Intermediate visual acuity without spectacles following bilateral ReSTOR® implantation

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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).
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:

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

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 ≥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).

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.

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

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

TABLE II - INTERMEDIATE UNCORRECTED VISUAL ACUITY (logMAR)

<table>
<thead>
<tr>
<th>Distance</th>
<th>50 cm</th>
<th>60 cm</th>
<th>70 cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD)</td>
<td>0.21 (0.18)</td>
<td>0.21 (0.13)</td>
<td>0.22 (0.14)</td>
</tr>
<tr>
<td>Median (min-max)</td>
<td>0.17 (~0.18–0.60)</td>
<td>0.20 (~0.06–0.44)</td>
<td>0.20 (~0.04–0.48)</td>
</tr>
</tbody>
</table>
Overall satisfaction ratings are depicted in Figure 5 with 95.8% of patients reporting values $\geq 8$ (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
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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.

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