

Impact of trifocal and trifocal toric intraocular lenses on spectral-domain OCT retinal measurements

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Acknowledgements and Disclosure: The authors have no proprietary interest in any of the materials mentioned in this article.

Précis: monofocal, trifocal and trifocal toric intraocular lenses induce similar changes on overall retinal OCT measurements.

ABSTRACT

Purpose: To assess whether trifocal and trifocal toric intraocular lenses (IOL) affect the measurement of retinal parameters using spectral-domain optical coherence tomography (OCT).

Methods: This cross-over study included patients undergoing implantation of a trifocal IOL: AcrySof® IQ PanOptix™, a trifocal toric IOL: AcrySof® IQ PanOptix™ Toric, and a monofocal IOL: AcrySof® IQ. The monofocal group was considered as the control group. The refractive target was emmetropia in all cases. Mean average macular thickness, macular volume and retinal fiber nerve layer (RFNL) thickness were measured with the Cirrus HD-OCT®. All measurements were performed before and three months after the surgery.

Results: The study analyzed 150 eyes of 150 patients (50 for each IOL group). Macular thickness and macular volume showed statistically significant differences before and after the surgery for the three groups ($p < 0.05$ in all cases). RFNL thickness was found to be similar before and after the surgery in all groups ($p > 0.05$ in all cases). Mean difference values (before and after the surgery) in the monocular, trifocal and trifocal toric group for macular thickness, macular volume and RFNL thickness were: 4.9 ± 7.8 , 7.9 ± 10.0 and $7.7 \pm 13.7 \mu\text{m}$, respectively; 0.1 ± 0.2 , 0.2 ± 0.4 and $0.2 \pm 0.3 \text{mm}^3$, respectively; and 0.8 ± 5.5 , 1.3 ± 6.0 and $0.8 \pm 6.7 \mu\text{m}$, respectively. Mean differences were found to be similar for the three groups.

Conclusion: The trifocal and the trifocal toric IOLs under study did not induce an additional impact on spectral-domain OCT retinal measurements compared to monofocal IOLs.

Key words: trifocal, trifocal toric, intraocular lenses, cataract surgery, Optical Coherence Tomography

Disclosure: The authors declare no conflict of interest.

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INTRODUCTION

Population ageing will surely be the distinctive trait of populations during the twenty-first century. In fact, it is expected that by 2050, 1 in 6 people in the world will be over 65 years of age.¹ One of the major consequences of population ageing related to visual health is that retinal conditions are already a significant and increasing problem worldwide.² Another critical consequence is presbyopia, representing one of the two most common human ocular afflictions in the world.³

Aiming to compensate the visual symptoms of presbyopia, multifocal intraocular lenses (IOL) have been a widespread solution for patients who want to have spectacle independence.^{4,5} Trifocal IOLs distribute the light into three different foci (far, intermediate and near). Furthermore, today it is possible to find novel designs of trifocal IOLs, including trifocal designs that compensate the corneal astigmatism of patients that undergo cataract surgeries.

Optical Coherence Tomography (OCT) is the most commonly used technique in the exploration and follow up of the posterior pole.⁶⁻¹² Some authors have suggested that multifocality could induce some artifacts or changes in OCT retinal measurements.^{13,14} In addition, regardless multifocal and/or monofocal lens designs, the distortion of the image induced by moderate amounts of astigmatism has also showed to have an impact on oct measurements.^{15,16}

Related to this, only a few studies have analyzed the impact of trifocal IOLs on OCT retinal measurements¹⁷⁻¹⁹ and no studies have analyzed the potential impact of toricity in trifocal IOLs on OCT measurements. Therefore, the aim of this study was to determine whether trifocality and astigmatic compensation combined with trifocality

may have an effect on the measurement of retinal parameters through a widely used spectral-domain OCT device.

METHODS

This cross-over study was conducted in Clínica Rementería, Madrid, Spain, and included patients undergoing routine cataract surgery and implantation of two different versions (non-toric and toric) of the same model of diffractive trifocal IOL. Patients implanted with a monofocal IOL were also included in the study.

The study followed the tenets of the Declaration of Helsinki and was reviewed and approved by the pertinent Ethics Committee. Informed consent was obtained from all patients after the nature of the study had been explained.

As in previous similar studies performed at the clinic,²⁰ all subjects underwent an ophthalmological examination, which included refraction, screening for ocular conditions and/or systemic diseases, slit-lamp biomicroscopy and fundus examination. Exclusion criteria were: amblyopia, abnormal iris, ocular pathologies other than cataracts or previous ocular surgery. Patients with intra- or post-operative complications were also excluded. Toric IOLs were implanted in patients with 1 D or more preoperative corneal astigmatism.²⁰ Only one eye of each patient was evaluated in this study.

Patients who met the inclusion criteria underwent cataract surgery with phacoemulsification routine and IOL implantation previously described.²⁰ All surgeries were carried out by two experienced surgeons (L.A.R, J.G.P) and the three groups had surgeries performed by both surgeons. Toric IOL implantation was guided by the VERION® System (Alcon Laboratories, USA).²⁰

The monofocal IOL considered for the study was the Alcon AcrySof® IQ SN60WF (Alcon Laboratories, USA). This is a single-piece hydrophobic acrylic IOL with ultraviolet filter and a yellow tint for blocking blue light radiation (blue light filtering chromophore). The lens presents a refractive index of 1.55 at a wavelength of 550nm. The optical zone has 6.0mm and the overall diameter of the lens is 13.0mm. It presents an anterior asymmetric biconvex aspheric design with negative spherical aberration.²¹

The trifocal IOL was the AcrySof® IQ PanOptix™ (Alcon Laboratories, USA) and its characteristics have been described in previous investigations.^{20,22} The PanOptix IOL is also a single-piece hydrophobic acrylic IOL with ultraviolet and blue light filtration. At the same time, it presents a refractive index of 1.55 at a wavelength of 550 nm. The anterior surface has a negative spherical aberration. In this case, the optical zone of the IOL is diffractive in the central 4.5 mm of the anterior surface with 15 diffractive annuli. It has an outer refractive annulus (from 4.5mm to 6.0mm). This lens has been described as panfocal with quadrifocal IOL technology.²² This quadrifocal design distributes the incoming light into four foci: distance, 120cm, 60cm and 40cm. However, the optical design of the diffractive zone has been modified in order to redistribute the energy of the 120 cm focus to the distance focus. Therefore, the quadrifocal design actually offers a trifocal function for far, intermediate (60cm / +2.17D add) and near distance (40cm / +3.25 D add).^{20,22}

The third lens considered in the study was the AcrySof® IQ PanOptix™ Toric IOL (Alcon Laboratories, USA). This lens is the toric version of the AcrySof IQ PanOptix IOL and presents the same material trifocal concepts. However, the posterior surface of the lens is biconical, creating a toricity to correct corneal astigmatism. The

AcrySof IQ Panoptix Toric is available in five ranges from model T2 to T6 (from 1.0D to 3.75D of astigmatism).²⁰

Finally, all patients were evaluated before, one day after each procedure, one week, one month and three months after the surgery. This study presents the results before and three months after the surgery. All eyes were scanned on a single Cirrus HD-OCT® instrument (Carl Zeiss, Meditec, Dublin, CA, USA). The procedure was performed in one eye of each participant and all measurements were obtained by the same experienced ophthalmic technician. According to the study protocol, a correct retinal layer segmentation was visually confirmed after each examination. Any incorrect segmentation implied a repetition of the OCT scan until a perfect automatic segmentation was reached. At the same time, the scan signal strength on the OCT device is displayed on a scale of 0 to 10, with 10 being maximum. Following the manufacturer's instructions, signal strength values ≥ 6 are acceptable. Then, those measurements with a signal strength under 6 were discarded. The signal strength was calculated for the three groups. The OCT retinal measurements assessed in all cases were: mean average macular thickness, macular volume and retinal fiber nerve layer (RFNL) thickness.

Statistical analysis was conducted using SPSS for Windows V.20.0 (SPSS Inc, Chicago, IL). The Kolmogorov-Smirnov test was used to evaluate the normality of the data distributions. Due to the normality of the data, the pre- and post-operative data of each parameter were compared by means of the Student's t-test. A repeated measures analysis of variance (ANOVA) was used to gauge any statistically significant difference of the data within the three groups. Differences were considered to be statistically significant when the P value was <0.05 (i.e. at the 5% level). The XL-STAT statistical software (Windows 10, 64 bits, USA) was also employed. A two-One-Sided-Test

(TOST) was used to assess the equivalence of the study population. The equivalence of two samples was confirmed when the P value related to unilateral T test was <0.05 .

RESULTS

The study considered 150 eyes from 150 subjects with a mean age of 69.1 ± 7.9 years. Subjects were divided into three groups: 50 with monofocal IOL, 50 with trifocal IOL, and 50 with trifocal toric IOL implantation. Table 1 shows the preoperative characteristics of all the groups. The only parameter that showed statistically significant differences for the three groups was the mean age ($p=0.01$). A multivariate regression was performed, and the estimated coefficients showed no significant influence in this particular sample for any of the parameters analyzed. (Macular thickness: $B= 0,144$ microns/year; $p = 0,226$; 95% C.I $-0,90$ to $0,377$; RFNL: $B=-0,027$ microns/year; $p=0,708$; 95% C.I $-0,176$ to $0,114$; Macular volume: $B= -0,004$ cubic microns/year; $p=0,212$; 95% C.I $-0,011$ to $0,003$).

At the same time, mean preoperative and postoperative signal strength values for the monofocal, trifocal and trifocal toric group are showed in table 1 (Supplemental Digital Content 1, <http://links.lww.com/IJG/A497>). Signal strength increased after monocular IOL implantation ($p<0.001$) and was similar after trifocal ($p=0.07$) and trifocal toric ($p=0.23$) IOL implantation. All surgeries were successfully performed and there were no intra or postoperative complications.

Table 2 shows the results of the three parameters (mean average macular thickness, macular volume and RFNL thickness) before and after IOL implantation for the three groups. For the three IOL groups, there were statistically significant differences for both macular thickness and macular volume ($p<0.0001$ for all cases).

The only parameter that showed no statistically significant differences before and after the surgery was RFNL thickness ($p > 0.05$ for the groups).

Mean values of the differences (before and after the surgery) for the three groups are compared and presented in Table 2 (Supplemental Digital Content 2, <http://links.lww.com/IJG/A498>). The differences for macular thickness, macular volume and the RFNL thickness, measured before and after the surgery, were similar and no statistically significant differences were found for the three groups ($p > 0.05$ for all cases). In addition, the study populations showed to be equivalent (P values related to the unilateral T test were < 0.05 for all cases).

DISCUSSION

OCT is a non-invasive, valuable and widespread tool for detecting and monitoring retinal diseases. Its importance relates to the current demographic situation, which means that retinal pathologies will be a key factor in eye care and global health systems. At the same time, current trifocal IOLs are becoming highly popular worldwide among surgeons that intend to offer spectacle independence to their patients after cataract surgery. Since optical issues such as multifocality of the IOLs could induce artifacts in OCT measurements,¹³ the aim of the current study was to assess whether the implantation of trifocal IOLs could affect retinal parameters measured with the Cirrus HD spectral-domain OCT. In addition, a trifocal toric IOL with the same IOL platform was also considered in order to determine whether toricity for the astigmatic correction could induce additional changes in OCT measurements. In order to have a control group, patients implanted with monofocals were also analyzed.

As overall retinal parameters, macular thickness and macular volume were analyzed. Observing the results of these two parameters (Table 2), we can see that for

the three groups (monofocal, trifocal and trifocal toric IOL), the results showed a statistically significant increment of macular thickness and macular volume after the surgery. Despite the statistical differences, in order to assess whether trifocal and trifocal toric IOL designs may modify the measurements compared to monofocals, the differences between the pre- and post-operative macular thickness and macular volume values for the three groups were compared (Table 2 Supplemental Digital Content 2, <http://links.lww.com/IJG/A498>). The results showed no statistically significant differences among the three IOL groups. Therefore, this suggests that both trifocality and astigmatic correction with trifocal toric IOLs do not have an additional impact on OCT measurements compared to monofocal IOLs for macular thickness and macular volume values.

In relation to these parameters, a previous study assessed the impact of multifocal diffractive IOLs on macular thickness and macular volume through OCT.¹⁷ The results showed no differences between multifocal and monofocal IOL groups. As in our work this previous study suggested that, despite the fact that the image quality of the retina through multifocal differences could be lower, this issue did not affect the accuracy of the OCT measurements. However, this study did not analyze the parameters before the surgery and the multifocal IOL design was different (it was diffractive but it was also bifocal). Direct comparisons with this study should therefore be made with caution.

Furthermore, RFNL thickness was also analyzed as a specific retinal layer. In this case, the results shown in Table 2 suggest that for the three groups, despite a slight increment, no statistically significant differences were found after the surgery. Previous authors have shown a higher mean RFNL thickness layer after cataract surgery,²³⁻²⁵ probably due to a better image quality of the retina. Focusing the analysis on trifocal

IOLs, research conducted by Bella et al. also reported an increment of RFNL thickness after the cataract surgery.¹⁸ However, in this study the authors did not compare the trifocal IOL group results with a monofocal IOL group. Concerning this comparison, in a later study this research group analyzed and compared RFNL values before and after cataract surgery both with a monofocal and a trifocal IOL group.¹⁹ Similarly, they reported that for both IOL groups the mean RFNL thickness increased after the surgery, with the values being higher for the trifocal group. The study did not provide an explanation for these differences between monofocal and trifocal IOL results and suggested that future studies could confirm them. Indeed, our results do not fully confirm such significant differences. Nevertheless, it should be mentioned that the IOLs of both studies have different optical designs^{20,26} and no direct comparisons should be made. Hence, it would be interesting to conduct future studies with homogeneous samples, similar devices and technicians, control groups and different trifocal lenses in order to assess whether differences between IOL designs have an effective impact on RFNL thickness measurements after the surgery.

As with the other parameters, and apart from the simple comparative of pre- and post-surgery RFNL values, our most significant analysis involved comparing the mean values of the differences (pre- and post-surgery RFNL mean difference value) among the three groups. The results in Table 2 (Supplemental Digital Content 2, <http://links.lww.com/IJG/A498>) show that the differences in RFNL values for the three groups were not significant, suggesting that trifocal and trifocal toric designs do not have an additional impact on RFNL thickness measurements compared to monofocal IOLs.

We would also like to note that the impact of toricity of trifocal IOLs on OCT measurements has not been studied before and no comparisons with other studies can be

made. However, astigmatism and the effect on OCT measurements was assessed by Hwang et al.¹⁵ and Langenbacher et al.¹⁶ The results of these studies suggested that the distortion of the image induced by moderate amounts of astigmatism could induce changes in some retinal measurements such as RFNL. On the other hand, some authors reported that, if toric lenses are well implanted, the toricity itself should not induce significant changes if compared to monofocal designs.²⁷ Then, a correct alignment of toric IOLs is important for avoiding errors on OCT measurements, being this alignment crucial for high cylinder IOLs.

In our study, astigmatism was corrected by the toric IOL implant and this possibility was ruled out. In addition, as previously mentioned, this study analyzed whether the toric design itself could have an impact on the measurements, suggesting that this trifocal toric design has no impact compared to a monofocal. Thus, future studies should analyze whether high amounts of astigmatism and the different toric designs available on the market (it could include IOLs or contact lenses) could induce changes in retinal images via OCT devices.

In general, studies that considered multifocal and/or trifocal IOLs for OCT measurements are scarce and showed some variability in their results. Regarding these studies, it was suggested that differences could be due to differences in the samples, the nature of the cataracts of the samples and the difference in the optical designs of the IOLs, among other things. Considering both the reported variability and the potential changes in OCT measurements after cataract surgeries, it is clearly important to pay attention to retinal management of all patients that have undergone cataract surgery,²³⁻²⁵ particularly those with potential or diagnosed retinal pathologies.²⁸ At the same time, in order to gain a deeper insight into the impact of trifocal and trifocal toric IOLs on OCT measurements for the management and detection of posterior pole conditions, it would

be interesting to conduct future studies which analyze more retinal parameters, and to complement these results with other key diagnostic tests such as visual fields.

In conclusion, some OCT measurements may undergo changes after the implantation of monofocal, trifocal and/or trifocal IOLs. However, the results of this study suggest that trifocality and toricity for astigmatic correction with the trifocal IOLs under study do not induce additional changes in OCT measurements. Thus, the retinal management and the analysis of the retinal images of these patients by means of spectral-domain OCT devices should be similar to those of patients implanted with monofocal IOLs.

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Table 1. Preoperative characteristics of the eyes included in the study. Values provided are mean \pm standard deviation.

	Number of eyes	Age (years)	Photopic Pupil (mm)	Axial Length (mm)	IOL power (D)
AcrySof IQ	50	74.5 \pm 5.7	3.6 \pm 0.7	23.8 \pm 1.0	20.9 \pm 3.3
PanOptix	50	66.2 \pm 8.5	3.8 \pm 0.9	23.4 \pm 1.2	22.2 \pm 3.4
PanOptix Toric	50	65.7 \pm 8.2	3.7 \pm 0.8	23.5 \pm 1.3	21.5 \pm 4.2
p value		0.01	0.30	0.25	0.14

IOL: intraocular lens

Table 3. Mean average values of the three parameters (macular thickness, macular volume and retinal fiber nerve layer (RFNL) thickness), before and three months after the surgery for the three intraocular lens groups (monofocal, trifocal and trifocal toric). Values provided are mean \pm standard deviation.

		Before the surgery	After the surgery	p value
Monofocal	Macular thickness (μm)	255.7 \pm 23.9	260.3 \pm 20.9	<0.001
	Macular Volume (mm^3)	9.9 \pm 0.5	10.0 \pm 0.4	<0.001
	RFNL (μm)	86.7 \pm 8.6	87.5 \pm 8.6	0.13
Trifocal	Macular thickness (μm)	256.5 \pm 20.5	264.4 \pm 20.9	<0.001
	Macular Volume (mm^3)	10.1 \pm 0.6	10.3 \pm 0.6	<0.001
	RFNL	90.1 \pm 8.5	91.4 \pm 8.3	0.07

	(μm)			
	Macular thickness (μm)	258.16 \pm 23.4	265.1 \pm 22.4	<0.001
Trifocal Toric	Macular Volume (mm^3)	10.0 \pm 0.6	10.1 \pm 0.7	<0.001
	RFNL (μm)	91.1 \pm 11.9	91.9 \pm 11.8	0.20

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Table 2 (Supplemental). Preoperative and postoperative signal strength values for the three groups. The signal strength values follow a scale of 0 to 10, with 10 being maximum. Values provided are mean \pm standard deviation.

	Number of eyes	Preoperative signal strength	Postoperative signal strength	p value
AcrySof IQ	50	7.1 \pm 1.5*	7.9 \pm 1.2 *†	p < 0.001
PanOptix	50	7.7 \pm 1.3	7.4 \pm 1.3	p = 0.07
PanOptix Toric	50	7.6 \pm 1.7	7.4 \pm 1.2	p = 0.23

Table 4 (Supplemental). Mean differences before and after the surgery for the three retinal parameters (macular thickness, macular volume and retinal fiber nerve layer (RFNL) thickness) for the three intraocular lens groups (monofocal, trifocal and trifocal toric). Values provided are mean \pm standard deviation.

	Monofocal	Trifocal	Trifocal Toric	p value
Macular thickness (μm)	4.9 \pm 7.8	7.9 \pm 10.0	7.7 \pm 13.7	p=0.08
Macular Volume (mm^3)	0.1 \pm 0.2	0.2 \pm 0.4	0.2 \pm 0.3	p=0.09
RFNL thickness (μm)	0.8 \pm 5.5	1.3 \pm 6.0	0.8 \pm 6.7	p=0.31