ABSTRACT: Purpose. To evaluate the optical quality of the eye before and after the insertion of an Artisan phakic intraocular lens for the treatment of high myopia. Methods. Consecutive patients implanted with the Artisan lens by a single surgeon between June 2001 and April 2002 were enrolled prospectively. One eye per subject was tested. The wavefront aberration was calculated from images recorded with a Hartmann-Shack sensor. This wavefront aberration was expressed as a Zernike polynomial expansion from the third up to the seventh order. Root mean square wavefront error was used as a parameter of optical quality. Point-spread function and modulation transfer function were also computed from the wavefront aberration. Results. The mean age of the four patients (four eyes) was 46 ± 11 years. The preoperative mean spherical equivalent was −14.13 ± 3.19 D (range, −20.50 to −9.75 D), with a best-corrected visual acuity of 20/25 or better in three of the four eyes. No complications were encountered. Postoperatively, the mean spherical equivalent was 0.22 ± 0.30 D (range, −0.75 to +0.38 D). An uncorrected visual acuity of 20/40 or better was observed in three eyes. Overall, for each combination of order (third, fourth, and fifth to seventh) and pupil size (3, 4, and 5 mm), the mean postoperative root mean square values for the four subjects were lower than the mean preoperative values. However, because of the small size of the study population (four patients), this improvement did not reach a statistically significant level. Conclusion. Preliminary data using the Hartmann-Shack wavefront sensor have not revealed a tendency toward deterioration of the optical performance after the insertion of an Artisan lens for the treatment of high myopia. The Hartmann-Shack sensor was a useful tool for the objective assessment of the image optical quality of eyes with a phakic intraocular lens. (Optom Vis Sci 2003;80:167–174)

Key Words: Hartmann-Shack sensor, optical aberration of the eye, retinal image quality, phakic intraocular lens, high myopia, refractive surgery
been described elsewhere. In the illumination pathway, a narrow 633-nm laser beam, acting as a beacon source, was projected on the subject's retina. In the registration pathway, a microlens array, conjugated with the pupil's plane, produced an image of spots on the CCD plane of a camera. The spatial displacement of each spot relative to the optical axis of the corresponding microlens was proportional to the local slope of the WA. The shape of the WA was obtained by integrating these slopes. This WA was expressed as a Zernike polynomial expansion from the third up to the seventh order. Root mean square (RMS) wavefront error was used as a parameter of optical quality. Calculations were made for pupil diameters of 3, 4, and 5 mm. For each eye, point-spread function (PSF) and modulation transfer function (MTF) were also computed from the WA. The two-dimensional MTF was derived for a 5-mm pupil. Estimates of the one-dimensional MTF's were calculated as the radial average of the two-dimensional MTF's.

**Procedure**

During the recording of the Hartmann-Shack images, the subject's head was stabilized by means of a chin rest mounted on a three-axes micrometric stage. The amount of light reaching the eye respected the American National Standard for the Safe Use of Lasers. Measurements were performed with correction, spectacles or contact lenses, after pharmacological dilation and cycloplegia (5% phenylephrine hydrochloride and 0.8% tropicamide). All calculations were repeated three times.

**Patient Selection**

Patients were recruited at the Department of Ophthalmology of Maisonneuve-Rosemont, a hospital affiliated with the University of Montreal, Canada. Consecutive patients implanted with the Artisan lens by a single surgeon (MP) between June 2001 and April 2002 were enrolled prospectively. Only the first eye to be operated was tested. Inclusion and exclusion criteria are listed in Table 1. Enrollment was preceded by a complete ophtalmic examination to rule out the presence of any factors likely to interfere with the transmission and reflection of light. The Lens Opacities Classification System III was used to assess the absence of cataract in all patients. Scores ≥1.0 (from 0.1 to 5.9) for cortical or posterior subcapsular cataract and scores ≥1.0 (from 0.1 to 6.9) for nuclear opalescence or color were rejected. The research protocol followed the tenets of the Declaration of Helsinki and was approved by the ethics committee of the Maisonneuve-Rosemont Hospital. Signed informed consent was obtained from all subjects after explanation of the nature and possible consequences of the study.

**Lens**

The Artisan lens is manufactured from Perspex CQ-UV polymethylmethacrylate (PMMA). This convex-concave IOL is available in negative and positive powers ranging from −23.50 to +12.00 D. In the present study, two lens models were used: the 204 in three eyes and the 206 in one eye. The 206 model has a 5-mm optic, whereas the 204 model has a 6-mm optic. The latter is recommended for patients who are prone to glare and halos at night. A 5- or 6-mm posterior limbal incision was made, with a 1-mm-long scleral tunnel. Two limbal 1-mm paracentesis incisions were also made at the 2 and 10-o’clock positions. The haptics of the Artisan phakic anterior chamber lens were fixated to the midperipheral iris stroma, and the superior wound was closed with three 10.0 nylon sutures. Patients with no contraindications underwent a corneal flap before the insertion of the Artisan lens in case laser-assisted in situ keratomileusis would be required later.

**Clinical Parameters**

Axial length was measured before surgery with the Humphrey Ultrasonic Biometer (Model 810, Carl Zeiss, Oberkochin, Germany). In all cases, the power of the lens was calculated with the Van der Heijde formula. The Orbscan II (Bausch & Lomb Surgical, Claremont, CA) was also used for preoperative corneal topography. Visual acuity, refraction, and slit lamp examination were done on each visit. Routine follow-up appointments were scheduled at 1 day, 2 to 3 weeks, 4 to 6 weeks, 4 to 6 months, 12 months, and 18 to 24 months after surgery.

**RESULTS**

We report a total of four eyes of four white patients with a minimum postoperative follow-up of 10 weeks. Their preoperative characteristics are given in Table 2. These include age, axial length, anterior chamber depth, central corneal curvature, refraction, spherical equivalent, and best-corrected visual acuity. Lens model and power are also listed, as well as postoperative data, including refraction, spherical equivalent, and visual acuity. Two eyes (GL and FA) underwent a corneal flap dissection before IOL insertion, but no patients underwent laser-assisted in situ keratomileusis after the insertion of the lens. There were no persistent adverse events nor complications encountered after insertion of the Artisan lens.
lens in these four highly myopic eyes. A discrete glare and halos were noted in one patient.

The pre- and postoperative RMS wavefront error for third- through seventh-order Zernike coefficients are given for each studied eye in Fig. 1. For a 5-mm pupil, a postoperative decrease in RMS was observed in three of the patients, with an increase in one patient (CB). The distribution of mean RMS for third-, fourth-, and fifth- to seventh-order aberrations before and after surgery is detailed in Fig. 2. For a 5-mm pupil, a postoperative decrease in mean RMS was observed for all studied orders.

Pre- and postoperative MTF’s, PSF’s, and WA maps for a 5-mm pupil are illustrated in Fig. 3. For subjects FA, KV, and GL (Fig. 3 A, B, and C), the MTF and PSF improved after surgery. This improvement was more discrete for GL. For subject CB (Fig. 3D), MTF and PSF both deteriorated after surgery. WA maps generally corroborated these results. In the wrapped representation of the WA maps, each step corresponds to one wavelength (0.633 µm in our case), and the more aberrated the optical system of the eye, the higher the number of contour lines.

Table 3 summarizes the mean pre- and postoperative RMS values for the third, fourth, and fifth to seventh orders, for 3-, 4-, and 5-mm pupils. The data from each subject used to construct this table were analyzed. Analysis of variance with repeated measures was conducted to evaluate the relative influence of surgery and pupil size for each studied order on the RMS. The analysis was performed for two repeated factors (surgery and pupil size). For all orders, no interactions were found between the two factors, surgery and pupil size, which implies that the conclusions for each factor were independent.

For all studied orders, pupil size was the only factor to have a statistically significant influence on the RMS (p < 0.05). In all

### TABLE 2.

<table>
<thead>
<tr>
<th>Patient characteristics</th>
<th>FA</th>
<th>KV</th>
<th>GL</th>
<th>CB</th>
<th>Mean ± SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>48</td>
<td>24</td>
<td>52</td>
<td>58</td>
<td>46 ± 11</td>
</tr>
<tr>
<td>Eye OD OS OS OS 4 (4)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Axial length (mm)</td>
<td>31.48</td>
<td>26.78</td>
<td>31.10</td>
<td>27.10</td>
<td>29.12 ± 2.18</td>
</tr>
<tr>
<td>Anterior chamber depth (mm)</td>
<td>3.44</td>
<td>3.35</td>
<td>3.82</td>
<td>3.20</td>
<td>3.45 ± 0.18</td>
</tr>
<tr>
<td>Central corneal curvature (D)</td>
<td>45.12/46.94</td>
<td>43.38/45.30</td>
<td>41.50/43.50</td>
<td>44.50/46.00</td>
<td>43.38/45.66</td>
</tr>
<tr>
<td>Refraction</td>
<td>−22.00 +3.00 × 45</td>
<td>−14.00 +0.75 × 180</td>
<td>−13.50 +1.75 × 70</td>
<td>−10.00 +0.50 × 60</td>
<td>n/a</td>
</tr>
<tr>
<td>Spherical equivalent (D)</td>
<td>−20.50</td>
<td>−13.63</td>
<td>−12.63</td>
<td>−9.75</td>
<td>−14.13 ± 3.19</td>
</tr>
<tr>
<td>BCVA (Snellen)a</td>
<td>20/70</td>
<td>20/25</td>
<td>20/25</td>
<td>20/20</td>
<td>20/30b</td>
</tr>
<tr>
<td>Lens model/power</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>—</td>
</tr>
<tr>
<td>Corneal flap</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>—</td>
</tr>
<tr>
<td>LASIK</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>—</td>
</tr>
<tr>
<td>Time after surgery (wk)</td>
<td>25.0</td>
<td>23.3</td>
<td>20.4</td>
<td>11.1</td>
<td>20 ± 4.4</td>
</tr>
<tr>
<td>Refraction</td>
<td>−0.75 +1.00 × 125</td>
<td>−0.25 +1.25 × 180</td>
<td>−1.25 +1.00 × 25</td>
<td>−0.50 +0.50 × 70</td>
<td>n/a</td>
</tr>
<tr>
<td>Spherical equivalent (D)</td>
<td>−0.25</td>
<td>0.38</td>
<td>−0.75</td>
<td>−0.25</td>
<td>−0.22 ± 0.30</td>
</tr>
<tr>
<td>UCVA</td>
<td>20/50</td>
<td>20/25</td>
<td>20/40</td>
<td>20/40</td>
<td>20/40b</td>
</tr>
<tr>
<td>BCVA</td>
<td>20/30</td>
<td>20/20</td>
<td>20/20</td>
<td>20/20</td>
<td>20/25b</td>
</tr>
</tbody>
</table>

a Abbreviations: BCVA, best-corrected visual acuity; LASIK, laser-assisted in situ keratomileusis; UCVA, uncorrected visual acuity.
b The mean was calculated by transposition to Log MAR scale.
cases, the mean RMS values increased with pupil enlargement from 3 to 4 mm (Table 3). For the fifth to seventh order, however, a decrease was observed in pre- and postoperative mean RMS with pupil enlargement from 4 to 5 mm. We have no explanation for this localized decrease.

Surgery was found to have no statistically significant effect on the RMS. However, for each combination of order and pupil size, the mean postoperative RMS values for the four subjects were lower than the mean preoperative values in all cases. Consequently, the surgery was beneficial for all orders and pupil sizes, but because of the small size of the study population (four patients), this improvement did not reach a statistically significant level. Considering the means and standard deviation observed for each order and pupil size, more subjects would be needed to detect a statistically significant difference between pre- and postoperative RMS values.

For example, a sample size of 66 subjects would be required to detect a difference of 0.031 μm between pre- and postoperative mean RMS for third-order aberrations with a 3-mm pupil (estimated standard = 0.087, power = 80%, and alpha = 0.05).

The order of abberation had no statistically significant effect on the RMS. However, the mean RMS value for the four subjects tended to decrease with increasing order.

**DISCUSSION**

We report here the first direct objective measurements of ocular WA and retinal image quality before and after the insertion of a phakic IOL (Artisan). Contrary to what has been obtained with photorefractive keratectomy,9, 10 and laser-assisted in situ keratomileusis,12–15 our preliminary results with the Hartmann-Shack wavefront sensor have not revealed a tendency toward deterioration of optical performance after the insertion of an Artisan lens for the treatment of high myopia. In fact, three of the four studied eyes showed a decrease in RMS error and an improvement in MTF. Overall, mean postoperative RMS values for the third, fourth, and fifth to seventh orders, for 3-, 4-, and 5-mm pupils were lower than preoperative values (Table 3). The decrease in RMS for 5-mm pupils was associated with an improvement in MTF (Figs. 1 through 3).

Preoperative aberrations were very high in our four patients, and the magnitude of the preoperative RMS appeared to be proportional to the severity of myopia. This is in agreement with previous reports on the optical quality of the myopic eye.6–8 Using a subjective crossed-cylinder technique, Applegate59 observed a trend for aberrations to increase with the degree of myopia for a 7-mm pupil (23 subjects with spherical equivalent ranging from +0.25 to −9.25 D). Collins et al.7 compared the optical aberrations of 21 young myopes (−1.75 to −7.00 D) with those of 16 young emmetropes and found lower fourth-order aberrations in the myopes group, with no significant difference in third-order aberrations. However, an objective aberroscope technique was used with photographs of the aberroscope image on the retina, and a high proportion of the aberroscope grids recorded in myopic eyes were too distorted to be processed, which led the authors to conclude that the decrease in image quality seen in myopes had been underestimated. With a laser ray-tracing method, Marcos et al.8 studied 22 eyes from 14 young subjects with myopias ranging from −0.6 to −13.00 D. The RMS for third- to seventh-order aberrations was increased by 1.5 μm in a 13 D range. Third- and fourth-order aberrations were also increased significantly as a function of myopia. More recently, He and colleagues30 performed similar experiments in young subjects (10 to 29 years) and noted greater RMS values in myopic (N = 179; −0.75 to −9.00 D) than in emmetropic (N = 137; less than −0.50 D) eyes. Paquin and co-workers31 studied monochromatic aberrations in 34 young adults (−1.00 to −9.25 D) with a Hartmann-Shack wavefront sensor. They found that the increase in the RMS of the aberration was proportional to the degree of myopia. This was demonstrated for pupils of 5 and 9 mm. Using the same technique, Simonet et al. performed similar findings in a group of 58 myopes, 12 hyperopes, and 10 emmetropes with spherical equivalent refractive errors.

**TABLE 3.**

Pre- and postoperative RMS error for third, fourth, and fifth to seventh order Zernike for the four studied eyes, for 3-, 4-, and 5-mm pupil sizes.

<table>
<thead>
<tr>
<th>Pupil Size</th>
<th>RMS (μm) Mean ± SEM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preoperative (N = 4)</td>
</tr>
<tr>
<td>Third order</td>
<td>3 mm</td>
</tr>
<tr>
<td></td>
<td>4 mm</td>
</tr>
<tr>
<td></td>
<td>5 mm</td>
</tr>
<tr>
<td>Fourth order</td>
<td>3 mm</td>
</tr>
<tr>
<td></td>
<td>4 mm</td>
</tr>
<tr>
<td></td>
<td>5 mm</td>
</tr>
<tr>
<td>Fifth to Seventh order</td>
<td>3 mm</td>
</tr>
<tr>
<td></td>
<td>4 mm</td>
</tr>
<tr>
<td></td>
<td>5 mm</td>
</tr>
</tbody>
</table>

**FIGURE 2.**

Mean RMS error for third-, fourth-, and fifth- to seventh-order aberrations before (black bars) and after (white bars) surgery. Error bars represent SEM. Calculations were made for 5-mm pupils.
ranging from $-20.75$ to $+9.75$ D. In all of these studies, the measurements were taken with the patient’s correction (Badal system, trial lenses, or spectacles). The range of aberrations found in our patients before insertion of the Artisan lens was similar to what has been reported previously in highly myopic subjects.

Two patients, FA (soft toric lens, Keraflex) and KV (soft lens), were wearing contact lenses at the time of the preoperative Hartmann-Shack measurements, and two others (GL and CB) were wearing spectacles. After surgery, none of them was wearing contact lenses, but one patient (GL) was wearing spectacles. Spherical aberration and coma are negligible in spectacles because of the relatively low surface curvatures of such lenses. With contact lenses, however, spherical aberration is important because of their high surface curvatures. Coma, coma-like aberrations, and defocus that are due to field curvature and astigmatism are also non-negligible when the lens is decentered. Atchison confirmed that an eye wearing a rigid contact lens can produce significant levels of spherical aberration in the ocular system for soft lenses with back vertex power greater than $+3.00$ or $-6.00$ D and for rigid lenses of power more positive than $-3.00$ D. As mentioned by Atchison, tear film neutralization of corneal asphericity does not occur with soft contact lenses, so that aberrations with well centered soft contact lenses will be considerably influenced by corneal asphericity, unlike rigid lenses. Hammer and Holden extended Cox’s analysis to study the effect of aspheric rigid contact lenses on spherical aberration. On-eye aberration was found to become strongly more positive as the p value of the contact lens front surface increased. It became more negative as the back surface p value rose, but the tendency was weaker.

In our small study, the influence of the type and amount of correction worn during the Hartmann-Shack measurements could not be assessed. We measured the optical aberrations generated by the entire optical system, including the eye and the correction when present (contact lens or spectacle), and before surgery, these corrections were for high levels of myopia. Despite the small number of eyes studied, it seemed that higher myopes improved most after the surgery. This raises a question about the proportion of this improvement related to the elimination of contact lens wear. In any case, it should be said that even if contact lenses did add optical aberrations to the eye, the correction provided by spectacles or rigid contact lenses can significantly alter the shape of the wavefront, leading to a reduction in overall aberration.
aberrations to the optical system before surgery for two of our patients, this additional burden represented a daily reality for the patient, which seemed to have been alleviated after surgery.

Our knowledge of the effect of intraocular lenses on the optical quality of the eye is still limited. Mierdel et al. measured optical aberrations in 10 postcataract extraction eyes and 10 emmetropic control eyes with a video aberroscope based on Tscherning’s aberroscope. WA was represented mathematically in Zernike polynomials. The first 14 Zernike coefficients were calculated. No statistically significant difference was found between the two groups, except for the coefficient K5, which indicated increased astigmatism in the 90° or 180° axis. Variability of the coefficients was also significantly higher in the postcataract extraction group, especially the coefficients for spherical aberration or astigmatism. Artal et al. in a preliminary study, measured the optical quality of both eyes of a young patient with monocular pseudophakia using an objective double-pass technique. The MTF was found to be degraded in the eye implanted with the monofocal IOL compared with the normal contralateral eye. The MTF of this pseudophakic young eye was also found to be similar to the mean MTF of a group of five older subjects (aged 60 to 70 years) implanted with the same monofocal IOL as the younger patient. They also compared these five older pseudophakic subjects with five phakic normal subjects of similar age. Mean MTF was comparable in both groups, which led them to propose that the optical performance of a monofocal IOL is approximately the same as that of the old crystalline lens, both performing worse than the younger crystalline lens. Although their experimental setup was not capable of measuring intraocular scatter, they limited the effect of scattering by subtracting a background value from the aerial images before computing MTF. This image processing allowed them to conclude that the MTF decline in older subjects was primarily due to an increase in optical aberrations exceeding intraocular scattering. Navarro et al. studied retinal image quality (double-pass technique) of the eyes of five patients implanted with monofocal IOL’s. They used a young healthy eye as reference. In all cases, the pseudophakic eyes showed an important decrease in MTF with respect to the young phakic eye, and this difference increased monotonically with spatial frequency. The mean ratio between the reference and the monofocal IOL MTF’s was about 2.5. Guirao et al. recently compared the retinal image quality (double-pass technique) and the corneal aberrations of 20 pseudophakic and 20 normal phakic patients of similar age (56 to 80 years and 60 to 70 years, respectively). The average retinal image quality obtained from MTF was found to be similar in both groups and, in both cases, was worse than that of a third group of 20 normal young subjects (20 to 30 years). Because corneal aberrations were also similar for both groups of older subjects and because of the good optical quality of isolated IOL’s in air, the authors concluded that the ideal substitute for the natural lens would not be an IOL with perfect isolated optical performance, but rather one designed to compensate for the aberrations of the cornea.

Considerable variability in image quality has been observed among individuals with the same type of monofocal IOL’s. It has also been demonstrated that retinal image quality is more severely reduced with bifocal or multifocal IOL’s than it is with monofocal IOL’s. Moreover, image optical quality is dependent on the optical design of the lens. Uchio et al. estimated with a computed ray-tracing system the spherical aberration of eyes implanted with four types of polymethyl methacrylate IOL’s. Convex-plano IOL’s with the more curved surface facing the cornea had the smallest spherical aberration, except for high power. Biconvex IOL’s with a more curved anterior surface had the smallest spherical aberration at high power. Biconvex IOL’s with a more curved posterior surface had the largest spherical aberration. The above conclusions, however, are not directly applicable to the Artisan lens because this convex-concave IOL (with the convex surface facing the cornea) is inserted in front of the natural lens, which constitutes an optical system entirely different from that of the standard pseudophakic eye, where the pseudophakic IOL replaces the natural lens.

Artal et al. have demonstrated that in young and normal phakic subjects, the corneal front surface and internal optics aberrations partially compensate each other, resulting in an improved retinal image. Under the simplistic assumption that surgery involves only the natural lens and/or the IOL and that corneal and internal aberrations compensate each other, it could be hypothesized that a theoretically aberration-free IOL (diffraction-limited) should give better results in a phakic eye than in a pseudophakic eye. In the case of a pseudophakic IOL, extraction of the natural lens eliminates any potential compensation from the natural lens. To maximize retinal image quality, the ideal pseudophakic IOL would then need to be designed to compensate for the corneal aberrations. However, if an aberration-free phakic IOL is fixated and well-centered in front of a normal natural lens, a preexisting well-balanced cornea-lens coupling would be preserved. It must be remembered, however, that the prediction of image optical quality with a phakic lens will also depend on several other parameters, such as variability across subjects, surgical wound healing, age, and preoperative refraction. It must also be remembered that the cornea-lens compensation described by Artal et al. was only reported for near-emmetropic eyes and seems to vanish with age.

The degree to which the surgical wound has influenced the architecture of the anterior segment and the optics of the eye remains unknown. Superior wounds with a scleral tunnel, such as those created for the insertion of Artisan lenses, usually induce <1.25 D of astigmatism when used for cataract surgery. Astigmatism, however, did not directly affect our results because the first three orders of the Zernike decomposition, including piston, tilt, regular astigmatism, and defocus, were not taken into account in this study. Comparison of the corneal aberrations calculated from pre- and postoperative corneal topographies would be the only way of assessing the influence of this corneoscleral wound on the optics of the eye. Guirao et al. found no difference in mean corneal aberrations between 20 pseudophakic and 20 normal phakic patients of similar age. A 6-mm superior limbal incision was made quite similar to that used for the insertion of the Artisan lens, suggesting that the cataract wound probably does not significantly affect the optical quality of operated eyes.

Because of the small size of our series, we preferred to describe our results without extrapolation or prediction of what could have been found with a broader range of lens powers, including lenses for the correction of hyperopia. Further experiments are planned to complete the preliminary results presented in this paper.

The Hartmann-Shack sensor appeared to be a very useful tool for the objective assessment of the optical quality of the image in an eye with a phakic IOL. This technique is easy to perform for the

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REFERENCES


CONCLUSIONS

In conclusion, this paper is the first attempt to demonstrate the influence of an implanted Artisan lens on ocular aberration and retinal image quality in the living human eye. Although additional data are needed to reach a solid general conclusion, our results indicate that the average retinal image quality could be improved after the insertion of this phakic lens.

ACKNOWLEDGMENTS

This work was supported by the Quebec Research in Vision Network (Fonds de la recherche en santé du Québec), the Fonds de recherche en ophtalmologie de l’Université de Montréal, and the Canadian Institutes of Health Research (CIHR MT-13385).

We thank M. Chagnon, MSc, Department of Mathematic and Statistics, University of Montreal for the statistical analysis of the results. We also thank D. Descovich-Toncillo, MD, for her participation in data collection and P. Thompson, MD, for the vector analysis. Finally, we acknowledge the editorial assistance provided by O. Da Silva, BA, LLB, Research Center, Center hospitalier de l’Université de Montréal.

Results from this work were presented in part at the Association for Research in Vision and Ophthalmology Annual Meeting, May 5–10, 2002, Fort Lauderdale, FL.

Received May 13, 2002; revision received September 19, 2002.

Optometry and Vision Science, Vol. 80, No. 2, February 2003

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