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Enhancing patient outcomes after cataract, corneal and refractive surgery

Edited by
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Enhancing patient outcomes after cataract, corneal and refractive surgery

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Table of contents

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Editorial: Enhancing patient outcomes after cataract, corneal and refractive surgery

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Editorial on the Research Topic
Enhancing patient outcomes after cataract, corneal and refractive surgery

The field of ophthalmic surgery continues to evolve at an unprecedented pace, driven by technological advances, refined surgical techniques, and an increasingly sophisticated understanding of patient-centered care. The Research Topic titled "*Enhancing patient outcomes after cataract, corneal and refractive surgery*" published in Frontiers in Medicine presents thirteen carefully curated studies that collectively illuminate the current state of these surgical disciplines and point toward future directions for improving patient outcomes. These contributions span the entire spectrum of contemporary ophthalmic surgical practice, from advanced intraocular lens technologies to novel surgical techniques and comprehensive outcome assessments.

Contemporary advances in intraocular lens technology

Extended depth of focus and enhanced monofocal IOLs

The evolution of intraocular lens technology represents one of the most significant advances in modern cataract surgery, with particular emphasis on providing patients with extended ranges of functional vision while minimizing photic phenomena. The Research Topic includes pivotal research on non-diffractive enhanced depth-of-focus (EDOF) IOLs, which demonstrate remarkable potential in challenging patient populations. The work by Elvira and colleagues examining visual outcomes with non-diffractive EDOF IOLs in patients with age-related macular degeneration represents a paradigm shift in surgical decision-making for this complex population. Recent evidence suggests that patients with AMD who undergo cataract surgery with EDOF IOL implantation can achieve functional spectacle-free vision ranges while maintaining contrast sensitivity within acceptable

parameters. These findings are particularly significant given that traditional teaching has advocated for monofocal IOLs in AMD patients due to concerns about visual quality degradation (Elvira et al.) (1).

Complementing this research, the comprehensive review by Levy and colleagues on mini-monovision outcomes with monofocal, enhanced monofocal, and EDOF lenses provides crucial clinical guidance for optimizing presbyopia correction strategies. The systematic analysis demonstrates that mini-monovision with EDOF IOLs achieves spectacle independence rates of 63.4% compared to 51% and 55% for monofocal and enhanced monofocal lenses, respectively (Levy et al.). This approach offers superior intermediate and near visual acuity while maintaining excellent distance vision, with a mean logMAR binocular uncorrected intermediate visual acuity of 0.08 ± 0.07 (Levy et al.).

Post-refractive surgery considerations

The increasing prevalence of patients with previous refractive surgery presenting for cataract extraction has necessitated specialized approaches to IOL selection and power calculation. The investigation by Fan and colleagues on wavefront-shaping intraocular lenses in post-LASIK patients demonstrates that modern EDOF IOLs can provide excellent visual outcomes in this challenging population. Post-LASIK eyes achieved superior uncorrected near visual acuity compared to virgin eyes, with defocus curves maintaining visual acuity close to 0.3 logMAR even at −3.0 diopters (Fan et al.).

This superior performance in post-LASIK eyes may be attributed to the interaction between residual corneal higher-order aberrations and the wavefront-shaping properties of modern EDOF lenses, creating a synergistic effect that enhances depth of focus. Such findings challenge traditional assumptions about visual quality in post-refractive surgery patients, suggesting that appropriately selected presbyopia-correcting IOLs may offer significant advantages over conventional monofocal lenses (Fan et al.) (2, 3).

Precision in IOL power calculation

Intraoperative aberrometry vs. preoperative biometry

The quest for refractive predictability has led to significant advances in IOL power calculation methodologies, particularly for challenging cases, such as those with short and long eyes. The comparative study by Tañá-Rivero and colleagues examining intraoperative aberrometry vs. preoperative biometry represents a significant contribution to understanding optimal approaches for IOL power selection in extreme axial lengths (Tañá-Rivero et al.).

Contemporary research demonstrates that intraoperative aberrometry exhibits superior performance in eyes with long axial lengths (>25.0 mm) compared to traditional biometry-based formulas, with significantly lower mean absolute errors and reduced instances of hyperopic surprises. In short eyes (<22.1 mm), intraoperative aberrometry performs comparably to the most advanced biometry-based formulas, including Barrett Universal II and Hill-RBF, suggesting its utility as a valuable adjunctive tool rather than a replacement for sophisticated preoperative calculations (Tañá-Rivero et al.) (4, 5). The clinical implications are substantial, as accurately calculating IOL power in extreme axial lengths remains one of the most significant challenges in modern cataract surgery.

Surgical technique innovations

Advanced techniques for complex cases

The management of complex cataracts continues to challenge even experienced surgeons, necessitating innovative approaches to minimize complications and optimize outcomes. The clinical trial by Huang and colleagues, investigating the artificial lens cushion plate technique for hard-core cataracts, demonstrates significant advances in protecting the corneal endothelium during challenging cases (Huang et al.). This technique demonstrates remarkable efficacy in preserving corneal endothelial cells, with significantly lower endothelial cell loss rates compared to conventional phacoemulsification ($p < 0.05$). The reduced ultrasonic energy requirements and decreased total energy consumption associated with this approach represent important advances in managing the most challenging nuclear densities while maintaining surgical safety (Huang et al.) (6).

Astigmatism management and tolerance

Understanding premium IOL performance with residual astigmatism

The comprehensive analysis by Mu and colleagues examining astigmatism tolerance in patients with trifocal and EDOF IOLs provides crucial clinical insights for optimizing patient selection and managing expectations (Mu et al.). The study demonstrates that both EDOF and trifocal lenses show reduced tolerance for oblique astigmatism compared to with-the-rule or against-the-rule astigmatism, with EDOF lenses generally demonstrating superior objective visual quality regardless of astigmatism magnitude or axis (Elvira et al.; Mu et al.). These findings have significant implications for surgical planning, suggesting that astigmatism correction should be prioritized when considering presbyopia-correcting IOLs, particularly when residual astigmatism exceeds −1.00 diopter. The differential tolerance patterns between lens types provide valuable guidance for IOL selection in patients with varying degrees of corneal astigmatism (Mu et al.).

Surgical training and competency

Resident education and patient safety

The evaluation of surgical training outcomes represents a critical component of maintaining high standards in ophthalmic

surgery. The comparative study by Wu and colleagues examining phacoemulsification outcomes between resident and attending physicians provides valuable insights into surgical education and patient safety (Wu et al.).

Contemporary research demonstrates that resident-performed phacoemulsification can achieve excellent visual outcomes comparable to attending-performed surgery, with over 95% of patients achieving 20/40 or better vision. However, the learning curve analysis reveals that surgical competency continues to improve well beyond the first 80 cases, with significant reductions in complication rates and improved surgical efficiency occurring throughout residency training (Wu et al.) (7, 8). The implications for residency training programs are substantial, with recent increases in minimum case requirements from 45 to 86 procedures appearing well-justified based on learning curve data. These findings support the importance of structured surgical curricula, adequate supervision, and sufficient case volume in developing competent cataract surgeons (8).

Complications and management strategies

Corneal epithelial healing complications

The comprehensive case series by Yan and colleagues, addressing delayed corneal epithelial healing after refractive surgery, highlights an important but underrecognized complication that can significantly impact patient outcomes (Yan et al.). The management strategies presented, including the use of amniotic membrane transplantation in severe cases, provide valuable clinical guidance for managing this challenging complication (Yan et al.).

Recent systematic reviews indicate that epithelial healing complications occur in 0.02–17.1% of refractive surgery cases, with higher rates associated with photorefractive keratectomy compared to LASIK. Risk factors include prolonged contact lens wear, previous ocular surface disease, and certain surgical techniques, emphasizing the importance of careful preoperative assessment and patient counseling (9, 10).

Emerging technologies and assessment methods

Advanced imaging and measurement techniques

The comparative analysis by Ning and Zhang examining different topographic measurement systems for pupil offset assessment in myopic populations demonstrates the continuing evolution of preoperative assessment technologies (Ning et al.). The integration of Scheimpflug tomography, Placido disc, and combined systems provides increasingly sophisticated approaches to characterizing corneal and anterior segment anatomy (Ning et al.).

These advances in imaging technology are particularly relevant for refractive surgery planning and IOL selection, where precise characterization of corneal irregularities and optical aberrations is crucial for optimizing outcomes. The ability to accurately measure pupil dynamics and centration parameters has significant implications for the performance of presbyopia-correcting IOLs and patient satisfaction.

Psychosocial impact and quality of life

Mental health considerations in cataract surgery

The cross-sectional study by Wang and colleagues examining the relationship between untreated cataracts and depression symptoms provides important insights into the broader impact of visual impairment on patient well-being (Wang et al.). The demonstration that age-related cataracts without surgical intervention are associated with exacerbated depression symptoms underscores the importance of timely surgical intervention and comprehensive patient care (Wang et al.). Contemporary research consistently demonstrates that successful cataract surgery not only improves visual function but also has significant positive impacts on quality of life, mental health, and overall patient wellbeing. These findings support the concept that cataract surgery should be considered not merely as a vision-restoring procedure but as a comprehensive intervention with broad health and social benefits (11, 12).

Future directions and research trends

Bibliometric analysis and research evolution

The bibliometric analysis by Zhang and colleagues examining trends in implantable collamer lens surgery research provides valuable insights into the evolution and future directions of refractive surgery research (Zhang et al.). The analysis reveals an increasing interest in ICL surgery as a safe and effective alternative to corneal refractive procedures, particularly for correcting high myopia (Zhang et al.) (13). Current trends indicate growing emphasis on patient-reported outcomes, long-term safety profiles, and optimization of surgical techniques for different patient populations. The continuous refinement of ICL designs, including the development of central hole technology, eliminates the need for peripheral iridotomy, representing significant advances in patient safety and surgical convenience (Zhang et al.) (13, 14).

Clinical implications and recommendations

Based on the comprehensive evidence presented in this Research Topic, several key clinical recommendations emerge:

IOL selection strategy

Enhanced monofocal and EDOF IOLs with mini-monovision approaches offer excellent alternatives to traditional monofocal

lenses, providing improved spectacle independence while maintaining acceptable visual quality. In post-refractive surgery patients, wavefront-shaping IOLs may provide superior outcomes compared to conventional lenses (Levy et al.; Fan et al.) (15).

Astigmatism management

Residual astigmatism exceeding −1.00 diopter should be addressed surgically when implanting presbyopia-correcting IOLs, with particular attention to oblique astigmatism, which is less well-tolerated than with-the-rule or against-the-rule astigmatism (Mu et al.) (16).

Surgical training

Residency programs should ensure adequate case volume and structured training curricula to optimize learning curves and patient safety. The learning curve for phacoemulsification extends well beyond initial case requirements, emphasizing the importance of ongoing skill development (7, 8).

Complication management

Early recognition and aggressive management of epithelial healing complications following refractive surgery are crucial for preventing long-term sequelae. Amniotic membrane transplantation represents an effective treatment option for severe cases resistant to conventional therapy (Yan et al.).

Conclusion

The Research Topic "*Enhancing patient outcomes after cataract, corneal and refractive surgery*" provides compelling evidence of the rapid evolution occurring in ophthalmic surgery. From advanced IOL technologies that provide excellent outcomes in challenging patient populations to innovative surgical techniques that minimize complications, these contributions represent significant advances in our ability to optimize patient care.

The integration of precise preoperative assessment, advanced surgical techniques, and comprehensive outcome evaluation creates a framework for evidence-based practice that prioritizes both visual function and patient satisfaction. As we continue to refine these approaches, the ultimate goal remains unchanged: providing each patient with the safest, most effective surgical intervention that optimizes their individual visual needs and quality of life.

The future of cataract, corneal, and refractive surgery lies in the continued evolution of personalized medicine approaches, where advanced technologies, refined surgical techniques, and comprehensive patient assessment combine to deliver truly customized surgical solutions. The research presented in this Research Topic provides an excellent foundation for this ongoing evolution, offering both immediate clinical applications and direction for future investigation.

Author contributions

MN: Investigation, Conceptualization, Visualization, Software, Funding acquisition, Resources, Project administration, Writing – review & editing, Methodology, Data curation, Supervision, Validation, Formal analysis, Writing – original draft. RK: Investigation, Funding acquisition, Software, Conceptualization, Writing – review & editing, Resources, Writing – original draft, Supervision, Project administration, Data curation, Methodology, Visualization, Formal analysis, Validation.

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Conflict of interest

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Comparison of effect and safety of phacoemulsification surgery performed by resident and attending physicians

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Aim: The objective of this study is to compare the effect and safety of phacoemulsification surgery performed by resident and attending physicians.

Methods: This was a retrospective study. Eyes with cataract who underwent phacoemulsification surgery at the First Affiliated Hospital of Ningbo University between January 2021 and December 2023 were reviewed. All the patients were followed up for at least 12 months and were divided into two groups according to the surgery performer. SPSS was used to analyze data, considering $p < 0.05$ significant.

Results: Overall, 316 patients with cataract in group 1 (surgery performed by resident physician, $n = 181$) and group 2 (surgery performed by attending physician, $n = 135$) were reviewed. There were no statistically significant differences in patient demographics variables and cataract grade between the groups. The resident surgeon used more cumulative dissipate energy (15.00 ± 7.25 vs. 10.83 ± 6.52, $p < 0.001$) and operation time (20.46 ± 5.69 vs. 12.59 ± 4.61 min, $p < 0.001$) to complete the surgery. Also, the ECL in group 1 was higher (14.87 ± 5.00 vs. 10.77 ± 4.46, $p < 0.001$). The eyes had significant visual improvement in both groups postoperatively ($p < 0.05$), but at the 12-month follow-up, eyes in group 2 had better best-corrected visual acuity [0.10 (0.00, 0.22) vs. 0.10 (0.10, 0.22) logMAR, $p = 0.039$]. Except for month 1, the intraocular pressure was no statistical difference in group 1 and group 2 (14.65 ± 2.52 vs. 15.30 ± 2.34 mmHg, $p = 0.019$). Cases in group 1 were more likely to undergo intraoperative and postoperative complications (37 vs. 14, $p = 0.031$), including cornea edema ($p = 0.025$), capsule tear ($p = 0.044$), and posterior capsular opacification ($p = 0.027$).

Conclusion: The effect of phacoemulsification surgery performed by the resident physician is satisfying, but compared to the attending physician, the higher probability of complications should be paid more attention.

KEYWORDS

phacoemulsification, cataract surgery, resident, attending, effect, safety

1 Introduction

Cataract, one of the most common causes of visual loss, presents a growing challenge on a global scale. With the aging population, the prevalence of cataract is on the rise. Surgery is the most effective treatment for cataract, from intracapsular cataract extraction (ICCE) to femtosecond laser-assisted cataract surgery (FLACS), surgery techniques have developed for hundreds of years (1). Although some studies proved a higher rate of complications compared with extracapsular cataract extraction (ECCE) or ICCE techniques, with the advantage of high efficiency and satisfying visual outcome, phacoemulsification still becomes the preferred cataract surgery technique (2).

Based on the learning curve, phacoemulsification presents challenges in mastery, complications like posterior capsule rupture, transient elevated intraocular pressure, and corneal edema are prone to encounter, especially for surgeons with less experience (3). Taravella et al. (4) found nucleus disassembly and removal, cortex removal, and capsulorhexis were quite hard for residents. Hosler et al. (5) reported that compared to attending physicians, resident needs more phacoemulsification operative times and costs. In the past, the vast majority of phacoemulsification operations were performed by attending or higher-level physicians (6). As technology develops, it is possible for residents to learn phacoemulsification efficiently and safely by using the cataract surgery simulator (7). Therefore, more and more experienced resident surgeons are devoted to the technique (8).

Up to now, there has been no study to evaluate the effect and safety of phacoemulsification operated by residents and attending surgeons. The purpose of this study was to compare the effect and safety of phacoemulsification surgery performed by experienced resident and attending physicians, providing data to measure the feasibility and practicality of resident physician operating phacoemulsification surgery.

2 Materials and methods

2.1 Subjects

This was a retrospective study and has been approved by the Ethics Review Committee of the First Affiliated Hospital of Ningbo University (057RS-YJ01). The study was conducted in accordance with the tenets of the Declaration of Helsinki. The resident received virtual reality simulation training using the HelpMeSee simulator and performed 50 phacoemulsification surgeries with or without the help of other surgeons. The resident passed the evaluation according to The Ophthalmology Surgical Competency Assessment Rubric (OSCAR) and had the ability to perform phacoemulsification independently. The attending physician was a skilled doctor with at least 10 years of experience in phacoemulsification cataract surgery and performed over 3,000 phacoemulsification surgeries. Patients with any of the following criteria were excluded from the study: other diseases that can seriously affect vision, traumatic cataract, congenital cataract, follow-up less than 12 months, and history of previous intraocular surgery. In all, 316 cases of phacoemulsification cataract surgery performed by resident and attending physician from January 2021 through December 2023 were evaluated.

2.2 Surgical procedure and follow-up

Standard phacoemulsification cataract surgery was used in each patient, including the following steps: paracentesis and wound construction, capsulorhexis, hydrodissection, nucleus sculpting, nucleus disassembly and removal, cortex removal, intraocular lens (IOL) insertion, ophthalmic viscosurgical device removal, and wound integrity (9). All surgical steps were performed according to the same standard procedure except for the processing of nucleus. The attending surgeon used the phaco chop technique while the resident used the divide and conquer technique (10). The same phacoemulsification machine was used for all surgery.

The following parameters were obtained at preoperative, 1-day, 1-month, 3-month, 6-month, and 12-month postoperatively: best-corrected visual acuity (BCVA), and intraocular pressure (IOP). Patient age, sex, ocular history, follow-up time, intraoperative and postoperative complications such as capsule tear, vitreous loss, cornea edema, posterior capsular opacification (PCO) et al. were also reviewed. Cataract grade including nuclear opacity (NO) and nuclear color (NC) were recorded preoperatively using The Lens Opacities Classification System, version III (LOCS III) (11). Endothelial cell density (ECD), and endothelial cell loss (ECL) calculated as (ECD preoperatively-ECD postoperatively/ECD preoperatively) × 100, were assessed pre and post-operatively at 1 month. Cumulative dissipated energy (CDE), as a value for phaco energy, along with operation time were recorded as intraoperative variables. BCVA was converted into logMAR values and followed the standards: counting fingers = decimal acuity of 0.014 and hand motion = decimal acuity of 0.005 (12).

2.3 Statistical analysis

Statistical analysis was performed with SPSS software version 20.0 (SPSS, Inc., Chicago, IL, USA). Continuous variables were reported as mean ± SD, median (25% percentile, 75% percentile) and rage. Frequency distributions and percentages were used for categorical variables. Normality tests and homogeneity of variance analysis are carried out on continuous variables. Comparison of age, NO, NC, ECD, ECL, CDE, operation time, preoperative, and postoperative IOP between the two groups was assessed by independent sample t-test. Mann–Whitney U test was used to compare the follow-up time and BCVA. Categorical variables were analyzed with the Pearson chi-square test or Fisher's exact test. A p-value <0.05 was defined as statistically significant.

3 Results

Three hundred sixteen eyes of 316 patients met the inclusion criteria, a total of 1 attending and 1 resident surgeon performed all the phacoemulsification surgeries independently. The resident surgeon completed 181 cases (group 1) and the attending surgeon performed 135 cases (group 2). None of the procedures had to be converted to ECCE or need extra surgery. The mean age of the patients was 60.83 ± 8.10y (42-83y), among them, 65 cases with diabetes and 82 cases with hypertension. After 13.67 ± 2.59 (12–25) months follow-up, the mean BCVA improved from 0.76 ± 0.44 to 0.14 ± 0.14 logMAR postoperatively (p <0.05). There was no statistically significant

TABLE 1 Demographic variables and follow-up time in Group 1 and Group 2.

	Group 1 ($n = 181$)	Group 2 ($n = 135$)	$t/z/x^2$	p value
Age, *y*	60.15 ± 7.63	61.75 ± 8.64	−1.710[a]	0.088
Sex (male:female)	71:110	61:74	1.129[c]	0.288
Follow-up time, *m*	12 (12, 14)	12 (12, 15)	−0.914[b]	0.361
Diabetes, *n* (%)	36 (19.89)	29 (21.48)	0.120[c]	0.729
Hypertension, *n* (%)	50 (27.62)	32 (23.70)	0.619[c]	0.432
Cataract grade NO	3.21 ± 0.56	3.31 ± 0.63	−1.594[a]	0.112
Cataract grade NC	2.45 ± 0.61	2.56 ± 0.71	−1.476[a]	0.141
MED, *n* (%)	20 (11.05)	13 (9.63)	0.167[c]	0.683

Group 1, surgery performed by the resident; Group 2, surgery performed by the attending; NO, nuclear opacity; NC, nuclear color; MED, merge other eye diseases; [a]Independent sample t-test; [b]Mann–Whitney U test; [c]Pearson chi-square test.

TABLE 2 Intraoperative variables and clinical outcomes in Group 1 and Group 2.

	Group 1 ($n = 181$)	Group 2 ($n = 135$)	t/z	p value
ECD, cell/mm^2				
Preoperative	2,529.28 ± 390.69	2,456.73 ± 420.69	1.580[a]	0.115
Postoperative	2,155.85 ± 370.13	2,192.69 ± 393.15	−0.852[a]	0.395
ECL, %	14.87 ± 5.00	10.77 ± 4.46	7.544[a]	<0.001
CDE	15.00 ± 7.25	10.83 ± 6.52	5.279[a]	<0.001
Operation time, min	20.46 ± 5.69	12.59 ± 4.61	13.184[a]	<0.001
BCVA, logMAR				
Preoperative	0.60 (0.40, 0.96)	0.70 (0.40, 1.00)	−1.167[b]	0.243
1-day	0.22 (0.10, 0.30)	0.22 (0.10, 0.30)	−0.102[b]	0.919
1-week	0.10 (0.07, 0.22)	0.10 (0.10, 0.22)	−0.473[b]	0.636
1-month	0.10 (0.05, 0.22)	0.10 (0.05, 0.22)	−0.550[b]	0.583
3-month	0.10 (0.10, 0.22)	0.10 (0.00, 0.22)	−0.775[b]	0.438
6-month	0.10 (0.10, 0.22)	0.10 (0.00, 0.22)	−1.634[b]	0.102
12-month	0.10 (0.10, 0.22)	0.10 (0.00, 0.22)	−2.603[b]	0.039
IOP, mmHg				
Preoperative	13.10 ± 3.50	13.38 ± 3.44	−0.709[a]	0.479
1-day	17.05 ± 4.19	17.25 ± 3.42	−0.456[a]	0.649
1-week	15.11 ± 3.04	15.26 ± 2.29	−0.486[a]	0.627
1-month	14.65 ± 2.52	15.30 ± 2.34	−2.356[a]	0.019
3-month	14.63 ± 2.20	15.09 ± 2.21	−1.845[a]	0.066
6-month	14.78 ± 2.41	15.00 ± 2.05	−0.878[a]	0.381
12-month	15.19 ± 2.56	15.39 ± 2.09	−0.744[a]	0.457

Group 1, surgery performed by the resident; Group 2, surgery performed by the attending; ECD, endothelial cell density; CDE, cumulative dissipate energy; ECL, endothelial cell loss; BCVA, best-corrected visual acuity; IOP, intraocular pressure; [a]Independent sample t-test; [b]Mann–Whitney U test.

difference in patient demographics, follow-up time, NO and NC grade between groups (Table 1).

The median preoperative BCVA in group 1 and group 2 was 0.60 (0.40, 0.96) and 0.70 (0.40, 1.00) logMAR, respectively ($p = 0.243$, Table 2). There were no statistically significant differences in postoperative BCVA between the two groups except at the 12-month follow-up, the median BCVA was better in group 2 than the group 1 [0.10 (0.00, 0.22) vs. 0.10 (0.10, 0.22) logMAR, $p = 0.039$]. In all, the BCVA in 296 cases (93.67%) reached 20/40 or higher at the last follow-up, with 165 cases (91.16%) in group 1 and 131 cases (97.03%) in group 2. Of those that did not achieve a best-corrected visual acuity of 20/40 or better, diabetic retinopathy, cystoid macular edema and postoperative complications were the main reasons. Besides 1 month postoperatively (14.65 ± 2.52 vs. 15.30 ± 2.34 mmHg, $p = 0.019$), no statistically significant differences were found in the IOP between the two groups before and after the surgery (Table 2). 9 patients (2.85%) occurred high IOP that need local IOP lowering medications after surgery, among them, 7 cases in group 1 and 2 cases in group 2. All

TABLE 3 Complications in Group 1 and Group 2.

	Group 1 ($n = 181$)	Group 2 ($n = 135$)	x^2	p value
Total complications, n (%)	37 (20.44)	14 (10.37)	4.675	0.031
Cornea edema, n (%)	24 (13.26)	7 (5.19)	5.046	0.025
High IOP, n (%)	7 (3.87)	2 (1.48)		0.315
PCO, n (%)	27 (14.92)	9 (6.67)	4.913	0.027
Serious complications	12 (6.62)	1 (0.74)		0.018
Lens cortex residual, n (%)	2 (1.10)	0 (0.00)		0.513
Capsule tear, n (%)	6 (3.31)	0 (0.00)		0.044
Vitreous loss, n (%)	4 (2.21)	1 (0.74)		0.407

Group 1, surgery performed by the resident; Group 2, surgery performed by the attending; IOP, intraocular pressure; PCO, posterior capsular opacification.

cases of intraocular pressure ultimately returned to the normal range, and there were no cases had high IOP or glaucoma.

The ECD between the groups was not statistically different. The resident surgeon used more CDE (15.00 ± 7.25 vs. 10.83 ± 6.52, $p < 0.001$) and operation time (20.46 ± 5.69 vs. 12.59 ± 4.61 min, $p < 0.001$) to complete the surgery. Also, the ECL in group 1 was higher (14.87 ± 5.00 vs. 10.77 ± 4.46, $p < 0.001$). 51 (16.14%) patients had complications of varying severity, 12 (6.62%) cases in group 1 had serious complications including lens cortex residual, capsule tear, or vitreous loss, while only 1 (0.74%) case in group 2 had undergone capsule tear, no statistically significant difference was found ($p = 0.018$, Table 3). There were no cases of dropped nucleus in both group. Intraoperative and postoperative complications were observed in 37 (20.44%) cases performed by the residents and 14 (10.37%) cases performed by the attending physician ($p = 0.031$). Early complications such as cornea edema in group 1 were more than the cases in group 2 (24 vs. 7, $p = 0.025$). Cases completed by the resident surgeon were more likely to have PCO in long-term follow-ups (27 vs. 9, $p = 0.027$). Capsule tear was also more likely to occur in patients performed by the resident (6 vs. 0, $p = 0.044$). Anterior vitreous loss occurred in 5 cases, it was managed by trimming the anterior vitreous without the need for additional complex vitreoretinal surgery. Two cases underwent lens cortex residual in group 1, and the last BCVA of them reached 0.6 and 0.8, respectively. No cases required a second or complex vitreoretinal surgery.

4 Discussion

In comparison to other countries, China has the largest elderly population worldwide, the avoidable blindness like cataract is becoming a troubling challenge. However, the Cataract Surgical Rate (CSR) in China is far lower than the developed countries (13), the per million people CSR only reached 2,205 (8), which is far below demand. This underscores the increasing need for more cataract surgeons in the near future. But cataract surgeries are not easy to have a good grasp., especially for those without systematic training surgeons. Kaplowitz et al. (14) pointed to mastering phacoemulsification surgery skills, a minimum of 70 operations are needed for inexperienced surgeons. Different reports have indicated complications were more likely to happen for the surgeries performed by the residents (15, 16). Teaching operation skills is a time-consuming process, especially with a patient that is awake and under the microscope. Fortunately, as the technique developed, virtual reality cataract surgery simulation came out, which can greatly reduce the number of surgeries, time, and cost required to master cataract surgery techniques (7, 17). Montrisuksirikun et al. (18) suggested after simulation training, surgery complications were less likely to happen and the operation would be completed faster and safer.

In our study, the resident was systematically trained for phacoemulsification surgery, including wet laboratory and visual reality surgery simulation learning using the HelpMeSee simulator. Although in the beginning, the resident probably required help in certain surgery procedures, after performing 50 phacoemulsification surgeries, the resident was skilled enough to get a satisfying score in OSCAR evaluation and could complete the surgery independently. Because of the limitations in retrospective research, some patients were lost to follow-up, we observed 316 patients in all. The attending physician performed more complex cataract surgeries or combined vitreoretinal surgeries, which did not meet our inclusion criteria. So only 135 cases were performed by the attending doctor in this study. The visual outcome was satisfying, the BCVA of cases performed by the resident improved from 0.60 (0.40, 0.96) to 0.10 (0.10, 0.22) logMAR, with 165 cases (91.16%) reached 20/40 or higher at the last follow-up, no statistically significant difference was found compared to cases completed by the attending physician. This also confirms previous research findings that the improvement in vision acuity after cataract surgery performed by the resident is desirable (19).

Many factors such as age, different types of cataracts, and ocular conditions et al. can affect the effectiveness of surgery (19). To this end, we exclude cases with traumatic cataract, congenital cataract, or other diseases that can seriously affect vision to keep the confounding factors as few as possible. We also avoid including complex and high-risk cataract surgeries in research to optimize the outcomes of surgeries. No statistical difference was found in patient demographics, follow-up time, cataract grade, ECD, and preoperative BCVA in two groups, which makes the results more convincing. Some studies researched the outcome and complication rate of cataract surgeries performed by the resident (15, 16, 20), but to the best of our knowledge, this is the first study in China to compare the efficacy and safety of the resident surgeon trained in virtual reality surgery simulation with the attending surgeon in phacoemulsification. Besides, no study compared the IOP status after surgery performed by the resident or attending physicians. Nucleus and cortex incomplete removal can affect the visual outcome and increase intraocular pressure, which are also the hardest steps for cataract surgery (4). So

we take IOP into consideration, 7 patients in group 1 and 2 patients in group 2 needed topical antiglaucoma medications, the difference in IOP between the two groups was not statistically significant.

Phacoemulsification surgery is challenging work with many serious complications could occur, any of which could cause damage to the visual acuity or even surgery failure (21, 22). The overall rate of complications was reported from 5 to 37% previously (23–25), in this study, we found 16.10% of cases encountered different degrees of complications, including early postoperative complications like cornea edema and late postoperative complications such as PCO. The major serious complications including lens cortex residual, capsule tear, and vitreous prolapse were more likely to happen for those operations performed by the resident (6.62% vs. 0.74%), slightly lower than previous studies in total (15, 23–25), we thought the resident with experience in visual reality cataract simulator training can explain the difference. We found more patients had cornea edema in group 1, and the difference was statistically significant. We believe this may related to the higher energy used and longer duration of phacoemulsification when surgery was performed by the resident, as well as the instrument was more likely to touch the corneal endothelium during the operation process. Wong et al. (10) proved a significant advantage of the phaco chop over the divide and conquer technique in phaco power and duration. It is the direction that residents can devote to in future phacoemulsification surgeries. Although all the cornea edema was relieved in 2 weeks and did not influence the final visual outcome, some patients still complained about poor visual improvement in the early postoperative period. It is quite necessary to have good propaganda and education before the surgery. PCO is a multifactorial common complication in the late-term follow-up after cataract surgery (26, 27). In our study, patients in group 1 were more likely to have PCO, which may explain the worse visual outcome at the 12-month follow-up. We consider the incomplete polishing of the posterior capsule by the resident physician during surgery may be the cause of this phenomenon. More cases had a vitreous loss in group 1, though the difference was not statistically significant, more attention should be paid to decreasing capsule tear and vitreous prolapse.

Hosler et al. (5) indicated the resident physician takes an average of 12 min longer per eye compared to the attending surgeon to complete phacoemulsification surgery, which is similar to our finding. Capsulorhexis, nucleus removal, and cortex removal were the hardest part for residents during the operation, and more time was needed (4). Regretfully, due to the limit of retrospective study, the time cost of different surgery steps was not recorded and we could not compare this indicator between groups. Meanwhile, a questionnaire could also be designed to obtain subjective feelings of resident physicians about the difficulty of different steps. For future prospective studies, we are looking forward to using the Najjar-Awwad risk score (28) to evaluate the risk of patients undergoing phacoemulsification surgery, to ensure the preoperative eye condition is as similar as possible, and to make sure the surgery is safer for resident physicians to perform. In addition, longer follow-up is needed to compare the long-term effects of surgery.

To conclude, we can state that the effect of phacoemulsification surgery performed by the resident physician is satisfying, but compared to the attending physician, the higher probability of complications should be paid more attention.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by the Ethics Review Committee of the First Affiliated Hospital of Ningbo University (057RS-YJ01). The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

SW: Data curation, Formal analysis, Investigation, Writing – original draft, Writing – review & editing. DY: Data curation, Methodology, Writing – review & editing. SH: Data curation, Investigation, Writing – review & editing. XL: Conceptualization, Investigation, Writing – review & editing. YS: Conceptualization, Funding acquisition, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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From inception to innovation: bibliometric analysis of the evolution, hotspots, and trends in implantable collamer lens surgery research

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Background: As one of several refractive surgeries, Implant Collamer Lens (ICL) surgery offers stable biocompatibility and consistent, high-quality visual outcomes. ICL has become an effective complement to corneal refractive surgery, gradually becoming one of the mainstream methods for correcting refractive errors. This study employs bibliometric methods to analyze research on ICL surgery to understand the progress, hotspots, and potential future trends in this field.

Methods: This study performed a bibliometric analysis of all ICL-related articles collected from the Web of Science Core Collection database between January 1st, 1996, and December 31st, 2023. The CiteSpace 6.2.R4 tool, Excel and the Web of Science website were used to analyze data by country, institution, keywords, and clusters of keywords. Additionally, an in-depth interpretation and analysis were conducted on the field's high-impact articles.

Results: Since the first clinical application report of ICL, there have been a total of 875 studies. The number of papers published annually has shown an overall increasing trend. Studies published from China are the most numerous, accounting for 29.14% ($n = 255$) of the total. Among the institutions, Fudan University and Kitasato University both have published more than 50 papers, with Kitasato University having the highest H-index of 26. The journals with the top 10 publication volumes are all specialized in ophthalmology. The burst keywords since the introduction of ICL surgery have been "intraocular lens," "refractive surgery," and "cataract surgery." The current burst keywords include "visual quality," "vector analysis," "axial length," etc. The results of keyword clustering included ICL, pIOL, high myopia, axial length, optical quality, refractive surgery, ICL implantation, and pupil size. In the High-impact Articles, it was found that the high-impact articles predominantly focus on the safety, efficacy, and predictability of ICL surgery.

Conclusion: Research on ICL has grown since its clinical introduction, with the advent of the central hole ICL sparking a surge in recent hotspots, particularly in China. Current hotpots in the field of ICL surgery are "visual quality," "ICL implantation," "vector analysis," "axial length," "evo ICL," "ICL v4c," and "ICL." ICL surgery research trends have evolved from implantation techniques to biological parameters associated with ICL surgery and the benefits of new ICL designs.

KEYWORDS

implantable collamer lens, ICL, refractive surgery, bibliometric, hotspot, trend

1 Introduction

Implantable collamer lens (ICL) is a minimally invasive surgical lens implanted in the eye for the correction of refractive errors such as myopia, hyperopia, and astigmatism. The ICL as a Phakic intraocular lens (pIOL) for posterior chamber lenses has been widely used in recent years for the correction of refractive errors (1, 2). Compared to the Artisan IOL (a type of anterior chamber IOL), the ICL has a broader range of applications (including high myopia with or without astigmatism), more stable safety and effectiveness, as well as more advanced model designs (3, 4). Therefore, it has become the market leader in pIOLs. There are four sizes of ICL (12.1 mm, 12.6 mm, 13.2 mm, and 13.7 mm) designed to fit various white-to-white corneal diameters. The selection of these sizes is typically based on specific ranges of white-to-white corneal diameter and anterior chamber depth. The appropriate ICL size is essential for ensuring postoperative vault and reducing the risk of complications (5). This surgical option has become increasingly relevant as the incidence of myopia, particularly high myopia, has risen worldwide (2). Despite its shorter development time, ICL surgery is favored for its wide correction range and effectiveness. Advancements in ICL design, like the central hole ICL, have simplified the procedure by eliminating the need to preoperatively create a hole in the iris (6, 7). The continuous refinement of ICL surgery has led to stable biocompatibility and consistent, high-quality visual outcomes (8).

The development of ICL surgery ongoing since its inception in 1986, Professor Fyodorov innovated the first collar-stud style posterior chamber intraocular lens, heralding a new era in ophthalmic surgery (9). The groundbreaking design of this lens served as the prototype for the "Visian implantable collamer lens," subsequently developed by STAAR Surgical Company. The proprietary material used for the ICL surgery, known as "Collamer, "is a combination of methyl methacrylate and porcine collagen, which provides the lens with unique optical properties and biocompatibility (8). The introductory research on ICL surgery was published in 1996, sparking sustained interest and a steady stream of research in the field. Figure 1 has organized schematic diagrams of several classic models used in clinical applications. The original V0 (collar-stud style), during the upgrade process from V1 to V4, gradually perfected the structure of haptics and vault, and expanded the optical zone. The V4c with "Central FLOW" technology, and the subsequent V5 which has a larger optical zone compared to V4c (V4c has an optical zone of 6.2 mm-7.3 mm, while V5 has an optical zone of 6.3 mm-7.6 mm) (10, 11). Toric ICLs have different curvatures on the vertical and horizontal axes, and the added markings can help doctors to position more accurately during surgery, making Toric ICL effective in the treatment of astigmatism (12).

Before the V4c lens, patients receiving ICL surgery models like V4a or V4b needed a YAG laser peripheral iridotomy to ensure postoperative aqueous humor circulation and prevent complications. The V4c lens, with its central hole, has streamlined this process, enhancing aqueous humor flow and reducing the risk of postoperative intraocular pressure elevation (13). Additionally, the central hole promotes natural aqueous humor circulation, potentially lowering the incidence of postoperative cataracts (14–16). Consequently, the V4c lens has contributed to a reduced rate of complications post-ICL implantation (17). Supporting this advancement, Shimizu, K and colleagues have demonstrated through fluid dynamics simulations and the study of aqueous humor flow distribution between the ICL posterior surface and the crystalline lens anterior surface that the central hole ICL can indeed increase the circulation of aqueous humor (18).

Building upon these pivotal developments, the current study meticulously charts the history of ICL surgery research and pinpoints the pivotal hotspots, while elucidating the trends and evolutionary trajectories in this specialized realm since the first clinical trials were documented.

2 Materials and methods

Bibliometric tools have been employed to analyze articles on ICL surgery, utilizing graphical and visualization methods to enhance intuitiveness and comprehensibility. This current study harnesses both general and high-impact articles from the ICL academic domain for bibliometric analysis, focusing on contributing countries, institutions, publishing journals, and emerging keywords (19). Through detailed observation of the distribution and trends over the years, including the network of collaborating countries, keyword usage, and research domains within the ICL surgery field, this analysis uncovers development trajectories and potential gaps in the research (20). Visualization of such data enables the identification of focal research areas pursued by institutional teams across different nations, delineating the research domains they contribute to and the intrinsic relationships within the literature. This is instrumental in mapping out the hotspots and providing foresight on future trends in ICL surgery research.

Bibliometric analysis is performed by determining the search strategies and selecting articles. The search strategy includes limiting databases, search terms, language, document type, and publication date. This article uses the Web of Science Core Collection (WoSCC) as the source of bibliometric data. WoSCC encompasses a variety of research journals and provides various bibliometric indicators (such as titles, institutions, countries/regions, publication years, categories, and keywords). To ensure the accuracy and authority of the retrieved data, the indexes chosen are SCI-Expanded (SCIE) and SSCI.

Given the development history of the ICL surgery, the search strategy for this study involves a combination of topic search (TS), title search (TI), abstract search (AB), and keyword plus (KP) within the Web of Science database using a specific set of terms related to ICL. The strategy is as follows: (((TS = ("Implantable Collamer Lens*" OR "ICL" OR "EVO" OR "Visian" OR "Phakic Intraocular Lens*" OR "Phakic IOL")) OR TI = ("Implantable Collamer Lens*" OR "ICL" OR "EVO" OR "Phakic Intraocular Lens*" OR "Phakic IOL")) OR AB = ("Implantable Collamer Lens*" OR "ICL" OR "EVO" OR "Phakic Intraocular Lens*" OR "Phakic IOL")) OR KP = ("Implantable Collamer Lens*" OR "ICL" OR "EVO" OR "Phakic Intraocular Lens*" OR "Phakic IOL").

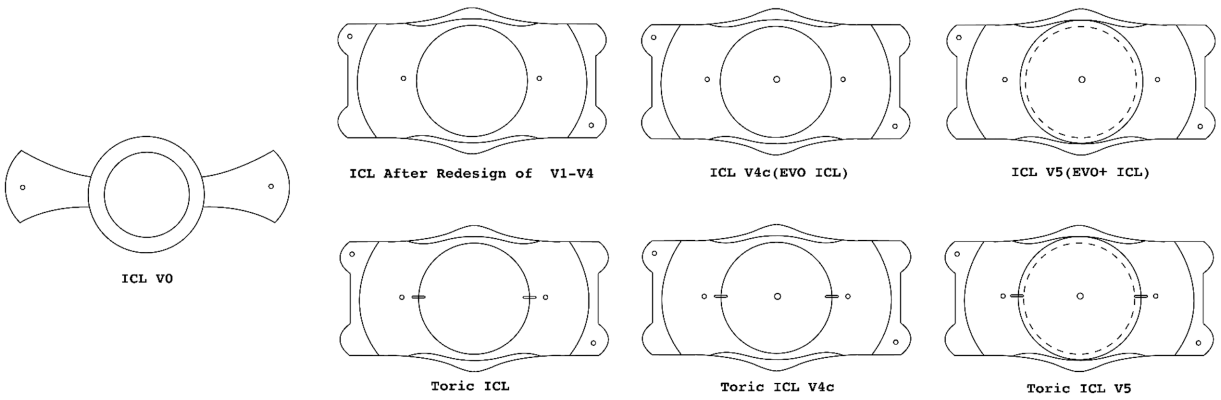

FIGURE 1
ICL model development. The dotted line represents the ICL V4c optical zone.

The document type has been specified as "Articles," and the search is confined to the English language. Within the Web of Science database, the "Ophthalmology" category has been selected from "Citation Topics Meso" based on the Leiden algorithm (21), which sorts research publications according to the patterns of citations and references between them. Ophthalmology specialists further exclude articles unrelated to ICL. This method ensures the inclusion of all articles relevant to the field of ICL surgery, spanning the publication dates from January 1, 1996, to December 31, 2023. The objective of adopting this strategy is to encompass a thorough compilation of literature that enriches the understanding of the ICL surgery domain within the stipulated timeframe.

To ensure accuracy and relevance, two professional researchers specializing in ophthalmology independently performed the data screening. They eliminated records that did not pertain to ICL throughout the search sequence. The subsequent collection of articles was then processed for bibliometric and visualization analyses, with the search and analytical methodology depicted in Figure 2.

To analyze the collaborative networks of countries or regions, institutions, journals, as well as keywords, the study employed CiteSpace 6.2.R4 software and Excel. Concurrently, the WoSCC database's analysis function served to assess the volume of publications annually and to quantify the contributions per country or region.

3 Results

3.1 Distribution of articles by year

Over 28 years, the study encompasses 875 articles, collectively cited 16,032 times, including 7,917 self-citations, resulting in an average citation rate of 18.32 per article. The foundational article in this domain was presented in 1996 in the Journal of Cataract and Refractive Surgery, detailing the implantation of a posterior chamber phakic lens composed of collamer to correct myopia in patients. Although the study observed no progression of cataract formation at that stage; it was unable to definitively ascertain the long-term safety of this surgical procedure (22).

Figure 3 illustrates the temporal distribution of publications and citation numbers within the field of ICL surgery research. A sharp increase in the number of published studies is observed between 2019 and 2020, akin to a rocket-like ascent, with a more gradual rise noted in the years following 2020. This rapid increase can be attributed primarily to a surge in research related to the post-operative stability of the corneal endothelial cells in ICL surgery, as well as studies involving "vector analysis" and other parameter analyses. Additionally, the citation trends have mirrored this upward trajectory.

3.2 Countries or regions

This study's articles span across 65 countries and regions. A collaborative network map visualized in Figure 4 indicates the article output of each country, with the size of the labels and nodes being directly proportional to their article count. China, with 255 papers, Spain with 137, and the United States with 124, have the most prominent labels and nodes, signifying their leadership in publication output. Moreover, the density of connections between the nodes signifies the extent of collaboration among these countries or regions; with a denser network reflecting stronger collaborative ties.

Table 1 enumerates the top 10 countries or regions based on their article numbers. It includes their centrality scores, which mirror the intensity of collaboration, alongside H-index values representing their scholarly impact (23). Notably, Spain and the United States exhibit high centrality scores, at 0.50 and 0.51, respectively, coupled with robust H-index values of 33 for Spain and 31 for the United States. China leads the count in articles with 255 entries but has a lower centrality score of 0.03, although it maintains a respectable H-index of 22, indicating substantial influence.

3.3 Institutions

Table 2 presents the top 10 institutions ranked by their research article output, highlighting Fudan University and Kitasato University as leaders with over 50 articles each. Every institution listed in the top 10 has contributed a minimum of 20 articles to the field. Kitasato University stands out with the most significant scholarly impact,

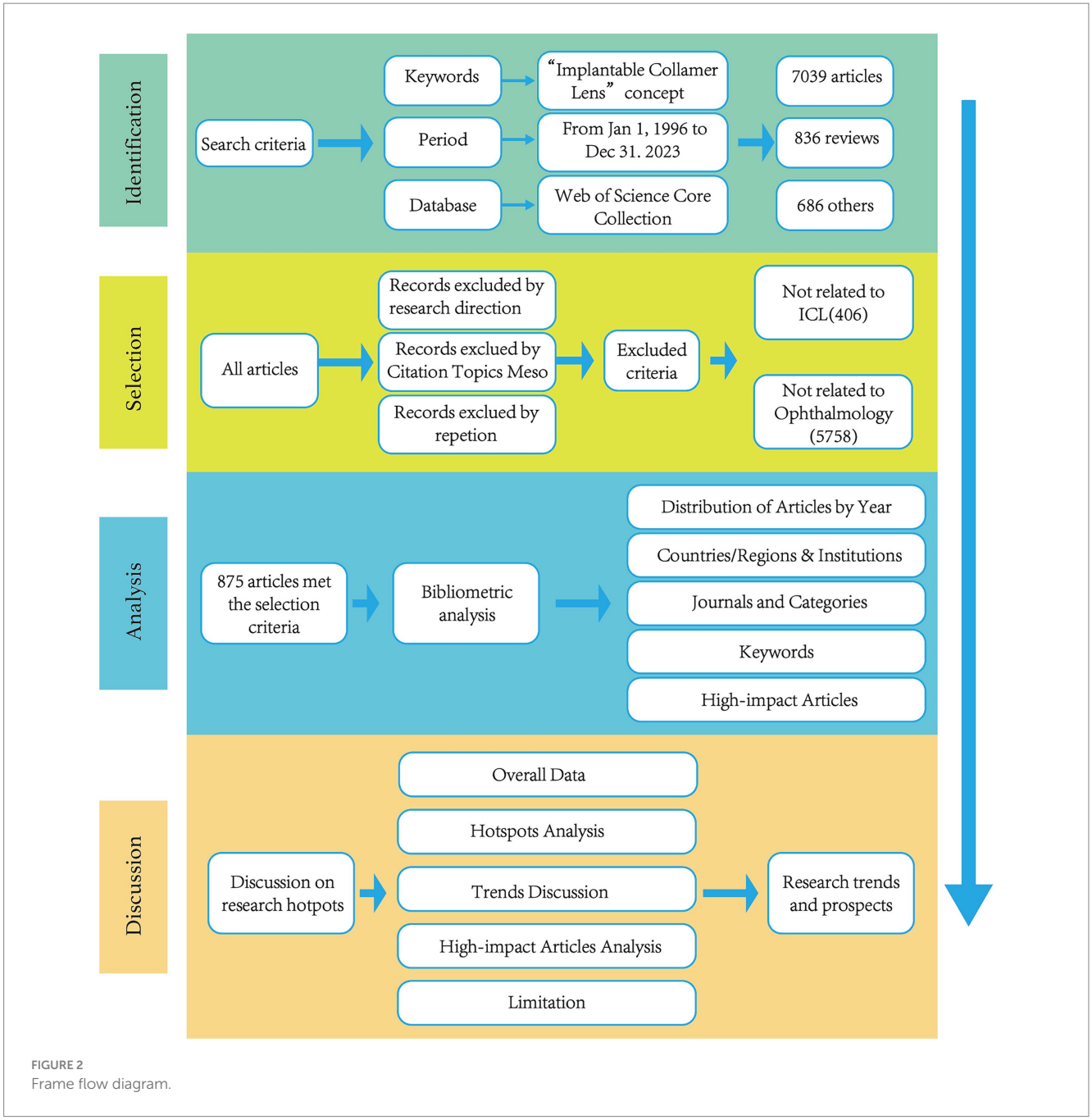

FIGURE 2
Frame flow diagram.

boasting an H-index of 26. Geographic analysis of these prominent institutions reveals that four are located in China, four in Japan, one in Spain, and one in Egypt.

3.4 Journals and categories

The corpus of this study consists of 875 articles distributed across 92 different journals. Table 3 synthesizes information on the top 10 journals, ranked by their publication volume within this field. In addition to listing the journals, it denotes the percentage of the total publications that they constitute and their calculated H-indexes specific to the discipline. At the forefront, the Journal of Cataract and Refractive Surgery leads with 169 articles, followed by the Journal of Refractive Surgery with 136 articles. These journals hold H-indices of 39 and 34, with impact factors of 2.8 and 2.4 in 2022, respectively. Given the field's specific focus, all journals featured in the top 10 are exclusively ophthalmology-oriented.

3.5 Keywords

Employing CiteSpace for co-citation keyword analysis, keywords were extracted from bibliographic entries for text processing and analytical scrutiny, The analysis was configured with a Time span of 1996–2023, a Slice Length of 1 year, and a Selection Criterion of the g-index with k set at 25. Figure 5 vividly

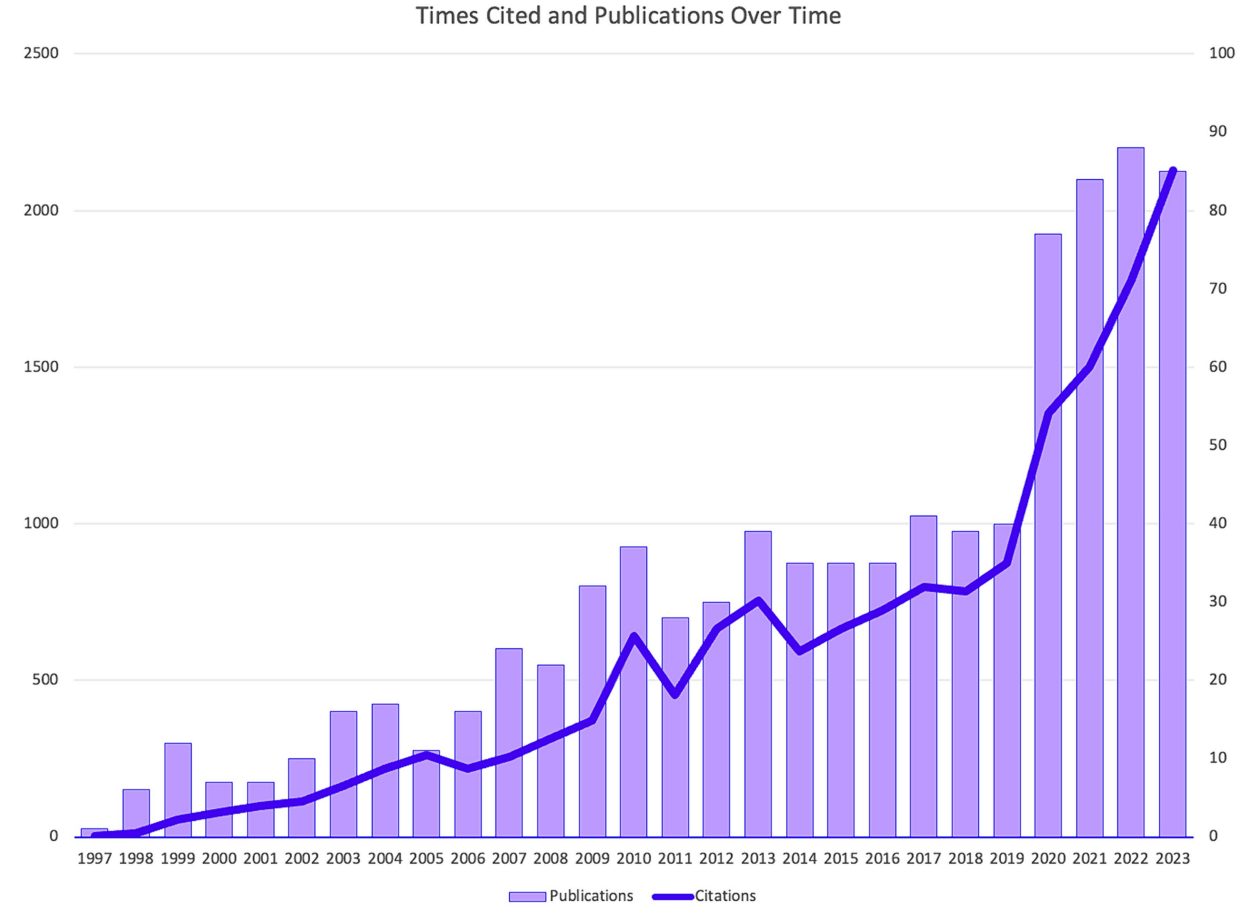

FIGURE 3
Times cited and publications over time.

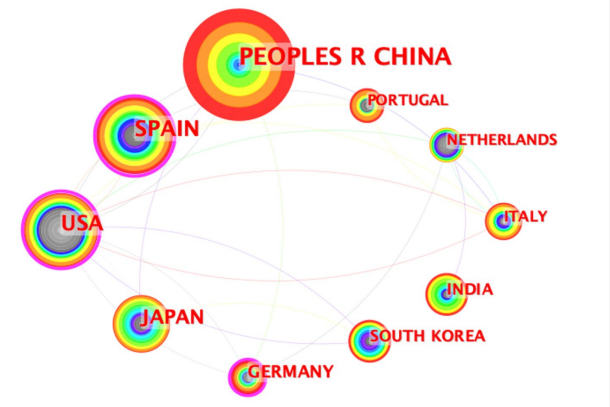

FIGURE 4
Cooperation of countries or regions.

TABLE 1 Top 10 countries or regions with articles on ICL surgery.

Rank	Country or region	Counts	Centrality	H-index
1	China	255	0.03	22
2	Spain	137	0.50	33
3	United States	124	0.51	31
4	Japan	85	0.01	32
5	Germany	47	0.24	17
6	South Korea	34	0.00	19
7	India	34	0.00	11
8	Italy	28	0.05	11
9	Netherlands	27	0.03	13
10	Portugal	26	0.00	14

showcases the 25 most frequently cited keywords. The intensity of each keyword's depiction reflects its citation frequency and visibility across the timeframe. Red squares denote periods with noticeable increases in keyword usage. "Active time" is defined as the period during which a keyword has been continuously utilized. Recently emerged keywords are those that appeared in the literature within the last 3 years. An initial keyword burst highlighted terms like "intraocular lens" and "refractive surgery." Prolonged active use of keywords such as "intraocular lens," "refractive surgery," and "cataract surgery" dates back to 1999. Recently, there has been a noticeable uptick in keywords including "visual quality," "vector analysis," "axial length," "evo ICL," "implantable collamer lens v4c," and "implantable collamer lens."

TABLE 2 Top 10 Institutions with articles on ICL surgery.

Rank	Institution	Country/ Region	Counts	H-index
1	Fudan University	China	70	13
2	Kitasato University	Japan	60	26
3	University of Valencia	Spain	47	20
4	Shanghai Res Ctr Ophthalmol and Optometry	China	41	11
5	Chinese Academy of Medical Sciences and Peking Union Medical College	China	34	6
6	Sanno Hospital	Japan	30	15
7	University of Oviedo	Japan	30	18
8	Nagoya Eye Clinic	Japan	23	11
9	Egyptian Knowledge Bank (EKB)	Egypt	22	10
10	Zhejiang University	China	20	9

TABLE 3 Top 10 journals with articles on ICL surgery.

Rank	Journal	Record count	% of 875	Impact factor	H-index
1	Journal of Cataract and Refractive Surgery	169	19.3	2.8	39
2	Journal of Refractive Surgery	136	15.5	2.4	34
3	BMC Ophthalmology	55	6.3	2.0	10
4	American Journal of Ophthalmology	46	5.3	4.2	23
5	European Journal of Ophthalmology	31	3.5	1.7	9
6	Graefe's Archive for Clinical and Experimental Ophthalmology	27	3.1	2.7	13
7	International Journal of Ophthalmology	26	3.0	1.4	8
8	International Ophthalmology	26	3.0	1.6	6
9	Ophthalmology	24	2.7	13.7	19
10	Indian Journal of Ophthalmology	23	2.6	3.1	7

3.6 High-impact articles

High-impact articles are significant markers of research impact and are recognized as key achievements within their respective fields. Table 4 lists the 10 articles most frequently cited in the area of ICL surgery research. This list encompasses: pivotal clinical trials on ICL approved by the United States Food and Drug Administration (FDA) (24–26); seminal clinical studies from 1998 evaluating posterior chamber intraocular lenses crafted from collamer material aimed at correcting refractive errors (27, 28); and comprehensive retrospective analyses on ICL interventions for refractive error corrections. These studies collectively measure outcomes such as uncorrected visual acuity (VA), best-corrected visual acuity, adverse events, and both surgical and postsurgical complications, including the extent of lens opacity. Their primary focus lies on assessing the safety, efficacy, and predictability of ICL surgeries. Table 4 also incorporates the limitations identified during these research endeavors.

4 Discussion

4.1 Overall data

ICL surgery, a notable solution for refractive error correction, has seen advancements in material and structural design since its inception. The inceptive ICL was implanted in 1993, representing the first generation of prototypes. Traditional ICL models, preceding the V4c model, necessitated a preoperative laser peripheral iridotomy or an intraoperative iridectomy to avert pupillary block (29). The newer V4c ICL iteration and subsequent models, featuring a central hole, cultivate better aqueous humor flow and preserve central vision (30). An uptick in clinical utilizations of ICL from 1996 to 2023 is highlighted by publication analyses. With ongoing evolution, ICL surgery research hotspots and citations exhibit a growing pattern. Current article trends reveal a peculiar decline in the number of articles in 2023, yet citations continue to ascend. Given the worldwide surge in myopia prevalence, research in this domain is poised for further expansion. Between 2020 and 2023, articles remained robust, averaging over 75 papers annually, which dovetails with China's significant research output—contributing 178 articles—and broader clinical application of ICL surgery (31).

Aligned with the ongoing progress in ICL surgery, this research delineates not only the trends within the ICL surgery domain but also discerns hotspots, prolific countries/regions, institutions, and keyword clusters. Figure 2 identifies China as the leading contributor in terms of publication volume, albeit with minimal centrality, attributable to the comparatively recent initiation of ICL research in the country. Before 2010, a mere 8 Chinese articles featured in this bibliometric analysis; the subsequent upswing is possibly linked to China's vast population and the growing prevalence of myopia (32). Spain, the United States, and Japan showcase high H-index scores, signaling an earlier embrace of ICL surgeries and heightened scrutiny in the sector. Analysis of institutions producing prolific research reveals that both China and Japan count four institutions each among the top 10, indicating extensive ICL surgery research activity in these territories. Specialty journals such as the "Journal of Cataract & Refractive Surgery" and the "Journal of Refractive Surgery" lead in published and cited articles numbers. Journals like "American Journal of Ophthalmology" and "Ophthalmology," despite featuring fewer than 50 articles, still achieve a commendable H-index. Notably, the four mentioned journals are the source of 9 out of the 10 most impactful papers. This suggests that publishing ICL-related research in these established journals could elevate academic prominence and impact for researchers in the field.

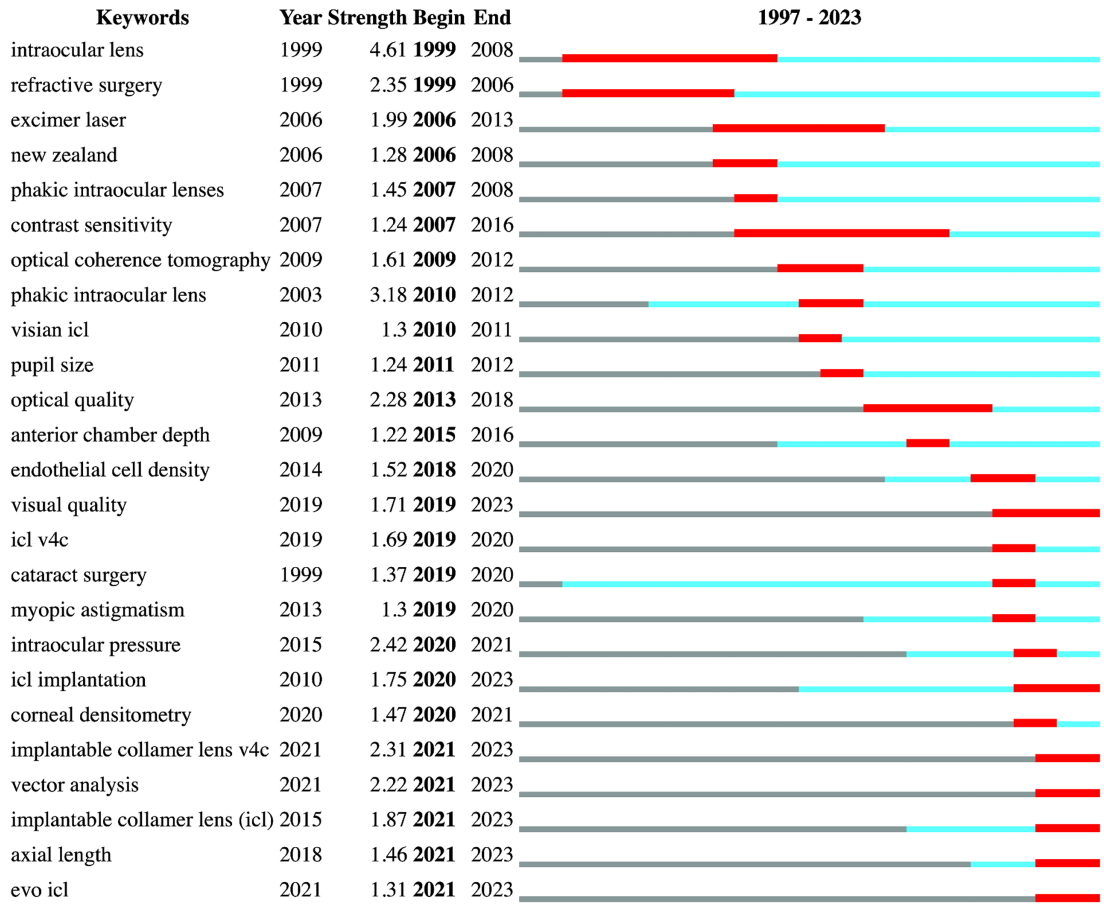

FIGURE 5
Keywords with the strongest citation bursts.

4.2 Hotspots analysis

In bibliometric studies on keyword bursts and clusters, the centrality of ICL surgery within ophthalmic research is evident. High myopia, optical quality, and pupil size are among the keywords drawing significant attention. This focus reflects the importance of ICL surgery in correcting refractive errors without altering the natural refractive media, which often results in stable or enhanced postoperative visual quality. Furthermore, the anterior or posterior chamber of the eye, due to its implication in the risk of ICL surgery complications, features prominently in current research. This field's interest is seen in the prevalence of keywords such as "pupil size," "anterior chamber depth," "white-to-white," and "vault" among ophthalmic researchers.

Since the advent of widespread research in this domain, attention to high myopia correction has been prevalent. An early study published in J. Cataract Refract. Surg. in 1996 already evidenced ICL surgery as a viable treatment for high myopia, despite the lack of long-term safety data at that time (22). With the evolution of ICL, various models have emerged for patient selection, alongside alternative refractive surgeries, hence the importance of optical quality comparisons between different ICL models (33) and refractive procedures (34). Research has substantiated that ocular parameters can influence ICL surgery outcomes. For instance, pupil size is critical for lens positioning and impacts surgical success (35). Anterior chamber depth is vital for proper ICL sizing and placement to prevent postoperative complications (36). White-to-white measurements are essential for lens sizing (37) and significantly affect the postoperative vault—the interval between the ICL and the crystalline lens (38). Moreover, this vault is informed by several ocular factors, like white-to-white and anterior chamber depth, which cumulatively determine the prognostic results of ICL procedures.

An analysis of various keywords related to ICL surgery revealed that early research in the field of ICL focused on ICL surgery to evaluate the safety, efficacy, and postoperative refractive outcomes of ICL surgery (39, 40). From the keywords "excimer laser" and "refractive surgery," we found that many studies were conducted in this field comparing and combining ICL surgery with other refractive surgeries, and in many of these studies, ICL surgery achieved favorable results. In many of these studies, ICL surgery has resulted in good visual quality (41–43). In the study of ICL surgical complications, we found that cataract surgery has been active for a long time and is exploding during 2019–2020, which is associated with the possibility of complications cataracts in ICL surgery (24).

TABLE 4 High-impact articles.

Rank	Article title and year	Source title	Authors	Cited	Limitation
1	United States Food and Drug Administration clinical trial of the implantable collamer lens (ICL) for moderate to high myopia - Three-year follow-up(2004)	Ophthalmology	Sanders, DR et al.	304	For patients with high myopia, the risks associated with ICL surgery may be increased.
2	US food and drug administration clinical trial of the implantable contact lens for moderate to high myopia(2003)	Ophthalmology	Vukich, JA et al.	208	Correction for severe myopia may face limitations; moreover, there is individual variability within the outcomes.
3	Posterior chamber phakic intraocular lens for myopia of −8 to −19 diopters(1998)	Journal of Refractive Surgery	Zaldivar., R et al.	179	Compared to pIOL, ICL is associated with a higher risk of subsequent cataract formation, and the surgery could be a risk factor for future retinal detachment.
4	Safety of posterior chamber phakic intraocular lenses for the correction of high myopia: Anterior segment changes after posterior chamber phakic intraocular lens implantation(2001)	Ophthalmology	Jiménez-Alfaro, I et al.	158	Postoperative complications following ICL implantation may include loss of endothelial cells and decreased lens transparency, and the long-term contact of ICL with the iris and the natural lens has the potential to cause enduring complications.
5	Eight-Year Follow-up of Posterior Chamber Phakic Intraocular Lens Implantation for Moderate to High Myopia(2014)	American Journal of Ophthalmology	Igarashi, A et al.	155	Myopic regression following ICL implantation may be correlated with factors such as lens nucleus sclerosis, corneal expansion, corneal edema, matrix synthesis, compensatory epithelial proliferation, and axial elongation.
6	Toric implantable collamer lens for moderate to high myopic astigmatism(2007)	Ophthalmology	Sanders, DR et al.	134	/
7	Anterior subcapsular opacities and cataracts 5 years after surgery in the Visian implantable collamer lens FDA trial(2008)	Journal of Refractive Surgery	Sanders, DR	126	There is a certain rate of cataract occurrence in the course of correcting high myopia with ICL, particularly regarding the risk of anterior subcapsular opacities and clinically significant cataracts.
8	Staar Collamer posterior chamber phakic intraocular lens to correct myopia and hyperopia(1998)	Journal of Cataract and Refractive Surgery	Rosen, E; Gore, C	125	There are numerous contraindications to ICL surgery including unhealthy corneal endothelium, abnormal corneal shapes (e.g., keratoconus), lens opacification or incipient cataracts, a history of iritis, glaucoma, pigment dispersion syndrome, lens capsule exfoliation syndrome, and diabetic eye disease. The size of the pupil also has a certain impact on the ICL surgery.
9	Long-term results of implantation of phakic posterior chamber intraocular lenses(2004)	Journal of Cataract and Refractive Surgery	Lackner, B et al.	124	/
10	Four-Year Follow-up of Posterior Chamber Phakic Intraocular Lens Implantation for Moderate to High Myopia(2009)	Archives of Ophthalmology	Kamiya, K et al.	122	The pupil size can potentially influence the ICL surgery to a certain extent, and there are risks associated with cataract development and loss of corneal endothelial cells.

The advent of new ICL variations like the Visian, Toric, and EVO/EVO+ lenses exemplifies the field's dynamic nature. Distinctive for its central hole, has simplified the procedure by eliminating the need to preoperatively create a hole in the iris (6, 7), the V4c model of ICL encourages aqueous humor flow and cuts down complication risks such as cataracts and pupillary block (44, 45). This design innovation has sparked research interest in recent years. As Figure 5 shows the burst words, "visual quality," "ICL implantation," "vector analysis," "axial length," "evo ICL," "ICL v4c," and "ICL" have become the current hotspots.

The ICL V4c represents a completely redesigned approach compared to previous ICL models, offering numerous benefits. The central hole of the ICL V4c facilitates the natural flow of aqueous humor, maintaining normal intraocular pressure and reducing the risk of postoperative complications such as corneal edema, glaucoma, and cataract. The central hole contributes to the stability of the ICL within the eye, minimizing the potential for rotation or displacement, which is crucial for maintaining the intended refractive outcomes and ensuring the long-term safety of the

surgery (46). The central hole in the V4c and subsequent models allows for more precise determination of vault dimensions, which is essential for the effective function and comfort of the ICL. Vault dimensions, as an important postoperative observation indicator, show that the ICL V4c demonstrates good long-term effects and stability (47). In the long-term follow-up after V4c ICL implantation, no significant difference in endothelial cell density was observed between pre-operative and post-operative measurements (47).

4.3 Trends discussion

Research within the ICL domain, with a sustained focus on "visual quality," has ventured into analytical concepts like "vector analysis," "corneal densitometry," and "axial length." Several factors determine the image quality after ICL surgery, including the lens's optical properties, the stability of its placement, and its effects on axial alignments. Vector analysis, in particular, is crucial for astigmatism management in ICL surgical procedures, enhancing the precision of refractive results and overall visual quality. Its utility spans comparisons across surgical methods and devices, promoting refinements in ICL surgical techniques (48).

Technological advancements in diagnostic tools have steered ICL prognosis studies from broader complications toward a nuanced evaluation of anterior segment metrics. Corneal densitometry, signifying corneal clarity, assists in tracking corneal healing, while "axial length" is instrumental for selecting ICLs (49), forecasting refractive power, and managing surgical risks.

Various measurement devices related to ICL surgery, such as ultrasound biomicroscopy (UBM) and anterior segment optical coherence tomography (AS-OCT), play a significant role in enhancing the precision and safety of ICL surgery. UBM, with its high-resolution ultrasonic imaging, can delve into the structures of the anterior segment of the eye, especially the ciliary body and zonular fibers behind the iris, making it the gold standard for anterior segment imaging. AS-OCT generates high-resolution cross-sectional images of the anterior segment using near-infrared light. Corneal topography is used to assess the shape and regularity of the cornea, and these examinations are crucial for determining patient suitability for ICL surgery and customizing the lens (50). In addition to this, white-to-white corneal diameter measurement is typically conducted using a wavefront aberrometer (Wavelight) or other optical devices to determine the size of the ICL. Assessment of the anterior chamber depth ensures there is adequate space after ICL implantation to prevent contact with the natural lens, thereby reducing the risk of complications (51).

Recent research has focused on developing new methods for ICL size selection based on measurements obtained from these devices. For instance, one study utilized ocular biometric parameters measured with a Heidelberg anterior segment optical coherence tomography device to formulate the optimal lens size, emphasizing the importance of accurate size selection in preventing postoperative complications (50). By integrating these parameters, predictive models related to ICL can be developed to improve the predictability and safety of ICL implantation (52). Furthermore, the integration of advanced measurement tools such as UBM and AS-OCT into ICL surgery has not only improved preoperative assessment but also enhanced the accuracy of ICL size selection, leading to better postoperative outcomes. As these technologies continue to evolve, ophthalmologists gain deeper insights into the structures of the anterior segment, facilitating more precise surgical planning and patient care (51).

Further bibliometric analysis reveals the prominence of specific keywords in the discourse on prognostic ICL surgery research, with "vault, ""central hole," and "pupillary block" recurring as key concepts. These keywords have been identified with notable frequency, appearing 39, 42, and 12 times, respectively, underscoring their significance in the literature and highlighting their relevance to the prognostic aspects of ICL surgery research. The vault refers to the vertical distance between the posterior surface of the ICL and the anterior surface of the natural lens, which is an important indicator for evaluating the safety of ICL implantation surgery (53). Low vault values risk ICL contact with the crystalline lens, heightening complication odds like cataract development or pigmentary dispersion syndrome. Conversely, excessive vaults can elevate intraocular pressure, potentially causing glaucoma. Because central hole designs in ICLs benefit aqueous humor dynamics and lower elevated intraocular pressure and pupillary block risks, examining the complications associated with new ICL iterations presents a forward-looking research trajectory (54).

The integration of artificial intelligence (AI) in the field of ICL surgery, has led to significant advancements. Machine learning algorithms are now utilized to predict the optimal vault height of phakic IOLs using metrics from AS-OCT, enabling a more precise and personalized assessment of ICL sizing (55). Additionally, AI facilitates the analysis of vast datasets to identify patterns that enhance surgical strategies and predict postoperative outcomes (56). Image recognition through AI allows for detailed evaluation of the anterior segment, ensuring accurate ICL placement. Predictive modeling with AI further assists in foreseeing surgical results, including visual acuity and potential complications, thereby providing surgeons with invaluable insights to make informed decisions (57).

4.4 High-impact articles analysis

Upon a thorough review of 10 high-impact articles, it is clear that the safety and long-term prognostication of ICL surgery have consistently been a research priority. In early ICL clinical studies, a demand emerged to refine the power calculation formula, aiming to raise the forecast accuracy for postoperative visual quality (27). Research reporting on the United States FDA's ICL trials highlighted various adverse events and complications during the trial stages (24, 25). Due to the more recent introduction of ICL surgery relative to other corrective procedures, a dearth of long-term outcome data was noted, prompting newer studies to pursue extended follow-up durations (58). Advancements in research have solidified the understanding of ICL's safety, efficiency, and outcome predictability. Early ICL surgery research has had a considerable influence on later studies. In the last 5 years, shifting attention has been noticed toward the role of ocular biological measures (59), refining ICL calculation methodologies (60), integrating big data with artificial intelligence for outcome prediction (57), and conducting retrospective analyses with extended follow-up periods (61).

With the innovation of ICL surgical practice, its significant improvement in safety, stability, and outcome predictability has been validated. Looking to the future, as data analytics and algorithmic modeling rapidly advance, the development of nuanced ICL measurement formulas and clinical outcome predictive models stands out as the next research wave in the ICL surgery domain. These innovations are projected to fine-tune surgical planning and enhance the visual results for patients.

4.5 Limitation

4.5.1 Limitation of ICL surgery

As an invasive procedure, ICL surgery carries risks of trauma-related complications, including conjunctival or intraocular hemorrhage, corneal epithelial damage, and corneal Descemet's membrane detachment. Ancillary issues such as anterior or posterior chamber angle injury and traumatic cataract can occur (62). The procedure may also disrupt the ocular surface microenvironment, possibly inducing dry eye syndrome (63). The corneal incision might cause refractive astigmatism, posing a correction challenge (64). Residual viscoelastic substances could obstruct the anterior chamber angle, leading to severe complications like ischemia or permanent ciliary body paralysis (65). Postoperative complications comprise abnormal ICL positioning (dislocation, rotation, inversion) (66), elevated intraocular pressure, and secondary glaucoma (67). Early postoperative cataracts are linked to surgical trauma; later-stage ones are usually due to contact with the natural lens (68). Other common issues include irregular vaulting, corneal endothelium loss, and night vision disturbances (69).

High-impact articles also discuss conditions contraindicating ICL, such as compromised corneal endothelium, irregular corneal morphology, lens opacities or incipient cataracts, a history of iridocyclitis, glaucoma, and pigment dispersion syndrome, all impacting the procedure's suitability (28).

4.5.2 Limitation of bibliometric

Limitations of bibliometric analyses stem from data selection constraints. Relying on WoSCC data for the SCIE and SSCI indexed articles in the "Ophthalmology" category may result in overlooking seminal works on ICL materials and structure. Such exclusions could skew the representativeness of research cluster findings.

The H-index is influenced by the time of publication and may not fully capture the enduring impact of research, as it does not account for the potential delay in citations or the variability in citation practices across different fields (70).

By only considering articles indexed in SCIE and SSCI and published in English, pivotal studies on ICL material innovation and clinical trials may be omitted. Bibliometrics, while quantitatively robust, focusing on citation counts and publication volumes, may not fully capture the qualitative impact of research. Additionally, the 'citation lag' affecting newly published research might not instantaneously represent the true impact of these works.

5 Conclusion

Since the first publication in 1996, the field of ICL surgery has shown a year-on-year increasing trend in research output. The surge in publications over the past 3 years may be related to the significant amount of research conducted in China. Among the nations researching ICL surgery, China has the highest number of publications, while Spain, the United States, and Japan have higher H-index scores, indicating their substantial academic impact. Most literature in this field is published in professional ophthalmology journals.

During our research, we identified the following hotspots in the development of ICL: (1) hotspots regarding surgery and complication management, including terms like "ICL," "refractive surgery," and "cataract surgery"; (2) biometric parameters related to ICL surgery such as "anterior chamber depth," "pupil size," "visual quality," "vector analysis," "axial length," "white-to-white," and "vault"; (3) novel ICL models like "evo ICL" and "ICL V4c."

In the trend research of ICL surgery, we have noticed that from the initial exploration of ICL implantation to various biological parameters associated with ICL surgery, and the benefits of new ICL designs in managing postoperative complications. The safety, efficacy, and predictability of ICL surgeries have always been the focal points, as demonstrated by high-impact articles. AI-involved research may be the future trend in the field of ICL surgery.

As an invasive ocular procedure, ICL surgery carries certain risks, including complications related to anterior or posterior chamber trauma. Our research has identified limitations: we analyzed the publication volume and citation counts in the field of ICL surgery from 1996 to 2023, but these metrics may not fully reflect the quality of the literature. Moreover, the latency in citation data may have prevented us from capturing the latest research developments in this field promptly.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

Author contributions

QZ: Writing – original draft, Writing – review & editing. DG: Writing – original draft. KL: Writing – original draft. KD: Writing – original draft. YW: Writing – original draft. CP: Writing – original draft. ZY: Writing – review & editing. WY: Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Tolerance to induced astigmatism of patients with trifocal or extended depth of focus intraocular lens implantation

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Background: Residual astigmatism is common after cataract surgery involving implantation of an intraocular lens, yet the tolerance of presbyopia-correcting intraocular lens to astigmatism of different magnitudes and axes is poorly understood. Here we compared visual acuity and quality in the presence of induced astigmatism after implantation of a trifocal or extended-depth-of-focus (EDOF) intraocular lens, the two widely used presbyopia-correcting intraocular lenses.

Methods: At least 3 months after implantation of a TFNT00 or ZXR00 intraocular lens, patients were analyzed by slit-lamp examination, non-contact tonometry, subjective refraction, iTrace aberrometry, and corneal topography. After correction of residual astigmatism, astigmatism of different magnitudes on different axes was induced using cylindrical lenses, and overall visual acuity was measured, while objective visual quality was measured using the Optical Quality Analysis System II. Subjects were also asked about subjective visual quality using the Visual Function-14 questionnaire.

Results: Comparison of 18 individuals who received a trifocal lens and 19 who received an EDOF lens showed that objective visual quality was better in the EDOF group regardless of the magnitude or axis of the induced astigmatism. In both groups, astigmatism of at least −1.00 DC influenced distant vision more severely when the axis was 45° than 0° or 90°, meanwhile astigmatism of at least −1.50 DC influenced near and intermediate vision more severely when the axis was 45° than 0° or 90°.

Conclusion: Trifocal or EDOF intraocular lenses are less tolerant of oblique astigmatism than astigmatism with or against the rule. EDOF lenses may provide better objective visual quality than trifocal lenses in the presence of astigmatism, regardless of its magnitude or axis.

KEYWORDS

astigmatism, cataracts, presbyopia-correcting, intraocular lens, tolerance, visual quality

Introduction

Cataracts, which affect up to 17% of the global population at any one time, are the most frequent cause of reversible blindness (1). Prognosis for individuals with cataracts has improved tremendously through medical advances, with phacoemulsification and implantation of an intraocular lens restoring good vision quality to many. Increasingly attractive are intraocular lenses that correct presbyopia, such as trifocal and extended-depth-of-focus (EDOF) lenses, because they can obviate the need for glasses after cataract surgery (2). While these lenses can provide excellent near, intermediate and distant vision, they are associated with higher risk of adverse visual phenomena, such as glare and halos, than monofocal lenses are (3, 4). In addition, residual astigmatism after cataract surgery is quite common, exceeding 1.00 DC in up to 56% of patients in one study (5), and it is unclear to what extent presbyopia-correcting lenses are tolerant of residual astigmatism. Previous studies have compared the tolerance to induced astigmatism between small-aperture, mono-or multi-focal intraocular lenses implanted in pseudophakic eyes (6–8), but we are unaware of tolerance comparisons between trifocal and EDOF intraocular lenses implanted into pseudophakic eyes. Establishing the astigmatism tolerance of trifocal and EDOF lenses is important because residual astigmatism as low as 0.75 DC can reduce satisfaction with vision after cataract surgery (9).

Here we examined such tolerance in individuals after implantation of trifocal or EDOF lenses by inducing astigmatism of different magnitudes along different axes and then measuring overall visual acuity and visual quality.

Methods

Study participants

The protocol for this study was approved by the Ethics Review Board of West China Hospital, Sichuan University (approval 1,312, 2021), and the study was registered on December 15, 2021 in the Chinese Clinical Trial Register (ChiCTR2100054362). Participants were prospectively recruited from among all adults scheduled for cataract surgery at the Department of Ophthalmology of West China Hospital between May 2020 and October 2022 who (a) had nuclear or cortical cataracts without posterior polar cataracts or concomitant intraocular disease, (b) had preoperative intraocular pressure < 21 mmHg, and (c) elected to undergo implantation with a PanOptix TFNT00 trifocal intraocular lens (Alcon Laboratories, Fort Worth, TX, United States) or the Tecnis Symfony ZXR00 EDOF intraocular lens (Johnson & Johnson Vision, Santa Ana, CA, United States) during cataract surgery. After being thoroughly informed about the functions of different IOLs, patients choose the type of intraocular lens based on their individual conditions.

We excluded patients who had (a) pre-or postoperative abnormality of the cornea, macula, or optic nerve; (b) postoperative development of secondary cataracts or significant intraocular lens displacement; (c) pre-or postoperative ocular inflammation; (d) history of ocular surgery; or (e) postoperative intraocular pressure > 21 mmHg. We also excluded patients who failed to complete follow-up.

Preoperative examinations

Prior to cataract surgery, all patients were examined for uncorrected distance visual acuity (UDVA), best corrected distant visual acuity (BCDVA), uncorrected and corrected near visual acuity, refraction, intraocular pressure based on non-contact tonometry, biometrics based on partial coherence interferometry (IOL Master 700, Carl Zeiss Meditec, Jena, Germany), corneal tomography (CASIA 2, Tomey, Nagoya, Japan) and topography (Topographic Modeling System, Tomey, Nagoya, Japan). The macula and retina were examined using optical coherence tomography (Heidelberg Engineering, Heidelberg, Germany) and scanning laser ophthalmoscopy (Optos, Marlborough, MA, United States), while corneal aberration was evaluated using an iTrace visual function analyzer (Tracey Technologies, Houston, TX, United States).

Cataract surgery and intraocular lens implantation

The surgeries on all patients were performed by the same experienced clinician using the Stellaris system (Bausch & Lomb, Rochester, NY, United States). After topical anesthesia and pupillary dilation, cataract surgery was performed with a clear corneal self-sealing incision 2.0 mm long, continuous curvilinear capsulorhexis with a diameter of 5.0–5.5 mm, hydro-dissection and-delineation, phacoemulsification, irrigation and aspiration of the residual lens cortex, and insertion of either TFNT00 or ZXR00 lens.

After surgery, all patients were instructed to take eye drops containing 0.3% tobramycin and 0.1% dexamethasone (Alcon-Couvreur, Puurs, Belgium) four times a day during week 1, three times a day during week 2, twice a day during week 3, and once a day during week 4. All patients were also asked to take eye drops containing 0.1% sodium diclofenac (Sinqi Pharmaceutical, Shenyang, Liaoning, China) four times a day for 4–6 weeks depending on the degree of postoperative inflammatory response.

Follow-up and assessment of astigmatism tolerance

All patients were followed up according to routine procedures in our department. For the present report, a single set of measurements from a follow-up visit conducted at least 3 months (actually ranged from 6 months to 1 year) after surgery was analyzed. Uncorrected near, intermediate and distant visual acuity were measured, and refractive examination, non-contact tonometry, slit-lamp examination and corneal topography were performed. The modulation transfer function and wavefront aberrations were measured at a pupil diameter of 4 mm using the iTrace aberrometer. Subjects were asked to rate their subjective visual experience and satisfaction on the Visual Function-14 questionnaire (10).

Residual refractive errors were corrected, then BCDVA, best intermediate visual acuity (BIVA) and best near visual acuity (BNVA) were measured. Subjects were asked to wear cylindrical lenses that induced astigmatism of −1.00, −1.50 or-2.00 DC along the axes of 0° ("with the rule"), 45° ("oblique") or 90° ("against the rule"). Under each of the nine situations, visual acuity was measured at near (40 cm), intermediate (60 cm) and far (5 m) distances using international standard logarithmic near-, intermediate-, and far-vision visual acuity charts. Results were converted to the LogMAR visual acuity scale for statistical analysis. Acuity was tested immediately after inducing astigmatism to avoid neural adaptation (11).

TABLE 1 Preoperative characteristics of individuals undergoing cataract surgery involving implantation of a trifocal or EDOF intraocular lens.

Characteristic	Trifocal group	EDOF group	*p**
No. eyes/patients	18/18	19/19	
Age, yr	62.5 ± 6.4	62.3 ± 7.3	0.775
Sex			0.495
Male	7 (39)	5 (26)	
Female	11 (61)	14 (74)	
Axial length, mm	25.3 ± 1.91	23.94 ± 1.73	0.046
Anterior chamber depth, mm	3.24 ± 0.43	3.16 ± 0.33	0.165
Corneal refractive power, D	43.67 ± 1.18	44.05 ± 1.65	0.136
Corneal astigmatism, D	0.7 ± 0.4	0.46 ± 0.28	0.113

Values are *n*, *n* (%) or mean ± SD, unless otherwise noted. EDOF, extended depth of focus; IQR, interquartile range (quartile 1, quartile 3); SD, standard deviation. *Based on Fisher's exact test for sex or the independent-samples *t*-test for all other variables.

TABLE 2 Postoperative examination results of individuals at least 3 months after cataract surgery involving implantation of a trifocal or EDOF intraocular lens.

Characteristic	Trifocal group (*n* = 18)	EDOF group (*n* = 19)	*p**
Spherical diopter, D	0.03 ± 0.32	−0.22 ± 0.42	0.118
Cylindrical diopter, D	−0.28 ± 0.45	−0.32 ± 0.30	0.663
Equivalent spherical diopter, D	−0.13 ± 0.36	−0.36 ± 0.35	0.057
Corneal refraction, D	43.67 ± 1.17	44.09 ± 1.68	0.101
Corneal astigmatism, D	0.69 ± 0.41	0.53 ± 0.29	0.128
κ angle, mm	0.285 ± 0.178	0.207 ± 0.124	0.105
α angle, mm	0.318 ± 0.152	0.405 ± 0.146	0.105
Corneal spherical aberration, D	0.224 ± 0.057	0.226 ± 0.089	0.245
Total ocular higher-order aberration, μm	0.135 ± 0.097	0.157 ± 0.181	0.845
Corneal higher-order aberrations, μm	0.102 ± 0.126	0.085 ± 0.060	0.461
Intraocular pressure, mmHg	13.2 ± 1.9	13.3 ± 1.9	0.964

Values are mean ± SD. EDOF, extended depth of focus. *Based on the independent-samples *t*-test in the case of the three corneal parameters of curvature, astigmatism and spherical aberration; or based on the non-parametric Mann–Whitney *U* test in the case of other parameters.

Objective visual quality was measured in terms of the modulation transfer function cutoff frequency (MTF cutoff), Strehl ratio (SR), and objective scatter index (OSI) using a dual-channel Optical Quality Analysis System II (Visiometrics, Terrassa, Spain). Contribution of residual refractive errors to these three measurements was removed by using additional lenses or the system's built-in low-order aberration correction. Visual quality was measured under the nine situations of induced astigmatism as described above.

Before measuring objective visual quality, we ensured that pupil diameter exceeded 4 mm, and we asked subjects to blink several times to ensure that the ocular surface was uniformly covered by tears.

Statistical analysis

Data were analyzed using SPSS 26.0 (Chicago, IL, United States) and GraphPad Prism 8.3.0 (GraphPad Software, San Diego, CA, United States). Continuous data were reported as mean ± standard deviation if normally distributed, or as median (interquartile range) if skewed. Differences in continuous, normally distributed variables were assessed for significance using the independent-samples *t*-test in the case of pairwise comparisons, or using ANOVA in the case of comparisons involving at least three groups. Differences in continuous, skewed variables were assessed for significance using the Mann–Whitney *U* test in the case of pairwise comparisons, or using the Kruskal–Wallis test followed by Dunn's method in the case of comparisons involving at least three groups. Categorical data were reported as frequency (percentage). Pairwise differences in categorical variables were assessed for significance using the chi-squared test if the expected frequency in either group was greater than 5, or using Fisher's exact test otherwise. A sample size of 16 subjects provided adequate power to detect this difference at a significance level of 0.05 using a two-sided paired *t*-test. Differences were considered statistically significant if associated with $p < 0.05$.

TABLE 3 Responses on the Visual Function-14 questionnaire and self-report of other visual function measures at least 3 months after cataract surgery involving implantation of a trifocal or EDOF intraocular lens.

Score or measure	Trifocal group (*n* = 18)	EDOF group (*n* = 19)	*p**
Visual Function-14 questionnaire scores**			
Total	95.95 ± 9.50	94.94 ± 12.97	0.167
Distant tasks	96.94 ± 8.24	96.36 ± 10.62	0.707
Intermediate tasks	98.15 ± 6.61	99.56 ± 3.31	0.500
Near tasks	96.76 ± 8.48	99.12 ± 4.64	0.297
Fine tasks	88.57 ± 14.02	77.63 ± 20.79	0.063
Incidence of adverse visual effects			
Starbursts	7 (38.9)	8 (42.1)	1.000
Glare	5 (27.8)	2 (10.5)	0.232
Halos	8 (44.4)	6 (31.6)	0.508
Satisfaction with postoperative visual function***	90.56 ± 7.25	91.58 ± 8.34	0.649
Proportion of individuals reporting satisfaction ≥90 points	14 (77.8)	14 (73.7)	1.000
Likelihood of recommending the same intraocular lens to family or friends***	87.78 ± 23.15	91.58 ± 17.4	0.279
Proportion of individuals reporting ≥90% likelihood of recommending the same lens	14 (77.8)	15 (78.9)	1.000

Values are *n* (%) or mean ± SD, unless otherwise noted. EDOF, extended depth of focus. *Based on Fisher's exact test in the case of the incidence of starbursts, glares and halos; or based on the Mann–Whitney *U* tests in all other cases. **Original scores, which could vary from a minimum of 0 to a maximum of 4, were converted to a 100-point scale. Higher score indicates better visual perception. ***Original scores on a 10-point scale were converted to a 100-point scale.

Results

The final analysis included 37 eyes from 37 participants, comprising 18 eyes in the trifocal group and 19 in the EDOF group. The two groups did not differ significantly in any of the preoperative characteristics examined, except that the trifocal group showed a

significantly longer axial length (Table 1). This is consistent with such individuals' greater requirement for good near vision.

Postoperative data for all study participants were collected at follow-up visits that occurred at least 3 months after cataract surgery.

Comparison of the trifocal and EDOF groups in the absence of induced astigmatism

In the absence of induced astigmatism, the trifocal and EDOF groups did not differ significantly in postoperative refraction or in any of the corneal parameters examined, including curvature, astigmatism or spherical aberration (Table 2). Similarly, the two groups did not differ significantly on any of the items on the Visual Function-14 questionnaire (Table 3), although the EDOF group tended to report higher incidence of starbursts, while the trifocal group tended to report higher incidence of glare and halos. Nevertheless, the two groups reported similarly high satisfaction with visual function provided by their implanted lens.

In the absence of induced astigmatism, the trifocal group showed significantly better BNVA than the EDOF group but the two groups did not differ significantly in UDVA, BCDVA or BIVA (Figures 1A–C). The EDOF group showed significantly better modulation transfer function cutoff, Strehl ratio and objective scatter index (Figures 1D–F). In fact, mean values of all three parameters were within the normal range in the EDOF group but not in the trifocal group. Nevertheless, the two groups showed similar uncorrected visual acuity and reported similar satisfaction with their visual function.

Comparison of the trifocal and EDOF groups in the presence of induced astigmatism

Induced astigmatism of −1.00 DC did not significantly affect the acuity of near vision in either group, regardless of whether the axis was 0, 45 or 90° (Figure 2). It slightly affected intermediate vision, primarily in the trifocal group when the axis was 45°. In contrast, it

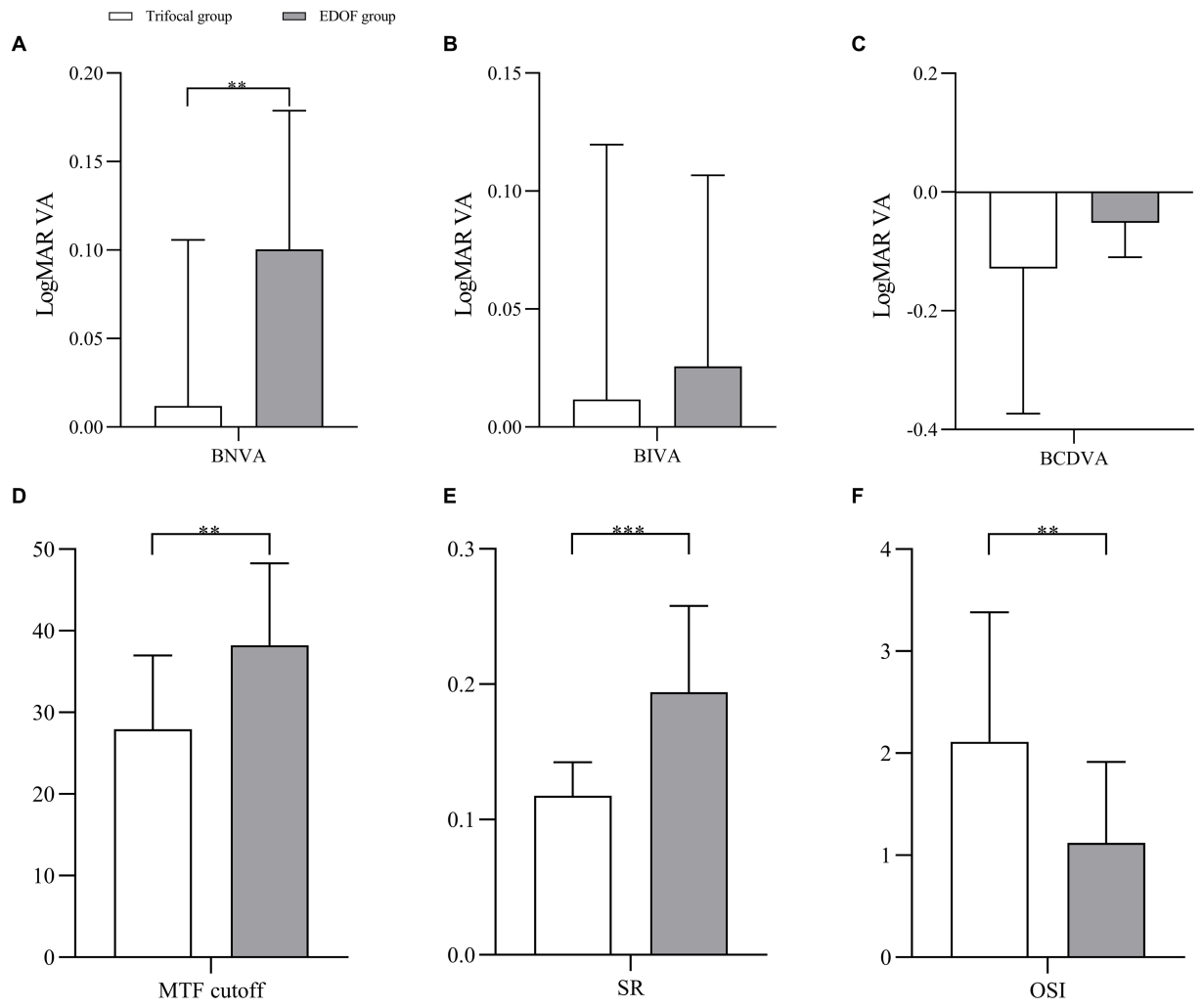

FIGURE 1
Pairwise comparison of **(A)** near vision, **(B)** intermediate vision, **(C)** distant vision, **(D)** MTF cutoff, **(E)** SR, and **(F)** OSI between individuals who received trifocal or EDOF intraocular lenses in absence of induced astigmatism. BNVA, best near visual acuity; BIVA, best intermediate visual acuity; BCDVA, best corrected distant visual acuity; EDOF, extended depth of focus; LogMAR VA, visual acuity in terms of the logarithm of the minimum angle of resolution; MTF, modulation transfer function; OSI, objective scatter index; SR, Strehl ratio. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$.

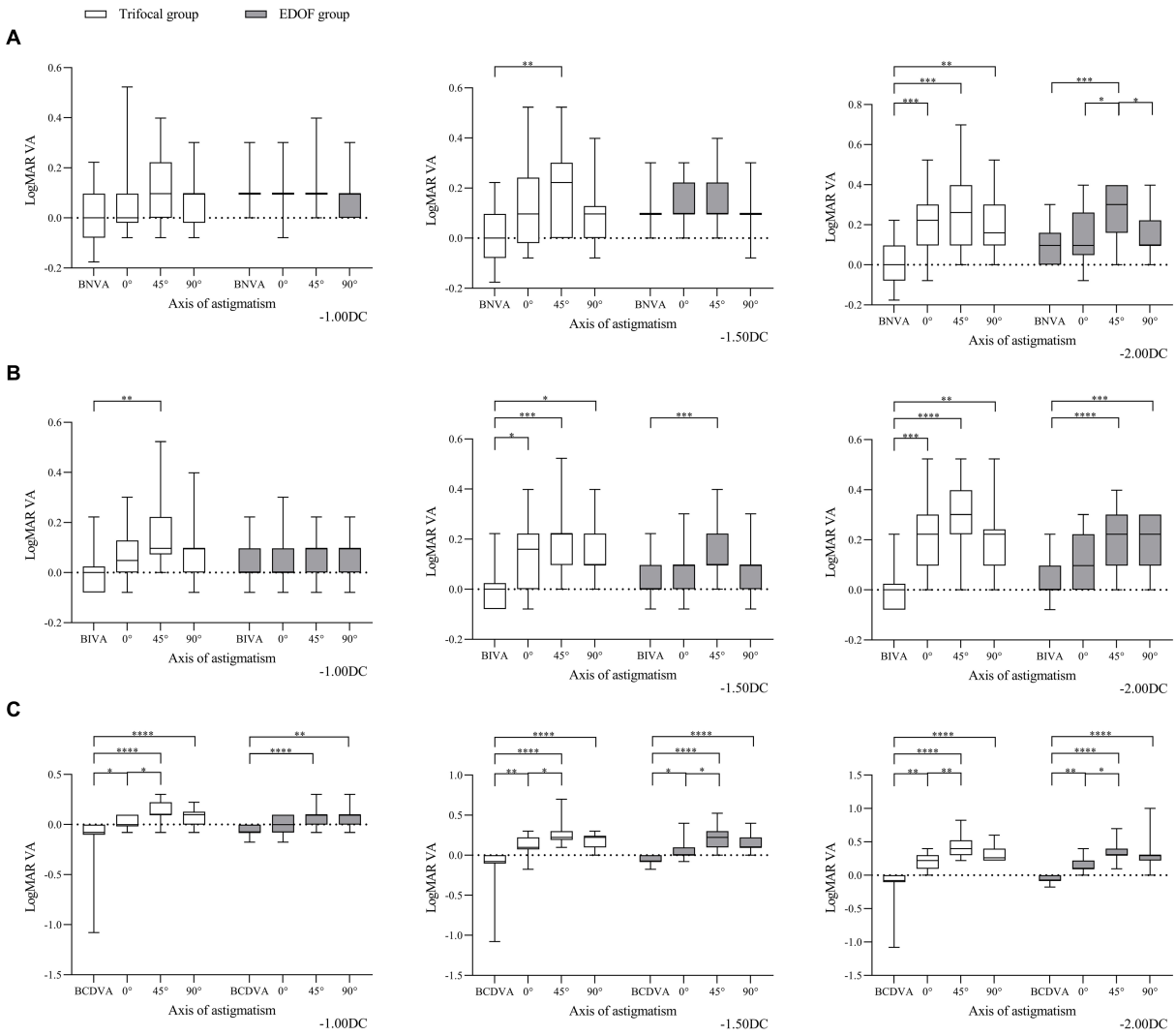

FIGURE 2
Comparison of best corrected acuity of **(A)** near vision, **(B)** intermediate vision and **(C)** distant vision under the specified magnitudes of induced astigmatism at different axes between individuals who received trifocal or EDOF intraocular lenses. Measurements were made after astigmatism of −1.00, −1.50 or −2.00 DC was induced at the indicated axis values at least 3 months after implantation. BCDVA, best corrected distant visual acuity; BIVA, best intermediate visual acuity; BNVA, best near visual acuity; EDOF, extended depth of focus; LogMAR VA, Logarithm of the Minimum Angle of Resolution visual acuity. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$.

significantly diminished distant vision in both groups when the axis was 45 or 90°; only distant vision in the trifocal group was significantly reduced when the axis was 0°.

Induced astigmatism of −1.50 DC did not significantly affect near vision in the EDOF group, regardless of the axis, whereas it did significantly affect near vision in the trifocal group at an axis of 45°. Similarly, it significantly reduced intermediate vision in the EDOF group only at an axis of 45° but in the trifocal group at all three axis values. It significantly reduced distant vision in both groups, regardless of the axis, with the most severe reduction occurring at an axis of 45°.

Induced astigmatism of-2.00 DC significantly reduced near vision in the trifocal group regardless of the axis, but in the EDOF group only at an axis of 45°. Similarly, it significantly reduced intermediate vision in the trifocal group regardless of the axis, but in the EDOF group only at axes of 45 or 90°. It significantly reduced distant vision in both groups, regardless of the axis, with an axis of 45° associated with more severe reduction than 0°.

In other words, when the axis of induced astigmatism was 0°, the trifocal group experienced significant loss of near vision only at −2.00 DC, whereas the EDOF group did not experience significant loss even at that magnitude (Figure 3). The trifocal group experienced significant loss of intermediate vision from −1.50 DC, compared to −2.00 DC in the EDOF group. Both groups experienced significant loss of distant vision from −1.50 DC. When the axis of induced astigmatism was 45°, both groups experienced significant loss of near and intermediate vision from −1.50 DC, and they experienced significant loss of distant vision already from −1.00 DC. When the axis of induced astigmatism was 90°, similar to when the axis was 0°, the trifocal group experienced significant loss of near vision only at −2.00 DC, whereas the EDOF group did not experience significant loss even at that magnitude. The trifocal group experienced significant loss of intermediate vision from −1.50 DC, compared to −2.00 DC in the EDOF group. In contrast to when the axis was 0°, the trifocal group experienced significant loss of distant vision from −1.00 DC, compared to −1.50 DC in the EDOF group.

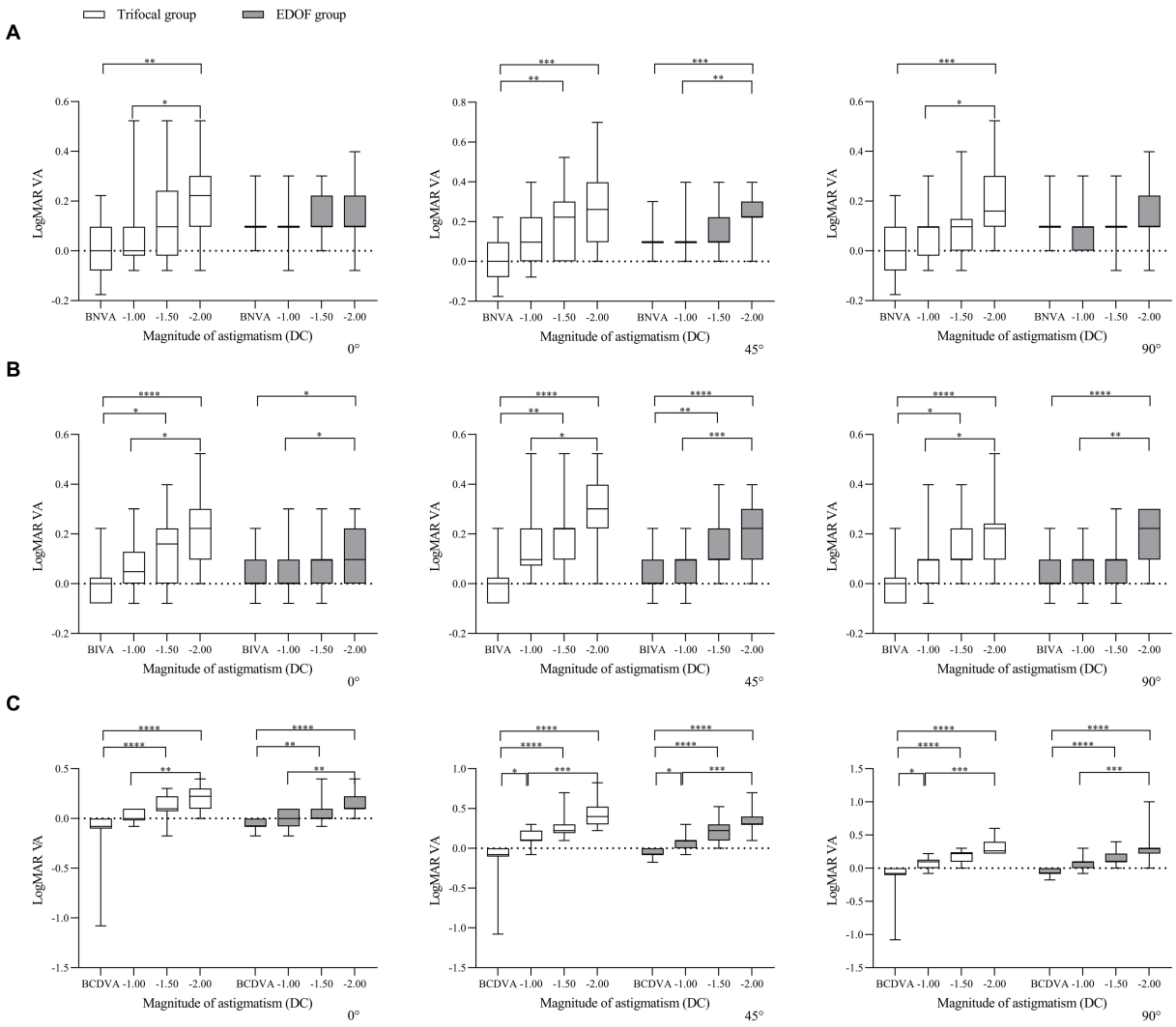

FIGURE 3
Comparison of best corrected acuity of **(A)** near vision, **(B)** intermediate vision and **(C)** distant vision under induced astigmatism of different magnitudes at the specified axes between individuals who received trifocal or EDOF intraocular lenses. Measurements were made after astigmatism of −1.00, −1.50 or −2.00 DC was induced at the indicated axis values at least 3 months after implantation. BCDVA, best corrected distant visual acuity; BIVA, best intermediate visual acuity; BNVA, best near visual acuity; EDOF, extended depth of focus; LogMAR VA, Logarithm of the Minimum Angle of Resolution visual acuity. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$.

Consistent with these findings on visual acuity, we found that objective visual quality, as measured in terms of modulation transfer function, Strehl ratio and objective scatter index, was better for the EDOF group than the trifocal group in the presence of induced astigmatism. Astigmatism of −1.00 DC significantly reduced the modulation transfer function cutoff in both groups at axis values of 45° or 90°, while it also reduced the cutoff at an axis of 0° in the trifocal group (Figure 4). In contrast, the same magnitude of astigmatism significantly reduced the Strehl ratio in both groups, but only when the axis was 90°; it significantly reduced the objective scatter index in both groups only when the axis was 45 or 90°. Regardless of axis, induced astigmatism of −1.50 or −2.00 DC significantly reduced all three visual quality parameters in both groups.

In other words, regardless of the axis of induced astigmatism, the three visual quality parameters in both groups declined significantly from −1.50 or −2.00 DC (Figure 5). When the axis was 90°, the only parameter to decline significantly in the EDOF group was modulation transfer function cutoff from −1.00 DC.

Regardless of the type of intraocular lens or axis of induced astigmatism, all the parameters of visual acuity and quality in our analysis declined with worsening astigmatism (Figure 6).

Discussion

Residual astigmatism could affect retinal image quality by preventing light from focusing properly on the retina and resulting in blurred or distorted vision at all distances, and its impact on the retinal image quality of trifocal IOLs was the most pronounced when compared to EDOF and monofocal IOLs (12). Residual astigmatism affects a substantial proportion of patients after cataract surgery (4), prompting us to assess the tolerance of increasingly popular trifocal and EDOF

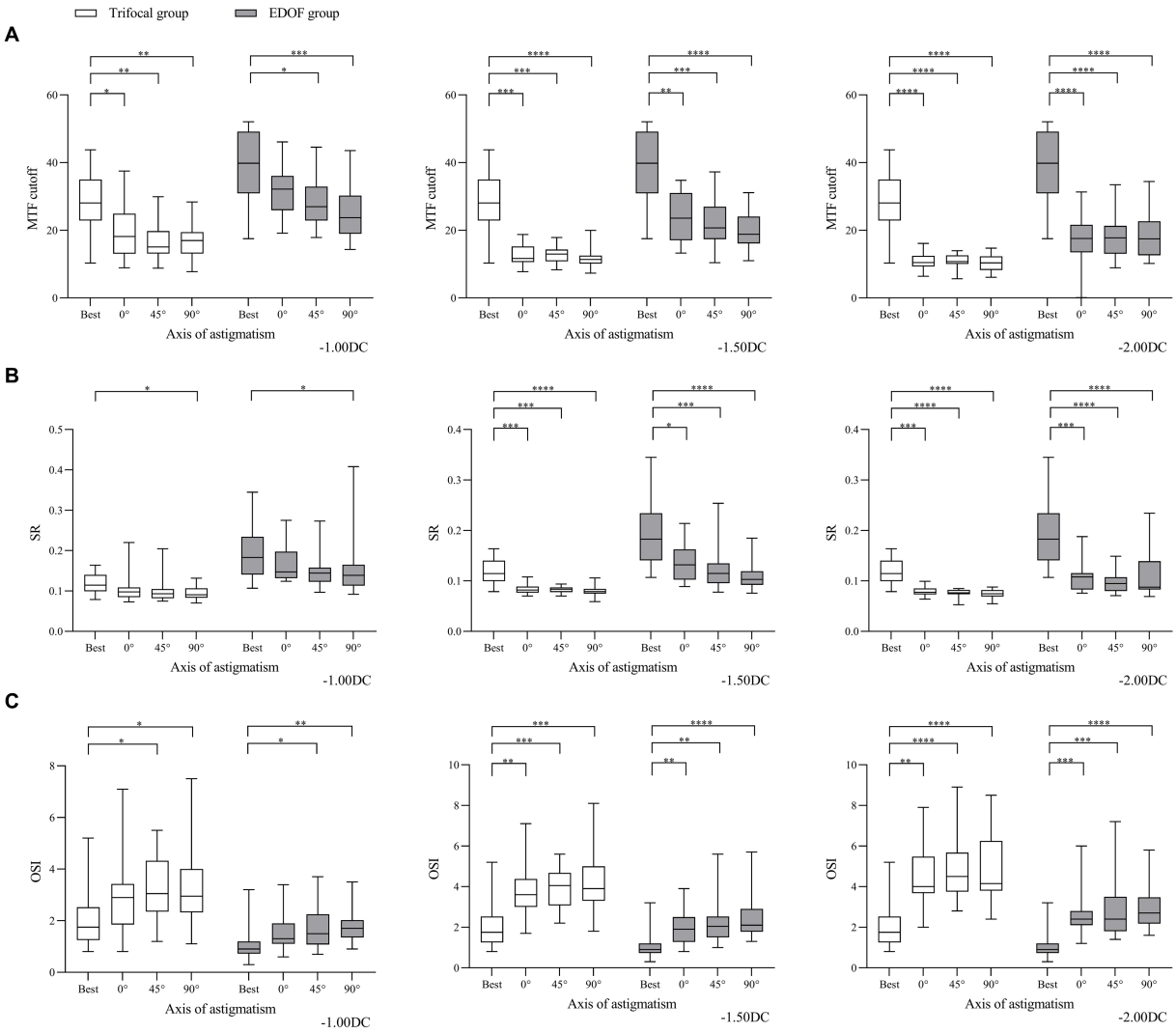

FIGURE 4
Comparison of objective visual quality under the specified magnitudes of induced astigmatism at different axes between individuals who received trifocal or EDOF intraocular lenses in terms of **(A)** MTF cutoff, **(B)** OSI and **(C)** SR. Measurements were made after astigmatism of −1.00, −1.50 or −2.00 DC was induced at the indicated axis values at least 3 months after implantation. EDOF, extended depth of focus; MTF, modulation transfer function; OSI, objective scatter index; SR, Strehl ratio. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$.

lenses for astigmatism. Our analysis suggests that, regardless of the magnitude and direction of residual astigmatism, EDOF lenses are more tolerant to it. Both lens types are more tolerant to astigmatism when it is with or against the rule than when it is oblique. These results may help guide the choice of intraocular lens during cataract surgery.

We found that, depending on whether astigmatism was oblique, with the rule or against the rule, EDOF lenses tolerated astigmatism up to −1.00 DC or even −1.50 DC, whereas trifocal lenses tolerated astigmatism as strong as −1.00 DC only when astigmatism was with the rule. Our results are consistent with previous analyses suggesting that EDOF lenses can tolerate up to −1.50 DC (13), segmented refractive multifocal intraocular lenses, up to −1.00 DC (14); and diffractive multifocal lenses, up to −0.50 DC (9). One study has suggested that astigmatism worse than −1.00 DC should be corrected during implantation of multifocal intraocular lenses (15).

Not only the magnitude but also the direction of induced astigmatism affected visual acuity and quality after lens implantation in our sample, consistent with the vectorial nature of astigmatism (16), which must be considered during cataract surgery and corneal refractive surgery (17, 18). In fact, visual acuity in our subjects decreased with worsening severity of induced astigmatism, regardless of its axis. We also found that when the magnitude of astigmatism was held constant, its impact on visual acuity was smaller when its direction was with the rule than when it was oblique or against the rule, consistent with numerous studies in various countries about the effect of astigmatism on natural eyes (11, 19, 20), eyes that underwent laser refractive surgery (21), and pseudophakic eyes implanted with monofocal intraocular lenses (22, 23).

We found that induced astigmatism of −1.00 DC at an axis of 0° only slightly affected near, intermediate and distant vision, which is consistent with another study reporting that it reduced intermediate and distant vision less than at 90° (24). We did not find that astigmatism of −1.00 DC significantly improve near visual acuity due to the relatively small sample size, in contrast to a previous study (22, 25), although such astigmatism at an axis of 90° showed a tendency to improve near vision in some of our EDOF patients. The impact of astigmatism of −1.00 DC on near vision should be explored in larger

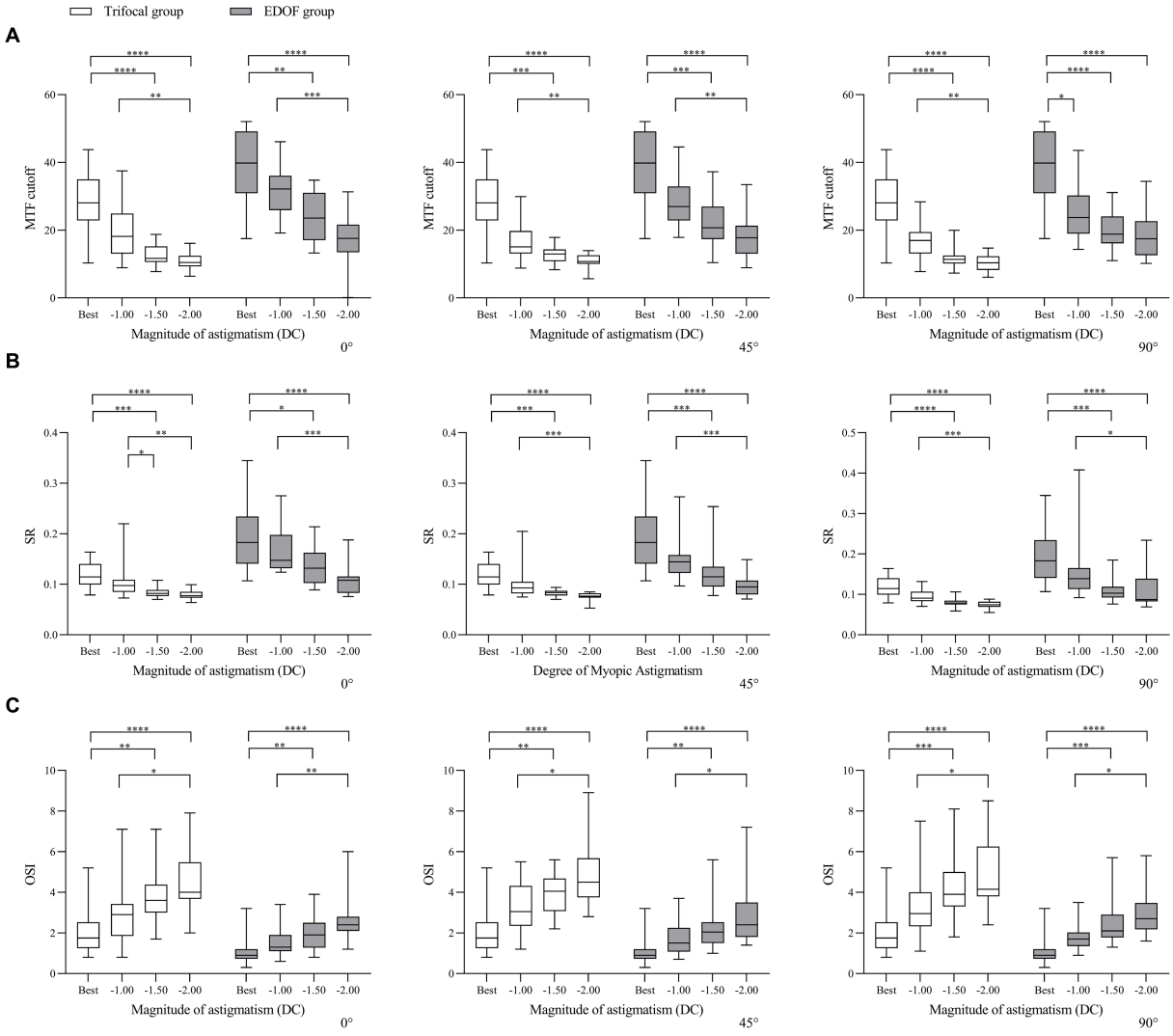

FIGURE 5
Comparison of objective visual quality under induced astigmatism of different magnitudes at the specified axes between individuals who received trifocal or EDOF intraocular lenses in terms of **(A)** MTF cutoff, **(B)** OSI and **(C)** SR. Measurements were made after astigmatism of −1.00, −1.50 or −2.00 DC was induced at the indicated axis values at least 3 months after implantation. EDOF, extended depth of focus; MTF, modulation transfer function; OSI, objective scatter index; SR, Strehl ratio. *$p < 0.05$, **$p < 0.01$, ***$p < 0.001$, ****$p < 0.0001$.

samples. We found that such astigmatism reduced distant visual acuity, consistent with previous work (25).

Before induction of astigmatism, the trifocal group in our study showed abnormal values for all three visual quality parameters, whereas the EDOF group showed normal values. Nevertheless, the two groups did not differ significantly in uncorrected visual acuity or satisfaction with visual function. This may reflect that the diffractive trifocal lens creates a mismatch between objective visual quality outcomes and subjective visual perception. While this should be explored in future work, it may be explained, in part, by a previous finding that diffractive multifocal intraocular lenses display more stray light (26). The trifocal lens may generate more stray light because it has more rings than an EDOF lens, and the edge of each ring can give rise to stray light (27). Greater stray light may also explain why the other two visual quality parameters were worse in our trifocal group.

We found the impact of astigmatism at −1.50 and −2.00 DC to be substantial regardless of axis. We caution against interpreting this to mean that the impact is axis-independent, given the possibility that axial dependence was "drowned out" because of the strong magnitude. Future work should explore how the impact of mild astigmatism on objective visual quality depends on axis.

Our EDOF group reported lower incidence of glare, halos, and other optical phenomena than the trifocal group, which is consistent with previous studies (28, 29). Indeed, our trifocal group reported better near visual perception when performing fine tasks, based on the Visual Function-14 questionnaire. These findings may reflect that trifocal intraocular lenses are designed to provide distinct focal points for near, intermediate and distant vision. EDOF lenses, in contrast, are designed to offer moderate clarity at multiple distances, which may result in less sharp near vision.

Our comparison of the two types of intraocular lenses should be reliable because the two groups did not differ significantly in age, and none of the study participants had other eye comorbidities or history of ocular surgery. We set the artificial pupil diameter to 4 mm during all measurements, and we corrected refractive error before inducing astigmatism. In these ways, our two groups showed negligible differences in factors known to affect visual quality as measured using the Objective Quality Analysis System (30–32).

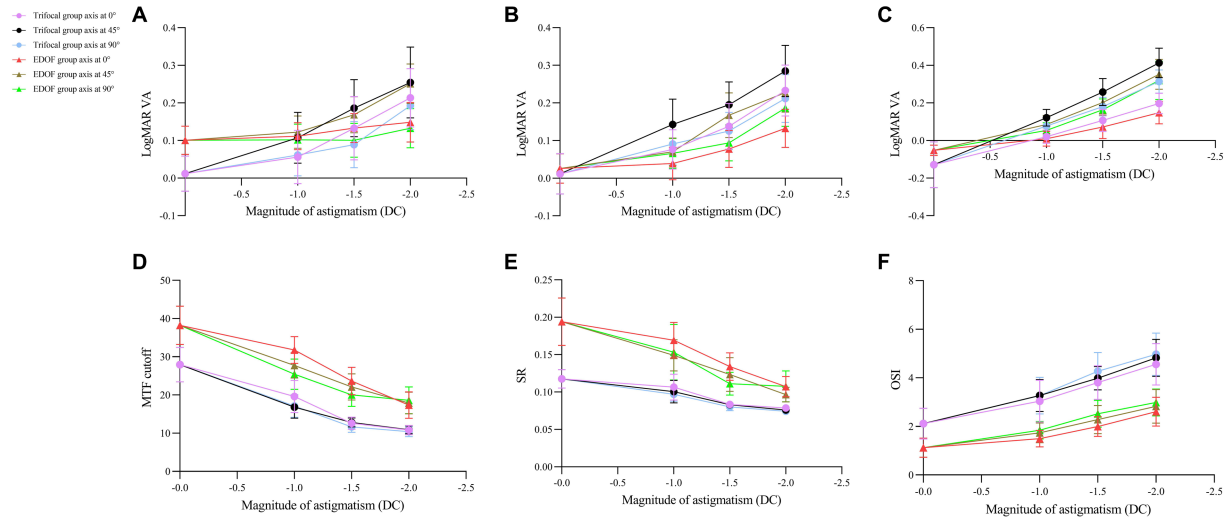

FIGURE 6
Dependence of visual acuity and quality on magnitude of induced astigmatism in individuals who received trifocal or EDOF intraocular lenses. Measurements were made after astigmatism of −1.00, −1.50 or −2.00 DC was induced at axis values of 0, 45, or 90° at least 3 months after implantation. The following parameters were assessed: **(A)** near visual acuity, **(B)** intermediate visual acuity, **(C)** distant visual acuity, **(D)** MTF cutoff, **(E)** SR, and **(F)** OSI. EDOF, extended depth of focus; MTF, modulation transfer function; OSI, objective scatter index; SR, Strehl ratio.

Our findings should be verified and extended in larger studies. Such work should also permit subgroup analysis to clarify, for example, potential relationships between astigmatism and types of adverse visual effects.

Conclusion

Trifocal and EDOF intraocular lenses are less tolerant of oblique astigmatism than astigmatism with or against the rule. Both lens types are more tolerant of astigmatism with the rule than against it. EDOF lenses may provide better objective visual quality than trifocal lenses in the presence of astigmatism, regardless of its magnitude or axis. Although both intraocular lenses can give rise to glare and halos, they are associated with high satisfaction with vision and willingness among patients to recommend the same lens to others.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Ethics Review Board of West China Hospital, Sichuan University (approval 1,312, 2021). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

JM: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Visualization, Writing – original draft. TX: Data curation, Investigation, Writing – review & editing. FX: Data curation, Investigation, Writing – review & editing. WG: Data curation, Investigation, Writing – review & editing. CS: Data curation, Investigation, Writing – review & editing. HC: Data curation, Supervision, Writing – review & editing. WF: Conceptualization, Supervision, Validation, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Observations of the efficacy of the artificial lens cushion plate technique in hard-core cataract surgery

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Objective: To evaluate the efficacy of intraocular lens (IOL) cushion plate technology in reducing corneal endothelial cell loss during hard-core cataract surgery compared with conventional ultrasonic emulsification.

Methods: Seventy-six patients with hard-core cataracts who underwent surgery at our institution from April 2019 to June 2022 were included. The patients were divided into an observation group (IOL cushion plate technology, 38 patients) and a control group (conventional ultrasonic emulsification, 38 patients). Surgical outcomes, including the corneal endothelial cell loss rate, best corrected visual acuity (BCVA), and central corneal thickness (CCTc), were compared between the two groups.

Results: Preoperative patient characteristics were similar between the groups. Postoperatively, both groups demonstrated similar BCVA and CCTc values on days 7 and 30. However, compared with the observation group, the control group presented a significantly greater rate of corneal endothelial cell loss on postoperative days 7 and 30 ($p < 0.05$). Intraoperative complications and postoperative complications were notably greater in the control group ($p < 0.05$). The observation group had reduced ultramilk time and total energy consumption ($p < 0.05$).

Conclusion: IOL cushion plate technology offers advantages in preserving corneal endothelial cells during hard-core cataract surgery, potentially improving surgical safety and efficacy.

KEYWORDS

IOL cushion plate technique, hard-core cataract, complications, corneal endothelial cells, central corneal thickness (CCT)

1 Introduction

Cataracts are a common eye disease that occurs in the elderly population and requires surgical treatment. The surgical treatment of cataracts mainly involves suction removal of cloudy lenses and replacement of transparent an IOL to improve the clinical symptoms of patients and promote the recovery of their visual function. In the process of formulating the surgical plan, the actual situation of the patient needs to be fully considered, and one of the key concerns is the hardness of the cataract crystalline nucleus (1). Cataracts, specifically those classified as

hard-core (grades IV ~ V), are associated with increased surgical complexity and risk. These risks include posterior capsule rupture, vitreous loss, and zonular dehiscence, among others. In the mature or overmature stage of senile cataracts, most hard-core cataract lens nuclei are dark yellow, dark tan or black, and visual dysfunction is severe. In the surgical treatment of hard-core cataract patients, ultrasonic emulsification is generally chosen as the treatment method, which often requires an increase in ultrasound energy during the operation, but there is a risk of intraocular tissue damage (2). To reduce the risk of surgical treatment, strengthening the protection of the cornea and posterior capsule is necessary, and the use of IOL cushion plate technology can reduce the ultrasound energy to a certain extent, prevent damage to the posterior capsule, and reduce corneal irritation, which in turn is conducive to rapid and good postoperative recovery (3). In this study, 76 hard-core cataract patients who underwent surgical treatment at our hospital from April 2019 ~ June 2022 were selected as research subjects to explore the impact of the application of IOL pad technology on surgical efficacy and patients' postoperative recovery.

2 Information and methods

2.1 General information

The study included 76 patients with hard-core cataracts who underwent surgical treatment at our institution between April 2019 and June 2022. Using the random number table method, the participants were divided into an observation group and a control group, with 38 individuals in each group. Table 1 presents the general patient information. Patients with hard-core cataracts, categorized as grade IV ~ V density according to the Emery-Little classification, met the criteria for inclusion in this research.

2.2 Methods

Surgical equipment: An Infiniti ultrasonic emulsifier made by American Alcon Company, German Zeiss OPMI Lumera T microscope was used.

Surgical procedure: Proparinamine hydrochloride eye drops were applied before surgery, ocular surface anesthesia was applied (1 ~ 2 drops/min, 2 ~ 3 times), and main and side incisions were made at 11:00 and 2:00 at the angle of the scleral margin. A viscoelastic agent was injected into the anterior chamber. If necessary, the anterior capsule membrane was stained with Taipan orchid, and continuous circular tearing of the capsule was performed. The capsule was separated from the cortical water, and an ultrasonic emulsification head was placed in the anterior chamber, penetrating the suprapapillary head deep enough toward the center of the nucleus to fix the lens nucleus and perform intercepted cleavage of the nucleus.

2.2.1 Observation group

Before emulsification of the remaining half of the nuclear fragment (Figure 1A), a cohesive viscoelastic material was carefully injected beneath the nuclear fragment (Figure 1B). This action gently nudged the fragment in the direction opposite the corneal incision (Figure 1C). A foldable intraocular lens (IOL) was subsequently inserted into the well-inflated capsular bag, which was positioned posteriorly to the nuclear fragment (Figures 1D,E). Finally, the remaining piece of the nuclear fragment was emulsified and extracted from within the capsular bag (Figures 1F–H).

2.2.2 Control group

The nucleus was initially segmented into four parts via the phaco-chop technique. These nuclear segments were subsequently emulsified one after the other through ultrasonication. In the absence of a cortical shell within the capsular bag, meticulous care was exercised during emulsification of the final nuclear segment, ensuring that it was positioned more anteriorly, between the iris plane and the anterior chamber, to facilitate the procedure. After ultrasonic emulsification of all the nuclei, a viscoelastic agent was injected into the capsular bag, and the IOL was implanted.

Finally, the crystal cortex was aspirated, the viscoelastic agent was removed, the mouth was closed with water, and the eye was wrapped with Dengbisu ophthalmic ointment.

2.3 Observation indices

① Treatment effect: The best corrected visual acuity (BCVA) was detected while a corneal endothelial cytometer (Solvay SW-7000 type) was used, and the corneal endothelial count (ECCr) value was determined. Anterior segment optical correlation tomography (Zeiss Cirrus HD-OCT 4000 type) was applied to measure the central corneal thickness (CCTc), the changes at 7 d and 30 d after surgery were compared, and the surgical efficacy was evaluated. ② Complications: The occurrence of iris injury, corneal edema, uveitis, posterior capsular rupture and other complications was observed during and after surgery.

2.4 Statistical processing

SPSS 21.0 statistical software was used to process and analyze the data, and the measurement data are expressed as the mean ± sd, which

TABLE 1 General information of the two groups of patients.

Group	*n*	Age	Sex (m/f)	Nuclear classification (grade 4/5)	Preoperative visual acuity	
					<0.1	≥0.1
Observation group	38	68.34	13/25	30/8	8	30
Comparison group	38	71.84	15/23	29/9	5	33
χ^2/t		0.385	0.226	0.076	0.835	
P		0.894	0.634	0.783	0.361	

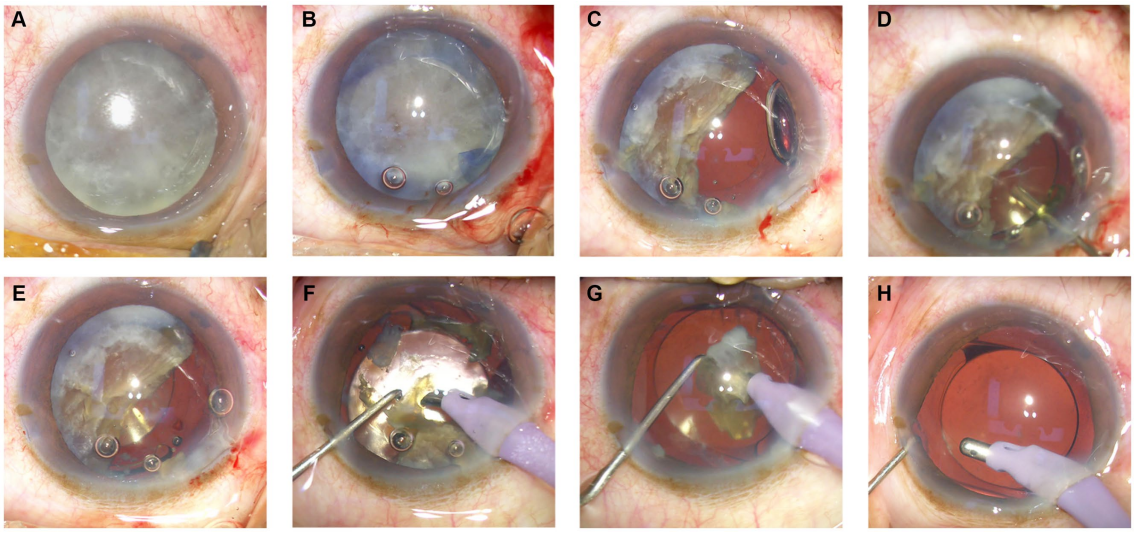

FIGURE 1
Overview of the artificial lens cushion plate technique.

conformed to a normal distribution and was assessed by the t value. The count data are expressed as (%), which was tested by the χ^2 test, and $p < 0.05$ indicated that the difference was statistically significant.

3 Results

3.1 Postoperative recovery of hard-core cataract patients in the two groups

The central corneal thickness (CCTc) and best corrected visual acuity (BCVA) were examined on days 7 and 30 after surgery, and no statistically significant differences in the CCTc and BCVA indices were detected between the two groups (Figures 2A,B). In addition, detection of the corneal endothelial cell loss rate (ECCr) revealed that the ECCr of the control group was significantly greater than that of the observation group on the 7th postoperative day ($p = 0.0045 < 0.005$), and the ECCr of the control group was significantly greater than that of the observation group on the 30th postoperative day ($p = 0.0001 < 0.001$) (Figure 2C).

3.2 Intraoperative and postoperative complications in patients with hard-core cataracts in both groups

During the intraoperative and postoperative periods, we observed complications such as iris injury, corneal edema, uveitis, and posterior capsule rupture. We found that the complication rate in the control group was greater than that in the observation group, and the difference in the complication rate between the two groups during the intraoperative and postoperative periods was statistically significant ($p < 0.05$). For detailed information on both groups, please refer to Table 2.

As shown in Table 2, the complication rates for various issues (iris damage, corneal edema, and rupture of the posterior capsule membrane) in the observation group were lower than those in the control group. The observation group had only 1 case of corneal edema, with an overall complication rate of 2.63%, whereas the control group had 1 case of iris damage, 4 cases of corneal edema, and 1 case of rupture of the posterior capsule membrane, resulting in an overall complication rate of 15.79%. Statistical analysis indicated that the difference in complication rates between the two groups was significant ($\chi^2 = 3.934$, $p < 0.05$).

3.3 Comparison of energy application

The difference in the total amount of balancing fluid between the two groups was not statistically significant ($p > 0.05$) (Figures 3A,B), the intraoperative total amount of ultra milk time in the observation group was less than that in the control group, the total energy consumed by the ultra milk in the observation group was less than that in the control group, and the difference between the two groups was statistically significant ($p < 0.05$), as shown in Figure 3C.

4 Discussion

The success rate of ultrasonic emulsification for hard-core cataracts is limited because of patient characteristics, including large hard lens cores, poor capsule elasticity, fragile suspensory ligaments, and low corneal endothelial cell counts (4). The posterior capsule is thinner than the anterior capsule, making capsular bag collapse likely (5). Intraoperative mechanical trauma and turbulent flow can damage the corneal endothelium and lens posterior capsule, resulting in serious complications, such as posterior capsule rupture, vitreous detachment, and nucleus drop into the vitreous cavity (6). Postoperative complications include corneal edema and compensatory failure, as well as drug-induced side effects such as dry eye syndrome (7). To overcome these problems

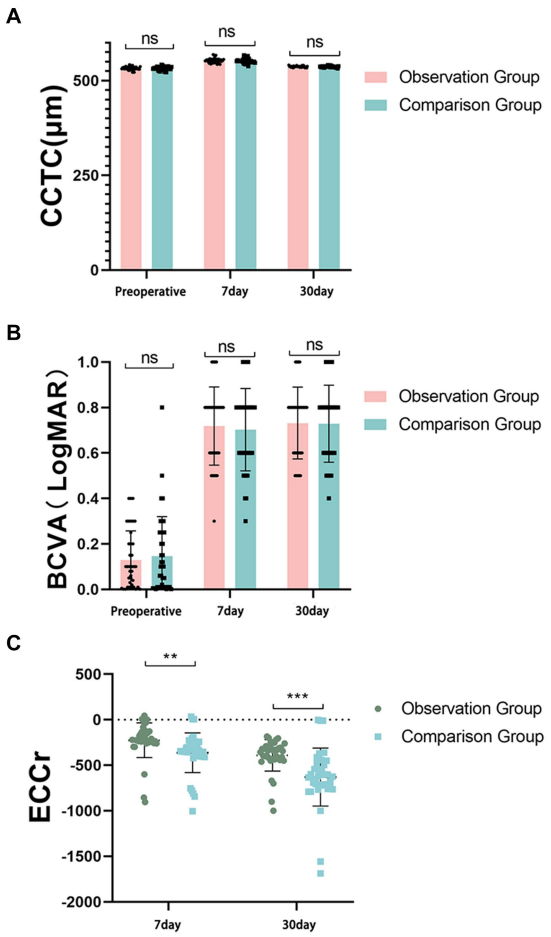

FIGURE 2
Observations of postoperative recovery in two groups of patients with sclerocorneal cataracts. **(A)** The central corneal thickness (CCTc) was not significantly different between the two groups. **(B)** The best corrected visual acuity (BCVA) was not significantly different between the two groups. **(C)** The ECCr in the control group was greater than that in the observation group on postoperative day 7 post-operation, $^{**}p = 0.0045 < 0.005$. The ECCr in the control group was greater than that in the observation group on day 30 post-operation, $^{***}p = 0.0001 < 0.001$.

in hard-core cataract surgery, we modified traditional ultrasonoemulsification by implanting an IOL before complete removal of the lens nucleus instead of stepwise removal of the lens material followed by ultrasonic emulsification until all lens material was removed.

In this study, in the comparison of the BCVA, ECCr and CCTc, the rate of corneal endothelial cell loss in the observation group was lower than that in the control group at 30 d after surgery. Compared with the control group, the observation group had fewer complications, such as iris damage, corneal edema, and uveitis during and after surgery; the total ultrasonic emulsification time of the observation group was less than that of the control group during surgery; and the total energy consumed by ultrasonic emulsification in the observation group was less than that in the control group. It is suggested that the surgical operation be carried out in accordance with the conventional ultrasonic emulsification surgical treatment process, during which the IOL cushion plate technique is applied to lower the position of ultrasonic emulsification and provide protection for the posterior capsule membrane (8). In the process of surgical treatment, ultrasound energy can be reduced to decrease the stimulation of the corneal endothelium and avoid a reduction in corneal endothelial cells. The application of IOL cushion plate technology has a good effect on maintaining corneal atrial water barrier function and preventing corneal edema (9).

IOL cushion plate technology was first used in wrong or unsatisfactory IOL replacement surgery when the IOL is used as a pad but not in the process of nuclear emulsification (10). Luo et al. (1), Parkash et al. (8), and Hua et al. (11) applied this technique to nuclear phacoemulsification in hard nucleus cataracts and confirmed that this technique can effectively protect the posterior capsule of the lens, which is consistent with our conclusion. In a randomized study by Luo et al. (1), 80 dense cataract cases were split into two interventions. In Group I, the IOL was placed after complete nucleus removal, whereas in Group II, it was inserted prior to removing the last nuclear quarter. No significant disparity in corneal thickness between groups was observed at any measurement. Notably, Group II demonstrated less corneal endothelial cell depletion on days 7 and 30 post-surgery. Specifically, on day 7, cell loss averaged 10.29% in Group II versus 14.37% in Group I ($p < 0.05$). By day 30, these values were 16.88 and 23.32%, respectively ($p < 0.05$). Furthermore, the initial day's mean CCT was markedly lower in Group II than in Group I (13.50% vs. 19.42%, $p < 0.05$) (1). Parkash et al. (8) discussed how the intraocular lens (IOL) acts as a scaffold, offering the benefit of a stable barrier or support over the undamaged posterior capsule. When there is stable support over the relaxed posterior capsule, the use of an IOL scaffold in a Morgagnian cataracts can prevent posterior capsule rupture and prevent the complications associated with it. This method also stabilizes the capsular bag by allowing it to expand during surgery (8). In the study by Hua et al. (11), 12 patients with Morgagnian cataracts underwent modified IOL implantation in the capsular bag post-capsulorhexis. In three hypermature cases with small, rigid nuclei, the IOL was inserted directly after complete capsulorhexis, shielding the posterior capsule during phacoemulsification. In the remaining nine cases, which had larger, softer nuclei, the IOL was placed after partial nuclear emulsification. All procedures were successful, with no complications to the posterior capsule or vitreous loss, indicating effectiveness in protecting the posterior capsule during phacoemulsification (11).

Phacoemulsification surgery in cases of hard cataracts can lead to endothelial damage through several mechanisms: extended phacoemulsification time and increased ultrasound energy use, air bubbles and localized temperature elevations, mechanical trauma from instrument insertion, and collisions with lenticular debris, particularly swirling debris (12–16). Additionally, biochemical stressors such as oxidative damage from free radicals produced during ultrasonic energy application have been identified (17). Consequently, we speculate that the IOL cushion plate technology may protect the corneal endothelium by gently pressing the nucleus down with the posterior capsule shielded by the artificial lens cushion plate during surgery, increasing the depth of the anterior chamber to facilitate remaining phacoemulsification within the capsular bag. The specific mechanism might involve the deepened anterior chamber, which not only distances the phaco tip from the corneal endothelium, thereby reducing direct or indirect damage from energy and temperature, but also decreases the likelihood of swirling lenticular debris coming into

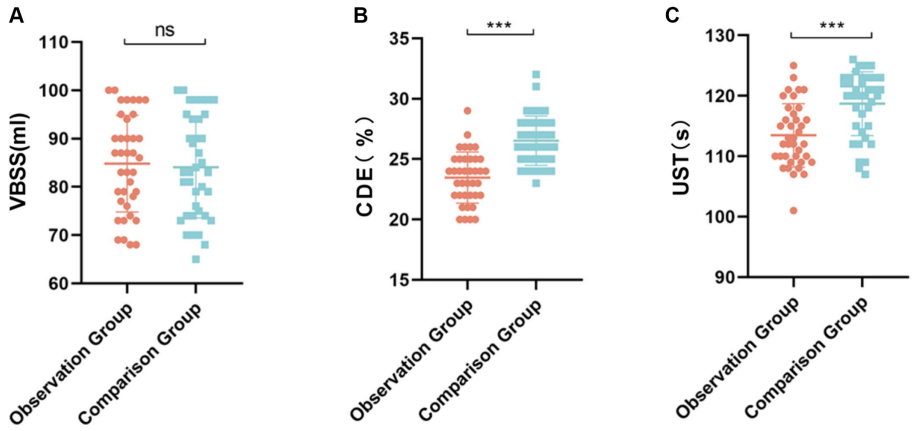

FIGURE 3
Intraoperative energy application in the two groups of patients. **(A)** The total volume of balanced salt solution used was not significantly different between the two groups, ns $p > 0.05$. **(B)** The phacoemulsification energy consumption of the observation group was significantly lower than that of the control group, ***$p < 0.001$. **(C)** The observation group had a significantly shorter phaco time than did the control group, ***$p < 0.001$.

TABLE 2 Intraoperative and postoperative complications in two groups of patients with sclerotic cataracts [*n* (%)].

Group	Iris damage	Corneal edema	Rupture of the posterior capsule membrane	Complications
Observation group ($n = 38$)	0 (0)	1 (2.63)	0 (0)	1 (2.63)
Comparison group ($n = 38$)	1 (2.63)	4 (10.52)	1 (2.63)	6 (15.79)
χ^2				3.934
p value				<0.05

contact with the corneal endothelium. In our study, the application of IOL cushion plate technology resulted in a significant reduction in corneal endothelial cell loss rate on the 7th and 30th postoperative days within the observation group compared to the control group.

Regarding the shorter phacoemulsification time and lower energy consumption observed in the observation group, these differences could be attributed to the modified surgical technique that, which allows for a more efficient emulsification process. The cushioning effect of the IOL may facilitate nucleus fragmentation, thereby reducing the need for prolonged ultrasonic energy application. This improved efficiency may not only increase the safety of the procedure by reducing thermal and mechanical stress on intraocular tissues but also may minimize the risk of potential complications such as corneal burn or capsular rupture.

The complication rate in our study did not significantly differ between the observation and control groups. However, the types of complications, their clinical management, and the implications for patient recovery are critical aspects to consider. For example, while the rate of posterior capsular rupture is low, it remains a severe complication that can lead to further surgical challenges and affect visual outcomes. Future studies should aim to provide a more comprehensive analysis of complication profiles and their management to better understand the clinical implications of IOL cushion plate technology.

The surgical effects were evaluated via BCVA and CCTc measurements. The BCVA serves as a direct indicator of a patient's visual function post-surgery, whereas the CCTc provides information on corneal integrity and potential edema, which can indirectly impact visual acuity. The findings of our study suggest that both the BCVA and CCTc are valuable metrics for assessing surgical success and patient recovery, reinforcing the importance of multifaceted outcome evaluations in cataract surgery research.

In our study, the use of IOL cushion plate technology resulted in a lower corneal endothelial cell loss rate on the 7th and 30th postoperative days in the observation group than in the control group. This reduction in endothelial cell loss is likely attributable to the protective barrier provided by the IOL cushion, which minimizes direct contact and mechanical stress on the corneal endothelium during phacoemulsification. The reduced ultrasonic energy and time required for nucleus emulsification with the IOL cushion plate technology also contributed to this protective effect. By preserving the integrity of the corneal endothelium, this technique may enhance long-term corneal health and visual acuity, underscoring the importance of endothelial cell preservation in cataract surgery outcomes. In our clinical work, we found that IOL cushion plate technology is not limited to the treatment of hard-core cataracts but can be used to create padding before removing the lumpy and flocculent cortex that is tightly adherent to the posterior capsule during routine cataract echo capillarization, which reduces the probability of aspiration of the anterior posterior capsule during the process of removal and prevents rupture of the posterior capsule membrane. In addition, in some special cases, such as high intraocular pressure leading to significant corneal edema, insufficient corneal endothelium, and poor corneal endothelial cell function, to avoid

further damage to the corneal endothelium during surgery, IOL cushion plate technology can be applied, which would require a large amount of data to be confirmed in the clinic.

We acknowledge the limitations of our study, including the small sample size, its retrospective design, and the lack of long-term follow-up data. These factors may limit the generalizability and completeness of our findings. In this study, the maximum observation time was only 1 month, and we were unable to compare the occurrence of postoperative cataracts between the two groups. The implantation of the IOL first hinders the complete removal of the cortex to a certain extent, and the step of "posterior capsular polishing" cannot be implemented, so whether there is any effect needs to be further explored. To address these limitations, future prospective studies with larger cohorts and extended follow-up periods are necessary to validate the benefits of IOL cushion plate technology and assess its long-term impact on patient outcomes, including the development of PCO and other late-onset complications. Additionally, further research should explore the nuances of individual patient differences and device efficiency to refine surgical techniques and optimize patient care.

In summary, the application of IOL pad technology during ultrasonic emulsification has obvious advantages for the treatment of patients with hard-core cataracts. The intraoperative surgical operation is simple and can reduce the amount of ultrasound energy and time used during ultrasonic emulsification. In addition, the application of IOL pad technology can increase the depth of the anterior chamber for intracapsular ultrasonic emulsification, which can be far from the cornea and greatly reduces the chances of damaging the corneal endothelium. Moreover, the implantation of the IOL first protects the posterior capsule more reliably. The posterior capsule is more reliably protected after IOL implantation, which creates favorable conditions for the successful completion of cataract surgery.

Data availability statement

The original contributions presented in the study are included in the article/Supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by Ethics Committee of Putian First Hospital. The studies were conducted in accordance with the local legislation and institutional requirements. Written informed consent for participation was not required from the participants or the participants' legal guardians/next of kin in accordance with the national legislation and institutional requirements. The manuscript presents research on animals that do not require ethical approval for their study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

ZH: Writing – original draft, Writing – review & editing. MZ: Methodology, Investigation, Writing – original draft. MX: Investigation, Writing – original draft. LC: Investigation, Software, Writing – original draft. XS: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Writing – original draft, Writing – review & editing.

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Conflict of interest

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Supplementary material

The Supplementary material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2024.1406578/full#supplementary-material

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Accuracy of intraoperative aberrometry versus preoperative biometry for intraocular lens power selection in short and long eyes

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Background: To compare the accuracy of intraoperative wavefront aberrometry using the ORA VLynk system with different biometry-based formulas in short and long eyes after cataract surgery.

Methods: This prospective study considered 48 eyes with axial lengths of <22.1 mm and 48 eyes with axial lengths of >25.0 mm. All eyes were implanted with the monofocal AcrySof IQ IOL, the power being determined using the ORA VLynk. The postoperative spherical equivalent (SE) at 3 months was compared to that predicted preoperatively using the SRK/T, Hoffer Q, Haigis, Holladay 2, Barrett Universal II, and Barrett True K formulas and intraoperatively using the ORA VLynk. Mean numerical and absolute errors and the percentage of eyes within ±0.50 D/1.00 D of their target were obtained.

Results: For long eyes, the mean absolute error values were 0.35, 0.52, 0.34, 0.30, 0.29, 0.27, and 0.24D for SRK/T, Hoffer Q, Haigis, Holladay 2, Barrett Universal II, Barrett True K, and ORA VLynk, respectively ($p < 0.001$). These values were 0.55, 0.45, 0.49, 0.40, 0.44, 0.44 and 0.50 D for short eyes, respectively ($p < 0.001$). The proportions of long eyes within ±0.50 D of the target were 77.08, 50, 75, 85.42, 83.33, 79.17, and 87.50%, respectively; and 50, 66.67, 60.42, 66.67, 60.42, 60.42, and 58.33%, respectively, for short eyes.

Conclusion: The ORA VLynk performs better than all biometry-based formulas in long eyes and, in short eyes, it is as effective as SRK/T, Haigis, Barrett Universal II, and Barrett true K, with the Hoffer Q and Holladay 2 being the most accurate; however, the differences between the calculation methods were small.

Clinical trial registration: Identifier DRKS000028106.

KEYWORDS

intraoperative aberrometry, short, long, intraocular lens, phacoemulsification, cataract

1 Introduction

Cataract surgeons frequently see patients who have been submitted to previous corneal refractive surgeries such as radial keratotomy, photorefractive keratectomy (PRK) or laser *in situ* keratomileusis (LASIK). In this type of patient, the intraocular lens (IOL) power calculation is more challenging despite the use of next generation formulas and/or available calculators. The use of intraoperative wavefront aberrometry, utilised by many surgeons, may help to provide patients with the best possible refractive and visual outcomes. This has proved useful in post-PRK/LASIK and eyes with radial keratotomy (1–8). This technology has also been shown to be beneficial in non-post-refractive surgery eyes (9) and eyes with low (10) or high (11) amounts of corneal astigmatism.

The Optiwave Refractive Analysis System (ORA, Alcon Laboratories, Inc.; Fort Worth, TX, United States) is an intraoperative wavefront aberrometry system that measures the whole refractive system (anterior and posterior cornea) allowing surgeons to determine the IOL power required for the eye. In addition, ORA may be useful in other situations in which IOL power calculations are difficult, for example eyes with high axial myopia or hyperopia. Several clinical studies have published refractive outcomes using the ORA system versus preoperative biometry to select IOL power for short and long eyes (12–16). These studies compare the accuracy of the ORA system with conventional biometry-based formulas in eyes implanted with different types of IOLs: monofocal, toric, and multifocal. To our knowledge, no prospective studies have assessed the accuracy of the ORA VLynk and preoperative biometry formulas in short and long eyes when the same IOL was implanted.

The main purpose of this study was, therefore, to compare the accuracy of intraoperative aberrometry using the ORA VLynk system with different conventional biometry-based formulas in short and long eyes implanted with the same monofocal IOL after cataract surgery. The postoperative refraction was compared with the preoperative and intraoperative predictions in order to evaluate the accuracy of each method.

2 Materials and methods

This prospective comparative clinical study was approved by the Ethics Committee at Investigación con Medicamentos de Cádiz (Cádiz, Spain) and the Valencia regional committee on postmarketing studies, CAEPRO (Valencia, Spain). All the procedures adhered to the tenets of the Declaration of Helsinki, patients recruited to the study provided written informed consent before they were enrolled, and the study was registered in the German Clinical Trials Register (DRKS000028106). The inclusion criteria were patients over 40 years of age who were willing and able to attend the study visits, who presented cataract or refractive lens exchange with an axial length of either <22.1 mm or > 25.0 mm and valid ORA VLynk measurements taken during the surgery.

The exclusion criteria were corneal opacity, previous radial keratotomy or other corneal surgery, previous anterior or posterior chamber surgery, vitrectomy, laser iridotomy, diabetic retinopathy, history of retinal detachment, patients with acute or chronic disease, keratoconus, amblyopia and/or strabismus, and pregnancy. All patients included in the study underwent a complete ophthalmological examination with routine cataract evaluation measurements measuring Snellen decimal monocular best-corrected distance visual acuity (CDVA), manifest refraction, and optical biometry performed with the IOLMaster 700 swept source optical coherence tomographer (Carl Zeiss Meditec AG, Jena, Germany). The IOL power calculation was based on this measurement considering the SRK/T, Hoffer Q, Haigis, Holladay 2, Barrett Universal II, and Barret True K formulas for all eyes. The predicted postoperative spherical equivalent (SE) was calculated for each condition. In addition, all patients underwent ORA VLynk analysis, which also generated a predicted postoperative SE that was used for comparison. The power of the implanted IOL was determined using the ORA VLynk. The targeted refraction in all cases was emmetropia.

Phacoemulsification was performed using the Centurion Vision System (Alcon Laboratories, Inc.; Fort Worth, TX, United States) through a 2.2-mm temporally located clear corneal incision considering a historical level of surgically induced astigmatism by an incision of <0.25 D. A 5 mm diameter circular anterior capsulotomy centred on the capsular bag was performed and, after cataract removal and posterior capsule polishing, the capsular bag was filled with 1.0% sodium hyaluronate (Provisc, Alcon Laboratories, Inc.; Fort Worth, TX, United States). The AcrySof IQ monofocal IOL (Alcon Laboratories, Inc.; Fort Worth, TX, USA) was implanted in all the eyes. The postoperative examination at 3 months post-surgery included CDVA and manifest refraction measurements.

The primary outcome measurements included the difference between the predicted target and the actual postoperative SE for each method. This difference is referred to as the mean arithmetic error. The mean absolute error (absolute value of the arithmetic error) and median absolute error were also calculated. The secondary endpoint included the proportion of eyes within ±0.25 D, ±0.50 D, ±0.75 D and ± 1.00 D of the SE target refraction for each method.

2.1 Statistical analysis and sample size

The statistical analysis was carried out using SPSS software (22.0 version, IBM Corp., Armonk, New York, United States). All the measurements are shown as the mean ± standard deviation (SD). The normality of the distribution was checked using the Shapiro–Wilk test. Statistically significant differences between the different calculation methods were assessed using Friedman repeated measures analysis of variance. The Tukey test was used for post-hoc analysis to compare the data between methods whenever the Friedman test revealed significant differences between the values obtained. This test gave us the significance level for paired differences between the individual conditions of comparison between methods. The statistical significance limit was set to a p value of <0.05 in all cases. Data from a similar study (14) was used to compute the required sample size for an analysis of variance model with 1 group, 5 repetitions, a statistical power of 0.9, a significance of 0.05 and an estimated correlation among repeated observations of 0.8. Given these conditions, the minimum required sample size was 23 independent observations for each group; for this reason, a target cohort of 25 subjects per group was considered large enough to account for potential dropouts.

3 Results

In this study all eyes ($n = 96$) were implanted with the same IOL, the AcrySof IQ IOL. Table 1 shows the main characteristics

TABLE 1 Demographic characteristics and preoperative measurements of participants shown as means, standard deviations (SD) and ranges.

	Long eyes	Short eyes
Eyes (*n*)	48	48
Sphere (D)	−5.81 ± 4.59 (−16.50 to 0.50)	2.28 ± 2.61 (−3.00 to 8.00)
Refractive Cylinder (D)	−1.32 ± 0.80 (0 to −3.00)	−0.84 ± 0.74 (0 to −2.75)
Spherical Equivalent (D)	−6.47 ± 4.57 (−16.50 to 0.25)	1.86 ± 2.47 (−3.00 to 7.13)
CDVA (decimal)	0.62 ± 0.26 (0.10 to 1.00)	0.59 ± 0.25 (0.05 to 1.00)
IOP (mmHg)	13.19 ± 3.58 (6.00 to 17.50)	17.61 ± 4.70 (11.00 to 32.00)
K1 (D)	43.16 ± 1.14 (40.67 to 45.67)	44.74 ± 1.73 (40.58 to 48.92)
K2 (D)	44.17 ± 1.17 (41.62 to 46.88)	45.73 ± 1.63 (42.76 to 49.54)
Axial length (mm)	26.23 ± 1.18 (25.01 to 29.24)	21.65 ± 0.45 (20.03 to 22.05)
ACD (mm)	3.55 ± 0.48 (2.35 to 5.55)	2.69 ± 0.35 (2.01 to 3.23)
LT (mm)	4.53 ± 0.39 (3.87 to 5.61)	4.81 ± 0.46 (2.74 to 5.33)
WTW (mm)	12.11 ± 0.36 (11.40 to 12.90)	11.59 ± 0.33 (10.90 to 12.20)
IOL power (D)	13.19 ± 3.58 (6.00 to 17.50)	26.18 ± 1.94 (22.00 to 30.00)

CDVA: corrected distance visual acuity; IOP: intraocular pressure; K: keratometry; ACD: anterior chamber depth; LT: lens thickness; WTW: white-to-white; IOL: intraocular lens power.

TABLE 2 Outcomes (mean ± standard deviation and range) reported using the different calculation method for long and short eyes.

Method	Mean error	Mean absolute error	Median absolute error
Long eyes			
SRK/T	0.29 ± 0.30 (−0.35 to 1.06)	0.35 ± 0.24 (0.02 to 1.06)	0.31
Hoffer Q	0.51 ± 0.36 (−0.25 to 1.62)	0.52 ± 0.33 (0.02 to 0.86)	0.50
Haigis	0.31 ± 0.28 (−0.15 to 1.04)	0.34 ± 0.25 (0.01 to 1.04)	0.30
Holladay 2	0.21 ± 0.31 (−0.47 to 0.86)	0.30 ± 0.22 (0.02 to 0.86)	0.28
Barrett Universal II	0.26 ± 0.26 (−0.24 to 0.90)	0.29 ± 0.23 (0.02 to 0.90)	0.24
Barrett true K	0.21 ± 0.28 (−0.49 to 0.90)	0.27 ± 0.22 (0.01 to 0.90)	0.22
ORA VLynk	0.16 ± 0.27 (−0.27 to 0.83)	0.24 ± 0.20 (0.01 to 0.83)	0.18
P value	<0.001	<0.001	
Short eyes			
SRK/T	0.29 ± 0.60 (−1.17 to 1.53)	0.55 ± 0.37 (0.01 to 1.53)	0.52
Hoffer Q	−0.01 ± 0.54 (−1.53 to 1.05)	0.45 ± 0.30 (0.01 to 1.52)	0.40
Haigis	0.29 ± 0.54 (−1.29 to 1.47)	0.49 ± 0.37 (0.01 to 1.47)	0.45
Holladay 2	−0.03 ± 0.52 (−1.59 to 1.03)	0.40 ± 0.33 (0.00 to 1.59)	0.28
Barrett Universal II	0.21 ± 0.51 (−1.20 to 1.08)	0.44 ± 0.33 (0.01 to 1.20)	0.44
Barrett true K	0.25 ± 0.50 (−0.90 to 1.35)	0.44 ± 0.33 (0.00 to 1.35)	0.36
ORA VLynk	0.24 ± 0.54 (−1.04 to 1.25)	0.50 ± 0.31 (0.00 to 1.25)	0.46
P value	<0.001	<0.001	

of the study population. 53 patients (34 females) with a mean age of 71.94 ± 8.18 years were included in the study. There were no complications in any of the cases during surgery and follow-up.

The mean residual SE was −0.05 ± 0.31 D for long eyes and 0.10 ± 0.53 D for short eyes. The preoperative and postoperative CDVAs for long eyes were 0.62 ± 0.26 and 0.96 ± 0.12, respectively, and 0.59 ± 0.26 and 0.94 ± 0.16, for short eyes. There was statistically significant postoperative improvement in CDVA ($p < 0.001$). Table 2 was created to compare the accuracy between the ORA VLynk and the IOL calculation formulas. This table shows the outcomes reported for the different methods using the mean error, mean absolute error and median absolute error. Figure 1 shows the proportion of eyes within ±0.25 D, ±0.50 D, ±0.750 D and ± 1.00 D of the target SE refraction and Figure 2 the interquartile range. It indicates that for long eyes the ORA VLynk performs better than all the other IOL calculation formulas with the minimum value for the mean absolute error (0.24 D) and median absolute error (0.18 D,) and the highest percentages of eyes within ±0.50 D (87.50%) and ± 1.00 D (100%). For short eyes, the Holladay 2 IOL formula performed best, with a mean absolute error of 0.40 D, a median absolute error 0.28D, and 66.67 and 95.83% of eyes for ±0.50 D and ± 1.00 D, respectively.

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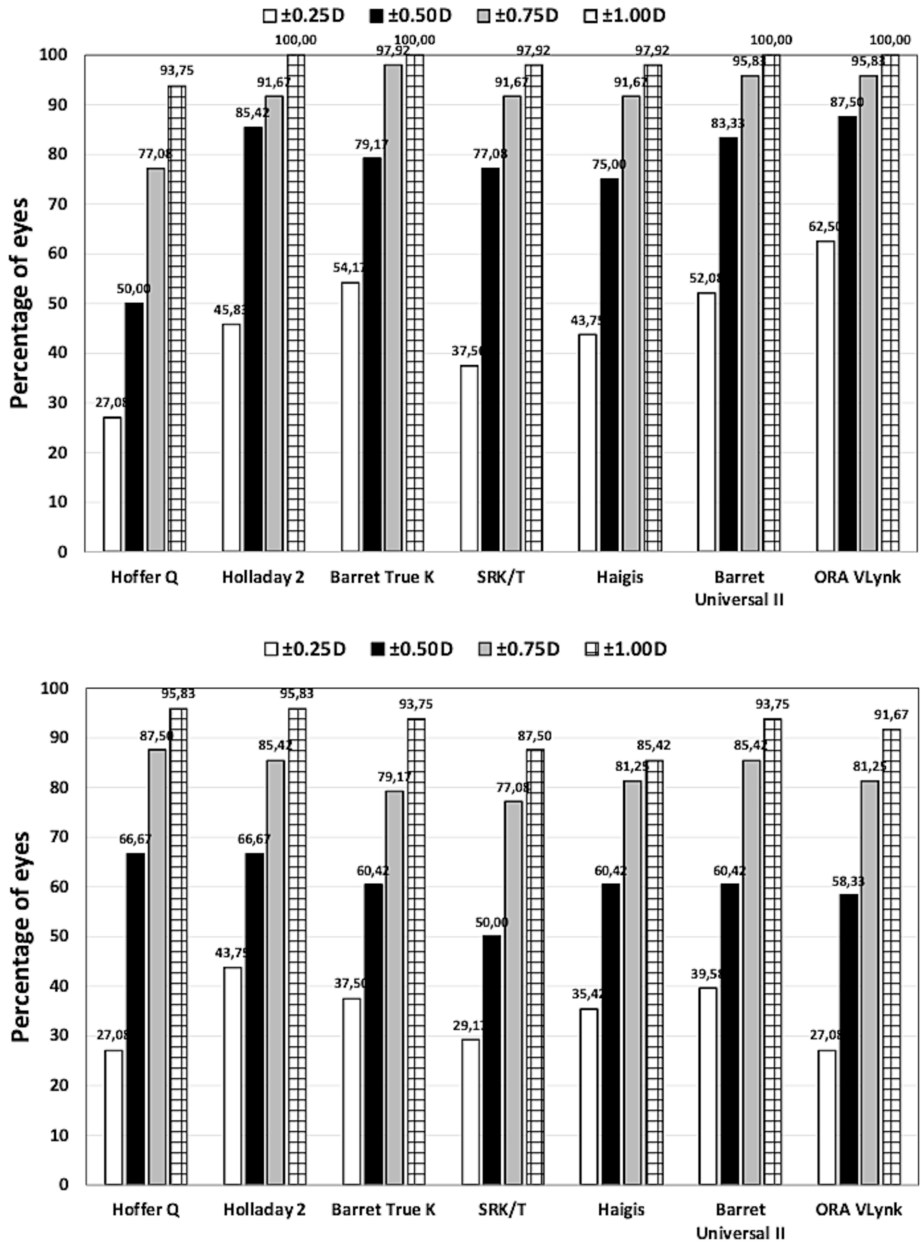

FIGURE 1
Proportion of eyes within ±0.25 D, ±0.50 D, ±0.750 D and ± 1.00 D of the target spherical equivalent refraction for long (top) and short (bottom) eyes using different calculation methods.

Since we found a statistically significant difference between the different mean errors, a Tukey test for pairwise analysis was run on this parameter to discover the differences between the calculation methods. The outcomes obtained for long and short eyes are shown in Table 3. For long eyes, the ORA VLynk had the lowest mean numerical error and the difference was statistically significant when compared to the biometry-based formulas, except for Holladay 2 ($p = 0.272$). Hoffer Q performed statistically worse than the other biometry-based formulas and ORA VLynk ($p \leq 0.007$). For short eyes, the Hoffer Q and Holladay 2 formulas had the lowest mean numerical error and were not significantly different from one another ($p = 0.932$). Specifically, the outcomes of the ORA VLynk were comparable with those of SRK/T, Haigis, Barrett Universal II, and Barrett true K ($p > 0.9$).

4 Discussion

Previously published clinical studies have pointed out the benefit of using intraoperative wavefront aberrometry in long and short eyes. Table 4 shows the main characteristics of studies that used the ORA system, indicating the axial length considered, the number of eyes included, the formulas used, the type of IOLs implanted, and postoperative follow-up. All of these, except for Bansal et al. (16) and our study, were retrospective.

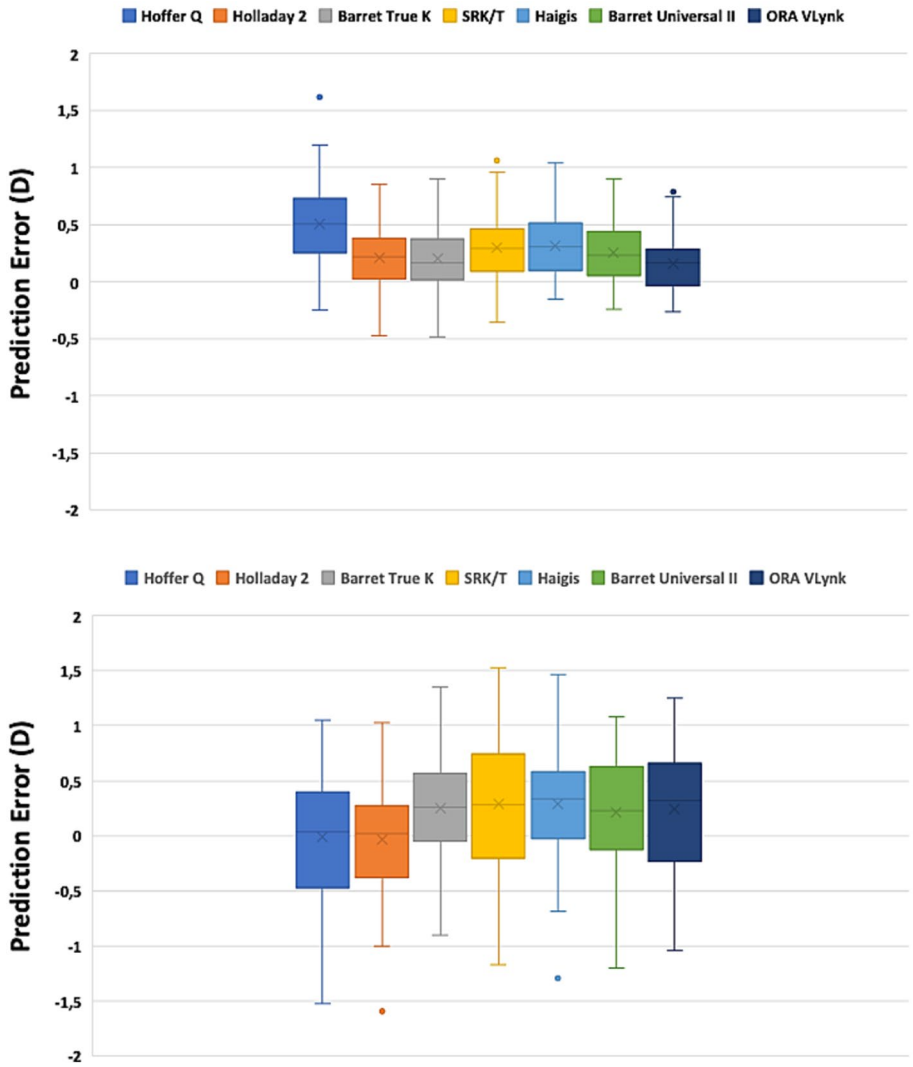

FIGURE 2
Box plot graph for the long (top) and short (bottom) eyes using different calculation methods.

In our work, the improved performance shown by the ORA Vlynk for long eyes compared to the biometry-based formulas was expected and is consistent with the findings reported by other studies. Three studies have been carried out on long eyes (see Table 3 for details). In the first, Hill et al. (12) used 51 eyes with an axial length of >25.0 mm to retrospectively compare the accuracy of ORA with several formulas. They concluded that ORA was better than all formulas based on preoperative biometry and as effective as the AL-optimised Holladay 1 formula in predicting residual refractive error and reducing hyperopic outcomes. Specifically, they also indicated that the performance of Hill-RBF was similar to that of the fourth-generation formulas. It should be noted that they analysed the mean numerical error and not the mean absolute error when comparing accuracy. When compared to our study, only mean numerical error, the outcomes were found to be quite similar (within about a quarter of a diopter, see Table 5). We fully agree with this study since our outcomes revealed that the ORA VLynk had the lowest mean numerical error and the difference from the biometry-based formulas was statistically significant, except for Holladay 2 ($p = 0.272$). In the second study, Sakai et al. (15) also retrospectively compared this technique with IOL calculation formulas in eyes with axial lengths of ≥25 mm with emmetropic (0 to −0.50D, $n = 39$) and myopic (−2.00 to −5.00D, $n = 22$) targets. ORA was revealed to be the most accurate method for predicting postoperative refraction in eyes with an emmetropic target, whereas the Barrett Universal II formula was found to be the most accurate for eyes with a myopic target. These authors also indicated that a myopic shift in the refractive outcome should be considered when ORA is used to target myopia. Soifer et al. (14) analysed 121 highly myopic eyes to assess whether ORA improves the accuracy compared to the Barrett Universal II formula. They concluded that ORA demonstrated similar refractive results to the Barrett Universal II formula, and may provide an additional benefit for eyes with an axial length of ≥27 mm. Our results, comparing the mean absolute error, were better than those found by these authors (see Table 5), with the ORA VLynk being significantly more accurate than the Barrett Universal formula II (see Table 3; $p = 0.002$). In eyes with a long axial length, hyperopic surprise has often been reported. Yokoi et al. (17) evaluated the refractive error after cataract surgery in 568 highly myopic eyes (≥26.50 mm) selecting the

10.3389/fmed.2024.1466885

TABLE 3 Post hoc analysis using the different calculation method for long and short eyes.

	P value						
Method	SRK/T	Hoffer Q	Haigis	Holladay 2	Barrett Universal II	Barrett True K	ORA VLynk
Long eyes							
SRK/T	—	—	—	—	—	—	—
Hoffer Q	<0.001*	—	—	—	—	—	—
Haigis	0.961	0.007*	—	—	—	—	—
Holladay 2	0.260	<0.001*	0.021*	—	—	—	—
Barret Universal II	0.996	<0.001*	0.694	0.647	—	—	—
Barrett true K	0.939	<0.001*	0.395	0.893	0.999	—	—
ORA VLynk	<0.001*	<0.001*	<0.001*	0.272	0.002*	0.010*	—
Short eyes							
SRKT/	—	—	—	—	—	—	—
Hoffer Q	<0.001*	—	—	—	—	—	—
Haigis	1.000	<0.001*	—	—	—	—	—
Holladay 2	<0.001*	0.932	<0.001*	—	—	—	—
Barrett Universal II	0.973	<0.001*	0.961	<0.001*	—	—	—
Barrett true K	1.000	<0.001*	1.000	<0.001*	0.995	—	—
ORA VLynk	0.999	<0.001*	0.998	<0.001*	1.000	1.000	—

*Statistically significant.

IOL power with the SRK/T formula and reported a mean refractive error of +0.45 ± 0.79 D and a mean absolute refractive error of +0.72 ± 0.47 D, with 70% of the refractive errors being within ±1.00 D of the targeted refraction. Their findings showed that the postoperative refractive error was significantly greater in eyes whose axial length was ≥31.0 mm than in eyes with shorter axial lengths. The outcomes of our study show small postoperative mean errors.

Table 6 shows the proportion of eyes within ±0.50 D and ± 1.00 D of the target spherical equivalent refraction reported in different clinical studies using several calculation methods. For long eyes, our results showed slightly higher percentages compared to those found by Hill et al. (12), Soifer et al. (14), and Sakai et al. (15). We found the best outcomes for the ORA Vlynk, in agreement with the findings of Soifer et al. (14). Hill et al. (12) found best percentage outcomes for the A-optimised Holladay 1 formula (82.4 and 100% for ±0.50 D and ± 1.00 D, respectively).

Additionally, three studies on short eyes have been published (see Table 3). Specifically, Sudhakar et al. (13) retrospectively compared the accuracy of ORA with several formulas in 51 eyes with an axial length of <22.1 mm and concluded that for short eyes it did not differ significantly from the best preoperative biometry-based methods. Our results revealed better outcomes using the Hoffer Q and Holladay 2 formulas, with ORA VLynk being comparable to the SRK/T, Haigis, Barrett Universal II, and Barrett true K formulas (Table 3, $p > 0.9$). Sudhakar et al. (13) also compared the outcomes of the different methods after optimisation in eyes that received a monofocal IOL. They found that although optimisation did change the performance of many of the formulas with regard to the proportion of eyes within ±0.50/1.00 D of the target SE, the differences reported were small and not significant. They indicated that ORA remained one of the best-performing methods but it was not statistically significant to the others. They also discussed the possible factors relating to the poor performance of biometry-based methods for calculating IOL power in short eyes, suggesting that this was related to effective lens position determination, the high powered IOL implanted, and/or manufacturing processes. Soifer et al. (14) also retrospectively analysed 23 highly hyperopic eyes, and Bansal et al. (16) in their prospective study to compare ORA with different IOL power calculation formulas in 65 short eyes (<22 mm) concluded that ORA was more effective in predicting IOL power than Haigis, SRK/T, and Barrett Universal II, although it was equivalent to Hoffer Q. They also indicated that Hoffer Q was superior to all formulas in terms of the percentage of patients within 0.50 D of their target refractions and the percentage of patients going into hyperopic shift. This agrees with the outcomes we found in our series of short eyes (see Tables 2, 3). Analysing the mean absolute error value in detail, our results were similar to those found by these authors: about half a diopter for the SRK/T, Holladay 2, Barrett Universal II, Hoffer Q, Haigis, and ORA VLynk calculation methods (see Table 5).

It has been reported that for eyes with an axial length of <22.0 mm the predictive accuracy is less precise: within ±0.50 D ranged between 21 and 71% (18) and between 45 and 75% (19) as a function of the formula used. In fact, it seems that there is no general consensus on which the best biometry-based formula is for these eyes, since some outcomes indicate that Haigis produced the smallest mean absolute error (19), while others consider Holladay 2 to be more precise (20), others found that Barrett Universal II was the most accurate (21), and yet others that Hill-RBF (22, 23) yielded the lowest numerical error. Our results (Table 2) indicate that all these biometry-based formulas and the ORA VLynk show a mean absolute error ranging from 0.40 to 0.50 D. In relation to the

TABLE 4 Clinical studies using the Optiwave Refractive Analysis System (ORA) in short and long eyes.

Authors	Year	Axial length (mm)	Eyes	Formulas	IOL implanted	Follow up
Hill et al. (12)	2017	>25.0	51	SRK/T Holladay 1 A-optimized Holladay 1 Holladay 2 Barrett Universal II Hill-RBF	30 eyes with monofocal IOL (Akreos AO60, AF-1 FY-60 AD or AcrySof MN60MA) 13 eyes with toric IOL (Tecnis ZCT150, Tecnis ZCT225, Tecnis ZCT300, or Tecnis ZCT400) 8 eyes with multifocal IOL (Tecnis ZMB00)	21–60 days
Sudhakar et al. (13)	2019	<22.1	51	Hoffer Q Holladay 2 Haigis Barrett Universal II Hill-RBF	37 eyes with monofocal IOL (Akreos AO60, AF-1 FY-60 AD or SA60AT) 9 eyes with toric IOL (Tecnis ZCT150, ZCT225, ZCT300 or ZCT400) 5 eyes with multifocal IOL (Tecnis ZKB00 or ZLB00)	20–60 days
Soifer et al. (14)	2021	≥25 ≥27 <22	107 14 23	Barrett Universal II	NA	4 weeks or later
Sakai et al. (15)	2022	≥25	61 39* 22**	SRK/T Holladay 1 Hoffer Q Holladay 2 Haigis Barrett Universal II	13 eyes with monofocal IOL 20 eyes with toric IOL 28 eyes with multifocal IOL	1 week-2 months
Bansal et al. (16)	2022	<22	65	SRK/T Hoffer Q Haigis Holladay 2 Barrett Universal II Hill-RBF	All eyes with monofocal IOL (59 with AcrySof IQ and 6 with AcrySof SA60AT)	4 weeks
Current study	2023	>25.0 <22.1	48 48	SRK/T Hoffer Q Haigis Holladay 2 Barrett Universal II Barret True K	All eyes with monofocal IOL (AcrySof IQ)	3 months

IOL: intraocular lens; NA: not available; *: emmetropia target (0 to −0.50D); **: myopia target (−2.00 to −5.00D).

proportion of eyes within ±0.50 D and ± 1.00 D, Table 6 shows that the outcomes of this and previous studies are quite similar when comparing the different methods individually: 40–70% and 80–90% being within ±0.50 D and ± 1.00 D, respectively; we found the highest percentages for the Holladay 2 and Hoffer Q biometry-based formulas.

Raufi et al. (24) retrospectively compared the outcomes of ORA to Barrett Universal II and Hill-RBF 2.0 in a large population (949 eyes) and found that axial length stratification (<22.75 mm, 22.75 to 24.5 mm, 24.5 to 26.25 mm, and > 26.25 mm) did not influence statistical differences in the IOL prediction methods. Thus, if a surgeon were to specifically use Hill-RBF or Barrett Universal II, there would be no advantage gained by supplementing these with ORA. These authors concluded that ORA is, however, still promising in eyes with a history of corneal refractive surgery and in eyes needing toric IOLs, for example. It has also been reported that certain factors, such as speculum-induced pressure, eyelid pressure, and intraoperative corneal changes, may affect the variability of the ORA system (2); additionally, after crystalline lens extraction, variations in the aphakic intraocular pressure, corneal incision, and hydration may also contribute to measurement errors and variable IOL selection (14).

TABLE 5 Mean numerical error (mean absolute error) reported in different clinical studies using several calculation methods.

Authors	SRK/T	Holladay 1	A-optimized Holladay 1	Holladay 2	Barrett Universal II	Hill-RBF	Hoffer Q	Haigis	Barret true K	ORA VLynk
Long eyes										
Hill et al. (12)	0.20 ± 0.06 (NA)	0.33 ± 0.06 (NA)	−0.02 ± 0.06 (NA)	0.24 ± 0.06 (NA)	0.19 ± 0.06 (NA)	0.22 ± 0.06 (NA)				0.06 ± 0.06 (NA)
Sakai et al. (15)*	NA (0.38 ± 0.36)	NA (0.59 ± 0.40)		NA (0.47 ± 0.37)	NA (0.35 ± 0.33)		NA (0.56 ± 0.39)	NA (0.44 ± 0.35)		0.04 ± 0.39 (0.28 ± 0.27)
Current study	0.29 ± 0.30 (0.35 ± 0.24)			0.21 ± 0.31 (0.30 ± 0.22)	0.26 ± 0.26 (0.29 ± 0.23)		0.51 ± 0.36 (0.52 ± 0.33)	0.31 ± 0.28 (0.34 ± 0.25)	0.21 ± 0.28 (0.27 ± 0.22)	0.16 ± 0.27 (0.24 ± 0.20)
Short eyes										
Sudhakar et al. (13)				−0.14 ± NA (0.53 ± NA)	0.11 ± NA (0.51 ± NA)	0.07 ± NA (0.49 ± NA)	−0.08 ± NA (0.54 ± NA)	0.26 ± NA (0.60 ± NA)		0.00 ± NA (0.48 ± NA)
Bansal et al. (16)†	−0.02 ± 0.56 (0.46 ± 0.32)			−0.23 ± 0.66 (0.54 ± 0.44)	0.01 ± 0.60 (0.49 ± 0.34)	−0.06 ± 0.53 (0.40 ± 0.35)	−0.24 ± 0.55 (0.42 ± 0.42)	−0.20 ± 0.82 (0.63 ± 0.56)		−0.10 ± 0.50 (0.37 ± 0.35)
Current study	0.29 ± 0.60 (0.55 ± 0.37)			−0.03 ± 0.52 (0.40 ± 0.33)	0.21 ± 0.51 (0.44 ± 0.33)		−0.01 ± 0.54 (0.45 ± 0.30)	0.29 ± 0.54 (0.49 ± 0.37)	0.25 ± 0.50 (0.44 ± 0.33)	0.24 ± 0.54 (0.50 ± 0.31)

*Target emmetropia; †without optimization.

TABLE 6 Proportion of eyes within ±0.50D (±1.00D) of the spherical equivalent target refraction reported in different clinical studies using several calculation methods.

Authors	SRK/T	Holladay 1	A-optimized Holladay 1	Holladay 2	Barrett Universal II	Hill-RBF	Hoffer Q	Haigis	Barret true K	ORA VLynk
Long eyes										
Hill et al. (12)	74.5 (96.1)	62.8 (90.2)	82.4 (100)	79.1 (90.7)	73.9 (96.1)	76.7 (93.0)				80.4 (98.0)
Soifer et al. (14) ≥25 mm ≥27 mm					79.4 (96.3) 64.3 (92.9)					75.7 (98.1) 71.4 (92.9)
Sakai et al. (15)										84.6 (97.4)
Current study	77.08 (97.92)			85.42 (100)	83.33 (100)		50.00 (93.75)	75.00 (97.92)	79.17 (100)	87.50 (100)
Short eyes										
Sudhakar et al. (13)				43.1 (88.2)	52.9 (86.3)	60.8 (90.2)	49.0 (86.3)	52.9 (80.4)		58.8 (88.2)
Soifer et al. (14)					52.2 (91.3)					52.2 (87.0)
Bansal et al. (16)†	63.08 (93.85)			53.85 (80.00)	60.0 (95.38)	70.77 (96.92)	69.23 (93.85)	50.77 (84.62)		67.69 (95.38)
Current study	50.00 (87.50)			66.67 (95.83)	60.42 (93.75)		64.58 (95.83)	60.42 (85.42)	60.42 (93.75)	58.33 (91.67)

†Without optimization.

5 Conclusion

To our knowledge, this is the first study to prospectively assess the accuracy of the ORA VLynk and preoperative biometry-based formulas in short and long eyes when the same IOL was implanted. The outcomes reported in our study suggest that for long eyes implanted with the same monofocal IOL the ORA VLynk system performs better than all conventional biometry-based formulas. For short eyes, The ORA VLynk appears to perform as well as SRK/T, Haigis, Barrett Universal II, and Barrett true K, although Hoffer Q and Holladay 2 are the most accurate biometry-based formulas. However, the differences between all the calculation methods are small. We believe that this approach reduces undesired postoperative refractive errors and patients with long or short axial lengths could benefit from the use of this technology. Future research should explore the efficacy of ORA VLynk in long and short eyes implanted with premium IOLs, and eyes with corneal diseases, such as keratoconus.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Ethics Committee at Investigación con Medicamentos de Cádiz (Cádiz, Spain) and the Valencia regional committee on postmarketing studies, CAEPRO (Valencia, Spain). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

PT-R: Conceptualization, Funding acquisition, Methodology, Supervision, Writing – original draft, Writing – review & editing. PO-V: Conceptualization, Investigation, Methodology, Writing – review & editing. PT-S: Formal analysis, Validation, Writing – review & editing. ST-S: Formal analysis, Validation, Writing – review & editing. RR-M: Conceptualization, Formal analysis, Validation, Writing – review & editing. RM-M: Conceptualization, Formal analysis, Writing – review & editing.

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Conflict of interest

Pedro Tañá-Rivero participates in clinical studies for Alcon Laboratories, AST Products, BVI, Carl Zeiss Meditec, Hoya, HumanOptics, and Johnson&Johnson. Paz Orts-Vila participates in clinical studies for Alcon Laboratories, AST Products, BVI, Carl Zeiss Meditec, Hoya, HumanOptics, and Johnson&Johnson. Ramón Ruiz-Mesa participates in clinical studies for Alcon Laboratories, Bausch&Lomb, Biotech, Carl Zeiss Meditec, Cristalens, Hoya, Medicontur, and Sifi. Robert Montés-Micó declares a consultant contract with Staar Surgical AG and BVI through the University of Valencia outside the submitted work.

The remaining authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Age-related cataract without surgery is related to exacerbated depression symptoms: a cross-sectional study of Chinese adults from Anhui, China

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Objective: The present study sought to evaluate the relationship between age-related cataracts, a prevalent ocular condition among the elderly, and the occurrence of depressive symptoms within a cohort of Chinese adults residing in Anhui, China.

Methods: A survey involving 252 Chinese individuals aged 65 years and older was conducted at Lu'an People's Hospital. Depressive symptoms were assessed using the Hamilton Depression Scale (HAMD) consisting of 17 items, while age-related cataracts were clinically classified according to the Lens Opacities Classification System (LOCS) III. Depressive symptoms were identified by a HAMD score exceeding 7. Logistic regression analyses were employed to determine the odds ratios (OR) and 95% confidence intervals (CI) pertaining to the association between age-related cataracts and depressive symptoms.

Results: Cataract patients aged 65 years and older had significantly higher scores of depressive symptoms than those under 65 years (mean scores of 8.17 ± 3.26 versus 5.18 ± 1.86, $p < 0.001$). In addition, patients aged 65 years and above exhibited a diminished quality of life relative to patients aged under 65 years. The findings indicated that adults experiencing depressive symptoms reported lower monthly incomes ($p = 0.036$), lower educational attainment ($p = 0.044$), and living alone ($p = 0.007$). Furthermore, fewer elderly patients with depressive symptoms received surgical treatment (15 patients) than those without depressive symptoms (61 patients), with a significant difference ($p = 0.011$). Multivariate analysis revealed that the presence of depressive symptoms was significantly correlated with a lack of formal education ($p = 0.048$), reduced income ($p = 0.003$), solitary living arrangements ($p = 0.025$), and the presence of cataracts without surgical intervention ($p = 0.007$).

Conclusion: These findings suggested a significant association between age-related cataracts and depressive symptoms among older adults. Specifically, cataracts that remain untreated surgically were notably linked to depression in elderly patients. It is recommended that initiatives and resources be directed toward surgical treatment programs for cataracts in individuals exhibiting depressive symptoms.

KEYWORDS

age-related cataract, depression, surgery, elderly, cross-sectional study

Introduction

Age-related cataract is recognized as the primary cause of mild to moderate visual impairment globally (1, 2). As life expectancy increases and the population ages, the prevalence and impact of age-related cataracts are anticipated to rise, thereby presenting a significant public health challenge on a global scale. Economic evaluations conducted in the United States consistently indicated that the medical expenses associated with age-related cataracts substantially surpass those related to other major ocular conditions (3). A recent investigation revealed considerable variability in average treatment costs per patient across various conditions, including refractive error correction (ranging from $12 to $201 per patient per procedure), cataract surgery (ranging from $54 to $3,654 per patient per procedure), and glaucoma (ranging from $351 to $1,354 per patient per procedure) (4). Consequently, cataracts impose significant economic burdens on individuals, communities, and nations.

Depression is a long-lasting and often recurring mental health disorder that is common among older adults, but its connection to cataracts is not well understood. Previous studies have shown that depression is frequently encountered in eye care settings, often going unnoticed or untreated (5–7). Many investigations have looked into the link between visual impairment and depression, but the findings have been inconsistent. For example, a study of 339 socially vulnerable adults over 50 in Armenia revealed that those with visual impairment had a significantly higher risk of depression than those without visual impairment, even after accounting for other factors (8). In contrast, a European study found that older adults with visual impairments had a notably higher prevalence of major depressive disorder and anxiety than those with normal vision (9). However, other studies have shown no significant relationship. A population-based study in the United States involving 2,520 individuals aged 65 to 84 years found no link between visual acuity or its changes and the development of depressive symptoms (10). In addition, a study of younger United States adults aged 20 to 39 found no correlation between visual acuity and depressive disorders after adjusting for various factors (11). While some studies suggest that cataract surgery may lead to improvements in depressive symptoms (12–15), there is still limited understanding of how cataracts relate to depression, especially in the Chinese population.

Investigating the risk factors associated with depression within the Chinese population holds significant public health relevance, given that the Chinese represent the largest ethnic group globally and may experience a substantial prevalence of depression. Furthermore, mental health issues are often accompanied by social stigma in Chinese cultural contexts. Research that examines the possible link between cataracts and depressive symptoms in the general population could guide clinical strategies for cataract management and impact public health policies. This study sought to assess the relationship between age-related cataracts and depressive symptoms in a community-based group of older Chinese adults aged 65 years and older. In addition, we aimed to assess whether the association between cataracts and depressive symptoms can be attributed to visual problems without immediate surgical intervention.

Methods

Study population

The research was a cross-sectional survey carried out in Lu'an, China, with the objective of assessing the patterns, predictors, and prevalence of common health outcomes among elderly individuals aged 65 years and older in eastern China. The methodology of the study has been detailed in a previous study (15). A total of 252 participants aged 65 years or older and 569 individuals under the age of 65 were recruited from our hospital for this investigation. A cataract diagnosis was confirmed through at least one inpatient or two outpatient assessments by an ophthalmologist, using the ICD-9-CM diagnosis code 366. The index date refers to the date when the cataract was first diagnosed. Participants in the cataract group were then divided into those who underwent surgery and those who did not undergo surgery to evaluate the impact of cataract surgery on depression risk. This research was approved by the Institutional Review Board of Lu'an People's Hospital (2023LL027). All participants provided written informed consent during the recruitment phase of the study.

Questionnaires

Cataract grading was performed using a slit-lamp examination (model SL-1E; Topcon) on both eyes of each participant in the study. This evaluation involved a clinical assessment of lens opacity based on the Lens Opacities Classification System (LOCS) III (16). The LOCS III system includes the assessment of nuclear opalescence (NO), cortical cataract (C), and posterior subcapsular cataract (PSC). A LOCS III score of 4.0 or higher for NO was considered indicative of a significant nuclear cataract, while scores of 2.0 or higher for C and PSC were regarded as significant, respectively (13). The presence of any cataract was defined as having at least one subtype in one eye.

To assess depressive symptoms, the 17-item Hamilton Depression Scale (HAMD) was used to gage the frequency of symptoms reported by participants over the last 2 weeks (17). The HAMD consists of 17 items divided into five categories. This scale employs a 5-point Likert scale, where 0 indicates no symptoms and 4 signifies extremely severe symptoms. A total HAMD score above 7 suggests the presence of depression (18). The scale has been validated for use in the general Chinese population and was translated into Chinese by Wang et al. for depression screening (19).

Furthermore, the Hamilton Anxiety Scale (HAMA) was used to assess patients' mental states, featuring two subscales: psychic anxiety and somatic anxiety. The HAMA consists of 14 items, each rated on a 5-point Likert scale from 0 (no symptom) to 4 (extremely severe symptoms).

Quality of life was measured using the 36-item Short Form Survey (SF-36), a self-administered tool designed to evaluate health-related quality of life (QoL) across eight areas: physical functioning (PF), role limitations due to physical issues (RP), and others (20). Scores for each dimension ranged from 0 to 100, with higher scores indicating a better QoL. The SF-36 has been validated in a Chinese context by Ren et al. (21).

Assessment of covariates

The evaluation of factors related to visual acuity was performed using a Snellen vision chart with tumbling-E optotypes (Precision Vision, La Salle, IL). Measurements were taken for each eye separately under lighting conditions of approximately 500 lux from a distance of 4 m, with participants wearing their prescribed vision aids, such as glasses or contact lenses, if necessary. The light levels in the examination room during the visual acuity test were measured using a light meter. Furthermore, a risk factor questionnaire was verbally administered by trained research assistants, and the information included participants' socioeconomic status, lifestyle habits, medical history, and medication use. Diabetes mellitus was defined as either fasting glucose levels or doctors' diagnosis of diabetes along with the use of diabetes medications. Hypertension was identified based on the WHO diagnostic criteria for hypertension and the patients' medical history, including the use of antihypertensive medications.

Statistical analysis

Data analyses were conducted using SPSS 16.0 (SPSS Inc., Chicago, IL). Participants who had cataract surgery in both eyes were not included in the analysis as their vision was severely affected. Binary logistic regression models were used to calculate odds ratios (ORs) and 95% confidence intervals (CIs) to examine the relationship between age-related cataracts and depressive symptoms. In the multivariate analysis, the model included only age, gender, cataract status, and other variables that showed significant differences in univariate comparisons ($p < 0.05$). The interactions between age-related cataracts and other variables related to depressive symptoms were assessed using an OR value. A p-value of less than 0.05 is indicative of statistical significance.

Results

Demographic characteristic between cataract patients with ≥65 years and < 65 years

A total of 252 individuals aged 65 years and older and 569 individuals under 65 years participated in this study. The mean age of cataract patients aged 65 years and older was significantly greater than that of patients under 65 years (70.58 ± 4.16 vs. 45.67 ± 7.26, $p < 0.001$). No significant differences were observed between the two groups in terms of gender distribution or complications (see Table 1).

Mental health and quality of life between cataract patients with ≥65 years and < 65 years

The analysis revealed no significant difference in the Hamilton Anxiety Rating Scale (HAMA) scores between the two groups ($t = 1.258$, $p = 0.369$). However, it is noteworthy that cataract patients aged 65 years and older had significantly higher Hamilton Depression Rating Scale (HAMD) scores (8.17 ± 3.26 vs. 5.18 ± 1.86, $p < 0.001$) than those under 65 years (Figure 1). In addition, cataract patients aged 65 years and older had lower scores in the following domains: role physical (RP) (54.50 ± 11.53 vs. 62.16 ± 14.38, $p = 0.004$), bodily pain (BP) (57.84 ± 18.21 vs. 65.44 ± 11.26, $p = 0.002$), general health (GH) (55.89 ± 14.41 vs. 65.58 ± 13.57, $p < 0.001$), vitality (VT) (58.26 ± 11.33 vs. 65.28 ± 17.19, $p = 0.001$), and role emotional (RE) (52.87 ± 14.20 vs. 63.17 ± 14.21, $p < 0.001$) when compared to their younger counterparts. These findings are summarized in Table 1.

TABLE 1 The demographic characteristics, mental health, and quality of life between cataracts patients with different age.

	Cataracts with aged ≥65 years (n = 252)	Cataracts with aged <65 years (n = 569)	$t/\chi 2$	p
Age (years, x ± s)	70.58 ± 4.16	45.67 ± 7.26	10.268	**<0.001**
Gender (n)				
Men	127	282	0.049	0.825
Women	125	287		
Complications				
Hypertension (n)	51	97	1.203	0.273
Diabetes mellitus (n)	59	102	3.335	0.068
Cancers	5	11	0.252	0.616
Mental health				
HAMA	5.18 ± 2.13	5.23 ± 1.99	1.258	0.369
HAMD	8.17 ± 3.26	5.18 ± 1.86	5.287	**<0.001**
Quality of life (SF-36)				
PF	65.21 ± 14.38	66.37 ± 15.27	−1.018	0.398
RP	54.50 ± 11.53	62.16 ± 14.38	−4.366	**0.004**
BP	57.84 ± 18.21	65.44 ± 11.26	−5.012	**0.002**
GH	55.89 ± 14.41	65.58 ± 13.57	−7.896	**<0.001**
VT	58.26 ± 11.33	65.28 ± 17.19	−5.216	**0.001**
SF	59.46 ± 17.89	61.88 ± 13.16	−1.287	0.321
RE	52.87 ± 14.20	63.17 ± 14.21	−8.012	**<0.001**
MH	65.39 ± 11.69	64.36 ± 14.58	0.578	0.601

PF, physical functioning; RP, physical problems; BP, bodily pain; GH, general health; VT, vitality; SF, social functioning; RE, role limitations due to emotional problems; and MH, mental health. Bold values mean $p < 0.05$.

Basic information between cataract patients with depression and without depression symptoms

Table 2 presents a summary of the characteristics of the study participants categorized by the presence of depressive symptoms, as assessed by the Hamilton Depression Rating Scale (HAMD). The findings indicated that adults exhibiting depressive symptoms reported lower monthly income ($p = 0.036$), lower levels of education ($p = 0.044$), and living alone ($p = 0.007$). Furthermore, a smaller number of elderly patients with depressive symptoms had undergone surgery (15 vs. 61, $p = 0.011$) than those without depressive symptoms.

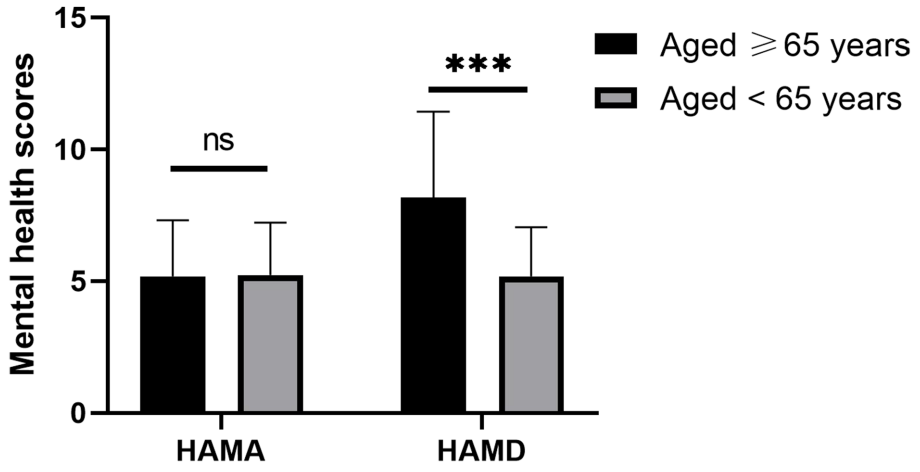

FIGURE 1
HAMA and HAMD between cataract patients of different ages. *** $p < 0.001$.

Multivariate logistic regression analysis

The relationships between depressive symptoms, cataract surgery, and various risk factors were analyzed using a multiple logistic regression model, with the findings presented in Table 3. The multivariate analysis revealed that the presence of depressive symptoms was significantly correlated with a lack of formal education ($p = 0.048$), lower income levels ($p = 0.003$), living alone ($p = 0.025$), and the occurrence of cataracts without surgical intervention ($p = 0.007$).

Discussion

In this community-based survey involving Chinese adults aged 65 years and older, we found that age-related cataracts, encompassing both bilateral and unilateral forms, were significantly correlated with the presence of depressive symptoms as assessed by the HAMD after adjusting for a comprehensive array of potential confounding variables. This correlation was determined to be independent of socioeconomic status, lifestyle factors, and presenting visual acuity. Notably, the relationship between age-related cataracts and depressive symptoms was influenced by the educational attainment of the individuals. These findings offer preliminary insights into the potential link between cataracts and depression. It is imperative for ophthalmologists to recognize the heightened risk of depression in patients with cataracts and to implement screening for depressive symptoms or refer patients for counseling within clinical settings. Furthermore, the results underscore the importance of timely cataract surgery as a means to mitigate the risk of depression among older adults.

Immediate Sequential Bilateral Cataract Surgery (ISBCS) demonstrates outcomes that are comparable to those of delayed sequential surgeries while exhibiting a low incidence of bilateral endophthalmitis. Furthermore, ISBCS has the potential to be both cost-effective and efficient (22). The current study represents a population-based investigation that directly evaluates the association between cataracts and depressive symptoms. Our study found a strong link between age-related cataracts and a higher chance of experiencing depressive symptoms, especially among those without formal education, which is consistent with earlier research findings (23). Numerous studies have indicated that visual impairment may serve as an independent risk factor for depression; however, the results across various studies have been inconsistent (6–9). These discrepancies may stem from differences in study design and the characteristics of the populations examined, including the varied instruments employed for screening depressive symptoms. It is important to note that visual acuity reflects a composite effect of various ocular disorders, and there is limited evidence regarding the specific impact of individual eye disorders on depression or depressive symptoms. Other research has demonstrated a significant reduction in depressive symptom scores following cataract surgery in older populations (10–14). Nevertheless, there is a paucity of population-based data exploring the relationship between cataracts and depression or depressive symptoms. This suggests that the relationship between cataracts and depressive symptoms may not be solely attributable to poor visual acuity but could also involve other vision-related factors such as halos, contrast sensitivity, and light adaptation. In addition, emotional factors, including apprehension regarding surgical procedures and frustration stemming from limitations in daily activities, may have further contributed to the observed effects on depressive symptoms in this study.

It is recognized that depression is associated with many diseases, such as digestive disorders (24), while the relationship between cataracts and depressive symptoms remains unclear. The biological mechanisms that elucidate the associations between cataracts and depressive symptoms remain inadequately understood and require further investigation. It is well-documented that age-related cataracts are the predominant cause of visual impairment among the elderly population. The resultant vision loss may diminish individuals' capacity to engage in activities of daily living and hinder their ability to communicate. However, our findings suggest that this association

TABLE 2 Characteristics of study participants by the status of depressive symptoms.

	Elderly patients with depression (*n* = 78)	Elderly patients without depression (*n* = 174)	*t*/χ2	*p*
Age (years, x ± s)	70.13 ± 4.28	71.02 ± 4.16	1.268	0.259
Gender (*n*)				
Men (*n*)	46	85	2.211	0.137
Women (*n*)	32	89		
Surgery (*n*)				
Cataract with surgery (*n*)	15	61	6.455	**0.011**
Cataract without surgery (*n*)	63	113		
Individual monthly income (> 1,000 Yuan) (*n*)	24	78	4.418	**0.036**
No formal education (*n*)	42	70	4.044	**0.044**
Living alone (*n*)	41	60	7.332	**0.007**
Smoking history (*n*)	26	52	0.300	0.584
Alcohol intake (*n*)	20	38	0.439	0.507
Tea consumption (*n*)	19	44	0.025	0.875
Hypertension (*n*)	28	43	3.329	0.068
Diabetes mellitus (*n*)	21	38	0.766	0.378

Bold values mean $p < 0.05$.

TABLE 3 Multivariate analyses of the associated factors for the presence of depressive symptoms.

	Multivariate analysis		
	OR	95% CI	*p*
Age groups			
65–69 years		Reference	
≥ 70 years	1.16	0.84–1.62	0.311
Sex			
Male		Reference	
Female	1.21	0.87–1.66	0.287
Educational level			
Formal education		Reference	
No formal education	1.43	0.96–2.05	**0.048**
Monthly income			
≥ 1,000 Yuan		Reference	
< 1,000 Yuan	1.55	1.15–2.09	**0.003**
Living alone or not			
No		Reference	
Yes	1.48	1.01–1.96	**0.025**
Cataract with surgery			
Yes		Reference	
No	1.53	1.10–1.81	**0.007**

Bold values mean $p < 0.05$.

is independent of the vision loss attributable to cataracts. One possible explanation for this observation is that both age-related cataracts and depression may share common risk factors, such as oxidative stress (25). Meanwhile, previous reviews indicated that pathophysiological conditions, such as inflammation and neurodegeneration, could play a role in both depression and specific eye disorders. In addition, physical symptoms and changes in bodily functions, such as disturbances in circadian rhythms caused by eye diseases, may also affect the mood of patients (26). Alternatively, individuals experiencing depression may be less inclined to seek treatment for cataracts compared to those with stable mental health. In addition, our study revealed that the correlation between age-related cataracts and depressive symptoms was more pronounced among individuals lacking formal education. Adults with varying educational backgrounds may confront distinct psychosocial challenges due to differences in lifestyle, responsibilities, or circumstances. Furthermore, perceived financial barriers to accessing eye care services and a lack of awareness regarding the potential benefits of cataract surgery may deter many individuals with limited education from pursuing medical assistance. The interaction effect identified in this study indicates a complex relationship among ocular disorders, socioeconomic status as indicated by educational attainment, and mental health, which warrants further exploration.

The findings of our study carry significant public health implications that warrant attention. Mental health issues among the elderly population represent a critical concern in China and other nations, often remaining under-identified and inadequately addressed. Given that cataracts can be effectively treated through surgical intervention, it is advisable to allocate efforts and resources toward cataract surgery programs for older adults experiencing depression, particularly in rural regions where educational levels may be low. In addition, there is a need for further randomized controlled trials to investigate the effects of cataract surgery on depressive symptoms within these demographics.

It is essential to acknowledge certain limitations. Cultural factors may significantly influence mental health, suggesting that findings from the Chinese population may not be readily applicable to other ethnic groups due to substantial cultural disparities. Moreover, despite controlling for a broad range of confounding variables in our multivariate analysis, the possibility of residual confounding cannot be dismissed. The cross-sectional design of the study also limits our ability to ascertain whether age-related cataracts precede depressive symptoms. It remains plausible that factors associated with depression could lead to environmental exposures contributing to the development of cataracts.

In summary, our research identifies a significant association between age-related cataracts and depressive symptoms among older Chinese adults, particularly those with lower educational attainment. Although the direction of causality remains ambiguous in this cross-sectional analysis, our findings illuminate the intricate relationship between aging, vision impairment, cataracts, and depression, suggesting a potential role for cataract surgery in enhancing mental health outcomes among the elderly.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by this study was conducted following the tenets of the Helsinki Declaration and was approved by the Institutional Review Board of Lu'an People's Hospital (2023LL027). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

TW: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing. HL: Writing – original draft, Writing – review & editing. QC: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Changes in corneal curvature and astigmatism in senile cataract patients after phacoemulsification

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Purpose: Analysis of changes in corneal curvature and astigmatism after phacoemulsification for senile cataracts.

Methods: Retrospective collection of clinical data from patients who underwent uncomplicated phacoemulsification at the First Affiliated Hospital of Soochow University. The changes in total corneal curvature, anterior surface curvature, posterior surface curvature, and astigmatism were measured by the Sirius system. The axial length was measured by Lenstar 900.

Results: The total corneal curvature and anterior surface curvature at 3 months were all larger than those before phacoemulsification, and the difference was statistically significant ($p < 0.05$). Compared with preoperative results, there was no significant change in corneal posterior surface curvature and astigmatism 3 months after surgery ($p > 0.05$). Changes in corneal curvature and astigmatism were not significantly correlated with age at 3 months after surgery ($p > 0.05$). Postoperative astigmatism was increased with the growth of axial length, while corneal curvature was decreased ($p < 0.05$).

Conclusion: Phacoemulsification can lead to increased postoperative corneal curvature in elderly cataract patients, and with the growth of the axial length, the corneal astigmatism was increased.

KEYWORDS

senile cataract, phacoemulsification, corneal curvature, axial length, astigmatism

1 Introduction

With the continuous advancement of microsurgical techniques, artificial lenses, and intraocular lens (IOL) power measurement formulas, traditional cataract restoration surgery can no longer meet the living requirements of elderly patients, especially the presbyopia caused by monofocal IOL, which reduces the quality of life of patients. More and more elderly patients are choosing multifocal IOL. In order to meet their daily needs as much as possible, skilled surgical techniques, accurate measurement of eye parameters, and calculation of IOL power are required. At present, multifocal IOL is increasingly being used in clinical practice, improving the overall visual acuity of elderly cataract patients after surgical treatment and reducing glasses dependence after cataract surgery (1, 2). However, the presence of astigmatism affects the effectiveness of multifocal IOL. Astigmatism is a refractive error caused by the cornea and lens, which can lead to visual fatigue, ghosting, and decreased vision. After cataract surgery, the astigmatism caused by the cornea can often be greatly reduced due to the implantation of Toric IOL. However, if corneal astigmatism was ignored before surgery or appropriate treatment measures were not taken during surgery, it may affect the surgical outcome (3, 4).

At present, there are several methods for measuring preoperative corneal astigmatism: Pentacam anterior segment analysis system (Oculus Optikgeräte GmbH; Wetzlar, Germany),

IOL-Master (Carl Zeiss Meditec AG, Jena, Germany), TMS-5 (Tomey Corporation, Nagoya, Japan), Sirius anterior segment analysis system (Oculus Optikgeräte GmbH; Wetzlar, Germany), and iTrace (Tracey Technologies Corp., Houston, TX) (5–8). At present, biometric instruments based on the Scheimpflug principle have been widely used in the field of ophthalmology. The Pentacam 3D anterior segment analysis system applies the Scheimpflug optical principle to obtain multiple images of the anterior segment through rotational tomography, obtain anterior and posterior surface curvature, total corneal thickness, ACD and other anterior segment parameters (9).

The Sirius system is a 3D anterior segment analysis system launched by Italian CSO company. It consists of a 360-degree rotating Scheimpflug camera and a Placido disc with 22 rings. It can capture 25 Scheimpflug images and a Placido image covering the anterior surface of the cornea within 1–2 s. The images include 35,632 and 30,000 data points, respectively. The anterior and posterior surface morphology, anterior chamber depth, and lens data of the cornea are calculated using proprietary software (10). Currently widely used in the diagnosis of anterior segment diseases, studies have shown that the Sirius system has high reproducibility and reproducibility in analyzing anterior segment parameters (11). Pentacam and Sirius system had good consistency in measuring anterior chamber depth and corneal curvature in cataract patients, providing a new option for measuring anterior segment parameters in clinical cataract patients (12, 13).

Previous studies have mainly observed the effect of Toric IOL on corneal astigmatism after cataract surgery, or the effect of cataract surgical incisions on astigmatism, but there has been relatively little research on postoperative corneal changes in elderly cataract patients. Research has found that the incidence of astigmatism is higher in elderly patients. After cataract surgery, corneal astigmatism shows a long-term inverse trend with age, but some scholars believe that there was no regular change (14, 15). Therefore, this study evaluated the changes in corneal biological parameters before and after surgery in age-related cataract patients using the Sirius system, exploring their characteristics and correlations, in order to provide assistance for clinical preoperative evaluation and IOL selection.

2 Materials and methods

2.1 Study design and patient selection

Patients who underwent cataract surgery at the First Affiliated Hospital of Suzhou University from July 31, 2017 to May 31, 2018 were collected through the hospital information system. Patients with II-IV grade nuclear hardness who were over 60 years old and had no surgical complications were included in the study. Patients with a history of ophthalmic surgery, corneal disease, uveitis, glaucoma, severe dry eye syndrome, posterior staphyloma, or poor fixation due to eye disease were excluded. The study adhered to the tenets of the Declaration of Helsinki. All patients have signed informed consent forms. After being reviewed and approved by the hospital ethics review committee.

2.2 Instrument and examinations

All patients underwent Lenstar LS900 and Sirius system examinations under natural pupil and relative darkroom conditions. The inspection was conducted by the same skilled inspector on the same day. Firstly, the patient underwent a Lenstar LS900 examination. After blinking several times, patients were instructed to place the jaw support on the lower jaw, pressed the forehead tightly against the forehead support, observed the instrument markings, and measured when the focusing aperture was at its minimum. Each measurement consists of 16 rapid and continuous scans with a total of three measurements taken and averaged. Then the corneal parameters were checked by the Sirius system. During the filming process, instructed the examinee to keep their eyes wide open, and avoid blinking. In order to ensure accurate and reliable inspection results, Sirius had strict quality control standards (included with the instrument): when the Scheimpflug image area was ≥90%, the center positioning was ≥90%, and the Placido disk coverage area was ≥80%, the inspection results could be accepted. Three measurements that meet the standards were taken. Three months after surgery, Sirius system examination was performed using the same operating method.

2.3 Surgical technique

After making a lateral incision at 2 o'clock, inject viscoelastic agent into the anterior chamber, and make a 2.2 mm single plane corneal incision at 10 o'clock. Continuous circular capsulorhexis with a diameter of about 6 mm was performed. The lens nucleus is emulsified and the cortex was removed using Alcon's Centurion phacoemulsifier. Tecnis ZCB00 IOL (Abbott Medical Optics, Santa Ana, CA) were implanted in the lens capsule. All surgeries were performed by the same physician (Lu PR). Postoperative routine administration of tobramycin dexamethasone and levofloxacin eye drops were used for anti-inflammatory and anti-infective treatment.

2.4 Statistical analysis

SPSS version 19.0 (SPSS, IBM Corp., Armonk, NY, United States) was used for analysis. The normality of the continuous data was tested using Kolmogorov–Smirnov test. Normal distribution econometric data was represented by mean ± standard, Preoperative and postoperative corneal curvature and astigmatism changes were analyzed using paired *t*-tests. Spearman rank correlation is used to perform correlation analysis on various parameters. *p*-value of 0.05 is considered statistically significant.

3 Results

3.1 General results

A total of 76 cases (76 eyes) were collected in this study, including 46 males (46 eyes), 30 females (30 eyes), 38 left eyes, and 38 right eyes. Age ranges from 60 to 92 years old, with an average age of (71.2 ± 7.15) years. The mean axial length was 24.3 ± 1.98 mm (range from 21.17 to 29.09). The mean surgical duration was 7.03 ± 0.95 min, CDE value was 5.71 ± 5.35. There were no complications during the final follow-up after the surgery.

3.2 Changes and correlation of total corneal curvature, anterior surface curvature, and posterior surface curvature in cataract patients before and after surgery

As shown in Table 1, the median (range) flat axis of total corneal curvature before surgery was 43.42D (40.34 ~ 47.27D), the postoperative range was 43.47D (40.46 ~ 47.55D), the steep axis range was 44.24D (40.51 ~ 48.04D), the postoperative range was 44.29D (40.58 ~ 48.09D), the average range was 43.84D (40.43 ~ 47.58D), and the postoperative range was 44.83D (40.52 ~ 47.73D). Compared with preoperative, the total corneal curvature after surgery had increased, and the difference was statistically significant ($p < 0.05$). The preoperative range of corneal anterior surface curvature was 43.39D (40.37 ~ 47.42D), postoperative range was 43.53D (40.53 ~ 47.51D), steep axis range was 44.40D (40.55 ~ 48.18D), postoperative range was 44.49D (40.58 ~ 48.29D), average range was 43.88D (40.46 ~ 47.8D), and postoperative range was 43.92D (40.56 ~ 47.85D). Compared with preoperative, postoperative corneal anterior surface curvature also had increased, and the difference was statistically significant ($p < 0.05$). The flat axis range of corneal posterior surface curvature was −6.12D (−6.78--5.62D), postoperative was −6.12D (−7.08-5.23D), steep axis range was −6.47D (−8.8–5.92D), postoperative was −6.47D (−10.65–5.89D), average range was −6.31D (−7.52–5.84D), postoperative is-6.29D (−8.08-5.80D), and there was no statistically significant difference compared to preoperative ($p > 0.05$). The Spearman correlation analysis results showed a significant positive correlation between the anterior corneal surface curvature and the total corneal curvature, indicating that as the refractive power of the anterior corneal surface increases, the total corneal refractive power also increases; The posterior corneal surface refractive power was significantly negatively correlated with the total corneal refractive power, and significantly positively correlated with its absolute value, indicating that as the posterior corneal surface refractive power increases, the total corneal refractive power decreases, as shown in Table 2.

3.3 Changes and correlation of astigmatism in cataract patients before and after surgery

The preoperative median (range) of corneal surface astigmatism and total astigmatism were −0.75D (−3.08–0.08D) and −0.61D (−2.75–0.05D), while postoperative astigmatism were −0.65D (−2.58–0.05D) and −0.61D (−2.44–0.12D). Compared with preoperative astigmatism, the difference had not statistically significant ($p > 0.05$), as shown in Table 3. The Spearman correlation analysis results showed a significant positive correlation ($p < 0.05$) between total corneal astigmatism and anterior corneal surface astigmatism. The correlation with corneal posterior surface astigmatism was relatively small, indicating that corneal posterior surface astigmatism had a relatively small impact on total astigmatism, as shown in Table 4.

3.4 Correlation between age, axial length, corneal refractive power, and astigmatism

The Spearman correlation analysis of age, axial length, corneal refractive power, and astigmatism were shown in Tables 5, 6. There was a mild positive correlation between preoperative age and total corneal curvature, but there was no significant correlation between the two after 3 months ($p > 0.05$). The axial length was negatively correlated with total corneal curvature, anterior surface curvature, and posterior surface curvature, indicating that as the axial length increases, corneal curvature decreased. The axial length was positively correlated with total corneal astigmatism and anterior surface astigmatism, indicating an increase in postoperative astigmatism as the axial length increased.

4 Discussion

Senile cataracts are the main cause of visual impairment in elderly patients, and phacoemulsification combined with IOL implantation

TABLE 2 Correlation analysis between corneal anterior and posterior surface curvature and total curvature.

Curvature	TCC			
	Preoperative		Postop 3 months	
	r_s	*P* value	r_s	*P* value
ACC	0.997	0.000	0.994	0.000
PCC (absolute value)	0.749	0.000	0.788	0.000

Postop, postoperative; ACC, anterior corneal curvature; PCC, posterior cornea curvature; TCC, total corneal curvature.

TABLE 1 Changes in corneal curvature in elderly cataract patients before and after surgery (mean ± SD).

Curvature		Preoperative	Postop 3 months	*t* value	*p* value
ACC	Flat value	43.65 ± 1.62	43.75 ± 1.65	−2.633	0.010*
	Steep value	44.50 ± 1.65	44.56 ± 1.68	−1.927	0.058
	Average value	44.06 ± 1.60	44.16 ± 1.64	−2.505	0.014*
PCC	Flat value	−6.16 ± 0.27	−6.13 ± 0.30	−1.469	0.146
	Steep value	−6.51 ± 0.45	−6.53 ± 0.57	0.281	0.780
	Average value	−6.34 ± 0.30	−6.33 ± 0.34	−0.141	0.888
TCC	Flat value	43.61 ± 1.59	43.71 ± 1.62	−2.721	0.008*
	Steep value	44.38 ± 1.63	44.49 ± 1.68	−2.884	0.005*
	Average value	44.00 ± 1.59	44.10 ± 1.63	−3.001	0.004*

Postop, postoperative; ACC, anterior corneal curvature; PCC, posterior cornea curvature; TCC, total corneal curvature; *paired *T*-test.

TABLE 3 Changes in corneal astigmatism in elderly cataract patients before and after surgery (mean ± SD).

Astigmatism (absolute value)	Preoperative	Postop 3 Months	*t* value	*P* value
AA (D)	0.83 ± 0.59	0.80 ± 0.56	0.795	0.429
PA (D)	0.35 ± 0.42	0.40 ± 0.61	−0.585	0.560
TCA (D)	0.78 ± 0.57	0.78 ± 0.50	0.132	0.974

Postop, postoperative; D, diopters; TCA, total corneal astigmatism; AA, anterior corneal astigmatism; PA, posterior corneal astigmatism.

TABLE 4 Correlation analysis between corneal anterior and posterior surface astigmatism and total astigmatism.

Astigmatism (D)	TCA			
	Preoperative		Postop 3 months	
	r_s	*P* value	r_s	*P* value
AA	0.848	0.000	0.796	0.000
PA	−0.026	0.822	0.053	0.650

Postop, postoperative; D, diopters; TCA, total corneal astigmatism; AA, anterior corneal astigmatism; PA, posterior corneal astigmatism.

TABLE 5 Correlation between age and corneal curvature and astigmatism.

	Preoperative		Postop 3 Months	
	r_s	*p* value	r_s	*P* value
TCC	0.227	0.049	0.155	0.181
TCA	−0.018	0.874	0.015	0.895
ACC	0.225	0.050	0.143	0.219
AA	−0.120	0.303	−0.115	0.323
PCC	0.167	0.149	0.216	0.061
PA	0.079	0.497	−0.078	0.504

Postop, postoperative; D, diopters; TCA, total corneal astigmatism; AA, anterior corneal astigmatism; PA, posterior corneal astigmatism; ACC, anterior corneal curvature; PCC, posterior cornea curvature; TCC, total corneal curvature.

TABLE 6 Correlation between axial length and corneal curvature and astigmatism.

	Preoperative		Postop 3 months	
	r_s	*P* value	r_s	*P* value
TCC	−0.416	0.000	−0.406	0.000
TCA	0.251	0.029	0.283	0.013
ACC	−0.421	0.000	−0.420	0.000
AA	0.311	0.006	0.313	0.006
PCC	−0.367	0.001	−0.389	0.001
PA	−0.100	0.389	−0.051	0.663

Postop, postoperative; TCA, total corneal astigmatism; AA, anterior corneal astigmatism; PA, posterior corneal astigmatism; ACC, anterior corneal curvature; PCC, posterior cornea curvature; TCC, total corneal curvature.

was the main clinical treatment for cataracts, effectively improving the patient's vision. With the advancement of medicine and the increasing expectations of elderly patients for postoperative visual quality, more and more elderly patients choose multifocal IOL or Toric IOL in order to achieve better visual quality. Accurate measurement of corneal biological parameters was also a necessary condition to ensure the quality of cataract surgery, and as age increases, corneal biomechanics decreases (16). According to statistics, 41.8% of patients over 60 years elder in Hong Kong have astigmatism greater than 1.0 D, indicating that the likelihood of patients needing astigmatism correction increases with age (17). Therefore, it is particularly important to evaluate and understand the characteristics of curvature and astigmatism changes in elderly patients before and after cataract surgery, which has important guiding significance for the selection of IOL and the treatment of cataracts. In cataract patients, some clinical scholars currently believe that the influence of corneal posterior surface refractive power and posterior surface astigmatism on total corneal refractive power and total astigmatism is relatively small and can be ignored, while others believe that ignoring posterior surface curvature may lead to differences in clinically significant corneal curvature estimates (18, 19). In the past, corneal curvature and astigmatism values were mostly measured using corneal topography. The corneal topography measuring instrument designed based on the Placido disc uniformly projects 28 circular rings onto the corneal surface through a projection system, and converts them based on the mirror reflection angle of the anterior corneal surface. The corneal curvature values at the same location may vary due to different measurement directions and reference point axes, and the influence of corneal posterior surface curvature is ignored. In this study, the Sirius anterior segment analysis system was used, which combines the Placido ring with the Scheimpflug camera to accurately measure corneal thickness, total corneal refractive power, corneal anterior and posterior surface curvature radius, and high repeatability (11). Currently, with the increasing aging population, more and more patients require phacoemulsification surgery for cataracts, while corneal biomechanical properties were decreased with age. The postoperative corneal changes in elderly patients are not yet clear. Therefore, through this three-dimensional function, it is possible to effectively understand the preoperative and postoperative eye conditions of elderly patients, providing reference for surgical incision construction, intraoperative energy use, and preoperative IOL selection.

This study analyzed the changes in corneal curvature before and after surgery in elderly cataract patients. The total corneal curvature and anterior surface curvature increased compared to before surgery at 3 months after surgery. The curvature of the posterior surface of the cornea showed no significant difference compared to preoperative values. Spearman correlation analysis showed that the total curvature of the cornea was significantly positively correlated with the anterior surface curvature, and significantly negatively correlated with the posterior surface curvature. In addition, although previous studies have found that disregarding the corneal curvature of the posterior surface during preoperative IOL calculation and surgical design can have a certain impact on the postoperative corneal refractive state (20, 21). This study found that the curvature of the posterior surface of the cornea did not change significantly. This is consistent with previous

research findings that cataract surgery has a relatively small impact on the posterior surface of the cornea (22). Some studies have also found that the influence of posterior corneal curvature in Barrett formula and Kane formula for measuring the power of artificial lenses was minimal (18). This study found that there was no significant difference in corneal anterior surface astigmatism, posterior surface astigmatism, and total astigmatism after 3 months of surgery compared to before. The reason for this was considered to be due to differences in surgical incision size and method. This study used a 2.2 mm transparent corneal incision. Previous studies found that the incidence of corneal endothelial dislocation, high-order aberration, and degree of corneal edema after surgery with a 2.2 mm corneal incision was lower, and the recovery was faster (23, 24). These results indicate that the surgical induced astigmatism caused by a transparent 2.2 mm corneal incision is relatively small. The Spearman correlation analysis results show that elderly cataract patients were prone to increased astigmatism after surgery with the growth of the axial length. The possible reasons for this may be: Long axial length elder patients have a decrease in corneal biomechanics, thinning of corneal thickness, and are prone to corneal deformation (25, 26); Long axial length elder patients have a decrease in corneal endothelial density and changes in cell morphology, which can lead to postoperative corneal edema and even decompensation (27, 28). Therefore, the repeated entry of the handle and the use of high energy should be minimized as much as possible to minimize the impact on the cornea during surgery.

Due to the small sample size of this study, there are certain limitations in the research results. Firstly, the changes in corneal curvature and astigmatism after surgery have not been dynamically observed. Secondly, the inclusion of patients with long axial length was small, which may lead to bias. Thirdly, the impact of postoperative corneal incision morphology and phacoemulsification time on corneal astigmatism has not been evaluated, and the simple surgical time may be biased. Fourthly, for standardization, all corneal incisions are performed at the 10 o'clock position. The results of this study may not reflect astigmatism induced by other corneal quadrants. In the future, a large sample size cross-sectional survey is needed for in-depth research, in order to further improve the postoperative visual quality of elderly patients with refractive cataracts and reduce refractive errors.

In summary, for elderly cataract patients with long axial length, the choice of multifocal intraocular lens should be carefully considered to avoid an increase in postoperative corneal astigmatism that may affect the surgical outcome. The Sirius anterior segment analysis system can accurately evaluate the dynamic changes in corneal curvature and astigmatism before and after surgery, providing a basis for the selection of artificial lenses, surgical incision construction, and intraoperative use of ultrasound energy, which has great clinical significance.

Data availability statement

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

Ethics statement

The studies involving humans were approved by the Ethics Committee of the First Affiliated Hospital of Soochow University. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

Y-HX: Writing – original draft. Y-QL: Writing – review & editing. Z-GC: Methodology, Supervision, Writing – review & editing.

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Conflict of interest

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Comparison of Scheimpflug tomography, Placido disc, and combined Placido Scheimpflug in the measurement of pupil offset in myopic population

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Introduction: This study aimed to compare the consistency of pupil offset measurements obtained using the Pentacam, Keratron Scout, and Sirius devices.

Methods: This retrospective cross-sectional study included 146 young myopic individuals (292 eyes) scheduled for refractive surgery at Dalian Third People's Hospital between January 2023 and December 2023. Three devices were utilized to measure the chord mu of the pupil deviation along with the Cartesian distances of the X and Y coordinates (Px, Py) associated with the pupil offset. Repeated-measures analysis of variance was used to compare differences in pupil offset acquisition across various devices. Additionally, the intraclass correlation coefficient (ICC) and Bland–Altman plot were utilized to assess the consistency among the three devices.

Results: Chord mu, measured using the Pentacam, Keratron Scout, and Sirius devices, were 0.18 ± 0.10, 0.21 ± 0.11, and 0.18 ± 0.11, respectively. The Px values were 0.00 ± 0.14, -0.02 ± 0.16, and -0.01 ± 0.13, respectively, while the Py values were 0.09 ± 0.13, 0.10 ± 0.15, and 0.10 ± 0.13. The ICCs for the three device measurements, chord mu, Px, and Py, were 0.817, 0.900, and 0.855, respectively. When comparing the three devices, the 95% limits of agreement (LoA) for mu and Px measured using the Sirius and Keratron Scout were the narrowest, ranging from −0.15 to 0.08 and −0.11 to 0.13, respectively. Additionally, the 95% LoA for Py measured using the Sirius and Pentacam was the narrowest, ranging from −0.13 to 0.15. The pupil centers in both eyes were predominantly located above the apex of the cornea.

Conclusion: Sirius, Keratron Scout, and Pentacam have good consistency in pupil shift measurement in young myopic patients, and the three devices can be used as references in clinical practice.

KEYWORDS

pupil offset, kappa angle, Sirius, Pentacam, Keratron Scout, Scheimpflug tomography, Placido disc

1 Introduction

The distance and direction of the pupil center relative to the corneal apex, measured in the corneal plane, are referred to as the pupillary offset (1). The corneal apex is the point where the coaxial visual light is reflected, corresponding to the first Purkinje image. Since it remains unaffected by variations in pupil size, the corneal apex serves as a more stable reference point than the pupil center, positioning it closer to the visual axis corneal intercept (2). In corneal refractive surgery, precise positioning of the cutting center is essential for achieving optimal

postoperative visual outcomes. Eccentricity during the cutting process can increase higher-order corneal aberrations, leading to visual quality issues, including glare, halos, and monocular diplopia (3–5). Research indicates that compared to the pupil ablation center, the corneal vertex center alignment strategy yields superior visual and refractive outcomes (6). Consequently, the accurate measurement of pupillary shift prior to refractive surgery is essential for enhancing postoperative visual quality. The Pentacam (Oculus Inc., Wetzlar, Germany) acquires corneal tomography images using a high-resolution rotating Scheimpflug camera, while the Keratron Scout (Optikon, Rome, Italy) captures the tangential curvature topography of the cornea through a Placido disk. Additionally, the Sirius (Schwind Eye-Tech-Solutions Ltd., Germany) system gathers corneal data by integrating both a Scheimpflug camera and a Placido disk. These devices are widely used to obtain pupil offset data (7, 8). The purpose of this study was to investigate the consistency of Pentacam, Keratron Scout, and Sirius in measuring pupil offset in myopia refractive surgery candidates and to provide a reference for refractive surgery ablation centers.

2 Materials and methods

2.1 Research subjects

This retrospective cross-sectional study involved 146 myopic individuals (292 eyes) who were scheduled to undergo refractive surgery at Dalian Third People's Hospital between January 1, 2023, and December 31, 2023. The cohort consisted of 81 males and 65 females, with ages ranging from 18 to 52 years. Inclusion criteria included stable refraction over the past 2 years, cessation of soft contact lens use for at least 1 week, rigid gas permeable (RGP) lens use for a minimum of 1 month, and orthokeratology lens use for at least 3 months. Additionally, participants needed to have a best-corrected visual acuity of ≥0.8 (on the decimal chart). The exclusion criteria were congenital eye developmental abnormalities, glaucoma, cataracts, keratoconus, frustrated keratoconus, active corneal inflammation, severe dry eye, corneal scarring, and a history of eye trauma or surgery. Additionally, individuals who were unable to cooperate during the examination were excluded. This study adhered to the Declaration of Helsinki and was approved by the Ethics Committee of the Dalian Third People's Hospital (No. 2024–101-001). In accordance with the requirements set forth by the ethics committee, the waiver of patient informed consent was granted. The authors did not have access to any information that could identify individual participants during or after the data collection process.

2.2 Method of examination

All measurements in this study were conducted in a uniform, windowless examination room, utilizing indoor light as the sole lighting source (ambient brightness set at 60 lux). This approach was implemented to minimize the influence of external light sources during the examination and to ensure a consistent environment for the assessment of all three devices when examining patients. All measurements were performed by the same examiner. The subject was instructed to maintain an upright head position with the lower jaw resting on the chin rest and the forehead positioned close to the forehead rest position. Prior to measurement, the subject was asked to blink several times to ensure tear film stability. The subjects were then required to keep their eyes open and focus on the target, with three consecutive measurements taken for each eye. The best quality image (quality specification = OK) was used for analysis to ensure the accuracy and reliability of the results. When measuring subjects, it is essential to maintain an interval of more than 5 min between the use of different devices. Sirius and Keratron Scout utilize a polar coordinate system to represent the pupil offset, that is, the planar distance (chord mu) and the angle between the pupil center and the corneal apex (the coordinate origin). The Pentacam measurement results utilize the XY Cartesian coordinate system, in which the pupil offset is defined as the vertical distance (Px and Py) between the corneal vertex, which serves as the coordinate origin, and the center of the pupil. The plane distance was calculated in millimetres (mm). The two coordinate systems were converted using built-in formulas in Excel software (2019, Microsoft Corp., Redmond, USA).

2.3 Statistical analysis

Statistical analyses and graph creation were conducted using MedCalc software (version 22.001; MedCalc, Ostend, Belgium) and OriginPro (version 2024; OriginLab, Northampton, USA). Measurement data are presented as mean ± standard deviation, range, and 95% confidence interval. The Shapiro–Wilk test was used to assess data normality. Repeated-measures analysis of variance was used to compare the overall differences in the chord my and Px and Py components. Assuming a significance level (α) of 0.05 for a two-sided test and a type II error (β) of 0.1, which corresponds to a test power of 0.9, the calculated sample size is determined to be at least 50 participants. The Bonferroni test was used for *post hoc* pairwise comparisons. The intraclass correlation coefficient (ICC) was used to assess the reliability of the measurements obtained using the three devices. Following the guidelines established by Terry K. Koo, an ICC estimate with a 95% confidence interval of <0.5 signifies poor reliability, while a range between 0.5 and 0.75 indicates acceptable reliability. Reliability in the medium range, classified as values between 0.75 and 0.9, indicates good reliability, while values above 0.90 signify excellent reliability (9). Bland–Altman analysis was employed to assess the consistency of the pairwise detection results among the three instruments, with the 95% consistency limit (mean ± 1.96 standard deviations) calculated as the consistency evaluation index. A polar coordinate scatter plot was used to illustrate the distribution of pupil shifts across the eyes. Statistical significance was set at $p < 0.05$.

3 Results

This study involved 292 eyes of 146 refractive candidates, comprising 81 males and 65 females. The demographic data and ocular parameters of the subjects are presented in Table 1. When measured by Pentacam, the average chord mu was 0.18 ± 0.10 (range: 0.02–0.57), the average Px was 0.00 ± 0.14 (range: −0.38 to 0.55), and the average Py was 0.09 ± 0.13 (range: −0.22 to 0.47). In contrast, when using the Keratron Scout to measure pupil offset, the average chord mu was 0.21 ± 0.11 (range: 0.01–0.64), the average Px was −0.02 ± 0.16 (range: −0.40 to 0.49), and the average Py was 0.10 ± 0.15

TABLE 1 Demographic data and ocular parameters of the subjects.

Parameter	Mean ± SD	Range	95% CI
Number of eyes (n)	292		
Sex (male/female)	81/65		
Age, years	24.60 ± 7.01	17–52	23.79–25.41
Spherical, D	−4.59 ± 1.99	−10.25 to 0.25	−4.82 to 4.36
Cylindrical, D	−0.93 ± 0.68	−4.75 to 0	−1.00 to 0.85
BCVA	1.17 ± 0.08	0.8–1.2	1.16–1.18
Corneal keratometry, D	43.95 ± 1.60	37.4–49.1	43.76–44.13
Axial length, mm	26.03 ± 0.98	23.73–28.36	25.91–26.14

BCVA, best corrected visual acuity.

(range: −0.29 to 0.60). Measurements taken with Sirius indicated an average pupil offset chord length of 0.18 ± 0.11 (range: 0.01–0.69), an average Px of −0.01 ± 0.13 (range: −0.33 to 0.46), and an average Py of 0.10 ± 0.13 (range: −0.31 to 0.65). The overall difference in the repeated measurement variance analysis of pupil offset across different devices is statistically significant ($p < 0.05$; see Table 2). A histogram illustrating the chord-length distribution of pupil deviation, as measured by the three devices, is presented in Figure 1. The proportions of the Pentacam, Keratron Scout, and Sirius devices that recorded pupil offset chords mu greater than 0.20 mm were 36.3% (106 eyes), 44.2% (129 eyes), and 34.6% (101 eyes), respectively. Additionally, the proportions of chords mu exceeding 0.41 mm were 3.4% (10 eyes), 4.8% (14 eyes), and 3.1% (9 eyes), respectively.

Table 3 presents the results of the pairwise comparison of the repeated-measures ANOVA conducted on the pupil offset across different devices. There was no statistically significant difference between chord mu and Py of the Sirius and Pentacam, or between Px and Py of the Sirius and Keratron Scout, with p-values of 0.416, 0.237, 0.118, and 0.472, respectively. The differences in pupil offset indicators between the Keratron Scout and Pentacam were statistically significant (both $p < 0.05$).

As illustrated in Table 4, the chords mu, Px, and Py of the pupil deviation measured using the three devices exhibited good consistency with ICCs of 0.817 (0.783–0.847), 0.900 (0.880–0.917), and 0.8553 (0.8276–0.8797), respectively. As illustrated in Figure 2, the Bland–Altman method was employed to assess the consistency of the pupil offset and to calculate the 95% limits of agreement (LoA). The Sirius and Keratron Scout demonstrated strong consistency in measuring chord mu and Px, with the 95% LoA being the narrowest at −0.15 to 0.08 and −0.11 to 0.13. Additionally, the measurement consistency of Py between Sirius and Pentacam was good, with the 95% LoA being the narrowest at −0.13 to 0.15.

Figure 3 illustrates the distribution of the pupil offsets. The upper half quadrants of both the left and right eyes exhibited a majority distribution. Specifically, the distribution percentages of the Pentacam, Keratron Scout, and Sirius devices in the upper half quadrant of the right eye were 71.92% (105 eyes), 77.40% (113 eyes), and 82.88% (121 eyes), respectively. The corresponding percentages for the left eye were 79.45% (116 eyes), 71.92% (105 eyes), and 74.66% (109 eyes).

4 Discussion

The cautery center for corneal ablation surgery is crucial for achieving optimal visual quality during the postoperative period. Most laser corneal refractive surgery platforms use the pupil center as a reference point. However, in cases with a large kappa angle, using the pupil as the cutting center can result in eccentric cutting, which may increase high-order aberrations, glare, and halos following surgery as well as visual quality issues such as monocular diplopia and diminished night vision (5, 10, 11). Reinstein et al. revealed that utilizing the corneal apex as the ablation center strategy resulted in no significant differences in postoperative safety, accuracy, induced astigmatism, contrast sensitivity, or night vision impairment between the two groups with pupil offsets chord mu of <0.25 mm and > 0.55 mm (12). The corneal vertex, being closer to the ideal cutting center (visual axis), serves as a more stable and preferred reference center for surgical procedures (2, 6). Accurate measurement of the relative position of the pupil center and the corneal apex (pupil offset) is critical to the success of surgery. Corneal topography devices such as Pentacam, Keratron Scout, and Sirius are commonly used to obtain pupil offset measurements. However, the measurement principles of these three instruments differ, and there are currently relatively few comparative studies that assess pupil deflection using all three instruments simultaneously. Therefore, this study aimed to compare the consistency and differences in pupil deflection measurement results among the three instruments to provide insights for clinical applications.

Previous research has demonstrated that the intra-class correlation coefficients of the Pentacam and Keratron Scout for measuring the pupil offset chords mu, Px, and Py in young myopic individuals are 0.82, 0.84, and 0.81, respectively (13). These findings suggest that the two devices exhibited good consistency. Furthermore, this study demonstrates that the intraclass correlation coefficients (ICC) for the three devices measuring pupil deviation, chord mu, Px, and Py, were 0.817, 0.900, and 0.855, respectively. These values are consistent with or even superior to those reported in the aforementioned study, indicating that the three devices exhibit strong consistency. The 95% consistency limit analysis of pupil offset indicated that Sirius and Keratron Scout exhibited superior consistency in measuring chord mu and Px, whereas Sirius and Pentacam demonstrated enhanced consistency in measuring Py. In clinical practice, it is recommended that more consistent equipment be used to compare different pupil offset components to enhance the accuracy of data collection.

This study found that the pupil offset chord mu, as measured using Pentacam, Keratron Scout, and Sirius, were 0.18 ± 0.10, 0.21 ± 0.11, and 0.18 ± 0.11, respectively. Sun et al. used Pentacam to assess pupil offset characteristics in Asians with high myopia (14). The average chord mu was found to be 0.18 ± 0.09 mm, which aligns closely with our findings, suggesting that young individuals in the same region exhibit similar pupil offset values. Reinstein et al. used Orbscan II to assess the pupil offset in 125 individuals with 250 myopic eyes (15). They reported a chord mu of 0.27 ± 0.14, which is greater than the measurements obtained in our study. The observed differences may be attributed to variations in the measuring equipment, as well as those related to race and region. Previous studies have demonstrated that, in wavefront aberration-guided corneal refractive surgery, a decentration of <0.2 mm can preserve good optical quality when the pupil diameter is 3.0 mm (16). Liu et al.

TABLE 2 Measurements of pupil offset and pupil diameter for three devices.

Parameter	Mean ± SD	Range	95% CI	F	*p* value
Chord Mu-Pentacam (mm)	0.18 ± 0.10	0.021–0.57	0.17–0.20	44.54	<0.001
Chord Mu-Keratron Scout (mm)	0.21 ± 0.11	0.01–0.64	0.20–0.22		
Chord Mu-Sirius (mm)	0.18 ± 0.11	0.01–0.69	0.17–0.19		
Px-Pentacam (mm)	0.00 ± 0.14	−0.38 to 0.55	−0.01 to 0.02	17.28	<0.001
Px-Keratron Scout (mm)	−0.02 ± 0.16	−0.40 to 0.49	−0.03 to 0		
Px-Sirius (mm)	−0.01 ± 0.13	−0.33 to 0.46	−0.02 to 0		
Py-Pentacam (mm)	0.09 ± 0.13	−0.22 to 0.47	0.07–0.10	4.50	0.012
Py-Keratron Scout (mm)	0.10 ± 0.15	−0.29 to 0.60	0.08–0.12		
Py-Sirius (mm)	0.10 ± 0.13	−0.31 to 0.65	0.08–0.11		
PD-Pentacam (mm)	3.26 ± 0.23	1.70–5.50	3.10–3.30	231.64	<0.001
PD-Keratron Scout (mm)	3.87 ± 0.55	2.25–5.77	3.77–3.94		
PD-Sirius (mm)	3.48 ± 0.50	2.30–5.27	3.37–3.55		

PD, pupil diameter; SD, standard deviation; CI, confidence interval.

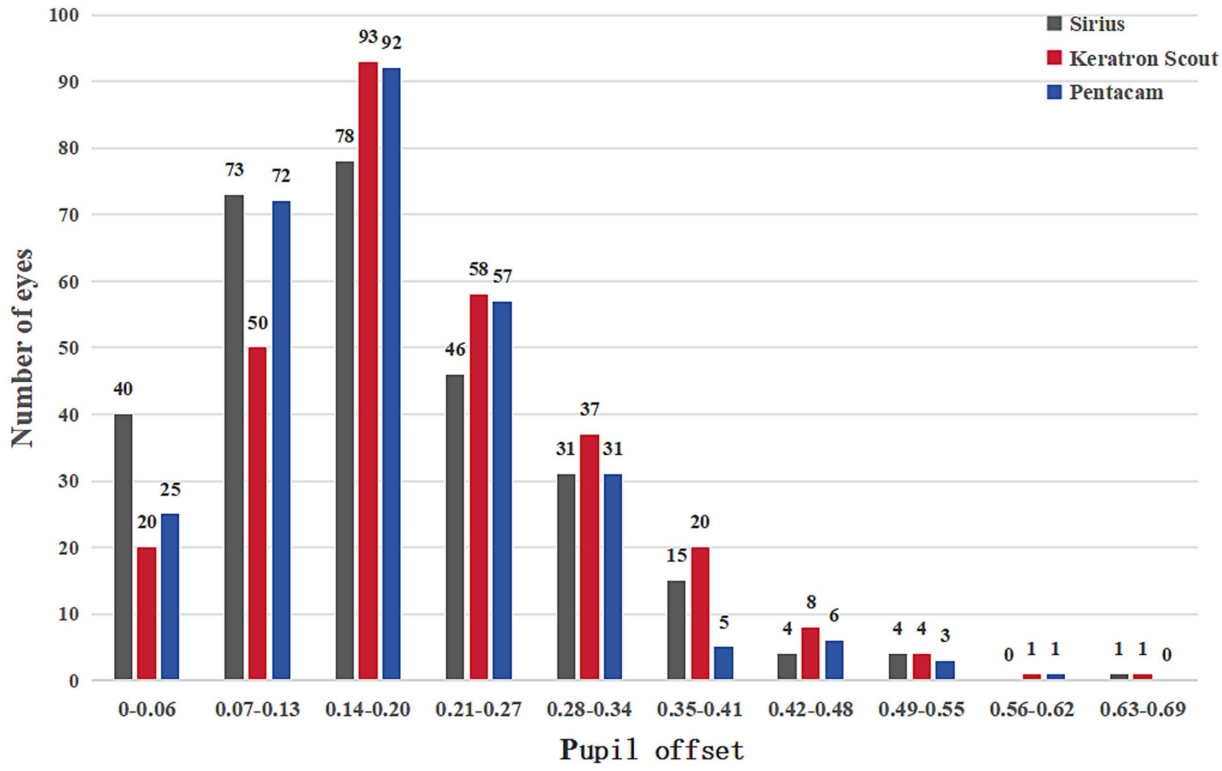

FIGURE 1
The Bland-Altman diagram illustrates the pairwise comparison of the consistency of the three devices in measuring the pupil offsets.

analyzed the relationship between postoperative higher-order aberrations and preoperative pupil offset following femtosecond laser-assisted *in situ* keratomileusis (5). They found that when the chord mu exceeded 0.2 mm, there was a more pronounced increase in postoperative higher-order aberrations. In this study, the proportion of pupil offset was greater than 0.2 mm, while the chord mu ranged from 34.6 to 44.3%. Additionally, the proportion of chord mu exceeding 0.4 mm was between 3.1 and 4.8%, which was consistent with the findings of Sun et al. (14). Therefore, individuals with significant pupil deviation should prioritize the alignment strategy of the cutting center and adjust the pupil offset to ensure optimal postoperative visual quality.

Through repeated-measures analysis of variance, post-hoc pairwise comparisons revealed that the differences in string mu, Px, and Py between the Pentacam and Keratron Scout, as well as the differences in Px between the Pentacam and Sirius and in string mu

TABLE 3 *Post hoc* test of repeated measures ANOVA on pupil offset measurements using three devices.

Parameter	Mean ± SD	95% CI	p value
Chord Mu: Sirius-Pentacam	−0.006	−0.015 to 0.004	0.416
Chord Mu: Sirius-Keratron Scout	−0.033	−0.041 to 0.025	<0.001
Chord Mu: Keratron Scout-Pentacam	0.027	0.018–0.037	<0.001
Px: Sirius-Pentacam	−0.014	−0.023 to 0.006	<0.001
Px: Sirius-Keratron Scout	0.007	−0.001 to 0.016	0.118
Px: Keratron Scout-Pentacam	−0.022	−0.032 to 0.012	<0.001
Py: Sirius-Pentacam	0.007	−0.003 to 0.018	0.237
Py: Sirius-Keratron Scout	−0.005	−0.014 to 0.004	0.472
Py: Keratron Scout-Pentacam	0.013	0.001–0.024	0.025
PD: Sirius-Pentacam	0.221	0.141–0.301	<0.001
PD: Sirius-Keratron Scout	−0.387	−0.448 to −0.327	<0.001
PD: Keratron Scout-Pentacam	0.609	0.544 to 0.674	<0.001

PD, pupil diameter; SD, standard deviation; CI, confidence interval.

TABLE 4 Intraclass correlation coefficient (ICC) test of pupil shift for three devices.

Parameter	ICC	95% CI
Chord Mu (mm)	0.817	0.783–0.847
Px (mm)	0.900	0.880–0.917
Py (mm)	0.855	0.828–0.880

ICC, intraclass correlation coefficient; CL, Confidence interval.

between the Keratron Scout and Sirius, were all statistically significant. The differences in certain pupil offset parameters between the three devices can be attributed to several factors. The measurement principles were different for three devices. Pentacam employs a 360-degree rotating Scheimpflug camera to conduct tomographic scanning of the cornea. It captures 25 cross-sectional Scheimpflug images within a span of 2 s and gathers 69,000 data points to reconstruct the three-dimensional structure of the cornea (17, 18). The Keratron Scout corneal topographer measures the shape of the anterior surface of the cornea using a small cone Placido disk, providing instantaneous measurement (8). Siriu integrated a rotating Scheimpflug camera with a corneal topography system and a Placido disk, enabling the acquisition of 35,632 points on the anterior surface of the cornea and 30,000 points on the posterior surface. This combination produced reliable anterior segment measurements (7).

The distribution of the pupil center relative to the corneal apex can be represented by the XY Cartesian coordinate system. Qin et al. analyzed data from 113 patients with cataracts, comprising 60 right eyes and 53 left eyes (19). Their study revealed that the pupil centers of most patients were located on the temporal side of the corneal apex. In contrast, our study indicated that the pupil centers of both eyes were predominantly distributed in an upward direction. These differences may be attributed to variations in age distribution, lens transparency, and sample sizes between the two studies. Differences in the pupil diameter measurements obtained using various devices may result in different pupil offsets. Although all three devices were utilized in the same examination room during the measurement process, discrepancies in color, intensity, and range of illumination across different devices can lead to variations in pupil diameter. Our results indicate that the pupil diameter, ranked from largest to smallest, is as follows: Keratron Scout, Sirius, and Pentacam.

Huang et al. found that in eyes with high astigmatism undergoing femtosecond laser small incision microlens extraction, an eccentricity >0.2 mm results in increased coma and spherical aberration following surgery (20). Liu et al. found that for individuals undergoing SMILE surgery when the chord mu was <0.2 mm, there was no significant difference in postoperative total eccentric displacement and higher-order aberration between the pupil center group and the tear film mark center group (21). The average differences in the string mu of the three devices range from 0.01 to 0.03 mm, with Px measuring between 0.01 and 0.02 mm and Py at 0.01 mm. Although these differences were statistically significant, they did not have a significant impact on clinical practice.

This study had several limitations. First, the population primarily included myopic individuals planning to undergo refractive surgery, whereas emmetropic and hyperopic individuals were not represented. Research has indicated that there are notable differences in pupil deviation among individuals with varying refractive statuses (15). Second, pupillary shifts have been extensively utilized in the field of refractive cataract surgery (19). The population included in this study predominantly comprised younger individuals; older adults were excluded. Finally, this study did not comprehensively account for other ocular parameters. Future research should aim to incorporate a larger sample size, a broader spectrum of refractive statuses, and age distributions to analyze the relationship between additional ocular parameters and pupil deviation, thereby providing valuable insights into the clinical practice of refractive surgery.

5 Conclusion

In summary, the Pentacam, Keratron Scout, and Sirius exhibited strong consistency in measuring pupillary shifts among young patients with myopia. Consequently, the three devices can be used as reliable references for one another in clinical practice.

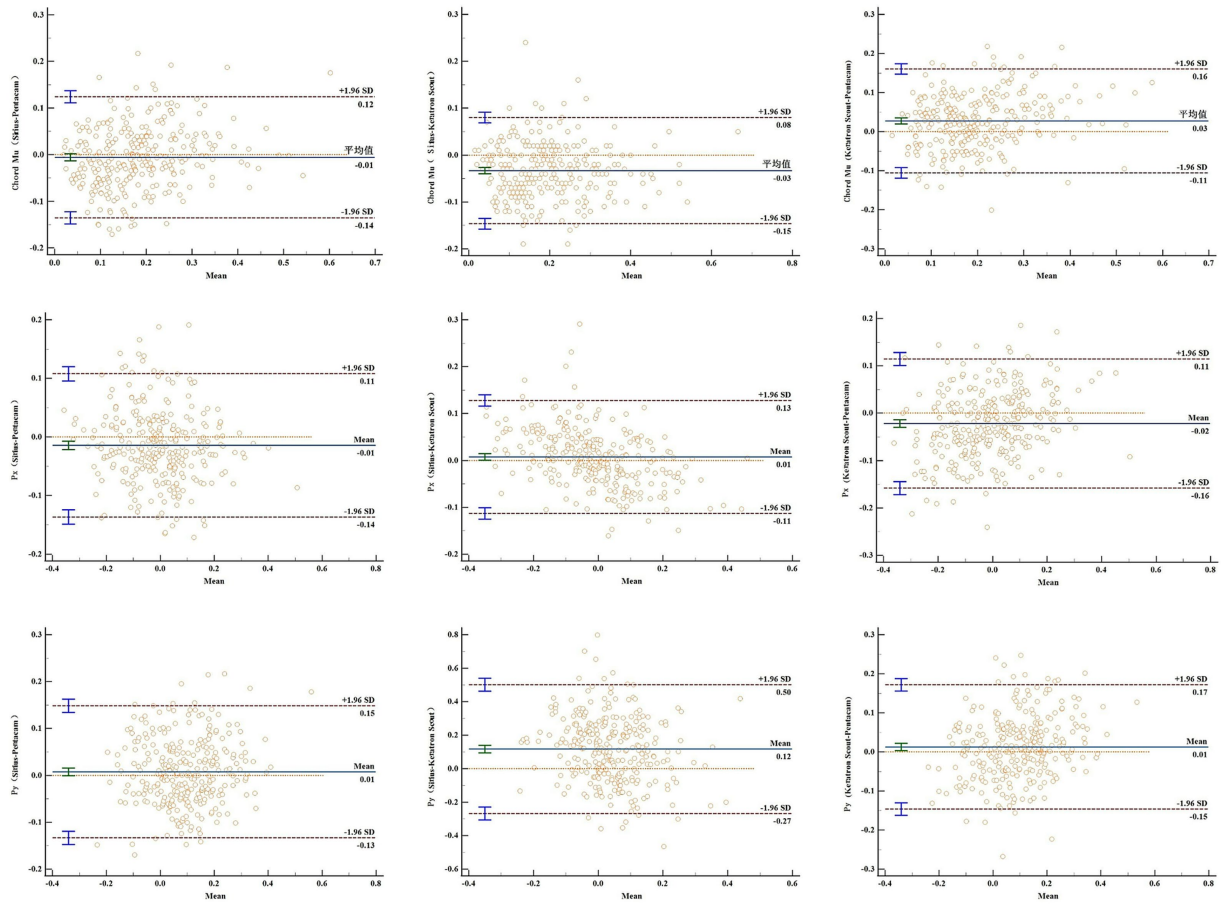

FIGURE 2
Histogram of pupil offset chord mu distribution measured using three devices.

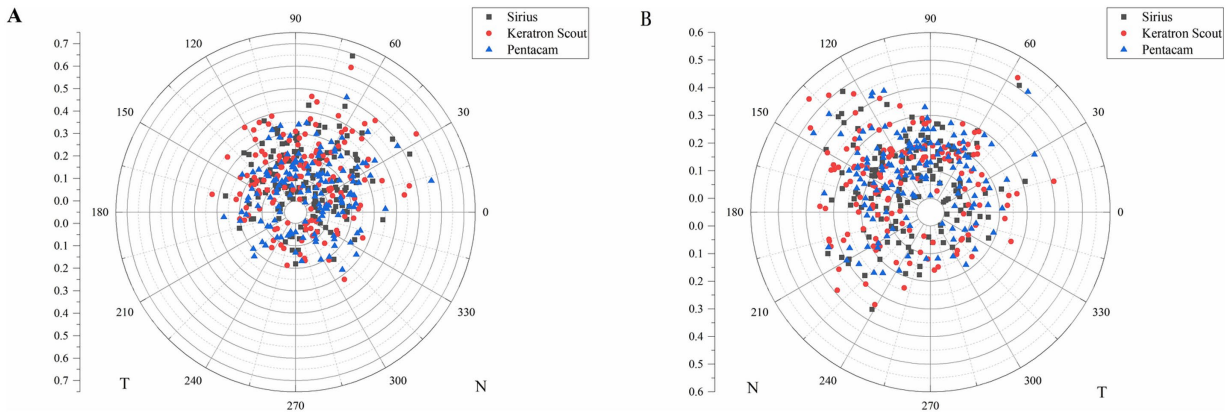

FIGURE 3
The distribution of pupil offset of the right (A) and left (B) eyes in the polar scatter plot. T: temporal, N: nasal.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Ethics Committee of the Dalian Third People's Hospital. The studies were

conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants or the participants' legal guardians/next of kin because this study is a retrospective analysis, and waiving informed consent will not adversely affect the rights or health of the research participants; rather, it will help to protect their privacy.

Author contributions

JN: Conceptualization, Investigation, Software, Supervision, Validation, Visualization, Writing – original draft, Writing – review & editing. LZ: Conceptualization, Data curation, Methodology, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Outcomes of mini-monovision with monofocal, enhanced monofocal and extended depth-of-focus intraocular lenses

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Purpose: Mini-monovision is a vision correction technique that allows for a broader spectrum of spectacle independence while minimizing anisometropia. This systemic review aims to evaluate the clinical outcomes of pseudophakic mini-monovision with three types of intraocular lenses (IOLs): monofocal, enhanced monofocal, and extended depth of focus (EDOF).

Methods: A comprehensive literature search was conducted using PubMed and MEDLINE to identify studies reporting mini-monovision outcomes within the three categories of IOLs up to July 2024. Inclusion criteria were studies with more than 20 patients, target refraction to achieve mini-monovision difference in the fellow eye, and minimum follow-up of 3 months. The primary outcome measure was uncorrected binocular intermediate visual acuity (UCIVA). The secondary outcomes were binocular uncorrected distance visual acuity (UCDVA), binocular uncorrected near visual acuity (UCNVA), patient-reported outcomes measures (PROMs), spectacle independence, contrast sensitivity, photic phenomenon, enhancement surgeries and IOL exchange.

Results: A total of 113 studies were screened, of which 19, with a total of 1,530 patients, were eligible for inclusion in this review. Mean logMAR binocular UCIVA was 0.16 ± 0.01, 0.11 ± 0.06, 0.08 ± 0.07 (p = 0.41), and mean logMAR UCDVA was 0.08 ± 0.05, 0.04 ± 07, 0.04 ± 0.04 (p = 0.36), in the monofocal, enhanced monofocal, and EDOF groups, respectively. The mean spectacle independence rate was 51% ± 22.1, 55% ± 35.4 and 63.4% ± 24.6 (p = 0.05), respectively, in the monofocal, enhanced monofocal and EDOF groups. A comparable low incidence of halos and glare was observed when enhanced monofocal lenses were evaluated against traditional monofocal lenses. EDOF lenses have, however, demonstrated mixed results. The complications, IOL exchange, and excimer laser enhancement rates were low across all groups.

Conclusion: While enhanced monofocal and EDOF IOLs may provide slightly better binocular intermediate visual outcomes and higher spectacle independence compared to monofocal lenses with regards to mini-monovision and intermediate vision performance, the differences are not statistically significant. All three IOL types exhibit high patient satisfaction

rates when choosing a mini-monovision approach with decreased dependence on spectacles.

KEYWORDS

mini-monovision, enhanced monofocal intraocular lenses, extended depth of focus intraocular lens, monofocal intraocular lens, intermediate visual acuity

Introduction

In the ever-evolving landscape of cataract surgery, the scales have now tilted more toward providing refractive correction rather than its original purpose of visual rehabilitation. Advances and innovations in technology have significantly improved the surgical management of presbyopia (1). Given the change in visual needs over time, patients' expectations for excellent visual performance and spectacle independence not only for distant vision but also for intermediate and near, mainly due to daily tasks that require this range of vision (tablet and smartphone reading, working on computers, driving), have substantially increased (2). Current armamentarium of pseudophakic presbyopia corrections for cataract surgeons primarily include (1) implantation of multifocal intraocular lenses (IOLs), (2) implantation of extended-depth of focus (EDOF) IOLs (3), (3) implantation of accommodative IOLs, and (4) pseudophakic monovision with monofocal IOLs (4).

Multifocal IOLs usually provide high rates of spectacle independence; however, they could be associated with visually significant photic phenomena due to light distribution into multiple foci, especially if patient selection is inappropriate (5–7). Traditional monovision with monofocal IOLs, wherein the dominant eye is targeted for distance emmetropia and the non-dominant is targeted for a near emmetropia leaving a residual myopic error, has been used to overcome the photic phenomena of multifocal IOLs. More recently, mini-monovision with monofocal IOLs, wherein the non-dominant eye is targeted for a relatively smaller residual myopia of −0.75 D to −1.50 D, has been employed and has achieved similar results. This technique also helps in reducing to a greater extent the rate of positive dysphotopsias, being harmless for stereopsis compared to traditional monovision (8). When the non-dominant eye is chosen for distance vision, the technique is crossed monovision. The prevalence of monovision or mini-monovision after cataract surgery is rarely reported in the literature and varies according to clinical practices and the studied population, ranging from 22 to 34% (9). The prevalence can depend on factors such as patient preference, surgeon recommendation, and pre-surgical considerations like the patient's tolerance to anisometropia (9).

In the hybrid monovision technique, a diffractive multifocal IOL is implanted in the non-dominant eye, whereas a monofocal IOL is implanted in the dominant eye (2). The most widely used approach is the implantation of monofocal IOL in both eyes because of the relatively low-cost of monofocal lenses and satisfying performances for far vision restoration (8, 10).

Extended depth of focus IOLs create an elongated focal point to extend the range of vision and decrease photic phenomena by eliminating overlapping far and near images, thereby accepting some compromise for near-vision (3, 11, 12). The mini-monovision approach has also been successfully adopted with EDOF IOLs (13–20). Another strategy is to employ so-called enhanced monofocal IOLs. These IOLs possess a high-order aspheric anterior surface with a continuous change in power from the periphery toward the lens center (21). This characteristic creates a modified anterior surface with a small central zone designed to extend the depth of focus and consequently improve intermediate vision while maintaining good performance at a distance (22–24) and higher patient satisfaction than classic monofocal IOL (25–28). This maintains a profile similar to photic phenomena in aspheric monofocal IOLs (28). Mini-monovision with these enhanced monofocal IOLs also improves patient satisfaction with low dysphotopsia (21, 29, 30).

The primary objective of this study was to review published literature regarding the efficacy of pseudophakic mini-monovision using monofocal, enhanced monofocal and EDOF IOLs in the correction of presbyopia after cataract extraction in comparison to each other, based on objective parameters, including visual acuity (VA) at near, intermediate and distance and possible complications postoperatively and subjective parameters like patient satisfaction and spectacle independence.

Materials and methods

A comprehensive literature search was conducted to identify studies reporting mini-monovision outcomes after cataract surgery. We included studies that specify mini-monovision refraction targeting in their abstract. We compared three different intra-ocular lens types: monofocal, enhanced monofocal and EDOF IOLs. Inclusion criteria were retrospective or prospective studies published until August 2024 with a minimum of 20 patients and a minimum follow-up of 3 months published in peer-reviewed journals. Studies not published in the English language were excluded.

A systematic literature search for related studies was carried out on PubMed and MEDLINE using the Medical Subject Headings (MeSH) terms "mini-monovision," "monovision," "monofocal," "pseudophakic mini-monovision," "enhanced monofocal," "EDOF" and "extended depth of focus." The Boolean operators "AND" and "OR" combined these MeSH terms and search studies on mini monovision with either of the three IOLs. The initial search was performed without any filters or language restrictions. Data published in any other language but English was excluded from the study. The titles and abstracts resulting from the searches were reviewed. A full-text copy of all potentially relevant studies was reviewed for eligibility, and only those studying mini monovision

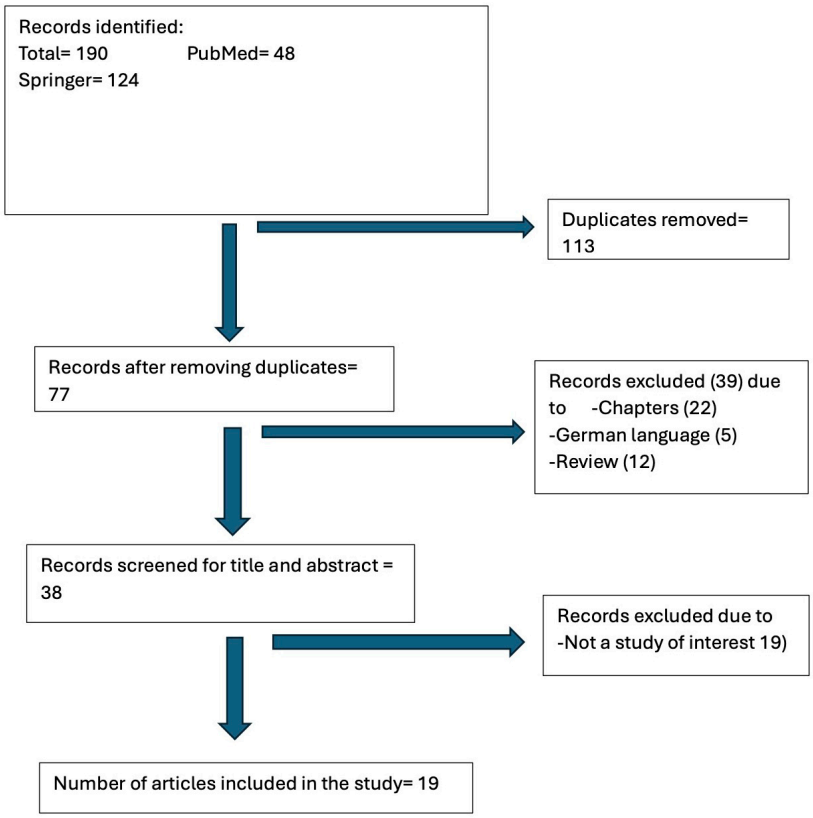

FIGURE 1
Study flowchart.

using monofocal, enhanced monofocal or EDOF IOLs were included in the study.

The risk of bias in the articles was assessed using the RoB version 2 tool which considered the following factors: Random sequence generation and allocation concealment (selection bias), blinding of participants (performance bias), blinding of outcome assessment (detection bias), missing outcome data (attrition bias) and selective reporting (reporting bias).

Data collection was performed on an Excel 365 spreadsheet (Microsoft, Redmond, WA, United States) outlining all the relevant parameters. The primary outcome measure was uncorrected binocular intermediate visual acuity (UCIVA). The secondary outcomes were binocular uncorrected distance visual acuity (UCDVA), binocular uncorrected near visual acuity (UCNVA), patient-reported outcomes measures (PROMs), spectacle independence, contrast sensitivity, photic phenomenon, enhancement surgeries and IOL exchange. One review author inputted the data into the spreadsheets; another author re-checked and validated it. Any disagreements regarding the inclusion or exclusion of the studies were resolved through discussion among the authors. We used the data from the latest follow-up visit. The Kolmogorov–Smirnov test was performed to assess the normality of the data distribution, and it was found to have a normal distribution. Then, statistical analysis was performed using Single-factor ANOVA to assess the differences across groups. The level of statistical significance is set at $P < 0.05$. All visual acuity data were standardized by converting them to logMAR format when originally presented in Snellen or decimal formats. This conversion allowed for uniformity in the measurement scale, enabling more precise statistical interpretation and comparison across datasets. Of all the studies in the three different categories, only Sevik et al. (16) and Lee (20) from the EDOF group reported statistical powers of 0.8 and 0.9, respectively.

Results

This review included a total of 19 studies published over 17 years involving 1,530 patients (Figure 1). A total of one German article, four German Conference abstracts, 22 chapters and 12 Review articles were excluded (Supplementary Table 1). There were seven studies within the monofocal group (31–37) four in the enhanced monofocal group (22, 38–40), and eight in the EDOF group (13–16, 20, 41–43). The included studies are summarized in Table 1 and the overall demographics in Table 2.

Primary outcome

In the monofocal group the binocular UCIVA was reported only in three of these studies (33, 35, 36). Two studies found a mean of 0.16 ± 0.01 logMAR (criteria of monovision as target postoperative refraction between −0.75 D and −1 D) (35, 37) and one (34) described 0.3 logMAR or better in 73% of the patients

TABLE 1 All included studies.

	Study	Number of patients	Mean age	Gender (Female%)	F/U period (months)	Refractive aim in the non-dominant eye	Binocular UIVA (LogMar)	Binocular UDVA (LogMar)	Binocular UNVA (LogMar)	Spectacle independence (%)	Limitations
Monofocal lens											
1	Wróbel-Dudziñska et al. (31)	463	63.5 ± 11.29	48	120	−0.75 to −1.5	NA	0.16 ± 0.20	0.05 ± 0.1	72	Retrospective, non-comparative.
2	Goldberg et al. (32)	56	67.5	44	6	−1.25 to −1.50	NA	0.09 ± 0.09	0.15 ± 0.14	73	Limited number of activities assessed in the questionnaire, and the lack of comparison data on patient satisfaction outcomes with other options.
3	Hafez and Helaly (37)	30	56.3 ± 5.5	33.00	3	−1 to −1.5	0.17 ± 0.14	0.09 ± 0.07	0.31 ± 0.19	43	Retrospective, small sample size, lack of comparative group, short follow-up.
4	Chen et al. (33)	20	NA	50	3	−0.50 to −1.25	NA	Better than 0.2 in all the patients	Better than 0.3 in all the patients	35	Retrospective, small sample size, short follow-up.
5	Zhang et al. (34)	22	67	68.18	3	−2.00ˉ	0.3 or better in 73%	0.1 or better in 86%	0.1 or better in 91%	77	Retrospective, small sample size, short follow-up.
6	Wilkins et al. (35)	73	68.7 ± 12	57.5	4	−1 to −1.5	0.15 ± 0.12	0.06 ±0.16	0.01 ±0.12	25.8	Short follow-up
7	Labiris et al. (36)	38	59.5 ± 10.4	52	6	−1.25	NA	0.02	0.14	31.4	Small sample size.
Enhanced monofocal lens											
1	Park et al. (22)	25	71.92 ± 9.98	−52	3	−0.75	0.12 ± 0.09	0.1 ± 0.11	0.06 ± 0.06	80	Short follow-up, small sample size., Short follow-up
2	Beltraminelli et al. (38)	37	73.24 ± 1.13	51.35	3	−0.50 to −1.25	0.1	0.1	0.35	NA	Retrospective, small sample size, short follow-up.
3	Dell et al. (39)	383	60.07 ± 8.37	47.8	1	= −0.50 D	0.18 ± 0.18	−0.03 ± 0.1	0.42 ± 0.19	Overall satisfaction 93.2	Retrospective, short follow-up.
4	Sandoval et al. (40)	37	70 ± 4	37.84	3	−0.75 D	0.04	0	0.21	30	Retrospective, small sample size, short follow-up.

(Continued)

10.3389/fmed.2025.1522383

TABLE 1 (Continued)

	Study	Number of patients	Mean age	Gender (Female%)	F/U period (months)	Refractive aim in the non-dominant eye	Binocular UIVA (LogMar)	Binocular UDVA (LogMar)	Binocular UNVA (LogMar)	Spectacle independence (%)	Limitations
EDOF lens											
1	Won et al. (13)	27	63.19 ± 3.95	59.3	3	−0.1 to −0.5	−0.03 ± 0.07	0.07 ± 0.1	0.22 ± 0.12	NA	Retrospective, small sample size, short follow-up.
2	Campos (14)	20	65.00	50	3	−0.50	0.18 ± 0.16	0.09 ± 0.25	0.32 ± 0.10	65.00	Retrospective, small sample size, short follow-up.
3	Tomagova et al. (41)	62	70.60	44	3	−0.50	0.13 ± 0.11	−0.02 ± 0.07	0.4 ± 0.20	34.00	Retrospective, non-comparative, short follow-up
4	Kim et al. (42)	61	61.80	59	24	−0.60	0.056 ± 0.04	0.086 ± 0.09	0.14 ± 0.05	85.00	Retrospective, non-comparative
5	Sevik et al. (16)	14	63.43	42.86	6	−0.50	−0.03 ± 0.07	−0.03 ± 0.05	0.15 ± 0.07	85.70	Small sample size
6	Fernandes et al. (15)	63	68.50	74	3	−0.75	NA	0.05 ± 0.01	0.16 ± 0.03	75.00	Short follow-up
		66	68.00	68	3	−0.75	NA	0.06 ± 0.01	0.21 ± 0.02	75.00	
7	Vasavada et al. (43)	33	60.96	45.7	6	= 0.5 to = 0.75 D	0.07 ± 0.08	0.028 ± 0.05	0.22 ± 0.03	24.20	Small sample size
8	Lee (20)	30	61.60	53	3	−0.50	0.1 ±0.1	0.06 ± 0.12	0.27 ± 0.10	NA	Retrospective, small sample size, non-comparative, short follow-up.

F/U, follow up; UCIVA, uncorrected intermediate visual acuity; UCDVA, uncorrected distance visual acuity; UCNVA, uncorrected near visual acuity; EDOF, extended depth of focus.

10.3389/fmed.2025.1522383

TABLE 2 Overall demographics.

IOL type	Number of studies	Follow-up period (months)	Number of patients	Age (years)	Gender (female %)
Monofocal	7 (30–36)	20.7 ± 43.8	100.3 ±63.8	63.7 ± 5	40.8 ± 22.3
Enhanced monofocal	4 (21, 3–39)	2.5 ± 1.2	120.5 ± 203.3	68.8 ± 7.3	47.3 ± 2.3
EDOF	8 (13–16, 40–43)	8.4 ± 9.6	44 ± 22.4	64.1 ± 3.7	58.1 ± 15.5

TABLE 3 The secondary outcomes.

Outcome	Monofocal	Enhanced monofocal	EDOF	*P*-value
Binocular UCDVA	0.08 ± 0.05 (*n*=5)	0.04 ± 0.07 (*n*=4)	0.04 ± 0.04 (*n*=8)	0.34
Binocular UCNVA	0.13 ± 0.11 (*n*=5)	0.26 ± 0.16 (*n*=4)	0.20 ± 0.11 (*n*=8)	0.36
Spectacle independence	51 ± 22.12% (*n*=7)	55% ± 35.4 (*n*=2)	63.4 ± 24.6% (*n*=6)	0.79
Contrast sensitivity*	1.69 ± 0.4 (*n*=2)	–	1.55 ± 0.03 (*n*=3)	–

*Pellie Robson contrast sensitivity test.

(criteria of mini-monovision as target postoperative refraction approximately −2 D) (Table 1). In the enhanced monofocal group the mean binocular UCIVA was 0.11 ± 0.06 logMAR (criteria of mini-monovision as target postoperative refraction between −0.50 D and −0.75 D) and in the EDOF group the mean binocular UCIVA was 0.08 ± 0.07 logMAR (criteria of mini-monovision as target postoperative refraction in all studies up to −0.75 D), respectively. No statistically significant difference was found between the different intraocular lens types ($p = 0.41$) (Table 1).

Secondary outcomes

There was no statistically significant difference when comparing mean binocular UDCVA, UCNVA and spectacle independence rates between the different intraocular lens types. The main secondary outcomes are presented in Table 3.

Patient-reported outcomes measures

Spectacle independence

The mini-monovision technique demonstrated that the three types of IOL groups achieved an overall spectacle independence of 50% or more. Patients reported high satisfaction levels, with low rates of needing refractive correction for distance and intermediate vision. Additionally, no statistical differences were observed between the groups ($p = 0.78$). Within the monofocal group, patients reported a high satisfaction rate with high variability of nearly complete spectacle independence from 25 to 77% (31–37). In the enhanced monofocal group–all studies showed a high satisfaction rate ranging from 84 to 96%, (22, 40) with most patients reporting they would recommend the procedure to others (39). EDOF group– patients showed a high satisfaction rate and variable complete spectacle independent rate from 24 to 75% (13–16, 41–43).

Quality of vision

Studies comparing contrast sensitivity performance in enhanced monofocal lenses versus traditional monofocal lenses found good performance and no statistically significant difference under low and high luminance conditions for any spatial frequency (22, 38, 40, 44).

In the monofocal group, studies observed minimal to no occurrences of clinically significant photic phenomena. Although some studies reported an absence of halos and glare, it is important to note that these studies did not directly inquire about patients' experiences (31, 32, 37). As expected, significantly fewer complaints of positive photopic phenomena were found compared to those reported with multifocal lenses (1–3, 34–36). A comparable low incidence of halos and glare was observed when enhanced monofocal lenses were evaluated against traditional monofocal lenses (22, 39, 40, 44). EDOF lenses have, however, demonstrated mixed results. Some studies found a similar rate of positive photopic phenomena as in traditional monofocal lenses (16, 20, 43) whilst others experienced frequent halos and glare (14, 41).

Rates of repeat surgical procedures

Intraocular lenses exchange can be offered in cases of patient dissatisfaction due to non-resolved, intolerable, positive dysphotopsias, residual refractive error, or refractive surprise. IOL exchange rate and secondary corneal enhancement therapy were reported only within the monofocal groups. Only two studies provided data on the incidence of secondary corneal enhancement procedures performed via laser vision correction. One study recorded an incidence of 1%, whereas the other reported an incidence of 9.7% (31, 35). Four studies (31, 32, 34, 35) provided data on intraocular lens exchange rate. Goldberg et al. (32) reported an exchange rate of 3.6%, corresponding to two patients, while three other studies indicated no cases of IOL exchange (2–4).

Risk of bias

Six randomized controlled trials [Labiris et al. (36), Sandoval et al. (40), Wilkins et al. (35), Sandoval et al. (17), Sevik et al. (16), Vasavada et al. (43)] were assessed for risk of bias using RoB tool version 2 under five domains (Table 4). Four trials employed the method of computerized randomization and were assessed as low risk. The methods of randomization and allocation concealment employed by Sandoval et al. (40) and Sevik et al. (16) have not been

TABLE 4 Risk of bias.

Signaling questions	Labiris et al. (36)	Sandoval et al. (40)	Wilkins et al. (35)	Sevik et al. (17)	Fernandes et al. (16)	Vasavada et al. (43)
Domain 1: risk of bias arising from the randomization process						
Was the allocation sequence random?	Y/PY	NI	PY/Y	PY/Y	NI	Y/PY
–	Custom computer randomization program used	Not specified	A minimization program was used	Online integer generator used	Not specified	Computer generated random number tables used
Was the allocation sequence concealed until participants were enrolled and assigned to interventions?	Y/PY	NI	PY/Y	Y/PY	Y/PY	Y/PY
Did baseline differences between intervention groups suggest a problem with the randomization process?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Risk-of-bias judgment	Low	Some concerns	Low	Low	Some concerns	Low
Domain 2: risk of bias due to deviations from the intended interventions (effect of assignment to intervention)						
Were participants aware of their assigned intervention during the trial?	NI	PN/N NI	N/PN	Y/PY	PN/N	Y/PY
Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	PY/Y		PY/Y	NI	NI	NI
Were there deviations from the intended intervention that arose because of the trial context?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Was an appropriate analysis used to estimate the effect of assignment to intervention?	Y/PY	Y/PY	Y/PY	Y/PY	Y/PY	Y/PY
Risk-of-bias judgment	Low	Low	Low	Low	Low	Low
Domain 2: risk of bias due to deviations from the intended interventions (effect of adhering to intervention)						
Were participants aware of their assigned intervention during the trial?	NI	Y/PY NI	Y/PY	Y/PY	Y/PY	Y/PY
Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?	NI	–	PY	NI	NI	NI
Were important non-protocol interventions balanced across intervention groups?	Y/PY	Y/PY	NI	Y/PY	Y/PY	Y/PY
Were there failures in implementing the intervention that could have affected the outcome?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Was there non-adherence to the assigned intervention regimen that could have affected participants' outcomes?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Was an appropriate analysis used to estimate the effect of adhering to the intervention?	NI	NI	NI	NI	NI	NI
Risk-of-bias judgment	Low	Low	Low	Low	Low	Low
Domain 3: missing outcome data						
Were data for this outcome available for all, or nearly all, participants randomized?	Y/PY	Y/PY	Y/PY	Y/PY	Y/PY	Y/PY
Risk-of-bias judgment	Low	Low	Low	Low	Low	Low

(Continued)

TABLE 4 (Continued)

Signaling questions	Labiris et al. (36)	Sandoval et al. (40)	Wilkins et al. (35)	Sevik et al. (17)	Fernandes et al. (16)	Vasavada et al. (43)
Domain 4: risk of bias in measurement of the outcome						
Was the method of measuring the outcome inappropriate?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Could measurement or ascertainment of the outcome have differed between intervention groups?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Were outcome assessors aware of the intervention received by study participants?	Y/PY	Y/PY	PN/N	PN/N	PN/N	PN/N
Could assessment of the outcome have been influenced by knowledge of intervention received?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Risk-of-bias judgment	Low	Low	Low	Low	Low	Low
Domain 5: risk of bias in selection of the reported result						
Were the data that produced this result analyzed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?	NI	NI	NI	PN/N	PN/N	PN/N
Is the numerical result being assessed likely to have been selected, on the basis of the results, from	–	–	–	–	–	–
.... multiple eligible outcome measurements (e.g., scales, definitions, time points) within the outcome domain?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
... multiple eligible analyses of the data?	PN/N	PN/N	PN/N	PN/N	PN/N	PN/N
Risk-of-bias judgment	Low	Low	Low	Low	Low	Low
Overall risk of bias						
Risk-of-bias judgment	Low	Some concerns	Low	Low	Some concerns	Low

Y, yes; PY, probably yes, NI, not included; N, no; PN, probably no.

specified, and there could be some concerns pertaining to the risk of bias in these trials. Low risk of bias was seen in the rest of the domains for all trials. Assessment of risk of bias using RoB 2 tool could not be performed for the remaining thirteen studies, as they are observational studies.

Discussion

Our review of 19 studies, including 1,530 patients, found that the mini-monovision technique in cataract surgery, whether using traditional monofocal lenses or more advanced options like enhanced monofocal or EDOF lenses, can be an effective alternative for patients seeking glasses independence (Table 1). The definition of mini-monovision targeting low myopia varies in the literature from a residual refractive error of −0.75 D to −2.00 D in the non-dominant eye (Table 1).

Traditional cataract surgery, involving monofocal lens implantation, significantly improves visual acuity, predominantly for distance vision. However, these lenses offer a limited depth of focus, resulting in a considerable reliance on refractive correction for various daily activities in the intermediate and near vision ranges. The increasing working age and the increased use of computers, tablets, and smartphones as an integral part of almost every daily activity results in decreased functional vision and the need for a cost-effective solution (45). Today, we can offer several types of IOLs to help our patients gain functional vision at a broader range of distances (2), Patients have varying needs and personalities, and some may have ocular comorbidities that can impact their vision. Considering these factors, it's essential to tailor the choice of intraocular lens to each individual. Multifocal IOLs can provide a wide range of vision; however, they may also lead to an increase in positive dysphotopsias, and a decrease in contrast sensitivity and overall visual quality. Therefore, these lenses are not suitable for everyone (5, 46, 47). As discussed earlier, enhanced monofocal and EDOF IOLs can improve depth-of-focus while providing better intermediate visual acuity and maintaining vision quality similar to monofocal IOLs (48).

We found no statistically significant differences in binocular UCIVA, UCDVA and UCNVA between the three lens types (Table 1). Enhanced monofocal and EDOF lenses, engineered to provide a broader range of vision, did not show significant

clinical advantages in this review with regard to UCIVA with mini-monovision (Tables 1, 3). Current literature suggests enhanced monofocal lenses perform slightly better or are comparable to standard monofocal lenses in the distance and intermediate vision (20). In contrast, EDOF lenses are associated with improved intermediate and near visual acuity outcomes (25–30, 49–51).

Patient satisfaction was homogeneously high across all three groups, with most patients reporting positive experience and a decreased need for refractive correction. Spectacle independence rates were reported across all three groups, with rates above 50% in most studies. Enhanced monofocal and EDOF lenses showed slightly incremental improvement, but the difference was not statistically significant. This suggests that monofocal lenses still provide reasonable spectacle independence when using the mini-monovision technique. Although we did not find statistically significant difference in the primary outcomes of UCIVA between the groups, it has to be noted the mean UCIVA was best with EDOF, followed by enhanced monofocal and then monofocal lens (Table 1). Similarly although there was no statistically significant difference in mean percentage of patients achieving spectacle independence (Table 3), spectacle independence was highest in EDOF, followed by enhanced monofocal and then monofocal groups, respectively (Table 3). The lack of statistical significant despite of changes in mean UCIVA and spectacle independence may be attributable to low number included studies in each group, variable definition of mini-monovision used and variations in study designs.

Contrast sensitivity is essential for good functional vision, particularly in low-light settings. It significantly affects visual performance and the ability to distinguish objects and details in those challenging conditions. Contrast sensitivity performance showed no significant differences between traditional monofocal and enhanced monofocal lenses under low and high luminance conditions, confirming that both IOL types offer comparable outcomes. However, EDOF lenses showed some variability, with studies reporting similar or higher halos and glare rates than monofocal lenses (38, 52, 53).

Extended depth of focus lenses are categorized: diffractive, refractive, and hybrid. Halos and glare are particularly associated with diffractive lens designs. Diffractive EDOF IOLs use microstructures to split light into multiple focal points, extending the depth of focus. This can result in scattering, creating positive visual aberrations like halos, especially in low lights. Refractive EDOF IOLs are generally less prone to these effects but can still cause halos and glare if their refractive zones lead to variations in light entering the eye. Overall, these artefacts arise from the lens's attempt to provide extended vision ranges, which can lead to imperfections in light processing (3, 12, 54). This suggests a need for caution when recommending EDOF lenses to patients sensitive to photic phenomena. Interestingly, enhanced monofocal lenses displayed a low incidence of halos and glare, supporting their value for patients desiring minimal photic disturbances (22, 39, 40, 44). Our review raises an important question–should we offer mini-monovision to all patients undergoing cataract surgery? Patients need to be assessed thoroughly before surgery to understand their needs and functional vision requirements. One way to provide this insight is to use the validated questionnaires in addition to open conversation (55). According to the patient's ocular history and vision needs, the suitable type of IOL can be selected with the appropriate refractive target. The mini-monovision approach can be particularly beneficial for patients with a high priority on distance vision but requiring only functional intermediate vision. Mini-monovision may provide a reasonable solution by incorporating mild anisometropia. Such a tailored approach, including enhanced monofocal IOLs, should be considered standard practice in cases where full presbyopia correction is either not possible, or not deemed necessary or desired, thereby helping patients achieve greater satisfaction in both visual function and vision-related quality of life.

High levels of safety were found with all lens types using the mini-monovision technique. We describe low rates of IOL exchange and secondary corneal enhancement procedures. IOL exchange was rarely done, which on sight contrast to multifocal IOLs, which are associated with higher rates of IOL exchange due to dissatisfaction with visual quality or photic phenomena. Only two studies provided data on the incidence of secondary corneal enhancement procedures performed via laser vision correction. One study recorded an incidence of 1%, whereas the other reported an incidence of 9.7% (31, 35). Four studies (31, 32, 34, 35) provided data on intraocular lens exchange rate. Goldberg et al. (32) reported an exchange rate of 3.6%, corresponding to two patients, while three other studies indicated no cases of IOL exchange (2–4). There are different reasons for IOL exchange, Goemaere et al. (56) reported a 15 years studies regarding IOL exchange and found IOL opacification to be the primary reason (28%), with multifocal IOL being second with 15%. Dissatisfaction with multifocal IOL can be effectively addressed, not only by exchanging to monofocal IOL but also by selecting an alternative multifocal IOL design (57, 58). Laser vision correction as a secondary enhancement procedure was reported only in two studies (31, 35), with incidences ranging from 1 to 9.7%, suggesting that while secondary interventions are rare, but sometimes necessary to optimize visual outcomes in patients with residual refractive errors (59).

The definition of mini-monovision remains ambiguous, with no clear consensus on the precise refractive targets or optimal range of anisometropia. Traditionally, monovision involves correcting one eye for distance vision and the other for near (60, 61) but mini-monovision aims for a smaller interocular difference, providing a broader range of functional vision with minimal discomfort. In this review, most studies in the monofocal group targeted the myopic eye from −0.75 D up to −1.5 D and one even −2.00 D, (31–37) as opposed to the enhanced monofocal and EDOF lens, where the target was up to −0.75 D (13–16, 20, 41–43). This course can be explained by the broader range of focus these lenses provide. While the ideal target may vary between patients, this range offers a practical compromise for functional vision across distances.

The limitations included an unequal number of studies in each group and variations in study design; some studies had two arms and differing follow-up durations, which may have affected the outcomes. Additionally, not all parameters were reported consistently across the studies, and there is no standard definition of mini-monovision. Furthermore, the outcomes of the enhanced monofocal and EDOF IOLs may vary based on their refractive or diffractive optical designs too and this review does not differentiate the IOLs based on their refractive or diffractive designs. Pertaining to the risk of bias in the trails, two studies did not mention the method of randomization employed. This could raise some concerns regarding risk of bias in these trials. No robust studies

comparing two groups of lenses directly for mini-monovision outcomes were identified. Moreover, not all included studies report the statistical power. Further studies are request comparing these three groups of IOLs with adequate statistical power to ensure statistical significance for UCIVA and spectacle independence with mini-monovision.

In summary, our review suggests that, whilst enhanced monofocal and EDOF IOLs may provide slightly better intermediate visual outcomes and higher spectacle independence compared to monofocal lenses with regards to mini-monovision and intermediate vision performance, the differences are not statistically significant. All three IOL types exhibit high patient satisfaction rates when choosing a mini-monovision approach with decreased dependence on spectacles. Monofocal and enhanced monofocal showed the lowest incidence of positive dysphotopsia and comparable contrast sensitivity performance. These findings support using all three lens types depending on patient preferences. Future studies should focus on long-term outcomes and employ standardized tools for evaluating visual performance and patient satisfaction.

Author contributions

IL: Data curation, Formal analysis, Investigation, Methodology, Project administration, Resources, Validation, Visualization, Writing – original draft, Writing – review and editing. RS: Data curation, Formal analysis, Methodology, Project administration, Resources, Writing – original draft, Writing – review and editing. RM: Data curation, Formal analysis, Investigation, Methodology, Resources, Writing – original draft, Writing – review and editing. MN: Conceptualization, Formal analysis, Investigation, Methodology, Resources, Supervision, Validation, Visualization, Writing – original draft, Writing – review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2025.1522383/full#supplementary-material

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Visual performance, light distortion and patient reported outcomes with a new bi-aspheric non-diffractive extended depth of focus intraocular lens

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Background: To evaluate refractive, visual, and patient-reported outcomes three months after bilateral implantation of a novel bi-aspheric, non-diffractive extended depth of focus (EDOF) intraocular lens (IOL) using PhaseRing technology to achieve good vision across distances with reduced dysphotopsia.

Methods: Twenty-two patients received bilateral Asqelio EDOF IOLs (AST VisionCare Inc.) and were evaluated 3 months post-surgery. The main outcomes assessed were refractive error, monocular and binocular visual acuities at distance, intermediate (67 cm) and near (40 cm), low contrast visual acuity, defocus curves, contrast sensitivity, and patient questionnaires.

Results: The average postoperative spherical equivalent was -0.31 ± 0.30 D. Astigmatism of ≤ 1.00 D was present in all eyes (100%, $n = 44$), with 75% ($n = 33$) showing astigmatism of ≤ 0.50 D. Every patient attained a corrected distance visual acuity (CDVA) of 20/25 or better and a distance-corrected intermediate visual acuity (DCIVA) of 20/32 or better. Contrast sensitivity met or exceeded normal levels under both photopic and mesopic conditions, with and without glare, except at 12 cycles per degree under mesopic conditions with glare. Light distortion index was comparable to published reports on monofocal IOLs and other non-diffractive EDOF IOLs, and lower than diffractive multifocal IOLs. Post-surgery, 90.9% ($n = 20$) of patients reported being satisfied with their vision. No significant visual symptoms were reported.

Conclusion: Asqelio™ EDOF IOL offers an efficient design, providing good clinical outcomes for distance and intermediate vision, while some patients reach functional levels of near vision. Its non-diffractive design minimizes dysphotopsia and reduces light distortion compared to other presbyopia-correcting IOLs.

KEYWORDS

extended depth of focus, non-diffractive, intraocular lens, phacoemulsification, cataract

1 Introduction

Cataracts stand as a leading cause of blindness globally, with cataract surgery ranking among the most commonly performed procedures worldwide. After the extraction of the cataract, the implantation of an intraocular lens (IOL) is performed to compensate for the lost power of the extracted lens and at the same time correct the patient's ametropia, which is done in some cases without waiting for the cataract to develop, in what is known as refractive lensectomy. The use of monofocal IOLs allows for the correction of the patient's ametropia and can provide excellent vision at a single distance (typically far), but falls show at providing good vision at multiple distances (i.e., far and near). The introduction of bifocal IOLs in the 1990s revolutionized patient care by offering near vision correction alongside ametropia correction. Trifocal IOLs, emerging in the European market in 2012, further enhanced patient outcomes by incorporating an intermediate vision focus, reducing reliance on corrective eyewear across a broader range of distances.

The approval of the first extended depth of focus (EDOF) lens by the FDA in 2016 (1) marked a milestone in vision correction. Subsequently, various EDOF models have entered the international market. Numerous studies have since investigated the visual and refractive efficacy of this type of lenses (2–4). A meta-analysis contrasting trifocal and EDOF IOLs indicates that while trifocal IOLs offer performance in near vision, they tend to induce more photic phenomena (5). Variations in multifocal IOLs stem from their optical principles (6), needing enhanced optical performance in modern IOLs to optimize reading capabilities and enhance patients' quality of life post-cataract surgery (7, 8).

The present study aims to assess the clinical performance, light distortion and patient reported outcomes three months after bilateral implantation of Asqelio^{TM} EDOF IOL following cataract surgery or refractive lensectomy. This is the first report on the clinical outcomes after implantation with this new non-diffractive EDOF IOL design.

2 Material and methods

This prospective, single-arm observational post-marketing study was approved by the Ethics Committee of Hospital Clínico San Carlos in Madrid, Spain, and was conducted in accordance with the principles outlined in the Declaration of Helsinki. Written informed consent was obtained from all patients before their participation, and the potential consequences of the study were thoroughly explained. Study registration was also carried out at www.clinicaltrials.gov (registration number: NCT06229756).

Inclusion criteria included patients of at least 50 years of age who were submitted to cataract surgery seeking spectacle-independence and bilaterally implanted with Asqelio^{TM} EDOF IOL (model ELIO130C), transparent intraocular media, other than the cataract preoperatively, and a potential visual acuity of 20/25 or better. Exclusion criteria included preoperatory corneal astigmatism exceeding 0.75 D, patients not providing informed consent, patients with concomitant ocular conditions, previous corneal surgery or trauma, extremely shallow anterior chamber, non-age-related cataracts, pregnancy, rubella, and those currently participating in other clinical investigations or expecting to undergo another ocular surgery during the study period.

2.1 Intraocular lens

The Asqelio^{TM} EDOF IOL is manufactured by AST VisionCare, Inc. (previously AST Products, Inc.) (Billerica, MA, USA) via its proprietary Phase-Ring^{TM} technology. It is a one-piece foldable posterior chamber, UV absorbing optical implantable lens with non-diffractive design for the correction of presbyopia. The lens features a bi-aspheric geometry, spherical aberration of −0.27 microns, 360-degree sharp edge and Phase-Ring^{TM}-structured design on its posterior surface to extend the depth of focus for intermediate to near distances while maintaining distance vision. It has a total diameter of 13.0 mm with an optical zone of 6.0 mm and is manufactured in a power range from −10.00 to +40.00 D in 0.50 D increments. Crafted from a hydrophobic acrylic soft material, characterized by its glistening-free properties, the lens has a refractive index of 1.5 and an Abbe number of 50.

2.2 Surgical procedure

A limbal incision of 2.2 mm was performed, followed by standard phacoemulsification using the Centurion® Vision System (Alcon Labs Inc., Fort Worth, TX, USA). After removing the cataract and polishing the posterior capsule, the capsular bag was filled with 1.0% sodium hyaluronate (Provisc^{TM}, Alcon, Fort Worth, TX, USA) to maintain the capsular space and facilitate IOL implantation. All patients were prescribed moxifloxacin 5 mg/mL (Vigamox^{TM}; Alcon), prednisolone 10 mg/mL (Pred-Forte^{TM}; Allergan, Inc., Irvine, CA, USA), and diclofenac-Lepori 1 mg/mL, administered in tapering doses over the first four weeks after surgery.

2.3 Preoperative and postoperative assessment

Before surgery, patients underwent comprehensive ophthalmologic examinations, including slit-lamp evaluation, measurements of logMAR uncorrected distance visual acuity (UDVA) and corrected distance visual acuity (CDVA), subjective and objective refraction assessments, intraocular pressure measurement, funduscopy, corneal topography, and biometry using the IOLMaster® 700 (Carl Zeiss Meditec AG, Jena, Germany). The Barrett Universal II and Hoffer Q formulas were utilized for intraocular lens (IOL) calculations. The dominant eye was targeted for emmetropia, while slight myopia was aimed for in the non-dominant eye.

Three months post-implantation, patients underwent postoperative evaluations. Standard ophthalmologic assessments, including refraction and slit-lamp biomicroscopy, were

conducted. Specifically, monocular and binocular logMAR UDVA, CDVA, uncorrected intermediate visual acuity (UIVA), and distance-corrected intermediate visual acuity (DCIVA) at 60 cm, as well as uncorrected near visual acuity (UNVA) and distance-corrected near visual acuity (DCNVA) at 40 cm, all measured under photopic conditions. DCNVA was also assessed monocularly and binocularly under mesopic conditions (3 cd/m^2). Early treatment diabetic retinopathy study (ETDRS) charts were used for the measurements. Monocular and binocular defocus curves were generated with best distance correction using the ETDRS chart located at 4 m under photopic conditions, covering vergences from +2.00 to −5.00 D in 0.50 D increments (including 0.25 D steps between 0 and ± 0.50 D). All data were presented as mean ± standard deviation (SD) and ranges.

Binocular contrast sensitivity was tested with distance correction under photopic conditions (85 cd/m^2), both with and without glare, for spatial frequencies of 3, 6, 12, and 18 cycles per degree (cpd), and under mesopic conditions (3 cd/m^2) for spatial frequencies of 1.5, 3, 6, and 12 cpd, using the Clinical Trial Suite® (M&S Technologies, Inc., IL, USA). Log absolute contrast threshold values were determined for each patient, spatial frequency, and luminance level combination. Mean values and standard deviations were calculated, and corresponding contrast sensitivity values (log CS) were derived from these thresholds to plot the contrast sensitivity function.

Light distortion was determined using the Light Distortion Analyzer (LDA) system, first under monocular conditions and then binocularly. In this assessment, patients responded to small peripheral light stimuli presented around a central light source, providing feedback to the system. Based on these responses, the LDA calculated several indices that quantify the size and regularity of distortion surrounding the central light source—specifically, the distortion index, the radius of the best-fit circle, and the irregularity of the best-fit circle (9).

Patient-reported outcomes were gathered through questionnaires. The Catquest-9SF (10), a widely recognized 9-item questionnaire, was used to determine limitations in daily activities due to poor vision, selected for its documented responsiveness in cataract surgery. This questionnaire consists of nine items with four response options, ranging from 1 ("no difficulty/very satisfied") to 4 ("very great difficulty/very dissatisfied"), along with an additional "cannot decide" option treated as missing data. Items labeled A and C1 to C7 focus on difficulty levels, while item B addresses patient satisfaction.

Subjective visual symptoms were assessed using a questionnaire based on a validated quality-of-vision instrument (11). This questionnaire explores the frequency, intensity, and bothersomeness of ten common visual symptoms: glare, halos, starbursts, foggy vision, blurred vision, distortion, double vision, fluctuations in vision, difficulty focusing, and difficulty judging distances or depth. To aid in understanding, patients were shown simulated images depicting each symptom. They were then asked to rate each symptom on frequency (from 1 "Never" to 4 "Very often"), intensity (from 1 "None" to 4 "Severe"), and bothersomeness (from 1 "None" to 4 "A lot").

Adverse events were recorded based on both solicited inquiries and spontaneous patient comments, as well as from observations made by the investigator.

TABLE 1 Demographic characteristics of participants shown as means, standard deviations (SD) and ranges.

	Values
Patients (*n*)	22
Sex (male/female)	11/11
Age (y)	67.95 ± 8.40 (55 to 83)
Sphere (D)	0.17 ± 5.15 (−11.50 to 7.00)
Refractive cylinder (D)	−0.63 ± 0.52 (−2.50 to 0.00)
Spherical equivalent (D)	−0.14 ± 4.15 (−11.75 to 7.00)
IOP (mmHg)	16.52 ± 3.17 (11 to 24)
CDVA (logMAR)	0.12 ± 0.20 (0.00 to 1.20)
K1 (D)	43.23 ± 1.35 (40.01 to 45.93)
K2 (D)	43.74 ± 1.38 (40.37 to 46.12)
Corneal astigmatism (D)	0.51 ± 0.22 (0.00 to 0.74)
Axial length (mm)	23.91 ± 1.58 (21.01 to 28.03)
ACD (mm)	3.16 ± 0.49 (1.99 to 4.20)
CCT (μm)	557.80 ± 37.47 (498 to 644)
LT (mm)	4.59 ± 0.34 (3.57 to 5.36)
WTW (mm)	12.02 ± 0.36 (11.20 to 12.60)
IOL spherical power (D)	20.68 ± 5.47 (9.00 to 33.00)

IOP, intraocular pressure; CDVA, corrected distance visual acuity; K, keratometry; ACD, anterior chamber depth; CCT, central corneal thickness; LT, lens thickness; WTW, white-to-white; IOL, intraocular lens power.

2.4 Sample size and statistical analysis

The study's estimated sample size was determined using the highest standard deviation observed in the defocus curve of typical monocular visual acuity (12). Specifically, a standard deviation of 0.24 logMAR at +2.00 diopters blur, a 95% confidence interval, and a maximum allowable margin of error of 0.10 logMAR were applied, resulting in a minimum required sample size of 22 patients.

Categorical variables were presented as frequencies and percentages, while continuous variables were summarized using means and standard deviations. Cumulative histograms of postoperative refractive error and refractive cylinder were constructed to evaluate refractive accuracy. Additionally, a cumulative histogram of postoperative visual performance was generated to assess the efficacy of refractive correction.

3 Results

A total of 22 consecutive patients were enrolled in the study, with a mean age of 67.95 ± 8.40 years (ranging from 55 to 83 years); half of them were female (n = 11, 50%). The preoperative demographic characteristics are summarized in Table 1. Standardized graphs depicting refractive and visual acuity outcomes at the three-month follow-up were constructed in line with established reporting guidelines (13).

For the assessment of predictability, Figure 1 presents a histogram of postoperative spherical equivalent refraction relative to the intended target, while Figure 2 illustrates the postoperative refractive astigmatism. Concerning the spherical equivalent, the

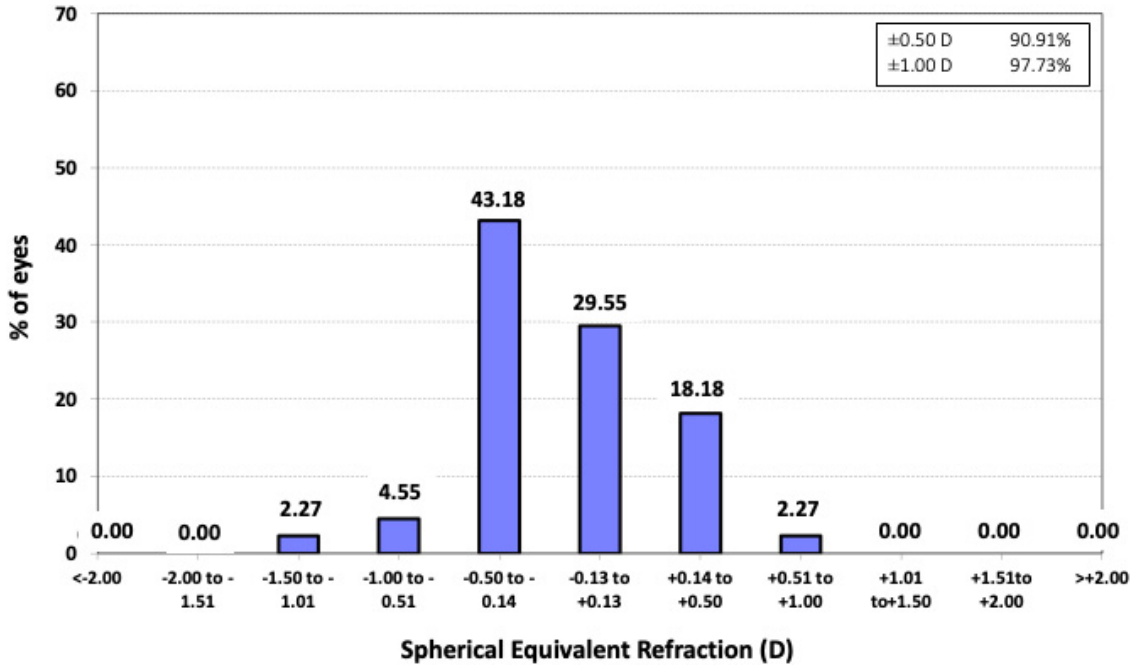

FIGURE 1
Histogram of postoperative spherical equivalent refractive accuracy 3 months after surgery relative to the intended target refraction.

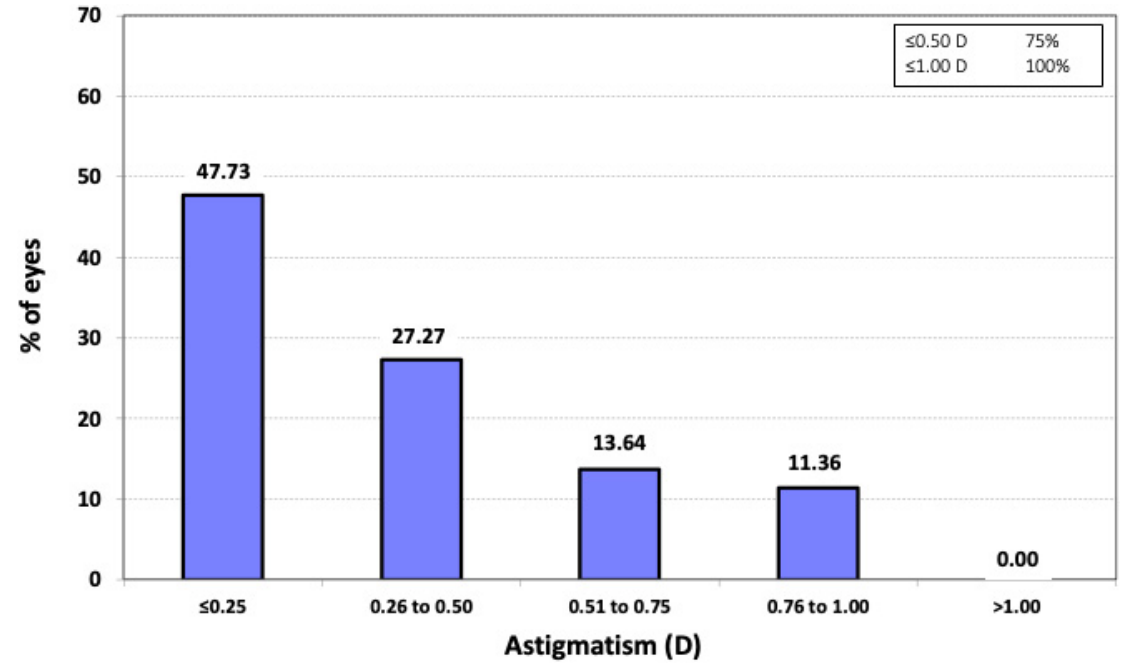

FIGURE 2
Histogram of the prevalence of postoperative refractive astigmatism at 3 months after surgery.

largest proportion of eyes, 43.18% (n = 19), fell within the range of −0.50 to −0.14 diopters (D), followed by 29.55% (n = 13) within the ± 0.13 D range, highlighting a high refractive accuracy, with the vast majority of patients achieving results close to the planned refraction. Overall, 97.73% (n = 43) of eyes were within ± 1.00 D of the target refraction, and 91% (n = 40) were within ± 0.50 D. The mean postoperative spherical equivalent was −0.31 ± 0.30 D, ranging from −1.50 D to +0.25 D.

Regarding astigmatism, all eyes (100%, n = 44) exhibited postoperative refractive cylinder values of ≤ 1.00 D, and 75% (n = 33) had values of ≤ 0.50 D. The mean postoperative refractive cylinder was −0.41 ± 0.33 D, with a range from 0 to −1.0 D.

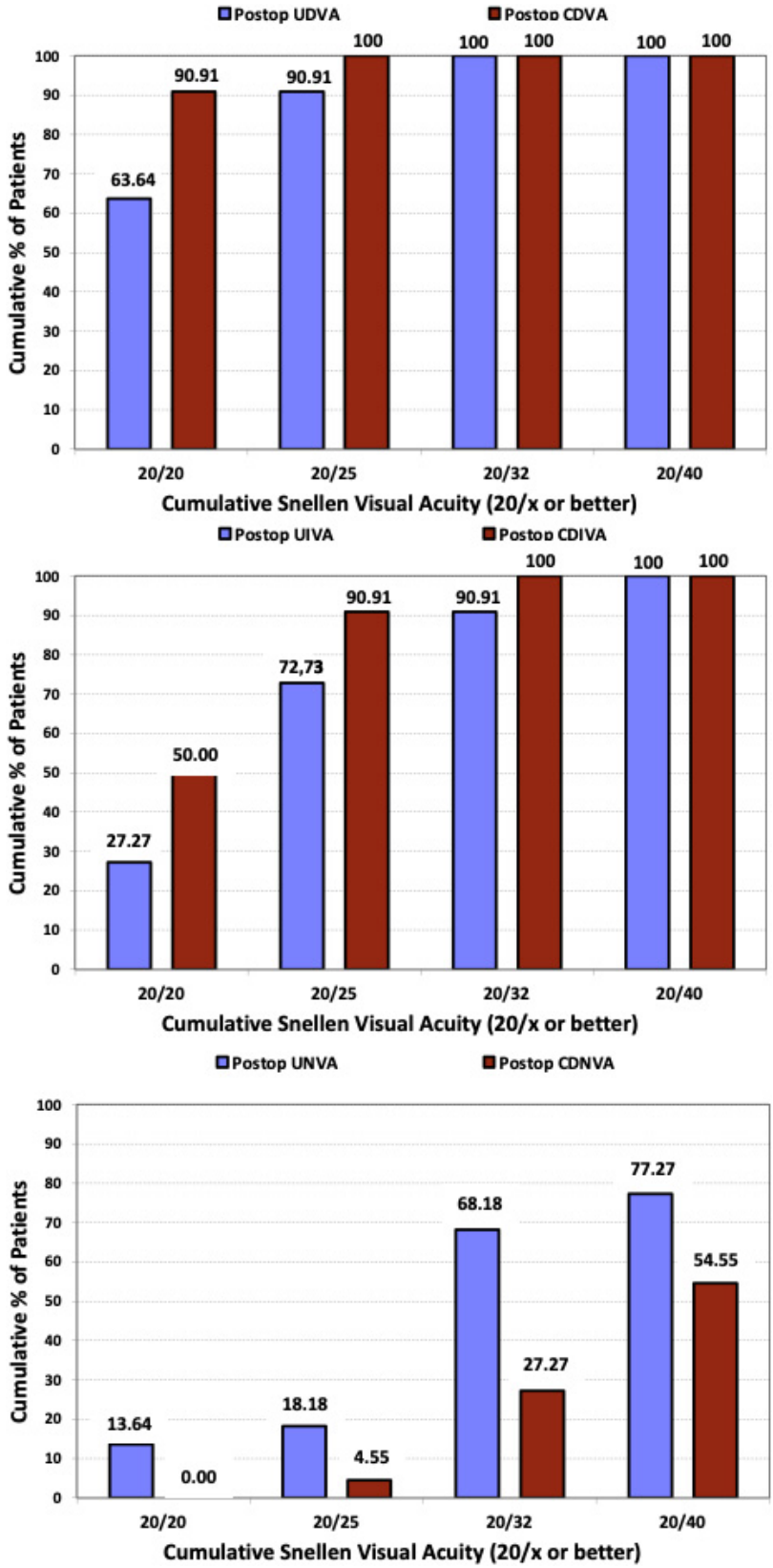

FIGURE 3
Cumulative proportion of patients having a given photopic binocular: uncorrected distance visual acuity (UDVA) and best-corrected distance visual acuity (CDVA) values **(upper)**; binocular uncorrected intermediate visual acuity (UIVA) and distance-corrected intermediate visual acuity (DCIVA) values **(middle)**; uncorrected near visual acuity (UNVA) and distance-corrected near visual acuity (DCNVA) values **(lower)**, at 3 months after surgery.

TABLE 2 LogMAR visual acuity outcomes of patients implanted with the Asqelio EDOF intraocular lens shown as means, standard deviations (SD) and ranges.

	Monocular	Binocular
UDVA	0.10 ± 0.12 (−0.08 to 0.40)	0.02 ± 0.08 (−0.12 to 0.20)
CDVA	0.01 ± 0.06 (−0.08 to 0.18)	−0.03 ± 0.05 (−0.10 to 0.10)
UIVA	0.16 ± 0.13 (−0.10 to 0.40)	0.07 ± 0.10 (−0.10 to 0.30)
DCIVA	0.10 ± 0.11 (−0.10 to 0.40)	0.03 ± 0.08 (−0.10 to 0.20)
UNVA	0.30 ± 0.14 (0.00 to 0.54)	0.20 ± 0.13 (−0.04 to 0.40)
DCNVA	0.37 ± 0.12 (0.10 to 0.70)	0.31 ± 0.11 (0.10 to 0.50)
Low contrast CDVA	0.36 ± 0.12 (0.18 to 0.64)	0.29 ± 0.09 (0.20 to 0.50)
Low contrast DCIVA	0.41 ± 0.10 (0.20 to 0.70)	0.33 ± 0.11 (0.14 to 0.60)
Low contrast DCNVA	0.52 ± 0.15 (0.18 to 0.96)	0.45 ± 0.15 (0.12 to 0.70)

UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; UIVA, uncorrected distance intermediate visual acuity; DCIVA, corrected distance intermediate visual acuity; UNVA, uncorrected distance near visual acuity; DCNVA, corrected distance near visual acuity.

To evaluate the efficacy of the procedure, Figure 3 presents the cumulative postoperative binocular logMAR UDVA and CDVA (A), UIVA and DCIVA (B), and UNVA and DCNVA (C), respectively. All patients (100%) showed cumulative CDVA of 20/25 or better, and DCIVA of 20/32 or better. Specifically, 90.91% (n = 20) of patients showed an UDVA of 20/25 or better compared to 100% (n = 44) for CDVA, 72.73% (n = 16) of patients showed an UIVA of 20/25 or better compared to 90.91% (n = 20) for DCIVA, and 18.18% (n = 4) of patients showed an UNVA of 20/25 or better compared to 4.55% (n = 1) for DCNVA. Table 2 presents detailed measurements of visual acuity at different distances under both photopic and mesopic conditions. The monocular and binocular defocus curves with best correction for distance (Figure 4) show that visual acuity remained relatively stable across a wide range of defocus levels, indicating a smooth and extended depth of focus. The best performance was observed at 0.00 D (distance vision), with a gradual decline as defocus increased. The results show binocular vision maintained better performance than monocular vision at all vergences. A binocular visual acuity of 0.2 logMAR (20/32) or better was maintained up to −2.00 D of defocus, which corresponds to approximately 50 cm, demonstrating the lens's ability to provide functional intermediate vision, and supporting the effectiveness of the lens in providing extended vision while maintaining good distance acuity.

Figure 5 illustrates the mean contrast sensitivity function measured under photopic conditions (85 cd/m^2) with glare (A) and without glare (B), and under mesopic conditions (3 cd/m^2) with glare (C) and without glare (D). Since the CTS system does not provide reference ranges for normal contrast sensitivity in healthy subjects under these conditions, for this analysis the normal ranges for non-operated eyes over 60 years old reported by Escaf et al. (14) using the Functional Acuity Contrast Test (FACT) were used. The results indicate that contrast sensitivity was within or above normal levels under both photopic and mesopic conditions, regardless of the presence of glare. The only exception was mesopic contrast sensitivity at 12 cycles per degree (cpd) with glare, where the mean value fell slightly below the normal range.

Regarding the questionnaires, the Catquest-9SF results (Table 3) showed that 90.9% of patients were either satisfied (13 out of 22) or very satisfied (7 out of 22) with their vision after surgery, with none reporting being very unsatisfied. This table presents the average scores and frequency of responses to questions related to difficulties in performing daily activities, as assessed by the Catquest-9SF. In most cases, the results indicate higher percentages for no difficulty (R4) in performing any of those activities [ranging from 63.6% (n = 14) to 90.9% (n = 20)], except for reading the newspapers, where half of the patients reported some difficulty and 40.91% (n = 9) reported no difficulty. Table 4 summarizes the results of the visual symptom questionnaire. No significant visual symptoms were reported in terms of frequency, intensity, or bothersomeness following the implantation of the Asqelio EDOF IOL. Halo was the only relevant visual symptom, with only 18.19% (n = 4) of patients reporting their presence quite often or very often, but none experiencing severe bothersome.

Light distortion parameters obtained under monocular and binocular conditions are displayed in Table 5.

No adverse events were reported for any subject enrolled in the present study.

4 Discussion

EDOF IOLs are increasingly being implanted alongside trifocal lenses. They provide a continuous extended range of vision without generating specific focal points for particular distances, offering good VA results for distance and intermediate ranges comparable to multifocal IOLs, though with somewhat poorer near VA (15). The technologies used to create the extended range in these IOLs vary considerably among different platforms (3, 16). Due to this variability, the American Academy of Ophthalmology reached a consensus on the criteria for defining and evaluating the performance of EDOF IOLs (17). Based on these recommendations, the US Food and Drug Administration established several clinical criteria for EDOF IOLs in the American National Standards Institute (ANSI)/AAO Standard Z80.35–2018 (18).

According to these criteria, EDOF IOLs should provide a monocular depth of focus at 0.2 logMAR that is at least 0.50 diopters (D) greater than that of a monofocal control. Additionally, the monocular photopic DCIVA at 66 cm should exceed that of a monofocal control lens, with at least 50% of eyes achieving a VA of 0.2 logMAR or better. Finally, the mean monocular photopic CDVA should be non-inferior to that of a monofocal control IOL. Assessments of mesopic contrast sensitivity and visual symptom questionnaires are also required, although there are no specific criteria regarding visual quality or disturbances.

At the present moment, three IOLs in the EDOF IOL category may be considered as non-diffractive EDOF IOLs that do not use spherical aberration as source of EDOF but refractive elements to reshape the wavefront: Acrysof® IQ Vivity® (Alcon Inc., USA) (now also a version with the new Clareon material is available), Lucidis® (SAV-IOL SA, Switzerland), and Asqelio™ EDOF (AST VisionCare, Inc., USA). The present study constitutes the first report on the clinical outcomes with the Asqelio™ EDOF IOL.

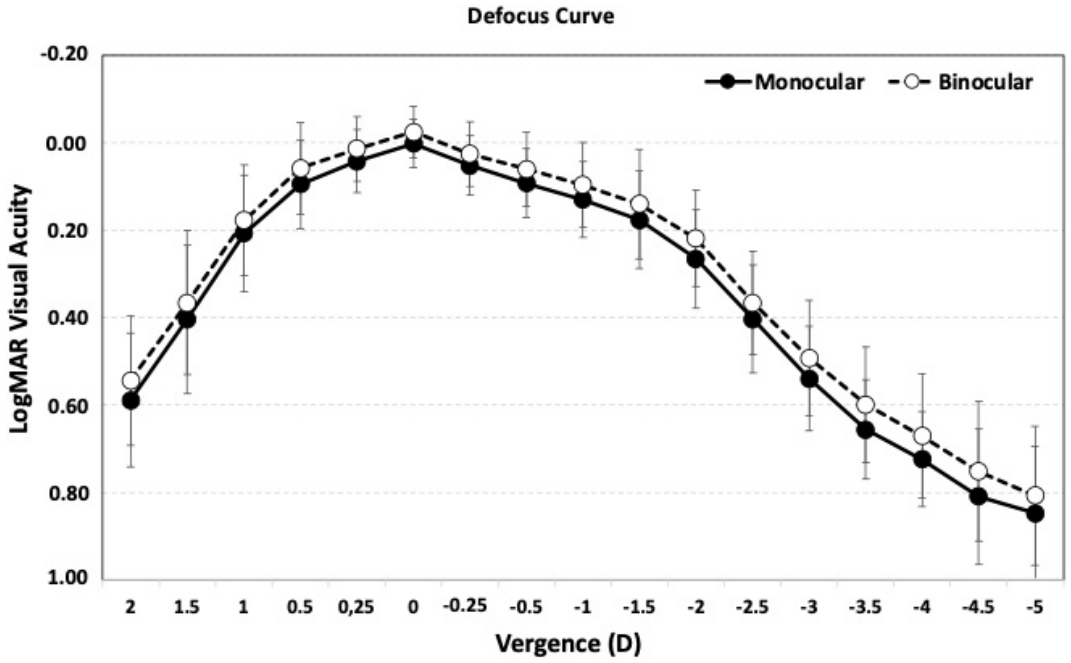

FIGURE 4
Mean, high-contrast, photopic, monocular and binocular logMAR visual acuity with best correction for distance, as a function of the chart vergence. Error bars represent standard deviation.

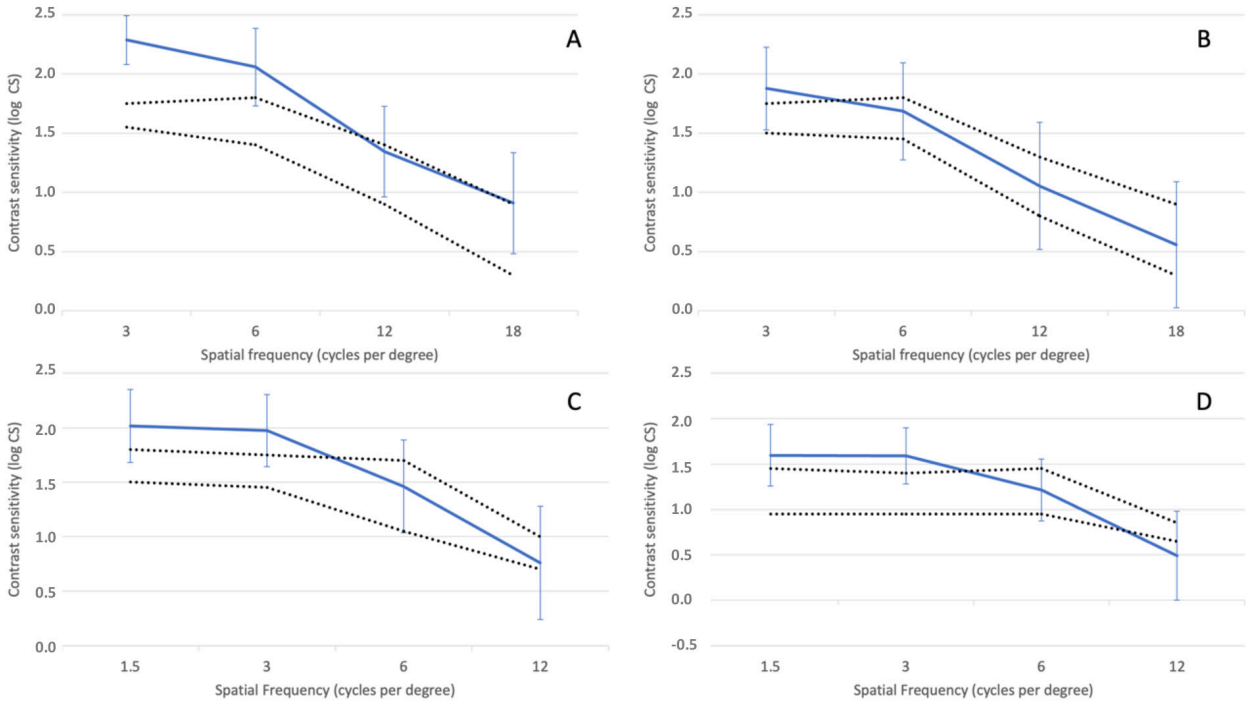

FIGURE 5
Contrast sensitivity function determined under photopic conditions (85 cd/m^2) without **(A)** and with induced glare **(B)** and under mesopic conditions (3 cd/m^2) without **(C)** and with induced glare **(D)** Dotted lines delimit the normal range for non-operated eyes above 60 years of age using the Functional Acuity Contrast Test (FACT) (11). Error bars represent the 95% confidence intervals.

Analyzing the visual performance of Asqelio^{TM} EDOF obtained in the present study, all patients (100%) showed cumulative CDVA of 0.1 LogMAR or better, and DCIVA of 0.2 LogMAR or better. Specifically, 90.91% of patients showed an UDVA of 0.1 LogMAR or better compared to 100% for CDVA, 72.73% of patients showed an UIVA of 0.1 LogMAR or better compared

TABLE 3 Summary of patient-reported difficulties and satisfaction with their vision as per Catquest-9SF.

	Mean ± SD	Response frequencies (%)				
		R1	R2	R3	R4	R5
Do you find that your sight at present in some way causes you difficulty in your everyday life?	3.73 ± 0.55	0.00	4.55	18.18	77.27	0.00
Are you satisfied or unsatisfied with your current vision?	3.23 ± 0.61	0.00	9.09	59.09	31.82	0.00
Do you have difficulty. . .						
. . .Reading text in newspapers?	3.23 ± 0.87	9.09	0.0	50.00	40.91	0.00
. . .Recognizing the faces of people you meet?	3.73 ± 0.46	0.00	0.00	27.27	72.73	0.00
. . .Seeing the prices of goods when shopping?	3.68 ± 0.48	0.00	0.00	31.82	68.18	0.00
. . .Seeing to walk on uneven surfaces?	3.91 ± 0.29	0.00	0.00	9.09	90.91	0.00
. . .Seeing to do handicrafts, woodwork etc.?	3.68 ± 0.78	4.55	4.55	9.09	81.82	0.00
. . .Reading subtitles on TV?	3.64 ± 0.49	0.00	0.00	36.36	63.64	0.00
. . .Seeing to engage in an activity/hobby?	3.86 ± 0.35	0.00	0.00	13.64	86.36	0.00

Response coding: R1 (yes, extreme difficulty), R2 (yes, great difficulty), R3 (yes, some difficulty), R4 (no, no difficulty), R5 (cannot decide) for difficulties and R1 (very unsatisfied), R2 (fairly unsatisfied), R3 (fairly satisfied), R4 (very satisfied), R5 (cannot decide). SD, standard deviation.

to 90.91% for DCIVA, and 18.18% of patients showed an UNVA of 0.1 LogMAR or better compared to 4.55% for DCNVA. The difference observed between uncorrected and corrected visual performance, particularly for near vergences, results from attempting a slight residual myopia in the non-dominant eye, known as mini-monovision, which has been reported to give good clinical outcomes with similar types of IOLs (19) and is common practice in the study center, aiming to expand the range of binocular clear vision. Considering this, the visual performance with the IOL is good under both monocular and binocular conditions.

In a sample of 20 patients implanted with the Acrysof® IQ Vivity® IOL, Sabur and Unsal (20) reported a mean monocular CDVA of 0.02 ± 0.04 LogMAR, DCIVA of 0.18 ± 0.09 and DCNVA of 0.30 ± 0.11LogMAR. These outcomes are comparable to those found in the present study, with mean values of 0.01 ± 0.06, 0.10 ± 0.11, and 0.37 ± 0.12 for monocular CDVA, DCIVA and DCNVA, respectively. With regards to binocular VA values, Sabur and Unsal (20) reported mean values of 0.01 ± 0.03, 0.13 ± 0.07 and 0.24 ± 0.10. Binocular VA values found in the present study were slightly better, −0.03 ± 0.05, 0.03 ± 0.08 and 0.20 ± 0.13 LogMAR for CDVA, DCIVA and DCNVA, respectively. In their study, they compared the outcomes of the non-diffractive EDOF IOL against the TECNIS Eyhance® (Johnson & Johnson Surgical Vision, Inc, USA), categorized as an enhanced monofocal IOL. They concluded that visual performance for distance and intermediate vision was similar between both IOLs, with near vision being significantly better for the EDOF IOL.

van Amelsfort et al. (21) found that adjusting for emmetropia in the dominant eye and inducing slight myopia in the nondominant eye (-0.25 D to -0.50 D) led to improved near visual acuity, greater patient satisfaction, and higher levels of spectacle independence. Similarly, Newsom and Potvin (22) demonstrated that targeting -0.75 D of myopia in the nondominant eye resulted in an improvement of more than one line in near visual acuity compared to other studies focusing on bilateral emmetropia.

In a randomized double-blind comparison study between Acrysof® IQ Vivity® and TECNIS Symfony® (Johnson & Johnson Surgical Vision, Inc, USA), a diffractive EDOF IOL, Scheepers and Hall (23) found binocular VA values of −0.03 ± 0.05, 0.04 ± 0.08 and 0.22 ± 0.12 LogMAR for CDVA, DCIVA and DCNVA, respectively, in patients implanted with the Vivity refractive EDOF 3 months after surgery, very much in agreement with those found in the present study with Asqelio™ EDOF IOL. These were not significantly different from those obtained in patients implanted with the Symfony IOL, which were, respectively, of −0.03 ± 0.05, 0.03 ± 0.10 and 0.26 ± 0.11 LogMAR.

Sabur and Unsal (20) reported binocular defocus curve outcomes with bilateral implantation of the non-diffractive Acrysof Vivity EDOF IOL. According to their mean binocular defocus curve, CDVA peaked at 0 D, with a progressive decline that reached 0.1 LogMAR around −1.25 D vergence and 0.2 LogMAR around −2.0 D. Similar profile was reported by Pantanelli et al. (24) comparing Acryso IQ Vivity to a monofocal control. They also showed two more lines of vision at intermediate and near vergences compared to the control IOL. In the present study, Asqelio™ EDOF IOL showed a similar behavior, with a mean binocular defocus curve that peaked at 0 D and had a similar progressive decline, reaching 0.2 LogMAR at −2.0 D.

According to the literature, eyes implanted with an EDOF IOL should experience fewer dysphotopsia and less loss of contrast sensitivity compared with those fitted with a conventional multifocal IOL (25–28). Sabur and Unsal (20) obtained similar contrast sensitivity outcomes in Acrysof® IQ Vivity® patients and Eyhance® enhanced monofocal IOL, with differences not being statistically significant at any spatial frequency or light condition. In the present study, contrast sensitivity values obtained with Asqelio™ EDOF showed either within or above normal range under both photopic and mesopic conditions, both with and without glare being induced. Given that the CTS system does not provide with a reference range of normality for healthy subjects under photopic and mesopic conditions with and without glare, it must be noted that the normal ranges for non-operated eyes above 60 years of age used by Escaf et al. (14). using the

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TABLE 4 Summary of patient reported visual symptoms (mean score, type of symptom and frequency of responses) as per visual quality questionnaire.

		Frequency (%)			
	Mean ± SD	R1	R2	R3	R4
Glare					
Frequency	1.23 ± 0.43	77.27	22.73	0.00	0.00
Intensity	1.36 ± 0.79	77.27	13.64	4.55	4.55
Bothersome	1.18 ± 0.39	81.82	18.18	0.00	0.00
Halo					
Frequency	1.78 ± 0.89	54.55	27.27	13.64	4.55
Intensity	1.64 ± 0.79	54.55	27.27	18.18	0.00
Bothersome	1.32 ± 0.48	68.18	31.82	0.00	0.00
Starburst					
Frequency	1.32 ± 0.57	72.73	22.73	4.55	0.00
Intensity	1.36 ± 0.66	72.73	18.18	9.09	0.00
Bothersome	1.18 ± 0.39	81.82	18.18	0.00	0.00
Hazy vision					
Frequency	1.18 ± 0.39	81.82	18.18	0.00	0.00
Intensity	1.18 ± 0.39	81.82	18.18	0.00	0.00
Bothersome	1.23 ± 0.53	81.82	13.64	4.55	0.00
Blurred vision					
Frequency	1.14 ± 0.47	90.91	4.55	4.55	0.00
Intensity	1.14 ± 0.47	90.91	4.55	4.55	0.00
Bothersome	1.09 ± 0.29	90.91	9.09	0.00	0.00
Distorted vision					
Frequency	1.00 ± 0.00	100.00	0.00	0.00	0.00
Intensity	1.00 ± 0.00	100.00	0.00	0.00	0.00
Bothersome	1.00 ± 0.00	100.00	0.00	0.00	0.00
Double vision					
Frequency	1.00 ± 0.00	100.00	0.00	0.00	0.00
Intensity	1.00 ± 0.00	100.00	0.00	0.00	0.00
Bothersome	1.00 ± 0.00	100.00	0.00	0.00	0.00
Fluctuation in vision					
Frequency	1.09 ± 0.29	90.91	9.09	0.00	0.00
Intensity	1.09 ± 0.29	90.91	9.09	0.00	0.00
Bothersome	1.09 ± 0.29	90.91	9.09	0.00	0.00
Difficulty focusing					
Frequency	1.18 ± 0.38	81.82	18.18	0.00	0.00
Intensity	1.23 ± 0.53	81.82	13.64	4.55	0.00
Bothersome	1.14 ± 0.35	86.36	13.64	0.00	0.00
DIFFICULTY perceiving distances/depth					
Frequency	1.14 ± 0.64	95.45	0.00	0.00	4.55
Intensity	1.09 ± 0.43	95.45	0.00	4.55	0.00
Bothersome	1.05 ± 0.21	95.45	4.55	0.00	0.00

Response coding (frequency/severity/bothersome): R1 (never/none/none), R2 (occasionally/mild/a little), R3 (quite often/moderate/quite a bit), R4 (very often/severe/a lot). SD, standard deviation.

TABLE 5 Light distortion parameters obtained under monocular and binocular conditions.

	Monocular (n = 33)		Binocular (n = 16)	
	Mean ± SD	Range	Mean ± SD	Range
LDI (%)	11.36 ± 5.47	5.33 to 25.47	8.51 ± 4.33	3.18 to 20.13
BFC radius	26.93 ± 6.23	18.7 to 41.3	23.24 ± 5.69	14.7 to 36.7
BFC irregularity	0.341 ± 0.24	0.01 to 1.07	0.40 ± 0.19	0.12 to 0.71

LDI, light distortion index; BFC, best fit circle; SD, standard deviation.

Functional Acuity Contrast Test (FACT) were used as a reference here.

With regards to light distortion, Guarro et al. (29) concluded that diffractive EDOF IOL models induced similar visual disturbances that were worse than those produced by the non-diffractive EDOF model. In their study they found glare, halos, and starbursts to be similar between the non-diffractive EDOF IOL studied, AcrySof® IQ Vivity®, and a monofocal control IOL. The mean LDI values they obtained for the non-diffractive EDOF IOL were 14.36 ± 10.25 (range 4.46 to 42.62) monocularly, and 8.24 ± 3.86 (3.82, 16.31) binocularly. These results are in agreement with those found in the present study in patients implanted with Asqelio™ EDOF, showing that the light distortion of Asqelio™ EDOF and Acrysof® Vivity® is very similar both monocularly and binocularly. These outcomes are considerably better than those reported in the literature using the same method with other presbyopia-correcting IOLs (30, 31).

Patient-reported outcomes show 90.9% of patients as satisfied or very satisfied with their vision after bilateral implantation of Asqelio™ EDOF, while none of the patients' reports being very unsatisfied. The Catquest-9SF outcomes show no difficulty for performing most of the daily activities, except for reading the newspapers, where half of the patients reported some difficulty, as expected given the close distance range needed. Regarding visual disturbance symptoms, literature shows that diffractive EDOF IOLs perform worse than non-diffractive EDOF IOLs (19), and no significant differences in visual disturbances were found compared to a monofocal lens (29). In the study by Guarro et al. (29), the most frequent visual symptom reported by patients implanted with Acrysof® IQ Vivity® was starbursts, with 4.5% of patients reporting it as very frequent and 13.6% as moderately severe and quite bothersome. These were slightly different in the study by Pantanelli et al. (24), who found glare as the most frequent visual symptom, with 4.2% of patients reporting very frequent and very bothersome. In the study by Newsom and Potvin (22), halos and starbursts had increased frequency (18 and 39%, respectively), severity (33 and 55%, respectively), and bothersome (21 and 18%, respectively). In the present study, patient reported outcomes with Asqelio™ EDOF show halo as the most frequent visual symptom, with 4.5% of patients reporting as very frequent, but none of them considered it as bothersome.

5 Conclusion

To conclude, the present study supports that the Asqelio™ EDOF IOL is an efficient IOL design providing good clinical outcomes at distance and intermediate distances, while some patients may also reach functional near vision. Its non-diffractive design also benefits the lack of relevant dysphotopsia and reduced light distortion compared to other presbyopia-correcting IOL designs. The high level of patient satisfaction reported after implantation makes it a valuable option for patients seeking spectacle independence with no visual disturbance, and very good visual outcomes.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by the Ethics Committee of the Hospital Clínico San Carlos (Madrid, Spain). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

ST-S: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – original draft, Writing – review and editing. PT-S: Formal analysis, Methodology, Writing – review and editing. BE-G: Data curation, Formal analysis, Methodology, Writing – review and editing. PO-V: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Writing – review and editing. PT-R: Formal analysis, Funding acquisition, Investigation, Methodology, Writing – original draft, Writing – review and editing.

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Conflict of interest

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Management of delayed corneal epithelial healing after refractive surgery: five case reports

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Background: Transepithelial photorefractive keratectomy using Smart Pulse Technology (SPT-TransPRK) is currently the leading method for superficial refractive surgery, offering advantages such as a non-contact procedure, shorter operation times, and excellent patient cooperation. Laser ablation of the corneal epithelium, Bowman's membrane, and the stroma can effectively correct refractive errors. Thus, the complete healing of the corneal epithelium post-surgery is essential for ensuring good vision. Refractive surgeons should enhance their understanding of corneal wound healing mechanisms and focus on the repair of the corneal epithelium following refractive surgery to ensure the quality of visual health of patients.

Case presentation: A total of five patients experienced varying degrees of delayed corneal epithelial healing following refractive surgery. In Case 1, unhealthy corneal epithelial debris was removed, and ophthalmic ointment was applied to cover the eyes instead of using bandage contact lenses (BCLs) to reconstruct the corneal epithelial barrier. This approach was also successfully implemented in Case 2. Furthermore, amniotic membrane transplantation (AMT) can quickly establish a corneal barrier and promote corneal epithelial regeneration, especially in cases of extensive corneal epithelial detachment. The remaining three patients were suspected of having corneal viral infections based on their medical history and the observation of corneal pathology using a slit lamp microscope. To prevent further infection and promote regeneration, topical steroid drops were discontinued early, and topical antiviral and corneal epithelial regeneration medications were administered alongside systemic antiviral therapy. Steroid drops were resumed after corneal epithelial healing to effectively prevent post-refractive haze.

Conclusion: Delays in corneal epithelial healing after refractive surgery should be taken seriously. BCLs, steroids, and both topical and systemic antiviral therapies should be properly utilized when there is a delay in corneal epithelial healing.

KEYWORDS

delayed corneal epithelial healing, refractive surgery, corneal virus infection, persistent epithelial defects, trans-PRK

Introduction

Transepithelial photorefractive keratectomy (TransPRK) was introduced in the late 1990s as an alternative to conventional photorefractive keratectomy (PRK) for corneal refractive surgery (1). This procedure was developed to replace traditional PRK and has evolved with advancements in technology and equipment. One notable advancement is the integration of transepithelial photorefractive keratectomy with Smart Pulse Technology (SPT-TransPRK), which has become the standard approach for personalized surface ablation. SPT allows for a more precise distribution of laser emissions in a fullerene 3D model, resulting in cleaner laser cut and a smoother post-ablative stromal bed surface. This enhanced precision supports the migration of corneal epithelial cells, potentially contributing to the rapid recovery of the corneal epithelium and the reduction of postoperative ocular surface pain following SPT-TransPRK (2, 3). SPT-TransPRK is widely recognized as a safe and effective surgical procedure (4, 5). Currently, the average number of refractive surgery cases in China is approximately 1 million per year (6). Despite the widely recognized safety, efficacy, and predictability of photorefractive keratectomy, clinicians must remain vigilant regarding the overall risks associated with refractive surgery. Delayed corneal epithelial healing after SPT-TransPRK is rare; however, the factors influencing postoperative corneal epithelial healing are complex. This study reports five cases of delayed corneal epithelial healing after SPT-TransPRK that occurred between 2019 and 2023. We aim to summarize the treatment plan for this condition by analyzing the etiology of persistent epithelial defects (PED) in different individuals. This study aims to raise awareness among refractive surgeons regarding the importance of thorough preoperative screening and treatment to enhance the overall safety and effectiveness of refractive surgery.

Case presentation

Case 1

The patient was a 32-year-old woman who underwent cycloplegic refraction, resulting in −2.25 −0.75 × 164 in the right eye (OD) and − 2.25 −1.25 × 15 in the left eye (OS). In 2018, SPT-TransPRK was performed after a thorough assessment that ruled out contraindications (The details of contraindications are documented in the Supplementary material section). The patient reported no prior history of herpes simplex virus infection. Preoperatively, anti-inflammatory eye drops were administered, and bandage contact lenses (BCLs) were fitted in both eyes. Postoperatively, anti-inflammatory and anti-infective eye drops were used (The details of medical guidance are provided in the Supplementary material section). During the 1-week postoperative assessment, the patient's uncorrected vision acuity (UCVA) was 20/30 in the right eye and 20/25 in the left eye. A delay in the complete healing of the corneal epithelium was observed in both eyes (see Figure 1A), leading to a diagnosis of bilateral delayed corneal epithelial healing. Accumulation of corneal epithelial debris was noted beneath the BCL in the right eye, necessitating its replacement with a new lens; the original BCL for the left eye remained in place. However, there was no improvement in bilateral corneal epithelial regeneration after 1 week (see Figure 1B). Following the replacement of the BCL in the right eye, the left BCL was removed, and treatment commenced with 0.3% sodium hyaluronate eye drops administered once per hour, 0.5% levofloxacin eye drops three times a day, loteprednol etabonate ophthalmic suspension three times a day, and carbomer eye gel once nightly. Three weeks post-surgery, the right eye exhibited photophobia and had a UCVA of 20/25. A central corneal epithelial defect measuring 3 mm in diameter was observed in the right eye (see Figure 1C). Given that the BCL had been worn consistently in the right eye, it was

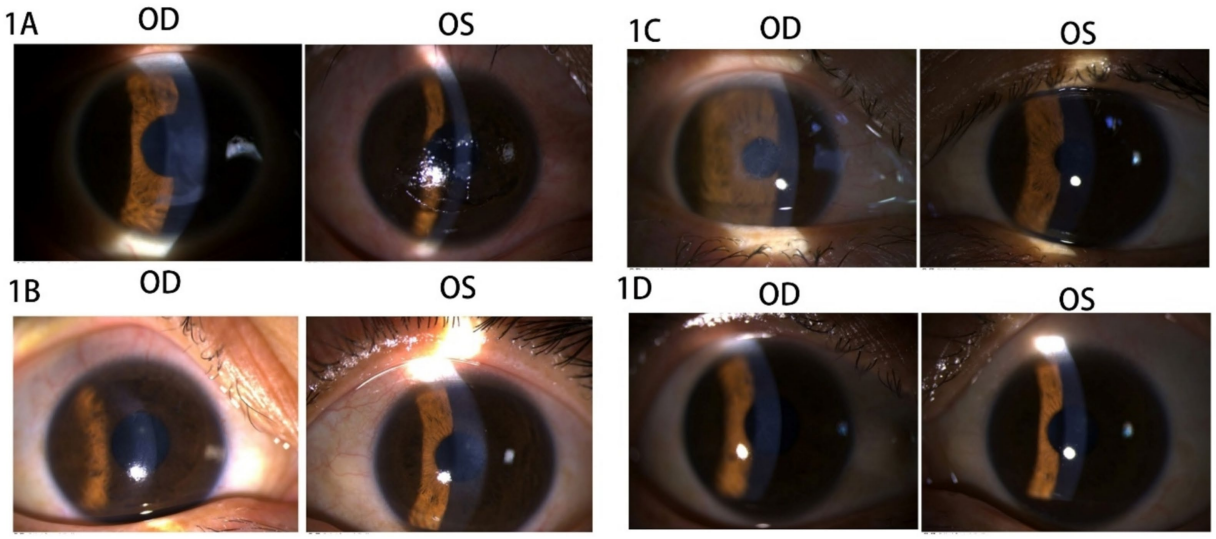

FIGURE 1
Images of the anterior segment of the cornea in Case 1. **(A)** The corneal epithelium was not completely healed in both eyes during 1 week. **(B)** The corneal epithelial regeneration was not been improved within 1 week. **(C)** The central corneal epithelium defect of 3 mm in diameter was observed in the right eye at 3 weeks after the surgery. **(D)** At 4 weeks postoperatively, the bilateral cornea returned to be transparent.

hypothesized that its presence may have interfered with epithelial regeneration. Consequently, the BCL was removed, and the eye was treated with tobramycin dexamethasone ophthalmic ointment, gatifloxacin eye gel, and deproteinized calf blood extract eye gel, applied three times daily. At the four-week postoperative evaluation, both corneas were transparent, and the UCVA improved to 20/20 for both eyes (OU) (refer to Figure 1D).

Case 2

The patient was a 30-year-old woman with a cycloplegic refraction of −4.25 -0.75 × 88 in the right eye (OD) and − 4.25 -0.25 × 76 in the left eye (OS). She had a 12-year history of using soft corneal contact lenses (SCLs), which were removed 1 month prior to surgery. In 2018, SPT-TransPRK was performed after ruling out any contraindications. Details regarding contraindications, her history of herpes simplex virus infection, and the preoperative and postoperative management are provided in Case 1. The BCLs were removed 1 week postoperatively due to epithelial healing. However, recurrent corneal epithelial defects frequently occurred in both eyes within 2 months following surgery. The patient reported worsened foreign body sensations, pain, and photophobia in both eyes. An exam revealed slight punctate defects in the corneal epithelium of the right eye, which had a UCVA of 20/20. In the left eye, epithelial debris accumulated in the central cornea, resulting in a UCVA of 20/40 (Figure 2A). Consequently, the patient underwent corneal debridement in the left eye, and new BCLs were prescribed for both eyes. Postoperative care included routine medication. After 2 weeks, punctate erosions of the corneal epithelium were noted in both eyes, with UCVA of 20/32 in the right eye and 20/25 in the left eye (Figure 2B). The patient was advised to apply deproteinized calf blood extract eye gel along with tobramycin-dexamethasone ophthalmic ointment three times daily after removing the BCLs.

Nevertheless, there was no significant improvement after 1 week. The patient was instructed to use an autologous serum for 1 week, during which the UCVA decreased to 20/40 OU, and sodium fluorescein staining revealed diffuse staining in both eyes (Figure 2C). Deproteinized calf blood extract eye gel and tobramycin-dexamethasone ophthalmic ointment were applied three times daily to both eyes during hospitalization. After 2 days, the corneal

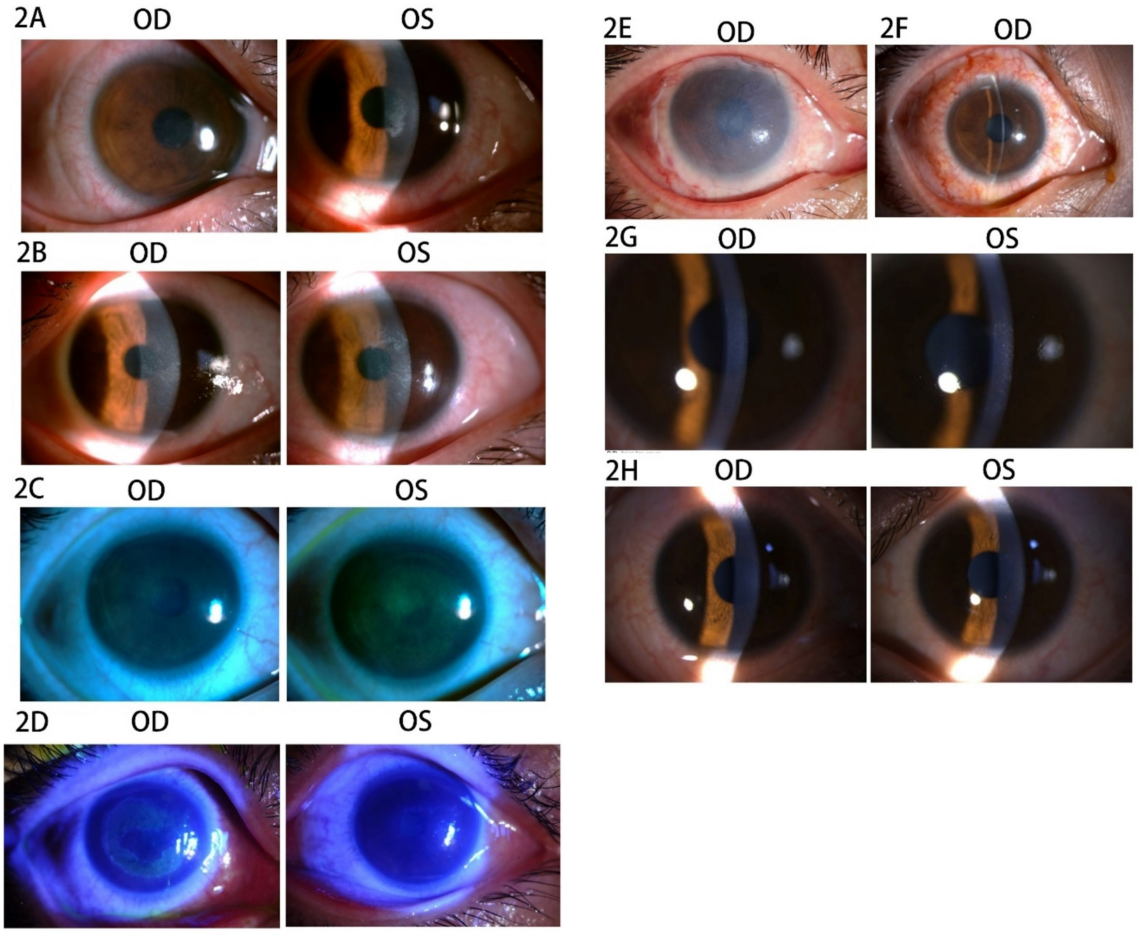

FIGURE 2
Images of the anterior segment of the cornea in Case 2. **(A)** The corneal epithelium showed slight punctate defects in the right eye, and the epithelium debris accumulated in the central cornea in the left eye. **(B)** The punctate erosion of corneal epithelium was observed in both eyes. **(C)** The sodium fluorescein staining revealed diffuse staining in both eyes. **(D)** The corneal epithelium of the left eye was visibly repaired, whereas the right eye exhibited extensive epithelial erosion after 2 days. **(E)** The amniotic membrane in the right eye. **(F)** The stitches were removed at 2 weeks after the AMT. **(G)** The cornea was transparent at 5 months after SPT-TransPRK. **(H)** The cornea was transparent at 9 months after SPT-TransPRK.

epithelium of the left eye showed visible repair, whereas the right eye displayed extensive epithelial erosion (Figure 2D). The patient then underwent amniotic membrane transplantation (AMT) in the right eye to restore the corneal epithelial barrier (Figure 2E). After AMT, tobramycin dexamethasone ophthalmic ointment was administered once at night, along with ofloxacin ophthalmic ointment three times daily and recombinant bovine basic fibroblast growth factor eye gel (rb-bFGF) four times daily in the right eye. The stitches were removed 2 weeks post-AMT, and the corneal epithelial healing was completed, achieving a UCVA of 20/25 OU (Figure 2F). At 5 and 9 months after SPT-TransPRK, the patient's UCVA was 20/20 OU, and the cornea appeared transparent (Figures 2G,H).

Case 3

The patient was a 21-year-old woman with a cycloplegic refraction of −6.00 −0.50 × 55 OD and −3.75 −0.50 × 174 OS. SPT-TransPRK was performed in 2020, and contraindications were excluded. Details regarding contraindications, history of herpes simplex virus infection, and the preoperative and postoperative management of the patient can be found in Case 1. On the 6th postoperative day, the corneal epithelium of the left eye had not healed well, and the BCL continued to be retained. By the 12th postoperative day, the epithelial surface of the left eye lacked smoothness. Consequently, BCLs were removed, and the patient was instructed to apply ganciclovir ophthalmic gel four times daily. One month postoperatively, a slight opacity zone was observed underneath the epithelium, below the pupil of the left eye (Figure 3A). At that point, the patient was advised to stop using steroid drops. After 1 week, the patient experienced photophobia in the left eye, and infiltration was noted in the opacity zone (Figure 3B). Follow-up history indicated that the patient frequently experienced a burning sensation in the left eye and applied cold air directly to it. Therefore, it was suspected that prolonged exposure to the air-conditioned environment could lead to a viral infection. The patient was instructed to apply eye gel three times daily (ganciclovir ophthalmic gel, gatifloxacin eye gel, and ofloxacin eye ointment) along with oral acyclovir once daily. After 1 week, the infiltrated spots in the superficial stromal layer of the left cornea subsided, and the previously mentioned antiviral therapy was continued for another week (Figure 3C). After an additional week, the left corneal epithelium had healed, and the subepithelial corneal opacity was alleviated (Figure 3D). Steroid medication was resumed, and antiviral treatment was discontinued. After three weeks, the corneal epithelium was healed and stable (Figure 3E).

Case 4

The patient was a 27-year-old man with a cycloplegic refraction of −4.25 −0.25 × 75 OD and −3.00 −0.25 × 88 OS who had a history of wearing soft contact lenses (SCLs) for 9 years preoperatively, with a discontinuation period of 1 month. Bilateral eyelid strength was tight, with no contraindications. SPT-TransPRK was performed in 2019. The details of contraindications, the history of herpes simplex virus infection, and the preoperative and postoperative management of the patient were described in Case 1. At 10 days postoperatively, the patient returned to the clinic with a foreign body sensation and decreased vision (UCVA of 20/30 OU) in both eyes, and the corneal epithelial surface lacked smoothness (see Figure 4A). The patient was instructed to use vitamin A palmitate eye gel along with other conventional postoperative medications. Symptoms of eye irritation

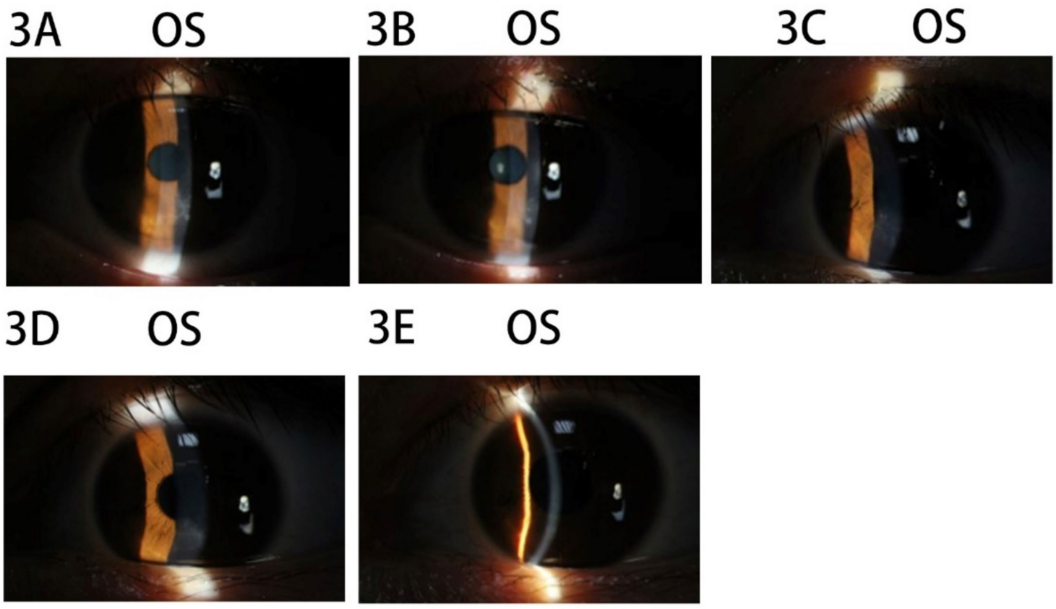

FIGURE 3
Images of the anterior segment of the cornea in Case 3. **(A)** The slightly opacity zone underneath epithelium below the pupil of the left eye. **(B)** The infiltration spot in the opacity zone in the left eye. **(C)** The infiltrated spots in the superficial stromal layer of the left cornea subsided. **(D)** The left corneal epithelium had healed and the subepithelial corneal opacity was alleviated. **(E)** The corneal epithelium was healed and stable.

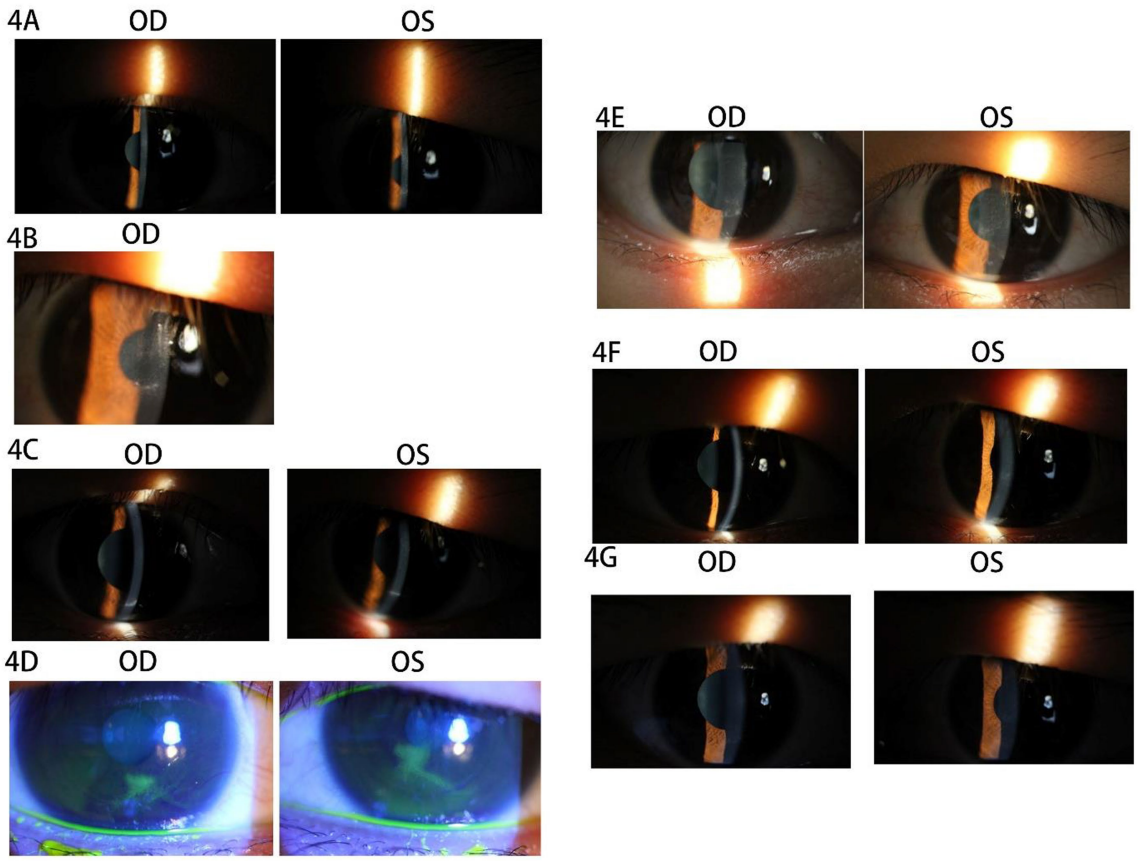

FIGURE 4
Images of the anterior segment of the cornea in Case 4. **(A)** Tthe corneal epithelial surface lacked smoothness in both eyes. **(B)** The accumulation of epithelial cell debris was below the pupil area. **(C)** The patient's corneal epithelial cell debris accumulated the lower eyelid margin at 2 months postoperatively. **(D)** The dendritic staining of sodium fluorescein was orbserved after 1 week. **(E)** The rough corneal epithelia and haze grade 2 were observed in both eyes. **(F)** After 1 week, the corneal epithelium of both eyes healed well with haze grade 2. **(G)** The corneas of both eyes were transparent and smoothy at 4 months postoperatively.

were alleviated, and the right corneal epithelium healed with a UCVA of 20/20.

The left corneal epithelial surface exhibited roughness, presenting with a UCVA of 20/30. Additionally, there was a noted accumulation of epithelial cell debris beneath the pupil area (refer to Figure 4B). The patient received treatment involving corneal debridement and a bandage contact lens (BCL) in the left eye, leading to complete healing within 1 week. However, 2 months postoperatively, the patient experienced a sudden decrease in UCVA (20/30 OU) alongside further accumulation of corneal epithelial cell debris at the lower eyelid margin (see Figure 4C). Notably, corneal epithelial debridement with BCL application was performed in both eyes during this period. One week subsequent to the procedure, the patient reported ocular irritation and demonstrated dendritic staining upon sodium fluorescein application (refer to Figure 4D). A suspected diagnosis of bilateral viral keratitis was made, potentially attributed to a preceding cold illness occurring 2 weeks prior. The patient was advised to discontinue the use of steroidal drops and to apply an eye gel regimen four times daily, which included ganciclovir ophthalmic gel, gatifloxacin eye gel, and deproteinized calf blood extract eye gel, in conjunction with oral acyclovir once per day. Following this treatment plan, the patient's symptoms showed significant improvement, achieving a UCVA of 20/20 OU, alongside rough corneal epithelia and a haze grade of 2 in both eyes (see Figure 4E) after 1 week. Ocular topical and systemic antiviral therapy were continued for an additional 3 weeks. At the conclusion of this period, it was observed that the corneal epithelium of both eyes had healed adequately, maintaining a haze grade of 2 (refer to Figure 4F). The haze was subsequently treated with fluticasone 0.1% eye drops administered four times daily, following the cessation of antiviral therapy in both eyes. Notably, by 4 months postoperatively, the corneas of both eyes appeared transparent and smooth (refer to Figure 4G).

Case 5

The patient was a 31-year-old man who presented with cycloplegic refraction measurements of −3.00 −0.25 × 3 OD and −1.50 −0.25 × 180 OS. He had a documented history of wearing soft contact lenses for 6 years, which were discontinued 3 months prior to the surgical intervention. Upon examination, the patient exhibited bilateral tight strength of the upper eyelids, and there were no noted contraindications. The specifics of any contraindications, along with the medical history of herpes simplex virus infection, as well as the preoperative and postoperative management strategies, are detailed in

Case 1. The SPT-TransPRK procedure was conducted in 2022. The bilateral corneal diameters measured 11.1 mm OD and 11.3 mm OS, while the treatment optical zone and ablation zone dimensions were recorded at 6.8/7.97 mm OD and 7.1/8.04 mm OS, respectively. At 1 week postoperatively, the right corneal epithelium had healed appropriately, with UCVA recorded at 20/20. Conversely, the left corneal epithelial cell debris had accumulated beneath the bandage contact lens (BCL), with UCVA measuring 20/25.

Based on the patient's prior experience with the treatment, left cornea debridement was performed, and the BCL was replaced. The left corneal epithelium healed within a week. One month postoperatively, the corneal epithelium appeared normal, with objective refraction measurements of −2.00 −0.25 × 98 OD and −1.75 −0.75 × 44 OS, and UCVA measuring 20/25 OD and 20/30 OS. The steroid was switched to prednisolone acetate eye drops four times daily due to insufficient refractive correction following surgery, while the other medications remained unchanged. Four days later, the patient reported pain and secretion in both eyes, along with punctate infiltration of the cornea in both eyes, and was prescribed ganciclovir ophthalmic gel three times daily (Figure 5A). Two days later, the patient experienced acute sharp pain and secretion in both eyes, with conjunctival ciliary congestion and a suspected arborization infiltrative zone on the temporal side. Sodium fluorescein staining revealed diffuse detachment in the corneal epithelium of both eyes (Figure 5B). Confocal microscopy showed corneal epithelial cell edema, activated Langerhans cells in the basal layer, activated stromal cells, and inflammatory cells in the superficial stroma without evidence of fungal mycelium or amoebic cysts (Figure 5C). The patient had experienced a cold 4 days earlier and was also dealing with work stress, emotional anxiety, and poor nighttime rest. A diagnosis of corneal viral infection was suspected based on the patient's history and ocular symptoms. The patient was advised to discontinue steroid use and to apply ganciclovir eye gel and gatifloxacin eye gel three times daily, along with systemic antiviral therapy (acyclovir 0.25 g + 0.9% physiological saline). One day later, the patient noted bilateral corneal epithelium detachment, accompanied by significant secretion and conjunctival ciliary congestion (Figure 5D). Bacterial and fungal culture tests were conducted on the secretions from both eyes, and levofloxacin drops were used to rinse both eyes. The BCL was applied, and ofloxacin ophthalmic gel was added to the previous regimen to prevent bacterial infection. After 1 day, the bilateral cornea appeared clear without infiltration, and bacterial culture results returned negative. The ofloxacin ophthalmic gel was discontinued and replaced with oral valacyclovir, which was taken twice daily in addition to the original treatment. The area of corneal epithelial defect decreased, with a small amount of secretion observed in the corneas of both eyes after 1 day.

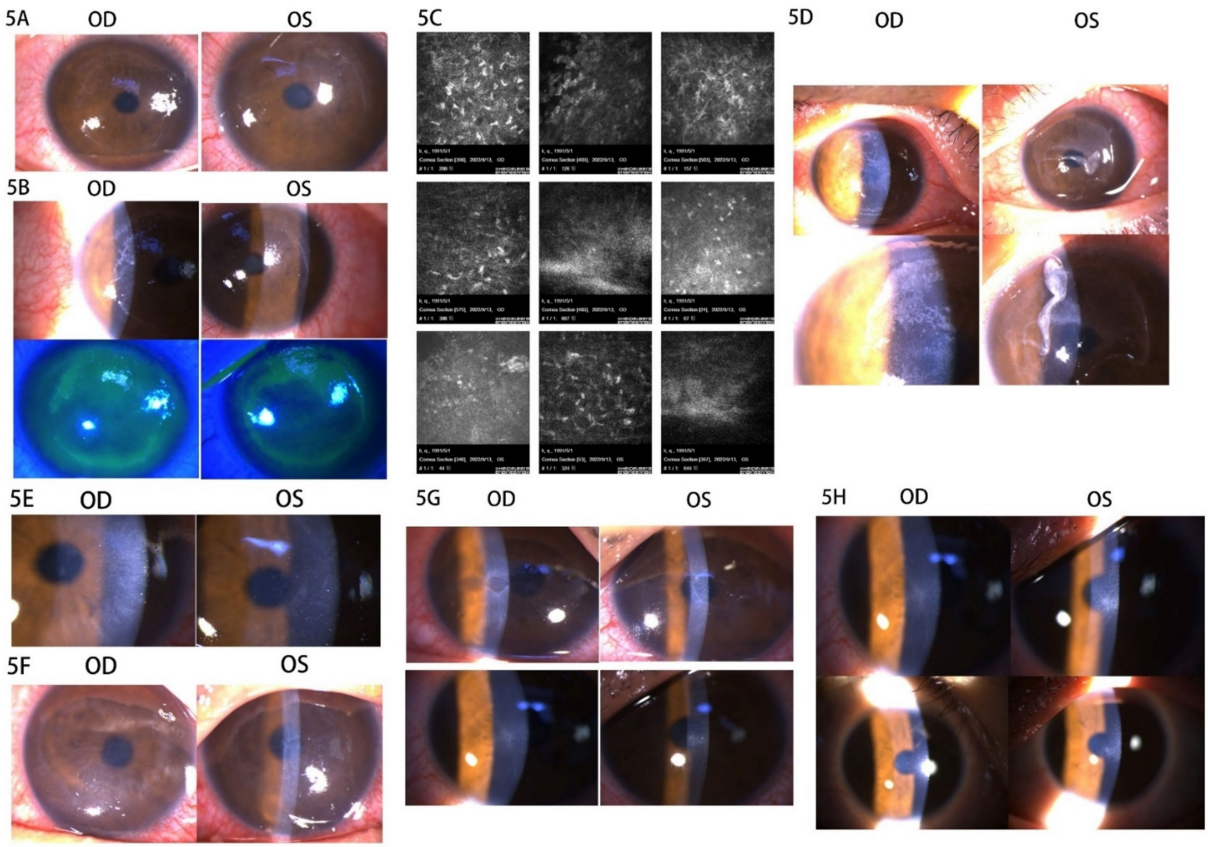

FIGURE 5
Images of the anterior segment of the cornea in Case 5. **(A)** The punctate infiltration of cornea was in both eyes. **(B)** The conjunctival ciliary congestion, suspected arborization infiltrative zone on the temporal side, and sodium fluorescein staining showed diffuse detachment in the corneal epithelium of both eyes. **(C)** The confocal microscopy images. **(D)** The bilateral corneal epithelium detachment with secretion and conjunctival ciliary congestion. **(E)** The right corneal epithelium was repaired with corneal edema and the left corneal epithelium was defective. **(F)** The cornea of both eyes healed no better than before. **(G)** The epithelial defect gradually decreased in 1 week. **(H)** The corneal epithelium had healed with haze grade of 0.5.

The rb-bFGF eye gel was added to the previous treatment, and levofloxacin drops were administered eight times a day. One day later, the right corneal epithelium was repaired with corneal edema, while the left remained defective (Figure 5E). Levofloxacin drops were reduced to six times a day. After 2 days, the corneas of both eyes had not healed any better than before, so the deproteinized calf blood extract eye gel was added to the treatment (Figure 5F). The epithelial defect gradually decreased within 1 week (Figure 5G). The patient was instructed to continue the consolidated antiviral therapy for 2 weeks and to resume steroids. After 2 weeks, the corneal epithelium had healed with a haze grade of 0.5, and post-refractive medication was continued in both eyes (Figure 5H).

Discussion

The delayed healing of corneal epithelial tissue after refractive surgery is generally defined as corneal injury healing that lasts longer than 3 days. We reviewed relevant literature on corneal epithelial healing. Actin microfilaments within the corneal epithelium anchor to the corneal stroma through E-cadherin-mediated adhesion molecules, coordinating the migration of the epithelium (7). The adhesion complex of the corneal epithelium comprises hemidesmosomes, anchoring filaments, the lamina densa of the basal lamina, and anchoring fibers (8). Stock et al. (9) observed that hemidesmosomes became visible at the site of the corneal epithelial defect 24 h after injury, and an incomplete lamina densa of the basal lamina was noted beneath the hemidesmosome at 7 days post-injury in a guinea pig corneal epithelial injury model (Figure 6). When the proliferative epithelium covers the defect, basal cells begin to secrete laminin to initiate basement membrane reconstruction. These cells then differentiate into pterygoid epithelial cells and start migrating, creating a tight epithelial barrier with pterygoid epithelial cells linked by hemi-bridges (10). The basal cells receive biological signals from both the epithelium and keratocytes to stimulate the synthesis of basement membrane component proteins, which contribute to the stability of the basement membrane (11). Consequently, the lamina densa of the basal lamina is not fully repaired in the early postoperative period, leading to instability in the corneal epithelium and its inability to form a barrier. Persistent corneal epithelial defects may also involve fibrosis and keratocyte apoptosis (12, 13). Therefore, the healing of the corneal epithelium following refractive surgery should be a primary concern for refractive surgeons.

Refractive surgery is recognized as a relevant model of corneal injury, where inflammatory mediators trigger a cascade of biological responses (14). Initially, epithelial removal was viewed as a key factor influencing the healing of the corneal epithelium. Shapira et al. (15) indicated that alcohol-assisted or laser-assisted epithelial removal has a negligible effect on epithelial healing compared to the traditional mechanical method, which does not significantly impact long-term visual quality. In this study, the surgical procedure implemented in all cases was the SPT, characterized by a smoother stromal layer that facilitates corneal epithelial migration, as previously mentioned. Prompt corneal barrier reconstruction is crucial to prevent risk factors from infiltrating the tissue and avert subsequent pathological developments. Consequently, BCLs are widely used in superficial refractive surgery to alleviate postoperative ocular surface discomfort, enhance early postoperative visual acuity, expedite re-epithelialization, prolong drug contact with the ocular surface, and reduce the risk of postoperative infection (16). Notably, refractive surgeons must closely monitor the duration of BCL usage. Prolonged use of BCLs may lead to the accumulation of epithelial debris, tear proteins, and inflammatory mediators (17). Qiao's research revealed that lysozyme deposition was detected on the inner surface of BCLs within 1 h (18). The patient referred to in Case 1 experienced the accumulation of corneal epithelial fragments beneath the BCL during the healing process, which necessitated a replacement BCL. Additionally, considering the extended use of the BCL without complete regeneration of the corneal epithelium, three types of eye ointment were utilized to protect the eyes as an alternative to BCLs.

Typically, refractive surgery patients receive SCLs to correct myopia. However, prolonged use of SCLs is often associated with various ocular surface complications, including infectious and non-infectious keratitis, allergic reactions, hypoxia, toxic reactions, mechanical damage, and dry eye (19, 20). Case 2 involved a patient with a 12-year history of BCL use prior to the procedure, which may lead to punctate detachment of the corneal epithelium, frequently occurring 2 months postoperatively. Therefore, upon reviewing this case, our team will focus on the preoperative corneal epithelial health of this specific group of patients in our future work. The amniotic membrane

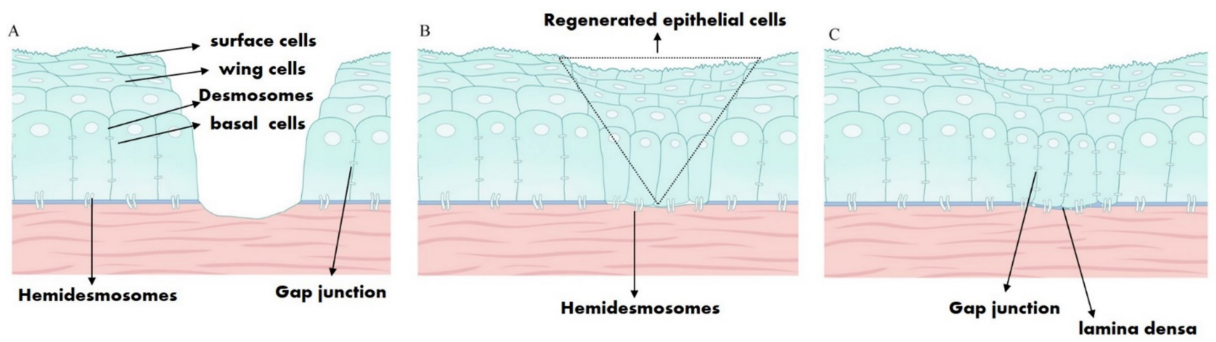

FIGURE 6
Schematic diagram illustrating the healing of corneal epithelial injury. **(A)** The corneal epithelial cells, hemidesmosomes, basement membrane, anchoring fibers, and anterior stroma were all damaged as a result of corneal epithelial injury. **(B)** Regenerated epithelial cells covered the defect, and hemidesmosomes were observed after 24–72 h. **(C)** The incomplete lamina densa of the basal lamina was observed.

TABLE 1 The summary of all the cases in this study.

	Case 1	Case 2	Case 3	Case 4	Case 5
Age	32	30	21	27	31
Risk factor	BCL size	SCL wearing history	Presumed viral infection	Presumed viral infection	Presumed viral infection
Soft contact lens wear duration	None	12 years	None	9 years	6 years
Dry eye	None	None	None	None	None
Pre-op herpes simplex infection	None	None	None	None	None
Duration of PED	3 weeks	3 months	1 month	1 month	2 weeks
Etiology of PED	BCL size	Preoperative SCL wearing history	Presumed viral infection	Preoperative SCL wearing history, eyelids' mechanical forces, and presumed viral infection	Presumed viral infection and the large ablation zone
The responded treatment	Replaced the BCLs with eye ointment wrapping	AMT	Topical and systemic application of ganciclovir earlier	Topical and systemic application of ganciclovir earlier	Suspension of steroid eye drops and topical and systemic application of ganciclovir earlier

is considered a scaffold for epithelial cell migration after corneal injury and releases proteases, growth factors, and anti-inflammatory cytokines, which help prevent epithelial cell apoptosis (21). Moreover, no immune rejection occurred after transplantation (22). The corneal epithelium in Case 2 had not regenerated despite multiple medications, and since prolonged corneal epithelial defects could increase the risk of corneal infections, AMT was performed to quickly restore the corneal barrier, reducing the stimulation of the corneal stroma by inflammatory factors in the tear fluid and the formation of corneal haze.

Patients in cases 3–5 experienced varying degrees of viral infection due to delayed corneal epithelial healing. The causes of viral infection after refractive surgery included surgical injury, long-term postoperative steroid use, excimer laser activation of the virus, and reduced systemic immunity (23). Wu et al. (24) reported two cases of herpesvirus keratitis following SPT-TransPRK in 2022, which were treated with early topical antiviral drugs combined with systemic antiviral therapy. The surgeon diagnosed a "presumed viral infection" based on the history and corneal pathology without conducting PCR testing in this case series. Antiviral therapy had a positive effect on these three cases. The patient in Case 3 experienced a relatively mild corneal infection, and antiviral medications were administered when punctate infiltration was observed in the cornea. Steroids were suspended, effectively controlling the viral infection. In Case 4, the patient had a history of wearing SCLs for up to 9 years before the refractive surgery and presented with tight skin tension on both eyelids. As previously indicated, long-term use of SCLs could lead to abnormal epithelial metabolism. Similarly, the mechanical forces from the eyelids could directly affect the adhesion of the corneal epithelium (25). Therefore, these two factors may be potential reasons for delayed corneal epithelial healing. The selection of refractive surgery methods for patients with tight eyelid skin should be considered carefully to avoid delayed corneal epithelial healing. Furthermore, prolonged use of BCLs after surgery may not benefit corneal wound healing due to the combined effects of eyelid force and BCLs. The antiviral treatment strategy was noted in Case 3.

In Case 5, the surgery was designed to create a large treatment optical zone and ablation zone relative to the patient's corneal diameter. The corneal nerve originates from the trigeminal ganglion, and the density of corneal nerves is more abundant beneath the basal cells of the corneal epithelium, which are arranged in a wheel-like pattern (26). Studies show that corneal nerves are often damaged after refractive surgery and regenerate incompletely within 1 year postoperatively (27). The corneal nerves directly influence the sensitivity and regeneration of the cornea (28). Therefore, rb-bFGF eye drops and deproteinized calf blood extract eye gel were incorporated into the treatment protocol alongside corneal debridement and anti-infection measures in Case 5. Treatment for this case primarily involved debridement, the application of antiviral and antibacterial drugs, and systemic antiviral therapy, all of which proved effective. Notably, when the cornea is suspected of being infected with a virus, steroids should be suspended promptly, and adequate doses of antiviral therapy should be initiated. The characteristics of all cases in the study are summarized in Table 1.

Mitomycin C (MMC) at a concentration of 0.02% is widely used in refractive surgery as an anti-fibrotic agent that inhibits keratocyte fibrosis (29). However, Kremer's case report indicated that the intraoperative use of MMC could result in delayed corneal epithelial healing (30), possibly due to MMC contacting the corneal limbus. In these five case reports, MMC was applied for only 20 s within the laser ablation zone, thereby excluding its role in the delayed healing observed.

In summary, delayed corneal epithelial healing after refractive surgery is rare. The study's limitations primarily involve insufficient sample sizes; however, without prompt treatment, the quality of vision in post-refractive surgery patients can be significantly compromised. Therefore, we compiled all instances of delayed healing since the onset of refractive surgery at our medical center and shared our successful management experiences, focusing on etiological analysis and treatment strategies. In other words, when corneal epithelial healing is inadequate, a thorough review and analysis of the patient's consultation information should be conducted to identify potential causes of delayed healing and determine additional treatment options.

Data availability statement

The original contributions featured in the study are included in the article and Supplementary material. Any further inquiries can be directed to the corresponding author.

Ethics statement

The studies involving humans were approved by the Ethics Review Committee of The Third People's Hospital of Dalian (2023-109-001). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

CY: Writing – original draft, Writing – review & editing. LJ: Data curation, Writing – review & editing. QZ: Data curation, Writing – review & editing. XL: Data curation, Methodology, Writing – review & editing. TY: Data curation, Writing – review & editing. FZ: Methodology, Writing – review & editing. YM: Project administration, Writing – review & editing. JX: Funding acquisition, Methodology, Supervision, Writing – original draft, Writing – review & editing. LZ: Funding acquisition, Methodology, Supervision, Writing – original draft, Writing – review & editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

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Visual outcomes and spectacle independence of a non-diffractive wavefront-shaping intraocular lens in post-LASIK patients

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Purpose: To compare visual outcomes, depth of field (DOF), spectacle independence, and patient satisfaction of cataract patients with and without previous myopic laser in situ keratomileusis (LASIK) surgery who received a non-diffractive extended range-of-focus (EROF) intraocular lens (IOL).

Setting: Xiamen Eye Center, Xiamen, China.

Design: Prospective case series.

Methods: A total of 50 eyes of 41 patients implanted with the Vivity IOL were divided into Post-LASIK and Virgin groups. Outcome measures included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), uncorrected intermediate visual acuity (UIVA), uncorrected near visual acuity (UNVA), refractive outcomes, defocus curves, subjective DOF, spectacle independence, and Visual Function questionnaire (VF-14) after 3 months postoperatively.

Results: Postoperatively, 70% of the Post-LASIK and 86.7% of the Virgin group had refractive error within ± 0.50 D (P = 0.28). The majority of both groups achieved 20/25 or better UDVA, with no significant differences between groups for UDVA, CDVA and UIVA ($P > 0.05$). The UNVA was significantly better in the Post-LASIK group (0.31 ± 0.08 logMAR) than Virgin group (0.45 ± 0.10 logMAR, $P < 0.001$). The Post-LASIK group showed a smoother curve with a wider landing area, and better subjective DOF compared to the Virgin group ($P < 0.001$). Spectacle independence at near ranges in bright light was higher in the Post-LASIK group (81.3 % vs 48 %, P = 0.033). Both groups reported high visual satisfaction, but the Post-LASIK group had fewer difficulties with near-distance tasks in the VF-14 questionnaire.

Conclusion: In post-LASIK eyes, this wavefront-shaping EROF IOL was well-tolerated and provided an extended range of vision with significantly better UNVA, fewer difficulties in daily activities and higher spectacle independence for near vision compared to normal eyes.

KEYWORDS

cataract, LASIK surgery, wavefront-shaping, depth of field, spectacle independence, EROF IOL

Introduction

Laser in situ keratomileusis (LASIK), one of the most widely performed corneal refractive surgeries worldwide, has a history spanning nearly 25 years. In the United States, over 20–25 million eyes have undergone LASIK surgery in the past 20 years. (1) However, patients who had LASIK in its early years are now reaching the age where cataracts commonly develop. Ophthalmologists are increasingly faced with the challenge of managing patients who have undergone myopic LASIK and now require cataract surgery. These patients often wish to pursue spectacle independence again and have higher expectations regarding the refractive outcome, due to their positive experiences with initial corneal refractive surgery. However, selecting a multifocal intraocular lens (IOL) for patients with reshaped corneas remains challenging. Although a history of LASIK surgery is not a contraindication for the use of multifocal IOLs, these patients typically have higher amounts of corneal higher-order aberrations (HOAs), spherical aberration (SA) and lower keratometry, which complicate IOL power prediction and can lead to refractive errors and inferior outcomes for those expecting spectacle independence (2–7). Additionally, many studies have shown that diffractive multifocal IOLs can decrease contrast sensitivity and induce adverse visual symptoms, such as glare and halos (8–10). Therefore, a non-diffractive EROF IOL is a reliable choice for post-LASIK eyes, as it has shown high tolerability to residual refractive errors and low photic phenomena because of its unique optical design (11, 12).

The AcrySof IQ Vivity IOL is a new non-diffractive wavefront-shaping EROF lens, designed with a patented X-Wave technology. According to the manufacturer, this EROF IOL consists of a 2.20 mm wavefront-shaping optic in the central part of the anterior surface to stretch and shift the wavefront without splitting light (12, 13). This design extends the focal range instead of creating multiple focal points, and appears to be less prone to image degradation and artifacts compared to diffractive IOLs while maintaining a functional range of vision (14, 15).

Previous studies of healthy eyes have confirmed that the Vivity IOL provides a continuous range of focus rather than discrete foci at specific distances, offering good visual acuity (VA) results for far and intermediate distances, though near vision was poorer compared to previous multifocal IOLs (16–20). Some in vitro experiments have also shown that the Vivity IOL exhibits minimal spurious light comparable to monofocal IOLs and features an estimated extended range of focus of 1.75 diopters (D) (21, 22). Therefore, this study aims to compare visual outcomes, subjective depth of field (DOF), spectacle independence, and patient satisfaction in patients with and without previous myopic LASIK surgery who received a non-diffractive wavefront-shaping EROF IOL.

Materials and methods

Study design

In this prospective clinical trial, 50 eyes from 41 patients underwent cataract surgery with the implantation of an EROF lens (AcrySof IQ Vivity) between September 2023 and March 2024 at the Department of Cataract, Xiamen Eye Center, Affiliate Xiamen University, China. They were divided non-randomly into two groups: 20 eyes of 16 patients with prior myopic LASIK surgery formed the study group (Post-LASIK), and 30 eyes of 25 patients without LASIK surgery formed the control group (Virgin).

All investigations adhered to the tenets of the Declaration of Helsinki, and informed consent was obtained from all patients. Approval was obtained from the ethics committee at the institution (Approval Number: XMYKZX-KY-2024-047). Patients were informed of the advantages of this non-diffractive EROF IOL and the potential problems, including the need for spectacle correction for certain activities, loss of contrast, and the requirement for sufficient light for adequate visual function.

Inclusion and exclusion criteria

Inclusion criteria for the study group were as follows: a history of myopic LASIK surgery with a centered optical zone, visually significant cataracts interfering with daily activities, and implantation of a non-diffractive EROF IOL (AcrySof IQ Vivity). For the Virgin group, inclusion criteria included clinically significant age-related cataracts affecting daily functioning, no other ocular pathology, and no history of prior ocular surgery, with all patients receiving implantation of a Vivity IOL. Exclusion criteria were preoperative astigmatism exceeding 1.0 D in corneal topography, previous LASIK with small optical zones (5.0 mm or less), preoperative total irregular astigmatism, mainly corneal HOAs in the 4.0 mm zone of corneal topography higher than 0.6 D, and ocular pathologies that could potentially influence the postoperative refraction results.

Preoperative and postoperative assessments

All patients underwent a routine preoperative ophthalmologic examination, including measurement of corrected distance visual acuity (CDVA) and uncorrected distance visual acuity (UDVA) at 4 m using the Early Treatment Diabetic Retinopathy Study charts under photopic conditions, uncorrected intermediate visual acuity (UIVA) at 66 cm, uncorrected near visual acuity (UNVA) at 40 cm, keratometry, axial length (AL), IOL power and target spherical equivalent (SE) by optical biometry (IOLMaster 700, Carl Zeiss Meditech AG), slit lamp evaluation and fundoscopy. Corneal tomography (Pentacam HR, Oculus Optikgeräte GmbH) was performed to confirm the regularity of the previous ablation and astigmatism, and to measure corneal HOAs (4.0 mm zone), spherical aberration (SA) in the 6.0 mm zone and pupil size.

Comprehensive, postoperative refractive measurements were performed at least 3 months after cataract surgery. At the last postoperative visit, the following parameters were measured: CDVA, UDVA, UIVA, UNVA, manifest refraction spherical equivalent (MRSE), mean prediction error (MPE), mean absolute error (MAE), and the percentage of eyes within ± 0.5 D, ± 1.0 D, ± 1.5 D, and ± 2.0 D of target refraction. The defocus curve was measured from +1.50 to −4.00 D in steps of 0.50 D. The MPE was defined as the postoperative SE minus the predicted residual refractive error, with positive values indicating a hyperopic shift and negative values indicating a myopic shift. VA was expressed in logarithmic minimum angle (logMAR). To minimize accommodative effects, patients were instructed to fixate at the designated testing distances with full fogging. All measurements were performed by the same experienced optometrist to ensure consistency.

Subjective DOF assessments

Depth of field was defined as the range of focusing errors for which the image of the target appears to have the same clarity, contrast, and form as the optimal in-focus image (23, 24). Defocus curves could be used to measure subjective defocus tolerance for EDOF IOLs (25, 26). According to the peer-reviewed literature, criterions to define what is optimal or not, vary from 0.10 logMAR to 0.20 logMAR or 0.30 logMAR in pseudophakic eyes (26, 27). In our study, the subjective DOF was obtained from the defocus curve by identifying the range of vergences that provided a visual acuity value of $\leq$ 0.1 and 0.2 logMAR.

Patient satisfaction and spectacle independence

To subjectively measure patient satisfaction, a translated, modified and validated Chinese version of the Visual Function Index (VF-14) questionnaire (see Supplementary materials) was used on a scale of 0–4 points (28). The Chinese-translated VF-14 matches the Chinese socio-cultural norms to enhance item comprehension. It includes items such as visual lifestyle activities (reading small print/newspaper/large font, recognizing familiar people, seeing stairs, reading signs, doing fine handwork, signing names, playing games, taking part in sports, cooking, watching TV, driving at day, and driving at night); and overall satisfaction ("Would you choose this IOL again?"). Responses for visual lifestyle activity items were scored on a five-point Likert scale from 0 ("No difficulty") to 4 ("Unable to do the activity"). The response category "not applicable" was considered missing data, and the overall satisfaction with the IOL was either yes or no. Additionally, at the 3 months follow-up, spectacle independence was expressed using the Intraocular Lens Satisfaction (IOLSAT, ITT number: 60043935) questionnaire. This proprietary Alcon questionnaire asks subjects about their visual performance at various distances in both bright and dim light. All tests and evaluations were performed by the same group of professionals.

Surgical technique

Cataract surgeries were performed by one experienced surgeon (G.B. Zhang) under topical anesthesia. A standardized phacoemulsification was performed through a 2.2 mm temporal corneal incision using the Centurion active-fluidics System (Alcon Laboratories, Inc.). The same EROF IOL (DFT015, AcrySof IQ Vivity) was inserted into the capsular bag. The first available negative-power IOL was selected using the Barrett true-K formula for post-LASIK eyes and the Barrett Universal-II formula for normal eyes, based on the optical biometry with the optimized constant provided by manufacturer. After surgery, all patients received the same treatment consisting of a combination of levofloxacin (Cravit) and dexamethasone (Tobradex) eye drops four times a day during the first week, and then gradually tapered over the following 3 weeks.

Sample size

The sample size calculation was based on a previous study of cataract patients with prior myopic LASIK surgery who were implanted with an EDOF IOL (29). We selected UNVA as the primary outcome measure because achieving functional near vision without corrective lenses is not only a key performance indicator of non-diffractive EROF IOLs but also an important goal for many post-LASIK cataract patients, particularly given their history of seeking spectacle independence. In that study, the UNVA in the two groups were 0.13 ± 0.13 logMAR and 0.46 ± 0.10 logMAR, respectively. To detect a clinically significant difference between the two groups in our study, we used PASS 15.0.5 software to calculate the sample size based on the available data. The results showed that at least eight samples were required in each group, with a total of at least 16 samples needed for this study (alpha = 0.05 and power = 0.9).

Statistical analysis

Descriptive values were given as the mean ± standard deviation. Data were tested for normal distribution using the Shapiro-Wilk test. An independent *t*-test was used to compare

normally distributed variables between the groups. Non-normally distributed data were analyzed using the Mann–Whitney U test. Categorical data were compared using the Pearson chi-squared test. A *P*-value less than 0.05 was considered statistically significant. All statistical analyses were performed using SPSS statistical software (version 19.0, IBM SPSS, Inc.).

Results

Preoperative data

Overall, 41 patients (50 eyes) completed the study, with 16 patients (20 eyes) in the study group (Post-LASIK) and 25 patients (30 eyes) in the control group (Virgin). There were no significant differences between the two groups in terms of age (Post-LASIK: 52.4 ± 6.3 years, range 41–61; Virgin: 55.6 ± 11.1 years, range 27–73; $P = 0.203$), gender, CDVA, UDVA, UIVA, UNVA, IOL power, pupil size and target SE (all $P > 0.05$, Table 1). However, because of the history of prior LASIK surgery in the study group, significant differences were observed between the two groups in terms of mean keratometry, AL, corneal HOAs and SA (both $P < 0.05$). The preoperative data were summarized in Table 1.

TABLE 1 Patient demographics and preoperative data.

Parameter	Group		*P*-value
	Post-LASIK	Virgin	
Eyes	20	30	–
Mean age (y)	52.4 ± 6.3	55.6 ± 11.1	0.203
Sex			
Male	10	11	0.248
Female	6	14	–
Mean CDVA (logMAR)	0.49 ± 0.15	0.58 ± 0.23	0.191
Mean UDVA (logMAR)	0.72 ± 0.18	0.76 ± 0.20	0.471
Mean UIVA (logMAR)	0.52 ± 0.18	0.56 ± 0.17	0.461
Mean UNVA (logMAR)	0.63 ± 0.17	0.62 ± 0.21	0.880
Mean keratometry	39.68 ± 1.74	43.94 ± 1.35	< 0.001
Mean AL	26.93 ± 1.82	24.29 ± 1.38	< 0.001
HOAs	0.34 ± 0.12	0.25 ± 0.09	0.028
SA	0.70 ± 0.16	0.36 ± 0.16	< 0.001
Pupil size	3.01 ± 0.49	2.97 ± 0.46	0.736
IOL power	19.0 ± 2.9	18.8 ± 3.9	0.945
Target SE	−0.11 ± 0.07	−0.15 ± 0.09	0.135

CDVA, corrected distance visual acuity; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity; logMAR, logarithmic minimum angle; AL, axial length; HOAs, higher-order aberrations; SA, spherical aberration; IOL, intraocular lens; SE, spherical equivalent.

Postoperative refraction

Figure 1 illustrates the visual and refractive outcomes. The majority of both groups achieved 20/25 or better UDVA (73.3% vs 80.0% for without a history of LASIK surgery vs with, $P = 0.84$) (Figure 1A). There were no significant differences in the UDVA, CDVA and UIVA between the two groups (all $P > 0.05$) (Table 2). Interestingly, the UNVA was significantly better in the Post-LASIK group (0.31 ± 0.08 logMAR) than in the Virgin group (0.45 ± 0.10 logMAR, $P < 0.001$). Postoperative MRSE showed that both groups achieved a slight myopic result as intended preoperatively, with no significant differences between the groups ($P > 0.05$, Table 2). There was a slight myopic shift in both groups regarding the MPE: −0.16 ± 0.46 D (range −1.07 to +0.68 D) for the Post-LASIK group and −0.09 ± 0.22 D (range −0.61 to +0.31 D) for the Virgin group. Because the MPE does not describe the performance as precisely as the MAE, only descriptive data without *P*-values were delivered (30). Furthermore, the MAE was higher in the Post-LASIK group (0.40 ± 0.27 D), with a statistically significant difference compared to the Virgin group (0.20 ± 0.14 D, $P = 0.007$) (Table 2). Postoperative refractive error was with in ± 0.50 D of plano in 70% of eyes with previous LASIK surgery and 86.7 % of eyes without LASIK surgery ($P = 0.28$) (Figure 1C). Likewise, the percentage of eyes with postoperative refractive cylinder of 0.50 D or less was 75% in the Post-LASIK group and 90% in the Virgin group (Figure 1D).

Defocus curves and DOF

Figure 2 shows the mean defocus curves of the two groups 3 months postoperatively. Both groups exhibited similar defocus curves, with maximum visual acuity close to 0 logMAR. Interestingly, the Post-LASIK group showed a smoother curve with a wider landing area compared to the Virgin group (Figure 2). The defocus VA from +1.5 to −2.0 D was not statistically significantly different between the two groups. However, at defocus curves of −2.5 and −3.0 D, the Post-LASIK group demonstrated significantly better VA than the Virgin group (both $P < 0.01$).

Mean DOF results for each group are represented in Table 3. Regardless of whether a 0.1 logMAR or 0.2 logMAR criteria was used to measure subjective DOF, the Post-LASIK group exhibited a better depth of focus than the Virgin group (all $P < 0.05$) (Table 3).

Spectacle independence and patient satisfaction

Table 4 shows the postoperative levels of spectacle dependence in the two groups. There was no statistically significant difference in reported frequency of glasses use between the two groups for distance and intermediate vision in both bright light and dim light conditions (all $P > 0.05$). However, 81.3% (13 of 16 patients) in the Post-LASIK group reported higher levels of spectacle independence at near ranges, particularly in bright light, compared to the Virgin group [48.0 % (12 of 25 patients), $P = 0.033$] (Table 4). In dim light at near ranges, although the Post-LASIK group appeared to have a higher proportion of spectacle independence compared to

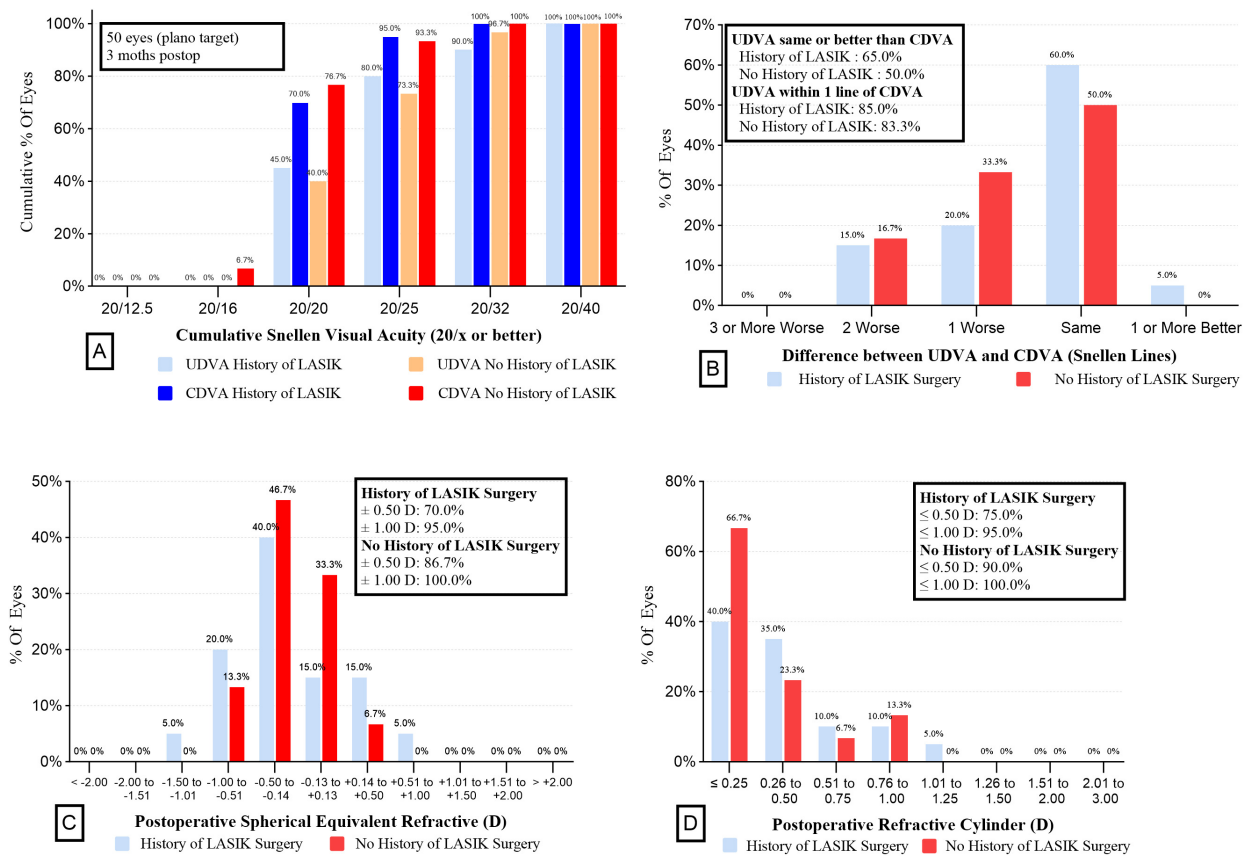

FIGURE 1
Refractive outcomes for wavefront-shaping EDOF IOL in the two groups. **(A)** UDVA and CDVA in the two groups. **(B)** Difference between UDVA and CDVA in the 2 groups. **(C)** Postoperative spherical equivalent refractive in the 2 groups. **(D)** Postoperative refractive cylinder in the 2 groups. EDOF, extended depth-of-focus; IOL, intraocular lens; UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity.

the Virgin group (68.8% VS 48.0%, $P = 0.192$), this difference was not statistically significant. Overall, 75 % (17 of 24 patients) of the Post-LASIK group and 52 % (17 of 24 patients) of the Virgin group reported complete spectacle independence.

The VF-14 questionnaire was answered by all patients, as shown in Table 5. The questionnaire indicated a high level of satisfaction with daily life activities at far and intermediate distances for both groups (all $P > 0.05$) (Table 5). At near distances, patients in the Virgin group reported greater difficulty for reading small print, newspapers or fill out forms (mean scores: 2.64 ± 0.91, 1.92 ± 0.86, 1.20 ± 0.64, respectively) than the Post-LASIK group (1.81 ± 0.91, 0.63 ± 0.62, 0.63 ± 0.50, all $P < 0.01$). Finally, visual satisfaction was high for both groups, with 87.5% of post-LASIK patients expressing that they would undergo surgery again with the same type of IOL compared to 80% of the Virgin group ($P = 0.844$).

TABLE 2 Postoperative visual acuity and prediction error.

Parameter	Group		*P*-value
	Post-LASIK	Virgin	
UDVA (logMAR)	0.09 ± 0.10	0.09 ± 0.09	0.720
CDVA (logMAR)	0.04 ± 0.06	0.02 ± 0.07	0.283
UINA (logMAR)	0.18 ± 0.06	0.22 ± 0.07	0.110
UNVA (logMAR)	0.31 ± 0.08	0.45 ± 0.10	< 0.001
MRSE (D)	−0.28 ± 0.49	−0.24 ± 0.27	0.759
MPE (D)	−0.16 ± 0.46	−0.09 ± 0.22	–
MAE (D)	0.40 ± 0.27	0.20 ± 0.14	0.007

UDVA, uncorrected distance visual acuity; CDVA, corrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity; MRSE, manifest refraction spherical equivalent; MPE, mean prediction error; MAE, mean absolute error; logMAR, logarithmic minimum angle; D, diopters.

Discussion

Nowadays, with the increasing availability of various IOL types and implantation strategies, selecting the appropriate IOL has become a complex task, particularly for special patient groups, such as those with a history of LASIK surgery. There is a widespread belief that implanting diffractive multifocal IOLs in post-LASIK patients carries risks due to increased corneal HOAs, inaccuracies in IOL power calculations, and reduced contrast sensitivity (31–33). Consequently, non-diffractive EROF IOLs appear to be a preferable choice. Firstly, these IOLs create one continuous elongated focus rather than several foci, making them more tolerant of postoperative residual refractive errors in post-LASIK patients. Additionally, the wavefront-shaping Vivity IOL, which incorporates negative SA, can counteract the positive

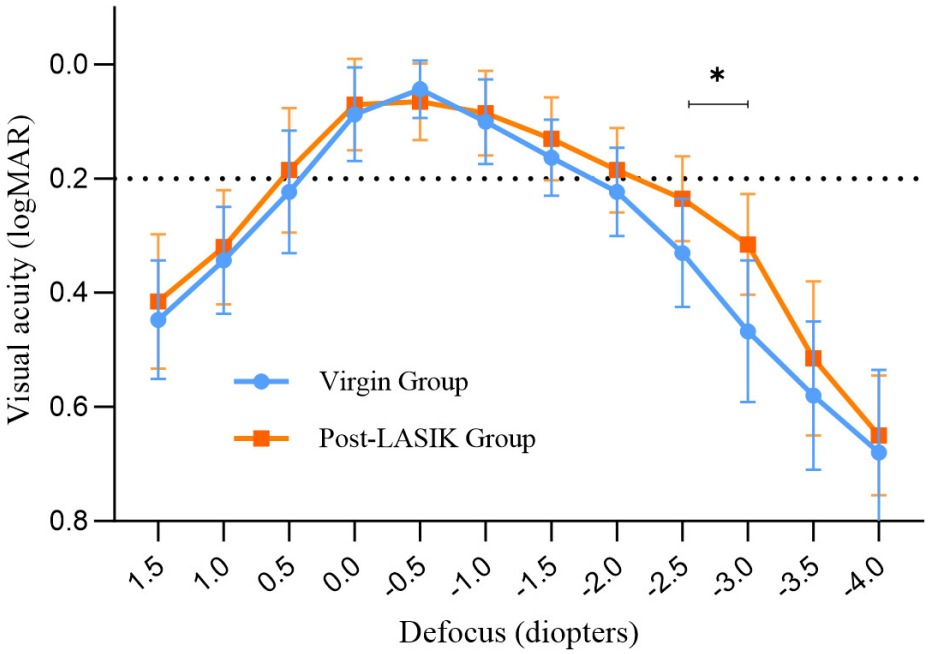

FIGURE 2
Monocular defocus curves for the two groups. *Indicates a statistically significant difference between the two groups at −2.5D and −3.0D.

TABLE 3 Subjective DOF in two groups.

Group	Subjective DOF	
	0.1 logMAR criterion	0.2 logMAR criterion
Virgin	1.70 ± 0.66	2.67 ± 0.53
Post-LASIK	2.08 ± 0.82	3.38 ± 0.62
P-value	0.043	0.001

DOF, depth of field; logMAR, logarithmic minimum angle.

TABLE 4 Summary of Intraocular Lens Satisfaction (IOLSAT) questionnaire results.

Condition	Percentage of subjects never or rarely needing glasses (%)		*P*-value
	Post-LASIK (*N* = 16)	Virgin (*N* = 25)	
Bright light			
Distance ("far away")	87.5	92.0	1.0
Intermediate ("arm's length")	93.8	88.0	0.948
Near ("up close")	81.3	48.0	0.033
Dim light			
Distance ("far away")	81.3	88.0	0.886
Intermediate ("arm's length")	75.0	84.0	0.760
Near ("up close")	68.8	48.0	0.192
Overall	75.0	52.0	0.141

corneal SA induced by myopic LASIK (6). To our knowledge, this is the first prospective and comparative study to report on the visual outcomes, subjective DOF, spectacle independence and patient satisfaction following the implantation of the non-diffractive EROF (Vivity) IOL in patients with and without previous myopic LASIK surgery.

As we know, corneal refractive surgery results in increased corneal HOAs and SA, and similar findings were observed in our study. Although there was a significant difference in HOAs between the two groups, we excluded cases with HOAs greater than 0.6 D (in the 4.0 mm zone) and those with off-center ablation to ensure more regular corneas and enhance the comparability of the data between the two groups. Residual refractive error is a common source of postoperative dissatisfaction following the implantation of advanced technology IOLs (34, 35). Christopher et al. reported that patients who had previously undergone refractive surgery and were implanted with EDOF IOLs achieved excellent outcomes, with 77% of eyes within ± 0.50 D (36). Similar results were observed by Palomino-Bautista et al. (37) with 61.6% of eyes being within ± 0.5 D of target refraction after LASIK surgery and subsequent EDOF IOL implantation. In this trial, 70% of eyes in the Post-LASIK group were within ± 0.5 D, which is slightly inferior to the Virgin group (86.7 %), but consistent with previous studies. Furthermore, the MAE was higher in the Post-LASIK group (0.40 ± 0.27 D) compared to the Virgin group (0.20 ± 0.14 D), indicating that IOL power calculation in patients who have undergone LASIK remains less predictable than in those with healthy eyes. Notably, there was no significant difference between the two groups in the number of eyes within ± 0.50 and ± 1.00 D of postoperative refractive error and refractive cylinder, suggesting that the non-diffractive EROF IOL provides

TABLE 5 Subjective scores of the VF-14 questionnaire 3 months postoperative.

Situation	Score (mean ± SD)		*P*-value
	Post-LASIK (*N* = 16)	Virgin (*N* = 25)	
Far distance			
1. Reading signs, such as traffic signs, street signs, store signs, advertising board, or plate number;	0.19 ± 0.40	0.12 ± 0.33	0.556
2. Taking part in sports, such as playing Ping-Pong or badminton, doing exercise, shadowboxing;	0.31 ± 0.48	0.28 ± 0.46	0.826
3. Watching TV;	0.25 ± 0.45	0.32 ± 0.48	0.635
4. Day driving such as automobile, motorcycle;	0.63 ± 0.50	0.60 ± 0.50	0.874
5. Night driving such as automobile, motorcycle;	1.13 ± 0.72	0.92 ± 0.76	0.388
Intermediate distance			
6. Reading large font, such as a large-print book newspaper, numbers on a telephone, wall clock;	0.38 ± 0.50	0.60 ± 0.64	0.288
7. Recognizing familiar people when they are close to you;	0.25 ± 0.45	0.36 ± 0.49	0.466
8. Seeing steps, stairs, or curbs;	0.44 ± 0.51	0.60 ± 0.71	0.567
9. Playing games, such as card games, mahjong, chess;	0.44 ± 0.51	0.56 ± 0.58	0.542
10. Cooking;	0.50 ± 0.52	0.56 ± 0.58	0.807
Near distance			
11. Reading small print, such as labels on medicine bottles, a telephone book, price list, watch;	1.81 ± 0.91	2.64 ± 0.91	0.007
12. Reading a newspaper or a book;	0.63 ± 0.62	1.92 ± 0.86	0.000
13. Signing your name or filling out forms.	0.63 ± 0.50	1.20 ± 0.64	0.005
Patient satisfaction			
14. Would you choose this IOL again?	87.5%	80.0%	0.844

VF-14, Visual Function Index -14; Score from 0 ("No difficulty") to 4 ("Unable to do the activity") for all items. The response category "not applicable" was considered missing data.

good tolerance for postoperative refractive outcomes in post-LASIK patients.

Interestingly, our data showed that postoperative UNVA was better in the Post-LASIK group compared to the Virgin group, with significant differences in the defocus curves between the two groups at near distances (−2.5 D and −3.0 D). The defocus curve of the Post-LASIK group maintained a VA close to 0.3 logMAR (20/40 Snellen, 0.5 decimal), even at −3.0 D, and exhibited a smoother curve with a wider landing area than the Virgin group. Previous studies have demonstrated that patients with smaller pupils implanted with the Vivity IOL might benefit from the pinhole effect, which can enhance the wavefront-stretching effect (38, 39). In our study, there was no significant difference in pupil size between the two groups. Hence, we speculate that the reasons for better UNVA and a wider defocus curve in the Post-LASIK group may be twofold: firstly, our exclusion criteria limited the impact of high HOAs on visual quality; secondly, Cheng et al. (40) showed that SA, coma, and secondary astigmatism could expand the depth of focus. In our study, for this non-diffractive wavefront-shaping EROF lens, the increased corneal SA, changes in the anterior and posterior corneal surfaces, and flattening of corneal curvature following myopic laser surgery all contribute to an extended depth of focus.

Depth of field is one of the most crucial outcomes in our trial, as it indicates how well the IOL performs across patients with varying ocular conditions. According to the criteria of American Academy of Ophthalmology (AAO), an EDOF IOL should provide a monocular negative depth of focus of at least 0.5 D greater than that of a monofocal control at a 0.2 logMAR level. Some trials have shown that the non-diffractive wavefront-shaping technology meets the AAO EDOF criteria while limiting the level of visual disturbances (16, 41, 42). In our study, subjective DOF was defined as the range of distances on the defocus curve where VA remains above a predetermined value, such as 0.1 or 0.2 logMAR criterion. All subjective DOF measurements in both groups exceeding 1D of defocus imply the effectiveness of the EROF IOL properties. In a previous optical bench simulation of post-LASIK eyes, the Vivity IOL achieved a DOF of 2.54 ± 0.31 D, demonstrating considerable immunity to the presence of HOAs and maintaining a quite constant DOF for a large range of corneal positive SA (11). In our real-world clinical study, the subjective DOF in post-LASIK eyes, measured using the 0.1 logMAR and 0.2 logMAR crierion, was 2.08 ± 0.82 D and 3.38 ± 0.62 D, respectively, both significantly higher than in Virgin eyes. These results suggest that the Vivity IOL exhibits a larger range of DOF and appears particularly suitable for post-LASIK surgery eyes. Although limited information is provided by manufacturers about the optical function of this wavefront shaping IOL, some in vitro experiments have demonstrated that the

EDOF IOL functions by increased spherical aberration of different order (22, 43, 44). Specifically, after corneal myopic LASIK surgery, changes in corneal asphericity and regularity, combined with the complex anterior surface design of the Vivity IOL, may contribute to the extended DOF considerably.

Consistent with previous studies (45, 46), our research demonstrated that both groups exhibited a high level of spectacle independence for far and intermediate distances, never or rarely needing glasses. However, at near distances in bright light, patients with prior LASIK surgery showed higher spectacle independence compared to Virgin group (81.3% vs 48%). This might be due to a better UNVA, a greater DOF or a lower expectation for improved outcomes after surgery in the Post-LASIK group. During preoperative discussions, the ophthalmologist likely emphasized the potential drawbacks of the IOL and the uncertain outcomes for these post-LASIK cataract patients. Consistently, the overall percentage of subjects reporting they rarely or never needed glasses was higher in patients with prior LASIK surgery (75% vs 52% in the Virgin group), driven primarily by higher percentages at near distances in both bright light and dim light conditions. In our study, although the MAE was significantly higher in post-LASIK patients, postoperative VF-14 scores, especially for near activities such as reading small print, reading newspapers, and signing names, were better than in Virgin group. Additionally, postoperative satisfaction with the non-diffractive EROF IOL was very high and, when interviewed, about 87.5% of patients said that they would choose the same IOL again. These findings also confirm the greater tolerance and broader indications of the Vivity IOL in patients who have undergone LASIK surgery.

A limitation of this study was that the patients included in the Post-LASIK group all had well-centered, regular corneal ablation patterns and were satisfied with the visual quality after laser surgery. These may have partially enhanced the effect of the Vivity IOL. Therefore, the authors emphasize that, the results of this study should not be generalized to patients with poor visual quality after refractive surgery, decentered ablations, or excessively high HOAs. Additionally, contrast sensitivity and photic phenomena were not measured in our study. Many studies have shown that visual disturbances with the Vivity IOL are similar to those with monofocal IOLs and superior to diffractive multifocal IOLs (14, 19, 20, 46). This study did not include these data as it was not focused on comparing different types of IOLs. Furthermore, another shortcoming of this non-randomized study was the small sample at a single center, along with an imbalance between the two groups, which may have introduced potential bias. To confirm our findings, a long-term prospective study with more participants from diverse groups of surgeons, hospitals, and races would be required to determine the actual differences between the two groups. Finally, the preoperative axial length differences between the two groups somewhat weaken the reliability of the study's results. Nonetheless, this is a meaningful comparative study to confirm the safety and efficacy of the Vivity IOL implantation and to measure subjective DOF in patients with previous LASIK surgery.

With the introduction of this new class of non-diffractive EROF IOL, a highly satisfactory solution is provided for the individual patients, but it also emphasizes the need for meticulous patient selection. Further research is necessary to refine our understanding of how changes in HOAs and corneal SA after LASIK surgery may result in better near vision with EROF IOL.

Conclusion

The Vivity IOL may be a viable option for patients with previous LASIK surgery who wish to reduce their dependence on glasses but are not candidates for multifocal IOLs. In cataract patients with prior LASIK surgery, this non-diffractive wavefront-shaping EROF IOL provided an extended range of vision with significantly better near vision while delivering similar distance and intermediate vision, a wider DOF, fewer difficulties for daily activities, and a higher rate of spectacle independence for near vision compared to normal eyes.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Xiamen Eye Center and Eye Institute of Xiamen University (Approval Number: XMYKZX-KY-2024-047). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study. Written informed consent was obtained from the individual(s) for the publication of any potentially identifiable images or data included in this article.

Author contributions

WF: Conceptualization, Data curation, Formal Analysis, Resources, Software, Writing – original draft, Writing – review and editing. MZ: Project administration, Resources, Supervision, Writing – review and editing. GZ: Investigation, Methodology, Visualization, Writing – review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fmed.2025.1509889/full#supplementary-material

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Visual outcomes with a non-diffractive enhanced depth-of-focus IOL in patients with age-related macular degeneration

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Purpose: To evaluate visual function in eyes with age-related macular degeneration (AMD) implanted with a non-diffractive enhanced depth-of-focus (EDOF) intraocular lens (IOL) after cataract surgery.

Design: Prospective, observational, non-randomized clinical study.

Methods: Twenty-two eyes from 22 patients diagnosed with AMD and cataracts were submitted to standard cataract surgery with a non-diffractive EDOF IOL implantation (AcrySof IQ Vivity). We measured monocular uncorrected and best-corrected-distance visual acuity (UDVA and CDVA), uncorrected- and distance-corrected-intermediate visual acuity (UIVA and DCIVA), uncorrected- and distance-corrected-near visual acuity (UNVA and DCNVA), manifest refractive spherical equivalent (MRSE) and cylinder, monocular defocus curve and patient-reported outcome questionnaires (Catquest-9SF and NEI VFQ-25). Follow-up visits were carried out at 1, 3 and 6 months post-surgery.

Results: At 6 months post-surgery all eyes were within ± 0.50 D with a mean MRSE of −0.19 ± 0.20 D, 95.45% had a refractive cylinder of ≤ 0.50 D with a mean cylinder of −0.24 ± 0.27 D. The mean values of postoperative monocular CDVA, DCIVA, and DCNVA were 0.02 ± 0.08, 0.16 ± 0.11, and 0.26 ± 0.15 logMAR, respectively. The defocus curve showed good visual acuity at distance and intermediate with a depth-of-focus of about 1.60 D. A total of 81.82% of patients did not report any difficulty with their vision in their everyday-life and 86.36% reported being quite satisfied to very satisfied with their current vision. The NEI VFQ-25 showed that all values improved significantly ($p < 0.05$) after the surgery in the different parameters analyzed except for ocular pain ($p = 0.390$) and color vision ($p = 0.333$).

Conclusion: The use of a non-diffractive EDOF IOL in AMD eyes with cataracts is a safe and effective surgical approach for visually correcting aphakia, providing good visual acuity at far and intermediate distances.

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Our outcomes support the use of non-diffractive EDOF IOLs in patients with AMD diagnosed with cataracts aiming to obtain spectacle-independence at far and intermediate distances.

KEYWORDS

age-related macular degeneration, enhanced depth-of-focus, cataracts, intraocular lens, patient satisfaction

Introduction

Cataract surgery has been reported to effectively improve visual function in patients with age-related macular degeneration (AMD) (1–6). This surgery with IOL implantation is an appropriate solution in AMD patients with clinically significant cataracts. The severity of the AMD, and whether it is exudative or non-exudative, can lead to vision issues that impact intraocular lens (IOL) selection (7). However, the use of specific multifocal IOLs is often not considered for patients with certain retinal disorders, such as AMD, or at risk of developing these. These IOLs, using two or three focal points may reduce contrast sensitivity in healthy patients in some circumstances (8) and it has been argued that this reduction may be significant in eyes with pre-existing contrast sensitivity impairment, such as those with concurrent diseases (9). However, two studies have assessed the visual outcomes of multifocal IOLs in patients with AMD and concluded that a significant proportion of this type of patient benefits from the IOL's multifocality (10); there is also no evidence to suggest that patients with AMD should be advised against using a multifocal IOL (11). Additionally, a recent review of multifocal IOLs and retinal diseases concluded that there is no evidence suggesting that patients with certain retinal diseases should be advised against multifocal IOLs (12). Those authors also pointed out the reduction in contrast sensitivity that should be considered to contraindicate the use of multifocal IOLs.

Enhanced depth-of-focus (EDOF) IOLs are lenses designed to elongate a single-focal-point to increase the area of focus and improve the quality of vision at different distances. Based on this technology, these lenses aim to reduce altered contrast sensitivity compared to traditional multifocal IOLs. However, there is some controversy about the possible difference between these two types of IOLs in terms of contrast sensitivity, since some studies consider that patients implanted with an EDOF have better contrast sensitivity values than those receiving trifocal IOLs (13), both either under photopic and scotopic conditions (14), while others have found comparable outcomes and no particular advantage of EDOFs over trifocal lenses in terms of contrast sensitivity (15–17). We therefore consider that the use of either an EDOF or trifocal IOL should be based on the surgeon's judgment, taking into account the patient's eye characteristics. We believe that a non-diffractive smooth surface is expected to obtain good visual outcomes without affecting contrast sensitivity in eyes with AMD and can allow good retinal fundus visualization that may be needed in these patients. It has been reported that a final corrected distance visual acuity (CDVA) of $\leq$ 0.3 logMAR is significantly associated with patient satisfaction in patients with neovascular AMD after cataract surgery (6). Providing good CDVA and, where possible, good vision at intermediate distances may be beneficial for daily visual tasks in AMD patients diagnosed with cataracts. A recent retrospective study using EDOF IOLs in patients with early AMD has shown that this type of IOL provides improved near vision proportional to far vision in these patients (18).

The aim of this clinical prospective study was to provide more clinical evidence on the use of the AcrySof IQ Vivity EDOF IOL in a series of eyes diagnosed with AMD and implanted with this model, through measuring visual acuity at different distances and assessing visual function using two patient-reported outcome questionnaires.

Materials and methods

This study was done in a single center, being observational and prospective. It followed the Declaration of Helsinki, with all patients with the signed informed consent before. The Ethics Committee of the Hospital Clínico San Carlos in Madrid (Spain) and the Valencian regional committee on postmarketing studies CAEPRO in Valencia (Spain) approved the study. In addition, it was registered in the German Clinical Trials Register with the following number: DRKS00030673.

Intraocular lens and surgery

All eyes were implanted with the AcrySof IQ Vivity EDOF IOL (Alcon Labs, Fort Worth, TX, United States). This model is a non-diffractive lens with ultraviolet and blue light filtering made of hydrophobic acrylate/methacrylate copolymer material (n = 1.55). The IOL has a biconvex wavefront-shaping optic for the spherical model and biconvex toric wavefront-shaping optic for the toric model. The optic diameter is 6.0 mm and the overall diameter is 13.0 mm. It presents a Stableforce modified-L haptics (haptic angle of 0 degrees). The spherical power of the lens is from + 10.00 to + 30.00 D and for toric lenses with powers of 1.00, 1.50, 2.25, 3.00, and 3.75 D. Standard phacoemulsification cataract surgery was performed through a 2.2 mm, clear, temporal corneal incision using a topical anesthetic and the Centurion$^{<reg>(</reg>}$ vision system (Alcon Labs, Fort Worth, TX, United States) with a 5 mm diameter capsulorhexis.

Patients and assessment

Patients underwent a full eye analysis, including preoperative CDVA, refraction, and anterior and posterior segment examination. The inclusion criteria were: age-related cataract surgery patients, candidates for AcrySof IQ Vivity with IOL

10.3389/fmed.2025.1505401

power calculation ranging from + 10 to + 30 D, targeted to plano, patients, based on a fundus examination, macular optical coherence tomography (OCT) or autofluorescence, presenting mild pathology where a trifocal lens is not recommended for one or both eyes, drupes (drupelets or small drusen < 63 μm) in one or both eyes, early AMD with medium drusen of 63–125 μm without AMD-related pigment changes and pigment epithelium alterations without a geographic component, mild alteration observed in a macular OCT study, with partial loss of the ellipsoid line. The exclusion criteria were: advanced or intermediate AMD, other ocular co-morbidities or disease, and previous ocular surgeries.

The IOLMaster 700 biometer (Carl Zeiss Meditec AG, Jena, Germany) was used and the IOL power calculation was carried out using the Barrett Universal II formula, being emmetropia the target refraction. All patients were bilaterally implanted with the AcrySof IQ Vivity IOL (non-toric or toric model, as required) but only one eye per patient was considered for the analysis. If both eyes presented AMD, and were therefore eligible according to the inclusion and exclusion criteria, the eye included in the analysis was choose at random.

Three follow-up visits post-surgery were carried out (1, 3 and 6 months), being analyzed for the last post-operative visit. During these visits, we measured monocular logMAR uncorrected-distance visual acuity (UDVA), CDVA, uncorrected- and distance-corrected-intermediate visual acuity (UIVA and DCIVA, at 66 cm), and uncorrected- and distance-corrected-near visual acuity (UNVA and DCNVA, at 40 cm). subjective refraction, detailed by sphere, cylinder, and the manifest refraction spherical equivalent (MRSE), was recorded at all the postoperative visits, and double-angle tool (19) was used for vector analysis. At 6 months, we also recorded the monocular defocus curve (from + 1.00 to −3.00 D, in 0.50 D increments), to study the useful range of vision. Patients were also asked to complete two patient-reported-outcome questionnaires before surgery and at 6 months post-surgery: the Catquest-9SF and the 25-item National-Eye-Institute-Functional-Questionnaire (NEI VFQ-25), plus the additional questions in Appendix I. The first determines patient satisfaction and difficulties in daily life when carrying out certain activities using nine questions with four response options ranging from 4 (very great difficulty-very dissatisfied) to 1 for (no difficulty-very satisfied), and an additional option (cannot decide), which is treated as missing data. Its usefulness in cataract surgery patients has previously been reported (20–22). The NEI VFQ-25 measures vision-health-related-quality-of-life (23); it has been validated in different languages (24–26) and used in patients implanted with EDOF IOLs (27–29). This test generates different vision-targeted sub-scales. To obtain the score for the NEI VFQ-25, the instructions for the test were followed, converting each item to a 0–100 scale so that the lowest and highest possible scores were set at 0 and 100 points, respectively (the scores representing the achieved % of the total possible score, with 100% being the best possible score and 0% the worst). Also, surgical complications or adverse events were recorded.

Sample size calculation and analysis

Based on a sample size of 22 eyes, a 95% confidence interval, and a standard deviation (SD) of 0.12 logMAR (30) for distance-visual-acuity, the precision for the primary outcome estimate is 0.07 logMAR. This is considered appropriate for the objective of this study. Mean, SD, and minimum and maximum values were considered for the descriptive analysis of the continuous variables and categorical variables were described as %. The Student's *t*-test due to the normal distribution was used to compare the outcomes before and after the surgery according to the results of the NEI VFQ-25 questionnaire. The significance level was considered $p < 0.05$.

TABLE 1 Demographics and preoperative measurements of participants shown as means, standard deviations (SD), and ranges.

	Mean value ± SD (range)
Eyes (*n*)	22
Sphere (D)	0.41 ± 2.72 (−6.25 to 5.25)
Refractive cylinder (D)	−1.10 ± 1.02 (−4.50 to 0.00)
Spherical equivalent (D)	−0.14 ± 2.60 (−6.80 to 4.88)
CDVA (logMAR)	0.16 ± 0.14 (0.00 to 0.50)
K1 (D)	43.79 ± 1.27 (41.34 to 46.14)
K2 (D)	44.81 ± 1.33 (41.98 to 47.35)
Axial length (mm)	23.33 ± 1.01 (21.36 to 26.27)
ACD (mm)	3.12 ± 0.29 (2.63 to 3.59)
IOL spherical power (D)	21.50 ± 2.89 (13.00 to 28.00)
IOL cylindrical power (D)	1.70 ± 0.79 (1.00 to 3.75)

CDVA, corrected distance visual acuity; K, keratometry; ACD, anterior chamber depth; IOL, intraocular lens.

Results

Patients

We examined 22 eyes from 22 patients (14 males) diagnosed with AMD and cataracts. Table 1 shows the demographic and preoperative characteristics of the patients (73.9 years). The mean preoperative CDVA was 0.16 ± 0.14 logMAR. Eight eyes were implanted with the non-toric IOL model and 14 with the toric model (mean cylindrical IOL power 1.70 ± 0.79 D). No complications or adverse events were found either during the surgery or up to the final follow-up visit of the study.

Refraction

Figure 1A shows the distribution of MRSE post-surgery indicating that 54.50% of eyes (n = 12) were within ± 0.13 D and 45.50% (n = 10) were in the range −0.14 to −0.50 D. All the implanted eyes were within ± 0.50 D. The mean MRSE was −0.19 ± 0.20 D, ranging from −0.50 to 0.00 D. The analysis of the refractive cylinder in Figure 1B revealed that 68.18% (n = 15) of eyes were within ≤ 0.25 D and 95.45% (n = 21) were within ≤ 0.50 D, the mean refractive cylinder being −0.24 ± 0.27 D, ranging from 0 to −1.00 D. Double-angle plots of are shown in Figure 1C for the preoperative corneal astigmatism and in in Figure 1D for the postoperative refractive astigmatism. The mean absolute

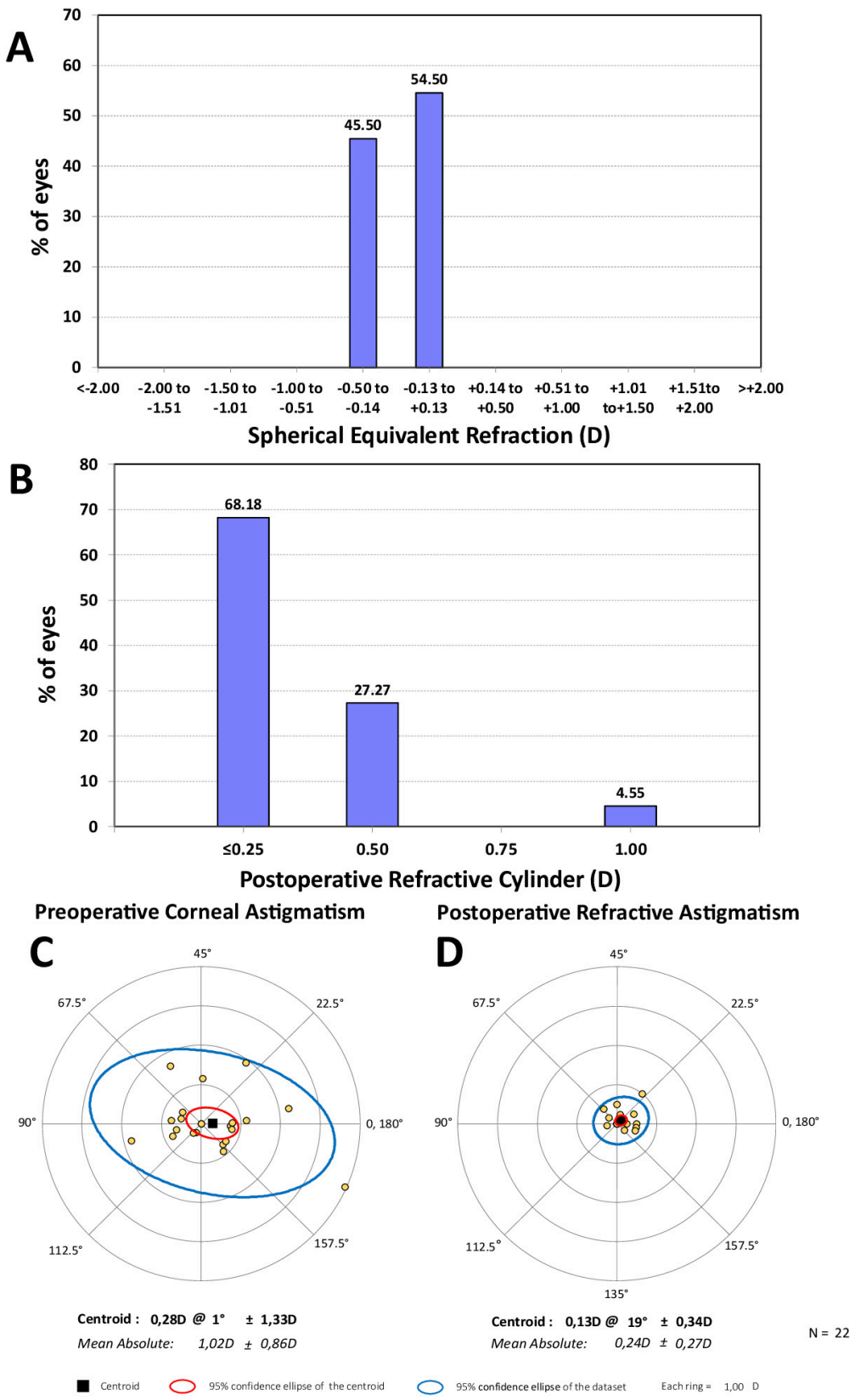

FIGURE 1
Distribution of spherical equivalent refraction **(A)** and refractive cylinder **(B)** 6 months post-surgery, and double-angle plots for preoperative corneal astigmatism **(C)** and postoperative refractive astigmatism **(D)** 6 months post-surgery applying the double-angle tool. Centroids, mean absolute values with standard deviations, and 95% confidence ellipses of the centroid and dataset are also shown.

preoperative corneal astigmatism was 1.02 ± 0.86 D and the mean absolute postoperative refractive astigmatism was 0.24 ± 0.27 D.

Visual acuity at different distances

With regard to the visual acuity outcomes, Figure 2 provides the cumulative percentage of eyes that achieved given monocular UDVA and CDVA values (A), and UIVA, DCIVA, UNVA, and DCNVA scores (B) at 6 months post-surgery. The CDVA was ≥ 20/25 in 77.27% (n = 17) of eyes and ≥ 20/32 in 100% (n = 22). The DCIVA was ≥ 20/25 in 27.27% (n = 6) of eyes and ≥ 20/32 in 68.18% (n = 15), while the DCNVA was ≥ 20/32 in 13.64% (n = 3) and ≥ 20/40 in 31.82% (n = 7) of eyes. The average values for the postoperative monocular UDVA, UIVA, and UNVA were 0.08 ± 0.09, 0.15 ± 0.12, and 0.33 ± 0.14 logMAR, respectively. For corrected distance, CDVA, DCIVA, and DCNVA, these values were 0.02 ± 0.08, 0.16 ± 0.11, and 0.26 ± 0.15 logMAR, respectively. Figure 3 depicts the mean monocular defocus curve, with a peak for far vision (0 D), followed by a steady reduction with negative vergences corresponding to intermediate and near vision. The depth-of-focus was defined as the lens power range that achieved a mean acuity of ≥ 20/32 from 0 D, which for our results it was about 1.60 D.

Patient-reported outcomes questionnaires

Patients were asked to answer the Catquest-9SF and NEI VFQ-25 questionnaires prior to their surgery as well as at 6 months post-surgery. Figure 4 shows the distribution of the answers in percentages for the different questions on the Catquest-9SF questionnaire pre- and post-operatively, summarizing the patient-reported limitations in certain daily activities and their satisfaction with their current vision. A total of 81.82% of patients reported having no difficulties in their everyday life. A total of 86.36% of patients reported being quite satisfied to very satisfied. For various specific tasks, between 50% and 90.91% of patients reported no difficulty performing them, with reading text in newspapers presenting the lowest value. Figure 5 shows the NEI VFQ-25 scores (mean and SD) before and after surgery for the different vision-targeted questions and a health rating question. Note that all values improved significantly ($p < 0.05$) after the surgery for the different parameters analyzed except for ocular pain ($p = 0.390$) and color vision ($p = 0.333$), where no differences were reported.

Discussion

We demonstrate the effectiveness of cataract surgery with a non-diffractive EDOF IOL implantation in AMD patients. The visual acuity outcomes reveal that patients show mean CDVA, DCIVA, and DCNVA values of 0.02 ± 0.08, 0.16 ± 0.11, and 0.26 ± 0.15 logMAR, respectively. The design of the lens offers an extended range of vision, particularly for intermediate vision graphically described in Figure 3 (note that the lens offers a depth-of-focus of about 1.6 D). Our results reveal excellent refractive outcomes, in both MRSE and astigmatism correction (see Figures 1A, B), with 100% of eyes being within ± 0.50 D of MRSE and a mean postoperative MRSE of −0.19 ± 0.20 D and 95.45% of eyes with a refractive cylinder of ≤ 0.50 D and a mean postoperative value of −0.24 ± 0.27 D. The reduced postoperative refractive astigmatism, shown in Figure 1D, should also be noted. Our results showed similar refractive and visual acuity values to healthy eyes implanted with this IOL model (31–33). For example, the multicounty study of Bala et al. (31) analyzed 156 patients implanted with this lens (non-toric) at 6 months post-surgery and found that close to 85% of patients achieved a mean MRSE of ≤ 0.50 D (84.7%, mean of −0.15 ± 0.32 D) and mean monocular values of −0.008 ± 0.007, 0.161 ± 0.013, and 0.414 ± 0.013 logMAR, for CDVA, DCIVA, and DCNVA, respectively. Similarly, McCabe et al. (32), in 107 patients also implanted with the non-toric IOL, also reported that at 6 months 91.6% of eyes achieved a MRSE within ± 0.50 D (mean 0.049 ± 0.345 D) with a mean monocular value of 0.016 ± 0.009, 0.148 ± 0.012, and 0.359 logMAR for CDVA, DCIVA, and DCNVA, respectively. Specifically, the toric model in eyes with low corneal astigmatism, Pastor-Pascual et al. (33) looked at 47 eyes implanted with the AcrySof IQ Vivity Toric T2 at 3 months and found that 100% of eyes had a MRSE within ± 0.50 D (mean −0.10 ± 0.17 D), and mean values of −0.02 ± 0.08, 0.14 ± 0.09, and 0.23 ± 0.12 logMAR for CDVA, DCIVA, and DCNVA, respectively. The defocus curves in these studies showed similar outcomes, for example, Bala et al. (31) determined, in binocular conditions, that patients achieved ≤ 0.0 logMAR from + 0.50 to −0.50 D, < 0.1 logMAR down to −1.50 D, and < 0.2 logMAR down to −2.00 D; McCabe et al. (32) found an increase of 0.54 D at 0.2 logMAR under monocular conditions compared to the monofocal AcrySof IQ IOL; and Pastor-Pascual et al. (33) reported a monocular depth-of-focus of about 1.75 D in their cohort.

Our patient-reported questionnaires revealed good outcomes in terms of satisfaction (86.36% quite satisfied-very satisfied) and difficulties when performing various visual tasks, as per Catquest-9SF (see Figure 4). This correlates with the outcomes of the NEI VFQ-25 questionnaire with post-surgery improvement being reported for the main parameters analyzed (see Figure 5). It is interesting to note the improvement in near (73.48 versus 92.99, $p < 0.001$) and distance activities (80.32 versus 96.21, $p < 0.001$) and driving (79.69 versus 95, $p = 0.007$) after the surgery. Rementería-Capelo et al. (34) analyzed patient satisfaction in 25 patients with ocular pathologies after AcrySof IQ Vivity EDOF IOL implantation using the Catquest-9SF questionnaire (six patients with glaucoma; four with cornea guttata; three patients with dry AMD; two each with amblyopia, ocular hypertension, and corneal leucoma; and one with epiretinal membrane, macular telangiectasia, lagophthalmos, homonymous hemianopia, previous LASIK surgery and daltonism). In a comparison with a healthy control group of patients implanted with the same lens, they found the coexisting pathology group showed a higher level of satisfaction than patients in the control group ($p = 0.016$), and patients in the control group reported higher difficulties reading newspapers ($p = 0.030$). The authors indicated that there were no other significant differences between groups and patients indicated they would undergo the surgery again using the same IOL. They also indicated that their main limitation in the study was the wide range of ocular pathologies included and the low number of

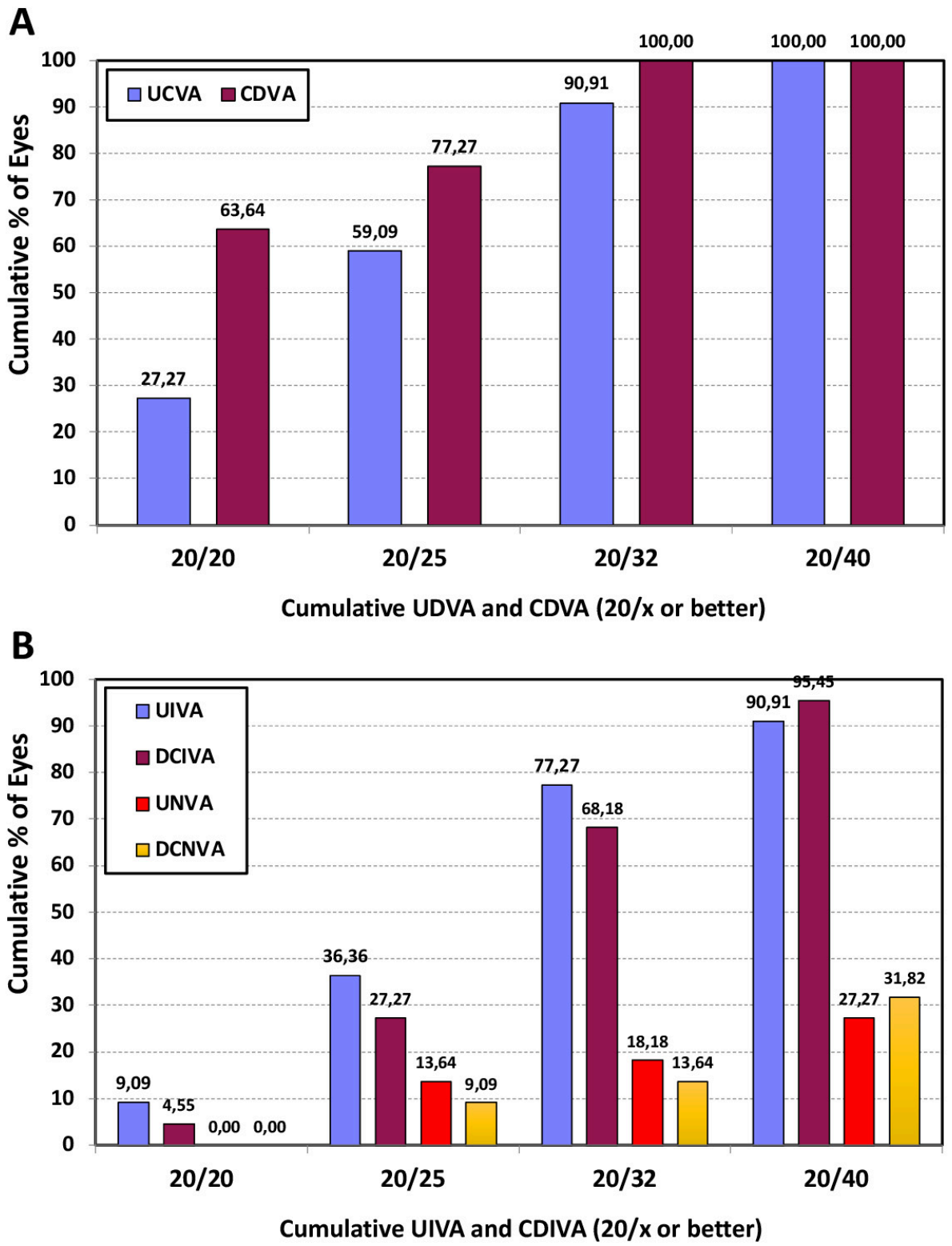

FIGURE 2
Cumulative percentage of eyes at 6 months post-surgery with different degrees of uncorrected and best-corrected distance visual acuity (UDVA and CDVA) **(A)**, and uncorrected and distance-corrected intermediate visual acuity at 66 cm (UIVA and DCIVA) and uncorrected and distance-corrected near visual acuity at 40 cm (UNVA and DCNVA) **(B)**.

each pathology. Labiris et al. (35) analyzed 30 patients implanted bilaterally with the toric and non-toric Vivity IOL and analyzed the outcomes at 6 months post-surgery, using the NEI-VFQ-25 questionnaire. They found mean values for total, near and distance activities of 87.56 ± 8.89, 85.77 ± 9.72, and 88.73 ± 10.34, respectively (see Figure 5 for a comparison with our results).

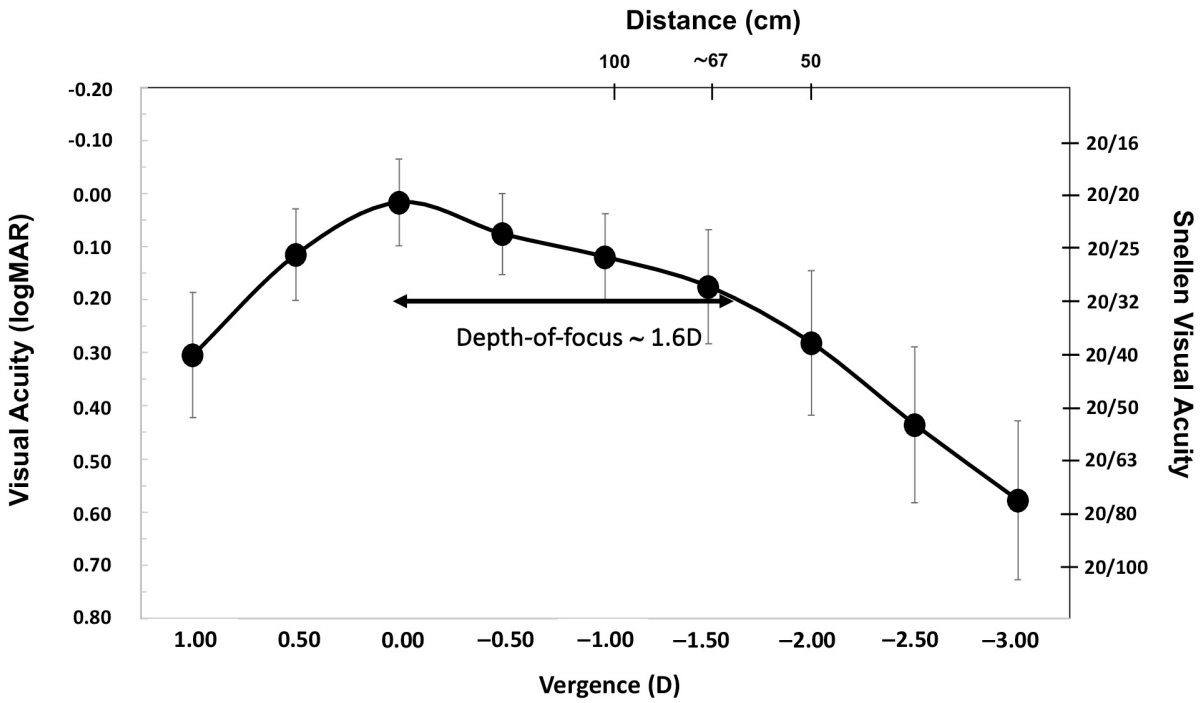

FIGURE 3
Mean monocular logMAR visual acuity with best correction for distance based on the vergence chart for AcrySof IQ Vivity) intraocular lens (IOL) at 6 months post-surgery. The error bars show the standard deviation. The right y-axis shows the Snellen visual acuity in feet and the top x-axis is the distance (cm). Depth-of-focus was defined as the range of lens powers that achieved a mean acuity of 20/32 or better (from 0 D of vergence).

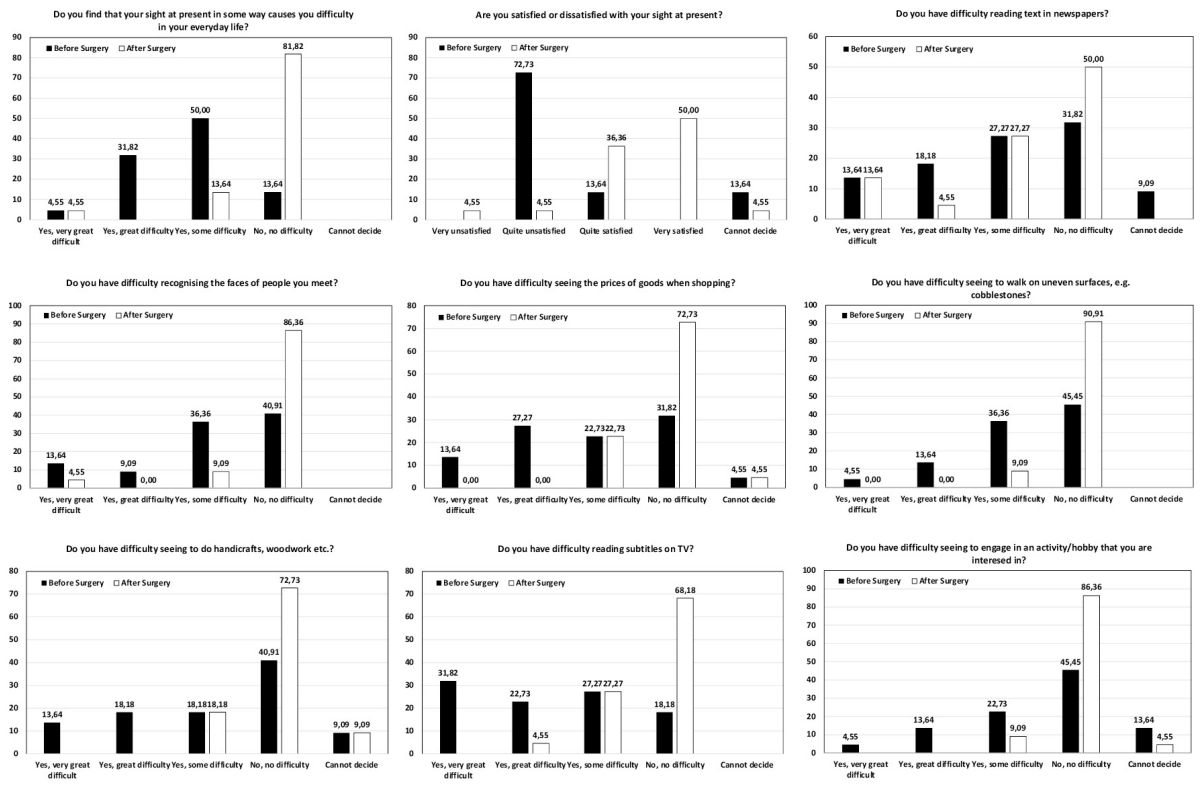

FIGURE 4
Distribution of the answers (percentage) for the different questions in the Catquest-9SF questionnaire before and after the surgery.

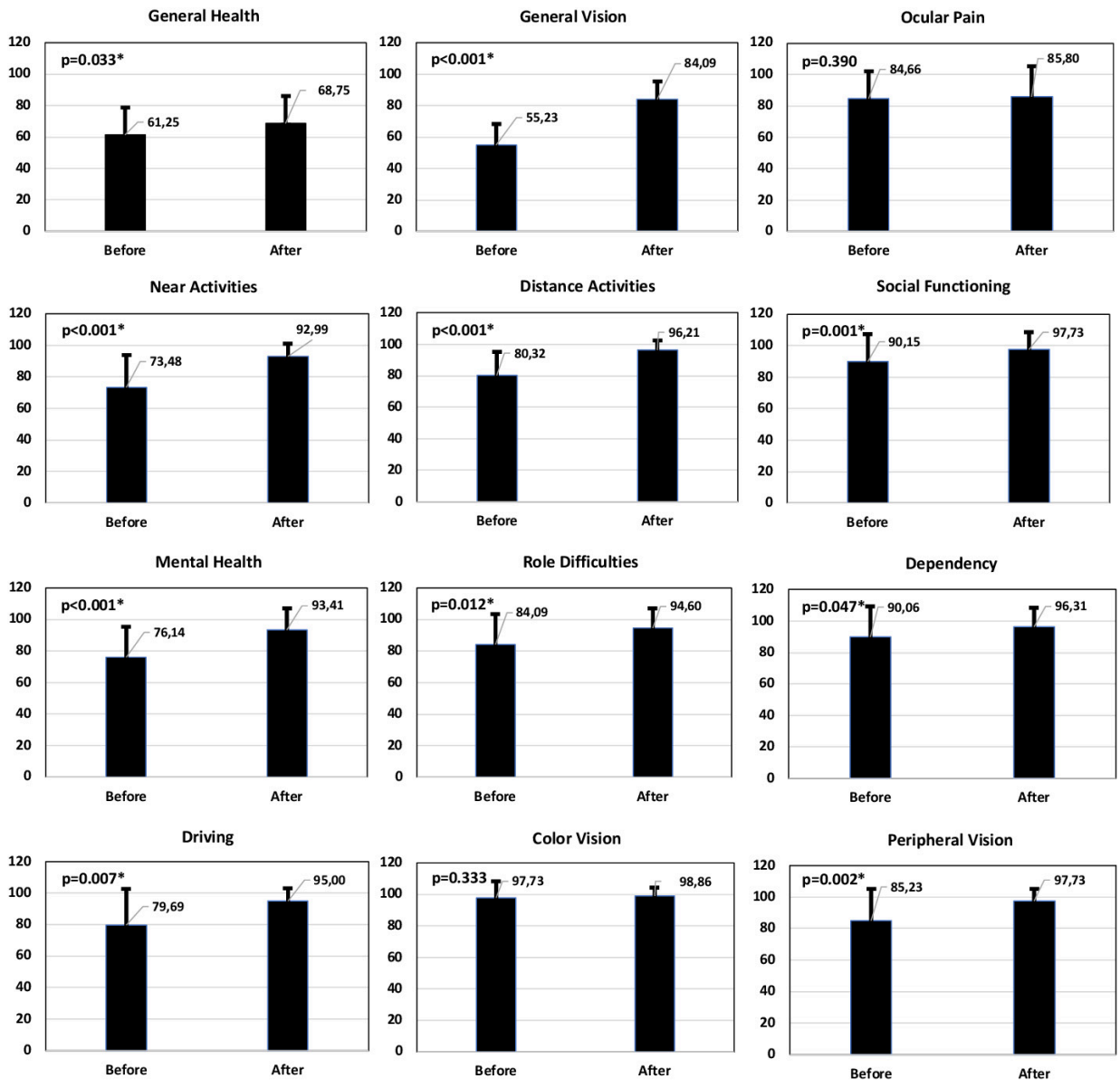

FIGURE 5
Mean and standard deviation NEI VFQ-25 score (percentage) for different vision-targeted sub-scales and a single general health rating question before and after the surgery. Note that the scores represent the achieved percentage of the total possible score, with 100% being the best and 0% the worst possible score. The Student's *t*-test was conducted to evaluate the significance of the differences between before and after the surgery. The asterisk * indicates a statistically significant difference ($p < 0.05$).

These authors compared this group of patients with two other groups, with bilateral PanOptix IOL and mix-and-match, reporting significant better outcomes for these two groups compared to the patients with bilateral Vivity IOLs.

Few studies have analyzed the use of presbyopia-correcting IOLs in patients with AMD. Two studies analyzed the implantation of multifocal IOLs in this type of patient; we know that a direct comparison with our outcomes is not possible due to the different IOL design, but we do consider it interesting to discuss the results. The first study reported the outcomes of 36 AMD eyes implanted with Array multifocal refractive IOLs and compared these with a control group that received monofocal IOLs (10). The authors concluded that the Array IOL provides distance vision comparable to those of the monofocal IOL and found a significant percentage of these patients benefited from the IOL's multifocality (10). In relation to complementary procedures, they indicated that retinal visualization was not impaired, and fluorescein angiography and laser photocoagulation could be performed without difficulty when required in eyes with multifocal IOLs (10). Note that this is not expected with the Vivity IOL due to its design. In this sense, Al-Amri et al. (36) have evaluated the clinical retinal image quality of different IOLs and found that the Vivity IOL showed comparable outcomes to the monofocal AcrySof SA60AT ($P > 0.05$). These authors indicated that the Vivity IOL performs similarly to monofocal IOLs in relation to the *in vivo* clinical retinal optical image quality, without any measurable compromise from the

addition of the wavefront-shaping technology of this lens (36). In the other study, Gayton et al. (11) implanted the bifocal diffractive AcrySof ReSTOR IOL targeting −2.0 D in eyes with AMD and a CDVA of 20/50 or worse to provide an uncorrected near of + 5.2 D. This was a specific multifocal-magnification strategy. They examined 20 eyes 6 months after the surgery and found a CDVA improvement in 14 eyes (70%) and improved CNVA in 17 eyes (85%). These authors administered the VFQ-25 questionnaire and found that all patients (n = 13) reported a significant improvement in visual-related items but not general health. Specifically, the score changes from preoperative levels to 6 months post-surgery were the following: general health (−8 ± 16), general vision (24 ± 14), ocular pain (5 ± 18), difficulty with near-vision activities (15 ± 31), difficulty with distance-vision activities (14 ± 24), limitations in social-functioning (13 ± 25), mental health (23 ± 28), role limitation (19 ± 29), dependency (18 ± 31), driving difficulties (11 ± 32), limitations with color vision (4 ± 29), and limitations with peripheral-vision (16 ± 16). These authors concluded that their preliminary results suggest that this procedure holds promise for the visual rehabilitation of AMD eyes with cataracts. Our results do not consider this type of strategy providing our patients good distance and intermediate visual acuity not using diffractive designs that may affect retinal visualization (see defocus curve plotted in Figure 3).

As we have mentioned, a retrospective-study using the Vivity IOL in patients with early AMD has been published (18). Thananjeyan et al. (18), in a 2 years pilot study assessed 51 eyes (28 patients) with seven early, 17 intermediate and 27 late-stage AMD based on the Beckman clinical-classification implanted with the AcrySof IQ Vivity IOL. Of eyes with late AMD, 17 had wet AMD. They reported a postoperative monocular CDVA and DCNVA at 50 cm of 0.20 ± 0.25 logMAR and N9 (range N5/N36), respectively. A total of 6/5–6/6 Snellen CDVA was found in 29.4% of eyes, and 6/7–6/12 Snellen CDVA in 52.9% of eyes; and 15.7%, 31.4% and 29.4% of eyes had near visual acuities of N6, N8, and N10, respectively. In addition, they measured quality of life using the VF-14 questionnaire and found that all patients reported improvement in daily-activities after the surgery, with 75% of patients reporting no symptoms of dysphotopsia in routine-clinical follow-up visits. The authors also indicated dysphotopsia was not reported to be a limiting factor, and 96% were satisfied with the degree of spectacle-independence and their quality of life post-IOL implantation (with primary spectacle use being for fine near vision tasks). In this cohort, all eyes with clinically classified early and intermediate AMD were able to achieve functional-near-visual-acuity, and eyes with clinically classified late AMD showed a larger spread of CDVA and DCNVA (18). The authors suggested that this could be due to greater variability in visual impairment with disease progression and/or secondary to anti-VEGF therapy in eyes with wet AMD. These authors also measured contrast sensitivity and found that patients achieving satisfactory vision, with Snellen levels of 6/5–6/12, had a contrast-sensitivity within the low normal range, and lower values were obtained in patients with more advanced stages of AMD who had a poorer CDVA. They concluded that the use of this IOL model in these patients allows a range of spectacle free vision and adds a range of satisfactory near and intermediate vision that would not be achieved with a monofocal IOL implantation. They indicated that this lens should be considered in clinical practice for patients with disease, thereby affording them the benefits of multifocality that patients without AMD achieve, while preserving contrast-sensitivity. We broadly agree with them and our outcomes support the use of this lens (18).

We should consider the following limitations of our study: relatively low number of participants, 6 months follow-up, and the lack of contrast sensitivity measurements and a control group to compare the outcomes obtained. However, we have discussed our findings in light of the outcomes reported in previous work in healthy eyes implanted with the same EDOF IOL, and the subsequent follow-up. We believe that despite of not considering a direct control group to compared directly the outcomes reported in our series, the comparison with previous literature on healthy eyes published is valid since the examination protocol and tests were similar or the same in some metrics. Then, can be directly compared in this sense. However, we consider that future studies should include normal healthy patients and eyes with different AMD severities, and, as it is a new procedure, longer follow-ups are required to support long-term safety levels.

In conclusion, the outcomes of our study suggest that cataract surgery with non-diffractive EDOF IOL implantation in AMD patients is satisfactory and efficient in terms of providing good visual acuity at far and intermediate distances. We, therefore, support the use of the AcrySof IQ Vivity in patients with AMD diagnosed with clinically significant cataracts in an aim to obtain spectacle independence at far and intermediate distances.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

The studies involving humans were approved by Human Ethics Committee of the Hospital Clínico San Carlos (Madrid, Spain). The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

JE: Conceptualization, Data curation, Formal Analysis, Funding acquisition, Investigation, Methodology, Supervision, Writing – original draft, Writing – review and editing. PD: Conceptualization, Formal Analysis, Investigation, Methodology, Supervision, Writing – review and editing. BE-G: Investigation, Methodology, Writing – review and editing. PT-S: Investigation, Methodology, Writing – review and editing. PO-V: Formal Analysis, Investigation, Methodology, Supervision, Writing – review and editing. PT-R: Conceptualization, Data curation, Formal Analysis, Methodology, Supervision, Writing – review and editing.

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Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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