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Comparison of postoperative visual acuity between two TECNIS multifocal intraocular lenses with different collocations

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两种 TECNIS 多焦点人工晶状体不同组合方式植入术后视力对比

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摘要

目的:对比双眼均植入 Tecnis Symfony ZXR00(ZXR00)、双眼分别植入 ZXR00 和 Tecnis ZMB00(ZMB00)以及双眼均植入 ZMB00 患者术后视力、视觉质量及患者满意度。

方法:回顾性病例对照研究。收集 2020-08/2021-12 行白内障超声乳化吸除联合人工晶状体(IOL)植入的白内障患者 117 例(234 眼),根据 IOL 不同分为三组:37 例(74 眼)双眼植入 ZMB00 为 MM 组;44 例(88 眼)双眼分别植入 ZXR00 和 ZMB00 为 MR 组;36 例(72 眼)双眼均植入 ZXR00 为 RR 组。观察三组患者术后 3 mo 裸眼远视力(UDVA,5 m)、裸眼中视力(UIVA,80 cm)、裸眼近视力(UNVA,40 cm)、矫正远视力(CDVA)、离焦曲线、立体视及 VF-14、QoV 视觉质量评分表问卷调查。

结果:MM 和 MR 组 UNVA 优于 RR 组($P<0.05$);而 MM 组与 MR 组不具有统计学差异。RR 组 UIVA 最优。三组的 UDVA、CDVA 和立体视均不具有统计学意义($P>0.05$)。术后 3 mo 时 MR、MM、RR 组 40 cm 近立体视锐度分别为 107.27±80.53、105.67±83.79、108.69±97.66(20-400)弧秒($P>0.05$)。MR、MM、RR 组的满意度均达到 90%以上。

结论:三组术后均具有良好的远、中、近视力和双眼近立体视。其中,MR 组具有更优异的全程视力。三组患者术后满意度均较高,可以根据患者的不同需求选择合适的多焦点人工晶状体。

关键词:连续视程人工晶状体(EDOF);Tecnis ZMB00;离焦曲线;人工晶状体植入;白内障

Abstract

• AIM: To investigate the effect of different lens combinations on visual acuity, visual quality and patient satisfaction by comparing mixed implantation of Tecnis Symfony ZXR00 (ZXR00) and Tecnis ZMB00 (ZMB00) lenses, bilateral implantation of ZMB00 lenses, and bilateral implantation of ZXR00 lenses.

• METHODS: This retrospective case-control study included 117 patients with cataracts (234 eyes) who underwent phacoemulsification combined with intraocular lens (IOLs) implantation from August 2020 to December 2021. The 3 groups included 36 patients (72 eyes) who underwent bilateral implantation of ZXR00 (RR group), 37 patients (74 eyes) who underwent bilateral implantation of ZMB00 (MM group), and 44 patients (88 eyes) who underwent implantation with a combination of ZXR00 and ZMB00 (MR group). The uncorrected distance visual acuity (UDVA, 5 m), uncorrected intermediate visual acuity (UIVA, 80 cm), uncorrected near visual acuity (UNVA, 40 cm), corrected distance visual acuity (CDVA), defocus curve, stereopsis and VF-14 and QoV

visual quality scale of the patients in the three groups were assessed at 3-month follow-up.

• RESULTS: Bilateral UNVA in the MM and MR group were significantly better than that in the RR group ($P<0.05$). Bilateral UIVA was the best in the RR group. There were no significant differences in bilateral UDVA, CDVA and stereopsis among the groups ($P>0.05$). Values for near-stereoscopic acuity at 40 cm were 107.27±80.53, 105.67±83.79, and 108.69±97.66 (20-400) arcsec in the MR, MM, and RR groups, respectively ($P>0.05$). Satisfaction rates exceeded 90% in all groups.

• CONCLUSION: All groups achieved good distance, intermediate, and near visual acuity and near-stereoscopic vision postoperatively. Mixed implantation with ZXR00 and ZMB00 lenses achieved excellent full-range vision and resulted in high satisfaction. These results may aid in developing individualized clinical treatment plans.

• KEYWORDS: extended depth-of-focus (EDOF); Tecnis ZMB00; defocus curve; intraocular lens implantation; cataracts

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INTRODUCTION

Modern cataract surgery primarily involves phacoemulsification with lens implantation to achieve a clear and comfortable range of vision. The emergence of multifocal intraocular lenses (MIOLs) and extended depth-of-focus (EDOF) intraocular lens (IOLs) has made full-range vision possible. Bifocal IOL have been associated with good near and far vision at different distances depending on the degree of near attachment, although vision at medium distances is relatively limited[1-2]. In contrast, EDOF IOL can achieve EDOF at medium and far distances[1,3]. However, for some patients with special needs for near visual acuity, EDOF IOL are inadequate[4].

The ZXR00 and ZMB00 IOLs were developed from the TECNIS platform and are advantageous as they are both made of hydrophobic acrylate material with a 360° square edge design that can reduce the incidence of posterior cataracts. Furthermore, they have a negative spherical aberration design that neutralizes the corneal positive spherical aberration and achieves zero spherical aberration correction in the whole eye, and the diamond cold cutting technology used to develop the lenses avoids flash formation. In addition, both lenses incorporate unique optical technologies.

The Tecnis ZMB00 (Johnson & Johnson Vision, Santa Ana, CA, USA) is an all-optical IOL with a posterior surface diffractive MIOL based on the principle of Huygens-Fresnel diffraction: light split into near and far focus, where the refractive force of the near focal point is mainly determined by the height and spacing of the wave rings. ZMB00 is a one-piece bifocal IOL with a light energy distribution of 50% at both the near and far focal points. The posterior surface was designed with 29 diffraction steps; the center ring has a transverse diameter of 1 mm; and the additional degree is +4.0 D. As the diffraction area is 6 mm, it does not depend on the pupil size[2]. However, ZMB00 lenses are limited in terms of middle distance vision[1,5].

Tecnis Symfony ZXR00 (Johnson & Johnson Vision) is a one-piece EDOF IOL with a posterior surface diffraction design, a central ring of 1.6 mm, and an additional degree of +1.75 D. The EDOF has a unique design principle. When light passes through different gradual steps of the IOL, light waves with synchronous amplitude become desynchronized. When two diffractive rays reach the macular area near the steps, the number of propagated waves differs by >2000. It is possible that light energy will resonate in a certain area to elongate the focus, which is the principle of EDOF. In addition, the ZXR00 features an achromatic design to improve contrast sensitivity and can provide whole-range visual acuity to patients[3], albeit with limitations in near vision[6-7]. To sum up, we compared the ability of three implantation methods to ensure full range of vision in these patients. Specifically, we aimed to investigate the advantages and disadvantages of bilateral implantation of ZXR00, mixed implantation of ZXR00 and ZMB00, and bilateral implantation of ZMB00.

SUBJECTS AND METHODS

Ethical Approval This study was approved by the ethics committee of Second Hospital of Jilin University (No. 2022057). The research was carried out in accordance with the principles of the Declaration of Helsinki.

Patients A total of 117 patients with cataracts (234 eyes) who underwent phacoemulsification combined with IOL implantation at the Ophthalmology Department of the Second Hospital of Jilin University from August 2020 to December 2021 were enrolled and classified into three groups according to the method of IOL implantation. The exclusion criteria were as follows: 1) diseases of the cornea, retina, or optic nerve; 2) refractive system turbidity other than cataracts; 3) history of eye surgery; 4) corneal astigmatism >0.75 D; 5) kappa angle ≥0.3 mm or alpha angle ≥0.5 mm; 6) other examination and follow-up difficulties.

The 3 groups included 36 patients (72 eyes) who underwent bilateral implantation of ZXR00 (RR group), 37 patients (74 eyes) who underwent bilateral implantation of ZMB00 (MM group), and 44 patients (88 eyes) who underwent implantation with a combination of ZXR00 and ZMB00 (MR group), respectively. There were no statistically significant differences in age or sex among the three groups ($P>0.05$; Table 1).

Table 1 Demographic characteristics of patients in each group

Measurement	MR (n=44)	MM (n=37)	RR (n=36)	P
Sex (male/female)	21/23	17/20	11/25	0.229
Age ($\bar{x}\pm s$, years)	58.07±13.12	53.24±11.58	60.02±8.42	0.031
Pre-CDVA ($\bar{x}\pm s$, D)	0.39±0.227	0.38±0.208	0.40±0.221	0.906
AL ($\bar{x}\pm s$, mm)	23.48±1.414	23.55±1.646	23.74±1.340	0.411
CYL ($\bar{x}\pm s$, D)	−0.29±0.258	−0.31±0.254	−0.27±0.349	0.877

Tecnis 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; D: Diopters; MR: The group who implanted with a combination of ZXR00 and ZMB00; MM: The group who received bilateral implantation of ZMB00; RR: The group who received bilateral implantation of ZXR00.

Preoperative examination Patients in both groups underwent detailed preoperative examinations, including optometry, keratometry, corneal topography, *etc*. IOL calculations were performed using an IOLMaster 700 system (Zeiss, Germany). The Barrett formula was used to calculate IOL degree. The reserved residual spherical diopter among the three groups ranged from 0 to −0.25 D. Surgical astigmatism was defined as 0. 50 D. All patients underwent phacoemulsification and IOL implantation performed by a single experienced ophthalmologist.

Postoperative examination The study involved complete preoperative and postoperative visits (90 to 100 days after surgery) in each group. All patients underwent optometry and a standard assessment using a logarithmic visual acuity chart to obtain the uncorrected near, intermediate, distance, and corrected distance visual acuity. Comprehensive optometry (Japan TOPCON) was used to draw binocular defocus curves, starting from −2.0 D. A spherical lens of 0.5 D was added each time to simulate the visual conditions at different distances, with the diopter as the abscissa and visual acuity as the ordinate. A Titmus test was used to measure stereoacuity at 40 cm, and patient satisfaction was investigated using the Chinese version of the Visual Function Index (VF-14) and Quality of Vision (QoV) scale. Each item on the VF-14 is assigned a value: 4 points = no difficulty, 3 points = somewhat difficult, 2 points = moderate difficulty, 1 points = very difficult, 0 points = unable to perform activities, not applicable. For the QoV scale, participants rated their experience with light phenomena as follows: never (0 points), occasionally (1 point), often (2 points), always (4 points). Satisfaction was rated as very satisfied, satisfied, average, or unsatisfactory.

Statistical Analysis This was a retrospective case-control study. SPSS software (version 26.0, IBM Corp., Armonk, NY) was used, and the measurement data are expressed as the mean ± standard deviation ($\bar{x}\pm s$). The Shapiro-Wilk test was used to determine whether the data samples conformed to a normal distribution, with a significance level of 5%. Groups compared in pairs used Mann-Whitney U tests. Differences among the three groups were assessed *via* Kruskal-Wallis analysis, and differences were considered statistically significant at P<0.05.

RESULTS

Visual Acuity Corrected distance visual acuity and visual acuity without correction for distance, intermediate, and near vision were measured at 3 mo postoperatively are summarized in Table 2 and Figure 1. No statistically significant was found among 3 groups on uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA; P>0.05). RR and MR groups had the best visual acuity for intermediate, and difference was statistically significant compared with MM groups (P<0.001, P<0.001). MR and MM groups had excellent near vision, and statistically significant differences was found compared with RR group (P<0.001, P=0.003).

Defocus Curves In the MR group, the defocus curves (Figure 2) for both eyes exhibited double peaks, with good distance vision in the range of +0.5 to −0.5 D, good intermediate vision in the range of −1.0 to −2.0 D, and good distance vision in the range of −2.5 to −3.5 D. The MM group exhibited a bimodal defocus curve, with good distance vision within the range of +0.5 to −0.5 D, good near vision within the range of −2.5 to −4.0 D, and good intermediate vision within the range of −0.5 to −2.5 D range. The RR group exhibited the best distance and intermediate visual acuity between 0.5 and −2.5 D, and the curve changed smoothly.

Near Stereoacuity At 3 mo postoperatively, values for near-stereoscopic acuity at 40 cm were 107.27±80.53, 105.67±83.79, and 108.69±97.66 (20-400) arcsec in the MR, MM, and RR groups, respectively, and no statistically significant difference was found (P>0.05). Stereoscopic acuity of 100 arcsec or greater was achieved in 45.5% (n=20/44) of patients in the MR group, 50.0% (n=19/38) of patients in the MM group, and 47.2% (n=17/36) of patients in the RR group.

Questionnaire Results Mean VF-14 scores were 41.34±3.93, 41.27±2.22, and 42.67±3.68 in the MR, MM, and RR groups, respectively. There were no statistically significant differences in total VF-14 scores of three groups (P>0.05). Mean QoV scale scores in the MR, MM, and RR groups were 10.36±2.47, 10.95±3.38, and 10.31±2.83, respectively (P>0.05). In the MR, MM, and RR groups, 96.0%,

93.0%, and 95.0% of the total number of patients reported being satisfied and very satisfied. There was no significant difference in the scores of glare, halo, starburst and shadow among the three groups.

DISCUSSION

Rapid advancements in medical technology have enabled continuous improvements in quality of life. Accordingly, cataract surgery has entered the era of refractive surgery, with an emphasis on restoration of sight. MIOLs and EDOF IOLs have allowed for improved visual quality in patients with cataracts, although each lens type has its own strengths and limitations. As the number of patients implanted with MIOLs continues to increase, we have observed that some patients undergo implantation with a combination of two different MIOLs. We, therefore, aimed to investigate the effect of these combinations on clinical outcomes by comparing hybrid implantation of ZXR00 and ZMB00 lenses, bilateral implantation of ZMB00 lenses, and bilateral implantation of ZXR00 lenses.

At the 3-month follow-up, UDVA and CDVA were less than 0.1 LogMAR in each group, indicative of excellent distance vision due to the designs of the ZMB00 and ZXR00. Indeed, multiple studies have shown that the distance vision of the ZXR00 IOL is not only better than that provided by MIOLs[8], but also better than that provided by monofocal IOLs[9]. In this study, uncorrected intermediate visual acuity (UIVA) was significantly better in the RR and MR groups than in the MM group ($P<0.001$). In addition, only one patient in the RR group had a postoperative median visual acuity of 0.4 LogMAR, and the median visual acuity of the other patients was above 0.3 LogMAR. The superior UIVA in the MR and RR groups highlights the superiority of the EDOF IOL ZXR00. In addition, there was no significant difference in UIVA between the RR and MR groups ($P>0.05$). The defocus curves were between -0.5 and -2.0 D and were comparable between the RR and MR groups, also suggesting that intermediate visual acuity in the MR group was not inferior to that in the RR group.

Song *et al*[10] compared bilateral implantation of AcrySof IQ PanOptix with mixed implantation of ZXR00 and ZLB00, reported that the mixed group exhibited better intermediate and distance visual acuity postoperatively. UNVA was the best in the MM group, with 0.18±0.143 LogMAR, which is consistent with previous research findings[5]. Although there was no significant difference in UNVA between the MM and MR groups, both values were significantly better than those in the RR group. Furthermore, in the defocus curves, the peaks for the MR and MM groups were located around -3.0 D[11], and the curves were relatively consistent with one another. In summary, these results indicate that the MR group attained excellent distance vision, equivalent to the UIVA, in the RR group and the UNVA in the MM group, thus ensuring excellent whole-range vision. Kim *et al*[12] observed that patients implanted with a combination of ZXR00 and ZLB00 (+3.25 D) also achieved good full-range visual acuity, high contrast sensitivity, and high satisfaction. As postoperative visual acuity in both eyes is generally better than that in individual eyes[13], it also avoids the insufficiency of monocular ZXR00 and ZMB00 to a certain extent, making mixed implantation a good choice for patients who have full vision requirements.

Stereoscopic vision refers to the perceptual ability of the visual organ to judge the position of objects in three-dimensional space, and it is an advanced visual function based on the simultaneous vision and fusion functions of both eyes. Our results indicate that there were no significant differences in stereoscopic vision among the three groups. Hayashi *et al*[14] compared combined binocular implantation of SN6AD1 (+3.00 D) and SN6AD3 (+4.00 D) with binocular implantation of SN6AD1, also reporting no significant differences in near-stereoscopic vision between the two methods. Bissen-Miyajima *et al*[15] also argued that there are no significant differences in stereoscopic vision among MIOLs with similar design principles, even with differences in additional degree.

Although the questionnaire responses reflect the subjective experience of the patient, results can be considered very reliable[16]. Scores on the VF-14, which reflects vision-related quality of life after cataract surgery, did not significantly differ among the three groups. In the RR group, 20 (54%) patients had difficulty reading small fonts (such as instructions, address books, price labels, bank receipts, and water and electricity bills), versus only 3 (6%) patients in the MR group. No patients in the MM group reported severe difficulty with reading small fonts. Two (5%) patients in the RR group, 4 (8%) in the MR group, and 35 in the MM group (80%) reported some difficulty with participating in recreational activities (mahjong, poker, chess), which may be related to the better intermediate vision in RR group and the better near vision in MM group. Importantly, the MR group achieved good intermediate and near vision at the same time.

The QoV scale reflects the impact of optical interference on vision after cataract surgery. Although differences in QoV scores among the groups were not significant, scores in the MM group were slightly lower than those in the other two groups, which may be related to the lower rate of light energy utilization for ZMB00 lenses[1]. Koo *et al*[17] compared bilateral implantation of ZMB00 and ZXR00 lenses with bilateral implantation of ZXR00 (preserving -0.5 D myopia), observing more frequent adverse optical interference in patients who underwent bilateral implantation with ZXR00 lenses, which may have been related to residual degree.

The major limitation of this study is that postoperative observations are subjective indicators that can be influenced

Table 2 Postoperative visual acuity following intraocular lens implantation in each group

Parameters	MM (n=37)	MR (n=44)	RR (n=36)	Comparison	P
UNVA	0.18±0.142	0.23±0.105	0.31±0.133	MM *vs* MR	0.116
				MM *vs* RR	0.000
				MR *vs* RR	0.003
				MM *vs* MR *vs* RR	0.000
UIVA	0.41±0.152	0.21±0.089	0.19±0.143	MM *vs* MR	0.000
				MM *vs* RR	0.000
				MR *vs* RR	0.514
				MM *vs* MR *vs* RR	0.000
UDVA	0.08±0.084	0.05±0.070	0.08±0.103	MM *vs* MR	0.192
				MM *vs* RR	0.987
				MR *vs* RR	0.237
				MM *vs* MR *vs* RR	0.348
CDVA	0.08±0.082	0.05±0.068	0.07±0.089	MM *vs* MR	0.138
				MM *vs* RR	0.786
				MR *vs* RR	0.278
				MM *vs* MR *vs* RR	0.305

Tecnis Symfony ZXR00 and Tecnis ZMB00 were manufactured by Johnson & Johnson Vision, Santa Ana, CA, USA. UNVA: Uncorrected near visual acuity; UIVA: Uncorrected intermediate visual acuity; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; MR: The group who implanted with a combination of ZXR00 and ZMB00; MM: The group who bilateral implanted with ZMB00; RR: The group who bilateral implanted with ZXR00.

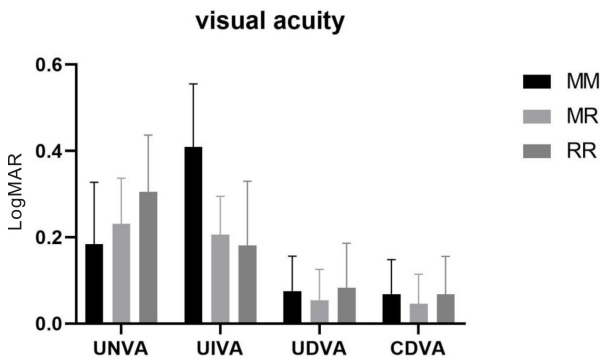

Figure 1 Bilateral visual acuity in the three groups. UNVA: Uncorrected near visual acuity; UIVA: Uncorrected intermediate visual acuity; UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; MR: The group who implanted with a combination of ZXR00 and ZMB00; MM: The group who bilateral implanted with ZMB00; RR: The group who bilateral implanted with ZXR00.

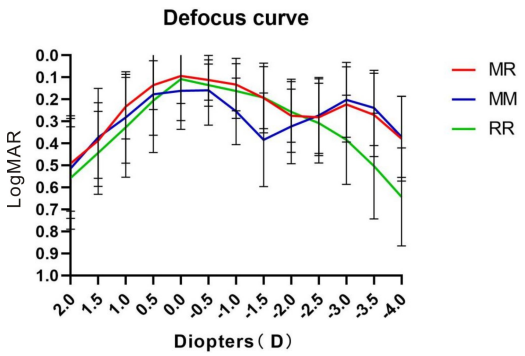

Figure 2 Defocus curves for the three groups. MR: The group who implanted with a combination of ZXR00 and ZMB00; MM: The group who bilateral implanted with ZMB00; RR: The group who bilateral implanted with ZXR00.

by psychological factors in each patient. Furthermore, as the sample size was small, trends may be more pronounced with larger sample sizes. Future research will be more objective and perfect if the sample size can be increased and objective visual quality inspection indicators can be added.

We compared patients with bilateral implantation of ZXR00 lenses, mixed implantation of ZXR00 and ZMB00 lenses, and bilateral implantation of ZMB00 lenses. All three groups achieved good distance, intermediate, and near visual acuity and near-stereoscopic vision postoperatively. Among them, the group that underwent mixed implantation with ZXR00 and ZMB00 lenses achieved excellent full-range vision and reported high satisfaction. These results may aid in the development of precise, individualized clinical treatment plans according to different patient needs and treatment goals.

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