

TECNIS PureSee™ IOL Compendium



TECNIS
PureSee™ IOL
with TECNIS SIMPLICITY® Delivery System

PREFACE

The TECNIS PureSee™ IOL is the first purely refractive presbyopia-correcting extended depth of focus (EDOF) IOL from the TECNIS™ platform designed to deliver a continuous range of high-quality vision, increased tolerance to refractive errors, and low levels of visual symptoms comparable to a monofocal IOL.^{1,2,3} Built on the existing strengths of the TECNIS™ IOL platform, the TECNIS PureSee™ IOL utilizes proprietary refractive technology that enables a continuous change in power to distribute light from far to near with monofocal-like dysphotopsia profile while providing enhanced image contrast under all lighting conditions.^{1,3,4}

This compendium provides a consolidated summary of peer reviewed publications and conference presentations that discuss the efficacy and clinical characteristics of the TECNIS PureSee™ IOL. The research and information presented in this compendium were compiled from published literature across the globe as well as papers and presentations from ophthalmology conferences. This compendium is not comprehensive.

The cut-off date for inclusion in this compendium is June 30th, 2024

References:

1. TECNIS PureSee™ IOL with TECNIS Simplicity™ Delivery System, Model DENooV – DFU INT – Z311782, current revision
2. Data on File, Johnson & Johnson Vision, 2023, DOF2023CT4029
3. Data on File, Johnson & Johnson Vision, 2023, DOF2023CT4012
4. Data on File, Johnson & Johnson Vision, 2023, DOF2023CT4036

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Tolerance to Refractive Error with a New Extended Depth of Focus Intraocular Lens



Black DA, Bala C, Alarcon A, Vilupuru S.



Eye (Lond). 2024;38(Suppl 1):15-20.

OVERVIEW



Study Design

- Optical bench study
- Prospective, multi-center, randomized, subject/evaluator-masked study



Study IOL(s)/Number of eyes/patients and Study Duration

Preclinical Optical Bench Analysis:

- 46 physiological eye models with TECNIS PureSee™ IOL ZENooV, TECNIS Eyhance™ IOL ICB00, TECNIS™ 1-Piece Monofocal IOL ZCB00, TECNIS Symphony™ IOL ZXR00, TECNIS™ Multifocal IOL ZLB00

Clinical Sub-analysis*:

- TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / 31 out of 60 bilateral subjects / 3-, 6-month follow-ups
- TECNIS Eyhance™ IOL ICB00 (Johnson & Johnson Vision) / 29 out of 57 bilateral subjects / 3-, 6-month follow-ups

*Subjects that had absolute spherical equivalent >0.25 D in one or both eyes were included in the subgroup evaluation.



Key End Points

- Simulated visual acuity (sVA) and simulated dysphotopsia profile in the presence of ± 0.50 D sphere and 0.75 D astigmatism defocus, monocular best-corrected distance visual acuity (CDVA), binocular uncorrected distance visual acuity (UDVA), visual symptoms, patient satisfaction and dependency on glasses, monocular distance-corrected mesopic contrast sensitivity

KEY TAKEAWAYS

Results

Preclinical Results:

- In the presence of ± 0.5 D sphere defocus and $+0.75$ D astigmatism, $>92\%$ of eyes with TECNIS PureSee™ IOL achieved 0.10 logMAR or better monocular uncorrected sVA, which is at the level of the monofocal IOLs, ZCB00 and ICB00, and better than the TECNIS™ Multifocal IOL, ZLB00.
- Compared to TECNIS Symphony™ IOL, TECNIS PureSee™ IOL provided comparable, high sVA in the presence of hyperopia and astigmatism but better results in the presence of myopia.
- TECNIS PureSee™ IOL provided low levels of dysphotopsias comparable to the monofocal IOLs even in the presence of small amounts of defocus (± 0.50 D).

Tolerance to Refractive Error with a New Extended Depth of Focus Intraocular Lens

KEY TAKEAWAYS

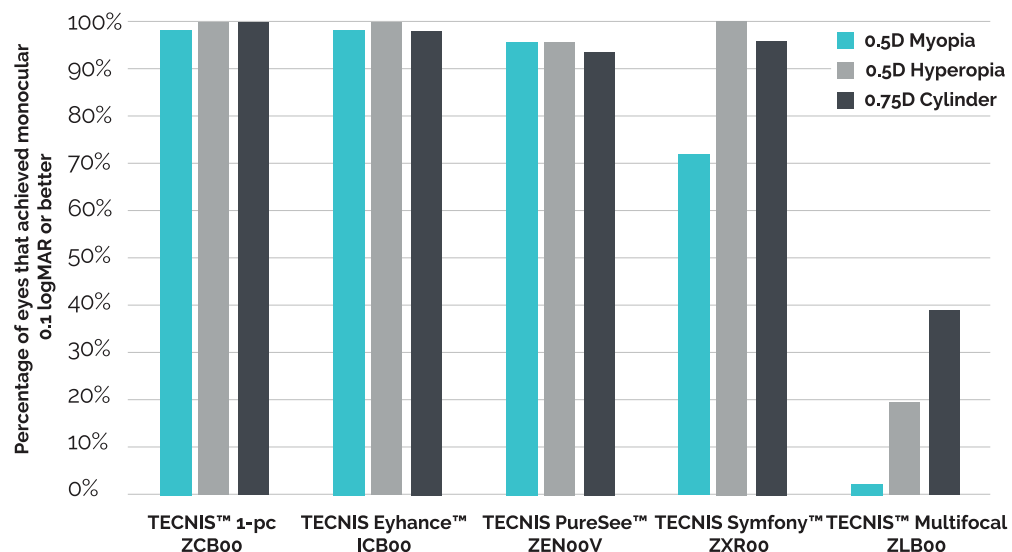
Results

Visual and Refractive Outcomes:

- The mean spherical equivalent and absolute cylinder were similar between the two subgroups: TECNIS PureSee™ IOL (0.36 ± 0.19 D and 0.47 ± 0.30 D, respectively) and TECNIS Eyhance™ IOL (0.46 ± 0.25 D and 0.47 ± 0.31 D, respectively).
- Mean monocular CDVA was -0.06 ± 0.07 logMAR for TECNIS PureSee™ IOL and -0.06 ± 0.09 for TECNIS Eyhance™ IOL.
- Mean binocular UDVA was -0.03 ± 0.08 logMAR for TECNIS PureSee™ IOL and -0.02 ± 0.11 for TECNIS Eyhance™ IOL. 96.8% of TECNIS PureSee™ IOL and 96.6% of TECNIS Eyhance™ IOL patients achieved 0.1 logMAR or better.
- Monocular mesopic contrast sensitivity, with and without glare, was comparable between the two groups.

Patient-Reported Satisfaction and Symptoms:

- 93.5% of patients in the TECNIS PureSee™ IOL group vs 82.8% of the TECNIS Eyhance™ IOL group reported being "completely satisfied" with their distance vision without glasses.
- 87%, 100%, and 100% of TECNIS PureSee™ IOL patients reported to "never, rarely, or sometimes" experience halos, starbursts, and glare, respectively, compared to 93%, 93%, and 100% of TECNIS Eyhance™ IOL patients.

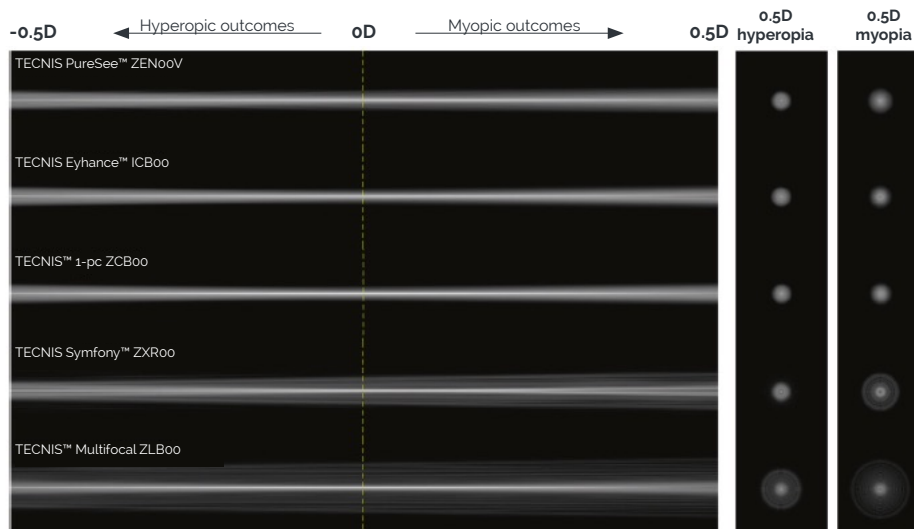


Percentage of eyes that achieved 0.10 logMAR or better monocular uncorrected simulated visual acuity (sVA). Results for test (ZENooV) and control (ICBoo) IOLs, and addition TECNIS™ platform IOL designs (ZCBoo, ZXRoo and ZLBoo).

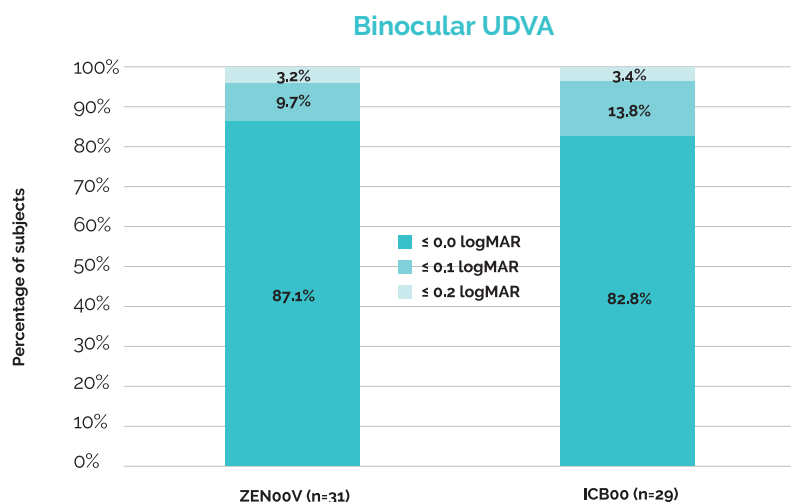
Tolerance to Refractive Error with a New Extended Depth of Focus Intraocular Lens

KEY TAKEAWAYS

Results



Dysphotopsia profile simulations from -0.5 D to +0.5 D of defocus simulated for a 5 mm pupil aperture with test (ZENooV) and control (ICB00) IOLs, and additional TECNIS™ platform IOL design (ZCB00, ZXR00 and ZLB00). The vertical line illustrates the distance focus (0 D).



Percentage of patients with absolute SEQ of >0.25 D in one or both eyes achieving binocular uncorrected distance visual acuity (UDVA) of 0.0, 0.1, and 0.2 logMAR. Results for ZENooV (test) and ICB00 (control) groups at 6 months.

Conclusions

The TECNIS PureSee™ IOL provides high tolerance to small amounts of post-op refractive errors, as demonstrated by the alignment between preclinical and clinical findings. The clinical outcomes showed high quality distance vision, dysphotopsia comparable to a monofocal IOL, and high patient satisfaction, even in the presence of refractive error, thus matching the design expectations of the TECNIS PureSee™ IOL.

Optical and Clinical Simulated Performance of a New Refractive Extended Depth of Focus Intraocular Lens

 Alarcon A, Del Aguila Carrasco A, Gounou F, Weeber H, Cánovas C, Piers P.

 Eye (Lond). 2024;38(Suppl 1):4-8.

OVERVIEW



Study Design

- Optical bench study



Study IOL(s)/Number of eyes/patients and Study Duration

- TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision)
- TECNIS Symphony™ IOL ZXRoo (Johnson & Johnson Vision)



Key End Points

- Simulated visual acuity (sVA – measured from an average eye model and from computer simulations in realistic eye models with corneal higher-order aberrations), tolerance to defocus (evaluated using computer simulations of uncorrected distance sVA under defocus), dysphotopsia profile (halo pictures obtained using an IOL-telescope and simulated images in a realistic eye model under defocus)

KEY TAKEAWAYS

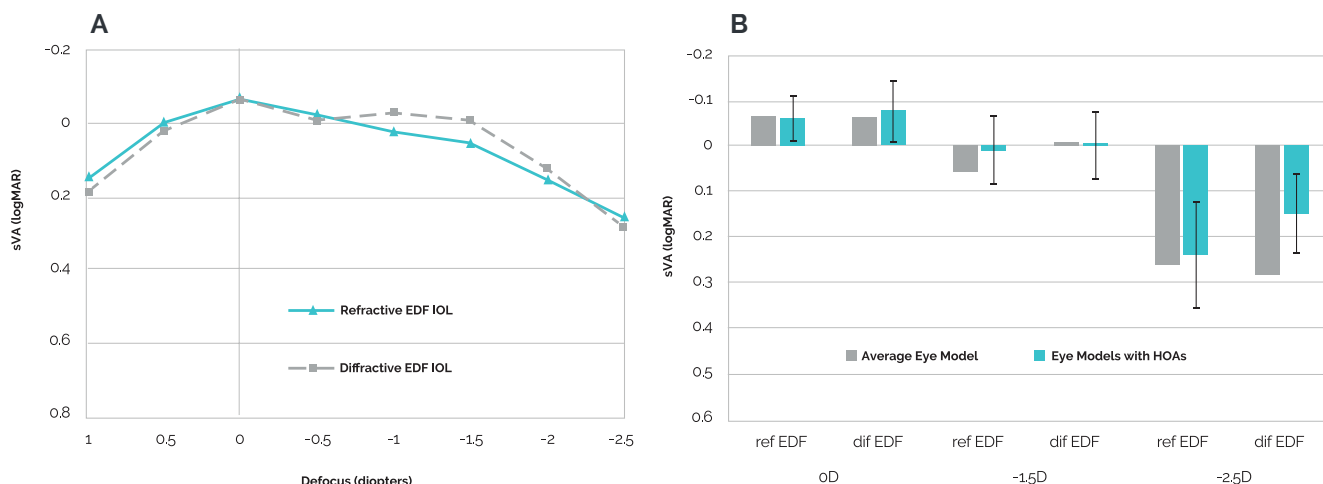
Results

- The TECNIS PureSee™ IOL provided a similar range of vision as the TECNIS Symphony™ IOL, -2.2 D above 0.2 logMAR binocular sVA, with the same distance and comparable intermediate and near sVA.
- Computer simulations showed that the addition of higher-order aberrations did not reduce the average performance at any distance of the TECNIS PureSee™ IOL as compared to the average eye model measurements.
- Computer simulations to evaluate the effect of decentration showed that the sVA provided by the TECNIS PureSee™ IOL decreased by 0.03 and 0.04 logMAR for 0.5 and 1 mm decentration, respectively, and by 0.05 and 0.09 logMAR for the TECNIS Symphony™ IOL.
- With ± 0.5 D of defocus, there was no difference in uncorrected distance sVA between the two lenses in the presence of hyperopia, but in the presence of myopia, 24% more eyes with TECNIS PureSee™ IOL achieved monocular sVA of 0.1 logMAR or better when compared to TECNIS Symphony™ IOL.
 - 96% of TECNIS PureSee™ IOL and 100% of TECNIS Symphony™ IOL eyes achieved 0.1 logMAR or better in the presence of hyperopia.
 - 96% of TECNIS PureSee™ IOL and 72% of TECNIS Symphony™ IOL eyes achieved 0.1 logMAR or better in the presence of myopia.
- Halo pictures showed that TECNIS PureSee™ IOL provided lower levels of dysphotopsia than the TECNIS Symphony™ IOL, and similar levels to the monofocal IOL even in the presence of ± 0.5 D defocus.

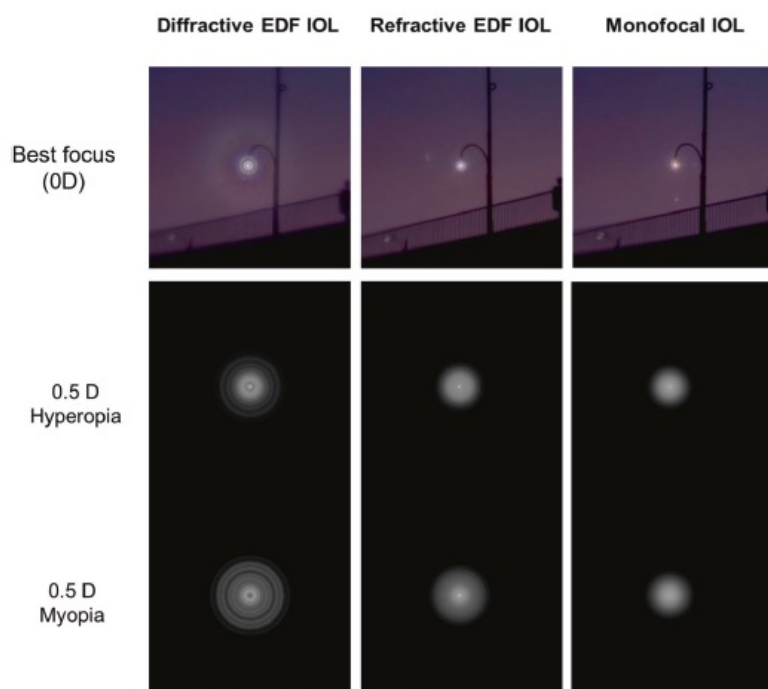
Optical and Clinical Simulated Performance of a New Refractive Extended Depth of Focus Intraocular Lens

KEY TAKEAWAYS

Results



Simulated through focus visual acuity. **A** Simulated binocular visual acuity (sVA) calculated from optical bench measurements in an average physical eye model. **B** sVA measured in the average corneal eye model (Average Eye Model) and computer simulated in realistic eye models with varying corneal higher order aberrations (Eye models with HOAs) for far (0D), intermediate (-1.5D) and near (-2.5D) for the refractive (ref EDF) and the diffractive (dif EDF) EDF IOLs. Figures provide mean values $\pm$ standard deviation.



Halo measurements at best focus (0D) and simulations of a point light source under myopia and hyperopia

Conclusions

Optical bench measurements and computer simulations show that the new refractive EDF IOL, TECNIS PureSee™ IOL, is expected to provide a similar range of vision as the diffractive TECNIS Symphony™ IOL, higher tolerance to refractive errors, and a dysphotopsia profile similar to that of a monofocal IOL, even in the presence of refractive errors.

Quality of Vision Clinical Outcomes for a New Fully-Refractive Extended Depth of Focus Intraocular Lens

 Corbett D, Black D, Roberts TV, et al.

 Eye (Lond). 2024;38(Suppl 1):9-14.

OVERVIEW



Study Design

- Prospective, multi-center, randomized, subject/evaluator-masked study



Study IOL(s)/Number of eyes/patients and Study Duration

- TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / 60 bilateral subjects / 3-6-month follow-ups
- TECNIS Eyhance™ IOL ICB00 (Johnson & Johnson Vision) / 57 bilateral subjects / 3-6-month follow-ups
- *Historical visual acuity and visual symptoms data on TECNIS™ 1-Piece Monofocal IOL ZCB00 (n=131) at 6 months are presented for comparison purposes.*



Key End Points

- Monocular uncorrected and best-corrected visual acuities at distance (UDVA, CDVA), intermediate at 66 cm (UIVA, DCIVA), and near at 40 cm (UNVA, DCNVA), mean post-op manifest refraction spherical equivalent (MRSE), mean post-op refractive cylinder, results from Patient Reported Visual Symptoms Questionnaire (PRVSQ), monocular defocus curve, monocular mesopic contrast sensitivity

KEY TAKEAWAYS

Results

Visual Acuties and Refractive Outcomes:

- Mean monocular CDVA was -0.06 ± 0.08 logMAR for TECNIS PureSee™ IOL and -0.05 ± 0.08 for TECNIS Eyhance™ IOL.
- Mean monocular DCIVA was 0.13 ± 0.08 logMAR for TECNIS PureSee™ IOL and 0.18 ± 0.14 for TECNIS Eyhance™ IOL ($p=0.0127$).
 - TECNIS PureSee™ IOL demonstrated superior and more consistent outcomes, with 81.7% of eyes achieving 0.20 logMAR or better monocular DCIVA compared to 60.3% in the TECNIS Eyhance™ IOL group.
- Mean monocular DCNVA was 0.37 ± 0.10 logMAR for TECNIS PureSee™ IOL and 0.43 ± 0.16 for TECNIS Eyhance™ IOL ($p=0.0137$).
- Mean post-op MRSE and cylinder for TECNIS PureSee™ IOL was 0.08 ± 0.32 D and 0.44 ± 0.35 D, respectively, compared to -0.20 ± 0.41 D and 0.39 ± 0.26 D for TECNIS Eyhance™ IOL, respectively.
- 91.7% of TECNIS PureSee™ IOL and 87.9% of TECNIS Eyhance™ IOL first eyes achieved absolute MRSE within ± 0.50 D of emmetropia.
 - None of TECNIS PureSee™ IOL eyes had a MRSE exceeding ± 1.00 D, compared to 1.7% of TECNIS Eyhance™ IOL eyes.
 - None of TECNIS Eyhance™ IOL eyes had refractive cylinder exceeding ± 1.00 D, compared to 6.7% of TECNIS PureSee™ IOL eyes (all within 1.00 to 1.50 D).

Quality of Vision Clinical Outcomes for a New Fully-Refractive Extended Depth of Focus Intraocular Lens

KEY TAKEAWAYS

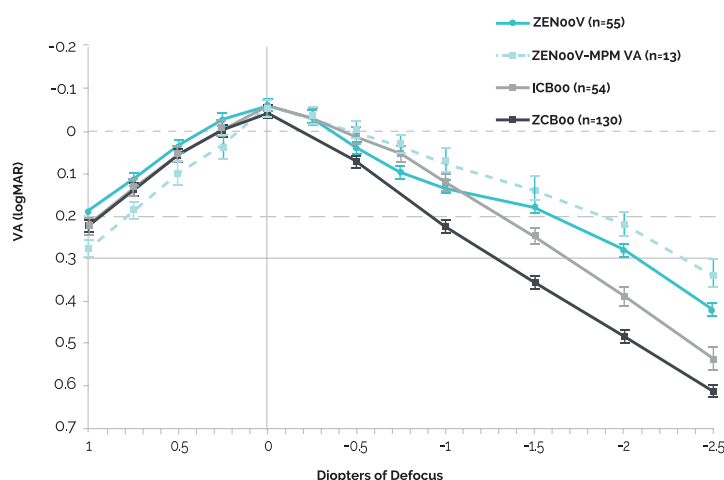
Results

Range and Quality of Vision:

- The monocular negative defocus range, where VA of 0.20 logMAR or better was achieved, extended to -1.6 D for TECNIS PureSee™ IOL and -1.3 D for TECNIS Eyhance™ IOL at 3 months.
 - The defocus range of TECNIS PureSee™ IOL increased by 0.3 D when a maximum plus for maximum visual acuity refraction (MPMVA) was used.
 - The TECNIS PureSee™ IOL with MPMVA refraction surpassed TECNIS Eyhance™ IOL and TECNIS™ 1-Piece Monofocal IOL by -0.6 D and -1.0 D, respectively, in maintaining VA of 0.20 logMAR or better.
- Monocular mesopic contrast sensitivity, with and without glare, was comparable between the two groups.
- PRVSQ results revealed no significant differences between TECNIS PureSee™ IOL and the monofocal IOLs in frequency or bothersome level of visual symptoms.

	Frequency of Symptom: Never, Rarely or Sometimes experienced			Bothersomeness of Symptom: Did not experience, were not bothered, or were slightly bothered		
	Halo	Starburst	Glare	Halo	Starburst	Glare
TECNIS PureSee™ IOL (n=60)	88.3%	96.7%	100%	91.7%	95.0%	95.0%
TECNIS Eyhance™ IOL (n=57)	91.3%	94.7%	100%	96.5%	100%	98.2%
TECNIS™ 1-Piece IOL (n=131)	95.4%	96.2%	98.5%	94.7%	93.9%	96.2%

Monocular distance-corrected defocus curves



Mean monocular, distance corrected defocus curves at 3 months for ZENooV and ICB00 ranging from +1.00 D to -2.50 D and at 6 months for ZCB00 (historical control), ranging from +1.00 D to -2.50 D. The defocus curve for ZENooV from +1.00 D to -2.50 D, obtained with maximum plus refraction (MPMVA) sub-study, is also depicted. Error bars represent $\pm$ SE.

Conclusions

The TECNIS PureSee™ IOL provides excellent distance and intermediate plus functional near vision while maintaining high-quality vision, contrast sensitivity, and a dysphotopsia profile comparable to a monofocal IOL. Although modern multifocal IOLs are more likely to provide better near vision and, therefore, more spectacle independence than EDOF IOLs, each individual patient needs to weigh whether that improvement outweighs the adverse effects of multifocal IOLs (increased rates of dysphotopsia and loss in contrast).

Comparison of Functional Outcomes, Presence of Dysphotopsia, and Patient Satisfaction at 3 Months after Implantation of Two Extended Depth of Focus Intraocular Lenses



Galan B.



Presented at the Societatea Română de Cataractă și Chirurgie Refractivă (SRCCR), Eforie Nord, Romania, 2024

OVERVIEW



Study Design

- Prospective, single-center study



Study IOL(s)/Number of eyes/patients and Study Duration

- TECNIS PureSee™ IOL (Johnson & Johnson Vision) / 20 bilateral subjects / 3-month follow-up
- AcrySof™ Vivity™ IOL (Alcon) / 20 bilateral subjects / 3-month follow-up



Key End Points

- Binocular distance-corrected visual acuities at distance (DCVA) and intermediate (DCIVA), near reading speed, contrast sensitivity, defocus curve, patient satisfaction questionnaire

KEY TAKEAWAYS

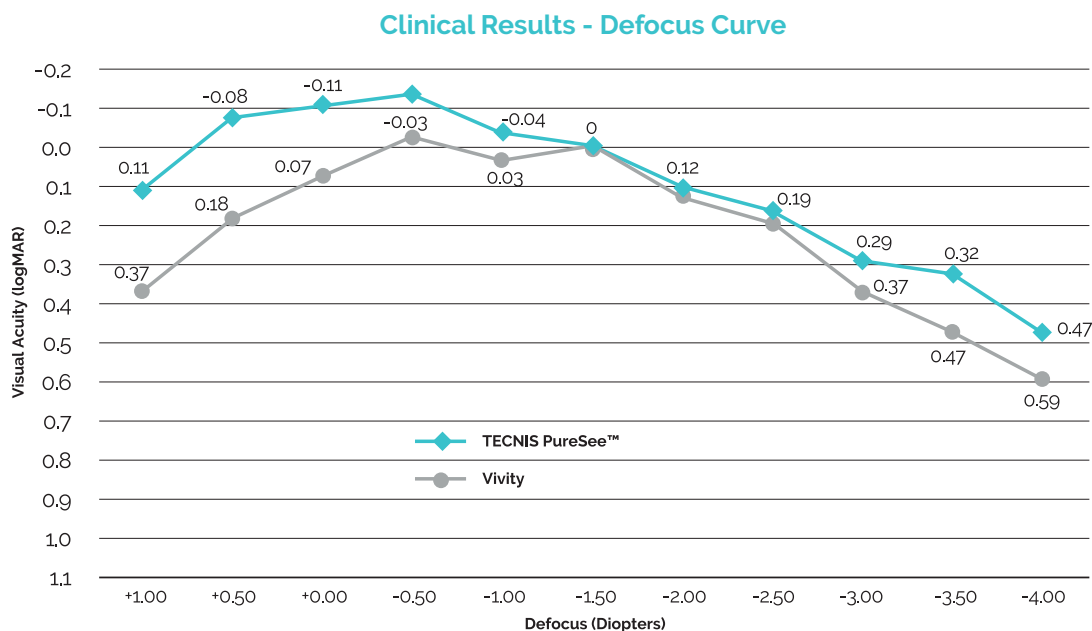
Results

- Mean DCVA from TECNIS PureSee™ IOL was significantly better than that from Vivity™ IOL: -0.069 ± 0.047 logMAR vs 0.002 ± 0.036 logMAR ($p < 0.0001$), respectively.
- Mean DCIVA from TECNIS PureSee™ IOL and Vivity™ IOL were comparable: 0.104 and 0.165 logMAR at 63 cm (normal contrast letters), 0.184 and 0.26 logMAR at 63 cm (low contrast), 0.041 and 0.078 logMAR at 100 cm (normal contrast), and 0.131 and 0.179 logMAR at 100 cm (low contrast), respectively.
- TECNIS PureSee™ IOL patients demonstrated significantly faster reading speed than those with Vivity™ IOL: 166.4 ± 17.9 words/min vs 128.1 ± 9.0 words/min for 0.45 logRAD print size ($p < 0.0001$), respectively.
- TECNIS PureSee™ IOL showed better tolerance to residual refractive error than Vivity™ IOL, as demonstrated by results from induced refractive error on top of distance correction:
 - Sphere of +1 D: TECNIS PureSee™ IOL 0.033 vs Vivity™ IOL 0.115 logMAR
 - Sphere of -0.75 D: TECNIS PureSee™ IOL 0.072 vs Vivity™ IOL 0.18 logMAR
 - Cyl of -1 x 90: TECNIS PureSee™ IOL 0.059 vs Vivity™ IOL 0.132 logMAR
 - Cyl of -1 x 180: TECNIS PureSee™ IOL 0.055 vs Vivity™ IOL 0.147 logMAR
- Contrast sensitivities were comparable and within the normal range for both IOL groups.
- Patient satisfaction was similar between the two IOL groups.
 - 100% of patients from both groups were extremely or very satisfied with their vision in general.
 - 100% of TECNIS PureSee™ IOL patients reported to never or occasionally experience visual disturbances (halos/glare) at dusk/night vs 90% (18/20) of Vivity™ IOL patients.

Comparison of Functional Outcomes, Presence of Dysphotopsia, and Patient Satisfaction at 3 Months after Implantation of Two Extended Depth of Focus Intraocular Lenses

KEY TAKEAWAYS

Results



Conclusions

In this study cohort, patients implanted with the purely refractive EDF TECNIS PureSee™ IOL demonstrated statistically superior best-corrected distance vision, better tolerance to residual refractive error, and faster reading speed compared to patients implanted with AcrySof™ Vivity™ IOL. Contrast sensitivity, patient satisfaction, and reported incidence of photic phenomena were similar in both groups.

Evaluation of Tolerance to Residual Refractive Errors Following Implantation with a Refractive Extended Depth of Focus (EDF) IOL



Bala C, Black D, Vilupuru V, Alarcon A, Tsai L.



Presented at the American Society of Cataract and Refractive Surgery (ASCRS), Boston, California, 2024

OVERVIEW



Study Design

- Prospective, multi-center, randomized, subject/evaluator-masked study



Study IOL(s)/Number of eyes/patients and Study Duration

- TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / 60 bilateral subjects* / 6-month follow-up
- TECNIS Eyhance™ IOL ICB00 (Johnson & Johnson Vision) / 58 bilateral subjects* / 6-month follow-up

*Data collected from sub-group analysis of subjects with residual error of >0.25 D in one or both eyes to study effect of residual refractive error on distance vision and patient satisfaction



Key End Points

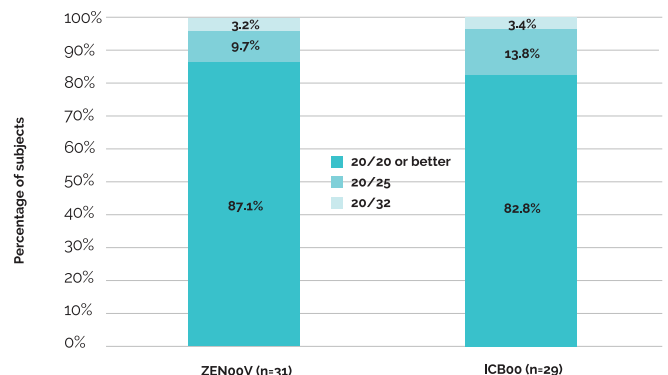
- Binocular uncorrected distance vision (UCDVA), post-op manifest spherical equivalent (SEQ), patient-reported glasses wear and satisfaction

KEY TAKEAWAYS

Results

- There were similar magnitudes of absolute SEQ in both groups – TECNIS PureSee™ IOL: 0.36 ± 0.19 D, TECNIS Eyhance™ IOL: 0.46 ± 0.25 D.
- 87% of TECNIS PureSee™ IOL subjects vs. 83% of TECNIS Eyhance™ IOL subjects with mild residual refractive error achieved 20/20 or better binocular UCDVA.
- 100% of TECNIS PureSee™ IOL subjects with residual refractive error vs 97% of TECNIS Eyhance™ IOL subjects did not need or wear glasses/contacts post-op.
- 94% of TECNIS PureSee™ IOL subjects with residual refractive error vs 83% of TECNIS Eyhance™ IOL subjects were satisfied with their vision without glasses/contacts.

Binocular UDVA



Conclusions

The purely refractive EDF TECNIS PureSee™ IOL provides excellent distance vision comparable to a monofocal and high patient satisfaction, even in the presence of mild post-op residual refractive error.

Visual Performance Outcomes of a Refractive Extended Depth of Focus Intraocular Lens

 Bala C, Vilupuru V, Alarcon A, Tsai L.

 Presented at the American Society of Cataract and Refractive Surgery (ASCRS), Boston, California, 2024

OVERVIEW



Study Design

- Prospective, multi-center, randomized, subject/evaluator-masked study



Study IOL(s)/Number of eyes/patients and Study Duration

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- TECNIS Eyhance™ IOL ICB00 (Johnson & Johnson Vision) / 58 bilateral subjects / 3-, 6-month follow-ups
- *Historical visual acuity and visual symptoms data on TECNIS™ 1-Piece Monofocal IOL ZCB00 (n=131) at 6 months are presented for comparison purposes.*



Key End Points

- Monocular distance-corrected visual acuities at distance (DCVA) and intermediate (DCIVA), monocular defocus curve, monocular mesopic contrast sensitivity, patient-reported visual symptoms and satisfaction

KEY TAKEAWAYS

Results

- ZENooV demonstrated statistically superior DCIVA as compared to ICB00 ($p=0.0127$), with 82% of ZENooV eyes vs. 60% of ICB00 eyes achieving 0.20 logMAR (20/32) or better.
- ZENooV demonstrated comparable DCVA as compared to ICB00, with 100% of ZENooV eyes vs. 97% of ICB00 eyes achieving 0.10 logMAR (20/25) or better.
- Monocular defocus curves showed that ZENooV provided +0.7 D greater range of vision than ZCB00 at 0.2 logMAR, and 82% of ZENooV eyes achieved DCIVA of 0.2 logMAR or better, thus meeting the ANSI standard for extended-depth-of-focus (EDF) classification.
- Monocular mesopic contrast sensitivities, with and without glare, were comparable between the two groups.
- ZENooV demonstrated low levels of bothersome visual symptoms at 6 months: $\geq 93\%$ of subjects did not experience or were not/slightly bothered by halos, starbursts, and glare.
 - Only 0%, 2% ($n=1$), and 2% ($n=1$) of subjects were extremely bothered by halos, starbursts, and glare, respectively.
- There was high patient satisfaction for vision across all distances without correction: 96%, 92%, and 70% of subjects reported that they were completely/mostly satisfied without glasses for distance, intermediate, and near, respectively.
 - 97% of subjects would recommend this lens to family and friends.

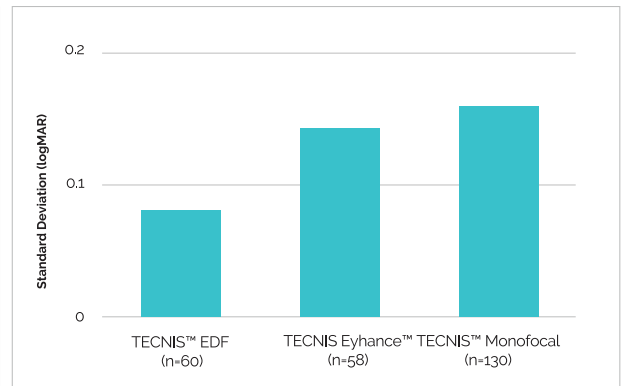
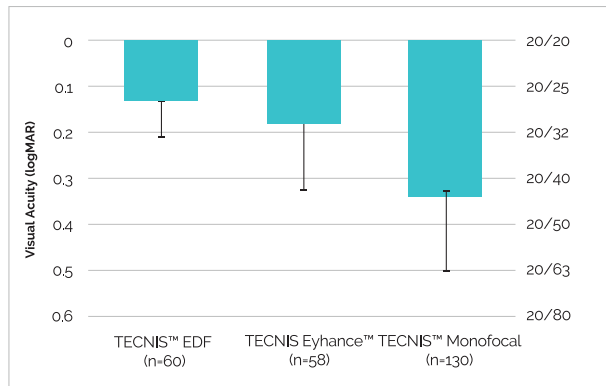
Visual Performance Outcomes of a Refractive Extended Depth of Focus Intraocular Lens

KEY TAKEAWAYS

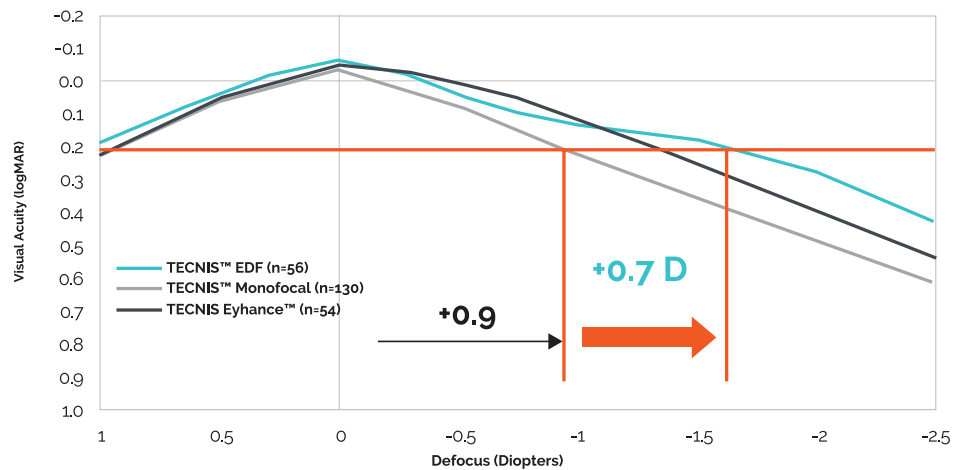
Results

Statistically Superior intermediate vision to TECNIS Eyhance™ (P-value = 0.0127)

Consistent with less variability in outcomes



Monocular Depth of Focus at 6 Months



Conclusions

TECNIS PureSee™ IOL provides a consistent depth of with functional near vision while delivering high-quality distance vision, contrast, and low rates of bothersome visual focus symptoms comparable to a monofocal.

Improvement in Outcomes with Refinement of Refractive Methodology in Patients Implanted with Refractive Extended Depth of Focus Intraocular Lenses

 Black D, Hoffman M, Smith N, Vilupuru V, Alarcon A, Shamp W, Tsai L.

 Presented at the European Society of Cataract and Refractive Surgeons (ESCRS), Vienna, Austria, 2023

OVERVIEW



Study Design



Study IOL(s)/Number of eyes/patients and Study Duration



Key End Points

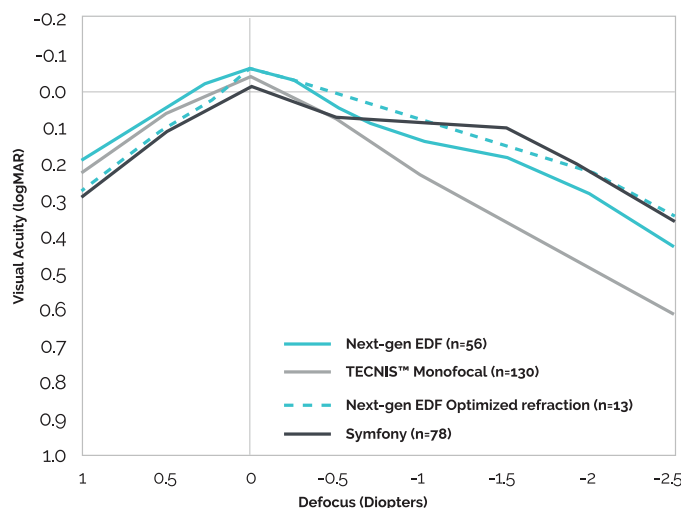
- Prospective, randomized, subject/evaluator-masked study
- Main cohort: TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / 56 bilateral subjects evaluated with standard refraction
- Subgroup: TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / subgroup of 13 bilateral subjects from main cohort re-assessed with max plus for max distance vision (MPMV) refraction technique
- Monocular best-corrected visual acuities at distance (BCDVA), intermediate (DCIVA), and near (DCNVA), post-op manifest refraction, monocular defocus curve

KEY TAKEAWAYS

Results

- Compared to the standard refraction group, the MPMV subgroup demonstrated 0.25 D more hyperopic manifest refraction using the "push plus" MPMV technique.
- There were no differences in BCDVA between the two groups, but defocus testing revealed a 0.5-line improvement in DCIVA at -1.50 D (66 cm) and 1-line improvement in DCNVA at -2.50 D (40 cm) with the MPMV technique compared to standard refraction.
- Defocus curves revealed a wider depth of focus with MPMV technique (1.9 D) compared to standard refraction (1.6 D).

Monocular Defocus Curve



Conclusions

Accurate refraction is critical in optimizing the full range of vision offered by an IOL with high tolerance to refractive errors and for IOL constant optimization. Utilizing the maximum plus refraction technique for TECNIS PureSee™ IOL can provide a wider depth of focus and improvements in DCIVA and DCNVA as compared to standard refraction technique.

Six-Month Visual Performance Outcomes of a Purely Refractive Extended Depth of Focus Intraocular Lens

 Bala C, Corbett D, Vilupuru V, Alarcon A, Tsai L.

 Presented at the European Society of Cataract and Refractive Surgeons (ESCRS), Vienna, Austria, 2023

OVERVIEW



Study Design

- Prospective, multi-center, randomized, subject/evaluator-masked study



Study IOL(s)/Number of eyes/patients and Study Duration

- TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / 60 bilateral subjects / 6-month follow-up
- Historical visual acuity and visual symptoms data on TECNIS™ 1-Piece Monofocal IOL ZCB00 (n=131) at 6 months are presented for comparison purposes.*



Key End Points

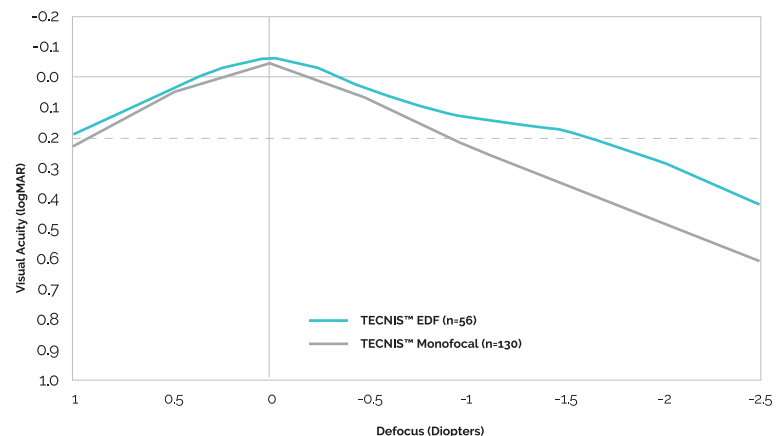
- Monocular best-corrected visual acuities at distance (BCDVA), intermediate (DCIVA), and near (DCNVA), monocular defocus curve, patient-reported visual symptoms

KEY TAKEAWAYS

Results

- The TECNIS PureSee™ IOL ZENooV meets all ANSI Z80.35 criteria for EDF IOL classification.
- Criteria #1: statistical superiority in mean DCIVA over a monofocal IOL.
 - Mean DCIVA was 0.13 logMAR for ZENooV and 0.34 logMAR for ZCB00 (2 lines better than ZCB00).
- Criteria #2: at least 50% of eyes achieve DCIVA within 0.2 logMAR.
 - 82% of ZENooV eyes achieved DCIVA within 0.2 logMAR vs 18% of ZCB00 eyes (60% more eyes than ZCB00).
- Criteria #3: at least +0.50 D greater range of vision than a monofocal at 0.2 logMAR.
 - ZENooV showed +0.7 D greater range of vision than ZCB00 at 0.2 logMAR.
- Criteria #4: mean BCDVA is non-inferior to that of a monofocal (within 1 line).
 - Mean BCDVA was -0.06 logMAR for ZENooV and -0.05 logMAR for ZCB00 (non-inferior BCDVA to ZCB00).
- The mean DCNVA (not an ANSI EDF criteria) for ZENooV was ~2 lines better than ZCB00 (ZENooV 0.37 logMAR vs ZCB00 0.52 logMAR).

Monocular Defocus Curve at 6 Months



Conclusions

The purely refractive EDF IOL, TECNIS PureSee™ IOL ZENooV, fulfills the ANSI EDF criteria when compared to its parent TECNIS™ monofocal IOL ZCB00 by providing excellent intermediate vision, extended range of vision, and non-inferior distance vision.

Clinical Evaluation of Tolerance to Residual Refractive Errors with a Refractive Extended Depth of Focus IOL

 Black D, Alarcon A, Vilupuru V, Tsai L.

 Presented at the European Society of Cataract and Refractive Surgeons (ESCRS), Vienna, Austria, 2023

OVERVIEW



Study Design

- Prospective, multi-center, randomized, subject/evaluator-masked study



Study IOL(s)/Number of eyes/patients and Study Duration

- TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / 31* out of 60 bilateral subjects / 6-month follow-up
- TECNIS Eyhance™ IOL ICB00 (Johnson & Johnson Vision) / 29* out of 57 bilateral subjects / 6-month follow-up

*Subjects that had absolute spherical equivalent >0.25 D in one or both eyes were included in the subgroup evaluation.



Key End Points

- Binocular uncorrected distance vision (UCDVA), post-op spherical equivalent (SEQ) and refractive cylinder, patient-reported glasses wear and satisfaction

KEY TAKEAWAYS

Results

- There was similar magnitude and distribution of mean residual refractive error in both groups.
 - SEQ: 0.36 ± 0.19 D for TECNIS PureSee™ IOL, 0.46 ± 0.25 D for TECNIS Eyhance™ IOL.
 - Refractive cylinder: 0.47 ± 0.30 D for TECNIS PureSee™ IOL, 0.47 ± 0.31 D for TECNIS Eyhance™ IOL.
- Binocular UCDVA was comparable between the two groups: -0.03 ± 0.08 logMAR for TECNIS PureSee™ IOL, -0.02 ± 0.11 logMAR for TECNIS Eyhance™ IOL.
- 87% of TECNIS PureSee™ IOL subjects vs. 83% of TECNIS Eyhance™ IOL subjects with mild residual refractive error achieved 20/20 or better binocular UCDVA.
- 100% of TECNIS PureSee™ IOL subjects with residual refractive error vs 97% of TECNIS Eyhance™ IOL subjects did not need or wear glasses/contacts post-op.
- 94% of TECNIS PureSee™ IOL subjects with residual refractive error vs 83% of TECNIS Eyhance™ IOL subjects were satisfied with their vision without glasses/contacts.

Conclusions

The TECNIS PureSee™ IOL ZENooV provides high tolerance to residual refractive error, as demonstrated by excellent uncorrected distance vision and high patient satisfaction in The TECNIS PureSee™ IOL patients with mild residual refractive error.

Superior Intermediate and Uncompromised Distance Quality of Vision with a Purely Refractive Extended Depth of Focus IOL

 Bala C, Vilupuru V, Alarcon A, Tsai L.

 Presented at the European Society of Cataract and Refractive Surgeons (ESCRS), Vienna, Austria, 2023

OVERVIEW



Study Design

- Prospective, multi-center, randomized, subject/evaluator-masked study



Study IOL(s)/Number of eyes/patients and Study Duration

- TECNIS PureSee™ IOL ZENooV (Johnson & Johnson Vision) / 60 bilateral subjects / 3-, 6-month follow-ups
- TECNIS Eyhance™ IOL ICB00 (Johnson & Johnson Vision) / 58 bilateral subjects / 3-, 6-month follow-ups
- *Historical visual acuity and visual symptoms data on TECNIS™ 1-Piece Monofocal IOL ZCB00 (n=131) at 6 months are presented for comparison purposes.*



Key End Points

- Monocular best-corrected visual acuities at distance (BCDVA) and intermediate (DCIVA), binocular defocus curve, monocular mesopic contrast sensitivity, patient-reported visual symptoms

KEY TAKEAWAYS

Results

- TECNIS PureSee™ IOL demonstrated statistically superior monocular DCIVA as compared to TECNIS Eyhance™ IOL ($p=0.0127$), with 82% of TECNIS PureSee™ IOL eyes vs. 60% of TECNIS Eyhance™ IOL eyes achieving 0.20 logMAR (20/32) or better.
- TECNIS PureSee™ IOL demonstrated comparable monocular BCDVA as TECNIS Eyhance™ IOL, with 100% of TECNIS PureSee™ IOL eyes vs. 97% of TECNIS Eyhance™ IOL eyes achieving 0.10 logMAR (20/25) or better.
- Binocular TECNIS PureSee™ IOL defocus curve showed excellent, balanced distance vision over ± 0.50 D defocus as well as functional near vision at 40 cm.
- Monocular mesopic contrast sensitivities, with and without glare, were comparable between the two groups.
- TECNIS PureSee™ IOL demonstrated low levels of bothersome visual symptoms at 6 months: $\geq 93\%$ of subjects did not experience or were not/slightly bothered by halos, starbursts, and glare.
 - Only 0%, 2% ($n=1$), and 2% ($n=1$) of subjects were extremely bothered by halos, starbursts, and glare, respectively.

Conclusions

The TECNIS PureSee™ IOL utilizes refractive technology based on continuous changes in power, that distributes light from far to near, to enable a consistent depth of focus with functional near vision while delivering high-quality distance vision, contrast under low light conditions, and dysphotopsia profile comparable to a monofocal IOL.

Optical Bench Evaluation of New Extended Depth of Focus Intraocular Lenses

 Pande M, Alarcon A, Del Águila-Carrasco AJ, Canovas C.

 Presented at the European Society of Cataract and Refractive Surgeons (ESCRS), Vienna, Austria, 2023

OVERVIEW

 Study Design	 Study IOL(s)/Number of eyes/patients and Study Duration	 Key End Points
Optical bench study	- TECNIS PureSee™ IOL DEN00V (Johnson & Johnson Vision) - LuxSmart™ IOL YSMART (Bausch + Lomb) - AcrySof™ IQ Vivity™ IOL DFT015 (Alcon) <i>Bench testing performed in a physical eye model that accounts for the average spherical and chromatic aberration of the cornea: 0.27 μm and 1.04 D, respectively. Measurements were collected in white light for different pupils from 2 to 5 mm.</i>	Modulation transfer function (MTF) at 50 c/mm, monocular simulated visual acuity (sVA)

KEY TAKEAWAYS

Results

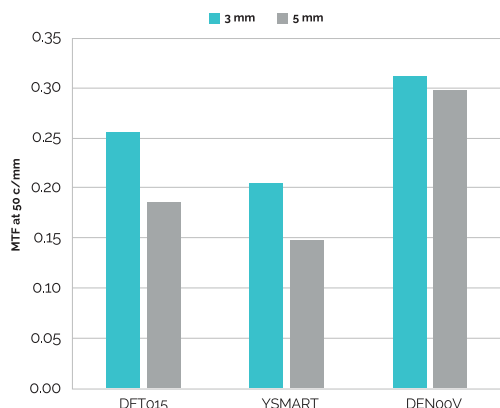
- The MTF of TECNIS PureSee™ IOL was 20% and 36% higher than that of DFT015 for 3- and 5-mm pupil sizes, respectively, and 35% and 53% higher than that of YSMART.
- All three EDF IOLs increased the depth of focus (DOF) as compared to a monofocal IOL.
 - DOF for the average photopic pupil size (3-mm) was 0.8 D for TECNIS PureSee™ IOL, 0.6 D for DFT015, and 0.4 D for YSMART.
- In photopic conditions (2- and 3-mm pupils), TECNIS PureSee™ IOL provided superior range of vision, with similar intermediate VA and between 1- and 1.5-lines better near VA, than both DFT015 and YSMART.
- In mesopic conditions (4-mm), the three IOLs provided similar intermediate and near VAs.
- TECNIS PureSee™ IOL showed the smallest reduction in MTF among the tested IOLs when pupil opened from photopic (3-mm) to mesopic (5-mm) light conditions.

Optical Bench Evaluation of New Extended Depth of Focus Intraocular Lenses

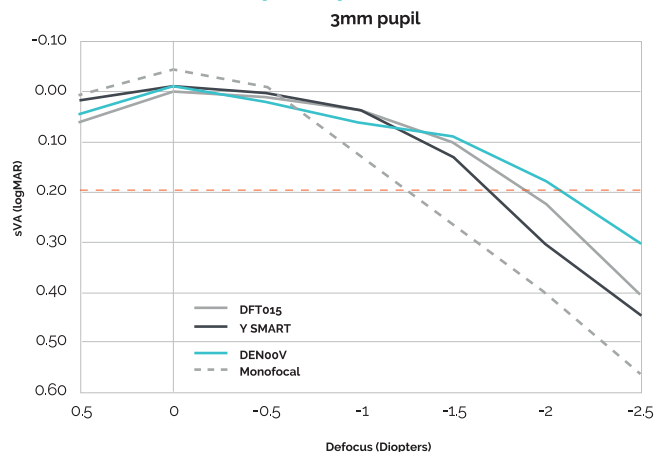
KEY TAKEAWAYS

Results

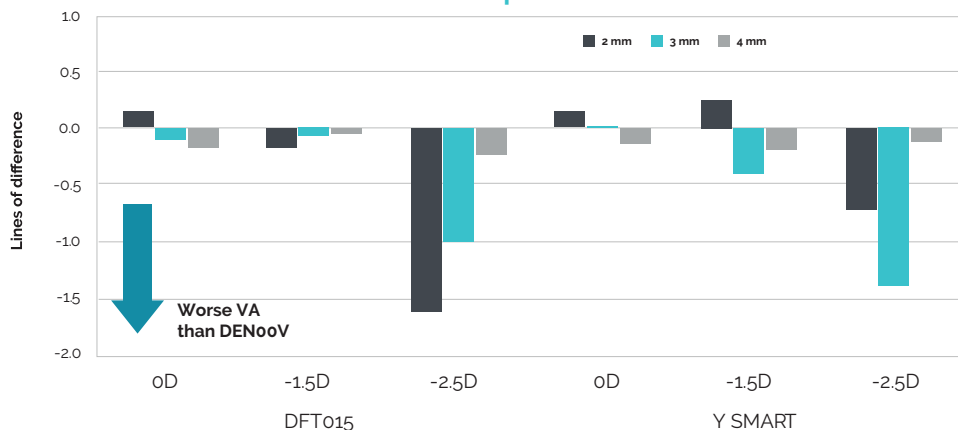
Distance image quality in photopic and mesopic conditions



Simulated monocular VA in photopic condition



Difference in sVA respect to model DEN00V



Decrease in image quality when pupil opens from photopic (3mm) to mesopic (5mm) light conditions

Conclusions

Optical bench testing showed that the TECNIS PureSee™ IOL DEN00V provided higher distance image quality for photopic and mesopic pupils than AcrySof™ IQ Vivity™ and LuxSmart™ IOLs. While all three IOLs provided similar intermediate sVA, DEN00V demonstrated superior photopic near sVA than the other two IOLs as well as the smallest reduction in MTF when going from photopic to mesopic light conditions.

Chromatic Aberration of Four Extended Depth of Focus Intraocular Lenses Compared to Monofocal Lenses

 Auffarth G, Del Águila-Carrasco AJ, Weeber H, Alarcon A, Canovas C.

 Presented at the European Society of Cataract and Refractive Surgeons (ESCRS), Vienna, Austria, 2023

OVERVIEW



Study Design

- Optical bench study



Study IOL(s)/Number of eyes/patients and Study Duration

- EDOF1: Diffractive EDOF – compensates for average corneal SA [TECNIS Symphony™ IOL (Johnson & Johnson Vision)]
- EDOF2: "Wavefront-shaping" EDOF – partially compensates for average corneal SA [Vivity™ IOL (Alcon)]
- EDOF3: Zonal SA-based refractive EDOF – SA neutral [Luxsmart™ IOL (Bausch + Lomb)]
- EDOF4: Purely refractive EDOF – compensates for average corneal SA [TECNIS PureSee™ IOL (Johnson & Johnson Vision)]
- M: Monofocal – compensates for average corneal SA [TECNIS™ 1-Piece Monofocal IOL (Johnson & Johnson Vision)]
- EM: Enhanced monofocal – compensates for average corneal SA [TECNIS Eyhance™ IOL (Johnson & Johnson Vision)]
- Bench testing performed in a physical eye model that accounts for the average spherical and chromatic aberration of the cornea. Measurements were obtained for five pupil sizes (1 to 5 mm, in 1 mm steps).



Key End Points

- Through-focus monochromatic modulation transfer function (MTF) at 50 c/mm, longitudinal chromatic aberration (LCA)

KEY TAKEAWAYS

Results

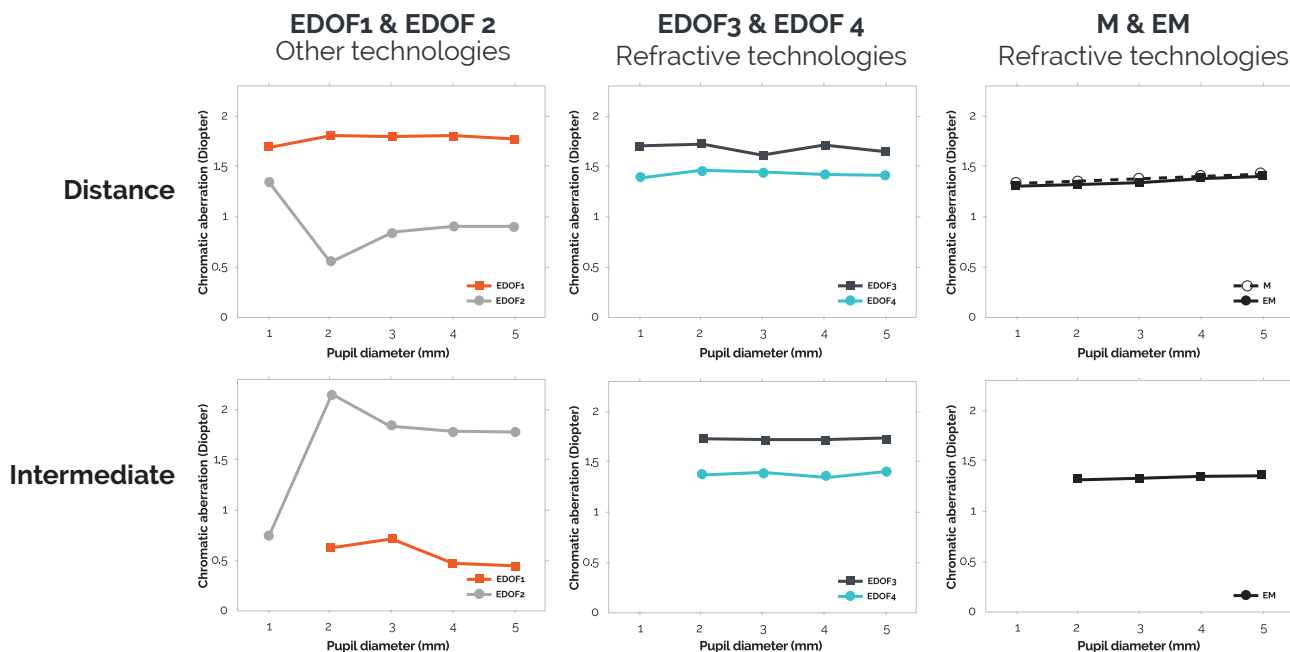
- For distance vision, the maximum through pupil change in LCA was comparable for all lens models (about 0.10 D), except for the diffractive EDOF IOL (EDOF1), that showed a change in LCA of 0.79 D.
- For intermediate vision, the maximum through pupil change in LCA was less than 0.10 D for all lens models, except for the diffractive EDOF (EDOF1) and "wavefront-shaping" EDOF (EDOF2) IOLs, that showed changes in LCA of 0.27 D and 1.40 D, respectively.

Chromatic Aberration of Four Extended Depth of Focus Intraocular Lenses Compared to Monofocal Lenses

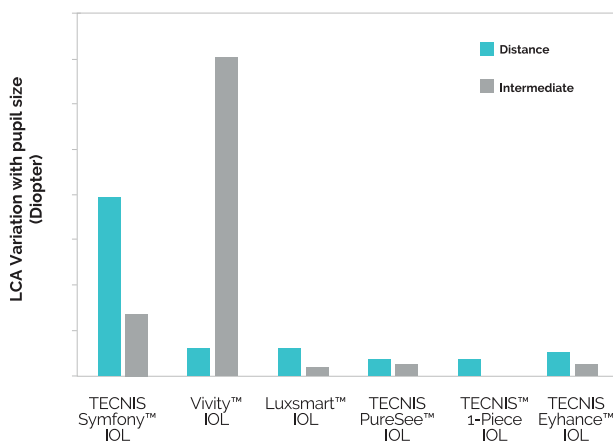
KEY TAKEAWAYS

Results

Chromatic Aberration and Pupil Size



LCA Variation with Pupil Size



Conclusions

The optical bench study results showed that chromatic aberration remained constant across all pupil sizes for all refractive IOLs tested (refractive monofocal and EDOF IOLs), while IOLs based on other technologies (diffractive, wavefront-shaping) showed abrupt changes in chromatic aberration with pupil size.

