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ORIGINAL RESEARCH

Patient Satisfaction and Visual Function Following Implantation of Trifocal or Extended Range of Vision Intraocular Lenses

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Purpose: To compare the trifocal TFNT00 and extended depth-of-focus (EDF) ZXR00 intraocular lenses (IOLs) with respect to overall satisfaction with near and distance vision, visual acuity, dysphotopsia symptoms, spectacle dependence, and mesopic best corrected contrast sensitivity (MBCCS).

Materials and Methods: This non-randomized, retrospective, single-centre, comparative study took place at the Kensington Eye Institute in Toronto, Canada. Subjects implanted with either the TFNT00 IOL (n = 11) or ZXR00 IOL (n = 13) were assessed up to 4 years post operatively. Overall satisfaction with distance and near vision, corrected distance visual acuity, uncorrected visual acuity at distance, intermediate (60 cm) and near (40 cm) (UNVA), dysphotopsia symptoms, spectacle dependence and monocular MBCCS were evaluated.

Results: Forty-eight eyes of 24 subjects (mean age 68 years, 54% female) were assessed. There was no difference in overall satisfaction; both groups had a median score of 10/10 for overall distance vision, and 7/10 and 8/10 for near vision for EDF and trifocal, respectively. MBCCS at the higher spatial frequencies was significantly better with the ZXR00 IOL. Potentially clinically relevant but not statistically significant differences were found; the trifocal group (vs the EDF group) had better binocular UNVA (20/24 vs 20/32) and less spectacle dependence at least some of the time (54% vs 85%).

Conclusion: The ZXR00 may be preferred for those who want optimal contrast sensitivity in dim lighting. Consistent with previous studies, the TFNT00 trifocal IOL may be a better choice for those who want to optimize UNVA. More studies in North America are required to further investigate spectacle dependence.

Keywords: trifocal lens, extended depth-of-focus lens, cataract surgery, patient satisfaction, visual acuity, contrast sensitivity

Introduction

The goal of cataract surgery has evolved to not only restore vision but to also provide some spectacle independence.[1,2] Although bifocal intraocular lenses (IOLs) were first introduced in the 1980s[1,3] and trifocal IOLs more recently,[4–6] monofocal IOLs are still considered the current standard.[1] Multifocality is an optical compromise; two or more focal points on the retina are associated with dysphotopsias (such as halos and glare) and up to 50% loss of contrast sensitivity (CS).[6,7,9,10] Hence, multifocal IOLs account for over a third of the justifications used for IOL model exchange.[7] In 2015, TNFT00 IOL (AcrySof®IQ PanOptix™, Alcon), a nonapodized diffractive trifocal IOL was introduced to improve vision at an intermediate distance, and due to an intermediary 4.5 mm diffractive zone, was less dependent on pupil size.[7,8] In 2016, the extended range of vision ZXR00 IOL (TECNIS Symfony® IOL Johnson & Johnson Vision, Inc.), using a proprietary achromatic diffractive echelette design was the first extended depth of focus (EDF) IOL to be introduced. EDF lenses are designed to correct for corneal chromatic aberration to enhance CS[9,11] The TFNT00 IOL was found to be

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better than the ZXR00 IOL for near vision (40 cm) in twelve studies,[7,12–22] and two studies[7,17] found the ZXR00 IOL to be better for intermediate vision. Two studies[13,18] found the ZXR00 IOL to have superior mesopic and photopic CS 3 months after surgery, whereas three found no difference.[7,14]

In this study, we compared the trifocal TFNT00 and EDF ZXR00 IOLs with respect to overall subjective satisfaction with near and distance vision, visual acuity (VA), and mesopic CS. To the best of our knowledge, this is only the second published study comparing visual and patient satisfaction outcomes of these IOLs in North America, and the second worldwide and first in North America to use the CSV-1000E to measure CS. It has been suggested that the CSV1000E may have the advantage of reduced uneven lighting, ceiling effect, or poor test-retest reliability.[23]

Materials and Methods

Participant Enrollment

This non-randomized, observational, comparative trial was performed at the Kensington Eye Institute (KEI), Toronto, Canada. Approval from the Research Ethics Board at the University of Toronto was obtained. The principles of Good Clinical Practice were adhered to in accordance with the Declaration of Helsinki. Informed consent was obtained prior to participation. From June to August 2019, we recruited participants after reviewing all the records of patients who were implanted with either TFNT00 (trifocal) or ZXR00 (EDF) IOLs, between January 2015 and April 2019. Inclusion criteria were the following: ability to understand and sign a consent form, 18–85 years of age, sequential bilateral implantation with either the TFNT00 or ZXR00 IOL, a minimum of 3 months since their second surgery, and less than 1.50 diopters (D) of refractive cylinder post-operatively. Exclusion criteria were the following: pregnancy or lactation, clinically significant corneal pathology, severe glaucoma, macular pathology, diabetic retinopathy, age-related macular degeneration, amblyopia, previous refractive surgery, neuro-ophthalmic disease, active ocular inflammation, and subjects participating in a concurrent investigational drug or device study. Prior to phacoemulsification with IOL implant, all participants underwent a comprehensive ophthalmic exam including slit lamp and fundus exam, Goldmann applanation tonometry, biometry (ZEISS Medical Technology, IOLMaster 500, Oberkochen, Germany), corneal tomography (LASIK Technology, Pentacam, Charlotte, NC, USA), and topography (NIDEK, Medmont E300 USB, San Jose, California, USA).

Assessment of Study Outcomes

Under photopic conditions (85 cd/m^2), we measured monocular and binocular uncorrected and corrected distance VA using the Early Treatment Diabetic Retinopathy Study (ETDRS) chart (Vectorvision, CSV-1000 ETDRS System, Greenville, Ohio, USA), and uncorrected intermediate (60 cm; ideal computer distance[24]) and near (40 cm) VAs using the ETDRS intermediate and near acuity charts (Precision Vision, ETDRS format intermediate and near vision, chart 1, Woodstock, Illinois, USA). After the participant adapted to mesopic room lighting conditions for 5 minutes, we tested monocular best corrected CS (MBCCS) at 2.5 m (8 ft) using the CSV-1000E CS grating charts (Vectorvision, Inc., Greenville), with spatial frequencies of 3, 6, 12, and 18 cycles/degree. We created mesopic ambient lighting of less than 3 cd/m^2 by lowering the room light and then simulated a chart background luminance (GOSSEN, Foto-und Lichtmesstechnik, MAVO-MONITOR USB, Nurnberg, Germany) of 3 cd/m^2 by using neutral density filters (Tiffen Company., Hauppauge, NY, USA) placed in front of the eye to reduce the luminance level at the chart from 85 cd/m^2 to 3 cd/m^2.[25] The examiner who performed VA, manifest refraction, and CS measurements was masked to the participant's IOL type. Participants completed 2 questionnaires: overall satisfaction with near and distance vision on a scale from 0 (worst) to 10 (best) and the spectacle dependence questionnaire.[12] All participants received optical coherence tomography (OCT) imaging (Zeiss, Cirrus HD – OCT, Aalen, Germany) to rule out macular pathology that could affect their VA and CS. For those with a monocular corrected distance VA of less than 20/20 in either eye, we also performed slit-lamp biomicroscopy, Goldmann applanation tonometry, and a dilated fundus examination to rule out pathology that could affect their VA at their study visit.

Analysis

The primary outcome measure was overall satisfaction with near vision and distance vision. Secondary outcomes included the following: logarithm of Minimum Angle of Resolution (logMAR) Uncorrected and Corrected Distance

VA (UDVA; CDVA), Uncorrected Intermediate and Near VA (UIVA; UNVA), Manifest Refraction Spherical Equivalent (MRSE); Mesopic Best Corrected CS (MBCCS), and responses to the spectacle dependence questionnaires. Continuous data was tested using non-parametric t-tests (Wilcoxon rank-sum test) and categorical variables were tested using Fisher's exact test due to low cell counts. For MBCCS, a random effects model with a random intercept was used to account for correlation arising from repeated measures within the same individual. After employing a conservative Bonferroni correction for multiple comparisons, the nine comparisons for Uncorrected VA would have a corrected two-sided significance level of 0.0056 (0.05/9), and the eight MBCCS comparisons would have a corrected two-sided significance level of 0.0062 (0.05/8). An interaction between IOLs and MBCCS was tested and included in the model, as it was statistically significant (P= 0.005).

Results

We attempted to contact the 75 potential participants that were identified as eligible in the medical records, from which 24 (13 female) were enrolled: 11 implanted with the TFNT00 IOL and 13 with the ZXR00 IOL. One surgeon had performed surgery on 21 of the participants (8 TFNT00; 13 ZXR00) and a second surgeon performed surgery on three (3 TFNT00). Table 1 lists the characteristics of the two IOL groups including target refraction, MRSE, and time after surgery. All visits occurred at least 6 months after the second surgery except for two in the trifocal group, who were assessed 4 months after surgery. There were no statistically significant differences in gender, age, or MRSE between the two IOL groups.

Table 1 Characteristics of Trifocal TFNT00 and EDF ZXR00 Participants

Baseline Characteristics	TFNT00 (n =11)	ZXR00 (13)	P-value
Age (median [IQR])	67.8 (7.808)	66.5 (0.875)	0.683
Age range	54–80 years	55–74 years	
Gender (male - n [%])	7 (63.6)	4 (30.8)	0.217
MRSE 1st Eye (mean [SD])	0.011 (0.33)	−0.24 (0.49)	0.137
MRSE 2nd Eye (mean [SD])	−0.023 (0.51)	− 0.125 (0.454)	0.769
MRSE range	−0.75D to +1.00D	−1.00D to +0.75D	
Refractive target	All plano except 2; −0.75D and −1.50D	All plano except 3; −0.50D, −0.50D, −0.75D	
Time after second surgery (mean [SD])	13.0 months (8.89)	32.5 months (8.18)	
Time after second surgery range	4–27 months	22–47 months	
Toric IOL	4 eyes of 3 subjects	4 eyes of 3 subjects	

Note: Characteristics of study population.
Abbreviations: IQR, interquartile range; SD, standard deviation; MRSE, Manifest Refraction Spherical Equivalent; D, diopter.

Table 2 Satisfaction with Near and Distance Vision

	Median (IQR*)		P-value
	TFNT00 (n = 11)	ZXR00 (n = 13)	TFNT00 vs ZXR00
Overall Satisfaction with Near Vision	8.00 [7.00, 9.50]	7.00 [6.00, 10.00]	0.790
Overall Satisfaction with Distance Vision	10.00 [9.00, 10.00]	10.00 [10.00, 10.00]	0.391

Note: Median (*Interquartile range) of participant satisfaction rating on a scale of 0 (worst) to 10 (best) with respect to overall near and distance vision.

Table 3 Visual Acuities and Mesopic Best Corrected Contrast Sensitivities for Trifocal TFNT00 and EDF ZXR00 IOLs

	Median (IQR*)		P-value
Secondary Outcomes	**TFNT00**	**ZXR00**	**TFNT00 vs ZXR00**
Binocular Corrected Distance Visual Acuity (logMAR) Snellen equivalent	−0.0436 (0.086) 20/18	−0.183 (0.371) 20/13	0.066
Binocular Uncorrected Distance Visual Acuity (logMAR) Snellen equivalent	−0.02 (−0.06, 0.08) 20/20	−0.04 (−0.08,0.00) 20/19	0.504
Binocular Uncorrected Intermediate Visual Acuity (logMAR) Snellen equivalent	0.04 (−0.01, 0.13) 20/23	0.02 (−0.02, 0.06) 20/22	0.684
Binocular Uncorrected Near Visual Acuity (logMAR) Snellen equivalent	0.08 (0.02, 0.12) 20/24	0.16 (0.12, 0.28) 20/32	0.007
MBCCS 3 cycles/degree	1.17 [1.17, 1.49]	1.34 [1.17, 1.45]	0.632
MBCCS 6 cycles /degree	1.38 [0.98, 1.55]	1.38 [1.21, 1.55]	0.322
MBCCS 12 cycles/degree	0.61 [0.00, 0.83]	0.91 [0.61, 1.25]	**0.003***
MBCCS 18 cycles/degree	0.00 [0.00, 0.17]	0.64 [0.17, 0.81]	**0.001***

Notes: Median (*Inter Quartile Range) and p-values for visual acuity (logMAR: logarithm of Minimum Angle of Resolution and Snellen equivalent) and Mesopic Best Corrected Contrast Sensitivity (MBCCS) at spatial frequencies of 3, 6, 12 and 18 cycles/degree. *Statistically significant: after employing a conservative Bonferroni correction for multiple comparisons, the nine comparisons for Uncorrected VA would have a corrected two-sided threshold of significance level of 0.0056 (0.05/9), and the eight MBCCS comparisons would have a corrected two-sided significance level of 0.0062 (0.05/8). Bolded values represent those comparisons that are significant after applying Bonferroni correction.

For overall satisfaction with respect to near and distance visions, there was no statistically significant difference between the two IOL groups (Table 2). The median near vision satisfaction score was 7/10 (interquartile range 6, 10) for the EDF group and 8/10 (interquartile range 7, 9.5) for the trifocal group. Five (40%) of the EDF group and 2 (20%) of the trifocal group rated their near vision satisfaction as 6/10 or less. For overall distance vision satisfaction, both groups had a median score of 10.

Table 3 lists the comparisons between the groups with respect to VAs. The binocular mean (± standard deviation) UNVA at 40 cm was better in the trifocal group by more than one line; 0.07 (0.08) (Snellen equivalent of 20/24) compared to 0.20 (0.11) (Snellen equivalent 20/32) for the ZXR00 group. This difference was statistically significant (p = 0.007) prior to employing the Bonferroni correction, and approached significance after this conservative correction significance level of 0.0056. Binocular UNVA of 20/20 (logMAR value of zero) or better was achieved for none of those with the EDF IOL, and for 2 (18.2%) of those with trifocal IOL. Binocular UNVA of 20/50 (logMAR of 0.4) (newsprint) or better was achieved with all participants in both groups. There was no significant difference (*P*=0.066) between mean (± SD) binocular CDVA which was −0.183 (0.371) (Snellen equivalent of 20/13) for the EDF group and −0.044 (0.09) (Snellen equivalent of 20/18) for the trifocal group. Thirty-eight eyes had a CDVA of 20/20 and the remaining 6 (3 in each group) had a CDVA of 20/25. There was no statistically significant difference in binocular UDVA, CDVA, or UIVA between the two IOL groups.

The mean monocular MBCCS for each spatial frequency is shown in Table 3. The EDF IOL performed significantly better (*P*=0.001) than the trifocal IOL at the higher spatial frequencies of 12 and 18 cycles/degree and the gap between the groups increased with higher spatial frequencies. This difference between groups remained statistically significant after employing a conservative correction for multiple comparisons.

The largest discrepancy in responses to spectacle dependence was with regard to the need for spectacles "for any purpose"; 11 (85%) of those with EDF IOLs indicated a necessity for spectacles compared to 6 (54%) of those with trifocal IOLs (Table 4).

Table 4 Spectacle Dependence Questionnaire Responses

Question	Number (%)		P-value
	TFNT00	ZXR00	
How often do you wear glasses for any purpose?			**0.216**
Always	0 (0.0)	2 (15.4)	
Sometimes	6 (54.5)	9 (69.2)	
Never	5 (45.5)	2 (15.4)	
How often do you wear glasses for near tasks?			**1**
Always	2 (18.2)	3 (23.1)	
Sometimes	6 (54.5)	7 (53.8)	
Never	3 (27.3)	3 (23.1)	
How often do you wear glasses for intermediate tasks?			**0.835**
Always	2 (18.2)	2 (15.4)	
Sometimes	1 (9.1)	3 (23.1)	
Never	8 (72.7)	8 (61.5)	
How often do you wear glasses for distance tasks?			**0.717**
Always	1 (9.1)	1 (7.7)	
Sometimes	1 (9.1)	0 (0.0)	
Never	9 (81.8)	12 (92.3)	

Notes: Spectacle dependence questionnaire Adapted with permission from Wolters Kluwer Health, Inc.: Monaco G, Gari M, Di Censo F, Poscia A, Ruggi G, Scialdone A. Visual performance after bilateral implantation of 2 new presbyopia-correcting intraocular lenses: trifocal versus extended range of vision. J Cataract Refract Surg.2017;43(6):737–747. https://journals.lww.com/jcrs/Abstract/2017/06000/Visual_performance_after_bilateral_implantation_of.6.aspx.[12]

Discussion

We found no statistically significant difference in overall near or distance vision satisfaction between the two IOLs, better binocular UNVA with the trifocal IOL of more than one line, and significantly better CS at higher spatial frequencies with the EDF IOL. Binocular UNVA at 40 cm in the trifocal group was statistically significantly better prior to employing the Bonferroni correction; and this difference approached statistical and clinical significance after the conservative correction. This is consistent with results from previous studies.[7,12–20] Moshirfar et al support this finding at one month postoperatively, however they found no significance at three months postoperatively.[21] Near vision satisfaction was rated 6/10 in 7 subjects (5 ZXR00 and 2 TNFT00) which emphasizes the importance of (1) careful consideration of IOL selection and target refraction, and (2) counselling patients regarding the limitations and benefits of multifocal IOLs.

We found the EDF IOL group performed significantly better at the higher spatial frequencies of 12 and 18 cycles/degree, despite our small sample size and after employing a conservative correction for multiple comparisons. Two studies[7,22] found no difference in CS between the IOL types, one of which suggests was due to inadequate sample size. Cochener et al[15] postulated theoretical superiority of EDF IOLs over the multifocal diffractive IOLs due to the EDF IOL design that aims to enhance contrast through compensation of the chromatic and spherical aberrations.[4,15] Two studies[13,18] found that the ZXR00 IOL provided better CS than the TFNT00 IOL and our results support these findings.

Binocular UDVA was not different between the two groups, consistent with previous studies.[7,12–16,18–22] One study found binocular UDVA to be superior for the ZXR00 IOL over the TFNT00 IOL.[17] For UIVA, we found no difference between groups, consistent with previous studies;[14,15,20] however, two studies[12,17] found superiority of the ZXR00 over the TFNT00 IOL. Mencucci et al[13] also found that the EDF IOL performed statistically significantly better than the trifocal IOL at test distances of 80 cm and at 60 cm. We found VA at 60 cm not significantly different between IOLs, consistent with Bohm et al.[16] The discrepancies in findings between studies may be due to small sample sizes, testing distances, and differences in populations.

Of note, the EDF group had a higher proportion of those requiring spectacles for any purpose at least some of the time (84.6% for the EDF vs 54.5% for the trifocal group). Although this potentially clinically relevant difference was not found to be statistically significant, the findings warrant further investigation in North America with larger samples. Similarly, three studies[16,19,20] found superiority of spectacle independence with the TFNT00 IOL compared to the ZXR00 IOL. Contrary to previous studies that found both IOLs provided spectacle independence for the majority of daily activities,[7,12–15,21,22] over half of the participants among both groups in our study specified the need for spectacles "for any purpose" or "for near tasks" at least some of the time. This difference in findings between the previous studies and ours may be due to differences in lifestyle choices and expectations.

Our study also has limitations. For all instances where no statistical significance was found, our sample size may have been inadequate to detect a difference. Despite our small sample, we found MBCCS at the higher spatial frequencies was statistically significantly better with the EDF IOL. Secondly, the IOL groups were not randomized; however, the purpose of this study was to compare groups using "real world" outcomes which provide important information to clinicians.[26] Thirdly, although we enrolled participants non-consecutively, we approached all eligible participants to minimize selection bias. Fourth, although the mean and range of the follow-up time of the 2 IOL groups were different, we do not believe that this would impact our overall conclusion since all but two participants were assessed at a minimum of 6 months post-operatively, and 6 months is considered the time required to ensure full neuroadaptation.[27] Despite two in the trifocal group being assessed prior to 6 months, the trifocal group performed better than EDF group for binocular uncorrected near vision. However, this may contribute to the better performance of the EDF IOL for MBCCS at the higher spatial frequencies. Last, by performing a slit lamp only on those with less than 20/20 VA, we may have missed some subtle posterior capsular opacities or glistenings. However, since patient satisfaction was 10/10 for distance vision, it is unlikely that subtle opacities would affect reading vision and CS, and for glistenings, the IOLs used in this study have been shown not to significantly change optical performances such as VA and CS.[28,29]

Future studies should evaluate the effects of LED headlights under mesopic conditions, given their more common use in newer vehicles.[30] FDA regulations indicate that the illuminance of halogen glare beams should be 2.5 cd/m^2 [12] however we were unable to find standardized guidelines as to how to test glare under mesopic conditions while using neutral density filters and a chart in a light box.[28]

Conclusion

Our findings indicate overall satisfaction for distance vision was excellent for both the TFNT00 and ZXR00 IOL, although over half in both groups specified the need for spectacles at least some of the time. Binocular UNVA was better with the PanOptix™ IOL and MBCCS at the higher spatial frequencies was statistically significantly better with the ZXR00 IOL. Although the results of this study are not generalizable, consistent with previous studies, the trifocal TFNT00 IOL may be preferred by those who strive for the best possible UNVA, with the understanding that their mesopic contrast sensitivity may be compromised. The EDF ZXR00 IOL may perform better at higher spatial frequencies in mesopic conditions; however, careful consideration of target refraction may be required to optimize near vision. These findings, as well as the observation of less spectacle dependence with the trifocal group, require further investigation in North America with a larger sample to confirm whether these differences between groups are significant.

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