ORIGINAL RESEARCH

Evaluation of Short-Term Safety and Efficacy of Myopia Correction with a Novel Posterior Chamber Phakic Intraocular Lens

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ABSTRACT

Introduction: This study aims to evaluate the short-term safety and efficacy of the Loong Crystal®PR lens, a novel posterior chamber phakic intraocular lens (PIOL) that utilizes advanced optical and material designs.

Methods: The single-center retrospective case series included 67 eyes of 34 patients with moderate and high myopia who underwent the PR implantation from February to July 2025. Corrected distant visual acuity (CDVA) and anterior chamber depth (ACD) were measured preoperatively. Uncorrected distant visual acuity (UDVA), refractive errors, higher-order aberrations (HOAs), intraocular pressure (IOP), and endothelial cell density (ECD) were measured preoperatively, at 1 week, and at 1 month postoperatively. The central and peripheral vault were measured on the operating day, at 1 week, and at 1 month after surgery.

Results: At 1 month postoperatively, 95.5% of eyes achieved UDVA equal to or better than the preoperative CDVA. The efficacy index was 1.17 ± 0.19 at 1 month postoperatively. Also, 94.0% of eyes achieved UDVA of 20/20 or better and 94.0% of eyes had residual spherical equivalent (SE) refraction within ± 1.00 D at 1 month postoperatively, demonstrating excellent visual outcomes and refractive predictability. No significant difference in ECD was observed 1 month postoperatively (3118.27 ± 180.95 cells/mm^2) compared to the preoperative value (3081.12 ± 288.08 cells/mm^2). Stable central and peripheral vaults remained at 376.27 ± 168.95 μm and 485.72 ± 179.62 μm, at postoperative 1 month, respectively, compared to the surgery-day values of 373.51 ± 182.41 μm and 486.24 ± 172.41 μm, respectively. There were no significant differences of HOAs at postoperative 1 month compared to the preoperative outcomes.

Conclusions: The Loong Crystal® PR lens demonstrates good, predictable efficacy and stability

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in correcting myopia, with a low risk of adverse events and complications at 1 month postoperatively, indicating its short-term safety and efficacy.

Keywords: PIOL; Myopia correction; Safety; Visual outcome; Vault

Key Summary Points

Why carry out this study?

Some traditional posterior chamber phakic intraocular lenses (PIOLs) exhibit a trend of decreased vault over time. To achieve clinically safe and optimal outcomes, it is important to develop a novel PIOL with good safety and stability, especially for vault.

This study evaluated short-term intraocular safety, efficacy, and refractive predictability following implantation of the Loong Crystal® PR lens.

What was learned from the study?

The Loong Crystal® PR lens demonstrated good efficacy and refractive predictability, with no observed short-term adverse events or surgery-related complications.

The peripheral vault of the lens is wider than the central vault, and the vault maintained good stability after 1 month of surgery.

INTRODUCTION

Myopia is the most common eye disorder in the world and has become a major global public health concern [1]. The increasing prevalence of myopia, especially in younger populations, is associated with factors such as genetic predisposition and environmental influences [2]. Traditional methods of correcting refractive errors, such as spectacles and contact lenses, are non-invasive and effective but are limited in their optical quality and complications include a decrease in endothelial cell density and corneal edema associated with long-term wearing of contact lenses [3, 4].

In response to these limitations, surgical interventions involving posterior chamber phakic intraocular lens (PIOL) implantation has provided a safe, effective, and reversible surgical method for myopia correction [5–7]. PIOLs provide precise and predictable refractive outcomes with the added benefit of being reversible compared to corneal refractive surgeries such as laser-assisted in situ keratomileusis (LASIK) and small-incision lenticule extraction (SMILE) [8].

The traditional Visian Implantable Collamer Lens (ICL;STAAR Surgical, Monrovia, California, USA), a PIOL, has been widely used to correct refractive errors with good outcomes [9, 10], while the thicker profile of the ICL necessitates heightened attention by surgeons to monitor the vault in order to mitigate the elevated risk of corneal edema, cataract, and other complications [11].

In this study, we used an innovative PIOL to correct myopia. The Loong Crystal® PR lens, developed by Eyebright Medical Technology (Beijing) Co., Ltd., China, utilizes an innovative zero-spherical aberration aspheric design, introduces ultraviolet absorbers, and is made of Balacrylic™, a hydrophilic balanced acrylic material with a higher refractive index of 1.50. It features a larger optical zone (6.0 mm) and a thinner profile, which offers excellent biocompatibility, stability, and optical performance. Furthermore, the PR is available in more sizes, providing patients with more options to achieve exceptional optical quality.

This retrospective study aims to evaluate the postoperative outcomes of the PR implantation in patients with moderate-to-high myopia, focusing on safety, vault stability, and visual and refractive outcomes at 1 month postoperatively.

METHODS

Patients and Study Design

This single-arm, single-center, retrospective clinical study included 34 patients with myopia (67 eyes) and with or without astigmatism

(within ± 2.5 D), undergoing the PR implantation at Nanchang Bright Eye Hospital (Jiangxi, China) between February and July of 2025. The follow-up periods were 1 week and 1 month postoperatively. All patients underwent comprehensive preoperative examinations and signed informed consent forms to participate in the study. This study was approved by the Nanchang Bright Eye Hospital Ethics Committee and adhered to the principles of the Declaration of Helsinki.

The inclusion criteria for the study group were as follows: age of 21 to 45 years; myopia ranging from -3.25 D to -18.00 D; corrected distant visual acuity (CDVA) better than 0.3 logMAR; uncorrected distance visual acuity (UDVA) worse than 0.5 logMAR; no use of rigid gas permeable lens or toric soft contact lens for more than 2 weeks; stable refraction for 1 year (change in spherical equivalent (SE) within ± 0.75 D in 1 year); strong desire to get rid of glasses. Exclusion criteria included a history of ocular surgery in the intended eye, any ocular pathology or other diseases that could potentially cause complications, or confound the study results.

The Loong Crystal® PR Lens

The Loong Crystal® PR lens is a one-piece, foldable PIOL with a quadrangular plate haptic design and developed by Eyebright Medical Technology (Beijing) Co., Ltd., China. The lens features a central hole to facilitate aqueous humor circulation with monofocal, aspherical, and zerospherical aberration optical design. The optical zone diameter is 6.0 mm, and it is available in ten sizes: 11.5, 11.8, 12.1, 12.4, 12.7, 13.0, 13.3, 13.6, 13.9, and 14.2 mm.

Ocular Assessments

Visual acuity assessments included UDVA and CDVA. Manifest refraction was performed to measure spherical power, cylindrical power, and cylindrical axis. Anterior chamber depth (ACD) was measured using a Pentacam imaging system (Oculus, Germany). Non-contact intraocular pressure (IOP) was measured using a noncontact tonometer (Canon, Japan). Slit-lamp examinations (Topcon Corporation, Japan) were conducted to evaluate the pupil, natural crystalline lens, cornea, conjunctiva, iris, and other potential abnormalities. The central and peripheral vault were performed using optical coherence tomography (OCT, Zeiss rescan 700, Germany). Endothelial cell density (ECD) was assessed using a specular microscope (SP-2000P, Topcon Corporation, Japan). Spherical aberration, coma, or total higher-order aberrations (tHOAs) were measured by ray tracing technology (iTrace, Tracey Technology, USA).

Surgical Procedures

All surgical procedures were performed by experienced ophthalmic surgeons. Preoperatively, a rapid-acting mydriatic agent was administered for moderate pupil dilation, then the surgical eye was disinfected and given surface anesthesia. During the surgical procedure, the operative field was adequately exposed, and a corneal limbal incision of 3 mm or less was created. Viscoelastic agent was selectively introduced into the anterior chamber, and the PR was then injected and its orientation was confirmed according to the positioning holes. The lens was carefully slid behind the iris, anterior to the natural crystalline lens, and positioned within the posterior chamber. Then the viscoelastic agent was thoroughly removed, and miotic agent was selectively administered, followed by its removal. Finally, a watertight closure of the incision was performed, and its water-tightness was examined. Anti-inflammatory and antibiotic eye drops were prescribed to prevent infection and manage inflammation.

Statistical Analysis

All statistical analyses were conducted using SPSS (version 24.0, IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean $\pm$ standard deviation (SD). The Shapiro–Wilk test was applied to assess the normality of the variables. The independent samples t test was employed for analyzing normally distributed data, while the Mann–Whitney U test was used for non-normally distributed data. A

p value of less than 0.05 was considered statistically significant.

RESULTS

Baseline

A total of 34 patients (67 eyes) were included for the study cohort, including 14 (41.2%) males and 20 (58.8%) females with a mean age of 26.4 ± 8.2 years. The average spherical power was − 8.14 ± 2.04 D, with a cylindrical power of − 0.88 ± 0.99 D, and the mean SE was − 8.58 ± 2.08 D. The average preoperative tHOAs was 0.27 ± 0.08 µm. Preoperative mean UDVA and CDVA were 1.55 ± 0.23 logMAR and 0.01 ± 0.03 logMAR, respectively. Other ocular parameters included average ECD of 3081.12 ± 288.08 cells/mm^2, IOP of 15.70 ± 1.83 mmHg, and ACD of 3.26 ± 0.26 mm. The demographic data and preoperative assessments of the patients are presented in Table 1.

IOP and ECD

The PR demonstrated excellent short-term safety in this study (Fig. 1 and Table 2). At 1 week and 1 month postoperatively, IOP showed a statistically significant difference compared with the preoperative baseline ($p < 0.05$), however, this difference was not considered clinically significant, and all values remained within the safe range (Fig. 1A) [12, 13]. ECD remained stable throughout the follow-up period, with a preoperative mean ECD of 3081.12 ± 288.08 cells/mm^2, 3088.88 ± 205.78 cells/mm^2 at 1 week postoperatively and 3118.27 ± 180.95 cells/mm^2 at 1 month postoperatively. No significant reduction of ECD was observed compared to preoperative values ($p > 0.05$), indicating no significant loss of endothelial cells in the early postoperative period (Fig. 1B), consistent with the results of similar products [14]. No occurrences of severe complications were observed, such as corneal edema, retinal detachment, intraocular lens displacement, or cataract formation at 1 month postoperatively. Neither device defects nor secondary surgical interventions were reported.

Table 1 Patient profile

Parameters	Mean ± SD	Range
Age (years)	26.4 ± 8.2	17.0, 43.0
Gender (male/female)	14/20	
Sphere (D)	− 8.14 ± 2.04	− 12.50, − 4.50
Cylinder (D)	− 0.88 ± 0.99	− 2.50, 2.25
SE (D)	− 8.58 ± 2.08	− 12.75, − 4.50
UDVA (logMAR)	1.55 ± 0.23	0.70, 1.70
CDVA (logMAR)	0.01 ± 0.03	0.00, 0.10
ECD (cells/mm^2)	3081.12 ± 288.08	1803.00, 3502.00
IOP (mmHg)	15.70 ± 1.83	12.00, 20.00
ACD (mm)	3.26 ± 0.26	2.73, 3.89
Spherical aberration (µm)	0.06 ± 0.08	− 0.03, 0.17
Coma (µm)	0.16 ± 0.07	0.06, 0.26
tHOAs (µm)	0.27 ± 0.08	0.12, 0.39

SE spherical equivalent, *UDVA* uncorrected distant visual acuity, *CDVA* corrected distant visual acuity, *ECD* endothelial cell density, *IOP* intraocular pressure, *ACD* anterior chamber depth, *tHOAs* total higher-order aberrations

Vault

The average central and peripheral vault of the intraocular lens on the day of surgery were 373.51 ± 182.41 µm and 486.24 ± 172.41 µm, respectively, with all eyes exhibiting a wider peripheral vault than central vault (Fig. 2A and Table 3). Besides, there was no significant reduction of central vault and peripheral vault at 1 month postoperatively compared to immediate postoperative measurements ($p > 0.05$) (Fig. 2B, C, and Table 3). These results demonstrate favorable short-term safety, stability, and the ability to maintain an ideal vault status of the PR.
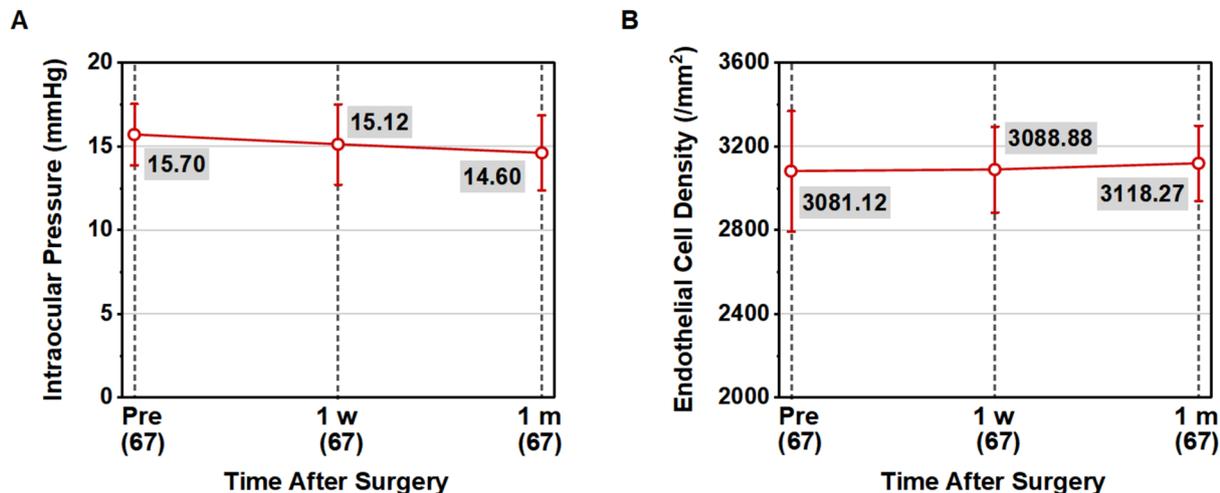
Fig. 1 Preoperative **A** intraocular pressure (IOP) and **B** endothelial cell density (ECD) versus postoperative 1 week and 1 month

Table 2 Descriptive statistics of IOP and ECD

Parameters Mean ± SD (range)	Preoperative	1 week	p value[1]	1 month	p value[2]
IOP (mmHg)	15.70 ± 1.83 (12.00, 20.00)	15.12 ± 2.40 (12.00, 23.00)	0.034	14.60 ± 2.24 (10.00, 19.00)	0.004
ECD (cells/mm²)	3081.12 ± 288.08 (1803.00, 3502.00)	3088.88 ± 205.78 (2058.00, 3424.00)	0.563	3118.27 ± 180.95 (2145.00, 3456.00)	0.890

p value[1] is the p value between preoperative data and postoperative 1-week data

p value[2] is the p value between preoperative data and postoperative 1-month data
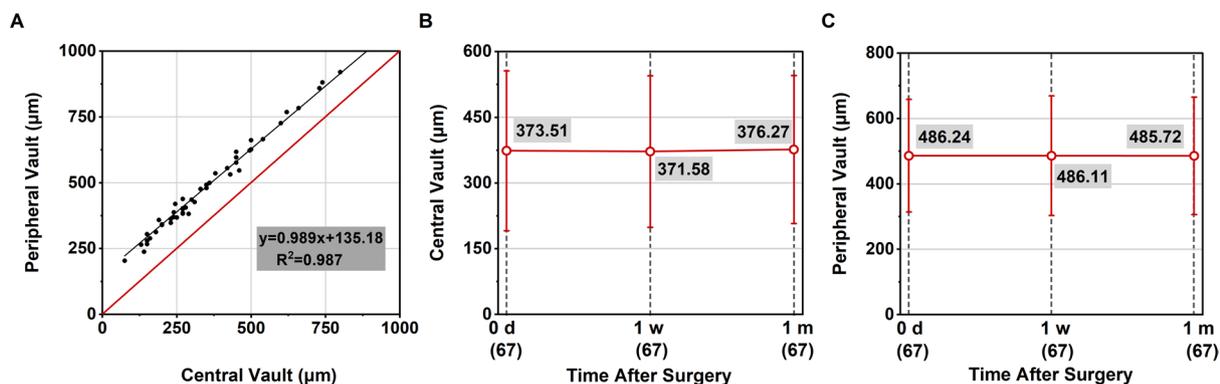
Fig. 2 **A** Peripheral vault versus central vault on the day of surgery (0 day). **B** Central vault on the day of surgery versus postoperative 1 week and 1 month. **C** Peripheral vault on the day of surgery versus postoperative 1 week and 1 month

Table 3 Descriptive statistics of the central and peripheral vault

Parameters Mean ± SD (range)	The surgery day (0 day)	1 week	p value[1]	1 month	p value[2]
Central vault (μm)	373.51 ± 182.41 (75.00, 910.00)	371.58 ± 173.09 (90.00, 840.00)	0.908	376.27 ± 168.95 (90.00, 810.00)	0.759
Peripheral vault (μm)	486.24 ± 172.41 (203.00, 1011.00)	486.11 ± 183.09 (201.00, 996.00)	0.956	485.72 ± 179.62 (197.00, 975.00)	0.911

p value[1] is the p value between data on the day of surgery and postoperative 1-week data

p value[2] is the p value between data on the day of surgery and postoperative 1-month data

UDVA and Efficacy Index

There were 86.6% and 95.5% of eyes achieved UDVA equal to or better than the preoperative CDVA at postoperative 1 week and 1 month, respectively (Fig. 3A). UDVA at postoperative 1 week and 1 month were −0.01 ± 0.08 and −0.05 ± 0.07 logMAR, respectively, both significantly better than the preoperative UDVA of 1.55 ± 0.23 logMAR ($p < 0.05$). 82.1% of eyes achieved UDVA of 20/20 or better, 97.0% reached 20/25 or better, and 97.0% attained 20/32 or better at 1 week postoperatively. By the 1-month follow-up, these rates increased to 94.0%, 98.5%, and 98.5%, respectively. Furthermore, all eyes in the follow-up period achieved a UDVA of 20/40 or better (Fig. 3B). The efficacy indices (postoperative UDVA/ preoperative CDVA) were 1.09 ± 0.19 and 1.17 ± 0.19 at 1 week and 1 month postoperatively, respectively (Table 4).

Manifest Refraction

The residual refractive errors of 1 week and 1 month after the surgery are shown in Table 5—71.6% of eyes were within ± 0.5 D of the attempted SE correction, and 94.0% of eyes were within ± 1.0 D at 1 week postoperatively (Fig. 4A). 83.6% of eyes were within ± 0.5 D of the attempted SE correction, and 94.0% of eyes were within ± 1.0 D at 1 month postoperatively (Fig. 4B). Furthermore, the achieved SE correction at both postoperative 1 week and 1 month versus target SE correction were fitted using linear regression, with a slope close to 1.00 (Fig. 4A and B). 94.0% of eyes had a residual SE refraction within ± 1.00 D at both 1 week and 1 month postoperatively (Fig. 4C and D). These results demonstrated that the PR implantation surgery exhibits high predictability.
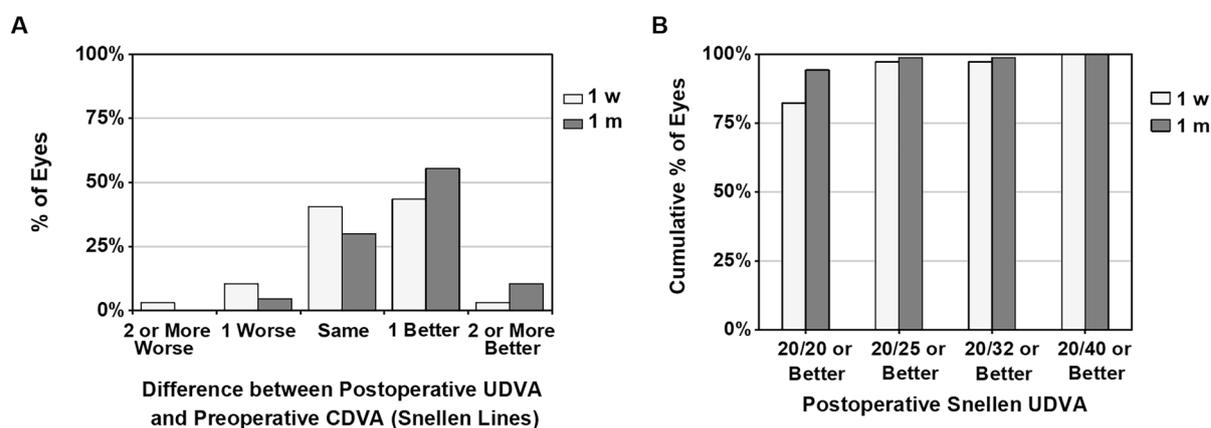
Fig. 3 Visual outcomes of achieved uncorrected distant visual acuity (UDVA) at postoperative 1 week and 1 month

Table 4 Descriptive statistics of visual outcomes

Parameters Mean ± SD (range)	Preoperative	1 week	p value[1]	1 month	p value[2]
UDVA (logMAR)	1.55 ± 0.23 (0.70, 1.70)	− 0.01 ± 0.08 (− 0.18, 0.22)	0.000	− 0.05 ± 0.07 (− 0.18, 0.22)	0.000
Efficacy index	/	1.09 ± 0.19 (0.60, 1.67)	/	1.17 ± 0.19 (0.75, 1.67)	/

p value[1] is the p value between preoperative data and postoperative 1-week data

p value[2] is the p value between preoperative data and postoperative 1-month data

Efficacy indices = postoperative UDVA/preoperative CDVA

Table 5 Descriptive statistics of refraction

Parameters Mean ± SD (range)	Preoperative	The surgery day (0 day)	1 week	p value[1]	1 month	p value[2]
Sphere (D)	− 8.14 ± 2.04 (− 12.50, − 4.50)	0.51 ± 0.86 (− 2.50, 2.50)	0.33 ± 0.74 (− 1.50, 3.00)	0.000	0.35 ± 0.48 (− 0.75, 2.00)	0.000
Cylinder (D)	− 0.88 ± 0.99 (− 2.50, 2.25)	− 0.87 ± 0.83 (− 4.50, − 0.25)	− 0.67 ± 0.54 (− 3.75, 0.50)	0.001	− 0.47 ± 0.34 (− 1.75, 0.50)	0.000
SE (D)	− 8.58 ± 2.08 (− 12.75, − 4.50)	0.08 ± 0.80 (− 2.63, 2.38)	0.00 ± 0.66 (− 1.88, 2.88)	0.000	0.11 ± 0.44 (− 1.13, 1.25)	0.000

p value[1] is the p value between preoperative data and postoperative 1 week data

p value[2] is the p value between preoperative data and postoperative 1 month data

Wavefront Aberrations

There were no significant differences in spherical aberration, coma, or tHOAs at postoperative 1 week and 1 month compared to the preoperative measurements (Table 6), indicating that the zero-spherical aberration aspheric design of the PR did not introduce additional higher-order aberrations. These results indicated that implantation of the PR maintain preoperative optic wavefront characteristics while achieving the targeted refraction outcomes.

DISCUSSION

PIOLs have been widely used for correcting the global public health issue, refractive errors, due to their safety and efficacy. In this retrospective study, we employed an innovative PIOL, the Loong Crystal® PR lens, for the correction of myopia, demonstrating excellent short-term visual outcomes, refractive predictability, stability, and safety.

The visual outcomes of the PR were highly notable, with 94.0% of eyes achieved UDVA of 20/20 or better at 1 month postoperatively. 95.5% of eyes achieved UDVA equal to or better than the preoperative CDVA at 1 month postoperatively, which may be attributed to the PIOL's implantation in the ciliary sulcus, with its optical zone closest to the pupil entrance. This positioning allows for imaging that is most similar to the natural retinal imaging, resulting in clearer vision compared to glasses, thus enabling the postoperative UDVA equal to or better than the preoperative CDVA [15]. These results were similar to previous studies on PIOLs, including those using ICL, which also demonstrated
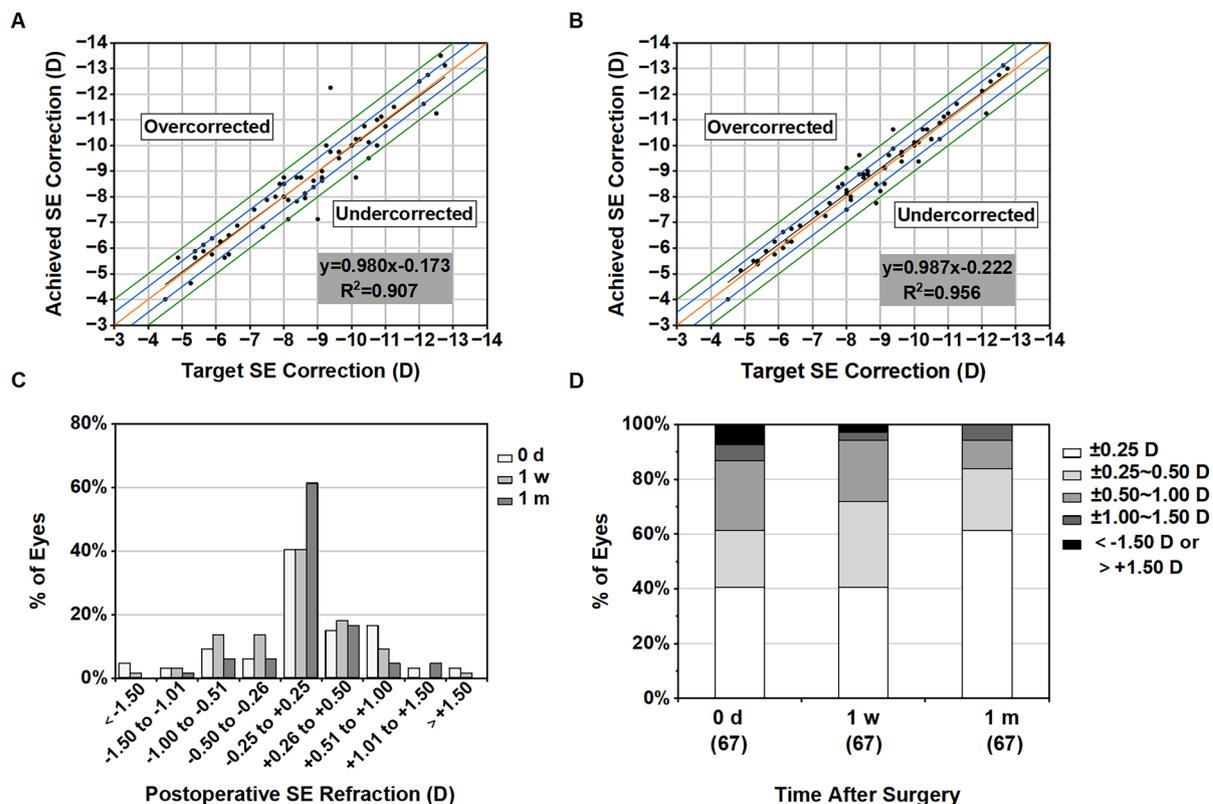
Fig. 4 The linear regression plot of achieved spherical equivalent (SE) correction versus target SE correction at both postoperative **A** 1 week and **B** 1 month. The *orange solid line* represented achieved correction = attempted correction, the *blue solid line* represented achieved correction = attempted correction ± 0.50 D, and the *green solid line* represented achieved correction = attempted correction ± 1.00 D. **C, D** Postoperative SE refraction

Table 6 Descriptive statistics of higher-order aberrations

Parameters Mean ± SD (range)	Preoperative	1 week	p value[1]	1 month	p value[2]
Spherical aberration (μm)	0.06 ± 0.08 (− 0.03, 0.17)	0.06 ± 0.09 (− 0.04, 0.18)	0.758	0.07 ± 0.09 (− 0.03, 0.19)	0.625
Coma (μm)	0.16 ± 0.07 (0.06, 0.26)	0.15 ± 0.06 (0.05, 0.27)	0.517	0.16 ± 0.06 (0.07, 0.29)	0.819
tHOAs (μm)	0.27 ± 0.08 (0.12, 0.39)	0.28 ± 0.10 (0.12, 0.41)	0.854	0.29 ± 0.09 (0.14, 0.45)	0.636

p value[1] is the p value between preoperative data and postoperative 1-week data

p value[2] is the p value between preoperative data and postoperative 1-month data

excellent visual outcomes [6, 10, 16, 17]. Furthermore, 94.0% of eyes had a residual SE refraction within ± 1.00 D at 1 month postoperatively, and the achieved correction closely matched the intended correction, demonstrating refractive predictability of the PR. Similarly, in a study of

ICL implantation with a one-month follow-up, 94.0% of eyes were within a SE target of ±1.00 D [9]. Besides, no significant differences of higher-order aberrations were observed at postoperative 1 month compared to the preoperative outcomes, demonstrating no additional higher-order aberrations were introduced at 1 month after the implantation of the PR. The facts that the PR utilizes an innovative zero-spherical aberration aspheric design and features a larger optical zone of 6.0 mm contribute to its excellent visual outcomes.

No persistent high IOP, corneal edema, cystic macular edema, iritis, or other severe complications were reported. The lens maintained ECD stability, with no significant loss of endothelial cells from preoperative to postoperative 1-month assessments. Although at 1 month postoperatively, IOP showed a statistically significant difference compared to preoperative baseline ($p < 0.05$), this difference was not considered clinically significant, as all values remained within the safe range. No significant decrease in ECD at postoperative 1 month was observed compared to preoperative values ($p > 0.05$), which is consistent with the results of similar products.

The vault status of PIOLs is closely associated with postoperative safety [18]. It ensures proper lens positioning and prevents contact with the natural crystalline lens or corneal endothelium. Previous studies indicate that a vault of less than 250 μm is associated with an elevated risk of cataract formation [19, 20], while a vault exceeding 750 μm may increase the risk of glaucoma and pupillary block [21, 22]. Consequently, the optimal vault for ICL was suggested to be between 250 μm and 750 μm [23]. On one hand, the peripheral vault of the ICL is lower than the central vault [24], which requires surgeons to closely monitor the peripheral vault to prevent related complications. On the other hand, previous studies have shown that the central vault of the ICL tends to decrease over time [25, 26]. For example, in a long-term follow-up study, the mean central vault decreased from 510±238 μm to 439±231 μm ($p < 0.05$), with most eyes exhibiting a reduction in vault of less than 2 μm per month [26].

However, the PR, with a biconcave design and refractive index of 1.50 contrast to lower refractive index of the ICL with 1.442 [27], features a thinner profile and wider peripheral vault than the central vault, contribute to a wider safe range of vault and reduced risk of related complications. The PR exhibited an ideal central vault of 376.27±168.95 μm and peripheral vault of 485.72±179.62 μm, with a wide range from 90 to 810 μm of central vault at 1 month postoperatively. No significant decrease in the central and peripheral vault was observed, indicating that the vault remained stable after 1 month of surgery. No adverse events or related complications were observed, suggesting that the excellent short-term tolerance for vault of the PR.

This study had some limitations. First, data from both eyes of the same patient may introduce statistical bias. Second, the absence of a control group, relatively small sample size, and short follow-up period of the study were factors that warrant further investigation. A long-term study with a large sample size and a control group is needed to assess the durability of the visual and refractive outcomes, as well as IOP, ECD, vault stability, and risk of potential complications such as cataract.

CONCLUSIONS

The use of PIOLs for correcting refractive errors has been widely applied due to their safety, efficacy, reversibility, predictability, and precision. The Loong Crystal® PR lens with its advanced design and biocompatible materials, has shown advantages to provide favorable short-term safety, predictability and visual outcomes in this study. The thinner profile, larger optical zone, and stable vault status contribute to its superior visual outcomes for correcting myopia and reduced risk of complications. Further studies with longer follow-up periods, a large sample size and a control group are essential to confirm the long-term safety and efficacy of this lens, but the current results suggest that the Loong Crystal® PR lens implantation is a promising safe and effective surgical method for correcting moderate to high myopia.

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Declarations

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