Visual Acuity after Cataract Surgery in Patients with Age-Related Macular Degeneration

Age-Related Eye Disease Study 2 Report Number 5

Age-Related Eye Disease Study 2 Research Group*
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Objective: To evaluate visual acuity outcomes after cataract surgery in persons with varying degrees of severity of age-related macular degeneration (AMD).

Design: Cohort study.

Participants: A total of 1232 eyes of 793 participants who underwent cataract surgery during the Age-Related Eye Disease Study 2, a prospective, multicenter, randomized controlled trial of nutritional supplements for treatment of AMD.

Methods: Preoperative and postoperative characteristics of participants who underwent cataract extraction during the 5-year trial were analyzed. Both clinical data and standardized red-reflex lens and fundus photographs were obtained at baseline and annually. Photographs were graded by a centralized reading center for cortical and posterior subcapsular lens opacities and for AMD severity. Cataract surgery was documented at annual study visits or by history during the 6-month telephone calls. Analyses were conducted using multivariate repeated-measures regression.

Main Outcome Measures: Change in best-corrected visual acuity (BCVA) after cataract surgery compared with preoperative BCVA.

Results: Adjusting for age at time of surgery, gender, interval between preoperative and postoperative visits, and type and severity of cataract, the mean changes in visual acuity were as follows: eyes with mild AMD (n = 30) gained 11.2 letters (95% confidence interval [CI], 6.9–15.5), eyes with moderate AMD (n = 346) gained 11.1 letters (95% CI, 9.1–13.2), eyes with severe AMD (n = 462) gained 8.7 letters (95% CI, 6.7–10.7), eyes with noncentral geographic atrophy (n = 70) gained 8.9 letters (95% CI, 5.8–12.1), and eyes with advanced AMD (central geographic atrophy, neovascular disease, or both; n = 324) gained 6.8 letters (95% CI, 4.9–8.8). The visual acuity gain across all AMD severity groups was statistically significant from preoperative values (P < 0.0001).


*Supplementary material available at www.aaojournal.org.
3 studies showed that cataract surgery was safe in patients with AMD, including eyes treated with ranibizumab, and that visual acuity improvement generally was observed.16

The Age-Related Eye Disease Study (AREDS), a multicenter trial of oral supplementation containing vitamin C, vitamin E, β-carotene, zinc, and copper (the AREDS formulation) that reduced the 5-year risk of advanced AMD developing by 25%,17 did not demonstrate any harmful or beneficial effects on the development or progression of cataracts.18 Furthermore, cataract surgery did not increase the risk of AMD progression10 and showed that patients with varying severities of AMD had improved visual acuity outcomes after surgery.20

Recent results from the subsequent Age-Related Eye Disease Study 2 (AREDS2) demonstrated that the addition of lutein and zeaxanthin to the AREDS formulation did not affect significantly the rates of cataract surgery or moderate vision loss.21 The addition of lutein and zeaxanthin to the AREDS formulation did have an incremental beneficial effect on reducing the risk of progression to advanced AMD in the main effects analyses, especially when lutein and zeaxanthin were substituted for β-carotene in the original AREDS formulation. However, the addition of omega-3 polyunsaturated fatty acids (specifically docosahexaenoic acid [350 mg] and eicosapentaenoic acid [650 mg]) had no effect on the progression to advanced AMD.22

The objective of this study was to evaluate visual acuity outcomes after cataract surgery among participants in the AREDS2 cohort.

Methods

Participants and Study Design
Details of the AREDS2 study design and methods are reported elsewhere23 and briefly are summarized here. A total of 4203 participants 50 to 85 years of age were enrolled in the study from October 2006 through September 2008 at 82 retinal specialty clinics across the United States. Participants were determined to be at high risk of advanced AMD developing, defined as either having bilateral large drusen or nonfoveal geographic atrophy (GA) or having large drusen or nonfoveal GA in 1 eye and advanced AMD (neovascular AMD or central geographic atrophy [CGA]) in the fellow eye. Institutional review board approval was obtained at each clinical site, and participants signed informed consent for the study. The study was conducted in accordance with the tenets of the Declaration of Helsinki.

Participants were assigned randomly to 4 groups: placebo, lutein (10 mg) plus zeaxanthin (2 mg), docosahexaenoic acid plus eicosapentaenoic acid (1 g total), or lutein plus zeaxanthin and docosahexaenoic acid plus eicosapentaenoic acid. All participants also were offered the AREDS formulation, and those who agreed to participate were assigned randomly to 1 of 4 groups, all receiving 500 mg vitamin C, 400 IU vitamin E, and 2 mg cupric oxide and 1 of the following 4 groups with either no β-carotene or low zinc: 15 mg β-carotene plus 80 mg zinc, 15 mg β-carotene plus 25 mg zinc, 80 mg zinc oxide, or 25 mg zinc.

A comprehensive eye examination, which included assessment of best-corrected visual acuity (BCVA) and red-reflex lens and fundus photographs, was obtained at baseline and annually thereafter. Telephone calls were made to each participant 3 months after randomization and every 6 months thereafter in between study visits to obtain information about cataract surgery, AMD treatment, and any adverse events. Photographs were graded for lens opacities and severity of AMD by trained and certified examiners using a standardized protocol at the University of Wisconsin Fundus Photograph Reading Center, Madison, Wisconsin. Fundus photographs were graded for drusen characteristics (type, area), pigmentary abnormalities (increased pigment or either hypopigmentation or hyperpigmentation), GA, and presence of abnormalities characteristic of neovascular AMD (retinal pigment epithelial detachment, serous or hemorrhagic sensory retinal detachment, subretinal hemorrhage or subretinal pigment epithelial hemorrhage, subretinal fibrous tissue). In the present study, the AREDS AMD severity (AAS) scale24 was used to classify patients into 1 of 5 categories: mild AMD (AAS 1–3), moderate AMD (AAS 4–6), severe AMD (AAS 7–8), noncentral GA (AAS 9), and advanced AMD (CGA, neovascular AMD, or both; AAS 10–11).

The study ophthalmologist examined the anterior segment using slit-lamp biomicroscopy at the annual visit to diagnose or confirm the presence of pseudophakia or aphakia. The severity and progression of cortical and posterior subcapsular cataract (PSC) opacities on the red-reflex lens photographs and the presence of pseudophakia or aphakia were graded at the reading center. Our analysis included only eyes that underwent cataract surgery during AREDS2. Eyes that were pseudophakic or aphakic at baseline were excluded from the study.

Lens Opacity Grading

Masked grading of the red-reflex lens photographs was performed to assess the severity of cortical and PSC opacities. The data quality for photograph grading has been reported previously,22 showing a 93% agreement for the presence of cortical opacities and 97% agreement for the presence of PSC. The AREDS2 grid25 was overlaid digitally on the fundus photographs for evaluation, and the area of lens involvement in sectors of the grid was used to grade the opacities. Cortical and PSC opacities appear as darkly shaded interruptions of the red-orange fundus reflex, and any lens area that is darkened was considered to be involved. Grading for cortical and PSC opacities was performed for the study visit closest from the patient’s surgery date. The reader estimated the percentage of cortical opacity for the entire visible lens. Eyes were classified into 1 of 3 cortical opacity groups, ignoring PSC opacity: group 1, cortical = 0%; group 2, cortical >0% and ≤5%; and group 3, cortical >5%. The PSC opacities were graded within a 5-mm diameter circle of the central lens. Eyes were classified into 1 of 3 PSC opacity groups, ignoring cortical opacity: group 1, posterior subcapsular = 0%; group 2, posterior subcapsular >0% and ≤5%; and group 3, posterior subcapsular >5%. Nuclear opacities were not included in the analysis because they were not graded by standardized photographs, but rather by clinical slit-lamp examination, which may be subject to considerable variability.

The primary outcome of our analysis was the change in BCVA after cataract surgery as compared with before surgery. The documented BCVA before surgery and first recorded postoperative BCVA were used for analysis. Change in visual acuity was the difference in BCVA score between the closest preoperative and postoperative study visits.

Statistical Analysis

A multivariate model using repeated-measures regression analysis was used. Because some patients contributed both eyes to the analysis, we accounted for the correlation between eyes within a
person by specifying a compound symmetry covariance structure. The MIXED procedure of the SAS system (SAS software version 9.3; SAS Inc., Cary, NC) was used. Risk factors included in the model were age at the time of cataract surgery, gender, preoperative AMD level, time between assessment of preoperative and postoperative visual acuity, and cataract opacity groups. Nominal statistical significance was set at 0.05.

Results

Of the 8406 eyes (4203 participants) in the AREDS2 study, 3762 eyes (2092 participants) underwent cataract surgery, with 2370 surgeries performed before enrollment in the study and 1392 undergoing surgery during the study. A total 1232 eyes of 793 patients with the required postoperative visual acuity assessments were included in this study. There were 460 (58%) women and 333 (42%) men. Mean age ± standard deviation at the time of first surgery was 77.1 ± 6.0 years (median, 78 years; range, 54–90 years). These patients (eyes) could have any number of years of follow-up.

Ocular characteristics of eyes that underwent cataract surgery are summarized in Table 1. The preoperative visual acuities are depicted in Figure 1. The mean time ± standard deviation from the last recorded preoperative visual acuity to the operative date was 5.9 ± 3.6 months (median, 6.0 months; interquartile range, 2.8–8.8 months), and the mean time ± standard deviation from the operative date to assessment of postoperative BCVA was 7 ± 3.6 months (median, 7.0 months; interquartile range, 4.0–10.1 months). The mean time ± standard deviation between measurement of preoperative and postoperative visual acuities

Table 1. Ocular Characteristics of Eyes Undergoing Cataract Surgery (n = 1232)

<table>
<thead>
<tr>
<th>Mild Age-Related Macular Degeneration</th>
<th>Moderate Age-Related Macular Degeneration</th>
<th>Severe Age-Related Macular Degeneration</th>
<th>Noncentral Geographic Atrophy</th>
<th>Central Geographic Atrophy, Neovascular Age-Related Macular Degeneration, or Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. (%)</td>
<td>30 (2.4)</td>
<td>346 (28.1)</td>
<td>462 (37.5)</td>
<td>70 (5.7)</td>
</tr>
<tr>
<td>Cortical cataract, No. (%)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>19 (63.3)</td>
<td>264 (76.3)</td>
<td>341 (73.8)</td>
<td>53 (75.7)</td>
</tr>
<tr>
<td>Group 2</td>
<td>1 (3.3)</td>
<td>41 (11.8)</td>
<td>67 (14.5)</td>
<td>10 (14.3)</td>
</tr>
<tr>
<td>Group 3</td>
<td>10 (33.3)</td>
<td>41 (11.8)</td>
<td>54 (11.7)</td>
<td>7 (10)</td>
</tr>
<tr>
<td>PSC, no. (%)*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>24 (80)</td>
<td>296 (85.5)</td>
<td>388 (84)</td>
<td>59 (84.3)</td>
</tr>
<tr>
<td>Group 2</td>
<td>4 (13.3)</td>
<td>45 (13)</td>
<td>70 (15.2)</td>
<td>11 (15.7)</td>
</tr>
<tr>
<td>Group 3</td>
<td>2 (6.7)</td>
<td>5 (1.4)</td>
<td>4 (0.9)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>

PSC = posterior subcapsular cataract. *Group 1, cortical/PSC = 0%; group 2, cortical/PSC >0% and ≤5%; group 3, cortical/PSC >5%.

Figure 1. Bar graphs showing the (A) preoperative and (B) postoperative visual acuity of eyes analyzed. Percentages are shown for eyes with varying degrees of preoperative visual acuity and age-related macular degeneration (AMD) severity. The visual acuity score is represented as Snellen equivalents. GA = geographic atrophy; NV = neovascular.
Cortical cataract

As visual acuity after cataract surgery also was observed across all preoperative visual acuity of 20/40 or worse, a statistically significant mean gain of visual acuity after cataract surgery was found. The gain in visual acuity increased with increasing severity of cortical or PSC grade. Eyes with no cortical opacity (group 1) had a mean gain of 8.3 letters ($P < 0.0001$; $95\%$ CI, 6.5—10.0 letters), those in group 2 gained 8.9 letters ($P < 0.0001$; $95\%$ CI, 6.5—11.4 letters), and eyes in group 3 gained 10.9 letters ($P < 0.0001$; $95\%$ CI, 8.4—13.3 letters). Eyes with no PSC opacity had a mean gain of 5.4 letters ($P < 0.0001$; $95\%$ CI, 4.1—6.6 letters) after cataract surgery, those with group 2 PSC gained 7.4 letters ($P < 0.0001$; $95\%$ CI, 5.4—9.4 letters), and those with group 3 PSC gained 15.3 letters ($P < 0.0001$; $95\%$ CI, 10.8—19.8 letters). In eyes with preoperative visual acuity of 20/40 or worse, a statistically significant improvement in visual acuity was observed across all cortical and PSC groups (Table 3).

In an analysis that further divided the advanced AMD group into those with CGA only ($n = 73$) and those with neovascular AMD with or without CGA ($n = 251$), eyes with CGA had a mean gain of only 4.4 letters ($P = 0.005$; $95\%$ CI, 1.3—7.5 letters), whereas those with neovascular AMD had a mean gain of 7.5 letters ($P < 0.0001$; $95\%$ CI, 5.4—9.5 letters). Visual acuity gain between these 2 groups was not statistically significant ($P = 0.14$).

Because diabetes can affect lens clarity, we analyzed whether diabetes was a significant factor for visual acuity change after surgery. Patients with a history of diabetes ($n = 107$) had a mean gain of 9.0 letters (95% CI, 6.5—11.6 letters), whereas those without diabetes ($n = 686$) had a mean gain of 9.4 letters (95% CI, 7.5—11.4 letters). This was not statistically significant between the 2 groups ($P = 0.71$).

Table 2. Adjusted* Gain in Visual Acuity Score after Cataract Surgery at a Mean Postoperative Period of 7 Months ($n = 1233$)

<table>
<thead>
<tr>
<th>Group</th>
<th>Estimate (Gain of Letters on Visual Acuity Score)</th>
<th>95% Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMD severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild AMD</td>
<td>11.2</td>
<td>6.9—15.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Moderate AMD</td>
<td>11.1</td>
<td>9.1—13.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Severe AMD</td>
<td>8.7</td>
<td>6.7—10.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Noncentral GA</td>
<td>8.9</td>
<td>5.8—12.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Central GA, neovascular AMD, or both</td>
<td>6.8</td>
<td>4.9—8.8</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

AMD = age-related macular degeneration; GA = geographic atrophy; PSC = posterior subcapsular cataract.

*Adjusted for age at time of surgery, gender, years between preoperative and postoperative acuity, and AMD severity, cortical cataract, or posterior subcapsular cataract.

1Group 1, cortical/PSC = 0%; group 2, cortical/PSC >0% and ≤5%; group 3, cortical/PSC >5%.

was 12.9±3.1 months (median, 12 months; interquartile range, 11.7—13.2 months).

Results of the multivariate repeated-measures regression analysis are shown in Table 2. Adjusting for gender, age at the time of surgery, years between preoperative and postoperative acuity, and cortical and PSC severity groups, a statistically significant mean gain of visual acuity after cataract surgery was observed across all AMD severity groups. Patients with mild AMD gained 11.2 letters ($P < 0.0001$; 95% confidence interval [CI], 6.9—15.5 letters), patients with moderate AMD gained 11.1 letters ($P < 0.0001$; 95% CI, 9.1—13.2 letters), patients with severe AMD gained 8.7 letters ($P < 0.0001$; 95% CI, 6.7—10.7 letters), patients with noncentral GA gained 8.9 letters ($P < 0.0001$; 95% CI, 5.8—12.1 letters), and patients with advanced AMD gained 6.8 letters ($P < 0.0001$; 95% CI, 4.9—8.8 letters). There was no statistically significant difference between genders, with women showing a mean visual acuity gain of 9.3 letters ($P < 0.0001$; 95% CI, 7.3—11.3 letters) and men showing a mean gain of 9.4 letters ($P < 0.0001$; 95% CI, 7.4—11.5 letters). In eyes with preoperative visual acuity of 20/40 or worse, a significant gain in visual acuity after cataract surgery also was observed across all AMD severity groups (Table 3).

The postoperative visual acuity as a function of preoperative visual acuity is depicted graphically in Figure 2. After cataract surgery, the proportion of patients improving by more than 10 letters was 36.7% in the mild AMD group, 32.3% in the moderate AMD group, 25.7% in the severe AMD group, 21.4% in the noncentral GA group, and 23.5% in the advanced AMD group. The percentage of patients improving by more than 15 letters was 20%, 15%, 12.1%, 14.3%, and 14.5% in the mild, moderate, severe, noncentral GA, and advanced AMD groups, respectively (Fig 3).

Table 3. Adjusted* Gain in Visual Acuity Score after Cataract Surgery Based on Preoperative Age-Related Macular Degeneration Severity and Lens Opacities in Eyes with Preoperative Visual Acuity of 20/40 or Worse ($n = 733$)

<table>
<thead>
<tr>
<th>Group</th>
<th>Estimate (Gain of Letters on Visual Acuity Score)</th>
<th>95% Confidence Interval</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMD severity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mild AMD</td>
<td>15.0</td>
<td>8.2—21.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Moderate AMD</td>
<td>14.3</td>
<td>11.6—17.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Severe AMD</td>
<td>9.9</td>
<td>7.4—12.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Noncentral GA</td>
<td>10.7</td>
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<tr>
<td>Central GA, neovascular AMD, or both</td>
<td>7.1</td>
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AMD = age-related macular degeneration; GA = geographic atrophy; PSC = posterior subcapsular cataract.

*Adjusted for age at time of surgery, gender, years between preoperative and postoperative acuity, and AMD severity, cortical cataract, or posterior subcapsular cataract.

1Group 1, cortical/PSC = 0%; group 2, cortical/PSC >0% and ≤5%; group 3, cortical/PSC >5%.
This study highlights the visual acuity outcomes of a large cohort of patients who underwent cataract surgery during the AREDS2 study, with analysis using standardized and validated photographic techniques for grading AMD severity, lens opacities, and BCVA at all study visits. This population is unique in that all patients had at least a moderate risk for AMD. After adjusting for covariates, a statistically significant gain in visual acuity after cataract surgery was found among all levels of AMD severity.

Concurrence of AMD and cataract is common among the aging population, and ophthalmologists often are faced with the decision of whether to perform cataract surgery on these patients. Although prior studies have described worsening maculopathy after surgery,12–14 our present study, similar to previous results in AREDS,20 demonstrated that visual acuity improved after cataract surgery in patients with intermediate to advanced AMD. We also showed a correlation with higher improvement in visual acuity with increasing severity of cortical and PSC opacities.

Compared with the original AREDS study,7 the AREDS2 cohort showed a greater mean improvement in visual acuity across all AMD severity groups. There may be several possible explanations for this observation. First, baseline vision before cataract surgery was worse in the AREDS2 cohort compared with AREDS participants. Because change in visual acuity was used as our primary outcome measure,

Discussion

This study highlights the visual acuity outcomes of a large cohort of patients who underwent cataract surgery during the AREDS2 study, with analysis using standardized and validated photographic techniques for grading AMD severity, lens opacities, and BCVA at all study visits. This population is unique in that all patients had at least a moderate risk for AMD. After adjusting for covariates, a statistically significant gain in visual acuity after cataract surgery was found among all levels of AMD severity.

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Compared with the original AREDS study,7 the AREDS2 cohort showed a greater mean improvement in visual acuity across all AMD severity groups. There may be several possible explanations for this observation. First, baseline vision before cataract surgery was worse in the AREDS2 cohort compared with AREDS participants. Because change in visual acuity was used as our primary outcome measure,
patients with worse baseline vision likely would show a greater gain in visual acuity after surgery. Second, technological advances in cataract surgery techniques over the past decade have reduced complication rates and have improved visual outcomes greatly. Furthermore, the grading for lens opacities differed between the 2 studies. The AREDS used slit-lamp photographs to grade nuclear opacities and retroillumination photographs to grade cortical and PSC opacities. The AREDS2 used only red-reflex photographs for grading cortical and PSC opacities; slit-lamp photographs were not obtained to evaluate nuclear cataracts.

The advent of anti—vascular endothelial growth factor (VEGF) intravitreal injections has revolutionized the treatment of, and improved the visual prognosis for, patients with AMD. Anti-VEGF agents were the standard AMD treatment for patients enrolled in the AREDS2 cohort; these therapies were not available when AREDS was being conducted in the 1990s. Before the introduction of anti-VEGF agents, cataract surgery was believed to increase the risk of neovascular hemorrhage and leakage, resulting in worsening visual deterioration. Older treatment methods, which included argon laser photocoagulation and photodynamic therapy, could, at best, only limit vision loss. Significant risk for laser-induced retinal damage, recurrent CNV, and permanent vision loss were not uncommon. In contrast, anti-VEGF agents have been shown to stabilize vision in more than 90% of cases and to improve vision in

![Graph showing the change in visual acuity after cataract surgery with varying Age-Related Macular Degeneration (AMD) severity.](image-url)
more than 30% of cases. Rosenfeld et al showed that cataract surgery was beneficial in patients with neovascular AMD who received monthly ranibizumab injections during the Anti-VEGF Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization trial and the Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular AMD phase 3 studies, with a mean visual acuity improvement of 10.4 letters 3 months after surgery. Thus, the use of these anti-VEGF agents at least in part may account for the improvement in visual acuity after cataract surgery seen in neovascular AMD patients.

Strengths of the study include a large, well-defined population, longitudinal patient follow-up, and a standardized protocol for assessing lens opacities and visual acuities. The primary outcome (change in BCVA before and after surgery) of this study is an easily quantifiable measure. This study has several limitations. The distribution of eyes across the different AMD severity groups was not uniform, ranging from 2.4% of eyes in the mild AMD group to 37.5% of eyes in the severe AMD group. Fixed-interval follow-up on all patients was not possible because of the requirement for only annual study visits, and long-term follow-up data were available only for a relatively small number of eyes, especially those in the mild AMD group, which may have limited the power for this subanalysis. This may explain the smaller gain in visual acuity among patients with mild AMD compared with the other AMD groups in the long-term follow-up analysis. There also could have been a selection bias to enroll a select group of patients into the study. The AREDS2 cohort was highly educated, well nourished, and predominantly white. Issues of greater access to care, threshold for undergoing cataract surgery, and the tendency for healthier behaviors may bias the results of the study. As such, the results of this study may not be generally applicable to all AMD patients. In addition, the primary focus of the AREDS2 study was on retinal outcomes, but we were able to analyze lens outcomes by incorporating red-reflex photographs for grading of cortical and PSC opacities. Assessment of nuclear opacities requires specialized slit-lamp photography, which was not readily available in all 82 clinical sites; data on nuclear opacities were incomplete and were not used for analysis in this study. We acknowledge that nuclear opacities account for a substantial proportion of overall lens opacities, and our results must be interpreted in this context.

In summary, our findings demonstrate that AMD patients achieved a significant improvement in visual acuity after cataract surgery across varying AMD severity. Patients with concurrent visually significant cataract and AMD should not be discouraged from undergoing cataract surgery, because they may benefit from visual improvement after surgery.

References

Footnotes and Financial Disclosures

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