Long-term Visual Function and Patient Satisfaction After Bilateral Implantation and Combination of Two Similar Multifocal IOLs

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ABSTRACT

PURPOSE: To evaluate the visual outcome, spectacle independence, and patient satisfaction after implantation of two Acrysof ReSTOR (Alcon Laboratories, Inc., Fort Worth, TX) intraocular lenses (IOLs) with different addition power or their combination in both eyes.

METHODS: One hundred twenty eyes of 60 patients with bilateral multifocal IOL implantation were divided into three groups of 20 consecutive patients each: the SV25T0 (the T0 group), the SN6AD1 (the D1 group), or a combination of both the SN6AD1 and SV25T0 (the combined group). Patients were observed 18 months postoperatively for visual acuity (40, 50, and 60 cm, and 4 m), defocus curves (range: +1.0 to -4.0 diopters), and contrast sensitivity. Quality of vision, patient satisfaction, and spectacle independence were evaluated by the National Eye Institute Refractive Error Quality of Life Instrument-42 questionnaire.

RESULTS: The D1 group achieved better results for near vision \( (P < .01) \), whereas the T0 group achieved better intermediate vision \( (P = .01) \). The combined group showed a wider range of spectacle independence at all distances evaluated \( (P < .05) \). The contrast sensitivity was similar within the groups. The incidence of glare was lower for the T0 group \( (P = .054) \). The combined group had better results in terms of expectation \( (P = .021) \) and activity limitation \( (P = .003) \).

CONCLUSION: Although the bilateral implantation of the same multifocal IOL can maximize the vision for near or intermediate distances, the combination of these IOLs in both eyes can increase the range of spectacle independence without compromising the contrast sensitivity and quality of vision.


Recently, several different IOLs have been developed to extend the range of functional vision and to correct presbyopia. Although these IOLs were reported to achieve good visual outcomes without the use of corrective lenses, optical side effects, such as decreased contrast sensitivity, glaring, and halos, were observed.1-4

Two models of Acrysof ReSTOR IOLs with different addition power are currently available: the SN6AD1 +3.0 diopters (D) lens and the SV25T0 +2.5 D lens. Both IOLs have an outer refractive zone and a central zone of 3.6- and 3.4-mm diameters, respectively, with an apodized diffractive surface. The diffractive zone consists of concentric steps of gradually decreasing height from the center to the periphery, creating multifocality. The SN6AD1 has 9 steps and a +3 D addition power for near vision. The SV25T0 has 7 steps and a +2.5 D addition power. The refractive part of the lens was created for distance vision.2,5,6 Because the pupil enlarges, the portion of light directed to the near focal point decreases, whereas the light directed to the distant focal point increases. The IOL performs as a distance-dominant lens when the viewer focuses on a distant object and as a near-dominant lens when the viewer focuses on a near object. The alternative image becomes defocused in both conditions, but this can cause a reduction of contrast sensitivity and the production of glare and halos.2

Several studies demonstrated that bilateral implantation of the SN6AD1 IOL provides good near visual acuity and good distance vision, but it does not perform well in terms of intermediate visual acuity and produces a perceivable loss of contrast sensitivity.2,3,6,7 On the other hand, the...
SV25T0 IOL has a lower addition for near vision and should allow for good intermediate visual acuity and distance vision, although this lens might not perform as well in terms of near visual acuity as the SN6AD1 IOL. Furthermore, thanks to a larger central button and smaller/lower steps, this lens should permit a higher visual quality and contrast sensitivity with fewer symptoms in terms of visual disturbance. A recent study compared the SN6AD1 and SV25T0 IOLs to evaluate lens performance through monocular measurements. The current study aimed to compare the binocular visual acuity and quality of vision, spectacle independence, and satisfaction in three groups of patients: one bilaterally implanted with the SN6AD1 IOL, one bilaterally implanted with the SV25T0 IOL, and a combination implanted with the SN6AD1 IOL in one eye and with the SV25T0 IOL in the fellow eye.

**PATIENTS AND METHODS**

**Study Design**

This prospective nonrandomized single-blind observational study comprised 60 patients affected by bilateral senile cataract who underwent extraction and multifocal IOL implantation. The Department of Neurological and Movement Sciences of the University Hospital of Verona approved the study and deemed submission/approval by our local ethics committee not necessary because patient care would not be modified by the study protocol. This study was conducted in accordance with the tenets of the Declaration of Helsinki.

Patients were divided into three groups of 20 consecutive patients. The T0 group received the SV25T0 IOL in both eyes, the D1 group underwent bilateral implantation of the SN6AD1 IOL, and the combined group received the SV25T0 IOL in one eye and the SN6AD1 IOL in the contralateral eye. In the combined group, the SV25T0 IOL was always implanted at the time of first surgery and the SN6AD1 IOL in the contralateral eye. Patients were unaware of which eye had the SN6AD1 or SV25T0 IOL.

The inclusion criteria were age between 50 and 70 years and patients’ desire for spectacle or contact lens independence for distance and near vision. Exclusion criteria were corneal astigmatism greater than 1.00 D, myopia greater than 6.00 D, amblyopia, previous anterior or posterior segment surgery, and history of other ocular pathologies impairing visual function. Patients with myopia greater than 6 D were excluded (in case of long axial length, which can cause high myopic defects) to reduce the risk of an incorrect IOL calculation and a less accurate refractive outcome.

Before surgery, all patients underwent a complete ophthalmologic examination including manifest refraction, slit-lamp evaluation, tonometry, and funduscopy. Corneal topography and an evaluation of the pupil size were performed using the C.S.O. Eye-Top topographer (Costruzione Strumenti Oftalmici S.R.L., Scandicci, Italy). Furthermore, the stereopsis was investigated with the Lang stereotest I containing a car, star, and cat (disparities: car = 550, star = 600, and cat = 1,200 seconds of arc) at a distance of 40 cm, with near best correction. Only patients with a positive result (correctly localized and named all hidden objects) during the Lang stereotest were included in the study. Axial length was measured with the IOLMaster (Carl Zeiss Meditec, Jena, Germany) and IOL spherical power was calculated using the SRK-T formula with targeted refraction for emmetropia.

Patients were assigned to a group after they were interviewed on their lifestyle habits, job, and daily activities, such as working at a computer, reading, watching television, and driving a car at day or night. All patients were informed about the characteristics of the IOLs, expected performance outcomes in terms of visual acuity, and the possibility of becoming spectacle independent following surgery. The choice of lens (SN6AD1, SV25T0, or combination) was based on their responses and the final choice was always left to the patient. After receiving an explanation of the nature and possible consequences of the surgical procedure, all patients provided a written informed consent.

Patients were observed postoperatively with the best standard patient care. They were also evaluated postoperatively at 18 months following a specific study protocol. The same ophthalmologist (RM), who was blinded to which IOL was implanted, performed all functional examinations.

**Surgical Technique**

All cataract extractions were performed by the same experienced surgeon (EP) under topical anesthesia (lidocaine) using a standardized procedure consisting of sutureless phacoemulsification with 2.2-mm clear corneal incision. A continuous curvilinear capsulorhexis smaller than the IOL optic was created (ideally with a 0.5-mm overlap). Postoperative topical therapy included topical netilmicin, dexamethasone, and bromfenac.

**Visual Performance Assessment**

Binocular uncorrected and corrected visual acuity was measured at 4 m for distance, 50 and 60 cm for intermediate, and 40 cm for near. All visual acuities were assessed using standard high contrast logMAR (Early Treatment Diabetic Retinopathy Study).
**DEFOCUS CURVE**

Defocus curves were obtained by measuring the binocular visual acuity when reading a logMAR chart at 4 m. Evaluations were performed for uncorrected visual acuity and after correcting the patient for best distance visual acuity in both eyes, while viewing the distant chart. This was the “zero” mark and represented a peak for all lenses tested. Correction for best distance was necessary to remove variability due to residual refractive errors. To produce defocusing, a sequential progression of lenses with an increment of 0.50 D were used one at a time. The range of this sequence was from +1.0 to -4.0 D. At each step, visual acuity was measured. The relationship between lens vergence and distance defocus was the key to interpreting the resultant defocus curve. Viewing a distant object through a -1.00-D lens is optically equivalent to viewing an object at 1 m, and viewing a distant object through a -4.0-D lens is optically equivalent to viewing an object at 25 cm. The defocus curve provides an objective measure of expected vision at different distances.

**CONTRAST SENSITIVITY**

Contrast sensitivity is the lowest contrast level that could be detected by a patient for a given size target. In this study, the binocular contrast sensitivity at 3, 6, 12, and 18 cycles per degree were assessed using a CSV-1000 chart (Vector Vision, Greenville, OH) without dazzle, ensuring the best visual acuity with or without lens correction. To plot the curve, we converted the results in log units using a specific table for the CSV-1000.11

**POSTERIOR CAPSULE OPACIFICATION ASSESSMENT**

A third ophthalmologist (GP) acquired digital photographs with retroillumination and a video slit lamp. These images were used to evaluate posterior capsular opacification. The intensity of central posterior capsular opacification (behind the IOL optic) was subjectively scored by the same ophthalmologist using a scale from 0 to 4 (0 = none, 1 = minimal, 2 = mild, 3 = moderate, and 4 = severe).8

**SATISFACTION AND SPECTACLE INDEPENDENCE**

All patients completed the Italian version of the National Eye Institute Refractive Error Quality of Life Instrument-42 (NEI RQL-42) questionnaire during the 18-month follow-up visit. The results were collected and evaluated anonymously without patient-identifying information. The survey responses were scored according to the NEI RQL-42 version 1.0 manual.12 The answers were converted into a 100-point scale, where higher scores indicated a higher self-reported quality of life. Each subscale consisted of one or more questions and, therefore, each subscale score was the average of those questions specific to that subscale.12,13

**STATISTICAL ANALYSIS**

Sample size estimates for the study were based on the primary outcome measure of visual acuity at the 18-month follow-up. For α = 0.05 and β = 0.85, a sample size of 19 patients per group was sufficient to detect mean differences of one standard deviation or greater with Student’s t test. Anticipating a 5% loss to follow-up over the original 18-month duration of the study, we enrolled 20 patients per group.

All statistical tests were evaluated at a two-sided alpha level of 0.05. Statistical analysis was performed using SPSS 20.0 (IBM, Armonk, NY).

The presence of statistically significant differences between the three groups was evaluated with one-way analysis of variance. Post-hoc comparisons between the three groups were performed with the Mann–Whitney test or Tukey test.

**RESULTS**

The mean patient age was 60.6 ± 5.7 years (range: 50 to 70 years); there were 32 men and 28 women. Table 1 shows the patient characteristics of the three groups. None of the patients presented a lack of stereopsis on the Lang stereotest. The three groups did not present statistically significant differences in terms of age, ratio of men to women, spherical equivalent, or pupil diameter. All surgical procedures were uneventful, and all IOLs were implanted in the capsular bag. The mean interval between surgical procedures of the first and second eyes was 42.8 ± 11.3 days (range: 25 to 62 days).

All reported data are those obtained at the 18-month follow-up visit after the second eye surgery. None of the patients were lost during follow-up. Five patients developed a significant posterior capsule opacification (two mild and three moderate), which required a Nd:YAG laser posterior capsulotomy. In no case was IOL tilt or decentration observed either with an intact capsule or after capsulotomy.

Table 2 shows the postoperative binocular visual acuity outcomes. In terms of uncorrected near visual acuity, the D1 group achieved the best results at a distance of 40 cm. The difference in the results obtained in the T0 group compared to both groups was statistically significant (P < .001). The combined group showed a slightly lower visual acuity than the D1 group (P = .004), but better than the T0 group (P < .001). The T0 group showed the best performance in terms of uncorrected intermediate visual acuity, whereas statistically significant differences at 50 cm were observed only between the D1 group and the other two groups (P =
.008 and .002). Statistically significant differences at 60 cm were observed between the D1 group and T0 group (P < .001) and the combined group showed a higher visual discrimination compared to the D1 group (P < .001). All groups showed an excellent uncorrected visual acuity. No statistically significant differences were found in terms of corrected near, intermediate, and distance visual acuity.

The total mean postoperative sphere was 0.07 ± 0.43 D in the combined group, 0.15 ± 0.36 D in the T0 group, and -0.03 ± 0.41 D in the D1 group. A one-way analysis of variance between patients to compare the effect of group on postoperative sphere indicated that there was not a significant difference between means at the P < .05 level for the three conditions [F (2.57) = 0.464, P = .631]. The mean astigmatism was -0.39 ± 0.47, -0.45 ± 0.38, and -0.32 ± 0.43 D, respectively. A one-way analysis of variance between patients to compare the effect of group on postoperative astigmatism indicated that there was not a significant difference between means at the P < .05 level for the three conditions [F (2.57) = 0.462, P = .633]. No patient required an excimer laser enhancement after surgery.

The binocular defocus curves showed that all groups produced the full range of vision from near to distance (Figure 1). The combined, T0, and D1 groups presented two logMAR peaks at 0 D and either -2, -2, or -2.5 D, respectively. Nevertheless, in the combined group a wider range of good visual acuity was observed (logMAR < 0.01 [range: -1.5 to -2.5 D]). The near peak was approximately 40 cm for the D1 group, whereas the intermediate peak was approximately 66 cm for the T0 group. The distance peaks in all groups showed a mean distance visual acuity better than 0.05 logMAR.

Figure 2 shows the contrast sensitivity results. No statistically significant differences between the three groups were observed at any cycles per degree. Evaluation of the NEI RQL-42 questionnaire showed statistically significant differences between the three groups for the expectations (P = .019), activity limitations (P = .009), and appearance (P = .046) subscales (Figure 3). Post-hoc evaluation indicated that the combined group was significantly better in terms of expectation and the activity limitations domain compared to the T0 group (P = .021) and the D1 group (P = .003), respectively. In terms of glare, the T0 group showed the best results (P = .054; trend toward statistically significant). Statistically significant differences were not found for the other 10 subscales.

**DISCUSSION**

In this study, the evaluation of a group of patients implanted with multifocal IOLs with different near powers was performed to assess whether a wider range of vision was achievable. Patients implanted with the IOL with higher additional power performed better for near distances with the best uncorrected visual acuity between 30 and 40 cm, whereas the group implanted with a lower additional power showed a high rate of spectacle independence at 60 cm. The combined group showed a wider range of spectacle independence with satisfactory results at all distances and a good visual acuity was observed from 40 to 60 cm. All three groups showed a good distance visual acuity.

The concept of combining different technologies of multifocal IOLs has been extensively discussed. Jacobi et al. introduced and developed the concept of asymmetrical bilateral multifocal IOL implantation.14

The mix and match technique consists of the combination of refractive and diffractive multifocal IOLs in an attempt to achieve the best benefit from both technologies, resulting in a better quality of vision along with a wider range of spectacle independence. Traditionally, refractive multifocal IOLs perform better for intermediate than for near distance.15,16 Thus, refractive multifocal IOLs are usually combined with a diffractive multifocal IOL in the non-dominant eye. Studies have shown how the concept of mixing and matching multifocal IOLs allows a wide range of vision at different distances with a high level of patient satisfaction.15,17,18 However, the main shortcoming of refractive multifocal IOLs seems...
to be the higher rate of photic phenomena compared to the diffractive multifocal IOLs.\textsuperscript{19} This drawback can penalize the mix and match technique in terms of quality of vision and patient satisfaction. Similarly, the mini-monovision strategies consist of the implantation of a refractive multifocal IOL in the dominant eye, leaving the non-dominant eye slightly myopic after IOL implantation to increase visual function at near distances. Vice versa, diffractive multifocal IOLs have been combined with mini-monovision strategies to increase visual function at intermediate distances.\textsuperscript{17,20} The introduction of diffractive multifocal IOLs with lower near additions yielded better results at intermediate distance without decreasing near and distance visual acuity.\textsuperscript{6,7,22}

![Figure 1](image1.png)

**Figure 1.** Mean binocular defocus curves 18 months postoperatively. \( * = P < .05 \) (one-way analysis of variance); Mix = combined group; 2.5 = the T0 group; 3.0 = the D1 group

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Combined Group</th>
<th>T0 Group</th>
<th>D1 Group</th>
<th>ANOVA Combined Group vs T0 Group</th>
<th>ANOVA Combined Group vs D1 Group</th>
<th>ANOVA T0 Group vs D1 Group</th>
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<tr>
<td>Uncorrected</td>
<td></td>
<td></td>
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<tr>
<td>40 cm</td>
<td>0.100 ± 0.046</td>
<td>0.192 ± 0.067</td>
<td>0.049 ± 0.058</td>
<td>&lt; .001</td>
<td>&lt; .001</td>
<td>&lt; .001</td>
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<tr>
<td>50 cm</td>
<td>0.045 ± 0.051</td>
<td>0.034 ± 0.056</td>
<td>0.108 ± 0.077</td>
<td>&lt; .001</td>
<td>0.001</td>
<td>0.002</td>
</tr>
<tr>
<td>60 cm</td>
<td>0.060 ± 0.050</td>
<td>0.044 ± 0.058</td>
<td>0.138 ± 0.063</td>
<td>&lt; .001</td>
<td>&lt; .001</td>
<td>&lt; .001</td>
</tr>
<tr>
<td>4 m</td>
<td>0.105 ± 0.084</td>
<td>0.104 ± 0.089</td>
<td>0.113 ± 0.087</td>
<td>.937</td>
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ANOVA = analysis of variance

\( ^{\text{a}} \)Expressed as logMAR

In terms of quality of vision, the concepts of loss of contrast sensitivity and side effects were previously discussed and identified as the main drawback in patients implanted with multifocal IOLs.\textsuperscript{5}

Madrid-Costa et al. conducted a comparative study of the optical quality of three different multifocal IOLs: the SN6AD1, SV25T0, and a trifocal IOL AT LISA tri 839 MP (Carl Zeiss Meditec, Dublin, CA).\textsuperscript{21} They evaluated, in vitro, the contrast sensitivity in terms of modulation transfer function. Modulation transfer function is an objective measurement of contrast sensitivity representing the loss of contrast produced by the optics of the eye on a sinusoidal grating as a function of spatial frequency.\textsuperscript{24} The SV25T0 IOL achieved a
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better contrast sensitivity for distance vision compared to the SN6AD1 IOL. The authors explained that this result was most likely due to the design of the lens, aimed at retaining more light for far vision. Pedrotti et al. evaluated the modulation transfer function of the SN6AD1 IOL and SV25T0 IOL using a Hartmann Shack aberrometer.9 They did not find a statistically significant difference between IOLs. In our study, the contrast sensitivity showed similar results between the three groups. Further studies with a larger number of patients are required to elucidate this concept.

In our study, patient satisfaction was evaluated by the NEI RQL-42 questionnaire. The Visual Function-14, the National Eye Institute Visual Functioning Questionnaire, and the Activity of Daily Vision Scale were used previously to assess the benefit of cataract surgery.25,26 This questionnaire was chosen because it incorporates items that evaluate glare symptoms and night driving, which are related with the impact of spherical aberration on the patient’s quality of life. The lower rate of glare showed in this study by the T0 group could be related to the different distribution of light to distance and near foci with varying pupil size caused by the lower number and wider steps of this IOL. Gundersen and Potvin hypothesized that the higher ratio of distant to near light produced by the SV25T0 IOL design could improve the overall quality of vision.8 They did not find a statistically significant difference between the SN6AD1 IOL compared to the SV25T0 IOL in terms of quality of vision. The combined group achieved the best results in terms of expectation and activity limitation, supporting the hypothesis that combining these two IOLs helps patients obtain a larger spectrum of activity. The other subscales showed similar results between the groups. These results were probably due to the limited design differences between the two lenses that have the same basic structure and are made of the same material. In no case did the patients request an IOL exchange. The good level of satisfaction in all three groups confirms the importance of an accurate preoperative assessment where a proper discussion with the patients about their needs and the explanation of the possibility of side effects and of the neuroadaptation period result are essential.

The results of this study are possibly biased by the choice of not considering the ocular dominance in the combined group, implanting all patients with the lower addition IOL at first surgery. Previous studies established the importance of the eye dominance in monovision because the patients’ acceptance rate results in better correction of the dominant eye for distance vision and the non-dominant eye for near vision.27 In this study, it was not possible to establish eye dominance because, to our knowledge, an infallible method to define the dominant eye in patients affected by bilateral cataract has not been reported in the literature. Another limitation of this study is the lack of a comparison with a group bilaterally implanted with a trifocal IOL. This could be critical to assess the differences in terms of intermediate visual acuity and quality of vision, mainly if compared with the combined group. Further limitations are the relatively long gap between surgeries, the non-randomization of patients within the groups, and the limited number of patients. Studies with larger samples and randomized groups are required to confirm the results of this study.

The combination of these two diffractive multifocal IOLs that only differ in design for addition power can improve vision for near or intermediate distances compared to the bilateral implantation of either lenses. The minimal difference induced by the combination does not
not seem to be influenced by the quality of vision and patient satisfaction. Thus, combining these two different multifocal IOLs should be considered a valid option when patients wish to reduce their dependence on spectacles following cataract surgery. Achieving an absolute spectacle independence by combining different IOLs will probably require numerous progressive studies to determine the physiologically acceptable limits for lens differences.

**AUTHOR CONTRIBUTIONS**

Study concept and design (RM, EP, GM); data collection (RM, MP, GP, IM); analysis and interpretation of data (RM); writing the manuscript (RM, EP); critical revision of the manuscript (RM, EP, MP, GP, IM, GM); supervision (RM, GM)

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