• Clinical Research •

Visual performance and quality outcomes after implantation of hybrid multifocal-extended depth of focus intraocular lenses

Xu-Dong Song[1], Zhao-Hui Li[2], Hong Zhang[3], Huai-Jin Guan[4], Rong-Feng Liao[5], A-Yong Yu[6], Hui Song[7], Ning-Li Wang[1]

[1]Beijing Institute of Ophthalmology, Beijing Tongren Eye Center, Beijing Tongren Hospital, Capital Medical University, Beijing 100730, China
[2]Department of Ophthalmology, the Third Medical Center of Chinese PLA General Hospital, Beijing 100039, China
[3]Tianjin Medical University Eye Hospital, Tianjin Medical University Eye Institute, Tianjin 300384, China
[4]Eye Institute, Affiliated Hospital of Nantong University, Nantong 226001, Jiangsu Province, China
[5]Department of Ophthalmology, the First Affiliated Hospital of Anhui Medical University, Hefei 230022, Anhui Province, China
[6]The Affiliated Eye Hospital of Wenzhou Medical University, Wenzhou 325027, Zhejiang Province, China
[7]Tianjin Eye Institute, Tianjin Key Lab of Ophthalmology and Visual Science, Tianjin Eye Hospital, Tianjin 300020, China
Correspondence to: Ning-Li Wang. Beijing Institute of Ophthalmology, Beijing Tongren Eye Center, Beijing Tongren Hospital, Capital Medical University, Beijing 100730, China. wningli@vip.163.com
Received: 2026-04-22 Accepted: 2026-09-18

Abstract

● **AIM:** To compare the visual performance and quality outcomes 12mo after implantation of two hybrid multifocal-extended depth of focus (EDF) intraocular lenses (IOLs) and a multifocal IOL.

● **METHODS:** Prospective, multicentered, randomized, and open-label study. Subjects were implanted with either a hybrid multifocal-EDF IOL (AM3UH or AM4UH) or a multifocal IOL (SN6AD1). The primary outcome measure was the percentage of patients achieving monocular distance-corrected near visual acuity (DCNVA) of 0.30 logMAR or better at 6mo postoperatively. Postoperative monocular distance, intermediate, and near visual acuity, refractive error, contrast sensitivity (CS), defocus curves, intraocular pressure (IOP), corneal endothelial cell density (ECD), subjective visual quality, and complications were evaluated and compared among the AM3UH, AM4UH, and SN6AD1 groups.

● **RESULTS:** A total of 153 patients (153 eyes) with cataract were enrolled, including 40 patients (40 eyes) in the AM3UH group, 33 patients (33 eyes) in the AM4UH group, and 80 patients (80 eyes) in the SN6AD1 group. A total of 145 patients (145 eyes) completed the 12-month follow-up, with 8 patients lost to follow-up (2 patients from the AM3UH group, 2 patients from the AM4UH group, and 4 patients from the SN6AD1 group). At 12mo postoperatively, the AM3UH group achieved the best uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate visual acuity (DCIVA) among these three groups and demonstrated distance visual acuity comparable to that of the SN6AD1 group, while the monocular distance, intermediate, and near visual acuity in the AM4UH group were comparable to those in the SN6AD1 group. Defocus curves demonstrated that the AM3UH group provided continuous vision with significantly better visual acuity across defocus from +1.0 to -2.0 D than the SN6AD1 group (P=0.005; P=0.005; P=0.006; P<0.001; P<0.001; P<0.001; P=0.032), and the AM4UH group achieved significantly better visual acuity at -0.5 D (P=0.024). The incidence of halos in the AM3UH group was significantly lower than that in the SN6AD1 group (P=0.021). There were no statistically significant differences among three groups in CS, IOP, ECD, and other photic phenomena.

● **CONCLUSION:** The hybrid multifocal-EDF IOL effectively improves postoperative visual acuity and provides a more continuous range of vision, with good safety and subjective visual quality.

● **KEYWORDS:** cataract surgery; intraocular lenses; hybrid multifocal-extended depth of focus; visual performance and quality

DOI:10.18240/ijo.2026.12.08

Citation: Song XD, Li ZH, Zhang H, Guan HJ, Liao RF, Yu AY, Song H, Wang NL. Visual performance and quality outcomes after

implantation of hybrid multifocal-extended depth of focus intraocular lenses. *Int J Ophthalmol* 2026;19(12):2382-2389

INTRODUCTION

Cataract remains the leading cause of blindness worldwide, and phacoemulsification with intraocular lens (IOL) implantation remains the only effective treatment[1-2]. With rising expectations for quality of life and continuous advancements in modern technology, cataract surgery has evolved from a traditional vision-restoring procedure into refractive surgery. Patients increasingly seek not only restoration of distance vision but also good intermediate and near vision, or even continuous full-range visual acuity, with the goal of reducing spectacle dependence while addressing multiple visual needs associated with conditions such as cataract, myopia, and presbyopia.

Conventional monofocal IOLs cannot meet the demands for vision at multiple distances[3]. Although bifocal IOLs have improved near vision to some extent, their intermediate vision and overall postoperative visual performance remain unsatisfactory[4-6]. While extended depth of focus (EDF) IOLs can provide good distance and intermediate vision, their near visual performance is somewhat limited[7-9]. In response, researchers have further upgraded IOL designs by combining depth-of-field extending technology with diffractive multifocal designs, aiming to overcome the limitations of both bifocal and EDF IOLs and provide patients with excellent distance, intermediate, and near visual acuity. The Tecnis Synergy ZFR00 IOL (Johnson & Johnson, USA) is a representative model of this category[10-11]. As a new hybrid multifocal-EDF IOL, the Proming® IOL adopts a similar design, featuring a high-order aspheric EDF profile on the anterior surface combined with a diffractive multifocal structure on the posterior surface, aiming to achieve clear and continuous vision across all distances. Current evaluations of its *in-vitro* optical performance and small-sample clinical trials have confirmed that this IOL can provide clear postoperative full-range vision[12-13]. However, large-sample clinical studies are still required to further evaluate its postoperative clinical outcomes. This study compares the two models of hybrid multifocal-EDF IOLs with a conventional diffractive multifocal IOL, further evaluating visual performance and quality outcomes of the hybrid multifocal-EDF IOLs at 12mo postoperatively.

PARTICIPANTS AND METHODS

Ethical Approval The study adhered to the principles of the Declaration of Helsinki and was approved by the ethics committees of all participating ophthalmic medical institutions (Approval No.TERC2015-38). It was also registered with the Chinese Clinical Trial Registry (No. ChiCTR-OOC-17013895). Written informed consent was obtained from all participants.

Participants This was a prospective, multicenter, randomized, and open-label study. A total of 153 patients (153 eyes) scheduled to undergo phacoemulsification combined with multifocal IOL implantation were enrolled from December 2015 to December 2018 at 7 ophthalmic medical institutions. Inclusion criteria were age ≥18y, cataract hardness grades 1–3 in the operative eye, and a desire for spectacle independence. Exclusion criteria included ocular comorbidities, uncontrolled elevated intraocular pressure (IOP), irregular corneal astigmatism or astigmatism greater than 1.0 D, corneal endothelial cell density (ECD) of <2000 cells/mm², or the use of medications that could affect visual acuity.

Grouping Methods Patients were randomly assigned to receive either the hybrid multifocal-EDF IOL or the SN6AD1 IOL using a central dynamic randomization system (minimization randomization method implemented through an interactive web response system), with one eye per patient included in the study. For patients assigned to receive the hybrid multifocal-EDF IOL, the specific IOL type (AM3UH or AM4UH) was determined according to patient preference.

Intraocular Lenses The study IOL was the Proming® IOL [models: AM3UH, AM4UH, manufactured by Eyebright Medical Technology (Beijing) Co., Ltd., China]. As a hybrid multifocal-EDF IOL, it offers a diopter range from -10.0 to +36.0 D in 0.5 D increments, with additional diopters of +2.8 D (AM3UH) and +3.2 D (AM4UH). Within the central 4.0 mm optical zone, it features a diffractive multifocal design, while the periphery beyond 4.0 mm incorporates a high-order aspheric refractive zone. Utilizing an EDF aspheric design, the IOL redistributes light normally focused at a single point across an extended range, enhances continuity between focal points and providing a continuous range of vision[14].

The AcrySof® ReSTOR® SN6AD1 IOL (Alcon Laboratories, Inc., USA) is a diffractive, aspheric multifocal IOL with a diopter range from +6.0 to +34.0 D in 0.5 D increments and an add power of +3.0 D. Utilizing the principles of Huygens-Fresnel diffraction and refraction, it distributes light between distant and near focal points, with the wavefronts gradually blending to form the visual image[15].

Surgical Technique At each participating center, surgeries were performed by the same experienced ophthalmologist. All procedures strictly adhered to a predefined surgical protocol, which included topical anesthesia, creation of a 3.0-mm clear corneal incision using a surgical knife [TRIMMER® Disposable Ophthalmic Knives, Eyebright (Suzhou) Medical Devices Co., Ltd., China], injection of an ophthalmic viscosurgical device (OVD), and creation of a central continuous curvilinear capsulorhexis approximately 5.0–5.5 mm in diameter.

Table 1 Preoperative data of patients in the three groups *n* or mean±SD

Parameters	AM3UH group (*n*=40)	AM4UH group (*n*=33)	SN6AD1 group (*n*=80)	*P*
Sex (M/F)	17/23	12/21	34/46	0.818
Age (y)	66.83±7.61	64.65±9.32	63.72±10.39	0.243
IOL power (D)	20.60±2.70	20.83±2.27	20.34±2.78	0.648
UDVA (logMAR)	0.76±0.34	0.67±0.39	0.67±0.32	0.384
UNVA (logMAR)	0.69±0.34	0.71±0.29	0.67±0.30	0.822
BCDVA (logMAR)	0.56±0.39	0.49±0.33	0.50±0.31	0.627
AL (mm)	23.41±1.05	23.34±0.98	23.53±0.97	0.684
ACD (mm)	3.01±0.45	2.86±0.49	3.01±0.43	0.253
Mean-K (D)	43.94±1.62	44.10±1.85	44.43±1.68	0.371
IOP (mm Hg)	14.88±2.75	14.20±2.77	14.23±3.17	0.502

P-value from χ^2 test (categorized variable) or analysis of variance (ANOVA; continuous variable) among the AM3UH, AM4UH, and SN6AD1 groups. IOL: Intraocular lens; UDVA: Uncorrected distance visual acuity; UNVA: Uncorrected near visual acuity; BCDVA: Best-corrected distance visual acuity; AL: Axial length; ACD: Anterior chamber depth; Mean-K: Mean keratometry; IOP: Intraocular pressure; logMAR: Logarithm of the minimum angle of resolution; SD: Standard deviation; M: Male; F: Female.

Phacoemulsification with lens aspiration was then performed, followed by implantation of the IOL. The OVD was carefully removed, and the incision was allowed to self-seal.

Preoperative and Postoperative Examinations A comprehensive ophthalmic examination was performed preoperatively and at 1d, 1wk, 1, 3, 6, and 12mo postoperatively. The examination included biometric measurements, visual acuity testing, refractive assessment, slit-lamp biomicroscopy, non-contact tonometry, corneal endothelial cell evaluation, contrast sensitivity (CS) testing, defocus curve measurement, visual symptom questionnaires, and documentation of any complications.

Monocular visual acuity assessment included uncorrected distance visual acuity (UDVA), best-corrected distance visual acuity (BCDVA), uncorrected intermediate visual acuity (UIVA), distance-corrected intermediate visual acuity (DCIVA), uncorrected near visual acuity (UNVA), distance-corrected near visual acuity (DCNVA), measured using a standardized logarithm of the minimum angle of resolution (logMAR) chart. Preoperative axial length (AL) and anterior chamber depth (ACD) were measured using optical biometry, and mean keratometry (average of the flat and steep keratometry readings) was obtained by corneal topography. Residual refractive error was determined by manifest refraction using a phoropter. Monocular defocus curves were obtained using the same phoropter under best-corrected conditions, with measurements taken at dioptric increments from +1.50 to -4.50 D in 0.50 D steps. CS was measured under best-corrected conditions using a CS tester. Testing was performed under four lighting conditions: photopic (85 cd/m^2), photopic with glare (135 lx), mesopic (3 cd/m^2), and mesopic with glare (28 lx). At each of five spatial frequencies [1.5, 3.0, 6.0, 12.0, and 18.0 cycles per degree (c/d)], three measurements were obtained and averaged for the final result. The Chinese version of the Visual Function Questionnaire-14 (VF-14) was administered to evaluate postoperative visual function and quality of life[16]. Visual symptoms of glare, halos, ghosting, diplopia, and blurred vision were assessed using a questionnaire, and the severity was graded on a 5-point scale: none, slight, mild, moderate, and severe.

Statistical Analysis Statistical analyses were performed using SPSS version 22.0. Data normality was examined with the Shapiro-Wilk test. Continuous variables are summarized as means and standard deviations, with between-group differences evaluated by one-way analysis of variance (ANOVA) and Bonferroni-adjusted post hoc comparisons. Visual symptoms, as an ordinal categorical variable, were analyzed using the Kruskal-Wallis *H* test with Bonferroni-adjusted post hoc comparisons and are reported as frequencies. Other categorical variables are reported as frequencies and compared using the χ^2 test. Statistical significance was defined as a two-sided *P*-value of less than 0.05.

RESULTS

This study enrolled 153 cataract patients (153 eyes; 40 received the AM3UH IOL, 33 received the AM4UH IOL, and 80 received the SN6AD1 IOL), including 63 males and 90 females. The mean age was 64.73±9.62y (range: 36 to 84y). Baseline characteristics, including sex, age, IOL power, UDVA, UNVA, BCDVA, biometric measurements, and IOP, showed no statistically significant differences among three groups (all $P>0.05$), indicating well-balanced and comparable baseline profiles across all groups (Table 1). Of the 153 enrolled patients, 145 patients (145 eyes) completed the 12-month follow-up, with 8 patients lost to follow-up, including 2 patients in the AM3UH group, 2 patients in the AM4UH group, and 4 patients in the SN6AD1 group.

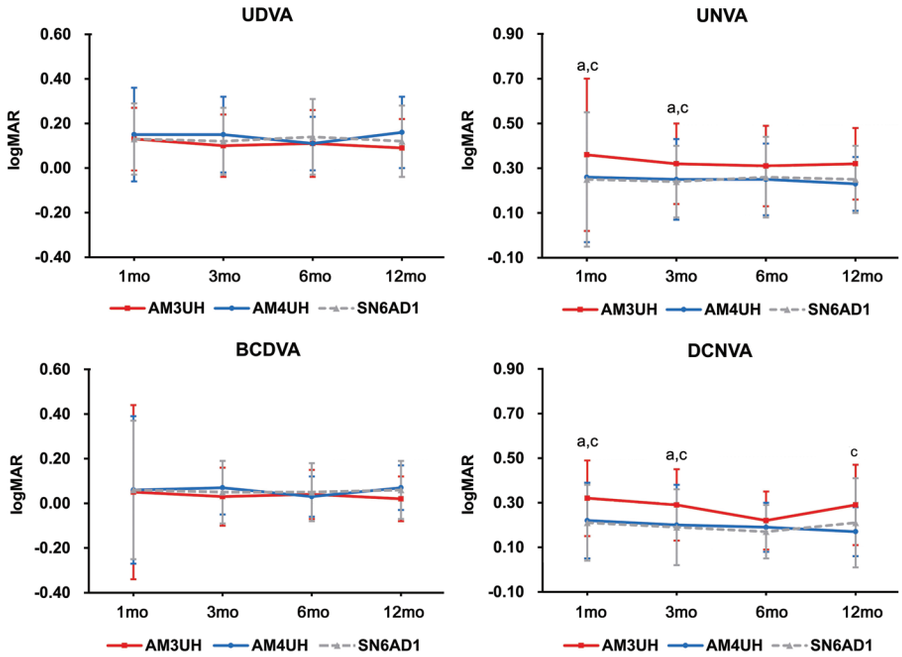


Figure 1 Monocular visual acuity at different postoperative follow-up time points [a]*P*<0.05 AM3UH *vs* SN6AD1, [c]*P*<0.05 AM3UH *vs* AM4UH, Bonferroni adjustment. logMAR: Logarithm of the minimum angle of resolution; UDVA: Uncorrected distance visual acuity; UNVA: Uncorrected near visual acuity; BCDVA: Best-corrected distance visual acuity; DCNVA: Distance-corrected near visual acuity.

Table 2 Comparison of monocular visual acuity (logMAR) at 12mo postoperatively mean±SD

Parameters	AM3UH group	AM4UH group	SN6AD1 group	ANOVA	
				P	Bonferroni post hoc analysis
UDVA	0.09±0.13	0.16±0.16	0.12±0.16	0.162	
UIVA	0.09±0.07	0.15±0.11	0.20±0.13	0.006	[a]*P*=0.004; [b]*P*=0.421; [c]*P*=0.525
UNVA	0.32±0.20	0.23±0.14	0.25±0.20	0.092	
BCDVA	0.02±0.10	0.07±0.09	0.06±0.14	0.196	
DCIVA	0.08±0.07	0.13±0.08	0.19±0.11	0.001	[a]*P*=0.001; [b]*P*=0.136; [c]*P*=0.611
DCNVA	0.29±0.18	0.17±0.11	0.21±0.20	0.012	[a]*P*=0.060; [b]*P*=0.876; [c]*P*=0.015

[a]AM3UH *vs* SN6AD1, [b]AM4UH *vs* SN6AD1, [c]AM3UH *vs* AM4UH. UDVA: Uncorrected distance visual acuity; UIVA: Uncorrected intermediate visual acuity; UNVA: Uncorrected near visual acuity; BCDVA: Best-corrected distance visual acuity; DCIVA: Distance-corrected intermediate visual acuity; DCNVA: Distance-corrected near visual acuity; ANOVA: Analysis of variance; logMAR: Logarithm of the minimum angle of resolution; SD: Standard deviation.

Visual Acuity There were no statistically significant differences in monocular UDVA and BCDVA among the three groups at any follow-up visit (all *P*>0.05). At 6mo postoperatively, the percentages of patients achieving DCNVA of 0.30 logMAR in the AM3UH, AM4UH, and SN6AD1 groups were 97.5%, 97.0%, and 97.5%, respectively. At 12mo postoperatively, the AM3UH group demonstrated significantly better UIVA and DCIVA than the SN6AD1 group (*P*=0.004; *P*=0.001). For near visual acuity at 12mo postoperatively, no statistically significant differences were observed in monocular UNVA among the three groups (*P*=0.092), whereas DCNVA was significantly better in the AM4UH group than in the AM3UH group (*P*=0.015). Monocular visual acuity outcomes of the three groups at 1, 3, 6, and 12mo postoperatively are shown in Figure 1 and Table 2.

Residual Refractive Error A significant difference among groups for manifest spherical equivalent (SE) was observed at 6mo postoperatively. After Bonferroni correction, only the AM4UH group exhibited a higher SE (more hyperopic) compared to the SN6AD1 group (*P*=0.037) at 6mo postoperatively. At 1, 3, and 12mo postoperatively, no statistically significant differences were found in the mean manifest SE among three groups (*P*=0.194, *P*=0.077, *P*=0.340; Figure 2A).

The distribution of residual refractive error at 12mo is shown in Figure 2B. In the AM3UH, AM4UH, and SN6AD1 groups, 79%, 77%, and 80% of eyes were within ±0.5 D, respectively. The comparisons of these distributions among groups showed no statistically significant differences (*P*=0.168).

Contrast Sensitivity CS under photopic, photopic with glare, mesopic, and mesopic with glare conditions showed no

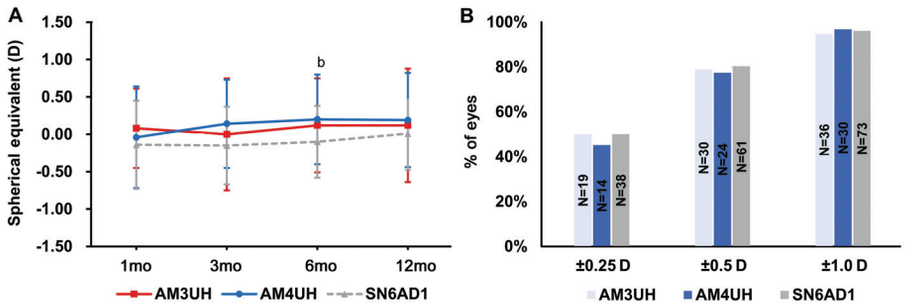


Figure 2 Residual refractive error postoperatively A: Residual refractive error at different postoperative follow-up time points; B: Distribution of the residual refractive error at 12mo postoperatively. [b]*P*<0.05 after Bonferroni adjustment for the AM4UH group versus the SN6AD1 group.

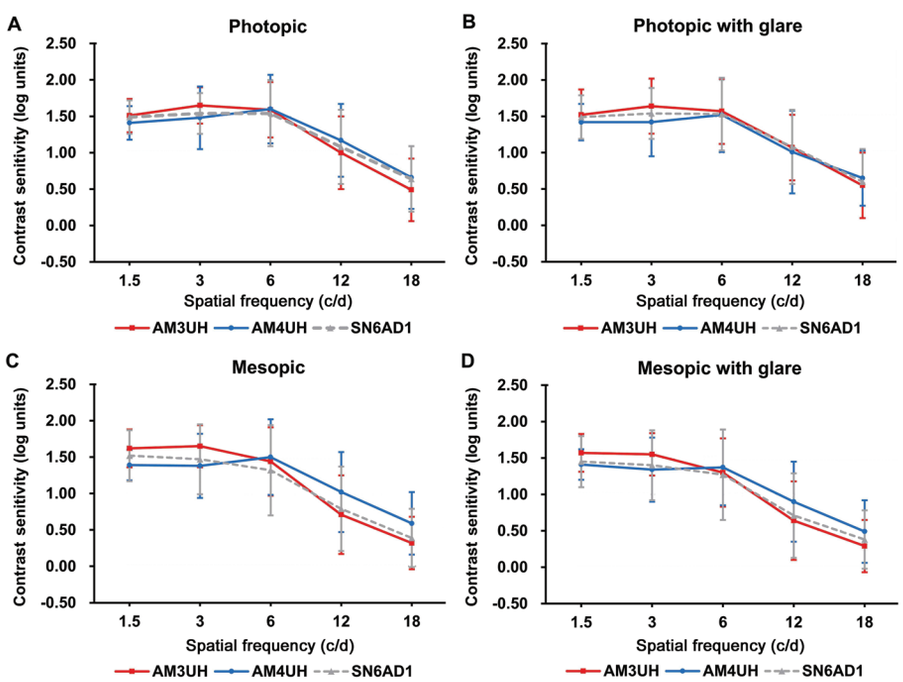


Figure 3 Contrast sensitivity at 12mo postoperatively with photopic (A), photopic with glare (B), mesopic (C), and mesopic with glare (D) conditions c/d: Cycles per degree.

statistically significant differences among three groups across all spatial frequencies tested (all *P*>0.05; 1.5, 3, 6, 12, and 18 c/d; Figure 3).

Defocus Curves The 12-month postoperative defocus curves for the three groups are shown in Figure 4. The AM3UH group showed a significantly better visual acuity across defocus from +1.0 to -2.0 D than the SN6AD1 group (*P*=0.005; *P*=0.005; *P*=0.006; *P*<0.001; *P*<0.001; *P*<0.001; *P*=0.032). The AM4UH group showed visual acuity comparable to the SN6AD1 group, with a significantly better visual acuity at -0.5 D (*P*=0.024). The defocus ranges for 0.20 logMAR or better were approximately 2.5 D for the AM3UH group, 1.0 D for the AM4UH group, and 0.5 D for the SN6AD1 group.

IOP and ECD At 3, 6, and 12mo postoperatively, no statistically significant differences were observed in IOP and ECD among three groups (all *P*>0.05). At 12mo postoperatively, the IOP values in the AM3UH, AM4UH, and SN6AD1 groups were 12.35±2.48, 12.37±2.82, and 12.85±2.74 mm Hg, respectively, and the corresponding ECD values were 2204.86±451.37, 2324.59±494.63, and

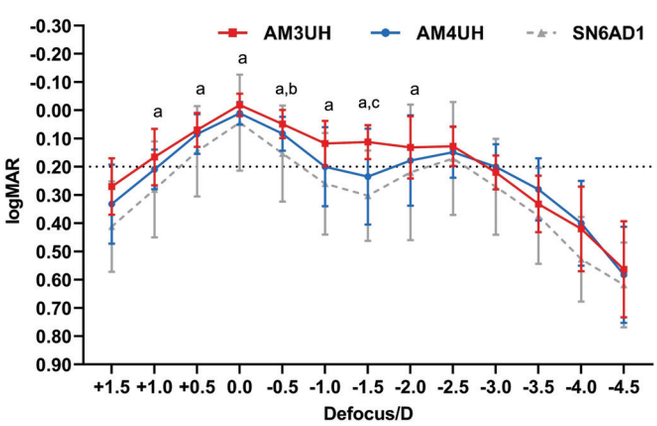


Figure 4 Defocus curves for each model of multifocal IOL at 12mo postoperatively [a]*P*<0.05 AM3UH *vs* SN6AD1, [b]*P*<0.05 AM4UH *vs* SN6AD1, [c]*P*<0.05 AM3UH *vs* AM4UH. IOL: Intraocular lenses; logMAR: Logarithm of the minimum angle of resolution.

Table 3 Comparison of the rates of visual symptoms at 12mo postoperatively

Symptoms	None (%)	Slight (%)	Mild (%)	Moderate (%)	Severe (%)	*P*
Glare						0.149
AM3UH	92.11	5.26	2.63	0	0	
AM4UH	90.32	6.45	3.23	0	0	
SN6AD1	80.00	13.33	0	5.33	1.33	
Halos						0.020[a]
AM3UH	94.74	5.26	0	0	0	
AM4UH	74.19	16.13	9.68	0	0	
SN6AD1	73.33	17.33	4.00	5.33	0	
Ghosting						0.503
AM3UH	94.74	5.26	0	0	0	
AM4UH	90.32	6.45	0	3.23	0	
SN6AD1	88.00	8.00	1.33	0.00	2.67	
Diplopia						0.737
AM3UH	97.37	2.63	0	0	0	
AM4UH	93.55	6.45	0	0	0	
SN6AD1	94.67	5.33	0	0	0	
Blurred vision						0.802
AM3UH	84.21	10.53	2.63	2.63	0	
AM4UH	77.42	19.35	0	3.23	0	
SN6AD1	80.00	14.67	2.67	2.67	0	

P-values from Kruskal-Wallis *H* test among the AM3UH, AM4UH, and the SN6AD1 groups. [a]Bonferroni post hoc: the AM3UH group versus the SN6AD1 group: *P*=0.021; the AM4UH group versus the SN6AD1 group: *P*=1.000; the AM3UH group versus the AM4UH group: *P*=0.107.

2240.97±438.28 cells/mm², respectively.

Subjective Visual Quality At 12mo postoperatively, the VF-14 scores in the AM3UH, AM4UH, and SN6AD1 groups were 93.06±8.11, 87.92±13.09, and 91.25±9.48, respectively, and no statistically significant differences were observed in the VF-14 scores among three groups (*P*=0.232).

Except for statistically incidence of halos in the AM3UH group compared to the SN6AD1 group at 12mo postoperatively (*P*=0.021), there were no statistically significant differences in the incidence of other visual symptoms among three groups (Table 3).

Complications No complications such as wound leakage, severe endophthalmitis, hyphema, pupillary block, IOL dislocation, or persistent elevation of IOP occurred during surgery or throughout the 1-year follow-up period.

DISCUSSION

Proming® IOLs (AM3UH/AM4UH) are hybrid multifocal-EDF IOLs that combine a posterior diffractive multifocal design with an anterior high-order aspheric EDF design[12,17], while AcrySof® ReSTOR® IOL (SN6AD1) is a diffractive multifocal IOL. They are commonly used in clinical practice, with different near additions. Therefore, this study compared the SN6AD1 IOL with the AM3UH or AM4UH IOLs, focusing on postoperative visual acuity, safety, and subjective visual quality.

At 12mo postoperatively, monocular UDVA and BCDVA in the three groups was <0.20 logMAR, with no statistically significant differences among three groups, indicating that these IOLs provide satisfactory distance vision. In terms of intermediate visual acuity, UIVA in the AM3UH group was 0.09±0.07 logMAR, consistent with previously reported outcomes for similar lenses[18]. The AM3UH group demonstrated significantly better UIVA and DCIVA than the SN6AD1 group (*P*=0.004; *P*=0.001), which may be attributed to the EDF aspheric design that modulates spherical aberration to extend the depth of focus and enhance intermediate visual performance[19]. However, the AM3UH group showed slightly worse DCNVA compared to the AM4UH group, which may be attributed to its lower add power[20], whereas the higher near addition of AM4UH enhances near visual acuity at the cost of continuity at intermediate distances. Furthermore, the AM4UH group exhibited comparable intermediate and near visual acuity to the SN6AD1 group, with no statistically significant differences.

In terms of refractive outcomes at 12mo, 79%, 77%, and 80% of eyes were within ±0.5 D in the AM3UH, AM4UH, and SN6AD1 groups, respectively, demonstrating comparable refractive predictability. Although a statistically significant difference in residual refraction was observed between the AM4UH and SN6AD1 group at 6mo postoperatively, this was

due to the AM4UH group values being >0 and the SN6AD1 group values being <0, and the absolute difference between them was small. This indicates that both achieved a relatively precise refractive correction. This outcome is similar to that reported for the ZFR00 IOL, which had a target postoperative SE of 0.09±0.14 D[21], consistent with the postoperative result in the AM4UH group of this study (0.19±0.63 D). Furthermore, this intergroup difference did not persist until 12mo post-surgery.

CS is a key outcome measure following IOL implantation, reflecting the visual system's ability to distinguish differences in luminance of static images[22]. Furthermore, the reduction in CS is a major cause of dissatisfaction among patients receiving multifocal IOLs[23]. In this study, no statistically significant differences in CS were observed among three groups under different conditions across all spatial frequencies. Moreover, all values fell within the normal range for this age group (≥60y)[24], indicating that CS remained at an acceptable level with both AM3UH and AM4UH implants. Comparison of the multifocal IOLs in this study with the traditional monofocal IOL reported in a previous study[25] showed that the differences remained within <0.3 log units, meeting the requirements for "simultaneous vision IOLs" specified in International Organization for Standardization (ISO) 11979-7:2024.

The defocus curves revealed that the AM3UH group exhibits the best continuity in visual acuity without a significant decline. The AM3UH group demonstrated a relatively wide negative defocus range of 2.5 D, with distance, intermediate, and near visual acuities reaching 0.20 logMAR or better, consistent with previous reports on the ZFR00[26-27]. The continuous visual range provided by the AM3UH IOL may be attributed to its EDF aspheric design, which bridges focal points to extend visual performance across distance, intermediate, and near ranges. These visual acuity results indicated that the AM3UH IOL meets the requirements for "full visual range (FVR) IOL" as defined in ISO 11979-7: 2024. The defocus curve of the AM4UH group most closely resembled that of the SN6AD1 group, with both IOLs showing two peaks at 0 and -2.5 D. The negative defocus range of the AM4UH group for achieving 0.20 logMAR was approximately 1.0 D, and exhibited a more pronounced decline in visual acuity at -1.5 D compared to the AM3UH group. This curve profile is very similar to that previously reported for another hybrid multifocal-EDF IOL (Artis Symbiose® Plus, France, add power +3.25 D)[28]. Besides, a conventional monofocal IOL has been reported to achieve 0.20 logMAR over a negative defocus range of only 0.5 D[29], which is 2.0 D and 0.5 D narrower than the ranges observed in the AM3UH and AM4UH groups in this study, respectively. Additionally, the defocus curve of the SN6AD1 group in our study was consistent with the findings reported by de Vries *et al*[30] and Li *et al*[31].

At 12mo postoperatively, the incidence of halos in the AM3UH group was significantly lower than that in the SN6AD1 group (P=0.021). This suggests that this design offers a potential advantage in reducing patients' discomfort from halos. No statistically significant differences were observed in the incidence of other visual symptoms among three groups. Furthermore, no significant differences were found in the VF-14 scores among three groups. Participants in all three groups reported satisfactory postoperative visual quality.

This study has several limitations. First, the assessment of postoperative visual quality was not comprehensive, lacking objective evaluations such as higher-order aberrations. Second, as an open-label clinical study, both patients and investigators were aware of the IOL model assigned, which may have introduced some subjective bias. Future studies should implement a masked design to minimize this potential bias.

In conclusion, all three IOLs demonstrated comparable performance in terms of refractive predictability, CS, and safety. The hybrid multifocal-EDF IOLs (AM3UH and AM4UH) provided improved postoperative visual acuity, an extended range of continuous vision, and favorable subjective visual quality. The AM3UH IOL fulfills the requirements for an FVR IOL specified in ISO 11979-7:2024.

ACKNOWLEDGEMENTS

Authors' Contributions: Study concept and design (Song XD, Wang NL); data collection, analysis and interpretation (Song XD, Li ZH, Zhang H, Guan HJ, Liao RF, Yu AY, Song H); manuscript preparation (Song XD), critical revision of the manuscript (Wang NL). All authors read and approved the final manuscript.

Data Availability Statement: The data used to support the findings of this study are available from the corresponding author upon reasonable request.

AI-Generated Content Disclosure: No AI tools were used in the preparation of this manuscript.

Conflicts of Interest: Song XD, None; **Li ZH,** None; **Zhang H,** None; **Guan HJ,** None; **Liao RF,** None; **Yu AY,** None; **Song H,** None; **Wang NL,** None.

REFERENCES

1 Cicinelli MV, Buchan JC, Nicholson M, *et al*. Cataracts. *Lancet* 2023;401(10374):377-389.

2 Yu JG, Ye T, Xiang Y. Comparison of visual outcomes of enhanced monofocal versus conventional monofocal intraocular lenses: a meta-analysis of randomized controlled trials. *Int Ophthalmol* 2026;46(1):318.

3 Beltraminelli T, Rizzato A, Toniolo K, *et al*. Comparison of visual performances of enhanced monofocal versus standard monofocal IOLs in a mini-monovision approach. *BMC Ophthalmol* 2023;23(1):170.

4 Rampat R, Gatinel D. Multifocal and extended depth-of-focus intraocular lenses in 2020. *Ophthalmology* 2021;128(11):e164-e185.

5 Cho JY, Won YK, Park J, *et al*. Visual outcomes and optical quality of accommodative, multifocal, extended depth-of-focus, and monofocal intraocular lenses in presbyopia-correcting cataract surgery: a systematic review and Bayesian network meta-analysis. *JAMA Ophthalmol* 2022;140(11):1045-1053.

6 Imburgia A, Gaudenzi F, Mularoni K, *et al*. Comparison of clinical performance and subjective outcomes between two diffractive trifocal intraocular lenses (IOLs) and one monofocal IOL in bilateral cataract surgery. *Front Biosci* (*Landmark Ed*) 2022;27(2):41.

7 Tavassoli S, Ziaei H, Yadegarfar ME, *et al*. Trifocal versus extended depth of focus (EDOF) intraocular lenses after cataract extraction. *Cochrane Database Syst Rev* 2024;7(7):CD014891.

8 Xu J, Zheng T, Lu Y. Comparative analysis of visual performance and astigmatism tolerance with monofocal, bifocal, and extended depth-of-focus intraocular lenses targeting slight myopia. *J Ophthalmol* 2020;2020:9283021.

9 Li BW, Huang H, Huang MS, *et al*. Changes in visual performance after implantation of different intraocular lenses. *Int J Ophthalmol* 2024;17(7):1273-1282.

10 Ozturkmen C, Kesim C, Karadeniz PG, *et al*. Visual acuity, defocus curve and patient satisfaction of a new hybrid EDOF-multifocal diffractive intraocular lens. *Eur J Ophthalmol* 2022;32(5):2988-2993.

11 Dick HB, Ang RE, Corbett D, *et al*. Comparison of 3-month visual outcomes of a new multifocal intraocular lens vs a trifocal intraocular lens. *J Cataract Refract Surg* 2022;48(11):1270-1276.

12 Huang H, Liao X, Lan CJ, *et al*. *In vitro* assessment of the optical performance for various near addition bifocal extended depth of focus IOLs. *Chin J Optom Ophthalmol Vis Sci* 2025;27(3):191-200.

13 Yu F, Wang K, Chen LL, *et al*. Comparison of clinical efficacy between diffractive multifocal intraocular lens and regional refractive intraocular lens in treatment of senile cataracts. *Chin J Ocul Traum Occupat Eye Dis* 2025;47(1):1-7.

14 Ang RE, Picache GCS, Rivera MCR, *et al*. A comparative evaluation of visual, refractive, and patient-reported outcomes of three extended depth of focus (EDOF) intraocular lenses. *Clin Ophthalmol* 2020;14:2339-2351.

15 Son HS, Labuz G, Khoramnia R, *et al*. Ray propagation imaging and optical quality evaluation of different intraocular lens models. *PLoS One* 2020;15(2):e0228342.

16 Khadka J, Huang JH, Mollazadegan K, *et al*. Translation, cultural adaptation, and Rasch analysis of the visual function (VF-14) questionnaire. *Invest Ophthalmol Vis Sci* 2014;55(7):4413-4420.

17 Li QY, Wan XH. Grasp the product characteristics and reasonable use of multifocal intraocular lenses. *Chin J Ophthalmol Med (Electronic Edition)* 2025;15(02):65-70.

18 Chang DH, Hu JG, Lehmann RP, *et al*. Clinical performance of a hybrid presbyopia-correcting intraocular lens in patients undergoing cataract surgery in a multicenter trial. *J Cataract Refract Surg* 2023;49(8):840-847.

19 Weeber HA, Piers PA. Theoretical performance of intraocular lenses correcting both spherical and chromatic aberration. *J Refract Surg* 2012;28(1):48-52.

20 Wang MM, Corpuz CCC, Fujiwara M, *et al*. Visual and optical performances of multifocal intraocular lenses with three different near additions: 6-month follow-up. *Open Ophthalmol J* 2015;9:1-7.

21 Shin DE, Lee H, Koh K. Comparative analysis of a presbyopia-correcting intraocular lens that combines extended depth-of-focus and bifocal profiles with a standard monofocal intraocular lens. *BMC Ophthalmol* 2022;22(1):302.

22 McGwin G, Scilley K, Brown J, *et al*. Impact of cataract surgery on self-reported visual difficulties comparison with a no-surgery reference group. *J Cataract Refract Surg* 2003;29(5):941-948.

23 Woodward MA, Randleman JB, Stulting RD. Dissatisfaction after multifocal intraocular lens implantation. *J Cataract Refract Surg* 2009;35(6):992-997.

24 Hohberger B, Laemmer R, Adler W, *et al*. Measuring contrast sensitivity in normal subjects with OPTEC® 6500: influence of age and glare. *Graefes Arch Clin Exp Ophthalmol* 2007;245(12):1805-1814.

25 Auffarth GU, Gerl M, Tsai L, *et al*. Clinical evaluation of a new monofocal IOL with enhanced intermediate function in patients with cataract. *J Cataract Refract Surg* 2021;47(2):184-191.

26 Kim J, Kim TI, Seo KY, *et al*. A comparative study of two presbyopia-correcting intraocular lenses combining bifocal and extended depth-of-focus profiles. *Int Ophthalmol* 2024;44(1):54.

27 Jiao Y, Liu JJ, Chang XK, *et al*. Early clinical outcomes of tecnis synergy intraocular lens implantation that combines extended depth-of-focus and diffractive multifocal profiles. *Chin J Optom Ophthalmol Vis Sci* 2024; 26(11):861-868.

28 Whang WJ, Kim TI, Tchah H, *et al*. Clinical outcomes of a new four-haptic hydrophobic presbyopia-correcting intraocular lens. *Sci Rep* 2023;13(1):8357.

29 Wang JH, Luo JW, Yang WY, *et al*. Efficacy and comfort following the implantation of extended depth of focus, multifocal, and monofocal intraocular lenses in cataract patients. *BMC Ophthalmol* 2024;24(1):423.

30 de Vries NE, Webers CAB, Montés-Micó R, *et al*. Visual outcomes after cataract surgery with implantation of a +3.00 D or +4.00 D aspheric diffractive multifocal intraocular lens: Comparative study. *J Cataract Refract Surg* 2010;36(8):1316-1322.

31 Li HL, Liu DL, Gao H, *et al*. Visual performance following bilateral implantation of refractive rotationally asymmetric bifocal intraocular lens (LS-313 MF30) or apodized diffractive bifocal intraocular lens (ReSTOR SN6AD1). *Ther Clin Risk Manag* 2021;17:917-926.