

Long-term follow-up of a multifocal apodized diffractive intraocular lens after cataract surgery

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PURPOSE: To report the long-term performance of the AcrySof ReSTOR SA60D3 intraocular lens (IOL) after cataract surgery.

SETTING: University Hospital Maastricht, Maastricht, The Netherlands.

METHODS: This prospective clinical trial comprised 44 eyes (22 consecutive patients) having cataract surgery with implantation of the ReSTOR IOL. Monocular and binocular uncorrected distance visual acuity, best corrected distance visual acuity, uncorrected near visual acuity, best distance-corrected near visual acuity, spectacle dependence, undesired visual symptoms, patient satisfaction, and incidence of posterior capsule opacification were analyzed 6 months and 3 years postoperatively.

RESULTS: The mean uncorrected distance acuity (logMAR) was 0.046 ± 0.099 at 6 months and 0.115 ± 0.173 at 3 years and the mean best corrected distance acuity, -0.040 ± 0.075 and -0.018 ± 0.093 , respectively. Binocular uncorrected and best-corrected near acuities (logMAR) were 0.009 ± 0.029 at 6 months and 0.014 ± 0.035 at 3 years. All patients achieved a binocular uncorrected and best distance-corrected near acuity of 20/25 or better at 6 months and 3 years. On a quality-of-life questionnaire, patients reported good distance, intermediate, and near acuity without complaints of severe glare or halos. Complete spectacle independence for distance and near acuity was achieved by 83.7% and 81.9% of patients, respectively, at 6 months and 85.0% and 75.0% of patients, respectively, at 3 years. Four eyes (9.1%) required neodymium:YAG capsulotomy.

CONCLUSIONS: Cataract surgery with the AcrySof ReSTOR SA60D3 IOL provided good, stable distance and near visual acuities over a 3-year follow-up, leading to low spectacle independence and high patient satisfaction.

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The visual performance of patients after cataract extraction is greatly dependent on the choice of intraocular lens (IOL). Although monofocal IOLs provide excellent visual function, for many patients the limited depth of focus does not allow clear vision at both distance and near. Pseudoaccommodating IOLs were developed to offer pseudophakic patients the possibility of satisfactory distance and near vision and independence from spectacles.^{1,2} Multifocal IOLs, which use refraction^{3–5} or diffraction,^{6–9} and accommodating¹⁰ IOLs were developed to provide patients with spectacle independence. The AcrySof ReSTOR SA60D3 IOL (Alcon Laboratories) incorporates a hybrid diffractive–refractive concept that has been shown to result in good visual outcomes after cataract,^{11–20} clear lens,²¹ or piggy-back²² IOL surgery. Previous studies have examined

the visual outcomes over a short period (1.5 to 12.0 months); however, to our knowledge, no long-term studies of this type of IOL are available.

The purpose of this study was to assess the visual performance 3 years after cataract surgery with bilateral implantation of the AcrySof ReSTOR SA60D3 IOL.

PATIENTS AND METHODS

Study Design

This prospective study comprised 44 eyes of 22 consecutive patients who had cataract surgery and bilateral implantation of the AcrySof ReSTOR SA60D3 multifocal IOL at the University Hospital Maastricht, The Netherlands, between December 2003 and November 2004. The tenets of the Declaration of Helsinki were followed, and full ethical approval was obtained from the University Hospital Maastricht.

Informed consent was obtained from all patients after a full explanation of the nature and possible consequences of the study and surgery was given. Patients were considered for participation if they were between 43 years and 85 years of age, required binocular IOL implantation, and were motivated to achieve spectacle independence. Exclusion criteria included preoperative astigmatism greater than 2.00 diopters (D), occupational night driving, history of glaucoma or retinal detachment, corneal disease or previous corneal or intraocular surgery, abnormal iris or pupil deformation, macular degeneration or retinopathy, neuro-ophthalmic disease, and a history of ocular inflammation.

Intraocular Lens Characteristics

The AcrySof ReSTOR SA60D3 multifocal IOL uses apodization, diffraction, and refraction. The apodized diffractive region of the IOL, situated within the central 3.6 mm optic zone, comprises 12 concentric steps of gradually decreasing (1.3 to 0.2 mm) height, creating multifocality from distance to near (2 foci). The refractive part of the optic surrounds the apodized diffractive region. This area directs light to a distance focal point for larger pupil diameters and is dedicated to distance vision. The overall diameter of the IOL is 13.0 mm, and the optic diameter is 6.0 mm. The IOL power used in this study ranged from +17.00 to +25.00 D and incorporated a +4.00 D near addition power at the IOL plane, or about +3.25 D at the corneal plane.¹²

Preoperative Examination

Before cataract surgery, patients had a full ophthalmologic examination including manifest refraction, keratometry, slitlamp biomicroscopy, Goldmann applanation tonometry, and binocular indirect ophthalmoscopy through a dilated pupil. Axial length and anterior segment size were measured using the IOLMaster (Carl Zeiss). The SRK/T formula was used for IOL power calculation, and the targeted refraction was emmetropia.

Surgical Technique

All surgeries were performed by the same experienced surgeon (R.N.) using phacoemulsification with the Legacy coaxial phaco machine (Alcon Laboratories), topical anesthesia, and a 3.0 mm clear corneal incision along the steep corneal meridian. Phacoemulsification was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag.

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Parameters

LogMAR visual acuity charts were used for vision testing. For uncorrected distance visual acuity and best corrected distance visual acuity, patients were tested using the 100% contrast Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Precision Vision) under photopic lighting conditions. Uncorrected near visual acuity and best distance-corrected near visual acuity measurements were obtained using a handheld near logMAR chart at a standard distance of 33 cm. Binocular intermediate distance-corrected visual acuity was tested at 60 cm.

Contrast sensitivity function was determined using the CSV-1000 system (Vector Vision, Inc.). This instrument consists of a translucent chart with background illumination calibrated at 85 cd/m², thereby providing independence from room illumination. Examinations were performed unilaterally with best spectacle refractive correction in place, if applicable, and with an undilated pupil. Absolute values of log contrast sensitivity function were obtained for each combination of eye and spatial frequency, and means and standard deviations were calculated. Results were compared with population norms from a 50-year to 75-year age group.²³ In addition, absolute values were normalized for each spatial frequency by dividing the mean log contrast sensitivity function through the mean log contrast sensitivity function from the population norm, as described previously.²⁴

Intraocular lens decentration was determined by measuring the distances between the center of the diffractive structure and the center of the pupil on the vertical and horizontal axes using a slitlamp (Haag-Streit). A difference of 0.5 mm or more between the 2 distances on 1 axis was considered to represent significant IOL decentration.

An assessment of patient satisfaction, visual phenomena, and spectacle dependency was performed at the 6-month and 3-year postoperative visits. Patients rated the quality of vision without spectacles for distance, near, and intermediate vision on the following scale: 1 = excellent; 2 = good; 3 = satisfactory; 4 = not so good; 5 = bad. Items related to intermediate vision tasks were the capability to perform fine handiwork, games, or cooking, which patients rated on the following scale: 1 = no problem; 2 = a little difficult; 3 = quite difficult; 4 = very hard; 5 = impossible. Patients rated visual disturbances (eg, glare and halos) on the following scale: 1 = severe; 2 = moderate; 3 = mild; 4 = none. To assess spectacle dependency, patients were asked about their requirement for spectacle wear at distance and near vision on the following scale: 1 = always; 2 = most of the time; 3 = quite often; 4 = some of the time; 5 = never.

Postoperative assessments were routinely performed at 1 week, 1, 3, and 6 months, and 3 years after the surgery. The 6-month and 3-year examinations were performed by the same ophthalmic technician, who was unaware of the objective of the study.

Statistical Analysis

Data analysis was performed using SPSS for Windows (version 14.0, SPSS, Inc.). Normality was checked by the Shapiro-Wilk test, and the *t* test was performed to compare outcomes at 6 months and 3 years. Differences were considered to be statistically significant when the *P* value was less than 0.01.

RESULTS

The mean age of the 22 patients was 74.2 years \pm 8.7 (SD) (range 43 to 85 years). Table 1 shows the patients' demographics. All patients completed the 3-year follow-up.

Visual Outcomes

Table 2 shows the mean and distance and near visual acuities 6 months and 3 years after surgery.

Distance Visual Acuity At 3 years, all patients had a binocular best corrected distance acuity of 20/40 or better and 95%, of 20/25 or better. No statistically significant differences were found between the 6-month and 3-year visits in monocular and binocular uncorrected distance acuity and best corrected distance acuity ($P > .01$) (Table 2).

Near and Intermediate Visual Acuity At 3 years, all patients had monocular best distance-corrected near acuity and binocular uncorrected and best distance-corrected near acuity of 20/25 (Table 2). No statistically significant differences were found between the 6-month and 3-year visits in near acuity under monocular and binocular conditions ($P > .01$). Binocular distance-corrected intermediate vision was 0.357 at 3 years.

Refractive Changes

Table 3 shows the postoperative refractive results. There was no statistically significant difference between the 6-month and 3-year results ($P > .1$). The spherical equivalent (SE) was 0.14 ± 0.34 D at 6

months and 0.09 ± 0.37 D at 3 years ($P = .22$). Emmetropia was achieved in 43.2% of eyes at 6 months and 45.5% at 3 years. At 3 years, 90.9% of eyes were within ± 0.50 D and all eyes were within ± 1.00 D.

Contrast Sensitivity

Six months postoperatively, the mean postoperative monocular best-corrected contrast sensitivity was 1.62 ± 0.26 log units at 3 cycles per degree (cpd), 1.76 ± 0.41 log units at 6 cpd, 1.32 ± 0.37 log units at 12 cpd, and 0.91 ± 0.29 log units at 18 cpd. The mean normalized contrast sensitivity was 1.04, 0.98, 0.88, and 0.98 at 3 cpd, 6 cpd, 12 cpd, and 18 cpd, respectively. Three years postoperatively, the mean postoperative monocular best corrected contrast sensitivity was 1.57 ± 0.25 log units at 3 cpd, 1.63 ± 0.20 log units at 6 cpd, 1.12 ± 0.37 log units at 12 cpd, and 0.65 ± 0.30 log units at 18 cpd. The mean normalized contrast sensitivity was 1.01, 0.91, 0.75, and 0.70 at 3 cpd, 6 cpd, 12 cpd, and 18 cpd, respectively.

Self-Reported Quality of Vision, Visual Disturbances, and Spectacle Dependency

The mean self-reported quality of vision rating without spectacles for distance vision was 1.84 ± 0.69 at 6 months and 2.11 ± 1.15 at 3 years. For near vision, the mean rating was 1.78 ± 0.67 and 2.22 ± 1.17 , respectively. No statistically significant differences were found between values at 6 months and 3 years for distance, near, or intermediate vision ($P > .01$).

Table 4 shows the results of the quality-of-life questionnaire detailing the capability of conducting handiwork, games, or cooking. The mean patient-reported visual disturbance ratio for glare was 3.80 ± 0.41 at 6 months and 3.75 ± 0.55 at 3 years. The mean patient-reported visual disturbance ratio for halos was 3.95 ± 0.22 and 3.80 ± 0.52 , respectively. No patient reported severe visual disturbances (eg, halos and glare) at either time point.

Table 5 shows patient-reported spectacle dependence for distance and near vision. At 6 months, 83.7% of patients reported that they never wore spectacles for distance vision compared with 85.0% at 3 years. Full spectacle independence at near was recorded by 81.9% of patients at 6 months and 75.0% at 3 years.

Complications, Capsulotomies, and Intraocular Lens Centration

No intraoperative complications or potentially sight-threatening postoperative complications (eg, persistent corneal edema, pupillary block, retinal detachment, endophthalmitis) occurred. No additional

Table 1. Demographic characteristics of patients.

Characteristic	Value
Eyes (n)	44
Age (y)	
Mean \pm SD	74.2 \pm 8.7
Range	43 to 85
Sex (M/F)	8/14
Keratometry (D)	
Mean \pm SD	
K1	44.37 \pm 1.86
K2	43.55 \pm 1.94
Range	40 to 48
IOL power (D)	
Mean \pm SD	21.70 \pm 2.17
Range (D)	17 to 25
Axial Length (mm)	
Mean \pm SD	22.99 \pm 0.88
Range	21.26 to 24.53

IOL = intraocular lens

Table 2. Visual acuity results 6 months and 3 years after IOL implantation.

Parameter	Acuity at 6 Months			Acuity at 3 Years			P Value
	Mean	Number (%)		Mean	Number (%)		
		20/40 or Better	20/25 or Better		20/40 or Better	20/25 or Better	
Distance (6 m) acuity (logMAR)							
Monocular uncorrected	0.128 ± 0.130	42/44 (95.5)	23/44 (52.3)	0.197 ± 0.185	34/44 (77.3)	21/44 (47.7)	.021
Monocular best distance-corrected	0.012 ± 0.086	44/44 (100.0)	41/44 (93.2)	0.052 ± 0.110	44/44 (100.0)	35/44 (79.5)	.027
Binocular uncorrected	0.046 ± 0.099	22/22 (100.0)	19/22 (86.4)	0.115 ± 0.173	20/22 (90.9)	18/22 (81.8)	.056
Binocular best distance-corrected	-0.040 ± 0.075	22/22 (100.0)	22/22 (100.0)	-0.018 ± 0.093	22/22 (100.0)	21/22 (95.5)	.199
Near (33 cm) acuity (logMAR)							
Monocular uncorrected	0.020 ± 0.109	43/44 (97.7)	42/44 (95.5)	0.058 ± 0.081	43/44 (97.7)	42/44 (95.5)	.032
Monocular best distance-corrected	0.034 ± 0.060	44/44 (100.0)	43/44 (97.7)	0.065 ± 0.087	44/44 (100.0)	44/44 (100.0)	.027
Binocular uncorrected	0.009 ± 0.029	22/22 (100.0)	22/22 (100.0)	0.014 ± 0.035	22/22 (100.0)	22/22 (100.0)	.332
Binocular best distance-corrected	0.009 ± 0.029	22/22 (100.0)	22/22 (100.0)	0.014 ± 0.035	22/22 (100.0)	22/22 (100.0)	.332

interventions (eg, corneal refractive surgery for residual astigmatism) were required.

Four eyes (9.1%) required neodymium:YAG (Nd:YAG) capsulotomy for posterior capsule opacification (PCO). Two capsulotomies were performed within the first year after surgery; the mean time between IOL implantation and capsulotomy was 15 ± 12.7 months. Visual acuity was 20/40 or better in all eyes having an Nd:YAG capsulotomy. No IOL decentration was noted during the follow-up period.

DISCUSSION

Postoperative follow-up of patients is the main difficulty when conducting longitudinal studies. However, such analysis in patients with multifocal IOLs is necessary to assess the long-term performance and possible changes that can occur in visual acuity over time. To our knowledge, the only other longitudinal study of multifocal IOL performance was by

Slagsvold,²⁵ who evaluated the visual performance of the 3M diffractive multifocal IOL 8 years after implantation.

The purpose of the present study was to analyze the long-term (3 years) changes in visual performance in patients who had bilateral implantation of the AcrySof ReSTOR SA60D3 IOL. In this prospective study, no serious surgical events occurred and no IOL was explanted. The study was of patients with low degrees of astigmatism, a regular corneal shape on corneal topography, and preexisting hyperopia (36.4%), emmetropia (9.1%), or myopia (54.5%). At the 6-month postoperative visit, both distance and near visual acuities were good and compared favorably with those reported in other studies of cataract patients with this IOL.^{12,19,20} The binocular mean uncorrected distance acuity and best corrected distance acuity was 0.046 logMAR and -0.040 logMAR, respectively. Kohnen et al.¹² report mean values of 0.04 logMAR and -0.05 logMAR, respectively, in 127 patients. Alfonso et al.¹⁹ found similar values (0.060 logMAR and 0.034 logMAR, respectively) in 325 patients, as did Vingolo et al.²⁰ (0.06 logMAR and 0.05 logMAR,

Table 3. Differences in refraction between 6 months and 3 years postoperatively.

Parameter	6 Months	3 Years	P Value
Mean SE (D) ± SD	0.14 ± 0.34	0.09 ± 0.37	.22
Sphere (D)			
Mean ± SD	0.53 ± 0.54	0.52 ± 0.56	.46
Range	-0.50 to +2.00	-0.25 to +2.00	
Cylinder (D)			
Mean ± SD	-0.79 ± 0.66	-0.88 ± 0.67	.12
Range	0.00 to 2.50	0.00 to 2.75	
% SE ± 0.5 (D)	84.1	90.9	—
% SE ± 1.0 (D)	100.0	100.0	—

SE = spherical equivalent

Table 4. Self-reported quality-of-life questionnaire results 6 months and 3 years postoperatively.

Activity	Mean Score* ± SD		P Value
	6 Months	3 Years	
Handiwork	1.30 ± 0.67	1.30 ± 0.67	1.000
Games	2.13 ± 2.80	1.25 ± 0.71	0.422
Cooking	1.67 ± 0.58	1.00 ± 0.00	0.339

*1 = no problem; 2 = a little difficult; 3 = quite difficult; 4 = very hard; 5 = impossible

Table 5. Spectacle dependence at distance and near 6 months and 3 years postoperatively.

How Often Do You Wear Glasses for Seeing Objects at...	Percentage	
	6 Months	3 Years
Distance		
Always	14.3	15.0
Most of the time	0	0
Quite often	0	0
Some of the time	0	0
Never	83.7	85.0
Near		
Always	9.1	10.0
Most of the time	0	10.0
Quite often	4.5	0
Some of the time	4.5	5
Never	81.9	75.0

respectively) in 100 patients. For near vision, uncorrected acuity and best distance-corrected acuity were 0.009 logMAR in our study. Kohnen et al.¹² found mean values of 0.09 logMAR and 0.05 logMAR, respectively; Alfonso et al.,¹⁹ of 0.013 logMAR and 0.011 logMAR, respectively; and Vingolo et al.,²⁰ of 0.10 logMAR and 0.07 logMAR, respectively. In our study, all patients achieved binocular best corrected distance acuity and best distance-corrected near acuity of 20/25 or better. Similar percentages were found by Kohnen et al.¹² (97.5% and 83.9%, respectively), Alfonso et al.¹⁹ (92% and 98.5%, respectively), and Vingolo et al.²⁰ (98% and 98%, respectively). Three years after surgery, both distance and near visual acuities remained good and did not differ significantly from those reported at the 6-month visit. The mean monocular and binocular uncorrected distance acuities were 20/25 and 20/20, respectively, and the mean monocular and binocular uncorrected near acuities, 20/20 and 20/20, respectively. The mean monocular and binocular best distance-corrected near acuity and best corrected distance acuity value was 20/20. All patients achieved binocular best distance-corrected near acuity and best corrected distance acuity of 20/25 or better. No comparison with previous studies can be made due to the lack of available long-term data on this type of IOL.

No statistically significant refractive changes were observed between the 6-month and 3-year postoperative visits. The SE was less than 0.25 D at both examinations. At 6 months and 3 years, 43.2% and 45.5% of eyes, respectively, were emmetropic and all eyes were within ± 1.00 D of the intended correction. This provides further information on the accuracy of the IOL power selection and stability of the IOL in the capsular

bag after implantation. These results agree with those of Fernández-Vega et al.²¹ at 6 months (SE <0.25 D; 100% of eyes within ± 1.00 D).

In our study, the mean contrast sensitivity function was comparable to normal values at the 2 lower spatial frequencies. At 3 cpd and 6 cpd, the mean log contrast sensitivity function was within ± 1 SD of the mean normal log contrast sensitivity function. At 12 cpd and 18 cpd, the differences in mean log contrast sensitivity function between our cohort and normal values were larger. Souza et al.¹⁴ found a lower mean log contrast sensitivity function in patients with the AcrySof ReSTOR IOL than in patients with a monofocal AcrySof SA60AT IOL (Alcon Laboratories), although the difference between the 2 types of IOLs was only significant in the monocular assessment and not in the binocular assessment. Vingolo et al.²⁰ also found a lower mean log contrast sensitivity function between the 2 types of IOLs. The difference, however, was only significant when measured using the static rather than the dynamic program of the device. A more pronounced loss of contrast sensitivity function after implantation of zonal progressive multifocal IOLs has been reported.^{26,27}

Previous quality-of-vision studies^{12,14,19,20} report a high level of satisfaction in patients with the AcrySof ReSTOR SA60D3 IOL over a 6-month follow-up. In our study, patients with this IOL achieved good visual acuity for distance and near vision at 6 months and 3 years. The self-reported quality-of-life questionnaire showed that the AcrySof ReSTOR SA60D3 IOL offers good distance, intermediate, and near visual acuity. The task that scored the lowest at 6 months was the ability to play games, with a score of 2 (a little difficulty); this improved at the 3-year visit to a score of 1 (no problem). In general, the ability to perform the 3 visual tasks was good, without reported problems at 6 months or 3 years. Patients were asked to rate visual disturbances (glare or halos), and none of them classified these as being severe at the 6-month or 3-year visit. One could argue that the apodized (step-height blending) diffractive optic of the AcrySof ReSTOR SA60D3 IOL plays a role in minimizing these phenomena by distributing the amount of energy traveling to the distance and near focal points according to pupil size, thus minimizing visual disturbances such as glare or halos under lower lighting levels. Other studies found high percentages of patients with complaints of halos and glare. Souza et al.¹⁴ report that 40% of patients had mild to moderate glare complaints and 50% mentioned nighttime halos. In a study by Chiam et al.,¹⁶ 21.3% of patients had moderate glare complaints and 16.3% and 3.8% reported moderate halos and severe halos, respectively. Kohnen et al.¹² found that 24.6% and 8.5% of patients reported moderate

glare and severe glare, respectively, while 16.1% and 4.2% reported moderate halos and severe halos, respectively. Thus, a high percentage of patients have mild or moderate complaints of halos and glare, but severe complaints are rare. As Kohnen et al.¹² point out, the complaints diminish with time, probably due to neural adaptation. This might be the explanation for the lower ratios of glare and halos in the current study. In addition, a recent study showed that implantation of the AcrySof ReSTOR IOL results in decreased intraocular straylight compared with the level in an age-matched noncataractous population.²⁸

At 6 months, spectacle independence for distance vision and near vision was 83.7% and 81.9%, respectively. Kohnen et al.¹² found similar percentages (88% for distance; 84.6% for near). Vingolo et al.²⁰ reported a higher percentage of total spectacle independence (92%). At 3 years, 85% of patients reported spectacle independence for distance activities and 75%, for near activities.

Posterior capsule opacification is the most common complication of modern cataract surgery, with an incidence up to 50% at 2 years.²⁹ It has been speculated that as multifocal IOLs distribute light to 2 foci, even minor PCO might create symptoms. With the 3M posterior concave IOL, the Elschnig pearl-type of PCO occurred more frequently than the fibrotic type.²⁵ The Elschnig type necessitates an Nd:YAG capsulotomy at an earlier time than the fibrotic type. Slagsvold²⁵ reports that there was no difficulty focusing on the capsule after implantation of the 3M IOL; however, laser pits on the optic of this injection-molded IOL were somewhat more distinct and irregular than those on other types of poly(methyl methacrylate) (PMMA) IOLs. Data from the U.S. Food and Drug Administration study⁶ showed the occurrence of Nd:YAG capsulotomy in eyes with the 3M IOLs was 10% at 4 to 6 months.⁶ Slagsvold²⁵ reported that 50% of eyes were treated during the 8-year follow-up; at the time of capsulotomy, 2 of 3 eyes had a visual acuity of 20/40 or better. Slagsvold concluded that patients with the 3M IOL do not require earlier capsulotomies than patients receiving monofocal PMMA IOLs. In our study, 4 eyes (9.1%) required Nd:YAG capsulotomy during the 3-year follow-up—2 at 6 months and 2 at 24 months. Given our results, the use of Nd:YAG capsulotomy for the treatment of PCO after AcrySof ReSTOR SA60D3 IOL implantation is a relatively safe, noninvasive method to improve visual acuity.

Accurate IOL centration is vital for the success of all IOL implantations, and the necessity of accurate IOL centration increases when using multifocal designs. With its ring structure, the degree of decentration with the AcrySof ReSTOR SA60D3 IOL was easy to assess and in all cases, the IOL was well centered.

In conclusion, our study showed that the AcrySof ReSTOR SA60D3 IOL provided our patients with a satisfactory full range of vision and a low incidence of visual disturbances and PCO during the 3-year follow-up. The frequency of spectacle wear was reduced for both distance and near, and the IOL provided enhanced quality of life when implanted bilaterally.

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