European Journal of Ophthalmology / Vol. 18 no. 5, 2008 / pp. 733-738

Intermediate visual acuity without spectacles following bilateral ReSTOR® implantation

C. CUQ[1], C. SPERA[2], C. LAURENDEAU[3], A. LAFUMA[3], G. BERDEAUX[2]

[1]Nouvelle Clinique de L'Union, L'Union
[2]Alcon Laboratories, Rueil-Malmaison
[3]Cemka Eval, Bourg-la-Reine - France

PURPOSE. *This survey determined uncorrected visual acuity (VA) at near, intermediate, and far distances in cataract patients implanted with ReSTOR®, and assessed patient satisfaction.*
METHODS. *Consecutive cataract patients implanted bilaterally with ReSTOR® were followed up at least 4 months. The Early Treatment Diabetic Retinopathy Study scale was used to measure VA for near (40 cm), intermediate (50, 60, and 70 cm), and distance vision, with VAs expressed in logMAR and adjusted for distance using Bennett's (1993) formula. Satisfaction was self-rated on a visual analogue scale ranging from 0 (poor) to 10 (high).*
RESULTS. *Twenty-four consecutive patients (mean age 67.6 years) were operated upon by a single surgeon and followed up for a mean of 336.5 days after second eye surgery. Average postoperative VAs for uncorrected distance were 0.06 logMAR and intermediate VAs were 0.21 logMAR at both 50 cm and 60 cm and 0.22 logMAR at 70 cm. These levels of uncorrected intermediate VA would allow patients to read Word® computer text in Times New Roman font 8 zoomed to 100%, at 70 cm from the monitor screen. The authors found that 23/24 patients (96%) no longer wore spectacles. The remaining patient required correction for astigmatism as this refraction error is not yet correctable by ReSTOR®. Average self-rated satisfaction was 8.54.*
CONCLUSIONS. *In an everyday surgical practice, none of the studied bilateral ReSTOR® cataract patients without astigmatism required spectacles when followed up 6 months or later. Intermediate VA was compatible with reading and led to high patient satisfaction. (Eur J Ophthalmol 2008; 18: 733-8)*

KEY WORDS. *Cataract surgery, Intermediate visual acuity, multifocal IOL*

Accepted: March 18, 2008

INTRODUCTION

Surgical extraction of the crystalline is the only effective treatment for cataract, which in association with an intraocular lens (IOL) can generally (80%) provide a good best-corrected visual acuity ≥8/10, depending on associated ocular pathologies and follow-up duration (1-5).
Originally, IOLs were monofocal and designed to correct distance visual acuity. Hence, after implantation most patients needed spectacles for near vision. Subsequently, multifocal IOLs (MIOLs) were developed to free patients from spectacles after both cataract and presbyopia surgery, by applying the principle of simultaneous vision.
Further improvements in IOL technology allowed cataract patients to be implanted with multifocal IOLs providing better visual acuity at various distances and allowing some degree of spectacle independence (6). Today, MIOLs permit functional near, intermediate, and distance vision for everyday life with acceptable patient satisfaction (7-19).

 1120-6721/733-06$25.00/0

More recently, a new apodized IOL (ReSTOR®) was marketed which combines near and distance vision efficacy without adverse effects and enables more than 80% of treated patients to avoid spectacles altogether. In a clinical study ReSTOR® achieved higher rates of spectacle independence for both distance (88.0%) and near vision (84.6%) than reported with previous MIOLs. ReSTOR® also provided qualitatively better visual acuity, greater spectacle independence, and tolerable unwanted photic phenomena (18-20), when assessed by clinicians and patients.

A prospective, controlled study of patients implanted with ReSTOR® showed that intermediate visual acuity was less than near or far acuity (21), but did not reduce patients' satisfaction assessments (15). Accordingly, we performed a retrospective study to assess intermediate visual acuity and reading capability, without spectacles, on a cohort of everyday surgical practice patients with bilateral ReSTOR® implants.

METHODS

The present retrospective study is based on a cohort of patients with bilateral age-related cataracts and ReSTOR® implants inserted between March 2005 and August 2006. The study was performed in accordance with French law, i.e., files were deposited with the Commission Nationale de l'Informatique et des Libertés and every effort was made to inform patients of the subsequent findings.

Inclusion criteria conformed to that for ReSTOR® specified in the EC product labeling. Patients with age-related cataract and astigmatism <1 diopter were evaluated. The second eye was usually implanted within 2 to 6 weeks following the first eye. A routine follow-up visit was scheduled 4 to 12 months after the second implant, according to local practice. All patients agreed to give requested information at the follow-up visit.

As no existing scale specifically measures intermediate visual acuity, we used the Standard logarithmic Visual Acuity Chart 2000 "New ETDRS" Chart 1 for testing at 40 cm (Precision Vision, La Salle, IL) (22), which provides visual acuity measured at different distances. We performed measurements at the following intermediate distances: 50, 60, and 70 cm.

In order to obtain distance visual acuity (DVA) at distances other than 40 cm, the following formula (23) was used:

$$DVA_{real} = -\log_{10}\left[\frac{Distance(m)}{0.4*10^{Measured\ DVA}}\right]$$

For example, a measured DVA of 0.3 logMAR at a distance of 50 cm was adjusted to provide a real DVA of 0.2 logMAR.

The following measurement procedure adjusted observed 40 cm intermediate visual acuities in everyday living activities. First, the 40 cm "New ETDRS" reading chart was photocopied onto transparent film at 100% zoom. Second, the transparent film was superimposed upon a newspaper page (*Le Figaro*, page 1, ed. 22 November 2006, Paris, France) and logMAR chart fonts corresponding to the different font sizes used in the paper's title, subtitle, text, and fine print were identified. As newspapers are usually read at 40 cm, the same distance as the logarithmic visual acuity chart, the identified logMAR font sizes corresponded to those on the newspaper page. Third, a text document created with Microsoft Office Word software (Microsoft, San Francisco, CA, USA) was displayed on a 17 inch Dell flat computer monitor, model 1707FP, resolution 1024 x 768/75 Hz (Dell, Round Rock, TX, USA). The document was comprised of three lines of Times New Roman text (style regular, color black, no effect, in font sizes 8, 10, and 12, respectively). Finally, the original transparent film was superimposed upon the monitor screen so that the logMAR chart font sizes, corresponding to the three displayed font sizes, could be identified. As computer monitors are usually viewed at 70 cm the relevant logMAR font sizes were adjusted to the actual (displayed) font sizes by applying the preceding formula.

After cataract surgery, the best eye DVA was taken as proxy for bilateral vision. Clinically relevant astigmatism was defined as a $\geq$1 diopter spherical index. Patients self-evaluated their global vision satisfaction on a 10-point Likert scale, anchored at 0 (very poor satisfaction) and 10 (very high satisfaction). Data processing and analyses were performed with SAS software for Windows (Statistical Analysis System, Version 9.1.3). The analysis was descriptive with continuous variables described by their mean, median, extreme values, and distribution function and categorical variables scored as the frequency of each modality.

RESULTS

Data were retrieved for 24 successive patients (mean age 67.6, range 58–79 years; males 37.5%) implanted with bilateral ReSTOR® IOLs between March 29, 2005, and August 29, 2006. Best-corrected visual acuity before surgery was 0.21±0.13 and uncorrected visual acuity was 0.26±0.15 logMAR. All implantations were carried out by one surgeon and no complications occurred. The average time between the two implants was 15.3 days and the average follow-up interval after the second implant 336.5±154.1 days.

Table I presents the minimum visual acuity estimates needed for various reading activities. For example, a newspaper article at 40 cm requires a visual acuity of at least 0.6 logMAR (Snellen 10/40), whereas a visual acuity of at least 0.46 is needed to read a Microsoft Word document at 70 cm with 100% zoom, displayed in Times New Roman font 10, on a flat 17 inch Dell monitor screen (model 1707FP, resolution 1024 x 768 / 75 Hz).

Figure 1 shows the distribution functions of corrected VA values before cataract surgery. Documentation for all 48 eyes showed 29 with VA values <0.2 logMAR (Snellen 20/32). Six of 21 patients (28.6%) had astigmatism (unilateral n=5; bilateral n=1) as defined in Methods.

TABLE I - TEXT AND FONT SIZES AT DIFFERENT DISTANCES AND MINIMUM VISUAL ACUITY FOR READING

Reading distance	Text and font sizes	Minimal visual acuity for reading (logMAR)
40 cm (newspapers)	Title	1.3
	Headings	0.8
	Text	0.6
	Fine print	0.3
70 cm (computer)	Times New Roman, font 12	0.56
	Times New Roman, font 10	0.46
	Time New Roman, font 8	0.36

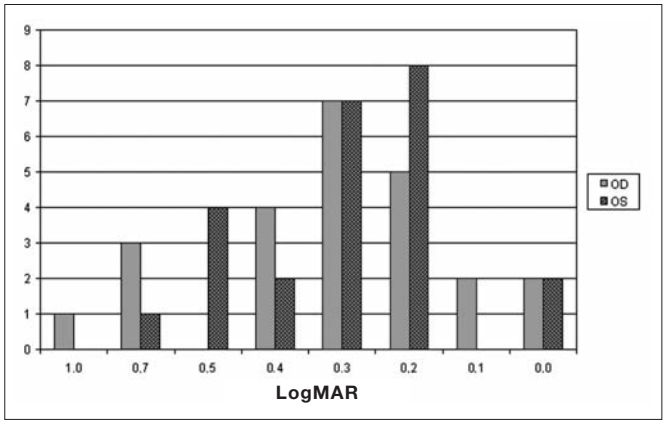

Fig. 1 - *Frequencies of corrected (left: OS; right: OD) distance VA before surgery (LogMAR).*

The postoperative manifest refraction at the last visit was as follows: sphere +0.64 D (0.48), cylinder –0.94 D (0.83), and spherical equivalent +0.16 D (0.58). Bilateral (i.e., best eye) uncorrected VA values at the visit following the second cataract surgery are summarized by a distance VA distribution function (Fig. 2) showing mean values ≤0.1 logMAR (Snellen 20/25) for 23 of 24 patients (95.8%), and intermediate VA functions at 50, 60, and 70 cm (Fig. 3) with mean values (Tab. II) of 0.21 logMAR (Jaeger 4) at both 50 cm and 60 cm, and 0.22 logMAR (Jaeger 4) at 70 cm. Intermediate VA values ≤0.3 logMAR (Jaeger 5) were obtained in 75% of patients at 70 cm, 87.5% at 60 cm, and 83.3% at 50 cm.

After cataract surgery one patient with a spherical correction >1 diopter (1.5 D in both eyes) was the sole case to use spectacles among the 24 patients. Hence, the incidence rate of total spectacle independence was 95.8% in this cohort of patients.

Figure 4 is based on the visual acuity values in Table I and our clinical evaluations. It indicates that 95.8% of our patients would be able to read a Word document in Times New Roman font 10, unaided by spectacles, when seated 70 cm from the screen. Their ability to read computer text without spectacles would increase, of course, with font size.

TABLE II - INTERMEDIATE UNCORRECTED VISUAL ACUITY (logMAR)

Distance	50 cm	60 cm	70 cm
Mean (SD)	0.21 (0.18)	0.21 (0.13)	0.22 (0.14)
Median (min–max)	0.17 (–0.18–0.60)	0.20 (–0.06–0.44)	0.20 (–0.04–0.48)

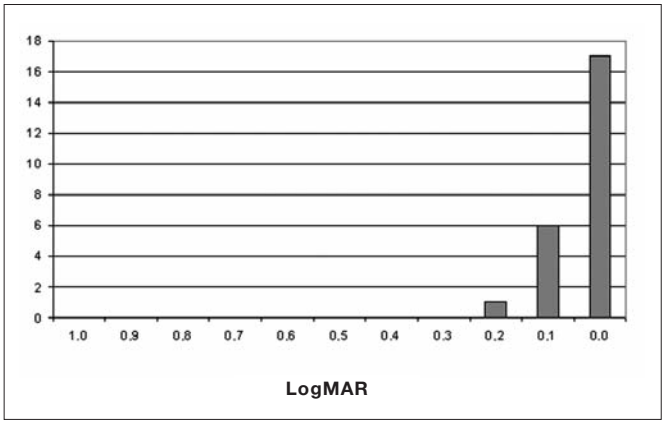

Fig. 2 - *Bilateral ('best eye') uncorrected distance visual acuity after surgery (LogMAR).*

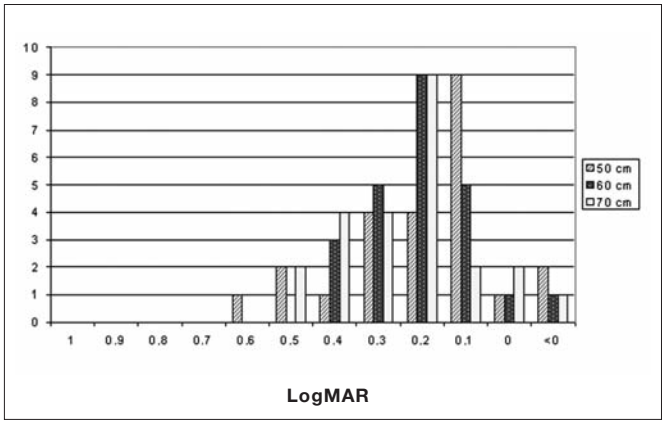

Fig. 3 - *Frequencies of intermediate uncorrected visual acuity (LogMAR) at 50, 60 and 70 cm.*

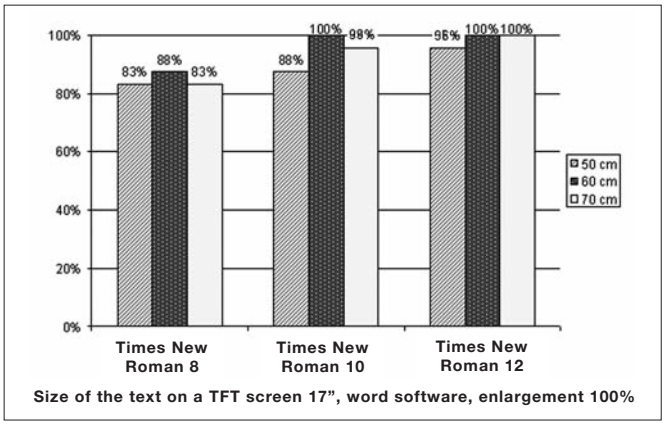

Fig. 4 - *Percent accuracy in reading computer screen texts with out spectacles, according to font sizes.*

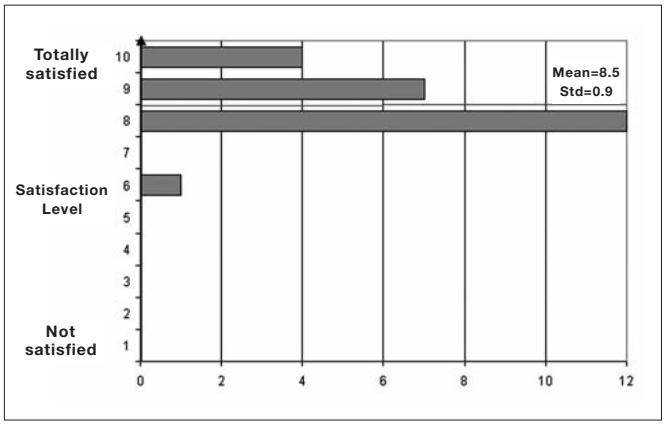

Fig. 5 - *Patient satisfaction with vision after cataract surgery.*

Overall satisfaction ratings are depicted in Figure 5 with 95.8% of patients reporting values ≥8 (mean 8.5). The single score of 6 was declared by the patient with astigmatism.

At intermediate distances an association between visual acuity and self-reported satisfaction (Fig. 6) was observed at 50 cm (patients with scores >8 had better VA), but not at 60 or 70 cm, suggesting that improved VA contributed little at these greater distances.

DISCUSSION

Our retrospective analysis of 24 successive patients given bilateral ReSTOR® implants showed that intermediate VA improved to 0.2 logMAR, or more, and would enable all

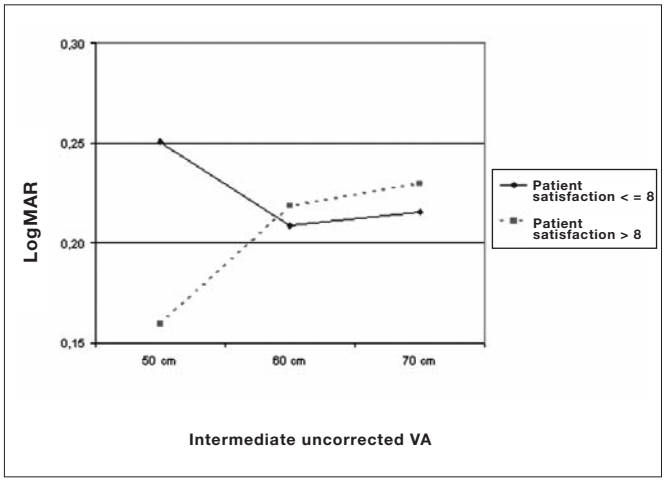

Fig. 6 - *Relationship between visual acuity and self-rated satisfaction.*

patients to read newspapers without spectacles. Almost all patients (96%) should be able to read small font (Times New Roman font 10) on a computer screen at 70 cm. Only one patient, with residual astigmatism, needed spectacles after cataract surgery. After surgery, all patients should be able to perform the above daily visual activities without spectacles.

We measured intermediate VA with a 40 cm ETDRS chart. The logMAR acuity reading is the log of the minimum angle of resolution (MAR) in arc minutes, required to distinguish the object–usually based on the spacing of lines/bars in the object–for instance, an optotype that is 20/20 is usually considered 5 minutes of arc high by 5 wide, therefore the MAR is 1 minute (which lets us distinguish the arms of the optotype of the EDTRS new chart). Near logMAR charts are typically designed for use at 40 cm. Charts are designed for a specific distance, but can be used at other distances based on the size of the letters and the expected angular subtense of the angle. To convert the chart at one distance to the chart at a standard distance (to facilitate comparison), the angular subtense has to be considered. The formula used is not a testing method, but a mathematical conversion of the chart distance to determine the true MAR of the given letter size. It presumes that the MAR is independent of distance (which is a common assumption with charts, as our eyes really measure angular subtenses of objects, not actual size).

Alfonso et al (21) reported similar results with ReSTOR®, but found that intermediate visual acuity decreased at 40 cm and 70 cm. However, this was considered minor by patients as most could read without spectacles. They rated their satisfaction high on a 10-level Likert scale, similar to our patients.

A study published by Pepose et al (24) compared ReSTOR® with other multifocal implants and reported an intermediate distance VA of 20/34 (0.23 logMAR) in a cohort of 12 patients implanted with bilateral ReSTOR® lenses. Their results were similar to ours, with patient satisfaction mainly sensitive to uncorrected VA at 50 cm and almost insensitive to VA at 60 and 70 cm. This suggests that near and distance visual acuities are critical factors for patient satisfaction, while true intermediate VA may be perceived as less important. Although this conclusion holds in general, it does not preclude the possibility that particular patients may require sharp intermediate VA, which should be investigated by surgeons before deciding to implant ReSTOR®.

Our study suffers from several limitations. First, the sample size was small and more patients are needed for precise estimates. Second, we recognize that our method for comparing visual acuity with newspaper and computer texts was indirect and that the ideal measurement would be specific paper and computer texts based on an established logarithmic scale. This would be an interesting project for future evaluation. Third, only one surgeon participated in the survey, hence a multicenter survey is needed for extrapolation to general ophthalmic practice. However, it could also be considered as a warrant of the same standard surgical technique avoiding bias determined by different surgeons. Fourth, patients' outcome assessments were limited to a single global measurement. The inclusion of a quality-of-life instrument targeting the various benefits of freedom from spectacles, as perceived by patients (25), would define and quantify the benefits. Fifth, reading ability is not strictly driven by near or intermediate VA (a J1+ patient may feel uncomfortable at reading) and we did not incorporate a true reading evaluation; however, our patients expressed an excellent global satisfaction which encompasses reading activities. Finally, benefits should be balanced against the extra costs incurred with ReSTOR® implantations (26).

This study shows that visual acuity at intermediate distances after bilateral ReSTOR® implants measured at follow-up, approximately 1 year later, should enable almost all patients to read newspapers and use a computer at normal distances without spectacles. All patients unaffected by residual astigmatism were freed of spectacles and expressed high satisfaction.

ACKNOWLEDGEMENTS

This analysis was supported by an unrestricted grant from Alcon France SA, Rueil-Malmaison, France.

The analysis was done by Cemka-Eval, Bourg-la-Reine, France.

The authors thank Dr. Robert Pigache for reviewing the English language.

Proprietary interest: Dr. Gilles Berdeaux and Dr. Claudio Spera are employed by Alcon France. Dr. Cuq has been participating in clinical trials initiated by Alcon Research Ltd. Dr. Antoine Lafuma and Ms. Caroline Laurendeau have no proprietary interest.

Reprint requests to:
Gilles Berdeaux, MD
Alcon France
4 rue Henri Sainte-Claire Deville
F-92563 Rueil-Malmaison Cedex, France
gilles.berdeaux@alconlabs.com

REFERENCES

1. Anmarkrund N, Bergaust B, Bulie T, Sand AB. Evaluation of a flexible one-piece open-loop anterior chamber lens Symflex 350B 3–4 years after implantation. Acta Ophthalmol 1993; 71: 796-800.
2. Pötzsch DK, Lösch-Pötzsch M. Four year follow-up of the Memorylens. J Cataract Refract Surg 1996; 22: 1336-41.
3. Schmack WH, Gerstmeyer K. Long-term results of the foldable CeeOn edge intraocular lens. J Cataract Refract Surg 2000; 26: 1172-5.
4. Milazzo S, Turut P, Artin B, Charlin JF. Long-term follow-up of three-piece, looped, silicone intraocular lenses. J Cataract Refract Surg 1996; 22 (Suppl 2): 1259-62.
5. Linnola RJ, Holst A. Evaluation of a 3-piece silicone intraocular lens with poly(methyl methacrylate) haptics. J Cataract Refract Surg 1998; 24: 1509-14.
6. Javitt JC, Steinert RF. Cataract extraction with multifocal intraocular lens implantation: a multinational clinical trial evaluating clinical, functional, and quality-of-life outcomes. Ophthalmology 2000; 107: 2040-8.
7. Javitt JC, Wang F, Trentacost DJ, Rowe M, Tarantino N. Outcomes of cataract extraction with multifocal intraocular lens implantation: functional status and quality of life. Ophthalmology 1997; 104: 589-99.
8. Javitt JC, Jacobson G, Schiffman RM. Validity and reliability of the Cataract TyPE Spec: an instrument for measuring outcomes of cataract extraction. Am J Ophthalmol 2003; 136: 285-90.
9. Lindstrom RL. Food and Drug Administration study update. One-year results from 671 patients with the 3M multifocal intraocular lens. Ophthalmology 1993; 100: 91-7.
10. Rossetti L, Carraro F, Rovati M, Orzalezi N. Performance of diffractive multifocal intraocular lenses in extracapsular cataract surgery. J Cataract Refract Surg 1994; 20: 124-8.
11. Steinert RF, Post CT Jr, Brint SF, et al. A prospective, randomized, double-masked comparison of a zonal-progressive multifocal intraocular lens and a monofocal intraocular lens. Ophthalmology 1992; 99: 853-61.
12. Steinert RF, Aker BL, Trentacost DJ, Smith PJ, Tarantino N. A prospective comparative study of the AMO ARRAY zonal-progressive multifocal silicone intraocular lens and a monofocal intraocular lens. Ophthalmology 1999; 106: 1243-55.
13. Vaquero M, Encinas JL, Jimenez F. Visual function with monofocal versus multifocal IOLs. J Cataract Refract Surg 1996; 22: 1222-5.
14. Gimbel HV, Sanders DR, Raanan MG. Visual and refractive results of multifocal intraocular lenses. Ophthalmology 1991; 98: 881-8.
15. Blaylock JF, Si Z, Vickers C. Visual and refractive status at different focal distances after implantation of the ReSTOR multifocal intraocular lens. J Cataract Refract Surg 2006; 32: 1464-73.
16. Chiam PJ, Chan JH, Aggarwal RK, Kasaby S. ReSTOR intraocular lens implantation in cataract surgery: quality of vision. J Cataract Refract Surg 2006; 32: 1459-63.
17. Souza CE, Gerente VM, Chalita MR, Soriano ES, Freitas LL, Belfort R Jr. Visual acuity, contrast sensitivity, reading speed, and wavefront analysis: pseudophakic eye with multifocal IOL (ReSTOR) versus fellow phakic eye in non-presbyopic patients. J Refract Surg 2006; 22: 303-5.
18. Souza CE, Muccioli C, Soriano ES, et al. Visual performance of AcrySof ReSTOR apodized diffractive IOL: a prospective comparative trial. Am J Ophthalmol 2006; 141: 827-32.
19. Kohnen T, Allen D, Boureau C, et al. European multicenter study of the AcrySof ReSTOR apodized diffractive intraocular lens. Ophthalmology 2006;113:584.e1; Epub 2006 Feb 14.
20. 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.
21. Alfonso JF, Fernandez-Vega L, Baamonde MB, Montes-Mico R. Prospective visual evaluation of apodized diffractive intraocular lenses. J Cataract Refract Surg 2007; 33: 1235-43.
22. Ferris FL, Kassoff A, Bresnick GH, Bailey IL. New visual acuity charts for clinical research. Am J Ophthalmol 1982; 94: 91-6.
23. Bennett AG, Rabbetts RB. Clinical Visual Optics, 1st Ed. Oxford: Butterworth Heinemann, 1993.
24. Pepose JS, Qazi MA, Davies J, et al. Visual performance of patients with bilateral vs combination Crystalens, ReZoom, and ReSTOR intraocular lens implants. Am J Ophthalmol 2007; 144: 347-57.
25. Arnould B, Benmedjahed K, Berdeaux G, GiL-Campos I, Vigneux M, Guillemin I. Patients' perception of life free of glasses after cataract surgery: Development of the freedom from glasses value scale (FGVS®). Value in Health 2008; 11: A296.
27. Cuq C, Lafuma A, Jeanbat V, Berdeaux G. A European survey of patient satisfaction with spectacles after cataract surgery and the associated costs in four European countries (France, Germany, Spain and Italy). Ophthalmic Epidemiol 2008 (in press).