



Clinical outcomes and functional visual performance: comparison of the ReSTOR apodised diffractive intraocular lens to a monofocal control

R J Cionni, D F Chang, E D Donnenfeld, et al.

Br J Ophthalmol 2009 93: 1215-1219

doi: 10.1136/bjo.2008.146647

Updated information and services can be found at:

<http://bjo.bmj.com/content/93/9/1215.full.html>

These include:

References

This article cites 17 articles, 1 of which can be accessed free at:

<http://bjo.bmj.com/content/93/9/1215.full.html#ref-list-1>

Email alerting service

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To order reprints of this article go to:

<http://bjo.bmj.com/cgi/reprintform>

To subscribe to *British Journal of Ophthalmology* go to:

<http://bjo.bmj.com/subscriptions>

Clinical outcomes and functional visual performance: comparison of the ReSTOR apodised diffractive intraocular lens to a monofocal control

R J Cionni,¹ D F Chang,² E D Donnenfeld,³ S S Lane,⁴ J P McCulley,⁵ K D Solomon⁶

¹ Salt Lake City, Utah, USA;

² Los Altos, California, USA;

³ Long Island, New York, USA;

⁴ Stillwater, Minnesota, USA;

⁵ Dallas, Texas, USA;

⁶ Charleston, South Carolina, USA

Correspondence to:

Dr R J Cionni, 1945 CEI Drive, Cincinnati, OH 45242, USA; rcionni@cincinnati.eye.com

Accepted 15 February 2009

ABSTRACT

Aims: To compare clinical outcomes of patients bilaterally implanted with SN60D3 intraocular lenses (IOLs) with outcomes of bilateral monofocal controls, and to determine the validity of implanting an apodised diffractive lens in a healthy patient population.

Methods: Six unmasked US investigators prospectively enrolled 72 patients aged ≤ 70 years with bilateral cataracts in otherwise healthy eyes. Patients underwent routine cataract extraction via phacoemulsification with SN60D3 implantation. Visual outcomes were assessed 1 week, 1 month and 6 months postoperatively. Patients completed two subjective surveys. As controls, 51 patients who were 6 months postoperative to bilateral implantation of AcrySof monofocal IOLs also were assessed.

Results: Corrected and uncorrected distance visual acuity was similar across groups. For uncorrected near and intermediate visual acuity, statistically significant differences were found favouring the SN60D3 group ($p < 0.0001$). Contrast sensitivity was significantly better in monofocal patients at 6 cpd and 18 cpd under various lighting conditions. The Functional Evaluation and the Questionnaire demonstrated that SN60D3 patients achieved significantly higher levels of functional vision and spectacle freedom ($p < 0.0001$).

Conclusion: Despite mildly decreased contrast sensitivity when compared with a monofocal IOL, the SN60D3 provided high patient satisfaction, excellent functional vision, and high rates of spectacle freedom.

Opacities of the natural crystalline lens occur with age, rendering loss of the ability to perform routine tasks such as driving and reading. This loss of functional vision negatively impacts patient quality of life.^{1,2} Cataract surgery with a standard monofocal intraocular lens (IOL) greatly improves best-corrected visual acuity, but emmetropic patients remain largely dependent upon spectacles for near and intermediate tasks. The availability of multifocal IOLs made functional vision across a broader range of distances (including intermediate and near distances) possible. However, these lenses present another set of challenges, including halo and glare.³⁻⁶

The multifocal IOL studied here is a third-generation multifocal IOL, the spherical AcrySof ReSTOR SN60D3 apodised diffractive IOL. Current literature indicates that the majority of patients implanted with SN60D3 IOLs obtain spectacle freedom for reading at far and near distances, and report only mild glare and halos associated with little to no interference with daily

activities.^{3,4,7} However, questions still remain regarding the choice to implant the SN60D3 over a standard monofocal IOL. Intermediate vision is lower in patients with this lens than in patients with some other presbyopia-correcting IOLs,^{8,9} though the newer aspherical SN6AD3 provides better intermediate vision than did its predecessor, the spherical SN60D3.¹⁰ Patients with larger pupil sizes may be disadvantaged regarding near and intermediate vision in low light conditions;^{11,12} however, this disadvantage should be at least partially addressed by the aspherical redesign of the SN6AD3 model.

In order to determine the validity (from a patient viewpoint) of implanting a SN60D3 IOL over a monofocal IOL, this study assessed patient satisfaction and real-world patient function, as well as standard visual outcome data, in bilaterally implanted patients.

PATIENTS AND METHODS

Patient cohort

From 29 April 2005 to 1 May 2007, six unmasked investigative sites prospectively enrolled 95 patients for bilateral SN60D3 implantation (group 1). Patients were ≤ 70 years of age with operable bilateral cataracts and no coexisting conditions listed in the "Cautions" section of the AcrySof ReSTOR product insert (eg, retinal conditions, amblyopia, severe corneal dystrophy, etc). All patients had ≤ 1 D of astigmatism preoperatively. Four of the six sites also enrolled 51 patients previously implanted with bilateral AcrySof monofocal (SA60AT, SN60AT or SN60WF) IOLs (group 2). The monofocal sample size was smaller due to the following restrictions: 6 (SD 1) month postoperative, ≤ 1 D astigmatism, free of conditions mentioned above. To closely simulate real-world scenarios, IOL discounts were not provided to either group: group 1 patients paid the additional premium for the multifocal IOL. The investigation was conducted under IRB supervision. Patients gave consent in accordance with the Declaration of Helsinki.

Group 1 patients were administered a preoperative exam (≤ 35 days prior to surgery) and a monocular exam at 1 week postoperative. Binocular postoperative exams followed at 30 (7) days and at 6 (1) months. Control patients were evaluated 6 (1) months postoperatively.

Surgical method

Surgeries were performed under the routine surgical regimen of the respective investigators.

Investigators performed sutureless phacoemulsification through a clear corneal incision (≤ 3.0 mm). Investigators targeted emmetropia to +0.25 hyperopia (both patient populations). Foldable IOL insertion (Monarch II injector) into the capsular bag took place through a capsulorhexis with a ~ 5.5 mm diameter. Second eye surgery was performed within 30 days of first eye surgery. Postoperative adjustments were delayed, pending study completion.

Visual outcome measures

Distance visual acuity (VA) testing was performed with a standard 4 m Early Treatment of Diabetic Retinopathy Study chart at all non-operative study visits. Intermediate and near VA testing was conducted with the Sloan 40 cm near card. The following formula was used to convert intermediate and near VA readings: recorded VA = $-\log[\text{observed distance}/(0.4 \times 10^{\text{observed VA}})]$.

Visual acuity testing included binocular uncorrected (UCVA) and best corrected (BCVA) tests at far (4 m), intermediate (50 cm) and near (31 cm and patient-preferred) distances.

Binocular contrast sensitivity testing was performed at the 6-month visit. Subjects were placed 2.4 m from the Vector Vision CSV-1000 retroilluminated translucent chart. The test was performed with best correction under four lighting conditions: photopic (>85 cd/m²), photopic with glare, mesopic (~ 3 cd/m²) and mesopic with glare. Pupillometry was carried out during both the photopic and mesopic testing conditions. A Titmus Fly Ring Stereotest was administered at the 6-month visit.

Functional vision/subjective measures

The functional vision evaluation (evaluation) was administered at the 6-month visit. The evaluation is not a validated instrument but was designed to evaluate the level of patient function during near, intermediate and distance activities. Three rounds of questioning comprise the evaluation. The first (subjective questions assessing spectacle freedom) and second (objective questions to assess reading performance) rounds require patients to use a computer. The assessment was intentionally computer-driven in order to compel patients to decipher words on the screen. The third round (objective questions requiring environmental interaction) required patients to answer questions about common household props (eg, a magazine, soup cans, etc) placed around the room. Sample questions can be read in table 1. When compared with outcomes on typical clinical assessments such as VA testing, these objective questions may be a better indication of lens performance.

The Quality of Life Vision Questionnaire (Questionnaire) to evaluate visual performance during daily life was self-administered via computer with the patient logging on to a testing website. Subjects could complete the Questionnaire at the investigative site or at home if internet access was available. The same Questionnaire was completed preoperatively, and 1 week, 1 month and 6 months postoperatively. The Questionnaire is not a validated instrument but was designed to assess the difficulty level ("none," "little," "moderate," or "extreme") of performing daily tasks without the use of spectacles. Sample questions can be read in table 1.

STATISTICAL METHODS

Statistical analysis was performed by an independent biostatistician using the SAS system (Version 9.1, SAS Institute, Cary,

Table 1 Representative questions of the evaluation and questionnaire

Sample evaluation questions

How often do you wear glasses to use a computer?

0 = I never wear glasses for this activity ...

10 = I always wear glasses for this activity

11 = NA

How much difficulty do you have driving at night?

No difficulty at all

A little difficulty

Moderate difficulty

Extreme difficulty

I do not drive

Examine the eye-drop bottle. What is the expiration date?

2008/01

2006/07

2006/01

2007/07

Cannot read the expiration date

Sample questionnaire questions

Do you have difficulty reading a newspaper or book without glasses?

No difficulty at all

A little difficulty

Moderate difficulty

Extreme difficulty

I wear glasses to perform this activity

I never perform this activity

Do you notice halos around light?

Yes

No

If yes, how would you rate them?

Mildly bothersome

Moderately bothersome

Severely bothersome

North Carolina). All patients completing 6-month visual acuity data were analysed. Of this group, those completing the 6-month evaluation and questionnaire (respectively) were included in the statistical analyses of these assessments. Between-group comparisons were performed using the Wilcoxon test for quantitative variables and the χ^2 test for categorical variables. Correlation analyses were conducted using the Cochran–Mantel–Haenszel test for general association with adjustment for type of IOL implanted. The significance level was 0.05 for all tests.

RESULTS

Patient cohort

Seventy-two (72) group 1 (SN60D3) patients completed the 6-month study visit and were included in the data analysis. Group 1 was 40% male and 60% female with an average age of 63 (6) years. The group's average preoperative spherical equivalent (SE) was -1.0 (3.0) D, and the mean 6 month postoperative SE was 0.11 (0.39) D. Group 2 (monofocal control) was 30% male and 70% female, 67 (8) years of age with a mean 6-month postoperative SE of -0.1 (0.4) D. The two groups were comparable in 6-month SE ($p = 0.21$).

Visual outcome measures

Table 2 reports binocular UCVA and BCVA results at all four distances.

Statistically significant differences were found between groups for photopic pupil size ($p = 0.015$) and mesopic pupil size

Table 2 Mean logMAR visual acuity results by group

	Group 1	Group 2	p Value
Uncorrected visual acuity			
Distance (4 m)	0.05	0.06	p = 0.67
Intermediate (50 cm)	0.16	0.34	p<0.0001*
Near (31 cm)	0.19	0.63	p<0.0001*
Near (patient preferred)	0.11	0.65	p<0.0001*
Best-corrected visual acuity			
Distance (4 m)	0.00	0.00	p = 0.74
Intermediate (50 cm)	0.25	0.42	p = 0.0025*
Near (31 cm)	0.15	0.73	p<0.0001*
Near (patient preferred)	0.10	0.66	p<0.0001*

*Statistical significance.

(p = 0.0002), with group 1 having larger pupils under both conditions. The mean photopic and mesopic pupil sizes (respectively) were 3.6 (0.8) mm and 4.9 (0.9) mm for group 1, and 3.2 (0.7) mm and 4.3 (0.8) mm for group 2.

Contrast sensitivity testing revealed a small number of significant differences favouring group 2 (fig 1). No difference in stereoacuity was detected between groups (p = 0.33).

Functional vision/subjective measures Evaluation

Spectacle freedom was significantly different between groups (p<0.0001). Table 3 compares spectacle freedom for common activities by group and the results of uncorrected near reading tasks. Both groups were satisfied with their ability to view the computer monitor during the evaluation (9.4 for group 1 and 9.3 for group 2 on a 10-point scale).

Excellent vision was reported in 62.3% of apodised diffractive patients at 6 months postoperative, while 34.8%, 1.5% and 1.5% reported good, fair and poor, respectively. The rating by

monofocal patients was statistically significantly different at 27.3% excellent, 45.5% good, 21.2% fair and 6.1% poor (p<0.0001 for each rating). Ninety per cent of group 1 patients and 94% of group 2 patients would choose the procedure again, and 88% of patients in either group would recommend the same procedure to a friend.

Table 4 provides visual disturbance data for the two groups.

Questionnaire

Results of the 6-month questionnaire also showed spectacle freedom to be significantly different (p<0.0001) between groups (70.3% of group 1 and 17.4% of group 2). Spectacle freedom during many day-to-day activities was statistically significantly different between groups. This difference favoured group 1 and included reading small print; reading a newspaper or book; using a computer; reading a restaurant menu; doing fine handwork; writing checks, paying bills or filling out forms; playing games; and shopping (all items p≤0.01). Halo (p<0.0001) and glare (p = 0.01) problems also showed significant

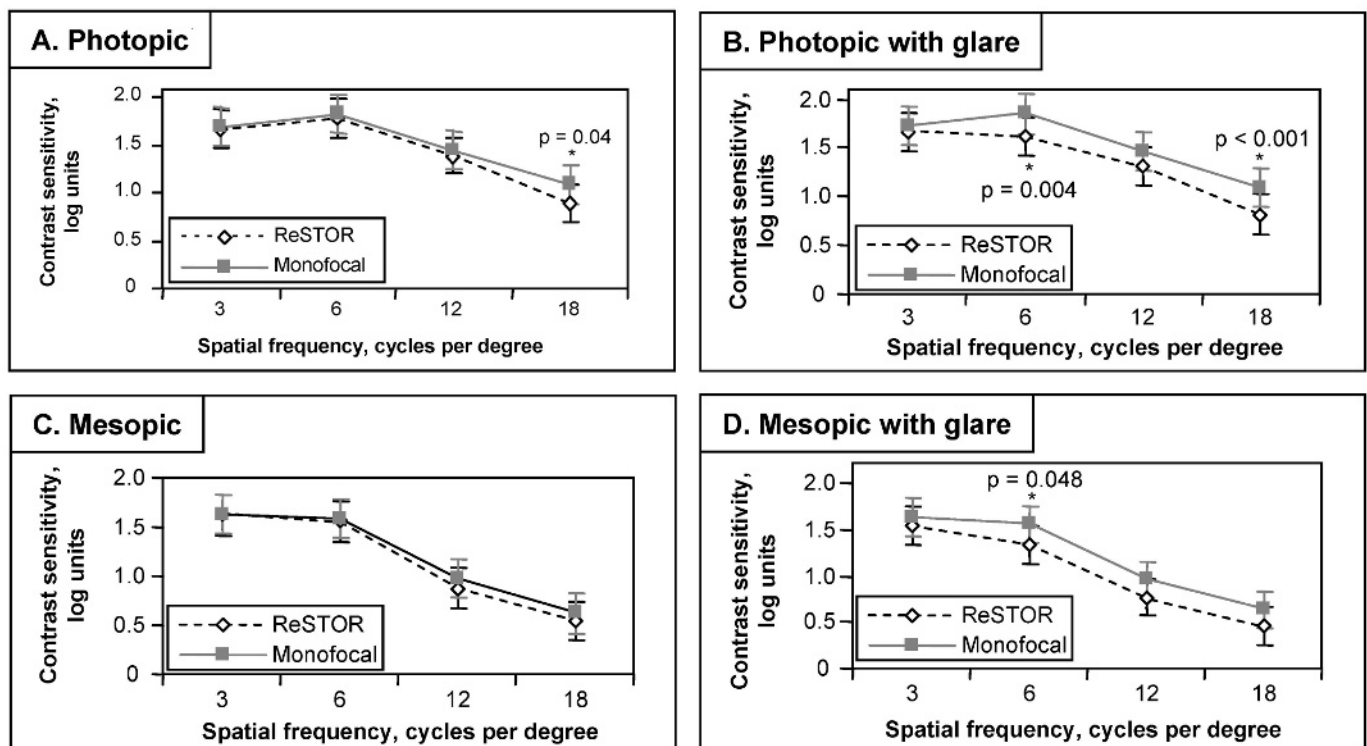


Figure 1 Six-month postoperative contrast sensitivity for the apodised diffractive and monocular lens groups under (A) photopic conditions, (B) photopic with glare conditions, (C) mesopic conditions and (D) mesopic with glare conditions.

Table 3 Evaluation results of spectacle freedom questions and performance on environmental interaction questions

	ReSTOR (group 1) (%)	Monofocal (group 2) (%)	p Value
Overall spectacle freedom	80.6	12.1	<0.0001
Functional task—percentage spectacle freedom			
Reading newspaper/book	75.0	2.9	<0.0001
Reading dimly lit menu	76.1	2.9	<0.0001
Using computer monitor	70.7	23.1	<0.0001
Driving at night	90.9	61.3	0.0005
Environmental interaction questions—percentage of correct answers			
Wall Street Journal—stock price	97.0	35.3	<0.0001
Magazine—picture caption	100	57.6	<0.0001
Medicine box—dosing instructions	100	65.5	<0.0001
Droptainer—expiration date	100	78.1	<0.0001
Nutrition bar—ingredients	100	61.8	<0.0001
Soup cans—description	100	100	NA
Street map—intersection	100	79.4	0.0001
Mobile phone—number on screen	100	91.2	0.0143
Wall poster—title	100	98.5	0.4773
Clock on wall—time	100	100	NA

differences between groups, with group 2 experiencing less. No significant difference existed between groups for patient-reported satisfaction (median of 9 for both groups on a 10-point scale). Satisfaction was correlated with patients' rating of postoperative vision ($p = 0.013$).

DISCUSSION

Several studies in the literature compare the apodised diffractive lens with a monofocal control.^{3 4 13–15} This study separates itself as a large, multisite investigation focusing on visual function, or the ability of the patients to operate within their surroundings postimplantation of the apodised diffractive IOL. Additionally, the study's patient population was not very elderly—still young enough to be potentially more demanding of the ability to interact with computers, drive at night, take part in hobbies, etc, without the use of spectacles.

Though the visual outcome data presented in this paper add to the body of knowledge on the apodised diffractive IOL, survey data are of greater interest. These assessments not only examined commonplace subjective measures such as spectacle freedom, patient satisfaction and patient vision rating but also required patients to report spectacle freedom for many categories of activities including work-related activities, everyday tasks and social situations. Most uniquely, the evaluation tested patient ability to interact with props in the examination room. Patients were required to read and correctly identify information important to quality of life (eg, reading a restaurant menu) and everyday tasks (eg, reading an expiration date on a medicine bottle). This information validates the use of a multifocal lens in a cataract population of an active and self-reliant age. Additionally, this type of information is likely helpful in the decision-making process of presbyopia-correcting IOL patients.

According to the surveys (questionnaire and evaluation), the percentage of patients achieving spectacle freedom differed significantly between the two groups. The percentage of spectacle freedom differed between these two assessments by ~10%. This may be due to the influence of at-home reporting for the questionnaire. In group 1, the percentage of patients

reporting complete spectacle freedom was lower for the on-line questionnaire (70.3%) than for the in-office evaluation (80.6%). An explanation for this phenomenon may be that patients demonstrated the best results to the doctor. Supporting this theory, the result of the questionnaire's overall spectacle freedom was more in line with patient reported spectacle freedom for individual tasks (table 3).

Though group 1 multifocal patients obtained a much higher percentage of spectacle freedom, both groups reported an average satisfaction rating of 9 on a 10-point scale (10 being completely satisfied). This lack of difference (despite spectacle freedom dissimilarity) may be because monofocal pseudophakes were retrospectively enrolled and thus had no expectation of spectacle freedom. Additionally, group 1 patients paid more, making it likely that the group 1 patients had higher expectations and would be harder to please. The fact that multifocal patients were just as satisfied as monofocal patients, despite a higher expectation, makes a case for the validity of implanting the SN60D3 in this patient population.

The two surveys also examined visual disturbances. In line with the current literature,^{3 4 15} a larger percentage of group 1 patients reported halo and glare, even though a postoperative window of 6 months was provided for neural adaptation. Surprisingly, despite reduced contrast in night-time driving conditions (clinical outcome data) and a higher percentage of reported glare and halos, a lesser percentage of SN60D3 patients (11.8%) than monofocal patients (21.2%) reported moderate to extreme difficulty driving at night. Unimpaired night driving requires not only good distance vision and lower levels of glare, but also good near-to-intermediate visualisation of the dashboard. This could explain why group 1 had a lower incidence of extreme difficulty with night driving than group 2 and makes the point that functional data are important in the assessment of lens performance.

The most unique aspect of the surveys, the interaction with props, best demonstrates the functionality of the SN60D3. Both apodised diffractive and monofocal patients had no problems answering questions about distant objects such as a time on a wall clock or the title of a poster. Differences began to surface

Table 4 Patients reporting visual disturbances by group

	ReSTOR (group 1)	Monofocal (group 2)
Night-time vision problems (%)	43.5	23.5
Percentage reporting halo	65.0	23.5
Halo rating	2.7 (1.8)	2.6 (2.2)
Percentage reporting glare	60.9	44.1
Glare rating	3.1 (1.9)	3.2 (1.7)

A seven-point scale, with zero equating to "none," was used for halo and glare ratings.

with more intermediate tasks such as viewing a cell phone screen and reading a street map. These differences became greater as interactions became closer, such as reading ingredients on a nutrition bar and reading dosing instructions on a medicine box. These results correspond with visual acuity data, including BCVA. The significant differences between the two groups in BCVA at near and intermediate distances demonstrates that the pseudoaccommodation of the multifocal IOL is truly due to the optic design rather than due to residual astigmatism or myopia. This conclusion based on subjective outcomes is in accordance with objectively measured defocus curves for patients with bilateral SN60D3 lenses.¹⁷

Regarding clinical outcomes, the majority of this study's findings are similar to other published data. Deviating slightly from the literature are differences in pupil size.^{15 16} SN60D3 patient pupil sizes were slightly larger than those previously reported, and a significant difference was found between the pupil size of the two groups under mesopic and photopic conditions. This difference is likely due to age differences between groups. Age difference aside, the photopic pupil size (3.6 mm) corresponds relatively closely with a previous finding that a pupil size of 3.75 mm balances near and distance visual acuities for patients implanted with an apodized diffractive lens.¹¹ The pupil size of group 1 may be related to the optimum function of the lens.

In conclusion, compared with a monofocal lens, the AcrySof ReSTOR IOL provided better visual acuities at near and intermediate distances, and similar acuity for distance vision. The bilaterally implanted ReSTOR lens also provided patients with greater functional vision at near and intermediate distances without glasses. Greater daily-living functionality may be attributed to higher rates of spectacle freedom in ReSTOR patients.

Acknowledgements: Statistical analysis was provided by J Song.

Funding: This study was supported by a grant from Alcon Laboratories, Inc. (hereafter called Sponsor) in Fort Worth, Texas (USA). After investigator counsel, the Sponsor provided the protocol. The Sponsor entered study data and employed the third-party statistician who performed the statistical analysis. The Sponsor and the investigators

collaborated on the writing effort with full investigator review and guidance of the manuscript. The investigators led the decisions to publish and submit the paper, with Sponsor approval.

Competing interests: RJC, MD: Consultant, Alcon Laboratories Inc. DFC, MD: Consultant for AMO, Alcon and Visiogen, but has no direct financial interest in any product mentioned. EDD, MD: Consultant, Alcon, AMO, Bausch and Lomb. SSL: Consultant and Medical Monitor, Alcon. JPM, MD: Consultant, Alcon Laboratories, Inc. KDS, MD, Consultant, Alcon Laboratories, Inc.

Ethics approval: Ethics approval was provided by RCRC IRB Texas.

Patient consent: Obtained.

Provenance and peer review: Not commissioned; externally peer reviewed.

REFERENCES

1. **Brenner M**, Curbow B, Javitt J, *et al*. Vision change and quality of life in the elderly. Response to cataract surgery and treatment of other chronic ocular conditions. *Arch Ophthalmol* 1993;**111**:680–5.
2. **Lee P**, Spritzer K, Hays R. The impact of blurred vision on functioning and well-being. *Ophthalmology* 1997;**104**:390–6.
3. **Chiam P**, Chan J, Aggarwal R, *et al*. ReSTOR intraocular lens implantation in cataract surgery: Quality of vision. *J Cataract Refract Surg* 2006;**32**:1459–63.
4. **Souza C**, Muccioli C, Soriano E, *et al*. Visual performance of AcrySof ReSTOR apodized diffractive IOL: a prospective comparative trial. *Am J Ophthalmol* 2006;**141**:827–32.
5. **Javitt J**, Steinert R. Cataract extraction with multifocal intraocular lens implantation: A multinational clinical trial evaluating clinical, functional, and quality-of-life outcomes. *Ophthalmology* 2000;**107**:2040–8.
6. **Håring G**, Dick HB, Krummenauer F, *et al*. Subjective photic phenomena with refractive multifocal and monofocal intraocular lenses: Results of a multicenter questionnaire. *J Cataract Refract Surg* 2001;**27**:245–9.
7. **Blaylock J**, Si Z, Vickers C. Visual and refractive status at different focal distances after implantation of ReSTOR multifocal intraocular lens. *J Cataract Refract Surg* 2006;**32**:1464–73.
8. **Toto L**, Falconio G, Vecchiarino L, *et al*. Visual performance and biocompatibility of 2 multifocal diffractive IOLs: Six month comparative study. *J Cataract Refract Surg* 2007;**33**:1419–25.
9. **Chiam P**, Chan J, Haider S, *et al*. Functional vision with bilateral ReZoom and ReSTOR intraocular lenses 6 months after cataract surgery. *J Cataract Refract Surg* 2007;**33**:2111–17.
10. **Alfonso JF**, Fernández-Vega L, Valcárcel B, *et al*. Visual performance after AcrySof ReSTOR aspheric intraocular lens implantation. *J Optom* 2008;**1**:30–5.
11. **Alfonso JF**, Fernández-Vega L, Baamonde MB, *et al*. Correlation of pupil size with visual acuity and contrast sensitivity after implantation of an apodized diffractive intraocular lens. *J Cataract Refract Surg* 2007;**33**:430–8.
12. **Alvarez-Rementería L**, Montés-Micó R. Pseudoaccommodating intraocular lens implantation in patients with irregular nonreactive pupils. *J Cataract Refract Surg* 2007;**33**:1823–5.
13. **Rocha KM**, Chalita MR, Souza CE, *et al*. Postoperative wavefront analysis and contrast sensitivity of a multifocal apodized diffractive IOL (ReSTOR) and three monofocal IOLs. *J Refract Surg* 2005;**21**:808–12S.
14. **Lehmann R**, Waycaster C, Hileman K. A comparison of patient-reported outcomes from an apodized diffractive intraocular lens and a conventional monofocal intraocular lens. *Curr Med Res Opin* 2006;**22**:2591–602.
15. **Vingolo E**, Grenga P, Iacobelli L, *et al*. Visual acuity and contrast sensitivity: AcrySof ReSTOR apodized diffractive versus AcrySof SA60AT monofocal intraocular lenses. *J Cataract Refract Surg* 2007;**33**:1244–7.
16. **Hütz W**, Eckhardt B, Röhrig B, *et al*. Reading ability with 3 multifocal intraocular lens models. *J Cataract Refract Surg* 2006;**32**:2015–21.
17. **Montés-Micó R**, Ferrer-Blasco T, Charman WN, *et al*. Optical quality of the eye after lens replacement with a pseudoaccommodating intraocular lens. *J Cataract Refract Surg* 2008;**34**:763–8.