Functional reading acuity and performance: Comparison of 2 accommodating intraocular lenses

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PURPOSE: To compare functional reading acuity and speed with 2 models of accommodating intraocular lenses (IOLs).

SETTING: Four of 12 investigative sites in a U.S. Food and Drug Administration (FDA) clinical study.

METHODS: In this observational study, which was part of an ongoing FDA clinical trial, the MNRead functional reading test was used to compare the reading performance of patients with bilateral Tetraflex IOLs (Group 1) and a consecutive series of patients with bilateral Crystalens IOLs (Group 2) presenting at approximately 1 year postoperatively at 4 ophthalmic practices. The 2 groups were well matched for age, sex, mean postoperative time, and mean level of postoperative corrected distance visual acuity. All examinations were scored at a central reading center.

RESULTS: Group 1 comprised 96 patients and Group 2, 55 patients. Patients in Group 1 read better than those in Group 2 at print sizes of 20/63 ($P = .004$), 20/50 ($P = .002$), 20/40 ($P = .001$), 20/32 ($P = .003$), and 20/25 ($P = .001$). A statistically significantly higher proportion of patients in Group 1 than in Group 2 read 80 words per minute or more throughout the range of print sizes ($P = .002$).

CONCLUSION: Near reading ability was better with the Tetraflex accommodating IOL than with the Crystalens accommodating IOL at all print sizes between 20/25 and 20/63.

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Reading, a crucial tool for communication, ranges from being a necessity (occupational, information gathering) to being a passionate hobby. The loss of reading ability can significantly reduce a person's independence, leading to a loss in quality of life.[1–4] Often, regaining functional reading ability is a principal motivation in a patient's decision to have cataract surgery.[1,2,4]

One option to alleviate the loss of reading vision without spectacles is the accommodating intraocular lens (IOL). This alternative offers clear vision at near and distance, helping cataract patients attain independence from spectacles without the compromises inherent when a multifocal IOL is implanted.[5–12] The U.S. Food and Drug Administration (FDA) approval of the Crystalens accommodating IOL (Bausch & Lomb) established the feasibility of such an IOL design.

The Tetraflex accommodating IOL is currently in the FDA clinical trial. A study in England recently reported good near visual results with the IOL.[13] The Tetraflex (model KH3500, Lenstec, Inc.) is a single-piece posterior chamber IOL with flexible 10-degree anteriorly angulated closed-loop haptics and a spherical optic. The hydrophilic IOL can be inserted through a small (2.50 to 3.00 mm) clear corneal incision. It is made of a medical-grade hydroxyethyl methacrylate

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(26% water content) and a polymerizable ultraviolet blocker. The 5.75 mm optic has square edges.

As part of the FDA clinical trial, the mechanism of action of the Tetraflex IOL was elucidated using the iTrace aberrometer (Tracey Technologies). Aberrometry data showed that the IOL had statistically significantly more change in higher-order aberrations (HOAs) (distance to near focus) than a monofocal control IOL with regard to total HOAs (34% increase), coma (20% increase), spherical aberration (39% increase), and trefoil (39% increase) (Lenstec, Inc., unpublished data). This increase in aberrations when looking at near presumably results in increased depth of focus. Although a direct comparative study has not been performed, we believe that these changes occurred without the halos, night glare, and decreased contrast sensitivity seen with multifocal IOLs.[5–12] The purpose of this study was to compare near functional reading ability in patients with this IOL and in a matched population with another model of accommodating IOL.

PATIENTS AND METHODS

As part of the multicenter FDA clinical study, the MNRead functional reading test (Lighthouse, Optelec Low Vision Products) was administered as a substudy 1 year postoperatively to all Tetraflex IOL patients (Group 1) at 4 of 12 investigative sites. As the study progressed, testing was added at 6 months and 2 years to determine stability of reading ability over time. A consecutive series of patients with bilateral Crystalens 5.0 IOLs (model AT-50SE) (Group 2) who returned to the practices that were collecting MNRead data from the clinical trial and who were between 0.75 to 1.50 years postoperative were also enrolled for comparative purposes.

Distance manifest refraction and corrected distance acuity (CDVA) were obtained in both eyes using an Early Treatment of Diabetic Retinopathy Study illuminated logMAR chart (Precision Vision) at 4 m. The infinity-corrected manifest refraction (referred to as the adjusted manifest refraction) in each eye was obtained by subtracting 0.25 diopter from the distance manifest refraction to account for the 4 m testing distance. This adjusted manifest refraction was placed in front of both eyes for MNRead testing. Reading luminance was standardized for testing at 85 candelas [cd]/m^2 $\pm$ 5% tolerance.

The MNRead acuity chart consists of individual sentences of 10 standard-length words at print sizes of 1.3 (20/400) to -0.5 (20/6) in 0.1 logMAR intervals standardized to a 40 cm (16-inch) reading distance. As the patients held the MNRead card at 40 cm, a digital sound recorder was begun. Starting at the largest print size, patients were instructed to read each sentence as quickly as possible. Only the sentence to be read was exposed. When the patient completed a sentence, the next sentence was exposed. Patients were instructed to continue reading the smaller print sizes until they could not read any word in a sentence. Patients were encouraged to guess even when they believed the words were unreadable. When the patients could not read any of the smaller sentences, the digital recorder was turned off and the recording was sent to a central reading center for scoring. The technician performing the scoring was masked to which IOL the patient had received. Time to read a given sentence (in seconds) was measured with a stopwatch, and the number of word errors for each sentence was recorded. Reading speed in words per minute (wpm) for each sentence was calculated as follows: [60 $\times$ (10 minus number of word errors)]/(reading time in seconds). A subset of 10 cases from each IOL group was randomly chosen (technician masked) and rescored a few days later to determine repeatability of measurements. The graphs of wpm by print size for the test and retest measurements were virtually superimposable, and the mean wpm at all print sizes between 20/25 and 20/63 differed by no more than 1.6 wpm between the test and retest measurements. A graph of the test (x-axis) versus retest (y-axis) values of the 20/50 print size yielded a best-fit line with a slope of 1.0 and a correlation coefficient of 0.995, also indicating high repeatability.

Statistical Analysis

Ordered category and continuous variable comparisons between the 2 IOL groups were tested for statistical significance using the Wilcoxon Mann-Whitney U test, which is a nonparametric 2-sample test applicable for unequal sample sizes between groups. A probability of 5% or less ($P < .05$) was considered statistically significant; however, the probability was modified by the incremental application of the Bonferroni correction for multiple significance testing described by Benjamani and Hockberg.[14] The null hypothesis was that the value produced by the Tetraflex IOL was the same as that produced by the Crystalens IOL; thus, 2-sided tests were used to compare values between the 2 IOL groups. StatXact4 software (Cytel Software Corp.) and Microsoft Excel software (Microsoft Corp.) were used for all tabulations of data and statistics.

RESULTS

Group 1 comprised 96 patients and Group 2, 55 patients; in Group 1, 46% of patients were men and in Group 2, 60% ($P = .10$, Fisher exact test). The mean patient age at the time of IOL implantation (first eye) was 68.9 years $\pm$ 7.2 (SD) in Group 1 and 69.2 $\pm$ 7.8 years in Group 2 ($P = 0.84$, Student t test). The mean CDVA was -0.02 logMAR ($20/20^{+1}$) in Group 1 and 0.00 logMAR (20/20) in Group 2 ($P = .13$, Student t test). The mean time from surgery to MNRead testing was 13.4 months and 13.3 months, respectively ($P = 0.67$, Student t test). Thus, the groups were comparable in age, sex, and postoperative time and were within ± 1 letter of corrected logMAR acuity.

Figure 1 shows a comparison of mean reading speed at various print sizes. The speed was similar up to a print size of 20/80, at which point patients in Group 2 began reading more slowly than patients in Group 1. The reading speed was statistically significantly better in Group 1 than the Group 2 at print sizes of 20/63 ($P = .004$), 20/50 ($P = .002$), 20/40 ($P = .001$), 20/32 ($P = .003$), and 20/25 ($P = .001$).

Figure 2 shows the proportion of patients who could read 80 wpm or more by print size. A statistically significantly higher proportion of patients in Group 1 than in

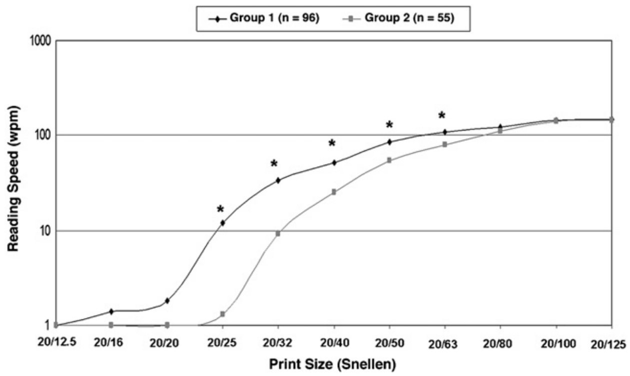

Figure 1. Mean reading speed (on a logarithmic scale) for various print sizes. The asterisks show print sizes at which Group 1 performed statistically significantly better than Group 2.

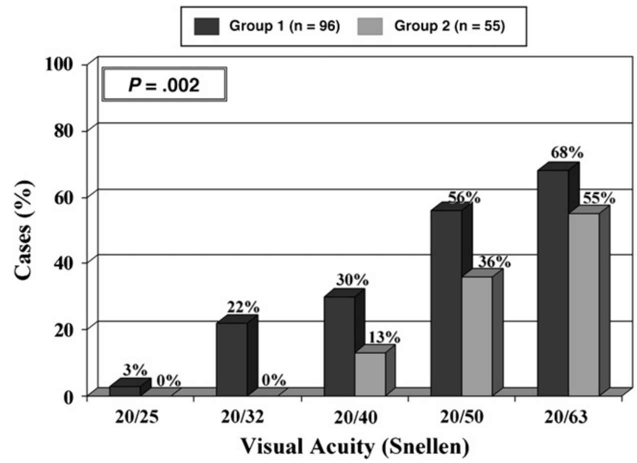

Figure 2. Percentage of patients who could read more than 80 wpm by print size 1 year postoperatively.

Group 2 read 80 wpm or more throughout the range of print sizes ($P = .002$, Wilcoxon 2-sample test).

DISCUSSION

In ophthalmic practice, we usually assess near-vision performance by measuring the capability of the patient to recognize a series of individual letters on a near-vision chart. A valid issue with these near-vision tests is whether they are the correct way to evaluate near vision and whether the perceived value of the tests is not overstated when assessing near-vision outcomes after refractive surgery. It is reasonable to conclude that a more functional activity, such as reading words and sentences, would be more useful when measuring patient outcomes. In this study, we chose a minimum reading speed of 80 wpm as a clinically relevant endpoint because it represents the lower limit for recreational sense-capturing reading.[15,16]

There is a common agreement among the experts in the field that the best definition of *reading* is the ability to derive meaning from text.[17,18] Using that definition, the implication is that successful reading depends on having comprehension skills and strategies that would imply a certain level of education. However, the primary goal of ophthalmologists is to decipher the reading ability of their patients regardless of the intellectual level of the person tested; thus, to eliminate the intellectual biases, we used the MNRead acuity chart in our comparison. These charts were developed at the Minnesota Laboratory for Low Vision Research under funding by the National Institutes of Health. The test sentences provide samples of normal reading material, demanding corresponding visual-processing capabilities and eye-movement control. The vocabulary in the sentences is selected from words appearing with high frequency in second- and third-grade reading material. Reading performance can be measured objectively using 2 variables: reading speed (number of words per minute or per second) and reading rate (number of correctly read words per minute or per second).[19,20] Bailey and Lovie[21] used unrelated words of similar legibility to simultaneously determine reading acuity and speed. This method was applied to the MNRead acuity chart as well as to Radner Reading charts.[22]

The measurement of reading speed, while not strictly speaking an objective examination because it requires a patient's response, is quantifiable, and we believe it provides much more information about functional near vision than reading letters on a standard near-acuity chart. Reading is the endpoint patients want to reach. Conventional acuity charts assess only the ability to read individual letters on an eye chart but do not necessarily directly correlate with performance on real-world tasks.

Although one usually thinks of good reading vision as the ability to read 20/20 or 20/25 print sizes, it has recently been pointed out that commonly read print objects, such as telephone directories, stock quotations, or newspaper print, are all larger than 20/40 print.[23] Richter-Mueksch et al.[3] suggest that reading the 20/50 line would be a good criterion for reasonable reading performance. Regarding this, in our study, patients with Tetraflex IOLs had significantly better reading speed at all 5 clinically relevant print sizes than patient with Crystalens IOLs, and a significantly greater proportion in the former group could read 80 wpm or more throughout the range of print sizes.

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