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## **CORRELATION BETWEEN FRACTIONAL CLEARANCE AND OPTICAL OUTCOMES OF LASIK MYOPIA CORRECTION**

**Abstract:** Excimer laser pulses using the LASIK method ablate the corneal stroma, achieving its remodeling to the desired optical characteristics. Besides correcting ametropia, it is desirable to minimize the induction of higher-order optical aberrations (HOA), as they affect the occurrence of glare and halos in night vision conditions. Fractional clearance (FC) represents the ratio of the treated optical zone (OZ) to the pupil diameter in scotopic lighting conditions. This study aims to examine the relationship between the enlargement of the treated OZ diameter and the increase in FC index on postoperative HOA levels. A prospective study included 37 subjects (74 eyes) with myopia treated with the LASIK method. The eye with a higher residual stromal bed value was treated with an OZ diameter of 7.0 mm, and the other eye of the same patient with an OZ diameter of 6.5 mm. After 6 months, an objective evaluation of optical outcomes was performed using an Analyzer device. The mean FC value in the group of eyes treated with OZ 6.5 mm is 2.138 (SD 0.30), and in the group treated with OZ 7.0 mm is 2.325 (SD 0.37), statistically significant ( $t=3.64$ ;  $p<0.001$ ). A smaller induction of all measured HOA was found when a wider OZ of 7.0 mm was treated, with the statistically significant reduction observed in spherical aberration induction. The increase in FC index is proportional to the enlargement of the treated OZ diameter. With an increase in FC value, the level of all HOA decreases after the LASIK procedure, with the most significant reduction observed in spherical aberration induction.

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Enlargement of OZ to 7.0 mm, when corneal structural characteristics allow it, improves postoperative optical outcomes.

**Keywords:** fractional clearance, optical zone, LASIK, higher-order optical aberrations

## ***INTRODUCTION***

LASIK (Laser-Assisted in Situ Keratomileusis) represents one of the most frequently performed refractive surgical procedures for the correction of ametropias (1,2). In addition to myopia, LASIK is applied in the correction of other refractive anomalies, including hyperopia and astigmatism, with considerable clinical success (3). Through the application of excimer laser pulses, precise ablation of the corneal stroma is performed, thereby achieving corneal remodeling and correction of the existing refractive error. The quality of postoperative vision depends not only on achieving the desired refraction, but also on minimizing unwanted optical effects.

Beyond the correction of the underlying ametropia, one of the primary objectives of the LASIK procedure is the minimization of induced higher-order aberrations (HOA), which directly contribute to subjective visual disturbances such as glare and halo phenomena under scotopic conditions (4,5). Patients with elevated levels of HOA frequently report dissatisfaction with visual quality despite achieving satisfactory visual acuity as measured under standard photopic illumination conditions (6).

The optical zone (OZ) refers to the diameter of the central corneal surface treated during the LASIK procedure. The standard recommended OZ diameter is 6.5 mm (7). However, the selection of OZ diameter exerts a direct influence on postoperative optical outcomes, particularly under conditions of reduced illumination when the pupil is dilated (8,9). A larger OZ facilitates better correspondence between the treated corneal surface and the pupil diameter under scotopic viewing conditions, which is of particular relevance for the quality of night vision. Expanding the treatment OZ diameter requires greater consumption of corneal stromal tissue during ablation; consequently, the decision regarding OZ diameter must be grounded in careful preoperative evaluation of the structural characteristics of the cornea.

The fractional clearance (FC) represents the mathematical ratio between the diameter of the treated optical zone and the scotopic pupil diameter (10). According to existing research, the FC value should reach a minimum of 1.1, that is, the treated OZ diameter should exceed the scotopic pupil diameter by at least 17%, in order to reduce the induction of postoperative HOA (10). This ratio has demonstrated greater validity as an indicator of postoperative optical quality than the individual values of OZ or pupil diameter in isolation, given that the homogeneity of pupil diameter between both eyes of the same patient indicates that the applied OZ diameter is the decisive determinant of the FC value (10,11).

Contemporary diagnostic systems, such as the Scheimpflug rotating camera (Oculus) and the excimer laser software platform (Wavelight Allegretto Q 400), allow for precise prediction of postoperative central pachymetry, stromal volume consumption, and residual stromal bed (RSB) thickness, forming the basis for the safe expansion of OZ in selected patients (2,12). An individualized approach that accounts for the specific structural characteristics of the cornea, including its curvature and morphology, has proven essential for achieving optimal outcomes (12). On the basis of these predictive parameters, it becomes possible to make an informed decision to expand the treatment diameter from the standard 6.5 mm to 7.0 mm in patients whose corneal structural characteristics permit such expansion, thereby achieving a higher FC index and, consequently, improved postoperative optical outcomes.

This study aims to examine the association between expansion of the treated optical zone diameter (from the standard 6.5 mm to 7.0 mm) and the resultant increase in the fractional clearance index on postoperative levels of higher-order aberrations following LASIK treatment of myopia.

## ***MATERIALS AND METHODS***

A prospective clinical study was conducted at the Department of Ophthalmology of the Military Medical Academy in Belgrade. The study enrolled 37 patients (74 eyes) who underwent LASIK refractive correction using the Wavelight Allegretto Q 400 Hz excimer laser. Eyes with myopia and myopic astigmatism were included. The refractive spherical equivalent of the enrolled eyes ranged from  $-1.75$  Dsph to  $-10.0$  Dsph, with an astigmatic component of up to  $-2.75$  Dcyl.

Inclusion criteria were as follows: age between 18 and 45 years, stable refraction over the preceding 12 months (change of less than 0.50 Dsph), refractive spherical equivalent between  $-1.75$  and  $-10.0$  Dsph with an astigmatic component not exceeding  $-2.75$  Dcyl, central corneal pachymetry of at least 480  $\mu\text{m}$ , predicted postoperative residual stromal bed (RSB) thickness of at least 300  $\mu\text{m}$ , uncorrected visual acuity of at least 0.1, and best-corrected visual acuity of at least 0.8 on the Snellen scale. Exclusion criteria included: keratoconus or suspected keratoconus, progressive myopia, signs of dry eye syndrome (Schirmer test  $<10$  mm/5 min), presence of cataract or other anterior or posterior segment pathology, systemic disease, systemic corticosteroid therapy, pregnancy, or breastfeeding.

Preoperative evaluation comprised a complete ophthalmological examination including visual acuity assessment, subjective and objective refraction, anterior segment biomicroscopy, applanation tonometry, funduscopy under mydriasis, and corneal imaging with a Scheimpflug rotating camera (Oculus). Scotopic pupil dia-

meter was measured using a pupillometer under low-luminance conditions of 0.04 cd/m<sup>2</sup> during the preoperative assessment.

Oculyzer analysis was performed to evaluate central and peripheral pachymetry, anterior and posterior corneal elevation, and to simulate the ablation profile for both optical zone diameters (6.5 mm and 7.0 mm), with prediction of postoperative RSB thickness, stromal volume consumption, and corneal thinning progression. Treatment decisions regarding the optical zone (OZ) diameter were made for each eye individually on the basis of these data.

The LASIK procedure was performed under topical local anesthesia (Tetracaine 0.5%). A corneal flap of 100 µm thickness was created using a femtosecond laser. Following flap elevation, stromal ablation was carried out with the Wavelight Allegretto Q 400 excimer laser operating at a frequency of 400 Hz. The transition zone extended an additional 1.5–2.0 mm beyond the treated OZ diameter.

Eyes were divided into two groups according to the OZ diameter applied during excimer laser treatment:

- Eyes treated with OZ 6.5 mm (n = 37)
- Eyes treated with OZ 7.0 mm (n = 37)

The criterion for OZ diameter selection was based on excimer laser software evaluation of the predicted postoperative RSB thickness for each eye, simulated for both 6.5 mm and 7.0 mm OZ treatments. In each patient, the eye with the greater predicted postoperative RSB thickness was treated with OZ 7.0 mm, while the eye with the lesser RSB value was treated with OZ 6.5 mm.

Fractional clearance (FC) for each eye was calculated according to the following formula:

- $FC = \text{treated optical zone diameter (OZ)} / \text{scotopic pupil diameter}$

An FC value >1.17 was considered optimal in accordance with published recommendations in the literature.

Follow-up examinations were conducted at 24 hours, 7 days, 1 month, 6 months, and 12 months postoperatively. Each examination included assessment of corrected and uncorrected visual acuity for each eye, anterior segment imaging, and analysis using the Oculyzer and Analyzer platforms. At the six-month follow-up, objective evaluation of optical outcomes was performed using a wavefront aberrometer (Analyzer), which measured higher-order aberration values including total aberration (RMS - Root Mean Square), spherical aberration (SPHA), defocus aberration (DFOK), higher-order astigmatism (ASTIG), and coma (COMA).

Statistical analysis was performed using Student's t-test for the comparison of continuous variables between groups. Pearson's correlation coefficient was used to assess the correlation between fractional clearance and postoperative HOA values. Statistical significance was defined as  $p < 0.05$ .

## RESULTS

The mean FC value in the group of eyes treated with OZ 6.5 mm was 2.138 (SD 0.30), while in the group treated with OZ 7.0 mm, it was 2.325 (SD 0.37). Student's t-test demonstrated a statistically highly significant difference between the groups ( $t = 3.64$ ;  $p < 0.001$ ) (Table 1).

**Table 1. Fractional clearance - ratio of optical zone diameter to pupil diameter**

Group	Mean Value	Standard Deviation	Student's t-test (t)	Probability (p)
6,5 mm	2,13	0,30	3,64	p < 0,001
7 mm	2,32	0,37		

Fractional clearance (the ratio of optical zone diameter to pupil diameter) was statistically highly significantly greater in the group in which the OZ diameter was 7.0 mm compared to the group with a diameter of 6.5 mm. Table 2 presents the correlation between fractional clearance and various optical aberration parameters before and after surgery in the group treated with OZ 6.5 mm.

**Table 2. Correlation between fractional clearance and other parameters (pre- and postoperative; OZ 6.5 mm group)**

Parameter (x)	Parameter (y)	Correlation Coefficient (r)	Significance
Fractional Clearance	SPHA		
	Pre-operative	0,0607	p = 0,721
	Post-operative	-0,0943	p = 0,579
	RMS		
	Pre-operative	0,2860	p = 0,086
	Post-operative	0,1482	p = 0,381
	DFOK		
	Pre-operative	0,2485	p = 0,138
	Post-operative	-0,0048	p = 0,977
	ASTIG		
	Pre-operative	-0,1111	p = 0,513
	Post-operative	0,2245	p = 0,182
	COMA		
	Pre-operative	0,1425	p = 0,400
Post-operative	0,1290	p = 0,447	

No statistically significant correlation was identified between fractional clearance and individual HOA parameters in the group treated with OZ 6.5 mm. A correlational trend approaching but not reaching statistical significance was observed solely between fractional clearance and preoperative RMS values.

Comparison of postoperative HOA induction between groups demonstrated that the group treated with the larger OZ of 7.0 mm exhibited lower induction of all measured HOA parameters. The most notable reduction was observed in the induction of spherical aberration (SPHA), where the difference between groups reached statistical significance. Induction of coma aberration, higher-order astigmatism, and defocus aberration was also lower in the OZ 7.0 mm group, although these differences did not attain statistical significance.

Regression analysis revealed a statistically significant positive correlation between fractional clearance values and surgical outcome as measured by the difference between preoperative and postoperative higher-order astigmatism values ( $r = 0.3301$ ;  $p = 0.046$ ) (Figure 1). Higher fractional clearance values were associated with smaller changes in higher-order astigmatism following the LASIK procedure, indicating a more favorable postoperative optical outcome.

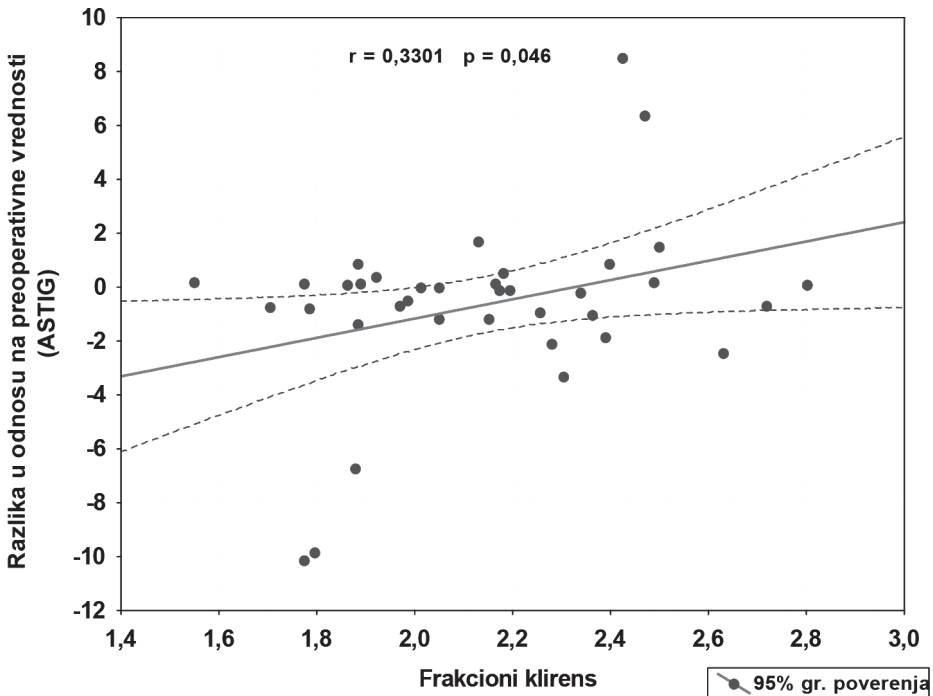


Figure 1. Correlation between fractional clearance and surgical outcome (difference between preoperative and postoperative numerical values of higher-order astigmatism)

## **DISCUSSION**

This prospective study demonstrates that expanding the treated optical zone diameter from the standard 6.5 mm to 7.0 mm during LASIK correction of myopia results in a statistically significant increase in the fractional clearance index and a reduction in postoperative induction of higher-order aberrations, most notably spherical aberration.

Fractional clearance represents a clinically relevant parameter that quantifies the relationship between the treated optical zone diameter and the scotopic pupil diameter (10). Our results demonstrate that expanding the OZ from 6.5 mm to 7.0 mm yields a statistically significant increase in FC from 2.138 to 2.325 ( $p < 0.001$ ), representing an increase of approximately 9%. According to recommendations, the FC value should reach a minimum of 1.17 in order to minimize HOA induction (10). Both groups in our study exceeded this threshold, suggesting that the standard OZ of 6.5 mm is adequate for the majority of patients. Nevertheless, our results indicate that further expansion to 7.0 mm in patients with appropriate corneal structural characteristics may confer additional benefits in terms of HOA reduction.

Both groups achieved FC values substantially above the minimum recommended threshold of 1.17, which accounts for the absence of a significant correlation between FC and individual HOA parameters in the OZ 6.5 mm group. This suggests the existence of a threshold effect. While achieving the minimum FC value of 1.17 is critical, further increases beyond this threshold may exert a less pronounced yet still meaningful effect on HOA reduction.

Our results demonstrate that OZ expansion leads to a reduction in all measured HOA parameters, with the most pronounced decrease in spherical aberration. This is a significant finding, as spherical aberration is the most commonly induced HOA during LASIK and directly affects visual quality under mesopic and scotopic illumination conditions (4,5). Patients with elevated postoperative spherical aberration frequently report dissatisfaction with night vision quality, glare from intense light sources, and reduced contrast sensitivity (4,6).

The mechanism by which a larger OZ reduces HOA induction is multifactorial (8,9,11). First, a larger OZ ensures that the patient views through the treated portion of the cornea even when the pupil is maximally dilated under scotopic conditions, thereby preventing light rays from passing through the transition zone between the treated and untreated corneal surfaces. Second, a larger OZ facilitates a smoother transition between the central treated zone and the peripheral untreated cornea, reducing the refractive index gradient and thereby minimizing irregular refraction at the periphery of the ablation zone. Third, a larger OZ attenuates the effect of microstructural changes in the stromal tissue that arise during the post-ablation healing process, which may contribute to HOA induction.

It is important to note, however, that OZ expansion is not without limitations. A larger OZ necessitates deeper stromal ablation and greater tissue consumption, which may preclude its application in patients with higher refractive errors or thinner corneas (2,12,13). In our study, the decision to expand the OZ was made individually for each eye based on predictive software analysis of the excimer laser system, ensuring that postoperative residual stromal bed thickness remained above the safety threshold of 300  $\mu\text{m}$ . This approach allows the benefits of a larger OZ to be maximized while maintaining corneal structural integrity.

Our findings are consistent with those of previous studies examining the influence of OZ diameter on postoperative optical outcomes (7,10,14). Bühren et al. introduced the concept of fractional clearance as a predictor of optical quality following LASIK, emphasizing that the ratio between OZ and pupil diameter is a more meaningful predictor than the individual values of these parameters in isolation (10). Our study corroborates this concept, demonstrating that focusing on achieving an appropriate FC value represents a more practical approach to LASIK treatment planning than the uniform application of a standard OZ diameter across all patients.

The importance of long-term postoperative follow-up has been demonstrated in studies of topography-guided LASIK procedures, which have shown stability of achieved outcomes over one year (14). Similarly favorable outcomes have been reported following LASIK for other refractive anomalies, including hyperopia and presbyopia, confirming the broad applicability of this technique (3,16).

An individualized approach to LASIK treatment planning that accounts for the specific structural characteristics of the cornea, including its curvature profile (flat, normal, or steep), has proven to be a critical determinant of optimal outcomes (12). These findings are particularly relevant in the context of complex clinical scenarios, such as patients with prior refractive procedures, where a highly precise approach is required (15,17,18).

Studies have demonstrated that the OZ diameter must be at least 17% wider than the patient's scotopic pupil diameter to reduce HOA induction by 50% (10). In our study, both groups achieved FC values substantially above this threshold (means of 2.138 and 2.325, respectively), which accounts for the relatively low level of postoperative HOA observed across both groups.

Our study carries several important clinical implications. First, it confirms that expanding the OZ from 6.5 mm to 7.0 mm in patients with adequate corneal structural characteristics yields a measurable improvement in optical outcome in terms of HOA reduction (1,2). This may translate into an improvement in subjective visual quality, particularly under night-time viewing conditions, which is of considerable importance for patient satisfaction (6). Second, the findings underscore the importance of an individualized approach to LASIK treatment planning (12). Rather than applying a standard OZ diameter uniformly across all patients, the decision should be grounded

in preoperative evaluation of corneal structural characteristics, the magnitude of the refractive error, and scotopic pupil diameter. Contemporary diagnostic and software systems enable precise predictive analysis, rendering an individualized approach both feasible and safe (13). Third, the study affirms the clinical utility of the fractional clearance concept (10,11). Calculation of the FC value is straightforward and can readily be integrated into routine preoperative assessment. Focusing on achieving an optimal FC value ( $>1.17$ , ideally  $>2.0$ ) may assist surgeons in determining the appropriate OZ diameter.

This study has several limitations that should be considered when interpreting the results. First, the relatively small sample of 37 patients limits the statistical power to detect smaller inter-group differences. Studies with larger participant cohorts would be required to confirm these findings and to examine additional variables that may influence postoperative optical outcomes. Second, the six-month follow-up period is comparatively short. Long-term studies, as demonstrated in research with a one-year follow-up of topography-guided procedures (14), are needed to assess the stability of outcomes and to determine whether the benefits of a larger OZ are sustained over time or diminish as a result of corneal remodeling and adaptation processes. Third, the study did not incorporate subjective measures of visual quality such as patient satisfaction questionnaires or contrast sensitivity testing (6). Although objective HOA reduction suggests an improvement in visual quality, direct correlation with patients' subjective experience would strengthen the clinical relevance of the findings. Fourth, the study was designed so that each patient received a different OZ diameter in each eye, enabling direct within-patient comparison. However, this design does not permit assessment of whether patients subjectively perceive a difference between their eyes in the course of daily activities.

## ***CONCLUSION***

The results of this study demonstrate that expanding the treated optical zone diameter from 6.5 mm to 7.0 mm during LASIK correction of myopia leads to a statistically significant increase in the fractional clearance index and a reduction in postoperative induction of higher-order aberrations, particularly spherical aberration. The increase in the fractional clearance index is proportional to the expansion of the treated optical zone diameter. Higher fractional clearance values correlate with lower levels of higher-order aberrations following LASIK treatment of myopia, with this correlation being most pronounced with respect to spherical aberration.

When the structural characteristics of the cornea are adequate to permit safe expansion of the optical zone diameter, expansion from 6.5 mm to 7.0 mm yields a more favorable postoperative optical outcome. The decision to expand the optical zone diameter should be grounded in individualized preoperative evaluation of the

ablation profile and prediction of postoperative residual stromal bed thickness using contemporary excimer laser software systems. Achieving an optimal fractional clearance value should be regarded as one of the primary objectives in LASIK treatment planning, alongside maintenance of corneal structural safety with a residual stromal bed of no less than 300  $\mu\text{m}$ .

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