US FDA Clinical Trial of the Tetraflex Potentially Accommodating IOL: Comparison to Concurrent Age-matched Monofocal Controls

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ABSTRACT

PURPOSE: To assess the efficacy of the Tetraflex (Lenstec Inc) intraocular lens (IOL) to provide enhanced near reading ability and spectacle independence relative to a monofocal control IOL in bilaterally implanted eyes tested binocularly.

METHODS: A prospective, age-matched, non-randomized US Food and Drug Administration clinical trial of 255 Tetraflex and 101 monofocal IOL control patients was performed. To date, 239 Tetraflex and 96 control patients were examined at 12 months postoperatively.

RESULTS: At 12 months postoperative, the Tetraflex patients read better than the controls at print sizes of 20/80 ($P=.04$), 20/63 ($P=.01$), 20/50 ($P<.001$), 20/40 ($P=.001$), 20/32 ($P<.001$), and 20/25 ($P=.001$). The proportion of patients reading at a speed of $\geqslant$80 words per minute was significantly higher with the Tetraflex IOL ($P=.003$). Ninety-six percent of Tetraflex patients reported never wearing glasses for distance compared with 80% of control patients ($P<.001$). Seventy-five percent of the Tetraflex patients reported near spectacle wear either never or only occasionally for small print and/or dim light (21% never) compared with 46% of control patients ($P<.001$) (9% never). Near add power requirement for corrected near visual acuity was less in the Tetraflex group ($P<.001$); 28% of Tetraflex patients required $\leqslant$1.25 diopters of near add, compared to only 7% of control patients. Spectacle independence, as measured by the proportion of patients with uncorrected distance visual acuity of 20/25 or better and various degrees of uncorrected near visual acuity, was also significantly better ($P<.001$) as was distance-corrected near visual acuity ($P<.001$).

CONCLUSIONS: The results support the efficacy of the Tetraflex IOL to provide enhanced near reading ability and spectacle independence relative to a monofocal IOL control. [*J Refract Surg*. 2010;26(10):723-730.]

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At present, there is a great interest among patients and ophthalmologists (on behalf of their patients) to provide the cataract surgical candidate with the option of an intraocular lens (IOL) that offers clear vision at both near and distance without the compromises inherent in a multifocal IOL. The commercialization of the Crystalens Accommodative IOL (Bausch & Lomb, Rochester, New York) established the feasibility of such a lens design.

The Tetraflex presbyopic posterior chamber IOL (Lenstec Inc, St Petersburg, Florida) is a single-piece intraocular lens with highly flexible 5° anteriorly angulated "closed loop" haptics and a 5.75-mm optic with square edges designed to prevent glare effects and reduce the risk of posterior capsular opacification. The lens is inserted through a commercially available 2.2-mm cartridge using standard posterior chamber IOL insertion techniques, which allow for insertion through a small (2.5- to 3.0-mm) clear corneal incision. The IOL is manufactured completely from medical grade hydroxyethylmethacrylate (HEMA, 26% water content) containing a polymerizable ultraviolet blocker. Because accuracy of IOL power calculation is critical to obtaining good uncorrected distance and near vision, the Tetraflex IOL is manufactured to tighter tolerances and available in smaller increments of power for the central range of powers (diopter [D] increments of 0.20 D between IOL powers of 18.00 and 25.00 D) than standard monofocal IOLs.

The presumed mechanism of action involves an increase in higher order aberrations when looking at near objects due to a change in the optic contour caused by vitreous pressure and/or ciliary muscle contraction with accommodative effort.

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Dr Sanders is a consultant to Lenstec Inc and STAAR Surgical. Ms Sanders has no proprietary interest in the materials presented herein. The proprietary interests of the members of the Tetraflex Presbyopic IOL Study Group are noted in the Appendix.

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This conclusion is supported by a substudy performed as part of the US Food and Drug Administration (FDA) clinical trial using the iTrace aberrometer (Tracey Technologies Inc, Houston, Texas) where the increase in total higher order aberrations when looking from a distance to a near accommodative target demonstrated a 34% increase relative to a monofocal control IOL; there was a 20% increase in coma, 39% increase in spherical aberration, and 39% increase in trefoil (unpublished data, August 2008).

The purpose of this study is to demonstrate effectiveness of the Tetraflex IOL relative to an age-matched monofocal control with regard to enhanced near reading ability and spectacle independence.

PATIENTS AND METHODS

As part of the US multi-center FDA clinical study of the Tetraflex presbyopic IOL, 255 patients received Tetraflex IOLs and 101 patients received monofocal control IOLs (model CQ2015, 3-piece hydrophilic acrylic IOL; STAAR Surgical, Monrovia, California), which were bilaterally implanted at 12 clinical sites. Of the 255 Tetraflex patients enrolled, 239 (93.7%) have been examined at 1 year postoperatively: 4 patients died before 1-year follow-up, 6 patients missed the appointment but were seen at a later period, and 6 patients were lost to follow-up. Of the 101 control patients enrolled, 96 (95%) have been examined at 1 year postoperatively: 1 patient died before 1-year follow-up, 1 patient missed the appointment but was seen at a later period, and 3 patients were lost to follow-up.

Enrollment criteria for both the Tetraflex and control IOLs included patients 18 years or older with the presence of bilateral cataracts requiring cataract extraction with good visual potential, clear intraocular media other than cataract, corrected distance visual acuity (CDVA) worse than 20/40 or cataract with glare acuity worse than 20/30 in both eyes, and keratometric astigmatism <1.00 D. Patients were excluded if they had glaucoma, maculopathy, or were chronically taking any medication that may affect accommodation, including first-generation antihistamines, anticholinergic agents, or anti-psychotic and antidepressant medications whose drug label mentioned blurry vision for near. The IOLMaster (Carl Zeiss Meditec, Dublin, California) was used for all IOL power calculations using manufacturer recommended A-constants or surgeon factors. Investigators were allowed to use the power calculation formula of their choice. Target refraction for the first eye operated was −0.25 to −0.375 D. If the first eye resulted in myopia (as planned), emmetropia was the target refraction for the fellow eye. If the first eye was emmetropic or hyperopic, the target refraction for the fellow eye was −0.25 to −0.375 D. Targeted refractions for first and fellow eyes were identical for the Tetraflex and control IOLs.

Although enrollment criteria for the Tetraflex and control IOLs were identical, patients enrolled in the two groups at the discretion of the investigators were aware of whether they were to receive the Tetraflex or a standard monofocal control IOL; however, the technicians performing the testing procedures were masked as to which group an individual patient belonged. Patients in the two groups were age matched as a requirement for the study. The groups were also tested to determine whether they were similar with regard to gender, 1-year CDVA, and 1-year manifest refraction spherical equivalent (MRSE).

TESTING METHODS

Minnesota Low-vision Reading Test (MNRead). The MNRead functional reading test (Lighthouse International, New York, New York) was performed as a substudy 1-year postoperatively in all Tetraflex and control patients presenting at 4 of the 12 investigative sites. As the study progressed, testing was added at 6 months and 2 years postoperatively in the Tetraflex group to determine stability of reading ability over time.

Distance manifest refraction was obtained in both eyes using an ETDRS illuminated logMAR chart (Precision Vision, La Salle, Illinois) at a distance of 4 m. The "infinity corrected" manifest refraction (referred to as the adjusted manifest refraction) for each eye was obtained by subtracting 0.25 D 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 cd/m^2 ± 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, and starting at the largest print size, the patient was instructed to read each sentence as quickly as they were able. Only the sentence to be read was exposed and after each sentence was completed, the next sentence was exposed. Patients were instructed to continue reading the smaller print sizes until they could not read any words 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 where the technician doing the scoring was masked as to whether the patient

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received a Tetraflex or control IOL. Time in seconds to read a given sentence 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: (60 × (10 minus # of word errors))/(reading time in seconds).

A masked test of repeatability (test-retest) of scoring in 20 cases demonstrated high repeatability with average wpm at all print sizes between 20/25 and 20/63 differing by no more than 1.6 wpm between the test and retest measurements.

Patient Survey. Patients were asked at 1 year postoperatively about distance spectacle wear, near spectacle wear, and percentage of time that they used near correction. They were also specifically asked about severity of glare and halos.

Visual Acuity Measurements. Distance visual acuity measurements (uncorrected distance [UDVA] and CDVA) were taken with ETDRS logMAR charts at 4 m with illumination standardized to 85 cd/m^2 ± 5% tolerance. The near add required for CDVA was also obtained. Near acuities (uncorrected [UNVA] and distance-corrected near visual acuity [DCNVA]) were obtained using an ETDRS logMAR visual acuity near chart at 40 cm, with illumination standardized to 85 cd/m^2 ± 5% tolerance. Distance-corrected near visual acuity was obtained with the adjusted manifest refraction in place. All visual acuity measurements were taken binocularly.

Statistical Analysis

Binomial comparisons between Tetraflex and control groups were performed with Fisher's exact test, whereas ordered category and continuous variable comparisons such as MNRead wpm, subjective survey data, and visual acuity data were performed with the Wilcoxon Mann-Whitney U test. A probability less than or equal to 5% ($P \leq .05$) was considered statistically significant; however, this probability was modified by the incremental application of the Bonferroni correction for multiple significance testing described by Benjamani and Hochberg.[1] The null hypothesis was that the value produced by the Tetraflex lens was either the same as or worse than (lower value) that produced by the control lens; thus, one-sided tests were used to test for the Tetraflex value being better than (higher value) that of the control. StatXact4 (CYTEL Software Corp, Cambridge, Massachusetts) and Microsoft Excel (Microsoft Corp, Redmond, Washington) were used for all tabulations of data and statistics.

RESULTS

Patient Population

Fifty-nine percent of the Tetraflex patients were female versus 56% of the control patients (P=.64 with Fisher's exact test). Mean age at the time of implantation (primary or first eye in bilaterally implanted patients) was 67.7±7.8 years in the Tetraflex group and 66.8±9.3 years in the control group (P=.36 with t test). Mean CDVA at 1 year was −0.06 logMAR (20/20^{+3}) in the Tetraflex group and −0.05 logMAR (20/20$^{+2½}$) in the control group (P=.69 with t test). Thus, the groups were comparable with regard to age, gender, and CDVA. One year postoperative MRSE for all eyes in the Tetraflex group was −0.10±0.4 D (range: −1.75 to +1.875) and −0.20±0.5 D (range: −1.50 to +1.50 D) in the control group. Thus, there were small differences in refractive error between the Tetraflex and control patients, with the control patients being on average 0.10 D more myopic. The proportion of cases within ±0.50 D and ±1.00 D of emmetropia in the Tetraflex group was 83.6% and 97.8%, respectively, whereas the proportion of cases within ±0.50 D and ±1.00 D of emmetropia in the control group was 80.6% and 94.2%, respectively. Mean postoperative sphere in the Tetraflex group was −0.26±0.47 D, and mean cylinder was 0.39±0.38 D. Mean postoperative sphere in the control group was −0.37±0.51 D and mean cylinder was 0.37±0.36 D.

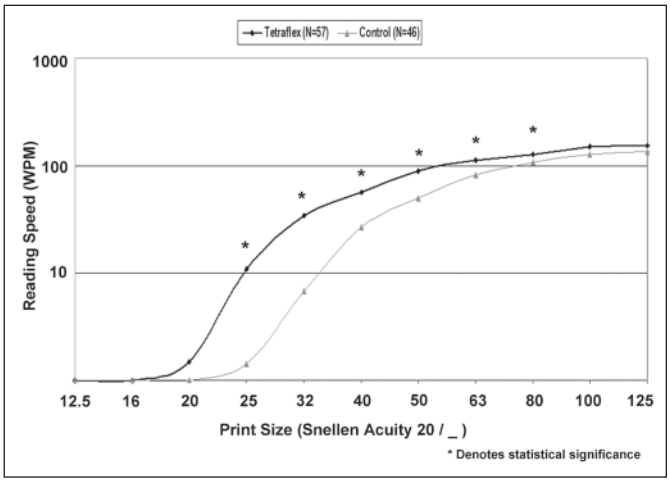

Figure 1. Comparison of Tetraflex and control groups with regard to average reading speed in words per minute (wpm) (on a logarithmic scale) for various print sizes in Snellen equivalents of logMAR values at 1 year postoperatively. Asterisks demonstrate print sizes at which the Tetraflex group is statistically significantly better than the control group. Not shown on the graph were five print sizes larger than 20/125 (20/160, 20/200, 20/250, 20/330, and 20/400) where no significant differences were noted between the Tetraflex and control groups with regard to reading speed.

Effectiveness Outcomes

MNRead. Figure 1 provides a comparison of average reading speed at various print sizes. Reading speed in wpm (on a logarithmic scale) is given on the y-axis and print size in Snellen equivalents of logMAR values is

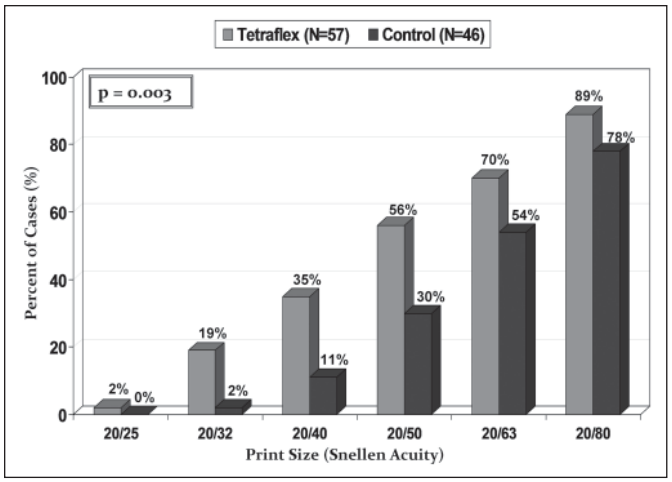

Figure 2. Comparison of Tetraflex and control groups with regard to proportion of patients that could read ⩾80 words per minute (wpm) by print size at 1 year postoperatively. The Tetraflex IOL demonstrated a statistically significantly greater proportion of patients reading 80 wpm across the range of print sizes than the control lens (*P*=.003).

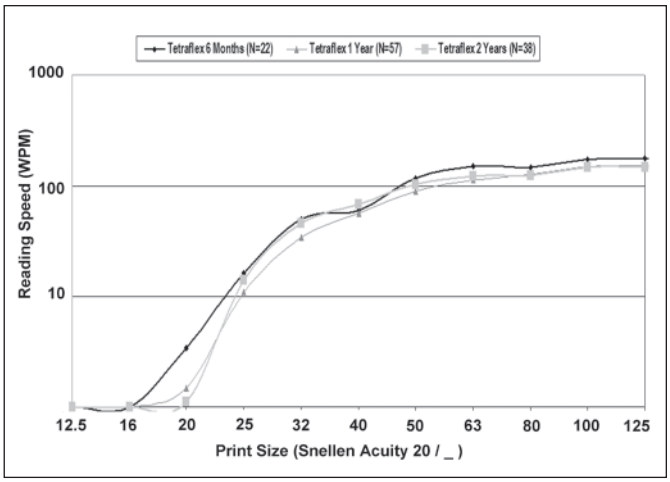

Figure 3. Comparison of Tetraflex patients tested at 6 months and 1 and 2 years postoperatively with regard to average reading speed in words per minute (wpm) (on a logarithmic scale) for various print sizes in Snellen equivalents of logMAR values. No statistically significant differences were noted in reading speed.

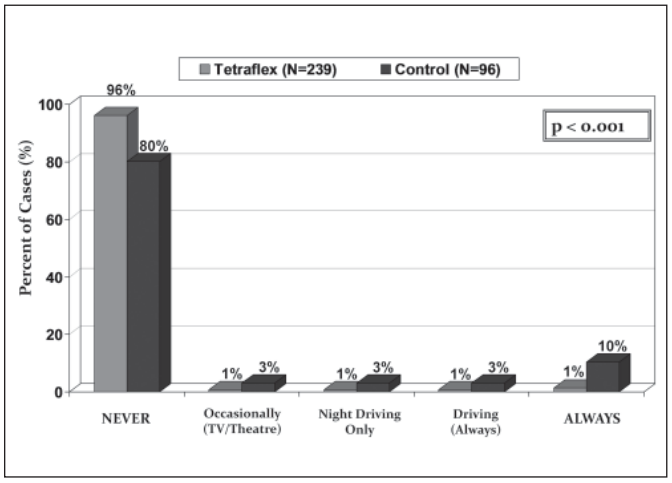

Figure 4. Comparison of Tetraflex and control groups with regard to patients' responses to when they wore spectacles for distance at 1 year postoperatively. The Tetraflex group demonstrated significantly more spectacle independence for distance (*P*<.001).

given on the x-axis. The graphs are similar from larger print sizes down to a print size of 20/80, at which the monofocal IOL control patients began to lose the ability to read in terms of speed relative to the Tetraflex IOL. The Tetraflex IOL was statistically significantly better than the control IOL at print sizes of 20/80 (*P*=.04), 20/63 (*P*=.01), 20/50 (*P*<.001), 20/40 (*P*=.001), 20/32 (*P*<.001), and 20/25 (*P*=.001).

Figure 2 presents the proportion of patients who could read ⩾80 wpm in the Tetraflex and control groups by print size. A minimum reading speed of 80 wpm was chosen because it represents the lower limit for recreational sense capturing reading.[2,3] This figure demonstrates that the proportion of patients reading at a speed of ⩾80 wpm is significantly better with the Tetraflex IOL than with the control IOL throughout the range of print sizes from 20/25 through 20/80 (*P*=.003). Nineteen percent of Tetraflex patients could read ⩾80 wpm at the 20/32 print size compared to only 2% of monofocal IOL control patients; 35% of Tetraflex patients could read ⩾80 wpm at the 20/40 print size compared to only 11% of the monofocal IOL control patients.

Figure 3 demonstrates 6-month and 1- and 2-year MNRead data for Tetraflex patients, demonstrating no significant loss of reading ability between 6 months and 2 years postoperatively at any print size tested. The minor differences observed at the 20/25 and 20/20 print sizes are at the points in the graph where average wpm is ⩽17 wpm.

Patient Survey. Figure 4 presents the patients' responses to when they wore spectacles for distance. Of the Tetraflex patients, 96% stated they never wore distance correction whereas 80% of the control cases never wore spectacles. Only 1% of the Tetraflex patients stated that they always wore distance correction; 10% of the control patients answered similarly. The distribution between these groups was statistically significant (*P*<.001).

Figure 5 presents the patients' responses to when they wore spectacles for near. Of the Tetraflex patients, 75% stated that they never or occasionally wore near correction for small print or dim light, whereas 46% of control patients answered similarly. Twenty-six percent of the Tetraflex patients stated that they always wore near correction, whereas 54% of the control cases answered similarly. The distribution between these groups was statistically significant (*P*<.001).

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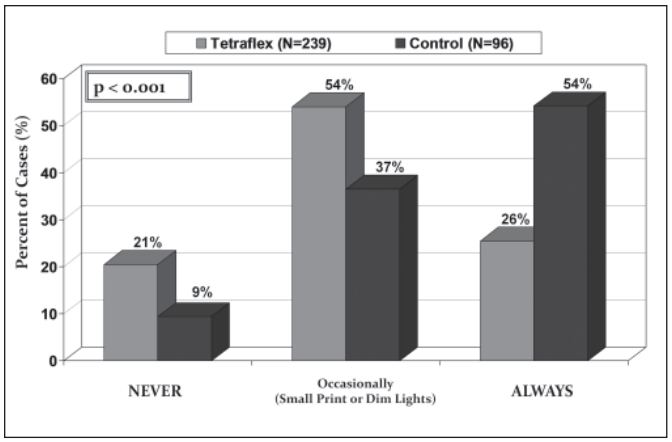

Figure 5. Comparison of Tetraflex and control groups with regard to patients' responses to when they wore spectacles for near at 1 year postoperatively. The Tetraflex group demonstrated significantly more spectacle independence for near ($P<.001$).

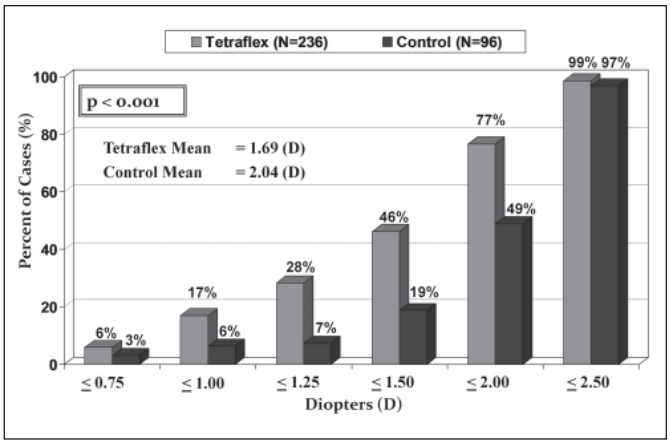

Figure 6. Comparison of Tetraflex and control groups with regard to add power requirement for corrected near visual acuity at 1 year postoperatively. The Tetraflex IOL required statistically significantly less add power than the control lens ($P<.001$). Add power was not collected on 3 patients at 1 year postoperatively.

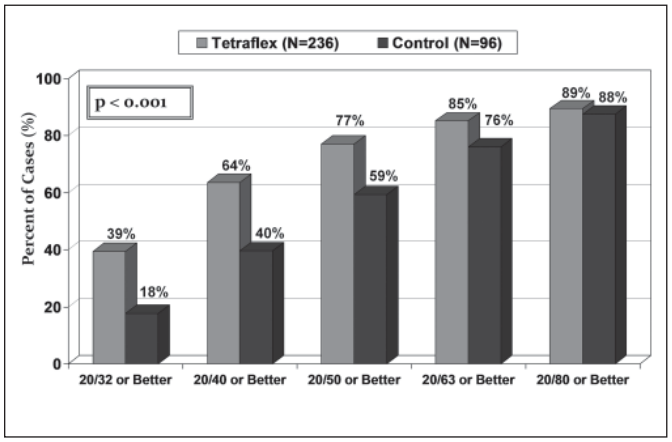

Figure 7. Comparison of Tetraflex and control groups with regard to the proportion of patients who could see 20/25 or better for distance and various degrees of near acuity at 1 year postoperatively as a measure of spectacle independence. The Tetraflex IOL had a statistically significantly higher proportion of patients seeing better than the control lens patients ($P<.001$). Near acuity was not collected on 3 patients at 1 year postoperatively.

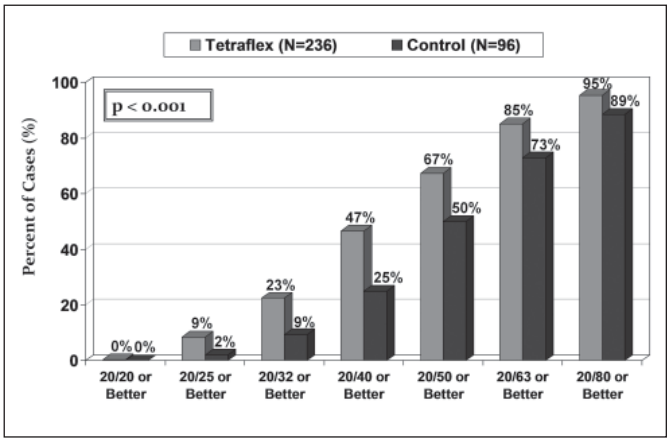

Figure 8. Comparison of Tetraflex and control groups with regard to distance-corrected near visual acuity for various print sizes at 1 year postoperatively. The Tetraflex IOL had a statistically significantly higher proportion of patients seeing better than the control lens patients ($P<.001$). Distance-corrected near acuity was not collected on 3 patients at 1 year postoperatively.

At 1 year postoperatively, 14 (5.9%) of 239 Tetraflex patients reported moderate/marked glare compared to 11 (11.5%) of 96 control patients ($P=.11$). Severe glare was reported in 2 (0.8%) of 239 Tetraflex patients compared to 2 (2.1%) of 96 control patients ($P=.32$). At 1 year postoperatively, 9 (3.8%) of 239 Tetraflex patients reported moderate/marked halos compared to 9 (9.4%) of 96 control patients ($P=.06$). Severe halos were reported in 1 (0.4%) of 239 Tetraflex patients compared to 1 (1%) of 96 control patients ($P=.49$).

Add Power Required for Corrected Near Visual Acuity. As shown in Figure 6, a decreased requirement for add power is present at 1 year postoperatively for the Tetraflex IOL relative to the control. Of the Tetraflex patients, 28% required ≤1.25 D of near add for CNVA whereas 7% of control patients required this add. Forty-six percent of Tetraflex patients required ≤1.50 D of add, and 19% of control cases required this add. The Tetraflex IOL was statistically significantly better than the control lens as measured by this parameter ($P<.001$).

Spectacle Independence. In addition to the patient survey, another measure of possible spectacle independence would be the ability to simultaneously see well for UDVA and UNVA. Figure 7 demonstrates the proportion of patients who could see 20/25 or better for distance and various degrees of UNVA 1 year postoperatively. Sixty-four percent of Tetraflex patients and 40% of control cases could see the 20/25 line for distance and the 20/40 line for near. Of the Tetraflex patients, 77% could see the 20/25 line for distance and

the 20/50 line for near, and 59% of the control patients could see this well. The Tetraflex IOL was statistically significantly better than the control lens ($P<.001$).

Distance-corrected Near Visual Acuity. Distance-corrected near visual acuity was better in the Tetraflex group than in the control group for the print sizes tested, as shown in Figure 8. Whereas 47% of patients receiving the Tetraflex IOL could read the 20/40 print size, only 25% of control patients could see this well. Of the Tetraflex patients, 67% could see 20/50 or better compared to 50% of control patients. The Tetraflex IOL was statistically significantly better than the control lens ($P<.001$).

Predictability. Predictability within ±0.50 D was observed in 83.6% of Tetraflex patients and 74% of control patients. Achieved predictability within ±1.00 D was noted in 97.8% of Tetraflex patients and 93.1% of control patients. No surgical enhancement procedures to improve predictability were performed in either group. The defocus equivalent was within ±0.50 D in 82.3% of Tetraflex patients and 85.3% of control patients. Defocus equivalent within ±1.00 D was noted in 96.6% of Tetraflex patients and 97.3% of control patients.

Safety Outcomes

Corrected Distance Visual Acuity. Of the 478 eyes implanted with the Tetraflex IOL examined at 1 year postoperatively, only 5 (1%) had CDVA worse than 20/40; all 5 eyes had 20/50 vision at 1 year due to posterior capsular opacification. Four of these 5 eyes had subsequent YAG capsulotomy and CDVA of 20/40 or better at last follow-up.

Complications/Adverse Events. The only significant IOL-related complication/adverse event was the malpositioning of 5 (1%) Tetraflex IOLs at the time of surgery, which required secondary repositioning within the first postoperative month. All 5 IOLs were successfully repositioned and visual acuity at last reported follow-up, 1 to 2 years postoperatively, was 20/25 or better in all cases. Three (60%) of the 5 repositionings occurred at a single investigative site that only performed 42 (8.2%) of the 510 Tetraflex surgeries, for a repositioning rate of 7.1%. The remainder of the sites had 2 repositionings of 468 implantations for a repositioning rate of 0.4%. Thus, this single site had almost 18 times the secondary surgery rate as the other sites and this difference was significant ($P=.005$). No late dislocations or "Z" distortions were observed in this series with 478 eyes examined at 1 year and 356 eyes examined at 2 years postoperatively. No significant complications/adverse events occurred in the control group.

DISCUSSION

This study compared the Tetraflex presbyopic IOL to a standard monofocal IOL made of a similar hydrophilic material. The study groups were not randomly assigned and patients were aware of the type of IOL implanted, both of which could introduce potential bias, especially with regard to some of the subjective examinations. Mitigating the potential bias includes the facts that the groups were masked to the technicians performing the testing procedures; the groups were concurrently enrolled, with the same enrollment criteria; were successfully age-matched; had similar corrected visual potential at 1 year postoperatively (within ½ letter of acuity); and only differed in average postoperative manifest refraction by 0.10 D.

Most striking is the Tetraflex patients' improvement in functional reading ability relative to the control IOL in the range of 20/25 to 20/80 print sizes with distance correction. Although reading speed is dependent on factors other than near visual acuity, the fact that there were 7 print sizes larger than 20/80 tested where there was no significant difference in reading speed between Tetraflex and control IOLs suggests the groups were comparable in their reading ability in the absence of print size limitations.

The finding of stability of functional reading ability between 6 months and 2 years with the Tetraflex IOL is an important observation given that its mechanism of action depends on some type of dynamic movement or change with accommodative effort.

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 the telephone directory, stock quotations, or newspaper print are all larger than 20/40 print.[4] Richter-Mueksch et al[5] suggested that reading the 20/50 line would be a good criterion for reasonable reading performance. Approximately 75% of Tetraflex patients reported that they never wore reading glasses or only occasionally did for small print or in dim light. This correlated well percentage-wise with the ability to read ⩾80 wpm at 20/63 to 20/80 print sizes.

We were surprised at the patients' reported improvement in distance spectacle independence with the Tetraflex relative to the control IOL (96% vs 80% never wearing distance spectacle correction), given the relatively modest differences in average refractive error. This may be related to the improved near vision in the Tetraflex group and some patients' preference for wearing bifocals even though they have good distance vision without spectacles in the control group. This interpretation is further supported by the fact that both the Tetraflex and control groups had 91% of patients reporting UDVA of 20/25 or better.

The decreased requirement for spectacle add power to achieve CNVA, although an indirect measure, sug-

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gests that the Tetraflex IOL provides patients with an extra accommodative effect relative to the monofocal control IOL.

Spectacle independence, as measured by simultaneous ability to see well for distance and near without correction, has been reported as an important benefit of multifocal IOLs.[6] Similarly, DCNVA is an intuitively obvious measure of accommodation or pseudoaccommodation.

Although all of the parameters tested for near tasks and spectacle independence were statistically significantly better in the Tetraflex group, it is clear that the Tetraflex IOL performs best relative to the control IOL under actual reading conditions and in the patients' own subjective experience of their spectacle independence and need for reading glasses. The differences between the Tetraflex and control IOLs were not as great when testing the patients' ability to read individual letters on an eye chart. This may be because there are no time constraints placed on the patient to read the eye chart and, with time and effort, even patients with standard monofocal IOLs can discern letters. Clearly, this ability does not necessarily translate into good functional reading performance.

The trade-offs between an accommodative and multi-focal IOL are clear. Although multifocal IOLs allow excellent near vision down to the 20/20 or 20/25 level without the use of spectacles, they can result in detrimental visual symptoms caused by a simultaneous superimposition of images on the retina. These include loss of clarity, loss of low contrast acuity, and complaints of halo and glare.[6-9] Our study showed an incidence of moderate/marked glare of 8.4% for the Tetraflex lens compared to a reported 21.5% in the US FDA trial of the AcrySof ReSTOR IOL (Alcon Laboratories Inc, Ft Worth, Texas).[6] Similarly, the incidence of severe glare was 0.8% for the Tetraflex lens compared to a reported 4.8% in the ReSTOR study.[6] The incidence of moderate/marked halos was 5.1% for the Tetraflex lens compared to a reported 19.1% with the ReSTOR lens, and the incidence of severe halos was 0.4% for the Tetraflex lens compared to a reported 5.0% in the ReSTOR study.[6]

Patients have a variety of preferences and needs in regard to their daily lives. Emphasizing the importance of reading for personal convenience in everyday life is crucial to understanding patients' needs in terms of IOLs. Although the near visual acuity level of accommodative lenses is not as crisp as multifocal IOLs, they restore functional near vision to the majority of patients with a low incidence of visual disturbances. Individual patient needs must be evaluated to determine whether crisp, precise near vision possibly accompanied by visual symptoms, as seen with multifocal IOLs, or acceptable "social reading" vision without these symptoms, as seen with accommodative IOLs, is required.

Because the haptics of the Tetraflex IOL are flexible, it is important to ensure that they are completely unfolded at the time of surgery. If the closed looped haptic is folded onto itself on one side only, optic tilt will occur. If both haptics are folded anteriorly upon themselves, the IOL will sit more posteriorly in the capsular bag sometimes with a hyperopic refraction. Either of these presentations is easily remedied by repositioning of the haptics. With proper training in implantation technique, malpositioning of the haptics is rare. One site in our study had a relatively high rate of repositioning, which we believe was due to improper handling of the Tetraflex IOL at surgery. The remaining 11 sites had a repositioning rate of 0.4%.

AUTHOR CONTRIBUTIONS

Study concept and design (D.R.S.); data collection (D.R.S., M.L.S.); analysis and interpretation of data (D.R.S.); drafting of the manuscript (M.L.S.); critical revision of the manuscript (D.R.S.); statistical expertise (D.R.S.); administrative, technical, or material support (M.L.S.)

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APPENDIX

TETRAFLEX PRESBYOPIC IOL STUDY GROUP

The participants in the Tetraflex Presbyopic IOL Study Group, as of November 2008, were as follows:

Eye Centers of Florida, Fort Myers, Florida: David C. Brown, MD*; Midwest Eye Center, Cincinnati, Ohio: David Schneider, MD, James Sanitato, MD; Dougherty Laser Vision, Camarillo, California: Paul J. Dougherty, MD*, Stephen K. Anderson, MD; Hunkeler Eye Institute, Overland Park, Kansas: John Hunkeler, MD, Jeffrey Boomer, MD; Center for Excellence in Eye Care, Miami, Florida: William Trattler, MD, Frank Spektor, MD, Carlos Buznego, MD; St Luke's Cataract and Laser Institute, Tarpon Springs, Florida: James Gills, MD*, Pit Gills, MD; Carolina Eye Associates, Southern Pines, North Carolina: Robert G. Martin, MD, Neil Griffin, MD; The Barnett Dulaney Perkins Eye Center, Phoenix, Arizona: Scott Perkins, MD, Robert Rivera, MD; Berkeley Eye Center, Houston, Texas: Michael Caplan, MD; Davis Duehr Dean Medical Center, Madison, Wisconsin: John A. Vukich, MD; Loden Vision Centers, Goodlettsville, Tennessee: James Loden, MD; InView Vision, Atlanta, Georgia: George O. Waring III, MD; Center for Clinical Research, Chicago, Illinois: Donald R. Sanders, MD, PhD*, Monica Sanders, BS

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**Paid consultants to or financial interest in Lenstec Inc, St Petersburg, Florida.*

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