Visual Performance of AcrySof ReSTOR Apodized Diffractive IOL: A Prospective Comparative Trial

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• PURPOSE: Evaluate the visual performance of the AcrySof ReSTOR intraocular lens (IOL) and compare it with the monofocal SA60AT IOL.

• DESIGN: Prospective, nonrandomized, clinical trial.

• METHODS: Forty patients (80 eyes) from the Federal University of São Paulo were enrolled in two groups. Twenty-five patients were assigned to the ReSTOR group and 15 patients to the monofocal group. Inclusion criteria were corneal astigmatism <1.0 diopter, potential acuity meter >0.2 logMAR units, and no associated ocular diseases. Parameters analyzed included distance uncorrected and best-corrected visual acuity, near uncorrected and distance corrected visual acuity, intermediate visual acuity, contrast sensitivity (Pelli-Robson chart), stereopsis (Titmus test), reading speed, wavefront measurement (LADARWave aberrometer), and a quality-of-life questionnaire. MAIN OUTCOME MEASURE: Distance and near uncorrected and best distance corrected visual acuity, contrast sensitivity, and reading speed.

• RESULTS: Distance uncorrected and best-corrected visual acuity in the ReSTOR group were not statistically different from the monofocal group ($P = .66$). Near uncorrected and distance corrected visual acuity were statistically better in the ReSTOR group than the monofocal group (0.16 ± 0.13 vs 0.62 ± 0.09, $P < .001$, and 0.14 ± 0.12 vs 0.62 ± 0.07, $P < .001$, respectively). The ReSTOR group demonstrated less spherical aberrations compared with the monofocal group ($P < .001$). Monocular photopic contrast sensitivity was statistically lower in the ReSTOR group ($P < .001$). Stereopsis and reading speed were not statistically different between the groups.

• CONCLUSION: The AcrySof ReSTOR IOL provides a satisfactory full range of vision and achieves a more satisfactory quality of life when compared with the monofocal SA60AT IOL, but with lower contrast sensitivity. (Am J Ophthalmol 2006;141:827–832. © 2006 by Elsevier Inc. All rights reserved.)

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Alcon Laboratories Inc, Fort Worth, Texas, provided the 50 multifocal intraocular lenses, AcrySof ReSTOR, used in this study.

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THE PHYSIOLOGIC PHENOMENON OF LOSS OF ACCOMmodation that occurs with aging reduces the ability to focus at varying distances, decreasing the near visual acuity.[1,2] Spectacle correction, monovision, corneal myopic astigmatism, and, recently, new intraocular lens (IOLs) designs are considered alternatives to reestablish unaided near vision.[3–5]

Cataract surgery techniques and IOL designs have lately improved to provide the best quality of vision in pseudophakic patients, attempting to mimic the prepresbyopic crystalline lens.[6,7] The new apodized diffractive AcrySof ReSTOR IOL (Alcon Laboratories Inc, Fort Worth, Texas, USA) was designed to achieve satisfactory distance, intermediate, and near visual acuity and lessen spectacle dependence without compromising visual performance.

Even with the potential benefits of multifocal IOLs, monofocal IOLs are still the widespread standard of care in cataract surgery.[8–14]

The purpose of this prospective study was to evaluate the visual performance of a new apodized, diffractive IOL (AcrySof ReSTOR) and to compare it with a standard monofocal IOL (AcrySof SA60AT) (Alcon Laboratories Inc, Fort Worth, Texas, USA).

METHODS

FORTY PATIENTS (80 EYES) FROM THE CATARACT INSTItute at the Federal University of São Paulo were enrolled in this institutional, prospective, nonrandomized clinical trial. All participants signed an informed consent, and the

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Institutional Review Board of the Federal University of São Paulo approved the protocol.

Twenty-five patients (50 eyes) were allocated to the AcrySof ReSTOR IOL group and 15 patients (30 eyes) to the monofocal AcrySof SA60AT group. Inclusion criteria for both groups were as follows: cataract in both eyes classified by the Lens Opacity Classification System III, corneal astigmatism less than 1.0 diopter (D), potential acuity meter better than 0.2 logarithm of minimal angle of resolution (logMAR) units, IOL power between +18.0 diopters and +25.0 diopters, and capability of understanding and signing the informed consent. Exclusion criteria were age under 21 years old; pregnancy; prior refractive, glaucoma or penetrating keratectomy surgery; degenerative optical diseases; and associated ocular or systemic disease that could interfere with final results. Intraoperative exclusion criteria were significant vitreous loss with inability to place the IOL in the capsular bag and anterior chamber hyphema.

Patients were scheduled for clinical evaluation preoperatively and one day, one week, and one, three, and four months postoperatively. Standard comprehensive ophthalmic examination, including manifest refraction, biomicroscopy, intraocular pressure measurement, and funduscopy, was performed at all visits under controlled illumination. Photopic measurements were performed at 180 candelas/m^2 (cd/m^2) with use of the Early Treatment Diabetic Retinopathy Study (ETDRS) chart luminance, and mesopic at 3 cd/m^2 luminance (Gossen Starlite, und Lichtmesstechnik GmbH, Nurnberg, Germany).

Keratometry was performed manually (OM4 keratometer, Topcon, Paramus, New Jersey, USA). Immersion ultrasound biometry was performed in all patients by only one experienced examiner using the Axis II (Quantel Medical Inc, Bazeman, Montana, USA). IOL power was targeted for emmetropia with the Holladay I and SRK-T formulas according to the measured axial length.

Uncorrected and best-corrected distance visual acuities were measured in logMAR units, monocularly and binocularly, with an ETDRS chart at 4 m with 100% contrast (No. 2106, Precision Vision, Aurora, Colorado, USA). A +0.25 diopters was added at each uncorrected measurement to correct for the optical infinity. Uncorrected, distance corrected, and best-corrected near visual acuities were measured in logMAR units, monocularly and binocularly, with an ETDRS near chart (No. 2106, Precision Vision) at the best distance chosen by the patients and with 100% contrast. The spherical addition power was limited to +1.25 diopters (ReSTOR group) and +3,00 (monofocal group) to ensure the best-corrected near visual acuity. Uncorrected and distance corrected intermediate visual acuities were measured in logMAR units at 50, 60, and 70 cm of distance with an ETDRS near chart (No. 2106, Precision Vision).

Visual acuity measurements from the four-month postoperative visit were used for statistical analysis purposes.

Cataract surgery was performed in all patients by three experienced surgeons. Standard technique in all patients consisted of sutureless phacoemulsification with using the Legacy 2000 Series and Infinity phacomachines (Alcon Laboratories Inc, Fort Worth, Texas, USA), with clear cornea incisions up to 3.0 mm and 5.0- to 5.5-mm capsulorrhexis, and using the Monarch II IOL injector (Alcon Laboratories Inc). The surgery in the fellow eye was performed within 30 days in every patient.

AcrySof ReSTOR apodized diffractive IOL has a single-piece biconvex optic. The optics is made of high refractive index (1.55) hydrophobic flexible acrylic material with ultraviolet wavelength–absorbing properties (AcrySof material, Alcon Laboratories Inc, Fort Worth, Texas, USA). The anterior surface has apodized, diffractive concentric rings in the central 3.6-mm area, distributing the light for a full range of vision. Step heights decrease smoothly from 1.3 μm in the central zone to 0.2 μm at the diffractive periphery. The lens incorporates a +4.0 (D) add at lens plane equal to a +3.2 (D) at spectacle plane.

The AcrySof SA60AT IOL is a monofocal, single-piece, anterior asymmetric biconvex, 6.0-mm optics acrylic IOL. The single-piece design and acrylic material are the same as used in the AcrySof ReSTOR IOL.

Contrast sensitivity was measured monocularly and binocularly with best distance correction at the three-month postoperative visit with the the Pelli-Robson chart (Clement Clarke International, London, United Kingdom). The test was performed at uniform room illumination, and chart luminance of 85 cd/m^2, varying between 60 to 120 cd/m^2 (Gossen Starlite, Nurnberg, Germany). The test distance was set at 1 m, which corresponds to a spatial frequency of approximately one cycle per degree.

The stereopsis was measured by the Titmus Stereo Test (Stereo Optical Co, Chicago, Illinois, USA). The patients wore a polarized pair of glasses, and the book was placed at a distance of 40 cm. Patients had to identify the three-dimensional figure in each line.

Wavefront measurements were performed with the LADARWave aberrometer (LADARVision, Alcon Laboratories Inc, Fort Worth, Texas, USA) that uses a Hartmann-Shack sensor. All examinations were performed under pupil dilation with cyclopentolate 1%, analyzing a 5-mm pupil size with up to sixth-order Zernike terms. Total aberration and higher-order aberrations were evaluated, as well as the amount of spherical aberration and coma.

Patients were tested on the MNREAD-P, a Portuguese validated version of the MNREAD chart. They were tested in the following order: binocular, right eye, and left eye. Print size (in logMAR units) was the independent variable, and reading speed was the dependent variable. Patients were tested at the near, best reading distance (between 30 cm to 40 cm), uncorrected in the ReSTOR group and best near corrected in the Monofocal group, with use of the

TABLE 1. Age, Gender, and Preoperative Best-Corrected Visual Acuity of ReSTOR and Monofocal Groups

Variable	ReSTOR (n = 25)	Monofocal (n = 15)	Test
Age (y)			Student's *t* test $t = 1.59$ (NS)
• SD	68.3 ± 9.2	63.4 ± 9.9	
• Median	72.0	65.0	
• Minimum to maximum	49–78	46–78	
Gender			Qui-square $\chi^2_1 = 0.19$ (NS)
• Female	7 (28%)	6 (40%)	
• Male	18 (72%)	9 (60%)	
Preoperative best-corrected visual acuity	0.44 ± 0.24 logMAR	0.50 ± 0.26 logMAR	Kruskal-Wallis and Tukey test

standard MNREAD protocol.[18] Student *t* test was performed to compare the Monofocal and ReSTOR patients.

Stereopsis, wavefront analysis, and reading speed measurements were also taken at the three-month postoperative visit.

An assessment of patient satisfaction was applied at the four-month postoperative visit. This assessment follows the US Food and Drug Administration requirements. Patient satisfaction was based on the following main questions: patient's activities without glasses, visual disturbances spontaneously mentioned, quality of vision (distance and near), and differential quality of vision (night vision, overall near and far vision).

The same two examiners conducted all the tests performed in the patients from both groups, following a strict methodology and the same sequence of tests. Examiners were masked to groups in all tests performed except for reading speed and biomicroscopy.

Statistical analysis was performed with the Mann-Whitney test for comparisons between the groups for all parameters evaluated except for reading speed and age comparisons (Student *t* test), and preoperative best-corrected distance visual acuity (Kruskal-Wallis and Tukey test).

RESULTS

THE MEAN AGES OF THE RESTOR AND MONOFOCAL GROUPS were 68.3 ± 9.2 and 63.4 ± 9.9 years, respectively. The mean preoperative best-corrected distance visual acuity was 0.44 ± 0.24 logMAR units for the ReSTOR group and 0.50 ± 0.26 logMAR units for the monofocal group ($P = .38$) (Table 1).

One patient (one eye) from the ReSTOR group was excluded from the study because of posterior capsular rupture and vitreous loss that did not allow the placement of the IOL in the capsular bag.

The mean monocular uncorrected distance visual acuity (Figure 1) and best-corrected distance visual acuity in the ReSTOR group were not statistically significantly different from the monofocal group: 0.06 ± 0.09 vs 0.07 ± 0.09 ($P = .88$), and 0.02 ± 0.17 vs −0.01 ± 0.07 ($P = .66$), respectively.

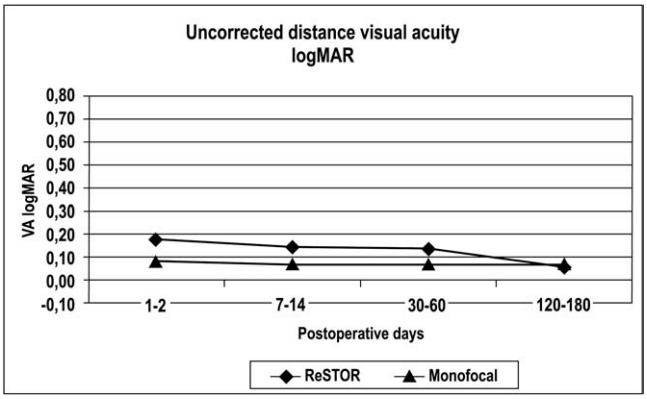

FIGURE 1. Monocular uncorrected distance visual acuity in the ReSTOR and monofocal groups in logMAR units.

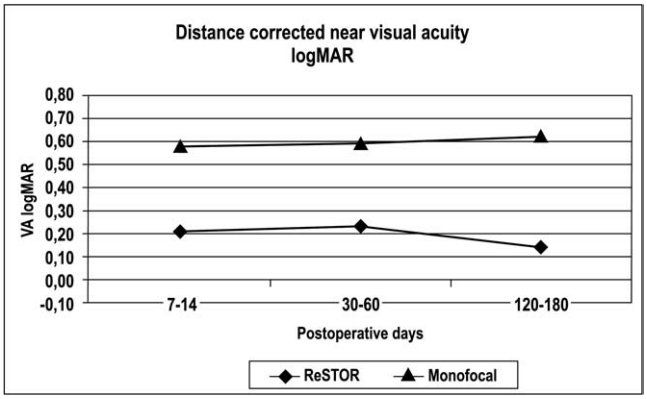

FIGURE 2. Monocular distance-corrected near visual acuity in the ReSTOR and monofocal groups in logMAR units.

The mean monocular uncorrected and distance corrected near visual acuities (Figure 2) were statistically significantly better in the ReSTOR group compared with the monofocal group: 0.16 ± 0.13 vs 0.62 ± 0.09 ($P < .001$), and 0.14 ± 0.12 vs 0.62 ± 0.07 ($P < .001$), respectively.

TABLE 2. Uncorrected and Best-Corrected Binocular Near Visual Acuity in the ReSTOR and Monofocal Groups

Variable	N	Mean	SD	Median	Minimum	Maximum
Uncorrected near visual acuity						
ReSTOR	24	0.09	0.10	0.06	–0.02	0.44
Monofocal	15	0.61	0.05	0.62	0.46	0.66
Best-corrected near visual acuity						
ReSTOR	24	0.02	0.10	–0.02	–0.14	0.34
Monofocal	15	0.14	0.05	0.14	0.02	0.22

TABLE 3. Coma, Spherical, High-Order, and Total Aberrations in the ReSTOR and Monofocal Groups

Variable	N	Mean	SD	Median	Minimum	Maximum
Coma						
ReSTOR	49	0.14	0.09	0.12	0.00	0.53
Monofocal	30	0.15	0.07	0.15	0.06	0.30
Spherical aberration						
ReSTOR	49	0.09	0.05	0.09	–0.04	0.20
Monofocal	30	0.24	0.07	0.25	0.12	0.37
Higher-order aberration						
ReSTOR	49	0.36	0.15	0.33	0.19	0.92
Monofocal	30	0.40	0.12	0.38	0.22	0.69
Total RMS						
ReSTOR	49	0.72	0.25	0.72	0.25	1.32
Monofocal	30	0.79	0.22	0.78	0.41	1.22

RMS = root mean square.

The mean binocular uncorrected and best-corrected near visual acuities were statistically significantly better in the ReSTOR group compared with the monofocal group ($P < .001$) (Table 2).

The mean binocular uncorrected intermediate visual acuity was statistically significantly better in the ReSTOR group compared with the monofocal group at a distance of 50 cm, 0.20 ± 0.16 vs 0.35 ± 0.08 ($P < .002$), but not for 60 cm and 70 cm. The mean binocular distance corrected intermediate visual acuity was statistically significantly better in the ReSTOR group at 50, 60, and 70 cm: 0.18 ± 0.12 vs 0.39 ± 0.09 ($P < .001$); 0.23 ± 0.12 vs 0.38 ± 0.05 ($P < .001$); and 0.26 ± 0.11 vs 0.37 ± 0.05 ($P < .001$), respectively.

In the wavefront analysis, the ReSTOR group induced statistically significantly less spherical aberrations than the monofocal group ($P < .001$). For all the other parameters evaluated, there was no statistical difference (Table 3).

Ninety-two percent of the patients in the ReSTOR group and 87% in the monofocal group achieved a stereopsis of 50 seconds of arc or better. The power analysis to detect differences between both groups was only 31%.

The monocular photopic measurement of contrast sensitivity was statistically significantly lower in the ReSTOR group ($P < .001$), but binocular photopic measurement of contrast sensitivity between both groups was not statistically significantly different ($P = .06$).

The maximum reading speed and the critical print size between the uncorrected ReSTOR group and the monofocal group with near correction were not statistically different ($P = .18$ and $P = .62$, respectively) (Figure 3).

The quality-of-life questionnaire revealed that both groups were comparable in satisfaction regarding distance activities without glasses in different lighting conditions, but for near activities such as reading a newspaper, the ReSTOR group performed better than the monofocal group ($P < .001$). Only four patients spontaneously mentioned visual disturbances in the ReSTOR group. Considering the specific assessment about quality of vision where details about visual disturbances were asked, approximately 40% of the patients in the ReSTOR group experienced

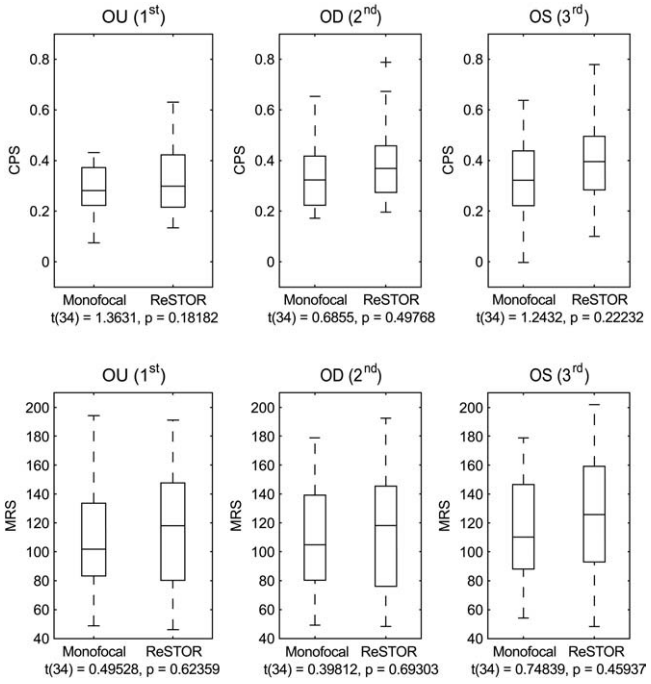

FIGURE 3. Critical print size (CPS) and maximum reading speed (MRS) in seconds in the ReSTOR and monofocal groups. CPS is the smallest print that the patient can read with maximum speed.

mild to moderate glare compared with 13% in the monocular group. In the ReSTOR group, 50% of the patients mentioned nighttime halos compared with 20% in the monocular group. Despite the nighttime halos, 96% of patients in the ReSTOR group related that they had good quality near vision and 100% said that they had good quality distance vision. Overall satisfaction was comparable in both groups.

DISCUSSION

ASIDE FROM OBJECTIVE VISUAL ACUITY MEASUREMENTS at different distances, contrast sensitivity, stereopsis, reading speed, total and higher-order aberrations (HOAs), and the evaluation of a patient's perception of quality of vision and the impact in his or her life combine to indicate the optical quality and visual performance of any implanted IOL.

The results observed in this study have some limitations owing to the fact that this is a nonrandomized clinical trial with uneven groups, which could in turn lead to a bias of selection. To minimize that, we conducted a sequential prospective trial with the first 25 patients included in the ReSTOR group and the following 15 patients in the monofocal group.

The AcrySof ReSTOR IOL resulted in a high monocular and binocular uncorrected distance and near visual acuity, as well as binocular intermediate visual acuity. The diffractive IOL obtained a better performance in uncorrected monocular and binocular near and binocular intermediate visual acuity compared with the standard SA60AT monofocal IOL. These findings are in concordance with the literature, where multifocal IOLs achieve a significantly better near visual acuity than monofocal IOLs.[16–18] All binocular visual acuity measurements were superior to the monocular measurements. This finding has already been published in the literature for multifocal IOLs.[19,20]

Although there were no statistical differences between the two groups in uncorrected and best-corrected distance visual acuity, the vision in the ReSTOR group tended to improve over several months postoperatively. This improvement also occurred with respect to the near visual acuity.

The uncorrected near vision obtained with the ReSTOR IOL was as good as the best-corrected near vision with the monofocal IOL and was sufficient to conduct most of the common activities requiring near vision, without the need of correction.

In the study, both uncorrected and distance corrected intermediate visual acuities were statistically better in the ReSTOR group for a distance of 50 cm and distance corrected at 60 and 70 cm.

Contrast sensitivity in the multifocal IOL group in this study was in concordance with the data published by Rubin and associates[21] for multifocal IOL implants (1.65 ± 0.08) and better than the data reported by Elliot and Whitaker and Souza and associates.[22,23] The monocular photopic contrast sensitivity was statistically significantly lower in the ReSTOR group ($P < .001$), but binocular measurements between both groups were not statistically significantly different ($P = .06$), although the ReSTOR group obtained a lower contrast sensitivity.[8–14,24] The clinical significance of this difference is unknown and appears not to adversely affect the ReSTOR patient's quality of life.

Stereopsis is an important tool in evaluating the performance of any implanted IOL and patient satisfaction. This study observed no difference between both groups ($P = .26$), and over 90% of the patients achieved stereopsis of 50 seconds of arc or better, although the power analysis was low.

Reading is one of the most important near visual activities performed by humans. Good performance on a static reading chart cannot simulate the real performance of an IOL. The ReSTOR IOL performed well and similar to the SA60AT with correction in terms of reading speed and critical print size. The advent of new IOL models such as this diffractive IOL may help patients reduce their dependence on spectacles for distance and near reading.[15,25]

Several quality-of-life studies reported a high level of satisfaction among patients implanted with diffractive or refractive IOLs because of their improved reading ability.

This study demonstrated that all the ReSTOR patients could read without glasses compared with other studies in the literature (60% to 80%).[16,26]

The quality-of-life questionnaire that the patients completed at the four-month postoperative visit revealed that the ReSTOR patients were more satisfied and more easily performed near activities such as reading a newspaper without glasses, compared with the monofocal group. Nighttime visual disturbances such as mild to moderate halos and glare were noticed more in the ReSTOR group compared with the monofocal group.

In conclusion, the AcrySof ReSTOR IOL provided a satisfactory full range of vision, with less dependence of spectacles and with less induced spherical aberrations compared with the AcrySof SA60AT monofocal IOL.[27] A few patients spontaneously mentioned that they noticed mild to moderate halos and glare. Although the monocular contrast sensitivity was slightly lower than in the monofocal group, the clinical significance is unknown and ReSTOR patients demonstrated a more satisfactory quality of life and improved spectacle freedom.

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Biosketch

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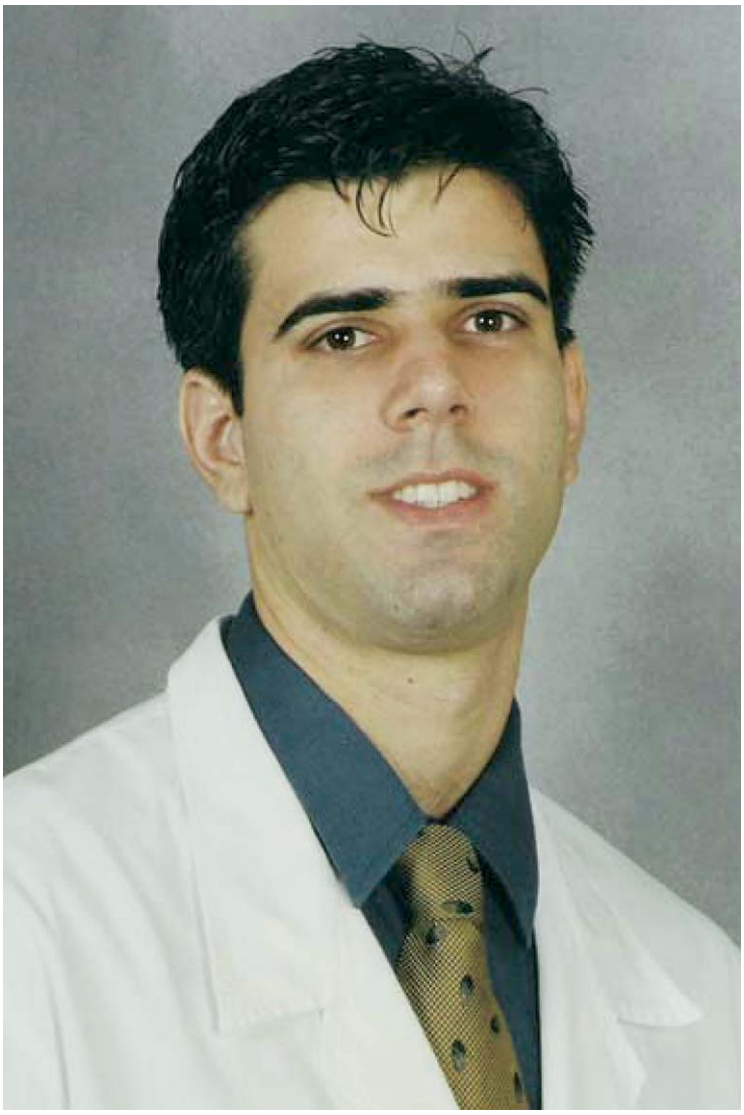

Biosketch

Eduardo S. Soriano, MD, received his Medical degree and his residency from Federal University of São Paulo, Brazil, in 1991 and 1996, respectively. He did his clinical Fellowship at The Wilmer Eye Institute, Johns Hopkins University, in 1999. Dr Soriano received his Post Doctoral degree in Molecular Biology from Federal University of São Paulo, in 2000. Currently, Dr Soriano is a Director, of Cataract Service, in the Federal University of São Paulo.