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Modulation transfer function and optical quality after bilateral implantation of a +3.00 D versus a +4.00 D multifocal intraocular lens

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PURPOSE: To determine whether the improvement in intermediate vision after bilateral implantation of an aspheric multifocal intraocular lens (IOL) with a +3.00 diopter (D) addition (add) occurs at the expense of optical quality compared with the previous model with a +4.00 D add.

SETTING: Department of Ophthalmology, University of São Paulo, São Paulo, Brazil.

DESIGN: Prospective randomized double-masked comparative clinical trial.

METHODS: One year after bilateral implantation of Acrysof Restor SN6AD1 +3.00 D IOLs or Acrysof Restor SN6AD3 +4.00 D IOLs, optical quality was evaluated by analyzing the in vivo modulation transfer function (MTF) and point-spread function (expressed as Strehl ratio). The Strehl ratio and MTF curve with a 4.0 pupil and a 6.0 mm pupil were measured by dynamic retinoscopy aberrometry. The uncorrected and corrected distance visual acuities at 4 m, uncorrected and distance-corrected near visual acuities at 40 cm, and uncorrected and distance-corrected intermediate visual acuities at 50 cm, 60 cm, and 70 cm were measured.

RESULTS: Both IOL groups comprised 40 eyes of 20 patients. One year postoperatively, there were no statistically significant between-group differences in the MTF or Strehl ratio with either pupil size. There were no statistically significant between-group differences in distance or near visual acuity. Intermediate visual acuity was significantly better in the +3.00 D IOL group.

CONCLUSION: Results indicate that the improvement in intermediate vision in eyes with the aspheric multifocal +3.00 D add IOL occurred without decreasing optical quality over that with the previous version IOL with a +4.00 D add.

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The Acrysof Restor intraocular lens (IOL) (Alcon Laboratories, Inc.) was designed to achieve distance, intermediate, and near visual acuity without compromising visual performance.¹ After the introduction of the 3-piece model (MA60D3),² the first 1-piece spherical version (SA60D3),³ and the model with blue light-filtering chromophore (Acrysof Natural Restor SN60D3),⁴ an aspheric design was incorporated into the optic of the IOL (model SN6AD3)^{5–8} to provide better optical quality. The aspheric model has the same platform as the original spherical IOL; however, the symmetric biconvex design and an anterior aspheric optic were used with the aim of generating fewer higher-order aberrations (HOAs), and negative

spherical aberration was incorporated to compensate for positive corneal spherical aberration.^{5–8}

In an attempt to meet patient needs for more functional intermediate vision, a new IOL model (Acrysof Restor SN6AD1) was developed. This multifocal IOL has the same symmetric biconvex design and anterior aspheric optic but a lower addition (add). Findings in previous studies^{8–15} provide evidence that the +3.00 diopter (D) add version yields better intermediate vision and a more comfortable reading distance than the +4.00 D add version.

The aim of this study was to determine in vivo whether the improvement in intermediate vision after bilateral implantation of the aspheric multifocal IOL

with a +3.00 D add occurs at the expense of optical quality compared with that after bilateral implantation of the aspheric multifocal IOL with a +4.00 D add. To our knowledge, this is the first study to use *in vivo* analyses of optical quality parameters, such as the modulation transfer function (MTF) and point spread function (PSF) (expressed as the Strehl ratio), in patients with the +3.00 D add Acrysof Restor SN6AD1 IOL.

PATIENTS AND METHODS

This prospective randomized double-masked comparative clinical study^A included patients referred for cataract surgery. After approval by an institutional review board, patients older than 40 years of age with bilateral visually significant cataract were enrolled consecutively in a randomized fashion. The first patient recruited was asked to pick 1 of 2 cards to decide the type of IOL that would be bilaterally implanted. The next patient enrolled received the opposite of the previous patient. All patients provided informed consent, and the study adhered to the tenets of the Declaration of Helsinki.

Patients with bilateral visually significant cataracts with corneal astigmatism less than 1.0 D were eligible for inclusion in the study. Exclusion criteria were previous intraocular surgery and any ocular disease (eg, corneal opacity or irregularity, dry eye, amblyopia, glaucoma), retinal abnormalities, surgical complications, IOL tilt on slitlamp examination, IOL decentration greater than 0.4 mm estimated by retroillumination, and an incomplete follow-up.

Patients received Acrysof Restor SN6AD1 aspheric multifocal IOLs with a +3.00 D add or Acrysof Restor SN6AD3 aspheric multifocal IOLs with a +4.00 D add. The apodized diffractive 3.6 mm central area of the +4.00 D IOL consists of 12 concentric steps of gradually decreasing height, creating bifocality from near to far and providing +4.00 D of near add at the lens plane. The apodized diffractive 3.6 mm central area of the +3.00 D IOL consists of 9 concentric steps of gradually decreasing height. In addition, the center-most region of the 3.6 mm area is larger than in the +4.00 D add version (0.856 mm versus 0.742 mm), creating bifocality from near to far and providing +3.00 D near add at the lens plane.⁸⁻¹⁵

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Immersion ultrasound biometry (Ocuscan RxP, Alcon Laboratories, Inc.) was performed in all cases by the same experienced examiner. All eyes were targeted for emmetropia.

The same experienced surgeon performed all surgeries. The technique included standardized small-incision phacoemulsification and IOL implantation in the capsular bag.

The primary outcome measures were the MTF value and the PSF, expressed as Strehl ratio, 1 year after cataract surgery. Secondary efficacy measures included visual acuity at different distances.

Patients were examined preoperatively and 1, 7, and 30 days; 3 and 6 months; and 1 year postoperatively. This paper reports the 1-year postoperative results. The same observer, who was unaware of the objectives of the study, assessed visual acuity postoperatively. For distance vision, monocular uncorrected (UDVA) and corrected visual acuities were measured in logMAR scale at 100% contrast using Early Treatment of Diabetic Retinopathy Study (ETDRS) charts (Precision Vision) under photopic conditions (target luminance 85 candelas [cd/m^2] at 4 m. Monocular uncorrected near visual acuity and distance-corrected near visual acuity were measured using the Logarithmic Visual Acuity Chart 2000 New ETDRS (Precision Vision) at 40 cm under photopic conditions ($85 \text{ cd}/\text{m}^2$). Monocular distance-corrected intermediate visual acuity was measured at 50 cm, 60 cm, and 70 cm with the same chart used for near assessment; however, values were corrected for use of the 40 cm chart, as previously described.¹⁶ The visual acuity values were converted to logMAR notation for statistical analysis. Light conditions were controlled with a luxometer (Gossen-Starlite).

The pupil diameter was measured using a Colvard pupillometer (Oasis Medical) under photopic ($85 \text{ cd}/\text{m}^2$), mesopic ($3 \text{ cd}/\text{m}^2$), and low mesopic ($1.5 \text{ cd}/\text{m}^2$) conditions.

Higher-order aberrations were measured with an OPD-Scan aberrometer (Nidek Co., Ltd.), which uses dynamic skiascopy-based ocular aberrometry and Placido-disk corneal topography to obtain wavefront data. The aberrometer references the wavefront aberrations on the corneal vertex, not on the line of sight. In the dynamic skiascopy wavefront sensor, the retina is scanned with an infrared slit-shaped light beam and the reflected light is captured by an array of rotating photodetectors over a 360-degree area within the eye in 1-degree increments. The system scans up to 1440 points and studies the relationship between the light source and the reflected component. The time difference of the reflected light is used to determine the aberrations. The aberrometer software was used to obtain the MTF and the PSF, which was expressed as the Strehl ratio. The Strehl ratio is the ratio between the intensity of the real PSF and the intensity of the diffraction-limited PSF.

The MTF and the Strehl ratio were calculated based on the effect of the HOAs. The Strehl ratio was reported in logarithmic format (log Strehl). The mean MTF values were calculated in a logarithmic plot. Log base 10 contrast sensitivity values were used to construct a graph for each spatial frequency tested. The investigator and the patient were masked to which multifocal IOL had been implanted.

Measurements were repeated at least 3 times to obtain a well-focused, aligned image of the eye. Measurements were analyzed with a 4.0 mm pupil and a 6.0 mm pupil. After data were obtained under scotopic conditions, the pupils were dilated with 2 drops of cyclopentolate 1.0% administered 15 minutes apart. Measurements were taken 45 minutes after the last cyclopentolate drop was instilled.

Patients were asked to complete a questionnaire on lifestyle activities. The questionnaire, which has been described,¹⁰ is based on the subscales and the satisfaction scale of the National Eye Institute Visual Functioning Questionnaire-25.¹⁷ In this study, the questionnaire included questions about the difficulty the patient had reading standard newspaper print, reading the name and expiration date on an eyedrop bottle (type size Jaeger 3), and reading time on a watch. Spectacle independence was also measured using a previously published method.¹⁸ The visual disturbance and visual lifestyle activities rating scales were as follows: 0 = no difficulty; 1 = minimal difficulty; 2 or 3 = moderate difficulty; 4 = severe difficulty. The satisfaction scale ranged from 0 to 10 (1 = least satisfied; 10 = most satisfied). Patients also had the option of reporting each parameter as not applicable to them personally. The spectacle-use rating scale was as follows: always need spectacles, sometimes need spectacles, or never need spectacles. Patients were also asked whether they would have the same IOL implanted again.

Statistical analysis was performed using SPSS for Windows software (version 11.5, SPSS, Inc.). Normality was checked using the Kolmogorov-Smirnov test. When parametric analysis was not possible, the nonparametric Mann-Whitney *U* test was used to compare data between the 2 IOL groups. The analysis of primary outcome measures was based on non-normal distribution of the data. When parametric analysis was possible, the Student *t* test was used to compare the outcomes. Categorical variables were compared using the Fisher exact probability test. In this analysis, a sample size of at least 16 patients per group would allow an effect size of 0.85; these sample sizes took into account a significance level of 5% and a power of 95%. A sample size of 16 patients per group would allow detection of a minimum clinical relevant difference in postoperative visual acuity of 2 Snellen lines (10 letters) with a standard deviation of 0.15. All statistical tests were performed at an α level of 0.05.

RESULTS

Eighty eyes of 40 patients (17 men [42.0%], 23 women [58.0%]) were enrolled in this study. The +3.00 D IOL group comprised 12 women and 8 men and the +4.00 D IOL group, 11 women and 9 men. The 2 groups were comparable in age and sex. Table 1 shows the preoperative patient characteristics and the postoperative pupil size under various lighting conditions. There was no significant difference between the 2 IOL groups in any parameter. No patient was lost to follow-up.

There were no intraoperative complications. One year postoperatively, all IOLs were well centered, and no IOL was tilted. There were no cases of posterior capsule opacity, clinically significant cystoid macular edema, prolonged intraocular pressure increase, or prolonged corneal edema.

One year postoperatively, all eyes had an improvement in UDVA. At 1 year, the total mean postoperative SE refraction was 0.11 D \pm 0.15 (SD) in the +3.00 D IOL group and 0.12 \pm 0.16 D in the +4.00 D IOL group and the mean astigmatism was 0.34 \pm 0.31 D

Table 1. Patient characteristics.

Characteristic	Mean \pm SD		P Value
	+3.00 D IOL Group	+4.00 D IOL Group	
Age (years)	57.9 \pm 7.3	56.7 \pm 7.4	.483*
SE (D)	-0.16 \pm 0.57	-0.19 \pm 0.62	.898 [†]
CDVA (logMAR)	0.36 \pm 0.09	0.35 \pm 0.10	.684 [†]
K1 (D)	43.19 \pm 1.5	43.31 \pm 1.5	.784 [†]
K2 (D)	43.71 \pm 1.3	43.79 \pm 1.6	.837 [†]
IOL power (D)	21.31 \pm 2.0	21.47 \pm 2.5	.798 [†]
Axial length (mm)	22.19 \pm 2.1	22.35 \pm 2.3	.531 [†]
Corneal SA	0.29 \pm 4.2	0.30 \pm 3.1	.678 [†]
Postop pupil size (mm)			
Low mesopic (1.5 cd/m ²)	4.67 \pm 0.26	4.71 \pm 0.15	.880 [†]
Mesopic (3.0 cd/m ²)	4.23 \pm 0.45	4.19 \pm 0.45	.766 [†]
Photopic (85 cd/m ²)	3.58 \pm 0.35	3.56 \pm 0.40	.383 [†]

cd = candelas; CDVA = corrected distance visual acuity; IOL = intraocular lens; K = keratometry; SA = spherical aberration; SE = spherical equivalent

*Student *t* test

[†]Mann-Whitney *U* test

and 0.35 \pm 0.32 D, respectively. The differences between the 2 groups were not statistically significant ($P = .622$ and $P = .767$, respectively).

Table 2 shows the monocular visual acuity results at 1 year by IOL group. There were no statistically significant differences in distance or near visual acuity between the 2 IOL groups ($P > .05$). The +3.00 D IOL

Table 2. Monocular visual acuity 1 year after surgery.

Test Distance	Mean (LogMAR) \pm SD		P Value*
	+3.00 D IOL Group	+4.00 D IOL Group	
Distance (4 m)			
Uncorrected	0.032 \pm 0.07	0.023 \pm 0.12	.565
Corrected	-0.007 \pm 0.08	0.002 \pm 0.02	.475
Intermediate (70 cm)			
Uncorrected	0.172 \pm 0.11	0.232 \pm 0.22	.032 [†]
Distance corrected	0.182 \pm 0.10	0.222 \pm 0.20	.042 [†]
Intermediate (60 cm)			
Uncorrected	0.082 \pm 0.12	0.135 \pm 0.12	.012 [†]
Distance corrected	0.079 \pm 0.08	0.127 \pm 0.13	.025 [†]
Intermediate (50 cm)			
Uncorrected	0.045 \pm 0.07	0.115 \pm 0.15	.002 [†]
Distance corrected	0.032 \pm 0.06	0.092 \pm 0.09	.004 [†]
Near (40 cm)			
Uncorrected	0.022 \pm 0.08	0.027 \pm 0.02	.735
Distance corrected	0.005 \pm 0.06	0.022 \pm 0.02	.362

IOL = Intraocular lens

*Mann-Whitney *U* test

[†]Statistically significant result

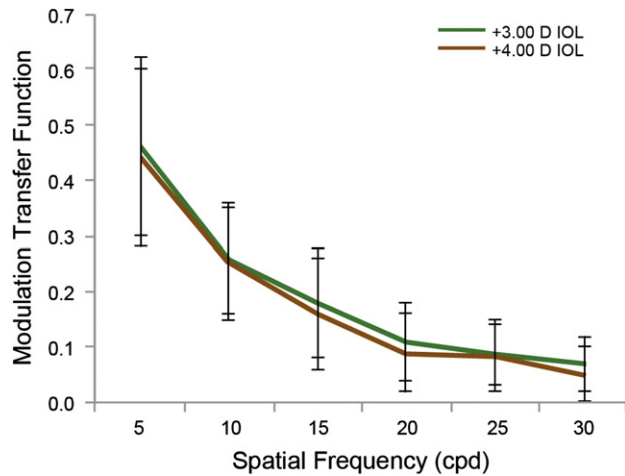


Figure 1. Modulation transfer function curve with a 4.0 mm pupil diameter at different spatial frequencies 1 year after surgery (cpd = cycles per degree; IOL = intraocular lens).

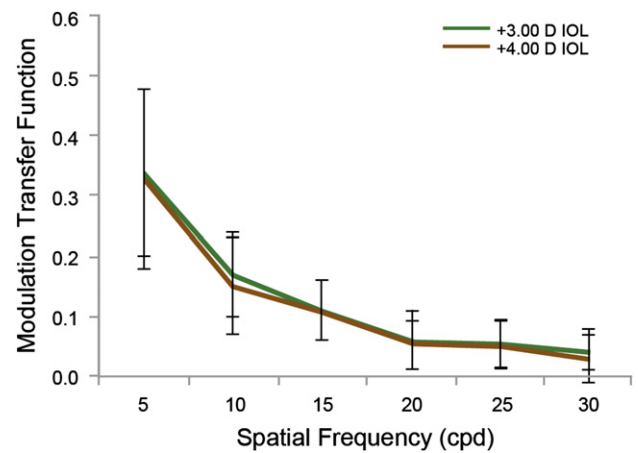


Figure 2. Modulation transfer function curve with a 6.0 mm pupil diameter at different spatial frequencies 1 year after surgery (cpd = cycles per degree; IOL = intraocular lens).

group had statistically significantly better intermediate acuity than the 4.00 D IOL group at all distances ($P < .05$).

Figure 1 shows the MTF function curves at different spatial frequencies with a 4.0 mm pupil, and **Figure 2** shows the curves with a 6.0 mm pupil. One year post-operatively, there were no statistically significant between-group differences at any spatial frequency with either pupil size ($P > .05$, Mann-Whitney *U* test).

Figure 3 shows the log Strehl values with a 4.0 mm pupil and a 6.0 mm pupil. At 1 year, there were no statistically significant between-group differences with either pupil size ($P = .564$ and $P = .435$, respectively; Mann-Whitney *U* test).

Table 3 shows the visual disturbance, visual activity, and patient satisfaction scores. There was no statistically significant difference in any score between the

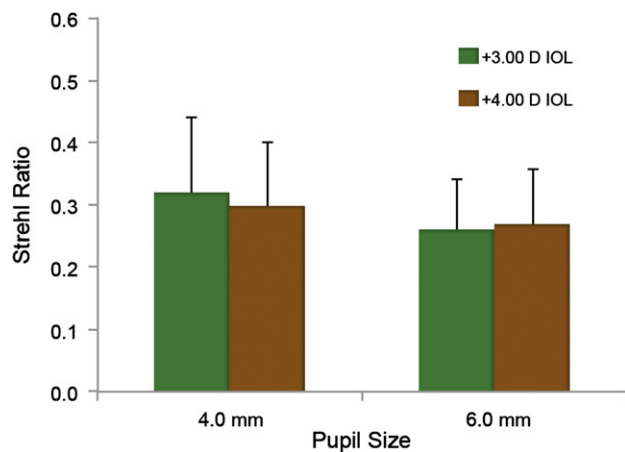


Figure 3. Point-spread function expressed as the Strehl ratio with a 4.0 mm pupil and a 6.0 mm pupil 1 year after surgery (IOL = intraocular lens).

2 IOL groups. Eighteen patients (90.0%) in both IOL groups said they never used spectacles for any distance. All patients in both groups said they would have the same IOL implanted again.

DISCUSSION

Both multifocal IOLs used in our study have proved to be effective for presbyopic patients.²⁻⁸ Previous studies⁸⁻¹⁵ report that the Acrysof Restor SN6AD1 aspheric multifocal IOL with a +3.00 D add provided better vision at intermediate distances than the multifocal IOL with the same platform but the higher add of +4.00 D (Acrysof Restor SN6AD3). To determine whether the lower add improves intermediate vision at the expense of optical quality, we analyzed 3 indicators of optical quality; that is, spherical aberration, the PSF, and the MTF.¹⁹⁻²³ To minimize bias, we used 2 multifocal IOL models of the same material and by the same manufacturer.

The major finding in this study was that the improvement in intermediate vision with the +3.00 D add IOL did not decrease optical quality compared with the +4.00 D add IOL. This confirms the hypothesis that the differences in the optic of the +3.00 D IOL (mainly the number of concentric steps and the center-most area) would not affect image quality.

We used the MTF and Strehl ratio as image-plane metrics to evaluate the optical quality at the fovea. The MTF defines how optical systems (the IOL in this study) modulate contrast sensitivity on a sinusoidal grating as a function of spatial frequency. No statistically significant differences between the +3.00 D IOL and the +4.00 D IOL were found. The PSF can theoretically be expressed through measurements derived from these functions, such as the width (blur circle

Table 3. Visual disturbance and visual lifestyle activity scores 1 year postoperatively in patients with bilateral IOLs (excluding items for which patients gave a score of minimum or no difficulty).

Parameter	Mean Score \pm SD		P Value*
	+3.00 D IOL Group	+4.00 D IOL Group	
Visual disturbance			
Halos	1.05 \pm 0.94	1.10 \pm 0.91	0.333
Glare	0.90 \pm 0.85	1.00 \pm 0.79	0.428
Night vision	1.00 \pm 0.91	1.20 \pm 0.95	0.162
Depth perception	1.15 \pm 0.93	1.10 \pm 0.85	0.333
Visual activity			
Using computer	1.25 \pm 0.96	1.30 \pm 0.97	0.162
Using cell phone	1.30 \pm 0.97	1.20 \pm 1.00	0.261
Reading watch	1.15 \pm 0.93	1.25 \pm 1.01	0.493
Driving at night	1.25 \pm 0.91	1.10 \pm 0.96	0.186
Driving in the rain	1.05 \pm 0.94	1.10 \pm 0.91	0.327
Satisfaction	8.50 \pm 0.94	8.35 \pm 1.08	0.453

IOL = intraocular lens

*Student *t* test

diameter) or height (Strehl ratio) of the intensity distribution.¹⁹ The Strehl ratio parameter theoretically evaluates IOLs over the whole frequency spectrum and is independent of the refractive power of the tested IOL.²⁰ In our study, no statistically significant differences between the 2 multifocal IOL models were found.

Moreno et al.²⁴ studied the MTF and PSF in patients with the Acrysof Restor SN6AD1 IOL or the Acrysof Restor SN6AD3 IOL. They found a significant correlation between the width of the PSF and the IOL power, showing that the optical quality was worse in eyes with the +4.00 D add IOL. The authors state that more powerful IOLs could have a more limited optical performance because of larger amounts of HOAs. Thus, the MTF cutoff frequency was inversely correlated with IOL power. In our study, there were no significant differences between groups with respect to IOL power. Therefore, IOL power had no influence on the PSF and MTF results in our study.

The difficulty obtaining data in eyes with diffractive IOLs had little effect on our results because ours was a comparative study of 2 diffractive IOLs of a very similar design. Therefore, the 2 groups we studied had the same limitations in terms of wavefront analyses. However, because wavefront measurement was not a primary outcome in the study, we decided not to consider the wavefront data.

The use of wavefront sensors in eyes with multifocal diffractive IOLs is challenging. Diffractive IOLs, by their nature, create discontinuities in the wavefront, yielding multifocal wavefronts. Large changes in optical power due to different wavelengths and the

division of light into more than a single order are intrinsic features of the diffractive elements of the IOL. When diffractive IOLs are implanted, a simultaneous-vision effect is created, with 2 wavefronts of different curvature emerging from the IOL. Most wavefront sensors measure the wavefront slope and then calculate the mean value of the slope to obtain the ocular wavefront. However, integrating a function results in an extra constant term. Commercial wavefront sensors assume that this constant provides a smooth, continuous wavefront.²⁵

Because in theory multifocal IOLs provide 2 emergent wavefronts, it is reasonable to ask which wavefront the aberrometer device actually obtains and measures. As Charman et al.²⁶ discussed, if there is a point source on the patient's retina, as provided for example in a Hartmann-Shack aberrometer, theoretically 2 wavefronts will emerge from the eye; that is, a regular (flat) wavefront produced by the distance correction and a converging spherical wavefront produced by the diffractive near addition. The aberrometer sensor will detect and record 2 superimposed spot patterns. One will be undistorted, indicating an aberration-free emmetropic eye, and the other will show progressively greater radial displacement of the spots toward the axis as the zonal radius increases, indicating a myopic eye. However, the results of the refraction generated by the wavefront are also a measurement of refraction for distance and not for near. This was confirmed in part by the refraction results obtained from the wavefront devices showing that they measure distance.²⁶

A main practical drawback of Zernike polynomials is that when considering asymmetric ocular optics (eg, multifocal IOLs), the polynomials cannot accurately represent the optical properties, resulting in an inadequate description of the eye's image-forming properties. Other metrics for quantifying the optical quality of the eye and predicting image optical quality at the fovea, such as MTF and Strehl ratio, may be more accurate in evaluating asymmetric optics.^{26,27}

The responses on the patient questionnaires were correlated with the visual findings for far and near because both patients in both groups reported a high level of satisfaction and a high level of spectacle independence. On the other hand, both groups had similar levels of visual disturbance. One year postoperatively, the incidence of symptoms, such as halos and glare, was lower than that reported by Kohnen et al.¹⁰ 6 months after surgery. These results provide evidence that visual disturbances attributed to multifocal optics often decrease in the year following surgery.

In summary, based on our findings, we believe that the improvement in intermediate vision with the Acrysof Restor SN6AD1 aspheric multifocal IOL with a +3.00 D add does not occur at the expense of optical

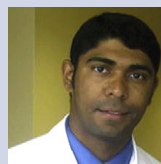
quality compared with the previous version with a higher add of +4.00 D (Acrysof Restor SN6AD3).

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