scientific reports

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Q-value individualized CLEAR lenticule extraction preserves corneal asphericity and minimizes spherical aberration while maintaining optical zone predictability

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Refractive surgery enhances visual performance by reshaping the cornea. At the same time, optical aberrations typically increase, affecting visual quality. An essential factor for minimizing the induction of optical aberrations after refractive surgery is the preservation of corneal asphericity. To address this challenge, corneal lenticule extraction for advanced refractive correction (CLEAR) considers individual Q-values to generate an aspheric laser resection profile. This study aims to evaluate the effect of CLEAR on corneal asphericity, spherical aberration and optical zone diameter. Sixty eyes of 30 patients underwent refractive correction for myopia or compound myopic astigmatism with the CLEAR application. Three months postoperatively, the Q-value increased from −0.13 ± 0.09 to 0.01 ± 0.27, resulting in an oblate shift of 0.14 ± 0.25 from the preoperative state. The preoperative SA was 0.24 ± 0.06 µm, remaining stable at 0.24 ± 0.13 µm postoperatively. The planned optical zone of 6.50 mm resulted in an achieved effective optical zone of 5.93 ± 0.40 mm, a mean reduction of −0.57 ± 0.40 mm. Therefore, myopia and compound myopic astigmatism correction with CLEAR resulted in minimal positive shift in Q-value, limited difference between planned and effective optical zone, and no overall induction of spherical aberration.

Keywords CLEAR, Lenticule extraction, Q-value, Asphericity, KLEx

Oblate changes in corneal shape (positive Q-value shifts) are associated with the induction of spherical aberration (SA) and reduced effective optical zone (EOZ)[1–7] which are linked to visual disturbances under mesopic conditions, such as glare, halos, ghost images, and reduced contrast sensitivity[8–10]. In both excimer laser and kerato-refractive lenticule extraction (KLEx) surgery, increases in Q-value are associated with smaller postoperative EOZs, emphasizing the need to minimize alterations in corneal shape[4–7]. Positive shifts in Q-value following KLEx surgery have also been associated with increased spherical aberration (SA)[7,11] contributing to degraded vision in dim light conditions[12,13]. Optimizing postoperative visual quality in refractive surgery therefore requires maintaining corneal asphericity. To address this challenge, the Corneal Lenticule Extraction for Advanced Refractive Correction (CLEAR) procedure incorporates a Q-value–individualized aspheric resection profile designed to minimize changes in corneal asphericity. Custom-Q laser ablation profiles for myopia correction have been proposed to limit the postoperative shift toward a more oblate corneal shape, thereby reducing SA induction and minimizing the difference between planned and effective optical zone (OZ)[14–16]. However, the effect of such aspheric profiles in lenticule extraction surgery remains to be fully evaluated. The present study aims to assess the consequences of the CLEAR procedure on corneal asphericity (Q-value change), SA and OZ diameter at 3 months post-surgery.

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Methods

This retrospective, consecutive case-series study data analysis included 30 patients (60 eyes) having undergone KLEx surgery at the Silmäsairaala Pilke Eye Clinic in Tampere, Finland, from February 2023 to June 2023. Included patients were at least 21 years old, had stable refraction over the past year, a preoperative corrected distance visual acuity (CDVA) of 0.10 LogMAR (20/25 Snellen) or better, had no ocular or systemic diseases and presented to follow-up examinations at 3 months postoperatively. Patients had preoperative myopia or compound myopic astigmatism with manifest refraction spherical equivalent (MRSE) ranging from −0.75 to -8.50 D, with manifest sphere up to -8.25 D and manifest cylinder up to -3.75 D. Soft contact lens wearers were advised to stop wearing their lenses at least two weeks prior to surgery. The study was approved by the Ethics Committee of Finland (approval No.FIN-20231201). All patients were informed about the surgical procedure and provided written consent for inclusion of their data in research. This study followed the tenets of the Declaration of Helsinki.

Preoperative and postoperative evaluation

All patients were evaluated in the clinic according to a standard preoperative assessment for refractive surgery. An extensive ophthalmic examination was conducted, including monocular uncorrected distance visual acuity (UDVA) and CDVA measurement, subjective and manifest refraction measurement, pupillometry in scotopic conditions, slit-lamp evaluation, corneal topography and tomography, corneal pachymetry, optical coherence tomography (OCT), tonometry and fundoscopy. Postoperative data consisted of UDVA, CDVA, manifest refraction and corneal topography and tomography.

Corneal asphericity and corneal spherical aberration measurement

Preoperative and postoperative Q-value and SA measurements were performed with the Scheimpflug tomography system (GALILEI G6, Ziemer Ophthalmic Systems AG, Port, Switzerland) under scotopic conditions. Patients were advised to keep fixating on a target immediately after blinking to minimize the potential effect of tear film on corneal imaging. SA data were analyzed over a 6.0 mm central diameter and Q-value over an 8.0 mm diameter. Corneal SA and corneal asphericity (Q-value) were analyzed for the anterior corneal surface.

Effective optical zone measurement

The maps of the difference in anterior curvature between the preoperative and postoperative measurements were obtained using a Scheimpflug tomography system. The EOZ boundary was defined as the area on the subtractive map outlined by a change of 0.00 D while moving the cursor from the center to the periphery, along the corneal semi-meridian[6,17,18]. The mean EOZ diameter was defined as the average value of the diameters that were measured from 6 different corneal meridians at 30-degree intervals (Fig. 1) according to a procedure described elsewhere[6].

Surgical technique

One surgeon (J. J. J.) performed all surgeries. CLEAR treatments were performed with the low energy FEMTO LDV Z8 femtosecond laser platform (Ziemer Ophthalmic Systems AG, Port, Switzerland). Individual Q-values were entered for each patient's eyes to allow the CLEAR algorithm to generate a personalized, aspheric resection profile. The default lenticule cap thickness was 120 µm but was occasionally reduced to meet the residual stromal thickness limit of 250 µm. The planned optical zone (POZ) diameter was 6.5 mm in all cases. Intraoperative adjustment for cyclotorsion and lenticule centration on the first Purkinje reflex were performed in all cases, based on corneal marking at the slit-lamp along the horizontal and vertical meridians (centered on the first Purkinje reflex). After suction application, the axis of the lenticule treatment was aligned on the corneal marks. A personalized nomogram was used in the planning of all treatments, taking into account the attempted refractive correction, and corneal curvature[19]. The target refraction was adjusted based on patient age. The lenticule dissection and extraction was performed using a standard technique described in detail in the literature[20] from a 3.0 mm access incision created at 12 o'clock. Lenticule interface dissection and lenticule removal were achieved without difficulties in all cases. No intraoperative or postoperative complications were observed. Postoperative medications included dexamethasone (1 mg/ml) and chloramphenicol (2 mg/ml) 4 times daily for 2 weeks.

Statistical methods

Microsoft Excel (2016, Microsoft Corporation, Redmond, WA) was used for descriptive statistical analysis and graphs. Power BI (Microsoft Corporation, Redmond, WA) was used to generate standard graphs. Shapiro-Wilk normality tests, Student's t-tests and Pearson correlation analyses were conducted using R Software (R version 4.1.1, Vienna, Austria).

Results

Thirty patients (60 eyes) were included in the study. Preoperative patient characteristics are summarized in (Table 1). At 3 months postoperatively, the UDVA was −0.02 ± 0.06 LogMAR and the CDVA was −0.04 ± 0.05 LogMAR. 90.0% of eyes achieved a UDVA of 0.00 LogMAR (20/20 Snellen) or better (Supplementary Fig. 1). At 3 months postoperatively, the attempted versus achieved spherical equivalent indicated high predictability of refractive correction (R^2 = 0.960) (Supplementary Fig. 2) with a mean spherical equivalent refraction of 0.00 ± 0.34 D (Table 2). The mean preoperative Q-value was −0.13 ± 0.09 (ranging from −0.32 to 0.10), indicating a prolate shape of the average cornea in operated patients (Fig. 2a). After CLEAR, the mean Q-value underwent an oblate shift, with a mean value of 0.01 ± 0.27 (ranging from −0.53 to 0.66). The mean Q-value therefore increased by 0.14 ± 0.25 (ranging from −0.42 to 0.80) after the surgery ($P < 0.001$). The mean SA for the anterior

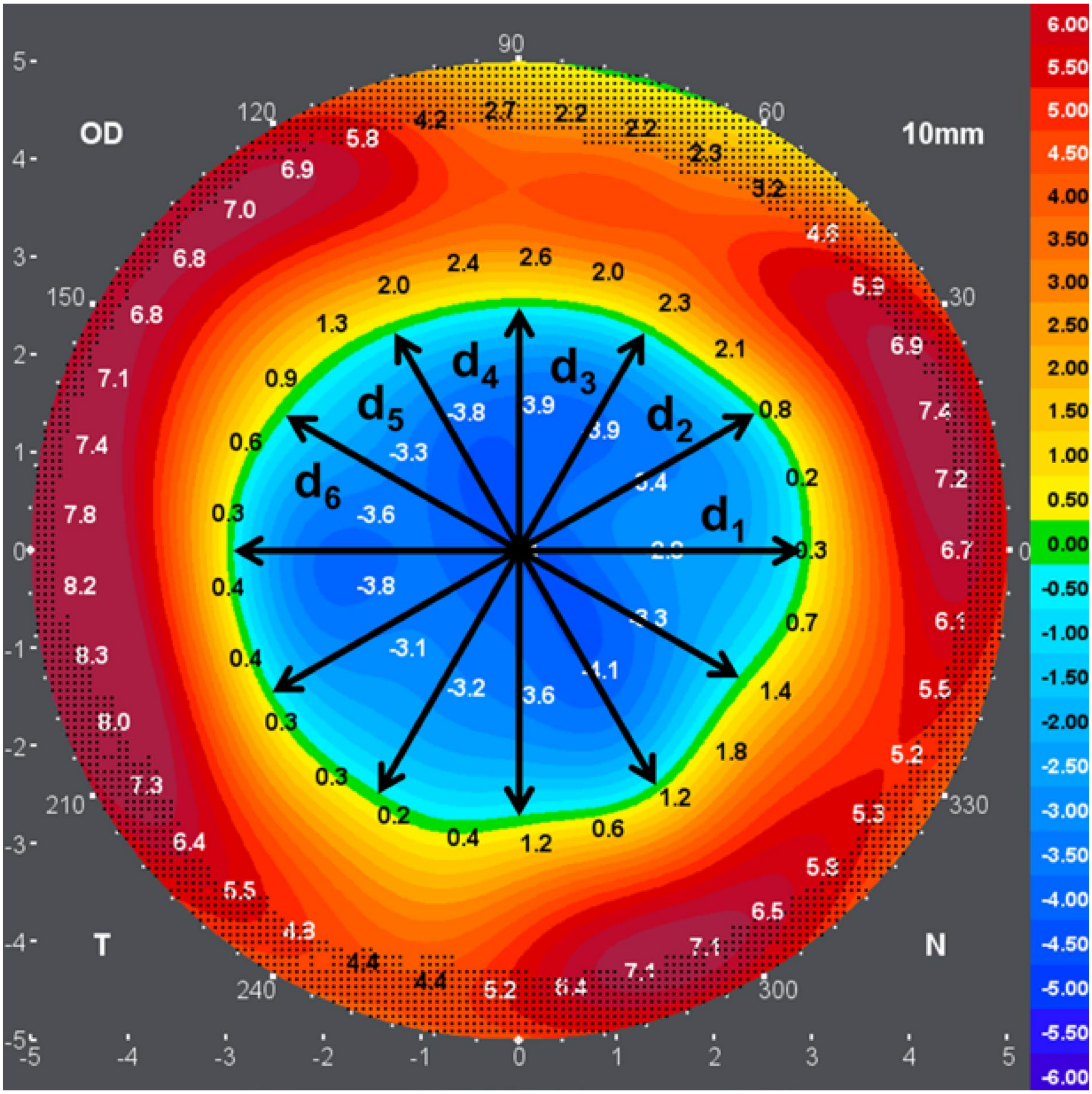

Fig. 1. Effective optical zone (EOZ) measurement at different corneal meridians on the tangential curvature difference map generated by the Scheimpflug tomography system.

corneal surface at 3 months after CLEAR surgery was 0.24 ± 0.13 μm (ranging from 0.00 μm to 0.54 μm), stable from 0.24 ± 0.06 μm (ranging from 0.12 to 0.40 μm) preoperatively ($P = 0.901$) (Fig. 2b). The mean POZ was 6.50 ± 0.00 mm and the mean EOZ at 3 months after CLEAR surgery was 5.93 ± 0.40 mm (ranging from 5.17 to 6.74 mm), resulting in a significant difference between POZ and EOZ of -0.57 ± 0.40 mm (ranging from – 1.33 to 0.24 mm; $P < 0.001$) (Fig. 2c). A strong, statistically significant, positive linear correlation was found between the induction of SA and the change in Q-value ($r = 0.865$; $P < 0.001$) (Fig. 3a). A moderate, statistically significant, negative correlation was found between the planned to effective OZ discrepancy and the change in Q-value ($r = -0.519$; $P < 0.001$) (Fig. 3b). Linear regressions analysis and correlation analysis were performed to explore the relationship between changes in Q-value, induced SA and OZ discrepancy with preoperative manifest spherical equivalent refraction (MRSE) (Fig. 4). Changes in Q-value, induced SA and OZ discrepancy were all statistically significantly correlated to preoperative MRSE. Changes in Q-value showed a moderate positive correlation ($r = 0.496$; $P < 0.001$) with preoperative MRSE. Induced SA showed a strong positive correlation with preoperative MRSE ($r = 0.694$, $P < 0.001$) and EOZ showed a strong negative correlation with preoperative MRSE ($r = -0.684$; $P < 0.001$). Finally, a weak positive correlation was found between the preoperative manifest refractive cylinder (MRCYL) and OZ discrepancy ($r = 0.268$; $P = 0.039$) (Fig. 5).

Age (years)	
Mean (SD)	31.30 (4.77)
Range	21, 39
Preop CDVA (LogMAR)	
Mean (SD)	-0.04 (0.04)
Range	0.05, -0.08
Preop sphere (D)	
Mean (SD)	-2.70 (1.71)
Range	-0.50, -8.25
Preop cylinder (D)	
Mean (SD)	-0.91 (0.68)
Range	0.00, -3.75
Preop MRSE (D)	
Mean (SD)	-3.15 (1.69)
Range	-0.75, -8.50

Table 1. Preoperative characteristics ($n = 60$ eyes). CDVA = corrected distance visual acuity; MRSE = manifest refraction spherical equivalent; SD = standard deviation; D = diopters.

CDVA (LogMAR)	
Mean (SD)	-0.04 (0.05)
Range	0.10, -0.08
UDVA (LogMAR)	
Mean (SD)	-0.02 (0.06)
Range	0.15, -0.08
MRSE (D)	
Mean (SD)	0.00 (0.34)
Range	1.00, -0.75

Table 2. Refraction and visual acuity at 3 months ($n = 60$ eyes). CDVA = corrected distance visual acuity; UDVA = uncorrected distance visual acuity; MRSE = manifest refraction spherical equivalent; SD = standard deviation; D = diopters.

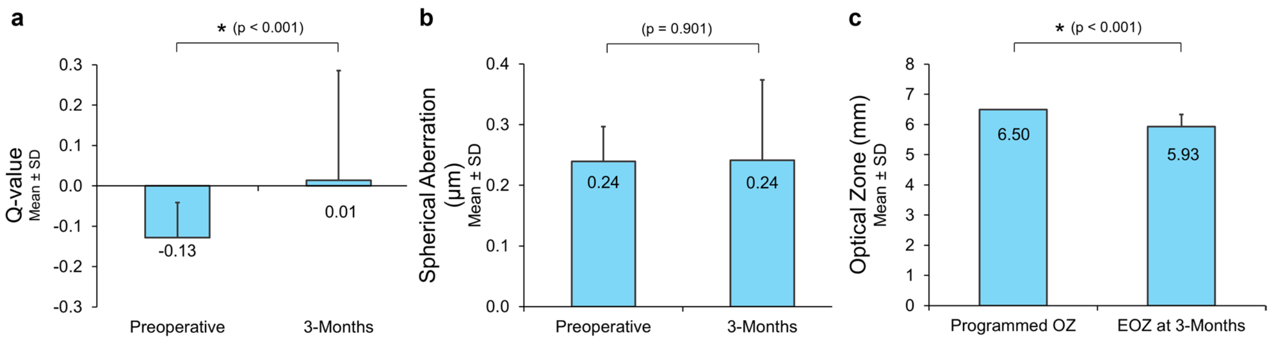

Fig. 2. (**a**) Corneal asphericity of the anterior corneal surface preoperatively and 3 months after CLEAR. There was significant difference between pre- and post-CLEAR Q-values measured at 8 mm diameter (Student's t-test, $P < 0.001$, $n = 60$ eyes). (**b**) Spherical aberration of the anterior corneal surface preoperatively and 3 months after CLEAR, measured at 6 mm diameter. There was no significant difference between pre- and post-CLEAR in the changes of spherical aberration (Student's t-test, $P = 0.901$, $n = 60$ eyes). (**c**) Planned optical zone (OZ) and effective optical zone (EOZ) 3 months after CLEAR. There was significant difference between POZ and the EOZ (Student's t-test, $P < 0.001$, $n = 60$ eyes).

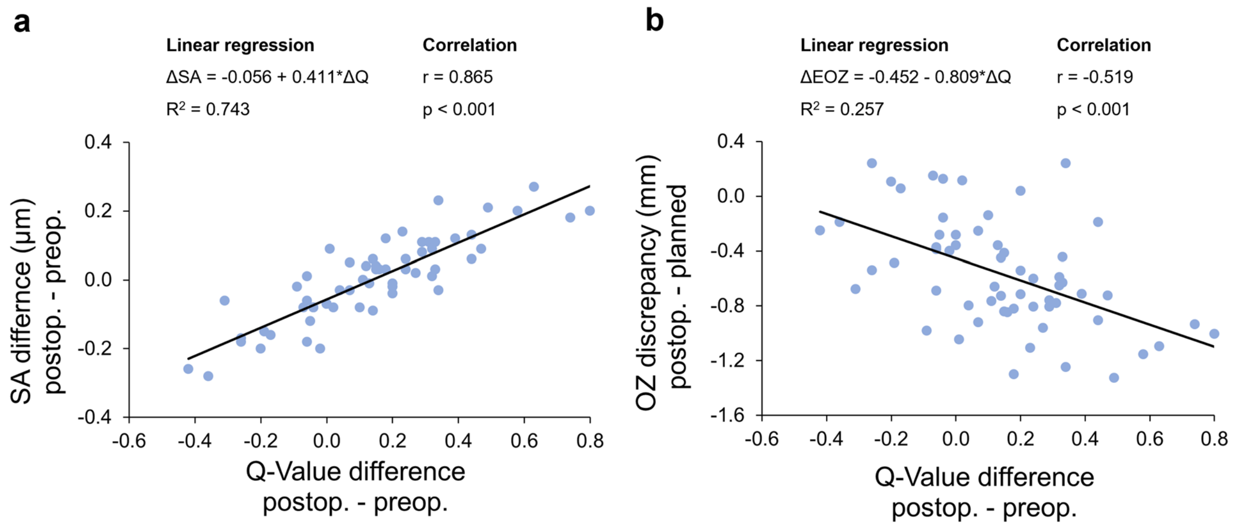

Fig. 3. (**a**) Correlation between post-surgery induced spherical aberration measured at 6 mm diameter (SA) and change in Q-value measured at 8 mm diameter. (**b**) Correlation between effective optical zone (EOZ) reduction and change in Q-value. $n = 60$ eyes.

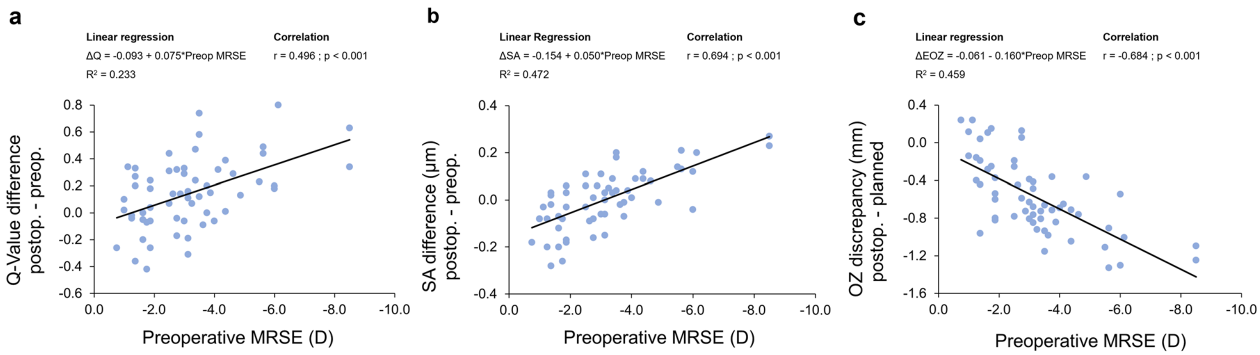

Fig. 4. (**a**) Change in corneal asphericity (Q-value, measured at 8 mm diameter) plotted as a function of preoperative manifest refraction spherical equivalent (MRSE) 3 months after CLEAR. (**b**) Induced spherical aberration (SA, measured at 6 mm diameter) plotted as function of preoperative manifest refraction spherical equivalent (MRSE) 3 months after CLEAR. (**c**) Reduction in the effective optical zone (EOZ) plotted as function of preoperative manifest refraction spherical equivalent (MRSE) 3 months after CLEAR. $n = 60$ eyes.

Discussion

Aspheric algorithms designed to compensate for the spherical aberrations induced by standard corneal laser ablation profiles provide clinically equivalent advantages to wavefront-guided profiles in terms of safety and refractive efficacy[14,16,21] and lead to improved visual outcomes[22]. The current study examines changes in corneal asphericity, induced spherical aberration (SA), and effective optical zone (EOZ) following the use of an individualized aspheric femtosecond laser resection profile integrated in the CLEAR application. This aspheric profile is specifically designed to preserve the preoperative Q-value of the cornea, thereby minimizing postoperative shape alterations. Our analysis focused on the anterior corneal surface, as previous studies on lenticule extraction surgery have reported minimal changes in Q-value and limited induction of higher-order aberrations (HOAs) in the posterior corneal surface following the procedure[11,12,23]. In the study at hand, analyses were performed 3 months after CLEAR treatment, when EOZ is typically considered stable[24,25]. Furthermore, studies on changes in corneal asphericity after laser in situ keratomileusis (LASIK) showed stable asphericity data after 3 months[3].

The first notable finding of this study is the low amount of oblate shift in anterior corneal Q-value observed after CLEAR (+0.14) compared to previously reported lenticule extraction on other platforms[11,26,27]. Zhang et al. showed a mean positive change of Q-value of the anterior corneal surface of about + 1.0 at 6 months after surgery[11] while Yu et al. observed a mean positive increase of Q-value of around + 0.8 at 3 months after surgery[27]. The Q-value aspheric algorithm implemented in CLEAR and aimed at preserving the preoperative anterior

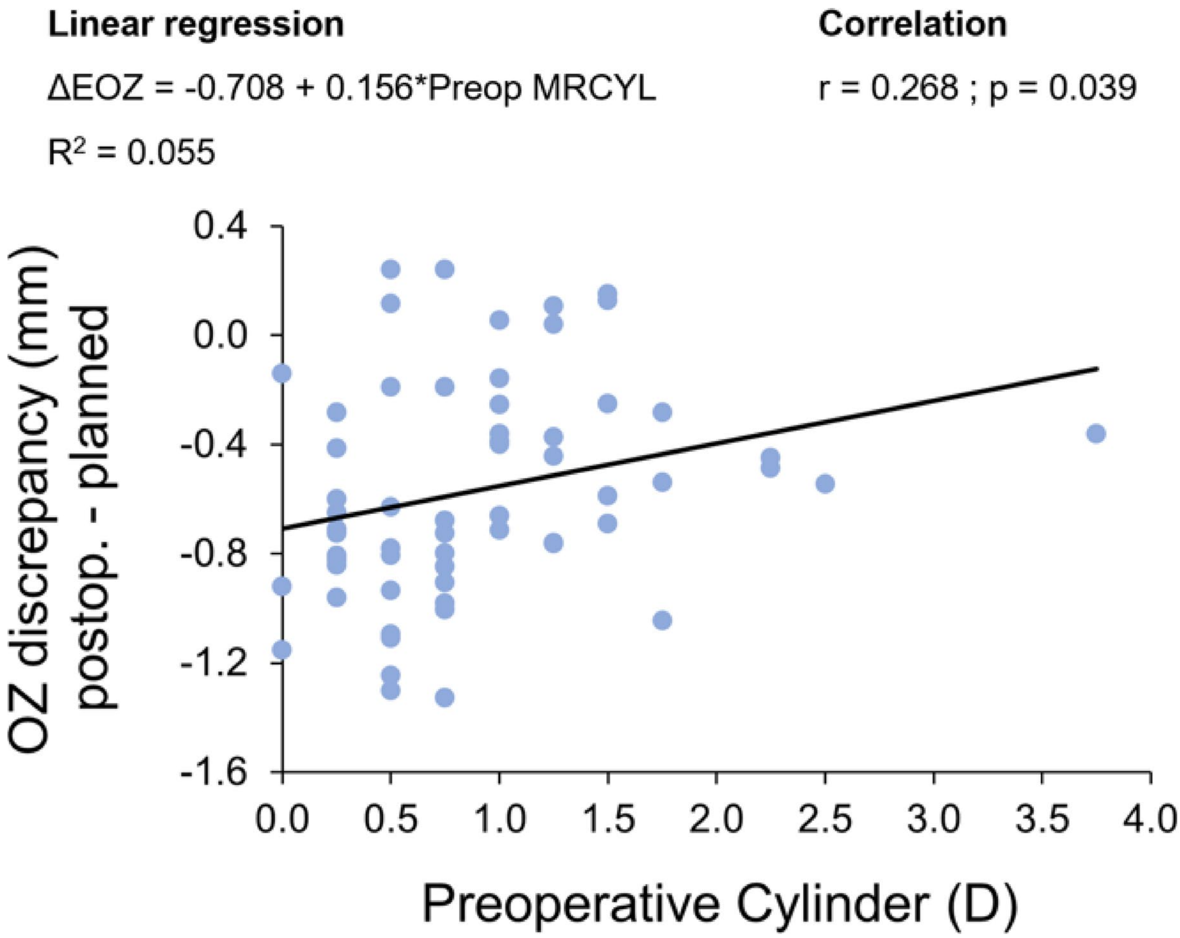

Fig. 5. Correlation between preoperative manifest refractive cylinder (MRCYL) and reduction in the effective optical zone (EOZ). The low R-squared value indicates that the OZ discrepancy cannot be predicted by the amount of preoperative manifest refractive cylinder. $n = 60$ eyes.

corneal asphericity may explain the limited amount of positive increase in Q-value. Several studies on laser refractive surgery have identified changes in corneal asphericity as a key factor in SA increase[28–30]. In line with this, we observed a strong linear correlation between the change in Q-value and induced SA. However, since the average change in Q-value was minimal, there was no overall induction of SA post-surgery.

We also observed a strong correlation between preoperative MRSE and planned to effective OZ discrepancy, in agreement with previous lenticule extraction studies[7,25]. Also consistent with published reports is the observation that the smaller the increase in Q-value, the less the OZ discrepancy[6,7]. The mean OZ discrepancy diameter observed in this study (0.57 mm) compares favorably with published results obtained on different lenticule extraction laser platforms using comparable preoperative MRSE and set POZ, where OZ discrepancy ranged from 1.16 mm to 1.45 mm[6,7,24,31]. The individualized resection profile in CLEAR likely contributes to minimizing the oblate shift in Q-value and the associated OZ discrepancy, similar to how aspheric ablation profiles in LASIK have been shown to result in larger EOZs than conventional ablation profiles[15,32]. A limitation of the current study is that the specific contribution of the aspheric profile was not directly assessed, as it is a built-in feature of the CLEAR application. Furthermore, this study included data from a limited number of patients ($n = 60$ eyes). It remains to be shown if the results obtained here are representative of a greater population. In conclusion, the modest positive change in Q-value following CLEAR surgery was correlated with both induced SA and planned to effective OZ discrepancy, confirming previous observations. The Q-value–individualized aspheric femtosecond laser resection profile in the CLEAR application appears effective in preserving preoperative anterior corneal asphericity, thereby limiting postoperative SA induction and minimizing OZ discrepancy.

Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Received: 8 April 2025; Accepted: 13 August 2025
Published online: 19 August 2025

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Author contributions

JJ was solely responsible for the conception, design, data collection, analysis, manuscript writing, and final approval of the submitted version.

Declarations

Competing interests
The authors declare no competing interests.

Ethics approval and consent to participate
The study was approved by the Ethics Committee of Finland (approval No.FIN-20231201). This research followed the tenets of the Declaration of Helsinki.

Consent for publication
All patients were informed about the surgical procedure and provided written consent, including consent for inclusion of their data in research.

Additional information
Supplementary Information The online version contains supplementary material available at https://doi.org/10.1038/s41598-025-16271-3.

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