AMERICAN ACADEMY OF OPHTHALMOLOGY®

Visual and Patient-Reported Outcomes of a Diffractive Trifocal Intraocular Lens Compared with Those of a Monofocal Intraocular Lens

Satish Modi, MD, FRCS(C),[1] Robert Lehmann, MD,[2] Andrew Maxwell, MD, PhD,[3] Kerry Solomon, MD,[4] Robert Cionni, MD,[5] Vance Thompson, MD,[6] Jeffrey Horn, MD,[7] Michael Caplan, MD,[8] Bret Fisher, MD,[9] Jerry G. Hu, MD,[10] Elizabeth Yeu, MD[11]

Purpose: To evaluate the effectiveness and safety of a trifocal intraocular lens (IOL), the TFNT00 (Alcon, Fort Worth, TX), versus a monofocal IOL, the SN60AT (Alcon).

Design: Food and Drug Administration–approved, prospective, multicenter, nonrandomized, parallel-group, assessor-masked, confirmatory trial.

Participants: Patients enrolled were 22 years of age or older with a diagnosis of bilateral cataract with planned removal by phacoemulsification with a clear corneal incision.

Methods: Consented participants selected their preferred IOL, which was implanted sequentially into each eye of patients meeting eligibility criteria.

Main Outcome Measures: The coprimary effectiveness outcomes were mean photopic monocular best-corrected distance visual acuity (BCDVA; 4 m) and distance-corrected near visual acuity (DCNVA; 40 cm) at 6 months after surgery. Secondary effectiveness outcomes included mean monocular distance-corrected intermediate visual acuity (DCIVA; 66 cm) and proportion of participants responding "never" to question 1 of the Intraocular Lens Satisfaction questionnaire (regarding frequency of spectacle use in the past 7 days). Safety outcomes included frequency of "severe" and "most bothersome" visual disturbances.

Results: Two hundred forty-three patients underwent cataract surgery with bilateral implantation of the TFNT00 (n = 129) or SN60AT (n = 114) and were followed up for 6 months. Noninferiority of TFNT00 to SN60AT in mean photopic monocular BCDVA (95% upper confidence limit of the difference was <0.1 logarithm of the minimum angle of resolution [logMAR] margin), and superiority in mean photopic monocular DCNVA (difference of 0.42 logMAR; $P < 0.001$) and DCIVA (difference of 0.26 logMAR; $P < 0.001$) were demonstrated. The proportion of patients never requiring glasses overall was superior for TFNT00 versus SN60AT (80.5% and 8.2%, respectively). Starbursts, halos, and glare were the most frequently rated severe symptoms with TFNT00; however, less than 5% of patients were very bothered at month 6.

Conclusions: The TFNT00 exhibited superior monocular DCNVA and DCIVA to a spherical monofocal IOL, with comparable monocular BCDVA. Binocular visual acuity was 20/25 or better for distance to near (+0.5 D to −2.5 D), resulting in high levels of spectacle independence. Less than 5% of patients were very bothered by the photic visual disturbances associated with the TFNT00 at 6 months after surgery. *Ophthalmology 2021;128:197-207 © 2020 by the American Academy of Ophthalmology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).*

The incidence of cataract rises with each decade of life from 40 years of age onward, with a prevalence of 68.3% reported for United States adults 80 years of age and older,[1] and the overall prevalence in the United States population is predicted to double to 50 million by 2050.[2] The current standard-of-care treatment for cataract is small-incision phacoemulsification with foldable intraocular lens (IOL) implantation.[3] Monofocal IOLs are designed to focus light on a single focal point, facilitating distance vision; however, their lack of accommodation for near and intermediate distances[4] leads to a high level of spectacle dependency in recipients,[5] with studies reporting relatively low levels of overall patient satisfaction and perceived quality of life.[6] Multifocal IOLs have more than 1 focal point to provide vision over a range of distances, reducing the frequency of spectacle dependence in comparison with monofocal IOLs.[5–7] However, this comes at the cost of reduced contrast sensitivity and increased photic phenomena.[4,5,8–12] In addition, some multifocal IOLs have been associated with compromises in either intermediate or near vision.[13] In an attempt to address this issue, a method of blended implantation involving implanting a multifocal

https://doi.org/10.1016/j.ophtha.2020.07.015
ISSN 0161-6420/20

IOL in one eye with an intermediate focus point and a multifocal IOL in the contralateral eye with a near focus point aims to extend range of vision.[14] Although blended implantation of multifocal IOLs can improve overall range of vision for patients, evidence suggests this approach provides no significant advantage in terms of visual acuity compared with bilateral implantation of the same lens[15] or unilateral implantation of a single multifocal IOL.[16]

Diffractive trifocal IOLs are designed with 3 optical focal points to provide functional distance, intermediate, and near vision.[17–19] The AcrySof IQ PanOptix (model TFNT00; Alcon, Fort Worth, TX) is a nonapodized, single-piece hydrophobic acrylic trifocal IOL.[20] The TFNT00 model has a nonsequential diffractive structure in the central 4.5-mm portion of the 6.0-mm biconvex central optical zone, which is located on the aspheric anterior surface.[21] The TFNT00 uses proprietary technology (ENLIGHTEN optical technology) to redistribute light from the first diffractive intermediate-order vision (120 cm) to the distance vision (refractive order).[20] This creates an enhanced distance add power to accompany the +2.17-diopter (D) intermediate add power (60 cm; second diffractive order) and +3.25-D near add power (40 cm; third diffractive order) at the IOL plane,[20–22] providing a range of vision from intermediate to near, while preserving distance vision. This novel diffractive structure has been shown to provide high light use, transmitting 88% of light to the retina at the simulated 3.0-mm pupil size,[20] 50% of which is allocated to distance vision, with 25% to intermediate vision and 25% to near vision.[20,23] The nonsequential diffractive optics also have been shown to allow TFNT00 to achieve a peak intermediate distance of 60 cm, which may benefit patients who need to perform tasks at arm's length.[21,24] Bench studies have verified this intermediate peak of 60 cm for the TFNT00.[21] Clinical investigations outside the United States have demonstrated a continuous range of vision from near to distance in TFNT00 recipients[24–26]; however, available evidence of the performance of TFNT00 as compared with a monofocal IOL is limited. The current study was conducted to evaluate the effectiveness and safety of the TFNT00 compared with a spherical monofocal IOL.

Methods

Study Design

This was a United States Food and Drug Administration–approved, prospective, multicenter, nonrandomized, parallel-group, assessor-masked, confirmatory trial to evaluate the effectiveness and safety of the TFNT00 when implanted in the capsular bag in the posterior chamber for the visual correction of aphakia in adult patients. Patients in the control group were implanted with the single-piece spherical monofocal SN60AT IOL (Alcon). Patients were not charged for either the lens or implantation of the lens, regardless of their choice of lens for the study. The study was carried out between November 1, 2017, and September 27, 2018, and was conducted in accordance with the tenets of the Declaration of Helsinki, International Organization for Standardization standards 11979-7:2014 and 14155:2011, and the Code of Federal Regulations. Institutional review board approval was received for this study. Written informed consent was obtained from all patients. Inclusion criteria included an age of 22 years or older; diagnosis of bilateral cataract with planned removal by phacoemulsification with a clear corneal incision, clear intraocular media other than cataract, a projected best-corrected distance visual acuity (BCDVA) of 0.20 logarithm of the minimum angle of resolution (logMAR) or better, a calculated lens power within the available range (15.0–26.5 D), and preoperative regular keratometric astigmatism of less than 1.00 D in both eyes. Exclusion criteria included clinically significant corneal abnormality, disease, or degeneration that could affect postoperative visual acuity; previous refractive surgery or corneal transplantation; any ocular pathologic features or degenerative disorders that could affect postoperative BCDVA; and any expected requirement for ocular secondary surgical interventions (SSIs; except neodymium:yttrium–aluminum–garnet capsulotomy) during the study.

Study Procedures

Consented participants selected the IOL they preferred, which was implanted sequentially into each eye after eligibility was confirmed. Cataracts were removed using femtosecond laser-assisted cataract surgery techniques (LenSx; Alcon). The second eye surgery was performed 7 to 30 days after the first. Postoperative visits were scheduled 1 to 2 days, 7 to 14 days, and 30 to 60 days after each eye's surgery and 120 to 180 days after the second eye surgery. Emmetropia was targeted in both eyes. A sponsor-provided electronic visual acuity system (Clinical Trial Suite; M&S Technologies, Inc, Niles, IL) was used for all study visual acuity and defocus testing. Uncorrected and corrected visual acuity was measured at distance (4 m), intermediate (66 cm), and near (40 cm). For defocus testing, patients were fitted with their best-corrected distance refraction, and visual acuity was measured between +1.50 D and −2.50 D in 0.5-D defocus steps, except in the region between +0.50 D and −0.50 D, which was measured in 0.25-D steps. Binocular contrast sensitivity was assessed with the sponsor-provided CSV-1000HGT contrast sensitivity unit (Vector Vision, Inc, Greenville, OH). Assessments under photopic conditions were carried out at frequencies of 3, 6, 12, and 18 cycles per degree, with chart or screen background luminance of approximately 85 cd/m^2. Assessments under mesopic conditions were carried out both with and without glare at frequencies of 1.5, 3, 6, and 12 cycles per degree. For mesopic conditions, participants were fitted with neutral density filters to reduce their perception of the chart luminance to approximately 3 cd/m^2. Visual acuity measurements incorporated automated Early Treatment Diabetic Retinopathy Study charts (M&S Technologies, Inc) using algorithms in accordance with the American National Standards Institute (ANSI) Z80.21-2010 (R2015) and International Organization for Standardization standard 8596:2009. Patients were asked proactively to rate their experience of visual disturbances subjectively using the Questionnaire for Visual Disturbance (QUVID) developed and validated by Alcon. The QUVID consists of picture-referenced items that ask patients to report their experience of halos, glare, starbursts, hazy vision, blurred vision, double vision, and negative dysphotopsia (dark area) in terms of frequency, severity, and bothersomeness. A 5-point response scale is provided from "never" to "always" for frequency, from "none" to "severe" for severity of the patient's worst experience, and from "not bothered at all" to "bothered very much" for how much patients were bothered by the presence of specific photic phenomena. A rating of "bothered very much" is referred to as a "most bothersome" disturbance. The validated Intraocular Lens Satisfaction (IOLSAT) questionnaire, developed by Alcon, was used to assess each participant's satisfaction; need for spectacles overall and at near, intermediate, and far distances; and quality of vision

without spectacles. The QUVID and IOLSAT questionnaires were developed and recognized as validated based on guidance from the Food and Drug Administration.[27]

Effectiveness and Safety Outcomes

All primary and secondary outcomes were assessed at month 6. The coprimary effectiveness outcomes were mean photopic monocular BCDVA (4 m) and mean photopic monocular distance-corrected near visual acuity (DCNVA; 40 cm) for the first operative eye. Secondary effectiveness outcomes included mean photopic monocular distance-corrected intermediate visual acuity (DCIVA; 66 cm) for the first operative eye and the proportion of participants who responded "never" to question 1 of the IOLSAT questionnaire (regarding frequency of spectacle use in the past 7 days). The coprimary safety outcomes were the cumulative rate of SSIs related to the optical properties of the IOL for the first operative eye and the mean binocular contrast sensitivity with and without glare for photopic and mesopic conditions. Other safety outcomes included the rate of severe and most bothersome visual disturbances and the cumulative rates of adverse events (AEs) in the first operative eye.

Sample Size Calculation

The required sample size of 250 participants was planned for bilateral implantation of study IOLs in a 1:1 ratio to ensure that at least 226 eligible participants, 113 in each arm, completed the study to power the primary and secondary objectives at 83% or more. This assumes a drop-out rate of 10%, a 0.1-logMAR noninferiority margin, 0.0 expected difference, 0.18 standard deviation, and 5% type I error for BCDVA; a 0.1-logMAR expected difference, 0.18 standard deviation, and 2.5% type I error for DCNVA and DCIVA; and a 20% expected difference with a 2.5% type I error in spectacle independence.

Statistical Analysis

The all-implanted analysis set (all eyes with successful implantation plus at least 1 postoperative visit) was the primary analysis set for all effectiveness end points, except the defocus curve. The safety analysis set (all eyes with attempted implantation) was the primary analysis set for all safety end points, except contrast sensitivity. The best-case analysis set (all eyes successfully implanted with ≥1 postoperative visit, no preoperative ocular pathologic features or macular degeneration, no major protocol violations) was the primary analysis set for defocus curve and contrast sensitivity.

Least-squares mean differences from a mixed-effects model (fixed effect for treatment; random effect for site) with 95% (BCDVA) or 97.5% (DCNVA and DCIVA) upper confidence intervals (CIs) were used to assess coprimary and secondary effectiveness visual acuity end points. A 95% upper confidence limit (UCL) of less than 0.1 logMAR was considered to support noninferiority of the TFNT00 compared with the SN60AT for monocular photopic BCDVA, whereas a 97.5% UCL of less than 0.0 logMAR supported superiority of the TFNT00 compared with the SN60AT for monocular photopic DCNVA and DCIVA. An estimated Mantel-Haenszel common difference in proportions of patients with a "never" response (TFNT00 − SN60AT; site included as a stratification variable) with 2-sided 95% CI was used to assess the superiority of the TFNT00 compared with the SN60AT for the secondary IOLSAT questionnaire effectiveness end point, with a 97.5% lower confidence limit of the common difference of more than 0% considered to support superiority. Descriptive statistics were used to compare contrast sensitivity, severity and bothersomeness of visual disturbances, and rates of SSIs and AEs.

Results

Patient Disposition and Demographics

A total of 250 participants were enrolled across 12 sites in the United States. Of these, 243 eligible patients (18–22 per site) were implanted successfully with the TFNT00 (n = 129) or SN60AT (n = 114) IOLs (Fig 1). Two participants in the TFNT00 group and 3 in the SN60AT group were implanted unilaterally. Two TFNT00 recipients discontinued participation after implantation of the study IOLs and were considered lost to follow-up. One patient who was implanted unilaterally with the SN60AT and subsequently underwent explantation was excluded from the all-implanted analysis set. Three patients in the SN60AT group were excluded from the best-case analysis set because of macular degeneration and exclusion criteria. Patient demographics and baseline characteristics largely were similar between groups, although a higher proportion of SN60AT recipients were 65 years of age or older compared with TFNT00 recipients (Table 1). Study participants were primarily White, women, and of non-Hispanic/Latino ethnicity. Axial length, anterior chamber depth, corneal and lens thickness, photopic and mesopic pupil size, and absolute manifest refraction spherical equivalent also were similar between groups.

Visual Outcomes

Monocular Distance-Corrected Visual Acuity. The coprimary effectiveness outcomes were achieved for the first operative eyes at month 6 (Table 2). Noninferiority of the TFNT00 to the SN60AT in mean BCDVA was established, based on a 95% UCL of 0.04 logMAR for the difference in least-squares means between the 2 groups, which was less than the 0.1-logMAR margin. The TFNT00 demonstrated superiority to the SN60AT in mean DCNVA based on an estimated 97.5% UCL of less than 0.0 logMAR. A statistically significant difference of approximately 4 logMAR lines was observed in favor of the TFNT00 for DCNVA ($P < 0.001$). Secondary effectiveness outcomes for visual acuity also were achieved for the first operative eyes at month 6. The TFNT00 demonstrated superior mean photopic DCIVA compared with the SN60AT based on an estimated 97.5% UCL of less than 0.0 logMAR. A statistically significant difference of at least 2.5 logMAR lines was observed in favor of the TFNT00 for DCIVA ($P < 0.001$). These results were supported by the demonstration of noninferiority of the TFNT00 to the SN60AT in mean BCDVA and superiority of the TFNT00 to the SN60AT in mean DCNVA and DCIVA in the second operative eye at month 6.

Binocular Distance-Corrected Visual Acuity. Binocular distance-corrected visual acuity results for TFNT00 compared with SN60AT demonstrated similar differences to those for monocular distance-corrected visual acuity (Table 3). Both the TFNT00 and SN60AT groups achieved a mean binocular BCDVA better than 0.0 logMAR at month 6 (−0.062 logMAR [95% CI, −0.074 to −0.051 logMAR] vs. −0.086 logMAR [95% CI, −0.098 to −0.074 logMAR], respectively). The observed difference in favor of the SN60AT compared with the TFNT00 for mean binocular BCDVA was not clinically relevant (corresponding to 1 letter). The TFNT00 exhibited a clinically, significantly better mean DCIVA compared with the SN60AT (<0.0 logMAR and >0.2 logMAR, respectively) and a mean binocular DCNVA of approximately 4 logMAR lines better than that of the SN60AT (0.050 logMAR and 0.406 logMAR, respectively).

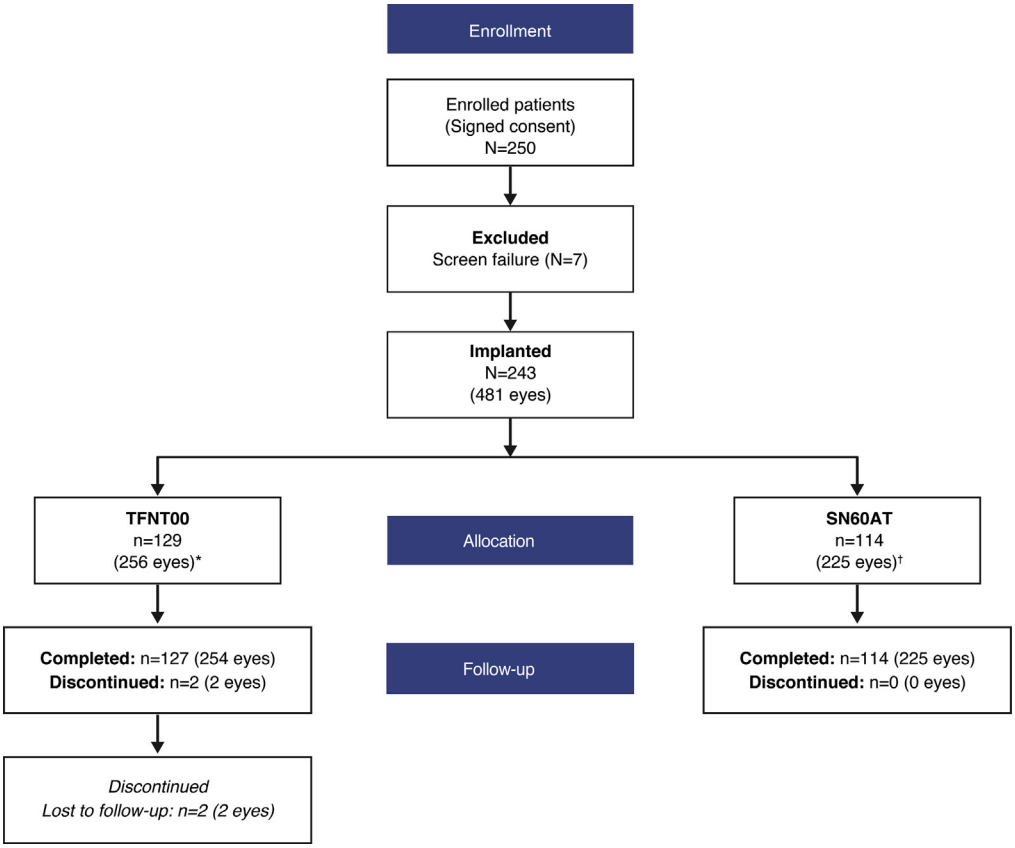

Figure 1. Diagram showing patient flow. *Patients 2828.00005 and 5127.00022 were implanted unilaterally. †Patients 3828.00001 and 6097.00022 were implanted unilaterally.

Table 1. Demographic Statistics and Baseline Characteristics (All-Implanted Analysis Set)

Characteristics	TFNT00 (n = 129)	SN60AT (n = 114)	Overall (N = 243)
Age (yrs)			
<65, no. (%)	45 (34.9)	22 (19.3)	67 (27.6)
≥65, no. (%)	84 (65.1)	92 (80.7)	176 (72.4)
Mean (SD)	65.8 (7.31)	69.0 (6.46)	67.3 (7.09)
Female gender, no. (%)	85 (65.9)	79 (69.3)	164 (67.5)
Race, no. (%)			
White	113 (87.6)	96 (84.2)	209 (86.0)
Black	8 (6.2)	11 (9.6)	19 (7.8)
Native American or Alaska Native	0 (0)	0 (0)	0 (0)
Asian	7 (5.4)	1 (0.9)	8 (3.3)
Native Hawaiian or other Pacific Islander	0 (0)	2 (1.8)	2 (0.8)
Other	1 (0.8)	4 (3.5)	5 (2.1)
Ethnicity, no. (%)			
Hispanic or Latino	4 (3.1)	7 (6.1)	11 (4.5)
Not Hispanic or Latino	124 (96.1)	106 (93.0)	230 (94.7)
Not reported	1 (0.8)	1 (0.9)	2 (0.8)
Eye measurements (first eye), mean (SD)			
Axial length (mm)	23.67 (0.94)	23.58 (0.87)	23.63 (0.91)
Mesopic pupil size (mm)	4.98 (1.07)	4.97 (1.04)	4.98 (1.06)
Photopic pupil size (mm)	4.14 (0.93)	4.10 (0.89)	4.12 (0.91)
Anterior chamber depth (mm)	3.27 (0.41)	3.24 (0.42)	3.26 (0.41)
Corneal thickness (μm)	548.11 (34.42)	549.92 (33.59)	548.96 (33.97)
Lens thickness (mm)	4.34 (0.51)	4.44 (0.48)	4.39 (0.50)
Absolute MRSE (D)	1.63 (1.56)	1.46 (1.21)	1.55 (1.40)

D = diopter; MRSE = manifest refraction spherical equivalent; SD = standard deviation.

Table 2. Primary Effectiveness End Points at 6 Months in the First Eye (All-Implanted Analysis Set)

Effectiveness End Point	TFNT00 (n = 127)	SN60AT (n = 113)	TFNT00 − SN60AT
Monocular BCDVA (logMAR)*			
Least-squares mean	−0.014	−0.039	0.024
SE	0.0083	0.0087	0.0103
95% UCL			0.041
Monocular DCNVA (logMAR)†			
Least-squares mean	0.105	0.529	−0.424
SE	0.0119	0.0127	0.0174
95% CI	0.081−0.128	0.504−0.554	−0.458 to −0.390
P value			< 0.001
Monocular DCIVA (logMAR)†			
Least-squares mean	0.070	0.327	−0.257
SE	0.0108	0.0114	0.0153
95% CI	0.048−0.092	0.304−0.350	−0.287 to −0.227
P value			< 0.001

BCDVA = best-corrected distance visual acuity; CI = confidence interval; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; logMAR = logarithm of the minimum angle of resolution; SE = standard error; UCL = upper confidence limit.
*Noninferiority hypothesis.
†Superiority hypothesis.

Defocus Curve. Binocular defocus testing was consistent with the visual acuity results. The TFNT00 exhibited greater visual acuity at the defocus range of −1.0 to −2.5 D (100−40 cm), with a difference of 4 lines of logMAR visual acuity at −2.5 D (Fig 2). The TFNT00 recipients maintained a mean visual acuity of 0.1 logMAR or less between the defocus range of +0.5 and −2.5 D (200 and 40 cm). Both groups achieved a similar mean visual acuity of 20/20 (≤0.03 logMAR) at the defocus range of +0.5 to −0.5 D.

Spectacle Independence. Based on the IOLSAT questionnaire, a higher proportion of patients in the TFNT00 group compared with the SN60AT group indicated never needing eyeglasses to see overall (80.5% and 8.2%, respectively). The proportions of patients never requiring eyeglasses for distance were similar between the TFNT00 and SN60AT groups (95.9% and 84.5%, respectively). However, more TFNT00 recipients compared with SN60AT recipients reported never requiring eyeglasses "up close" (83.6% and 8.2%, respectively) and "at arm's length" (94.3% and 40.9%, respectively).

Table 3. Supportive Effectiveness End Points: Binocular Distance-Corrected Visual Acuity at 6 Months (All-Implanted Analysis Set)

Effectiveness End Point	TFNT00 (n = 127)	SN60AT (n = 111)
Binocular BCDVA (logMAR)		
Mean (SD)	−0.062 (0.066)	−0.086 (0.063)
95% CI	−0.074 to −0.051	−0.098 to −0.074
Binocular DCIVA (logMAR)		
Mean (SD)	−0.007 (0.079)	0.230 (0.124)
95% CI	−0.021 to 0.007	0.207−0.253
Binocular DCNVA (logMAR)		
Mean (SD)	0.050 (0.070)	0.406 (0.148)
95% CI	0.038−0.062	0.378−0.434

BCDVA = best-corrected distance visual acuity; CI = confidence interval; DCIVA = distance-corrected intermediate visual acuity; DCNVA = distance-corrected near visual acuity; logMAR = logarithm of the minimum angle of resolution; SD = standard deviation.

Refractive Outcomes

At month 6, most first eyes in the TFNT00 (65.4%) and SN60AT (60.2%) groups showed a manifest refraction spherical equivalent of +0.25 D or less, and no eyes showed a manifest refraction spherical equivalent of more than 1.0 D. Most first eyes in the TFNT00 (84.3%) and SN60AT (83.2%) groups were within 0.5 D or less of the target refractive error at month 6. Results for the second eyes were similar to those for the first eyes.

Safety Outcomes

Adverse Events. The rates of SSIs in the first operative eye were low for the TFNT00 (0.8%) and SN60AT (1.8%) groups (Table 4). Each study group had 1 incident of IOL extraction for the first operative eye. The TFNT00 explant was the result of subjective reports of dissatisfaction with the level of vision, which were determined to be related to the optical properties of the IOL. The SN60AT explant was the result of posterior capsule rupture and device dislocation (2.5-mm decentration, but no tilt, 2 days after surgery) and was determined not to be related to the optical properties of the IOL. One SN60AT patient required intraocular injections for age-related macular degeneration in the first operative eye, although these SSIs also were deemed by the investigator not to be related to the optical properties of the IOL. Similarly, none of the 3 SSIs reported in the second operative eyes (TFNT00, 1.6%; SN60AT, 0.9%) were considered related to the optical properties of the IOL. In the TFNT00 group, these included vitreous prolapse and device dislocation (15° tilting, 120 days after surgery). In the SN60AT group, this included intraocular injections for age-related macular degeneration. All other ocular AEs in both groups occurred at a rate of less than 5%, except for posterior capsule opacification (13.2% in the TFNT00 first eyes and 15% in the TFNT00 second eyes) and increased intraocular pressure (5.4% in the TFNT00 first eyes and 5.3% in the SN60AT first eyes). The rates of posterior capsulotomy in the TFNT00 and SN60AT groups were 13.2% and 2.6% in the first operative eyes, respectively, and 11.8% and 3.6% in the second operative eyes, respectively. No participants discontinued as a result of an AE and no deaths were reported in the study.

Contrast Sensitivity. Mean binocular contrast sensitivity was reduced for the TFNT00 compared with the SN60AT group at 6,

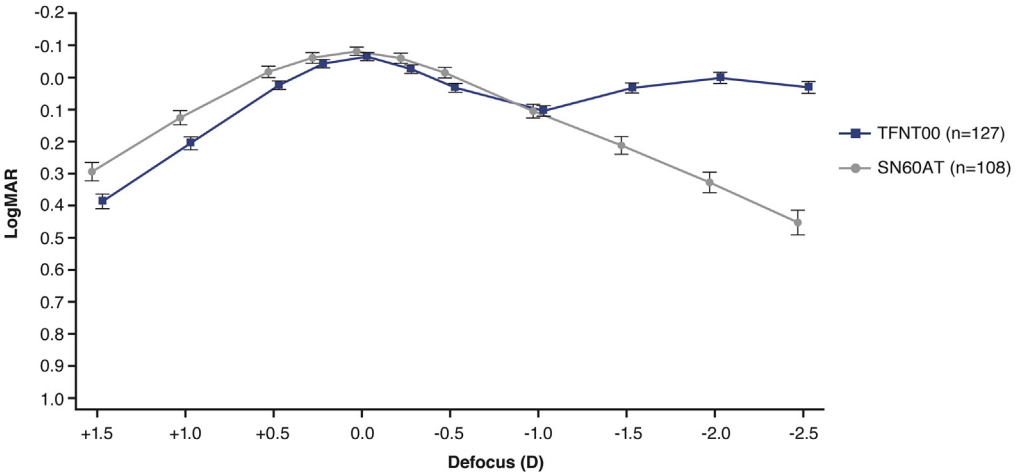

Figure 2. Graph showing binocular defocus. D = diopter; logMAR = logarithm of the minimum angle of resolution.

12, and 18 cycles per degree in photopic conditions with or without glare and at 6 and 12 cycles per degree in mesopic conditions with or without glare (Fig 3). The maximum difference in means observed between the 2 groups was 0.11 log units for any spatial frequency.

Visual Disturbances. Visual disturbances of starbursts, halos, and glare were the most frequently rated severe symptoms in the TFNT00 and SN60AT groups. Starbursts, halos, and glare were experienced at higher rates in the TFNT00 group compared with the SN60AT group at 1 and 6 months (Table 5). The incidence of severe starbursts increased from 1 to 6 months after surgery for TFNT00 recipients (11.4% [95% CI, 6.4%−18.4%] vs. 16.0% [95% CI, 10.1%−23.6%], respectively) and SN60AT recipients (0.9% [95% CI, 0.0%−5.0%] vs. 1.8% [95% CI, 0.2%−6.5%], respectively). The incidence of severe halos and glare experienced in the TFNT00 and SN60AT groups decreased from 1 to 6 months after surgery. Starbursts, halos, and glare also were rated as the most bothersome symptoms by patients in the TFNT00 group; 5% or less of TFNT00 and SN60AT recipients rated these symptoms as "bothered very much" (starbursts, 4.8% [95% CI, 1.8%−10.2%] and 0.9% [95% CI, 0.0%−5.0%]; halos, 2.4% [95% CI, 0.5%−6.7%] and 0.9% [95% CI, 0.0%−5.0%]; and glare, 1.6% [95% CI, 0.2%−5.6%] and 0.9% [95% CI, 0.0%−4.9%], respectively). A higher proportion of SN60AT recipients compared with TFNT00 recipients reported they were "not bothered at all" by starbursts, halos, and glare (79.8%, 83.6%, and 69.4% vs. 55.2%, 51.2%, and 54.8%, respectively; Fig 4).

Patient Satisfaction. The proportion of recipients reporting being satisfied or very satisfied with their vision at month 6 was similar between the TFNT00 and SN60AT groups (95.3% and 90.9%, respectively). The numbers of recipients who reported being very satisfied were 74.0% and 60.0% in the TFNT00 and SN60AT groups, respectively. In addition, 99.2% of patients said they would have the TFNT00 implanted again and 98.4% said they would recommend the TFNT00 to their family or friends, compared with 87.4% and 95.5% of SN60AT recipients, respectively. Among patients who experienced a severe visual disturbance (TFNT00, n = 31; SN60AT, n = 3), 93.5% (n = 29) of TFNT00 recipients were satisfied or very satisfied with their vision at month 6, compared with 33.3% (n = 1) of SN60AT recipients. Furthermore, at month 6, 96.7% (n = 30) of TFNT00 patients who experienced a severe visual disturbance said they would have the same lens implanted again and 93.5% (n = 29) said they would recommend TFNT00 to their family or friends, compared with 66.6% (n = 2) of SN60AT recipients.

Table 4. Adverse Events in the First Eye (Safety Analysis Set)

	TFNT00 (n = 129)			SN60AT (n = 114)			TFNT00 − SN60AT	
	No. (%)	95% Confidence Interval	Event	No. (%)	95% Confidence Interval	Event	No. (%)	95% Confidence Interval
Secondary surgical interventions								
Any	1 (0.8)	0.02−4.24	—	2 (1.8)	0.21−6.19	—	−1 (−1.0)	−13.53 to 11.58
Related to optical properties	1 (0.8)	0.02−4.24	—	0 (0)	0−3.18	—	1 (0.8)	−11.79 to 13.32
Not related to optical properties	0 (0)	0−2.82	—	1 (0.9)	0.02−4.79	—	−1 (−0.9)	−13.42 to 11.68
Not applicable to optical properties	0 (0)	0−2.82	—	1 (0.9)	0.02−4.79	—	−1 (−0.9)	−13.42 to 11.68
Ocular serious adverse events (including serious adverse device effects)								
Lens extraction	1 (0.8)	0.02−4.24	1	1 (0.9)	0.02−4.79	1	—	—
Intraocular injection	0 (0)	0−2.82	0	1 (0.9)	0.02−4.79	3	—	—
Age-related macular degeneration	0 (0)	0−2.82	0	1 (0.9)	0.02−4.79	1	—	—
Device dislocation	0 (0)	0−2.82	0	1 (0.9)	0.02−4.79	1	—	—
Posterior capsule rupture	0 (0)	0−2.82	0	1 (0.9)	0.02−4.79	1	—	—
Retinal tear	1 (0.8)	0.02−4.24	1	0 (0)	0.00−3.18	0	—	—

— = not reported.

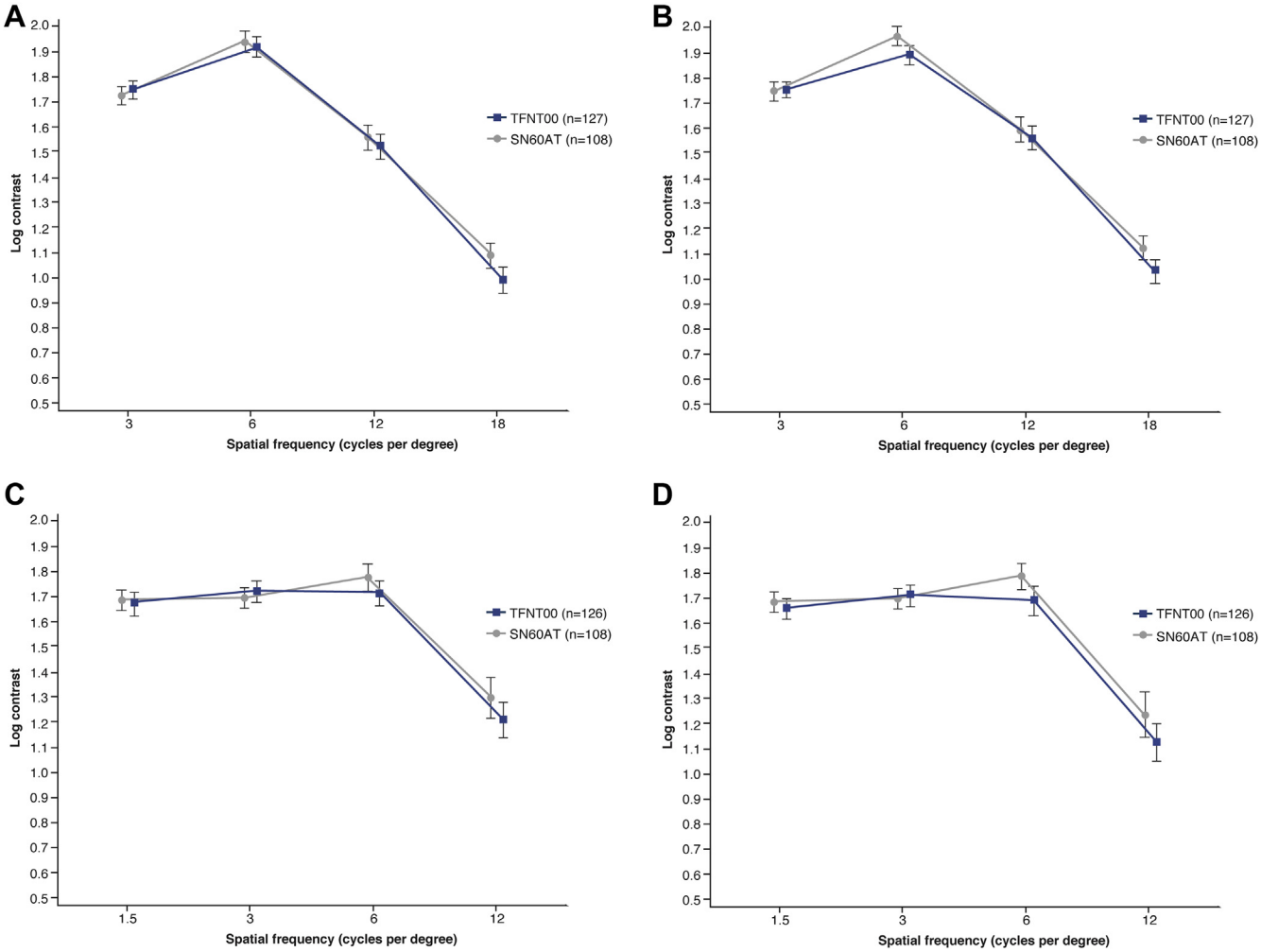

Figure 3. **A**, Graph showing mean binocular photopic contrast sensitivity without glare. **B**, Graph showing mean binocular photopic contrast sensitivity with glare. **C**, Graph showing mean binocular mesopic contrast sensitivity without glare. **D**, Graph showing mean binocular mesopic contrast sensitivity with glare.

Discussion

Diffractive trifocal IOLs provide an extended range of vision, from near to intermediate to distance.[17–19] However, dividing incoming light into 3 foci may decrease the amount of energy directed to each of these points, which consequently may affect visual acuity at all distances.[28] Prior studies have highlighted this issue, reporting enhanced intermediate, but reduced near and distance, visual acuity, as well as optical qualities for trifocal IOLs compared with AcrySof IQ ReSTOR +3.0-D[28] and +2.5-D bifocal IOLs.[29]

The TFNT00 is an IOL with 4 focal points and nonsequential diffractive optics, which allow light redistribution to create a functional trifocal with an enhanced distance power[20] and +2.17-D intermediate (60 cm) and +3.25-D near (40 cm) add powers, with the aim of providing a range of vision from intermediate to near, while preserving distance vision.[21,22] Patient demand for functional intermediate vision has grown with the increasing use of handheld devices and computers in daily life.[22] The TFNT00 was designed to target an intermediate focal point of 60 cm, which is a distance associated approximately with computer use.[30–32]

The present study evaluated the effectiveness of TFNT00 in providing a continuous range of vision in comparison with a spherical monofocal IOL, the SN60AT. In agreement with previous studies,[22,25] the TFNT00 exhibited a high level of distance, intermediate, and near visual acuity. The current study demonstrated that compared with a spherical monofocal IOL, the TFNT00 displayed comparable monocular BCDVA and superior monocular DCNVA and DCIVA. Visual acuity results were supported by the outcome of the defocus curves, where a clinically relevant difference in visual acuity in favor of the TFNT00 was observed at the defocus range of −1.0 to −2.5 D (100−40 cm). Patient-reported outcomes based on the validated IOLSAT questionnaire indicated that TFNT00 recipients were better able to engage in activities that required a range of vision while being spectacle free, particularly at intermediate and near distances, compared with SN60AT recipients.

Table 5. Visual Disturbances at 1 and 6 Months (Safety Analysis Set)

	TFNT00 (n = 129)		SN60AT (n = 114)		TFNT00 − SN60AT	
	No./Total (%)	*95% Confidence Interval*	*No./Total (%)*	*95% Confidence Interval*	*%*	*95% Confidence Interval*
1 mo						
Patients with severe visual disturbance						
Starbursts	14/123 (11.4)	6.4–18.4	1/110 (0.9)	0–5.0		
Halos	28/127 (22.0)	15.2–30.3	1/109 (0.9)	0–5.0		
Glare	6/125 (4.8)	1.8–10.2	3/110 (2.7)	0.6–7.8		
Patients with a most bothersome visual disturbance						
Starbursts	4/123 (3.3)	0.9–8.1	0/110 (0)	0–3.3		
Halos	3/127 (2.4)	0.5–6.7	1/109 (0.9)	0–5.0		
Glare	1/125 (0.8)	0.0–4.4	0/110 (0)	0–3.3		
6 mos						
Patients with severe visual disturbance						
Starbursts	20/125 (16.0)	10.1–23.6	2/109 (1.8)	0.2–6.5	14.2	1.4–26.7
Halos	16/127 (12.6)	7.4–19.7	1/110 (0.9)	0–5.0	11.7	−1.1 to 24.2
Glare	4/126 (3.2)	0.9–7.9	2/111 (1.8)	0.2–6.4	1.4	−11.3 to 14.1
Patients with a most bothersome visual disturbance						
Starbursts	6/125 (4.8)	1.8–10.2	1/109 (0.9)	0–5.0	3.9	−8.9 to 16.6
Halos	3/127 (2.4)	0.5–6.7	1/110 (0.9)	0–5.0	1.5	−11.3 to 14.2
Glare	2/126 (1.6)	0.2–5.6	1/111 (0.9)	0–4.9	0.7	−12.0 to 13.4

Both the TFNT00 and SN60AT groups demonstrated good patient satisfaction outcomes. More than 95% of TFNT00 recipients were satisfied or very satisfied with their vision, as well as indicating that they would have the same lens implanted again and would recommend it to family or friends, compared with 87.4% or more of SN60AT recipients for the same outcomes.

In line with previous studies,[25] the TFNT00 exhibited an acceptable safety profile. No patients discontinued the study as a result of an AE; one SSI related to the optical properties of the TFNT00 was reported, and neither group exceeded the Food and Drug Administration grid rate for SSIs. No reports of IOL tilt or decentration in the first implanted eyes occurred for the TFNT00 group. One patient in the TFNT00 group demonstrated tilt in the second eye, and this was resolved by repositioning the IOL. The incidence of posterior capsulotomy was higher among TFNT00 recipients than SN60AT recipients, which is in accordance with previous studies comparing AcrySof multifocal with AcrySof monofocal IOLs.[33] However, the rates of posterior capsulotomy among the TFNT00 group were higher than those reported in previous studies of the same lens.[34] It should be noted that the large majority (79.5%) of posterior capsulotomies were performed at only 2 sites during the study. All but 1 patient who underwent posterior capsulotomy reported being satisfied or very satisfied with their vision. All patients who underwent posterior capsulotomy indicated they would have the same lens implanted again.

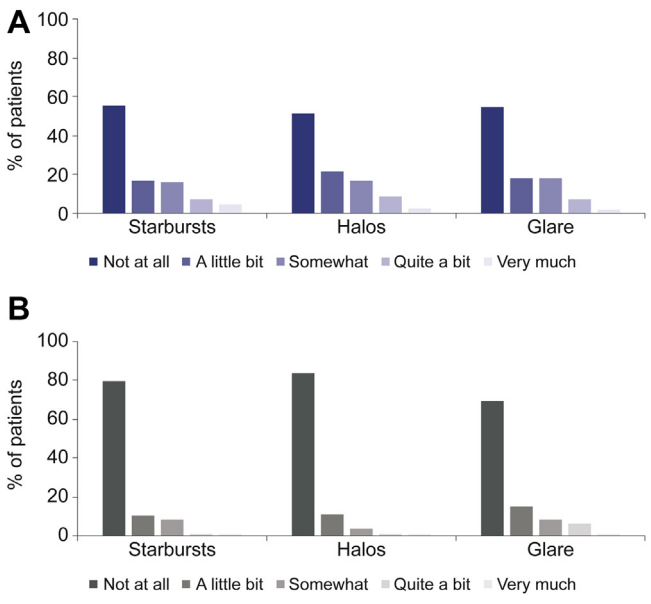

Figure 4. Bar graphs showing level of bother experienced from a visual disturbance at month 6 in (**A**) TFNT00 recipients and (**B**) SN60AT recipients.

Multifocal IOLs are commonly associated with reduced contrast sensitivity.[4,6,7,10,35–37] The splitting of light among multiple focal points leads to a fraction of the light entering the lens being used to produce an image at a given distance, resulting in reduced contrast on the retinal image.[35] Reduced contrast sensitivity with multifocal IOLs has been described at multiple[6,8,36] spatial frequencies, with or without glare.[4] The present study compared TFNT00 contrast sensitivity with that of a spherical monofocal IOL, SN60AT, which has been shown to be associated with good contrast sensitivity outcomes.[10] Contrast sensitivity outcomes were analyzed in the best-case analysis set. The mean contrast sensitivity was reduced slightly for TFNT00 recipients compared with those who received the SN60AT at higher spatial frequencies, regardless of photopic or mesopic conditions or presence of glare. However, these observed differences were less than levels of clinical significance.[38] These results are in agreement with previous studies that have demonstrated good contrast sensitivity outcomes in TFNT00 recipients.[34,39,40] It is important to note that contrast sensitivity differences observed may have been different if the comparator IOL had been an aspheric

monofocal IOL. Reports have shown that spherical monofocal IOLs[41,42] have reduced contrast sensitivity compared with aspheric monofocal IOLs.

A common feature of multifocal[5] and trifocal[17–19,43,44] IOLs is the increased incidence of visual disturbances, which consist of photic phenomena such as starbursts, halos, or glare.[45] Recipients of diffractive trifocal IOLs have reported these photic phenomena.[17–19,45] In the current study, visual disturbances were assessed using the QUVID questionnaire developed and validated by Alcon. Patients were asked proactively to rate the severity of the visual disturbances they experienced on a 5-point response scale from none to severe. The current study described the frequency of severe visual disturbances as a safety outcome.[44–46] The TFNT00 recipients experienced severe starbursts, halos, and glare, with more patients experiencing severe starbursts and halos in the TFNT00 group compared with the SN60AT group at months 1 and 6. A reduction in TFNT00 recipients experiencing severe halos and glare between months 1 and 6 was observed, as is expected over time.[44,45,47]

Visual disturbances are a common source of patient dissatisfaction with,[48] and are a reason for explantation of, multifocal IOLs.[49] Therefore, when determining the prevalence of visual disturbances, it is also important to assess the patients' perspective regarding how much they are bothered by the presence of such photic phenomena. Using the QUVID questionnaire, patients rated the level of bother experienced by visual disturbances, ranging from "not bothered at all" to "bothered very much," the latter being considered as "most bothersome." Less than 5% of TFNT00 recipients rated being bothered very much by the visual disturbances they experienced. However, a greater number of patients in the SN60AT group compared with the TFNT00 group were not bothered at all by visual disturbances. Despite the higher occurrence of bother with visual disturbances, patient-reported satisfaction among TFNT00 recipients who experienced a severe visual disturbance were comparable with those of the entire TFNT00 group, with 96.7% of implanted patients reporting that they would have the same lenses implanted again and 93.5% saying they would recommend it to their family or friends.

Limitations of the present study include nonrandomization and how patients were unmasked to implanted IOLs. The fact that patients self-selected which IOL they wished to receive had the potential to introduce bias, particularly for subjective results. The use of a spherical monofocal IOL as the control rather than an aspheric monofocal IOL in this study also can be considered a limitation, because the latter is associated with superior contrast sensitivity outcomes.[41,42]

In summary, this study demonstrated that when compared with a spherical monofocal IOL (SN60AT), the TFNT00 trifocal IOL provides a continuous range of vision from distance to near, with increased spectacle independence. Despite a comparative decline in contrast sensitivity and increased visual disturbances, patient satisfaction remained high for the TFNT00 trifocal IOL.

Acknowledgment

The authors thank Joseph Wright for editorial assistance in the preparation of the manuscript, with funding from Alcon Research LLC.

Footnotes and Disclosures

Originally received: March 27, 2020.
Final revision: July 2, 2020.
Accepted: July 7, 2020.
Available online: September 28, 2020. Manuscript no. D-20-00516

[1] Seeta Eye Centers, Poughkeepsie, New York.
[2] Lehmann Eye Center, Nacogdoches, Texas.
[3] California Eye Institute, Fresno, California.
[4] Carolina Eyecare Physicians, LLC, Mount Pleasant, South Carolina.
[5] The Eye Institute of Utah, Salt Lake City, Utah.
[6] Vance Thompson Vision, Sioux Falls, South Dakota.
[7] Vision For Life, Nashville, Tennessee.
[8] Berkeley Eye Center, Houston, Texas.
[9] Eye Center of North Florida, Panama City, Florida.
[10] Texas Eye and Laser Center, Hurst, Texas.
[11] Virginia Eye Consultants, Norfolk, Virginia.

Disclosure(s):
All authors have completed and submitted the ICMJE disclosures form.
The author(s) have made the following disclosure(s): A.M.: Consultant and personal fees – Alcon
K.S.: Consultant, grant, and personal fees – Alcon
R.C.: Consultant – Alcon
J.H.: Consultant and personal fees – Alcon
V.T.: Consultant and personal fees – Alcon
B.F.: Consultant and grant support – Alcon
J.G.H.: Grant, personal fees, and nonfinancial support – Alcon
E.Y.: Consultant – Alcon
Sponsored by Alcon Research LLC, Fort Worth, Texas. The sponsor participated in the design of the study; data management; data analysis; interpretation of the data; and preparation, review, and approval of the manuscript.
HUMAN SUBJECTS: Human subjects were included in this study. The study was conducted in accordance with the tenets of the Declaration of Helsinki, International Organization for Standardization standards 11979-7:2014 and 14155:2011, and the Code of Federal Regulations. Institutional review board approval was received for this study. The Sterling Institutional Review Board (Atlanta, Georgia) was used for all 12 investigative sites. Written informed consent was obtained from all patients.
No animal subjects were included in this study.
Author Contributions:
Conception and design: Modi
Analysis and interpretation: N/A
Data collection: Modi, Lehmann, Maxwell, Solomon, Cionni, Thompson, Horn, Caplan, Fisher, Hu, Yeu
Obtained funding: Maxwell, Solomon, Cionni, Thompson, Fisher, Hu, Yeu; Study was performed as part of the authors' regular employment duties.

Overall responsibility: Modi, Lehmann, Maxwell, Solomon, Cionni, Thompson, Horn, Caplan, Fisher, Hu, Yeu

Abbreviations and Acronyms:
AE = adverse event; **BCDVA** = best-corrected distance visual acuity; **CI** = confidence interval; **D** = diopter; **DCIVA** = distance-corrected intermediate visual acuity; **DCNVA** = distance-corrected near visual acuity; **IOL** = intraocular lens; **IOLSAT** = Intraocular Lens Satisfaction; **logMAR** = logarithm of the minimum angle of resolution; **QUVID** = Questionnaire for Visual Disturbance; **SSI** = secondary surgical intervention; **UCL** = upper confidence limit.

Key Words:
binocular vision, cataract, contrast sensitivity, diffractive, monofocal intraocular lenses, monocular vision, multifocal intraocular lenses, nonapodized, spectacle dependence, trifocal intraocular lenses, visual acuity.

Correspondence:
Satish Modi, MD, FRCS(C), Seeta Eye Centers, 23 Davis Avenue, Poughkeepsie, NY 12603. E-mail: smodieyes@aol.com.

References

1. Congdon N, Vingerling JR, Klein BE, et al. Prevalence of cataract and pseudophakia/aphakia among adults in the United States. *Arch Ophthalmol*. 2004;122:487–494.
2. National Eye Institute. NEI data: cataracts. https://nei.nih.gov/eyedata/cataract; 2018. Accessed 31.07.19.
3. Olson RJ, Braga-Mele R, Chen SH, et al. Cataract in the adult eye Preferred Practice Pattern®. *Ophthalmology*. 2017;124:P1–P119.
4. Wang SY, Stem MS, Oren G, et al. Patient-centered and visual quality outcomes of premium cataract surgery: a systematic review. *Eur J Ophthalmol*. 2017;27:387–401.
5. Javitt J, Brauweiler HP, Jacobi KW, et al. Cataract extraction with multifocal intraocular lens implantation: clinical, functional, and quality-of-life outcomes. Multicenter clinical trial in Germany and Austria. *J Cataract Refract Surg*. 2000;26:1356–1366.
6. Cillino S, Casuccio A, Di Pace F, et al. One-year outcomes with new-generation multifocal intraocular lenses. *Ophthalmology*. 2008;115:1508–1516.
7. Zhao G, Zhang J, Zhou Y, et al. Visual function after monocular implantation of apodized diffractive multifocal or single-piece monofocal intraocular lens randomized prospective comparison. *J Cataract Refract Surg*. 2010;36:282–285.
8. Zeng M, Liu Y, Liu X, et al. Aberration and contrast sensitivity comparison of aspherical and monofocal and multifocal intraocular lens eyes. *Clin Exp Ophthalmol*. 2007;35:355–360.
9. Kohnen T, Allen D, Boureau C, et al. European multicenter study of the AcrySof ReSTOR apodized diffractive intraocular lens. *Ophthalmology*. 2006;113:584.e1.
10. Vingolo EM, Grenga P, Iacobelli L, Grenga R. Visual acuity and contrast sensitivity: AcrySof ReSTOR apodized diffractive versus AcrySof SA60AT monofocal intraocular lenses. *J Cataract Refract Surg*. 2007;33:1244–1247.
11. Alfonso JF, Fernandez-Vega L, Amhaz H, et al. Visual function after implantation of an aspheric bifocal intraocular lens. *J Cataract Refract Surg*. 2009;35:885–892.
12. de Silva SR, Evans JR, Kirthi V, et al. Multifocal versus monofocal intraocular lenses after cataract extraction. *Cochrane Database Syst Rev*. 2016;12:CD003169.
13. Hutz WW, Eckhardt HB, Rohrig B, Grolmus R. Intermediate vision and reading speed with array, Tecnis, and ReSTOR intraocular lenses. *J Refract Surg*. 2008;24:251–256.
14. Yildirim Karabag R, Gunenc U, Aydin R, et al. Visual results following implantation of a refractive multifocal intraocular lens in one eye and a diffractive in the contralateral eye. *Turk J Ophthalmol*. 2018;48:6–14.
15. Gundersen KG, Potvin R. Comparison of visual outcomes and subjective visual quality after bilateral implantation of a diffractive trifocal intraocular lens and blended implantation of apodized diffractive bifocal intraocular lenses. *Clin Ophthalmol*. 2016;10:805–811.
16. Yoon SY, Song IS, Kim JY, et al. Bilateral mix-and-match versus unilateral multifocal intraocular lens implantation: long-term comparison. *J Cataract Refract Surg*. 2013;39:1682–1690.
17. Cochener B, Vryghem J, Rozot P, et al. Clinical outcomes with a trifocal intraocular lens: a multicenter study. *J Refract Surg*. 2014;30:762–768.
18. Mojzis P, Pena-Garcia P, Liehneova I, et al. Outcomes of a new diffractive trifocal intraocular lens. *J Cataract Refract Surg*. 2014;40:60–69.
19. Marques EF, Ferreira TB. Comparison of visual outcomes of 2 diffractive trifocal intraocular lenses. *J Cataract Refract Surg*. 2015;41:354–363.
20. Kohnen T, Herzog M, Hemkeppler E, et al. Visual performance of a quadrifocal (trifocal) intraocular lens following removal of the crystalline lens. *Am J Ophthalmol*. 2017;184:52–62.
21. Carson D, Xu Z, Alexander E, et al. Optical bench performance of 3 trifocal intraocular lenses. *J Cataract Refract Surg*. 2016;42:1361–1367.
22. Gundersen KG, Potvin R. Trifocal intraocular lenses: a comparison of the visual performance and quality of vision provided by two different lens designs. *Clin Ophthalmol*. 2017;11:1081–1087.
23. Cochener B, Boutillier G, Lamard M, Auberger-Zagnoli C. A comparative evaluation of a new generation of diffractive trifocal and extended depth of focus intraocular lenses. *J Refract Surg*. 2018;34:507–514.
24. Kohnen T. First implantation of a diffractive quadrafocal (trifocal) intraocular lens. *J Cataract Refract Surg*. 2015;41:2330–2332.
25. Alcon Research Ltd. Investigation of AcrySof® IQ PanOptix™ presbyopia-correcting intraocular lens (IOL) model TFNT00. https://clinicaltrials.gov/ct2/show/NCT02529488; 2018. Accessed 01.06.20.
26. Alcon Research Ltd. Clinical investigation of visual function after bilateral implantation of two presbyopia-correcting trifocal IOLs. https://clinicaltrials.gov/ct2/show/results/NCT02691741; 2017. Accessed 03.09.20.
27. United States Food and Drug Administration. Patient-reported outcome measures: use in medical product development to support labeling claim. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims; 2019. Accessed 02.06.20.
28. Montes-Mico R, Madrid-Costa D, Ruiz-Alcocer J, et al. In vitro optical quality differences between multifocal

apodized diffractive intraocular lenses. *J Cataract Refract Surg*. 2013;39:928−936.
29. Madrid-Costa D, Ruiz-Alcocer J, Ferrer-Blasco T, et al. Optical quality differences between three multifocal intraocular lenses: bifocal low add, bifocal moderate add, and trifocal. *J Refract Surg*. 2013;29:749−754.
30. Jaschinski W. The proximity-fixation-disparity curve and the preferred viewing distance at a visual display as an indicator of near vision fatigue. *Optom Vis Sci*. 2002;79:158−169.
31. Charness N, Dijkstra K, Jastrzembski T, et al. Monitor viewing distance for younger and older workers. Proceedings of the Human Factors and Ergonomics Society. 3. New York: 52nd Human Factors and Ergonomics Society Annual Meeting; 2008:1614−1617.
32. United States Department of Labor. Occupational safety and health administration: Computer workstations eTool. https://www.osha.gov/SLTC/etools/computerworkstations/components_monitors.html; 2019. Accessed 02.06.20.
33. Shah VC, Russo C, Cannon R, et al. Incidence of Nd:YAG capsulotomy after implantation of AcrySof multifocal and monofocal intraocular lenses: a case controlled study. *J Refract Surg*. 2010;26:565−568.
34. García-Pérez JL, Gros-Otero J, Sanchez-Ramos C, et al. Short term visual outcomes of a new trifocal intraocular lens. *BMC Ophthalmol*. 2017;17:72.
35. Cao K, Friedman DS, Jin S, et al. Multifocal versus monofocal intraocular lenses for age-related cataract patients: a system review and meta-analysis based on randomized controlled trials. *Surv Ophthalmol*. 2019;64(5):647−658.
36. Ji J, Huang X, Fan X, Luo M. Visual performance of AcrySof ReSTOR compared with a monofocal intraocular lens following implantation in cataract surgery. *Exp Ther Med*. 2013;5:277−281.
37. Martinez Palmer A, Gomez Faina P, Espana Albelda A, et al. Visual function with bilateral implantation of monofocal and multifocal intraocular lenses: a prospective, randomized, controlled clinical trial. *J Refract Surg*. 2008;24:257−264.
38. International Organization for Standardization (ISO). 11979-7: 2014. Ophthalmic implants—intraocular lenses—part 7: clinical investigations of intraocular lenses for the correction of aphakia. https://www.iso.org/standard/55684.html; 2014. Accessed 21.04.20.
39. Vilar C, Hida WT, de Medeiros AL, et al. Comparison between bilateral implantation of a trifocal intraocular lens and blended implantation of two bifocal intraocular lenses. *Clin Ophthalmol*. 2017;11:1393−1397.
40. Alió JL, Plaza-Puche AB, Alio Del Barrio JL, et al. Clinical outcomes with a diffractive trifocal intraocular lens. *Eur J Ophthalmol*. 2018;28:419−424.
41. Trueb PR, Albach C, Montes-Mico R, Ferrer-Blasco T. Visual acuity and contrast sensitivity in eyes implanted with aspheric and spherical intraocular lenses. *Ophthalmology*. 2009;116:890−895.
42. Schuster AK, Tesarz J, Vossmerbaeumer U. The impact on vision of aspheric to spherical monofocal intraocular lenses in cataract surgery: a systematic review with meta-analysis. *Ophthalmology*. 2013;120:2166−2175.
43. Escandon-Garcia S, Ribeiro FJ, McAlinden C, et al. Through-focus vision performance and light disturbances of 3 new intraocular lenses for presbyopia correction. *J Ophthalmol*. 2018;2018:6165493.
44. Piovella M, Colonval S, Kapp A, et al. Patient outcomes following implantation with a trifocal toric IOL: twelve-month prospective multicentre study. *Eye (Lond)*. 2019;33:144−153.
45. Almulhim AK, Alarfaj KM, Altaisan AA, et al. Visual outcomes and patient satisfaction after bilateral implantation of a new trifocal diffractive intraocular lens. *Saudi J Ophthalmol*. 2018;32:310−317.
46. Escandón-García S, Ribeiro F, McAlinden C, et al. Through-focus vision performance and light disturbances of 3 new intraocular lenses for presbyopia correction. *J Ophthalmol*. 2018;2018:1−8.
47. Ganesh S, Brar S, Pawar A. Long-term visual outcomes and patient satisfaction following bilateral implantation of trifocal intraocular lenses. *Clin Ophthalmol*. 2017;11:1453−1459.
48. de Vries NE, Webers CA, Touwslager WR, et al. Dissatisfaction after implantation of multifocal intraocular lenses. *J Cataract Refract Surg*. 2011;37:859−865.
49. Kamiya K, Hayashi K, Shimizu K, et al. Multifocal intraocular lens explantation: a case series of 50 eyes. *Am J Ophthalmol*. 2014;158:215−220.e1.