Original Article

Comparison of U.S. FDA premarket approval studies between two non-diffractive extended depth of focus lenses (AcrySof IQ Vivity versus TECNIS PureSee)

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ABSTRACT

Background: Several recent clinical studies have directly compared TECNIS PureSee with lenses from the Vivity platform; however, direct comparative clinical data specifically involving AcrySof IQ Vivity remain limited. Therefore, we aimed to indirectly compare the visual and patient-reported outcomes of two non-diffractive extended depth of focus (EDOF) intraocular lenses (IOLs), AcrySof IQ Vivity and TECNIS PureSee, using data from their respective FDA premarket approval (PMA) studies.

Methods: In this indirect cross-trial comparison, aggregate 6-month outcomes were compared from the FDA Summary of Safety and Effectiveness Data for the Vivity (107 implanted subjects) and PureSee (116 subjects in the intent-to-treat population; 115 in the safety population) PMA studies. The principal binocular visual-acuity threshold comparisons included 106 Vivity subjects from the All-Implanted population and 113 PureSee subjects from the Safety Population with observed 6-month data. Both were prospective, randomized, masked trials of bilateral implantation against a monofocal control from the same manufacturer. Outcomes included binocular visual acuity thresholds at distance, intermediate, and near, depth of focus at the 0.20 logarithm of the minimum angle of resolution (logMAR) threshold, mesopic contrast sensitivity, ISO 11979-7 safety endpoints, visual symptoms, and spectacle independence. Categorical visual acuity outcomes were compared using chi-square or Fisher's exact tests, with absolute risk differences and 95% confidence intervals (CIs) and Holm adjustment for multiple comparisons. Contrast sensitivity, visual symptoms, spectacle independence, and defocus curves were summarized descriptively.

Results: At distance, the PureSee FDA trial reported more subjects reaching 0.00 logMAR or better for uncorrected distance visual acuity (68.1% versus 44.3%; risk difference [RD], −23.8 percentage points [pp]; 95% CI, −35.8 to −10.7; Holm-adjusted $P < 0.05$) and best-corrected distance visual acuity (92.0% versus 73.6%; RD, −18.5 pp; 95% CI, −28.3 to −8.6; Holm-adjusted $P < 0.05$). At intermediate distance, the Vivity FDA trial reported more subjects reaching distance-corrected intermediate visual acuity of 0.00 logMAR or better (40.6% versus 10.6%; RD, +29.9 pp; 95% CI, +18.6 to +40.4; Holm-adjusted $P < 0.001$). No near-vision threshold comparison remained significant after Holm adjustment. Monocular depth of focus was 1.53 D for Vivity and 1.77 D for PureSee, representing gains of +0.54 D and +0.64 D over their respective monofocal controls. Descriptively, more Vivity eyes were unable to detect the mesopic contrast reference pattern at 6 and 12 cpd with and without glare. Visual symptoms and spectacle independence were also reported descriptively because the trials used different questionnaires. Each trial met the safety and performance endpoint limits applicable to its respective ISO 11979-7 edition.

Conclusions: At the 0.00 logMAR threshold, PureSee reported higher proportions of subjects reaching corrected and uncorrected distance acuity, while Vivity reported a higher proportion reaching distance-corrected intermediate acuity. No near-vision threshold difference remained significant after multiplicity adjustment. Contrast sensitivity and patient-reported outcomes were interpreted descriptively because of differences in testing and questionnaire methods. Overall, the two FDA trials showed different patterns of visual performance, supporting the need for prospective head-to-head comparison.

KEYWORDS

intraocular lens, visual contrast sensitivity, visual acuity, AcrySof IQ Vivity, TECNIS PureSee

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INTRODUCTION

Premium intraocular lenses (IOLs) have been developed to expand functional vision beyond the distance-focused outcomes of standard monofocal lenses. Multifocal designs achieve this by splitting light into separate focal points, but that split comes at a cost: increased dysphotopsia, including halos and glare, and in some studies reduced contrast sensitivity [1]. Extended depth of focus (EDOF) IOLs were developed to address this tradeoff, providing a more continuous range of vision while limiting these visual disturbances [2].

EDOF designs can be diffractive or non-diffractive [3]. Wavefront-shaping IOLs are one non-diffractive approach to extending depth of focus. Rather than splitting light into discrete focal points, a wavefront-shaping optic reshapes the wavefront at the lens so that light forms an elongated focal range [4]. The AcrySof IQ Vivity IOL (Alcon Laboratories, Inc., Fort Worth, TX, USA) uses a central 2.2-mm transition zone on the anterior optic that stretches and shifts the wavefront [4]. The TECNIS PureSee IOL (Johnson & Johnson Vision, Irvine, CA, USA) instead uses a purely refractive modulated power profile on the posterior surface, while the anterior aspheric surface compensates for corneal spherical aberration [5, 6]. Although both are non-diffractive EDOF IOLs, their labeled indications differ: Vivity's labeling highlights improved intermediate and near visual acuity, whereas PureSee's emphasizes improved intermediate visual acuity while maintaining distance vision [6, 7].

Both lenses have demonstrated safety and effectiveness in their respective U.S. Food and Drug Administration (FDA) Premarket Approval (PMA) studies [6, 7]. Several recent clinical studies have directly compared TECNIS PureSee with lenses from the Vivity platform [8, 9]; however, direct comparative clinical data specifically involving AcrySof IQ Vivity remain limited. Among these, Koh et al. compared PureSee with AcrySof IQ Vivity in a real-world cohort of 85 bilaterally implanted patients [8]. However, to our knowledge, no published study has compared the publicly available FDA Summary of Safety and Effectiveness Data (SSED) documents from these two trials. The present study was therefore designed to provide a side-by-side analysis of data reported in the FDA SSEDs for these two non-diffractive EDOF IOLs, including visual acuity (VA) thresholds, depth of focus, mesopic contrast sensitivity, visual symptoms, spectacle independence, and adverse events.

METHODS

Visual and clinical outcomes and patient-reported visual symptoms from two FDA pivotal trials were extracted from their respective SSEDs and compared for participants assigned to bilateral implantation with either the TECNIS PureSee® (PMA P980040/S176) or AcrySof® IQ Vivity (PMA P930014/S126) IOL. Data extraction and verification were performed and rechecked against the original FDA source documents; any discrepancies or transcription errors were resolved by reference to the original SSED. In this analysis, the FDA PMA trials are referred to as the PureSee and Vivity studies.

The Vivity trial treated patients between October 2017 and October 2018, whereas the PureSee trial treated patients between June 2024 and April 2025. Both were prospective, randomized, parallel-group trials with bilateral implantation (Table 1). Randomization occurred within each source trial against a manufacturer-specific monofocal control: the AcrySof SN60WF for Vivity and the TECNIS DCB00 for PureSee. Vivity was conducted across 11 US sites and PureSee across 9 US sites. The two trials therefore enrolled independent patient populations at different sites and time periods, and there was no randomization between Vivity and PureSee.

The Vivity EDOF arm included 107 subjects in the All-Implanted population. One subject was not bilaterally implanted and therefore did not contribute to binocular assessments, resulting in N = 106 for binocular VA outcomes. The PureSee EDOF arm included 116 subjects in the intent-to-treat (ITT) population and 115 in the Safety Population. Of the 115 subjects, 113 had observed 6-month data; two were classified as discontinued/early study exits. The PureSee monocular distance-corrected intermediate VA (DCIVA) estimates at 66 and 100 cm and the monocular defocus curve were based on the ITT population of 116 subjects, with missing data handled by multiple imputation as reported in the PureSee SSED. Other PureSee values were obtained from the Safety Population with observed-case analysis, as identified for each outcome. We performed no additional imputation. Denominators for patient-reported outcomes varied according to item-level response availability and are reported for each outcome. For other outcomes with missing or unavailable responses, analyses used the available data and outcome-specific denominators reported in the respective SSEDs. Both studies targeted emmetropia and included a primary 6-month postoperative evaluation.

Table 1. Study and lens characteristics

Characteristic	Vivity	TECNIS PureSee
PMA number	P930014/S126	P980040/S176
FDA approval	Feb 26, 2020	Mar 11, 2026
EDOF mechanism	Non-diffractive; anterior wavefront-shaping	Purely refractive; posterior OptiCurve modulated power profile
Monofocal control	AcrySof SN60WF	TECNIS DCB00
Design	Prospective, randomized, masked, bilateral	Prospective, randomized, masked, bilateral
Treatment period	Oct 2017 – Oct 2018	Jun 2024 – Apr 2025
US sites	11	9
Implanted EDOF subjects in the All-Implanted or Safety Population (first eyes)	107	115
Follow-up	6 months	6 months
Refractive target	Emmetropia	Emmetropia
VA measurement	ETDRS logMAR, photopic	ETDRS logMAR, photopic

Abbreviations: PMA, premarket approval; FDA, U.S. Food and Drug Administration; Feb, February; Mar, March; EDOF, extended depth of focus; Oct, October; Jun, June; Apr, April; U.S., United States; VA, visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study; logMAR, logarithm of the minimum angle of resolution. Note: The PureSee intent-to-treat population included 116 randomized subjects; 115 subjects comprised the implanted Safety Population.

The studies shared several inclusion and exclusion criteria, as described in their respective PMAs [6, 7]. Each enrolled adults 22 years or older with bilateral cataract, best-corrected distance VA (BCDVA) of 20/40 or worse, clear intraocular media other than cataract, and less than 1.0 D of preoperative keratometric astigmatism. Both excluded subjects desiring monovision or with prior intraocular/corneal surgery, irregular corneas, or significant ocular surface disease. Postoperative assessments were performed after each eye, with a primary 6-month evaluation. The 6-month visit was used for the main VA, depth-of-focus, contrast sensitivity, questionnaire, and safety outcomes. Preoperative assessments overlapped in several areas, while PureSee additionally listed corneal topography and potential acuity testing.

Uncorrected distance VA (UCDVA) and BCDVA were measured at 4 m. Uncorrected intermediate VA (UCIVA) and DCIVA were measured at 66 cm, and uncorrected (UCNVA) and distance-corrected near visual acuities (DCNVA) at 40 cm, monocularly and binocularly. Both studies also reported depth of focus from defocus curves at the 0.20 logarithm of the minimum angle of resolution (logMAR) threshold, mesopic contrast sensitivity with and without glare at 1.5, 3, 6, and 12 cycles per degree (cpd), ISO safety outcomes, visual symptoms, and spectacle independence. Vivity used Questionnaire for Visual Disturbances (QUVID) and Intraocular Lens Satisfaction questionnaire (IOLSAT) for visual symptoms and spectacle independence, respectively, while PureSee used Patient-Reported Visual Symptoms Questionnaire (PRVSQv2) and Patient-Reported Spectacle Independence Questionnaire-v2 (PRSIQv2). Outcomes measured in only one study, including low-contrast VA for Vivity and mesopic VA and 100 cm intermediate VA for PureSee, were reviewed but not formally compared.

Both PMA studies shared their core primary endpoints, evaluating BCDVA noninferiority to a monofocal control, DCIVA superiority at 66 cm, and a depth-of-focus increase of at least 0.50 D at the 0.20 logMAR threshold. They did, however, evaluate near and intermediate vision differently. PureSee additionally treated intermediate VA at 100 cm as a co-primary endpoint and reported near VA at 40 cm only descriptively, whereas Vivity evaluated 40 cm near VA as a formal secondary endpoint. Formal comparisons were therefore limited to outcomes reported by both studies at comparable distances and formats. Values are reported as Vivity versus PureSee throughout.

Analyses were performed using Microsoft Excel (Microsoft Corp., Redmond, WA, USA) and Python 3.13.5 on aggregate data reported in the FDA SSEDs for the Vivity and PureSee PMA studies. Python-based analyses used NumPy 2.3.5 and SciPy 1.17.0. Data were extracted and verified by one reviewer, who rechecked the extracted values against the source SSEDs. Any discrepancies identified during verification were corrected by reference to the source documents. Because patient-level data were not available, normality could not be formally assessed. Continuous

outcomes were compared using Welch's *t*-test when mean, standard deviation (SD), and sample size were available. Mean differences are reported with Welch 95% confidence intervals (CIs). Categorical outcomes were compared using Pearson chi-square test without continuity correction when all expected cell counts were ≥5, and the Fisher exact test when any expected cell count was <5. Race was compared using the Fisher–Freeman–Halton exact test for the 2 × 5 contingency table. The two-sided *P*-value was calculated by exact enumeration using the observed row and column margins. Effect estimates for binary outcomes are reported as absolute risk differences (RD) (Vivity minus PureSee) in percentage points (pp), with 95% CIs calculated using the Newcombe method based on Wilson score intervals. These 95% CIs are unadjusted pointwise intervals and were not adjusted for multiple comparisons. Statistical significance after multiplicity adjustment was determined using the Holm-adjusted *P*-values. No between-study VA comparison was prespecified as a confirmatory hypothesis before examination of the FDA data; therefore, the threshold comparisons were considered exploratory. To account for multiple testing across the 23 testable binocular VA threshold comparisons in Table 4, *P*-values were adjusted using the Holm step-down procedure. Both raw and Holm-adjusted *P*-values are reported, with statistical significance after multiplicity adjustment defined as an adjusted $P < 0.05$.

Visual acuity threshold outcomes were compared when both SSEDs reported the same logMAR cutoff at comparable testing distances. Mean VA values, defocus curves, contrast sensitivity outcomes, visual symptom outcomes, and spectacle independence outcomes were summarized descriptively when reporting differences prevented formal comparison. Defocus-curve coordinates were manually extracted from the published SSED figures using WebPlotDigitizer (Ankit Rohatgi, Automeris LLC) and replotted descriptively because patient-level data and per-point variance estimates were unavailable. Vivity defocus-curve data were extracted from Figure 6 of the Vivity SSED [7], and PureSee data were extracted from Figure 8 of the PureSee SSED [6]. Axes were calibrated using the labeled defocus and logMAR values, and the plotted mean data points were manually digitized. The depth-of-focus values reported in Table 5 (1.53 D for Vivity and 1.77 D for PureSee) were taken directly from the respective SSEDs rather than calculated from the digitized curves. As a reproducibility check, the 0.20 logMAR crossing of each digitized monocular curve was estimated by linear interpolation between the adjacent extracted points bracketing 0.20 logMAR. The resulting crossings were approximately −1.55 D for Vivity and −1.80 D for PureSee. The extracted coordinates used for the interpolation are provided in Supplementary Table S1.

Supplementary Table S1. Monocular defocus curve data points at 6 months

Defocus (D)	Vivity (n = 107)	PureSee (n = 116)
+1.50	0.506	—
+1.00	0.300	0.229
+0.50	0.112	0.048
+0.25	0.048	−0.012
0.00	0.000	−0.045
−0.25	0.030	−0.026
−0.50	0.061	—
−1.00	0.124	0.095
−1.50	0.188	0.145
−2.00	0.315	0.236
−2.50	0.521	0.348

Abbreviations: D, diopters; n, number; logMAR, logarithm of the minimum angle of resolution; SSED, FDA Summary of Safety and Effectiveness Data. Note: Values are mean monocular logMAR visual acuity digitized from the defocus curve figure in each SSED (Vivity, Figure 6; PureSee, Figure 8) [6, 7]. Negative defocus is myopic. Dashes indicate positions not extracted for PureSee. The two curves are based on different analysis sets. The Vivity curve uses observed acuities from the 107 subjects implanted with the lens; the PureSee curve uses the 116 subjects randomized to the lens, with missing values estimated by multiple imputation. As a check on extraction accuracy, the 0.20 logMAR crossing interpolated from these points was −1.55 D for Vivity and −1.80 D for PureSee, compared with defocus ranges of 1.53 D and 1.77 D stated in the respective SSEDs.

For contrast sensitivity, the reported values and the proportion of eyes unable to detect the reference pattern at each spatial frequency were summarized descriptively. Because equivalence of the testing protocols could not be fully verified from the publicly available FDA documentation, no formal between-study statistical comparisons were performed. Visual symptom outcome responses were collapsed into harmonized categories of "not bothered," "any bother," and "clinically meaningful bother"; no formal between-study comparisons were performed because the trials used different validated questionnaires and response categories. Spectacle-independence outcomes were also summarized descriptively because questionnaire formats differed between trials.

Visual symptom outcomes were summarized descriptively because the Vivity and PureSee FDA SSED documents used different directed questionnaire response scales. Vivity used the QUVID, and PureSee used the PRVSQv2, which are distinct validated instruments with different response categories. To allow descriptive presentation of broadly similar levels of symptom bother, responses were collapsed into harmonized categories: "not bothered," "any bother," and "clinically meaningful bother." "Not bothered" included patients who did not experience the symptom or who reported being not at all bothered for Vivity and similarly included PureSee's combined categories of "did not experience or not reported" and "not at all bothered." "Any bother" included all responses above no symptom/no bother. "Clinically meaningful bother" responses were deemed clinically higher: "quite a bit" or "very much" for Vivity and "moderately," "very," or "extremely bothered" for PureSee. These groupings were used for descriptive summarization and were not considered to establish measurement equivalence between QUVID and PRVSQv2. No formal statistical comparisons were performed between the harmonized categories. Outcome-specific denominators were used as reported in the FDA SSEDs. For Vivity, visual-symptom analyses included 106 respondents for halos, starbursts, and double or multiple vision and 105 respondents for glare-related symptoms. The reason for the one-response difference was not specified in the SSED. PureSee visual-symptom analyses included 113 respondents. No missing responses were imputed.

For the spectacle-independence analysis, the Vivity SSED reported the proportion of subjects "rarely or never needing eyeglasses or contact lenses," whereas the PureSee SSED reported frequency of spectacle wear across categories ranging from "none of the time" to "all of the time." To allow for broad visual comparison of spectacle independence, PureSee responses of "none of the time" and "a little of the time" were combined and compared descriptively with the Vivity "rarely or never" category. Because Vivity also stratified spectacle independence by bright and dim lighting conditions while PureSee did not, distance-, intermediate-, and near-vision outcomes were displayed with separate Vivity bright-light and dim-light bars alongside the harmonized PureSee value. Formal statistical comparisons were not performed because questionnaire wording and lighting-condition stratification differed between PMA studies.

RESULTS

The Vivity study included 107 patients implanted with the EDOF lens and the PureSee study included 115 patients. No significant differences were detected in mean (SD) age (68.8 [7.82] versus 69.0 [6.9] years, $P > 0.05$), the proportion of male subjects (44.9% versus 38.3%, $P > 0.05$), or mean (SD) corneal astigmatism (0.516 [0.245] versus 0.51 [0.244] D, $P > 0.05$) (Table 2). The overall race distribution differed significantly between the two study populations ($P < 0.001$), with the Vivity population consisting of 98.1% (n = 105) White subjects compared with 80.9% (n = 93) in the PureSee study. The PureSee study included greater proportions of Black or African American subjects (11.3% versus 0.9%) and Asian subjects (4.3% versus 0.0%). Hispanic or Latino ethnicity was also more common in the PureSee study (15.7% versus 1.9%, $P < 0.001$). Axial length and baseline BCDVA were not reported for the PureSee cohort and therefore could not be compared.

Mean monocular and binocular VA values are shown in Table 3. Monocular DCIVA (66 cm) was 0.148 logMAR for Vivity and 0.15 logMAR for PureSee, and monocular DCNVA (40 cm) was 0.359 and 0.34 logMAR, respectively.

Uncorrected and corrected binocular visual acuities reaching each threshold at distance, intermediate, and near are depicted in Figures 1 and 2. At distance, a greater proportion of PureSee subjects reached binocular UCDVA of 0.00 logMAR or better (44.3% versus 68.1%; Holm-adjusted $P = 0.008$) and binocular BCDVA of 0.00 logMAR or better (73.6% versus 92.0%; Holm-adjusted $P = 0.006$). No other distance thresholds remained significant after Holm adjustment.

At intermediate distance, more Vivity subjects achieved binocular DCIVA of 0.00 logMAR or better (40.6% vs 10.6%; RD, +29.9 pp; Holm-adjusted $P < 0.001$). Differences at the DCIVA 0.10 threshold and UCIVA 0.00 and 0.10 thresholds were significant using the unadjusted P-values but did not remain significant after Holm adjustment. At

the 0.20- and 0.30-logMAR thresholds, there were no significant differences with either the raw or Holm-adjusted *P*-values.

At near, no threshold comparison remained statistically significant after Holm adjustment. The Vivity trial reported numerically higher proportions at DCNVA 0.20 logMAR or better (43.4% versus 29.2%; raw $P = 0.029$, adjusted $P = 0.46$) and UCNVA 0.30 logMAR or better (84.9% versus 71.7%; raw $P = 0.018$, adjusted $P = 0.33$), but these differences did not remain significant after Holm adjustment.

Table 2. Baseline patient characteristics

Parameter	Vivity (n = 107)	PureSee (n = 115)	Difference (95% CI)	*P*-value
Age (y), Mean ± SD	68.8 ± 7.82	69.0 ± 6.9	−0.2 (−2.2 to 1.8)	0.841
Sex (Male), n (%)	48 (44.9)	44 (38.3)	6.6 (−6.3 to 19.2)	0.319
Race, n (%)				
White	105 (98.1)	93 (80.9)	—	**< 0.001** [a]
Black or African American	1 (0.9)	13 (11.3)	—	
Asian	0 (0.0)	5 (4.3)	—	
Native Hawaiian or Other Pacific Islander	0 (0.0)	1 (0.9)	—	
Other	1 (0.9)	3 (2.6)	—	
Ethnicity, Hispanic or Latino, n (%)	2 (1.9)	18 (15.7)	−13.8 (−21.6 to −6.5)	**< 0.001** [b]
Corneal astigmatism (D), Mean ± SD	0.516 ± 0.245	0.51 ± 0.244	0.006 (−0.059 to 0.071)	0.855
Axial length (mm), Mean ± SD	23.64 ± 0.77	Not reported	—	—
Baseline BCDVA (logMAR), Mean ± SD	0.230 ± 0.1877	Not reported	—	—

Abbreviations: n, numbers; CI, confidence interval; y, years; SD, standard deviation; %, percentage; D, diopters; mm, millimetres; BCDVA, best-corrected distance visual acuity; logMAR, logarithm of the minimum angle of resolution; SSED, Summary of Safety and Effectiveness Data. Note: *P*-values < 0.05 are shown in bold; age and corneal astigmatism were compared using Welch's *t*-test; sex and Hispanic or Latino ethnicity using Pearson's chi-square test without continuity correction; and race using the Fisher–Freeman–Halton exact test for the 2 × 5 contingency table. All tests were two-sided. Differences are reported as Vivity minus PureSee, in percentage points for categorical variables, with Newcombe 95% CIs for differences in proportions and Welch 95% CIs for differences in means. No CI is reported for race because it was assessed as a single global comparison across categories. [a] Global comparison of race distribution across reported categories. American Indian or Alaska Native was 0 in both studies; multiracial was reported as 0 for Vivity and was not separately reported for PureSee. [b] Hispanic or Latino ethnicity was analyzed separately from race; ethnicity was unknown for 1 Vivity subject (0.9%). Axial length and baseline BCDVA were not reported in the PureSee SSED and were not compared.

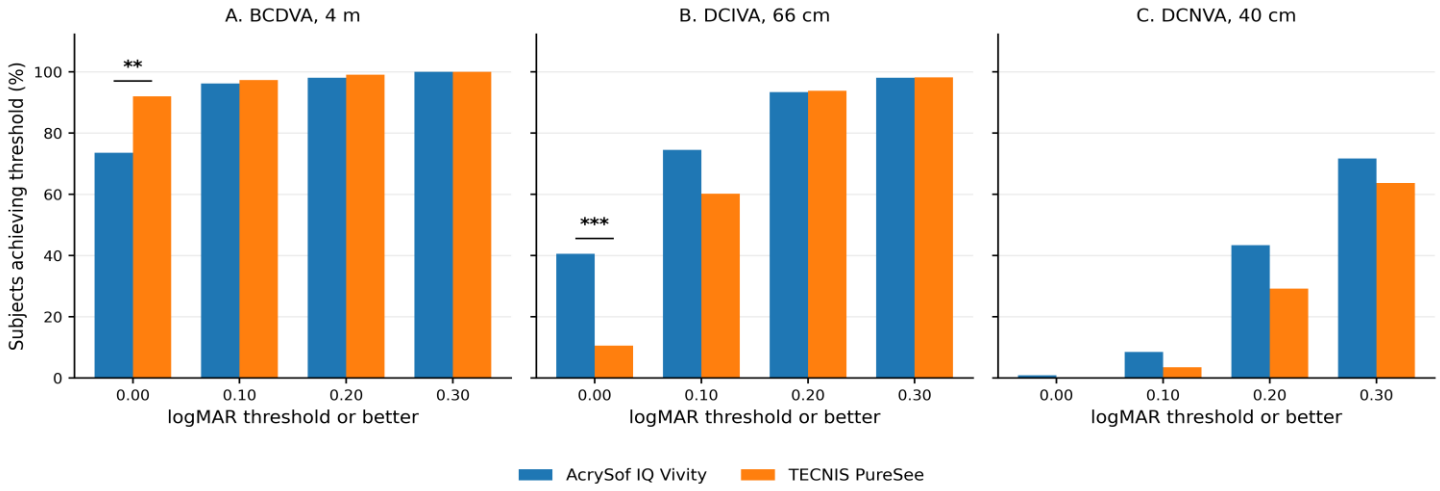

Figure 1. Distance-corrected binocular visual acuity thresholds at 6 months: Bars represent the percentage of subjects achieving each logMAR threshold or better for Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) and PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA). Asterisks indicate Holm-adjusted statistical significance: **P < 0.01, ***P < 0.001. Abbreviations: BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; logMAR, logarithm of the minimum angle of resolution.

Table 3. Mean visual acuity at 6 months

Endpoint (logMAR)	Vivity	PureSee	Descriptive mean difference (Vivity – PureSee), logMAR
Monocular, distance-corrected			
BCDVA (4 m)	0.016 (N = 107) [a]	−0.04 (N = 113) [b]	+0.056
DCIVA (66 cm)	0.148 (N = 107) [a]	0.15 (N = 116) [c]	−0.002
DCNVA (40 cm)	0.359 (N = 107) [a]	0.34 (N = 113) [b]	+0.019
DCIVA (100 cm)	Not tested	0.10 (N = 116) [c]	—
Binocular (Mean ± SD where reported)			
UCDVA (4 m)	0.035 ± 0.102 (N = 106) [d]	−0.01 (N = 113) [b]	+0.045
BCDVA (4 m)	−0.028 ± 0.084 (N = 106) [d]	−0.07 (N = 113) [b]	+0.042
UCIVA (66 cm)	0.058 ± 0.083 (N = 106) [d]	0.09 (N = 113) [b]	−0.032
DCIVA (66 cm)	0.054 ± 0.093 (N = 106) [d]	0.10 (N = 113) [b]	−0.046
UCNVA (40 cm)	0.208 ± 0.104 (N = 106) [d]	0.25 (N = 113) [b]	−0.042
DCNVA (40 cm)	0.253 ± 0.118 (N = 106) [d]	0.28 (N = 113) [b]	−0.027

Abbreviations: logMAR, logarithm of the minimum angle of resolution; BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; SD, standard deviation; UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity; UCNVA, uncorrected near visual acuity; FDA, U.S. Food and Drug Administration; ITT, intent-to-treat; PMA, premarket approval; SSED, Summary of Safety and Effectiveness Data. [a] Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) All-Implanted population (N = 107); least-square estimates as reported in the SSED. [b] PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA) Safety Population (N = 113); observed-case analysis. [c] PureSee ITT population (N = 116); multiple imputation as reported in the SSED. [d] Vivity All-Implanted population; N = 106 for binocular outcomes because one implanted subject was not bilaterally implanted. Values are logMAR; lower values indicate better visual acuity. The descriptive mean difference is calculated as Vivity minus PureSee; because lower logMAR indicates better visual acuity, a negative difference favors Vivity and a positive difference favors PureSee. Vivity binocular visual acuity values are presented as mean ± SD as reported in the SSED. PureSee visual acuity values are presented as means only because standard deviations were not reported. Values are presented at the precision reported in each device's FDA PMA documentation; Vivity values were reported to three decimal places and PureSee values to two. Therefore, visual acuity outcomes were compared descriptively and were not statistically compared.

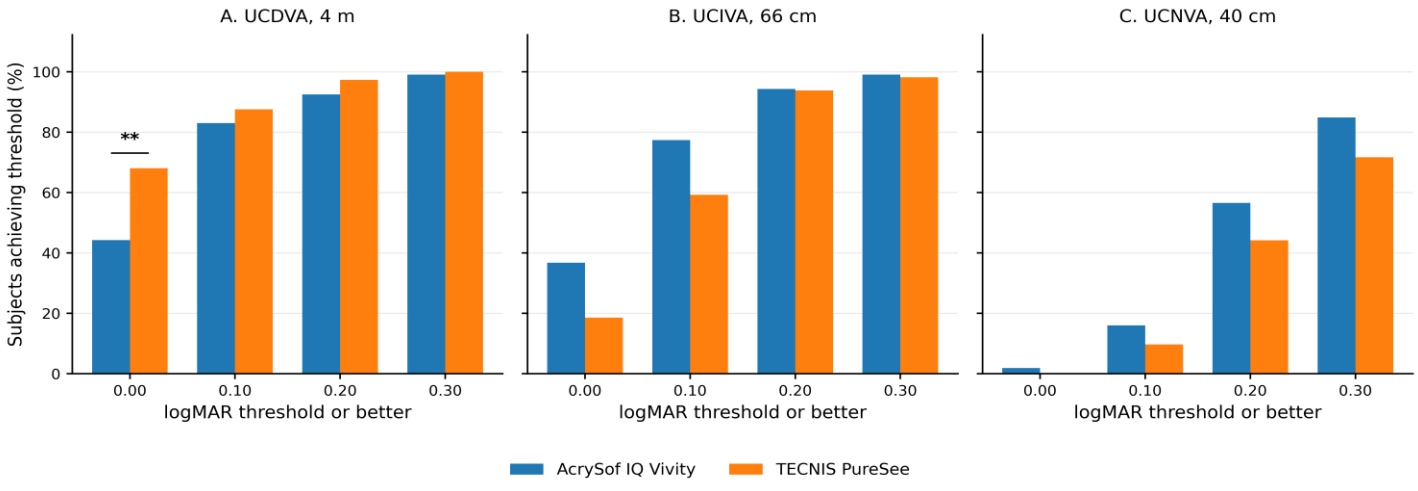

Figure 2. Uncorrected binocular visual acuity thresholds at 6 months: Bars represent the percentage of subjects achieving each logMAR threshold or better for Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) and PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA). Asterisks indicate Holm-adjusted statistical significance: **$P < 0.01$. Abbreviations: UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity; UCNVA, uncorrected near visual acuity; logMAR, logarithm of the minimum angle of resolution.

Table 4. Distance-corrected and uncorrected binocular visual acuity: distribution of subjects by logMAR threshold.

logMAR threshold	Vivity, n (%)	PureSee, n (%)	Risk difference, pp (95% CI)	Test	*P*-value	Holm-adjusted *P*-value
Distance: BCDVA (4 m)						
0.00 or better	78 (73.6)	104 (92.0)	-18.5 (-28.3 to -8.6)	Chi-square	<0.001	**0.006**
0.10 or better	102 (96.2)	110 (97.3)	-1.1 (-6.9 to +4.3)	Fisher	0.71	> 0.99
0.20 or better	104 (98.1)	112 (99.1)	-1.0 (-5.8 to +3.2)	Fisher	0.61	> 0.99
0.30 or better	106 (100.0)	113 (100.0)	+0.0 (-3.5 to +3.3)	—	—	—
Intermediate: DCIVA (66 cm)						
0.00 or better	43 (40.6)	12 (10.6)	+29.9 (+18.6 to +40.4)	Chi-square	<0.001	**< 0.001**
0.10 or better	79 (74.5)	68 (60.2)	+14.4 (+1.9 to +26.1)	Chi-square	0.024	0.41
0.20 or better	99 (93.4)	106 (93.8)	-0.4 (-7.6 to +6.5)	Chi-square	0.90	> 0.99
0.30 or better	104 (98.1)	111 (98.2)	-0.1 (-5.0 to +4.5)	Fisher	> 0.99	> 0.99
Near: DCNVA (40 cm)						
0.00 or better	1 (0.9)	0 (0.0)	+0.9 (-2.4 to +5.2)	Fisher	0.48	> 0.99
0.10 or better	9 (8.5)	4 (3.5)	+5.0 (-1.6 to +12.1)	Chi-square	0.12	> 0.99
0.20 or better	46 (43.4)	33 (29.2)	+14.2 (+1.5 to +26.4)	Chi-square	0.029	0.46
0.30 or better	76 (71.7)	72 (63.7)	+8.0 (-4.4 to +20.0)	Chi-square	0.21	> 0.99
Distance: UCDVA (4 m)						
0.00 or better	47 (44.3)	77 (68.1)	-23.8 (-35.8 to -10.7)	Chi-square	<0.001	**0.008**
0.10 or better	88 (83.0)	99 (87.6)	-4.6 (-14.2 to +4.9)	Chi-square	0.34	> 0.99
0.20 or better	98 (92.5)	110 (97.3)	-4.9 (-11.8 to +1.2)	Chi-square	0.098	> 0.99
0.30 or better	105 (99.1)	113 (100.0)	-0.9 (-5.2 to +2.4)	Fisher	0.48	> 0.99
Intermediate: UCIVA (66 cm)						
0.00 or better	39 (36.8)	21 (18.6)	+18.2 (+6.4 to +29.5)	Chi-square	0.003	0.051
0.10 or better	82 (77.4)	67 (59.3)	+18.1 (+5.7 to +29.6)	Chi-square	0.004	0.079
0.20 or better	100 (94.3)	106 (93.8)	+0.5 (-6.4 to +7.3)	Chi-square	0.87	> 0.99
0.30 or better	105 (99.1)	111 (98.2)	+0.8 (-3.6 to +5.3)	Fisher	> 0.99	> 0.99
Near: UCNVA (40 cm)						
0.00 or better	2 (1.9)	0 (0.0)	+1.9 (-1.7 to +6.6)	Fisher	0.23	> 0.99
0.10 or better	17 (16.0)	11 (9.7)	+6.3 (-2.7 to +15.5)	Chi-square	0.16	> 0.99
0.20 or better	60 (56.6)	50 (44.2)	+12.4 (-0.9 to +25.0)	Chi-square	0.068	> 0.99
0.30 or better	90 (84.9)	81 (71.7)	+13.2 (+2.2 to +23.7)	Chi-square	0.018	0.33

Abbreviations: logMAR, logarithm of the minimum angle of resolution; CI, confidence interval; BCDVA, best-corrected distance visual acuity; DCIVA, distance-corrected intermediate visual acuity; DCNVA, distance-corrected near visual acuity; UCDVA, uncorrected distance visual acuity; UCIVA, uncorrected intermediate visual acuity; UCNVA, uncorrected near visual acuity; pp, percentage points. Data are n (%) of subjects reaching each threshold (Vivity N = 106, PureSee N = 113; 6-month evaluable population). Effect estimates are reported as the absolute risk difference (Vivity minus PureSee) with 95% CIs calculated using the Newcombe method based on Wilson score intervals. These 95% CIs are unadjusted pointwise intervals and were not adjusted for multiple comparisons. A positive risk difference indicates a higher proportion reaching that threshold in the Vivity trial, and a negative risk difference indicates a higher proportion in the PureSee trial. Comparisons were made using Fisher's exact test when any expected cell count was less than 5 and Pearson chi-square without continuity correction otherwise; the test used is identified for each row. Adjusted *P*-values were calculated by the Holm step-down procedure across all 23 testable comparisons in this table. Statistical significance after adjustment was determined using the Holm-adjusted *P*-values. Bold indicates Holm-adjusted $P < 0.05$. Dash indicates not calculable because both groups were at 100%; the CI is still reported and reflects the precision available at that threshold.

Both lenses extended the range of focus relative to their monofocal controls (Table 5). The monocular distance-corrected depth of focus at the 0.20 logMAR threshold, as reported in the respective SSEDs, was 1.53 D for Vivity and 1.77 D for PureSee, a gain over the respective monofocal control of +0.54 D and +0.64 D. The binocular depth of focus was 2.15 D for PureSee (+0.61 D over control); Vivity did not report a binocular value.

The monocular distance-corrected defocus curves of the two EDOF lenses were overlaid descriptively (Figure 3). In the descriptive overlay, the reported curves showed little separation through the distance and intermediate defocus range, with divergence at greater negative defocus, where the PureSee trial curve extended slightly further into the near range.

Table 5. Depth of focus

Depth of focus at 0.20 logMAR	Vivity	PureSee
Monocular range (D)	1.53	1.77
Monocular gain vs. own control (D)	+0.54	+0.64
Binocular range (D)	Not reported	2.15
Binocular gain vs. own control (D)	Not reported	+0.61

Abbreviations: logMAR, logarithm of the minimum angle of resolution; D, diopters. Note: Values were compared descriptively because per-point standard deviations were not reported. The absolute depth-of-focus ranges are presented descriptively; no formal equivalence or between-study statistical comparison was performed. Gains versus the respective monofocal controls cannot be directly compared because the studies used different control lenses.

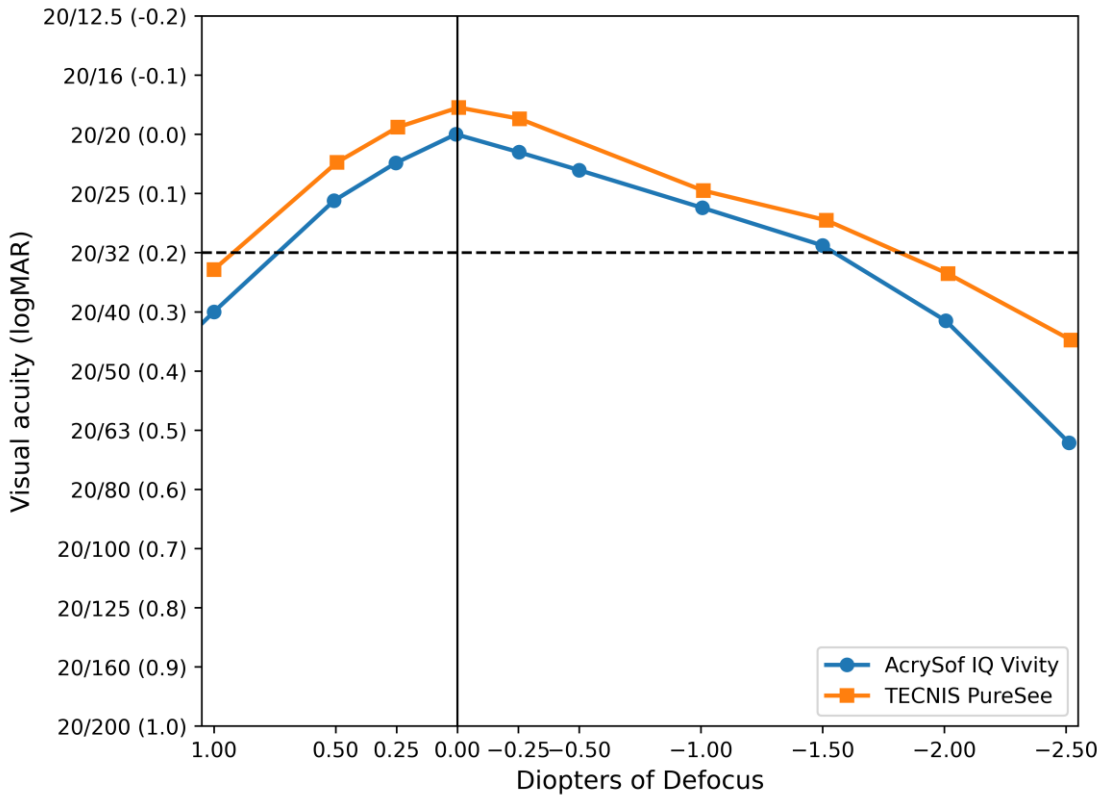

Figure 3. Monocular defocus curve at 6 Months: Defocus curves were graphically extracted from FDA SSED figures and overlaid descriptively across the shared defocus range. The Vivity curve (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) represents observed data from 107 implanted subjects, while the PureSee curve (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA) represents the intent-to-treat population of 116 randomized subjects, with missing values handled by multiple imputation as reported in the PureSee SSED. The dashed horizontal line indicates the 0.20 logMAR threshold used to define depth of focus. Lower logMAR values indicate better visual acuity. Statistical comparisons were not performed because patient-level data were unavailable and comparable variance estimates at each defocus level were not reported for both lenses. Abbreviations: logMAR, logarithm of the minimum angle of resolution.

Mesopic contrast sensitivity values were summarized descriptively because the Vivity SSED reported medians and the PureSee SSED reported means (Table 6). Both FDA reports also provided the proportion of eyes unable to detect the reference pattern at each spatial frequency (Table 6 and Figure 4). The largest descriptive differences in contrast detectability were observed at 6 and 12 cpd. Without glare, 19 / 107 (17.8%) Vivity eyes versus 0 / 113 (0%) PureSee eyes were unable to detect the pattern at 6 cpd, and 46 / 107 (43.0%) versus 0 / 113 (0%), respectively, at 12 cpd. With glare, 20 / 107 (18.7%) versus 0 / 113 (0%) were unable to detect the pattern at 6 cpd, and 56 / 107 (52.3%) versus 0/113 (0%) at 12 cpd. Because equivalence of the contrast-sensitivity testing protocols could not be verified from the publicly available FDA documentation, these findings are presented descriptively and were not formally statistically compared.

Table 6. Mesopic contrast sensitivity at 6 months

Spatial frequency	Condition	Vivity	PureSee
Contrast sensitivity, log units (Vivity = Median, PureSee = Mean) — descriptive only			
1.5 cpd	**Without glare**	1.52	1.95
3 cpd	**Without glare**	1.34	2.00
6 cpd	**Without glare**	1.38	1.65
12 cpd	**Without glare**	0.61	0.98
1.5 cpd	**With glare**	1.52	1.73
3 cpd	**With glare**	1.34	1.81
6 cpd	**With glare**	1.38	1.50
12 cpd	**With glare**	≤0.61	0.88
Eyes unable to detect the reference pattern, n / N (%) unable to detect			
6 cpd	**Without glare**	19 / 107 (17.8)	0 / 113 (0)
12 cpd	**Without glare**	46 / 107 (43.0)	0 / 113 (0)
3 cpd	**With glare**	1 / 107 (0.9)	0 / 113 (0)
6 cpd	**With glare**	20 / 107 (18.7)	0 / 113 (0)
12 cpd	**With glare**	56 / 107 (52.3)	0 / 113 (0)

Abbreviations: cpd, cycles per degree. Note: Vivity contrast-sensitivity values are reported as medians in log units; the Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) SSED did not numerically report an interquartile range or range. PureSee values are reported as means in log units; standard deviations (SDs) were displayed graphically as ±1 SD in the PureSee SSED but were not numerically reported and therefore could not be included. Because the studies used different summary measures and equivalence of the contrast-sensitivity testing protocols was not established, these outcomes are presented descriptively and no formal between-study statistical comparisons were performed. The proportion of eyes unable to detect the reference pattern is presented as n / N (%). Rows in which both studies reported 0% unable to detect the pattern are not shown.

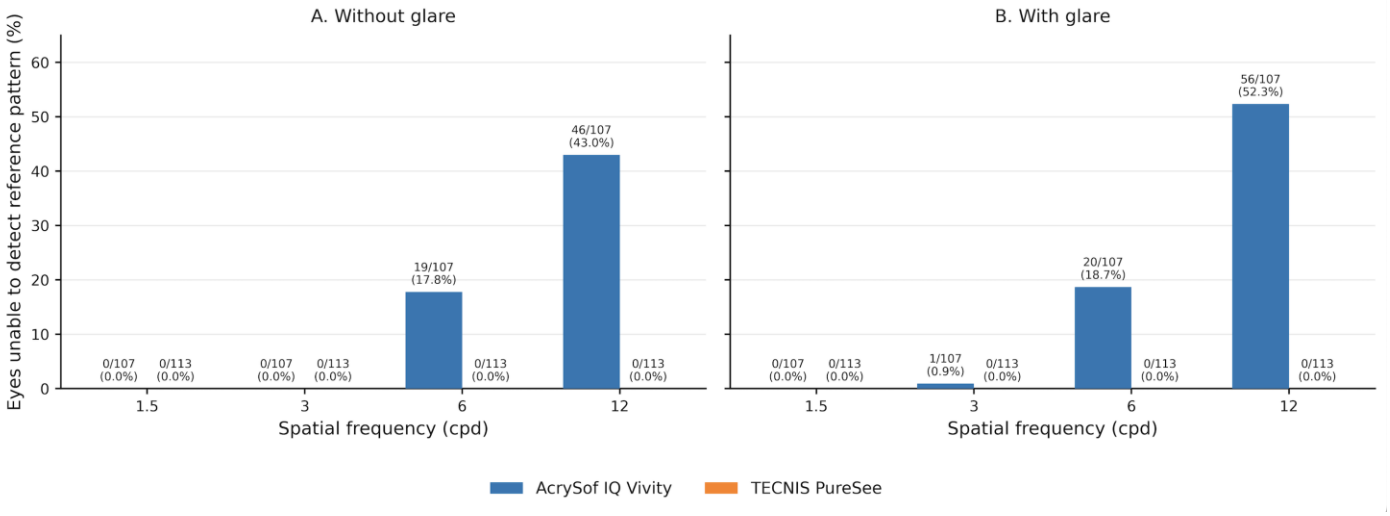

Figure 4. Percentage of first eyes unable to detect the mesopic contrast-sensitivity reference pattern at 6 months without glare (A) and with glare (B). Each bar is labeled with the numerator, denominator, and percentage, n / N (%). Higher percentages indicate poorer contrast detectability. Within each spatial-frequency pair, Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) is shown on the left and PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA) on the right. Results are presented descriptively. The source trials reported contrast-sensitivity values using different summary measures (Vivity, medians; PureSee, means), and equivalence of the testing protocols was not established; therefore, no formal between-study statistical comparisons were performed. Abbreviations: cpd, cycles per degree.

Table 7. Visual symptom bothersomeness reported in the Vivity and PureSee FDA trials at 6 months

Visual symptom	Vivity, n / N (%)	PureSee, n / N (%)
Not bothered (did not experience or not at all bothered)		
Halos	88 / 106 (83.0)	93 / 113 (82.3)
Starbursts	78 / 106 (73.6)	88 / 113 (77.9)
Double / multiple vision	104 / 106 (98.1)	99 / 113 (87.6)
Glare-related	82 / 105 (78.1)	94 / 113 (83.2)
Any bother (any response above no symptom / no bother)		
Halos	18 / 106 (17.0)	20 / 113 (17.7)
Starbursts	28 / 106 (26.4)	25 / 113 (22.1)
Double / multiple vision	2 / 106 (1.9)	14 / 113 (12.4)
Glare-related	23 / 105 (21.9)	19 / 113 (16.8)
Clinically meaningful bother (moderate-or-worse)		
Halos	2 / 106 (1.9)	10 / 113 (8.8)
Starbursts	3 / 106 (2.8)	14 / 113 (12.4)
Double / multiple vision	0 / 106 (0.0)	7 / 113 (6.2)
Glare-related	4 / 105 (3.8)	7 / 113 (6.2)

Abbreviations: FDA, U.S. Food and Drug Administration; n / N, number of subjects with the outcome/number of subjects assessed; PRVSQv2, Patient-Reported Visual Symptoms Questionnaire version 2; QUVID, Questionnaire for Visual Disturbances; SSED, Summary of Safety and Effectiveness Data. The two trials used different validated directed questionnaires (QUVID for Vivity and PRVSQv2 for PureSee) with different response categories. Responses are presented descriptively and are not considered directly equivalent between questionnaires. "Not bothered" included subjects who did not experience visual disturbances or reported not being bothered at all. "Any bother" included "a little bit" bothered or greater for Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) and "slightly bothered" or greater for PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA). "Clinically meaningful bother" included "quite a bit" or "very much" for Vivity and "moderately," "very," or "extremely bothered" for PureSee. These groupings were used to summarize the reported questionnaire responses and were not considered validated equivalent categories across instruments. No formal between-study statistical comparisons were performed. Denominators are shown for each outcome and reflect available responses reported in the respective FDA SSEDs.

Visual symptom outcomes were reported descriptively because the Vivity and PureSee trials used different validated questionnaires and response scales (Table 7). In the Vivity trial, any bother was most frequently reported for starbursts (26.4%) and least frequently for double or multiple vision (1.9%). Clinically meaningful bother was uncommon across all symptoms, ranging from 0% for double or multiple vision to 3.8% for glare-related symptoms. In the PureSee trial, any bother was most frequently reported for starbursts (22.1%) and least frequently for double or multiple vision (12.4%). Clinically meaningful bother ranged from 6.2% for double or multiple vision and glare-related symptoms to 12.4% for starbursts. Because QUVID and PRVSQv2 use different response categories, these percentages were not formally compared between trials.

Spectacle independence was reported by visual distance (Table 8 and Figure 5). At distance, 94.1% of Vivity subjects in bright conditions and 93.1% in dim conditions reported high spectacle independence, compared with 93.8% of PureSee subjects. At intermediate, the corresponding values were 87.3%, 84.3%, and 80.5%, respectively. At near, the values were 46.1% and 39.2% for Vivity in bright and dim conditions and 43.4% for PureSee. Because questionnaire wording and lighting conditions differed between studies, no formal statistical comparison was performed.

Table 8. Harmonized spectacle independence at 6 months, by visual distance.

Visual distance	Vivity (bright)	Vivity (dim)	PureSee
Distance (%)	94.1	93.1	93.8
Intermediate (%)	87.3	84.3	80.5
Near (%)	46.1	39.2	43.4

Table is shown as descriptive only. Values are the proportion reporting low spectacle dependence ("rarely or never" for Vivity Intraocular Lens Satisfaction questionnaire [IOLSAT]; "none or a little of the time" for PureSee Patient-Reported Spectacle Independence Questionnaire-v2 [PRSIQv2]). Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) stratified by bright and dim lighting while PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA) did not. The overall/global spectacle-independence question is not shown because the two instruments define "overall" differently (Vivity includes complete spectacle freedom while PureSee asks a separate global frequency question), making a single overall figure non-comparable. No statistical comparison was performed.

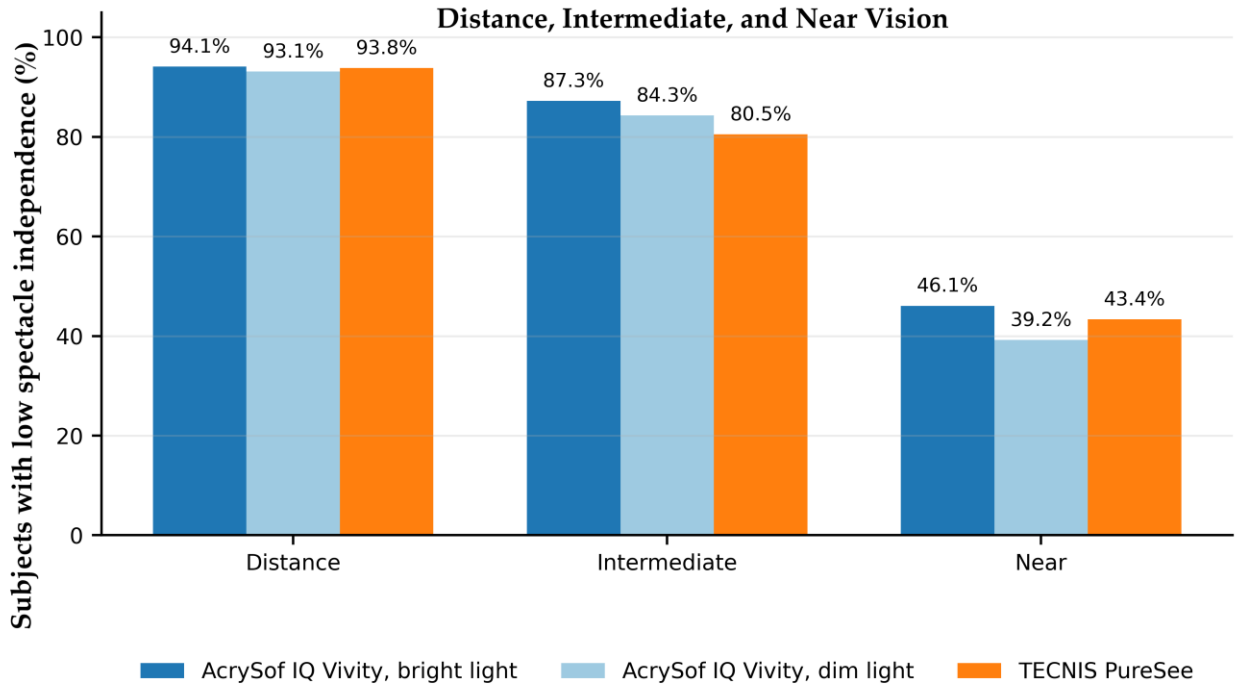

Figure 5. Harmonized spectacle independence at 6 months: For PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA), low spectacle dependence was defined as spectacle wear "none of the time" or "a little of the time." For Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX), low spectacle dependence was reported as "rarely or never needing eyeglasses or contact lenses." Vivity distance, intermediate, and near outcomes were stratified by bright and dim lighting, whereas PureSee outcomes were not lighting-specific. Values are presented descriptively. No formal statistical comparison was performed.

Table 9. Cumulative and persistent serious adverse events

Adverse event	ISO SPE %	Vivity, n / N (%)	PureSee, n / N (%)
Cumulative serious adverse events			
Cystoid macular edema	3.0	1 / 213 (0.5)	3 / 230 (1.3)
Hypopyon	0.3	0 / 213 (0.0)	0 / 230 (0.0)
Endophthalmitis	0.1	0 / 213 (0.0)	0 / 230 (0.0)
Lens dislocation (posterior chamber)	0.1	0 / 213 (0.0)	0 / 230 (0.0)
Pupillary block	0.1	0 / 213 (0.0)	0 / 230 (0.0)
Retinal detachment	0.3	0 / 213 (0.0)	0 / 230 (0.0)
Secondary surgical intervention	0.8	2 / 213 (0.9)	1 / 230 (0.4)
Device/optical-related	—	0 / 213 (0.0)	0 / 230 (0.0)
Persistent serious adverse events			
Corneal stromal edema	0.3	0 / 213 (0.0)	0 / 226 (0.0)
Cystoid macular edema	0.5	0 / 213 (0.0)	2 / 226 (0.9)
Iritis	0.3	0 / 213 (0.0)	0 / 226 (0.0)
Raised IOP requiring treatment	0.4	0 / 213 (0.0)	0 / 226 (0.0)

Abbreviations: SPE, Safety and Performance Endpoint; IOP, intraocular pressure. Note: Data are reported per eye as n / N (%). Vivity (AcrySof IQ Vivity IOL, Alcon Laboratories, Inc., Fort Worth, TX) was evaluated using ISO 11979-7:2014 SPE rates and PureSee (TECNIS PureSee IOL, Johnson & Johnson Vision, Irvine, CA) using ISO 11979-7:2024 SPE rates; the numerical rates shown were the same for the listed events. Vivity included 213 implanted eyes; PureSee included 230 eyes for cumulative events and 226 for persistent events. For PureSee, secondary surgical intervention excluded wound burp. SPE percentages are reference rates; safety success was based on prespecified one-sided 95% confidence limits rather than the observed percentage alone. No formal between-study statistical comparison was performed.

Both trials met the prespecified statistical success criteria for the ISO 11979-7 safety and performance endpoints applicable to their respective editions (2014 for Vivity and 2024 for PureSee) (Table 9). Cumulative serious adverse events were infrequent in both trials. Cystoid macular edema occurred in 1 / 213 (0.5%) Vivity eyes and 3/230 (1.3%) PureSee eyes, while secondary surgical intervention occurred in 2 / 213 (0.9%) and 1 / 230 (0.4%), respectively. None of the secondary surgical interventions were related to the IOL or its optical properties. No retinal detachments, endophthalmitis, lens dislocations, or pupillary block occurred in either group, and raised intraocular pressure requiring treatment was 0.0% for both. Given the small number of events, no statistical comparison was performed between studies.

DISCUSSION

The two FDA trials showed different patterns of visual performance across the outcomes evaluated. The PureSee trial reported higher proportions of subjects reaching the finest distance thresholds, while the Vivity trial reported a higher proportion reaching the finest DCIVA threshold after Holm adjustment. Several additional intermediate and near threshold differences were nominally significant based on unadjusted *P*-values but did not remain significant after Holm adjustment. Descriptively, more Vivity eyes were unable to detect the contrast-sensitivity reference pattern at 6 and 12 cpd with and without glare.

The two FDA reports showed a descriptive difference in the reported frequency of inability to detect the reference pattern at 6 and 12 cpd, with and without glare, with higher reported frequencies in the Vivity trial and no corresponding events reported in the PureSee trial. This pattern is directionally consistent with Koh et al. [8], who reported better photopic and mesopic contrast sensitivity with PureSee than Vivity in a bilateral clinical cohort. A more recent retrospective comparison by Kang et al. [9] similarly found higher contrast sensitivity with PureSee at higher spatial frequencies against Clareon Vivity. Because equivalence of the contrast-sensitivity testing protocols was not established, the present FDA comparison cannot determine whether the difference in reported frequencies reflects a true between-lens difference or whether lens design contributed to it. Vivity uses anterior X-WAVE optics that stretch and shift the wavefront within the central 2.2 mm of the optic, extending focal range by introducing controlled aberration [4]. PureSee instead uses a posterior refractive modulated power profile, with an anterior aspheric surface that compensates for corneal spherical aberration [6]. Prior work has shown that spherical aberration is negatively correlated with mesopic contrast sensitivity at 3, 6, and 12 cpd with glare [10]. These design and optical findings provide possible mechanistic context but do not establish the cause of the difference observed between the FDA reports.

Given the limited availability of published studies directly comparing AcrySof IQ Vivity and TECNIS PureSee, this discussion also considers studies comparing Clareon Vivity and TECNIS PureSee. According to Alcon, AcrySof IQ Vivity and Clareon Vivity use the same non-diffractive X-WAVE optical design but differ in lens material [9, 11]. The Clareon and AcrySof materials differ mainly in optical clarity characteristics, such as glistenings and surface haze, that accumulate with time after implantation [12, 13]. The direct comparisons cited here reported outcomes at two to three months and are therefore used as supportive evidence regarding the shared optical design rather than as direct clinical evidence for AcrySof IQ Vivity. Differences related to lens material may still contribute to clinical outcomes.

Distance outcomes showed the clearest adjusted between-study differences. More PureSee subjects reached 0.00 logMAR or better for both UCDVA (44.3% versus 68.1%; RD, −23.8 pp; Holm-adjusted $P < 0.05$) and BCDVA (73.6% versus 92.0%; RD, −18.5 pp; Holm-adjusted $P < 0.05$). No significant differences were detected at the remaining distance thresholds either before or after Holm adjustment. The difference was therefore concentrated at the finest distance threshold rather than across the full range of distance acuity thresholds. This pattern is consistent with prior PureSee studies reporting strong distance optical quality and visual performance relative to monofocal controls [5, 14].

Intermediate outcomes showed the most consistent pattern across the FDA data and published comparisons. At the 0.00 logMAR DCIVA threshold, 40.6% of Vivity subjects and 10.6% of PureSee subjects reached this level (RD, +29.9 pp; Holm-adjusted $P < 0.001$). Several additional intermediate differences were significant before adjustment but did not remain so after correction. The direction of this finding is consistent with recent head-to-head studies. Koh et al. [8] reported better UCIVA with AcrySof IQ Vivity at 6 months, while another study found better intermediate acuity at 66 cm with Clareon Vivity at 2 months [9]. Jeong et al. [15] also found better monocular UIVA at 80 cm with Clareon Vivity at 1 month, although the difference was not significant at 3 months and outcomes at 66 cm were similar. Optical bench testing with a model eye also showed relatively higher intermediate-focus modulation transfer function (MTF) with Clareon Vivity [16]. Together, these studies show a directionally similar pattern in reported intermediate outcomes; however, differences in study design and Vivity platform limit direct comparison and preclude attributing a consistent lens-specific advantage.

Near outcomes varied across the FDA data and published literature. None of the near threshold comparisons remained significant after Holm adjustment; the higher proportion reported with Vivity for DCNVA of 0.20 logMAR or better (43.4% versus 29.2%) did not survive correction (raw $P < 0.05$, adjusted $P = 0.46$). Published comparisons have similarly varied. Koh et al. reported significantly better UNVA with Vivity [8], while Jeong et al. found better monocular UNVA at 40 cm with PureSee at 1 month, with no significant difference by 3 months [15]. Because several of these comparisons used uncorrected near acuity, differences in postoperative refraction may also contribute to variation across studies; refractive outcomes could not be directly compared between the two FDA *SSED*s in the present analysis. Overall, the available evidence does not show a consistent near-vision advantage for either lens.

The defocus findings were less consistent across datasets and were interpreted descriptively. In the FDA SSEDs, monocular distance-corrected depth of focus at the 0.20 logMAR threshold was 1.53 D for Vivity and 1.77 D for PureSee and the extracted curve extended slightly further into negative defocus with PureSee. Koh et al., by contrast, found PureSee better at positive defocus but Vivity better at −1.50 and −2.00 D, the range closer to intermediate/near vision [8]. These differences may reflect variation in study design and curve generation rather than a true contradiction, particularly because the FDA curves were graphically extracted and Koh et al. reported a more limited negative defocus range.

Patient-reported visual symptoms were interpreted descriptively because the two FDA trials used different questionnaires and response scales. In the Vivity trial, any bother was most frequently reported for starbursts (26.4%) and glare-related symptoms (21.9%), while clinically meaningful bother was uncommon across all symptom categories (0%–3.8%). In the PureSee trial, any bother ranged from 12.4% for double or multiple vision to 22.1% for starbursts, while clinically meaningful bother ranged from 6.2% to 12.4%. These percentages were not formally compared between trials because QUVID and PRVSQv2 have different response categories and the harmonized categories have not been validated as equivalent measures. The harmonized PureSee percentages for clinically meaningful bother appear higher, although this may reflect differences in how the two instruments define their response categories rather than a true difference between lenses. Koh et al., using a single dysphotopsia instrument, reported significantly lower dysphotopsia with PureSee than Vivity [8]. Other PureSee studies have similarly reported dysphotopsia profiles comparable to a monofocal control [14, 17]. This difference could be a reflection of different questionnaires being used. Studies using each trial's own instrument suggest that population differences may also contribute. A study using PRVSQ after bilateral PureSee implantation reported bothersome symptom rates in a similar range to the PureSee trial [14], while a study using QUVID after bilateral AcrySof

IQ Vivity implantation in a cohort with mild primary open-angle glaucoma reported considerably higher glare bother than the Vivity trial [18]. Because each used the same instrument as the corresponding trial, this difference may reflect population and setting rather than questionnaire design.

This study has several limitations. It was an indirect comparison of two separate FDA trials, and Vivity and PureSee subjects were not randomized against each other. The trials were conducted approximately seven years apart and differed in investigational sites, enrolled populations, demographic composition, and monofocal control lenses. These differences introduce potential between-study heterogeneity and confounding, so observed differences cannot be attributed solely to the implanted IOL. Accordingly, this analysis should be interpreted as a descriptive, hypothesis-generating comparison of two separate FDA trials rather than a head-to-head comparative-effectiveness study. The trials also differed in their analysis populations and handling of missing data. Vivity outcomes were based on the All-Implanted population, whereas PureSee used either the ITT population with multiple imputation or the Safety Population with observed-case data, depending on the outcome. Absolute values should therefore be compared with caution, and each lens's performance relative to its own control should not be used interchangeably. The analysis was also limited to aggregate SSED data, so patient-level adjustment and subgroup analyses were not possible. Differences in reporting affected several comparisons. Vivity did not report monocular threshold data, limiting formal threshold comparisons to binocular measurements. PureSee did not report SDs for the VA means or preoperative distance acuity; therefore, mean logMAR values were summarized descriptively, and baseline distance acuity could not be compared. Contrast-sensitivity testing was also limited by incomplete reporting of testing conditions in the PureSee SSED, which prevented verification that the two trials used equivalent testing protocols; these outcomes were therefore interpreted descriptively. Patient-reported outcomes were similarly limited by questionnaire differences: visual symptoms and spectacle independence were assessed with different instruments and response scales, requiring descriptive harmonization into shared categories. These cross-trial summaries should be interpreted cautiously and should not be treated as direct comparisons. Because the questionnaires used different response categories and thresholds, the displayed proportions in the harmonized "clinically meaningful bother" category may reflect categorization differences rather than true between-lens differences. These data should therefore be interpreted descriptively. Multiple inferential comparisons were performed across VA thresholds; multiplicity adjustment was therefore applied as described in the Statistical Analysis section. Postoperative refractive outcomes also could not be directly assessed because they were reported in different formats in the two SSEDs, which may limit interpretation of differences in uncorrected VA. Finally, all outcomes were limited to 6-month FDA follow-up, so longer-term between-study differences could not be assessed. Published longer-term data are more established for AcrySof IQ Vivity, with follow-up of subjects from the original FDA trial showing maintained distance vision and extended intermediate and near performance at approximately 3 years [19]. Comparable long-term data for PureSee are not yet available, reflecting its more recent introduction. A prospective head-to-head trial would address many of the limitations inherent to this indirect comparison. More consistent reporting across FDA SSEDs would also help, since differences in questionnaire selection, summary statistics, testing protocols, and threshold reporting limited how much of the available data could be formally compared.

CONCLUSIONS

In this indirect comparison of FDA PMA data, the PureSee FDA trial reported higher proportions of subjects reaching the finest corrected and uncorrected distance acuity threshold, while the Vivity FDA trial reported a higher proportion reaching the finest distance-corrected intermediate acuity threshold. No near-vision threshold difference remained significant after Holm adjustment. Descriptive differences were also observed in contrast sensitivity and patient-reported outcomes, although differences in testing methods and questionnaires limited direct comparison of these outcomes. Both trials met the safety and performance endpoint limits applicable to their respective ISO 11979-7 editions. Because this was an indirect comparison of separate FDA trials, these findings are hypothesis-generating and cannot determine comparative superiority, equivalence, or patient-specific treatment benefit. Further prospective head-to-head studies are needed to determine whether these differences persist under the same study conditions.

ETHICAL DECLARATIONS

Ethical approval: This study used only publicly available, aggregate, de-identified data from FDA Summary of Safety and Effectiveness Data documents. The investigators had no access to patient-level identifiable information and had no interaction with study participants. Therefore, new informed consent was not required. No new patient enrollment or collection of identifiable private information occurred as part of this secondary analysis. The study was approved by the Hoopes Vision Ethics Committee.

Conflict of interest: Zahra Adamji, Hanna Pawlowski, Sanjana Molleti, Zahraa O. Alomar, Mina M. Sitto, Phillip C. Hoopes, and Majid Moshirfar report no relevant financial or non-financial relationships with Alcon, Johnson & Johnson Vision, or other intraocular lens manufacturers, including consultancy, speaker fees, research or travel support, advisory roles, patents, or equity interests. Alcon and Johnson & Johnson Vision had no role in the conception or design of the study, data extraction or analysis, manuscript preparation, or the decision to submit the manuscript for publication. All data were obtained from publicly available FDA SSED documents, and neither manufacturer provided funding, data, or other support.

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The source aggregate data are publicly available in the FDA SSEDs cited as References 6 and 7. The extracted aggregate dataset, FDA source-page mapping, WebPlotDigitizer coordinates, Excel workbook and formulas, and executable Python code used to reproduce the statistical analyses and figures are available from the corresponding author upon reasonable request.

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