CLINICAL AND EXPERIMENTAL OPTOMETRY
https://doi.org/10.1080/08164622.2021.2009737

RESEARCH

Comparison of visual performance between two aspheric monofocal intraocular lens models

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ABSTRACT

Clinical relevance: It is important to distinguish between visual acuity, optical quality and quality of vision when outcomes obtained with intraocular lenses are evaluated. These parameters, that include objective and subjective tests, should be assessed to obtain results that is not biased.

Background: To assess the difference in visual and optical quality between two monofocal intraocular lens models.

Methods: : This was a prospective, parallel and randomised clinical study conducted at Miranza IOA, a private clinic in Madrid, Spain. Sixty patients were implanted bilaterally, 30 per group, with two aspheric IOLs with induced spherical aberration of −0.27 µm for Group A and −0.20 µm for Group B. Visual outcomes obtained at 1 and 3 months after surgery included both uncorrected (UCVA) and corrected monocular distance visual acuity (DCVA), objective scattering index (OSI), modulation transfer function (MTF) cut-off, Strehl Ratio (SR), contrast sensitivity defocus curve (CSDC), intraocular lens spherical aberration (SA), and longitudinal chromatic aberration of the eye. Activity limitations in daily life was assessed using CatQuest-9SF questionnaire.

Results: There were statistically significant differences for DCVA (004 LogMAR; p = .008) and SR (0.03; p = .003) between groups. Outcomes related to CSDC showed statistically significant differences for vergences between −0.50 D and +1.00 D (3 mm pupil) and for vergences of 0.00 D and +0.50 D (4.5 mm pupil) between groups. Overall, Group A showed better results regarding visual and optical quality, including a lower longitudinal chromatic aberration result in comparison to Group B. Patient satisfaction evaluated with CatQuest-9SF showed that Group A achieved better outcomes, although the differences were statistically significant only for the 'Reading text on television' item (p = 0.027).

Conclusions: Both intraocular lens models showed excellent quantity of vision, optical and visual quality as well as high patient satisfaction. Despite this, the the Group A model provided slightly better outcomes than the Group B model.

ARTICLE HISTORY
Received 1 September 2021
Revised 12 October 2021
Accepted 18 November 2021

KEYWORDS
Monofocal intraocular lens; optical quality; quantity of vision; visual quality

Introduction

Cataract surgery with standard monofocal intraocular lens (IOL) implantation allows myopic or hyperopic patients to achieve emmetropia. According to the European Registry of Quality Outcomes for Cataract and Refractive Surgery (EUREQUO), monofocal IOLs were still used in more than 95 per cent of cases in 2017.[1]

This surgery is being performed at an increasingly younger age since the general population[2,3] has become much more demanding and has higher expectations in terms of visual quality; in fact, the procedure becomes in many cases a refractive surgery in which the patient also tries to have optimum optical quality that will provide them with good visual quality, especially in distant vision and, hence, the best quality of life possible.[4,5]

Quantity of vision and quality of vision are concepts that are often correlated in most people; however, in certain situations – such as in the presence of severe corneal dystrophies, glaucoma, after refractive surgery or intraocular lens implantation – such correlation level may be notably weaker.

The level of success (or failure) of a refractive procedure is usually based on criteria such as the safety index, the efficacy index, stability and predictability. All these metrics are based on pre-vs.-post-operative visual acuity values obtained with high contrast visual charts and hence, they describe solely the patient's quantity of vision.[6,7] In fact, some patients of the authors, despite having achieved a visual acuity of 6/6, still complain of poor visual quality. They report that under certain conditions – specially low lighting – their vision lacks contrast, they perceive a ridge around objects, they see halos, or have other symptoms. Therefore, in the context of modern cataract surgery, our goal should not be limited to achieving 6/6.[8]

To evaluate advance IOL designs such as trifocal and extended depth of focus IOL (EDOF), clinical and in-vitro outcomes with monofocal IOLs are used as reference to compare with. At such the American Academy of Ophthalmology task force requirement for EDOF IOLs defines the need to provide a monocular depth of focus at least 0.50 D wider than the one given by a monofocal control group IOL at 0.2 logMAR.[9]

In this context, the goal of the present study was to assess the differences between two monofocal IOL models (TECNIS® ZCB00 and Clareon® CNA0T0), in terms not only of visual acuity, but also of optical and visual quality.

Methods

This was a parallel, prospective, and randomised study that included – according to the sample calculation – a total of 60 patients; i.e., 30 patients per IOL group: Group A was implanted with TECNIS® ZCB00 lens the and Group B was

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implanted with Clareon® CNA0T0 IOL. Patients were assigned to Group A or B according to a randomisation table created prior to recruitment.

All patients enrolled in the study underwent bilateral symmetric IOL implantation, but only right eyes were measured for monocular variables.[10]

The study adhered to the tenets of the Declaration of Helsinki and was approved by the local Ethics Committee (Madrid's Clinico San Carlos University Hospital, CI 19/179-O_P). The patients signed the informed consent before being enrolled in the study.

The inclusion criteria established for the study were: Age over 50, potential visual acuity better than 0.2 LogMAR; corneal astigmatism below 1.50 D (for 'with-the-rule' astigmatism) and below 1.00 D (for oblique or 'against-the-rule' astigmatism); no history of eye surgery or eye trauma; no abnormalities that could compromise the surgical procedure, such as pseudoexfoliation syndrome; and no comorbidities that could affect the final outcome of the procedure.

All patients underwent a full ophthalmologic examination both pre- and post-operatively. Preoperative examinations included manifest refraction and monocular distance visual acuity, corneal topography, pupillometry, slit-lamp biomicroscopy, tonometry and funduscopy and macular OCT. The power of the IOL was calculated by applying Barrett Universal II formula; the data for the eyes were collected using optical interferometry (IOL Master 700; Carl Zeiss Meditec., Jena, Germany). The constant for Barrett Formula was 2.04 for TECNIS® ZCB00 and 1.94 for Clareon® CNA0T0.

The surgical procedure was similar for both lenses. All surgeries were carried out by the same surgeon (FP) under topical anaesthesia. Anterior capsulotomy and nuclear fragmentation were performed with a femtosecond laser (CATALYS Precision System, Johnson & Johnson, Santa Ana, CA). A 2.2 mm temporal corneal incision and a paracentesis were made with a surgical knife, and for lens phacoemulsification a commercial microsurgical system (Centurion Vision System; Alcon Laboratories, Inc., Fort Worth, TX) was employed. The chosen IOL was then implanted into the capsular bag with a single-use injection system. All surgeries were supported by the computer-assisted cataract surgery system (CALLISTO Eye from Zeiss' Cataract Suite Markerless; Carl Zeiss, Jena, Germany).

Post-operative follow-up visits were scheduled at 24 h, 1 week, 1 month and 3 months after the procedure, according to the clinical protocol, although – for the sake of clarity and brevity – the data shown in the present paper are the ones collected at the 1-month or 3-month follow-up visits. The follow-up eye examinations included visual acuity (VA) at 4 metres assessed with the Clinical Trial Suite (M&S Technologies, Niles, IL, USA), objective index scattering (OSI), modulation transfer function (MTF) cut-off and Strehl's Ratio (SR) measured with OQAS-HD Analyser (Optical Quality Analyser System, Visiometrics, Spain), contrast sensitivity defocus curve (CSDC), measuring the spherical aberration (SA) of the IOL, and the longitudinal chromatic aberration (LCA) of the eye. Moreover, the patient was administered the CatQuest-9SF questionnaire. The values of OSI, MTF-cut off, SR and CSDC were measured at 1-month follow-up visit and the VA, SA, LCA and questionnaire at 3-month follow-up visit.

Pupils, under photopic and mesopic conditions, were measured with OPD III Scan (Nidek Technologies, Gamagori, Japan)

The Clinical Trial Suite is a software that consists of a variety of visual acuity and contrast sensitivity testing algorithms that seamlessly step the user through the eye charts presented and directly respond to user input regarding correct/incorrect results. The OQAS-HD Analyser is a double-pass system that provides objective measurements of the image formed onto the retina, by combining the quantification of optical aberrations and forward plus backward light scattering caused by loss of ocular transparency.

All tests were done monocularly – more specifically, only the right eye of the patient was assessed – except for the questionnaire, where the answers had to be based on the binocular status of the patient.

The OSI, MTF cut-off frecuency and SR measurements were conducted with ~~an~~ undilated pupil. The OSI is defined as the ratio of the light of peripherally annular area versus that of the central peak, quantifies intraocular scattering. The MTF cut off provided by OQAS is the cut off frequency (cycle per degree, cpd) at 1% of maximum MTF. The Strehl ratio is the ratio of the area under the MTF curve between the measured eye and the ideal eye.[11] Pupil diameter was set at 4 mm with the OQAS. Astigmatism was corrected by placing the appropriate cylindrical lens in front of the eye. Since tear film quality may affect light scattering, all the measurements were taken immediately after an eye blink, under dim conditions.

The contrast sensitivity defocus curve was generated with the Multifocal Lens Analyser (MLA).[12,13] This is a professional APP for measuring the Visual Acuity Defocus Curve and Contrast Sensitivity Defocus Curve in multifocal procedures. It was devised to measure VA using a crowded Snellen E that changes its size in 0.1 logMAR steps; the threshold is then determined through a staircase procedure. Furthermore, low contrast visual acuity (LCVA) can be measured with the same optotype and following a similar procedure, but in this case the optotype size is kept constant while its contrast changes in 0.1 log-unit steps.[12] In this case, the optotype size will correspond to a visual acuity of 0.3 logMAR,[14] changing its contrast along the range from 0 to 1.9 logarithmic units of CS (logCS) in 0.1 logCS steps.

Once the pupil has been dilated with mydriatic drops, calibrated aperture diaphragms mounted in a trial frame with 10 mm distance from the vertex were used as the entrance pupil (EP) to guarantee that the contrast sensitivity defocus curves are generated with a constant pupil size in all patients. Two contrast sensitivity defocus curves were measured with pupils of 3.0 mm and 4.5 mm respectively.

Spherical aberration of the IOL was determined using a Nidek OPD-Scan III retinoscopic aberrometer. This device is able to measure corneal and total eye aberrations separately, and to compute internal-optics aberrations from them. The following optical-zone diameters, or equivalently, EP sizes, were used for aberration measurement: 3 mm, 4 mm, 4.5 mm, 5.0 mm, and 6.0 mm.

The system used by Millán et al.[15] was used for longitudinal chromatic aberration (LCA) measurements. This system relies on the Scheiner disc, with double pinhole, and the sequential illumination with two monochromatic light sources whose wavelengths are 455 nm and 625 nm.

Finally, the *CatQuest-9SF* questionnaire consists of 9 questions, where two of the items correspond to the measurement of visual disability, and 7 focus on several activities. This was assessed at the 3-month visit.

Table 1. Preoperative demographic data.

	TECNIS® ZCB00	CLAREON® CNA0T0	*p*-value
Gender (male/female; %)	37.1/ 62.9	34.1/ 65.9	
Age (mean ± SD)	70.62 ± 8.11 (range: 56 to 84)	72.90 ± 6.67 (range: 62 to 85)	0.188
Spherical equivalent (D)	−0.75 ± 3.09 (range: +4.25 to −8.75)	−0.77 ± 2.87 (range: +5.00 to −5.75)	0.501
CDVA (LogMAR)	0.20 ± 0.19 (range: 0.00 to 1.00)	0.18 ± 0.11 (range: 0.00 to 0.42)	0.658
Pupil diameter, photopic (mm)	3.04 ± 0.52 (range: 2.23 to 4.29)	3.23 ± 0.55 (range: 2.28 to 4.73)	0.324
Pupil diameter, mesopic (mm)	4.11 ± 0.68 (range: 2.71 to 5.37)	4.64 ± 0.73 (range: 3.46 to 6.18)	0.084
AXL (mm)	23.77 ± 1.42 (range: 21.58 to 26.65)	23.35 ± 0.92 (range: 21.77 to 25.54)	0.124
ACD (mm)	3.10 ± 0.31 (range: 2.59 to 3.72)	2.94 ± 0.34 (range: 2.28 to 3.58)	**0.040**
Kmax (D)	44.48 ± 1.60 (range: 41.26 to 49.05)	44.32 ± 1.18 (range: 42.16 to 46.43)	0.619
IOL power (D)	20.72 ± 4.16 (range: 14.00 to 27.50)	21.38 ± 2.86 (range: 15.00 to 26.50)	0.423

AXL, axial length; ACD; anterior chamber depth; Kmax, maximum corneal curvature. P-values in bold indicated statistically significant differences.

Intraocular lenses

The two IOL models under evaluation were the TECNIS® ZCB00 (Johnson & Johnson, Ireland) and the Clareon® CNA0T0 (Alcon Laboratories, Inc., Fort Worth, TX, USA).

The TECNIS® monofocal 1-piece IOL (ZCB00) is a biconvex lens with an anterior aspheric surface. It is made of acrylic hydrophobic material and has an UV-blocking filter. It was designed to provide a negative SA of −0.27 µm for a 6 mm eye EP (that corresponds to 5.3 mm at the IOL plane).[16] The lens has frosted continuous 360° posterior square edge. Its Abbe number is 55 and it has a refractive index of 1.47.

The Clareon® IOL is an automated, disposable, preloaded IOL delivery system. The lens is fabricated from a new hydrophobic acrylic material designed to reduce glistening and surface haze. The lens has a posterior aspheric surface with a thinner central area (according to the specifications provided by the manufacturer), and it is designed to produce −0.20 µm of SA for a 6.0 mm EP. It has a refractive index of 1.55 and its Abbe number is 37.

Statistical Analysis Data analysis was performed using IBM SPSS Statistics version 25.

The sample size was calculated based on the results published by Bellucci et al.,[17] relating to visual acuity, to recognise statistically significant differences with a standard deviation assumed to be 0.08, accepting an alpha risk of 0.05 and a beta risk of 0.2.

For all quantitative variables, synthesis tables containing mean, standard deviation, maximum and minimum were measured. The normality of all data samples was evaluated using the Shapiro-Wilk test. The Student t test for unpaired data or Mann-Whitney test was used for comparisons between the 2 IOL groups. P-value less than 0.05 was considered statistically significant.

Results

Table 1 summarises mean preoperative demographic and anatomical data. There were no statistically significant differences between the two patient groups (those implanted with the TECNIS® ZCB00 IOL and those with the Clareon® CNA0T0 IOL) for any of the parameters, except for anterior chamber depth (ACD), whose $p = 0.040$. No significant intra-op or post-op complications were noted in either arm.

Table 2 summarises mean postoperative values (collected at the 1- or 3-month follow-up visit). The side-by-side comparison of visual-acuity outcomes yielded statistically significant difference in quantity of vision between the two groups (DCVA, $p = 0.008$); more specifically, the TECNIS® achieved better outcomes.

As for the optical-quality metrics measured with OQAS, statistically significant differences were also observed for OSI and SR (p = 0.050 and p = 0.003, respectively), with the TECNIS® group achieving better results. In addition, statistically significant lower LCA (and thus, a better outcome) was obtained in the TECNI®S group of patients.

Figure 1 shows the contrast sensitivity curves for both IOLs for a 3.0 mm (Figure 1A) and a 4.5 mm pupil (Figure 1B), respectively. In the TECNIS® group, the CS curves obtained with both pupils were quite similar with maximum CS of 1.0. In contrast, in the Clareon® group, there was a reduction of the maximum value of CS when pupil widens. For both pupil sizes in the −0.50 D to +1.00 D vergence range, those patients implanted with the TECNIS® IOL obtained better outcomes, the differences being statistically significant for vergences between −0.50 D and +1.00 D (3 mm pupil) and for vergences of 0.00 D and +0.50 D (4.5 mm pupil).

The level of spherical aberration (SA) induced by the IOL in the implanted eye with a 5.0 mm EP amounts to −0.244 µm and −0.145 µm for the TECNIS® and Clareon® models

Table 2. Postoperative outcomes for the two IOLs under assessment.

	TECNIS® ZCB00	CLAREON® CNA0T0	*p*-value
UCVA (LogMAR)	0.13 ± 0.23 (range: −0.06 to 1.0)	0.11 ± 0.14 (range: −0.08 to 0.66)	0.680
DCVA (LogMAR)	0.01 ± 0.04 (range: −0.10 to 0.15)	0.05 ± 0.09 (range: −0.08 to 0.40)	**0.008**
OSI	1.49 ± 1.27 (range: 0.10 to 6.00)	2.07 ± 1.39 (range: 0.40 to 5.4)	0.050
MTF cut-off (cycles/ degree)	29.33 ± 10.53 (range: 9.20 to 49.92)	25.55 ± 10.03 (range: 9.65 to 45.85)	0.118
SR	0.16 ± 0.04 (range: 0.08 to 0.26)	0.13 ± 0.04 (range: 0.08 to 0.22)	**0.003**
LCA (D)	0.83 ± 0.33 (range: 0.40 to 1.64)	1.23 ± 0.49 (range: 0.46 to 2.25)	0.050

UCVA, ~~ncorrected~~ distance visual acuity; DCVA, distance-corrected visual acuity; OSI, objective scattering index; MTF, modulation transfer function; SR, Strehl's ratio; LCA, longitudinal chromatic aberration. P-values in bold indicated statistically significant differences.

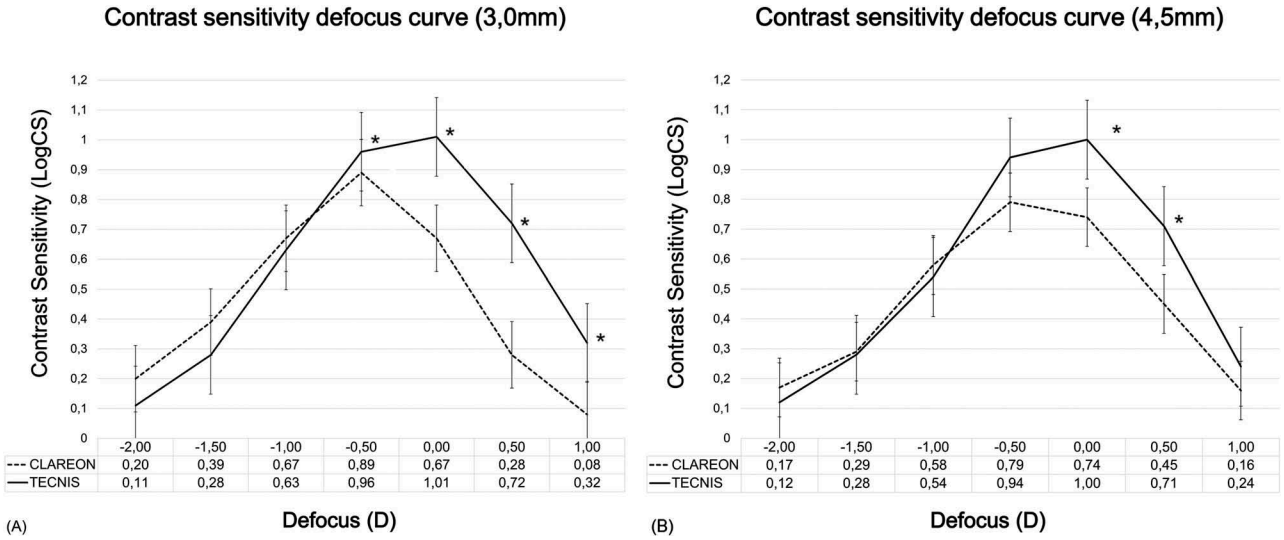

Figure 1. Contrast sensitivity curve (LogCS units) as a function of defocus (−2.00 D to +1.00D) obtained with A: 3.0 mm pupil and B: 4.5 mm pupil. The continuous line represents mean values for the TECNIS® IOL group while the dashed line corresponds to the Clareon® IOL group. The curve was generated by means of the automated MLA software. *statistically significant vergences.

respectively (See Table 3 and Figure 2). Statistically significant differences between the two IOL models emerged from the SA measurements for 5.0 mm pupil, as shown in the last column of Table 3.

Figure 3 shows the results of each question included in the CatQuest-9SF questionnaire, which was answered 3 months after surgery to patients from the TECNIS® group (black bars) and the Clareon® group (grey bars). As can be inferred from the plot, the TECNIS group achieved better outcomes although the differences were statistically significant only for the 'Reading text on television' item ($p = 0.027$).

Discussion

Quantity of vision, optical quality and visual quality are concepts that often appear to be close or similar: quantity of vision is defined by the visual acuity of the subject; i.e., by the ability of the visual system to provide spatial resolution.[18] It is commonly measured with high contrast tests. On the other hand, optical quality refers to the quality of the retinal image, which is affected by objective factors such as diffraction, ocular aberrations, or intraocular scattering. Visual quality (or quality of vision) is a subjective entity directly linked to the perception of vision of the patient and the way it allows or impedes them to develop certain activities. In addition to the quality of the retinal image, it depends on multiple factors; not only visual ones but also psychological factors. Visual quality is commonly assessed by administering quality-of-life or specific quality-of-vision questionnaires.

After cataract surgery, the three concepts depend on the ocular and neural characteristics of the patient and the optical performance of the implanted IOL. While quantity and quality of vision are commonly assessed *in vivo*, once the IOL has been implanted in the eye, the optical quality of an IOL is usually tested *in vitro*, i.e. on optical-bench. Yet, there are adaptive optics simulators that allow the patient to experience visual correction before surgery.[19]

In respect of quantity of vision, assessed through the VA metric, there were not statistically significant differences in UCDVA, but the TECNIS® IOL yielded better, statistically significant DCVA than the Clareon® IOL. The VA outcomes for the TECNIS® ZCB00 IOL are in line with those reported by other authors.[20–22] On the contrary, the result obtained f here or DCVA in the Clareon® IOL group (0.05 ± 0.09 logMAR) is worse than the one reported by Negishi (−0.09 ± 0.07 logMAR).[23]

Some parameters can assist in correlating patient perception (i.e., visual quality) with the optical quality of the eye: OSI, MTF, SR or LCA. High OSI, large LCA, and low MTF or SR values result in poor visual quality as perceived by the patient.[24] With respect to chromatic aberration, Marcos *et al*,[25] recently assessed LCA with a psychophysical test in a group of 10 patients implanted with the Clareon® IOL model; they reported a mean LCA value of 1.23 ± 0.05 D. These values are totally in line with those from the present study (1.23 ± 0.49 D, Table 2). Similarly, the values obtained with the TECNIS® IOL (0.83 ± 0.33 D, Table 2) are also in good agreement with those published by Millán et al[15] also for the TECNIS: they reported an average value for LCA of 0.69 ± 0.21 D.

Table 3. Comparison of spherical aberration values (in microns) for the two IOLs under assessment, as a function of optical-zone diameter.

	Spherical Aberration		
Optical zone diameter	TECNIS® ZCB00	Clareon® CNA0TO	*p*-value
3.0 mm (corneal plane) 2.6 mm (IOL plane)	−0.019 ± 0,02 (range: −0.07 to 0.06)	−0.015 ± 0,03 (range: −0.06 to 0.10)	0.555
4.0 mm (corneal plane) 3.5 mm (IOL plane)	−0.059 ± 0,06 (range: −0.21 to 0.15)	−0.060 ± 0,02 (range: −0.12 to 0.02)	0.956
4.5 mm (corneal plane) 3.9 mm (IOL plane)	−0.103 ± 0,08 (range: −0.34 to 0.10)	−0.094 ± 0,04 (range: −0.17 to 0.09)	0.671
5.0 mm (corneal plane) 4.4 mm (IOL plane)	−0.244 ± 0, 09 (range: −0.53 to −0.02)	−0.145 ± 0,08 (range: −0.33 to 0.19)	**0.001**

P-values in bold indicated statistically significant differences.

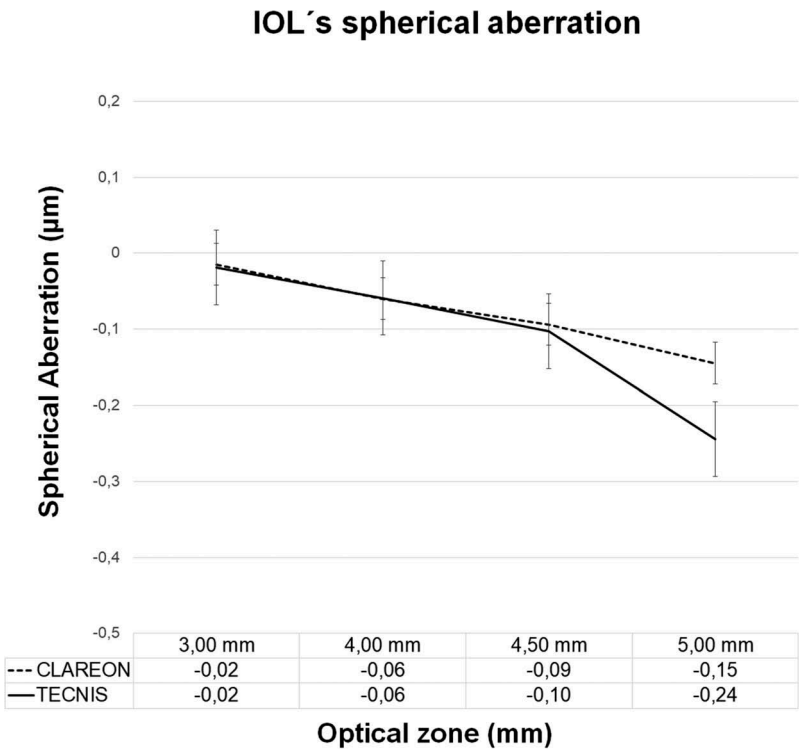

Figure 2. Spherical aberration (µm) (mean ± SD) versus the optical zone (pupil size) for the two IOLs under assessment. Continuous line: TECNIS® group. Dashed line: Clareon® group. *statistically significant pupil condition.

The differences found between the two IOL models in terms of LCA are consistent with the dispersive features of the respective IOL optical materials. The higher the Abbe number of the material, the lower the chromatic dispersion. In monofocal purely refractive IOLs, this feature is directly linked to a lower LCA.[26] In addition, the TECNIS lens provided better outcomes for the three objective parameters of optical quality that were measured with the OQAS device (namely, MTF, OSI, and SR); these differences were just statistically significant for the SR. The present results for the TECNIS IOL group are very similar to those reported by Chen[22] for the same IOL model corresponding to the 6-month follow-up examination. Experimental data obtained with the OQAS device for the Clareon IOL model does not appear to have been published previously; most studies published so far on this lens have focused mainly on the lens material and its properties.

The human cornea is naturally aspheric, usually showing greater curvature in its central region and flattening out as we move towards the periphery (prolate shape). The presence of high levels of spherical aberration usually causes a decrease in retinal image contrast and affects visual quality, particularly under mesopic conditions.[27] On average, corneal spherical aberration is slightly positive (between +0.27 and +0.30 µm for an entrance pupil of 6 mm)[28] and remains stable throughout the lifetime of an individual. Some studies suggest that it might not be necessary to fully correct spherical aberration; in fact, it has been claimed that it is advisable to leave the eye with a slightly positive (+0.10 µm) residual aberration.[29,30]

In respect of the level of SA induced by the implanted IOLs, manufacturers usually report the value of the Zernike $z_{4,0}$ coefficient for a 6.0 mm EP: −0.27 µm and −0.20 µm for the Tecnis® and Clareon® designs, respectively. When pupil size diminishes, these values need to be scaled down accordingly. The iris pupil (IP) plane is usually referred to as the IOL plane since the front surface vertex of the IOL is virtually at the IP plane[16] and thus, the IP size is referred to as the IOL-pupil. In schematic eyes such as, for instance, Gullstrand relaxed nº 1 and Le Grand, it is straightforward to find that the ratio between IOL-pupil to EP is about 0.88. Thus, EPs of 6.0 mm and 5.0 mm would correspond to IOL-pupils of ≈5.3 mm and ≈4.4 mm, respectively.

For the TECNIS model and for a 5.0 mm EP (4.4 mm IOL-pupil), a pseudophakic ocular SA of −0,244 µm is in excellent agreement with values measured in-vitro with the same monofocal ZCB00 IOL model: −0,26 µm (4.5 mm IOL-pupil),[31] and with Tecnis® Symfony EDOF IOL, which shares the same aspheric design: −0,239 µm (4.5 mm IOL-pupil)[32] and −0.20 µm (4.7 mm IOL-pupil).[33]

In the case of the Clareon® model, there have been no previous reports of measures of pseudophakic ocular SA versus pupil size with this IOL. Nevertheless, the value reported here of −0.145 µm (5.0 mm EP) can be compared to that reported by Jun et al.,[34] who found −0.175 µm (5.0 mm EP) after *in-vivo* measurements in patients implanted with the Acrysof IQ SN60WF. The Acrysof IQ SN60WF IOL design induces the same amount of SA (−0.20 µm for 6.0 mm EP) as the Clareon® IOL.

Nevertheless, it is important to highlight the fact that pupil size varies with age, so all results that are affected by the pupil size can change over time. According to Fernández et al,[35] mesopic and photopic pupil size decreases 0.28 and 0.15 mm per decade, respectively. In the present study, the percentage of patients with a pupil less than or equal to 3.5 mm under photopic conditions was 87.5% for Tecnis group and 82.3% for Clareon group. These values are in agreement with those reported by Fernandez et al, in a group of patients aged over 70 years, where they showed a percentage of 97,3%. For mesopic conditions, the pupil size was greater than 5 mm

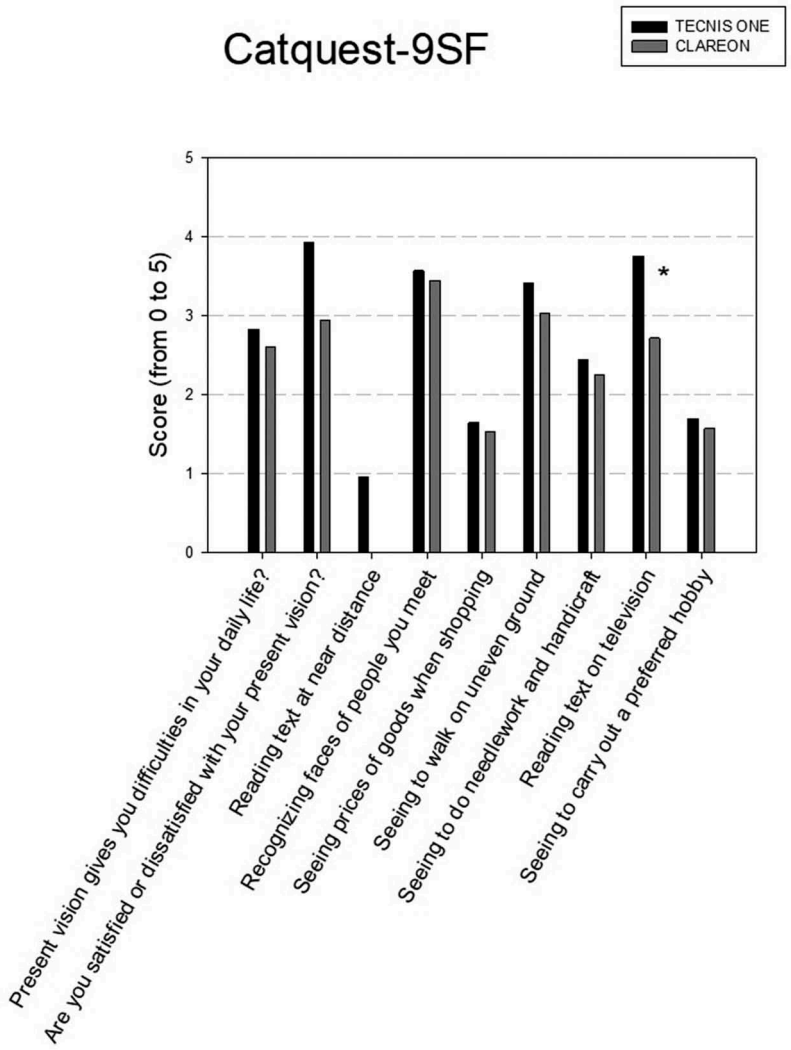

Figure 3. CatQuest-9SF Questionnaire results 3 months after surgery, for the TECNIS® IOL group (black bars) and the CLAREON® IOL group (grey bars). Scores are ordered from bad (0) to excellent (5). *statistically significant difference between the two groups.

for 10.4% in the ZCB00 group and 13.7% for the Clareon group. The patient reported by Fernandez et al with that pupil size was 8.1%. For this reason, as pupil size changes over time, the influence of the results on patients can also change as a result.

Comparing the pseudophakic ocular SA results between the Tecnis® and Clareon® groups, the present results show that, within the central 4.5 mm optical zone, the two lenses lead to undistinguished (with statistical significancy) spherical aberration patterns. This fact indicates that, in terms of the IOL-induced spherical aberration, patients with small pupils would not be affected by the implantation of either Tecnis® ZCB00 or Clareon® CNA0TO IOL. Statistically significant differences between the two IOL models emerged only from the 5.0 mm EP measurements (See Table 3 and Figure 2).

With regard to the contrast sensitivity defocus curves for both pupil sizes, the TECNIS IOL gave rise to the best outcomes, particularly for vergence values close to zero. These differences, in addition to being statistically significant, may also be clinically relevant and provide better optical and visual quality to TECNIS lens wearers.

Patient-perceived (i.e., subjective) visual quality was assessed by through the CatQuest-9SF questionnaire. The scores were higher in the TECNIS IOL group, which means better subjective visual quality, even though the score differences between the two groups were statistically significant only for one questionnaire items – regarding distance-vision visual acuity; i.e., 'reading texts on television'.

The present study has several limitations. The OQAS-HD Analyser was conducted with undilated pupil, so, although the mean mesopic pupil size was larger than 4 mm for both groups, optical quality measurements were performed using a standard pupil diameter of 4 mm. This could act as a confounding factor which explains the lower OSI in the Tecnis group (pupil 4.11 vs 4.64 for the Clareon group under mesopic conditions). On the other hand, pupil diameter was only measured preoperatively and the pupil could be reduced a 10% in the postoperative period where measurements were taken.

Conclusion

According to the outcomes of the present study, patients implanted with either one of the two IOL models under analysis showed excellent optical quality, quantity of vision and visual quality in distance vision, although the TECNI®S ZCB00 model did provide slightly better outcomes, which were statistically significant, compared to the Clareon® CNA0T0 model.

Disclosure statement

Q7 No potential conflict of interest was reported by the author(s).

Funding

This study was partially funded by an unrestricted research grant from Johnson and Johnson Vision.

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