 cm)	0.54 ± 0.15 20/69.3	0.57 ± 0.13 20/74.3	0.54 ± 0.16 20/69.3	0.776
CNVA (40 cm)	0.59 ± 0.15 20/77.8	0.61 ± 0.15 20/81.5	0.55 ± 0.17 20/71.0	0.465

SE = spherical equivalent; UDVA/CDVA = uncorrected/corrected distance visual acuity; UIVA/CIVA=uncorrected/corrected intermediate visual acuity; UNVA/CNVA = uncorrected/corrected near visual acuity.
*Analysis of variance (ANOVA)

Complications

Intraoperatively, one IOL had to be exchanged due to a broken haptic. No ocular adverse events occurred during the course of the study and slitlamp examinations revealed no glistening, IOL decentration or tilt in any of the cases.

DISCUSSION

The purpose of this study was two-fold. First, we evaluated the impact of blue-light filtering (Aspira-aAY group) on visual function and second, we examined the possible benefits of aspheric optics (Aspira-aA(Y)

Table 4. Overall contrast sensitivity scores (i.e. the contrast sensitivity for all tested spatial frequencies) in each IOL group under different illumination levels.

Spatial frequency (cpd)	Aspira-aAY	Aspira-aA	AS	*P*-value*
Photopic	1.47 ± 0.28	1.38 ± 0.29	1.27 ± 0.33	0.072
Photopic with glare	1.47 ± 0.24	1.42 ± 0.28	1.30 ± 0.34	0.112
Mesopic	1.02 ± 0.37	0.97 ± 0.33	0.83 ± 0.32	0.154
Mesopic with glare	0.71 ± 0.46	0.60 ± 0.38	0.49 ± 0.42	0.176

* Analysis of variance (ANOVA)

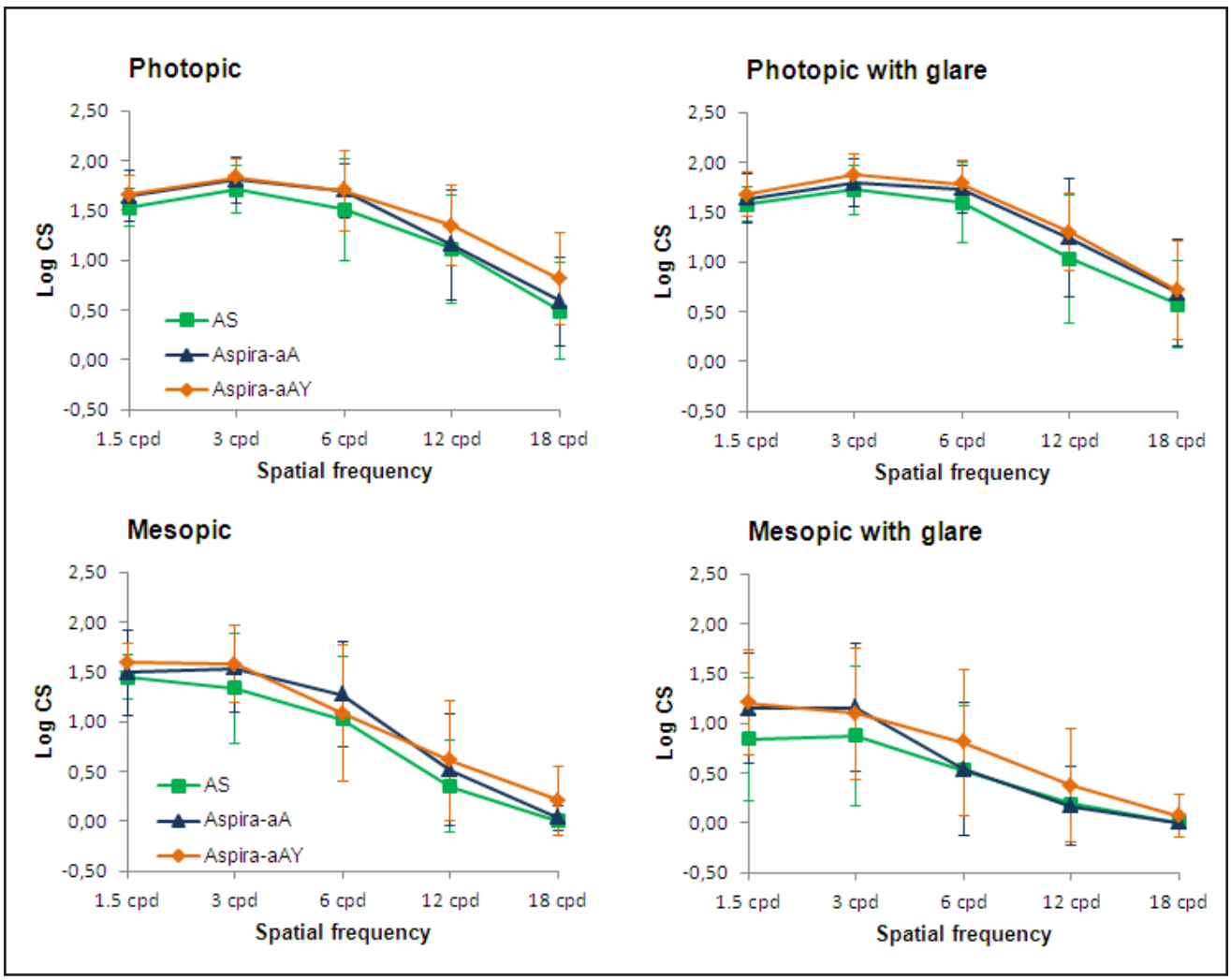

Figure 2. Monocular mean log contrast sensitivity under photopic (85 cd/m²) and mesopic (3 cd/m²) conditions without and with glare measured 1-year postoperatively.

Table 5. Error scores for the FM 100-hue test (boxes 3 and 4) with the spherical clear IOLs (AS), aspheric clear IOLs (Aspira-aA) and aspheric yellow IOLs (Aspira-aAY) under photopic conditions.

Parameter	Aspira-aAY	Aspira-aA	AS	*P* value*
Boxes 3+4				
Mean ± SD	56.0 ± 30.0	61.1 ± 29.1	66.0 ± 34.2	0.366
Range	(20 – 141)	(12 – 115)	(8 – 154)	
Box 3 (blue/green hues)				
Mean ± SD	31.0 ± 19.0	36.9 ± 19.4	39.0 ± 23.4	0.324
Range	(8 – 82)	(12 – 80)	(4 – 95)	
Box 4 (purple/pink hues)				
Mean ± SD	24.7 ± 12.6	24.1 ± 11.9	27.0 ± 14.6	0.788
Range	(8 – 53)	(0 – 43)	(4 – 59)	

*Analysis of variance (Kruskal-Wallis)

groups) *versus* spherical optics (AS group) on visual performance.

The three hydrophilic acrylic IOLs studied here differ only slightly. The Aspira-aA and Aspira-aAY lenses are identical in every way except for the yellow colouring agent. The AS IOL is the former spherical model of the aspheric Aspira-aA IOL without a posterior 360° square-edge barrier and features a slightly smaller optic and total diameter.

Patient preoperative characteristics were similar in the three study groups. One-year postoperatively, mean subjective refraction and mean visual acuity outcomes for far, intermediate and near were comparable between the 3 IOL models with no statistically significant differences. All IOL groups achieved good CDVA including 75.0% of eyes having 20/20 or better in the AS group; 63.3% in the Aspira-aA group and 78.6% in the Aspira-aAY group. These data are in line with those reported in previous studies showing similar visual acuity outcomes between aspheric *versus* spherical IOLs[30] and between yellow-tinted *versus* clear IOLs[18-21].

Unilateral examination of contrast sensitivity did not show any significant differences between the Aspira-aAY and Aspira-aA groups under photopic and mesopic conditions, with and without glare at any spatial frequency. Our data also showed a tendency towards lower contrast sensitivity scores in the AS IOL group as compared with the Aspira-aA(Y) IOL groups, although the results were not statistically significant except for the pairwise comparison with the Aspira-aAY under mesopic conditions without glare at the frequency of 18 cpd (P = 0.006). Since preoperative patient characteristics were similar between groups as well as the postoperative mean CDVA, we can assume that the overall slightly worse contrast sensitivity performance of the AS IOL may be attributed to its spherical design. However, we acknowledge that a larger sample size or a crossover study design would be required to yield clearer results. Nonetheless, these outcomes suggest that contrast sensitivity under all lighting conditions tested here is not impaired by the blue-light filtering Aspira-aAY IOL implantation. This result adds to the growing body of literature showing that yellow-tinted IOLs do not compromise photopic and mesopic vision. Higher contrast sensitivity in patients with diabetic retinopathy has even been reported in eyes implanted with the yellow-tinted AcrySof Natural *versus* the contralateral eyes implanted with the clear AcrySof SA60AT[31].

The results of the impact of blue light-filtering IOLs on color vision have not been straightforward. Depending on the study design including, and in particular, the sensitivity of the method used to test color perception and follow-up length, study conclusions have been distinct. While most studies found no significant difference in color vision between eyes with or without blue light-filter in photopic and mesopic conditions[32], some showed reduced vision with the yellow-tinted IOLs in the blue light spectrum, particularly, in dim light conditions[18, 20, 25, 26,32].

In our study, we evaluated separately box 3 (blue/green hues) and box 4 (purple/pink hues) of the FM 100-hue test under photopic conditions. One year postoperatively, the three IOLs groups performed similarly with no statistical difference in the mean error scores (box 3 and box 4). These results are in agreement with those of Wang et al.[20], showing no difference in color discrimination under photopic conditions in the green-to-blue band of the FM 100-hue test between blue light-filtering IOLs (AF-1 (UY), Hoya), clear IOLs (MC611MI, HumanOptics) and photochromic IOLs (Medennium). Similar outcomes have been reported by others[25,26]. Although, Mester et al.[18] showed overall higher

mean total error scores in the same light spectrum in eyes implanted with the yellow AF-1 (UY) IOL as compared with the fellow eyes implanted with the clear AF-1 (UV) IOL under photopic conditions, the difference was significant for the first 6 months postoperatively but not at the 1-year follow-up visit. In contrast, all studies mentioned above observed some color discrimination impairment in the blue light spectrum under mesopic conditions in eyes with the yellow-tinted IOLs. But none of them reported any significant difference in overall color discrimination or discomfort in mesopic conditions when subjective perception evaluation was carried out by a questionnaire to the patients[32].

Finally, when asked about their overall satisfaction with the procedure, 82.1% of the Aspira-aAY patients reported to be "very satisfied" and 17.8% "satisfied". Similar levels of satisfaction were obtained with the Aspira-aA with 89.4% of patients being "very satisfied" and 10.5% "satisfied". None of the patients with aspherical IOLs were unsatisfied. Only patients in the spherical IOL group reported lower levels of satisfaction with 66.6% being "very satisfied"; 29.2% "satisfied" and 4.2% "moderately satisfied".

In conclusion, no significant differences in terms of visual acuity, contrast sensitivity, color vision and patient satisfaction between the blue-light filtering Aspira-aAY and the Apira-aA IOLs were observed in this study. Although the potential advantages of the yellow-tinted IOLs in reducing the risk of developing AMD has not been demonstrated clinically yet[21], they seem to provide similar outcomes than clear IOLs without additional substantial risks. Finally, our study also confirmed the results of previous reports showing a trend for overall better performance of aspherical IOLs *versus* spherical IOLs in terms of functional vision and patient satisfaction.

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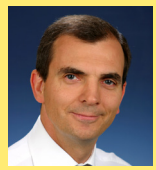

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