

Comparison between OPD-Scan results and visual outcomes of monofocal and multifocal intraocular lenses

Comparação dos resultados do OPD-Scan e performance visual das lentes intraoculares monofocal e multifocal

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ABSTRACT

Purpose: To compare the visual outcome, contrast sensitivity and wave-front analysis of patients that underwent cataract surgery and implantation of AcrySof SN60D3 multifocal intraocular lens with those who received the AcrySof SN60AT monofocal IOL. **Methods:** This was a prospective clinical trial of forty eyes that received the multifocal IOL and thirty-two eyes that received the monofocal IOL after phacoemulsification. **Results:** Values for total and spherical aberrations in the multifocal group were statistically lower than in the monofocal group. In the monofocal group, 75% achieved uncorrected intermediate visual acuities between Jaeger 1 and 6. In the multifocal group, 75% of the eyes achieved more than Jaeger 6. At least 87.5% of the multifocal group and 6.3% of the monofocal group achieved monocular uncorrected near acuity of 20/30 (J2, N5) or better. And 90.0% of the eyes in the multifocal group and 37.5% in the monofocal group achieved an uncorrected near acuity of 20/40 (J3, N6) or better. The mean spherical error was 0.11 D in the multifocal group and -0.18 D in the monofocal group (p=0.0379). The SN60D3 group compared to SN60AT group had low contrast sensitivity (log units) with statistically significant differences in 6.0 cpd in photopic conditions (p=0.014) and the SN60D3 group compared to SN60AT group had higher contrast sensitivity (log units) under mesopic conditions (p=0.044). **Conclusion:** The multifocal IOLs induced less spherical aberration than monofocal IOLs and predictably good uncorrected distance and uncorrected near acuities. However, contrast sensitivity was lower in the multifocal group.

Keywords: Intraocular lenses; Lens implantation, intraocular; Cataract; Phacoemulsification; Visual acuity

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INTRODUCTION

Cataract surgery has evolved over the past few years with new surgical techniques, instrumentals, devices and intraocular lenses (IOLs) designs⁽¹⁾. Despite excellent visual acuity restoration, most patients with monofocal IOLs remain dependent on spectacles for near vision. Multifocal IOLs address this limitation and should provide patients with satisfactory uncorrected distance as well as near vision. Multifocal IOLs may be classified as accommodative or pseudoaccommodative. Accommodative IOLs intend to restore accommodation within the capsular bag. Pseudoaccommodative IOLs, which may be refractive or diffractive, use different portions of the lens to

allow for distance and near viewing according to pupill size and object position. AcrySof Restor multifocal IOL is an apodized diffractive multifocal IOL. For these IOLs, the incoming light is divided between the apodized powers corresponding to both distance and near vision. When viewing an object, the portion of the AcrySof multifocal IOL used for focusing it depends on the distance of the object from the viewer. For example, a distant image only stays in focus through the portion of the IOL devoted for distance viewing, whereas it remains defocused through the portion of the IOL designed for near viewing⁽²⁻⁶⁾. This approach conserves efficiency for mesopic activities when the pupil is larger, such as night driving, but reduces near vision under mesopic conditions⁽⁷⁾.

For phakic eyes, the worsening optical aberrations and contrast sensitivity associated with aging is primarily attributed to various changes of the lens⁽⁷⁾. With the rapid advances in microsurgical technology, most patients contemplating cataract surgery have ever-higher expectations for the visual outcome following phacoemulsification and IOL placement⁽⁸⁾. Aspheric, multifocal, and accommodative IOLs are all excellent options that may provide improved quality of vision for these patients who may engage in a wide range of daily visual tasks⁽⁹⁾.

The development of new devices such as the Hartmann-Shack aberrometer and the Optical Path Difference Scan (OPD-Scan) provide new opportunities to study the quality of vision associated with various types of IOLs. For the OPD-Scan, optical aberrations are measured via the distance that light travels through different paths as it traverses the eye⁽¹⁰⁻¹¹⁾. The integration of wavefront technology and lens-based surgery constitutes a step forward for achieving improved functional vision and ultimately, the quality of life of cataract patients⁽¹²⁻¹³⁾. Improvement in ocular biometry and microsurgical techniques for cataract surgery has resulted in less refractive errors, quicker visual recovery, lower intraoperative complications, and better quality of vision^(5,14-17).

AcrySof SN60D3 multifocal and AcrySof SN60AT monofocal IOLs do not present specific design to correct high order aberrations (HOAs). However, some reports state that apodization may reduce spherical aberrations⁽¹⁰⁻¹³⁾. Therefore, HOAs should be assessed and compared when studying IOLs.

The purpose of this study is to compare the visual outcome, contrast sensitivity and aberrometry using the OPD-Scan in patients with AcrySof SN60D3 multifocal IOL with those who received the AcrySof SN60AT monofocal IOL.

METHODS

This was a non-randomized comparative prospective study comprised of 72 eyes of 36 patients who underwent phacoemulsification and PCIOL insertion from March 1st to December 28th, 2006. This study was conducted according to established ethical standards for clinical research and approved by ethical committees of the institutional review board of "Faculdade de Medicina da Universidade de São Paulo".

Criteria for inclusion in the study were: 1) Ages between 45 and 75, 2) Less than 1.0 diopter of corneal astigmatism, 3) Lack of substantial ocular pathology other than cataract, 4) Absence of prior ocular surgery, 5) No history of topical hypotensive medications, and 6) Pupillary size of 3.5 mm or greater under mesopic and photopic conditions as measured by the Colvard pupillometer (Oasis Corporation, Glendora, CA, USA). Exclusion criteria included: 1) Any systemic or ocular condition (e.g. diabetes mellitus and age-related macular degeneration) that may affect visual acuity and contrast sensitivity, 2) Any intraoperative or postoperative complication, such as the lack of definite "secured-in-the-bag" IOL fixation, or IOL decentration of more than 0.5 mm.

The patients were divided into one of 2 groups of IOL implantation as follows: AcrySof[®] Natural[®] lens (SN60AT, Alcon Laboratories, Fort Worth, TX, USA) for the monofocal group (32 eyes, 16 patients), AcrySof[®] Restor[®] lens (SN60D3, Alcon Laboratories, Fort Worth, TX, USA) for the multifocal group (40 eyes, 20 patients).

All IOL calculations were performed with the immersion ultrasonic technique using the Ocuscan RXP biometer (Alcon Laboratories, Fort Worth, TX, USA) and IOL-Master Optical biometer (Carl Zeiss Meditec, Jena, Germany) by the author (AFPM) who has considerable experience with this technique. Depending on the axial length readings, IOL powers were selected according to Hoffer-Q, Holladay I or SRK/T formula⁽¹⁸⁾. Target refraction was plano (0 D), or the first positive value for the multifocal group and target refraction was plano (0 D), or the first negative value for the monofocal group.

All surgeries were performed by the same senior surgeon (CTN) with the same technique, described as follow: under topical anesthesia, a 2.75 mm self-sealing clear-cornea incision on the steepest meridian axis was created. After injection of cohesive and dispersive viscoelastic material with soft-shell technique, a continuous curvilinear capsulorhexis was created and hydrodissection was achieved with a solution of 1% non-preserved lidocaine in balanced salt solution⁽¹⁹⁾. Cataracts were extracted with Akahoshi pre-chop technique and by conventional phacoemulsification with Infiniti Vision System (Alcon Laboratories, Fort Worth, TX, USA). After cortical aspiration, the IOL was placed in the bag with careful centration using Royale[®] (Asico, Chicago, CA, USA) delivery system. Starting on the day of surgery, all operated eyes received a topical 4th generation quinolone (0.3% gatifloxacin) 4 times a day for 7 days, and topical corticosteroid (0,1% dexamethasone) 4 times a day with a tapering dosage for 30 days.

A complete ophthalmic examination was performed for all visits. Visual acuity for distance (6 meters), intermediate (70 centimeters), and near (33 centimeters) for uncorrected and best corrected visual acuities were performed with a standardized Early Treatment Diabetic Retinopathy Study (ETDRS) chart (N^o 2106, Precision Vision, Aurora, Colorado, USA) by a single masked examiner under the same conditions including identical background luminance. Postoperative examination also included detailed slit-lamp biomicroscopy, intraocular pressure

measurements, indirect ophthalmoscopy and assessment of patient's with spectacle correction.

Pupillary diameters were measured under the same conditions for both groups, including identical background luminance provided by the Ginsburg box photometer (85 cd/m² and 6 cd/m²) by means of a Colvard pupillometer (Oasis Corporation, Glendora, CA, USA). Analysis of wavefront aberrations with the OPD-Scan (Nidek Co. Ltd., Gamagori, Japan) included one measurement of each eye at 3 months after surgery. The reporting of optical aberrations was made according to standard and well-accepted methodology after appropriate calculations were performed with specific software for pupils with a dilatation of at least 6 mm⁽²⁰⁾.

The RMS of total HOAs and other aberrations were calculated at each control for each patient examination as the mean value of 3 consecutive measurements at 6 mm. Measurement by the OPD-Scan wavefront aberrometer from each eye was evaluated at 3 months. The parameters analyzed included: total aberration (TT), high root-mean-square (RMS) of HOA from the third to fourth orders; RMS of the total spherical aberration (TSA); RMS of total coma (TC); RMS of total trefoil (3FOIL) and tetrafoil (4FOIL).

Contrast sensitivity was measured by the VCTS® 6000 (Vistech Consultants Incorporation, Dayton, OH, USA) under photopic and mesopic conditions. The chart used displays sine-wave gratings at 5 standard spatial frequencies, from 1.5 to 18 cycles/degree (cpd). Log calculations of the obtained values were then taken to obtain the contrast sensitivity values that were entered in the database for statistical analysis.

Data was analyzed using the Statistical Program for Social Sciences (SPSS, Chicago, USA) version 10.0. The following statistical analyses were performed: Kruskal Wallis test, Fisher exact test and the Student T-test. Mean and standard deviations were recorded. A P-value of less than 0.05 was considered to be significant.

RESULTS

There was no significant difference for the 2 groups in preoperative outcome of wavefront analysis ($p=0.817$) and visual acuity ($p=0.729$). There was no statistical difference between the 2 groups for age ($p=0.87$), gender ($p=0.92$), and right or left eye ($p=0.37$). The mean age for the monofocal group was 65.13 ± 7.34 years, and the mean age for the multifocal group was 62.65 ± 8.11 years. The postoperative course was uneventful for both groups.

Postoperative wavefront analysis is shown in table 1. There were no significant differences in mean root-mean-square values of higher-order aberration, total coma, trefoil and tetrafoil between both groups. The mean values for total aberrations (TOTAL; $p=0.015$) and total spherical aberrations (TSA; $p=0.001$) in the SN60D3 multifocal group were statistically lower when compared to those for the SN60AT monofocal group.

All patients had distant monocular UCBVA (uncorrected best visual acuity) of 20/30 or better. Uncorrected distance acuity of 20/20 was achieved in 95% of the eyes in the multifocal group and in 100% of the patients of the monofocal group ($p>0.017$). Distance BCVA of 20/20 was achieved in all multifocal and monofocal eyes (Table 2).

In the monofocal group, 75% of the patients achieved an uncorrected intermediate visual acuity between Jaeger 1 and 6, but 25% of the patients achieved an intermediate visual acuity between Jaeger 1 and 6, with corrected distance vision. In the multifocal group, 75% of the patients were not able to see Jaeger 6 with and without optical correction for distance vision. A significantly higher proportion of eyes in the multifocal group (85%) compared to the monofocal group (6.3%) achieved an monocular uncorrected near acuity of 20/30 (J2, N5) or better, and all eyes in the multifocal group and 37.5% in the monofocal group achieved an uncorrected near acuity of 20/40 (J3, N6) or better. In the multifocal group, all patients achieved a binocular uncorrected near acuity of 20/30 or better (Table 3).

The mean spherical error was 0.11 D in the multifocal group and -0.18 D in the monofocal group ($p=0.0377$). There were no statistically significant differences in cylindrical errors between the multifocal and monofocal groups (0.29 D versus 0.38 D) (Table 4).

The results of contrast sensitivity under photopic conditions testing are shown in figure 1. The SN60D3 group presented contrast sensitivity values (log units) lower in the 6.0 cpd spatial frequency compared to the SN60AT monofocal group. No statistical differences were detected at 1.5 cpd (KW=7.271; $p=0.029$), 3.0 cpd (KW=3.699; $P=0.16$), 12 cpd (KW=2.99; $p=0.22$) and 18 cpd (KW=4.85; $p=0.089$).

The results of contrast sensitivity under mesopic conditions testing are shown in figure 2. The SN60D3 group presented contrast sensitivity values (log units) higher in the 6 cpd spatial frequency compared to the SN60AT group ($p=0.01$) with statistically significant differences (Figure 2). No statistical difference was detected in 1.5 cpd (KW= 0.59; $p=0.721$), 3.0 cpd (KW=2.63; $p=0.31$), 12 cpd (KW=3.43; $p=0.21$) and 18 cpd (KW=1.61; $p=0.49$).

All patients in both groups did well. As expected, the majority of monofocal group (96.5%) required glasses for near vision. The multifocal group was satisfied and did not need glasses for distance, intermediate, or near vision.

DISCUSSION

In this study, OPD-Scan analysis from the third to the eighth orders in a selected sample of 72 eyes, with a narrow range of refractive errors (range, -1.25 to 0.50 diopters) and a relatively wide age range (49-78 years) was investigated. The SN60D3 group showed inferior values ($p<0.05$) of total and spherical aberration compared to the SN60AT group. An experimental study showed significantly more spherical aberrations in eyes

| Aberrations | IOL type | | Kruskal-Wallis test p value |
|-----------------|-------------------|-------------------|----------------------------------|
| | SN60AT (n=32) | SN60D3 (n=40) | |
| TOTAL | | | |
| Median \pm SD | 1.942 \pm 0.556 | 1.287 \pm 0.543 | $p=0.015^*$ |
| Range | 0.972 to 2.957 | 0.731 to 2.451 | |
| HOA | | | |
| Median \pm SD | 0.205 \pm 0.884 | 0.313 \pm 0.702 | $p=0.097$ |
| Range | 0.517 to 1.162 | 0.289 to 1.521 | |
| COMA | | | |
| Median \pm SD | 0.334 \pm 0.184 | 0.289 \pm 0.155 | $p=0.598$ |
| Range | 0.033 to 0.804 | 0.118 to 0.599 | |
| 3FOIL | | | |
| Median \pm SD | 0.431 \pm 0.261 | 0.521 \pm 0.301 | $p=0.736$ |
| Range | 0.191 to 0.953 | 0.115 to 1.311 | |
| 4FOIL | | | |
| Median \pm SD | 0.200 \pm 0.114 | 0.190 \pm 0.073 | $p=0.672$ |
| Range | 0.051 to 0.559 | 0.035 to 0.317 | |
| SPHERIC | | | |
| Median \pm SD | 0.494 \pm 0.202 | 0.166 \pm 0.118 | $p=0.001^*$ |
| Range | 0.007 to 0.618 | 0.017 to 0.515 | |

IOL= intraocular lens; n= eyes; SD= standard deviation; TOTAL= total aberration; HOA= high order aberration; SPHERIC= total spherical aberration; COMA= total coma; 3FOIL= trefoil; 4FOIL= tetrafoil

| Distance visual acuities | IOL type | | t Student test p value |
|---------------------------|-------------------|-------------------|-----------------------------|
| | SN60AT (n=32) | SN60D3 (n=40) | |
| Uncorrected | | | |
| Average \pm SD (logMAR) | 0.009 \pm 0.027 | 0.028 \pm 0.062 | $p=0.277$ |
| Range (logMAR) | 0 to 0.100 | 0 to 0.222 | |
| Best corrected | | | |
| Average \pm SD (logMAR) | 0.006 \pm 0.160 | 0.015 \pm 0.052 | $p=0.513$ |
| Range (logMAR) | 0 to 0.046 | 0 to 0.180 | |

IOL= intraocular lens; n= eyes; SD= standard deviation

with spherical IOL's in comparison to eyes with aspherical IOL's⁽¹⁴⁾. Rocha and associates reported the same results when comparing multifocal aspheric IOL's with monofocal spherical IOL's using the Ladarvision aberrometer⁽²¹⁾. It is possible to hypothesize that the apodization, the gradual tapering of the diffractive steps from the center to the periphery of the Restor lens reduces spherical aberration in a way similar to that of an aspheric IOL. Regarding studies investigating ocular aberrations, a highly inverse relationship was found in the correlation between wavefront technology and visual performance only for those eyes with data sets of a high range of aberrations and acuities^(12-13,21-25).

The effects of aberrations on visual function are complex and not completely understood^(12-14,26). More attention should be devoted to the relation between wavefront analysis and visual performance, and reassessment of their clinical significance is needed.

The difference in mean spherical errors between the groups could be explained by the slightly different target postope-

orative refraction. The postoperative refraction was intended to be slightly hyperopic or emmetropic for the SN60D3 group, whereas the postoperative refraction was targeted to be slightly myopic for the SA60AT group. In the monofocal group, 75% of the patients achieved an uncorrected intermediate visual acuity, but 25% of the patients achieved an intermediate visual acuity, with corrected distance vision. In the multifocal group, 25% of the patients were able to intermediate vision with and without optical correction for distance vision. This study found no significant differences in both uncorrected and corrected distance visual acuities. The monofocal group was statistically superior for uncorrected intermediate visual acuity, but no difference was found for intermediate visual acuity between both groups when corrected for distance vision. Previous studies comparing other types of diffractive multifocal IOLs and monofocal IOLs showed similar results⁽²⁷⁻³⁰⁾.

Studies of different diffractive multifocal IOLs found that 86.8% to 91.3% of eyes had an uncorrected near visual acuity

Table 3. Comparison of uncorrected intermediate and near visual acuities (Jaeger chart) between SN60AT and SN60D3 IOLs

| Visual acuities | IOL type | | Fisher test p value |
|-----------------|---------------|---------------|------------------------|
| | SN60AT (n=32) | SN60D3 (n=40) | |
| Intermediate | % (n) | % (n) | |
| J1 - J2 | 6.25% (2) | 0 | p=0.4340 |
| J3 - J4 | 25% (8) | 5% (2) | p=0.1390 |
| J5 - J6 | 43.75% (14) | 20% (8) | p=0.0810 |
| > J6 | 25% (8) | 75% (30) | P=0.0480* |
| Near | % (n) | % (n) | |
| J1 - J2 | 6.25% (2) | 85% (34)* | p=0.0001* |
| J3 - J4 | 31.25% (10) | 15% (6) | p=0.2120 |
| J5 - J6 | 12.5% (4) | 0 | p=0.1890 |
| > J6 | 49.55 (16) | 0 | p=0.0003* |

IOL= intraocular lens; n= eyes

Table 4. Comparison of refractive results (diopters) between SN60AT and SN60D3 IOLs

| Refractive errors | IOL type | | t Student test p value |
|-------------------|----------------|----------------|---------------------------|
| | SN60AT (n=32) | SN60D3 (n=40) | |
| Spherical | | | |
| Average ± SD | -0.180 ± 0.377 | 0.110 ± 0.282 | p=0.0377* |
| Range | -1.25 to +0.25 | -0.25 to +0.50 | |
| Cylindrical | | | |
| Average ± SD | 0.375 ± 0.242 | 0.288 ± 0.147 | p=0.1790 |
| Range | 0 to +0.75 | 0 to +0.75 | |

IOL= intraocular lens; n= eyes; SD= standard deviation

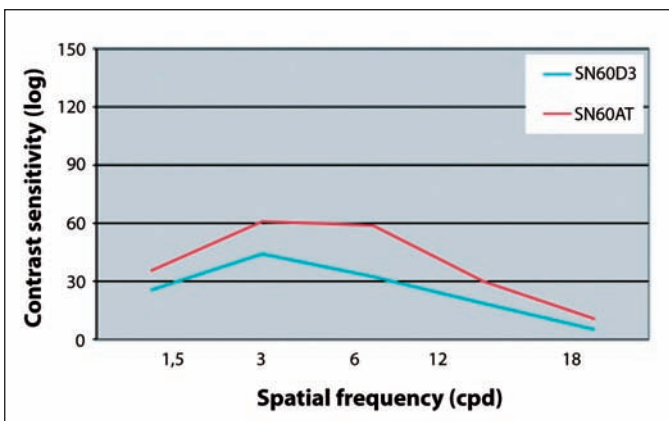


Figure 1 - Comparison of contrast sensitivity in photopic conditions between Multifocal SN60D3 and Monofocal SN60AT intraocular lens

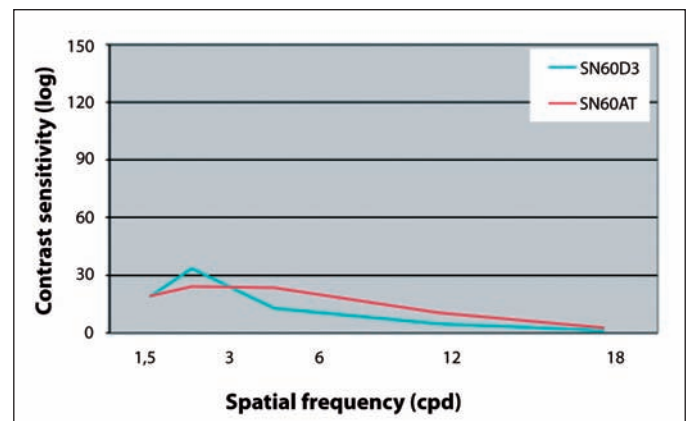


Figure 2 - Comparison of contrast sensitivity test in mesopic conditions between Multifocal SN60D3 and Monofocal SN60AT intraocular lens

of 20/40 (J3, N6) or better^(3-4,30). In the present study, all patients in SN60D3 multifocal group achieved 20/40 (J3, N6) or better. These results were achieved by strict patient selection. Patients who did not want to use optical aids, particularly for the intermediate range of vision, were counseled appropriately regarding the multifocal IOL. With these points in mind, the AcrySof ReSTOR SN60D3 IOL can provide a higher degree of spectacle independence without intolerable visual symptoms. Published reports have consistently showed that multifocal IOL's provide good near visual acuity⁽²⁸⁻³⁰⁾.

According with this study and previous published reviews, the monocular contrast sensitivity at photopic and mesopic conditions with the SN60AT IOLs was higher than the SA60D3^(17,30). Under mesopic conditions contrast sensitivity showed lower values when compared to photopic conditions. Other study showed lower contrast sensitivity under mesopic conditions in multifocal IOLs with refractive technology⁽²⁸⁾. The difference between both IOLs was higher in photopic conditions, probably because the mesopic condition shows lower values than the photopic condition.

In conclusion, this study showed that the multifocal PCIOL (AcrySof SN60D3) provided as good distance visual acuity under high contrast and other conditions as the monofocal PCIOL (AcrySof SN60AT). However, contrast sensitivity was lower in the multifocal group, except in mesopic condition in low spatial frequency. There were also less spherical aberrations with the multifocal group in comparison to the monofocal group. This has yet to be correlated with visual performance in further studies. Near-distance visual acuity was predictably achieved and higher in the multifocal group. Questionnaires should be applied in further studies to assess the impact of spectacle independence in relation to differences in contrast sensitivity and spherical aberrations.

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RESUMO

Objetivo: Comparar a performance visual, sensibilidade ao contraste e de wavefront com OPD-Scan em pacientes submetidos a cirurgia de facoemulsificação com implante de lente intraocular AcrySof SN60D3 multifocal e AcrySof SA60AT monofocal. **Métodos:** Quarenta olhos com a lente intraocular multifocal e trinta e dois olhos com a lente intraocular monofocal. A avaliação oftalmológica contou com medida da acuidade visual para longe, intermediária e curta distância, sem correção e com a melhor correção óptica, teste de sensibilidade ao contraste e análise de frente de onda por meio do aberrômetro OPD-Scan. **Resultados:** As aberrações total e aberrações esféricas no grupo multifocal foi estatisticamente inferior comparada com o grupo monofocal. No grupo monofocal 75% apresentaram acuidade visual monocular intermediária sem correção entre Jaeger 1 e 6, no grupo multifocal 75% apresentaram mais que Jaeger 6. Aproximadamente 87,5% do grupo multifocal e 6,3% do grupo monofocal apresentaram acuidade visual monocular sem correção para perto de 20/30 (J2, N5), ou melhor, e 90,0% dos olhos do grupo multifocal e 37,5% do grupo monofocal apresentaram acuidade visual monocular sem correção para perto de 20/40 (J3, N6) ou melhor. A média de erro esférico foi de 0,11 D no grupo multifocal e -0,18 D no grupo monofocal ($p=0,0379$). O grupo monofocal apresentou superioridade estatística na sensibilidade ao contraste em condições fotópicas ($p=0,014$) e mesópicas ($p=0,0044$) a 6 cpq quando comparada ao grupo multifocal. **Conclusão:** A lente intraocular multifocal apresentou menos aberrações esféricas comparada à lente intraocular monofocal, da prevista multifocalidade sem correção para longe e perto. Entretanto, o grupo multifocal apresentou baixa sensibilidade ao contraste.

Descritores: Lentes intraoculares; Implante de lente intraocular; Catarata; Facoemulsificação; Acuidade visual

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