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Comparison of bilateral implantation of extended depth-of-focus intraocular lens and mix-and-match implantation of extended depth-of-focus intraocular lens with a diffractive bifocal intraocular lens

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双眼微单视焦深延长型人工晶状体与混合搭配双焦点人工晶状体植入疗效对比

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摘要

目的:比较双眼微单视焦深延长型人工晶状体与混合搭配双焦点人工晶状体植入的临床疗效。

方法:回顾性病例对照研究。收集白内障患者 130 例(260 眼),分为双眼植入 Tecnis ZXR00 人工晶状体 RR 组 70 例(140 眼),目标屈光度分别为 0--0.25 D(正视眼)和 -0.5 D--0.75 D(视近眼),及双眼分别植入 Tecnis ZXR00 和 Tecnis ZMB00 人工晶状体 RM 组 60 例(120 眼),目标屈光度均为 0--0.25 D。比较两组患者术后 3 mo 裸眼远、中、近距离视力、矫正远视力、高阶像差、调制传递函数、离焦曲线、立体视及 VF-14 问卷调查。

结果:RR 组具有更好的双眼中视力,RM 组具有更好的双眼近视力(均 $P<0.05$);RM 组有更好的 MTFs 值及更低的高阶像差(均 $P<0.05$)。两组间立体视和 VF-14 问卷得分差异不具有统计学意义($P>0.05$)。

结论:微单视植入焦深延长型人工晶状体明显提高近视力。根据患者需求选择人工晶状体的不同的搭配植入方式以达到精准治疗的目的。

关键词:焦深延长型人工晶状体(EDOF);Tecnis ZMB00;离焦曲线;微单视;混搭视力

Abstract

• AIM: To compare the clinical outcomes of extended depth-of-focus intraocular lenses (EDOF IOLs) using either micromonovision implantation or mixed implantation of EDOF and diffractive bifocal IOLs.

• METHODS: This retrospective clinical trial included 130 patients (260 eyes), who were divided into two groups. Group RR comprised 70 patients (140 eyes) bilaterally implanted with ZXR00 IOLs (Tecnis ZXR00, where one target was -0.5 D to -0.75 D and the other was 0 to -0.25 D). Group RM comprised 60 patients (120 eyes) unilaterally implanted with both ZXR00 and ZMB00 IOLs (Tecnis ZMB00, 0 to -0.25 D). Postoperative outcomes were compared after 3 mo, including visual acuity, defocus curves, stereoacuity, modulation transfer functions (MTFs), higher-order aberrations, and Visual Function-14 (VF-14) questionnaire responses.

• RESULTS: Group RR had superior bilateral intermediate vision, while the group RM had superior bilateral near vision (both $P<0.05$). Group RM also exhibited superior MTFs and reduced higher-order aberrations (both $P<0.05$). Stereoacuity and VF-14 questionnaire results showed no statistically significant difference between groups ($P>0.05$).

• CONCLUSION: The implantation of micromonovision has significantly improved near vision. IOLs and their collocation can be customized according to individual patient needs to achieve precise treatment and provide cataract patients with high-quality vision.

• KEYWORDS: extended depth-of-focus (EDOF) intraocular lens; Tecnis ZMB00; defocus curve; micromonovision; mix-and-match vision

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INTRODUCTION

Phacoemulsification cataract surgery has evolved into a form of refractive surgery. The primary goals of modern cataract surgery are removing the cataract and restoring clear, comfortable vision. The development of multi-focal intraocular lenses (MIOLs) and extended-depth-of-focus (EDOF) intraocular lenses (IOLs) has enabled the restoration of full-range vision. Bifocal IOLs provide good near and distance vision according to different degrees of attachment; however, their intermediate vision is relatively limited[1]. EDOF IOLs offer an extended depth of focus for intermediate and distance vision, providing excellent visual acuity at these distances. However, for patients who require high near-visual acuity, EDOF IOLs may be inadequate[1-2]. To address the need for a full range of vision, we compared micromonovision implantation using the Tecnis ZXR00 IOL (Johnson & Johnson Vision) [targeting 0 to −0.25 diopters (D) in one eye (R0 eyes) and −0.5 D to −0.75 D in the other eye (Rn eyes)] to a mix-and-match approach using the ZXR00 and Tecnis ZMB00 IOLs (Johnson & Johnson Vision; both targeting 0 to −0.25 D). Micromonovision is an adaptation of monovision with binocular anisometropia ranging from 0.5 D to 3.0 D. The micromonovision design with a target of −0.5 D to −0.75 D can ensure postoperative vision quality, visual acuity, and stereoscopic vision, while also extending the depth of focus[3]. Studies have shown that this design with the ZXR00 lens ensures a full range of vision[3-4]. We analyzed the advantages and disadvantages of both implantation methods to select the most suitable treatment plans based on individual patient needs.

SUBJECTS AND METHODS

Subjects The inclusion criteria for this study were as follows: preoperative ocular axial length of 22-26 mm, kappa distance < 0.3 mm, alpha distance < 0.5 mm, corneal spherical aberration (pupil 4 mm) <0.3 μm, pupil diameter 3.0-5.5 mm in a dark room, and postoperative refractive diopters ≤0.75 D. Participants with a history of ocular trauma or surgery, pupillary abnormalities, evident strabismus, or ocular/systemic conditions affecting visual acuity (except cataracts) were excluded. This study was approved by the Ethics Committee of our institution (No. 2022057) and adhered to the principles of the Declaration of Helsinki. Overall, 130 patients with cataracts (260 eyes) who underwent phacoemulsification combined with IOL implantation at our institution's Ophthalmology Department between September 2020 and August 2021 were enrolled and divided into two groups based on the IOL implantation. Seventy patients (140 eyes) received bilateral ZXR00 IOLs (Group RR), while 60 patients (120 eyes) received a mix of ZXR00 and ZMB00 IOLs (Group RM). There were no significant differences between the groups (Table 1).

Preoperative examination Patients in both groups underwent detailed preoperative examinations, including assessments of visual acuity, intraocular pressure, slit-lamp biomicroscopy, fundoscopy, B-ultrasound, optical coherence tomography, keratometry, corneal topography, and corneal specular microscopy. ITRACE were used for kappa distance, alpha distance, corneal spherical aberration and pupil diameter. IOL calculations were conducted using the IOL Master 700 (Zeiss, Germany). The degree of the IOL was calculated using the Barrett formula. For the group RR, the target residual spherical diopter was 0 to −0.25 D for one eye and −0.5 D to −0.75 D for the other eye. For the group RM, the target diopter was 0 to −0.25 D for both eyes. After routine preoperative examinations, all patients were informed of the potential risks and consented to surgery. An experienced ophthalmologist conducted phacoemulsification and IOL implantation. Patients had binocular surgery between 15 and 30 days apart.

Postoperative examination The study included complete postoperative visits between 90 and 100 d after surgery for both groups. All patients underwent detailed examinations, including assessments of monocular and binocular uncorrected distance visual acuity (UDVA) at 5 m, uncorrected intermediate visual acuity (UIVA) at 80 cm, uncorrected near visual acuity (UNVA) at 40 cm, and corrected distance visual acuity (CDVA). Monocular and binocular defocus curves were generated using automatic comprehensive optometry (Japan TOPCON), starting from −2.0 D with incremental additions of 0.5 D spherical lenses to simulate various visual conditions. The diopter was plotted on the x-axis, and visual acuity on the y-axis. Contrast spatial frequencies at 5.0, 10.0, 15.0, and 20.0 cycles per degree (c/d) in modulation transfer functions (MTFs) were measured,

Table 1 Demographic characteristics of patients in each group $\bar{x}\pm s$

Measurements	Group RR (70/140)	Group RM (60/120)	P
Sex (male/female)	29/41	30/30	>0.05
Age (years)	58.60±1.64	55.48±12.23	>0.05
Pre-CDVA (decimal)	0.41±0.22	0.38±0.22	>0.05
AL (mm)	23.61±1.43	23.55±1.57	>0.05
CYL	−0.39±0.47	−0.43±0.35	>0.05

Tecnics Symfony ZXR00 and Tecnis ZMB00 were manufactured by Johnson & Johnson Vision (Santa Ana, CA, USA). Pre-CDVA: Preoperative corrected distance visual acuity; AL: Axial length; CYL: Cylinder.

along with whole-eye higher-order, comatic, and trefoil aberrations using the ITRACE visual function instrument. The Titmus test measured stereoacuity at 40 cm. Patient satisfaction was assessed using the Chinese version of the Visual Function - 14 (VF - 14) questionnaire, with satisfaction rated as very satisfied, satisfied, average, or unsatisfactory.

Statistical Analysis This was a retrospective case-control study. SPSS software (Version 26.0, International Business Machine Corp.) was used for statistical analysis, and measurement data were expressed as mean±standard deviation ($\bar{x}\pm s$). The data from both groups were normally distributed and showed homogeneity of variance. An independent t-test was used for analysis, with differences considered statistically significant at $P<0.05$.

RESULTS

Visual Acuity In the group RR, the UNVA was 0.34±0.116 LogMAR in R0 eyes and 0.29±0.105 LogMAR in Rn eyes, a statistically significant difference ($P=0.02$; Table 2, Figure 1). The UIVA was 0.16±0.171 LogMAR in R0 eyes and 0.14±0.159 LogMAR in the group RM, which was not significantly different ($P=0.56$). There were no significant differences in the UDVA and CDVA between the groups ($P=0.36$; $P=0.06$).

In the group RM, the UNVA was 0.26±0.131 LogMAR for ZMB00 implantations and 0.35±0.117 LogMAR for ZXR00, a statistically significant difference ($P=0.00$; Table 2; Figure 2). The UIVA was 0.30±0.150 LogMAR for ZMB00 implantations and 0.18±0.122 LogMAR for ZXR00, also a statistically significant difference ($P=0.00<0.05$). There were no significant differences in the UDVA and CDVA between eyes with ZMB00 and ZXR00 implantations ($P=0.15$; $P=0.27$).

There were no significant differences between the groups RR and RM regarding bilateral UDVA, CDVA, and residual astigmatism ($P=0.34$, $P=0.22$, and $P=0.73$, respectively; Table 2). However, the group RM had significantly better UNVA than the group RR ($P=0.00$). Conversely, the group RR had significantly better UIVA than the group RM ($P=0.00$).

Defocus Curves The defocus curves (Figure 2) for the group RR showed excellent distance visual acuity from +0.5 D to −0.5 D, fair intermediate distance visual acuity from −1.0 D to −2.0 D, and good near visual acuity from −2.5 D to −3.5 D. The bilateral defocus curves slightly higher than either one in the group RR. In the group RM, there was good distance visual acuity from +0.5 D to −0.5 D and good near visual acuity from −2.5 D to −4.0 D. Additionally, the group RM maintained good intermediate distance visual acuity from −0.5 D to −2.5 D. The bilateral defocus curves in the group RM have similar near vision with ZMB00 IOL defocus curve, equal intermediate distance visual acuity with ZXR00 IOL defocus curve.

Modulation Transfer Function In the group RR, the mean MTF of the R0 eye exceeded that of the Rn eyes; however, the difference was not significant ($P>0.05$). The differences in spatial frequencies at 5.0, 10.0, 15.0, and 20.0 c/d with a 3 mm pupil between the two groups were also not significant ($P=0.08$, $P=0.50$, $P=0.86$, and $P=0.21$, respectively). In the group RM, the mean MTFs and spatial frequencies at 5.0, 10.0, 15.0, and 20.0 c/d with a 3 mm pupil for ZXR00 implantations were significantly higher than those for ZMB00 implantations ($P=0.01$, $P=0.01$, $P=0.02$, $P=0.03$, and $P=0.03$, respectively; Figure 3).

Total Higher-order Aberrations In the group RR, higher-order, comatic, and trefoil aberrations of Rn eyes were as good as R0 eyes ($P=0.29$, 0.28, and 0.15, respectively). In the group RM, ZXR00 implantations had significantly fewer higher-order, comatic, and trefoil aberrations than ZMB00 implantations ($P=0.03$, $P=0.04$, and $P=0.03$, respectively; Figure 3).

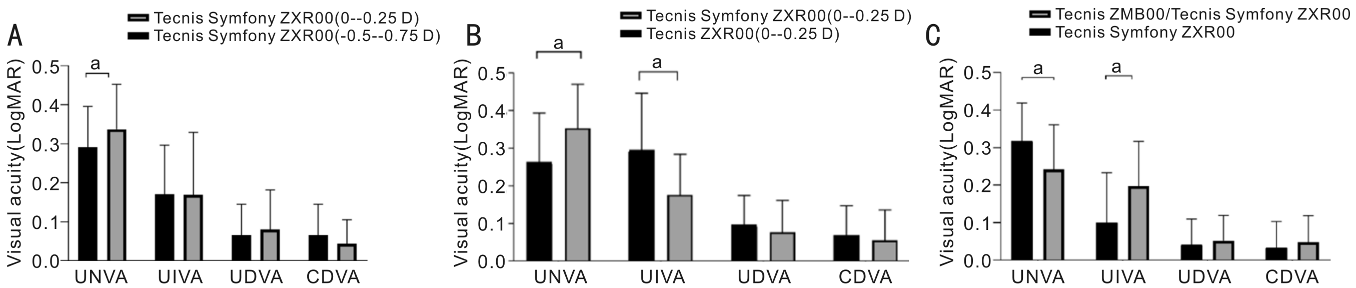

Figure 1 Visual acuity. A: Visual acuity in the group RR; B: Visual acuity in the group RM; C: Bilateral visual acuity in the group RR and group RM. [a]Statistically significant difference ($P<0.05$). UNVA: Uncorrected near visual acuity; UIVA: Uncorrected intermediate visual acuity; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity.

Table 2 Postoperative bilateral visual acuity following intraocular lens implantation in each group($\bar{x}\pm s$, LogMAR)

Measurements	Group RR	Group RM	P
UNVA (40 cm)	0.32±0.102	0.24±0.119	<0.05
UIVA (80 cm)	0.10±0.132	0.20±0.119	<0.05
UDVA	0.04±0.069	0.05±0.067	>0.05
CDVA	0.03±0.069	0.05±0.070	>0.05

UNVA: Uncorrected near visual acuity; UIVA: Uncorrected intermediate visual acuity; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity.

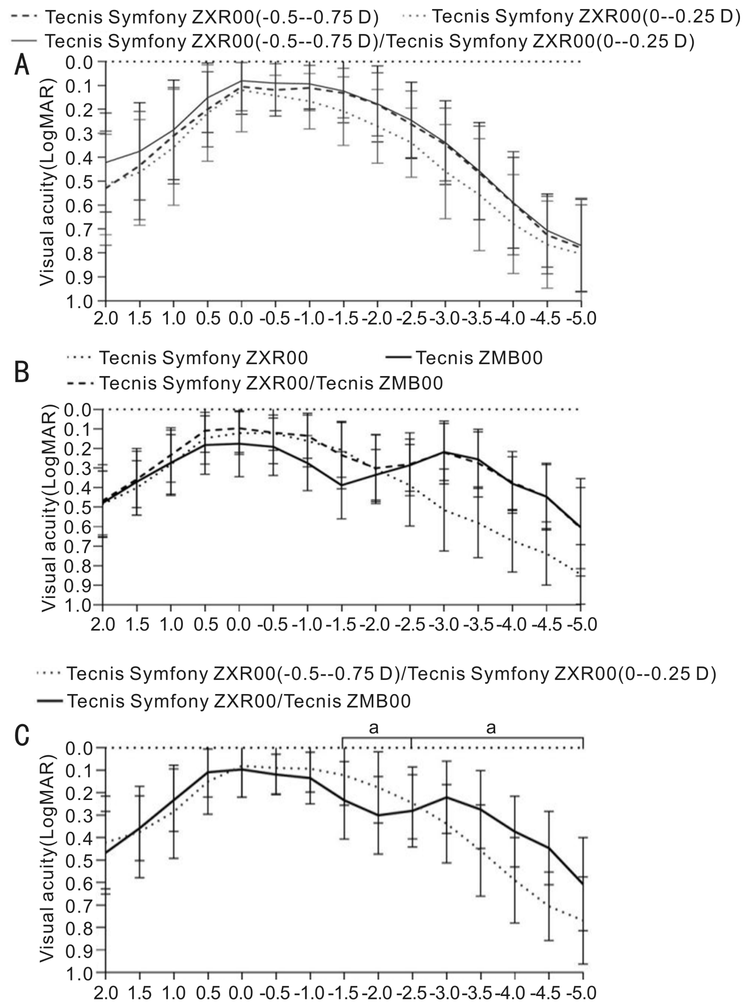

Figure 2　Defocus curves.　[a]Statistically significant difference ($P<0.05$). A: Defocus curves in the group RR; B: Defocus curves in the group RM; C: Defocus curves for bilateral in the group RR and the group RM.

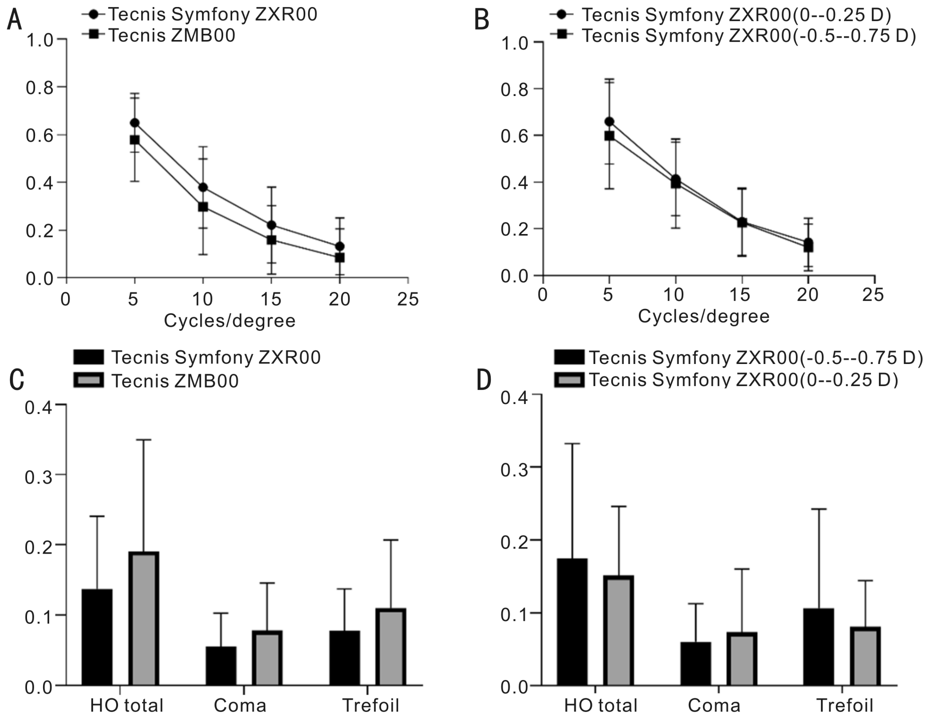

Figure 3　Higher-order aberrations and modulation transfer functions.　A: MTF curve in the group RM, spatial frequencies at 5.0, 10.0, 15.0, and 20.0 c/d for ZXR00 implantations were significantly higher than those for ZMB00 implantations; B: MTF curve in the group RR, the difference between both eyes was not statistically significant; C: Higher-order aberrations in the group RR. ZXR00 implantations had significantly fewer higher-order, comatic, and trefoil aberrations than ZMB00 implantations; D: Higher-order aberrations in the group RM, the difference between both eyes was not statistically significant.

Near Stereoacuity Near stereoacuity at 40 cm was 80.7±77.15 arcsec (range, 20-400 arcsec) in the group RR and 96.63±79.49 arcsec (range, 20-400 arcsec) in the group RM, the difference was not significant ($P>0.05$). In the group RR, 43% (30/70) of patients had stereoacuities of ≥100 arcsec, whereas in the group RM, 65% ($n=39/60$) of patients had stereoacuities of ≥100 arcsec.

VF-14 Questionnaire and Satisfaction The mean VF-14 scores were 40.97±2.58 points in the group RR and 40.05±3.32 points in the group RM. The difference in total VF-14 questionnaire scores between both groups was not statistically significant ($P=0.08$). In the group RR, 35 patients (50%) had difficulty reading small fonts (*e.g.*, instructions, address books, price labels, bank receipts, and water and electricity bills), 5 patients (8%) in the group RM reported similar difficulties. Ten (14%) patients in the group RR and 60 (67%) in the group RM reported some difficulty in recreational activities (mahjong, poker, and chess). The percentage of patients who reported being either satisfied or very satisfied was 92% in the group RR and 93% in the group RM. Six patients in the group RR expressed average satisfaction.

DISCUSSION

MIOLs and EDOF IOLs have been increasingly utilized in clinics to improve vision and visual quality in patients with cataracts and to address presbyopia. MIOLs do not provide a truly complete range of vision, and EDOF IOLs are slightly deficient in near vision but with better visual quality during clinical uses. Therefore, to meet the different needs of patients with cataracts, micromonovision implantation of ZXR00 lenses or mix-and-match implantation of ZXR00 and ZMB00 lenses can be considered.

In this study, we did not strictly differentiate between dominant and non-dominant eyes. According to Seijas *et al*[5], eye dominance is related to uncorrected and corrected distance visual acuity and contrast sensitivity, as improvement in these factors in the non-dominant eye following cataract surgery can make it the dominant eye. Additionally, in a phenomenon known as crossed monovision, the non-dominant eye is used for distance vision and the dominant eye for near vision. Studies have shown no significant differences between crossed and conventional monovision regarding uncorrected vision, stereoacuity, and patient satisfaction[6].

In the group RR, the UNVA of R0 eyes significantly surpassed that of Rn eyes ($P<0.05$). However, although the UIVA of R0 eyes exceeded that of Rn eyes, the difference was not significant ($P>0.05$). These results suggest that preserving certain diopters can partially improve intermediate and near visual acuity[1-3]. The visual acuities for far and intermediate distances in both eyes were greater than 0.4 LogMAR. Near visual acuity could also reach 0.5 LogMAR, indicating superior distance and intermediate visual acuities and satisfactory near visual acuities[7]. In the group RM, where ZXR00 and ZMB00 IOLs were mixed and matched, the UIVA of ZXR00 IOLs surpassed that of ZMB00 IOLs[8]. Group RM showed significantly improved postoperative UNVA compared to the group RR ($P<0.05$), with a peak value at approximately 33 cm[9]. Lee *et al*[10] proposed that the near vision of mixed ZMB00 and ZKB00 (+2.75 D) implantation was better than that of ZXR00 implantation in micromonovision. Additionally, the group RR demonstrated excellent intermediate visual acuities. Paik *et al*[11] compared three methods for improving intermediate vision: bilateral implantation of ZXR00 IOLs in micromonovision, bilateral implantation of FineVision IOLs (+1.75 D/+3.50 D), and bilateral mixed implantation of ZLB00 (+3.25 D) and ZKB00 (+2.75 D) IOLs. The results showed that ZXR00 IOLs in micromonovision provided the best intermediate vision. Moreover, the group RR exhibited superior visual acuity ranging from 0 to -2.5 D, representing good visual acuity beyond 40 cm.

Higher-order aberrations account for 10% of total aberrations, including spherical, comatic, and trefoil aberrations. After 3 mo, the comatic and trefoil aberrations in Rn eyes slightly surpassed those in R0 eyes ($P>0.05$). In Group RM, aberrations in eyes with ZMB00 implantations were significantly higher than in eyes with ZXR00 implantations ($P<0.05$). Paik *et al*[11] also demonstrated that ZXR00 IOLs had less visual interference and provided more comfort compared to monofocal and trifocal IOLs.

MTF is an objective measure of image quality, indicating the contrast between the output and input images at different spatial frequencies. High spatial frequencies reflect the details of small objects, whereas low spatial frequencies reflect the contours of objects[12]. In healthy individuals, the mean MTF value is greater than 30%. In the group RR, MTF values in R0 eyes were significantly higher than in Rn eyes ($P<0.05$), indicating that R0 eyes had clearer vision at low spatial frequencies of 5.0 and 10.0 c/d. In the group RM, MTF values for ZXR00 implantations were higher than those for ZMB00 implantations ($P<0.05$), indicating that ZXR00 provided clearer visual quality.

Patients with stereoacuity had the highest binocular function. We found no statistically significant difference in stereoacuity between micromonovision and mixed-and-matched implantation. Hayashi *et al*[13] compared the combined binocular implantation of SN6AD1 (+3.00 D) and SN6AD3 (+4.00 D) lenses with the bilateral implantation of SN6AD1 lenses alone and found no statistical difference in near-stereoscopic vision between the two methods. Similarly, Bissen-Miyajima *et al*[14] reported no significant differences in stereoscopic vision when employing similar design principles with different additional degrees of MIOL.

Overall, questionnaire and satisfaction in both groups exceeded 90%. Table 3 lists recent comparative studies on MIOLs such as ZMB00 and ZXR00. Considering the general near vision of ZXR00, researchers have explored micromonovision implantation with a binocular difference of 0.75 D, which significantly improves near vision. The visual acuity limitations of ZMB00 lenses can be addressed by

Table 3　Comparative studies on multifocal intraocular lenses

Author	Study design	IOL	Patients	Key Findings
Liu *et al* (2019)[15]	Prospective	ZXR00/ZMB00	109	ZXR00 proved to be remarkable in distance and intermediate vision, defocus curve smoothness, CSs, and visual comfort, while ZMB00 achieved better near vision.
Paik *et al* (2020)[16]	Prospective	ZKB00(+2.75) &ZLB00 (+3.25) /ZXR00/FineVision	60	The ZXR00 group had significantly worse binocular visual acuity than the Trifocal group. The ZXR00 group had relatively lower values in contrast sensitivity tests.
Turhan *et al* (2021)[17]	Prospective	ZXR00 implantation with micromonovision	15	Bilateral ZXR00 implantation led to excellent outcomes for far and intermediate vision, satisfactory outcomes for near vision, and good tolerance to micromonovision at the end of the 6 mo.
Moshirfar *et al* (2021)[18]	Prospective	ZXR00/PanOptix	146	The PanOptix demonstrated an initial superiority at near distances, but after three-months, the two IOLs had similar outcomes.
Cochener (2018)[3]	Prospective	ZXR00 implantation with micromonovision	411	Mini-monovision of around 0.75 D after implantation of the Tecnis ZXR00 IOL provided a complete visual rehabilitation.
de Medeiros *et al* (2017)[9]	Prospective	PanOptix/ZMB00 &ZXR00	40	The mixed group exhibited a better performance for very short distances and for intermediate and long distances ≥-1.50 D of vergence.
Bissen-Miyajima *et al* (2019)[14]	Prospective	ZMB00&ZMB00/ ZMB00&ZKB00/ ZMB00&ZLB00	56	Staged implantation of different add powers obtained better binocular intermediate visual acuity without degradation of visual function.

IOL: Intraocular lens.

combining them with other lenses (*e.g.*, ZLB00 and ZKB00). These strategies were incorporated into the design of our study, which includes a large sample size. However, the retrospective nature of this study is a limitation. As mentioned in the literature, the patient's dominant eye is not static and may be transformed by cataract aggravation or improved visual acuity after cataract surgery, but due to the small sample size of the cited literature, we considered the absence of preoperative predominance eye examination as a limitation of this study. A prospective comparative case series with a follow-up period longer than 3 mo would be more robust. In the group RR, the R0 eyes showed excellent intermediate vision, while the ZMB00 implantation group in the group RM exhibited excellent near vision. Both groups demonstrated improved overall visual acuity. Group RR had superior intermediate visual acuity, whereas the group RM had superior near vision. Therefore, ZXR00 implantation with micromonovision is more suitable for patients with high-to-medium vision requirements, while mixed implantation of ZXR00 and ZMB00 lenses is ideal for patients with higher near-vision needs. In conclusion, IOLs and their configurations can be customized according to patient needs to achieve precise treatment and provide patients with cataracts with good visual quality.

Conflicts of Interest: Li T, None; Li ZY, None; Guo R, None; Hu XM, None; Zhang H, None.

Authors' contributions: Li T and Zhang H designed the study; Li T, Li ZY, Hu XM, and Guo R conducted research; Li T analyzed the data and wrote the paper.

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