Quality of vision after cataract surgery after Tecnis Z9000 intraocular lens implantation

Effect of contrast sensitivity and wavefront aberration improvements on the quality of daily vision

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PURPOSE: To compare ocular performance and quality of vision in pseudophakic eyes with an aspherical intraocular lens (IOL) or a conventional spherical IOL.

SETTING: Bretonneau University Hospital, Tours, France.

METHODS: Twenty patients (40 eyes) were randomly divided in 2 equal groups to bilaterally receive the aspherical Tecnis Z9000 IOL (AMO) or the spherical CeeOn Edge 911 IOL (AMO). Contrast sensitivity was measured and ocular wavefront analysis performed before surgery and 6 months after. Patients completed the Activities of Daily Vision Scale (ADVS) to evaluate patient-centered visual outcomes. Other examinations included refraction before and after mydriasis and pupil diameter.

RESULTS: The mean postoperative best corrected visual acuity (logMAR) was 0.03 ± 0.05 (SD) in the Tecnis group and 0.01 ± 0.05 in the CeeOn Edge group ($P = .41$). Refractive evaluation with mydriasis showed a mean myopic shift as low as −0.02 ± 0.36 diopter (D) in the Tecnis group and −0.51 ± 0.37 D in the CeeOn Edge group ($P = .001$). Mesopic contrast sensitivity at high spatial frequencies was significantly better in the Tecnis group ($P<.001$), while contrast sensitivity under photopic and glare conditions was not different between the 2 groups. Spherical aberration was significantly lower in the Tecnis group, which had a mean Z_4^0 of 0.01 ± 0.06 μm, than in the CeeOn Edge group, which had a mean Z_4^0 of 0.16 ± 0.12 μm ($P<.001$). The global score on the ADVS was not statistically different between groups; however, quality of distance vision was better in the Tecnis group than in the CeeOn Edge group (mean 99.0 ± 2.0 versus 89.2 ± 3.4) ($P<.001$).

CONCLUSION: Implantation of an aspherical IOL with a negative spherical aberration resulted in reduced ocular spherical aberration and improved mesopic contrast sensitivity and led to better subjective quality of vision.

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A better knowledge and understanding of optical aberrations that significantly contribute to decreased visual function are now achievable with technical advances in ophthalmology.[1–4] If the aberrometer has gradually become an valuable diagnostic tool to create individual ablation profiles in refractive surgery, it has also turned out to be a powerful method to objectively measure aberrations present in pathologic and surgically altered eyes, thus providing a means to predict optical performance.[5–11] In recent years, contrast sensitivity and contrast acuity measurements have emerged as additional tools in ophthalmology and have provided a wealth of information about quality of vision. Unlike standard visual acuity tests, their measurements evaluate visual function across a wide range of sizes and conditions of luminance and glare[12] that appear in the everyday environment, providing a more realistic assessment of the patient's quality of vision.[13,14]

With improvement in the quality of life and the resulting expansion of the elderly population, the prevalence of cataract cases will continue to rise. The population is on average older, and the environment has become more demanding for older people, who therefore need to regain excellent quality of vision. This became feasible with the improvement of surgical techniques and the development of a new-generation of intraocular lenses (IOLs) designed to reduce ocular spherical aberrations and improve

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contrast sensitivity. Optical studies show that spherical diopters, such as with conventional IOLs, distort the peripheral wavefront, leading to a corrupted retinal image that becomes blurred. Converting spherical-profile IOLs to aspherical prolate IOLs would therefore reduce this peripheral wavefront decay, also called spherical aberration.

The Tecnis Z9000 IOL (AMO) was developed for this purpose.[15,16] It has a modified prolate anterior surface that introduces a negative spherical aberration to the optical system to compensate for the positive spherical aberration of the cornea.[2,17–19] This is in contrast to conventional IOLs, which add positive spherical aberration to the ocular system. This balance produces a sharp image on the retina and could optimize quality of vision.

In this interindividual prospective study, patients had implantation of the same IOL in both eyes to enable us to combine contrast sensitivity and wavefront aberrations measurements with patient-centered visual outcomes. The control group comprised patients who had bilateral implantation of the CeeOn Edge 911 IOL (AMO), which is identical to the Tecnis IOL except it has a spherical surface.

PATIENTS AND METHODS

Patients

Twenty patients (40 eyes) scheduled for cataract surgery were randomly assigned to bilaterally receive the prolate aspherical Tecnis Z9000 IOL or the spherical CeeOn Edge 911 IOL. Patients were blind to which IOL they received.

Inclusion criteria included myopia or hyperopia less than 4.00 diopters (D) spherical equivalent; no ocular surface pathology; normal 24-hour intraocular pressure (IOP); no neural or retinal pathology, especially with no macular dysfunction; and no systemic disease such as diabetes or vascular pathology.

Ethics committee approval for the study protocol was obtained. All patients signed an informed consent form before preoperative examinations.

Intraocular Lenses and Surgical Technique

The Tecnis Z9000 IOL shares basic design features with the CeeOn Edge 911 IOL including a 3-piece biconvex 6.0 mm square-edged optic with a refractive index of 1.46 and angulated cap C polyvinylidene fluoride haptics. The only difference between the 2 IOLs is in the shape of the anterior surface: The Tecnis IOL is characterized by an aspherical prolate anterior surface designed to introduce a negative spherical aberration (Z_4^0) of −0.27 μm, while the CeeOn Edge 911 IOL has a spherical biconvex design that introduces a positive spherical aberration.

The surgical procedure was performed by the same surgeon and was identical in all patients to minimize differences between groups in surgically induced aberrations.[11,20,21] Surgery consisted of topical anesthesia, 2 limbal incisions of 3.0 mm and 1.0 mm, a 5.0 mm continuous capsulorhexis, phacoemulsification cataract extraction, IOL implantation with an injector, IOL centration, and a sutureless incision.

Eye Examinations and Visual Quality Test

All patients had a full ocular examination 7 days before surgery. It included refraction; best corrected visual acuity (BCVA) measurements using Early Treatment Diabetic Retinopathy Study (ETDRS) charts; aberrometry (WaveScan, Visx); contrast sensitivity evaluation under photopic, mesopic, and glare conditions (Moniteur Ophtalmologique, Metrovision); biomicroscopic evaluation; IOP measurement; ocular fundus evaluation; and multifocal electroretinogram examination (Moniteur Ophtalmologique) to ensure that the loss of visual acuity was linked to cataract only.

Postoperative examinations were performed 6 months after surgery in a masked manner (ie, by an independent physician) and included refraction before and after pharmacologically induced mydriasis by tropicamide and phenylephrine hydrochloride (Neo-Synephrine 1%); BCVA measurements using ETDRS charts; pupillometry; contrast sensitivity evaluation under photopic, mesopic, and glare conditions; and aberrometry without pupil dilation. Subjective quality of vision was evaluated with the 22-item Activities of Daily Vision Scale (ADVS) questionnaire,[22,23] which evaluates day and night driving, best corrected distance and near vision, and glare disability.

Preoperative and postoperative contrast sensitivity testing was performed with photopic lighting of 80 cd/m^2, mesopic lighting of 0.15 cd/m^2, and a glare source of 25 000 cd/m^2 at low spatial frequencies (0.75 cycles per degree [cpd] and 1.75 cpd), intermediate frequencies (3.5 cpd and 7 cpd), and high frequencies (13 cpd and 30 cpd). In each patient, contrast sensitivity tests were performed with the best correction under every lighting condition to prevent a decrease in response sensitivity. Aberrometry was performed under mesopic conditions without pharmacological mydriasis after 5 minutes of adaptation (0.15 cd/m^2).

Statistical Analysis

All data are given as mean ± SD. Visual acuity is reported as logMAR values. Wavefront aberration data were recorded for a 5.0 mm pupil. Data were controlled for normality (plot graph and D'Agostino omnibus normality test) and homogeneity of variances (modified Levene test) to perform the adequate parametric *t* test. The few data that did not meet these criteria (age, IOL power, refraction, and Z_3^3) were analyzed with the nonparametric Mann-Whitney *U* test and Spearman correlation test. As multiple comparisons were performed, an adjustment of the probability level of significance on the main outcomes (BCVA, refraction, myopic shift, contrast sensitivities, wavefront aberrations, and ADVS items) was applied. According to the Bonferroni procedure, the nominal *P* values were considered to be significant when less than 0.0022 to maintain an overall type I error equal to 0.05.

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RESULTS

Patients

The mean age of the patients was 79.3 ± 8.2 years in the Tecnis group and 77.9 ± 5.2 years in the CeeOn Edge group (P = .46). The male-to-female ratio was 0.33 and 0.50, respectively. The mean IOL power was 21.4 ± 1.80 D in the Tecnis group and 21.90 ± 1.60 D in the CeeOn Edge group (P = .21).

Visual Acuity and Myopic Shift

The 6-month postoperative BCVA was similar in both groups; the mean was 0.03 ± 0.05 in the Tecnis group and 0.01 ± 0.05 in the CeeOn Edge group (P = .40). The mean refraction without mydriasis was 0.81 ± 1.30 D and 0.40 ± 1.01 D, respectively, for sphere (P = .54) and −1.36 ± 1.40 D and −0.71 ± 0.40 D, respectively, for astigmatism (P = .64).

A change in refraction with mydriasis occurred in both groups, and there was a significant difference between the 2 IOLs. The myopic shift was small in the Tecnis group (mean −0.02 ± 0.36 D) compared with that in the CeeOn Edge group (mean −0.51 ± 0.37 D) (P = .001). Figure 1 shows the difference in refraction before and after pharmacologically induced mydriasis; that is, myopic shift.

Pupil diameters under mesopic conditions without pharmacologically induced dilation were not significantly different between the 2 groups. The mean was 5.1 ± 0.7 mm in the Tecnis group and 5.0 ± 1.1 mm in the CeeOn Edge group (P = .77).

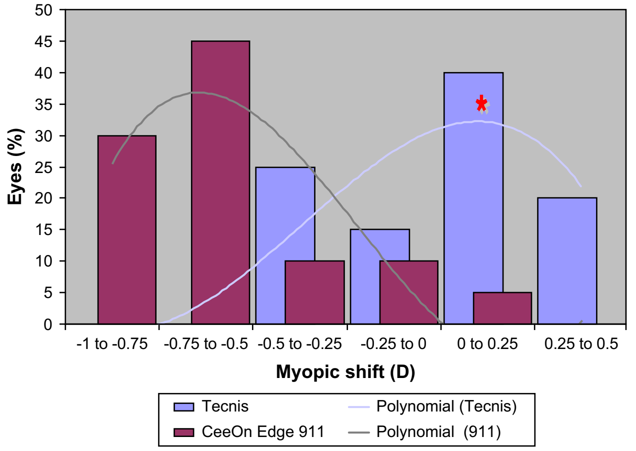

Figure 1. Comparative distribution of myopic shift after pharmacologically induced mydriasis in both groups (* = between-group difference in myopic shift is significant).

Contrast Sensitivity

Postoperative direct comparison between the 2 IOLs showed similar enhancement of contrast sensitivity under photopic conditions and with glare at all tested spatial frequencies (Figure 2, *A* and *B*). The Tecnis IOL performed significantly better than the CeeOn Edge IOL under mesopic conditions (Figure 2, *C*) at high spatial frequencies (mean 9.9 ± 5 dB versus 4 ± 2.69 dB) (P = .001). There was no correlation between mesopic contrast sensitivity and myopic shift (P = .42) or nonmydriatic refraction (P = .20).

Wavefront Aberrations

The postoperative ocular root-mean-square (RMS) values for higher-order aberrations (HOAs) calculated for a 5.0 mm pupil were similar between the 2 groups; the mean was 0.32 ± 0.08 μm in the Tecnis group and 0.33 ± 0.18 μm in the CeeOn Edge group (P = .96). Further analysis using Zernike polynomial decomposition showed similar 3rd-order aberrations in both groups (Figure 3), with mean total coma $Z_3^{1,-1}$ values of 0.15 ± 0.06 μm in the Tecnis group and 0.11 ± 0.07 μm in the CeeOn Edge group (P = .08) and mean total trefoil $Z_3^{3,-3}$ values of 0.21 ± 0.06 μm and 0.24 ± 0.15 μm, respectively (P = .81). In contrast, 4th-order spherical aberration was significantly lower (close to zero) in the Tecnis group than in the CeeOn Edge group; the mean Z_4^0 value was 0.01 ± 0.06 μm and 0.16 ± 0.12 μm, respectively (P <.001) (Figure 3). Figure 4 shows the aberrometry data calculated for a 5.0 mm pupil of a Tecnis IOL patient with spherical aberration Z_4^0 close to zero and a CeeOn Edge IOL patient with a positive Z_4^0.

In all patients, spherical aberration was significantly correlated with the myopic shift (rho = −0.66; P <.001). There was no correlation between spherical aberration and mesopic contrast sensitivity (P = .21).

Visual Disability

Improvement in the ADVS global score in the Tecnis group was not statistically significant; the mean global score was 95.4 ± 4.9 in the Tecnis group and 88.2 ± 2.9, in the CeeOn Edge group (P = .04). However, evaluation of the ADVS subheadings (Figure 5) showed patients with Tecnis IOLs reported better best corrected distance vision than patients with CeeOn Edge IOLs; the mean was 99.0 ± 2.0 and 89.2 ± 3.4, respectively (P = .001). Furthermore, the distance vision score was negatively correlated with spherical aberration in both groups (R^2 = 0.79; P <.001). Other evaluated visual functions were not statistically different between the groups.

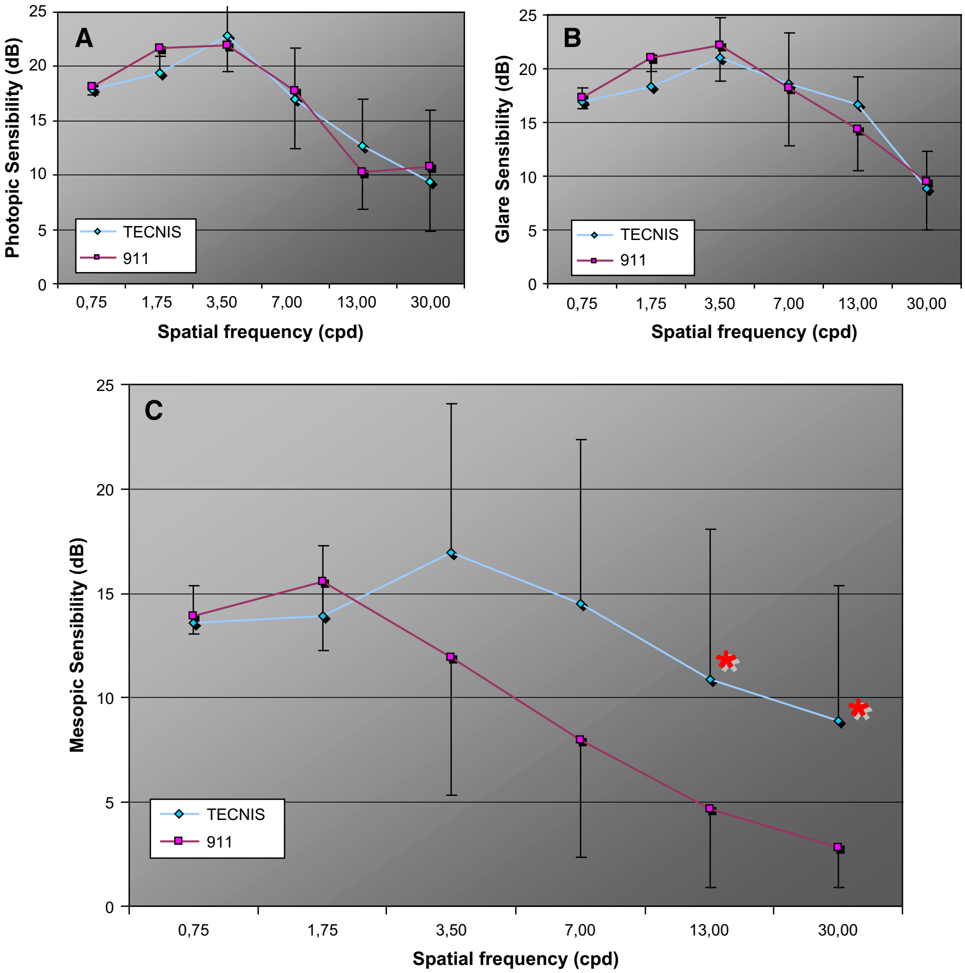

Figure 2. Comparison of contrast sensitivity between the Tecnis group and CeeOn Edge group. *A*: Under photopic conditions. *B*: With glare. *C*: Under mesopic conditions (* = contrast sensitivity in the Tecnis group was significantly enhanced compared with the CeeOn Edge group at high frequencies of 13 cpd and 30 cpd; $P = .001$). Data are expressed as mean ± SD.

DISCUSSION

Advances in wavefront technology have opened a new door to the measurement of ocular aberrations[1–4,16–18] and allowed the development of a new type of IOL designed to compensate for the positive spherical aberration of the cornea, which is one of the most important aberrations contributing to visual deterioration of the pseudophakic eye.[15,16] In this study, we compared the performance of such an IOL, the aspherical Tecnis Z9000, with that of its conventional counterpart, the spherical CeeOn Edge IOL. We first addressed whether the potential benefit of the Tecnis IOL in terms of optical quality and contrast sensitivity could be attributed to its specific design or other factors. Previous investigators used a control IOL that differed from the Tecnis IOL in design, dimension, and/or material. In contrast, we used the CeeOn Edge 911 IOL, which is identical to the Tecnis IOL except it has a spherical surface. To minimize confounding factors, our study included patients who shared several features including age, preoperative refraction, and IOL power and who did not have general or ocular abnormalities other than cataract. Multifocal electroretinogram evaluation ensured perfect macular function.

Six months postoperatively, we measured a significant reduction in myopic shift and higher-order spherical aberration Z_4^0 as well as significantly better mesopic contrast sensitivity at high spatial frequencies in patients with the Tecnis IOL. Spherical aberration was also correlated with myopic shift in both groups.

There is accumulating evidence that supports the functional vision benefits of the Tecnis IOL over spherical IOLs. Enhancement of contrast sensitivity under mesopic conditions in patients with the Tecnis IOL has been reported by Kershner,[24] Packer et al.,[25] Mester et al.,[26] and Ricci et al.[27] In contrast, Martinez et al.[28] did not find statistical improvement in contrast sensitivity in eyes with the Tecnis IOL compared with eyes with a spherical IOL. In this context, it is worth pointing out that contrast sensitivity assessment using contrast sensitivity patch charts is insensitive because of a ceiling effect.[29,30] This effect corresponds to

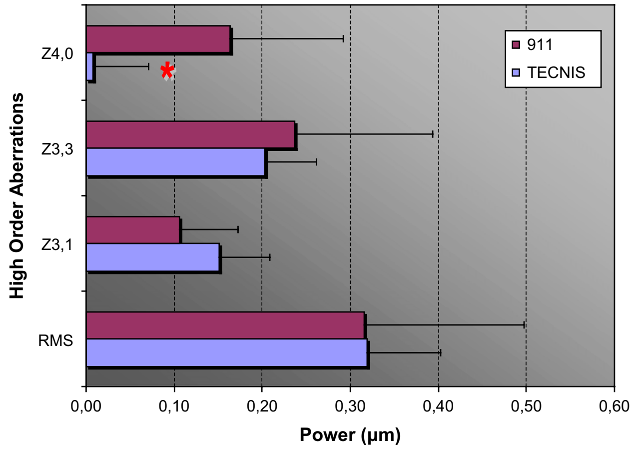

Figure 3. High RMS and HOAs (spherical Z_4^0, trefoil Z_3^3, coma Z_3^1) (* = spherical aberrations significantly lower and close to zero in the Tecnis group than in CeeOn Edge group; $P<.001$).

the portion of patients who can see the minimum intensity target, and this makes comparisons irrelevant. The progressive system of contrast sensitivity assessment we used did not lead to such an effect.

Objective measurement of optical quality with wavefront sensors has shown a significant reduction in spherical aberrations in patients with the Tecnis IOL compared with patients with conventional IOLs.[26,31,32] Our study strengthens these findings and, in particular, corroborates the results of Bellucci et al's[32] initial investigation. In their preliminary study, spherical aberration was significantly reduced with the Tecnis IOL, with values close to zero, while coma and trefoil aberration values were not significantly different between the IOLs studied. We found a significant reduction in spherical aberration in the Tecnis group that was associated with better mesopic contrast sensitivity, although neither outcome was statistically correlated. This finding is in line with those in previous studies reporting visual benefits of the Tecnis IOL.

Furthermore, in Bellucci et al.'s initial study, the myopic refractive shift with mydriasis that occurred with the Tecnis IOL was significantly lower than the shift with the CeeOn Edge IOL and other IOLs. In our study, a myopic refractive shift with mydriasis as low as -0.02 ± 0.36 D was also observed with the Tecnis IOL, compared with -0.51 ± 0.37 D with the CeeOn Edge IOL ($P = .001$). The difference in myopic shift between groups, however, was greater than expected in proportion to the respective Z_4^0 values. This could be explained by the conditions of measurements, in which the myopic shift was evaluated after pharmacologically induced mydriasis and aberrometry was performed under mesopic conditions but without dilation. In fact, our primary goal was to evaluate the functional vision in patients with bilateral prolate aspherical IOLs in

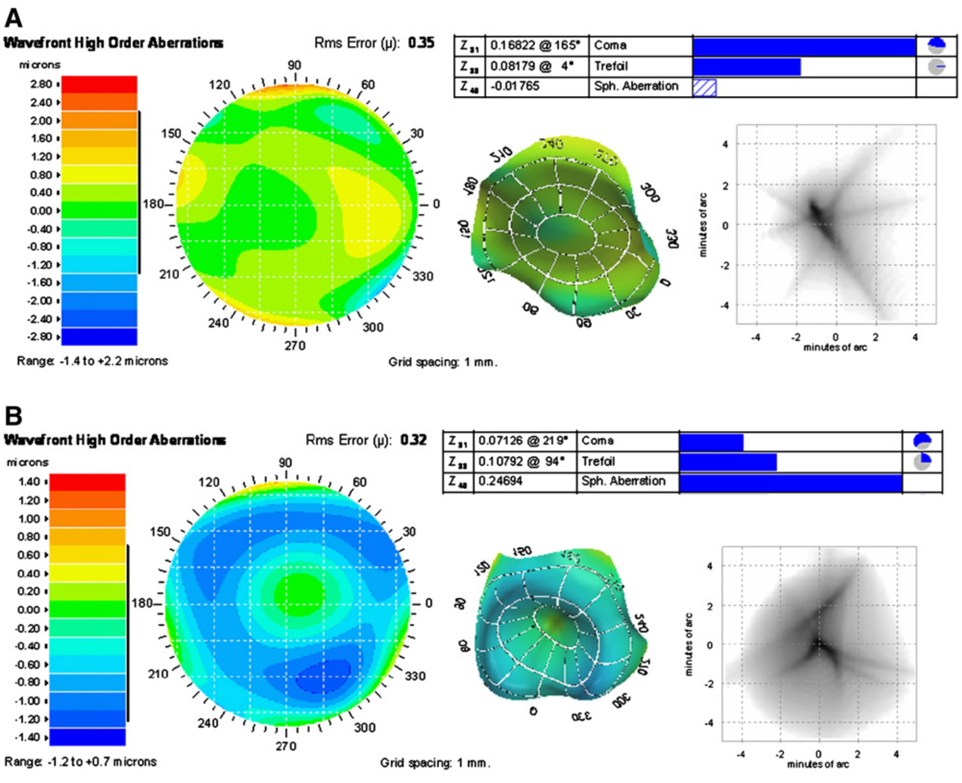

Figure 4. Example of wavefront data (aberrometry) for 2 patients, 1 with a Tecnis IOL (*A*) and 1 with a CeeOn Edge IOL (*B*). Spherical aberration (Z_4^0) is close to zero (−0.018 μm) in the Tecnis patient, while the CeeOn Edge patient has a positive Z_4^0 (+0.247 μm).

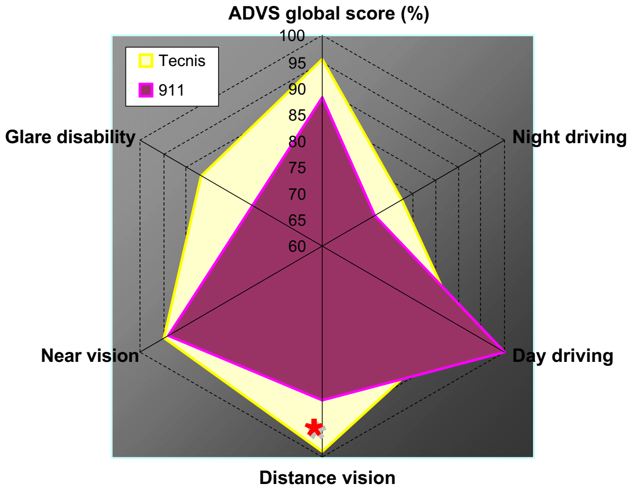

Figure 5. Comparison of ADVS global score and ADVS subheadings between groups (* = significant improvement in corrected distance vision in Tecnis group compared with CeeOn Edge group; $P = .001$).

physiological situations, leading us to perform both aberrometry and contrast sensitivity without pharmacological mydriasis, unlike in the previously mentioned studies.

To our knowledge, no published study has used a questionnaire on quality of vision to assess subjective binocular visual results in patients with Tecnis IOLs. Thus, we performed an interindividual prospective study with bilateral implantation of the same IOL in each group. This enabled us to evaluate patient-centered visual perceptions of pseudophakic patients and compare the outcomes between aspherical and conventional IOLs. There was a trend toward a higher ADVS global score in patients with Tecnis IOLs than in patients with CeeOn Edge IOLs, but with low adjusted statistical significance ($P = .04$). However, by assessing questionnaire subheadings, we found patients with Tecnis IOLs reported better corrected distance vision than patients with CeeOn Edge IOLs ($P = .001$). Every patient completed the questionnaire 6 months after cataract surgery wearing best corrected spectacles to minimize the influence of postoperative variations in refraction, even if not significantly different. The better subjective distance vision indicates that the Tecnis IOL's objective optical performance is associated with a real subjective improvement in daily vision in patients who have cataract surgery. However, the ADVS questionnaire evaluates only visual abilities required to do some everyday life tasks; it does not directly evaluate visual comfort or quality of life.[33] Further clinical studies should be performed to assess these aspects.

Several recent studies confirm that conventional spherical IOLs produce optical aberrations that cause optical blur and visual complaints. In contrast, the development of prolate aspherical IOLs has been a major step toward the reduction of these aberrations, resulting in improved visual quality in pseudophakic patients. Still, questions remain. What would be the consequences of decentered or tilted aspherical IOLs on the quality of visual function?[34] Bench measurements of the Tecnis IOL indicate that if decentration is 0.5 mm and tilt is less than 7 degrees, the optical performance of the IOL would exceed that of a conventional spherical lens.[15] An early study by Mester et al.[26] did not find noticeable tilt in 74 eyes with a Tecnis IOL and found only 1 case of decentration between 0.5 mm and 1.0 mm. We did not observe modified mean optical aberrations such as 3rd-order coma. The optical depth of field between the Tecnis IOL and spherical IOLs has not been compared in vivo. However, Holladay et al.[15] suggest that theoretically, the Tecnis IOL does not influence depth of field. Piers et al.[35] showed that with spherical aberration correction using adaptive optics, the range of functional vision is not decreased and the average visual performance is as good as or better than when spherical aberration is corrected for as much as 1.00 D of defocus. In our study, the absence of difference in quality of near vision between the Tecnis group and CeeOn Edge group could reinforce the theoretical results in these 2 studies; however, further studies are needed to evaluate the effects of reduced spherical aberration on the depth of field.

In conclusion, our data showed improved optical quality and contrast sensitivity with the Tecnis IOL compared with its spherical counterpart. Moreover, these objective performances were associated with better patient-centered visual outcomes, particularly quality of distance vision, leading to better visual comfort in everyday life for patients with bilateral Tecnis IOLs. These objective and subjective benefits could be attributed to the IOL's specific design and reinforce the relevance of aspherical IOLs in everyday visual perception of pseudophakic patients.

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