

# European Multicenter Study of the AcrySof ReSTOR Apodized Diffractive Intraocular Lens

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**Objective:** To report the safety and effectiveness of the AcrySof ReSTOR apodized diffractive intraocular lens (IOL), model MA60D3, when implanted into the capsular bag.

**Design:** Multicenter European study including university clinics, eye hospitals, and private ophthalmic surgical centers.

**Participants:** One hundred twenty-seven subjects implanted in cataractous eyes in an open multicenter study.

**Intervention:** After phacoemulsification, the foldable 3-piece hydrophobic acrylic apodized diffractive IOL was implanted in the capsular bag using a Monarch injector with an A-cartridge. The mean preoperative patient age was  $68.4 \pm 12$  years. Intraocular lens implant power ranged from 18.0 to 25.0 diopters (D) in 0.5-D increments.

**Main Outcome Measures:** Distance visual acuity (VA), near VA, spectacle dependence, unwanted visual symptoms, and patient satisfaction.

**Results:** At the 6-month postoperative visit, binocular (both eyes simultaneously) mean uncorrected distance and near logarithm of the minimum angle of resolution VAs for the MA60D3 were  $0.04 \pm 0.14$  and  $0.09 \pm 0.12$  ( $n = 118$ ), respectively. In addition, 88.0% and 84.6% of ReSTOR subjects achieved spectacle independence for distance and near vision, respectively. Glare and halos were reported as severe by only 8.5% and 4.2% of patients, respectively. Ninety-two percent of patients stated that they would choose to have the same lens implanted again after the first implant, and 95.7% answered likewise after the second implant.

**Conclusions:** The AcrySof ReSTOR MA60D3 IOL demonstrated excellent near VA without compromising distance vision. Spectacle independence and patient satisfaction were high, whereas unwanted photic phenomena were clinically acceptable. *Ophthalmology* 2006;113:578–584 © 2006 by the American Academy of Ophthalmology.



Despite advances made in small-incision surgery, restoration of functional distance and near vision independent from additional correction remains a goal for ophthalmic surgeons. Monofocal intraocular lenses (IOLs) require surgeons to correct either distance or near vision. Multifocal IOLs address this limitation using the principle of simultaneous vision.<sup>1</sup> Incoming light is divided between 2 lens powers, one for distance vision and one for near vision. The

distance of the user from the object determines the predominating power. When one views a distant object, the image from the near power is greatly defocused and very faint, so only the object in the distance is seen. Likewise, when one views a near object the image produced by the distance power is greatly defocused and faint. Clinically, multifocal IOLs have been reported to provide patients with functional

Originally received: June 3, 2005.

Accepted: November 8, 2005.

Manuscript no. 2005-484.

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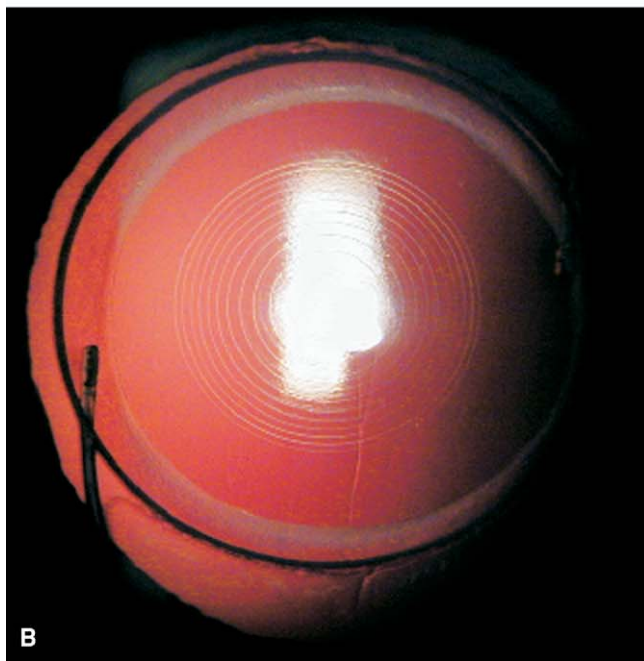
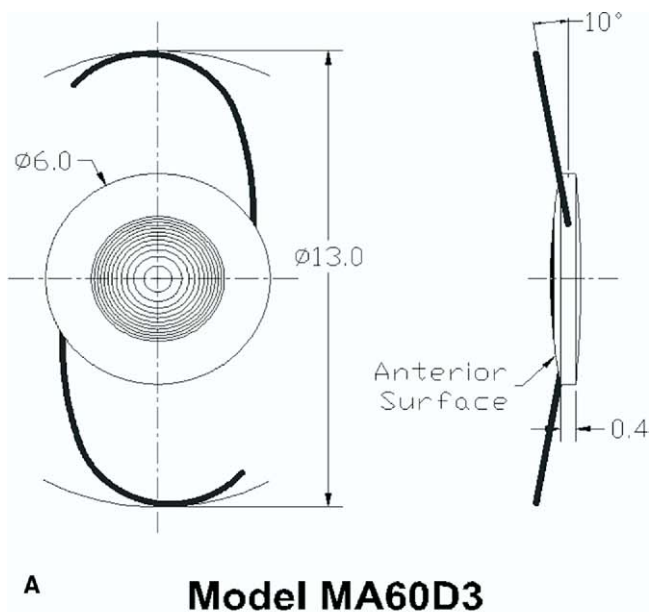
Presented as a scientific paper at: American Academy of Ophthalmology annual meeting, October, 2004; New Orleans, Louisiana.

The study was supported by Alcon (Fort Worth, Texas) as a clinical investigational project.

The authors have no proprietary interest in any of the devices used in the study.

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**Figure 1.** The AcrySof apodized diffractive intraocular lens, model MA60D3. **A**, Schematic drawing. **B**, Intraocular lens implanted into the capsular bag.

near and distance vision with acceptable satisfaction.<sup>2-9</sup> Reduced image contrast and unwanted visual phenomena, including glare and halos, have also been associated with multifocal IOL performance.<sup>2-5,8,10-15</sup>

The AcrySof apodized diffractive IOL, model MA60D3 (ReSTOR), is a posterior chamber lens developed by Alcon Research, Ltd. (Fort Worth, TX) (Fig 1). The lens has a biconvex optic that contains a diffractive structure in the central 3.6 mm on the anterior surface of the optic. The optic is composed of the same proprietary acrylic material that has been used in AcrySof lenses since 1995. This

material has been shown to provide excellent clinical benefits through its high refractive index (1.55), flexibility, and biocompatibility.<sup>16-18</sup> The lens can be folded before insertion, allowing placement through an approximately 3.5-mm incision with a Monarch II injector A-cartridge (Alcon Research).<sup>19</sup> The AcrySof ReSTOR MA60D3 has a 6.0-mm-diameter biconvex optic and an overall length of 13.0 mm. The modified-C haptics are comprised of blue-core polymethyl methacrylate with 10° angulation. Twelve diffractive zones in the central 3.6-mm region divide light between 2 foci. The diffractive steps gradually reduce in height and spacing from the lens center to the edge of the diffractive region (apodization). The outer refractive region has no diffractive zones and is strictly refractive. The add power of the lens is +4.0 diopters (D).

The goal of the current study was to investigate the safety and efficacy of the AcrySof ReSTOR IOL when implanted into the capsular bag after phacoemulsification—according to its intended use, which includes bilateral implantation. Bilateral implantation of simultaneous vision IOLs is associated with better visual outcomes.<sup>3,8,20-23</sup>

## Patients and Methods

Eight European investigators implanted 127 subjects with the AcrySof ReSTOR IOL MA60D3 in their first eye. Of the 127 subjects, 119 had bilateral implantation with a second study IOL. No separate control group was included in this study, but the clinical results were compared with the Food and Drug Administration (FDA) Grid of Historical Controls contained in annex B of the intraocular lens guidance document issued in October of 1999. Adult ( $\geq 21$  years old at the time of surgery) subjects of any race and gender, who were appropriate for bilateral cataract surgery, were considered for enrollment in the study. Requirements for participation in the study included a potential postoperative visual acuity (VA) of 20/40 (0.34 logarithm of the minimum angle of resolution [logMAR]) or better in study eye(s) and  $\leq 1.0$  D of astigmatism preoperatively. For reference, Table 1 (available at <http://aaojournal.org>) shows the Snellen equivalents for logMAR VA values.

The AcrySof ReSTOR IOL MA60D3 was implanted into the capsular bag after cataract removal by phacoemulsification. Serious adverse events were occurrences considered to be potentially sight threatening. In this study, visual disturbances (glare/flare, halos, distorted near or far vision, blurred near or far vision, problems with night vision, double vision, and problems with color perception) were reported as serious adverse events if they were (in the opinion of the investigator and in conjunction with patient questionnaire scores) incapacitating to the patient.

Logarithm of the minimum angle of resolution acuity charts were used for VA testing, and results were obtained as logMAR acuities (although the data in this article are shown as logMAR acuities and/or their Snellen equivalents; Table 1 [available at <http://aaojournal.org>]). For uncorrected distance VA and best-corrected distance VA (BCDVA), patients were tested using the 100% contrast Early Treatment Diabetic Retinopathy Study chart under photopic lighting conditions with an additional spherical add power of +0.25 D to correct for optical infinity (the +0.25 D was in place only for uncorrected VA testing, and BCDVA was obtained with manifest refraction). Visual correction via manifest refraction was applied to provide optimum distance vision.

Uncorrected near VA and distance-corrected near VA measurements were obtained using a handheld near logMAR chart at a

standard distance of 33 cm and at a distance the subject identified as providing the best near vision (best distance). Best-corrected near VA measurements were obtained using the handheld near logMAR chart at a standard distance of 33 cm only. Because the handheld near logMAR chart was designed for use at 40 cm, the results obtained at other distances (standard distance or best distances) were converted to reflect the change in apparent letter size that results from the change in distance.

In addition to the VA testing using the 100% contrast logMAR charts, low contrast VA testing was also performed. Low contrast VA testing included both 25% and 9% contrast logMAR charts viewed at 4 m under photopic lighting conditions.

To assess the incidence and impact of visual phenomena such as glare and halos, subjects were asked to rate the impact of any observed phenomena. The subjects were specifically queried about glare (trouble seeing street signs due to bright light or oncoming headlights), halos (rings around lights), distorted near vision (straight lines looking crooked close up), distorted far vision (straight lines looking crooked at distance), blurred near or far vision, problems with night vision, double vision with both eyes or with other (nonoperated eye) closed, and problems with color perception. Patients rated the effect of each phenomenon on a scale from 0 to 7, with 0 meaning not observed; 1, easily tolerated; and 7, incapacitating. A rating of 1 to 2 was interpreted as mild, a rating of 3 to 5 was defined as moderate, and a rating of 6 to 7 was defined as severe.

## Results

One hundred twenty-seven patients were enrolled in the study and underwent implantation with the AcrySof ReSTOR IOL in their first eyes. Of the 127, there were 80 (63.0%) females and 47 (37.0%) males; 126 (99.2%) were white, and 1 (0.8%) was black. One hundred nineteen patients underwent implantation in the second eye with the study lens, 117 of whom were successfully observed for 330 to 420 days after the first implant.

### Clinical Results: Efficacy

All postoperative binocular (both eyes tested simultaneously) VA results were obtained 120 to 180 days after the second AcrySof ReSTOR IOL implant and are summarized in Table 2.

**Distance Visual Acuity. Uncorrected Binocular.** Among the all-implanted population, 99.1% of patients (117/118 [the test was not performed for 1 patient]) achieved uncorrected binocular distance VA of 20/40 (0.34 logMAR) or better, and 83.9% (n = 99) achieved VA of 20/25 or better. Mean uncorrected binocular distance VA was 0.04 logMAR (20/20) (n = 118).

**Best-Corrected Binocular.** All 118 patients (100%) who re-

ceived bilateral IOL implants achieved binocular BCDVA of 20/40 or better, and 97.5% (115/118) achieved 20/25 or better. Mean BCDVA was  $-0.05$  logMAR (better than 20/20). Best-corrected distance VA for monocular vision after the first implant and binocular vision after bilateral implants surpassed the FDA grid rate of 92.5%. The AcrySof ReSTOR IOL was compared with historical controls for BCDVA; historical controls for the other testing parameters do not exist.

**Low-Contrast Best Corrected.** Of 123 patients tested 120 to 180 days after the first implant, monocular BCDVA was 0.34 logMAR (20/40) or better for 94.3% of patients (n = 116) at the 25% contrast level and for 59.3% of patients (n = 73) at the 9% contrast level. Overall, a slight improvement was observed in low-contrast distance VA when the second eye was tested 120 to 180 days after the second implant: 95.8% of patients (113/118) scored 20/40 or better at the 25% contrast level, and 68.6% (81/118) scored 20/40 or better at the 9% contrast level. Mean values for monocular BCDVA for both the first and second implants were 20/25 at 25% contrast levels and 20/40 at 9% contrast levels.

**Near Visual Acuity. Uncorrected Binocular.** After implantation of the second AcrySof ReSTOR IOL in 119 patients (testing not performed in 1 subject), binocular uncorrected near VA at the standard distance of 33 cm was 0.34 logMAR (20/40) or better for 97.5% of patients (n = 115) and 0.14 logMAR (20/25) or better for 66.9% of patients (n = 79). Similarly, when tested at best distance, 97.5% of patients (n = 115) achieved binocular uncorrected near VA of 0.34 logMAR (20/40) or better, and 71.2% (n = 84) achieved 0.14 logMAR (20/25) or better.

**Distance-Corrected Binocular.** The manifest refraction obtained for BCDVA was applied during testing for distance-corrected near VA. When tested at the standard distance of 33 cm, 98.3% of patients (n = 116) in the all-implanted population achieved binocular distance-corrected near VA of 0.34 logMAR (20/40) or better, and 83.9% of patients (n = 99) achieved 0.14 logMAR (20/25) or better. When tested again at best distance, 98.3% of patients (n = 116) achieved near VA of 20/40 or better, and 80.5% (n = 95) achieved 20/25 or better.

**Best Corrected.** For best-corrected near VA, the manifest refraction obtained for BCDVA was applied during testing, and if necessary, additional spherical add power up to  $\pm 1.25$  D was also applied. At the standard distance of 33 cm, 99.2% of patients (117/118) in the all-implanted population achieved binocular best-corrected near VA of 0.34 logMAR (20/40) or better, and 84.7% (n = 100) achieved 0.14 logMAR (20/25) or better.

### Clinical Results: Safety

Safety data indicate few issues related to patient tolerance of the AcrySof ReSTOR implant. Overall, 7 adverse events were re-

Table 2. Visual Acuity Results, Binocular (Both Eyes), 120–180 Days after the Operation

	Mean	20/40 or Better	20/25 or Better
Distance			
Uncorrected—all implanted	0.04 logMAR (20/20)	117/118 (99.1%)	99/118 (83.9%)
Best corrected—all implanted	$-0.05$ logMAR ( $>20/20$ )	118/118 (100%)	115/118 (97.5%)
Near			
Uncorrected at standard distance—all implanted	0.09 logMAR (20/25)	115/118 (97.5%)	79/118 (66.9%)
Uncorrected at best distance—all implanted	0.09 logMAR (20/25)	115/118 (97.5%)	84/118 (71.2%)
Distance corrected at standard distance—all implanted	0.05 logMAR (20/25)	116/118 (98.3%)	99/118 (83.9%)
Distance corrected at best distance—all implanted	0.06 logMAR (20/25)	116/118 (98.3%)	95/118 (80.5%)
Best corrected at standard distance—all implanted	0.04 logMAR (20/25)	117/118 (99.2%)	100/118 (84.7%)

logMAR = logarithm of the minimum angle of resolution.

Table 4. Photic Phenomena in the All-Implanted Population: 120–180 Days after Second Intraocular Lens Surgery

Photic Phenomenon	n	None or Mild	Moderate	Severe
		(0, 1, and 2) (%)	(3, 4, and 5) (%)	(6 and 7) (%)
Glare	118	66.9	24.6	8.5*
Problems with night vision	117	88.9	8.5	2.6
Problems with color perception	118	99.2	0.8	0.0
Halos	118	79.7	16.1	4.2
Distorted near vision	117	96.6	1.7	1.7
Distorted far vision	118	98.3	1.7	0.0
Blurred near vision	118	90.7	7.6	1.7
Blurred far vision	118	90.7	7.6	1.7
Double vision with both eyes	118	94.9	3.4	1.7

\*When data from subjects of this study are combined with the results of subjects from a similar study conducted in the United States, the incidence of severe glare reduces to 4.9% (AcrySof ReSTOR package insert).

ported in 7 subjects in the first or second eye (Table 3 [available at <http://aaojournal.org>]). Of the 127 subjects implanted as part of the clinical investigation, only 2 cases of secondary surgical intervention for implant replacement were reported. One replacement was due to visual disturbances. The other case was due to biometry error, emphasizing the importance of accurate biometry for optimal visual outcomes. The other adverse events were typical for cataract surgery: 2 cases of CME, 1 case of flat macular edema, 1 case of macular edema with fibrinous reaction, and 1 case of cystic maculopathy.

### Quality-of-Life Results

Patients were asked to complete a questionnaire at the preoperative visit, at 30 to 60 days after the first implant, and at 120 to 180 days after the second implant to identify and rate the effects of various issues. The questionnaire also allowed subjects to rate the level of satisfaction with their vision as well as the impact visual performance had on their lifestyle.

### Self-Reported Rating of Satisfaction

The questionnaires allowed patients to indicate whether they would choose to implant the identical lens model again. Ninety-two percent (103/112) stated that they would choose to have the same lens implanted again after the first eye implant, and 95.7% (112/117) answered the same way after the second eye implant.

### Visual Phenomena

For glare at 120 to 180 days after the second implant, of the 118 patients who answered the question 8.5% (n = 10) rated their observation as severe in effect, 24.6% (n = 29) rated it as moderate, and 66.9% (n = 79) rated it as none or mild. Halos were reported as severe by 4.2% of patients, moderate by 16.1%, and absent or mild by 79.7% of patients. Table 4 summarizes the photic phenomena experienced in the all-implanted population 120 to 180 days after the second IOL surgery.

Apart from halos (which slightly increased), the mean rating of the visual disturbances decreased after second eye implantation compared with assessment after first eye implantation.

Table 5. Spectacle Dependency for Distance Vision in the All-Implanted Population

How Often Do You Wear Glasses for Seeing Objects at a Distance?	At 30–60 Days after First IOL Surgery		At 120–180 Days after Second IOL Surgery	
	n	%	n	%
None of the time	84	73.7	103	88.0
Some of the time	8	7.0	3	2.6
Half of the time	4	3.5	1	0.9
Most of the time	3	2.6	4	3.4
All of the time	15	13.2	6	5.1
Total	114	100.0	117	100.0

IOL = intraocular lens.

### Frequency of Spectacle Wear

Frequency of spectacle wear was measured on a 3-point categorical scale: always, sometimes, or never. Preoperatively, 93.5% of patients (116/124) reported that they sometimes or always wore spectacles, and 6.5% (8/124) reported that they never wore spectacles. Three patients did not complete the preoperative assessments. At 30 to 60 days postoperatively after the first surgery, significantly more patients reported that they never wore spectacles (43.9% [50/114]). At 120 to 180 days postoperatively after the second surgery, 74.4% of patients (87/117) reported that they never wore spectacles.

### Spectacle Dependency for Distance Vision

Spectacle dependency for distance vision was measured on a 5-point scale: all of the time, most of the time, half of the time, some of the time, and none of the time. Preoperatively, 26.6% of patients (33/124) reported that they did not wear distance vision spectacles any of the time, compared with 73.7% (84/114) at 30 to 60 days postoperatively after the first surgery and 88% (103/117) at 120 to 180 days after second eye surgery (Table 5).

### Spectacle Dependency for Near Vision

Preoperative full independence from spectacle wear was 18.5% (23/124), compared with 49.1% (56/114) at 30 to 60 days after the

Table 6. Spectacle Dependency for Near Vision in the All-Implanted Population

How Often Do You Wear Glasses for Seeing Objects Close at Hand?	At 30–60 Days after First IOL Surgery		At 120–180 Days after Second IOL Surgery	
	n	%	n	%
None of the time	56	49.1	99	84.6
Some of the time	27	23.7	14	12.0
Half of the time	2	1.8	0	0.0
Most of the time	4	3.5	2	1.7
All of the time	25	21.9	2	1.7
Total	114	100.0	117	100.0

IOL = intraocular lens.

first surgery postoperatively and 84.6% (99/117) at 120 to 180 days after the second surgery (Table 6).

### Self-Reported Vision Rating without Spectacles

Preoperatively, the mean self-reported vision rating without spectacles (on a scale of 0–10) was  $4.6 \pm 1.7$ . The mean self-reported rating without spectacles rose to  $6.8 \pm 1.7$  at 30 to 60 days after the first surgery and to  $8.6 \pm 1.3$  at 120 to 180 days after the second surgery. This result suggests that the overall subject rating for vision without spectacles noticeably improves after unilateral surgery, and this improvement is enhanced further after bilateral surgery.

## Discussion

Multifocal IOLs are designed to provide functional distance and near vision after cataract surgery. As basically 2 different types of multifocal technology exist (diffractive and refractive), the difference between these lenses is discussed. A theoretical study on model eyes showed that diffractive multifocal IOLs are superior to refractive multifocal IOLs for near vision, whereas for distance vision they are comparable.<sup>24</sup> Clinical studies also confirm the superiority of the diffractive over the refractive principle for near vision<sup>3,9,14,25–27</sup> and have shown that refractive multifocal IOLs are significantly more pupil dependent.<sup>26,28–30</sup> A pupil diameter of  $<4.5$  mm cannot provide useful near VA.<sup>28</sup> Therefore, mean pupillary size in a normal cataract population needs to be considered.

When evaluating a multifocal IOL, intermediate vision also needs to be evaluated. A study by Weghaupt et al<sup>25</sup> showed that results for distance and near VAs are very satisfactory with a diffractive multifocal IOL, whereas for intermediate distances VA may be limited to activities that do not require optimal vision. In the current study, excellent results for far and near VAs were found for the apodized diffractive IOL model MA60D3, whereas intermediate distance vision was not tested. However, results of the MA60D3 United States study (package insert for AcrySof ReSTOR IOL apodized diffractive IOL) indicate that intermediate VA is clinically satisfactory (approximately 20/40), with excellent results (approximately 20/20) for near and far VAs.

In addition to distance and near VAs, other factors contribute to functional vision; therefore, multiple variables are used to establish efficacy.

### Low-Contrast Acuity

With any multifocal IOL, the division of incoming light to more than one focus must physically produce retinal images of reduced contrast. Data published by Post<sup>4</sup> show a decrease in contrast sensitivity/acuity at the limits of contrast and resolution (4% contrast level) with a diffractive multifocal IOL (3M, Minneapolis, MN) compared with a monofocal IOL. These clinical findings by Post were not manifest in patient awareness. The results of the current study are consistent with Post's findings: low-contrast acuity was poorer than high-contrast VA, and patients did not actively

report an inconvenience caused by reduced contrast perception. Also, data from an FDA study about a diffractive multifocal IOL (3M) show a small contrast sensitivity loss that was considered clinically insignificant.<sup>31</sup>

### Visual Phenomena/Glare/Halo/Patient Satisfaction

In various studies evaluating diffractive<sup>6,32,33</sup> and/or refractive<sup>34–36</sup> multifocal IOLs, visual phenomena, mainly glare and halos, have been proven to be increased relative to monofocal IOLs; however, rates of self-reported patient satisfaction remain high with simultaneous vision IOLs. The results of the subjective questionnaire on perceived optic phenomena and quality of life in this study of the AcrySof ReSTOR IOL MA60D3 demonstrated lower rates of visual symptoms in comparison to published values from multifocal studies, and high rates of patient satisfaction consistent with other studies.<sup>3,27,34,37</sup>

### Refractive Intraocular Lenses

Steinert et al observed statistically significant differences in rating of visual symptoms reported by subjects implanted with a zonal–progressive multifocal IOL (Array, Advanced Medical Optics, Inc., Santa Ana, CA) in comparison to the monofocal control.<sup>3</sup> Difficulties with halos, glare/flare, and blurred far vision were reported most frequently, and at higher proportions in the zonal multifocal IOL subjects than in the monofocal subjects. Regarding reports of severe difficulties, 10.5% ( $n = 95$ ) of zonal–progressive IOL subjects reported severe difficulties with glare/flare, 15.3% ( $n = 98$ ) with halos, and 4% with blurred far vision.<sup>3</sup> Javitt and Steinert also reported a statistically significant ( $P < 0.0001$ ) higher degree of bother with glare, halos, or rings around lights for the multifocal Array IOL subjects versus monofocal IOL subjects.<sup>34</sup> In comparison, lower proportions of these visual symptoms were reported as severe by the ReSTOR IOL subjects in this study, as evidenced by 8.5% (10/118) for glare/flare, 4.2% (5/118) for halos, and 1.7% (2/118) for blurred far vision. In addition, with respect to glare and flare, when data from subjects of this study are combined with those of a similar study conducted in the U.S. only 4.9% ( $n = 440$ ) of subjects rate the occurrence as severe (AcrySof ReSTOR IOL package insert).

Conversely, glare and halos have been reported not to differ statistically significantly between a monofocal IOL and a zonal–progressive multifocal IOL, whereas corneal irregularities, astigmatism  $> 1$  D, and age over 70 years were found to be highly correlated with visual phenomena, although not clinically significant.<sup>35</sup> In Pieh et al's study, halos were detected in all (24) patients with a refractive multifocal IOL under clinical setting conditions, and 23 patients reported seeing halos at night, whereas only 1 patient was disturbed by this phenomenon.<sup>36</sup> Patients receiving refractive multifocal IOLs (Array) were more likely to report halos, although their overall visual function and satisfaction were rated higher than those in the monofocal control group.<sup>34</sup>

## Diffractive Intraocular Lenses

In a trial about patient satisfaction after implantation of a diffractive IOL (Pharmacia 811E), patients scored glare and halos on a subjective scale, resulting in very low values.<sup>38</sup> Visual phenomena have been reported to be more severe with diffractive IOLs than with monofocal IOLs, but not leading to less patient satisfaction.<sup>6</sup> No difference in glare sensitivity and color perception after monocular implantation of a diffractive IOL (3M) and monofocal IOL implantation in the fellow eye could be found in Ruther et al's study.<sup>33</sup> Glare and contrast sensitivity were found to be increased and decreased, respectively, in subjects with diffractive versus monofocal IOLs, with no clinical significance to these results.<sup>32</sup>

In the current study, variables included distance VA (uncorrected, best corrected, and contrast) and near VA (uncorrected, distance corrected, and best corrected). We found that the AcrySof ReSTOR IOL was effective in each VA parameter, illustrating the ability of the lens to provide a range of focus that allows patients to achieve clear (20/40 or better) near and distance vision.

The AcrySof ReSTOR IOL provided clear vision, with a low incidence of severe visual disturbances. Rates of postoperative complications did not differ from those expected after an intraocular surgical procedure, and compared optimally to the FDA historical control grid; however, a larger sample size is necessary to detect rare but potentially important events that might occur less frequently. The favorable performance and safety profile of the AcrySof ReSTOR IOL, compared with other multifocal IOLs, might be attributed to the sophisticated technology it employs, apodization, which renders to the diffractive portion of the optic gradual decreases in step height and spacing, allowing for a smooth transition of the distribution of light energy between distance and near focal points (Fig 2). This creates a blend of near and distance vision, reducing the potential for glare, halos, and other visual disturbances. The data from the current study support the benefits of this design approach.

In addition to illustrating the effectiveness of the AcrySof ReSTOR IOL, mean low-contrast distance VA improved during binocular testing, compared with monocular testing, providing evidence that binocular implantation is beneficial for the patient.

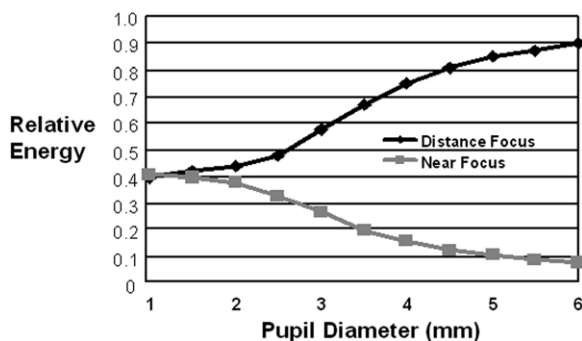


Figure 2. Relative light energy distribution of the ReSTOR lens as a function of pupil size. From Davison JA, Simpson MJ. History and development of the apodized diffractive intraocular lens. *J Cataract Refract Surg*. In press.

Investigation of key end points such as intermediate VA, VA as a function of pupil size, and contrast sensitivity were not included in this clinical trial; however, they were further explored in the U.S. clinical investigation (Alcon Research, data on file) upon recognition of the increase in clinical interest and relevance in these parameters. The ReSTOR IOL performed well in key objective and subjective end points and in the evaluation of these additional parameters relative to functionality.

Our study found that patients were satisfied with their IOL performance, and most would have the AcrySof ReSTOR implanted again. Frequency of spectacle wear was greatly reduced for both distance and near vision, with patients having rated their vision without spectacles to be noticeably better after each successive surgery. These findings suggest that the AcrySof ReSTOR IOL can provide enhanced quality of life for active patients who wish to reduce their dependency on spectacles. This technology offers surgeons a feasible way of meeting patient expectations of an enhanced lifestyle as a result of reduced spectacle dependence.

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Table 1. Logarithm of the Minimum Angle of Resolution (logMAR) Visual Acuity and Snellen Equivalent

logMAR	Snellen
≤0.04	20/20 or better
0.05–0.14	20/25
0.15–0.24	20/30
0.25–0.34	20/40
0.35–0.44	20/50
0.45–0.54	20/60
0.55–0.64	20/80
≥0.65	Worse than 20/80

Table 3. Adverse Event (AE) Incidence Rates

AE	MA60D3				ISO/FDA Grid AE Rate (%)
	First Eye (n = 127)		Second Eye (n = 119)		
	n	%	n	%	
Cumulative hypopyon	0	0	0	0	0.3
Cumulative intraocular infection/endophthalmitis	0	0	0	0	0.1
Cumulative macular edema	2	1.6	2	1.7	3.0
Cumulative cystic maculopathy	1	0.8	0	0	NA
Cumulative pupillary block	0	0	0	0	0.1
Cumulative retinal detachment/retinal detachment repair	0	0	0	0	0.3
Cumulative lens dislocation	0	0	0	0	0.1
Cumulative secondary surgical intervention (IOL replacement)	2	1.6	0	0	0.8
Cumulative hyphema	0	0	0	0	2.2
Persistent corneal edema	0	0	0	0	0.3
Persistent iritis	0	0	0	0	0.3
Persistent raised IOP requiring treatment	0	0	0	0	0.4

FDA = Food and Drug Administration; IOL = intraocular lens; IOP = intraocular pressure; ISO = International Organization for Standardization; NA = not applicable.