• Clinical Research •

Predictive factors for outcomes of photorefractive keratectomy in myopic eyes

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Abstract

● **AIM:** To analyze the two-year visual and refractive outcomes as well as the safety, and efficacy of photorefractive keratectomy (PRK) surgery for myopia.

● **METHODS:** In this prospective cohort study, 63 eligible patients were recruited, including 45 women (71.4%) and 18 men (28.6%). Demographic characteristics along with pre- and post-operative clinical data including visual acuity, refraction, maximum ablation, spherical and cylindrical error, and residual stromal bed (RSB) were evaluated.

● **RESULTS:** The mean age of the patients was 35.42±8.16y (range 22 to 55y). The mean spherical and cylindrical error before surgery were -2.23±1.58 D (range -5 to +0.25) and -1.24±0.94 D, respectively (range -3.75 to 0.00). The mean efficacy and safety of PRK surgery at 2y follow-up were 0.98±0.06 and 1.01±0.04 respectively. The lower age was significantly correlated with a higher amount of efficacy index (P<0.001, r=-0.42). Also, the lower amount of preoperative myopia and spherical equivalent (SE) were correlated with a higher safety index (P<0.001, r=-0.44; P<0.001, r=-0.46).

● **CONCLUSION:** The two-year efficacy and safety of PRK for the treatment of low myopia is excellent. Younger age and lower amount of refractive error are correlated with higher efficacy and safety indices of the surgery.

● **KEYWORDS:** photorefractive keratectomy; myopia; refractive error; refractive surgery

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INTRODUCTION

Corneal refractive laser surgery is one of the most commonly performed procedures in the field of ophthalmology[1]. Surgical techniques and technologies have evolved rapidly over the past few decades, and recent advances have rendered refractive surgery as one of most predictable, safe and efficacious elective procedures performed[2]. Currently, more than 90% of patients with different types of refractive errors obtain clear vision through various correcting options[1]. However, concerns remain regarding refractive surgeries' safety and efficacy, as some studies have reported various complications such as loss of best-corrected visual acuity (BCVA), iatrogenic ectasia and regression[3-4]. Photorefractive keratectomy (PRK), small incision lenticule extraction (SMILE), and laser-assisted *in situ* keratomileusis (LASIK) are all surgical techniques used to correct refractive errors[5]. PRK is known for preserving corneal biomechanics better than other techniques[6-7]. This is because in PRK, the epithelial layer of the cornea is completely removed, allowing the underlying corneal tissue to retain its natural strength and integrity[8]. In contrast, LASIK involves creating a corneal flap, which leads to significant corneal biomechanical weakening[9]. SMILE also involves creating a small incision in the cornea, although it is smaller than the flap created in LASIK[10]. Preserving corneal biomechanics can be particularly beneficial for individuals with thin corneas or those engaged in activities that put significant stress on the eyes, such as contact sports[11]. By minimizing the biomechanical impact of corneal ablation and maintaining the natural strength of the cornea, PRK has been hypothesized to reduce the risk of complications related to corneal stability in

these cases[12]. PRK, is considered safe, but is associated with more discomfort in the early postoperative period compared to other techniques due to removal of the epithelial layer of the cornea[4]. PRK also leads to excellent visual outcomes and effective correction of myopia, but visual recovery is typically slower than LASIK or SMILE and may take several weeks or months[13]. Additionally, PRK is still carried out in cases involving superficial scarring, epithelial dystrophies, recurrent erosions, after penetrating keratoplasty, thin corneas, and refractive retreatments[4]. To ensure successful outcomes and minimize potential risks it is crucial to examine predictive parameters affecting the long-term safety and efficacy of PRK. This helps to optimize the procedure and tailor it to individual patient's needs, leading to better visual outcomes and higher patient satisfaction[14]. The present study sought to evaluate the predictive factors for the long-term safety and efficacy of PRK surgery in myopic candidates.

PARTICIPANTS AND METHODS

Ethical Approval This study was approved by the Institutional Review Board (IRB) of the Islamic Azad University of Medical Sciences, Mashhad (Ethical code IR.MUMS.MEDICAL.REC.1401.003-grant number 162437145). Informed consent was obtained from all participants prior to their inclusion in the study. The research adhered to the principles outlined in the Declaration of Helsinki.

Study Design In a prospective cohort study, which was conducted between 2021 and 2023 in Noorafarin Eye Clinic, Mashhad, Iran. A total of 63 patients aged 22 to 55y were included. The study included candidates for refractive surgery who were 18 years of age or older, with a stable manifest refraction over a 12-month period undergoing surgery during a three-month period in 2021. Only subjects suitable for PRK were recruited. Refractive correction included myopia less than -6.0 D, and astigmatism less than -2.0 D with a total spherical equivalent (SE) of -8.0 D or less. Subjects with a history of ocular surgery or any eye disease including previous corneal ulcer, ocular herpes, glaucoma, subclinical and forme-fruste keratoconus, patients with systemic diseases such as autoimmune diseases, vascular collagen diseases, diabetes, history of systemic isotretinoin use during the last 6mo prior to surgery, pregnancy and breastfeeding were excluded from the study. Contact lens wearers were instructed to discontinue their use for 4wk before surgery.

Surgical Technique All procedures were performed by a single experienced surgeon (Zarei-Ghanavati S). Patients received 0.5% tetracaine drop and had the periocular area cleaned with 10% povidone-iodine in the perioperative stage. The ocular surface was thoroughly rinsed with balanced salt solution (BSS). Corneal epithelium was circularly removed by a hockey blade and laser ablation was performed using. The ablation procedure was performed using the Schwind Amaris® 1050RS excimer laser (SCHWIND eye-tech-solutions GmbH, Kleinostheim, Germany). The optical zone was at least 6.50 mm in all patients and Aspheric (Triple-A) technique was used[15]. At the completion of laser ablation, a sponge soaked in 0.02% mitomycin-C was applied to the corneal surface for a period of 5s for each diopter of refractive error corrected. The ocular surface was again irrigated with BSS and a silicone hydrogel bandage contact lens (ULTRA, Bausch & Lomb, NY, USA) was applied and removed after one week.

Postoperatively patients were treated with 5 mg/mL levofloxacin (OFTAQUIX, Santen Pharmaceutical, Osaka, Japan) every 6h for 1wk and 1% betamethasone (Betasonite-Sina Daru, Tehran, Iran), every 6h for one month. Additionally single-dose Artelac advanced artificial tears (Bausch & Lomb, NY, USA) were used every 3h for three months. Follow-up examinations were performed on the first postoperative day, 1 and 24mo.

Measurements Patients were examined and evaluated preoperatively and two years postoperatively to collect uncorrected visual acuity (UCVA), BCVA, and refractive parameters were evaluated. Cycloplegic refraction and subjective refraction were performed by the same optometrist and considered for planning of refractive surgery. The primary measures used to assess the success of the surgery were the safety index and efficacy index, which were determined during the final follow-up appointment. The safety index was defined as BCVA after treatment divided by BCVA before treatment (BCVA post/BCVA pre). The efficacy index was defined as UCVA after treatment divided by BCVA before treatment (UCVA post/BCVA pre)[3]. In terms of the safety index value, if it exceeds the threshold of 0.85, it means that the patient has experienced a minimal loss of visual acuity after undergoing surgery. On the other hand, if the safety index value falls below 0.85, it indicates that the patient has lost two or more lines of visual acuity, which is considered unacceptable by most refractive surgeons[3]. Losing two lines generally suggests that the procedure was not successful in terms of safety. Regarding the efficacy index value, if it is above the threshold of 0.8, it signifies that the patient has lost up to two lines of UCVA, which is typically tolerated by most patients. However, if the efficacy index value is below 0.8, it means that the patient has lost more than two lines of UCVA, which is concerning for both surgeons and patients. A loss of more than two lines suggests that the procedure was unsuccessful in terms of efficacy[3].

Statistical Analysis Data analysis was performed using SPSS software version 23.0 (IBM Corp., Armonk, NY, USA). Data normality was checked using the one-sample Kolmogorov-Smirnov test and parametric tests were used for data that

Table 1 Demographic information of patients

Variables	Mean±SD	Minimum	Maximum
Cycloplegic spherical error (D)			
Pre	-1.99±1.36	-4.50	-0.50
Post	+0.41±0.55	-1.50	+1.25
Cycloplegic cylindrical error (D)			
Pre	-1.24±0.94	-4.00	+0.00
Post	-0.28±0.29	-1.50	+0.25
Cycloplegic SE (D)			
Pre	-3.05±1.36	-5.50	-0.75
Post	+0.29±0.60	-1.75	+1.25
Dry spherical error (D)			
Pre	-2.23±1.58	-5.00	+0.25
Post	-0.16±0.44	-2.00	+0.75
Dry cylindrical error (D)			
Pre	-1.24±0.94	-3.75	0.00
Post	-0.28±0.27	-1.5	0.00
Dry SE (D)			
Pre	-3.10±1.31	-6.00	-1.00
Post	-0.31±0.48	-2.00	+0.50
UCVA (logMAR)			
Pre	+0.30±0.35	0.00	+1.00
Post	+0.02±0.09	0.00	+0.69
BCVA (logMAR)			
Pre	0.00±0.02	0.00	+0.09
Post	0.00±0.00	0.00	0.00
Refractive surgery data			
Attempted spherical correction (D)	-2.52±1.40	-5.06	0.00
Attempted cylindrical correction (D)	-1.30±0.93	-3.73	0.00
Attempted SE (D)	-3.11±1.33	-5.83	-0.40
Optical zone (mm)	6.96±0.15	6.50	7.50
Max laser ablation (μm)	70.59±26.30	26.00	161.00
RSB (μm)	391.78±38.26	350.00	497.00

SD: Standard deviation; SE: Spherical equivalent; UCVA: Uncorrected distance visual acuity; BCVA: Best-corrected distance visual acuity (logMAR); RSB: Residual stromal bed.

demonstrated a normal distribution. In the analysis of data with a nominal scale, Chi-square test was used. Pearson correlation coefficient (r) was used to evaluate the correlation between variables for all analyses a significance level of $P<0.05$ was considered.

RESULTS

This study consisted of 63 eyes from 63 patients, including 45 women (71.4%) and 18 men (28.6%). The average age of patients was 35.42±8.16y (range 22 to 55y). The average SE before surgery was -3.10±1.31 D (range -6.00 to -1.00 D). The mean spherical error before surgery was -2.23±1.58 D (range -5 to +0.25) and the mean cylindrical error before surgery was -1.24±0.94 D (range -3.75 to 0.00; Table 1). The efficacy and safety index of PRK surgery were satisfactory, with 100% of patients experiencing no loss of corrected visual acuity during the follow-up period. The relationship between the attempted and achieved SE values after PRK surgery showed a notable linear correlation ($P=0.01$, $r^2=0.74$). Two years' post-surgery, 63.0% ($n=40$) of patients had an SE within ±0.50 D, and 86% ($n=53$) exhibited less than 1.00 D of residual refractive astigmatism. The overall mean safety and efficacy indices were 1.01±0.04 and 0.98±0.06, respectively. As shown in Table 2, the amount of efficacy index was significantly different in patients with different ranges of myopia ($P=0.02$), but it was not significantly different in different levels of SE and cylindrical error ($P>0.05$).

The mean efficacy index was not significantly different between genders ($P=0.30$). Also, the Pearson test, showed that the lower age was significantly correlated with a higher amount of efficacy index ($P<0.001$, $r=-0.42$). Based on the

Table 2 The mean efficacy index in different refractive errors and genders *n*(%)

Variables	Below cut-off (≤0.8)	Above cut-off (>0.8)	P^a
Spherical error (D)			0.02
0 to -2	1 (33.3)	28 (47.5)	
-2 to -4	0	24 (40.7)	
-4 to -6	2 (66.7)	7 (11.8)	
Cylindrical error (D)			0.38
0 to -2	3 (100)	47 (79.7)	
-2 to -4	0	12 (20.3)	
Gender			0.30
Male	0	18 (30.5)	
Female	3 (100.0)	41 (69.5)	
SE			0.40
Low myopia (0 to -3.00 D)	1 (33.3)	33 (55.9)	
Moderate myopia (-3.00 to -6.00 D)	2 (66.7)	26 (44.1)	

[a]χ^2 test. SE: Spherical equivalent.

Pearson test, the lower amount of preoperative myopia and SE were correlated with a higher safety index (P<0.001, r=-0.44; P<0.001, r=-0.46).

DISCUSSION

Refractive surgery is becoming increasingly popular for the correction of refractive errors with a multitude of techniques available and capable of delivering excellent outcomes. Refractive surgeons must have a thorough comprehension of the parameters that affect the safety and efficacy of refractive surgery procedures[8].The effect of predictive parameters on the long-term efficacy and safety of PRK refractive surgery were evaluated in this study. Based on the findings of this study, PRK demonstrates excellent long-term efficacy and safety, making it a robust option for individuals with myopia. To minimize the impact of confounding factors, such as differences in surgeons and equipment, our study was limited to surgeries performed by a single surgeon using a consistent technique. In our analysis, considering the notable safety levels observed above the predefined cut-off, a statistically significant evaluation of the influence of predictive factors on PRK surgery safety remained elusive. The findings of our study reported that 95.0% (n=59) of patients showed no decrease in post-operative BCVA compared to preoperative BCVA. However, 73.0% (n=46) of patients showed a linear relationship between the attempted and achieved SE obtained after the surgery. Similar results by Alio *et al*[16], reported PRK is a safe refractive procedure. This retrospective-prospective observational study followed up 33 eyes of 33 patients for 15y and safety index was 1.18. PRK has a strong safety profile, especially in terms of reducing the risk of intra and postoperative flap-related complications[4]. Some studies suggest that PRK may offer better visual quality, particularly in low-light conditions or for individuals with higher levels of refractive error[17-18]. This is because PRK avoids potential issues related to flap creation or lenticule extraction, which can impact induced higher order aberrations, corneal biomechanics and subsequently visual outcomes[19]. Our findings showed that 100% and 95.0% of all evaluated eyes were above the safety and efficacy thresholds. Moreover, a higher efficacy index was found to be significantly correlated with younger age. Similar results have been published by Gomel *et al*[3] who reported increasing age was associated with decreasing safety and efficacy of laser refractive surgery. This retrospective cohort study followed up 8775 eyes in 4623 patients for 3-12mo. This result may be attributed to the fact that younger patients have better and faster healing properties in their corneas due to higher tear production and better corneal sensitivity, resulting in improved recovery rates after refractive surgery[20-21]. Furthermore, in this study, high residual stromal bed (RSB) was significantly correlated with a higher efficacy index. Previous studies also reported that low RSB is identified as a risk factor for developing ectasia after refractive surgery and reduces the effectiveness of surgery[22]. In this study, the mean efficacy and safety of PRK surgery at 2y follow-up were 0.98±0.06 and 1.01±0.04, respectively. Castro-Luna *et al*[23] in a similar study, reported a safety index of 1.09 two years after PRK surgery and concluded that the technique was safe and efficacious. Sajjadi *et al*[24], compared PRK and femto-LASIK out comes in 120 eyes of 60 patients for 6mo. Also, Almahmoud *et al*[25], compared 240 eyes in advanced surface ablation (ASA) group to 138 eyes in IntraLase femtosecond LASIK (iLASIK) group for 3mo. They reported that in short-term follow-up, PRK was effective and safe. According to our findings, although lower SE was not associated with a higher efficacy index, most patients with low to moderate myopia showed an efficacy index above the cut-off levels and spherical

error was significantly correlated with the efficacy index. Based on other studies, refractive outcomes are more favorable in cases of mild myopia compared to high myopia[16,26]. In individuals with high myopia, optical correction results in "minification" and surgical correction of this high degree of myopia can surpass the visual acuity achieved with corrective eyewear. This phenomenon could contribute to the comparable efficacy observed between individuals with high myopia and those with lower degrees of myopia following PRK. Gomel *et al*[3] found that the male gender was significantly correlated with efficacy above the cut-off level but corneal thickness did not correlate with high efficacy index. The results of this study suggest no significant relationship between corneal thickness, gender and efficacy index and further studies with larger number of patients and longer follow-up are required to enhance our knowledge about the other predictive factors for successful PRK surgery. This may assist clinicians in better pre-operative consultation, decision-making, and patient selection. It is important to note that while the safety index is widely measured by the formula post-operative BCVA divided by pre-operative BCVA, this metric does not fully encompass patients' satisfaction, particularly when post-operative refractive error is present. In the present study, the minority of patients were hyperopic after PRK surgery which in most cases it was less than 1.00 D. Hyperopia may be intentionally targeted in certain patients, especially those at risk for regression due to age or other factors. However, this outcome can still influence patients' satisfaction. This clinical consideration emphasizes that while objective measures like the safety index are useful, they should be supplemented with a holistic approach to patient care.

Our study has some limitations including a modest sample size and inclusion of mild to moderate degrees of myopic astigmatic refractive error. Also, the observation time can be expanded in the future studies.

In conclusion, PRK is a safe and efficacious procedure after two years of follow-up with a higher efficacy and safety indices correlated with younger age and lower amount of refractive error.

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Data Availability: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest: Shams SS, None; **Hassanzadeh S,** None; **Zarei-Ghanavati S,** None; **Ziaei M,** None; **Bayati S,** None.

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