



Full Length Article

Effect of mild posterior capsule opacification on visual outcomes in trifocal diffractive pseudophakic eyes: A multicenter prospective study



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ABSTRACT

Purpose: To elucidate the impact of mild PCO on the visual outcomes in patients with hydrophilic trifocal IOLs, and to identify objective indicators that can assist in determining the need for Nd:YAG laser capsulotomy.

Methods: This is a prospective observational study. 189 patients implanted trifocal IOL who underwent Nd:YAG laser posterior capsulotomy were recruited. Patients were classified into four grades according to PCO morphology. The distance, intermediate, and near visual acuity (VA), dysfunction lens index (DLI), contrast sensitivity (CS) and visual function (VF-14) scores were measured before and 1 month after Nd:YAG laser capsulotomy.

Results: Before Nd:YAG laser capsulotomy, a significant correlation was observed between PCO grading and uncorrected distance (UDVA), intermediate (UIVA), near (UNVA) visual acuity, corrected distance VA (CDVA), DLI, and VF-14 scores (All $P < 0.001$). However, in patients with PCO grade 1 (mild), post-capsulotomy UNVA, DLI, medium and high spatial frequency CS under photopic condition and VF-14 scores were significantly improved compared with pre-capsulotomy values (all $P < 0.05$). The area under the receiver operating characteristic curve for DLI was 0.830 ($P < 0.001$), with a corresponding cut-off value of 7.225, indicating its usefulness in assessing the need for Nd:YAG laser capsulotomy in cases of mild PCO.

Conclusions: Mild PCO initially impairs near visual acuity in patients with trifocal IOLs and concurrently diminishes both subjective and objective of visual quality. The DLI can serve as an auxiliary diagnostic indicator to assess whether patients with mild PCO may benefit from Nd:YAG laser capsulotomy.

1. Introduction

After the implantation of a trifocal intraocular lens (IOL), patients usually obtain stable long-standing vision and a higher rate of being independent of spectacles, which has led to the growing popularity of this technique among patients with cataracts accompanied by presbyopia or high myopia.^{1,2} However, it is important to note that some patients with hydrophilic trifocal IOL implants may experience the development of posterior capsule opacification (PCO) within 1–3 years after the surgery.³ Reports indicate that PCO incidence with implantation of the AT Lisa Tri

839 MP (Carl Zeiss Meditec, Jena, Germany) hydrophilic IOL with hydrophobic surface coating is approximately 7.5%–14.3% at 1 year and 34% at 4 years.^{2,4,5} PCO can lead to decreased vision and contrast sensitivity (CS) and increased glare.^{3,6} PCO, which can occur as early as 3–4 months post-surgery, tends to have a relatively minor impact on the visual function of patients implanted with monofocal IOLs.^{7,8} However, patients with multifocal IOLs behave more sensitive to mild PCO, and it can affect visual acuity (VA) and visual quality compared with monofocal IOLs made from the same material and design earlier.^{6,7}

The most effective treatment for PCO is neodymium:yttrium-

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aluminum-garnet (Nd:YAG) laser capsulotomy⁴; however, it results in potential complications, such as cystoid macular edema, elevated intraocular pressure, and dislocation or tilting of the intraocular lens.^{9,10} Undeniably, the impact of advanced PCO on vision and the requisite need for Nd:YAG treatment are significant.⁷ However, research is limited on the effects of mild PCO on the vision and quality of trifocal diffractive pseudophakic eyes. Additionally, definitive criteria for the ideal timing of Nd:YAG laser capsulotomy in trifocal pseudophakic eyes, especially with mild PCO, are yet to be established.

This multicenter observational study aimed to examine the effects of mild PCO on VA and the subjective and objective visual quality of hydrophilic trifocal diffractive IOLs in pseudophakic eyes and to identify objective indicators for helping determine the optimal timing of treatment for mild PCO.

2. Methods

2.1. Study design and participants

Between January 2022 and April 2023, 1276 eyes were implanted with AT Lisa Tri 839 MP IOLs by four experienced cataract surgeons from four centers. A standard cataract phacoemulsification procedure was employed, followed by anterior and posterior capsule polishing using the same technique postoperatively. A total of 245 eyes who underwent Nd:YAG laser capsulotomy were screened. Thirty-four eyes were excluded from the study due to the second eye of the same patient receiving Nd:YAG laser treatment. Fourteen eyes were excluded because of loss of follow-up data, three did not achieve a corrected distance VA (CDVA) of 0.1 logarithm of the minimum angle of resolution (logMAR) after laser surgery, two had a previous history of mild endophthalmitis, two had excluded because of severe dry eye that fails to respond to treatment and affects VA, one had dislocation of IOL after capsulotomy. Data were obtained from the following four research centers in Shanghai, China: Eye and Ear, Nose, and Throat Hospital, Fudan University; Shanghai Heping Eye Hospital; Shanghai Xinchijie Eye Hospital; and Shanghai Bright Eye Hospital.

The study was approved by the ethics committees of the four hospitals and performed in accordance with the principles of the Declaration of Helsinki (IRB Number: HXYK-SHHP-2020-0004) ([ClinicalTrials.gov](https://www.clinicaltrials.gov/ct2/show/study?term=NCT06092164), identifier NCT06092164). All patients provided written informed consent prior to enrollment.

The inclusion criteria were as follows: (1) age ≥ 20 years; (2) all of the patients had previous uneventful phacoemulsification surgery with AT Lisa Tri 839 MP implantation; and (3) patient-reported decrease in VA significantly lower than their postoperative best vision with PCO grading ≥ 1 . The exclusion criteria were as follows: (1) other ocular comorbidities, such as corneal, fundus, and optic nerve diseases; (2) postoperative complications; and (3) a history of corneal refractive surgery such as LASIK and LASEK ([Supplementary Fig. 1](#)).

2.2. Pre-capsulotomy and post-capsulotomy examinations

All patients included in this study were examined twice, both before and 1 month after Nd:YAG laser capsulotomy. Patients underwent a comprehensive examination including UDVA at 5 m, UIVA at 80 cm, UNVA at 40 cm, and CDVA at 5 m, using the logarithmic VA charts, intraocular pressure measurements, slit-lamp evaluation, optical coherence tomography (Cirrus HD-OCT, Carl Zeiss Meditec, Dublin, CA), B-scan ultrasonography, optomap (Optos Dayton, Carl Zeiss Meditec AG), and funduscopy to check for fundus diseases. After mydriasis, retroillumination images of the PCO were evaluated. The dysfunction lens index (DLI) was evaluated using a HOYA iTrace ray-tracing aberrometry system (Tracey Technologies, Houston, TX, USA). CS was evaluated using the Optec 6500 (Stereo Optical Co., Inc., Chicago, IL, USA) with optimal distance correction. Functional vision was assessed using the modified VA and Visual Function Index 14 (VF-14).

2.3. PCO grading

PCO grading was performed by two experienced senior ophthalmologists in each center according to a previously reported method⁸: grade 0 (without PCO), no opacity or opacity appearing only on the peripheral capsule; grade 1, wrinkling or opacity of the capsule limited in a circle 4 mm in diameter and centered on the visual axis, but the posterior polar retina can be viewed clearly; grade 2, central/paracentral opacity worse than grade 1 that slightly affects the detailed observation of the macula, but with no effects on the observation of the cup/disc ratio; grade 3, central/paracentral opacity worse than grade 2, making the cup/disc ratio difficult to ascertain; grade 4, central/paracentral opacity as defined above, but making fundus observation difficult or impossible (Representative images of different PCO grades are shown in [Supplementary Fig. 2](#)).

2.4. Wavefront measurement

The objective visual quality of the patients was analyzed using an iTrace ray-tracing system (Tracey Technologies, Houston, TX, USA). Three measurements for each eye were conducted in a dark room. The wavefront was measured in a 3-mm optical zone set by the software. The DLI,¹¹ an objective metric provided by the iTrace system, quantifies lens performance based on internal higher-order aberrations (HOAs), pupil size, and contrast sensitivity. This index evaluates overall lens performance on a scale from 0 (very poor) to 10 (excellent). The DLI values were recorded for each eye both before and one month following Nd:YAG laser capsulotomy and included in our study analysis.

2.5. Contrast sensitivity

Monocular CS was evaluated using the Optec 6500 (Stereo Optical Co., Inc., Chicago, IL, USA) with optimal distance correction. Measurements were undertaken at spatial frequencies of 1.5, 3, 6, 12, and 18 cycles per degree (cpd) without glare, under photopic (background luminance of 85 cd/m²) and mesopic conditions (background luminance of 3 cd/m²). Unseen patches were assigned the value of the last visible patch, ensuring that all participants were able to discern at least one patch. For statistical analysis, the log₁₀ values of CS were utilized, consistent with the methodology of preceding studies.¹²

2.6. Visual Function Index-14 questionnaire

Pre-capsulotomy and post-capsulotomy patient satisfaction was assessed using the VF-14 questionnaire.¹³ The VF-14, ranging from 0 to 100, determines how troublesome vision-related daily activities (e.g., reading and driving) are for patients, with a higher score representing better functioning. Each participant completed a questionnaire under the guidance of four ophthalmologists from the four research centers who recorded the subjective visual quality of the patients before and 1 month after Nd:YAG laser capsulotomy.

2.7. Nd:YAG capsulotomy

Nd:YAG laser capsulotomy was performed by four experienced surgeons from four centers using Lumenis Selecta Duet. After adequate pupil dilatation and local anesthesia in all patients, contact lenses with coupling agents were placed on their corneas to facilitate precise focusing. The energy level of the Nd:YAG laser device was set to 1.6–1.8 mJ. Focusing was then performed until the posterior capsule was penetrated, and the posterior capsule was circumferentially incised with a diameter of 4 mm to avoid IOL damage. After Nd:YAG laser posterior capsulotomy, patients routinely used a 1% prednisolone acetate ophthalmic suspension (Allergan, Ettingen, Germany) three times a day for 7 days.

2.8. Statistical analysis

All statistical analyses were performed using SPSS software (version 26.0; SPSS Inc., Chicago, Illinois, USA). All VA data were converted to equivalent logMAR units. Descriptive statistics are reported for quantitative variables as the mean ± standard deviation (SD). Normality was assessed using the Kolmogorov–Smirnov test. A sample size of 189 achieves 79% power to detect a difference of −0.20 between the null hypothesis correlation of 0.00 and the alternative hypothesis correlation of 0.20 using a two-sided hypothesis test with a significance level of 0.05. We conducted correlation analysis and calculated the Pearson correlation coefficient (r). A general linear model was used to analyze the patterns of visual quality changes across the different stages of PCO statistically. Paired-sample t-tests were used to compare VA and VF-14 scores and CS before and after Nd:YAG laser capsulotomy. The area under the receiver operating characteristic (ROC) curve (AUC) was calculated. The optimal cut-off value was determined based on the Youden's index. *P* values < 0.05 were considered statistically significant.

3. Results

3.1. Baseline characteristics

In total, 189 patients (189 eyes) met the inclusion criteria and were subsequently enrolled in the study. The patients' pre-capsulotomy characteristics are presented in Table 1, with results expressed as the mean ± SD. Patients who experienced PCO had a mean age of 51.69 ± 11.05 years and reported the onset of subjective vision loss at a mean time of 12.23 ± 4.73 months after cataract surgery. The mean time from cataract surgery to PCO requiring Nd:YAG laser capsulotomy was 457.02 ± 149.25 days (Table 1). The 1-year PCO incidence with Nd:YAG laser capsulotomy was 10.2%.

3.2. Relationship between PCO grades and visual outcomes before laser capsulotomy

Before undergoing Nd:YAG laser posterior capsulotomy, we identified a significant positive correlation between PCO grade and various measures of VA: UDVA ($r = 0.767, P < 0.001$), UIVA ($r = 0.656, P < 0.001$), UNVA ($r = 0.688, P < 0.001$), and CDVA ($r = 0.783, P < 0.001$), as illustrated in Fig. 1. These findings suggest an inverse relationship between PCO severity and VA. To further investigate the association between PCO grade and subjective as well as objective visual quality metrics, additional analyses were performed (Fig. 1). The analyses uncovered that both the VF-14 ($r = -0.723, P < 0.001$) and the DLI ($r = -0.808, P < 0.001$) scores were inversely correlated with PCO grade.

Table 1
The baseline characteristics of patients in the study before Nd:YAG capsulotomy.

Characteristic	Mean ± SD (n = 189)	Range (min, max) (n = 189)
Age (years)	51.59 ± 11.52	20, 78
Males/Females (%)	39%, 61%	–
Axial length (mm)	26.20 ± 2.38	22.05, 31.79
Decreased time of vision (months)	12.23 ± 4.73	4, 24
Difference between Nd:YAG time and operation time (days)	457.02 ± 149.25	124, 715
CCC type,	67%, 33%	–
Manual/femtosecond (%)		
With/without CTR (%)	47%, 53%	–
PCO Grade 1 (n, %)	26 (14%)	–
PCO Grade 2 (n, %)	58 (31%)	–
PCO Grade 3 (n, %)	56 (30%)	–
PCO Grade 4 (n, %)	49 (25%)	–

CCC: continuous curvilinear capsulorrhexis; CTR: capsular tension ring; PCO: posterior capsule opacity.

Notably, the DLI demonstrated the most substantial negative relationship with PCO grading.

3.3. Comparison of VA and quality before and 1 Month after laser capsulotomy

Supplementary Fig. 3 displays the mean difference in VA and subjective and objective visual quality results before and after laser capsulotomy in all patients with different grades of PCO ($P < 0.001$). Additionally, Table 2 outlines the outcomes of VA and subjective and objective visual quality before and 1 month after laser capsulotomy in patients with mild PCO (PCO grade 1). Our findings indicate that laser capsulotomy significantly improves the whole-course VA and subjective and objective visual quality in patients with intermediate-to late-stage PCO. However, in patients with mild PCO, near VA and subjective and objective visual quality significantly improved after laser capsulotomy. Fig. 2 shows the variations in CS at different spatial frequencies for patients categorized under PCO grade 1, both before and after capsulotomy, under both Photopic (as shown in Fig. 2a) and Mesopic (as depicted in Fig. 2b) lighting conditions. Statistically significant improvements in CS were observed post-treatment at spatial frequencies of 6.0 cycles per degree (cpd) (from 1.55 ± 0.27 to 1.86 ± 0.26), 12.0 cpd (from 1.04 ± 0.20 to 1.45 ± 0.31), and 18.0 cpd (from 0.66 ± 0.17 to 0.91 ± 0.29) under Photopic conditions ($P < 0.05$). No significant changes were noted at other spatial frequencies or under Mesopic lighting ($P > 0.05$).

3.4. Subjective visual quality questionnaire classification of the PCO grade 1 group before and 1 Month after Nd:YAG laser capsulotomy

The VF-14 questionnaire was used to evaluate patient satisfaction. While the mean VF-14 scores in the PCO grade 1 group were significantly improved after capsulotomy, only the near VA satisfaction scores improved significantly (Fig. 3). We found that the patients showed significant improvements in their near vision satisfaction scores when reading small prints, newspapers, or large prints, doing fine work, and writing checks ($P < 0.01$).

3.5. DLI cut-off value for Nd:YAG laser capsulotomy

Fig. 4 presents the AUC and the optimal cut-off value of the DLI for distinguishing eyes with an improvement in UNVA by one or more lines on the vision chart after capsulotomy. The AUC for the DLI was 0.830 ($P < 0.001$), indicating strong discriminatory power. ROC curve analysis determined that the optimal DLI cut-off value was 7.225, achieving a sensitivity of 80.0% and specificity of 82.3%.

4. Discussion

Our study reports the effects of mild PCO on visual acuity and quality in AT Lisa Tri 839 MP trifocal diffractive pseudophakic eyes and, for the first time, utilizes the iTrace system to quantify DLI scores to assess the influence of PCO on VA and visual quality. Our findings indicate that mild PCO appeared to affect near VA prior to exerting a detrimental effect on intermediate and distant VA. Moreover, DLI may serve as an early objective indicator that could facilitate the early identification of patients with mild PCO who are candidates for Nd:YAG laser capsulotomy.

We conducted a two-year follow-up of 1276 eyes who were implanted with a AT Lisa Tri 839 MP IOLs across four research centers. During the follow-up period, the mean duration from cataract surgery to PCO requiring laser capsulotomy was 457.02 ± 149.25 days. The 1-year PCO incidence with Nd:YAG laser capsulotomy was 10.2%. According to the previous reports, PCO occurred in cases with this IOL approximately 458.00 ± 230.00 days post-surgery,⁴ with a rate of Nd:YAG laser capsulotomy in one year ranging from 7.5% to 14.3%.^{2,4,14,15} In contrast, a study reported that the 1-year incidence of PCO after laser capsulotomy in eyes with hydrophilic acrylic monofocal IOLs of same material and

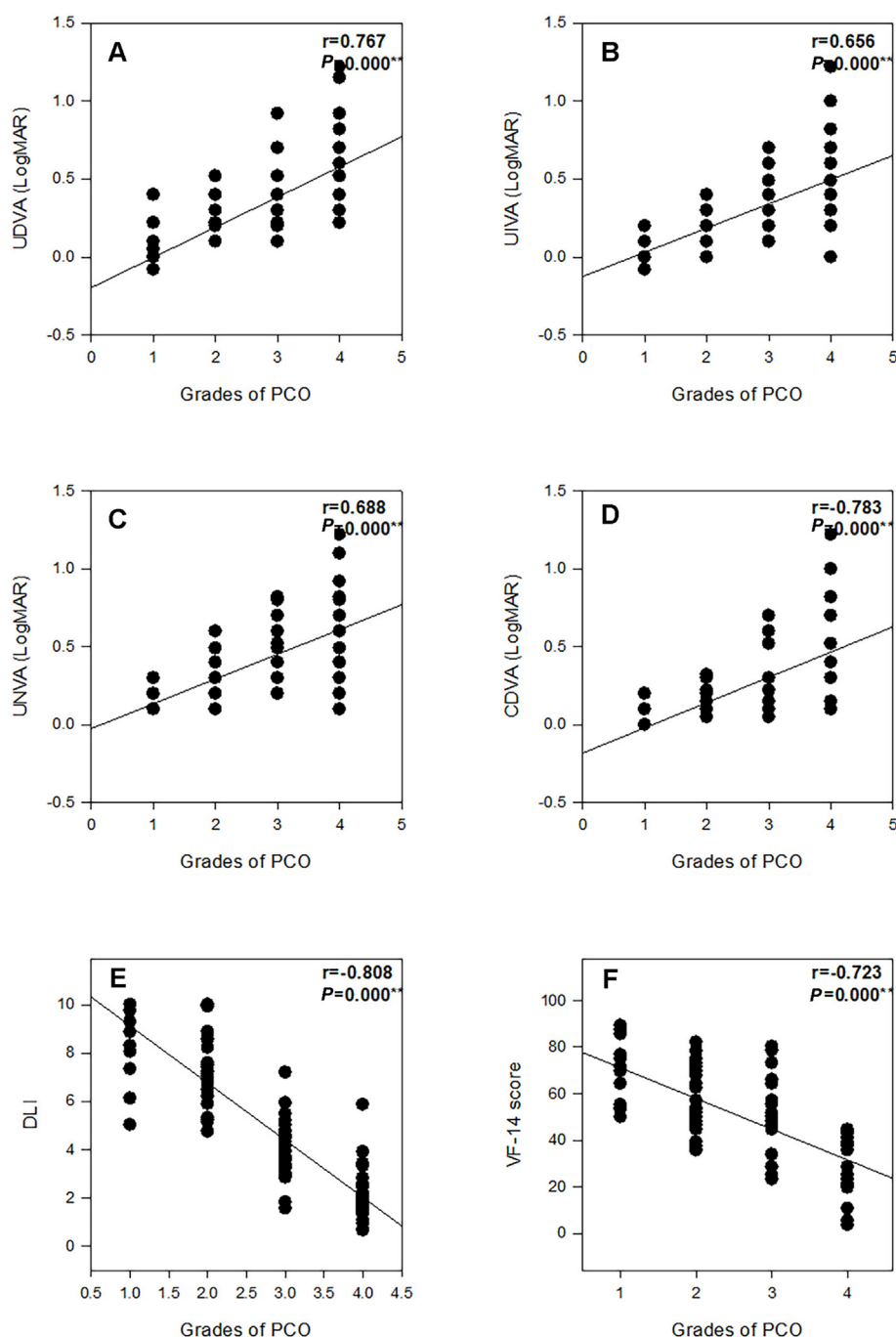


Fig. 1. Relationships between various parameters. (A) UDVA (pre-capsulotomy) and grades of PCO, (B) UIVA (pre-capsulotomy) and grades of PCO (C) UNVA (pre-capsulotomy) and grades of PCO, (D) CDVA (pre-capsulotomy) and grades of PCO, (E) DLI (pre-capsulotomy) and grades of PCO, and (F) VF-14 scores (pre-capsulotomy) and grades of PCO. r Pearson's correlation coefficient; $*P < 0.05$, $**P < 0.01$. DLI, dysfunction lens index; UDVA, uncorrected distance visual acuity; UIVA, uncorrected intermediate visual acuity; UNVA, uncorrected near visual acuity; CDVA, corrected distance visual acuity; DLI, dysfunction lens index.

design was reported to be 4.8%.¹⁶ The incidence of PCO necessitating laser capsulotomy one year after implantation of the AT Lisa Tri 839 MP IOL is markedly greater than monofocal IOLs. Among the patients with PCO who underwent laser capsulotomy, the distribution of different levels of PCO is as follows: grade 1 PCO accounts for 14%, grade 2 PCO for 31%, grade 3 PCO for 30%, and grade 4 PCO for 25%. Compared to previous research findings, patients with trifocal IOLs tend to undergo laser capsulotomy earlier. This phenomenon suggests that, compared to monofocal IOLs, PCO has a more significant impact on the vision function of trifocal IOLs and tends to occur earlier.¹⁷ Similarly, previous studies^{6,7} have suggested that patients with diffractive multifocal IOLs (MIOLs) may be more sensitive to PCO, experience more rapid visual loss, and require earlier posterior capsulotomy than patients with monofocal IOLs. This has been attributed to reduced CS and lower tolerance for

PCO-induced visual impairment in MIOLs.⁶

To date, there are few studies reporting the effect of mild PCO on visual outcomes in patients with trifocal IOL. In clinical scenario, we found that patients who had been implanted with trifocal IOL and developed grade 1 PCO often complained of a decrease in their near vision, such as experiencing blurriness while reading books or newspapers. However, their distance and intermediate vision remained unaffected. Upon examination, we discovered that these patients showed a significant decline in near vision as well as in objective visual quality indicators, such as the DLI. Following laser capsulotomy, there was no significant improvement in UDVA and UIVA values compared to the pre-capsulotomy values. However, both UNVA and DLI showed significant improvements. Moreover, patients with mild PCO exhibit a marked improvement in medium and high spatial frequency CS under photopic

Table 2
Visual function parameters of PCO of the grade 1 group before and 1 month after Nd:YAG laser capsulotomy.

Characteristic	Pre-capsulotomy (n = 26)	Post-capsulotomy (n = 26)	P value
UDVA (logMAR)	0.006 ± 0.041	0.004 ± 0.049	0.904
UIVA (logMAR)	0.067 ± 0.102	0.004 ± 0.072	0.068
UNVA (logMAR)	0.164 ± 0.102	0.014 ± 0.047	0.000**
CDVA (logMAR)	0.013 ± 0.029	0.000 ± 0.000	0.096
DLI	7.389 ± 2.290	9.723 ± 0.572	0.001*
VF-14 score	70.408 ± 12.247	88.963 ± 8.611	0.000**

UDVA: uncorrected distance visual acuity; UIVA: uncorrected intermediate visual acuity; UNVA: uncorrected near visual acuity; CDVA: best corrected distance visual acuity; logMAR: log of the minimum angle of resolution; DLI: dysfunctional lens index; Data are expressed as mean ± standard deviation (SD). **P* < 0.05, ***P* < 0.01.

conditions. While medium spatial frequencies play a significant role in daily visual tasks, high spatial frequencies are critical for discerning an object's fine details.¹⁸ Additionally, there was a significant improvement in the scores for near vision-related items in the VF-14 questionnaire. Furthermore, the patients reported a substantial increase in satisfaction with their near VA. These findings suggest that mild PCO has an earlier effect on near VA in trifocal diffractive pseudophakic eyes than on distance or intermediate VA. The observed decrease in near vision has compromised their capacity to distinguish between fine details. This can be attributed to the diffraction ring of Lisa Tri 839 MP, which resulted in a light distribution of 50% in the distance, 20% in the middle, and 30% in the near range.¹⁹ As a result, patients with Lisa Tri 839 MP have a higher light requirement when viewing objects, particularly at close distances, and the presence of mild PCO further reduces light distribution and CS, leading to a greater impact on the patients' near vision in the early stages, which worsens as PCO progresses. Based on these findings, if a patient reports a decrease in near vision during clinical follow-up, and other factors causing the reduction in near vision are ruled out, the occurrence of PCO should be considered.

The decision to perform Nd:YAG laser capsulotomy in clinical practice is subjective and relies on visual acuity and slit-lamp examination findings currently.⁶ However, these measures have limitations in accurately assessing visual impairment in individuals with PCO, especially in case of mild PCO associated with trifocal IOLs.^{20,21} The mild PCO observed under slit-lamp are often considered to have minimal impact on visual acuity and may therefore be overlooked. Consequently, there is a

pressing need to identify more objective methodologies that can offer improved guidance for clinical interventions in such cases.

DLI is an objective visual quality metric used to evaluate the extent of visual impairment and the lens opacity. Previous research has primarily utilized DLI to assess cataract severity.²² In this study, iTrace wavefront analysis system was employed to examine the correlation between the DLI and PCO grade. Our results revealed a strong linear correlation between the DLI and PCO grade, with a significant increase in the DLI following laser capsulotomy in patients with mild PCO. These findings suggests that the DLI can serve as a promising objective indicator to assess the impact of mild PCO on visual function and could assist in determining the optimal intervention timing for these patients. To determine the optimal cut-off value of the DLI, we classified eyes into two groups based on whether gaining improvement by at least one line on the vision chart following Nd:YAG laser capsulotomy. ROC curve analysis was conducted on these groups, demonstrating that a DLI value of 7.225, with logMAR UNVA ≤ 0.1 as a threshold for visual improvement post-capsulotomy, yielded a sensitivity of 80.0% and specificity of 82.3%, respectively, serving as a criterion for referral for laser capsulotomy for these patients.

This study had some limitations that should be acknowledged. First, the study was limited to a single type of trifocal IOL (AT LISA Tri 839 MP). Second, we did not evaluate the effect of PCO morphology on visual function. Future research with larger cohorts, a greater variety of trifocal IOLs and a more comprehensive evaluation of PCO morphology could yield deeper insights into how these factors interplay and influence the mild PCO in patients implanted with trifocal IOLs.

5. Conclusions

Our study found that mild PCO initially affects near vision in eyes implanted with trifocal IOLs and also reduces both subjective and objective visual quality. Therefore, ophthalmologists need to pay attention to patients' complaints about decreased near vision and assess the presence of PCO and the potential need for Nd:YAG laser capsulotomy. Furthermore, DLI, an objective indicator may assist ophthalmologists in determining whether mild PCO patients require Nd:YAG laser capsulotomy.

Study approval

The study was approved by the ethics committees of the four hospitals and was performed in accordance with the principles of the Declaration of Helsinki (IRB Number: HXYK-SHHP-2020-0004) (ClinicalTrials.gov, identifier NCT06092164).

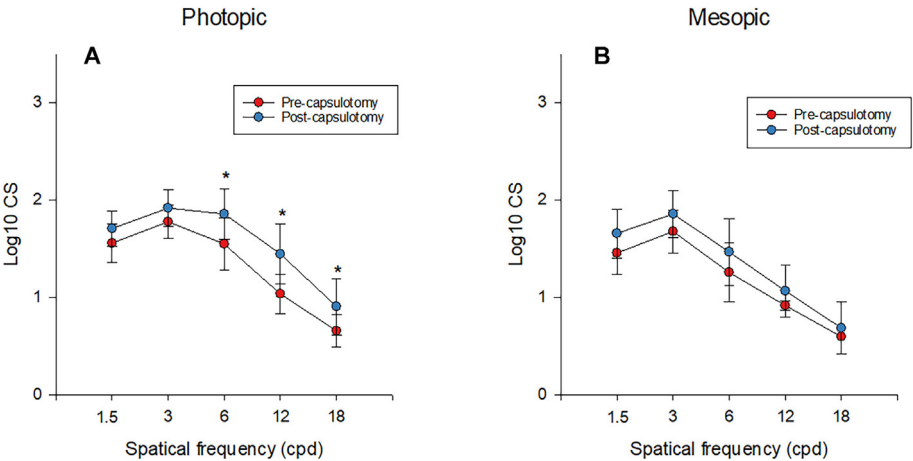


Fig. 2. Monocular contrast sensitivity curves of the grade 1 group before and one month after Nd:YAG laser capsulotomy. The monocular contrast sensitivity data at different spatial frequencies were obtained without glare under photopic (A) and mesopic (B) conditions. CS, contrast sensitivity; cpd, cycles per degree. **P* < 0.05.

VF-14 questionnaire

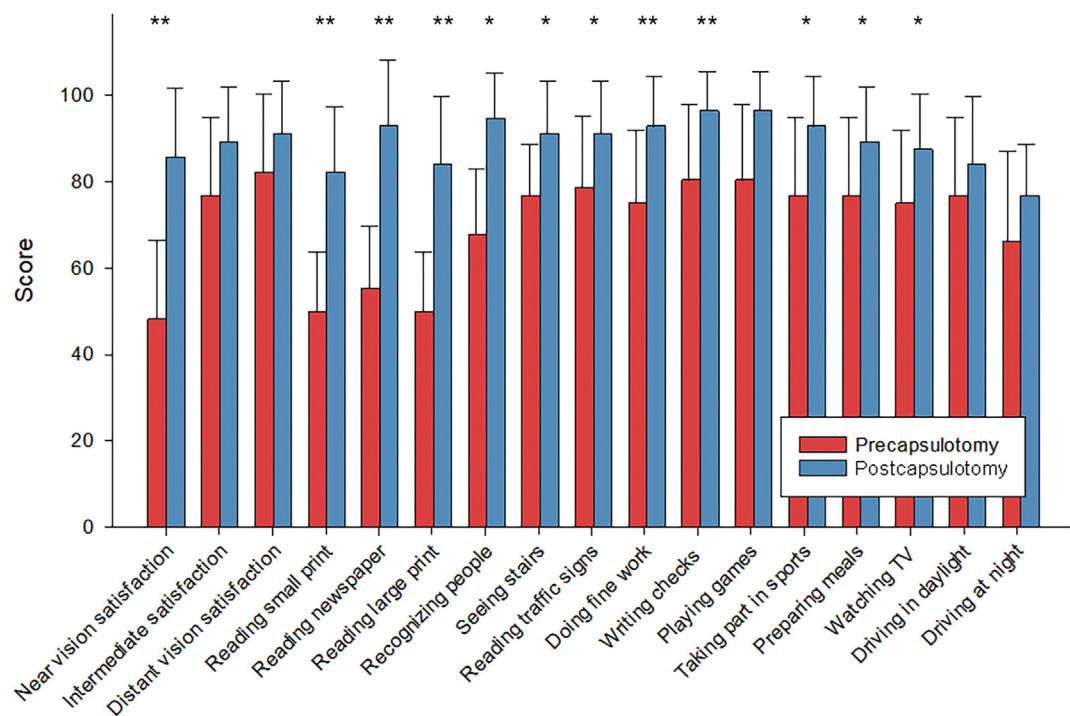


Fig. 3. Subjective visual quality questionnaire classification bar chart of PCO of the grade 1 group before and one month after Nd:YAG laser capsulotomy. X axis, VF-14 questionnaire; Y axis, score of visual satisfaction; and * $P < 0.05$, ** $P < 0.001$. PCO, Posterior capsular opacification.

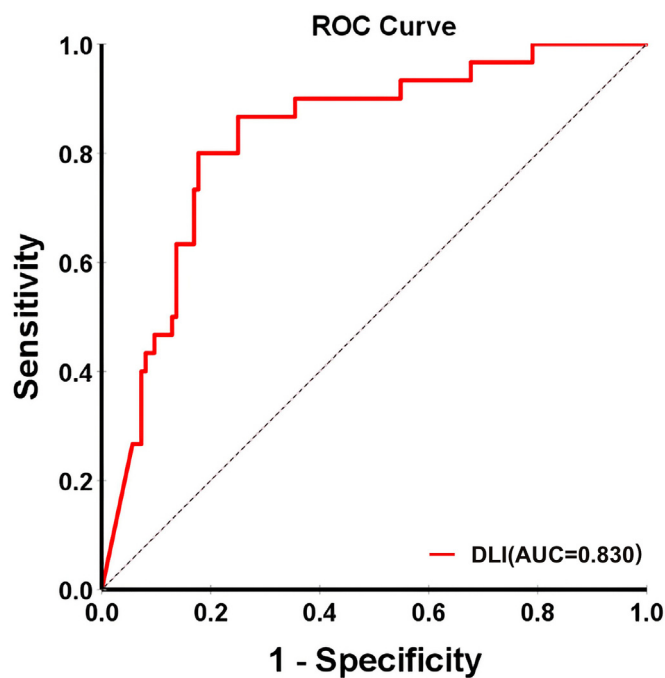


Fig. 4. The ROC curve corresponding to the value of the DLI predicting improvement of at least one line in UNVA on the vision chart. DLI, dysfunction lens index; UNVA, uncorrected near visual acuity.

Author contributions

JY and HG designed the research; LZ, JS, XG, AW, LC and SN were involved in patient examination and data collection; XC and LZ analyzed the data. LZ and RS wrote the first draft of the manuscript. JY and HG critically revised the manuscript. LZ and RS contributed equally to this work. All authors commented on previous versions of the manuscript. All authors reviewed the results and approved the final version of the manuscript.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.aopr.2025.02.002>.

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