


The PanOptix Trifocal IOL vs the ReSTOR 2.5 Active Focus and ReSTOR 3.0-Add Multifocal Lenses: A Study of Patient Satisfaction, Visual Disturbances, and Uncorrected Visual Performance

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Purpose: To compare spectacle independence, patient-reported outcomes (PROs), and dysphotopsia after multifocal intraocular lens (IOL) implantation with the AcrySof PanOptix trifocal or the ReSTOR +2.5/3.0 D or ReSTOR +2.5 D mini-monovision multifocal IOL.

Patients and Methods: Prospective, open-label, multicenter analysis of PROs, spectacle independence, and satisfaction among patients undergoing cataract surgery who had been implanted at least 1 month previously with AcrySof IQ PanOptix or PanOptix Toric trifocal (n = 59) IOLs bilaterally. Results were compared to outcomes from a similar study with the AcrySof ReSTOR 2.5/3.0 or the ReSTOR ActiveFocus 2.5 mini-monovision lens [n = 191].

Results: Spectacle independence was significantly higher in the PanOptix cohort, with 83% of patients “never” needing glasses for any activity versus 36% in the ReSTOR 2.5 mini-monovision and 34% in the ReSTOR 2.5/3.0 cohorts. No significant differences in patient satisfaction rates were reported between the three cohorts. Glare and halo were rated “extremely” noticeable more with the PanOptix (10%) than with the ReSTOR 2.5 mini-monovision (1%) or ReSTOR 2.5/3.0 (3%). BCVA differences were not statistically significant, and no new safety concerns were reported.

Conclusion: The AcrySof PanOptix trifocal provides significantly greater spectacle independence across all measured activities than the AcrySof ReSTOR multifocal IOLs.

Keywords: cataract surgery, spectacle independence, glare, multifocal intraocular lens

Plain Language Summary

In this prospective, open-label, multicenter analysis evaluating patient-reported outcomes 1 month after scheduled cataract surgery, patients preferred the AcrySof PanOptix trifocal lens for its ability to provide substantially better spectacle independence over the AcrySof ReSTOR multifocal lens.

Introduction

The United States is experiencing a longevity revolution, with 20% of Americans over age 65 still in the workforce and more than half of this age cohort embracing smartphone technology.^{1,2} Americans are remaining active well into their 60s and

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70s, increasing their need to improve and/or maintain their visual function at all three points of focus (near, intermediate, and distance) post-cataract surgery.³ This driving force has increased patient expectations for complete spectacle independence across near, intermediate, and distance vision.^{4,5}

A variety of strategies to provide patients with spectacle independence have been implemented, including advanced surgical techniques and the introduction of premium accommodative and multifocal IOLs. The latter of these provide patients with better overall visual acuity (VA) in intermediate and distance and greater spectacle independence at near than monofocals.^{6,7} Diffractive IOLs have a reported 1.75 times greater likelihood of spectacle independence than other multifocal IOLs.⁷ Even with these advancements, however, patient-reported outcomes (PROs) note more frequent dysphotopsia and worse contrast sensitivity, especially with low light or glare, with multifocal IOLs than with monofocal lenses. Further, patient satisfaction rates with premium lenses directly correlate with their ability to be spectacle-free.^{6,8–14}

Our previous work compared PROs, satisfaction rates, and spectacle independence between blended or bilateral multifocal IOLs in patients who underwent cataract surgery (AcrySof IQ ReSTOR +2.5 D and ReSTOR +3.0 D, Alcon, Ft. Worth, Texas).¹⁵ We found that the combination of a ReSTOR +2.5 D and ReSTOR +3.0 D resulted in higher patient satisfaction rates for intermediate vision than bilateral ReSTOR +3.0 D implants, but that overall PRO differences were not statistically significant.

To date, patient-reported satisfaction beyond glare/halo has not been compared between the ReSTOR +2.5/3.0 D, the ReSTOR +2.5 D mini-monovision, or the AcrySof IQ PanOptix or PanOptix Toric trifocal (Alcon). This study was designed to assess whether satisfaction rates, spectacle independence, and effect of unwanted visual phenomena would differ between the PanOptix and the two ReSTOR lenses previously evaluated.

Patients and Methods

This trial was a prospective, open-label, multicenter analysis of PROs and satisfaction among patients who underwent bilateral cataract surgery at least 1 month previously with AcrySof IQ PanOptix or PanOptix Toric trifocal IOLs. Comparison was made to two previous cohorts of multifocal IOL patients who had undergone similar surgery and responded to a similar questionnaire in a similar time frame.¹⁵ In that study, the 2.5 mini-monovision cohort received the AcrySof IQ ReSTOR ActiveFocus +2.5 D or

AcrySof IQ ReSTOR ActiveFocus +2.5 D add toric implant bilaterally, with the dominant eye targeted for emmetropia and the nondominant eye targeted for -0.5 sphere. The “2.5/3.0” cohort was implanted with the AcrySof IQ ReSTOR ActiveFocus +2.5 D implant in the dominant eye and the AcrySof IQ ReSTOR +3.0 D multifocal lens the nondominant eye. To determine the sample size needed for this analysis, a calculation was performed based on a 10% margin of error, a 95% confidence interval, and a response distribution of 80%. This resulted in a sample size of 62 patients.

In this study, patients were eliminated if their residual refractive error in either eye deviated from plano by more than 0.5 D of sphere or 0.75 D of cylinder. (An explanation of how we accounted for this difference in our methodology is outlined in the “Subcohort Analysis” section).

In all cohorts, all eyes underwent phacoemulsification cataract surgery using either a manual or a femtosecond laser-assisted technique, with a target refraction as close to plano as the available lens powers allowed, erring on the side of the first myopic lens choice when necessary. Patients in all cohorts were excluded if they had significant ocular pathology that could alter their perception of the outcome of surgery, or if they had more than grade 1 posterior capsule opacity (PCO). All aspects of this study were conducted under the surveillance of Aspire Institutional Review Board (Santee, CA, USA) following the principles of the Declaration of Helsinki, and patients completed an informed consent process to participate. Reasonable requests to the corresponding author for original data will be honored for a period of 2 years from the publication date of this study. Patients were asked to complete a validated questionnaire, assisted by a research staff member, that evaluated their satisfaction with the surgery and with their spectacle independence (See [Supplemental Information](#)). Objective outcomes included final refraction, bilateral best-corrected visual acuity (BCVA) on a Snellen chart across all distances, and presence of posterior capsular opacification (PCO), if any.

PRO Questionnaire

The PRO questionnaire (MDBackline, Laguna Beach, CA, USA) was specifically developed and validated to evaluate the satisfaction, spectacle independence, and effect of unwanted visual phenomena of patients who have undergone cataract surgery with presbyopia-correcting lenses. The assessment of these subjective outcomes differentiates this questionnaire from the National Eye Institute Visual Function Questionnaire-14 (VF-14 QOL) and other general-use visual

function questionnaires. This questionnaire has available for use in U.S.-based cataract practices since 2014; results generated from this questionnaire have been used in other studies as well.^{16,17}

Subcohort Analysis

To account for the difference in exclusion factors between this study and the previously published study,¹⁵ we examined the raw data to perform a subcohort analysis of overall satisfaction and overall spectacle independence (our primary and secondary endpoints) for the subset of 2.5 mini-monovision and 2.5/3.0 patients who met those same refractive criteria.

Results

Demographics

There were 59 patients enrolled; mean age was 69±9.6 years. Differences between the PanOptix cohort and the two comparator cohorts were not statistically significant ($P = 0.72$, Figure 1). There was a higher percentage of patients who underwent femtosecond laser-assisted cataract surgery in the PanOptix cohort ($n=52$, 88%) than in the 2.5 mini-monovision cohort ($n=57$, 56%) or the 2.5/3.0 cohort ($n=18$, 22%).

Patient Satisfaction

No statistically significant differences were noted in overall satisfaction among the cohorts, with “very satisfied” being reported in 84.7% of the PanOptix cohort, 74.5% of the 2.5 mini-monovision cohort, 74.1% of the 2.5/3.0 cohort (Figure 2). Patients were “very likely” or “somewhat likely” to refer friends and family for the same procedure in 99% of the PanOptix cohort, 96% of the 2.5 mini-monovision cohort, and 88% of the 2.5/3.0 cohort. The difference between the PanOptix and the 2.5/3.0 cohorts was statistically significant ($P < 0.01$, Chi squared test). Conversely, one patient (2%) in the PanOptix cohort, four patients (4%)

in the 2.5 mini-monovision cohort, and four patients (4%) in the 2.5/3.0 cohort reported they were either “very” or “somewhat” dissatisfied with their vision. Qualitative analysis of free-text responses from patients who reported dissatisfaction showed that dissatisfaction was generally related to unwanted visual phenomena (glare/halos) in the PanOptix cohort, the need for reading glasses in the 2.5 mini-monovision cohort, and glare/halos in the 2.5/3.0 cohort, with some patients in all three cohorts describing ocular surface discomfort or other complaints (i.e, implant cost) that were not related to the quality of the implants themselves or their vision.

Subgroup analysis was performed on patients in both the 2.5 mini-monovision and 2.5/3.0 cohorts to evaluate patients ± 0.5 D of sphere and ± 0.75 D of cylinder. In the 2.5 mini-monovision cohort, 74 patients (73%) met the criteria, as did 33 patients (80%) in the 2.5/3.0 cohort. In this subgroup, overall satisfaction was “very satisfied” in 85% of patients with PanOptix, in 82% of patients with 2.5 mini-monovision, and in 70% with 2.5/3.0. “Somewhat satisfied” was reported by 12%, 14%, and 24%, respectively. None of the differences in satisfaction were statistically significant.

Spectacle Independence

Overall spectacle independence (Figure 3) for all visual activities combined was significantly higher in the PanOptix cohort, with 83% of patients “never” needing glasses for any activity versus 36% in the 2.5 mini-monovision and 34% in the 2.5/3.0 cohorts ($P < 0.0001$, Chi-squared test). “Frequent” use of glasses was reported by 14% of patients with PanOptix, 11% with 2.5 mini-monovision, and 34% with 2.5/3.0 ($P < 0.0001$ for PanOptix vs both other cohorts, Chi-squared test).

For PanOptix patients, the only activity requiring spectacles was reading. Reading glasses were required in 17% of PanOptix patients, 64% with 2.5 mini-monovision, and 60% with 2.5/3.0 ($P < 0.0001$ for PanOptix vs each cohort, Chi-squared test). For other activities (computer use, driving, watching TV, and sports/hobbies), none of the PanOptix patients reported a need for spectacles, and a low rate of 20% or less need for spectacles was reported for all lenses and all activities (Figure 4).

In the subgroup analysis (± 0.5 D of sphere and ± 0.75 D of cylinder), there was no need for spectacles for any activity reported by 83% of patients with PanOptix, 35% with 2.5 mini-monovision, and 33% with 2.5/3.0 ($P < 0.0001$ for both PanOptix vs 2.5 mini-monovision and vs 2.5/3.0, Chi-squared test). There was also no statistically

	2.5/3.0	2.5 Mini-mono	Panoptix
N (meeting criteria)	89	102	59
Age (yrs): Mean \pm SD	72.1 \pm 7.6	71 \pm 8.1	69 \pm 9.6
	P<0.72 for 2.5/3.0 vs Panoptix		
Age range	52 – 99	35-91	41-100

Figure 1 Patient demographic data.

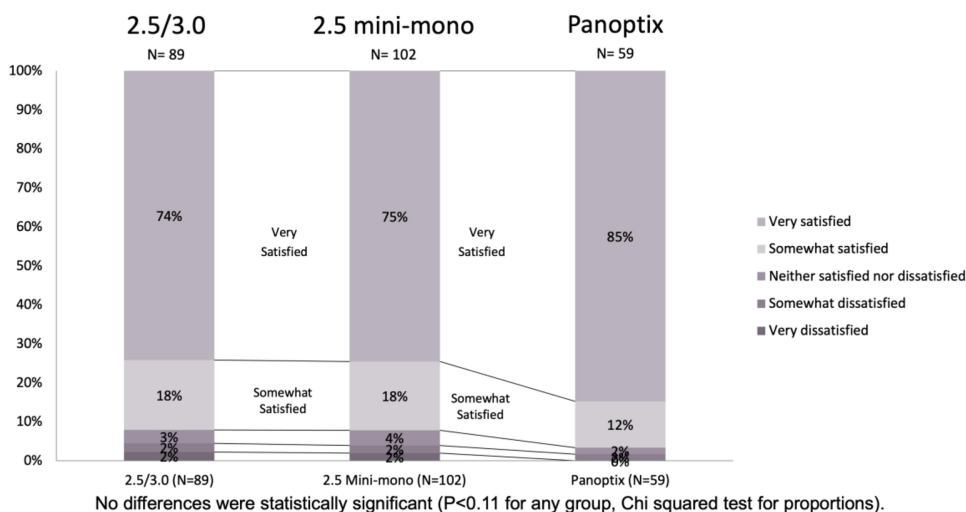
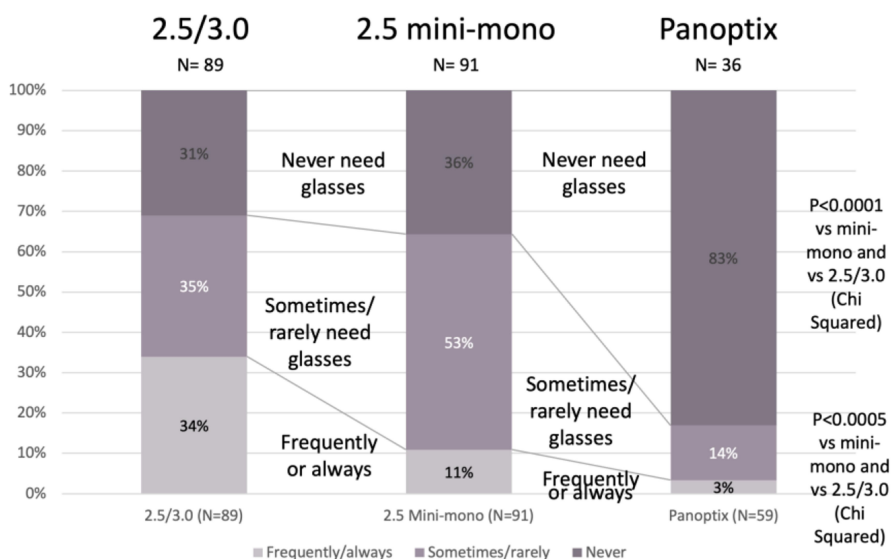


Figure 2 Overall patient satisfaction.



Patients with Panoptix had significantly less need for spectacles for any activity than patients with Either 2.5/3.0 or 2.5 mini-monovision.

Figure 3 Overall spectacle independence.

significant difference in outcomes between patients who underwent femtosecond laser-assisted cataract surgery and those who underwent manual phacoemulsification; that bore out for each additional outcome measure as well.

Glare and Halos

There were no differences in reported glare or halo between any of the cohorts. Severity was reported as “not at all” by 37% of patients with PanOptix, 42% with 2.5 mini-monovision, and 33% with 2.5/3.0. “Extremely” was reported

by 10% with PanOptix, 1% with 2.5 mini-monovision, and 3% with 2.5/3.0 ($P < 0.07$, Chi-squared test; Figure 5).

BCVA

BCVA of 20/20 or better in both eyes was achieved by 76% of PanOptix patients ($n=59$), 65% with 2.5 mini-monovision ($n=94$), and 64% with 2.5/3.0 ($n=72$). BCVA of 20/25 was achieved by 93%, 90%, and 90%, respectively. All patients had BCVA of 20/40 or better. These differences were not statistically significant.

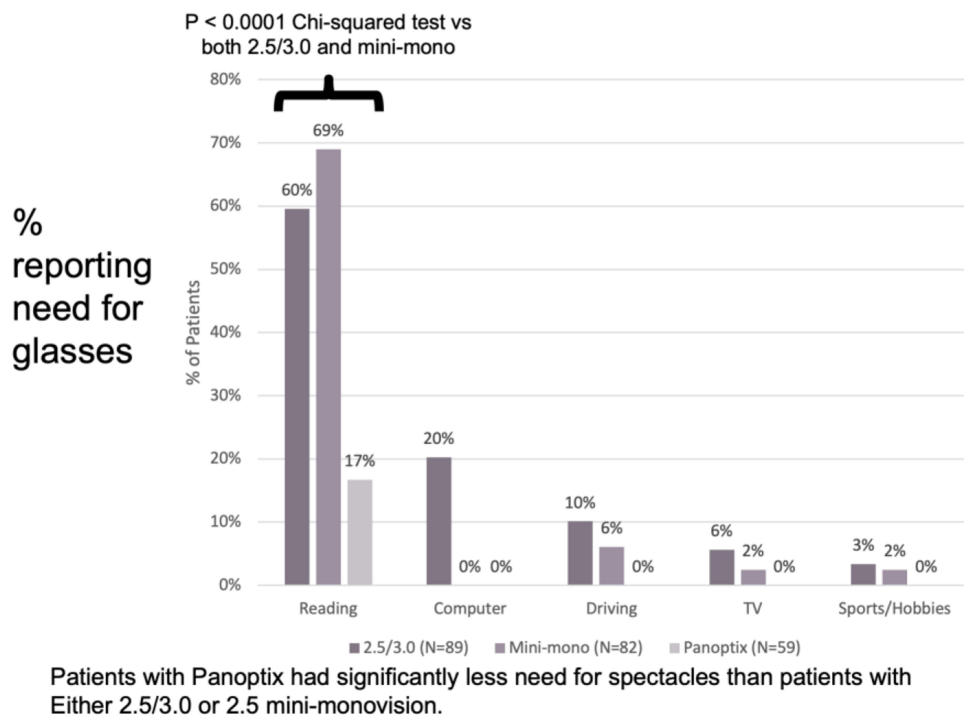


Figure 4 Need for spectacle use.

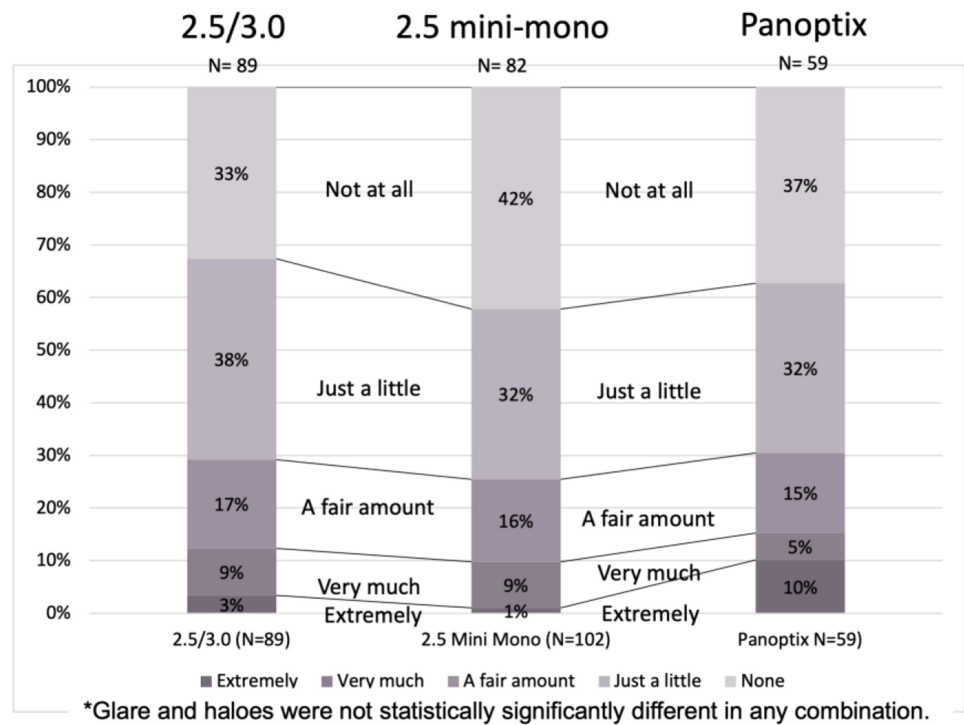


Figure 5 Incidence of glare and haloes.

Femtosecond Laser Use

Femtosecond lasers were available to surgeons for all patient cohorts and were used for surgery in 52 (88%) of 59 PanOptix patients, 28 (27%) of 102 2.5 mini-

monovision patients, and 18 (22%) of 83 2.5/3.0 patients, where these data were recorded (P < 0.002 and P < 0.0001 for PanOptix vs 2.5 mini-monovision and 2.5/3.0, respectively, Chi-squared test).

Discussion

Optimizing visual outcomes and increasing postoperative patient satisfaction are the primary goals of cataract surgeons today. Now more than ever, patients desire to be completely free of spectacles after cataract surgery and require optimal vision at all focal points to maintain independence and productivity in the workforce.^{18,19} A number of advanced premium lenses have been developed to accommodate this need, including the AcrySof IQ PanOptix trifocal and the AcrySof IQ ReSTOR +2.5 and +3.0, among others. Despite these advancements, residual refractive error and spectacle dependence are common complaints among patients implanted with premium lenses,^{10,12,14,20} and often result in patient dissatisfaction.

This study shows a statistically significant difference in spectacle independence between PanOptix and the AcrySof IQ ReSTOR +2.5 and +3.0. In this study, the PanOptix was able to produce complete spectacle independence in 83% of patients, which, anecdotally, was surprisingly high. Although others have claimed spectacle independence of up to 87.5% with earlier generation multifocal lenses,²¹ this has not been the general experience of the authors and other experienced surgeons (personal communications with JAH). All patients were enrolled prospectively and answered the same questionnaire, thereby alleviating the potential concern about differing measurement techniques or study design. It is the authors' belief that the spectacle independence achieved with the PanOptix has the potential to greatly impact patient care by providing a much higher level of spectacle independence than other lenses.

Although not statistically significant, patients reported higher rates of overall satisfaction with the PanOptix over both ReSTOR lenses. Notably, however, patients in the PanOptix cohort reported more bothersome glare and halo (10%) when asked specifically about this phenomenon compared to only 1% and 3% in ReSTOR 2.5 mini-monovision and ReSTOR 2.5/3.0 cohorts, respectively. Glare and halo are common side effects of multifocal lenses, occurring 3.5 times more often in multifocal than in monofocal lenses, and only lead to IOL exchanges in extreme cases.^{22–25} While the PanOptix lens caused more bothersome glare and halo symptoms, PanOptix had more than twice the frequency of complete spectacle independence of the compared to ReSTOR lenses in those studies. We postulate that, as a driver of patient satisfaction, spectacle independence supersedes glare and

halo symptoms, and we rarely recommend ReSTOR lenses to patients now that PanOptix is available in the US.

This study has several limitations. Comparisons were made against raw data from a previous study that did not exclude refractive outliers, which may have introduced unintended biases in favor of the ReSTOR cohorts. To compensate, however, we performed a subgroup analysis of patients who did meet the same refractive criteria, and there was no change in our primary or secondary outcomes (satisfaction and spectacle independence) of this study.

More patients underwent cataract surgery with femtosecond lasers in this study than in the previous one. However, the two main benefits of femtosecond lasers are touted to be refractive accuracy and less traumatic surgery, a proxy for which is BCVA. We eliminated any bias of refractive accuracy by performing a subgroup analysis and found BCVA was similar between the three cohorts. The differences in spectacle independence is likely an effect of the IOL design and not the femtosecond laser.

These limitations are more than offset by the strengths of the study, including that it was a prospective study across several clinics. Because these were premium lens patients, they were already motivated to be cognizant of minor changes in visual outcomes. This may have explained the very low percentages (<5%) who were dissatisfied with any of the premium lenses evaluated. Finally, the primary outcomes measure of spectacle-free vision, was achieved in a surprisingly high number of patients, given the propensity for photopsia in premium lenses. Although the percentage of patients in the PanOptix cohort who noticed glare and halo was substantially higher than in the other groups, patients were not negatively impacted by them, which suggests they were either minor or transient. We believe from personal interaction with patients that the high spectacle independence achieved with this lens offsets complaints from glare and haloes that would otherwise be a greater concern. This may also explain the widespread adoption and acceptance of this lens among surgeons in Europe and the US, where it has been most widely used. We welcome future studies with larger cohorts to bolster our findings. In today's demanding cataract surgery arena, our results may help cataract surgeons with their IOL recommendations.

Conclusion

The PanOptix multifocal IOL increases the likelihood of complete spectacle independence compared to the ReSTOR +2.5 D mini-monovision and the ReSTOR +3.0 D lenses. Overall patient satisfaction rates were higher for the PanOptix, but so were the rates of dysphotopsia.

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Disclosure

Dr John A Hovanesian reports grants, personal fees from Alcon, during the conduct of the study; personal fees from Alcon, outside the submitted work. Dr Quentin Allen is a consultant for Alcon. The authors report no other conflicts of interest in this work.

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