Title

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Journal

Journal of Refractive Surgery, 37(2)

ISSN

1081-597X

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Publication Date

2021-02-01

DOI

10.3928/1081597x-20201111-02

Peer reviewed

Multifocal and Extended Depth of Focus Intraocular Lenses: A Comparison of Data from the United States Food and Drug Administration Premarket Approval Trials

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ABSTRACT

PURPOSE: To review and compare the results of unpublished premarket approval studies for recent multifocal and extended depth of focus (EDOF) intraocular lenses.

METHODS: Lenses without previously published premarket approval trials were identified and clinical and patient-reported outcomes were reviewed and compared.

RESULTS: Lenses included the DFT/DAT (Acrysof Vivity) EDOF lens, the TFNT/TFAT (PanOptix) trifocal lens, and the SV25T (ReStor ActiveFocus) lens (all from Alcon Laboratories, Inc), as well as the ZXR/ZXT (Tecnis Symfony and Symfony Toric), the ZLB00 (Tecnis Multifocal +3.25), and the ZKB00 (Tecnis Multifocal +2.75, all Tecnis lenses from Johnson & Johnson Vision). All lenses produced equivalent distance vision and superior intermediate and near vision compared to monofocal controls. Patient-reported difficulty with glare, halos, and starbursts was higher in the multifocal and EDOF lens cohort compared to monofocal controls. Spectacle independence was higher in the multifocal and EDOF cohort with the exception of the SV25T (ActiveFocus) lens, which was not significantly different than the control lens.

CONCLUSIONS: Clinical trial data from the U.S. Food and Drug Administration premarket approval studies supports multifocal and EDOF lenses as an effective treatment for aphakia and presbyopia.

[*J Refract Surg*. 2021;37(2):98-104.]

Multifocal and extended depth of focus intraocular lenses (EDOF IOLs) have the potential to both correct the distance focal point of the eye and provide one or more near focal points for the treatment of presbyopia.[1] Numerous lenses have been introduced to the market worldwide, and a significant subset of them have been approved for use in the United States by the U.S. Food and Drug Administration (FDA). The aim of this study was to compare the visual and patient-reported outcomes of the pivotal FDA approval trials between lenses that are available in the United States for which outcomes have not previously been published.

PATIENTS AND METHODS

This study was deemed exempt from review by the Institutional Review Board of the University of California, San Francisco, because it only used de-identified outcomes data from publicly available sources. The online database of the FDA was searched to identify the Summary of Safety and Effectiveness (SSE) documents for the multifocal and EDOF IOLs approved for use in the United States as of August 1, 2020. The SSE is the document published by the FDA that includes the outcomes data presented for approval.

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Submitted: August 4, 2020; Accepted: October 30, 2020

Supported by an unrestricted departmental grant from Research to Prevent Blindness and the NEI Core Grant NIH-NEI EY002162 (Department of Ophthalmology).

Dr. Schallhorn is a consultant for Carl Zeiss Meditec and Vanda Pharmaceuticals, and has equity in Long Bridge Medical, none of which are related to this study.

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doi:10.3928/1081597X-20201111-02

The PubMed database was searched for publications that included FDA approval data that had been published in the peer-reviewed literature. Publication of the SSE data for the SN6AD12, SN6AD32, and SND1Tx3 (all by Alcon Laboratories, Inc) were identified in the peer-reviewed literature, and so these lenses were excluded from the current study.

Study design, visual acuity data, contrast sensitivity data, and patient-reported outcome data was obtained from the SSE documents. Data for the monofocal control IOLs from each study were also included. All visual acuity data presented are binocular acuity at 6 months postoperatively, with the exception of the data for the SV25T, ZKB00, and ZLB00. For the SV25T, the data were reported in the SSE as monocular corrected acuity and binocular uncorrected acuity. For the ZKB00 and ZLB00, distance-corrected near acuity was evaluated monocularly. All defocus curve data presented are monocular, using best available distance spectacle correction. Summary statistics were calculated. A two-tailed *t* test was used to compare visual acuities between lenses. The Fisher's exact test was used to compare proportions of patients achieving levels of visual acuity between lenses.

RESULTS

The SSE data for the following lenses were unavailable in the peer-reviewed literature, and thus were included in this study: SV25T (ReStor Acrysof ActiveFocus; Alcon Laboratories, Inc),[2] TFNT/TFAT (PanOptix; Alcon Laboratories, Inc),[3] DFT/DAT (Acrysof Vivity; Alcon Laboratories, Inc),[4] ZXR/ZXT (Tecnis Symfony and Symfony Toric; Johnson & Johnson Vision),[5] ZLB00 (Tecnis Multifocal +3.25; Johnson & Johnson Vision), and ZKB00 (Tecnis Multifocal +2.75; Johnson & Johnson Vision).[6] The ZKB00 and ZLB00 were submitted to the FDA jointly, and are included in the same SSE. The included lenses represent several different optic designs and near focal points[7] (**Table A**, available in the online version of this article).

Studies evaluating the DFT/DAT, SV25T, and ZXR/ZXT were designed as multi-site randomized controlled trials with patient and evaluator masking (**Table B**, available in the online version of this article). Patients were allocated on a 1:1 ratio to the study lens or a monofocal control lens, with bilateral IOL implantation. Surgeons were not masked. Studies evaluating the TFNT/TFAT and ZKB00/ZLB00 were multi-center, prospective non-randomized studies with masking of the outcome evaluator. Inclusion and exclusion criteria were similar between studies. All patients in both the multifocal and monofocal control groups in all studies had planned bilateral implantation with a target for bilateral emmetropia. All studies excluded patients with corneal cylinder greater than 1.00 diopters (D), as well as patients with any significant corneal or retinal pathology, or pathology that could precipitate complex cataract surgery. The DFT/DAT study specifically excluded patients with a lens power outside of the 18.00 to 25.00 D range when targeted for emmetropia. The ZXR/ZXT and ZKB00/ZLB00 studies specifically excluded patients with a lens power outside of the 16.00 to 28.00 D range when targeted for emmetropia. The primary outcome was at 6 months postoperatively for all studies.

The comparator lens was a monofocal lens for all studies. For the ZXR/ZXT and ZKB00/ZLB00 studies, the monofocal lens was the aspheric ZCB00. For the SV25T and DFT/DAT studies, the comparator lens was the aspheric SN60WF (Alcon Laboratories, Inc). For the TFNT/TFAT study, the comparator lens was the spherical SN60AT.

VISUAL ACUITY

Visual acuity results are provided in **Table C** (available in the online version of this article). Acuities are provided, when available, as both distance-corrected and uncorrected. Because residual myopia may have the result of improving uncorrected near and intermediate acuity, distance-corrected intermediate and near acuities provide a better picture of the optical range of the lens. All lenses exhibited excellent corrected distance visual acuity that was not statistically inferior to the control IOL used in each study. For all studies, a non-inferiority margin of 0.1 logMAR was used.

Near visual acuity was evaluated at 40 cm for all lenses in the study. Due to the effect of potential residual myopia on intermediate and near acuity, the distance-corrected measurements were used for comparison. The TFNT/TFAT had a distance-corrected near Snellen equivalent of 20/25, which was the distance-corrected near acuity of all lenses included ($P < .001$ for all comparisons). All studies reported superior intermediate and near acuity of the multifocal or EDOF lens to the control monofocal lens ($P < .001$) for all comparisons.

Intermediate acuity was evaluated at 66 cm for all lenses with the exception of the SV25T lens, which was evaluated at 53 cm. Intermediate acuity results were not evaluated for the ZKB00/ZLB00 lenses in the SSE. Compared to the DFT/DAT and the ZXR/ZXT, the TFNT/TFAT had better distance-corrected intermediate distance acuity at 66 cm ($P < .003$ for both comparisons). Cumulative acuity results are shown in **Figure 1** for the lenses that had available data.

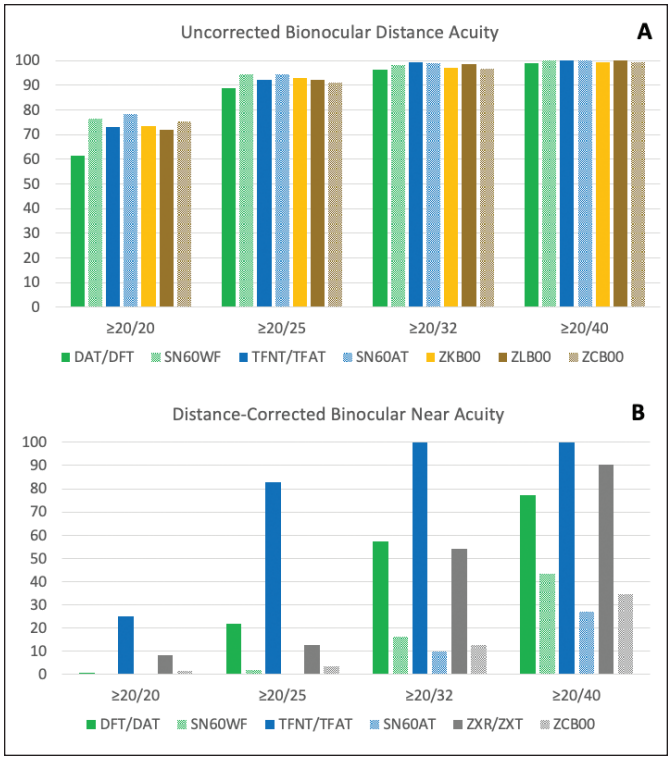

Figure 1. Percentage of patients obtaining visual acuity at each level. (A) Distance acuity is given as binocular uncorrected and (B) near acuity is given as distance-corrected. Data for the control monofocal lens from each study are presented next to the multifocal lens in the patterned boxes. The near acuity values are statistically significantly different by Fisher's exact test ($P < .001$ for each level of acuity), the distance acuity values were not significantly different ($P > .08$ for all comparisons). The DFT/DAT (Vivity), SN60WF, TFNT/TFAT (PanOptix), and SN60AT lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), and ZKB00, ZLB00, and ZCB00 lenses are manufactured by Johnson & Johnson Vision.

The defocus curves for lenses included in this study are shown in **Figure 2**. All defocus curves were reported as binocular using best spectacle distance correction.

Contrast Sensitivity

Mesopic contrast sensitivity without glare is shown in **Figure 3**. Values shown are the mean for the TFNT/TFAT, and the median for all other lenses. Contrast sensitivity measurements were taken as binocular for the TFNT/TFAT, SV25T, and ZKB00/ZLB00 lenses, and monocular for the ZXR/ZXT and DFT/DAT lenses. Photopic contrast sensitivity was inconsistently reported, and is thus not included in this study. All measurements were taken using VectorVision charts (Vector Vision, Inc). Measurements for the SV25T, TFNT/TFAT, and DFT/DAT were taken using the CSV-1000 sine wave grating, and the ZXR/ZXT, ZKB00, and ZLB00 using the Early Treatment of Diabetic Retinopathy chart. Be-

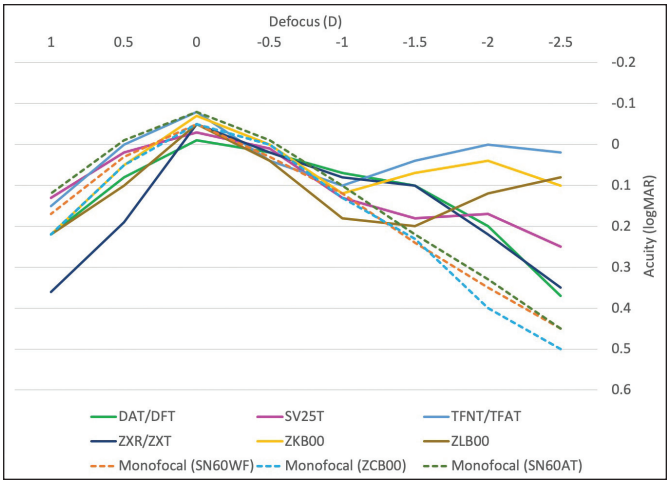

Figure 2. Defocus curves for the included lenses. All defocus curves are binocular, with distance correction. The DFT/DAT (Vivity), SV25T, and TFNT/TFAT (PanOptix) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), ZKB00, and ZLB00 lenses are manufactured by Johnson & Johnson Vision. D = diopters

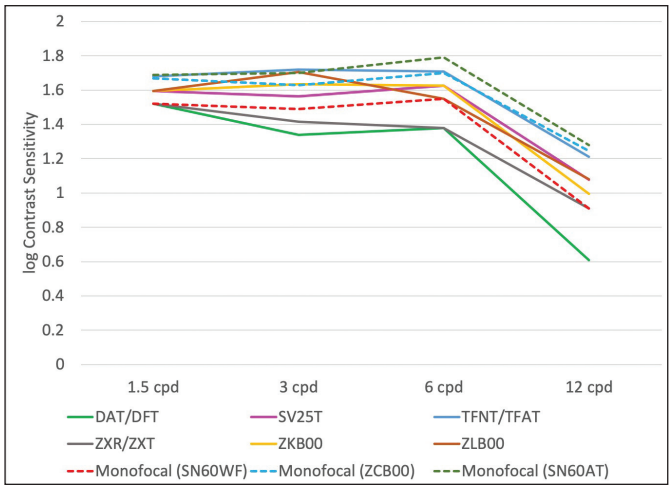

Figure 3. Mesopic contrast sensitivity without glare for included multifocal lenses. All values shown are median contrast sensitivity, with the exception of data for the TFNT/TFAT, which was reported as mean. The DFT/DAT (Vivity), SV25T, and TFNT/TFAT (PanOptix) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), ZLB00, and ZKB00 lenses are manufactured by Johnson & Johnson Vision.

cause most studies reported the median value and there was a significant variation in the instrument used and binocular versus monocular measurements, direct comparison is impossible. The median contrast sensitivity values for the highest spatial frequency were lower for the DFT/DAT and ZKB00 lenses.

Mesopic contrast sensitivity without glare was lower for all multifocal and EDOF IOLs than the control IOL, especially at higher spatial frequencies. The TFNT/TFAT was compared to a spherical lens (the SN60AT), whereas all others were compared to an

TABLE 1

Reported Rates of Spectacle Independence for the Included Lenses

Study	Spectacle Independence (%)		*P*
	Multifocal IOL	Control IOL	
DAT/DFT	21.6	3.6	< .001[a]
TFAT/TFNT	80.5	8.2	< .001
SV25T	Not provided	Not provided	Not statistically significant (value not provided)
ZXR/ZXT[b]	85	59.9	< .001
ZKB00	61.3	2.1	< .001
ZLB00	75	2.1	< .001

IOL = intraocular lens
[a]Statistical test not provided in original study, statistic calculated for the current study using the chi-squre test.
[b]Combined rates of spectacle use none of the time/rarely reported. For all other lenses, spectacle use is reported none of the time.
The DFT/DAT (Vivity), TFNT/TFAT (PanOptix), and SV25T (ActiveFocus) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), ZKB00, and ZLB00 lenses are manufactured by Johnson & Johnson Vision.

TABLE 2

Reported Rates of Visual Symptom Severity in the Included Studies[a]

Lens	Glare				Halo				Starburst			
	None	Mild	Moderate	Severe	None	Mild	Moderate	Severe	None	Mild	Moderate	Severe
DAT/DFT	77.1	14.3	8.6	0	78	18	8.5	0.9	66	17	13.2	3.8
SN60WF	73	17.1	9.9	0	82.7	12.7	3.6	0.9	61.8	13.7	11.8	2.7
TFNT/TFAT	49.2	29.3	18.3	3.2	36.2	28.8	12.6	44	12.8	27.2	16	–
SN60AT	67.6	17.1	13.5	1.8	77.3	15.5	6.4	0.9	73.4	17.5	7.3	–
SV25T	39.9	35.9	20.9	3.3	37.3	30.1	22.2	10.5	55.6	24.8	11.8	7.8
SN60WF	49.4	33.8	13.1	3.8	61.9	26.9	7.5	3.8	61.9	26.9	7.5	3.8
ZXR/ZXT	42.2	36.1	15.0	5.4	40.8	31.3	21.1	6.8	42.2	28.6	21.1	8.2
ZCB00	57.4	23.6	15.5	3.4	70.9	16.2	10.1	3.4	74.3	12.2	9.5	4.1
ZKB00	76.8	–	21.8	1.4	69.0	–	25.4	5.6	–	–	–	–
ZLB00	69.1	–	25.5	5.4	57.9	–	32.2	10.7	–	–	–	–
ZCB00	80.7	–	12.4	6.9	84.1	–	–	13.8	2.1	–	–	–

[a]Rates are percentage of patients reporting that level of visual symptom. The ZKB00/ZLB00 study did not report levels of mild symptoms nor starburst symptoms.
The DFT/DAT (Vivity), TFNT/TFAT (PanOptix), SN60WF, SN60AT, and SV25T (ActiveFocus) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), ZCB00, ZKB00, and ZLB00 lenses are manufactured by Johnson & Johnson Vision.

aspheric lens. With the DFT/DAT, more patients were unable to see the reference pattern under mesopic conditions than patients receiving the control IOL (17.8%, n = 19 versus 3.4%, n = 4). The number of patients unable to see the reference pattern was not reported for other lenses.

Spectacle Independence

Reported rates of spectacle independence for the multifocal and EDOF lenses ranged from 21.6% for the DFT/DAT to 85% for the ZXR (**Table 1**). Values for the ZXR lens are given as spectacle independence all/most of the time, whereas the other lenses have values for spectacle independence all of the time. For all lenses, with the exception of the SV25T, there was a statistically significant higher percentage of patients reporting spectacle independence with the multifocal or EDOF lens versus the control monofocal lens. There was no difference in reported rates of spectacle independence between the SV25T lens and the control monofocal lens (SN60WF).

Patient-Reported Outcomes

Patient-reported outcomes are difficult to compare between lenses, given the fact that each study used a unique proprietary questionnaire. The only valid comparisons that can be drawn from these data are the comparisons between the multifocal or

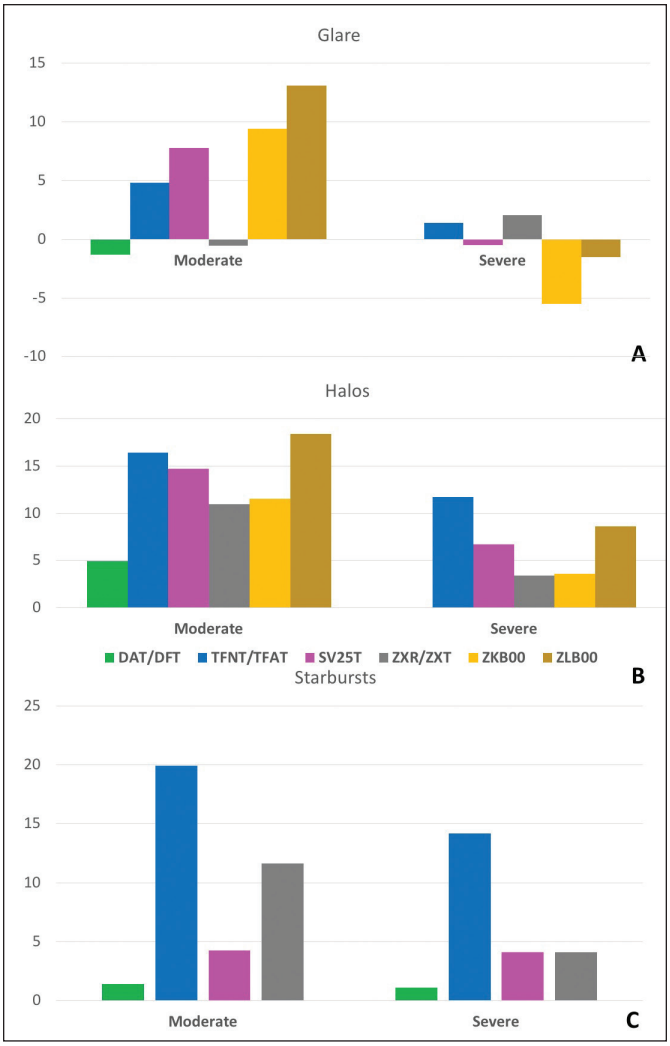

Figure 4. Patient-reported outcomes data for (A) moderate and severe glare, (B) halos, and (C) starbursts. Data reported are the difference in percentage of patients reporting each level of visual symptom between the control monofocal lens and the multifocal lens. Negative numbers indicate that more control patients reported that level of visual symptom, positive numbers indicate that more multifocal patients reported that level of visual symptom. The ZKB00/ZLB00 (Johnson & Johnson Vision) study did not report values for starbursts or for mild visual symptom severity. The DFT/DAT (Vivity), SV25T, and TFNT/TFAT (PanOptix) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), ZKB00, and ZLB00 lenses are manufactured by Johnson & Johnson Vision.

EDOF lens and the control monofocal lens that was used in its approval study. Data for patient-reported severity of three consistently reported visual symptom variables (glare, halos, and starbursts) are shown in **Table 2**. The difference in the percentage of patients reporting different moderate and severe visual symptoms were compared within studies between the study multifocal or EDOF lens and the control monofocal lens (**Figure 4**). Across all studies, there tended to be a higher rate of moderate and severe visual symptoms reported in patients receiving the multifocal or EDOF lens versus patients receiving the control monofocal lens.

TABLE 3
Reoperations Due to Optical Properties of Lens[a]

Lens	No. (%)
DFT/DAT	0
Control IOL	0
TFNT/TFAT	1 (0.8%)
Control IOL	0
SV25T	0
Control IOL	0
ZXR/ZTX	0
Control IOL	0
ZKB00	1 (0.7%)
ZLB00	1 (0.7%)
Control IOL	0

IOL = intraocular lens
[a]During the ZXR/ZXT study, one ZXR and one ZCB00 patient reported a desire to have the IOL removed that the investigator deemed likely to the optical properties of lens, but this was not done during the study period. The DFT/DAT, TFNT/TFAT, and SV25T lenses are manufactured by Alcon Laboratories, Inc, the ZXR/ZXT, ZKB00, and ZLB00 lenses are manufactured by Johnson & Johnson Vision.

Secondary Interventions

Few secondary interventions for patient dissatisfaction secondary to the optical properties of the lens were reported in any study (**Table 3**). One patient receiving the TFNT/TFAT lens and one patient receiving the ZLB00 lens underwent lens removal. One patient receiving the ZKB00 lens underwent lens repositioning for decentration. In the ZXR/ZXT group, one patient receiving the EDOF lens and one patient receiving the control monofocal ZCB00 lens expressed a desire to have the lens removed that the investigators believed was due to the optical properties of the lens, but this was not performed during the study period.

DISCUSSION

Multifocal and EDOF lenses represent an increasingly popular option for the correction of presbyopia after cataract surgery. During the past several years, many new lenses have been introduced to the United States market. Unfortunately, publication of rigorous comparative data regarding these lenses has not kept pace with the rate that they have been introduced, and there is a significant amount of important data kept within the SSE documents on the FDA website.

Careful examination of the data from the pivotal approval trials for the lenses included in this study revealed several common themes. They all demonstrate non-inferior distance vision to monofocal control lenses and improved intermediate and near vision, which is comparable to previously published outcomes.[7-13] Commensurate with its trifocal nature and higher add power, the TFNT/TFAT lens reported the best distance-corrected near and intermediate acuity of all lenses evaluated. Most lenses, with the exception of the SV25T (ActiveFocus) lens, also yielded a measurable increase in spectacle independence compared to a control monofocal lens. Comparison of the defocus curves revealed acuity peaks commensurate with lens design and the near focal point (or points).

These lenses all also resulted in a decrease in mesopic contrast sensitivity compared to a monofocal control lens, most notable at higher spatial frequencies, which is consistent with measurements from other multifocal lenses.[14-16] Because there were different methodologies used between studies, it is difficult to directly compare contrast sensitivity measurements between studies. Interestingly, the TFNT/TFAT was compared to a spherical control lens (the SN60AT). Spherical lenses have consistently demonstrated reduced contrast sensitivity compared to aspheric lenses.[17]

The patient visual experience is, in many ways, the most important point of any refractive procedure. Due to the heterogeneity of the questionnaires used in these studies, direct comparisons between different multifocal or EDOF lenses are impossible. This is, unfortunately, also the state of patient-reported outcomes in the literature, with a multitude of different questionnaires impairing any comparative attempt (Alió et al[1] provides an excellent summary of previously published patient-reported outcomes). However, comparisons between each multifocal or EDOF lens and the control monofocal lens that it was studied against are valid because the same questionnaire was used. These comparisons reveal that the severity of patient-reported visual symptoms tends to be greater in multifocal or EDOF lenses compared to their monofocal controls. This difference is most notable for the TFNT/TFAT and the ZLB00. The higher effective add power for these two lenses likely plays a role in the increase in visual symptoms. Although lens explantation for visual symptoms has been reported in the literature,[1] it occurred uncommonly in the studies included here (< 1%).

A full understanding of the tradeoffs between visual disturbances and acuity is a difficult task, because of the inherently personal tolerance of balance between visual phenomena and acuity. The lack of, and difficulty developing, a clear defined measure of this balance has been, perhaps, the greatest limitation in the adoption of advanced technologies for IOLs. One of the conditions of the approval for the ZXR lens was the future development of a patient-reported outcomes questionnaire for use in the evaluation of presbyopia-correcting lenses. This effort is now well underway, coordinated through the American Academy of Ophthalmology and the industry leaders in the field (F. Lum, email, August 1, 2019).[5] The development of a consistent and validated way for comparing different lens technologies holds great promise to assist surgeons and navigate the available options. For now, unfortunately, it remains difficult to draw conclusions on patient-centric outcomes based on the available data.

Comparative knowledge of the near acuity focal points of the available lenses and their rates of patient-reported visual phenomena can be helpful for surgeons as they navigate the increasingly complex world of multifocal and EDOF lenses. Having an excellent grasp of the properties of the available lenses can aid in patient selection and, ultimately, improve patient outcomes.

AUTHOR CONTRIBUTIONS

Study concept and design (JMS); data collection (JMS); analysis and interpretation of data (JMS); writing the manuscript (JMS); critical revision of the manuscript (JMS)

REFERENCES

1. Alió JL, Plaza-Puche AB, Férnandez-Buenaga R, Pikkel J, Maldonado M. Multifocal intraocular lenses: an overview. *Surv Ophthalmol*. 2017;62(5):611-634. doi:10.1016/j.survophthal.2017.03.005
2. U.S. Food and Drug Administration. Premarket Approval Application P040020/S050; Summary of Safety and Effectiveness. 2015.
3. U.S. Food and Drug Administration. Premarket Approval Application P040020; Summary of Safety and Effectiveness. 2019.
4. U.S. Food and Drug Administration. Premarket Approval Application P930014/S126. 2020.
5. U.S. Food and Drug Administration. Premarket Approval Application P980040/S065; Summary of Safety and Effectiveness. 2016.
6. U.S. Food and Drug Administration. Premarket Approval Application P080010; Summary of Safety and Effectiveness. 2009.
7. Negishi K, Hayashi K, Kamiya K, et al; Survey Working Group of the Japanese Society of Cataract and Refractive Surgery. Nationwide prospective cohort study on cataract surgery with multifocal intraocular lens implantation in Japan. *Am J Ophthalmol*. 2019;208:133-144. doi:10.1016/j.ajo.2019.07.019
8. Lane SS, Javitt JC, Nethery DA, Waycaster C. Improvements in patient-reported outcomes and visual acuity after bilateral implantation of multifocal intraocular lenses with +3.0 diopter addition: multicenter clinical trial. *J Cataract Refract Surg*. 2010;36(11):1887-1896. doi:10.1016/j.jcrs.2010.05.028

9. Lehmann R, Modi S, Fisher B, Michna M, Snyder M. Bilateral implantation of +3.0 D multifocal toric intraocular lenses: results of a US Food and Drug Administration clinical trial. *Clin Ophthalmol*. 2017;11:1321-1331. doi:10.2147/OPTH.S137413

10. Cochener B; Concerto Study Group. Clinical outcomes of a new extended range of vision intraocular lens: International Multicenter Concerto Study. *J Cataract Refract Surg*. 2016;42(9):1268-1275. doi:10.1016/j.jcrs.2016.06.033

11. 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(8):507-514. doi:10.3928/1081597X-20180530-02

12. Sandoval HP, Lane S, Slade S, Potvin R, Donnenfeld ED, Solomon KD. Extended depth-of-focus toric intraocular lens targeted for binocular emmetropia or slight myopia in the nondominant eye: visual and refractive clinical outcomes. *J Cataract Refract Surg*. 2019;45(10):1398-1403. doi:10.1016/j.jcrs.2019.05.019

13. Nuijts RM, Jonker SM, Kaufer RA, et al. Bilateral implantation of +2.5 D multifocal intraocular lens and contralateral implantation of +2.5 D and +3.0 D multifocal intraocular lenses: clinical outcomes. *J Cataract Refract Surg*. 2016;42(2):194-202. doi:10.1016/j.jcrs.2016.02.009

14. Alió JL, Kaymak H, Breyer D, Cochener B, Plaza-Puche AB. Quality of life related variables measured for three multifocal diffractive intraocular lenses: a prospective randomised clinical trial. *Clin Exp Ophthalmol*. 2018;46(4):380-388. doi:10.1111/ceo.13084

15. Pedrotti E, Bruni E, Bonacci E, Badalamenti R, Mastropasqua R, Marchini G. Comparative analysis of the clinical outcomes with a monofocal and an extended range of vision intraocular lens. *J Refract Surg*. 2016;32(7):436-442. doi:10.3928/1081597X-20160428-06

16. Alfonso JF, Puchades C, Fernández-Vega L, Merayo C, Montés-Micó R. Contrast sensitivity comparison between AcrySof ReSTOR and Acri.LISA aspheric intraocular lenses. *J Refract Surg*. 2010;26(7):471-477. doi:10.3928/1081597X-20090728-04

17. Awwad ST, Warmerdam D, Bowman RW, Dwarakanathan S, Cavanagh HD, McCulley JP. Contrast sensitivity and higher order aberrations in eyes implanted with AcrySof IQ SN60WF and AcrySof SN60AT intraocular lenses. *J Refract Surg*. 2008;24(6):619-625. doi:10.3928/1081597X-20080601-12

TABLE A

Characteristics of Included Lenses

Lens	Manufacturer	Design	Optical Properties	Add IOL Plane (Spectacle Plane)	Year of FDA Approval	Power Range (D)	Toric Power (Lens Plane, D)
ZLB00[a]	Tecnis Multifocal +3.25	Bifocal	Aspheric anterior, diffractive posterior	+3.25 (+2.37)	2014	+5.00 to +34.00, 0.50 D increments	Not available
ZKB00[a]	Tecnis Multifocal +2.75	Bifocal	Aspheric anterior, diffractive posterior	+2.75 (+2.01)	2014	+5.00 to +34.00, 0.50 D increments	Not available
ZXR/ZXT[a]	Tecnis Symfony/ Symfony Toric	Extended depth of focus	Aspheric anterior, achromatic diffractive posterior	+1.758	2016	+5.00 to +34.00, 0.50 D increments	1.50 to 3.75, 0.75 D increments
DFT[b]/DAT[a]	AcrySof Vivity	Extended depth of focus	"Wavefront-shaped" anterior/spherical posterior	–	2020	+15.00 to +25.00, 0.50 D increments	1.50 to 3.00, 0.75 D increments
SV25T[b]	AcrySof IQ ReSTOR +2.50	Bifocal	Apodized aspheric diffractive anterior/ spherical posterior	+2.50 (+2.00)	2015	+6.00 to +30.00, 0.50 D increments	1.50 to 3.75, 0.75 D increments
TFNT[b]/TFAT[a]	AcrySof IQ PanOptix	Trifocal	Aspheric diffractive anterior/spherical posterior	+2.17; +3.25 (+1.65; +2.35)	2019	+6.00 to +30.00, 0.50 D increments; +31.00 to +34.00, 1.00 D increments	1.50 to 3.75, 0.75 D increments

IOL = intraocular lens; FDA = U.S. Food and Drug Administration; D = diopters
[a]Ultraviolet light–blocking material.
[b]Blue-blocking material.
The DFT/DAT (Vivity), TFNT/TFAT (PanOptix), and SV25T (ActiveFocus) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), ZKB00, and ZLB00 lenses are manufactured by Johnson & Johnson Vision.

TABLE B

Trial Parameters for the Included Summary of Safety and Effectiveness Data

Lens	Study Design	Group	No. of Patients	Female (%)	Age (y)	Preop Corneal Cylinder (D)	Loss to Follow-up (%)
DFT/DAT (Vivity)	RCT, subject/ evaluator masked	Multifocal IOL DFT/DAT	107	55.1	68.60 ± 6.60	0.51 ± 0.26	0
		Control IOL (SN60WF)	113	56.6	68.80 ± 7.20	0.51 ± 0.26	1.8
TFNT/TFAT (PanOptix)	Prospective, evaluator masked	Multifocal IOL TFNT/TFAT	129	65.9	65.80 ± 7.31	0.48 ± 0.27	1.6
		Control IOL SN60AT	114	69.3	69.00 ± 6.46	0.54 ± 0.27	0
SV25T (ActiveFocus)	RCT, subject/ evaluator masked	Multifocal IOL SV25T	163	61.9	–	–	6.1
		Control IOL SN60WF	166	58.8	–	–	3.6
ZXR/ZXT (Symfony)	RCT, subject/ evaluator masked	Multifocal IOL ZXR/ZXT	148	61.5	68.00 ± 7.50	0.51 ± 0.25	0.7
		Control IOL ZCB00	151	57.0	67.90 ± 7.90	0.53 ± 0.22	2
ZKB00/ZLB00 (Tecnis)	Prospective, evaluator masked	Multifocal IOL ZKB00 +2.75	147	50.3	67.60 ± 6.90	0.51 ± 0.23	1.4
		Multifocal IOL ZLB00 +3.25	150	67.3	67.90 ± -6.80	0.49 ± 0.25	0
		Control IOL ZCB00	148	57.4	68.50 ± 6.90	0.54 ± 0.27	1.4

D = diopters; RCT = randomized controlled trial; IOL = intraocular lens
The DFT/DAT (Vivity), SN60WF, TFNT/TFAT (PanOptix), and SV25T (ActiveFocus) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony) and ZCB00 lenses are manufactured by Johnson & Johnson Vision.

TABLE C

Visual Acuity Results[a]

	Distance		Intermediate		Near	
Study	**logMAR**	**Snellen**	**logMAR**	**Snellen**	**logMAR**	**Snellen**
Distance-Corrected Binocular						
DFT/DAT	-0.028 ± 0.084	20/19	0.083 ± 0.054	20/24	0.253 ± 0.118	20/36
SN60WF	-0.071 ± 0.086	20/17	0.196 ± 0.133	20/31	0.391 ± 0.149	20/49
TFNT/TFAT	-0.062 ± 0.066	20/20	-0.007 ± 0.079	20/25	0.05 ± 0.07	20/25
SN60AT	-0.039 ± 0.009	20/20	0.327 ± 0.011	20/40	0.529 ± 0.013	20/63
SV25T	–	–	–	–	–	–
SN60WF	–	–	–	–	–	–
ZXR/ZXT	0.034 ± 0.106	20/20	0.032 ± 0.086	20/20	0.229 ± 0.114	20/32
ZCB00	0.013 ± 0.118	20/20	0.227 ± 0.140	20/32	0.426 ± 0.159	20/50
ZKB00	-0.073 ± 0.101	20/23	–	–	0.170	20/30
ZLB00	-0.062 ± 0.075	20/23	–	–	0.106	20/26
ZCB00	-0.085 ± 0.076	20/16	–	–	0.488	20/60
Distance-Corrected Monocular						
DFT/DAT	0.016 ± 0.094	20/21	0.148 ± 0.124	20/28	0.359 ± 0.152	20/46
SN60WF	-0.036 ± 0.094	20/18	0.312 ± 0.124	20/41	0.515 ± 0.152	20/65
TFNT/TFAT	-0.014 ± 0.091	20/19	0.070 ± 0.125	20/23	0.105 ± 0.136	20/25
SN60AT	-0.039 ± 0.096	20/18	0.327 ± 0.117	20/42	0.529 ± 0.0.138	20/68
SV25T	0.025 ± 0.009	20/21	0.322 ± 0.014	20/42	0.426 ± 0.014	20/53
SN60WF	0.03 ± 0.009	20/21	0.512 ± 0.013	20/65	0.632 ± 0.013	20/86
ZXR/ZXT	-0.021 ± 0.082	20/19	0.087 ± 0.114	20/24	0.241 ± 0.142	20/35
ZCB00	-0.040 ± 0.093	20/18	0.256 ± 0.088	20/36	0.459 ± 0.183	20/58
ZKB00	-0.022 ± 0.087	20/19	–	–	0.252 ± 0.143	20/36
ZLB00	-0.012 ± 0.085	20/19	–	–	0.179 ± 0.129	20/30
ZCB00	-0.036 ± 0.087	20/18	–	–	0.555 ± 0.609	20/71
Uncorrected Binocular						
DFT/DAT	0.035 ± 0.102	20/22	0.054 ± 0.093	20/23	0.208 ± 0.104	20/32
SN60WF	–	–	–	–	–	20/44
TFNT/TFAT	–	–	–	–	–	–
SN60AT	–	–	–	–	–	–
SV25T	0.01 ± 0.126	20/20	0.25 ± 0.146	20/36	0.34 ± 0.163	20/44
SN60WF	-0.01 ± 0.103	20/20	0.34 ± 0.17	20/44	0.46 ± 0.19	20/58
ZXR/ZXT	-0.045 ± 0.077	20/20	0.002 ± 0.085	20/20	0.146 ± 0.112	20/25
ZCB00	-0.075 ± 0.081	20/16	0.134 ± 0.0.142	20/50	0.328 ± 0.167	20/40
ZKB00	0.008 ± 0.101	20/20	–	–	0.135	20/27
ZLB00	0.016 ± 0.100	20/21	–	–	0.097	20/25
ZCB00	-0.005 ± 0.112	20/20	–	–	0.443	20/55
Uncorrected Monocular						
DFT/DAT	–	–	–	–	–	–
SN60WF	–	–	–	–	–	–
TFNT/TFAT	–	–	–	–	–	–
SN60AT	–	–	–	–	–	–
SV25T	–	–	–	–	–	–
SN60WF	–	–	–	–	–	–
ZXR/ZXT	0.114 ± 0.142	20/26	0.104	20/25	0.323 ± 0.146	20/42
ZCB00	0.088 ± 0.149	20/24	0.342	20/44	0.544 ± 0.174	20/70
ZKB00	0.102 ± 0.136	20/25	–	–	0.238	20/35
ZLB00	0.112 ± 0.131	20/26	–	–	0.185	20/31
ZCB00	0.078 ± 0.134	20/24	–	–	0.568	20/74

[a]Monocular acuities are from the first implanted eye. Near acuity was evaluated at 40 cm for all lenses. Intermediate acuity was evaluated at 66 cm for all lenses with the exception of the SV25T lens, which was evaluated at 53 cm. Snellen equivalent is provided for all logMAR values. For all multifocal lenses, the distance-corrected intermediate and near acuities were statistically significantly better than those of the monofocal control (P < .001 for all comparisons, for both binocular and monocular acuities).

The DFT/DAT (Vivity), TFNT/TFAT (PanOptix), and SV25T (ActiveFocus) lenses are manufactured by Alcon Laboratories, Inc, and the ZXR/ZTX (Symfony), ZCB00, ZKB00, and ZLB00 lenses are manufactured by Johnson & Johnson Vision.