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Visual function and optical quality after bilateral implantation of zonal refractive multifocal IOL in elderly patients

*Chen Jun**, *Qiu Xinying**, *Zhu Jie*, *Wei Yuanjian*

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Department of Ophthalmology, Nanping First Hospital Affiliated to Fujian Medical University, Nanping 353000, Fujian Province, China

* Co-first authors: Chen Jun and Qiu Xinying

Correspondence to: Wei Yuanjian. Department of Ophthalmology, Nanping First Hospital Affiliated to Fujian Medical University, Nanping 353000, Fujian Province, China. yuan334700@163.com

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高龄老人双眼植入区域折射型多焦点IOL的视觉功能和光学质量研究

陈 俊*,邱欣颖*,朱 捷,魏远建

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作者单位:(353000)中国福建南平市,福建医科大学附属南平第一医院眼科

*陈俊和邱欣颖对本文贡献一致

作者简介:陈俊,毕业于广西医科大学,硕士研究生,副主任医师,研究方向:白内障及微创青光眼;邱欣颖,毕业于福建医科大学,硕士研究生,住院医师,研究方向:白内障和青光眼。

通讯作者:魏远建,毕业于福建医科大学,硕士研究生,主任医师,研究方向:白内障及玻璃体视网膜疾病. yuan334700@163.com

摘要

目的:评价80岁及以上老年人双眼植入区域折射型多焦点人工晶状体的视觉功能和光学质量。

方法:采用单中心前瞻性非随机对照临床研究,根据患者(80岁及以上白内障患者)个人偏好,接受双眼植入LS-313 MF30或CT Asphina 409MP。术后评估包括矫正及未矫正的远、中、近视力,以及离焦曲线。使用视觉功能问卷(VF-14)、脱镜率和患者满意度调查进行主观评估,分析眩光、光晕和星芒等光干扰现象。

结果:与409MP组(13例26眼,85.77±2.20岁)相比,MF30组(8例16眼,85.38±2.56岁)在矫正和未矫正的中、近视力方面表现更优,而远视力在两组之间相当。MF30组的离焦曲线在0.00 D和3.00 D处有两个峰值,表明焦深更广。MF30组患者具更高的脱镜率和满意度。虽然眩光(28.% *vs* 18.5%,$P=0.584$)、星芒(9.5% *vs* 3.7%,$P=0.567$)和光晕(23.8% *vs* 11.11%,$P=0.438$)在MF30组中更常见但它们通常较轻,并不显著影响日常活动。

结论:区域折射型多焦点人工晶状体为80岁及以上老年患者提供更好的远近视觉、更高的脱镜率和满意度。尽管MF30的光干扰现象更常见,但它们通常较轻,并不显著影响日常活动。

关键词:区域折射型多焦点人工晶状体;80岁及以上;LS-313 MF30;白内障手术;前瞻性非随机对照临床研究

Abstract

• AIM: To evaluate the visual function and optical quality in adults aged 80y and older following the bilateral implantation of zonal refractive multifocal intraocular lens (IOL, LS-313 MF30).

• METHODS: A single-center, non-randomized, prospective clinical trial was conducted, involving cataract patients aged 80 y and older. Patients received bilateral implantation of the LS-313 MF30 or CT Asphina 409MP, based on personal preference. Postoperative assessments included uncorrected and corrected visual acuity at distance, intermediate, and near ranges, as well as defocus curve. Subjective evaluations were performed using the visual function (VF-14) questionnaire, spectacle independence rates, and patient satisfaction surveys. Photic phenomena such as glare, halos, and starbursts were also analyzed.

• RESULTS: The MF30 group (16 eyes from 8 participants, 85.38±2.56 y) exhibited superior uncorrected and corrected intermediate and near visual acuity compared to the 409MP group (26 eyes from 13 participants, 85.77±2.20 y), while distance visual acuity was comparable between groups. The defocus curve of the MF30 group revealed two peaks at 0.00 D and -3.00 D, indicating a broader depth of focus. Patients in the MF30 group reported higher rates of spectacle independence and greater satisfaction. While photic phenomena such as glare (28.6% *vs* 18.5%, $P=0.584$), starburst (9.5% *vs* 3.7%, $P=0.567$) and halos (23.8% *vs* 11.11%, $P=0.438$) were more prevalent in the MF30 group, they were generally mild and did not significantly impact daily activities.

• CONCLUSION: Zonal refractive multifocal IOLs provide elderly patients with improved distance and near vision, greater spectacle independence, and greater satisfaction. Although photic phenomena were slightly more frequent with MF30, they are generally reported as non-disruptive and do not affect their daily life compared to monofocal IOLs.

• KEYWORDS: zonal refractive multifocal intraocular lens; aged 80 years and older; LS-313 MF30; cataract surgery; non-randomized prospective clinical trial
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INTRODUCTION

Refractive cataract surgery is a common procedure aimed at restoring vision in patients with cataracts while simultaneously addressing pre-existing refractive errors. This surgery typically involves the removal of the cloudy natural lens and its replacement with a multifocal intraocular lens (IOL) designed to improve visual acuity at various distances[1]. With the aging population, cataract surgery has become increasingly prevalent, particularly among older adults, who often experience a decline in both visual function and quality of life due to cataracts[2].

The population aged 80 y and older presents unique challenges for multifocal IOL implantation. The implantation of multifocal IOLs in this age group offers several advantages, such as the potential for reduced dependence on glasses and improved functional vision at multiple distances. However, physiological changes associated with aging, such as reduced neuroadaptation capacity and decreased macular function—even in the absence of overt morphological abnormalities—can diminish contrast sensitivity and visual performance[3]. Concerns regarding visual disturbances, such as neuroadaptation failure, as well as the risk of decreased contrast sensitivity, must be carefully weighed against the benefits[2,4].

The zonal refractive multifocal IOL (Lentis Mplus LS-313 MF30, Teleon, Netherlands) is a rationally asymmetrical refractive multifocal IOL designed to optimize visual performance and reduce the typical adverse effect of other multifocal IOLs[5]. Unlike diffractive multifocal IOLs, which are associated with approximately 20% loss of scattered light and reducing contrast sensitivity, the MF30 minimizes light loss (approximately 7%), thereby potentially improving contrast sensitivity and reducing visual disturbances[6]. These features make it a promising option for patients aged 80 y and older, who may be more sensitive to optical imperfections and less adaptable to visual changes. Prior studies have shown that the MF30 can achieve satisfactory outcomes in terms of distance and near vision, with a high degree of patient satisfaction[7-11]. However, these studies often excluded the oldest age groups, particularly in individuals aged 80 y and above, leaving a gap in understanding the specific challenges and benefits for this demographic. The purpose of this study is to evaluate the visual function and optical quality in adults aged 80 y and older following the bilateral implantation of zonal refractive multifocal IOLs.

PARTICIPANTS AND METHODS

Ethical Approval This single-center non-randomized prospective clinical trial was performed. The study was approved by the Ethics Committee of Nanping First Hospital Affiliated to Fujian Medical University. The study adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from each patient prior to the start of the study.

Participants This study included patients undergoing cataract surgery between September 2023 and September 2024 at the Nanping First Hospital Affiliated to Fujian Medical University. The inclusion criteria were aged 80 y and older. No active ocular diseases were present, except for cataracts or mild dry eye. The angle κ was within 0.5 mm, with no abnormalities in pupil function. Preoperative corneal astigmatism was 1.00 diopter (D) or below. Spherical aberration within ±0.25 μm, corneal HOA < 0.5 μm were included in the study. The exclusion criteria included instability of the zonules or capsule, a history of refractive surgery, dislocation of IOL, or any other ocular condition (such as amblyopia, retinal diseases, or optic nerve disorders) that could negatively impact postoperative visual outcomes, corneal endothelial cell count < 1000 cells/mm^2, any clinical evidence of Fuchs endothelial dystrophy or corneal guttata. According to the actual needs, patients were implanted with MF30 or monofocal IOLs bilaterally (CT Asphina 409 MP, Carl Zeiss, Germany).

Preoperative Examination Preoperative assessments included uncorrected distance visual acuity (UDVA), tonometry, endothelial cell count, corneal topography, biometry (Lenstar LS 900, Haag-Streit AG, Switzerland), slit-lamp evaluation, optical coherence tomography and scanning laser ophthalmoscopy. Based on the examination results from lenstar 900, the Barrett Universal II Formula was used to select IOL power. The IOL power was chosen to target emmetropia±0.25 D.

Surgical Technique All surgeries were performed by the same experienced ophthalmologist (Zhu J). After topical anesthesia was administered, a 2.8-mm temporal corneal incision was made. The anterior capsule of the lens was accessed and incised through capsulorhexis, followed by hydrodissection, wherein a balanced salt solution was instilled around the lens to facilitate separation. The phacoemulsification handpiece was then introduced to emulsify the lens, which was subsequently aspirated. After comprehensive irrigation and aspiration to eliminate any residual material, a folded IOL (MF30 or 409MP) was positioned within the capsular bag. The surgeon conducts final irrigation to ensure optimal fluid dynamics and inspects for any

remnants, as the incision typically seals without sutures.

Postoperative Follow-up and Assessments All patients were evaluated at 1 wk, 1 mo, and 3 mo postoperatively. Specifically, visual acuity was measured at each visit. We measured UDVA and corrected distance visual acuity (CDVA) at 5 m, uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate visual acuity (DCIVA) at 80 cm, as well as uncorrected near visual acuity (UNVA) and distance-corrected near visual acuity (DCNVA) at 40 cm. Additionally, a monocular defocus curve was tested by adding spherical lenses ranging from +1.00 to -4.00 D in 0.50 D increments, allowing us to evaluate the depth of focus based on visual acuity thresholds.

Subjective assessment is equally important in understanding the overall effectiveness of multifocal IOLs. The Visual Function index-14 (VF-14) questionnaire will be utilized to assess vision-related quality of life and satisfaction with visual function. Optical side effects, including glare, halos, and stabursts, are common concerns among patients receiving multifocal IOLs. Understanding the prevalence and impact of these side effects is crucial for patient counseling and managing expectations. We categorized these effects into three severity levels: never, occasionally, and always. Furthermore, the rate of spectacle independence for both distance and near vision will be evaluated. We will classify patients based on their need for corrective lenses into three categories: completely spectacle-free, occasionally needing glasses, and consistently needing glasses. Finally, patient satisfaction will be assessed through a straightforward grading system, including three levels: very satisfied (indicating a willingness to choose the same IOL again or recommend it to others), somewhat satisfied, and dissatisfied (indicating intolerable visual disturbances).

Statistical Analysis Statistical analysis of the data was performed using SPSS 23.0. Measurement data were expressed as mean±standard deviation ($\bar{x}\pm s$). If the data satisfied a normal distribution and homogeneity of variances, a paired t-test was used. For non-normally distributed ranked data, the Mann-Whitney U test was applied. Comparison of rates was performed using the chi-square test or Fisher's exact test. The significance level was set at $\alpha=0.05$.

RESULTS

The demographic and preoperative clinical data of patients enrolled in each group were summarized in Table 1. No statistically significant differences were observed between the two groups in terms of age, sex, preoperative UDVA, axial length, corneal endothelial cell count, corneal astigmatism, angle κ, pupil diameter, tear break-up time or Schirmer I test (Table 2).

Postoperative monocular visual acuity was assessed at 1 wk, 1 mo, and 3 mo. Within each group, UDVA and CDVA remained stable across all visits, with no statistically significant changes. The MF30 group demonstrated significantly better UIVA, DCIVA, UNVA, and DCNVA compared to the 409MP group (Tables 3 and 4).

Table 1 Characteristics of IOL

Parameters	LS-313 MF30	CT Asphina 409MP
Type	Zonal refractive multifocal	Monofocal
Optic design	Biconvex, aspheric, a sector-shaped near-vision area with a +3.00 D addition	Biconvex, aspheric
Material	Hydrophilic with hydrophobic surface	Hydrophilic with hydrophobic surface
Haptics	4-haptic	4-haptic
Optic diameter	6.0 mm	6.0 mm
Total diameter	11.0 mm	11.0 mm

IOL: Intraocular lens.

Table 2 Preoperative patient demographics

Demographics	MF30	409MP	*P*
Participants/eyes (*n*)	8/16	13/26	-
Male/female (*n*)	3/5	4/9	0.32
Age (y)	85.38±2.56	85.77±2.20	0.69
UDVA (LogMAR)	0.64±0.18	0.70±0.17	0.29
Axial length (mm)	23.28±0.88	23.04±0.68	0.32
Corneal endothelial cell count (/mm^2)	2308.63±199.49	2361.19±254.25	0.49
Corneal astigmatism (D)	0.56±0.25	0.56±0.24	0.94
Angel κ (mm)	0.21±0.2	0.19±0.10	0.61
Pupil diameter (mm)	3.49±0.36	3.56±0.52	0.65
Corneal HOA (μm)	0.23±0.09	0.22±0.10	0.69
Tear break-up time (s)	8.59±1.90	8.63±1.68	0.94
Schirmer I test (mm)	9.98±2.78	8.58±2.10	0.07

UDVA: Uncorrected distance visual acuity; LogMAR: Logarithm of the minimum angle of resolution; D: Diopter; HOA: Corneal higher-order aberration.

Table 3 Measurements of uncorrected visual acuities after IOL implantation ($\bar{x}\pm s$, LogMAR)

Postoperative visit	MF30	409MP	*P*
UDVA			
Postoperative 1 wk	0.22±0.05	0.20±0.08	0.313
Postoperative 1 mo	0.18±0.07	0.16±0.09	0.352
Postoperative 3 mo	0.16±0.08	0.15±0.08	0.616
UIVA			
Postoperative 1 wk	0.44±0.06	0.49±0.08	0.030
Postoperative 1 mo	0.41±0.04	0.48±0.09	0.006
Postoperative 3 mo	0.39±0.04	0.47±0.08	0.003
UNVA			
Postoperative 1 wk	0.31±0.08	0.77±0.10	<0.001
Postoperative 1 mo	0.28±0.08	0.77±0.11	<0.001
Postoperative 3 mo	0.28±0.08	0.77±0.12	<0.001

IOL: Intraocular lens; UDVA: Uncorrected distance visual acuity; UIVA: Uncorrected intermediate visual acuity; UNVA: Uncorrected near visual acuity.

Table 4 Measurements of corrected visual acuities after IOL implantation ($\bar{x}\pm s$, LogMAR)

Postoperative visit	MF30	409MP	*P*
CDVA			
Postoperative 1 wk	0.16±0.05	0.15±0.08	0.450
Postoperative 1 mo	0.15±0.05	0.14±0.08	0.723
Postoperative 3 mo	0.14±0.05	0.13±0.07	0.734
DCIVA			
Postoperative 1 wk	0.39±0.03	0.47±0.09	0.002
Postoperative 1 mo	0.38±0.04	0.47±0.10	0.001
Postoperative 3 mo	0.38±0.04	0.45±0.09	0.001
DCNVA			
Postoperative 1 wk	0.26±0.07	0.75±0.10	<0.001
Postoperative 1 mo	0.24±0.07	0.74±0.09	<0.001
Postoperative 3 mo	0.23±0.07	0.74±0.10	<0.001

IOL: Intraocular lens; CDVA: Corrected distance visual acuity; DCIVA: Distance-corrected intermediate visual acuity; DCNVA: Distance-corrected near visual acuity.

Figure 1 illustrated the monocular defocus curves for the two groups at 1 and 3 mo. The MF30 group provided superior intermediate and near vision compared to the 409MP group, providing a range of stable proper vision. In the MF30 group, two peaks were observed approximately at 0.00 and −3.00 D, whereas in the 409MP group, only one peak was observed at 0.00 D.

At the final visit, participants completed questionnaire evaluations (Table 5). The percentage of patients achieving a VF-14 score of 90 or higher was higher in the MF30 group compared to the 409MP group (87.5% *vs* 38.5%, P = 0.067). In terms of spectacle independence, the MF30 group reported significantly higher rates than the 409MP group (87.5% *vs* 15.4%, P = 0.002). Patient satisfaction was higher in the MF30 group compared to the 409MP group (75.0% *vs* 38.5%, P=0.183). Glare (28.6% *vs* 18.5%, P= 0.584), starburst (9.5% *vs* 3.7%, P = 0.567) and halos (23.8% *vs* 11.11%, P=0.438) severity were higher in the MF30 group, though there were no statistically significant differences between the two groups (Figure 2).

DISCUSSION

To evaluate visual function and optical performance in adults aged 80 y and above after bilateral implantation of zonal refractive multifocal IOLs, cataract patients were divided into two groups: MF30 and 409MP. As a result, eyes with zonal refractive multifocal IOLs effectively enhance both far and near vision, finding similar good distance visual acuities when compared to monofocal IOLs[10,12]. Despite the advanced age of the patients and challenges in visual quality, patient satisfaction after implantation of zonal refractive multifocal IOLs remain high. Although photic phenomena persist, they are generally reported as non-disruptive and do not affect their daily life.

The MF30 group exhibited superior uncorrected and corrected intermediate and near visual acuity compared to the 409MP group, while distance visual acuity was comparable between groups. This improvement in visual performance could lead to a better quality of life, enabling patients to perform daily tasks with greater ease and comfort. In contrast, the comparison of distance visual acuity revealed that both groups performed

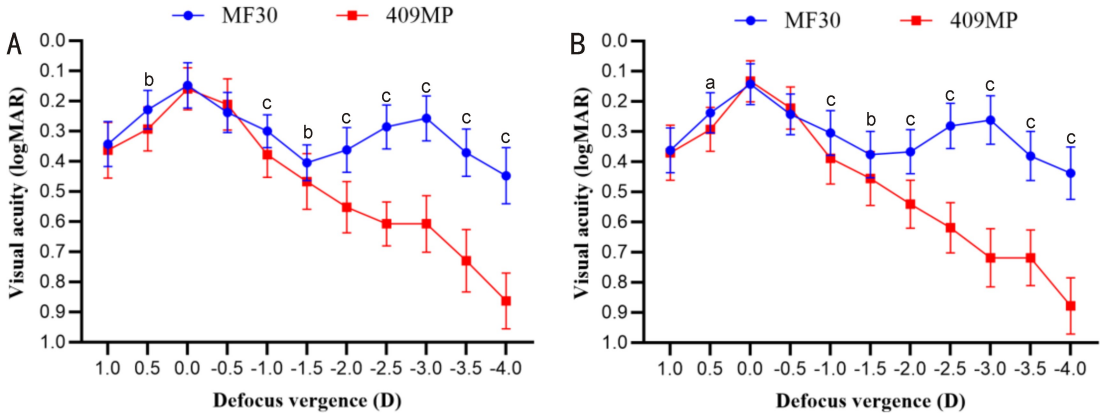

Figure 1 **Mean monocular defocus curves in the MF30 group and 409MP group at 1 mo (A) and 3 mo (B)** [a]$P<0.05$, [b]$P<0.01$, [c]$P<0.001$.

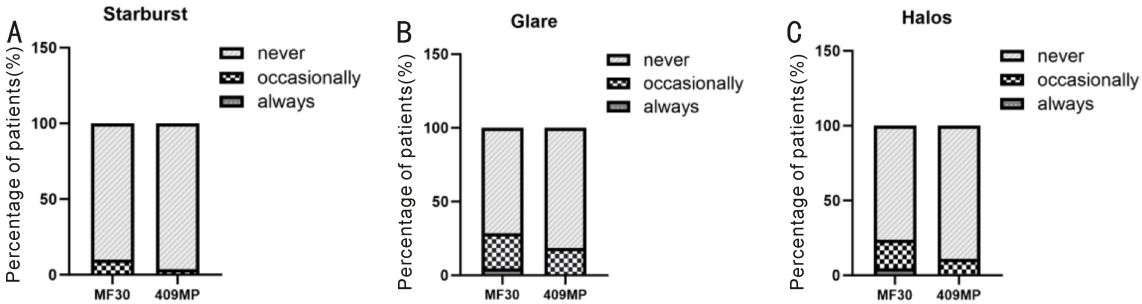

Figure 2 **Severity of halo (A), starbursts (B), and glare (C) in the MF30 group and 409MP group.**

Table 5 **Subjective assessment based on questionnaires conducted at 3 mo after IOL implantation**

Categories	MF30	409MP	*P*
VF-14 score			
VF-14 score>90%	7 (87.5%)	5 (38.5%)	0.067
Spectacle independence			
Completely spectacle-free	7 (87.5%)	2 (15.4%)	0.002
Occasionally needing glasses	1 (12.5%)	8 (61.5%)	0.067
Consistently needing glasses	0	3 (23.1%)	0.257
Satisfaction			
Very satisfied	6 (75.0%)	5 (38.5%)	0.183
Somewhat satisfied	1 (12.5%)	6 (46.2%)	0.173
Dissatisfied	1 (12.5%)	2 (15.3%)	>0.9999

IOL: Intraocular lens; VF-14: Visual Function index-14.

similarly, indicating that both optical interventions are effective for distance vision needs. Studies of Álvarez-García *et al*[7] and Nuzzi *et al*[10] showed MF30 provided good performance for monocular and binocular distance and near visual acuity, similar to our study.

The defocus curve serves as an essential method for assessing the visual performance of multifocal IOLs[13]. Several clinical studies have shown that patients with zonal refractive multifocal IOLs can obtain good near and far vision[10,14-16]. Similar to these previous studies, our study revealed that the MF30 groups achieved high overall satisfaction and greater independence from distance and near glasses. The growing reliance of elderly Chinese individuals on smartphones rather than computers or driving highlights their prioritization of near vision functionality. This preference underscores the importance of multifocal IOLs that optimize near vision, such as the MF30, over alternatives like the MF15, which emphasize intermediate vision.

Subjective questionnaires are frequently considered crucial for evaluating patients' personal experiences. As we previously stated, MF30 has an innovative design specifically intended to reduce photic phenomena. While some patients may still experience photic phenomena such as glare and halos, the overall patient satisfaction indicates that MF30 are more accommodating of minor refractive errors or other optical imperfections, maintaining excellent vision quality and reducing the need for glasses.

Historically, the population aged 80y and older have often been excluded from receiving multifocal IOLs due to factors such as higher - order aberrations, dry eye disease,

degenerative ocular conditions, and reduced neuroadaptation capacity, which can adversely affect contrast sensitivity and overall visual performance[17-18]. These factors necessitate stricter patient selection criteria to ensure optimal outcomes. A thorough assessment of each patient's unique visual needs and health status is essential to make informed decisions regarding this intervention in older adults. The MF30 design makes light focus on a specific area for near vision, while another section of the lens is in charge of focal point for distance. This design allows MF30 to provide effective near and distance vision, with similar contrast sensitivity to monofocal IOLs[19]. Additionally, MF30 operate independently of pupil size and show reduced sensitivity to lens decentration[20].

The extent of cost-effectiveness was also sensitive to patient age, probability of spectacle dependence, and satisfaction[21]. The higher cost also limits the choice of multifocal IOLs for elderly patients[22-23]. Fortunately, the implementation of the centralized procurement policy for IOLs by the National Healthcare Security Administration (NHSA) has significantly reduced the cost of multifocal IOLs in China, making them more accessible to a broader population (Announcement of centralized procurement policy for IOLs and Sports Medicine Medical Consumables Organized by the National Government. https://hc.tjmpc.cn:10128/public/show14416.html). This policy has been instrumental in promoting the patient's satisfaction, particularly among elderly patients who may benefit from improved visual outcomes.

One limitation of our study is its non-randomized design, as patients were grouped based on personal preferences rather than random allocation. This approach may introduce selection bias and limit the generalizability of our findings. Additionally, our study focused on early postoperative outcomes following MF30 implantation, leaving long-term visual and optical quality outcomes to be explored in future research. At the beginning of the study, we considered using the CSV-1000 to test the contrast sensitivity. However, most of the elderly patients are difficult to complete this test, which made data collection very challenging.

In conclusion, thebilateral implantation of zonal refractive multifocal IOLs provides cataract patients aged 80 y and older with improved visual quality and a higher degree of spectacle independence compared to monofocal IOLs. Although photic phenomena were slightly more frequent with MF30, they are generally reported as non-disruptive and do not affect their daily life.

Conflicts of Interest: Chen J, None; Qiu XY, None; Zhu J, None; Wei YJ, None

Authors' Contributions: Chen J and Qiu XY performed research and analyzed data. Wei YJ designed the research and analyzed the results. Zhu J and Wei YJ provided suggestions for research and data analysis. Chen J and Qiu XY wrote the manuscript. All authors contributed to and approved the final version of the manuscript.

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(以综合评价总分为序)

期刊名称	核心总被引频次		核心影响因子		综合评价总分	
	数值	排名	数值	排名	数值	排名
国际眼科杂志	**2278**	**1**	**1.067**	**2**	**75.3**	**1**
中华眼科杂志	1881	2	0.961	3	73.4	2
眼科新进展	1157	4	0.947	4	72.9	3
中国中医眼科杂志	1314	3	1.114	1	50.2	4
中华实验眼科杂志	877	5	0.593	8	49.3	5
中国眼耳鼻喉科杂志	446	8	0.624	6	48.4	6
中华眼底病杂志	609	7	0.603	7	46.1	7
中华眼视光学与视觉科学杂志	767	6	0.752	5	42.2	8
临床眼科杂志	329	9	0.359	10	36.3	9
中华眼科医学杂志电子版	151	12	0.113	12	32.7	10
中国斜视与小儿眼科杂志	243	11	0.493	9	27.5	11
眼科	301	10	0.237	11	22.6	12

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