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Visual and Optical Outcomes yielded by two Aspheric Monofocal Intraocular Lens Models

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Keywords:	cataract, contrast sensitivity, visual acuity, presbyopia

Abstract:	Purpose: To assess the difference in visual acuity and optical quality between two monofocal intraocular lens (IOL) models Material and Methods: Prospective, parallel and randomized clinical study. Sixty patients were implanted bilaterally, 30 per group, with IOL TECNIS® ZCB00 or Clareon® CNA0T0. Visual outcomes obtained at 1 and 3 months after surgery included both uncorrected and corrected monocular distance visual acuity (UCVA and DCVA, respectively), objective index scattering (OSI), modulation transfer function cut-off(MTF), Strehl Ratio (SR), contrast sensitivity (CS) defocus curve, IOL's spherical aberration (SA), and eye's longitudinal chromatic aberration (LCA). Patient's satisfaction was assessed using CatQuest-9SF questionnaire at 3 months postoperatively. Results: Regarding all the parameters assessed, there were statistically significant differences for DCVA (p = .008), OSI (p= .050) and SR (p= .003) between groups. Outcomes related to CS defocus curve 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, IOL TECNIS® showed better results regarding visual acuity and optical quality, including a lower LCA result in comparison to Clareon®. Patient's satisfaction evaluated with CatQuest-9SF showed that TECNIS group achieved better outcomes although the differences were statistically significant only for the 'Reading text on television' item (p = 0.027). Conclusion: Both IOL models showed excellent quantity of vision, optical and visual quality as well as high patient's satisfaction after cataract surgery. Despite it, the TECNIS® ZCB00 model did provide slightly better outcomes, yet statistically significant, than the Clareon® CNA0T0

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Short Title

Visual and optical outcomes with aspheric monofocal intraocular lenses models

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Abstract

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Material and Methods: Prospective, parallel and randomized clinical study. Sixty patients were implanted bilaterally, 30 per group, with IOL TECNIS® ZCB00 or Clareon® CNA0T0. Visual outcomes obtained at 1 and 3 months after surgery included both uncorrected and corrected monocular distance visual acuity (UCVA and DCVA, respectively), objective index scattering (OSI), modulation transfer function cut-off(MTF), Strehl Ratio (SR), contrast sensitivity (CS) defocus curve, IOL's spherical aberration (SA), and eye's longitudinal chromatic aberration (LCA). Patient's satisfaction was assessed using CatQuest-9SF questionnaire at 3 months postoperatively.

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Conclusion: Both IOL models showed excellent quantity of vision, optical and visual quality as well as high patient's satisfaction after cataract surgery. Despite it, the TECNIS® ZCB00 model did provide slightly better outcomes, yet statistically significant, than the Clareon® CNA0T0 one.

Keywords

Quantity of vision, optical quality, visual quality, monofocal intraocular lens

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 are still used in more than 95 per cent of cases.(1)

This surgery is being performed at an increasingly younger age since the general population 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.(2, 3)

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.(4, 5) As a matter of fact, some of our patients, despite having achieved a visual acuity of 20/20, 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 20/20.(6)

To evaluate advance IOL designs such as trifocal and 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 0.5 D wider than the one given by a monofocal control group IOL at 0.2 logMAR.(7)

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.

Materials and Methods

This was a parallel, prospective, and randomized study that included—according to the sample calculation—a total of 60 patients; i.e., 30 patients per IOL group (TECNIS and Clareon). All patients enrolled in the study underwent bilateral symmetric IOL implantation.

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). 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 greater 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 procedure's final outcome.

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 IOL's power was calculated by applying Barrett's formula; the eye's data were collected using optical interferometry (IOL Master 700; Carl Zeiss Meditec., Jena, Germany).

All surgeries were carried out under topical anesthesia. Anterior capsulotomy and nuclear fragmentation were performed with a femtosecond laser (CATALYS Precision System, Johnson & Johnson, Santa Ana, CA, USA). A 2.2 mm corneal incision and a paracentesis were made with a surgical knife, while for lens phacoemulsification a commercial microsurgical system (Centurion Vision System; Alcon Laboratories, Inc., Fort Worth, TX, USA) was employed. The IOL— the model that had been randomly assigned to the patient—was then implanted into the capsular bag with a single-use injection system. All surgeries were supported by a computer-assisted cataract surgery system (CALLISTO Eye from Zeiss' Cataract Suite Markerless; Carl Zeiss, Jena, Germany).

Once the procedure was completed, patients were treated with a combination of antibiotics, corticosteroids, and anti-inflammatory eye drops (moxifloxacin, dexamethasone and bromfenac).

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 3-month or 1-month follow-up visits. The follow-up eye examinations included visual acuity (VA) at 4 meters 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 (Optical Quality Analyzer System, Visiometrics, Spain), contrast sensitivity (CS) defocus curve, measuring the IOL's spherical aberration (SA), and the eye's longitudinal chromatic aberration (LCA). Moreover, the patient was administered the CatQuest-9SF questionnaire.

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

The OSI, MTF cut-off frecuency and SR measurements were conducted with the patient's 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 (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. Pupil diameter was set at 4 mm with the OQAS. The patient's 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 MLA software,(8, 9) which 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.(8) In this case, the optotype size will correspond to a visual acuity of 0.3 logMAR,(10) 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 10mm distance from the vertex, are 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 3.0mm and 4.5mm respectively.

As for the IOL's spherical aberration, it was determined using Nidek's OPD-Scan III retinoscopic aberrometer (Nidek Technologies, Gamagori, Japan). 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: 3mm, 4mm, 4.5 mm, 5.0 mm, and 6.0 mm.

For the longitudinal chromatic aberration (LCA) measurements, we used the system described by Millán *et al.*(11). 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 of them focus on several activities.

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 6mm eye EP (that corresponds to 5.3mm at the IOL plane). (12) 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 biomaterial of the lens is a new hydrophobic acrylic one 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 6.0mm EP. It has a refractive index of 1.55 and its Abbe number is 37.

Results

Table 1 summarizes 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.

Table 2 summarizes 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 differences in quantity of vision between the two groups (DCVA, p = 0.008); more specifically, it was the TECNIS® one that 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.

Figures 1 shows the contrast sensitivity curves for both IOLs for a 3.0 mm (Fig. 1A) and a 4.5 mm pupil (Fig. 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.

Table 3 summarizes the statistical differences (*p* values) between the two IOLs in terms of contrast sensitivity, for the two pupil sizes and defocus values. More specifically, 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).

Regarding the level of spherical aberration (SA) induced by the IOL in the implanted eye with a 5.0mm EP, it amounts to -0.244 μm and -0.145 μm for the TECNIS® and Clareon® models respectively (See Table 4 and Figure 2). Statistically significant differences between the two IOL models emerged from the SA measurements for 5.0 mm pupil, as shown in Table 4's last column.

Finally, 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 it 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 subject's visual acuity; i.e., by the visual system's ability to provide spatial resolution.(13) 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. Lastly, visual quality (or quality of vision) is a subjective entity directly linked to the patient's perception of vision 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 patient's ocular and neural characteristics 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 patient's 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.(14)

If we focus on 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. Our VA outcomes for the TECNIS® ZCB00 IOL are in line with those reported by other authors.(15-17) On the contrary, the result we obtained for DCVA in the Clareon® IOL group (0.05 ± 0.09 logMAR) is worse than the one reported by Negishi (-0.09 ±0.07 logMAR).(18)

Some parameters can help us correlate the patient's perception (i.e., visual quality) with the eye's optical quality : 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.(19) Regarding chromatic aberration, Marcos *et al*,(20) 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 our 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* (11) also for the TECNIS: they reported an average value for LCA of 0.69 ± 0.21 D. The differences found between the two IOL models in terms of LCA are consistent with the dispersive features of the respective IOL optical materials. We recall that 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.(21) 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 not only statistically significant but they may also have clinical relevance, especially as far as OSI is concerned. Our results for the TECNIS IOL group are very similar to those reported by Chen (17) for the same IOL model corresponding to the 6-month follow-up examination. We have not found in the literature any experimental data obtained with the OQAS device for the Clareon IOL model, since most of the studies published so far on this lens focus 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.(22) On average, corneal spherical aberration is slightly positive (between +0.27 and +0.30 μm for an entrance pupil of 6mm)(23) and remains stable throughout a person's lifetime. Intraocular lenses having negative spherical aberration mimic a young crystalline lens that balances out the cornea's average positive spherical aberration.(24) Some studies suggest that it might not be necessary to fully correct spherical aberration; in fact, they claim that it is advisable to leave the eye with a slightly positive (+0.10 μm) residual aberration.(25, 26) Given the relatively minor differences between the various aspheric lens models available, deciding which one to choose for a given patient is rather challenging. Nonetheless, many surgeons are relying specifically on the IOL's asphericity value to guide their IOL selection, in an attempt to find the model that best suits the patient's optical system. The choice of the IOL in terms of its SA features is even more significant in patients with previous corneal surgery, where the aberrometric pattern of the patient's cornea may significantly depart from the one corresponding to an average healthy cornea. Regarding the level of SA induced by the implanted IOLs, we highlight that what manufacturers usually report is the value of the Zernike $z_{4,0}$ coefficient for a 6.0mm EP: -0.27 μm and -

0.20 μm for the Tecnis® and Clareon® designs respectively. When pupil size diminishes, these values have to be scaled down accordingly. In addition, to properly compare results of SA among different studies it is important to know what it is the *pupil* they are really referring to. When one looks at the Iris Pupil (IP) -or equivalently the aperture stop of the eye- what is seen is the anterior image of the IP formed by the cornea. This image is the Entrance Pupil (EP) and clinical aberrometers measure the patient's wavefront and calculate the Zernike aberration coefficients at this plane. The IP plane is usually referred to as the IOL plane since the front surface vertex of the IOL is virtually at the IP plane(12) 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 6.0mm and 5.0mm would correspond to IOL-pupils of ≈5.3mm and ≈4.4mm, respectively. We have found for the TECNIS model and for a 5.0 mm EP (4.4mm IOL-pupil), pseudophakic ocular SA of -0,244 μm, which is in excellent agreement with values measured *in-vitro* with the same monofocal ZCB00 IOL model: -0,26 μm (4.5mm IOL-pupil),(27) and with Tecnis® Symfony EDOF IOL, which shares the same aspheric design: -0,239 μm (4.5mm IOL-pupil)(28) and -0.20 μm (4.7mm IOL-pupil).(29)

In the case of the Clareon® model, we have not found in the literature measures of pseudophakic ocular SA versus pupil size with this IOL. Nevertheless, our value of -0,145 μm (5.0mm EP) can be compared to the one reported by Jun et al.,(30) who found -0,175 μm (5.0 mm EP) after *in-vivo* measurements in patients implanted with the Acrysof IQ SN60WF. We recall that the Acrysof IQ SN60WF

IOL design induces the same amount of SA (-0.20 μm for 6.0mm EP) as the Clareon® IOL.

Comparing the pseudophakic ocular SA results between the Tecnis® and Clareon® groups, our results show that, within the central 4.5mm 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 5.0mm EP measurements (See Table 4 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.

Finally, 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'.

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 it has to be said that the TECNI®S ZCB00 model did provide slightly better outcomes, yet statistically significant, than the Clareon® CNA0T0 one.

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Tables

Table 1. Preoperative demographic data, axial length (AXL), anterior chamber depth (ACD), maximum corneal curvature (Kmax) and implanted IOL power. D stands for diopters. The p-value column highlights in boldface those outcomes that yield statistically significant differences.

	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

Table 2. Postoperative outcomes for the two IOLs under assessment, in terms of: Uncorrected distance visual acuity (UCVA), Distance-corrected visual acuity (DCVA), Objective Scattering index (OSI), Modulation transfer function cut-off (MTF cut-off), Strehl's Ratio (SR) and Longitudinal chromatic aberration (LCA). D stands for diopters. The p-value column highlights in boldface those outcomes that yield statistically significant differences.

	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**

Table 3. p-values resulting from comparing contrast sensitivity outcomes with both IOLs (TECNIS® vs. Clareon®) as a function of defocus (from -2.00 D to +1.00 D) and pupil size (3.0 mm and 4.5 mm). The p-value column highlights in boldface those outcomes that yield statistically significant differences.

	3.0 mm pupil (*p*-value)	**4.5 mm pupil (*p*-value)**
-2.00 D	0.326	0.833
-1.50 D	0.394	0.837
-1.00 D	0.493	0.378
-0.50 D	**0.020**	0.125
0.00 D	**0.002**	**0.044**
+0.50 D	**0.001**	**0.033**
+1.00 D	**0.041**	0.093

Table 4. Side-by-side comparison of spherical aberration values (in microns) for the two IOLs under assessment, as a function of optical-zone diameter. The p-value column highlights in boldface those outcomes that yield statistically significant differences.

Optical zone diameter	Spherical Aberration		*p*-value
	TECNIS® ZCB00	**Clareon® CNA0TO**	
3.0 mm (corneal plane) **2.6 mm** (IOL plane)	-0.019 (range: -0.07 to 0.06)	-0.015 (range: -0.06 to 0.10)	0.555
4.0 mm (corneal plane) **3.5 mm** (IOL plane)	-0.059 (range: -0.21 to 0.15)	-0.060 (range: -0.12 to 0.02)	0.056
4.5 mm (corneal plane) **3.9 mm** (IOL plane)	-0.103 (range: -0.34 to 0.10)	-0.094 (range: -0.17 to 0.09)	0.671
5.0 mm (corneal plane) **4.4 mm** (IOL plane)	-0.244 (range: -0.53 to -0.02)	-0.145 (range: -0.33 to 0.19)	**0.001**

Figures

Figure 1. Contrast sensitivity curve (LogCS units) as a function of defocus (-2.00 D to +1.00 D) 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. The asterisks (*) indicate those vergences for which statistically significant differences were found.

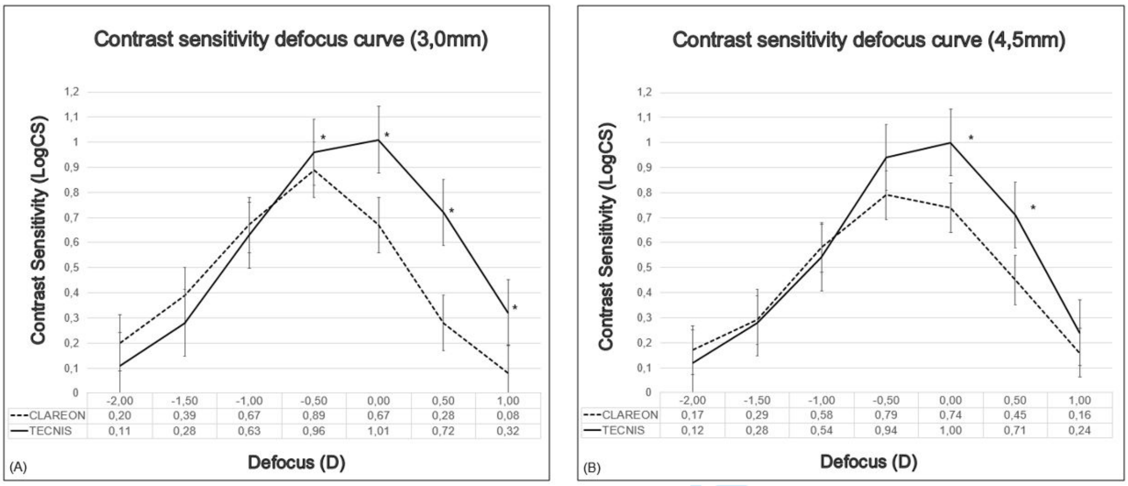


Figure 2. Spherical aberration (μm) (mean±SD) versus the optical zone (pupil size) for the two IOLs under assessment. Continuous line: TECNIS® group. Dashed line: Clareon® group. The asterisk (*) indicates the pupil condition for which statistically significant difference was found.

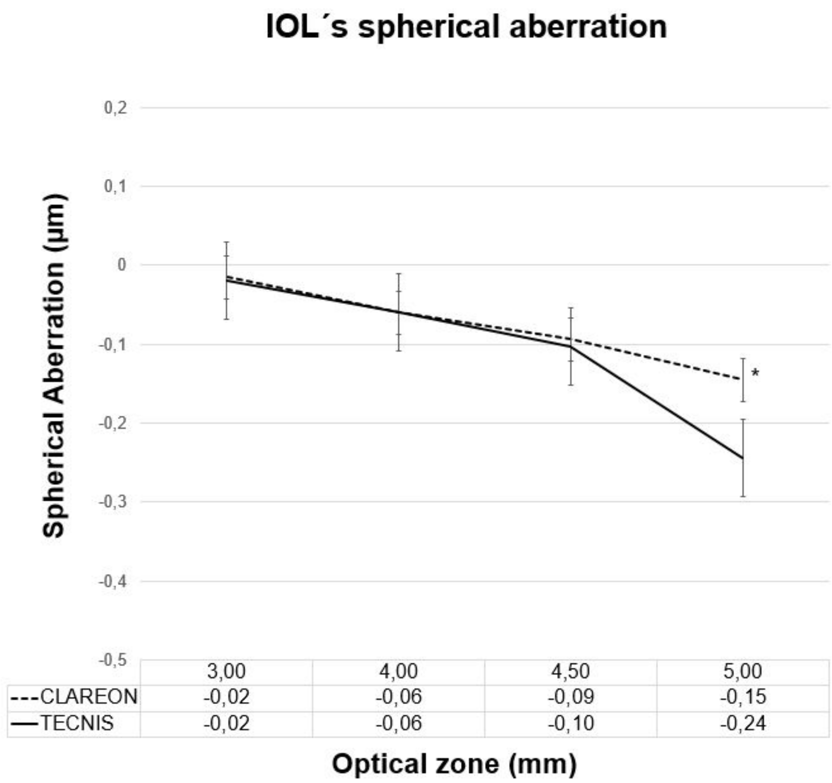
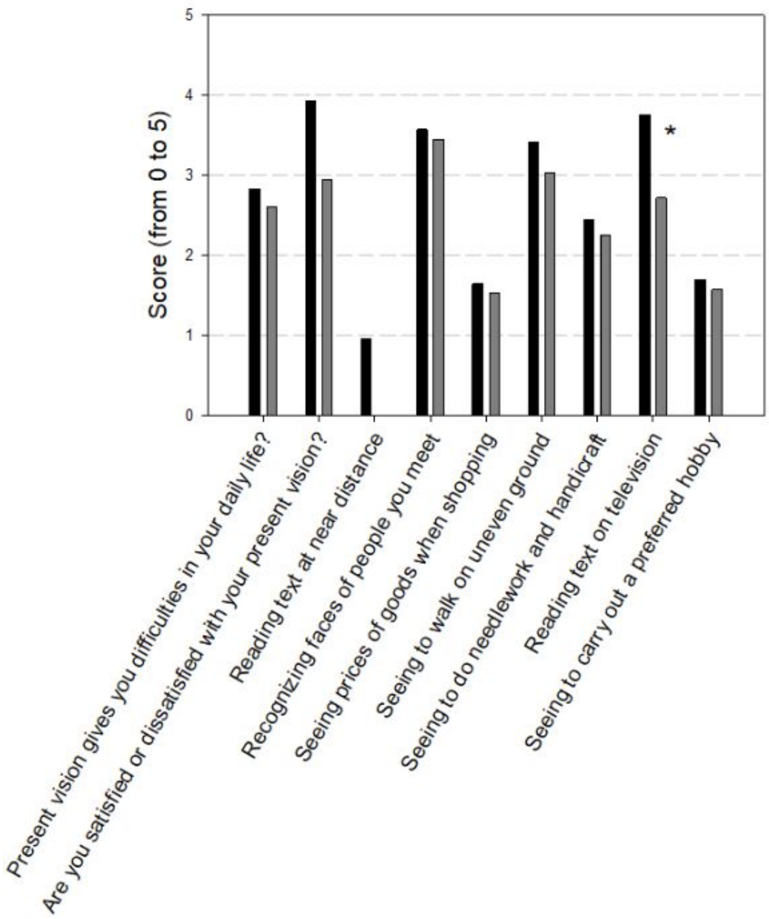


Figure 3. CatQuest-9SF Questionnaire results 3 months after surgery, for the TECNIS® IOL group (black bars) and the CLAREON® IOL group (gray bars). Scores are ordered from bad (0) to excellent (5). The asterisk indicates statistically significant difference between the two groups.



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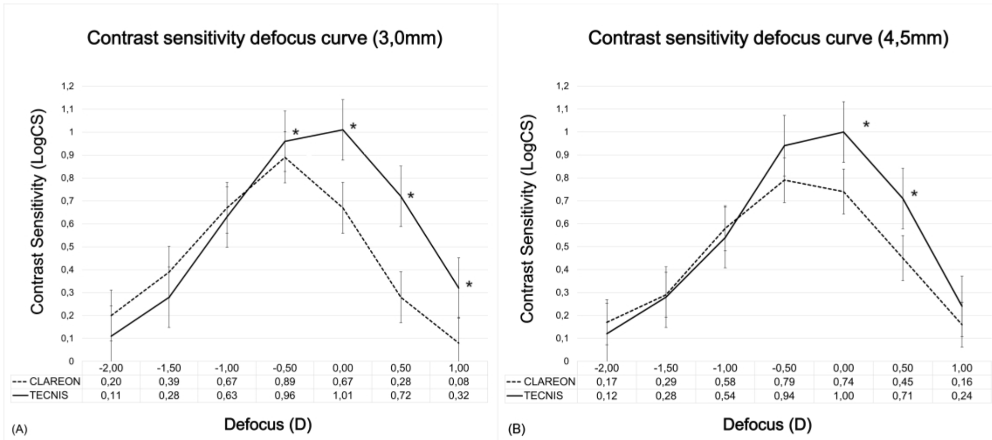

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